Point of care testing in family practice: common myths debunked

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Point of care tests (POCTs, also known as 'near patient' or 'bedside' tests) can save patients and healthcare practitioners the trouble and wait of sending samples to the lab. They may also help optimise prescribing decisions (by helping doctors make 'on the spot' diagnoses and decisions), reducing referrals (to more expensive specialists) and in decreasing costs (because of reduced referrals).[1-9]

Because of these many potential benefits, it is not surprising that an international survey suggested that doctors would like to use POCTs more than they currently do. [10] A wide range and growing number of POCTs are now available to general practitioners (GPs, 'family doctors' in the United States), [11,12] and industry is developing even more. [13] Embracing these potential benefits, the National Health Service (NHS) in England is even supporting development of a 'Lab in a bag': a mobile diagnostics service.[14]

In parallel with these developments, concerns about the evidence-base for the patient benefits of POCTs have been noted, already over 15 years ago, [15] because simplicity and convenience do not necessarily imply patient benefits. [16] As with any other health care interventions, we require sufficient evidence that a new POCT will actually improve patient outcomes or increase health care efficiency. [17] So far, the documented effectiveness of POCT remains problematic, with few high quality studies focusing on patient outcomes and most studies at best investigating analytical and clinical accuracy, but not clinical outcomes. [18-21]

Hence while the promises of POCTs hold intuitive appeal, beliefs about the potential benefits and harms of POCTs are too often based on a number of assumptions that we will discuss in this commentary. Some of these assumptions may lead to overestimating the benefits of POCTs, while others can lead to underestimating them. Providing evidence for the beneficial consequences of POCTs is especially important against the background of increased public awareness of overdiagnosis, [22] and the harms of introducing tests without proper evaluation. [23-25]

Physicians' desire to use tests

An international survey revealed that general practitioners in many countries would like to use more POCTs to help diagnose and manage a range of clinical conditions, ranging from urgent referrals and immediate treatment decisions, such as the decision to treat with antibiotics. [10] The desire to reduce uncertainty and diagnostic error through additional testing is understandable. However, unintended consequences of increased POCT use can cause failure to produce patient benefits or lack of cost-effectiveness. Other factors also need to be considered to evaluate whether a POCT will benefit patients. These include: usability (is the test sufficiently dummy proof to be used in busy clinical practice by non-laboratory workers?), and quality control (can feasible long-term quality control be assured including running control tests?).

In some cases, the POCT might not influence clinician decision making at all. [26] For example troponin tests are highly desired by family physicians, [10] yet have been shown to

save costs at the expense of missed diagnoses. [27] POCT use cannot just be recommended based on availability and clinician desire.

Analytic accuracy

Professionals in the laboratory medicine community have expressed concerns about the lower analytical and clinical accuracy of POCT. Yet empirical comparisons have shown that POCT accuracy is not always inferior. Some POCTs perform equally well or better, [28-32] while others perform worse than comparable laboratory tests. [33-35]

More importantly, poorer measurement accuracy may have limited or no consequences if the errors in the POC apply mainly to results far above – or below – the action threshold. If the actual test result is uncertain, but we are certain *enough* that the result is positive, that suffices to guide decisions. Since clinical actions affect patient outcomes, and testing influences outcomes insofar it guides these actions, test positivity is what only matters. In that case, the uncertainty about the actual test result will have no substantial effect on outcomes. A similar argument can be made for uncertain but clearly negative POCT results.

Sometimes a POCT can improve patient outcomes even if its accuracy is lower. For example if the alternative is no test at all (because of expense/delay of the laboratory test), then even an imperfect POCT can improve upon clinical judgment alone.

Diagnostic accuracy and clinical effectiveness

Even if a POCT is as accurate as a laboratory test, it does not mean it will improve patient outcomes. For example, POC D-dimer tests in combination with clinical decision rule have been shown to have good diagnostic accuracy for excluding pulmonary embolism and deep venous thrombosis. However these required further development and clinical evaluation of their implementation in daily practice. [36-38] It is possible that more patients are being tested with POCT than before, with lab-based D-dimer tests, and this may increase the number of false positives, exposing more people to the harms of CT-associated radiation.
Yet sometimes demonstrating that a POCT has a specified level of sensitivity and specificity may be sufficient to demonstrate its clinical value. Diagnostic accuracy could be sufficient to demonstrate clinical performance if one test is intended to simply replace another one within the same care pathway. For example POC D-dimer tests have been evaluated both against lab-based D-dimer testing and against the clinical 'gold' standard (typically imaging). There is no need for a perfect correlation between POCT results and lab-based results; with sufficiently high concordance between positive and negative classifications, the management consequences and, hence, patient outcomes, will be comparable.

So called management studies monitor the outcomes of a specific diagnostic strategy, that is used systematically in all suspected patients. Demonstrating acceptable safety is additional evidence that the strategy is feasible and effective. If there are doubts about whether introducing a new POCT has unintended negative consequences, randomized trials comparing the new POCT (within a new pathway) with an existing care pathway may be

required. [19,39,40] Additionally, the use of POCT and the outcomes could be carefully monitored after its introduction.

Healthcare costs

Sometimes POCTs are cheaper than comparable laboratory tests. That does not necessarily mean that POCTs reduce overall healthcare costs. Other factors clearly the cost-effectiveness of POCT-based testing strategies such as: the total number of patients tested, the costs of further testing, and other clinical management actions influenced by the POCT results. Many attempts to evaluate cost-effectiveness of POCTs in model-based analyses are naively extremely simplistic; they just replace one test with another in an identical care pathway, ignoring these further factors. [41] Precisely because of the ease of use, introducing a POCT typically lowers the threshold for testing, with serious implications for its cost-effectiveness because additional tests are done that would not have been done if a sample had to be sent to a laboratory. Hence, replacing one test with another (POC) test in modeling studies ignores the possibility that tests will be performed more liberally, with implications for costs as well as for pre-analytical errors. Actual evidence about cost-effectiveness of POC testing is mixed. An Australian trial, for example, indicated that POC testing resulted in a reduction in costs for some tests (albumin to creatinine ratio) but increased costs for others (international normalized ratio). [42] In a Dutch cost-effectiveness study on CRP for respiratory infections several models were presented and proven to be cost-effective. [43]

Barriers to dissemination

Even if clinical trials indicate that care pathways involving POCTs benefit patients and are cost-effective, the POCT remains to be successfully implemented. For example, reliable POCT tests for C-reactive protein have been available for decades and evidence of their effectiveness in acute cough is accumulating, [6,44] and their use in now suggested in the NICE guideline on pneumonia. [45] Nevertheless, widespread implementation in the UK is still limited, [46] and clinicians expressing concern about overuse of tests. [47] Practitioners and patients may have reservations about POCT use which affects uptake, [48,49], and practitioner/patient views need to be taken into account when designing a plan to make POCTs more widely used. A recent survey of GPs across five developed nations found consistently that between 41% and 83% of clinicians expressed a desire for POCTs to help them diagnose pulmonary embolism or deep vein thrombosis. [10] Likewise, a recent systematic review of practitioner attitudes towards POCTs revealed that while primary care clinicians believed POCTs helped target treatment, manage chronic conditions, and could improve communication, they also had concerns about POCT test accuracy, over-reliance on tests (and undermining of clinical skills), and cost. [50] Patient views are also important. Some POCTs - such as HIV tests - lead to sensitive issues practitioners will have to discuss with patients, and the possibility that patients might not like the test [51]. In such cases gaining patient perspectives could also be

essential for identifying barriers for implementation or conditions for a careful introduction of POCT.

POCTs need evidence-based evaluation

Most POCTs are easy to use, they seem to provide quick answers, and they can be cheaper than laboratory tests. Yet whether they improve practice or reduce costs requires an evidence-based approach. Establishing the benefits of POCTs demands rigorous evidence comparing the analytical performance, diagnostic accuracy, patient benefits, and costs of care pathways involving point of care tests against traditional care pathways, involving standard laboratory tests, or no testing. Such rigorous evidence is to be preferred over assumptions about the value of POCTs.

Ethical approval

Not applicable

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Competing interests

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