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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.

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President's Message: 24th World Congress in Malaysia

I visited Malaysia this fall and am happy to report to you about the upcoming 24th World Congress of Pathology. Malaysia is a modern country (independent from England for 50 years the celebration of which will be in 2007). Thus, I strongly ask all of you to work with the publicity of WASPaLM Congress in your countries.

The meeting with the organizing committee was very well prepared for both parts and consequently it was very fruitful. I was kindly welcomed. In the first part of the meeting we had a site inspection with the presence of hotel events manager. It was defined as follows:

a) – The place of the Ballroom – Welcome reception
b) – The room for the Bureau Meeting that will be the same for the House of Delegates with a new arrangement
c) – The Convention Center, exhibition and lecture halls
d) – The place of the President's dinner and Gala dinner
e) – The hotel's rooms

The hotels in Malaysia are very cheap (less than 100 dollars/day) as it is the food. The Sunway Lagoon Resort is very beautiful with huge swimming pools. It is beside the Convention center. The Sunway Pyramid is a one-year-old hotel, located in the same building of the Convention center and the shopping mall although it is cheaper than Sunway Lagoon. There is not swimming pool (perhaps it can be used the other hotel)

The organizing committee could gather 16 attendees representing important supply companies including: Abbott, Roche, Dade Behring, Olimpus among others. Dr. Leslie has been working for two years with them and will keep doing it. He has been managing with the sales of the booths or asking the suppliers to pay for some activities or support Lunch Symposiums.

The discussion of the Scientific Program with Dr. Cheong was exciting. Prof. Gillery from the French Society will lecture on HbgA1c, four noted professors from Japan will speak, Dr. Robbie Bacchus will chair the Presidential Table, Dr. Otavio Fernandez from Brazil will talk about globalization and miniaturization, and the Italian societies will host a lunch symposium on clinical laboratory medicine.

Free registration will be provided for professors and members of the Bureau.

The organizing committee is working hard and conscious. The great problem of this Congress is the concern of the possibility of having a low number of attendees, which it does not draw attention of the suppliers, the sales of the booths, and the anxiety with the financial result. All members of WASPaLM are asked to encourage their colleagues to attend to make this a very successful World Congress.

All together!

Marilene Melo, M.D.

2006 Bureau Meeting Reflects Challenges for WASPaLM

The Bureau met in Chicago, United States of America, from 27—29 July 2006. Those attending included **Dr. Marilene Melo**, Brazil; **Dr. Michael Oellerich**, Germany; **Dr. Mário Flávio Alcântara**, Brazil; **Dr. Robbie Bacchus**, United Kingdom; **Dr. Gonec Ciliv**, Turkey; **Dr. Raj Dash**, USA; **Dr. Alfred Hartman**, USA; **Dr. David Davies**, Australia; **Dr. Gamze Mocan Kuzey**, Turkey; **Dr. Mikio Mori**, Japan; and **Dr. Paul Raslavicus**, USA. Administrative staff included **Dr. Masami Murakami**, Japan; **Dr. Ikunosuke Sakurabayashi**, Japan; and **Mr. Susumu Kanda**, Japan. Guests of the Bureau were **Dr. Fred Rodriguez**, President of the American Society for Clinical Pathology and **Dr. John Ball**, the society's executive vice present.

Actions taken by the Bureau at this meeting are listed below with and without commentary. They are listed in the order in which they were discussed.

Action Item # 1: Reconfirm that Taiwan will be an active member in the future. Bureau is open to participation of mainland China in WASPaLM.

Action Item # 2: The practice of pathology at the beginning of the 21st century is a team activity involving both medical specialists and specialized non-medical scientists. This is being reflected in changes in membership of many current and potential future Constituent Societies of WASPaLM. Pathology with Laboratory Medicine, however, is an aspect of specialist

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2006 Bureau Meeting (continued)

medical practice recognized when the organization was first established. Our current Bylaws would exclude these societies from membership and therefore need to be amended. The amendment to the Bylaws proposed by the Bureau increases flexibility in eligibility for an organization to become a Constituent Society without departing from the fundamental purposes for which WASPaLM was established. The amendment will be placed before the House of Representatives in Malaysia for a vote.

Section 3.2 Qualifications. (a) Membership in the Association as a Constituent Society shall be open to national or international societies whose governing body is composed of at least 50% lawfully qualified physicians specializing in the practice of pathology and/or laboratory medicine.

Action Item #3: Bureau recommends to strive for CME accreditation for the World Congresses and ask the Constituent Societies to become active in this. For the upcoming Malaysia meeting, the Bureau members are encouraged to contact their societies regarding CME accreditation. For the Sydney meeting, RCPA will begin the process of investigating CME accreditation.
Action Item # 4: 1. Allocate funds for a single 2007 educational program to be directed by Dr. Bacchus in India. The budget will accommodate a cost of up to 10,000 USD for this program, 7,000 USD will be derived from the Japanese office and 3,000 USD from the US-WASPaLM account. Collaboration and sponsorship with other organisations such as IAP is encouraged.

2. Allocate funds for a single 2007 educational workshop to be directed by Dr. Mario Flavio Alcantara in Latin America (Accreditation Workshop, Lima, Peru). The budget will accommodate a cost of 2,000 USD for this program to be derived from the Japanese office.

3. A detailed budget for allocation of provided funds will be circulated to the bureau for review.

Action Item # 5: The President-Elect prepare a report for the Bureau detailing the risks covered by the various Directors insurance policies and associated costs of these policies to be submitted for review electronically within the next 3 months.
Action Item # 6: Allocated US $100 per month to support an administrative assistant for the Secretary-Treasurer for two years. Thereafter, this expenditure will be re-evaluated.
Action Item # 7: Dr. Oellerich and Dr. Travers will draft a policy regarding the disbursement of funds from accounts and recommends that a single individual be granted the authority for control all WASPaLM funds.
Action Item # 8: : Chair of the ethics committee of WASPaLM and the President will provide a statement for South American countries addressing the issues of:

1. illegal honorary splitting and
2. securing and protecting potentially dangerous biohazardous materials that could be misued.

Action Item # 9: Dr. Davies will provide a condensed version to the President for use as an article in Bulletin directing readers to sources of information for Pathology Update 2006. Dr. Davies will seek approval of the RCPA for permission to publish certain aspects of the "pathology update 2006" CD onto the website (copy provided to the Bureau members).
Action Item # 10: An on-site visit by the President to Malaysia to evaluate the upcoming Congress in 2007 is authorized.
Action Item # 11: The Bureau should agree in principle to invite Dr. Vercauteren to Bureau meeting in Malaysia, explore political and administrative ramifications, and to engage in contingency planning if costs of travel must be covered by Bureau.
Action Item # 12: 1. Dr. Hartmann will provide a written outline highlighting WASPaLM's involvement in standard setting activities.

2. Dr. Dash will post this document on the WASPaLM website.

3. Dr. Hartmann will inquire whether draft documents may be disseminated to constituent societies for review and what type of information may be posted to the WASPaLM website (with registration level security if requested). Dr. Hartmann will identify what authority and responsibilities WASPaLM, as a liason member, has in regards to ISO generated information.

4. Dr. Hartmann will report back to the Secretary who will distribute to the Bureau.

ACTION Item # 13: Dr. Davies will draft a position statement in regards to WASPaLM ethics as proposed above for review by the Bureau.

In spite of the demanding schedule the Bureau were able to host Drs. Ball and Rodriguez on a cruise around the city of Chicago, sponsored by a generous donation from ***Roche***. Some photographs of those attending the meeting are included on the next page. The Bureau accepted a number of new members. The following were admitted as **Constituent Societies**: Brazilian Society of Pathology, Romanian Society for Laboratory Medicine, The Hong Kong College of

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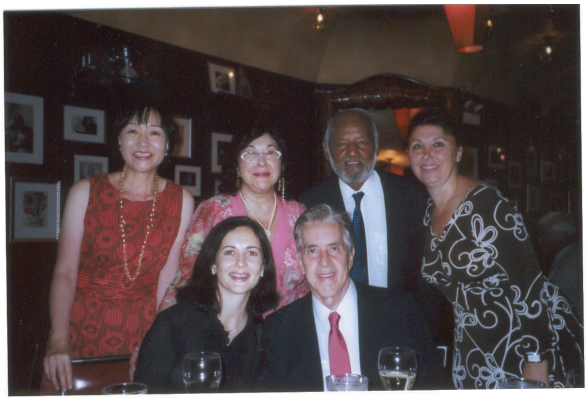
Chicago Bureau Meeting (*continued from page 3)*

Pathologists, The Faculty of Pathologists of the Royal College of Pathologists (Ireland), Israel Association of Pathologists, Federacion Mexicana de Patologia Clinica. New **associate societies** include Sociedad Boliviana de Patoliga/Medicina de Laboratorio, Cuban Society of Clinical Pathology, Sociedad Ecuatoriana de Patologia/ Medicina Laboratorial, Sociedad Peruana de Patologia Clinica.

Back Row: Michael Oellerich, Susan Raslavicus, Fred Rodrigues, Al Hartmann, Jenny Davies, David Davies.
Front Row: Paul Raslavicus, Marilene Melo, Linda Hartmann

Back Row: Susumo Kanda, Ikunosuke Sakurabayashi, Mikio Mori, Raj Dash
Front Row: Marilene Melo, Mrs. Sakurabayashi, Nina Dash



Back Row: Reiko Mori, Marilene Melo, Robbie Bacchus, Gamze Mocan Kuzey
Front Row: Elizabeth Alcantara, Mario Flavio Alcantara

International Liaison Committee of Presidents

President-elect **Dr. Henry Travers** represented WASPaLM at the 2006 annual meeting of the International Liaison Committee of Presidents in Washington, D.C., USA. The meeting was attended by the presidents of societies of pathology in the United States, the United Kingdom, Ireland, Scotland, Australia-New Zealand, and Hong Kong. The agenda was full, but some time was devoted to a discussion of WASPaLM and its value to national pathology societies. The major roles for WASPaLM at present include:

- Sponsoring World Congresses of Pathology together with a national organisation that is a member of WASPaLM.
- Sponsors education programmes for counties in the developing world.
- Has direct communication with ISO and WHO. WASPaLM is a non-governmental organization in official relations with WHO.

A number of suggestions were proposed to WASPaLM from the ILCP:

1. WASPaLM could ensure that the ISO standards evolve and keep up to date. This would, however, require active participation from member societies. It was clear that members of ILCP already have links to ISO via their own national accreditation schemes.

2. Could WASPaLM function to co-ordinate the development of international standards? However, WASPaLM currently does not have an administrative function to support this.

3. WASPaLM could convene a meeting of /seek opinions from the Presidents of the pathology organisations to discuss the way forward.

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International Liaison Committee of Presidents (*continued from page 4*)

4. WASPaLM could have role in promoting an international week of pathology. There was no clear way identified to address the issue of establishing a regular income for WASPaLM.

Other topics covered by the ILCP included the development of new funding models for pathology in England that appears to be very similar to that currently used in the United States; models for training pathologists; maintenance of certification; proposed new requirements in the US for pathologist interpretation of immunohistochemical tests for her-2/neu; the practical delivery of pathology services; and an update of SNOMED.

Maintenance of Competence in Pathology

The American Board of Pathology is the last Board not to require recertification. Certified pathologists have lifelong certification. Beginning in 2006 all new pathologists will receive a certification to practice that will expire at a maximum of 10 years. In order to maintain certification the ABP requires compliance with 4 components of practice: (1) maintaining a state license; (2) participation in continuing education and 10 self assessment units over the 10 years; (3) modular examinations in the AP & CP and the sub-specialist areas of practice; and (4) written statements from 4 referees on the individual's ability to practice, laboratory accreditation, participation in quality assurance, evidence of use of practice guidelines.

In the United Kingdom there are no mandatory requirements for recertification. For consultants working in the NHS an annual appraisal is a contractual requirement. A proposal for revalidation of doctors is currently under consideration. Chief Medical officer was asked by the Government to produce proposals for revalidation of doctors. The CMOs consultation paper outlines some options. These includes a requirement for re-licensing (maintain name on the medical register) and recertification (5 year renewal to allow the individual to practice in their speciality). Re- certification may be based on a combination of annual appraisal, multi source feedback, CPD and an examination. These changes would be linked to new roles for the GMC with each NHS organisation appointing a local GMC representative to oversee the regulation of the medical profession. The consultation period closes in November.

Hong Kong, Ireland and South Africa had similar systems that require mandatory CPD. There was general concern about the practicalities , cost and value of introducing re-certification schemes that require a mandatory examination.

Changes Come to SNOMED

SNOMED was developed by CAP. As electronic medical records develop there is an increasing need for an international coding system. SNOMED has been licensed to the National Library of Medicine in the USA and to the NHS in the UK. In view of the need for an international coding standard the future of SNOMED has recently been reviewed.

All countries were invited to attend a meeting in December 2005. Nine countries accepted the invitation. The intellectual property rights for SNOMED have now been transferred to the Charter Member countries. These countries will now oversee the use and further development of SNOMED. CAP will continue to provide support for the development of the terminology. The Charter member Countries will determine the budget and will contract with CAP for the development of SNOMED.

Each country has a unique regional centre for SNOMED that is in addition to the core SNOMED. If a country wants to move a new code from the regional list to the core list then this will need agreement form the other members. One of the most important areas that needs to be developed is the coding for uncertainty e.g. " The diagnosis is suggestive of ...."

American Society for Clinical Oncology Worries about Accuracy of Her-2 Testing

Oncologists in the USA have been concerned about the reliability of HER- 2 results since these determine which patients receive Herceptin. Studies in clinical trials had suggested that 18% of results from local laboratories may be incorrect.

A group then developed guidelines for HER- 2 testing requiring laboratories to perform tests on at least 1000 samples per year. One large laboratory that had taken on this testing used technologists to report HER-2 . A review by an NIH statistician showed that there was no statistical basis for the minimum requirement of 1000 samples per year. The CAP found there had been no pathology input into the process and many of the recommendations were flawed. The guidelines have been rewritten and are now published.

Following the intervention by CAP the guidelines have been rewritten and the importance of engaging pathologists in the process has been made.

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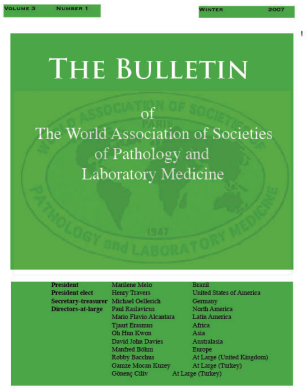
WASPaLM Secretary-Treasurer is Fellow of the Royal College of Pathologists—London

Professor Michael Oellerich, secretary-treasurer of the World Association of Societies of Pathology and Laboratory Medicine was awarded Fellowship in the Royal Society of Pathologists—London in ceremonies there on 22 November 2006.

Presenting the certificate of fellowship is Professor Adrian Newland, President of the Royal College.

New Format for the Bulletin

This will be the last issue of the Bulletin in its current format. Beginning with the first issue of 2007 the **Bulletin** will have a new format. The **Bulletin** will be formatted using Adobe Creative Suite with *InDesign* as the design program. A sample of the title page is shown below.


THE BULLETIN

of

The World Association of Societies of Pathology and Laboratory Medicine

World Pathology Foundation Awards Gordon Signy Fellowships

The trustees of the World Pathology Foundation have awarded three Gordon Signy Fellowships for 2007. They were selected from among 10 applicants. The WPF provided US$5,000 each for studies abroad. The awardees are:

Dr. Aline Helen da Silva, Brazil, for training at the University of California at San Francisco

Dr. Antonio Hugo Jose Froes Marques Campos, Brazil, for training at Centro Nacional de Investigaciones Oncologicas Molecular Pathology Programme, Spain

Dr. Leticia Trivellato Gresta, Brazil, for training at the Mayo Clinic in the United States

WASPaLM Comments on COIMS Ethics Revisions

The World Association of Societies of Pathology and Laboratory Medicine submitted a number of comments COIMS Guidelines for the Use of Human Subjects in Biomedical Research. The comments were drafted by **Prof. David Davies** and were approved by the Bureau. An abbreviated summary of these comments is given below.

1. **Provide a synopsis for general use by individual medical practitioners and biomedical scientists**
2. **Use of Diagnostic Specimens for Research.** Pathologists and practitioners of laboratory medicine are custodians of large numbers of specimens of human tissue and body fluid submitted for diagnostic uses but which have potential for secondary uses in a wide range of research. The specimens are submitted on behalf of a patient who may not have had any direct interaction with the laboratory or any of its agents. Procedures currently in use do not provide any information to laboratories about the views of the patient from whom the specimen was obtained about whether they would or would not be agreeable to use of their specimens for research.

Some types of specimen, notably fixed tissue, paraffin blocks and sections may be held by laboratories for many years possibly after the death of the person from whom they were obtained. Some investigations now possible were not developed at the time many specimens of this type were collected. *While de-identification of specimens may address privacy concerns it eliminates clinico-pathological correlation, which may be of major importance.* Furthermore there may be difficulties if during the course of the research either as its primary purpose or coincidentally information becomes available relevant to the health and well being of the person from whom the sample was derived.

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Comments on COIMS Ethical Guidelines *(Continued from Page 6)*

These issues have to be taken into account when complying with Guideline 4 on research involving primarily the use of biological specimens, which also require use of medical record data particularly relating to disease outcomes. The new Guideline 24 is also relevant to this. Both guidelines are of particular relevance to WASPaLM, its Constituent Societies and many of their individual members.

3. **Individual informed consent**. The section in the commentary on the use of medical records and biological specimens goes some way in recognizing the issues referred to above and the need to reconcile them with strict compliance with Guideline 4. The fundamental principle is accepted that the "default" state must be individual informed consent, but the concept of this being waived by an ethical review committee is essential under some circumstances. In relation to some uses of human tissue, however, it must be noted that in some jurisdictions this waiver by an ethical review committee has been overridden by statute law. CIOMS may need to draw this to attention in this Guideline. *Where there is no statutory limitation on the ability of an ethical review committee to waive requirements for informed consent it is suggested that, in the context of use of diagnostic specimens for research, this would be facilitated if jurisdictions and institutions had in place effective "opt out" provisions available to persons who would not want their diagnostic specimens to be used for any purpose other than their immediate medical management*. While this would not remove research using diagnostic specimens from oversight of an ethical review committee, it would make a decision by the committee about waiving informed consent easier. Accordingly the proposal referred to in the additional commentary (lines 348-351) and again under new Guideline 24 (lines 933-935) is supported.

The additional commentary to this Guideline considers the difficult question of *waiving of consent even when personally identifiable data is available*. While in some situations irreversible de- identification (anonymization) is appropriate when using residual diagnostic specimens, for some types of research this may diminish its value through inability to provide correlation with medical record data e.g. long term follow up of disease outcome. Irreversible anonymization may also present a problem if the research discloses findings, either directly or coincidentally, which may be relevant to the health of the patient or family members. *It is suggested that problems arising from irreversible de-identification could be avoided while minimizing risk of unnecessary disclosure of personal information could be achieved by a procedure in which the "key" to identification is held by a third party.* That third party would only release of information to meet specific requirements or contingencies.
This would be an arrangement similar to that of "escrow" used in some types of financial and legal practice and, latterly, to enable access to otherwise secure source code for software in the event of a major system failure.

4. **Disclosure and review of potential conflicts of interest**. This guideline should not be limited to epidemiological research. As soon as practicable it should be incorporated into a consolidated revision of the 2002 CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects. While conflict of interest is often perceived only in pecuniary terms the commentary on this guideline recognizes that this is not always the case. As far as possible the structure of a project should be such that, provided the original design is followed and data are reliable, no third party should be able to affect publication even when the results do not support the hypothesis on which the research proposal was based.

5. **Use of stored biological samples and informed consent**. The document has identified this as a logical extension of Guideline 4. It is of particular relevance to epidemiological research particularly as broadly defined in this document to include investigations using the tools of molecular genetics. In contrast to Guideline 4, this new guideline is concerned with present day practice of specimen and data collection, but this material may be used for research not only immediately but possibly also at some time in the future. As noted, the data that may be generated may be limitless in amount and its nature may not be anticipated at the time the sample is collected. The commentary usefully identifies three separate classes of repository for samples for these studies and discusses some differences to be adopted with approach to consent for their use and its waiving.

For repositories such as "banks" of "normal" or "pathological" tissue, the intention for it to be used for research should be clear and explicit when the tissue collection/donation is made. It would be expected that, at that time, consent would obtained for use of the tissue for one or more of: specified immediate research, other types of future research foreseeable by the organization managing the repository, other medical or biological type research not foreseeable at the time of collection.