

DHI Exchange

HbA1c Remote Service Exploration

The purpose of this paper is to summarise the outputs from a series of discovery workshop hosted by the Scottish Health & Industry Partnership (SHIP), West of Scotland Innovation Hub and the Digital Health & Care Innovation Centre (DHI) to progress innovation activities around remote methods for HbA1c blood testing for people with Diabetes.

1. Introduction

The Scottish Health and Industry Partnership (SHIP) is a Scottish Government initiative hosted by the Chief Scientist Office (CSO) of the Chief Medical Officer Directorate and the Enterprise and Innovation Division of the Economic Development Directorate. It is aimed towards strengthening Scotland's innovation activities in health and social care to solve real problems and improve the quality, efficiency, and sustainability of healthcare. SHIP will support Scotland's economy through activities that strengthen its life sciences sector, attract investment into Scotland, develop large-scale innovation projects and support the growth of robust businesses.

The Digital Health & Care Innovation Centre (DHI) is part of the Scottish Funding Council's Innovation Centre Programme, which is designed to support transformational collaboration between universities and businesses. Our vision is "innovation in digital health and care will help the people of Scotland live longer, healthier lives and provide sustainable and inclusive growth for our economies." Our networks, reach and capabilities ensure we bring the right people together and provide them with the means to identify, design, evaluate and invest in new innovations to the country's prioritised health and care challenges.

To support and inform development of the Small Business Research Initiative (SBRI): [Diabetes Care - Remote HbA1c Monitoring](#), SHIP and DHI have collaborated to scope the challenge area to support overcoming the issues in developing innovative care pathways. The joint project team agreed to a series of workshops to build understanding and consensus around the current and future state context for the introduction of remote HbA1c to enhance the route to impact at scale. The workshops brought together SHIP, DHI, Scottish Government policy teams and clinical experts from across NHS Scotland.

NHS Scotland aspires to:

1. An equivalent or better service for distribution of sampling kit to patients and return of samples to labs or results direct into NHS systems.
2. Routes to demonstrate future scalability and usability beyond the SBRI Challenge.

The SBRI team, within this, specifically aims to facilitate:

A) Data driven approach to risk stratification and prioritisation: Identification of a clinically meaningful patient population at risk of Type 2 Diabetes (T2DM) or with existing diabetes in whom at home HbA1c may help support a virtual/hybrid care model.

B) Demonstrate an effective user-friendly self-collection blood test kit, validation of the sample volume, quality and analytical performance. This includes the ability to distribute to identified patients ensuring

linkage within the request of sample to patient, return for analysis and instructions for use of test and return of samples by the patient.

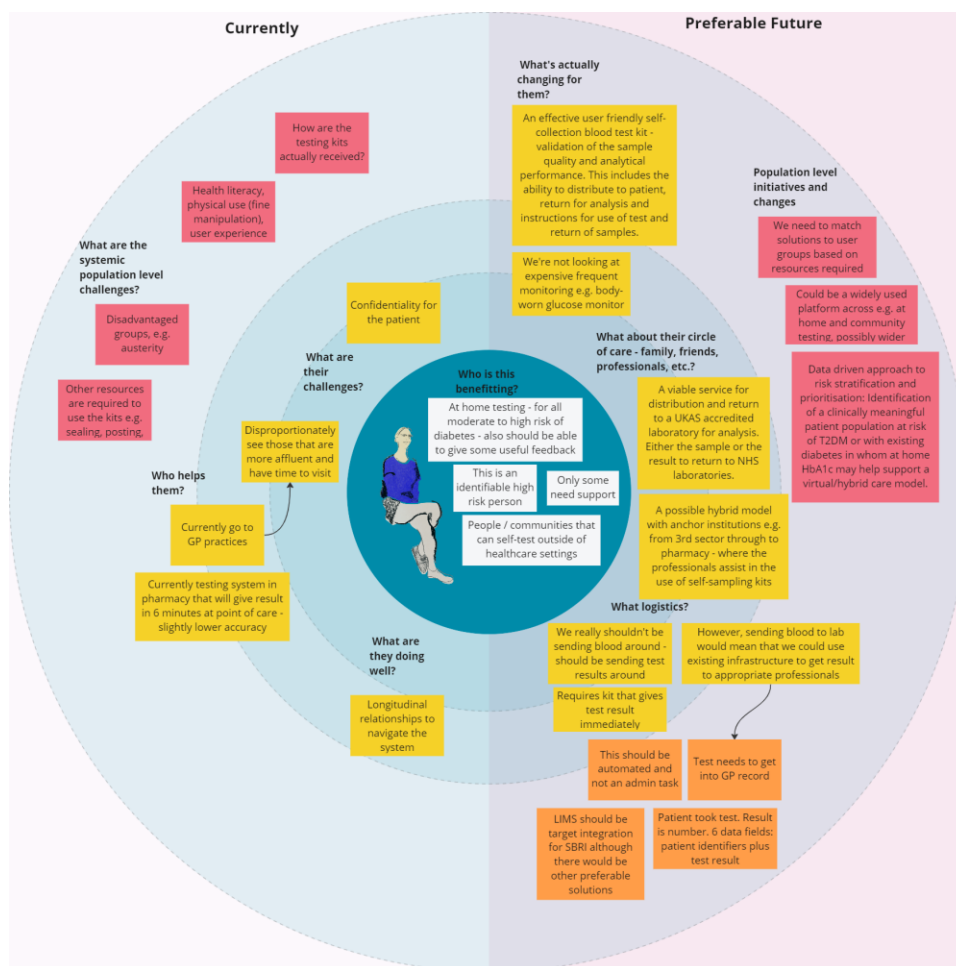
C) Demonstrate viable service for distribution of self-collection kit to patients and return to a UKAS accredited laboratory or by a UKAS accredited point of care testing facility (POCT) (ISO15189) method for analysis. Either the sample or the result to return to NHS infrastructure for integration within the patient record.

The focus is on technical and business readiness for the test kit distribution, use, return and result transmission. It should be acknowledged that adoption and implementation will require integration with clinical pathways and technical requirements that out of scope of the SBRI.

2. Current State

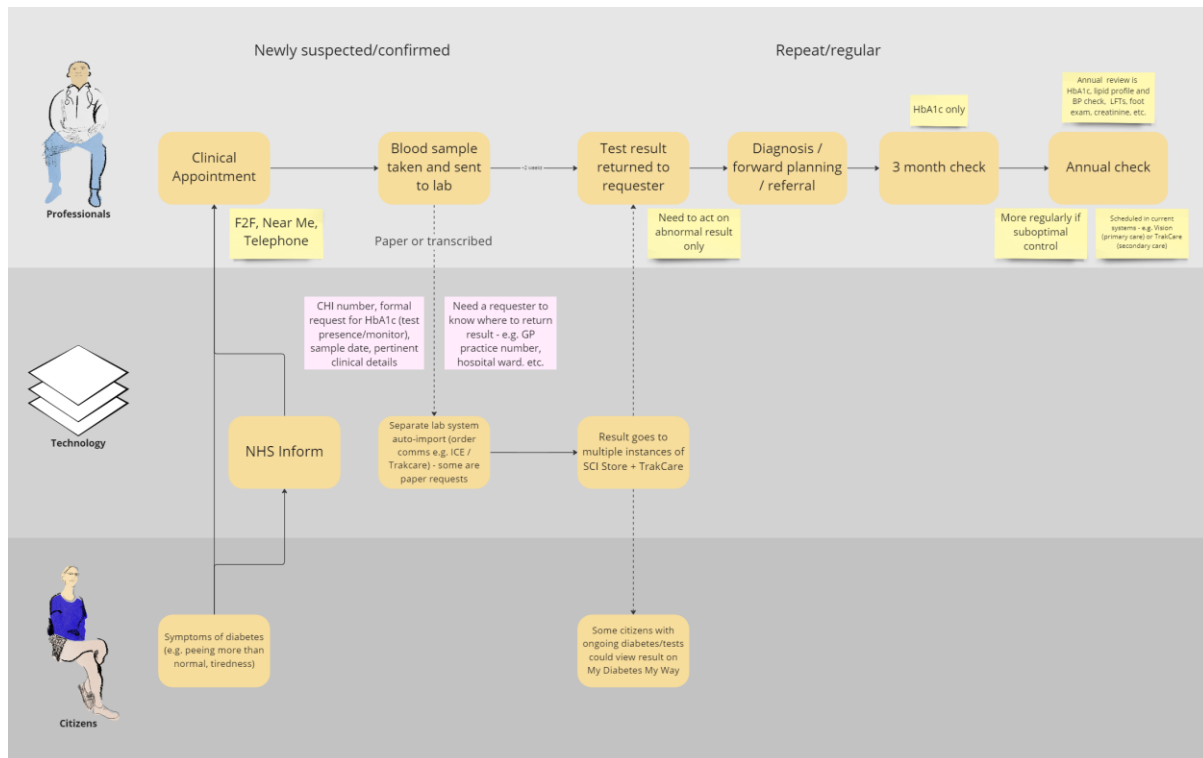
2.1. Initial Scoping

The first exercise started with who this is benefiting, their current needs and services and some initial discussion of a preferable future state.



2.2. Current State

The second exercise was to outline the high-level clinical service patient flow for typical HbA1c sampling requirements.



This highlighted that:

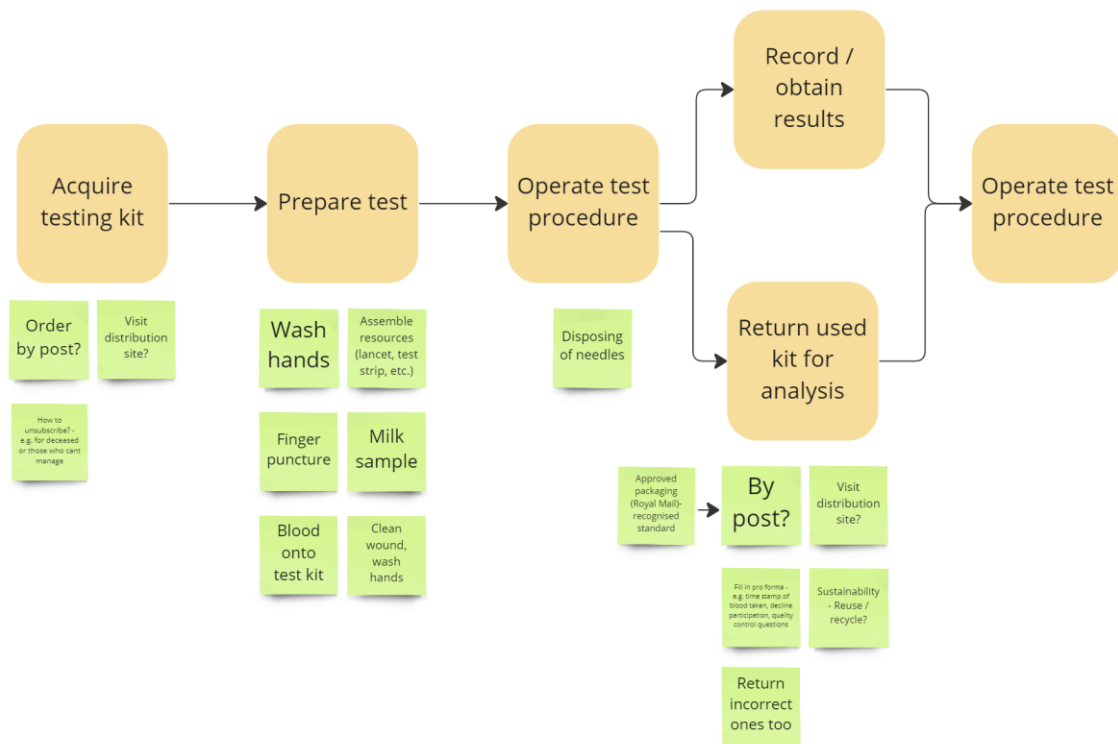
- 1) There were several standard touch points for HbA1c testing – divided into two main categories:
 - a. One off testing – on the way to diagnosis and at the 3-month review.
 - b. Repeat testing – as part of annual checks.
- 2) In some populations or processes there will be more frequent testing.
- 3) There is not currently any patient initiated HbA1c testing.
- 4) Clinicians trigger or schedule the test request from order comms tools within their main primary care (EMIS / Vision) or secondary care (TrakCare) systems.
- 5) These tools send a bundle of information that accompanies the test order, and blood work and then the test result through multiple systems and processes. This bundle includes CHI number, sample data, pertinent clinical details and requesting clinic/ward/practice (needed for result delivery).
- 6) There is no routine direct access to HbA1c test results for most of the population.
- 7) There is a pharmacy based HbA1c (both testing and analysis) model being trialled in Scotland

The scale of current use was discussed. [The Scottish Diabetes Survey \(2021\)](#) has recently been published which provides updated population-based information on the current update of Diabetes national Nine process of care/treatment targets including data on those accessing HbA1c testing. A focus on rural populations initially may demonstrate a better cost / benefit ratio whilst also contributing to other key government targets like Net Zero. An indicative volume was offered by NHS Highland: 6451 HbA1c tests in NHS Highland in January 2023 (only 197 of these were in secondary care. This equates to roughly 77,000 tests / year in NHS Highland – with the vast majority requested in primary care.

3. Future State

Part of the purpose of the SBRI is to work with industry to develop new future state processes and pathways. For reference, the following indicative test flow and user capacities might be useful in designing the future home testing model offered by industry bidders.

Citizen Home Test Flow (Possible Future)



Capacities / Resources Required



Hybrid Test Flow

Alternative solutions of supported testing in pharmacy or care homes may also be considered obviating need for fixed point of care testing devices.

Rate limiters:

To enable innovators to deliver solutions a number of considerations were highlighted:

- 1) Cost of analysis / lab infrastructure as volume increases (actual testing kits are relatively low cost).
- 2) Patient competence / willingness to participate - requires consideration of the support model and the availability of safe spaces - so may need to consider how to provide these in the community (ideally somewhere they already go / access).

Cost considerations:

- 1) While test kits will be relatively cheap, if they are distributed at scale on a repeat / annual basis then the costs could ramp up. There needs to be a semi-automated method to allow people to opt out to avoid waste.
- 2) Analysis will be the bulk of the cost. It is assumed that this will be more cost effective delivered in house in NHS labs - but this will need additional staff and infrastructure if deployed at scale.

Investment cases / business models should consider that if we can scale this for HbA1c which requires a whole blood sample then we can do it for other tests that require whole blood.

4. Population

The patient population is broadly defined in the SBRI as those at risk of T2DM or with existing diabetes. However, an understanding of the relative development / delivery effort and the health economic impact of supporting different populations within this definition is useful to consider access issues and potential impact. Solutions should consider the potential to demonstrate cost and clinical effectiveness during the project.

A longlist of populations was plotted on an effort / impact matrix and with the following narrative. The table below offers some narrative from this initial scoping and is illustrative of the sorts of factors that should be considered for modelling and validation of solutions.

Diagnosis of Diabetes - was immediately discounted as a viable group. They are a hard to define and find cohort that are likely having some healthcare contact anyway (e.g., GP) so there would be minimal gain.

Population	Impact	Effort
Pre-Diabetes \ prevention including risk management	Very high - increased outreach, better access, earlier intervention for large population over a long period of impact	Very High - Not currently resourced, so would need more investment at scale. Would need to increase engagement and competence in large groups of people.
Secondary prevention – e.g., gestational diabetes	High - Large population of at-risk in this group with long term impact consequences as with pre-diabetes group. However, this group has a huge amount of contact with healthcare services and could probably be tested when on-premises for another reason.	Medium – Already identified population. Competencies more present in existing diabetics. Would/should have annual test anyway. Routine monitoring would have to extend beyond 1 year really to start to detect T2DM.
Type 2 Diabetes (1-off 3-month review after change/diagnosis)	Medium - Useful in between annual review to measure effects of change in treatment/lifestyle e.g., T2DM Remission Interventions Highly variable cohorts e.g., secondary from alcoholism.	Medium - Competencies more present in existing diabetics. High uptake already - 87% of type 2 patients have had an HbA1c in the last 15 months.
Type 1 Diabetes (1-off 3-month review after change/diagnosis)	Medium - Significant backlog from Covid. Only HbA1c at 3-month check post diagnosis – could drop an appointment altogether for a decent sized population.	Medium - Already identified population. Competencies more present in existing diabetics.

	Many people with Type 1 Diabetes will have continuous monitoring which will give HbA1c – makes this less useful.	
Type 1 Paediatrics and Adolescent	<p>Lower - More frequent testing for children (e.g., 3 monthly) increasing impact. Non engagers are a high proportion of young deaths and complications</p> <p>However, roughly 70% are already using continuous monitoring – limited the impact.</p>	Lower - Activated and educated parent group helping children may increase uptake.
Type 1 Diabetes as part of annual review	<p>Lowest – Annual review includes multiple things dependent on in person contact e.g., Nine care processes some require physical examination (eyes/feet) – so remote test in isolation has limited impact.</p>	Lowest - Competencies more present in existing diabetics.

5. Digital Infrastructure

5.1. Test Result Delivery

This section outlines future consideration for integration of any solution into NHS Scotland’s systems. There are three main options for getting the test data into NHS systems:

- 1) The blood sample is captured and analysed by external UKAS accredited labs (ISO15189) and then reported into the NHS systems
- 2) The sample is captured and sent into NHS Labs who share the data.
- 3) The home test kit can show a result to the patient in their home in the moment, and they can convey this into the NHS (e.g., covid).

For (1) - Citadel Health's Evolution v Lab is the new Laboratory Information Management System (LIMS) for most health boards. It is likely to be a cloud based, single instance for the whole of Scotland. This would be the key integration target to demonstrate results coming into the NHS. For this route the supplier must be able to specify who requested the test to enable successful delivery to the right system.

The other consideration is how the test is ordered. If clinically triggered, then the SBRI product would need to take instruction / data from an order comms system (e.g., ICE for primary care or TrakCare for secondary care). Other methods for triggering testing could include a) citizen request, b) using a batch extract from e.g., GP system/ SCI Diabetes to generate a list.

Ideally not only the requester would be able to see the result - but this would only be possible with national level integration work with the roll out of the new LIMS system.

The National LIMS would be available for dev activity from September 2023 but would need to be limited to sandbox / test environment work at this stage for any public internet facing activity.

5.2. Citizen Access

The remote HbA1c method should ultimately offer fundamental change to scale effectively within current constraints - e.g., not needing to be activated by GP review. In general, we need to minimise physical / in person patient contact points that may otherwise bottleneck the system.

As a target there needs to be: Informational guidance materials that go with the sampling kit pack (e.g., leaflet that may point to a website. Healthy Literacy and Language Use will need to be factored into these materials to optimise conditions for a successful test.

As a stretch there could be: Consideration of what to do with results in the 'normal' range - i.e., can we do anything to reassure or inform the patient without incurring undue clinical effort or cost? This may for example be achieved by linking the test result delivery to MyDiabetesMyWay or an equivalent online portal for direct patient access.

As a high stretch there could be: For certain cohorts a route to citizen self-access online to trigger sampling kit dispatch may be appropriate.

The current scope of the SBRI is target only - but consideration of these stretch goals may help influence design decisions at this stage.

6.0 Recommendations

Based on the discussions outlined in this document, DHI would recommend that applicants:

- Consider population size / HbA1c testing volume data (ideally broken down by sub-population) to allow future sustainable business model development.
- Consider early, how you would integrate new sources of data into LIMS systems (either existing local or via the new national contract).
- Gather information on how tests are ordered and from which systems so applicants can consider how their new capability is triggered.
- Can explore if there is potential for live use of the LIMS integration as part of an SBRI or follow up activity – start an early resource / capacity / security conversation with the LIMS (local or national teams as appropriate) to ensure priority.