Review Article

Critical Care Telemedicine: Evolution and State of the Art*

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Objectives: To review the growth and current penetration of ICU telemedicine programs, association with outcomes, studies of their impact on medical education, associations with medicolegal risks, identify program revenue sources and costs, regulatory aspects, and the ICU telemedicine research agenda.

Data Sources: Review of the published medical literature, governmental documents, and opinions of experts from the Society of Critical Care Medicine ICU Telemedicine Committee.

Data Synthesis: Formal ICU telemedicine programs now support 11% of nonfederal hospital critically ill adult patients. There is increasingly robust evidence of association with lower ICU (0.79; 95% CI, 0.65–0.96) and hospital mortality (0.83; 95% CI, 0.73–0.94) and shorter ICU (−0.62 d; 95% CI, −1.21 to −0.04 d) and hospital (−1.26 d; 95% CI, −2.49 to −0.03 d) length of stay. Physicians in training report experiences with telemedicine intensivists that are positive and increased patient safety. Early studies suggest that implementation of ICU telemedicine programs has been associated with lower numbers of malpractice claims and costs.

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The requirements for Medicare reimbursement and states with legislation addressing providing professional services by telemedicine are detailed.

Conclusions: The inclusion of an ICU telemedicine program as a major part of their critical care delivery paradigm has been implemented for 11% of critically ill U.S. adults as a solution for the problem of access to adult critical care services. Implementation of an ICU telemedicine program is one practical way to increase access and reduce mortality as well as length of stay. ICU telemedicine research including comparative effectiveness studies is urgently needed. (*Crit Care Med* 2014; 42:2429–2436)

Key Words: financial implications; history; outcomes; quality improvement; risk management; ICU telemedicine

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The state of the art for ICU telemedicine programs is rapidly changing under new public pressures for efficiency and cost containment in a paradigm of increasing societal needs for critical care services based on our aging population and stagnant workforce expansion (1). This review reports the growth of ICU telemedicine in the context of its history, summarizes the published evidence of its association with outcomes, alternative implementation strategies, studies of its impact on medical education, associations with medicolegal risks, program revenue sources and costs, regulatory aspects, and the ICU telemedicine research agenda.

GROWTH OF ICU TELEMEDICINE

The current prevalence of ICU telemedicine support in the United States, defined as inclusion of a continuous model ICU telemedicine program as part of an adult critical care delivery system, is 11% of the nonfederal hospital ICU beds. This rate approaches the penetration of bedside intensivist-led ICU models, which has recently been estimated to be 14% (2). Projections using the reported prevalence and annual growth rate of 1% per year (3) indicate that critical care delivery models that include telemedicine support will be more common in the United States than those using bedside intensivist-led programs by the year 2016. In addition to the continuous telemedicine care approach, episodic care models continue to grow. In early 2013, there were 175 active robotic devices, 56 of which are known to be supporting ICU patients in 25 North American ICUs that have been activated more than 10,000 times (4). The growth in the number of commercial vendors with technologies that include both audio and video mobile components into the episodic care space suggests that the number of physicians that use telemedicine tools to support critically ill patients may be larger than estimates of formal programs suggest.

THE HISTORY OF TELEMEDICINE

The term "telemedicine" is generally regarded as a broadly inclusive term for medical services delivered over distance using communication technologies. By this broad definition, telemedicine first began in 1906 with Einthoven, the father of electrocardiography (ECG). He investigated ECG transmission over telephone lines, publishing his findings in the *Archives Internationales de Physiologie* (5, 6). The definition of telemedicine has evolved over time as technology has improved. The current Merriam-Webster dictionary defines telemedicine as "the practice of medicine when the doctor and patient are widely separated using two-way voice and visual communication" (7).

During the 1960s, researchers nationwide began developing sophisticated computerized physiologic monitoring systems using process control computers commonly found in industrial automation applications. Weil et al (8) described the development of a seminal Shock Research Unit at the Los Angeles County General Hospital. The unit's process control computer system became operational in 1965.

The efforts of other pioneers in the field of computerized patient monitoring systems set the stage for telemedicine in the hospital environment (9, 10). All of these early demonstration projects resulted in medical analog data being converted into digital format. These data could then be easily transmitted down the hall, and eventually across the country, as long distance networks and the Internet were implemented.

The National Aeronautics and Space Administration (NASA) was instrumental in the development of technology used to transmit telemetry data from astronauts and demonstrated that physiologic variables could be successfully transmitted over great distances to allow NASA to monitor the effects of zero gravity on human physiology (11).

The 1980s saw an expansion of telemedicine due to ongoing advances in communication technologies, along with increased governmental support. During this period, ICU telemedicine consultative services were first documented (12). It was 2 decades after the failure of this consultative model that approaches which better integrated off-site intensivists with ICU teams were investigated. Investigators at Johns Hopkins University School of Medicine conducted a 16-week trial of 24-hour remote ICU care (using historic controls from a similar period from the previous year), showing a reduction in severity-adjusted ICU and hospital mortality rates by 60% and 30%, respectively (13). This established that remote ICU care could be performed effectively with substantial outcomes benefits when compared with historical controls.

Computerized data collection, analysis, display, and decision-making strategies have evolved to include comprehensive patient monitoring systems, clinical pathology laboratory systems, clinical decision support, picture archiving and communication systems, and radiology information systems. All of these modern technologies support and empower telemedicine architectures. In the ICU environment, the intensivist model is recognized as providing benefits by improving patient safety and quality of care (14), and like other telemedicine tools, ICU telemedicine programs are increasingly being used to increase access to high-quality critical care.

Recent advances in telecommunication technologies have led to more alternative forms of ICU telemedicine. Detailed descriptions of the spectrum of approaches to ICU telemedicine and available technologies have recently been published (15).

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ICU TELEMEDICINE PROGRAM OUTCOME STUDIES

There is a growing body of knowledge regarding comprehensive/continuous ICU telemedicine programs that comprised mainly of clinical practice studies that report the outcomes of implementation in one or more ICUs. Program implementation has generally been associated with lower mortality and shorter length of stay (LOS), but this has not been the case universally (13, 16–24) (**Table 1**), and studies including Thomas and Morrison have failed to find significant improvements. A recent meta-analysis (25) of published studies that mostly use a before and after design concluded that the risk of dying in the ICU for the ICU telemedicine group was 0.79 of that of the preintervention group (95% CI, 0.65–0.96), the relative risk for dying in the hospital was 0.83 (95% CI, 0.73–0.94), and the implementation of an ICU telemedicine program was associated both with shorter ICU (–0.62 d; 95% CI, –1.21 to –0.04 d) and hospital LOS (–1.26 d; 95% CI, –2.49 to –0.03 d). One striking aspect of studies that report outcomes is the heterogeneity of approach with regard to the intervention itself. The processes and care delivery procedures that change at the time of ICU telemedicine program implementation are often not well characterized. A recent task force on ICU telemedicine concluded that we need both improved tools for measuring these changes and a better understanding of the links among ICU processes and outcomes (26). Following the suggestions of the task force has allowed new insights into why outcomes vary.

Results from clinical practice trials are reflective of outcomes under conditions encountered in practice and interpretation should be guided by consideration of how closely the conditions, under which the trial was conducted, reflect those present where implementation is being considered. In addition, there are several important potentially confounding factors that can bias results when strict randomization is not used. These include quality improvement initiatives, changes in staffing patterns, changes in work hours or schedules, and the introduction of new treatments or preventive strategies that are concurrent with the intervention. Two of the studies (Kohl et al [24] and Lilly et al [27]) listed in Table 1 adjusted or controlled for trends that occur over time like the introduction of a quality assurance project or new treatment modalities. Other important considerations are the extent to which the statistical analyses employed prevented false attribution due to the play of chance and changes in the ICU population due to effects of the intervention on case mix or volume. Before and after studies of interventions that increase access to ICU services will alter the study population in a nonrandom manner. Accordingly, increased efficiency of care delivery can reduce the number of cases for whom ICU admission was declined, were transferred to another institution, or transitioned to palliative care. Managing these cases increases volume and acuity with little effect on fixed costs and a disproportionately small impact on variable costs. Although increases in volume and acuity that exceed the costs of care have welcome effects on financial outcomes, they represent changes in the population that complicate interpretation of before and after studies.

Another challenge to aggregating the results of these before and after studies is that introduction of an ICU telemedicine program is a complex multifaceted intervention that impacts several ICU care delivery processes that can be different among the studies being aggregated. The current meta-analysis approach to this problem is limited by its inability to

TABLE 1. Outcomes of ICU Telemedicine Program Implementation

	n		Duration (Mo)		Acuity[a]		Hospital Mortality		Hospital Length of Stay (d)	
Study	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Rosenfeld et al (13)	225	201	8	4	41	38	11.6%	4.5%	9.2	9.3
Breslow et al (16)	1,396	744	12	6	39	38	12.9%	9.5%	12.8	11.1
Marcin et al (17)	116	47	11	24	7.5	9.6	NR	NR	NR	NR
Thomas et al (18)	2,034	2,108	32	25	35	34	12.0%	9.9%	9.8	10.7
Zawada et al (19)	188	2,445	12	30	38	44	NR	NR	10.1	7.8
McCambridge et al (20)	954	959	16	10	57	58	21.4%	14.7%	9.1	9.2
Morrison et al (21)	1,371	1,430	4	4	49	47	9.9%	10.1%	7.7	7.9
Lilly et al (22)	1,529	4,761	22	13	45	58	13.6%	11.8%	13.3	9.8
Willmitch et al (23)	6,504	18,152	12	36	2.8	2.95	12.3%	11.3%	11.4	10.4
Kohl et al (24)	246	1,499	12	12	46	54	11%	6%	15.6	15.1
Lilly et al (27)	11,558	107,432	12.5	32	47	53	11%	10%	10.3	9.7

NR = not reported.

[a]Acute Physiology and Chronic Health Evaluation III/IV score or Pediatric Risk of Mortality (Marcin), Simplified Acute Physiology Score II (Thomas), or APR-DRG (Willmitch).

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precisely identify individual process factors for the studies that they include. Studies that have performed primary analyses of datasets that include measures of processes and outcomes have identified components of an ICU telemedicine intervention that are associated with larger reductions in mortality and LOS. These factors include higher frequency of intensivist case review within 1 hour of ICU admission (23), more frequent review of performance data with hospital leadership, higher levels of adherence to ICU best practices (23), more rapid responses to alerts and alarms, more frequent interdisciplinary rounds, and more effective ICU committee as judged by ICU clinical leaders (27). In each case, the changes in process impacted outcomes in the direction expected from the safety and quality literature.

The effects of episodic ICU telemedicine technologies have been less well documented and studied. There is evidence that the time required for a neurointensivist or neurosurgeon to evaluate and intervene for an acute neurological deterioration of a critically ill adult is significantly shorter when a robotic ICU telemedicine technology is available (28). Furthermore, the practicality of interactive consultation using telemedicine tools to provide urgent confirmation of neurological findings, neuroradiological review of the head CT scan, calculation of the National Institutes of Health Stroke Scale score, and the ability to make a valid recommendation regarding the administration of tissue plasminogen activator for patients suffering a stroke is now well established (29–32). Telestroke programs are increasingly being used to improve access to these services (32). Recent investigations have provided evidence that these programs can provide cost savings (33).

ICU TELEMEDICINE AND MEDICAL EDUCATION

Concerns regarding potential unintended effects on the educational processes for residents and fellows because of the presence of an ICU telemedicine program within a teaching hospital have prompted an increasing number of studies. The potential of limiting a resident's sense of independence and preventing experiential learning through micromanagement is a valid concern. Studies of the impact of ICU telemedicine programs on residents and fellows to date have not detected micromanagement impedance to experiential learning and in fact most have welcomed access to a critical care specialist to assist with off-hour management questions that do not rise to the level of awakening or interrupting an off unit bedside attending physician.

The ICU telemedicine paradigm uses clinical decision-support systems, which are able to detect impending instability and intercept serious medical errors. Given this, the ICU telemedicine team is better equipped to augment the learning process through real-time feedback regarding a suboptimal care plan or a missed diagnosis than can be supported by traditional means (34). The interception and prevention of adverse events is advantageous to the resident or fellow because it also prevents the emotional toll of errors that harm patients and enhances tacit knowledge cultivation. The ICU telemedicine intensivist can also provide feedback to a bedside faculty supervisor regarding resident performance as well as earlier recognition of educational gaps and opportunities. Continuously available systems also provide a platform for mentoring of less experienced ICU nurses by seasoned ICU registered nurses and nurse practitioners that staff the support center. Bedside faculty members can employ the ICU telemedicine intensivist to provide additional monitoring and oversight for those residents and fellows that may benefit from varying levels of off-hour support.

Survey studies of residents and fellows inform us that ICU telemedicine is readily accepted and is seen by house staff as improving their care of patients. One report from a training institution where residents rotate in medical ICUs with, and without, telemonitoring found that 82% of residents felt this technology improved patient care and improved the care they deliver when on call (73%) (35). The majority preferred to train in an ICU with telemonitoring (62%) (36). They noted that ICU telemedicine was useful in ventilator management (70%), initial management of an unstable patient (64%), code supervision (64%), management of acute respiratory change (62%), blood gas and acid base interpretation (62%), goal-directed therapy and management (61%), and respiratory failure recognition (60%). ICU telemedicine was least helpful with end-of-life issues (45%) and assisting in central catheter placement (42%). A second institution reported their findings after changing the first call for patient-related issues to an ICU telemedicine team during the overnight period. Seventy-seven percent of the residents felt that the integration of an ICU telemedicine team improved patient safety. Thirty-seven percent of residents felt that the addition of the ICU telemedicine program was a valuable educational experience, but 51% were neutral about the addition (37). A majority of residents (63%) felt they were better able "to focus on urgent patient issues." In addition, 51% reported the change increased their ability to "experience uninterrupted periods of rest" (37). The experience, to date, indicates that the additions of an ICU telemedicine program provide more, and welcome, off-hour resources for residents and fellows.

LEGAL AND REGULATORY ASPECTS OF ICU TELEMEDICINE

Legal and regulatory aspects of ICU telemedicine include requirements for licensure, credentialing, privileging, malpractice liability (38), and payment for services (39). The tenth amendment relegates health and safety policy to the states, accordingly each state has vested medical boards with the power to require licenses for practicing medicine. This has resulted in requirements for telemedicine physicians and affiliate practitioners to hold a valid license in each state where they are providing evaluation and management services including consultation (38). Case law makes it clear that breeching these requirements can result in criminal penalties (40). ICU telemedicine providers must also meet Centers for Medicare and Medicaid Services requirements for credentialing and privileging (38). Telemedicine programs are required to perform professional practice reviews and most use performance metrics related to

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interventions and vigilance that can be generated from the systems that the providers use. Standardization of these measures is desirable because it would also enable meaningful interprogram comparisons. Current technologies are compliant with privacy law, and most institutions use the notification or consent standards that they specify for other forms of monitoring such as oximetry and telemetry.

Current legal opinion holds that telemedicine providers meet legal requirements for liability claims when they have a physician-patient relationship and breech a duty to conform to the standard of care that results in sustained harm with ascertainable damages (35). A commonly expressed concern among providers is that the use of telemedicine tools in the management of critically ill adults could increase the frequency of malpractice claims and costs. Typically, the reasoning is that since the providers are not on-site, they will be perceived to be in a less defensible position. The legally appropriate comparison is to current practice that includes the delivery of remote orders and remote assessment telephonically. There is long experience with care plans that have been crafted after verbal reports from nurses, physicians in training, and other professional disciplines at the bedside. Experience has taught us that telephone orders are not a leading cause of malpractice claims. There may be comfort in knowing that with an ICU telemedicine program that provides continuous monitoring, the availability of first-hand information, direct observation of the effects of treatments, direct order writing, and more timely documentation of review and action plans, the frequency of claims has been reduced at large self-insured institutions.

Importantly, the extent to which these theoretical advantages translate into reduced frequency of claims and incurred costs is now being measured. The best information regarding the association of ICU telemedicine programs with medicolegal risks comes from a large multistate, nonprofit healthcare system that implemented an ICU telemedicine service covering 450 ICU beds that are located in five states that uses activity-based cost accounting methods and presents externally audited financial reports. The ICU telemedicine program was implemented in phases starting in 2006 with the majority of individual ICU telemedicine implementations completed before 2010. The frequency of malpractice claims and incurred costs for critically ill adults were significantly lower at sites with an ICU telemedicine program than at those that had not implemented ICU telemedicine (**Fig. 1**) (mean and CIs calculated and plotted using SigmaPlot version 11 (SAS Institute, Cary, NC); study performed under a waiver of informed consent from the University of Massachusetts Human Subjects Committee). After full implementation, annual incurred costs were less than half a million USD. Implementation of the ICU telemedicine program was associated with a reduction in claims volume to less than half what it had been before the implementation of a continuous monitoring ICU telemedicine program (Fig. 1, upper panel). Importantly, these large cost-per-claim reductions that were observed in the adult ICU population were not observed in groups of patients of that healthcare system that were not supported with an ICU telemedicine program. A second large self-insured healthcare system has not had malpractice claims for critically ill adult patients over more than 5 years of ICU telemedicine experience. Although these early results and the lack of malpractice reports from electronic searches of case law are promising, it is premature to conclude that continuous monitoring ICU telemedicine programs are expected to reduce the frequency and costs of malpractice claims for future implementations. On the other hand, there is no suggestion that medicolegal risk is increased.

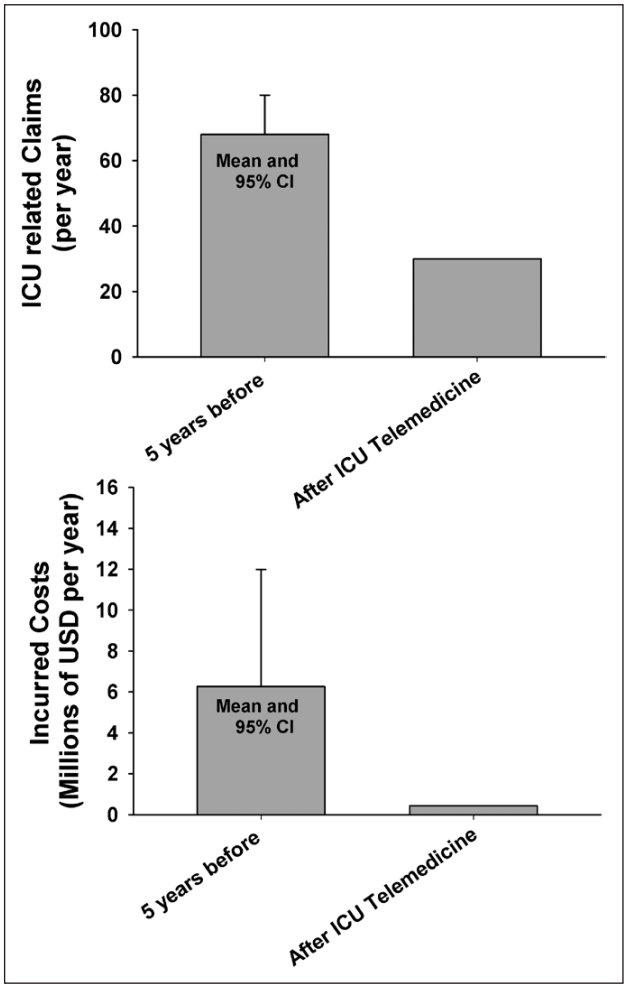

Figure 1. ICU-related claims and incurred costs for the 5 years before and in the year after implementation of an ICU telemedicine program.

FACTORS TO TAKE INTO ACCOUNT WHEN CONSIDERING AN ICU TELEMEDICINE SOLUTION

The foremost consideration is to determine the goals of the organization, and the obstacles to those goals, that the ICU telemedicine program can address. In many instances, ICU telemedicine solutions are implemented to fill gaps in ICU physician availability and to leverage existing intensivist resources across larger

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or geographically dispersed populations. A critical consideration and prerequisite for the success of an ICU telemedicine solution, like most other technologies that involve changes in clinician behavior, is whether the leadership team can broke change in the current organizational climate. Although the process of change management is outside the scope of this discussion, organizations need to perform a critical assessment of the cultural and organizational barriers that might compromise operational improvement. Acceptance and support of nursing, pharmacy and other critical care disciplines, is an equally important component of successful implementation. Last but not the least, an ICU telemedicine program requires information system's support for data access, transmission, audio-video conferencing capabilities, remote access, and interfaces to electronic medical records and other electronic sources of patient information including laboratory tests and information from bedside monitors and devices. Current practice varies with regard to the hours of intensivist staffing of the support center. Programs that support ICUs that do not have on-site provider coverage or use ICU telemedicine intensivists to manage patient flow across several ICUs often provide 24/7 intensivist support. Detailed descriptions of the financial investment involved, human resources, including physician and nursing requirements, technical aspects, organizational readiness, and intellectual property considerations are presented as **supplemental data** (Supplemental Digital Content 1, http://links.lww.com/CCM/B20) and have been published (41, 42). The effective use of ICU telemedicine resources has allowed many hospitals that do not have on-site intensivists to manage high-acuity critically ill patients.

PROGRAM REVENUE AND PROFESSIONAL SERVICE REIMBURSEMENT

Reimbursement, or payment, for telemedicine services is rapidly evolving. Currently, reimbursement for ICU telemedicine services is very restricted. There is very limited experience with remuneration for ICU telemedicine patient evaluation and management even in states with mandates and that reimburse for other telemedicine services (43). An outstanding compilation of the current requirements for each state is presented by the Center for Connected Health Policy (43). The current status of Medicare/Medicaid and private payer reimbursement, regulatory issues for ICU telemedicine providers, and nonprofessional sources of revenue are presented as supplemental data (Supplemental Digital Content 1, http://links.lww.com/CCM/B20).

ICU TELEMEDICINE RESEARCH

The Critical Care Societies Collaborative, made up of the American Association of Critical Care Nurses, American College of Chest Physicians, American Thoracic Society, and Society of Critical Care Medicine, convened a panel to review current research and make recommendations for research in ICU telemedicine (26). Studies to date do not consistently describe the organization and management of participating ICUs prior to introducing the ICU telemedicine program, nor is there consistency in defining the tele-ICU intervention. Thus, the preexisting clinical context is difficult to evaluate, and the ICU telemedicine program, which often introduces multiple interventions at the same time, makes it difficult to understand the specific mechanism of the effect. In order to improve ICU telemedicine research, there should be a standardized lexicon for describing the preimplementation ICU environment and for defining the ICU telemedicine intervention.

Key knowledge gaps include the optimal structure of ICU telemedicine programs, identifying key components and best practices in ICU telemedicine, and the relation of the intervention to the structure and organization of the ICU. There is opportunity in the areas of how ICU telemedicine is delivered, the relative contribution of the components of this bundled intervention to patient care outcomes, and the effect on evidence-based ICU practices. More research is needed on outcomes for patients, providers, and hospital systems. Ideally, comparative effectiveness studies, controlling for temporal, patient, organizational, and system level confounders can be designed. With more standardization in the delivery of ICU telemedicine, multi-institutional clinical research in the field of critical care medicine could be implemented.

SUMMARY

Critical care delivery models that include a formal ICU telemedicine program are continuing to grow and are projected to be more common than bedside intensivist-led, closed ICU models (currently 14% of ICUs) by 2016. The inclusion of an ICU telemedicine program as a major part of a critical care delivery paradigm is increasingly considered as a potential solution for the problem of inadequate access to adult critical care services and as a practical way to control costs and reduce the levels of variation among providers with regard to how critical care services are delivered. Implementation of an ICU telemedicine program has been advocated by policy groups as a practical way to meet the objectives of the patient safety movement (44). A continuously available and comprehensive ICU telemedicine program combines critical care board-certified physicians and other critical care professionals with electronic systems that allow real-time intervention and longitudinal performance tracking. This approach is based on well-established engineering principles that leverage real-time oversight by experienced critical care professionals to increase quality and efficiency and reduce costs of care (44). The ability of remotely located continuously available ICU team members to make critical care evaluation and management services more available is now being explored. The ability of ICU telemedicine programs to increase adherence to ICU best practices and of the intermittent form to shorten times to specialist intervention is increasingly accepted. Meta-analyses of ICU telemedicine program implementation report improved mortality, LOS, and document substantial and unexplained variation among implementations. Research is needed to provide insight into this variation. There is increasing information regarding the costs of

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implementing an ICU telemedicine program (42), and these costs are expected to decrease as more vendors appear to be entering the market. The transition to accountable care organizations and value-based reimbursement paradigms has created an urgent need for studies that better define the effects of program implementation on ICU case volume, acuity, and the societal costs of care.

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REFERENCES

1. Angus DC, Kelley MA, Schmitz RJ, et al; Committee on Manpower for Pulmonary and Critical Care Societies (COMPACCS): Caring for the critically ill patient. Current and projected workforce requirements for care of the critically ill and patients with pulmonary disease: Can we meet the requirements of an aging population? *JAMA* 2000; 284:2762–2770
2. Lilly CM, Zuckerman IH, Badawi O, et al: Benchmark data from more than 240,000 adults that reflect the current practice of critical care in the United States. *Chest* 2011; 140:1232–1242
3. Lilly CM, Thomas EJ: Tele-ICU: Experience to date. *J Intensive Care Med* 2010; 25:16–22
4. Reynolds EM, Grujovski A, Wright T, et al: Utilization of robotic "remote presence" technology within North American intensive care units. *Telemed J E Health* 2012; 18:507–515
5. Einthoven W: Le telecardiogramme. *Arch Int Physiol* 1906; 4:132–164
6. Blackburn H Jr: Translation of The Telecardiogram by W. Einthoven. *Am Heart J* 1957; 4:14
7. Merriam-Webster, Inc: Merriam-Webster online. 1996. Available at: http://www.m-w.com/. Accessed May 21, 2013
8. Weil MH, Shubin H, Rand W: Experience with a digital computer for study and improved management of the critically ill. *JAMA* 1966; 198:1011–1016
9. Sheppard LC, Kouchoukos NT, Kurtts MA, et al: Automated treatment of critically ill patients following operation. *Ann Surg* 1968; 168:596–604
10. Osborn JJ, Beaumont JO, Raison JCA, et al: Measurement and monitoring of acutely ill patients by digital computer. *Surgery* 1968; 64:1057–1070
11. Bashshur R, Lovett J: Assessment of telemedicine: Results of the initial experience. *Aviat Space Environ Med* 1977; 48:65–70
12. Gundy BL, Jones PK, Lovitt A: Telemedicine in critical care: Problems in design, implementation, and assessment. *Crit Care Med* 1982; 10:471–475
13. Rosenfeld BA, Dorman T, Breslow MJ, et al: Intensive care unit telemedicine: Alternate paradigm for providing continuous intensivist care. *Crit Care Med* 2000; 28:3925–3931
14. Pronovost PJ, Angus DC, Dorman T, et al: Physician staffing patterns and clinical outcomes in critically ill patients: A systematic review. *JAMA* 2002; 288:2151–2162
15. Reynolds HN, Rogove H, Bander J, et al: A working lexicon for the tele-intensive care unit: We need to define tele-intensive care unit to grow and understand it. *Telemed J E Health* 2011; 17:773–783
16. Breslow MJ, Rosenfeld BA, Doerfler M, 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* 2004; 32:31–38
17. Marcin JP, Nesbitt TS, Kallas HJ, et al: Use of telemedicine to provide pediatric critical care inpatient consultations to underserved rural Northern California. *J Pediatr* 2004; 144:375–380
18. Thomas EJ, Lucke JF, Wueste L, et al: Association of telemedicine for remote monitoring of intensive care patients with mortality, complications, and length of stay. *JAMA* 2009; 302:2671–2678
19. Zawada ET Jr, Herr P, Larson D, et al: Impact of an intensive care unit telemedicine program on a rural health care system. *Postgrad Med* 2009; 121:160–170
20. McCambridge M, Jones K, Paxton H, et al: Association of health information technology and teleintensivist coverage with decreased mortality and ventilator use in critically ill patients. *Arch Intern Med* 2010; 170:648–653
21. Morrison JL, Cai Q, Davis N, et al: Clinical and economic outcomes of the electronic intensive care unit: Results from two community hospitals. *Crit Care Med* 2010; 38:2–8
22. Lilly CM, Cody S, Zhao H, et al; University of Massachusetts Memorial Critical Care Operations Group: Hospital mortality, length of stay, and preventable complications among critically ill patients before and after tele-ICU reengineering of critical care processes. *JAMA* 2011; 305:2175–2183
23. Willmitch B, Golembeski S, Kim SS, et al: Clinical outcomes after telemedicine intensive care unit implementation. *Crit Care Med* 2012; 40:450–454
24. Kohl BA, Fortino-Mullen M, Praestgaard A, et al: The effect of ICU telemedicine on mortality and length of stay. *J Telemed Telecare* 2012; 18:282–286
25. Wilcox ME, Adhikari NK: The effect of telemedicine in critically ill patients: Systematic review and meta-analysis. *Crit Care* 2012; 16:R127
26. Kahn JM, Hill NS, Lilly CM, et al: The research agenda in ICU telemedicine: A statement from the Critical Care Societies Collaborative. *Chest* 2011; 140:230–238
27. Lilly CM, McLaughlin JM, Zhao H, et al: A multi-center study of ICU telemedicine reengineering of adult critical care. *Chest* 2014; 145:500–507
28. Vespa PM, Miller C, Hu X, et al: Intensive care unit robotic telepresence facilitates rapid physician response to unstable patients and decreased cost in neurointensive care. *Surg Neurol* 2007; 67:331–337
29. Audebert HJ, Schwamm L: Telestroke: Scientific results. *Cerebrovasc Dis* 2009; 27(Suppl 4):15–20
30. Silva GS, Farrell S, Shandra E, et al: The status of telestroke in the United States: A survey of currently active stroke telemedicine programs. *Stroke* 2012; 43:2078–2085
31. Schwamm LH, Rosenthal ES, Hirshberg A, et al: Virtual TeleStroke support for the emergency department evaluation of acute stroke. *Acad Emerg Med* 2004; 11:1193–1197
32. Pervez MA, Silva G, Masrur S, et al: Remote supervision of IV-tPA for acute ischemic stroke by telemedicine or telephone before transfer to a regional stroke center is feasible and safe. *Stroke* 2010; 41:e18–e24
33. Switzer JA, Demaerschalk BM, Xie J, et al: Cost-effectiveness of hub-and-spoke telestroke networks for the management of acute ischemic stroke from the hospitals' perspectives. *Circ Cardiovasc Qual Outcomes* 2013; 6:18–26
34. Myers MA, Reed KD: The virtual ICU (vICU): A new dimension for critical care nursing practice. *Crit Care Nurs Clin North Am* 2008; 20:435–439

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35. Kuszler PC: Telemedicine and integrated health care delivery: Compounding malpractice liability. *Am J Law Med* 1999; 25:297–326
36. Mora A, Faiz SA, Kelly T, et al: Resident perception of the educational and patient care value from remote telemonitoring in a medical intensive care unit. *Chest* 2007; 132:Meeting Abstract
37. Coletti C, Elliott DJ, Zubrow MT: Resident perceptions of a tele-intensive care unit implementation. *Telemed J E Health* 2010; 16:894–897
38. Spradley P: Telemedicine: The law is the limit. *Tulane J Technol Intellect Prop* 2011; 14:307–334
39. Gupta A, Sao D: The constitutionality of current legal barriers to telemedicine in the United States: Analysis and future directions of its relationship to national and international health care reform. *Health Matrix* 2011; 21:385–405
40. Hagelseth vs. Superior Court: Superior Court of San Mateo County. Docket Number A115390. 2007
41. Fifer S, Everett W, Adams M, et al: Critical Care, Critical Choices: The Case for Tele-ICUs in Intensive Care. Cambridge, MA, New England Healthcare Institute, Massachusetts Technology Collaborative, 2010, pp 1–64
42. Kumar G, Falk DM, Bonello RS, et al: The costs of critical care telemedicine programs: A systematic review and analysis. *Chest* 2013; 143:19–29
43. Center for Connected Health Policy: State Telehealth Laws and Reimbursement Policies: A Comprehensive Scan of the 50 States and the District of Columbia. Oakland, CA, California Health Care Foundation, 2013, pp 1–184
44. Ries M: Tele-ICU: A new paradigm in critical care. *Int Anesthesiol Clin* 2009; 47:153–170

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