

Implementing a quality assurance system for point-of-care blood glucose monitoring

Claire Portogallo, Ian Barlow

Point-of-care testing (POCT) is defined as any analytical test performed for an individual by a healthcare professional outside the conventional laboratory setting (Kost, 2002). Such analysis thereby provides an immediate test result, facilitating rapid patient management decisions, and is now considered an indispensable element of everyday clinical routine (Jahn and Van Aken, 2003). In this article, the authors recount their experience of implementing a quality assurance system for POCT blood glucose monitoring.

In the past decade there has been a rapid increase in the scope and frequency of point-of-care testing (POCT), whereby a diagnostic test – such as blood glucose measurement – is carried out in a convenient and timely manner close to the site of patient care, e.g. the hospital bedside.

Unfortunately, however, there have been an increasing number of reports of unreliable results causing a risk to patients (Jahn and Van Aken, 2003). These incidents have been caused by use of faulty or ill-maintained equipment, unsatisfactory analytical technique, lack of quality checks and inappropriate testing due to lack of understanding of the technology and pathology involved. If the tests are not performed with care and attention to technique, after appropriate training, the results can be erroneous and dangerous (Sharpe, 1993).

The Department of Health and Social Services (DHSS, 1987; 1989) issued at least two hazard notices concerning the potential risk of POCT to patients, and various

professional bodies involved have all recognised the need for guidance and control in this area (Medical and Healthcare products Regulatory Agency, 2005; 2008).

To practice competently, the user of POCT equipment must have the knowledge and skills for safe and effective practice when working without direct supervision; they must recognise and work within the limits of competence, keeping knowledge and skills up-to-date and take part in appropriate learning and practice activities that maintain and develop their competence and performance (Nursing and Midwifery Council, 2008).

Blood glucose meters

Blood glucose meters (BGMs) are a good example of POCT, and central to result quality is high-quality training, robust internal quality control (QC), external quality assurance (QA) schemes and effective process management. These issues were emphasised by a Scottish Health hazard warning (Scottish

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2. Blood glucose meters (BGMs) are a good example of POCT, and central to result quality is high-quality training, robust internal quality control, external quality assurance (QA) schemes and effective process management.
3. Standardisation to a single BGM enabled implementation of a comprehensive QA scheme.

Key words

- Blood glucose monitoring
- Inpatient care
- Point-of-care testing

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1. Different models of blood glucose meter (BGM) do not correlate perfectly with each other, and can (and do) give slightly different results.
2. The team achieved full unification of BGMs across secondary care and the community (initially 250 BGMs, but, more recently, nearly 1000 BGMs as the quality assurance scheme is being expanded across the county) approximately 8 years ago.
3. In the authors' area, laboratory staff work very closely with DSNs and are involved in all BGM training programme sessions so that the importance of quality principles are understood by all newly trained BGM operators.

Health Service, 1987) published in response to a number of critical clinical incidents that had occurred as a consequence of inpatients being treated on the basis of erroneous BGM results. Healthcare professionals were therefore encouraged to improve BGM result quality and reduce risks to patients.

In response to the Scottish Health Service (1987) warning, most UK pathology laboratories, including the authors', began to develop QA initiatives. However, in the authors' opinion, effective and successful QA can only be achieved by collective team-working involving all key stakeholders; notably the laboratory, DSNs (both from primary and secondary care) and also the BGM operators themselves. Without this holistic approach, the different groups will work independently and quality initiatives may fail to deliver their objectives. The result will inevitably mean a fragmented approach to quality, with a suboptimal impact on inpatient diabetes care.

Therefore, about a decade ago, a team of dedicated healthcare professionals were assembled in the authors' Trust to begin development and delivery of a comprehensive coordinated plan to address the critical issues of BGM training, QC, QA and enable effective BGM quality management, thereby minimising risks to people with diabetes.

Different models of BGM do not correlate perfectly with each other, and can (and do) give slightly different results. Therefore, the first phase of the plan was to review the various types of BGMs in use across the authors' area, with a view to standardisation using a single product. This was considered of paramount importance because informed QA result interpretation from different BGM types can be virtually impossible, particularly if the number of individual BGM types is small.

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DSN and biochemistry department. Prior to standardisation there were about six different models of BGM in use.

Underpinning the success of this was the very close working of these key workers, which in the authors' opinion was key as it helped convey a full and comprehensive understanding of the scientific principles, concepts and benefits of analytical QA to BGM operators. In the authors' area, laboratory staff work very closely with DSNs and are involved in all BGM training sessions so that the importance of quality principles are understood by all newly trained BGM operators.

Moreover, the authors believe that DSNs "selling" these concepts to primary care teams must also have an in-depth knowledge of analytical quality, and it is only by working closely with laboratory staff that this can be achieved.

Quality assurance programme

Standardisation to a single BGM type enabled implementation of a comprehensive QA scheme, which entailed fortnightly distribution of a stabilised, sterile, defibrinated horse blood sample supplemented with glucose to a known concentration. The QA sample results, along with a simple but effective statistical interpretation, are then posted to BGM operators within a monthly cycle. Initially this was fortnightly, but due to expanding numbers of operators this has now changed to monthly, which means that any inaccurate results or BGMs can be intercepted and investigated in a timely manner. Typically, biomedical staff from the laboratory will contact specific BGM operators if their own result is out of consensus (outside two standard deviations of the distribution target mean), and remedial action taken as appropriate.

The authors' QA programme is unique in a number of ways. A survey by Barlow and Beer (2001) showed that only four laboratories in the UK issue whole blood samples. Most other laboratories distribute serum/plasma material on a monthly basis, which is arguably less effective in terms of appropriateness of the QA

material; important matrix effects/limitations have been highlighted in the past with regard to the use of aqueous QC materials (Barlow et al, 1999). The use of a whole blood sample also allows supplementation of the glucose concentration to whatever level is desired, thereby verifying BGM performance over the entire analytical range.

The day-to-day management of the QA scheme is the responsibility of the biochemistry department manager, but ultimate accountability is via the secondary care POCT committee – chaired by the local consultant biochemist. DSNs also sit on this committee to ensure that appropriate policy is written and adhered to, but again the key to success is team work.

Medical devices and specialist medical equipment are used everyday by most healthcare professionals to support care and treatment of inpatients with diabetes.

Resuscitation equipment in clinical areas is routinely checked every day, yet may only be used infrequently, whereas BGMs are used frequently every day (the authors estimate up to 40 times a day), yet are very often not checked because the same importance does not seem to be held for a small device. Healthcare professionals play a pivotal role in ensuring that equipment is used safely and for the purpose it was intended (Cogley, 2008).

Local policy

A hospital policy was written by the primary and secondary care DSNs in the Northern Lincolnshire and Goole Hospitals NHS Trust, with significant input from the consultant biochemists. This policy includes all aspects of blood glucose monitoring at point of care, and includes appendices such as the Standard Operating Procedure. The policy aims to:

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1. Every 2–3 months an audit is carried out by the company that provides the blood glucose meters (BGMs), and every ward and department that uses a BGM is assessed using a “pass or fail” system on nine criteria.
2. After a successful cascade training event, the key trainer then issues the user with a certificate of attendance and completes a competency form, which is in the blood glucose policy document, and returns this to the DSN.
3. All training days are led by a designated DSN and nurse advisors both from the device manufacturer and the lancet company.

- Provide information and guidelines regarding glucose monitoring to standardise procedures.
- Improve QA and QC, and set out training mechanisms.
- Minimise unnecessary testing and costs.
- Minimise risks to patients and improve quality of care.

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Feedback

After each audit the nurse advisor feeds the results back to both the DSN and the consultant biochemist. Every area that has scored one or more fails will be contacted (previously by telephone but currently by letter) and the point(s) they have failed on will be highlighted and ward or department managers asked to action. If an area continues to fail, the DSN (who is a member of the POCT committee) will highlight this at the committee and this is brought to the attention of the modern matrons and clinical governance leads. A discussion will also take place between the DSN and the ward manager, and there is a possibility a BGM may be withdrawn from the clinical area

until staff have been re-trained (this has never had to be done, and patient care would not be affected as testing could be done with a different BGM and by a member of staff from another area). If all nine criteria are passed the staff are sent a congratulatory letter, as very often we are told when we fail but not when we perform well.

Education and training

BGM training days are held throughout the year, and all relevant staff are invited to attend. A “cascade training” system is in place such that key staff, once trained, can then disseminate training to other staff in their area using a “cascade training pack” available on the Trust’s intranet site. After a successful cascade training event, the key trainer then issues the user with a certificate of attendance and completes a competency form, which is in the blood glucose policy document, and returns this to the DSN. Their name is then added to a password-protected database of “competent” users which sits on the Trust intranet. Access to this database is only permissible to POCT committee members.

All training days are led by a designated DSN and nurse advisors both from the device manufacturer and the lancet company. This team approach ensures that blood glucose

Table 1. An example of an audit on the blood glucose meter, and relevant equipment, in clinical areas.

Strip lot number	In date	Strip insert	Calibration bar	Code correct	Solutions	Solutions in date	Health and safety	Regular QC	Range correct
53861	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
53861	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
53774	Yes	No	Yes	Yes	Yes	Yes	Yes	No	No
53975	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
53975	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
53975	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
53861	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
53861	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
53882	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
53882	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes

monitoring and training is effective. Staff are informed about the importance of all aspects of blood glucose monitoring, and incidents that have occurred in the UK as a direct result of faulty equipment or incorrect use are also highlighted.

A practical session is embedded into these sessions. Training sessions are held hourly, on an appointment basis, and ward managers are notified about non-attendees. The team are regularly looking at ways to improve attendance and online training is shortly to be introduced.

Future plans

Recently, the primary and secondary care Trusts for greater Lincolnshire went out to joint tender for BGMs, with the contract being awarded to a single supplier. This means that the QA programme can now be developed further, and it is the authors' intention to extend the QA programme described above to the entire county of Lincolnshire (over 1000 BGMs). Recent innovation has also seen electronic QA result submission via the internet. Future plans include extending the scheme to nursing and care homes and emailing rather than posting results, along with the online training and possible accreditation.

Conclusion

The authors, as key members of the group that set up the QA system, feel that they have come a long way in helping to reduce risk to inpatients with diabetes in their Trust. A point-of-care committee was established, and as a result it is ensured that all equipment used at point of care is quality controlled, quality assured and a training log is held of all users (and updated).

Standardisation of equipment used has been introduced, and in relation to blood glucose testing at the patient's bedside, regular annual training is held and names of staff members who attend are added to a database. All BGMs used in the clinical areas are audited, and any areas who fail are notified with a standard procedure of escalation if they continue to

fail. All BGMs are quality assured too, again with an escalation procedure if anyone fails to return samples or the result falls out of the expected range.

The authors are striving to continuously improve the service and are introducing online training to help improve further the staff attendance at training. ■

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