



Annual Report 2005

Highlights of the Year

- 19th International Congress, Orlando, USA
- 16th European Congress (Euromedlab), Glasgow, UK
- 10th Bergmeyer Conference, Eibsee, Germany
- IFCC Awards presentation during the ICCLM in Orlando
- 3rd Course on Clinical Molecular Biology, Milan, Italy
- Course on Evidence Based Laboratory Medicine, Budapest, Hungary
- JCTLM Workshop on Traceability, Paris, France
- New Layout of the IFCC Web site

2005 Triennial Council Meeting

At the Council meeting in Orlando representatives of Member Societies used the opportunity to receive the tri-annual reports from the Executive Board (EB) and the Division chairs and to elect the EB for the next three years.

The following colleagues were elected to serve on the **IFCC EB from 2006 to 2008**: Jocelyn Hicks (US), President; Validmir Palicka (CR), Vice-President; Päivi Laitinen (FI), Secretary; Ghassan Shannan (SY), Treasurer; Nobert Madry (DE), Corporate Representative; and Joseph Lopez (MY), Daniel Mazziotta (AR), Michael Thomas (UK), Members. Mathias Müller (AT) will continue as Past President.

President's Message

The main objective of Laboratory Medicine is to provide meaningful, accurate results for risk assessment, diagnosis of conditions, follow-up and monitoring treatment of patients. It is mandatory that all steps in the diagnostic process provide adequate confidence and will satisfy the quality requirements and expectations of clinicians. Many guidelines for quality management have been published focusing on process optimisation and economic aspects. However, in most of these quality systems, the medico-patient relationship of laboratory medicine is missing and the role of diagnostic laboratories either as a provider of a service or as a clinical partner in decision making is often not considered.

Clinical Chemistry and Laboratory Medicine have focused previously mainly on analytical measurements and intra laboratory processing. Quality assurance and Reference Systems have been implemented with some success. Of course, there is still a need for further global improvement for new technologies such as immunometric and molecular biology methods. However, in

order to play a greater role in clinical medicine a change of paradigm for Clinical Chemistry and Laboratory Medicine is currently taking place. For laboratory diagnostics to be considered as an integrated medical discipline, evidence based test requesting, the clinical usefulness of tests and the interpretation of laboratory reports will be essential. The inter-disciplinary clinical consulting process will expand laboratory obligations nearer to the patient. This will have an enormous socio-economic impact. Laboratory physicians and scientists will be essential in a patient oriented environment. It will be one of our discipline's obligations to evaluate continuously the validity and clinical utility of new diagnostic tests linking them with clinical outcome. To achieve this, globally harmonised analytical measurement procedures are essential. In addition, the increasing number of clinical tests and the complexity of data from investigating normal and abnormal gene forms and their expression, will force us to manage and interpret these observations through bioinformatic tools in order to be able to share our knowledge with clinicians.

IFCC continuously reviews and updates its concepts. The international character of the Federation allows developing national or regional concepts to world-wide accepted standards of excellence. Several new directions are being pursued in close collaboration with international, regional, professional and industrial partners thus expanding the base of expertise and knowledge. In this context, the following partners have to be highlighted: BIPM, CLSI, ILAC, IRMM, IUPAC, WHO, IUPAC. In addition, it has been one of the Executive Board's objectives to meet during regional and national congresses with colleagues from Member Societies and Corporate Members. These visits are occasions where the needs and mutual expectations can be discussed and partnerships and joint activities be established.

This Annual Report is the final one from the Executive Board which served during 2003 – 2005. This is also an opportunity to thank all the officers who have supported the Board in fulfilling the challenging, enjoyable work over the past three years. In this kind of organisation, the Board members are more visible to the outer world, but their success is totally dependent on the achievements of the Divisions and their working parties.

The scientific reputation of the Federation continues to grow, especially in the areas of standardisation and reference materials. Several projects were conducted by the Scientific Division (Chair: Jean-Claude Forest) to further promote the concept of Reference Systems (Reference Measurement Procedure, Reference Material, Reference Laboratories, Reference Intervals). This concept is the major basis for the implementation of global traceability of laboratory tests pursued by the Joint Committee of Traceability in Laboratory Medicine (JCTLM), a collaboration with the BIPM and ILAC. More than 200 certified reference materials and approximately 150 reference measurement procedures useful for the establishment of traceability are accessible on the BIPM website. In collaboration with the BIPM, IEC, ILAC, ISO, IUPAC, IUPAP and OIML, the Joint Committee for Guides in Metrology (JCGM) founded in the 1990s has been revitalized; the objectives of the JCGM are to maintain and develop the international vocabulary of basic and general terms in metrology (VIM) and the guide to the expression of uncertainty in measurement (GUMM). Both are pertinent for appropriate reporting of test results. In collaboration with the IRMM, NIST and WHO, certified reference materials for the prothrombin G20210A mutation, myoglobin, Troponin I, Lp(a) and a new batch for Apo B have been finalised. With the recommendations on amylase and ALP, most enzyme measurement procedures have now been adopted for 37°C. In order to implement these fundamentals in the clinical

field, continuing discussions with medical associations such as the International Diabetes Federation, American Diabetes Association, European Association of Diabetes Societies, the Japanese Diabetes Society, the American College of Cardiology and the European Society of Cardiology have been held. The Global Campaign for Diabetes Mellitus (Chair: Sverre Sandberg) is based on the same policy, bringing together patients, clinicians and laboratory professionals.

The Education and Management Division (Chair: Gerard Sanders) has expanded its role in analytical quality, continuous education and training pertinent for the future of our profession. This Division successfully initiated several programmes using visiting lecturers and established a number of technology courses. A first training course in reviewing literature towards objective criteria for diagnostics has recently been initiated. A major objective has been the rationale use of laboratory tests based on evidence based publications. Another ongoing activity is to provide high level educational material using the traditional printed and the new electronic media. Without the continuous support from the member societies and corporate members several of these projects would be impossible.

The Communications and Publications Division (Chair: Andrew Wootton) continuously updates the IFCC web site providing the membership with news and developments in the discipline. Besides several links and databases relevant for laboratory diagnostics, the transmission of lectures and IFCC symposia held during IFCC Congresses, has been added. Thus, those who cannot participate in meetings have the opportunity to receive this information and share this with congress participants. It is obvious that keeping up with the fast expanding role of electronic communication is a difficult task. This Division is also the link of the Federation to established scientific journals and

coordinates the publication of IFCC recommendations and documents.

The Congress and Conference Division (Chair: Albert Frazer) participated in the organisation of the International Congress in Orlando and the European Congress in Glasgow. These activities are extremely important for the IFCC and its membership bringing a specific IFCC-flair to these meetings and using these opportunities to advertise the Federation's achievements.

An international volunteer organization needs professional support based on modern logistics to be useful for the global membership. During the last few years, the Office in Milan with the collaboration of Emmezeta (CEO: M. Zaniboni) has developed a stable base for the Federation. The Office is now staffed with 3 dedicated, multilingual staff who make life easier for IFCC officers. We are grateful to the office staff for carrying out the administration and keeping the communication between IFCC and its members.

With the end of 2005, the term of this Executive Board, a group of dedicated colleagues and friends, will be finished. It will be up to the membership to reflect on our activities of the past years and whether the Federation has been successful in dealing with the challenges of this world and whether accomplishments in many ongoing projects, initiatives and organizational matters have been made. I can assure you that the board members and the divisional chairs did their best to act as a team of dedicated colleagues. I am using this opportunity to thank Matthew McQueen, Carl Burtis, Renze Bais, Christopher Lam, Hartmut Wetzel, Jean-Claude Forest, and Gerard Sanders who are all leaving after devoting much time, effort and their considerable talents to the benefit of the IFCC. On behalf of them I also want to thank you, as our members, for having given us the opportunity to serve in the Federation and to become acquainted with different cultures. I am confident that with the new

leadership your needs and expectations will be met and IFCC's global role in Clinical Chemistry and Laboratory Medicine will continue to expand.

Mathias M. Müller
President

Executive Board (EB)

In 2005, the EB met in Vienna, Orlando and Milan. The meeting in Orlando was held prior to the XIXth International Congress of Clinical Chemistry and Laboratory Medicine hosted by the American Association for Clinical Chemistry and the final meeting for 2005 was held in the IFCC Office in Milan. Traditionally, this final meeting of the year is a review and budget-planning meeting and the EB was joined by the Chairs of Divisions who reviewed the previous year's activities and presented their draft budgets. The details can be seen in the Divisional reports below. In addition, the newly elected members of the EB for 2006-2008 were present as observers.

Due to the successful partnership with Emmezeta Congressi in organising IFCC sponsored Congresses and the hosting of the IFCC Office, the contract between IFCC and Emmezeta was renewed for 2005 – 2009.

As agreed during the Council meeting in Orlando, the legal domicile of the IFCC was changed from Lausanne to Pfaeffikon (Canton Schwyz). This decision will give Tax Free Status to the Federation in the future and had been recommended by our Swiss lawyers.

Humphreys & Gates were appointed as financial auditors for the next three years.

During EuroMedlab 2005 in Glasgow the respective Councils and Board of FESCC and EC4 decided to move both European organisations towards unification and amalgamation. The time-frame for forming one organisation with one constitution and one board was agreed upon and combined

elections will be held at Euromedlab 2007 in Amsterdam.

In consultation with EC4 President, Dr Rob Jansen, it has been agreed to have a closer collaboration on scientific issues between EC4 and IFCC. The first joint project will be on kidney function tests (glomerular filtration rate).

As had been agreed when the Joint Committee on Traceability in Laboratory Medicine (JCTLM) was formed, the IFCC contributes financially to the running of this important Committee with the costs of the Secretariat shared between BIPM and IFCC. The contribution is paid by each organisation in installments over a two year cycle with the IFCC's contribution being for 2005-06. A link to the list of Reference measurement Procedures and Reference Materials endorsed by the JCTLM is available on the BIPM and IFCC web-sites.

The International Association for Pediatric Laboratory Medicine (IAPLM) approached the IFCC with the possibility of being integrated into the Federation. During 2005, an agreement was reached between the IFCC President and Professor K Kohse, President of the IAPLM: the Association will be disbanded and an IFCC Task Force for Laboratory Pediatric Medicine, chaired by Prof. Kohse will be formed. The major objectives of this new TF will be the organisation of a bi-annual congress on Pediatric Laboratory Medicine and to collaborate with the IFCC working parties on specific points relevant for Pediatric Laboratory Medicine.

Membership

At the meeting in Vienna, the EB discussed how the IFCC needs to develop so that it can continue to play a significant role in the future of the profession. One of the issues still to be resolved is that there are significant differences between our National Societies which may have an effect on the ability to move forward. A number of

National Societies have only limited membership and feel threatened by medically qualified laboratory personnel. In addition, there are societies within some countries that represent a greater proportion of relevant laboratory staff than does the IFCC National Member. Opening up the membership was discussed at the General Conference in 2004 and the EB is aware that this is a delicate issue that must be considered carefully.

Significant milestones were reported for a number of National Societies.

The Austrian Clinical Chemistry Society and the Austrian Society of Laboratory Medicine had merged to form the Austrian Society of Laboratory Medicine and Clinical Chemistry.

The National Societies of Sweden, Guatemala and Honduras celebrated their 50th Anniversaries in 2005 and were presented with their Anniversary plaques at the Council meeting in Orlando.

The 50th Anniversary of the Yugoslavia (Serbia/Montenegro) Society was celebrated with a FESCC Symposium on June 10, 2005 in Belgrade where the Society was presented with an IFCC Plaque.

Nineteen reports were received from IFCC NS as a response to the request for information on their activities during 2005. These reports were discussed and are included in the full Annual Report which is available on the IFCC website.

The Pakistan Society was welcomed as a new full IFCC member. This new membership was approved unanimously by the Members via a mail ballot.

The EB welcomed Mitsubishi Chemicals and Immunotrack Diagnostics, a Finnish diagnostic company as new Corporate Members.

Professional Scientific Exchange Program

This programme provides scholarships for young colleagues to be trained in science, new technologies and management. It is also envisaged that by these visits, twinning between laboratories in different regions and continents will develop. In 2005, a total of 5 scholarships were granted. The recipients came from Costa Rica, China, Nigeria, Serbia-Montenegro and Vietnam. The training was in institutions in Austria, Italy, Thailand, UK, and USA. The scholars were trained in microbiology, molecular biology, pharmacogenetics and quality assurance. The IFCC believes that this programme contributes to the global expertise of our profession and should be promoted and used more by our member societies. The program enables new competencies for young colleagues which will be beneficial for their respective home institutions and the profession in their country.

Treasurer's Report

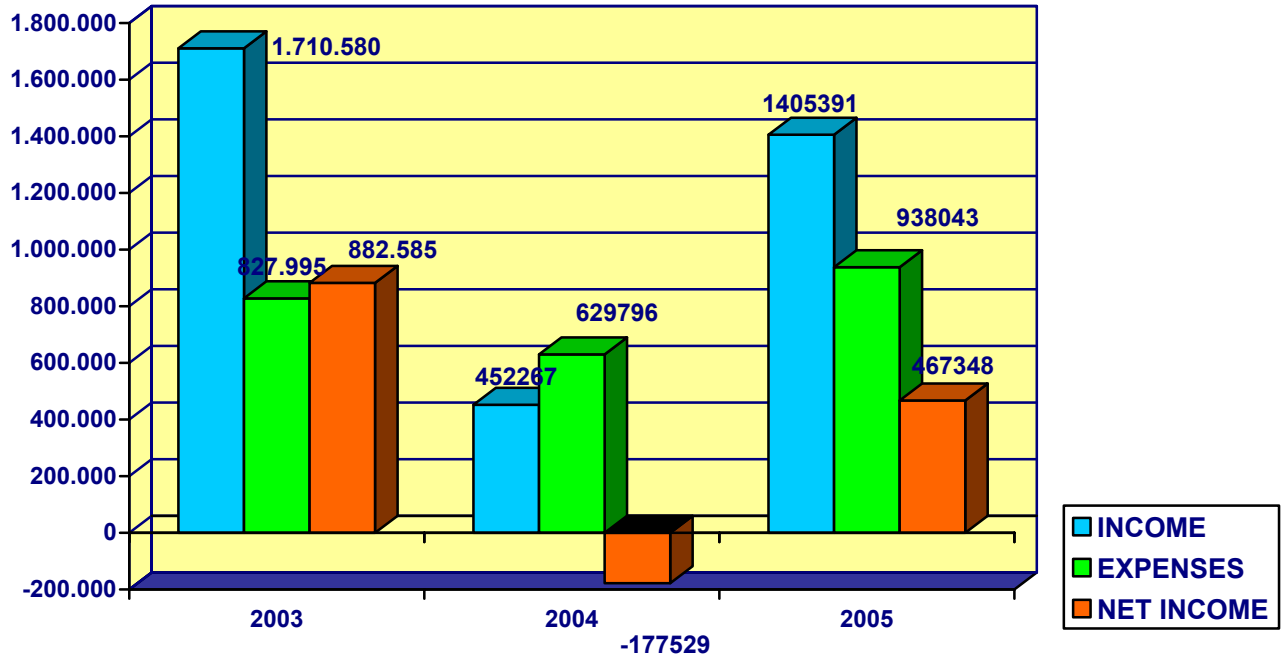
The year 2005 was a very good year financially for IFCC. This was largely due to the fact that there was income from the highly successful EuroMedLab Congress in Glasgow, UK, and from the excellent triennial International Congress of Clinical Chemistry and Laboratory Medicine held in conjunction with the AACC in Orlando, Florida, US. Corporate Member dues have continued to increase due to several more diagnostic companies joining IFCC. We generally did well with Full Member and Affiliate Member dues, although there are a few countries that have not paid.

Our major expenses for 2005, as in all years, have been in supporting our major Divisions: Communications and Publications Division, Conference & Congress Division, Education and Management Division and the Scientific Division. Other expenses include the support of Special Projects, the IFCC Office in Milan and the Executive Board.

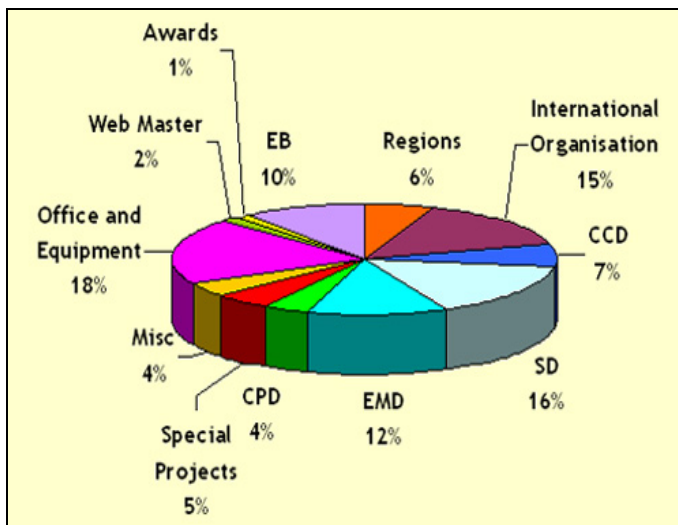
IFCC Finances

A quick view of IFCC finances for 2003-2005

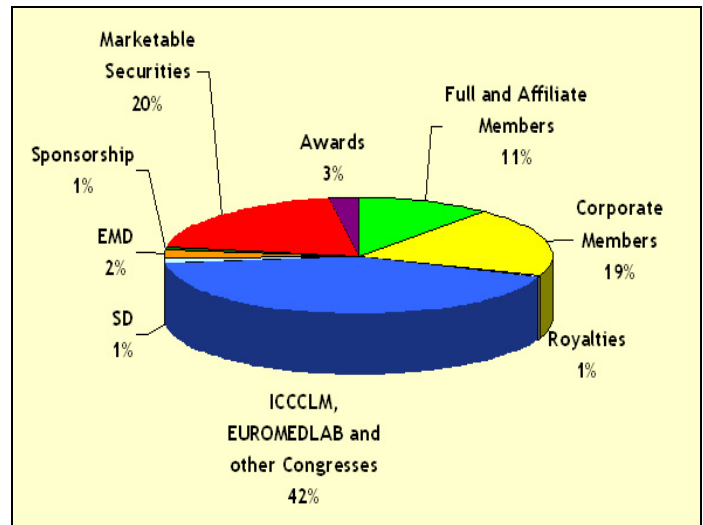
SWISS FRANCS



Major Expenses



Major Income



We continued to fine tune our financial accounting for IFCC. Our audit for 2005 was performed again by Humphreys & Gates Chartered Accountants and went very well. With the help of the Financial Advisory Committee we are continuing to seek ways to improve the income for IFCC, and have developed a financial plan to assist in this effort. A major step which we have taken was to place our investments with Dresdner Bank (Switzerland) in Geneva. We have since realized the best ever level in our reserves. This should allow us to support more programs in 2006.

The relationship with Banca Intesa has greatly helped our processing of claim forms. Using the IFCC Office for bookkeeping has been a very positive experience. I appreciate very much the assistance of Lisa Ionescu.

The year 2006 will not be as successful financially as we will see no income from Congresses.

I wish the new Treasurer, Dr Ghassan Shannan much success.

Jocelyn M. B. Hicks
Treasurer, IFCC

Awards Committee

Members of the 2003-2005 Awards Committee conducting the nominations and selection of awardees were: Chairman C. Burtis (Vice-President, USA), J. Krahn (Canada), P. Laitinen (Finland), G. Shannan (Syria) and E. Topic (Croatia). The Awards Committee was assisted by Christine Tarrajat (Belgium) for the IFCC-EDMA Award and by James Nichols (USA), Marcel Levy (The Netherlands), and Kira Goertz (Roche-AU) for the IFCC-Roche Award.

Awards

At the IFCC Awards dinner on July 23, 2005, the following Distinguished Awards were bestowed:

IFCC/Bayer Distinguished Clinical Chemist Award

This award recognizes an individual who has made outstanding contributions to the science of Clinical Chemistry and Laboratory Medicine or the application of clinical chemistry to the understanding or solution of medical problems.

Presented to Gerard M. Siest.

Dr. Siest is professor of biochemistry and molecular biology at the University Henri Poincaré Nancy I and clinical laboratory director and research director at the Centre for Preventive Medicine in Nancy, France. He has contributed to the field through research, teaching, and service to a variety of organizations. His research has resulted in some 600 publications and he is currently editor-in-chief of *Clinical Chemistry and Laboratory Medicine*. He has mentored numerous scientists who have gone on to leading scientific and professional roles in many countries. Dr. Siest has shown extraordinary energy in organizing international meetings, most notably a series of outstanding conferences in Pont-à-Mousson that continued for 26 years. He has held major leadership roles in scientific and professional organizations, including serving as IFCC president for six years.

IFCC/Bayer Henry Wishinsky International Service Award

This award honors an individual who has made unique contributions to the promotion and understanding of Clinical Chemistry and Laboratory Medicine throughout the world.

Presented to Jack Ladenson.

Dr. Ladenson is the Oree M. Carroll and Lillian B. Ladenson Professor of Clinical Chemistry at the Washington University School of Medicine in St. Louis. As director of clinical pathology projects for the nonprofit organization Pathologists Overseas, Dr. Ladenson has made remarkable contributions to the improvement of clinical laboratory services in developing countries such as Eritrea, Bhutan, Kenya, Nepal, and Madagascar. For example, in Eritrea, he was responsible for establishing a full-service laboratory and system of smaller regional laboratories and has also contributed to the larger public health issues in Eritrea. Dr. Ladenson sees his efforts in Eritrea as a model for other countries and is beginning a similar effort in Bhutan.

IFCC/Beckman Coulter Distinguished Contribution in Education Award

This award honors an individual who has made extraordinary contributions in establishing and developing educational material for our discipline to improve training and educational programs worldwide or in a region.

Presented to William Marshall

Dr. Marshall is a consultant clinical biochemist and clinical director of pathology at the London Clinic and was formerly a reader in clinical chemistry in Guy's, King's, and St. Thomas' School of Medicine in London. His contribution to education has come through academic and professional teaching and through writing. For example, he is the primary author of two best-selling textbooks: *Clinical Chemistry* and *Clinical Biochemistry: Metabolic and Clinical Aspects*. He has served the IFCC in various capacities, particularly as a member of the Education Division.

IFCC/Abbott Award for Distinguished Contributions in Molecular Diagnostics

This award honors an individual who has made unique contributions to the promotion and understanding of Clinical Chemistry and Laboratory Medicine throughout the world.

Presented to Carl Wittwer

Dr. Wittwer is professor of pathology at the University of Utah Medical School and director of flow cytometry and new technology at Associated Regional and University Pathologists in Salt Lake City. In the early 1990s he developed rapid-cycle PCR amplification techniques requiring only 10 to 15 minutes. In the mid-1990s, he adapted flow cytometry optics to thermal cycling for real-time monitoring of PCR. Since 2003, he has directed an effort to simplify DNA analysis so mutation scanning and genotyping can be performed with a minimum of processing steps. He is the primary inventor of the LightCycler system, with more than 4,000 units placed worldwide. Dr. Wittwer holds 13 US patents, has published more than 100 research articles and is editor of the book series, "Rapid Cycle Real-Time PCR."

IFCC/EDMA Award

At the occasion of the IFCC EUROMEDLAB Congress in Glasgow 2005 the IFCC/EDMA-Award for Evidence of Effectiveness of Laboratory Tests were presented to K. Decochez, Belgium.

After the Glasgow Congress, EDMA leadership informed IFCC leadership that they were terminating their sponsorship and support of this award.

IFCC/Roche Award

During the International Congress in Orlando, five finalists competed for the IFCC/Roche Award in Advances in Critical Care Medicine with each making a presentation at the IFCC/Roche Symposia. Winners of this competition were:

First Place

Dr. Mohammad Vasei¹

Dept. of Pathology
Shiraz Medical School
Shiraz
71344 Iran
IRAN

“Urinary 5-hydroxy indole acetic acid as a test for early diagnosis of Acute Appendicitis”

Second Place

Dr. Dieter Mesotten

Dept. of Intensive Care Medicine
University Hospital Gasthuisberg
B-3000 Leuven
BELGIUM

“The contribution of important metabolic changes to the improved outcome of critical illness by intensive insulin therapy “

Third Place

Dr. Thomas Müller

Dept. of Laboratory Medicine
Konventhospital Barmherzige
Brüder
Seilerstaette 2
A-4021 Linz
AUSTRIA

“Diagnostic accuracy of B-type natriuretic peptide (BNP) and amino terminal proBNP (NT-proBNP) in the emergency diagnosis of heart failure“

After the symposium, President Mueller, Vice-President Burtis, and Vice-President Palicka met with representatives from Roche. The latter were willing to continue support and sponsorship of this award in 2008 but requested significant changes in

¹ Because of problems with obtaining a visa, Dr Vasei did not attend the Congress and Dr Shannon made the presentation. He is commended for doing an excellent job!

format. After considerable discussion, a scholarship format was agreed upon.

New Award - Distinguished Award for Laboratory Medicine and Patient Care

In addition to the five awards that are presented at the ICC every three years, an agreement has also been reached with Ortho Diagnostics to add a Distinguished Award for Laboratory Medicine and Patient Care to the IFCC awards programme. This award will honor an individual who has made unique contributions in Laboratory Medicine, especially in improving patient care and having a world-wide impact in clinical medicine.

Carl Burtis
Chair, Awards Committee

Communication and Publications Division (CPD)

10.1 Activities and Reports

Three committee meetings were held in 2005, two by telephone conference call and one face-to-face meeting.:March 2005 (teleconference), Orlando July 2005 (full committee meeting). September 2005 (teleconference). In addition, a web workshop was held in November in Milan.

10.3.1 Working Group – eJIFCC

The publication schedule was adhered to, consisting of 4 issues per year (see Appendix 1). The website now has an archive of the complete set of issues since the change to the electronic version.

10.3.2 Working Group – IFCC News

The change to a publication schedule of 6 issues per year has been a success (see Appendix 2). Archives of newsletters back to 2001 are now available on the website.

The use of editorial articles from each of the various divisions and IFCC officers has been valuable in publicizing the activities of the IFCC.

10.3.3 Working Group – Web-Site

With the appointment of a new editor, Grazyna Sypniewska (Poland) who attended training sessions in Milan in November, there has been a redefinition of duties.

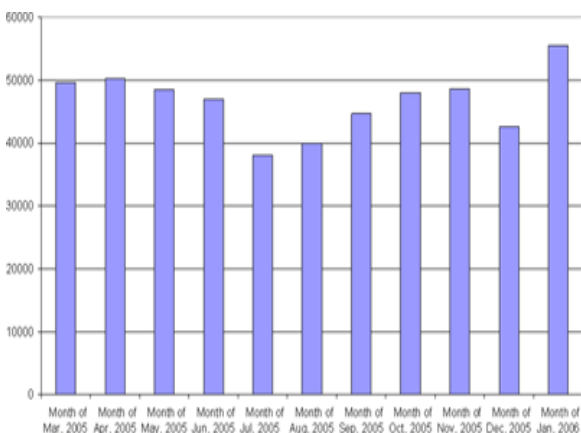
Access continues to climb and is now 1600 sessions per day or 50,000 per month.

The principal focus is on the proposed move to a new platform with a complete rewrite to take advantage of new facilities. These will include a rewritten bookstore, provision of wiki and discussion board facilities.

A pilot program is being established to explore the provision of web pages to National Societies or other Working Groups.

A separate directory for the C-EBLM has been established to provide a webspace for this activity. Included is a database of systematic reviews and meta-analysis in laboratory medicine. The searchable database access provided is a marked improvement, creating an important resource.

A similar website for the C-ECD is in the process of being set up.



10.3.4 Working Group - Spanish (Ibero-american) Nomenclature and Translations

Responsibility for editing the Rincon IberoAmericano web pages has been centralised to the IFCC office. This part of the web site continues its strong success thanks to the vigorous efforts of its editorial team.

10.4.1 Documents from Committees & Working Groups - Report of the Editor of Documents

The database continues to be updated as publications are forthcoming. See appendix 3 for 2005 content list.

10.4.2 Monographs

The monograph “Managing Change in the Clinical Laboratory” has now been printed and distributed.

10.9 Corporate Member Activities

A new corporate member is being sought following Werner Poppe’s resignation. His contribution in improving communication and participation with the corporate members is gratefully acknowledged.

10.20 Membership

Andrew Wootton (Chair)
Craig Webster (Vice-Chair and Multimedia)
Peter Lehmann (Secretary/Editor Documents)
Ellis Jacobs (Editor IFCC News)
David Williams (Editor eJIFCC)
Grazyna Sypniewska (Web editor)
Vacant (Corporate Representative)

C Webster was appointed as Vice-Chair and Multimedia Editor. Grazyna Sypniewska was appointed as Website Editor. Werner Poppe resigned as corporate representative and a call for nominations has been made. A call for nominations for News Editor will also be made in 2006.

10.30 Budget

Considerable efforts have been made to reduce expenditure. These have successfully reduced costs without compromising the activities of the Division.

10.40 Multimedia

The importance of multimedia for IFCC educational activities is recognized by the appointment of a division member to develop this area.

Sessions from the Orlando Congress were recorded and will be made available for download.

The new podcasting project has launched the first two episodes. The concept will be a regular series of radio-style audio broadcasts and will include interviews with individuals prominent in Clinical Chemistry and some educational case material. It is hoped that this will provide opportunities for National Societies to share news of their activities.

Andrew Wootton,
Chair CPD

Congress and Conference Division (CCD)

International Congresses of Clinical Chemistry and Laboratory Medicine

The 2005 International Congress of Clinical Chemistry and Laboratory Medicine (ICCCLM) was held in Orlando, U.S.A., from 24 – 28 July 2005. It was a joint meeting of the XIX ICCCLM and the 2005 Annual Meeting of the American Association for Clinical Chemistry.

The next International Congress (XX ICCCLM) will be held in Fortaleza, Brazil from 28 September to 04 October 2008. This congress will be hosted by the Brazilian Society of Clinical Analyses. The main working bodies of the congress have been established. Emmezeta Congressi will arrange the exhibition.

In 2011, the IFCC WorldLab 2011 (XXI ICCCLM) will be held concurrently with the IFCC–FESCC EuroMedLab from 15–20 May 2011 in Berlin, Germany. This congress will be hosted by the German Society of Clinical Chemistry and Laboratory Medicine (DKGL).

One of the major responsibilities of CCD during 2005 was finalizing proposals for IFCC symposia at the Orlando congress and assisting the organizing committee for

Fortaleza and Berlin.

Regional Congresses

There are four regions within the IFCC structure and each regional federation organises its own Regional Congresses of Clinical Chemistry and Laboratory Medicine (RCCCLM). There were two RCCCLMs during 2005. The European RCCCLM, the 16th IFCC-FESCC European Congress of Clinical Chemistry and Laboratory Medicine, EuroMedLab 2005 was held in Glasgow, Scotland from 08 - 12 May 2005. The total of participants was 3,286 from 83 countries. The organising committee was chaired by Dr. Graham Beastall, the former chairman of CCD. Due to high number of delegates and the sold-out exhibition space, the congress was an economic success as well as being very successful scientifically. From the perspective of CCD, the Glasgow congress organization was an excellent model for future member societies on how to plan, organise, promote and report on a scientific congress on laboratory medicine. The next EuroMedLab will be held in Amsterdam, Netherlands from 03 – 07 June 2007. Its theme is “Your future in patient care”. The Organizing Committee President is Prof. Gerard T B Sanders and the International Scientific Steering Committee President is Prof. M A Blankenstein.

The 2009 EuroMedLab will be held in Innsbruck, Austria.

The XI Arab Congress of Clinical Biology will be held in Damascus, Syria from 29 April – 02 May 2006. This congress will be chaired by Dr. Ghassan Shannan. The 2009 Arab Congress is scheduled for Beirut, Lebanon. The XVII Latin American Congress of Clinical Biochemistry (COLABIOCLI) will be held in Asuncion, Paraguay from 04 – 07 April 2006.

The 11th Asian Pacific Congress of Clinical Biochemistry, will be held in Beijing, China from 14 – 19 October 2007.

IFCC General Conference

IFCC Member societies and Corporate Members were sent questionnaires in 2005 concerning various aspects of the IFCC General Conferences. The responses were collated by CCD and a summary submitted to the EB for their consideration.

IFCC Specialist Congresses

The 10th Bergmeyer Congress was held in Garmisch-Partenkirchen, Germany from 14 – 16 March, 2005. The topic of the meeting was “Diabetes and Cardiovascular Disease”. I Vermes serves as CCD representative on the steering committee for this congress sponsored by Roche Diagnostics.

The Beckman Coulter Protein Conference 2005 planned as a satellite meeting of EuroMedLab 2005 Glasgow was cancelled by Beckman Coulter due to very low registration numbers prior to the meeting scheduled for May 2005

IFCC Auspices

CCD provides IFCC Auspices to high quality conferences in the area of clinical chemistry and laboratory medicine that apply for the meeting to be held under IFCC auspices. This arrangement is mutually beneficial for IFCC member societies and meeting planners. It enables IFCC to promote congresses of interest to its members and strengthens IFCC image as a supporter of high level laboratory science. The organisers of congresses get lots of publicity through the information channels of IFCC. During 2005, IFCC Auspices were awarded to nine conferences.

Meetings and Membership

CCD had three meetings, one in Glasgow, Scotland in connection of the EuroMedLab 2005 Glasgow, the second during the Orlando ICCCLM congress and the third meeting in Amsterdam that included a visit to the RAI congress centre, the venue for the 2007 EuroMedLab.

Several changes in CCD membership took place at the beginning of 2005. Joseph Lee (HK) and Josefina Mora (ES) completed their terms of office as CCD members. CCD warmly acknowledges the great contributions of all of them to the congress and conference activities of IFCC. Lasse Viinikka (FI) completed his term as chair of CCD the end of 2005 and Albert Fraser (CA) was appointed CCD Chair effective January 2005.

Tomris Ozben (TK) and Sunil Sethi (SG) were welcomed as new members of CCD in 2005. At the end of 2005, Andreas Rothstein (CO) completed his term as CCD member. A new member representing the Latin American region will be appointed in 2006.

Albert Fraser
Chair CCD

Education and Management Division (EMD)

GENERAL REMARKS

In 2005, the Education and Management Division continued its activities. Symposia were held at International Congresses and Courses were given. The Visiting Lecturer Program was successful as well.

For the next year it is expected that those Committees in the Division that did not contribute much in 2005 will become more active. The focus of the Division still will be more on developing countries.

ACTIVITIES AND REPORTS

The Division had its main meeting in 2005 during the International Congress of Clinical Chemistry in Orlando in July 2005. The Division met there as a whole, and the different groups met separately. As usual, for every group within EMD, the following items were dealt with:

- give an overview of their activities in the last year
- bring forward future plans, activities and meetings
- indicate where co-operation with other groups within the Division is relevant
- Review membership
- indicate the budget necessary for the activities

COMMITTEES

9.02.00 Executive Committee (EC)

In 2005 the Executive Committee of the Division consisted of

Chair: GTB Sanders (NL); Vice Chair: M. Burritt (US); Members: J Smith (UK), L Lai (MY), L Vankrieken (BE, Corp, Rep).

Short philosophy of the Division and the EC: The Executive Committee of the Education and Management Division (EMD-EC) considers it as its task to implement a strategy for the Division, and monitor the progress of the activities derived from it. It guides the Division and its Committees and Working groups, and takes care of planning (strategy), follow-up, budget monitoring.

EMD-EC has been actively focusing more on the clinical side of the profession and EBLM, the use of modern media, courses on new technologies (molecular biology, flow cytometry), and teaching clinical chemistry in developing countries. This means that EMD tries to increase participation in regional and international congresses. An important part of our activities is aimed at developing countries in order to raise the quality of clinical chemistry practice in these countries. The Visiting Lecturer Program is an important tool to reach this goal.

It is the intention of the Executive Committee of the EMD to continue this strategy in the future.

EMD-EC met in Wales (UK) in January and had a meeting during the ICCC in Orlando

in July.

9.02.04 Committee on Clinical Molecular Biology Curriculum (C-CMBC)

Chair : M. Ferrari (IT); Members: S. Kraiss (US), H. Sprecher (IL), M. Neumaier (DE)

Activities: Molecular Biology teaching and training of trainers.

Courses in Clinical. Molecular Biology Techniques:

- 3rd Course 5-9 July 2005 Milan, Italy
- Vietnam 27-29 October 2005
- Tunisia 30 November – 2 December 2005

Symposia at International Congresses:

- Glasgow 2005: "Genotyping in the postgenomic era" and Dr Ferrari lectured on : "High throughput genotyping" in the Session: Biochip/Biotechnology.
- Orlando 2005: "New Analytical Techniques of Molecular Diagnostics" Moreover the Chair gave an another lecture in the Edutrak proposed by Steve Wong entitled Global Genomic Personalized Medicine in which he will present "European Regulatory Policy for Genomic Tests and Update on Genotyping Methodologies and Clinical Applications".
- A joint session IFCC(C-CMBC)/AACC(Molecular Path Div) at Clin Chem Meeting, Mexico (3/2005) was held.

The Chair was invited by NCCLS to be member of their Committee on Molecular Methods.

In Progress: organization of courses in the following meetings.

Educational course: Indonesian Association for Clinical Chemistry 10/2006
COLABIOCLI, 4/06 Paraguay
APFCB, Beijing, 2007

9.02.05 Committee on Analytical Quality (C-AQ)

Chair : K. Sikaris (AU) ; Members: G. M. Henriksen (DK), C. Ricos (ES), Y. Bilty (LB)

Education in relation to Analytical Quality

- Education Courses EQA / IQC
- Cooperation with other IFCC committees
- Management in relation to analytical quality
- Establishment of EQA
- Serum Donation Project requests (SERO)
- Regional Promotion of EQA
- Standards
- IFCC review of ILAC G13 standard for External Proficiency Testing

The Committee presented a full day workshop at the 19th ICCA in Orlando. Title: "The quality of Point of care Testing."

The Chair has performed a Visiting lecturer tour in November 2005 in Nigeria.

Plans are to improve collaboration between EQA providers globally by organizing an international meeting; a letter of invitation has been sent out.

The Committee will organize a symposium at the Damascus meeting (29/4 – 2/5, 2006).

9.02.07 Committee on Evidence Based Laboratory Medicine (C-EBLM)

Chair: A.R. Horvath (HU); Members: J. Watiné (FR), R. Christenson (US), P. Bunting (CA)

TERMS OF REFERENCE OF C-EBLM:

1. Promote the understanding and the methodology of EBLM
2. Support of rational laboratory use by implementation of results from EBLM to daily practice by educating laboratory professionals.
3. International dissemination of and collaboration in EBLM

Activities:

- IFCC-FESCC Euromedlab Congress, Glasgow
8-12 May 2005, Glasgow, Scotland, 16th IFCC-FESCC Congress of Clinical Chemistry and Laboratory Medicine – Invited talk on the evidence of thyroid testing – *AR Horvath*
- 2005 ICCA/AACC, Orlando
C-EBLM full day symposium on The Role of Evidence-based Laboratory Medicine, 24-28 July 2005, Orlando, Florida. XIX ICCA/AACC Annual Meeting.–
Coordinator: AR Horvath, with contribution of members of C-EBLM
- 1st IFCC/FESCC EBLM Course
21-24 September 2005, Budapest, Hungary – *Coordinator: AR Horvath, with contribution of members of C-EBLM and the Cochrane SRDST-MG*
This high level course was an enormous success.
- Rita Horvath and Joseph Watiné participated in the G-I-N Conference in Lyon December 5-7, 2005.
- Publication of EBLM teaching materials
2006: IFCC booklet and/or CD-ROM –
Coordinator: AR Horvath, with contribution of members of C-EBLM

The Committee will organize a symposium at the Asunción meeting in April 2006.

Database on Systematic Reviews

The Committee has put a lot of effort into a searchable Database on Systematic Reviews. Most of this work has been done by Joseph Watiné. Supported by the staff of the IFCC Office it has been published on the IFCC Web-site.

<http://www.ifcc.org/divisions/EMD/c-eblm/database.asp>.

9.02.08 Committee on Education and Curriculum Development (C-ECD)

Chair: L. Allen (CA); Members: N. E. Fink (AR), D. Juretic (HR) RWK Chiu (HK), EY Sozmen (TU), B. Dufour (US)

The Committee has 32 corresponding

members.

This committee has been restructured and now includes the Working Group on Reviewing Educational Documents (WG-REM, 9.03.05).

Projects:

La Plata Master Course; this ended in 2005 with the last two students visiting a foreign laboratory.

9.02.09 committee on Clinical Laboratory Management (C-CLM)

Chair: W. de Kieviet (NL); Members: E. Frank (IN), H. Stekel (AT)

For the Committee on Clinical Laboratory Management (C-CLM, 9.02.09) a new Chair and members have been appointed. Time has been devoted to discuss objectives and goals.

Rationale

EMD-EC believes that it is essential that part of the improvement of the quality of a laboratory, especially in developing countries, should come from clinical laboratory (quality) management expertise. The need for basic financial and managerial skills has been repeatedly stated during numerous meetings and visits to various member countries.

Terms of Reference

1. The primary focus of the committee will be to provide basic management skills to the widest possible audience most in need of these resources, i.e., the developing/emerging member nations. The main aim of these actions will be the improvement of the quality of the diagnostic process, leading to a better performance of clinical chemistry worldwide.

2. The committee will focus on the production of accessible, practical and adaptable basic management tools. For example: introduction of basic quality systems, basic financial concepts; basic budgeting; essential economics; cost vs price calculations; personnel management;

effective use of computerised tools, including the internet for basic management functions.

A symposium is foreseen in Beijing in 2007.

9.03.04 Working Group on EPO (WG-EPO)

Chair: L. Thomas (DE); Members: C. Brugnara (US), M. Cazzola (IT), J. Cook (US), J. Iino (JP), W. Oosterhuis (NL), P. Lehmann (DE, Corp Member, Roche Diagnostics)

The project is in its final stage.

9.03.05 Working Group on REVIEWING of Educational Materials (WG-REM)

The WG-REM was created to review the educational materials for potential distribution and/of publication by IFCC. No material was offered for review and thus, the WG was closed and the activities transferred to C-ECD (9.02.08).

9.03.07 Working Group on Distance Learning

This WG on Distance Learning is a sub-committee within C-ECD (9.02.08)

Chair (Acting): D Juretic (HR); Member: P Kocna (CS)

Scope: Liaise with Associate Members of the Committee on Education and Curriculum Development to determine educational needs of their countries/regions and work with them to improve education in clinical laboratory science worthwhile through the Project on Distance Education

A Questionnaire on distance education was sent out to the IFCC membership and the responses have been evaluated. On the basis of the answers the committee has set out its further strategy:

Develop IFCC portal, including process to change information regularly

Select material from societies' websites to

put on IFCC portal

9.04 SPECIAL PROJECTS

9.04.01 Visiting Lecturers Program (VLP)

Chair: M. Burritt (US)

Sponsors: DPC and Dade-Behring

The following travels of lecturers to developing countries have been supported in 2005.

Dr. Sverre Sandberg (Norway) presented lectures at a conference organized by the Regional Association of Clinical Laboratory Diagnostics in St. Petersburg, Russia (an Affiliate Member of the IFCC) from 28 May-5 June in St. Petersburg. Subjects included EBLM.

Dr. Emilia Martinez (Mexico) lectured at the III Central American Forum and II National Forum on Quality Assurance and Advances in Diagnostic Microbiology in Tegucigalpa, Honduras on 29-30 June. Other VLP have been requested by the Honduran National Society. Subjects include elaboration of the quality manual and steps for the accreditation process.

Dr. Xavier Fuentes Arderiu (Spain) presented lectures in Uruguay at the V Congress of Bioclinical Chemistry from September 16-18. Subjects include quality in the clinical laboratory, biological variation and errors/uncertainties in medicine. Note: the Uruguayan Society has formed a working group through the IFCC to help translate quality documents into Spanish for the Latin American countries. Other VLP speakers from past years (Drs. Fernandez and Grazia), along with Dr. Arderiu, have addressed these topics and have provided support for this effort.

The VLP supported a speaker at the Course of EBLM organized by the C-EBLM IFCC/FESCC and the Screening and Diagnostic Tests Methods Group of the

Cochrane Collaboration in Budapest on 21-24 September. This course had an excellent review by the participants.

Dr. Camilo Fernandez lectured at a national seminar/meeting on Accreditation and Quality Improvement in Clinical Laboratories on 5-8 October sponsored by the Guatemalan Society of Clinical Chemistry.

Dr. Callum Fraser (UK) presented lectures at the XIV Congress of the Chilean National Society in Vina del Mar, on 19-21 October. Subjects included the impact of biological variables in the clinical laboratory and interpretation of clinical chemistry laboratory data.

Dr. Carmen Melchor (Mexico) has presented lectures at the VIII Ecuadorian National Congress and III International Congress of Chemical Biochemistry at Manta, Ecuador on 26-27 October. Subjects included molecular mechanisms of bacterial resistance, safety management and the role of the laboratory in nosocomial infections.

Dr. Ken Sikaris (Australia) presented lectures at the annual meeting of the Nigerian Association of Clinical Chemistry in Clabar Cross River State, South East Nigeria on 23-24 November. Subjects include QC/QA and external proficiency testing.

For 2006 already three lectureships have been planned.

9.04.02 Course on Flow Cytometry

Chair: G. Rothe (DE); Co-chair: A. Thews (CH); Members: D. Barnett (UK), M. Maerer (DK), M. O'Gorman (IL,US), A. Orfao (ES)

Activities: flowcytometry course and symposium.

With the support of Beckman Coulter a Course was held from 7-9 October 2005 (Bremer Zentrum für Laboratoriums-

medizin, Bremen, Germany) “Strategies for the Diagnostic Monitoring of the Specific Immune Response”
Symposium and Wet-lab Sessions
University of Mainz, and Beckman-Coulter
Co-operation.

Gerard Sanders
Chair EMD

Scientific Division (SD)

During 2005, the following members served on the SD Executive Committee: Jean-Claude Forest (CA) (Chair), Mauro Panteghini (IT) (Vice-Chair), Howard Morris (AU) (Secretary), Ian Young (UK), Nader Rifai (USA), Ulf-Hakan Stenman (FI), Rolf Hinzmann (DE) (Corporate Representative), and Matthias Muller (AT) (EB-Liaison). Three representatives of International Organizations were invited to attend the meeting as consultants: Jos HH Thijssen (JCTLM), Heinz Schimmel (IRMM) and David Bunk (NIST). Two meetings were held during the year; May 12-13 (Glasgow, UK in conjunction with the FESCC Congress) and September 30-October 1 (Milan, Italy).

Relationship with International Organizations

The Scientific Division has pursued the expansion of its activities with international organizations to promote the implementation of the concept of traceability in laboratory medicine and the implementation of reference measurement systems.

- **Joint Committee on Traceability in Laboratory Medicine (JCTLM)**

The Joint Committee for Traceability in Laboratory Medicine (JCTLM) including its two working groups has continued to develop its program. The Working Group on Reference Measurement Procedures (RMPs) and Reference Materials (RMs) has commenced its program of identifying and

reviewing against agreed criteria (ISO standards 15193 and 15194). It has published lists of higher order certified RMs and RMPs required for industry to comply with the EC directive regarding *in vitro* diagnostic medical devices. List 1 and List 2 have been published. A final version of the Quality Manual was presented to a meeting of the JCTLM Executive Board in November. The second Working Group on Reference Laboratories has drafted criteria for acceptance as a Reference Laboratory.

- **Institute for Reference Material and Measurement (IRMM)**

Close collaboration with IRMM continues with practical joint ventures such as preparation of Certified Reference Materials for the following analytes: AST, ALP, myoglobin, haemoglobin A2, a new preparation of CRM470, BNP, progesterone, T3 & T4, Prothrombin factor II wild type and Factor II mutant as genetic reference materials.

- **Clinical and Laboratory Standards Institute (CLSI) (formerly NCCLS)**

The working relationship between CLSI and IFCC continues. Joint projects with CLSI are reviewed on a regular basis. The documents on Quality Assessment Programs for Molecular Methods (MM14) and Performance of Cellular Immune Functional Assays (I/LA 26), have been completed.

Current ongoing joint CLSI/IFCC projects include the following: Analysis of Body Fluids; Molecular Methods for Microarrays; Sample Collection and Handling for Molecular Test Methods; Determining Clinical Utility of Genetic Tests; Body Fluid Analysis for Cellular Composition; Metrological Traceability and its Implementation; Mass Spectrometry in the Clinical Laboratory: A Guideline to Implementation, Operation and Quality Assurance; IFCC project proposal on Total Plasma Homocysteine; IFCC project proposal on Immunosuppressive Drug

Monitoring; Use of External RNA Controls for the Quality of Gene Expression Measurements with Microarrays and by Real-Time PCR (RT-PCR); Expression of Uncertainty of Measurement in Clinical Laboratory Medicine.

- **National Institute of Standards and Technology (NIST)**

A large number of projects are underway at NIST and some are of considerable interest to IFCC. These include: preparation of primary reference material for cardiac troponin I (cTnI), serum reference materials (SRM) for electrolytes, glucose, lipids, creatinine, homocysteine and folate, non-peptide hormones, and drugs of abuse. Each SRM preparation will consist of analytes at 3 levels in serum. NIST Clinical Reference Methods are under development for C-reactive protein and BNP in serum.

- **ICCLM**

The SD participated in the XIXth ICCLM held 24-29 July 2005 organising two symposia; "Achieving Standardization in Laboratory Medicine – A Hard but Feasible Task" and "Monitoring Immunosuppressive Drugs".

- **Regional and other congresses**

The SD participated in the 16th IFCC-FESCC European Congress of Clinical Chemistry and Laboratory Medicine held 8-12 May 2005 organising a symposium: "Traceability in Laboratory Medicine".

Activities of Committees and Working Groups

The Committees (Cs), which are theme-oriented, carry out much of the scientific and professional activities of the Scientific Division. Their work is often in close collaboration with other international organizations. For more specific tasks, the activities are normally accomplished through Working Groups (WGs). During the

IFCC-FESCC Congress (Glasgow, UK May 2005) the SD Executive Committee had the opportunity to meet with representatives of the C-MD and C-PP. At the meeting held in Milan the SD Executive Committee met with the Chairs of the C-RIDL and WG-SHbA2.

- **Committees**

- **C-Nomenclature, Properties and Units (C-NPU)**

This IFCC/IUPAC Committee is responsible for the maintenance of the generic database, which is now available through the IFCC website. C-NPU is currently investigating long term maintenance of the database and wider utilization at the international level. Discussions have commenced to identify common interests between the C-NPU database and that of the CLSI. The discussions also involve members of LOINC over common interests between these three databases in this field. A member of the committee is representing IFCC on the Subcommittee on Vocabulary in Metrology and Guides to Expression of Uncertainty of Measurement in Metrology (GUMM) of the Joint Committee on Guidelines and Metrology (JCGM) of the International Organization for Standardization (ISO). It is pleasing to note that following representation from the IFCC, the latest version of VIM (VIM3) will be freely available on the BIPM web site for partner organisations. Projects currently ongoing include Unitage and Nomenclature of HbA1c, Properties and Units for Urinary Calculi, Terminology for observations in scientific communication and translation of the C-NPU database elements and properties into French.

- **C-Molecular Diagnostics (C-MD)**

The priority area of activity is to establish a network of IFCC Molecular Diagnostics Centres, each with a focus on a particular area of clinical interest in this field. The first three areas will focus on haemochromatosis,

factor V Leiden and apolipoprotein E. The purpose of these centres is to enhance technology transfer of clinical testing expertise to laboratories that provide clinical services in these areas and a document describing their roles is currently being prepared. A call for applications will then be issued on the IFCC web site and to national representatives. The committee is working closely with the EMD C-Molecular Biology Curriculum to prepare a position paper titled « Guidelines for the Use of Molecular Diagnostics in Laboratory Medicine » Discussions with IRMM and EuroGenTest have been initiated to establish a list of nucleic acids reference materials for clinical laboratories in molecular diagnostics.

- **C-Plasma Proteins (C-PP)**

Data for the first (pre-CRM470) samples for several countries including France, Italy, and the Czech Republic of the International Quality Assurance project remain to be collected. Publication of data from all reporting countries will proceed because the study does show a persistent bias for several proteins among manufacturers. The possibility of using world-wide, common reference intervals in multiple racial and ethnic groups has been explored but is not possible at this time because of persisting concentration/calibration differences among the assays from the different manufacturers. The committee has developed a simplified protocol for transferring values from reference materials such as CRM470 to commercial protein assays. Position papers on the comparison of agarose gel electrophoresis with capillary electrophoresis, and on other methods (such as quantification of serum immunoglobulin free light chains) for the detection of M components are in the final stages of preparation. The committee is presently involved in the following projects;

- (1) collaboration with IRMM for the development and certification of a new lot of CRM470, to be called CRM470-R.
- (2) evaluation of the impact of new technologies for the study of human plasma proteome on

laboratory medicine (in connection with HUPO). A WG to undertake the standardisation of carbohydrate-deficient transferrin has been formed under the Chair of A. Helander (SE).

- **C-Standardization of Markers of Cardiac Damage (C-SMCD)**

The C-SMCD has continued its work on standardization of various cardiac markers. A secondary RM has been selected for myoglobin in close collaboration with IRMM. IRMM is continuing to work on the reference method for the certification of the selected material (IRMM/IFCC 458) as well as to further characterise this material. In collaboration with the AACC Subcommittee for Cardiac Troponin standardization and NIST, a candidate primary reference material for cTnI (human CIT tertiary complex NIST SRM 2921) was selected to be used for cTnI assay standardization. Further to the preparation of this primary reference material, discussions are underway for the preparation of a secondary matrix reference material using a serum-based matrix for cTnI for which the values can be assigned by an immunoassay method that is calibrated using the primary material. The aim is for the material to demonstrate equimolarity. Purity studies on BNP and NT-proBNP materials supplied by companies marketing these antigens are underway in preparation for a project for the standardisation of the BNP assay. The aim is to work for the standardisation and harmonisation of BNP assays. Work on NT-proBNP assays will continue at a later stage. The C has decided that the preparation of reference material for BNP (recombinant or synthetic BNP material) is a useful starting point. A document titled "Quality specifications of BNP assays" was published (Clin Chem 2005;51:486). A document in the form a theoretical review on new markers of ischaemia and plaque disruption in acute coronary syndrome patients was published (Clin Chem 2005;51 :810). The committee is in the process of collecting clinical and analytical data on all manufactured cardiac troponin and natriuretic peptide assays that

will be placed on a link on the IFCC website, to serve as a repository for evidence based information as assays evolve over time.

- **C-Reference Systems for Enzymes (C-RSE)**

Work on standardisation of the amylase and ALP assays and certification of the AST reference material has continued. The C will proceed with the project to standardise the lipase measurement noting that significant technical issues need to be resolved. The C is continuing to monitor the performance of the laboratories in the Network. Recognising the requirement for support of such laboratories, the IFCC is considering the development of a business plan.

- **C-Point of Care Testing (C-POCT)**

The C continues to develop its priorities for pursuing projects. It was noted that industry was well represented on the C.

- **C-Traceability in Laboratory Medicine (C-TLM)**

The Committee continues to support the activities of the JCTLM within the IFCC. Criteria for identifying reference laboratories of the JCTLM have been defined. A Procedure Manual has been prepared describing the steps to be followed by laboratories participating in IFCC Ring Trials for Reference Laboratories. It is available at www.dgkl-rfb.de:81 The major topics covered in the manual include: Description of Process; Rules to be Admitted; Frequency of Exercises.

- **C-Reference Intervals and Decision Limits**

Following a review of the current state of theory and documents in the field, it was agreed that the initial project is to assist with the production of the CLSI/IFCC Joint Document on Reference Intervals. The

second task will be to produce a practical document for use in clinical laboratories.

- **Working Groups**

- **WG-Selective Electrodes and Biosensors (WG-SEB)**

A review of current projects is underway.

- **WG-Reference Methods for Apolipoproteins (WG-MA)**

Technical issues remain to be resolved with regard to the production and characterisation of SP3-08 Apo B reference material. These issues relate to ISO guide 15194 requirements for uncertainty information. After completion of the studies, the material will be submitted through IFCC to WHO for recognition.

- **WG-Human Chorionic Gonadotrophin (WG-SHCG)**

A meeting with colleagues from interested diagnostic companies agreed that the Working Group would focus on investigating the appropriateness (or otherwise) of commercially available hCG methods for use in oncology. Most of these methods are approved only for use in pregnancy. This is a regulatory issue of major concern to clinical laboratories using the tests to monitor cancer patients. Specimens of selected specifically to address this question have been prepared and will be analysed by the different methods early in 2006. The results will form part of a manuscript currently being prepared by the hCG Working Group on the implications of use of the six International Reference Reagents previously prepared by the Working Group on between-method comparability. The frequency of false positive and false negative results in assays for hCG and the clinical implications of these results are of considerable concern. Recommendations about appropriate action to be taken by user laboratories – both to identify and to remedy these errors - are

being developed. The availability of a reference method for hCG would effectively address both these issues and it was agreed that this issue would continue to be actively considered.

- **WG-Standardisation of Thyroid Function Tests (WG-STFT)**

The WG has agreed on a clear plan of action. Total T4 is the first measurand to be standardised, as almost all the elements of the reference measuring system for it are available. Work on the development of commutable serum matrix-based reference materials is underway. Progress has been made with the development of a sensitive equilibrium dialysis-ID-LC/tandem MS measurement procedure for the measurement of free T4.

- **WG-Glycohemoglobin (HbA1c) (WG-HbA1c)**

A method for value assignment has validated providing further confirmation that the Master Equation representing the correlation between the IFCC reference system and the US NGSP, Swedish and Japanese systems is correct. The network of 14 laboratories is participating in twice yearly Ring Trials with an imprecision of less than 1%. It is agreed that this network should participate in the JCTLM structure. The Clinical Implementation Group continues work to reach agreement on the name of the analyte and its units. The C-NPU has made a significant contribution to the debate. A large HbA1c/glucose Equivalence study in co-operation with the IDF, EASD and ADA, including at least 6 centres and specimens from subjects with normal glucose homeostasis, Type 1 diabetes and Type 2 diabetes is underway. The data will be analysed to investigate the relationship between HbA1c and glucose to provide evidence as to the suitability or otherwise of reporting HbA1c as a 'mean blood glucose'.

- **WG-Monitoring Immunosuppressive Drugs (WG-MID)**

During 2005, this WG has mainly concentrated its efforts on organizing or participating in symposia and/or workshops such as the XIXth ICC. Its work has now come to a close.

- **WG-Standardization of Haemoglobin A₂ (WG-HbA₂)**

The preparation of primary reference materials for HbA₀ and HbA₂ has been accomplished. In the next year two more batches of materials, as programmed at the beginning of this project will be prepared, in order to have robust data on the purification procedure and outcome. Primary calibrators have been prepared at six levels (from 0 to 7 % HbA₂) and sent to the MS labs for analysis. The preparation is underway of the first batch of secondary reference materials, at 3 levels of HbA₂. The materials will be sent to the IRMM for testing. Development of the reference method in two laboratories has progressed but some technical issues remain to be resolved. Pre-analytical variability is under investigation and the results of this study will be presented in a manuscript that is in preparation. Inter-lab variability is also under investigation, using fresh blood samples in an EQAS performed in Sicily among 48 laboratories using a single technique (HPLC). The data indicate an interlaboratory CV of 6 % to 8 %. It is likely that the variability among different analytical techniques (HPLC, electrophoresis, minicolumns) could be even higher. These findings point out the necessity of having better harmonization among different techniques for HbA₂.

- **WG-Standardisation of Carbohydrate-Deficient Transferrin (WG-CDT)**

The WG met with representatives of CDT assay kit manufacturers and agreed that the initial aim is to establish a reference system for CDT. Over the longer term it is proposed

that recommendations for the clinical use of CDT testing will be developed. The work of the WG will focus on the following: (1) improved structural definition of disialotransferrin; (2) investigation of available calibrator material; (3) investigation of MS to validate HPLC and/or CE as the candidate reference methods; (4) establishment of a network of laboratories to evaluate and implement candidate reference methods.

- **WG-Standardisation of Cystatin C Assays (WG-SCC)**

A plan has been adopted to develop reference material and identify a reference procedure for this measurand. Manufacturers of assay kits have been contacted and informed of the WG's activities. Recombinant material is available.

- **WG-Standardisation of Glomerular Filtration Rate Assessment (WG-GFRA)**

The following goals for future activities have been adopted. (1) Support the international circulation of relevant documents and education materials, such as NKDEP documents of the "Rationale for use and reporting estimated GFR" and "Suggestions for laboratories for routine reporting of estimated GFR". (2) Prepare an IFCC recommendation for the use of specific methods (e.g enzymatic assays) for creatinine measurement, including a systematic review of the literature in the field. (3) In cooperation with C-TLM, establish of an IFCC reference laboratory network for creatinine assays. (4) In cooperation with NKDEP, develop guidelines to coordinate the global introduction of standardized creatinine assays together with the new GFR estimating equation and to educate laboratory professionals regarding the importance of assessing chronic kidney disease (CKD) risk.

- **WG-Standardisation of Microalbumin Assay in Urine (WG-SMA)**

An overview of current analytical procedures has been discussed together with the apparent lack of correspondence between immunochemical and HPLC assays, particularly in urine from individuals with diabetes. The general discussion produced many questions, particularly about the HPLC system. In keeping with the need to focus on clinical relevance, a case history based international investigation "How do General Practitioners Test For and Manage Microalbuminuria in Diabetes Care in Different Countries?" has been instigated. At a second meeting findings on immunounreactive albumin and the HPLC system have been presented for review. Currently, consideration is being given to the next step to assess if harmonization of the existing analytical systems with a common calibrator can sufficiently reduce inter-laboratory variation and make unnecessary the more challenging process of standardization.

- **Project Proposals**

Four project proposals have been received and dealt with during this year. Two have been accepted (WG-Standardisation of Pregnancy Associated Protein-A and WG-Standardisation of Growth Hormone) and two are pending.

Howard Morris
Secretary SD

Reports from Regional Organisations

Arab Federation of Clinical Biochemistry (AFCB)

Executive Board: The EB of the AFCB met twice in 2005. Several topics were discussed including the evaluation of the X Congress which was held in Monastir, Tunisia. A representative of Syria presented a full

report on the progress of the XI congress which is scheduled 29 April – 2 May 2006 in Damascus, Syria. The organizing committee is expecting large participation from Syria, Arab Countries, Europe and other parts of the world.

The EB has decided to encourage the AFCB members who have not joined the IFCC to apply for the IFCC membership. The AFCB secretary will provide advice and assistance to those members who are willing to join.

Continuous Medical Education Programme: The societies in Tunisia and Syria have established scientific programs to help scientists improve their knowledge in the field of Laboratory Medicine. The programs include lectures, symposia, seminars and workshops.

The Syrian Clinical Laboratory Association in collaboration with the Syrian Diabetic Society, held a conference on Diabetes Management in Syria in the coastal resort city of Latakia, 10 – 12 November 2005. The conference attracted about 500 participants. Several lecturers from Syria, Jordan, Lebanon, Saudi Arabia and Egypt presented their research and experience in the management of diabetes.

The Tunisian Society held their annual conference in May in Al-Hammamat City, Tunisia with significant participation from Tunisian colleagues and other AFCB countries. A new Executive Board was elected during this meeting. Dr. Hedilli was elected as President.

The Tunisian Society in collaboration with IFCC organized a two day symposium on Molecular Biology 30 Nov – 1 Dec. The Tunisian Society offered free registration and accommodation for one young scientist from each member of the AFCB. The symposium attracted about 20 scientists from various Arab Countries. The symposium proved to be a good and productive activity.

The Egyptian Society held their annual conference 17 – 19 December 2005. The conference attracted large number of scientists from Egypt.

The AFCB has expressed their willingness to continue such cooperation with IFCC to organize further Symposia on different topics.

Asian Pacific Federation of Clinical Biochemistry (APFCB)

Educational Activities, 2005-2007

Since its inception in 1999, the **APFCB Travelling Lectureship** has evolved to a regular, approximately biennial activity of the APFCB. Thus far, we have had 4 lecturers and for 2006-2007, Professor Chris Lam was the enthusiastic choice. About 10 members have expressed an interest in a visit from the Travelling Lecturer. Most of Professor Lam's visits will be undertaken in 2006 and will culminate, we hope, at the APCCB in Beijing in 2007. His tour will be sponsored by Roche Diagnostics.

This is the third year of the **APFCB-Beckman Coulter Education Symposium** series of lectures and Dr Ken Sikaris was chosen as this year's lecturer. Dr Sikaris visited China, Thailand Indonesia and India. The APFCB has received a commitment from Beckman Coulter for continued funding of this series.

Professor Andrea Rita Horvath of Hungary, an expert on evidence-based laboratory medicine, will be the IFCC Visiting Lecturer to the APFCB region in 2006. As with the previously VL, Professor Jean-Claude Forest, who visited the region in 2003 and 2004, Professor Horvath's tour is being arranged by the AFPCB while the cost of her international air-travel will be met by the IFCC. All local costs will be borne by the host associations. The APFCB considers this arrangement as a very efficient means of administering the Visiting Lectureship as it ensures a wide audience is reached.

Specialized Meetings

The APFCB is proud to be associated with two meetings that were held in 2005, both of which were held in Singapore and organised by the SACB in partnership with bodies outside our region. These were: (i) a meeting on Laboratory Automation was organised in May jointly by the SACB and AACC; (ii) the International Congress of Pediatric Laboratory Medicine, which was held from 3-6 September. The latter was jointly organised with the International Association of Pediatric Laboratory Medicine, under the auspices of the APFCB and IFCC and other bodies.

Scientific Activities

The Scientific Committee will undertake two projects.

HbA_{1c}: A proficiency testing exercise to assess the variation of the measurement of HbA_{1c} among laboratories in our region. This project is coordinated by the CACB and the results are currently being reviewed. Funding for part of this project was received from Bio-Rad.

Reference values: A study of reference values of various populations in the Asia-Pacific region is being coordinated by Professor Kiyoshi Ichihara of Japan in cooperation with the APFCB. This is a two part project that will involve sample collection from various parts of our region and determination of reference values by data-mining of patients' samples from selected hospitals. This project is being funded, among others, by Dade Behring.

APFCB Publications

Web-site: The existing APFCB web-site has served us well since 1999. However, there is a need to take it to the next level to reflect the increase in our activities. A revamp of the site is presently being undertaken by our corporate member JenCo. The APFCB Executive wishes to express its immense gratitude to Dr Andrew Wootton of the

AACB for constructing the original site and maintaining it, on a voluntary basis. We are also grateful to the AACB for allowing the APFCB the use of the surplus memory, without charge, on the server that it leases for its own site.

APFCB News: We will continue with the publication of the APFCB News in its present form. The present editorial team took over publication in 2002 and has since published an issue annually. Advertisement income has been sufficient to make the News a self-sustaining entity. The News will continue with its educational slant and we have been fortunate to receive the support of many contributors from outside the region. The News is distributed to members and is additionally, sent to selected individuals and organisations outside the APFCB region.

Finance

Financial Management of the APFCB: In an age when it is expensive to be a member of a professional organisation, the APFCB remains one of the few, perhaps the only, professional organisation in this part of the world, that does not collect a subscription from its main members. Even the subscription for corporate and affiliate membership is small. Our only source of regular, albeit varying income, is the surplus remitted by the host of the Asian-Pacific Congresses of Clinical Biochemistry (APCCBs) that is held triennially. Through prudent financial management, we have a healthy but by no means excessive bank balance. Like our ancestors we are "hunter-gatherers" calling upon the generosity of our corporate members every time we need to fund an activity.

While the APFCB essentially remains a voluntary organisation, the Executive Committee recognised the need to seek professional help in the management of the financial and statutory affairs of the APFCB. Towards this end, the Executive Committee has appointed Solidtrack Management Pte. Ltd. of Singapore to assume these

responsibilities. The responsibilities of SolidTrack will include the maintenance of accounts, preparation of the annual tax returns, liaison with the Registry of Societies of Singapore (ROSS) and responsibility for all payments and collections. The registered address of the APFCB is that of SolidTrack.

Donations: The escalation of activities of the APFCB in recent years has not escaped the attention of our well-wishers. It has resulted in various offers to work collaboratively on projects and to offers of financial support. In November last year a donation was received from colleagues in Japan that underwrote the entire cost of publication of the 2003 APFCB News. At the beginning of this year, a donation of CHF5000 was received from the IFCC for use at our discretion. Both donations were unsolicited and received with gratitude. They are a clear reflection of the high esteem with which people hold the APFCB.

The APFCB Philanthropic Fund

The EC and Chairs have decided on the creation of an APFCB Philanthropic Fund to assist young clinical biochemists with scholarships and travelling grants to present their research at meetings within the region. In addition, it will be used to provide assistance to Council members who are unable to attend Council meetings due to financial difficulties. The IFCC donation has been used to seed the fund.

11 APCCB, Beijing 2007

The APFCB office-bearers have been in contact with the organisers of the Beijing APCCB. The congress will coincide with the Silver Jubilee of the establishment of the APFCB which was officially registered in Singapore in 1982.

Membership

The membership of the APFCB continues to grow. At the Council meeting of March 2002 in New Delhi, the membership stood at just 12 voting members which were association and societies of clinical

biochemistry within the Asia-Pacific region. Today, just 30 months later, the membership stands at 13 voting, 15 corporate and 1 affiliate member.

The two amendments to the constitution that were made at the Council meetings at New Delhi (March 2002) and in Perth (September 2004) have allowed the admission of corporate members and affiliates, respectively, and contributed this growth.

Reports from National Societies (NS)

These are available on the full Annual Report on the IFCC website.

IFCC Publications, 2005

The following publications appeared in 2005 as a result of IFCC projects. A number of other papers are in progress and are available through the IFCC Web Site.
Bergmeyer Conferences-Roche Diagnostics
Master Discussions:

Kallner A, Müller MM, Poppe W. 10th Bergmeyer Conference-Roche Master Discussion. Diabetes Mellitus and Cardiovascular Disease. Scand J Clin Lab Invest 2005; 65 (Suppl. 240):1-156.

SD 8.1 Scientific Division

Panteghini M, Forest JC. Standardization in laboratory medicine: new challenges. Clin Chim Acta 2005; 355:1-12.

8.2.6 Committee on Nomenclature, Properties and Units

Nordin G, Klintonberg B, Persson B, Forsum U. Can a laboratory investigation be called anything? "The NPU system" sorts out the concepts and gives systematic stringency. Lakartidningen 2005; 102:1308-1315.

SD-C 8.2.19 Committee on Standardisation of Markers of Cardiac Damage

Apple FS, Panteghini M, Raykilde J, Mair J, Wu AH, Tate J, Pagani F, Christensen RH, Jaffe AS. Quality specifications for B-type natriuretic peptide assays. Clin Chem 2005; 51:486-493.

Apple FS, Wu AH, Mair H, Ravkilde J, Panteghini M, Tate J, Pagani F, Christenson RH, Mockel M, Danne O, Jaffe AS. Future biomarkers for detection of ischemia and risk stratification in acute coronary syndrome. Clin Chem 2005; 51:810-824.

SD-C 8.2.21 Committee on Reference System of Enzymes

Ferard G, Imbert-Bismut F, Messous D, Piton A, Ueda S, Poynard T, Lessinger JM. A reference material for traceability of aspartate aminotransferase (AST) results. Clin Chem Lab Med. 2005; 43:549-553.

SD-C 8.2.22 Committee on Point of Care Testing

Ben Rayana MC, Burnett RW, Covington AK, D'Orazio P, Fogh-Andersen N, Jacobs E, Kulpmann WR, Kuwa K, Larsson L, Lewenstam A, Maas AH, Mager G, Naskalski JH, Okorodudu AO, Ritter C, St John A. Guidelines for sampling, measuring and reporting ionized magnesium in undiluted serum, plasma or blood. Clin Chem Lab Med 2005; 43:564-569.

D'Orazio P, Burnett RW, Fogh-Andersen N, Jacobs E, Kuwa K, Kulpmann WR, Larsson L, Lewenstam A, Maas AH, Mager G, Naslalski JW, Okorodudo AO. Approved IFCC Recommendation on Reporting Results for Blood Glucose (Abbreviated). Clin Chem 2005; 51:1573-1576.

SD-WG 8.3.16: Working Group on Standardization of HCG Measurements:

Bristow A, Berger P, Bidart JM, Birken S, Norman R, Stenman UH, Sturgeon C. Establishment, value assignment, and characterization of new WHO reference reagent for six molecular forms of human chorionic gonadotropin. Clin Chem 2005; 51:177-182.

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