

DERBYSHIRE COUNTY COUNCIL**CABINET MEMBER FOR HEALTH AND COMMUNITIES****3 March 2014****Report of the Director of Public Health****NHS Health Check Programme:- Point of Care Testing:-
Maintenance and Quality Assurance Programme****1. Purpose of Report**

To seek approval to extend the Point of Care Testing (POCT) contract for the provision of maintenance and quality assurance of the Cholestech LDX with Alere Ltd.

2. Information and analysis

The NHS Health Check programme is a mandated programme provided by general practices on behalf of the Derbyshire County Council through a Basket of Services contract which practices have with Derbyshire CCGs.

The programme is a national primary prevention cardiovascular risk assessment programme that is targeted at people who do not have an existing cardiovascular disease and who are aged 40-74. Cardiovascular diseases (e.g. heart attack, stroke) are important causes of premature mortality and morbidity and significantly contribute to inequalities in health.

Cardiovascular diseases are preventable in terms of the risk factors that influence them. The risk factors include age, gender (increased risk in males), smoking, overweight/obesity, physical inactivity, *raised cholesterol*, high blood pressure, diabetes and kidney disease.

Cardiovascular diseases are caused by hardening of the arteries and diabetes accelerates this process. Identifying people at risk of developing diabetes e.g. obesity is an important component of the programme.

Of a Derbyshire population of approximately 770,000 people there are 237,000 people who are eligible for a NHS Health Check. The programme runs on a 5 yearly cycle i.e. a fifth of the eligible population is invited every year which is approximately 47,000 people. It is expected that 60% of the people invited will accept the offer of a NHS Health Check, i.e. 28,000 NHS Health Checks each year. An objective of the programme is to increase this to 75% uptake. 'Invitations' and 'uptake' are the performance measures used.

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An outline of the programme has been provided in previous papers to Cabinet Members.

Within the Memorandum of Understanding with the CCGs for the provision of the programme within the Basket of Services contract. Public Health Derbyshire is responsible for the maintenance and quality assurance of the point of care testing equipment (POCT). This equipment has been supplied to practices including the provision of maintenance and quality assurance of the devices i.e. Cholestech LDX reader. These devices are provided by Alere Ltd.

Alere Ltd is the only the company which manufacture the devices. GP practice staff use the Cholestech LDX machine to undertake the cholesterol testing as part of the NHS Health Check.

A point of care test takes a very small sample of blood from a finger pin prick and the sample is read by the analyser. This is done within the practice.

The sample result is used with other clinical variables e.g. blood pressure, smoking status to calculate the cardiovascular risk score.

An advantage of POCT is that the NHS Health Check can be completed as a 'one stop' assessment. Some practices do not use POCT but send the patients' blood sample to a hospital laboratory for analysis. These patients have to return to the practice to complete the NHS Health Check.

The Quality Assurance programme for the equipment is currently provided by Alere and Derby Royal Hospital. The Alere contract was agreed in 2010 through an NHS procurement exercise. Alere has provided Cholestech LDX devices to all Derbyshire County practices which have been purchased from the public health budget with the former Derbyshire County Primary Care Trust.

Alere is the world's leading provider of near patient testing diagnostics. Integrated information technologies are extending diagnosis from the laboratory into the wider healthcare environment, at home and in the community. This can mean that clinicians wherever they are have seamless real-time access to accurate and actionable diagnostic information that supports clinical decision making and bringing diagnosis closer to the patient reduces unnecessary delays.

The Cholestech LDX is at present the best reader on the market. This device is only provided by Alere who bought the original USA Company. This device has been tested against a 'gold standard' (a venous blood sample) by the POCT Dept. at Royal Derby Hospital.

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For the purpose of cholesterol measurement within the NHS Health Check the device performs just as well as a venous blood sample. There is also a separate evaluation from Wolverhampton a summary of which is shown in the Appendix 1.

The quality assurance programme provided runs throughout the year providing:

Internal Quality Control (IQC) this is provided by Bolton Trust and is in addition to the contract with Alere.

This involves sending reference samples to practices every two months. These reference samples test the cholesterol readers for accuracy and reliability.

External Quality Assurance (EQA) is provided by Welsh External Quality Assessment Scheme (WEQAS) but administered locally from the POCT Department Royal Derby Hospital each quarter. The key objective of EQA is continuous quality improvement within laboratory medicine. The EQA programme compares the Derbyshire programme with other programmes nationally that are using the Cholestech LDX device.

Under the renewed contract Alere will provide a coordinated web based quality assurance programme (currently paper based) whereby all IQC and EQA results will be entered by practices onto a web based programme, AegusPOC. This will ensure the POCT systems deliver the same high standards as laboratory testing for venous sampling. The service will strengthen quality assurance, training, accreditation, governance and information management for the DCC NHS Health Check programme.

The revised POCT support from Alere fulfils the quality and governance management for DCC as commissioners and is flexible in enabling the delivery of GP based and community based NHS Health Checks.

The benefits to the DCC NHS Health Check programme governance and risk management are:

- Clinical governance for POCT for the DCC Health Check programme (accredited laboratory standards)
- Support to each GP practice undertaking health checks
- Timely identification of GP practices who are not performing quality controls
- Audit trails of quality control results
- On-going maintenance and support for 2 years

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- 24/7 technical support to GP practices via a dedicated call centre/out of hours helpline
- Implementation, project management and roll out
- Certified POCT training for practice based staff undertaking the NHS Health Check (twice a year)
- Unlimited access to eLearning for POCT
- 4 POCT refresher sessions for GP practice staff previously trained

AegisPOC supports the model for a 'one stop shop' approach to look at the patients' health and wellbeing status with immediate results which allows health providers to intervene earlier. The AegisPOC Data manager provides an effective management tool that offers real-time data to support commissioning decisions.

All of the above will be outlined in a service specification which will provide a revised maintenance and support proposal for the 73 Alere Cholestech LDX readers including the Aegis Data Management System to support the delivery of the NHS Health Check programme in Derbyshire.

3. Performance

Consistent laboratory quality results for each GP practice with immediate communication and management for all risk/s identified and timely communication of that risk.

AegisPOC Data manager will ensure standardisation and consistency of approach across Derbyshire, guaranteeing the integrity of the POCT for the Health Check process.

4. Financial Considerations

The following table outlines the costs:

The current budget is

Year	Maintenance and Support	AegisPOC Data manager	Total	Annual cost per device
1	£14,599.91	Included	£14,599.91	£200.00
2	£14,599.91	Included	£14,599.91	£200.00

Payment schedule:

- 2 x annual payments of £14,599.91
- Term: Alere maintenance for the Alere Cholestech LDX Platforms for 2 years
- Delivery costs approximately £1,000

Total price: £30,199.92

All prices stated exclude vat.

NHS Health Check Budget

The current maintenance and quality assurance (IQA Bolton) is £13k in addition the EQA programme with Derby Royal Hospital is £12k i.e. £25k/pa. We aim to budget for all GP practices undertaking the NHS Health Check to come under the new contract i.e. a further 27 practices.

A comparative costing exercise has been undertaken between POCT and traditional venous blood samples. This showed little difference in costs between the methods when patient travel costs are included.

A number of other programmes within the East Midlands use the Cholestech LDX device. If this device remains the best on the market it may be worth considering with Public Health England and local councils a joint procurement exercise in the near future.

5. Legal Considerations

Regulation 4 of the Local Authorities (Public Health Functions and Entry to Premises by Local Healthwatch Representatives) Regulations 2013 require local authorities to provide, or secure the provision of, HCs for all eligible people in their area aged between 40 and 74.

6. Other Considerations

In preparing this report the relevance of the following have been considered – equality of opportunity, environmental, transport, property and prevention of crime and disorder. The major consideration of this report is on health and prevention of acute illness and long term conditions.

7. Call-in

Is it required that call-in be waived in respect of the decisions proposed in the report?

No.

8. Background Papers

Hardwick paper to Cabinet Ministers October 2013

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TCR Licence paper to Cabinet Ministers November 2013

MHRA device bulletin. Management and use of IVD point of care test devices DB2010(02) February 2010

Buyers' guide: point of care testing for cholesterol measurement September 2009

9. Officer's Recommendation

For Cabinet Member to approve the proposal to extend the contract with Alere Ltd for 2 years.

Elaine Michel
Director of Public Health