

INTERFACE

SOCIETY FOR TECHNOLOGY IN ANESTHESIA

P.O. BOX 382 • HASTINGS, MICHIGAN 49058 • (800) 875-2525 • (616) 945-5110

JULY 1991 • VOLUME 2 • NO.3

Justifying New Technology

THE CMPEROR'S NEW CLOTHES REVISITED

Fredrick K. Orkin, M.D., M.B.A. Associate Professor of Anesthesia University Of California, San Francisco

wo years ago, I wrote an editorial urging that anesthesia technology be subjected to outcome studies and cost-effectiveness analyses. I remain concerned that in the absence of such evaluations, we might adopt ineffective, excessively costly, and even harmful medical technology - not only electronic devices, but also drugs, procedures, clinical protocols and practice standards. Why should these studies be done in anesthesiology? How can they be done given the realities in health care?

Technology and Health Care

This year, health care costs for corporate America increased 24% over the previous year. Last year, health care costs amounted to 14% of corporate payrolls, compared to only 5% in 1980. Overall health care costs are approaching \$2 billion per day while an estimated 37 million Americans are uninsured. These unbridled costs have encouraged corporate America to join in a unique coalition with blue collar workers and liberal congressman in calling for a universal health insurance program with spending controls.

see page 23

et's face it, "high tech" medicine is fascinating and seductive. One look at a sleek color monitor displaying every physiologic parameter imaginable and it is easy to become convinced it is necessary for good patient care. But will that very expensive monitoring system reduce morbidity or mortality? The answer to that question is elusive. Most medical technology in use today has not been subjected to scientific scrutiny documenting a positive impact on outcome. Some clinicians would suggest that new technology may be worthless or potentially cause harm unless outcome studies are performed to document If we followed that efficacy.1 recommendation however, new advances of potentially great benefit could be inordinately delayed, and few clinicians would give up the devices they are comfortable with that have never passed the outcome test. Several approaches have been tried in an effort to evaluate the efficacy of new technology. It is essential to understand these methods when evaluating new technology, especially given the increasing, and very appropriate, concern over the cost of technological advances.

INSIDE THIS ISSUE:

- * Justifying Technology
- Pharmacokinetic Drug Administration
- * STA SIG on Compuserve

STA Deadline for Abstracts: October 1, 1991

(see page 21)

TABLE

Event Incidence	Sample Size
1/10	871
1/100	9368
1/1000	94,343
1/50000	4,720,741

Legend: Sample size indicates the number of patients that must be studied to document that a new treatment reduces the incidence of an event by one-half.

Outcome Studies Are Desirable

There is no doubt that outcome studies, those studies that evaluate the impact of a new treatment on morbidity and mortality, are the most desirable method for evaluating any new advance. Unfortunately, there are significant practical obstacles to performing such studies. The first difficulty is studying enough patients to show a statistically significant effect due to the new treatment. For example, assuming an anesthetic related mortality of one per fifty thousand anesthetics, one would need to study more than 4.7 million patients to demonstrate an impact of a new device on mortality! (See Table) Clearly an impact of a new treatment on anesthesia mortality is impossible to document.

One can also evaluate the impact on morbid events which occur more frequently than death such as myocardial infarction. Assuming an incidence of 10%, almost 900 patients would still be required to obtain statistically significant results (see Table). Furthermore, it is difficult to control for the many factors that may contribute to postoperative myocardial infarction besides

see "TECHNOLOGY" page 23



Prospective Data on Pulse Oximetry From Denmark

J.S. Gravenstein, M.D.
Graduate Research Professor
Department of Anesthesiology
University of Florida College of Medicine
Gainesville, FL

Anesthesiologists from many countries have adopted pulse oximetry as a benign monitoring routine during anesthesia, and now to a growing extent also in the postanesthesia care unit. The recent decline in malpractice insurance rates has occurred in response to the assumed benefits of pulse oximetry and capnography. Scientific data to document such benefits, however, have yet to be presented.

Prospective randomized studies of the benefits of pulse oximetry are difficult or impossible to conduct once the method has become a routine in a hospital because clinicians are then unwilling to deny their patient the assumed benefits of monitoring O_2 saturation with the pulse oximeter (S_pO_2). Three years ago, however, pulse oximetry had not been generally accepted in Denmark, and, therefore, the opportunity to conduct a large scale prospective study of the method arose.

The Study

In five participating hospitals, 20,000 patients were recruited into the study. Half of the patients were monitored with, and half without, pulse oximetry during general or regional anesthesia. All patients were adults and all ASA physical status classifications were accepted. Outpatients and patients scheduled for neurosurgical or thoracic procedures were excluded. The patients were classified by demographic, physical, and clinical descriptors. Blinded randomization by codes contained in an envelope — was done after the patient had been assigned to an operating room. All aspects of anesthesia care, from preoperative medication to choice of anesthesia and treatment in the PACU were kept in harmony with each participating hospital's routine and were unaltered whether or not the pulse oximeter was used.

Intra-anesthetic and PACU events that required attention or intervention were classified under one or more of 39 carefully

"Three years ago the opportunity to conduct a large scale prospective study of pulse oximetry arose."

defined terms covering airway and ventilation, heart and circulation, nervous system, and a miscellaneous group including nausea, vomiting, shivering, oliguria, drug overdose, and curarization. Each term was clearly defined, for example, oliguria was defined as urine output below 20 ml in 2 hours. Postoperative complications were similarly assessed from a list of clearly defined possibilities before the patient's discharge, or no later than the seventh day postoperatively; possible complications included items such as pneumonia, atelectasis and pulmonary embolism.

Data from this extensive study conducted by Dr. J.T. Moller are now undergoing statistical analysis and results are expected at the time of the ASA meeting in October, 1991.

INTERFACE is the official newsletter of the Society for Technology in Anesthesia. The newsletter is published quarterly and mailed directly to the membership of the society. Copies are also distributed to companion societies in Europe and Japan. The editor invites suggestions, contributions and commentary about published items. Please send all correspondence to:

Jeffrey M. Feldman, MD

Editor, STA Newsletter
Department of Anesthesiology
Yale University School of Medicine
333 Cedar St.

New Haven, CT 06510 Phone: 203-785-2802 FAX: 203-785-6664

E-Mail: FELDMAN@YALEMED.BITNET

The newsletter is printed on recycled (and recyclable) paper.

Malpractice Insurers Recognize Technology

(Based upon an interview with Denise Funk, Executive VP and Chief Operating Officer, Connecticut Medical Insurance Company, Glastonbury, CT.)

Recent reductions of malpractice premiums for anesthesiologists who follow the American Society of Anesthesiologists including monitoring guidelines, capnography and oximetry, are striking. The Connecticut Medical Insurance Company (CMIC), the largest malpractice carrier in the state, has reduced malpractice premiums for anesthesiologists who follow these guidelines by 31% over three years. Since data are not available to document improved outcome due to the use of monitoring technology, it is striking that the insurance industry has chosen to reduce premiums solely for the use of such technology. These insurers have remained solvent after these reductions implying that either the previous premiums were inflated or, that there has been a true reduction in risk exposure for anesthesiologists that follow the monitoring guidelines.

The Medical Malpractice Joint Underwriters Association (JUA) of Massachusetts was the first insurer to reduce premiums for anesthesiologists following ASA monitoring guidelines including capnography and oximetry "where appropriate." That decision was based upon the fact that the greatest risk exposure is due to respiratory complications leading to hypoxic injury or death, and the impression that these devices would reduce serious losses. Many other insurers, including the CMIC, followed the Massachusetts JUA lead. CMIC based their decision on loss data that accumulated during the time that oximetry and capnography were introduced.

CMIC was organized in October, 1984 to provide malpractice insurance to Connecticut physicians. According to Denise Funk, CMIC Chief Operating Officer, from

concluded on page 20

TULY 1991



PERSPECTIVES ON TECHNOLOGY

TOPIC: PHARMACOKINETIC DRUG ADMINISTRATION

"Though newer, fast acting IV agents are well suited to PK infusion, the biggest obstacle to overcome may well be tradition."

The Industrial Perspective

Noel L. Johnson Abbott Critical Care Systems Mountain View, CA

Identification of New Concepts

An important key to success in developing critical care products is to understand the market and anticipate future customer needs. Working closely with clinicians to identify new concepts, and funding promising research, is one way to stay abreast of emerging medical trends.

Pharmacokinetic (PK) model-based infusion of intravenous (IV) anesthetic agents, a topic of increasing interest in anesthesia, first yielded published clinical results more than a decade ago. Early researchers made the analogy between a) using PK infusion algorithms to achieve desired plasma concentrations of IV anesthetics and b) using the calibrated vaporizer to achieve a desired MAC of a potent inhalation agent.

Early clinical studies demonstrated that when compared to intermittent bolus and continuous infusion methods of drug delivery, PK infusion produced anesthesia with greater hemodynamic stability, reduced need for supplemental anesthetics or vasoactive drugs and decreased total drug dosages. When used for narcotic administration, PK infusion avoided the relative anesthetic overdose that can occur with conventional infusion, allowed better prediction of wake up time without the use of naloxone and shortened patient recovery times.

These early results attracted industrial interest and support.

Support for Clinical Research

Since nearly all new product ideas come from clinicians, industry must actively support clinical research on emerging technologies. It is equally important for clinicians to pursue industry sponsorship and expertise to turn concepts into successful commercial products. For example, early clinical experience with alfentanil demonstrated it is most effectively delivered by continuous infusion. This was found in large part because Janssen guided the clinical research and Bard developed an infusion pump specifically for alfentanil. Through this collaborative effort between industry and clinicians, the first successful operating room IV anesthesia system was developed. Continuous infusion of IV anesthetics, though not yet universally accepted in clinical practice, is much more wide spread now due to the availability of Bard OR pumps. As continuous infusion dosing techniques become more prevalent, interest grows in the application of PK model-based infusion.

"In a few years CCIPs will consist of an inexpensive silicon card that plugs into a pump that would be purchased anyway."

The Clinical Perspective

Steven L. Shafer, M.D.
Assistant Professor of Anesthesiology
Stanford University School of Medicine
Palo Alto, CA

Computer Controlled Infusion Pumps

The computer controlled infusion pump (CCIP) is a recent advance in clinical pharmacology that may substantially improve intraoperative drug titration. A CCIP administers an intravenous drug based upon a pharmacokinetic model of the drug. When programmed with accurate pharmacokinetic parameters, the CCIP can rapidly achieve, and maintain, any desired plasma drug concentration more accurately than is possible using simple infusion regimens.

The potential advantages of a CCIP are apparent when one considers the three compartment model typically used to describe the pharmacokinetic profile of intravenous anesthetics. After an intravenous bolus of drug, the concentration in the central compartment is initially high. The concentration then falls exponentially due to elimination and distribution to other compartments. Constant rate infusions do not account for the exponential nature of the changing concentration and therefore will not maintain a constant plasma concentration. The CCIP can provide a combination of either bolus drug delivery or changing rate infusion according to a pharmacokinetic model and therefore maintain a constant concentration.

Clinical Experience

The Computer Assisted Continuous Infusion (CACI) pump developed by Alvis and Reves was one of the first CCIPs used to administer intravenous anesthetics. Their results with fentanyl were similar to the results reported by Ausems for alfentanil.² Glass used the CACI II software to administer fentanyl to 24 surgical patients and found a median absolute prediction error of 21% when comparing target to measured serum concentrations.³

Ausems compared CCIP administration of alfentanil to intermittent alfentanil boluses in 20 healthy female patients.⁴ The patients receiving alfentanil by CCIP had significantly fewer hypertensive and tachycardiac episodes than those receiving alfentanil by intermittent bolus injection. Ausems also studied the accuracy of alfentanil administered by CCIP in 15 healthy female patients.² The average prediction error was 32%, which is somewhat worse than the 18% median error in another study of alfentanil administration by CCIP using a different pharmacokinetic parameter set.⁵

20

The Industrial Perspective

continued from page 19

Identification of Risk Factors

PK infusion must both simplify the practice of IV anesthesia and improve patient care to become successful. However, many issues are controversial. For most drugs, there are a wide variety of pharmacokinetic constants published. Which constants should be used? Should they be based upon arterial or venous measurements of plasma concentration?

Variations in PK values may be due to weight, age, sex, nationality, disease state or even time. Where should the population limits be drawn so that a set of PK constants accurately apply to a given individual? Further, what is an acceptable accuracy for desired versus actual plasma concentration? These issues and others must be resolved before commercialization is possible.

Though newer, fast acting IV agents are well-suited to PK infusion, the biggest obstacle to overcome may well be tradition. Intermittent bolus techniques have been successfully used for decades, and demonstrating the feasibility and efficacy of PK infusion will take time.

The Future

The most desirable method to deliver IV agents is to utilize a pharmacodynamic system that can monitor the physiologic variables of interest, and automatically control drug infusion to maintain those variables within a range specified by the anesthesiologist. For most drugs, however, pharmacodynamic infusion control is not possible. This is due to either a lack of physiologic feedback or insufficient understanding of the important physiological processes. For some IV drugs, however, the relationship between pharmacodynamic effect and serum concentration is sufficiently well described that PK infusion may be a more rational method of delivery than currently practiced dosing techniques.

Active industrial support of clinical research should provide the marketplace with well designed new products. As commercial PK model-based infusion systems become increasingly available, anesthesiologists can judge for themselves if industry has in fact provided a tool to improve healthcare and if the early analogy to the calibrated vaporizer and MAC is valid.

The Clinical Perspective

continued from page 19

Pharmacokinetic Parameters **Important**

Lemmens described poor clinical results using a computer controlled infusion of alfentanil in elderly patients. 6 He reported a high incidence of hypotension, bradycardia, and muscle rigidity. Nine of 18 patients required naloxone at the conclusion of the anesthetic. These patients were obviously overdosed, demonstrating the importance of using accurate pharmacokinetic parameters in a CCIP.

Other Agents

CCIPs have also been developed for administration of propofol with good results. Schüttler used CCIP administration of both propofol and alfentanil to administer "total intravenous anesthesia." He reported, "smooth induction, good control during anesthesia, and fast recovery without major side effects."7

In our own work we have used CCIPs to administer fentanyl, alfentanil, sufentanil, thiopental, propofol, lidocaine, diazepam, midazolam, detomidine. dexmedetomidine to volunteers, patients, dogs, horses, and rats. It is our clinical impression from these studies that a CCIP really does improve the ability to titrate intravenous anesthetics.

Is the improved drug titration possible with a CCIP worth thousands of (increasingly scarce) dollars? Probably not. Fortunately, CCIPs require very little computing power and, infusion pumps are more intelligent becoming anesthesiologists look for additional features in these devices. In a few years CCIPs will consist of an inexpensive silicon card that plugs into a pump that would be purchased anyway. Pharmacokinetically controlled drug administration will then become extremely attractive to clinicians. In the meantime, any reader with a PC interested in CCIP infusion can obtain CCIP software, at no charge, simply by writing to me at Anesthesiology (112A), PAVAMC, 3801 Miranda Avenue, Palo Alto, CA 94304. �

References:

- 1. Alvis JM et. al. IEEE Trans Biomed Eng 32:323-329, 1985.
- 2. Ausems ME et. al. Br. J. Anaesth. 57:1217-1225, 1985.

- 3. Glass PS et. al. Anesthesiology 73:1082-1090, 1990.
- 4. Ausems ME et. al. Anesthesiology 68:851-861, 1988.
- 5. Raemer DB et. al. Anesthesiology 73:66-72, 1990.
- 6. Lemmens HJ et. al. Anaesthesia 43:850-856, 1988.
- 7. Schüttler J et. al. Anaesthesia 43: Suppl 2-7, 1988.

Malpractice Insurers Recognize Technology

continued from page 18

1984 to 1986, there were several claims against anesthesiologists for hypoxic injury that could have been avoided by using appropriate monitoring technology. Since 1987, no losses related to hypoxic injury have been reported by CMIC insured anesthesiologists. CMIC surveyed practitioners they insured and found



"Since 1986, no losses related to hypoxic injury have been reported by CMIC insured anesthesiologists."

universal adoption of capnography and oximetry. Actuarial analysis of the CMIC experience and similar information from other insurers has supported the reduction of risk classification, and therefore premiums, for anesthesiologists.

The data utilized by the insurance industry do not document a correlation between the use of monitors and a reduced incidence of hypoxic injury. Rather, these data only measure the reduction in claims reported by anesthesiologists. Since the most striking change in anesthesia practice in recent years is adoption of capnography and oximetry, the correlation to a reduced incidence of hypoxic injury has been assumed. �

- I. Feldman, MD



PCOMING EVENTS

ESCTAIC Annual Meeting

Second Annual Meeting of the European Society for Computing and Technology in Anesthesia and Intensive Care. October 9 through 12, 1991. Goldegg Castle, Salzburg, Austria. Contact:

> Dr. Leo Moser Anaesthesiologie PO Box 30 A5014 Salzburg, Austria

ASA Annual Meeting

American Society of Anesthesiologists Meeting. October 26 through 30, 1991. San Francisco, California. Contact:

American Society of Anesthesiologists 515 Busse Highway Park Ridge, III 60068 (800) 562-8666

STA '92

Second annual meeting of the Society for Technology in Anesthesia, January 29 through February 1, 1992. US Grant Hotel, San Diego, CA. See article at right for complete information.

STA '92:

"There's a Problem to Solve!"

The second annual meeting of the Society for Technology in Anesthesia will be held in San Diego, CA, January 30 through February 1, 1992. The theme for the meeting will be Decision Making in Anesthesia: Design of the Workstation. A series of focused lectures, participatory workshops and open forums will allow participants to share questions and insights with colleagues while learning the background necessary to redesign the anesthesia workstation. After the scientific presentations and tutorials on the first day, a workshop on system design the second day will prepare participants for a design exercise that evening. Multiple teams will compete with one another in the design process, and on the morning of the third day, results of the work of each group will be presented for debate and analysis.

Representatives from industry, experts in design techniques and colleagues who have learned from frustration what the workstation should do will be participating. Plan to attend this unique meeting in sunny San Diego.

Abstracts Invited for STA '92 Due October 1, 1991

We invite participants to present abstracts at the STA second annual meeting. The format for the scientific sessions will be Poster Presentations preceded by approximately 1 minute verbal summaries. Demonstrations of a non-commercial

nature are also encouraged.

STA will publish accepted abstracts in the meeting Proceedings and in the April 1992 issue of the Journal of Clinical Monitoring.

Abstracts should be 250-500 words plus tables, figures and references. Please include the following information: Title, Author(s)' names and degrees and affiliations. The abstracts should be organized to include Introduction, Methods, Results and Discussion sections. In addition, please provide a Summary Sentence at the end.

Since abstracts will be typeset professionally, we prefer a monospaced font (eg. Courier 12 point) printed with a letter quality printer. A printed copy of the abstract must be received by mail, but we welcome an electronic version on disk (ASCII or word processor format) or via Email. Please also enclose a cover letter or README file with mailing address, telephone number, FAX number, E-mail address if available and any resources required for a demonstration. Submissions should be sent to:

James H. Philip, MD

STA Scientific Chairman
75 Francis St. • Boston, MA 02115
Tel: (617) 732-7330
Fax: (617) 732-6798
E-mail: 241-8308@MCI.com

For complete info regarding STA '92:

Gerri Kuzava

STA Executive Secretary
P.O. Box 382

Hastings, Michigan 49058

(800) 875-2525 or (616) 945-5110.

Medical Special Interest Group of the Human Factors Society

Many aspects of technology in anesthesia involve designing medical equipment so that it is easy to use, that is the "human factor" in technology. The Human Factors Society (HFS) is a large multidisciplinary organization of professionals working on human factors

issues in research and industrial settings. The Society has a section related to medicine called the Special Interest Group on Medical Systems and the Functionally Impaired (SIGMSFI). This group publishes a newsletter 3-4 times per year which includes news of meetings and symposia, abstracts, news from related groups, etc. The editor encourages interesting contributions to the newsletter.

SIGMSFI would like to foster membership from the medical community and invites members of STA to join. This is our chance to make our voice heard in the wider human factors community. You do

NOT have to be a member of the HFS to join this Special Interest Group. Membership in the SIGMSFI costs ONLY \$4.00. If you are interested in becoming a member send a check to Paula Sind, Ph.D.:

Paula Sind, Ph.D. SIGMSFI Chairperson/President School of Psychology Florida School of Technology 150 W. University Blvd Melbourne, FL 32901

- David M. Gaba, MD

SIGnatures

Notes from the STA Special Interest Group



The Society for Technology in Anesthesia Special Interest Group (SIG) is now fully functional on the CompuServe Information Service. We are using Section 6 of the Medical SIG (MedSIG). This can be reached from any "!" prompt on CompuServe by typing GO MEDSIG and then a carriage return. The two main areas of interest are the Bulletin Board and the Libraries. The bulletin board contains messages which can be posted by any interested party. As new messages are added to the bulletin board, older messages are ultimately deleted so that one should check the board at least once a week to avoid

missing information. Recent topics discussed include the Ohmeda Rascal II gas monitor, volunteering for work with the STA, use of heated humidifiers, monitoring during MRI scans, and functionality of long tubing for non-invasive blood pressure devices.

New Addition to the Library

The exciting news from the library (Library 6) is that Mike Gorback from Duke University has been kind enough to post a number of graphics files of airway anatomy and intubation from his new book on Emergency Airway Management (BC Decker, Phila, PA). These files are in ".GIF" format and may be downloaded to your computer and displayed on your video screen. A "viewer" program is required, and one of these may be downloaded from the Graphics Support Forum on CompuServe (GO GRAPHICS). (My personal favorite of these is VPIC.) The images are in 640x480 resolution, 256 colors, and guite beautiful. (They are intended for IBM and compatible computers with advanced VGA boards, but there are conversion programs which allow them to be viewed on other computers, and to be printed in monochrome or color.) A listing of the figures that are available can be found in (a) a master catalog for all the MedSIG libraries, (b) by selecting DIR or BROWSE in Library 6 and (c) in Mike Gorback's message which for now has been held in the Message Section 6. These files are fairly large and will require 5-20 minutes to download at 2400 baud.

Frequent users of Compuserve will be interested in ways to use the service more efficiently and reduce on-line charges. The TAPCIS or AutoSIG programs available on CompuServe will automatically log into CompuServe, check your mail, visit your favorite SIGs, etc., and then log off. You can then review your mail and messages and compose your replies off-line, and then have the program redial and post your replies. These programs may save connect time, but the fact is that most users find these programs so efficient that they get involved in more SIGs, receive more mail and ultimately spend MORE money on CompuServe than before! Caveat emptor!

If you have not yet investigated the STA SIG, sign on and become a part of this growing forum. CompuServe starter kits are still available while supplies last. To receive a starter kit contact Dr. Frank Block, OSU Dept. of Anesthesiology, 410 West 10th Avenue, Room N-429, Columbus, Ohio 43210, FAX: 1-614-293-8983.





Drum performance at "Shogun" Banquet.

ISCAIC:

A Memorable Event

The 6th ISCAIC, International Symposium on Computing in Anesthesia and Intensive Care, was held in Hamamatsu, Japan, April 15-18. Thanks to extensive planning by Professor Kazuyuki Ikeda, Chairman of the Organizing Committee, and many others, the meeting was a spectacular academic and cultural success. Of the 391 participants, 101 traveled from 22 foreign countries.

Scientific presentations underscored the broad impact of computing in anesthesia and intensive care. New technologies were presented and old technologies reexamined. Topics included advanced decision-making support, computer-assisted controlled infusions (CACI) and computer-based

simulations. Many presentations were followed by lively discussions.

All participants were treated to gracious and thoughtful hospitality. For example, although the official language was English, every panel had a bilingual member to assist with questions. Numerous candid photographs were taken by our hosts of participants and their families during parties and excursions. These "souvenirs" were thoughtfully made available throughout the meeting. A lakeside party was preceded by a cruise and followed by a traditional Japanese (hand-held) fireworks display.

The 6th ISCAIC will not soon be forgotten.

- Julian Goldman, MD

TECHNOLOGY

continued from cover page

the technology being studied.

Identifying a control group can also be a problem for outcome studies. If the treatment being studied is widely believed to contribute to quality care, it is difficult to deny that treatment to a group of patients on ethical grounds. Given the difficulties of performing these outcome studies, other approaches have been used to evaluate the efficacy of technology.

Alternatives to Outcome Studies

Changes in patient status that are generally agreed to be undesirable, eg. hemoglobin desaturation, can also be used to evaluate new technologies. The logic to this approach is that a new device which reduces the incidence of hemoglobin desaturation must improve outcome. This type of study has been attempted to evaluate the use of a pulse oximeter to measure hemoglobin desaturation.2 That study found that when clinicians were not made aware of the pulse oximeter data, there were more episodes of measured oxygen saturation (SpO2) below 85%. The investigators intervened when SpO₂ was less than 85% and there were no adverse outcomes. Since no difference in outcome was measured, it is impossible to conclude that the pulse oximeter was beneficial.

The ongoing ASA closed claims study has also attempted to justify the use of technology.³ Reviewers were asked to analyze 1,175 closed malpractice claims to determine if currently available technology could have prevented a negative outcome had it been in use at the time of the event. The reviewers determined that 31.5% of the incidents could have been prevented by additional monitoring, and that in 93% of those cases pulse oximetry and capnography would have been most useful.

The malpractice industry has also lent credibility to the use of technology despite the absence of scientific data documenting efficacy. The Massachusetts Joint Underwriting Association provides malpractice coverage for anesthesiologists in that state, and was the leader in reducing malpractice premiums to those anesthesiologists who institute monitoring standards which include pulse oximetry and capnography. This policy insures that all anesthesia providers will use these devices and discussions about their utility become irrelevant.

Pulse oximetry and capnography have been the most visible additions to monitoring technology in anesthesia in recent years. Since airway complications are the primary cause of serious anesthesia-related mishaps, it is not surprising that these two devices have become so widely used. Many other advances such as automated recordkeepers. computer-controlled infusion pumps and noninvasive cardiac output monitors have engendered much enthusiasm but little evidence to document patient benefit. If we seek to document an impact on outcome, these devices will likely never become widely used. Nevertheless, a careful analysis of the cost effectiveness of these devices is becoming increasingly important.

In this issue, some perspectives on justifying the use of technology are presented. Readers are invited to send commentary on this controversial topic. •

References:

- 1. Keats AS, Anesth Analg 1990; 71:113-119.
- 2. Cote et.al., Anesth 1988;68:184.
- 3. Tinker et.al., Anesth 1989;71:541.

- J. Feldman, MD

The Emperor's New Clothes Revisited

continued from cover page

Over two decades, technology accounted for 25 to 50 per cent of health care cost increases. Given that health care indices (e.g., longevity, infant mortality) in the US indicate a lesser quality of care than in countries devoting less of their economies to health care, there has been increasing suspicion, supported by research, that health care technology is less beneficial than expected. Examples identified in our specialty include excessive preoperative testing (blood tests, ECG, chest x-ray) and the sanctity of a preoperative hemoglobin greater than 10 g/dL. That respiratory catastrophes still occur, despite the use of pulse oximetry, suggests that we have overestimated the value of this technology.

Underlying the inappropriate use of technology is inadequate knowledge of its value. "Technology assessment" has therefore become a major activity. A federal agency has been expanded to support

prospective, multi-institutional studies of medical technology; among its first patient outcome research team (PORT) studies are five-year studies of the treatment of gallbladder disease, back pain, cataracts, and prostatic disease. Cost-effectiveness will soon be an evaluation criterion for coverage under Medicare which, like other insurers, has already begun tracking patient outcomes to determine the greatest benefit for the available funding.

Studying Technology in Anesthesiology

Our specialty has been among the more aggressive in implementing sophisticated technology, but it lags behind other specialties in performing meaningful evaluation. Although the task is as complicated as it is necessary,2 we have made it more difficult by focusing on uncommon events. In addition, we misapply the term "medical outcome," which is broadly defined as "a change in a patient's current and future health status." We have been fixated on intermediate events such as myocardial ischemia and pulmonary aspiration rather than focusing on true outcomes. The rest of medicine is focusing on death (to which we pay attention although it is rarely associated with anesthesia care), functional status, quality of life, and costeffectiveness among other measures of outcome of medical technology.

Some will respond immediately that such outcomes are not directly related to anesthesia care but rather confounded by other aspects of the surgical experience. Precisely for that reason, since anesthesia care is inextricably part of the broader experience, we should join with surgical and nursing colleagues, as well as others with the requisite technical skills, in cooperative studies. When possible, new technology should be limited to a few study sites. Recognizing that new technology will have a more difficult time establishing itself in an increasingly cost-oriented society, we should also work with manufacturers to conduct evaluations. In this way we can prevent the proliferation of undesirable technology while the resources we save will enable better use of technology, help fund basic biomedical study and encourage innovation at the most fundamental level.

References:

- Orkin FK.Anesthesiology 70:567-571, 1989
- 2. Fineberg and Hiatt. N Engl Med 301:1086-1091