ifcc

International Federation of Clinical Chemistry and Laboratory Medicine

Annual Report 1998

Highlights of the Year

- General Conference in Seville, Spain
- New IFCC Award for Distinguished Contributions to Education
- IFCC-EDMA Prize for Evidence of Effectiveness of Laboratory Tests
- Continued EB liaison through Regional and major National Conferences
- Agreements with COLABIOCLI and with the Arab Federation of Clinical Biology
- Discussions on Outcomes Evaluation and Evidence-Based Medicine
- IFCC-Roche Conference, Singapore
- IFCC-Beckman European Conference

President's Message

It has been a busy and productive year. The Executive Board has been using the Strategic Plan as the major guide for the directions to be taken by the International Federation of Clinical Chemistry and Laboratory Medicine. Communication with our National Societies and Corporate Members has continued to be a theme for 1998.

The first meeting of the Executive Board for 1998 took place during the IFCC General Conference in Seville, March 26th to 30th. Apart from the important discussion during this conference, it continues to present an excellent opportunity for all the branches of IFCC to meet and interact with each other. This conference continues to play a vital part in identifying ourselves to each other as a scientific and clinical family.

The second Executive Board meeting took place in Chicago in August and gave us the opportunity to meet with the AACC and also with our Corporate Members, the European Diagnostics Manufacturers Association and the National Committee for Clinical Laboratory Standards (NCCLS).

The Asian Pacific Federation of Clinical Biochemistry conference in Kuala Lumpur in October allowed us to meet our Malaysian hosts as well as representatives from many other countries in the region.

In 1998 our approach to collaboration with regional organisations was strengthened with the signing of a formal agreement between IFCC and the Latin American Confederation of Clinical Biochemistry

(COLABIOCLI) and also a separate agreement with the Arab Federation of Clinical Biology (AFCB). The Executive Board members also took part in many other National and Regional meetings. The personal contact established in such situations is a vital part of understanding the needs of our members.

On behalf of our National Societies and Corporate Members we had input to the European Commission on possible legislation which would have an adverse effect on the functioning of our profession. We have also been able to intervene directly with the governments of two of our National Societies to protect the interests of our profession.

Critical issues for the success of IFCC which have been addressed during 1998 and will continue to be addressed during 1999, include the Technical Secretariat organisation together with the staffing and resources it requires if it is to further serve the growing communication and management needs of IFCC. The Federation is becoming a highly professional organisation in an age of rapidly changing technology. The second key issue was the decision to end the paper publication of JIFCC and to put significant resources into electronic publishing. Such decisions are always controversial. After much consideration and debate the Executive Board believes that it has to give the leadership necessary for the Federation to move forward with this new, rapidly developing communication tool.

We are looking forward to exciting scientific and social programs during the International Congress of Clinical Chemistry in Florence, Italy in June, 1999. We will be reporting to you there on the work of the last three years. We also hope to see that the new voting process during the Council meeting will be a success.

My sincere thanks to all of you for your communication, ideas and questions during the past year. I look forward to seeing many of you in Florence. If you have any questions please do not hesitate to contact any member of the Executive Board.

M J McQueen

Executive Board (EB)

EB met three times in 1998, in Seville, Chicago, and Kuala Lumpur. During these meetings EB took the opportunity to meet with Regional organisations, with the AACC (our largest member), and with representatives of National Societies and other organisations concerned with in-vitro diagnostics and laboratory medicine.

The General Conference of IFCC was held in Seville and provided a focus and meeting point for all the Divisions and most of the Committees and Working Groups in our organisation. Around 150 people attended and in addition to open and closed meetings there was a scientific presentation on Micromachines and Microminiaturisation by Professor Larry Kricka. A Conference Dinner provided insights into the production of sherry, and revealed an unexpected talent for flamenco dancing in the EMD Chairman.

Awards

The IFCC awards which will be presented at the triennial meeting in Florence were advertised for nominations in 1998. In addition to the long-standing Distinguished Clinical Chemist and Distinguished International Contribution awards, an new award on the same level for Distinguished Contribution to Education will be presented for the first time. Discussions with AVL led to continuation of the IFCC-AVL

prize for work in critical care medicine, and the European Diagnostic Manufacturers Association (EDMA) have agreed to sponsor a prize for work on the effectiveness of laboratory tests.

Professional Scientific Exchange Programme

This programme for young colleagues (< 40 years) in our discipline was established in 1998. It is open for laboratories in all countries where an IFCC member society is active.

The objectives of this new IFCC Programme are:

- to promote international twinning between laboratories and to facilitate the exchange of laboratory scientists of IFCC member societies.
- to support exchange of knowledge between laboratories based on visits of young scientists to top laboratories in the field.
- to increase high-level education through science and scientific activities in Clinical Chemistry and Laboratory Medicine and to transfer the knowledge of new technology among IFCC member societies.

EB has formed a Task Force (M M Müller, Chair; E Magid and P Mocarelli, Members) for evaluation of applications and for facilitating the exchanges. In 1998 a total of nine applications were received and six scholarships were granted: two long term visits (1year) and four short term visits (1 to 3 months)

The applicants came from Croatia, Bulgaria, Macedonia, Romania, and Vietnam. They visited laboratories and departments in Austria, France, Hong Kong, Sweden, UK, and USA.

The topics of the long term visits were related to molecular biology of Parkinson's Disease and atherosclerosis. During the short term visits young colleagues were trained in electrophoresis, molecular biology, ELISA, chromatography, and oxygen radicals measurement. It is hoped that our young colleagues will again take advantage of this programme in 1999.

Communication and Publications Division (CPD)

During 1998, a new name was adopted for the former Publications Division. This reflects its evolving role, from an original responsibility for publication of IFCC Documents towards providing educational information and news about IFCC and Clinical Chemistry for members of all our societies. In parallel with this, the availability of electronic means of communication through the World Wide web and the use of email provides an opportunity for direct delivery of information. The main events and achievements of the Division in 1998 year involve the IFCC Web Page (www.ifcc.org).

The Division as a whole met in Seville at the IFCC General Conference in March and again in Miami in September. Other meetings took place between the Chair and the Executive Board, and at the Technical Secretariat in Nancy for those involved in development of the Web Site. During 1998 Bernard Gouget (France) served as CPD Chair and Gordon Challand (UK), Johan Waldenström (Sweden), Andreas Rothstein (Columbia), Stephanie Wells (USA) (Corporate Representative) and Xavier Fuentes Arderiu (Spain) (Chairman of the WG on Spanish Nomenclature and Terminology) were the other members.

The CPD saw its main objectives as being to:

- provide IFCC Members with high quality publications pertaining to Clinical Laboratory sciences

- establish and strengthen the means of communication within and between IFCC Divisions, Committees, Working Groups and Regional Organisations and between IFCC Officers and IFCC Members.

The importance of these objectives is indicated by the change in the name to include Communications as the first activity.

The IFCC Web Site

During 1998, the main focus of IFCC Web activity moved to the Technical Secretariat at Nancy. This move will allow better interaction with IFCC staff and provide more up-to-date information, while reducing the load on volunteers. The information available includes:

- IFCC Handbook
- Strategic Plan
- A section for each of the Divisions
- Links to World Lab and other IFCC meetings
- Forms for Visiting Fellowships
- A meetings database
- Links to societies and Corporate Members
- Publications- complete or in abstract form
- Diccionario Ingles-Espanol
- Bergmeyer Conference abstracts
- Information and programme for IFCC-Roche Genomics Meeting

In 1996, the IFCC Web site at http://www.ifcc.org was a significant advance for the Federation, with its focus on education, IFCC Publications, and on advertising the IFCC and its activities. In 1998 there was a further evolution both in the physical location, and in the role played in internal and external communication for the IFCC.

Physically the file store is in a server close to the Technical Secretariat in Nancy. This facilitates the sharing of specialist manpower resources with similar local activities.

The current site map mirrors the organisational structure of IFCC with dedicated subdirectories for the EB and each of the Divisions (SD, EMD, CPD, CCD). The type of material present is equivalent to the content of the IFCC Handbook, recent Strategy Papers, and for some Divisions, extra material which has been developed with specific Working Groups or Committees.

As with paper-based publications, there are many tasks in disseminating information through the WWW. Commissioning and writing of articles, editorial review, and preparation of copy for publication are all required. The technical tasks will be undertaken by a Working Group of three people with the assistance of Technical Secretariat staff.

JIFCC

A major change in direction was agreed to in 1998, driven in part by the difficulties in financing the paper JIFCC through advertising and in part by the opportunities for better distribution offered by the world wide web. From the start of 1999 only the electronic version will be produced, and IFCC hopes that societies where few members have Web access will download and reprint the material locally. The vision for JIFCC includes:

- Provision of educational and scientific articles in a timely manner
- Continued improvement in the quality of articles
- 2-3 years planning ahead for publications
- An increase in the number of articles in areas of laboratory medicine other than clinical chemistry
- One 'themed' issue each year
- Plan to publish one article in each of pathophysiology/clinical issues, technology/ scientific developments, and management in each issue
- Publish all relevant IFCC documents, position papers, recommendations, etc., either in whole or in summary
- Rewritten instructions to the authors to achieve more uniformity in the published articles
- Availability of abstracts in Spanish

IFCC News

IFCC News will continue under the editorship of Andreas Rothstein. The News will appear not only on the IFCC Web Site but also in a special section of the journal *Clinical Chemistry and Laboratory Medicine* (CCLM), following an agreement with the publisher Walter de Gruyter.

New agreement with 'Clinical Chemistry and Laboratory Medicine'

During the year a new arrangement for initial publication of IFCC Documents in CCLM was reached. In addition to appearance of such papers and IFCC News in a special IFCC section, and their free availability through the CCLM Web Site, IFCC has been granted a number of free electronic subscriptions and intends to make these available to one colleague nominated by each IFCC Member society. There will also be reduced rate subscriptions available for the paper CCLM through National Societies.

Work is proceeding within CPD on public relations, translations (particularly into Spanish), and other projects. A number of closed and open meetings will be held at the ICCC in Florence to communicate the CPD's activities and directions to registrants.

Congress and Conference Division (CCD)

During 1998, preparations were made for the transition between the first Chairman of this Division, Oren Zinder, and the new Chairman, Graham Beastall. Other Members of the Division during 1998 were Francesco Dati (Germany), Thomas Moyer (USA), Jerzy Naskalski (Poland), Hermann Wisser (Germany), Paul Whitlock (Beckman Instruments: Corporate representative).

The CCD met twice during 1998, once at the IFCC General Conference in Seville, Spain in March, and secondly at the 8th Asian-Pacific Congress of Clinical Biochemistry in Kuala Lumpur, Malaysia in October.

Conference Guidelines

The main projects of the CCD for 1998 were:

- Continue drafting the basic documents defining the work of the CCD
- Solicit bids for the 2005 IFCC Congress, evaluate them, and submit a recommendation to the

Executive Board

- Interact with the 1999 IFCC Florence Congress organisers and those of the 2002 IFCC Kyoto Congress to follow up on the organisation of these meetings
- Interact with the organisers of the future IFCC Regional congresses
- Review requests for IFCC Auspices for professional conferences
- Solicit nominations for membership on the CCD to fill vacancies from January 1, 1999

The document "Guidelines for IFCC International Congresses" was completed, and approved by the Executive Board. This document includes guidelines on submission of bids to host an IFCC Congress, relationships between the organisers and the IFCC, and requirements for undertaking the organisation of the Congress on behalf of the IFCC. This document was instrumental in assisting the societies who applied to host the 2005 Congress in their efforts to make a full and complete application, and to understand their responsibilities should they be selected to host the 2005 Congress.

The "Guidelines for IFCC Regional Congresses" was also completed, and approved by the Executive Board. This was a completely new document detailing the requirements for hosting an IFCC Regional Congress, the obligations of the IFCC to the host society, and the responsibilities and obligations of the host society to the IFCC in the organisation of the Regional Congress. The final draft of the document, prior to definitive approval by the EB (since obtained), was disseminated to the four IFCC regions (AFCB, APFCB, COLABIOCLI, FESCC) for their comments. The final, approved, document was sent to the societies organising the Regional Congresses so that they could utilise them in their preparations for up-coming regional congresses.

The "Guidelines for the IFCC General Conference" was awaiting final submission to the EB. This document details the complete procedure for the soliciting of bids to host the Conference, its organisation, and the responsibilities of each participant in the organisation. These include: The IFCC Secretary, the IFCC Treasurer, the CCD, the IFCC-TS, and the host society. A major input into the formulation of this document was made following the experience of the 1998 IFCC General Conference in Seville.

The CCD has begun in the formulation of a new document designated: "Guidelines for Obtaining IFCC Auspices for Conferences and Meetings". This document, now in its second revision, details the requirements necessary for the recognition of a congress, conference, meeting, or symposium, whose organisers would like to obtain the "seal of approval" of the IFCC for their meeting. This recognition by the IFCC, the premier international organisation in the fields of laboratory medicine, is felt by many to be an important and visible recognition of the scientific, educational, and practical worth of the meeting. It is intended to support more active registration, more prominent speakers, and a more active corporate support. In addition, by its granting of "Auspices" the IFCC assists in the promotion of the meeting through the IFCC publications and electronic bulletin boards. The final draft of this document is now in its last revision.

The CCD is in the planning stages of designing and writing an interactive CD to be used in conjunction with the IFCC Web Site, to assist potential congress organisers to obtain the maximum information necessary regarding dates, venues, and application procedures, for future conferences. This information "package" will also include registration data and all other information from former IFCC-supported congresses, etc, in order to facilitate applications to host a future IFCC meeting. An initial draft has been made, and will be revised and improved during 1999. This project will be carried out with the collaboration of the Communication and Publications Division.

Future Congresses

The CCD met on two occasions with the organisers of the Florence Congress, and was impressed with the

progress that this organisation had made. The CCD also met twice in 1998 with the organisers of the Kyoto Congress. In Kuala Lumpur, the complete organising committee was present at the meeting. T. Moyer of the CCD made a site-visit to Kyoto on behalf of the CCD, and saw the situation at first-hand. It would seem that most of the problems such as exhibition space have been resolved, or that possible solutions have been proposed.

The CCD met in Seville with the organisers of the next Arab Federation Congress to be held in Rabat Morocco in May 3-6, 2000. This was a very productive meeting, and a close collaboration between the organisers and the CCD was established.

Education and Management Division (EMD)

The EMD activities were overseen by Peter Wilding (USA), Chair; and Marek Dominiczak (UK), Michael Mayer (Israel), Risto Heikkinen (Finland), Daniel Mazziotta (Argentina) and Ian Wilkinson (Canada) as Members. They met in Seville, and again in London in November, to review and set directions for this Division.

Courses

Courses were held in Warsaw, Poland, and Xian, China in May 1998. Topics included the work of the Committee on Financial Laboratory Management, quality management and molecular biology. In each case EMD members participated and collaborated with local organisers.

Preparations were also made during 1998 for the Master Course on Education to be held as a satellite meeting before the Florence ICCC. Open meetings to publicise the work of EMD will also be held during the ICCC.

Committees and Working Groups

ANALYTICAL QUALITY

Projects in Latin America were undertaken in 1998 and proposals for similar activities in Bulgaria, India and Iran are under consideration. These projects consist of distribution of donated control sera and reports on test performance for participants. Information on outcomes was presented at the IFCC General Conference and at a number of meetings within Latin America. Follow-up and continuation of EQA activity in participating countries is important and may be helped through further serum donations or through local production.

FINANCIAL LABORATORY MANAGEMENT

During 1998, the Committee completed field studies of Laboratory Organisation and Management in Slovakia and the Czech Republic. This produced valuable information and the possibility of similar studies in other countries is being explored. This Committee is now able to offer courses which relate to many aspects of Laboratory Management, including computers in laboratory management, communications, and management development and training.

SYSTEMATIC REVIEWS IN LABORATORY MEDICINE

Papers have been commissioned as examples of systematic reviews, and a lecture on Systematic Reviewing at the Baltic Conference led to significant contacts. A database of approximately 35

appropriate reviews is being compiled from the responses to a questionnaire.

CURRICULUM DEVELOPMENT

A proposal for a Committee to work on the topic of curriculum development has been produced. The intention is to examine curricula for medical students and for Clinical Chemists, and such a Committee might have links with Working Groups for specific areas of the world.

Scientific Division (SD)

During 1998, the following people served on the Scientific Division of IFCC: Carl A. Burtis (US) (Chairman), Jean Claude Forest (Canada) (Vice-Chairman), Renze Bais (Australia) (Secretary), Yoshihisa Itoh (Japan), John G Ratcliffe (UK), Rudolph Tauber (Germany), Jos HH Thijssen (Netherlands), Andrew St. John (CH) (Corporate Representative).

Having completed his two terms of office, Renze Bais left the SD on December 31, 1998. He has been replaced by Yoshihisa Itoh (Japan). Jos Thijssen will replace Renze as secretary effective January 1, 1999. In addition, Andrew St. John has joined the SD as its Corporate Representative.

Meetings of SD were held in Seville, Spain in March and in Regensburg, Germany in September 1998

Committees and Working Groups

SD projects are conducted through Committees and Working Groups. The active units during 1998 are listed below.

ADVANCED TECHNOLOGY (C-AT)

Effective December 31, 1998, this Committee will be closed and converted into a Working Group on Microtechnology (WG-M) with L Kricka as Chair. Two documents are being prepared: (1) Potential application, limitation and evaluation of nano- and micro-analytical technology and (2) Report on Anti-animal antibody interferences in immunological assays. C-AT members collaborated with the organisation of the 1st Cherry Blossom Symposium on Clinical Laboratory Automation and Robotics, Kochi, Japan, March 29 - April 1, 1998.

NOMENCLATURE, PROPERTIES AND UNITS (C-NPU)

During 1998, four documents were submitted to SD for publication. All four documents were accepted as IFCC Technical Reports; one for publication on the IFCC web site, and the other three for publication in relevant journals. Some of the documents have been sent to other international organisations, which may endorse them as relevant to their speciality. Drafts are in progress on tumour markers, dynamic function tests, properties and units in molecular biology, and harmonisation of coding schemes between IUPAC and LOINC. Documents are under consideration in the areas of flow cytometry, definitions of basic concepts in human health, quality assurance related nomenclature, basic metrological concepts and definitions in clinical laboratory sciences, and concepts and terms in toxicology.

Xavier Fuentes-Arderiu has actively collaborated in the preparation of the experimental standard ISO/DIS 15189 Quality Management in Medical Laboratories in the frame Working Group 1 of the ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems.

MOLECULAR BIOLOGY TECHNIQUES IN CLINICAL CHEMISTRY (C-MBT)

To define a priority list of areas needing the Committee's attention, a questionnaire has been prepared to assess the status of such techniques. External quality control programs will also be identified and sources of well-defined DNA and cell banks located. A pilot study was conducted in Finland in which 12 labs (48% of all labs) completed this questionnaire. Results indicated that such tests are mainly used for identification of microorganisms and mutations, HLA-genotyping, and for analysis of genetic defects in haematological diseases, and only in selected cases of monogenic disorders (fragile-X). The situation in other countries will be evaluated with a slightly modified questionnaire.

PLASMA PROTEINS (C-PP)

The introduction of IFCC BCR CRM470 has resulted in significant changes in reference values for some proteins. This, together with the inadequacy of some of the original studies on which many of the reference intervals for plasma proteins are based, means that new reference intervals for several plasma proteins are now urgently needed. This problem was addressed in a meeting in March 1995 in Frankfurt by German professional societies with the participation of 12 diagnostic companies. A consensus was achieved on the adoption of interim reference intervals. Reference interval data have been derived statistically from some 25,000 samples received by the Foundation for Blood Research, Scarborough, Maine since 1990. This has provided detailed age related reference intervals for all the major plasma proteins that are in the process of publication. The Committee proposes to compare these data with small well-defined groups of different ethnic origin to determine whether these ranges could form the basis of a recommendation.

A project for calibration of CRM 470 for immunoglobulin IgG subclasses is now active under the joint management of C-PP and Dr R Hamilton on behalf of the College of American Pathologists. An analytical protocol is being drawn up and a meeting is proposed to discuss the value assignment. Seven laboratories from the USA and Europe have offered to participate, free of charge, in the value assignment.

An International quality assurance survey to assess the value of CRM 470 aims to document the uptake of CRM 470 as the prime reference material in use by organisations producing calibration materials and kits for serum protein estimations and to assess the degree of harmonisation produced. Samples were distributed to 3930 laboratories in eleven countries in February-March 1993 prior to the release of CRM 470. The second distribution will soon take place. The data obtained from all the surveys will be examined for trends reflecting increased usage of CRM 470 and published.

STANDARDISATION OF CLINICAL FLOW-CYTOMETRY (C-SCFC)

The goals of the C-SCFC are to prepare and organise documents, recommendations and workshops leading to the standardisation of clinical flow cytometric measurements. In pursuit of these goals, the C-SCFC has prepared documents on the flow cytometric immunophenotyping of haematological malignancies, absolute CD4+ T lymphocyte counting, and ploidy analysis of exfoliated bladder tumour cells. In addition, documents from the European Working Group on Clinical Cell Analysis on enumeration of CD34+ haematopoietic stem and progenitor cells and on characterisation of platelet function were endorsed.

The Committee has also prepared a electronic Database on quality assurance studies on clinical applications of flow cytometry. (Orfao A. http://www.usal.es/)

The Committee is collaborating with the International Society for Analytical Cytology, the European Working Group on Clinical Cell Analysis, and the Sociedad lbérica de Citometria, and a workshop on

flow cytometry has been organised for the IFCC Congress in Florence.

MARKERS FOR BONE TURNOVER AND BONE DISEASE (C-MBTBD)

Bone formation markers have been described that are derived from different phases of bone formation: matrix synthesis, matrix maturation and matrix mineralisation. For each phase there are several assays available. Matrix synthesis is measured by the assays for the carboxy- (PICP) or aminoterminal (PINP) propeptides of type I procollagen. Matrix maturation is reflected by alkaline phosphatase assays and matrix mineralisation by osteocalcin. All these assays are performed in serum. The initial goal of the C-MBTBD is to begin efforts to standardise assays for one analyte from each assay family: PINP, bone ALP and osteocalcin. Most of the bone degradation markers are collagen cross-links or telopeptides. Because the Centers for Disease Control and Prevention is working on the standardisation of the pyridinoline cross-links, the C-MBTBD committee intends to concentrate on the type I collagen telopeptide assays Ntx, CrossLaps and ICTP.

STANDARDISATION OF MARKERS OF CARDIAC DAMAGE (C-SMCD)

The C-SMCD was created by IFCC in 1997, inviting members from the established American and European groups to become members of this Committee. The C-SMCD now has 24 Associate Members, 18 appointed by National Societies and six appointed by Corporate Members.

The first meeting of the Committee was held in Seville, during the IFCC General Conference. In this occasion, an open meeting was also held to present the project of the Committee to all interested people.

C-SMCD met for a second time in Sorrento (Italy) before a two day expert panel meeting (May 25-26, 1998) on cardiac markers organised by Roche Diagnostics. During this meeting, M. Panteghini gave a presentation entitled "Towards a comprehensive approach in standardisation of markers of cardiac damage: the role of the IFCC Committee". The proceedings of this meeting have been recently published as Supplement (November 1998) of the European Heart Journal. Members of the C-SMCD also met in Chicago (July 1998) during AACC annual meeting.

The current activities of the C-SMCD are to:

- Produce a position paper on the "Use of biochemical markers in acute coronary syndromes"
- Conduct an international survey on the use of cardiac markers
- Participate in the Bergmeyer Conference (February 1999)
- Organise an open meeting with companies interested in C-SMCD
- Organise a satellite meeting of the IFCC WorldLab
- Schedule an open meeting during the WorldLab 99.
- Propose, in cooperation with the AACC Subcommittee on Troponin I, the preparation and evaluation of proposed Reference Materials and different pairs of antibodies for this marker.
- Standardise immunoassays for myoglobin determination.

STANDARDISATION OF COAGULATION TESTS (C-SCT)

This Committee was organised in 1998 and is a joint activity of the IFCC and the ISTH. The initial goal of the C-SCT is to bring together the expertise of IFCC in Reference Method development for substances of "traditional" clinical chemistry and the expertise of the SSC of the ISTH in the development of Reference Preparations ("Standards"). The initial efforts of the C-SCT are directed to developing guidelines for standardisation of those coagulation tests that are amenable to the complementary Reference Method -

Reference Preparation approach. These guidelines are intended to describe strategies by which the many variables that influence the accuracy and comparability of coagulation tests can be controlled and the information content of the assays improved. Prerequisite to this is the development of reference methods and reference preparations that can be concordant with fundamental metrological principles. One subgroup of the C-SCT is drafting provisional guidelines for reference methods and reference preparations for a proteinase precursor and its proteinase activation product (Protein C and activated Protein C), and a proteinase inhibitor (antithrombin). A second sub-group is defining requirements for control of pre-analytical variables for coagulation testing The challenge of "post-analytical" considerations will be the focus of a third sub-group.

SELECTIVE ELECTRODES (WG-SE)

Dr WR Külpmann has taken over as Chair of this group. Work is proceeding on total carbon dioxide, ionised chloride, and ionised magnesium methods.

STANDARDISATION OF IMMUNOASSAYS FOR URINARY PROTEINS (WG-SIUP)

This WG was closed as it was not possible to obtain the necessary corporate funding to develop and certify an International Reference Preparation for Urine Proteins.

STANDARDISATION OF HUMAN CHORIONIC GONADOTROPIN (WG-SHCG)

The goal of the WG is to assist users and manufacturers in improving the clinical utility of hCG assays by:

- Encouraging adoption of unambiguous nomenclature for hCG-related molecules.
- Organising production of reference preparations for six important molecular forms of hCG.
- Working to improve the quality of control materials for hCG assays.

Good progress has been made towards each of these objectives, and it is anticipated that this project will serve as a model for improved standardisation of other protein immunoassays.

STANDARDISATION OF LP (a) (WG-LP (a))

The IFCC lipoprotein(a) standardisation project aims to improve Lp(a) measurement by introducing a secondary reference material for use by manufacturers of diagnostic assays. Four proposed reference materials (PRMs) have been compared for their analytical performance, commutability, and method harmonisation in 27 optimised Lp(a) test systems.

On the basis of these results and documented stability, PRM 2B will be used as the common calibrator in the final harmonisation study. Provided there is improved comparability of Lp(a) values of samples tested in standardised assays, PRM 2B will be certified as the secondary reference material for Lp(a).

STANDARDISATION OF HbA1c/ GLYCOHEMO-GLOBIN (WG-HbA1c)

The goal of the WG-HbA1c is to develop a scientifically based reference system that will act as the basis for ultimate standardisation of all HbA1c assays.

The reference system is based on HbA1c, which is the major glycohemoglobin in human blood. It is **biochemically characterised as the stable adduct of glucose to the N-terminal Valine of the β-chain of** HbA0: [N-(1-deoxyfructosyl)haemoglobin]. Both HbA0 and HbA1c were isolated, purified to homogeneity and characterised. Mixtures of HbA0 and HbA1c were used successfully to calibrate the new

reference methods.

Two candidate reference methods have been developed which specifically measure the glycated N-terminal residue of the β-chain. After haemoglobin is cleaved into peptides by a proteolytic enzyme, the specific glycated and non-glycated N-terminal hexapeptides of the β-chain are subsequently measured by either HPLC/MS or by HPLC followed by capillary electrophoresis with UV detection. For the implementation and maintenance of the new reference system, an international network of 12 reference laboratories has been established.

For the adjustment of calibrators of routine methods a candidate secondary reference material with negligible matrix-effect has been developed. Long-term stability and suitability for all kind of methods has been tested in a intercomparison study.

For implementation, commercial assays will be adjusted to this new reference system. Secondary reference materials and a transfer protocol will be provided to all interested parties including diagnostic companies in order to enable them to adjust their routine tests to the new reference system. Reference intervals for non-diabetics and target values for optimal therapy in patients will also be adjusted. A future activity of the WG is to 'translate' the HbA1c values observed in the DCCT and other important clinical trials into values based on the new reference system.

PSA STANDARDISATION (WG-PSA)

NIBSC is evaluating the Stamey/IFCC PSA preparations for storage, stability and other characteristics to determine suitability for WHO standards. If suitable, NIBSC will then submit a formal application to WHO for having the preparations considered as a WHO standard.

CALIBRATORS IN CLINICAL ENZYMOLOGY (WG-CCE)

During the year considerable progress was made in establishing six IFCC reference methods for enzymes at 37^{o}C, training collaborating laboratories in anticipation of re-certification of BCR reference materials, and development of enzyme reference materials for amylase and lipase at 37^{o}C.

At the meeting at the IRMM on June 16, 1998, it was resolved to develop IFCC reference procedures for the measurement of catalytic activities of enzymes at 37° C. Protocols were discussed with the laboratories who had agreed to participate in a training exercise for the re-certification of the BCR enzyme reference materials. On the basis of the participants' comments the documents were modified and agreed upon.

In order to evaluate the new reference procedures and to demonstrate the ability of the participating reference laboratories to carry out the analytical work according to the requirements of the standard operating procedures, it was decided to perform a training exercise prior to the re-certification campaign. Based on the experience of the training exercise the reference laboratories will start with the re-certification campaign for the CK-, LD-, GGT-, and ALT- BCR reference preparations in February 1999. The results of re-certification will be reported at the IFCC WorldLab 99 in Florence.

For Amylase, it will be necessary to transfer the IFCC 30°C method to a 37°C standard operating procedure. A first draft will be prepared for the WG meeting in June 1999 in Florence. For ALP the selection of an appropriate buffer (AMP, MEG or DEA) will be most critical. For Lipase there exists a BCR reference material. An IFCC reference procedure including the preparation of a suitable substrate needs to be developed urgently.

The IRMM plans the provision of additional reference materials for ALP and AST. Commercial suppliers are providing two different preparations for each of the enzymes. A selection will be made on the basis of commutability studies.

STANDARDISATION OF CORTISOL MEASUREMENTS (WG-SCM)

The IFCC Working Group for Standardisation of Cortisol Measurements is preparing and validating a panel of cortisol reference materials to be used to standardise cortisol test systems. This panel of samples consists of 35 sera obtained from 'single blood donations' whose cortisol content have been established by an ID GC/MS method in two reference laboratories. The next step is to distribute aliquots of the panel to the companies who have declared their interest in evaluating their cortisol test system. The mathematical relationship between the results will then be used to evaluate the validity of the manufacturers' calibration procedure. It is anticipated that this project will serve as a pilot study and model for standardising test systems for other steroid hormones of clinical interest.

PATIENT SAMPLE IDENTIFICATION (WG-PSI)

Sample misidentification can result in severe consequences for the patient. To explore this critical area of health care delivery with an integrated vision of the problem, the IFCC has organised a Working Group on Patient/Sample Identification (WG-PSI). Its first activity has been to develop a questionnaire to be used to collect information from a variety of hospitals about their systems for sample/patient identification.

In addition, the WG is considering the need to:

- harmonise the requirements of a fail-safe identification system and protection of confidentiality, with special focus on electronic transfer of data
- develop a permanent identification for long term storage of samples
- resolve the requirement to store a larger amount of information on a tube to ensure easy identification at any time and in any place without the help of a data base (self-informative tube)
- resolve the potential conflict between the above mentioned concept and the need to reduce the volume of drawn blood (and consequently the size of tubes
- Apply these concepts to containers of biological materials other than tubes (e.g. smears or small paraffin-embedded histological pieces).

Relations with International Organisations

Collaboration with other international scientific or standardisation organisations is a vital part of SD's work. Continuing relations with the organisations listed below have helped in the development of many SD projects.

Four projects (urinary proteins, enzyme calibrator, hCG, HbA1c) have been identified as possible joint projects between the IFCC and the Institute for Reference Material and Measurement (IRMM). Meetings between representatives of the IFCC and IRMM have been held and joint draft proposals have been prepared for the enzyme calibrator material and HbA1c.

The IFCC President, Professor McQueen, Vice-President, Professor Műller and SD Chair, Dr Burtis met with the President and Executive Director of the National Committee for Clinical Laboratory Standards (NCCLS) in Chicago at the AACC Congress. It was agreed that there would be continued cooperation between the two bodies.

The IFCC was asked to nominate a member to the NCCLS Subcommittee on Free (Non-Protein-Bound)

Hormones: Definition of Quantities, Specimen Choice, and Methods of Quantitative Analysis. Professor Thienpont, Chair of the WG-SCM was nominated and has agreed to serve in this capacity.

Collaboration is also proceeding with the National Institute of Biological Standards and Control (NIBSC). Stability studies of PSA reference materials, with a view to submission as a WHO standard by autumn 1999, are still in progress. Close collaboration continues with WG-HCG on the preparation of standards for HCG-related substances.

A joint Committee between the IFCC and the International Society for Thrombosis and Haemostasis (ISTH) has been formed and had its inaugural meeting at the General Conference. A second meeting of this Committee was held in Ljubljana, Slovenia in conjunction with the 44th Annual Meeting of the Scientific and Standardisation Committee (SSC) of the International Society on Thrombosis and Haemostasis (ISTH).

International and Regional Congresses

Communication of SD programs and results is aided by participation in international meetings, through symposia and poster presentations. In 1998 the SD were active at the 8th Asian-Pacific Congress of Clinical Chemistry Kuala Lumpur. In conjunction with the C-MBTBD, a symposium on Bone Markers was organised for this Congress.

Planning is well advanced for participation in the 17th International Congress of Clinical Chemistry in 1999, in the WASP triennial congress in Sao Paulo, Brazil, and the first AFCB Congress in Rabat, Morocco in 2000.

Conferences

ARNOLD O. BECKMAN EUROPEAN CONFERENCE

A successful meeting entitled Frontiers in Molecular Basis of Disease: Cytokines, Apotoses, Acute Phase Reactants was held in Regensburg on 17-19 September, 1998.

IFCC ROCHE CONFERENCE

The first IFCC/Roche conference was held in Singapore, March 15-18, 1998 at Raffles City Convention Centre, Singapore. The title of the Conference was Human Genomics: The Basis of the Medicine of Tomorrow. The C-MBT was involved in the preparation of the program and also organised and conducted a training workshop on molecular biological techniques.

Nominations Committee

The Nominations Committee for the 1999 EB elections was chaired by Dr Mary Burritt, and other members were José Abol Corrêa, Peter Garcia-Webb, Gerard Siest and Yang Zhen-Hua. In consultation with the Executive Board, the Rule governing voting procedures at the Council meeting was revised to reduce the time taken in conducting the ballot. Nominations for EB officers and members were sought from Member societies and will be voted on at the June 1999 meeting of Council.

Publications

The following publications appeared in 1998 as a result of IFCC projects. A number of other reports are in process and may be available through the IFCC Web Site.

D'Orazio P, Fogh-Andersen N, Larsson L (Editors) *Proceedings of the 17th International Symposium on Blood Gases and Electrolytes*, Nice, France June 4-7 1998.

Ferard G, Edwards J, Kanno T, Lessinger JM, Moss DW, Schiele F, Tietz NW, Vassault A. Validation of an enzyme calibrator - an IFCC guideline. *Clinical Biochemistry* 1998,31:495-500.

Ferard G, Edwards J, Kanno T, Lessinger JM, Moss DW, Schiele F, Tietz NW, Vassault A. Interassay calibration as a major contribution to the comparability of results in clinical enzymology. *Clinical Biochemistry* 1998;31:489-494 .

Finke A, Kobold U, Hoelzel W, Weykamp C, Miedema K, Jeppsson JO. Preparation of a candidate primary reference material for the international standardisation of HbA1c determinations. *Clinical Chemistry and Laboratory Medicine* 1998;36:299-308.

Johnson AM. Selection and use of value transfer protocols. *Clinical Biochemistry* 1998; 31:447-8.

Lorentz K. Approved recommendation on IFCC methods for the measurement of catalytic concentration of enzymes. Part 9. IFCC method for alpha-amylase (1,4-alpha-D-glucan 4-glucanohydrolase, EC 3.2.1.1). International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Committee on Enzymes. *Clinical Chemistry and Laboratory Medicine* 1998,36:185-203.

Mayer M, Wilkinson I, Heikkinen R, Orntoft T, Magid E. Improved laboratory test selection and enhanced perception of test results as tools for cost-effective medicine. *Clinical Chemistry and Laboratory Medicine* 1988;36:683-690.

Neumaier M, Braun A, Wagener C. Fundamentals of quality assessment of molecular amplification methods in clinical diagnostics. *Clinical Chemistry* 1998;44:12-26.

Tate JR, Rifai N, Berg K, Couderc R, Dati F, Kostner GM, Sakurabayashi I, Steinmetz A. International Federation of Clinical Chemistry standardisation project for the measurement of lipoprotein(a). Phase 1. Evaluation of the analytical performance of lipoprotein(a) assay systems and commercial calibrators. *Clinical Chemistry* 1998;44:1629-1640.

Whicher JT. Secondary reference materials. *Clinical Biochemistry* 1998;31:441-6.

Whicher JT. BCR/IFCC Reference material for plasma proteins. *Clinical Biochemistry* 1998;31:459-65.

Enquiries about the IFCC may be sent to:

IFCC Technical Secretariat, 30 Rue Lionnois, F-54000 Nancy, France. Fax 33 3 83 32 13 22, Email Chantal.Thirion@ifccts.u-nancy.fr