

# A Group Discussion: What's Ahead for Medical Technology Innovation and Use

Ronald S. Newbower, Moderator

*Editor's note: On Oct 31, 2007, several experts in medical technology participated in a roundtable conference call to discuss the future of medical technology. An edited transcript of the discussion follows. As moderator, Ronald S. Newbower both asked questions and participated in the discussion. His questions appear below as bold italics; his comments do not.*

***Ron Newbower: What are the big picture issues that will drive technology in the future or in a sense filter the winners from the losers? How can technology help in healthcare, by being cost effective and increasing patient safety in a risk adverse society, not just by facilitating more reimbursable procedures?***

***Thomas Skorup:*** Over the last 40 years we've learned how to measure, monitor, and image the body. In the future we will move those technologies from the organ level to the molecular level. The trend is toward more personalized care, with private rooms and genetic

testing in its various pieces. With the baby boomers moving into retirement, we'll be adding more patients into the healthcare system and have fewer people to deliver that healthcare. The successful technologies will support efficient, safer care. And I think it's going to be a much more capable marketplace in the next couple of decades.

***Kimber Richter:*** Home healthcare is going to become a big issue and the products that can fill that need will succeed. We will see software integrated into all kinds of products helping to make that happen.

***Jeff Cooper:*** Home healthcare will be a key driver of technology changes. I think consumers in this country and in the developing world will also drive changes. We're going to see different kinds of technology that will surprise us and drive a lot of what we do. Changes will focus at the "low end" of technology for reasons of cost

## Participants

**Ronald S. Newbower, PhD** is co-founder of, and chief technology officer with, the Center for Integration of Medicine and Innovative Technology (CIMIT), a consortium founded by Massachusetts General Hospital (MGH), Brigham & Women's Hospital, and the Massachusetts Institute of



Technology. The group strives to bring technologists and clinicians together to innovate in ways that make positive impacts in healthcare with medical technologies. His personal research over his career with MGH has ranged from minimally invasive physiologic sensors, to the influence of and reduction of human error in anesthesia, to the implementation of truly integrated monitoring systems for acute care. He founded MGH's department of biomedical engineering, and subsequently served as senior vice president for research for MGH for 15 years, overseeing the largest hospital-based research program in the country.

**Jeffrey B. Cooper, PhD** is the director of biomedical engineering for Partners Healthcare, an integrated health system located in Boston founded by Brigham & Women's Hospital and Massachusetts General Hospital. He is also executive director of the Center for Medical Simulation and professor of anesthesia at Harvard Medical School. He led the teams that conducted one of the first studies of errors in medicine and developed one of the first micro-processor-based medical devices, an electronic anesthesia system. He is currently most interested in organizing for the evolving convergence of biomedical and information technologies.



**Bryanne Patail** is a biomedical engineer with the VA National Center for Patient Safety, which was established in 1999 to develop and nurture a culture of safety throughout the Veterans Health Administration. He has di-



and, in the United States, because of the way insurance reimbursement is working.

**Jeff Secunda:** Remote monitoring is a key technology for the future and it is already being implemented. It cuts across all the issues that we've talked about: an aging population, different locations for healthcare delivery, and controlling the cost of healthcare delivery. We see this trend already in monitoring of cardiac devices—pacemakers and implantable cardioverter defibrillators—via phone lines or the internet. We see it in telemedicine applications being used in military settings and in rural healthcare. Policymakers need to recognize remote monitoring as something better for the public: for their health, and as a more cost effective way of delivering healthcare.

**Bryanne Patail:** The clinical engineering profession was created because of safety reasons—the electrical safety scare of the late 1960s. The pendulum has swung and now, some clinical engineers are relegated to be just repairmen. I think we need to push the pendulum back toward clinical engineers working hand in hand in the clinical environment with clinicians, safety managers,

and risk managers.

AAMI also has a role to play in this future. AAMI should continue to do what it's good at, developing quality consensus standards with the multidisciplinary members we have, and cultivating more interest from clinicians to join AAMI. The tried and true “gold standard” in the development of consensus standards for medical devices and technologies will continue to be in demand in the future as new innovative technologies are introduced into the marketplace. For example, nanotechnologies show much promise in diagnosis and treatment, but the risks associated with these technologies will eventually require some kind of standard to protect the patients and healthcare workers. Similarly, new applications of voice recognition in healthcare will need standards to ensure that devices will “fail to safe” when unrecognized commands, voices, and noises are made in the vicinity.

**Newbower:** *If the paradigm for monitoring chronic health conditions like, for example, high blood pressure or diabetes, shifts away from episodic monitoring via doctor visits and toward continuous remote monitoring, who's going to deal with that huge influx of new data? How can it be managed, and how can technology help?*

rected clinical engineering programs at large healthcare institutions, including William Beaumont Hospital in Michigan, and now works on prospective and retrospective risk assessment for the VA's 153 hospitals.

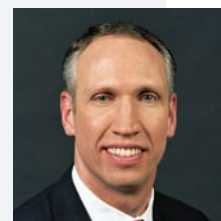
**Kimber Richter, MD** of FDA is deputy director for medical affairs within the Center for Devices and Radiological Health's Office of Compliance. She has a background working in the medical device industry for a number of years doing both regulatory and clinical product safety work. She has been with FDA for 12 years working in pre-market approvals and in the post-market arena, on the compliance safety side of medical device regulation. She also serves on AAMI's Board of Directors.

**Jeff Secunda** is an associate vice president of technology & regulatory affairs for the Advanced Medical Technology Association (AdvaMed) in Washington, DC, representing manufacturers of medical devices, diagnostic products, and medical



information systems. Secunda was vice president of research and development for a medical sensor firm in Texas from 1996 to 2003. Secunda has more than 20 years' experience in clinical and biomedical engineering, including positions at Massachusetts General Hospital and Children's Hospital in Boston, where he founded and directed the department of biomedical engineering from 1982 to 1995. Secunda was an adjunct assistant professor of biomedical engineering at the Boston University School of Engineering.

**Thomas Skorup** is the vice president for applied solutions for ECRI Institute, a non-profit organization focused on researching best approaches to improving patient care. His background is in biomedical engineering and healthcare administration. For more than 20 years, he has worked closely with hospitals, health systems and ministries of health to forecast, plan, and manage the unique challenges that healthcare technology poses to healthcare service delivery.



**Secunda:** Right now, healthcare providers get a very limited snapshot of critical physiological parameters. Remote monitoring allows potentially continuous monitoring that will give a more complete picture of what's happening. Ultimately the physician will be using software tools to aggregate, trend, and analyze the information generated by remote monitoring devices.

**Richter:** It might not even always be physicians. You might see other members of the office staff involved, especially as the technology becomes customary, simplified and user-friendly. The nurse or even another individual in the office could be printing the data out, doing summaries, or pulling out key information over time. It will become routine practice.

**Patail:** The systems themselves could accept that influx of data, sort out those that have violated preset parameters outside the normal range, and call your attention to the relevant information. People used to have to look at that data and decide how to react. Now there are smart systems that can call out the abnormal data for you, sorting the great influx of normal data away from the abnormal data.

**Skorup:** This issue also highlights the changing role of the hospital in the healthcare system. Who will be the keeper of this information? Hybrid players are starting to emerge. Hospitals are diversifying into home care and other areas. We're also seeing continuing care providers playing a much stronger role, and we're increasingly talking to them about this telemedicine technology and applications.

**Cooper:** It may evolve that care is increasingly provided at the less complex level, rather than through physicians or nurses. In many domains—from psychiatrists to psychologists and social workers, from ophthalmologists to optometrists and opticians—the provider of care is moving away from the need for high training because the technologies are smarter and it's easier and possible to do things more safely.

Of course the same thing is happening with patients as well. We're all taking care of ourselves in ways that people didn't think possible 40 years ago, taking our own blood pressure, and administering our own at-home tests.

Home care givers now do many things that used to be done in a hospital setting. That whole sector really needs to be nurtured—more and more people are being cared for at home and those people who are caring for them will

also need a certain level of training, but more importantly access to the information to do just-in-time training.

Technology has a huge role to play here in making things simple, easy and safe.

**Newbower:** *Will the current culture of healthcare make it so difficult to make these changes within the current framework that a disruptive business model will arise? We're already seeing retail medical clinics where the convenience is far greater than driving to an emergency room and the cost is not much greater than what co-pays have risen to.*

**Cooper:** I was in the airport the other day and they were selling flu shots for \$35. Compared to getting an appointment at your primary care physician, driving downtown, and paying for parking and a \$20 co-payment, it's a good option.

**Skorup:** I think this is just the beginning on the screening end. I think this trend will continue with mammograms, various blood tests. You can go online today and order genetic tests as a consumer. Screening is the beginning piece; it's an easy place to put your big toe in the water. However, it's a big step to go from there to primary care.

**Secunda:** I think it's all well and good to talk about providing care at retail locations, but there's a huge cost associated with the last year of life. That type of care is going to keep hospitals very much in business, unless there are major cultural changes. The heroic, agonizing last few months of care in the intensive care unit is a huge consumer of resources. We need to direct medical technology toward improving the quality and reducing the costs of those last few months.

**Newbower:** *Will the hospitals specialize in the more sophisticated areas of care, taking the high end of the healthcare business while the low end is delivered in more convenient, less sophisticated environments?*

**Patail:** I doubt that. Hospitals are beginning to realize that they are in the healthcare business and not just in the hospital business. They are already moving to get involved with wellness care. In some cases they are contracted to take care of a population based on the number of lives they are taking care of and how well they want to keep them. These types of incentives will keep them involved in the whole continuum of care, not just taking care of acute patients.

**Skorup:** We're already seeing some of what I'll call a more virtual hospital model where hospitals are going to the patients through satellite medical centers as an effort to align their services closer to the patient. Hospitals will begin to triage the patient to see if they can effectively be treated in a lower acuity care setting.

**Cooper:** I wonder if the trend will continue toward hospitals helping patients to die more gracefully and not demanding that heroic care be continued. There won't be that expectation of spending all of that effort in the last six months because society will take a shift away from there.

**Richter:** Hospitals are beginning to offer this type of care. I just had a family member go through this situation and the hospital that she was in had a palliation team that deals with patients who aren't going to get better. Within two days of the time she was hospitalized, they moved her to an inpatient hospice situation where the facilities are nicer and oriented toward family visitation. The care there is very different. I think this trend will be increasing.

At the same time you're also going to need the high tech, high-urgency trauma interventions for car accidents and other emergencies. I think you're going to end up with two different kinds of care and two different teams of healthcare givers.

**Newbower:** *Perhaps hospitals can work to avoid spending a lot of money in the fruitless extension of low-quality end-of-life, but can provide more compassionate care. What devices and systems can make it easier to shift such patients into more appropriate venues? Is this another area of opportunity?*

**Skorup:** Yes, I think it is. One of the key things technology can do is help us to better identify when we may have reached that end-of-life stage. We need more clarity in making those decisions.

As an example, a few years ago, we were looking at using bone marrow transplants to treat for metastatic breast cancer. The evidence eventually showed that going to that heroic measure was actually shortening life span and diminishing quality of life. We need more clarity to understand which technologies provide benefits and which do harm. I think we will have a better understanding of that in the future. If patients are given better information about their likely

outcomes, they may have an easier time moving into a palliative care unit sooner.

**Secunda:** Objectivity is well and good but we are a nation of different cultures. Responses to end-of-life situations are very culturally based. There are some who will say, "It doesn't matter if there's only another 10 minutes of life, I want heroics" and there are those who take a different approach. We will always be dealing with this issue on a cultural, emotional level as well as on an informational level.

**Newbower:** *What about the process of developing new products, bringing them to the public, and regulating them once they're on the market? What challenges will we be facing in the future?*

**Secunda:** The science of determining the safety and effectiveness of devices and monitoring devices once they're on the market is vital. Bringing new technologies to market is a very sensitive area, and the public does not have much tolerance for mistakes.

In a recent case, a medical device was pulled off the market because of apparent safety concerns. It now appears that this judgment was based on incomplete information. As more information became available the picture changed: things turned out to be better than expected.

The effects of decisions to pull products off the market are dramatic. Companies can become more risk adverse so that they're not willing to spend deep for innovation because of the potential for unforeseen transient events sinking their effort.

Congress set up the regulatory system to balance pre-market evaluations with postmarket surveillance. It's very important that we utilize that model. We need to adopt a robust system of collecting device experience and patient experience so that we can rely on more than just randomized clinical trials that can only provide a snapshot of real-world device performance.

**Richter:** I would agree with that. I think that we're running into difficulties when we get so enchanted with the new blockbuster technology that we don't necessarily take the steps to review it in the ordered way that we might do with a more standard sort of product. Then, when you get your first postmarket information about a problem, you're perhaps not prepared to put it in the context that you would with a product that you know better.

I think that the public still has great confidence in

medical device innovations. The devices are doing so many incredible things, offering so many advances to help patients with so many chronic and acute problems. That confidence remains despite problems that have been identified in specific device areas.

There's still a lot of excitement about what medical devices can bring to quality of life and patient care. We do need to find better ways identify problems before a device gets to market; to use the quality systems in different ways; and perhaps to handle these postmarket issues as they arise a little bit differently in the future.

**Secunda:** Historically, drugs and devices have been separate products and have been regulated differently. It is typically much easier to measure the direct action of a device. Now, with combination products like the drug eluting stent, the regulatory picture becomes less clear.

**Richter:** I think it may be easier to identify and correct problems with devices. If a different material is in use and is causing a problem, you can correct it. If a design change is causing a problem, you can correct it. If we identify something that's less than optimal, that can be intentionally changed. The next generation of a device can be created, tested, and shown to be better.

Drugs are rather different. Specific chemicals react in different people very differently. When a problem occurs, they don't have the same opportunities we might have with devices to design and test an improvement fairly quickly and continue to move the performance of these products forward. So yes, new types of regulation will be necessary for these combination products.

**Newbower:** *Is the nature of all this progress going to accentuate the divide between first-tier and third-tier medical care? What about those who do not have the time, skill, resources and inclination to manage home monitoring and home-based healthcare?*

**Cooper:** I think that technologies will be created for the "down-market," developing countries where people have fewer resources. For instance, there is an effort by an international organization to develop a really cheap oximeter and to put one in every operating room setting around the entire world.

However, I see that divide increasing. People who don't have access to the internet in particular are in dan-

ger of being left out of these advances. The only solution is making cheaper internet access available.

**Skorup:** I have worked in a lot of developing countries, in Africa, Asia, and some other places. I think the educational divide will strongly affect how people get their healthcare. The reality is that there is a sizeable gap. No level of investment in technology or healthcare is going to change that.

**Newbower:** With better designs, we can make the technology transparent to the user. My 97-year-old mother uses e-mail and a cell phone. She doesn't have a clue how any of those underlying technologies work, but they both have an accessible user interface. Both technologies have gotten to the point where they're just an appliance. Education is not the issue in using a telephone anymore. Perhaps that's another technology opportunity. With good enough designs and low enough cost, we can make the infrastructure transparent to the user.

**Newbower:** *Studies show that most patients do not comply with their treatment regimen, including medications and physical therapy. We go to great lengths to use tests and procedures to determine the proper regimen that patients often don't follow. How can technology help with that problem?*

**Secunda:** Remote monitoring has the potential to help in this area as well. Physiological parameters can provide evidence as to whether the patient is being compliant. A remote drug dispensing system has been developed that is programmed to unlock a medication compartment, call the patient to take their medication, record whether or not the patient took out the medication, and then report patient compliance information to the prescribing physician. That's a great example of where technology could even impact the behavior of patients.

**Cooper:** Yes, that's here and now. We can expect more of that reminder monitoring, getting people to do more of what they're supposed to do.

**Skorup:** Look at Microsoft Share Point technology in the workplace as an example of a workflow automation tool that provides programmable prompts and reminders. That could be a precursor to this type of proactive reminder for patients.

**Newbower:** *What about other patient-safety issues that are going on in hospitals now, like the refusal of Medicare to reimburse for treatment of hospital-acquired infections? How can technology help hospitals address those issues?*

**Secunda:** Devices are now being developed with modified materials that have been treated to deny pathogens a viable surface on which to flourish. Traditional and newer materials are being coated with antibiotic materials that prevent infectious organisms from traveling into the body along device surfaces.

**Patail:** Preventing patient falls is another tremendous opportunity where technology can improve patient safety. Within the VA, falls are the most common adverse events on which we've collected data over the past six or seven years. We have a tremendous opportunity to work with a systems approach to solving those problems. It's not glamorous, but it's in the mundane areas that clinical engineers can really contribute to solving those types of problems.

**Newbower:** *What are the drivers that will help encourage innovators, companies, and others to solve these problems? Is it just litigation? The cost of losses? Because if a patient falls and gets injured and it doesn't cost the system anything, there's no return on investment for whatever the technology might be that would help.*

**Patail:** In the VA, we've got a certain pot of money to deal with. The more money we save, the better off we are. We found that a hip fracture caused by a fall costs approximately \$20,000 to \$30,000. Mitigating falls at a reasonable price is better than paying for them after the fact. In this closed-loop system we incur the costs or the savings, the consequences of what we do.

**Newbower:** Recently, the Centers for Medicare and Medicaid Services (CMS) has begun refusing to pay for the treatment of certain hospital-acquired infections. This is another way of closing the loop, and forcing the hospital to incur the costs of adverse actions or inactions. The reimbursement system is giving adverse feedback for negative consequences. As more and more buyers of healthcare services adopt this approach—like different automotive groups and other groups that are huge buyers of healthcare like CMS—that will probably cause people to invest in solving those problems.

**Newbower:** *What public policy changes might be necessary to allow technology advances to address the societal needs we've been discussing?*

**Richter:** We talk about patients taking more responsibility and making more of their own decisions and learning things via the internet. At the same time, we also have pressure from very low risk tolerance. To move forward with some of these new paradigms, there's going to have to be some change in the physician malpractice situation. Doctors will need to be able to allow their patients to make more decisions and follow their own cultural preferences, without the doctors feeling that they're at substantial risk if they don't follow specific hierarchical procedures for testing and treating.

As we have patients more in control, some of their choices may not always be the ideal choice based on traditional medical hierarchies of care. I think there has to be some protection for the physicians to sort out how this is all going to work so that if patients choose certain things, it's not the physician's responsibility if the outcome is not positive.

**Newbower:** It may help if reimbursement policies change to make providers financially accountable for preventable consequences. Any policy change that rewards doing the right things and does not pay for doing the wrong things makes a lot of sense. Patients are bearing more of the personal cost for healthcare in this country and I think we're going to continue to see that influence the marketplace in a major way.

**Newbower:** *What technologies are needed to allow the patient to collaborate with healthcare givers in their care?*

**Skorup:** The shared electronic health record is a very powerful concept. The goal is to have one record that is the sole source of information per patient so there aren't stacks of paper in three different hospitals across the country that represent their experience. It's a key way to avoid many of the errors that are committed because of the incomplete picture of who the patient is and what they've been through in the past.

**Newbower:** Physicians can feel threatened about that loss of control of information and about the inundation of questions that may arise or confusion from shared re-

cords. But the result from not using them is that there are errors, errors that could have been corrected. For the shared medical record to really be accepted, we've got some cultural issues to deal with amongst providers.

**Newbower:** *What about the perceived or real influence of the cost of technology in healthcare?*

**Secunda:** Some people like to focus on the percentage of the gross domestic product that goes towards healthcare and how that is a bad trend. But looking at the question from another perspective, better health is what society wants. There will be discrepancies in how healthcare is delivered, whether you look at developing countries versus already developed countries, or regions within a country. It is the role of government and non-governmental agencies to smooth out those differences and to improve healthcare through better access to technology across the board for all economic situations.

**Newbower:** Technology is so often pointed to as the villain in healthcare costs. Yet, you're pointing out that the technology—for example, replacing arthritic knees allowing people to increase quality of life, implantable defibrillators to avert tragic sudden death or disability, and all of those new things that cost money—are not just about inflation. It's not just new technology driving up costs. It's about quality of life. If we're really going to get the full benefit of opportunities from new technologies, there is a public relations issue involved here of positioning technology more on the side of the angels than of the villains.

**Skorup:** In healthcare, we have to decide how we want to deliver care and then choose the right technologies to help to accelerate the ability to get to that point, rather than just embracing technology for the sake of the technology itself. The question when looking at new technologies is, "What value does it provide?" I believe that we're making better decisions today than we did even five or ten years ago, choosing what technologies are going to help us to provide better patient outcomes.

**Newbower:** In this country, classic reimbursement systems do not necessarily reward good choices. They reward those that are most profitable to the providers. Not that the providers in the past didn't have the best intent, but they literally couldn't survive unless they made money. The best

way to make money was to have a decent mix of high-margin procedures along with the money-losing practices of psychiatry and primary care. Somehow the system is going to have to change. Inherently healthcare delivery in this country is a long way from being a closed-loop economic system

**Secunda:** That's a really good point. While FDA regulations ensure safe and effective devices, CMS regulates which of those devices get paid for. The national health priorities, however, are somewhat vague. The Centers for Disease Control also gets involved with setting health priorities. We have to find better ways to cope with chronic medical conditions like diabetes, congestive heart failure, and asthma. These diseases affect millions of people and cost billions of dollars every year.

We need a national healthcare policy that promotes solutions to these problems. Technology can play a significant role in preventing and improving their treatment. We must promote appropriate incentives for development of such technologies.

**Patail:** Cultural change is necessary as well. People must move in some kind of progression to more healthy living, just as people have gradually accepted wearing seatbelts for their own safety. It has to reach the tipping point where consumers are demanding it. Today, consumers go out and look for safety features in their cars and almost every single car ad talks about safety features. It took 30 years for car safety to evolve, but there may be a metaphor there for healthcare that could happen faster.

**Newbower:** Building on the metaphor with car safety, who can be the leaders in making better choices? The VA, we've identified as one. CMS is another, and the private insurers refusing also to reimburse for preventable errors. They would create a market for improved technologies and help change cultural behaviors. AAMI can also play a role, as can the Agency for Healthcare Research and Quality.

I find it interesting that we've focused on this conversation on frontline basic issues that cut across the millions of people in daily healthcare and we haven't gone up market to talk about, for example, functional magnetic resonance imaging and what it might do for influencing healthcare. We all seem to be aware where the real action is: we've got some serious issues with frontline healthcare delivery. ■