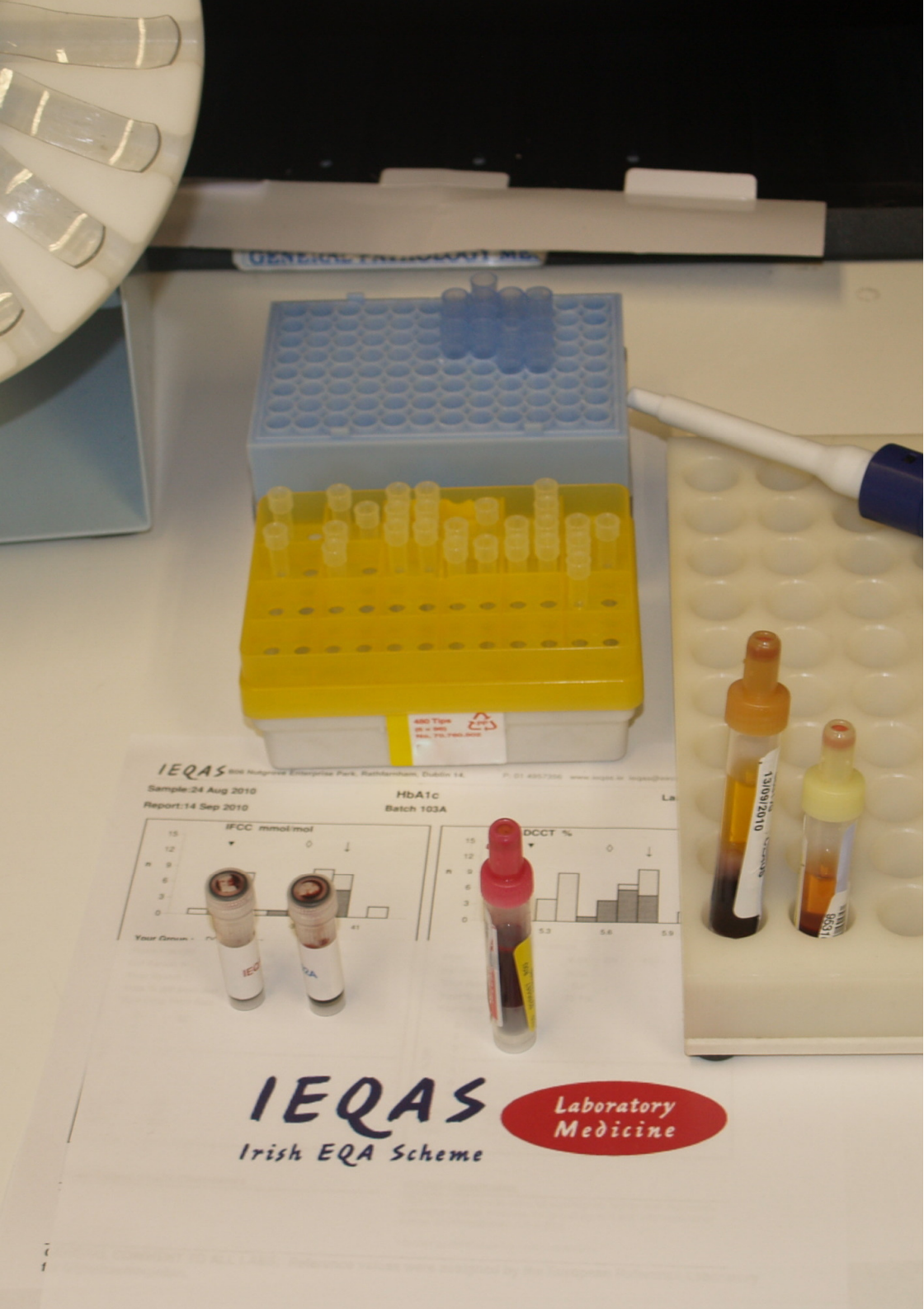
IEQAS
Sample:24 Aug 2010
Report:14 Sep 2010
HbA1c
Batch 103A
IFCC mmol/mol
DCCT %
IEQAS
Irish EQA Scheme
Laboratory Medicine

# Contents

# Acknowledgements

We would like to thank the following for their generous support towards the running of the Conference today

## Major Sponsors

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*Cover Photograph:*
*Dr Peadar McGing, Mater Misericordiae Hospital, Dublin*

# Plenary Programme

***09:45 – 12:50 (approx)***

***Registration Tea/Coffee from 09:15***

**INTRODUCTION**

**09:45** **Chairman's address**
Dr Ned Barrett, IEQAS/Mid Western Regional Hospital, Limerick

**09:55** **Opening address**
Dr Joe Devlin, Director, Quality, Safety & Risk, HSE

**10:15** **IEQAS annual review**
Ms Patricia Howley, IEQAS

**PLENARY SESSION: ACCREDITATION**

*Chair: Dr Sean Cunningham, SVUH*

**10:25** **Accreditation in Irish hospital laboratories 1990-2015**
Mr Tom Moloney, AMLS/Joint Working Group on Irish Laboratory Accreditation

**10:45** **The Irish National Accreditation Board (INAB): Laboratory Accreditation**
Dr Emma Scott-McGrane, Accreditation Officer, Irish National Accreditation Board

***11:15 – 11:45 Tea/Coffee***

**11:45** **Accreditation of hospital laboratories - experiences gained**
Dr Johanna Andersson, Sweden/INAB Assessor

**12:15** **Accreditation of Point of Care testing (ISO 22870) – addressing the practicalities**
Mr Paudy O'Gorman, AMNCH Tallaght

**12:35** **Questions and discussion**

***12:50 – 14:00 LUNCH***

# Afternoon Workshops (parallel)

***14:15 – 16:00 (approx)***

**CLINICAL CHEMISTRY**

*Chair: Mr Alan Carr IEQAS/AMNCH Tallaght*

**14:00** **Standardisation: can we do better?**
Ms Hazel Graham, IEQAS

**14:10** **Toxicological assays in Ireland: an audit**
Mr John Herbert, National Poisons Information Centre

**14:40** **Harmonisation of reference ranges: survey report**
Dr Peadar McGing, Mater Misericordiae Hospital

**14:55** **What have we learnt from international standardisation of $HbA_{1c}$?**
Dr Ophelia Blake, St James's Hospital

**15:20** **Case study**
Ms Mary Stapleton, Cork University Hospital

**HAEMATOLOGY**

*Chair: Ms Dympna Murphy, IEQAS/AMNCH Tallaght*

**14:00** **Blood Cell Morphology scheme review 2009-2010**
Dr Kanthi Perera, Midland Regional Hospital, Tullamore

**14:45** **Sysmex analysers-platelet optical counting; review of IEQAS data**
Mr Ivan Shirley, IEQAS/SVUH

**14:55** **Case studies**
1. Ms Kim Maguire, Beacon Hospital
2. Ms Heather Baker, AMNCH Tallaght
3. Mr Sean Rooney, OLCH Crumlin
4. Ms Nora Kinsella, St James's Hospital
5. Ms Pauline Forsythe, St James's Hospital

## TRANSFUSION

*Chair: Mr Gerry Judge IEQAS/AMNCH Tallaght*

**14:00** **How hot is your fridge- a guide to temperature mapping**
Ms Mary White, NSAI National Metrology Laboratory

**14:45** **Sample storage - room temperature or 4°C?**
Ms Donna Lui, AMNCH Tallaght

**15:10** **Genotyping problems solved**
Mr Mark Lambert, Irish Blood Transfusion Service

**15:30** **Blood for your eye**
Ms Aoife Conroy, UCH Galway

**15:45** **Case study**
Ms Elaine O'Leary, Coombe Women's & Infants Hospital

# IEQAS

Since 1981, IEQAS has offered External Quality Assessment (EQA) schemes to Irish laboratory medicine, with the aim of achieving and maintaining the best possible quality through a continuous process of monitoring, education, training and support.

**Steering Committee**

| | |
|---|---|
| Barrett, Ned[2] | Chairman<br>Consultant Clinical Biochemist, Mid-Western Regional Hospital, Limerick. |
| Shirley, Ivan[1] | Vice-Chairman<br>Chief Medical Scientist, St Vincent's University Hospital. |
| Boran, Gerard[3] | Consultant Chemical Pathologist, AMNCH, Tallaght. |
| Brady, John[1] | Chief Medical Scientist, Our Lady's Children's Hospital, Crumlin. |
| Carr, Alan[1] | Senior Medical Scientist, AMNCH, Tallaght. |
| Graham, Hazel | IEQAS Quality Manager. |
| Howley, Patricia | IEQAS Operations Manager. |
| O'Sullivan, Niamh[3] | Consultant Microbiologist, Our Lady's Children's Hospital / Coombe Women's Hospital. |
| Smith, Tom[2] | Principal Biochemist, St Vincent's University Hospital. |

**Associated Professional Bodies**

[1] Academy of Medical Laboratory Science
[2] Association of Clinical Biochemists in Ireland
[3] Royal College of Physicians of Ireland, Faculty of Pathology

**Additional Sub-Committee members**

| | |
|---|---|
| Blake, Ophelia | Principal Biochemist, St James's Hospital. |
| Clarke, Frank | Lecturer, School of Biological Sciences, Dublin Institute of Technology. |
| Driscoll, Therese | Senior Medical Scientist, AMNCH, Tallaght. |
| Judge, Gerry | Chief Medical Scientist, AMNCH, Tallaght. |
| McGing, Peadar | Principal Biochemist, Mater Misericordiae Hospital. |
| Murphy, Dympna | Chief Medical Scientist, AMNCH, Tallaght. |
| Nolan, John | Consultant Endocrinologist, St James's Hospital. |
| O'Gorman, Paudy | POCT Manager, AMNCH, Tallaght. |
| Perera, Kanthi | Consultant Haematologist, Midland Regional Hospital, Tullamore. |
| Quirke, William | Medical Scientist, Mid-Western Regional Hospital, Limerick. |
| Reece, Rowland | Principal Biochemist, St Vincent's University Hospital. |

**Operations Management**

Graham, Hazel (Quality Manager)
Howley, Patricia (Operations Manager)
Cooke, Anne (Scheme Administrator)

# Abstracts

## Chairman's address

*Dr Ned Barrett, IEQAS and Consultant Biochemist, Mid Western Regional Hospital, Limerick*

**Abstract**
The Irish External Quality Assessment Scheme for Laboratory Medicine (IEQAS) was launched in May 1981. From the beginning, virtually all clinical laboratories in the state have participated in the scheme. The scheme is educational rather than regulatory in nature. It monitors the quality of results reported in Irish Laboratory Medicine and offers professional advice and guidance as necessary.

Of itself, passive participation in External Quality Assessment is not enough to drive quality improvement. IEQAS reports must be understood and interpreted correctly so as to prompt corrective actions and guide quality improvement. The Annual Participants' Conference provides a valuable opportunity for all of us to learn from the experiences of our colleagues and the wisdom of our invited guest speakers.

The support of all the professional bodies in Irish Laboratory Medicine has been crucial to the success of the scheme. The IEQAS Steering Committee coordinates the work of various Haematology, Clinical Chemistry and Transfusion Review Groups and Specialist Sub-Committees. The demand for IEQAS services has grown considerably in recent years and this has presented new challenges for the Scheme and its staff at a very difficult time for the publicly-funded health services.

**Biography**
Dr Ned Barrett is Chairman of the Steering Committee of the Irish External Quality Assessment Scheme for Laboratory Medicine (IEQAS). He is Consultant Clinical Biochemist at the Mid-Western Regional Hospital in Limerick and Chairman of the HSE's Project Team entrusted with the implementation of the International Standardisation of $HbA_{1c}$ measurement in Ireland.

## Opening address

*Dr Joe Devlin, Director, Quality, Safety and Risk, HSE*

**Biography**

Dr Joe Devlin, MD, FRCPI (UCD 1988) has been Director for Quality, Safety and Risk, HSE since 2009.

Joe began his general professional training in Dublin Teaching Hospitals from 1988 to 1992 and was a Research Fellow/Honorary Lecturer in Rheumatology, University of Birmingham from 1992 to 1995. He was a Senior Registrar/Honorary Lecturer in Rheumatology and General Medicine in University of Leeds from 1995 to 1998 and Consultant Rheumatologist/Honorary Senior Lecturer in United Leeds Teaching Hospitals from 1998 to 2003. He continued as Consultant Rheumatologist in Waterford Regional Hospital from 2003 to 2009 and was Lead Clinician, Department of Medicine in Waterford Regional Hospital from 2004 to 2009.

Joe has particular interests in Healthcare Information/Electronic Healthcare Record (Co-chair NHO healthcare records group 2006 to present), Clinical Leadership, Clinical Governance, Clinical Audit and Patient Safety.

## IEQAS annual review 2009/2010

*Ms Patricia Howley, Operations Manager, IEQAS*

### Schemes

Sixty-two different institutions (58 hospitals) participate in schemes with IEQAS. The number of individual registrations has again increased in 2010 (by ~10%); we now have 687 different analysers and POCT meters in 79 different schemes.

This year, six new schemes have been introduced following requests from participants. IEQAS has expanded into the area of EQA for POCT meters: POCT Lipids and POCT $HbA_{1c}$.

**Labquality have asked us to remind participants to always use their Labquality Client Code when returning results**.

The current schemes are:

ABO & Rh grouping
Alcohol in serum
Angiotensin Converting Enzyme
Antibody screening/compatibility testing
Antiglobulin test, direct
Antistreptolysin titre
APTT, fibrinogen
Blood Cell Morphology
Blood culture
Blood Gas
C Reactive Protein
C. difficile, cult & toxin detection
Chlamydia pneumoniae, antibodies
Coeliac disease
Conjugated Bilirubin
CSF
D-dimer
Drug abuse screen & confirmation in urine
Drug monitoring (therap drugs)
ESR
ESR for Alifax users
Faecal Blood
Full Blood Count
Fungal culture
General Bacteriology
General Clinical Chemistry
Gram stain Blood culture –
Gram stain Blood culture +
Gram stain colonies
H. pylori antibodies
H. pylori antigen detection
Haemoxymeter
$HbA_{1c}$
$HbA_{1c}$ variants
Herpes simplex 1 & 2 antibodies
Hormones/Haematinics
Infectious mononucleosis
Lipids and Lipoproteins
LMW-Heparin/antiFXa
Measles virus antibodies
Mycobacterial culture & smear
Mycobacterial smear
Mycoplasma pneumoniae, antibodies
Myocardial Markers
Natriuretic peptides, B-type
Neisseria gonorrhoea culture
Parasites in Faeces
POCT Lipids scheme
Pregnancy Test
Protein in CSF
Proteins, Immunochemical determinations

PSA
PT (INR)
Rheumatoid factor & citrullic antibodies
Rotavirus & adenovirus, antibody detection
RS virus, antigen detection
Synovial fluid crystals
Throat strep culture
Thyroid gland antibodies
Tumour Markers
Urine Culture
Urine strip test B
Urine, quantitative chemistry

**New for 2010**

Borrelia burgdorferi antibodies
CMV antibodies
Hepatitis B&C
Mumps virus
TSH Receptor antibody
Varicella zoster virus

**Achievements and Plans**

ISO 9001: In December 2009, IEQAS passed a surveillance audit to maintain certification to ISO 9001:2008 standard.

Participant Satisfaction Survey: The survey was sent to all participants in August 2010. We contacted Labquality with a number of questions raised on specific issues e.g. expansion of electronic result reporting and faster turnaround times. We are pleased to report that Labquality have started an IT project to upgrade and modernise their entire system for electronic reporting. This should address many of the issues mentioned. A summary report of the survey is included in this booklet.

International standardisation for HbA1c assay: This was driven by a HSE Project Team, chaired by Dr Ned Barrett; team members included Hazel Graham and IEQAS sub-committee member Dr Ophelia Blake. IEQAS were actively involved from June 2009 and dual reporting (IFCC and DCCT) was implemented nationwide on 1st July 2010. This project has taken considerable effort but has proved very worthwhile; achievements include a webpage www.hse.ie/go/diabetes with information for people with diabetes, health care professionals, laboratory professionals, and suppliers (the first two are also in printed leaflet form). As part of the agreed Verification Process, two special distributions, each with three patient samples, were circulated by IEQAS to ensure concordance of both laboratory analysers and POCT meters with the IFCC Reference System. Results were assessed by the IEQAS $HbA_{1c}$ Review Group and certificates of concordance were issued.

EQA is a new concept for many POCT $HbA_{1c}$ users and considerable time has been spent assisting them through the process. It is

hoped that this project will encourage more sites to join the routine IEQAS $HbA_{1c}$ scheme.

Post-analytical EQA scheme for automated haematology: EQALM (European Committee for External Quality Assurance Programmes in Laboratory Medicine), of which IEQAS is a member, offered this web-based scheme via IEQAS. A small number of Irish labs participated this year and in the pilot in 2009. The results will be presented at the EQALM Conference in Lisbon on 11/12 October and will be available shortly after that. The next survey will be in February 2011.

Special Survey: A pilot survey on Harmonisation of Reference Ranges was conducted with the assistance of IEQAS. The results will be presented during the Clinical Chemistry workshop this afternoon.

POCT for Lipids – Pharmacies: Following the trial with the Irish Pharmacy Union and Trinity College for POCT lipid testing in pharmacies countrywide, IEQAS is now running a routine scheme in conjunction with our Welsh colleagues WEQAS.

We wish to thank all members of the Steering Committee and other IEQAS sub-committees for their continued support and commitment. We would like to thank the staff in The Diabetes Centre, St James's Hospital and Dr Ophelia Blake for assistance with donor samples for $HbA_{1c}$, especially during the verification runs. Thanks also to the laboratories in AMNCH Tallaght and OLCH Crumlin for use of their facilities for storage and distribution.

Despite the difficult economic climate, we have managed to continue to provide a wide ranging EQA service. Measures taken to minimise costs have included negotiating with landlord and suppliers; IEQAS staff have also taken a reduction in pay. I would like to thank my colleagues Hazel Graham and Anne Cooke for their continued professionalism, hard work and dedication.

**Biography**

Patricia Howley joined IEQAS in 1999, and took over as Operations Manager in 2007. Patricia graduated from NUIG with a BSc in Chemistry and received an MSc in Quality and Safety in Healthcare Management in 2009 from the Royal College of Surgeons in Ireland.

## Accreditation in Irish hospital laboratories 1990-2015

*Mr Tom Moloney, Executive Officer, AMLS and Joint Working Group on Irish Laboratory Accreditation*

**Abstract**

The structured drive to improve the quality of patient care has a long history in medicine, going back to the early 20th Century, and has drawn extensively on experience in industry. Pathology developed these initiatives and has introduced tools such as External Quality Assessment, Inspections and Quality Management. In latter years these techniques have been incorporated in formal Accreditation schemes.

Although hospital laboratory accreditation was established in the US and Australia in the 1960s it did not figure prominently in the UK until the 1990s. The establishment of Clinical Pathology Accreditation (CPA) in the UK in 1992 prompted the professions in pathology in Ireland to set up a Joint Working Group on Irish Laboratory Accreditation. The Working Group engaged with CPA and the Irish National Accreditation Board (INAB) seeking the optimum system. Many Irish laboratories pursued accreditation, particularly since 2000, with the majority using CPA.

An international standard, ISO 15189 specifically aimed at medical laboratories has been published and is gaining widespread acceptance. An EU Directive, EU 765/08, mandates the use of ISO 15189 for Transfusion Laboratories and accreditation is offered through INAB. The Joint Working Group has issued a document summarising Current Issues in Accrediting Irish Laboratories. It is acknowledged that these issues are complex.

Recently the status of CPA has changed following the Carter Review and its role in Ireland will of necessity change.

INAB has recently established (2010) a Medical Advisory Committee with representatives of the various stakeholders in Pathology. More recently INAB set up a series of discipline-specific task force groups that will identify topics requiring development of guidelines, based on best practice, for meeting the standards. Some of these, such as Retention of Records, apply across all disciplines; others will be discipline specific.

Following on high profile failures in the health system we can expect an even greater emphasis on regulation. Hospitals will be

licensed soon. The Health Information and Quality Agency will play a pivotal role in highlighting quality deficiencies. Accreditation may become legally mandatory. In practice accreditation is de facto mandatory as laboratories bidding for contracts are required to be accredited.

These topics will be considered in this presentation along with the positive and negative aspects of accreditation of hospital laboratories.

**Biography**
Tom Moloney is Executive Officer with the Academy of Medical Laboratory Science (AMLS) providing administrative support to the AMLS Council.

He retired from the public service in 2007 after 45 years to take up his current post. From 1979 until his retirement he was the Laboratory Manager in the Mater Misericordiae University Hospital in Dublin. Prior to this he held posts in the Mater Haematology laboratory, Dr Steeven's Hospital, Meath Hospital, and the Irish Blood Transfusion Service. His laboratory career began in 1962 in the Pharmacology Department in UCD.

He is professionally qualified in Haematology- Blood Transfusion and Microbiology. He has a BA, and Diplomas in Industrial Relations, Health and Safety and Quality Management.

He was a committee member of the Medical Laboratory Scientists Association for 27 years of which 21 were in the role of Deputy Secretary. Over the years he has been an active member of various AMLS and IBMS committees. In recent years he has taken a keen interest in Accreditation and Lean and Six Sigma process improvement techniques.

In the mid 1990s he was one of the early enthusiasts for accreditation and was a key member of the team that led the Mater Hospital to become CPA accredited. From that time he has been a member of the Joint Working Group on Irish Laboratory Accreditation and currently chairs the committee.

## The Irish National Accreditation Board (INAB): Laboratory Accreditation

*Dr Emma Scott-McGrane, Accreditation Officer, Irish National Accreditation Board*

**Abstract**
The presentation will describe INAB; its background, roles and activities. An overview of the accreditation process for Laboratories will be described. In addition, the international recognition of INAB will be explained as well as the benefits of INAB accreditation.

**Biography**
Emma Scott McGrane joined the Irish National Accreditation Board in March 2006 as Senior Accreditation officer. She is responsible for a portfolio of applicant and accredited testing (including medical testing) and calibration laboratories. After completing a BSc in Chemistry from UCD she completed a post graduate degree and was awarded a PhD in Organic Chemistry from Kingston University in 2004. The role of an Accreditation Officer is both challenging and rewarding; challenging due to the fact that INAB continues to experience significant growth in demand for its accreditation services (from an increasingly diverse applicant base), and rewarding due to the value and assurance it provides to its existing customer base.

## Accreditation of hospital laboratories – experiences gained

*Dr Johanna Andersson, Sweden, and INAB Assessor.*

**Abstract**
Accreditation of hospital laboratories in Ireland began in 2004 with the Bon Secours Hospital Laboratory in Cork – an accreditation of all disciplines, based on ISO 15189. The EU directive on blood banking, translated into Irish law, accelerated the accreditation process and involved haemovigilance procedures.

Experiences gained during the last 5 or 6 years:

- Quality and technical systems are in place
- Documentation is in general good
- Internal audits are improving
- The level of continual education is quite varied
- Focus is still very much on internal procedures and not on the users of the laboratory
- Quality indicators are not completely understood and therefore not used as optimally as they could be

**Biography**
Dr Johanna Andersson, a chemist by profession, has worked in clinical biochemistry for more than 30 years in a hospital complex called NU Healthcare which is based in western Sweden, north of Göteborg. Her last years in the laboratory were spent as Laboratory Director for the Department of Laboratory Medicine which included clinical biochemistry, haematology, microbiology and transfusion medicine.

In Sweden, hospital laboratory accreditation began in the early 1990´s, with Salgren´s University Hospital in Göteborg being the first laboratory to receive an accreditation. Johanna started working for SWEDAC, the Swedish accreditation body, in 1994 and is still an active assessor. In 2003, she started working for the Irish National Accreditation Board, INAB, and has since then had the opportunity to visit and assess a large number of hospital laboratories in Ireland. Continual improvement is the driving force both for laboratories and for assessors.

## Accreditation of Point of Care testing (ISO 22870) – addressing the practicalities

*Mr Paudy O'Gorman, AMNCH Tallaght*

**Abstract**

The earliest form of useful diagnostic laboratory testing is thought to have been the visual, olfactory and gustatory analysis of urine carried out in the immediate vicinity of the patient's bedside early in the nineteenth century.

The first hospital based clinical laboratory was opened in Johns Hopkins in the latter part of the nineteenth century. Throughout the next 100 years the development of increasingly expensive and sophisticated equipment led to the centralisation of testing in hospital labs or at reference sites often located thousands of miles away from the patient.

In the 1960's methodology for the semi-quantitative measurement of glucose in urine was developed followed in the 1970's by the development of quantitative glucose measurement using portable meters so that analytical testing began to return to the near patient environment.

Over the last 40 years Point of Care Testing has evolved at an ever increasing rate with continuous development of increasingly complex and compact analysers facilitated by developments in micro-fluidics and microelectronics. The worldwide POCT market is expected to double over the next five to seven years.

The early and middle parts of the 20th century saw the first attempts at standardisation of laboratory practices across different sites. The CAP performed its first accreditation inspection of laboratory services in the early 60's and some 40 years later in 2003 ISO published its 15189 standard followed in 2006 with the publication of the 22870 annex to these standards.

It is now broadly accepted by the international scientific community that good laboratory practice demands competence to perform testing be demonstrated through accreditation.

Achievement of conformance to ISO 22870 'POCT-Requirements for Quality and Competence' will require laboratories to strengthen, and in some cases develop, hospital wide governance structures. Medical scientists must develop and lead training and

competency assessment schemes which review the practices of all grades of staff that may perform a test in any area of the hospital.

**Biography**
Paudy O' Gorman has worked as a Medical Scientist in AMNCH, Tallaght for over a decade. He was appointed to the role of Point of Care Testing Manager in 2007. In this role he deals with all issues pertaining to POCT throughout the hospital including device selection, staff training and Quality Management.

Paudy is currently a member of the POCT Consultative Group sub-committee and the IEQAS POCT advisory group. Paudy graduated from DIT, Kevin St. in 1997 with a degree in Biomedical Science and received a Masters in Clinical Biochemistry from Trinity College Dublin in 2007.

# Clinical Chemistry Workshop

## Standardisation: can we do better?

*Ms Hazel Graham, Quality Manager, IEQAS*

**Abstract**
Different laboratories use a variety of analysers, methods, calibrators, reference ranges and units of measurement. Are there areas in which standardisation - or at least some form of pragmatic harmonisation - could minimise confusion and potential mismanagement of patients? This presentation gives some examples, with particular emphasis on clinical chemistry. LDH: why do two-thirds of labs report pyruvate-to-lactate while the others report the reverse reaction, which gives a result ~50% lower? Creatinine: why do we use a non-specific reagent when there is a more specific reagent available? Albumin: most labs report BCG while others are moving to BCP; results can be quite different on some samples. For EQA samples, difference between method groups is often referred to as 'matrix effect'; do patients exhibit matrix effects; if we tested the same patients on the four common analytical platforms would we get identical results? Why are there multiple units of measurement in use for many therapeutic drugs, e.g. mmol/L, mg/L and mg/dL for salicylate? Are definitions for test profiles consistent throughout the country (eg liver function tests)? Are haemolysed samples treated the same way in all hospitals?

IEQAS have a facility for Special Surveys which might be useful for any further investigation.

**Biography**
Hazel Graham has worked with IEQAS since 1992 and is currently the Quality Manager. Previous work experience included various laboratory/management related roles, including 15 years with Warner Lambert, Dun Laoghaire, Co Dublin (now Pfizer), manufacturer of sterile pharmaceuticals and diagnostic reagents. She has an honours degree in Biochemistry and a post graduate Diploma in Quality Control, both from Trinity College Dublin.

## Toxicological assays in Ireland: an audit

*Mr John Herbert, National Poisons Information Centre (NPIC)*

**Abstract**
Two investigators compiled a questionnaire on the provision of pharmaceutical and chemical analyses by acute hospital laboratories in Ireland. 65 assays were chosen by cross-referencing the internet website www.assayfinder.com (accessed November 2008) with POISINDEX® System, a poisons information database. Assays were included in the questionnaire if serum/blood/plasma concentrations were reported in the medical literature. Respondents were asked to indicate which analyses were currently available, the units in which results were reported, if they were provided on-call (i.e. out of normal working hours), and whether analyses results were qualitative and/or quantitative. The NPIC produced a "Directory of Laboratory Assays" based on data obtained from the questionnaire. Based on the results received, a subset of data was analysed further: the provision of 15 quantitative analyses specifically relating to management of the poisoned patient. There is a wide availability of these 15 toxicological investigations in acute Irish hospital laboratories. Most of these analyses are available on a 24-hour basis. The units in which results are reported varied dramatically in some assays. Only one hospital laboratory provided the full complement of these 15 analyses. The laboratories in paediatric hospitals perform very few toxicological assays. Three acute hospital laboratories did not provide any of the toxicological analyses. Nationally, 19 acute hospital laboratories (48.7%) carried out at least 10 out of the 15 toxicological investigations.

**Biography**
John Herbert is a Specialist in Poisons Information at the National Poisons Information Centre, Beaumont Hospital. John was educated at Dublin City University and the University of Wales, College of Medicine. He worked briefly in the Toxicology Laboratory of Beaumont Hospital before moving to the National Poisons Information Centre where he has been working for more than 10 years.

## Harmonisation of reference ranges: survey report

*Dr Peadar McGing, Principal Biochemist, Mater Misericordiae Hospital*

**Abstract**
Reference range harmonisation has long been a strong desire of the clinical users of laboratory services. It is considered that reference range differences between pathology laboratories may confuse end users and may increase the risk of errors and mismanagement of patients.

In 2007 Dr Jonathan Berg, a Consultant Biochemist in Birmingham, initiated a project called Pathology Harmony, part of which focussed on harmonisation of reference ranges. The outcome of the Phase 1 project was agreement to harmonise ranges for ten analytes, which it was accepted there was no scientific basis for having different ranges. The UK's Dept of Health has undertaken an expansion of the Pathology Harmony project to all regions of the NHS.

There is now an opportunity for laboratories in this country to address the issue of reference ranges harmonisation, using the methods and information from Pathology harmony. A working group comprising representatives from ACBI, AMLS, IEQAS, and RCPI Faculty of Pathology has been set up to address this issue.

Through IEQAS, the working group has carried out a pilot study of reference ranges in Irish labs for sodium, potassium, and urea. The survey also investigated attitudes to harmonisation. The results of this survey will be presented and discussed at this workshop.

**Biography**
Peadar McGing is Principal Biochemist in Mater Hospital, and a Fellow of the Royal College of Pathologists. Peadar is currently Chairman of the Scientific Committee of the Association of Clinical Biochemists in Ireland and a sub-committee member of IEQAS. Peadar is a graduate of UCC (BSc) and TCD (MSc, PhD). His hobbies include athletics, tennis, writing, and photography.

## What have we learnt from international standardisation of HbA1c?

*Dr Ophelia Blake, Principal Biochemist, St James's Hospital*

**Abstract**

In 1995 the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) embarked on the development of a reference method that would be specific for $HbA_{1c}$ and lead to worldwide standardisation based on a metrologically sound international measurement and reporting unit ($HbA_{1c}$ expressed in mmoles of $HbA_{1c}$ per mole of total Hb=$[HbA_{1c}]$ + $[HbA_0]$).

The HSE working with the associated health professionals led the initiative to implement the reporting of $HbA_{1c}$ in the new IFCC units (mmol/mol) in Ireland. This was launched on the 1st of July 2010 and will ensure global standardisation and harmonisation of $HbA_{1c}$ results.

Currently, all Irish clinical laboratories and POCT areas measuring $HbA_{1c}$ have their assays traceable to the IFCC calibrator and enabled dual reporting of $HbA_{1c}$ (ie results of $HbA_{1c}$ reported in both mmol/mol (IFCC) and % (DCCT)). In Ireland, all manufacturers / suppliers of $HbA_{1c}$ assays are now compliant to the EU IVD Directive 98/79 EC.

Analytical, pre-analytical and post analytical issues from all the laboratories, both private and public, and POCT areas will be discussed. A register of all POC devices in the hospital and community areas has been set up and certificates of compliance in the IEQAS verification process have been issued.

IFCC Standardisation for $HbA_{1c}$, which is accuracy based, has the potential to improve inter-laboratory harmonisation, commutability of results across Ireland, common reference ranges and perhaps even common target and therapeutic ranges. The national test code is $HbA_{1c}$ and not A1c or any other abbreviation.

A coordinated communication campaign was organised to inform all stakeholders (including clinical laboratories, $HbA_{1c}$ assay manufacturers and suppliers, diabetologists, diabetic nurses, general practitioners, diabetic patients and all health care

professionals involved in managing diabetic patients) of the transition to the new IFCC units for $HbA_{1c}$ throughout the country. The HSE assigned the task of leading the implementation of the International Standardisation of the $HbA_{1c}$ assay in Ireland to its Diabetes Expert Advisory Group (Diabetes EAG). The EAG appointed Dr Ned Barrett as Chair of the project team which consisted of members from the HSE, ACBI, AMLS, IEQAS and RCPI Faculty of Pathology.

**Biography**

Ophelia Blake FIBMS, MIBiol, MSc, PhD, FRCPath, is a Principal Biochemist in the Clinical Biochemistry Department of St. James's Hospital, Dublin. Ophelia has interests in endocrinology, quality management and accreditation. She has served on the Scientific Committee of the ACBI and is the regional tutor of the ACB. Ophelia is a member of the IEQAS $HbA_{1c}$ Review Group and of the HSE project team set up to implement the international standardisation of $HbA_{1c}$ measurement in Ireland.

# Haematology Workshop

## Blood Cell Morphology review scheme 2009-2010

*Dr Kanthi Perera, Consultant Haematologist, Midland Regional Hospital, Tullamore*

**Abstract**
During the last year IEQAS circulated 6 morphology cases. Although the availability of slides is limited, we managed to send very informative slides to cover red cell, white cell and platelet abnormalities. The presentation will review some of the morphological abnormalities in each case with a brief review of the diagnosis, to include how you could arrive at the diagnosis.

**Biography**
Dr Kanthi Perera graduated from the Faculty of Medicine, University of Colombo, Sri Lanka, initiated her post-graduate training in Sri Lanka and completed it at The Royal London Hospital in England. She was appointed as the first Consultant Haematologist in the National Cancer Hospital in Colombo and gave the leadership for the establishment of the first stem cell transplant unit in the country at the National Cancer Hospital. Dr Perera was hugely involved with both undergraduate and postgraduate teaching in the country. She moved to Ireland in 2001 and held a temporary consultant post in Mid-Western Regional Hospital, Limerick for 3 years and in UCH Galway for 9 months and is now Consultant Haematologist at the Midland Regional Hospital in Tullamore. Dr Perera carries out regular morphology teaching for SpRs and is a member of IEQAS Haematology Review Group.

## Sysmex analysers - platelet optical counting; review of IEQAS data

*Mr Ivan Shirley, Vice-Chairman IEQAS and Chief Medical Scientist, Haematology Laboratory, SVUH*

**Abstract**
The technologies employed for Platelet counting, by different Haematology analysers, have advanced significantly in the last 10 to 15 years. These include electronic impedance, optical density and immunological methods. This has resulted in more accurate and valuable results for the patient but has led to difficulties with EQA schemes.

This presentation will review the data collated from IEQAS surveys over the last two years.

**Biography**
Ivan Shirley FAMLS is Chief Medical Scientist in the Haematology Department in St Vincent's University Hospital, Dublin. He has served on the Haematology Review group of IEQAS for 12 years and the Steering Committee for 9 years. In 2007 he was appointed Vice Chairman of the Steering Committee.

# Transfusion Workshop

## How hot is your fridge – a guide to temperature mapping

*Ms Mary White, NSAI National Metrology Laboratory*

**Abstract**
Confidence in the quality of blood samples is achieved by the storing of the packs in a temperature controlled fridge at 4ºC+/-2ºC. This is best achieved by continuous monitoring of the temperature of the fridge with traceable and calibrated thermometers. To verify this monitoring there is a requirement by the Irish Medicines Board (IMB) to have a fridge temperature mapped at regular intervals to confirm that all blood samples (Load) are stored at the same temperature. It is the responsibility of the user to ensure that the mapping is carried out correctly.

This paper addresses key factors that should be taken into account when having your fridge temperature mapped.

- The type of sensors used, are they calibrated and are they accurate enough?
- Explanation to the terms: Calibration, Traceability to National Standards, Uncertainty of Measurement and Accuracy
- How many sensors are required for temperature mapping?
- Response time and performance of sensors placed in air, liquid or blocks.
- Acceptable recovery times
- Mapping empty and full loads
- Acceptable duration times for temperature mapping.
- Errors associated with temperature mapping, radiation effect
- Relevant Standards and latest Guidelines for Temperature Mapping

**Biography**
Mary White is the Technical Manager of the Temperature and Humidity Laboratory at the NSAI/National Metrology Laboratory in Dublin. The laboratory maintains the Irish National Temperature and Humidity Standards. The Laboratory has been offering a temperature and humidity calibration service to Irish Industry for the last 26 years. The laboratory offers a variety of services including training courses, consultancy service assisting companies

set up a temperature calibration service in-house or seeking accreditation. The laboratory has carried out a number of temperature audits for companies seeking accreditation in temperature mapping.

Internationally, NSAI/NML represents Ireland's interest at EURAMET (European Association of National Metrology Institutes). Mary is the EURAMET contact person for Thermometry in Ireland. The laboratory participates in a number of EURAMET temperature inter-comparisons. One of the key roles of EURAMET is to develop technical guidance documents.

In 2010, NSAI/NML has been central to the development of a new European Guideline on Temperature Mapping. Mary was one of the co-authors of the latest document entitled Calibration Guide EURAMET/cg/20/v.01 "Calibration of Climatic Chambers, Requirements for the Accreditation of Calibration Laboratories"

She had previously represented the National Accreditation Board on European Accreditation Technical Committees from 1994 to 2001.

## Sample storage - room temperature or 4°C?

*Ms Donna Lui, AMNCH Tallaght*

**Abstract**
Currently BCSH Guidelines suggest that EDTA whole blood samples can be stored at 18°C for up to 48 hours and at 4°C for up to 7 days without a risk of deterioration. Evidence regarding the use of stored samples for pre-transfusion testing remains scarce. The objective of this study is to determine the length of time samples can be optimally stored, under what conditions and where antibody detection remains optimal. The study also aims to establish accurate variables for non-separated group and save samples such as transport and storage conditions. The effects of storage on EDTA whole blood samples at room temperature and 4°C were monitored by repeated antibody screening at time intervals which were determined by the suggested working limits. Results show that antibodies remain detectable in the serum of non-separated EDTA samples for up to 48 hours at room temperature in 94% of the patients tested. Antibody detection was lost in 7% of samples stored at 4°C by day 5 and an additional 7% by day 7. This preliminary study is still ongoing, aiming not only to broaden data in terms of number but also type of antibody investigated. Future

studies planned aim to examine the effect of whole blood storage on more specific aspects of transfusion such as crossmatching.

**Biography**
Donna Lui is currently working in the Blood Transfusion Laboratory in AMNCH, Tallaght where she has been since graduating from DIT in 2008. She will commence studying for an MSc in Transfusion and Transplantation Science at the University of Bristol, in October 2010.

## Genotyping problems solved

*Mr Mark Lambert, Irish Blood Transfusion Service*

**Abstract**
In the past decade, the use of molecular methods has become well established in Transfusion Medicine. These range from single sample testing for patient typing to high-throughput micro-array systems for donors. Many countries have introduced patient blood group genotyping, where it proves invaluable when investigating certain patients.

Molecular Blood Grouping is of particular use for multi-transfused patients, patients from more diverse ethnic backgrounds and ante-natal patients. A greater range of blood groups can be typed and unusual groups (e.g. Cdes) can be identified. In ante-natal patients, foetal RHD status can be established by non-invasive testing of the maternal plasma.

In this workshop we will discuss briefly the molecular basis of blood groups, technologies used and applications. Particular attention will be given to the application of blood group genotyping in the investigation of patients (including ante-natal) and will be illustrated with some interesting case studies. Some time will also be given for questions.

**Biography**
Mark studied Biomedical Science at DIT Kevin St, graduating in 1996 with a BSc (Appl Sci) from Trinity College Dublin. He started working with the IBTS in 1996, becoming a Senior Medical Scientist in the Red Cell Immunohaematology Referral Laboratory in 2001. Mark completed an MSc in Molecular Medicine (TCD) in 2002. He has a keen interest in Blood Group Genotyping and is currently developing Molecular Blood Grouping at the IBTS.

## Blood for your eye

*Ms Aoife Conroy, UCHG*

**Abstract**
Autologous Serum Eye drops (ASE's) are a serum-derived product used to treat patients with severe dry eye and ocular surface defects and can also be used to promote ocular healing post operatively. Serum contains higher levels of growth factors and immunoglobulins than therapeutic tear substitutes which are composed mainly of electrolytes and water.

ASE's are a relatively new therapy pioneered by Fox and co-workers in 1984 as a therapy for Sjörens syndrome. They found that treatment with ASE's lead to an improvement in the condition in just 3 weeks. The exact mechanism of ASE's is not fully understood. However, growth factors such as epidermal growth factor (EGF), vitamin A, transforming growth factor beta (TGF-ß) and fibronectin all of which are present in serum contribute to the beneficial effect of ASE's. ASE's are also proven to lubricate the eye more effectively than pharmaceutical tear substitutes.

The process of preparing Autologous Serum Eye drops involves extracting a specified volume of autologous whole blood from the patient. The unit is then centrifuged twice and the serum is removed using a plasma extractor. The serum is then diluted to 50% with sterile normal saline in a grade A Laminar Air Flow Hood. It is dispensed into dropper bottles in aliquots of 2ml, labelled for the specific patient and frozen. The bottles can then be issued to the patient for home use. They should be stored frozen and thawed daily before use. Use is dictated by the ophthalmic consultant.

**Biography**
Aoife studied Biomedical Science in DIT, since graduating in 2006; she has worked in the Blood and Tissue Establishment, Galway University Hospital as a Medical Scientist. Galway Blood and Tissue Establishment have a licensed clean room and tissue facility and currently deal with the following tissues: bones, tendons, cornea, sclera, amniotic membrane and stem cells. Aoife is responsible for establishing the Autologous Serum Eye drop programme in Galway University Hospital which is now fully licensed by the Irish Medicines Board.

# Participant Satisfaction Survey

**Introduction**

As part of IEQAS quality policy, a Participant Satisfaction Survey was issued to all participants in August 2010. All information submitted was treated as confidential and we would like to thank all who participated as your suggestions and comments are always welcome.

**Results**

Survey forms were sent to all participants registered with IEQAS (n=157); in total 91 (58%) responded, although not all answered every question. The majority of respondents were from Clinical Chemistry, Blood Transfusion, Haematology and Coagulation laboratories. Endocrinology, Immunology, Microbiology, Virology and Cytology laboratories were also represented.

**Case studies for IEQAS conference**

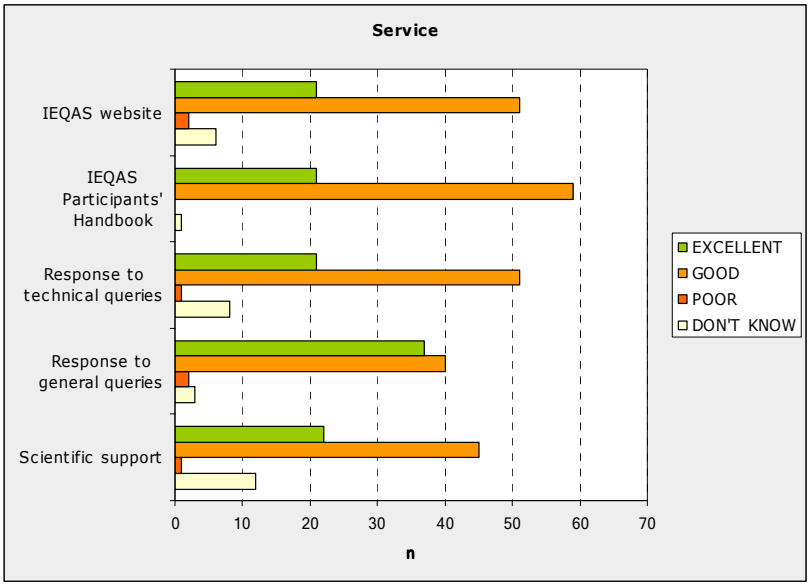
Participants were asked to submit case studies for presentation at the conference; all are included in today's programme.

**Special surveys**

Several suggestions were made, with varying degrees of information. All suggestions will be examined for feasibility by the Steering Committee. One suggested survey, the harmonisation of reference ranges, has already been started and preliminary results will be presented during the Clinical Chemistry workshop.

**Rate the service**

Participants were asked to rate IEQAS service (compare to other EQA providers) under four different headings of excellent, good and poor and don't know. The results are very encouraging, as shown in the following graph:




Participants were also asked for comments/suggestions about the service provided by IEQAS including the schemes from Labquality and WEQAS (POCT). The majority of these comments related to Labquality.

We have responses from Labquality for the following queries:

1. Participants would like to submit results on-line for more schemes.
   *Labquality have started an IT project in which their system will be modernised and improved. Improvements include increasing the number of electronic schemes. They are happy to receive comments and any ideas on this project and they should be sent to the project manager: Jonna.pelanti@labquality.fi*
2. The turn-around time between submitting results and getting reports is too long.
   *Labquality have asked all their EQA co-ordinators to improve this*.
3. Overall scoring by Labquality and consistency between IEQAS scoring and Labquality scoring was suggested.
   *Within their IT project Labquality will look into an overall scoring system and see which schemes would be suitable for implementation.*

4. Some participants feel that CueSee system is not user friendly.
   *Labquality have received this feedback from several clients and will endeavour to create a more user friendly result form on their new system.*
5. The 'Interpretation of Report' page on the Labquality website has been unavailable for some time.
   *The new version is under construction and the first part of the Guidelines will be available in October.*
6. Incorrect scores have occasionally been assigned.
   *Where this occurs Labquality will correct the errors and publish new reports.*
7. Labquality website is slow to access at times.
   *This problem should be resolved when the IT project is complete.*
8. A receipt for faxed results to Labquality would be desirable.
   *Labquality are unable to provide this at present but hope that with the improvements to the site that this will no longer be an issue.*

**$HbA_{1c}$**

During the year IEQAS assisted the HSE in implementing International Standardisation. Participants were asked if they found the role of IEQAS useful to their lab. Of those laboratories that perform $HbA_{1c}$ analysis, all but one stated that the role of IEQAS was helpful. Comments from those who took part in the project included:
"Excellent communication at all times, never felt out of the loop."
"Any future projects should be financed by HSE directly."
"Very useful in that it gave us independent external confirmation of our standardisation."

**Additional comments and suggestions**

These included:
"Essential that IEQAS are involved in any change in standardisation in future."
"Very good EQA facility with added bonus of being Irish."
"IEQAS very helpful and approachable."

**Conclusion**

This was again an extremely useful survey and we are very encouraged by the general satisfaction of the vast majority of our participants and with your very constructive suggestions.

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