

ACCE News

Volume 2, Number 1 October - November, 1991

A Message from the President

ACCE is well over one year old now. We have survived the dangerous neonatal period, dodged the hazards of infancy and are learning to walk and talk like the big kids.

In May, in Washington DC, we held our first annual general membership meeting. It was well attended with lively discussions and much enthusiasm. Special recognition was given to Tom Judd for his work in organizing the Advanced Clinical Engineering Workshop (see article on Page 8) and Yadin David for his efforts in founding ACCE and serving as its first president.

So, what's been happening? The ACCE officers and committee chairman are working hard to alleviate some of our growing pains. The design of the membership certificate is almost finished and each member will receive one soon. An expanded set of informational materials is being prepared, and will be distributed. Procedures are being established to handle the membership applications and renewals more efficiently. A financial plan is under development and a membership directory is being planned (perhaps with on-line computer access in the future).

Beyond these administrative issues, several committees are active with projects completed, underway, or in the planning stages. One of the primary objectives of ACCE News is to keep you informed of these activities. In particular, we want every member to be aware of the numerous opportunities to promote the clinical engineering profession by volunteering to help with committee projects.

I will take this opportunity to welcome David Harrington as Editor for the ACCE News. Ira Tackel will continue as publisher, and his production is responsible for the handsome design and layout that you see before you. Many thanks to all who make this publication a reality.

There is no longer any doubt that ACCE was the right idea at the right time. Let us continue to generate new ideas and put out the effort that it will take to keep the clinical engineering profession moving in the right direction.

Matt Baretich

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A Message from the Past President

It is hard to believe how fast time flies, especially when you feel great about what you are doing. Regardless of whether you want to be vacationing, working, socializing or promoting your profession, it is that combination of circumstances and individuals that tells you, *this is it!* You know something is happening and you feel good about it. I have just completed my term as the first president of the ACCE and this position somehow falls in this category of combined circumstances.

We have all had the experience of explaining what our field is that we so proudly practice in. I too felt, at times, that trying to explain it may be just *treading water*. However, now that the ACCE has begun operations, we are in the midst of a change because together we have made a commitment to build our field. Things have begun to shape up and that makes me feel good. We are only one year old and yet a review of our accomplishments will tell you that our colleagues are actively volunteering their time and other resources to the common vision we call ACCE. An organization is only as good as the actions of its membership. Here are some of those actions from our first year:

- The establishment of an independent professional association that is based on a highly qualified membership and mutual respect for that common vision.
- Our membership is continuously growing.
- Committees and task forces were initiated and produced some landmark documents.
- An open election of officers was held.

- An annual meeting was held.
- The ICC Board voted the ACCE to membership on that board.
- Newsletters were published.
- The evolution of the society was covered by periodicals covering the medical field.
- We co-sponsored the Advanced Clinical Engineering Workshop and provide all the practicum locations, along with all but four of the classroom instructors.
- Spread the message of ACCE at meetings throughout the World.
- Provided input to various FDA panels and the CDRH Committees.
- Were represented at the national conference to develop and initiate a plan for cardiovascular quality assurance.

Now you can understand why it feels so good to be a part of ACCE's first year. Let us keep the momentum going and continue the building. It is a wonderful feeling to be part of the clinical engineers who are working together to promote a common vision.

Finally, I would like to express my gratitude to the Board of Directors, Officers and all you members who have worked so hard to make this first year a success. I felt privileged and honored to serve you all. Thank you for being a friend.

Yadin David

MAY BOARD MEETING

The following *Definition of a Clinical Engineer* was approved:

Introduction

Advancements in technology accelerated multidisciplinary approaches to healthcare management. Clinical engineering, a profession based on both engineering and the life sciences, developed in response. By presenting an updated definition of the term clinical engineer, the American College of Clinical Engineering (ACCE) provides a better understanding of the profession.

Definition

A clinical engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology.

Education

A clinical engineer has at least a bachelor's degree in engineering from a program approved by the Accreditation Board for Engineering and Technology (ABET) or has proven through professional practice and examination to have the knowledge and skills of an engineer.

Clinical engineering is a relatively new profession. Colleges and universities developed formal curricula during the 1970s. Academic programs grant bachelor's, master's and doctoral degrees in clinical and biomedical engineering. The curriculum includes courses in physical and life sciences, mathematics, humanities, management, and engineering. Several traditional disciplines such as electrical, mechanical, chemical, and computer engineering provide the foundation for clinical engineering. The life science courses usually include biochemistry, biology, physiology, and anatomy. The multi-disciplinary combination of engineering and life sciences is a distinctive academic difference between clinical engineers and other engineers.

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Undergraduate curricula in clinical engineering meet the academic requirements for entering degree programs in medicine. Clinical engineers may pursue advanced degrees in engineering, business administration, healthcare management, and technology assessment. Educational institutions employers and professional societies provide continuing education for clinical engineers.

Although an engineering degree is the major preparation for the profession, some individuals, by virtue of their academic training and experience, developed the skills and knowledge equivalent to those of a formally trained engineer. Some early leaders in the field have backgrounds in the life sciences or physical sciences because formal courses in clinical engineering were not available to them. The international Certification Commission (ICC) recognized that preparation in its criteria for certification in clinical engineering.

The ACCE affirms that the minimum preparation for new practitioners in clinical engineering is a Bachelor of Science in Engineering from an accredited institution.

Practice

Applying engineering and management principles to the technology and systems of healthcare institutions, clinical engineers work with healthcare providers to support patient care. They may design, modify, and analyze medical devices and systems.

In addition to the academic emphasis on the life sciences, practice in the clinical environment of healthcare institutions further differentiates clinical engineers from other engineers. Clinical engineering is a specialty within biomedical engineering. Universities, hospitals, or medical instrumentation companies that conduct research employ bio-

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medical engineers primarily to perform basic or applied research or teach.

Equipment Management: Clinical engineers develop, implement, and direct equipment management programs. Specific tasks include evaluation and selecting new technology, preparing specifications and requests for proposals, installing and accepting new equipment, providing operator training and applications assistance, interfacing devices, and managing repairs and scheduled maintenance. They investigate medical device-related incidents and manage hazard alert and reporting systems. The primary concern is to cost-effectively provide safe and reliable technology for healthcare delivery.

Clinical engineers may supervise medical physicists, safety engineers, industrial hygienists, nurses, other clinical engineers, or biomedical equipment technicians. Clinical engineers manage all types of medical devices including equipment found in intensive care, clinical laboratory, respiratory therapy, anesthesiology, neurology, physical therapy, ultrasound, radiology, radiation therapy, nuclear medicine, and operating rooms. Clinical engineers' involvement in healthcare technology goes beyond medical devices to include communication networks, telephone systems and computers. Clinical engineers practice within a highly regulated industry.

Construction and Renovation: Clinical engineers develop and manage building renovation and construction projects, coordinating equipment needs and budgetary requirements. They work with architects, administrators, and clinicians in the design and layout of instrumentation, support structures, furnishings and utility systems.

Consulting: Some clinical engineers, having obtained clinical and engineering experi-

ence, consult with hospitals on technology management. Clinical engineers may develop consulting practices or work for firms that provide clinical engineering services to healthcare institutions.

Manufacturing: Medical device manufacturers employ clinical engineers to assist in human factors, product design, development, testing, clinical verification, quality assurance, regulatory compliance, incident investigations, and field service. They consult with healthcare institutions regarding systems design, equipment installation, and training programs.

Radiation Safety Clinical engineers trained in radiation physics manage the radiation safety support for healthcare institutions. This role includes providing training in radiation physics; designing image quality assurance programs; maintaining and distribution of radiation safety information; conducting compliance surveys of radiation equipment; monitoring and documenting personnel radiation levels; maintaining necessary registrations; and assuring compliance with the requirements of voluntary standards organizations and Local, State, and Federal regulatory agencies.

Teaching: Clinical engineers hold academic appointments and teach in schools of engineering, medicine, nursing, allied health, dentistry, or veterinary medicine. Besides teaching courses in degree programs, clinical engineers present in-services and continuing education courses for healthcare professionals. Clinical engineers develop and present many of the periodic courses that accreditation agencies require for those who operate medical devices. Those include courses in electrical, radiation, and laser safety.

Research: Clinical engineers, independently or in collaboration with physicians and other practitioners, perform research in the clinical environment. Research areas include electrophysiology; metabolic studies; image

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1991 - 1992**

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All of the above members are up for reelection at the annual meeting in 1992.

The following two MEMBER AT LARGE terms expire at the annual meeting in 1993.

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THE ANNUAL MEETING – MAY 13, 1991

The annual meeting was held on May 13, 1991, at the Marriot Hotel in Washington, D.C.

Then president, Yadin David, reviewed the first year of ACCE, introduced the new and outgoing Board Members and asked the various committees to offer reports. Some of the highlights were membership totaling 103 at that time.

The Advocacy Committee presented the following statement:

"The Advocacy Committee shall serve as a catalyst for action in support of the professional stature of the clinical engineer.

Through publicity, the committee shall promote clinical engineering in the media, academia, professional societies and hospital administration.

With vigilance, the committee shall perform watchdog and oversight activities, especially in the media, journals, advertisements, meetings and professional societies.

In defence of exclusivity, the committee shall protect and preserve those elements of the profession that makes clinical engineers unique and exclusive. It shall promote the security of the niche of clinical engineering and encourage and promote recognition of the clinical engineering profession by law and regulation".

Further developments from the committee will be reported in future editions of the ACCE News.

A work draft of the proposed "Code of Ethics" was presented"

CODE OF ETHICS

As a member of the American College of Clinical Engineering, I subscribe to the established Code of Ethics in that I will:

- Strive to prevent a person from being placed at risk of injury due to dangerous or defective devices or procedures.
- Accurately represent my level of responsibility, authority, experience, knowledge and education.
- Reveal any conflicts of interest that may affect information provided or received.
- Protect the confidentiality of information from any source.
- Work towards improving the delivery of health care to all who need it.
- Work towards the containment of costs by the better utilization of technology.
- Promote the profession of clinical engineering.

During the question and answer period, many attendees participated. The annual meeting adjourned with very positive responses from the attendees.

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acquisition, processing, display and storage; medical device evaluations; computer simulation and modeling; signal acquisition and processing; interactions of energy with tissues; patient data management systems; and artificial organs.

Design: Clinical engineers frequently design or improve medical devices because they understand the clinical environment, the principles of the equipment, and how the equipment is used. Clinical engineers understand the importance of clinical constraints when designing and modifying medical systems. Technology transfer from the research and clinical testing environment to the commercial market is a growing field for clinical engineers. Their collaboration with clinical staff is vital in medical device design and development.

Technology Assessment: Clinical engineers evaluate the costs, benefits, and risks associated with acquiring new but unproven technology. They lead or support technology assessment committees. Clinical engineers analyze the business, financial, and managerial strength of companies and forecast trends in healthcare technology.

Summary: According to the needs of their institution and their individual interests and skills, clinical engineers practice a combination of the activities above. Clinical engineers are uniquely prepared to effectively lead the management of healthcare technology.

Membership

The following new members were voted in:

Alex Altshuler	Les Edwards
Dennis Autio	Thomas Eichel
Daniel Benson	Mark English
Jack Berger	Brenton Fearron
David Berkowitz	Barry Foster
Rupal Dave	Emanuel Furst
Gregory Davis	Kelly Galanopoulos
Augusto DeMelo	Stephen Grimes
Roger Eddy	Jay Hall

Henry Hamarman
Joseph Happ
Terrance Hensler
Edward Hines
John Hughes, Jr.
George Johnson
Charles Kemmerer
Alan Levenson
Patrick Lynch
Allen May
Spears McAllester
Charles McCullough
David McCusker
Micheal Mirsky
Paul Ostrowski
Thomas O'Dea
Joseph Prizio
Francine Reibman-Myers

Hector Rivera
Thoms Roeble
Michael Rohaly
Jeffery Secunda
Gary Slack
Elloit Sloan
J.M. Smith
Julien Stedman
John Storch
John Swope, MD
Richard Tevis
Pedro Tonarelli
James Virgulto
Fred Wainwright
Anthony Werner

AUGUST BOARD MEETING

August 9, 1991

Membership

11 new members were voted in along with three students:

Ernesto Hernandez	Jorge Villimil
Tom O'Dea	Luis Lara-Estrella
Jeff Secunda	Raul Alvarado
Kelly Galanopoulos	Adirana Velazquez
Diogenes Hernandez	Chuck Jones
Lucio Flavio Brito	

The new students are:

Ana Marie Ospina
Gerson Machado
Dave Rupal

The present membership total is 118, plus three students.

Public Affairs

An electronic bulletin board is being investigated.

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NEXT BOARD MEETING

Saturday, November 2, 1991, Edel Weiss Room, Hilton Disney World, Florida, at 6:00 P.M.. EST.

FDA NEWS

AAMI, ECRI, FDA, AAHA, AHCA and AORN, are sponsoring seminars around the country on the Safe Medical Device Act of 1990. Two members of ACCE, Jeff Secunda and Joe Dyro are presenters in the clinical engineering sections.

At publication time, the FDA has not issued guidelines for reporting. The best estimate is January we will see the guidelines being issued. More to follow in the next issue of ACCE NEWS.

The FDA is moving away from using the ISO 9000 series for the GMP regulations. This is still in the early stages but bears watching closely.

There are numerous openings on the FDA advisory panels which will be ideal for ACCE members. It takes several years for an appointment, but it is an area that we can make an impact. If you are interested in being nominated, please contact Joe Dyro, the Advocacy Committee chairman.

ADVANCED CLINICAL ENGINEERING WORKSHOP

Two years of hard work by Tom Judd, Benseng Wang, Yadin David and Frank Painter bore fruit between May 15, to June 7, 1991, when 24 people from developing countries came to Washington D.C. for the first ever Advanced Clinical Engineering Workshop. The primary goal was to educate technology managers in methods of improv-

ing utilization of technology in health care delivery. But in reaching that goal, several other very important objectives were achieved. ACCE members from 11 States came to Washington to provide instruction to the 24 students. Many freely gave time and expenses to do the teaching. This showed a major commitment to our profession and ACCE. After the formal classroom the students went to some 11 different sites around the country for two additional weeks of practical instruction. The students brought back to their countries a knowledge that they developed, and a network of contacts who can be called upon to help when they have problems. The ACCE members also reinforced their own networks. The ACCE participants, in addition to Tom, Frank and Binseng were Yadin David, Larry Fennigkoh, Bob Morris, Jim Wear, Gailord Dolan, Joe Bronzino, Ira Tackel, Mark Brody, Joe Dyro, David Harrington and Mark English.

To all a great job well done and to those who could not participate, please consider joining us the next time.

NOTE TO MEMBERS

This Newsletter is your vehicle to communicate with other clinical engineers who feel the same as you do about the profession of clinical engineering. The newsletter will be published six times per year, October, December, February, April, June and August. The closing date for publication is the first day of the month of the publication date. If you have anything you want to have published, please submit it. If you have any suggestions as to what should be in the newsletter, please send it in; Should we have letters to the editor? Should we have a feedback column? Should we publish product problems, advisories, or recalls? Your input is needed to make this the best professional newsletter. Please fax any ideas to (617) 956-4736. Other members on the editorial board of the ACCE News are listed on the front page. Please help us make this a great newsletter.