IEQAS

Irish External Quality Assessment Scheme

2014
Participants' Conference

Programme
and
Book of Abstracts

Publication sponsored by LABQUALITY

Contents

IEQAS Programme 2015

IEQAS provides schemes directly, in addition to many from other EQA providers.

- ONE-STOP-SHOP for all orders and queries
- No VAT payment is required; prices in Euro

IEQAS-operated schemes

- Local advice & expertise
- Special Surveys

HbA_{1c}
Quarterly
2 Fresh single-donor blood samples (donors with diabetes)
Scored vs Reference Value
Suitable for Laboratory and POCT meters

Clinical chemistry (general)
Monthly
>3 untreated patient pools
>1 with Reference Values

Full Blood Count
2 Bi-monthly samples (analytes include RDW)

Blood Cell Morphology
Bi-monthly, educational (not scored)
Annual review at IEQAS Conference

PSA Pilot
for NCCP Designated Cancer Centres
Quarterly EQA
Common IQC

WEQAS POCT Lipids
Bi-monthly
Suitable for pharmacies, clinics and health screening

General Histopathology

on behalf of Faculty of Pathology RCPI for
Histopathologists with full/part generalist practice

12 slides twice annually

Peer review

CPD Certificates

Labquality (Finland)

IEQAS sole distributor in Ireland.

Over 150 schemes available.

Changes for 2015 will be listed on IEQAS Order Form but include:

Electronic result submission and reports for all schemes, with electronic notifications. Option to retain paper reports (additional charge).

Report results from multiple analysers (many schemes).

Reduced price if reporting fewer analytes (some schemes).

New schemes
Faecal calprotectin; Procalcitonin; Glucose meters Contour;
HbA_{1c} liquid samples POCT; INR HemoSense INRatio POCT;
Urine strip test B 15 mL; Streptococcus, group B (GBS) detection.

Discontinued schemes
Chlamydia trachomatis nucleic acid detection
– alternative scheme: Chlamydia trachomatis and Neisseria gonorrhoeae nucleic acid detection.

Drug abuse screening and confirmation in urine
– alternative scheme: Drug abuse screening in urine (expert laboratory confirmatory results included in report).

NOKLUS/EQALM

Post-analytical automated haematology survey

Participants interpret results and a plot from their main haematology instrument, along with a short case history.

LABQUALITY

Quality Assessment Services

EQAS

International external quality assessment services

- Over 150 schemes for medical laboratories
- Over 20 schemes for point-of-care testing
- Schemes for preanalytical phase

Highlights of 2015 program

- Possibility to report multiple results from one sample set in most schemes
- New limited versions of existing multi-analyte schemes schemes for 1–5 examinations
- Electronic result forms in all schemes

IQAS

Controls, calibrators and reference materials for internal quality assurance

- Reference serum panels: clinical chemistry and vitamin D
- B-Trol controls for hematology analyzers
- StrepAAg control for point-of-care testing

EDUCATION

Labquality Days 2015

- 5–6 February 2015 in Helsinki
- Quality goals and quality trends as main topics
- Internationally recognized speakers

Welcome

Welcome to this year's IEQAS Participants' Conference. Now in its 33rd year, IEQAS is one of the longest-standing quality initiatives in the Irish health service. We provide External Quality Assessment (EQA) schemes for laboratory medicine (including primary care), offering professional advice and guidance as necessary.

The scheme is educational rather than regulatory in nature and provides a means of external audit that operates continuously, thus helping laboratories to achieve their aim of continuous quality improvement.

An increasingly important role for IEQAS is participation in national and international initiatives that have the objective of improving quality of analysis in laboratory medicine, such as standardisation and harmonisation of analysis.

IEQAS is a non-trading, non-profit professional association directed by a Steering Committee consisting of nominees from the major professional bodies involved in Irish laboratory medicine.

Mr John Brady, Chairman
Dr Tom Smith, Vice-Chairman
Ms Hazel Graham, Quality Manager
Ms Patricia Howley Operations Manager
Ms Anne Kane, Scheme Administrator

On behalf of the IEQAS Steering Committee

Plenary Programme

Registration Tea/Coffee from 09:15

First Plenary Session

Chair: Mr John Brady#, Our Lady's Children's Hospital

09:45 **Opening**
Mr John Brady#, IEQAS Chairperson

10:00 **ISO 15189:2012 - Implications of Update**

- INAB perspective:
Dr Adrienne Duff, INAB

- Laboratory perspective:
Mr Brian Kelleher, St James's Hospital

11:00 **IQC Practice Survey Report:**
Dr Sean Cunningham, Joint Working Group for Irish Laboratory Accreditation

11:20 – 11:50 Tea/Coffee

Second Plenary Session

Chair: Mr Tom Smith#, SVUH

11:50 **IVD Vigilance System, working together in 2014 and beyond:** Dr Judith Martin, HPRA

12:20 **Unique EQA Schemes for Pre-analytics:** Ms Jonna Pelanti, Labquality

12:50 **IEQAS Annual Report**
Ms Patricia Howley#, IEQAS

Member of IEQAS Steering Committee * Specialist Advisor to IEQAS

13:00 – 14:15 LUNCH

Afternoon Workshops (parallel: each 14:15 – 16:00 approx)

CLINICAL CHEMISTRY

Chair: Ms Paula O'Shea, President ACBI

14:15 **Master comparisons with native sera and patient percentile monitoring – A valuable quality management tool for laboratories and manufacturers**
Dr Katleen Van Uytfanghe & Dr Dietmar Stöckl, University of Ghent, Belgium

14:45 **IQC…A Quest for Consistency**: Dr Graham Lee, Mater UH

15:30 **'Corrected' Ca survey report – what are we doing and what should we be doing?**
Dr Peadar McGing*, Mater UH

15:45 **eGFR update:** Mr Rowland Reece, SVUH

HAEMATOLOGY

Chair: Ms Therese Driscoll, Tallaght*

14:15 **Annual Blood Cell Morphology scheme review**
Dr Kanthi Perera*, MRH Tullamore

15:15 **Update on ICSH standardisation projects: Critical values management survey and harmonisation for units of measurement:** Mr Richard McCafferty*, St James's Hospital

15:45 **Case Study: An investigation of aplastic crisis in a patient with Hereditary Spherocytosis**: Mr Steven Cullen, Tallaght Hospital

MICROBIOLOGY

Chair: Dr Susan Fitzgerald#, SVUH

14:15 **Integrating the lean concept into microbiology; the SVUH experience:** Ms Niamh O'Connell, SVUH

14:45 **The introduction of an automated urine analyser into the routine diagnostic laboratory**: Ms Niamh Murphy, St James's Hospital

15:15 **Introduction of PCR for detection of faecal pathogens into the routine diagnostic laboratory:** Ms Colleen Cunningham, Waterford Regional Hospital

TRANSFUSION

Chair: Mr Gerry Judge#, Tallaght

14:15 **Hemosafe, locked, stocked and issued:** Mr Ken Gregg, Cavan General Hospital

14:45 **Antibody Screen positive - could it be Bombay?** Mr Mark Lambert, IBTS

15:15 **Octaplas for Therapeutic Plasmapheresis - how much do you need?** Ms Blaithin Tormey, Tallaght Hospital

l# Member of IEQAS Steering Committee * Specialist Advisor to IEQAS

IEQAS

Steering Committee

Brady, John[1]	Chairman Laboratory Manager, Our Lady's Children's Hospital
Smith, Tom[2]	Vice-Chairman Principal Biochemist, St Vincent's University Hospital
Barrett, Ned[2]	Formerly Consultant Clinical Biochemist, University Hospital, Limerick
Carr, Alan[1]	Senior Medical Scientist, AMNCH Tallaght
Fitzgerald, Susan[3]	Consultant Microbiologist, St Vincent's University Hospital
Graham, Hazel[5]	IEQAS Quality Manager
Griffin, Damian[3]	Consultant Chemical Pathologist, Galway University Hospital
Howley, Patricia[5]	IEQAS Operations Manager
Judge, Gerry[4]	Chief Medical Scientist, AMNCH Tallaght
Murphy, Dympna[4]	Chief Medical Scientist, AMNCH Tallaght
Shirley, Ivan[1]	Chief Medical Scientist, 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
[4]Co-opted by Steering Committee
[5]IEQAS Operations Management

Additional Specialist Advisors

Boran, Gerard	Consultant Chemical Pathologist, AMNCH Tallaght
Clarke, Frank	Lecturer, School of Biological Sciences, DIT
Driscoll, Therese	Senior Medical Scientist, AMNCH Tallaght
Kane, Anne	IEQAS Scheme Administrator
McCafferty, Richard	Chief Medical Scientist, St James's Hospital
McGing, Peadar	Principal Biochemist, Mater University Hospital
O'Kelly, Ruth	Principal Clinical Biochemist, Coombe Women & Infants University Hospital
O'Sullivan, Niamh	Consultant Microbiologist, Our Lady's Children's Hospital / Coombe Women & Infants University Hospital
Perera, Kanthi	Consultant Haematologist, Midland Reg Hosp Tullamore
Reece, Rowland	Principal Biochemist, St Vincent's University Hospital

Operations Management

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

IEQAS
Irish External Quality Assessment Scheme

2014 Annual Conference supported by sponsorship from

MEDICON IRELAND LIMITED	General sponsorship
biomnis YOUR PARTNER IN PATHOLOGY	Bags
LABQUALITY	Book of Abstracts
CUBICIN®	Microbiology Workshop & General sponsorship
Abbott Diagnostics	Badges and stationery
Roche	First Plenary Session
BECKMAN COULTER	Morning coffee
ACBI	Clinical Chemistry Workshop
	Transfusion Workshop

Stationery also provided by Accuscience and AMLS

We also wish to thank all members of the IEQAS Steering Committee and other Specialist Advisors for their continued support and commitment.

Abstracts: Plenary

ISO 15189:2012 - Implications of update
(a) INAB perspective

Dr Adrienne Duff, Manager, INAB

Abstract

The third revision of ISO 15189 (Medical laboratories – requirements for quality and competence) was published in 2012 and it was agreed that there be a three year transition of accredited laboratories to this version of the standard. This presentation will review the key changes from the previous version and consider the INAB and laboratory transition plans in ensuring accreditation to the 2012 version. Some examples of issues arising from assessments to date will be discussed.

Biography

Adrienne Duff graduated from University College Dublin with a degree and PhD in Chemistry. She has worked for many years in both the public and private sectors. Adrienne joined INAB in 2002 as a senior accreditation officer where she gained experience in all accreditation schemes. She was appointed Manager of INAB in September 2008.

ISO 15189:2012 - Implications of update
(b) Laboratory perspective

Mr Brian Kelleher, Quality Manager, St James's Hospital

Abstract

The ISO produced an updated version of the standard for medical laboratories in November 2012. There are changes both major and minor between ISO 15189:2012 and the previous 2007 standard. INAB asked all existing accredited laboratories to submit a transition plan with a view to conducting inspections against the new standard from May 2014 onwards.

With the exception of Blood Transfusion, the Department of Laboratory Medicine in St. James's Hospital was accredited previously by CPA and the transition to ISO 15189 presented some particular challenges, especially in the integration of essentially separate departmental Quality Management Systems into a single integrated QMS.

The most significant additions to the standard are:

Clause 4.2.1. Definition and control of laboratory processes, and

Clause 4.14.6 Risk Management of laboratory processes

The St. James's Laboratory approach to implementation of these new requirements will be described, along with an update on efforts by the Academy of Medical Laboratory Sciences to develop a set of templates that would allow a consistency of approach by laboratories country-wide to process mapping and risk assessment.

Biography

Brian Kelleher (FAMLS) has been the overall Quality Manager of the Department of Laboratory Medicine in St. James's Hospital since 2008. He holds an M.Sc. in Clinical Medicine from Trinity College Dublin and the Diploma in Quality Management – Lean Healthcare Systems from the University of Limerick. He previously worked as a Medical Scientist in the Department of Haematology in St. James's Hospital.

IQC practice survey report

Dr Sean Cunningham, Joint Working Group for Irish Laboratory Accreditation

Abstract

The Joint Working Group on Irish Laboratory Accreditation (JWG ILA) has been aware of anecdotal reports that some INAB assessors considered that there is a lack of uniformity among Irish laboratories in the application and use of internal quality control (IQC) procedures.

Therefore the JWG ILA decided to draft and issue an IQC questionnaire survey to obtain information on current practice in Irish laboratories. It was considered that this would be a first step which could lead to a consensus on IQC procedures and possibly to an agreed IQC Policy. The IQC Survey was issued to Quality Managers in Irish hospital laboratories and was intended for blood sciences laboratories generating numerical results. We were interested in capturing data from both routine and specialised areas and requested that the survey should be completed by each major section of the Blood Sciences Laboratories.

Sixty responses were received which included 28 from Clinical Biochemistry Laboratories and 26 from Haematology / Coagulation Laboratories. While the Survey responses demonstrated that many laboratories have a similar approach to IQC procedures, the results also identified a number of areas in which there are significant differences in procedures, for instance, in the frequency of running controls and in the rejection criteria used. These and other responses will be further discussed in the presentation.

Biography

Dr Cunningham obtained his BSc Hons and PhD in Biochemistry from UCD and an MSc in Clinical Biochemistry from TCD.

He was initially employed as a Clinical Biochemist in the Mater Hospital and was later Principal Clinical Biochemist at the Endocrine Laboratory in St Vincent's University Hospital. In 1994 he became Consultant Clinical Biochemist and Director of the Clinical Biochemistry Laboratory at St Vincent's. He retired from this post at the end of 2012, but has remained as Consultant Clinical Biochemist to St Luke's Hospital, Rathgar.

He is author or co-author of over 60 publications.

He was winner of the AMES Medal 1984, presented by the Association of Clinical Biochemists (UK) and was awarded the

Nordisk Medal Award Lecture 1999, invited by the Irish Endocrine Society.

He is a past President of the Association of Clinical Biochemists in Ireland (ACBI) and was a member of ACBI Council many years.

He is currently Chairman of the JWG ILA and is a member of the INAB Medical Advisory Committee.

He was involved in Point of Care Testing for many years and is currently a member of an IFCC Working Group on Glucose Meters for use in Critical Care areas.

IVD Vigilance System, working together in 2014 and beyond

Dr Judith Martin, IVD Product Manager, Health Products Regulatory Authority *(HPRA formerly IMB)*

Abstract

The medical device vigilance system was set up under the Medical Device Directives with the objective of minimising the risk to the safety of patients, users and others. The vigilance system achieves its objectives in four principle ways:

•analysing manufacturer and user vigilance reports submitted to the relevant authorities (in the case of Ireland the HPRA);

•evaluating incidents reported by the relevant authorities;

•disseminating information to minimise the chances of incident reoccurrence or to alleviate the consequences of same;

•updating, modifying and, where necessary, removing devices from the market.

There is a mandatory requirement for manufacturers to report vigilance issues in line with the European Guidelines on a Medical Devices Vigilance System (MEDDEV 2.12-1).

The HPRA currently operates a voluntary reporting system for users, whereby a user, healthcare professional or, indeed, any individual who identifies a medical device safety issue can report it directly to the HPRA. Genuine engagement and effective communication with external stakeholders has been identified by the HPRA as a priority for 2014 and beyond. The HPRA strongly encourages health professionals and members of the public who have encountered a medical device safety issue to report the incident. Increased reporting levels may contribute to the early detection of adverse trends and/or safety issues. By enhancing its relationship with health professionals and members of the public, the HPRA hopes to increase incident reporting and to establish an effective regulatory feedback loop regarding device performance.

Biography

Judith Martin joined the Health Products Regulatory Authority, formerly the Irish Medicines Board (IMB), in 2008 as Product Manager for in vitro diagnostic medical devices (IVDs). In 2012 her role expanded to include infusion/transfusion/dialysis products and blood-related products, among other medical devices. In her role, Judith manages vigilance issues across this range of medical devices. She also represents the HPRA on the Point of Care

Consultative Group at National level and on the IVD Technical Working Group at a European level. Prior to joining the HPRA, Judith worked as technical support manager with an IVD manufacturer. Judith holds an honours degree in biotechnology. She completed her PhD and postdoctoral studies in the areas of biotechnology, biochemistry and microbiology during her five-year tenure at Alltech Ireland.

Unique EQA schemes for Pre-analytics

Ms Jonna Pelanti, Head of ICT and Production, Labquality

Abstract

External quality assessment (EQA) of clinical laboratories traditionally consists of simultaneous analysis of identical samples by the participants. The samples are analyzed, the results submitted and the applied methods reported. The results are compared to those obtained by users of the same methods. This is however only a small part of the whole measuring process in a laboratory which, particularly in countries with highly developed analytics, is already a highly refined process. Any significant variation in the mean results can only be caused by human error or gross defects in the equipment, for example in pipetting devices. EQA reports traditionally concentrate on showing the analytical accuracy of results.

Lately, however, many articles have expressed the view that most analytical errors occur before the samples arrives in the laboratory, i.e. at the pre-analytical stage. Errors occur particularly in sampling and sample handling. Figures vary from one source to another but it can be said that about 50 % of measurement errors occur at the pre-analytical stage. About 20-45% of errors occur after the actual analysis, at the post-analytical stage. [1, 2]

Errors in the pre-analytical phase include e.g. wrong test request, wrong sample time, erroneous patient identification, inappropriate sample container, hemolysis, clotting or errors in transportation or storage. Some of the errors that have happened might go unnoticed and it is important that everybody participating in the sampling and analysis process understand the importance of the pre-analytical phase.

Pre-analytical errors may endanger the patient but they may also lead to financial losses due to the need for repeat samples, extra working time and materials. In traditional EQA, such errors are not revealed at all because this part of the process is not examined. To examine the quality of the total process and to further refine the total process, performance must therefore be examined at every stage.

Labquality, the Finnish EQA organization, started pre-analytical EQAS in 2014. The new pre-analytical EQA schemes provide unique means to assess a larger part of the total laboratory testing process and not just the commonly surveyed analytical phase.

Managing all phases of the total testing cycle is equally important to ensure patient safety. Altogether four pre-analytical schemes are available for the areas of Clinical chemistry, Phlebotomy and POC testing, Microbiology and Blood gas analysis. In these schemes, real life case studies are presented and a multiple choice questionnaire probing the pre-analytical phase is filled out by the participants. The goal is to provide a comprehensive view on the appropriateness of the pre-analytical phase to the participants. The approach of the schemes is educational and the results are not scored.

The experiences in 2014 have been very positive and enthusiastic and the participation for these rounds is expected to grow. Labquality aims to provide laboratories and POCT units with tools for extending quality assurance beyond the commonly assessed analytical phase, and will continue to provide pre-analytical EQAS. In this presentation the design and results of these pre-analytical schemes will be presented.

1. Errors in a stat laboratory: types and frequencies 10 years later, Carraro P., Plebani M., Clin Chem 53 (7) (2007) 1338-42.

2. Toward optimal laboratory use. Problems in laboratory testing in primary care, Nutting PA, Min DS, Fischer PM, Stull TM, Pontius M, Seifert M Jr, Boone DJ, Holcomb S, JAMA 275 (8) (1996) 635-9.

Biography

Jonna Pelanti has a master of science in technology degree from Helsinki University of Technology and a clinical biochemist degree from Helsinki University faculty of medicine. She began her professional training in Helsinki University central hospital in 2001 when working with her master's thesis on measurement of nitric oxide in human samples. After graduating from Helsinki University of Technology she went on to work with the detection of forbidden substances in animals in the Finnish food safety authority Evira. In 2007 she began her specialization training as clinical biochemist in the hospital district of Helsinki and Uusimaa.

After graduating from Helsinki University faculty of medicine Jonna joined Labquality where she first started as an EQA coordinator and is now heading the company's ICT and EQA production and is a part of the management team. Jonna's main responsibility is to develop Labquality's new IT-system LabScala which is a web based portal used by Labquality's customers and employees.

Jonna is interested in external quality assurance in general and as a science. She finds that it is important to work towards a more unified level of results in laboratory medicine through co-operation between EQA-providers, customers and relevant institutions and organisations. She has, thanks to her technology background, an interest and knowledge in information technologies. She is fascinated with developing external quality assurance and eventually patient safety through professional utilisation of modern IT solutions.

IEQAS annual report 2013/2014

Ms Patricia Howley, Operations Manager, IEQAS

Now in our 33rd year, IEQAS continues to provide and expand a wide-ranging EQA service. We currently have participants in over 85 different schemes run either by IEQAS directly or in collaboration with other European EQA schemes. IEQAS has ISO:2008 certification and passed our most recent surveillance audit with no citations.

An increasingly important role for IEQAS is participation in national and international initiatives that have the objective of improving quality of analysis in laboratory medicine, such as standardisation and harmonisation of analysis. Initiatives include:

- NCCP Harmonisation of PSA assay: IEQAS is continuing to assist the National Cancer Control Programme with this project. A pilot EQA scheme, with four single-donor samples per year is now running for the NCCP Designated Cancer Centres. Common IQC material is also planned.
- Histopathology EQA scheme: administered by IEQAS on behalf of the Faculty of Pathology, Royal College of Physicians of Ireland, with over 80 participants.
- EQALM: IEQAS is a member of the European Organisation for EQAP in Laboratory Medicine and provides our participants with EQALM occasional surveys.
- Health Products Regulatory Authority: IEQAS have regular contact with the HPRA; individual participant performance is never discussed and remains the responsibility of the participant.
- Empower Project for Clinical Chemistry: IEQAS participants have been invited to join this international project by Prof Linda Thienpont (Ghent, Belgium), which aims to provide a platform for laboratory/manufacturer dialogue and assay improvement. Dr Katleen Van Uytfanghe & Dr Dietmar Stöckl will present the project later today.
- POCT: Patricia Howley represents IEQAS on the National POCT Committee. Our EQA scheme for POCT Lipids, offered in collaboration with our WEQAS colleagues, is growing due to new 'Guidance on the Provision of Testing Services in Pharmacies' published by the Pharmaceutical Society of Ireland in Feb 2014. Patricia Howley gives

regular presentations to pharmacists about the need for quality checks on Cardiovascular Risk Assessment training days, organised by the Irish Heart Foundation and The Irish Pharmacy Union.

- ICSH: Jointly with the Academy, IEQAS have affiliated with the International Council for Standardisation in Haematology; Richard McCafferty is the Irish representative. An international survey on International Practise on critical values was undertaken and will be presented later today.
- Labquality Finland: IEQAS is the sole distributor in Ireland for this international EQA provider, which has 4500 laboratories from more than 40 countries participating in their programme of >150 different schemes. These should be ordered directly with IEQAS, who are also responsible for any queries you may have throughout the year. A presentation on their recently introduced unique EQA schemes for pre-analytics is included in today's programme.

We wish to thank all members of the Steering Committee and other IEQAS Specialist Advisors for their continued support and commitment. We welcome two new Specialist Advisors: Anne Kane and Richard McCafferty and thank outgoing advisors Eileen Byrne, Clare Mulligan, Paudy O'Gorman, Paula O'Shea and William Quirke.

Thanks also to the staff in Tallaght, SVUH, Mater University Hospital and OLCH Crumlin for facilitating IEQAS with sample preparation, storage and distribution.

Our order forms for 2015 will be sent out shortly. A summary of all schemes offered by IEQAS, and the changes for 2015, is included with this booklet. We plan to include delegate places for next year's conference on the Order Form.

Biography
Patricia Howley BSc, MSc (Quality & Safety in Healthcare Management), joined IEQAS in 1999 as Scheme Administrator. She became Operations Manager in 2007. Patricia represents IEQAS on the National POCT Group.

Abstracts: Clinical Chemistry Workshop

IQC...A Quest for Consistency

Dr Graham Lee, Principal Biochemist, Mater University Hospital, Dublin

Abstract:
Multiple options exist at each stage in the development of an IQC programme. This may contribute to reported inter-laboratory disparity both in its delivery and the level of quality attained. We propose a framework for the development of an IQC programme and the promotion of a national standardised approach. In this workshop we will explore various stages in the design and delivery of an IQC programme and will provide practical experiences and examples of six-sigma metric based approaches.

Biography
Graham Lee is Principal Biochemist in Clinical Biochemistry & Diagnostic Endocrinology at the Mater University Hospital, Dublin (2010 to present).

Pre-registration training years (4yrs) in Belfast Trust (Royal Victoria & City Hospitals) & Royal Derby Foundation Trust before HPC registration as Clinical Scientist in Biochemistry in 2009. Fellow of the Royal College of Pathologists since 2010. Research interests include Cardiomyocyte Hypertrophy (PhD); Microvascular complications of Diabetes (Post-Doctoral Research Fellow); Phaeochromocytoma and biochemical diagnosis; Cardiac biomarkers.

Graham has the position of ACB regional tutor (Jan 2013) & tutor with School of Biomedical Sciences (Current tutoring modules: MSc in Clinical Chemistry and Post-graduate Diploma in Clinical Biochemistry). Expert member of UK NEQAS Specialist Advisory Group for Interpretative Comments

Master comparisons with native sera and patient percentile monitoring – A valuable quality management tool for laboratories and manufacturers

Dr Katleen Van Uytfanghe, University of Ghent & Dr Dietmar Stöckl, STT Consulting

Abstract

Background

Classical external quality assessment (EQA) is well established, however, the need for integrated EQA-services recently emerged, among others to empower clinical laboratories for future tasks, e.g., contribution to the development and implementation of global health-care policies. Also, ISO 15189 accreditation requires laboratories to identify and monitor quality indicators. From this perspective, we developed the Empower project.

Methods

The project comprises 4 pillars: (i) master comparisons with panels of frozen single donation sera, (ii) virtual EQA-1 and (iii) - EQA-2 based on data readily available in the laboratory, i.e., patient- and internal quality control (IQC) results, and (iv) conceptual/statistical education about analytical quality. The pillars (i) to (iii) are conducted across laboratories and manufacturers. The master comparisons aim at participation of 20 laboratories per manufacturer, and encourages the latter to include also their in-house laboratories. It is essential that the participants use homogeneous systems, i.e., instrument, calibrator and reagent from the same manufacturer. Virtual EQA-1 (patient percentile monitoring) requires the laboratories to calculate and send the daily medians of the results for outpatients. We plot the moving median of the collected data in time. The participants can consult a graphical user-interface to monitor the mid- to long-term stability of their performance in comparison to other peer group laboratories.

Results

The value of the master comparisons is in showing the intrinsic quality of assays as performed under 'field' conditions, the performance of the individual laboratory within its peer group and the calibration fix-point and interchangeability of results between laboratories/manufacturers. Monitoring of patient data gives evidence about the mid- to long-term analytical variation of testing in the individual laboratory, backed-up by information on peer group performance. It also enables to uncover biases between

different instruments in a laboratory, as well as occurrence of shifts/drifts. The observation of biases may also help laboratories to understand the sometimes fluctuating flagging frequency of results.

Conclusions
The Empower project reflects on the mid- to long-term analytical stability of laboratory/assay performance and enables to uncover all major bias components/sources. Hence, it is a new integrated tool for modern quality management. Its major asset is that it works with data generated from commutable samples, and linked to observations in daily IQC practice. It strengthens the position of laboratories in their claims from manufacturers, facilitates the dialogue at the laboratory-clinician interface, and is a tool for the discipline to derive realistic quality specifications. On longer term, it might establish a constructive relationship between laboratories, manufacturers, clinicians and health policy makers, so that together they can build towards a common understanding about manageable quality of performance to the benefit of the patient.

Biography
Dietmar Stöckl (born 1954), PhD, Analytical Chemist
1982: PhD-thesis "Negative Chemical Ionization Mass Spectrometry", University of Cologne.
1983/4: Mass spectrometric structure elucidation in pharmaceutical research (Kali Chemie, Hannover, Germany).
1984/5: Post-doc at the Joint Research Centrum of the European Community, Ispra, Italy: "Indoor air pollution". During that stay: Work at the Norwegian Institute of Air Research (NILU, Lillestrøm, Norway).
1985/7: Research position at the University of Göttingen: "Mass spectrometric investigation of plant hormones".
1988/95: Institut für Standardisierung und Dokumentation im medizinischen Laboratorium eV (INSTAND, Düsseldorf, Germany): "Establishment and head of the reference laboratory".
Since 1995: Establishment of the scientific consulting bureau STT Consulting and free researcher in the laboratory of Prof. Dr. L. Thienpont (University of Ghent, Laboratory of Analytical Chemistry, Belgium, until September 2011).
Main interests: The role of analytical quality in laboratory medicine; the psychology of decision making.

Specific connection to EQAS:
-1988/95: Institut für Standardisierung und Dokumentation im medizinischen Laboratorium eV (INSTAND, Düsseldorf, Germany): "Establishment and head of the reference laboratory".
-Member of European External Quality Assessment Organizers Working Group A: Analytical goals in Laboratory Medicine. 1991-1996 (initiated by A. Uldall).
-Member of European External Quality Assessment Organizers Working Group B: Target Values in EQAS. 1991-1996 (initiated by A. Uldall).
Specific connection to EQAS (work done with Linda Thienpont)
-Development of concepts for modern EQAS; in particular, matrix-free assessment of test-system bias by use of single donations with and without reference method target values.
-Newest development: The "Empower Project" that conceptually integrates assessment of quality and stability of diagnostic assays by use of master comparisons with single-donation sera and continuous monitoring of results already available in the laboratory (IQC-results; patient results).
-More than 15 publications directly linked to EQAS.

Katleen Van Uytfanghe (born 1979), PhD, Analytical Chemist
2001: Master of Science in Chemistry, UGent
2007: PhD degree in Pharmaceutical Sciences, UGent - "Reference measurement procedures for free testosteron, (free) thyroxine and insulin in human serum"

Katleen Van Uytfanghe is a postdoctoral fellow in the Laboratory for Analytical Chemistry at Ghent University, where she is the quality manager and technical supervisor of the ISO17025 and ISO15195 accredited reference laboratory. She also supervises the doctoral students. Besides this, she is the scientific secretary of the International Federation of Clinical Chemistry and Laboratory Medicine Committee for Standardization of Thyroid Function Tests.
She has expertise in development and validation of higher order reference measurement procedures and profound experience with method comparison data.

‘Corrected’ Ca survey report – what are we doing and what should we be doing?

Dr Peadar McGing, Principal Biochemist, Mater University Hospital, Dublin

Abstract

Calcium in blood is approximately 50% bound to proteins (predominantly albumin), 3% complexed, and 47% ionised (“free”). Ionised calcium is what the body responds to but we measure total calcium because currently it is not possible to measure ionised calcium on automated platforms.

In patients with hypoalbuminaemia the amount of bound calcium falls even though the ionised calcium may be normal. The result is an apparent hypocalcaemia when total calcium is measured. The response to such a result varies between acting as if it is true (and treating the patient), ‘correcting’ for the low albumin by an appropriate or inappropriate correction formula, assuming the patient is not hypocalcaemic (whether true or not), or measuring the actual ionised calcium.

This workshop will focus on whether ‘corrected’ / ‘adjusted’ calcium calculation is appropriate, and if it is deemed appropriate who should do the calculation (lab or end-user), what calculation should be used, and how does one derive a formula specific to one’s own lab’s methods. All views will be welcome.

Biography

Dr Peadar McGing is a Principal Biochemist in the Mater University Hospital. He is also a Specialist Advisor to IEQAS, and regularly provides patient samples for IEQAS Clinical Chemistry distributions. He has a special interest in “correction” of calcium results by the laboratory in cases of hypoalbuminaemia and is looking forward to hosting a lively workshop where the disparate approaches to this issue can be discussed.

eGFR update

Mr Rowland Reece, Principal Biochemist, St. Vincent's University Hospital, Dublin

Abstract

The IEQAS eGFR scheme has been running since June 2012 and scoring participating laboratories since January 2013. Initial data were presented at IEQAS 2012. Initially 14 laboratories signed up to the scheme. Current overall performance for 18 participating laboratories is good; however, not all laboratories reporting creatinine are also reporting eGFR (66% participation).

The data will be discussed in this context.

The introduction of the 2009 CKD-EPI equation (KDIGO 2012 Clinical Practice Guidelines) and its impact on laboratories and IEQAS, if any, will be discussed.

Biography

Rowland Reece, FRCPath., is Principal Clinical Biochemist in St.Vincent's University Hospital Dublin. He previously worked in UCHG and Beaumont hospitals.

He is a Specialist Advisor to IEQAS

Abstracts: Haematology Workshop

Blood Cell Morphology Scheme review 2013-2014

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

Abstract

During the last year IEQAS circulated 6 morphology cases. 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.

Update on ICSH standardisation projects: Critical values management survey and harmonisation for units of measurement

Mr Richard McCafferty, Chief Medical Scientist, St James's Hospital, Dublin

Abstract

The International Council for Standardization in Haematology (ICSH) was originally founded as a standardizing committee associated with the European Society of Haematology in 1963. It is a not-for-profit organisation that aims to achieve reliable and reproducible results in laboratory analysis in the field of diagnostic haematology.

The ICSH coordinates Working Groups of experts to examine laboratory methods and instruments for haematological analyses, to deliberate on issues of standardization and to stimulate and coordinate scientific work as necessary towards the development of international standardization materials and guidelines.

Many national laboratory professional bodies and EQA schemes worldwide are affiliated to the ICSH and contribute to its work. Both IEQAS and the Academy of Medical Laboratory Science are formally affiliated as of 2014. Irish laboratories have already contributed, through IEQAS, to ICSH surveys in relation to several projects, which include (1) Peripheral blood film review and reporting, (2) Standardization of units for Haematology reporting and (3) Communication of critical results. These projects aim to produce published guidelines or recommendations for best practice internationally. This presentation will include an overview of the work of the ICSH and an update will be given on the detailed progress in particular in regard to the latter two projects. The current position in Ireland in regard to the standardization of units of measurement will also be presented.

Biography

Richard McCafferty has been Chief Medical Scientist in Haematology at St James's Hospital since 1997 and has over 20 years experience at a senior level in haematology laboratory management. He has been Chair of the Haematology Advisory Body of the Academy of Medical Laboratory Science since 2006 and has led the organisation of blood cell morphology workshops and seminars or short courses in haemostasis, diagnosis of haematological malignancy, haemoglobinopathies and flow cytometry, presented by Irish and international speakers.

Case Study: An investigation of aplastic crisis in a patient with Hereditary Spherocytosis

Mr Steven Cullen, Tallaght Hospital and DIT

Abstract

Background: Patients with Hereditary Spherocytosis have an increased dependence on erythropoiesis due to the reduced life span of the spherocytes. For these patients, any condition that causes a reduction in erythropoiesis is far more dangerous than it would be in a healthy individual.

Case Details: A 36 year old woman with known Hereditary Spherocytosis is admitted to A&E after collapsing with flu like symptoms.

Methods: Full blood count & Differential, Blood Film Microscopy, Serology.

Biography

Steven Cullen is a 4th year Biomedical Science Student, Dublin Institute of Technology.

Abstracts: Microbiology Workshop

Integrating the lean concept into microbiology; the SVUH experience

Ms Niamh O'Connell, Senior Medical Scientist, SVUH

Abstract

Lean is a systematic approach to identifying waste or non-value added activities. The main objective of lean, when applied to a laboratory, is to deliver quality patient laboratory results, at the lowest cost, within the shortest time-frame while maintaining user satisfaction.

St. Vincent's University Hospital Microbiology department currently receives around 150,000 specimens annually and is part of a major academic teaching hospital. In March 2013, Biomerieux performed a laboratory workflow assessment with the aim of creating a roadmap of recommendations for the transformational improvement of the laboratory. Drivers of this project included increasing workloads, reduced budget and staff shortages.

Following a three day observation period that included staff interviews, recommendations for improvement were made including the implementation of a functional-cell concept by the centralisation of sample reception, processing and reading areas, productivity gains by streamlining and automating, matching staff with the workload, continuous blood culture entry, electronic test ordering system and changes to the paper report. The laboratory's changes made to date include changes to the workflow and introduction of automated systems.

These changes have led to a greatly improved laboratory workflow and staff engagement in the in the process improvement project has led to greater workload flexibility.

The improvements to the process are proving beneficial to the laboratory staff and service users. Lean projects can produce organisational benefits such as more efficient staff, changes to the way processes are performed, improved cost-effectiveness, higher process quality and overall, better value for money. However, there are limitations to what can be achieved with lean methodology in the healthcare setting.

Biography

2008 Graduated from DIT with honours BSc. And commenced my career as Medical Scientist in Microbiology in SVUH.

2009 Publication: Sherlock O, O'Connell N, Creamer E, Humphries H. 2009. 'Is it really clean? An evaluation of the efficacy of four methods of determining hospital cleanliness'. Journal of Hospital Infection 72: 140-146.
2011 Oral presentation: ISCM Autumn meeting, RCPI.
2012 Graduated from UCC/CIT with MSc in Biomedical Science. As part of the MSc, I studied lean and quality management.
2013 Poster presentation: Presented at ECCMID, Berlin.
2013 Appointed Senior Medical Scientist in Microbiology in SVUH.
2014 Publication: Paper on ESBLs submitted for publication to the Journal of Hospital Infection, September 2014.

The introduction of an automated urine analyser into the routine diagnostic laboratory

Ms Niamh Murphy, Senior Medical Scientist, St James's Hospital, Dublin

Abstract

Automation in Microbiology is progressing at a very rapid rate. This talk will outline the process of introducing the Sysmex UF-1000i urine analyser and the subsequent validation of the analyser to the routine microbiology laboratory in St James's Hospital.

We shall look at the modifications required to the workflow on the urine bench, the analysis principle of the UF-1000i and the benefits and challenges encountered in switching from conventional microscopy to flow cytometry.

Biography

- BA(mod) in Microbiology from Trinity College Dublin
- Higher Diploma in Training and Education from the University of Galway
- MSc in Medical Mycology from University College London.

Niamh is a senior Medical Scientist working in the Microbiology Laboratory of St James Hospital.

Introduction of PCR for detection of faecal pathogens into the routine diagnostic laboratory

Ms Colleen Cunningham, Waterford Regional Hospital

Abstract

Current isolation methods for detection of diarrhoeal-associated bacteria rely on selective stool culture but these techniques are laborious, time consuming and lack sensitivity. The multiplex EntericBio real-time PCR assay uses target specific hydrolysis probes to simultaneously detect Campylobacter, Salmonella, verotoxins 1 and 2 for verotoxigenic Escherichia coli (VTEC) and Shigella directly from stool specimens.

In July 2012, the regional microbiology laboratory in University Hospital Waterford, which processes an average 10,000 stools per annum, evaluated the applicability of a new testing algorithm for the detection of enteric pathogens. The commercially available EntericBio real-time Gastro Panel I PCR system which is performed without DNA extraction or pre-enrichment steps was validated against culture methodologies using 458 stool samples. Sample processing requires approximately four hours to complete with pipetting steps and the PCR protocol is carried out on automatic platforms, thereby minimising the staff hands on time required. The study demonstrated an increase in pathogen detection rates from 6.1% to 12.2% and the PCR inhibition rate was 0.07%. Compared to culture, the overall sensitivity, specificity, PPV and NPV of the real-time PCR assay was calculated to be 95.45%, 99.5%, 96.9% and 99.3%, respectively. The real-time PCR system demonstrated superior results to culture for Campylobacter and VTEC but convalescent carriage of Salmonella requires an enrichment step. No Shigella was detected by PCR or culture during the study.

In December 2012, the EntericBio PCR system was introduced in the microbiology laboratory as a screening tool for stool specimens. The PCR assay has facilitated the streamlining of the workflow of the enteric laboratory by reducing the staff hands on time for a full PCR run (46 specimens) by 62% and the turnaround time for results by approximately 78%. Use of the system in 2013 increased detection rates of Campylobacter by 15% compared with the same period in 2012. Over 50% more E.coli O157 cases were also reported and 116 non-O157 VTEC infections were diagnosed in the South-East of Ireland in 2013. The EntericBio PCR system reduces laboratory waste, increases staff productivity, eliminates

negative specimens and provides rapid presumptive positive results to optimise patient care.

Biography

I have worked in the Microbiology Department, University Hospital Waterford for the last six years. In 2012, as part of my MSc in Biomedical Science, I carried out the first clinical investigations of the commercially available EntericBio real-time PCR system. During the research, I worked closely with members of the Biological Sciences department in Cork Institute of Technology (CIT) to confirm discrepant results. I have presented the results of this research at the Irish Society of Consultant Microbiologist (ISCM) conference and LabCon.

Abstracts: Transfusion Workshop

Hemosafe, locked, stocked and issued

Mr Ken Gregg, Senior Medical Scientist, Cavan General Hospital

Abstract

Drawing from 5 years' experience with the hemosafe fridge as both a stock and issue fridge this presentation will endeavour to set out and explain the following areas.

1. What is a hemosafe?
2. Why choose the hemosafe?
3. How the hemosafe is used for both stock and X Matched red cells?
4. Implementation of the hemosafe including interfacing issues
5. Training around the hemosafe
6. Pros, cons and issues as seen within Cavan General Hospital
7. The future of hemosafe in CGH Blood Transfusion including the management of blood products and the use of the hemosafe for either remote issue or electronic issue.

Biography

Ken Gregg FIBMS, FAMLS, DMLM

Currently Senior Medical Scientist in Blood Transfusion Department of Cavan General Hospital and with responsibility for the CGH LIMS.

Currently in my 43rd year as a Medical Scientist, have worked for 27 years in N Ireland where I worked in various Belfast Hospitals before moving to Enniskillen and spent 24 years there, which included a short period in Omagh. During this time I have had two major secondments, the first to project the implementation of OCM in Erne Hospital Enniskillen and second to project manage the development of a Microbiology module for the Regional Laboratory Information Management System. Also during these years I was the N Ireland representative on the Council for Professions Supplementary to medicine where I introduced the initiative "Training for Trainers" and reworked the Transfusion Sciences training manual. In my later years there I co-founded the Northern Ireland Transfusion Discussion Group (NITS) and lead the initiative North / South Transfusion meetings under the title "Irish Blood Bankers"

In 1999 I moved to Monaghan General Hospital where I had the dubious honour of overseeing the closing of the laboratory there and then moved with the rest of the Monaghan staff to Cavan General Hospital. During this time I have had many years of involvement with the Academy of Medical Sciences including chairing the Transfusion Advisory Body and while on Council helped developed the online training and CPD module of the Academy website.

Outside of work I have an interest in farming and a lifelong passion for Motor Sport which has now carrying on into the 3rd generation.

Antibody Screen positive - could it be Bombay?

Mr Mark Lambert, Senior Medical Scientist, IBTS

Abstract

The majority of samples sent to a hospital blood transfusion laboratory will be not contain irregular red cell allo-antibodies. Providing units for transfusion poses no problems. If the patient's antibody screen is positive, then further investigation is required. More often than not the identification of these red cell antibodies are well within the capability of the hospital transfusion laboratory; being single specificity or simple multiple-specificities.

What happens if the specificity is not easy to identify? All panel cells are positive (IAT ± enzyme-treated) and the patient's auto-control is negative. The patient has an allo-antibody, but which one? Is it an allo-antibody to a high frequency antigen?

Depending on the patient's ethic background and enzyme-sensitivity (or resistance), the specificity can be varied [e.g. African (U, Jsb, Joa); Asian (Jk3, Oka); Caucasian (Kpb, Lan); Indian (Inb, H)].

A 57 year old male Caucasian patient was referred to the IBTS for investigation and provision of 2 units to cover bladder cancer resection (previous history of TURP). All cells gave 3+ reactions by IAT and 4+ by papanised cells and by 'cold'-panel cells. Both auto-control and DAT were negative. Based on these reactions and the patient's ethnic origin additional tests were performed.

The antibody was conclusively identified as anti-H and the patient's cells typed as H- (a Bombay individual). The patient's two brothers have also been identified as Oh with anti-H. They have been assessed for donor suitability and are being recruited as 'Bombay' donors for the UK frozen blood bank.

Sequencing of FUT1 and FUT2 has identified the cause of this Oh phenotype as compound heterozygosity for two novel mutations in FUT1: 310C>T and 496G>T.

Biography

Mark graduated in 1996 DIT Kevin St/ Trinity College Dublin, becoming a permanent staff member at the IBTS in 1998. In 2001 he became Senior Medical Scientist in the Red Cell Immunohaematology Referral Laboratory. The following year he completed his MSc in Molecular Medicine (TCD) and is currently reading for a PhD in Genetics (part-time) at Trinity College Dublin.

Mark is a Fellow of the Academy of Medical Laboratory Science (FAMLS) and a Member of the Institute of Biomedical Science (MIBMS), the International Society of Blood Transfusion (ISBT) and the Irish Society of Human Genetics (ISHG). In 2014 he became a Chartered Scientist (CSci) with the Science Council UK.

Octaplas for Therapeutic Plasmapheresis - how much do you need?

Ms Blaithin Tormey, Senior Medical Scientist, Tallaght Hospital

Abstract

A 53 yr old female patient was transferred to Tallaght hospital with fever, renal impairment, reduced level of consciousness, thrombocytopenia and a DAT Negative haemolytic anaemia. These symptoms were indicative of a Microangiopathic Haemolytic Anaemia type condition such as Thrombotic Thrombocytopenic Purpura (TTP) or Haemorrhagic Uraemic Syndrome (HUS). The treatment for TTP/HUS is plasma exchange with frozen plasma. As plasma exchange was not available on admission plasma infusion was initiated on day 1. Plasma exchange was commenced on day 3.

It was recommended that the volume of plasma replaced was 1.5 times the patient's plasma volume and the blood bank's role in this procedure was to provide the required volumes of thawed plasma in a timely fashion. In this case each procedure required approximately 30bags of Octaplas. As the patient's blood group was B Rh D Positive this was our entire stock of B Octaplas. Extra stocks had to be ordered in. This presented storage problems in the Blood Bank and greater levels of communication with the IBTS. The patient underwent frequent plasmapheresis over a 3 week period and blood parameters such as Hb, platelet count, LDH were monitored regularly.

This case presented a number of logistical problems for the Hospital, the Blood Bank and the IBTS and these will be discussed.

Biography

Blaithin Tormey BSc, MSc, FAMLS is a Senior Medical Scientist in the Blood Transfusion Department of Tallaght Hospital since 2004.

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