PrescQIPP Community Interest Company

Point of Care Testing

This bulletin reviews point of care testing (POCT), its place in therapy, advantages, limitations and considerations for commissioning.

Details or recommendations on any individual test are beyond the scope of the bulletin and are not included.

Recommendations

- Establish whether there is a clinical need for POCT to provide rapid 'on site' results.[1]
- Consider the clinical governance issues and clinical and cost-effectiveness in using POCT as an alternative to laboratory testing.[1,2]
- Consider the benefit to patients of introducing POCT.[2]
- The 5 year forward plan of reducing antimicrobial resistance, states to maximise the use of NICE guidance, including the MIBs, to assess new diagnostic tests and offer prescribers advice on their use.[3]
- Consider involving the local hospital laboratory in the management of POCT services.[2]
- Ensure that arrangements are in place for training, management, quality assurance (QA), quality control (QC), health and safety policy and the use of standard operating procedures (SOPs). SOPs must be reviewed at frequent specified intervals.[2]

POCT is defined by the Medical Devices Agency in its document 'Management and Use of In Vitro Diagnostic Point of Care Test Devices', as 'any analytical test performed for a patient by a healthcare professional outside the conventional laboratory setting'. Other terms commonly used to describe POCT include; near patient testing, bedside testing, extra-laboratory testing or disseminated/decentralised laboratory testing. With POCT, laboratory tests can be performed at the point of care e.g. wards, operating theatres, general practice, community hospitals, minor injury units.[2]

Diagnostic testing informs decisions about treatment, speciality referral and hospital admission. Over the past few decades, diagnostic technologies have become cheaper, smaller, more portable and in some cases more accurate.[1] There are now an increased number of POCTs which provide rapid on-site results. POCT may have potential to improve outcomes in primary care by optimising prescribing decisions (through better diagnostic certainty), reducing referrals, improving efficiency of care, communication, shared decision making with the patient and by offering potential savings.[1] As a result, the demand for accurate, simple to use POCT equipment within primary care settings is becoming increasingly important.[4]

A survey of 2,770 primary care clinicians across five countries showed that respondents in all countries wanted Point Of Care (POC) tests to help them diagnose acute conditions (infections, acute cardiac disease, pulmonary embolism/deep vein thrombosis), and some chronic conditions (diabetes, anaemia). Based on the list of POC tests provided, the most common tests currently used were: urine pregnancy, urine leucocytes or nitrite and blood glucose (appendix 1). The most commonly reported tests respondents expressed a wish to use in the future were: D-dimer, troponin and chlamydia. The

UK and the USA reported a higher actual and desired use for POC tests than Australia, Belgium and the Netherlands.[1] Another survey also reviewed conditions which would be most helpful to UK GPs for diagnosis, reduction of referrals, and monitoring of chronic conditions. A total of 1109 (68%) GPs responded to the survey. The most frequently cited conditions were urinary tract infections for diagnosis (47% of respondents), pulmonary embolism/deep vein thrombosis for referral reduction (47%) and international normalised ratio (INR)/anticoagulation for monitoring (49%).[5]

An obstacle in assessing priorities is that clinicians may currently be unaware of some newly available technologies, and are unlikely to know what could feasibly be developed in the (near) future. Likewise, industry may not be familiar with the tests or research avenues that are likely to benefit general practice. In spite of the many benefits of understanding which POC tests clinicians find useful, there has been little effort to assess primary care clinician needs (or perceived needs) for POC tests.[1]

The UK's five-year national action plan, 'Tackling antimicrobial resistance 2019-2024', states that the UK does not make the best use of available diagnostic tests. The UK regulatory requirements for diagnostics make it difficult to assess the value of any new diagnostic test in the context of the overall AMR agenda. The plan also states that the NHS is not equipped to get new diagnostics into front-line use quickly. Uncertainty about requirements for research evidence, lack of engagement to understand frontline needs, and 'silo budgeting' all serve to delay the uptake of new diagnostic technologies. Clearer guidelines and new methods for demonstrating the value of AMR diagnostics (including case studies, pilot studies and cost-effectiveness models) could help change the behaviour of health commissioners and practitioners and increase the uptake of diagnostics.[3]

The plan also states, to support the rapid uptake of diagnostics, the UK will:[3]

- Ensure that antimicrobials and diagnostics are a priority area.
- Use modelling and test-pilot data to develop alternative funding models for faster diagnostics that support targeted treatment. This includes commissioning work to develop a method for assessing the value of new technologies that considers not only cost-effectiveness but the value proposition at a system level.
- Maximise use of NICE guidance, including the medical technology innovation briefs, to assess new diagnostic tests and offer prescribers advice on their use.
- Streamline the regulation process to help get new diagnostics through as quickly as possible, including developing evidence-based guidance for using tests.[3]

Barriers to implementing the plan include concerns about accuracy, over-reliance on tests and limited usefulness. Concern about the evidence base for the effectiveness of POC tests was noted over 20 years ago and remains a problem, with few high-quality studies focusing on patient outcomes rather than test accuracy.[1] As a result, management of a POCT service should take account of several important areas, including clinical governance and public health considerations. Poor use of POCT, leading to the production of wrong results, can lead to patient harm and may have medicolegal implications. Under the terms of the Consumer Protection Act (1987) the use of instruments for purposes for which they are not intended will lead to liability transfer from the manufacturer to the user.[2]

Table 1 on the next page lists examples of POC tests currently available.

Table 1: Examples of POC tests

Analysers[2]	Examples (not exhaustive)
Analysers and kits for HbA1c	A1cNow+, Afinion, DCA Vantage, Quo-Lab, Quo-Test - see NHS Purchasing and Supply Agency Buyers' guide for Point of care devices for the measurement of HbA1c at: https://www.healthcheck.nhs.uk/commissioners-and-providers/delivery/point-of-care-testing/
Bilirubinometers	NEO-BIL Plus
Blood gas analysers	ABL90 FLEX PLUS
Blood glucose meters	There are many available, see separate PrescQIPP comparison of blood glucose testing meters and strips - https://www.prescqipp.info/our-resources/bulletins/bulletin-212-diabetes-testing-strips/
Cardiac testing: BNP, troponin, D dimer	Cobas H 232 System Kit
Cholesterol tests	Accutrend Plus, Cardiochek PA, Cholestech LDX, BeneCheck PLUS - see NHS Purchasing and Supply Agency Buyers' guide to POCT for cholesterol measurement at: https://www.healthcheck.nhs.uk/commissioners-and-providers/delivery/point-of-care-testing/
Coagulometers	CoaguChek DG14 - https://www.nice.org.uk/guidance/dg14
Electrolyte analysers	Sensa-core, Hycel
MRSA screening tests	Xpert MRSA
Pregnancy tests	Various
Rapid test kits for infectious disease markers	Nycocard CRP, Alere Afinion CRP, FebriDx CRP, AQT90 Flex, iChromaCRP, AFIAS CRP, QuikRead go CRP, CRP+Hb, Eurolyser CRP MIB114 - https://www.nice.org.uk/advice/mib114
Urinalysis test strips*	Glycosuria – Diastix, Medi-Test Glucose Ketonuria – Ketostix, GlucoRx KetoRx Sticks 2GK Proteinuria – Albustix, Medi Test Protein 2 Drug Tariff Part IXR-Chemical Reagents - http://www.drugtariff.nhsbsa.nhs.uk/#/00787224-DD/DD00786710/Part%20IXR%20-%20Chemical%20Reagents%20

*The PrescQIPP bulletin on diabetes testing strips advises that testing of glucose present in the urine is not routinely recommended as it is less accurate than blood glucose testing. This method is unsuitable for detecting hypoglycaemia because glucose is only present in the urine when the blood glucose level is relatively high (>10mmol/litre).

Evidence

The evidence base for the effectiveness of diagnostic services is well known to be limited. There is also very limited literature on cost effectiveness. One reason suggested for this is that the reimbursement strategies employed in laboratory medicine for many years are based on the complexity of the test procedure, and the delivery as a cost-per-test service.[6] This also makes it difficult to compare laboratory testing with POCT. A BMJ cost minimisation analysis aimed to determine if POCT is less costly than laboratory testing to the National Health Service (NHS) in delivering the NHS Health Check (NHSHC) programme in the primary care setting. The study only looked at the cost-saving in the use of POCT up to the point of cardiovascular disease risk score presentation and did not include full health economic modelling to determine cost effectiveness. In nine practices, the total expected cost of using POCT to deliver a routine NHSHC was lower than the laboratory-led pathway with savings of £29 per 100 invited patients up to the point of cardiovascular disease risk score presentation. The study found

that using POCT minimised did not attend (DNA) rates associated with laboratory testing and enabled NHSHC completion in one sitting.[7]

Another study undertaken in genitourinary medicine clinics in the UK showed similar reductions in cost with POCT. Pathways using a POC nucleic acid amplification test (NAAT) for asymptomatic and symptomatic patients and chlamydia or gonorrhoea tests were shorter and less expensive than most of the current pathways. It was estimated that POCT as part of a sexual health screen for symptomatic patients, or as stand-alone chlamydia or gonorrhoea testing, could reduce costs per patient by as much as £16 or £6, respectively. In both cases, healthcare professionals' time would be reduced by approximately ten minutes per patient.[8]

Further specific guidance is provided by the MHRA on blood glucose meters and in vitro diagnostic medical devices.[9,10]

Advantages of POCT

- Improved turnaround time; rapid access to patients' results and facilitates timely clinical decision making.[2,11]
- Potential for better monitoring of certain conditions where frequent testing is desirable.[2]
- Smaller sample and reagent volumes - POCT methods may be less clinically invasive.[2]
- Advantageous in remote areas where access to a laboratory is limited.[2]
- Removes transportation delays.[11]
- POCT may offer an easier-to-access service e.g. for the elderly.[2]
- Economic considerations: although POCT is generally more expensive than laboratory testing, it may offer wider economic benefits with a reduced number of clinic visits, reduced length of stay in hospital and fewer hospital admissions.[2]
- Greater patient involvement in their own care.[2]
- Improved patient experience.[2]
- Availability outside normal laboratory core hours.[2]
- Costs are reducing as competition in the market expands.[11]
- Existing markets such as the USA and Australia are driving demand with new emerging markets in Asia and China.[11]

Limitations of POCT in primary care

- Poor quality of analysis.[2]
- Poor record keeping.[2]
- Need for training in result interpretation.[2]
- Unnecessary duplication of equipment.[2]
- Failure to detect erroneous results.[2]
- The availability of an array of tests may tempt users to perform unnecessary or inappropriate testing.[2]
- Data recording may be complex and less robust - less recording of results in patient records.[2]
- Incompatibility with laboratory results – reference ranges and results may differ from those used by the established laboratory service making comparisons difficult.[2]
- Without the economies of scale that come from centralised laboratory testing, POCT can be expensive.[2]
- Fragmented service delivered around POCT.[11]
- Insufficient staff training in device usage.[11]
- Little or no external accreditation within Quality Assurance & Governance.[11]

Table 2 lists NICE appraisals of the devices which can guide decision making.

Table 2: Table of devices and comparison of costs of POC tests used in primary care as listed in NICE Medtech innovation and diagnostic briefings (MIBs/DG). (See NICE guidance for cost effectiveness. Liaise with laboratories locally to compare costs.)

Therapeutic area	Test	Instrument(s)	NICE guidance	Intended place in therapy	Fulfilling antimicrobial stewardship programmes	Sample type	Direct cost of instrument excluding VAT	Direct cost of test excluding VAT
Asthma	Fractional exhaled Nitrous oxide (FeNo)	• NIOX VERO	NG80	FeNo testing recommended for performing objective tests for asthma	N/A	Exhaled breath	£1795 for NObreath	£3
		• NObreath	DG12				£2640 for NIOX VERO	£4.58 - £5.03
Lower respiratory tract infections	CRP testing	• QuikRead go CRP	MIB78	NICE CG191 recommends to consider CRP testing for people presenting with lower RTIs in primary care if after a clinical assessment a diagnosis of pneumonia has not been made and it is not clear whether antibiotics should be prescribed. FebriDx detects raised levels of C-reactive protein (CRP) and Myxovirus resistance protein A (MxA), a marker for viral infection in peripheral whole blood. Note: The FebriDx 'high' CRP reading suggests CRP levels of 65mg/l or more, which is lower than the 100mg/l level recommended in NICE CG191.	Yes	20 microlitre blood sample	£1050	£4.30 CRP test kits cost £215 for 50 single use tests
		• Alere Afinion CRP	MIB81			1.5 microlitre blood sample	£1200	£3.50
		• FebriDx CRP	MIB114			2 x 5 microlitre blood samples	Analyser not needed	£11.25 - £12.75

Therapeutic area	Test	Instrument(s)	NICE guidance	Intended place in therapy	Fulfilling antimicrobial stewardship programmes	Sample type	Direct cost of instrument excluding VAT	Direct cost of test excluding VAT
Group A streptococcus (strep A) throat infection in people >5yrs old	Rapid antigen detection test	• Clearview exact strep A cassette/ dipstick • BD Veritor plus system group A strep • Strep A rapid test • NADAL strep A / plus/scan test • OSOM strep A test kit • QuikRead Go Strep A test kit • Alere Test Pack Plus Strep A • Bionexia Strep A plus/ dipstick • Biosynex Strep A • Sofia Strep A FIA	DG38	Designed to give a more accurate confirmation of the presence of bacterial infection than clinical evaluation, including clinical scoring systems for acute sore throats (NG84). This is aimed at improving antibiotic prescribing in line with local guidelines, which may help to reduce antimicrobial resistance. The quick 'time to result' of the tests compared with laboratory testing aims to help treatment decisions to be made during a single GP or community pharmacy visit, without the need to wait for laboratory tests results.	Yes	A throat swab	Apportioned cost for the instrument is included in the cost per test	£0.64 - £35 Molecular assay costs are higher.
	Molecular assay	• Alere i Strep A /2 • Cobas Strep A assay						

Therapeutic area	Test	Instrument(s)	NICE guidance	Intended place in therapy	Fulfilling antimicrobial stewardship programmes	Sample type	Direct cost of instrument excluding VAT	Direct cost of test excluding VAT
Atrial Fibrillation	ECG	• AliveCor Heart Monitor / Kardia Mobile and AliveECG app (The AliveCor Heart Monitor was rebranded as Kardia Mobile in October 2016. AliveCor Heart Monitor and Kardia Mobile are functionally identical.)	MIB35 DG35	The NICE diagnostic guidance on lead-I ECG devices for detecting symptomatic atrial fibrillation using single time point testing in primary care recommended that there was not enough evidence to recommend the routine adoption of lead-I ECG devices (imPulse, Kardia Mobile, MyDiagnostick and Zenicor-ECG) to detect atrial fibrillation when used for single time point testing in primary care for people with signs or symptoms of the condition and an irregular pulse. Further research is recommended to show how using lead-I ECG devices in this way affects: • the number of people with atrial fibrillation detected, compared with current practice of the guidance and • primary and secondary care services, particularly how ECGs generated by the devices would be interpreted in practice, including staff time needed to interpret the ECG traces and associated costs (see section 6.2 of DG35). Centres currently using these devices for this indication are encouraged to take part in research and data collection.	N/A	Pocket-sized ECG recorder and a mobile device application for analysis and communication of the results. Two fingers from each hand are placed on the AliveCor Heart Monitor to record an ECG, which is transmitted wirelessly to the AliveECG app.	£62.49	N/A

Therapeutic area	Test	Instrument(s)	NICE guidance	Intended place in therapy	Fulfilling antimicrobial stewardship programmes	Sample type	Direct cost of instrument excluding VAT	Direct cost of test excluding VAT
Coagulation status in atrial fibrillation or heart valve disease	INR	• CoaguChek XS system	DG14	For self monitoring coagulation status in adults and children on long term vitamin K antagonist (warfarin) therapy who have atrial fibrillation or heart valve disease if: • the person prefers this form of testing and • the person or their carer is both physically and cognitively able to self monitor effectively.	N/A	Blood sample	£299	£2.85/test (approx. 35 tests needed per year)
Acute kidney disease	Creatinine	• ABL800 FLEX • StatSensor • i-STAT Alinity	DG37	Alternative to current laboratory based creatinine testing in people needing contrast-enhanced imaging.	N/A	Very small samples of whole blood, serum, plasma or a combination of these.		Incremental cost of POC testing is around £9 per test compared to current practice. DG37 Resource impact statement
		• ABL90 FLEX PLUS • Epoc Blood Analysis System • Piccolo Express • Dri-chem NX500		These 4 devices are not recommended for use as there are insufficient data to assess their diagnostic accuracy.				

Therapeutic area	Test	Instrument(s)	NICE guidance	Intended place in therapy	Fulfilling antimicrobial stewardship programmes	Sample type	Direct cost of instrument excluding VAT	Direct cost of test excluding VAT
Inflammatory bowel disease (IBD)	Faecal calprotectin (FC)	• IBDoc (home use) • Calprosmart Home (home use) • Quantum Blue (point of care)	DG11	For diagnosis use FC tests in conjunction with clinical symptoms, monitoring and blood tests (CRP and erythrocyte sedimentation rate [ESR]) to distinguish between IBD and non-IBD.	N/A	Faecal sample	N/A	£23.25 - £85.85
		• Calprosmart Office (point of care) • Calfast (point of care)	MIB132	For monitoring use alongside clinical observations and patient-reported symptom severity in people having drug treatments for IBD, such as anti-TNF therapies.				
Adenoviral conjunctivitis	Adenovirus	• AdenoPlus	MIB46	POC test used as an alternative to existing laboratory tests that are currently carried out for managing persistent or high risk infectious conjunctivitis.	Yes	Tear fluid	N/A	£1.50 A box of 10 single use tests costs £150
Hepatitis C virus	Hepatitis C virus antibodies	• OraQuick HCV	MIB24	The OraQuick HCV is a POC test intended for use in people aged 11 years or older who show signs and symptoms that may be due to HCV infection, or who have risk factors for HCV infection.	Yes	Oral fluid, whole blood, plasma or serum.	N/A	£12 - £15 per test

Considerations for commissioning

MHRA guidance recommends that good practice is the establishment of a multidisciplinary POCT committee to oversee POCT. All stakeholders should be represented in a POCT committee e.g. laboratory staff, clinicians, nursing staff, specialist nurses, pharmacists, IT and finance.[2]

The following checklist is recommended before implementation of POCT:

- Establish a clinical need.
- Consider the available evidence for the performance of the test.
- Consider the benefit to patients of introducing POCT.
- Consider involving the local hospital laboratory in the management of POCT services. Liaise with laboratories locally to check costs before decommissioning or implementing new services. There may need to be an incentive or service level agreement for the lab to be involved.
- Laboratory staff can provide advice on a range of issues including the purchase of devices, training, interpretation of results, troubleshooting, quality control, quality assessment and health and safety.
- Ensure that comparable analytical results are consistently generated regardless of location.
- Lines of accountability for POCT management must be clear. These should be clearly written into local policies and procedures and should cover the following areas:
  - Training
  - Instructions for use
  - Standard operating procedures
  - Health and safety
  - Quality assurance
  - Maintenance
  - Accreditation
  - Record keeping
  - Audit
  - Adverse incident reporting.
- Arrangements for training, management, quality assurance (QA) and quality control (QC), health and safety policy and the use of standard operating procedures (SOPs) must be made and reviewed at frequent, specified intervals.
- Consider the clinical governance issues in using POCT as an alternative to laboratory testing.
- Managers of POCT services must be aware of their responsibilities under clinical governance, including:
  - Consultation and patient involvement
  - Clinical risk management
  - Clinical audit
  - Research and effectiveness
  - Staffing and staff management
  - Education, training and continuing personal and professional development
  - Use of information to support clinical governance and healthcare delivery.
- Assessment of the service by an external accreditation body is recommended.
- Adverse incidents must be reported to the MHRA.
- Clear, comprehensive record keeping and documentation is vital.
- Everyone involved in POCT should know what to do in the event of any abnormal result or unsatisfactory QC result.[2]

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The use and application of this guidance does not override the individual responsibility of health and social care professionals to make decisions appropriate to local need and the circumstances of individual patients (in consultation with the patient and/or guardian or carer). Terms and conditions

Appendix 1.

Point-of-care tests that at least 25% of respondents in at least one country reported currently using, ranked in descending order according to total percentage of general practitioners that reported using the tests.

	Australia (n=298)	Belgium (n=319)	The Netherlands (n=639)	UK (n=1109)	USA (n=405)	Total (n=2770)
Urine pregnancy test	68% (203)	61% (193)	94% (603)	80% (887)	86% (350)	81% (2236)
Urine leucocytes or nitrite	NA	87% (275)	96% (611)	90% (993)	88% (355)	81% (2234)
Blood glucose	74% (221)	87% (278)	96% (616)	69% (760)	82% (334)	80% (2209)
INR	48% (144)	12% (37)	1% (6)	43% (476)	47% (189)	31% (852)
Haemoglobin	10% (29)	3% (8)	58% (371)	16% (174)	50% (202)	28% (784)
Faecal occult blood	6% (19)	18% (56)	2% (14)	13% (143)	83% (335)	20% (567)
Throat swab for group A streptococci	6% (19)	4% (12)	1% (4)	15% (164)	86% (348)	20% (547)
C reactive protein	3% (8)	3% (10)	48% (305)	15% (163)	10% (42)	19% (528)
Quantitative β-human chorionic gonadotropin	6% (18)	19% (59)	22% (138)	17% (193)	28% (112)	19% (520)
HbA1c	6% (17)	2% (6)	6% (38)	17% (183)	40% (162)	15% (406)
Nose/throat swab for influenza	7% (20)	1% (3)	0% (2)	6% (61)	60% (242)	12% (328)
Platelet count	4% (11)	0% (1)	1% (3)	15% (163)	28% (112)	10% (290)