Tele-ICUs

Interim Findings about Remote Monitoring and Management of Patients in Intensive Care Units: A FAST Initiative Technology Analysis

Discussion Draft

for the New England Healthcare Institute

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Executive Summary

- Tele-ICU systems are a relatively new technology developed to enable the limited number of US intensivists to provide closer management of Intensive Care Unit patients.
- ICU care is an important component of component of healthcare in the US:
 - There are approximately 6000 ICUs in the United States 3900 of these provide care for adults;
 - Approximately \$180 billion is spent annually in ICUs in the United States, representing 7% of healthcare spending, or 1% of the US GDP; and
 - There are fewer than 6000 intensivists in the US, and less than 15% of hospitals with ICUs are estimated to staff their ICUs with trained intensivists.
- The goal of tele-ICU systems is to achieve the clinical outcomes found with the intensivist model of ICU care that has been show to:
 - Reduce mortality by about 30%;
 - Reduce ICU length of stay by up to 3 days; and
 - Reduce hospital length of stay by up to and 9 days.
- Because of these findings, in 2000 the Leapfrog Group recommended the intensivist model ICU care.
- Assessing the effects of tele-ICUs are complicated by several factors, including:
 - The short time tele-ICU systems have been in use limits the amount of longitudinal data available for analysis;
 - Most collected data has limited adjustments for patient severity;
 - Many tele-ICU systems are implemented as one of several clinical or technological innovations such as computerized order entry and quality improving care bundles;
 - There is a learning curve for physicians and nurses working in the tele-ICU control center about to how to successfully practice this type of tele-medicine; and
 - The culture shift that ICU critical care staffs go through to learn how to work with their tele-ICU colleagues can be a lengthy process.
- The limited data that has been collected indicates that tele-ICUs do appear to have the potential to improve clinical and economic outcomes, and a Stakeholder Working Group convened as part of this FAST Initiative project, concluded that a 10% reduction in ICU length of stay (LOS), and hospital mortality for ICU patients are realistic outcomes for tele-ICU systems in their first year of operation.
- The barriers to broader adoption of tele-ICU systems include:
 - Financial barriers of paying the several million dollars (or up to \$100,000 per ICU bed) to install and then operate a tele-ICU system;

- The lack of reimbursement for tele-ICU monitoring or management of ICU patients;
- Organizational challenges to make a tele-ICU system work effectively in an existing clinical culture. Effectively implementing change management processes to create the clinical collaborations needed to extract value from the tele-ICU system is generally a long-term process; and
- Uncertainties about return on investment (ROI) calculations Although one expert posited that an ROI calculation based solely upon expected ICU LOS reductions should be sufficient when aligned with the other direct and indirect positive clinical effects tele-ICU systems can achieve.
- Overcoming these barriers would be assisted by demonstration and research projects to:
 - Show the value of tele-ICU systems for secondary direct and indirect benefits such as:
 - Avoidance of complications in the ICU though implementation of quality protocols focusing on:
 - ✓ Stress Ulcer Prophylaxis
 - ✓ DVT Prophylaxis
 - ✓ Central Line Associated Bloodstream Infections
 - ✓ Ventilator Associated Pneumonia Prevention
 - ✓ Ventilator Days
 - ✓ Glycemic Control
 - ✓ Medication Errors
 - More efficient delivery of care, and improved productivity of clinical staff
 - Improved staff morale, decreased turnover, and extension of clinicians' productive work-life
 - Enhanced educational and training opportunities
 - Increased patient, family and community perception of quality of care
 - Increased revenue from improved billing and coding
 - Underwrite the purchase and installation of tele-ICU systems with one time grants;
 - Provide reimbursement for tele-ICU physicians' services; and
 - Provide higher reimbursement to healthcare delivery systems that meet certain standards for ICU management (such as those from the Leapfrog Group) or can demonstrate improved outcomes for specific ICU related conditions.
- NEHI will continue to advance its work on tele-ICUs as part of its FAST Initiative by:
 - Working with partner organization to implement the recommendations from this report; and
 - Working with local and national organizations to rapidly conduct the highest priority demonstration and education projects to demonstrate how to create clinical and economic value from tele-ICU systems – both where they currently exist and for new installations.

Table of Contents

		Page
1.	Introduction	5
2.	Benefits of the Intensivist Model of ICU Care	8
3.	Overview of Technology	12
4.	Evidence about Tele-ICU's Potential to Change Mortality	16
5.	Evidence of Tele-ICU's Potential to Change Costs of Care	20
6.	Other Cross-Cutting Quality and Cost Aspects of Tele-ICUs	23
7.	Barriers to Broader Dissemination and Value Creation	25
	Financial	
	Organizational and Cultural	
	Other	
8.	Overcoming the Barriers to Successful Adoption and Value Creation	32
9.	Conclusions and Recommendations	38
Ap	opendices:	
	A – Overview of FAST Initiative	43
	B – List of Expert and User Interviews	45
	C – Current Manufacturers	46
	D – Dissemination of Tele-ICU Systems	48
	E – Wild Cards that Could Change Quality, Cost or Value Projections	50
	F – Leapfrog 2006 ICU Staffing Leap and Criteria	51
	G – Joint Commission's National Hospital Quality Measures for ICUs	58
	H – Literature Sources	60

1. Introduction & Overview

There are an estimated 6,000 Intensive Care Units (ICUs) in the US, with 87,000 beds providing over 20 million patient days of care, and total budgets represent roughly 7% of US healthcare spending, or 0.6-1.0% of the US Gross National Product.¹ ICU patients often have multiple organ system problems, require constant monitoring, and have a high risk of death. Monitoring ICU patients is done with intensive and invasive technologies (such as arterial catheters and mechanical ventilators), and a high ratio of clinicians to patients. Physicians who specialize in such critical care medicine are called intensivists.²

Despite the close monitoring of ICU patients, they may have subtle and easily overlooked signs that could indicate an impending adverse event. During this time, an intervention may prevent a serious event such as shock, cardiac arrest, or pulmonary distress.³ Research has demonstrated improved clinical outcomes using an "intensivist model" of care that involves intensivists closely monitoring and managing ICU patients, and it has been estimated that if the ICU physician staffing recommendations put forward by the Leapfrog Group were met for urban ICUs, then about 53,000 adult deaths related to ICU care in urban hospitals could be avoided.⁴ Another broader estimate put the total number of annual preventable deaths for ICU patients at 134,000.⁵

However, because there is a growing shortage of trained intensivists, providing this close clinical monitoring and management in all ICUs is not possible. There are less than 10,000 critical care physicians in the US, and it is estimated that more than three times this many would be required to staff all adult ICUs. Filling this gap will be difficult even if policies to train more intensivists are initiated today, because of a declining number of physicians in critical care training, the lag time for this training, and expected age-related retirements.⁶ In addition, the demand for intensivists continues to expand, and is expected to grow significantly after 2007 leading to a 35% increased shortfall of available intensivist hours by 2035.⁷ Along with the expected shortage in physician intensivists, a shortage of critical care trained nurses is also anticipated.⁸

One possible solution to this problem is to enable an intensivist to remotely monitor and manage dozens of patients simultaneously in multiple ICUs with a tele-ICU system. Tele-ICU systems are composed of hardware and software that collects, analyzes and

¹ Pronovost (2002), Halpern (2004)

² Definitions of intensivists vary, in part because the sub-specialty certification is relatively recent and many physicians who specialize in critical care are not certified. The Leapfrog group's intensivist definition encompasses most of these factors. (See Appendix F, footnote #2). Also see Appendix 2 in Brilli (2001).

³ One experienced intensivist likened this time to the "golden hour" for treating and transporting trauma patients. In both cases, effective intervention during a critical time period dramatically effects clinical outcomes.

⁴ Young (2000), Leapfrog (2004)

⁵ Pronovost (2004)

⁶ Ewart (2004), Macciolli (2006), HRSA (2006)

⁷ Halpern (2004), Derek (2000)

⁸ Dracup (2004), Irwin (2004),

transmits information back and forth between the physical ICU and the tele-ICU command center. These systems also have the capability to track and analyze patient data and alert ICU and command center clinicians when a patient may be heading towards an adverse event.

Tele-ICUs can also enable more rapid and complete adoption of quality improving protocols with ICUs. Recent research from organization such as the Institute for Healthcare Improvement has demonstrated that such standardized protocols for the treatment and prevention of common serious conditions such as stress ulcer prophylaxis, ventilator associated pneumonia and glucose control can improve outcomes.⁹ One unpublished abstract reported that a tele-ICU system enabled improved compliance with the ventilator related complication preventive interventions of head of bed elevation, DVT prophylaxis, and ulcer prophylaxis to essentially 100% from 59%, 76% and 84% respectively.¹⁰ Thus, tele-ICUs can improve ICU outcomes for individual patients by improving direct monitoring and management as well as enabling better systematic delivery of care by promoting and monitoring adherence to validated protocols.

By improving clinical outcomes, tele-ICUs should also reduce the costs of care for ICU patients.¹¹ But calculating actual financial effects of tele-ICUs can be a complicated task because most hospitals accounting systems are designed around billing and reimbursement rather than actual costs of care. In addition, assessing the clinical and economic effects of tele-ICUs is complicated by the methodological difficulties in isolating the effects of tele-ICU's monitoring and management from other initiatives -- such as practice protocols, CPOE, or electronic medical records -- a health system may have installed around the same time as the tele-ICU system.¹² It is also possible that there are synergistic rather than simply additive effects amongst the technologies and practice protocols. For example, while a quality-improving bundle of practice guidelines can improve quality of care, tele-ICU monitoring or other technologies such as a sophisticated EMR could help improve compliance with the clinical guidelines.

However, these potential benefits of tele-ICUs can only occur if clinicians in both the physical and tele-ICU work together and use it. The role of tele-ICUs in promoting the adoption and adherence to clinical protocols can also foster the teamwork and collaboration needed for tele-ICU systems to successfully improve direct patient care.

Thus, the ability of tele-ICU systems to affect patient care is not only dependent upon the quality of the tele-ICU system's hardware and software, but it is also strongly influenced by organizational and clinical factors within a healthcare delivery system and

⁹ <u>www.IHI.org</u>

¹⁰ Parkview (2006)

¹¹ The reduction in the cost of care should be seen for the entire hospitalization since a large percentage of the costs of caring for a patient who spends any time in the ICU is due to their ICU care, and by avoiding complications in the ICU should also reduce the length of the non-ICU hospital stay.

¹² As one researcher interviewed noted, hospitals' mortality rates in the US appears to be trending downward by 0.5-1.0% per year, and determining the exact causes the this decline is difficult.

their pre-tele-ICU performance characteristics. The operations of tele-ICU systems, the factors that affect their ability to change clinical and economic outcomes related to ICU care, and how to practically measure and assess these outcomes and the overall value of tele-ICUs to healthcare delivery systems in the United States are the subjects of this report.

2. Benefits of the Intensivist Model of ICU Care:

An estimated 4.4 to 5.7 million adult patients are admitted to ICUs each year in the US.¹³ This number is predicted to increase rapidly as the population ages.¹⁴ Intensive care units range from general medical or surgical ICUs, to more specialized care centers, such as neurosurgical, trauma or cardiac ICUs. Total annual spending in US ICUs is estimated to be about \$180 billion, which equals about 7% of all US healthcare spending.

Mortality:

Reported ICU and in-hospital mortality rates for patients discharged from the ICU vary widely because of the wide range of patient illnesses and conditions in ICU patient populations:

- In-ICU mortality from 1.5% to 51%; and
- In-hospital mortality for discharged ICU patients from 1.5% to 74%, although a hospital mortality of about 12% is generally cited as an average figure.¹⁵

Therefore, ICU and hospital mortality rates are most meaningful when adjusted for case mix severity. There are a number of distinct methodologies for doing severity adjustment for evaluations of ICU outcomes that vary in both complexity and accuracy. These methodologies have been adopted by adopted by various organizations. For example, the majority of California hospitals recently started using the Mortality Prediction Model (MPM II) for risk adjusting their reported hospital mortality.¹⁶ It should also be recognized that while these risk prediction methodologies are useful for research and health system evaluation and management, they require periodic updating, and have practical and technical limitations, including how new interventions change risks for certain diseases and physiological conditions, and the problem of trying to use these risk prediction models for individual patients – particularly for individuals deemed to be at high or low risk.¹⁷

In addition to differing case mix severity, using mortality rates to measure clinical outcomes can also be confounded by differing hospital practice patterns, such as using ICUs for palliative care for terminal patients. Such factors helps to explain the wide ranges of overall mortality rates reported in the literature noted above.

In addition, survival of these patients after hospital discharge remains largely unstudied. Therefore, determining what portion of ICU patient deaths averted may be considered

¹³ Leong (2005), Pronovost (2004)

¹⁴ The US's 6,000 ICUs contain about 66,200 adult and 20,610 pediatric/neonatal ICU beds, and care for about 55,000 patients each day. (Personal Communication, Eric Chandler, SCCM 3/23/06) At present there appears to be no pediatric or neonatal tele-ICU systems.

¹⁵ Pronovost (2002), Zimmerman (1998)

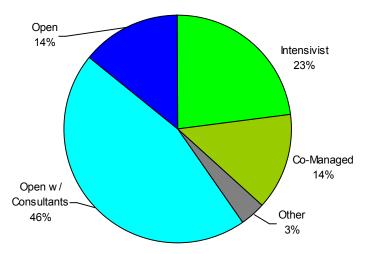
¹⁶ CHART (2006)

¹⁷ Thibault (1997), Kramer (2005), Berge (2005)

lives saved in terms of long-term or normal life expectancy is uncertain. However, at least one study of the most gravely ill ICU patients has shown that a greater number than expected can survive to hospital discharge, but most of these patients have significant disabilities. ¹⁸

Considerable research has been focused on whether mortality rates can be reduced by increased use of intensivists in ICUs.¹⁹ In "Intensivist Model," or "Closed" ICUs, intensivists provide all or most of the physician patient care. The presumption is that in an intensivist model ICU, patients' problems are identified sooner, leading to more rapid and complete interventions, and lower mortality rates. The opposite of this is an "open" ICU where the ICU patient's physician of record is a community physicians with hospital admitting privileges. An intermediate step between these two are "Co-Managed" (or "Transitional") ICUs, where management of ICU patients are conducted jointly by the community physicians and intensivists.²⁰

One study from 1997 indicated that 23.1% of patients were treated by full-time intensivists, while 13.7% had a "consultant intensivist" (i.e. co-managed) model, 45.6% had a number of consultants working with the patient's primary care physician, with none designated as a specific consulting intensivist, 14.2% had a single non-intensivist physician, and 3.4% use some other model.²¹ (See Chart below)



¹⁸ Berge (2005)

¹⁹ Intensivists are physicians that specialize in critical care medicine. There are varying definitions of what physicians qualify as an intensivist (board-certification became available in the 1980s.) The Leapfrog Group defines intensivists as board-certified in critical care medicine, or in emergency medicine, of in selected other specialties prior to 1987 and who have provided at least 6 weeks of full-time ICU care annually since 1987. Leapfrog (2004b)

²⁰ Brilli (2000) [Note: The Leapfrog Group uses the term "co-managed" rather than "transitional," and this report has adopted that terminology.]

²¹ Brilli (2000)

The weight of published evidence and professional opinion strongly supports the logic that more intensivist management of ICU patients leads to better outcomes. An assessment of peer-reviewed articles on the effects of intensivist staffing of ICUs found that most (11 of 16) of the reviewed studies comparing similar ICUs found a statistically significant decrease in hospital mortality and most (11 of 15) also found a statistically significant decrease in ICU mortality.²² One assessment of the mortality reduction that can be attributed to an "intensivist model" of staffing has yielded estimates ranging from 15% to 60% over conventional or open models where patient management is directed by, or largely shared with, physicians who are not dedicated critical care specialists.²³ A systemic review of the literature found a similar reduction of hospital mortality of 23-50%²⁴

The Leapfrog Group estimates that focusing only on the 84% of adult ICU admissions that occur in urban hospitals, if their standards for ICU physician staffing were met (i.e. intensivist coverage for adult admissions increased from 21% to 100%), then the inhospital mortality rate at these hospitals could be reduced 30% from baseline, and about 53,000 adult deaths would be avoided, while another researcher has estimated that reducing the mortality rate from 12% to 8% would prevent 134,000 deaths annually.²⁵

ICU Length of Stay (LOS): Similar to the findings for mortality rates, there is substantial evidence that the intensivist model can lead to reduced length of stay (LOS), both in the ICU and in hospital, and 6 of 13 studies found a statistically significant decrease in hospital (LOS), and 11 of 17 found a significant decrease in ICU LOS:²⁶

	Low Intensity Staffed ICU ²⁷	High Intensity Staffed ICU
ICU LOS	2-13 days	2-10 days
Hospital LOS	8-33 days	7-24 days

Studies examining the impact of a shift to the intensivist model from conventional models also report a shortening of both ICU and hospital LOS.²⁸ The intensivist model has also been associated with a lower LOS in specific patient groups, such as individuals with aortic aneurysms.²⁹

Recommendations for Intensivist Care in ICUs:

²² Pronovost (2002) One article of the 16 reported only ICU, not hospital mortality rates.

²³Young (2000.)

²⁴ Rothschild (2001), Pronovost (2004)

²⁵ Leapfrog (2004)

²⁶ Pronovost (2002)

²⁷ "Low intensity staffed ICU" refers to ICUs with no critical care physicians or elective consultation with a critical care physician. "High intensity staffed ICU" refers to a closed ICU or mandatory consultation with a critical care physician. ²⁸ Carson (1996), Pronovost (2002)

²⁹ Pronovost (1999)

Such findings have lead to strong policy support for increased use of "intensivist model" staffing for ICUs. This evidence, and the consensus of experts that intensivist patient management improves outcomes, led the Leapfrog Group, the Society for Critical Medicine, and the American College of Critical Care Medicine to recommend for intensivist staffing of ICUs and the management of ICU patients.³⁰

One of the chief impediments to implementing these recommendations across the US is an insufficient supply of intensivists. There are estimated to be fewer than 6,000 intensivists practicing in the US – less than one for every ICU – and less than 15% of US hospitals with ICUs are estimated to staff those units with dedicated intensivists. although larger ICUs have a greater likelihood of having intensivist coverage, so the percentage of patients without intensivist coverage would be smaller than the percentage of ICUs without such coverage.³¹

The supply of intensivists is unlikely to increase. Teaching hospitals have decreased the numbers of fellowship programs in critical care for financial reasons, intensivists report an early retirement age due to workplace stress, and some trained intensivists appear to be choosing not to work in ICUs because of reimbursement limitations.³²

Therefore, one of the solutions to enabling more ICUs to have intensivist coverage – such as that recommended by the Leapfrog group - is to utilize tele-ICU technologies to enable a single intensivist and a few critical nurses to monitor and assist in the clinical management of dozens of ICU patients in geographically dispersed ICUs.³³

 ³⁰ Milstein (2000), Brilli (2001), Haupt (2003), Pronovost, (1999), Pronovost (2002), Leapfrog (2004), Appendix F
 ³¹ Leong (2005), Brilli (2001)

 $^{^{32}}$ The average expected age of retirement for critical care physicians is about 60. HRSA (2006)

³³ The Leapfrog Group's standards include a definition of "Intensivist Presence via Telemedicine." See Appendix F, footnote #6

3. Overview of the Technology

A tele-ICU system is composed of the essential **hardware** and **software**, and making these components operate effectively requires adequate **staff organization**, and **clinical processes**. These latter two factors can be addressed both before installation of the tele-ICU's hardware and software and promoted afterward as the tele-ICU system creates larger care teams with more clinical coordination across a healthcare delivery system's ICUs.

Hardware: The hardware components of a tele-ICU can be divided into two parts: The part that transmits patient data (including video and voice) from the physical ICU to the tele-ICU center, and the part that collects and assembles the patient's clinical data. This second part includes devices that monitor the patients' physiological status (e.g. EKG, and oxygen monitors), the treatments they are receiving (e.g. the infusion rate for a specific medicine, or the settings on a respirator), and their medical records. Together these hardware components ideally provide the tele-ICU and physical ICU clinicians with the same patient data.

Hardware Components

- Computer systems to collect, assemble and transmit information
- Communications lines, i.e. T1 or T3
- Physiological monitors
- Therapeutic devices
- Medical records
- Video feed, (with angle and zoom adjustments)
- Audio communications
- Video display panels

Software: The software for a tele-ICU includes the programs that make all of the monitoring and information transmission hardware function properly. One of the challenges facing tele-ICU software is interfacing with, and electronically accepting data from, the other electronic information systems that serve the ICU, e.g. labs, medications, nursing flow sheets, physicians' notes, etc. As with many sophisticated software products, building patches to achieve this interoperability between initially incompatible systems is possible, but can take time and money. And if the systems are from competing companies, there may not be cooperation in making these systems work well together.³⁴

³⁴ There are currently 3 companies offering tele-ICU systems in the US. These firms provide the software components of the tele-ICU systems, while working with the healthcare system to making certain that the health system's hardware (both new and existing) is compatible with the software to the greatest extent possible. At this time, none of these companies provides their own video systems, or data transmission lines, but they work with the health system to obtain these components from other vendors.

Tele-ICUs systems also include software applications that analyze the patient's physiological condition, (and the trends in their conditions) to alert clinicians if the patient's condition is worsening or trending towards a significant adverse event.³⁵ For example, a patient's heart rate might be slowly increasing, and while a normal pulse alarm might be set to trigger at a heart rate of 100, a software program monitoring the patient and their trending upward heart rate (along with other measures such as blood pressure, respiration rate and blood oxygenation), could alert the clinicians before a alarm for any one of these parameters alone. This software capability enables clinicians to focus on patient care without trying to constantly monitor all of their patients' physiological parameters. This type of assistance is increasingly valuable as the complexity of medical care grows faster than the ability of the human brain to integrate and analyze the expanding amount of available raw data.

The more sophisticated monitoring and software algorithms can be adjusted for individual patients according to the multiple medical conditions often present in ICU patients. The breadth of these triggers may also be set narrowly, i.e. alarms only occur for life threatening conditions like cardiac arrest, or broadly, i.e. to include reminders about protocols to adjust ventilator settings or to repeat certain tests. The sensitivity and breadth of the alarm triggers can be adjusted as the tele-ICU staff becomes more familiar with the systems functionalities.

An additional benefit of the tele-ICU system is that because of the electronic nature of the data being transferred and analyzed, tele-ICU systems also allow for data archiving and analysis for quality improvement, and to document the tele-ICU system's performance.

However, practical challenges in this area include the reality that updating and refining these software systems require validation before being accepted by clinicians in both the tele and physical ICUs, and transitioning to an electronic medical record or clinical flow-sheet can be an organizational challenge as discussed below.

Software Components

- Software to operate hardware and enable data transmission
- Algorithms for alerting clinicians to potentially actionable situations
- Adjustable triggers for alerts and alarms
- Data capture and analysis capabilities to enable retrospective quality review and improvement

<u>Staff Organization</u>: The clinician component of tele-ICUs (both in the tele-ICU itself and the individuals providing direct patient care in the actual ICU) is what makes the hardware and software pieces work as an integrated system. It is also the most important and variable component of tele-ICU system. As will be discussed later in this section, if this component of the tele-ICU system is not effectively using the information

³⁵ Schoenberg (1999)

provided by the hardware and software, then the value of a tele-ICU system can be dramatically diminished. One critical aspect of the staff organization is the authority of the tele-ICU physicians to directly manage patient care. In some systems, this authority can be set for individuals at any of up to 4 levels ranging from "only in a dire emergency such as a cardiac arrest," to complete authority to manage the patient. In open ICUs, where many or most patients have non-intensivist community practitioners as their physicians of record, the authority granted to the tele-ICU physicians can have significant implications in the ability of the tele-ICU system to affect clinical or cost outcomes.

The technical computer and IT staffs from the tele-ICU, the hospitals (or health systems), and the system's vendor, are also important components of a tele-ICU's staff organization. To minimize "down-time" for the hardware and software, and to ensure timely updating and maintenance of these system, these groups must also work well together.

Staff Organization Components

- Tele-ICU staff, including physicians, nurses, clerical support staff and IT support staff
- Physical ICU staff (same as above, but in the ICUs where the patients are located)
- Hospital (or health system) IT management and staff
- Tele-ICU system (or components) management and technical staff

<u>Clinical Processes</u>: For the tele-ICU staff to operate most efficiently with the clinicians in the physical ICUs, the two groups must have common understandings of their roles, standard procedures, and protocols. Without this standardization, it would be extremely difficult for them to manage similar patient situations in different ways. Specifically, a tele-ICU center monitoring patients in several ICUs that each uses different protocols for managing common, serious ICU conditions (such as sepsis or pulmonary distress) will provide much less value, than if they have coordinated their care around agreed upon protocols and standards.

While all patient care should be individualized, research over the last several years has shown dramatic quality improvements – including avoidance of adverse events – with the adoption of validated approaches to care. The role of tele-ICUs in promoting the adoption and adherence to clinical protocols can also foster the teamwork and collaboration needed for tele-ICU systems to successfully improve direct patient care. Therefore, not only does the adoption of such standardized processes increase the impact that tele-ICU monitoring can bring to patient care, but the standardization of these processes themselves can improve the quality of care.

It has also been speculated, but apparently not studied, that establishing the use of these protocols for ICU patients improves care and preventive interventions for non-ICU

patients with the same conditions through the diffusion of the practices and protocols via peer-to-peer clinician education.

Clinical Processes Component

- Standardized and validated process and protocols for common clinical conditions
- Acceptance of the use of these processes and protocols by clinicians and staff in both the physical and tele-ICUs

4. Evidence about Tele-ICU's Potential to Change Mortality

Studies examining how tele-ICUs can change outcomes for ICU patients are complicated because they are often not implemented as an isolated change to ICU care management. Rather, multiple changes may be started within short periods of time, e.g., tele-monitoring by intensivists, electronic medical records, CPOE, or care protocols for sepsis, ventilator management or glycemic control. In addition, the development and commercial availability of remote monitoring of ICU patients using tele-ICU systems has been a relatively recent phenomenon. Most systems have been operating less than 2 years, and formal analyses of these systems are only now occurring.³⁶ Therefore, at present the evidence demonstrating that tele-ICU systems can reproduce the dramatically improved outcomes associated with the intensivist model, or what factors involved with installing a tele-ICU system might yield the greatest improvement in clinical or economic outcomes is not comprehensive or complete. On the other hand, as discussed below, the available analyses do indicate that tele-ICU systems can improve quality, and while perhaps biased, one qualitative area of agreement among the leadership of tele-ICU systems was that if they or a family member was in an ICU, they would want them managed with a tele-ICU system.³⁷

Tele-ICU Impact on Mortality:

By extending the ability of the limited supply of intensivists to cover more patients, tele-ICU systems may achieve the reductions in mortality similar to those ascribed to the intensivist model. However, at present, there is not comprehensive published evidence to support a claim of reduced mortality from tele-ICUs -- one published study and some preliminary unpublished findings:

<u>Sentara study</u>. This single study is a comparison of outcomes in two ICUs of a regional hospital, Sentara, in southern Virginia before and after installation of the first tele-ICU system in the United States. The newly installed tele-ICU was observed for a 6-month period. Mortality and other outcomes were compared to those seen in these open, conventional ICUs for a previous 12-month.

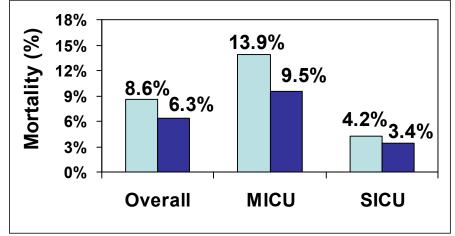
This study of a small number of patients had several methodological flaws and found a 25% reduction in overall mortality (averaged for ICU and hospital mortality) as well as improvements in other outcomes discussed below. It should be noted that mortality rates in these ICUs before installation were at the low end of the range reported in other literature, and with the tele-ICU system, reductions in mortality were only significant for the 10 bed Medical ICU and not the 8 bed Surgical ICU. However, this difference may have been partially due to the tele-ICU intensivists being allowed to participate in the care of 80% of the MICU private patients but only

³⁶ The first tele-ICU system in the US was installed at Sentara Health System in Virginia in 2000.

³⁷ It should be noted that these clinical care clinicians were working in mostly healthcare delivery systems that lacked comprehensive intensivist coverage prior to their tele-ICU systems.

Tele-ICU Report DISCUSSION DRAFT – 8/1/06

35% of SICU private patients.³⁸ It should be noted that VISICU supported most of the costs of the study and several of its officers were co-authors.³⁹



Source: Breslow, et. al. Critical Care Medicine, 2004.

Lehigh Valley Health System (PA). This hospital system installed a tele-ICU system in 2004. Their tele-ICU command center is connected to 6 ICUs at two hospitals: a community hospital and a university hospital. A pre-post assessment of outcomes in the community hospital ICUs indicates a reduction in mortality which were summarized in a telephone interview as:

- All-cause hospital mortality for ICU patients declined from 15% to 10%;
- Mortality for moderate severity ICU patients (APACHE II scores of 10-20) declined from 15% to 5%;
- Mortality for low severity patients' (Apache II <10) was unchanged.⁴⁰

Memorial Hermann Health System (Houston, TX)

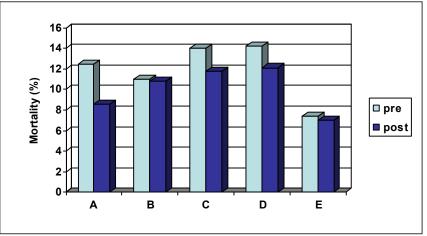
Preliminary data from this multi-hospital health system that has a tele-ICU system monitoring 8 open ICUs with about 140 beds, indicates reductions in mortality across five of their ICUs that have been operating since October 2004:

³⁸ Leong (2005)

³⁹ Breslow (2004)

⁴⁰ Telephone interview with S. Matchett, MD, Director of Telemedicine at Lehigh Valley Health System March 20, 2006. Mortality analysis for high severity patients was not significant due to the small number of these patients This analysis compared mortality rates for 3 months prior to initiation of their tele-ICU system with the same calendar months during its operations in the following year.

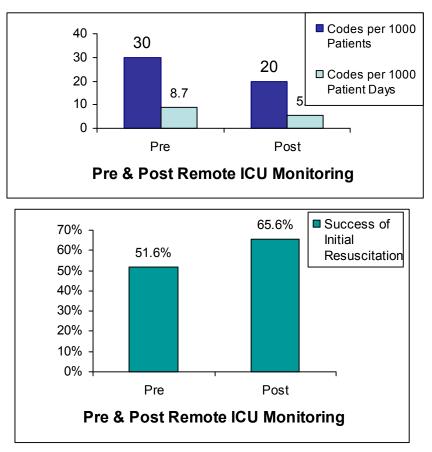
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Source: Dr. Liza Weavind, Medical Director, Memorial Hermann eICU®. Unpublished data

Health First:

Preliminary data from the Health First system indicates lower rates of cardiopulmonary codes and higher rates of survival from the initial code resuscitation. However, it has also been verbally reported that their overall hospital mortality rate for patients admitted to an ICU has not changed.



Source: "Remote ICU Management Improves Outcomes in Patients with Cardiopulmonary Arrest," J. P. Shaffer, et. al., Critical Care Medicine 2005; 33:A5

<u>Other Outcome Assessments in Progress.</u> Other hospital systems have not yet been able to replicate Sentara's published findings of a 25% drop in mortality with a tele-ICU system.

Sutter Health System has two tele-ICU command centers connected to 30 ICUs with 180 beds.⁴¹ They have not observed any sustained trend for either decreases or increases in ICU or in hospital mortality, but they believe that this may be because prior to installing their tele-ICU system, they had:

- Relatively good intensivist coverage;
- A relatively low rate of ICU mortality; and
- Mostly open ICUs.

They speculate that the combination of these factors may be precluding them from observing a significant drop in mortality with their tele-ICU system. Sutter continues to assess mortality and other outcomes – such as incidence of sepsis – and has observed clinical process improvements from standardizing their use of a number of accepted care protocols across the ICUs connected to their tele-ICU system. For Sutter, this standardization was also facilitated by most of the intensivists in the community being organized in a single practice group before the tele-ICU system was installed, and thus were was accustomed to joint decision-making.

Cornell Medical Center observed a 15% reduction in adjusted mortality in their Medical ICU when they compare the 12 months before installation to the 18 months afterward for their tele-ICU system.⁴²

Other assessments of tele-ICU outcomes are in progress at individual healthcare systems, including one by researchers at the University of Texas at Houston of the Memorial Hermann tele-ICU that is funded by he Agency for HealthCare Research and Quality.

⁴¹ They operate two command centers – one in Sacramento and one near San Francisco – to facilitate access by the intensivists who also work in their physical ICUs.

⁴² Personal Communication, June 2006, Dr. Callahan. Data being prepared for publication.

5. Evidence about Tele-ICU's Potential to Change Costs of Care

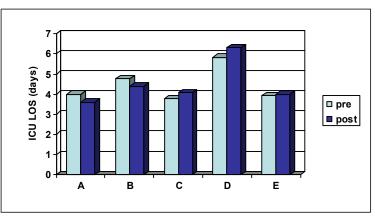
Calculating actual financial effects of tele-ICU systems is a complicated task because most hospitals' accounting systems are designed around billing and reimbursement rather than tracking actual costs on a per patient basis. Therefore, LOS in the ICU and the hospital (after discharge from an ICU) are standard units of measure for the cost of critical care. Given the high costs of patient days in ICUs, interventions that reduce LOS can significantly reduce overall costs. While many studies have used a 3:1 cost ratio for ICU to non-ICU hospital days, one study on two hospitals found that the first ICU day was about 400-500% the cost of an average post-ICU day, and subsequent ICU days were about 250-280% as costly as an average post-ICU day.

Tele-ICU Impact on Length of Stay (LOS)

The only peer reviewed, published assessment of tele-ICUs reported LOS data is from Sentara. This study reported statistically significant reductions in hospital LOS only for patients in the Surgical ICU, and reductions in ICU LOS for both ICUs: 5.62 to 4.84 days for the Medical ICU, and 3.30 to 2.59 days in the Surgical ICU. However, the percentage of patients where the tele-ICU intensivists were able to intervene in patient care different greatly between the MICU and SICU, and the accuracy of these financial conclusions has been questioned.⁴⁴

Memorial Hermann Health System (Houston, TX)

Some preliminary data (with risk adjustment based upon hospital billing information rather than specific clinical criteria), from this multi-hospital health system has shown mixed results for ICU LOS among 5 of their ICUs:





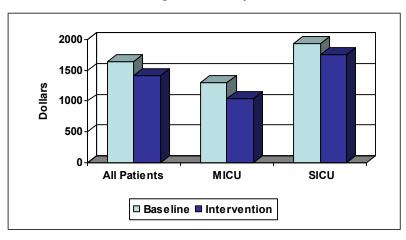
Despite differences in calculating actual costs of care for ICU patients, and adjusting for patient severity some, analyses have included information about overall financial

⁴³ Haplpern (2004), Rapoport (2003)

⁴⁴ Breslow (2004) For 1 of the 2 Sentara Hospitals the hospital length of stay reported for ICU patients was reported, in background financials, as reduced by 2 days. "Sentara-Norfolk ICU Financial Analysis" December 2001, unpublished briefing submitted to VISICU by Cap Gemini Ernst & Young. Available upon request from VISICU.

Tele-ICU Report DISCUSSION DRAFT – 8/1/06

performance. For example, the Sentara study included some financial results for average ICU daily costs, although as noted above, the accuracy of this data has been questioned.

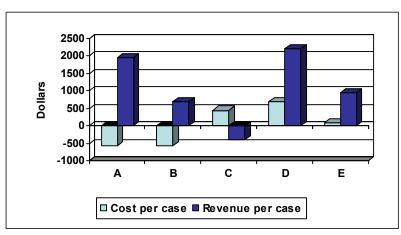




In addition, one tele-ICU system has observed mixed results for costs, revenues and overall financial performance of their ICUs following installation of their tele-ICU system:

Memorial Hermann Health System (Houston, TX)

Similar to their LOS findings, this multi-hospital health system has reported mixed financial effects of their tele-ICU system across five of their ICUs:

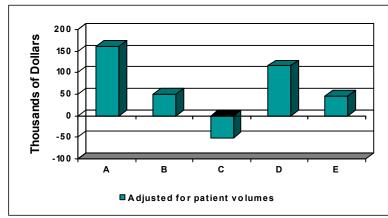


Change in Costs & Revenue per Case

Source: Dr. Liza Weavind, Medical Director, Memorial Hermann eICU®. Unpublished data

Change in ICU Monthly Financial Performance

Source: Breslow (2004)



Source: Dr. Liza Weavind, Medical Director, Memorial Hermann eICU®. Unpublished data

Calculating the overall financial performance of a tele-ICU system can involve simple or complex calculations related to the acquisition and operating costs compared to the performance changes produced by the tele-ICU system. One tele-ICU system director has proposed that the business case for a tele-ICU system be made primarily on its ability to reduce ICU LOS. A secondary factor should be an estimate of any increased volume of ICU patients that result from freeing up ICU beds.⁴⁵ The financial analysis based on these two factors should be equal to or greater than the amortized acquisition and annual operating costs:

Figure 1. Proposed ROI Calculation for a Tele-ICU System Based upon ICU LOS & Patient Volume

[AcC + OpC] ≤ [Savings from Decreased ICU LOS + Revenue from Increased ICU Patient Volume] AcC = Acquisition Costs; OpC = Operating Costs

⁴⁵ This can be achieved if beds are made available due to shorter LOS, and this effect was considered to be partially responsible for the positive revenue results presented in the Sentara study which found an increase of 7% more patients per month over their two ICUs. They calculated that this increased ICU revenues \$3.14 million over the 6-month study period and an analysis of these calculations has led one researcher to conclude that the findings could not be generalized to other settings according to an internal and unpublished evaluation. Another healthcare delivery system's pre-tele-ICU analysis indicated a negative value of \$750,000 if they achieved a 10% decrease in ICU LOS. But if they also added one additional patient per day to their ICU volume, the projected value changed to a positive \$2.5 million.

6. Other Cross-Cutting Quality and Cost Aspects of Tele-ICUs

In addition to the two core factors of reducing ICU LOS and increasing patient volume described in the previous section, there are a number of other factors that – while much harder to measure or financially quantify -- could be included in calculations of the overall financial impact of a tele-ICU system.

Of course, as with estimating changes to ICU LOS or patient volume, individual ICUs and healthcare delivery systems will certainly face different assumptions about outcomes for these other factors depending upon their organizational characteristics, clinical and community cultures, financial situations, and payer mixes.

These other factors that could be added to ROI and other value calculations include:

- A. Avoidance of complications in the ICU. This result is believed to underlie the ability of the tele-ICU system to directly reduce the ICU LOS, and indirectly the hospital LOS.
- **B.** More efficient delivery of care. By enabling the implementation and standardized protocols for treating and preventing common clinical situation and complications, more time and resources can be directly at treating patients' primary conditions, rather than addressing their subsequent problems. This factor is obviously a corollary of A above.
- **C. Improved productivity of clinical staff.** Aside from A and B above, the electronic information systems that are often installed or adopted along with a tele-ICU system, such as CPOE or an integrated EMR, can save staff time both in charting, as well as the time it takes to deliver care. For example, Lehigh Valley Health Network has noted that the electronic patient flow sheet for nurse charting part of their tele-ICU system has had a significant impact on the productivity of the ICU nurses. After implementation of these systems, ICU nurses increased their direct patient care time by 75 minutes each per 12-hour shift. Over a 30-day period, this equals 1000 hours of increased patient care with a 28 bed ICU with 15 nurses per 12-hour shift. Similarly, the CPOE system installed as part of their tele-ICU system decreased by almost 100 minutes (157 pre v. 65 post) the time it took to get an order for an antibiotic from being placed to being charted as having been delivered to the patient.
- **D. Improved staff morale and decreased turnover.** By improving the work-life satisfaction of clinical staff there can be less staff turnover, and since there is such high demand for both experienced critical care nurses and intensivist trained physicians, the costs of recruiting and training new hires can be very high.⁴⁶
- E. Extension of the productive work-life of clinical staff. Clinicians who become disabled or who have life/family situations that prevent them from working in the physical ICU can still be productive clinicians while working in the tele-ICU command center where the physical demands and scheduling may be more

⁴⁶ See "AACN Standards for Establishing and Sustaining Healthy Work Environments," AACN, 2005

accommodating than in the physical ICU. This benefit could expand the pool of available experienced critical care physicians and nurses, and thus help moderate any increase in compensation that could arise from the national shortage of these specialists. In addition, enabling these clinicians to continue working rather than retire or go on disability, could also improve a health system's overall finances. A corollary of D above, is that having a productive work environment may help keep intensivists working longer, which could partially alleviate the growing shortage of intensivists, since a recent study found that the average retirement age for critical care physicians was in the mid-50s.⁴⁷

- F. Enhanced educational and training opportunities. By having experienced intensivists and critical care nurses dedicated to the management of ICU patients and available to junior clinical staff and students at times when these types of resources are not present in the physical ICU, i.e. at night, there is an opportunity to conduct useful education and training exchanges rather than simply to focus on addressing the immediate clinical situation, which can be the situation when conferring with an on-call attending physician not in the tele-ICU.
- G. Increased patient, family and community perception of quality of care. By having intensivist physicians available around the clock, patients families – and by extension the community – will have a perception that care is better organized and that quality is higher.
- **H. Meeting Leapfrog standards.** Meeting these standards for intensivist coverage (See Appendix F), provides a stamp of approval for ICU care that can be used both to increase reimbursements from private payers who participate in the Leapfrog Group, but also to promote an improved image of quality care.
- I. Increased revenue from improved billing and coding. One tele-ICU system in Wisconsin reported that they were able to increase their revenue 30% because the tele-ICU system increased the accuracy of their billing.⁴⁸
- J. Reimbursement for services. Although physicians conducting remote monitoring and management of ICU patients with a tele-ICU system are not reimbursed for these services – as they would be if they were physically in the ICU – establishing some way for payers to directly compensate physicians or health systems for tele-ICU physicians services is an ongoing discussion, and would create a significant incentive to increase the adoption of tele-ICU systems.
- K. Grants to acquire tele-ICU systems or services. While payers are not directly reimbursing for tele-ICU management, several have provided grants to health systems to acquire and install tele-ICU systems. In addition, philanthropic organizations may also be helping to support local health systems to acquire or expand their tele-ICU services.49

Additional aspects of calculating an ROI for tele-ICUs will be discussed at the end of the next section: "Barriers to Broader Dissemination and Value Creation."

⁴⁷ HRSA (2006)

 ⁴⁸ Verbal report from Dr. Hine, at Froedtert-Medical College of Wisconsin, April 28, 2006.
 ⁴⁹ "LVH gets \$500,000 grant," The Morning Call, July 11, 2006.

7. Barriers to Broader Dissemination and Value Creation

While tele-ICUs are spreading, there are multiple, interrelated barriers to acquisition and successful operation of a tele-ICU system. These barriers can be categorized into financial, organizational and other:

Financial Barriers to Acquisition:

The costs for acquiring and operating a tele-ICU system can be divided into:

- Acquisition, installation, and training costs; and
- Ongoing operating and maintenance costs
- <u>Acquisition, Installation and Training.</u> Acquisition and training costs include the purchase and installation of hardware and software, and training the critical care staff how to operate the new systems.

A health system's actual acquisition costs will depend upon the starting capabilities of the devices in the ICUs, and how easily these can be integrated into the tele-ICU system. For example, the more clinical devices and information services (such as clinical labs and pharmacy) that can electronically deliver their information directly to the tele-ICU's electronic medical record (EMR), the less retrofitting or manual data entry will be required to make the tele-ICU system optimally functional. If either retrofitting or manual data entry is required, this increases either up-front acquisition costs or ongoing operating costs for additional staff. This process can also delay appropriate clinical monitoring and intervention by the tele-ICU intensivists. The extent to which electronic data exchange is a problem is currently unclear. All current manufactures claim complete interoperability, but some early users of the VISICU system report the need for significant hand data entry in their tele-ICU command centers.

The HealthTech Center has estimated the acquisition costs to a purchasing hospital system of the hardware and software to create a tele-ICU average \$48,500 per ICU bed connected to the command center.⁵⁰ Hospitals that have installed full systems report costs of over \$2 million for installing a tele-ICU center and its components beyond what they have spent on ICU electronic medical record systems.⁵¹

The estimated \$ 2-5 million to set up a command center, acquire and install the tele-ICU systems, and pay the initial salaries for the tele-ICU staff, may be a challenge for hospitals and health systems that lack significant financial reserves or borrowing capacity. This may be of particular concern if the tele-ICU system is not fully compatible with the physical ICU's hardware or software systems, thus requiring additional expenses to upgrade the physical ICU components, or purchase and install an EMR system for the physical ICUs. Hospitals without such resources may

⁵⁰ Personal communication?

⁵¹ FAST interviews with hospital systems. A list of organizations with whom interviews were conducted is in Appendix B.

be in locations where the shortage of intensivists is most severe and the leverage of tele-ICU coverage could have highest value. An alternative to purchasing and running a tele-ICU is for a hospital to buy tele-ICU monitoring and management services from another tele-ICU system. One independent tele-ICU has been established specifically to fill this market niche, and some healthcare delivery systems with tele-ICUs are considering providing tele-ICU services to local and regional independent hospital ICUs.⁵²

 Operating Costs. Operating and maintenance costs include expenses for staffing the tele-ICU command center, licensing fees for the software, and any periodic upgrades to the hardware or software. Additional costs could be associated with implementing new standardized care processes with the healthcare professionals in the ICU and the tele-ICU.

One published study of a tele-ICU managing two units calculated 6 month operating costs of \$248,000 for hardware and software leasing, technical support, and operating expenses, with physician staffing costs adding an additional \$624,000.⁵³ Other hospitals and health systems have verbally reported higher operating costs of upwards of \$1.5 million per year.

The operating costs of a tele-ICU can be significant, i.e. in the range of \$1-2 million annually for a single command center. These costs would include both the cost of hardware maintenance, software licenses and upgrades, as well as the salaries for the tele-ICU intensivist nurses and physicians. As noted above, additional operating costs may occur if the tele-ICU system is not completely interoperable with the electronic information from the hospital's information systems, and the extent of this problem and how fast it might be resolving is currently unclear.

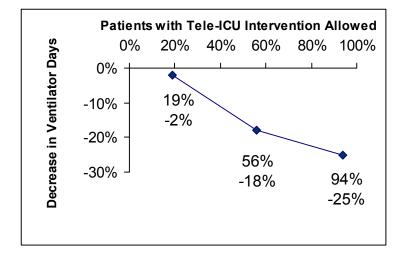
Organizational Barriers to Successful Operation of Tele-ICUs:

• The ability of tele-ICUs clinicians to influence care is also crucial to the success of a tele-ICU system. While tele-ICUs have been characterized as an "extra set of eyes" watching over the critically ill ICU patients, these "eyes" need to be effectively connected to care at the bedside. If the tele-ICU clinicians are not empowered by the ICU patient's physician of record (either directly or through hospital protocols), then they may know what needs to be done, but are unable to help the patient directly or via a surrogate. The potential importance of this ability can be seen in some preliminary data from the INOVA health system in Virginia. Their tele-ICU system monitors several ICUs, with each ICU having markedly different percentages of patients where the command center intensivists are empowered to intervene in patient care. Data from three of their

⁵² Creating a free-standing tele-ICU command center that would provide monitoring and management services to ICUs was the original business model for VISICU, but organizational and cultural barriers prompted them to shift to selling and servicing tele-ICU systems owned and operated by healthcare delivery systems.

⁵³ Breslow (2004)

ICUs indicates that a greater ability to participate in patient care translates into fewer ventilator days per patient:



Source: "Impact of Remote ICU Management on Ventilator Days," E. R. Cowboy, et. al., <u>Critical Care</u> Medicine 2005; 33:A1

This "intervention ability" effect may also be responsible for the different outcomes observed in the Sentara study between their MICU and SICU, since 80% of the private admitting physicians in the MICU allowed tele-ICU involvement with care, whereas it was only 35% in the SICU.⁵⁴

Another recent report found that mortality and ICU LOS were reduced more in a hospital that had most of its physicians allowing their patients to be managed by the tele-ICU compared to another hospital connected to the same tele-ICU system which had most of their physicians not allowing this type of patient management by the tele-ICU.⁵⁵

Another organizational barrier to success for a tele-ICU system is having the clinicians in both the physical ICU and the tele-ICU accepting and embracing the clinical value provided by the tele-ICU's systems, while also understanding its limitations. This success depends upon a collaborative relationship between the tele-ICU staff and the ICU staff. If the tele-ICU presence is resented or mistrusted by the ICU clinicians, then the value that the tele-ICU can provide will not be realized. Similarly, positioning the tele-ICU staff as supervisory or administrative could lead to conflict rather than collaboration. Overall, the members of the tele-ICU and physical ICU teams need to be seen as part of a larger team – just as the pharmacists and pathologists working on other parts of the hospital are part of the extended team working with the ICU staffs.

⁵⁴ Breslow (2004)

⁵⁵ Zawada (2006) (APACHE III mortality was reduced 76.5 v 16%, and ICU LOS was reduced 33% v. -2%)

Several tele-ICU system medical directors referred to the need to have physician and nurse champions in each ICU to both promote teamwork, and to encourage physicians to empower the tele-ICU physicians to be actively engaged in patient management decisions. The degree to which physicians in an open ICU allow the tele-ICU physicians to manage their patients, typically evolves as the comfort level with the tele-ICU system increases. One tele-ICU Medical Director reported that the percentage of patients under full management authority in their open ICU increased from an initial 20% to 70% over time. However, another tele-ICU Medical Director that faces significant resistance from community physicians remarked that a better title for the job would be "Change Management Director." One published report describing a healthcare delivery system's pre-implementation planning process, described it as involving weekly meetings of the project team for almost a year after the specific tele-ICU product was selected and the actual implementation date.⁵⁶

Another tele-ICU medical director discussed the need for education of ICU nurses so they think to call the tele-ICU first rather than the attending physician who may be at home. One way this tele-ICU system that covers multiple ICUs that are geographically distant is addressing this "out of sight, out of mind" situation, is to have the tele-ICU physicians visit each of the ICUs where they normally do not work. This, "putting a face with the tele-ICU voice" helps facilitate the working relationship between the tele-ICU center and the ICU staffs. The timeframe for making this culture shift is seen as 2-5 years – the same as this tele-ICU medical director said is cited for generally business operations to undergo a culture and operations change.

- The critical care clinicians need to be distributed appropriately among the physical and tele-ICUs in order to help establish a one-team approach. Such distribution can include rotation of clinicians between the physical and tele-ICUs, and requiring a certain level of expertise and experience to work in the tele-ICU where they may be directing care being provided by their peers in the physical ICU.
- The hospital IT executives and staff need to embrace the tele-ICU system, since they will be crucial for its proper installation, interface with existing hospital systems, maintenance, and ongoing support for both the physical and tele-ICU staffs. There also needs to be a good and collaborative working relationship between the hospital IT departments and the staff from the tele-ICU system or its components.

Other Barriers to Adoption:

 Health system leaders may be reluctant to invest millions of dollars in a tele-ICU system if they perceive that intellectual property protections (such as patents on

⁵⁶ Rabert (2006)

tele-ICU formation or alert algorithms) may limit their choices of tele-ICU systems or the ability of manufacturers to upgrade or modifying their tele-ICU systems in the future. Although the three companies with tele-ICUs currently installed in the US hospitals are involved in patent disputes around tele-ICU formation and alerting algorithms, and the status of these matters is in flux, it appears that these disputes will not inhibit the development or use of tele-ICU systems.⁵⁷

- A tele-ICU system may not be appropriate for all ICUs. About 15% of adult and virtually all neonatal ICUs are already staffed 24/7 with intensivists, so telemonitoring intensivists of these same patients may have little additional value. Also, the current monitoring algorithms are designed for adult patients and thus implementing a tele-ICU system in a pediatric or neonatal ICU (PICU or NICU) would presumably not be advisable at this time. However, as noted above, as the technology and health systems evolve, this situation may change, and tele-ICUs may become valuable for these types of ICUs where staffing or technology currently makes them questionable investments. (Also see Appendix E "Wild Cards.")
- Projecting Return on Investment (ROI). Calculating an appropriate ROI for the acquisition and operation of a tele-ICU system may be difficult for the leadership of a hospital or healthcare delivery system given the uncertainties of the outcomes that the tele-ICU system will yield because of variables such as staff acceptance, ability to integrate all the electronic systems, implementation of standardized processes of care, etc. As noted above, one healthcare system's pre-implementation calculations showed that if they had a 10% decrease in ICU LOS without any increase in patient volume, the net present value (NPV) would be a negative \$750,000, but if they had the same drop in LOS with one new patient per day in the ICU, the NPV becomes a positive \$2.5 million. The actual change in LOS and mortality a healthcare delivery system could expect by implementing intensivist coverage with a tele-ICU system would depend upon their baseline performance data.

The effect of a tele-ICU system on reimbursements for ICU care will depend upon the health system's payer mix. For payers using a DRG system, there will be little or no immediate change in revenue unless the complexity of their cases are reduced through the avoidance of complications. For HMOs that own the hospitals in their system, changes in non-fixed costs would benefit them directly. And for the remaining rare patients whose payers' reimburse hospitals on a cost-based fee schedule, (or for uninsured patients who may be presented with a bill based on some version of "actual costs" to the hospital), the financial effects to the hospital produced by a tele-ICU system will translate to reduced costs for these payers to the extent that the hospital's charge system reflects actual costs.

⁵⁷ iMDsoft, has filed an interference proceeding with the US Patent Office, claiming that it, its prior patent claims make many of VISICU's claims invalid. Cerner has sued VISICU on the grounds that VISICU's patents are invalid.

However, a healthcare delivery system may also see an increase in revenue with a tele-ICU system if it enables more accurate billing. One tele-ICU system noted 30% increase in their collections for ICU services from this effect.

Because third party payers have not generally paid for physicians providing clinical oversight of patients via tele-ICU systems, hospitals must budget for the costs of the physicians working in the command center without the expectation of reimbursement – either directly to the physician, or to the health system for the physician's services. Paying four FTE physician intensivists to cover a total of 14 shifts per week in the command center staffed would require a hospital to budget thousands of dollar per day for physician salaries.

Third party reimbursement to physicians for critical care services can range up to \$300/hour, with Medicare's allowable fees being somewhat less:

CPT Code	Description	Medicare National Average Allowable Charge
99291	Critical care, evaluation and management of the critically ill or critically injured patient, first 30 - 74 minutes	\$198.00
99292	Critical care, evaluation and management of the critically ill or critically injured patient, each additional 30 minutes (list separately in addition to code for primary service)	\$99.00

While there has been considerable discussion about payers providing reimbursement for these telemedicine services, none currently do, and an application for the creation of a CPT code for tele-ICU monitoring was recently reported to have been tabled by the American Medical Association's CPT Editorial Committee.⁵⁸ However, there is some experimentation in providing financial incentives for tele-ICU services. Two payers have reportedly made financial contributions to the initial purchase of tele-ICU systems, and a community organization recently gave an existing healthcare system a grant to expand their tele-ICU system.⁵⁹ Also, a physician-hospital organization reportedly is paying their physicians a yearly bonus for permitting the tele-ICU physicians to participate at a high level in managing care for the PHO physicians' patients in an open ICU. In addition, the data and quality reporting capabilities of tele-ICU system may help healthcare delivery systems meet payers expanding pay-for-performance expectations in the future.

An additional concern given the organizational and cultural barriers to the successful adoption of a tele-ICU system is that if the provision of tele-ICU services is seen as providing a positive ROI simply through the provision of services without any changes to patient LOS or complications, (see below) then the rush for acquisition and operation could occur without adequate staff preparation and education.

⁵⁸ "Current Controversies," National Assoc. of Medical Directors of Respiratory Care, Mar/April 2006.

⁵⁹ BlueCross Blue Shield plans in Illinois and Maine (Personal communications) and "LVH gets \$500,000 grant," The Morning Call, July 11, 2006.

Figure 2: Theoretical ROI Calculation for a Tele-ICU System Based upon Reimbursement:

[AcC + OpC] ≤ [Revenue from Reimbursement for Tele-ICU Services]

AcC = Acquisition Costs; OpC = Operating Costs

As has been seen in other tele-ICU systems, without adequate organizational preparation and buy-in, the clinical value both for direct patient care and improvements in protocol adoption and adherence can be significantly decreased or delayed. Therefore, from the payers perspective, any reimbursement for tele-ICU services could be expected to be tied to clinical outcomes or process measures consistent with the increasing emphasis on pay-for-performance within the US healthcare system.

8. Overcoming Barriers to Successful Adoption and Value Creation

For hospital and health system administrators, and 3rd party payers, determining how to invest in tele-ICU technology and create incentives for its adoption and appropriate use is a complicated proposition. As described at the end of Section 5, one tele-ICU director believes that the financial ROI case should be based upon direct cost savings represented by reductions in ICU LOS and the potential for increased patient volume.⁶⁰ Other positive effects could be included in this analysis as secondary and supporting reasons for investing in a tele-ICU system or services.

These other factors for measuring the clinical and economic value of tele-ICU systems include those listed at the end of Section 5, and some other specific measures that a healthcare delivery system could use to estimate the value they could receive from a tele-ICU system include:⁶¹

- 1. Stress Ulcer Prophylaxis
- 2. DVT Prophylaxis
- 3. Central Line Associated Bloodstream Infections
- 4. Ventilator Associated Pneumonia Prevention
- 5. Ventilator Days
- 6. Glycemic Control
- 7. Medication Errors

The other challenge hospital administrators and 3rd party payers face in considering financial support for a tele-ICU system is how to ensure that installing a system will yield the cost improvements that are expected. As described above, there are many operational and organizational challenges to making a tele-ICU system perform so that it improves the quality of care, and hence reduces costs.

Many tele-ICU systems have apparently been implemented without the overt expectation for a positive financial ROI. Rather, the overall expectation was that by meeting the Leapfrog Group's recommendations tele-ICU coverage would produce improved outcomes equivalent to those achieved by direct on-site intensivists staffing, (e.g. mortality, LOS, and operating costs).⁶²

Therefore, tele-ICUs are most likely to benefit those ICUs without current intensivists coverage, or for whatever cultural or organizational reasons have poorer than expected outcomes.

⁶⁰ See Figure 1, page [21]

⁶¹ The first four of these measures are the measures recommended by the Joint Commission's National Hospital Quality Measures for ICUs – see Appendix G

⁶² From interviews with tele-ICU Medical Directors.

Other important parameters that might be considered in predicting the likelihood a tele-ICU system will operate successfully within an existing healthcare delivery system are what degrees of clinical or economic value the system could produce include:

- Organization and culture of the medical community, and how willing they would be to embrace the tele-ICU system.
- Type of ICUs and current care organization that could be served by the tele-ICU:
 - Adult, PICU or NICU
 - Medical, Surgical, Neurological, Trauma
 - Open, Co-Managed, Semi-Closed, Closed, etc.
- Current level of adoption of validated protocols for treating common serious conditions, such as sepsis, glucose control, or ventilator management;
- Current technological state of the hospital's information systems, including EMR, radiology, pharmacy, clinical laboratory, etc.
- Availability of intensivists to staff the tele-ICU center
- Nursing staff characteristics that may affect staffing patterns and organizational change such as union status and contractual limitations.

A crucial element to overcoming these barriers to successful implementation of tele-ICU services is to have acceptance of the system and its services by critical care clinicians before installation. This can be accomplished with educational and "town hall" meetings to present the technology, case studies of its use elsewhere, and data on how it improves patient care and providers' work-life.⁶³ The need for these types of educational and informational sessions depends upon how familiar the clinician community (both critical care clinicians and community physicians who admit patients to the ICU) is with a tele-ICU system. For example, expansion of tele-ICU services by Sentara to other hospital ICUs in the geographic area around Hampton, VA is relatively easy since their system has been operational for over 5 years and it is widely known to the clinicians in the area. On the other hand, for clinicians in areas where there are no tele-ICU systems (e.g. see Map in Appendix D), the educational and information needs would be expected to be extremely large, and the process can take considerable time and involve extensive community discussion.

Other challenges to conducting successful educational and information sessions for clinicians in communities unfamiliar with the technology and operation of tele-ICU systems are similar to the adoption of other new medical breakthroughs and can include physician's concerns about loss of autonomy, financial barriers or disincentives, lack of physician awareness about the innovation, and lack of patient demand or awareness. These factors are not unique to tele-ICUs, and have been described for much simpler innovations such as the use of beta-blockers after myocardial infarction or regular retinal exams for diabetics.

A significant challenge to conducting educational and information sessions that change the perspectives of clinicians and healthcare system administrators is the scarcity of definitive evaluations of the value of tele-ICU systems. One way to address this

⁶³ Rabert (2006)

problem would be through focused evaluations and pilot projects to both demonstrate the effectiveness of tele-ICUs and lower the financial barriers to acquisition.

The metrics from these evaluations could include not only ICU LOS and hospital mortality, but also the full range of outcomes and process changes discussed above. In addition, these programs could be done both prospectively for systems preparing to install new systems or expand existing ones, or retrospectively for healthcare delivery systems looking to assess the performance of their tele-ICU system.

In an ideal world all these evaluations would be comprehensive and use comparable methodologies and risk adjustments. While, in the real world, most existing tele-ICU systems are conducting evaluations of their systems without an overall consistency for how these evaluations are conducted and what factors are measured. However, directors of many tele-ICU systems are trying to reach some agreement on these matters.⁶⁴ In discussing this challenge with the Stakeholder Working Group established for this FAST Initiative (See Appendix A), ICU LOS and hospital mortality were determined to be the most appropriate and simplest to measure for evaluating the clinical and economic performance of tele-ICU systems. It was also noted that the majority of California hospitals are reporting ICU outcomes and process measures using the Mortality Prediction Model II for risk adjustment.⁶⁵ Of course, individual healthcare systems will want to measure additional parameters as part of their management and evaluation activities as determined by their structure and ongoing needs because to the extent that they will be used to guide future operational investments and management initiatives, they should be planned with the concept in mind that organizations inherently manage what they measure.

From the perspectives of 3rd party payers – including insurers and employers – demonstration projects to evaluate the best ways to provide financial incentives for valuable implementation and operation of tele-ICU systems should also be considered because their financial ROI calculations may be different than the healthcare delivery system's, e.g. increased patient volume might be a negative factor. These projects would ideally be conducted at tele-ICU systems that have capabilities for measuring clinical and economic outcomes. The demonstration projects could include:

- Grants for purchasing and installing tele-ICU systems;
- Providing reimbursement for tele-ICU physicians' services when they are able to management interventions, i.e. they can both monitor and participate in the management of ICU patients; and
- Providing higher reimbursement to healthcare delivery systems that meet certain standards for ICU management or can demonstrate improved outcomes for specific ICU related conditions.

Grants Underwriting Tele-ICU Purchase:

⁶⁴ Personal communication from Amy Imm, MD – Chair of VISICU users group 2006-2007, June 2006.

⁶⁵ CHART 2006. It was also reported that the MPM methodology was selected over APACHE because it is less complex and time consuming, although it may also be less predictive.

The first of these could be relatively easy to structure and accomplish, and could involve simple grants to acquire and install a tele-ICU system, grants that are tied to certain performance measures (such as number of monitored beds by a certain date, or a requirement that a certain percentage of ICU patients are being actively managed by the tele-ICU), and grants to smaller hospitals to underwrite a portion of the infrastructure and educational costs for them to purchase tele-ICU services from another tele-ICU system.

Reimbursement for Tele-ICU Services:

Reimbursement of a healthcare system for intensivist services from a tele-ICU currently does not occur. For leading payers such as Medicare, while payment for these services is routine when the physician is physically at the patient's bedside, payment for telemedicine is not currently occurring. The reasons for this are both historical and financial. Historically physicians have not been paid for telephone or other consultations where they did not physically see the patient. And in recent years, Medicare has operated under a roughly zero-sum budgeting process, where increased spending in one area needs to be offset by roughly equal decreases in other areas. In this environment, if Medicare was going to reimburse for tele-ICU services, then payment for some other services would need to be reduced. In addition, current Medicare regulations they do not allow for reimbursment for telemedicine services.

The situation for private payers is somewhat different than Medicare – both in their ability to pay for additional things without necessarily directly reducing spending for something else, and in their not being prohibited by regulation from paying for telemedicine services. However, because most private payers use Medicare's reimbursement coding system and follow many of its rules, there are significant barriers to widespread payment for individual tele-ICU services.

To overcome these limitations, demonstration projects could be established to provide reimbursement for physicians services for ICU patients through a tele-ICU system. These payments could go directly to the physicians and thus reduce the need for the healthcare delivery system to cover the salaries of these physicians, or to the healthcare delivery system to partially offset these salary and other costs.

<u>Higher Reimbursement for Having Intensivist Coverage or Improved Outcomes:</u> Another avenue for healthcare delivery systems to receive reimbursement for tele-ICU services would be to increase payment to the hospital for the care of patients for the days they are in the ICUs connected to the tele-ICU system. One of the methodological challenges to this, is that the DRG payment system, because it is based upon diagnosis and not services delivered, does not distinguish patients between patients who have and have not been in the ICU. While additional DRG categories could be created to indicate that patient have been in the ICU, and how long they spent in the ICU, this could be a cumbersome process, could take a long time to develop, and if reimbursement was based upon these codes, it could create financial incentives for patients to be sent to the ICU or to spend more days in the ICU.

An alternative to expanding or appending DRG codes would be a demonstration project that would provide an higher payments for care for patients with DRGs that have a high likelihood of requiring ICU care if the hospital has tele-ICU services. Such DRGs could cover conditions such as respiratory failure, acute MI, stroke, or severe trauma. This type of project would be able to demonstrate the appropriateness of these higher DRG payments for the selected conditions, and could include requirements for specific data collection to demonstrate improved clinical outcomes and a calculation of the ROIs for the healthcare delivery system and the payer.

A Medicare demonstration program that has some similarities to this type of program is the Premier Hospital Quality Incentive Demonstration which provides financial incentives for hospitals that demonstrate higher quality for 5 conditions based upon their performance on quality related process and outcome measures.⁶⁶ This demonstration provides higher DRG payments to hospitals in the top two deciles during this 3 year demonstration project. In addition, hospitals will receive lower DRG payments if they score below performance baselines for the lower two deciles from the first year. As noted above, the extension of this type of demonstration project to ICU coverage and care is limited by its being tied to specific diagnoses.

Another alternative is to provide overall higher payments for healthcare delivery systems that meet specific process measures for their ICUs. This is the approach adopted by the Leapfrog Group, i.e. meeting their ICU physician staffing standards through intensivists physically present in the ICU or through tele-ICUs is part of the evaluation process for the hospital to receive higher contract payments from the private payers who participate in the Leapfrog Group.⁶⁷ To be successful this approach does not distinguish between tele-ICU versus physical intensivist coverage, and thus does not provide a financial incentive for both physical and tele-ICU intensivist services.

In addition, to be successful this approach needs to include the ability of the intensivists (either physically present or in the tele-ICU system) to actively manage care for ICU patients – a factor that is included in the Leapfrog Group's standards. (See Appendix F) While evaluations of ICUs shifting from open to closed status have not been extensively conducted, a review of available studies suggests a reduction in mortality and costs.⁶⁸ One study of non-cardiac medical patients in an ICU that transitioned from an open to a closed format found that hospital mortality remained in the 20-30% range despite an increase in patient severity, and that there was a dramatic increase (from 7 to 41%) in the nursing staff's confidence in the clinical decisions of their patients' primary care physician.⁶⁹ Moreover, the consensus amongst experts in critical care medicine is that closed or co-managed ICUs produce better outcomes.

⁶⁶ The 5 conditions are heart attack, heart failure, pneumonia, coronary artery bypass graft, and hip and knee replacement. Also see <u>www.cms.hhs.gov/HospitalQualityInits/35_HospitalPremier.asp</u>.

⁶⁷ Milstein (2000) Also see <u>https://leapfrog.mestat.com</u>

⁶⁸ Brilli (2001)

⁶⁹ Carson (1996)

Therefore, demonstration projects to assess how to overcome the significant organizational, cultural and financial barriers to successfully adoption of tele-ICU systems should include how to move from open toward co-managed or closed ICUs. Such demonstrations could be integrated into the reimbursement demonstrations discussed above, or conducted independently.

9. Conclusions and Recommendations

Technologies to permit remote monitoring and management of patients by specialty trained clinicians is a growing trend in the US healthcare system. The use of telemedicine for improving the care of intensive care unit patients was prompted by the finding that care of ICU patients by dedicated intensivists improves outcomes, the worsening national shortage of intensivists, and the advancements in computer, data transmission and data analysis technologies that make such remote monitoring and management possible.

The first practical implementation of a tele-ICU system occurred in 2000, and since then more than 30 systems have been installed. However, because of the complexity of these systems and the care of ICU patients, improving clinical and economic outcomes with tele-ICU systems has not been simple or easy. Depending upon the clinical culture of the healthcare delivery system and its community of physicians, there can be various financial, organizational and culture barriers to a successful adoption.

What has been seen from the limited analyses of existing tele-ICU systems is that there is evidence of overall improved clinical and economic outcomes for the healthcare delivery systems. However, the positive economic outcomes may not translate into a financial picture that could convince healthcare payers to reimburse for tele-ICU services because not all or enough of the financial benefit might return to them. Despite this lack of clear ROI for payers, the Leapfrog Group – a group of large national payers – has included intensivist coverage (through either physical presence in the ICU or via telemedicine) to be one of their criteria for qualifying healthcare delivery systems for higher payments for caring for the employees and beneficiaries covered by these employers.

While tele-ICUs have been adopted to cover about 10% of all adult ICUs that previously lacked intensivist coverage, there remains thousands of ICUs without such coverage. Because the initial costs for purchasing a tele-ICU system equipment, training staff and paying for the ongoing operating costs of the tele-ICU system (or purchasing tele-ICU services from another tele-ICU system) can approach \$100,000 per ICU bed the first year, and about half of that in subsequent years, in the face of uncertain ROIs, financial limitations and competing technology, infrastructure and training priorities, many healthcare delivery systems may not be able to justify the time and money for tele-ICU services.

Recommendations:

To lower the barriers to adopting more tele-ICU systems and better overall ICU coverage by intensivists, there are a number of demonstration projects and policy initiatives that could be implemented:

• More payers could follow the lead of the Leapfrog Group and provide financial incentives to healthcare delivery systems for having intensivist coverage for their ICUs. These incentives could be in the form of higher per patient payments to

the healthcare delivery system from each payer, or providing reimbursement to the intensivists in the tele-ICU command center in a manner similar to the reimbursement they already provide to these same clinicians when they see patients in the ICU.

- National, local and regional payers and community groups could provide financial support for the initial purchase of tele-ICU hardware and staff training. This has been done in a few instances already, and may be most beneficial in the future for the acquisition of tele-ICU services by independent hospitals outside of large urban areas that do not have the number of ICU beds to justify obtaining their own tele-ICU system and also may be unlikely to have the intensivists needed to staff the tele-ICU command center. While it could be argued that these hospitals have higher priority technology needs, obtaining tele-ICU services may provide a catalytic cultural focus that can help facilitate the adoption of these other technologies as well as a number of non-technological care improving practices and protocols.
- To help convince more payers, clinicians, and financial administrators of healthcare delivery systems that tele-ICU systems and services can really improve the clinical and economic outcomes for "their" patients and at "their" ICUs, focused demonstration projects and analyses should be conducted around the core outcomes of interest, e.g. ICU LOS, hospital mortality, as well as any additional clinical outcomes that are felt to be important to the local ICU culture, i.e. comparing open v. co-managed ICUs, workplace productivity, nursing retention and work satisfaction, etc. While the goals for these demonstrations will vary by baseline characteristics of the healthcare delivery systems, reductions of ICU LOS and hospital mortality of 10% from baseline were deemed reasonable by our Stakeholder Working Group, and this level of reduction is conservatively supported by the literature and expert opinion.⁷⁰
- In addition, as new tele-ICU systems are installed, efforts should be made to preplan for evaluating their performance, while realizing that the effectiveness of a tele-ICU system to change outcomes may take several months, and that even at one year, the full benefits may not be seen. All demonstrations and analyses of these types should also be constructed to demonstrate how to most efficiently conduct risk adjustments and measure the outcomes of interest.

For example, the California initiative for reporting quality data requires limited data collection windows to facilitate both data collection and reporting. The ICU outcome measures are based upon 200 consecutive patients or 3 months (whichever comes first), and ICU process measures are collected over approximately 14 days within a 30 day period.⁷¹ These limited data collection

⁷⁰ Lee (2002), Pronovost (2004)

⁷¹ See <u>https://chart.ucsf.edu</u>

requirements are consistent with the overall goals of this project (which was initiated by state legislation in 1991), to:⁷²

- Develop agreed upon measure sets for hospital reporting;
- Increase standardization of these measures;
- Provide high quality data management and reporting; and
- Provide transparency of hospital performance data.
- Two additional types of analysis that could be useful either retrospectively or prospectively – would be to assess:
 - What types of ICUs and patient characteristics, (i.e. by diagnostic group and/or severity), tele-ICU services provide the greatest value; and
 - What is the optimal staffing structure for a tele-ICU command center, (i.e. physicians, nurses, and other staff based upon the number of monitored beds for what types of ICUs.)

Information of this type would be useful for planning tele-ICU services for ICUs where coverage of all beds may not be financial possible, and where such partial coverage would require triaging of patients or potentially creating a virtual step-down sub-unit of beds within an ICU.

• A final area for demonstration would involve determining how to best educate clinical staffs about how to best utilize tele-ICU services. These types of demonstrations could involve both how to create and promote physician and nurse champions in each ICU, as well as how to promote the use of tele-ICUs for the adoption and monitoring of quality improving protocols and practices. While there have been attempts by organizations such as the Institute for Healthcare Improvement, the adoption of validated quality improving care practices is notoriously slow in the US healthcare system.⁷³ While there are verbal reports and preliminary analyses that tele-ICU systems have been important for the adoption and adherence to care improving protocols in the ICU (and speculation that these changes have diffused to other areas of the hospital), there is not believed to be any analyses or demonstrations about how to most effectively use tele-ICU systems or services as an enabling technology to maximize this benefit.⁷⁴

Next Steps:

• NEHI, working with partner organizations will be working with their tele-ICU Stakeholder Working Group on how to prioritize and execute the recommendations from this interim report. This process will include how to fund the highest priority demonstration and educational projects, and who are the

⁷² February 8, 2006, Letter from CHART (California Hospital Assessment and Reporting Task Force) Project Manager to JCAHO Core Measure Vendors

⁷³ www.IHI.org

⁷⁴ Parkview (2006)

most appropriate partner organizations for conducting these demonstrations.

- NEHI, working with local and national healthcare delivery organizations and payers will secure funding and technical guidance for conducting rapid demonstration projects that the Working Group and these organizations feel would provide them with the most important information for making decisions about the highest value implementation for tele-ICU systems.
- NEHI will participate in educational activities to help stakeholders of all types to understand the opportunities, issues, challenges and possible solutions related to the adoption of tele-ICU systems and services in response quality problems in ICU care and the national shortage of intensivists. Since there has recently been increased interest in tele-ICU technology and implementation, there could be opportunities for NEHI to partner with other organizations in these efforts.⁷⁵
- NEHI, working with its FAST Initiative Steering Committee and tele-ICU Working Group will evaluate the findings summarized in this interim report and consider how the evaluation of tele-ICU technologies should proceed according to the FAST Initiative's initial methodology to help promote the fast adoption of significant technologies.⁷⁶ These discussions will also how improve the initial methodology to be more efficient bringing other technologies through the FAST Initiative process.

⁷⁵ Advisory Board (2006), UHC (2006)

⁷⁶ See Appendix A for description of the FAST Initiative and its process

Appendices

- A Overview of FAST Initiative
- **B** List of Expert and User Interviews
- **C** Current Manufacturers
- **D** Dissemination of Tele-ICU Systems
- E Wilde Cards that Could Change Quality, Cost or Value Projections
- F Leapfrog 2006 ICU Staffing Leap and Criteria
- G Joint Commission's National Hospital Quality Measures for ICUs
- H Literature Sources

Appendix A – Overview of FAST Initiative:

The FAST initiative is a major policy project of the New England Healthcare Institute (NEHI) in collaboration with the Health Technology Center (HTC). The project seeks to create and test methods by which payers, providers, and policymakers can actively speed the adoption of selected high value innovations. The FAST Initiative will provide a vehicle for payers and providers to:

- Select from emerging technologies those with potential for improved patient outcomes and cost savings;
- Identify each selected technology's highest value applications (by patient groups, treatment settings, or appropriate organizational preparation and support); and
- Define and resolve the barriers to adoption of the innovation.

Role of the Tele-ICU Stakeholder Working Group:

The role of the Stakeholder Working Group will be to help the FAST Initiative come to one of the following conclusions about tele-ICUs:

- Should Work to accelerate the adoption of tele-ICUs with emphasis on its areas of highest valued uses;
- Do nothing to further the adoption of tele-ICUs; or
- Further evaluate the value of tele-ICUs.

To help reach one of these conclusions, the Stakeholder Working Group will be asked to discuss the value of tele-ICU systems in a two-step process. The first step will be to decide what are the important metrics for determining the value of tele-ICU systems. Such metrics could include:

- Mortality (ICU and/or hospital)
- Length of stay (ICU and/or hospital)
- Financial ROI
- Joint Commission Measures (VAP Prevention, SUD Prophylaxis, DVT Prophylaxis, Central Line Infections)
- System-wide process changes
- Protocol implementation (such as glycemic control, sepsis treatment)
- Workforce productivity

The second step will be to determine what evidence levels for the important metrics tele-ICUs must achieve for there to be compelling evidence that US hospitals and healthcare systems should be adopted faster.

The metrics and evidence levels the Working Group identifies as important then may be used by researchers -- working in collaboration with the FAST Initiative -- to design and implement research projects to determine if and how such performance of tele-ICU systems can be achieved.

A corollary question for both the researchers and the Working Group will be what are the parameters of US hospitals and healthcare systems that may determine their ability to achieve these levels of value from tele-ICU systems?

Fast Process:

[Insert Image]

Appendix B: List of Expert and User Interviews:

Name	State	City/Region	Notes
Sutter	CA	Sacramento/SF	2 Command Centers
Loma Linda	CA	Loma Linda	No system currently, but intensivist trained at Memorial Hermann
Health First	FL	Cape Canaveral	
Advocate	IL	Chicago	
Beth Israel	MA	Boston	Have Intensivist Coverage - No Tele-ICU System
Univ. of Maryland	MD	Baltimore	Mobile monitoring system – not full tele-ICU
Borgess	MI	Kalamazoo	
Advanced ICU Care	мо	St. Louis	Independent tele-ICU Center
Cornell	NY	New York City	Installed 2003 – Removed 2005
OhioHealth	OH	Columbus	
Lehigh Valley	PA	Allentown	
UPenn	PA	Philadelphia	
UT Houston	ТХ	Houston	AHRQ Funded Study
Memorial Hermann	ТХ	Houston	
INOVA	VA	Fairfax	
Sentara	VA	Hampton Roads	
University of Wisconsin	wi	Madison	Planning for Tele-ICU
Froedtert/Medical College of Wisconsin	WI	Milwaukee	2005
American Association of Critical Care			
Nurses	CA	Aliso Viejo	AACN
AHRQ	DC	Washington	Agency for Healthcare Research & Quality
SCCM	IL	Chicago	Society for Critical Care Medicine
CMS	MD	Baltimore	Centers for Medicare and Medicaid Services
iMDSoft	MA	Needham, MA	Manufacturer
Cerner	MD/MO	Baltimore/Kansas City	Manufacturer
VISICU	MD	Baltimore, MD	Manufacturer

Organizations Represented on Stakeholder Working Group:

- INOVA
- American Association of Critical Care
 Nurses
- Center for Medical Technology Policy (CMTP)
- Cerner Corporation
- iMDsoft
- Lehigh Valley Health System

- Massachusetts Technology Collaborative
- Memorial Hermann
- OhioHealth
- Pacific Business Group on Health
- Sutter Health Institute for Research & Education
- The Permanente Federation
- VISICU

Appendix C. Current Manufacturers:

The US market has one dominant vendor, VISICU who entered the market in 2000. Two other vendors, iMDSoft and Cerner, entered the US market in the past 2 years. These latter two companies offer multiple health information products.

US Market.

VISICU. The leading US vendor is VISICU, which was founded in Baltimore in 1998 by two intensivists. All but two tele-ICU systems in the US are VISICU's products. The firm claims installation of 28 ICUs with 2300 beds and contracts for another 7 eICUs®^{1, 2} serving about 150 hospitals and over 300 ICUs. VISICU is backed by Sterling and other venture capital firms, and became a publicly traded company on April 11, 2006 when it made an Initial Public Offering.

Cerner. This diversified health care systems and data company offers a tele-ICU product, Critical Care/ Critical Connections that has been installed in a hospital system in Kalamazoo, MI. Their approach to tele-ICU monitoring is similar to iMDSoft's in that it is built off their existing EMR and electronic charting of ICU nursing and physicians information. However, their smart alarms and data analysis focuses on severity adjustment analysis based upon their APACHE system.

iMDSoft.

iMDSoft's core products are clinical information systems called the MetaVision Suite, which includes a clinical information system for ICUs called MVICU and a similar system for the operating room environment called MVOR. Many of these systems are installed in Europe, and a few in the US. The MVICU clinical information system includes smart alarms that can be based upon multiple physiological parameters, and customized for each patient. These alarms are "open-sourced" and thus can be modified and added to by the health system customer. (MCIVU users can add or retrieve such customized alarms from a central library maintained by the company.)

iMDSoft's tele-ICU product (called MVCentral) is based upon its MVICU clinical information system. This system was first installed at the Lehigh Valley Health System in Allentown, PA. This installation in essence created the MVCentral system through a customized joining and modification of the MVICU clinical information system with data transmission and two-way video conferencing capabilities created by a local company. This new MVCentral product enables the tele-ICU staff to have access to the same clinical information system (including embedded and customizable smart alarms) as the physical ICU staff, while also having two way video conferencing capabilities to the patients' ICU rooms and the ICU family room.

¹ Personal Communication, Brian Rosenthal, March, 30, 2006.

² The term eICU® is trademarked by VISICU and, therefore, reserved to refer only to their product. (c.f. <u>http://www.visicu.com/eICU_usage.pdf</u>)

iMDSoft was founded in Israel and its US headquarters are in Needham, MA.

[Insert Picture] iMDSoft MVCentral monitoring station at Lehigh Valley Health System From ACT, Dec. 2004/Jan. 2005; <u>www.AcuityCare.net</u>

"<u>Home-Grown" Tele-ICUs.</u> In theory, hospitals and health systems could assemble their own tele-ICU systems, since many components of commercial systems can be purchased separately or developed internally. While "smart" data bases that track patient care, queue changes in care, and sound alarms may be patent or copyright protected, such systems could theoretically be custom-developed, or built internally. However, the costs and risks of doing so would seem to be prohibitive compared to buying commercially available systems, and despite rumors of the existence of such "home grown" tele-ICU systems, none have been found.³

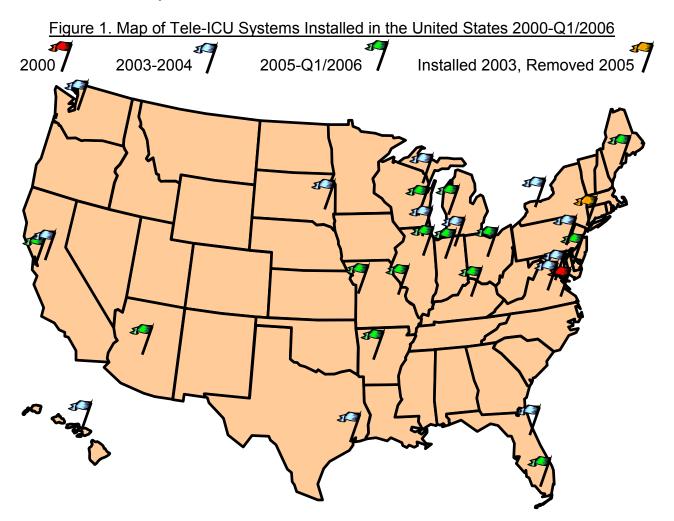
Others. Although VISICU, the market leader in remote ICU monitoring, entered this space from the remote monitoring and algorithms technology, other companies – including Cerner and iMDSoft – are entering this business area from their expertise and platforms in EMR and related technologies for critical care. Some other companies that are reported to be exploring tele-ICU products are EPIC and Eclipsys.

³ Nenov (1996) described a home-grown remote monitoring system that used the world wide web and personal computers to allow access to near real time data without significant data management from a single neurosurgical ICU. In addition, The Advisory Board 2006 report "The eICU: Beyond the Hype," referred to the iMDSoft system in Lehigh Valley as a "home grown" system.

Appendix D. US Dissemination of Tele-ICU Systems:

<u>**Commercial Systems.**</u> The first US commercial vendor of tele-ICUs was founded in 1998. There are now approximately 30 tele-ICU centers coordinating care for approximately 300 adult ICUs. Given the estimate of 3,000 US adult ICUs, this indicates a market penetration of roughly 10 percent of US adult ICUs.¹ Most of this growth has come since 2002 and apparently, all but two tele-ICUs have been installed by VISICU, the dominant US company.

<u>Rate of Dissemination</u>. As is indicated by figure 1, the rate of new installations increased noticeably in 2005.



¹ As noted in the introduction, there are approximately 6,000 US ICUs. Given that only 3,900 of those ICUs are for adult care and tele-ICUs are used only to manage adult care, we are estimating their dissemination as 300/3,900 not 6,000.

The pattern of where tele-ICUs are and are not being installed is not easily defined. A majority of installations since 2003 appear to be at private, relatively well-funded hospital systems in suburban and urban areas. Academic medical centers (many of which use the intensivist model), are not on the main track of dissemination. With some exceptions, neither are inner city hospitals or smaller rural hospitals. Thus, some areas where intensivist shortages are reported most severe and tele-ICUs may have the greatest value, may not be on the current track of dissemination. Hospitals facing financial strains – such as poorer, inner city hospitals – may not be target customers for the commercial systems because they are unable to make the necessary capital investments or fund the ongoing operating costs. Thus, the penetration of tele-ICUs into smaller, less well-funded and remote hospitals at this time appears to be much lower than the estimated 7% national dissemination. Further, if the 15% of ICUs currently estimated to have adequate intensivist coverage with tele-ICU systems, are excluded from this calculation, then tele-ICU penetration approaches 10%

It is possible that extensions to inner city and rural ICUs could fall in a second wave of dissemination. Hospitals that have acquired and established successful use patterns for their tele-ICUs could extend their command center coverage to hospital units where the intensivist shortage is most severe and the hospital or health system doesn't have the number of ICU bed to support an independent tele-ICU system, so they may be better served by obtaining tele-ICU services from another tele-ICU center or joining or forming a consortium of hospitals in a similar situation.²

Whether this will happen as a natural pattern of growth in response to need is unclear, but several health systems in the Midwest appear to be headed in this direction, including one tele-ICU center that is not affiliated with a hospital, but was established specifically to provide tele-monitoring services to community hospitals anywhere in the US.

² This was the case for Froedert in Wisconsin. Although their "Quality Consortium(?)" was not formed specifically around a tele-ICU, it was the first initiative undertaken by this multi- hospital consortium.

Appendix E. Wild Cards That Could Change Quality, Cost or Value Projections

Changing Nature of ICUs. The Health Tech Center has forecast that by ~2012, the "ICU without walls" will be a dominant model of hospital critical care. This a model in which critical care patients are disseminated throughout the hospital rather than clustered in the ICU, will be the dominant model in US healthcare.³ The current design of tele-ICU technology is focused on the ICU as a distinct area of the hospital. Several commentators assert that the IT systems for the tele-ICUs are perpetuating rather than helping to redesign hospital care processes. Tele-ICU technology could also be used to monitor critical ill patient being transported to hospitals, or for ICU patients being moved within the hospital for tests or procedures. A few hospitals are already experimenting in using mobile tele-ICU monitoring components in these situations.

Advancing tele-Monitoring Technology. Although at the current time, the display, processing power and transmittal bandwidth required for remote monitoring require that a separate physical command center be established and staffed for effective remote monitoring of ICU patients. However, as mobile processing power and bandwidth increase, and technologies that allow for mobile video displays increases, it is possible that remote monitoring of ICU patients could occur at mobile locations, i.e. via a laptop or other mobile computing/communication devices.

Advances in Algorithms and Decision Support Technologies. As patient monitoring algorithms become more sophisticated, they may make remote monitoring by critical care physicians less valuable. If such algorithms increasingly take on Al characteristics, (such as has occurred with EKG machines), they will be able to standardize care directly. The ultimate evolution of this process would be something akin to the fictional holographic doctor on Star Trek.

³ HealthTech Center, *Hospital Workforce Productivity*, 2005.

Appendix F– Leapfrog 2006 ICU Physician Staffing Leap and Criteria:

Leapfrog ICU Physician Leap Standards

(see below for scoring to achieve or approach standards)

A hospital fulfilling this leap assures that all patients in its adult or pediatric general medical and/or surgical ICUs are <u>managed or co-managed</u>¹ by physicians <u>certified in critical care</u> <u>medicine</u>² who:

• Are <u>ordinarily present in the ICU³</u> (on-site, or via telemedicine that meets Leapfrog specifications) during daytime hours a minimum of 8 hours per day, 7 days per week, and during this time provide clinical care <u>exclusively</u>³ in the ICU; and

Because sub-specialty certification is not offered in emergency medicine, emergency medicine physicians will be considered "certified in Critical Care Medicine" if they are board-certified in emergency medicine and have completed a critical care fellowship at an ACGME-accredited program.

On an interim basis, two other categories of physicians are considered by Leapfrog to be "certified in Critical Care Medicine":

Physicians who completed training prior to availability of subspecialty certification in critical care in their specialty (1987 for Medicine, Anesthesiology, Pediatrics and Surgery), who are board- certified in one of these four specialties, and who have provided at least six weeks of full-time ICU care annually since 1987. (The weeks need not be consecutive weeks.)

Physicians board-certified in Medicine, Anesthesiology, Pediatrics or Surgery who have completed training programs required for certification in the subspecialty of Critical Care Medicine but are not yet certified in this subspecialty.

³ Ordinarily and Exclusively Present in the ICU: "Ordinarily present in the ICU" refers to direct presence in the ICU (or presence via telemedicine) of an intensivist during the 8-hour period. While it need not be the same intensivist for the entire 8-hour duration, it is expected that the ICU(s) are primarily staffed by dedicated ICU intensivists who are ordinarily and exclusively present in the ICU(s). "Presence" does not mean staffed part-time by multiple physicians who are not ordinarily and exclusively dedicated to the ICU, nor does it mean the cumulative time that one or more intensivists spend in the unit visiting, rounding, consulting, or responding to pages.

The standard allows for normally expected intensivist activities outside of the ICU related to their responsibilities in the ICU (e.g. evaluating patients proposed for ICU admission), as long as intensivists are ordinarily present in the ICU and return immediately when paged. An intensivist present in one ICU immediately adjacent to another can be considered present in both units as long as s/he can respond to demands in both units as if s/he would if both units were one larger unit. While tele-intensivists can be used to meet the presence requirement, some on-site intensivist presence is still necessary to meet the Leapfrog specifications.

"Exclusively" means that when the physician is in the ICU, s/he has no concurrent clinical responsibilities to non-ICU patients.

¹ **Managed or Co-Managed**: The intensivist, when present (whether on-site or via telemedicine), is authorized to diagnose, treat, and write orders for a patient in the ICU on his/her own authority. Mandatory consults or daily rounds by an intensivist are not sufficient to meet the managed/co-managed requirement. However, an ICU need not be close-staffed to meet this requirement.

² Certified in Critical Care Medicine: A physician who is "certified in Critical Care Medicine" is a board-certified physician who is additionally certified in the subspecialty of Critical Care Medicine. Certification in Critical Care Medicine is awarded by the American Boards of Internal Medicine, Surgery, Anesthesiology and Pediatrics.

- At other times . . . ;
 - Return more than 95% of ICU pages within 5 minutes, based on a <u>quantified analysis</u>⁴ of pager response time;* and
 - Can rely on a physician or <u>FCCS-certified non-physician "effector"</u>⁵ who is in the hospital and able to reach ICU patients within 5 minutes in more than 95% of cases, based on a quantified hospital analysis of pager response time.*

* This may exclude low-urgency pages, if the paging system can designate low-urgency pages or if the hospital has an alternative scientific method for documenting high-urgency pages that are not returned within 5 minutes.

If you have no licensed or staffed adult or pediatric general medical and/or surgical ICU beds, then this section does not apply to your hospital. Simply answer "No" to the first question and finish the section. Your results will be displayed as 'N/A' on the public Web site.

Notes:

- 1. When a hospital publicly documents favorable ICU performance via scientifically rigorous and comparable performance assessment systems endorsed by The Leapfrog Group, favorable performance will replace or supplement the physician staffing Leap. The Leapfrog Group is currently collaborating with JCAHO and operators of ICU performance measurement systems to specify the terms "favorable performance," "scientifically rigorous," "publicly document," and "comparable."
- 2. Intensivist "presence" may be accomplished via telemedicine per Leapfrog's specifications (<u>More Information</u>⁶).

As an example . . .

- the number of urgent pages made to intensivists when they are not present in the unit (whether on-site or via telemedicine);
- the number of urgent pages made to other physicians or FCCS-certified effectors when no physician or FCCS-certified effector is physically present in the unit; and
- the number of times that responses exceed 5 minutes for those respective pages.

Hospitals can then cost-effectively estimate whether they meet the 95% timely response standards by dividing the average number of log exceptions per day by the average number of pages per day.

⁵ **FCCS-Certified "Effector":** FCCS certificates are awarded to nurses and doctors upon their successful completion of a brief course developed by the Society for Critical Care Medicine to improve/confirm critical care knowledge and skills. For more information visit <u>http://www.sccm.org/education/fccs_courses/index.asp</u>. At present, this is the only such course recommended by The Leapfrog Group's expert advisory panel. Intensivists or any other physicians who are certified in critical care medicine (or eligible based on residency training or fellowship) need not also be FCCS certified.

⁶ **Intensivist Presence via Telemedicine:** To meet the Leapfrog ICU requirement for intensivist presence in the ICU via telemonitoring, a hospital must affirm that its telemonitoring intensivist presence fulfills the following 10 key features based on a modification of the approach reported in Critical Care Medicine (Rosenfeld, B. et al. "Intensive care unit telemedicine: Alternate paradigm for providing continuous intensivist care," *Critical Care*

⁴ **Quantified Analysis of Pager Response Times:** Providers can monitor pager response times in multiple ways, as long as the data collection process is non-biased and scientific.

Providers could maintain an exception log in the ICU(s) on six randomly sampled days per year. On those days, ICU nurses could record:

3. On an interim basis, other categories of physicians may be considered by Leapfrog to be "certified in Critical Care Medicine" (More Information²).

[Scoring Criteria – Also see Attachment 4]

1)	Does your hospital opera	te any <u>adult or pediatric general</u>	Yes
	medical/surgical ICU bec	<u>ls</u> ⁷ ?	No

Medicine, Vol. 28, No. 1, pp. 3925-3931.) Note that, as with other Leapfrog specifications, these features must be met under ordinary circumstances.

- 1. An intensivist who is physically present in the ICU ("on-site intensivist) performs a comprehensive review of each ICU patient each day and establishes and/or revises the care plan. The tele-intensivist has immediate access to information regarding the on-site intensivist's care plan at the time monitoring responsibility is transferred to him or her by the on-site intensivist. When care is transferred back to the on-site intensivist, the tele-intensivist communicates (rounds) with the on-site intensivist to review the patient's progress and set direction.
- 2. When an intensivist is not on-site in the ICU managing or co-managing all ICU patients, a tele-intensivist is monitoring and able to manage all ICU patients for the remaining 24 hours per day, 7 days per week. "Monitoring" means the tele-intensivist has no other concurrent responsibilities, is immediately available to communicate with ICU staff, and is in the physical presence of the tele-ICU's patient monitoring and communications equipment. "Manage" means authorized to diagnose, treat, and write orders for a patient in the ICU on his/her own authority.
- 3. A tele-intensivist has immediate access to key patient data, including:
 - a) physiologic bedside monitor data (in real-time);
 - b) laboratory orders and results;
 - c) medications ordered and administered; and,
 - d) notes, radiographs, ECGs, etc. on demand.
- 4. Data links between the ICU and the tele-intensivist are reliable (>98% up-time) and secure (HIPAA compliant).
- 5. Via A-V support, tele-intensivists are able to visualize patients with sufficient clarity to assess breathing pattern, and communicate with on-site personnel at the bedside in real time.
- 6. Written standards for remote care are established and include, at a minimum:
 - a) tele-intensivists are certified by a national medical specialty board in critical care medicine;
 - b) tele-intensivists are licensed to practice in the legal jurisdiction in which the ICU is located;
 - c) tele-intensivists are credentialed in each hospital to which he/she provides remote care (can be special telemedicine credentialing);
 - d) activities of the tele-intensivist are reviewed within the hospital's quality assurance committee structure;
 - e) there are explicit policies regarding roles and responsibilities of both the on-site intensivist and the teleintensivist; and,
 - f) there is a process for educating staff regarding the function, roles, and responsibilities of the teleintensivist.
- 7. Tele-ICU care is proactive, with routine review of all patients at a frequency appropriate to their severity of illness.
- 8. A tele-intensivist's patient workload ordinarily permits him or her to complete a comprehensive assessment of any patient within five minutes of the request for assistance being initiated by hospital staff.
- 9. There is an established written process to ensure effective communication between the on-site care team and the tele-intensivist.
- 10. The tele-intensivist documents patient care activities and this documentation is incorporated into the patient record.

⁷ Adult or Pediatric General Medical/Surgical ICUs: The IPS Leap applies only to adult and pediatric general medical and surgical ICUs. When responding to this section, ignore units dedicated exclusively to patients with highly specialized conditions. E.g., ignore any Coronary Care Unit (CCU) that is distinct and separate from other adult/pediatric general medical/surgical ICUs. (If the same ICU is used for both coronary intensive care as well as other general medical-surgical conditions, include this unit in your responses.) Other examples of highly specialized

If 'Yes', continue:

2)	Are all patients in these ICUs managed or co- managed by one or more physicians who are certified in critical care medicine? (<u>More Information</u> ⁸)	Yes, all are certified Yes, based on expand certified No	
3)	 3) Is one or more of these physicians ordinarily present in each of these ICUs during daytime hours for at least 8 hours per day, 7 days per week, and do they provide clinical care exclusively in one ICU during these hours? (More Information³) 		Yes No
4)	4) When these physicians are not present in these ICUs on-site or via telemedicine, do they return more than 95% of pages from these		Yes No

units to ignore when responding are: neonatal intensive care units, separate trauma, burn, cardiovascular, cardiothoracic, neurology, or neurosurgery units. "Dedicated exclusively" means that general med-surg patients are not also cared for in these specialized units (except in rare overflow situations). If they are, then the IPS Leap applies to those units as well. Also ignore intermediate care or step-down units when responding to this section.

⁸ All Patients Managed or Co-managed by Intensivist:

"Managed or co-managed" means that the intensivist, when present (on-site or via telemedicine), is authorized to diagnose, treat, and write orders for a patient in the ICU in his/her own authority. Mandatory consults or daily rounds by an intensivist are not sufficient to meet the managed/co-managed requirement. However, to meet this requirement, an ICU need not be "closed", i.e., the intensivist becomes the attending of record during the patient's ICU stay.

"All patients" means any patient in the ICU.

"Physician certified in critical care medicine" (intensivist) means a board-certified physician who is additionally certified in the subspecialty of Critical Care Medicine. Certification in Critical Care Medicine is awarded by the American Boards of Internal Medicine, Surgery, Anesthesiology and Pediatrics.

Because sub-specialty certification is not offered in emergency medicine, emergency medicine physicians are considered certified in critical care if they are board-certified in emergency medicine and have completed a critical care fellowship at an ACGME-accredited program.

On an interim basis, two other categories of physicians are considered by Leapfrog to be "certified in Critical Care Medicine":

- Physicians who completed training prior to availability of subspecialty certification in critical care in their specialty (1987 for Medicine, Anesthesiology, Pediatrics and Surgery), who are board-certified in one of these four specialties, and who have provided at least six weeks of full-time ICU care annually since 1987. (The weeks need not be consecutive weeks.)
- Physicians board-certified in Medicine, Anesthesiology, Pediatrics or Surgery who have completed training programs required for certification in the subspecialty of Critical Care Medicine but are not yet certified in this subspecialty.

If you can answer Yes to question #2, but only if some or all of the physicians considered intensivists fall under these two interim definitions, answer "Yes, based on expanded definition of certified".

units within five minutes	, based on a <u>quantified analysis</u> ⁴ of pager	
response time?		
(This percentage may ex	clude low-urgency pages, if the paging	
system can designate low	-urgency pages or if the hospital has an	
alternative scientific met	hod for documenting high-urgency pages	
that are not returned with	in 5 minutes.)	
5) When these physicians a	re not present on-site in the ICU or not able	Yes
to reach an ICU patient v	vithin 5 minutes, can they rely on a	No
physician or FCCS-certif	ied non-physician "effector" ⁵ who is in the	
hospital and able to reach	n these ICU patients within five minutes in	
more than 95% of the cas	ses, based on a <u>quantified analysis</u> ⁴ of pager	
response time?		
(This percentage may ex	clude low-urgency pages, if the paging	
	-urgency pages or if the hospital has an	
	hod for documenting high-urgency pages	
that are not returned with	in 5 minutes.)	

If you answered "No" to any of questions #2-5 in this section, please answer the following questions for adult and pediatric general medical and/or surgical ICUs.

	1
6) Are all patients in these ICUs managed or co-managed by one or	Yes
more physicians certified in critical care medicine who are either:	No
• ordinarily present on-site in these units;	
• for at least 8 hours per day, 4 days per week, and	
• providing clinical care exclusively in one ICU during these	
hours?	
OR	
• present via telemedicine for 24 hours per day, 7 days per week	
when an intensivist is not present on-site,	
• meeting the other Leapfrog ICU requirements for intensivist	
presence in the ICU via telemedicine,	
• with an intensivist on-site at least 4 days per week to establish	
or revise daily care plans for each ICU patient?	
(More Information ³)	
7) If not all patients are managed or co-managed by physicians certified	Yes
in critical care medicine, are some patients managed by these	No
physicians?	
8) What is the date, if any, by which your hospital commits to meet the	ММҮҮҮҮ
Leapfrog IPS Leap fully?	e.g. 042006
9) Does your hospital have a board-approved budget that is adequate to	Yes
meet this commitment?	No
10) Does a clinical pharmacist make daily rounds on patients in these	Yes
ICUs?	No
11) Does a physician certified in critical care medicine lead daily multi-	Yes

Tele-ICU Report DISCUSSION DRAFT – 8/1/06

disciplinary rounds <i>on-site</i> on all patients in these ICUs?	No
12) When certified physicians are on-site in these ICUs, do they have	Yes
responsibility for all ICU admission and discharge decisions?	No

Leapfrog Scoring Algorithm for ICU Physician Staffing:

Fully implemented means:

- 1. All patients in adult and pediatric general medical and surgical ICU(s) are managed or comanaged by one or more physicians who are certified in critical care medicine (intensivists) (answered "Yes"to # 2); and
- One or more intensivist(s) is/are present in each ICU during daytime hours on-site for at least 8 hours per day, 7 days per week or via telemedicine 24 hours per day, 7 days per week, and provide(s) clinical care exclusively in this ICU during these hours (answered "Yes" to #3); and
- 3. When intensivists are not present (on-site or via telemedicine) in these ICUs, one of them returns more than 95% of pages from these units within five minutes. (answered "Yes" to #4); and
- 4. When an intensivist is not present (on-site or via telemedicine) in the ICU, another physician or FCCS-certified non-physician "effector" is on-site at the hospital and able to reach ICU patients within five minutes in more than 95% of the cases (answered "Yes" to #5).
- 5. When telemedicine is employed as a substitute for on-site time, it must meet the ten requirements [see footnote #6 to Attachment 3] including some on-site intensivist time to manage the ICU patients' admission, discharge, and care planning.

Good progress means:

- 1. All patients in adult/pediatric medical ICU(s) are managed or co-managed by one or more physicians who are certified in critical care medicine (intensivists) when those physicians are present, whether on-site or via telemedicine (answered "Yes" to #2); and
- 2. The hospital commits to meet the Leapfrog IPS standard fully by 03/31/2007 (answered < 04/2007 for #8); and
- 3. The hospital has a board-approved budget that is adequate to meet the IPS commitment (answered "Yes" to #9); and
- 4. The hospital has implemented either of the following practices:
 - a. Intensivists are present and manage or co-manage all patients in all ICUs either on-site at least 8 hours per day, 4 days per week or via telemedicine 24 hours per day, 4 days per week with on-site daily care planning at least 4 days per week (answered "Yes" to #6); use of telemedicine requires that additional Leapfrog telemedicine specifications are met; **or**
 - b. Clinical pharmacists make daily rounds on adult medical/surgical ICU patients (answered "Yes" to #10).

and

- 5. An intensivist:
 - a. leads daily, multi-disciplinary team rounds on-site (answered "Yes" to #11), or
 - b. makes admission and discharge decisions when on-site (answered "Yes" to #12).

A hospital that received **Good progress** partial credit in any two prior years of 2003-2005 survey versions based on commitment dates that have since lapsed will not be eligible for **Good progress** by committing to fully meet the leap at a future date.

Good early stage effort means:

- 1. The hospital commits to meet the Leapfrog IPS standard fully by 03/31/2007 (answered < 04/2007 for #8); and
- 2. The hospital has a board-approved budget that is adequate to meet the IPS commitment (answered "Yes" to #9); and
- 3. Some patients in the ICU(s) are managed or co-managed by an intensivist when present onsite or via telemedicine (answered "Yes" to # 6 or Yes to #7). Use of telemedicine requires that additional Leapfrog telemedicine specifications are met.

Willing to report publicly means:

The hospital responded to all the Leapfrog survey questions, but it does not yet meet the criteria for agood early stage effort.

Did not disclose this information means:

The hospital did not respond to this section of the survey, or the hospital was asked to complete the survey but has not submitted one.

N/A -- Standard does not apply means:

Appendix G - Joint Commission's National Hospital Quality Measures for ICUs:

(From Specifications Manual for National Hospital Quality Measures – ICU Version 1.0)

ICU Measure Overview

The ICU measure set is comprised of 6 measures. Four have been recommended for national implementation, while two measures are to be implemented as test measures not to be publicly reported or include in the Joint Commission accreditation process until additional information on training needs, reliability, and the impact of reliability on the predicted outcomes can be ascertained.

Measures recommended for national implementation

- ICU 1 VAP Prevention Patient Positioning
- ICU 2 SUD Prophylaxis
- ICU 3 DVT Prophylaxis
- ICU 4 Central Line Associated Bloodstream Infection

Test Measures

- ICU 5 ICU LOS (Risk Adjusted)
- ICU 6 Hospital Mortality for ICU Patients

Hospitals electing to collect data on the ICU measure set for the ORYX initiative will be expected to collect data on all measures in the set including the test measures with data collection to begin with July 2005 ICU admissions.

Based on results of testing, and the recommendation from the ICU Advisory Panel to obtain information on intensivist use in ways other than through collection of performance measure data, information on ICU structure and intensivist usage will be included on selection forms filled out by hospitals that elect the ICU measures as one of the measure sets used to fulfill the ORYX requirements.

The ICU measure set is unique in a variety of ways as illustrated below:

- This measure set is setting specific rather than condition specific and therefore not driven by ICD-9-CM codes.
- Two measures in the set are risk adjusted (ICU 5: ICU LOS, and ICU 6: Hospital
- Mortality for ICU Patients), however, unlike risk models used for existing measures, the required data elements for risk adjustment are not derived solely from administrative data.
- The data element *ICD Population Size* will be collected for the measure set, but is measure specific. For ICU 1-4, the population size will be defined by *ICU Patient Days*. For ICU 5, the population size is determined by the number of case level records with ICU discharge in the reporting month and with age at ICU admission equal to or greater than 18 years. Multiple ICU encounters for the same patient are included. For ICU 6, the population size is determined by the number of ICU case level records for the specific

hospital discharge month and an age at ICU admission equal to or greater than 18 years. The count includes no duplicates.

- The measure set lends itself to concurrent rather than retrospective data collection. As a result, many of the general data elements collected for existing measure sets (i.e., ICD-9-CM codes, discharge date, discharge disposition) may not be collected for several of the measures in the ICU measure set. Data elements required for collection are identified in the Alphabetical Data Element List preceding the Data Dictionary.
- This measure set contains the first measure reported as a ratio (ICU 4 Central Line Associated Bloodstream Infection). Measurement systems should reference the section on Steps to Calculate Rates and Measurements to understand measure calculation, and the ORYX Technical Implementation Guide for the required data elements for transmission.
- Measure constructs differ from existing measures on several levels.
 - Some measures in the set (i.e., ICU 4 Central Line Associated Blood Stream Infection) have data elements that are reported in aggregate [total number of central line days for the reporting healthcare organization (the denominator for ICU 4)], whereas the measure numerator, blood stream infections, are reported at a patient level.
 - While this set contains several proportion measures, the construct differs from existing measures in that the unit of measurement is at the day level rather than an episode of care. For example, for ICU 1, 2, and 3, the denominator is ventilator days, and the numerators are ventilator days with the HOB elevated to 30 degrees, SUD prophylaxis administered, or DVT prophylaxis administered. Therefore, each day there is an opportunity for the day to be placed in the denominator and/or the numerator during the reporting month. This differs significantly from existing measures such as in the AMI set for Aspirin prescribed at discharge where a single event during an episode of care places the patient in the denominator and potentially in the numerator.
- Because the unit of measurement for several measures in the set (ICU 1, 2, 3, 4) is at the day level, data may be collected daily and reported at the end of the observation month. Therefore, *Discharge Date* is not the driver for monthly data collection and reporting for these four measures, rather observation month.

Appendix H - Literature:

- 1. Advisory Board (2006) "The eICU: Beyond the Hype."
- 2. Anthony (2001) Anthony, L.C. et. al., "The eICU: It's not just telemedicine," Crit. Care Med. 29, No 8 (Suppl.) N183-9
- 3. Bekes (2004) Bekes, C. "PRO: Multiplier," Criti. Care Med. 32, No. 1 287-8
- 4. Berge (2005) Berge K. H., "Resource Utilization and Outcome in Gravely III Intensive Care Unit Patients With Predicted In-hospital Mortality Rates of 95% or Higher by APACHE III Scores: The Relationship With Physician and Family Expectations," Mayo Clinic Proceedings
- 5. Breslow (2004) Breslow, M. J., et. al. "Effect of a Multiple-Site Intensive Care Unit Telemedicine Program on Clinical and Economic Outcomes: An alternative paradigm for intensivist staffing," Crit. Care Med. 32, No. 1 31-38
- Brilli (2001) Brili, R. J., et. al., "Critical Care delivery in the intensive care unit: Defining clinical roles and the best practice model Critical Care Med. 29 No. 10, 2007-19. [Also see Guideline at <u>http://www.guideline.gov/summary/summary.aspx?&doc_id=5304&nbr=003627</u>]
- Carson (1996) Carson, S.S., et. al.. "Effects of Organizational Change in the Medical Intensive Care Unit of a Teaching Hospital: A Comparison of 'Open and "Closed Formats," <u>JAMA</u>, 276(4) 322-28
- 8. Chalfin (2004) Chalfin, D.B., "Implementation of standards for intensivist staffing: Is it time to jump aboard the Leapfrog bandwagon?" Crit. Care Med., 32 No. 6 1406-7
- 9. CHART (2006) California Hospital Assessment and Reporting Taskforce, Newsletter 1(2), page 2. <u>https://chart.ucsf.edu/docs/Chartnewsletter2.208.06.pdf</u>
- 10. Derek (2000) Derek, A. C., "Current and Projected Workforce Requirements for Care in the Critically III and Patients with Pulmonary Disease: Can We Meet the Requirements of an Aging Population," JAMA 284(21), 2762-2770
- 11. Dracup (2004) Dracup, K, "Navigating the Future of Critical Care," Am. Journall of Crit. Care, 13 No. 3, 187-8.
- Ewart (2004) Ewart, G. W. et. al., "The Critical Care Medicine Crisis: A call for Federal Action – A White Paper from the Critical Care Professional Societies," Chest, 125, 1518-1521.

- Haplern (2004) Halpern N. A., et. al., "Critical care medicine in the United States 1985-2000: An analysis of bed numbers, use, and costs," Crit. Care Med., 32 No. 6 1254-59
- Haupt (2003) Haput M. T., et. al., "Guidelines on crucial care services and personnel: Recommendations based on a system of categorization of three levels of care," Crit. Care Med 31 No. 11 2677-83 [Also see Guideline at <u>http://www.guideline.gov/summary/summary.aspx?doc_id=4915&nbr=003512</u>]
- 15. HRSA (2006) Health Resources and Services Administration's Report to Congress "The Critical Care Workforce: A study of the Supply and Demand for Critical Care Physicians"
- 16. Irwin (2004) Irwin, S. R., et. al., "The Critical Care Professional Societies Address the Critical Care Crisis in the United States," CHEST, 125, 1512-1513
- 17. Kelly (2004) Kelly, M. A., et. al., "The Critical Care Crisis in the United States: A Report from the Profession," CHEST 2004, 125, 1514-1517
- 18. Knaus (1985) Knaus, W. A., et. al., "APACHE II: A severity of disease classification system," Crit. Care Med., 13 No. 10 818-829
- Knaus (1991) Knaus, W. A., et. al., "The APACHE III Prognostic System: Risk Prediction of Hospital Mortality for Critically III Hospitalized Patients," CHEST, 100(6), 1619-36
- Kramer (2005) Kramer, A.A. et. al., "Combating 'Grade Inflation' in Measuring Risk Adjusted Mortality: Updated APACHE Mortality Predictions," CHEST, 128 (4): 150S
- 21. Leapfrog (2004) Beikmeyer, J.D., and Dimick J.B., "The Leapfrog Group's Patient Safety Practices, 2003: The Potential Benefits of Universal Adoption," The Leapfrog Group, February 2004
- 22. Leapfrog (2004b) The Leapfrog Group, "Fact Sheet: ICU Physician Staffing, April, 2004
- 23. Lee (2002) Lee, J.S. "Intensivist Staffing in Intensive Care Units (ICUs)," Research Synthesis, AcademyHealth, accessed 7/17/06 at www.academyhealth.org/syntheses/icu.htm
- 24. Lemshow (1988) Lemeshow S., et. al., "Predicting the Outcome of Intensive Care Unit Patients," Journal of American Statistical Association, 83 No 402, 348-356

- Lemeshow (1993) Lemeshow, S., et. al., "Mortality Probability Models (MPM II) Based on an International Cohort of Intensive Care Unit Patients," JAMA, 270(20) 2478-86
- Leong (2005) Leong, J. R., et. al., "Journal Club Critique: eICU program favorably affects clinical and economic outcomes," Critical Care 9 E33 (<u>http://ccforum.com/content/9/5/E22/</u>) [Commentary on Breslow (2004)]
- 27. Maccioli (2006) Maccioli, G. A., and Cohen N. H. "The Opportunity of Critical Care Medicine," American Society of Anesthesiologists Newsletter, 70 (4)
- 28. Milstein (2000) Milstein, A., et. al., "Improving the safety of Health Care: The Leapfrog Initiative," Eff. Clin.I Pract. 6: 313-316
- 29. Nenov (1996) Nenov, V. and Klopp, J.I, "Remote Analysis of Physiological Data from Neurosurgical ICU Patients," Journal of the American Medical Informatics Assn., Vol. 3, 318-327
- 30. Parkview (2006) Abstract from Parkview Health submitted to the ACCP, "ICU process improvement: Using telemedicine to enhance compliance and documentation for the Ventilator Bundle" (Provided by B. Rosenfeld from VISICU)
- 31. Peters (2004) Peters, S. G., "CON: Is the tele-intensive care unit ready for prime time?" Crit. Care Med. 32, No. 1 288-90
- 32. Pollack (1987) Pollack, M. M., et. al., "Accurate Predication of the Outcome of Pediatric Intensive Care: A New Quantitative Method," NEJM, 316 No. 3, 134-39
- Pronovost (1999) Pronovost, P.J., et. al. "Organizational Characteristics of Intensive Care Units Related to Outcomes of Abdominal Aortic Surgery," <u>JAMA</u>, 281(14) 1310-1317
- 34. Pronovost (2002) Pronovost, P.J., et.al. "Physician Staffing Patterns and Clinical Outcomes in Critically III Patients," JAMA 288 No. 17, 2151-62
- 35. Pronovosgt (2004) Pronovost, P.J., et. al., "Interventions to Reduce Mortality among Patients Treated in Intensive Care Units," Journal of Critical Care, 19 No. 3 158-164.
- Rabert (2006) Rabert, A.S., and Sebastian, M.C., "The Future is Now: Implementation of a Tele-Intensivist Program," The Journal of Nursing Admin., 36 No, 1, 49-54.
- 37. Rapoport (2003) Rapoport, J., et. al., "Length of Stay Data as a Guide to Hospital Economic Performance for ICU Patients," 41, No 3 386-97

- Rothschild (2001) Rothschild, J. M. "Closed" Intensive Care Units and Other Models of Care for Critically III Patients," Chapter 38 in "Making Health Care Safer: A Critical Analysis of Patient Safety Practices." Evidence Report/Technology Assessment: Number 43. AHRQ Publication No. 01-E058.
- 39. Schoenberg (1999) Schoenberg, R., et. al. "Making ICU Alarms Meaningful: a comparison of traditional vs. trend-based algorithms," Proc. AMIA Symp. 379-83.
- 40. Shorr (2004) Shorr A.F., et. al., "No longer the 'expensive scare unit'?" Crit. Care Med. 32 No 6, 1408-9
- 41. Thibault (1997) Thibault G. E.. "Prognosis and Clinical Predictive Models for Critically III Patients," Appendix D in "Approaching Death: Improving Care at the End of Life," National Academy Press, 456 pages.
- 42. UHC (2006) University HealthSystem Consortium "UHC Technology Report: Intensive Care Unit Telemedicine," March 2006
- 43. Young (2000) Young, M. Birkmeyer, J., "Potential Reductions in Mortality Rates Using and Intensivist Model to Manage Intensive Care Units," Eff. Clin. Pract., 6, 284-9
- 44. Zawada (2006) Zawada, E. T., et. al, "Relationship Between Levels of Consultative Management and Outcomes in a Telemedicine Intensivists Staffing Program (TISP) in a Rural Health System. "Abstract from the Avera ICU Research Group, Avera Health System submitted to the ACCP (Provided by B. Rosenfeld from VISICU)
- 45. Zimmerman (1998) Zimmerman J. E., et., al., "Evaluation of Acute Physiology and Chronic Health Evaluation III predictions of hospital mortality in an independent database," 26(8) 1317-26