The ACLI Medical Section AIDS Committee met at Seattle, Washington, on Friday, September 22, 1989. The meeting, attended by 25 company medical directors, members of ACLI staff, and representatives of 12 laboratories, manufacturers and service organizations, was chaired by Robert K. Gleeson, MD.

The first presentation was by Cambridge BioScience on recombinant technology. The genetic makeup of HIV is the key to future diagnostic and therapeutic modalities. The presenter reviewed the technical basis of recombinant technology and discussed in some detail Cambridge BioScience's five minute antibody slide test which is FDA approved and is called Recombigen HIV-1 LA. It is intended only as a screening test and only under certain specified conditions. Also discussed was the Recombigen HIV EIA, which includes recombinant ENV and GAG proteins for antibody detection. That test was not yet FDA approved though was under FDA scrutiny as of the date of the meeting.

HIV-2 testing was discussed by a representative of Genetic Systems. HIV-2 also causes AIDS, though may be less virulent and have a much longer incubation period. Routes of transmission are the same as for HIV-1. Only a small number of cases have been reported in the United States, although prevalence is quite significant in West Africa. There is a very significant cross-sensitivity of the HIV-1 test for HIV-2, although the viruses can be distinguished on Western Blot. There is a specific HIV-2 test, and some blood centers are already testing for HIV-2.

A Du Pont representative discussed the FDA regulatory process in some detail. The FDA directly regulates manufacturers of in vitro diagnostic products. Both a product license application and an establishment license application are necessary for each new product, and any significant change in a product requires an amendment. His estimate was that most licenses require on the order of 18 to 24 months for approval, and most amendments take 3 to 12 months to process. He indicated that in his opinion the FDA would expect any urine HIV-1 antibody test submitted for FDA approval to show the same sensitivity and specificity as currently licensed FDA antibody tests performed on blood.

Two presentations on urine HIV testing were given. The first was by Genetic Systems. Their representative indicated that HIV antibodies in the urine have demonstrated Western Blot patterns that are identical to Western Blot patterns of unmatched serum samples. The representative discussed a problem of false positives found in one study—which, upon investigation, turned out to be due to a certain preservative in the urine which had altered the optical density. They also discussed some false negatives which occurred on AIDS patients, at least one of which was being treated with Gangcyclovir. A sensitivity range overall of between 93% and 97% was suggested, with specificity on the order of 98%.

A representative of Du Pont also discussed urine HIV-1 antibody testing, making the point that urine is used for viral diagnosis in other contexts (for example, antibody to cytomegalovirus). Technology now exists to detect HIV antibodies in urine with ELISA and Western Blot testing even in people without renal dysfunction. The titer of antibody is now known, though, to be much lower than the serum titer. Du Pont indicated the need for further work to rule out potential interferences in assay performance, such as pH, medications, specific gravity, antibody stability, microbial contaminants, and pathological conditions.

The Committee discussed urine HIV testing at some length. The following issues were raised:

1. Sensitivity and specificity: it is very important to scrutinize the sensitivity and specificity figures of a particular test. Even a test with sensitivity and specificity figures well into the 90s, if applied in low prevalent populations, can generate a tremendous number of false positive results. The result could be that only a small percentage of all positive tests would actually be true positives.

2. There is a relative lack of medical literature on this subject, and a current lack of clinical acceptance of urine HIV testing generally. One major issue in this regard is the current lack of understanding of why the HIV antibody gets into the urine to begin with.

3. There is some evidence that technical considerations can significantly interfere with the assay: bacterial overgrowth, variations in pH, variations in specific gravity, the presence of drugs in the urine and other considerations all require scrutiny.

4. When does the antibody show up in the urine relative to seroconversion? No one present offered an answer to this most important question.

The Committee next discussed criteria for a positive Western Blot test. The Committee reviewed the current FDA approved Western Blot criteria and noted the CDC endorsement of the less stringent criteria of the ASTPHLD (see the 7/21/89 issue of MMWR). Removal of P31 from the criteria was felt not to alter sensitivity or specificity, so that using these criteria a positive could reflect just envelope alone. The Committee discussed the potential impact of using broader criteria for Western Blot interpretation on the number of indeterminants. The Committee agreed that it is reasonable to recommend that the ACLI support some broadening of the criteria but still.
limiting support to criteria developed by highly authoritative and nationally recognized bodies.

Mr. Jack Blaine of the ACLI provided a legislative update. He indicated that the earlier legislative and regulatory focus on restricting insurers' right to test has changed to one of protecting the rights of the applicant—informed consent, counseling, confidentiality and notification requirements are examples. He reviewed the ACLI's most recent compilation of AIDS legislation and regulations (dated 9/20/89).

Finally, Dr. Curtis Lashley, President of the ACLI Medical Section, discussed the intent of the program committee to bring to the membership the best and most current information on AIDS at the ACLI Medical Section meeting in 1990 in Banff.

The next meeting of the AIDS Committee is in Washington, DC, on February 6, 1990 at ACLI Headquarters.

Mark E. Battista, MD
Vice Chairman

New Book

The American College of Physician Executives has released a new publication that may be of interest to medical directors. In *Physician Leaders: Past and Future Challenges*, Norbert Goldfield, MD, and David Nash, MD, MBA, analyze the path by which physicians have become involved in management roles in the health care field and assess the future of the medical management profession. The authors prepared for this new monograph by an extensive and thorough search of the literature on medical management and by interviews with key physician leaders in the health care field. The result, probably, is a publication that will stand as a landmark in the development of a new specialty of medicine—the physician executive.

Drs. Goldfield and Nash arrive at some significant findings from their research, all of which, they say, will need further development and testing as the medical management profession grows. Organizations seeking to hire physicians for management roles will need to be more precise in defining their physician manager needs. There is a range of physician leader types, the authors submit, and organizations must be sure that they are seeking the kind of physician leader who will work best in their environments.

In the future, the authors say, physician leaders will be either "developers" of the interventions that will be used to control health care costs or "communicators" of those interventions to other physicians. The development of quality standards has the potential for separating physician leaders, particularly communicators, from the physicians. But it also has the potential for bridging the gap between these physician groups and between communicators and developers in the physician leader group.

What this new publication shows most clearly is that the world of medicine is in for even more dramatic changes. The challenge for physician leaders, they say, as it is for the medical profession at large, will be to maintain some control over the health care system.

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