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EDITORIAL

Point of Care Testing: A Discipline that is Growing

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Traditionally, diagnostic testing is carried out on patients' samples (blood, urine etc) in pathology laboratories by skilled scientists. Transport to the laboratory and subsequent processing (often in batches) can sometimes lead to long turnaround times for the patient and the clinician.

Point of care (POC) or 'near patient' testing refers to testing and reporting at the site of patient care and is usually undertaken by non-laboratory personnel. POC technology has a number of attractions as there is a fast turnaround time and this can have enormous benefits for the patient and the clinician. However, there are concerns that accuracy of the results and costs that comes with this emerging technology. Within hospitals, POC devices are used in emergency centres, operating theatres and intensive care units. The regulation of these devices in hospitals tends to be under the umbrella of accredited laboratories using International standards ISO 22870 (POCT) and ISO 15189 (quality management) and these ensure internal quality control (QC) and external quality assessment are undertaken regularly. Manufacturers of the POC devices also try to ensure accuracy of results by the use of the internal QC that meets necessary standards. Current devices in hospital clinical medicine are wide ranging and can be single handheld devices or on a platform which can cover areas of biochemistry, haematology and microbiology.

Devices commonly used outside the regulatory umbrella of the laboratory are less controlled and there is limited access to governance, training of personnel and device selection. Some of the best-known devices used by patients themselves are for glucose monitoring, pregnancy testing and most recently is COVID antigen testing.

The potential for POCT is huge if we can ensure correct regulation which in turn gives confidence to the users in terms of accuracy and precision. The rapid turn-around and the effect on clinical decision-making would have enormous benefits in developing countries, conflict areas and for paramedics attending multi-trauma victims. The ability to have some detailed blood values prior to hospital admission could also save many lives in the future. A recent study undertaken in primary care in Germany (292 participants

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– response rate 14.5%) showed that although certain aspects of POCT was widely accepted there were limitations around cost, concerns about diagnostic accuracy and difficulties into integration into practice routines (e.g. time and personnel). It was shown that six devices were regularly used by the majority of GP's which were urine dipstick tests (99%), glucose (urine [91%] and plasma [69%]), SARS-CoV-2 (80%), urine microalbumin (77%), troponin I/T (74%) and prothrombin time [1].

Multi-discipline Nature of POCT

Traditionally, most POCT devices were developed for biochemistry tests but there are more haematology and microbiology tests being incorporated onto the platforms, making POCT a stand alone multidiscipline specialty. The fast-evolving nature of the POCT sector means that issues such as training and accreditation are still evolving, and educational programmes are being developed to suffice this growing need [2]. The governing body of most biomedical scientists in the United Kingdom are introducing training programmes to meet this need [3]. As POCT becomes more accepted and regulated with appropriate training, then we may see laboratory science change to accommodate the changing nature of POCT for acute diseases. Currently POC devices available are those for testing cholesterol, coagulation, infectious disease, cardiovascular disease, pregnancy testing and fertility, haematology, urinalysis, drugs of abuse, faecal occult testing, tumour cancer markers to name a few.

The Future of POCT

The expansion of these new and novel technologies has allowed certain diseases to be controlled in real time. The best example of this is continuous glucose monitoring where devices can be attached to the patient and a sensor continually monitor blood glucose levels in the interstitial fluid beneath the skin. The sensor is linked to a reader and alerts the patient when their blood glucose is too high or too low. Wearing sensors capable of continuously monitoring human physiological signals in real-time would allow many diseases to be more closely monitored and treated accordingly. Intelligent sensors that detect various changes in body fluids such as blood, sweat, and wound fluid are being developed for commercialisation applicability [4]. The combination of POCT with nano-diagnostics technology is avidly being researched to develop fully integrated POCT systems in healthcare. The technology and platforms are always expanding as confidence and price allows clinicians to easily use devices and have the results in real time. This will in the future certainly change the landscape of pathology testing for some disciplines and services.

Rapid and early detection of infectious and foodborne pathogens using POCT may control and prevent future outbreaks. Currently of great concern is the increasing incidence of acute respiratory tract infections (RTI), which leads to high mortality in children and adults worldwide. During the COVID pandemic, rapid antigen detection kits were made freely available in the UK for patients to self-test. These were based on lateral flow technology and simple instructions given. Other global health threats such as hepatitis C virus is another infectious disease to watch. POCT lateral flow test kits have been developed based on reverse transcriptase-recombinase aided amplification lateral flow detection (RT-RAA-LFD) with a 100% positive and negative concordance rates with qPCR. The RT-RAA-LFD assay established was deemed suitable for the rapid clinical detection of HCV at the community level and in remote areas [5].

Market Trends

A report on the global POCT market [6] states that it is now a multi-billion-pound growth industry. Key points of the report showed that the USA had the highest revenue share (46%) in 2022 and that the major product capturing the highest revenue (27%) was glucose monitoring (8.91 billion USD). Lateral flow assays accounted for 36% of the revenue share and pregnancy and fertility testing products segment is expected to grow significantly over the next few years. The use of biosensors in POCT continues to grow with the compound annual growth rate reaching 9.2%. Other technologies used in the POCT market are dipsticks, microfluidics, molecular diagnostics, immunoassays, flow-through, solid phase and agglutination assays [6,7]. The current trend is towards smart devices with mobile healthcare which will enable personalised monitoring and management. The use of mobile phones and associated apps to assist with these developments has allowed expansion. In addition, less time spent in emergency healthcare establishments is key and with health care worker shortages and increase in certain diseases for example diabetes, then POCT is set to grow especially following development of small portable devices that are linked via tele medicine. The report predicts that the market will be worth £34bn by 2026 on the back of an expected annual growth rate of 8.4%.

Making Savings?

In the UK, it is hoped that introduction of POC tests for illnesses such as influenza could save the NHS millions per year. This is yet to be evaluated fully to demonstrate the full cost effectiveness of the introduction of such tests. A recent paper published by the BMJ, showed that the expected cost of using POCT to deliver, National Health Service Health Check (NHSHC) in the primary care setting was lower than the laboratory-led pathway with savings associated with POCT were estimated at £29 per 100 patients [8]. Nine GP practices participated in the study (7 using POCT and 2 without). They concluded that screening in a single visit while offering satisfactory accuracy of testing in primary care, that POCT has clear advantage over the laboratory-based assessment. Sending samples to a laboratory can be time consuming whilst POCT offers lower hospital admissions and economic savings for preventable chronic conditions. Since the introduction of antibiotic stewardship across the UK, GPs are more likely to adopt POCT to screen for respiratory diseases and reduce antibiotic usage [9]. However, unless the funding model is changed and the cost of the tests (including equipment, consumables and time) are fully reimbursed, then the GP practice can lose money. This is one of the factors that has hindered the uptake of POCT in the primary care setting in the UK.

In conclusion, advances in technology and miniaturisation could result in more affordable POC devices with added functionality to support different clinic needs in routine general practice and emergency care settings. There is a need for the analytical processes, from sample collection to result, to be achieved in a few simple steps in real time to support delivery health care in one visit, making it more convenient for the patient and more efficient for the clinician. Lower costs and increased quality of devices /platforms and consumables will make POCT more affordable from the healthcare perspective. POCT is likely to be improved over the next few years by combining some of the techniques to enhance the range, accuracy and cost.

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