Public Health England

Protecting and improving the nation's health

NHS Health Check content review

Feasibility study on using a validated risk assessment score for the diabetes filter

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Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

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Executive summary

The accuracy of identifying people who might be at high risk of diabetes is improved by using a validated risk score and this is the approach advised in NICE guidance.[1] The current filter used in the NHS Health Check programme to determine who should have a blood test to check for diabetes is not validated. It is also known to miss about one third of people at high risk of diabetes and over-include people who are offered a blood test for diabetes who are subsequently found not to have diabetes or impaired glucose regulation. This feasibility study therefore assesses the benefits, costs and risks that would be involved in replacing the current simple filter based on BMI and hypertension with a validated diabetes risk tool.

The purpose of assessing diabetes risk within the NHS Health Check is to identify individuals who should receive a second stage blood test for diabetes. By identifying the group who are at high risk of diabetes, for whom it would be cost-effective to provide lifestyle and therapeutic interventions, it it is possible to delay the onset of diabetes and its micro and macro-vascular complications in a substantial proportion of them. Any change to the current diabetes filter, in addition to being operationally and financially feasible, would need to show an improvement in the primary outcome of identifying those at risk for whom intensive lifestyle interventions are beneficial.

However, what seems initially to be a straight forward issue of operational and financial feasibility of a small content change is complicated by issues of effectiveness of the proposed change. This is because type 2 diabetes is now recognised as a group of disorders of glucose metabolism with different pre-cursor states depending on the criteria and method of diagnosis, rather than being a single disease entity. Overlap between the types of disorder of glucose metabolism is only around one third, though each disorder leads to the same complications but at different rates for different gender and ethnic groups. Knowing which type of defined disorder of glucose metabolism the NHS Health Check filter is predominantly picking up and which pre-cursor state is important to ensure that the primary aims of preventing macro-vascular and micro-vascular complications are maximised. The validated diabetes risk assessment tools referred to in the NICE guidance predict different diabetes end-points and therefore will have different levels of effectiveness in achieving the primary aim of the NHS Health Check diabetes filter. Furthermore the NICE guidance[1] advises that only those identified as

[1] NICE public health guidance 38 “Preventing type 2 diabetes: risk identification and interventions for individuals at high risk”

“high risk” by the validated tools are assessed further by blood test but “high risk” is not further defined for these tools since they differ between tests and also even between research papers on the same test. Risk scores from validated risk tools are used to determine whole practice population risk stratification for diabetes as well as determining individual level risk as would be the case in the NHS Health Checks and these two purposes are sometimes confused.

The feasibility study therefore explored issues of diabetes end-points and risk levels in order to inform the decision about changing from the existing filter.

There are three validated risk scores developed for use in the UK, two of which had better test characteristics – the QDiabetes Score and the Diabetes UK/Leicester Risk Assessment Tool (DUK/LRA). These two scores were used to assess the likely costs, benefits and risks of introducing them into the NHS Health Check to replace the current filter which is based on BMI adjusted for ethnicity and presence of hypertension. NICE guidance PH 38 does not specify any particular diabetes risk assessment tool.

Operating requirements

QDiabetes requires two additional questions necessitating an additional 30 to 45 seconds within the NHS Health Check. With the Leicester Risk Assessment (LRA) score there is one additional question and an additional clinical measurement of waist circumference is required. The importance of the accuracy of measurement of waist circumference using a simple “no-touch” technique in practice needs to be determined compared to the more complex procedure used in research and could lead to mis-classification of risk. Overall for both risk assessment tools resources and time commitments to conduct the risk assessment are marginal.

Providers will also need access to a validated risk assessment tool in order to be able to calculate a diabetes risk score. This can be achieved in a number of ways: firstly, a national template integrating the risk assessment score algorithms into the four main GP information systems in England could be developed. The Qdiabetes template is already available within EMIS practice systems and it is possible to add this to the EMIS NHS Health Checks template. DUK/LRA is available on Systmone from a commercial supplier (Health Diagnostics) and the algorithm is a simple scoring system which could be incorporated into practice systems. Secondly, local providers could take action to integrate a tool into their clinical system. However, depending on the tool of choice this could lead to licensing fees nationally in the region of £20,000 per annum. Thirdly, local providers could use the tools that are

freely available online. However, some providers may not be able to access the website where the free tools are hosted. Providers would also then have to navigate between the website and patient clinical record.

Benefits

Overall if the cut-off for the diabetes risk assessment tools used as part of the NHS Health Check were set at medium and high level – while noting that the interpretation of this varies for the different end-points and do not define equal groups – then:

- for both Qdiabetes and LRA fewer additional blood tests would be required than using the current NHS Health Check diabetes filter. There would be an estimated minimum of 10% fewer (50% to 40%, table 2) to a maximum of 17% fewer tests (55%-38%) depending on which test is used and on what population
- both risk assessment tools would increase the proportion of people found to be at risk of diabetes or impaired glucose tolerance but the way in which these risks are measured differs between the two tools and the current NHS Health Checks filter making direct comparison difficult
- for QDiabetes an additional 15% (82-67) of people at high risk of diabetes - defined as a risk of 1 in 7 of being added to a diabetes register in the next ten years - will be detected (overall risk of 14%) and 12% fewer people who don't have diabetes will be unnecessarily tested by blood test for diabetes risk
- for DUK/LRA an additional 14% of people with current diabetes or impaired glucose tolerance measured by impaired fasting glucose or impaired glucose tolerance will be identified - cut-off ≥25 means a 14% risk of having intermediate hyperglycaemia of whom 33% develop diabetes- overall estimated diabetes risk of 4% in 11 years - while 5% more people who don't have diabetes will have unnecessary blood tests to assess diabetes risk
- an estimated national saving of £1m to £3.2 m in costs of diabetes blood tests (depending on which test is used and which validated questionnaire) can be expected
- long term savings on the annual costs of care of someone with diabetes of £1300 per annum

Costs

- the addition time of the practitioner, approximately 45 seconds, to complete the additional question(s) and/or waist circumference, to record this information and calculate the risk score
- the time/funding to develop the IT infrastructure to support the operational requirements
- additional costs of intensive lifestyle interventions (around £305 per five years) for those identified with intermediate hyperglycaemia will increase by around 15% but it is a key aim of the programme to identify these people

Risks

- the key risks are political and technical. NICE guidance recommends only further testing of those at high risk on the validated risk tool but this would lead to missing more people than at present. This could be mitigated against by recommending that medium AND high risk groups are go on for further testing. However, this goes beyond existing NICE guidance
- there are confusing and complex technical issues in relation to definition of diabetes and intermediate hyperglycaemia that mean it is difficult to directly compare outcomes. This could be mitigated against through further research to evaluate the different tools against a standard end point
- there are no significant risks in relation to equality impact assessments and the introduction of a validated diabetes risk tool is likely to improve health inequalities relating to deprivation

Three options were appraised and on balance the recommendation for further consideration by the NHS Health Check expert scientific and clinical advisory panel is that a UK derived validated diabetes risk tool replaces the current filter and that individuals at medium and high risk go on to receive secondary blood tests. The full set of recommendations are summarised on page 39.

Background

Introduction

The NHS Health Check best practice guidance confirms that a diabetes filter should be used as part of the check to identify groups of people at high risk of diabetes. Whole population screening for diabetes is not cost-effective. Therefore the purpose of the diabetes filter is to: assess which people should receive a blood test for diabetes; and identify those at high risk of diabetes for whom it would be cost-effective to provide lifestyle and therapeutic interventions that would delay the onset of diabetes and its micro-vascular and in particular its macro-vascular cardio-vascular complications. Any change to the current diabetes filter, in addition to being operationally and financially feasible, would therefore need to show an improvement in the primary outcome of identifying those at risk for whom intensive lifestyle interventions are beneficial in reducing cardio-vascular disease as part of the NHS Health Check programme.

In July 2012 NICE[2] advised that adults should be assessed for their risk of diabetes using a stepped approach of a:
i) validated diabetes risk assessment score
ii) blood test for those identified at high risk to assess more accurately their future risk of diabetes

This advice was designed to apply alongside assessment of risk of diabetes within the NHS Health Check, as well as for other ages. However, it's primary aim was to identify a population-wide approach to the identification and prevention of diabetes which is defined primarily by micro-vascular risks of diabetic retinopathy, nephropathy (neuropathy is a micro-vascular complication but is not usually used to define diabetes).

The current NHS Health Check filter for diabetes is not based on a validated risk score and uses a simple filter of raised BMI (Body Mass Index) adjusted for ethnicity or high blood pressure. Validated diabetes assessment tools use some combination of an average of eight of the following risk factors;[3] sex; age; ethnicity; family history of diabetes; ever found to have high blood glucose; personal history of cardio-vascular disease; waist circumference;

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[2] NICE public health guidance 38 "Preventing type 2 diabetes: risk identification and interventions for individuals at high risk"
[3] Noble D, Mathur R, Dent T, Meads C, Greenhalgh T. Risk models and scores for type 2 diabetes: systematic review. *BMJ* 2011;343:d7163 doi: 10.1136/bmj.d7163 (Published 28 November 2011)

BMI; blood pressure; diet; medication (including steroids); smoking; physical activity.

The accuracy of correctly identifying those people who are truly at high risk of diabetes (known as the sensitivity of the test) and those who are truly not at high risk (known as the specificity of the test) is much improved by using a validated assessment tool.

However, the clarity of the previous statement is blurred to some extent by the fact that type 2 diabetes is now recognised as a group of disorders of glucose metabolism with different pre-cursor states depending on the criteria for diagnosis, rather than being a single disease entity. Knowing which type of disorder of glucose metabolism the NHS Health Checks filter is predominantly picking up and which pre-cursor state is important to ensure that the primary aims of prevention of both macro-vascular and micro-vascular complications are maximised. The validated diabetes risk assessment tools referred to in the NICE guidance predict different diabetes end points and therefore will have different levels of effectiveness in achieving the primary aim of the NHS Health Checks diabetes filter.

Furthermore the NICE guidance[4] advises that only those identified as "high risk" on the validated questionnaire are assessed further by blood test but high risk is not further defined for the questionnaires since they differ between tests that are predicting different end-points and also between papers on the same test depending on the purpose of the risk score. Risk scores from validated questionnaires are used to determine whole practice population risk stratification for diabetes as well as determining individual level risk as would be the case in the NHS Health Checks.

The current position in relation to diagnosis of diabetes and its precursor state intermediate hyperglycaemia, the preferred term for what has been called "pre-diabetes" or "Impaired Glucose Regulation", has been clarified by an International Expert Committee (IEC) in 2009 and subsequently by WHO in 2011. This included HbA1c as an additional diagnostic criteria for both the diagnosis of diabetes and intermediate hyperglycaemia. However, the overlap in the groups of people identified as having diabetes and intermediate hyperglycaemia by HbA1c and the existing criteria from an Oral Glucose Tolerance Testing is low. In the UK overlap between diagnosis by HbA1c and OGTT (either FPG or 2 hr plasma glucose) for diabetes was a

[4] NICE public health guidance 38 "Preventing type 2 diabetes: risk identification and interventions for individuals at high risk"

third for each. The two tests from the OGTT (FPG and 2hr plasma glucose) also have a low overlap and similarly with their respective pre-cursor states: impaired fasting glucose (IFG) and impaired glucose tolerance (IGT). The IEC emphasised that these measures all recognised different aspects of impaired glucose metabolism and that future longitudinal studies were needed to identify the complication rates and impact of prevention on each of these types of disorder which are all classified as “diabetes” or intermediate hyperglycaemia. These studies are beginning to come through and show that the predictive power for all is good for micro-vascular complications albeit defining different populations but vary for macro-vascular complications depending on how these are defined (mortality or incident cases)

The sensitivity of the current NHS Health Check diabetes filter has been found to be 66.8%[5] for identifying people with diabetes or with non-diabetic hyperglycaemia (sometimes referred to as pre-diabetes) meaning that a third of people at high risk of diabetes are missed; the specificity was 51%[6] meaning that the current filter only identifies correctly half of the people who are not at high risk of diabetes. In contrast the accuracy of validated tests is better than this. Using a summary measure of the ability of a test to discriminate between those with and without a disease (known as the AUC) Noble[2] has compared seven different validated tools and found that they are 22-34% better than chance (see annex A). Not included in Noble’s study is the Diabetes UK/Leicester Risk Assessment score (DUK/LRA) for diabetes that had an AUC of 0.72 meaning that it was 22% better than chance at accurately discriminating those with diabetes. The DUK/LRA tool was developed specifically for use in UK populations with mixed ethnicity, specifically Asian and is now available to the public on the Diabetes UK website[7]. NICE does not advise using any particular diabetes risk assessment tool (annex B), suggesting that each area should make its own decision about which risk score to use based on the demography of the local population. Three of the tools were developed on UK populations: DUK/LRA, QDiabetes and Cambridge Risk Score. A comparison of QDiabetes and CRS showed that Qdiabetes had better test characteristics[8] and therefore this feasibility study focusses on DUK/LRA and Qdiabetes.

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[5] Smith S; Waterall J; Burden ACF. An evaluation of the performance of the NHS Health Check programme in identifying people at high risk of developing type 2 diabetes. BMJ Open 2013;3: e002219. doi:10.1136/bmjopen-2012-002219

[6] Re-analysis of the Smith et al paper shows that specificity is 51% not 37% as reported.

[7] http://riskscore.diabetes.org.uk/type2risk/

[8] Hippesley-Cox J; Coupland C, Robson J, Sheikh A; Brindle P. Predicting risk of type 2 diabetes in England and Wales: prospective derivation and validation of QDScore. BMJ 2009; 338:b880 doi:10.1136/bmj.b880

Background and purpose of the feasibility study

Durham County Council with County Durham and Darlington NHS Foundation Trust has developed a far reaching strategy to address the identification of diabetes and those at high risk of diabetes, integrated into the NHS Health Checks (known as Check4life) and reduction of risk of diabetes via the Just Beat It programme.

As part of this approach they have worked with Health Diagnostics to integrate the Leicester Diabetes Risk Assessment tool into the NHS Health Checks assessment package that is compatible with SystmOne primary care software. This provided an opportunity to assess the costs and benefits of adding the Leicester Diabetes Score to the NHS Health Checks. As a comparison estimates of the likely impact of using the QDiabetes score have been made in this feasibility study as this has good test characteristics (AUC 0.8; 30% better than chance) and it was developed using England-wide general practice data.

Furthermore the Qdiabetes does not require any additional physical measurement while the Leicester Risk Assessment Score requires the measurement of waist circumference. The purpose of assessing the feasibility of implementing one of two risk scores is to provide a range of estimates of the likely costs and benefits and not to advise the use of one or the other or either over and above other potential candidate scores (see annex A).[9] The Cambridge Risk Score was also developed in the UK but not on a population which is ethnically diverse.

Progress to date

The proposal has now reached phase 3 – feasibility study - of the content review process for NHS Health Checks[10] having passed initial screening (phase 1) and has been welcomed for consideration by the programmes Expert Scientific and Clinical Advisory Panel (phase 2). As part of phase 2 the initial Health Equality Impact Assessment suggested that the change to a validated diabetes risk tool would most likely have a positive impact but proposed that the feasibility study should also look to identify any issues or unintended consequences that arise from its use and impact on the protected characteristic groups or inequality.

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[10]www.healthcheck.nhs.uk/commissioners_and_healthcare_professionals/programme_governance/escap/content_review_process/

Description of the proposed content change

The intention of the proposed content change is to replace the current diabetes filter which requires the practitioner to make a judgement about who to test for diabetes on the basis of BMI (adjusted for ethnicity) or raised blood pressure. Instead practitioners would use a computerised validated diabetes risk tool that considers risk factors such as sex; age; ethnicity; family history of diabetes; “ever found to have high blood glucose”; personal history of cardio-vascular disease; waist circumference; BMI; blood pressure; diet; medication (including steroids);smoking; physical activity.

Feasibility study scope – in and out

In-scope is to investigate the costs, benefits, risks and operational requirements of replacing the current diabetes filter with a validated risk tool for diabetes and producing recommendations for action to ESCAP. Out-of-scope is which validated risk tool to use; what blood test to use as follow-up and how to manage people identified at risk.

Also out-of-scope are diabetes risk stratification tools that rank the risk of individuals of developing diabetes by using routinely available data on GP information systems. This is because the scope of this study is the filter that is used within the NHS Health Check wherever they take place (within general or as part of outreach sessions) to assess which patients from assess further for risk of diabetes within the context of a comprehensive check for cardio-vascular risk.

Description of associated technology

It is helpful to support implementation by providing access to validated risk tools via the main primary care information systems EMIS, Vision and SystmOne and Microtest etc., this may be done through an embedded template. Templates are also required for outreach NHS Health Check services. Three of the validated diabetes risk assessment tools (see annex A) require clinical measurement of waist circumference which is additional to the current clinical measurement requirements for NHS Health Checks (LRA, ARIC and AUSDRISK). Other tools require clinical data from lipid profiles that are likely to be available as a result of the NHS Health Check (see annex A).

Outline of the feasibility study

Aim

To assess the costs, benefits risks and operating requirements of replacing the current NHS Health Checks diabetes filter with a validated diabetes risk score using the Leicester Diabetes Score and the Qdiabetes score as examples.

Objectives

1. To assess the training and operating requirements for using the two different validated risk tools for diabetes
2. To assess where the proposed new content falls within the current NHS Health Check care pathway
3. To determine any additional resources required:
   i) personnel time ii) management time iii) equipment
4. To report the benefits (outcomes, strategic, and operational) found within the feasibility study and extrapolate to potential national benefits
5. To understand the derivation, validation and other key differences between the two tests that may have a bearing on the recommendations of this study from a review of the literature
6. To report the costs (operating and other potential pathway costs) from the feasibility study and extrapolate to potential national costs
7. To identify risks and potential mitigations: political, economic, social: including equality impact assessment; technical
8. To provide an option appraisal and recommendations to ESCAP.

Methods

A visit to County Durham was completed to observe the use of the Leicester Risk Assessment tool in practice. Key stakeholders were interviewed about practical issues relating to implementation of the tool and any associated risks and benefits, including the practicalities of adding measurement of waist circumference to the NHS Health Checks process and the use of the computerised algorithm to determine diabetes risk. Training in the use of the tool in practice was also observed. Data from Durham Community and General Practice NHS Health Checks was analysed to determine the proportion of people requiring follow-up blood test assessment for diabetes using the current diabetes filter and the Leicester tool and the likely impact of implementation of the Leicester diabetes risk score. A desktop assessment of the likely impact of the implementation of the Qdiabetes tool was also completed.

The developers of Qdiabetes were contacted to request further analysis of the data on sensitivity and specificity of the test to enable a more direct comparison with the current filter and the LRA. Contact the developers of the LRA to understand interpretation of the test in relation to future risk. Contact both developers in relation to the current state of play regarding development of templates that could be used as part of the NHS Health Checks.

A review of the literature was completed on these two risk tools, the nature of diabetes diagnoses and cut-off points for its pre-cursor states of intermediate hyperglycaemia measured by impaired fasting glucose; impaired glucose tolerance and average glycated haemoglobin measured by HbA1c.

Study findings and implications for national roll-out

Operating requirements

Standard operating procedure

The data items required by two diabetes risk assessment tools are set out in table 1. It also identifies the operational implications for additions to the NHS Health Check if one or other were adopted into the programme.

Table 1. Comparison of data items for the QDiabetes and LRA diabetes risk tools.

Data	**Current NHS Health Checks**	**Leicester Risk Assessment tool**	**Implications of LRA for NHS Health Check procedure**	**QDiabetes**	**Implications of QDiabetes for NHS Health Check procedure**
Age	collected	required	none	required	none
Gender	collected	required	none	required	none
Ethnicity	collected	required	none	required	none
Family history of diabetes	Not collected. Only family history of CHD collected	required	Additional question about family history of diabetes	required	Additional question about family history of diabetes
BMI	collected	required	none	required	none
Ever had high blood pressure	Known as people with high blood pressure are ineligible for NHS HC	required	none	required	none
Waist circumference	Not collected though some services already measure waist circumference[11].	required	Measurement of waist circumference.	-	-
UK postcode	Collected for general records	-	-	required	
Smoking status	collected	-	-	required	
History of CHD	Ineligible so part of pre-check screen	-		required	None
Taking regular steroid tablets?	Not collected as part of NHS HC	-	-	required	An additional question about steroid tablets for outreach clinics (already on GP systems

[11] Research works. Public Health England. Understanding the implementation of NHS Health Checks. February 2013

Table 1 above shows that the additional requirements are for the:

Leicester tool

1. An additional question about family history of diabetes
2. Waist circumference (which may already be measured in some programmes)

QDiabetes

1. An additional question about family history of diabetes
2. An additional question about regular use of steroid tablets unless the check is conducted within a GP practice since the information is already recorded via the electronic prescription

Care pathway mapping

For services that provide point of care testing the diabetes questions and algorithm would need to be completed before taking blood for the lipid profile to avoid having to take additional blood for the diabetes blood test. Services that require lipid blood tests prior to the NHS Health Check could request patients to complete the QDiabetes or Leicester Risk Assessment tool on line to determine if they are high risk and need a diabetes blood test in addition or these services can request the additional diabetes blood test as an additional test after the NHS Health Check.

Management and supply requirements

The Leicester Risk Assessment tool requires a waist circumference measurement. Therefore, there would be a small amount of additional administrative time buying clinical self-securing spring loaded clinical tape measures for greater accuracy of recording for outreach clinics. GP practices should already have these tape measures. Average cost spring loaded, self-securing is £6.00; average cost of an ordinary tape measure 50p. The QDiabetes tool does not require waist circumference measurement.

Technology requirements

The NICE guidance requires the validated tool to be computerised. This means that it is more likely to be used correctly. Not all systems currently have a computerised prompt for the diabetes filter and therefore the current

approach means that some people with diabetes or intermediate hyperglycaemia ("pre-diabetes") are being missed. Audits of all those who require a follow-up blood test their management will be more straightforward with a computerised system.

The different options for integrating QDiabetes and LRA into the NHS Health Check templates are set out in the following sections.

QDiabetes

Currently QDiabetes has a template for EMIS systems which is provided free of charge[12] to licence holders with development and licence costs absorbed by EMIS. EMIS currently covers 53% of UK practices (www.emis-online.com/investors).

Important for integration of a validated diabetes risk assessment tool into the NHS Health Check is that EMIS Web contains both a template for a doctor/patient consultation as well as a batch processor.[13]

There would be two costs associated with integrating QDiabetes risk assessment tool into a primary care information system, namely licencing costs from QDiabetes and the system supplier's own development costs. QDiabetes has quoted £20,000 licencing costs to provide a national solution for all four main system suppliers. The system suppliers may decide to absorb the additional development costs as a commercial decision as they have done for QRISK 2. EMIS has already absorbed the development costs. The algorithm for QDiabetes is published as open source software linked to QDiabetes.org. This is there primarily to ensure the algorithm's transparency, and for the academic community. Use of QDiabetes.org is free for personal educational and research use only and therefore is available for use by the general public. For clinical use a licence must be obtained. Implementers are advised to use professionally supported software development kits for

[12] www.emis-online.com/risk-assessment-tool-to-help-gps-prevent-diabetes

[13] There is also a 'batch processor' tool which enables calculation of the QDiabetes score across the entire eligible practice population in the relevant age range using information already stored in the GP computer system. This enables the practice to generate a rank ordered list of patients by risk score so that priority can be given to assess those at highest risk. There is a publically accessible screencasts which gives practices instructions on how this is done and also how to use and adapt the embedded template which complement the user documentation provided by EMIS, www.emisnug.org.uk/video/running-calculation-eg-qrisk-group-patients-batch-add. emisnug.org.uk/video/adding-calculation-template-emis-web

systems in clinical use. A single national investment of £20,000 per annum licensing cost across the four information system would cover testing and accreditation of systems so that there is confidence that a QDiabetes score is the same for a given patient, no matter which system their score is calculated upon. QDiabetes is updated annually. Integration of Qdiabetes into the information system means that all relevant patient data is extracted automatically and accurately, improving workflow for the person providing the NHS Health Check.

The other option for using the QDiabetes score, pending development of a template for non-EMIS systems, would be to use the online tool. However, this may be difficult in practice as it means practitioners have to move between the patient record and the internet and because some local security settings may prohibit access to the website where the QDiabetes tool can be freely accessed: www.QDiabetes.org. This approach may be more feasible for providers delivering NHS Health Checks as part of a community outreach programme.

DUK/LRA

The scoring system for the DUK/LRA is simple and freely available online. System suppliers could therefore incorporate this into the NHS Health Check template within their systems if they chose to do so. Alternatively, local NHS Health Check providers could access the DUK/LRA scoring system online or look to build it into a clinical template to support its use during the NHS Health Check consultation rather than having to navigate between the patient record and the online tool.

Personnel requirements

Time to take a waist circumference measurement

In Durham, the time taken to measure waist circumference was less than 30 seconds using the simple practical technique of the person holding the tape measure against their belly button and turning round the tape held by the health care assistant. Time to assess waist circumference using the technique described in the research by finding the lower costal margin and the top of the anterior superior iliac crest (which can be difficult in an obese person), determining the mid-point and passing a tape measure around the person, would take slightly longer.

Since a difference of 1cm in waist circumference measurement could make a difference to which risk category people are allocated to – particularly between the cut-offs at 90cm; 99cm; 109 cm, best practice guidance should

recommend that the research technique should be used for people with measurements of 89-91; 98-100 and 108-110 cm to improve accuracy of risk allocation.

Time for the additional questions

In Durham, time for the additional question for the Leicester diabetes score on the family history of diabetes took 15 seconds. The additional time for the question on steroids for QDiabetes would take less than 15 seconds if this were part of an outreach service, otherwise this is already recorded on GP systems. Total additional time depending on which risk score was used is less than 15 seconds for tests not requiring waist circumference (QDiabetes) and up to 45 seconds for those that do require waist circumference (LRA).

Training requirements

Familiarisation with the components and scoring for the risk score can be done on-line[14,15] and takes approximately five minutes. Training in understanding the meaning of a high risk score and how to explain this to the patient also takes approximately five minutes.

Training in taking an accurate waist circumference measurement was observed to take three minutes and there is an additional on-line video demonstrating the simple no-touch technique available via the Durham Check4Life team at minute ten on the video. The definitive technique (described in the previous section) requires touching the person, takes longer and is more difficult to achieve in practice as it can be difficult to find anatomical landmarks, particularly on obese individuals, but should be taught for patients.

[14] QDiabetes www.qdscore.org/index.php

[15] Leicester Risk Assessment http://riskscore.diabetes.org.uk/2013?_ga=1.16147190.1146015646.1397722494

Benefits and costs

Benefits: feasibility study findings and predicted national benefits

Analysis of three data sets from County Durham show that:

- using the current diabetes filter 51% in the community sample would require follow-on blood tests for diabetes (table 2) compared to 38% using the Leicester score (a 26% reduction)
- using the current diabetes filter 50% in the GP sample currently require follow-on blood tests (table 3) compared to 28% (table 4) (44% reduction) using the Leicester risk assessment score

The figures in these County Durham cohorts for the proportion of people requiring follow-on blood tests are comparable to the 55% identified by the current NHS Health Checks filter in the Heart of Birmingham study by Smith et al.[16] The two figures for the GP sample are not directly comparable since the data on those requiring a follow-on blood check for diabetes using the existing filter are from the first five years of the programme; the later data for the Leicester tool are on a sample that has already filtered out all those found to be hypertensive or have diabetes from the first five years of the programme. The percentage reduction in tests is likely to be nearer that estimated in the community sample.

[16] Smith S; Waterall J; Burden ACF. An evaluation of the performance of the NHS Health Check programme in identifying people at high risk of developing type 2 diabetes. BMJ Open 2013;3:e002219. doi:10.1136/bmjopen-2012-002219

Table 2. Durham County Community Outreach NHS Health Check sample 24 months December 2011 to December 2013 comparing the numbers requiring follow-on blood test between the existing diabetes filter and high risk individuals identified by the Leicester tool.

National Quintile of deprivation 1=most deprived)	Average age	N	Number requiring diabetes blood test according to current filter[17] (%)	Number requiring diabetes blood tests if Leicester diabetes score is high >=16 cut-off point*	Difference in number of follow-on blood tests (% reduction)
1	52.4	580	240 (41)	203 (35)	37 (15)
2	52.4	601	278 (46)	230 (38)	48 (17)
3	51.0	1021	496 (49)	393 (38)	103 (21)
4	49.4	1197	660 (55)	456 (38)	204 (31)
5	46.4	874	520 (59)	347 (40)	173 (33)
Totals		4273	2194 (51)	1629 (38)	565 (26)

- Some studies describe ≥16 as moderate and ≥25 as high but the original paper determined that a cut-off point of >=16 was high risk. This equates to a 1 in 7 chance of developing diabetes in the next ten years.

Table 3. Durham County General Practice NHS Health Check original sample five years (2008-13) showing the proportion requiring follow-on blood test using the existing diabetes filter, n=95180

BMI	**SBP**	**DBP**	**Number**	**%**
>=30	-	-	30,477	32
<30	>=140	-	15,594	16
<30	<140	>=90	1,459	2
Total Diabetes risk filter	-	-	47,530	50

[17] BP >=140/90 OR BMI >=30 for white and other ethnicities except South Asians BMI>=27.5

Table 4. County Durham General Practice NHS Health Check – first 600 Check4life patients receiving the Leicester diabetes score. September to December 2014

Leicester diabetes risk score	Count	%
Low 0-6	166	28
Increased 7-15	264	44
High 16+	170	28%
Moderate high 16-24	150	25%
Very high 25-47	20	3%
Total	600	

Outcomes

To understand the likely outcomes of the change from the current diabetes filter to the use of a validated risk assessment tool it is important to understand the nature of the two diabetes risk score tools, such as the differences in the diabetes end point and how they would operate in practice.

- **QDiabetes**: assesses *future* ten-year risk of entry to a GP practice diabetes register – unknown what proportion is defined by OGTT or HbA1c but anecdotally GP registers of diabetes are thought to be defined by HbA1c
- **DUK/LRA:** assesses *prevalent* risk of being found to have intermediate diabetes or diabetes defined by OGTT
- **Current filter:** assesses *prevalent* risk of being found to have intermediate diabetes or diabetes defined by HbA1c

Table 5.1 summarises the key differences between the two main UK-based diabetes risk assessment scores. This shows strengths of both.

- **QDiabetes** is based on a large, representative sample that is regularly updated and provides an individualised risk of being added to a primary care register for diabetes within the next ten years (including missed cases of diabetes) and currently has a freely available template to the largest GP information system users (EMIS)
- the **LRA** provides a standardised diagnosis of current risk of impaired glucose regulation or current undiagnosed diabetes identified by a standardised test – the Oral Glucose Tolerance Testing. Impaired glucose regulation determined by fasting glucose and fasting glucose tolerance is the measure used in intervention studies to show that intensive lifestyle interventions can reduce progression to diabetes by 30-60% (see table 5.1)

- the **current diabetes filter** was assessed for the diabetes end point of prevalent diabetes and intermediate hyperglycaemia using HbA1c. Sensitivity for diabetes recognition alone is reasonable at 76% and for intermediate hyperglycaemia is 64%[18]

The limitations of each approach are:

- **QDiabetes**: it is unknown what diabetes outcome is represented by "entry to a primary care diabetes register". As this could be determined by HbA1c or OGTT it is not known how predictive this diabetes end point is for micro-vascular and macro-vascular complications and their preventive interventions. Anecdotally it is thought to be mainly diagnosis by HbA1c. HbA1c diagnosed diabetes are more prevalent than OGTT diagnosed diabetes and only overlaps in 33% of cases. HbA1c diabetes identifies a group with lower cardiovascular (CVD) overall risk and risk factors and are more likely to be South Asian and have a lower waist to hip circumference[19]
- **DUK/LRA:** is based on cross sectional data and can only accurately predict current status. Therefore, for intermediate diabetes the risk represents the *risk of a risk*, which is confusing and its interpretation potentially misleading[20]
- **current filter**: is based on cross sectional data and cannot be assessed for long term risk of diabetes. Since its performance for identification of diabetes and pre-diabetes was assessed by HbA1c, the same issues about the nature of HbA1c diagnosed diabetes apply. For intermediate hyperglycaemia HbA1c was not found to be a discriminator of risk for White Europeans compared to South Asians[21]

[18] Smith S. 2014 Personal communication – reanalysis of data from Smith S et al 2013.
[19] Mostafa S.A.,M. J. Davies, D. Webb, L. J. Gray, B. T. Srinivasan, J. Jarvis, K. Khunti. The potential impact of using glycated haemoglobin as the preferred diagnostic tool for detecting Type 2 diabetes mellitus. Diabetic Medicine, 2010:27, 762–769
[20] http://riskscore.diabetes.org.uk/2013?gclid=COBnp63wscMCFcSWtAod2y4ARg
[21] Mostafa SA, Khunti K, Srinivasan BT, Webb D, Gray LJ, Davies MJ. The potential impact and optimal cut-points of using glycated haemoglobin, HbA1c, to detect people with impaired glucose regulation in a UK multi-ethnic cohort. Diabetes research and clinical practice 2010; 100-108

Table 5.1. Key differences between the two UK-based validated diabetes risk scores QDiabetes, LRA; (see table 5.2 for test characteristics)

Difference	**QDiabetes**	**LRA**
Size of validation data set	44,348 diabetes cases out of a population of 954,025 (4.6%)	135 cases of diabetes out of a population of 3171 (4.3%)
Representativeness of the validation data set to England as a whole	Large data set from across England	Focussed data sets from Leicester and Cambridge
Diabetes end point	Future risk of diabetes diagnosis (based on entry onto GP diabetes register); method of diagnosis of diabetes could be OGTT or HbA1c but most likely to be HbA1c but this is unknown	Standardised case ascertainment by current prevalence of IGR: IFG 6.1-6.9 mmol/ or IGT7.8-11.0 mmol/l and current diabetes IFG >7.00mmol/l on 2 occasions
Future prediction of individualised risk	QDiabetes can provide an individualised quantified risk of future diabetes diagnosis by general practice	The risk score is for prevalent cases and does not provide an individualised future risk, though one can be imputed it is not individualised
Endpoint linked to evidence for intervention	No RCTs showing risk reduction in those with a predicted future risk of diabetes registration (however the majority of those on GP registers are likely to be diagnosed by HbA1c)	5 RCTs showing documented 30-60% reductions in Type 2 diabetes incidence in adults with impaired fasting glucose or impaired glucose tolerance through intensive lifestyle change programme interventions[22]

[22] Five randomised controlled trials, conducted in China (1), Finland (2), USA (3), Japan (4) and India (5) have documented 30-60% reductions in Type 2 diabetes incidence in adults with impaired fasting glucose or impaired glucose tolerance through intensive lifestyle change programme interventions.

References

1. Pan et al. Effects of diet and exercise in preventing NIDDM in people with impaired glucose tolerance. The Da Qing IGT and Diabetes Study. Diabetes Care 1997; 20: 537-44.
2. Tuomilehto et al. Prevention of Type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. NEJM 2001; 344: 1343-1350.
3. Diabetes Prevention Program Research Group. Reduction in the incidence of Type 2 diabetes with lifestyle intervention or metformin. NEJM 2002; 346: 393-403.
4. Kosaka et al. Prevention of type 2 diabetes by lifestyle intervention: a Japanese trial in IGT males. Diab Res Clin Pract 2005; 67: 152-162.
5. Ramachandran et al. The Indian Diabetes Prevention Programme shows that lifestyle modification and metformin prevent type 2 diabetes in Asian Indian subjects with impaired glucose tolerance (IDPP-1). Diabetologia 2006; 49: 289-297.

Updatable	Can be updated regularly to adapt to changing demographic and risk profile of England	Not readily updated
Template ready for integration into the NHS Health Check	EMIS software (53%) England primary care population have access to the QDiabetes algorithm as part of the licence agreement. The other GP systems (microtest, SystmOne and Vision) already have a QRISK template. QDiabetes 2 additional variables on top of those already collected to assess CVD risk.	A commercially available template is available which is integrated into the NHS Health Check template and compatible with SystmOne In development is a template for a similar product the LRPDS but this is not the same as the LRA
Accessibility to the public of algorithm and calculator	The algorithm and the calculator are both available to the public freely on QDiabetes website www.QDiabetes.org	The calculator is available to the public freely via Diabetes UK website and has a simple scoring system
Inclusion of measure of deprivation	QDiabetes incorporates a measure of material deprivation which is established as a risk factor for diabetes and will therefore prevent widening health inequalities	LRA doesn't include deprivation within the algorithm
Waist circumference	Not required	Required

Table 5.2 summarises the test and operating characteristics of two UK based diabetes validated tools filters. The table is not a direct comparison but is an attempt to bring together metrics for the different tools to illustrate key differences that may exist. The metrics for QDiabetes come from the latest version of the QDiabetes data set. The metrics for the LRA comes from different cohorts who have different characteristics (e.g. may already have one risk factor which will then lead to it being a higher risk population and having a higher sensitivity precisely because of how the cohort has been selected). A more robust comparison would be if these metrics can be calculated for one population.

The sensitivity (true positives) of the existing diabetes filter is 67%[10] meaning that around one third of people at high risk of developing diabetes or who already have diabetes are being missed. The sensitivities of the two validated risk scores on their revalidation samples[1] vary by the level of risk. NICE guidance 38 advises that only those found by a validated diabetes risk score to be at high risk should receive a blood test to further determine diabetes risk. However, high risk is not defined for the risk assessment tool (see annex C). For the purposes of this study high risk for QDiabetes is defined as the top decile of risk in a population (equates currently to a 26% or more risk of developing diabetes in the next ten years); moderate to high risk is defined as the top 40% at risk (equating to a 1 in 7 (14%) of developing diabetes in the next ten years. Roughly equivalent groups for LRA are high risk score ≥ 25 (equating to a risk of developing diabetes in the future of 1 in 3 (33%)) and moderate to high risk as a cut-off score of ≥16 (equating to a risk of developing diabetes in the future of 1 in 7 (14%).

At high risk:

- both the QDiabetes and LRA have lower sensitivities than the existing filter – 38% and 35% respectively versus 67% meaning that many more people would be missed with potential high risk of diabetes than with the current system

At high AND medium risk:

- QDiabetes, at a risk level of 14% risk of developing diabetes in the next 10 years has a sensitivity of 82% meaning that just 18% with a 1 in 7 risk would be missed. The specificity is 62% meaning that 38% would be tested who are later found not to be at high risk of diabetes
- LRA at a cut-off point of ≥16 (risk level of 14% -1 in 7 chance of developing diabetes in the next ten years) sensitivity is 81%; meaning that just 19% at that level of risk of developing within ten years diabetes might be missed. Specificity is 45% meaning that 55% of people are tested unnecessarily

The specificity of the existing NHS Health Checks filter is mid-range at 51%[24] meaning that around a half of those receiving a blood test for diabetes were not subsequently found to have intermediate hyperglycaemia or diabetes; the specificity for the LRA tool at the level of risk of 14% (cut off point 16) is 45% meaning that over half of all those receiving a blood test for diabetes were

[1] Revalidation samples are samples of patients who were not part of the original studies used to derive the risk scores. Revalidation samples give more of an indication about how risk scores might operate in real life.

[24] Re-analysis of the data in the Smith et al 2013 paper suggests this is 51% (rather than the reported 35%) - the authors are reviewing this and will be submitting a correction.

not found to be at high risk of diabetes. QDiabetes at the same risk level has good specificity of 62% meaning that only just over one third (38%) of the people who don't develop diabetes will be tested further.

Overall if the cut-off for the diabetes risk assessment tools used as part of the NHS Health Checks were set at medium and high level – (1 in 7 risk of future diabetes in the next ten years) then:

- for both QDiabetes and LRA fewer additional blood tests would be required – an estimated minimum of 10% fewer (50% to 40%, table 2) to a maximum of 17% fewer tests (55%-38%) depending on which test is used and on what population
- both risk assessment tools would increase the proportion of people found to be at risk of diabetes or impaired glucose tolerance, but the way in which these risks are measured differs
- for QDiabetes an additional 15% (82-67) of people at high risk of diabetes will be detected and 12% (62-50) fewer will be unnecessarily tested
- for LRA an additional 14% of people with current diabetes or impaired glucose tolerance measured by impaired fasting glucose or impaired glucose tolerance will be identified, while 5% more or 5% less are tested unnecessarily depending on the accurate measure of specificity of the current filter.

Table 5.2. Comparison of the UK derived, LRA and QDiabetes risk score tools at different risk thresholds compared to the existing diabetes filter for the NHS Health Check

Diabetes risk identification method	**Diabetes end point and time period of follow-up**	**Sens it-ivity %**	**Specif - icity %**	**Test +ve (above the cut-off point) %**
Current NHS Health Check diabetes filter	Current prevalence IGR: HbA1c ≥6.0 - 6.4 % or diabetes HbA1c ≥6.5%[25]. (76% specificity for diabetes alone)	67	51[10, 26]	50-55[25,27]
High risk				
QDiabetes[25] High risk:top 10% risk ≥16.4%	Ten-year risk of developing diabetes (26% risk) measured by entering GP register for diabetes (diabetes Read code C10)	38	91	10[25], 6.1[24]
LRA[28] High risk score ≥ 25	Current prevalence of IGR: IFG 6.1-6.9 mmol/ or IGT7.8-11.0 mmol/l (who have 1 in 3 (33%) risk of developing diabetes in the future And current diabetes IFG >7.00mmol/l on two occasions (I in 14 (7%) chance of having diabetes now)	35	84	3[29]
High and medium risk				
QDiabetes High and medium risk: top 40% risk[30]	Ten-year risk of developing diabetes (1 in 7; 14% risk)	82	62	40[19]

[25] Smith S; Waterall J; Burden ACF. An evaluation of the performance of the NHS Health Check programme in identifying people at high risk of developing type 2 diabetes. BMJ Open 2013;3:e002219. doi:10.1136/bmjopen-2012-002219

[26] Reanalysis of the Smith et al data shows that specificity is 51%. The authors are currently reviewing this

[27] Table 2.

[28] L. J. Gray, N. A. Taub, K. Khunti, E. Gardiner, S. Hiles, D. R. Webb, B. T. Srinivasan and M. J. Davies. The Leicester Risk Assessment score for detecting undiagnosed Type 2 diabetes and impaired glucose regulation for use in a multi-ethnic UK setting.. Diabetic Medicine 2010: 27, 887–895

[29] DIABETIC Medicine Abstracts of the Diabetes UK Professional Conference, 5–7 March 2014. A41 (P229) Categorising individuals at high risk of Type 2 diabetes is dependent on which validated risk assessment is used BJ Gary et al.

Leicester Risk Assessment[16] High and medium risk: ≥16	Current prevalence of IGR: IFG 6.1-6.9 mmol/ or IGT 7.8-11.0 mmol/l 1 in 7 (14%) risk of being in a high risk group for developing diabetes in the future which has a 1 in 3 chance (overall estimated 4% risk) And current diabetes now IFG>7.00 mmol/l I in 33 (3%) chance of having diabetes now	81	45	38[15]

IGR: impaired glucose regulation defined as either: Impaired fasting glucose (6.1-6.9 mmol/l) or Impaired fasting glucose tolerance (7.8-11.0 mmol/l) or HbA1c ≥6.0 -6.4%. NB the figures in the table show the % found following application of the risk assessment score with subsequent follow-up testing.

Other benefits

Savings on diabetes blood tests

Table 6 shows that there are potentially between £1m and £3.2m of savings from unnecessary diabetes blood tests if a QDiabetes or DUK/LRA were introduced instead of the current filter.

Savings on costs of care for people with diabetes

The validated risk tools identify additional people at risk of diabetes compared to the current filter. If these people are managed well with intensive lifestyle management it is known that progression to diabetes can be prevented in 30-60% of people (based on a group defined by OGTT). It is also known that good control of cardiovascular risk factors, particularly hypertension is important in reducing CVD risk in those with intermediate hyperglycaemia.

Long term savings on the annual costs of care of someone with diabetes is £1300 per annum.

Strategic

Alignment of the NHS Health Check protocol with NICE public health guidance 38 makes strategic sense – ie, aligning two national policies and

[30] Hippesley-Cox 2015. Analysis of QDiabetes test characteristics for 40-75 years on QDiabetes 2015 database v39. www.qresearch.org/PowerPointpresentations/QDiabetes%20risk%20thresholds.pdf

ensuring that NHS Health Check contents are based on the best currently available evidence.

Table 6. Potential savings from unnecessary second stage blood tests for diabetes and diabetes risk in England under different scenarios

Diabetes risk identification method	Number for testing	HbA1c single cost (£)	OGTT single cost (£)	HbA1c Total cost (£m)	OGTT costs Total cost (£m)
Current filter: high estimate 55% (Smith et al)	790,916	14	24	11.1	19.0
Current filter: low estimate 50%(Durham data)	719,015	14	24	10.1	17.3
Qdiabetes 40% compared to high current estimate (15% fewer)	118,637	14	24	1.7	2.8
Qdiabetes 40% compared to high current estimate (10% fewer)	71,901	14	24	1.0	1.7
LRA 38% compared to high current estimate (17% fewer)	134,456	14	24	1.9	3.2
LRA 38% compared to low current estimate (12% fewer)	86,282	14	24	1.2	2.1

Costs: feasibility study and predicted national costs

Operating costs

These were found to be minimal.

Other pathway costs

Operating costs of providing intensive lifestyle treatment (around £305 per five years – Durham) and rigorous management of hypertension are likely to increase by around 15% with the adoption of a validated risk tool. Early management of diabetes has been shown to be cost effective.[31]

[31] NICE PH guidance 38. Costing report

Risks and mitigations

Table 7 shows the main risks of adopting a validated risk tool and proposes some potential mitigations. Risks are explored under the following headings: political; economic; social including equality impact assessment; technical.

Table 7. Key risks and mitigations for the content change
QDS = Qdiabetes; DUK/LRA= Leicester Risk Assessment score

Risk	**Potential mitigation options**
Political	
NICE guidance advises further testing in those with high risk scores using a validated tool. Analysis from this study suggests that sensitivity is more in line with the current approach if people with high to moderate risk scores are tested further. However, identifying people at medium and high risk contradicts current NICE guidance	• liaise with NICE to consider whether this issue can be considered as part of an update to NICE guidance • advise clearly in good practice guidance and content change that medium and high risk groups should be further screened for diabetes risk to avoid missing more people than current practice • the primary purpose of NICE public health guidance 38 was to inform population health care screening for diabetes while NHS Health Checks is a more targeted group and the medium to high risk is consistent with the NICE cost effectiveness study on this topic[32]
The technical evidence base for the use of diabetes risk assessment scores by a two-stage process is complicated and could be seen to add to current criticisms about the evidence based approach to the NHS Health Check programme	• QDS and DUK/LRA both out perform the current filter in ability to identify those at high risk of diabetes. They identify different high risk groups but there is 33% overlap and each diabetes end point is valid in its own right. Introduction of the content change will reduce the number of people receiving blood tests for diabetes
Economic	
There is limited availability of templates for the four major primary care information systems for the two risk	• national coordination of the development of templates for each of the primary care information systems would increase accessibility • national funding of licence costs for both DUK/LRA

[32] SCHARR 2011. Prevention of type 2 diabetes: risk identification and interventions for individuals at high risk Economic Review and Modelling

assessment tools.	(none as freely available) and Qdiabetes (maximum £20,000 each to cover all four primary care systems would improve availability. Alternatively, system providers could absorb the cost of integrating a risk tool into their systems which would improve availability • Qdiabetes is readily available for EMIS practices, but practices would need to undertake some minimal programming to integrate it into local NHS Health Checks templates • DUK/LRA template for NHS Health Check is commercially available on Systmone
Social (including Equality Impact Assessment)	
LRA requires waist circumference assessment that might impact on uptake of NHS Health Checks by some ethnic minorities if a female practitioner is not available for women	• ensure female practitioner for the delivery of checks in high ethnic minority areas • ask LRA team to assess how important the differences are between waist circumference measured by the "no-touch technique"[33] and the protocol technique[34] and provide adjustments if necessary • choose a risk assessment tool that does not require waist circumference measurement in high ethnicity areas
Technical	
The diabetes end points differ between the different risk assessment tools – the current filter assesses prevalent impaired glucose regulation and diabetes measured by HbA1c; LRA assesses the same endpoint but measured by OGTT and Qdiabetes measures ten-	• a prospective head to head study linked to impact of intervention would help to establish comparability between tools. Shorter term studies such as those below should be called for • use a single national database with a number of years' data such as Health Survey for England (that includes waist circumference data) to assess the overlap and differences in identified high risk groups and future diabetes incidence predicted by Qdiabetes, DUK/LRA and the current filter

[33] The patient holds the tape measure on their belly button and turns around the tape that the health care assistant is holding. This is however a different measure from that specified within the LRA development protocol. The belly button may vary in position depending on obesity and age.

[34] Protocol technique for measurement of waist circumference requires the identification of the lower rib and the top of the anterior iliac crest, take the mid-point and pass the tape measure round the person at this level. After a breath out the measurement is taken. This requires touching the person, takes longer and is more difficult to achieve in practice as it can be difficult to find these anatomical landmarks on an obese individual

year future risk of developing diabetes measured by entry to a primary care diabetes register for which it is not currently possible to characterise what proportion are determined by HbA1c and what proportion by OGTT.	• re-run Qdiabetes analysis on subset of Qdiabetes data that has waist circumference and OGTT results to compare outcomes between current filter, QDS and DUK/LRA Qdiabetes and LRA risk and the existing filter • as validated tools increase identification of at-risk group and will reduce unnecessary tests ensure that there is full evaluation of the implementation until the above trials can be established and report their findings
Evidence of intervention linked to results from Oral Glucose Tolerance Testing not to HbA1c Qdiabetes end point of entry onto a primary care diabetes register will include a proportion diagnosed by OGTT but anecdotally it is thought that most are defined by HbA1c. HbA1c defined diabetes is ethnographically different and has lower CVD risk and therefore the scale of the advantages found in OGTT trials cannot be assumed to confer to those at risk of entering a primary care diabetes register	• WHO guidance[35] advises that HbA1c can be used for the diagnosis of diabetes and intermediate hyperglycaemia • HBA1c is as good if not a better guide to micro-vascular complications[21] • evaluate current implementation of diabetes risk filter and compare outcomes with Qdiabetes and LRA practices in terms of reduction from baseline of micro and macro vascular incident complications • consider recommending use of both tools and follow-up by both HbA1c and OGTT until the research is clearer
Difficulty providing advice to local authorities on how to choose between diabetes risk tools	• the main differences between the two UK based risk tools are listed in tables 5.1 and 5.2. Local primary care software and availability of templates will mean that pragmatic decisions will be made until results are available from head to head studies linked to impact of intervention. The only statement that can be made is that “Qdiabetes is the more powerful predictive tool for an outcome which is probably of HbA1c diabetes while DUK/LRA provides prevalent risk of OGTT diagnosed diabetes and its pre-

[35] WHO 2011 Use of Glycated Haemoglobin (HbA1c) in the Diagnosis of Diabetes Mellitus. WHO/NMH/CHP/CPM/11.1

	cursors." Both HbA1c and OGTT diabetes are predictive of CVD and IGT is predictive of CVD in women only[36]
Misclassification of risk due to inaccurate measurement of waist circumference from "no-touch technique"	• repeat waist circumference for all measurements within 1cm of each cut-of point, i.e., 89-91; 98-100 and 108-110cm

[36] Cederberg H et al. Post challenge glucose, A1c and fasting glucose as predictors of Type 2 diabetes and CVD. Diabetes Care 2010; 33:2077-2083

Equality impact assessment

Deprivation

Table 8 summarises data from the Durham community sample (n=4273). Applying the current diabetes filter would mean that 51% of people attending the NHS Health Check would have had a blood test for further assessment of their diabetes status. The DUK/LRA would have identified 38% on this sample. The sample was an outreach sample targeting people from more deprived areas of County Durham and those who were unlikely to visit their GP surgery. This is reflected in the younger age of this group, which ranged from 52.4 years in quintile one (the most deprived quintile nationally) to 46.4 (the least deprived quintile nationally).

Both filters identified more people from the least deprived area 59% of the quintile five group for the existing filter and 39% for the LRA. This might be because people in the more deprived areas are more likely to already be on diabetes and CVD registers and hence not eligible for the NHS Health Check. However, the existing diabetes filter is known to miss a third of people with diabetes or those at high risk of diabetes (table 5.2) and it can be seen that the LRA has much less variability in the proportion identified across the quintiles – lowest is 35% compared to highest of 39%. In comparison the existing filter identified 41% in the most deprived group compared to 59% in the least deprived group. This suggests that some people at high risk of diabetes might be being missed by the current filter and that the DUK/LRA would reduce any health inequalities that might be introduced by the use of a diabetes filter.

QDiabetes includes a data item to assess the Townsend deprivation score and therefore is sensitive to changing need with increasing deprivation.

Table 8. Comparison between the existing diabetes filter of the NHS Health Check and the LRA in the proportion of people who are high risk and require further blood test assessment of diabetes risk by deprivation quintile

			Current diabetes filter		LRA	
Quintile of deprivation	**n**	**Average age (yrs)**	**Require blood test**	**%**	**Require blood test**	**%**
1	580	52.4	240	41.4	203	35.0
2	601	52.4	278	46.3	210	34.9
3	1021	51	496	48.6	393	38.5
4	1197	49.4	660	55.1	456	38.1
5	874	46.4	520	59.5	347	39.7
Total	**4273**		**2194**	**51.3**	**1609**	**37.7**

Protected characteristics

Table 9 shows that all three filters work slightly better in women; QDiabetes performs slightly less well in older age groups (not known for the other two); the current is better for Asian groups; DUK/LRA might be better for white groups and the QDiabetes can be calibrated for all the main ethnic groups and hence is more sensitive to ethnicity. There are no perceived impacts on other characteristics except that for some religious groups the need to take a waist circumference measurement might be problematic for some women if the health care assistant is male. There is a no-touch technique but it differs from the protocol advised method of measurement of waist circumference and may over or underestimate waist circumference and hence risk mis-allocation of risk in groups where this might be a problem.

Table 9. Screening for equality impact on people with protected characteristics and use of different diabetes filters in the NHS Health Check

	Current filter	**QDiabetes**	**DUK/LRA**
Age	No known	Marginally worse for those over 60 yrs (decreased prediction by 2%)	Not known
Sex	Performs better in women than in men 38% at risk missed in men 29% at risk missed in women	AUROC slightly better for women: 0.85 Men: 0.83	Slightly better for women AUROC: Women 0.71 Men 0.73
Ethnicity	Better sensitivity for Asian groups: Asian: 69% Other: 63%	Sensitive to ethnicity differences for all major census ethnic groups	For development data slightly better for “other ethnicity” for validation data (STAR) slightly better for white AUROC: White:0.73 Other 0.68
Disability	No impact	No impact	No impact
Gender reassignment	No impact	No impact	No impact
Sexual orientation	No impact	No impact	No impact
Marriage and civil partnership	No impact	No impact	No impact
Pregnancy and maternity	n/a	n/a	n/a
Religion and belief	No impact	No impact	Some religious women consider having waist circumference taken by a man difficult if the health care assistant is a male. In practice no problems reported

Option appraisal

Option A: retain the current diabetes filter
Given the complexities of the current state of science of diabetes, its precursors and their relationships to micro-vascular and macro-vascular disease and their prevention there is a simplicity with staying with the current filter that picks up 76% of prevalent cases of diabetes and 67% of all cases of HbA1c diabetes. However, QDiabetes picks up a higher proportion of cases over a ten-year risk (81%) and requires fewer people to be tested and DUK/LRA picks up more prevalent cases and requires fewer cases to be tested. Therefore the do nothing option is not recommended.

Option B: adopt the use of any validated risk tool and diagnostic testing for people at medium to high risk
This would involve replacing the current diabetes filter with a validated risk tool and, in line with NICE guidance PH 38, enabling local areas to decide which tool to use. In order for this option to address the concerns raised about the sensitivity and specificity of the current filter PHE would need to go beyond current NICE guidance to recommend that individuals at high and **medium** risk go on for further diagnostic tests.

Option C: adopt the use of a specific validated risk tool and diagnostic testing for people at medium to high risk
This would build on option B by specifying the tool that should be used in the delivery of the NHS Health Check. While this option would reduce development costs and would provide a standardised approach there is currently insufficient evidence to recommend this option at present.

Conclusion and recommendations

This report highlights that the science behind diabetes risk scores and prediction tools for diabetes is not perfect. Furthermore, rigorous comparisons between the different tools and the current filter are not possible due to different diabetes end points. Nevertheless the use of a validated risk score to identify individuals at medium and high risk for a diagnostic test would a) improve detection of those at risk of developing diabetes in the future; b) reduce the current number of blood tests and; c) reduce or lead to a small increase in the proportion of people receiving false positive results. The costs of introducing this change are marginal and the benefits would accrue from identification of an additional 14-15% of people at risk of developing diabetes in the future.

Recommendations

1. That option B is adopted. This involves replacing the current NHS Health Check diabetes filter with a computerised validated risk assessment tool, as recommended in the NICE PH38 guidance. Furthermore, individuals identified at either MEDIUM or HIGH risk should then be offered a diagnostic test to assess diabetes risk. This goes beyond the NICE guidance PH 38 which recommends only that high risk people are followed up with a blood test. But at that risk level more people at risk of developing diabetes that could benefit from intervention would be missed than using the current filter.

2. Research is conducted to ascertain: i) how well QDiabetes and DUK/LRA discriminate people at risk of diabetes currently on the same data set; ii) how well they perform prospectively in determining future development of diabetes determined by HbA1c and OGTT; iii) how well these tests perform in predicting micro-vascular and macro-vascular disease; iv) how well each of the tests discriminate those who would benefit most from intensive life-style support to reduce future development of diabetes.

3. Recommend that NICE reviews PH guideline 38 at the earliest opportunity to assess the evidence in relation to:
   - validated diabetes questionnaires for the range of diabetes end-points and for a range of cut-off points of risk
   - the differing strategic aims of population segmentation of the general practice population for the purpose of identifying prevalent diabetes and diabetes risk and for the purposes of providing individuals taking

the NHS Health Checks an individualised risk score predictive of response to a preventive approach to reduce micro and macro-vascular complications of diabetes

3. Local decision making on which tool to use is supported by sharing information on the pros and cons of each of the UK developed tools listed in annex A.

4. To support local implementation by exploring the possibility of funding the development of NHS Health Check templates for the two diabetes risk scores that were developed in the UK on ethnically diverse populations (QDiabetes and the DUK/LRA).

5. To support local implementation by giving NHS Health Check commissioners a five-month period to prepare to operationalize this change.

6. The NHS Health Check competence framework is updated to include measurement of waist circumference using the simple no-touch belly button technique with checking by the research technique for those with measurement close to the cut-off points: 90cm; 99cm and 109cm (to avoid potential mis-allocation to the wrong risk group).

7. Evaluation should be actively encouraged. There is a need to assess the impact of the change on: the number of HbA1c tests; OGTTs; numbers entering the diabetic register and how they were diagnosed; numbers identified with diabetic hyperglycaemia and progression to micro-vascular and macro-vascular disease; interventions and their intensity.

8. The adoption of a validated risk tool should be reviewed in three years when further studies have been conducted to assess if a single diabetes risk assessment tool should be recommended.

Glossary of terms

AUC	Area under curve. A summary measure of how well a screening test operates to discriminate between those with and without a disease. It measures the area under a curve which is a plot of the false positive rate (people identified by a test as potentially being at risk of a disease who do not have that disease) against the true positive rate (people who are identified by the test to have the disease who actually do have it)
AUROC	As above – more precise term: area under receiver operating curve
Cut-off point	The score above which people are determined to be at a particular risk level
Diabetes end point	Description of the way in which diabetes and/or diabetes risk is defined within the study e.g. entry to a primary care diabetes register; intermediate diabetic hyperglycaemia defined by HbA1c 6.00-6.4%; or IGR: IFG 6.1-6.9 mmol/ or IGT 7.8-11.0 mmol/l
IFG	Impaired fasting glucose – a product of an OGTT. IFG defined as 6.1-6.9 mmol/l
IGR	Impaired glucose regulation – a term used to define the group of people who do not have diabetes but have a higher risk of developing diabetes and its complications in the future. Usually determined by OGTT results giving IFG 6.1-6.9 mmol/ or IGT7.8-11.0 mmol/l
Intermediate hyperglycaemia	The current preferred term for hyperglycaemia (high blood sugar) that is not at the level required for a diagnosis of diabetes but that confers additional future risk of diabetes and its complication. Defined by WHO as: HbA1c 6.00-6.4%; IFG 6.1-6.9 mmol/ or IGT7.8-11.0 mmol/l
Macro-vascular complications of diabetes	Macro-vascular complications are those from CVD – heart disease and stroke, and are a principal cause of higher mortality in people with diabetes. Macro-vascular disease outcomes are predicted mainly by non-glycaemic control measures such as strict control of blood pressure and lipid management. All causes mortality in people with diabetes is optimal at levels ≥7.5; a slightly higher HbA1c range than that required for micro-vascular control

Micro-vascular complications of diabetes	The complications such as diabetic retinopathy affecting sight; diabetic renal disease affecting kidney function and neuoropathy affecting peripheral sensation affecting risk of ulceration and amputation. Micro-vascular disease is associated with glucose control – the better it is the fewer complications occur
OGTT	Oral glucose tolerance test. A test to diagnose diabetes and impaired glucose regulation. It is a fasting test of blood glucose followed by a glucose challenge (75gm oral dose of glucose for adults) and a minimum of a two-hour post glucose challenge blood test.
Pre-diabetes	A term that has been used to describe intermediate hyperglycaemia but is no longer preferred as people can move and in and out of this state and it implies an inevitable progression to diabetes which is not the case (particularly with intensive lifestyle interventions)
Sensitivity	A screening test characteristic that defines the proportion of *true positives* identified by the test – e.g., in relation to diabetes – how many people who actually have diabetes or intermediate hyperglycaemia determined by HbA1c levels or OGTT are identified correctly by the score
Specificity	A screening test characteristic that defines the proportion of *true negatives* identified by the test – e.g. in relation to diabetes – how many people who do *not* have diabetes or intermediate hyperglycaemia are correctly identified by the risk score

Annex A. Comparison of validated tools

Components of seven diabetes risk models or scores with potential for adaptation for use in routine clinical practice from:
Noble D, Mathur R, Dent T, et al. Risk models and scores for type 2 diabetes: systematic review. BMJ 2011;**343**.

Score/study name, country, reference	Risk factors included in score	AUROC	Calibra-tion	External validation		
				Year, country	AUROC	Calibration
ARIC (Atherosclerosis Risk in Communities), Germany, Schmidt 200546	Age, ethnicity, waist circumference, height, systolic blood pressure, family history of diabetes, fasting plasma glucose levels, triglyceride levels, high density lipoprotein cholesterol levels	0.8	NS	2010,19 USA	0.84	Hosmer-Lemeshow P<0.001, after recalibration P>0.10
Ausdrisk, Australia, Chen 201037	Age, sex, ethnicity, parental history of diabetes, history of high blood glucose, use of antihypertensive drugs, smoking, physical inactivity, waist circumference	0.78	Hosmer-Lemesho w P=0.85	Not externally validated but has been studied as part of an intervention to improve outcomes		
Cambridge risk score, UK, Rahman 200863	Age, sex, use of current corticosteroids, use of antihypertensive drugs, family history of diabetes, body mass index, smoking	0.74 with threshold of 0.38	NS	2010,10 UK*	0.72	Hosmer-Lemeshow P=0.77

Score/study name, country, reference	Risk factors included in score	AUROC	Calibra-tion	External validation		
				Year, country	AUROC	Calibration
FINDRISC, Finland, Lindstrom 200368	Age, body mass index, waist circumference, use of antihypertensive drugs, history of high blood glucose, physical inactivity, daily consumption of vegetables, fruits, and berries	0.85	NS	2010,53 Holland, Denmark, Sweden, UK, Australia*	0.76	Hosmer-Lemeshow P=0.27
Framingham Offspring Study, USA, Wilson 200751	Fasting plasma glucose levels, body mass index, high density lipoprotein cholesterol levels, parental history of diabetes, triglyceride levels, blood pressure	0.85	NS	2010,19 USA	0.78	Hosmer-Lemeshow P<0.001, after recalibration P>0.10
San Antonio risk score, clinical model, USA, Stern 200249	Age, sex, ethnicity, fasting plasma glucose levels, systolic blood pressure, high density lipoprotein cholesterol levels, body mass index, family history of diabetes in first degree relative	0.84	Hosmer-Lemeshow P>0.2	2010,19 USA; 2010,55 Iran*; 2010,10 UK*; 2010,66 Iran*	0.83; 0.83; 0.78; 0.78	Hosmer-Lemeshow P<0.001, after recalibration P>0.10; Hosmer-Lemeshow P≤0.001, after recalibration P=0.131; Hosmer-Lemeshow P=0.42; Hosmer-Lemeshow P=0.264
QDScore, UK, Hippisley-Cox 20098	Age, sex, ethnicity, body mass index, smoking, family history of diabetes, Townsend deprivation score, treated hypertension, cardiovascular disease, current use of corticosteroids	0.83 men, 0.85 women	Brier score: 0.078 men, 0.058 women	2011,57 UK	0.80 men, 0.81 women	Brier score: 0.053 men, 0.041 women

LRA was not considered in this study as it was based on cross sectional data. Comparable data to the above are given below

LRA, UK, Gray, 2010	Age, gender, ethnicity, FH diabetes, BMI, ever had hypertension, waist circumference	0.69 All 0.68m, 0.71f	Fifths	2010, UK (STAR)	0.72	NS

Annex B. Extract from NICE guidelines 38 – rationale for no recommendation for a single risk assessment score

"Risk-assessment tools, based on the presence or absence of various risk factors, are used to identify people at high risk of type 2 diabetes among European populations. There are two broad approaches. Either they use the data routinely available in UK general practice computer databases (such as age, gender, body mass index [BMI] and family history of diabetes). Or they comprise self-assessment questionnaires which are completed manually or online. Examples of the former are the Cambridge diabetes risk score, the QDiabetes risk calculator and the Leicester practice score. Examples of the latter are the Diabetes Risk Score assessment tool (available to health professionals on the Diabetes UK website), the online Diabetes Risk Score and FINDRISC. The Diabetes Risk Score was developed and validated in Leicester for identifying those at high risk of impaired glucose regulation and type 2 diabetes in multi-ethnic populations in the UK. It is, in turn, based on FINDRISC, a Finnish self-assessment questionnaire. FINDRISC is based on robust data and has been validated as a risk-assessment tool in cross-sectional studies and, prospectively, in other European populations.

3.5 The PDG focused on risk-assessment tools validated for use in the UK and which help identify people from different ethnic groups who are at high risk of diabetes. It debated the difference between tools measuring current risk (for example, FINDRISC and scores based on it) and prospective risk (for example, QDiabetes risk calculator). This included their use of cross-sectional or prospective cohort data. Both approaches were acknowledged to have limitations. The PDG felt it was important that the tools were validated against blood glucose measures. Equally important was the need to have a range of tools available that are suitable for use in any environment where risk assessment could take place. The PDG concurred that the choice of tool is likely to depend on the population being assessed, whether it has been validated for use with that population, the risk-assessment setting and supporting infrastructure (such as compatibility with IT systems)".

Annex C. Defining high risk

Definition of high risk

The definition of “high risk” on a validated score is not defined in NICE guidance 38. It suggests the terms low, intermediate and high are used for risk scores but the risk score developers do not follow a single format. High risk in the NICE guidance is defined for people with non-diabetic hyperglycaemia who have an HbA1c between 6.0% and 6.4%, or FPG (fasting plasma glucose) as 5.5-6.9mmol/l as having a high risk of developing diabetes.

The variation in definition of high risk can be seen in a number of studies. Rohini[37] defines high risk as risk of ≥ 20% chance of developing diabetes in the next ten years and uses Qdiabetes to determine this. Hippesley-Cox uses the top decile of risk (13% in the study comparing the CPRD dataset with the EMIS data[38]). At this level the sensitivity of Qdiabetes falls to 45% and the specificity rises to 91%. Gray[39] found that different risk tools identified varying proportions of the population as high risk:

Cambridge Risk Score 14%
FINDRISC 7%
QDIABETES 6%
LRA (Leicester) 3%

The Leicester Risk Assessment “high risk” score described in the original derivation paper[40] actually equates to a very high risk score of ≥ 25 with a 1 in 3 chance of having intermediate hyperglycaemia who themselves have a and a 1 in 3 chance of developing diabetes (a risk of a risk). Later practice guides have defined high risk as a cut-off point of ≥16. For the purposes of this study a score of >=16 (moderate/high risk) has been used as the risk at this level of developing diabetes in the next ten years is 1 in 7 (14%) and sensitivity is 81% and specificity 45%.

The Smith, Waterall and Burden (2013) diabetes end point assesses the ability of the current NHS Health Check diabetes filter to identify both those with prevalent (undiagnosed) diabetes and with prevalent intermediate hyperglycaemia – a group with high risk of progression to diabetes.

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[40] L. J. Gray, N. A. Taub, K. Khunti, E. Gardiner, S. Hiles, D. R. Webb, B. T. Srinivasan and M. J. Davies. The Leicester Risk Assessment score for detecting undiagnosed Type 2 diabetes and impaired glucose regulation for use in a multi-ethnic UK setting.. Diabetic Medicine 2010: 27, 887–895

References

Please see footnotes, throughout the document.