

# Developing a national digital NHS Health Check for local use: Blood self-sampling services

## Market Engagement Brief

### 1. Purpose

DHSC is conducting market engagement to understand more about existing end-to-end pathology services in England that can supply, distribute, receive, analyse and send results from self-sampling or self-testing cholesterol and blood glucose (HbA1c) kits that meet the requirements of the planned digital NHS Health Check.

The outcome of the market engagement will inform decisions and the approach to procuring the required pathology services for the digital NHS Health Check in a private Beta phase. This information will also be used to support decisions on the approach to cholesterol and blood glucose sampling/testing for the digital NHS Health Check when considering rollout at national scale.

### 2. Summary

The NHS Health Check programme aims to prevent heart disease, stroke, diabetes and kidney disease, and some cases of dementia among adults aged 40-74 years.

An [evidence-based review](#) of the programme, published in 2021, found that the NHS Health Check has the potential to achieve greater impact through use of a digital approach to 'transform all aspects of the NHS Health Check, including accessibility, scale, conduct and delivery'. The review recommended a digital approach to improve participation and engagement in the NHS Health Check.

The Government's commitment to develop a digital NHS Health Check has since been announced, with a commitment to deliver from late Spring 2024 and forms a part of DHSC's [Plan for Digital Health and Social Care](#).

The Department of Health & Social Care (DHSC) is developing a digital version of the NHS Health Check, that will be offered alongside the option to attend the existing in-person check, that will give users more choice about where and when to have a check and empower people to take action to improve their health independently. A digital NHS Health Check (digital check) will enable people to self-check at home, only directing people to primary care where further clinical assessment and treatment is required.

The procurement relating to the development of the full digital NHS Health Check solution is being progressed separately to this market engagement.

The digital check, which is expected to be available through the NHS App via mobile phone, tablet and computer, will require participants to provide a range of information to complete a full NHS Health Check. This includes:

1. Demographic information, including age, sex and ethnicity.
2. Behavioral information about cardiovascular disease (CVD) risk factors, such as smoking status, alcohol use and physical activity through validated tools.

3. Biometric information, including height and weight to calculate Body Mass Index (BMI), blood pressure, cholesterol and blood glucose (HbA1c)<sup>1</sup>.

The digital check will support participants to record this information at home or in convenient locations in the community, depending on what is being measured and how this measurement is being taken. For example, the ambition is for the digital check to support participants to order, complete and return a home blood self-completed sample or test for cholesterol and, if required, a blood glucose test (HbA1c).

Where appropriate, the results from the assessment – which will outline the person’s risk of CVD – will be held online via the NHS app, with personalised advice on what action they can take to reduce their risk. It will direct people to services such as stop smoking and weight management, where appropriate. Those found to be at higher risk of CVD will be flagged to GPs for clinical care. The results from the assessment will be added to the electronic patient record, held within their GP practice and will alert the GP if urgent action needs to be taken following the assessment. The digital check will be delivered alongside the current in-person service and is not a replacement for the face-to-face offer.

DHSC expect the digital NHS Health Check will commence private Beta from Spring 2024. Over the course of four years, DHSC aims to support local authorities to deliver up to one million digital checks. DHSC is undertaking market engagement to understand if there are existing end-to-end services in the marketplace that can provide the full pathology service requirements – a cholesterol and/or blood glucose (HbA1c) self-sample or self-test that meets the programme standards<sup>2</sup> – that allow people to complete their full digital check at home or chosen location - outside of a healthcare setting. The details of this requirement are detailed in [Section 3: Overview of requirements](#). The outcomes of the exercise will inform the:

1. approach to procuring the required pathology services for the digital check in a private Beta phase, where it will be tested as part of the full service with a small number of users; and
2. the approach to delivering the pathology services when rolling out a digital check at national scale.

The procurement relating to the development of the digital NHS Health Check platform/solution is being progressed separately.

### **3. Background**

#### **Background**

CVD is the second biggest killer in England. It affects around 6.4 million people, is the largest contributor to disability adjusted life years and accounts for around a quarter of the life expectancy gap between the richest and poorest in England.

The NHS Health Check is a key part of the CVD prevention pathway. The programme, established in 2009, aims to prevent heart disease, stroke, diabetes and kidney disease, and some types of dementia. Since 2013, local authorities in England have been legally responsible for commissioning the NHS Health Check programme as set out in the [Local](#)

---

<sup>1</sup> Note, all participants require a cholesterol test. A blood glucose (HbA1c) test is only required for selected individuals identified as being at risk of developing type 2 diabetes.

<sup>2</sup> [NHS Health Check - National guidance](#)

[Authorities Functions Regulations](#). The Government's Public Health Grant to local authorities highlights provision of the NHS Health Check as a prescribed function, with general practice most commonly commissioned by local authorities to provide the service.

The regulations require adults aged 40 – 74 years, who do not have an existing diagnosis of CVD, to be invited for a free check every 5 years. During an NHS Health Check, the top risk factors, blood pressure, cholesterol, physical activity, smoking, alcohol consumption and BMI, are assessed. Where required, blood sugar is also assessed in some people that are at an increased risk of type 2 diabetes. This information is then used to calculate a person's CVD risk.

As part of an NHS Health Check, all eligible individuals are made aware of their results and are supported to consider behavioural changes that will reduce their chance of heart attack or stroke within the next 10 years. All attendees are also made aware that the risk factors that are 'good for the heart, are good for the head', raising awareness of the risk factors for dementia. Additionally, attendees over 65 years are also told about the signs and symptoms of dementia and signposted to memory services, where appropriate.

The results from a check are recorded onto medical records and shared with individuals to raise awareness of the risk factors and support behaviour change, where relevant. Where appropriate, individuals are also supported to access further clinical diagnostic tests and drug treatment, for example diagnosing and treating high blood pressure (hypertension).

### **NHS Health Check delivery**

Since the current programme began in 2013, the overall national uptake of the NHS Health Check has never exceeded 50%. Therefore, there is still a large proportion of the eligible population that the existing face-to-face check is not reaching.

### **Digital NHS Health Check vision**

The vision for the digital NHS Health Check is to increase the flexibility and reach of the NHS Health Check through the creation of an innovative, accessible national digital service, delivered alongside local face-to-face offers, that helps people understand and take action to engage with their cardiovascular health.

The aim is that the digital NHS Health Check will offer participants the same tests as set out in legislation through an additional, flexible mode of delivery. By capitalising on digital engagement during the pandemic, we want to improve and increase participation and reduce variation between areas by enabling people to self-check at home or to complete online with the support of friends and family, carers, community-based health care professionals or volunteers. The check will empower users to take actions to improve their health independently, link to national services, and enable general practice to initiate clinical care where appropriate.

The intention is to launch a digital NHS Health Check which meets the existing [legal requirements](#) for the NHS Health Check, which covers the following elements:

- Identify eligible population.
- Invite eligible individuals.
- Questionnaires and biometrics, including cholesterol and blood glucose (HbA1c) if required.
- Communicate results to the end user and their general practitioner.
- Provide personalised advice on actions people can take to reduce their risk of CVD.
- Refer people for clinical follow up and to prevention services.

The intention is that the digital check can be self-completed independently by eligible people and used by providers to facilitate delivery of high-quality in-person checks in community and primary care settings according to local commissioning models.

Our ultimate aim is to develop a digital service that, in combination with the face-to-face service, can help to transform the way users engage with and providers deliver a NHS Health Check, and provide end-to-end data on patient journeys enabling us to understand opportunities for improvement.

### **Current status of the digital NHS Health Check**

Following successful Discovery and Alpha phases, DHSC is now preparing for the private Beta phase, where the digital platform will be built and commence testing with a small number of end users.

This next phase will help to refine the solution, validate assumptions and inform the best approach for rollout at scale.

## **4. Overview of requirements**

Cholesterol is a major modifiable risk factor for vascular disease and can be reduced by dietary change and physical activity, but medicines may also be required depending on the degree of elevated risk. A critical requirement of the NHS Health Check is therefore the capacity to collect blood samples and analyse them for cholesterol and, where appropriate, blood glucose (HbA1c) among eligible participants in line with [programme standards](#). This information, combined with demographic and behavioural information, height, weight and blood pressure for the participant, is essential to calculate the individual's 10-year risk of CVD and complete the NHS Health Check.

Currently, most NHS Health Checks are delivered by a healthcare professional with access to point-of-care testing devices that can analyse cholesterol and blood glucose (HbA1c) samples during an NHS Health Check consultation, or via a venous blood sampling that will be sent to a laboratory where blood samples can be tested.

Data required: cholesterol must be measured as the ratio of total serum cholesterol to high density lipoprotein cholesterol.

Key points: a random cholesterol test should be used for this assessment. A fasting sample is not required. To enable eligible people to self-complete their full NHS Health Check – including the blood testing elements – at home, DHSC aims to learn more about end-to-end pathology services available on the market for self-sampling and self-testing for cholesterol and blood glucose (HbA1c) at home. For the purposes of this exercise, we have defined these terms as such:

- Self-sampling refers to self-administered sampling of blood through the appropriate product/s, which is then sent to an offsite laboratory for analysis.
- Self-testing refers to self-administered sampling of blood through the appropriate product/s, which then provides a near instant result to the user either directly or through an external digital solution.

**DHSC would like to identify providers that can provide the blood self-sampling kits and the full end-to-end pathology services required to supply and distribute self-sampling and self-testing kits, receive completed blood samples (where applicable), analyse samples for cholesterol and HbA1c (if needed), and process test results for the digital NHS Health Check.**

DHSC is not seeking responses from providers that can provide the full digital NHS Health Check solution or pathway.

### **Minimum expected requirements**

Respondents to this market engagement must provide an end-to-end pathology service that is able to:

1. Store and provide the appropriate kit/s required for blood self-sampling or self-testing to test cholesterol and/or blood glucose (HbA1c), in line with national [programme guidance](#).
2. Provide a secure Restful API interface to receive kit orders from the digital NHS Health Check service.
3. Safely distribute the kit/s to eligible individuals to complete the blood self-sample or self-test, ensuring suitable transport conditions are met to ensure kit is not compromised.
4. Ensure kit packages fit through a standard letterbox.
5. Provide instructions and demonstrate to end users how to use the kit/s to safely collect the blood self-sample and conduct the self-test, if required.
6. If required, provide return packaging and instructions on how to return the kit/s to ensure they can be easily posted to the lab, analysed in appropriate timescales, ensuring suitable transport conditions are met to ensure kit is not compromised where relevant.
7. Be able to manage replacement kits for those that are broken, spoiled or do not arrive within agreed windows.
8. Have the ability to link the new kit back to the digital NHS Health Check platform and provide an update to the digital NHS Health Check platform that a replacement order has been made via a Restful API.
9. Analyse the self-samples in accordance with industry standards and programme guidance.
10. Demonstrate success rates in processing the viable kits returned.
11. Provide order status updates to the digital NHS Health Check platform at pre-defined points in the pathway via a Restful API.
12. Provide the results, including flagging abnormal results, to the digital NHS Health Check platform via a Resultful API for processing in line with programme standards. The digital platform will provide the result to the participant and their clinician, as outlined in legislation.
13. Meet UK GDPR legislation and data storage requirements.
14. Adhere to NCSC Secure Design Principles and Protecting bulk personal data principles.
15. Be certified for ISO27001 (2013 or 2022) and demonstrate alignment to ISO27002 (2022).
16. Comply with NCSC CAF.
17. Have the ability to manage stock of kits and demonstrate resilience and business continuity provisions to ensure orders are not rejected in the event of a temporary stock issue.
18. Be able to put systems in place to agree any system outages or maintenance windows with the digital NHS Health Check platform with sufficient notice.
19. Arrange to put SLAs in place to agree the timings between sending the kit(s) after order and the time to process and send the result on receipt of completed test.

20. Show it (or its suppliers) has all the relevant ISO certifications, such as ISO 13485 and ISO 15189.
21. Provide relevant data for monitoring and evaluation purposes.
22. Test samples and results must be processed within UK laboratories.

In addition to the above requirements, each category of service you submit information about has specific requirements.

### **Cholesterol testing requirements.**

Category A: For cholesterol self-sampling analysed through a pathology laboratory, the cholesterol self-sampling kit and laboratory services must:

1. Provide a non-fasting 5-lipid panel (including total and HDL), consistent with the NHS Health Check requirements.
2. Self-sampling kits must be licensed for self-sampling and be compliant with medical device regulations where applicable, which includes UKCA or CE marking as applicable.
3. The end-to-end service must be available for use on the UK market currently (i.e., it has passed all necessary approvals and can be used with the intended groups and for the intended purpose outlined above).

Category B: For cholesterol self-testing with rapid results either directly to the user or through an external digital solution, the cholesterol test kit must:

1. Provide a non-fasting 5-lipid panel (including total and HDL), consistent with the NHS Health Check requirements.
2. Self-testing kits must be licensed for self-use and be compliant with UK Medical Device regulations (the Medical Devices Regulations 2002, and general product safety regulations 2005).
3. Provide a rapid 5-lipid panel result safely to the user and must be able to demonstrate this through user testing.
4. The test must have been validated against industry standard laboratory methods (have comparable accuracy).
5. Be available for use on the UK market currently (i.e., it has passed all necessary approvals and can be used with the intended groups and for the intended purpose outlined above).

It is desirable that the cholesterol sampling device has:

1. Have the ability to integrate with an external digital product to provide the result (rather than a separate app).

### **Blood glucose testing requirements**

In addition to the above requirements, each category of service you submit information about has specific requirements.

Category C: For blood glucose (HbA1c) self-sampling analysed through a pathology laboratory, the HbA1c self-sampling kit and laboratory services must:

1. Provide a blood glucose result, consistent with the NHS Health Check requirements.
2. Self-sampling kits must be licensed for self-sampling and be compliant with medical device regulations where applicable, which includes UKCA or CE marking as applicable.

3. The end-to-end service must be available for use on the UK market currently (i.e., it has passed all necessary approvals and can be used with the intended groups and for the intended purpose outlined above).

**Category D:** For blood glucose (HbA1c) self- testing with rapid results either directly to the user or through an external digital solution, the blood glucose (HbA1c) testing kit and analysis of the sample must:

1. Provide a blood glucose result, consistent with the NHS Health Check requirements.
2. Self-testing kits must be licensed for self-use and be compliant with UK Medical Device regulations (the Medical Devices Regulations 2002, and general product safety regulations 2005).
3. Provide a blood glucose result safely to the user and must be able to demonstrate this through user testing.
4. The test must have been validated against industry standard laboratory methods (have comparable accuracy).
5. Be available for use on the UK market currently (i.e., it has passed all necessary approvals and can be used with the intended groups and for the intended purpose outlined above)

It is desirable that the HbA1c sampling device has:

1. The ability to integrate with an external digital product to provide the result (rather than a separate app).

### **Combined cholesterol and blood glucose testing requirements**

**Category E:** For combined cholesterol and blood glucose (HbA1c) self-sampling collected through a single blood sample and analysed through a pathology laboratory, the combined kit and laboratory services must:

1. Provide a non-fasting 5-lipid panel (including total and HDL) and blood glucose result, consistent with the NHS Health Check requirements.
2. Self-sampling kits must be licensed for self-sampling and be compliant with medical device regulations where applicable, which includes UKCA or CE marking as applicable.
3. The end-to-end service must be available for use on the UK market currently (i.e., it has passed all necessary approvals and can be used with the intended groups and for the intended purpose outlined above).

## **5. Request for further information**

Following the market engagement exercise we may issue a request for further information for interested suppliers to complete if more information is required.

Not submitting a response to our request for further information will not impact your ability to engage with any future formal commercial process should there be one which would be fair, open and transparent.

## **6. Timeline**

Launch of Prior Information Notice: **4 January 2024**

Closing Date for Responses: **19<sup>th</sup> January 2024 at 12:00 and shall be submitted through the Atamis e-portal system.** Your response must also include the following information (not

included in any word count): Organisations' name, Organisations' address and Contact person and e-mail address for contact.

Launch Request for Further Information: To be confirmed.