

Annual Report 2001

Highlights of the Year

- General Conference, Dubrovnik, Croatia
- 14th IFCC-FESCC European Congress of Clinical Chemistry Prague, Czech Republic
- Latin American Confederation of Clinical Biochemistry (COLABIOCLI) Florianopolis, Brazil
- IFCC/Roche Bergmeyer Conference: Diagnostics in Autoimmune Diseases Garmisch, Germany
- IFCC/Beckman Coulter Conference: Recent Advances in Plasma Proteins Prague, Czech Republic
- Implementation of New IFCC Office in Milan, Italy
- Discussion on Joint Committee on Traceability in Laboratory Medicine (JCTLM)
- Memorandum of Understanding and Collaboration with NCCLS
- Reference Methods/Materials: Enzymes at 37°C; HbA₁c; Six hCG preparations,
- Revision of Web Page
- Master Course in Clinical Laboratory Sciences, University of La Plata, Argentina

 Presentation of 2001 IFCC-EDMA Award For Evidence of Effectiveness of Laboratory tests

President's Message

As we enter into the year 2002, it is important to reflect on our activities of the past year. As indicated in the list of our highlights and discussed in more detail later in this report, 2001 was a very good year for the Federation with significant progress and accomplishments being made in many ongoing projects and many new activities were initiated. However, I would be remiss if I did not mention the terrorist attacks of September 11, 2001 and the effect that they have had on the entire world. Not only have the world's television stations and newspapers stunned us with reports of the horrendous loss of life and the grief of the families of the victims in the initial attacks but have shocked us with subsequent images of bewildered and frightened refugees, death and maiming of innocent children and adults, and enormous destruction within modern and ancient cities. We all have been disturbed by these events and our hearts go out to these people and I believe that is our responsibility to strive to make this a world a better place and one where love can thrive and hate will wither.

The attacks also underscored how truly global our world has become as they had an immediate and persuasive impact on the world's financial and transportation networks that are just now returning to normal. Although not on the same scale, the attacks also had an effect on the activities of our Federation and our colleagues in the Asian-Pacific region including (1) a rescheduling of the 9th Asian Pacific Congress of Clinical Biochemistry in New Delhi to March 2002; (2) a relocation of the fall meeting of the Executive Board from New Delhi, India to Milan, Italy where the meeting was held at the new IFCC Office, and (3) restricting travel by IFCC officers and representatives.

We have known for a long time that the discipline of Clinical Chemistry and Laboratory Medicine is a global one as clinical laboratories worldwide are experiencing similar problems of reimbursement, training and availability of experienced staff, quality assurance, problems with internal and external communication, and globalisation in general. Consequently, the Federation has directed its activities to assist our members in meeting their needs. For example, the Technical Secretariat was closed and a new office organised and opened in Milano, Italy. In addition, we have funded and pursued standardisation efforts, revised and enhanced our communication tools, organised conferences and congresses that are well managed and informative, and enhanced our efforts in education and management.

Because of an expanding workload, it was obvious that more administrative and logistics support was needed to support the needs of the Federation. Consequently, in 2001, the Technical Secretariat in Nancy was closed and a new IFCC Office was organised and opened in Milan. The IFCC Office is staffed with qualified and experienced personnel using modern office equipment and carries out the administrative and communication activities of the organisation under the management of the EB.

The Scientific Division (Chair: Jean-Claude Forest) continues to develop close collaborative ties with international organisations devoted to laboratory medicine. For example, the Scientific Division in collaboration with the IRMM, CIPM, BIPM, NIST, NML, NCCLS and supra-national manufacturer organisations (EDMA, AdvaMed) have helped to organise discussion on a Joint Committee on Traceability and Laboratory Medicine (JCTLM) whose goal is to develop worldwide a concept of traceability, comparability and equivalence of measurement results in laboratory medicine. A workshop promoting the establishment of a global, interdisciplinary JCTLM will be held in 2002 in Paris. In addition, close collaboration with IRMM, IUPAC, NCCLS, ISTH, IATDMCT, NIBSC and WHO has also allowed the undertaking of joint ventures in the field of the establishment of reference measurement procedures, reference materials and guidelines. After discussions between NCCLS and IFCCS for several years, a Memorandum of Understanding between both organisations, has finally been signed. On basis of this memorandum several joint NCCLS-IFCC projects on bone markers, thyroid function tests, sample collection and handling for molecular test methods, and microarrays were initiated. Again this year, numerous publications were

produced by Committees and Working Groups, as well as reference procedures, guidelines and reference materials. Furthermore, following the ISO-CEN System, the Scientific Division is currently developing networks of reference laboratories.

The Congress and Conference Division (Chair: Graham Beastall) took the lead role in organising the successful IFCC General Conference, which was held in Dubrovnik, Croatia. The Division notes with pleasure the successes of the Regional Conferences in Prague, Czech Republic and Florianopolis, Brazil. The Division continues to work closely with the organisers of Kyoto 2002 and the forthcoming congresses in the four IFCC Regions. The Division is taking a higher profile in the organisation of the IFCC Master Conferences and has responsibility for approving IFCC Auspices for conferences in related fields of Laboratory Medicine.

During the year, the Communication and Publications Division (Chair: Bernard Gouget) focused on integrating new technologies of communication and putting in place interactive networks in order to take on the challenges of information networks for knowledge management and for relationships between individuals. With the new millennium the CPD strategy was oriented towards interprofessional, interlinguistic. interregional approaches and meetings. A broad survey undertaken during the general conference was used to identify the needs of the IFCC membership for products and services. As a consequence, the web site was redesigned in 2001 with a dynamic look using cascading style sheets to become a dynamic portal to international resources for laboratory medicine. Site management is still by our web coordinator Craig Webster (UK), with regular updates carried out by the IFCC office staff in Milan (IT).

The Education and Management Division (Chair: Gerard Sanders) continues to be involved in training, education, evidence based laboratory medicine, quality assurance programs in many countries of the world. The latter including Argentina, India, Lebanon, Dominican Republic, and Iran. In addition, the Division has taken the lead in supporting the IFCC Global Campaign to

improve the Diagnosis and Management of Diabetes. A course in Molecular Biology Techniques is being developed. The Division has also participated in activities of the Collaboration, an initiative that ultimately will create a systematically compiled database (Bayes Library) of standardised and critically appraised information on the characteristics of any type of test used in health care. In education, an article on Clinical Case Material for Teaching Clinical Chemistry and Laboratory Medicine was put on the IFCC Website. Also an outline for a Course on Curriculum Development can be found there. Several of these carried-out activities are being in close collaboration with the national societies and regions, and are supported by Corporate Members.

The Federation is a voluntary organisation that accomplishes its goals through the dedication and hard work of many of individuals ready to serve this organisation. This active participation of enthusiastic experts in IFCC programs has brought progress in the Federation's key elements such as standardisation, education, and laboratory management that has advanced and promoted communication between clinical laboratorians worldwide. We all need to acknowledge and commend these colleagues for their hard work on our behalf in meeting our needs and expectations, and in expanding the vision and role of the International Federation of Clinical Chemistry and Laboratory Medicine.

Mathias M. Müller President

Executive Board (EB)

Meetings

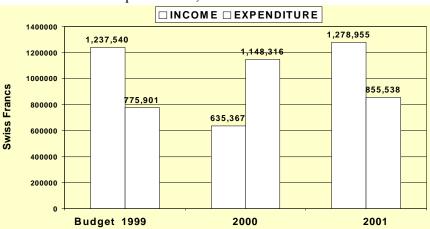
The EB met three times in 2001, in Dubrovnik, Prague and Milan. The meeting in Dubrovnik was held during the 7th IFCC General Conference and the meeting in Prague was immediately prior to the 14th European Congress of Clinical Chemistry. The final meeting for the year was in Milan at the new IFCC Office which enabled the EB to meet the office staff, see the facilities of the office and review its activities. At the meeting in Dubrovnik, discussion focused on the status and future of the IFCC Office, whether the IFCC should establish Reference Laboratory Networks in collaboration with metrology institutes and industry and on Congress guidelines, namely the financial considerations and IFCC responsibilities. It had been identified there is a need to increase IFCC income and to change the basis of the income so much of the meeting focused on this. One possibility discussed were new arrangements for the way congress budgets are developed and a more significant role of the IFCC in IFCC endorsed congresses and conferences. For the IFCC to maintain its core activities, there is a need for about CHF 300,000 in extra net revenue per year.

As representatives from all IFCC Affiliated Regional Organisations were present at the General Conference, there was the opportunity to discuss the relationship between their organisation and the IFCC. With COLABIOCLI, fruitful discussions were held on how to best help the Latin-American Countries to get Corporate Members involved in their meetings. In addition, discussions on the possibility of holding a specific regional conference "Predictive New entitled Markers in Cardiovascular Disease" was discussed and the IFCC gave a commitment to support such a conference both with speakers and in helping to obtain sponsorship. As there is no formal agreement with the APFCB, the IFCC is currently unable to give any funds to the Federation although it does support the Federation in other ways. The financial arrangements with other regional groups were explained to representatives of the APFCB who agreed to consider this and other alternatives.

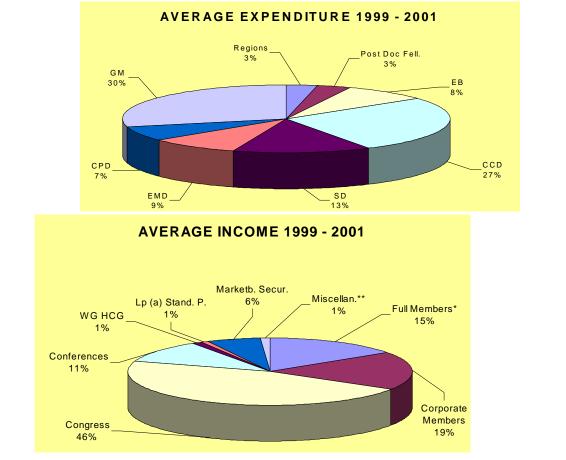
There was a meeting with members of the board of the Federation of European Societies of Clinical Chemistry (FESCC) who presented their strategic plan of which the major points were organising the European Congress, running Education Programs in the region and accreditation. FESCC represents Alps-Adria, Balkans, Baltic and Selected National Societies and one pleasing outcome of the meeting was that the FESCC Board reiterated that they consider themselves the European branch of IFCC, similar to other regional organisation. It was agreed that the formal documents confirming this should be signed in Prague. The activities of FESCC for the last three years were detailed showing their

A quick view of IFCC finances for 1999-2001

As shown in the first Figure below, income and expenditure were broadly in balance over the three years 1999-2001. As usual, the year which contained the International Congress of Clinical Chemistry showed a positive outcome whereas in 2000, expenditure exceeded income. The overall result across the 1999-2001 triennium was a surplus of 372,107 Swiss Francs.



The major sources of income are Members' and Corporate Members' subscriptions, ICCC profits, and contributions towards Scientific Division projects and conferences. The patterns of IFCC income and expenditure are shown in the two pie chart below. The major items of expenditure are within Congress Conference Division (CCD) and the Scientific Division (SD) and in maintaining the infrastructure of our organisation. The three other Divisions account for just over a third of the expenses.



emphasis on education and accreditation. Future activities included meetings and courses in Estonia, Croatia and Slovenia.

The EB also met with the President-elect of NCCLS, Dr Donna Meyers with whom it was agreed that the two organisations would work more closely together and run joint projects. A formal agreement was outlined which was be prepared for signing in July.

An initiative for the establishment of a Joint Committee on Traceability in Laboratory Medicine (JCTLM) had been started at a meeting in January 2001 in Paris. At this meeting Metrology Institutes, IRMM and IFCC participated. It is envisaged to create a forum of collaboration including IVD industry and to establish a global reference system, as proposed by IFCC. At the meeting in Paris, the IFCC President was asked to contact IVD industry associations for nominating individuals to the JCTLM consortium.

The Global Campaign on Diabetes was launched at the General Conference and received the endorsement of those attending. A St John and K Miedema were asked to prepare a report for circulation summarising the ideas brought forward during the Workshops which were well attended. Those attending the meeting also heard a report from the Chair of the Task Force on Ethics who presented an overview of this group and indicated that Forensic DNA Fingerprinting and Serum and Tissue Banks were to be the initial projects for consideration.

One of the major items discussed by the EB was the Expressions of Interest received for the relocation of the IFCC Office. Eight submissions were received and after some discussion it was decided the IFCC Office should be established independent of a National Society. The three submissions from Professional Groups were then further evaluated and it was agree that negotiations would commence with Emmezeta Congressi of Milan with the aim to establish the Office by July 1st, 2001.

The second meeting in 2001 was in Prague but as this meeting occurred relatively shortly after the Dubrovnik meeting, the President indicated the meeting should focus on principals and future developments within the IFCC. These include our

involvement in Reference systems, BIPM, the need for a Public Relations initiative and strategy for broadening and improving communication with National Societies, Corporate Members and individual members.

It was agreed that the Public Relations program should be a specific task of the Members of the EB and they were asked to prepare a questionnaire to be sent to all National Societies to gain information on their thoughts about the IFCC, expectations and ideas for future projects.

A meeting with representatives of Emmezeta Congressi was also held and they were asked to draw up a draft agreement regarding running IFCC Congresses. This umbrella contract would be used as the basis of all future negotiations for running Congresses. Part of the agreement was that Emmezeta Congressi would have the status of preferred provider. The draft contract with FESCC was also discussed and after some minor changes the agreement was signed during the Prague Congress.

A major outcome from this meeting was the signing of the agreement between IFCC and Emmezeta Congressi regarding the IFCC Office. It was decided that the office would use space and facilities within the Emmezeta Congressi structure but operate independently. For industrial purposes, the staff will be employed by Emmezeta Congressi but be contracted to the IFCC and be responsible to the IFCC for their working tasks. Applicants were interviewed on 9th June just after the EB meeting and Lisa Ionescu and Emanuela Maffioli were selected. The EB also expressed it thanks to Ms Chantal Thirion who had run the IFCC Office in Nancy for the past ten years.

The final meeting of the year was held at the new office in Milan. Originally it had been planned to hold this meeting in New Delhi at the 14th Asian Pacific Congress of Clinical Chemistry but due the tragic event in September, the Congress was postponed until 2002. The EB had the opportunity to view the facilities and meet the staff and were extremely impressed with the progress made in such a short time. There had significant progress in developing the database of IFCC contacts and in the redesign and development of the IFCC web page. Much of the daily updating of the web was being transferred to the office.

The major items discussed at this meeting were the Budget 2001 and forecast and development of budget 2002. The strategic matters discussed included IFCC involvement in Reference systems and in the formation of the JCTLM in conjunction with BIPM, the reports from the Public Relations group and the issue of Intellectual Properties rights. The President also indicated that the name change from Clinical Chemistry to Clinical Chemistry and Laboratory Medicine, instituted by the previous EB, had occurred at a very opportune time and that the Federation was in a strong position to become a leader in determining the future of the profession. As is normal for the last meeting of the year, the Divisional Chairs were also present which gave the opportunity to review the activities of the Divisions and discuss future strategic directions. The Chairs also took part in the development of the budget for 2002.

One item that was finalised and signed was the agreement between IFCC and Emmezeta Congressi regarding the running of Congresses. It was also considered that there should be legal protection for IFCC associated logos and the IFCC Office was asked to investigate registering the Euromedlab Conference logo. As part of formalising these issues, it was also decided to establish contact with the former IFCC lawyers in Laussanne, Switzerland. This may become important as the IFCC continues to develop commercial initiatives.

The outcomes from the Public Relations program developed at the previous EB meeting, which was the responsibility of the EB Members were discussed. 78 Questionnaires were mailed to Member Societies with 28 answers received by November and 36 questionnaires mailed to Corporates of which 14 answered. The group decided to send the same questionnaire to the societies that did not reply. Rosa Sierra Amor and Chris Lam were asked to make personal representation to the Societies in Latin America and Asia, respectively. The group were asked to prepare a report for publication by the end of January, 2002 after reviewing all questionnaires received. The EB also requested that the group come up with recommendations on how better to involve the National Societies and Corporate Members in IFCC activities.

A draft on Intellectual Property Rights based on McMaster University guidelines had been circulated and a 2nd draft based on revision, prepared by the Vice-President was distributed at the meeting to serve as the basis of the discussion and changes. Further changes were made and legal advise will be sought from lawyers at the University of Amsterdam and INSERM. It was decided that once a workable document was available, IFCC Committee and Working Group members would be asked to sign on a volunteer basis for current proposals but for new proposals, signing it would be mandatory.

Public Relations

In an attempt to find out how Member societies value the activities guided by IFCC, the EB realized the importance of having a Public Relations initiative that linked us to our Member societies and Corporate members closer.

Therefore, encouraged by this idea, the Members of the EB, Ghassan Shannan, Rosa Sierra-Amor and Chris Lam in conjunction with the IFCC Office commenced a project on Public Relations. A positive response was obtained, which gave more accurate and precise information on the participation of IFCC members in our divisions, committees and working groups. The first questionnaire was sent out in September 2001. Although, not all Member societies and Corporate members replied to the questionnaires, valuable information was presented at the EB meeting in Milan last November. This task continued by sending another questionnaire in late December, which encouraged several more societies to reply that they were interested in getting more involved in IFCC activities.

This activity will continue and a report of the result for distribution to our membership was being prepared.

Professional Scientific Exchange Program

In 1998 this twinning program between two laboratories in different countries was founded so that young colleagues could participate in visits abroad. During 2001, 7 applications were received and 5 approved; unfortunately two granted scholarships had to be cancelled due to personal and political reasons. A total of 3 visits abroad took place in 2001. The scholarship recipients came from Bulgaria and Yugoslavia and were trained in laboratories in Austria and the UK. The topics and

techniques dealt with during these visits were related to tissue culture, flow-cytometry and establishment of gut resorption tests. Already one of the visit reports has been published in eJIFCC. The EB considers this program important for our young scientists and their future and National Societies are encouraged to promote the program and to submit applications.

Awards Committee

The IFCC Awards program includes the following five awards: Distinguished Clinical Chemist and Distinguished International Services-Henry Wishinsky Awards (sponsored by Baver): Distinguished Contributions to Education Award (sponsored by Beckman-Coulter); Award for Evidence of Effectiveness of Laboratory Tests (sponsored bv the European Diagnostics Manufacturers Association); and the Award in Advances in Critical Care Medicine (sponsored by Roche). In 2002, a new award will be presented for distinguished contributions in Molecular Diagnostics. This new award will be sponsored by Abbott Diagnostics. The IFCC is grateful to the sponsors of these awards for their generous contributions in sponsoring these awards.

The winning paper for the 2001 IFCC/EDMA AWARD was:

Umans-Eckenhausen MA, Defesche JC, Sijbrands EJ, Scheerder RL, Kastelein JJ: Review of first 5 years of screening for familial hypercholesterolaemia in the Netherlands.Lancet. 2001 Jan 20;357(9251):165-168.

Runner-up papers were:

Owen A, Khan W, Griffiths KD: Troponin T: Role in altering patient management and enabling earlier discharge from a district general hospital. Ann Clin Biochem. 2001 Mar;38(Pt 2):135-138

Becker C, Piironen T, Pettersson K, Hugosson J, Lilja H: Clinical value of human glandular kallikrein 2 and free and total prostate-specific antigen in serum from a population of men with prostate-specific antigen levels 3.0 ng/mL or greater. Urology. 2000 May;55(5):694-699.

These top three entries were presented at the IFCC/EDMA symposium at EuroMedLab 2001 in

Prague on Sunday 27 May. It was a very successful symposium chaired by Carl Burtis (IFCC) and John Place (EDMA). EDMA has agreed to sponsor the Award again in 2003.

Members of the 2000-2002 Awards Committee are Chair Carl Burtis (Vice-President) and Ann Gronowski (USA), Adolph Grünert (Germany) and John Whitfield (Australia). The Awards Committee was ably assisted by B van Weemen (Netherlands), Wieland Hölzel (Germany), and John Place (EDMA-BE) for the IFCC/EDMA Award and by Ildiko Amann-Zalan (Roche-DE) for the IFCC-Roche Award.

Corporate Members

Seven new Corporate Members joined the IFCC in 2001. These were First Medical, Chronolab AG, Drew Scientific, Olympus GmbH, Response Biomedical Corp, Walter de Gruyetr GmbH and GIT Verlag GmbH. The EB was extremely pleased that the number of Corporate Members has increased recently despite the number of mergers that have occurred between diagnostic companies.

There were two meetings between the Corporate Members and the EB and Divisional Chairs, one in Prague at the European Congress and the other in Chicago at the AACC meeting in July. These meetings gave the opportunity to discuss projects and ideas that were mutually beneficial to both the IFCC and our Corporate Members.

Communication and Publications Division (CPD)

During 2001, the CPD-Executive committee members were Bernard Gouget (FR), Chair, Andrew Wootton (AU), Vice-chair, Craig Webster (UK), Web-coordinator, Johan Waldenström (SE), Editor in Chief eJIFCC, Ellis Jacobs (US), News Editor. During the General Conference in Dubrovnik, Peter Lehmann (US) was appointed as the new Editor of documents with Julie Williams (US) as corporate representative. Unfortunately she was obliged to resign as she left Bayer Inc. and consequently her position as CPD-CR member. A call for nomination was sent for ballot, Heiko Ziervogel (DE) from Philips was appointed as new Corporate representative for 2002. Chris W K Lam (HK) was the supporting EB liaison. The CPD structure is composed not only of an executive committee but also 4 working groups chaired by the respective executive committee's members: WG-WWW, WG IFCC news, WG eJIFCC – a true medical practice focusing on the challenges for editorial office, and the WG- Ibero American Nomenclature and Translation (Chair: Xavier Fuentes Arderiu).

The CPD met once as a whole group in Dubrovnik (CR), March 2001. Partial meetings allowed exchanges with the Web-coordinator during the web courses in Milano, the News Editor and Corporate Members at the AACC meeting in Chicago where Bernard Gouget, CPD chair received the 2001 AACC award for international travel fellowship.

The CPD was very active at the IFCC meetings: Vera Cruz (MX), Euromedlab (Prague), COLABIOCLI (Florianapolis (BZ)), Damascus (SY) with the Arabic Confederation of Clinical Biochemistry. At each congress, the CPD managed the new IFCC booth and chaired scientific sessions on the use of the Internet and the role of laboratory medicine in the evolution of health information systems.

In 2001, IFCC-CPD reinforced its involvement with electronic communications, insisting on a new IFCC image that confirms its worldwide leadership in clinical chemistry and laboratory medicine, reaffirming that the activities of IFCC on the Web truly reflect the constructive, dynamic evolution that the Web is bringing to clinical sciences, today and tomorrow.

Activities at EUROMEDLAB (Prague May 2001)

With the participation of Rosa I Sierra Amor (MX), former CPD liaison and EB member, SS Ehrmeher (US), A. Pesce and L Kaplan publishers (US), the CPD organised a workshop on telebiology and laboratory medicine. This allowed the promotion of the Internet as a tool for information and electronic services as it impacts on good laboratory practices. The former secretary Chantal Thirion, out of kindness and with great success demonstrated through practical examples the efficacy of the use of the Internet, how to surf the web and subscribe automatically to IFCC activities.

Activities at XV Latin American Congress in Clinical Biochemistry in Florianopolis (BZ) auspiced by COLABIOCLI (July 2001)

IFCC-CPD offered an active booth that served as a meeting point for all colleagues. They met for meetings, for obtaining copies of the IFCC Handbook, reading information about ICCC in Kyoto 2002, and planning activities with IFCC Working Groups. IFCC activities were displayed on posters that helped identify the different divisions, committees, and IFCC website.

Xavier Fuentes Arderiu, chair of the Working Group on Ibero-american Nomenclature and Translations (WG-IANT), held a meeting with his members, LF Kijner (EQ),RA Echevarria (CU), UM Tiburcia (BR).The Rincon Ibero-americano (RIA) segment of the IFCC web-site is operational with two sections:

- Libros: showing the covers and table of contents of recommended books and CDs relevant to clinical chemistry and laboratory medicine.

- e-book: "Manual de estilo para la redaccion de textos científicos y professionales". This is available in pdf format.

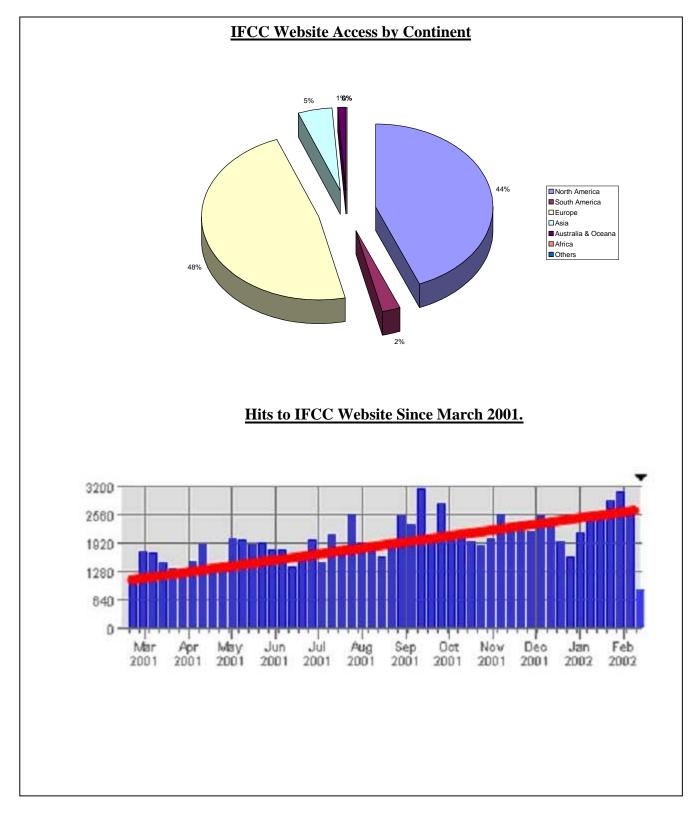
Activities with AFCB during the Laboratory Medicine Conference in Damascus (SY) (September 2001).

The CPD chair participated in the Conference as he presented a lecture in the laboratory management symposium. Additionally, he met Executive Board members of the Arab Federation of Clinical Biology (AFCB) with representatives from Morocco, Tunisia, Egypt, Sudan, Yemen, Jordan, Lebanon, Iraq and Syria to initiate upcoming publicity for the 10th Conference of AFBC held in May 2004 in Monastir, Tunisia

IFCC website

IFCC web management. The web site was redesigned in 2001 with a new dynamic look, a stronger and more recognizable profile design that uses cascading style sheets offering a friendly portal to international resources for laboratory medicine. The web coordinator continues to manage the site, with regular updates carried out by the IFCC office in Milan (IT) with the help of Emanuela Maffioli. **Statistical report**: There is increasing activity on the website. The traditional method of assessing this activity has been to count the hits on its web pages. The web site currently averages 175,850 hits per

month. When a user enters a web site, a session is created for that user on the web server. The session is closed when a user leaves the web site. During a session a user may view a number of pages.



The IFCC web site has a porous structure and users are able to enter at any point in the web site. In (80%). The contribution from the US is overestimated due to the nature of network traffic.

IFCC bookstore: IFCC offers a virtual bookstore on its website, first orders are already filled.

Collaboration with Corporate members

The CPD chair attended the CM meetings in Prague (May) and in Chicago (July). He actively participated to recruit a new corporate member, Chronolab, and to convince three corporate members to advertise on the web by buying *e*banners: Radiometer, Chronolab and Wako.

IFCC recommendations and other documents

The categories of IFCC publications were clarified in order to illustrate the individuals responsible for as well as delineate the process of publication.

Publication	Responsible Individual
Documents:	
a. C/WG Recommendations	Editor of Documents
b. C/WG Position papers	
c. C/WG Technical Reports	
d. C/WG Reviews	
e. C/WG Guidelines	
Minutes (all units)	Secretaries of unit
Annual Report	EB Secretary/Chair
IFCC News	Editor, IFCC News
eJIFCC	Editor, eJIFCC
Handbook	EB Secretary/Chair
Conference Proceedings	Special Editor/Editor of
_	Documents*
Monographs, Books	Special Editor/Chair/Editor
	of Documents*
Promotional Materials	Chair and Vice
Multimedia	Chair/Corporate
	Representative

* CPD Editor of Documents has a liaison function.

List of IFCC publications: Peter Lehmann has compiled the IFCC publications with input and assistance from Carl Burtis (EB), the Chairs & Secretaries of the SD, EMD and CPD and the IFCC office. The list includes documents and papers published in journals, conference proceedings and monographs. The entries are listed according to the IFCC-EB numbering system and in chronological order, without consideration of the publication/document type. All future IFCC publications are edited to ensure the nomenclature terms of user location, the vast majority of the web site traffic is generated by the USA and Europe and units used conform to approved IFCC recommendations.

The Editor of documents coordinated the publication of division/committee/working group publications with journal editors, particularly CCLM. Several publications are at the final review/publication 8.2.20 stage: SD/C (Coagulation) – Guideline, SD/WG 8.3.19 (Glycohemoglobin) - Guideline, SD/C 8.2.21 (Enzyme Reference Systems)- Recommendations; SD/WG 8.3.16 (hCG) - Technical Reports (2). A technical report on the katal from SD/C 8.2.6 (Nomenclature Properties and Units) has been published in (IUPAC) Pure and Applied Chemistry.

Publications in CCLM. The list of the members receiving a free on line access was updated. The agreement with IFCC and Walter de Gruyter allowed the publication in CCLM of 3 issues of IFCC news, and different IFCC documents as reference measurement procedure for substance concentration determination of total CO2, clinical case material for teaching clinical chemistry, quality specifications for cardiac troponin assays and an article on total quality management. In addition, there were several abstracts of meetings organised by FESCC: International society on thrombosis and haemostasis, meetings from the German societies (Rostock Sept 2001), European symposium on clinical lab and IVD Industry, and SIBIOC 2001, 33rd National congress of the Italian society of clinical biochemistry and molecular biology.

The copyrights for these contributions are held by IFCC. In conjunction with the paper version of CCLM, the IFCC website has a link to the CCLM website which allows the consultation of IFCC documents by all members at no cost.

eJIFCC

The *eJIFCC* is a wholly electronic publication coordinated by the Editor in Chief and the *eJIFCC*-WG, which is comprised of representatives from the IFCC regions. A subscription mailing list is implemented, which allows readers to be quickly informed of a new issue. *eJIFCC* is one of the most visited sections on the website. The journal has received an ISSN number 1650-3414. The instructions to the authors were updated according to criteria for electronic communications. Three issues were published in 2001, promoting a multidisciplinary approach that focuses on the patient.

- Volume 13, n°1 discussed quality specifications and optimal analytical performance for the reliability of laboratory tests as well as articles with a patient approach on biochemical markers and bone turnover.

- Volume 13, n°2 illustrated the ethos and ethics in genetic diagnosis illustrated by the hereditary hemochromatosis

- Volume 13, n°3 emphasized the role of IFCC in promoting standardisation in laboratory medicine and its involvement in reference materials (ApoloproteinsA-1 and B and lipoprotein(a).

IFCC news

Ellis Jacobs expanded the membership of the WG-IFCC news with a better representation from the national members: Roman Galimany (SP), Joseph Lopez (MA), Howard Morris (AU), Stella Raymondo (UR), Ghassan Shannan (SY), Rosa I Sierra-Amor (MX). Four electronic versions of the IFCC news were prepared in 2001 (January, April, July, October) including an editorial from the CPD chair. They were placed on the IFCC website, as well as automatically e-mailed to all individuals who subscribed to the news. Additionally, each edition of the IFCC news was printed in Lab Medica International (Globotech Publishing, circulation 28 000) and in Clinical Chemistry and Laboratory Medicine. The July-August issue of Lab Medica International also contained a copy of the Annual report 2000. This is in order to expand availability throughout the world, especially for those who do not have access to the internet and to reach a new readership.

eHandbook 2000-2002

The *e*-Handbook 2000-2002 was updated on the web by Chantal Thirion (FR), former IFCC secretary, Lisa Ionescu (IT) and Emanuela

, IFCC office, Milan(IT). A database is already in place allowing simultaneous changes on the web. In addition, a Handbook CD-Rom is available on request.

50 th year anniversary book 1952-2002

Bernard Gouget and Andrew Wootton revised and enriched the CPD section, and organised with John Lines (UK) and Roy Sherwood (UK) the layout and the final graphic design of the book.

IFCC package and external communication

Since its opening, the CPD has worked closely with the IFCC office in Milan (IT) meeting on numerous occasions to develop the website, to create the IFCC database and organise the archives, allowing a more extensive collaboration with IFCC membership. A new graphic chart has been firmly implanted in 2001 by a new IFCC brochure following the enriched version of the Handbook 2000-2002. The new image was set out in folders distributed at each meeting, celebrating current and forthcoming events, with a greeting card featuring a painting by Hans Steffens(DE), IFCC pens, and bookmarks. The chart was also implemented for the creation of new posters (EB, Divisions, CM, Full members,...) as well as for the use of IFFC officers. They are available through the web site on a pdf file. The CPD also undertook the organisation of the IFCC booths at Vera Cruz (MX), Prague (CZ), Florianopolis (BZ), Damascus (SY). In addition, Ellis Jacobs produced 5000 examples of the 50th anniversary pin.

Perspective

The CPD made considerable efforts to broaden the image, leadership, and scientific credentials of the IFCC and is continuously thinking about technological advances that make IFCC more efficient in terms of internal communication and interaction with its membership. Already active with its website, electronic and printed publications featuring a new image, the CPD is constantly exploring new ways to confirm the leadership of IFCC in clinical chemistry and laboratory medicine worldwide. The new multimedia techniques, Internet and "cyber space" are priority areas for exploration. The CPD continues to focus its efforts on the new IFCC website in order to provide an extensive forum whose ongoing intention is to transcend boundaries and to contribute to the improved quality of IFCC services and products that furnish interactive networks of reliable and accurate information fostering trust and strong relationships between individuals.

Congress and Conference Division (CCD)

Although CCD only met twice during 2001 (Dubrovnik and Barcelona) it was a very busy year for the Division.

IFCC General Conference

The big event in the first quarter of the year was the IFCC General Conference, which was held in the historic city of Dubrovnik in Croatia. CCD had the responsibility for organising what is in effect a midterm business and planning meeting for all IFCC functional units. With considerable assistance from the Croatian Society the meeting was a great success - a great deal of business was conducted, including the launch of the IFCC Global Strategy on Diabetes, and yet there was still time to absorb the delights of Dubrovnik and Croatian culture.

International Congresses

CCD has a key role in supporting the organisers of the triennial International Congress of Clinical Chemistry and Laboratory Medicine (ICCC). The 18th ICCC, to be held in Kyoto, Japan in October 2002, progressed very well during 2001. CCD met once with the organisers and although a second meeting planned for New Delhi had to be cancelled in the aftermath of September 11th it is clear that everything is on track for a great ICCC.

The 19th ICCC will be held in Orlando, USA in August 2005. CCD is delighted that the organising committee for this congress was established during 2001 and that key priorities have been identified.

The 20th ICCC will be held in the year 2008. Invitations to host this congress were issued to all IFCC Full Member Societies in September 2001 with a closing date for applications of February 2002. The decision on the successful venue will be announced in Kyoto.

Regional Congresses

Two highly successful Regional Congresses of Clinical Chemistry and Laboratory Medicine (RCCC's) were held during 2001. The European RCCC was held in June in the majestic city of Prague in the Czech Republic. A very successful congress, managed to blend a new format of scientific programme with an infinite amount of culture. The COLABIOCLI congress, held in Florianopolis, Brazil in July was a very large congress and exhibition held in modern surroundings and judged by all present to be an outstanding success.

CCD continued to work during the year with the organisers of Barcelona 2003 and Perth (Australia) 2004 and commenced work with the organisers of Costa Rica 2003, Tunis 2004 and Glasgow 2005 – the next five in the series of RCCC's.

IFCC Specialised Conferences

CCD contributed to two specialised conferences during 2001. In March the latest in the series of IFCC Bergmeyer Conferences was held in Garmisch Partenkirchen, Germany on the theme of Autoimmune Disease. This meeting achieved a very high scientific standard, enjoyed by the invited audience of experts in this area. In May the first IFCC Beckman Coulter Protein Conference was held as a satellite meeting to the Prague RCCC. More than 200 interested participants, who had the opportunity to present their original work, attended this event, again a high scientific standard was achieved.

IFCC Auspices

CCD awards IFCC Auspices to high quality conferences in the area of Clinical Chemistry and Laboratory Medicine. Under a mutually beneficial arrangement IFCC helps with the promotion of approved conferences whilst the organisers promote the role of IFCC as supporters of the conference. During 2001 some 10 conferences received IFCC Auspices.

IFCC Guidelines and Support Materials

During 2001 CCD revised its guidelines for the organisers of ICCC's and RCCC's and it prepared new guidelines for the organisation of IFCC Specialised Conferences. In addition, CCD finalised its support package entitled 'How to Organise a Congress or Conference' – this will be available from the IFCC website in 2002.

Membership

CCD was fortunate to enjoy a stable membership during 2001. Furthermore, all members will continue to serve IFCC during 2002 – despite all its hard work CCD likes to think of itself as the 'happy Division'!

Education and Management Division (EMD)

In the year 2001 all ranks of the Education and Management Division (EMD) have intensified their activities. With great enthusiasm the Executive Committee, the Committees and Working Groups have begun with new plans, that in most cases will not lead immediately to tangible results, but they mark the initiatives for the future of EMD. Although in the next paragraphs activities will be dealt with in more detail, in short we can say that the Committee on Molecular Biology Curriculum (now: Committee on Clinical Molecular Biology Curriculum) revived under its new chair. For the Committee on Curriculum Development (now: Curriculum Committee on Education and Development) also the chairmanship changed. A difficult decision had to be taken by closing the Committee on Financial Laboratory Management.

The division started with new forms developed to give short updates of the activities and projects of committees and working groups; also new project proposal forms were introduced.

EC and Committee Chairs express their thanks to Craig Webster for an outstanding job in creating the new Web Site format. His ongoing support, in a later stage together with Emanuela Maffioli of the IFCC secretariat has been excellent. EMD has started in 2001 to put more information on the IFCC Web Site, which will be continued in the next year.

EMD EXECUTIVE COMMITTEE (EC)

The Executive Committee (EC) consisted of Gerard Sanders (NL) Chair, Ian Wilkinson (CA) Vicechair, Sue Evans (US, Corporate Representative) Secretary, and Michael Mayer (IL) Member. EC met three times: in March during the IFCC General Conference in Dubrovnik, in Croatia, in June in Cape Town, South Africa, adjacent to the national congress of the Federation of South African Societies of Pathology, and in October in Garderen, the Netherlands, as part of the meeting of the EC with the Committee and Working Group chairs.

In South Africa EMD members participated in a Clinical Chemistry – IFCC symposium in which lectures were given on subjects concerning the consolidation of laboratories, patient – oriented management, evidence based laboratory medicine, and the interaction between science and service in the clinical laboratory.

The EC has been in contact with different colleagues who have produced education materials, which were offered to EMD for publication. We very much appreciated these initiatives, which show that EMD is need of a good reviewing process, in co-operation with the other Divisions. In the year to come this needs to be set up to ensure that the best publications will be made available to the membership of IFCC.

EMD continued to develop and improve the "Contents of the Division" table that was initiated at the meeting in South Africa. These discussions on future strategy have learned that EMD will put more efforts in discerning good teaching materials for the IFCC membership, directing attention to distant learning, and in combination with the Publications Division paying more attention to the public awareness for our profession. In relation to this latter point, the Global Campaign (vide infra) is seen as an important tool. Concerning distant learning the Division wishes to start with a WG on this subject; the EB agreed in principle to the proposal of forming a WG on Distant Learning but the final decision depends on a project proposal from the EMD. For this WG there will probably two tasks - Review of educational publications (printed, electronic) – Stimulate initiatives to create programs in this field.

Together with the World Association of Societies of Pathology and Laboratory Medicine a start was made to come to a joint document on the post graduate education in clinical pathology and laboratory medicine. In the IFCC this task was delegated to the EMD. The existing document made by EC4 (European Communities Confederation on Clinical Chemistry) on the contents of post graduate education in our disciplines was taken as a basis. The exchange of ideas has started and the discussion is going on. The EMD has given its support to the start and development of the Global Campaign for IFCC to improve the Diagnosis and Management of Diabetes. This activity is ongoing, but some delay has occurred, and it is expected that in 2002 at the Kyoto congress more will be heard of this essential initiative.

Committee on Financial Laboratory Management (C-FLM)

Risto Heikkinen (FI) has resigned as Chair, C-FLM. Since it was very difficult to discern active project proposals for this committee, the EB decided after extensive discussion to close this committee for the moment. This means that whenever new ideas in the field come up, or the membership of IFCC requires activities in the field of financial management, it can be revived. With this measure the field studies, especially to discern countries where the Master Course on Laboratory Medicine could be held, are being postponed.

In the future, the Division may need to focus on general laboratory management, which would include areas such as accreditation, and laboratory and financial management.

Committee on Clinical Molecular Biology Curriculum (C-CMBC)

The name of this committee was changed from Committee on Molecular Biology Curriculum to Committee on Clinical Molecular Biology Curriculum, since EMD is primarily involved in clinical applications of molecular biology.

The Committee on Clinical Molecular Biology Curriculum started its activities under the new chair, Maurizio Ferrari (IT), an experienced educator in the field of clinical molecular biology.

Plans are now being developed for Courses in Molecular Biology Techniques (3 to 5 day courses). This is a challenging activity, since this includes a practical session. This limits the possible spots in the world where a course on molecular biology can be held: one must have laboratories with the expertise and appropriate facilities. The inclusion of a practical session also limits the number of participants.

A second assignment for C-CMBC are courses in teaching Molecular Biology in Laboratory Medicine, which is a more challenging issue.

Committee on Analytical Quality (C-AQ)

The Committee Activities consisted of: Serum Donation Projects, Network of Reference Laboratories for Enzyme Measurement (NERLM), Software for EQAS Management and Data handling, Courses & Publications, Co-operation with IRMM/IMEP –17 and Developing Guidelines on EQAP. The Committee held a meeting in Antwerp (BE) in October.

Serum donation projects for quality assurance purposes took place in India, Lebanon, Dominican Republic and Iran. The help of some corporate members, national institutes, and some national societies who made this activity possible is greatly acknowledged. Without their help this program never would have been as successful as it is now.

The Network of Reference Laboratories for Enzyme Measurement continued its work with .

assigning values for ALT and AST to EQAS control material in Argentina, and developing the SOPs for the measurement of both enzymes. The NRLEM will add GGT as a new enzyme. For this purpose, reagents, calibrators and controls will be distributed between the laboratories in Hannover and in La Plata.

After experience with the Software for EQAS Management was gained in several countries Mexico, Venezuela, and Costa Rica have become new users.

A Training Course for Self-Preparation of Control Materials was run in Rio de Janeiro (BR). Attention was payed to materials for Hematology, Parasitology, Bacteriology, Urine, Immunology and Instrumental Control.

Together with IRMM/IMEP–17, for sixteen analytes and enzymes in serum, a quality assurance program is run in 50 participant countries by both Reference and Routine laboratories. The outcome of this project will be a topic of discussion for next C-AQ meeting when contact will be established with local EQAS organisers for the co-ordination of the program.

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

Introduction: Evidence based medicine has become accepted practice in the provision of modern healthcare. Interestingly, to date, the approach has had limited impact on laboratory medicine. Despite the crucial importance of the appropriate use of diagnostic tools in clinical decision making, many diagnostic tests, clinical findings and items from medical history have not been subjected to rigorous evaluation in studies following modern standards of clinical epidemiology. Thus, in order to support the validity and effectiveness of clinical decisions, and to disseminate the results of evidence-based practice the Committee on Evidence-Based Laboratory Medicine (C-EBLM) within the Education and Management Division of IFCC has taken this approach forward in 2001 with the following activities:

1. Good quality systematic reviews on the clinical usefulness of diagnostic tests.

For better systematic reviews in laboratory medicine, standardised methodology needs to be worked out. To address this problem, C-EBLM has co-operated in an international collaborative project that has been started by a Swiss group of primary physicians and epidemiologists, in association with the Diagnosis and Screening Methods Group of the Cochrane Collaboration. This initiative is called the Bayes Collaboration, which will create a systematically compiled database (Bayes Library) of standardised and critically appraised information on the characteristics (sensitivity, specificity) and discriminatory power (predictive values, likelihood ratios, etc.) of any type of test used in health care. In addition, the database will contain information on the prevalence of diseases and conditions in different settings and patient groups and provide a user-friendly interface and search engine. The Bayes Library will support and improve patient outcome by integrating EBLM into the diagnostic decisions, education and training of laboratories. By the process of constant questioning and reviewing evidence for rational diagnosis of diseases, it is also a practical tool to generate new research ideas in laboratory medicine. The Bayes Project is sponsored through non-IFCC resources. Andrea Rita Horvath (HU) is co-ordinating the participation of C-EBLM in the Bayes Project.

2. Development and implementation of evidencebased guidelines.

C-EBLM does not achieve its aims by simply providing the evidence, C-EBLM is also engaged in the implementation of evidence into daily use, and integration of this process with quality management in laboratories. One way of achieving this aim, is the development and implementation of evidencebased guidelines, followed by monitoring the effect of implementation.

For example in Norway, the Norwegian center for quality improvement of primary care laboratories

(NOKLUS), with the co-ordination of Sverre Sandberg (NO) extended the scope of quality assessment from the technical control of the analytical phase to the pre- and post-analytical phase of laboratory service by carrying out an audit on the appropriateness of the physicians' use of tests and their interpretation of test results. The method is educational and resulted in several publications in 2001.

3. Knowledge management systems of critically appraised data in laboratory medicine.

Several attempts have been made by committee members to make research evidence and systematic reviews on the performance characteristics of laboratory tests accessible at the point of clinical decisions. With the contribution of Wytze Oosterhuis (NL), C-EBLM has a website link to a database of systematic reviews in laboratory medicine, that provides a short overview of the key messages and a list of specifications of the original references (<u>http://www.ckchl-mb.nl/ifcc</u>).

The Japanese Society of Laboratory Medicine, with the co-ordination of the International Clinical Pathology Center/C-EBLM Project (Chair: Tadashi Kawai), has also developed a website in Japanese of critically appraised data on the effectiveness of laboratory investigations, including a collection of likelihood ratios, predictive values, etc. (http://ebd.umin.sc.jp/eblm/).

The so-called Bayes Collaboration leading to the Bayes Library was mentioned already.

Another approach has been started in Hungary, with the co-ordination of Horvath (HU), to provide an evidence-based decision support system directly linked to patient data. This approach is based on the Oxford Clinical Intranet system and ae demo version of the Hungarian Clinical Intranet on evidence-based diagnosis of hyperkalaemia has been prepared. The program is part of a project in Hungary, sponsored by the Department for International Development of the UK Government (http://tudor.szote.u-szeged.hu).

4. Training and education.

In order to raise the awareness and skills of the profession and the public about the methods of EBLM, committee members have delivered several talks, seminars and workshops both locally and internationally.

5. Communication and dissemination.

The concept of EBLM and the activities of the committee were communicated both to the community of IFCC and to the lay public. Within IFCC, the Committee chairman has circulated a

letter to all national societies of laboratory medicine and called for interested parties to join the efforts of C-EBLM. Several societies responded and nominated contact persons. At present the committee has 13 contact persons / associate members.

6. Good quality primary research of diagnostic accuracy.

C-EBLM was indirectly involved in setting standards for reporting of diagnostic accuracy. With the contribution of IFCC, several attempts have been made to achieve this aim (e.g. DE Bruns: Towards a Checklist for Diagnostic Accuracy, Clin. Chem. 2000; 46(7): 893-895, and the STARD group initiative for establishing <u>STA</u>ndards for <u>Reporting of Diagnostic</u> accuracy).

In conclusion, C-EBLM was very active in 2001. Committee members and/or the committee's associate members, have published some 20 papers in total to disseminate EBLM in international journals and in their own countries. They gave about 20 lectures on the subject of EBLM at international congresses. At 4 web sites the activities can be retrieved.

The committee has organised two meetings during 2001 to evaluate the work done and to initiate further activities. One at the IFCC General Conference, 8-11 March 2001, Dubrovnik (CR), and the other at EUROMEDLAB 2001, 26-31 May 2002, Prague (CZ). Two members of C-EBLM attended the 9th Cochrane Colloquium, Bayes Library Workshop, 7-13 October 2001, Lyon (FR).

Committee on Education and Curriculum Development (C-ECD)

In 2001 the name of this committee was changed to Committee on Education and Curriculum Development (C-ECD), in order to better reflect its activities.

Terms of reference: The mission of C-ECD is to play a leadership role in education and curriculum design in laboratory medicine at an international level.

The aim is to facilitate internationalisation of education in laboratory medicine by promoting, developing and assisting in development of collaborative programmes between different centers, countries and societies in the areas of:

- Curriculum development

- Development of templates for teaching and training and dissemination to the IFCC membership
- Define the core knowledge of laboratory medicine and to ensure the input of laboratory medicine into core curricula
- Explore new ideas and directions in teaching laboratory medicine
- Produce assessment reports on available educational materials
- Multi-professional learning
- Development of international teaching materials

The membership of the Committee has changed over the year. Marek Dominiczak (UK) stepped down as Chair at the meeting in Dubrovnik and Lynn Allen (CA) was appointed as Chair. Mario Pazzagli (IT) stepped down from the Committee after completion of his first term. Replacement members are being sought.

The Committee has continued its work on a number of educational activities.

Status of current projects:

1. Course on Curriculum Development.

This course is designed to assist laboratory professionals

who request help in the development or update of educational programs in laboratory medicine. The final outline (template) was completed and the course was put on the EMD section of the IFCC Web Site.

2. Distance Learning Websites.

It is planned to contribute to distance learning objectives of the EMD by compiling resource information on websites with good educational topics in clinical areas. The plan is to 1) develop criteria to evaluate website educational material, 2) search for websites with good educational material, and 3) list sites against syllabus topics to provide resource information for distance education. This project will start with an inventory of existing information.

3. Educational Modules in Laboratory Medicine.

Plans are also underway to develop educational modules for the IFCC website on the teaching of clinical topics in laboratory medicine.

4. Clinical Case Material for Teaching in Clinical Chemistry.

A compilation of clinical case material to serve as a resource for teaching has been prepared. The article was published in CCLM in September 2001

(CCLM; 2001; 39(9):875-889) This has been posted on the EMD section of the IFCC Web Site. Revision will be considered in 2003.

5. Associate Members.

A letter was sent to all Associate Members in January 2001. A questionnaire was developed and sent in September 2001. The next steps are to establish a dialogue with each of the Associate Members, and to work with them to improve education in clinical laboratory sciences.

6. Proposed Master Program in the Asia Pacific Region.

The purpose is to promote the establishment of a Masters Program in the Asia Pacific Region, based on the experience with the La Plata Course. Communication has been established with the Chair of the Education Committee, APFCB. Discussion on this topic by APFCB was postponed to the APFCB meeting in New Delhi in March 2002.

7. Future plans.

The Terms of Reference need to be revised. Recruitment of new members is required to fill vacancies on the Committee.

The Committee oversees the Master program in La Plata.

Working Group - Master in Clinical Laboratory Science (WG-MLS); La Plata Course

This Project was set up by the IFCC and the National University of La Plata (UNLP), La Plata, Argentina to develop a two year Course leading to the degree of Master in Clinical Laboratory Sciences at National University of La Plata (UNLP), La Plata, Argentina.

The key contributors are Nilda Fink as Program Director at UNLP; and Lynn Allen from C-ECD who provides IFCC support.

Status:

The first year and half of the second year of the Masters Program have been completed. The visits of the four Visiting Professors, in Genetics (Nov00), Hematology (Jun01), Tumor Markers (Nov01) and Laboratory Management (Nov01) have been completed. Reports have been received from the Visiting Professors for 2 visits, and are pending for the Nov01 visits. Student Visits to overseas laboratories for 2 months between July and December 2000 are being planned; 2 of the 3 sites have been arranged (McMaster University, University of Toronto), and the third is pending.

Next Steps are:

- Development of a Certificate recognizing the participation of the Visiting Professors, the students on Student Visits and the host laboratories for the Student Visits. Development underway.
- Handbook on La Plata, to serve as a model for Masters Programs in other parts of the world is being written.
- Since this course is running well, plans are being made to commence a second cycle of the La Plata Program (2002-2004). It is the intention that participation from the South American region will be sought.

Visiting Lecturers Program

The Mission of the VLP is to promote and share knowledge and skills in clinical chemistry with all National Societies of IFCC. The key objectives are to support international exchange of lecturers and contribute to the creation of educational networks and partnerships which would bring together activities of different IFCC regions and between National Societies

Under the chairmanship of Mary Burritt (US) three new forms have been made available on the updated Web Site. One with which the member societies can apply for a visiting lecturer; this has made the application process very easy.

The two others serve as evaluation forms for the hosting society and the lecturer. In this way it was hoped to obtain as much information as possible to further improve this essential program.

There have been two approved VLPs this year.

- Camillo Fernandez (SP)- Visited Uruguay, Argentina, and Venezuela in September
- Rita Horvath (HU)– was planned to lecture at the Syria National Society Congress. Due to the terrorist attack in US, this visit was cancelled.

EMD realized that the challenge now appears to be the identification of National Societies desiring VLPs.

Special Projects/Courses

Course in Flowcytometry: A Steering Committee under guidance of Gregor Rothe (DE) is organizing a yearly symposium on and a course in Flowcytometry, with the support of Beckman Coulter. In 2001 this course at the University of Mainz was brought under the auspices of the EMD. In March the symposium under IFCC responsibility as part of the Beckman Coulter Course took place.

A Course Handbook (German/English) will be published in co-operation with the IFCC Communication and Publications Division (CPD). At the IFCC Office e-commerce possibilities for registration will be initiated.

Scientific Division (SD)

During 2001, the following members served on the SD Executive Committee : Jean-Claude Forest (Canada) (Chair); John Ratcliffe (UK) (Vice-Chair); Thijssen (Netherlands) Jos H. (Secretary): Yoshihisa Itoh (liaison of Kyoto 2002, Japan); Thomas Moyer (USA); Rudolf Tauber (Germany); Rolf Hinzmann (Germany) (Corporate Representative). Two meetings were held, in Dubrovnick and in Milan. Heinz Schimmel attended the two meetings as observer from IRMM.

Relationship with International Organisations

Collaboration with International Organisations devoted to laboratory medicine has continued to grow during 2001, becoming a major endeavour of the Scientific Division. This is exemplified by the establishment of a Joint Committee on Traceability in Laboratory Medicine (JCTLM). The aim of the Joint Committee is to support worldwide traceability, comparability and equivalence of measurement results in laboratory medicine (see below).

Institute for Reference Material and Measurement (IRMM)

Several projects of Committees and Working Groups are now conducted in close collaboration with IRMM. For example, a new batch of material for total plasma proteins is being prepared by IRMM to become an IRMM/IFCC Reference Material and C-PP will coordinate tests on homogeneity, stability and assignment of values by the biuret method, aminoacid analysis and by refractometry. The Chair of C-MBT collaborates with IRMM on an EU Project on « Genetic Disorders » and the preparation of reference material for PCR analysis of Factor V R-506Q mutation (Factor V Leiden). Conjoint involvement of both organisations has lead to the establishment of primary reference procedures for the measurement of catalytic activities of enzymes at 37°C through the Committee on Reference System of Enzymes (C-RSE). The Committee on Standardisation of Markers of Cardiac Damage (C-SMCD) is currently involved with IRMM on the preparation of reference material for myoglobin . IRMM is also coordinating two other important projects ; the commercialization of excess materials from the purified HCG fractions prepared for reference materials (WG-HCG), and certification of primary and secondary reference material for HbA₁C (WG-HbA1C).

National Committee for Clinical Laboratory Standards (NCCLS)

Several joint projects with NCCLS involving SD-Committees and Working Groups are presently underway or considered : clinical utility of bone markers, homocysteine standardisation, thyroid function tests, monitoring of immunosuppressive drugs.

A conjoint document titled : *« Point-of-Care Connectivity : Approved Standard (POCT1) »* has been published by NCCLS acknowledging the participation and endorsement of the IFCC as well as of CIC.

National Institute of Biological Standards and Control (NIBSC)

Collaboration between NIBSC and IFCC through WG-HCG has lead to the production of six new candidate HCG-related preparations that were submitted and accepted by WHO in November 2001 as international standards with assigned values in molar units.

International Association for Therapeutic Drug Monitoring and Clinical Toxicology (IATDMCT)

A Joint Working Group on Laboratory Practice Guidelines on Monitoring Immunosuppressive Drugs is actively involved in the preparation of several monographs.

International Society of Thrombosis and Haemostasis (ISTH)

The Joint Committee on Standardisation of Coagulation Tests (C-SCT) has produced a position paper titled : « Approaches to the Development of a Reference System for Future Standardisation of Laboratory Tests for Haemostasis » that has been accepted by both organisations and will be published in *Thrombosis and Haemostasis* as well as in a Clinical Chemistry oriented Journal. Conjoint activity is currently being pursued.

European Commission

The project : « In Vitro Diagnostic Procedures in Diagnosis and Monitoring of Thyroid Disease » has been funded by the European Commission. IFCC is one of the seven principal contractors and was one of the initiators of the project. Through a newly created Working Group, IFCC will play a significant role in conducting the project.

As mentioned above, through C-MBT, IFCC is involved in a European Commission initiative related to genetic tests for rare diseases.

National Institute of Standards and Technology (NIST)

IFCC-SD is pursuing its collaboration with NIST through the initiative to establish a Joint Committee on Traceability in Laboratory Medicine (JCTLM).

Conductivity Industry Consortium (CIC)

IFCC is an affiliated member of the Consortium and SD has participated actively in the preparation of the document (POCT1, see above under NCCLS).

WHO

The availability of the first international standard for total PSA (Ref 96/670, mixture of PSA-ACT complex and f-PSA: 90:10) and the first international standard for free PSA (96/668), contributed by a previous Working Group in collaboration with NIBSC, had a marked impact on removing inter-assay variations in the measurement of PSA in blood (Ward et al, Ann Clin Biochem 2001;38:633-51). The collaboration has continued this year by submission by NIBSC and WG-HCG, of the six preparations to the Expert Committee on Biological Standardisation of WHO. The preparations were accepted as international standards with values expressed in molar terms. Data will be provided to establish conversion factors to International Units.

Joint Committee on Traceability in Laboratory Medicine (JCTLM)

Scientific Division has continued its involvement in the global initiative to create a Joint Committee on Traceability in Laboratory Medicine (JCTLM). Two representatives (Chair and Secretary), with the President of IFCC, have participated in three meetings with representatives from «Bureau international des poids et mesures (BIPM) », CIPM, IRMM, NIST. NML and supra-national manufacturer organisations (EDMA, AdvaMed) to develop the concept of traceability in laboratory medicine and its application through directives, such as the European IVD Directive (98/79/EC) which takes effect in 2003. A workshop, bringing together professional organisations, metrology institutes, IVD industries, international laboratory accreditation bodies, reference material producers, to develop a common pragmatic approach to implement such directives, will take place in Paris in June 2002. The Chair of SD is co-responsible for the preparation of the workshop program.

International and Regional Congresses

During the 14th European Congress of Clinical Laboratory Chemistry and Medicine (EUROMEDLAB, Prague 2001), SD was responsible for a symposium in two parts entitled : « Global Aspects of Regulation for in vitro Diagnostics ». Both parts of the symposium were attended by more than 250 people. Due to the September 2001 events, the Asian Pacific Congress in New Delhi was cancelled and with it the lecture on IFCC standardisation activities.

SD is represented on the Scientific Advisory Board of the XVIII Congress in Kyoto 2002. SD has organised a symposium (SS-4) titled : «*Standardisation in Clinical Chemistry and Laboratory Medicine* » summarizing the activities of the Division in this area. Also, a number of Committees and Working Groups will be responsible for, or will participate in, other activities of the Scientific Program.

Activities of Committees and Working Groups

Nomenclature, Properties and Units (C-NPU)

Several projects were prepared in close collaboration with IUPAC, including new ones on *« Properties in Chemical Sciences », « Requests in Clinical Laboratories »,* and *« Concept and Traceability of Measurements »,* development of communication standards, such as HL-7 and the LOINC, is under discussion. Work was undertaken to locate the IFCC/IUPAC code system (« elephant » database) on the IFCC web site. A

member of the Committee continues to represent IFCC at the Sub-Committee on Vocabulary in Metrology (VIM) and Guides to Expression of Uncertainty of Measurement in Metrology (GUMM) of the Joint Committee on Guidelines and Metrology (JCGM) of the International Organisation for Standardisation (ISO).

Molecular Biology Techniques in Clinical Chemistry (C-MBT)

Since the European Commission is now funding preparation of reference material for Factor V Leiden, the mandate of the Committee has been changed and a new proposal has been accepted to work on *« Preparation of a Certified Reference Material for PCR Analysis : Plasmid DNA Analysis of the Prothrombin G20210A Mutation ».* The project will be carried out in collaboration with IRMM. The Chair of the Committee commenced a second term in January 2002.

Plasma Proteins (C-PP)

The Committee prepared a series of papers covering all aspects of the work accomplished over the last few years for publication as a separate issue of CCLM (see Publications). As mentioned above, the C is working closely in collaboration with IRMM to develop a new standard for total protein. The project on determining the value for soluble transferrin receptor in CRM470 is underway.

Standardisation of Markers of Cardiac Damage (C-SMCD)

This Committee pursued three main projects : *Myoglobin* : A reference material was chosen from five candidates and a reference method based on electron spray MS selected. A new batch of the selected material is being prepared by IRMM. The project in cooperation with AACC for *Troponin I Standardisation* continues. Possible reference materials have been identified and are currently being evaluated.

Evaluation of Imprecision of Troponin Assay: A series of eight serum pools, were distributed for evaluation of imprecision around the decision level for myocardial infarction. Manufacturers and members of the Committee are participating.

The Committee published four papers related to these activities during the year (see publications)

Standardisation of Coagulation Tests (C-SCT)

Further to the acceptance of their position paper by ISTHM and IFCC, this C is working on a project proposal to establish a reference method for kinetic measurement of antithrombin III, sensitive to antithrombin as well as to conventional heparin.

Reference System of Enzymes (C-RSE)

This Committee, previously named « Committee on Calibrators in Clinical Enzymology», worked in close collaboration with IRMM on the preparation of a series of documents titled : « IFCC Primary Reference Procedures for the Measurement of Catalytic Activity Concentration of Enzymes at $37^{\circ}C$: Parts 1 to 6 ». These documents concern creatine kinase, lactate dehvdrogenase, alanine aminotransferase, aspartate aminotransferase and gamma-glutamate transferase. The document was accepted by SD, approved by EB, and a mail ballot sent to National Representatives. The Committee established a Network of Reference has Laboratories based on the ISO-CEN System. The list of the Network of Reference Laboratories, including names of persons responsible, is being prepared. New projects on amylase, alkaline phosphatase and lipase are underway.

Selective Electrodes and Point-of-Care Testing (WG-SEPOCT)

The name has been expanded to « Working Group on Selective Electrodes and Point-of-Care Testing ». to reflect its increasing involvement in point-of-care testing. Members of the Working Group are involved in organizing a Joint Meeting (AACC, JSCC, CIC, IFCC) in September 2002 in Monterey, USA, on « *Critical Care and Point-of-Care Testing* ». The Working Group has been involved in various projects (see Publications) :

- 1. Guidelines for the measurement of the substrate concentation of serum ionized magnesium by ion-selective electrodes in undiluted serum, plasma or whole blood.
- 2. Recommendation for measurement of a convention for reporting ionized chloride by ion-selective electrodes in undiluted serum, plasma or whole blood.
- 3. Recommendation on reporting results for blood glucose.
- 4. Revision of the pH document taking into account new buffers for calibration.
- 5. Reference material for magnesium.

Reference Methods for Apolipoproteins (WG-MA)

The international reference reagent for ApoB SP3-07 is now depleted. Approval for the preparation of a replacement has been granted. A new 2000 vials of a human serum preparation to be named SP3-08 is considered as the candidate Second International Apo B Reference Reagent. The SP3-08 apo human serum pool will be prepared according to the NCCLS C37-A guidelines.

Standardisation of Human Chorionic Gonadotropin (WG-SHCG)

As described above, the six preparations were submitted to WHO-ECBS for the November meeting. The preparations were accepted as reference reagents for immuno procedures with assigned values in molar terms. This completes a major phase of the work of this Working Group and represents a very significant step forward in the standardisation of the measurement of HCG in biological fluids. The excess materials from the purified preparations will be looked after by IRMM in collaboration with IFCC and various options are currently being studied to make these preparations available for distribution.

Three manuscripts related to this project are being prepared, focusing respectively on the preparation, evaluation and application of the reference materials with publication expected in 2002. Educational activities to encourage better understanding of the clinically relevant forms of HCG related molecules and interpretation of HCG results, will be undertaken.

Standardisation of LP(a) (WG-LP(a))

The document of the WG on the «*Preparation of a Secondary Reference Reagent for Lipoprotein* (a) » has been accepted and the procedure will be submitted to WHO for recognition.

Standardisation of HbA₁C/Glycohemoglobin (WG-HbA₁C)

The WG prepared a document titled : « *IFCC Reference Methods for Measurement of HbA*₁*C in Human Blood* ». After approval by the Scientific Division, the document was voted upon by the National Representatives. The manuscript is published in the January 2002 Issue of CCLM. A reference range study was performed using the new IFCC reference method giving results somewhat lower than previous recommended decision targets.

Representatives of the Working Group were invited by the European Association for the Study of Diabetes (EASD) to participate in a meeting in Dusseldorf, January 17, 2002, in order to present the new IFCC reference system and to discuss the impact of its introduction in clinical practice with representatives of EASD, the International Diabetes Federation (IDF), and the American Diabetes Federation (ADF).

Nanotechnology (WG-NT)

The WG has undertaken a comprehensive review of microtechnology and nanotechnology, exploring the current status of this emerging technology for assessing impact on the future of clinical laboratory medicine. A first part consisting of a database on microarray chips, containing over 600 references, was published in Clinical Chemistry. Work is underway to compile further information on microchips, bioelectronic chips, and nanotechnology, and the information will be published as a printed document and will also be available on an electronic form as database via the internet. So far, more than 3000 references have been tabulated

Standardisation of Osteocalcin Measurements (WG-SOM)

A collaboration was established with NCCLS through the Sub-Committee on Biochemical Markers of Bone Disease. This will develop guidelines for use of biochemical markers of bone turnover in bone disease. The WG is developing a proposal on osteocalcin standardisation measurements in collaboration with IRMM.

Intracellular and Cell-Surface Markers (WG-ICSM)

This newly-formed Working Group is currently establishing its intervention program.

Standardisation of Total Plasma Homocysteine Measurements (WG-SHM)

A first meeting was held in Sorrento (Italy), June 21, and another meeting was scheduled at the AACC meeting in Chicago. With broad representation of academic and industrial experts, the membership and direction of the WG has been agreed.

Standardisation of Thyroid Function Test (WG-STFT)

Following funding of the project by the European Commission, SD has established a Working Group with experts already involved in the development of « In Vitro Diagnostic Procedures in Diagnosis and Monitoring of Thyroid Disease ». The Working Group will work on aspects related to the funded project.

Project proposals

Five project proposals have been received and dealt with by the Scientific Division during the year.

IFCC Publications, 2001

The following publications appeared in 2001 as a result of IFCC projects. A number of other papers are in progress and may be available through the IFCC Web Site.

Allen LC, Dominiczak MH, Pulkki K, Pazzagli M: Clinical Case Material for Teaching Clinical Chemistry and Laboratory Medicine. Clin Chem Lab Med 2001;39:875–889.

Apple FS, Murakami M, Panteghini M, Christenson RH, Dati F, Mair J, Wu AH. International survey on the use of cardiac markers. Clin Chem 2001;47:587-588.

Apple FS, Wu AHB. Myocardial infarction redefined: role of cardiac troponin testing. Clin Chem 2001;47:377-9.

Burnett RW, D'Orazio P, Fogh-Andersen N, Kuwa K, Kulpmann WR, Larsson L, Lewenstam A, Maas AH, Mager G, Spichiger-Keller U: IFCC recommendation on reporting results for blood glucose. Clin Chim Acta 2001;307:205-209.

Dybkaer R. Unit Katal for Catalytic Activity. Pure Appl Chem 2001;73:927-31.

Henny J, Petit-Clerc C, Fuentes-Arderiu X, Petersen PH, Queraltó JM, Schiele F, Siest G: Need for Revisiting the Concept of Reference Values. Clin Chem Lab Med 2000; 38:589–595.

Kallner A, Müller MM, Hölzel W, Shoenfeld Y: Biochemical Markers for Autoimmune Diseases -Current Status and Future Trends. 8th Bergmeyer Conference - IFCC-Roche Diagnostics Master Discussion. Scand J Clin Lab Invest 2001;61, Suppl 235: 1-98.

Kricka LJ, Fortina P: Microarray technology and

applications: an all-language literature survey including books and patents. Clin Chem. 2001;47:1479-1482.

Kricka LJ: Microchips, microarrays, biochips and nanochips: personal laboratories for the 21st century. Clin Chim Acta. 2001 May;307:219-223.

Panteghini M. Recent approaches to the standardisation of cardiac markers. Scand J Clin Lab Invest 2001;61:95-102.

Panteghini M. Recent approaches in standardisation of cardiac markers. Clin Chim Acta 2001;311:19-25.

Panteghini M. Cardiac marker testing following surgery [Letter]. Ann Clin Biochem 2001; 38:287-8.

Panteghini M. Update on cardiac troponin standardisation [Brief report]. Biochim Clin 2001; 25:275-6.

Panteghini M, Ceriotti F, Schumann G, Siekmann L. Establishing a reference system in clinical enzymology. Clin Chem Lab Med 2001; 39:795–800.

Panteghini M, Gerhardt W, Apple FS, Dati F, Ravkilde J, Wu AH. Quality specifications for cardiac troponin assays. Clin Chem Lab Med 2001;39:175-179.

Proceedings of the 2000 Arnold O. Beckman/IFCC European Conference Conference, Paris, France October 12–13, 2000. Frontiers in Molecular Basis of Diseases: Cell Biology of Neuronal Dysfunction. Clin Chem Lab Med 2001; 39:293-367.

The IFCC International Directory of Laboratories for the Biochemical Diagnosis of Porphyria. On IFCC Website.

IFCC Reference Measurement Procedure for Substance Concentration Determination of Total Carbon Dioxide in Blood, Plasma or Serum. International Federation of Clinical Chemistry and Laboratory Medicine. Working Group Selective Electrodes. Clin Chem Lab Med. 2001;39:283-8.

Whicher JT, Johnson AM. The Present State of Protein Analysis and Interpretation. CCLM 2001;39:1017-1018

The Clinical Aspects of Plasma Proteins

Carlson J. From Paper Electrophoresis to Computersupported Interpretation of Capillary Electrophoresis - Clinical Plasma Protein Analysis in Malmö, Sweden. CCLM 2001;39:1020-1024

Ichihara K, Sato K. Evidence-Based Laboratory Interpretation System Built on a Large Collection of Case Records with Well-Defined Diagnoses. CCLM 2001;39:1035-1044

Merlini G, Bellotti V, Andreola A, Palladini G, Obici L, Casarini S, Perfetti V. Protein Aggregation. CCLM 2001;39:1065-1075

Merlini G, Marciano S, Gasparro C, Zorzoli I, Bosoni, T, Moratti R. The Pavia Approach to Clinical Protein Analysis. CCLM 2001;39:1025-1028

Ritchie RF. How the Foundation for Blood Research (FBR) Has Managed Serum Protein Testing for New England Clinicians. CCLM 2001;39:1029-1034

Ritchie RF. A Knowledge-Based System to Aid with the Clinical Interpretation of Complex Serum Protein Data. CCLM 2001;39:1045-1053

Whicher JT, Rifai N, Biasucci LM. Markers of the Acute Phase Response in Cardiovascular Disease: An Update. CCLM 2001;39:1054-1064

Analytical Aspects and Development of CRM 470

Blirup-Jensen S. Protein Standardisation I: Protein Purification. Procedure for the Purification of Human Prealbumin, Orosomucoid and Transferrin as Primary Protein Preparations. CCLM 2001;39:1076-1089

Blirup-Jensen S. Protein Standardisation II: Dry Mass Determination. Procedure for the Determination of the Dry Mass of a Pure Protein Preparation. CCLM 2001;39:1090-1097

Blirup-Jensen S. Protein Standardisation III: Method Optimization. Basic Principles for Quantitative Determination of Human Serum Proteins on Automated Instruments Based on Turbidimetry or Nephelometry. CCLM 2001;39:1098-1109

Blirup-Jensen S, Johnson AM, Larsen M. Protein Standardisation IV: Value Transfer. Procedure for the Assignment of Serum Protein Values from a Reference Preparation to a Target Material. CCLM 2001;39:1110-1122

Dati F, Johnson AM, Whicher JT. The Existing Interim Consensus Reference Ranges and the Future Approach. CCLM 2001;39:1134-1136

Itoh, Y, Ichihara, K. Standardisation of Immunoassay for CRM-Related Proteins in Japan: From Evaluating CRM 470 to Setting Reference Intervals. CCLM 2001;39:1154-1161

Johnson AM, Whicher JT. Effect of Certified Reference Material 470 (CRM 470) on National Quality Assurance Programs for Serum Proteins in Europe. CCLM 2001;39:1123-1128

Johnson AM, Ledue, TB. Commutability of Serum Protein Values: Persisting Bias among Manufacturers Using Values Assigned from the Certified Reference Material 470 (CRM 470) in the United States. CCLM 2001;39:1129-1133

Palomaki, GE, Neveux, LM. Using Multiples of the Median to Normalize Serum Protein Measurements CCLM 2001;39:1137-1145

Peterson, PH, Whicher JT, Johnson AM, Itoh Y, Carlström, AB. on behalf of the International Federation of Clinical Chemistry and Laboratory Medicine Committee on Plasma Proteins ; Strategy for Determining Racial and Environmental Similarities and Differences for Plasma Proteins. CCLM 2001;39:1146-1153

IFCC CPD publications

Gouget B, Barclay J. Telebiology and the language of the on line web. Clin Chem Lab Med 2001;39 (special suppl.): 104

Gouget B., Otter M. The role of laboratory Medicine in the evolution of healthcare Information system. Annals of Lab. Scientific News by the Syrian Clinical. Association of Clinical Chemistry 2001; 6:15-16.

Gouget B. Pervasive and persuasive... LabMedica Int. 2001; 18(3): 4 Gouget B. Ethos and Ethics in genetic diagnosis *EJIFCC*. 2001;13(1): http://www.ifcc.org/ejifcc/vol13n°1/1301200101.htm

Gouget B. On your marks- GO! Clin Chem Lab Med 2001; 39(8): 772 LabMedica Int. 2001; 18(4): 6

Compiled by Renze Bais Secretary, IFCC Executive Board Gouget B. In vitro, in silico, in extenso. LabMedica Int. 2001; 18(5): 4

Gouget B. Global standardisation is an achievable goal. LabMedica Int. 2001; 18(6): 4

Sierra-Amor R.I. Assets and obstacles in telebiology training. Clin Chem Lab Med 2001; 39 (special suppl.): 104

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