

Somerset NHS Health Check Programme Service Specification

Contents

Τ		National and Local Context	
	1.1	National Context	2
	1.2	Somerset Context	2
2	Ain	ns and Objectives of Service	5
	2.1	Health and Well-Being Board Strategic Priorities	5
	2.2	Improve Health Outcomes	5
	2.3	Service Objectives	5
	2.4	Service Outcomes	7
3	Ser	vice Description and Care Pathway	8
	3.1	Invitation Process	8
	3.2	Eligibility criteria	<u>e</u>
	3.3	Somerset NHS Health Check Assessment	10
	3.4	Lifestyle Advice	
	3.5	Reporting NHS Health Check Results	13
	3.6	Guidelines for Managing Individual's Risk	13
4	J	Performance Measures	
	4.1	Public Health Outcomes Framework	
	4.2	Somerset Measures	
5	Ser	vice Requirements and Standards	
	5.1	Patient Confidentiality, Clinical Governance and Information Governance	
	5.2	Staff Training	
	5.3	Point of Care Testing (POCT) Requirements	18
	5.4	Other Medical Device Requirements	19
	5.5	Marketing & Promotion	
	5.6	Software Application Operational Requirements	21
	5.7	Software Application Hosting Requirements	
	5.8	Information Governance	22
	5.9	Data Management	
	5.10	Quality Standards	25
	5.11	Service User Feedback	26
	5.12	Reporting Incidents	
	5.13	Reducing barriers	26
	5.14	Reducing inequalities	
	5.15	Infection Control	27
	5.16	Interdependencies with Other Services	27
	5.17	Reports to Commissioner	28
6	Ap	pendices	30



1 National and Local Context

1.1 National Context

- 1.1.1 Delivery of The NHS Health Check programme is a mandatory Public Health Service for Somerset County Council. The NHS Health Check is a national risk assessment and management programme for those aged 40 to 74 living in England, who do not have an existing vascular disease, and who are not currently being treated for certain risk factors. It is aimed at preventing heart disease, stroke, diabetes and kidney disease and to raise awareness of dementia. An NHS Health Check should be offered once every five years.
- 1.1.2 The programme systematically targets the top seven causes of premature mortality:
 - Hypertension,
 - Smoking,
 - Cholesterol,
 - Obesity,
 - Poor diet,
 - Physical inactivity, and
 - Alcohol consumption
- 1.1.3 The programme incorporates current NICE recommended public health guidance, ensuring it has a robust evidence base. Economic modelling suggests the programme is clinically and cost effective.

1.2 Somerset Context

1.2.1 Somerset covers an area of 3,450 square kilometers, and is divided into five districts: Mendip, Sedgemoor, South Somerset, Taunton Deane and West Somerset. Somerset's population is classified as around 52% urban and 48% rural, making it one of the ten most rural counties in England. West Somerset in particular, has the sixth lowest population density of any local authority in England. One third of people live in one of the county's four largest towns: Taunton, Yeovil, Bridgwater and Frome.



- 1.2.2 The total population estimate for Somerset as of June 2018 was 559,399 and this is projected to increase to 583,500 by 2025. The annual percentage increase in Somerset's population (up 0.8%) was above the South West rate (0.7%) and the England and Wales rate (0.6%).
- 1.2.3 Inward migration from the UK continues to be the major component in Somerset's increasing population: 3,899 more people moved into Somerset from elsewhere in the UK than moved out, in the year to June 2018.
- 1.2.4 The percentage of the population aged 40 to 74 in Somerset is 46.8% in 2017. The age profile is weighted slightly towards people of older age; and the median age in Somerset is 47 compared to 40 nationally.
- 1.2.5 The increase in the ageing population has particular implications for services in Somerset as age is a key risk factor for many common health conditions. As Somerset has a population older than the national average, and the 65+ age group is projected to rise further, this will increase numbers of people with cardiovascular disease, cancer and diabetes still further. Projected increases for dementia and heart failure are particularly high.
- 1.2.6 Somerset has 7.2% of its population in the most deprived national quintile and 13.6% of the population in the least deprived quintile.
- 1.2.7 It is estimated that 34.4% (89,397) of the population aged 40 to 74 are ineligible for an NHS Health Check due to existing CVD or other long-term condition.
- 1.2.8 The number of people expected to be eligible for an NHS Health Check over the next five years is 170,593 or 34,119 people per year.



1.2.9 Baseline research in 2013 showed that the distribution of the eligible population across deprivation quintiles was as follows:

Deprivation Quintiles	Total Population Aged 40 to 74	Population Aged 40 to 74 Eligible for NHS Health Check over 5 years	Population Aged 40 to 74 Eligible for NHS Health Check each year
1 (Hi)	44,595	31,693	6,339
	•	·	•
2	48,318	34,394	6,879
3	53,588	38,348	7,670
4	52,551	37,780	7,556
5 (Lo)	51,543	37,059	7,412
Total All	250,595	179,273	35,855

Somerset population aged 40 to 74 by deprivation quintiles (2013)

1.2.10 Distribution of the annual eligible population across each of the 5 District Councils in 2013 was as follows:

District Council	Population Aged 40 to 74 Eligible for NHS Health Check over 5 years	Population Aged 40 to 74 Eligible for NHS Health Check each year
Mendip	39,545	7,909
Sedgemoor	39,315	7,863
South Somerset	52,033	10,407
Taunton Deane	37,015	7,403
West Somerset	11,365	2,273
Total All	179,273	35,855

1.2.11 Further information on the health profiles for Somerset at county and district levels is available at Somerset Intelligence.



2 Aims and Objectives of Service

2.1 Health and Well-Being Board Strategic Priorities

The Somerset Health and Wellbeing Boards has set out the key strategic priorities for the county in Improving Lives in Somerset Strategy for 2019 – 2028. The Somerset NHS Health Check programme is linked to:

 Priority Four: Improved health and wellbeing and more people living healthy and independent lives for longer

The Strategy aims to improve the lives of people in Somerset over the next ten years with the following overarching outcomes for health and wellbeing:

- 1. Increased healthy life expectancy taking account of the quality of life as well as the length of life
- 2. Reduced inequality in life expectancy and healthy life expectancy between communities –achieved through greater improvements in more disadvantaged communities.

2.2 Improve Health Outcomes

The Somerset NHS Health Check Service aims to improve the health outcomes and quality of life amongst Somerset residents by identifying individuals at an earlier stage of vascular change and provide opportunities to empower them to substantially reduce their risk of cardiovascular morbidity or mortality. In turn this will lead to a reduction in the incidence of acute cardiovascular events in the Somerset population.

2.3 Service Objectives

The Service is designed to meet the following objectives:

- 2.3.1 Ensure the provider identifies and invites people who are eligible for an NHS Health Check during the period of this agreement. This will include use of the NHS Digital list of people aged 40 to 74 in Somerset as well as utilising other means such as social media to raise awareness of the NHS Health Check offer.
- 2.3.2 Maximize the reach and take-up of the NHS Health Check offer within the confines of the resources of this contract.



- 2.3.3 Ensure that the most appropriate mix of invitation methods are used to encourage take-up of the programme and, in particular increase uptake amongst relatively deprived and hard-to-reach groups.
- 2.3.4 Utilise social media to increase awareness of the NHS Health Check programme and encourage take-up of the offer of an NHS Health Check.
- 2.3.5 Optimise uptake of NHS Health Checks by:
 - providing an accessible service for working individuals by offering appointment times which include evening and weekend appointments.
 - utilising a range of delivery channels and venues such as subcontracting arrangements with GPs and pharmacies as well as outreach delivery at workplaces and community locations.
 - offering appointments in a range of venues which maximise uptake and are available at times which suit a 24/7 lifestyle.
- 2.3.6 Assess the specific health risks of the eligible population following an initial assessment of CVD risk based on QRisk2 score or when a new risk assessment tool is published by the national NHS Health Check team and in agreement with the commissioner.
- 2.3.7 Communicate CVD risk using QRisk2 and Heart Age scores, offer lifestyle advice, signpost to local lifestyle service as appropriate and discuss any recommendation for further clinical investigation. Those who receive a check understand the link between lifestyle behaviours and cardiovascular disease and the steps they can take to reduce their risk are clearly identified.
- 2.3.8 At the end of the appointment, individuals are to be given a copy of the results of each element of their NHS Health Check which includes lifestyle advice discussed, agreed signposting to support services and any recommendation for follow-up with their GP.
- 2.3.9 Where abnormal parameters are identified during the assessment, the assessor must indicate within the results forwarded to the GP that a referral is recommended/required and highlight the reason. The assessor must have discussed with the client that a referral to their GP has been recommended/requested for further investigation.
- 2.3.10 The client felt that they had been treated with respect and were able to ask questions about any aspect of the NHS Health Check assessment they did not understand.
- 2.3.11 Notify the person's GP of the complete results of their NHS Health Check including the relevant clinical codes. Indicate if the person has



- been signposted to a lifestyle support service(s) and if they have been advised to see their GP for further clinical investigation.
- 2.3.12 The individual's results are to be electronically transmitted to the GP via an approved communication method (such as the pathology EDT system) to allow the clinically coded results to be automatically added to the patient record.
- 2.3.13 Target carers (unpaid) for an NHS Health Check. Carers have been identified as a group with a particularly high risk of developing CVD. This risk is highlighted in The Survey of Carers in Households 2009/10, commissioned by the Department of Health.
- 2.3.14 Improve the take-up of NHS Health Check by men who are less likely to have an NHS Health Check but are likely to have a higher CVD risk. This risk was highlighted by the Men's Health Forum in that:
 - 1 man in 5 dies before the age of 65,
 - 2 men in 5 die before the age of 75
- 2.3.15 Recall eligible individuals for an NHS Health Check every 5 years.

2.4 Service Outcomes

Outcomes for this Service are guided by the national <u>NHS Health Check</u> programme as well as the <u>Improving Lives in Somerset Strategy 2019-2028</u>. Specific outcomes for the NHS Health Check are:

- To enable the early detection of hypertension
- To enable the prevention and early detection of diabetes
- To enable the early detection of chronic kidney disease
- To identify individuals with a high risk of future cardiovascular disease
- To reduce smoking prevalence in the adult population
- To identify level of potentially harmful drinking
- To increase population level awareness of dementia
- To increase population level awareness of the importance of regular physical activity and healthy eating
- To explain the results of an NHS Health Check to individuals which clarifies their current risk and identifies new behaviours which they could adopt to reduce their risk
- To signpost and encourage participation in local support services, or independent activities to encourage behaviour change



3 Service Description and Care Pathway

3.1 Invitation Process

- 3.1.1 NHS Health Checks is a 5-year call/recall programme, therefore a maximum of 20% of the <u>eligible population</u> (approximately 34,000 people) should receive an invitation for an NHS Health Check each year. A range of approaches are to be used to provide the Somerset NHS Health Check offer that deliver a flexible and targeted distribution of invites across different groups such as by age, gender, district and areas of greatest deprivation. These must include at a minimum:
 - Mailing invitation letters utilising the contact list generated for Somerset County Council by NHS Digital. This is a list of approximately 270,000 people (eligible and ineligible) aged 40 to 74 who are registered with a Somerset GP Practice. A maximum of 20% of the people on the NHS Digital list should be offered an NHS Health Check each year.
 - Collaboration with a wide range of local organisations and businesses to deliver NHS Health Checks at community venues and workplaces.
 - Utilisation of social media to promote the NHS Health Check programme to the public where those who are eligible can selfrefer.
 - The NHS Health Check offer may also be made by telephone call, email, text or other means as appropriate. Where the NHS Health Check is delivered opportunistically this is to be counted as an opportunistic invite.
 - Maintenance of the Somerset NHS Health Check website to provide information on the NHS Health Check, the location of delivering venues with booking details as well as information on lifestyle support services for after the NHS Health Check.
 - 3.1.2 Invitations made should be proportional:
 - across all Somerset districts: Mendip, Sedgemoor, South Somerset and Taunton Deane and West Somerset. For the purposes of evaluating the invitation reach, Taunton Deane and West Somerset will be considered as separate districts.
 - The invitation should be proportional across men and women (50/50), with targeted messaging to improve take-up of the offer by men.



- The invitation should be in a form that encourages increased take-up in areas of greatest deprivation.
- 3.1.3 If there is no take-up of the initial offer of an NHS Health Check, a second (follow-up) offer of an appointment is to be given within 3 months of the initial offer.
- 3.1.4 A record is to be kept of the date and outcome of all invitations for an NHS Health Check as follows:
 - Initial invitation and form of invite (ie letter, telephone, text or opportunistic)
 - Follow-up invitation(s) (if initial invite not taken up)
 - Date of completed NHS Health Check
 - Date and reason if NHS Health Check is refused
 - Date of DNA if individual failed to attend booked appointment where outreach checks are delivered and DNA's for subcontracted delivery where possible.
- 3.1.5 All invitations and promotional activity must include reference to the Somerset NHS Health Check website to include information on locations where NHS Health Checks are delivered including with options available to book an appointment including on-line booking.

3.2 Eligibility criteria

To be eligible for an NHS Health Check, the individual must be registered with a GP Practice in Somerset or be a Somerset resident and is aged between 40 and 74 years (inclusive). In addition:

- the individual must **NOT** have been diagnosed by their GP with one of the following conditions:
 - diabetes
 - o CHD
 - heart failure
 - atrial fibrillation
 - hypertension
 - stroke/TIA
 - o renal disease (stages 3 to 5) / CKD
 - o familial hypercholesterolaemia
 - Peripheral Arterial Disease (PAD)
- the individual is also excluded if they:
 - are on statins



- o are on the palliative care register
- o have received an NHS Health Check in the last 5 years

3.3 Somerset NHS Health Check Assessment

The NHS Health Check is a face-to-face risk assessment, carried out in a setting or an area which allows for a private conversation. The appointment must run for a minimum of 20 minutes to ensure individuals are fully risk assessed and provided with lifestyle information and support, and recommended follow-up where appropriate.

- 3.3.1 The Somerset NHS Health Check assessment is to be delivered utilising a web-based application that can also be used in an offline mode. This application must:
 - Present a series of forms to guide the delivery staff through the assessment that ensures a systematic, complete and accurate NHS Health Check is undertaken regardless of where the NHS Health Check is delivered or by whom.
 - Include within the forms (where appropriate) contextual information to aid delivery staff in their discussions about the assessment.
 - Include fields within the forms to record the result of each element of the NHS Health Check and provide a verification check for possible anomalous results.
 - Produce consistent lifestyle advice messages and signposting based on a set of criteria for each element of the NHS Health Check as agreed with the commissioner.
 - Generate the results of the NHS Health Check (either as a print out or electronic copy) at the end of each assessment, including what a healthy reading would be, advice provided and any recommendation for lifestyle follow-up or GP referral.

Operational and hosting requirements for this application are outlined in Sections 5.6 and 5.7.

- 3.3.2 The Somerset NHS Health Check Service must include the following elements all undertaken at the time of the NHS Health Check appointment:
 - 1. Age
 - 2. Gender
 - 3. Ethnicity



- 4. Smoking status
- 5. Family history of coronary heart disease
- 6. Chest and/or calf pain on exertion Somerset programme
- 7. Blood pressure, systolic (SBP) and diastolic (DBP)
- 8. Pulse rhythm (irregular pulse / AF)
- 9. Body mass index (height and weight)
- 10. Waist circumference Somerset programme
- 11. General practitioner physical activity questionnaire (GPPAQ)
- 12. Alcohol risk assessment (use AUDIT-C or FAST. If >3 then full AUDIT score)
- 13. Non-fasting cholesterol test: total cholesterol, HDL cholesterol and total/HDL ratio (point of care)
- 14. Dementia awareness for all ages (40 to 74) *Somerset programme*
- 15. The Somerset programme also includes a Falls Risk Assessment (FRAT), mental well-being assessment, when last seen by GP and family history of CVD
- 16. Diabetes assessment using a validated type 2 diabetes risk assessment tool or the diabetes filter as described in the NHS Health Check Best Practice Guidance. Where the diabetes risk threshold is triggered:
 - Provider's community outreach staff are to complete and record an HbA1c test.
 - Provider's sub-contractors are to complete and record a non-fasting glucose test.
- 17. Cardiovascular risk score: a score relating to the person's risk of having a cardiovascular event during the ten years following the NHS Health Check, derived using an appropriate risk engine (ie QRisk2) that will predict cardiovascular risk
- 18. Heart Age result (for comparison against chronological age)
- 3.3.3 Non-fasting cholesterol blood test and glucose test (where the diabetes threshold has been triggered) are to be completed during the NHS Health Check assessment using approved Point of Care Test equipment as referenced below in Section 5.3 Point of Care Testing Protocol.
- 3.3.4 A full list of NHS Health Check elements to be recorded at the time of the assessment is given in Appendix G. The full dataset is to include the



associated read codes. The dataset may be amended to reflect changes to national and/or local requirements.

3.4 Lifestyle Advice

- 3.4.1 Individuals receiving an NHS Health Check must be given adequate time to ask questions and obtain further information about their risk and results.
- 3.4.2 Individuals are to receive a report of their assessment either as a printout or an electronic copy. This report must include personalised feedback to include the results of the risk assessment which incorporates:
 - all readings recorded during the assessment including the risk assessment score (currently QRisk2) and Heart Age with an explanation of the meaning of both.
 - agreement on lifestyle changes (as appropriate),
 - recommendation on referral to lifestyle support services (as appropriate) to include individual's agreement or rejection of the referral(s); and
 - referral to individual's registered GP with an explanation for the reason for the referral.
- 3.4.3 Information on maintaining/adopting a healthy lifestyle is to include leaflets or links to the appropriate websites
 - Healthy Living for Strong Bones leaflet (National Osteoporosis Society).
 - Vascular Dementia leaflet (National NHS Health Check leaflet).
 - Any other relevant literature or links to websites to support lifestyle change or to support Public Health messages.
- 3.4.4 Discussion and joint agreement on initial improvements to lifestyle.
- 3.4.5 Signposting to local services to support lifestyle changes. Local services will be identified by commissioner
- 3.4.6 Referral to individuals registered GP for further investigation:
 - Where the need for a referral to the GP has been identified, the results forwarded to the GP must include notification of the reason for the referral; and
 - The need for referral to the GP must be explained to the client with confirmation that they understand the reason for the referral.



3.5 Reporting NHS Health Check Results

Results of the NHS Health Check assessment including outcome of any self-management agreement, signposting to support service(s) and referral to GP are to be handled as follows:

- A complete copy of the results is to be given to the individual (either as a print out or as an electronic copy) at the end of the appointment.
- Confirm with the client that the results of their NHS Health Check will be returned to their registered GP within 4 working days of the appointment when the risk assessment is conducted outside of the individual's GP practice.
- A copy of the result of the NHS Health Check is to be forwarded to the individual's registered GP within 4 working days of completion of the assessment. These results must:
 - include the relevant clinical codes,
 - o identify signposting to lifestyle support services, and
 - o include notation of where GP referral has been indicated.

The results are to be communicated by means of electronic data transmission (EDT) approved by the commissioner or by post if the GP Practice has not signed up to EDT.

- 3.5.1 Ensure that privacy and confidentiality is maintained in regard to the method employed to communicate the results of the risk assessment to the person receiving the NHS Health Check assessment as well as the person's GP with due regard to the Data Protection Act 2018.
- 3.5.2 A complete record of the results is to be securely stored by the provider for reporting purposes and to respond to any possible issues that may arise relating to the NHS Health Check that was delivered. The full data flow is described more fully below in Section 5.9 Data Management.
- 3.5.3 The client is to be asked if they are willing to provide an email address to be contacted at the end of the quarter to participate in a post NHS Health Check follow-up satisfaction and lifestyle survey.

3.6 Guidelines for Managing Individual's Risk

- 3.6.1 Guidelines for assessing and managing an individual's risk are summarised below and visually presented in Table 1:
 - o **Individuals with ≥ 20% risk** are referred to their GP for further investigation and are removed from 5-year recall.
 - Individuals with ≥10 -19% risk and who have one or more lifestyle risk factors should be offered lifestyle advice, signposted to



- appropriate local lifestyle service, or encouraged to independently initiate behaviour change. Individuals are to be advised that they should follow-up with their GP if they have any concerns regarding the results and should be recalled at 5 years.
- o **Individuals with < 10% risk** should be offered general advice on maintaining a healthy lifestyle and are to be recalled at 5 years.

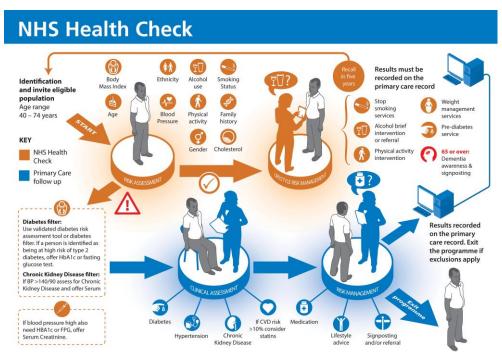


TABLE 1 – NHS Health Check Programme, Best Practice Guidance



4 Performance Measures

4.1 Public Health Outcomes Framework

Performance will be measured at a population level through:

- Take up of NHS Health Check programme by those eligible NHS Health Check offered
- Take up of NHS Health Check programme by those eligible NHS Health Check take-up

4.2 Somerset Measures

Additional Somerset performance measures include:

- Sub-contracted providers must achieve a minimum threshold of 6 NHS Health Checks delivered each month as a marker of quality.
- Delivery of NHS Health Checks are proportional to the eligible populations across the 5 district areas.
- Delivery of NHS Health Checks are proportional to the eligible populations across the quintiles of deprivation with an emphasis on meeting or exceeding delivery to people in most deprived areas, quintile 1.
- Equitable delivery of checks between men and women.
- The provider and sub-contracted providers undertake and pass regular IQC/EQA POC tests.
- Quarterly surveys of people completing an NHS Health Check to be completed and reported within 5 weeks of the quarter end. This is a quality marker of the Service delivered and therefore must achieve the following:
 - Survey responses are received from a minimum of 10% of the people who have received a NHS Health Check during the quarter to be reported.
 - Respondents indicate a ≥90% recommendation (recommend or strongly recommend) on the Friends and Family Test.
 - The number of responses to the survey should be proportional to the number of checks delivered across the delivery channels (provider outreach, sub-contracted GPs, sub-contracted pharmacies etc).
 - Additional performance measures may be specified at the discretion of the commissioner.



5 Service Requirements and Standards

5.1 Patient Confidentiality, Clinical Governance and Information Governance

In delivering the NHS Health Check programme the commissioned provider must ensure that their staff are compliant with patient confidentiality, clinical and information governance requirements and must adhere to current and future national and local programme standards to ensure the delivery of a secure, effective and high-quality service. This requirement extends to consortium arrangements and/or sub-contractors where those organisations and their staff are involved with the collection, storage or transmission of client data. This is more fully described in Sections 5.8 and 5.9.

5.2 Staff Training

- 5.2.1 The minimum standards for providers delivering the Somerset NHS Health Checks programme are described in the National NHS Health Check Competence Framework, June 2014. It describes the Core Competences and Technical Competences required to carry out an NHS Health Check. It also refers to the Code of Conduct and the Care Certificate that all people carrying out an NHS Health Check should aspire to. The Framework sets out clear competences required of providers in general practice, pharmacy, commercial and other settings, with an enhanced focus on behaviour change skills for better health outcomes.
- 5.2.2 **Core Competences:** All individuals delivering the NHS Health Check must be able to demonstrate competence against the following Core Competences:
 - 1. Personal development
 - 2. Effective communication
 - 3. Equality, diversity and inclusion
 - 4. Duty of care
 - 5. Safeguarding
 - 6. Person-centred care and support
 - 7. Handling information
 - 8. Infection prevention and control
 - 9. Health and safety
 - 10. Moving and assisting



Staff can achieve the Core Competences by being assessed either against a National Occupational Standard (NOS) or via a qualification unit that is based upon the NOS.

5.2.3 <u>Technical Competences:</u> In addition to the Core Competences, people carrying out an NHS Health Check should be able to carry out an identified range of Technical Competences as follows:

Competences		National Occupational Standards	Page
1	Programme knowledge	CHS227	13
2	Information governance	N/A - ref NHS Health Check IG data	14
		flow pack	
3	Invitation	<u>CHS167</u>	15
4	Client consent	<u>CHS167</u>	17
5	Risk assessment	CVD EF3	18
		GEN77	
		CHS217	
6	Interpreting results	CHS19	20
7	Communication of risk	CHS45	21
8	Consent to share data	CHS167	22
9	Brief intervention/	HT2	23
	signposting/referral	SCDHSC0026	
10	Communication with GP	CHS221	25

NHS Health Check technical competence overview

- 5.2.4 The technical competences and their underpinning criteria should be used to identify the training requirements for those who will be involved in the delivery of the NHS Health Check programme. It should be noted that the skills/standards for delivering the NHS Health Check are not confused with the diagnostic tests that are taken following onward referral of at-risk clients. Clinical follow-up is the responsibility of the appropriate clinician such as the client's GP.
- 5.2.5 The staff delivering the NHS Health Check must be competent in collecting, communicating and recording the NHS Health Check results and risk score, and understand the variables used by the risk engine to calculate the risk score. In summary, staff will be able to:
 - Competently and efficiently undertake and record all elements of Somerset's NHS Health Check Programme as described in Section 3 Service Description & Care Pathway.



- Explain and discuss the results of the NHS Health Check, including the cardiovascular risk score and Heart Age, with each person. This communication will be face-to-face and tailored to the individual to maximise their understanding.
- Communicate risk in everyday, jargon-free language so that individuals understand their level of risk and what changes they can make to reduce their risk.
- Use behaviour change techniques (such as motivational interviewing and goal setting) to deliver appropriate lifestyle advice and how it can reduce their risk.
- Create a two-way dialogue to explore individual values and beliefs to facilitate a client-centred risk-reduction plan.
- Signpost or refer to local support services and/or GP as appropriate
- 5.2.6 All staff delivering NHS Health Checks will have attained the required level of competency as outlined above as well as comply with any future requirements issued by the National NHS Health Check programme on workforce competencies.
- 5.2.7 All staff delivering NHS Health Checks will adhere to the patient confidentiality and information governance requirements outlined in Section 5.8 Information Governance.

5.3 Point of Care Testing (POCT) Requirements

- 5.3.1 The provider and all sub-contracted providers are to undertake:
 - non-fasting blood tests for cholesterol (total cholesterol, HDL cholesterol and total/HDL cholesterol ratio)
 - glucose test when the diabetes filter (or other diabetes threshold approved by the commissioner) is met. This test will be at a minimum an HbA1c for community outreach NHS Health Checks and a non-fasting random glucose test for sub-contracted providers.
- 5.3.2 These tests are to be completed at the time of the NHS Health Check appointment using Point of Care Test (POCT) equipment as follows:
 - POCT device used must be capable of performing to an analytical specification for the use that the measurement is intended.
 - Use of POCT equipment must adhere to:
 - Medicines and Healthcare Regulatory products Agency (MHRA) guidelines on <u>Management and Use of IVD Point of Care Test Devices</u>
 - o Public Health England's <u>NHS Health Check programme standards</u>.



- POCT equipment used must be enrolled in a nationally approved Internal Quality Control (IQC) and External Quality Assurance (EQA) programmes.
- Staff using POCT must be trained in correct use of the equipment (as
 directed by the manufacturer) and comply with the quality control and
 reporting requirements as described in the Standard Operating Procedures
 (SOP) developed by the Provider. Provider to agree SOP with the
 commissioner.
- All IQC and EQA results, faults, repairs and maintenance must be documented and held by the provider of the NHS Health Checks Service.
- Adverse incidents involving medical devices will be reported to the manufacturer, the MHRA and to the commissioner.
- Consumables, IQC, EQA and overall responsibility for the POCT device remain with the provider.
- The provider will report monthly to the commissioner on the results of IQC and EQA.

5.4 Other Medical Device Requirements

The provider and all sub-contracted providers must ensure all equipment used for the NHS Health Check is: fully functional, used regularly, CE marked, validated, maintained and is recalibrated according to the manufacturer's instructions. This includes height and weight measuring devices and blood pressure monitors. Where appropriate, it should also be checked that devices are compliant with the Medicines and Healthcare products Regulatory Agency (MHRA)requirements.

The provider should familiarise themselves with and ensure compliance to:

- <u>Medical devices regulation and safety</u>. Medicines and Healthcare products Regulatory Agency (MHRA). March 2017
- Blood pressure measurement devices, MHRA. December 2013

5.5 Marketing & Promotion

- 5.5.1 The provider is to undertake marketing and promotional activity that is wide ranging to maximise awareness of the programme. This promotional activity should be in a format that will appeal to different targeted populations and which is designed to improve take-up of the offer especially amongst men and the harder to reach population.
- 5.5.2 The provider is responsible for the management of the invitation contact list from NHS Digital of the population aged 40 to 74 who are



- registered with a Somerset GP (approximately 270,000 names and addresses).
- 5.5.3 This list will be used to issue the initial invite, follow-up invites as appropriate and to identify those people eligible to be recalled for an NHS Health Check in 5-years. To achieve this each contact on the list is to have a date record of the initial invite, follow-up invite (as appropriate) and the date an NHS Health Check was completed. This will be used to support insight into take-up of the NHS Health Check offer.
 - 5.5.4 In managing and using the NHS Digital List, the provider is bound by the Information Governance and Data Management requirements as described in Sections 5.8 and 5.9 below and any future requirements.
 - 5.5.5 The NHS Digital List will need to be refreshed at a minimum of every 6 months to ensure the most up to date contacts are used. The cost of the refresh will be borne by the provider.
 - 5.5.6 At the contract end the provider will transfer the up to date NHS Digital List to a specified organisation, in a suitable format as directed by the commissioner. Upon the satisfactory completion of the transfer and on written confirmation from the commissioner, the provider will remove this list and all associated records from their systems.
- 5.5.7 The provider is to develop and maintain a website for the Somerset NHS Health Check programme to include (but not limited to):
 - Information about the programme
 - Eligibility criteria
 - Locations in Somerset where NHS Health Checks are delivered.
 This should include the capability for people to book an appointment on-line.
 - Information on lifestyle support with links to websites with additional lifestyle information as agreed with the commissioner.
 - A blog on achieving and maintaining a healthy lifestyle.
- 5.5.8 The provider is to maintain a social media presence to raise awareness of the Somerset NHS Health Check programme that links to the website.
- 5.5.9 All marketing and promotional material (including form letters and leaflets) must be approved by the commissioner prior to dissemination.



5.6 Software Application Operational Requirements

The provider must utilise a web-based application to deliver the Somerset NHS Health Checks programme. The key elements of this are that the application:

- 5.6.1 Is structured to deliver a complete and systematic Somerset NHS Health Check to ensure consistency of the NHS Health Check delivered regardless of who delivers it or where it is delivered.
- 5.6.2 Includes a screen by screen view for each element of the NHS Health Check being assessed, which includes fields to record the results of the assessment as well as contextual information to aid delivery staff in their discussions about the assessment.
- 5.6.3 Produces consistent lifestyle advice messages and signposting based on a set of criteria for each element of the NHS Health Check as agreed with the commissioner.
- 5.6.4 Can be used by any sub-contracted service provider as well as the provider's delivery staff to ensure each element of the NHS Health Check is delivered in a consistent and systematic way regardless of who delivers the assessment or where it is delivered.
- 5.6.5 Has an offline capability, so NHS Health Checks can be delivered by the outreach staff in communities where there is limited or no internet access and with the capability to upload results later when a connection is available.
- 5.6.6 Delivers real-time commissioner reports of completed NHS Health Check assessments through a range of on-line, date searchable reports to include but are not limited to:
 - Summary of number of NHS Health Checks completed by the delivering venue, by the client's registered GP practices.
 - The detailed results of each check completed (anonymised)
 - The detail of the NHS Health Checks that are terminated early due to very high readings such as blood pressure.
- 5.6.7 The results of the NHS Health Check are sent securely to the client's registered GP. Results to be downloaded to the patient record are to be sent via electronic data transmission. This is currently completed using the pathology reporting system.
- 5.6.8 The complete set of results must be securely stored. At the end of the contract the provider will transfer the complete set of records to a specified organisation, in a suitable format as directed by the commissioner. Upon the satisfactory completion of the transfer and on



- written confirmation from the commissioner, the provider will remove these NHS Health Check results and all associated records from their systems.
- 5.6.9 The application must have the capability to be easily updated when changes to national or local requirements dictate.

5.7 Software Application Hosting Requirements

Somerset County Council requires a Software-as-a-Service (SaaS) solution; hosted and fully managed by the provider or sub-contracted by the provider. Any obligations identified below would also apply to any sub-contractor of this solution.

- 5.7.1 The on-line system must be browser-based, browser and operating system independent and install no software on local machines.
- 5.7.2 The off-line system should be built primarily for the operating system used by the provider's outreach delivery staff, that the data is appropriately secured and then deleted once it has been uploaded to the central system.
- 5.7.3 Evidence to be provided, including Certificates where requested
- 5.7.4 The solution must be hosted in a tier 3 data centre and provide:
 - Compliance with the 14 Cloud Security Principles: https://www.ncsc.gov.uk/guidance/implementing-cloud-security-principles
 - Full Disaster Recovery
 - o Recovery Point Objective (RPO) 1 hour
 - Recovery Time Objective (RTO) 4 hours
 - ISO 27001 Certified or equivalent
 - ISO 9001 Certified or equivalent

5.8 Information Governance

- 5.8.1 In delivering this Service, the provider will comply with all current and future relevant legislation, regulations and statutory circulars which are applicable to the services provided. These include but are not restricted to:
 - The Equality Act 2010
 - Data Protection Act 2018
 - General Data Protection Regulation (GDPR)
 - The Client Access to Personal Files Act (1987)
 - Employment Law and Relevant EU Legislation



- Freedom of Information Act 2000
- Caldicott Committee Report 1997
- Computer Misuse Act 1990
- Human Rights Act 1998
- Access to Public Health Records Act 1990
- Open Database Connectivity standards
- e-Government Interoperability Framework (eGIF) standards
- 5.8.2 Systems used to collect, store or transmit client data will be required to fully comply with all Somerset County Council information governance policies.

 These include but are not limited to the following policies.
 - Data Protection Policy
 - Acceptable Use Policy
 - Information Control and Compliance Policy
 - Records Management Policy
 - Information Transparency Policy
 - Legal Responsibility Policy
- 5.8.3 The Somerset County Council Caldicott Guardian or Guardians must be assured of the data security arrangements for the collection, storage and transmission of client data.
- 5.8.4 Under the NHS Code of Practice for Health and Social Care 2016, patient identifiable client records must be held for a minimum period of 8 years. At the end of the contracted period (or in the event of the agreement being terminated early) **ALL** NHS Health Check data related to this Service and held by the provider or held by any organisation sub-contracted by the provider, must be securely transferred to any new service provider or organisation as directed by the commissioner, in a format acceptable to the receiving organisation. Upon written notification from the commissioner that the data has been satisfactorily transferred the provider, and any organisation they have sub-contracted with, will remove ALL Somerset NHS Health Check data from their systems.
- 5.8.5 Patient identifiable data (PID) can only be held for as long as it is required. The provider must therefore be able to safely, securely and completely remove **ALL** Somerset NHS Health Check data related to this Service from all systems where this data is held, including data held by sub-contracted organisations, at the end of the contract as directed by the commissioner.



- 5.8.6 In the event of a data breach the commissioner must be immediately informed. All staff dealing with the collection, storage or transmission of client data (whether as part of a consortium arrangement or as a sub-contractor) should report any incidents or suspected incidents immediately. All incidents that result in the unauthorised disclosure of personal or sensitive data must be reported to the provider's Information Governance Manager who may inform the Information Commissioner's Office (ICO). The commissioner will inform the Somerset County Council Information Governance Manager when notified.
- 5.8.7 It will be expected that any organisation delivering the Service will abide by and comply with these policies and have parallel policies in place within their organisation. The provider has the responsibility to ensure that any consortium or sub-contractor delivering any part of this Service on behalf of the provider is compliant with and abides by these policies.
- 5.8.7.1 For the purposes of this contract the successful provider will need to comply with the responsibilities of a data processor as defined in Article 28 of the General Data Protection Regulation. The provider/processor shall not engage another processor without prior specific written authorisation of the commissioner as the data controller.

5.9 Data Management

- 5.9.1 Privacy and Confidentiality will be maintained throughout the commissioning process, with due regard to the Data Protection Act 2018.
- 5.9.2 All data processors must meet the standards of the NHS Digital Data Security and Protection Toolkit. The Toolkit is an online system which allows NHS organisations and partners to assess themselves against Department of Health Information Governance policies and standards. The Toolkit contains a number of requirements which vary according to the type of organisation using the Toolkit.
- 5.9.3 The three main data flows for the NHS Health Check are:
 - 1. Identifying and inviting the eligible population.
 - 2. Reporting of the anonymised NHS Health Check results to the commissioner for performance monitoring, evaluation and quality assurance.



- 3. Results of all completed checks are forwarded to the individuals registered GP.
- 5.9.4 The provider as the data processor will be contractually bound to:
 - Only use the patient contact data for the purposes of inviting patients for an NHS Health Check
 - Retain data for the duration of the contract to perform their contractual function and any necessary follow up, and to dispose of the data as directed by the commissioner.
 - Otherwise process data in line with the Data Protection Act 2018.

5.10 Quality Standards

- 5.10.1 To achieve a high standard of care, review and risk assess local pathways against national guidance and standards, the provider will:
 - Work with the commissioner to develop, implement and maintain appropriate risk reduction measures
 - Provide agreed performance data and evidence of quality to the commissioner at agreed intervals
 - Review implementation routinely through audit and ensure appropriate staff training for delivery of the programme. To audit practice, the Service should seek the views of patients who attend for an NHS Health Check; asking their experience of, and satisfaction with the NHS Health Check together with suggestions for service improvement
 - Ensure appropriate links are made with internal governance arrangements, such as risk registers
 - Must ensure they meet the Equality Act 2010 requirements by ensuring reasonable adjustments are made for disabled people, those with sight or hearing impediment, learning disability and whose first language is not English. Community venues need to be fit for purpose and have the equipment needed to conduct an NHS Health Check.
 - The provider must ensure that the NHS Health Check Service they deliver adheres to all relevant current and future national and local guidelines and standards.
- 5.10.2 The provider will complete and submit to the commissioner the Contract Management Quarterly Review Form and associated



documentation as set out in section 5.17 within 3 weeks of the end of each quarter. The provider will meet with the commissioner within 5 weeks of the end of the quarter to review the performance of the contract and present future plans for the Service.

5.11 Service User Feedback

Comments, compliments and complaints collectively generate service user feedback which is important in helping to maintain, improve and develop services. Through the Contract Review process, the commissioner is to be notified of all user feedback and actions taken by the provider to resolve any complaints received. If a complaint is serious in nature or cannot be resolved to the satisfaction of the user, the details of the complaint and actions taken are to be forwarded to the commissioner to investigate.

5.12 Reporting Incidents

- 5.12.1 The aim is to ensure timely notification of Incidents occurring within Public Health commissioned services and a co-ordinated response to both the investigation and sharing of learning, when incidents occur within Public Health or NHS Services.
- 5.12.2 The provider must immediately notify the commissioner when they are notified of, or suspect, that an incident related to the delivery of the Service has occurred. The commissioner will initiate an incident reporting system to confirm the nature and extent of the incident, agree the actions to be taken by the provider to resolve the incident and to incorporate any lessons learned into the delivery of the Service.

5.13 Reducing barriers

In addition to the requirements within the main body of the contract, the Service will contribute to reducing barriers to access by:

- Ensuring client's personal circumstances are taken into consideration when arranging appointments.
- Ensuring premises from which the Service is offered are compliant with disability discrimination law.



 Ensuring that all clients receive a welcoming and friendly reception on attending the Service.

5.14 Reducing inequalities

The Service will contribute to reducing inequalities by:

- Providing a welcoming responsive service to all.
- Offering service information in a range of formats and languages.
- Promoting the use of interpreting services where required.
- Undertaking with commissioners mapping exercises to monitor the demography of clients, where the Service is delivered and the degree to which particular groups of clients are engaging or not engaging with the Service.
- Undertaking targeted promotional campaigns to client groups not considered to be engaging with the Service.

5.15 Infection Control

The Service will be delivered in accordance with all relevant national or local infection control procedures, in particular the application of:

- The Health and Social Care Act 2008: code of practice on the prevention and control of infections.
- NICE CG139: Healthcare-associated infections: prevention and control in primary and community care, with attention given to:
 - Hand decontamination
 - Use of personal protective equipment
 - Safe use and disposal of sharps

5.16 Interdependencies with Other Services

The provider will not work in isolation but must work in collaboration with commissioners and partners to ensure that:

- the needs of the service user are met.
- a positive experience of the Service is achieved, and
- service outcomes are attained.

The provider shall develop positive working partnerships to facilitate integrated working with the following organisation in order to increase signposting and / or referrals (this is not an exhaustive list):

• Somerset GP practices and staff



- Somerset pharmacies
- Somerset County Council
- District Councils
- Community health and social care services
- Health promotion and behaviour change services
- Leisure, sport and exercise providers
- Somerset Stop Smoking Service
- Somerset Drug and Alcohol Programme

5.17 Reports to Commissioner

- 5.17.1 The contracted organisation will provide the commissioner with access in real-time to the following data, which includes the capability to specify date ranges for activity review:
 - Summary of the number of checks completed by each delivering sub-contractor or by community venue if outreach checks and by the client's registered GP practice.
 - A complete set of pseudonymised data collected for each check delivered. An outline of this dataset is given in Appendix G - NHSHC Data Elements To Be Captured.
- 5.17.2 The provider organisation will also provide the commissioner with the following data within three weeks of the end of each quarter which indicates by each delivery channel (ie GP, pharmacy, outreach etc), the number of people who:
 - Were invited for an NHS Health Check.
 - Took up the offer of an NHS Health Check.
 - Agreed to be contacted in 3 months to participate in an on-line, post-NHS Health Check follow-up survey (and also provided an email address).

5.17.3 Client Feedback Survey

The provider organisation will develop (in conjunction with the commissioner) an on-line, post-NHS Health Check survey to be undertaken quarterly and will provide the commissioner with the following results of the survey:

 The number of people who received an NHS Health Check for the period being surveyed.



- The number of people who agreed to participate in the follow-up survey for the period being surveyed and provided an email address.
- The number of people who completed the on-line survey.
- A summary of the results of the survey
- The detail of the survey results including all feedback provided by the respondents.

5.17.4 Quarterly Contract Review Reports

The provider will meet with the commissioner within 4 weeks of the end of each quarter. The provider will complete the following templates and forward to the commissioner at least 1 week prior to the scheduled contract review:

- Contract Management Review Form (Appendix F)
- Appendix A Accreditation and Policies
- Appendix B Finance Template
- o Appendix C Incident Form
- Appendix D Staff Training
- Appendix E Lessons Learnt Log
- IQC/EQA results for POCT equipment
- o Quarterly Key Performance Indicators are as follows:
 - Percentage of Checks offered
 - Percentage of Checks delivered and take-up rate
 - Number of venues where Checks were delivered
 - Proportion of Checks delivered by deprivation quintiles
 - Proportion of checks completed by delivery channel across deprivation quintiles
 - Proportion of checks completed by delivery channel
 - Proportion of checks delivered across 5 Somerset districts
 - Client satisfaction survey results
- The provider will present to the commissioner a review of the past quarter which includes performance against forecasted activity, forecast for current and future quarters and service development plans.

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Additional performance reports and/or amendments to the Key Performance Indicators may be specified by the commissioner.



6 Appendices

Appendix A	Accreditations and Policies	Appendix A - Accreditations and F
Appendix B	Finance Template	Appendix B - Finance Template.xls
Appendix C	Incident Form	Appendix C- Incident form.docx
Appendix D	Staff Training	Appendix D - Staff training.xlsx
Appendix E	Lessons Learnt Log	Appendix E - Lessons Learnt Log.)
Appendix F	Contract Management Review Form - Quarterly	Appendix F - Contract Manageme
Appendix G	NHSHC Data Elements to be Captured	Appendix G NHSHC Data Elements to be