Market consultation

For the development of a national digital NHS Health Check: self-sampling cholesterol and HbA1c blood testing services

Project: C296916

Version Number: 1.0

Date: 15/07/2024

# Introduction

 For avoidance of doubt THIS IS NOT a call for competition. This information note and accompanying attachments are being made publicly available to any organisations which are interested in the self-sampling cholesterol and HbA1c blood testing services procurement.

This exercise is intended to provide potential bidders with the opportunity to view and comment on the requirements for the blood self-sampling services of the digital NHS Health Check, if they wish to do so. This builds on a commitment to engage with the market, by sharing information and seeking input from the market to enable us to develop the final Invitation to Tender (ITT) in a fair and transparent manner. This exercise is to ensure that the final Invitation to Tender provides all tenderers with a clear understanding of the Department of Health and Social Care’s requirement and help reduce the number of questions that may be raised in the tender period.

**Next steps**

The Department of Health and Social Care (The Department) will make the final decision on the content of the invitation to tender (ITT) documentation having considered feedback.

The ITT will be released to the market as soon as practical after receipt of potential bidder(s) comments though the procurement timetable has not been finalised at this stage.

The ITT will include the final specification, pricing schedule, evaluation criteria and terms and conditions.

The ITT process will include the publication of:

* a contract notice
* the ITT documents
* a draft contract

**guidance for completion**

This questionnaire forms part of the market engagement activity to support the procurement of self-sampling cholesterol and HbA1c blood testing services for the digital NHS Health Check.

The purpose of this questionnaire is to explore the market reaction to the proposed facility. We hope to identify critical success factors and potential barriers in order to inform the formal procurement process. To maximise the success of this subsequent procurement process we request that suppliers are open and honest in their responses and provide as much detail as possible.

Prior to completing this questionnaire, suppliers are requested to read the market consultation information which sets out the background and the proposed service requirements.

Participation in this market consultation is voluntary. It is not required to provide an answer to every question if particular questions are not relevant.

The Department wishes to encourage participation at this stage in order to ensure a wide number of responses. The market engagement processes described above do not form part of the formal procurement process. When the formal procurement process commences any supplier may join the competition and all supplier bids will be evaluated on the same basis.

* + 1. The completed questionnaire should be returned via email ccsinbox@dhsc.gov.uk quoting “Cholesterol and HbA1c Self-sampling Testing Services” no later than **Friday 26 July 2024, 5pm.**

The Freedom of Information Act 2000 (FOIA) applies to the Department. You should be aware of the Department's obligations and responsibilities under the FOIA to disclose, on written request, recorded information held. Information provided by you in connection with this procurement exercise, or with any contract that may be awarded as a result of this exercise, may therefore have to be disclosed in response to such a request, unless the Department decides that one of the statutory exemptions under the FOIA applies. The Department may also include certain information in the publication scheme which it maintains under the FOIA.

In certain circumstances, and in accordance with the code of practice issued under section 45 of the FOIA or the Environmental Information Regulations 2004, the Department may consider it appropriate to ask you for your views as to the release of any information before a decision on how to respond to a request is made. In dealing with requests for information under the FOIA, the Department must comply with a strict timetable and the Department would, therefore, expect a timely response to any consultation within two working days.

You may provide information which is confidential in nature and which you may wish to be held in confidence. You must give a clear indication which type of material is to be considered confidential and why it is considered to be so, along with the time period for which it will remain confidential in nature. The use of blanket protective markings such as "commercial in confidence" will no longer be appropriate. In addition, marking any material as confidential or equivalent should not be taken to mean that the Department accepts any duty of confidentiality by virtue of such marking. Please note that even where you have indicated that information is confidential the Department may be required to disclose it under the FOIA if a request is received.

The Department cannot accept that trivial information or information which by its very nature cannot be regarded as confidential should be subject to any obligation of confidence.

In certain circumstances where information has not been provided in confidence, the Department may still wish to consult with you about the application of any other exemption such as that relating to disclosure that will prejudice the commercial interests of any party.

The decision as to which information will be disclosed is reserved to the Department notwithstanding any consultation with you.

Whilst the Department expects to proceed to procurement in due course, there is no obligation to do so as a consequence of this early market engagement activity.

The publication of any documents at this stage is intended to provide potential bidders with the opportunity to view and comment on a draft specification for the requirement. The Department does not intend to be bound by any information at this stage. The Department makes no commitment to accept recommendations or suggestions. Once published, the Invitation to Tender will contain the final requirements in relation to this service. All previous versions, including any documents published at this stage should be disregarded.

Regards,

**Corporate and Clinical Services**

**Commercial Directorate
Department of Health and Social Care**

**Market consultation information**

**Name of Supplier:**

**are you a SME?** ☐ Yes ☐ No

**are you registered in Atamis?** [Welcome (site.com)](https://atamis-1928.my.site.com/s/Welcome)☐ Yes ☐ No

Name of authorised representative submitting the questionnaire:

Position:

Email address:

For and on behalf of:

Date:

Additional contact names in case follow up questions are required:

|  |  |  |
| --- | --- | --- |
| Name | Title/position | Email |
|   |   |   |
|   |   |   |
|   |   |   |

**(This should be completed by the supplier or a partner or an authorised representative in his / her own name and on behalf of the company / organisation completing this questionnaire)**

**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 cholesterol and HbA1c kits that meet the requirements of the digital NHS Health Check private Beta phase. Only suppliers that can fulfil both the cholesterol **and** HbA1c requirements should respond.

This follows an initial exercise in January – February 2024 and seeks to further 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 self-sampling for the digital NHS Health Check when considering rollout at national scale.

# 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 Department of Health and Social Care aim to deliver a digital NHS Health Check from 2024.

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 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. Behavioural 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), waist circumference, blood pressure, cholesterol, and HbA1c for some participants

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 HbA1c.

Where appropriate, the results from the assessment – which will outline the person’s risk of CVD – will be available 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. The results from the assessment will be added to the electronic patient record, held within their GP practice. The digital check will be delivered alongside the current in-person service and is not a replacement for the face-to-face offer.

The digital NHS Health Check has commenced private Beta in 2024, which will be used to inform the approach to wider rollout across other local authorities.

DHSC is undertaking market engagement to understand if there are existing end-to-end services in the marketplace that can provide the cholesterol and HbA1c self-sampling tests that meeting programme standards – allowing eligible people to complete their digital check at home or chosen location – outside of a healthcare setting. The details of this requirement are detailed below. The outcomes of the exercise will inform the 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 further rollout to other local authorities.

# 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. There is no single universally recognised blood test for high risk of diabetes, or for diabetes itself. Fasting plasma glucose tests or a HbA1c test can be used.

A critical requirement of the NHS Health Check is therefore the capacity to collect blood samples and analyse them for cholesterol and, where appropriate, 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 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:** cholesterol must be measured as the ratio of total serum cholesterol to high density lipoprotein cholesterol.
* **Blood glucose:** the programme requires either fasting plasma glucose or HbA1c. HbA1c testing does not require fasting, and therefore is the required approach for the digital NHS Health Check.

**Key points:**

* For the purposes of this exercise, we have defined self-sampling as self-administered sampling of blood through the appropriate product/s, which is then sent to an offsite laboratory for analysis.
* a random cholesterol test should be used for this assessment. A fasting sample is not required.
* a non-fasting HbA1c test is required. 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 for cholesterol and HbA1c at home.

[[1]](#footnote-2)**DHSC is seeking to gain a better understanding of the market capacity and interest in delivering the blood self-sampling kits and the full end-to-end pathology services required to supply and distribute self-sampling kits, receive completed blood samples, analyse samples for cholesterol and HbA1c, and process test results for the digital NHS Health Check.**

The full draft requirements can be found at **Appendix A: Specification, Section 4: The Service Requirements.**

**Section A: Service and test kits**

Do you have a live service available on the UK market that offers **end-to-end cholesterol and HbA1c self-sampling** that meets the requirements outlined in Appendix A: Specification, Section 4: The Service Requirements?

 [ ]  Yes

 [ ]  No

If not, please provide further detail.

Do you have the capability to provide patients with regular updates on the status of their test kits? For example, providing text message or email updates on delivery timelines, prompts to take the test, or notifications if their kit is about to expire.

 [ ]  Yes

 [ ]  No

If yes, please provide further detail.

How long before the kit and its constituent parts typically expire?

Please provide detail on pack contents, as required.

Do you offer a venous blood sampling (phlebotomy) service for users who do not wish to collect a self-sample?

 [ ]  Yes

 [ ]  No

If yes, what proportion of users typically require this service?

**Section B: Accuracy and void rates**

What is the typical level of accuracy your **cholesterol** self-sampling product can achieve against the gold standard (i.e. venous sampling)? Please respond to this with a % rate and attach validated evidence to support your response.

 [ ]  >99% accuracy

 [ ]  95-99% accuracy

 [ ]  90-94.99% accuracy

 [ ]  85-89.99% accuracy

 [ ]  80-84.99% accuracy

 [ ]  75-79.99% accuracy

 [ ]  70-74.99% accuracy

 [ ]  <70% accuracy

Based on the above, please provide sensitivity, specificity, negative and positive predictive values.

What is the typical error or void rate (%) of returned tests for the **cholesterol** service and what proportion of these are due to poor specimen collection or insufficient sample volumes?

Please respond here.

What is the typical level of accuracy your **HbA1c** self-sampling product can achieve against the gold standard (i.e. venous sampling)? Please respond to this with a % rate and attach validated evidence to support your response.

 [ ]  >99% accuracy

 [ ]  95-99% accuracy

 [ ]  90-94.99% accuracy

 [ ]  85-89.99% accuracy

 [ ]  80-84.99% accuracy

 [ ]  75-79.99% accuracy

 [ ]  70-74.99% accuracy

 [ ]  <70% accuracy

Based on the above, please provide sensitivity, specificity, negative and positive predictive values.

What is the typical error or void rate of returned tests for the **HbA1c** service, and what proportion of these are due to poor specimen collection or insufficient sample volumes?

Please respond here.

**Section C: integration**

There will be two distinct integrations required for a supplier to connect with the digital NHS Health Check:

**Home self-sampling test ordering:** The digital NHS Health Check will send requests to the supplier via this API.

**Home self-sampling test results:** The digital NHS Health Check will create an API for suppliers to send cholesterol and HbA1c self-sampling test results back to the digital solution to allow participants to receive their full NHS Health Check result.

Draft specifications for these integrations are outlined further in **appendices B** and **C**.

Based on the two required integrations outlined above, do you have an existing API for home self-sampling test ordering?

 [ ]  Yes

 [ ]  No

How long would you expect the integration between your service and the digital NHS Health Check to take?

 [ ]  <4 weeks

 [ ]  4-6 weeks

 [ ]  6-8 weeks

 [ ]  >8 weeks

Please provide further rationale as to support your above answer.

If you have conducted similar integrations of this nature, what wider considerations or risks should be factored in for an integration of this nature.

If yes, please provide any further detail on the scale of the integration, and wider considerations and risks that should be factored in for an integration of this nature.

The digital NHS Health Check will be providing participants’ results to both the participant and their GP. Provided you were supplied with the relevant GP details, does your service integrate with the NHS England pathology messaging API to also provide the cholesterol and HbA1c results back to the GP in the event the cholesterol and/or HbA1c result falls outside of clinically acceptable parameters and requires more immediate GP follow up?

 [ ]  Yes

 [ ]  No

**section d: cost**

All prices and rates requested on self-sampling kits shall be inclusive of all disbursements and any other costs or expenses necessary for the proper delivery of the services as described in the draft specification (Appendix A) except for the integration with the digital NHS Health Check platform.

Most digital NHS Health Check participants will only require a cholesterol self-sampling kit. What would the end-to-end unit price for each **cholesterol** device/kit be for <5,000 kits?

 ☐ <£5 per unit

 ☐ £5-10 per unit

 ☐ £10-15 per unit

 ☐ £15-20 per unit

 ☐ £20-£30 per unit

 ☐ >£30 per unit

Please provide your specific unit price, if willing.

Those participants who meet the diabetes filter will require a cholesterol and HbA1c self-sampling kit. What would the end-to-end unit price for each **cholesterol and HbA1c** device/kit be for <5,000 kits?

 ☐ <£5 per unit

 ☐ £5-10 per unit

 ☐ £10-15 per unit

 ☐ £15-20 per unit

 ☐ £20-£30 per unit

 ☐ >£30 per unit

Please provide your specific unit price, if willing.

How much would it cost to integrate with the digital NHS Health Check through an API?

Note there will be two distinct integrations required:

* + **Home self-sampling test ordering:** The digital NHS Health Check will send requests to the supplier via this API.
	+ **Home self-sampling test results:** The digital NHS Health Check will create an API for suppliers to send cholesterol and HbA1c self-sampling test results back to the digital solution to allow participants to receive their full NHS Health Check result.

 ☐ <£10k

 ☐ £10-20k

 ☐ £20-30k

 ☐ £30-40k

 ☐ £40k

Based on the above, please provide any further detail required on what these costs will cover.

If you offer an additional phlebotomy service (answered “yes” in question 4, above) what is the unit price?

 ☐ <£5 per unit

 ☐ £5-10 per unit

 ☐ £10-15 per unit

 ☐ £15-20 per unit

 ☐ £20-£30 per unit

 ☐ >£30 per unit

Please provide your specific unit price, if willing.

Are there additional costs that you would expect are factored into a procurement of this nature?

 ☐ Yes

 ☐ No

If yes, please provide any further detail on the additional costs expected and the approximate scale.

**Section E: specification**

The timeline for the procurement is set out below.

|  |  |
| --- | --- |
| **Event** | **Completed by** |
| ITT issued to Tenderers | 05/08/2024 |
| Closing date for submission of tenderers’ questions | 23/08/2024 |
| Answers to tenderers’ questions circulated to all tenderers by  | 30/08/2024 |
| **Closing date for receipt of tenders**  | **06/09/2024** |
| Evaluation period including internal approvals (on or around)  | 20/09/2024 |
| Standstill period completed  | 30/09/2024 |
| Anticipated contract signature date  | 04/10/2024 |

Do you think that the timetable is feasible? If no, provide reasons and what could be changed to facilitate wider participation.

Please provide any further detail here.

A draft specification for our proposed procurement for cholesterol and HbA1c self-sampling for the digital NHS Health Check private Beta phase is outlined at Appendix A: Specification.

Are the service level agreements included in the draft specification (see Appendix A: Specification) achievable? If not, why not? What additional service level agreements might you expect are included in a specification of this nature to demonstrate resilience, security, performance and accessibility of your service?

Please provide any further detail here.

Does the draft service specification document (see Appendix A: Specification) provide you with a clear understanding of the service being procured? Is it structured in a clear and straightforward way? Would you require any additional information? Could you deliver against this specification? If not, why not?

Please provide any further detail here.

Assuming the Department chooses to go live with a procurement in line with the draft specification and provided your service meets the requirements set out in the specification, would you intend to bid for the opportunity?

 ☐ Yes

 ☐ No

 ☐ Not sure

If no or unsure, please provide your rationale here.

Please use this section to provide any additional information which you feel might be of value or to highlight any additional items that need to be taken into consideration. If you have any other comment or questions to raise regarding this procurement, please list them below. We will endeavour to answer all the questions by compiling a Q&A document that will be issued at tender stage.

Please provide additional information here.

**thank you for taking the time to complete this questionnaire**

1. [NHS Health Check - National guidance](https://www.healthcheck.nhs.uk/commissioners-and-providers/national-guidance/) [↑](#footnote-ref-2)