

# ACB News

The Association of Clinical Biochemists • Issue 429 • 20th January 1999



**College  
and IBMS  
Merger  
Proposals**

**MDA Incident  
Form to  
Photocopy**

**Project  
EVETSIN  
Outcome**

**Evidence  
Based  
Clinical  
Chemistry**



## About ACB News

The monthly magazine  
for Clinical Science

The Editor is responsible for the final content. Views expressed are not necessarily those of the ACB.

### Editor

Dr Jonathan Berg  
Department of Clinical Biochemistry  
Sandwell District General Hospital  
West Bromwich, West Midlands B71 4HJ  
Tel: 0973-379050/0121-607-3261  
Fax: 0121-765-4224  
email: JonathanBerg@compuserve.com

### Associate Editor

Dr Richard Spooner  
Biochemistry Department  
Gartnavel General Hospital  
Glasgow G12 0YN  
Tel: 0141-211-3470/3353  
Fax: 0141-211-3455

### Situations Vacant Editor

Dr Simon Olpin  
Neonatal Screening Laboratory  
Pathology Block, Room C8  
Sheffield Children's Hospital  
Western Bank, Sheffield S10 2TH  
Tel: 0114-271-7267

### Focus Handbook Editor

Dr Sandra Rainbow  
Norfolk and Norwich Hospital

### Display Advertising & Inserts

PRC Associates  
The Annexe, Fitznells Manor  
Chessington Road, Ewell Village  
Surrey KT17 1TF  
Tel: 0181-786-7376  
Fax: 0181-786-7262

### ACB Administrative Office

Association of Clinical Biochemists  
2 Carlton House Terrace  
London SW1Y 5AF  
Tel: 0171-930-3333  
Fax: 0171-930-3553

### ACB Chairman

Dr Ian Barnes  
Department of Chemical Pathology  
Old Medical School  
University of Leeds, Leeds LS2 9JT  
Tel: 0113-233-5679  
Fax: 0113-233-5672

### ACB Secretary

Dr Mike Thomas  
Department of Chemical Pathology  
The Royal Free Hospital  
Pond Street  
London NW3 2QG  
Tel: 0171-794-0500 Ext. 3464  
Fax: 0171-794-9537

### ACB Home Page

<http://www.acb.org.uk>

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# ACB News

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The proof reader for this issue was Dr Rosanna Penn, Birmingham.

Front cover:

Brighton is the venue of the next ACB training course. Details in this issue.



## The ACB National Scientific Meeting and Exhibition

17 - 21 May 1999

Tel: 01223-516103

Fax: 01223-500978 for details

# Working Together . . . or Divide and Rule?

**M**any readers will be aware that the Royal College of Pathologists and the Institute of Biomedical Science jointly released a discussion document just before Christmas outlining merger proposals. It is not clear what prompted the discussions leading to the proposals. For the College it may be the wish to play an extended role in modern NHS laboratories. For the IBMS there is the attraction that some of their membership will be eligible to be examined for MRCPATH, though against this such staff will lose their distinct professional organisation.

These proposals would affect far more than just IBMS and College members if they were implemented. All the other professional organisations in Pathology, and their members, would be affected by such radical change. So far a very small number of individuals have been involved in formulating these proposals, working in an environment of strict confidentiality. It is quite natural that many outside this group feel concerned and uneasy at the way these discussions have been conducted. The situation has been difficult for the ACB Chairman, who I know has been working hard to try and represent us under difficult circumstances, whereby he has not been able to properly discuss developments with the ACB Council or even close colleagues on the ACB Executive.

## A Single Voice for Pathology

We do need to separate any business consideration in the College and IBMS discussions from that of professional representation. Fundamental to the professional side of the IBMS/College proposal is the concept that a new expanded Royal College of Pathology would form the 'single voice' to meet with Government and the Department of Health and to promote pathology to the outside world. However, this will only happen if the other professional bodies also support the concept and it is regrettable that they have not so far been consulted. Since arriving in a pathology department in 1978 I have felt that the ACB has been at the forefront of

many of the positive developments that have taken place in our working environment. The exclusion of the ACB from the current discussions is ironic since we have been a relatively progressive and enlightened organisation, often willing to look at change for reasons other than narrow self-interest, while other organisations have been much less so inclined.

## Inclusive, Not Exclusive Ways Forward

Unless all professional organisations, and their members, are actively involved in the next phase of the debate the current proposals may achieve exactly the opposite outcome to that desired. I have been a strong advocate of pathology professions uniting to have a common voice, but this should be done in an inclusive and not an exclusive way. Collaboration between professional bodies may be more effective than preemptive acquisition and merger. One could propose a number of alternative strategies whereby organisations could both maintain their identity and contribute to a common voice for pathology.

The present proposals risk alienating some of the most forward thinking and hard-working scientific and medical minds in NHS Pathology. However, I hope and believe that what is potentially a very divisive stance will quickly lead to sensible proposals that can properly involve everyone who will be affected. If this is not the case then there will be discord not harmony and a great opportunity will have been missed.

Although it was not made that explicit, the document is consultative and has been sent to members of the College and IBMS for comment and feedback. I would encourage readers to engage in debate locally before responding to the organisations concerned. The ACB Chairman will also welcome your views and ACB News looks forward to letters on this subject. ■

*Jonathan Berg FRC Path.*

## Carbon Monoxide Measurement

A recent Department of Health letter from the Chief Medical Officer and the Chief Nursing Officer highlighted the problems of death from carbon monoxide. Carbon monoxide causes the death of 50 people each year and is thought to seriously injure another 200. Carbon monoxide poisoning is almost certainly under-diagnosed, with children, pregnant women and those with cardiovascular disease all being at increased risk.

The letter, 'Carbon Monoxide: The Forgotten Killer' (PL/CMO/98/5, PL/CNO/98/8) has been widely circulated within the NHS. If you have not seen a copy then it is available on the internet at:

<http://www.open.gov.uk/doh/cmoh/cmoh/htm> ■

## The New Grade A Training Record

The revised Grade A training record is now available free of charge to all Grade A trainee clinical biochemists. It was revised under the auspices of the ACB Education Committee by Ruth Draper, Ed Lamb and Paul Newland, to whom the committee's grateful thanks are due. To ensure its widest possible distribution to Grade A trainees, the Education Committee invites those who require it to contact their ACB Regional Tutor. ■

## Fournier Award

The winner of the 1998 Fournier Lipidology Award is Miss Jane McEneny of the Department of Clinical Biochemistry at Queen's University, Belfast. The title of her winning paper was 'Assessment of VLDL subfractions, composition and susceptibility to oxidation in patients with non-insulin-dependent diabetes mellitus'.

The award presentation was made at the Royal Society of Medicine during the recent British Hyperlipidaemia Association healthcare section meeting.

Applications for the 1999 awards are now available from Denise Read at:

Fournier Pharmaceuticals Ltd  
22-23 Progress Business Centre  
Whittle Parkway  
Slough SL1 6DG  
Tel: 01753 740400  
Fax: 01753 740444

The closing date for entries is 12th March 1999. ■

## Internet Patent Search Service Launched

A system to provide access via the Internet to distributed databases of patent specifications published by the patent offices of Europe, has been launched on the Patent Office web site. Called Esp@ceNet, the system makes it possible for anyone with Internet access to search patent specifications published in the last two years. This free service provides a common interface to the published patent application databases of the UK Patent Office, the European Patent Office (EPO) and other European national patent offices, as well as access to the PCT database of published patent applications.

Esp@ceNet is of immediate and practical use to those wishing to get an early idea of the patentability of a product or process, or the state of the art of a technological field. Esp@ceNet can also be used to identify inventors or the most actively inventive companies in a given field or to monitor the activities of known competitors.

In Esp@ceNet, patents can be searched by publication number, application number, priority number, publication date, applicant, inventor, IPC classification and title. Wildcards can be used to identify groups of patents. When a patent is identified, the user can pull up its bibliographic data, and images of the full specification, including the description of the invention, the patent claims and the drawings.

Welcoming Esp@ceNet, Patent Office head of marketing Brian Caswell said: "Esp@ceNet is the result of successful collaboration between the UK Patent Office, the EPO and other European patent offices. It forms an important part of the Patent Office's programme to bring patents to the people by cutting costs and improving access to the system".

Published patents contain a vast store of publicly available technical and commercial information. Companies ignore this resource at their risk as 80% of the technical information published in patent specifications is not to be found anywhere else. The European Commission has estimated that up to £20 billion is wasted in Europe on research which repeats work already carried out and described in published patent specifications.

Esp@ceNet can be found on the Patent Office's website at [www.patent.gov.uk](http://www.patent.gov.uk) ■

## Good News for Delegates and Visitors to the Focus 99 Exhibition

Delegates are going to find some tremendous advantages at the first Focus meeting to be held at the G-MEX Centre in Manchester. The space and geography of the venue affords a truly integrated meeting, where all the refreshments and lunches will be served in informal style from points located among the exhibition stands. The posters will be interspersed within the hall and the lecture theatres will be accessed directly from the exhibition.

Some companies at Focus 99 have booked larger stands than usual and will be displaying a wide range of

products, reflecting both the growing together of disciplines within Pathology and the continued merging of companies in the healthcare profession. Recognising the importance to delegates of keeping up-to-date on product developments, efforts have been made to ensure that even those planning to take in most of the science on offer, will also have time to spend in the exhibition during the long lunch breaks and at the end of each day. Laboratory professionals not planning to register for the meeting will find a visit to Manchester well worthwhile, just to take in the exhibition. ■

## Job Share Guide Launched

The Job Share Guide addresses many of the perceived disadvantages which worry employers and dispels the myth that job sharing costs employers money. The Job Share Guide combines questions and answers about job sharing, sample case studies, a job share checklist and model job share policy. The pack is primarily aimed at staff representatives, but will also provide sound, practical advice for anyone who wants to set up a job share arrangement.

Kamlesh Bahl, Chairwoman of the Equal Opportunities Commission said: 'It is important that we dispel the outworn prejudices which often surround the idea of job sharing. Flexible working practices make sound business sense. Employers who recruit job sharers get the benefit of 'two for one' in terms of a wider range of ideas, experience and skills. It is especially important that the NHS, as the biggest employer of women in Europe, and at a time of staff shortages, retains skilled, trained employees. This pack will be an invaluable resource for negotiators and a practical source of information for anyone who wants to make a success of job sharing.

Key issues the job share pack deals with include:

- What are the benefits of job sharing to employers?
- Will employing two people to do one job increase costs?
- Are people working less than part-time really committed to their jobs?

Copies of the guide should be available from your Human Resources department. ■

## Reporting Adverse Incidents Involving *In Vitro* Diagnostic Medical Devices

The Medical Devices Agency (MDA) has previously distributed a leaflet to raise awareness of the fact that *in vitro* diagnostic medical devices (IVDs) come under the remit of the MDA and to encourage reporting of adverse incidents involving IVDs. In order to make the reporting of adverse incidents easier, the MDA have developed (in association with MDA's IVD Advisory Committee) a dedicated form. A version of this has been reproduced in the centre of this ACB News. The MDA would be grateful if you would use this form and let us have your suggestions and/or comments concerning the form's layout, ease of use etc. The initial report should contain as much detail as possible, but it is not necessary to complete every section if this would delay the report.

This is the first time that the Medical Devices Agency has had a form dedicated to IVDs. Comments will be valuable in enabling the MDA to ensure that the form is as 'user friendly' as possible.

Should you require further information concerning the MDA and reporting adverse incidents, please contact the Adverse Incident Centre on 0171-972-8080.

Information on adverse incident reporting can be found on the MDA website at <http://www.medical-devices.gov.uk/aicrept.htm> ■

## Transport of Samples by Royal Mail

Royal Mail regulations for inland postage of infectious substances changed from 1st January 1999 to comply with IATA regulations (much inland post now goes by air), and require UN602 packaging (essentially specimen tube inside a tube inside a 'torpedo' inside a marked cardboard box; total cost £4-£5 + £1 postage). **All diagnostic specimens will be classified as infectious substances**, and the previous regulations for packaging pathological specimens no longer apply. The Royal Mail circular of mid-December to all doctors did not make this fully clear, but laboratories (and their customers!) need to be aware of the

regulations as ignoring them may lead to prosecution.

The good news is that neither individual registration of packages nor 48 hours' notice of shipment are required, and there is a 'transition period'. We understand that the regulations are unlikely to be enforced fully until April (with a request for extension submitted), which is fortunate as there seems to be a shortage of UN602 containers. At present all diagnostic specimens (including those for screening etc, which are less restricted under IATA rules) must be classified as infectious, though we understand that a committee is being formed to consider exemption requests.

What about EQA specimens? Most are tested to the same level as blood for transfusion, and these are properly classified as non-infectious biological products, which are not dangerous goods and therefore not restricted under UN/IATA rules. Unfortunately the present Royal Mail regulations also class these (including pregnancy test kits!) as 'infectious substances' and require UN602 packaging. UK NEQAS is preparing a case for exemption on behalf of all EQAs, with CPA support, to avoid this inappropriate wastage of scarce NHS resources.

- Thanks to David Bullock of the UK NEQAS Executive for this update. ■

## Congratulations George!

We are delighted to announce that Professor George Elder, ACB President, has been awarded the Commander of the Order of the British Empire (CBE) in the New Years Honours list ■



## ACB Travel Grants

Thinking of attending Focus 99 in Manchester or the XVI ICCG in Florence?

Found all the finance you need yet?

If not remember that the ACB Education Committee awards travel grants to attend scientific meetings.

Full details can be found on page 32 of the ACB Members' handbook.

Contact Mr Philip Hyde  
ACB Education  
Committee Secretary  
for application forms on  
Tel: 01205-364801 ext 3339  
Fax: 01205-356548

# ACB Training Course No. 4: Brighton

**Sunday 11th April to Friday 16th April 1999**

The next ACB training course will be held at the University of Sussex in Brighton. Lectures will be held on site. This course is primarily aimed at those intending to take the MRCPPath but the course is also registered for CME and will welcome everyone who wishes to update and refresh their current knowledge.

- **Porphyrrias**
- **Iron**
- **Haematology**
- **Genetics**
- **Clinical Cases**
- **Medical Informatics**
- **Management Topics**



*For further information please contact:*

*Dr Bernard Rocks or Elizabeth Hall on*

*Tel: 01273-696955 at the Royal Sussex County Hospital.*

*Application forms are available from the Association of Clinical Biochemists Office,  
2 Carlton House Terrace, London SW1Y 5AF. Tel: 0171-930-3333. Fax: 0171-930-3553*

# What has Project EVETSIN produced for Clinical Biochemists?

By Dr Joan Pearson, *Clinical Biochemist on EVETSIN Project Research*

**P**roject EVETSIN, which ended in June 1998, submitted its final report to the Department of Health in September 1998. The report concluded with fourteen recommendations on the training of MLSOs, MTOs and clinical scientists; these were backed up with specific evidence in 22 annexes to the report (four of these related to our profession: the survey report, two cases studies of regional training schemes and an examination of clinical liaison skills and how they are learned).

The Department of Health, after peer review of the report, asked the recently formed National Advisory Group for Scientists and Technicians (NAGST, which replaces ACCESS) to discuss the report and make recommendations; this process will have been completed by February 1999. The contents of the report will be circulated to various organisations, including employers, but at the time of writing, decisions have not been made about how and when this will be done. We will publish the response and recommendations by NAGST as soon as possible.

EVETSIN's thirteen recommendations which are applicable to our profession (one related solely to MTOs) are given below:

- Dedicated time should be allocated to training coordinators and trainers: and they should receive training for this role.
- Systems for internal assessment, prior to external verification, of competence of trainees should be more robust.
- Learning outcomes and training plans should be sufficiently clear and detailed to support self-directed learning and accompanied by a written statement of what trainees are entitled to receive.
- Quality assurance of training should be strengthened to ensure that items 1-3 are properly implemented, including monitoring of trainee support and the evaluation of trainee

experience.

- External examiners should monitor both the internal assessment and the quality control system and this function also needs to be properly funded.
- All professions should have a higher training scheme leading to recognised standards of competence which are consistent with job requirements for that career stage and enable personal training plans to be designed.
- The training needs of Grade B clinical scientists who missed out on either scheme-based Grade A training or higher training need to be investigated and addressed.
- Some trainee and supervisor time needs to be dedicated to achieving the intended learning outcomes.
- Certificates of competence should be introduced for extended roles and backed up by appropriate training.
- Recruitment and retention should feature in management training programmes.
- Pathways for transfer between professional groups should be further clarified.
- Training plans should be developed and regularly updated by Trusts and Education Consortia, and linked to strategic plans for developing pathology and other service employing scientists.
- Consideration to be given to how the work of professional associations in developing and updating education and training programmes, in maintaining robust assessment and quality assurance and in promoting continuing professional development, can be best sustained at the level now needed.

Anyone who would like to discuss the EVETSIN Report is welcome to contact Joan Pearson direct. ■

# Evidence-Based Clinical Biochemistry

Reported by Lisa Bailey, Kathryn MacKinnon and Catherine Wardle, Liverpool

**M**embers from two regions attended this first joint venture at the Moat House Hotel, Chester, to take part in a lively two-day meeting on the integration of evidence-based medicine (EBM) into routine clinical biochemistry practice. This report will focus on the topics that we and other members considered to be the highlights of the meeting.

## Collecting the Evidence

The meeting opened with a comprehensive overview of evidence-based clinical biochemistry from Mr Andy Bufton of the Evidence-Based Medicine Group. During his talk, he reviewed the origin of EBM and how we clinical scientists must play an important role in the continuing education of clinicians and GPs to ensure effective health care intervention and the correct use of laboratory results to influence clinical practice. At present, collecting sound evidence is a laborious task involving collection of data from journals and papers; however, only about 1% are scientifically sound as many studies show bias from poor trial design. In order to address this problem, Andy explained that we require better collection of evidence through prospective and retrospective audit, collection of information from large numbers of patients with a defined clinical problem and the use of randomised trials across hospitals. The importance of collecting data in 'real time' was stressed. Andy concluded by reminding us that in the future, purchasers of laboratory services will do so based on outcomes resulting from robust evidence rather than activity. These issues are currently being addressed by a Joint ACB/Industry working group and Equinox.

## Total and "Free" Thyroxine Debated

Dr Geoff Beckett from the Royal Infirmary, Edinburgh, gave a review of thyroid hormone testing strategies describing the evidence behind the use of several testing methods. First line TSH alone appears to be the method adopted by most District General Hospitals, whilst two analytes are normally measured by larger teaching hospitals. While the use of first line TSH alone has obvious cost implications, we must be confident that a single test can give accurate classification of all patients, as the diagnosis of hypopituitarism, thyroid hormone resistance and TSH secreting tumours would be missed if TSH alone was used as a first line investigation. Geoff recommended the use of third generation assays and posed the question that it may be time to reassess our reference ranges due to increased assay sensitivity and the previous inclusion of patients with probable non-thyroidal illness. The use of TSH and FT4 offers the best testing combination, allowing assessment of

*A Joint North West  
and Wales  
Regional Meeting  
held on  
14th-15th  
October 1998  
in Chester*



# MDA Adverse Incident Report

## Guidelines for Completing a Form

### What do you do if an adverse incident occurs in your laboratory?

All adverse incidents involving *in vitro* diagnostic medical devices (IVDs) should be reported to the Medical Devices Agency (MDA). The MDA can then investigate what has gone wrong and, by communicating information to other users, help prevent the problem occurring again. Unfortunately, many adverse incidents go unreported because staff in pathology laboratories are either unaware of MDA's role in investigating adverse incidents, or they are unsure of how to report such incidents.

In an attempt to encourage the reporting of adverse incidents MDA has launched a new reporting form specifically designed for use by laboratory professionals. The form has been carefully designed, with clear wording and a 'tick-box' format, to minimise effort and thus encourage people to report incidents.

To report an incident, or to obtain copies of the new form, please contact: MDA Adverse Incident Centre, Medical Devices Agency, Hannibal House Elephant and Castle, London SE1 6TQ. Tel: 0171-972-8080 or Fax: 0171-972-8109. Further information on reporting adverse incidents is also available on MDA's web site at: [http://www.medical-devices.gov.uk.aic\\_rept.htm](http://www.medical-devices.gov.uk.aic_rept.htm)

### What is an adverse incident?

An adverse incident may be defined as "An incident which produces, or has the potential to produce, unwanted effects involving the safety of patients, users and others. Unwanted effects may include misdiagnosis or inappropriate treatment".

### What is an IVD?

Broadly, a device is an *in vitro* diagnostic medical device (IVD) when the manufacturer has intended its use for the *in vitro* diagnostic examination of specimens derived from the human body. IVDs include: test kits, analyser systems, near patient testing devices and specimen receptacles.

### What is the MDA?

The Medical Devices Agency is an Executive Agency of the Department of Health. Its primary task is to safeguard public health by ensuring that medical devices, including the *in vitro* diagnostic medical devices (IVDs), meet appropriate standards of safety, quality and performance and comply with relevant Directives of the European Union.

The MDA relies on clinical laboratory professionals, other IVD users and IVD manufacturers to report adverse incidents. This produces an on-going post-market surveillance system for IVDs, which contributes to the quality of those devices, the results they produce and therefore patient care.

# MDA Adverse Incident Report

## Origin of Report

Hospital/Institution .....

Laboratory .....

Reporter .....

Position .....

Telephone number .....

Consultant-in-charge (if known) .....

Local reference number .....  
(if available)

**This report confirms a**    **telephone report**

## Device description (tick one only)

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> Clinical Chemistry | <input type="checkbox"/> Microbiology                 | <input type="checkbox"/> Self/Home Testing   |
| <input type="checkbox"/> Haematology        | <input type="checkbox"/> Cytopathology/Histopathology | <input type="checkbox"/> Genetic Testing     |
| <input type="checkbox"/> Immunology         | <input type="checkbox"/> Extra-Lab Testing            | <input type="checkbox"/> Specimen Receptacle |

## Product

- |  |   |  |
|--|---|--|
| <input type="checkbox"/> Test kit – Colorimetric | <input type="checkbox"/> Instrumentation/<br>Software | <input type="checkbox"/> Calibrators   |
| <input type="checkbox"/> Test kit – Immunoassay  | <input type="checkbox"/> QC materials                 | <input type="checkbox"/> Reagent       |
| <input type="checkbox"/> Test kit – Other        |   | <input type="checkbox"/> Reagent strip |

## Details of Device – Instrumentation

Product Name

Model

Manufacturer

Supplier

Serial No.       Approximate Age

Is there is CE-mark?    YES       NO

Further details can be given on additional sheets if necessary.

Please send completed form to: Medical Devices Agency, Adverse Incident Centre, Hannibal House, Elephant and Castle

# Report In Vitro Medical Devices

## Details of Device – Kits, Reagents and Specimen Receptacles

Brand Name

Analyte/Marker

Manufacturer

Supplier

Batch No.  Expiry Date

Is there is CE-mark? YES  NO

### Nature of defect/details of incident

Contact name for further details

Telephone number

### Action taken by staff/manufacturer/supplier

non-thyroidal illness and elimination of binding protein anomalies. These views were also apparent in a later session by Mr Jeff Seneviratne describing an audit of first-line TFTs. A lively debate followed both talks discussing the pros and cons of total T4 versus FT4. While NEQAS reports show more laboratories measure FT4 than total T4, analytical problems continue to plague the use of the former and also at present there is no defined reference method for FT4. It was evident from these presentations that we should be aware of the pitfalls of TFTs whichever strategy we adopt within our own laboratory.

## **FSH Sensitivity to Menopause**

Dr William Fraser (Royal Liverpool University Hospital) encouraged active audience participation with his overview of evidence from tests for the menopause and HRT. We were asked our views on biochemical testing for the menopause and assessment of adequacy of HRT at the start of the talk and again at the end to see if hearing 'the evidence' had altered our views. Bill explained that clinical symptoms often precede the menopause by 6-7 years, so using the onset of symptoms for diagnosis of the menopause can be problematic. The plethora of biochemical tests available also leads to some confusion in test selection (indicated by an initial show of hands). The problems are further compounded by fluctuating serum gonadotrophin levels for several years during the onset of the menopause. Evidence was provided showing measurement of FSH to be the most sensitive indicator of the menopause as levels increase progressively in women from around 40 years of age. Serum oestradiol was advocated for the determining the adequacy of HRT. However knowledge of assay specificity is important as synthetic oestradiol preparations are not measured in some assays. From a clinical perspective, while HRT offers positive benefits such as alleviation of vasomotor symptoms and protection from osteoporosis, the negative aspects were also mentioned, such as an increased risk of breast cancer with prolonged use.

## **Chiron Win for Rachel Still**

Following tea and a look at the exhibition stands provided by the companies supporting the meeting, we were treated to 7 high quality members papers competing for the Chiron Award. This was won by Miss Rachel Still from Swansea for her talk entitled 'Assays for plasma homocysteine and methylmalonic acid and their clinical application'. During her talk Miss Still described the metabolism of homocysteine and methylmalonic acid and the development of sensitive HPLC methods to allow their determination in plasma. The use of these assays for diagnosis and monitoring was illustrated by a case of methylmalonic aciduria.

A reception and dinner in the hotel provided a well earned drink and meal for speakers and participants alike and allowed informal discussion of the days proceedings. Following presentations to Dr Davies and Dr Nicol who were retiring from the Welsh Region, the evening went into full swing with dancing from 'Kiss the Pink' until the early hours.

## Troponin Yet Again

The following morning had a cardiac theme. Interestingly, the association between consumption of wine and cardiovascular disease was not mentioned; perhaps this had been covered in adequate detail by some member the previous evening? Dr Paul Collinson (Mayday Hospital, Croydon) started the session with an informed look at evidence-based biochemical testing in suspected acute coronary syndromes. Dr Collinson demonstrated how clinical effectiveness may be monitored by diagnostic efficiency, outcome measures and impact on patient management and illustrated this by the use of several cardiac markers and algorithms in the diagnosis of acute myocardial infarction (AMI). Despite measurement of Troponin (Tn) T and TnI being more expensive, evidence showed they are superior both diagnostically and prognostically compared to CK and have a direct impact on the length of hospital stay, thus an overall cost benefit. Dr Collinson concluded by stating that ECG should remain as the initial test for diagnosis of AMI and only patients with ST segment elevation respond to thrombolysis and the decision to thrombolysed should not be based on biochemical test results.

## Extraordinary Acronyms

Dr Sandeep Gupta (St George's Hospital, London) explored the fascinating link between chronic infection and atherosclerosis. Infection has already been implicated in several other diseases (e.g. peptic ulcers, Crohn's disease) and 50-60% of the prevalence of coronary heart disease (CHD) can not be explained by traditional risk factors such as smoking, hypertension and hyperlipidaemia. Evidence exists implicating *C. pneumoniae* in the pathogenesis of CHD, as 50% of atherosclerotic plaques contain this virus and many patients with CHD have persistently elevated IgG titres indicating the presence of chronic infection. Dr Gupta described the use of the antibiotic azithromycin in patients post-AMI leading to decreased IgG titres and a lower risk of subsequent events. However, he stressed that more work must be undertaken and further evidence must be collected before we can advise coronary care clinicians to commence antibiotics. Several studies with extraordinary acronyms (WIZARD, MARBLE, STANIMA and ACADEMIC) are now underway and may provide the evidence we require.

Continuing on the cardiac theme, Dr Ian McDowell (Cardiff) completed the morning's scientific programme with an update on homocysteine and CHD reminding us of the link between mild homocysteinaemia and vascular disease. Studies carried out in Cardiff showed homocysteine causes dysfunction of epithelial cells and disruption of the flow-mediated vasodilatation response. While increased homocysteine levels do respond to folic acid supplements, evidence is not yet available to show this reduces the risk of coronary events. Furthermore, there is still no good evidence indicating the routine measurement of homocysteine.

We are grateful to the NW Regional ACB for contributing towards our expenses which allowed us to attend such an informative meeting. We hope that this joint meeting will encourage more interaction and discussion between our regions especially as the take-home message appeared to be for us to share our experiences of evidence-based clinical biochemistry. ■

## Bio-Rad Announces Newborn Screening Distribution Agreement

Bio-Rad Laboratories has announced the signing of a distribution agreement with Quantase Ltd. Under the terms of the agreement, Bio-Rad will have exclusive worldwide rights to distribute the Quantase line of diagnostic tests for newborn screening. The current market for newborn screening testing is estimated to be more than \$50 million worldwide and is growing at the rate of approximately 10% a year.

Bio-Rad's Diagnostic Group supplies diagnostic testing equipment, reagents and newborn screening systems to the clinical diagnostics industry. Its products are used by the clinical laboratory to diagnose patient disorders and to monitor patient therapy efficiently.

This agreement expands an already broad range of newborn screening products and services offered to the clinical laboratory by Bio-Rad. In the United States, and in most developed nations around the world, babies are

required to have a blood test shortly after birth to screen for several serious diseases. The purpose of this screening is to protect children with these diseases before any symptoms arrive.

Bio-Rad will begin the distribution of Quantase's tests for phenylketonuria (phenylalanine), galactosaemia (TGAL), glucose-6-phosphate dehydrogenase deficiency (G-6-PD) and cystic fibrosis (immunoreactive trypsinogen) immediately.

Quantase is a Scottish biotechnology company specialising in the design and manufacture of neonatal diagnostics. As market leader in the two key product areas of PKU and galactosaemia, Quantase aims to become one of the world leaders in the diagnosis and follow-up of inherited metabolic disorders, by developing new market segments and introducing innovative products. ■

## DPC Play Host to their Immulite Users

DPC recently held a highly successful user group meeting for Immulite®, their continuous random access immunoassay analyser. Attended by over 100 Immulite users and guests, the meeting provided an ideal forum for exchanging ideas and user experience, as well as an opportunity to learn about the latest developments at first hand from DPC. The placement of DPC's one hundredth Immulite at Great Ormond Street Hospital gave cause for celebration at the meeting, and a commemorative plaque was presented to Mr Vijay Ramanadiao from the hospital.

The meeting was chaired by Mike Hallworth, Consultant Biochemist at the Royal Shrewsbury

Hospital, who presided over presentations by guest speakers. These included Dr Bill Fraser from the Royal Liverpool University Hospital, whose paper was entitled "Biochemical Markers of Bone Metabolism".

Presentations were also made by three UK NEQAS scheme organisers. Jonathan Middle from the University of Birmingham discussed Immulite's steroid performance; Colin Selby of Nottingham City Hospital gave two papers on SHBG, its clinical significance and its performance using the Immulite system. Cathy Sturgeon of the Clinical Biochemistry Department at Edinburgh's Royal Infirmary considered the question of improving comparability in tumour marker testing. ■



## Chiron Diagnostics ACS: Systems User Group Meeting

Reported by Ian Hanning, Biochemistry Department, Bronglais General Hospital, Aberystwyth

This meeting was held in the delightful surroundings of Keble College, Oxford and attended by 155 delegates. As for previous meetings, the chairmen were Alisdair McBain and Mike Wheeler.

The meeting commenced with an excellent Plenary Lecture given by Paul Collinson of the Mayday University Hospital, entitled 'Economic Aspects of Biochemical Cardiac Testing'. This was a very topical subject, with many members of the audience in the process of securing funding for cardiac troponin measurements. Paul has managed to introduce, what I consider to be, the ideal control group for his studies in the form of Royal Marines undergoing commando training. Despite elevation of CK to 1500 U/L troponin I (measured by the ACS:180) remained below 0.5  $\mu$ /L. For a group of 990 patients screened using Troponin I, 22 had acute MI and 22 unnecessary admissions were prevented, giving a bed cost saving of £99,470, for an additional reagent cost of £1,200. Obviously, flexibility with budgets within Trusts is required to enable laboratories to increase their expenditure in order to make these savings elsewhere. Thankfully, some Trusts

have already adopted such an approach and are enjoying both cost savings and improved diagnostic capabilities.

### Agreed Testing Protocols

The next lecture was the keynote address, given by Rick Jones of Leeds General Infirmary, entitled 'Mechanisms of Coping with Increasing Workloads'. As always, Rick gave an interesting and thought-provoking lecture and identified many areas where the appropriate and imaginative use of IT could help us to cope. This included the use of agreed testing protocols in defined clinical situations.

Following afternoon refreshments, there were six breakout sessions: ACS:Centaur, Haematinics, 75p v 95p, Neonatal TSH, ACS:180 SE and Down's Screening, which I attended. This was an ideal forum for laboratories using identical analytical techniques to compare data, including medians, detection rates etc and data from a pre-circulated questionnaire were summarised by the chairman, Colin Selby from the City Hospital, Nottingham.

This was a very enjoyable scientific meeting and a great source of information, which was facilitated by the open forum format of the meeting. ■





# Letters

## Readers speak out

### Attempts at Re-education Appear Fruitless

It is sad to learn from correspondence in December ACB News that Mr Sanderson is entering another phase of acute anxiety about the diagnosis of cystic fibrosis. It appears that he is either unwilling or unable to benefit from the help and advice offered to him several months ago. I fear that any further attempts to assist in his re-education through correspondence in these columns would be fruitless.

I am however quite certain that his professional colleagues still practising in Leeds have clear and effective strategies in place for the laboratory diagnosis of cystic fibrosis. Perhaps they might be kindly disposed to invite Mr Sanderson to visit them one day so that he can review current practice and data at first hand. Only then will there be a chance of dispelling his conviction that current practice is little better than determining whether or not the patient tastes salty.

**Anthony F. Heeley**

**Consultant Biochemist/Director**

Biochemical Genetic Diagnostic Unit

Peterborough Hospitals NHS Trust

Peterborough PE3 6DA

### More on Financial Risk of Meeting Organisation

I read with interest the letter from Katharine Hayden outlining her experiences with meetings promotion. I would like to comment on the last but one paragraph where she says that it might have been premature for us to cancel our recently planned meeting.

Obviously, there can be no hard and fast rules on whether or not to cancel a meeting, as it will depend on individual circumstances. In our case, the hotel selected was a very popular venue for conferences and meetings, and the crisis was precipitated by a request from another commercial organisation to

book the hotel at the same time as we intended to hold the meeting. As their booking was firm (as against our provisional one), the hotel offered to give us first refusal provided we confirmed our booking within two weeks.

We did indulge in many telephone calls to stimulate interest, and the Regional Committee agonised over whether or not to cancel for a considerable period of time. However, the final tally of 26 delegates registered by the deadline of 1st October, as against 100 rooms booked justified the decision to cancel, and saved us from a considerable financial embarrassment.

Of course, we could have stuck to our guns and indulged in some frantic marketeering, but the potential for financial loss was high and on advice we were informed that the level of risk was unacceptable.

I would endorse the statement made that it would be a very useful practice for members planning to attend a meeting to send in a registration form while awaiting approval from their Trusts, and that intending delegates book early.

Cancelling a meeting that has taken considerable time and effort to put together is frustrating, and has a negative effect on the organisers in that it is unlikely that they will wish to repeat the experience. Hopefully, there will not be much need for cancellations of future meetings, otherwise there would be considerably fewer meetings around in future.

**Dr D.G. Williams**

Department of Biochemistry

Sunderland Royal Hospital

Kayll Road

Sunderland

### Sweating It Out

Having been directly 'quoted' in the long running correspondence on cystic fibrosis diagnosis (December ACB News, page 24) I feel some clarification is necessary. I certainly do not agree that the quality of sweat testing is "totally unacceptable and likely to remain so".

After organising several sweat testing meetings and workshops I recognise that many laboratories are acutely aware of the necessity to monitor the quality of all parts of the sweat-testing procedure including sweat stimulation, collection, analysis and interpretation. Indeed the Sweat Workshop in Birmingham last July was the forum for a variety of reports of evidence-based approaches to achieving this. These included regular in-house review of all patients' results, regional audits, and development of written guidelines. Following on from the workshop at least three further regional audits are underway and introduction of a UK NEQAS is imminent. A number of UK laboratories will be actively contributing to the next revision of the American NCCLS sweat testing guidelines.

As scientists we have to ask searching questions, analyse the results and then act on them. Mr Sanderson proposes we abandon sweat testing and neonatal screening by immunoreactive trypsin (issue 406, p29-30 and issue 428 p24). Anyone currently active in this field will know how enormously the definition of cystic fibrosis has widened in the last decade since the identification of the gene. Any early

thoughts that mutation testing would replace the sweat test were quickly dispelled as the number of identified mutations rose exceptionally. Today immunoreactive trypsin, mutation testing, sweat tests, nasal potentials, and specialised microbiology all have their part to play in making the diagnosis of a condition with a wide spectrum of severity. A single test with 100% specificity and sensitivity and an unmeasurable error rate simply does not exist.

As practising clinical biochemists it is our responsibility to assess available methodology, and to offer appropriate testing and interpretation in a range of different clinical situations. For the majority of patients an abnormal sweat test result will continue to be the cornerstone of diagnosis of cystic fibrosis. We have a duty to assess, maintain and improve our current performance, rather than abandon the test.

**Dr Jean M. Kirk**

**Acting Consultant Biochemist & Head of Department**

Department of Paediatric Biochemistry

Edinburgh Sick Children's NHS Trust

Edinburgh

**Forthcoming Meetings** Forthcoming Meetings Forthcoming Meetings

**Beckman-Coulter 2nd European Protein Conference**

**Stockholm**

**9th-12th September 1999**

As part of this meeting Beckman-Coulter are sponsoring a total of four awards. The awards will include two different sections: Current Clinical Applications and Research and Prospectives.

There will be two awards of 6.000 ECU each and two of 3.000 ECU each.

Competitors must be under 40 years of age on 31st March 1999 and should be active in this field in public or private organisations based in Europe. The paper must be the result of work carried out by the applicant.

The entries will be judged by the International Jury, whose decision is final.

Entries should be original. If the the paper has been accepted for publication, it must not appear in print before 15th September 1999 or it will be excluded.

For further details of this meeting or to receive full details of the award submission rules please contact

Beckman-Coulter in your European country. In the UK please contact: Liz Murphy or Colin Love, Beckman Instruments Ltd, Kingsmead Business Park, London Road, High Wycombe, Buckinghamshire HP11 1JU. Tel: 01494-441181.

**6th Congress of the International Association for Therapeutic Drug Monitoring and Clinical Toxicology**

**Cairns, Australia**

**13th-17th September 1999**

The meeting will include eleven symposia, thirteen workshops, breakfast roundtables and free communications. Full details are available at [www.iatdmct.org](http://www.iatdmct.org).

The deadline for submission of abstracts is 28th February 1999.

**European Meeting on Biomarkers of Organ Damage and Dysfunction (Embody) 2000**

**Robinson College  
Cambridge  
3rd-7th April 2000**

Monday 3rd April

12.00 Registration and Lunch

**Plenary Session: Assessing and Utilizing the Diagnostic and/or Prognostic Power of Biomarkers**

Chairperson: Dr Muir Gray

14.00 Introduction

14.15 Evidence-based Medicine: Evaluation of Biomarkers  
Dr Andrew Moore, Oxford

14.45 Statistical Approaches to Rational Biomarker Selection  
Linda Sharples, Cambridge

16.00 Coffee

**Plenary Session: Two Novel Approaches to the Analysis and Clinical Application of Biomarkers**

16.30 Intelligent Systems (to be confirmed)

17.00 Artificial Neural Networks (to be confirmed)

17.30 Close

19.00 Welcome Reception at Robinson College

Tuesday 4th April

**Plenary Session: Biomarkers of Renal and Bone Damage or Dysfunction**

Chairperson: Professor C Price

08.50 Introduction

09.00 Biomarkers of Renal Disease  
Chris Price, UK

09.45 Biomarkers of Bone Disease  
Richard Eastell, UK

10.30 Coffee

Symposium on Kidney Disease 1

Chairperson: to be confirmed

11.00 Keynote Lecture (to be confirmed)

11.15 Oral Communications

12.30 Lunch

13.30 Moderated Poster Session

Symposium on Kidney Disease 2

Chairperson: to be confirmed

14.00 Keynote Lecture (to be confirmed)

14.15 Oral Communications

15.45 Coffee

Free Communications on Kidney Disease 1

Chairperson: to be confirmed

16.15 Oral Communications

17.45 Concluding Remarks and Close

Symposium on Bone 1

Chairperson: Richard Eastell, UK

11.00 Key Lecture (to be confirmed)

11.15 Oral Communications

12.30 Lunch

13.30 Moderated Poster Session

Symposium on Bone 2

Chairperson: to be confirmed

14.00 Keynote Lecture (to be confirmed)

14.15 Oral Communications

15.45 Coffee

Free Communications on Bone Disease 1

Chairperson: to be confirmed

16.15 Oral Communications

17.45 Concluding Remarks

For further details contact: Pathology Clinical Research Unit, Box 232, Addenbrookes Hospital, Cambridge CB2 2QQ. Tel: 01223-217337. Fax: 01223-216862. Email: at@ebg.cam.ac.uk

**Professional Practice in Clinical Chemistry: A Review**

**Alexandria**

**Virginia**

**USA**

**18th-22nd April 1999**

**American Association of Clinical Chemistry and the National Academy of Clinical Biochemistry**

This five-day programme is an intensive review of fundamental and state-of-the-art practice in clinical chemistry. The course serves pathologists, clinical chemists, and other laboratory professionals who are preparing for certification exams or who wish to stay up-to-date on new developments in laboratory principles, instrumentation, and clinical chemistry. AACC is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians. Please call AACC for further details.

For further information, call AACC at (800) 892-1400 or visit AACC's web site at [www.aacc.org](http://www.aacc.org)

# A Warm and Generous Person

Dianne Baldwin, Kings College Hospital, London

**D**ianne Baldwin died peacefully on 26th November 1998, having undergone surgery and chemotherapy for colorectal cancer earlier in the year. Her entire professional life was spent at King's College Hospital, where she joined the Department of Chemical Pathology as a trainee biochemist in August 1962. She was a holder of the Mastership in Clinical Biochemistry (MCB) and Member of the Royal College of Pathologists.

Dianne's two major interests in the laboratory were quality assurance and trace metal analysis. She was Deputy Director of the King's Supraregional Assay Service Laboratory for Trace and Heavy Metals. Her professional standards were of the highest order and she was widely respected by colleagues both at King's and throughout the heavy and trace metal fraternity for her analytical skills and attention to detail. She was a generous collaborator and was the co-author of several research papers on Wilson's disease and genetic haemochromatosis. She had been commissioned by the Association of Clinical Biochemists' Clinical Laboratory Investigation Standing Committee to write a review on 'Heavy metal poisoning and its laboratory investigation', a project on which I was privileged to work with her. It was typical of Dianne that she was able to contribute enthusiastically and critically to the final revision of the manuscript while still in hospital only a few days after undergoing surgery. I corrected the proofs on the day that she died.

Dianne was an active member of the Southern Region Committee of the ACB but she was a private person, and few who worked with her knew her well. Many had no idea of her activities away from work, described with eloquence and affection by her friend Gerry Acher at her funeral: rockclimbing and hillwalking, swimming – she won a gold medal swimming butterfly in a Master's event in the last year of her life – her work with children, and her devotion to her sister and brother-in-law and their children. She was a warm and generous person. The fortitude and dignity she displayed during her illness was a humbling example to all of us who witnessed it. I never heard her complain.

Her funeral brought together family, friends and colleagues on a blustery late autumn day in Beckenham, where she had lived. The chapel was packed – many had to stand – and even in our sadness we were touched by the warmth of Dianne's personality and her love of life. ■



W.M.

## **Career Opportunities in the National Health Service for Trainee Clinical Biochemists – Grade A**

Graduates, undergraduates and post-doctoral candidates in biochemistry or chemistry are invited to apply for The National Health Grade A Training Scheme in Clinical Biochemistry.

Trainees will follow a training programme of about three years duration in which formal teaching and practical training in hospital laboratories are combined. Some programmes also include an appropriate MSc course.

Applicants should have, or expect to obtain, a first or upper second class honours degree in an appropriate subject. A higher degree is an advantage. Successful candidates will be appointed to Grade A Trainee Clinical Biochemists positions.

Successful completion of this scheme leads to eligibility to apply for a Grade B Clinical Biochemist post.

For vacancy details and an application form contact The National Clearing House for Clinical Scientists, Hyder, Old Road, Headington, Oxford OX3 7QU. Telephone: 01865-226662.

Closing date: Thursday 25th February 1999

### **Partnership Pathology Services A joint venture of Frimley Park and Royal Surrey County Hospitals**

## **Clinical Biochemist – Grade B**

(Starting scale in the range 8-13 depending on experience)

Applications are invited for this post which is based principally at the Royal Surrey County Hospital in the Supra Regional Assay Service (SAS) Peptide Hormone Laboratory of the integrated departments of Clinical Biochemistry and Haematology. The department has close links (including several joint and visiting appointments) with the University of Surrey.

The appointee will be expected to participate in the analytical, developmental, research, interpretative and clinical liaison aspects of the Peptide Hormone Laboratory. He/she will also be expected to contribute to the routine service commitments of the department, including participation, where appropriate, in the rota for clinical liaison and report authorisation.

Applicants will be expected to have completed a grade A training scheme, however, this is not an essential requirement. The successful candidate will be expected to have proven research interests, possibly marked by a postgraduate research degree and/or publications. The post-holder will be encouraged to study for further professional qualifications.

For further information or an informal visit please contact Dr Derrick Teale or Professor Gordon Ferns on 01483-464121. Application forms and a job description may be obtained from Emily Allaway, Personnel Officer, on 01483-406744.

The closing date for applications is Friday 19th February 1999.

### **To advertise your vacancy contact:**

**Dr Simon Olpin, Neonatal Screening Laboratory, Pathology Block,  
Sheffield Children's Hospital, Western Bank, Sheffield S10 2TH  
Tel: 0114-271-7267**

**Deadline: 26th of the month prior to the month of publication**

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