

IEQAS Conference 5<sup>th</sup> October 2005

## Abstracts

Welcome to the 13<sup>th</sup> annual IEQAS Participants' Conference. This is the fifth year we have held the conference in the Red Cow Hotel in Dublin.

I would like to thank the conference sponsors who have generously contributed to the cost of staging this event: Olympus Life & Material Science Europa GMBH (Irish Branch), Roche Diagnostics (Ireland). Also to associate sponsors: Claymon Laboratories, Cruinn Diagnostics; and workshop sponsors: Abbott Laboratories, Fannin Healthcare.

Thank you also to the speakers who have given their time and effort to make this event an informative and hopefully enjoyable experience for all the delegates. I would also like to thank all the participants for their feedback during the past year and to all those who have participated in our surveys. Last but not least, thank you to the Steering Committee members, advisors and specialist reviewers who have given their time and effort so generously throughout the year.

Hazel Graham  
Operations Manager

### Steering Committee

Mr Des Kenny (Chairman)	Dr Ned Barrett	Mr John Brady	Mr Alan Carr
Ms Hazel Graham (Operations Manager)	Dr Gerard Boran	Mr Ivan Shirley	Dr Niamh O'Sullivan
Ms Patricia Howley (Scheme Manager)	Dr Beatrice Nolan	Prof John O'Leary	

•Academy of Medical Laboratory Science      •Association of Clinical Biochemists in Ireland  
•Faculty of Pathology, Royal College of Physicians of Ireland

### Additional advisors / specialist reviewers

Ms Mary Byrne	Mr Frank Clarke	Mr Basil Crowe	Ms Therese Driscoll
Mr Gerry Judge	Ms Nora Kinsella	Prof John Nolan	Ms Dympna Murphy
Dr Kanthi Perera	Mr Rowland Reece	Dr Tom Smith	

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## **Plenary Session**

### ***IEQAS Annual Review,***

#### **Hazel Graham, IEQAS Operations Manager**

There are now 53 different institutions (mostly hospitals) currently registered in at least one IEQAS scheme, confirming the trend of increasing participation in IEQAS. The number of registrations with the various IEQAS schemes has risen from 33 (one scheme, Clinical Chemistry) in 1981 to 264 in 2005 (13 schemes).

2005 was a very busy and productive year and the increase in workload has necessitated relocating to a larger office in early October (Unit B06, Nutgrove Enterprise Park, Dublin 14, new phone/fax to follow). Alan Carr is working this year as IEQAS Project Manager (part-time). Frances Fitzharris continues to support us in the IEQAS office.

In early 2005 we launched a significant upgrade of our website, including a laboratory specific interface for submitting results and downloading reports. Approximately one-third of participants now submit their results electronically and the majority of participants no longer require paper copies of their reports.

Some of the projects initiated this year are:

Safety and Ethics policy for the use of fresh blood samples in EQA;

Review of international EQA schemes;

Survey to establish an inventory of EQA requirements in Ireland has been prepared and will be distributed soon;

We are almost ready to apply for ISO 9001 certification and also intend to apply for accreditation to ISO/IEC Guide 43-1 (Proficiency testing by interlaboratory comparisons) and ILAC-G13 (Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes).

We ran four Special Surveys: Full Blood Count (QC vs. Patient mode); Pre-analytical errors in Clinical Chemistry; HbA<sub>1c</sub> analysis in Haemoglobinopathy patients; Coagulation (PT, INR, APTT, Fibrinogen, D-Dimer).

Depending on the outcome of the Coagulation special survey, we may replace the current Labquality Coagulation scheme with a local IEQAS scheme next year.

IEQAS offers a number of Labquality schemes and monitors the performance throughout the year; however labs may join other Labquality schemes through IEQAS (e.g. D-Dimers, Haemoxymeters in 2005). IEQAS will introduce additional monitored Labquality schemes as the need arises. The Labquality brochure is available on our website; please let us know if there are any schemes you would like to join. In 2006, some Labquality schemes have increased in frequency and some are now Internet only.

We hope to expand into Microbiology in the area of anti-microbial susceptibility testing and plan a joint workshop with the ISCM. In the longer term we are also investigating EQA for Cervical Cytology; Des Kenny has been invited to represent IEQAS on the Irish Cervical Screening Research Consortium (ICSRC).

We welcome three new advisors to IEQAS sub-committees: Dr Tom Smith (St Vincent's Hospital Dublin), HbA<sub>1c</sub>; Dr Kanthi Perera (MWRH, Limerick), Blood Cell Morphology; Mr Rowland Reece (St Vincent's Hospital Dublin), Clinical Chemistry.

## ***Safety in Pathology Laboratories***

### **Professor Sir John Lilleyman, Medical Director, National Patient Safety Agency (UK)**

Despite being a very high risk industry, the National Health Service has been slow to recognise the fact and to take steps to develop a safety culture. Things are slowly beginning to change in the UK. Following the publication of a number of key reviews and reports in the 1990s, in 2001 the Department of Health established the NHS National Patient Safety Agency to promote incident reporting, learning from doing so and educating staff that safety is not simply about being careful. Its activities, covering data analysis, risk assessment, systems redesign, root cause analysis of adverse events and educational initiatives have taken some time to develop but are now beginning to gather momentum.

Errors mostly arise through poorly designed systems tasks, or processes, and the majority are associated with poor communication, misidentification, wrong medication, or inappropriate delay. As far as laboratories are concerned, most of the 2,500 problems reported to the NPSA in the first few months of 2005 related to wrong labels, discordant ID data, inappropriate samples, lost samples, and failure to communicate results. There were also some wrong tests and wrong results, but the biggest reported problem is misidentification.

So the NHS in general needs to improve its safety record, and this includes its laboratories. This means changing the attitudes and behaviour of the professions involved. The challenge is formidable since healthcare is huge, diverse and complex. It is characterised by myriads of small manual processes, and it will take some years for the shift to occur in all the thousands of departments involved. But the process has begun, and the early shoots of success are beginning to show in some institutions.

Key to this is the engagement of the professions involved in delivering front line services, because if they do not see the point of reporting and learning from things that go wrong, wrong things will continue to happen.

## ***The Application of Digital Slides in External Quality Assurance:***

**Dr Donal O'Shea, CEO Slidepath**

### **Digital slides**

A digital slide is a digital representation of an entire glass slide, examinable via a PC. Digital slides are often considered hybrids of static and dynamic telepathology in that they display static images (rather than real-time images), but mimic light microscopy by permitting the examiner to navigate between images representing the tissue at different magnifications. There is no requirement for the glass slide to be present during the examination. Their inherently digital nature means that they can be transmitted and modified in ways not possible with glass slides. For example, digital slides are examinable via the Internet, may be annotated and can be associated with multimedia content.

Digital slides however are not without their disadvantages. Because images are captured prior to digital slide examination, real-time adjustment of lighting and focusing parameters is not feasible, within the context of what is permissible with light and dynamic microscopy. While adherence to scanning protocols to ensure optimum digitisation reduces most requirements for these capabilities, some pathologists still prefer to have complete control over their microscopic environment. Some digital slide viewers allow the adjustment of lighting parameters, but this is performed on the static image, post-acquisition, rather than real-time. The inability to 'focus through' histological specimens in the z-plane is also a limitation of current digital slide systems, especially in examination of thick tissue sections and cytology. However, the continuing decrease in the cost of computer storage will negate the increased storage requirements of digitisation in multiple focal planes, and 'focus through' capabilities will be incorporated into new and existing scanning systems.

### **EQA**

The practice of performing External Quality Assurance (EQA) in pathology and laboratory medicine is intended to improve the quality of work and increase patient safety, by assessing the participants' ability to accurately diagnose sets of circulated cases. Undertaking such EQA work however incurs significant amounts of administrative overheads. Preparation and distribution of large quantities of slides, collection and analysis of diagnostic data are all expensive and time-intensive tasks. Additionally, participants do not examine identical slides. While very similar, different sections from the same paraffin block are never identical, and specimens such as needlecore biopsies are not suitable for use in EQA studies due to the limited quantity of tissue available for distribution. The use of telepathology for EQA possesses a number of advantages over conventional methodologies:

Slides are not required to be physically distributed to participants, speeding up the process, reducing costs and removing the inherent risk of damaged/lost slides.

All participants examine the same slide. Identical copies of the same digitised slide images are transmitted. The requirement to only digitise one slide permits the use of needlecore biopsies.

Fast and efficient data collection, providing the capability for real-time analysis and feedback from participants

Capability for monitoring examinations and analysing the diagnostic process utilised.

A fundamental shortcoming of conventional QA studies is their difficulty in detecting and elucidating sources of error and the reasons for inter-observer variability. Inability to locate diagnostic cues relevant to diagnosis, and inability to correctly identify diagnostic cues when successfully found are often cited as the two primary factors involved in failure to conclude an accurate diagnosis. Conventional studies are unable to monitor microscopic examinations, prohibiting extensive interrogation of the diagnostic process and therefore inhibiting more accurate analysis of the cause of diagnostic discordance. However, digital slides provide the capability for examiners to mark specific regions that they consider relevant to their diagnosis, or comment on regions identified by study administrators, providing a greater amount of diagnostic information than available with conventional studies.

## **Haematology Workshop**

### ***Annual Review of Haematology Schemes 2005***

**Ivan Shirley, St Vincent's University Hospital, Dublin 4**

Results from the Full Blood count, ESR, Haematinics and Infectious Mononucleosis schemes will be reviewed.

During the year a survey was carried out comparing External QC material processed via the Patient sample mode and the QC mode on analysers. The aim of the study was to investigate whether the QC mode would be a more suitable method for analysing EQA material. In general the differences in results between the two methods were not significant. These findings will be discussed.

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### ***Blood Transfusion Review***

**Gerry Judge, AMNCH, Tallaght, Dublin 24.**

Thirteen Irish Laboratories are registered in the Blood Transfusion scheme. The scheme consists of exercises in ABO & Rh grouping, Antibody screen and compatibility testing and Direct Antiglobulin test. Participants can opt for one or more of these.

Two exercises were sent in 2005 and results are available on the first of these. Irish Laboratories performed well. The antibody screen, compatibility test and antiglobulin tests were straightforward. The ABO blood grouping proved more difficult. The following observations from this exercise were made

It is important to identify and record mixed field reactions.

Interpretation of results should accommodate mixed field reactions

Grading of reaction strengths as recommended by the scheme is important

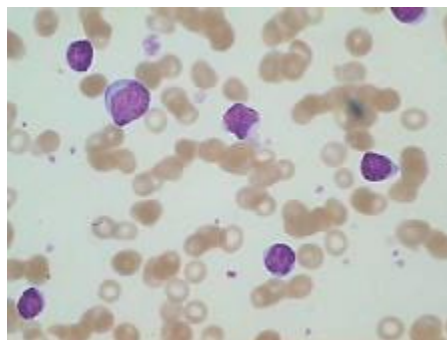
Twelve countries and 169 labs are registered for the ABO scheme. Of the respondents 50% use gel technology for ABO typing

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### ***BCM Review***

**Dr Ann Fortune, St James's Hospital, Dublin**

The blood films reviewed over the year will be discussed



### ***Coagulation survey report***

**Mary Byrne, National Centre for Hereditary Coagulation Disorders (NCHCD), St James's Hospital, James's Street, Dublin**

Due to circumstances beyond our control this report has been cancelled.

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### ***Immunophenotyping – Uses and QC***

**Sean Rooney, Our Lady's Hospital for Sick Children, Crumlin, Dublin 12.**

Flow Cytometry is rapidly becoming a widely used technology in the routine Haematology laboratory. The current and potential future applications to the routine lab will be discussed. Also the value and pitfalls of some of the various QA methodologies in use (or lack of!) will be presented.

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### ***Validation of the Sysmex XE2100 Haematology Analyser – A laboratory experience.***

**Patricia Gough, AMNCH , Tallaght, Dublin 24.**

An evaluation of the Sysmex XE2100 high-through-put haematology analyser was undertaken in order to replace a 6 year old Sysmex SE9500 analyser.

The instrument was evaluated according to guidelines published by the International Committee of Standardisation in Haematology (ICSH) for automated blood cell counters in order to assess the performance, advantages and limitations of this instrument and compare it to the SE9500 currently in use.

Over a period of weeks its analytical performance in terms of precision, reproducibility, linearity and carry over were assessed and results were found to be statistically comparable. The comparison with a significant number of leucocyte differential count results analysed in parallel with optical microscopy were favourable. Results of the side by side study are presented.

Excellent linearity was demonstrated for WCC, Hb, RCC, Platelet and Reticulocyte counts. Carryover was found to be insignificant for the same parameters in a normal population.

Short term stability studies showed no significant deviation, however long term stability studies showed significant changes between samples stored at room temperature and those stored at 4°C for a period from 12 hours up to 72 hours. Results were shown to be stable in refrigerated samples stored for up to 72 hours. Values for HCT, MCV, and MCH however were shown to be unreliable at just 12 hours when maintained at room temperature.

After reviewing the results of all studies the XE2100 was considered an acceptable replacement for the SE9500 and is now in normal laboratory service.

## **Clinical Chemistry Workshop**

### ***Survey of pre- and post- analytical errors***

**Ann Breen, MWRH, Limerick**

#### **Introduction**

The reduction of error must be seen as a goal in all areas of healthcare including laboratories. Clearly errors are not always synonymous with negligence, a culture that sees mistakes as an individual problem and blames and punishes the individual is failing to look for root causes and potential system improvements to protect both the patient and staff member. Systems must be designed to prevent and absorb error. Reason (2005) maintains that without a detailed analysis of incidents, and near misses, there is no way of uncovering causes of error. The IEQAS survey explores the current status of detecting, recording and evaluating pre-analytical errors in a representative sample of participating Clinical Chemistry Laboratories.

#### **Aim**

To provide a snapshot of participating laboratories attitude to aspects of pre-analytical error detection, recording and evaluation.

#### **Methodology**

A quantitative survey using structured questions was conducted on a purposive sample of thirty-seven Clinical Chemistry Laboratories. The survey was distributed by the IEQAS headquarters. The survey investigated the role of the laboratory in providing guidance to its users; it investigated the commonest type of pre-analytical error encountered, the most effective laboratory experiential means of reducing pre-analytical errors, the commonest reasons for pre-analytical errors, and the recording and reporting of user and laboratory pre-analytical errors. In addition the survey explored participant's perception of whether errors are person or system centred.

#### **Results**

The response rate to the questionnaire was 73% (N=27).

The survey found that 100% of respondents agreed that proper preparation of the patient, specimen collection and handling are essential for the production of valid results by the laboratory.

88% of respondents provide guidance to users on patient preparation, specimen collection, labelling and handling while 76% of respondents feel obliged to ensure that the users adhere to this guidance.

The commonest pre-analytical errors encountered by respondent laboratories are mislabelled specimens and incorrect sample type.

The most frequent reasons cited for pre-analytical errors are increased workloads, carelessness/lack of concentration, and not adhering to procedures/guidelines. The most effective experiential means of reducing pre-analytical errors are application of rejection criteria and communication with the user.

#### **Discussion /Conclusion**

These findings will be the subject of discussion at the afternoon Clinical Chemistry workshop.

### ***Evaluation of three different specimen types;***

(serum, plasma lithium heparin & serum gel separator) for analysis of certain analytes: clinical significance of differences in results and efficiencies in use

**Myra P. O'Keane & Dr Sean K. Cunningham**

**Department of Biochemistry, St Vincent's University Hospital, Dublin 4.**

There is a lack of consensus regarding the most appropriate specimen type for analysis of many biochemistry analytes. Identification of a single specimen type suitable for most analytes would result in significant savings and efficiencies. The aims of this study were to determine if results for renal and lipid profiles and phenytoin are interchangeable in serum (plain & gel) and plasma lithium heparin blood collection tubes and to investigate the stability of these analytes in serum and plasma (1) after prolonged contact with cells or gel at room temperature (RT, 20<sup>o</sup>C) and (2) aliquoted and stored at 4<sup>o</sup>C.

Primary specimens, plasma (P), serum (S) and gel (G), were simultaneously centrifuged once @ 3000g for 10 minutes. Two aliquots from each tube were separated and stored at 4<sup>o</sup>C for subsequent analysis at time 24 hours (T<sub>24</sub>) and 48 hours (T<sub>48</sub>). Triplicate samples (P, S & G) were analysed in duplicate for renal and lipid profiles and phenytoin at time 0 (T<sub>0</sub>), T<sub>24</sub> and T<sub>48</sub>.

Statistical significance (p<0.05) of differences from reference samples analysed at T<sub>0</sub> were determined by Friedman 1-way-ANOVA by rank, with the critical range test. Clinically significant differences were estimated as a function of imprecision and allowable bias.

While minor but statistically significant differences were found for many of the analytes, when clinically significant differences were examined at T<sub>0</sub>, all analytes in serum (plain & gel) and plasma were equivalent, except potassium, which showed a clinically significant increase in serum, plain (9.6%) and gel (7.1%), compared to plasma. All analytes, except CO<sub>2</sub> were stable when aliquoted, and stored at 4<sup>o</sup>C. Phenytoin was stable in serum (plain) and plasma at RT but showed a clinically significant decrease in concentration at RT over time in serum gel.

Plasma was found to be the specimen of choice for the measurement of all the analytes investigated in this study. It was most the most suitable for the analysis of potassium, provided that samples were analysed within two hours, otherwise, it was necessary to separate plasma from cells due to the instability of potassium over time. It was most favoured in terms of efficiency.

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### ***Equipment and Assay Validation in a clinical laboratory***

**Deirdre Bourke and Jeff Connell, National Virus Reference Laboratory**

Validation is a fundamental component of any Quality Management System. Validation is a process by which a high degree of assurance is generated and documented that a facility, instrument or assay is appropriate for its intended use. The National Virus Reference Laboratory (NVRL) is fully accredited by Clinical Pathology Accreditation (UK) Ltd and by the World Health Organisation as a National Laboratory for Poliovirus, Influenza, Rubella and Measles. The laboratory was set up over thirty years ago by the Department of Health and Children and University College Dublin to provide a national diagnostic and reference service for clinicians investigating virus infections. The current workload involves over 500,000 tests per annum. As with any busy clinical laboratory the validation process is often time constrained and staff limited. This workshop will outline the NVRL's current approach to the validation process of analytical instruments and diagnostic assays.