2006 Philip Kittredge Memorial Lecture

What to Do When Protocols Fail

Charles G Durbin Jr MD FAARC

Though advances in medical science have created improved therapies, often these are not widely provided throughout the health-care system. Also, there is growing recognition of the lack of safety in health-care delivery. The development of evidence-based, best practice, national guidelines has been encouraged to reduce unnecessary variation in care and for improving quality. Adoption of guidelines through local protocols has been disappointingly slow. This paper explores the parallel developments in safety and quality-of-care assessment, evidence-based medicine, guideline creation, and how development of national and international quality-improvement campaigns are promoting rapid change in care delivery processes. I discuss how this new opportunity can improve the quality of respiratory care and enhance the adoption of respiratory care protocols. *Key words: protocols, guidelines, best practice, translational research, clinical practice, respiratory care, quality improvement, evidence-based medicine.* [Respir Care 2007;52(3):324–336. © 2007 Daedalus Enterprises]

Introduction

Health care in the United States and most Western Countries is expensive, complex, undergoing constant change, and is underpinned by the principles of empirical science. Individual patient outcomes partly depend on where, from whom, and when care is obtained. Although specific patient factors (eg, smoking or family history) influence these outcome differences, health-care-system issues result in differences in quality of care received. Identification of the large differences in process and outcome has raised concern over the quality and safety of health care. In a publication released by the Institute of Medicine in 1999, "To Err Is Human," it was estimated that as many as 98,000 patients die per year in American hospitals as a result of system failures and medical accidents.[1] Types of medical errors noted and discussed in that landmark report are summarized in Table 1. These can be roughly divided into problems with care delivery systems and failure to apply known, appropriate, tested, and successful therapies to individual patients. In its 2000 publication "Crossing the Quality Chasm," the Institute of Medicine defined "quality" health care as composed of 6 domains: safe, effective, patient-centered, timely, efficient, and equitable (Table 2).[2]

This paper will concentrate primarily on the first 2 domains: safety, and effectiveness of care delivery. Several processes and activities in health care have been initiated from identifying failures of safety and effectiveness. Development of national guidelines and protocols has been encouraged to reduce inappropriate differences in care and to incorporate the latest, best practices at the bedside.

The parallel growth and evolution of evidence-based medicine (EBM) as a scientific discipline has contributed to the quality of guideline recommendations. This process has been going on for over 20 years, yet the availability of evidence-based guidelines alone has failed to deliver on the promise of improved care. This paper will detail the development of guidelines and protocols in general and in respiratory care in particular. It will highlight successes and failures and suggest what changes are necessary to move to the next stage of changing clinical practice.

The lack of ability to easily change and elevate clinical practice by disseminating new research findings is at the heart of a new area of study: translational research. The

Charles G Durbin Jr MD FAARC is affiliated with the Department of Anesthesiology, University of Virginia Health Science Center, Charlottesville, Virginia.

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Correspondence: Charles G Durbin Jr MD FAARC, Department of Anesthesiology, University of Virginia Health Science Center, PO Box 800710, Charlottesville VA 22908-0170. E-mail: cgd8v@virginia.edu.

Table 1. Types of Medical Errors

Diagnostic Errors
Errors in diagnosis
Delays in correct diagnosis
Failure to use indicated tests
Use of outmoded tests or therapy
Failure to act on results of monitoring or testing
Treatment Errors
Error in administering treatment
Error in performing operation, procedure, or test
Error in the dosage or method of administering a drug
Avoidable delay in treatment or responding to a test
Inappropriate care or treatment not indicated
Preventive Errors
Failure to provide prophylactic therapy
Inappropriate follow-up or monitoring of treatment
Other Errors
Communication failures
Equipment failures
Other system failures

Table 2. Characteristics of Quality in Health-Care Delivery

Safe	Avoids injuries to patients from the care that is intended to help them
Effective	Provides services based on scientific knowledge to all who could benefit (ie, avoids underuse), and does not provide services to those not likely to benefit (ie, avoids overuse)
Patient-centered	Provides care that is respectful of and responsive to individual patient preferences, needs, and values, and ensures that patient values guide all clinical decisions
Timely	Reduces waits and sometimes harmful delays for both those who receive and those who give care
Efficient	Avoids waste of equipment, supplies, ideas, and energy
Equitable	Provides care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, or socioeconomic status

aim of translational research is to understand how best to rapidly move what we know is (currently) better care from scientific studies to the bedside and widely apply these proven therapies. The difference between "usual" and "optimal" care continues to enlarge as the explosion in scientific discoveries continues. For many years, new information and the latest proven treatments were disseminated only through post-graduate continuing medical education, attendance at which is mandated for continued licensure. Despite these continuing education activities, incorporation of new treatments remains distressingly slow. The problem is not simply one of caregiver education; it involves altering a complex system of care that has a huge amount of inertia, and fundamentally transforming the way care is delivered.

Respiratory Care Guidelines and Protocols

Within the respiratory care community there has been a longstanding interest in standardizing and improving clinical practice. Long before the formal emergence of EBM in the 1990s and the above-mentioned reports from the Institute of Medicine,[1,2] leaders in respiratory care recognized that some respiratory procedures were ineffective and overused, possibly due to a misaligned reimbursement system and lack of quality scientific evidence on efficacy. The prescription of intermittent positive-pressure breathing, as often as every 4 hours, for all postoperative patients and most other hospitalized patients with any pulmonary diagnosis, resulted in large growth of respiratory care departments in the 1950s and 1960s, since Medicare and other insurers paid well for these services.[3] Studies showed that only patients with reduced capacity to inspire on their own actually benefited from RT-administered intermittent positive-pressure breathing, and other less time-consuming and self-administered maneuvers were equally effective in preserving and improving gas exchange and ventilatory function in most patients.[4–7] Sponsored by the American Thoracic Society and supported by the National Heart and Lung Institute, a conference on the scientific basis for respiratory therapy was held in 1973.[8] During that landmark conference, review of the scant supporting science resulted in a call for additional studies to justify many of the common respiratory treatments then in routine use. The respiratory therapy community was an early pioneer in demanding and disseminating a science-based clinical practice by its members.

Guidelines are usually detailed, general statements of important principles of care. At their best, they describe the "best practices" of care and are supported by scientific studies. Guidelines, in general, do not define what should be done in a specific patient situation. To apply a guideline to the clinical situation, it must be put into operation by creating a patient-care protocol or treatment algorithm based on the guideline. Protocols are standardized algorithms for clinical care; they can be very specific or more general in nature. For instance, a specific protocol for emergency, initial treatment of patients with chest pain suspicious for acute myocardial infarction would be to deliver an aspirin as soon as the diagnosis is entertained, unless the patient has a life-threatening contraindication (eg, asthma with nasal polyps or aspirin allergy). Emergency medical service personnel are generally applying this protocol; it is part of the familiar Advanced Cardiac Life Support algorithms, and even family members and victims are aware of and applying this recommendation. The scientific support for the guideline that mandates early

aspirin in suspected myocardial infarction is extensive, authoritative, widely distributed, available from the American Heart Association Web site, and summarized in the journal *Circulation*.[9]

An example of a more general protocol would be, "Patients with pulmonary symptoms or chronic pulmonary disease presenting to an emergency ward will be assessed by a respiratory therapist (RT) and treated according to protocol." The actual treatment decisions are then based on what the RT identifies during the patient evaluation, and treatment is provided according to a previously developed flow chart or algorithm. In this case the RT is empowered to apply whatever action is indicated, based on the specific patient findings, using locally developed or locally endorsed care plans. The information and science that support protocol use include the locally documented competence of the individual RT applying the algorithm; the basic educational curriculum completed by RTs, including patient assessment and therapeutic modalities; and the guidelines developed, published, and updated by the American Association for Respiratory Care (AARC) relating to the practice of respiratory care and the use of protocols.

The first use of the phrase, "respiratory care protocol" was published in RESPIRATORY CARE in 1981.[10] In that paper the authors described the use of algorithms for selecting therapeutic modalities in conjunction with patient assessment in providing care by RTs for pulmonary patients. The choice to order this care as a "respiratory care protocol" was offered to physicians, along with the usual menu of specific therapies, such as intermittent positive-pressure breathing, incentive spirometry, and others.

Guideline Development in Health Care

Three developments have influenced the growth of guidelines in health care: (1) general acknowledgement that there has been inadequate application of the known "best care," resulting in widespread differences in quality, (2) understanding and acceptance of the value of standardization of process and its application to health care, and (3) the evolution of EBM. Concern about quality and safety in health care was highlighted by the Institute of Medicine reports mentioned above.[1,2]

Standardization in health care is, at first blush, in direct opposition to medical training, which has always promoted individual judgment and personal responsibility for care decisions. The observed differences in treatment decisions and outcomes cannot simply be a result of good individual decisions and patient differences. Reducing inappropriate differences in care should improve outcomes. Standardization of process is a fundamental principle of the industrial revolution and an idea taken to its extreme in manufacturing over the past several centuries. Its application to health care is a relatively new concept.

Modern medicine developed as a "cottage" industry or profession, with each physician essentially creating his own product. The average length of training for a physician in 1890 was 2 months and required no academic preparation. It wasn't until the beginning of the 20th century that training in medicine was to become an academically rigorous activity. Under pressure from the American Medical Association, the Council on Medical Education requested that the Carnegie Foundation for the Advancement of Teaching conduct a survey to determine the status of American medical education. Abraham Flexner, a school master and educational theorist, led the effort and developed a report on the sorry state of medical education. This resulted in establishing the academic standards for medical education that are valid today.[11] These standards were rapidly accepted and propagated, based on the mandate that quality caregivers were necessary to improve public health, by ensuring that the latest scientific discoveries (eg, handwashing before surgery) were being applied by all medical practitioners. Importantly, these changes in medical education firmly established medicine as a science-based, academic discipline with specific and standard knowledge and skills required for practice. Licensure at the state level guaranteed the continued transition of medicine from an unregulated business to a regulated public service. The requirement of continuing medical education for continued licensure was envisioned as a method to guarantee improvement of physicians' knowledge and application of the latest discoveries to patient care.

Flexner wrote of American medicine, "We have indeed in America medical practitioners not inferior to the best elsewhere; but there is probably no other country in the world in which there is so great a distance and so fatal a difference between the best, the average, and the worst."[12] Even in 1910 the lack of consistency in health care was identified. Standardization, first of education, then of continuing practice was the proposed solution.

Since the Flexner report, the scientific method of proof integrated with personal experience has been the basis for evolution in the practice of medicine. As knowledge has expanded, medicine has become complex and more professional, and specialties and subspecialties of medicine have emerged as a result of (and to manage) this knowledge explosion. Public expectations of unlimited possibilities from medical discoveries has risen in parallel to these changes. In the early 1900s heath care was usually provided by a single doctor; now the various health-care tasks are divided among a group of physician and nonphysician experts, who frequently have different opinions on what constitutes the best care for an individual patient. EBM is a recent innovation in approaching clinical decisions, based on the quality of the science underlying the choices. The

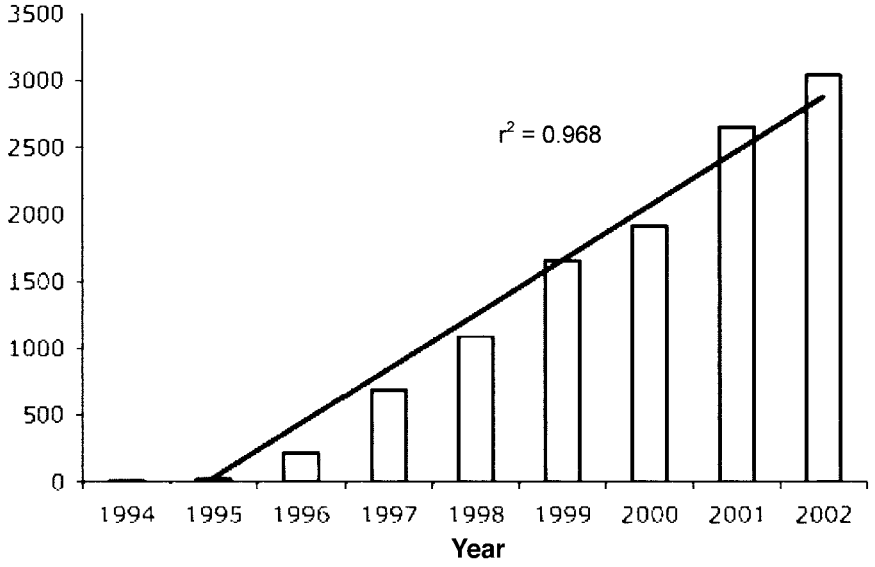


Fig. 1. Number of citations in MEDLINE that have referred to "evidence-based medicine" (From Reference 13, with permission.)

rapid recent growth of EBM is illustrated in Figure 1, which shows the increase in the number of citations containing the phrase "evidence-based medicine" in the MEDLINE database.[13]

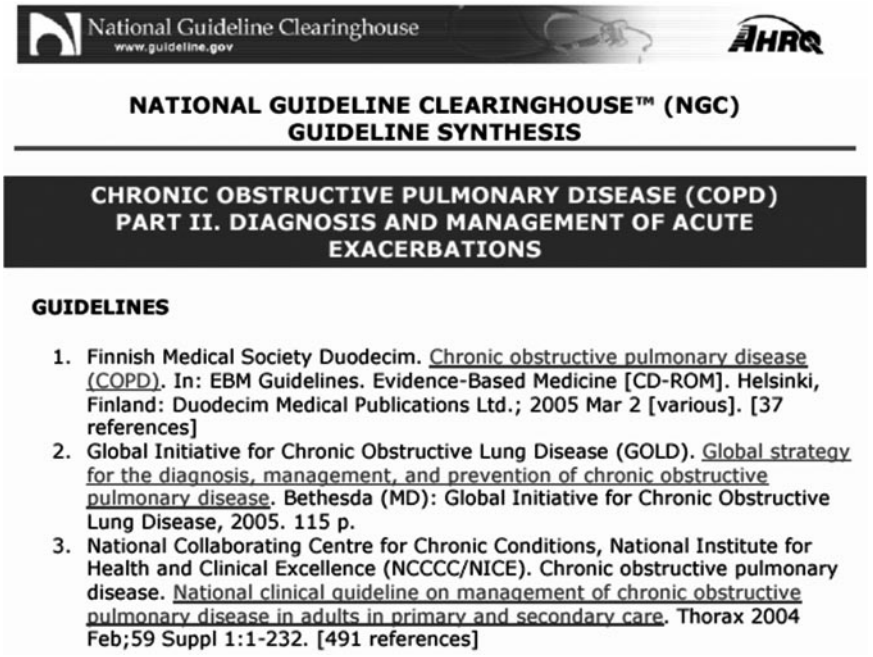
Rather than defend a particular specialty perspective with a list of studies in support of a treatment, EBM attempts to evaluate the strength of the cumulative evidence for or against a particular treatment. The strongest evidence comes from large randomized controlled clinical trials. Unfortunately, many treatments have never been subjected to that level of testing, so other, less strong evidence must be used to assess the value of the treatment. Combining the results from several smaller trials (meta-analysis) can often supply sufficient power to identify and quantify the treatment effect. Beyond this, lower levels of evidence, including uncontrolled trials and case reports, are also considered in grading treatment recommendations. The lowest level of evidence is expert opinion, which, unfortunately, is often the only available evidence for treatment guidelines. EBM has also introduced the discussion of economics into treatment decisions. Efficacy and efficiency are equally important in deciding if a new therapy or technology should be instituted or applied.

EBM has served to identify where quality data are needed to answer pressing clinical questions. Many routine care activities have never been rigorously studied for their impact on patient outcome. Since there is little money to be made in conducting such studies, and large clinical studies are very costly, it is unlikely that many of these interventions will ever be rigorously studied. The exception is when discontinuing a routine intervention could save substantial money for an institution, region, or country; there may be financing made available for such studies. Because of the nature of the Canadian medical system, many studies of routine care are being carried out in Canada, and EBM evaluations are being published from that work. The inception and growth of EBM has come from Canada, as a result of publicly mandated limitations on health-care spending and demand for equity and quality.

Another way to evaluate and improve routine care is with continued quality-improvement activities at the local level. By measuring clinical or economic outcomes before and after instituting a change in practice, an estimate can be made of the impact of the change on patient care. This approach has been very useful in generating evidence that supports some respiratory care equipment guidelines. For example, from compilation of multiple institutions' experience it was determined that extending the time between ventilator circuit changes (rather than changing the circuit every 24 hours, as previously recommended by the manufacturers and the Centers for Disease Control) reduces the frequency of ventilator-associated pneumonia (VAP). Although these studies were motivated by a desire to improve efficiency, they have also saved lives by preventing mortality from lung infections.

Guideline Promotion

The above 3 ideas and developments (maturation of EBM, recognition of the value of standardization in health care, and recognition of quality problems in American medicine) led the Institute of Medicine to recommend that professional medical societies and specialty organizations create and disseminate evidence-based, best-practice guidelines as an important way to change and improve patient care. Several national efforts to facilitate this process were


National Guideline Clearinghouse
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NATIONAL GUIDELINE CLEARINGHOUSE™ (NGC)
GUIDELINE SYNTHESIS

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)
PART II. DIAGNOSIS AND MANAGEMENT OF ACUTE EXACERBATIONS

GUIDELINES

1. Finnish Medical Society Duodecim. Chronic obstructive pulmonary disease (COPD). In: EBM Guidelines. Evidence-Based Medicine [CD-ROM]. Helsinki, Finland: Duodecim Medical Publications Ltd.; 2005 Mar 2 [various]. [37 references]
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. Bethesda (MD): Global Initiative for Chronic Obstructive Lung Disease, 2005. 115 p.
3. National Collaborating Centre for Chronic Conditions, National Institute for Health and Clinical Excellence (NCCCC/NICE). Chronic obstructive pulmonary disease. National clinical guideline on management of chronic obstructive pulmonary disease in adults in primary and secondary care. Thorax 2004 Feb;59 Suppl 1:1-232. [491 references]

Fig. 2. Browser screen-shot of the National Guidelines Clearinghouse synthesis of the treatment guidelines for exacerbations of chronic obstructive pulmonary disease (COPD). (From Reference 16.)

undertaken. One was the development of the United States National Guidelines Clearinghouse. Established as a public resource for evidence-based clinical practice guidelines, the clearinghouse is an initiative of the Agency for Healthcare Research and Quality (of the United States Department of Health and Human Services), in partnership with the American Medical Association and the organization America's Health Insurance Plans (formerly American Association of Health Plans). As of December 28, 2006, there were 2,010 guidelines listed, 13 of which where created and submitted by the AARC.[14]

To be included in the National Guidelines Clearinghouse, a guideline must meet the Institute of Medicine's definition of a clinical practice guideline and all of the following criteria:[15]

1. The guideline contains systematically developed statements that include recommendations, strategies, or information that assists physicians and/or other health-care practitioners and patients make decisions about appropriate health care for specific clinical circumstances.

2. The guideline must be produced under the auspices of a medical specialty association; relevant professional society; public or private organization; federal, state, or local government agency; or health-care organization or plan. A guideline developed or issued by an individual not officially sponsored or supported by one of those types of organizations does not meet the inclusion criteria.

3. Corroborating documentation must be available and verifiable that the guideline-development process included a systematic literature search and review of existing scientific evidence in peer-reviewed journals. A guideline is not excluded from the clearinghouse if corroborating documentation can be produced and verified detailing specific gaps in scientific evidence for some of the guideline's recommendations.

4. The full text of the guideline is available on request in print or electronic form (for free or for a fee), in English.

5. The guideline is current and the most recent version. Documented evidence must be available and verifiable that the guideline was developed, reviewed, or revised within the last 5 years.

In addition to listing the guidelines and providing links to the primary sources, the National Guidelines Clearinghouse offers some unique and very useful services. Guidelines are grouped if they apply to the same or similar clinical situation. The clearinghouse supplies a synthesis of the content of each guideline, and points of agreement and difference are described in a comparison table. For instance, the page on treatment of exacerbation of chronic obstructive pulmonary disease (COPD) synthesizes 3 separate guidelines (Fig. 2).[16] Figure 3 shows part of the synthesis comparison (explicit purpose of each guideline). For these particular guidelines, a free 37-page downloadable document contains the detailed analysis. Toward the end of the synthesis are sections that summarize the similarities and differences between the guidelines. For this COPD guideline analysis, similarities were noted in clinical and laboratory assessment techniques, medication recommendations, hospital and intensive care unit (ICU) ad-

Objective and Scope	
FMS (2005)	• Evidence-Based Medicine Guidelines collect, summarize, and update the core clinical knowledge essential in general practice. The guidelines also describe the scientific evidence underlying the given recommendations.
GOLD (2005)	• To recommend effective COPD management and prevention strategies for use in all countries • To increase awareness of the medical community, public health officials, and the general public that COPD is a public health problem • To decrease morbidity and mortality from COPD through implementation and evaluation of effective programs for diagnosis and management • To improve prevention and management of COPD through implementation and evaluation of effective programs for diagnosis and management • To encourage renewed research interest in this highly prevalent disease
NCCCC/NICE (2004)	• To develop a clinical guideline on the management of chronic obstructive pulmonary disease for use in the National Health Service (NHS) in England and Wales • To offer best practice advice on the identification and care of patients with COPD • To define the symptoms, signs, and investigations required to establish a diagnosis of COPD • To define the factors that are necessary to assess the severity of COPD, provide prognostic information, and guide best management • To provide guidance on the pharmacological and non-pharmacological treatment of patients with stable COPD and on the management of exacerbations • To discuss the interface with surgery and intensive therapy units

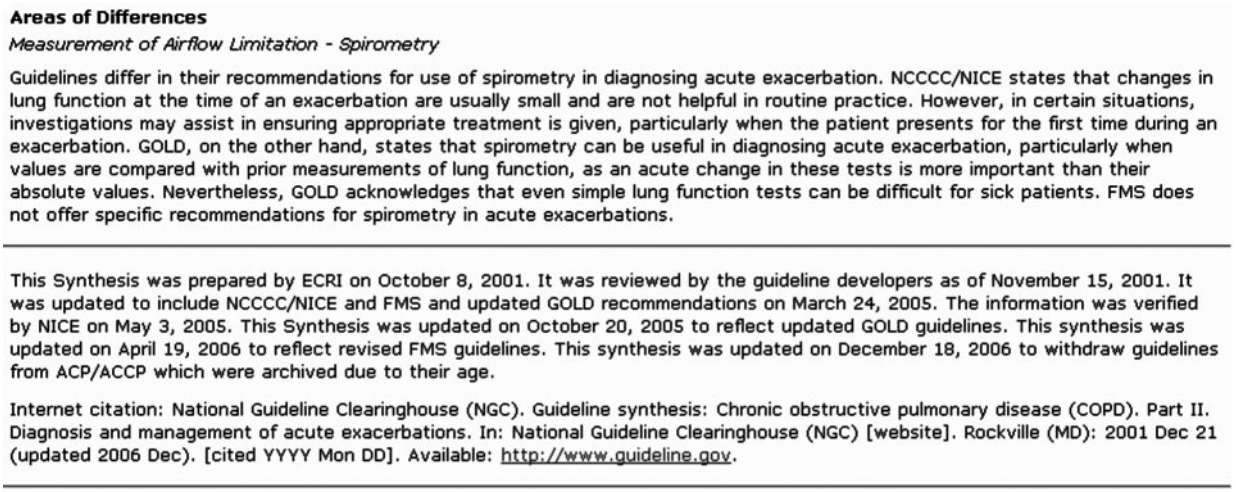
Fig. 3. Description of the 3 guidelines used in the National Guidelines Clearinghouse synthesis of the treatment guidelines for exacerbations of chronic obstructive pulmonary disease (COPD). (From Reference 16.)

mission suggestions, use of noninvasive mechanical ventilation, and discharge criteria. The only important matter of disagreement between the guidelines was on the use of spirometry for diagnosing an acute COPD exacerbation. This COPD guideline analysis was performed by ECRI and has been updated several times; the latest update was December 26, 2006 (Fig. 4).

Most professional organizations dedicated to patient care have created their own guidelines. Since not all such guidelines meet the relatively strict criteria of the National Guidelines Clearinghouse, they are not all available at that Web site. For instance, only some of the AARC's numerous respiratory care guidelines are available in the clearinghouse, though all of them are published in RESPIRATORY CARE and available at http://www.rcjournal.com/online_resources/cpgs/cpg_index.asp, where they are grouped into categories: evidence-based guidelines; expert panel guidelines; combined and retired guidelines; and links to guidelines from other organizations.

Impact of Guidelines on Care

The hope was that creating relevant guidelines would rapidly improve care as the guidelines were incorporated into care patterns. This translation of guidelines into actual patient care has been modest at best. As mentioned above, the effectiveness of aspirin during acute myocardial infarction is supported by a great deal of high-quality data, and the vast majority of clinicians believe aspirin should be administered, but adherence to this guideline is disappointing. In studies of pre-hospital aspirin administration to patients with convincing symptoms of myocardial in-



Areas of Differences

Measurement of Airflow Limitation - Spirometry

Guidelines differ in their recommendations for use of spirometry in diagnosing acute exacerbation. NCCCC/NICE states that changes in lung function at the time of an exacerbation are usually small and are not helpful in routine practice. However, in certain situations, investigations may assist in ensuring appropriate treatment is given, particularly when the patient presents for the first time during an exacerbation. GOLD, on the other hand, states that spirometry can be useful in diagnosing acute exacerbation, particularly when values are compared with prior measurements of lung function, as an acute change in these tests is more important than their absolute values. Nevertheless, GOLD acknowledges that even simple lung function tests can be difficult for sick patients. FMS does not offer specific recommendations for spirometry in acute exacerbations.

This Synthesis was prepared by ECRI on October 8, 2001. It was reviewed by the guideline developers as of November 15, 2001. It was updated to include NCCCC/NICE and FMS and updated GOLD recommendations on March 24, 2005. The information was verified by NICE on May 3, 2005. This Synthesis was updated on October 20, 2005 to reflect updated GOLD guidelines. This synthesis was updated on April 19, 2006 to reflect revised FMS guidelines. This synthesis was updated on December 18, 2006 to withdraw guidelines from ACP/ACCP which were archived due to their age.

Internet citation: National Guideline Clearinghouse (NGC). Guideline synthesis: Chronic obstructive pulmonary disease (COPD). Part II. Diagnosis and management of acute exacerbations. In: National Guideline Clearinghouse (NGC) [website]. Rockville (MD): 2001 Dec 21 (updated 2006 Dec). [cited YYYY Mon DD]. Available: http://www.guideline.gov.

Fig. 4. Browser screen-shot of the description of the differences between the 3 guidelines in Figures 2 and 3, and the chronological history of the comparison. (From Reference 16.)

farction, only 11–78% of patients received aspirin prior to or during transport.[17,18]

Another example, important in respiratory care, is low-tidal-volume (V_T) ventilation in patients with acute lung injury (ALI) or acute respiratory distress syndrome (ARDS). Seven years following publication of the ARDS Network trial that first found benefit from low-V_T ventilation (limited-pressure ventilation) in patients with ARDS,[19] the actual ventilation practice continues to be at variance with these recommendations, even in institutions that participated in the trial.[20,21]

Barriers to Guideline Implementation

Several authors have examined reasons for the failure of guideline adoption and adherence. Intrinsic barriers include issues related to the structure of the guideline, the clinical situation in which the guideline is supposed to be used, and unintended consequences of guideline application.[22] Complexity is another deterrent to guideline implementation. Factors such as difficulty in identifying to whom and when the guideline should be applied, where in the health-care system it should be applied, and who is responsible for implementation of each part of a guideline can prevent guideline acceptance and adoption. Complexity is an intrinsic characteristic of many guidelines, partly due to the vagaries of clinical care and the diagnoses to which they are to apply, and partly due to the differences in data and opinions that must be integrated to achieve consensus on a guideline.

The problem of complexity is illustrated by the guideline for treating individuals with chest pain, which stratifies patients into low-risk, intermediate-risk, and high-risk categories to predict the likelihood of an acute myocardial infarction. Identifying low-risk patients and reducing the amount of care for those patients was a primary motivator for this guideline development. The risk stratification is based on age, sex, history, associated risk factors, symptoms, electrocardiogram, and changes in electrocardiogram pattern. Even groups of experts familiar with the guideline often disagree on individual patient-risk-category assignment. This makes application of the treatment recommendations inconsistent. Low-risk patients may be discharged to home with clinic follow-up in 48 hours, which requires a clinic be available for the follow-up visit, and this availability is usually not under the control of the emergency-department physician who is attempting to follow the chest pain guideline. Lack of post-discharge care makes early discharge less likely or impossible. Patients categorized as high-risk are to be treated in a coronary care unit, according to the guideline. However, local demand for these acute-care beds is often exceeded and lower-risk high-risk patients are often triaged to a less intensive monitoring area. These patients would not have been admitted to the coronary care unit before the advent of the guideline. This latter example shows how (permanent and temporary) limitations of the local environment can affect national guideline implementation. It also demonstrates the unintended consequences of implementing a guideline, filling more coronary-care-unit beds with patients who would previously have been appropriately cared for in step-down areas.

We have discussed the external barriers to guideline adherence, and there are also important internal barriers.[23] Individuals may not be aware of the existence of a particular guideline, they may be unfamiliar with its content, or they may not agree with the guideline specifically or the idea of guidelines in general. The individual must believe

that the change that will result from a guideline is of value and that they have the ability to perform the required task, and they must have motivation to make a behavior change. It is relatively easy to augment provider education and knowledge, but influencing the other factors is less easy.

To successfully change clinical practice by instituting protocols within an individual institution, several essential elements have been identified. Encouragement and endorsement by the institutional leadership is a prerequisite for such a change. This support must be at the highest level if sustained change is to occur. This support needs to be affirmed by making available the appropriate resources to create, apply, and measure the impact of the changes in care. At the caregiver level, there must be a champion, usually a clinical leader, who embraces the change and spreads and maintains enthusiasm for the process. A multispecialty team should develop the protocol and involve as many different groups as necessary to adapt the national guideline to local realities.

Monitoring Success of Process Change

An essential part of the process is to monitor success. Initially this may simply be a measure of how frequently the desired care is appropriately applied, but the impact on clinical outcomes, patient and caregiver satisfaction, cost, and other important variables must also be part of the data-collection system. After a trial period, the protocol is modified if issues are discovered. If the measured variable improves, the protocol can be expanded to other areas of the institution, modified to achieve better results, or continued as "usual" care, and a different care-improvement issue can be addressed. Even with the above-mentioned resources, success in changing clinical behavior is not guaranteed.[24] One of the largest and most comprehensive meta-analyses of implementation strategies and their associated costs was commissioned in the United Kingdom. The conclusion of that massive study was that no single strategy was very effective, and the most cost-effective approach to enlisting caregivers in the change process was with brief, goal-directed, educational, lunch meetings.[25] Most efforts to induce change in clinical behavior are doomed to fail. In institutions that have been successful, considerable effort and expense have been expended to make modest gains.

Inducing Widespread Adoption of Guidelines

The cycle of process improvement described above is a concept taken from industrial "total quality management" and applied to health care. The concept is that quality can be incrementally improved by measuring an element associated with improved quality, making incremental changes in processes, and observing the effects on product (care) quality. Development of these methods and various styles of quality management have improved the quality of consumer goods and improved market share for some companies (eg, Toyota and General Electric). A similar improvement process cycle has been advocated by many health-care organizations, including the Institute for Healthcare Improvement, a not-for-profit organization dedicated to facilitating change and improving quality in health care throughout the world. Founded in 1991 and located in Cambridge, Massachusetts, the Institute for Healthcare Improvement describes itself as a reliable source of energy, knowledge, and support for a never-ending campaign to improve health care worldwide. The institute hopes to accelerate change in health care by cultivating promising concepts for improving patient care and turning those ideas into action.[26]

In addition to these voluntary efforts, 2 techniques have proven reliably effective in changing caregiver and institutional behaviors. They both directly or indirectly involve money. These methods are (1) linking financial rewards (or punishment) to the desired actions, and (2) requiring behavior change to maintain a license to operate or practice. The payer groups (insurance companies, the Centers for Medicare and Medicaid Services, the federal government) are aware of and concerned about the failure to adopt national guidelines and the impact of financial and regulatory pressures on clinician and institutional behavior. These financial and regulatory methods will be exploited more deliberately over the next several years to alter the direction of medicine in the United States. "Pay-for-performance" is a congressional mandate that will soon be instituted by Medicare; hospitals and physicians who fail to meet quality standards will suffer reduced payment for services. Though "pay-for-performance" would seem to suggest that superior performers would be rewarded, no new money was allocated by Congress, so the "reward" amounts to avoiding a reduction rather than receiving an increase for superior performance. Obviously, measuring quality is not easy, and separating individual physician performance from that of the institution is difficult. There is also the difficulty of developing meaningful outcome measures that are independent of, or at least corrected for, the severity of illness. Probably, a combination of outcome and process measures will be used to judge performance.

Though these techniques will change clinician and institution behavior, it is not clear that they will improve quality of care. The above discussion of guidelines mentioned the problem of unintended consequences. Mindless application of guidelines is not necessarily the best way to improve care. In fact, there are many different guidelines for similar clinical situations, and there may not be one best way to treat a particular patient. Deciding which guideline to impose is problematic. However, though this process is evolving and not likely to solve the problem, there is some

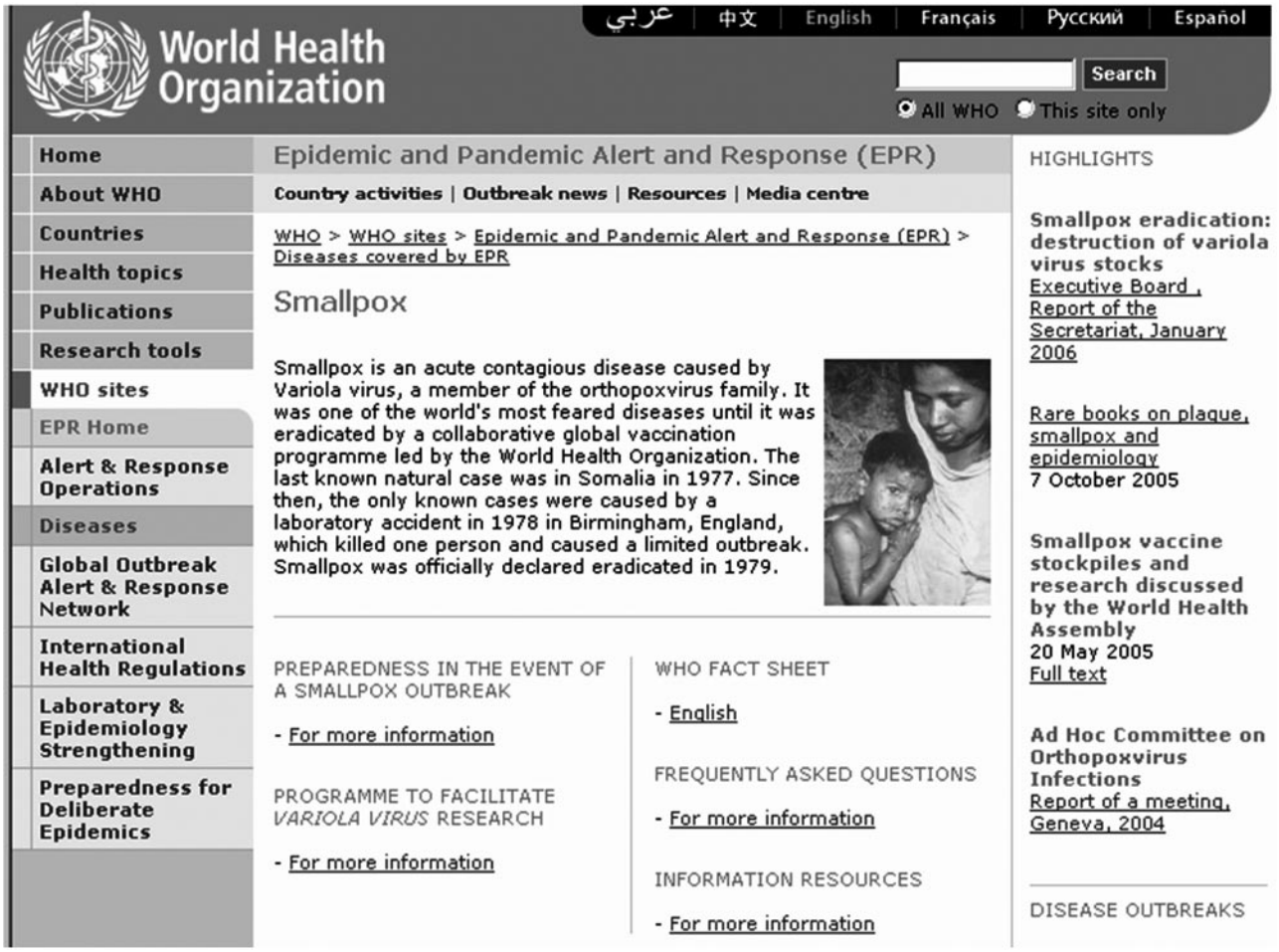


Fig. 5. Browser screen-shot of the World Health Organization's Victory Over Small Pox Web site. (From Reference 27, with permission.)

hope of new ways to improve care on a widespread basis. One of these ways is the *campaign*!

Campaigns to Improve Care

Whereas most guidelines are extremely detailed and directed to specific clinical conditions, campaigns are directed at groups of patients or diseases, and they incorporate essential elements of several guidelines. Campaign goals are often audacious. Campaigns incorporate success measures that impact huge numbers of patients and multiple groups of caregivers. They may attempt to eliminate a disease (eg, World Heath Organization's eradication of small pox campaign,[27] Fig. 5), improve health care for an underserved group (eg, the State Children's Health Insurance Program[28]), or improve safety of an entire health-care system (eg, Institute for Healthcare Improvement's 100,000 Lives campaign[26]). There are several ongoing campaigns that directly impact respiratory care delivery. I will discuss several concepts that have emerged from campaigns and can be used to improve respiratory care.

Instead of using guidelines, campaigns often use "care bundles." A "bundle" is a group of interventions related to a disease process, that, when executed together, result in better outcomes than when implemented individually. Providing each element of care within a bundle leads to more reliable total care for patients and should improve meaningful patient outcomes. The Institute for Healthcare Improvement's recently completed and successful 100,000 Lives campaign advocated several practices within care bundles that impact and are important to RTs. The "ventilator bundle" was designed to reduce the incidence of ventilator-associated pneumonia. The Institute for Healthcare Improvement Web site describes the ventilator bundle as follows:

> By definition, VAP is an airways infection that must have developed more than 48 hours after the patient was intubated. Preventing pneumonia of any variety seems at first blush to be a laudable goal. However, there are some reasons to be particularly concerned about the impact of pneumonia associated with ventilator use.

> VAP is the leading cause of death among hospital-acquired infections, exceeding the rate of death due to central-line infection, severe sepsis, and respiratory tract infections in the non-intubated patient. Perhaps the most concerning aspect of VAP is the high associated mortality. Hospital mortality of ventilated patients who develop VAP is 46%, compared to 32% for ventilated patients who do not develop VAP.[29]
>
> In addition, VAP prolongs time spent on the ventilator, length of ICU stay, and length of hospital stay after discharge from the ICU.[30] Strikingly, VAP adds an estimated cost of $40,000 to a typical hospital admission.[31]
>
> Reducing mortality due to VAP requires an organized process that guarantees early recognition of pneumonia and consistent application of the best evidence-based practices.

The key components of the ventilator bundle are:

1. Elevate the head of the bed
2. Perform daily "sedation vacations" and assess readiness to extubate
3. Prophylaxis against peptic ulcer
4. Prophylaxis against deep venous thrombosis[32]

Though the goal of reducing VAP is the theme, other important respiratory care activities are involved in the bundle. Weaning and extubation readiness is specifically assigned to RTs, which shortens the duration of mechanical ventilation.[33] Although this has been known for years, adoption of protocols to implement this process has been very slow.[34] Elevating the head of the bed is an important and shared responsibility—and very low cost! Though prophylaxis against ulcer and deep-venous thrombosis are not usually under direct control of the RT, it is the responsibility of all ICU team members to ascertain if these elements have been considered. By considering only a few, but very important, elements of care, and doing each perfectly, life-threatening complications are avoided and lives are saved. In the 5 years of the 100,000 Lives campaign it is estimated that over 122,000 patients survived who would have died unnecessarily. This claim is based on the mortality of patients in the participant ICUs before the campaign started and actual deaths reported during the campaign.

The difficulty in counting events that did not happen is obvious, but the value of the campaign is that the energy generated for change in clinical behavior was infectious, and improvements occurred that otherwise were not happening. Although only a few key elements of care were mandated and assessed, it is likely that other important elements also changed in the participating hospitals.

Another major benefit of a campaign is the celebration of success rather than punishment of failure (as with the pay-for-performance initiative). Campaigns offer opportunities to rapidly change culture and make changes that would otherwise take years to accomplish. Since the measurements of outcome and process are simple and easy to obtain, comparisons between units and institutions can be used to stimulate healthy competition to improve quality.

Another campaign that impacts the ICU and RTs is the Surviving Sepsis Campaign, which is a joint effort of the European Society of Intensive Medicine, the Sepsis Forum, the Society of Critical Care Medicine, and the Institute for Healthcare Improvement.[35] The goal is to reduce sepsis mortality by 25% by 2009. The basis of the partnership is the campaign's evidence-based guidelines to improve the care of severely septic patients, combined with the quality-improvement cycle advocated by the Institute for Healthcare Improvement. The Severe Sepsis Bundles, when completed together, will substantially reduce sepsis mortality by helping teams follow the timing, sequence, and goals of the individual elements of care. Hospitals use the bundles to create protocols specific to their institutions. However, all of the elements in the bundles must be incorporated in the protocols. The addition of other strategies not found in the bundles is not recommended. The bundle forms the basis for the measurements that improvement teams will conduct to follow their progress as they implement the changes. Hospitals are asked to implement 2 different Severe Sepsis Bundles. Each bundle articulates requirements for specific time frames.

The Severe Sepsis Resuscitation Bundle describes 7 tasks that should begin immediately and must be accomplished within the first 6 hours of presentation for patients with severe sepsis or septic shock:[35]

1. Measure serum lactate
2. Obtain blood cultures prior to antibiotic administration
3. Improve time to broad-spectrum antibiotics
4. Treat hypotension and/or elevated lactate with fluids
5. Apply vasopressors for ongoing hypotension
6. Maintain adequate central venous pressure
7. Maintain adequate central venous oxygen saturation

Some of these items may not be completed if the clinical conditions described in the bundle do not occur in a particular case, but clinicians must assess for them. The goal is to perform all the indicated tasks with all sepsis patients within the first 6 hours of identifying severe sepsis.

The Sepsis Management Bundle lists 4 management goals:

1. Administer low-dose steroids by a standard policy
2. Administer drotrecogin alfa (activated) by a standard policy
3. Maintain adequate glycemic control
4. Prevent excessive inspiratory plateau pressure

Efforts to accomplish these tasks should also begin immediately, but these items may be completed within 24 hours of identifying the severe sepsis or septic shock.

The only recommendation in the Treatment Bundle that is specific to respiratory care is the one on inspiratory plateau pressure. The literature and guidelines supporting that recommendation were mentioned above, where we noted the failure to practice low-V_T ventilation in patients with ARDS. By focusing only on inspiratory pressure and not including the (possibly) more important issue of V_T (based on predicted body weight), we can determine a simple measure of adherence with the recommendation: Is the inspiratory plateau pressure $<$ 30 cm H_2O?

In more detail, the Institute for Healthcare Improvement Web site provides the following from the Surviving Sepsis Campaign regarding this measure:

> Patients with sepsis are at increased risk for developing acute respiratory failure, and most patients with severe sepsis and septic shock will require endotracheal intubation and mechanical ventilation. Nearly 50% of patients with severe sepsis will develop ALI/ARDS. Patients with lung injury will have bilateral patchy infiltrates on chest x-ray, low P_{aO_2}:F_{IO_2} ratio ($<$ 300 mm Hg in ALI, $<$ 200 mm Hg in ARDS), and pulmonary capillary wedge pressure $<$ 18 cm H_2O, although this last measure is often clinically not available.
>
> High V_T coupled with high plateau pressure should be avoided in ALI/ARDS. Clinicians should use as a starting point a reduction in V_T over 1–2 hours to a "low" V_T (6 mL/kg of lean body weight) as a goal in conjunction with the goal of maintaining end-inspiratory plateau pressure of $<$ 30 cm H_2O.
>
> Mortality Reduction. The largest trial of a volume-limited and pressure-limited strategy showed a 9% decrease of all-cause mortality in patients ventilated with V_T of 6 mL/kg of estimated lean body weight (as opposed to 12 mL/kg) while aiming for a plateau pressure of $<$ 30 cm H_2O. The formal ARDS Network protocol for mechanical ventilation is available at http://www.ardsnet.org/lowvtrefcard.pdf and is encouraged for use in septic patients.
>
> Permissive hypercapnia (allowing P_{aCO_2} to increase above normal) can be tolerated in patients with ALI/ARDS if required to minimize plateau pressure and V_T. Although an acutely elevated P_{CO_2} may have physiologic consequences, including vasodilatation and increased heart rate, blood pressure, and cardiac output, allowing modest hypercapnia in conjunction with limiting V_T and minute ventilation has been demonstrated to be safe in small, nonrandomized series. No upper limit for P_{CO_2} has been established. Some authorities recommend maintaining pH at $>$ 7.20–7.25, but this has not been prospectively established. The use of hypercarbia is limited in patients with preexisting metabolic acidosis and is contraindicated in patients with increased intracranial pressure. Sodium bicarbonate infusion may be considered in select patients to facilitate use of permissive hypercarbia. Experimental models suggest that respiratory acidosis may confer protection against various forms of inflammatory injury.
>
> Positive End-Expiratory Pressure. Provide adequate supplemental oxygen to maintain a pulse-oximetry saturation of $>$ 90%. A minimum amount of PEEP [positive end-expiratory pressure] should be set to prevent lung collapse at end expiration. Setting PEEP based on severity of oxygenation deficit and guided by the F_{IO_2} required to maintain adequate oxygenation is one acceptable approach.
>
> For patients supported by mechanical ventilation or who are appropriate candidates for a pressurized face mask, PEEP or continuous positive airway pressure may be used to increase mean and end-expiratory airway pressures, allowing the reduction of the oxygen concentration to below potentially toxic levels (F_{IO_2} $<$ 0.60).[36]

In addition to the above description, a series of "tips" is provided to consider when addressing the inspiratory plateau pressure measure (Table 3).[36] The role of the RT is crucial for success in the Surviving Sepsis Campaign. Reducing sepsis mortality depends in large part on applying the appropriate V_T. Unlike the Saving 100,000 Lives campaign, the details of the sepsis protocols are left to each individual institution to develop. Uniform data are being collected from the Surviving Sepsis Campaign partner hospitals, and success stories are being shared. The success of the campaign will be measured by the reduction in mortality. The Surviving Sepsis Campaign offers an opportunity to rapidly improve care at the bedside, even in patients without sepsis. Since the ventilation principles are the same for all patients with ALI/ARDS, applying the low-V_T strategy to all patients at risk of ventilator-induced lung injury can occur by protocol once the institution or unit has committed to the Surviving Sepsis Campaign.

Besides the national and international attention these campaigns focus on clinical problems, the methods of data collection and evaluation to determine campaign success are important and can contribute to quality-improvement efforts in general. Using easy-to-determine, simple measures of process and outcome, there is little data collection burden and the clarity of the outcome success is unambiguous. Other initiatives are likely to take a similar data approach.

Table 3. Tips From the Surviving Sepsis Campaign to Help Achieve Optimal Ventilation

1. Create a standardized protocol that prompts users to use $V_T \leq 6$ mL/kg ideal body weight and to maintain plateau pressure < 30 cm H_2O.
2. Make execution of an ARDS-Network-like protocol the responsibility of the respiratory therapists.
3. Have stakeholders work in concert with the respiratory therapy department to create and deploy a clinical protocol for ALI/ARDS ventilation.
4. Avoid SIMV during the acute phase of illness. Instead, use mandatory modes such as assist-control ventilation or pressure-controlled ventilation to prevent spontaneous large V_T.
5. Do not allow peak pressure to govern ventilation. The key value is plateau pressure.
6. The weight to determine V_T should be the ideal body weight, not the fat or over-hydrated weight. The ideal body weight is calculated from the patient's height.
7. Do not worry about the P_{aCO_2} unless the pH is less than a threshold the clinical team cannot tolerate. Some intensivists are comfortable with pH as low as 7.10. Most clinicians like to see a pH > 7.21. Timid clinicians use pH in the range of 7.25–7.30. Where renal dysfunction prevents compensation, bicarbonate can be used to help maintain pH. However, constant bicarbonate infusions can contribute to CO_2 production. Tris-hydroxymethyl aminomethane (THAM) does not have that adverse effect.

From Reference 36
V_T = tidal volume
ALI = acute lung injury
ARDS = acute respiratory distress syndrome
SIMV = synchronized intermittent mandatory ventilation

Future Campaigns

Building on the success of the 100,000 Lives campaign, and including its 6 elements, the Institute for Healthcare Improvement has initiated a new 2-year campaign to prevent harm from medical errors in hospitalized patients. This new initiative is called the Protecting 5 Million Lives From Harm campaign.[37] The interventions retained from the 100,000 Lives campaign are:

1. Deploy a rapid-response team at the first sign of patient decline, before a catastrophic cardiac or respiratory event occurs.

2. Deliver reliable, evidence-based care for acute myocardial infarction to prevent deaths from heart attack.

3. Prevent adverse drug events by reconciling patient medications at every transition point in care.

4. Prevent central-line infections by implementing a series of interdependent, scientifically grounded steps.

5. Prevent surgical-site infections by following a series of steps, including reliable, timely administration of correct perioperative antibiotics.

6. Prevent ventilator-associated pneumonia by implementing a series of interdependent, scientifically grounded steps.

New interventions targeted at harm-prevention are:

1. Prevent methicillin-resistant *Staphylococcus aureus* infection by reliably implementing scientifically proven infection-control practices throughout the hospital.

2. Reduce harm from high-alert medications, starting with a focus on anticoagulants, sedatives, narcotics, and insulin.

3. Reduce surgical complications by reliably implementing the changes in care recommended by the Surgical Care Improvement Project.

4. Prevent pressure ulcers by reliably using science-based guidelines to prevent this serious and common complication.

5. Deliver reliable, evidence-based care for congestive heart failure, to reduce readmissions.

6. "Get boards on board" by defining and spreading new and leveraged processes for hospital boards of directors, so they can become far more effective in accelerating the improvement of care.

It is expected that over 4,000 United States and Canadian hospitals will join this campaign, and that an incredible number of harmful events (5 million) may be averted in the next 2 years. Respiratory therapists should be aware of this campaign's potential to advance respiratory protocols. Joining and supporting quality teams within participating institutions can further the agenda for respiratory care. When other methods have failed, joining a campaign can succeed in promoting best practices within respiratory care.

Summary

Modern medical care is complex, dangerous, and differs widely in quality. Efforts to advance what is known to be the best care in particular clinical situations to every bedside has resulted in development of practice guidelines. Advances in EBM have resulted in a large number of quality recommendations supported by science. But there is little evidence that these guidelines are being systematically applied or that care is improving from their availability. Respiratory care protocols developed from practice guidelines have been advocated for years but have failed to gain universal application. To dramatically change clinical practice requires a new approach. International campaigns based on rapid improvement change cycles have the potential to accelerate the change process. They also create an opportunity for the respiratory care community to implement respiratory care protocols as part of campaign care bundles.

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