Clarke’s Law: Luddites and the STA

Clarke’s Law (more properly, Arthur C. Clarke’s 3rd law):
Any sufficiently advanced technology is indistinguishable from magic.

Barry Gehm, corollary to Clarke’s Law: Any technology distinguishable from magic is insufficiently advanced.

Florence Ambrose, 2nd corollary to Clarke’s Law: Any technology, no matter how primitive, is magic to those who don’t understand it.

Luddites: from Wikipedia: The original Luddites claimed to be led by one Ned Ludd (also known as "King Ludd", "General Ludd" or "Captain Ludd") who is believed to have destroyed two large stocking frames that produced inexpensive stockings undercutting those produced by skilled knitters, and whose signature appears on a "workers' manifesto" of the time. The character seems to be based on a local folk tale about someone whose motives were probably quite different (frustration, and not anti-technology zealotry).

From the web (various sources): An individual who is against technological change. Luddite comes from Englishman Ned Lud, who rose up against his employer in the late 1700s. Subsequently, "Luddites" emerged in other companies to protest and even destroy new machinery that would put them out of a job. A neo-Luddite is a Luddite in the Internet age.

As anesthesiologists, innovators, and creators of technology we have a problem. Our technology has become so advanced that Clarke’s law, and its corollaries apply. When people are forced to deal with things they do not understand or comprehend (i.e. magic), they (the people), become prone to fear and Luddism. The disorder of thought extends into everyday life: cell phones and electromagnetic fields causing brain cancer, organic produce being superior and healthier than conventional, therapeutic touch and manipulation of the aura become equivalent to induction of anesthesia and monitoring of the EEG.

To counter this problem, we need to focus on education of our residents, our peers, the lay public, and policy makers. Each of these groups has its specific challenges and requirements. The first, our residents, are the easiest. We control the curriculum. To this end, John Doyle is creating resources on the web for education, for use by all of us.

The second, our peers, is more difficult. We can educate each other at the meeting, via the list serv, email, and personal exchanges. But a large gap exists between us as STA members and the anesthesiologists at large in the community. I would suggest that each of us as members act as a technological liaison officer between the STA organization and the larger group practice. Additionally, I would ask that all anesthesia departments, both academic and private practice, send a member to the STA on a yearly basis. As a next step, I am active in the state medical society and act as a conduit for technological information to the rest of the physician community. I encourage more technophiles to become active in the larger community of medicine to prevent misunderstandings from happening. (I’m afraid it is too late in some states like California, where proposition 65 means that all plumbing fixtures are labeled as hazardous because there are trace amounts of lead and other metals in them.) [See Page 3: “Panel Finds No Proof That Phthalates Harm Infant reproductive Systems”].

Manufacturers also can contribute. Most commercial medical device websites seem to have been designed by their public relations and advertising departments without any input from the engineers that actually created the product. I feel that every website from every medical company should contain links to each and every manual available, as well as the background of the operating principles of the device. Peter Schrieber of North American Drager was exemplary in this regard in his readily available “Operating Principles of the Narkomed Anesthesia Systems”. Ohmeda also had a book entitled “The Anesthesia Machine: Essentials for Understanding by Bowie and Huffman. No current manual on the operating principles of the newest generation of machines exist (to my knowledge).

Education of the lay public is an ongoing process. The ASA has public information available on-line and in booklets. We can interact with all of our patients and their families in the perioperative setting to make certain they understand the pertinent aspects of the technology we are using. Most importantly, the lay public needs to understand that the technology is not “magic”; that all technology can give false information; that our clinical judgment interacts with the monitoring and therapeutic technologies to deliver care.

Lastly, even getting an audience with policy makers is not easy. Once granted an audience, I find myself perplexed by the different logic structure used by people in politics. The question is not “is this a good idea/product/plan?” but “Who would vote for or against it, and why?” Decisions in the political arena are not based upon an investigation of the facts, but by a simple majority vote. Hence, items like the fear of DEHP in plastics, can become matters of law, without substantive data or a contemplation of the costs and risks of the alternatives, merely because no one wants to be seen as being for the increased or continued use of plastics and other non-renewable resources.

Thank you for providing me with this forum. Now let’s get back to work.

Sincerely,
The Editor
Panel Finds No Proof That Phthalates Harm Infant Reproductive Systems

An expert panel convened by the U.S. government has thrown cold water on a widely publicized study suggesting that hormone-like chemicals in consumer products are warping the reproductive systems of baby boys. Although animal studies raise concerns about infant exposure to these chemicals, known as phthalates, there is no solid human evidence that they are harming babies, the panel concluded last week after a 2.5-day meeting.

The panel, organized by the National Toxicology Program (NTP), put the burden of proof back on those who attribute harm to these so-called disruptors, calling the studies “inadequate,” as the panel’s report states.

The phthalate review, organized by the National Toxicology Program (NTP), puts the burden of proof back on those who attribute harm to these so-called disruptors, calling the studies “inadequate,” as the panel’s report states.

Vulnerable. Babies undergoing medical procedures may be at risk of effects from hormone-like chemicals called phthalates.

The NTP panel did find that Swan’s study broke new ground: It recommends repeating the work with a larger sample size. Swan says she’s in the middle of that, Bockelheide says others too will be looking at AGD, which he calls an “exciting” potential measure of endocrine effects in babies. “It’s the kind of study we need to have more of,” he says.

NATIONAL INSTITUTES OF HEALTH

NIH Aims to Create ‘Homes’ for Clinical Science

Elias Zerhouni’s mantra since taking the helm of the National Institutes of Health (NIH) 3 years ago has been “translational research”—meaning he wants to find better ways to move basic discoveries into the clinic. Last week, Zerhouni unveiled perhaps his most radical proposal yet for achieving that goal. As he explained in a commentary in the 15 October New England Journal of Medicine, NIH plans to create academic “homes” for clinical and translational science over the next 7 years and establish “a new... academic discipline.”

Research institutions are reeling with both excitement and anxiety. “It’s really long overdue,” says William Crowley, director of clinical research at Harvard’s Massachusetts General Hospital in Boston. One worry, however, is that by mandating such medically oriented homes, NIH will force institutions to train off clinical researchers instead of bringing them together with basic scientists. “The danger is separation. Many believe clinical and translational research should be part of the fabric of the whole institution,” says Howard Dickler, director of the research division of the Association of American Medical Colleges.

NIH says inclusion is the goal of the new plan, part of Zerhouni’s Roadmap, initiatives that pool money from all 27 NIH institutes and centers for common projects. The problem it addresses, notes Crowley, is that there are too few new clinical scientists in...
STA Meeting in San Diego

Board Meeting

Every table had a power strip

CIA Meeting

Keynote Speakers

Kirk Shelley Introduction
Ted Stanley spoke on his history
Dwayne Westenskow gave four examples of development

Lunch Meeting Speaker on “New Orleans Ghosts”

Dawn Applegate
Various funding avenues available
- including DOD and NASA
### Abstract Winners

<table>
<thead>
<tr>
<th>Excellence in Technology Innovation</th>
<th>&quot;Using PPG Morphology to Detect Blood Sequestration&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stephen P. Linder, PhD; Department of Computer Science, Thayer School of Engineering, Dartmouth College</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical Application of Technology</th>
<th>&quot;New Pulse Oximeter Measures Carboxyhemoglobin Levels in Human Volunteers&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steven J. Barker, PhD, MD; Department of Anesthesiology, University of Arizona</td>
<td></td>
</tr>
</tbody>
</table>

---

### Education Committee
- is moving forward on the creation of a web-repository of educational resources and links. Stay tuned for additions.
- Visit their website: [http://staeducation.homestead.com](http://staeducation.homestead.com)

---

### Kirk Shelley mentioned on Medgadget.com
“Kirk Shelley, an anesthesiologist at Yale University, has devised a way to noninvasively measure blood loss using a pulse oximeter.”

---

### Other Great Anesthesia Links:
- The Anesthesia Machine: [http://www.clinicalwindow.net](http://www.clinicalwindow.net)
- Medgadget: [http://www.medgadget.com](http://www.medgadget.com)
- Jim Philip’s STA photo archive: [http://www.anestech.org/meetings_staanualpostpics.htm](http://www.anestech.org/meetings_staanualpostpics.htm)

---

### Julian Goldman creates blog for Discussion of STA Issues
- This is in addition to the initiation of a listserv by Butch Loeb: [STAMEMBERS@listserv.arizona.edu](mailto:STAMEMBERS@listserv.arizona.edu)
  - (instructions located on the web at: [http://www.anestech.org/listserv.htm](http://www.anestech.org/listserv.htm))

---

### CONGRATULATIONS

Jeff Feldman was elected new **Section Editor** of the A & A Technology Section. He succeeds Steve Barker. The board interviewed 4 candidates for this position and elected Jeff.
- Congratulations and Good Luck !!!
**Update on the Virtual Anesthesia Machine Project:**

**APSF/UF transparent reality simulation of the 1993 FDA anesthesia machine pre-use check**

Sem Lampotang, Ph.D.
University of Florida

A study involving close to 900,000 patients in the Netherlands indicated that performance of the anesthesia machine pre-use check significantly reduced the risk of 24-h severe postoperative morbidity and mortality (Anesthesiology 2005, 102:257-68). Yet, preliminary results from a worldwide anonymous survey conducted over the web indicate that only 1 in 5 anesthesia providers performs an anesthesia machine pre-use check before every case (Anesthesiology 2005, 103:A1195).

To address the need for education and training, a transparent reality simulation (Educational Technology, Vol. 46, No. 1, 55:59, 2006) of the 1993 Food & Drug Administration anesthesia machine pre-use check has been completed with a research grant from the US Anesthesia Patient Safety Foundation and an award from IBM and is now available free of charge to everyone (after registration which is also free) at http://vam.anest.ufl.edu/members/preusecheck/curriculumtrack.php.

In a preliminary evaluation of the simulation, a majority of users indicated in a survey that they learned something new and that the simulation was realistic and will cause them to perform the pre-use check more regularly, more accurately and quicker.

The simulation was implemented as a set of simulation learning objects with content, practice and assessment components so that different national and regional checklists can be simulated by re-using and re-arranging tests common to the FDA pre-use check. Different anesthesia machine pre-use check guidelines from various countries can be viewed at http://vam.anest.ufl.edu/guidelines.html. The simulation helped to initiate the drafting of a Korean anesthesia machine pre-use checklist at Seoul National University by a team led by Dr. Wonsik Ahn, an STA member and an active contributor to the international VAM network. Translation of the simulation to Chinese, Japanese and Korean is underway. We invite volunteers from other countries to help translate the simulation into other languages.

James Szocik, MD
STA Member at Large

Regarding RESOLUTION 34-05A (DEHP (DiEthylHexyl Phthalate) Misplaced Trust) and RESOLUTION 35-05A (Reverse Onus in the Manufacture and Use of Chemicals) encompassing the following resolves:

1. RESOLVED: That MSMS work with the Michigan Hospital Association to make all health care hospital facilities free from DiEthylHexyl Phthalate (DEHP) within a short period of time.

2. RESOLVED: That MSMS urge the state of Michigan to adopt and advocate policies that prevent avoidable harm to the environment and human health by placing the burden of proof beyond a reasonable doubt for the safety of chemicals on those manufacturing, handling, importing or proposing to introduce into commerce such chemicals prior to their use; and be it further

3. RESOLVED: That MSMS urge the state of Michigan to adopt and advocate policies based on the precautionary principle, which holds that when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically. The burden of proof should be on the user or producer of a hazardous chemical or product to convince government authorities, beyond a reasonable doubt, that the product does not deserve to be restricted and that it is the least-damaging alternative available; and be it further

4. RESOLVED: That MSMS urge private parties that are manufacturing, handling, importing, or proposing to introduce into commerce chemicals that may be hazardous to human health or the environment to take such steps and otherwise observe such precautions as are needed to prevent or minimize damage to human health or the environment. These parties should carefully investigate the composition of the product and its properties from the perspective of health and environmental protection. The products shall be clearly labeled with data of importance from the point of view of protecting health and the environment; and be it further

5. RESOLVED: That MSMS urge the state of Michigan to adopt policies discouraging use of substances that are persistent and liable to bioaccumulate, and advocate adoption of federal laws and polices that ban the use of such substances.

I will provide commentary for the board to evaluate my conclusions that these resolutions should NOT be adopted.

Any attempt to impart information on the issue at hand must begin with background data followed by a discussion of the risks and benefits of various approaches.

**Background:**

Poly-vinyl chloride (PVC) plastics are nearly ubiquitous in the healthcare environment. The softeners, which make the PVC malleable for IV bags, tubing, ETT etc, are not chemically bound to the equipment. In particular, very small amounts of DEHP (Diethylhexyl phthalate) can leach out, especially with prolonged contact, high temperatures, and contact with lipids. Given the track history of such compounds as mercury, dioxin, DDT, etc. if a potential hazard exists, and then the Precautionary Principle states that in the absence of definitive evidence of...
RESOLUTION 34-05A DEHP
An Open Letter to the MSMS Board of Directors (Cont. from page 6)

safety, we should not use these substances for fear of long-term effects on individuals and the environment.

Benefits:
The history of plastics. PVC plastics have several characteristics that make them useful in a medical environment. They have replaced older materials by being superior in many ways. Glass IV bottles are heavy, breakable, unable to administer large volumes quickly under pressure, and need venting—creating a hazard for fatal air embolization. Red rubber endotracheal tubes contain latex, a known allergen precipitating potentially fatal anaphylaxis in some patients. Additionally, because the material is not transparent, a fatal obstruction can develop undetected by visual inspection. PVC also has uses that other modern materials cannot replicate. PVC tubes can bend without kinking, a feature not found in polyethylene, as well as having a greater transparency. Polycarbonates are clear and durable, but not flexible. Silicone based laryngeal mask airways are 20 times more expensive. PVC products can be made inexpensively and disposable to avoid the hazards associated with cleaning, sterilization and potentially fatal cross-contamination.

Risks:
Several studies have been done looking at DEHP exposures in animals and humans, under medical and non-medical circumstances. The potential risks include direct toxicity, carcinogenesis and reproductive toxicity. Since plastics are not limited to the medical environment, humans are exposed to DEHP in daily living. (3-30 mcg/kg/day, REF NTP Center for the Evaluation of Risks to Human Reproduction report http://cerhr.niehs.nih.gov http://cerhr.niehs.nih.gov/news/phthalates/DEHP-final.pdf). Medical treatments can increase the exposure level significantly, depending on the treatment (Trauma patients can be exposed to 8.5 mg/kg/day ref. NTP center report and http://www.fda.gov/cdrh/ost/dehp-pvc.pdf). No known human outcome studies are available, for any toxicity of DEHP. Therefore, human toxicity is extrapolated from animal data. The animal data can be summarized as follows: At very high daily doses, 1. reproductive effects were observed in male rats, 2. Cancer in rats, 3. no effect in primates. The relevance of animal studies are limited because metabolic pathway are different between rodents and humans. Therefore, regulatory agencies set levels for humans that are lower than the No Observed Adverse Effect Level in animal studies to provide a large margin of safety using 3 “uncertainty factors”. For most medical procedures humans are not exposed to levels even close to those considered even potentially hazardous. The exceptions are in massive trauma, exchange transfusions, and ECMO (Extra-corporeal membrane oxygenation), http://www.fda.gov/cdrh/ost/dehp-pvc.pdf.

To summarize the range of opinions about the toxicity of DEHP, I quote:

The divergent opinions on the safety of DEHP are due, in part, to differences in the interpretation of the scientific data and, in part, to differences in philosophical approach toward safety. Industry, in part, points to the lack of effects observed in DEHP-exposed patients as evidence of the safety of DEHP, along with data that suggest that the mechanism by which DEHP exerts certain effects in rodents is not applicable to humans. In contrast, groups such as HCWH (Health Care without Harm) embrace a precautionary approach that argues that patient exposure to DEHP should be minimized in light of adverse effects seen in experimental animals exposed to DEHP.


As a physician I agree with the more balanced approach taken by the FDA (referring to medical procedures having the highest risk of exposure to DEHP) stating:

“Most importantly, you should not avoid the procedures cited above simply because of the possibility of health risks associated with DEHP exposure. The risk of not doing a needed procedure is far greater than the risk associated with exposure to DEHP.” http://www.fda.gov/cdrh/safety/dehp.html

So is DEHP safe or not? Relative Risk Examples:

Medical care involves balancing risks. Every procedure taken, every test ordered, every action not taken, entails a potential complication, a potential false-positive or false-negative, a missed diagnosis or treatment. Some choices involve risks of greater or lesser magnitude. Where do DEHP and plastics fit on a risk scale? I was unable to find any clear relative risk data specifically regarding humans and DEHP. However, there are multiple other carcinogenic substances for which data is available. If we assume, that for a risk to be defined numerically it must be greater than one that is unmeasureable, we can use exposure to aflatoxin as a prudent example. Most people are unaware that peanuts are inevitably contaminated by a fungal toxin, aflatoxin. This toxin causes liver cancer in both animals and humans. The FDA has set an allowable level of this unavoidable carcinogen in peanuts at 20 mcg/kg (0.5 mcg/kg in milk) (ref http://www.cfsan.fda.gov/~comm/cp07002.html) Note to board: this data directly contradicts a statement made before the house that aflatoxin is not allowed in peanuts. The magnitude of this risk is such that eating 40 tablespoons of peanut butter increases one’s risk of dying by an estimated 1 in 1 million. (ref Wilson, Richard. Technology Review, February 1979, p.45). Are the groups fighting against the use of DEHP in medical devices willing to ban peanut butter as being a greater risk? I think not….

Risks and Costs:

Risks are unavoidable, but should be minimized. The cost associated with minimizing the risk increases dramatically as the risk is lowered, ie to lower a risk to zero entails infinite cost. A higher cost diverts resources from
more cost-effective areas. To quote Bruce Ames, professor of Biochemistry & Molecular Biology, Director National Institute of Environmental Health Sciences at University of California at Berkeley, “If you push in the wrong direction, then you're counterproductive. If we are spending $125 billion a year on EPA regulation, and it's not effective, that kills people, because it diverts resources from important things…” (ref http://reason.com/amesint.shtml) The money spent on eliminating DEHP would be better spent saving lives in other medical arenas.

**The Precautionary Principle:**

As stated in the resolve at the beginning of this letter the precautionary principle holds that when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically. The burden of proof should be on the user or producer of a hazardous chemical or product to convince government authorities, beyond a reasonable doubt, that the product does not deserve to be restricted and that it is the least-damaging alternative available.

There are several logical and scientific problems with the construct of the precautionary principle. Rather than proceeding on evidence, the precautionary principle impels us to action on LACK of evidence. This leads us to a tautology, since we can never prove a negative (no material can be proven safe, only safe to a relative degree). Science in general proceeds on the basis of positive, reproducible findings that are falsifiable. In contrast, the precautionary principle requires a negative proof which is impossible to ascertain.

To solidify the tautology involved in the precautionary principle, if we were to apply the same standards to products proposed as replacements to DEHP, we find that we cannot prove them to be safer or as efficacious as the current ones.

**Summary—Analysis**

Human beings are exposed to DHEP from PVC in multiple environments, including health care delivery. The risks are extremely low, and the risks from the alternatives are much higher. We should act to maintain the availability of any and all materials that are cost-effective in health care delivery. To adopt the precautionary principle will cripple health care and further worsen the financial crisis medicine is in today. It is imprudent and socially irresponsible to focus on extremely expensive measures of dubious benefit when the monies could be directed towards well-known beneficial medical interventions.

**Editorial:**

Health Care without Harm is an offshoot of Greenpeace and other extremist groups. Because they have had success on issues like mercury, a chemical that can be easily and cost-effectively eliminated from the health care environment, they have continued on, citing their prior success. But this is a logical fallacy. Just because a group was successful on one issue does not imply anything about the validity of its arguments regarding another issue.

Such groups pursue a slippery slope course of logic. If a substance cannot be proven a carcinogen, then they attempt to classify it as a reproductive toxin, if not a reproductive toxin, then an endocrine disruptor, if not an endocrine disruptor; then it induces miscarriages, then subtle neurologic findings; there will always be some question of safety left unanswered…each with a lower standard for causing harm.

As evidence of this I cite a report of Proposition 65 in California:

In Oct. 2003, California added DEHP to list of known reproductive toxicants regulated under Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986). Manufacturers have 1 yr to label affected products to be sold in CA as containing a reproductive poison. As of June 2004, the level of DEHP that is deemed toxic is still being worked out per OEHHA (Office of Environmental Health Hazard Assessment). Neither the federal government nor any other state has acted against DEHP. Specifically, it is now listed under Prop 65 as causing "developmental and male reproductive toxicity." Four other phthalates that are also under consideration for listing are: BBP, BDP, DnHP and DIDP (for causing combinations of developmental toxicity, male reproductive toxicity, & female reproductive toxicity). Note that DEHP was previously listed as a carcinogen under Prop 65 but was removed from list of human carcinogens in 2000 as a consequence of the decision in Baxter Healthcare Corp. vs. Denton that DEHP poses no risk of cancer to humans. (OEHHA had argued unsuccessfully that Baxter Healthcare, a supplier of DEHP-containing medical devices, had not shown any human risk). http://www.earthresource.org/campaigns/capp/california-regulations.html

Some manufacturers are creating low DHEP products to placate the activists demands, anticipating legislation that will create a need for such products and fearful of being regulated out of the market. Such an approach is self-defeating, like feeding an alligator in the hopes that it will eat you last. The belief of these activists is summarized as follows:

“PVC is a poisonous plastic—replacing phthalates won’t solve the problem.”


The goal of these groups is the elimination of modern materials from healthcare and the world and a return to their (Cont. on page 9)
The Society
The Society for Technology in Anesthesia is an international organization of approximately 175 physicians, engineers, students and others with an interest in anesthesia-related technologies. Membership is open to all who are interested. The journal, Anesthesia & Analgesia is STA’s official publication. An intermittent newsletter, Interface, is published and available on-line.