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President of WASPaLM
Marilene Melo
Brazil

BULLETIN OF THE WORLD
ASSOCIATION OF SOCIETIES
OF PATHOLOGY AND
LABORATORY MEDICINE



The World Association exists to promote pathology, pathologists and its Constituent Societies for the benefit of patients and the improved understanding of disease throughout the world.

www.waspalm.org

President's Message



As we have mentioned in our first bulletin, it is important to have the press media close to us to inform people about the benefits and progress of laboratory medicine . Here are some news I would like to point out regarding arthritis, cancer, and certain laboratory tests.

There is an examination that has the capacity of identifying **arthritis** at its very beginning. It's called **anti-cyclic citrullinated peptide antibody CCP test (CCP test)**. The test detects antibody to CCP and has a 75-80% sensitivity and a 91-99% specificity depending upon the patient population.

Now its known that women with BRCA1 and BRCA2 gene have an **80% risk of developing breast tumor**, and about 40% of **ovarian tumor**. The MSH1 and MSH2 substances are responsible for 90% of **intestinal tumor** cases.

As we all know very well, **Hemoglobin A_{1c}** levels are directly related to the probability of a patient's developing **diabetes** complications, as **retinopathy, kidney insufficiency, heart attack and stroke**.

There are tests that can indicate relative risk for **heart attack and stroke**. One of these indicators is the CRP (C-reactive protein), released by the liver, in response to inflammation such as that occurring through arterial fat accumulation. Another heart disease indicator is **homocystein** (amino acid), which is related to the risk of developing arterial thrombosis. The **PLAC** test, that measures the A2 phospholipase enzyme, an important arterial inflammation indicator.

In 2000, researchers developed the **anti-SR** test which is able to detect **lupus erythematosus**. It detects 20% of lupus patients who are negative with other screening tests. By this type of analysis, those patients can control the disease symptoms , before they become too severe.

Molecular biology is one of the fields that has advanced a lot recently, specifically for the invention of the **PCR** method, that copies specific pieces of genetic material, billions of times in few hours. It has also opened a track to a quantitative and qualitative virus and bacteria analysis and more general genetically related diseases, as **cancer**. Before the PCR discovery, the blood examinations for patients infected by viruses or bacteria were able just to identify those microorganism presence in the circulating blood. (The author of this discovery is an American hippie , the Chemist Kary Mullins, who won, through this feat, the 1993 Nobel).

I would like to thank all those who have sent us materials from their societies, helping WASPaLM to help Pathology and Laboratory Medicine knowledge around the world. If you didn't send any news from your Society yet, we encourage you to do it, remembering that the best we can do for our patients is the final objective of this Association, and the most noble aim of the health care area.

WASPALM Elections 2005

The following pathologists were elected through electronic ballot to serve on the Bureau of the World Association of Societies of Pathology and Laboratory Medicine for 2005-2007.

President	Marilene Melo	Brazil
President-elect	Henry Travers	United States
Secretary-Treasurer	Michael Oellerich	Germany
Directors at Large		
Africa	Tjaart Erasmus	South Africa
America, North	Paul Raslavicus	United States
America, South	Mario Flavio Alcantara	Brazil
Asia	Oh Hun Kwon	Korea
Australasia	David Davies	Australia
Europe	Manfred Boehm	Austria
At Large	Robbie Bacchus	United Kingdom
At Large	Gamze Mochan Kuzey	Turkey
At Large	Genenc Ciliv	Turkey



PATHOLOGY PRACTICE ISSUES OF INTERNATIONAL SIGNIFICANCE

In its official relations with the World Health Organization (WHO) and through the relationship of its Council of World Standards and Accreditation's (COWSA) relationship to the International Standards Organization (ISO), WASPaLM monitors and reviews developments throughout the world affecting pathology and laboratory medicine. Among the most important of these are laboratory accreditation, pathology manpower, and gene patents.

Accreditation

For laboratories, ISO 15189 becomes the international standard for laboratory accreditation as predicted by Dr. Kenneth McClatchey, then Secretary-General of WASPaLM, in Düsseldorf in 2001. It provides a framework for the design and improvement of process-based quality management systems by medical laboratories. Based on ISO 17025:1999, *General requirements for the competence of testing and calibration laboratories*, it provides specific requirements for its implementation in medical laboratories. The new standard is intended to promote a common approach to the quality management of medical laboratories and to all aspects of its operation, from patient preparation and identification to the collection and examination of clinical samples. The standard is available from ISO (www.iso.com) for 130 Swiss francs (about US\$100).

One confusing requirement in the standards has been introduction of procedures for "Measurement of Uncertainty" (MU). The Australasian Association of Clinical Biochemists has published an implementation guide for a number of analytes (*The Clinical Biochemist* 25(4), November 2004). The document is available by sending an email request to office@aacb.asn.au. Additional information on MU can be found for microbiology, immunology and the general laboratory. Further information can be found at www.rcpa.edu.au (click on publications and forms/document library/policies guidelines).

Pathology Manpower

In Australia there is a significant shortfall in the number of pathologists being produced annually. A similar trend operates in the United States. In the latter country, the trend is compounded by a shift away from private practice pathology laboratories toward pathologists employed by hospitals, large laboratory corporations and universities.

Gene Patents

As much as gene patents and patents on other technologies (e.g. polymerase chain reaction –PCR) have affected medical laboratories and pathologists, they are governed exclusively under patent laws in each country. Independent of the country, however, there are consequences of gene patents common to all. Because there are no alternatives to patented genes, limits are placed on research, treatment and diagnosis. A recent study of gene patents issued in the United States from January 2003 to May 2004. Within the 74 patents were 1167 claims over specific sequences of which 38% were "problematic" (i.e. they were poorly described, overly broad, lacked utility or novelty, or were indefinite).

Proposed policies to address the problem include banning patents on genes, narrowing their scope, exempting researchers and diagnosticians from having to adhere to the patents, creating a system of compulsory licensing, and improving the quality of patent examiners.

In March 2004 an Australian Law Reform Commission (ALRC) inquiry in a media release stated that there was widespread anxiety and uncertainty about whether genetic patents would stifle research and development in Australia's billion-dollar biotechnology industry and cause cost blow-outs and access problems for our healthcare system. The Commission President said allegations that individual patent holders were acting unreasonably - for example, by setting exorbitant license fees or severely restricting the use of a patented material or technology had set off alarm bells in Australia. He said "Interestingly, strong concerns about the adverse impact of patents on genetic R & D have even come from leading researchers who themselves hold numerous patents." While Australia had avoided some of the worst difficulties experienced in the US and Europe systems were required to ensure a calm, balanced and flexible approach is taken to patents on genetic materials and technologies. The Australian Law Reform Commission has now completed its major inquiry into the controversial subject of gene patents, culminating in the release of its 700-page report *Genes and Ingenuity: Gene Patents and Human Health* (ALRC 99), which was tabled in Federal Parliament on Tuesday 13 August 2004. An executive summary and the final report are available online at www.alrc.gov.au.



NEW SOCIETIES ADDED TO WASPALM DURING 2005:

INDIA THE ASSOCIATION OF PRACTICING PATHOLOGISTS (Associate Society)

The Council on World Standards Dr. Alfred Hartmann, United States

WASPALM and its member societies are represented on ISO by the Council on World Standards. The Council mainly follows ISO documents dealing with laboratory medicine, most specifically those from ISO Technical Committee 212. TC 212 met in Utrecht, Netherlands on 7-9 June 2004. Important documents from this Technical Committee include:

ISO / PDTR-18112

Technical Report: IN VITRO DIAGNOSTIC MEDICAL DEVICES FOR PROFESSIONAL USE-SUMMARY OF REGULATORY REQUIREMENTS FOR INFORMATION SUPPLIED BY THE MANUFACTURER

7-21-04 ISO/DIS 22870

POINT OF CARE TESTING (POCT) – Requirements for quality and competence

8-11-04 ISO/DTR 22367

Medical laboratories – Reduction of error through risk management and continual improvement

ISO/TC 212 N123

Patient safety by reducing laboratory error. Technical report proposes a methodology for finding and characterizing medical error that would be minimized with application of ISO 15189.

ISO/CD 17593

Clinical laboratory testing and in vitro diagnostic test systems – Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy.

ISO/18112

Clinical laboratory testing and in vitro Diagnostic test systems – In vitro diagnostic Medical devices

ISO 20776-1

Reference methods for in vitro testing of the susceptibility of antimicrobial agents against bacteria involved in infectious diseases

ISO 20776-2

Evaluation of performance of antimicrobial susceptibility devices

WASPALM member societies interested in these and other ISO standards under development may contact Dr. Hartmann at alfred.hartmann@mckennan.org.

Countries in Need

Dr. Robbie Bacchus, United Kingdom

1. Request received from the organising committee of Gulf Cooperating States for input and assistance in the organisation of a symposium on Blood Transfusion Practices and Policies for all Middle East Countries. This meeting is scheduled for February 2005 and has the support of the WHO.
2. Following the meeting of the Royal College International Forum discussion has continued with representatives from Iraq to identify ways of supporting their pathology services.



2005 WASPaLM Awards

THE FOLLOWING AWARDS WERE PRESENTED AT THE 23RD WORLD CONGRESS IN ISTANBUL IN MAY 2005

Gold Headed Cane	Kenneth McClatchey Past-President, WASPaLM Accepted by his widow, Marty McClatchey	United States
Gold Headed Cane	Mikio Mori Past-President, WASPaLM	Japan
Medal of Honor	Oh Hun Kwon Director-at-Large for Asia	Korea
Medal of Honor	Yun Jung Cho President, 22nd World Congress of Pathology	Korea
Certificate of Honor	Gamze Mocan Kuzey President, 23rd World Congress of Pathology	Turkey
Certificate of Honor	Oya Bayindir President, Turkish Society of Clinical Biochemistry	Turkey
Certificate of Honor	Yücel Güngen President, Ankara Society of Pathologists	Turkey
Certificate of Honor	Ozdem Ang President, Turkish Microbiological Society	Turkey

WASPALM in Official Relations with The World Health Organization

In March 2005 Dr. Susan Holck, Director of Government, Civil Society and Private Sector Relations of the WHO, informed WASPaLM that the WHO Board, in reviewing collaboration between WHO and WASPaLM for 2001 to 2003, decided to maintain the World Association of Societies of Pathology and Laboratory Medicine in official relations with WHO. In her letter, Dr. Holck said, "In making its decision, the Board expressed its appreciation of [WASPALM's] continuing support for WHO objectives and contribution to world health.

WASPALM will work with Dr. G. Vercauteren, Diagnostic Imaging and Laboratory Technology, during the period 2004 to 2006 in furthering the interests of WASPaLM societies for the benefit of patients worldwide.



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23rd WORLD CONGRESS OF PATHOLOGY—ISTANBUL, TURKEY

The 23rd World Congress of Pathology was held in Istanbul, Turkey from 26 to 30 May 2005. Three constituent societies in Turkey cooperated to create an exciting technical and scientific program. The Keynote Lecture, entitled *Reticulum cells and reticulum cell tumors*, was given by Dr. Juan Rosai on the 26th of May.

Meetings of the Bureau, the House of Representatives and the World Pathology Foundation (WPF) made up the “business” part of the meeting. The Gala Dinner and Auction raised over US\$2,200 to support the WPF and the Gordon Signy Fellowships it offers to pathologists from countries in need seeking advanced training in other nations. See the next issue of the *WASPALM Bulletin* (available 1 August 2005) for details of this meeting.



THE WASPALM WEB SITE: GATEWAY TO COMMUNICATION



The WASPALM Web Site will be updated further this year to provide member societies with the ability to change information themselves. In a far-flung and busy world, one of the most significant problems faced by an international organization is communication and accurate contact information. With this change, societies will be able to assure that their list of officers, official addresses, and identities as well as addresses of representatives are accurate and up to date.

To assure the secure operation of this part of the web site, there will be a special “log on” procedure, including a password. Dr. Raj Dash, the Informatics Secretariat, will be working to provide a simple, but straightforward method for maintaining the continu-

ity of this areas of the web site. An announcement will be made to all member societies when the programming is finished and the new features ready for use.

**A Message from
The
Secretary-Treasurer**
Henry Travers, MD
United States



Letters and information forms to update WASPALM records and for dues payments should be in the hands of all WASPALM member societies. If you have not received yours, please email me at henrytravers@sio.midco.net. Between July and September 2005, we will be transferring the Secretary-Treasurer’s office to Dr. Michael Oellerich in Germany. We will inform all of you of the new addresses. In the meantime, the WASPALM Web Site is always an up-to-date source of information and contact.

On a personal note, it has been a privilege to have served these past 5 years as your Secretary-Treasurer. WASPALM is a worthy organization that merits the attention of all pathology societies throughout our world. During these five years WASPALM has incorporated WASPALM in the United States, provided training for pathologists from Countries in Need (under the guidance of Dr. Robbie Bacchus), developed position statements on a variety of topics of interest to international pathology, represented WASPALM member societies in ISO, the WHO and CIOMS.