



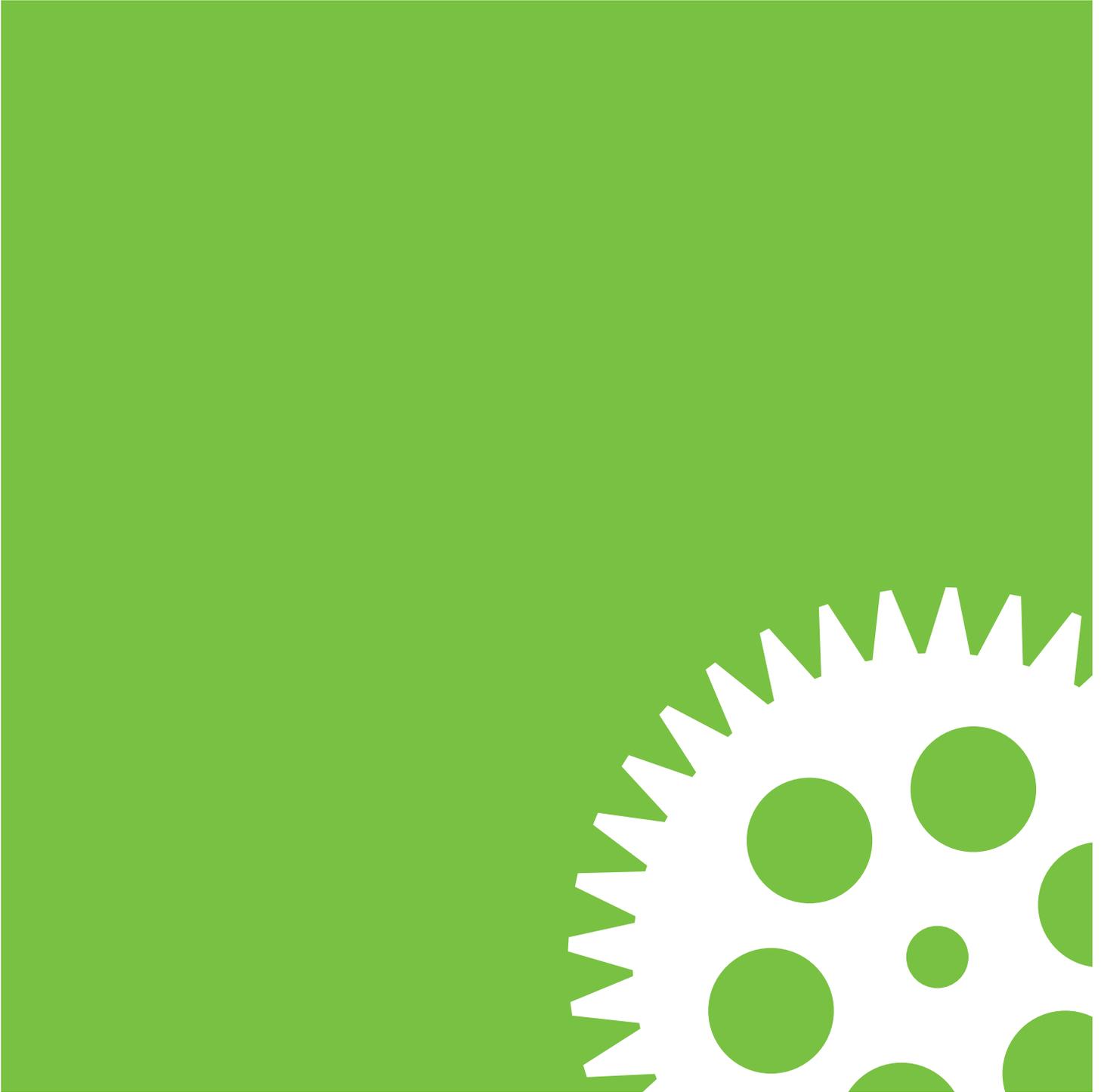
**NHS Improvement**

Delivering the NHS Health Check:  
A Practical Guide to Implementation

## A Practical Guide to Point of Care Testing

# Free NHS Health Check

Helping you prevent heart disease, stroke,  
diabetes and kidney disease.



## Introduction

In April 2008 Alan Johnson, Secretary of State for Health, announced plans for the NHS to introduce a systematic and integrated programme of vascular risk assessment and management. The NHS Health Check programme (formerly known as 'vascular checks') is an ambitious initiative which will offer preventative checks to all those aged 40-74 to assess their risk of vascular disease (heart disease, stroke, diabetes and kidney disease) followed by appropriate management and interventions. The proposals for the programme were set out in 'Putting Prevention First', published on 1 April 2008 and aim to ensure greater focus on the prevention of vascular disease and a reduction in health inequalities. Implementation of this programme began in April 2009 and full roll out is expected in 2012/13.

To support the development and implementation of the national programme, NHS Improvement, in conjunction with the Department of Health, has established a national Learning Network for the NHS Health Check in order to learn from, build upon and share the learning and experience of both existing and emerging vascular risk assessment and management programmes across the country.

Drawing on the work of the Learning Network's 'Test Bed' programme, case studies from the field and existing guidance, NHS Improvement has developed a series of short, practical guides covering various aspects of implementation and delivery of the NHS Health Check.

The intention is not to provide official guidance on 'how to do it'. The schemes and services referenced in the guides are not 'model' schemes endorsed by the Department of Health or NHS Improvement and in no way are the guides considered to be definitive. However, we hope that they will help commissioners and providers get to grips with some of the key challenges posed by local delivery of a major national vascular risk assessment and management programme including, for example, commissioning, checks in community settings, training, and informatics.

Each guide has been designed to stand alone in its own right but can be collected and collated as a complete set in a ring-bound folder.

To download PDFs of the guides, please visit [www.improvement.nhs.uk/nhshealthcheck](http://www.improvement.nhs.uk/nhshealthcheck)

The development of ***Delivering the NHS Health Check: A Practical Guide to Implementation*** has been a collaborative process. Generous thanks are extended to everyone who has contributed by sharing experiences, learning, knowledge and guidance.

Identical in structure to other guides in the series, this first guide, ***A Practical Guide to Point of Care Testing***, introduces the subject in the context of the NHS Health Check, sets out why it's important, and identifies some of the pros and cons to the use of Point of Care Testing (POCT). A number of issues and challenges to implementation are presented alongside practical 'solutions', drawing heavily on experience and learning from the field. Last, but by no means least, the guide points to other useful sources of guidance, advice and information.

## What is Point of Care Testing?

Point of Care Testing (POCT) is defined as 'Diagnostic testing that is performed near to or at the site of the patient care with the result leading to possible change in the care of the patient'<sup>1</sup>. In simple terms, it is laboratory testing performed in a non-laboratory setting, usually by appropriately trained non-laboratory staff.

Traditional, centralised laboratory testing invariably requires the transport of patients or specimens for analysis using well-established and sometimes lengthy procedures<sup>2</sup>. This increases the turnaround time for results being reported to clinicians and other relevant healthcare professionals. By contrast, POCT results are rapidly available and therefore have the potential to affect immediate patient management and improve outcomes.

Although laboratories offer a far greater range of tests, with emphasis on expertise, quality and reliability, recent years have seen a marked growth in the variety of tests that can be performed satisfactorily by POCT, largely as a result of technological advances and changes in clinical practice<sup>3</sup>.

In his review of NHS Pathology Services<sup>4</sup>, Lord Carter of Coles recommended that pathology services should work alongside PCTs and other community-based services to develop new pathways of care, to advise on the appropriate use of POCT and provide any necessary support.

### Why is it important?

Given that the burden of vascular disease falls disproportionately on people living in deprived circumstances and on particular ethnic groups, the NHS Health Check programme offers a real opportunity to make significant progress towards tackling health inequalities.



The national NHS Health Check initiative has been designed to ensure a systematic and consistent approach to vascular risk assessment and management across England. However, the Department of Health **Next Steps** guidance for PCTs, published in November 2008, and the more recent **Best Practice Guidance** on the NHS Health Check, make it clear that PCTs should adopt local models of delivery that suit the needs of their often diverse local populations.

<sup>1</sup>This definition is taken from ISO22870, (pdf format). This Standard, to be used in conjunction with ISO 15189, pertains specifically to point of care testing.

<sup>2</sup>Gutierrez SL, Welty TE. Point-of-Care Testing: An Introduction. *Annals of Pharmacotherapy* 2004; 38(1):119-125.

<sup>3</sup>Hobbs FDR, Delaney BC, Fitzmaurice DA, et al. A review of near patient testing in primary care. *Health Technology Assessment* 1997; 1: No.5, cited in DB 2002(03) Management and Use of IVD Point of Care Test Devices.

<sup>4</sup>Department of Health. Lord Carter. Report of the second phase of the review of NHS pathology services in England, 2008. [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_091985](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_091985)



**Next Steps** in particular outlines a number of approaches that PCTs might take in order to reach high risk groups, marginalized communities, and those who do not readily access health services, including offering NHS Health Check in a variety of different settings, from general practice and pharmacies to community centres and faith settings.

The provision of POCT in all these settings (including GP practices) has the potential to increase the feasibility, acceptability and convenience of NHS Health Check by allowing the tests and measurements required to be performed in both clinical and non-clinical environments, and by reducing the need for multiple visits or repeat appointments. Consequently, POCT may help reduce inequalities by increasing the ability of the health services to reach out to certain segments of the population that are difficult to contact or underserved by existing services.

### Issues and challenges

Both **Next Steps** and the recent **Best Practice Guidance** provide advice for PCTs using, or planning to use POCT to support their NHS Health Check programme. This includes advice on quality assurance, safety and training issues.

However, while POCT is seen to offer a variety of benefits over conventional laboratory testing, the potential advantages of quick turnaround times and convenience could be off set by the potential for inaccurate and unreliable results unless introduced discerningly. Identifying the need for POCT, weighing up the pros and cons of both laboratory and POC testing, and achieving the right balance in terms of local implementation of the NHS Health Check, play a vital role in maximizing the benefits and ensuring that quality and patient safety are not compromised. A strategic approach to the use of POCT is also important to achieve good integration with local phlebotomy and laboratory services across a care pathway.

Many PCTs already have NHS Health Check-type programmes in place. However, unlike the national offer, some have focused their efforts on actively seeking and diagnosing disease and identifying and treating only those at highest risk. Existing guidance on the NHS Health Check makes it clear that the national programme is a universal, systematic initiative to assess the risk of vascular disease in *all* adults aged between 40 and 74. In order to ensure that the NHS Health Check achieves its stated benefits, existing programmes will need to be consistent with the national offer. While prioritising high risk groups first may help to ensure that the programme makes a positive contribution to the reduction of health inequalities, an undue focus on 'case-finding' may lead to 'over-processing', e.g. routinely taking venous blood and sending it to a hospital laboratory for a plethora of tests, some of which are unnecessary and/or not required in the NHS Health Check. Performing tasks that add no value to the process or confer no additional benefit is clearly wasteful. Moreover, medicalising the NHS Health Check in this way may act as a further disincentive for those people who do not readily access health services.



The following table outlines some of the potential advantages and disadvantages of using POCT compared to laboratory-based testing for the NHS Health Check.

**Table 1: Potential advantages and disadvantages of POCT compared with conventional laboratory testing**

| Potential advantages of POCT   |
|--|
| <b>Short turnaround times</b> - results are usually available within a minute or two of analysis. This can result in more rapid intervention and allow a 'one stop' NHS Health Check.  |
| <b>Fewer time delays</b> - there is no requirement to transport specimens to a central laboratory, thereby reducing transport costs and turnaround time.   |
| <b>Direct discussion of result</b> - people can be seen, tested and consulted face to face and within a short time frame. This can improve compliance, adherence to, and optimisation of treatment and ensure greater involvement of people/ patients in their own care. |
| <b>Fewer visits/ consultations required</b> - no need for multiple appointments to discuss results and next steps.   |
| <b>More convenient for clients and more flexible for staff</b> - POCT is often highly portable and can be offered in a variety of locations.   |
| <b>Minimally invasive</b> - generally speaking, POCT devices require very small blood samples collected from a finger prick with nominal sample preparation. This can be useful for clients who are needle-phobic.   |
| <b>Reduction in overall healthcare costs<sup>5</sup></b> - Providing a more rapid result can save time and money and result in more effective use of resources <sup>6</sup> . For example, POCT can reduce the number of clinic visits/ unnecessary visits to GPs.       |
| <b>Reliable results</b> - provided point of care analysers are used by appropriately trained, competent and accredited operators adhering to the guidelines and procedures set out in a clinical governance framework (see 'disadvantages' below).                       |
| <b>Initial filtering</b> - in the NHS Health Check, POCT may be used to filter out those who are unlikely to have diabetes or non-diabetic hyperglycaemia and therefore do not require further testing or treatment.   |

<sup>5</sup>Indicative costs of POCT for the NHS Health Check were modelled in the Department's Impact Assessment for Vascular Risk Assessment and Management, published in November 2008. See paragraphs 23-25 and Table 2 on pages 14 and 15 of the Impact Assessment for further details.

<sup>6</sup>Price CP. Regular Review: Point of care testing. BMJ 2001; 322: 1285-1288, cited in Buyers' Guide to Point of Care testing for Cholesterol Measurement (CEP09020)

### Potential disadvantages of POCT

**Cost**<sup>5</sup> - POCT can be more expensive per test than laboratory testing as a result of the capital cost associated with purchasing the equipment and ongoing revenue costs of disposables and service charges. However, hospital pathology labs may have access to preferential rates and VAT reductions if POCT equipment is ordered via this route.

**Quality of sample** - results may not be comparable with those produced in a laboratory. High quality, reliable results can only be obtained if individuals are prepared appropriately and the correct techniques are used. This includes compliance with good practice guidelines and quality assurance procedures.

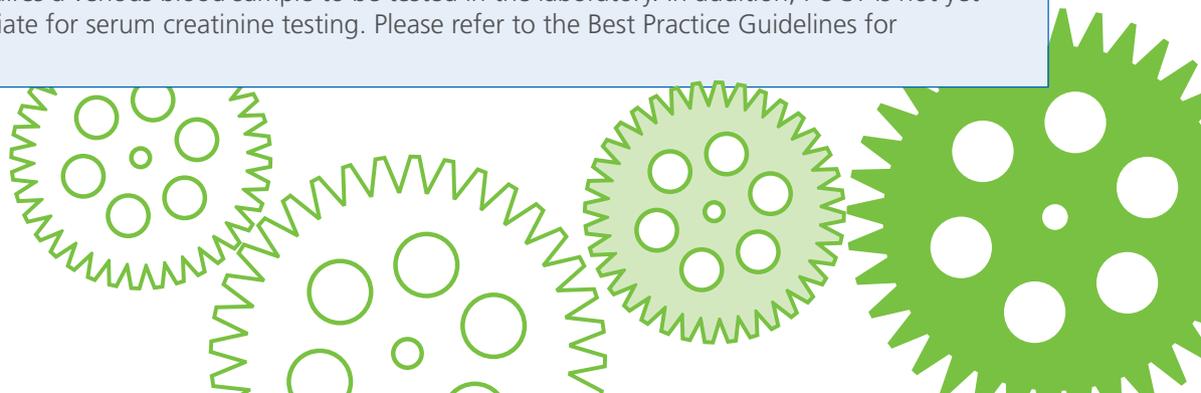
**Staff training and competence** - appropriate training, updating and monitoring is required to ensure accurate results. Given the universal and systematic nature of NHS Health Check, large numbers of staff may require training.

**Increased workload for existing staff** - staff may be unwilling or unable to allocate sufficient time to perform all necessary quality control procedures, maintain a proper audit trail and complete associated paperwork in addition to performing point of care tests.

**Safety** - the use of POCT requires clearly defined procedures for infection control, storage and disposal of clinical waste, needle stick injuries and spillages, hand washing etc., which need to be readily available or easily achieved. Operators need to retain practical skills by regular use.

**Record of results** - laboratory results are electronically transferred into patients' medical records via the laboratory and hospital information systems, but POCT results may need to be entered separately into patient records rendering data recording potentially more complex and less robust.

**Not appropriate for all testing** - the tests and measurements in the NHS Health Check are aimed at assessing risk of disease. Actual diagnosis of diabetes or non-diabetic Hyperglycaemia for those identified as being at risk requires a venous blood sample to be tested in the laboratory. In addition, POCT is not yet considered appropriate for serum creatinine testing. Please refer to the Best Practice Guidelines for further details.

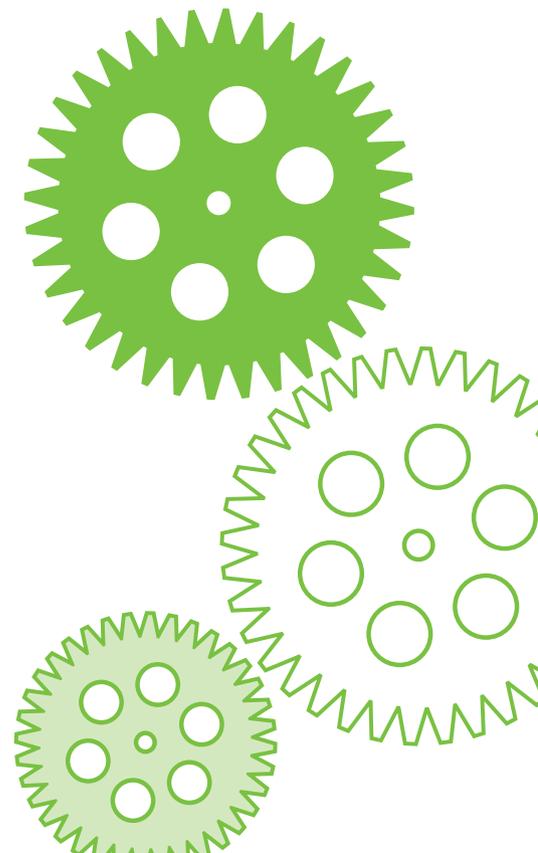


Those PCTs choosing to use POCT must also be mindful of the importance of strong clinical engagement and effective communications in the implementation of the NHS Health Check. Published guidance indicates that people identified as being at high risk of heart disease, stroke, diabetes or kidney disease at their first appointment should be referred to their GP (or other professional with suitable information and prescribing rights) for further tests, diagnosis, and/ or treatment. Failing to allay potential fears about the quality and accuracy of tests performed outside a laboratory or in a non-clinical environment may result in unnecessary duplication with GPs requesting repeat tests.

In order to improve quality assurance in this area, the Department of Health is working with the United Kingdom Accreditation Service (UKAS), Skills for Health and e-Learning for Healthcare to develop a flexible and robust accreditation service for POCT. This will involve determining the competences that practitioners need in this work, development of learning tools to support the

practitioners, finding appropriate ways of measuring these competences and developing an assessment and accreditation framework to underpin the testing itself. Further information can be obtained by emailing the Department of Health Pathology Modernisation Programme Team at [pathology.modernisation@dh.gsi.gov.uk](mailto:pathology.modernisation@dh.gsi.gov.uk)

In addition to a market review of all the systems currently available on the UK market, the Buyers' guide to point-of-care testing for cholesterol measurement (CEP 09020, September 2009), published by the Centre for Evidence-based Purchasing (CEP) provides an excellent overview of the technical, operational and economic considerations for point of care testing and can help commissioners make informed decisions about the utility of POCT with specific reference to the NHS Health Check. Similar guides are also available for blood glucose systems and POCT for the measurement of HbA1c (see 'Other sources of guidance and information').





## Potential solutions: Examples from the field

### **NHS County Durham and NHS Darlington**

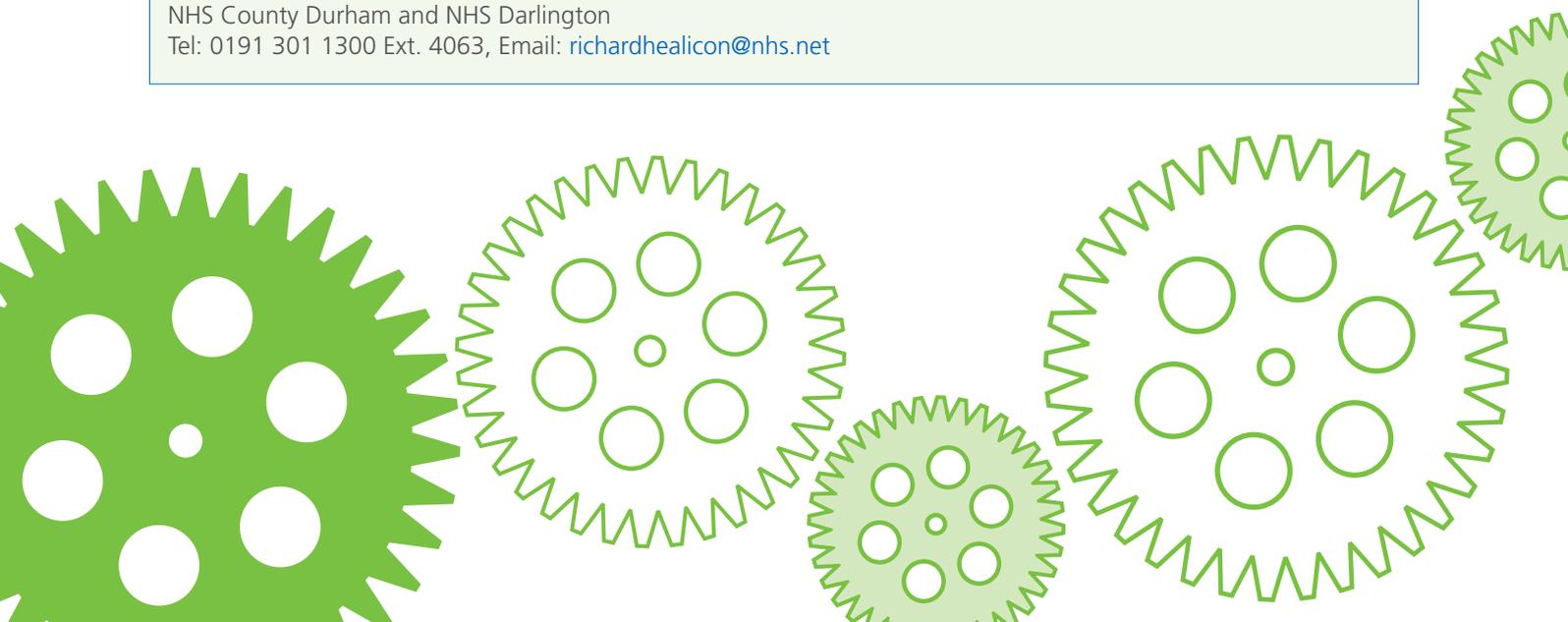
In October 2008, NHS County Durham and NHS Darlington launched a systematic risk assessment and management pathway to enable GPs to identify and manage those at high risk of cardiovascular disease (CVD). However, it was anticipated that the uptake of a CVD risk assessment programme based solely in general practice could potentially increase inequalities as many groups at most risk may not choose to access the programme in the general practice setting. For this reason, the PCTs agreed to pilot the delivery of CVD risk assessments in pharmacy, with a view to extending this to other community settings in the future.

The delivery of risk assessments outside general practice raised many practical and logistical issues which the pilot addressed. These included everything from establishing processes and procedures for needle stick injury and clinical waste disposal to ensuring suitable consultation facilities were available. In terms of the provision of POCT, the pilot considered effective procurement, quality assurance, operator training, and accreditation.

The PCTs consulted the local acute foundation trust and HEART UK regarding the procurement of suitable near patient testing equipment. Although there was some initial confusion over the advisory role of the trust, it was nonetheless important to maintain acute trust input into the process as they play an important role in the quality assurance. The chosen supplier provided specific training on the use of POCT to all pharmacy staff involved in delivering the checks, in addition to providing quality assurance, software support and promotional literature.

For further information, contact:

**Dr Richard Healicon**, Specialty Registrar in Public Health,  
Public Health County Durham and Darlington  
NHS County Durham and NHS Darlington  
Tel: 0191 301 1300 Ext. 4063, Email: [richardhealicon@nhs.net](mailto:richardhealicon@nhs.net)



### Stockport PCT

To complement its well-established GP-based Cardiovascular Disease Risk Factor Screening Programme (CVDRFSP), Stockport PCT sought to improve access to vascular checks by piloting approaches outside general practice. One such scheme built on an existing project at the local Wellspring Centre for homeless people and used POCT equipment. In the context of the pilot, POCT was reported to be "Very popular with clients. Is more expensive in cost per sample than routine screening using blood samples sent to the lab, but can be much more time-efficient for the health worker as it offers a one-off service (depending on fasting status) - especially valuable with a population such as homeless people vulnerable to disappearing from a service and not attending follow-up for results."

For further information, contact:

**Ms Jane Jefferson**, Public Health Specialist, Stockport PCT

Tel: 0161 426 5052/5090 Email: [jane.jefferson@nhsstockport.nhs.uk](mailto:jane.jefferson@nhsstockport.nhs.uk)

### Sandwell Healthy Hearts

Working alongside Sandwell PCT and community groups (Gujarati Indian, Punjabi Indian, South Indian, Eastern European, Irish, Afro-Caribbean, Yemeni, Bangladeshi, Pakistani, deaf people and visually impaired people), Healthy Hearts, a well-established social enterprise, undertook a series of mobile vascular risk assessment events with diverse local populations:

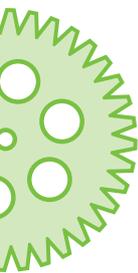
"Guidance and considerations for the delivery of community-based health checks using point-of-care technology has been gleaned from a decade of experience, which has been reviewed, standardised and made accessible. The delivery of vascular checks using this community-venue approach has the added benefits of community cohesion, and the potential to create a positive health experience for many hard to reach groups, and those groups facing barriers to access mainstream healthcare."

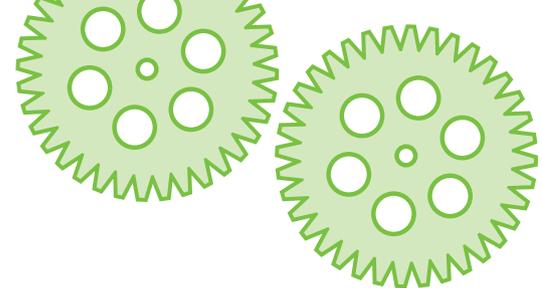
"The value of point-of-care testing should not be underestimated. Technology now allows varied biochemical tests to be conducted with the same precision and accuracy as hospital pathology analysers. Such approaches when used alongside stringent quality control and robust protocols allow a unique opportunity for the assessment, realisation and management of CVD risk within a single step which are key to widen the access of hard to reach groups."

For further information, contact:

**Jeetesh V Patel**, Healthy Hearts, SMRU, Hallam Street, West Bromwich, West Midlands B71 4HJ

Tel. 0121 507 3971 Email: [jeetesh.patel@swbh.nhs.uk](mailto:jeetesh.patel@swbh.nhs.uk)





### **NHS Bolton**

The Big Bolton Health Check (BBHC) aimed to identify all 30,000 people aged 45 and over in Bolton who were at high risk of developing cardiovascular disease in the next 10 years.

In the detailed evaluation of the process of implementing this major local programme, NHS Bolton summarised their experience of POCT, “near patient testing was originally seen as a key element of the BBHC, however, it was used less after discussions with the path lab. They agreed to allow blood samples to be processed in the evening and at weekends – meaning that tests could be carried out in GP practices all through the day and at weekends and not just in the mornings. They found NPT more expensive than using the lab and there were quality control issues, however when needed it produced a one stop shop which produced instant results.”

For further information, contact:

**Lynda Helsby**, Project Lead - Preventing Heart Disease Project, The BIG Bolton Health Check, NHS Bolton  
Tel: 01204 462102 Email: [lynda.helsby@bolton.nhs.uk](mailto:lynda.helsby@bolton.nhs.uk)

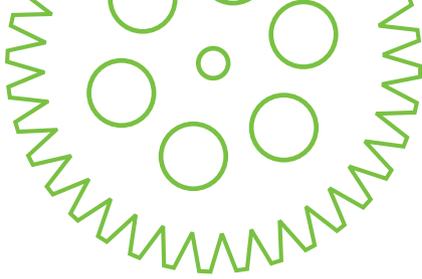
### **Newham PCT**

Newham PCT reported that, “part of our challenge is ensuring that the people of Newham respond to their health care invitations. We were keen to use the NHS Health Check programme to reach out to our community, so as to reduce our high levels of health inequality. To maximise every consultation opportunity, we implemented Point of Care Testing. The National Social Marketing Centre undertook a series of interviews and questionnaires with staff and people who were involved with the Health Checks. The feedback overwhelmingly indicated that POCT had enhanced the consultation experience.

All clinical practice staff and participating pharmacists attended training on how to use the POCT equipment, but we quickly recognised a gap in our process. Not all staff had been inoculated against Hepatitis B which meant we had to agree extra vaccination sessions with our occupational health service providers. Although Point of Care Testing is not a new concept, the requirement for the practices to engage in the monthly internal and external quality control processes proved challenging. Monthly feedback to the practices and detailed instruction and support is resolving this issue. Our experience of using POCT has been positive and we plan to use this technology for other campaigns in the future.”

For further information, contact:

**Helen Page**, Vascular Risk Programme Manager, Public Health Directorate, NHS Newham  
Tel: 0207 059 6611 Email: [helen.page@newhampct.nhs.uk](mailto:helen.page@newhampct.nhs.uk)



### **The Royal Free Hospital and NHS Camden**

As a part of its wider public health programme, The Royal Free Hospital NHS Trust in North West London launched a vascular checks outreach programme in local faith-based settings – two Hindu temples in Brent, supported by HEART UK and a Mosque in Camden, supported by NHS Camden.

The project benefited from having strong links with the hospital's cardiometabolic clinic and laboratory through the clinical lead - a consultant chemical pathologist. Due in part to the target audience and logistical challenges posed by the settings for the checks, the project employed both near patient and laboratory testing and was able to establish costs and feasibility data for both approaches.

One logistical problem common to both sites was the disposal of clinical waste, including sharps. As the evaluation report highlights, "It is illegal to transport clinical waste in an uncertified vehicle, so this was circumvented by carrying the waste to the nearest GP practice in both areas, from where it was removed through normal procedures. Restrictions also apply to transporting blood samples, so a courier was needed after each session to take them from the venue to the laboratory."

Running costs for the risk assessment sessions were falsely elevated as initially it was deemed necessary to ensure the validity of the near-patient testing equipment used by duplicating tests in the laboratory. Data on over 350 subjects who had measurements done by both methods showed that cardiovascular risk calculated using POCT and the laboratory methods were comparable irrespective of the risk calculator used including QRISK. The involvement of the POCT committee in the evaluation and the adherence to an appropriate quality assurance programme contributed to the success. The future predicted running costs per 'screen' based on POCT alone operated by junior staff were substantially reduced, from over £51 to £32.96.

The evaluation report concluded that, "Near-patient testing is ideal if possible as it enables a fuller discussion at the end of the screen and a 'one-stop' service. However, it is necessary to work with the local laboratory in using these methods for quality control and hence patient safety, and indemnity purposes."

For further information, contact:

**Dr Devi Nair**, BSc MSc MBBS FRCPath

Consultant Chemical Pathologist and Director SAS Centre for Cardiac Biomarkers.

Clinical Lead for Lipids and Cardiovascular Risk Prevention

Royal Free Hospital, London

Tel: 0207 472 6694 Email: [devaki.nair@royalfree.nhs.uk](mailto:devaki.nair@royalfree.nhs.uk)



## Other sources of guidance and information

### Best Practice Guidance for the Assessment and Management of Vascular Risk

The Department of Health has published the above document to support Primary Care Trusts (PCTs) in their implementation of the vascular risk assessment and management programme and will help ensure consistency, quality assurance and safety across England.

### Putting prevention first: Vascular checks risk assessment and management - next steps guidance for primary care trusts

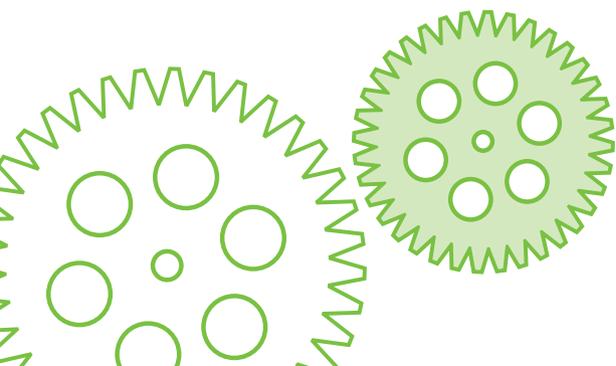
Putting prevention first, published in April 2008, outlined proposals for a system of vascular checks to be carried out in primary care. 'Next Steps' has been developed in consultation with PCT commissioners, those who will be carrying out the checks and the Learning Network, which has been set up to share learning across the NHS on vascular risk assessment



and management. It draws on some real life case studies and examples of how PCTs have already implemented vascular checks in their areas. It provides practical tools to support commissioning and links to existing resources and guidance.

### Putting prevention first: Vascular checks risk assessment and management - Impact Assessment

This document sets out the evidence base in support of implementing a national vascular risk assessment programme. The cost benefit analysis includes information on the unit costs of laboratory and POCT for the NHS Health Check.



### **DB 2002(03) Management and Use of IVD Point of Care Test Devices**

This bulletin, produced by the Medicines and Healthcare products Regulatory Agency (MHRA), provides advice and guidance on the management and use of point of care testing and in vitro diagnostics devices (IVDs) including:

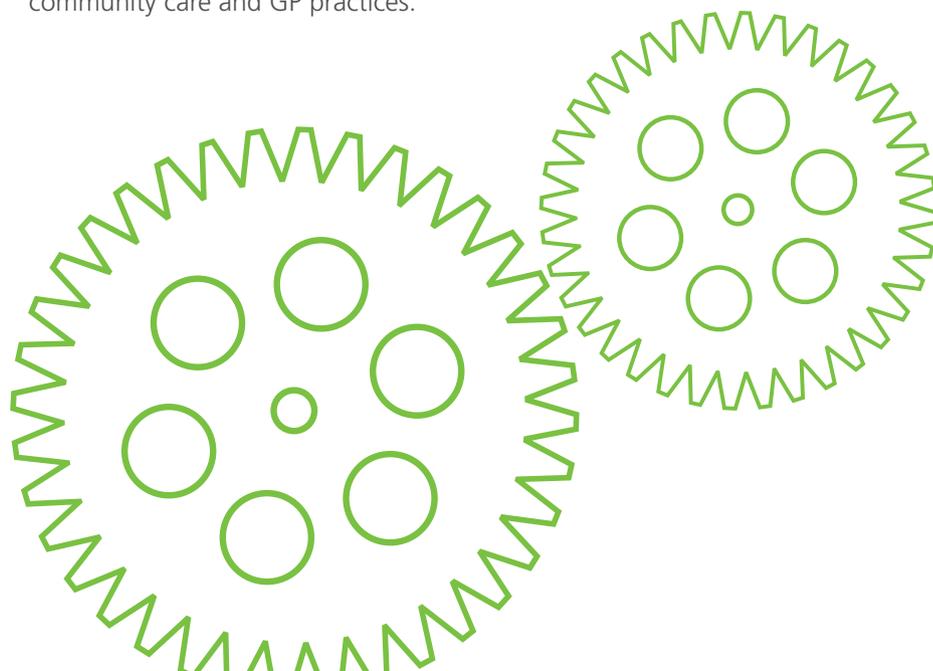
- the importance of identifying a clinical need before a decision is made to introduce POCT;
- clinical governance issues relating to the setting up and management of POCT;
- the need for local hospital pathology laboratory involvement in all aspects of a POCT service;
- the need for training, updating and monitoring of all staff involved in the POCT service;
- quality issues including:
  - accreditation by an external certification body;
  - the need for an appropriate quality control procedure;
  - membership of an External Quality Assessment Scheme (where available);

- the importance of health and safety;
- the need for standard operating procedures (SOPs) and for regular reviews and updates when necessary.

The bulletin is written for people involved in the management and use of point of care testing (POCT) services in primary and secondary care including managerial, scientific, technical, clinical and nursing staff. While many of the issues addressed are more relevant to the performance of POCT in a hospital environment, the principles are equally applicable to their use in outpatient clinics, community care and GP practices.

### **Buyers' Guide to Low Cost Non-Invasive Blood Pressure Monitors (CEP08035)**

This guide, published by the Centre for Evidence-based Purchasing (CEP) describes all of the low cost monitors on the market and explains the main differences. It focuses on the importance of clinical validation and follows up on the advice given in the note from the Chief Medical Officer (CMO) and in the Medicines and Healthcare products Regulatory Agency's Medical Device Alert and Device Bulletin.



**Buyers' Guide to Blood Glucose Systems (CEP08008)**

This guide, published by the Centre for Evidence-based Purchasing (CEP) reviews commercially available blood glucose systems, purchasing mechanisms and considerations, and provides an overarching view of the technical, operational and value/economic issues which need to be considered when purchasing a meter.

**Buyers' Guide to Point of Care Devices for the Measurement of HbA1c and Low Concentration Albumin in Urine (CEP08057)**

This buyers' guide describes POCT devices for haemoglobin A1c (HbA1c) and low concentration albumin in urine that are currently available in the UK. Technical, operational and economic considerations and information on purchasing are also presented.

**Buyers' Guide to Point of Care Testing for Cholesterol Measurement (CEP09020)**

This guide, published by the NHS Centre for Evidence-based Purchasing (CEP), reviews all commercially available lipid measurement systems for point-of-care total cholesterol and / or HDL cholesterol testing. It includes technical, operational, economic and purchasing considerations that are important when selecting a suitable system and highlights those devices suitable for the NHS Health Check programme.

Please note that all the guidance documents referenced in this guide can be downloaded from the NHS Health Check Learning Network website at:

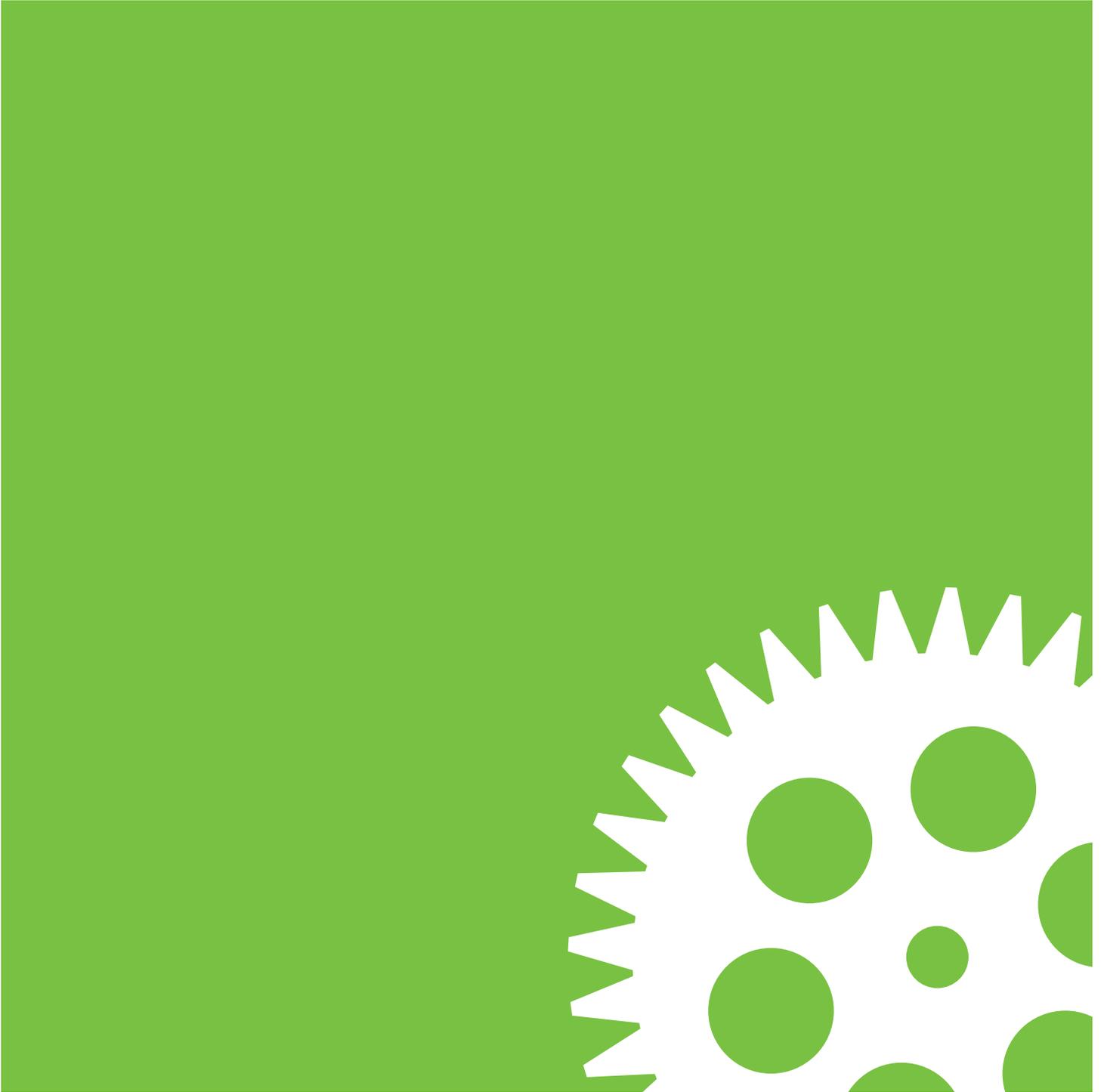
[www.improvement.nhs.uk/nhshealthcheck](http://www.improvement.nhs.uk/nhshealthcheck).

In addition, relevant documents published by the Department of Health are available at:

[www.dh.gov.uk/nhshealthcheck](http://www.dh.gov.uk/nhshealthcheck).

Other publications in the *Delivering the NHS Health Check: A Practical Guide to Implementation* series will be made available for download at: [www.improvement.nhs.uk/nhshealthcheck](http://www.improvement.nhs.uk/nhshealthcheck)







## NHS Improvement

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## NHS Improvement

3rd Floor | St John's House | East Street | Leicester | LE1 6NB

Telephone: 0116 222 5184 | Fax: 0116 222 5101

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