



Patient Safety Summit Conference

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to the

**American Association for Accreditation of
Ambulatory Surgical Facilities
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(AAAASFEF)**

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Conference Dedication

The Patient Safety Summit Conference is dedicated to the memory William W. Tipton Jr. MD. Bill Tipton or “Tip” as he was known to family and friends was an Orthopaedic surgeon who practiced in Sacramento CA for 25 years until 1994. At that time, he became Executive Vice President and CEO of the American Academy of Orthopaedic Surgeons (AAOS) in Rosemont, IL. He retired from the AAOS in March 2004.

Bill’s focus on medicine and surgery was always the patient. He maintained that if physicians and surgeons maintained their focus on the patient’s well being all the rest that went with medicine today would take care of itself; or at least could be addressed more effectively by practitioners and organized medicine. As a surgeon, Bill was very concerned with patient safety. During his tenure at the AAOS, Bill spearheaded various patient safety efforts such as “Sign Your Site”, an initiative to prevent wrong site surgery, and he initiated several programs designed to assure patient safety. When an initiative crossed organizational and professional entities, Bill never doubted that a way could be found to make it happen. His underlying philosophy was that “we can always craft a ‘win-win’ scenario.”

Subsequent to his retirement Bill and Lawrence E. (Larry) Rosenthal founded The Kaleidoscope Associates (TKA) to share their experiences and expertise with other not for profit professional and trade associations. This Patient Safety Summit Conference was Bill’s “baby” and he saw it as another opportunity to bring medicine and related healthcare together for a matter that was a part of his core values.

In May 2005, Bill died after enduring a long-term liver disease. We would like to think that his spirit is looking down on this Conference with a glass of fine wine in hand and saying, “Go for it! This is definitely a win-win for all concerned”

Those of us who knew and loved Bill as a colleague and friend we could think of no better tribute then the dedication of this Conference to his memory.

Introduction

The Patient Safety Summit Conference of 2007 convened on January 26, 2007 in Chicago at the Westin O'Hare Hotel is sponsored by the following organizations:

The Joint Commission
Accreditation Association for Ambulatory Health Care (AAAHC)
Healthcare Facilities Accreditation Program of the American Osteopathic
Association (AOA)
American Association for the Accreditation of Ambulatory Surgical Facilities
Educational Foundation (AAAASFEF)

The Conference was funded in part by a grant from the Agency for Healthcare Research and Quality (AHRQ). The grant was awarded to the American Association for Accreditation of Ambulatory Surgical Facilities Educational Foundation (AAAASFEF). AAAASFEF provided also "in kind" support services to the Conference.

The Conference also was initially endorsed by the following professional and regulatory organizations:

American College of Surgeons (ACS)
American Society of Plastic Surgeons (ASPS)
American College of Foot and Ankle Surgeons (ACFAS)
Federation of State Medical Boards (FSMB)

The conference's goals as articulated in the Conference Resource Book were as follows:

1. Establish baseline information on the status of accreditation as a strategy by which to improve the level of patient safety in office based surgical settings.
2. Creation of a series of initiatives that the accrediting agencies can collaborate on a continuing basis that will improve patient safety in the office based surgery (OBS) setting.
3. Provide evidence and a value equation that accreditation of OBS practices enhances patient safety.

The Conference moderators were Thomas R. Russell, MD, Executive Director of the ACS and Robert Singer, MD, President of the American Association for Accreditation of Ambulatory Surgery Facilities Education Foundation (AAAASFEF).

Seventy-six (76) persons attended the Conference representing 32 different organizations. A detailed list of Conference attendees and organizations represented is in Appendix B of this report.

The Conference consisted of three major sessions. These were the following:

1. Plenary Session consisting of invited speakers who were given specific topics and questions to address as part of their presentation
2. Action Planning Session, which built upon directions and consensus, developed because of the plenary session. All attendees participated in this session through breakout groups that were assigned specific charge to deliberate upon and to develop initial action plans for the four accrediting agencies to consider as a group subsequent to the Conference.
3. Conference Wrap-Up & Next Steps This section summarized what was learned and accomplished during the Conference, It concludes with the next steps that will be undertaken to move the agenda of utilization of accreditation as a strategy to improve patient safety in the office and ambulatory surgical setting.

The remainder of this report will follow the agenda of the Conference and will summarize the remarks of the speakers of the plenary session and the results of the work of the breakout groups in the Action Planning Session. The final section of the Report will summarize the recommended “next steps” for the accrediting agencies that was decided by the participants in the Wrap Up session of the Conference.

Plenary Session

Welcome and Introductions

Focus

1. Introductions
2. Dedication of the Conference to the memory of William W. Tipton, MD
3. Overall Summit Goals and Objectives
4. Program organization
5. Other comments

Speakers

Robert Singer, MD, President AAAASF EF

Thomas Russell, MD, Executive Director American College of Surgeons (ACS)

Dr Singer

Good morning and welcome to the first Summit Meeting on Patient Safety in the Office-Based Surgical Environment. I'm Dr. Robert Singer, current President of the American Association for Accreditation of Ambulatory Surgery Facilities Educational Foundation, one of the primary sponsors of today's meeting and a prior President of the American Association for Accreditation of Ambulatory Surgery Facilities.

I'd like to thank you for taking time from your busy schedules to attend this meeting and your willingness to address some significant issues facing each of our organizations. Amazingly, there are representatives for over 30 organizations present here today. Especially, I thank AHRQ for its generous Grant support of this conference.

I'm going to leave it to the other speakers that follow to frame our discussions and add historical context. I will set the stage with some anecdotal information.

Over the last 20 years, we've seen a migration of surgery from the hospital to the ambulatory surgery center and now increasingly to the office-based surgery facility. Whether it's factual or not, the figure that's most quoted is that surgical procedures are performed in over 40,000 office-based facilities. That's an amazing number. There are no statistics regarding the level of anesthesia being administered, who administers the anesthesia, the complexity of the surgery being performed, the training of who performs the surgical procedures, or, most importantly, the outcomes and safety record. We do know that less than 2,000 of

those 40,000 office-based facilities are accredited by the major accrediting organizations, and only 14 states currently mandate accreditation or licensure. And in those states, the aggressiveness of enforcement varies from non-existent to partial. We can make several authoritative statements about office-based surgery. One, there's a significant growth in the number of procedures being performed, but we have no way of accurately measuring the numbers outside of accredited facilities. Two, patients are at risk. We know the level of risk in our facilities but have no way of determining the level of risk in non-accredited facilities. Three, there's no standardized reporting of untoward events that's common to the various accrediting or licensing organization.

We have a truly unique opportunity here today, and we are seldom presented with a chance to make a significant difference for a large segment of our patients. We can engage in discussion, hopefully, of course, that it will impact positively on patient safety. While we attempt to do that within each of our respective organizations, I feel that as a cooperative group, we can make a far greater significant difference. In this room, all of the major entities are represented. Today, the only thing that can stop us from making huge strides for patient safety is organizational and personal ego, which, hopefully, we can put aside to identify some common shared thoughts of how to move forward for greater public safety. Let me repeat. The only thing that can stop us from making a huge stride for patient safety is us.

The opposite is also true. The people in this room can move in a single direction that will then be the direction that medicine takes on issues related to patient safety in office-based surgery. We'll only be successful to that extent that we're able to put aside our turf and engage in an open-ended discussion about the safety of patients. I challenge all of us for today, and hopefully for the future. Let's bring the best of organizations and ourselves to the table for the basic benefit of public safety.

Now, with that brief introduction, I'm now going to introduce Dr. Tom Russell, and I think we're privileged to have Dr. Russell here. He's the Executive Director of the American College of Surgeons, and will act as one of the moderators for today's session. This is your session, we hope it's interactive, and certainly with breakout sessions. I hope that we all come away with some beneficial and meaningful thoughts about patient safety. Thank you.

Dr. Russell

Well, good morning everybody. It's nice to be here, and it's a privilege for me to attempt to be a moderator this morning. I think we have a very good agenda, we

have some very good speakers. I'd like to acknowledge Larry Rosenthal, for making all this happen. There's been a tremendous amount of organization that has gone into this. I'd also like to say that this was a vision of Bill Tipton a number of years ago. I don't know whether many of you knew Bill, but Bill was an orthopedic surgeon and practiced actually for 25 years in Sacramento, California. I was in medical school with Bill in the 60's, and he was the Executive VP and CEO of the American Academy of Orthopedic Surgery after he had had a 25-year practice in Sacramento. And it was always his dream to have a Summit like this on outpatient surgery, so this is sort of, in Bill's memory, this is something that we'd like to dedicate to Bill today. He did a lot of things with safety at the Academy, such things like Sign your Site and issues like that, Bill was a real visionary with respect to safety, and it's nice that we take a moment today to recognize his life. He died, unfortunately, of advanced liver disease just a couple years ago before he could get a live transplant. So this conference today is in his memory.

In the way of background, I remember in the 70's being a surgeon in San Francisco, and realizing that I was now being asked to do hernia surgery in this outpatient arena that they had set up in the hospital, one or two little rooms, and I thought that would be impossible to do hernias as an outpatient, because, you know, and those were the days where we admitted people a day or two before surgery, the house staff had opportunities to do history and physicals and it was a very long tedious process. Well, not only could we do hernias, but also we do almost everything else in the ambulatory arena. It is amazing, in my humble opinion, what's happened over the last 30 years.

I think today we all recognize the value of doing surgery as an outpatient. The patients like it, the doctors like it, the other healthcare providers like it, the payers certainly like it, it's a win-win for everybody. And I think we're now moving into an arena where we have to now make certain that what's going on in the hospitals is also done in the ambulatory settings, whether it be an ambulatory surgical center or whether it be office-based facilities, we need to look at data, we need to have evidence-based, and we need to have best practices in the outpatient arena just like happening in the hospitals, because disasters are still happening. We had a very tragic accident here in Chicago in a dental office just a few months ago, and the dentist may go to jail, or, at least, he certainly will have his license taken away. So it's very sad and we have to make sure we get our arms around this.

I think in the outpatient arena, we can offer excellent care if we can comply with the regulations, the patients like it, and I think it's going to be more and more the wave of the future as we move out of the hospital into specialty hospitals and ambulatory surgical centers and into office-based facilities. But, obviously, in the year 2007, safety and quality is absolutely paramount.

So, what is the goal for today? What is – and this is really your conference, and at the breakout sessions, which will begin about 11:30, I think the three questions that we'd like to have addressed this morning, is the strategy of accrediting these outpatient facilities valid, and does it improve safety and quality? Now I think the people in this room would agree with that, that it does, it is a good model. But we need to discuss that and we need to go forward with that first goal.

A second goal is can we begin to collaborate? In medicine, we've been wonderful to be able to stay in these silos that we have created, and I was as guilty of this as anybody. I was in the surgical silo and I thought the world revolved around surgery. In this job, which I've had the pleasure of doing for seven years, I unfortunately have come to realize that there's more than surgery. So it's opened my eyes to be able to appreciate and be able to be more respectful of a lot of the other groups that are trying to do what I thought surgery was sort of driving, family doctors, internists, and all the other people that make up the profession, including people that work in the ambulatory arena. So can we collaborate, number two?

And the third goal is that can we get to the point where we have evidence and be able to set the standards and values and we can work together and start to report this stuff of the data and the outcomes in a unified way that the people who will be looking at what we do can understand it with one reporting mechanism? I think if we can come to some conclusions on those three areas, is there value in accrediting? Can we collaborate? And can we get the evidence and data reported?

These will be ambitious goals for today because that's not the way we've done things in the past. So be thinking about it. And I remind myself everyday of breaking down these little places that we've been working in and working in a more collaborative and equitable way with other groups, and I think that's really going to be the future of coming together and doing our own separate things, but also working for the common good.

So I think at that point, I will stop and hopefully be able to see some real progress at the end of the day.

There'll be a series of speakers, and then we'll begin the breakout sessions, as I mentioned, at 11:35.

General Medicine View of Accreditation and Patient Safety

Focus Questions:

1. What is the current level and impact of patient safety initiatives in medicine today?
2. What data exists on the impact of accreditation on matters of patient safety?
3. What legislation or regulations exist or will exist that will protect data on adverse events, sentinel events or complications reporting from litigation discovery?

Speaker:

William Munier, MD
Agency for Healthcare Research and Quality

Dr. Munier reviewed advances in quality and safety from a national perspective throughout the past thirty years. As part of this effort, he referenced contributions by the Joint Commission and other standards and accrediting organizations. Much of the effort during that time focused on the hospital venue.

The challenge then as it is now is to promote a “no blame” culture for providers, recognizing that such a culture is essential to facilitate accurate reporting of adverse events and a study of their causes. It is important to balance that reality with the need to hold those who make persistent errors or incompetent providers accountable. Institutions must be held accountable for addressing unsafe conditions without being subjected to adjudication in the press and the courts when they engage in efforts at improvement.

The new Patient Safety Organization (PSO) law is intended to be at least a partial answer to this issue. Dr. Munier reported on a recent study of hospital patient safety event-reporting systems that showed a very uneven landscape in terms of the sophistication and utility of hospital patient safety event reporting.

Dr. Munier next directed his comments to the question of the impact that accreditation could have. Using the experiences of the hospital environment, he stated, “I think that accreditation could be the most powerful force for change in the ambulatory setting, as it almost assuredly has been in the hospital setting.” Dr. Munier also noted, “Fortunately, professional organizations historically have met this need, and accreditation is by and large a private sector activity – not a governmental one. I think accreditation in the office-based setting could be the most important influence on patient safety and quality in the immediate future.”

Dr. Munier next directed his remarks to the matter of protection from discovery of adverse event reporting. He stated that the Patient Safety and Quality Improvement Act of 2005 is intended to create a culture of safety by providing privilege for deliberations on the part of providers. While privilege from discovery for peer review activities has existed in most states since the 1970s, it is limited in scope, and there has been some erosion of protection from litigation in the courts.

The Patient Safety Act has the potential to reverse this erosion by addressing directly the fear of malpractice litigation, the inadequate protection by state laws, and the inability to aggregate data on a large scale. The goals of the legislation are to encourage providers to engage in peer review and identify risks, hazards and threats to patient safety without fear of discovery of peer review deliberations in malpractice cases. The Act also encourages aggregation of data to accelerate learning as to the magnitude and causes of adverse events.

The Act provides for creation of patient safety organizations (PSOs) that work with providers to review and report on adverse events. PSOs can be public or private entities; they can be profit or non-profit organizations. The only organizations ineligible to be PSOs are insurance companies and their affiliates. PSOs can be free standing or components of a parent organization. Two aspects of the program are worth noting: 1) it is completely voluntary; and 2) there is no provision for Federal funding.

The importance of professional review of adverse events and the benefit of being able to deliberate without fear of litigation is significant enough that a wide variety of organizations has indicated interest in becoming a PSO. Dr. Munier pointed out that no one can predict precisely how many PSOs there will be until the Department of Health and Human Services begins receiving applications. Such applications will be solicited once final regulations governing the PSO Program have been promulgated.

The Act also calls for establishment of a "Network of Patient Safety Databases" (NPSD). The NPSD should facilitate exchange of data among PSOs and simplify the task of reporting events by employing common definitions and formats across the network. The NPSD thus should promote interoperability and accelerated learning, allowing dissemination of results and best practices. In addition, the NPSD should be able to provide benchmarking and trend reports, shedding light on the state of patient safety in the country.

In an effort to try to provide evidence for development of common definitions and formats, AHRQ began compiling an inventory of existing reporting systems two years ago. This inventory includes representation from many currently operating patient safety event-reporting systems. The scope of the inventory now includes Federal systems, such as those of CDC and FDA, state systems, private-sector systems, and international systems.

This inventory includes data elements, definitions, and encoding schemes. Preliminary analysis reveals some commonality in definitions and much variability. Few systems collect information on the complete improvement cycle; most are limited to collection of event data rather than actions taken as a result of analysis of data.

The Department's next steps are to publish proposed, then final, regulations; finish the inventory of reporting systems; develop a plan for supporting the Network of Patient Safety Databases; and solicit and review applications from prospective PSOs.

Finally, Dr. Munier addressed the issue of accreditation in the ambulatory setting. He suggested that requiring patient safety activities in the office-based setting as a condition of accreditation certainly could be a very powerful force for improving quality and safety. The PSO program can provide the environment – review of patient safety and quality will be protected from discovery – so it could be a very important facilitating factor. Issues to be addressed by accrediting bodies include: what patient safety activities should be required; how can they be measured; and how can the economic impact be minimized? In the ambulatory setting, with busy practitioners, there is little time to review charts, abstract data, and enter it into a reporting system. Whatever is done has to be very efficient in order not to reduce productivity.

Dr. Munier mentioned the enormous contributions made by the Summit's sponsoring organizations and suggested that they will continue to play an increasingly important role in improving quality and safety in office-based practice.

Construction of an Evidence-Based Reporting System That We Can All Agree to Work for and Support

Focus Questions:

1. In what manner will the necessary data be gathered and analyzed so that evidence-based decisions can be made to set directions for increasing the level of patient safety in the OBS practice setting?
2. What organizations are eligible to collect the data?
3. How can competitive advantage be prevented from becoming a factor?
4. How will this help to improve the level of patient safety in the OBS setting?

5. What should be the focus of the data points to assure that the focus of the system is on patient outcomes and focus on matters of safety?

Speakers:

Clifford Ko, MD, American College of Surgeons
Geoffrey Keyes, MD, AAAASF

Dr. Ko

In terms of patient safety in the office-based setting, our job was to figure out if construction of an evidence based reporting system can be developed and something that we can work for and support.

The first is, and these are very much more granular and getting down to the trees: What should be the focus of the data points? That is clearly a very important question because there is many things that could be measured, what should we measure. Second this is, how will the data be collected, and who should collect the data? That will clearly have an important impact on the outcome of how the data will be used. Third, is, how can competitive advantage be prevented from becoming a factor? Many of the agencies are working towards of figuring out how people are gaming the system and make it so that they cannot game it for either competitive edge or financial gains. Fourth, is really an important thing of how will data collection be used to help improve the level of patient safety in the outpatient setting? So, once we have the data, how do we give it back?

Having high quality data is essential because garbage in, garbage out, so we need to have high quality data. Having a data reporting system for outpatient procedures is possible, it just might not be as easy as we would expect, but it is possible.

Really, it's data, and for the surgeons in the audience, I'm sure you've all heard of Ernest Codman who 90 years ago said that every hospital should follow every patient it treats long enough to determine how we're doing. He was, at that time, called very eccentric, another word for crazy. That was 90 years ago. Maybe we started doing it five years ago when we started doing it wide spread. However, he had it right, and this is what we're trying to do now to show that we're having quality.

I spend a lot of time right now at the American College of Surgeons, the Division of Quality. In this Division, there are a number of programs for which we perform accreditation data collection and data reporting. We've had programs ongoing for the decades, and we have programs that we're just developing now, so I can tell you or relay to you how difficult it is to get data reporting systems for the ongoing accreditation programs now, but, again, it is possible.

Dr. Ko summarized the College's work for the following data collection projects for which it is the data collection organizational entity:

1. Commission on Cancer Approvals Program
2. Trauma Accreditation Program
3. Bariatric Accreditation Program
4. National Surgical Quality Improvement Program (NSQIP)

We can't always just look at outcomes. We have to look at what leads to the outcomes, the process of care. With this database, now that we have the outcomes, we're adding in processes of care so we can know a process to outcome link. This is a key thing, and what many databases should probably be emphasizing.

In terms of achieving optimal patient care, we have surgical care in our community, and this is how we look at it in our division. We have surgical care in our community and we do data collection, whether it's for trauma, cancer, or for the Bariatric accreditation programs. We need it to be high quality data. We then get the data, we audit it, we analyze it, and we give it back to the hospitals.

So just like me at a hospital getting my infection rate, tells me where I am, it tells me where I am against the benchmark. Importantly, we need to take this data and we need to figure out how to do better care, whether we can do best practices, whether we have quality improvement or what not. So, the data is also used to develop these programs. In our trauma program, they take the data, to figure out, those hospitals that have a problem in this area, that need to be tackled by the trauma program. The trauma programs start a collaborative. They start a best practices program, and a consulting program, so they can go back to the hospitals that have a program and go back into the community to figure out to get things better. Higher quality, better safety, better efficiency, all these things are the same, where we can go back to the community because that's really what it's all about.

What makes a good item to measure in a database? Pick items that is clinically relevant, something that is clinically meaningful. If you give somebody to an operating surgeon or a provider who is busy in the trenches they may say why are you measuring that? Well then, that might not be clinically relevant or meaningful. Therefore, the something has to be those two. It has to be valid, it has to be something that there has to be some evidence for, whether it's level 1 or not. It has to be something that's measurable. We would love to get many things, but they are just not measurable. Something that is feasible can be measured, as was highlighted in the prior talk; we need something that you do not need to go combing through charts as it takes a long time. When we do this, when we develop our measures, we are very cognizant of figuring out how long it is going to take to fill out a patient level data in a data set. Is it going to take five minutes, is it going to take 50 minutes? There's a huge difference. If it is going to

take 50 minutes, it could be the best data in the world, it is going to tell us the most things, people are not going to do it and nothing will be done.

Finally, it's important to have items that are mutable and modifiable, so you want to get something where we can – do something where we can improve what we're measuring.

There are some things that are, possible candidates' mortality, which may or may not be evident in these outpatient settings. Complications are a key thing. These could include but not be limited to infection, readmissions, wrong sites, surgeries, specimen labeling is for a lot of procedures and drug events. Then, there are process measures.

How will the data be collected? How can we prevent a competitive edge?

What we do at the College, we try to get as good a data as possible. For the cancer and the trauma programs, we have dedicated registrars, which might not be possible in an outpatient setting, but this is what we do. Some possible options are having physicians, or other staff do it, or having others do it.

How can we prevent gaming in the system? We need appropriate data points and appropriate sources and audits. Audits are a key thing to go back and to see whether the data is correct or not, and making sure that you are collecting and addressing the right data.

In summary, it is important to select measurable, clinically relevant, and clinically meaningful data points; they have to be feasible, as well. The quality of the data that you get is essential and largely dependent on the source, what you are getting and who is getting it? Safety and care may be improved through audit and feedback mechanisms, this has been shown over and over again, whether it is the problems at the College, or the Commission, the AHRQ. A data reporting system can be developed. It is not easy, and there are these issues and probably more that one has to deal with, but it can be developed and it likely will be iterative. Quality and quality improvement and quality measurement is iterative. We are not going to come out at the starting gate and have the perfect system.

Dr. Keyes

Dr. Keyes disclosed as he began his presentation that he has a financial interest in a company by the name of SurgiMetrix.

Data acquisition in outcomes provides a view of the end result of surgery, and outcomes need to be analyzed in conjunction with the documentation of the entire surgical process, and that's already been alluded to by Dr. Ko.

Dr. Keyes presented a chronology of the activities of AAAASF's data acquisition and analysis activities since 1999. The details of this historical record are contained in Appendix C, which contains copies of the PowerPoint presentation for this segment of the Plenary Session.

Although we are dealing with sick patients versus producing a product, the check off list concept for the management of the operative experience from preoperative, inter-operative, to post-operative has great merit. It is very simple to do, especially not only at the bedside prior to going to surgery, but for it to be entered into a computer. We anticipate most of them are usually right, it's a one button click, so it's really a time saving situation and allows us to get a great deal of data in a short period of time.

The question that was asked, though, in what manner should data be gathered and analyzed so that evidence-based decisions can be made to set directions for increasing level of patient safety in the outpatient surgery setting? There should be an Internet based demographic and procedural data entry system. The starting point is for surgery center compliance management with entry into the system. It allows for the entry of hospital-based information also because in order to analyze outpatient versus hospital, we need to have that data also, and finally allows the private practitioner to enter his data in a non-accredited setting as it is in most of the states at this time.

What should the focus of the data points be to assure that patient safety and outcomes are improved? First, data collection must reflect outcomes. Secondly, document compliance or standards in all aspects of patient care. Finally, provide a patient safety management system that teaches a methodology for safe surgical practice, integrates continuing medical education, improves risk management, and does not provide an individual tax burden to the physicians. Data collection, if it is too onerous, as was alluded to previously, becomes an expense for the physician, and as we all know, physicians are being taxed more and more, and time of entry is an important feature.

Compliance with standards leads to safe patient care, it leads to cost management, and it's an ongoing cycle of improvement as a result of those situations. Outcomes are only part of the answer, and we've demonstrated what we've done at Quad A as far as outcomes are concerned, but just knowing the fact that you have a hematoma doesn't tell you what transpired prior to the hematoma. What we need is staff credentialing, equipment maintenance, formulary management, consents and documentations, preoperative assessment, inter-operative management and post-operative care, and then that has to be combined with the outcomes and then we know we're managing all aspects of care to improve patient safety.

We are all familiar with the needed initial contact information. We need one or two separate forms with limited check off boxes so that the patient could be

followed through a routing experience, preoperative, inter-operative and post-operative at each station. Things that are documented should be easily entered into a computer so they can be shared in that central Internet procedural and data collecting system. The preoperative information should deal with the patient information history, physical, laboratory studies, physician orders, surgical consents, etc. The inter-operative information should include the anesthesia record and nursing notes. Post-operative information should include recovery room records, discharge records, release from responsibility, and documentation of post-operative course, post-operative phone call record, operative report, and pathology report. With the pathology report, there needs to be a numbering system so that when a pathology report is out, there's a check and balance system that lets the surgeon know that the pathology report has been received and signed off on that completes the cycle of care. Biopsies that are malignant aren't missed and it's just a safeguard of a system that should be designed.

Formulary data should be designed so that outdated medications and required standard medications are constantly upgraded and reviewed in order to provide the best possible care in the realm of medications.

Finally, the system ought to provide as a benefit to the surgeon in the outpatient center an ability to generate governing reports, and also to send governing reports and required reports to state and licensing agencies and specialty societies so that it's a one entry system. Right now, we have our societies asking for information so they can analyze data we have. Our boards are asking for information so they can recertify. We have our licensing boards asking for information, and eventually we will have the federal government asking for information. So we need a central system that lowers the amount of work that the individual surgeon has to do.

Committee reports, including the analysis of what transpired through all of the aspects of patient care in the surgery center should be documented, and those reports should be generated automatically from following safe patient care.

Quality assurance and peer review should be built into the system. We have already demonstrated how Quadruple ASF performs that function. And also, the management of personnel in terms of their orientation and credentialing, OSHA responsibilities, tuberculosis tests, hepatitis tests, etc., all of those things should be included so that the individual surgeon, who is managing a surgery center or the administrator, knows at a glance where everything stands in the surgery center. Not only will they know at a glance where things are, but also they will be able to throw it to the central collecting system so it can be analyzed on a broad scale.

How can competitive advantage be prevented from becoming a factor? I think competition is a good thing. Competition is probably what has made the American healthcare system the finest system in the world. It depends on from

what aspect you're looking at competition. I think the term competition can be looked at in many ways, and, generally speaking, it's a good thing. But data should be free flowing, it should be shared and it should be available to everyone involved in the improvement of patient care. How will this help to improve the level of patient safety? Pretty much by our being able to know what is happening. We will know outcomes; will know what went into the system to accommodate that outcome. In other words, we will know if somebody didn't do preoperative studies and get a bleeding time, and that they had a hematoma. We will know if their rate of hematoma is more than the people who are getting that type of information. Finally, it will teach a methodology of practice.

Many of us who are Board Certified and manage accredited surgery centers never really learned in medical school how to manage a small hospital. If a system's set up those documents the fact that you're doing certain things and provides a risk management tool, it also serves a benefit of a teaching tool and keeps things in a safe perspective.

What organizations are eligible to collect data? It really comes down to the patient-physician relationship. The ability to provide data to different organizations rests with the patient. If the patient in their operative consent gives the surgeon the ability to share his information with quality assurance and peer review, de-identified, and with other organizations, then that is the starting point. But the information should be shared by everyone in the healthcare industry in one way or another so they can all come to grips with means of improving patient care.

As I mentioned, Quadruple ASF and its for-profit subsidiary, Surgery Facilities Resources, has developed the program that I have described, and we're most interested in sharing this program equally and equitably with all of the accrediting associations and licensing organizations.

What is the current state regulatory environment and views of accreditation as a strategy for OBS practices as a means to improve levels of patient safety?

Focus Questions

1. What have been the successes? What have been the failures?
2. What has been the impact of these initiatives?
3. What are the hurdles and obstacles in achieving greater acceptance of a formalized program of improvement of the level of patient safety in the OBS setting through accreditation?

Speakers

Stacy Lankford, MD President-Elect FSMB
Roger Mecum, Pennsylvania Medical Association
Larry McPherson, Florida Board of Medicine

Dr Lankford

I want to give you a little background of our organization. We are 70 members that make up the Federation of State Medical Boards. Since we are 50 states, the mathematics might not be very logical at the beginning, but some states have DO Boards, some with an MD Board. We also have the territories and island possessions and commonwealth of Guam, Puerto Rico. We are a non-profit association that has been in existence since 1912. We are located between Dallas and Fort Worth on the campus of the Dallas-Ft. Worth Airport.

Our mission is the continual improvement in the quality, safety and integrity of healthcare through the development and promotion of high standards for physician licensure and practice. The last two words are important because Medical Boards license physicians and discipline physicians. There is only a couple of exceptions where there are two separate boards, one for license, and one for discipline.

The services that our organization provides to the member boards, includes services for our member boards, including the licensing exam.

The reason for office-based surgery regulation is obvious. As we heard this morning, there are increasing numbers of surgical procedures being performed, probably 65%. It is unregulated in most states. In 2001, our House of Delegates accepted a proposal to proceed with developing a policy on what should state medical boards do about this unregulated office-based surgery problem.

The committee was established in 2001. It was charged with developing recommendations to assist state medical boards in the oversight of unregulated office-based surgery and educate licensees as to appropriate standards for office-based surgery. The charges set forth three passive oversight, because we do not, as a federation, mandate any standards. We recommend best practices or appropriate policies. During this process, we adopted three recommendations. The states either accept the FSMB model guidelines, which includes accepting national accrediting organization standards, and/or make up their own individual state standards.

The FSMB model guidelines identified policies and procedures in the following critical areas:

1. Administration - in terms of governance; quality of care, clinical; and an area called miscellaneous. In terms of administration, the topics that

were dealt with were governance, such as laying out the organizational structure, the authority, responsibilities, accountability and the annual, at least, annual review of the governance. It was recognized that patients' rights were important and that these rights be in compliance with state and federal statutes.

2. Quality of Care - The committee thought there should be a system of quality assessment, such as, personnel credentialing, licensure, etc. This should be in a written format. Patient evaluation should be documented, history and physical. There should be ACLS training of personnel, when appropriate. Informed consent should be appropriate.
3. Medical Records - Medical records should be legible, complete, comprehensive, and they should be maintained for each patient.
4. Discharge - It is the responsibility of the surgeon and/or the individual responsible for the anesthesia care. Discharge should occur when they have met certain criteria. That there should be a system of emergency and transfer protocols. These should be written and in place in order to handle, medical emergencies that would arise in connection with the services provided at the facility.
5. Reporting requirements - The committee believed that these need to be structured consistent to encourage a free flow of information. The state agency should be designated to receive incident reports and reporting requirements should be consistent with all laws of confidentiality and other regulations.
6. Peer Review - The committee indicated their desire to have written procedures for credible peer review to determine the appropriateness of the clinical decision-making and the overall quality of care.
7. Clinical Services - The committee believed that these should be provided by qualified practitioners in an environment that insured patient safety. Anesthesia should be appropriate for the patient, the procedure and the setting. Monitoring should be appropriate. The surgical services should be performed only by healthcare practitioners licensed in the state in which he or she is practicing.
8. Ancillary services – These services should be provided in a safe and effective manner with appropriate ethical standards. These should include, but not be limited to, pharmacy, laboratory, pathology, radiology, etc. The facilities and equipment comply with applicable federal, state and local laws and codes and regulations.
9. Miscellaneous - was there because in 2001, now we are in 2007. One can't always tell what's coming down the road, so the committee at that time chose the category of miscellaneous, and they were identifying at that time liposuction, laser surgery, and advertising issues that might come into play that would be a problem.

A second pathway provides for accrediting of a nationally recognized organization in lieu of or in conjunction with specific state standards. This is kind of, what we're talking about today with the other organizations.

There is a third pathway in which a state could adopt individualized standards based on a combination of the standards outlined by our guidelines and by the other accrediting organizations. And of course, there are the national accrediting organizations.

We have 20 state medical regulatory authorities that have established the guidelines, the rules, regulations, and/or statutes for office-based surgery. We have 34 state medical regulatory authorities that do not have existing guidelines or statutes for office-based surgery, and others do not address this area at all. This is a concern for our organization, the Federation State Medical Boards. As a member service organization and we believe, it is very important that the member boards be aligned with appropriate oversight of this very important area for patient safety.

Mr. Mecum

The current environment in Pennsylvania has some unique features to it. First, we do have no specific regulations specific to office-based surgery. The medical society has long stood behind office-based surgery. The medical society has been long active in terms of trying to support office-based surgery, as well as the growth of ambulatory surgical facilities in Pennsylvania.

The Pennsylvania Department of Health does regulate ambulatory surgical facilities. It licenses these facilities and it accepts registrations for accredited Class A facilities and office-based surgery. If they are registered and accredited the ambulatory care regulations in our commonwealth requires a license of any of these facilities when performing procedures that utilize anything more than local anesthesia.

If accredited by the AAAHC, the AAAASF or JACHO then they must register with the Department of Health. If the office-based surgical unit is registered with the Department of Health, then now under new law in Pennsylvania, it is required to report to the state's patient safety authority.

This patient safety authority makes Pennsylvania unique. Pennsylvania had the first mandatory reporting requirement in the country for reporting of medical errors and the improvement of patient safety. In Pennsylvania, because the requirement is to report adverse events, those that negatively affect the patient, and those that are called incidents, which are near misses, we are still the only state in the country that requires the reporting of both those types of instances. It was created in legislation in 2002 that the medical society helped craft. In the peak of our liability crisis in 2000, 2001, 2002, when we were in negotiations with the Hospital Association, the Trial Lawyers Association and Senate leadership, we agreed to a three-part proposal.

In order for us to get significant tort reforms and to privatize our catastrophic loss fund, we needed to come to the table with a very aggressive initiative having to do with patient safety. The legislation did not come out exactly as we wanted, but we did have significant influence in how this legislation took place. Through the legislation on patient safety, this independent state agency, or the patient safety authority, was created, charged with the eliminating of medical errors or reducing medical errors in our state. It is non-regulatory in nature. It is non-punitive in nature. It analyzes and evaluates reports to the authority.

The state created over about a two-year period of time a web-based reporting system called the PA Patient Safety Reporting System. The database is confidential and is non-discoverable. It is important, and that was part of what the medical society fought long and hard to have included in the legislation. The reporting requirement includes all so-called serious events, adverse events, negative impact on patient, as well as incidence and those that are labeled as near misses.

Our activities in Pennsylvania have gotten a lot of national attention, and last year we won an award for advancing patient safety. The Patient Safety Authority reports quarterly with what is called an advisory. The advisory is a wonderful report of incidents that have come into the authority. It receives about 3,300 reports a week. There are 440 hospitals, birthing centers, ambulatory surgical facilities, and those that are registered office-based surgical sites that report into the Patient Safety Authority. These advisories have case studies in them. They are a wonderful educational tool. The hospitals in Pennsylvania say now that 75% of the hospitals have improved their internal systems as a result of the Patient Safety Advisory issued by the Patient Safety Authority.

An office-based surgical site that is registered and accredited, you must have a Patient Safety Committee that meets quarterly, It also must have a Patient Safety Officer. There is mandatory reporting on the areas of near misses or serious events. If there is a serious event, which is less than 5% of the total reporting to the authority, the facility must notify the patient and/or the family member when a serious event has occurred.

For the physician, it increases CME requirements. We also have an osteopathic and a medical board in Pennsylvania. The requirements are not common. There are some differences between the two.

In conclusion, in Pennsylvania, there is much that I could talk about because our state repealed CON some years ago. However, the large insurers and the hospitals are continuing to bring it back. Questions that come up about office-based surgery.

Although there is no specific regulations, that affect office-based surgery, other than reporting to the Patient Safety Authority if you're accredited. The office-based surgical programs actively participate and many of them actually

contacted the Authority to receive these advisories. The information that's gleaned from these advisories are put into use in offices that do office-based surgery in terms of creating a culture of the patient safety. The Medical Society is very proactive in this particular arena, and plan to stay that way. It also keeps very, very close connections with the regulatory authorities for the interest of patient focused care, patient centric care, as well as advocating the interest of our physician members.

Mr. McPherson

I want to cover four points this morning.

First, Florida has used national accreditation as part of its comprehensive office-based surgery program for several years. It has been successful. In Florida, we have 517 doctors who have registered to perform, what we call, Level 2 or Level 3 surgery in an office setting. Of those 517 physicians, we have 291 facilities. So, obviously, you'll have more than one M.D. at a facility. Of those 291 facilities, 86 are subject to annual state inspection by inspectors.

If there are deficiencies in the facility and that are not life threatening, and the practitioner or the facility owner makes corrections within 30 days, then that ends it. They don't have to go through a disciplinary process.

135 are nationally accredited. If the facility is nationally accredited, it does not have to subject itself to the state annual inspection at \$1,500.

Third, there are 70 facilities that are accredited by a state organization because of the way the legislation was enacted. The Board of Medicine, after several legal challenges is no longer accrediting.

The first point is, accreditation is used in Florida, and it has been successful. Second, we found in creating our office-based surgery program that it really opened up many avenues of communication with professional societies, practitioners, attorneys who represent licensees, and there really was a very positive experience that worked out through public hearings and compromise a very comprehensive system.

In 2000, when we really started, there were five deaths in Florida in office-based surgery settings following plastic surgery procedures. Since then, we've had fewer than 2 every year occurring in Florida. So we can tell, in terms of the tragedies that have occurred that there has been an improvement. We know this because in Florida, you have to report adverse incidents occurring in office-based surgery. These incidents are public, which is a lot different from if you had an adverse incident in a hospital in Florida. Those are confidential.

Individuals who get in trouble and have to send their patient to the hospital, it is going to be reported to us, so we were able to keep track of adverse incidents.

We do an annual report that you can find on our web site, www.FLHealthsource.com. Because of the reporting requirements and our ability through rule to get copies, on occasion, of office surgery logs, we were able to see how many surgeries were actually being performed on a yearly basis in our state and the types of surgeries performed. We also know what types of physicians were performing them. So, if you want to go on this web site and look for our office surgical care committee report, you'll actually see all the statistics, including charts, which summarize every incident that occurred.

There are three hurdles and obstacles. One is trying to keep track of people who move around from one facility to another. Second, we would like to improve on is our communication between the accrediting agencies and us. We require in our rule that licensees inform us when they lose their accreditation or there is a change in their accreditation. However, if something bad happens, they're not going to tell us. I know one of the nationals will if we ask, send us copies of their surveys. And in terms of our goals, we would like to see a better communication, both from our standpoint and from the nationals, in sharing information about survey or inspection reports. I am sure that the nationals would like to know if something of a disciplinary matter is occurring at one of their facilities, which is accredited. We should be doing a better job informing the nationals, and we would hope that we would receive the same from the nationals in getting copies of surveys so that we could identify areas of patient safety that we could address in the state system.

We have been very fortunate. The Board of Medicine is supportive of improving patient safety in office-based surgery. Fortunately, we have maintained a good reputation with all the stakeholders in Florida, so this has really been a successful process for us, and we would look forward to working with the nationals to make it even better.

Questions and Answers

Dr. Russell stated that some time was available in this segment for some questions. Questions were solicited. For purposes of this report the question will be proposed with the person asking the question identified and the responders also identified.

David Neilson, MD

Do any of you have a relationship with any of the national specialty societies, or do you see value in forwarding these reports to the society so they can assist with the education in moving those advisories forward? This is all news to me, but we've had our own medical error reduction

initiative, and having the kind of information that you develop on the states. Or does FSMB have a standard that we could use and that we could pass that reporting on that was specific to our specialty, we'd be willing to do that. Is there any experience in that regard with specialty societies?

Lankford - Well, from the Federation standpoint, we have a relationship with the ABMS but not in this arena. We're at the beginning of this, and what I presented today is our policy. Since it's a state based licensure, we haven't advanced beyond what I told you today.

Mecum - Well, in Pennsylvania, our relationship is obviously with the state chapters of the various specialty societies, and we have, at the state society level, what is called the Specialty Leadership Cabinet. The Specialty Leadership Cabinet is made up of representatives of each of the specialty groups in Pennsylvania. They review and discuss many of the patient safety data that flows out of the Patient Safety Authority with some frequency, including those that are listed in the advisory. The Medical Society also coordinates with the State Specialty Societies in creating on line CME for items that flow out of the Patient Safety Advisory bulletins that come out from the authority.

McPherson - Florida is very much like the Keystone state, we have a good relationship with the state specialty societies, the state Florida Medical Association, and so we frequently will see representatives from the specialty societies at our public meetings, and they also help us get information out to practitioners.

Singer - One of the things that, speaking of specialty societies the American Society for Aesthetic Surgery and the American Society of Plastic Surgeons, do require mandatory accreditation or licensing of any physician who is a member if they're going to do surgery. They do get feedback from those accrediting agencies if somebody has lost their privileges or has lost accreditation. I think that's a standard or a guideline I would throw out for all the specialties that require all of their members to operate only in accredited or licensed facilities. Being a plastic surgeon, I can tell you I am proud that plastic surgeons have taken that step of requiring it for safety.

Hector Villa, MD

I am with the American Society of Anesthesiologists; I chair the Ambulatory Surgery Committee. My question is for Dr. Mecum. Do you think in the Patient Safety Organization you're talking about, you receive the adverse incident reports, and at some level, I would imagine through licensure, the facilities are also required to report maybe their volumes? I know from having worked in Florida that looking at safety, it was critical not just to know how many bad accidents there were, but how many shots there were at having that bad accident. So my question is Do you have any

way to connect the dots so you can relate the volumes along with the incidence and create a rate of injury?

Mecum - Well, first of all, just, for a complete transparency, I appreciate be calling a doctor. I have worked for physicians for 34 years, so I at least ought to have an honorary degree. However, I'm a master's degree, and I'm their Chief Executive Officer, just so you understand. The mandatory reporting through the authority, even those the Act passed in 2003, did not take effect until June of 2004, so the authority has had the experience since that time. The experience have shown that about 97% of the reports that come in are what's called incidence or near misses. The serious events, that are the adverse events, where the patient has been harmed, comprise 2-1/2 to 3% of the amount. Yes, they do have track of those, although it is not, because the database is confidential. They can only produce numbers and percentages; they can't obviously produce anything beyond that. We also have in Pennsylvania, and have for many years, a Pennsylvania Healthcare Cost Containment Council, which is another quasi-state agency that collects all kinds of data and reporting data. They dovetail with the Patient Safety Authority on a number of things. The big issue right now is that we are the first state in the country, and the only state in the country, to publish hospital inquired infection data that's hospital specific. So, when it gets to adverse event reporting, there is some reporting of whether it's going up, whether it's going down, certain percentages, because of the confidential nature of the database it doesn't go beyond that.

Paul Collicott, MD

I would like to ask Mr. McPherson, who alluded to the fact that only one of the national accredited agencies would share information with you if you requested it and the others would not. Have you done an assessment on this as to the reasons why, because I noticed you said that the adverse events are public information, they're reportable? Is this the reason you don't get any information back from the National Accrediting Agencies?

McPherson - I thank you for the question. The incidents that are reported in Florida are public, so if a facility has an incident that requires a patient to be transferred to a hospital, that will result in an adverse incident which is public. Many of our facilities, are accredited, and we don't know how they're doing, how is the survey going, are they – do they have problems? And that's where we would like to know if an accrediting agency conducts a survey, we'd like to see the survey and like to see the report. That's what I would like to see in the future, more of that. Why these agencies don't do that I think is something that we can work out, and I think we can improve on that.

What is the accrediting agencies view of accreditation as a strategy for improving patient safety?

Focus Questions

1. What have been the successes? What have been the failures?
2. What has been the impact of these initiatives?
3. What are the hurdles and obstacles in achieving greater acceptance of a formalized program of improvement of the level of patient safety in the OBS setting?
4. Does accreditation equate to a safe environment?

Speakers

Alan Gold, MD – AAAASF

Roy Grekin, MD - AAAHC

Peter Angood, MD – The Joint Commission

Edward Glinski, DO – Healthcare Facilities Accreditation Program (HFAP) of AOA

Dr. Gold

What we've been asked to speak about in this panel is what the accrediting agencies views of accreditation are, is a strategy for improving patient safety. Now the concept of accreditation, in general, was really just to establish the physical plant, staffing, equipment and processing requirements to ensure the safest possible environment for office-based surgery. But the fact that we're all sitting here means that we acknowledge the fact that we really need to go beyond that. Those basic standards which all of the agencies have established really doesn't allow us to impact as much as we would like, or need to, on patient safety. And I realize that we're here for the same purpose, and this is sort of like preaching to the choir, and there are many different stakeholders involved in this, but beyond the people that are here, we need to also enlist the support of, not only the physicians that are practicing in those facilities, but their patients, government agencies, and, to a great degree, third party payers, those who may be paying for those services, in order to truly make a significant impact. So we all share this common culture of safety, and although that's a fairly recent buzzword, if you will, I think everyone really carries that as the major charge of the accrediting organizations.

The questions that we've been asked to answer on this panel are what have been the successes and what have been the failures in our efforts? As Dr. Singer just alluded to, one of the most significant factors, I think, in the success of Quad A has been a professional mandate, a mandate from both the American Society for Aesthetic Plastic Surgery, as well as the American Society of Plastic Surgeons that all of their members that operate in an office-based environment,

or anywhere out of the hospital setting, do so in an accredited facility. It was a significant effort on the part of those two organizations to have taken an immutable hard stand on this, and that if you do not operate in an accredited facility; you lose your membership in those very critical national associations.

One of the problems, though, is that, again, we're preaching to the choir, those are mainstream surgeons, and to a great degree, you know, you can't legislate morality or ethics and the ethical and moral guidelines that we have only apply to those who are ethical and moral. So, one of our challenges is to go beyond those physicians who are members of and are practicing under the guidelines of those national organizations, similar to the Plastic Surgery Societies.

One of the other successes is that some states have already accepted accreditation lieu of licensure, although that is a small minority, and some have accepted the standards, as New York has, of Quad A and some of the other accrediting agencies as guidelines, although not regulations, for office-based surgery. And some insurance carriers have actually recognized the advantages, or at least the financial advantages, to them of office-based surgery accreditation because if we can deal with them and show them the statistics that indicate the safety of surgery in that environment and the cost effectiveness, then they can help to drive patients to that environment.

Most importantly, I think, data really serves us well, as you heard in the earlier presentation. Quad A has taken some major initiatives in this regard and with over a million consecutive reported cases. We have been able to show extremely favorable mortality and morbidity statistics, either comparable or lower to those anticipated in the traditional hospital or ambulatory surgery settings, and we believe that we now have data on which to base our contention that adherence to those standards, or the standards of any accrediting organization, has improved patient safety.

Where have we failed? I think that governing agencies have not acknowledged the beneficial impact of accreditation, especially by non-government organizations on mortality and morbidity, or on maintaining or constraining the cost of medical care. Office-based facility accreditation is only required in a small minority of states, and an even smaller minority of major insurance carriers have been willing to encourage the use of office-based facilities, whether you're a participant or non-participant in their plans, through reasonable reimbursement. We're currently going through that in New York, and I can share that experience with you later, if you wish.

And finally, one of the failures is that the media has really paid very little attention to this, whether that's through our fault or the fact that it's not sexy enough as a topic to hit the media, you only read about the disasters and they really don't emphasize the importance of accreditation or oversight in the office-based setting.

What's the impact of the initiatives that we see here? Certainly, this Summit Conference is one. The fact that we're sitting here and discussing this. There is greater oversight and standardization in office-based surgical facilities. I think we have seen through the different accrediting organizations, and now through some early legislative efforts. This is an opportunity for us to meet collegially for the benefit of this initiative, and, most importantly, for the benefit of our patients. But we have a lot of hurdles to overcome and significant obstacles.

One is the resistance of facilities to regulation. No facility wants to be told by anybody else what they should do and how they should practice, and they're reluctant to accept that. They're reluctant because of the time involved in compliance and of what they feel is their constraint and their ability to function as they would like, and that's even greater amongst the physicians who own these facilities than amongst those that are managed by administrative organizations. No physician wants to be told what he or she can do by anybody, and that's a problem for us. Fortunately, again, some of the major national organizations are taking steps to mandate accreditation, but we're meeting significant resistance, even amongst our own physicians within the plastic surgery arena.

We have to face hospital and ASC competition, both for physicians to operate in those settings as opposed to the office-based setting, and legislatively, because of a very strong lobby that tries to constrain office-based surgical facilities. And by the Hospital Association, that drive for certificate of need requirements in different states to try to do that.

Previously, we've had a lack of hard data to show patient safety benefits, and that's been a problem for us. I think that you've heard the importance of that earlier. But can we equate accreditation to providing a safe environment? Yes, we can ensure that at some point in time the facility met the physical plant, staffing, equipment, process requirements that the various accrediting agencies have developed to ensure that environment. But we can't guarantee the maintenance of those standards between the inspections. In Quad A, we do it with an annual self-exam, self-reporting, but, again, that only constrains those people who feel constrained by the appropriateness of that action. There are people who are practicing in a less ideal way in their medical practices, and, therefore, will falsify the documentation or just not adhere, and that's a significant problem. And we can mandate the physical plant requirements, process requirements and paper work necessary, but we can't legislate or mandate good surgical skills and judgment, and so we're still going to have problems in terms of outcome in the office-based setting just as we do in every other setting.

So what I'd like to see here is, we're not here to promote ourselves as an individual organization speaking out from Quad A, but here to cooperate for a greater goal, and I think it affords us an opportunity for the very first time to do that. We need to be able to demonstrate to both the state and federal

governments that accreditation is necessary, necessary for our patients, for their outcomes, but that we can, as private, non-governmental organizations, do that equally as well, if not better, than the government organizations themselves. We should promote office-based surgical accreditation in every state, in those states that require it or are contemplating licensure, we should push for accreditation in lieu of licensure, that we should be able to demonstrate that it's not only acceptable but preferable, since we think that we can do it better without getting bogged down in the legislative mandates that may differ from state to state. We have to enlist the insurance carriers by showing them that accreditation will help save them money and the physicians by demonstrating to them the compliance with those standards will help to save them money and make them practice more efficiently and more productively. Thank you.

Dr. Grekin

The Accreditation Association for Ambulatory Healthcare is very well acquainted with the office-based surgery system. In fact, we have an entire set of standards and guidelines directed just towards that.

We have a subsidiary called the Institute for Quality Improvement, which is wholly separate, that exists solely to evaluate healthcare quality and facilitate improvement in the outpatient setting. They have done two studies regarding people's attitudes in the office space surgery setting towards medical event reporting, and have found in both instances, in 2001 and 2005, that the medical event reporting is much lower in that setting. And the studies also found, found that physicians practicing in that setting have said, and this is in quotes that "there's literally nothing that could necessarily motivate them to be involved in the medical event reporting system unless it was obviously forced upon them."

One reason for this is that in this setting, there's less routine or built-in oversight, in part, because most of the payment is fee for service. There is no insurance company or the third party payer mandating that certain types of oversight be involved. Another reason is that these systems are much smaller than a hospital or a larger ambulatory surgery center setting; they lack the infrastructure and resources that are available to those larger organizations to carry out these functions.

Lastly, because they are, in many cases, physicians operating by themselves, there's a concern that any medical event reporting isn't going to really be confidential because if there's only one person working in the facility.

At least 15 states do require adverse event reporting in office-based surgery settings right now. This is a more acceptable situation to physicians in that reporting directly to the state does help solve some of the confidentiality issues due to a lack of disclosure risk by the state. However, the problem right now is that there's no uniformity among the states as to what reportable events are, or

how they're defining them. This makes sharing of this information difficult and makes it harder to collate it and get the larger meaningful information out of it.

Another important issue that AAAHC have found is that the mandatory reporting systems, as they currently exist, are less likely to capture what we call "near miss" information. As the current systems currently exist they certainly capture major events, but if there is a wrong medication administered, or a medication administered to somebody with allergy and it doesn't result in a major event, then that isn't going to – that occurrence isn't going to be captured, and, therefore, we won't have the information on how to prevent the event in the future. Also, the current mandatory systems are less likely to provide information back to the practices that are going to allow them to alter their processes, such that they can improve the safety of their patients.

We think that federal activities in this regard may be a better guide for, not only accreditation but for the organizations gathering information on medical events or near misses. The Patient Safety and Quality Improvement Act, of 2005, which is leading to the development of PSO's (patient safety organizations) is a good step in this direction. It provides protection to these medical event-reporting programs. And, CMS is moving to give more of a bite, so to speak, or more enforcement to involvement in medical event reporting by being able to manipulate reimbursement based on people's participation, in such activities as pay for performance.

So AAAHC's role, and what we see as our successes here, is to establish standards, surveying for compliance of these standards, and then making accreditation decisions based on the surveys. We think that these reflect the recognition and analysis of medical events and near misses, as well as interventions that are ongoing in the practice. They also provide ways of approaching prevention of these events by ensuring that appropriate credentialing and privileging is going on, that OSHA regulations are adhered to, that the organizations have appropriate and operating anesthesia standards, and that they take medical records seriously and do a good job of that.

As with AAAASF, we have multiple standards throughout our survey regarding patient safety issues, medication safety, patient identification standards and the patient's role in patient safety, communication between the patient and the physician, infection prevention and prevention of surgical fire and wrong site surgery.

We also believe that our Institute for Quality Improvement helps everybody to better understand the accredited organization's current level of involvement in preventing patient safety related problems. It studies these organizations' involvement and their motivation for involvement in medical event reporting systems, and it surveys the processes and procedures that are already in place to prevent common medical events, such as, administering medicine to patients

with known allergies to the medicine, failure to inform patients about their abnormal test results, surgical infections, and, wrong site surgery.

We believe that our role and the Institute's role is to conduct these studies, but also to develop educational activities that focus on patient safety, and to that end, we have four conferences a year. We've involved ourselves in helping and supporting and advising others' efforts in this area by consulting to the ASC Quality Collaboration, Physician Consortium for Performance Improvement, and in the National Quality Forum (NQF). Our Institute studies, examines and reports on patient safety related issues.

So, in summary, we recognize that the office-based surgery system has special needs with regard to involvement in formalized programs, to improve and ensure patient safety. We believe that the office-based surgery setting is hindered by fee for service or patient payment and lack of resources and infrastructure available in other settings. That state mandatory reporting systems don't yet rate well with regard to the attributes that would motivate participation from this already reluctant ambulatory sector. At the current time, the federal government is leading the way to provide more unified protective medical event reporting via recent legislation.

We believe that we know the OBS setting, we have standards regarding safety, and we absolutely support research on quality improvement and specifically, patient safety.

We don't believe that the individual organizations, the accrediting bodies, are the best ones to collect medical event data at this moment. We think it will overwhelm the system, it will fragment it too much, and we do not have the ability to enforce participation.

We believe that the data collection would best be done at a more centralized setting, such as the states, but with facilitation and guidance from federal organizations, such as AHRQ (the Agency for Healthcare Research and Quality), so that we have a standard system across the country allowing us to make the most effective and valid use of the information that is gathered, while at the same time protecting the confidentiality of the responding physicians. It may well come to pass in the future that CMS may mandate such participation.

Thank you.

Dr Angood

First off, I'll make a disclaimer. We are no longer the Joint Commission on Accreditation of Healthcare Organizations, or JCAHO. We are something now The Joint Commission.

The Joint Commission, has been involved for quite some time on the issues of quality of care, customer service, the evidence of practices continuous commitment to safety, etc. We've got over 1,300 ambulatory settings accredited, and currently we have about 300 accredited office-based surgery programs. And in our standards, we tend to push toward the optimal achievable standards, and that's what gets reviewed during our accreditation surveys.

One of the important activities that we've been doing now for just over a decade is the reporting of sentinel events, and because it is tied into the accreditation and the review processes, we tend not to get as much in the way of reporting as we would like. Our own estimate is that we probably only get about 1% or 1-1/2% of the events that are actually going on out there, and this is in the hospital settings. But it's an important factor because to improve the reporting, we need to look for the mechanisms and the ways to help that occur. Certainly, the federal patient safety legislation is going to help us in that way. One of the differences in our database is that each of these sentinel events have undergone detailed root cause analysis as to what has been the problems underlying the occurrence of these sentinel events. And as you can see, many of these are related to surgical procedures, and, in fact, wrong site surgery still remains up there as our number 2 problem. But there are other issues, the post-operative complications, the administration of medications, the anesthesia-related events, infection problems and fires in the OR.

The reporting has improved, but it hasn't really come up to a level The Joint Commission is satisfied with. A previous slide focused on the point of communication. And that clearly is still the primary problem which we face for all of our systems-based issues. But what we have noticed in the last year, and we'll see if it maintains itself, is that there's been a shift from communication orientation to more focused in on competency credentialing and procedural compliance. And that's an important shift that we're going to follow. We see that across all of the different areas that we evaluate during our sentinel database review processes. Organization culture, care planning and leadership are also beginning to emerge and perhaps that's just the reporting, perhaps that is also our review processes.

Similarly, an outgrowth of the sentinel database has been the National Patient Safety Goals. Again, many of the areas do focus in on elements related to surgery and they have relevance in the office-based surgery arena, as well. Patient Identification, communication, medication safety, infection, reconciliation of meds, surgical fires, patient involvement, etc. One of the things that we do is track the compliance during our surveys as to how institutions are doing with achieving the goals and the requirements within the goals.

Specific to the office-based surgery environment, we followed this for a couple of years, and areas of non-compliance are: two identifiers for patient ID, still hitting

just under 10%, and the timeouts before surgery also is going up, almost 20%. That might be due to better surveying, it might be better reporting, but it's occurring, that's the main message there. Standardizing the abbreviations, that's everybody's bugaboo, it's always a problem, as well as compliance with CDC hand hygiene guidelines. You know, we don't do much more in office-based surgery other than do surgery, and sterility and adequate hand hygiene is a big part of that whole series of processes. There is the medication reconciliation process. Patients come in, they go out, quick turnarounds, how do we reconcile all of those issues? So those are the non-compliant statistics in the presentation that are hanging around, and the numbers that are increasing in non-compliance are of concern. Clearly, there's a shift into the outpatient arena, and root causes of wrong site surgery, That shift from communication on patient assessment issues is also moved down there into the competency and procedural compliance

In the presentation is a graph that shows us where the curve has gone in terms of trying to get rid of wrong site surgery, and it has not made a difference. We used to get about 5, 6 reports per month on wrong site surgeries. After the implementation of the Universal Protocol on Wrong Site Surgery, The Joint Commission receives eight reports per month. We think it's probably mostly related to improved reporting, but it's multi-factorial, and what we hear in these review processes is that the surgeons don't think it's their problem, it's the system that needs to look after these issues, the surgeons don't want to become engaged.

The Joint Commission is convening a second wrong site surgery summit at the end of February, bringing back the 60 or so organizations that originally brought consensus to this protocol, and we are specifically going to spend the day, evaluating what can be done to make sure that this wrong site surgery problem goes away. We haven't fixed it by just collaborating on a protocol, we need to get into the systems issues overall.

Within the ambulatory and office-based surgery settings, the presentation includes numbers in our database. As you would expect, there's relatively low numbers, but there's been 25 wrong site problems at the ambulatory and office-based surgeries, and 15 deaths. We recognize that our database is woefully inadequate, and that's a big part of the problem having all of this tied directly to accreditation for reporting problems. We have made strong efforts on the standards and in terms of trying to set optimally achievable standards. There are 135 different types of standards that organizations need to pay particular attention to. Our standards are going through a complete rewrite over the next 2 years or so in order to continue simplifying them, making them relevant, making them practical, and making them very directly related to what's going on in the ambulatory and office-based field.

There is a concept that I picked up out of the NASA literature during the reviews of the shuttle accidents -- the normalization of deviance is what we really need to

begin focusing upon in terms of systems change and organizational behaviors. This could be like one of those AA meetings. You know, my name's Peter Angood and I am a deviant. We all are "deviant" because we do the workarounds and the collective workarounds then wind up with this normalization of deviant behavior and then you wind up not being able to see what's going on that is interfering with the processes of care. And what the important factor in here is that just putting out information and education is not enough. We have to put in strong leadership, forcing functions, automation, as much as we can to try and drive process, but there's big resistances to all of this overall.

Some of the barriers are resources, technology, cultures, leadership, those are all the common things. There is an excellent study put out now almost a year and a half or so ago from Atkins & Cole in Texas. It really highlighted overall the number of barriers that are out there. Many of them, when you look at it closely, are systems oriented.

Well, I did mention The Joint Commission is much more than accreditation and its standards. What we have recognized is that you have to take a much broader platform in order to precipitate change, and we are doing that through our accreditation processes, our performance measurements, our information, and our public policies. We accredit nearly 15,000 programs.

In regard to Public policy, we've got far more out there than we had thought, and we continue to push that venue as best as we can, and some of these activities, as you can in the presentation material in terms of the number of downloads on policy issues from our website, relate directly to the surgical procedures.

When you look at some of the survey work out there, safety and quality seems to be very much on the forefront of CEOs thinking as well as the usual business parameters of revenue, capital and technology.

Medical staff development is a real bugaboo for many of us, and I alluded to that in some of our sentinel event – wrong site surgery data. We've got at least three generations of practitioners. They all have their own paradigms of what they want out of their care and their practices, and we have to be able to accommodate that. It's not enough just to expect it's going to be one strategy that's going to work for everyone. You could argue that surgeons engagement in safety initiatives is, you know, run like hell. I think that's a little bit false because most of us all really do want to do the right thing, but we find the systems issues often thwarting our best efforts overall, so we have to figure out how to do that.

Some of what we're doing is a hospital based initiative, but I think we need to think about it in the office-based settings. Now we're moving to mirror the six general competencies, including systems based practice, and then we're also focusing on areas of specific care, as well as ongoing evaluation, that includes

talking to the peers of the practitioners in those environments and getting evaluations of what the general sense of their competency is.

Does accreditation really equal safety? I don't think so. I think it needs to be a broad based strategy. It needs to have strong standards, good survey processes and it needs to be ongoing. The results of our unannounced survey process so far have been very, very positive. And most importantly, we need to put in the business case for why institutions and organizations should be following patient safety. We've got some activity going on with the World Health Organization to help build up and justify a business case, both at the institutional level as well as on a larger level, but, overall, I think it's a multifaceted approach. We really do need to do as much as we can collaboratively in this venue to push along these various fronts.

Thank you so much for the opportunity.

Dr. Glinski

Thank you for the invitation to address this important meeting. It's always good to collaborate with multiple aspects of the industry. Represented, we have state societies, physicians, administrators and the four accreditation agencies. I appreciate the comprehensiveness of the topic, and I certainly appreciate the inclusion of all.

I am a physician surveyor with the HFAP organization. I also have a free-standing ambulatory surgi-center in Oklahoma City. It's been in existence since 1984. That's significant because this history brings 20 some years to the table starting with going through the certificate of need process and culminating today with sharing with you some personal experiences including the accreditation journey. After the course, if you'd like, I can share some personal experiences that are relevant to our discussion today.

A little bit about HFAP for those of you that don't really know us that well. We've been accrediting hospitals under Medicare for over 30 years. It's important to realize that we are not limited to osteopathic facilities. It's common that we go into facilities where we are another agency of other accreditation agencies, as requested by the facility. The multiple accreditation choices speaks well of an organization, quite frankly, because they choose to have a cross-section and a broad range of standards in which to comply. And the bottom line winner, of course, is the public.

Currently, our accreditation customers are acute hospitals, that is acute hospitals, clinical laboratories, ambulatory care facilities, surgi-centers, ASCs, such as ours, mental health facilities, and the list goes on.

Certainly, our government recognition is that we've had deeming authority for Medicare/Medicaid and so forth that we share with the other accreditation agencies, as well.

Our other recognition is the National Community of Quality Assurance. Other recognized managed care organizations, and finally the insurance companies.

With respect to patient safety initiatives, in 2005 we adopted 29 of the 2,003 National Quality Forum, the 30 safe practices. In 2007, we had a total of 36 initiatives for acute hospital setting. Now it's important to realize that HFAP ambulatory care and ambulatory surgi-center standards link with the acute hospital standards. They link, thus, clinicians, nurses, administrators who are already familiar with the expectations when carried out into the ambulatory setting. We already have a group of people that are aware, that have an understanding, that understand the accountability, and is a cross section among all three professions.

I have chosen three safety initiatives. They are categories as patient safety initiatives, surgical site infections, medication safety and culture and safety.

With respect to the two surgical site infections, we concentrate on the surgical site infections and the hand washing guidelines. With respect to surgical site infections, "the organization adopts nationally recognized clinical practice standards that are effective, improving patient safety through the prevention of infection. We evaluate each preoperative patient for the risk of an SSI, and implement appropriate antibiotic prophylaxis and other preventive measures. Our hand washing guidelines are that "The facility adopts nationally recognized clinical practice standards that are identified as effective in improving patient safety."

With respect to medication safety, there are four medication standards that I want to present to you. The first is labeling medications and solutions on a sterile field. We recommend labeling medications and solutions regardless of the container used on and off the sterile field throughout the perioperative experience. Implement methods to differentiate and label look alike product solutions with similar names. It also recommends verification and confirmation of each medication solution and the matching label.

The second is standardization of the labeling, the methods for labeling, packaging and storing medications have been standardized throughout the facility to reduce the adverse events. So it's a standardization throughout, throughout the entire organization, that's the goal.

With respect to medication prevention, the facility has a work environment that facilitates attention to detail, promotes accurate filling and dispensing of medication orders. With respect to medication reconciliation, a process is in

place to reconcile medications at each key transitional point of healthcare. For example, upon admission, prepare a list of pre-admission medications, the patient validates the list, the admissions orders are compared against the pre-admission list, the complete list of medication is readily available to all of the prescribers. The complete list of medication is provided to the next unit, service or care setting upon transfer or discharge, adopting the continuity of care concept. And a copy of the complete list of medications is given to the patient at discharge.

With respect to the culture of patient safety, there are seven cultures of safety standards; they are listed in the handout. The first is establishing a culture of safety. We prioritize the safety events to be reported. (b) implement a non-punitive close call reporting system. Third, analyze patient events, and leadership is knowledgeable of the patient safety issues, so important.

Regarding the labeling of radiographs, the implementation there is a standardized protocol to prevent mislabeled or radiographs in the darkroom, flash mark x-ray images with correct patient information, mark left or right and/or on each image.

Informed consent is also an area that we need to consider, the risks, the benefits, the alternative procedures in treatments.

The patient is asked to recount what has been told about the purpose of proposed procedure, and finally, the bilingual sensitivity that I think is so important in our country. The patient assessment includes a relevant history of physical problems, of course, the allergies, the medication, the history and current events. With respect to risk assessment, the elective surgical patients are assessed to identify the levels of risk for acute ischemic cardiac event during surgery, and a high-risk patient receiving prophylactic beta-blocker, all treatment as appropriate. With respect to site verification, I was relieved I didn't see any sentinel events on the eye, by the way, thank you for that, involve the patient with site verification. Mark the surgical site, a process for handling discrepancies. Using the timeout prior to start of procedures to verify the patient identity, the correct side and site, the agreement on the procedure, the availability of the implants and the equipment, equipment in working order, and required documentation is available.

Within that culture, we address the employee health, the influenza vaccine; healthcare workers are vaccinated against influenza to protect themselves and the patients. The vaccinations are made available to all healthcare workers in the organization, and vaccination status is maintained and documented in HR files.

So, what is the advantage of accreditation? Let's cut to the chase. An accreditation organization provides the eyes and the oversight of a safe environment, that's it in a nutshell. The public is assured safety. An accreditation

organization provides standards that are universally accepted as important to provide a quality service and safe patient care.

So why be accredited in the ambulatory environment? It's the right thing to do for a uniform approach to clinical practice and patient safety.

Finally, as CMS discusses the implementation of paying for performance linking to reimbursement, perhaps accreditation perhaps can be linked to reimbursement. Practitioners that hold accreditation are perceived by third party payers and the community as providing a higher level of quality.

I'll be happy to answer any questions during the break, if you so choose, and feel free to contact Mr. Ruther, who's also in the audience, for further information, as well. Thank you very much.

Plenary Session Wrap-up

Dr. Russell

I will just say that I think this was a very enlightening session this morning. I think we've heard from all the key players. I want to emphasize the goals of the conference, you know, to verify the role of accreditation, and can we do this in a collaborative way?

And I was astounded by those statistics that were given earlier that we now accredit about 2,000 of the 40,000 institutions. I mean, that is quite remarkable. I think we are entering into a highly regulated environment. I keep telling myself, I think to do surgery in the future of any type, surgeons and others who perhaps will be delivering surgical services are going to need to have these tickets that's going to allow them to do it. I think it's going to (inaudible) much more regulation. I'm told by surgeons, we're over regulated today, and I think it's just the beginning. And I think that this is the wave of the future, so that's what this session is all about this afternoon. We're going to now break up into groups, and I hope we can do it, I hope the profession can do it. I don't think we should look to the government to do this. This is something, this is our responsibility, this is on our watch, and we have to do it with respect for others, it's just not all about what I do, or what I've done, or what my organization – it's what we should all do collectively. And so I hope that we can really be focusing in on this collaboration and leave behind perhaps biases that we've had in the past about other groups. I've had those and I'm trying to shed those things, I'm trying to get out of what I always thought was the only way to do things. So this is an exciting time.

The concluding segment of the morning Plenary Session was organized as breakout sessions to conduct some preliminary base line planning of what types and kind of actions the four accrediting organizations could begin to take to advance the strategy of accreditation to improve patient safety in the office based

setting. All participants and speakers were assigned to one of four-breakout session with the following charge:

What types of collaborative efforts can the accrediting agencies undertake in the following areas which will advance the level of patient safety in the office based surgical setting and to make fuller use of accreditation as a strategy by which to improve the levels of patient safety in the OBS?

Each breakout group was given one of the following specific charges:

- What research activities could be undertaken by the accrediting agencies given an agreed upon mechanism and system for collecting patient safety and protected adverse event reporting?
- Advocacy activities at the Federal and the State levels may be necessary to affect the acceptance of accreditation as a means of improving patient safety. Given acceptance of this premise what cooperative efforts can the accrediting organizations undertake in the advocacy arena at both the state and Federal levels
- It appears that education of the various interested and involved audiences is needed to improve patient safety and to increase the acceptance of accreditation as a patient safety strategy. At a macro level, what kind and type of education may be needed for each of the following audiences:
 - Physicians
 - Patients
 - Payers
 - Legislative and regulatory bodies (Federal and State)
 - Public and the media
 - Insurance industry
- What can the accrediting organizations, working collaboratively, undertake to project the value and the benefits of accreditation as a patient safety strategy?

Research Activities

The group responsible for this area of study recommended that the four accrediting agencies undertake the following initiatives through a collaborative coalition oriented manner. The scope goals and planned outcomes should be defined initially and the list of activities should be prioritized in such a manner that reflects the importance of the initiative as a foundation to the other recommendations contained in the proposals emanating from this breakout group.

1. Identify “good practice” approaches for safety, outcomes and processes.
2. Develop an evidence-based approach for all information developed by the coalition of the accrediting organizations. If this is not possible than make use of “Expert Opinion Panels”.
3. Evaluate “team oriented surgical approach” in terms of performance, communication and improvement of patient safety in OBS.
4. Track and report on costs and benefits analysis of accreditation
5. Develop a common, standardized, protected and mandatory database that all parties will use for purposes of detailed and aggregated reporting of incidents or “near incidents”.
6. Standardize areas of measure and variable definitions
7. Evaluate the differences between accredited and no-accredited environments within hospitals and outside of hospitals
8. Develop common benchmarking studies
9. Develop methods by which to identify and assess risk
10. Explore ways in which to make data reporting mandatory
11. Develop the methodology for aggregating standardized data
12. Develop multiple pathways by which standardized data can be gathered.
13. Define the manner in which aggregated data will be reported

Accomplish these recommended initiatives through consensus building with all of the accrediting parties. That the inclusive approaches begun with the Conference continue for all follow on work of the coalition.

Education Activities

The breakout group with this assignment focused its deliberations on education for physicians. It recommended that the accrediting agencies develop education programs in a collaborative manner that will address the following issues and concerns physicians have raised with respect to accreditation. Programs are to be developed around the following themes:

1. Demonstrate the advantage of accreditation to surgeons. Address and answer the question of “what’s in it for me?”
2. Provide information on how the structured process of accreditation can be linked to future “pay for performance” reimbursement models.
3. Develop educational programs that deliver the message that this is a way for physician groups to “take back” the leadership role regarding quality and safety.

Advocacy Activities

1. Develop a coalition of the accrediting agencies and professional organizations that would advocate at the state level mandatory accreditation of all out of hospital surgical facilities
2. Incorporate in the advocacy programs patient safety standards designed to protect patients. Go beyond mere facility accreditation.
3. Develop a PR campaign with a non-lobbying focus that will educate legislators, regulators, government agencies, consumer groups and professional associations as a means to advance the role of accreditation as a strategy to improve patient safety.
4. Include in the advocacy program the promotion of state and national reporting of OBS safety data.
5. The missions of all of the accrediting organizations are compatible with advocating and sometimes lobbying for accreditation and patient safety.

Action Planning Session

The intent and purpose of this session was to build upon the suggested initiatives developed in the last segment of the Plenary Session. The intended outcome was to begin the initial development of Action Plans that the accrediting agencies could complete in order to operationalize the identified activities. Since there was not time to address all of the initiatives the breakout groups that identified specific initiatives were asked to prioritize their lists and work on those of the highest priority first.

This section contains a narrative summary of potential action plans and initiatives that the accrediting agencies, working in collaboration could, in the future build upon. As part of the action planning initial draft action plans were developed during the second section of the breakout groups. In most cases these preliminary drafts while not yet ready for this Report will nonetheless form the basis for more in depth strategic and tactical planning by the accrediting agencies subsequent to the Conference.

Breakout Group 1

What research activities could be undertaken by the accrediting agencies given an agreed upon mechanism and system for collecting patient safety and protected adverse event reporting?

Reporting:

Paul Pomerantz, Executive Vice President, American Society of Plastic Surgeons
Breakout Group 1, Chair

Summary:

There was broad agreement that where the energy was, was the need to establish a standardized mandatory protected reporting system for patient safety. We believe that this was needed to support the studies and the data that needed to be done to accreditation. Specifically, to help make the argument that accreditation is – to prove that accreditation is better and safer than non-accreditation, but also to identify the practices and processes that serve to improve patient safety. So, again, our project was development of the standardized mandatory protected reporting system for patient safety.

We had a vigorous discussion about whom the stakeholders were, both for and against. There was a fairly significant list of stakeholders, some obvious, some not so obvious, including on the positive side, patient safety organizations, accrediting organizations, professional societies that we believe would be in support of this, state medical boards. We thought that third party payers would be in support of this. Research agencies, like the Agency for Healthcare Quality and Research, other federal agencies; such as, the Centers for Medicaid and Medicare services would be in support of this. Also, Consumer groups, such as, the AARP, employer groups were considered as positive stakeholders. We actually thought that Leap Frog and other business coalitions could be primary drivers of this when that issue came up. The group suggested that state governors and the information technology industry would be likely to support standards of reporting. The National Quality Forum was listed as a stakeholder, not necessarily as a supporter but somebody who would be a key player in this for us in the AMA physicians' consortium.

Groups who would be in opposition would be negative stakeholders. Potential negative stakeholders were identified. They included the following:

1. Trial lawyers potentially
2. Hospital lobby
3. Some states such as Florida having very specific statutes that provide for very open reporting and public access to data that might work against this kind of a mandatory system.

However, most of the concern identified was the resistance of individual doctors, not their professional societies. They would be concerned about another mandate potentially costly mandate, without the evidence or data to say that this is something that they needed to do.

The obstacles identified included the following:

1. Creating the proposition that would overcome the skepticism that would exist in the provider community.
2. Demonstrating that the data demonstrates what works and why it can't work
3. The cost and the financing of this effort was viewed as a key obstacle; and that

One of the arguments that we would be able to make is that certainly a voluntary approach that preceded a government-mandated approach would be a lot more preferable to the provider community. And, we believed that we would need to demonstrate that it is in the professionals' best interest.

Measures of success were discussed and some preliminary work was done on it. First, there would be contributions of data, from which information will be derived. Reports will be provided to establish baseline standardized measures. Further specific measures should be by the main stakeholders of the research activity.

We talked about a strategy and how we'd move forward. We believe that the first step would be to study what data is actually already being collected, and what the overlap is between the different accrediting organizations, state organizations, and others that are collecting data about office-based surgery.

The second strategy would be to create a data table and consensus process where all the stakeholders could get together to actually develop those data points.

That's as far as we got. Conceptually, we talked about another concept, which would be to work – through an existing system, such as the National Quality Forum, or perhaps another entity that already might have a mechanism, and influence in this particular area.

Other high priority projects were also discussed. These included the study of state processes in facilities for patient safety, to help advance the stakeholder agreement about what processes best serve patient safety.

Breakout Group 2

It appears that education of the various interested and involved audiences is needed to improve patient safety and to increase the acceptance of accreditation as a patient safety strategy. At a macro level, what kind and type of education may be needed for each of the following audiences:

Physicians
Insurance industry

Reporting

Michael Kulczycki, Executive Director – Ambulatory Accreditation,
The Joint Commission
Breakout Group 2 Chair

Summary

We focused on and rank ordered six action steps that our group was charged to deliberate. The charge to our group was to look at education issues focusing on the physician and the liability insurance community. We primarily spent our time on the physician community.

The action steps developed were as follows:

1. Educate specialty societies about an approach, which mandates accreditation for their members.
2. Focus on state medical boards, particularly using existing tools such as the FSMB Guiding Principles and the AMA Principles, both of which call for accreditation in lieu of regulation in the office-based setting.
3. Focus on culture change for the upcoming physician community to look at residency programs, fellowship programs, and medical schools.
4. Educate physicians on the proposition of what's in it for them, by trying to link accreditation as a structure, a groundwork that gives them the ability to be better able to respond to future requirements for performance measurement in a Pay for Performance environment.
5. Educate the two communities (physicians and liability insurers) with is the fact that we need better data, and one way to have that is have each accrediting body mandate data collection as part of the accreditation process.
6. Target liability insurance companies, although those efforts actually got folded into some of the other efforts.

Some of the things that this would accomplish would be to dispel myths about the accreditation process. We suggest an approach that models current successful examples. Any physician education model should focus on the following aspects:

1. Improved physician image.

2. Accreditation is a more cost effective approach than liability and malpractice situations.
3. The value of self-regulation versus government mandate
4. The AMA's work on its core principles for office-based surgery facilities.

Breakout Group 3

Advocacy activities at the Federal and the State levels may be necessary to affect the acceptance of accreditation as a means of improving patient safety. Given acceptance of this premise what cooperative efforts can the accrediting organizations undertake in the advocacy arena at both the state and Federal levels

Reporting

John Burke, Executive Director, Accreditation Association for Ambulatory Health Care (AAAHC)
Chairman, Breakout Group 3

Summary

We began our discussion with a quote that lobbying and advocacy may be an agency's best service to its constituency. That being said, there was considerable discussion on the proper role of accrediting bodies in lobbying and advocacy. It was generally agreed that it's in the interest of our respective missions to advocate and sometimes lobby on behalf of accreditation and patient safety. Our group also agreed that more research and available data at the national level is required to reinforce the important role of accreditation in OBS patient safety.

Our group's recommendation is to form a coalition involving the accrediting organizations and other natural stakeholders to advance the role of accreditation in patient safety.

The coalition should explore the following two strategies:

1. Establish a rapid strike force that would include a combination of both lobbying and public policy activities on specific issues, particularly focusing on the states.
2. Explore a national public policy PR campaign with a non-lobbying focus to educate legislators, regulators, government agencies, and perhaps consumer groups, as well as the professions themselves on the value of accreditation and patient safety.

We added a couple of caveats. One plank in this campaign may be to include the promotion of state and national reporting of OBS safety data. And another plank may be to form a taskforce or a subgroup to look specifically at the economic impact of patient safety issues, i.e., the cost of complications.

Breakout Group 4

What can the accrediting organizations, working collaboratively, undertake to project the value and the benefits of accreditation as a patient safety strategy?

Reporting

George Reuther, Director, Health Care Facilities Accreditation Program, AOA
Chair, Breakout Group 4

Summary

The guidewords of our session were those at the conclusion of the Plenary Session. They were “cooperation, collaboration and coalition”.

We decided that we would work with positive stakeholders, which included the four accreditation organizations and every organization that is represented here today. Then, we want to expand that to other groups. Moreover, we wanted to do pretty much what everyone else wants to do, create a coalition that is going to drive this process forward.

We discussed who would be positive stakeholders in this initiative. Among them would be anesthesiology associations, SOHN, the ACR, CRNA, the ASPN group, insurance carriers, malpractice carriers, and all the other groups that we could solicit. We want this to be an expanding coalition. We believe that we could come up with a name for the group. Someone suggested the Accreditation Consortium Team, or ACT, so we could all begin to act or act out.

We think that negative stakeholders might include state medical associations, and approximately 38,000 non-accredited physicians around the country, and perhaps some insurance carriers. They might give us a little bit of pushback, and so we felt that it would be important to gain the cooperatives – cooperation of all the associations here today.

The following were the action steps that we thought we should take:

1. Formalize what we have accomplished here today with the reporters coming up with the final notes of today’s activities.
2. Create a summary so that each of the organizations that are here today can take those back with a recommendation to their parent organizations for adoption and to support.

3. Follow that activity with soliciting and inviting other societies and organizations to join us in this activity, and then we would formally announce to the press the complete coalition announcing the activities that we intended to embark on, on behalf of public patient safety.

Such a press release that you want we free the coalition from trying to market it to all the millions of people that worry about going to the doctor all the time. We think if you do this as a press release, the press will notice this, it will be a positive thing for all the medical societies, and it will carry itself and carry its own weight.

The specific action plans developed by the breakout groups is presented in a planning template form in Appendix A. These plans are in their initial stages of development and will need to be completed subsequent to the Conference.

Conference Wrap-Up and Summation of What Was Learned, Accomplished and Identification of “Next Steps”

Drs. Singer and Russell presented the Conference “Wrap-Up and Follow-Up”

Dr. Singer

First, I would like to point out that I think all of the accrediting agencies; organizations have done a very good job. That has become clear today. The question before us is, “Can we do a better job and can we move forward?” I think the answer to this is “Yes, we can do better and we can move forward together” That is very clear to me.

Some of the things that have come clear to me are as follows:

1. There should be minimal requirements for any surgical facility that's doing anything beyond local anesthesia
2. To support that argument, we need common data; we will not get it unless it is mandated.
3. We do not have to rediscover the wheel of developing that data. There are mechanisms to look. In addition, we should look at improving those and perfecting those.
4. Any collection and reporting system needs to be not too complex, it needs to be not too expensive, and needs to be sensible so the facilities will comply and use it.

The issue of how to collect it, where to store it, is a minor thing. If we come away with the fact that we need the data, we can come up with the bright leadership of where to do that.

The last thing I kept hearing is cooperation and coalition. I think it needs, as we just heard, to be inclusive of the groups that are here and groups that are not here who are stakeholders. However, I would suggest that it not be too broad, too soon, so you have some modicum of control of where it is going to go. You can achieve more in states with cooperation than individually, or trying to be exclusive. The organizations have always tried to get a competitive edge for the small number of groups that are accredited across the country, missing the point that the vast numbers of facilities are unaccredited and it is in everybody's best interest to urge accreditation for everyone, and there is enough room for all of the players.

Before I turn this over for the final wrap up, I would like to compliment Jeff Percy, who is Quad A and quadruple A SFEF's Executive Director. When he first brought this to me and saying we can do this, we can bring this Summit together. I said, yeah, well, it has been tried before, I doubt it can be done. Well, I

am astounded. It not only was done, it achieved more than I ever thought it could be done. Moreover, it could not have been done without Larry Rosenthal's group who really oversaw it, and I think he deserves a tremendous round of applause.

When I made my introductory comments, I said you have to put your egos aside personally and organizationally. Now, I compliment you all on doing just that. I think what came out that I've heard of recommendations are so far beyond what anybody here expected coming in, we weren't sure we were even going to talk to each other, and here we came out with an idea that it needs to move forward, it needs to cooperate, and now we're going to hear what the next step is so we have some fruition to this so it doesn't evaporate after we leave the room. So I would like to compliment all of you, you all deserve a round of applause, and thank you.

Dr. Russell

I think we accomplished a good amount today. We all came together. I was impressed that in the sessions, people were not coming at it just from their viewpoint. They were trying to open up their eyes and their vision to a view that perhaps it is better to focus on the big issues of today rather than coming out as a small group.

In 2004 and 2005, we got these groups together and not much happened, At least the groups did come together. I think now this is another effort to move this agenda. The fact that you all came today and we talked about the issues I think is very important. Here is what I got out of the report summaries

1. There is a lot of unanimity of opinion around standardizing an effort to have mandatory reporting for ambulatory units and office-based units; I think that came through loud and clear.
2. I think the need for education is going to be very important, not only for the policymakers and so on, but also we need to do a lot of education amongst ourselves because not all doctors see it this way.
3. We have to be really be inclusive, that is another thing that came out of this. We were not totally inclusive today, there are some groups that are not here that need to be here, and I think the more, as we go forward. There are lots of other forces out there that are trying to do similar things, and we have to get a hold of that.
4. Another thing that came through is this cannot be mandated, we have to do it through education and through getting people to understand what we are trying to do. There is a need for public relations and reaching out to state and federal authorities about what we are trying to do. We have got to do this ourselves.
5. This is a professional obligation. It is not something that we should expect the government to do. It is our business, this is what we do, whether you are doctors or administrators of these activities, this is our

business and this is our absolute responsibility. If we do not do this, we have abdicated on a very important part of what we are all about.

The most important thing that I am thinking about as we wind up here is what is the next step? I don't want this to fizzle out, perhaps it didn't fizzle out, because we had to start somewhere in 2004 and then again in November of 2005 but what's going to be the next step so that we have some momentum and we can keep this going?

I think that that is the thing that we should focus on right now is we need to leave this room with some concrete plan to do something, and I would be open to any suggestions. I have some personal ideas, but as the moderator, it is not necessarily my role to do that, but does anybody have a concrete idea about what might be the next step?

Discussion ensued at the conclusion of Dr. Russell's remarks. The following summarizes the discussion and proposes actionable next steps for this effort.

George Reuther: I think that group 4 gave you a suggestion that you summarize what you have accomplished today and you send that out to us so that we can get endorsement from our parent organizations so that you know you have a solid group supporting everything we have talked about. In addition, when you do that, then you can offer that same document to additional groups and get their buy in. They do have a real large working group that can bring this forward.

Dr. Russell: Let me propose the concept of perhaps forming a smaller group, perhaps the execs of the four accrediting agencies getting together at some location in the foreseeable future to bring this further along. Let me suggest that. Is there any support for that idea?

Dr Keyes: Over lunch, one of the things that Michael Kulczycki, George Reuther, John Burke and I, talked about was that, just that. We need to get together some time within the next 30 days, along with Larry, to be able to identify both what the next steps have to be, what the consistent message has to be that we take back to the leadership of our organizations, and what we can do as execs of the four accrediting bodies to move this along.

Dr. Singer: I am going to suggest that, to take it out of the realm of just any organization of the accrediting organizations. I think it is important that you have a neutral broker, and I think that the College of Surgeons would be ideal. If Tom is willing to do that, I think that would be the proper format for doing that, bring it under that umbrella of meeting there. That does not have to be where it ultimately resides or the data or anything else, but at least for the next step, and I

think that it is important that Larry, who really facilitated this, be part of that, so that is what I would propose.

Dr. Russell: Well, certainly the American College of Surgeons is neutral. However, it is not neutral about is we want to promote patient safety.

The idea of getting a coalition now, beginning the movement, rather than just letting this drop, that we get the executives from these four accrediting agencies that were here today, and get them together, and the American College of Surgeons would be happy to use our facilities here in Chicago to host that meeting with no further strings attached, it's just something that we would facilitate the next step of this effort today.

All in favor of that. There was no opposition to the proposed meeting of the executives of the four accrediting agencies with Drs. Russell and Rosenthal.

A suggestion was made that some organizations near to O'Hare would also be willing to offer their facilities for future meetings.

Dr. Russell: Okay, well, very good. I appreciate everybody coming, and so let us go our own ways and we will work on this next effort to bring the coalition together. Thank you.

Appendix A

Conference Attendees and Participating Organizations

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| 1. Participating Organizations | 56 |
| 2. List of Attendees and Organizations | 57 |

Participating Organizations
Agency for Healthcare Research and Quality - AHRQ
Accreditation Association for Ambulatory Health Care - AAAHC
American Academy of Dermatology - AAD
American Academy of Facial Plastic & Reconstructive Surgery - AFPRS
American Academy of Orthopaedic Surgeons - AAOS
American Academy of Otolaryngology/Head and Neck Surgery - AAO/HNS
American Association for Accreditation of Ambulatory Surgical Facilities - AAAASF
American Association of Nurse Anesthetists - AANA
American Association of Oral and Maxillofacial Surgeons - AAOMS
American College of Foot and Ankle Surgeons - ACFAS
American College of Obstetricians & Gynecologists - ACOG
American College of Surgeons - ACS
American Medical Association - AMA
American Society of Aesthetic and Plastic Surgery - ASAPS
American Society of Anesthesiologists - ASA
American Society of Plastic Surgeons - ASPS
American Urological Association - AUA
Association of Perioperative Registered Nurses - AORN
Clarian Health Partners
Federation of State Medical Boards - FSMB
Florida Board of Medicine
H. Lee Moffitt Cancer Center
Healthcare Facilities Accreditation Program - American Osteopathic Association
Indiana Professional Licensing Agency
The Joint Commission
Medical Group Management Association - MGMA
Missouri Center for Patient Safety
Patient Safety Education Foundation - PSEF
Patient Safety Institute
Pennsylvania Medical Association
Renal Physicians Association - RPA
Society for Ambulatory Anesthesia SAMBA

Participants/Organization
Barbara Anderson American Association of Nurse Anesthetists
Peter Angood, MD The Joint Commission
William Brady American Academy of Dermatology
Gary Brownstein, MD American Association for Accreditation of Ambulatory Surgical Facilities
John Burke Accreditation Association for Ambulatory Health Care
Gary Caruthers Kansas Medical Society
Paul Collicott, MD American College of Surgeons
Richard D'Amico, MD American Association for Accreditation of Ambulatory Surgical Facilities
Bonnie Denholm, RN Association of Perioperative Registered Nurses
Stephen Duffy American Academy of Facial Plastic and Reconstructive Surgeons
Felmont Eaves, MD American Society of Aesthetic and Plastic Surgery
Richard Gentile, MD American Academy of Facial Plastic and Reconstructive Surgeons
Edward Glinski, DO Healthcare Facilities Accreditation Program of American Osteopathic Association
Alan Gold, MD American Association for Accreditation of Ambulatory Surgical Facilities
Christopher Gonzalez, MD American Urological Association
Meg Gravesmill Accreditation Association for Ambulatory Health Care
Roy Grekin, MD Accreditation Association for Ambulatory Health Care

Roxanne Guy, MD American Society of Plastic Surgeons
Phil Haeck, MD American Association for Accreditation of Ambulatory Surgical Facilities
Terry Hammons, MD Medical Group Management Association
C. William Hanke, MD American Academy of Dermatology
Robert H. Haralson, MD American Academy of Orthopaedic Surgeons
Ronald Henrichs American Academy of Dermatology
Elizabeth Hoy, MHA American Academy of Otolaryngology/ Head and Neck Surgery
Robin Hudson American Urological Association
Ronald Iverson, MD American Association for Accreditation of Ambulatory Surgical Facilities
Ramon L. Jimenez, MD American Association for Accreditation of Ambulatory Surgical Facilities
Girish P. Joshi, MD Society for Ambulatory Anesthesia
Carolyn Kerrigan, MD Patient Safety Education Foundation
Geoffrey Keyes, MD American Association for Accreditation of Ambulatory Surgical Facilities
Clifford Ko, MD American College of Surgeons
Brigid Krizek, RN American College of Obstetricians and Gynecologists
Michael Kulczycki – The Joint Commission
Sonam Kundeling, MD Renal Physicians Association
Carolyn Kurtz, JD Accreditation Association for Ambulatory Health Care
Naomi Kuznets, Ph.D. Accreditation Association for Ambulatory Health Care
Stacy Lankford, MD

Federation of State Medical Boards
Leo LeBel, CRNA, JD American Association of Nurse Anesthetists
Julie Letwat American College of Foot and Ankle Surgeons
Chris Mahaffey American College of Foot and Ankle Surgeons
Walter Maurer, MD Society for Ambulatory Anesthesia
Larry McPherson Florida Board of Medicine
Roger Mecum Pennsylvania Medical Association.
Becky Miller Missouri Center for Patient Safety
Donald Miller Bethseda Naval Hospital
William Munier, MD Agency for Healthcare Research and Quality
David Nielson, MD American Academy of Otolaryngology/ Head and Neck Surgery Foundation
John O'Leary American Society for Aesthetic and Plastic Surgery
Anne Oteham, RN Clarian Health Partners
Sandra Peters American Academy of Dermatology
Beverly K. Philip, MD BWH - Anesthesiology
John Pitman, MD American Association for Accreditation of Ambulatory Surgical Facilities
Paul Pomerantz American Society of Plastic Surgeons
Lawrence S. Reed, MD American Association for Accreditation of Ambulatory Surgical Facilities
Robert Rinaldi, PhD American Association of Oral and Maxillofacial Surgeons
Michael Rinebold Indiana Prof. Licensing
George Reuther Healthcare Facilities Accreditation Program of American Osteopathic Association

Karen Richards American Association of Oral and Maxillofacial Surgeons
Delaine Schmitz American Society of Plastic Surgeons
William Seward American Society of Plastic Surgeons
Robert Singer, MD American Association for Accreditation of Ambulatory Surgical Facilities
Patricia Sokol, RN, JD American Medical Association
Paul Stumpf, MD American College of Obstetricians and Gynecologists
James Thomas, DPM American College of Foot and Ankle Surgeons
Dennis Thompson, MD American Association for Accreditation of Ambulatory Surgical Facilities
Margaret Toepp, PhD American Medical Association
Hector Vila, MD Moffitt Cancer Center
Karin Wittich American Association of Oral and Maxillofacial Surgeons
David A. Wong, MD American Academy of Orthopaedic Surgeons
James Yates, MD American Association for Accreditation of Ambulatory Surgical Facilities

Appendix B

Plenary Session PowerPoint Presentations