JSTAIC Holds 10th Annual Meeting

Takaaki Kitano, MD, Oita, Japan
Naosuke Sugai, MD, PhD, Tokyo, Japan

The Tenth Annual Meeting of JSTAIC (Japanese Society for Technology in Anesthesia and Intensive Care) was held at the City Hall of Oita on the island of Kyushu on November 7, 1992. The meeting was organized by Dr. Natsuo Honda, Professor and Chairman, and his staff at the Department of Anesthesiology, Oita Medical University. The city of Oita is one of the first port cities opened to the west in the 16th century and the location of the first western style hospital in Japan, built by Louis Armeida, a Portuguese physician who came with the Jesuit priest, Francisco Xavier. The area is blessed with a beautiful bay and a number of hot springs in the surrounding hills.

An invited lecture was delivered by Dr. T. Nabeshima, Associate Professor of Electrical Engineering at Oita University who teaches information processing at the Oita Medical University. He talked about the use of computers in education and research, emphasizing the importance of information science in medical education. Dr. Nabeshima

Statue of Louis Armeida, a 16th century Portuguese physician, treating a patient with his assistants. (Oita City, Japan)

expressed a desire for more communication between the different disciplines interested in information processing.

Many Topics Discussed

Forty two papers were presented, 17 of which were presented using a personal computer of either the NEC 9801 series or Macintosh II. The majority of these presentations were by young anesthesiologists who are also computer fanatics.

Papers covered a wide variety of topics including patient monitoring, the use of computers for management of the operating room or ICU, pharmacokinetic analysis, publication of electric journals and others. Some of the more notable presentations follow:

INSIDE THIS ISSUE:

- ◆ Update on SMDA
- ◆ Anesthesia Technology in China
- ◆ AMIA Spring Congress

What's New in JCM

It is more than eight years since the first issue of the *Journal of Clinical Monitoring* (JCM), and many of the original goals have been met. These goals included a dedication to: 1) gather into one source new information relevant to clinical monitoring, 2) bridge a gap and accelerate the exchange of knowledge among the groups that share an interest in monitoring, 3) help the clinician apply new monitoring devices or explore new concepts, 4) help the innovator identify new needs or opportunities to improve existing systems, 5) help clinicians and engineers exchange information and knowledge and work together, 6) ensure that these groups understand each other. Although the Journal has been a success, with maturity comes an opportunity for introspection and change.

Clinical Focus

We realize how much our readers, clinicians as well as engineers and designers, value clinical relevance in the material we publish. Consequently, we are planning to redouble the emphasis on "Clinical"' in the title of our Journal. Part of that effort will be an expansion of the "Knowing Your Monitoring

President's Message

Jerry M. Calkins, PhD, MD

Exciting things are happening for STA members. I hope everyone has marked their calendars to attend the events at the October ASA annual meeting. Al Grogono's committee has done it again. Commander C.M. Wood, USN, a submariner, will be the featured speaker at the STA-sponsored dinner meeting. A breakfast panel will also be held entitled, "New Technology: Can we afford It? Can we afford not to use it?" These activities are always a nice diversion from the more typical ASA events and, we also have some special surprise events planned for the dinner. I look forward to seeing you in Washington D.C. in October.

Annual Meeting Plans

Each year the STA annual meeting seems to improve and 1994 is no exception. Nik Gravenstein's committee on the Annual Meeting is making great progress towards planning a super event for us in 1994. The meeting's theme is "Learning about Technology—Technology for Learning" and will be jointly sponsored with the Society for Education in Anesthesia (SEA) and the Anesthesia Patient Safety Foundation (APSF). As usual, many new and innovative topics will be presented including simulators, and new approaches to education. The venue of Orlando, Florida also offers a multitude of entertainment and educational activities. The meeting organizers are hard at work to develop an interesting program that includes the activities in the surrounding area. The meeting is scheduled for January 27-29, 1994. The meeting hotel is located right on the Disney World grounds, so plan on bringing your family. You can work while they play.

Committees Active

As I stated in the last issue of the *Interface*, I feel it is important that we

> ■ *"New ideas are always welcome and encouraged."*

use this column to bring the membership up-to-date on what is happening within the Society. From time-to-time, I would like to highlight some of the unsung heroes and heroines of our organization. These individuals put in a lot of volunteer time and effort to keep this Society running. Therefore, I would like to begin by focusing on some of our committees.

The Bylaws Committee is chaired by Allen K. Ream MS, MD and has two members at present, our secretary, Matthew B. Weinger, MD, and Alex Gerwer. These individuals have the task of making sure this Society operates and governs itself within a defined set of rules and regulations. The good news is that bylaws can be changed. The bad news is that it takes dedication to write the bylaws and keep them current. From time-to-time, you will be learning about some of the ways that we are changing our modus operandi, and it is extremely important that we do it within the legal confines of appropriate governance and policy.

The **Committee for Research** is a new committee being formed and is currently being chaired by Dwayne R. Westenskow, PhD. Richard Bartkowski, MD has joined Dwayne in this effort. This committee's role is to promote research for technology and its applications to anesthesia within the mission of STA. The committee is discussing many directions including development of position papers, directions for research, as well as, methods to fund research. There is an opportunity to help shape the direction of this com-

mittee. If you are interested in helping, please contact Dwayne or myself.

Another extremely important committee is the **Committee for Archives and History of STA**. Frank E. Block, Jr., MD, our immediate past secretary, has agreed to chair this committee. Frank and our current secretary, Matthew B. Weinger, MD, are in the process of putting together a memorable

The Role Of Standards in Computer-Based Patient Records

Robert Megargle, Chair, ASTM Committee E-31 on Computerized Systems
Department of Chemistry, Cleveland State University

There is growing consensus that computerization of patient records will yield tremendous advantages over handwritten records. Information should be more accurate due to a reduced chance of transcription error. Better medical decisions should be possible if more complete and accurate medical information is presented to careproviders as they are seeing the patient. There also should be substantial cost savings if automated systems take over much of the record keeping and billing work currently done by clerks. Better data should also enable regulatory reviews to be done at lower cost. The accumulating database of medical problems, interventions, and outcomes will be an enormous reservoir of information for medical research.

To be most useful the computer-based patient record (CBPR) should meet three criteria:

Medical information must be saved in a structured fashion. This is essential if we are to be able to retrieve stored information and analyze that information in a meaningful fashion. It is not sufficient to merely record medical data as digitized text since that will mandate that a knowledgeable person be available to read the information to understand its importance. We must structure and encode the information if we are to exploit the power of the computer to sort, organize, extract, correlate, and interpret the data.

The structure and meaning of medical information must be consistent for all institutions. The healthcare reform movement is well underway and is driving a tremendous demand for information to make decisions about appro-priate medical practice patterns. Multi-institutional studies are needed to gain the numbers necessary for meaningful analysis. Pooling data from many institutions can only be accomplished through consistent definitions of the data.

The patient record created at every location must be compatible. Ev-

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■ ...the CBPR involves concepts and data structures that are unique to particular medical specialities

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ery individual receives healthcare at a variety of locations throughout their lifetime. To build a comprehensive record of each person's medical history will require that data from all these locations be pooled as it is created. It will soon be possible to record this information on a credit card sized device which the patient can take from place to place.

Standards and ASTM

National standards are necessary to achieve the aforementioned objectives. Such standards should not attempt to define how computer systems should implement the CBPR. Instead, they should concentrate only on the logical structure and characteristics of the medical data, and on the mechanisms by which medical information is transmitted from one computer to another. The intent is to ensure that the information flow between different systems is facilitated, not to define any particular hardware or software approach. Indeed, the process of creating

the CBPR will be enhanced by competition between system vendors to build better systems.

The American Society for Testing and Materials (ASTM) was started about 95 years ago to develop standards for commerce and industry. Today, ASTM has about 34,000 members from over 80 countries and it publishes about 8500 standards annually in 68 volumes of the ASTM Book of Standards. It is the largest voluntary consensus standards writing body in the world. The ASTM organization itself has no technical expertise for the content of its standards. The expertise comes from volunteers who serve on about 134 technical committees covering a wide range of topics.

Typical ASTM volunteers are men and women of vision who understand how their own disciplines can be improved by standardization, and who have the initiative to commit their time and effort to develop these standards. Most standards in the United States are not government mandates, nor are they imposed by industry. They are developed in the private sector by bringing together builders, sellers, buyers, users, experts, and people with a common interest. Through a series of meetings and draft documents, standards evolve until there is consensus agreement about their content. ASTM then publishs the standards for general distribution.

Committee E-31 on Computerized Systems has been working for a number of years to develop standards in the area of medical computing systems. The current medical subcommittees of

Technology in Anesthesia in Continental China

Hong-Lin Du, MD, Department of Anesthesiology, Beijing Medical University
Naosuke Sugai, MD, PhD, Department of Anesthesiology, University of Tokyo

In the Chinese continent, the size of a medical university is much larger than that of the countries in the West. Each medical university receives about 300 freshmen every year. Before entering the medical university, a student must decide which specific faculty of the medical university is preferred, e.g. the faculty of general medicine, pediatrics, gynecology, surgery, or anesthesiology. These students are educated from the outset to be a specialist in their chosen discipline; those trained in general medicine can pursue specific training such as anesthesiology after finishing the medical university.

Education and Research in Medical Engineering

There are not many medical universities that offer training in anesthesiology. At present, only six faculties of anesthesiology exist within established medical universities. In these universities, physics for anesthesiology is taught to medical students training in anesthesiology. For practicing anesthesiologists, refresher course lectures on physics related to anesthesiology are held by the Chinese Society of Anesthesiology (CSA). These courses are offered for anesthesiologists all over the country typically in big cities like Beijing or Shanghai. Attendees come from all parts of China supported by the hospitals in which they work. Training in biomedical engineering is offered to non-physicians in ten non-medical universities throughout the country.

China has a population of more than one billion served by about 50,000 anesthesiologists, of these, only about 200 anesthesiologists are involved in medical engineering research. The research activities mostly involve funda-

mental topics such as the anesthesia machine and anesthesia breathing circuit. In one or two institutions, research on computer-controlled anesthesia is underway. Because of the limited availability of computers to anesthesiologists, however, their application to anesthesia is not popular. Professor Fang Zhen of Harbin Medical University is one of the few investigating computer applications to anesthesia.

Academic Activities

In January of 1992, the First National Congress on Respirator and Anesthesia Machine was held in Harbin, a city located in the northeast of China. About 200 people attended the congress and 150 papers were presented.

There is, however, no Chinese-language journal devoted to medical engineering in anesthesiology, but there are six journals which deal with medical engineering in general. Some of these journals have english language abstracts.

(1) *Chinese Journal of Physical Medicine* - Introduces theories and techniques of modern physics applied in medicine. Reports on ultrasonic diagnostics, magnetic medicine, electron microscopy, medical laser technique,

computer application in medicine and others topics.

(2) *Chinese Journal of Medical Instrumentation* - Introduces new medical instruments and modification of medical instruments.

(3) *Foreign Medicine* (Section of Biomedical Engineering) - Introduces progress and information on biomedical engineering outside China.

(4) *Chinese Journal of Biomedical Engineering* - Publishes original reports on research in biomedical engineering.

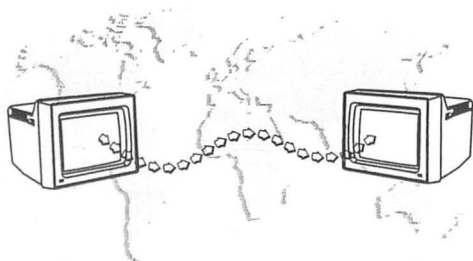(5) *Journal of Biomedical Engineering*

(6) *Medical Physics*

When one of the authors (H.D.) returned to China for holidays in September 1992, a great improvement in the supply of sophisticated medical instruments for anesthesiology was apparent. At Beijing Fuwei Hospital which deals with cardiovascular surgery, most of the monitors used in the operating suite are from the US or western Europe. With the annual GNP growth rate of about 10%, more sophisticated equipment will be available in the near future, and more emphasis on medical engineering will be both possible and necessary. (Hong-lin Du, MD is currently a visiting anesthesiologist from Beijing University in the Anesthesiology Department, University of Tokyo Faculty of Medicine.) ◆

SIGnatures
Notes from the STA Special Interest Group

Frank E. Block, Jr., MD
Assistant Professor of Anesthesiology
Ohio State University

The STA electronic forum remains active in the Subspecialty area, Section 6 of the MedSIG forum on CompuServe. A European subscriber asked for help in obtaining a medical book which she had ordered from the US, but had not received. A brief discussion focused on suitable adapters for monitoring CO_2 in non-intubated patients via the nostril. Another brief thread dealt with the possible role of pen computing for equipment interfaces and recordkeep-ing. There was some discussion about available computer-assisted instruction programs for anesthesiology. Another discussion dealt with the draft of the proposed new FDA anesthesia machine checklist.

One interesting and lengthy thread involved proper monitoring and proper use of sedation by non-anesthesiologists in procedure rooms (emergency rooms, cardiac cath, cardioversion, endoscopy, etc.). This discussion was particularly useful because of the participation of many physicians, both anesthesiologists and non-anesthesiologists. Should non-anesthesiologists be using Thiopental, Ketamine, Etomidate, Propofol, etc.? What is the ideal "cocktail" for conscious sedation? One subscriber suggested that "using a pulse oximeter to monitor respiration is like using the wheels of a plane to monitor altitude; by the time you hear the bump, it's too late!"

A sad message announced the recent death of Dr. Omar Prakash, who passed away on April 18 after a second heart attack. Dr. Prakash was known to many in STA for his lively conferences in Rotterdam and for his founding of the *International Journal of Clinical Monitoring and Computing.*

Library Files

We are continuing to upload to Library 6 the abstracts of articles scheduled for future publication in the *Journal of Clinical Monitoring.* Please let us know if you find these useful; otherwise the abstracts on CompuServe may be discontinued. Also in Library 6 is the COLLEC.EXE program and a required accompanying file called &IDREC.DAT. These files were supplied by Datex and can be used to log data from Datex monitors into an IBM-compatible PC computer. Datex does not warrant or support these programs, however.

Internet Listserver

The Anesthesia Internet Listserver remains alive and well. During the start-up phase of this listserver, Andrew Sopchak (>INTERNET:sopchaka@vax.cs.hscsyr.edu) placed everyone on the STA electronic mailing list on his Internet list. Many people were then inundated with a large volume of mail. Instructions for interacting with the listserver were published in the last issue of *Interface* (Vol.4, No. 2) including the commands for terminating communication with the listserver. Anyone with an interest in using the Internet services more extensively should consider Ed Krol's book, "The Whole INTERNET User's Guide and Catalog," published by O'Reilly & Associates (1-800-998-9938). The publisher can be reached via >INTERNET:nuts@ora.com if you prefer. This is one of many excellent texts which describe how to interact on the Internet.

There is also now an Anesthesia Gopher service being organized on the Internet. At present, this service is only available to Internet users, not those exclusively using CompuServe. This service allows you to browse various databases and download articles of interest. Internet people can set their gopher programs to access eja.anes.hscsyr.edu [139.127.220.1] on port 70. We welcome feedback on how this works!

A similar Listserver devoted to pediatric pain has also been proposed. Please contact Dr. Allen Finley at Dalhousie University, Halifax, Nova Scotia (>INTERNET:gafinley@ac.dal.ca) for more information.

There is now a large supply of CompuServe membership kits available free from the STA office in Richmond. These kits include a $10.00 credit for time on CompuServe. If you haven't tried CompuServe yet, here is your chance! Just call the office to receive a kit. ◆

UPCOMING EVENTS

ESCTAIC Annual Meeting

October 6–9, 1993
The European Society for Computing and Technology in Anesthesia and Intensive Care
Goldegg, Austria
Info: Dr. Leo Moser
Anaesthesiologie
P.O. Box 30
A5014 Salzburg, Austria.

ASA Annual Meeting

October 9–13, 1993
American Society of Anesthesiologists
Washington, DC Convention Center
Info: ASA
520 North Northwest Highway
Park Ridge, IL 60068
(708) 825-5586, FAX (708) 825-1692.

SCAMC 17

October 31–November 3, 1993
Symposium on Computer Applications in Medical Care
Sheraton Washington Hotel
Washington, DC.
Info: AMIA
4915 St. Elmo Avenue, Suite 302
Bethesda, MD 20814
(301) 657-1291, FAX (301) 657-1296

STA '94

January 27–29, 1994
Society for Technology in Anesthesia
Learning About Technology—
Technology for Learning,
(Co-sponsored by the Society for Education in Anesthesia and the Anesthesia Patient Safety Foundation.)
Walt Disney World Dolphin Hotel
Orlando, FL
Info: Kim Roberts
Executive Director
STA
11512 Allecingie Parkway
Richmond, VA 23235,
(804) 378-4959, FAX (804) 379-1386
(see ad on page 35 of this newsletter)

ASA Events a Tradition

The STA Education Committee continues the tradition of STA-sponsored social and educational programs at the annual meeting of the American Society of Anesthesiologists. That meeting will take place in Washington, D.C. this year from October 9 through 13. The annual dinner meeting of the Society will be held at 6:00 p.m. on Sunday October 10, 1993, and offers members an opportunity to meet friends, share a meal and enjoy an entertaining and informative lecture. The dinner is sponsored by Hewlett Packard, BOC Health Care, Marquette Electronics, Nellcor, Inc., North American Dräger, and Space Labs Medical, Inc.

The speaker for this year's dinner will be Commander C.M. Wood, USN (ret.). Commander Wood had a distinguish career in the Navy and has agreed to talk to the Society on the subject of "Nuclear Submarine, Twenty-Five Years and Beyond". Commander Wood graduated from the US Naval Academy in 1965. He served on diesel and nuclear submarines and was commanding officer of two ballistic missile submarines. During his 22 years in the Navy he spent almost five years submerged. After retiring from the Navy he worked for five years with the Illinois Department of Nuclear Safety in Springfield, Illinois. Most recently, he has been working on radiation dose reconstruction projects with the Centers for Disease Control in Atlanta, Georgia. His educational background also includes a Master of Science degree from Rensselaer Polytechnic Institute in Operations Research and Statistics, and a Masters of Arts degree from Webster University in Information Resources Management.

Annual Dinner Meeting
October 10, 1993
6:00 pm
Tickets: $50 members
$60 non-members
Contact: STA National Office
804-378-4959

Breakfast Panel
October 11, 1993
7:30 am
Contact: ASA Office
800-562-8666

The high cost of entertainment in Washington threatened to make this an expensive event. Fortunately, several sponsors have helped to defray the cost of the dinner meeting and allow STA to offer tickets for this dinner for only $50.00 for members and $60.00 for non-members. The dinner will be held at 701 Pennsylvania Avenue Restaurant (a five-star restaurant located between Capitol Hill and The White House offering superb international cuisine), Washington, DC. Tickets may be ordered now by contacting the STA National Office.

Breakfast Panel

The annual STA-sponsored breakfast panel will take place at 7:30 am, Monday, October 11, 1993. In previous years, this breakfast panel was held on Wednesday, the last day of the meeting, which made it difficult for many members to attend. The topic for this year's meeting is *New Technology: Can we afford it? Can we afford not to use it?* Dr. Alan W. Grogono will chair the panel. The speakers and topics include: Steven J. Barker , *Neurophysiological Monitoring,* Michael K. Cahalan, *Transesophageal Echocardiography,* James B. Eisenkraft, *Respiratory Monitoring,* Michael L. Good, *Automated Anesthesia Record Keepers,* Michael R. Roizen, *Electronic Medical Record Keeping,* and Steven L. Shafer, *Computer-Controlled Intravenous Anesthesia.*

The ASA will be forwarding information about the breakfast panel in the registration information for the annual meeting. Information and tickets can also be obtained by contacting the ASA office directly at 800-562-8666. ◈

- A. Grogono, MD

Electronic Patient Records:
Obstacles and Opportunities

Dean F. Sittig, PhD, Center for Biomedical Informatics, Vanderbilt University, Nashville, TN

The theme of the American Medical Informatics Association's Spring Meeting, held from May 9-12, 1993 at the Adam's Mark Hotel in St. Louis, Missouri was "Electronic Patient Records: Obstacles and Opportunities". A record number (625) of clinicians, scientists, engineers, and otherwise interested people from around the world attended 100 scientific and 16 panel presentations describing current advances in computer hardware, software, communications, and standards as they related to the design, development, and implementation of comprehensive electronic medical record systems.

Based on presentations at this meeting, it appears that the electronic medical record is an attainable goal from a technical standpoint. Many social, financial, and political barriers still remain, although business pressures and legislative initiatives are coalescing to make the electronic medical record a necessary strategic initiative. Many investigators believe that the combination of these forces will result in widespread implementation of EMRs in both

the in-patient and out-patient setting before the turn of the century.

Of particular interest to the anesthesia community, was a presentation on the LifeLog Anesthesia Information Management System by William T. Merritt, MD from Johns Hopkins Hospital in Baltimore, MD. Dr. Merritt emphasized the importance of combining data from physiologic monitors with data from other areas of the hospital such as the laboratory and admit/discharge/transfer modules of the hospital information system.

The Working Group on Anesthesiology/Critical Care & Emergency Medicine also met early in the morning of Tuesday, May 11. This group has not been especially active recently and much of the discussion involved whether there is a need to continue the working group activities. All partici-

pants felt there was sufficient overlapping interest to warrant sustaining the working group. A newsletter of the group's activities will be published through the AMIA offices. The group will plan to meet at the SCAMC meeting in the fall.

AMIA's next meeting, the 17th Annual Symposium on Computer Applications in Medical Care (SCAMC), will be held October 31-November 3, 1993 in Washington, DC. The theme of this year's conference will be "Patient-Centered Computing". The goal of this meeting is to demonstrate how techniques from the field of medical informatics can be used at the patient's bedside, in the physician's office, in the workplace, in our schools, and even within the home.

Next year's AMIA Spring Meeting will be held in San Francisco, CA from May 4-7, 1994. There will be two themes for this conference: "Medical Information and Record Systems -Integration at the Enterprise and Individual Level" and "The Use of Emerging Mobile Computing and Wireless Communication Systems". Conference organizers are especially interested in papers describing the synthesis of effective integration strategies, the identification and analysis of impediments of all sorts, the evaluation of the strengths and weaknesses of computing and communications technologies (particularly mobile), and the definition of future research and development priorities.

For more information on either the American Medical Informatics Association (AMIA) or the upcoming scientific meetings contact: AMIA, 4915 St. Elmo Ave., Suite 302, Bethesda, MD 20814, (301) 657-1291, (301) 657-1296 (fax), AMIA@camis.stanford.edu (e-mail) ♦

JSTAIC 10th Annual Meeting
continued from cover

■ Dr. M. Ohtsuka of Yokohama City University developed a system using a magneto-optic disk which files waveform data accessible in random fashion.

■ Dr. M. Ogawa of Kyoto Prefectural University constructed a visual database of disposable equipment used for patient monitoring using a multi media computer and an electronic still camera. The system helps to manage the materials used in the operating suite or ICU.

■ Dr. H. Hayami of Hyogo Medical College developed a computerized information network system for critical care practice using personal computers linked with a host computer. The system supports a real time bedside conference involving staffs of different facilities.

■ Dr. T. Saito of Okayama University reconstructed blood pressure wave forms by inverse fast Fourier transform method after obtaining the power spectrum and the phase information.

■ Dr. K. Suwa of Tokyo University reported on the publishing of an English language journal of the Japan Society of Anesthesiology "Journal of Anesthesia" in a diskette format starting in November 1992. The diskette also contains (1) selected free software from the Software Contests held by The Japan Society of Anesthesiology, (2) Journal Club and (3) Anesthesia/Medical News from various computer network bulletin boards.

On the evening of November 6, the organizing committee invited all the attendants to a buffet party where delicacies from the surrounding sea were served. Next year, the Department of Anesthesiology of Oita University will host the Annual Meeting of the Japanese Society for Clinical Anesthesia. ◆

The Role of Standards in Computer-Based Patient Records
continued from page 27

Table I. Medical Subcommittees of ASTM Committee E -31.

E-31.10 Hospital Pharmacy
E-31.11 Data Exchange for Clinical Results
E-31.12 Computer-Based Medical Records
E-31.13 Clinical Laboratory Systems
E-31.14 Clinical Laboratory Instrument Interfaces
E-31.15 Health Knowledge Representation
E-13.16 Data Exchange for Clinical Neurophysiology
E-31.17 Privacy, Confidentiality, and Access
E-31.18 Health Data Cards
E-31.19 Vocabulary for Computer-Based Patient Records Content and Structure

E-31 are listed in Table I. They have been addressing the problems of the computer-based medical record, mechanisms for transmitting various kinds of medical information, and other related issues.

CBPR and Anesthesiology

Of particular interest to anesthesiologists is the work of Subcommittees E-31.12, E-31.18, and E-31.19 which deal with the content, structure, and use of the CBPR. These subcommittees are in the process of developing or maintaining the standards that will achieve the important CBPR goals of common structure, consistency, and compatibility. While there are many aspects of the process that are general, much of the CBPR involves concepts and data structures that are unique to particular medical specialities. A national consensus on the content of a CBPR will require that professionals and medical specialty organizations join in the effort to define the requirements for each specialty. Such efforts for anesthesiology are now underway with the formation of a task group headed by David W. Edsall, MD within subcommittee E-31.12. People who are interested in contributing to this effort are urged to contact Dr. Edsall at (508)345-2332.

Editor's Note: Members of the STA National Database Committee are helping Dr. Edsall with his efforts at ASTM. By becoming involved with that committee, you can help STA support these important standards efforts, which will no doubt have a major impact upon the practice of anesthesiology. ◆

Call for Abstracts

STA 1994 Annual Meeting
co-sponsored by the Anesthesia Patient Safety Foundation
and the Society for Education in Anesthesia
January 27–29, 1994
Walt Disney World Dolphin Hotel • Orlando, Florida
Deadline: October 1, 1993
To request an abstract kit,
please contact the STA National Office at 804-378-4959
(Attention STA members—an abstract kit is included with this newsletter)

How Well is the Safe Medical Devices Act Working?

Marilyn Sue Bogner, PhD
Center for Devices and Radiological Health, Food and Drug Administration

Editor's Note: The Safe Medical Devices Act (SMDA) was signed into law in 1990 and reporting of medical device malfunctions by user facilities became mandatory as of November 1991. At that time, articles in this publication highlighted limitations that could impede the reporting process.(Interface Vol. 3, #1, 1992). Concerns were expressed in particular about the medicolegal exposure of reporting mishaps and the likelihood that voluntary reporting would be successful. The following article revisits these issues in light of the experience to date.

At the outset of the reporting process, the Center for Devices and Radiologic Health (CDRH) expected that user facilities would need some time to become familiar with the reporting requirements specified by SMDA. However, after 16 months, user facilities remain confused about what is reportable, how to complete the Test Form, and where to send individual Medical Device Reports (MDR), malfunction reports, and semi-annual reports.

Liability Concerns

Facilities have expressed concern that reports may be disclosed during liability actions initiated against them. SMDA states that User Facility Reports cannot be admitted into evidence or used in a civil action unless the facility or individual who made the report knew that it was false. The Act extends this protection to health care professionals who are not required to make reports, but do so voluntarily. The Act does not however, prohibit civil actions based upon the events that initiate the reporting process.

There are misconceptions about penalties for failing to report. Civil penalties are not in effect at this time, although they will be instituted after FDA conducts studies of user facility compliance and submits reports to Congress. FDA can however, enforce the MDR regulation under existing authority, and obtain an injunction against a facility that fails to comply with the MDR requirements of SMDA.

Although user facility personnel have been cooperative, compliance

APSF Seeks Adverse Event Reports

An editorial entitled "The Safe Medical Devices Act: A Lesson from Aviation not Learned" was aired in this publication at the time that the Safe Medical Devices Act was discussed.(Interface Vol 3, #1, 1992) The editorial highlighted the very successful incident reporting system in aviation called the Aviation Safety Reporting System (ASRS). The key to the success of the ASRS is the anonymity of the reports. That is, great effort is taken to insure that the reporting individual cannot be identified from the report.

The Anesthesia Patient Safety Foundation has begun an incident reporting system modelled after the ASRS. APSF invites anonymous reports of interesting safety-related events. Interesting reports will be published as the "Experience is the Best Teacher" column in the APSF newsletter along with comments as appropriate. Reports should be sent to: David M. Gaba, MD, Sec., Anesthesia Patient Safety Foundation, Anesthesiology Service, 112A Palo Alto VAMC, 3801 Miranda Avenue, Palo Alto, CA 94304.

with MDR appears to be minimal. As of this spring, from FDA's mailing list of about 80,000 user facilities, 2,834 reports have been received and only 664 of those reports were appropriate. During the same period, 47,605 reports of death and serious injury were received from device manufacturers under the 1984 MDR regulation. Since most MDR reports are sent to manufacturers by health care facilities, this discrepancy likely represents gross underreporting, perhaps due to continued misunderstanding of the regulations.

MEDWatch

Recognizing that user facilities are not yet compliant with SMDA, FDA is making efforts to improve reporting. Leaders of the FDA and organizations representing health professionals, consumers, and industry met recently in Rockville, MD, to launch MEDWatch, an FDA initiative to improve adverse events reporting. MEDWatch is a system to encourage and facilitate reports by health professionals on serious adverse events and problems with drugs, biologics, medical devices, and other regulated products. As part of the program, FDA Commissioner, David A. Kessler, MD, will hold a joint press conference with representatives from several organizations that have agreed to promote MEDWatch. The participants include, among others: James Todd, MD, executive vice president of the AMA; Gerald Mossinghoff, president of the Pharmaceutical Manufacturers Association; and Sidney Wolfe, MD, director of Public Citizens' Health Research Group.

NOTE: The foregoing commentary by Dr. Bogner in no way represents the official position of the FDA. ◆

What's New in JCM

Equipment" series. The broad approach to this section will continue and ideas and contributions for this section are welcome.

Electronic Publishing

We now rely more and more on the use of electronics in all areas of *JCM*. *JCM* was one of the first anesthesia-related journals to begin requesting an electronic version on disk of all submissions. All minor revisions are done in house, so we avoid the delay of mailing the manuscript back and forth to the author. Extensive revisions are implemented much more swiftly because comprehensive editorial comments are easier for authors to deal with electronically, as opposed to pages full of red ink. Our publisher (Little, Brown and Company) receives a disk with the final version of each accepted manuscript. They subsequently edit the copy for each article and then transfer the text electronically to the typesetting machine. We estimate that the electronic process speeds up the processing of a manuscript by four to six weeks.

Abstracts of all articles are now published on CompuServe thanks to the efforts of Frank Block, MD. Plans are now underway to distribute abstracts more widely on the Internet as well. Each issue of *Interface* describes how to use CompuServe and gain access to the STA forum where the abstracts are maintained. Volunteers are needed to distribute abstracts through the Internet and other systems. An Electronic Journal Club (EJC) is also being planned for discussion of articles from *JCM*. The plan is to include a short list of articles in each issue of the journal which will be discussed in an open forum. Active discussions that take place in the STA forum on CompuServe indicate there is a great deal of interest in this method of exchanging views. Michael Gorback, MD is developing this exciting innovation.

Changes in Format

Beginning in 1993, the Journal began to publish five issues per year, rather than four. This represents a step towards publishing the Journal on a bimonthly basis in the future. This will shorten the time between submission and publication, and will also provide readers with access to the most up-to-date literature. To assist our international audience, we have begun translating *JCM* abstracts into French, German, and Spanish. Thanks to the efforts of many people on the administrative team, Heidi Lenz, Mary Donchez, and David Dionne, and to our initial three translators, Drs. Gippert (German), Pierre Kalfon (French), and Jorge Urzua (Spanish), the translations are ready for the July 1993 issue. In keeping with the general trend amongst medical journals, structured abstracts are now required. They present the gist of an article in a convenient format, which will help not only the readers of the Journal but also those who have access only to the abstract. To keep *JCM* readers abreast of what is new in other journals, a new section is being introduced. In two pages, Dr. Gravenstein will present pithy, one or two sentence summaries of articles relating to monitoring and equipment from a selection of international journals. Contributions for this section are welcome.

The progress of the Journal has been rewarding. The Journal exists for the readers. We look forward to your comments and will do everything possible to tailor the Journal to the needs and interests of the readers. ◈

- **The Editors of the *Journal of Clinical Monitoring***

President's Message

edition of the history of STA. The history of STA dates back to the mid 70s, although the Society was not officially formed until the late 80s. Anyone with information about the many significant events dating back to the origins of STA should forward this information to Frank.
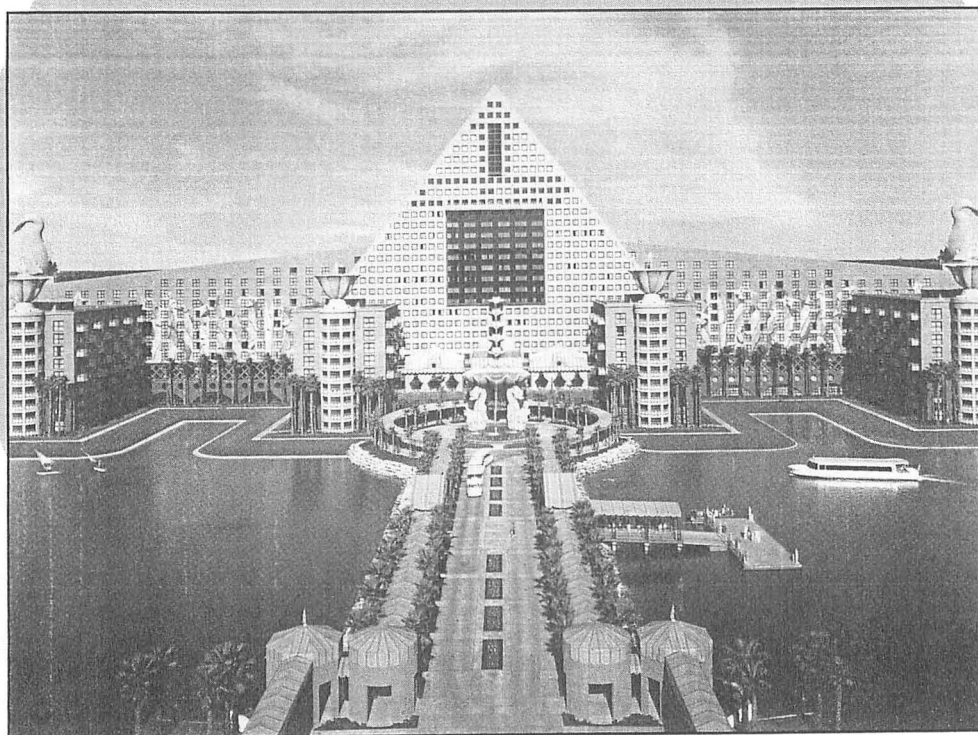
Make Membership a Priority

STA needs your help to grow and prosper! In addition to serving on committees, STA needs ideas for promoting itself and generating revenues. Our current major source of revenues is membership. I encourage all of you to invite your colleagues to join us. We are still suffering from indebtedness stemming from early efforts to promote the Society. As I have indicated in a previous issue, fiscal planning has improved, but additional revenues are still needed. The Committee for Membership and Promotions, chaired by Julian M. Goldman, MD, is exploring a number of ways by which we can make membership in STA more attractive. The videotapes of the STA '92 annual meeting on the anesthesia workstation are ready for distribution. If everyone orders the set of three, we can more than make up for the current shortfall. If you have additional ideas for promotion and development, please bring them to our attention.

I want to encourage all members to take an active part in STA. Action can take any form. Write a letter to the editor of the *Interface*. Become involved in committee activities. New ideas are always welcome and encouraged. We are off and moving but need an active, enthusiastic membership to prosper. I encourage you to take a role in the growth of STA and look forward to seeing you at future meetings. ◈

Plan Now To Attend!

1994 STA Annual Meeting

"Learning About Technology— Technology for Learning"

Walt Disney World Dolphin Hotel • Orlando, Florida
January 27–29, 1994

Co-Sponsored by the Society for Education in Anesthesia and the Anesthesia Patient Safety Foundation