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Medical informatics in the intensive care unit: An overview of technology assessment

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Effective patient care in the intensive care unit (ICU) depends on the ability of clinicians to process large amounts of clinical and laboratory data. Recently, medical informatics applications have been developed to store and display patient information and assist clinical decision-making. Despite the proliferation of these systems and their potential to improve patient care, there are no comprehensive health technology assessments incorporating considerations of safety, functionality, technical performance, clinical effectiveness, economics, and organizational implications. The objectives and methods of informatics evaluations depend on the type of application and the stage of development. Qualitative and quantitative nonrandomized evaluations of comprehensive information management systems such as electronic medical records, picture archiving, and communications systems should concentrate on technical and functional issues. Specific applications like clinical decision support systems and computerized patient care systems are designed to improve patient outcomes and clinical performance; randomized controlled trials to assess clinical effectiveness are important in their assessment. Although studies of these applications in the ICU setting are increasing, there are currently very few published, randomized trials.

Information technology in healthcare

Medical informatics is a relatively recent area of study with the objective of examining and optimally managing the flow of information in biomedicine and healthcare. The sub-disciplines and clinical applications of medical informatics have been recently reviewed.¹ These applications were initially developed to support hospital administrative functions and facilitate information retrieval through access to bibliographic databases. More recently, applications relevant to clinical practice have become available. The classification in Table 1 presents examples such as electronic medical records (EMR) for recording patient information, computerized physician order entry, picture archiving and communication systems (PACS) for displaying radiographic images, computerized patient care systems (eg, computerized mechanical ventilation²), and computerized clinical decision support systems (CDSSs). A CDSS is defined as any software designed to directly aid clinical decision-making, whereby characteristics of individual patients are matched to a computerized knowledge-base for the purpose of generating patient-specific assessments or recommendations.³ Unlike computerized patient care systems, the CDSS presents the recommendations to clinicians for consideration. The hardware platform for these applications depends on the developer and the application, and includes mainframes with distributed terminals, desktop workstations, laptops, tablets, and handheld computers. These devices can be networked with or without wires and over short or long distances (via the internet).

Because of the vast data-processing abilities of computers, information technology appears to have a natural application in the ICU. The ICU is a data-rich environment in which many more patient data points are available than the optimal number (reported as 3-7) healthcare workers can process.⁴ In the ideal ICU, as envisioned by medical informatics specialists, the electronic hub would be the EMR, networked to medical instruments, radiology data, CDSSs, and other reference tools.⁵ Therefore, the EMR would function as a scaffold on which other applications are mounted. In addition to helping clinicians care for their own patients, this infrastructure would also facilitate ICU telemedicine, a model of providing care to ICU patients by off-site intensivists⁶ that may mitigate the ongoing shortage of intensivists.⁷ Current barriers to more widespread implementation of this vision include the limited interoperability of the components, high initial



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Table 1: Clinical applications of medical informatics

- Clinical information systems
 - Electronic medical records (patient information)
 - Laboratory information systems
 - Picture archiving and communication systems (for radiographs)
- Computerized physician order entry
- Computerized patient care systems
- Clinical decision support systems
- Telemedicine
- Knowledge access and retrieval
 - Online resources
 - Resources installed on desktop, laptop, tablet, or handheld computers
- Communication systems
 - Text messaging and automated patient alerts via handheld devices

capital costs, concerns about data security, and unresolved questions of efficacy in improving patient outcomes.

Bedside applications of clinical informatics, like any other intervention in clinical medicine, are designed broadly to improve patient care. However, compared to most medications and devices, the evaluation of these applications poses some challenges related to the population (most informatics applications depend on healthcare workers as intermediaries, rather than interacting directly with patients), intervention (complexity and dependence on informatics infrastructure), and outcomes (generally focusing on the process of care rather than direct patient outcomes). This issue of *Critical Care Rounds* briefly reviews the process of health technology assessment (HTA) and outlines some of the methodological considerations particular to the assessment of information technology.

What is health technology assessment?

Health technology assessment (HTA) as been described as the counterpart of evidence-based medicine for policy-makers, where health technology is defined broadly to include clinical interventions (medications, medical devices, and procedures) and structural features of healthcare systems (such as organization and financing). A European HTA methodology working group has provided a comprehensive definition:

*“A multidisciplinary activity that systematically examines the technical performance, safety, clinical efficacy and effectiveness, cost, cost-effectiveness, organizational implications, social consequences, and legal and ethical considerations of the application of a health technology”*⁸

HTA methodology begins with a set of research questions that addresses some or all of these aspects. Explicit methods are developed for each question to ensure exhaustive data gathering, transparent appraisal of the evidence, and the formulation of conclusions. Standards for reporting have been proposed,⁹ and databases of HTA reports are available from the International Network of Agencies for HTA (INAHTA) (www.inahta.org) and the National Health Service Centre for Reviews and Dissemination (agatha.york.ac.uk/welcome.htm). Although HTAs are often designed for policy-makers, their role in policy

and funding decisions is controversial because their conclusions may conflict with competing values of patients, clinicians, and policy-makers.¹⁰⁻¹²

Phases in the assessment of informatics applications

Informatics developers and researchers must complete the interconnected and concurrent tasks of system design, development, and evaluation prior to subjecting an application to clinical effectiveness assessments.¹³ Stead et al reviewed this early development process, highlighting the contributions of quantitative and qualitative methodologies.¹⁴ In this article, we will discuss 3 phases of HTA as applied to fully assembled informatics applications:⁵

- **Phase I** focuses on safety and technical performance,
- **Phase II** evaluates clinical effectiveness using the most appropriate rigorous study design
- **Phase III** features comprehensive assessments in heterogeneous populations, incorporating a broad range of outcomes.

Each phase has distinct objectives, methods, and outcomes. Applications designed to directly improve patient outcomes (for example, CDSSs and computerized patient care systems) must be rigorously evaluated in all 3 phases. Other technologies (such as EMRs) are so comprehensive that they are better thought of as enabling the operation and evaluation of other specific applications. After extensive pre-clinical development, the assessment of an EMR thus focuses on Phase 1 issues of reliability, functionality, and completeness of documentation.

Phase I: Safety and technical performance

Specific safety considerations depend on the application, but include issues of reliability of computer-gathered patient data, technical robustness under a variety of operating conditions, and data security. Technical performance depends on components of hardware, the user interface, connections to external devices, and software (the internal knowledge base, algorithms, and logic). Evaluation of technical performance in the laboratory, in simulated clinical situations, or in the clinical setting side-by-side with standard care, enables the assessment of components individually, as a whole, and together with other applications. These issues must be addressed during technology development and pilot testing, prior to widespread clinical implementation. However, because technological failures can occur even in fully operational, mature systems, healthcare organizations have an ongoing responsibility for system maintenance, network and data protection, and planning for unexpected shutdowns.¹⁶

Applications that record information (EMRs linked to medical devices) or provide images (PACS) must demonstrate that computerized data collection can reliably and accurately capture information recorded in non-computerized systems or other computerized systems. PACS, for example, can store conventional radiographic films that are digitized, or images that are originally digitized. In the latter instance, the EMR must handle such issues as file compression, transmission, and presentation.

For CDSSs, technology assessors must pay special attention to the development of the knowledge base and algorithms. Because computers allow for widespread and rapid

diffusion of information, incorrect explicit instructions from a widely used CDSS have the potential for broad harm. Therefore, these systems must be developed with rigorous attention to the validity of the treatment recommendations. The evidence base to support recommendations varies depending on the complexity of the CDSS and includes pharmacokinetic models (for drug dosing¹⁷), literature-based research evidence, local practice-based evidence, and collaborative and iterative consensus development (for mechanical ventilation⁴). Frequent scheduled reevaluations of CDSSs are necessary to update the recommendations and rectify unanticipated problems.

Phase II: Clinical effectiveness

The methodology for assessing clinical effectiveness depends on the specific application and the outcomes chosen, which may include measures relevant to patients (health status and process of care) and clinicians (adherence to recommendations, satisfaction, and efficiency). In this section, we discuss CDSSs because clinical effectiveness is a crucial component of their evaluation. The design, development, evaluation, and ultimate implementation of CDSSs pose numerous methodological challenges.^{18,19} Data from a variety of qualitative and quantitative study designs are important for CDSS development and refinement,¹⁹ but the randomized controlled trial (RCT) is the most rigorous study design for the evaluation of clinical effectiveness.

Successful implementation of the CDSS is required to demonstrate a treatment effect in a randomized trial. Because CDSSs are complex interventions, adherence depends on features facilitating integration into clinician workflow. Shiffman et al developed a conceptual framework of 8 CDSS characteristics maximizing functionality and user acceptability.²⁰ Four are related to the EMR backbone (patient registration, recording of patient data, electronic mail capability [for clinician communication], and ability to aggregate patient data to produce summaries [eg, all patients grouped by clinician]). The other characteristics directly concern CDSS functionality (providing treatment recommendations, facilitating access to supporting evidence [eg, links to journal literature], user-friendly presentation of information, and allowing for manipulation of numerical data [eg, calculating 24-hour fluid balance]). Extending this framework to complex systems, Tierney et al pointed out that successful protocols must generate unambiguous and explicit instructions and account for most clinical situations.²¹ In addition, continuous updating of the evidence base, continuously available technical support, and a process of iterative CDSS refinement based on local experience will help to achieve local acceptance.

Randomized trials of CDSSs must be adequately powered to detect clinically important effects. Strategies include enrolling an adequate number of clinicians and patients, choosing responsive outcome measures, measuring the outcome on process variables after a run-in phase during which clinicians become familiar with the system, and maximizing ongoing clinician use of the CDSS and adherence to its recommendations.

Although concealment of allocation, an important methodologic feature to reduce bias,²² can be implemented for all RCTs, blinding of caregivers using the CDSS is not

possible. This unblinding raises the possibility of differential application of post-randomization co-interventions related to the outcome measure. For example, consider a hypothetical trial of a CDSS for fluid management in patients admitted to an “open” ICU (where the primary clinicians are surgical team members) after major surgery. Because the CDSS requires intensivist approval of its instructions, the effect of the CDSS will be confounded by greater intensivist involvement, which improves patient outcomes.²³ Therefore, co-interventions unrelated to the CDSS that could be unevenly distributed between intervention and control groups must be standardized or (less preferably) included in an exploratory analysis.

In most circumstances, the unit of allocation must be the ICU, rather than the patient, especially when the same physicians are responsible for the care of patients in both the intervention and control groups. Otherwise, physicians may indirectly apply the CDSS to the care of control group patients, resulting in contamination and a reduction in the observed treatment effect. However, randomizing groups or clusters of patients while drawing inferences about individuals requires consideration of the lack of independence among individuals within the cluster when calculating the sample size and performing the analysis.²⁴ A recent study,²⁵ examined 24 CDSS trials and found that none considered the effect of clustering when computing sample size and only half (58%) used appropriate methods in the analysis. In contrast, clinicians cannot learn from computerized patient care systems, in which approval of each instruction is not required. RCTs of these interventions are thus easier to design and analyze because the unit of randomization is the patient.

The choice of control group is another important design consideration. If the research objective is to evaluate CDSS efficacy in an ideal clinical setting (an “explanatory” RCT), the control group should have access to a comparable paper-based knowledge base. Otherwise, it will not be possible to identify the beneficial intervention: evidence-based guidelines (embedded in the CDSS) or patient-specific instructions (generated by the CDSS). However, the more usual objective is to evaluate CDSS effectiveness in a realistic clinical setting (a “management” RCT), in which case, making no effort to improve control group performance beyond usual care maximizes external validity.

Finally, the timing of the outcome assessment must be considered. As with other studies of protocol-based interventions, CDSS management trials should study the effects on process of care in the long term, after clinicians become familiar with the system and potentially begin to ignore or override it.

Phase III: Comprehensive assessments

Designed for policy-makers, these evaluations take a broad perspective and include not only clinical effectiveness, but also economic, organizational, ethical, and legal issues.

Comprehensive economic evaluations of informatics interventions must only follow a demonstration of beneficial effects on important patient or clinician outcomes. Several factors complicate these evaluations.

- First, applications are often interdependent and can only be evaluated as a package (eg, a CDSS together with an

EMR). In this example, the economic evaluation would compare a computerized approach to information management and decision-making to a traditional paper-based system that may include stand-alone computer applications.

- Second, some outcomes are difficult to quantify in economic terms (eg, the effects of a stand-alone EMR on clinical workflow and data security).

- Finally, the economic perspective chosen (hospital, government, clinician) must be explicitly stated, to appropriately choose the comparison group and collect all relevant cost data.²⁶

Another important research objective for informatics HTA is to determine the impact on the process and outcomes of continuous quality improvement (CQI). By facilitating CQI, networked informatics applications may have a profound impact on administrative practices in healthcare organizations. The applications can generate an electronic repository of patient registration, physiological, laboratory, imaging, intervention, and outcomes data. In a CQI model,²⁷ the clinical data repository can be analyzed and used to evaluate the quality of patient care (eg, prescription of appropriate venous thromboembolism prophylaxis and control of hyperglycemia) and generate local practice-based research. Therefore, clinicians can audit their practices, compare the results to a benchmark (ideally generated from evidence-based guidelines), implement strategies designed to improve practice, and assess the results.

The major legal and ethical consideration in the implementation of computerized systems with individual patient data is the protection of patient confidentiality. In the US, the federal government recently enacted privacy legislation (the Health Insurance Portability and Accountability Act of 1996) enhancing the protection of patient records. Although security mechanisms in EMRs (eg, recording every episode where a healthcare worker changes or accesses a patient record), are more robust than usual measures for paper-based records, the implications of privacy legislation on the accessibility of patient records for CQI initiatives and other practice-based research is unclear.

Which informatics applications have been assessed?

Given the myriad difficulties involved in rigorously evaluating informatics, how have we done so far? There are currently *no* comprehensive HTA reports of ICU informatics applications in the INAHTA database, and only a small number of evaluations in other clinical settings. Two examples demonstrate the challenge of technology assessment in the near absence of studies. The US Veterans Administration conducted a systematic review of the effects of PACS in general inpatient and outpatient settings on outcomes of diagnostic accuracy, integration into clinical workflow, and costs and quality of care. They found that the existing literature was insufficient to answer the research questions.²⁸ Similarly, a systematic review of the effect of nurse record systems,²⁹ in which one of the objectives was to evaluate

the effect of computer-based versus paper-based records on nursing and patient outcomes, found only one study of an electronic nurse care planning tool on general medical wards.³⁰ Both these systematic reviews were methodologically strong (exhaustive search strategy, duplicate abstraction of data, assessment of validity of included studies), but were limited by the lack of primary data.

There are more data about CDSS performance outside the ICU. A methodologically robust systematic review published in 1998,³ found 68 CDSS RCTs, two-thirds of which were published after 1992. Although only one trial¹⁷ enrolled critically ill patients, the methodological issues are generalizable. Forty-three of 65 studies assessing effects on physician performance showed a benefit, including studies of diagnostic aids, drug dosing systems, preventive care, disease management, laboratory test ordering, and other miscellaneous interventions. Of the 14 studies evaluating effects on patient outcomes, 6 showed a benefit and 5 of the remaining 8 were underpowered to detect a moderate effect size. A reassuring finding was that the internal validity of included studies increased over time. This systematic review did not perform meta-regression to identify determinants of CDSS success.

We searched for RCTs of informatics applications in ICUs indexed in MEDLINE (1966–November 2002) and EMABSE (1980–November 2002), using the exploded terms (computer-assisted decision-making or information systems) AND (mechanical ventilators or artificial respiration or ICUs or critical care or intensive care), limited to English-language RCTs. Although this search was not exhaustive, we identified only 3 randomized trials of informatics applications in the ICU, all stand-alone computerized patient care systems: one for mechanical ventilation of patients with acute respiratory distress syndrome (ARDS),^{2,31} one to facilitate weaning,³² and one to manage blood pressure after cardiac surgery.³³ We also found one ICU-based CDSS of aminoglycoside dosing¹⁷ in a systematic review.³ One article³¹ reported on the subgroup of ARDS patients from a larger trial.² Table 2 summarizes the 4 trials. Three were single centre trials enrolling fewer than 50 patients and evaluating short-term outcomes; the largest enrolled 200 patients, successfully exported a complex mechanical ventilation protocol from the development centre to 10 study sites, and applied the protocol for the entire duration of ventilation.

Other interventions that were evaluated using non-RCT designs included the use of handheld computers to facilitate access to information resources (surveys and focus groups³⁴) and to implement a guideline for weaning from mechanical ventilation (prospective before-after study³⁵). Also evaluated were telemedicine to enable intensivist participation in patient care in an open surgical ICU (prospective before-after study⁶); electronic nurse charting systems (nonrandomized controlled trial³⁶ and comparison of simultaneous collection of patient data by computer and manual methods³⁷); PACS (interrupted time series design³⁸);

Table 2: Randomized trials of informatics applications in the ICU

Trial	Description	Outcomes	Comments
Hickling, et al ¹⁷	P: 32 patients (1 centre) requiring aminoglycosides I: CDSS of drug dose and interval calculated by computer using measured drug clearance and volume of distribution, or manually calculated from estimates	Patients in therapeutic range at 48-72 hours: Computer group: 12/13 Manual group: 3/14 (p=0.0009) 4 patients (2/group) developed severe oliguria	Method of allocation: computer randomization Unit of randomization and analysis: patient Data on 5 patients excluded
Murchie, et al ³³	P: 45 patients (1 centre) after cardiac surgery requiring antihypertensive therapy I: Nitroprusside infusion: computer regulated or nurse regulated with computer-generated display of blood pressure control or nurse regulated without feedback	Time spent outside desired blood pressure range lower in computer regulated group (1.52%) than in nurse regulated with (8.02%) or without (12.14%) feedback	Method of allocation: not described
Strickland, et al ³²	P: 17 patients (7 surgical, 1 centre) ready to wean by study criteria I: Weaning by SIMV/PS directed by computer algorithm (based on RR, VT uploaded from ventilator) or physician for 48 hours; study physician supervised computer algorithm but agreement with each computer instruction not required	Patients weaned by 48 hours and spontaneously breathing 48 hours later: Computer group: 7/9 Physician group: 0/6 (p=0.136) Fewer ABGs in computer group	Method of allocation: sealed envelopes Control arm did not have weaning protocol Data on 2 patients excluded
East, et al ²	P: 200 patients (10 centres) with ARDS enrolled over 4 years I: CDSS directed mechanical ventilation based on manually entered patient data or non-protocol control	94% of 38,546 CDSS instructions followed No difference in survival or ICU length of stay Lower barotrauma score and maximum MODS in CDSS group	Protocol used for 35,000 hours in 111 patients in separate centre (linked to EMR) prior to RCT Method of allocation not described No patients excluded or lost to follow-up

Legend: ICU=intensive care unit, P=study population, I=intervention, SIMV/PS=synchronized intermittent mandatory ventilation/pressure support, RR=respiratory rate, VT=tidal volume, ABG=arterial blood gas, ARDS=acute respiratory distress syndrome, MODS=multiple organ dysfunction score, CDSS=computerized clinical decision support system, EMR=electronic medical record

and point of care blood testing after cardiac surgery (decision analysis model³⁹).

Conclusions

The standard of patient care is evolving to include the requirement of healthcare organizations to have computer-based patient records linked to physician order entry and decision support systems.^{40,41} This recommendation recognizes the potential of medical informatics to improve clinical decision-making, patient care, and assessment of quality of care. However, these technologies are expensive, complex, and challenging to implement and maintain. As we have shown, the primary evidence necessary to comprehensively assess informatics applications is lacking and there are formidable methodological challenges facing applied informatics research.

The important message for intensivists and ICU managers assessing commercially available products is

that the objectives and methods of an evaluation will depend on the specific application. Comprehensive clinical information systems are designed to record, store, and display patient information; evaluations should concentrate on functional issues of safety, usability, and integration into clinical workflow, data security, and compatibility. Comprehensive systems support specific applications designed to improve clinician performance and patient outcomes (CDSSs and computerized patient care systems). For these applications, randomized controlled trials are the gold standard to establish the extent of clinical benefit. Other methodologies provide complementary information important for complete assessments of economic and organizational implications. Finally, acquisition of medical informatics technology requires an organizational commitment to an ongoing iterative process of local reevaluation and system modification.

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