An evaluation of the performance of the NHS Health Check programme in identifying people at high risk of developing Type 2 diabetes

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An evaluation of the performance of the NHS Health Check programme in identifying people at high risk of developing Type 2 diabetes

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Article summary

Article focus

- The NHS Health Check programme (NHSHCP) was introduced in 2009 to improve case finding through assessment of vascular risk in the general population aged 40 to 74 years, without diagnosed existing vascular disease. The NHSHCP includes assessment of risk of diabetes using a diabetes screening test called a *filter* (based on ethnicity, body mass index (BMI) and blood pressure)
- Within Heart of Birmingham Primary Care Trust (HoB PCT), people from the Indian sub-continent represent the largest group (over 60%). A consistent finding within this migrant population (compared to the indigenous population), is a higher incidence and prevalence of premature coronary heart disease (CHD), at least partly as a consequence of diabetes. Consequently, the PCT were concerned with ensuring that the NHSHCP was effective in identifying early, those at high risk from Type 2 diabetes and cardiovascular disease
- Through the PCTs' GP data extraction facility, it was possible to review anonymised patient data with Read codes indicating that they had received an NHS Health Check. Subsequently, this data enabled a retrospective review of patients that might have diabetes or be at high risk for developing diabetes (from measurement of HbA1c at the time of their check), with the outcome had the check relied solely on the use of the NHS Health Check diabetes filter

Key messages

- This evaluation demonstrates the potential for the NHS Health Check programme to fail to identify people that are at high risk of having or developing diabetes
- Use of the current NHS Health Check may lead to a failure to identify a group of patients with normal body weight but at high risk from diabetes and cardiovascular disease
- More research is needed into risk identification approaches for populations at high risk of developing Type 2 diabetes and cardiovascular disease.

Strengths and limitations of this study

- This is possibly the first study of its size to evaluate the effectiveness of a risk identification tool for diabetes in a high risk, ethnically diverse population without diagnosed existing vascular disease
- Issues with the data included the initial inclusion of 951 patients with diagnosed diabetes due to changes to the Read code for diagnosed diabetes in line with Primary Care Quality and Outcomes Framework (QoF) requirements. In addition for some patients data on ethnicity was incomplete and for some, data was not available for BP and BMI (further analysis revealed that data was available but may have been recorded prior to the date of the NHS Health Check)

Abstract

Objective: To evaluate the performance of the NHS Health Check in identifying people at high risk of having or developing Type 2 diabetes.

Design: Retrospective evaluation of the performance of the NHS Health Check *diabetes filter* (based on ethnicity, body mass index (BMI) and blood pressure) in identifying people known to have Type 2 diabetes or non diabetes hyperglycaemia (HbA1c ≥ 42 mmol/mol recorded within 3 months of their NHS Health Check).

Setting: Heart of Birmingham Primary Care Trust (HoB PCT).

Subjects: 34,022 patients with a Read code in the GP clinical record indicating that they had attended an NHS Health Check over the period April 2009 to February 2012, 17,341 of whom were of Asian ethnicity (Indian, Pakistani, Bangladeshi, 'Other' Asian or Chinese).

Outcome measures: Primary outcome measure: proportion (%) of patients at risk of diabetes or non – diabetes hyperglycaemia (HbA1c ≥ 42 mmol/mol) not detected by application of the NHS Health Check *diabetes filter*. Secondary outcome measures included sensitivity and positive predictive value (PPV) of the NHS Health Check diabetes filter as a tool for identifying people at risk of diabetes or non – diabetes hyperglycaemia.

Results: In HoB PCT, simple application of the NHS Health Check diabetes filter failed to detect 1990/5968 (33.3% [95% CI, 31.2% to 35.4%]) of patients of known ethnicity at risk of having or developing diabetes (HbA1c ≥ 42mmol/mol). As a tool for detecting people at risk of diabetes in the Heart of Birmingham population, the NHS Health Check diabetes filter has a sensitivity of 66.5% [95% CI, 65.3% to 67.7%] and the PPV was 41.0% [95% CI, 40.0% to 42.0%]. Sensitivity and PPV of the NHS Health Check diabetes filter in the HoB PCT population is significantly greater for patients of Asian ethnic origin (sensitivity 68.7% [95% CI, 67.2% to 70.2%] vs 62.6% [95%CI, 60.5% to 64.6%] and PPV 49.7% [95% CI, 48.4% to 51.0%] vs 30.6% [95% CI, 29.2% to 32.0%]).

Conclusions The evaluation demonstrates the potential for the NHS Health Check programme to fail to identify people that are at high risk of having or developing diabetes. This is possibly the first study of its size to evaluate (in a UK clinical practice setting) the effectiveness of a risk identification tool for diabetes in a high risk, ethnically diverse population without diagnosed existing vascular disease. In each case, actual risk for diabetes had been obtained directly from measurement of HbA1c. In addition, use of the current NHS Health Check may lead to a failure to identify a group of patients with normal body weight but at high risk from diabetes and cardiovascular disease.

Introduction

Heart of Birmingham (HoB) is a primary care trust (PCT) area in inner city Birmingham. The area is characterised by a majority population from minority population groups (70% non-white) and is ethnically and culturally diverse. Within the Heart of Birmingham area, people from the Indian sub-continent represent the largest group (over 60%). A consistent finding within this migrant population (compared to the indigenous population), is a higher incidence and prevalence of premature coronary heart disease (CHD), at least partly as a consequence of diabetes[1]. People from South Asian backgrounds have a higher risk of developing Type 2 diabetes and they develop it on average five years earlier than white people[2]. The HoB population is also relatively young (66% aged under 40).

Diabetes prevalence is higher in areas experiencing deprivation, and people living in the 20% most deprived neighbourhoods in England are 56% more likely to have diabetes than those living in the least deprived areas[3]. HoB, with a substantially greater than average proportion of the population from black and minority ethnic (BME) groups and higher than average deprivation, is classified as a high risk area in terms of actual and forecast prevalence of diabetes and diabetes attributable deaths[4]. Early identification of risk of having or developing diabetes is therefore of importance in HoB in particular to ensure that risk for cardiovascular disease and premature death is appropriately managed.

According to the charity Diabetes UK, by 2025 there will be more than four million people with diabetes in the UK and most of these cases will be Type 2 diabetes[5]. In 2002, the Department of Health estimated that 5% of total NHS expenditure is used for the care of people with diabetes. This figure is now believed to be closer to 10% of total NHS expenditure which equates to £9 billion per year[2]. Early identification of risk of developing diabetes and intervention to reduce the incidence of diabetes and its complications are increasingly important strategies in reducing the economic impact from an ageing population and rapidly rising numbers of overweight and obese people.

The National Institute for Health and Clinical Excellence (NICE) recently published guidance on risk identification and interventions for people at high risk of Type 2 diabetes[6]. There is no single accepted way of identifying people who are at risk of diabetes or who have existing undiagnosed diabetes. Methods that have been developed include validated computer - based risk assessment tools applied to demographic and routine data in clinical information systems, and validated self assessment questionnaires such as FINDRISC[7] and the Diabetes Risk Score[8].

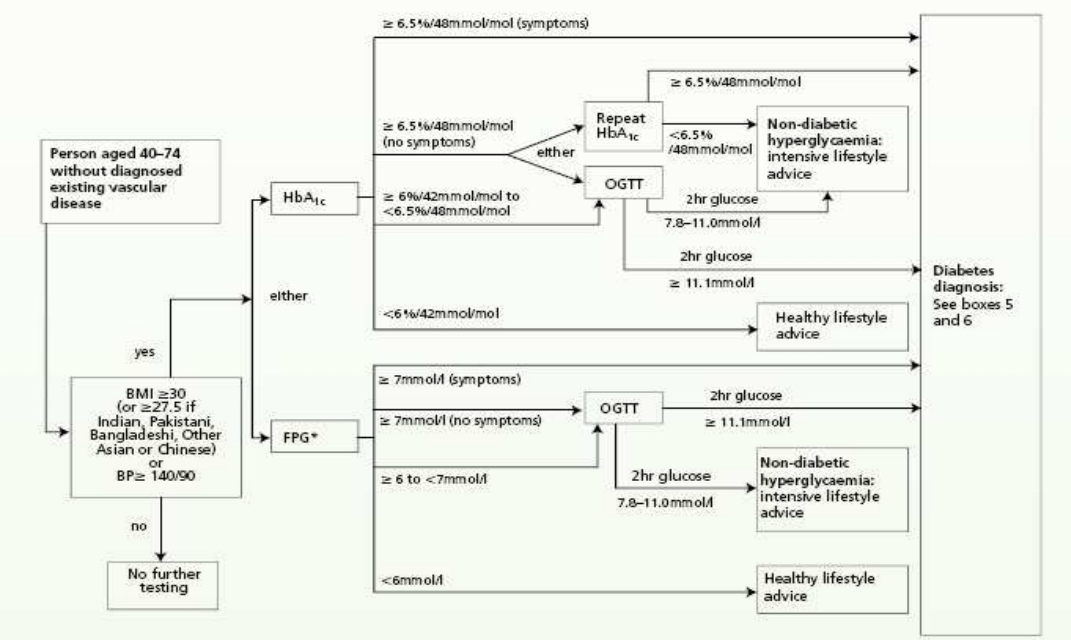
In 2009, the NHS Health Check programme (www.healthcheck.nhs.uk) was introduced to improve case finding through assessment of vascular risk in the general population aged 40 to 74 years without diagnosed existing vascular disease (table 1). The NHS Health Check uses a combination of physiological and biochemical tests, anthropometric measurements and an approved risk calculator to assess cardiovascular risk[9]. All participants are offered management strategies to reduce individual risk with the overall aim of reducing the incidence and prevalence of cardiovascular disease in the population.

Table 1: NHS Health Check Programme exclusions with diagnosed existing vascular disease

Atrial Fibrillation Chronic Kidney Disease (stages 3-5), Coronary Heart Disease, Diabetes Heart Failure	Hypertension Hypercholesterolaemia Peripheral Arterial Disease (PAD) Transient Ischaemic attack Stroke (TIA)

The NHS Health Check programme includes assessment of risk of diabetes using a diabetes screening test called a *filter* (based on ethnicity, body mass index (BMI) and blood pressure) to identify those participants that should also receive a blood test (either HbA1c or fasting plasma glucose (FPG)). This is described is diagrammatically in figure one.

Figure 1: Diagrammatic overview for identifying people at high risk of having or developing diabetes



Source: Putting Prevention First NHS Health Check: Vascular Risk Assessment and Management Best Practice Guidance (http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_098410.pdf)

Measuring BMI and blood pressure, using the thresholds employed in the NHS Check Programme (BMI ≥ 30 (or ≥ 27.5 if Indian, Pakistani, Bangladeshi, Other Asian or Chinese) or blood pressure ≥ 140/90mmHg or where the SBP or DBP exceeds 140mmhg or 90mmhg respectively) is considered a pragmatic means of identifying those at highest risk of diabetes without unnecessarily subjecting an excess of people receiving the NHS Health Check to blood testing for diabetes[9]. The filter however will potentially exclude people with diabetes with normal or low body weight.

Existing evidence regarding the relationship between weight and mortality in type 2 diabetes is conflicting and, for example, in the World Health Organization Multinational Study of

Vascular Disease in Diabetes, there was no clear relationship between BMI and cardiovascular mortality[10]. More recently Carnethon MR, et al found that after adjustment, hazard ratios comparing normal weight participants with diabetes with overweight/obese participants for total, cardiovascular, and non - cardiovascular mortality were 2.08 (95% CI, 1.52-2.85), 1.52 (95% CI, 0.89-2.58), and 2.32 (95% CI, 1.55-3.48), respectively[11]. Use of the NHS Health Check diabetes filter may therefore lead to a failure to identify a group a patients with normal body weight but at high risk from diabetes and cardiovascular disease.

Method

NHS Health Check Programme

NHS Health Checks are largely carried out in primary care settings. Best practice guidance has been issued to guide local areas in terms of the processes associated with the programme such as identification of appropriate patients and systems for call, recall and follow-up. Best practice guidance also describes standards for obtaining anthropometric measurements such as height and weight (from which to calculate BMI) and other measurements such as blood pressure and serum cholesterol[9]. Ethnicity is needed for diabetes risk assessment and should be recorded using the most recent Office for National Statistics categories that were first developed for the England and Wales Census in 1991. These categories have been expanded at each subsequent census (in 2001 and 2011)[13].

Study method

Recently, the World Health Organisation has stated that HbA1c alone can be used as a diagnostic test for diabetes provided that stringent quality assurance tests are in place, assays are standardised to criteria aligned to the international reference values, and there are no conditions present which preclude its accurate measurement[12]. An HbA1c of 48mmol/mol (6.5%) is recommended as the cut point for diagnosing diabetes (the SI unit for HbA1c is mmol/mol and is defined as mmol HbA1c per mol HbA_0 + HbA1c). In HoB PCT, given the high - risk population, a strategic clinical decision was made to request that GP practices offered *all* those attending the NHS Health Check programme, measurement of HbA1c (without application of the filter) to establish an individual's risk of diabetes or non – diabetic hyperglycaemia (HbA1c ≥ 42 mmol/mol).

Through the PCTs' GP data extraction facility, it is possible to review anonymised patient data with Read codes indicating that they have received an NHS Health Check. Subsequently, this data has enabled a retrospective review of patients that might have diabetes or be at high risk for developing diabetes (from measurement of HbA1c at the time of their check), with the outcome had the check included and relied solely on the use of the NHS Health Check diabetes filter.

Data was obtained on 34,022 patients that according to the GP practice Read code data, had received a NHS Health Check during the period April 2009 to February 2012. The data was analysed to identify those patients aged 40 – 74 years, previously without diagnosed existing vascular disease, who at the time of their check, were found to be at high risk or have a potential diagnosis of diabetes (HbA1c of 42 mmol/mol or greater). Data on ethnicity, blood pressure measurement and BMI for these patients (from their NHS Check) was used

to determine if the diabetes filter would have correctly identified them as being at risk of diabetes or non - diabetic hyperglycaemia and therefore candidates for a blood glucose test.

Issues with the data include the fact that it extended to patients > 74 years of age (although practices were only remunerated in respect of NHS Health Check patients aged 40 to 74 years without existing vascular disease) and, the inclusion of 951 patients with diagnosed diabetes. In 2007, the Read code for diagnosed diabetes changed in line with the requirements of the Primary Care Quality and Outcomes Framework (QoF). In HoB PCT this led to some previously diagnosed patients being misclassified within the practice clinical information systems and GP practices have been addressing this issue over time.

Ethical approval

This study represents an evaluation/audit of the performance of local NHS Health Check programme compared with the nationally prescribed programme and therefore research ethics approval was not sought. Each GP whose data was used in the course of this study has given prior consent for the data extraction facility (in this case Graphnet) and for AB, as clinical lead for this project (and other clinical aspects of the management of long term conditions in the PCT) to view and utilise clinical data to improve patient management.

Statistical Methods

To assess the performance of the NHS Health Check diabetes filter we calculated the proportion (%) of patients at risk of diabetes or non – diabetes hyperglycaemia (HbA1c of 42 mmol/mol or greater) for whom simple application of the filter would have not led to further testing. We also calculated the sensitivity and positive predictive value of the NHS Health Check filter as a tool for identifying people at risk of diabetes or non – diabetes hyperglycaemia in the HoB population. All estimates are presented with 95% confidence intervals.

Results

Figure 2: Study participants

↓	Patients with a Read code indicating NHS Health Check = 34,022
↓	Age group 40 to 74 years = 32,244
↓	Patients without diagnosed existing vascular disease = 31,293
↓	Patients with HbA1c measured within 3 months of NHS Health Check = 20,439
↓	HbA1c ≥ 42 mmol/mol = 6,998
↓	HbA1c ≥ 42mmol/mol, BMI/BP recorded within 3 months of NHS Check = 6,385

Figure 3: Blood Pressure component of the NHS Health Check diabetes filter

↓	Blood Pressure (≥140/90mmHg) = 2,250/6,385 = 35.2% [34.0% to 36.4%]

Overall 6,385 of the 6,998 patients with HbA1c ≥ 42 mmol/mol had both BMI and blood pressure recorded within 3 months of the NHS Check (further analysis revealed that data was available for those excluded but may have been recorded prior to the date of the NHS Health Check). Of these, 2,250 had raised blood pressure (defined as BP ≥ 140/90mmHg) and 4,135 had normal blood pressure. Thus in this population, raised blood pressure alone detected 2,250/6,385 (35.2% [34.0% to 36.4%]) of patients at risk of having or developing diabetes.

BMI component of the NHS Health Check diabetes filter

Figure 4: Asian ethnicity

↓	HbA1c ≥ 42mmol/mol & BMI/BP recorded within 3 months of NHS Check = 6,385
↓	Ethnicity: Indian, Pakistani, Bangladeshi, Other Asian, Chinese = 3,849
↓	BMI ≥ 27.5 = 2,142 / 3,849 = 55.6% [54.0% to 57.2%]

For the purpose of the NHS Health Check, patients whose ethnic origin puts them at greater risk of diabetes includes those of Indian, Pakistani, Bangladeshi, 'Other' Asian or Chinese origin. The diabetes filter is designed to detect patients at highest risk from within this group by targeting those with a BMI ≥ 27.5. For all other ethnic groups the filter operates at BMI ≥ 30.

Of the 6,385 patients with HbA1c ≥ 42mmol/mol and BMI and blood pressure recorded, 3,849 (with ethnicity recorded) were identified as belonging to the higher risk ethnic group and of these, 2,142 had a BMI ≥ 27.5 (figure 4). In this ethnic grouping raised BMI alone detected 2142 / 3849 (55.6% [54.0% to 57.2%]) of patients with HbA1c ≥ 42 mmol/mol at risk of having or developing diabetes.

Figure 5: Other ethnicity

↓	HbA1c ≥ 42mmol/mol & BMI/BP recorded within 3 months of NHS Check = 6,385
↓	Ethnic group 'other' = 2,119
↓	BMI ≥ 30.0 = 899 / 2,119 = 42.4% [40.3% to 44.5%]

Of the 6,385 patients with HbA1c ≥ 42mmol/mol and BMI and blood pressure recorded, 2,119 (with ethnicity recorded) were identified as belonging to the remaining ethnic groups and of these, 899 had a BMI ≥ 30.0 (figure 5).

In this ethnic grouping raised BMI alone detected 899 / 2,119 (42.4% [40.3% to 44.5%]) of patients with HbA1c ≥ 42 mmol/mol at risk or having of developing diabetes.

BMI appears to perform better than blood pressure as a filter for detecting risk of diabetes, detecting between 42.4% [40.3% to 44.5%] and 55.6% [54.0% to 57.2%] (according to ethnicity) of patients at risk versus 35.2% [34.0% to 36.4%] for blood pressure alone.

NHS Health Check Filter

Combining blood pressure and BMI as filters, overall in the HoB population, the NHS Health Check diabetes filter would have failed to identify 33.3% [31.2% to 35.4%] of patients of known ethnicity with BMI/blood pressure recorded and HbA1c ≥ 42mmol/mol (table 2).

Table 2: Summary results

NHS Check Patients (34,022)	**Total**	**Blood Pressure Normal = (<140/90 mmHg) BMI Normal= (< 27.5 'Asian', < 30 'Other')**	**% at risk of having / developing diabetes undetected by NHS Check diabetes filter**
Aged 40 – 74 years with HbA1c ≥ 42mmol/mol and BMI/BP recorded (ethnicity recorded 'Asian')	3,849	1,207	31.3% [28.7% to 33.9%]
Aged 40 – 74 years with HbA1c ≥ 42 mmol/mol and BMI/BP record (ethnicity recorded 'other')	2,119	783	36.9% [33.5% to 40.3%]
All ethnicities	5,968	1,990	33.3% [31.2% to 35.4%]

Sensitivity and positive predictive value are established measures of the performance of screening tests or tools and are important considerations in determining the effectiveness and acceptability of screening programmes.

Sensitivity relates to the test or tool itself and is defined as the proportion of people (in the screened population) with a disease or disease marker that the screening test or tool correctly identifies. Screening tests with high sensitivity lead to fewer false negative findings. Positive predictive value is the proportion of people that the test or tool identifies as positive that truly have the disease or condition under investigation. This is an important consideration in terms of the acceptability of screening programmes.

Summary data on the sensitivity and positive predictive value of the NHS Health Check diabetes filter in the HoB population are presented in table 3. It should be noted however that the NHS Health Check Programme diabetes filter itself is not a formally accepted screening test for diabetes

Table 3: Sensitivity and positive predictive value of the NHS Health Check diabetes filter and risk for diabetes (HbA1c ≥ 42mmol/mol) in the HoB population (d)

Ethnicity	Test & disease positive patients (a)	Total disease positive patients (b)	**Sensitivity (a/b x100)**	Test & disease positive patients (a)	Total test positive patients (c)	**Positive Predictive Value (a/c x 100)**
'Asian'	2,649	3,856	**68.7% [67.2 to 70.2]**	2,649	5,324	**49.7% [48.4 to 51.0]**
'Other'	1,341	2,141	**62.6% [60.5 to 64.6]**	1,341	4,376	**30.6% [29.2 to 32.0]**
All	3,990	5,997	**66.5% [65.3 to 67.7]**	3,990	9,727	**41.0% [40.0 to 42.0]**

(a) Patients with blood pressure ≥ 140/90mmHg and/or BMI ≥ 27.5/30.0 and HbA1c ≥ 42mmol/mol
(b) Patients with HbA1c ≥ 42mmol/mol
(c) Patients with blood pressure ≥ 140/90mmHg and/or BMI ≥ 27.5/30.0
(d) Patients with $HbA1_C$, BMI, blood pressure and ethnicity recorded (17,573).

Summary

In the Heart of Birmingham area, simple application of the NHS Check diabetes filter would have failed to detect 33.3% [31.2% to 35.4%] of patients of known ethnicity at risk of having or developing diabetes (HbA1c ≥ 42mmol/mol).

As a tool for detecting people at risk of diabetes in the Heart of Birmingham population, the NHS Health Check diabetes filter has a sensitivity of approximately 66%. The positive predictive value is 41% neither of which represents particularly good performance given that the Heart of Birmingham population is a high prevalence population for diabetes.

Sensitivity and positive predictive value of the NHS Health Check diabetes filter in the HoB population is significantly greater for patients (with HbA1c ≥ 42mmol/mol) 'Asian' ethnic origin.

Discussion

Data from the primary care quality and outcomes framework (QOF) 2010/11 (www.ic.nhs.uk) demonstrates that in the HoB area, the prevalence of Type 2 diabetes is high (8.9%) compared with prevalence for the West Midlands (6.2%) and for England as a whole (5.5%)[14]. It is imperative therefore that both primary and secondary prevention approaches

are developed to reduce the risk of developing diabetes and to reduce morbidity and mortality from diabetes and its vascular complications.

Following the introduction of the NHS Health Check programme in 2009, HoB PCT was concerned with identifying those assessed that were at risk of developing diabetes and the PCT encouraged practices to directly measure HbA1c in all individuals attending the programme rather than using the NHS Health Check diabetes filter to first identify those at risk and requiring further testing. It was acknowledged that HbA1c levels may be up to 0.4% higher in people of Black and Asian ethnic origin for the same degree of glucose tolerance[15].

Results from the NHS Check programme in Heart of Birmingham over the period April 2009 to February 2012 (based on 31,293 Health Check patients undiagnosed with existing vascular disease), revealed that 5,997 patients had an HbA1c ≥ 42mmol indicating that they could have diabetes or were at significant risk of developing it. However this study demonstrates that in only approximately two thirds of cases would the measurement of blood pressure and BMI (in accordance with the NHS Check diabetes filter) have led to blood testing for diabetes. In addition, positive predictive value for the NHS Health Check diabetes filter for diabetes and non - diabetes hyperglycaemia was 41%. HoB represents a high diabetes prevalence population and the positive predictive value the NHS Health Check diabetes filter will be less in lower prevalence populations.

This is a unique set of data and possibly the first evaluation of its size undertaken to test the effectiveness of a risk identification tool for diabetes in a high risk, ethnically diverse population without diagnosed existing vascular disease. In each case, actual risk for diabetes had been obtained directly from measurement of HbA1c. The evaluation clearly identifies the potential for the NHS Health Check to fail to identify people that are at high risk of having or developing diabetes. Given availability of such a unique dataset, further work will be undertaken to demonstrate the impact on sensitivity and positive predictive value from changing the current NHS Health Check thresholds for BMI and blood pressure. Given the depth of the available data it would also be of value to assess whether or not the use of other patient parameters such as waist circumference might improve the performance of the filter.

Further analysis will be undertaken to determine the effectiveness of the filter in subgroups relating to age, gender and ethnicity, its likely effectiveness at predicting those at high risk of CVD mortality, and the overall cost effectiveness of the measurement of HbA1c for all people in the NHS Health Check programme.

What is already known on this subject

Public health guidance on risk identification and interventions for individuals at high risk of Type 2 diabetes was published by NICE in July 2012. First, a risk assessment should be offered using either a validated computer-based risk assessment tool or a validated self-assessment questionnaire.

According to NICE, this guidance can also be used alongside the NHS Health Check programme, which uses its own risk identification tool or *diabetes filter* based on recording and measurement ethnicity, blood pressure and BMI.

Abbasi et al recently published a study concerned with external validation of prediction models for risk of developing diabetes and concluded that existing prediction models can perform well to identify those at high risk of future diabetes[16].

What this study adds

This is a unique set of data and possibly the first study of its size to evaluate in a clinical practice setting the effectiveness of a risk identification tool for diabetes in a high risk, ethnically diverse population without diagnosed existing vascular disease.

The evaluation clearly identifies the potential for the widely available NHS Health Check to fail to identify people that are at high risk of having or developing diabetes.

More research is needed to develop risk identification approaches for populations at high risk of developing Type 2 diabetes and cardiovascular disease.

Contributorship:

Dr AC Felix Burden provided access to the data for the evaluation. Jamie Waterall is the NHS Birmingham Public Health lead for prevention programmes including local implementation of the NHS Health Check. Dr Burden and Mr Waterall respectively provided expert advice on chronic disease management (and in particular diabetes) and the NHS Health Check programme. Sarah Smith was responsible for the data analysis, statistical analysis and for the preparation and submission of the manuscript.

Data sharing:

There is no additional data available

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Article summary

Article focus

- The NHS Health Check programme (NHSHCP) was introduced in 2009 to improve case finding through assessment of vascular risk in the general population aged 40 to 74 years, without diagnosed existing vascular disease. The NHSHCP includes assessment of risk of diabetes using a diabetes screening test called a *filter* (based on ethnicity, body mass index (BMI) and blood pressure).
- Within Heart of Birmingham Primary Care Trust (HoB PCT), people from the Indian sub-continent represent the largest group (over 60%). A consistent finding within this migrant population (compared to the indigenous population), is a higher incidence and prevalence of premature coronary heart disease (CHD), in part as a consequence of diabetes. Consequently, the PCT were concerned with ensuring that the NHSHCP was effective in identifying early, those at high risk from type 2 diabetes and cardiovascular disease.
- Through the PCTs' GP data extraction facility, it was possible to review anonymised patient data with Read codes indicating that they had received an NHS Health Check. Subsequently, this data enabled a retrospective review of patients that might have diabetes or be at high risk for developing diabetes (from measurement of HbA1c at the time of their check), with the outcome had the check relied solely on the use of the NHS Health Check diabetes filter.

Key messages

- This evaluation, which was based on a large population sample, demonstrates that the NHS Health Check programme diabetes filter failed to identify a third of people at high risk of having or developing diabetes (defined as HbA1c $\geq$ 42mmol/mol and measured around the time of their check).
- Use of the current NHS Health Check may lead to a failure to identify a group of patients with normal body weight but at high risk from diabetes and cardiovascular disease.
- Further policy development is required along with more research is into effective risk identification approaches for populations at high risk of developing type 2 diabetes and cardiovascular disease.

Strengths and limitations of this study

- This is possibly the first study of its size to evaluate the effectiveness of the NHS Health Check diabetes filter in clinical practice. Actual risk for diabetes was assessed from a single recorded measure of HbA1c around the time of the health check.
- For some patients data on ethnicity was incomplete and/or data was not available for BP and BMI (further analysis revealed that data was available but may have been recorded prior to the date of the NHS Health Check).
- The evaluation involved simple application of the NHS Health Check diabetes filter and did not take into account additional aspects of risk assessment such as family history of diabetes or other relevant comorbidities.

Introduction

According the Chief Medical Officer (CMO) for England, in 2010, cardiovascular disease (CVD) was responsible for around one in three premature deaths (under 75) in men and one in five premature deaths in women. Coronary heart disease (CHD) and stroke are the main causes of CVD mortality.[1]

Heart of Birmingham Primary Care Trust (HoBPCT) is a primary care trust area in inner city Birmingham covering a population of approximately 275,000. The main functions of primary care trusts are to understand and engage with their local population to improve health and wellbeing, and to commission a comprehensive and equitable range of high quality and responsive health services. The HoBPCT area is characterised by a majority population from minority population groups (70% non-white). Over the period 2008 to 2010, average life expectancy for men in the HoBPCT area was 75 years compared with 78 years for England.

In HoBPCT, people from the Indian sub-continent represent the largest group (over 60%). A consistent finding within this migrant population (compared to the indigenous population) is a higher incidence and prevalence of premature coronary heart disease (CHD), in part as a consequence of diabetes; people from South Asian backgrounds have a higher risk of developing type 2 diabetes and they develop it on average five years earlier than white people[2,3]. The National Institute for Health and Clinical Excellence recommends that all people with diabetes be considered to be at high premature cardiovascular risk for their age unless they: are not overweight, are normotensive, have no evidence of microalbuminuria, are a non-smoker, do not have a high-risk lipid profile and have no history of CVD and no family history of CVD[4].

The NHS Health (formerly vascular) Check programme (www.healthcheck.nhs.uk) was introduced in 2009 to improve case finding through assessment of vascular risk in the general population aged 40 to 74 years without diagnosed existing vascular disease (table1).

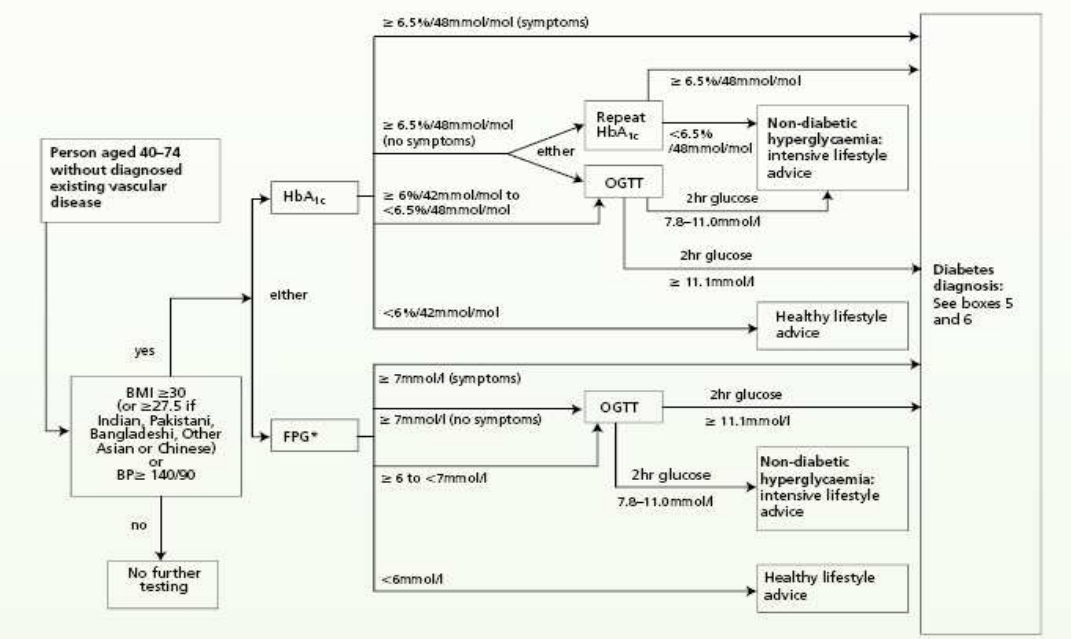
Table 1: NHS Health Check Programme exclusions with diagnosed existing vascular disease

Atrial Fibrillation Chronic Kidney Disease (stages 3-5), Coronary Heart Disease, Diabetes Heart Failure	Hypertension Hypercholesterolaemia Peripheral Arterial Disease (PAD) Stroke Transient Ischaemic Attack (TIA)

The NHS Health Check programme combines known risk factors for cardiovascular disease in an approved risk calculator (Framingham or QRISK ™ 2) to estimate individual 10 - year risk of cardiovascular disease. All participants are offered management strategies to reduce individual risk with the overall aim of reducing the incidence and prevalence of cardiovascular disease in the population.

The NHS Health Check includes assessment of risk of diabetes using a diabetes screening tool called a *filter* (based on ethnicity, body mass index (BMI) and blood pressure) to identify those participants that should also receive a blood glucose test (either HbA1c or fasting plasma glucose (FPG)). This is described is diagrammatically in figure one.

Figure 1: Diagrammatic overview for identifying people at high risk of having or developing diabetes



Source: Putting Prevention First NHS Health Check: Vascular Risk Assessment and Management Best Practice Guidance (http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets /documents/digitalasset/dh_098410.pdf)

This two stage screening procedure is based largely on evidence from two large population-based screening studies in the UK in Leicester involving both the South Asian and White European population in the city.[5]

The National Institute for Health and Clinical Excellence (NICE) recently published guidance on risk identification and interventions for people at high risk of type 2 diabetes[6]. There is no single accepted way of identifying people who are at risk of diabetes or who have existing undiagnosed diabetes. NICE however also recommends a two stage process starting with either a validated, computer - based risk assessment tools applied to demographic and routine data in clinical information systems e.g. the Cambridge risk score[7], or a validated self - assessment questionnaires such as FINDRISC[8] or the Diabetes Risk Score[9]. NICE also states that the guidance can be used alongside the NHS Health Check programme.

The diabetes filter employed in the NHS Check Programme (BMI ≥ 30 (or ≥ 27.5 if Indian, Pakistani, Bangladeshi, Other Asian or Chinese) or blood pressure ≥ 140/90mmHg or where the SBP or DBP exceeds 140mmhg or 90mmhg respectively) is considered feasible in practice and a pragmatic means of identifying those at highest risk of diabetes without

unnecessarily subjecting an excess of people to blood glucose testing. However the filter will potentially exclude people with diabetes with normal or low body weight.

Existing evidence regarding the relationship between weight and mortality in type 2 diabetes is conflicting. For example, in the World Health Organization Multinational Study of Vascular Disease in Diabetes, there was no clear relationship between BMI and cardiovascular mortality[10]. Carnethon et al found that after adjustment, hazard ratios comparing normal weight participants with diabetes with overweight/obese participants for total, cardiovascular, and non - cardiovascular mortality were 2.08 (95% CI, 1.52 - 2.85), 1.52 (95% CI, 0.89 - 2.58), and 2.32 (95% CI, 1.55 - 3.48), respectively[11].

Recently, the World Health Organisation has stated that HbA1c alone can be used as a diagnostic test for diabetes provided that "stringent quality assurance tests are in place, assays are standardised to criteria aligned to the international reference values, and there are no conditions present which preclude its accurate measurement"[12]. An HbA1c of 48mmol/mol (6.5%) is recommended as the cut point for diagnosing diabetes (the SI unit for HbA1c is mmol/mol and is defined as mmol HbA1c per mol HbA_0 + HbA1c).

Glycaemia, whether estimated by fasting glucose or HbA1c, has a continuous relationship with the risk of CVD[13]. An HbA1c of 42 – 48 mmol/ml may indicate the presence of impaired glucose regulation (non-diabetes hyperglycaemia) and people with impaired glucose regulation are 5 -15 times more likely to develop type 2 diabetes than those with normal glucose values.[14]

In HoB PCT, given the high - risk population, a strategic clinical decision was made to request that GP practices offered all those attending the NHS Health Check programme, measurement of HbA1c (without application of the filter), to establish directly an individual's risk of diabetes or non – diabetes hyperglycaemia. Through HoBPCTs' GP data extraction facility it is possible to identify from Read codes, patients that have received an NHS Health Check. This enabled retrospective review of patients at high risk for developing diabetes (from measurement of HbA1c at the time of their check) with the outcome had the check relied solely on the use of the NHS Health Check diabetes filter.

Method

NHS Health Check Programme

NHS Health Checks are largely carried out in primary care settings. Best practice guidance has been issued to guide local areas in the identification of appropriate patients and systems for call, recall and follow-up. Best practice guidance also describes standards for obtaining anthropometric measurements such as height and weight (from which to calculate BMI) and other measurements such as blood pressure and serum cholesterol[15].

Ethnicity is needed for diabetes risk assessment and should be recorded using the most recent Office for National Statistics categories that were first developed for the England and Wales Census in 1991. These categories have been expanded at each subsequent census (in 2001 and 2011)[16].

Study method

Data was obtained from GP records on 34,022 patients resident in HoBPCT that had received a NHS Health Check during the period April 2009 to February 2012.

Records were excluded if the patient was currently < 40 or > 74 years of age (n = 1,778) and therefore were outside of the NHS Health Check age range, or if the patient at the time of their NHS Health Check had already been diagnosed with diabetes (n = 951). Records were also excluded if data on HbA1c, blood pressure, BMI and ethnicity were not recorded within three months of their health check (n = 12,648)

The remaining data were analysed to identify those patients who at the time of their check were found to be at high risk of diabetes (HbA1c of 42 mmol/ml or greater) (n= 5,968). Data on ethnicity, blood pressure measurement and BMI for these patients (from their NHS Health Check) was used to determine if the diabetes filter would have correctly identified them as candidates for a blood glucose test. For the purpose of the NHS Health Check, patients whose ethnic origin puts them at greater risk of diabetes includes those of Indian, Pakistani, Bangladeshi, 'Other' Asian or Chinese origin. The diabetes filter is designed to detect patients at highest risk from within this group by targeting those with a BMI ≥ 27.5. For all other ethnic groups the filter operates at BMI ≥ 30.

Ethical approval

Advice was obtained from the local NHS R&D Consortium. It was determined that this study represents an evaluation undertaken as part of an ongoing PCT programme. For this reason it was not necessary to have R&D approval from the consortium or a favourable ethical opinion from an NHS research ethics committee.

In terms of the PCT data extraction facility, the PCT Professional Executive Committee (PEC) and GP locality leads previously provided approval for the vascular screening work programme, including evaluation and publication and for AB, as PCT clinical lead, to view and utilise clinical data to improve patient management and population health.

Statistical methods

To assess the performance of the NHS Health Check diabetes filter we calculated the proportion (%) of patients at risk of diabetes or non – diabetes hyperglycaemia (HbA1c of 42 mmol/mol or greater) for whom simple application of the filter would not have led to blood glucose testing.

We also calculated the sensitivity, positive predictive value and specificity of the NHS Health Check filter as a tool for identifying people at risk of diabetes or non – diabetes hyperglycaemia in the HoB population.

All estimates are presented with 95% confidence intervals.

Results

Figure 2: Study participants

↓	Patients with a Read code indicating NHS Health Check = 34,022
↓	Age group 40 to 74 years = 32,244
↓	Patients without diagnosed existing vascular disease = 31,293
↓	Patients with HbA1c measured within 3 months of NHS Health Check = 20,439
↓	BMI / blood pressure measured within 3 months of NHS Health Check and ethnicity recorded = 17,484
↓	Patients with HbA1c ≥ 42mmol/mol = 5,968

Application of the NHS Health Check Diabetes Filter

Combining blood pressure, BMI and ethnicity as filters, overall the NHS Health Check diabetes filter failed to identify risk of diabetes in 33.3% [31.2% to 35.4%] of 5,968 patients with HbA1c ≥ 42mmol/mol (table 2)

Table 2: Summary performance of the NHS Health Check diabetes filter

NHS Check patients (Aged 40 – 74 years with HbA1c ≥ 42mmol/mol and BMI/BP recorded)	**Total**	**Blood pressure normal = (<140/90 mmHg) BMI normal= (< 27.5 'Asian', < 30 'Other')**	**% at risk of diabetes not identified by application of the NHS Check diabetes filter**
Ethnicity 'Asian'	3,849	1,207	31.3% [28.7% to 33.9%]
Ethnicity 'Other'	2,119	783	36.9% [33.5% to 40.3%]
All ethnicities	5,968	1,990	33.3% [31.2% to 35.4%]

Summary data on the sensitivity, positive predictive value (PPV) and specificity of the NHS Health Check diabetes filter in the HoB population are presented in table 3. It should be noted however that the NHS Health Check Programme diabetes filter itself is not a formally accepted screening test for diabetes

Table 3: Sensitivity, positive predictive value and specificity of the NHS Health Check diabetes filter and risk for diabetes (HbA1c ≥ 42mmol/mol)

Sensitivity			
Ethnicity	Test & disease positive patients (a)	Total disease positive patients (b)	Sensitivity (a/b x100)
'Asian'	2,649	3,849	68.8% [67.2% to 70.3%]
'Other'	1,341	2,119	63.3% [60.5% to 64.6%]
All	3,990	5,968	66.8% [65.7% to 68.0%]
Positive Predictive Value			
Ethnicity	Test & disease positive patients (a)	Total test positive patients (c)	Positive Predictive Value (a/c x 100)
'Asian'	2,649	5,324	49.7% [48.4% to 51.0%]
'Other'	1,341	4,376	30.6% [29.2% to 32.0%]
All	3,990	9,700	41.1% [40.1% to 42.1%]
Specificity			
Ethnicity	Test & disease negative patients (d)	Total disease negative patients (e)	Specificity (d/e x100)
'Asian'	1,793	5,221	34.3% [33.0% to 35.6%]
'Other'	2,208	6,295	35.1% [33.9% to 36.3%]
All	4,001	11,516	34.7% [33.9% to 35.6%]

(a) Patients with blood pressure ≥ 140/90mmHg and/or BMI ≥ 27.5/30.0 and HbA1c ≥ 42mmol/mol
(b) Patients with HbA1c ≥ 42mmol/mol
(c) Patients with blood pressure ≥ 140/90mmHg and/or BMI ≥ 27.5/30.0
(d) Patients with blood pressure < 140/90mmHg and/or BMI < 27.5/30.0 and HbA1c < 42mmol/mol

(e) Patients with HbA1c < 42mmol/mol

In the Heart of Birmingham population, as a tool for identifying people at risk of diabetes, the NHS Health Check diabetes filter has a sensitivity of approximately 67%. Positive predictive value is 41%. This means that only two thirds of those at risk for diabetes would have been identified as candidates for blood glucose testing and, that of all the patients identified as being at risk for diabetes, less than half would have been found to be at risk following blood glucose testing. Sensitivity and positive predictive value of the NHS Health Check diabetes filter in the HoB population is significantly greater for patients of 'Asian' ethnic origin than those of other ethnicity (Sensitivity 68.8% [67.2% to 70.3%] versus 63.3% [60.5% to 64.6%], PPV 49.7% [48.4% to 51.0%] versus 30.6% [29.2% to 32.0%]. The NHS Health Check diabetes filter has a specificity of approximately 35% meaning that in Heart of Birmingham two thirds of people that were not at risk for diabetes would have been identified by the filter as requiring a blood glucose test.

Sub group analysis

The performance of the diabetes filter was reviewed separately in males and females and the results are included in table 4. The diabetes filter failed to identify a greater proportion of men than women at risk for diabetes (37.8% [36.1% to 39.6%] versus 28.7% [27.1% to 30.3%]).

Table 4: Performance of the NHS Health Check diabetes filter according to gender.

NHS Check Patients (34,022) **Aged 40 – 74 years with HbA1c ≥ 42mmol/mol and BMI/BP recorded**	**Total**	**Blood pressure normal = (<140/90 mmHg) BMI normal= (< 27.5 'Asian', < 30 'Other')**	**% at risk of diabetes not identified by application of the NHS Check diabetes filter**
Male			
Ethnicity 'Asian'	1,894	692	36.5% [34.4% to 38.7%]
Ethnicity 'Other'	1,071	439	41.0% [38.1% to 44.0%]
All ethnicities	2,965	1,121	37.8% [36.1% to 39.6%]
Female			
Ethnicity 'Asian'	1,955	517	26.4% [24.5% to 28.4%]
Ethnicity 'Other'	1,047	344	32.8% [30.1% to 35.8%]

All ethnicities	3,002	861	28.7% [27.1% to 30.3%]

Asian ethnicity

Due to the increased risk for diabetes in the South Asian population, the NHS Health Check diabetes filter was tested at the lower threshold for body mass index (23.0 Kg/m^2) in the 'Asian' subgroup. Results in the terms of sensitivity, positive predictive value and specificity of the diabetes filter at this BMI threshold are presented in table 5.

Table 5: Sensitivity, positive predictive value and specificity of the NHS Health Check diabetes filter (Asian BMI ≥ 23.0) and risk for diabetes (HbA1c ≥ 42mmol/mol)

Sensitivity			
Ethnicity	Test & disease positive patients (a)	Total disease positive patients (b)	Sensitivity (a/b x100)
'Asian'	3,471	3,849	90.2% [89.2% to 91.1%]
Positive Predictive Value			
Ethnicity	Test & disease positive patients (a)	Total test positive patients (c)	Positive Predictive Value (a/c x 100)
'Asian'	3,471	8,226	42.2% [41.1% to 43.3%]
Specificity			
Ethnicity	Test & disease negative patients (d)	Total disease negative patients (e)	Specificity (d/e x100)
'Asian'	632	5,221	12.1% [11.2% to 13.0%]

(a) Patients with blood pressure ≥ 140/90mmHg and/or BMI ≥ 23.0 and HbA1c ≥ 42mmol/mol
(b) Patients with HbA1c ≥ 42mmol/mol
(c) Patients with blood pressure ≥ 140/90mmHg and/or BMI ≥ 23.0
(d) Patients with blood pressure < 140/90mmHg and/or BMI < 23.0 and HbA1c < 42mmol/mol
(e) Patients with HbA1c < 42mmol/mol

Reducing the BMI threshold to ≥ 23.0 improves performance of the filter in identifying Asian patients at risk for diabetes from approximately 70% to 90%. However this improvement in the sensitivity of the filter is offset by a reduction in positive predictive value and more significantly specificity. As a result, many more patients would be subject unnecessarily to blood glucose testing.

Discussion

According to the charity Diabetes UK, by 2025 there will be more than five million people with diabetes in the UK and most of these cases will be type 2 diabetes[17].

In 2002, the Department of Health estimated that 5% of total NHS expenditure is used for the care of people with diabetes. This figure is now believed to be closer to 10% of total NHS expenditure, which equates to £9 billion per year[18]. Consequently, eearly identification of risk of developing diabetes and intervention to reduce the incidence of diabetes and its complications are increasingly urgent and important strategies.

In 2002 in the US screening guidelines were proposed by the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus[19]. Although testing is not recommended in the general population, screening is recommended for those 45 years of age and older; with repeated testing every 3 years if results are normal. Screening is also recommended at younger ages or at more frequent intervals for those who have one or more diabetes risk factors. Dallo and Weller identified that although these guidelines have been widely endorsed, one-third of cases are undiagnosed and complications at the time of diagnosis indicate that disease may have been present for several years, suggesting that either screening is not effective or that the guidelines are not being followed[20].

The performance of the US screening guidelines for identifying undiagnosed diabetes, have been examined in a national sample (The National Health and Nutrition Examination Survey (NHANES III)[20]. The relative importance of risk factors in identifying new cases of diabetes was obtained by comparing those with undiagnosed diabetes (from fasting plasma glucose) with those without diabetes. All the risk factors included in the screening guidelines had a strong association with diabetes; having hypertension or a positive family history of diabetes doubled the risk of having diabetes whilst age, obesity, a poor lipid profile, and gestational diabetes more than doubled the risk. Risk increased with increase in BMI and it was apparent that being ‘‘overweight’’ was a significant risk factor without the presence of obesity. Age was the risk factor most strongly associated with the detection of undiagnosed cases of diabetes however the authors caution against clinical screening strategies focused only on older adults (> 45 years of age) as potentially these could exclude minorities that develop diabetes at a younger age.

In the UK, the National Screening Committee has determined against screening the general adult population for diabetes, whilst recognising the need for a vascular risk management programme that includes diabetes (www.screening.nhs.uk/diabetes). In 2009, in response to this policy and the increasing human and healthcare burden from diabetes, the Department of Health in England introduced the NHS Health Check Programme, a vascular ‘check’ for people aged 40 to 74 years without diagnosed existing vascular disease. The NHS Health Check assesses 10 – year risk of cardiovascular disease; combining patient – level data (including physiological and biochemical tests and anthropometric measurements) in an approved risk calculator. It also employs a diabetes filter based on known risk factors (blood pressure, BMI and ethnicity) to identify patients at high risk for undiagnosed diabetes who should undergo blood glucose testing.

In our study, the NHS Health Check diabetes filter failed to identify a third of patients at high risk for diabetes (defined as HbA1C ≥ 42mmol/mol). Conversely, two thirds of those that

were identified by the filter as being at high risk had HbA1c < 42mmol/mol. Positive predictive value for those patients identified by the filter as being at risk, was 41%.

Heart of Birmingham represents a high prevalence population for diabetes and the positive predictive value the NHS Health Check diabetes filter will be less in lower prevalence populations.

National Institute for Health and Clinical Excellence guidelines on risk identification and intervention for people at high risk of type 2 diabetes are recommended for implementation alongside the NHS Health Check Programme[6]. However in the guidelines, risk identification relies on the use of validated computer-based risk assessment tools or validated self assessment questionnaires and extends to groups other than those aged 40-74 years, to include people of South Asian and Chinese descent aged 25-39 years (except for pregnant women) and other adults with conditions that increase the risk of type 2 diabetes such as cardiovascular disease and gestational diabetes. NICE also recommend considering a blood test for those aged 25 years or more of South Asian or Chinese descent whose BMI is greater than 23.0

The World Health Organisation (WHO) international classification of overweight was developed in 1993 and is based on a BMI cut-off point of 25kg/m^2. In 2002, a WHO expert consultation was convened to consider the interpretation of recommended body-mass index (BMI) cut-off points for determining overweight and obesity in Asian populations[21]. It was suggested that Asian populations have different associations between BMI, percentage of body fat, and health risks than do European populations, however the cut-off point for observed risk varies for different Asian populations. The consultation agreed that the WHO BMI cut-off point for overweight (25 kg/m^2) should be retained as an international classification, whilst agreeing the existence of further potential public health action points (23.0, 27.5, 32.5, and 37.5 kg/m^2) along the continuum of BMI.

We tested the BMI threshold for screening for diabetes in people of Asian ethnic origin in line with the WHO recommendations. Using a cut off point of BMI $\geq$ 23.0 for Asian patients (rather than $\geq$ 27.5 as per the NHS Health Check) dramatically increased the sensitivity of the diabetes filter in detecting those at risk of diabetes (to approximately 90%). However as a consequence, were this strategy to be adopted, the specificity of the filter would reduce to 12% and many more patients who were not at risk would be subjected to blood glucose testing.

Several risk scores have been developed to predict diabetes risk. These are based on a core set of readily available non invasive measures e.g. HDL cholesterol, blood pressure, family history, and a measure of adiposity (either body mass index or waist circumference) or on data from questionnaires[22]. More sophisticated risk scoring methods include fasting plasma glucose however this reduces the practicality of the approach. Full prediction models have been shown to be more discriminatory than single risk factors for predicting the risk of diabetes however most of these risk equations have been developed in research populations and several authors have identified that recalibration is needed before these equations can be used to estimate the risk of diabetes for individual patients[22,23].

Abbasi et al conducted a systematic review of to identify existing risk prediction tools for diabetes including both basic and 'extended' tools; the latter including biomarkers such as blood glucose concentration[23]. Twelve basic and thirteen extended models were subsequently validated in a random sub cohort (n=2506) of a Dutch prospective cohort study (European Prospective Investigation into Cancer (EPIC-NL). In the majority of cases the prediction tools overestimated the absolute risk of diabetes in the validation population. After adjustment for population incident risk, the performance of the prediction tools improved however on the whole significant deviations between estimated and observed risk remained. The authors concluded that prediction tools developed in study populations can be calibrated for use in external populations and are effective in identifying those at high risk but are less reliable for predicting absolute risk of diabetes.

Conclusion

This evaluation, which was based on a large population sample, demonstrates that the NHS Health Check programme diabetes filter failed to identify a third of people that are at high risk of having or developing diabetes. This is a unique set of data and possibly the first evaluation of the NHS Health Check diabetes filter in a clinical practice setting whereby actual risk for diabetes had been obtained directly from measurement of HbA1c.

Given availability of such a unique dataset, further work will be undertaken to demonstrate the impact on sensitivity and positive predictive value from varying the current NHS Health Check thresholds for BMI and blood pressure. Given the depth of the available data it would also be of value to assess whether or not the use of other patient parameters such as waist circumference might improve the performance of the filter. Further analysis will be undertaken to determine the overall cost effectiveness of direct measurement of HbA1c for all people in the NHS Health Check programme.

The NHS Health Check diabetes filter is intended to be both pragmatic and feasible in clinical practice. However, computer-based risk scoring tools for diabetes that have been validated for use in the UK population (as advocated by NICE) may be more effective in risk identification for diabetes.

What is already known on this subject

There is no single accepted way of identifying undiagnosed people at risk for diabetes. Several risk scores have been developed to predict diabetes risk and these can be calibrated to external populations.

Public health guidance has been published by NICE on risk identification in type 2 diabetes. This recommends that first, a risk assessment should be offered using either a validated computer-based risk assessment tool (validated for use in UK populations) or a validated self-assessment questionnaire. According to NICE, this guidance can also be used alongside the NHS Health Check programme, which uses its own risk identification tool or diabetes filter based on recording and measurement of ethnicity, blood pressure and BMI.

What this study adds

This is a unique set of data and possibly the first evaluation of the NHS Health Check diabetes filter in a clinical practice setting whereby actual risk for diabetes had been obtained directly from measurement of HbA1c. This evaluation demonstrates that the NHS Health Check programme diabetes filter failed to identify a third of people that were at high risk of developing diabetes.

Contributorship:

Dr AC Felix Burden provided access to the data for the evaluation. Jamie Waterall was the NHS Birmingham Public Health lead for prevention programmes including local implementation of the NHS Health Check. Dr Burden and Mr Waterall respectively provided expert advice on chronic disease management (and in particular diabetes) and the NHS Health Check programme. Sarah Smith was responsible for the data analysis, statistical analysis and for the preparation and submission of the manuscript.

Data sharing:

There is no additional data available

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An evaluation of the performance of the NHS Health Check programme in identifying people at high risk of developing Type 2 diabetes

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Article summary

Article focus

- The NHS Health Check programme (NHSHCP) was introduced in 2009 to encourage people to consider positive lifestyle changes and to improve case finding through assessment of vascular risk in the general population aged 40 to 74 years, without diagnosed existing vascular disease. The NHSHCP includes assessment of risk of diabetes using a diabetes screening test called a *filter* (based on ethnicity, body mass index (BMI) and blood pressure).
- In the UK, people from the Indian sub-continent experience a higher incidence and prevalence of premature coronary heart disease (CHD), in part as a consequence of diabetes. It is particularly important that those at highest risk in this population sub group are identified early.
- This study, to evaluate the NHSHCP diabetes filter, was conducted in a population where people of South Asian origin represent the largest group (over 60%). The study involved retrospective review of patients already identified as at high risk for diabetes (from measurement of HbA1c at the time of their NHS Check), with the outcome had the check relied solely on the use of the NHS Health Check diabetes filter.

Key messages

- This evaluation, which was based on a large, high - risk population sample, demonstrates that the NHS Health Check programme diabetes filter failed to identify a third of people at actual risk of having or developing diabetes (defined as HbA1c ≥ 42mmol/mol).
- Use of the current NHS Health Check diabetes filter may lead to a failure to identify a group of patients with normal body weight but at high risk from diabetes and cardiovascular disease.
- Further policy development is required along with more research into effective risk identification approaches for populations at high risk of developing Type 2 diabetes and cardiovascular disease.

Strengths and limitations of this study

- This is possibly the first study of its size to evaluate the effectiveness of the NHS Health Check diabetes filter in clinical practice and, offers a unique opportunity to evaluate the performance of the filter in a large population sample with actual risk for diabetes assessed from direct measurement of HbA1c.
- HbA1c was not measured in all patients attending the NHS Health Check and for some patients, data on ethnicity were incomplete and/or data were not available for BP and BMI (further analysis revealed that the data were available but may have been recorded prior to the date of the NHS Health Check).
- The evaluation involved simple application of the NHS Health Check diabetes filter and did not take into account additional aspects of risk assessment such as family history of diabetes or other relevant comorbidities.

Abstract

Objective: To evaluate the performance of the NHS Health Check in identifying people at high risk of having or developing Type 2 diabetes.

Design: Retrospective evaluation of the performance of the NHS Health Check diabetes filter (based on ethnicity, body mass index (BMI) and blood pressure) in identifying people at risk for Type 2 diabetes (HbA1c ≥ 42 mmol/mol recorded within 3 months of their NHS Health Check).

Setting: Heart of Birmingham Primary Care Trust (HoB PCT).

Subjects: 34,022 patients with a Read code in the GP clinical record indicating that they had attended an NHS Health Check over the period April 2009 to February 2012.

Outcome measures: Primary outcome measure: proportion (%) of patients at risk of diabetes or non – diabetes hyperglycaemia not detected by simple application of the NHS Health Check diabetes filter. Secondary outcome measures included sensitivity, positive predictive value (PPV) and specificity of the NHS Health Check diabetes filter.

Results: In HoB PCT, simple application of the NHS Health Check diabetes filter led to failure to detect 1990/5968 (33.3% [95% CI, 31.2% to 35.4%]) of patients of known ethnicity at risk of having or developing diabetes (HbA1c ≥ 42mmol/mol). The NHS Health Check diabetes filter has a sensitivity of 66.5% [95% CI, 65.3% to 67.7%] and the PPV was 41.0% [95% CI, 40.0% to 42.0%]. Specificity was 37.4% [95%CI, 33.9% to 35.6%]. Sensitivity and PPV of the NHS Health Check diabetes filter in the HoB PCT population is significantly greater for patients of Asian ethnic origin than for white people.

Conclusions: This evaluation, which was based on a large population sample, demonstrates that the NHS Health Check programme diabetes filter failed to identify a third of people at high risk of having or developing diabetes.

Introduction

According to the Chief Medical Officer (CMO) for England, in 2010, cardiovascular disease (CVD) was responsible for around one in three premature deaths (under 75) in men and one in five premature deaths in women. Coronary heart disease (CHD) and stroke are the main causes of CVD mortality[1].

In the UK, people from the Indian sub-continent experience a higher incidence and prevalence of premature coronary heart disease (CHD), in part as a consequence of diabetes; people from South Asian backgrounds have a higher risk of developing Type 2 diabetes and they develop it on average five years earlier than white people[2,3]. The National Institute for Health and Clinical Excellence recommends that all people with diabetes be considered to be at high premature cardiovascular risk for their age unless they: are not

overweight, are normotensive, have no evidence of microalbuminuria, are a non-smoker, do not have a high-risk lipid profile and have no history of CVD and no family history of CVD[4].

NICE recently published guidance on risk identification and interventions for people at high risk of type 2 diabetes[5]. There is no single accepted way of identifying people who are at risk of diabetes or who have existing undiagnosed diabetes. NICE recommends a two stage process starting with either a validated, computer - based risk assessment tools applied to demographic and routine data in clinical information systems e.g. the Cambridge risk score[6], or a validated self - assessment questionnaires such as FINDRISC[7] or the Diabetes Risk Score[8]. NICE states that this guidance can be used alongside the NHS Health Check programme.

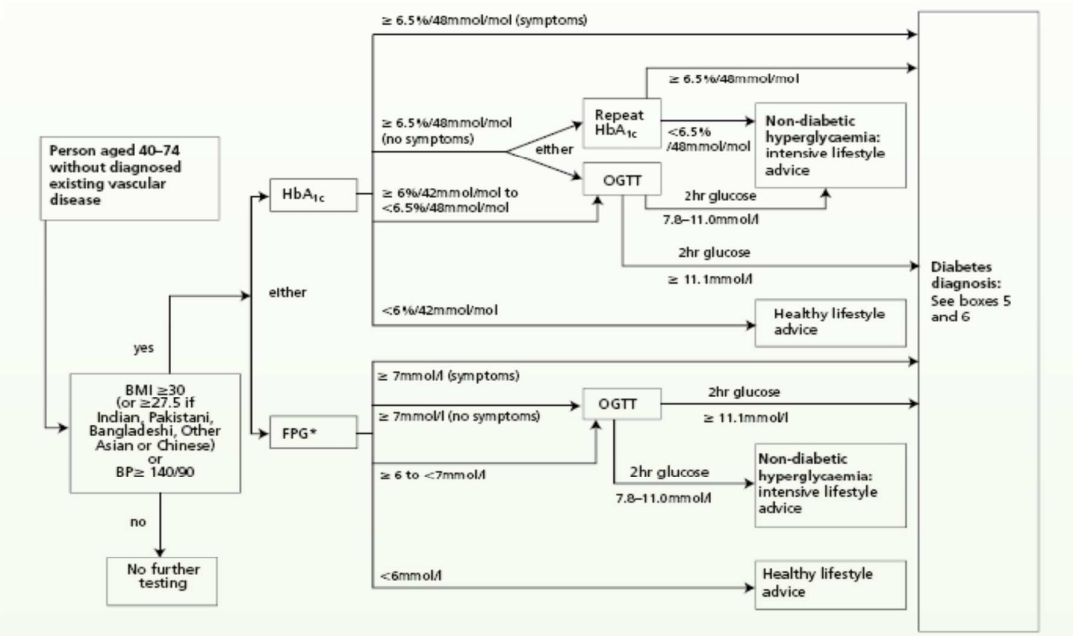
The NHS Health (formerly vascular) Check programme (www.healthcheck.nhs.uk) was introduced in 2009 with the combined aims of improving life expectancy and reducing health inequalities (by engaging with individuals to consider their modifiable risk factors) and improved case finding through assessment of vascular risk in the general population aged 40 to 74 years without diagnosed existing vascular disease (table1).

Table 1: NHS Health Check Programme exclusions with diagnosed existing vascular disease

Atrial Fibrillation Chronic Kidney Disease (stages 3-5), Coronary Heart Disease, Diabetes Heart Failure	Hypertension Hypercholesterolaemia Peripheral Arterial Disease (PAD) Stroke Transient Ischaemic Attack (TIA)

The NHS Health Check includes assessment of risk of diabetes using a diabetes screening tool called a *filter* (based on ethnicity, body mass index (BMI) and blood pressure) to identify those participants that should also receive a blood glucose test (either HbA1c or fasting plasma glucose (FPG)). This is described diagrammatically in figure one.

Figure 1: Diagrammatic overview for identifying people at high risk of having or developing diabetes



Source: Putting Prevention First NHS Health Check: Vascular Risk Assessment and Management Best Practice Guidance (http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets /documents/digitalasset/dh_098410.pdf)

Potentially, the diabetes filter will exclude people with diabetes with normal or low body weight. However, this two stage screening procedure is considered pragmatic and is based largely on evidence from two population-based screening studies in the UK in Leicester, involving both the South Asian and White European populations in the city[9].

Existing evidence regarding the relationship between weight and mortality in Type 2 diabetes is conflicting. For example, in the World Health Organization Multinational Study of Vascular Disease in Diabetes, there was no clear relationship between BMI and cardiovascular mortality[10]. More recently, Carnethon et al found that after adjustment, hazard ratios comparing normal weight participants with diabetes with overweight/obese participants for total, cardiovascular, and non - cardiovascular mortality were 2.08 (95% CI, 1.52 - 2.85), 1.52 (95% CI, 0.89 - 2.58), and 2.32 (95% CI, 1.55 - 3.48), respectively[11].

Glycaemia, whether estimated by fasting glucose or HbA1c, has a continuous relationship with the risk of CVD[12].

Recently, the World Health Organisation has stated that HbA1c alone can be used as a diagnostic test for diabetes provided that widely accepted criteria are met[13]. An HbA1c of 48mmol/mol (6.5%) is recommended as the cut point for diagnosing diabetes (the SI unit for HbA1c is mmol/mol and is defined as mmol HbA1c per mol HbA_0 + HbA1c). An HbA1c of 42 – 48 mmol/ml may indicate the presence of impaired glucose regulation (non-diabetes hyperglycaemia) and people with impaired glucose regulation are 5 -15 times more likely to

develop type 2 diabetes than those with normal glucose values[14]. Diabetes prevention programmes have demonstrated that early intervention through lifestyle modification such as diet and increased physical activity can improve glucose tolerance and delay progression to diabetes in people with impaired glucose regulation[15].

Heart of Birmingham primary care trust (HoBPCT) is a high - risk population for Type 2 diabetes and a strategic clinical decision was made to request that GP practices offered all those attending the NHS Health Check programme, measurement of HbA1c (without application of the filter), to establish directly an individual's risk of diabetes or non – diabetes hyperglycaemia. Utilising this unique set of population data, we conducted a study to evaluate retrospectively, the effectiveness of the NHS Health Check diabetes filter in identifying people at known actual risk of developing diabetes (HbA1c ≥ 42mmol/mol).

Method

Heart of Birmingham Primary Care Trust (HoBPCT)

HoBPCT is a primary care trust area in inner city Birmingham covering a population of approximately 275,000. The main functions of primary care trusts are to understand and engage with their local population to improve health and wellbeing, and to commission a comprehensive and equitable range of high quality and responsive health services. The HoBPCT area is characterised by a majority population from minority population groups (70% non-white). In HoBPCT, people from the Indian sub-continent represent the largest group (over 60%). Over the period 2008 to 2010, average life expectancy for men in the HoBPCT area was 75 years compared with 78 years for England.

NHS Health Check Programme

NHS Health Checks are largely carried out in primary care settings. Best practice guidance has been issued to guide local areas in the identification of appropriate patients and systems for call, recall and follow-up. Best practice guidance also describes standards for obtaining anthropometric measurements such as height and weight (from which to calculate BMI) and other measurements such as blood pressure and serum cholesterol for use in risk equations and risk assessment[16]. Ethnicity is needed for diabetes risk assessment and should be recorded using the most recent Office for National Statistics categories that were first developed for the England and Wales Census in 1991. These categories have been expanded at each subsequent census (in 2001 and 2011)[17].

Study method

Data were obtained from GP records for 34,022 patients in HoBPCT that had received a NHS Health Check during the period April 2009 to February 2012. Records were excluded if the patient was currently < 40 or > 74 years of age (n = 1,778) and therefore were outside the NHS Health Check age range, or if the patient at the time of their NHS Health Check had already been diagnosed with diabetes (n = 951). Records were also excluded if data on HbA1c, blood pressure, BMI and ethnicity had not been recorded within three months of their health check (n = 12,648).

The remaining data were analysed to identify those patients who at the time of their check were found to be at high risk of diabetes (HbA1c of 42 mmol/ml or greater) (n= 5,968). Data on ethnicity, blood pressure measurement and BMI for these patients (from their NHS Health Check) was used to determine if the diabetes filter would have correctly identified them as candidates for a blood glucose test. For the purpose of the NHS Health Check, patients whose ethnic origin puts them at greater risk of diabetes include those of Indian, Pakistani, Bangladeshi, 'Other' Asian or Chinese origin. The diabetes filter is designed to detect patients at highest risk from within this group by targeting those with a BMI ≥ 27.5. For all other ethnic groups the filter operates at BMI ≥ 30.

Ethical approval

Advice was obtained from the local NHS R&D Consortium. It was determined that this study represents an evaluation undertaken as part of an ongoing PCT programme. For this reason it was not necessary to have R&D approval from the consortium or a favourable ethical opinion from an NHS research ethics committee. In terms of the PCT data extraction facility, the PCT Professional Executive Committee (PEC) and GP locality leads previously provided approval for the vascular screening work programme, including evaluation and publication and for AB, as PCT clinical lead, to view and utilise clinical data to improve patient management and population health.

Statistical methods

To assess the performance of the NHS Health Check diabetes filter we calculated the proportion (%) of patients at risk of diabetes or non – diabetes hyperglycaemia (HbA1c of 42 mmol/mol or greater) for whom simple application of the filter would not have led to blood glucose testing. We also calculated the sensitivity, positive predictive value and specificity of the NHS Health Check filter as a tool for identifying people at risk of diabetes or non – diabetes hyperglycaemia in the HoB population. All estimates are presented with 95% confidence intervals.

Results

Figure 2: Study participants

↓	Patients with a Read code indicating NHS Health Check = 34,022
↓	Age group 40 to 74 years = 32,244
↓	Patients without diagnosed existing vascular disease = 31,293
↓	Patients with HbA1c measured within 3 months of NHS Health Check = 20,439

↓	BMI / blood pressure measured within 3 months of NHS Health Check and ethnicity recorded = 17,484
↓	Patients with HbA1c ≥ 42mmol/mol = 5,968

Application of the NHS Health Check diabetes filter

Combining blood pressure, BMI and ethnicity as filters, overall the NHS Health Check diabetes filter failed to identify risk of diabetes in 33.3% [31.2% to 35.4%] of 5,968 patients with HbA1c ≥ 42mmol/mol (table 2).

Table 2: Summary performance of the NHS Health Check diabetes filter

NHS Check patients (Aged 40 – 74 years with HbA1c ≥ 42mmol/mol and BMI/BP recorded)	**Total**	**Blood pressure normal = (<140/90 mmHg) BMI normal= (< 27.5 'Asian', < 30 'Other')**	**% at risk of diabetes not identified by application of the NHS Check diabetes filter**
Ethnicity 'Asian'	3,849	1,207	31.3% [28.7% to 33.9%]
Ethnicity 'Other'	2,119	783	36.9% [33.5% to 40.3%]
All ethnicities	5,968	1,990	33.3% [31.2% to 35.4%]

Summary data on the sensitivity, positive predictive value (PPV) and specificity of the NHS Health Check diabetes filter in the HoB population are presented in table 3. It should be noted however that the NHS Health Check programme diabetes filter itself is not a formally accepted screening test for diabetes

Table 3: Sensitivity, positive predictive value and specificity of the NHS Health Check diabetes filter and risk for diabetes (HbA1c ≥ 42mmol/mol)

Sensitivity			
Ethnicity	Test & disease positive patients (a)	Total disease positive patients (b)	Sensitivity (a/b x100)
'Asian'	2,649	3,849	68.8% [67.2% to 70.3%]

'Other'	1,341	2,119	63.3% [60.5% to 64.6%]
All	3,990	5,968	66.8% [65.7% to 68.0%]
Positive Predictive Value			
Ethnicity	Test & disease positive patients (a)	Total test positive patients (c)	Positive Predictive Value (a/c x 100)
'Asian'	2,649	5,324	49.7% [48.4% to 51.0%]
'Other'	1,341	4,376	30.6% [29.2% to 32.0%]
All	3,990	9,700	41.1% [40.1% to 42.1%]
Specificity			
Ethnicity	Test & disease negative patients (d)	Total disease negative patients (e)	Specificity (d/e x100)
'Asian'	1,793	5,221	34.3% [33.0% to 35.6%]
'Other'	2,208	6,295	35.1% [33.9% to 36.3%]
All	4,001	11,516	34.7% [33.9% to 35.6%]

(a) Patients with blood pressure ≥ 140/90mmHg and/or BMI ≥ 27.5/30.0 and HbA1c ≥ 42mmol/mol
(b) Patients with HbA1c ≥ 42mmol/mol
(c) Patients with blood pressure ≥ 140/90mmHg and/or BMI ≥ 27.5/30.0
(d) Patients with blood pressure < 140/90mmHg and/or BMI < 27.5/30.0 and HbA1c < 42mmol/mol
(e) Patients with HbA1c < 42mmol/mol

In the Heart of Birmingham population, as a tool for identifying people at risk of diabetes, the NHS Health Check diabetes filter has a sensitivity of approximately 67%. Positive predictive value is 41%. This means that only two thirds of those at risk for diabetes would have been identified as candidates for blood glucose testing and, that of all the patients identified as being at risk for diabetes, less than half would have been found to be at risk following blood glucose testing. Sensitivity and positive predictive value of the NHS Health Check diabetes filter in the HoB population is significantly greater for patients of 'Asian' ethnic origin than those of other ethnicity (Sensitivity 68.8% [67.2% to 70.3%] versus 63.3% [60.5% to 64.6%], PPV 49.7% [48.4% to 51.0%] versus 30.6% [29.2% to 32.0%]. The NHS Health Check diabetes filter has a specificity of approximately 35% meaning that in Heart of Birmingham two thirds of people that were not at risk for diabetes would have been identified by the filter as requiring a blood glucose test.

Sub group analysis

The performance of the diabetes filter was reviewed separately in males and females and the results are included in table 4. The diabetes filter failed to identify a greater proportion of men than women at risk for diabetes (37.8% [36.1% to 39.6%] versus 28.7% [27.1% to 30.3%]).

Table 4: Performance of the NHS Health Check diabetes filter according to gender.

NHS Check Patients Aged 40 – 74 years with HbA1c ≥ 42mmol/mol and BMI/BP recorded	Total	Blood pressure normal = (<140/90 mmHg) BMI normal= (< 27.5 'Asian', < 30 'Other')	% at risk of diabetes not identified by application of the NHS Check diabetes filter
Male			
Ethnicity 'Asian'	1,894	692	36.5% [34.4% to 38.7%]
Ethnicity 'Other'	1,071	439	41.0% [38.1% to 44.0%]
All ethnicities	2,965	1,121	37.8% [36.1% to 39.6%]
Female			
Ethnicity 'Asian'	1,955	517	26.4% [24.5% to 28.4%]
Ethnicity 'Other'	1,047	344	32.8% [30.1% to 35.8%]
All ethnicities	3,002	861	28.7% [27.1% to 30.3%]

Asian ethnicity

Due to the increased risk for diabetes in the South Asian population, the NHS Health Check diabetes filter was tested at the lower threshold for body mass index (23.0 Kg/m^2) in the 'Asian' subgroup. Results in the terms of sensitivity, positive predictive value and specificity of the diabetes filter at this BMI threshold are presented in table 5.

Table 5: Sensitivity, positive predictive value and specificity of the NHS Health Check diabetes filter (Asian BMI ≥ 23.0) and risk for diabetes (HbA1c ≥ 42mmol/mol)

Sensitivity			
Ethnicity	Test & disease positive patients (a)	Total disease positive patients (b)	Sensitivity (a/b x100)

'Asian'	3,471	3,849	90.2% [89.2% to 91.1%]
Positive Predictive Value			
Ethnicity	Test & disease positive patients (a)	Total test positive patients (c)	Positive Predictive Value (a/c x 100)
'Asian'	3,471	8,226	42.2% [41.1% to 43.3%]
Specificity			
Ethnicity	Test & disease negative patients (d)	Total disease negative patients (e)	Specificity (d/e x100)
'Asian'	632	5,221	12.1% [11.2% to 13.0%]

(a) Patients with blood pressure ≥ 140/90mmHg and/or BMI ≥ 23.0 and HbA1c ≥ 42mmol/mol
(b) Patients with HbA1c ≥ 42mmol/mol
(c) Patients with blood pressure ≥ 140/90mmHg and/or BMI ≥ 23.0
(d) Patients with blood pressure < 140/90mmHg and/or BMI < 23.0 and HbA1c < 42mmol/mol
(e) Patients with HbA1c < 42mmol/mol

Reducing the BMI threshold to ≥ 23.0 improves performance of the filter in identifying Asian patients at risk for diabetes from approximately 70% to 90%. However this improvement in the sensitivity of the filter is offset by a reduction in positive predictive value and more significantly specificity. As a result, many more patients would be subject unnecessarily to blood glucose testing.

Study limitations

Data were available only for those individuals that had responded positively to the invitation to attend for an NHS Health Check. The study population was therefore to a degree self - selected however, the fact that these probably represent the more motivated, health – seeking members of the population means that those with the greatest disease burden were probably under represented. Had the latter been included, it is likely that a greater proportion of people at risk for diabetes would have been identified initially, although the effectiveness of the diabetes filter is unlikely to have changed. Of 31,293 eligible patients that received an NHS Health Check, ethnicity, HbA1c, BMI and blood pressure were not recorded contemporaneously in 44.1% (13,809/31,263) of patients who were thus excluded. The population in HoBPCT is relatively homogeneous and unless this resulted in some significant selection bias this is unlikely to have impacted on the outcome of the study and a relatively large population sample was retained.

Discussion

According to the charity Diabetes UK, by 2025 there will be more than five million people with diabetes in the UK and most of these will be Type 2 diabetes[18]. In 2002, the UK Department of Health estimated that 5% of total NHS expenditure is used for the care of

people with diabetes. This figure is now believed to be closer to 10% of total NHS expenditure, which equates to £9 billion per year[19]. Early diagnosis of diabetes, good glycaemic control and management of other cardiovascular risk factors have been shown to reduce the incidence of the macrovascular and microvascular disease complications that contribute the most to the disease burden[20,21]. However early identification of risk of developing diabetes and intervention to reduce the incidence of diabetes are increasingly urgent and important strategies.

In 2002 in the US, screening guidelines were proposed by the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus[22]. Although testing is not recommended in the general population, screening is recommended for those 45 years of age and older; with repeated testing every 3 years if results are normal. Screening is also recommended at younger ages or at more frequent intervals for those who have one or more diabetes risk factors. Dallo and Weller identified that all the risk factors included in the screening guidelines had a strong association with diabetes; having hypertension or a positive family history of diabetes doubled the risk of having diabetes whilst age, obesity, a poor lipid profile, and gestational diabetes more than doubled the risk. Risk increased with increase in BMI and it was apparent that being ''overweight'' was a significant risk factor without the presence of obesity. And, although these guidelines have been widely endorsed, one-third of cases are undiagnosed and complications at the time of diagnosis indicate that disease may have been present for several years, suggesting that either screening is not effective or that the guidelines are not being followed[23].

In the UK, the National Screening Committee has determined against screening the general adult population for diabetes, whilst recognising the need for a vascular risk management programme that includes diabetes (www.screening.nhs.uk/diabetes). In 2009, in response to this policy and the increasing human and healthcare burden from diabetes, the Department of Health in England introduced the NHS Health Check programme, a vascular 'check' for people aged 40 to 74 years without diagnosed existing vascular disease. The NHS Health Check assesses 10 – year risk of cardiovascular disease; combining patient – level data (including physiological and biochemical tests and anthropometric measurements) in an approved risk calculator. It also employs a diabetes filter based on known risk factors (blood pressure, BMI and ethnicity) to identify patients at high risk for undiagnosed diabetes who should undergo blood glucose testing.

In our study, the NHS Health Check diabetes filter failed to identify a third of patients at high actual risk for diabetes (defined as HbA1C $\geq$ 42mmol/mol). Conversely, two thirds of those that were identified by the filter as being at high risk had HbA1c < 42mmol/mol. Positive predictive value for those patients identified by the filter as being at risk, was 41%. Heart of Birmingham represents a high prevalence population for diabetes and the positive predictive value of the NHS Health Check diabetes filter will be less in lower prevalence populations.

The World Health Organisation (WHO) international classification of overweight was developed in 1993 and is based on a BMI cut-off point of 25kg/m^2. In 2002, a WHO expert consultation was convened to consider the interpretation of recommended body-mass index (BMI) cut-off points for determining overweight and obesity in Asian populations[24]. It was suggested that Asian populations have different associations between BMI, percentage of

body fat, and health risks than do European populations, however the cut-off point for observed risk varies for different Asian populations. The consultation agreed that the WHO BMI cut-off point for overweight (25 kg/m^2) should be retained as an international classification, whilst agreeing the existence of further potential public health action points (23.0, 27.5, 32.5, and 37.5 kg/m^2) along the continuum of BMI.

We tested the BMI threshold for screening for diabetes in people of Asian ethnic origin in line with the WHO recommendations. Using a cut-off point of BMI ≥ 23.0 for Asian patients (rather than ≥ 27.5 as per the NHS Health Check) dramatically increased the sensitivity of the diabetes filter in detecting those at risk of diabetes (to approximately 90%). However as a consequence, were this strategy to be adopted, the specificity of the filter would reduce to 12% and many more patients who were not at risk would be subjected to blood glucose testing.

National Institute for Health and Clinical Excellence guidelines on risk identification and intervention for people at high risk of type 2 diabetes are recommended for implementation alongside the NHS Health Check Programme[5]. However in the guidelines, risk identification relies on the use of validated computer-based risk assessment tools or validated self - assessment questionnaires and extends to groups other than those aged 40-74 years, to include people of South Asian and Chinese descent aged 25-39 years (except for pregnant women) and other adults with conditions that increase the risk of type 2 diabetes such as cardiovascular disease and gestational diabetes. NICE recommend considering a blood test for those aged 25 years or more of South Asian or Chinese descent whose BMI is greater than 23.0.

Several risk scores have been developed to predict diabetes risk. These are based on a core set of readily available non - invasive measures e.g. HDL cholesterol, blood pressure, family history, and a measure of adiposity (either body mass index or waist circumference) or on data from questionnaires[25]. More sophisticated risk scoring methods include fasting plasma glucose however this reduces the practicality of the approach. Full prediction models have been shown to be more discriminatory than single risk factors for predicting the risk of diabetes however most of these risk equations have been developed in research populations and several authors have identified that recalibration is needed before these equations can be used to estimate the risk of diabetes for individual patients[25,26].

Abbasi et al conducted a systematic review of to identify existing risk prediction tools for diabetes including both basic and 'extended' tools; the latter including biomarkers such as blood glucose concentration[26]. Twelve basic and thirteen extended models were subsequently validated in a random sub cohort (n=2506) of a Dutch prospective cohort study (European Prospective Investigation into Cancer (EPIC-NL). In the majority of cases the prediction tools overestimated the absolute risk of diabetes in the validation population. After adjustment for population incident risk, the performance of the prediction tools improved however on the whole significant deviations between estimated and observed risk remained. The authors concluded that prediction tools developed in study populations can be calibrated for use in external populations and are effective in identifying those at high risk but are less reliable for predicting absolute risk of diabetes.

Conclusion

This evaluation, which was based on a large population sample, demonstrates that the NHS Health Check programme diabetes filter failed to identify a third of people that are at high risk of having or developing diabetes. This is a unique set of data and possibly the first evaluation of the NHS Health Check diabetes filter in a clinical practice setting whereby actual risk for diabetes had been obtained directly from measurement of HbA1c.

Given the availability of such a unique dataset, further work will be undertaken to demonstrate the impact on sensitivity and positive predictive value from varying the current NHS Health Check thresholds for BMI and blood pressure. Given the depth of the available data it would also be of value to assess whether or not the use of other patient parameters such as waist circumference might improve the performance of the filter. Further analysis will be undertaken to determine the overall cost effectiveness of direct measurement of HbA1c for all people in the NHS Health Check programme.

The NHS Health Check diabetes filter is intended to be both pragmatic and feasible in clinical practice. However, computer-based risk scoring tools for diabetes that have been validated for use in the UK population (as advocated by NICE) may be more effective in risk identification for diabetes.

What is already known on this subject

There is no single accepted way of identifying undiagnosed people at risk for diabetes. Several risk scores have been developed to predict diabetes risk and these can be calibrated to external populations.

Public health guidance has been published by NICE on risk identification in Type 2 diabetes. This recommends that first, a risk assessment should be offered using either a validated computer-based risk assessment tool (validated for use in UK populations) or a validated self-assessment questionnaire. According to NICE, this guidance can also be used alongside the NHS Health Check programme, which uses its own risk identification tool or diabetes filter based on recording and measurement of ethnicity, blood pressure and BMI.

What this study adds

This is a unique set of data and possibly the first population evaluation of the NHS Health Check diabetes filter in a clinical practice setting whereby actual risk for diabetes had been obtained directly from measurement of HbA1c. This evaluation demonstrates that the NHS Health Check programme diabetes filter failed to identify a third of people that were at high risk of developing diabetes.

Contributorship:

Dr AC Felix Burden provided access to the data for the evaluation. Jamie Waterall was the NHS Birmingham Public Health lead for prevention programmes including local implementation of the NHS Health Check. Dr Burden and Mr Waterall respectively provided expert advice on chronic disease management (and in particular diabetes) and the NHS

Health Check programme. Sarah Smith was responsible for the data analysis, statistical analysis and for the preparation and submission of the manuscript.

Data sharing:

No additional data available

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An evaluation of the performance of the NHS Health Check programme in identifying people at high risk of developing Type 2 diabetes

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Article summary

Article focus

- The NHS Health Check programme (NHSHCP) was introduced in 2009 to encourage people to consider positive lifestyle changes and to improve case finding through assessment of vascular risk in the general population aged 40 to 74 years, without diagnosed existing vascular disease. The NHSHCP includes assessment of risk of diabetes using a diabetes screening test called a *filter* (based on ethnicity, body mass index (BMI) and blood pressure).
- In the UKWithin Heart of Birmingham Primary Care Trust (HoB PCT), people from the Indian sub-continent experience represent the largest group (over 60%). A consistent finding within this migrant population (compared to the indigenous population), is a higher incidence and prevalence of premature coronary heart disease (CHD), in part as a consequence of diabetes. Consequently, the PCT were concerned with ensuring It is particularly important that the NHSHCP iwas effective in identifying early, those at highest risk in this population sub group are identified earlyat high risk . from type 2 diabetes and cardiovascular disease.
- Through the PCTs' GP data extraction facility, it was possible to review anonymised patient data with Read codes indicating that they had received an NHS Health Check. Subsequently, this data enabledThis study, to evaluate the NHSHCP diabetes filter, was conducted in a population where people of South Asian origin represent the largest group (over 60%). The study involved a retrospective review of patients already identified as that might have diabetes or be at high risk for developing diabetes (from measurement of HbA1c at the time of their NHS Ccheck), with the outcome had the check relied solely on the use of the NHS Health Check diabetes filter.

Key messages

- This evaluation, which was based on a large, high - risk population sample, demonstrates that the NHS Health Check programme diabetes filter failed to identify a third of people at high actual risk of having or developing diabetes (defined as HbA1c ≥ 42mmol/mol). and measured around the time of their check).
- Use of the current NHS Health Check diabetes filter may lead to a failure to identify a group of patients with normal body weight but at high risk from diabetes and cardiovascular disease.
- Further policy development is required along withg with more research is into effective risk identification approaches for populations at high risk of developing Ttype 2 diabetes and cardiovascular disease.

Strengths and limitations of this study

- This is possibly the first study of its size to evaluate the effectiveness of the NHS Health Check diabetes filter in clinical practice and, offers a unique opportunity to evaluate the performance of the filter in a large population sample with aActual risk for diabetes already s was assessed from direct measurement of a single recorded measure of HbA1c. around the time of the health check.

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- HbA1c was not measured in all patients attending the NHS Health Check and fFor some patients, data on ethnicity wereas incomplete and/or data wereas not available for BP and BMI (further analysis revealed that the data wereas available but may have been recorded prior to the date of the NHS Health Check).
- The evaluation involved simple application of the NHS Health Check diabetes filter and did not take into account additional aspects of risk assessment such as family history of diabetes or other relevant comorbidities.

Introduction

According to the Chief Medical Officer (CMO) for England, in 2010, cardiovascular disease (CVD) was responsible for around one in three premature deaths (under 75) in men and one in five premature deaths in women. Coronary heart disease (CHD) and stroke are the main causes of CVD mortality.[1]

Heart of Birmingham Primary Care Trust (HoBPCT) is a primary care trust area in inner city Birmingham covering a population of approximately 275,000. The main functions of primary care trusts are to understand and engage with their local population to improve health and wellbeing, and to commission a comprehensive and equitable range of high quality and responsive health services. The HoBPCT area is characterised by a majority population from minority population groups (70% non white). Over the period 2008 to 2010, average life expectancy for men in the HoBPCT area was 75 years compared with 78 years for England.

In HoBPCT, people from the Indian sub-continent represent the largest group (over 60%). In the UK, people from the Indian sub-continent experience A consistent finding within this migrant population (compared to the indigenous population) is a higher incidence and prevalence of premature coronary heart disease (CHD), in part as a consequence of diabetes; people from South Asian backgrounds have a higher risk of developing Ttype 2 diabetes and they develop it on average five years earlier than white people[2,3]. The National Institute for Health and Clinical Excellence recommends that all people with diabetes be considered to be at high premature cardiovascular risk for their age unless they: are not overweight, are normotensive, have no evidence of microalbuminuria, are a non-smoker, do not have a high-risk lipid profile and have no history of CVD and no family history of CVD[4].

NICE recently published guidance on risk identification and interventions for people at high risk of type 2 diabetes[5]. There is no single accepted way of identifying people who are at risk of diabetes or who have existing undiagnosed diabetes. NICE recommends a two stage process starting with either a validated, computer - based risk assessment tools applied to demographic and routine data in clinical information systems e.g. the Cambridge risk score[6], or a validated self - assessment questionnaires such as FINDRISC[7] or the Diabetes Risk Score[8]. NICE states that this guidance can be used alongside the NHS Health Check programme.

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The NHS Health (formerly vascular) Check programme (www.healthcheck.nhs.uk) ~~-~~was introduced in 2009 with the combined aims of improving life expectancy and reducing health inequalities (by engaging with individuals to consider their modifiable risk factors) and ~~to~~ improved case finding through assessment of vascular risk in the general population aged 40 to 74 years without diagnosed existing vascular disease (table1).

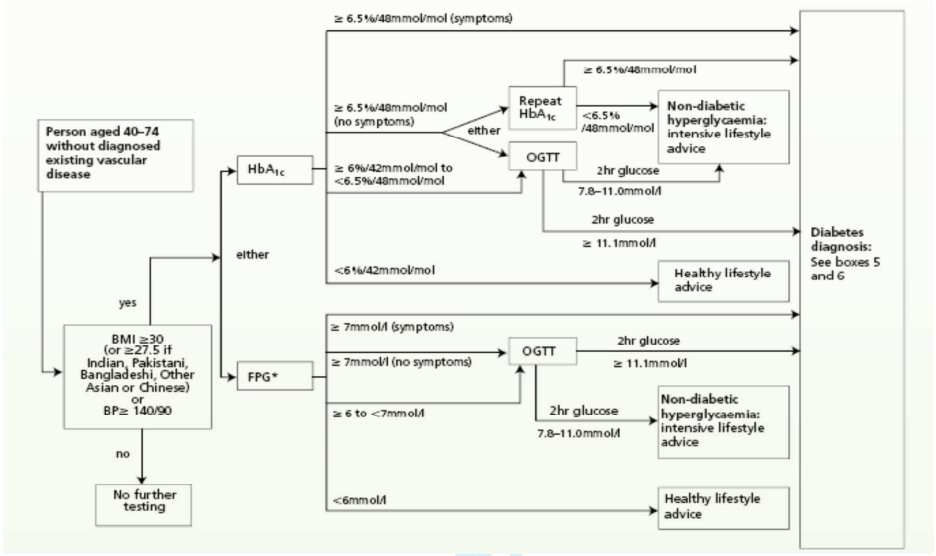
Table 1: NHS Health Check Programme exclusions with diagnosed existing vascular disease

Atrial Fibrillation Chronic Kidney Disease (stages 3-5), Coronary Heart Disease, Diabetes Heart Failure	Hypertension Hypercholesterolaemia Peripheral Arterial Disease (PAD) Stroke Transient Ischaemic Attack (TIA)

~~The NHS Health Check programme combines known risk factors for cardiovascular disease in an approved risk calculator (Framingham or QRISK™2) to estimate individual 10 - year risk of cardiovascular disease. All participants are offered management strategies to reduce individual risk with the overall aim of reducing the incidence and prevalence of cardiovascular disease in the population.~~

The NHS Health Check includes assessment of risk of diabetes using a diabetes screening tool called a *filter* (based on ethnicity, body mass index (BMI) and blood pressure) to identify those participants that should also receive a blood glucose test (either HbA1c or fasting plasma glucose (FPG)). This is described ~~is~~ diagrammatically in figure one.

Figure 1: Diagrammatic overview for identifying people at high risk of having or developing diabetes



Source: Putting Prevention First NHS Health Check: Vascular Risk Assessment and Management Best Practice Guidance (http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets /documents/digitalasset/dh_098410.pdf)

Potentially, the diabetes filter will exclude people with diabetes with normal or low body weight. However, ~~T~~this two stage screening procedure is considered pragmatic and is based largely on evidence from two ~~large~~ population-based screening studies in the UK in Leicester, involving both the South Asian and White European populations in the city~~.~~[95]. ~~The NHS Health Check diabetes filter will however potentially exclude people with diabetes with normal or low body weight.~~

Existing evidence regarding the relationship between weight and mortality in Type 2 diabetes is conflicting. For example, in the World Health Organization Multinational Study of Vascular Disease in Diabetes, there was no clear relationship between BMI and cardiovascular mortality[610]. More recently, Carnethon et al found that after adjustment, hazard ratios comparing normal weight participants with diabetes with overweight/obese participants for total, cardiovascular, and non - cardiovascular mortality were 2.08 (95% CI, 1.52 - 2.85), 1.52 (95% CI, 0.89 - 2.58), and 2.32 (95% CI, 1.55 - 3.48), respectively[117].

~~The National Institute for Health and Clinical Excellence (NICE) recently published guidance on risk identification and interventions for people at high risk of type 2 diabetes[86]. There is no single accepted way of identifying people who are at risk of diabetes or who have existing undiagnosed diabetes. NICE however also recommends a two stage process starting with either a validated, computer - based risk assessment tools applied to demographic and routine data in clinical information systems e.g. the Cambridge risk score[97], or a validated self - assessment questionnaires such as FINDRISC[108] or the Diabetes Risk Score[119]. NICE also states that the guidance can be used alongside the NHS Health Check programme.~~

~~The diabetes filter employed in the NHS Check Programme (BMI ≥ 30 (or ≥ 27.5 if Indian, Pakistani, Bangladeshi, Other Asian or Chinese) or blood pressure ≥ 140/90mmHg or where~~

~~the SBP or DBP exceeds 140mmhg or 90mmhg respectively) is considered feasible in practice and a pragmatic means of identifying those at highest risk of diabetes without unnecessarily subjecting an excess of people to blood glucose testing .~~ ~~However the filter will potentially exclude people with diabetes with normal or low body weight.~~
~~Existing evidence regarding the relationship between weight and mortality in type 2 diabetes is conflicting. For example, in the World Health Organization Multinational Study of Vascular Disease in Diabetes, there was no clear relationship between BMI and cardiovascular mortality[10]. Carnethon et al found that after adjustment, hazard ratios comparing normal weight participants with diabetes with overweight/obese participants for total, cardiovascular, and non - cardiovascular mortality were 2.08 (95% CI, 1.52 - 2.85), 1.52 (95% CI, 0.89 - 2.58), and 2.32 (95% CI, 1.55 - 3.48), respectively[11].~~

Glycaemia, whether estimated by fasting glucose or HbA1c, has a continuous relationship with the risk of CVD[152].

Recently, the World Health Organisation has stated that HbA1c alone can be used as a diagnostic test for diabetes provided that widely accepted criteria are met~~"stringent quality assurance tests are in place, assays are standardised to criteria aligned to the international reference values, and there are no conditions present which preclude its accurate measurement"[1322]~~. An HbA1c of 48mmol/mol (6.5%) is recommended as the cut point for diagnosing diabetes (the SI unit for HbA1c is mmol/mol and is defined as mmol HbA1c per mol HbA_0 + HbA1c).

~~Glycaemia, whether estimated by fasting glucose or HbA1c, has a continuous relationship with the risk of CVD[13].~~ An HbA1c of 42 – 48 mmol/ml may indicate the presence of impaired glucose regulation (non-diabetes hyperglycaemia) and people with impaired glucose regulation are 5 -15 times more likely to develop type 2 diabetes than those with normal glucose values~~.~~[1434]. Diabetes prevention programmes have demonstrated that early intervention through lifestyle modification such as diet and increased physical activity can improve glucose tolerance and delay progression to diabetes in people with impaired glucose regulation[154].
~~Glycaemia, whether estimated by fasting glucose or HbA1c, has a continuous relationship with the risk of CVD[15].~~

~~In~~
Heart of Birmingham primary care trust (HoBPCT) is a ~~PCT, given the~~ high - risk population for Type 2 diabetes and ~~,~~ a strategic clinical decision was made to request that GP practices offered all those attending the NHS Health Check programme, measurement of HbA1c (without application of the filter), to establish directly an individual's risk of diabetes or non – diabetes hyperglycaemia. ~~Through HoB PCTs' GP data extraction facility it is possible to identify from Read codes, patients that have received an NHS Health Check. This enabled retrospective review of patients at high risk for developing diabetes (from measurement of HbA1c at the time of their check) with the outcome had the check relied solely on the use of the NHS Health Check diabetes filter.~~ Utilising this unique set of population data, we conducted a study to evaluate retrospectively, the effectiveness of the NHS Health Check

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diabetes filter in identifying people at known actual risk of developing diabetes (HbA1c ≥ 42mmol/mol).

Method

~~**NHS Health Check Programme**~~

~~NHS Health Checks are largely carried out in primary care settings. Best practice guidance has been issued to guide local areas in the identification of appropriate patients and systems for call, recall and follow up. Best practice guidance also describes standards for obtaining anthropometric measurements such as height and weight (from which to calculate BMI) and other measurements such as blood pressure and serum cholesterol[15].~~

~~Ethnicity is needed for diabetes risk assessment and should be recorded using the most recent Office for National Statistics categories that were first developed for the England and Wales Census in 1991. These categories have been expanded at each subsequent census (in 2001 and 2011)[16].~~

Heart of Birmingham Primary Care Trust (HoBPCT)

HoBPCT ~~Heart of Birmingham Primary Care Trust (HoBPCT)~~ is a primary care trust area in inner city Birmingham covering a population of approximately 275,000. The main functions of primary care trusts are to understand and engage with their local population to improve health and wellbeing, and to commission a comprehensive and equitable range of high quality and responsive health services. The HoBPCT area is characterised by a majority population from minority population groups (70% non-white). In HoBPCT, people from the Indian sub-continent represent the largest group (over 60%). Over the period 2008 to 2010, average life expectancy for men in the HoBPCT area was 75 years compared with 78 years for England.

NHS Health Check Programme

NHS Health Checks are largely carried out in primary care settings. Best practice guidance has been issued to guide local areas in the identification of appropriate patients and systems for call, recall and follow-up. Best practice guidance also describes standards for obtaining anthropometric measurements such as height and weight (from which to calculate BMI) and other measurements such as blood pressure and serum cholesterol for use in risk equations and risk assessment[16].

Ethnicity is needed for diabetes risk assessment and should be recorded using the most recent Office for National Statistics categories that were first developed for the England and Wales Census in 1991. These categories have been expanded at each subsequent census (in 2001 and 2011)[17].

Study method

Data wereas obtained from GP records foron 34,022 patients resident in HoBPCT that had received a NHS Health Check during the period April 2009 to February 2012.

Records were excluded if the patient was currently < 40 or > 74 years of age (n = 1,778) and therefore were outside of the NHS Health Check age range, or if the patient at the time of their NHS Health Check had already been diagnosed with diabetes (n = 951). Records were also excluded if data on HbA1c, blood pressure, BMI and ethnicity had not been were not recorded within three months of their health check (n = 12,648).

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The remaining data were analysed to identify those patients who at the time of their check were found to be at high risk of diabetes (HbA1c of 42 mmol/ml or greater) (n= 5,968). Data on ethnicity, blood pressure measurement and BMI for these patients (from their NHS Health Check) was used to determine if the diabetes filter would have correctly identified them as candidates for a blood glucose test. For the purpose of the NHS Health Check, patients whose ethnic origin puts them at greater risk of diabetes includes those of Indian, Pakistani, Bangladeshi, 'Other' Asian or Chinese origin. The diabetes filter is designed to detect patients at highest risk from within this group by targeting those with a BMI ≥ 27.5. For all other ethnic groups the filter operates at BMI ≥ 30.

Ethical approval

Advice was obtained from the local NHS R&D Consortium. It was determined that this study represents an evaluation undertaken as part of an ongoing PCT programme. For this reason it was not necessary to have R&D approval from the consortium or a favourable ethical opinion from an NHS research ethics committee.

In terms of the PCT data extraction facility, the PCT Professional Executive Committee (PEC) and GP locality leads previously provided approval for the vascular screening work programme, including evaluation and publication and for AB, as PCT clinical lead, to view and utilise clinical data to improve patient management and population health.

Statistical methods

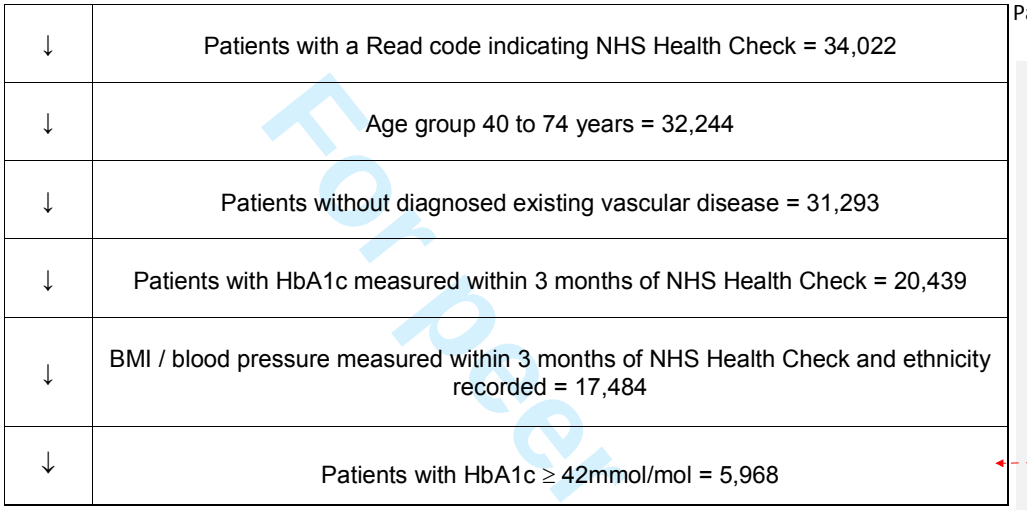
To assess the performance of the NHS Health Check diabetes filter we calculated the proportion (%) of patients at risk of diabetes or non – diabetes hyperglycaemia (HbA1c of 42 mmol/mol or greater) for whom simple application of the filter would not have led to blood glucose testing.

We also calculated the sensitivity, positive predictive value and specificity of the NHS Health Check filter as a tool for identifying people at risk of diabetes or non – diabetes hyperglycaemia in the HoB population.

All estimates are presented with 95% confidence intervals.

Results

Figure 2: Study participants



Application of the NHS Health Check dDiabetes fFilter

Combining blood pressure, BMI and ethnicity as filters, overall the NHS Health Check diabetes filter failed to identify risk of diabetes in 33.3% [31.2% to 35.4%] of 5,968 patients with HbA1c ≥ 42mmol/mol (table 2).

Table 2: Summary performance of the NHS Health Check diabetes filter

NHS Check patients (Aged 40 – 74 years with HbA1c ≥ 42mmol/mol and BMI/BP recorded)	Total	Blood pressure normal = (<140/90 mmHg) BMI normal= (< 27.5 'Asian', < 30 'Other')	% at risk of diabetes not identified by application of the NHS Check diabetes filter
Ethnicity 'Asian'	3,849	1,207	31.3% [28.7% to 33.9%]
Ethnicity 'Other'	2,119	783	36.9% [33.5% to 40.3%]
All ethnicities	5,968	1,990	33.3% [31.2% to 35.4%]

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Summary data on the sensitivity, positive predictive value (PPV) and specificity of the NHS Health Check diabetes filter in the HoB population are presented in table 3. It should be noted however that the NHS Health Check pProgramme diabetes filter itself is not a formally accepted screening test for diabetes

Table 3: Sensitivity, positive predictive value and specificity of the NHS Health Check diabetes filter and risk for diabetes (HbA1c ≥ 42mmol/mol)

Sensitivity			
Ethnicity	Test & disease positive patients (a)	Total disease positive patients (b)	Sensitivity (a/b x100)
'Asian'	2,649	3,849	68.8% [67.2% to 70.3%]
'Other'	1,341	2,119	63.3% [60.5% to 64.6%]
All	3,990	5,968	66.8% [65.7% to 68.0%]
Positive Predictive Value			
Ethnicity	Test & disease positive patients (a)	Total test positive patients (c)	Positive Predictive Value (a/c x 100)
'Asian'	2,649	5,324	49.7% [48.4% to 51.0%]
'Other'	1,341	4,376	30.6% [29.2% to 32.0%]
All	3,990	9,700	41.1% [40.1% to 42.1%]
Specificity			
Ethnicity	Test & disease negative patients (d)	Total disease negative patients (e)	Specificity (d/e x100)
'Asian'	1,793	5,221	34.3% [33.0% to 35.6%]
'Other'	2,208	6,295	35.1% [33.9% to 36.3%]
All	4,001	11,516	34.7% [33.9% to 35.6%]

(a) Patients with blood pressure ≥ 140/90mmHg and/or BMI ≥ 27.5/30.0 and HbA1c ≥ 42mmol/mol
(b) Patients with HbA1c ≥ 42mmol/mol
(c) Patients with blood pressure ≥ 140/90mmHg and/or BMI ≥ 27.5/30.0
(d) Patients with blood pressure < 140/90mmHg and/or BMI < 27.5/30.0 and HbA1c < 42mmol/mol

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(e) Patients with HbA1c < 42mmol/mol

In the Heart of Birmingham population, as a tool for identifying people at risk of diabetes, the NHS Health Check diabetes filter has a sensitivity of approximately 67%. Positive predictive value is 41%. This means that only two thirds of those at risk for diabetes would have been identified as candidates for blood glucose testing and, that of all the patients identified as being at risk for diabetes, less than half would have been found to be at risk following blood glucose testing. Sensitivity and positive predictive value of the NHS Health Check diabetes filter in the HoB population is significantly greater for patients of 'Asian' ethnic origin than those of other ethnicity (Sensitivity 68.8% [67.2% to 70.3%] versus 63.3% [60.5% to 64.6%], PPV 49.7% [48.4% to 51.0%] versus 30.6% [29.2% to 32.0%]. The NHS Health Check diabetes filter has a specificity of approximately 35% meaning that in Heart of Birmingham two thirds of people that were not at risk for diabetes would have been identified by the filter as requiring a blood glucose test.

Sub group analysis

The performance of the diabetes filter was reviewed separately in males and females and the results are included in table 4. The diabetes filter failed to identify a greater proportion of men than women at risk for diabetes (37.8% [36.1% to 39.6%] versus 28.7% [27.1% to 30.3%]).

Table 4: Performance of the NHS Health Check diabetes filter according to gender.

NHS Check Patients ~~(34,022)~~ **Aged 40 – 74 years with HbA1c ≥ 42mmol/mol and BMI/BP recorded**	**Total**	**Blood pressure normal = (<140/90 mmHg) BMI normal= (< 27.5 'Asian', < 30 'Other')**	**% at risk of diabetes not identified by application of the NHS Check diabetes filter**
Male			
Ethnicity 'Asian'	1,894	692	36.5% [34.4% to 38.7%]
Ethnicity 'Other'	1,071	439	41.0% [38.1% to 44.0%]
All ethnicities	2,965	1,121	37.8% [36.1% to 39.6%]
Female			
Ethnicity 'Asian'	1,955	517	26.4% [24.5% to 28.4%]
Ethnicity 'Other'	1,047	344	32.8% [30.1% to 35.8%]

All ethnicities	3,002	861	28.7% [27.1% to 30.3%]

Asian ethnicity

Due to the increased risk for diabetes in the South Asian population, the NHS Health Check diabetes filter was tested at the lower threshold for body mass index (23.0 Kg/m^2) in the 'Asian' subgroup. Results in the terms of sensitivity, positive predictive value and specificity of the diabetes filter at this BMI threshold are presented in table 5.

Table 5: Sensitivity, positive predictive value and specificity of the NHS Health Check diabetes filter (Asian BMI ≥ 23.0) and risk for diabetes (HbA1c ≥ 42mmol/mol)

Sensitivity			
Ethnicity	Test & disease positive patients (a)	Total disease positive patients (b)	Sensitivity (a/b x100)
'Asian'	3,471	3,849	90.2% [89.2% to 91.1%]
Positive Predictive Value			
Ethnicity	Test & disease positive patients (a)	Total test positive patients (c)	Positive Predictive Value (a/c x 100)
'Asian'	3,471	8,226	42.2% [41.1% to 43.3%]
Specificity			
Ethnicity	Test & disease negative patients (d)	Total disease negative patients (e)	Specificity (d/e x100)
'Asian'	632	5,221	12.1% [11.2% to 13.0%]

(a) Patients with blood pressure ≥ 140/90mmHg and/or BMI ≥ 23.0 and HbA1c ≥ 42mmol/mol
(b) Patients with HbA1c ≥ 42mmol/mol
(c) Patients with blood pressure ≥ 140/90mmHg and/or BMI ≥ 23.0
(d) Patients with blood pressure < 140/90mmHg and/or BMI < 23.0 and HbA1c < 42mmol/mol
(e) Patients with HbA1c < 42mmol/mol

Reducing the BMI threshold to ≥ 23.0 improves performance of the filter in identifying Asian patients at risk for diabetes from approximately 70% to 90%. However this improvement in the sensitivity of the filter is offset by a reduction in positive predictive value and more significantly specificity. As a result, many more patients would be subject unnecessarily to blood glucose testing.

Study Limitations

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Data were available only for those individuals that had responded positively to the invitation to attend for an NHS Health Check. The study population was therefore to a degree self - selected however, the fact that these probably represent the more motivated, health – seeking members of the population means that those with the greatest disease burden were probably under represented. Had the latter been included, it is likely that a greater proportion of people at risk for diabetes would have been identified initially, although the effectiveness of the diabetes filter is unlikely to have changed. Of 31,293 eligible patients that received an NHS Health Check, ethnicity, HbA1c, BMI and blood pressure were not recorded contemporaneously in 44.1% (13,809/31,263) of patients who were thus excluded. The population in HoBPCT is relatively homogeneous and u~~U~~nless this resulted in some significant selection bias ~~(which is unknown at this stage)~~ this is unlikely to have impacted on the outcome of the study and a relatively large population sample was retained.

Discussion

According to the charity Diabetes UK, by 2025 there will be more than five million people with diabetes in the UK and most of these ~~cases~~ will be T~~t~~ype 2 diabetes[1~~87~~].

In 2002, the UK Department of Health estimated that 5% of total NHS expenditure is used for the care of people with diabetes. This figure is now believed to be closer to 10% of total NHS expenditure, which equates to £9 billion per year[1~~98~~]. Early diagnosis of diabetes, good glycaemic control and management of other cardiovascular risk factors have been shown to reduce the incidence of the macrovascular and microvascular disease complications that contribute the most to the disease burden[20,21]. However ~~Consequently,~~ e~~e~~arly identification of risk of developing diabetes and intervention to ~~delay progression and~~ reduce the incidence of diabetes ~~and its complications~~ are increasingly urgent and important strategies.

In 2002 in the US, screening guidelines were proposed by the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus[2~~2~~1~~9~~]. Although testing is not recommended in the general population, screening is recommended for those 45 years of age and older; with repeated testing every 3 years if results are normal. Screening is also recommended at younger ages or at more frequent intervals for those who have one or more diabetes risk factors. Dallo and Weller identified that all the risk factors included in the screening guidelines had a strong association with diabetes; having hypertension or a positive family history of diabetes doubled the risk of having diabetes whilst age, obesity, a poor lipid profile, and gestational diabetes more than doubled the risk. Risk increased with increase in BMI and it was apparent that being "overweight" was a significant risk factor without the presence of obesity. And, ~~and, a~~lthough t~~Dallo and Weller identified that although t~~hese guidelines have been widely endorsed, one-third of cases are undiagnosed and complications at the time of diagnosis indicate that disease may have been present for several years, suggesting that either screening is not effective or that the guidelines are not being followed[2~~3~~2~~0~~].

~~The performance of the US screening guidelines for identifying undiagnosed diabetes, have been examined in a national sample (The National Health and Nutrition Examination Survey (NHANES III)[20]. The relative importance of risk factors in identifying new cases of diabetes~~

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~~was obtained by comparing those with undiagnosed diabetes (from fasting plasma glucose) with those without diabetes. All the risk factors included in the screening guidelines had a strong association with diabetes; having hypertension or a positive family history of diabetes doubled the risk of having diabetes whilst age, obesity, a poor lipid profile, and gestational diabetes more than doubled the risk. Risk increased with increase in BMI and it was apparent that being "overweight" was a significant risk factor without the presence of obesity. Age was the risk factor most strongly associated with the detection of undiagnosed cases of diabetes however the authors caution against clinical screening strategies focused only on older adults (> 45 years of age) as potentially these could exclude minorities that develop diabetes at a younger age.~~

In the UK, the National Screening Committee has determined against screening the general adult population for diabetes, whilst recognising the need for a vascular risk management programme that includes diabetes (www.screening.nhs.uk/diabetes). In 2009, in response to this policy and the increasing human and healthcare burden from diabetes, the Department of Health in England introduced the NHS Health Check p~~P~~rogramme, a vascular 'check' for people aged 40 to 74 years without diagnosed existing vascular disease. The NHS Health Check assesses 10 – year risk of cardiovascular disease; combining patient – level data (including physiological and biochemical tests and anthropometric measurements) in an approved risk calculator. It also employs a diabetes filter based on known risk factors (blood pressure, BMI and ethnicity) to identify patients at high risk for undiagnosed diabetes who should undergo blood glucose testing.

In our study, the NHS Health Check diabetes filter failed to identify a third of patients at high actual risk for diabetes (defined as HbA1C ≥ 42mmol/mol). Conversely, two thirds of those that were identified by the filter as being at high risk had HbA1c < 42mmol/mol. Positive predictive value for those patients identified by the filter as being at risk, was 41%.

Heart of Birmingham represents a high prevalence population for diabetes and the positive predictive value of the NHS Health Check diabetes filter will be less in lower prevalence populations.

~~National Institute for Health and Clinical Excellence guidelines on risk identification and intervention for people at high risk of type 2 diabetes are recommended for implementation alongside the NHS Health Check Programme[6]. However in the guidelines, risk identification relies on the use of validated computer based risk assessment tools or validated self assessment questionnaires and extends to groups other than those aged 40-74 years, to include people of South Asian and Chinese descent aged 25-39 years (except for pregnant women) and other adults with conditions that increase the risk of type 2 diabetes such as cardiovascular disease and gestational diabetes. NICE also recommend considering a blood test for those aged 25 years or more of South Asian or Chinese descent whose BMI is greater than 23.0~~

The World Health Organisation (WHO) international classification of overweight was developed in 1993 and is based on a BMI cut-off point of 25kg/m^2. In 2002, a WHO expert consultation was convened to consider the interpretation of recommended body-mass index

(BMI) cut-off points for determining overweight and obesity in Asian populations[24~~3~~1]. It was suggested that Asian populations have different associations between BMI, percentage of body fat, and health risks than do European populations, however the cut-off point for observed risk varies for different Asian populations. The consultation agreed that the WHO BMI cut-off point for overweight (25 kg/m^2) should be retained as an international classification, whilst agreeing the existence of further potential public health action points (23.0, 27.5, 32.5, and 37.5 kg/m^2) along the continuum of BMI.

We tested the BMI threshold for screening for diabetes in people of Asian ethnic origin in line with the WHO recommendations. Using a cut-off point of BMI ≥ 23.0 for Asian patients (rather than ≥ 27.5 as per the NHS Health Check) dramatically increased the sensitivity of the diabetes filter in detecting those at risk of diabetes (to approximately 90%). However as a consequence, were this strategy to be adopted, the specificity of the filter would reduce to 12% and many more patients who were not at risk would be subjected to blood glucose testing.

National Institute for Health and Clinical Excellence guidelines on risk identification and intervention for people at high risk of type 2 diabetes are recommended for implementation alongside the NHS Health Check Programme[58]. However in the guidelines, risk identification relies on the use of validated computer-based risk assessment tools or validated self-assessment questionnaires and extends to groups other than those aged 40-74 years, to include people of South Asian and Chinese descent aged 25-39 years (except for pregnant women) and other adults with conditions that increase the risk of type 2 diabetes such as cardiovascular disease and gestational diabetes. NICE ~~also~~ recommend considering a blood test for those aged 25 years or more of South Asian or Chinese descent whose BMI is greater than 23.0.

Several risk scores have been developed to predict diabetes risk. These are based on a core set of readily available non-invasive measures e.g. HDL cholesterol, blood pressure, family history, and a measure of adiposity (either body mass index or waist circumference) or on data from questionnaires[25~~4~~2]. More sophisticated risk scoring methods include fasting plasma glucose however this reduces the practicality of the approach. Full prediction models have been shown to be more discriminatory than single risk factors for predicting the risk of diabetes however most of these risk equations have been developed in research populations and several authors have identified that recalibration is needed before these equations can be used to estimate the risk of diabetes for individual patients[25~~4~~2,26~~5~~3].

Abbasi et al conducted a systematic review of to identify existing risk prediction tools for diabetes including both basic and 'extended' tools; the latter including biomarkers such as blood glucose concentration[26~~5~~3]. Twelve basic and thirteen extended models were subsequently validated in a random sub cohort (n=2506) of a Dutch prospective cohort study (European Prospective Investigation into Cancer (EPIC-NL). In the majority of cases the prediction tools overestimated the absolute risk of diabetes in the validation population. After adjustment for population incident risk, the performance of the prediction tools improved however on the whole significant deviations between estimated and observed risk remained. The authors concluded that prediction tools developed in study populations can be

calibrated for use in external populations and are effective in identifying those at high risk but are less reliable for predicting absolute risk of diabetes.

Conclusion

This evaluation, which was based on a large population sample, demonstrates that the NHS Health Check programme diabetes filter failed to identify a third of people that are at high risk of having or developing diabetes. This is a unique set of data and possibly the first evaluation of the NHS Health Check diabetes filter in a clinical practice setting whereby actual risk for diabetes had been obtained directly from measurement of HbA1c.

Given the availability of such a unique dataset, further work will be undertaken to demonstrate the impact on sensitivity and positive predictive value from varying the current NHS Health Check thresholds for BMI and blood pressure. Given the depth of the available data it would also be of value to assess whether or not the use of other patient parameters such as waist circumference might improve the performance of the filter. Further analysis will be undertaken to determine the overall cost effectiveness of direct measurement of HbA1c for all people in the NHS Health Check programme.

The NHS Health Check diabetes filter is intended to be both pragmatic and feasible in clinical practice. However, computer-based risk scoring tools for diabetes that have been validated for use in the UK population (as advocated by NICE) may be more effective in risk identification for diabetes.

What is already known on this subject

There is no single accepted way of identifying undiagnosed people at risk for diabetes. Several risk scores have been developed to predict diabetes risk and these can be calibrated to external populations.

Public health guidance has been published by NICE on risk identification in type 2 diabetes. This recommends that first, a risk assessment should be offered using either a validated computer-based risk assessment tool (validated for use in UK populations) or a validated self-assessment questionnaire. According to NICE, this guidance can also be used alongside the NHS Health Check programme, which uses its own risk identification tool or diabetes filter based on recording and measurement of ethnicity, blood pressure and BMI.

What this study adds

This is a unique set of data and possibly the first population evaluation of the NHS Health Check diabetes filter in a clinical practice setting whereby actual risk for diabetes had been obtained directly from measurement of HbA1c. This evaluation demonstrates that the NHS Health Check programme diabetes filter failed to identify a third of people that were at high risk of developing diabetes.

Contributorship:

Dr AC Felix Burden provided access to the data for the evaluation. Jamie Waterall was the NHS Birmingham Public Health lead for prevention programmes including local implementation of the NHS Health Check. Dr Burden and Mr Waterall respectively provided expert advice on chronic disease management (and in particular diabetes) and the NHS Health Check programme. Sarah Smith was responsible for the data analysis, statistical analysis and for the preparation and submission of the manuscript.

Data sharing:

There is no additional data available

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Figure 1: Diagrammatic overview for identifying people at high risk of having or developing diabetes

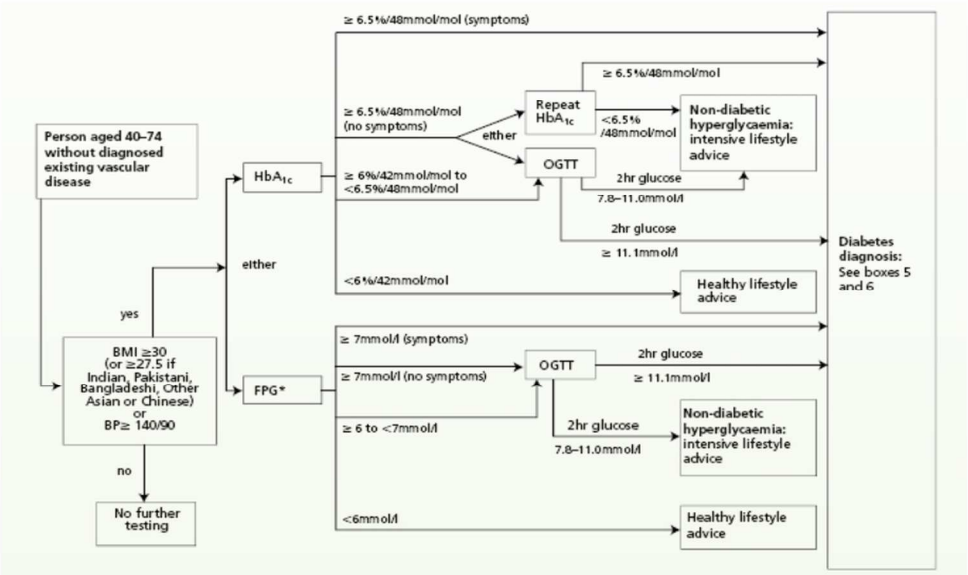

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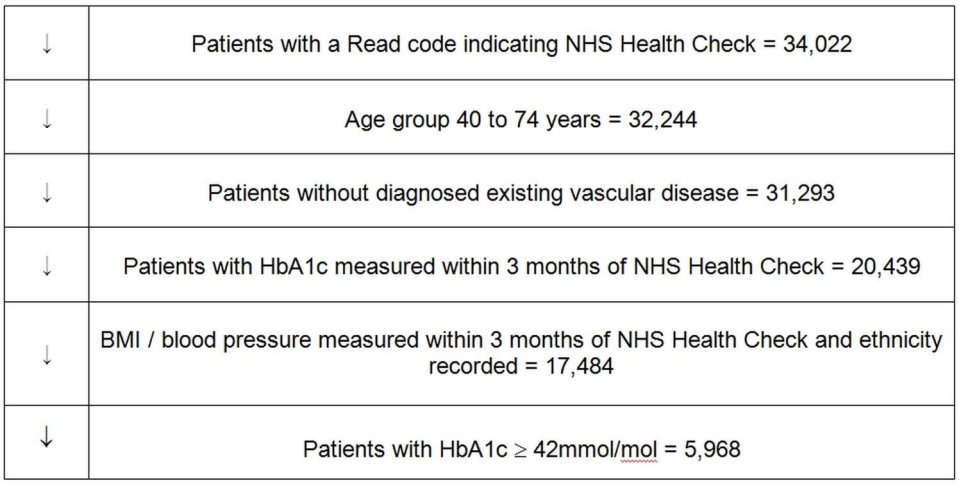
Figure 2: Study participants



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Correction

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

There is an error in table 3 of this paper. The error occurred because in calculating specificity in the analysis, the author used DBP cut off of 80 mm Hg instead of 90 mm Hg.
The specificity calculation should therefore be:

Specificity

Ethnicity	Test-negative & disease-negative patients (d)	Total disease-negative patients (e)	Specificity (d/e×100)
Asian	2545	5223	48.7% (47.4% to 50.1%)
Other	3280	6297	52.1% (50.1% to 53.3%)
All	5825	11520	50.1% (49.6% to 51.5%)

All other data analyses and the rest of the data presented are correct.
In addition, there are further corrections as follows:

ABSTRACT (page 1)

Results:
Specificity was 50.1% (95% CI 49.6% to 51.5%)

RESULTS (page 4) Column 2

The NHS Health Check has a specificity of approximately 50% meaning that in the Heart of Birmingham population, 50% of people that were not at risk for diabetes would have been identified by the filter as requiring a blood glucose test.

DISCUSSION (page 6) Column 2

Conversely, half of those that were identified by the filter as being at high risk had HbA1c <42 mmol/mol.

BMJ Open 2015;**5**:e002219. doi:10.1136/bmjopen-2012-002219corr1