Opinion

Contribution of Industry to PoCT Implementation

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During the last ten years Point-of-Care Testing (PoCT) has been shown to be among the fastest growing areas of laboratory medicine. The primary reason for this growth has been a demand for faster turnaround times to facilitate improvements in patient management. While in the past we were interested in providing STAT services for critical analytes such as in blood gas analysis, our focus now is on areas that will allow a more efficient way to manage patients as they encounter the healthcare system. Examples include patients self-managing their own INR, creatinine-based triage of patients undergoing radiological investigations, and the monitoring of diabetic patients using glucose, HbA_{1c}, and albumin/creatinine ratio measurements.

Such clinical demands have dictated PoCT needs and directed instrument design by manufacturers who must take into consideration requirements such as ensuring that quality control (QC) of the system can be maintained in the hands of non-clinical laboratory professionals by automating processes as much as possible. Barcode technology coupled with connectivity of the various PoCT devices to a central laboratory information system is now a reality, ensuring accurate documentation of the patient, the test, the time and the result reported. A key contribution of the In Vitro Diagnostics (IVD) industry which has a direct impact on the implementation of PoCT is in instrument design. If the design of the PoCT device meets the needs of the clinician and patient as well as providing an overall cost benefit, there is clear evidence that barriers to implementation are lowered significantly.

One thing is certain: PoCT is here to stay, a fact that most laboratories now recognise as an opportunity rather than a threat. The clinical laboratory professional is the best positioned health care provider able to utilise the potential benefits of PoCT to their fullest. Recent advances in the technology used in PoCT and target analytes measured will require even more understanding of pre-analytical variables, QC and quality assurance (QA). This is indeed the speciality of the clinical laboratory. The clinical laboratory must also be the principal adviser when a question arises as to whether it would be better to offer PoCT rather than perform the test in the laboratory.

Some clinical laboratory professionals are hesitant to take on the role as mentor to a provider of PoCT in addition to their normal duties because of workload and lack of resources. However, this extra responsibility can be shared by working in a partnership with all the PoCT stakeholders. In order to enjoy the potential benefits of PoCT, all relevant stakeholders must be partners in its implementation. Healthcare professionals such as doctors and nurses directly involved with the PoCT deliverables must understand and establish how PoCT results are used to manage the patient. Similarly, the laboratory is in the best position to assist with device selection through a critical appraisal of the analytical characteristics of PoCT devices, highlighting any potentially problematic pre-analytical and analytical areas that should be considered. In addition, ensuring that the PoCT devices continue to function as intended through sound QC and QA programmes can be achieved through a partnership between the laboratory and the end users. What then is the role of the PoCT supplier in this partnership?

The days are gone when the only contact with the PoCT supplier was at the point of sale with the purchasing of the devices and consumables from a company representative. The PoCT supplier in 2010 is a specialist for their PoCT product and possibly best able to provide advice on product functionality, its limitations and benefits. It must be appreciated that the supplier is a holder of significantly more information about the device than what is shown in the glossy brochure and the package insert. Unless the user is made aware of this fact, such information will never be passed on and used to meet local clinical and analytical needs. There are many areas where the supplier can now assist in an effective PoCT implementation:

a) **Device selection:** Although the final decision on selection is not with the supplier, provision of information essential

in choosing the most suitable device to fit the required purpose is key in this process. The supplier can assist with supplying published and unpublished evidence on their device that may form a useful addition to information collected by the selection team.

b) **PoCT implementation:** Selecting the device is only the 'end of the beginning'. Once the decision has been made to go with a specific device, the manufacturer can be a key partner in validating needs such as consumable stocks, appropriate storage facilities, placements and ordering processes. In addition, regular audits of the various areas where the PoCT device is used will help discover stores of expired consumables that could be used in error by a willing operator, resulting in potential errors in the results produced.

c) **Training:** This is an area where the supplier can be of great value to the PoCT user. Most suppliers now have suitably qualified and trained product specialists who will provide training on the use of the device to the end user and others responsible for the effective use of the PoCT system. A PoCT system needs to be available 24 hours a day, seven days a week, and reputable suppliers can provide training to operators during these hours to ensure all organisational work shifts are covered. Based on training on use of the device, the supplier can accredit and certify operators to ensure only appropriate staff use the PoCT device. The supplier can also follow up initial training with 'refresher' sessions to ensure operator certification remains valid as well as providing educational literature and training resources on CD or through the internet.

d) **Quality procedures:** QC and QA procedures regarding PoCT are arguably a key area where suppliers and the laboratory must work closely together. This is recognised by most professional associations: AACB through the AACB PoCT Working Group has put together guidelines to assist QC and QA of relevant procedures. Clinical laboratory scientists have designed and managed such procedures for a long time and have significant expertise in this area. However, QC and QA requirements for PoCT devices are very different to those normally required for laboratory-based procedures. The modern PoCT device by design recognises that the end user may not be as knowledgeable and diligent as a clinical scientist in QC/QA procedures, and therefore every attempt has been made by the manufacturer to automate such processes. Contrary to general belief, PoCT devices automatically perform hundreds of QC checks before a patient result is produced. Moreover, all PoCT suppliers have a recommended set of QC procedures which should be adhered to as a minimum by the end user. Recognising the value of QA programmes, suppliers have been working very closely with the RCPA-QAP programme in Australia to design, implement and in many circumstances fund these programmes for use by the various PoCT areas. Undoubtedly as new PoCT devices become available, the need for such programmes will expand, and the supplier will be an integral part in achieving this. Apart from the actual QC/QA programmes, most PoCT suppliers can provide expert advice on interpretation of the results of the programmes, assisting users with identification of trends and in general troubleshooting.

e) **Consultation:** As indicated previously, PoCT suppliers now employ product specialists, many of whom have significant expertise in their particular areas. For this reason, most professional associations, working parties, standards setting committees and government initiatives now utilise such expertise in their deliberations. The 2010 PoCT product specialist is a significant resource to any PoCT team. Consultation in terms of process improvements, troubleshooting and accreditation requirements is an integral part of ensuring the PoCT programme achieves its objectives. Naturally, this is a two-way consultation process. It is important that users' experiences, opinions and areas where the manufacturer could improve on their existing products are communicated to the supplier. Such feedback will form part of the next generation of devices resulting in better and more efficient patient management and service delivery.

In summary, at a hospital/clinic level, the contribution of the industry is in design of appropriate instrumentation, providing information, value-added services and playing an ongoing liaison/consultation role between users, professional bodies, regulators, standards committees and patient groups.

When we were asked to contribute to this PoCT edition of *The Clinical Biochemist Reviews*, we were encouraged to see confirmation of our belief that the manufacturer and supplier should be part of the PoCT partnership. The professional approach to this continuously expanding area of clinical medicine by bodies such as the AACB will ensure that the supplier and other medical teams as partners in PoCT settings deliver more efficient and effective patient care and management.

Useful Links

- AACB PoCT Guidelines. www.aacb.asn.au/web/POCT/
- AACC Critical and PoCT. http://www.aacc.org/members/divisions/cpoct/Pages/default.aspx
- NACB published guidelines. http://www.aacc.org/members/nacb/lmpg/onlineguide/publishedguidelines/poct/pages/default.aspx
- Royal College of Pathologists. Guidelines on point-of-care testing: http://www.rcpath.org/resources/pdf/Point-of-CareTesting-updatedOct04.pdf
- CLSI. Selection criteria for point-of-care testing devices; proposed guideline. http://www.clsi.org/source/orders/free/poct09-p.pdf

Dr George Koumantakis and Mr Les Watkinson are both members of the AACB PoCT Working Party Committee.

Competing Interests: Dr George Koumantakis has declared that he is an employee of Roche Diagnostics Australia. Mr Les Watkinson declares no competing interests.