AAHIVM Talking Points

Up Your Activism – Improve Your Outreach

The past year has been a very busy one for the Academy as it continues its mission of promoting excellence in HIV/AIDS care. The Academy has achieved recognition for professionals in HIV care and continues to act as a dynamic resource for HIV practitioners, providing essential services and information for those working on the front lines of HIV medicine.

Many members have approached the Academy wanting to know how to take a more proactive role in the organization. You have told us that you are keen to talk with your peers about the Academy and its mission but often find yourselves asking, “How do we describe what the Academy does?”

The Academy has developed a set of talking points to help you communicate the activities, programs, and initiatives of our organization. Talking points are illustrations of the most important things you want your audience to remember about your message. For the Academy, the core message of the talking points outlined below is the importance of continually improving the quality of HIV care and increasing access to that care.

We have developed talking points to provide you with the information you need to encourage others to assist in the Academy’s mission of promoting excellence in HIV health care. You can use this information as a tool in encouraging your peers to join the Academy and/or credential as an HIV Specialist. In addition, you can use this information to help educate public policy leaders, members of AIDS service organizations, and anyone else who may be interested in the Academy and our mission.

Use the talking points outlined below in all communications with those interested in the Academy’s cause. We have designed these talking points to support the idea that a national standard for quality HIV care, and increasing access to this high-quality care, should be a much higher national priority.

**Talking Points**

The Academy is working to improve the quality of HIV care, and to increase access to that care, in many ways:

**The Academy has helped improve the quality of HIV care by**

- Establishing a national standard of care through its Core Curriculum, a list of more than 200 Learning Objectives updated annually that together define the minimal knowledge needed to qualify as an HIV Specialist
- Creating and sustaining an HIV Specialist credentialing process to recognize HIV medical providers who possess up-to-date knowledge of HIV care
- Providing vital tools for HIV medical providers, including patient handouts, conference listings, a Job Bank, and practice management information
- Organizing advocacy and educational efforts for HIV medical care providers at national and state levels
- Maintaining a searchable national listing of HIV health care providers and credentialed HIV Specialists at its Website (www.aahivm.org) to link HIV patients to qualified providers
- Continuing to work to ensure the viability of HIV practices in maintaining and expanding access to health care
- Centralizing critical educational resources and providing needed practice support
- Assembling and continually updating a study guide containing clinical and factual data for the entire Core Curriculum

**The Academy’s Mission**

The American Academy of HIV Medicine is an independent organization of HIV Specialists and others dedicated to promoting excellence in HIV/AIDS care. Through advocacy and education, the Academy is committed to supporting health care providers in HIV medicine and to ensuring better care for those living with AIDS and HIV disease.
The Importance of External Validation and New Proposals on HIV Specialists

Changes in Our Definition

In September 2002, the Academy Board chose to simplify the definition of an HIV Specialist (see chart on page 3). In the process, the Academy retained the three crucial elements needed to demonstrate professional development: experience, education, and external validation.

Most of the current definitions of an HIV Specialist incorporate some combination of Continuing Medical Education (CME) units and clinical experience as the key criteria in evaluating knowledge and clinical competency. Like IDSA’s HIVMA and many other organizations’ definitions, the Academy’s definition incorporates experience with HIV patients and ongoing education, and requires that frontline providers who wish to be considered HIV Specialists meet these qualifications on a recurrent basis.

The Academy’s Difference: The Importance of External Validation

The Academy’s definition uniquely incorporates a component for external validation through our exam, which is heavily based on the most recent Learning Objectives of the AAHIVM Core Curriculum, and evaluates a provider’s up-to-date knowledge on HIV care. While this component of external validation is unique in the area of HIV medicine, it is certainly not unique in medical education.

Updates on the Specialty of HIV Medicine

While the Academy continues its credentialing efforts, IDSA’s HIVMA has announced that they are supporting and working toward creating a certificate of added qualification (CAQ) for HIV medicine. In December, at a meeting of the Forum for HIV Collaborative Research on the quality of HIV care, Dr. Daniel Kuritzkes announced the details of that process. Specifically, an application will be written and submitted to the American Board of Internal Medicine (ABIM). For ID-certified providers, they propose strengthening the HIV portion of programs around the country. For non-ID internists, the proposed changes include an additional one year fellowship in HIV Medicine and a board exam. So, in the future, to practice as an HIV Specialist, you would have two choices: either choose ID and pass the new strengthened program, or complete a residency in Internal Medicine plus an additional year of HIV fellowship and pass the board exam. This proposal would exclude NPs, PAs, and physicians who are not board-certified, and is likely to exclude Family Practitioners.

The Academy continues to support and advocate the formation of an HIV Specialty and welcomes new approaches. It has always been a priority of the Academy to

In fact, our intent is to lower barriers to entering HIV medicine by providing direct access to up-to-date knowledge and a credentialing process to provide external validation of that knowledge.
increase the number of HIV medical providers, and we have worked to provide tools and mechanisms to do so. It is our concern, however, that over time IDSA's proposal could actually decrease the number of HIV medical providers, because internists would be required to take additional education, and because of the exclusion of many others. This does not coincide with the goals of the Academy to improve the quality of HIV care and increase access to that care.

Depending on the source of the estimate, ID physicians currently account for approximately one third of the total HIV medical providers in the U.S. Any policy that limits the number of skilled practitioners of HIV medicine will have an impact on the availability of care. The Academy’s definition of an HIV Specialist is not intended to limit access to care for patients with HIV or to exclude experienced practitioners from providing care to HIV patients. In fact, our intent is to lower barriers to entering HIV medicine by providing direct access to up-to-date knowledge and a credentialing process to provide external validation of that knowledge.

To date, more than 1,000 providers have obtained the HIV Specialist designation through the Academy. As always, the Academy welcomes suggestions on its credentialing process as it continues to move forward with its mission.

The Academy is supported by unrestricted grants from our sustaining donors:

Academy Definition of an HIV Specialist

The Academy's full credentialing requirements for an HIV Specialist are as follows. Credentialing requirements must be met every two years:

- Maintain current and valid M D, D O, PA, or N P state licensure
- Provide direct, continuous, ongoing care for at least 20 H I V patients over the past two years
- Complete at least 30 hours of H I V-related C M E Category 1 credits* over the past two years
- Successfully complete the AAHIVM H I V Medicine Credentialing Examination at time of application

* CEUs for NPs. Any accredited training program over the past year will substitute for C M E.

How Many Times Have You Heard the Word HIPAA?
And . . . What Can You Do to Prepare for It?

We all know that privacy rules will have to be implemented in medical practices soon, based on the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Still, many will be caught off guard. Don’t let your practice be one of them. Before time runs out, your office manager should investigate and work toward developing a plan to be in full operation by April 2003. But don’t wait until then to expand your employees’ awareness and basic knowledge.

Yes, you will need to develop and adhere to a manual of privacy policies and procedures. New forms will be implemented, such as a notice of privacy practices, patient consent and authorization forms, request for limitations and restrictions of protected health information (PHI), request to inspect and copy protected health information, request for amendment of PHI, business associates contracts, and so on.

However, nothing will be as crucial as your employees’ understanding of what patient confidentiality and privacy mean.

When we train medical office employees, we teach them a golden rule:

- Common sense is not so common.

Use your common sense!

Here are some examples:

- Dr. Smith’s nurse calls her mom with the exciting news that her sister-in-law came to the office and had a positive pregnancy test.

- A receptionist calls a friend to share that a celebrity came to her doctor’s office. The physician is an HIV physician. The conclusion is made that this celebrity is infected or has been in contact with HIV.

These two people had access to this privileged information in the course of their employment, and their actions are definitely a breach of confidentiality. Do their employers have a confidentiality agreement in place? Are the employees aware that what they said might result in termination of employment?

New employees and volunteers should attend an orientation session to understand the ethical responsibility of maintaining patient privacy. Employees and

...See Prepare for HIPAA on page 7
Physician Liability for Failure to Obtain Informed Consent for HIV Drug Therapy

Thomas J. Bradley, JD; Helene G. Bradley, JD; and Brian A. Boyle, MD, JD

American common law has long recognized that all patients have a right to determine what will or will not be done to their bodies. Accordingly, before any medical therapy, a patient is entitled to be provided with information that he or she can use in deciding whether or not to consent to that particular course of therapy. The legal name for this concept is the doctrine of informed consent.

The doctrine of informed consent necessarily encompasses two separate concepts: (1) that there must be consent to any medical treatment, and (2) that the consent provided by the patient must be an informed one. Consent is usually considered invalid if it is obtained from a patient who did not receive all of the relevant and applicable information that would have allowed him or her to make an informed decision. Physicians who treat patients and who do not obtain informed consent from the them may subject them to liability. The purpose of this article is to discuss informed consent in the particular context of HIV drug therapy.

Informed Consent and HIV Therapy

Physicians treating HIV patients with drug therapy face heightened exposure for liability based on failure to obtain informed consent. Although the occurrence of side effects and toxicities is a known risk with any type of drug therapy, overall, the incidence of side effects and toxicities is somewhat greater with HIV medications compared with others.

Although the drugs used to treat HIV infection usually confer considerable benefit and extend life expectancy, they also have significant potential for side effects and toxicities, which at times can be fatal. Adequately informing patients of the potential risks and benefits of antiretroviral therapy presents unique and special challenges for HIV practitioners.

Of course, as a starting point, the mere occurrence of side effects or toxicities does not by itself create liability for the practitioner. Under certain circumstances, however, patients may be able to pursue a liability case against a practitioner when (1) they have suffered an injury as a result of a medication side effect or toxicity and (2) that medication side effect or toxicity was not brought to their attention by the practitioner such that they could provide informed consent to the therapy. Although standards vary from state to state, generally speaking, in most states, the practitioner must advise a patient of the risks and benefits of, and available alternatives to, a proposed plan of drug therapy. In assessing whether the practitioner should be held liable for failure to obtain an informed consent, the courts generally consider three basic issues: (1) whether the particulars of the situation imposed a duty to disclose upon the practitioner; (2) which particular risks, benefits, and alternatives should have been disclosed; and (3) assuming that the practitioner did breach his or her duty to disclose based on these two criteria, whether that breach was the proximate cause of the injuries sustained by the patient.

Tests for Liability

The particular tests for determining liability vary to some degree from state to state. The two primary models used are the “prudent patient” and the “prudent physician” models. The former focuses on the information that a reasonable patient would require, and the latter focuses on the standard of practice of physicians in a particular community. Both models objectively determine proximate cause—that is, a jury must determine whether the particular patient involved in the lawsuit would have consented to the procedure, but rather, whether an objective, “reasonable patient” would have done so.1 However, a minority of courts have used a subjective test for proximate cause (i.e., whether the particular patient in question would have consented).2

As discussed above, medical practitioners clearly have a duty to disclose to their patients the known risks of a drug before prescribing it; in fact, it should be assumed that the mere fact of writing a prescription imposes such an affirmative duty. The thornier issue is to determine exactly which risks, benefits, and alternatives must be disclosed. The law requires that all material information be disclosed. Materiality, to a large degree, requires the application of common sense to the situation. As a general rule, prudent practitioners should ask themselves what information they would like to have in order to decide whether to begin a particular course of drug therapy. Although extremely rare side effects or toxicities have been held by the courts to be immaterial by their nature, the likelihood of the occurrence of a side effect or toxicity as well as its potential severity is a
critical factor that bears heavily on the determination of materiality.\(^3\)

**Precautionary Measures**

Practitioners may take several precautions to limit their exposure to liability for failure to obtain informed consent:

*Provide complete information.* Err on the side of providing too much information rather than too little.

*Keep a written record of information given.* Make a record of the specific risks, benefits, and alternatives of which they advised the patient. At trial, it is much more persuasive to a judge or jury to produce a medical record made at the time the advice was given to the patient, rather than to rely on the practitioner’s recollection of what was said during an office visit, which may have lasted only a few moments and may have taken place several years before the trial. If, as is strongly recommended, notations concerning the advice given are made in the patient’s chart, they should be detailed. Avoid conclusory notations such as “patient advised of risks of medication.” The better practice, as well as the better protection, is to record details of the particular risks, benefits, and alternatives disclosed.

*Provide printed materials.* Practitioners should also consider providing patients with copies of materials the practitioners have drafted themselves or have culled from medical journals concerning the known risks of a particular course of drug therapy. A copy of a drug’s package insert can also be provided, although its technical language may require explanation. A patient to whom such material was provided will face a difficult time proving that he or she was not adequately advised before embarking on a course of treatment. It may also be advisable to develop a standard list of risks, benefits, and alternatives provided to patients for those HIV-related drugs or therapies that are frequently prescribed.

*Develop standard informing procedures.* The development of habits and routines will greatly aid practitioner in recalling whether the proper information was given to obtain informed consent. Practitioners may then testify as to their habits and routines, even though they may not recall all the details of an individual office visit, and may confidently and truthfully testify that they must have advised the patient in a particular manner because it is their standard practice to do so.

*Provide information on alternative therapies.* Because so many of the more commonly prescribed HIV drugs have serious side effects, it is incumbent on the practitioner to provide adequate guidance about less risky alternatives. Failure to consider and discuss more conservative courses of treatment invites a finding of malpractice, as the following case demonstrates.

In *Hutchinson v. United States* (91 F2d 560 [9th Cir. 1998]), a physician had prescribed the steroid prednisone for a patient with an asthmatic condition. It is well known that the use of prednisone involves a risk of the development of aseptic necrosis, which in this case did in fact develop. The theory of liability advanced against the prescribing doctor was that he failed to advise the patient that other drugs with far fewer risks of side effects were available for the treatment of the condition. Although the trial court ruled in favor of the physician and found that the reasonable patient would have consented to the use of prednisone, whether or not he was advised of the availability of more conservative drugs, the appellate court reversed that ruling. The appellate court found persuasive the evidence that the patient previously had obtained good results from more conservative drugs. Had the physician advised the patient more fully of the potential side effects of prednisone and offered the patient the opportunity to continue with the more conservative course of treatment, the doctor might well have avoided liability in this case.

This legal principle will almost certainly be applied to the prescription of HIV medications. Much like the medical principle of “First, do no harm;” this legal principle directs that if treatment outcomes are relatively equivalent, health care providers should prescribe the medications or regimens least likely to cause toxicity, especially in the case of medications whose toxicities may be severe or life-threatening. All HIV medications have some side effects or toxicities; however, patients and practitioners alike recognize that some carry higher risk than others. Some cases have already been filed regarding the use of HIV medications that have caused severe, life-threatening rash or hepatotoxicity, and others are certain to follow.

*Obtain a thorough patient history.* The unique side effects associated with some HIV medications also require that a physician obtain an extremely thorough medical history regarding the patient’s prior experiences with particular HIV medications. Without that knowledge, the practitioner may be unable to effectively advise the patient of particular risks. For example, certain antiretrovirals such as abacavir have the potential for a catastrophic reaction upon rechallenge. Practitioners will be unable to communicate effective advice regarding this risk if they are unaware that the patient had prior therapy with that particular medication. In other words, the risks are different for drugs whose effects depend on the patient’s past history with them. Obtaining the needed history can be difficult at times because patient memories often lapse, and some medications may come in combinations of which the patient may not be aware. Given this, it is incumbent upon the practitioner to obtain information the patient may not have. These efforts should include, at a bare minimum, asking the patient detailed questions regarding past medical therapy, showing the patient all of the involved pills in order to refresh his or her memory, reviewing medical records, and obtaining information from all physicians who previously cared for the patient.

The principles outlined in this article are general legal principles that provide some guidance regarding medical liability and appropriate steps that may be taken by health care providers to decrease their risk of malpractice litigation. Of course, the law is slightly different in every state, and for details of a particular state’s law one should consult a local lawyer. The abiding principle for both improving patient care and avoiding liability should be disclosure of all relevant information so that the patient can make an informed decision regarding treatment options.

For further information about this topic or for questions regarding the contents of this article, please send correspondence to TJBradleylaw@aol.com.

**Notes**

Renslow Sherer, MD, senior physician at the old and now the brand-new Cook County Hospital, Chicago, was there at the beginning of the HIV epidemic. And, he says it’s up to experienced providers like himself to make sure the newcomers put today’s trends in perspective.

“We’ve gone from managing a uniformly fatal illness – where we were organized to do things like arrange memorial services every few months, help with palliative and hospice care, and offer spiritual guidance and some relief from suffering – to being medication technicians,” he tells The Nexus. “We’re having great success, but the transition has changed the nature of our relationships with our patients.” Their expectations, he explains, have changed to the point where HIV-positive patients, “expect, if not a cure, at least long-term relative health and progress in reducing the toxicities of the medications and the frequency and number of pills in a regimen.”

Today’s veterans also have a duty to pass what they’ve learned on to a new generation of physician leaders, Sherer points out, so that their educational and practice management expertise can help lower the entry barriers to becoming an HIV Specialist. “It’s remarkable how often I tell stories of the dark early days of AIDS to ensure that young physicians remember how bad it was and how far we have all come,” he says. “This is an important responsibility for those of us who were there at the beginning of the epidemic. It’s equally important to impress young physicians with the growing complexity of HIV care through structured training, such as the self-learning modules in the Academy’s HIV Medicine Self-Directed Study Guide. A commitment to master HIV medicine is a serious one.

It was during just his second month as a general medicine attending in 1982 that Sherer saw his first patient with Pneumocystis pneumonia. “We were watching what was happening on the East and West coasts. Within several months, we began to get referrals and calls about young men with generalized lymphadenopathy.” That’s when he and Ron Sable, MD, “an activist in the gay community and a physician at County,” started what they called the Sable-Sherer Clinic in General Medicine within the hospital. It was so named, he notes, “so it wouldn’t be known as an ‘AIDS clinic’.”

That happened in May of 1983. “We had 140 patients in the first three years. Then came the rapid escalation, and by 1987 or so we had 1,600 patients. In those early years we saw the full spectrum of HIV patients. We had a large Haitian population, injection drug users, women, and an infant born to one of the Haitian women, which was clearly a case of heterosexual transmission. Like so many other places, we did the best with what we were seeing.” A large part of the clinic’s success, he emphasizes, “was due to Ron Sable’s reputation in the gay community. For indigent gay men in Chicago, it was the only place to go.”

The clinic was a template for many of the HIV services organizations operating today. “We did community outreach fairly early. We started a volunteer support service and offered prevention counseling and then testing when it became available. We also provided HIV prevention counseling in the walk-in screening and STD clinic at the hospital, and were among the early providers to make a link between prevention and care.” The clinic was part of the original demonstration project that preceded the 1989 Ryan White CARE Act.

“Long before the act came into being,” he recounts, “we at County and others learned that the best outcomes for our patients were gained by addressing the expressed needs of patients. In a public hospital system, that often meant assisting with the basics of life, such as food, housing, and transportation. The act was conceived with that experience in mind, and built upon by providing support for those services, along with primary medical care, that otherwise were unavailable to patients.”

The act, he adds, “enabled us all to learn how to manage and improve those services alongside existing health systems that were often dysfunctional and ill-equipped to handle the unique needs of people living with HIV. We were able to put the money where it was most needed, in primary care and support services. It was really very gratifying. The CARE Act had a huge impact here, as it did in most public hospitals and clinics.” He and his colleagues also quickly developed programs in each title of the act, including programs for women and
children under Title IV and HIV prevention programs for detainees at the Cook County jail under Title III.

The county government was “extraordinary in responding to the epidemic,” says Sherer. “They’ve responded to the HIV epidemic right from the beginning.” He points out that the space and facilities were no longer adequate to meet the need, the County partnered with Rush Medical College to develop and implement the CORE Center.

The CORE Center is a freestanding facility for the care, prevention, and research of HIV and related infectious diseases. Sherer terms it “a caregiver’s dream come true.” It has mental health services, case management, drug treatment, child daycare, complementary therapy, and STD screening all onsite. In addition, the center offers a volunteer area, a large conference and training area, and research wings. “We’ve been involved in clinical trials from the very beginning,” he notes. “Including the first AZT and fluconazole trials.” The clinic now has about 3,800 patients.

Sherer has also been the co-principal investigator of the Midwest AIDS Education and Training Center at the University of Illinois for about 15 years. The AETCs are funded by the federal Health Resources and Services Administration and are charged, he points out, with “providing education and training of health care workers in HIV care, with a focus on public and Ryan White–funded clinics. They target physicians and other providers who may be less experienced, because clinical experience in HIV clearly affects outcomes.”

That’s also key to his work with the Academy. Sherer points out, as part of the faculty that developed the Academy’s Core Curriculum. “It’s been a tremendous effort to define what it is that an HIV clinician needs to know,” he says. “Now, clinicians can easily take the self-assessment test and measure their knowledge against a reliable and timely standard. That hadn’t been done before. Textbooks fall out of date pretty quickly, and the mass of HIV medical knowledge has become enormous and increasingly complex.”

Now, he adds, it’s time for organizations like the Academy—and experienced providers like himself—to turn their attention outward. “In fact,” he says, “we need to look overseas. We who have the medications have a responsibility to use them to their best advantage because in so many parts of the world people are clamoring to have them. We also need to take some of the skills we’ve learned and use them to the advantage of the developing world.”

It’s happening already to an extent, he concludes. “There’s a great push from the global public health and activist communities to not ignore what’s happening in the developing world. We’ve neglected the developing world for decades, especially sub-Saharan Africa. But there’s a growing intolerance for such neglect that seems very deep. I’m encouraged by the growing global will to address these important issues.”

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**Prepare for HIPAA (continued from page 3)**

volunteers gain access to personal and medical information regarding a patient and information about your practice that otherwise they would not have obtained. Your employees’ and volunteers’ files should contain a confidentiality agreement designed to protect both patient and practice information from being shared outside the office.

Throughout the day, we may be leaking patient information without our knowledge. The window that separates the reception area from the waiting room is not sound-proof—receptionists should not relate to other employees, or to anyone, patient information so loudly that other patients can hear. And doctors should be sure to dictate in a private area. Other suggestions include:

- Not taking phone calls in patient rooms or out in the hall
- Closing exam room doors
- Not leaving charts or lab and X-ray results out in the open
- Making sure that phone messages and appointment lists are not visible to nonauthorized individuals
- Checking that information forwarded to your collection agency does not include a patient’s diagnosis

Under the privacy rule, physicians have the right to use and disclose patient medical information in order to carry out treatment, payment, or health care operations (also known as TPO), with the written consent of the patient. Make sure that there is a signed consent form in the patient’s chart.

Remember the three monkeys, **See no evil, Hear no evil, Speak no evil**? Make sure your office handles information in such a tactful way that unauthorized people cannot see, hear, or talk about your patients’ medical information.

The U.S. Department of Health and Human Services’ Office for Civil Rights provides guidance on HIPAA at http://www.cms.hhs.gov/hipaa/. For a copy of a confidentiality agreement, visit www.clinicalms.com, or you can find links to these documents on the Practice Management page at www.aahivm.org.

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1) Go to www.aahivm.org
2) Click on “Member Services”
3) Click on “Edit Your Profile”
4) Log in with your username & password

If you have any questions, call toll-free 866-241-9601 and ask for the membership coordinator.

Current Events & Information

AAHIVM Membership Reception

During the 10th Conference on Retroviruses and Opportunistic Infections

Tuesday, February 11, 2003
6:30 p.m. - 8:30 p.m.
Boston Marriott Copley Place
Salons A-D
110 Huntington Ave
Boston, MA 02116
617-236-5800

Samples of the first HIV Medicine Self-Directed Study Guide will be on display!