

SCIENTIFIC MEETING

"Improving Medical Device Safety: lessons from the past."

Dr Joel Nobel
President of ECRI

Date: Monday 4th November 1996

Venue: Chapman Hall , Institution of Engineers
11 Bagot Street , North Adelaide

Time: 6.00 pm for a 6.30 start.

Dr Joel Nobel is President and founder of ECRI and it is a privilege to have him here in Adelaide. Dr Nobel has extensive experience in engineering in healthcare and I'm sure you will find this presentation rewarding and informative.

We are all influenced in some way by the many publications to come out of ECRI , and presentations by ECRI people in the past , at our conference in 1990 , have always been very entertaining.

Don't miss this opportunity to listen to and meet one of the world's foremost authorities in our field.

This meeting is organised in conjunction with the Institution of Engineers who are sponsoring Dr Nobel's visit.

THIS ISSUE

[AS3551 Seminar](#)

[Report on Forensic meeting](#)

[High-tech health-we can , but should we?](#)

[Benchwarming is for benchwarmers](#)

[Testing of electrosurgical accessories](#)

Council For The Society for Medical and Biological Engineering (SA) Inc. 1996/1997

| | | | |
|--------------------------|--|---|-------------|
| president | John Robson | Flinders Medical Centre | 8204 5621 |
| Immediate past President | <u>Adrian Richards</u> | The Queen Elizabeth Hospital | 222 6533 |
| Vice President | Greg Smith | Helicon Technology | 223 2000 |
| Secretary | <u>Tim Staker</u> | The Queen Elizabeth Hospital | 222 6259 |
| Treasurer | John Kirby | The Queen Elizabeth Hospital | 222 6218 |
| Councillors | Roger Pirola | Accuson | 018 806 295 |
| | Maureen Merrick | Wakefield Memorial Hospital | 223 3555 |
| | Jo Harris | <u>Acute Care Systems</u> | 018 800821 |
| | Kevin O'Brien | Valleylab | 377 0833 |
| | Robin Woolford | Repatriation General Hospital | 275 1619 |
| Editor | Robin Woolford | | |

An important workshop is coming up on Monday 4th November , see separate flyer , on the new AS3551 standard. This standard sets some high demands on Biomedical Engineering departments , some of which will be difficult to achieve, although I believe that with a common sense approach the intent of AS3551 will be able to be met. It concerns me that in implementing this standard we may be more concerned with avoiding litigation than doing what is best for our patients. However , this is the standard by which we will all be judged and it is therefore important that anyone involved in the technology management process attend this workshop. It is important that we all apply this standard in a consistent and appropriate way.

The question as to whether high technology improves patient care outcomes is the subject of an article taken from the University of South Australia journal "New Outlook". I'm sure we have all had this discussion with medical staff when selecting new technologies or equipment. In all professions you get a group of people that must have the latest state of the art equipment , but fortunately , there are also people who ask the question "Will the technology significantly improve the outcome for the patient , or significantly reduce the cost of care?" The use of appropriate technology is just as important for us as it is when introducing equipment to third world countries.

Benchmarking has been discussed at conferences and in previous newsletters. A different viewpoint to benchmarking is presented by Arnold Mahachek in an article titled "Benchmarking is for Benchwarmers" from Biomedical Engineering and Instrumentation, Volume 30 No. 4.

Mr Mahachek mentions a book "Fad Surfing in the Boardroom:Reclaiming the Courage to Manage in the Age of Instant Answers" by Eileen C. Shapiro, published by Addison-Wesley Publishing Company, which he reviews in this journal , and I leave you with a definition of benchmarking from this book .

"The basis for great jobs in which the incumbents have no substantial responsibility other than to gallivant around the world , meet all sorts of interesting people , make occasional proclamations about all the neat things other companies do , and submit appropriately lavish expense reports."

Editor.

REPORT ON FORENSIC SCIENCE MEETING

This meeting was billed as a "triple treat of scientific super sleuths" and despite vigorous denials by those presenting, it turned out to be quite true. We were privileged to share the experiences of three knowledgeable forensic scientists and clinicians from diverse fields of expertise.

Associate Professor Lindsay Richards outlined to us the roles of the forensic dental unit to which he consults, one of the few units in existence where postgraduate specialist training in forensic dentistry can be undertaken. It s a highly respected unit worldwide with their services often being sought after outside of South Australia. Its functions centre around providing expert advice and testimony for the police department in criminal cases and performing body identifications on behalf of the coroner. Criminal work involves not only correlating a victims bite marks with a suspects teeth but are as diverse as the cases detailed where identifying characteristic impressions left on a piece of chewing gum and a bite mark left in a lamington at the scene of a crime provided key evidence. Coronial work somewhat more predicably mostly involves the use of dental records and features to identify unknown bodies and to spare relatives the pain of positively identifying the remains of victims of death by severe trauma or fire.

Sara Jones, as consultant podiatrist to the police department then took us on a completely different course. She eloquently detailed the role that footprints and wear patterns within shoes can play in criminal investigation. One's footprint for example is as uniquely identifying as a fingerprint, it is just that they are not as frequently left at the scene of a crime! However we were treated to a number of examples where perpetrators' shoes were left at the scene or nearby and the pivotal role that they can play in subsequent investigations. We mused over whether the verdict in OJ Simpson's trial would have been the same if it had been a shoe that was found at the scene of the crime rather than a glove!

Carrion breeding blowflies was the next topic on which we were educated. This was the speciality of James Wallman as a forensic entomological consultant. The range of flies existing in various parts of the state and the detail of their life cycles are what provides us with useful information in this field. Being mindful of a few variables such as temperature and the access that flies may have had to the body, the stages of development of larva can give a very accurate predication of time of death. Interesting cases were quoted both here and overseas where this had provided not only accurate but pivotal information. Other aspects of this field included determination of whether a body had been moved from its original place of infestation and hence presumably death, based upon the range of the species found and even the course followed by a vehicle determined by the species of insects found trapped in the radiator!!

What more can one say apart from the fact that it was a fascinating, informative and entertaining evening, a view shared by the 35 people who attended.

HIGH-TECH HEALTH - WE CAN, BUT SHOULD WE?

In Steven Spielberg's science-fiction blockbuster Jurassic Park, the Jeff Goldblum character criticises the fictional genetic manipulation that has resurrected Tyrannosaurus Rex: "Scientists were so preoccupied with whether they could, they didn't stop to think whether they should."

It's the best line in the film, and one echoed by Professor Edwina McConnell, professor at Texas Tech University Health Sciences Center and for the past six years a visiting professor at the University of South Australia School of Nursing. An expert in high-tech, critical care nursing, Dr Edwina McConnell agrees: "Unfortunately there's such a thing as a technological imperative," she said. "If we've got it, we have to use it, whether we should use it or not."

Whether we should because we can is a relatively new debate to Australia, and in the United States this debate has been prompted as much by economic constraints as by ethical considerations. Just the same, it could presage an imminent change in our attitude to health care and, in particular, to the routine use of costly technological tests.

Edwina McConnell last month addressed the Fifth International Conference in Adelaide of the International Federation of Women Entrepreneurs. Predictably enough, she emphasised the overwhelming influence of technology on our lives. "[It] affects if we are conceived, as well as how we are conceived...if we are born [and] how and where we are born...how we die, where we die, and in some instances when we die," she told delegates. She noted the coming of long-distance "telemedicine", of non-invasive diagnostic tools, of the development of "replacement parts" that will eventually take over from transplants - all heady twenty-first century stuff.

But what was distinctive in her address was a less than full-throated endorsement of technology as the be-all and end-all of modern medicine. "The introduction and use of sophisticated and costly health care technology do not guarantee improved outcomes," this internationally recognised authority told the conference. "[Those] depend on adequate nutrition and sanitation, and the education of women."

It was "appropriate technology" that was important. Professor McConnell noted growing reservations in the United States and here that a widespread, inappropriate use of technology was pushing up health care costs, to the eventual disadvantage of the whole community. Ultrasound foetal scanning is an example. "Ultrasound can be a misuse of technology," Professor McConnell said. (Ultrasound is routine in Australia for pregnant women, whether in a high-risk category or not.) "Pulse oximeter (to measure oxygen saturation in the blood during surgery) can be another. Not everyone may not need it, but nearly everyone has it. The reason is that if anything goes wrong and these technologies haven't been used, the patient's family can sue."

At present, not prescribing this technology can mean stepping outside the current definition of standard clinical care. This definition needs reworking, Edwina McConnell suggested, so that potential lawsuits no longer threaten perfectly ethical and conscientious doctors, nurses and hospital administrators who nevertheless need to justify expenditure.

However, society imposes its own terms on the medical profession. "And we are all seduced by high-tech," professor McConnell said, "- especially when it's our baby, our operation."

If legal issues loom large in the challenges facing high-tech medicine, so do ethical considerations, especially in defining 'quality of life' and setting, in an ageing world, possible limits on access to certain life-sustaining technologies. Haemodialysis is one. "In the UK, haemodialysis is not available over a certain age," Dr McConnell said.

Of course she confirmed the obvious - that high-tech is keeping people alive longer. Whether one day it will have to backtrack, with a central computer perhaps triggering some kind of electronic brainstorm around the time of one's 80th birthday, is one of the big ethical, and environmental, questions of the twenty-first century.

In the more prosaic present, nurses face a special challenge to make technology 'invisible'. Today registered nurses are seen more and more as technicians and less and less as carers. Professor McConnell would prefer them spending "less time staring at monitors and writing on charts and more time interacting directly with patients and their families."

She is adamant in this. "The humanistic view is critically important to nursing care. People want a nurse to care for their personal and psychological needs, to treat them as individuals, know their names and so on, but they also want them to be competent in handling the devices used in patient care."

This leads to a dilemma not yet fully resolved. If two hours of a nurse's shift are taken up with operating technological devices, two hours of her pre-technological duties have to go. "Care is limited to physical stuff - taking blood pressure, giving tablets, etcetera," McConnell admitted. "The patient's psycho-social needs go, as does the nurse's teaching time - instructing patients so they can pick up problems for themselves."

Practical or enrolled nurses and orderlies have taken over some of the duties. "But if a registered nurse makes a bed or bathes a patient, she's also noting skin tone and psychological state and other crucial factors."

There isn't an immediate solution, other than recognition that in nursing the bottom line must not be the dollar. "There's emphasis today on doing more with less," but, according to Professor McConnell, "nursing can't do the entirely."

In the USA, Edwina McConnell works part-time as a staff nurse on an adult surgical unit in Madison, Wisconsin, in order to maintain her clinical expertise. "And such is the advance of

technology," she said, "that 20 years ago the patients on this ward would have been in intensive care."

Her clinical experience has reinforced her holistic approach to nursing and a conviction that nothing can supplant interaction with patients. A gastric surgery patient with a nasogastric tube and an infusion pump once summed it up when she was discussing his nursing care with him. "My nurse has three arms," he said; "- one around the tube, one around the pump, and one around me. And she keeps us all together."

Reprinted from the University of South Australia magazine "New Outlook" , September 1996.

BENCHMARKING IS FOR BENCHWARMERS

ARNOLD R. MAHACHEK

Reading the book *Fad Surfing in the Boardroom: Reclaiming the Courage to Manage in the Age of Instant Answers* (see this month's *Off the Shelf*-brought to mind one of the worst management fads ever to take hold in health care - benchmarking! Various definitions of benchmarking is the search for industry best practices that lead to superior performance. Ford Motor Co. states that benchmarking is a "structured approach for learning from others and applying that knowledge." Milliken & Company call benchmarking "stealing shamelessly!" Tom Peters calls it "creative swiping!"

I spoke about the pitfalls of benchmarking during the "Technical Iconoclast" roundtable at the 1995 AAMI Annual Meeting. I meant my comments to be humorous and exaggerated. In the context of the harm that health care benchmarking can do, these words now seem serious and understated. My remarks from the roundtable follow.

Great disasters of the 20th century: the Titanic, the Hindenberg, the Edsel, Bhopal, the Challenger Launch, Chernobyl, Exxon Valdez, and health care benchmarking. All of these have at least two of the following four things in common: a lack of critical thinking, a lack of understanding of the fundamental principles about what was going on, and no lack of hubris.

Following are three reasons, out of many, why benchmarking in health care is a disaster. First, start with the history of health care in applying these techniques. Health care takes a technique that was developed in a for-profit, results-oriented, management environment and tries to apply it in a nonprofit, relationship-oriented, administrative environment, and then is mystified about why it doesn't work. It reminds me of a well-known phrase, "The purest form of insanity is to keep doing the same thing over and expect a different outcome."

The second reason is that benchmarking is a serial killer. The first thing it kills is a personal responsibility. Stolen property is always the first thing everybody denies responsibility for. "Gee, officer, I found these hubcaps by the side of the road" becomes "Don't get mad at me, boss- it wasn't my idea." The next thing benchmarking kills is the need for understanding fundamental management principles. "We don't need to. We're just going out to get it. It's already been done." Finally, it murders creativity in the cradle: "We don't need ideas. All we need is tracing paper."

The third reason is that benchmarking is a form of magical thinking. It's the kind of thinking of people who have seen too many Roadrunner cartoons: they actually believe that when you run off the cliff you won't fall if you don't look down. They want to be like Superman by putting on the benchmarking cape. They want to fly before they can crawl. In his book *Breakthrough Management: A New Model for Hospital Technical Services*, Gailord Gordon said that we shouldn't benchmark until we've got our departments running as businesses.

I'd like to add that you cannot get your department running as a business if you don't learn management skills. What's the first skill of management? Peter Drucker says, "Productivity is the first test of management competence." We have a long way to go in health care. I don't see people concentrating on productivity out there. They want to go out and fly with the eagles. The grim reality is that those aren't eagles: they're vultures, and they're going to clean your bones.

The first time I ran into benchmarking was 23 years ago at Corning Glassworks. I had the privilege of being there for a disaster. Corning Glassworks was proud. We had sold the world on the dubious process of heating food in an insulator. Now we were going to crown our achievement by putting in another layer of insulation. We were going to make a glass-topped stove. We didn't know how to make a stove; we just knew how to make the glass. So we benchmarked the stove, and we did the ultimate act of benchmarking. We didn't just copy the benchmark, we bought it - land, building, machines, employees. It was a failure.

My motto: millions for defense from benchmarking, but not one cent for tribute to benchmarking
[Audience question: What is your definition of benchmarking?]

I'm not talking about definitions. I've seen the finely crafted definitions of benchmarking, and they are superb. They have nothing to do with what's going on in health care. I'm talking about the act of benchmarking as done in health care, and it doesn't meet any of those definitions. It involves panicked, incompetent administrators trying to become managers with the help of a magic bullet.

[Question: Isn't your argument not about the practice of benchmarking but about the misunderstanding of how to use benchmarking as a tool to reach better managing practices?]

No, that's only part of the argument. Even if the practice were straightened out, it wouldn't work. You need a certain level of competence to practice benchmarking successfully, but once you achieve that level of competence, you probably won't bother. You don't need to - you're a manager.

Benchmarking, like the magic bullet, is being lauded, along with other such solutions, as a quick fix to becoming a manager. The fact is that becoming a manager is a long, arduous process requiring hard work and study and involving considerable risk. The vast majority of health care administrators are not managers.

[Question: So if you're an incompetent manager, benchmarking doesn't work?]

And if you're competent, you probably don't need it. In for-profit industry, benchmarking is successful in very few cases. At Corning Glassworks we had good, smart people, and it still didn't work, for the reasons I gave. Productivity is a much better tool management than benchmarking. Benchmarking in nonprofit health care is an extrapolation of another fondly held tool - comparisons to other hospitals. While benchmarking looks at process and methodology, comparisons make use of department costs and staff sizes. Academic hospitals, especially, seem unable to stop the meaningless comparisons among themselves. When the comparison idea proves unworkable, do its proponents stop and do some introspective analysis? No, they go to warp nine and say, "Why bother to compare when we can just import any practice that claims success?" The term "fad surfing" invokes a crystal clear image of the results: see the novice surfer on the wave? What happens next? Wipeout!

Arnold R. Mahachek is a senior management engineer on the central staff of The Johns Hopkins Hospital. He provides management science and industrial engineering services with emphasis on computer simulation of staffing requirements. He also serves as the hospital's capital equipment administrator.

Reprinted from "Biomedical Instrumentation and Technology", Volume 30, Number 4.

The following was taken from Hilary Bridel's BME mailing list. I'm sure many people are testing instruments to some degree. Earle Dundas would like to hear from you if you have any comments or suggestions.

ELECTRICAL SAFETY TESTING OF E.S.U. INSTRUMENTS

This Biomedical Engineering Department has been requested to perform electrical safety tests to insulation of instruments used in conjunction with electro-surgical generators.

The process in itself is relatively simple to perform, however, as guidelines are virtually non-existent, it is essential that some formal procedure be established.

As a result of this, I have commenced this discussion document and I am asking for comment from all interested parties with the aim of eventually producing suitable policy and procedure for such testing.

The following list of comments are designed to act as a "starter" for the purpose of discussion. Further contributions as questions and/or answers are most welcome and may be directed back to me as co-ordinator of the project.

1. Identification of instruments: All instruments require identification for the purpose of traceability. This I.D. will enable instruments to be included in an asset register and consequently, records of testing to be established.

How are such I.D. numbers/labels to be permanently fixed to such small instruments? Who would be responsible for fixing the I.D.?

I believe both the above problems would have to be addressed by the manufacturers and/or suppliers. In the event that suppliers are reluctant or even refuse to I/D the instruments, we could ask them to confirm their approach to quality assurance as we are the customer and a large part of QA is to provide a service that is satisfactory to us. There is also the question of

identification of instruments that are still within the warranty period. Without I/D, it is impossible to trace any instrument and, therefore, leaves some interesting questions unanswered.

2. Specifications of insulation used: Before proceeding with any form of testing, it is essential that specifications relating to working/breakdown voltage of materials used be determined.

Specifications of insulation used on instruments should be available from suppliers to enable safe testing procedures to be implemented to ensure only non-destructive tests are carried out.

3. What parts of what instruments are to be tested: Agreement would have to be reached regarding whether we test all parts of an instrument (including handles) or specify only those parts that may enter the body. The type of insulation used on handles, etc., will probably be powder coating and, if so, could be subject to "bubbling" when being applied. This, in turn, could result in unnecessary breakdown of insulation when applying a high voltage test. Consideration should be given to the level of risk associated with a handle compared to the main shaft of the instrument that is actually inserted into the body cavity.

This should also include the method of protection being adopted by the surgeon and support staff. "Double gloving" may be considered as the prime protection needed and, as such, the use of potentially destructive test voltages on the handle may not be necessary.

4. The test equipment: The safety factors of the unit being used for testing the instruments must be of prime importance. It has been suggested that testing may be carried out by staff of C.S.S.D. and, as these people are normally untrained in electricity, what we consider safe for a trained technician to use may not be suitable for other people. There are a couple of instruments currently available on the market that would be either suitable in their present state or could be mechanically adapted to suit.

5. Re-usable diathermy leads: The high voltage test generator could be suitable for testing diathermy leads and could be mechanically adapted to suit. If leads were to be considered for testing, they could be done in conjunction with handles of instruments etc. to determine the potential dangers associated with them.

6. Test voltages: Voltages to be used to test instrument insulation needs discussion. Is it necessary for tests to be carried out to the rated voltage of the insulation, or are we looking for areas of actual fracture or pinholes that have developed along the

shaft. It may be established that testing to a voltage level that could be reasonably expected to identify small pinholes or fractures is sufficient whereas using higher voltages may do more damage than good.

7. Input from Medical Administration: We must offer a similar level of safety to users as we do to patients and, therefore, we should seek input from all people who handle these instruments from time to time. These people may identify risks that are not evident to Biomedical Staff.

8. Access to instruments: It is essential that access be available at reasonable times to all instruments. This would require the co-operation of Theatre and CSSD Staff in particular to allow test schedules to be developed that would minimise disruption to all concerned.

9. Cost of testing: Testing of these instruments could be a complex matter and is likely to raise questions from Hospital administrators as to costs and benefits involved in supplying such a service. Before Biomedical Engineering could set a testing service in motion, Hospital administration would have to agree to staff/funding requirements. It may be a worthwhile exercise to have discussions with the Fund Managers who handle litigation on behalf of the Health Department.

Earle Dundas

North Coast Biomedical Engineering Services

Electro-medical Division

Lismore Base Hospital

PO Box 419

LISMORE NSW 2480

Phone: 61 66 202213 Fax: 61 66 202498 e-mail ; earled@doh.health.nsw.gov.au

CONFERENCE CALENDAR

Sept 8th 1997 Annual Biomedical Engineering Conference, Adelaide, SA

Sept 14-19 1997 World Congress on Medical Physics and Biomedical Engineering, Nice, France

Information on the above are available from the editor or president.

**THE PRODUCTION OF THIS NEWSLETTER HAS BEEN MADE POSSIBLE BY THE
GENEROUS ASSISTANCE
of Anne Richards.**

E. & O.E.

Change of address notification (Please cut off and return to Secretary if applicable)

Name:

Address: No/Street Phone number (W)

Town/Suburb (H)

State FAX number

Postcode

