Abstract

The innovation, apparent simplicity and functionality of POCT provide many challenges for health care funding authorities. In particular, the ability to determine the value which POCT may bring to the patient care process. The aim of this report is to summarise existing policies, procedures or guidelines which govern the use of point-of-care testing (POCT) and in particular, any mandatory requirements and quality management issues.

Formal policy and regulation generally applies to situations where service payments may be provided; that is, where a healthcare funding agency (government) or health insurer provides a service fee for POCT. Excluding home use and personal testing, in countries without specific overall regulation there is little information regarding the use of POC devices in the “private” healthcare setting or where patients are prepared to pay directly for testing services. This review provides a summary of international and Australian standards, “policy” and guidelines which apply to POCT.

Procedural guidelines provided by medical colleges are now largely described as “evidence-based” and evidence based medicine has become well established as a component of both undergraduate and postgraduate medical education. In the same manner, evidence-based laboratory medicine is an essential component of modern diagnostic laboratory practice and POCT procedures. The fundamental role of medical testing laboratories and POCT providers is to produce test results that are fit for their intended purpose. In order to determine whether a method is routinely producing results which are fit for purpose, there needs to be a relevant analytical goal against which the estimated uncertainty of measurement can be compared. These issues and the relevance of quality control and external quality assessment in POCT are fully discussed.
Review: Policies, procedures and guidelines for point-of-care testing

Preamble

This review is based on a report commissioned by RCPA Quality Assurance Programs Pty Ltd (QAP), and funded by the Australian Government Department of Health and Ageing through the Quality Use of Pathology Program. The final report was submitted to the Department in June 2011.

As indicated by the acknowledgements at the end of this article, the author is extremely appreciative of the invaluable comments and information supplied by many local and international experts. In particular, the help and advice provided by Ian Gardner and Janice Gill of the QAP, without whose support this review would not have been undertaken or completed. Their persistence in proof-reading several versions of this review is to be commended. However, the author is solely responsible for the content of the review, including any inconsistencies, errors or omissions.

The aim of the report was to summarise existing policies, procedures or guidelines which govern the use of point-of-care testing (POCT), particularly any mandatory requirements and quality management issues. For expediency, the review was largely limited to English speaking countries, or countries with clearly defined and publically available government policy. In addition, the terms *policy*, *requirement* and *guideline* are regularly used to describe aspects of POCT practice, with different authors or agencies applying these terms under slightly different circumstances or with a different emphasis. For the purpose of this review, appendix 1 summarises the *interpretations* which have been applied with respect to the terms *policy*, *requirement* and *guideline*. Appendix 2 provides a list of the many abbreviations encountered while researching this topic.

By its very nature, this type of review will always be incomplete and should be viewed as a snap-shot in time. Due to rapid progress in both the technology and the application of POCT, the measurands available and their implementation are subject to continuous change.

Introduction

Point-of-care testing is a popular means of providing laboratory testing at or near the site of patient care. An extensive literature demonstrates that POCT has the potential to improve patient treatment if undertaken within a comprehensive quality management system. The series of peer-reviewed articles which describe operational aspects of the Quality Assurance for Aboriginal and Torres Strait Islander Medical Services (QAAMS) and the Integrated Cardiovascular Clinical Network (iCCnet) programs attest to this statement.¹ ² However, a faster result is not necessarily equivalent to a result obtained from a traditional pathology laboratory and this difference requires a good understanding of the technology involved. In addition, concerns over the quality of POCT have resulted in a hierarchy of laboratory regulations in the USA and other countries, and POCT operational guidelines have been produced by many professional groups in order to maximise patient benefit and minimise testing errors. The International Organisation for Standardisation (ISO) and the Clinical and Laboratory Standards Institute in the USA (CLSI) have produced standards to address many of these perceived operational and technical issues.
Evidence-based medicine has now become the international standard for improving health care. Evaluation of new technologies and clinical procedures should thus be evaluated using an evidence-based medicine approach which includes technical, cost-effective and patient benefit perspectives. At the most elementary level, patients as consumers of health care expect that the quality of care provided be synonymous with freedom from medical error. This includes freedom from errors in laboratory and POC testing. For patient safety to be achieved within the current context (of laboratory and POC testing), quality goals for both analytical and clinical management must be given an appropriately high priority. It has also been stated that the Medical Journal of Australia (MJA) is second only to the British Medical Journal (BMJ) “in publishing the largest number of references indexed under the term evidence-based medicine in English-language journals.” This possibly suggests that Australian medical authors are both knowledgeable and supportive of the concepts of evidence-based medicine.3

The recent (third) edition of the internationally acclaimed text on POCT covers most of the current issues in the POCT debate (Point-of-care testing: Needs, opportunity and innovation. Edited by CP Price, A St John and LJ Kricka. AACC Press 2010). Professor Sharon Ehrmeyer in chapter 19 of this text makes an important observation, “Today, most healthcare organisations offer some point-of-care testing (POCT) as a means to improve healthcare delivery. POCT is rather broad in scope and covers any testing that is performed near the patient and outside of the conventional clinical laboratory, whether it is performed in a physician’s office, emergency department, intensive care unit, or an ambulatory care clinic. Although in most countries the highly trained laboratory professionals performing clinical laboratory testing are required to follow extensive government regulations to ensure quality test results, specific testing requirements are not identified for POCT, which is typically performed by individuals without formal laboratory training. In the United States, the federal government mandates minimum standards for all “laboratory” testing, regardless of where it is performed, and exerts control through regulatory policies, public law, and collaboration with professional organisations.” ….. “Many countries however, have professional organisations that recommend specific guidelines for POCT that include quality assurance practices and external quality assessment or proficiency testing.”4

The innovation and functionality of POCT brings many challenges for health care funding authorities. In particular, the ability to determine the value which POCT may bring to the patient care process. The penultimate sentence of chapter 1 in Point-of-care testing: Needs, opportunity and innovation, states that: “The four main challenges are, (a) producing the evidence to demonstrate that POCT improves outcomes, (b) changing clinical practice to deliver the benefit, (c) maintaining clinical governance for a more distributed laboratory medicine service, and (d) adjusting the resource allocation to reflect the likely increase in investment in the POCT technology, while recouping the resources from the point in the pathway at which the benefits are made.”5

Point-of-care testing - Definitions

Point-of-care testing (POCT) is a form of testing in which the analysis is performed where healthcare is provided close to or near the patient. Various definitions have been provided in the medical / scientific literature and alternative descriptions include: near patient testing (NPT), bed side testing, physicians office testing (POL), off site testing, alternative site testing, etc.
International standard ISO 22870, *Point-of-care testing (POCT) - Requirements for quality and competence*, defines POCT as: “testing that is performed near or at the site of a patient with the result leading to possible change in the care of the patient”.

This definition of POCT provides an accurate but rather general description of the application of POCT. In practice, POCT may be undertaken in many locations including:

- home use, self testing
- pharmacy
- paramedical support, ambulance
- nursing home or aged care centre
- general medical practice, primary care (US terminology: POL, physicians office laboratory)
- rural (remote) hospital or health clinic
- critical care facility in major hospital (ED, ICU, CCU, etc)
- hospital ward or hospital clinic
- sports clinic
- workplace drug screening.

An interesting definition suggested by an Irish group who recently completed a survey of POCT in Irish hospitals is “Point of care testing is defined as a quality-assured pathology service using analytical devices (including test kits and analysers such as blood gas and critical care analysers and meters for glucose, urinalysis and other metabolites) provided near to the patient rather than in the traditional environment of a clinical laboratory”.

The types of test and the manner in which a particular POCT device is used in each of the above situations may differ, the testing frequency will probably be different and the testing requirements or the fitness for purpose will almost certainly be different. In addition, if testing is required for diagnosis, monitoring or screening, different testing devices or testing regimes may well apply. The required fitness for purpose may also determine the quality management procedures and the specific requirements for quality control (QC) and external quality assessment (EQA). Thus, when discussing the application of POCT, the particular situation in which a given test or device will be used also requires consideration. **POCT is not a single unified entity; different circumstances may require different solutions.**

**International standards**

The international standard for POCT is ISO 22870, *Point-of-care testing – requirements for quality and competence*. This standard, produced by the International Organisation for Standardisation (ISO), gives specific requirements applicable to POCT and is intended to be used in conjunction with ISO 15189, *Medical laboratories – particular requirements for quality and competence*. The requirements of ISO 22870 “apply when POCT is carried out in a hospital, a clinic, or healthcare organisation providing ambulatory care”.

Patient self-testing is excluded from ISO 22870, but is covered specifically in ISO 15197 *In vitro diagnostic test systems – requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus*, and ISO 17593 *Clinical laboratory testing and in vitro medical devices – requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy.*
The term **standard** is itself defined by ISO as a document describing … “a set of rules that control how people develop and manage materials, products, services, technologies, processes, and systems.” ISO standards are developed by technical committees whose members represent many countries and professional groups and generally have very broad international support. Australia's representative (member organization) to ISO is Standards Australia (see item below, National standards and guidelines), which also provides a similar definition for the term standard.\(^8\)

Appendix 3 provides a list of international and Australian standards which contain laboratory or POCT quality procedures.

**Clinical practice guidelines (Guidelines)**

In a similar manner, the term **guideline** as used in medicine (or more often clinical practice guideline) is usually defined as … “systematically developed statements to assist practitioners with decisions about appropriate health care for patients in specific circumstances”.\(^9\) Guidelines are designed to support the decision-making processes in patient care. Clinical practice guidelines are based on the best available evidence derived from a systematic evidence-based review of available data (see section below, evidence-based medicine).

Standards and guidelines developed for POCT using evidence-based procedures are designed to assist with the implementation, management, operation and on-going quality assessment of the selected technology. With adherence to appropriate standards and guidelines, POCT provides significant benefits for both patients and healthcare providers. As stated in the introduction to ISO 22870 “Advances in technology have resulted in compact, easy-to-use *in vitro* diagnostic medical devices that make it possible to carry out some examinations at, or close to, the location of the patient. Point-of-care or near patient testing may benefit the patient as well as healthcare facilities.” Provided that “risk to the patient and to the facility can be managed by a well-designed, fully implemented quality management system that facilitates:

- evaluation of new or alternate POCT instruments and systems
- evaluation and approval of end-user proposals and protocols
- purchase and installation of equipment
- maintenance of consumable supplies and reagents
- training, certification and recertification of POCT systems operators
- quality control and quality assurance.”\(^6\)

**Australian standards and guidelines**

Many countries have developed their own “standards” for laboratory practice and POCT.

In Australia, the National Pathology Accreditation Advisory Council (NPAAC) advises the Commonwealth, state and territory health ministers on matters relating to the accreditation of pathology laboratories.\(^10\) NPAAC is also responsible for the development and maintenance of standards and guidelines which help define the quality procedures for the practice of pathology.\(^11\) NPAAC documents are updated regularly and current listings are available on the internet.\(^12\)
Standards Australia also plays a significant role with the development of national standards or promulgating standards developed by ISO. With regard to pathology, ISO 15189 is reproduced as Australian Standard AS 4633. In addition to coordinating activities with ISO, Standards Australia may develop specialized standards in its own right for “local” applications such as those which have been developed for urine and oral fluid drug of abuse testing and others as shown in appendix 3.

In association with ISO and AS standards, NPAAC is the principal Australian provider of standards for pathology. In this regard, AS 4633 / ISO 15189 has been confirmed by NPAAC as the principal standard which is used as the basis for accreditation of pathology laboratories in Australia. Other NPAAC standards are developed to cover specific areas as required or to provide more detailed information not specifically available in AS 4633 / ISO 15189.

In addition to NPAAC, other Government agencies have developed specific purpose standards and guidelines for defined applications. In particular, Interim standards for point-of-care testing in general practice were prepared by the Royal Australian College of General Practitioners in association with the Department of Health and Ageing general practice trials’ technical advisory committee. These approved standards were used as the basis for pathology testing during the Australian Government Point-of-care testing in general practice trial. The introduction to these interim standards provide a succinct overview of the requirement for appropriate POCT standards, which incorporate training and competency, clinical governance, quality control and the requirement for participation in an external proficiency testing program.

The Medical Services Advisory Committee (MSAC), who’s brief, is to advise the Australian Minister for Health and Ageing on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures, also provides application and assessment guidelines to assist with the preparation of application documentation. Current guidelines which may be applicable to POCT are: Guidelines for the assessment of diagnostic technologies - May 2007, and Funding for new medical technologies and procedures: application and assessment guidelines - September 2005.

In addition to government sanctioned standards and guidelines, the Australasian Association of Clinical Biochemists (AACB) and the Royal College of Pathologists of Australasia (RCPA) provide professional guidelines for POCT.

Australian Government point-of-care testing in general practice trial

Overview – POCT in general practice trial

The point-of-care testing in general practice trial (the trial) was an Australian Government funded multi-centre trial, to investigate and evaluate the safety, clinical effectiveness, cost effectiveness and satisfaction of POCT in a general practice environment which included urban, rural and remote geographic regions.

The trial was probably the most detailed and comprehensive of its type and provided an extensive set of data which has been well researched by members of the trial management committee. The accumulated data provides a strong evidence base in support of the conclusions which have been summarised under the headings: safety, clinical effectiveness,
cost effectiveness, satisfaction, geographic difference, regulatory framework and estimated Medicare Benefit Schedule (MBS) costs. The executive summary of the trial report provides an excellent overview of procedures used and outcomes obtained. Chapter 14 of the report addresses the particular issues of regulation and quality management for POCT. The key findings from Chapter 14 are summarised by the statements “The trial model provides a framework that has been proven to work within the current regulatory environment and is acceptable to all stakeholders. The trial model could form the basis of a framework for the implementation of POCT in general practice more broadly.” … “For POCT to be implemented (in general practice), an effective quality management system is essential. Clinicians need reassurance that their decisions are based on reliable, accurate and precise results to ensure that patient safety is not compromised.”

In addition to the trial report itself, members of the trial management committee have published supplementary assessments of the data and the associated quality management procedures, as evidence to support a number of important clinical outcomes in relation to POCT. A list of publications based on trial data or its associated management procedures is provided in appendix 4.

As outlined above, the trial was conducted using well defined quality standards which included training and competency assessment, clinical governance, quality control and the requirement for participation in an external proficiency program. This approach to quality management has been further described in various publications from members of the trial management committee as indicated in appendix 4 and provided by Shephard et al.

Transfer of information and conclusions

The answers to questions provided as part of the trial and conclusions derived from trial data provide important information as to the applicability of POCT in general practice. However, extrapolation of clinical or analytical information to situations where less effective quality management procedures are employed is probably inappropriate. Conclusions derived from high quality data (where consistent analytical performance can be demonstrated with quality control and external quality assessment, and where desirable quality goals have been achieved by internationally recognised methods, ) can not be transferred to situations in which the analytical results are provided at an inferior level of testing. The authors of the trial report also make a similar statement in the text of their summary to Chapter 14: “If POCT were to be implemented in general practice more widely, it would be necessary for a similar system (of quality management) to be adopted to ensure that the success seen in the trial could be translated into practice.”

This concept is also supported by Price and St John in their discussion regarding transferability of clinical trial data “… in applying results to other situations, it is important to ensure that the new situation has similar characteristics to that in the study (that is, observational studies in secondary care cannot necessarily be applied directly to primary care settings).”

National standards and guidelines from other countries

As noted previously, many countries have developed their own “standards” for laboratory practice and POCT. Most have been developed by expert professional committees in association with the relevant professional colleges and associations. Adherence to these “standards” is often a requirement for government funding, but compliance is also related
to the desire for quality testing and good patient care. The threat of litigation for poor quality testing may also be an incentive to comply with a local standard or professional guideline. This may well be an added incentive in the United States of America (US) for adherence to a professionally established protocol. This warning is clearly stated by Mr JR Bierig, a US malpractice lawyer presenting an opinion to the public enquiry by the US Food and Drug Administration (FDA) into the performance of blood glucose meters (see additional comments with regard to this enquiry below; US Food and Drug Administration enquiry into glucose meter performance). Mr Bierig stated:

“The best way to limit malpractice exposure … is to conduct QC in accordance with the manufacturer’s instructions – or, in the absence of such instructions, on a daily basis. In making this recommendation, I recognise that, glucose testing is a waived test under CLIA. Thus, federal law does not mandate QC on glucose meters. However, both the Joint Commission and the College of American Pathologists, as part of their respective accreditation programs, require QC in this area.”

“If a hospital or practitioner were sued in this context, the Joint Commission and CAP standards are likely to be put into evidence. Likewise, the package insert will almost certainly be introduced. And there will be testimony on the importance of QC. Thus, despite the waived status of this test under CLIA, malpractice considerations counsel strongly in favour of performing appropriate QC.”

Individual countries have their own standard(s) development agencies. Some are classed as “standards”, while others are described as “guidelines”. Whatever the terminology, the perceived status of the document(s) or the level of compliance, there is generally a high degree of acceptance by the respective national professional colleges and associations. In many cases, guidelines for POCT have been compiled jointly by pathologists, clinical biochemists, general medical practitioners and nurses.

Table 1 provides a summary of selected national and international quality management procedures for POCT; including the requirement for operator training, proof of competency, quality control and external quality assessment. Most jurisdictions provide statements regarding POCT which include mandatory quality procedures as defined by regulation or specific policy.

Some specific examples of country based “policy”, “standards” and “guidelines” are:

1. Canada
   - Ministry of Health and Long-Term Care, Ontario, Canada. Point-of-care testing policy and guidelines for hospitals with a licensed laboratory.
   - Ministry of Health and Long-Term Care, Ontario, Canada. Policies, procedures and quality assurance for point-of-care HIV testing in Ontario.
   - Cancer care Ontario, program in evidence-based care. Guaiac fecal occult blood testing laboratory standards.
2. **France**  
   o Point-of-care testing management protocol using ISO 22870 guidelines and French requirements (to be mandatory by 2016).\(^{38}\)

3. **Germany (Federal Republic of Germany)**  
   o Directive: the Federal Medical Council for quality assurance of medical laboratory tests (mandatory).\(^ {39}\)

4. **Ireland (Republic of Ireland)**  
   o Joint committee for POCT in primary care and community care. Guidelines for safe and effective management and use of POCT in primary and community care.\(^ {40}\)  
   o Joint committee for POCT. Guidelines for safe and effective management and use of POCT.\(^ {41}\)

5. **Spain**  
   o Soto AB et al. Proposed guidelines for point-of-care testing in Spain.\(^ {42}\)  
   o Spanish Society of Clinical Biochemistry and Molecular Pathology (SEQC). Guía para la implantación de pruebas de laboratorio en el lugar de asistencia al paciente, 2006.\(^ {43}\)

6. **United Kingdom**  
   o Department of Health (UK). Medical and healthcare products regulatory agency (MHRA). Management and use of IVD point-of-care test devices.\(^ {44}\)  
   o NHS Fife. Point-of-care devices.\(^ {45}\)  
   o Northern Health and Social Care Trust. Point-of-care testing policy, 2009.\(^ {46}\)  
   o Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust. Point-of-care policy, 2008.\(^ {47}\)  
   o Ashford and St Peter’s Hospitals Trust. Point-of-care testing policy, 2010.\(^ {48}\)  
   o Craigavon Area Hospital Group Trust. Point-of-care testing (POCT) policy, 2008.\(^ {49}\)  
   o Conway and Denbighshire NHS Trust. Near patient testing / point-of-care testing policy, 2005.\(^ {50}\)  
   o Clinical pathology accreditation (UK). Additional standards for point-of-care testing (POCT) facilities (mandatory if applying for accreditation).\(^ {51}\)  
   o NHS. Point-of-care testing in critical care.\(^ {52}\)  
   o Association of Clinical Biochemists. Guidelines for implementation of near patient testing, 1993.\(^ {53}\)  
   o Royal College of Pathologists (RCPath). Guidelines for point-of-care testing.\(^ {54}\)  
   o British Committee for Standards in Haematology. Guidelines for point-of-care testing: Haematology.\(^ {55}\)  
   o Welsh Scientific Advisory Committee. Point-of-care testing: The use of diagnostic equipment and procedures outside the diagnostic laboratory.\(^ {56}\)  
   o Northern Ireland. Department of Health, Social Services and Public Safety. Recommendations for the future of pathology services in Northern Ireland, 2007.\(^ {57}\)  
   o Northern Ireland. Health Estates policy, based on UK Medical Devices Agency (MDA), Management and use of IVD point of care test devices, 2002.\(^ {58}\)
7. **United States of America**

- The National Academy of Clinical Biochemistry (NACB). Evidence based practice guidelines for point-of-care testing.\(^{61}\)
- CLSI. Guidelines as indicated in appendix 5.
- Centers for Disease Control and Prevention (CDC). Good laboratory practices for waived testing sites.\(^{62}\)
- American Academy of Family Physicians. Office laboratory medicine.\(^{63}\)
- College of American Pathologists. Commission on laboratory accreditation. Point-of-care-testing checklist (mandatory if applying for accreditation).\(^{64}\)
- The Joint Commission. Standards for laboratory accreditation.\(^{65}\)

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**Evidence-based medicine and POCT**

**Evidence-based medicine and evidence-based laboratory medicine**

The development of evidence-based medicine (EBM) is just as important to laboratory medicine and POCT as to medical practice in its broadest context. The generally accepted definition of evidence-based medicine is that given by Sackett et al., namely “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of patients”.\(^{66}\) As discussed by Price, “this definition can readily be applied to laboratory medicine because:

- a request for a diagnostic test represents part of the decision-making process
- the relevance of the test to the clinical situation at hand and its *fitness for purpose*
- of the need for a critical appraisal of the evidence in terms of testing quality
- the continuing evolution of evidence, particularly of new tests or testing procedures requires continuous evaluation.”\(^{67}\)

The application of evidence-based medicine also provides an assessment of the most cost-effective manner for treating the *average* patient in order to obtain the best health outcome. Individual patients however, may vary considerably from this *average*. This deviation and the initiation of appropriate treatment is where clinical judgment is required.

The application of evidence-based medicine to diagnostic laboratory testing is now universally accepted by professional colleges and associations in the medical and clinical sciences. Procedural guidelines provided by medical colleges are now largely described as “evidence-based” and EBM has become well established as a component of both undergraduate and postgraduate medical education. In the same manner, evidence-based laboratory medicine (EBLM) is an essential part of modern diagnostic laboratory practice as reviewed by Price,\(^{68}\) Hawkins,\(^{69}\) Oosterhuis et al.,\(^{70}\) Christenson\(^{71}\) and Christenson et al.\(^{72}\) The place of EBM in Australian medical literature also appears well established as evidenced by the statement that the *Medical Journal of Australia* (MJA) is second only to the *British Medical Journal* (BMJ) “in publishing the largest number of references indexed under the term “evidence-based medicine” in English-language journals.”\(^{73}\)
Evidence-based laboratory medicine and POCT

In addition to traditional laboratory based testing, evidence-based procedures have also been applied to POCT by The National Academy of Clinical Biochemistry (NACB) with an extensive set of practice guidelines, Evidence-based practice for point-of-care testing.

However, if applying existing laboratory evidence to POCT procedures, it is important to confirm that:

- such evidence matches the patient or patient group being considered
- the accuracy and precision of the POCT system is appropriate for the proposed circumstances (see comments with regard to “fitness for purpose”, below)
- conclusions derived using high quality data are not transferred to situations in which the analytical results are provided at an inferior level of testing (as discussed previously)
- there is good concordance of the proposed POCT results with established laboratory procedures (such that reference intervals and action limits in current use are applicable)
- clinical practice guidelines (such as the WHO and/or NHMRC guidelines for the diagnosis and management of diabetes mellitus) are still applicable.

The importance of these cautions is clearly shown by the World Health Organisation (WHO) criteria for the diagnosis of diabetes mellitus, which provide the diagnostic criteria for diabetes currently used within Australia. The recommended diagnostic criteria for diabetes mellitus use plasma glucose measured in an accredited laboratory, not whole blood glucose measured with a POCT device. The revised evidence-based Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus from the NACB make this point even more strongly (Chapter 3, Glucose meters.

1. Use):

“A. Diagnosis/screening. The glucose-based criteria for the diagnosis of diabetes are based upon outcome data (the risk of micro- and macro- vascular disease) correlated with plasma glucose concentrations (both fasting and 2 h after a glucose load), assayed in an accredited laboratory. Whole blood is used in portable meters. Although most portable meters have been programmed to report a plasma glucose concentration, the imprecision of the current meters precludes their use in the diagnosis of diabetes. Similarly, screening by portable meters, although attractive because of convenience, ease and accessibility, would generate many false positives and false negatives.”

These revised guidelines have been jointly reviewed by the NACB and the Evidence Based Laboratory Medicine Committee of the American Association for Clinical Chemistry (AACC) and have also been approved by the American Diabetes Association. The full guidelines document is available electronically. A more concise summary is also available. Additional key points with respect to glucose and HbA1c are:

- to minimize glycolysis, “an effective glycolysis inhibitor such as citrate buffer should be used”
- “on the basis of biological variation, glucose measurement should have an analytical imprecision ≤2.9%, a bias ≤2.2% and a total error ≤6.9%”
- “there is insufficient published data to support a role for portable meters and skin-prick blood samples in the diagnosis of diabetes or for population screening”
- “laboratories should use only HbA1c methods that are certified by the National Glycohaemoglobin Standardisation Program …”
- “desirable specifications for HbA1c measurement are an intralaboratory CV <2% and an interlaboratory CV <3.5%.”
In addition, a recent systematic review of evidence-based publications describing POCT for HbA1c in the management of diabetes, found “no evidence of the effectiveness of POCT for HbA1c in the management of diabetes”.

**US Food and Drug Administration enquiry into glucose meter performance**

Statements critical of the performance and clinical use of glucose meters by the NACB and respected diabetes practitioners, have been further highlighted by the public enquiry by the US Food and Drug Administration (FDA) into the performance of blood glucose meters. Transcripts of the meeting are available (internet link available through reference 29). These transcripts discuss many of the performance aspects of blood glucose meters including issues of concern with regard to quality. They include:

- the analytical quality required for patient monitoring, detection of hypoglycemia, and tight glycaemic control
- the clinical requirements for glucose measurement, quality control requirements
- target concentrations for hypoglycemia and glycaemic control
- interferences in the common methodologies employed by blood glucose meters.

An overview of the discussions at the FDA enquiry is provided by Westgard. The role of biological variation in determining testing performance and fitness for purpose is discussed below.

**Improved patient outcome with POCT**

POCT is an increasingly popular means of delivering laboratory testing. When used appropriately, POCT has clearly been shown to improve patient outcome by providing a faster result with faster therapeutic intervention (Price and Kricka, Shephard and Gill, Francis and Martin, Tideman et al.,), and examples of evidence-based reports in support of POCT are provided by the NACB, Bubner et al., St John, and Price and St John. In addition, POCT methods generally require smaller sample volumes than those needed for central laboratory testing and minimise time-dependent changes in labile analytes such as glucose. However, when over utilized or incorrectly performed, POCT presents a significant patient risk and potential for increased healthcare costs.

**Fitness for purpose**

**Fitness for purpose and intra-individual biological variation**

The International Organization for Standardization (ISO) defines quality as the “totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.” In the medical context, this definition can be translated to mean that the quality of either laboratory or POCT must allow clinicians to practice good medicine. This definition also contains an implied requirement to understand the quality required to ensure satisfactory clinical decision making and to understand if a given test is fit for the purpose for which it is intended (that is, fit for purpose).

Australian Standard AS 4633 (ISO standard 15189; Medical laboratories – particular requirements for quality and competence) to which all accredited pathology laboratories in Australia must comply, makes an explicit statement to this effect:

AS 4633, 5.5.1: “The laboratory shall use examination procedures, ... which meet the needs of the users of laboratory services and are appropriate for the examinations”.

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The fundamental role of medical testing laboratories and POCT providers is to produce test results that are fit for their purpose. A test result must have appropriate analytical accuracy and precision in order for it to be considered fit for purpose; that is, suitable for the clinical purpose for which the test is being used. In order to determine whether a method is routinely producing results which are fit for purpose, there needs to be a relevant analytical goal against which the estimated uncertainty of measurement can be compared. Some methods have internationally agreed analytical goals (for example; glucose, cholesterol and haemoglobin A1c), but in their absence various approaches have been used to set goals for both inaccuracy (bias) and imprecision. A widely used and internationally recommended concept is to define the upper acceptable limit for imprecision as a proportion of the intra-individual biological variation of the measurand in question. With correct choice of the proportionality factor, analytical imprecision should not contribute significant additional variation to the test result when compared with the natural variation of the analyte being measured. A similar approach to goal-setting can be used for total analytical error (inaccuracy plus imprecision). These concepts are clearly described in the NPAAC document Requirements for the estimation of measurement uncertainty and the AACB publication Uncertainty of measurement in quantitative medical testing – A laboratory implementation guide.

**Quality goals**

Procedures for the determination of quality goals (quality specifications) based on clinical requirements have been reviewed by Fraser, Fraser and Scott, and Klee. A detailed discussion of POC glucose measurement and the relationship between analytical performance and clinical decision-making is given by Boyd and Burns and by Fraser and Scott. Shephard has also considered this issue in some detail for the Australian rural environment in relation to the QAAMS program, with publications discussing quality goal setting for haemoglobin A1c, lipids and urine albumin-creatinine ratio and related POCT quality issues (Shephard and Gill, Shephard etal, Gill and Shephard). The other two major Australian networks of POCT devices, iCCnet and Pathology Queensland, have also described their approaches to clinical governance, quality issues and quality control in POCT.

The practical problems associated with selecting appropriate quality goals (quality specifications) are exemplified by the most widely used POCT device, the glucose meter. The American Diabetes Association (ADA) and the National Academy of Clinical Biochemistry (NACB) have documented this dilemma in considerable detail. They reinforce the WHO recommendation that a laboratory measurement of plasma glucose be used for the diagnosis of diabetes mellitus, and not whole blood glucose measured on a glucose meter with the statement “Portable meters are used by healthcare workers in acute and chronic care facilities, in physicians’ offices, and by patients. Because of the imprecision and variability among meters, they should not be used to diagnose diabetes and have limited value in screening.” One of the issues which should also be considered as part of this argument, particularly for hospital in-patients whose insulin infusion (and consequent insulin dosage) is adjusted in association with POC glucose testing, is that relatively small changes in measured glucose are associated with relatively large changes in insulin infusion rate. Blood glucose monitoring is used to guide therapy in two distinct situations, one to adjust insulin dosage in diabetic patients, and one for adjusting insulin requirement in acutely ill patients on “tight glucose control”. The quality specifications for these two situations have been reviewed by Price. In a recent evaluation study by Freckmann etal, eleven of twenty seven home-use blood glucose monitoring systems (40%)
did not fulfill the rather generous minimum accuracy requirements of ISO 15197 (that is; +/- 0.83 mmol/L at blood glucose less than 4.2 mmol/L, or +/- 20% at blood glucose levels 4.2 or greater). From their study, Freckmann et al concluded that inaccurate results which lead to false treatment decisions by diabetic patients may cause severe health injury.

In addition to portable POC glucose meters, the fitness for purpose of portable devices which measure haemoglobin A1c (HbA1c) has also been questioned recently. The main reason for this concern is the questionable ability of some HbA1c devices to provide a clear analytical distinction between the recommended HbA1c treatment levels of 7.0% and 8.0%. To clearly distinguish between HbA1c values of 7.0% and 8.0%, an analytical (method) uncertainty (expressed as coefficient of variation, CV%) of less than 3.0% is required. Methods which produce analytical CV’s of 4.0% or greater are not considered appropriate, as this degree of analytical imprecision cannot distinguish changes in the HbA1c level of over 1% (that is, can not distinguish an HbA1c level of 7.0% from 8.0%). A more detailed discussion of these concepts and of the relationship between HbA1c measurement and analytical performance is given by White and Farrance. The direct influence of analytical imprecision and inaccuracy (bias) on the measurement of glucose and HbA1c for the diagnosis and prognosis of diabetes mellitus has been considered in more detail by Petersen et al.

“Minimum” or “appropriate” quality standards?

The term minimum standard is often used to describe the least permissible condition or procedure required to demonstrate a basic level of performance (or provision of test results in the current context). In circumstances where quality is not considered a necessary objective, minimum usually becomes synonymous with actual. When discussing any testing situation where quality is an important component of the expected outcome, appropriate standard(s) which provide the desired level of measurement uncertainty are required.

For POC and quantitative pathology testing in general, appropriate analytical tolerance levels are defined by quality goals based on biological variation or internationally recognized clinical decision values as described previously. The desirable analytical variability which is required to insure that a test is fit for purpose is fully discussed by Fraser, Fraser and Scott, and White and Farrance. Failure to meet appropriate standards and failure to demonstrate that quality once attained is also maintained, may jeopardize patient safety and contribute to a poor health outcome. Incorrect or misleading test results which initiate inappropriate treatment may cause more harm than no results at all.

Appropriate standards which support quality testing should be the desired approach, not minimum standards which provide the opportunity for quality failures.

Global changes in the use of POCT

In most countries, including Australia, there are no regulations which prevent the use of POCT. The main impediment to the widespread use of POCT is related to funding. In most countries where healthcare funding is provided by government or by a private health insurer, some form of regulation is required which governs the manner in which POCT may
be implemented. Regulations which apply to laboratory testing in general (and which includes POCT) are required to:

- assure patients and funding authorities that testing is *fit for purpose*
- assure patients and funding authorities that quality testing is being provided and maintained
- assure patients and funding authorities that device operators have the required skills and competencies
- assure patients and funding authorities that devices are being appropriately maintained
- assure users that POC devices comply with defined technical specifications
- ensure that testing is provided in a safe environment
- provide a consistent base for all testing procedures and provide some consistency between multiple service providers
- ensure that patient records are managed in an appropriate and consistent manner
- inhibit uncontrolled and inappropriate use of testing
- provide a mechanism for assessing the distribution of valuable healthcare dollars.

In many countries, reimbursement of testing costs is used to insure compliance with the required standard or guideline. That is, reimbursement for testing is only provided under specified circumstances and only if defined guidelines or quality procedures are being used.

Reimbursement arrangements with respect to POCT only appear problematical when performed outside of a formal accreditation system. Even though some POC testing is available as waived tests in the US (see discussion below), basic quality control is still required as specified by the manufacturer. In general, it would appear that when POCT is performed within an approved accreditation system, government or health insurer reimbursement is usually available. A tabular summary comparing reimbursement arrangements for several countries (Australia, France, Germany, Italy, Spain, United Kingdom and United States) is provided by Wittels et al.\(^{105}\)

**Australia: POC medical testing**

Australia is by no means backward in embracing POCT technology. Glucose meters have been widely available for many years, hospitals and accredited pathology laboratories have also been using a wide range of POC devices for a considerable time. With the possible exception of glucose, hospital based POCT is usually related to emergency or critical care testing and is often performed in association with an accredited pathology service if Medicare reimbursement is to be sought. POC networks such as QAAMS, iCCnet and the Pathology Queensland POCT network are well established. These networks use documented quality control procedures and participate in external proficiency testing programmes.

In addition, diagnostic companies supplying glucose meters to hospitals provide quality control materials and a specifically designed EQA program with support to hospital wards in the use these quality indicators. Even though this support is available, participation is generally not a specific requirement and so is often sporadic.

Payment for most types of POCT is available through Medicare, provided such testing is undertaken by an accredited pathology service (laboratory). To be accredited, the laboratory must comply with AS 4633 / ISO 15189 or for specific POCT applications ISO
Often overlooked but also very common in Australia, is the use of POCT in sports medicine and workplace screening for drugs of abuse. Certainly from a legal perspective, POCT drug (and ethanol) testing is usually only considered as a preliminary or screening procedure. Positive screening tests for drugs of abuse usually require confirmation by an accredited laboratory based on Australian standard AS 4308.

Australia: POC testing for drugs of abuse

In Australia and many countries, drug testing which is required for legal purposes (for example; workplace testing, where a positive test involves a penalty or dismissal), requires confirmatory testing to be performed. In Australia this would require compliance with Australian Standard AS 4308. The use of POCT for drugs of abuse in both medical and non-medical settings raises many issues, including; operator training, quality control, quality assurance, accuracy of results, limitations of the technology and economics. In particular, POC drug testing is generally designed to screen for the presence of designated drugs or groups of drugs. None are intended to serve as a definitive or confirmation test.

Both AS/NZS 4308:2008 Procedures for specimen collection and the detection and quantitation of drugs of abuse in urine and AS 4760:2006 Procedures for specimen collection and the detection and quantitation of drugs in oral fluid outline the procedures required for a laboratory to demonstrate its technical competency. They are prescriptive in the procedures required to ensure appropriate specimen collection, handling, storage, transport, on-site screening, the use of quality control and proficiency testing, initial testing and confirmatory testing.

The procedures are intended for (but not limited to) medico-legal, workplace, correctional services or court directed testing, of any or all of the following classes of drugs:

- amphetamine type substances.
- benzodiazepines.
- cannabis and metabolites.
- cocaine and metabolites.
- opiates.

The Standards cover all aspects of specimen collection and testing, and defines procedures which must be followed to allow proper legal scrutiny. These procedures include:

- specimen collection, storage, handling and dispatch (chain of custody)
- integrity and identity of the specimen
- general laboratory requirements
- laboratory screening procedures and test cut-off levels (cut-off drug concentrations), recording of results and reporting
- laboratory security, specimen reception, specimen integrity and storage
- quality control and proficiency testing (external quality assessment)
- laboratory confirmatory procedures
- laboratory personnel and training
Articles describing the relevance of POCT to drug detection and clinical toxicology with comments on the relevant quality issues have been published by Mighani, Watson and Valdes et al.

Canada

The administration and delivery of healthcare in Canada are the responsibility of each province (state) or territory. POC testing has generally been encouraged by Canadian healthcare providers due to the challenges of servicing large underpopulated areas. This in turn has led to an increased interest by regulation authorities in monitoring the quality of POCT and its implementation. For example, the Ministry of Health and Long-Term Care in the province of Ontario have a very well defined policy, which was updated in 2008. This mandatory policy applies to all “licensed hospitals”, including those hospitals “without a licensed laboratory” and to “long-term care homes”. The policy defines the management and technical requirements for POCT under the following categories:

- evaluation of new or alternative POCT instruments and systems
- precision and accuracy requirements to meet clinical needs
- evaluation and approval proposals and protocols
- purchase and installation of equipment
- maintenance of consumable supplies and reagents
- training, certification and recertification of POCT operators
- quality control and quality assurance
- health record management.

Professional organisations involved with the drafting of the Ontario policy were: Ontario Society of Clinical Chemists, Ontario Hospital Association, Ontario Medical Association, College of Physicians and Surgeons of Ontario, College of Medical Laboratory Technologists of Ontario, College of Nurses of Ontario, Ontario Long-Term Care Association, and Ontario Association for Non-Profit Homes and Services for Seniors.

Also on behalf of the Ontario Ministry of Health and Long-Term Care, specific guidelines were prepared in 2009 to cover patients on long-term oral anticoagulation therapy by an expert panel convened by the Ontario Medical Association. These guidelines state; “The target audience was anticoagulation clinics, pharmacies, long-term care facilities, community care services, physician/primary care offices and selected patients and/or caregivers”. “Recommendations were proposed following the consideration of INR POC international guidelines, devices licensed by Health Canada, device selection criteria, Quality Control (QC) and External Quality Assessment (EQA) programs, enablers and barriers, and training requirements.” The guidelines specify that:

- QC is required; with a system independent from the manufacturer of the device preferred
- operators must take part in an EQA program in order to validate the test system performance, at a minimum of once per year
- operators monitoring and performing POC INR testing on greater than 10 patients per day, should take part in a formal EQA program.

Similar “policy” guidelines have been established for POC HIV and occult blood testing.

In contrast to Ontario with its defined policies, the Ministère de la Santé et des Services sociaux in the province of Quebec, commissioned the Agence d’évaluation des technologies
et des modes d’intervention en santé (AETMIS), to review the role of POCT with a view to revising legislation and applicable regulations while assessing the need for governance oversight of POCT procedures. In this respect, aspects of Quebec legislation already acknowledge the concept of POCT as the legal definition of POCT is, “testing performed by qualified health professionals outside recognised and accredited public or private laboratories and outside health and social services institutions”. The executive summary of the AETMIS report (dated January 2008) provides a good overview of the recommendations. Other provinces with less well defined policies still appear to follow recognised guidelines. For example, the College of Physicians and Surgeons of Alberta provide detailed recommendations for the use of POCT outside of an accredited laboratory which includes documentation, staff training, quality control, etc, in Unaccredited point-of-care laboratory testing guidelines for physicians.35

Germany

In the Federal Republic of Germany, point-of-care systems appear to be mainly used within hospitals and medical practices. Other medical situations where POCT may be used include outpatient nursing care, home visits and pharmacies (lipid testing). Self-monitoring for glucose and INR are also common.111 Junker et al, in a detailed review of POCT in teaching hospitals and primary care state German medical device regulations and the German law on liability do not distinguish between conventional laboratory analyses and POCT.111 In addition, “the 2008 Directive of the German Medical Association on the Quality Assurance of Tests in Laboratory Medicine (RiliBAK 2008) does not stipulate any special regulations for POCT in comparison to those for a medical laboratory, the only exception being the unit use systems. Part A of the RiliBAK contains the fundamental requirements for quality assurance,” … “and applies both in hospitals and practices. Part B1 contains the specific requirements for the quality assurance of quantitative laboratory tests”. A computerized English translation of the RiliBAK is available on the internet.39

The term RiliBAK, which is used to describe the minimum quality requirements for medical laboratory tests actually means “guidelines” of the German Federal Medical Council (BAK).

New Zealand

New Zealand in many ways is similar to Australia. District Health Board (DHB) contracts for laboratory testing require accreditation to ISO 15189, but may exclude some forms of POCT from the contract. Laboratories that perform POCT testing under a DHB contract must be accredited to ISO 22870.

There are no regulations which govern POCT in general medical practice or in a community setting, but also no government reimbursement or testing fee even though District Health Boards may directly fund defined POCT projects. Such a DHB funded project has been described in the remote rural hospital of Rawene in New Zealand’s North.112 The report describes the changes in clinical practice and patient disposition
following the introduction of POCT in a rural hospital without immediate laboratory support. In addition to improved patient care, the report shows a global saving of approximately NZ $360,000 within the global DBH budget.

**United Kingdom (UK)**

Different operational healthcare policies may apply to England, Scotland, Northern Ireland and Wales. The National Health Service (NHS) is the name commonly used to refer to the four single-payer publically funded healthcare systems in the UK (collectively or individually), although only the health service in England uses the name *National Health Service* without further qualification. In addition, much of the decision making is now made through local *trusts*, which provide policy and guidance for healthcare providers within their jurisdiction.

The second phase of the review of the National Health Service (NHS) in England chaired by Lord Carter of Coles, defines a clear path for the reorganisation of pathology services. The report states that quality management procedures and an upgraded accreditation system should be mandatory for all pathology service providers, including providers of POCT. In particular, recommendation 12 states “…that all pathology service providers should be subject to mandatory accreditation by an organisation independent of the providers and the professions. Mandatory accreditation (including of point-of-care testing) gives members of the public and other NHS staff the confidence that the quality of the service has been independently verified as meeting objective service standards.” In addition, recommendation 14 states “… that all providers of pathology services (including providers of point-of-care testing) should be required to participate in clinical audit and other clinical governance activities, as a further means of underpinning quality; and that all staff involved in the delivery of pathology services, including technical and support staff, participate in relevant continuous professional development as part of maintaining their competence.”

Currently however, many of the NHS health trusts have developed their own policy statements with regard to POCT, but most (if not all) seem to follow a similar template and provide similar information. All include specific reference to quality control and quality assurance which are obligatory procedures for POCT operators. Six examples are provided for information. Trust “policy” statements are essentially mandatory requirements for testing services within their jurisdiction.

The UK Department of Health deals with non-devolved and other matters common to all systems. Various agencies within the Department of Health provide a plethora of guidelines and recommendations. These guidelines are used by local *trusts* and healthcare providers as recommendations or policy statements. For example, the Medicines and Healthcare Products Regulatory Agency (MHRA)

In a review of pathology services in Northern Ireland, the Department of Health, Social Services and Public Safety, made specific comment on the proposed management of POCT. In their final report *Recommendations for the future of pathology services in Northern Ireland* published in December 2007, the Department agreed “… that POCT should be managed under a regional framework in line with CPA accreditation standards and guidelines of the Royal College of Pathologists [recommendation 14].” In addition,
Northern Ireland also uses the Medical Devices Agency (MDA) documents, reissued under the auspices of Health Estates, an executive agency of the Department of Health, Social Services and Public Safety.\textsuperscript{58}

In a similar manner, the Welsh Scientific Advisory Committee (WSAC, which directly advises the Welsh Assembly Government on professional scientific and technological matters related to health issues\textsuperscript{118}), issued a policy guideline \textit{The use of diagnostic equipment and procedures outside the diagnostic laboratory}, which applies to POCT performed in non-laboratory sites which include “… secondary care sites: A&E, ITU, SCBU, general ward areas, theatres, diabetic clinics, and outpatient departments.” and “primary care sites to which this circular applies include: GP surgeries, Community Clinics, Health Centres, Anticoagulation Clinics, patients’ homes, and paramedical services including the ambulance service.”\textsuperscript{56}

In addition to policies and guidelines developed by the Department of Health and individual NHS jurisdictions, operational guidelines for specific POCT applications have been developed by professional groups such as the British Committee for Standards in Haematology\textsuperscript{55}, the Association of Clinical Biochemists\textsuperscript{53} and the Royal College of Pathologists\textsuperscript{54}. Two examples of clinical practice guidelines produced for general practitioners by the British Medical Association (BMA), provide specific instructions for POC drug testing and anti-coagulation monitoring.\textsuperscript{59,60} Both of these procedures require appropriate quality control and quality assurance. An outline of two approaches to the issues of accreditation and POCT are provided by Burnett\textsuperscript{119} and Thomas\textsuperscript{120}.

\textbf{United States of America (USA, US)}

\textit{Regulatory overview}

In 1988, the US government passed the Clinical Laboratory Improvement Amendments act (CLIA 88 or CLIA), which specified regulations and standards for all facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease.\textsuperscript{121} CLIA classifies tests by a complexity model rather than testing location or intended use and tests are defined as waived, of moderate complexity or high complexity. Waived tests include test systems cleared by the Food and Drug Administration (FDA) for home use and those tests approved for waiver under the CLIA criteria. The only criteria for non-accredited laboratories to perform waived tests is for the device to have been cleared by the FDA, for operators to follow manufacturer’s instructions as a minimum requirement (including perform quality control (QC) at the frequency defined in the manufacturer’s package insert), and to allow random inspection of the testing facility to establish compliance.\textsuperscript{122} Of note however, is that all laboratories which perform testing on human samples (with the exception of defined research laboratories and personal home use testing) are required to be certified (registered) by the Centers for Medicare and Medicaid Services (see below) in order to perform any testing procedure. In this regard, “laboratory” essentially means any site where testing occurs, including a hospital ward, a doctors office, community testing facility or ambulatory testing service.

The CLIA requirements are administered through the Centers for Medicare and Medicaid Services (CMMS), which regulate all laboratory testing (except research) performed on humans. CMMS is the agency which provides testing certificates; a laboratory which performs moderate complexity or high complexity tests requires a certificate of compliance.
and a laboratory which performs only waived tests may apply for a certificate of waiver. In total, CLIA covers approximately 200,000 laboratory entities. The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Medicaid and State Operations has the responsibility for implementing the CLIA program.\textsuperscript{123}

In addition to CMMS which administers the CLIA program, the Secretary of Health and Human Services under whose authority and oversight the CLIA program operates, is required to develop appropriate standards to assure consistent, accurate, and reliable test results by all clinical laboratories. To this end, the Secretary is authorized to establish advisory committee(s) to assist with this process. The Clinical Laboratory Improvement Advisory Committee (CLIAC) was established in 1992 “to provide scientific and technical advice and guidance to the Secretary and the Assistant Secretary for Health regarding the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated; the impact on medical and laboratory practice of proposed revisions to the standards; and the modification of the standards to accommodate technological advances”\textsuperscript{124}

A twenty year review of CLIA regulations with comments from the principal agencies involved with laboratory regulation and accreditation is provided by the CLIAC summary report for the meeting of February 2008, “Recognising 20 years of CLIA”.\textsuperscript{124} In addition, the complete set of CLIAC meeting summaries is available through the Centers for Disease Control and Prevention (CDC).\textsuperscript{125}

**Accreditation agencies**

Accreditation inspections are provided by a number of organizations, and laboratories are free to choose which of these they prefer. Laboratories may choose a state agency (usually a state department of health), or one of the inspection and accreditation agencies approved by CMS. Major accrediting agencies in the US include the College of American Pathologists (CAP), the Joint Commission (JC; previously the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)), and COLA (formally the Commission on Office Laboratory Accreditation, now just referred to as “COLA”). A brief history of JCAHO and COLA is given in the Clinical Laboratory Improvement Advisory Committee (CLIAC), summary report of meeting, “Recognising 20 years of CLIA”, February 2008.\textsuperscript{124}

COLA is an independent organization which was founded in 1988 to assist laboratories stay in compliance with (the then new) CLIA regulations.\textsuperscript{126} In 1993, the Health Care Financing Administration (now CMS) granted COLA authority as an accrediting agency. COLA is strongly supported by American medical colleges including the American Medical Association, the American College of Physicians, the American Academy of Family Physicians, the American Osteopathic Association and the College of American Pathologists. COLA currently accredits approximately 7,000 facilities, including many of the physician office and hospital laboratories (with physician office laboratories probably their primary market).

A succinct overview of the categorization of laboratory tests (waived, moderate and high complexity) and the US accreditation procedures and accrediting organizations is provided by Sautter and Lipford.\textsuperscript{127}
**Current issues with performance quality and fitness for purpose**

The original list of waived tests was relatively small and consisted mainly of “dipstick” tests for urine and some monitoring devices cleared by the FDA for home-use (for example blood glucose). However, the list of waivered tests has grown considerably over the years and was revised in 2008 to include a large number of analytes, including many which can be performed at POC. Tests which remain in the moderate complexity category (and thus require full accreditation) include blood gas instruments and all activated clotting time tests.

With the increased use of waived tests outside of the accredited laboratory environment, there has also been increasing concern as to the quality of results and the potential harm to patients. The identification of quality issues in waived testing sites has been compiled from on-site inspection reports obtained by CMMS during the period 1999 to 2003 and summarized by the CDC in their report and recommendations paper *Good Laboratory Practices for Waived Testing Sites, 2005.* In addition to a review of quality failures, the CDC document provides recommendations developed by CLIAC for improving the quality of waived tests. More recently, the on-going issues with regard to the quality of waived tests was discussed at length during the CLIAC meeting of February 2008.

In addition to the quality issues identified through CMMS inspections, there is currently an ongoing debate within the scientific community and within FDA with regard to the quality of blood glucose and haemoglobin A1c (HbA1c) testing devices. As indicated previously, queries have been raised as to their correct and intended use and their fitness for purpose. Many laboratories performing only waived tests however, do actually seek laboratory accreditation, follow one of the many professionally based POCT operational guideline documents, perform quality control, and participate in external quality assurance. Laboratories which perform moderate and high complexity tests which require full accreditation, often have all testing procedures (including any waived tests which they may perform) included within the accreditation. This will also depend on the internal “policy” of the chosen accrediting agency; for example, the College of American Pathologists (CAP) require all tests to be accredited, while some state accrediting agencies only mandate the minimum CLIA requirement.

**Professional support for accreditation**

Good support for accreditation of laboratories performing only waived tests is provided by the main medical college responsible for “general practitioners” or “family medicine physicians”. The American Academy of Family Physicians actively supports accreditation of the physician office laboratory (POL), both through its *family medicine residents training program* and its support for the COLA laboratory accreditation scheme.

To further assist laboratories with the accreditation process and to provide guidance in establishing and maintaining quality testing procedures, there are many “standards” and “guidelines” available. The Clinical Laboratory Standards Institute (CLSI) is the principal provider of “standards” to the pathology and associated diagnostic industry in the US, even though ISO 15189 is used by the major diagnostic laboratories and forms the basis for many of the CLSI, CAP and JC standards. A list of CLSI standards and guidelines relevant to POCT is provided as appendix 5.
Potential errors in POCT

Overview – errors in POCT

The influential Institute of Medicine report, *To Err is Human – Building a Safer Health System*, caused significant concern in the USA when it was released in 1999. This report, which describes and categorises errors in the American health system, claims “that at least 44,000 people, and perhaps as many as 98,000 people, die in hospitals each year as a result of medical errors which could have been prevented.” The report defines medical errors as “the failure of a planned action to be completed as intended or the use of the wrong plan to achieve an aim.” Medical errors in laboratory testing, including POCT, are mainly failures in testing procedures or failure to complete planned actions and are generally described as pre-analytical errors, analytical errors or post-analytical errors. In order to achieve appropriate test results which are fit for purpose, all aspects of the testing process must be addressed in an efficient and reliable manner. To achieve this goal, operational standards, rules and guidelines must be applied. These same rules apply whether the objective is central laboratory testing or POCT.

The advantages of POCT largely depend on proof of acceptable analytical performance. This concept dominates policy statements from government agencies of many jurisdictions, articles published in peer reviewed journals, and statements made by international commentators on POCT. Regardless of the particular assay or method, POCT, in common with all laboratory testing requires regular QC and EQA to assure acceptable performance. Tirimacco provides a good summary of these concepts “Although POCT appears to be deceptively simple, if incorrectly performed it may present a risk to patient care and, if used inappropriately or overused can lead to significant increases in the cost of patient care. To ensure results obtained are comparable to the traditional pathology laboratory, POCT should be implemented within a framework of quality standards.” … “This quality framework should include: operator education, training and competency, quality control, proficiency testing and accreditation.”

There is now a growing literature describing the potential and actual errors arising from poorly controlled POCT. In the USA, home glucose-testing devices account for the largest number of complaints filed with the FDA for any medical device. According to information provided by Plebani and Nichols, over 3200 incidents have been filed with the FDA in relation to blood glucose-testing devices with 16 deaths. In addition, poorly maintained blood gas analysers (and other POCT devices) that are carried from one patient to another, can act as reservoirs for anti-biotic resistant organisms and provide an easy path for the transfer of infection between patients. Thompson and Perz describe the investigation of 18 outbreaks of hepatitis B (HBV), with 15 (83%) in the past ten years (up to 2009) that were associated with improper use of blood glucose monitoring equipment. “At least 147 persons acquired HBV infection during these outbreaks, 6 (4.1%) of whom died from complications of acute HBV infection.” Nichols also describes nine patients at two nursing facilities in Southern California who were diagnosed with hepatitis B following infection transmitted in association with blood glucose monitoring and linked to failure of staff to change gloves and adequately clean the testing device between patients.

According to Sharp et al, inspection and accreditation processes have been very successful in achieving the goal of reducing POC testing error. In reviewing the impact of periodic inspection by the POCT manager, these authors “…found that inspection correlated directly with laboratory error.” That is, fewer errors were produced as the number of
inspections by the POCT manager increased:

- “During the 3-month period before the POCT staff was decreased 50%, the error rate averaged 2.0%.”
- “During a second period 5 months later, following suspension of POCT inspections by the POCT manager, the error rate averaged 2.7%.”
- “Finally, during a third period 6 months later, after the reinstitution of POCT inspections, the error rate averaged 1.1%.”
- “For the most recent 3-month period for which data are available, following 11 more months of POCT inspections, the error rate averaged 0.5%.”

Sharp et al suggest that these results “emphasize that the challenges to management of POCT are the same as those for clinical laboratory testing, and indicate the need for measures for continual and methodical surveillance of all laboratory testing.”

In a study of “errors in laboratory medicine”, Bonini et al found that the principal reasons for pre-analytical errors were: haemolysed specimen (54% of all pre-analytical errors), insufficient specimen (21% of all pre-analytical errors) and incorrect specimen (13% of all pre-analytical errors). In a traditional laboratory these types of error are relatively easy to detect. In a POCT situation, this type of error may well pass undetected with a compromised patient result being produced. In addition to pre-analytical errors, POCT in particular is prone to “native interferences” which alter the reactivity of the analytical process to produce errors which may largely go undetected. Haemolysis, which is undetected in poorly collected whole blood samples produces incorrect results in many circumstances. Heterophilic antibodies, ascorbic acid (vitamin C), INR tests due to inconsistent ISI values, patient haematocrit values higher or lower than the accepted POCT device range, provide just a few examples.

By their very nature, errors in POCT are often difficult to identify and little information exists which describes error rates associated with POCT itself. A recent study by O’Kane et al, evaluated a variety of POC tests over a 14-month period and concluded “The quality error rate for POCT is variable and may be considerably higher than that reported previously for central laboratory testing.” An interesting feature of these results, is the wide variability in reported error rate between test types; very low for “dip stick” tests, 0.52% for blood gas and electrolyte tests and 0.65% for HbA1c testing. Although the overall impact of POCT errors on patient care was considered low, with 51.8% of all reported errors considered to have no impact, 48.2% of errors were considered to have some impact on patient care.

Surveys of waived testing laboratories in the US

Since the commencement of the CLIA regulations in the USA there have been a number of surveys of waived testing laboratories, to review quality procedures and compliance with CLIA regulations. As described previously, waived tests include test systems cleared by the FDA for home use and those tests approved for waiver under the CLIA criteria. The published reviews of waived testing laboratories are broadly of two forms: (a) those conducted by or on behalf of CMS with results provided in a summarized de-identified CMS report, and (b), publications by professional commentators based on CMS report data and / or proficiency testing survey data.

To encourage improved testing in waived laboratories, in 2002 CMS initiated on-site visits to approximately 2% of laboratories that had been issued a certificate of waiver (COW) under CLIA. This was the first time that CMS had conducted inspections in all 50 states, although two previous surveys had included visits to a smaller number of states.
An overview of the survey process is provided on the CMS internet site. Results from a pilot study completed in 2001 formed the basis for concerns regarding waived laboratories. Data from this pilot survey has been reviewed by Meier and Jones who conclude that POCT “errors are relatively common, their frequency is amplified by incoherent regulation, and their likelihood of affecting patient care is amplified by rapid availability of POCT results and immediate therapeutic implications.”

Meier and Jones summarise the results of the CMS pilot report as follows:

- “CMS examiners found that 19% of testing personnel had been neither trained nor evaluated in the performance of the assays they carried out”
- “32% of the observed test operators could not locate test instructions when asked to refer to them”
- “25% of test operators failed to follow manufacturer’s directions”
- “7% of test operators did not perform required calibrations”
- “32% of test operators failed to perform quality control (QC)” (as specified)
- “20% (of test operators) physically separated (against manufacturer’s directions) internal QC test fields from patient test fields in card test format tests”
- “6% (of test operators) use expired reagent kits, whose integrity manufacturers would” no longer guarantee.

In a similar manner, Howerton et al. on behalf of the CDC, have summarised quality failures identified in waived testing sites on the basis of CMMS surveys conducted during 1999 – 2003, and studies of waived testing practices undertaken by CDC during 1999 – 2003.

This report, Good laboratory practices for waived testing sites described a similar catalogue of errors with the principal deficiencies being:

- 12% of sites did not have current manufacturer’s instructions
- 21% of sites did not routinely check new product inserts for changes
- 21% of site did not perform the minimum QC as specified by the manufacturer
- 18% of sites did not report test results with appropriate terminology or units
- 6% of sites did not comply with expiration dates
- 5% of sites did not perform the required function or calibration checks
- 3% of sites did not adhere to storage and handling instructions
- 3% of sites did not perform instrument maintenance
- 2% of sites did not use an appropriate specimen for the test

POCT, clinical trials and evidence-based practice

Actual clinical trials or large scale reviews to assess the effectiveness of POCT are much less numerous than publications which describe the potential risks associated with POCT, issues with specific tests or with specific devices. The evidence to support POCT has been recently reviewed by St John, with specific discussion including patient self-monitoring, POCT in the community (particularly POCT conducted within pharmacies), POCT in general practice and POCT in critical care areas including the emergency department. The NACB publication Laboratory Medicine Practice Guidelines - Evidence-based practice for point-of-care testing reviews much of the evidence in support POCT and provides informed discussion on many aspects of the subject. The document provides specific recommendations based on evidence obtained from an extensive literature review. Most of the tests which would usually be considered in the POCT environment are covered in detail. Chapter 1, Management, provides insight into the topic of quality management (QM), quality assurance (QA) and quality control (QC).
A selection of clinical trials or literature reviews whose principal aim was to compare outcomes with central laboratory testing or to evaluate clinical effectiveness are summarised in appendix 6 and include:

- Australian Government point-of-care testing in general practice trial.\textsuperscript{14}
- Kendall et al; Point-of-care testing, randomised controlled trial of clinical outcomes.\textsuperscript{142}
- Blattner et al; Changes in clinical practice and patient disposition following the introduction of point-of-care testing in a rural hospital.\textsuperscript{143}
- Hobbs et al; A review of near patient testing in primary care.\textsuperscript{144}
- Grieve et al; Near patient testing in diabetes clinics: appraising the costs and outcomes.\textsuperscript{145}
- Collinson et al; A prospective randomised controlled trial of point-of-care testing on the coronary care unit.\textsuperscript{146}
- Ryan et al; A multicenter randomised controlled trial comparing central laboratory testing and POCT cardiac marker testing strategies: the disposition impacted by serial POCT markers in acute coronary syndromes.\textsuperscript{147}
- Fitzmaurice et al; A randomised controlled trial of patient self management of oral anticoagulation treatment compared with primary care management.\textsuperscript{148}
- Fitzmaurice et al; Self management of oral anticoagulation: Randomised trial.\textsuperscript{149}
- Parry et al; Anticoagulation management in primary care: a trial-based economic evaluation.\textsuperscript{150}
- Wilson et al; Comparing the quality of oral anticoagulant management by anticoagulation clinics and by family physicians: a randomised controlled trial.\textsuperscript{151}
- Khunti et al; Randomised controlled trial of near-patient testing for glycated haemoglobin in people with type 2 diabetes mellitus.\textsuperscript{152}
- Al-Ansary et al; Point-of-care testing for HbA1c in the management of diabetes: A systematic review and metaanalysis.\textsuperscript{77}

Quality management

Overview - quality management

A question often asked by management or a regulatory authority relates to the cost of implementing a quality system. The real question to be asked however, is how much is poor quality going to cost (or how much is poor quality costing now)? The principal issue here, particularly when discussing health economics, is the influence of “cost shifting”. In the current context of laboratory or POC testing, poor quality in one sector of the health system adds costs to another sector as increased resource requirements. Poor quality in laboratory testing often results in increased doctor visits, additional unnecessary test procedures, inappropriately changed medication or additional unnecessary medication, and / or hospitalisation. The real cost of not identifying testing problems, of unnecessary repeat testing and poor patient outcomes, is often hidden until a quality system has been implemented. In quality management texts this is usually described as the 1-10-100 rule: that is, $1 of prevention is better than $10 of corrective action (or of appraisal costs or retesting costs), which is better than the $100 required to recover from a failure.

The NACB Laboratory Medicine Practice Guidelines - Evidence-based practice for point-of-care testing referred to previously, briefly describe the role of quality management and the requirement for QC and QA.\textsuperscript{61} They acknowledge the difficulty of providing evidence-based data with the statement “The literature about quality assurance (QA) and quality
management (QM) of POCT is by and large not evidence based, … due in large part, to the
difficulty of assessing the causal impact of POCT on medical errors.” However, the NACB
do explicitly state “QC and QA are integral components forming the basis of the QM
hierarchy of the clinical laboratory.” … “The performance goals of POCT are no different
from those of the traditional laboratory …”.

The Australian government point-of-care testing in general practice trial has also provided
confirmation that quality management practices are required for POCT. As indicated
previously, Chapter 14 of the report discusses the issues of regulation and quality
management for POCT.14,21 The particular quality management procedures used in the trial
were those described in *Interim standards for point-of-care testing in general practice*.13
The quality management system used in the trial included:

- device operator training and certification
- IQC (internal quality control) and EQA (external quality assessment)
- an accreditation program based on the (interim) standards for POCT in general
  practice.

For POCT to provide value in the general practice situation “ … an effective quality
management system is essential. Clinicians need reassurance that their decisions are based
on reliable, accurate and precise results to ensure that patient safety is not
compromised.”14,21

**Quality assurance, quality control and external quality assessment**

Quality assurance (QA) is that aspect of quality management focused on providing
confidence that quality requirements (quality goals, fitness for purpose) are being fulfilled.
The NACB *Laboratory Medicine Practice Guidelines - Evidence-based practice for point-
of-care testing* describe POCT QA as “ … all the measures taken to ensure that
investigations are reliable” … and include:

- correct identification of the patient
- appropriate test selection
- obtaining a satisfactory specimen
- analyzing it and recording the results promptly and correctly
- interpreting the result accurately
- taking appropriate action
- documenting all procedures for reference
- internal QC requirements
- correction of nonconformities
- participate in an EQA scheme (and perform adequately as part of clinical
governance).61

The terminology with regard to quality assurance may at times seem inconsistent.
Depending on the context or particular publication, quality assurance may also be
synonymous with proficiency testing, external quality assurance (EQA) or external quality
assessment (also designated as EQA). NPAAC, in their *Requirements for participation in
external quality assessment*, 2009, define external quality assessment (EQA) as “A program
in which multiple samples are periodically sent to members of a group of laboratories for
analysis and / or identification, in which each laboratory’s results are compared with those
of other laboratories in the group and / or with an assigned value, and reported to the
participating laboratory and others. Such a program may also compare an individual’s
results with their peer group.”153 This procedure allows testing sites to check the validity of
their own results by comparison to other sites, through a process of testing identical samples with unknown values.

Participation in EQA provides an assessment of accuracy by way of a performance comparison with all instruments and with other users of the same instrument. Issues with regard to commutability are probably even more contentious for POCT than for central laboratory procedures and this will certainly limit traceability to a primary standard. However, participation in EQA will still provide a comparative peer assessment which is a crucial element in the quality assurance process. Issues with regard to the current challenges and future directions of proficiency testing have been recently reviewed.

In its simplest form, quality control (QC; often referred to as internal QC or IQC) assesses the performance of a testing system in real time and compares it to previously accepted performance criteria. This concept was first applied to quantitative laboratory testing with the use of standardized control charts, by Levey and Jennings in 1950.

In addition to the many pre-analytical factors which require documentation and “control”, analytical QC as described by Gill and Shephard and Gill and Watkinson, generally require the analysis of a defined QC material to confirm that results are consistent with previously defined limits. Device manufacturer’s procedure manuals usually outline suggested QC procedures, and a plethora of publications provide both general and specific advice.

The requirements for quality control and quality assurance
As stated above, quality assurance (QA) and quality control (QC) are integral components of the quality management process. In addition, existing regulatory requirements from all jurisdictions and evidence-based practice guidelines are fully supportive of this quality management approach. Failure to ensure that testing processes are performing to specification contributes to inaccurate results and incorrect patient management, inappropriate or unnecessary medical treatment and poor patient outcome(s). Scientific and laboratory testing devices do not come with a lifetime performance guarantee. Continuous assessment is required to ensure on-going performance is maintained within manufacturer’s specification.

Standard 8 of NPAAC document Requirements for pathology laboratories, 2007, states:

- S8.1 “A pathology service must audit its operations as part of the quality system in order to determine compliance of the service with current regulatory and accreditation requirements”
- S8.2 “Laboratories must be continuously enrolled, participate and perform to an acceptable standard in external proficiency testing programs that cover all test methods performed in the laboratory where such programs are available”.

The NACB Laboratory Medicine Practice Guidelines - Evidence-based practice for point-of-care testing also state “QA goes beyond QC and focuses on the impact of laboratory testing on patient care. A QA program for laboratory services should establish:

- performance expectations that cover pre-analytical, analytical and post-analytical components of the service
- performance expectations after consultation with user physicians and other healthcare workers
• periodic audit to determine that the service is meeting its established performance expectations
• a program of performance comparisons to that of the central or core laboratory
• periodic review of the service patterns of practice against established, validated, external benchmarks
• review of the QA program findings by a management team.

As suggested previously, the required analytical performance of a test (fitness for purpose) is determined by its intended clinical use and not by the location where the testing occurs. This is also implicit in the CLIA regulations, which impose site-neutral standards for laboratory practice. Professional commentators on quality issues in POCT all appear to agree that accuracy and reliability of laboratory testing (which includes POCT), should be equivalent irrespective of the testing site in order that equivalent clinical decisions can be made.

The requirement for QA and QC in POCT is actually enhanced by the apparent simplicity of the technology. Persons without laboratory training frequently perform POC procedures in a clinical setting, where results are available for the immediate influence on patient treatment. As stated in Chapter 1 of the NABC guidelines, “Because POCT results are treated comparably to those generated by the central laboratory for patient care, it follows that the quality requirements are the same regardless of the testing site, process, or procedure. At the same time, the unique characteristics (of POCT) … add special requirements to QA/QC.”

The medical literature contains many articles which outline the importance of QA and QC for POCT. There are even more articles which describe the inaccurate performance claims of some device manufacturers (caveat emptor). Regulatory measures for laboratory testing or POCT are designed to guarantee that patients receive appropriate and cost effective results, and testing devices and procedures comply with the relevant technical standards. As discussed by Sautter and Lipford, “Inherent with POCT growth come challenges in performing high quality accurate testing. Decreasing laboratory errors and improving patient safety must also be considered …”.

The importance and detailed application of QA and QC in POCT is well described in any number of peer reviewed articles. In a similar manner, the application of ISO 22870 to POCT in the UK has been provided by Thomas.
Summary

There are many “official” and professionally based standards and guidelines which define the manner in which POC testing should be implemented, managed and the performance quality checked and maintained. Most professionally based guidelines follow a similar template and provide similar information which includes specific reference to quality control and quality assurance.

Table 1 provides a summary of the international requirements for quality management of POCT, including the requirement for operator training and proof of competency, QC and EQA. Most jurisdictions provide statements regarding POCT which include mandatory quality procedures as defined by regulation or specific policy.

Formal policy and regulation generally applies to situations where service payments may be provided; that is, where a healthcare funding agency (government) or health insurer provides a service fee for POCT. Excluding home use and personal testing, in countries without specific overall regulation there is little information regarding the use of POC devices in the “private” healthcare setting or where patients are prepared to pay directly for testing services.

Regulations which apply to laboratory testing in general (which includes POCT) are required to:

• assure patients and funding authorities that testing is fit for purpose
• assure patients and funding authorities that quality testing is being provided and maintained
• assure patients and funding authorities that device operators have the required skills and competencies
• assure patients and funding authorities that devices are being appropriately maintained
• assure users that POC devices comply with defined technical specifications
• ensure that testing is provided in a safe environment
• provide a consistent base for all testing procedures and provide some consistency between multiple service providers
• ensure that patient records are managed in an appropriate and consistent manner
• inhibit uncontrolled and inappropriate use of testing
• provide a mechanism for assessing the distribution of valuable healthcare dollars.

When considering the application of POCT and its wider introduction into the healthcare system, appropriate consideration should also be given to the influence which poor quality in one sector of the health system adds costs to another sector as increased resource requirements. Poor quality in laboratory and POC testing often results in increased doctor visits, additional unnecessary test procedures, inappropriately changed medication or additional unnecessary medication, and / or hospitalisation. The real cost of not identifying testing problems, of unnecessary repeat testing and poor patient outcomes, is often hidden until a quality system has been implemented.

“For POCT to be implemented (in general practice), an effective quality management system is essential. Clinicians need reassurance that their decisions are based on reliable, accurate and precise results to ensure that patient safety is not compromised.”

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Appendix 1. Definitions: policy, requirement and guidelines.

The terms *policy*, *requirement* and *guideline* are regularly used throughout the literature consulted in association with this review. Different authors or agencies may apply the terms under slightly different circumstances or with a slight difference in emphasis. For the purpose of this review, the following *interpretations* have been applied.

**Policy**: when used by a government department (for example, “health department policy”) or government agency (for example, British “NHS trust policy”), the term *policy* has generally been considered as a mandatory requirement.

**Requirement**: when used by a government department (for example, “health department requirement”) or government agency (for example, British “NHS trust requirement”), the term *requirement* has generally been considered as a mandatory requirement (particularly when appearing within a “policy” document).

When used as a general statement without further clarification or definition, the term *requirement* has generally been interpreted in the same manner as *guideline* (below).

**Guideline**: a statement of recommended or best practice. Guidelines are generally consensus recommendations for best practice but are not considered mandatory.

**Clinical practice guideline**: the term *guideline* when used in medicine (or more often clinical practice guideline) is usually defined as … “systematically developed statements to assist practitioners with decisions about appropriate health care for patients in specific circumstances” (refer to section 3 in the main part of this review).

The distinction between items which are mandatory requirements and recommended best practice is also applied to laboratory accreditation documents produced by the National Pathology Accreditation Advisory Council (NPAAC). NPAAC standards are equivalent to mandatory requirements, whereas guidelines provide more detailed information and recommendations with regard to preferred practice.
Appendix 2. Abbreviations.

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AACB</td>
<td>Australasian Association of Clinical Biochemists</td>
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<tr>
<td>AACC</td>
<td>American Association for Clinical Chemistry</td>
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<tr>
<td>ADA</td>
<td>American Diabetes Association</td>
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<tr>
<td>AETMIS</td>
<td>Agence d'évaluation des technologies et des modes d'intervention en santé (Canada)</td>
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<tr>
<td>AS</td>
<td>Australian Standard, Standards Australia</td>
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<tr>
<td>BMA</td>
<td>British Medical Association</td>
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<tr>
<td>CAP</td>
<td>College of American Pathologists</td>
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<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention (USA)</td>
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<tr>
<td>CLIA</td>
<td>Clinical Laboratory Improvement Amendments act (USA)</td>
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<tr>
<td>CLIAC</td>
<td>Clinical Laboratory Improvement Advisory Committee (USA)</td>
</tr>
<tr>
<td>CLSI</td>
<td>Clinical and Laboratory Standards Institute (formally NCCLS)</td>
</tr>
<tr>
<td>CMS</td>
<td>Centers for Medicare and Medicaid Services (USA)</td>
</tr>
<tr>
<td>COLA</td>
<td>Commission on Office Laboratory Accreditation (USA)</td>
</tr>
<tr>
<td>COW</td>
<td>Certificate of waiver (USA)</td>
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<tr>
<td>CPA</td>
<td>Clinical Pathology Accreditation (UK) Ltd.</td>
</tr>
<tr>
<td>EBLM</td>
<td>Evidence-based laboratory medicine</td>
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<tr>
<td>EBM</td>
<td>Evidence-based medicine</td>
</tr>
<tr>
<td>EQA</td>
<td>External Quality Assessment or External Quality Assessment</td>
</tr>
<tr>
<td>FAD</td>
<td>Field Application Document (NATA document)</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration (USA)</td>
</tr>
<tr>
<td>HbA1c</td>
<td>Haemoglobin A1c, glycated haemoglobin</td>
</tr>
<tr>
<td>HHS</td>
<td>USA, Department of Health and Human Services</td>
</tr>
<tr>
<td>iCCnet</td>
<td>Integrated Cardiovascular Clinical Network (South Australia)</td>
</tr>
<tr>
<td>INR</td>
<td>International Normalised Ratio, a derived measure of prothrombin time</td>
</tr>
<tr>
<td>IQC</td>
<td>Internal Quality Control or Quality Control (QC)</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organisation for Standardisation</td>
</tr>
<tr>
<td>JC or TJC</td>
<td>The Joint Commission (formally JCAHO)</td>
</tr>
<tr>
<td>JCAHO</td>
<td>Joint Commission on Accreditation of Healthcare Organizations (USA)</td>
</tr>
<tr>
<td>Acronym</td>
<td>Definition</td>
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<tr>
<td>MSAC</td>
<td>Medical Services Advisory Committee</td>
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<tr>
<td>MU</td>
<td>Measurement Uncertainty (synonymous with UM, Uncertainty of Measurement)</td>
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<tr>
<td>NACB</td>
<td>National Academy of Clinical Biochemistry</td>
</tr>
<tr>
<td>NATA</td>
<td>National Association of Testing Authorities</td>
</tr>
<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
</tr>
<tr>
<td>NPAAC</td>
<td>National Pathology Accreditation Advisory Council</td>
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<tr>
<td>NPT</td>
<td>Near patient testing, synonymous with POCT</td>
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<tr>
<td>PLAP</td>
<td>Pruebas en el lugar de asistencia al paciente (Spanish for tests at the site of patient care)</td>
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<tr>
<td>POC</td>
<td>Point-of-care</td>
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<tr>
<td>POCT</td>
<td>Point-of-care testing</td>
</tr>
<tr>
<td>POL</td>
<td>Physicians Office Laboratory</td>
</tr>
<tr>
<td>QA</td>
<td>Quality Assurance or Quality Assessment</td>
</tr>
<tr>
<td>QAAMS</td>
<td>Quality Assurance for Aboriginal and Torres Strait Islander Medical Services</td>
</tr>
<tr>
<td>QAP</td>
<td>RCPA Quality Assurance Programs Pty Ltd</td>
</tr>
<tr>
<td>QC</td>
<td>Quality Control or Internal Quality Control (IQC)</td>
</tr>
<tr>
<td>QM</td>
<td>Quality Management</td>
</tr>
<tr>
<td>RCPA</td>
<td>Royal College of Pathologists of Australasia</td>
</tr>
<tr>
<td>RCPPath</td>
<td>Royal College of Pathologists (UK)</td>
</tr>
<tr>
<td>SEQC</td>
<td>Sociedad Española de Bioquímica Clínica y Patología Molecular (Spanish Society of Clinical Biochemistry and Molecular Pathology)</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedure. A written document or instruction detailing all steps and activities of a process or procedure.</td>
</tr>
<tr>
<td>UM</td>
<td>Uncertainty of Measurement (synonymous with MU, Measurement Uncertainty)</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
</tbody>
</table>
## Appendix 3. International and Australian standards which define or are associated with laboratory and POCT quality procedures.

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 22870</td>
<td>Point-of-care testing – requirements for quality and competence.</td>
</tr>
<tr>
<td>ISO 15197</td>
<td>In vitro diagnostic test systems – requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus.</td>
</tr>
<tr>
<td>ISO 17593</td>
<td>Clinical laboratory testing and in vitro medical devices – requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy.</td>
</tr>
<tr>
<td>AS 4633 / ISO 15189</td>
<td>Medical laboratories – particular requirements for quality and competence.</td>
</tr>
<tr>
<td>NPAAC</td>
<td>Requirements for Pathology Laboratories, 2007</td>
</tr>
<tr>
<td>NPAAC</td>
<td>Requirements for the supervision of Pathology Laboratories, 2007</td>
</tr>
<tr>
<td>NPAAC</td>
<td>Requirements for quality management in medical laboratories, 2007</td>
</tr>
<tr>
<td>NPAAC</td>
<td>Requirement for Participation in External Quality Assessment, 2009</td>
</tr>
<tr>
<td>AS/NZ 4308</td>
<td>Procedures for specimen collection and the detection and quantitation of drugs of abuse in urine.</td>
</tr>
<tr>
<td>AS 4760</td>
<td>Procedures for specimen collection and the detection and quantitation of drugs in oral fluid.</td>
</tr>
<tr>
<td>Quality use of pathology committee for POCT in general practice trial</td>
<td>Interim standards for point of care testing in general practice.</td>
</tr>
</tbody>
</table>
Appendix 4. Point-of-care testing in general practice trial. Publications from members of the trial management group.


- Gialamas A; St John A; Laurence CO; Bubner T, and POCT, Management Committee. Point of Care Testing for patients with diabetes, hyperlipidaemia or coagulation disorders in the general practice setting: a systematic review. Family Practice 2010;27:17. http://fampra.oxfordjournals.org/content/27/1.toc


Appendix 5. Clinical and Laboratory Standards Institute (CLSI)*. Standards and guidelines which define or are associated with laboratory and POCT quality procedures

<table>
<thead>
<tr>
<th>POCT01-A2</th>
<th>Point-of-Care Connectivity; Approved Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>POCT02-A</td>
<td>Implementation Guide of POCT01 for Health Care Providers; Approved Guideline</td>
</tr>
<tr>
<td>POCT04-A2</td>
<td>Point-of-Care In Vitro Diagnostic (IVD) Testing; Approved Guideline</td>
</tr>
<tr>
<td>POCT05-A</td>
<td>Performance Metrics for Continuous Interstitial Glucose Monitoring; Approved Guideline</td>
</tr>
<tr>
<td>POCT07-A</td>
<td>Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline</td>
</tr>
<tr>
<td>POCT07-P</td>
<td>Quality Management: Approaches to Reducing Errors at the Point of Care; Proposed Guideline</td>
</tr>
<tr>
<td>POCT08-P</td>
<td>Quality Practices in Noninstrumented Near-Patient Testing: An Instructional Manual and Resources for Health Care Workers; Proposed Guideline</td>
</tr>
<tr>
<td>POCT09-A</td>
<td>Selection Criteria for Point-of-Care Testing Devices; Approved Guideline</td>
</tr>
<tr>
<td>AST04-A2</td>
<td>Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline</td>
</tr>
<tr>
<td>C30-A2</td>
<td>Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline</td>
</tr>
<tr>
<td>H49-A</td>
<td>Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline</td>
</tr>
<tr>
<td>H04-A6</td>
<td>Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard</td>
</tr>
<tr>
<td>EP23-A</td>
<td>Laboratory Quality Control Based on Risk Management; Approved Guideline.</td>
</tr>
</tbody>
</table>

* CLSI POCT guideline documents plus other laboratory standards and guidelines at: http://www.clsi.org/AM/Template.cfm?Section=Home&Template=Templates/CLSI_HomePage.cfm

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Appendix 6. Summary of the objectives and conclusions for the clinical trials involving POCT as discussed under the heading “POCT, clinical trials and evidence-based practice”.

- **Australian Government point-of-care testing in general practice trial (refer to item 5.0 above), reference 7.**
  
  **Overall summary – executive summary:**
  “The POCT trial in a General Practice setting was formulated with the notion that POCT could assist general practitioners and patients with the management of chronic illness. The trial provides evidence that POCT does have a role in assisting the primary health care team in the management of chronic disease, particularly in the areas of optimising therapy, engaging patients in their self-management and providing regular follow-up. For other aspects, such as general practitioners adhering to evidence-based guidelines, the results are less clear.

  The cost-effectiveness analysis showed that POCT was not cost-effective for any of the tests examined during the trial with the exception of urine ACR (albumin creatinine ratio) testing. However, the decision to fund POCT in a general practice setting needs to consider the positive health benefits of the intervention and potential societal gain of maintaining a patient within target range.”

- **Point-of-care testing: randomised controlled trial of clinical outcomes. Kendall et al, reference 124.**
  
  **Objectives:**
  “To describe the proportion of patients attending an accident and emergency department for whom blood analysis at the point of care brought about a change in management; to measure the extent to which point of care testing resulted in differences in clinical outcome for these patients when compared with patients whose samples were tested by the hospital laboratory.”

  **Conclusion:**
  “Point of care testing reduced the time taken to make decisions on patient management that were dependent on the results of blood tests. It also brought about faster changes in treatment for which timing was considered to be critical in about 7% of patients. These changes did not affect clinical outcome or the amount of time patients spent in the department.”

- **Changes in clinical practice and patient disposition following the introduction of point-of-care testing in a rural hospital. Blattner et al, reference 125.**
  
  **Objectives:**
  “To determine whether the practical impact of point-of-care (POC) laboratory testing justifies its use in a remote rural hospital (Rawene hospital New Zealand).”

  **Conclusions:**
  “POC testing helps address inequity in acute health care provision for a disadvantaged rural community by allowing rural clinicians access to necessary and critical investigations in a clinically relevant turn-around time.”

Objectives:
“To identify publications relating to near patient testing (NPT), the use of alternative delivery systems between laboratory and general practice, including electronic data interchange (EDI), and computerised diagnostic decision support (CDDS), in the primary care setting to answer the following questions:
- what is the availability of NPT for primary care
- what evidence is available to support the clinical effectiveness of NPT
- what evidence is available on the accuracy and reliability of NPT within primary care
- what evidence is available on the cost effectiveness of different NPTs
- how may CDDS improve the effectiveness of NPT
- what evidence is available that compares NPT and existing laboratory services
- what evidence is available on the cost-effectiveness of EDI or alternative delivery systems?”

Conclusions:
“There is little evidence to support the general introduction of NPT in general practice in preference to existing laboratory services, other than as part of a rigorous, controlled evaluation. There may be specific clinical areas where NPT may provide additional value to patients, particularly in the areas of early diagnosis, screening, and monitoring of chronic disease. The provision of additional diagnostic information during a consultation may enable primary care physicians to improve the quality and accuracy of their diagnoses, with potential benefit to patients. Such selective introduction of NPT should only take place after evaluation. Even if there is a substantial increase in NPT in primary care, the laboratory service will continue to provide its existing service, and may need to expand its role in support of quality control and training of practice staff. Although unevaluated, one potential means of introducing NPT into primary care is through laboratory outreach. Specific practice protocols that give details of the clinical indications for testing, staff training and the necessary quality control procedures may be required to support the introduction of NPT.”

Near patient testing in diabetes clinics: appraising the costs and outcomes. Grieve et al, reference 127.

Objectives:
“To compare the costs and consequences of providing test results by near patient testing (NPT) compared with conventional testing. The effect of the testing method on the process of care, the accuracy of testing, patient satisfaction, clinical attitudes, and health service and patient costs were investigated. A secondary aim was to generate hypotheses concerning the effect of the testing method on clinical outcome.”

Conclusions:
“A controlled trial compared the effect of the testing method on the process of care. A total of 599 patients were alternately allocated to either nurse NPT or conventional testing. The number of management changes to the patients’ diet, insulin or tablet therapy was recorded for all the patients. Results showed that patients were more likely to have a change in management related to their glycaemic control if they had been in the NPT rather than the conventional testing group (odds ratio 1.52; 95% confidence interval (CI) 1.02–2.26). Subgroup
analysis showed that patients with poor glycaemic control were more likely to have management changes in the NPT than in the conventional group (odds ratio 1.75; 95% CI 1.12–2.76). For patients with good control the number of management changes did not differ according to the testing method employed (odds ratio 0.92, 95% CI 0.35–2.44). This suggested that the process of care may be improved if results related to glycaemic control (HbA 1C) are provided by NPT. There did not seem to be any improvement in the process of care from providing lipid or creatinine results immediately, which suggests that the merits of NPT are likely to vary according to the test in question.”

**A prospective randomised controlled trial of point-of-care testing on the coronary care unit. Collinson et al, reference 128**

**Objectives:**
Perform “a prospective randomized controlled trial to compare measurement of the cardiac biomarker cTnT (cardiac Troponin T) by central laboratory testing (CLT) with point-of-care testing (POCT) performed in the coronary care unit (CCU). The staff involved in routine patient care performed the analyses. The objective was to assess the impact of POCT on patient management overall and in low risk (rapid rule-out) patients.”

**Conclusion:**
“A combination of rapid biochemical diagnosis and structured decision making reduces length of hospital stay.”

**A multicenter randomised controlled trial comparing central laboratory testing and POCT cardiac marker testing strategies: the disposition impacted by serial POCT markers in acute coronary syndromes. Ryan et al, reference 129.**

**Objectives:**
“Point-of-care testing reduces time to cardiac marker results in patients evaluated for acute coronary syndromes, yet evidence this translates to a decreased length of stay is lacking. We hypothesized that point-of-care testing decreases length of stay in patients being evaluated for acute coronary syndromes in the emergency department (ED).”

**Conclusion:**
“The effect of point-of-care testing on length of stay in the ED varies between settings. At one site, point-of-care testing decreased time to admission, whereas at another, point-of-care testing increased time to discharge. Potential effects of point-of-care testing on patient throughput should be considered in the full context of ED operations.”

**A randomised controlled trial of patient self management of oral anticoagulation treatment compared with primary care management. Fitzmaurice et al, reference 130.**

**Objectives:**
“To test whether patient self management is as safe, in terms of clinical effectiveness, as primary care management within the UK, as assessed by therapeutic international normalised ratio (INR) control.”

**Conclusion:**
“These are the first UK data to demonstrate that patient self management is as safe as primary care management for a selected population. Further studies are needed to elucidate whether this model of care is suitable for a larger population.”
Objectives:
“To determine the clinical effectiveness of self management compared with routine care in patients on long term oral anticoagulants.”
Conclusion:
“With appropriate training, self management is safe and reliable for a sizeable proportion of patients receiving oral anticoagulation treatment. It may improve the time spent within the therapeutic range for patients with initially poor control.”

Objectives:
“To determine the cost and cost-effectiveness of primary care based anticoagulation management in comparison with ‘traditional’ hospital care-based provision by means of a cost-effectiveness analysis using data from a Birmingham based multicentre randomized controlled trial.”
Conclusion:
“The costs per patient per year in primary care were £170 [95% confidence interval (CI) £149±190] vs. £69 (95% CI £57±81). Sensitivity analysis demonstrated that the cost in primary care could be reduced to under £100 per patient per year under plausible changes in the variables. Primary care provides similar levels of control to secondary care for patients on anticoagulation therapy. There is an increased cost of managing patients in primary care and at no point did primary care become a lower cost option than secondary care. Local decision-makers need to assess the increased cost of primary care anticoagulation management in terms of the potential reductions in high-cost serious adverse events.

• Comparing the quality of oral anticoagulant management by anticoagulation clinics and by family physicians: a randomised controlled trial. Wilson et al, reference 133.
Objectives:
To assess whether “better outcomes are achieved when anticoagulation is managed by anticoagulation clinics rather that family physicians.” A randomised controlled trial was performed “to evaluate these two models of anticoagulant care.”
Conclusion:
“Anticoagulation clinics provide better oral anticoagulant management than family physicians, but the differences were relatively modest.”

• Randomised controlled trial of near-patient testing for glycated haemoglobin in people with type 2 diabetes mellitus. Khunti et al, reference 134.
Objectives:
“To assess the effect and costs of rapid testing for glycated haemoglobin (HbA1c) in people with type 2 diabetes.” A pragmatic open randomised controlled trial.
Conclusion:
“Near-patient testing for HbA1c alone does not lead to outcome or cost benefits in managing people with type 2 diabetes in primary care. Further research is required into the use of rapid testing as part of an optimized patient management model including arrangements for patient review and testing.

Objectives:
“To perform a systematic review of current trials to determine whether POCT for HbA1c, compared with conventional laboratory testing, improves outcomes for patients with diabetes.”

Conclusions:
“There is an absence of evidence in clinical trials data to date for the effectiveness of POCT for HbA1c in the management of diabetes. In future studies attention to trial design is needed to ensure appropriate selection and stratification of patients, collection of outcome measures, and action taken upon HbA1c results when produced.”
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The author acknowledges the support provided by RCPA Quality Assurance Programs Pty Ltd, which was funded by the Australian Government through the Quality Use of Pathology Program to undertake this review.

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Table 1. Summary: National and international requirements for quality management of POCT.

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<th>Assessment &amp; selection of appropriate device/s for specified clinical task &amp; setting</th>
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<th>Quality Control (QC) of the device (including records &amp; corrective actions)</th>
<th>Assessment (EQA) of testing regime (including operator and comparative assessment)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUSTRALIA</td>
<td>Interim standards for POCT in general practice trial</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>Mandatory</td>
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<td></td>
<td>Assessment of intended clinical &amp; diagnostic purpose, taking into account benefits and disadvantages to patient, analytical performance, space requirement, testing costs &amp; IT to meet trial &amp; practice requirements.</td>
<td>Before introduction of POCT with on-going competency assessment. Formal training, competency assessment &amp; certification. Use of “Quality Manual” &amp; SOPs.</td>
<td>Labelling of samples with 2 unique identifiers, if specimen not immediately and wholly consumed by the testing process (eg. finger-stick specimen). Disposal of unlabelled samples before testing of next sample. Recording of result(s) in patient history.</td>
<td>Appropriate use of internal QC (minimum of 2 levels) plus electronic check where available. Standard pre-determined rules to reject or accept results. Record all results, non-conformities &amp; corrective actions.</td>
<td>Participation in an EQA for comparative assessment &amp; peer review. Frequency as specified by particular EQA program, test dependent. (NPAAC EQA requirements).</td>
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<td></td>
<td>Services which claim Medicare benefit (Category M and S laboratories)</td>
<td>Mandatory</td>
<td>Mandatory</td>
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<tr>
<td></td>
<td>No recommendations.</td>
<td>NPAAC standards, NATA assessment and accreditation.</td>
<td>NPAAC standards, NATA assessment and accreditation.</td>
<td>NPAAC standards, NATA assessment and accreditation. Controls as appropriate for test, low/normal/high. QC material independent of POCT manufacturer, (NATA FAD 5.6.1).</td>
<td>NPAAC standards, NATA assessment and accreditation. Frequency as specified by particular EQA program, test dependent.</td>
</tr>
<tr>
<td>QAAMS</td>
<td>Evaluation of testing device as ‘fit for purpose’.</td>
<td>Mandatory / Policy</td>
<td>Not specified.</td>
<td>Mandatory</td>
<td>Mandatory</td>
</tr>
<tr>
<td></td>
<td>Formal training with on-going competency assessment of device operators. Telephone support service.</td>
<td>Internal QC, 2 levels per month with onsite recording &amp; interpretation of QC results. QC ‘action sheet’ to determine acceptability for the continued testing of patients. Telephone support service. POCT Network review of QC results by supervisor.</td>
<td>Enrolment in the relevant RCPA QAP EQA program. Frequency as specified by particular EQA program, test dependent. 2 samples per month with 2 six monthly cycles per year. QA ‘action sheet’ for review. Telephone support service. POCT Network review of EQA results by supervisor.</td>
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<tr>
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<td><strong>AUSTRALIA cont’d</strong></td>
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<tr>
<td>iCCnet, SA</td>
<td>Evaluate diagnostic accuracy, efficacy, clinical effectiveness &amp; cost effectiveness (‘fitness for purpose’).</td>
<td>Mandatory Formal training with on-going competency assessment of device operators. Telephone support service</td>
<td>Mandatory Labelling of samples with 2 unique identifiers, if specimen is not immediately and wholly consumed by the testing process (e.g. finger-stick specimen). Disposal of unlabelled samples before testing of next sample. Recording of result(s) in patient history.</td>
<td>Mandatory Internal QC, minimum of one per month or after changes which may affect device performance. Set limits for QC acceptance.</td>
<td>Mandatory Enrolment in the relevant RCPA QAP EQA program. Frequency as specified by particular EQA program, test dependent. Generally, 2 samples per month with 2 six monthly cycles per year (INR, 4 samples per year).</td>
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<td><strong>CANADA</strong></td>
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<tr>
<td>Alberta (Physicians)</td>
<td>‘Fitness for purpose’ &amp; assessment of why POCT testing required. Device to be appropriate for intended purpose.</td>
<td>Guideline / Policy Training of personnel to be documented.</td>
<td>Guideline Defined safety requirements. Sample collection procedures, handling &amp; storage according to manufacturer’s instructions. Protocol required for patient preparation (fasting etc) and ID with name and client number.</td>
<td>Guideline Calibration and QC as per manufacturer’s instructions.</td>
<td>Guideline Participation in EQA program strongly recommended. Frequency determined by EQA provider for the particular test.</td>
</tr>
<tr>
<td>Ontario Ministry of Health (for hospitals &amp; long-term-care homes). Requirements based on ISO 22870.</td>
<td>Mandatory Determine ‘fitness for purpose’, clinical need, fiscal justification and resource requirements. Performance goals should be the same as a licensed laboratory.</td>
<td>Mandatory Training, certification and recertification of POCT operators. Ensure that only certified operators perform POCT.</td>
<td>Mandatory Definition, documentation and implementation of processes &amp; necessary procedures. Ensure that POCT results are recorded in the patient record in appropriate detail &amp; that the person performing the test is known.</td>
<td>Mandatory Establish procedures which identify non-conformities. QC as recommended by manufacturer with regular review by experienced person. Frequency determined by device used &amp; test performed.</td>
<td>Mandatory Participation in an EQA for comparative assessment &amp; peer review or regular comparison of results with a licensed laboratory. Frequency determined by EQA provider for the particular test.</td>
</tr>
<tr>
<td>Ontario, INR POCT (physicians &amp; patients)</td>
<td>Guideline Device must be thoroughly evaluated prior to clinical implementation and provide results comparable to an established laboratory method.</td>
<td>Guideline / Policy Operators must receive adequate training of key competencies with an annual review.</td>
<td>Guideline Unique patient identifiers associated with each result, patient record to include name, result, intended INR range, device &amp; test strip information.</td>
<td>Guideline QC external from POCT manufacturer is preferred. Recommendations regarding when to perform QC given.</td>
<td>Guideline EQA, minimum of twice per year (patients &amp; doctors). Operators with &gt;10 patients per day should participate in a formal EQA program.</td>
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<td><strong>CANADA cont’d</strong></td>
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<tr>
<td>Quebec (private sector) AETMIS</td>
<td>✷ Recommended for regulation Should only be performed when justified by the need for a rapid response and must remain a complementary adjunct to central laboratory services.</td>
<td>✷ Recommended for regulation Testing must be performed: - in a secure setting - with strict quality standards - by trained operators - with periodic audits - with QC &amp; EQA</td>
<td>✷ Recommended for regulation Each step in the testing procedure must be accurately recorded in the patient’s medical file &amp; any testing error(s) identified. Patient confidentiality must be maintained.</td>
<td>✷ Recommended for regulation Minimum requirement, manufacturers’ instructions. Actual frequency still to be defined.</td>
<td>✷ Recommended for regulation Participation in an appropriate EQA, details still to be defined.</td>
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<td><strong>FRANCE</strong></td>
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<tr>
<td>All ‘laboratories’, hospitals, &amp; tests performed outside of the medical laboratory (specific legal definition).</td>
<td>✷ Mandatory by 2016 ‘Fitness for purpose’ and limited to medically justified emergency situations or by genuine improvement in patient care based on clinical requirements. Device suitability based on analytical performance &amp; ergonomics.</td>
<td>✷ Mandatory by 2016 Staff to be ‘properly trained’ with on-going competency evaluation based on ISO 22870.</td>
<td>✷ Mandatory by 2016 French requirements for patient identification &amp; data management based on ISO 22870.</td>
<td>✷ Mandatory by 2016 QC materials, incident management &amp; biological validation of results as determined by “local” laboratory based on ISO 22870.</td>
<td>✷ Mandatory by 2016 Participation in an appropriate EQA.</td>
</tr>
<tr>
<td>Primary care ‘doctor’ &amp; patient self-testing, Private doctor testing &amp; patient self-testing are not considered “medical biology tests”.</td>
<td>✷ Unregulated</td>
<td>✷ Unregulated</td>
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### GERMANY

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<tbody>
<tr>
<td>Private practice may offer POCT as an adjunct to laboratory services.</td>
<td>POCT largely related to “unit use procedures”. Correct procedure for sample collection of high importance. Results to be appropriately recorded.</td>
<td>POCT largely related to “unit use procedures”. Correct procedure for sample collection of high importance. Results to be appropriately recorded.</td>
<td>POCT largely related to “unit use procedures”. Correct procedure for sample collection of high importance. Results to be appropriately recorded.</td>
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<td>POCT largely related to “unit use procedures”. Correct procedure for sample collection of high importance. Results to be appropriately recorded.</td>
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#### Mandatory
- Operators must receive adequate training of key competencies. Quality manual describing all aspects of test procedure required.
- Minimum requirement, manufacturers’ instructions but if these differ from the 2008 Directive of the German Medical Association, the stricter criteria apply. Daily or weekly depending on device.

#### Guidance
- Minimum requirement, manufacturers’ instructions. Possible mandated requirement for future accreditation.
- Participation in EQA program or inter-laboratory comparisons strongly recommended. Possible mandated requirement for future accreditation.

### REPUBLIC OF IRELAND

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<tr>
<td>Hospitals and clinics.</td>
<td>‘Fitness for purpose’ with clinical needs and effectiveness defined. Should only supplement laboratory testing. Procedures based on ISO 22870.</td>
<td>‘Guideline / Policy’ Operators must receive adequate training of key competencies with an annual review. Only certified operators to perform POCT.</td>
<td>‘Guideline / Policy’ Use of SOP’s which detail all aspects of testing. Recording of results in patient record, audit trail and corrective action documentation using paper or electronic format using Data Protection Act procedures.</td>
<td>‘Guideline / Policy’ Minimum requirement, manufacturers’ instructions. Possible mandated requirement for future accreditation.</td>
<td>‘Guideline / Policy’ Participation in EQA program or inter-laboratory comparisons strongly recommended. Possible mandated requirement for future accreditation.</td>
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#### Guideline / Policy
- Participation in EQA program or inter-laboratory comparisons strongly recommended. Possible mandated requirement for future accreditation.

### Primary and Community Care (clinic, doctor, pharmacy).

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<td>Hospitals and clinics.</td>
<td>‘Guideline / Policy’ Operators must receive adequate training of key competencies with an annual review. Only certified operators to perform POCT.</td>
<td>‘Guideline / Policy’ Use of SOP’s which detail all aspects of testing. Recording of results in patient record, audit trail and corrective action documentation using paper or electronic format using Data Protection Act procedures.</td>
<td>‘Guideline / Policy’ Minimum requirement, manufacturers’ instructions. Possible mandated requirement for future accreditation.</td>
<td>‘Guideline / Policy’ Device &amp; test dependent. “Unit use procedure”, minimum 2 levels of QC per month. “Collective use procedure”, test dependent, minimum of 2 levels of QC per day or per week.</td>
<td>‘Guideline / Policy’ Participation in EQA program or inter-laboratory comparisons strongly recommended. Possible mandated requirement for future accreditation.</td>
</tr>
<tr>
<td>Jurisdiction</td>
<td>Assessment &amp; selection of appropriate device/s for specified clinical task &amp; setting</td>
<td>Training &amp; competency of operators (&amp; ongoing skill maintenance)</td>
<td>Patient/sample ID &amp; secure recording of results</td>
<td>Quality Control (QC) of the device (including records &amp; corrective actions)</td>
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<tr>
<td><strong>SPAIN</strong></td>
<td>Hospitals, clinics, doctors (SEQC guidelines).</td>
<td>Guideline Justification &amp; assessment of need to conduct POCT testing. Selection of easy to use devices but with traceability of results to a recognised laboratory method.</td>
<td>Guideline Establishment of training programs &amp; controls for testing personnel.</td>
<td>Guideline All information to be integrated into patient’s medical records.</td>
<td>Guideline Participation in EQA programs recommended.</td>
</tr>
<tr>
<td><strong>NEW ZEALAND</strong></td>
<td>Health Board contracts with POCT included. Accredited to ISO 22870.</td>
<td>Mandatory Compliance with ISO 22870.</td>
<td>Mandatory Compliance with ISO 22870.</td>
<td>Mandatory Compliance with ISO 22870. QC program that ensures quality of testing &amp; provides reliable MU data.</td>
<td>Mandatory Compliance with ISO 22870. Participation in EQA program where available or inter-laboratory comparisons.</td>
</tr>
<tr>
<td><strong>UNITED KINGDOM</strong></td>
<td>Medicines &amp; Healthcare Products Regulatory Agency (MHRA/MDA) Guidelines (for NHS trust policy).</td>
<td>Guideline 'Fitness for purpose’ with clinical needs and effectiveness defined &amp; justified.</td>
<td>Guideline / Policy Operators must receive adequate training of key competencies with on-going review. Training record to be documented.</td>
<td>Guideline / Policy Use of SOP’s which detail all aspects of patient preparation, sample collection &amp; testing. All result information to be integrated into patient’s medical records. Testing records to include date &amp; time, device type, batch #, operator &amp; patient ID.</td>
<td>Guideline / Policy Participation in EQA program or parallel testing, or inter-laboratory comparisons strongly recommended.</td>
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<td><strong>England</strong> (NHS trust facilities, hospitals, clinics) Generally required to be accredited to CPA (UK) standard.</td>
<td>Mandatory ‘Fitness for purpose’ with clinical needs and effectiveness defined &amp; justified.</td>
<td>Mandatory Operators must receive training of key competencies with on-going review. Only certified operators to perform POCT.</td>
<td>Mandatory Use of SOP’s which detail all aspects of patient preparation, sample collection &amp; testing. All result information to be integrated into patient’s medical records</td>
<td>Mandatory Device &amp; test dependent. Generally defined by the “local” laboratory or equivalent to that used by the “local” laboratory.</td>
<td>Mandatory Enrolment in the relevant EQA program; device &amp; test dependent. Frequency as specified by the particular program. Generally supervised by “local” laboratory.</td>
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<td>Jurisdiction</td>
<td>Assessment &amp; selection of appropriate device/s for specified clinical task &amp; setting</td>
<td>Training &amp; competency of operators (&amp; ongoing skill maintenance)</td>
<td>Patient/sample ID &amp; secure recording of results</td>
<td>Quality Control (QC) of the device (including records &amp; corrective actions)</td>
<td>Assessment (EQA) of testing regime (including operator and comparative assessment)</td>
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<td>UNITED KINGDOM cont’d</td>
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<td>England (primary care doctors with special funding program).</td>
<td>Determined by individual practice</td>
<td>✷ Mandatory Each practice must ensure that all staff involved in providing any aspect of care under the program has the necessary training and skills.</td>
<td>✷ Mandatory Ensure that POCT results are recorded in the patient record. Maintain adequate records of the performance of the service.</td>
<td>✷ Mandatory The arrangements made for QC to be provided for approval.</td>
<td>✷ Mandatory Participation in EQA program, frequency as specified by EQA program.</td>
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<td>Scotland (NHS trust facilities, hospitals, clinics, patient self-testing).</td>
<td>Determined by individual trust requirements, but taking into account benefits &amp; disadvantages.</td>
<td>✷ Mandatory Operators must receive training of key competencies.</td>
<td>✷ Mandatory Manufacturers’ instructions as minimum requirement. Use of SOP’s which detail all aspects of patient preparation, sample collection &amp; testing.</td>
<td>✷ Mandatory Minimum requirement, manufacturers’ instructions. Record of non-conformities &amp; corrective actions to be kept.</td>
<td>✷ Mandatory Participation in EQA program, frequency as specified by EQA program.</td>
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<td>Wales (all facilities including primary care)</td>
<td>✷ Mandatory POCT defined as diagnostic test done by non-laboratory staff. ‘Fitness for purpose’ &amp; assessment of why POCT testing required.</td>
<td>✷ Mandatory Operators must receive training of key competencies. Only certified operators to perform POCT.</td>
<td>✷ Mandatory Results of all patient, QC &amp; QA samples to be recorded with, date, time &amp; operator details. Full audit trails documentation.</td>
<td>✷ Mandatory Mandatory; at agreed intervals on samples of known values. Generally determined by “local” laboratory.</td>
<td>✷ Mandatory Participation in EQA program, frequency as specified by EQA program.</td>
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<td>Northern Ireland (trust facilities, hospitals, clinics, primary care doctors). Required to be accredited to CPA (UK) standard.</td>
<td>✷ Mandatory ‘Fitness for purpose’ with clinical needs and effectiveness defined &amp; justified. According to RCPath guidelines</td>
<td>✷ Mandatory Operators must receive training of key competencies. Only certified operators to perform POCT. Training record to be documented.</td>
<td>✷ Mandatory Use of SOP’s which detail all aspects of patient preparation, sample collection &amp; testing. SOP must be written to CPA (UK) standard. A formal reporting procedure must be established.</td>
<td>✷ Mandatory Mandatory; at pre-determined intervals.</td>
<td>✷ Mandatory Participation in EQA program, frequency as specified by EQA program.</td>
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<td>UNITED STATES OF AMERICA</td>
<td>Waived tests (less complex tests as defined; including Na, K, Glucose, Hb, Lipids, Urea, Creatinine, Influenza, INR, HbA1c, FOB, Urine dipsticks). Appropriateness of waived test(s) “with no risk to human health”, as approved by the FDA.</td>
<td>✬ Mandatory Qualifications of supervisor &amp; those performing tests must be documented.</td>
<td>✬ Mandatory Manufacturers’ instructions, with records available to the inspecting authority (HHS).</td>
<td>✬ Mandatory Minimum requirement - manufacturers’ instructions.</td>
<td>✬ Guideline Announced &amp; unannounced inspections by HHS. EQA participation encouraged but not required for waived tests.</td>
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<td>Moderate complexity tests as defined, including blood gas, hepatitis testing, FBE, etc.</td>
<td>✬ Mandatory Specialised testing, requires full accreditation</td>
<td>✬ Mandatory Instructions for collection, labelling &amp; processing with specimen rejection policy. Use of SOP’s which detail all aspects of patient preparation, sample collection &amp; testing.</td>
<td>✬ Mandatory Requirements may differ depending on inspection agency. Example, CAP; daily QC testing at 2 levels with corrective action reporting. Manufacturer’s instructions validated.</td>
<td>✬ Mandatory Participation in EQA program, frequency as specified by EQA program. Split sample testing if EQA program not available.</td>
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