

# ACBNews

The Association for Clinical Biochemistry & Laboratory Medicine | Issue 655 | October 2018



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## About ACB News

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### Lead Editor

**Mr Ian Hanning**

Retired

Formerly Department of Clinical Chemistry

Hull Royal Infirmary

Email: editor.acbnews@acb.org.uk

### Associate Editors

**Mrs Sophie Barnes**

Department of Clinical Biochemistry

Charing Cross Hospital

Email: sophiebarnes@nhs.net

**Dr Gina Frederick**

Pathology Laboratory

Royal Derby Hospital

Email: gina.frederick1@nhs.net

**Mrs Nicola Merrett**

Department of Laboratory Medicine

University Hospital Southampton NHS

Foundation Trust

Email: nicola.merrett@uhs.nhs.uk

**Dr Christopher Pitt**

Department of Biochemistry

NHS Ayrshire & Arran

Email: christopher.pitt@aapct.scot.nhs.uk

**Dr Derren Ready**

National Infection Service

Public Health England

Email: derren.ready@phe.gov.uk

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Email: admin@acb.org.uk

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### ACB Administrative Office

Association for Clinical Biochemistry

& Laboratory Medicine

130-132 Tooley Street

London SE1 2TU

Tel: 0207-403-8001

Fax: 0207-403-8006

Email: admin@acb.org.uk

### ACB President

**Professor Ian Young**

Tel: 028-9063-2743

Email: president@acb.org.uk

Twitter: @ACBPresident

### ACB Home Page

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

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*Front cover: Mike Bosomworth, Director of Finance, taking a well-earned rest on his sponsored cycle ride across Canada*

# ACB News

The bi-monthly magazine for clinical science

Issue 655 • October 2018

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The Association for  
**Clinical Biochemistry &  
Laboratory Medicine**

*Better Science, Better Testing, Better Care*

## Hyperkalaemia Alert

In August the ACB received correspondence about NHSI safety alert NHS/PSA/RE/2018/006 relating to the management of hyperkalaemia: <https://www.cas.mhra.gov.uk/ViewAndAcknowledge/viewAlert.aspx?AlertID=102787>

While the content of this is clearly relevant to NHS laboratories, the ACB was not consulted about the alert and had no prior warning that it was to be released.

The ACB believes that good practice in UK laboratories should already address the issues highlighted, and in addition the importance of considering pre-analytical factors when interpreting results, but it is clearly important for all laboratories to review their procedures in light of the alert and supporting documents to ensure that they are appropriate. ■

## Director of Clinical Practice

In accordance with the provision of Articles 14 and Bye-law 6, nominations are called for the position of Director of Clinical Practice. Nominations for this position, duly countersigned, should be made on the nomination form on page 12 in this issue of ACB News and sent before 31st October 2018 to:

ACB Administrative Office, 130-132 Tooley Street, London SE1 2TU. ■

## Condolences

It is with regret that we must inform you of the sad news that ACB Retired and Founder Member, Miss Jean Walker Summerscales, died on 17th May 2018 at the age of 93.

Miss Summerscales joined the Association in 1953 as a Founder Member, was based in Leeds, and retired from full-time employment in 1992. ■

## FiLM 2019

Please note that FiLM 2019 will be held on 29th & 30th January 2019 at the usual venue, Austin Court, Birmingham. For further details, please see the advert on page 31. ■

## Sudoku

### This month's puzzle

	R	I				E	S	
	T						C	
H								I
T			Y		S			R
	S		T	R	I		E	
		M	R	E	H	C		
	C			T			Y	
R								M

## Solution for August

T	M	E	H	S	I	R	C	Y
Y	I	R	C	E	M	S	H	T
C	H	S	T	R	Y	M	E	I
S	T	H	I	Y	R	E	M	C
M	E	Y	S	H	C	T	I	R
I	R	C	M	T	E	Y	S	H
E	Y	I	R	C	S	H	T	M
H	S	M	Y	I	T	C	R	E
R	C	T	E	M	H	I	Y	S



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## Sponsored Cycle Ride . . . An Update (Week 8)

**Mike Bosomworth, Director of Finance**

This ride has proved to be a much bigger challenge than my ride across the USA, primarily I think because the roads are much more difficult, if not at times downright dangerous. On the whole, there is no alternative to the main transCanadian route (Highway 1 or 17 depending on the province). Consequently one just has to ride on a very narrow hardshoulder, or in the traffic itself.

The Canadians, who are extremely friendly at all times and patient when at a road junction, just seem to think that they have the right to drive at, or above the speed limit once on the highway, irrespective of what else may be present. The motorised vehicle is king! I have been run off the road more than once and even been reported to the police for riding on the highway! In Quebec Province the attitude to cycling is completely different, with hardshoulders or cycleways to ride on much of the time. Cyclists are far better tolerated if not welcome (*vivre La Quebec*).

Unfortunately, I developed saddle sores early in the ride and they were certainly a very real problem. Fortunately they did eventually begin to heal, but as they did, I developed what I think is metatarsalgia, especially in my right foot. The joys of long distance cycling!

I have been disappointed at the amount of wildlife that I have seen. No moose and one black bear that was laid at the side of the road. In Quebec I have followed the route of the whales, but sadly none seen.

Perversely, just as I hit unseasonably late snow in the Rockies in the US, here in Canada I hit a heatwave with temperatures up to 43°C in the Rockies and on the prairies.

Enough of the negatives. I have seen some fantastic sights e.g. the Rockies, the Hoodoos at Drumheller, the dinosaur provincial park in Saskatchewan. Lake



Superior region was superb and there, Agawa Bay was well worth the visit. The scenery in Quebec has been spectacular. I have been treated to beer and shared a BBQ with a guy at a motel in Manitoba. I have met some wonderful people and seen some amazing countryside.

I am now (10th September) on my way back to Quebec City having cycled as far up the Gulf of St Lawrence as Moisie, a small village about 20 miles north east of Sept-Iles. I think that I can now fairly claim to have cycled across Canada. Although cycling alone, I could not have done it without the support of family and friends back home and those that I have met along the way. This will almost certainly be my last solo long distance bike ride. It has been a real challenge (around 4,000 miles thus far) and at the time of writing I still have about 500 miles to ride back to Quebec city. That said it has been a real experience. As is true within the ACB, there are more genuine and friendly people in this world than the other kind. It is also true that challenges like this give time for reflection and make one appreciate just how important family and friends really are.

If you would like to sponsor me please visit: [www.virginmoneygiving.com/mikebosomworth](http://www.virginmoneygiving.com/mikebosomworth)

Many thanks to those who have already done so. ■



# RIQAS

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## Updated ACB Assay Verification/Validation Programs

**Dr Ed Wilkes, Dr Zahra Khatami and Professor Anders Kallner on behalf of the ACB Informatics Special Interest Group**

Updated versions of the ACB Assay Verification/Validation Programs, authored by Professor Anders Kallner, have recently been uploaded to the ACB website:

[http://www.acb.org.uk/whatwedo/science/best\\_practice/measurement\\_verification.aspx](http://www.acb.org.uk/whatwedo/science/best_practice/measurement_verification.aspx)

Previously referred to as spreadsheets A-D, these have now been renamed to the following:

- ◆ **Precision (imprecision) and trueness (bias)** – previously “Spreadsheet A”
- ◆ **Trueness (bias)**
  - a. From EQA materials - previously “Spreadsheet D”
  - b. From reference materials – previously “Spreadsheet C”
- ◆ **ROC analyses (NEW)**
- ◆ **Method comparison** – previously “Spreadsheet B”

### Instruction Documents

Each program is now associated with an instruction document (in PDF format) which

provides a brief background to the statistics used in each case. Each document and its associated program are listed under “Program & instructions”.

### Example Data

Dummy/example data are provided for each spreadsheet under the “Example data” heading. Instructions for analysing these data are given in the associated instruction document.

### Verification

These programs have been independently verified. Copies of the data used for their testing and the associated verification documents are listed under the “*Verification document & data*” heading in each case. The code contained within these documents can be copied and pasted into any instance of the R statistical computing environment (<https://www.r-project.org/>) and, given the provided test data in each case, reproduce the verification analysis. ■

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## ACB Scotland National Autumn Meeting

### Celebrating the Career of Dr Bill Bartlett

**Friday 9th November 2018**

**The Station Hotel, Perth PH1 8HE**

ACB Scotland would like to announce our forthcoming meeting.

Due to generous sponsorship, this meeting is free to attend for ACB Members. However, prior registration is compulsory and registration forms must be received.

To view the meeting programme and register visit:

[http://www.acb.org.uk/whatwedo/events/regional\\_meetings.aspx](http://www.acb.org.uk/whatwedo/events/regional_meetings.aspx)

*We would like to acknowledge the kind support for this meeting from BIOHIT Healthcare, Alexion and Siemens. ■*



## Sample Delivery

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## Hospital

Royal Devon & Exeter, Barrack Road, Exeter EX2 5DW

## Biologic Drug Therapy

Biologic therapies used in the treatment of patients, with cancers and inflammatory conditions, have rapidly expanded in recent years, revolutionising patient management. The cost to the NHS is currently over 1 billion pounds per year and although extremely effective in the majority of patients, some will lose response due to development of Anti-Drug Antibodies. Therapeutic drug monitoring to identify these individuals is essential to avoid both adverse side effects and the significant expense of prescribing high cost, ineffective treatment.

## Exeter Clinical Laboratory Biologic Monitoring Services

We are a national referral service currently providing Adalimumab and Infliximab testing for more than 150 hospitals across the whole of the UK and Ireland, performing greater than 17,000 tests per year.

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Infliximab total anti-drug-antibody	5 days	£29.50
Adalimumab drug	7 days	£29.50
Adalimumab total anti-drug-antibody	7 days	£29.50
Golimumab drug	4 weeks	£29.50
Golimumab free anti-drug-antibody	4 weeks	£29.50
Vedolizumab drug	4 weeks	Please contact laboratory for price
Remsima companion diagnostic	5 days	Free of charge
Inflectra companion diagnostics	5 days	Free of charge

We are expanding our biologics monitoring service to include drug and anti-drug-antibody levels for the following agents:

- Certolizumab
- Etanercept
- Ustekinumab
- Rituximab

Exeter Clinical Laboratories are a centre of excellence, internationally recognised for our research expertise and specialist services in gastroenterology and diabetes.

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## **British Mass Spectrometry Society 3rd Clinical and Forensic Specialist Group Meeting**

# **Mass Spectrometry in the Clinical Laboratory**

**Thursday 15th November 2018**

**The Foresight Centre – University of Liverpool  
1 Brownlow Street, Liverpool L69 3GL**

09:30-10:00	Registration
10:00-10:15	Introduction and Purpose of the Meeting <i>Andrew Davison and John Dutton, SIG leaders, BMSS</i>
10:15-10:45	Historical Development of the Triple Quad Mass Spectrometer <i>Simon Szwandt, Thermo Scientific</i>
10:45-11:15	Coffee Break
11:15-11:45	Theory and Principles of Mass Spectrometry <i>Chris Hopley, LGC, Teddington</i>
11:45-12:15	Method Validation in the Clinical Laboratory <i>Laura Owen, Salford Royal NHS Foundation Trust</i>
12:15-12:45	Quantitation in Mass Spectrometry <i>Lewis Couchman, ASI London</i>
12:45-13:30	Lunch
13:30-14:00	Automated Mass Spectrometry: Myth or Reality? <i>Sally Benton, Frimley Park Hospital</i>
14:00-14:30	High Resolution Mass Spectrometry and Toxicology <i>Chris Reeves, Manchester Royal Infirmary</i>
14:30-15:15	Coffee Break
15:15-15:45	From Mummies to Metabolites <i>Anna Milan and Andrew Davison, Royal Liverpool and Broadgreen University Hospital NHS Trust</i>
15:45-16:30	Mass Spectrometry-Based Discovery, Development and Delivery of Multiplexed Protein Tests for an Era of Precision Medicine <i>Prof Steve Pennington, University College Dublin</i>
16:30-16:40	Closing Comments and Discussion

Approved for CPD from Royal College of Pathologists  
and Institute of Biomedical Scientists

For further information and booking please visit:  
<http://www.bmss.org.uk/mscl2018/registration.shtml>

# SAVE THE DATE

## The All Wales Inherited Metabolic Disease Study Day

### Wednesday 6th March 2019

Venue : Cardiff

Target audience: Doctors, Nurses, Medical Trainees, Dieticians and Biochemists with an interest in metabolic disease as well as Acute Care Physicians, Endocrinologists and Paediatricians who wish to update their knowledge on acute general metabolic and storage disorders.

Topics to include metabolic encephalopathy, acute management of metabolic disease, storage disease, mitochondrial disorders, acute porphyria, etc.

Registration: £25.00 to include all refreshments and lunch.

CPD accreditation to be applied for.

*For further information and a registration form please contact:  
Jacqui McAleer, JM Associates, email: [jmassociates1@me.com](mailto:jmassociates1@me.com)*

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**Association for Clinical Biochemistry  
& Laboratory Medicine  
Council Nomination Form**

**Election of Officers/Council Members 2018**

We, the undersigned, being Members of the Association nominate

Name .....

Address .....

.....

.....

for election as Director of Clinical Practice.

Name 1. ....  
Capitals Signature

Name 2. ....  
Capitals Signature

Name 3. ....  
Capitals Signature

I am willing to undertake the duties and responsibilities of this office if elected.

.....  
Signature Date

Please note only Ordinary and Honorary Members of the ACB may be nominated for the position of Director of Clinical Practice.

If there is more than one nominee for this position, a ballot will be held with all voting members. (see Bye-Laws of the ACB items 2 & 3 and 8).

This form, duly countersigned, to be returned to:  
The Administrative Office  
Association for Clinical Biochemistry & Laboratory Medicine  
130-132 Tooley Street  
London SE1 2TU  
**before 31st October 2018**

## The Diggle Microbiology Challenge

These multiple-choice questions, set by Dr Mathew Diggle, are designed with Trainees in mind and will help with preparation for the Microbiology Part 1 FRCPATH exam.

### Question 9 from August's ACB News

Which drug potentiates the action of sulphonamides?

- A) Isoniazid B) Vancomycin C) Nitrofurantoin D) Trimethoprim E) Nalidixic Acid

### Answer

**D: Trimethoprim:** the sulphonamides and trimethoprim are two DNA synthesis inhibitors that demonstrate synergy as both compounds inhibit folate synthesis, but act on different reactions in the synthesis pathway. The sulphonamides act on early folate synthesis whereas trimethoprim acts on late folate synthesis, thus mopping up any pre-cursor molecules that were not inhibited by sulphonamide activity. Isoniazid is active against mycobacteria and inhibits mycolic acid synthesis. Vancomycin is a cell wall active agent that acts on peptidoglycan cross-linking. Nitrofurantoin is a DNA synthesis inhibitor that causes damage to macromolecules such as DNA and ribosomal proteins via the activity of reduced reactive intermediates. Nalidixic acid is also a DNA synthesis inhibitor, but which acts on DNA gyrase and topoisomerase.

### Question 10

What would you expect to see in a patient with Streptococcal impetigo?

- A) Elevated ASO B) Elevated ASS C) Elevated anti DNase B D) Elevated anti NAD  
E) Elevated anti hyaluronidase

The answer to Question 10 will appear in the next issue of ACB News – enjoy! ■

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- ⇒ golimumab (e. g. Simponi®)
- ⇒ vedolizumab (e. g. Entyvio®) **NEW!**

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# Deacon's Challenge

## No 198 - Answer

A 25 year old anorexic female was admitted via A&E with marked emaciation and the following plasma results:

Urea	=	1.5 mmol/L	Sodium	=	120 mmol/L
Creatinine	=	30 µmol/L	Potassium	=	2.5 mmol/L

On the ward a repeat blood revealed her plasma osmolality to be 248 mmol/L. A 6 h urine collection yielded the following results:

Volume	=	0.185 L
Osmolality	=	55 mmol/L

Calculate the free water clearance (in mL/min) and comment on your result.

The first step is to calculate the osmolar clearance ( $C_{osm}$ ) which is the volume of plasma from which all filterable solutes are removed in any given time period (usually expressed in mL/min). In principle the calculation is identical to any other clearance:

$$C_{osm} = \frac{U_{osm} \times V}{P_{osm}}$$

Where  $U_{osm}$  = urine osmolality = 55 mmol/L

$P_{osm}$  = plasma osmolality = 248 mmol/L

$V$  = urine flow rate in mL/min.

Multiply the volume of urine collected by 1,000 to convert from L to mL, divide by 6 to convert from 6 h to 1 h, then finally divide by 60 to convert from 1 h to 1 min:

$$V = \frac{0.185 \times 1,000}{6 \times 60} = 0.514 \text{ mL/min (to 3 sig figs)}$$

$$\text{and } C_{osm} = \frac{55 \times 0.514}{248} = 0.114 \text{ mL/min (to 3 sig figs)}$$

The calculated difference between the urine flow rate and the osmolar clearance is known as the free water clearance ( $C_{water}$ ):

$$C_{water} = V - C_{osm} = 0.514 - 0.114 = 0.40 \text{ mL/min (to 2 sig figs)}$$

The free water clearance is that excreted in addition to that required for excretion of the solute load. Since the value is positive it represents the volume of water extracted from the plasma per minute. In spite of this the patient is still hyponatraemic and is most likely the result of reduced solute available for excretion (particularly urea) due to poor intake (particularly of protein). The diluting capacity of the renal tubules is limited and the lowest attainable urine osmolality is about 50 mmol/L. With a medium protein diet



producing approx. 1200 mmol of solute (mainly urea) the maximum urine volume would be  $1200/50 = 24$  L per day. In starvation reduced intake (even with increased tissue breakdown) reduces the amount of solute available for excretion. If available solute were to fall as low as 100 mmol/day then the maximum urine output would be  $100/50 = 2$  L per day. If fluid intake were to exceed this value then the ability to excrete water would be seriously impaired resulting in hyponatraemia.

## Question 199

You are setting up an assay for serum adenosine deaminase in which 20  $\mu\text{L}$  of serum is first equilibrated at  $37^\circ\text{C}$  with 1.5 mL of buffer in a cuvette with 0.5 cm light path. The reaction is initiated by adding 25  $\mu\text{L}$  of substrate then monitored by measuring the rate of decrease in absorbance at 265 nm. Both substrate and product absorb at this wavelength with the absorbance of inosine being 43% of that due to adenosine.

Derive a factor to convert the rate of absorbance change (per minute) to units of adenosine deaminase activity (expressed as  $\mu\text{mol inosine}/\text{min}/\text{L serum}$ ). The molar absorptivity of adenosine is  $13,400 \text{ L}\cdot\text{cm}^{-1}\cdot\text{mol}^{-1}$ .

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Address for samples

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# The National Congenital Anomaly and Rare Disease Registration Service

Mary Bythell and Jeanette Aston, both from the Registration Service

**This report was submitted by invitation from the ACB News Lead Editor following Mailbase posting**

For most of us, September always has a 'back to school' feel, no matter how old we are or where we work. It is no different for the teams here at the National Congenital Anomaly and Rare Disease Registration Service (NCARDS) as we prepare to implement planned projects and explore new ideas. NCARDS, for those who haven't come across our organisation, is part of the National Disease Registration Service, which is in turn part of Public Health England. Our remit is to collect data on people with congenital anomalies and rare disease across England and to work closely with clinicians, patient groups, public health colleagues, researchers and charities to improve patient care and outcomes.

We now collect data routinely from 244 healthcare providers and have 100% coverage of births in England for congenital anomaly reporting. That is thanks to the great work of our NHS organisers, the staff at our eight regional centres, the UK's commitment to providing a world class strategy for tackling rare diseases, and the support of our stakeholders.

As we all returned from our various summer holidays last month we began to

focus on four projects that involve Clinical Biochemistry laboratories, each at various levels of progress.

## Wilson's Disease

This project involves the introduction of prospective reporting of new confirmed and suspected cases of Wilson's Disease by the Supra-Regional Assay Service (SAS). It is based on the existing reporting system for lead poisoning in children. The new system entails the submission of a short form to NCARDS via email when a test indicates Wilson's Disease. Laboratories will shortly receive a letter describing the reporting system, a copy of the form and instructions for safe completed form transfer.

This is part of a bigger national project on determining the prevalence of Wilson's Disease. We've been delighted by the support that we've received from the Clinical Biochemistry community on this project, including Dr Paul Cook (Southampton) and Godfrey Gillet (Sheffield), who are members of the Wilson's Disease Special Interest Group. Godfrey introduced us to the ACB Mailbase Discussion List, which has led to some rewarding interactions with our colleagues in Clinical Biochemistry. We will continue to use the Mailbase to update you on the progress of our work. Jeanette Aston, our Rare Disease Data Liaison, is the NCARDS contact on the Mailbase and can be contacted by email: [jeanette.aston@phe.gov.uk](mailto:jeanette.aston@phe.gov.uk)



*Jeanette Aston*

### **Non-Invasive Prenatal Screening**

At the same time, we've been preparing for the NHS Fetal Anomaly Screening Programme Non-Invasive Prenatal Testing (NIPT) Programme. We will be collecting data to support the evaluative roll out from the Clinical Biochemistry laboratories. Preparatory work is well underway and we thank those of you who have been involved with helping us to set up the required data feeds. This has been a massive undertaking and we will update you on the progress in a future *ACB News* edition.

### **Inherited Metabolic Diseases**

Before the end of the financial year, we aim to have systems in place for prospective reporting on confirmed and suspected cases of the newborn blood spot inherited metabolic diseases. This work will not only support our phenylketonuria (PHE) screening colleagues, but will allow us to collect identifiable data to support understanding, treatment and improved patient outcomes for these conditions. We will be in touch with heads of laboratories to discuss this soon.



*Mary Bythell*

### **ANCA-Associated Vasculitis**

Finally, Dr Fiona Peace (Nottingham) has been leading on a project with us to determine the national prevalence rates for some rare rheumatological conditions. We will be contacting Immunology laboratory colleagues in the coming months to scope how we might work together to get a better understanding of these conditions, particularly ANCA-associated vasculitis.

Nothing stands still for long and it can be hard to keep up in this fast changing environment. We rely on our clinical colleagues to help us to navigate the complexity and nuance of congenital anomalies and rare disease. What NCARDS offers is the potential to look at these issues from a national (England) perspective. We look forward to collaborating with you on these and other projects.

If you would like to discuss any of the projects mentioned in the article or have ideas for new ones, please contact Mary Bythell, Head of Rare Disease Registration for NCARDS by email: [mary.bythell@phe.gov.uk](mailto:mary.bythell@phe.gov.uk) ■



# Transforming NHSScotland's Laboratory Medicine Services: A Blueprint for a Future

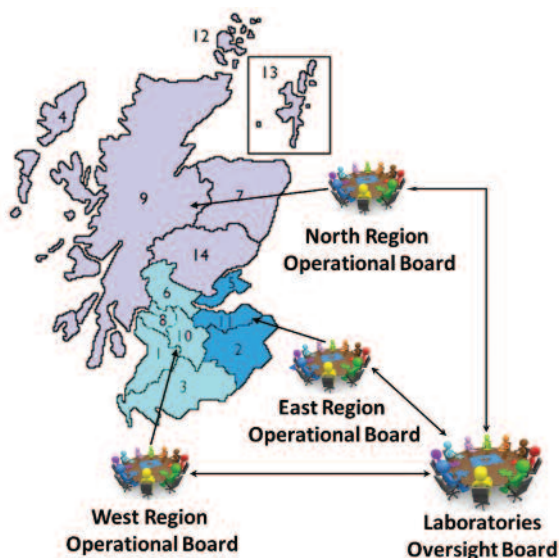
**Dr Bill Bartlett, Clinical Lead National Laboratories Programme NHS National Services Scotland; and Mr Paul Hawkins, Chief Executive NHSFife and Chair of the Laboratories Oversight Board**

NHSScotland provides healthcare to a population of approximately 5.3 million people across an area that constitutes a third of the UK land mass. It is a complex organisation that faces challenges around rising demand and many other drivers for change common to the rest of the UK. These drivers in combination with a fundamental requirement to deliver better care, better experience of care and better cost of care (Triple Aim) are driving the need for transformation of services. It follows that underpinning services, such as those provided by laboratories, must also undergo transformation to

deliver future requirements of the evolving healthcare system. Given the dependence of patient pathways and outcomes upon laboratory outputs, failure to deliver transformed services that are optimally configured to address both local and national priorities will compromise the value of investment in diagnostics and delivery of Triple Aim. New service configurations need to deliver equitability of access, efficiency in delivery, effectiveness in impact, resiliency and sustainability of service and be not least affordable. Taking all these issues into account, a process involving service

**Operational structures being developed to enable regional delivery of a distributed service model for laboratories that is nationally consistent**

1. NHS Ayrshire & Arran
2. NHS Borders
3. NHS Dumfries & Galloway
4. NHS Western Isles
5. NHS Fife
6. NHS Forth Valley
7. NHS Grampian
8. NHS Greater Glasgow & Clyde
9. NHS Highland
10. NHS Lanarkshire
11. NHS Lothian
12. NHS Orkney
13. NHS Shetland
14. NHS Tayside



providers and stakeholders has resulted in the agreement to move forward with the development of a Distributed Service Model (DSM) for laboratory services within NHSScotland. A blueprint and set of guiding principles have been developed to enable the DSM delivery under a new governance structure. This sees the establishment of a Laboratory Oversight Board to facilitate the development of the DSM through new Regional structures. NHS National Services Scotland (NSS) has been tasked by the Scottish Chief Executives group with delivery of a National Laboratories Programme which has been allocated £6.7m to progress initial key work to enable the DSM development.

The current National Laboratories Programme has arisen from work undertaken through the NHSScotland Shared Services Programme (SSP). That programme was extended to deliver a Health Portfolio that included laboratories in 2015. In 2016 a small team was established within the SSP Health portfolio tasked specifically to development of the laboratories element. That team worked with the laboratory service providers and other stakeholders through a number of workshops to develop a position paper on laboratory shared services that was presented to NHSScotland Chief Executives in October 2016. That paper included a detailed PESTEL and SWOT analysis of the current service model and also took into account work undertaken by NHSScotland's Managed Diagnostics Networks presented to the Diagnostic Steering Group in 2015. It resulted in a mandate to move forward to delivery of a strategic paper based on a proposal to develop a DSM for laboratory services in Scotland and to establish a small number of working groups around information technology, data and innovative technology (e.g. digital pathology). The position paper also identified a set of

guiding principles to be followed in the development of services to realise the concept of the DSM.

The DSM strategy paper was delivered in July 2017 and described the case for change with a high-level description of the proposed model emerging through extensive stakeholder engagement. The contention put forward was that stakeholders agreed that there is an opportunity to use the significant resources – workforce, facilities, equipment and finance – available to Health Boards to deliver laboratory services in a way that is more efficient, effective, equitable, resilient and affordable. The DSM concept is one of delivery of an optimal service configuration in the various localities across Scotland. The delivery units are to provide the correct volume, range and repertoire of tests reported within an appropriate timescale to meet the needs of the locality and configured as a whole to enable delivery of national priorities in the context of Triple Aim. A strategic aim of the DSM is therefore delivery of an optimal distribution of laboratory services across Scotland with concentration of workloads and sharing of expertise across wider geographical areas. The concept is one that addresses drivers for change and requires delivery of a functional distribution of service across the system to deliver whole healthcare system value and resilience rather than *de facto* centralisation in order to reduce the cost of the laboratory service.

Delivery of the DSM will depend upon coordination across and between laboratories and standardisation of operating procedures across services. In planning terms this will equate to a single virtual service functioning to consistent standards across the wider organisations while different aspects of service are delivered by the relevant operational unit at the most appropriate

## Desirable attributes of NHSScotland's future distributed service model for laboratory services



level whether national, regional, Health Board level, individual hospital or community.

The detailed strategy paper was approved and work subsequently undertaken to develop a full business case presented to CEs in April of 2018. This built on previous work with further input from an IT Group, a Data Group and DSM Design Group. The case reflected the requirement identified in the earlier position paper to take an incremental approach to the delivery of the DSM, the emerging regionalisation agenda arising from the publication of the Scottish Government's Health and Social Care Delivery Plan in 2016 and the need to have a new governance structure to support this agenda and further ensure and assure national consistency of service. The business case was accepted and funding was allocated to a National Laboratories Programme with the following Key deliverables from the business case:

- ◆ A new governance structure that supports the delivery of a DSM with

national consistency.

- ◆ A National Laboratories Blueprint for the DSM. Delivering a vision for the laboratory services focusing on process, organisation, technology and information.
- ◆ IT Connectivity, with all Scottish laboratories implementing NPEx for lab to lab electronic ordering.
- ◆ Data sharing, through development of a national data platform to support business and clinical intelligence requirements.
- ◆ A high level specification for LIMS to enable national consistency in a key procurement area.

It is important to note that the incremental approach is being taken with the view of achieving short to medium term benefits, adding value to laboratory services while maintaining a clear focus on the longer-term transformational change required to deliver the optimal DSM. The final form of the DSM will ultimately reflect function, meeting the needs of stakeholders, which in turn will be defined

by the requirements of NHSScotland's healthcare delivery model evolving in the context of the National Clinical Strategy.

Longer term benefits are anticipated that are both financial and non-financial, in part these will be achieved through the appropriate consolidation of services, facilities and equipment and whole system laboratory service redesign. The business case illustrated the potential benefits of laboratory service transformation with examples from current initiatives in Scotland. It also recognised the fact that delivery of optimised services with appropriate allocation of resources has the potential to deliver significant downstream benefits to overall healthcare delivery and the potential to address current risks (e.g. service resilience, requirement for investment in new technologies). Clearly there is a drive for change to address the issues of variation and waste within the current system, but this should be seen as an opportunity to identify resource to invest into developments that increase the effectiveness and thus value of the allocated resource envelope. Developments in technology, information and knowledge management, artificial intelligence, the medical evidence base and the emergence of new modes of practice (precision medicine) will challenge the delivery model and potentially enhance the value of redesigned services.

The scale and complexity of the task to be undertaken to deliver the DSM should not be underestimated. NHSScotland's clinical laboratory services are currently provided by 14 territorial and 2 special Health Boards (Scottish National Blood Transfusion Service, Golden Jubilee National Hospital) and have a projected spend of £1.5 billion over the next five years. Focusing on the territorial Boards it is estimated that over 3,800 full time equivalent staff are directly involved in service delivery across 27 sites out of 87

laboratories. In addition, total NHS service provision also includes a number of national services commissioned by NSS; there is therefore a considerable resource managed and applied through a complex model with multiple stakeholders involved in service provision and usage. Following the publication of the Health and Social Care Delivery Plan, the territorial Boards have been allocated to 3 regions for the purposes of planning:

#### **North Region**

NHSGrampian  
NHSHighland  
NHSOrkney  
NHSShetland  
NHSTayside  
NHSWestern Isles

#### **East Region**

NHSBorders  
NHSFife  
NHSLothian

#### **West Region**

NHSAyrshire & Arran  
NHSDumfries and Galloway  
NHSForth Valley  
HHSGreater Glasgow & Clyde  
NHSLanarkshire

The governance structure for the delivery of the DSM will be delivered via the formation of operational boards for laboratories in each of the three Regional structures feeding into a Laboratories Oversight Board (LOB). Those regional boards are seeking delegated authority from their constituent Health Boards to enable change. The LOB has a membership that enables input from regional, national and partnership perspectives and is chaired by Paul Hawkins the NHS CE for NHSFife. Included within the LOB's remit and purpose is the responsibility for aligning national and regional plans for laboratories transformational change and



ensuring that the Laboratories Programme aligns to the strategic direction of NHS Scotland. The latter will be enabled by the availability of the national laboratories blueprint. At the first meeting of the LOB it was agreed that the blueprint and guiding principles for the DSM should be embedded within the terms of reference of the Regional Operational Boards to enable delivery of a vision for services across NHSScotland shared and thus consistent.

The National Laboratories Blueprint (NLB) attempts to capture the here and now of the current laboratory services model, identifies the steps that need to be taken to deliver the desired future model for laboratory services and identifies the desired endpoints to be delivered by the DSM. It supports an incremental approach to transformation that if adopted by planners will enable delivery of the national strategy for laboratories and progression towards a DSM that will meet the needs of NHSScotland today and in the future.

The current focus on laboratories in Scotland presents both challenges and opportunity for those providing services. The approach has delivered a clear vision for the future of services that necessitates service transformation. This clearly

delivers challenge to the old order of things. The drivers for change impacting on the current service model are increasing in number and severity and drive the need for the transformation. Not all are adverse. The availability of new technologies and new approaches to service delivery that support new ways of working provide new opportunities for all working in laboratories. In addition the approach being taken to transformation in Scotland recognises the value of diagnostics in healthcare and has at its core a focus on value and not cost with a key focus being the Triple Aim. This is being increasingly recognised and is a positive for those proposing service developments. The combination of the DSM blueprint, the guiding principles, the new governance structures, increased understanding of the value of diagnostics in healthcare and the adoption of an incremental approach to change towards an optimal delivery model provides massive opportunities for the future of laboratory diagnostics in Scotland.

- ◆ Given the importance of this article, it is also published in the College Bulletin and in the IBMS Gazette. ■

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**[www.sharedservices.scot.nhs.uk/  
health-portfolio/programmes/laboratories/](http://www.sharedservices.scot.nhs.uk/health-portfolio/programmes/laboratories/)**

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# Biotin Interference in Immunoassays: The Kardashian Effect?

Mike Hallworth, Focus 2018 Chair

## Report of an Industry Sponsored Workshop at Focus 2018

Focus 2018 featured an industry workshop on biotin interference in immunoassays, sponsored by Abbott. The workshop was very well attended, reflecting the current interest in the topic, and was chaired by Mike Hallworth (Shrewsbury), who began with a short introductory presentation.

Mike opened by referring to a clinical case poster presented at Focus in 2017.<sup>1</sup> A premature male infant with multiple comorbidities began having seizures on day 13 of life. Thyroid function tests were done as part of the metabolic work-up on day 34 and showed free T4 (fT4) >100 pmol/L and TSH <0.02 mU/L, suggesting gross hyperthyroidism. The baby was clinically euthyroid, and the mother's thyroid function was normal. The child was started on carbimazole, and thyroid function tests on day 38 were normal. On further investigation, it was discovered that biotin had been prescribed, but was stopped on day 35. A diagnosis of pseudo-thyrotoxicosis secondary to biotin interference in the assays was made.

Biotin is a small, water soluble B vitamin – sometimes called vitamin B7 (or vitamin H in older terminology). The UK Nutrient Reference Value (NRV; formerly known as the recommended daily allowance, RDA) is 50 micrograms per day. Biotin is widely distributed in food, and biotin deficiency on a normal diet is rare.

Biotin is used in treating multiple sclerosis as part of a Phase 3 trial in large doses – 100-300 milligrams per day, and it is also used in smaller doses (5-30 mg/day) as treatment for some inborn errors of metabolism and some forms of alopecia. Those are fairly well-defined patient groups, and biotin interference in immunoassays has been relatively easy to spot in the past. However, high-dose biotin is now being promoted as a food supplement that improves hair growth, strengthens nails and improves skin, among other claimed effects. Such claims have been made by Khloe Kardashian,<sup>2</sup> among others, although there is little scientific evidence to support such a role for biotin. The preparations marketed for these purposes contain 5-10 milligrams of biotin, over 100 times the UK NRV. In contrast, standard multivitamin tablets such as those used in vitamin supplementation in pregnancy only contain two to three times the NRV, around 100-150 micrograms of biotin.

Biotin in high doses can cause a problem in immunoassays that use the biotin-streptavidin link as part of the assay architecture. The FDA in the United States issued a warning in November 2017 stating that biotin can significantly interfere with certain laboratory tests and cause incorrect test results which may go undetected.<sup>3</sup> This warning has served to increase the awareness of the problem, yet heightening the confusion surrounding it. Manufacturers who use the biotin-streptavidin link in some or all their immunoassays include Roche Diagnostics,

Siemens Healthcare Diagnostics, Beckman Coulter and Ortho-Clinical Diagnostics.<sup>4</sup> Manufacturers whose assays are not affected include Abbott Diagnostics<sup>4</sup> and Tosoh Bioscience.

In non-competitive sandwich assays such as those used for large molecules – e.g. peptide hormones like TSH – the analyte is sandwiched between the signal antibody and the biotinylated capture antibody, which links the sandwich to a streptavidin-coated solid phase. Excess biotin in the sample saturates the streptavidin binding sites preventing adherence of the antibody-antigen complex, falsely decreasing the detected signal and creating a falsely low result.<sup>4</sup> However, in competitive immunoassays such as used for small molecules like thyroid and steroid hormones, endogenous analyte competes with labelled analyte for the binding site on a biotinylated antibody. In this case, when excess sample biotin prevents binding of biotinylated antibody to the solid phase, the effect of reduced label binding is to mimic high analyte concentrations.<sup>4</sup> The scene is thus set in the thyroid area for a ‘perfect storm’ – biotin interference produces apparently suppressed TSH concentrations and apparently high thyroid hormone levels, and mimics thyrotoxicosis. In other clinical settings, falsely high steroid hormone concentrations (e.g. cortisol and testosterone) may lead to misdiagnosis of an adrenal tumour.<sup>5</sup>

The problem is that the patient may not know they are taking biotin, or how much they are taking (some of these products are labelled with their constituents in very small print), the laboratory will not know if the specimen contains biotin and the physician could make a diagnostic decision based on inaccurate laboratory results.

Mike concluded the presentation with several questions for discussion:

- ◆ How common is the problem?
- ◆ How big a dose is required to cause interference?
- ◆ How do we assess the clinical risk?
- ◆ Who is responsible if harm is caused because of interference?
- ◆ How can the interference be detected and prevented?
- ◆ How do we communicate the problem in a balanced way to clinicians and patients, given that not all manufacturers’ assays are affected and not all analytes are affected?

He introduced the panel – Dr Chris Chaloner, Consultant Paediatric Biochemist at the Manchester University NHS Foundation Trust, Mr Finlay MacKenzie, Director of Birmingham Quality, and Dr Gordon Avery, Scientific Affairs Manager for Abbott Diagnostics. Several members of the audience had had direct experience of the problem, and Lance Sandle (Trafford General Hospital) described a very recent case in his hospital. In terms of communicating the problem, one audience member stated that they put a comment about the potential for biotin interference on every immunoassay report issued, and others have called attention to the problem in laboratory handbooks and memos or newsletters to users. But how widely are these read? Do clinicians remember to ask about whether patients are taking biotin? Do the patients always know? If patients present as an emergency, it may not be possible to ask them.

There was also discussion about the pharmacokinetics of biotin interference, and how long patients need to be off biotin before valid results can be obtained. The half-life is stated as 8-18 hours, and Roche in their Biotin Toolkit<sup>6</sup> and package inserts publish advice that patients taking biotin doses >5000 micrograms should wait at least 8 hours after the last biotin administration before being tested. There

was discussion about whether the effects of biotin could persist for longer at very high doses such as those used in multiple sclerosis. Also, some commercial assays seem to be more robust than others, and the thresholds for interference are variously quoted in the literature in terms of dose or in terms of specimen biotin concentration, which adds to the confusion. The risk is currently not well quantified.

Discussion around detecting and avoiding the interference included the importance of good clinical liaison and awareness of the clinical picture – but if the effect of interference is to produce a false undetectable troponin result in a patient in the ED (as in the FDA safety report [3]), then this will be very hard to spot clinically. Obviously, rechecking results on a different platform that does not use the biotin-streptavidin link will help identify interferences – but again, you must suspect that they are present to go looking for them. It would be helpful to be able to measure biotin, possibly by mass spectrometry, both to assess the incidence of high concentrations in routine samples and to identify potential interference. There are papers in the literature which suggest pre-treating samples with a streptavidin solid phase to strip out any excess biotin before analysis.<sup>7</sup>

Other speakers from the audience emphasised the importance of two-way communication with users and with patients about the nature and limitations of laboratory testing, stressing that this is not the only form of interference we deal with, and a sense of perspective is required. The importance of a thorough understanding of the assays used in your laboratory was stressed. One interesting suggestion was that the Kardashians could be involved to help communicate the problems with biotin!

Mike closed by thanking the panellists and the audience for their time and their participation in what had been an interesting and productive workshop. He also thanked Abbott for organising such a topical and popular session.

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\* Disclosure: Mike received a fee from Abbott Diagnostics for chairing the workshop, but not for this article.



# Industry Insights: The 'B' Word

**Doris-Ann Williams, Chief Executive, BIVDA**



I almost feel that I need to apologise as I write this, as I think we are all weary of Brexit, which has been discussed almost as much as the weather over the past two years. However, once I got back from a great AACC meeting – have to love Chicago – it became very clear that Brexit had really come home to roost within Ministerial Offices in Whitehall, despite being in Parliamentary recess for the summer.

The main focus in August was getting everything aligned for the possibility of a 'no deal' Brexit. Until now, this had been off the table as have any discussions we have had with officials. The official line is still very much that they anticipate a deal being made and this is not a signal that industry (and UK citizens) should be alarmed. However, it is hard to avoid being cynical and this is exactly how I have seen this!

On 23rd August a number of technical notices relating to Life Sciences Regulation post-Brexit were published and these can be seen on the Department for Exiting the EU (DExEU) website. On the same day there was a letter sent to IVD suppliers

from the Secretary of State for Health and Social Care (DHSC), Matt Hancock, on ensuring supply of diagnostics (and other medical devices) in the case of a 'no deal' scenario. I have also been having discussions with officials in DHSC who are viewing Pathology services as critical. At least the message about 70% of information for patients is reliant on laboratory medicine has hit home.

The Government is looking at increasing stockholding at a national level and suppliers are now being asked to consider their own contingency plans and if they need to increase production. For many short shelf-life products this may not be possible, of course. It is hard to provide much detail as we are having a meeting on procurement issues in two days from when I write this, with DHSC officials there to talk to companies face to face; we have been keen to ensure they understand that most of Pathology reagents and supplies do not come through the NHS Supply Chain (now in category towers) but under the auspices of Managed Equipment Services.

The IVD industry position has to be that while we will do everything to keep support for patients as paramount, the industry cannot be expected to bail the Government out by absorbing all the cost, whether this is stockpiling in warehouses, picking up any extra customs costs, increasing production with no guarantee of additional stock being sold etc.

Within the industry our concerns remain focused on how the regulation will be impacted, whether staff will be impacted and how the supply chain will be impacted (raw materials and part finished product

are shipped constantly around the EU, regardless of where the final product may be manufactured).

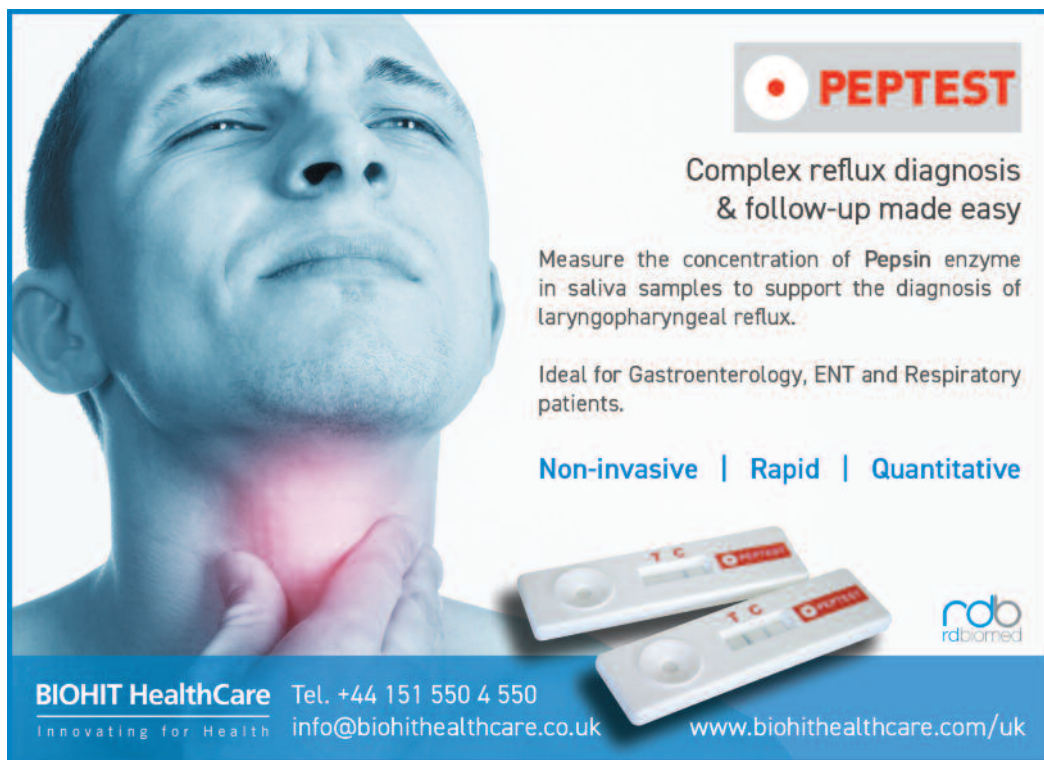
BIVDA will continue to keep dialogues going and the Pathology Alliance and its constituent member seems a great channel to do this. Please do also talk to your own suppliers, but remember that we are all in this mess together and they may very well not be able to give you any answers!

Meanwhile, changing the subject completely, the Secretary of State has

come out to state his three priorities for Health and Social Care:

- ◆ The NHS workforce
- ◆ Prevention
- ◆ Technology (not just digital or innovative products but enabling the NHS to be in a position to maximise their use).

So, I am looking forward to some useful input on these issues over the next few months. ■



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# National Audit Meeting

**Dr Natalie Hunt, Lancashire Teaching Hospitals**

The 2018 meeting was held at St Thomas' Hospital London. Dr Wassif, National Audit Lead, opened the meeting and announced that this year, for the first time, all 15 abstracts submitted to the National Audit Committee for this meeting will be published on the Annals of Clinical Biochemistry website. This should encourage more of our members to submit high quality abstracts next year.

The morning session was an interesting and thought-provoking series of talks and discussion around the clinical utility and implications of low calculated globulins by Dr Pecararo (University of Naples) and Professor Jolles (University Hospital, Wales). Interestingly, in Wales, a low calculated globulins is now the commonest reason for referral to the immunodeficiency service. Patients on clozapine represented a significant proportion of patients detected in primary care with low calculated globulins, highlighting this patient group is at increased risk of immunodeficiency.

A national survey of current practice, carried out and presented by Dr Zouwail (University Hospital, Wales) highlighted the variation in practice across the country. The discussion highlighted the need to continue to analyse total protein as part of a liver profile and to encourage laboratories to report calculated globulins (since, apart from a little IT intervention, this is in the unique position of being essentially a free addition to a biochemistry profile). A lack of agreed standards was highlighted, as was the need for a consensus cut-off for calculated globulins and appropriate actions to be taken by laboratories for results falling

outside agreed limits.

The afternoon session focussed on using troponin to facilitate early discharge from the emergency department. Professor Mills (Royal Infirmary of Edinburgh) took time out of his annual leave to give an excellent insight into the High-STEACS trial and pathway. This was very well received and made the audience think differently about using troponin cut-offs. The national audit, carried out and presented by Dr Jerina, was a re-audit of practice originally carried out in 2014. There is still a huge variation in practice across the country, in terms of the timing between troponin samples, cut-offs used for single rule in, for second sample positivity and for delta changes. The majority of participants in 2018 are using an admission and 3 hour troponin guided protocol compared to the majority in 2014 using an admission and 6 hour protocol. The audit highlighted the need for a revised ACB troponin working group consensus document to incorporate European Society of Cardiology (ESC) guidelines, as well as the results from the High-STEACS trial.

A selection of local audits from the UK were presented with a range of topics including AKI alerts in primary care by Jane Oakey, FSH in menopause by Dan Turnock and trace element requesting by Roger Bromley. Many delegates mentioned throughout the networking that all aspects of this meeting were translational to local practice and would improve patient care.

A worthwhile trip to London with time during lunch for a quick wander over Westminster Bridge to see Big Ben! ■

# Heather Mary Thornes

12 August 1949 to 2 July 2018

Heather was always proud to announce that she was born in Driffield, East Yorkshire, on 12 August 1949. Her parents, Geoff and Mary Warters, moved from Foxholes to Humble Bee Farm, Flixton, in 1954, and they survived initially with hand-pumped water from the well and no electricity, just paraffin or hand-pumped Tilly lamps.

Her first job was at Scarborough Hospital's Clinical Pathology Department and, after a few years, she moved to North Tees Hospital. She worked hard and eventually achieved the status of Consultant Biochemist. During this time, she worked part-time while she raised Joanna and Jonathan. She won all her battles with the hospital administration, first enabling women to wear trousers at work, then her various promotion battles with the Personnel Manager (he admitted later that she was his 'only failure'!). She managed to do a Business Management degree during this time, too.

When she retired, Heather took up the saxophone and she was a founder-member of the Buckrose Concert Band, in which she played the baritone saxophone. Nothing was allowed to interfere with her Wednesday evening band practices at Wetwang, or with most of the dozen or so concerts ('gigs') that the band played around Yorkshire every year, or on the Band's two trips to the Continent. The most memorable and emotional was when the band was invited to play at the Last-Post ceremony at the World War I Memorial in Ypres.

Heather was an active person and a keen gardener, always with several projects on the go, or thinking about what would be her next project! Associated with her gardening, she was on the Committee of



the Rillington Show, and she entered and won prizes for her jams and garden produce. More recently, she joined the Foxholes Art Group, and some of her work achieved Best in Class at the Rillington Show. Her next project, which she sadly will be unable to accomplish, was to become a Fellow of the Institute of Advance Motoring, the more advanced qualification offered by the IAM.

Heather is sorely missed by her husband, Gordon Malan, children Joanna and Jonathan, grandchildren Nina and Edith, and brother David Warters, and her many other family members and friends.

**Dr Gordon Malan**

## Note from the Editor

- ◆ Heather was also Chair of the (as it was then) ACB Northern Region and Regional Council Representative, 1996-1997. ■



# ACB News Crossword

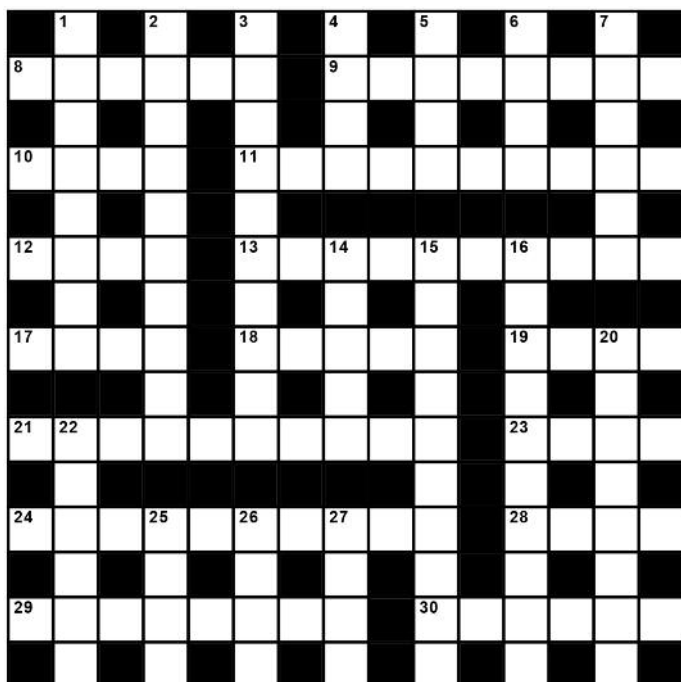
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## Across

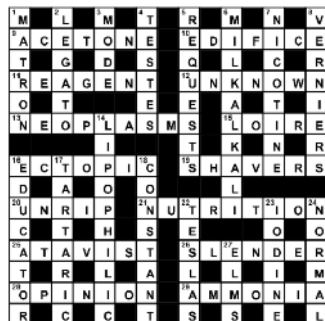
- 8 Father develops an eponymous disease (6)
- 9 Accident report retains doctor as advocate (8)
- 10 Decline heading for takeaways for food? (4)
- 11 Genesis of charged particles problem not left in isolation (10)
- 12 Eagerly expecting a character from Ezekiel (4)
- 13 Complete chemical process, reseal unit components (10)
- 17 Alternate puerperal end product (4)
- 18 Closely observing some turnkey in gaol (5)
- 19 Denial of French internet connection (4)
- 21 Potential energy transferred from exceptional athlete with tan (6,4)
- 23 Former graduate back for test (4)
- 24 Fracture clinic not a provider of peptide hormone (10)
- 28 Kind of blow that can lower analytical results (4)
- 29 Potentially is deadly: treated like this? (8)
- 30 Straight in with hard-line arguments (6)

## Down

- 1 Mother, take your time, act unwell (8)
- 2 Trained initial class: for example, conversion of old scientific scale (10)
- 3 Legal transfer of original antigens manuscript (10)
- 4 Prepare plasma for politician's doctor (4)
- 5 Charge carriers exploding: endless noise (4)
- 6 Metabolic problem following non-NHS gunshot treatment (4)
- 7 Clinic ignored problematic inconclusive blood type (6)
- 14 Fend off unrefined waste material (5)
- 15 Fitting point of view, held four-square (5,5)
- 16 Hansel rang about German histopathologist (10)
- 20 Distributed aid along an oblique line (8)
- 22 A burden on one having a neurological condition (6)
- 25 Inhibited unresponsive infection (4)
- 26 Investigate intestinal content (4)
- 27 Acknowledges greetings (4)



## Solution for August's Crossword



# FILM2019

## Frontiers in Laboratory Medicine

### Registration opening soon!

Fees to remain the same as last year.

- **Commissioning Health Care & Laboratory Medicine**
  - Hear about Accountable Care Organisations with examples from the NHS and USA
  - Understand better commissioning for Laboratory Medicine
- **Quality – Assurance & Improvement**
  - Getting it right first time (GIRFT) meet the Pathology GIRFT leads
  - Adding value with laboratory test utilisation and changing clinical practice
  - How could we use personalised reference ranges?
- **Innovation & New Models of Service Delivery**

Don't miss the opportunity to hear great topic discussions, attend your choice of break-out sessions as well as network with Laboratory Medicine colleagues.

**Tuesday 29<sup>th</sup> –  
Wednesday 30<sup>th</sup>  
January 2019**

**Austin Court  
Birmingham  
UK**

**Further information:**

[www.acb.org.uk](http://www.acb.org.uk)  
[enquiries@acb.org.uk](mailto:enquiries@acb.org.uk)

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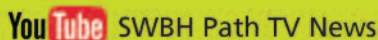
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