



INTERFACE

SOCIETY FOR TECHNOLOGY IN ANESTHESIA

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The Safe Medical Devices Act:

A Lesson from Aviation NOT Learned!

The goal of the recently enacted Safe Medical Devices Act is to identify potentially hazardous medical devices. Under the provisions of this act, facilities are required to report incidents that reasonably suggest a medical device has caused or contributed to death of, or serious injury to a patient. Although the goal of this act is laudable, there is legitimate concern on the part of institutions that, given the current malpractice climate, such reporting will increase liability exposure. Experience in aviation with incident reporting demonstrates that liability concerns impair the reporting process and therefore limit its utility.

In May 1975, the Federal Aviation Administration implemented the Aviation Safety Reporting Program to improve the flow of significant information to air safety investigations and research. Despite a limited waiver of disciplinary action to those who pro-

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Liability Exposure and the Safe Medical Devices Act

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Yale-New Haven Hospital
New Haven, CT

The Safe Medical Devices Act of 1990 (SMDA) requires "user facilities," including hospitals and ambulatory surgery facilities, to report to the manufacturer any medical device malfunction which results in "serious illness or injury" to a patient. Those malfunctions which result in death must also be reported to the FDA. Definitions of "device," "serious illness or injury," and "patient" are quite broad so that reporting responsibilities are substantial. A "device" is virtually anything used in patient care that is not a drug, including obvious devices such as pacemakers and defibrillators, as well as other items eg. suture materials and patient restraints. "Serious illness or injury" includes life threatening injury or illness, injury resulting in permanent impairment of a body function or damage to a body structure, and also injury or illness that "necessitates immediate medical or surgical intervention. The definition of a "patient" was broadened by the proposed regulations, to include persons typically considered patients, and individuals who are employees, or are affiliated with the facility. If "patient" remains defined in this fashion in the final regulations, occupational and staff injuries will, for the first time, be reportable to the device manufacturer and to the FDA.

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Update on the Safe Medical Devices Act

The Safe Medical Devices Act (SMDA) was signed into law by President Bush on November 28, 1990. The Act has 19 specific provisions that affect the regulation of medical devices. The current status of the SMDA is as follows.

◆ One of the most important provisions is the addition of User Facility Reporting (UFR) to the current Medical Device Reporting Regulation, MDR.

◆ UFR became effective on November 28, 1991 and requires medical device user facilities to report device related deaths to both the FDA and the manufacturer. In addition, device related serious injuries and illnesses must be reported to the manufacturer or to the FDA if the firm is unknown.

◆ The FDA published a proposed regulation for implementing the SMDA on November 26, 1991. Interested parties have until January 27, 1992 to comment upon the proposed regulation. Until a final regulation is enacted, the proposal should serve to guide the user community in developing reports since compliance with the SMDA is now mandated by law.

For more information, the legal departments of many hospitals are preparing to comply with the reporting requirements and should have the pertinent information. Published material explaining the details of the SMDA are available from the US Food and Drug Administration.

News From the Board of Directors

N. Ty Smith, MD

STA President

In a relatively short time, STA has grown from a small group of individuals, to a society with one of the most talented and interesting group of members of all the anesthetic societies. It is a society of innovators, leaders, and doers. One need only peruse the STA membership roster, or attend an annual meeting, to realize that these claims about the membership are not merely the product of exaggerated enthusiasm. With this foundation that continues to grow stronger, STA is poised to make even more significant contributions to the specialty.

STA is beginning to undertake projects that are exciting in breadth, scope, and implications for our future practice. The following describes specific projects that are in their nascent stage. Those members interested in more information, or in joining one of these projects, be sure to contact either a board member or one of the group leaders themselves.

Education

At the first STA dinner meeting (ASA '91), the members recognized that education of students and residents about technology was lacking and that STA should help. Towards that end, Wes Frazier and Jim Philip are chairing a task force on Education, Testing, and Certification in Technology. The initial thrust of the task force will be to outline the material that students and residents should learn vis-a-vis technology, particularly as it pertains to anesthesia and intensive care. Ultimately, the scope of the task force will be expanded to include all health care providers in anesthesia. As Wes Frazier observed, "The fundamental issue is not only deciding what residents should know and how they should learn it, but taking a close look at how technology is handled in an anesthesia care team." Testing will be

an early emphasis of the committee since it is an integral part of education. Recredentialing and recertification are longer term projects of this task force.

■ *"STA is beginning to undertake projects that are exciting in breadth, scope, and implications for our future practice."*

Technology Assessment

Technology assessment is another area where STA is becoming involved. Jeff Feldman and Al Perrino have begun to establish a relationship with ECRI. Michael Argentieri, the ECRI Vice President for Technology Management, has been extremely helpful with identifying areas of overlapping interests. Discussions to date clearly indicate that both STA and ECRI share the common goal of insuring that technology is safe and satisfies the needs of the user. Kaiser-Permanente of Northern California, under the direction of John Howse, MD, has developed the ability to perform extensive testing of medical equipment prior to purchase. Their equipment needs are so great that in-house evaluation has become cost effective. In addition, they have been very effective at influencing design features when shortcomings are identified. Dr. Howse has met with the STA board of directors to explore collaboration in the area of technology assessment as well.

A National Database

Another exciting development is the formation of a committee to explore implementation of a national anesthetic database under the direction of David

Edsall. The impetus for this effort was the realization that rapid progression of technology to implement detailed and useful quality assurance information has outpaced our ability to interpret the information. Furthermore, the proliferation of electronic systems for data collection facilitates sharing of information between institutions if properly coordinated. The committee consists of experts in database technology and information systems as well as clinicians attuned to the clinical, educational, research and administrative needs for such a database. The main goals of the committee are to address the complexities of developing such a large database. Such a database must contain information that is important to a large variety of users including clinicians, administrators, insurance companies and risk management groups. This type of information is potentially quite sensitive necessitating a great deal of attention to security. This is a difficult and challenging enterprise that will no doubt reap rich rewards in the future.

Preliminary meetings have been held on the founding of an international STA. Representatives of STA and sister societies in Europe and Japan have met to discuss the structure and goals of such a society. As developing countries throughout the world emerge (including the newly opened Eastern block), they will undoubtedly look to more technologically advanced countries for guidance. We who are more fortunate in having dealt with technology for a long time are obliged to help those who have not had this long experience.

Meeting Plans

As these committees pursue their work, STA will continue to sponsor the annual meeting and activities at the American Society of Anesthesiologists

see "News" page 7

Technology Issues 10% of ASA Abstracts

The scientific program of the 1991 annual meeting of the American Society of Anesthesiologists was as usual quite extensive and included almost 1200 papers presented in oral or poster formats. A large number of technology related presentations were made and 10% of the total abstracts addressed some aspect of technology in anesthesia. Although many of these abstracts are notable, it is not possible to publish all the pertinent presentations in the newsletter. The following are only a few examples of some notable developments. Individuals interested in additional information should peruse the equipment and technology abstracts published in the September 1991 supplement of Anesthesiology.

1. Gaughan SD et.al. Can an Anesthesia Machine Flush Valve Provide for Effective Jet Ventilation? *Anesthesiology* 1991;75(3A):A130.

A mechanical model was used to measure the flow, tidal volume and minute ventilation that could be generated by the anesthesia machine flush valve through different emergency airway configurations. Both Ohmeda (OH) and North American Drager (NAD) anesthesia machines were tested. All parameters measured were two to three times greater when using the NAD machine than the OH machine. These findings were attributed to a flow limitation of 55 L/min for the NAD machine flush valve, whereas the OH machine flush valve is pressure limited at 7-8 psi. The authors concluded that the flush valve on the OH machine cannot be used for effective jet ventilation.

2. Cahalan MK et.al. Automated Real-Time Analysis of Transesophageal Echocardiograms. *Anesthesiology* 1991;7(3A):A385.

This study reports upon intraoperative evaluation of left ventricular (LV) end-systolic (ESA), and end-diastolic areas (EDA) with and without an automated border detection device. The automated device provided reliable estimates of LV filling and ejection through continuous real-time measurement of ESA and EDA as long as adequate endocardial tracking was apparent.

3. Cigada M. In Vitro and In Vivo Evaluation of a Non-invasive Respiratory Monitor. *Anesthesiology* 1991;75(3A):A398.

A small lightweight device consisting of a silastic, cylindrical probe that changes intraluminal pressure when exposed to the temperature variation of inspired and expired gas at the nose was evaluated. Not only did the device accurately detect individual breaths under controlled conditions, but there was a significant correlation between the derived breath-by-breath area and tidal volume. This relationship suggests the device may be a useful, non-invasive method for quantitating tidal volume.

4. Fine PG et.al. A Neural Network for Quantification of Air Embolism. *Anesthesiology* 1991;75(3A):A465.

The authors extracted seven descriptive features from Doppler

ultrasound recordings during infusion of varying amounts of air into an anesthetized dog. These features were used to train a neural network to recognize the air infusion rate corresponding to a given set of Doppler ultrasound changes. The authors found that a neural network could be trained to recognize the air infusion rate with reasonable accuracy and emphasized the importance of analyzing multiple features of the Doppler signal not only frequency content and amplitude.

5. Rampil IJ. Cerebral Perfusion Mapping with Ultrasound Contrast. *Anesthesiology* 1991;75(3A):A1006.

This study evaluated the potential for albunex, an albumin based ultrasound contrast material, to create real-time, high resolution maps of brain perfusion. Five swine were studied using an ultrasound probe applied to the dura via a left parietal craniectomy. Albunex was injected into the left common carotid artery at end-tidal CO₂ values of 20, 35 and 80 mmHg. The author found that the contrast effect was readily apparent in all animals and that perfusion was proportional to end-tidal CO₂.

6. Perhag L. Method to Deliver a Preset Inspired Concentration of Anesthetic Regardless of Degree of Rebreathing. *Anesthesiology* 1991;75(3A):A1010.

These authors developed and tested a method for delivering isoflurane into the inspiratory limb of a circle system based upon measurement of returned concentration and flow in the inspiratory limb. Testing was performed using a test lung and pig model. Desired concentrations of isoflurane were reached in 40 to 60 seconds and held within 0.1% of the set value. Total isoflurane administered to a pig for one hour was 4.4 grams in the closed system and 37 grams in the open system. The authors concluded that the system was an effective method for controlling inspired gas concentrations and could be generalized to other inhaled gases.

7. Moller JT et.al. Pulse Oximetry Uncovers Hypoxemia and Decreases the Incidence of Evidence for Myocardial Ischemia during Anesthesia. A Prospective Study of 20,802 Patients. *Anesthesiology* 1991;75(3A):A1057.

Patients were randomly assigned to be monitored with or without pulse oximetry during anesthesia and in the PACU. A systematic evaluation of the incidence of hypoxemic episodes and adverse events was undertaken. Not surprisingly, the pulse oximetry group had a 19-fold higher incidence of noted hypoxic episodes over the non-pulse oximetry group. The only significant difference in adverse events was a greater incidence of evidence for myocardial ischemia (angina, ST segment changes) in the non-pulse oximetry group (26 vs. 12 patients). The authors concluded that an association between pulse oximetry, hypoxemia and myocardial ischemia requires future studies. ♦

- J. Feldman

STA Active at ASA Meeting

The tradition of STA-sponsored events continued at the recent meeting of the American Society of Anesthesiologists in San Francisco, California. The STA dinner and breakfast panel were both informative, enjoyable and well attended.

Cultural Aspects of Technology Acceptance

The STA annual dinner meeting was held at Le Meridien Hotel on Sunday, October 27. Following a very pleasant meal, those in attendance enjoyed a fascinating presentation by James L. Adams, Ph.D., Professor of Mechanical Engineering, Industrial Engineering and Engineering Management, Values Technology Science and Society at Stanford University and author of the well known book entitled Conceptual Blockbusting.

Dr. Adams lead us on a stimulating journey while he explored the cultural differences concerning science and technology. He explained the difficulty in communicating with non-technologically inclined individuals and made an eloquent and entertaining plea that we improve our communication skills with that group. He will be especially remembered for asking: "Do you re-

alize that there could be an equally large, if not larger, Society Against Technology in Anesthesia?"

Plan to attend next years' dinner meeting to be held Sunday evening during the ASA meeting in New Orleans.

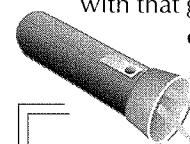
Power Failure Problems Illuminated

The STA-sponsored breakfast panel this year entitled "When the Lights Go Out" was organized by Alan W. Grogono and dealt with problems of power failure in the operating room. Both the members of the panel and the audience had many interesting comments about this challenging problem which, based upon the number of individuals with personal experience, is not as rare as one might think.

The discussion began with comments from J. Sandy Eames (Datascope Corp.) regarding prevention and back-up strategies. Mr. Eames reviewed the

typical back-up technologies namely generators, uninterruptable power supplies and batteries. David Paulus (University of Florida) described how one particular failure occurred emphasizing the importance of careful attention to proper maintenance and testing of back-up systems. Jeffrey Feldman and David Cullen both described their experience with providing patient care during power failure. Reynolds Saunders discussed the engineering aspects of preparation for power failure from the perspective of a southern California physician who could likely encounter prolonged power failure due to earthquake. Dr. Saunders emphasized the importance of developing a departmental plan which includes maintenance and testing of back-up systems. Finally, Arthur Keats suggested that, through education, we develop the ability to provide anesthesia totally in the dark, and that these clinical skills will be our back-up system. ♦

- A. Grogono



DON'T GET CAUGHT IN THE DARK

The following notes were made during the breakfast panel and represent a few of the important points which emerged during the presentations and contributions from the audience.

- ◆ Review your own institution's plans for power failure, particularly with regard to the magnitude of the disaster for which you should be prepared.
- ◆ Establish a system for regularly checking generators, batteries and other back-up equipment.
- ◆ Emergency generators should be tested under full load e.g., at 7:00 a.m., when all operating rooms are open and all monitoring can be turned on but with no patient yet critically at risk. The generator should run for long enough to be meaningful, e.g., 30 minutes. Insure that regular testing of the hospital generator does not deplete the fuel supply.
- ◆ Uninterruptable Power Supplies (UPS) are capable of supplying significant power needs and are widely used for computers but rarely used in the operating room.
- ◆ Emergency lighting with its own independent power supply should be installed in each operating room and maintained.
- ◆ Emergency telephone lines should be independent of any electronic exchange.
- ◆ Portable transport monitors should be charged, tested and available.
- ◆ "Walkie-talkies" (not portable telephones) should be available for communicating during total power failure.
- ◆ Self-inflating ventilation equipment and a flashlight with spare batteries should be available in a sealed, labelled bag in every operating room with spares kept secured elsewhere.
- ◆ Suction units should be available for the operating room, powered either manually or by venturi jets operated from wall or tank oxygen.
- ◆ Discover whether the supply of oxygen or vacuum is likely to be impaired by electrical power failure.

USING BATTERIES EFFECTIVELY

John F. Elwood, CBET

Yale-New Haven Hospital Engineering
New Haven, CT

■ *Editor's Note: When power fails in the operating room, battery power may be the only back-up allowing equipment to function. At the recent STA breakfast panel on power failure, it became clear that battery systems often fail to function when needed. The following discussion describes the important elements for insuring proper battery function.*

Medical applications demand high quality battery performance. Long life expectancy, leak-proof construction, wide operational temperature range and constant battery voltage are important features. One need only consider the varied medical devices, many of which are used to sustain life (eg. defibrillators, ventilators), to understand the importance of insuring proper battery function.

The performance to be expected from a battery is described by the amp-hour rating. This rating specifies the length of time the battery can deliver a given current. For example, a 2 amp-hour battery can deliver two amperes for one hour or one ampere for two hours. The actual current draw is determined by the load. Lead acid and nickel-cadmium (NiCad) batteries are typically used in medical applications and will be the focus of this discussion. Nickel hydride batteries can produce twice the energy density of NiCad batteries, but are currently too expensive to be widely used.

NICKEL CADMIUM BATTERIES

The nickel cadmium battery is a rechargeable 1.2 volt cell with a nickel anode, cadmium cathode and potassium hydroxide electrolyte. This battery has become extremely popular for many applications requiring low to moderate current (up to about 6 amperes). NiCad batteries can be recharged many times and comparatively little time is required to develop a full charge. This battery is completely sealed and has a self-sealing vent to prevent an explosion should the charger malfunction causing an increase in pressure. The long shelf life of this battery is also useful although it will discharge even when not in use so that either continuous or

frequent charging is desirable. NiCads maintain a stable voltage until they are 90% discharged but then the voltage falls rapidly. The solid packaging is rugged and allows for safe operation in any position.

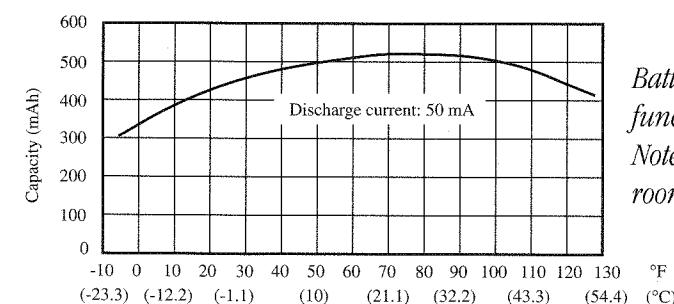
NiCad batteries do have disadvantages. A "memory" can develop if the battery is not allowed to discharge on a routine basis so that the battery will be unable to deliver current when necessary. Newer NiCad batteries have been developed that are not susceptible to the memory effect although they are not yet widely used. NiCad batteries are also potentially toxic which makes disposal problematic.

LEAD ACID BATTERIES

The lead acid battery is the most commonly used cell and consists of a lead dioxide cathode and a pure lead anode. They are termed wet cells because the electrolyte is composed of dilute sulfuric acid which can be either a liquid or a gel. Lead acid batteries are often used when large currents are required and can deliver these currents for extended periods of time.

■ *"Attention to charging is perhaps the most important determinant of battery life."*

Conventional medical lead acid batteries are completely sealed and therefore are usable in any position and leak proof.



Battery capacity as a function of temperature. Note peak capacity at room temperature, 24°C.

They cost less than NiCad batteries, have a 2 Volt cell, and a shelf life of over 2 years at room temperature. The discharge profile is not as steep as NiCad batteries so that the application can typically function longer into the discharge cycle. The disadvantages of lead-acid are primarily the weight of the battery and the electrolyte which can leak and cause damage. They also require relatively longer amounts of time to charge than NiCad batteries.

MAINTENANCE

Attention to charging is perhaps the most important determinant of battery life and will have a major impact upon whether or not the battery functions effectively when needed. Batteries should be promptly recharged after a significant discharge and fully charged prior to storage. NiCad batteries discharge spontaneously during storage and will require recharging if stored for any length of time. NiCad batteries susceptible to a memory effect should be intentionally discharged and recharged on a regular basis.

The type of charger can have a major impact on battery service. The best charger will taper current as the battery charges and ultimately stop charging, or provide a trickle charge, once a full charge is developed. When the batteries are replaced in a device, the charger may also need to be changed to match the batteries if optimal performance is desired.

Temperature can also have an impact upon battery life. The accompanying figure depicts the capacity of a battery as a function of temperature. The peak capacity occurs at room temperature with significant reductions in capacity at lower and higher temperatures. Charging batteries at temperatures other than room temperature will also reduce battery capacity. ♦

UPCOMING EVENTS

STA '92

Second annual meeting of the Society for Technology in Anesthesia, January 29 through February 1, 1992. US Grant Hotel, San Diego, CA. "Decision Making in Anesthesia: Design of the Workstation." US Grant Hotel, San Diego, CA. Contact:

Gerri Kuzava

STA Interface

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Hastings, Michigan 49058

(800) 875-2525

(616) 945-5110

Twelfth Medical Monitoring Technology Conference

Sponsored by the Dept. of Anesthesiology, Ohio State University, March 16 through 19, 1992. Marriott Mark Resort, Vail, Colorado. Contact:

Dept. of Anesthesiology
c/o Arlene Rogers
Ohio State University
410 W. 10th Ave.
Columbus, Ohio 43210

World Congress of Anesthesiologists

Tenth meeting of the WCA to be held in The Hague, The Netherlands, June 12-19, 1992. For information and a registration package contact:

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

Second Annual ESCTAIC Meeting

The second annual meeting of ESCTAIC, European Society for Computers and Technology in Anesthesia and Intensive Care, was held October 9-12 at Goldegg Castle, Austria, the same site as the inaugural meeting in 1990. Nestled in a picturesque valley surrounded by alpine meadows and gentle peaks, the medieval castle and village provided a spectacular backdrop for an information-packed conference. Most notable at this second meeting was attendance by many scientists from Eastern Europe, who expressed happiness at being permitted to travel.

Tutorials preceded the formal opening of ESCTAIC-2 on Wednesday, October 10th. Drs. B. Schwilk (D), L. Fries (D), M. Flottotto (D) and J. Koninger (D) presented an overview of electronic data processing including hardware, operating systems, and typical applications. In the next tutorial, F. Grob-Altag (D) eloquently described the characteristics and performance of neural networks and G. Kenny (GB) insightfully described and explained closed loop drug infusion applications for novices and experts alike.

The Scientific Program began on Thursday with the Technology Session chaired by W. Friesdorf (D) and J. Philip (USA) presenting the Keynote Address. The Teaching and Simulation Session was chaired by D. Tecklenburg (D), Patient Data Management Systems was chaired by B. Schwilk (D) and S. Ambruster (NL), and Fundamental Software Concepts was chaired by D. Engbergs (NL) and W. Coy (D). Standard Data Sets for Anesthesia and Intensive Care were discussed extensively by Working Groups.

On Friday, Scientific Sessions included Perioperative Applications chaired by Zbinden (CH) and V. Lanza (I), Audit chaired by B. Pollwein and A. Lack (UK), Organ Function and Decision Support chaired by P. Hallen (S) and H. Mrochen (D), Human Interface and Data Presentation chaired by G. Rau (D) and W. Koller (A), and a round table discussion led by B. Schwilk.

On Saturday, Scientific Sessions included Drug Administration/Infusion/Nutrition chaired by G. Kenny (UK) and Pauser (A) and a session on Information Systems chaired by Moser (A) and L. Fries (D).

■ *"Many scientists from Eastern Europe expressed happiness at being permitted to travel."*

Drs. W. Koller (A, Meeting Manager), B. Pollwein, (D Programme Coordinator) the other organizers, and P. Hallen (S, ESCTAIC President) deserve praise for a memorable Second Annual Meeting. All those fortunate to have attended the First or Second Annual Meetings look forward to the Third Annual European Society for Computers and Technology in Anesthesia and Intensive Care (ESCTAIC) Meeting, again in Goldegg Austria, scheduled for October 7-10, 1992. Additional information is available from Mag. Peter Schwab, Dr. Leo Moser, P.O. Box 30, A-5014 Salzburg Austria, Ph. 0662-43-62-15, FAX: 0662-43-62-16. ♦

- J. Philip

News

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meeting. STA 92, "Decision Making in Anesthesia: Design of the Workstation," has turned out to be one of the most exciting and widely anticipated events in the history of anesthesia. Here, finally, is a meeting with a difference, one in which each member of the audience is expected to participate in the design process and thereby influence his work style for perhaps decades to come. If you have not yet decided to attend STA '92 it is not too late! Contact the STA office in Hastings, Michigan, for further information.

STA 93 promises to continue the STA tradition of dynamic annual meetings since it will include the 7th International Symposium on Computing in Anesthesia and Intensive Care. The predominant theme will be Human Factors, including what we can learn from disciplines outside of medicine, such as the nuclear industry, aviation, and submarines. Alan Grogono is organizing the meeting, Paul Barash is Scientific Chairman and Matt Weinger, Frank Block, and David Gaba are in charge of the program.

This is a society for the membership. The board is dedicated to developing programs that enhance the understanding and development of technology related to Anesthesia and Intensive Care. We need to hear from the membership about other directions for STA. Examples of possible future activities are regional workshops, development of a detailed database on the members and support for research grants. More importantly, we need more people to get involved. Contact any of the board members with any ideas you may have. Finally, the annual meeting is an excellent forum to meet friends and exchange ideas - *Plan to Attend!* ♦

Medical Devices

continued from page 1

vided timely information about incidents, it became clear that the aviation community was reluctant to report to the FAA which was also responsible for regulation and enforcement. Consequently, the FAA asked NASA, an independent third party without enforcement authority, to assume the task of developing an incident reporting system. NASA recognized the potential utility of an incident reporting system for collecting human factors data about aviation incidents and enlisted the help of Battelle Corporation to develop the Aviation Safety Reporting System (ASRS) which started operating in April, 1976.

■ *"A regulatory agency cannot operate a successful reporting system since potential liability exposure inhibits reporting activities."*

The Aviation Safety Reporting System

The ASRS has grown considerably since its inception and now processes almost 3000 incident reports per month. The success of this program is credited to the role of a non-regulatory agency and the confidentiality and immunity for incident reporting. (Reports of criminal activities or accidents are not protected). Incidents are reported using a standardized form which is sent to a post office box. The reports are analyzed by three professionals (typically pilots and air traffic controllers) who will contact the individual that filed the report for clarification if necessary. The reports are then "sanitized" so that the reporting individual cannot be identified. Emergent hazards are reported to the FAA for correction but, again, the

identity of the reporter is protected. Reports are then coded for entry into a database of incidents that can be searched using a variety of keywords. Since the database is considered public domain, anyone can request a search which will be done free of charge. ASRS also reports notable findings in a monthly newsletter entitled "Callback" which is distributed to more than 60,000 aviation professionals.

The value of the ASRS program to aviation safety is well accepted. Not only have important safety problems been identified and corrected, but the database of coded incidents has become an invaluable research tool. In the history of the operation, no reporting individual has ever been identified and exposed to liability simply for filing an incident report.

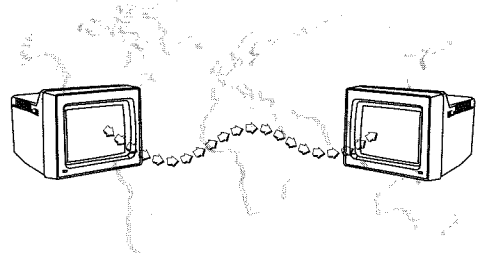
The lesson to be learned from the ASRS experience is clear. A regulatory agency cannot operate a successful reporting system since potential liability exposure inhibits reporting activities. An ASRS-like reporting system which offers confidentiality and immunity to the reporter, would satisfy the goals of the SMDA and offer the potential to identify a large number of safety problems in medicine. Unfortunately, the cost of such a program is likely to be considerable. It remains to be seen whether the FDA can address liability concerns sufficiently to develop a truly useful reporting system for medical devices. ♦

- J. Feldman

NOTE: For more information about the ASRS read Hardy R. Callback. Smithsonian Institution Press. Washington, DC. 1990.

SIGnatures

Notes from the STA Special Interest Group



Frank Block, MD
Assistant Professor of Anesthesiology
Ohio State University

There have been a number of requests for an example of the complete procedure for logging on to CompuServe and gaining access to the STA forum. This issue will therefore present a detailed description of the procedure. If you are interested in the forum give it a try! You cannot damage your computer and the costs are minimal especially if you sign on in the evening or night.

In order to log on, you must have the following items: 1) a CompuServe account and password, 2) a computer with a modem 3) suitable "terminal software" to communicate with other computers via your modem and 4) a phone line to attach to the modem. The quickest and easiest way to obtain a CompuServe account is to purchase a CompuServe starter kit at any Radio Shack or computer software store. The nominal cost of the kit is offset by an allowance of free time on CompuServe. The kit will include a directory of phone numbers to call for access to the network, and an initial password to sign-on. An alternative method for obtaining an account is to contact Frank Block at the STA meeting in San Diego. He will have starter kits available for distribution free of charge.

The following is an excerpt of a log-on session for a first-time user of the medical special interest group (MEDSIG) forum. The STA "area" can be found in that forum under Section 6, entitled Subspecialties. Commentary is provided in square brackets [] for clarification.

... Signing On to the STA CompuServe Forum

The notation <cr> means press the "carriage return" button (marked "Enter" or "Return" on some keyboards).

The first step in the process is to run your terminal emulation software and set up the modem to communicate with CompuServe. Most terminal software allows you to store parameters for communication permanently. The modem must be set for a baud rate that matches the phone number you dial for access, typically 1200 or 2400 baud. The other

modem parameters should be set for a 7 bit data word, odd parity and 1 stop bit. The next step is to instruct the modem to dial the access number. This can often be done automatically by the software, or you can type "ATDT" followed by the phone number and a carriage return. (NOTE: If you do not have a touch tone phone line type "ATDP"). If all is well so far the following will appear on the screen.

.....

CONNECT 2400 [This or a similar prompt will appear to indicate that you are connected to another modem for access to CompuServe.]

^C [Press and hold the "Control" key ("Ctrl") and "C" key together and then release both keys.]

User ID: 70147,440<cr> [Type in your account number at the "User ID" prompt.]

Password: [Here you type in your password and press <cr> - note that your password will NOT appear on the screen.]

CompuServe Information Service
11:52 EST Thursday 14-Nov-91 P
Last access: 23:24 25-Jun-90
What's New This Week
1 AIDS Resources Keep You Informed
...
Enter choice !GO MEDSIG<cr> [At ANY "!" prompt, you can type GO MEDSIG<cr>]

Professions MEDSIG
One moment please...

WELCOME!
Welcome to the AMIA/MedSIG Forum, a computer-based communications medium available to all interested in the health care fields....
[More instructions for signing on and interacting with the forum. May take several screens, read and press <cr>]

Press <CR> for more: <cr> [Press <cr> as the prompt suggests.]

Welcome to MedSIG Forum, V. 2G(31)

Forum messages: 92178 to 103035

News Flash: [Various news items may be included here.]

A special welcome to members of the Society for Technology in Anesthesia who joined with Frank Block in message section 6, Subspecialties.

[See, we made it!]
Press <CR> !

- MedSIG Forum Menu**
- 1 INSTRUCTIONS
 - 2 MESSAGES
 - 3 LIBRARIES (Files)
 - 4 CONFERENCING (0 participating)
 - 5 ANNOUNCEMENTS from sysop
 - 6 MEMBER directory
 - 7 OPTIONS for this forum
 - 8 JOIN this forum

Enter choice !2<cr>

[If you have not JOINed yet, you should select this option first, no additional cost will be incurred. Simply follow the menus as they appear. When you have joined the forum you will be returned to the MedSIG Forum Menu again. If you are not familiar with the manner in which CompuServe forums are organized select number 1, INSTRUCTIONS. Selecting number 2, MESSAGES, will allow you to interact on the forum.]

- MedSIG Forum Messages Menu**
Message age selection = [All]
- 1 SELECT (Read by section and subject)
 - 2 READ or search messages
 - 3 CHANGE age selection
 - 4 COMPOSE a message
 - 5 UPLOAD a message
- Enter choice !1<cr> [Here we will read the messages by section and subject.]

- MedSIG Forum Sections Menu**
Section names (#subjs/# msgs)
- 1 General/Profess. (36/133)
 - ...
 - 6 Subspecialties (3/4)
 - ...
- Enter choice(s) or ALL !6<cr> [Here we have chosen the STA section, which is part of Section 6.]

- MedSIG Forum Subjects Menu**
Subject (# msgs)
- Section 6 - Subspecialties
- 1 propofol (2)
 - 2 Anesthesia Mach./Nigeria (1)
 - 3 STA Meeting (1)
-

Liability

continued from page 1

There are two areas of liability exposure that are of particular concern to "user" facilities and their staff. First, there is potential liability for failure to file the required reports. Section 303 of the Federal Food, Drug and Cosmetic Act was amended by the SMDA to include substantial monetary penalties for failure to comply.

■ "... *most commentators believe that user device reports will become available in professional and product liability actions ...*"

However, the Act specifies that the civil penalties (which can be up to \$15,000 per violation) will not be assessed against user facilities until after the Secretary of Health and Human Services conducts a study to determine whether there has been "substantial" compliance with the user reporting requirements. The Secretary must report the results of the study after the Act has been in effect for 45 months. Penalties for failure to comply will become a potential liability only if the Secretary does not complete the study or, if the study indicates that compliance with user reporting requirements is lacking. Since penalties for failure to comply will not be assessed in the near future, liability associated with the contents of the required device reports is a more immediate concern.

Confidentiality Not Assured

In an effort to foster compliance with reporting, attempts have been made

to protect the reporting institution. The SMDA states that a report made by a user facility, any individual affiliated with the facility, or by a physician not required to report, shall not be admissible into evidence in a civil action involving private parties unless the report contained false information. The FDA also may not disclose the identity of the reporting user facility except in an enforcement action, a report to Congress, or to certain governmental employees, or in a communication to a device manufacturer whose product is the subject of a user report. Despite these protections, most commentators believe that user device reports will become available in professional and product liability actions even though the FDA may not produce them.

Methods of Disclosure

Device manufacturers are under no obligation to keep reports from users confidential. Manufacturer records of telephone conversations and other communications are regularly produced during relevant litigation. The user report itself may not be admissible, but associated correspondence will be admissible (including any report made by the manufacturer to the FDA). These problems may be of particular importance when the user facility and the manufacturer are in conflict about the cause of the device malfunction.

The FDA can be forced to produce information pertaining to a report under provisions of the Federal Freedom of Information Act (FOIA). If the manufacturer forwards a user report to the FDA to comply with the manufacturer reporting requirement, the user report is converted into a manufacturer report and public access (with the facility name deleted) will be possible. In addition, documents created by the FDA while investigating a user report are considered agency records and releasable under the FOIA.

Finally, although federal law offers some protection, medical and device records relevant to a patient incident are

discoverable under state law, even if the specific user report may not be.

Institutional Planning Essential

As a result of liability concerns, user facilities must carefully design the institutional reporting system. To avoid liability for failure to report, in-service education must insure that physicians and nurses, engineers, and others are aware of the reporting process. An office within the facility should be designated to determine if the incident is covered by the reporting requirements and to make the required report. The FDA has issued a suggested reporting form but has not yet required it to be used. Any reporting form which is used should be completed with care; factual data is to be included and conclusions based on incomplete investigation are to be avoided. Given the potentially sensitive nature of reported information, one cannot be too careful about insuring that the contents of the report are accurate. ♦

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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:

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COMPUSERVE

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The messages in the forum are listed by topic. Since we share this area with other subspecialties, there are likely to be a variety of topics active at any time. Simply choose the number of a topic in which you are interested and become a part of the discussion. You can also post original messages onto the forum area to initiate discussions. There is also a library for the subspecialty section which includes a number of graphic and text files that can be read or downloaded to your computer.

Remember, you can always end the connection to CompuServe by typing "bye<cr>" or "off<cr>" at any "!" prompt. When you sign on again, type "go MEDSIG" to return to the forum. Many STA members "visit" the forum regularly so that it is an excellent place to pose questions and comments.

If you have any questions or problems, please contact Frank Block at:

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Columbus, Ohio 43210.
Phone: 614-293-8552
FAX: 1-614-293-8983.
E-mail: 70147.440@compuserve.com
(note that is a period)
CompuServe mail: 70147,440
(note that is a comma)

♦

Nominations in Progress for New Board Member

One position on the STA Board of Directors is open for replacement as of the annual meeting in 1992. The nominating committee has identified the following three candidates who are willing to serve.

Ira Rampill

(University of California, San Francisco)

Steven Barker

(University of California, Irvine)

Paul Barash

(Yale University)

Additional nominations may be made by any five members at any time previous to the voting. According to the bylaws of the society, officers and members of the board are elected by a plurality of votes cast at the annual meeting. To nominate a candidate, or for more information, contact Allen Ream, STA Vice President and Chairman of the Nominating Committee, either directly or through Gerri Kuzava at the STA office.

The current officers and dates for re-election are:

<i>President:</i>	N. Ty Smith (1993)
<i>Vice President:</i>	Allen K. Ream (1993)
<i>Secretary:</i>	Frank Block (1993)
<i>Treasurer:</i>	Alan Grogono (1993)
<i>Board of Directors at large:</i>	
	J.S. Gravenstein (1992)
	Jerry Calkins (1993)
	Robert Chilcoat (1994)
	James Philip (1994)
	Dwayne Westenskow (1993)
<i>Newsletter:</i>	Jeffrey M. Feldman
<i>Education:</i>	Alan Grogono
<i>Membership:</i>	Julian Goldman
<i>National Anesthesiology Database:</i>	David Edsall
<i>Equipment Selection and Testing:</i>	Jeff Feldman
	Albert Perrino
	John Howse
<i>Task Force on Recertification and Recredentialing:</i>	Wesley Frazier