

Moving Forward: What Role Should AAMI Play in the Future?

Michael J. Miller, Moderator

Editor's Note: On Oct 24, 2007, several leaders of the medical technology community representing different segments of AAMI's diverse membership participated in a roundtable conference call to discuss the future of medical technology and AAMI's role in that future. An edited transcript of the discussion follows. As moderator, Mike Miller both asked questions and participated in the discussion. His questions appear below as bold italics; his comments do not.

Mike Miller: What are the important challenges, opportunities, or problems that AAMI and its members will encounter in the future?

Kim Trautman: From a technology standpoint, one of the major challenges is going to be the trend toward combination products that integrate traditional medical devices with other types of products—pharmaceuticals, biologics, and nanotechnology. The rise of nanotechnology is going to present a host of new challenges. These new and combined technologies are going to require drastic shifts by regulators and industry around the globe. Right now, these issues arising from new technologies are being handled differently everywhere.

AAMI will also need to expand its membership beyond its current bases in the biomedical community and the medical device manufacturing community. If we are going to see expansion in nanotechnology and combination products, shared expertise in these areas will be essential to the development of standards. AAMI's membership will have to keep pace with it.

Outsourcing will be a major issue in the future, for both hospital-based technology managers and the manufacturing community. Once upon a time, a medical device was made in a single facility controlled by a single individual. That scenario is no longer valid. Now, there are many virtual companies, many service providers, and many people from both healthcare delivery institutions and manufacturing businesses that are outsourcing their operations. Controlling all this outsourcing has stretched the healthcare system almost to its limits, and I think

we're starting to see some failures from that stretching. I know that from a regulatory standpoint there will be—and from an educational standpoint there should be—emphasis on maintaining good quality products and services when your control over suppliers is becoming more limited and stretched across the globe.

Mike Scholla: I agree with Kim about the challenges we'll face from the emergence of these new technologies. I believe that there is going to be quite a battle over how nanotechnology and innovative combination devices are regulated and who does the regulating. From an AAMI perspective, it can be difficult to write standards for combination products because they vary so much.

I also think that there is going to be a continual push within hospitals to reduce their infection rates, especially because beginning October 2008, Medicare will no longer reimburse hospitals if certain preventable infections occur during a patient's stay. That begs the questions of what hurdles will that create, and how will they be handled by the entire healthcare system.

Ray Laxton: I'm going to focus on the technology management challenges that I see ahead. AAMI will have to answer the question of how to best support the field of technology management, which has historically been difficult to define.

Currently, technology management is undergoing one of the biggest evolutions that we've seen in our field with the integration of biomedical and information technologies (IT). This change creates a significant opportunity for AAMI to identify and share best practices of collaborative work between the two disciplines and to provide a leadership role in developing educational resources for both technology and IT managers.

I believe that AAMI must continue to provide technology managers with better information that they can in turn use in a practical manner to shape key decisions in healthcare institutions for better outcomes. AAMI should seek to identify ways that technology managers

Participants



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Vera Buffaloe is president at Buffaloe Consulting, Inc. in Arvada, CO. She has been a consultant to the medical device industry since 1993 and involved with AAMI's government education programs for 10 years. She also served as an industry representative on AAMI standards committees.

Ray Laxton is executive director of client services with ARAMARK Healthcare Management Services in St. Charles, MO. He is chair of AAMI's Technology Management Council, and serves on AAMI's Board of Directors and Executive Committee.



Alan Lipschultz is director of clinical engineering at Christiana Care Health Services in Delaware, a two-institution, 1,000-bed hospital system. He has been the AAMI representative to the National Fire Protection Agency's NFPA-99 Committee on Medical Equipment for almost 30 years and is currently chair of the committee. Within AAMI, Lipschultz has served on the Board of Directors, the Annual Conference, the Standards Board, and AAMI's Technology Management Council.



can more closely align their functions with key indicators that affect healthcare as a whole, such as reducing medical errors, reducing hospital acquired infections, improving patient satisfaction, and improving the retention of clinical staff.

AAMI must also recognize the fact that resources for technology managers are dwindling, which will continue to impact training. Education methods must be developed in a way to compensate for those restraints.

Alan Lipschultz: I'd say the major issue for us as biomedical technology managers in hospitals is just the sheer quantity of new "stuff" that's being developed and coming through the pipeline. The challenge is to keep on top of technology changes, so I can sometimes educate my clinicians and sometimes catch up with them. The challenge really comes down to managing the sheer volume of information that's available, filtering all the data on new technologies to determine what's important and therefore what should we be talking about. Five or ten years ago we would have just given up because we knew we couldn't manage the data, but now there are some better tools out there for dealing with it.

Ken Maddock: I think if you take a step backward, all the technology used within healthcare supports patient care,

not just medical equipment. We have to focus on being facilitators of new technology, rather than gatekeepers. As Alan asks, how do we keep track of new technologies, making sure we can understand which ones are the right ones and promote those technologies, finding ways to get those technologies through the pipeline faster? Safety issues are important, but not to the point where our focus turns more to preventing problems than improving the way we provide care. After all, our primary goal is make people better, not just to keep people safe.

Vera Buffaloe: I see globalization as a key issue for U.S. medical device manufacturers. U.S. manufacturers sell their products worldwide, and their growth opportunities are in other world areas, not just in the United States. Standards must be harmonized so that U.S. manufacturers won't have to comply with different standards for different countries. International harmonization of regulation and standards has been a major concern for the medical device industry. AAMI has done significant work in this area already, and I think that it will become even more important to AAMI's members in the future.

Tammy Pelnik: There will be ongoing challenges associated with developing and marketing regulated medical products around the world. For manufacturers, organi-



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Ken Maddock is corporate director of biomedical technology services for the Baylor Healthcare System in Dallas, TX, a 13-hospital system with 2,800 licensed beds. He is the current chair of the United States Certification Commission, a member of the *Biomedical Instrumentation & Technology* editorial board, and is on the Executive Committee of the Technology Management Council.



Tammy Pelnik is vice president at the St. Vrain Group, Inc., a consulting firm located in Boulder, CO. She has been a member of AAMI's government programs faculty since 1998. She is also the editor of the *Supplement to the Quality System Compendium*, published in 2004, and the second edition of the *Quality System Compendium*, published in 2007. In

addition, she has supported ongoing activities to ensure that AAMI's government programs courses continue to reflect the state of the industry.

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Mike Scholla is senior consultant with Dupont Nonwovens located in Wilmington, DE. He is Treasurer of AAMI and serves on several Board Committees including the Executive Committee, Finance, Investment, and AAMI Foundation. He is a member of the Standards Strategy Committee, Sterilization Sciences Committee, and numerous working groups. Mike is also convenor of ISO/TC 198 WG7, which is responsible for global medical packaging standards.



Kim Trautman is FDA's medical device quality systems expert in Rockville, MD. She is a member of ISO/TC 210, the International Organization for Standardization committee on quality management and corresponding general aspects for medical devices, both on the U.S. technical advisory group (TAG) and at the international level. AAMI holds the secretariat for TC 210. Trautman is also actively involved with AAMI's quality systems educational program.



zations like the Global Harmonization Task Force are helping to establish more universal regulatory expectations. Similarly, AAMI's standards development activities will continue to support establishment of broad-based expectations for product safety and performance. As more and more manufactures seek to develop and market combination products, AAMI can support this trend both from a standards and an educational perspective. Regulations for combination product manufacturing and marketing are in their infancy and vary widely around the world. AAMI could serve as an advocate for this expanding segment of the industry. This is an area where the various departments at AAMI could collaborate to ensure that standards are responding to industry trends, that education includes appropriate coverage of standards, and that AAMI is presenting an internally consistent "product line."

Further, technology advances will continue to drive medical products toward increased complexity and connectivity (e.g., telemedicine). The resulting products will

carry much greater risks as well as potentially improved performance. AAMI must support manufacturers and medical product users to capitalize on technology while ensuring appropriate patient risk. This support includes education and standards that address proactive safe product development practices.

Miller: *Where does AAMI fit into this new healthcare landscape?*

Miller: AAMI is exploring whether to take the content developed in its standards and other programs and turn them into self-assessment and benchmarking tools. This initiative has the potential to tie together AAMI's diverse lines of service—standards, education, and healthcare technology management—and serve both of its main membership groups—the manufacturing community and the hospital community. The goal is to establish metrics and tie them to positive clinical outcomes.

Looking at AAMI's history you see that the indus-

try, FDA, and the healthcare community were motivated to write standards. Because they were willing to put time and effort and resources into it, they created a valuable body of knowledge. We then saw tremendous growth in AAMI's educational activity, building on this knowledge. We are now asking whether the logical next step is to take that body of knowledge and use it to build assessment and benchmarking tools so that the medical device community can use them in a constructive way toward producing safer and more effective products.

This effort has already begun in the quality systems area, where AAMI has taken its quality systems standards, worked with FDA to develop a *Compendium of Quality Systems Regulations and Industry Practices*, and used it to develop a successful education program. If AAMI provides members on a voluntary basis with a tool by which they can voluntarily benchmark and self-assess, this tool may enhance their ability to conform to FDA's regulations.

AAMI is also taking a serious look at how its other bodies of knowledge can be re-developed. For example, AAMI is already considering how technology management performance can be benchmarked through a shared database tool where hospital biomedical technology and clinical engineering departments could provide information on performance indicators. The accumulation of data voluntarily entered by a wide spectrum of participating hospitals would allow individual hospitals to measure their own performance or perhaps benchmark against other hospitals of similar size, location, resources, etc.

Leab Lough: The same type of web-based tool may serve the needs of medical device manufacturers to benchmark or self-assess in various functional areas such as quality systems, risk management, or sterilization. It would allow medical device companies to enter data anonymously. The more organizations that participate, the better the data would be, allowing companies to self-assess and to benchmark against the industry.

Trautman: AAMI is also designing a new part of its web site to focus on quality systems-related information called QS Connect (www.aami.org/qs). If the site becomes widely used, AAMI could develop a voluntary database for manufacturers to anonymously enter information about quality system performance, and a compendium of quality system information could result. It will depend,

of course, on how willing manufacturers will be to share that kind of data in an electronic format even if anonymous, but if successful, AAMI will have an opportunity to develop a new quality systems resource.

Maddock: In the area of technology management, I think you must focus on gathering data and sharing it before you try to set benchmarks. It's a trap to try to set standards or benchmarks without having that data. AAMI could be a location to start centralizing that data. Once you have the data, the benchmarks and standards are there. It's all in the data, you just have to carve it out.

The challenge we've always faced is, how do you get good data? If AAMI works to solve that particular problem, I think that would lead to a lot of other solutions.

Lipschultz: There have to be definitions on what kind of data do you want to collect. If I'm reporting apples and you're reporting oranges, we can't compare the data with any validity.

Maddock: I agree. When you're gathering data, you have to first get people to agree to some definitions. And you don't have to collect data from everyone, just enough of a sample to make it statistically significant.

Right now there's a lot of standard setting and benchmarking that's done in isolation without respect to whether you are really moving healthcare forward. The right data should show the connection between the things that a clinical engineering department does and positive clinical outcomes.

Buffaloe: AAMI is in the unique position of being able to bring together various perspectives from industry, clinical settings, biomedical technology professions, and FDA. AAMI has many years of experience in gathering information and consensus building through its standards committee activities. These data gathering tools we are discussing here really provide another way of integrating information from many different sources. Even though information tools are already on the market they often exist in "silos." AAMI has the ability to integrate many sources of knowledge and expertise in an effective and useful way.

Laxton: I like the idea of tying together the different aspects of AAMI and I believe we in the biomed field need to move in that direction as well. While we've long

focused on how we can achieve better productivity and how to better measure financial performance, it's time to focus more on how we can help hospitals improve the safe and effective use of medical technology to reduce medical errors and infection rates by integrating the biomed functions into a more participatory role in clinical practices. We are uniquely positioned with respect to time and technology to consolidate all three of the activities that AAMI undertakes and incorporate them into our practice as technology managers.

Maddock: We all want to help improve outcomes. That's why our functions exist. That's really what we're all doing, no matter which part of healthcare we touch.

Laxton: In the past, we have found it difficult to get senior hospital leadership to recognize the value that technology management brings to them. One reason is that we are such a small portion of their budget, even though we have a significant impact on a large portion of the institution's capital investments. I think that by tying our actions to their outcomes, we could get better recognition and become more valuable to the institution.

Pelnik: Continuing to support and establish new aspects of certification for the people who manage and maintain medical equipment at user facilities is critical. Having established a common body of knowledge, AAMI will need to ensure that its certification programs keep pace with the changing expectations of patient safety-focused medical practice.

Miller: *How much progress has been made and do you predict will be made toward the development of harmonized global medical devices regulations in the future? And how should AAMI's standards program change in the future?*

Trautman: We have success stories in harmonization of global regulations, and the quality systems requirements are probably the greatest success story from a fundamental requirements standpoint. Looking to the future, I don't see a lot of movement over the next five to 10 years. One goal would be for us as regulators to move toward a quality systems set of requirements for multiple commodities, to include devices, drugs, and biologics. ISO 9001, the generic quality systems standard, will be

coming out with a major revision that will probably be released in 2012 or 2013. This will undoubtedly move things forward.

As regulators, in the quality systems area, we've hit a pretty good mark. We still have a lot of work to do in terms of auditing techniques. There might be a need for some sort of certification in auditing, and that idea may grow in the next five to 10 years. We also have a lot of work to do as regulators in the area of harmonizing pre-market approvals of new devices. At this point, I'm not sure if there is a role for AAMI in the areas of auditing requirements or pre-approvals.

Miller: Some of AAMI's standards programs are facing challenges that are byproducts of its success. For example, one of AAMI's standards is being used as a mandatory standard by a government agency. The government agency is adopting the standard as it currently stands. Of course, standards quickly get out of date as new technologies are introduced. How standards are being used in the midst of rapidly changing technologies will be an ongoing challenge.

Another challenge is related to the fact that the standards are a very neutral frame of reference for education and discussion and there are limits on how AAMI can communicate or share the content of a standard. A Supreme Court decision has made standards developing organizations (SDOs) very careful about how they interpret standards. Very simply, an SDO can be held liable if problems arise from standard interpretations that it may have conveyed or communicated. Therefore, AAMI has had to take the position that, if we issue an interpretation, it must be an official one, as official as the standard.

AAMI staff often receives calls from its members who say "I don't understand the standard." In such cases, staff refers inquiries to committee chairs, who can provide some individual informal advice on the standard while taking caution not to provide an official interpretation.

We are now looking for a way to provide information on standards in an informal way without getting in trouble with the lawyers.

Pelnik: Continued collaboration with FDA is important. FDA's support and participation in the education program provides AAMI's membership with an opportunity to learn directly from regulators in a non-threatening environment. Better informed manufacturers should lead

to safer, more effective medical products. So ultimately the public health is served by AAMI's successful collaboration with FDA on the education program.

Miller: *What about the future of healthcare technology management? Will it become a defined function in hospitals, or do you see it becoming a distributed function throughout the hospital?*

Laxton: I don't know if we're ever going to reach consensus on a standardized name or even a common definition of what we do, and I don't know that those are the most important issues that we are facing. The functions of our roles are changing rapidly due to the nature of the technology that's being introduced into the healthcare environment and due to the changes in the healthcare environment itself. I think that's a good thing. Currently we are seeing those changes driving us to a more collaborative relationship between biomed and IT. I think those changes will also spur more communication and cooperation between biomed, clinical staff, and senior administration.

Maddock: I think that it's important for AAMI to promote a more global technology management function in hospitals. If we do that, then technology management will start to get the respect that it needs, which is important because it gives you the resources you need.

In many hospitals, there is inertia caused by people wanting to protect their territory and "silo" different activities. This approach leaves gaps in hospitals in which technology is only managed if it is specifically assigned to an existing silo—biomed, facilities, IT. A global technology management approach is needed to support and integrate all of these technologies that support patient care, and AAMI needs to help push it in that direction.

Miller: *There are many different models for how the biotechnology management function is handled in hospitals. One reason is that a "gold standard" does not yet exist for the biomedical technology management profession to push toward; plus, you'll always have differences mandated by hospital size, geography, etc. Would it be helpful for AAMI to put out a "gold standard" for the field?*

Maddock: I'm not so sure I completely agree with that.

A community hospital is not normally going to be in the same place technology-wise that a large academic medical center is going to be in because of the nature of their mission. I think because of that—and because of politics, because of economics and a lot of the different things that impact each institution—you're going to have different levels of support being provided. I think that AAMI should provide tools that best meet hospitals' needs depending upon where they're at in that particular spectrum. But you could still establish one overarching set of principles.

Laxton: Biomed departments can now report up to senior administration, materials managers, plant operations, and IT. Even if we created this overarching structure, and everyone said that's the gold standard, I don't think we would get there because of the other elements that are difficult to overcome. I agree that we need to look at the spectrum, say here are tools that can help you in different positions on that spectrum, and we need to develop access to those maybe through e-communities. We also need to develop more distance learning opportunities for people that cover a broad range of needs. ■

From AAMI's 2007 Strategic Plan

Several new initiatives were presented to the AAMI Board of Directors at its November 2007 meeting. Among them:

1. A study evaluating the status of healthcare technology management and its likely and desired direction.
2. An evaluation of a new service offered by a vendor that would take existing bodies of knowledge and convert them to self-evaluation, assessment, and benchmarking tools.
3. Testing new sales and operating approaches to standards with other countries.
4. Collaborations with other U.S. standards development organizations on international standards and sales
5. Utilization of new technologies to extend or expand services or create new services, e.g., Joint Commission e-forum, webinars, etc.
6. The evaluation of a potential role for AAMI in achieving consensus on new technologies or new uses of technologies relative to government and private sector cost reimbursement.