

THE RISE OF POCT.



We look at the **rapid ascent of POCT** – the tests that are **redefining diagnostics** and **breaking down barriers** between laboratories and patients.

This year, for the first time ever at IBMS Congress, there was a whole programme dedicated to point-of-care testing (POCT). There were nine sessions throughout the day, covering a wide variety of aspects of the rapidly emerging discipline.

The sessions were held in a packed hall – with many scientists standing, crowded around the back of the room to hear the speakers' insights.

Dr Sarah Glover, a Consultant Clinical Biochemist, is a clinical lead for POCT and was the chair for the Congress POCT programme.

"I'm really excited that we had a whole day on POCT at this Congress," she says. "It's always difficult to know how many people are going to turn up for a new session, but the room was full most of the morning and it was standing room only for much of the time. It's been really successful and the audience

have been really engaged in the topic.

"We decided we needed a dedicated programme because there are so many interesting topics and speakers coming through at the moment," she continues. "Previously, we've had individual sessions that have been well attended and POCT is a discipline which is growing and growing and that's only going to continue going forwards."

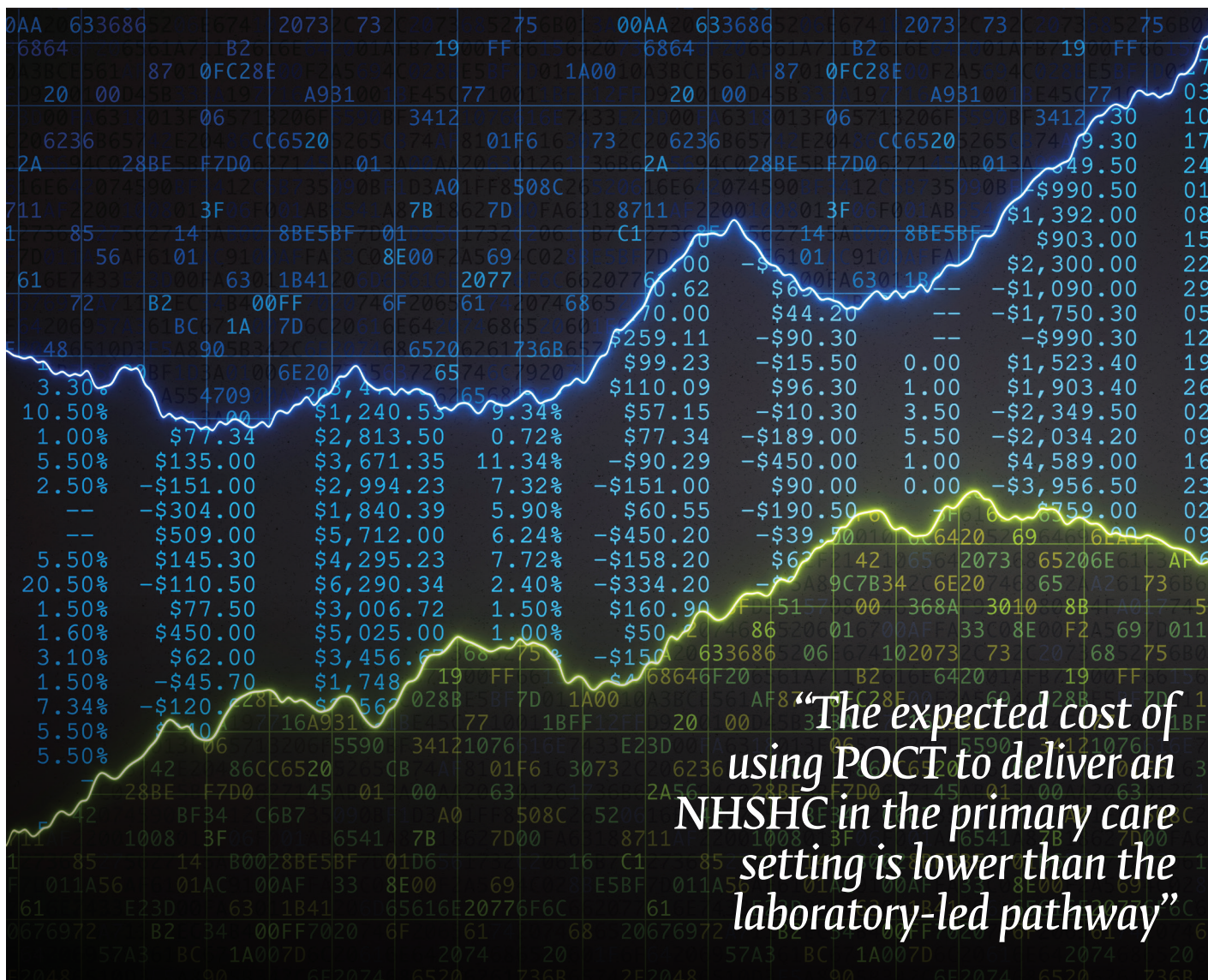
Market trends

A report on the global POCT market, published in October, states that it is now a multi-billion-pound industry "with intense competition and areas of growth".

It says that a major force driving the industry expansion is the effort to provide better patient care through the improved turnaround time that POCT offers.

While other forces include cost containment through less time spent in the accident and emergency and other critical care environments, the ageing population that requires proportionately

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greater healthcare, the increased incidence of certain diseases, health worker shortages, and technological advances allowing for small, portable, easy-to-use POCT devices.

The report predicts that the market will be worth £34bn by 2026 on the back of an expected annual growth rate of 8.4%.

It goes on to list 27 different areas currently within the POCT sector, from the common blood glucose testing kits, to prothrombin time testing kits and activated clotting time testing kits.

Making savings?

There is a seemingly constant stream of new tests and devices being developed and rolled out.

In October, the NHS Health Research Authority announced



that it had granted approval to start testing an antibiotic-induced hearing POC test in hospital trials.

It is due to be trialled in 1000 patients from two large UK intensive care units and is scheduled to start in November and run for six months. This represents the world's first ethical approval for a POC genetic test used to influence neonatal management in an acute setting.

POC tests have also been making newspaper headlines, for example *The Independent* ran the story “20 minute flu test could save the NHS up to £24m a year

and free up beds, manufacturer says”. Public Health England said there are a number of tests coming on to the market, and while some early adopter trusts have found benefits, there is yet to be a national

assessment of their cost-effectiveness.

But, while the data may not be available yet, research into the area indicates that cost savings are likely. A recent paper published by the BMJ sought to determine if POCT is less costly than laboratory testing in delivering the NHS Health Check (NHSHC) programme in the primary care setting.

Working with nine general practices (seven using POCT; two not using POCT) data were collected on cost, volume and type of pathology services performed.

Their paper concludes “the expected cost of using POCT to deliver an NHSHC in the primary care setting is lower than the laboratory-led pathway. Using POCT minimises did-not-attend rates associated with laboratory testing and enables completion of NHSHC in one sitting.”

NICKY HOLLOWOOD ON UKAS POCT ACCREDITATION

Our decision to apply for accreditation was a joint one with UKAS at our pre-inspection meeting as both parties felt it was achievable. Having an ongoing dialogue with UKAS regarding our expectations and what was achievable was central to us securing the accreditation as we were able to address any issues and solutions ahead of the assessment. We were also able to plan accordingly and identify any additional resources that we would need to achieve this.

The biggest challenges for us were mainly during the transition stage; continuing to run a POCT service that was functional for our users while developing and implementing new systems and ways of working. Going forward; now this transition has been completed the assessment visits are far more streamlined and there isn't the same preparation required for the visits as our service is continually changing and evolving.



The absolute starting point is to do a gap analysis; assess where you are and where you want to be and then you can determine how much work is needed and whether you have the resources to achieve this. There are some services that we haven't submitted for UKAS accreditation such as fetal fibronectin (and may never submit) as it would be too challenging to meet UKAS requirements for them. For these services we work towards UKAS requirements and implement the quality standards that we can achieve to ensure we standardise our POCT service as much as possible.

There are some POCT services that don't feel they can achieve this accreditation but may choose to work towards it by incorporating the ISO standards that they feel bring value to their service. Either way, the ISO standards are the main quality benchmark we have available to work towards.

A changing NHS

Nicky Hollowood is POCT Manager working in pathology at Harrogate and District NHS Foundation Trust. She says the scope and range of POCT devices available has "increased enormously", especially over the last decade. She continues: "This has been driven by technology improvements. The commercial scientific industry is able to produce smaller, portable diagnostic platforms with improved data management and operator functionality.

"As well as technology improving, the government's strategic plans for the NHS have increasingly been centred on moving care from the hospital to the community and reducing length of stay in hospital. The main focus being on prevention, early intervention and self-management.

"NHS strategic plans and technology

"We will enable staff to capture all health and care information digitally at the point of care"

improvements have both jointly contributed to an increase and a more widespread use of POCT devices across healthcare pathways."

This is a shift in focus that is immediately apparent in the NHS Long Term

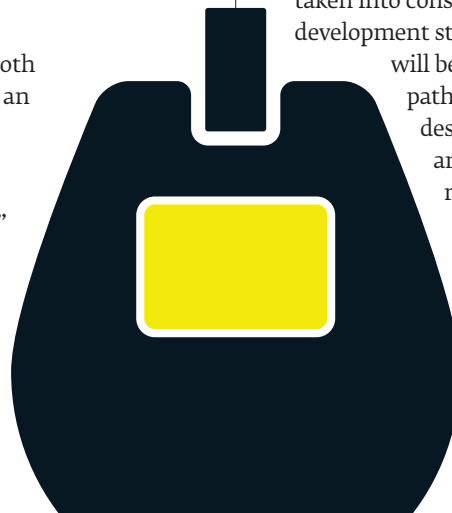
Plan, which aims to move the NHS forward so that in 10 years' time "we have a service fit for the future". The first section of the plan is titled "We will boost 'out-of-hospital' care, and finally dissolve the historic divide between primary and community health services". It goes on to mention the word "community" 140 times across its 136 pages and states: "We will enable staff to capture all health and care information digitally at the point of care, and optimise clinical processes to reduce administrative burden. We will support the workforce to develop the digital skills they need to make effective use of these tools and mobile access to digital services to allow health and care workers to work more flexibly."

Changing dynamics

In order to allow the capture of data at the point of care, the companies that are developing and manufacturing the kits are changing their focus. Nicky Hollowood says: "Traditionally, POCT devices have been developed for chemistry tests but we are increasingly seeing more haematology and microbiology tests being incorporated onto POCT platforms. The strategy for the development of POCT devices in industry is also shifting. In the early days, the key driving forces for POCT product developments were based around what tests could feasibly be replicated on a smaller platform with sufficient accuracy. Now we are seeing the commercial sector

taken into consideration during the development stage; where the device will be used, what care pathways they are being designed to support and what tests are needed to support this clinical service."

She continues: "When the product comes to market, there is a clear marketing strategy



around the intended use of the device and many platforms are now hosting an array of tests covering chemistry, haematology and microbiology specialties. This in itself is changing the dynamics of the POCT service as it is becoming more of a standalone multidiscipline speciality in its own right.”

The fast-evolving nature of the sector means that issues such as training and accreditation are still in flux and evolving in tandem with POCT.

Ben Courtney, Accreditation Manager at UKAS, explains the fluidity of POCT. “The UKAS approach is adaptable and collaborative with POCT,” he says.

“We want to understand what the problems are and devise an accreditation programme that suits biomedical scientists’ needs. Those thinking about seeking accreditation should conduct a gap assessment and then address those gaps – we want to see that you know what you are talking about. There are so many different ways that POCT can be delivered and will work.” He adds that those who seek accreditation who are unsuccessful should not worry about their lab accreditation – “think of it as an extension to scope,” he says “it has no impact on the accreditation of your lab”. Only a handful of labs have POCT UKAS accreditation at present, including Harrogate – see the box, on the previous page, for advice from Nicky Hollowood on how the trust sought and secured accreditation.

New qualification

It is also early days for POCT training, but it was announced at Congress that a new IBMS POCT qualification is set to launch at the start of next year. Lee Peters, Section Manager in Swansea Bay Health Board, who is currently completing a doctorate in POCT education for laboratory staff, outlines the qualification and explains the reasons behind it.

“There have been calls for a POCT qualification for some time, it’s always been bubbling below the surface,” he says.




NEW IBMS POCT QUALIFICATION

The new IBMS POCT qualification is a **Certificate of Expert Practice**

It comprises **six modules, each of which runs for two weeks**

- There are two reflective pieces of work required during the course and an exam at the end
- The course will cost £675 and is run in conjunction with Ulster University, which will host it online
- The pilot is due to launch in January 2020 and will be limited to 60 places
- The qualification is aimed at new and aspiring POCT staff.

 For more information, visit the **IBMS website** over the coming weeks.

POCT IN NUMBERS

£34bn 
The expected POCT market value by 2026

 **8.4%**
The predicted annual growth rate of sector


27 
There are 27 different areas within POCT

“But because of the scope and the increase in use and demand we thought that a POCT qualification was required.”

In August last year, the IBMS set up a working group which discussed the gaps in knowledge around POCT for biomedical scientists and over the following months the group designed a set of modules that were aimed to fill those gaps.

“Quality runs through these modules and you will be in a group with like-minded individuals and it’ll be interesting to see how other people are working with POCT,” says Lee Peters, before stressing: “Apart from the reflective pieces and the exams, everything can be done quite flexibly depending on your workload.” See box for more information on the qualification.

Breaking barriers

As more POCT tests are launched and more scientists train and become qualified in the discipline, as well as patients getting better, faster care, the nature and perception of laboratories may also start to change. “Traditionally the laboratory has been seen as the ivory tower,” says Dr Sarah Glover. “People don’t have access to the laboratory and probably don’t understand the processes. POCT brings that laboratory testing out to the patient, and the laboratory staff who are running POCT services are very much engaging with users – they are out there providing a face for the laboratory and asking how we can develop services which help patients, improve patient pathways and optimise patient experience. It’s becoming much more of a two-way dialogue, rather than the laboratory being seen as something that is behind closed doors.” 

 This month the IBMS launches its new series of monthly podcasts.

The first episode features interviews with Dr Sarah Glover and Lee Peters. To listen to the episode, which is an exclusive IBMS members-only benefit, visit the IBMS website.