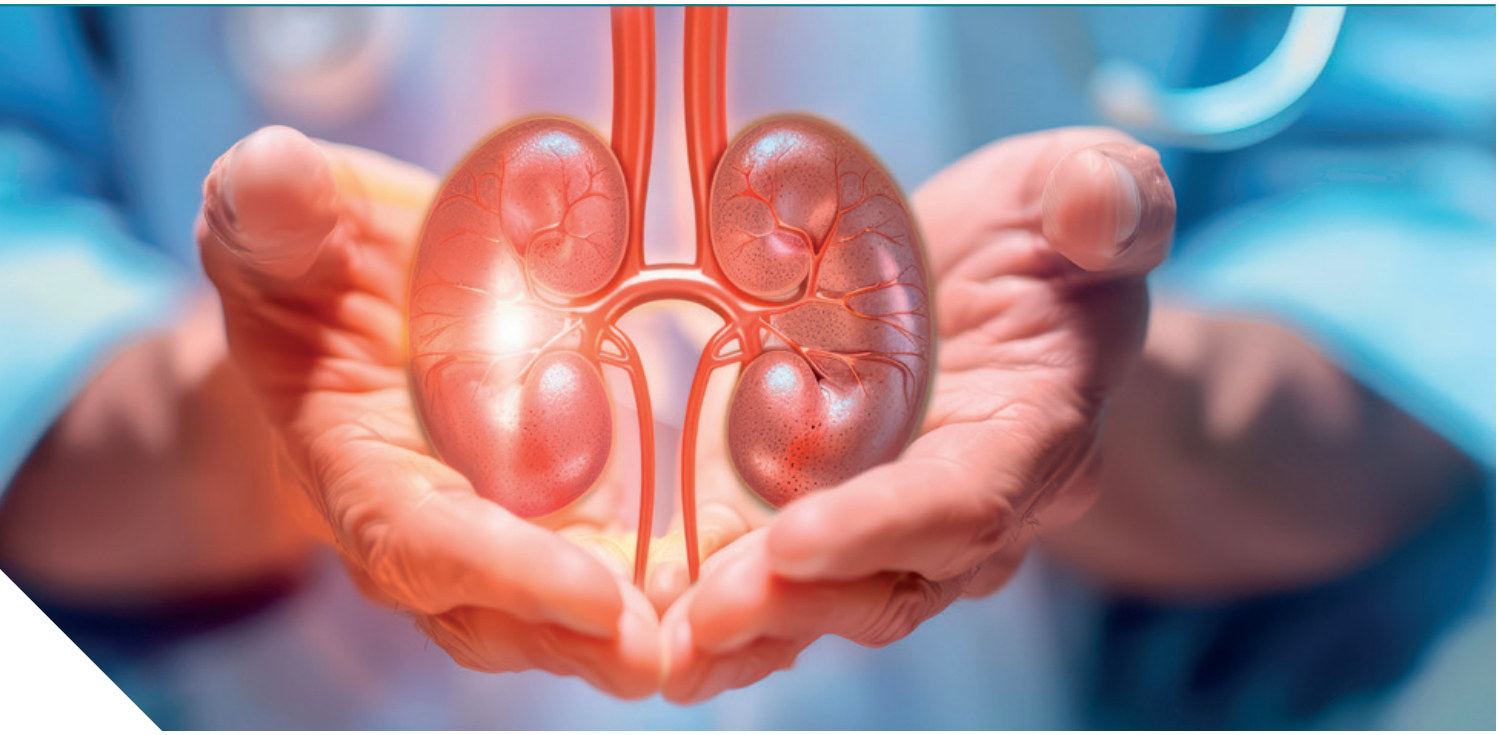

Dedication to external quality assessment was recognized and rewarded at this year's LabMedUK meeting

Congratulations to Finlay MacKenzie and Dr Rachel Marrington of Birmingham Quality [one of the main providers of clinical biochemistry external quality assessment (EQA) schemes in the UK] on receipt of their Impact Award presented at this year's LabMedUK meeting in Manchester. This prestigious award recognizes their outstanding work on patient-centric EQA for acute kidney injury and how it has formed part of the national recommendations to standardize acute kidney injury detection and alerting impacting thousands of patients. CLI chatted to the pair about their careers and work in EQA.

What was your pathway into this field?

Finlay MacKenzie (FM): I came into the field by accident, really. I used to work at St George's Hospital in Tooting, London. The head biochemist there was Dr Jennifer Nisbet, who was always stressing the importance of IQC and ensuring quality of analysis, so when a job to manage the Thyroid External Quality Assessment (EQA) Scheme came up in Birmingham in 1987, I applied and was successful. The new free T4 [thyroxine] assays and the new second generation TSH [thyroid stimulating hormone] assays were just coming out. My mentor in Birmingham was Dr David Bullock, who I worked with for many, many years. David retired about 10 years ago and he in turn had been influenced by Professor Tom Whitehead who was the father of chemistry EQA in the UK.

Rachel came to Wolfson EQA Laboratory (now Birmingham Quality) in 2005 as part of her training to be a trainee clinical scientist. She had already completed her PhD in bioanalytical chemistry. Rachel was one of the first people to choose to work with us doing EQA and she set up our Urine Chemistries and Urine Dipsticks EQA Schemes.

Rachel was also involved with me in some of the early stages of establishing an EQA scheme for estimated glomerular filtration rates (eGFR) for chronic kidney disease (CKD).

Rachel Marrington (RM): Yes, I first arrived at Birmingham Quality in 2005 as part of my training, I was the only person [on that training scheme] to choose to do a placement here at Birmingham Quality. When I returned to Heartlands Hospital, I did stay in contact with the department after I left and continued doing some project including work on lipids. This looked at the impact of using fresh serum [rather than frozen] on the analytical performance of lipid analytes such as cholesterol and HDL cholesterol, etc. I eventually became a full HCPC (Health and Care Professions Council) registered clinical scientist and then I obtained my full FRCPath. As I'd always had an interest in improving the quality of laboratories' output, 10 years after I left I came back to Birmingham Quality and I've been working here ever since! Much as I would have liked to have stayed at Birmingham Quality back in 2005, the experience of being in a routine laboratory, the challenges that I faced there – new automation, the evolving world – this has definitely been crucial and important for what I'm doing now. Network building is so important within this field – none of what we do is just working for yourself, it's all teamwork. The more people you know, the more experience you have. We want everybody's main objective to be about the patient, for improving patient outcomes. So, I really do appreciate the time that I had in a mainstream laboratory before coming back here and then being able to carry on my career within EQA.

What is EQA and what changes you have experienced over the years?

RM: Birmingham Quality is an NHS department within University Hospitals Birmingham NHS Foundation Trust. We operate EQA schemes and most of these are under the umbrella of the UK National External Quality Assessment Service (UK NEQAS; *https://ukneqas.org.uk/*). UK NEQAS is a charitable consortium of EQA laboratories evolving from NHS services in England, Scotland, Wales and Northern Ireland with over 50 years' experience and the aim is to improve patient care.

EQA has evolved a lot over the last 50 years. It's not just about looking at the analytical or performance of assays anymore, it is now about giving the assurance to a laboratory for the full service that they're providing. In addition to the testing process (from pre-examination to post-examination activities – or pre-analytical to post-analytical as it used to be called), the updated ISO 15189:2022 standard (*https://www.iso.org/standard/76677.html*) covers many other areas. We look at anything that could affect the clinical decision based on the laboratory report – from the handling and booking in of the specimen to how the results are interpreted.

FM: There can be a lot of confusion about whether the 'A' of EQA refers to assessment or assurance. We do assessment, but it is part of the wider assurance process along with internal quality control (IQC), training, quality management systems and the like. We do this by essentially acting as a mystery shopper. We send out specimens to all the laboratories that have signed up to our services. They do the analysis and we tell them how good, bad or indifferent they are. In general terms we can give a measure of relative bias; we can also give a view on absolute bias if we've got the right material, reference method target values and commutability, etc. Technically, in order to say you've got an absolute accuracy EQA programme, you need to have reference method target values on all of your specimens but that's not possible for all analytes not only because of the cost, but because reference methods don't exist. However, we offer a very intense external quality assessment programme which contrasts with some of the programmes which we believe are unable to properly probe laboratory performance and are at best tick-box exercises.

RM: The other thing that I would like to say here is that because we are so like a routine laboratory in the sense of our outcomes, our objectives, what we're trying to achieve, we also experience all the same challenges that the routine laboratory has. For example, increased workload, the decrease in staffing and specialized knowledge. Mainstream laboratories have had to go through a lot of network formation or consolidation of services and that's probably what we need to start to look at now. What we do is complicated but we're very fortunate at Birmingham Quality that a lot of our processes are in-house, which means that we can adapt very rapidly. For example, we have our own IT team and infrastructure. Everything that we've done has been written and developed in-house. If we have a new idea – and our acute kidney injury (AKI) work is a good example – the team can build something within days and weeks rather than having to put business cases together for it only to start to be discussed in six months' time. So, everything we do is bespoke and custom-built to our needs, but that presents its own challenges too! We prepare all our material in house. We don't subcontract, which once again gives us huge flexibility. Much as it can be a challenge for our laboratory staff, when we had the idea about AKI detection, we were able to just get on with it. The lab team were able to make the specimens the next week, there was no need to talk to anybody else. And yes, it was a bit more work for them but the whole experience with the AKI project has been felt by everybody in the department – the IT team, our admin team, the laboratory, our logistics/operations services, and the science team. But they've all seen the benefits from it as well because we've had some lovely feedback from people that we have shared with everybody and now we have received this award! It's really nice for everyone in the department to see the impact that they're actually having on clinical care because it's quite easy to feel far removed from the patient and to forget really how important you are to that patient's wellbeing. It couldn't happen without each and every one in the department.

Additionally, because we have such a good working relationship with manufacturers, we can instantly feedback if there are any problems or if there's anything that we've noted with a particular assay, which has happened from time to time. Another area of challenge is the legislation that manufacturers are now having to conform to which is making it more difficult for them to 'fix' in real time, even if they wanted to.

Tell me about the work that gained you your recent Impact Award and what do you feel are some of your other best/ favourite examples of improved practice that you have brought about?

RM: This Impact Award for is for our work on AKI which is within our UK NEQAS Acute and Chronic Kidney Disease programme (*https://shorturl.at/5yohq*). AKI is a derived analyte in the sense that it takes the creatinine concentration of a patient at that point in time and compares it to previous creatinine results for that patient in the last seven days or over the last 365 days looking for a change and the degree of change. There is then a complicated algorithm that you follow depending on the age of the patient, their previous creatinine result and when the sample was taken, to decide the stage of AKI for the patient. There are different management pathways for the patient according to how their AKI has been classified. Our approach to the EQA of AKI is very different to that for traditional EQA where we just send out a range of serum samples for creatinine analysis (either to determine estimation of Glomerular Filtration Rate (eGFR), which is part of CKD, or as part of our routine Clinical Chemistry EQA Scheme). >>

>> AKI is not particularly new, laboratories have been reporting AKI stages for over a decade. We had previously thought working on an EQA specific for AKI was probably a bit complicated but when we decided to get involved we were very surprised at how well it was received by the laboratory – the speed of implementation and the fact that labs did engage with it. It is different and complicated, but we had AKI EQA accredited within a few months and it has gone from strength to strength. We've had lots of positive feedback from service users about how it has impacted their work and what they're doing, which is one of the reasons why we think we won the Impact Award.

FM: The UK Kidney Association (UKKA) really appreciate this and the CKD work that we are doing. One of the key messages that we want to get across is that AKI isn't just a renal problem – it spans the whole spectrum of patients. The UKKA want to raise awareness of AKI in the same way that awareness of sepsis has been raised. Any patient in any part of the hospital, or any healthcare setting, may present with AKI, not just renal patients. Everyone needs to be aware of AKI and what to do with the alerts that are generated because successful intervention is often possible.

RM: The reason that this scheme is so different is that, yes, we send out specimens for creatinine analysis, but we also provide a patient scenario with the specimens and collection details for the specimens. We've tried to make this a bit more fun by having names and dates of births that mean something to us. For example, we have a pediatric case where the patient is called Boris because when we started this, Boris Johnson was the Prime Minister and was being in the portrayed in the media as being a petulant child. We had some trainees come here from Nottingham who contributed to a scenario so that patient became Robin (because of Robin Hood). Along with the patient demographics there is a clinical scenario and information about the date and time that the specimens were taken, which is important because of the way that the algorithm works to get the correct interpretation. The laboratories need to book in the specimens in the correct order that they had been taken, against the correct patient, and make sure that no other creatinine results have been noted against that patient.

Serum is manually aliquoted into tubes before dispatch to laboratories.
(Birmingham Quality)

FM: There is a three-month window over which everything has to be covered – it's not just on the day but you've got to know what you did a month ago and you've got to know what you did the month before that.

Example of the specimens that are sent out for creatinine analysis for acute kidney injury EQA.
(Birmingham Quality)

RM: Obviously labs report their numerical creatinine EQA result but now we're looking at how they interpret that result too. We thought there would be so much scope for error here because of the different ways that the laboratories work, with different people, and, as Finlay said, we're working over a three-month time period in terms of patient and specimen demographics, but the engagement has been amazing and we haven't had many errors. This means that the data quality is really good and we've been able to identify where there have been problems that have not been picked up for the last 10 years as nobody knew about them. It was a huge gap in that there wasn't a quality assurance process for AKI. The Think Kidneys NHS Patient Safety Alert to standardize the early identification of AKI was launched in 2014 and there was a lot of advertising at the time and promotion within renal communities and within laboratories but people have moved on so this scheme has brought AKI back to the forefront of what people are thinking and talking about. As Finlay said, it's not just people with renal disease – one in five emergency admissions to hospital will have AKI and the cost to the NHS is phenomenal, but it's highly treatable. And yet there was a huge lack of awareness across all areas. We did a national audit with the UKKA, the Get it Right First Time (GIRFT) team, and the Association for Clinical Biochemistry (now the Association for Laboratory Medicine) and in 2023 we jointly published 10 national recommendations that became part of the national guidance on AKI. I think the reason that the AKI EQA scheme worked so well was because it built on the strong foundations that we have with the renal network and colleagues working within biochemistry. In addition, Finlay did a lot of work in the early 2000s with the Department of Health.

FM: Yes, I worked with the Department of Health to find a way that eGFR for CKD could be rolled out nationally; however, it was known at the time that creatinine assays were not all giving the same answer, or the right answer, therefore it would make it very difficult to use a single equation. I worked within a small group looking at creatinine assay performance and developed assay-specific 'fudge' factors to allow the roll out to happen. In order to publicize this and to make sure people knew what it was, we called it SAUSAGES (Successfully Adopting UKNEQAS Slope Adjusted GFR Estimate Systems). The idea was that it was supposed to provide labs with approximately six months' breathing space to move from the Jaffe assay to the more specific enzymatic assays. Sadly, this still hasn't happened in all labs.

RM: In 2005, the majority of labs were using the Jaffe assay, which is a cheap but not a very specific assay for creatinine and is over 100 years old. Twenty years on, adoption of the enzymatic creatinine assay is still not complete and varies across Europe. However, the AKI EQA data has had an impact on patient care in many ways, which is why we won this award. The data has been used by labs to support their business

cases to move from the Jaffe to the enzymatic assay, it has supported identifying errors in the AKI algorithms in laboratory information management systems. Laboratories have just had the data to review and improve their processes for the handling of pediatric AKI requests and when there are compromised samples, for example 'wrong blood in tube'. We have also worked with the wider healthcare community through close collaboration with the UKKA, such as educating clinicians about the meaning (and limitations) of the data that they are given.

FM: Just in case you thought all we did was renal EQA, we do cover the majority of clinical biochemistry EQA and in that regard we are particularly proud of our work on steroids as it once again allows us to collaborate with clinicians, which we really like because you can see a direct impact for patients. Our data is used as part of guidelines which we are very proud of. A couple of examples here are that we do a lot of pre-analytical and post-analytical studies looking at interferences in assays, which are very common. We look at common things, such as patients on the steroid prednisolone and the interference this has in a cortisol immunoassay. Every five years or so we write a fresh commentary on it, which then goes on to be included in the training for the new doctors that are coming through and we've had feedback to say how useful this is for medics. Rather than just have it written in a textbook, they can actually see it in practice. The lab staff should know about it, but even then some of the younger ones coming through might not.

RM: Last year we looked at the interference of hormone therapies in breast cancer on immunoassays. This was for estradiol, and the interference results were shocking to some clinicians and caused some laboratories to completely change their practice, even though it's in the small print of a manufacturer's kit insert.

FM: Regarding cross reactivity, these instructions for use (IFUs) or kit inserts will state what the cross-reactivity is. So, they will say this compound will has got a 0.01 cross-reactivity. And you think that's great, the cross-reactivity is only 0.01. However, when you give patients a dose of the medication, it's 10,000 times the concentration of the analyte that you're trying to measure, so it has a huge impact. Although percentage-wise it's tiny, the circulating concentration of the drugs you're giving is massive. A lot of people don't understand cross reactivity, so we're having to explain that as well.

Going forward, how do you envisage EQA will develop to continue to improve laboratory practice?

RM: One of the challenges for EQA is the direction of travel towards point-of-care testing (POCT), which is brilliant from a patient perspective but the users of the technology are different to laboratory staff. We have worked for many years with laboratories, where the staff have got a scientific background – they understand us and what we're trying to do. However, with POCT, the users might be nurses whose priorities, rightly so, are very different and they don't appreciate that the device that they've got in front of them might give the wrong result or it might give a different result at a different time. So, one of the big challenges is trying to get them to understand why they actually need to engage with us as EQA providers. This actually is part a bigger picture. We're not just a supplier, like some EQA providers are, we really want to work with laboratories because we want to work with their clinicians and improve services for patients. What we do is not just a tick-box exercise of doing EQA or proficiency testing for their accreditation purposes.

However, recently, with the current financial pressures in the NHS and the wider society, I have begun to see people questioning whether they really need to spend time and money on EQA, but this is a really damaging viewpoint because we aren't 'extra'; we're not a bolt-on or add-on. What we're doing is integral to patient care – we don't want to be doing things just so that a laboratory can get more numbers out more quickly, we want to make sure that the numbers are correct.

FM: We still consider ourselves to be part of the laboratory community. We're not some sort of 'numbers-only' service. I think that we're different from some EQA providers because we consider the full process from start to finish. For example, we have an Interpretive Comments in Clinical Chemistry EQA programme (*https://shorturl.at/ME1HM*) which is solely post-analytical and has clinical cases which involves a marking process that is done by about 25 to 30 volunteers who commit to working a certain number of hours for nothing to assist us because they see it as beneficial to their clinical practice and the professions. However, one of the challenges is how laboratory life is moving on and it is hitting us as well is – we now have to persuade people that our schemes are a necessary and useful part of improving and maintaining a high quality of service for patients. If we weren't here our data would be sorely missed and patient care would ultimately suffer.

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