Review Article

The Evidence to Support Point-of-Care Testing

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Abstract
Point-of-care testing (PoCT) is now possible in many areas of clinical medicine. This review examines the evidence for its application in four areas: self-monitoring; community testing primarily in the pharmacy; general practice; and the emergency department. In all of these areas except pharmacy, randomised controlled trials of PoCT versus central laboratory testing have been performed, with the results of some of these trials supporting the use of PoCT. Aside from providing evidence, these trials and other observational studies have provided valuable information about how PoCT should be conducted. In particular they have shown that adoption of the technology is often insufficient to achieve a benefit and in some cases a change of care process is also required.

Introduction

The ability to move testing closer to the patient, so-called point-of-care testing (PoCT), has been possible for some three decades with continuing advances in technology that have produced steadily more sophisticated devices measuring an increasing range of analytes. The technological aspects of PoCT have tended to receive more attention but there is an increasing focus on how and where PoCT should be applied and the potential outcomes from PoCT.[1] This change in emphasis has come about in part because of the need to adopt an evidence-based approach to the introduction of new technology. In addition, healthcare reform being pursued by many western countries including Australia is encouraging the need to provide better and more convenient access to healthcare for all patients, particularly those with chronic diseases.[2] The potential for PoCT to be part of so-called patient-centric healthcare is obvious and, like acute care where PoCT was first applied, it is based on PoCT providing faster results and facilitating quicker clinical decisions. Some of the potential benefits that can be delivered by PoCT are shown in the Table.

Several years ago Lundberg suggested that it was time for the laboratory medicine profession to devote more of its resources to diagnostic outcomes research.[3] This was equally true for PoCT as it was for central laboratory testing, with little evidence at that time that PoCT was improving patient outcomes.[4,5] Of the studies that were performed, many were of poor design and failed to address the pertinent questions. That situation has changed with a substantial number of randomised controlled trials (RCTs) being performed that compare PoCT with central laboratory testing. This paper will examine some of the available evidence for PoCT in four different locations: patient self-monitoring in the home; community testing primarily in the pharmacy; general practice testing; and PoCT in critical care areas of the hospital including the emergency department (ED).

Patient Self-Monitoring

Self-monitoring represents the largest commercial market for PoCT, and in the case of self-monitoring for blood glucose (SMBG), it is one of the oldest applications with the first patents for glucose strips being lodged in 1963.[6] For some, SMBG is a classic example of the commonly cited problem in healthcare of a technology with significant costs being widely implemented without sufficient evidence to support its use. The area is particularly controversial in relation to non-insulin dependent (type 2) diabetes where in recent years there have been multiple studies including trials to assess the outcomes of SMBG. Unfortunately there has been a lack of consistency in study designs and the patient populations.

A recently-published systematic review and meta-analysis of seven RCTs of SMBG in type 2 diabetes showed a pooled reduction of HbA_{1c} of 0.22% (CI 0.34 to 0.11%) in patients who self-monitored compared to those who did not, a reduction similar to that shown in observational studies.[7] One of the difficulties of conducting RCTs in this area has been

Table. Some opportunities for the use of PoCT.

Setting	Application	Potential Benefit
Home	Management of long term conditions e.g. diabetes, heart failure, anticoagulant monitoring Early detection of complications e.g. infection in patients on chemotherapy	Better awareness of condition Motivation to manage condition Avoid need to attend hospital Avoid cost of transport Avoid time off work
Community pharmacy	Management of long term conditions Health checks	Person/patient convenience Better access to relevant population
Retail health clinic	Patient initiated testing e.g. flu test, strep A test, pregnancy test, cholesterol	Patient convenience Greater acceptance by patient Reduce need to visit GP Use when GP centre closed
Paramedical vehicle	Pre-hospital testing e.g. cardiac markers, blood gases Manage inter-hospital transport	Faster triage through ED Earlier intervention Reduce risks of inter-hospital transport
Urgent care centres	Urgent care for non-life-threatening conditions Rule-out testing	Avoid need to attend hospital ED Use when GP centre closed
Emergency room	Testing for rapid triage and treatment	Reduced length of stay in ED
Operating room	Monitoring operative procedures	Reduce post-operative care requirement Convert to day care
Intensive care	Monitoring vital parameters	Improve mortality and morbidity Reduce length of stay

GP,general practitioner; ED,emergency department.

in identifying which factor contributes to the better control since testing itself will have no effect if unaccompanied by education and modification of behaviour. Accordingly the NHS Diabetes Working Group in the UK has published a report including a further Systematic Review separating trials into those which determined the effects of just SMBG and those where the intervention was SMBG plus education and follow-up.[8] In the former, termed 'simple SMBG', the pooled reduction in HbA_{1c} was 0.21 % while in the latter trials, the reduction was 0.52%. These findings have emphasised the importance of therapy adjustment following testing as well as education, points now in the guidelines issued by bodies such as the International Diabetes Federation.[9] The recommendations also draw attention to the substantial cost of glucose strips and the fact that the modest benefits of testing must be weighed against these costs, particularly at a time when there is increasing attention being drawn to the cost-effectiveness of technology and interventions in general. It is now widely acknowledged that SMBG in type 2 diabetes should not be continued if patients are obtaining no benefit or it is damaging their quality of life.[8]

Although SMBG for type 1 diabetes is much less controversial, there is only one RCT of SMBG in these patients.[10] Outpatients on multiple daily insulin injections with HbA_{1c} levels >8.0% were randomised to SMBG or normal care for nine months. Those in the SMBG group achieved a significant reduction in HbA_{1c} of 0.4% compared to a non-significant reduction of 0.2% in the control group. These data are supported by observational studies showing the benefits of SMBG in type 1 diabetes.[7] Accordingly the guidelines of the American Diabetes Association recommend that given this evidence, patients taking insulin either by injection or pump should perform SMBG at least three times per day.[11]

Technology is also available for self-monitoring of oral anticoagulation therapy and the evidence to support this form of PoCT is probably stronger than that for SMBG although it is

a much less common practice than monitoring blood glucose. While the number of patients requiring anticoagulant therapy is increasing, primarily for treatment of atrial fibrillation, most patients are monitored through central laboratory testing or through their general practitioner (GP). However in some countries, the UK in particular, alternative models of care allow patients to monitor their own International Normalised Ratio (INR) and also to adjust their therapy. Several RCTs have been conducted but none has been conclusive on its own to the extent that published guidelines do not support this form of testing.[12]

However, a systematic review of 14 trials of INR self-monitoring has provided evidence to support self-monitoring and demonstrates the importance and value of meta-analysis as an evidence-based medicine tool.[13] Heneghan *et al*. showed from pooled estimates that in the self-monitoring group there were significant reductions of thromboembolic events (odds ratio 0.45, 95% CI 0.30-0.68), all cause mortality (0.61, 0.38-0.98) and major haemorrhage (0.65, 0.42-0.99). Significant reductions were also found in the trials of self-monitoring and self-adjusted therapy except that there was no reduction in major haemorrhage; however the reductions in thromboembolic events and death were greater than those in the group only self-monitoring.[13] While these data support both self-monitoring and self-dosing, it is clear that not all patients on anticoagulant therapy are capable of performing these tasks and those that can manage them require considerable education. Thus it seems likely, at least in Australia, that the major growth of PoCT for INR testing will be through the GP or possibly the pharmacy as discussed in the next section.

PoCT in the Community

So-called community testing usually refers to testing being conducted within pharmacies or by a service led by pharmacists in another community setting such as aged care facilities. Governments in many countries have expressed interest in using the pharmacy to provide better and more cost-effective access to healthcare, particularly for patients with chronic disease. This development recognises that pharmacists are now less involved with the process of supplying medicines and have the time and capability to provide more patient-centred services including PoCT.[14] Thus the fourth pharmacy agreement in Australia includes plans for the development of community-based services for management of diabetes and asthma, including measurement of blood glucose and lung function, and advice on patient results.[15] Similar plans and developments are taking place in the UK, Canada and South Africa.

The evidence to support testing in the pharmacy can be considered under three categories, the first of which is evidence of need. The rise in numbers of patients with chronic disease and the desire of many governments to provide better access to healthcare mean that alternative models of care are required, and the community pharmacy is well placed to provide better and easier access. Second, there is the question of evidence of acceptance – would patients prefer to use their pharmacy for some services currently provided by primary or secondary care? Research in the UK as part of a project on monitoring of diabetes and chronic heart disease indicated that 34% of patients chose their pharmacy to monitor their condition instead of their GP and of the 34%, 97% rated the pharmacy service better or equal to their GP. Obviously a key advantage of the pharmacy is its convenience, both in terms of location and opening hours.

The third category of evidence, perhaps the most important and unfortunately the least developed, concerns the benefits and outcomes of using pharmacies for services including PoCT. While the role of the pharmacy in *managing* chronic disease is often emphasised, several studies have also been conducted of pharmacies playing a role in *screening* for disease. Thus pharmacies in the UK and Switzerland have been operating diabetes screening programs involving blood tests and lifestyle advice. A study in Australia also looked at diabetes screening, comparing a questionnaire type program to one that involved a questionnaire and a blood test if the questionnaire answers indicated at least one risk factor. Clearly the aims of such programs are firstly, early and cost-effective identification of patients with diabetes, and secondly, their referral to a GP. In this particular program the pharmacies that provided a blood test as well as the questionnaire showed a higher rate of diagnosis of diabetes and at a lower cost than the questionnaire program alone.[16] Screening programs for cardiovascular risk, including cholesterol measurements, have also been conducted in the UK and rural Australian pharmacies but in the Australian study, they reported only on feasibility, not health outcomes.[17]

In the case of chronic disease management, the involvement of pharmacies is through what is known as 'Medicines Management' which is essentially a partnership between the patient and the practitioner to deliver the best outcome at the lowest cost. This obviously requires tailoring of therapy, and PoCT for analytes such as lipids and HbA_{1c} is useful for this task. Thus many studies have been conducted in this area for diabetes management[18] and some for lipid therapy only. One of the few RCTs using PoCT in the pharmacy was that of Peterson *et al*. who studied the effects of a pharmacist home visit program that measured cholesterol and provided lifestyle guidance as well as assessment of compliance with therapy. There was a significant fall in the serum cholesterol over the six months studied ($p<0.005$) in the intervention group

whereas there was no change in the control group who received standard medical care (p=0.26).[19] Other observational studies include Till *et al*.[20] who demonstrated how a pharmacist took responsibility for ordering the tests and for advice of treatment changes, and Nola *et al*.[21] who reported on a study with a design of randomised pre-test, post-test control group for screening individuals for hypercholesterolaemia and entering them in a pharmacist-led lipid lowering program. Both studies recorded favourable findings such as reduction in LDL-cholesterol and increased compliance with therapy following the introduction of the intervention which included PoCT.

However, despite the obvious attractiveness and convenience for the patient of checking the effectiveness of their therapy at the same time as the dispensing of lipid-lowering drugs, there remains the need for more research. While there may be difficulties in performing RCTs in the pharmacy environment, observational studies with larger numbers of subjects and for longer durations are required to prove the effectiveness or otherwise of this type of intervention. In addition, there needs to be some evidence that pharmacists are capable of performing PoCT to the requisite quality standards.

PoCT in General Practice

PoCT in general practice is common in many parts of the world including the US and Europe. High quality evidence in the form of RCTs to support that testing has, however, been lacking. Thus Hobbs *et al*. in a systematic review of PoCT in primary care found very few RCTs and few papers that addressed issues such as cost effectiveness or patient outcomes.[4] A more recent systematic review limited to lipids, HbA_{1c}, INR and urinary albumin/creatinine ratio (ACR) determinations identified more RCTs that have been conducted since the review in 1997 by Hobbs *et al*. but none was of sufficiently similar design to allow meta-analysis.[22]

Patients with diabetes mellitus represent a major component of chronic disease management, the majority of which is carried out in primary care by GPs or family physicians. This significant task is going to increase, both because of more people developing diabetes and the trend in many countries away from hospital care to ambulatory or community care. Although there is widespread acceptance of evidence that tight glycaemic control provides long-term benefits for the patient, there is also concern about major variations in care between practices.[23] This and subsequent similar studies have led to recommendations which stress the importance of structured diabetes care that includes regular recall and review of patients.[23]

Measurements of HbA_{1c}, ACR and lipids represent the biochemical cornerstones of such structured care. There is evidence in secondary care that provision of the results of these tests through PoCT at the time of the patient consultation results in a significant fall in the HbA_{1c}, presumably as a result of a more informed consultation with the physician or specialist nurse.[24,25] Similarly, there are now results available from RCTs in primary care of HbA_{1c} measured by PoCT, compared to normal care as provided by measurements from the central laboratory. Miller *et al*. were able to demonstrate improved outcomes when using PoCT for HbA_{1c} in a rural primary care clinic.[26] They showed greater intensification of therapy when the HbA_{1c} was available at the time of the consultation (51% compared to 32% of patients with no HbA_{1c} result available at the time of the clinic visit) and HbA_{1c} fell in the intervention group (8.4% to 8.1%, p=0.04). Clearly it is best if the use of PoCT or, at a minimum, the availability of the result, can be co-ordinated with the consultation process.

The RCT of Khunti *et al*. conducted in UK general practice randomised patients within practices to have their results by PoCT or from the central laboratory.[27] The PoCT results were available at the time of the consultation with the GP and the outcome measure was the proportion of patients achieving good metabolic control i.e. HbA_{1c} <7.0%. At the completion of the trial after 12 months there was no significant difference in the proportion of patients within the therapeutic range (37% vs 38%) but it is important to note that the management of patients within the PoCT group was not different from that in the group who had normal care. It is also possible that the difference between the results of the primary and secondary care trials may be due to the presence of better-controlled patients in the Khunti study compared to the Miller study, all of whom were on insulin.

The RCT of PoCT in Australian general practice was fundamentally different in design to the UK study because randomisation was on the basis of GP practices rather than patients and the trial was of a non-inferiority design.[28,29] Non-inferiority refers to the intervention being tested i.e. PoCT is no worse than normal care or results being obtained from the central laboratory. There was also the implicit understanding in the Australian trial that GPs would change their management based on the PoCT results. At the completion of the Australian trial the proportion of patients with HbA_{1c} results in the target range in the POCT group was 57% compared to 45% in the control group, and accordingly PoCT was judged to be non-inferior to normal laboratory testing.[30]

The Australian GP trial also tested PoCT compared to normal laboratory testing for other analytes including INR (see below), ACR and lipids. The trial showed that PoCT was also non-inferior for ACR, total cholesterol and total triglyceride but not for HDL-cholesterol.[30] Both of these GP trials have looked at the economics of PoCT versus laboratory testing. In

relation to ACR testing, PoCT was less expensive and more clinically effective than central laboratory testing while HbA_{1c} was clinically more effective but more expensive.[31] The UK trial data showed no difference between costs in the PoCT and control groups, but again this may be because there was no change in the management of the PoCT patients.[27]

An important and perhaps understudied aspect of PoCT is the potential patient satisfaction that may result from testing that is more convenient for the patient. This point is important if healthcare providers are going to live up to their promise of providing more patient-centred care. Once again, the UK and Australian GP trials provide contrasting results with Stone *et al*. indicating no significant differences in the satisfaction of UK patients receiving PoCT compared to those who had their HbA_{1c} levels from the central laboratory.[32] In contrast, the Australian trial found that satisfaction generally increased for patients, PoCT device operators and GPs over the course of the trial.[31] Although an observational study, Shephard *et al*. also found a significant increase in patient satisfaction after PoCT, with patients reporting that PoCT was convenient and motivated them to manage their condition better.[33]

The management of hyperlipidaemia is another significant task for the GP, both as part of diabetes management and as an independent condition. The results of PoCT for lipids were discussed above in the context of the Australian GP trial. To date the only other RCT in general practice which has examined the clinical effectiveness of PoCT for lipids is that of Ruffin *et al*. who found that PoCT had a significant impact on clinical decisions, with more coronary heart disease interventions in the PoCT group compared to the control group (68% vs 19% p=0.0001).[34] Observational studies include that of Cohen *et al*. who showed an improvement in within-group differences of total cholesterol levels after the introduction of PoCT.[35] Similarly, Shephard *et al*. showed in two studies of diabetes and hyperlipidaemia that PoCT patients achieved significant reductions in total cholesterol after the introduction of PoCT.[36,37]

Large numbers of people are now taking anticoagulants for a number of different conditions, the most common of which is non-valvular atrial fibrillation, contributing to a global annual growth of PoCT for INR of approximately 8%.[38] The management of anticoagulation status is primarily based on the measurement of prothrombin time (PT) or INR as a surrogate marker of immediate coagulation status. The difficulties of standardisation of this type of measurement are well known and various studies including an RCT have been published which address quality issues such as the degree of agreement between INR results by PoCT and those from the central laboratory.[39] Murray *et al*. discuss some of these quality issues in relation to providing a safe INR service outside of the laboratory.[40]

Compared to self-monitoring, there is a less extensive literature including a small number of RCTs on the use and clinical effectiveness of PoCT for INR in primary care.[22] The RCT of Shiach *et al*. analysed between-group differences and showed no significant improvement in the PoCT group compared to the control group in terms of time spent in the INR target range (p=0.2).[39] However Claes *et al*.[41] and Fitzmaurice *et al*.[42] measured both between- and within-group differences and found a significant improvement in the PoCT group at the end-of-study (within-group analysis) but no significant differences were found between the intervention and control groups.

Observational studies which have demonstrated clinical benefits from INR performed at point-of-care include Wurster *et al*. who found a significant improvement in the percentage of visits in which a patient's INR result was in the target range after PoCT was implemented.[43] In the more recent RCT of PoCT in Australian general practice described previously, there was no significant difference between the PoCT and control groups in terms of the number of patients with results in the target range for INR (57% PoCT vs 61.5% control, p=0.24).[30]

The Australian GP trial also included an examination of the relative costs of performing INR at point-of-care compared to the central laboratory. These costs were analysed in a similar comprehensive manner to those of the other analytes previously described. Thus in terms of the incremental cost effectiveness, INR by PoCT was both less clinically effective and more expensive in comparison to central laboratory testing. An examination of the cost effectiveness of INR testing has also been conducted as part of two other RCTs, both from a health care provider perspective. While Claes *et al.* found that PoCT provided net savings for the health care provider,[44] the findings of Parry *et al*. were similar to the Australian GP trial, with PoCT costs greater than usual care.[45] Lower costs of INR by PoCT from a patient perspective were reported in one observational study[46] while two other studies showed lower practice costs through a reduction in patient visits.[43,47]

Not surprisingly, studies of patient satisfaction with PoCT INR testing show that most patients like this type of testing. The increased patient and GP satisfaction scores from the Australian GP trial have been mentioned above. The study of Chaudry *et al*. is one of the few that has included statistical analysis of the satisfaction data and they found significantly more patients preferred the PoCT INR service compared to usual care.[48] In addition they documented that patients had improved capacity to make appointments, spent less time at the appointment, experienced less pain and received improved communication about their medication dosage.

PoCT in Critical Care Areas Including ED

ED or Casualty is an area of healthcare that probably receives more media attention than any other. Those working there are faced with considerable challenges, not the least of which is processing patients rapidly and effectively so that waiting times for patients do not exceed publicised targets. Because laboratory testing is integral to the assessment and treatment of patients presenting to ED, there was considerable hope that PoCT would reduce overall turnaround times but the evidence to support its use is mixed.

In the early days of PoCT adoption, two studies were performed which are still much cited today as they have provided important lessons in how to implement PoCT. The studies performed in EDs in the US and UK by Parvin *et al*. and Kendall *et al*. respectively were designed to test whether the rapid provision of a small group of routine tests by PoCT would reduce the time that patients stayed in the ED.[49,50] While in the case of the RCT performed by Kendall, clinical decisions were reached in a shorter time when results were provided by PoCT, neither study showed significant reductions in the time that patients spent in the ED. Subsequent studies including randomised trials have not produced substantially different conclusions with the possible exception being the trial of Murray *et al*. which showed that the mean time for patients in the ED receiving PoCT was 208 min compared to 262 min for patients receiving results from the central laboratory.[51] The lessons learnt from these studies are that many factors impact on the transit time through an ED and while laboratory tests are important, the provision of a limited menu is unlikely to reduce the time because of the need to wait for other key tests from the central laboratory.

Given the need for a larger test menu in order to influence operational outcomes such as waiting times, an alternative PoCT model is to establish a satellite laboratory within the ED as described by Lewandroski *et al*.[52] While this does have the required operational impact, it is very expensive in terms of staffing and only suitable for very large EDs. As a consequence of these findings most laboratories have moved to providing PoCT for tests which impact on specific clinical decisions. The most obvious example is that of cardiac markers such as troponin and BNP. Here also the situation is complicated by the difficulty of aligning PoCT results with those provided by the central laboratory, a difficulty likely to be exacerbated by the move towards newer generations of high sensitivity troponin assays and the redefinition of myocardial infarction.

While there are several studies comparing PoCT and central laboratory troponin, the focus has been on the clinical diagnostic utility rather than the operational impact in ED or other critical care areas. Observational studies have demonstrated that PoCT can reduce admissions to Coronary Care Units (CCUs)[53] or reduce the length of hospital stay.[54] The RCT of Collinson *et al*. was performed on patients being admitted to a CCU using a structured decision-making protocol that included PoCT.[55] The outcomes were reduced length of stay in the CCU facilitated by PoCT allowing more rapid transfer to a step-down facility with consequent reductions in costs per episode. Another RCT found that PoCT for troponin in the ED did not affect any outcome measures but it did reduce the time to initiation of therapy for ischaemia.[56] A more recent study in the UK has been performed at multiple EDs that used a panel of PoCT cardiac markers to initiate a rapid diagnostic protocol on admission. The results show that the PoCT patients had a significantly shorter length of stay and the same overall outcomes as the control patients.[57]

The diagnosis of heart failure using BNP measurement is another area that might benefit from PoCT but at time of writing no trials in EDs or other critical care areas have been performed to compare the two types of testing.

While the value of D-dimer measurements in the diagnosis of venous thromboembolism is well established, nearly all these studies have used central laboratory measurements. However the study of Lewandroski *et al*. compared D-dimer testing performed in an ED satellite laboratory to central laboratory measurement. The before- and after-study design showed a significantly reduced test turnaround time using PoCT with a consequent reduction in patient stay from 8.46 to 7.14 h ($p=0.016$). There was also a reduction in hospital admissions.[58]

Conclusions

Laboratory medicine lacks a robust evidence base for many different reasons – some legitimate, some less so. It is obviously important that we avoid the mistakes of the past and, despite the challenges, adopt an evidence-based approach to new technologies such as PoCT. In the last decade that challenge has been met and a number of important ground-breaking studies have been performed. Not all of these have necessarily supported PoCT, such as those in ED, but despite that, the results have informed practice for the future. Some key lessons that have been learnt include the fact that adoption of the technology is not sufficient to achieve improved outcomes; it is also necessary to consider whether the process of delivering care needs to change in order to reap the benefits of quicker results and faster decision-making.

This lesson is not unique to laboratory medicine. A recent review of healthcare commented that there is no shortage of innovative technology in healthcare. What is lacking is innovation in terms of the organisation and application of the technology.[59] Until now the patient, or perhaps more

correctly the consumer, has been a rather meek acceptor of services often delivered in a way and at a time that is far from convenient or even considerate of their needs. That state of affairs is rapidly becoming unacceptable and the patient-centric agenda will demand that many healthcare providers change their mode of operation. Laboratory medicine will have to be in the vanguard of that change given the key role that laboratory data play in many clinical decisions; and that raises the possibility of whether more testing will have to move closer to the healthcare consumer of the future.

Dr Andrew St John is a member of the AACB PoCT Working Party Committee.

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