Supplementary Brief

Page 34:
Question 1

i. *Please identify the different accreditation bodies operating in the UK as of 26.11.95.*
These would have been Clinical Pathology Accreditation (UK) Limited (CPA) and/or the King's Fund Organisational Audit process which has a specific section for pathology laboratories.
I have already sent you the Standards I had for CPA (1990's) at the time and for King's Fund.

ii. *Please describe the implication for 'standards' of accreditation with any of these bodies, generally and in particular:*

- *Accuracy and reliability of results of blood tests, especially those for electrolytes.*

This would not be specifically looked at apart from studying the external quality assurance (EQA) returns (for the laboratory service only). If there had been any problems with the EQA, letters would have been sent to the Head of Department from the Joint Working Group on Quality Assurance (a National Body).

- *Turnaround times for the results of blood tests during normal working hours, out of house and in urgent cases.*

This would not necessarily have been looked at in the mid-90's. However, **nowadays**, it would be looked as part of the 'vertical audits are undertaken regularly as part of the CPA Quality Management Process'. In addition, it would now form part of the 'Key Performance Indicators' and 'Quality Dashboard'.

iii. *The Inquiry has been informed that the Belfast City Hospital Trust and the Royal Group of Hospitals ..... The Inquiry has sought the following further information in relation to accreditation:*

a) *The dates that each hospital applied*
b) *The application for each hospital*
c) *Correspondence relating to the applications and their results*
d) *The certificates of successful accreditation*

I am afraid I am unable to answer any of these questions as I have never had this information.

iv. *Please state the significance/importance of a hospital's laboratory being accredited and explain the:*

Cont. over

a) *Process of applying for and being granted accreditation:*

Applicant departments assess themselves against the standards, complete a questionnaire to indicate compliance with or exemption from them and send it back. The Department is then visited by CPA Inspectors to confirm compliance with standards. A full report is subsequently sent to the Head of the applicant Department after the relevant Specialist Advisory Committee(s) have considered the inspectors assessment and any queries have been dealt with. If all is well, or the inspectors indicate areas that could be improved but are not such that they would affect the ability of the department to attain accreditation, Accreditation is granted.

Please see accompanying CPA Accreditation Handbook from 1999 (pages 3 – 25). I do not have anything prior to this.

b) *Means of ensuring that standards are being maintained, including whether through periodic audits and External Quality Assurance etc.*

This would have primarily been through EQA.
Accredited departments were subjected to re-inspection at intervals of four years. Nowadays, we have vertical and horizontal audits as part of our Quality Management Process.

2 point C:

'This is not the case (the laboratory taking an hour) for an 'urgent sample ..... .

i) *Please provide the basis for your statements in relation to 'turnaround' times, i.e. 40 minutes nowadays for a laboratory result and 20 minutes from a STAT machine.*
This is based on experience of the past in the 1990's, i.e. on STAT machines such the Beckman Astra.

ii) *Please explain what you think the 'turnaround' time in November 1995 (as opposed to 'nowadays') was from 'the time a sample is booked in to the time a result is produced.*
This is different to nowadays (2011).

iii) *Please explain what you mean by a STAT machine and :*

a) *Whether it includes a 'portable i-STAT machine'*
Not i-STAT machine, a STAT machine such as Beckman Astra

b) *How reliable the results of the STAT machines were as compared to laboratory tests.*

Reliability of the laboratory STAT machine would be included as part of the whole EQA process of the laboratory

Cont. over

3.

The Inquiry has received layout plans for the RBHSC and the main Royal Victoria Hospital showing the location of: the operating theatre, PICU and ……

i) Please comment upon the statements made about the blood gas machine in the correspondence from the DLS.

ii) Please also consider the comments about the laboratories and their proximity to the operating theatre in relation to 'turnaround' times for blood electrolyte tests

Paragraph 5: This seems reasonable: The only criticism is the log book. I am not sure when this investigation was first initiated, but if one is talking about a log book being kept for 15 years, i.e. 2010 when the report was written, I am not surprised that the log has not been retained.

Paragraph 6: The Anaesthetist was correct in saying that the analyser would not necessarily produce accurate sodium results because of anticoagulant heparin. The does depend very much on the volume of heparin present in the syringe as well as the type of heparin

Paragraph 7: I am not surprised to see that there is no documentary material relating to the use of IL blood gas analyser. During the mid-1990's, point of care testing (used to be called near patient testing) such as laboratory equipment was 'out with' the laboratory, operated by non-laboratory personnel and did not fall in the remit of CPA accreditation. Thus these issues as such would not have been addressed.

Paragraph 8: Again because of potential lack of POCT policy there is no reason why clinicians would have been informed as they would not necessarily had this as part of their training, e.g. the issues around heparin.

Paragraph 10: With a POCT policy there would have been records of those trained and authorised to use the machine.

Paragraph 11: With regard to turnaround time, I suspect the main factor affecting the turnaround time is not the time within the laboratory or to actually measure the sodium in the laboratory using a STAT analyser, it is most likely a portering issue.

Cont. over

Question 2

4. Point A

i) *Please comment upon Dr. Taylor's claim that at that time (i.e. the mid 1990's), the blood gas machine could not be relied upon to accurately analyse sodium levels when using heparin syringes as the sodium content ……*

I am a little confused: Is the Inquiry saying that Dr. T. would not rely on the blood gas analyser to measure sodium although it was common practice at the RBHSC. In fact, on further investigation, the IL machine that they had would not necessarily have been able to measure sodium. There would also be an issue about heparin. There has to be a special type of heparin to be used in the syringes which is 'electrolyte balanced heparin'. It also depends on the volume of heparin.

ii) *It would be helpful if you would describe and explain the levels of accuracy and reliability of such a machine……*

I cannot tell you the accuracy and reliability of a gas machine in 1995 compared with the laboratory.

5. I have already sent you current POCT policy from Luton & Dunstable NHS Trust. I do not have the policy from the mid-1990's but I sent you a chapter from my book 'Chapter 10: Guidelines on Point of Care Testing'. Published in '*Point of Care Testing*' Edited by CP. Price and J.M. Hicks. AACC Press. ISBN 1-89- 883: 23: 9
The only policy during the late 1990's (and certainly in 1998) would have been based on that chapter.
I cannot inform you of 1995.

6/12/11

Dr. D.B. Freedman
Consultant Chemical Pathologist

POINT-OF-CARE TESTING

POCT

Chapter 10

Guidelines on Point-of-Care Testing

Danielle B. Freedman

Pressure to centralize hospital facilities is leading to increased centralization of laboratory facilities. The trend toward centralization is driven by two key factors:

- reducing the overall cost of care by achieving economies of scale; and
- creating a greater critical mass of expertise in order to improve the overall quality of care, particularly in technologically sophisticated areas of medicine (1).

The economic pressure of rising health care costs has also called for faster turn-around of laboratory results (2) thereby adding to the pre-existing needs in particular clinical situations for rapid response testing. Interestingly, centralization of specialist services often creates the need for rapid turn-around of results at the peripheral sites, and in the community.

The clinical need for rapid response testing, and related perceived operational benefits, are viewed as a justification for the implementation of point-of-care testing (POCT). The operational benefits may be seen in purely economic terms: by reducing length of hospital stay and reducing the need for complex infrastructure support, for example, specimen collection and transportation. In addition, a more local testing arrangement may be more convenient for the patient.

The changing pattern of health care delivery is creating many opportunities for implementation of POCT (*Table 1*). Advances in analytical technology over the past three decades—from the apparently simple dipstick to the sophisticated biosensor and microfabrication technology—are making POCT feasible. For example, it is now possible to analyze plasma constituents from a whole blood sample without a pretreatment

Published in Point of Care Testing AACC press 1999

TABLE 1. Potential Sites for Point-of-Care Testing

PRIMARY CARE	SECONDARY/TERTIARY CARE
Physician offices	Emergency units
Community clinics	Admission units
Health centers	Intensive care units
Workplace clinics	Operating rooms
Drug stores	Wards
The home	Outpatient clinics

step. It is also possible to download the validated result directly into the patient's electronic record.

The development of central laboratory facilities has been complemented by a dramatic increase in the number, kind, and frequency of tests performed. As a consequence, questions about the need for such a level of testing as well as claims of abuse of testing have been raised (3,4). There is limited consensus on what is good practice in the utilization of laboratory services, and hospitals vary considerably in the repertoire of tests used. In more recent times there has been a move to establish guidelines for the use of particular tests, e.g., HbA_{1c} and urine microalbumin in diabetes mellitus, although the adoption of such guidelines is not uniform.

As we enter an era of evidence-based medicine, the introduction of new diagnostic tests and the choice of POCT should be based on proper evaluation employing the guiding principles of health technology assessment (5). The majority of the scientific literature on POCT to date has been concerned with technical performance and has placed less emphasis on clinical or operational benefits (6). Much of the early literature on POCT claimed that analytical performance did not match that of the central laboratory, and furthermore, that it was more costly (7). The latter argument is still contested by most commentators but arguments about analytical quality are less contentious, probably due to improvements in the quality of analytical devices and to the introduction of guidelines for the use of POCT (8).

The systematic assessment of POCT in individual settings will identify the analytical performance that is required as well as the clinical and operational benefits that can be achieved. However, any assessment will be worthless if the technology, in this case POCT,

is not applied according to good practice guidelines. This chapter discusses guidelines for good practice in POCT.

Context of POCT

To understand the challenges of POCT, it is important to appreciate the resources required for the provision of a testing service and how they are managed. The concepts of total quality management have been applied to the laboratory and have led to a better appreciation of where attention must be focused in order to achieve a high-quality product, and how importantly this can change with circumstances, e.g., automation, labor force availability, and hospital re-engineering (9). These concepts apply equally to POCT; in this respect, comparison with the central laboratory is instructive (10). POCT requires a different approach in that

- the number of tests performed is small;
- the staff are not generally given formal technical training in POCT as part of their core professional training;
- the immediate professional hierarchy does not have a technical background;
- the physical environment where POCT is performed is not always ideally suited for analytical work; and
- there may be unique health and safety issues.

While it is important to recognize the unique challenges of POCT, it is also important to recognize that certain standards of practice are equally applicable to the central laboratory and to POCT; accountability to the doctor and to the patient is no different. Thus practitioners must

- know what needs to be measured;
- identify the clinical requirement for the measurement;
- institute a reliable means of achieving a measurement of suitable quality;
- assess quality at all times;
- make the result of the measurement clear to the requesting doctor; and
- perform the measurement in a cost-effective manner (11).

Much clinical practice is based on centralized laboratory medicine services that may be subject to government and/or professional regulation/accreditation. POCT may be similarly managed, although it appears that there is little formal regulation of POCT throughout the world outside of the United States (see Chapter 13, "Regulatory Issues in Point-of-Care Testing"). In the absence of formal regulation, many countries have adopted professional guidelines on POCT as a means of assuring quality.

Implementation of POCT

Professional guidelines on POCT should facilitate the development of guidelines that can be used within the local organization (hospital, local health center, consortium of centers, or health visitor team) to govern the operation of individual POCT sites, and that take into account regional and/or national legislation.

Guidelines help health care professionals address the issues concerned with determining the rationale for POCT, critically appraising the need for adoption, implementing a POCT strategy, and maintaining the quality of the service. Typically such a decision process would involve a team of professionals, including the potential purchaser of the service, the trainer, the practitioner, and the decision maker (see later comments on POCT committee). The following guidelines are written in response to questions that are typically asked by team members involved in implementing a POCT strategy (12, 13).

Cost-Benefit Analysis

The first step in the introduction of a testing or intervention service is establishing clinical need so that all possible solutions can be fully examined (*Table 2*). For example, vacuum tube links for specimen transfer and intranet computer links for result transfer may make a centralized rapid testing facility available to several potential users (14) and avoid many delays in turn-around time that may be consequences of factors outside the laboratory's control (15). Thus, when judging the utility of a POCT solution, establish the nature of the tests that will be performed and the respective turn-around times required. While it may be easy to determine the operational benefit from producing a result more quickly in the POCT setting, e.g., by reducing the patient's overall length of hospital stay, the impact of POCT on patient outcomes can be more difficult to judge with objective evidence (16, 17). However, there are now multi-center studies of intensive care units that have, for example, related testing and therapeutic protocols to patient outcomes (18, 19).

It is important to undertake an economic assessment that compares the cost of delivering the service by central laboratory and POCT modalities. This should take into account the overhead costs associated with both modalities, such as staff training and quality assurance, in addition to the facilities overhead (20).

Risk Assessment

The infrastructure support for POCT may be quite different from that of the laboratory. Thus the technology may be quite different, the personnel from a different professional

TABLE 2. Assessment of Need for Point-of-Care Testing

Which patients need the test(s)?
Why is the test required?
What test(s) are required?
What is the problem with the current service?
What is the cost of the current service?
What is the cost of POCT?
Will POCT provide the required accuracy and precision?
Are there staff available to perform the test?
Is POCT acceptable to staff and/or patients?
Is the equipment suitable for POCT use?
Are there adequate facilities to perform POCT?
Are there adequate facilities for disposal of sample and consumables?
What are the clinical benefits of POCT?
Will POCT improve patient outcomes?
What are the operational benefits of POCT?

background, and the physical environment not ideal for analysis of biological specimens.

Individuals preparing a case for POCT should undertake a risk assessment. The assessment should focus on

- the technical performance of the device that will be used;
- the background of the staff who will be trained to perform the POCT, including their experience with similar devices, audit of quality control and quality assurance scheme performance;
- the creation of adequate guidelines for dealing with the interpretation of results, particularly those that are abnormal or unexpected;
- health and safety issues associated with the use of the POCT device and any disposable items, together with specimen collection and disposal; and
- procedures that ensure that the correct result is entered into the patient's record and relevant staff appraised so action can be taken.

Equipment Procurement

Identification of the specific clinical need for POCT will include the tests that are required as well as the analytical and operational goals. These specifications will help define the type of device that is required (*Table 3*) (21).

Users must have access to an independent evaluation of the device of choice. (The evaluation ideally has been undertaken in the setting for which POCT is envisaged.) In addition, users must compare analytical performance with the central laboratory service because patients will often be managed on data produced by both POCT and central laboratory technology (22).

Before making a purchase decision, determine whether the supplier's service (in terms of consumable delivery and service back-up) will meet your needs. A poor back-up service may require holding large stocks in-house as well as relying on local maintenance expertise, thereby increasing overhead costs (23).

TABLE 3. Issues Surrounding Requirements for POCT; Analytical and Operational Goals

What tests are required in this setting?
What accuracy and precision are required?
What is the required test turn-around time?
What is the average daily requirement?
What space is available to locate equipment?
What storage facilities are available?
What type of analyzer is available?
What is the size of the analyzer?
How easy is the analyzer/device to use?
How easy is the decontamination process?
Can all health and safety procedures be maintained?
What is the claimed analytical performance?
Are the results comparable with the laboratory?
What are the maintenance requirements?

Training and Certification

Staff required to undertake POCT will likely not have formal technical training in POCT as part of their core professional training (although some specialist intensive care nurses are required to manage a range of complex life support systems).

Any local guidelines on POCT should require all staff to be trained in the use of the relevant device and to demonstrate competence in its use. This basic requirement should then be supported by a commitment to maintain competence through participation in regular quality assurance and retraining as required.

For staff with little or no technical background, familiarization with the basic concepts of measurement and the terminology of POCT will be helpful (24). Training should cover the pre-analytical, analytical, and post-analytical phases of the testing process (*Table 4*). The pre-analytical phase should cover the preparation of the patient and collection of the appropriate sample, as well as the preparation of the POCT device. For example, it may be necessary to store consumable items at 4°C but bring them to room temperature immediately prior to use.

While the design of most POCT devices is intended to reduce analytical steps to a minimum, training should always recognize that most operators have a limited amount

TABLE 4. Elements of a Training Program

- Basic knowledge of the tests, clinical requirement, and pathophysiological context
- Type of sample requirement, including any time constraints (diurnal variation, drug therapy)
- Specimen collection
- Preparation of analytical device and consumables
- Performance of test
- Performance of quality control
- Documentation of test and quality control result
- Reporting of result to appropriate personnel
- Interpretation of result or where to get advice
- Health and safety procedures, e.g., disposal of specimen and consumables, clearing of test area

of technical expertise. The use of a pipette, for example, may be second nature to a laboratory professional but unfamiliar to patients and health care workers employed on the ward, in the clinic, or in the home.

Training should also strongly emphasize the post-analytical phase, including correct documentation of the result together with communication to the clinical decision maker. Part of this process will include completing appropriate quality control and its correct documentation. In addition to completion of any formal QC procedure, the validation of the whole procedure should also include a "reality check" on the result. This will involve instructing the operator in the purpose of the respective point-of-care test; the reference range and typical pathological range, together with any "alarm limits"; what to do with results; and whom to contact for further analytical or clinical advice.

Certification of a POCT operator should involve some form of competency testing at the conclusion of training. This may include a written test or formal interview by the trainer or supervisor, together with an analytical exercise using the test to demonstrate the precision on a number of replicates or analysis of samples of known analyte concentrations. At the satisfactory conclusion of this test, the operator should be given a certificate of competence and have his/her name entered in a register of competent practitioners, together with the date of certification. Competence may be checked at regular intervals, frequency guided in part by performance in the QC procedures as well as frequency of POCT use.

Quality Control and Quality Assurance

The maintenance of POCT quality is a complex issue as it often involves a large number of operators and employs single-use disposable devices. In addition, the workload may be small. (The subject of quality assurance is discussed in detail in Chapter 8, "Quality Control and Quality Assurance.") Good quality is based on good education and training supported by clear guidelines and the involvement of laboratory staff.

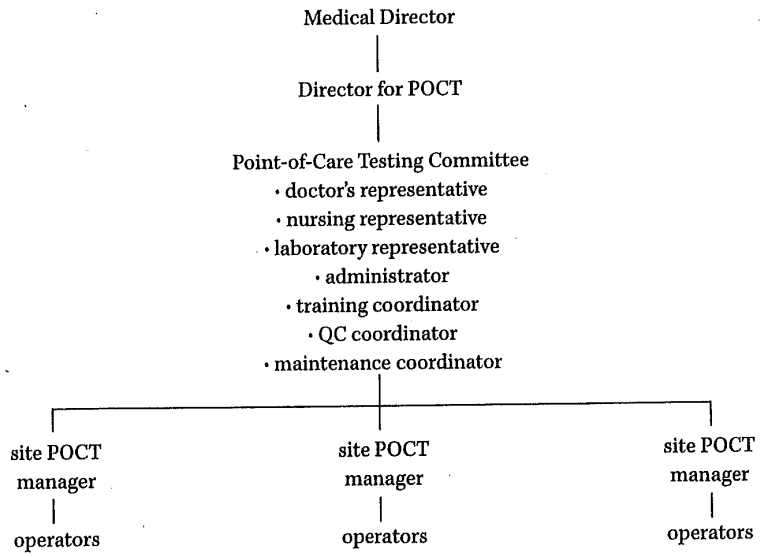
At a minimum, one QC sample should be analyzed per shift (25). However, if the POCT device is to be used less frequently, then it may be appropriate to analyze a QC sample with each patient sample. Whatever the protocol, results should be documented and evaluated with exactly the same thoroughness as the patient's test results. The device may incorporate procedural controls (as in the case of many immunoassay lateral flow devices); in this case, documentation of a positive result for such a procedural control is important. Some devices may include test simulator cards or even electronic QC procedures; these should be used according to the manufacturer's instructions. However, recognize that not all of these techniques provide "control" of the whole process (12).

developed guidelines for POCT which also suggest that the organization using POCT develops an appropriate POCT policy.

Such a policy should define the issues related to accountability with respect to the testing itself, to certification of those undertaking the testing, and to those responsible for training. Some guidelines advocate identifying a senior staff member to be responsible for the coordinating and licensing of POCT. The staff member may enlist the services of a committee responsible for coordination of activities, including new business cases for POCT, review of quality assurance programs, audit of use, and economic performance (26). A typical line of accountability is outlined in *Figure 1.*

The establishment of a POCT committee ensures that testing is managed effectively. Furthermore it ensures proper coordination of resources throughout the organization so that duplication among manufacturers is reduced, training and quality assurance activities are integrated, and maintenance support is centralized. The availability of a POCT committee also ensures that expertise can be shared, which will be of particular

FIGURE 1. A Proposed Organization Chart of Management and Accountability for Point-of-Care Testing



benefit to POCT service operators.

The laboratory should play a central role in the management of POCT; laboratory personnel have unique experience in the performance of analytical tasks as well as the discipline associated with maintenance of quality assurance and troubleshooting or fault finding. The laboratory is also a natural focal point for the organization of a local quality assurance scheme network and at the same time provides a reference point when questions arise concerning the accuracy of a specific sample on which an unexpected result has been obtained (26).

The involvement of the local laboratory is advocated in many of the guidelines prepared by professional bodies involved in the practice of laboratory medicine (13, 27–29). In addition, laboratory involvement is advocated in accreditation schemes (30) and is supported by relevant government departments (31). The involvement of the central laboratory in POCT may make the fulfillment of regulatory requirements easier (32). Some standards for accreditation, prepared by the near-patient testing working party of the Royal College of Pathologists, are summarized in *Table 7.*

Conclusions

POCT is an established part of clinical practice; commercially it is a $900 million market with a projected annual growth of 12% (24). POCT quality has improved dramatically as a consequence of more sophisticated technology and the introduction of performance guidelines. It remains unclear, however, whether the true benefits of POCT are being realized. The true benefit will only be achieved by the maintenance of close working relationships between those professions involved in providing diagnostic services and those involved in direct patient care. This partnership will ensure that the maximum benefit is gained from an integration of central laboratory and point-of-care testing. However, as POCT expands, it is important to understand the issues regarding responsibility for maintaining quality and confidentiality of data.

TABLE 7. Accreditation Standards for Point-of-Care Testing

ORGANIZATION AND MANAGEMENT

There is documentation to describe the strategy, organization, scope, and management of the provider unit (e.g., hospital) with regard to POCT.

There is a multi-disciplinary approach for the organization and management of POCT.

There must be procedures for choosing and obtaining equipment in collaboration with the clinical laboratory director to ensure proper performance and safety standards.

STAFFING AND DIRECTION

POCT is professionally directed by a consultant pathologist or clinical scientist of equivalent status.

There is a documented line of accountability for all staff involved in POCT analyses and QA.

There is evidence that POCT operators are assessed as competent.

FACILITIES AND EQUIPMENT

The equipment is appropriate, meets the demands of the service, and is properly maintained.

Designated space is available for the use of analytical equipment and handling of blood samples associated with POCT.

There is a safe working environment in accordance with current legislation.

POLICIES AND PROCEDURES

There are written procedures for obtaining samples for POCT, handling these samples, and safe disposal.

There is a written, signed, and dated procedure for the performance of each test, including Quality Control.

There is a record of all reagents, calibration, and QC material.

There are written procedures for the regular maintenance of equipment. This should also include procedures for decontamination of all equipment and working space.

There is a written procedure for recording results, which includes recognition that they originate from a POCT facility.

There is a written procedure for interpretation of results by staff other than the patient's medical practitioner.

STAFF DEVELOPMENT AND EDUCATION

There is a written program of training for all users of POCT equipment.

References

1. Henderson AR. Re-engineering and downsizing in health care: World-wide impact on laboratory medicine. Clin Chim Acta 1997;267:1–128.
2. Kost GJ. Guidelines for point-of-care testing. Am J Clin Pathol 1995;104:S111–S127.
3. Winkens RAG, Ament AJHA, Pop P, Reniers PHA, Grol RPTM, Knottnerus JA. Routine individual feedback on requests for diagnostic tests: An economic evaluation. Med Decis Making 1996;16:309–14.
4. van Walraven C, Naylor CD. Do we know what inappropriate laboratory utilization is? JAMA 1998;280:550–8.
5. Liberati A, Sheldon TA, Banta HD. Eur-assess project subgroup report on methodology. Methodological guidance for the conduct of health technology assessment. Int J Technol Assessment in Health Care 1997;13:186–219.
6. Hobbs FDR, Delaney BC, Fitzmaurice DA, Wilson S, Hyde CJ, Thorpe GH, et al. A review of near-patient testing in primary care. Health Technol Assessment 1997;1:1–231.
7. Witte DL. Measuring outcomes: Why now? Clin Chem 1995;41:775–80.
8. Price CP, Burrin JM, Nattrass M. Extra-laboratory blood glucose measurement: A policy statement. Diab Med 1988;5:705–9.
9. Westgard JO, Burnett RW, Bowers GN. Quality management science in clinical chemistry: A dynamic framework for continuous improvement of quality. Clin Chem 1990;36:1712–6.
10. Handorf GR. Assuring quality in laboratory testing at the point of care. Clin Chim Acta 1997;260:207–16.
11. O'Leary D. Global view of how alternate site testing fits in with medical care. Arch Pathol Lab Med 1995;119:877–80.
12. Goldsmith BM, Travers EM, Bakes-Martin R, Lau PY, Lamb LS, Phillips DL, et al. Point-of-care in vitro diagnostic (IVD) testing: Proposed guideline. NCCLS Document ST2-P 1995;15:1–69.
13. The Association of Clinical Biochemists. Guidelines for Implementation of Near Patient Testing. 1993. Available from the Association of Clinical Biochemists, Carlton House Terrace, London SW1Y 5AF UK.
14. Green M. Successful alternatives to alternate-site testing: Use of a pneumatic tube system to the central laboratory. Arch Pathol Lab Med 1995;119:943–7.
15. Saxena S, Wong ET. Does the emergency department need a dedicated STAT laboratory? Continuous quality improvement as a management tool for the clinical laboratory. Am J Clin Pathol 1993;100:606–10.

16. Parvin C, Lo S, Deuser S, Weaver L, Lewis L, Scott M. Impact of point-of-care testing on patients' length of stay in a large emergency department. Clin Chem 1996;42:711–7.
17. Kendall JM, Reeves B, Clancy MJ. Point-of-care testing: Randomized controlled trial of clinical outcome. BMJ 1998;316:1052–7.
18. Zimmerman JE, Shortell SM, Rousseau DM, Duffy J, Gillies RR, Knaus WA, et al. Improving intensive care: Observations based on organizational case studies in nine intensive care units. A prospective, multi-center study. Crit Care Med 1993;21:1443–51.
19. Rapoport J, Teres D, Lemeshow S, Gehlbach S. A method for assessing the clinical performance and cost-effectiveness of intensive care units: A multi-center inception cohort study. Crit Care Med 1994;22:1385–91.
20. Seamonds B. Medical, economic, and regulatory factors affecting point-of-care testing. A report of the conference on factors affecting point-of-care testing, Philalephia, PA. Clin Chim Acta 1996;249:1–19.
21. Ng RH. Selecting instrumentation for physician's office testing. Clin Lab Med 1986;6:305–15.
22. Macik BG. Designing a point-of-care program for coagulation testing. Arch Pathol Lab Med 1995;119;929–38.
23. Snyder JR, Wilkinson DS. Management in Laboratory Medicine. 3rd ed. New York, USA: Lippincott, 1998.
24. Bourlier KM. The Hitchhiker's Guide to Point-of-Care Testing. Washington, DC, USA: AACC Press, 1998.
25. Price CP. Quality assurance of extra-laboratory analyses. In: Marks V, Alberti KGMM, eds. Clinical Biochemistry Nearer the Patient II. London, UK: Bailliere Tindall, 1986;166–78.
26. Burnett D, Freedman D. Near-patient testing: The management issues. Health Services Management 1994:March:10–13.
27. Department of Health. Hazard Notice (HN). Blood gas measurements: The need for reliability of results produced in extra-laboratory areas. London, UK: Department of Health. HN (Hazard), 1987c;31.
28. Dybkaer R, Martin DV, Rowan RM (eds.). Good practice in decentralized analytical clinical measurements. European Committee for Clinical Laboratory Standards. International Federation of Clinical Chemistry and World Health Organization. Scan J Clin Lab Invest 1992; 209:1–116.
29. Freedman D. Guidelines for the implementation of point-of-care testing. Interna-

tional Federation of Clinical Chemistry 1999. [Online]. Available, IFCC website: http://194.79.144.120.
30. Burnett D. Understanding accreditation in laboratory medicine. London, UK: ACB Venture Publications, 1996.
31. England JM, Hyde K, Lewis SM, Mackie IJ, Rowan RM. Guidelines for near-patient testing: Hematology. Clin Lab Hem 1995;17:300–9.
32. Ehrmeyer SS, Laessig RH. Regulatory requirements (CLIA '88, JCAHO, CAP) for decentralized testing. Am J Clin Pathol 1995;104:S40–S49.