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The NHS Health Check in England: an evaluation of the first four years.

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Abstract: 252

Text 3791

Tables 6

Appendix (Fig 1, Table 1)

Abstract

Objectives: To describe implementation of a new national preventive programme to reduce cardiovascular morbidity.

Design: Observational study over four years April 2009 – March 2013.

Setting: 655 general practices across England from the QResearch database.

Participants: Eligible adults aged 40-74 years including attendees at an NHS Health Check.

Intervention: NHS Health Check: routine structured cardiovascular check with support for behavioural change and in those at highest risk, treatment of risk factors and newly identified co-morbidity.

Results: 1.68 million eligible people had an NHS Health Check in the period 2009-2012 and attendance quadrupled as the programme progressed (5.8% in 2010 to 30.1% in 2012). Attendance was relatively higher among older people, of whom 19.6% of those eligible at age 60-74 years attended and 9.0% at age 40-59 years. There was higher attendance by population groups at higher risk such as South Asians 19.2%, than White ethnic groups 17.4% and the more socially disadvantaged 14.9% than the more affluent 12.3%. Among attendees 7844 new cases of hypertension (38/1000 Checks), 1934 (9/1000 Checks) new cases of type 2 diabetes and 807 (4/1000 Checks) new cases of chronic kidney disease were identified.
Of the 27,624 people found to be at high CVD risk (20% or more 10 year risk) when attending an NHS Health Check, 19.3% (5325) were newly prescribed statins and 8.8% (2438) were newly prescribed antihypertensive therapy.

Conclusions: NHS Health Check coverage was lower than expected but showed year on year improvement. Newly identified co-morbidities were an important feature of the Checks and although only 1 in 5 of those at highest risk were treated, the scale of the programme is likely to make an important and improving health impact.

Introduction

The English national NHS Health Checks programme started in 2009, aiming to reduce cardiovascular disease (CVD) risks and events. Internationally it is the first of its kind, aiming to provide a routine structured clinical assessment and management for adults aged 40-74 years without pre-existing diabetes or CVD. This includes review of CVD risks, behavioural change support and treatment of newly identified risk factors or co-morbidity through integration with routine clinical provision in general practice. We describe an evaluation of the first four years of this national programme.

The NHS Health Check is a five year rolling programme which targets one-fifth of the eligible population each year, aiming to invite 3 million people at an annual cost of £165 million.[1-3] The Department of Health report that 2.4 million NHS Health Checks were undertaken in the two years 2011-2012.[4] Nationally, uptake is reported at around 50% of the eligible target population with considerable variability between provider organisations.[4-6] The NHS Health Check programme is now supported by NHS England and Public Health England following major changes in the NHS in 2013 when Primary Care Trusts (PCTs) were replaced by Clinical Commissioning Groups (CCGs) and responsibility for commissioning the programme was transferred to the Local Authorities.[7 8]

Stratification of CVD risk for the purposes of therapeutic intervention is a key component of the Check. Attendees receive personal advice to support behaviour change and treatment informed by CVD risk stratification. When the programme was introduced, NICE guidance and the NHS Health Check programme,[9 10] recommended statin treatment at a 10 year CVD risk of 20% or more and anti-hypertensive treatment with blood pressure sustained at 140/90mmHg or more. Co-morbidities, including diabetes and chronic kidney disease, are identified through blood testing in the high CVD risk group with appropriate management. Familial propensity to premature ischaemic heart disease is also identified.

There is robust trial and observational evidence of benefit from statins and anti-hypertensives in high risk people with and without established CVD.[11-16] In people at higher CVD risk, primary prevention of CVD using multiple risk factor intervention including treatment with statins and anti-hypertensives has been shown to be of benefit.[17] However, this has not been demonstrated in entire populations including people at lower CVD risk. For people at lower CVD risk (i.e. a 10 year risk of <10%) for whom behavioural change is the main intervention, the most effective prevention strategy remains unclear.[16]

Primary prevention based on assessment of cardiovascular risk is a topic of international interest and debate.[18-20] The study was commissioned by the Department of Health to provide an early view of implementation of the national programme. This study describes the results from the first four years of the NHS Health Check programme, the population coverage and characteristics of those who attended, their recorded CVD risks, new co-morbidity and treatment. Available information on non-attendees is also reported.

Methods

The study plan and this report conform to the STROBE recommendations for observational studies.[21] The Trent Research Ethics committee approved use of the pseudonymised QResearch database for research (http://www.qresearch.org).

QResearch is a large, nationally representative and validated primary care electronic database containing the health records of 13 million patients registered from 655 general practices using the Egton Medical Information System (EMIS) computer system for at least a year.

For the four years 1 April 2009 – 31 March 2013, we included in the study all eligible adults aged 40-74 years if they had been registered for at least a year. We excluded people ineligible for an NHS Health Check, defined by the Department of Health as people with pre-existing vascular disease including hypertension, ischaemic heart disease, stroke or transient ischaemic attack, atrial fibrillation, heart failure, peripheral arterial disease, chronic kidney disease, familial hypercholesterolaemia, diabetes and those already on statins.[22]

NHS Health Check attendance was identified by Read codes for CVD risk assessment or NHS Health Check completed. Read codes are used to code clinical data in primary care. We were unable to distinguish NHS Health Checks conducted in general practice from those conducted by a third party such as a community pharmacy. For people with an NHS Health Check we used the date of the Check as the index date for analysis. For those without an NHS Check during the study period we allocated an index date of 1st April in each year. The NHS Health Check is a rolling 5 year programme and the total eligible population each year, was divided by five to estimate the number eligible in any one year. Coverage was defined as the number of attendees in the year, as a proportion of one-fifth of the population eligible in that year.

People who attended a health check out of the total eligible population were described according to sex, age group (40 to 49, 50 to 59, 60 to 74) and ethnic group. Ethnic groups were combined into 2001 national Census categories: white (British, Irish, other white);

South Asian (Bangladeshi, Indian, Pakistani); black African; black Caribbean; Chinese; Other Asian; Other (any other recorded ethnic group including mixed ethnic groups) and ethnic group not recorded.

Deprivation was assessed using the Townsend score based on 2001 census-derived measures of overcrowding, car ownership and education available at lower super output area.[23] This was obtained by linking the individuals postcode to lower super output area (approximately 150 households). Townsend score was accessible for 99% of patients. We grouped individuals into fifths of deprivation, with quintile 1 indicating least deprived and quintile 5 most deprived.

Information on smoking status, alcohol intake, and risk factor recording was described for attendees and non-attendees. This included information recorded up to and including the date of the health check for attendees or the index date for non-attendees. Family history of ischaemic heart disease was coded as positive if a first degree relative had angina or a heart attack under age 60 years. Information on alcohol consumption was categorised by units consumed per day (non-drinker, <1, 1-2, 3-6, 7-9, >9+) although it was not nationally part of the NHS Health Check during the study period. Information was also extracted on whether a recorded CVD risk score was estimated by either Framingham or QRisk2 using the same time frame as specified above. Where a score was recorded we used it to identify people at high CVD risk, defined as a 10 year CVD risk of 20% or more. In some analyses high CVD risk was defined as a 10 year CVD risk of 10% or more

In people who attended a health check information was extracted on medications, new morbidities, risk factor recording and referrals on the date of the check or in the following 12 months. The equivalent information was extracted for non-attendees for the 12 months from their index date. New medication was defined as at least two statin or anti-hypertensive prescriptions within 12 months. New co-morbidities, including diagnosed hypertension, chronic kidney disease categories 3-5 including those with eGFR <60 mls/min/1.73m^2 and diabetes, were included if newly recorded within 12 months of an NHS Health Check. Abnormal measurements were not classified as a diagnosis unless a diagnostic code was recorded. For example a raised blood pressure was not classified as hypertension unless the diagnostic code for hypertension was recorded.

The data were analysed using STATA v13 (STATA Corps). We calculated proportions of people who attended by categories of age, sex and ethnic group. We calculated proportions

according to levels of smoking status, alcohol intake, and risk factors in those who did and did not attend an NHS health check. We also described CVD risk levels and outcomes in attendees following the Health Check. We did not carry out statistical comparisons of attendees at the NHS Health Check with non-attendees, as data was incomplete in the latter, which might have led to unaccounted differences in risk between the groups.

Results

Over the four year study period (1 April 2009 to 31 March 2013) 1,679,024 people were eligible for an NHS Health Check. Of these, 12.8% (214,295) patients were recorded as having had an NHS Health Check. (See **Figure 1** Flowchart p22)

One-fifth of the eligible population was considered available for attendance each year. **Table 1** shows coverage by financial year. In 2009/10 there were a total 1,430,174 people eligible of whom 286,035 (one-fifth) were considered eligible in the year and of these, 5.8% (16,613/286,035), attended an NHS Health Check. In 2010/11, 14.6% attended, in 2011/12 24.4% attended and in 2012/13, 30.1% attended.

Table 2 shows NHS Health Check coverage for different eligible population subgroups during the entire four year study period. Of those eligible aged 60-74 years, 19.6% attended and at age 40-59 years 9.0% attended. In the most deprived quintile, 14.9% attended and in the least deprived quintile, 12.3% attended.

70% (1,174,646/1,679,024) of the eligible population had ethnic group recorded. There was low attendance (2.1%) among the 30% of the eligible population without ethnicity recorded. Among those with ethnic group recorded coverage was highest among South Asians (Indian, Pakistani, Bangladeshi, other Asian) where 19.2% of the eligible population attended, and black Caribbeans 19.6%, and lowest in black Africans (15.7%) and Chinese (15.3%). In white people 17.4% attended.

Table 3 shows information on risk factor recording and CVD risk score recording among attendees and non-attendees prior to or at the NHS Health Check or the equivalent index date for non-attendees.

Smoking was recorded in 99.9% of attendees and 94.5% of non-attendees. 17.7% of attendees were smokers and 22.4% of non-attendees were smokers. Alcohol consumption was recorded in 95.9% of attendees and 80.3% of non-attendees. Among those in whom

alcohol consumption was recorded, heavy drinking (>9 units/day) was reported by 2.5% of attendees and 2.2% of non-attendees.

CVD risk using QRisk2 was assessed in 80.0% (171,441/214,295) of attendees and in 29.0% (424,523/1,464,729) of non-attendees and versions of Framingham were used in 15.5% (33,260/214,295) of attendees and 5.2% (76051/1,464,729) of non-attendees.

Of those attendees with QRisk2 scores recorded, 14.5% (24,869/171,441) were at high CVD risk (10 year risk of 20% or more), and 20.7% (4733/33,260) of those with Framingham scores recorded were at high CVD risk. 12.9% (27,624/214,295) of all attendees were recorded at high CVD risk (20% or more 10 year risk) using either QRisk2 or Framingham. Among non-attendees with QRisk2 recorded, 6.6% (27,902/424,523) were at high CVD risk and 8.6% of non-attendees were at high CVD risk (6547/76,051) using Framingham.

Considering a 10% CVD risk threshold, of those attendees with a QRisk2 score recorded, 46.6% (79,960/171,441) were high risk. In the non-attendees with a recorded QRisk2 score, 27.0% (114,564/424,523) were at 10% or more risk.

Table 4 records new co-morbidity identified at or in the 12 months after the NHS Health Check from 2009-12. This included 7844 new cases of hypertension (1 case per 27 NHS Health Checks), 1934 new cases of diabetes (1 new case for every 110 Checks) and 807 new cases of chronic kidney disease (1 new case in every 265 Checks).

Recording of new co-morbid conditions in the year after an NHS Check was higher in people attending NHS Health Checks than recording in the year after the index date in non-attendees.

In addition to those people with new co-morbidities diagnosed, risk factors requiring further follow-up were recorded in more than 1 in 5 of attendees. Raised blood pressure ≥140/90mmHg (but not recorded as a diagnosis of hypertension) was identified in 18.2% (26,126/140,995), obesity BMI ≥30 kg/m^2 in 15.0% (32,133/151,480) and raised fasting blood sugar (but not recorded as a diagnosis of diabetes) in 2.7% (1375/100,240).

33.9% of heavy and very heavy alcohol drinkers (1823/5376) were referred for further advice and in people who were obese (BMI ≥30 kg/m^2) 38.9% (12,430/32,133) received advice on weight reduction and 41.4% (13,309/32,133) on physical activity. 6.8% (2571/37,808) of smokers were referred to dedicated smoking cessation services.

New recurrent prescriptions for statins (two or more prescriptions within 12 months) were provided for 5.1% (10,900) of attendees and new recurrent prescriptions for anti-hypertensives for 3.9% (8497) of attendees. Equivalently 1 in 20 attendances resulted in recurrent statin prescriptions and 1 in 25 attendances resulted in recurrent antihypertensive prescriptions.

Table 6 (appendix) shows the characteristics of those at high CVD risk (>20% risk) who attended for an NHS Health Check. In total 12.9% (27,624/214,295) attendees were recorded at high CVD risk. Those at high CVD risk were older. 81.0% of high risk attendees in the 60-74 year age group compared to 34.0% of all attendees. Men comprised 78.3% in the high risk group and 47.9% amongst all attendees.

As expected all other risk factors were more prevalent in those at high CVD risk. Of the high CVD risk attendees 23.2% (4222/18,203) were obese and 28% were smokers. Blood pressure was ≥140/90mmHg in 30.0% (4772/15,905) at high CVD risk compared to 18.5% (26,126/140,995) in all attendees. Of those NHS Health Check attendees at high CVD risk 19.3% (5325/27,624) were prescribed recurrent statins and 8.8% (2438/27,624) were prescribed recurrent antihypertensive therapy.

Referrals to behavioural support

Table 5 shows that most referrals for behavioural interventions took place in people at lower CVD risk (<20% over 10 years). Of those people with behaviourally mediated risk factors recorded - smoking, obesity and high alcohol consumption - who were referred for further support during an NHS Health Check, 80.0% were not in the high CVD risk group. Of the smoking cessation referrals made in smokers, 17.1% (439/2571) were in smokers at high CVD risk and 82.9% were in people at lower risk. Of the dietary referrals made in people with BMI ≥30 kg/m^2, 13.6% (1691/12,430) were in people at high CVD risk and 86.4% were in people at lower risk. Similarly of the referrals for physical activity, 13.4% (1780/13,309) were in people at high CVD risk and 86.6% were in people at lower risk. Of the total referrals for alcohol reduction support for heavy or very heavy drinkers 16.5% (300/1823) were in people at high CVD risk and 83.5% were in people at lower risk.

5.7% (1139/7743) of smokers at high CVD risk were referred to accredited level 2 or 3 smoking cessation services. In people at high CVD risk with BMI ≥30, 40.0% (1691/4222) were referred to dietary and 42.2% (1780/4222) to physical activity support services and

33.1% (300/905) of those at high CVD risk recorded as drinking 7 or more units of alcohol per day were referred to alcohol reduction services.

These proportions of people at high CVD risk referred to smoking cessation, dietary, physical activity and alcohol services were very similar to the proportions referred in all attendees, of whom 6.8% (2571/37,808) were referred to smoking cessation, 38.7% (12,430/32,133) to dietary and 41.4% (12,430/32,133) to physical activity support services and 35.7% (1823/5101) of heavy drinkers were referred to alcohol reduction services: Tables 3 and 4.

Discussion

This is the first study to describe national results from the NHS Health Check programme. In 2012, the most recent year reported, 30.1% of the eligible population attended. Attendance was more likely at older ages, among more deprived people and among black Caribbean and South Asian than white ethnic groups.12.9% of all attendees were recorded at high CVD risk (20% or more 10 year risk).

New co-morbidity identified in the 4 year period included 7844 new cases of hypertension (1 case per 27 NHS Health Checks), 1934 new cases of diabetes (1 new case for every 110 Checks) and 807 new cases of CKD (1 new case in every 265 Checks). People attending NHS Health Checks were more likely than non-attendees to have co-morbid conditions identified in the year after an NHS Health Check compared with an equivalent date in non-attendees. However, records of risk factors were more incomplete in non-attendees and attendees were older. Black and South Asian ethnic minority groups accounted for 5.4% of attendees and 3.4% of non-attendees and people from the most deprived quintile made up 23.3% of attendees and 19.4% of non-attendees. Because of differences in the characteristics and recording of risk factors between attendees and non-attendees we have not made formal statistical comparisons between these groups.

In addition to those people with new co-morbidities diagnosed, risk factors such as raised blood pressure, raised blood sugar and obesity requiring further follow-up were recorded in more than 1 in 5 of attendees. Most referrals for behavioural interventions took place in people at lower CVD risk. Of those people with behaviourally mediated risk factors recorded - smoking, obesity and alcohol consumption - who were referred for further support during an NHS Health Check, 80% were not in the high CVD risk group. The proportion of people in

the high CVD risk group referred because of risk factors was similar to the proportion referred among all attendees.

1 in 20 attendances resulted in recurrent statin prescription and 1 in 25 attendances resulted in recurrent antihypertensive prescription. Of those NHS Health Check attendees at high CVD risk, 19.3% were prescribed recurrent statins and 8.8% were prescribed recurrent antihypertensive therapy.

This is a large and nationally representative study including records of social deprivation and ethnicity. Coverage of 30% was lower than expected, though attendance quadrupled during the course of the study reflecting the early phase of implementation and heterogeneous implementation. There was no evidence that older people, ethnic minority groups or those in the more deprived quintile were less likely to attend than other groups. Currently attendance at NHS Health Checks is reported as uptake in response to invitation rather than coverage, with attendance as a proportion of the eligible population, as reported in this paper.[4]

The NHS Health Check programme is an example of systematic implementation at national scale, of a stratified approach to advice and effective treatment in people at increased CVD risk. QRisk2 was used in 80% of NHS Checks reported in this study and has since been recommended as the risk algorithm of choice in the 2014 NICE guidance;[24] an example of successful translation of clinical decision support at scale.[25 26] This algorithm is fully integrated with the electronic primary care record, a key enabling factor for implementation.[27]

Limitations of the study

There is no nationally available data on the extent of provision of the NHS Health Check outside of general practices. However, this is likely to represent less than 10% of Checks undertaken as in most PCTs, the NHS Health Check was conducted almost entirely in general practice with limited use of community programmes targeting hard-to-reach groups or, in most areas, use of community pharmacies. Completeness of NHS Health Checks was not ascertained, but taking measurement of cholesterol recording of 91.5% as a proxy measure, risk ascertainment was generally well conducted.

Of the people referred with behavioural risk factors, 80% were at lower CVD risk, which indicates the wide distribution of risk factors and the potential for behaviour change if programmes can be shown to be effective. However, little is known about attendance at, or

quality of behavioural programmes even for those at increased risk. The impact of the NHS Health Check programme on people at lower risk is unknown and further research is required.[28]

The study is descriptive and was not designed to determine variability between practices or CCGs. The study has not assessed changes in risk factors or cardiovascular events between comparable groups. These comparisons are difficult in a non-randomised study especially if one group is at higher risk than the other or information is incomplete. For similar reasons we have not directly compared attendees with non-attendees because of the differences in characteristics and risk factor recording. Communication of results and patient behaviours following NHS Checks remains an under researched area.[29-31]

Implications for practice

A number of local studies suggest that the programme has been better implemented in some areas with coverage of 80% and statin prescription of up to 50% in high risk individuals in some CCGs.[32 33] Nationally uptake in 2011-12 was reported as 45%, with high levels of variability and better uptake in more deprived areas.[6 5] There is limited evidence of effectiveness[34] or comorbidities identified[35] and statin uptake in those at high risk was reported to be between 20-50% [5 36] which accords with national surveys of 32%.[37]

Despite a statin treatment rate of only 19% in high risk attendees in this study, this is likely to have a significant impact. Assuming that 1.2 million people attended a NHS Check each year in the five years since 2010, of whom 10% (120,000) were at high CVD risk averaging 2.5% per year, and 19.3% (23,160) of these people were treated with statins over this period and 8.8% (10,560) were treated with antihypertensives; if each treatment reduces cardiovascular risk by 20%, it is estimated that 2529 people would avoid a major CVD event over a five year period.[11 12] Higher uptake in more recent years and additional treatment in people at both high CVD risk and at lower CVD risk make this a conservative estimate and behavioural change will have further impact.[37]

The NHS Health Check programme has had a difficult birth. The efficacy of the programme has been challenged,[38-41] based largely on a review of 16 trials of health checks, of which 12 trials were undertaken more than 20 years ago before 1994[42-52], the year in which the landmark 4S trial established statin effectiveness.[53] This means that 12 out of 16 of the reported studies were conducted before statins or modern anti-hypertensive drugs were used.

Of the trials since 1994 only one[52] specifically recommended drug treatment for CVD risk, the other three offering no drug treatment.[54-56] None of the reported trials involved the use of statins.

Statins have also received considerable adverse publicity.[57]

There have also been organisational factors that have impacted on implementation of the programme. Major organisational change in the NHS in the context of financial austerity[58 59] led to one third of staff leaving PCTs in the transition to CCGs in April 2013[60] and commissioning responsibility for NHS Checks passed to Local Authorities. It is perhaps not surprising that in 2013, 27/151 PCTs nationally offered NHS Health Checks to fewer than 10% of eligible individuals and uptake could be substantially improved.[61] The most efficient means to deliver this programme remains an area for debate and a range of infrastructural issues and new research are currently being addressed by Public Health England.[62 63]

This study indicates limited though improving success in the early years of a major new national preventive programme. Coverage of 30% and 19% statin treatment of people at high CVD risk leave considerable room for improvement and further reduction in morbidity. New co-morbidity and abnormal risk factors were frequently identified in people who attended an NHS Health Check. The majority of referrals for abnormal risk factors were amongst people at lower CVD risk. This modest start to a major new programme at scale is likely to have made an important impact on CVD events.

Authors' contributions

John Robson initiated the study and has contributed to its design and implementation. Julia Hippisley-Cox contributed to the research question, design, data extraction, data analysis, interpretation and comments on the manuscript. Carol Coupland advised on the statistical analysis and interpretation. Isabel Dostal conducted a preliminary investigation in one CCG that informed the study design, preparation of the codesets and study specification. Sandra Eldridge and Vichithranie Madurasinghe supported the statistical analysis and interpretation and all authors including Chris Griffiths and Aziz Sheikh contributed to the study design and all authors contributed to the manuscript.

The views expressed in this publication are those of the authors and do not necessarily represent those of those of the Department of Health or institutions that fund or support the authors.

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Ethical approval

The Trent Research Ethics committee has approved use of the QResearch database for anonymised use of primary care data.

Competing interests

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that (1) JR, JHC, CC and AS are authors of QRisk, one of the CVD Scores widely used in the NHS Health Check programme. JR was Chair of a National Institute for Health and Care Excellence Guideline that recommended systematic use of CVD scores in 2008. JHC is also director of ClinRisk Ltd which produces open and closed source software to ensure the reliable and updatable implementation of clinical risk algorithms (including QRISK) within clinical computer systems to help improve patient care. CC is an associate professor of Medical Statistics at the University of Nottingham and a consultant statistician for ClinRisk Ltd. Neither JHC nor CC received fees from these sources for this work. The NIHR grant which funded this project provided funds to SE, JR,ID, JHC and CC for their contribution to the study. CG and the other authors have no additional relationships with that might have an interest in the submitted work in the previous 3 years; (3)

authors spouses, partners, or children have no financial relationships that may be relevant to the submitted work; and (4) the authors have no non-financial interests that may be relevant to the submitted work.

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Transparency Declaration

The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Table 1

Coverage of NHS Health Check programme in each year

Financial years	Patients with health check in financial year	20% of the eligible population on 1st April	% Coverage Attendance/one-fifth of eligible population
2009/10	16,613	286,035	**5.8%**
2010/11	41,832	286,383	**14.6%**
2011/12	69,978	286,669	**24.4%**
2012/13	86,042	285,784	**30.1%**

Table 2

Characteristics of people aged 40-74 years eligible for an NHS Health Check between April 2009 and March 2013 and those who attended

	Total eligible people	NHS Health Check attendees	% total eligible population with NHS Health Check
Total	**1,679,024**	**214,295**	**12.8%**
Female	846,797	111,740	**13.2%**
Male	832,227	102,555	**12.3%**
Age band (years)			
40-49	806,199	72,903	**9.0%**
50-59	499,725	68,428	**13.7%**
60-74	373,100	72,964	**19.6%**
Townsend quintile of deprivation			
1 (most affluent)	336,174	41,423	**12.3%**
2	334,996	40,342	**12.0%**
3	335,706	40,897	**12.2%**
4	335,302	41,557	**12.4%**
5 (most deprived)	334,652	49,974	**14.9%**
Townsend not recorded	2,194	102	**4.7%**
Ethnicity			
White	1,065,171	185,082	**17.4%**
Indian	16,842	2,987	**17.7%**
Pakistani	8,472	1,362	**16.1%**
Bangladeshi	4,925	1,460	**29.6%**
Other Asian	13,471	1,966	**14.6%**
Caribbean	12,908	2,531	**19.6%**
Black African	19,899	3,128	**15.7%**
Chinese	6,913	1,059	**15.3%**
Other	26,045	4,059	**15.6%**
Not recorded	504,378	10,661	**2.1%**

Table 3

Characteristics of eligible people who did and did not attend for an NHS Health Check

Recorded prior to or on the date of the NHS Health Check or relevant index date

	NHS Health Check No. (%)	No NHS Health Check No. (%)
Total	**214,295**	**1,464,729**
Smoking status recorded	214,020 (99.9)	1,384,707 (94.5)
Non smoker	117,968 (55.0)	768,276 (52.5)
Ex-smoker	58,244 (27.2)	306,397 (20.9)
Light smoker (1-9/day)	19,589 (9.1)	167,592 (11.4)
Moderate smoker (10-19/day)	11,052 (5.2)	83,585 (5.7)
Heavy smoker (20+/day)	7167 (3.3)	58,857 (4.0)
Alcohol intake		
Alcohol status recorded	205,506 (95.9)	1,175,900 (80.3)
Non drinker	53,485 (25.0)	292,289 (20.0)
Trivial <1 units/day	66,780 (31.2)	421,139 (28.8)
Light 1-2 units/day	37,398 (17.5)	205,572 (14.0)
Moderate 3-6 units/day	42,467 (19.8)	227,987 (15.6)
Heavy 7-9 units/day	3235 (1.5)	17,169 (1.2)
Very Heavy >9 units/day	1866 (0.9)	8842 (0.6)
Drinker - amount not recorded	275 (0.1)	2902 (0.2)
Risk factor recording		
Body mass index recorded	210,062 (98.0)	1,176,819 (80.3)
Systolic blood pressure recorded	213,690 (99.7)	1,316,926 (89.9)
Cholesterol recorded	195,994 (91.5)	633,548 (43.3)
Cholesterol/HDL recorded	174,345 (81.4)	433,594 (29.6)
Positive family history CHD	46,466 (21.7)	156,604 (10.7)
Mean body mass index (SD)	27.1 (4.5)	26.4 (4.6)
Mean cholesterol (SD)	5.5 (1.0)	5.4 (1.0)
Mean cholesterol/HDL (SD)	4 (1.3)	4 (1.2)
Mean SBP (SD)	130.8 (16.9)	128.4 (15.6)
Mean DBP (SD)	79.4 (10.0)	78.6 (9.4)
QRisk2 recorded	171,441 (80.0)	424,523 (29.0)
QRisk2 not recorded	42,854 (20.0)	1,040,206 (71.0)
QRisk2 score		
<5%	47,794 (22.3)	195,253 (13.3)
5-9.99	43,687 (20.4)	114,706 (7.8)
10-14.99	32,452 (15.1)	55,306 (3.8)
15-19.99	22,639 (10.6)	31,356 (2.1)
20+	24,869 (11.6)	27,902 (1.9)
Framingham score recorded	33,260 (15.5)	76,051 (5.2)
not recorded	181,035 (84.5)	1,388,679 (94.8)
Framingham score		

<5%	7152 (3.3)	20,532 (1.4)
5-9.99	10,196 (4.8)	25,898 (1.8)
10-14.99	6896 (3.2)	15,286 (1.0)
15-19.99	4283 (2.0)	7787 (0.5)
20+	4733 (2.2)	6547 (0.4)
20+ QRisk2 or Framingham	**27,624 (12.9)**	**32,481 (2.2)**

Table 4

Outcomes for people who did and did not have an NHS Health Check (number, %)

Recorded at NHS Health Check, relevant index date or in 12 months following these dates

	NHS Health Check No. (%)	No NHS Health Check No. (%)
Total patients	**214,295**	**1,464,729**
New diagnoses		
Chronic kidney disease (eGFR <60ml/min/)	807 (0.4)	2310 (0.2)
Type 2 diabetes	1934 (0.9)	5647 (0.4)
Hypertension	7844 (3.7)	16,184 (1.1)
Risk factor recording		
Body mass index recorded	151,480 (70.7)	144,756 (9.9)
Positive family history of premature CHD recorded	14,760 (6.9)	4720 (0.3)
Blood pressure recorded	140,995 (65.8)	242,928 (16.6)
eGFR recorded	59,021 (27.5)	160,843 (11.0)
Fasting glucose	35,801 (16.7)	78,934 (5.4)
Random glucose	64,439 (30.1)	102,568 (7.0)
Total cholesterol recorded	123,342 (57.6)	137,207 (9.4)
Cholesterol/HDL ratio recorded	118,930 (55.5)	115,011 (7.9)
Smoking status recorded	188,282 (87.9)	410,301 (28.0)
Risk factors identified		
Fasting glucose≥7mmol/L	954 (0.4)	2983 (0.2)
Random glucose≥ 11mmol/L	421 (0.2)	1291 (0.1)
Raised BP SBP ≥ 140mmHg or DBP ≥ 90mmHg	26,126 (12.2)	52,236 (3.6)
Obesity BMI≥ 30 kg/m^2	32,133 (15.0)	39,774 (2.7)
New referrals		
Current smokers referred to smoking cessation clinic	2571 (1.2)	9944 (0.7)
Weight referrals: BMI ≥ 30 kg/m^2	12,430 (5.8)	4441 (0.3)
Exercise referrals: BMI ≥ 30 kg/m^2	13,309 (6.2)	4082 (0.3)
Alcohol referrals: > 6 units/day	1823 (0.9)	1459 (0.1)
New medication		
2+ prescriptions for statins	10,900 (5.1)	15,086 (1.0)
2+ prescriptions for anti-hypertensives	8457 (3.9)	26,178 (1.8)

Table 5

Outcome of NHS Check for people at high CVD risk (10 year risk ≥20%)

Recorded at NHS Health Check or in 12 months following this date

	NHS Health Check risk ≥20% No. (%)	
Total CVD risk ≥20%	**27,624**	
New diagnoses		
CKD (wider definition)	235	(0.9)
Type 2 diabetes	489	(1.8)
Hypertension	2195	(7.9)
Cardiovascular disease	337	(1.2)
Coronary heart disease	206	(0.7)
Stroke	140	(0.5)
Risk factors identified		
Fasting glucose ≥7	256	(0.9)
Random glucose≥ 11	84	(0.3)
Raised BP SBP≥ 140 or DBP ≥ 90	4772	(17.3)
Obesity BMI≥ 30	4222	(15.3)
New referrals		
Smokers referred to smoking cessation clinic	439	(1.6)
Weight referrals in patients with BMI ≥30	1691	(6.1)
Physical activity referrals in patients with BMI ≥30	1780	(6.4)
Alcohol referrals in patients drinking > 6u/day	300	(1.1)
New medication		
2+ prescriptions for statins	5325	(19.3)
2+ prescriptions for antihypertensives	2438	(8.8)
Risk factor recording		
Body mass index recorded	18,203	(65.9)
Positive Family history CHD recorded	2660	(9.6)
Blood pressure recorded	15,905	(57.6)
eGFR recorded	8229	(29.8)
Fasting glucose	5694	(20.6)
Random glucose	8392	(30.4)
Total cholesterol recorded	14,876	(53.9)
Cholesterol/HDL ratio recorded	14,974	(54.2)

Appendix

Figure 1

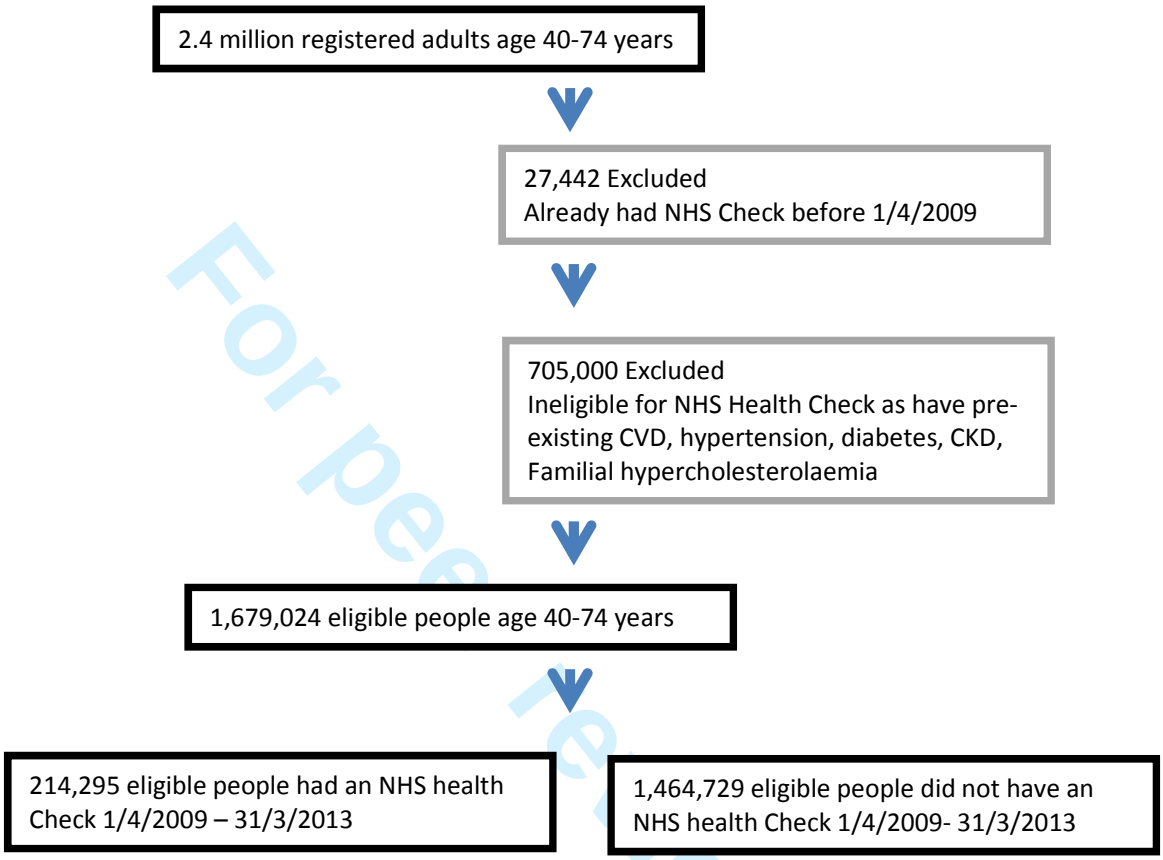

Table 6

Characteristics of people at high CVD risk who attended an NHS Health Check 1 April 2009 to 31 March 2013

Recorded at or prior to the date of the NHS Health Check

	NHS Health Check risk ≥20% No. (%)	
Total patients all CVD risks	**214,295**	
Total with CVD risk ≥20%	**27,624**	
Females	5992	(21.7)
Males	21632	(78.3)
Age band (years)		
40-49	778	(2.8)
50-59	4475	(16.2)
60-74	22,371	(81.0)
Townsend quintile		
1 (most affluent)	5135	(18.6)
2	5356	(19.4)
3	5301	(19.2)
4	5284	(19.1)
5 (most deprived)	6539	(23.7)
Ethnicity		
Ethnicity recorded	26,392	(95.5)
White	25,037	(90.6)
Indian	376	(1.4)
Pakistani	264	(1.0)
Bangladeshi	276	(1.0)
Other Asian	135	(0.5)
Caribbean	89	(0.3)
Black African	27	(0.1)
Chinese	17	(0.1)
Other	171	(0.6)
Not recorded	1232	(4.5)
Smoking status recorded	27,611	(100.0)
Non smoker	10,517	(38.1)
Ex-smoker	9351	(33.9)
Light smoker (1-9/day)	4024	(14.6)
Moderate smoker (10-19/day)	2199	(8.0)
Heavy smoker (20+/day)	1520	(5.5)
Alcohol intake prior to or at NHS Health Check		
Alcohol status recorded	26,765	(96.9)
Non drinker	6897	(25.0)

Trivial <1 units/day	7919	(28.7)
Light 1-2 units/day	4684	(17.0)
Moderate 3-6 units/day	6322	(22.9)
Heavy 7-9 units/day	601	(2.2)
Very Heavy >9 units/day	304	(1.1)
Drinker: amount not recorded	38	(0.1)
Risk factor recording prior to or at NHS Health Check		
Body Mass Index recorded	27,243	(98.6)
Systolic blood pressure recorded	27,600	(99.9)
Cholesterol recorded	26,241	(95.0)
Positive family history of premature CHD	9503	(34.4)
Mean body mass index (SD)	27.6	(4.2)

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

Title **The NHS Health Check in England: an evaluation of the first four years.**

	Item No	Recommendation	Pg #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	3-4
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4-5
Bias	9	Describe any efforts to address potential sources of bias	5-6
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4-6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	5-6
		(*b*) Describe any methods used to examine subgroups and interactions	5-6
		(*c*) Explain how missing data were addressed	5-6
		(*d*) If applicable, explain how loss to follow-up was addressed	5-6
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6 & 22
		(b) Give reasons for non-participation at each stage	6 & 22
		(c) Consider use of a flow diagram	22
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6 Tables 1,2
		(b) Indicate number of participants with missing data for each	ditto

		variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	Report numbers of outcome events or summary measures over time	6-9, Tables 3-5
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6-9 Tables 3-5
		(*b*) Report category boundaries when continuous variables were categorized	5
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	9-10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10-11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	11-12
Generalisability	21	Discuss the generalisability (external validity) of the study results	11-12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

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The NHS Health Check in England: an evaluation of the first four years.

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Abstract: 270

Text 3941

Tables 5

Appendix (Fig 1, Table 1)

Abstract

Objectives: To describe implementation of a new national preventive programme to reduce cardiovascular morbidity.

Design: Observational study over four years April 2009 – March 2013.

Setting: 655 general practices across England from the QResearch database.

Participants: Eligible adults aged 40-74 years including attendees at an NHS Health Check.

Intervention: NHS Health Check: routine structured cardiovascular check with support for behavioural change and in those at highest risk, treatment of risk factors and newly identified co-morbidity.

Results: 1.68 million eligible people had an NHS Health Check in the period 2009-2012 and attendance quadrupled as the programme progressed; 5.8% in 2010 to 30.1% in 2012. Attendance was relatively higher among older people, of whom 19.6% of those eligible at age 60-74 years attended and 9.0% at age 40-59 years. Attendance by population groups at higher CVD risk, such as the more socially disadvantaged 14.9%, was higher than that of the more affluent 12.3%. Among attendees 7844 new cases of hypertension (38/1000 Checks), 1934 new cases of type 2 diabetes (9/1000 Checks) and 807 new cases of chronic kidney disease (4/1000 Checks) were identified.
Of the 27,624 people found to be at high CVD risk (20% or more 10 year risk) when attending an NHS Health Check, 19.3% (5325) were newly prescribed statins and 8.8% (2438) were newly prescribed antihypertensive therapy.

Conclusions: NHS Health Check coverage was lower than expected but showed year on year improvement. Newly identified co-morbidities were an important feature of the NHS Health Checks. Statin treatment at national scale for 1 in 5 attendees at highest CVD risk is likely to have contributed to important reductions in their CVD events.

Strengths and weaknesses

- This is the first national study describing implementation of the new NHS Health Check programme 2009-12.
- It is based on a large representative sample of 655 general practices in England with 1.68 million people aged 40-74 years eligible for an NHS Health Check of whom 214,295 attended.
- Of those eligible 70% had ethnic group recorded and 99% socio-economic group recorded. In attendees, recording of ethnic group and major risk factors was over 90%.
- Non-attendees were younger, more likely to smoke and recording of cardiovascular risk was less complete.
- There is no information available about attendance for support for behavioural change following GP referral.

Introduction

The English national NHS Health Checks programme started in 2009, aiming to reduce cardiovascular disease (CVD) risks and events. Internationally it is the first of its kind, aiming to provide a routine structured clinical assessment and management for adults aged 40-74 years without pre-existing diabetes or CVD. The NHS Health Check includes review of CVD risks, behavioural change support and treatment of newly identified risk factors or co-morbidity through integration with routine clinical provision in general practice. We describe an evaluation of the first four years of this national programme.

The NHS Health Check is a five year rolling programme which targets one-fifth of the eligible population each year, aiming to invite 3 million people at an annual cost of £165 million.[1-3] The Department of Health report that 2.4 million NHS Health Checks were undertaken in the two years 2011-2012.[4] Nationally, uptake is reported at around 50% of the eligible target population with considerable variability between provider organisations.[4-6] The NHS Health Check programme is now supported by NHS England and Public Health England following major changes in the NHS in 2013 when Primary Care Trusts (PCTs) were replaced by Clinical Commissioning Groups (CCGs) and responsibility for commissioning the programme was transferred to the Local Authorities.[7 8]

Stratification of CVD risk for the purposes of therapeutic intervention is a key component of the NHS Health Check. Attendees receive personal advice to support behaviour change and treatment informed by CVD risk stratification. When the programme was introduced, NICE guidance and the NHS Health Check programme,[9 10] recommended statin treatment at a 10 year CVD risk of 20% or more and anti-hypertensive treatment with blood pressure sustained at 140/90mmHg or more. Co-morbidities, including diabetes and chronic kidney disease, are identified through blood testing in the high CVD risk group with appropriate management. Familial propensity to premature ischaemic heart disease is also identified.

There is robust trial and observational evidence of benefit from statins and anti-hypertensives in high risk people with and without established CVD.[11-16] In people at higher CVD risk, primary prevention of CVD using multiple risk factor intervention including treatment with statins and anti-hypertensives has been shown to be of benefit.[17] However, this has not been demonstrated in entire populations including people at lower CVD risk. For people at lower CVD risk (i.e. a 10 year risk of <10%) for whom behavioural change is the main intervention, the most effective prevention strategy remains unclear.[16]

Primary prevention based on assessment of cardiovascular risk is a topic of international interest and debate.[18-20] The study was commissioned by the Department of Health to provide an early view of implementation of the national programme. This study describes the results from the first four years of the NHS Health Check programme, the population coverage and characteristics of those who attended, their recorded CVD risks, new co-morbidity and treatment. Available information on non-attendees is also reported.

Methods

The study plan and this report conform to the STROBE recommendations for observational studies.[21] The Trent Research Ethics committee approved use of the pseudonymised QResearch database for research (http://www.qresearch.org).

QResearch is a large, nationally representative and validated primary care electronic database containing the health records of 13 million patients registered from 655 general practices using the Egton Medical Information System (EMIS) computer system for at least a year.

For the four years 1 April 2009 – 31 March 2013, we included in the study all eligible adults aged 40-74 years if they had been registered for at least a year. We excluded people ineligible for an NHS Health Check, defined by the Department of Health as people with pre-existing vascular disease including hypertension, ischaemic heart disease, stroke or transient ischaemic attack, atrial fibrillation, heart failure, peripheral arterial disease, chronic kidney disease, familial hypercholesterolaemia, diabetes and those already on statins.[22]

Read codes are used to code clinical data in primary care. NHS Health Check attendance was identified by Read codes for CVD risk assessment or NHS Health Check completed. We were unable to distinguish NHS Health Checks conducted in general practice from those conducted by a third party such as a community pharmacy. For people with an NHS Health Check we used the date of the Check as the index date for analysis. For those without an NHS Check during the study period we allocated an index date of 1st April in each year. The NHS Health Check is a rolling 5 year programme and the total eligible population each year, was divided by five to estimate the number eligible in any one year. Coverage was defined as the number of attendees in the year, as a proportion of one-fifth of the population eligible in that year.

The total eligible population and people who attended an NHS Health Check were described according to sex, age group (40 to 49, 50 to 59, 60 to 74) and ethnic group. Ethnic groups were combined into Office of National Statistics categories: white (British, Irish, other white); South Asian (Bangladeshi, Indian, Pakistani); black African; black Caribbean; Chinese; Other Asian; Other (any other recorded ethnic group including mixed ethnic groups) and ethnic group not recorded. [23]

Deprivation was assessed using the Townsend score based on 2001 census-derived measures of overcrowding, car ownership and education available at lower super output area.[24] This was obtained by linking the individuals postcode to lower super output area (approximately 150 households). Townsend score was accessible for 99% of patients. We grouped individuals into fifths of deprivation, with quintile 1 indicating least deprived and quintile 5 most deprived.

Information on smoking status, alcohol intake, and risk factor recording was described for attendees and non-attendees. This included the latest information recorded up to and including the date of the NHS Health Check for attendees or the index date for non-attendees. Family history of ischaemic heart disease was coded as positive if a first degree relative had angina or a heart attack under age 60 years. Information on alcohol consumption was categorised by units consumed per day (non-drinker, <1, 1-2, 3-6, 7-9, >9+) although it was not nationally part of the NHS Health Check during the study period. Information was also extracted on whether a recorded CVD risk score was estimated by either Framingham or QRisk2 using the same time frame as specified above. Where a score was recorded we used it to identify people at high CVD risk, defined as a 10 year CVD risk of 20% or more.

In people who attended a Health Check, information was extracted on medications, new morbidities, risk factor recording and referrals on the date of the check or in the following 12 months. The equivalent information was extracted for non-attendees for the 12 months from their index date. New medication was defined as at least two statin or anti-hypertensive prescriptions within 12 months. New co-morbidities, including diagnosed hypertension, chronic kidney disease categories 3-5 and diabetes, were included if newly recorded within 12 months of an NHS Health Check. Abnormal measurements were not classified as a diagnosis unless a diagnostic code was recorded. For example a raised blood pressure was not classified as hypertension unless the diagnostic code for hypertension was recorded.

The data were analysed using STATA v13 (STATA Corps). We calculated proportions of people who attended by categories of age, sex and ethnic group. We calculated proportions according to levels of smoking status, alcohol intake, and risk factors in those who did and did not attend an NHS Health check. We also described CVD risk levels and outcomes in attendees following the NHS Health Check. We did not carry out statistical comparisons of NHS Health Check attendees with non-attendees, as data was incomplete in the latter.

Results

Over the four year study period (1 April 2009 to 31 March 2013) 1,679,024 people were eligible for an NHS Health Check. Of these, 12.8% (214,295) patients were recorded as having had an NHS Health Check. (See **Figure 1** Flowchart Appendix p26)

One-fifth of the eligible population was considered available for attendance each year. **Table 1** shows coverage by financial year. In 2009/10 there were a total 1,430,174 people eligible of whom 286,035 (one-fifth) were considered eligible in the year and of these, 5.8% (16,613/286,035), attended an NHS Health Check. In 2010/11, 14.6% attended, in 2011/12 24.4% attended and in 2012/13, 30.1% attended.

Table 2 shows NHS Health Check coverage for different eligible population subgroups during the entire four year study period. Of those eligible aged 60-74 years, 19.6% attended and at age 40-59 years 9.0% attended. In the most deprived quintile, 14.9% attended and in the least deprived quintile, 12.3% attended.

70% (1,174,646/1,679,024) of the eligible population had ethnic group recorded. There was low attendance, 2.1% among the 30% of the eligible population without ethnicity recorded. Among those with ethnic group recorded, coverage was highest among South Asians (Indian, Pakistani, Bangladeshi, other Asian) of whom 19.2% of the eligible population attended, and black Caribbeans 19.6%, and lowest in black Africans 15.7% and Chinese 15.3%. In white people 17.4% attended compared to 16.9% in all other recorded ethnic groups.

Table 3 shows information on risk factor recording and CVD risk score recording among attendees and non-attendees prior to or at the NHS Health Check or the equivalent index date for non-attendees. Smoking status was recorded in 99.9% of attendees and 94.5% of non-attendees. Non-attendees were more likely to be smokers. 17.7% of attendees were smokers

and 22.4% of non-attendees were smokers. Alcohol consumption was recorded for 95.9% of attendees and 80.3% of non-attendees. Among those in whom alcohol consumption was recorded, heavy drinking (>9 units/day) was reported by 2.5% of attendees and 2.2% of non-attendees.

CVD risk using QRisk2 was assessed in 80.0% (171,441/214,295) of attendees and in 29.0% (424,523/1,464,729) of non-attendees and versions of Framingham were used in 15.5% (33,260/214,295) of attendees and 5.2% (76051/1,464,729) of non-attendees.

Of those attendees with QRisk2 scores recorded, 14.5% (24,869/171,441) were at high CVD risk (10 year risk of 20% or more), and 20.7% (4733/33,260) of those with Framingham scores recorded were at high CVD risk. 12.9% (27,624/214,295) of all attendees were recorded at high CVD risk (20% or more 10 year risk) using either QRisk2 or Framingham. Among non-attendees with QRisk2 recorded, 6.6% (27,902/424,523) were at high CVD risk and 8.6% of non-attendees were at high CVD risk (6547/76,051) using Framingham.

Of those attendees with a QRisk2 score recorded, 46.6% (79,960/171,441) had a CVD risk of 10% or more. In the non-attendees with a recorded QRisk2 score, 27.0% (114,564/424,523) were at 10% or more CVD risk.

New co-morbidity

Table 4 records new co-morbidity identified at or in the 12 months after the NHS Health Check from 2009-12. This included 7844 new cases of hypertension (1 case per 27 NHS Health Checks), 1934 new cases of diabetes (1 new case for every 110 Checks) and 807 new cases of chronic kidney disease (1 new case in every 265 Checks).

Recording of new co-morbid conditions in the year after an NHS Check was higher in people attending NHS Health Checks than recording in the year after the index date in non-attendees. However, in non-attendees missing data is a major issue which precludes simple direct comparison between attendees and non-attendees. Risk factors requiring further follow-up were recorded in more than 1 in 5 attendees. Raised blood pressure ≥140/90mmHg (but not recorded as a diagnosis of hypertension) was identified in 18.5% (26,126/140,995), obesity BMI ≥30 kg/m^2 in 15.0% (32,133/151,480) and raised fasting blood sugar (but not recorded as a diagnosis of diabetes) in 2.7% (954/35,801).

33.9% of heavy and very heavy alcohol drinkers (1823/5376) were referred for further advice and in people who were obese (BMI ≥30 kg/m^2) 38.7% (12,430/32,133) received advice on weight reduction and 41.4% (13,309/32,133) on physical activity. 6.8% (2571/37,808) of smokers were referred to dedicated smoking cessation services.

New recurrent prescriptions for statins (two or more prescriptions within 12 months) were provided for 5.1% (10,900) of attendees and new recurrent prescriptions for anti-hypertensives for 3.9% (8497) of attendees. Equivalently 1 in 20 attendances resulted in recurrent statin prescriptions and 1 in 25 attendances resulted in recurrent antihypertensive prescriptions.

Attendees at high CVD risk

Table 5 shows the characteristics of those at high CVD risk (≥20% risk) who attended for an NHS Health Check. In total 12.9% (27,624/214,295) attendees were recorded at high CVD risk. As expected, those at high CVD risk were older, with 81.0% of high risk attendees in the 60-74 year age group compared to 34.0% of all attendees. Men comprised 78.3% in the high risk group and 47.9% amongst all attendees.

As expected all other risk factors were more prevalent in those at high CVD risk. Of the high CVD risk attendees 23.2% (4222/18,203) were obese and 28% (7743/27,611) were smokers. Blood pressure was ≥140/90mmHg in 30.0% (4772/15,905) at high CVD risk compared to 18.5% (26,126/140,995) in all attendees. Of those NHS Health Check attendees at high CVD risk 19.3% (5325/27,624) were prescribed recurrent statins and 8.8% (2438/27,624) were prescribed recurrent antihypertensive therapy.

Referrals to behavioural support

Table 6 shows referrals for behavioural interventions in people at high CVD risk. Using data from Tables 3 and 4 it can be shown that most referrals took place in people at lower CVD risk (<20% over 10 years). Of those people with behaviourally mediated risk factors recorded - smoking, obesity and high alcohol consumption - who were referred for further support during an NHS Health Check, 80.0% were not in the high CVD risk group. Of the smoking cessation referrals made in smokers, 17.1% (439/2571) were in smokers at high CVD risk

and 82.9% were in people at lower risk. Of the dietary referrals made in people with BMI ≥30 kg/m^2, 13.6% (1691/12,430) were in people at high CVD risk and 86.4% were in people at lower risk. Similarly of the referrals for physical activity, 13.4% (1780/13,309) were in people at high CVD risk and 86.6% were in people at lower risk. Of the total referrals for alcohol reduction support for heavy or very heavy drinkers 16.5% (300/1823) were in people at high CVD risk and 83.5% were in people at lower risk.

5.7% (1139/7743) of smokers at high CVD risk were referred to accredited level 2 or 3 smoking cessation services. In people at high CVD risk with BMI ≥30kg/m^2, 40.0% (1691/4222) were referred to dietary and 42.2% (1780/4222) to physical activity support services and 33.1% (300/905) of those at high CVD risk recorded as drinking 7 or more units of alcohol per day were referred to alcohol reduction services.

These proportions of people at high CVD risk referred to smoking cessation, dietary, physical activity and alcohol services were very similar to the proportions of all attendees (Tables 3 and 4) who were referred, of whom 6.8% (2571/37,808) of smokers were referred to smoking cessation, 38.7% (12,430/32,133) of BMI ≥30 to dietary and 41.4% (13,309/32,133) of BMI ≥30 to physical activity support services, and 35.7% (1823/5101) of heavy drinkers were referred to alcohol reduction services.

Discussion

This is the first study to describe national results from the NHS Health Check programme. In 2012, the most recent year reported, 30.1% of the eligible population attended. Attendance was more likely over age 65 years,19.6% than in those under 65 years 9.0% and among those people in the most deprived quintile 14.9% versus the least deprived 12.3%. 12.9% of all attendees were recorded at high CVD risk (20% or more 10 year risk). There were differences in attendance between ethnic groups, though these could be due to missing data. Attendance in white people was similar to those with non-white ethnic group recorded.

New co-morbidity identified in the 4 year period included 7844 new cases of hypertension (1 case per 27 NHS Health Checks), 1934 new cases of diabetes (1 new case for every 110 Checks) and 807 new cases of CKD (1 new case in every 265 Checks). Records of risk factors were more incomplete in non-attendees who had a different CVD risk profile to those

who attended. Non-attendees were younger and more likely to be smokers than attendees. Because of differences in the characteristics and recording of risk factors between attendees and non-attendees we have not made formal statistical comparisons of new morbidity between these groups.

In addition to those people with new co-morbidities diagnosed, risk factors such as raised blood pressure, raised blood sugar and obesity requiring further follow-up were recorded in more than 1 in 5 of attendees. Most referrals for behavioural interventions took place in people at lower CVD risk. Of those people with behaviourally mediated risk factors recorded - smoking, obesity and alcohol consumption - who were referred for further support during an NHS Health Check, 80% were not in the high CVD risk group. The proportion of people in the high CVD risk group referred because of risk factors was similar to the proportion referred among all attendees.

1 in 20 attendances resulted in recurrent statin prescription and 1 in 25 attendances resulted in recurrent antihypertensive prescription. Of those NHS Health Check attendees at high CVD risk, 19.3% were prescribed recurrent statins and 8.8% were prescribed recurrent antihypertensive therapy.

This is a large and nationally representative study including records of social deprivation and ethnicity. Coverage of 30% was lower than expected, though attendance quadrupled during the course of the study reflecting the early phase of implementation. There was no evidence that older people, or those in the more deprived quintile were less likely to attend than other groups. South Asians who have higher CVD risks were more likely to attend than other ethnic groups. Though missing data might account for this, similar differences have been found in other studies.[25] Currently attendance at NHS Health Checks is reported as uptake in response to invitation rather than coverage, defined as attendance as a proportion of the eligible population as reported in this paper.[4]

The NHS Health Check programme is an example of systematic implementation at national scale, of a stratified approach to advice and effective treatment in people at increased CVD risk. QRisk2 was used in 80% of NHS Checks reported in this study and is fully integrated with the EMIS computer systems used by general practitioners in this study and has since been recommended as the risk algorithm of choice in the 2014 NICE guidance;[26] an example

of successful translation of clinical decision support at scale.[27 28] This algorithm is fully integrated with the electronic primary care record, a key enabling factor for implementation.[29]

Limitations of the study

There is no nationally available data on the extent of provision of the NHS Health Check outside of general practices. However, these were likely to represent less than 10% of NHS Health Checks undertaken, as in most PCTs the NHS Health Check was conducted almost entirely in general practice with limited use of community programmes targeting hard-to-reach groups or, with the exception of a few areas, community pharmacies. Completeness of NHS Health Checks was not ascertained, but taking measurement of cholesterol recording of 91.5% as a proxy measure, risk ascertainment was generally well conducted.

Of the people referred with behavioural risk factors, 80% were at lower CVD risk, which indicates the wide distribution of risk factors and the potential for behaviour change if programmes can be shown to be effective. Like other recent studies, referral rates were generally low[30] and little is known about attendance at, or quality of behavioural programmes even for those at higher CVD risk. Lack of consistent coding of referrals in earlier years of the NHS Health Check programme and the availability of local services for behavioural change may have contributed to low referral rates. The impact of the NHS Health Check programme on people at lower risk is unknown and further research is required.[31]

The study is descriptive and was not designed to determine variability between practices or CCGs. The study has not assessed changes in risk factors or cardiovascular events between comparable groups. These comparisons are difficult in a non-randomised study especially if one group is at higher risk than the other or information is incomplete. For these reasons we have not directly compared attendees with non-attendees. Communication of results and patient behaviours following NHS Health Checks remains an under researched area.[32-34]

Implications for practice

A number of local studies suggest that the programme has been better implemented in some areas with coverage of 80% and statin prescription of up to 50% in high risk individuals in some CCGs.[25 35] Nationally uptake in 2011-12 was reported as 45%, with high levels of

variability and better uptake in more deprived areas.[6 5] There is limited evidence of effectiveness[35] or comorbidities identified[36] and statin uptake in those at high risk was reported to be between 20-50%[5 25] which accords with national surveys of 32%.[37]

Despite a statin treatment rate of only 19% in high risk attendees in this study, this is likely to have had an important impact on CVD events in those treated. Assuming that 1.2 million people attended a NHS Check each year in the five years since 2010, of whom 10% (120,000) were at high CVD risk averaging 2.5% per year, and 19.3% (23,160) of these people were treated with statins over this period and 8.8% (10,560) were treated with antihypertensives; if each treatment reduces cardiovascular risk by 20%, it is estimated that 2529 people would avoid a major CVD event over a five year period.[11 12] Higher uptake in more recent years and additional treatment in people at both high CVD risk and at lower CVD risk make this a conservative estimate and behavioural change will have further impact.[37] These estimates assume that patients who are prescribed medications take them for a five year period and that the impact on outcomes is similar to that described in the trial meta-analyses cited.

The NHS Health Check programme has had a difficult birth. The efficacy of the programme has been challenged,[38-41] based largely on a review of 16 trials of health checks, of which 12 trials were undertaken more than 20 years ago before 1994[42-52], the year in which the landmark 4S trial established statin effectiveness.[53] This means that 12 out of 16 of the reported studies were conducted before statins or modern anti-hypertensive drugs were used. Of the trials since 1994 only one[52] specifically recommended drug treatment for CVD risk, the other three offering advice but no drug treatment.[54-56] The results of the Inter99 study of intensive lifestyle counselling published subsequent to this review[57] showed no reduction in CVD. Despite high quality review of trial evidence showing net benefit[11], statins have continued to received considerable adverse publicity[58 59] which has been refuted.[60]

There have also been organisational factors that have impacted on implementation of the programme. Major organisational change in the NHS in the context of financial austerity[61 62] led to one third of staff leaving many PCTs in the transition to CCGs in April 2013[63] and commissioning responsibility for NHS Checks passed to Local Authorities. It is perhaps not surprising that in 2013, 27/151 PCTs nationally offered NHS Health Checks to fewer than 10% of eligible individuals and uptake could be substantially improved.[64] The most efficient means to deliver this programme including delivery through pharmacies and likely economic

impact, remain subjects for further research and debate. A range of infrastructural issues and new research are currently being addressed by Public Health England.[65 66]

This study indicates limited though improving success in the early years of a major new national preventive programme. Coverage of 30% and statin treatment of 19% of attendees at high CVD risk leave considerable room for improvement. New co-morbidity and abnormal risk factors were frequently identified in people who attended an NHS Health Check. The majority of referrals for abnormal risk factors were amongst people at lower CVD risk. This modest start to a major new programme at scale is likely to have made an important impact on CVD events in people who have been treated with statins and anti-hypertensives or who improved adverse risk factors.

Authors' contributions

John Robson initiated the study and has contributed to its design and implementation. Julia Hippisley-Cox contributed to the research question, design, data extraction, data analysis, interpretation and comments on the manuscript. Carol Coupland advised on the statistical analysis and interpretation. Isabel Dostal conducted a preliminary investigation in one CCG that informed the study design, preparation of the codesets and study specification. Sandra Eldridge and Vichithranie Madurasinghe supported the statistical analysis and interpretation and all authors including Chris Griffiths and Aziz Sheikh contributed to the study design and all authors contributed to the manuscript.

The views expressed in this publication are those of the authors and do not necessarily represent those of those of the Department of Health or institutions that fund or support the authors.

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Ethical approval

The Trent Research Ethics committee has approved use of the QResearch database for anonymised use of primary care data.

Competing interests

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that (1) JR, JHC, CC and AS are authors of QRisk, one of the CVD Scores widely used in the NHS Health Check programme. JR was Chair of a National Institute for Health and Care Excellence Guideline that recommended systematic use of CVD scores in 2008. JHC is also director of ClinRisk Ltd which produces open and closed source software to ensure the reliable and updatable implementation of clinical risk algorithms (including QRISK) within clinical computer systems to help improve patient care. CC is an associate professor of Medical Statistics at the University of Nottingham and a consultant statistician for ClinRisk Ltd. Neither JHC nor CC received fees from these sources for this work. The NIHR grant which funded this project provided funds to SE, JR,ID, JHC and CC for their contribution to the study. CG and the other authors have no additional relationships with that might have an interest in the submitted work in the previous 3 years; (3) authors spouses, partners, or children have no financial relationships that may be relevant to the submitted work; and (4) the authors have no non-financial interests that may be relevant to the submitted work.

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Table 1

Coverage of NHS Health Check programme in each year

Financial years	Patients with health check in financial year	20% of the eligible population on 1st April	% Coverage Attendance/one-fifth of eligible population
2009/10	16,613	286,035	**5.8%**
2010/11	41,832	286,383	**14.6%**
2011/12	69,978	286,669	**24.4%**
2012/13	86,042	285,784	**30.1%**

Table 2

Characteristics of people aged 40-74 years eligible for an NHS Health Check between April 2009 and March 2013 and those who attended

	Total eligible people	NHS Health Check attendees	% total eligible population with NHS Health Check
Total	**1,679,024**	**214,295**	**12.8%**
Female	846,797	111,740	**13.2%**
Male	832,227	102,555	**12.3%**
Age band (years)			
40-49	806,199	72,903	**9.0%**
50-59	499,725	68,428	**13.7%**
60-74	373,100	72,964	**19.6%**
Townsend quintile of deprivation			
1 (most affluent)	336,174	41,423	**12.3%**
2	334,996	40,342	**12.0%**
3	335,706	40,897	**12.2%**
4	335,302	41,557	**12.4%**
5 (most deprived)	334,652	49,974	**14.9%**
Townsend not recorded	2,194	102	**4.7%**
Ethnicity			
White	1,065,171	185,082	**17.4%**
Indian	16,842	2,987	**17.7%**
Pakistani	8,472	1,362	**16.1%**
Bangladeshi	4,925	1,460	**29.6%**
Other Asian	13,471	1,966	**14.6%**
Caribbean	12,908	2,531	**19.6%**
Black African	19,899	3,128	**15.7%**
Chinese	6,913	1,059	**15.3%**
Other	26,045	4,059	**15.6%**
Not recorded	504,378	10,661	**2.1%**

Table 3

Characteristics of eligible people who did and did not attend for an NHS Health Check

Recorded prior to or on the date of the NHS Health Check or relevant index date

	NHS Health Check No. (%)	No NHS Health Check No. (%)
Total	**214,295**	**1,464,729**
Smoking status recorded	214,020 (99.9)	1,384,707 (94.5)
Non smoker	117,968 (55.1)	768,276 (55.5)
Ex-smoker	58,244 (27.2)	306,397 (22.1)
Light smoker (1-9/day)	19,589 (9.2)	167,592 (12.1)
Moderate smoker (10-19/day)	11,052 (5.2)	83,585 (6.0)
Heavy smoker (20+/day)	7167 (3.3)	58,857 (4.3)
Alcohol intake		
Alcohol status recorded	205,506 (95.9)	1,175,900 (80.3)
Non drinker	53,485 (26.0)	292,289 (24.9)
Trivial <1 units/day	66,780 (32.5)	421,139 (35.8)
Light 1-2 units/day	37,398 (18.2)	205,572 (17.5)
Moderate 3-6 units/day	42,467 (20.7)	227,987 (19.4)
Heavy 7-9 units/day	3235 (1.6)	17,169 (1.5)
Very Heavy >9 units/day	1866 (0.9)	8842 (0.8)
Drinker - amount not recorded	275 (0.1)	2902 (0.2)
Risk factor recording		
Body mass index recorded	210,062 (98.0)	1,176,819 (80.3)
Systolic blood pressure recorded	213,690 (99.7)	1,316,926 (89.9)
Cholesterol recorded	195,994 (91.5)	633,548 (43.3)
Cholesterol/HDL recorded	174,345 (81.4)	433,594 (29.6)
Positive family history CHD	46,466 (21.7)	156,604 (10.7)
Mean body mass index (SD)	27.1 (4.5)	26.4 (4.6)
Mean cholesterol (SD)	5.5 (1.0)	5.4 (1.0)
Mean cholesterol/HDL (SD)	4 (1.3)	4 (1.2)
Mean SBP (SD)	130.8 (16.9)	128.4 (15.6)
Mean DBP (SD)	79.4 (10.0)	78.6 (9.4)
QRisk2 recorded	171,441 (80.0)	424,523 (29.0)
QRisk2 not recorded	42,854 (20.0)	1,040,206 (71.0)
QRisk2 score		
<5%	47,794 (22.3)	195,253 (13.3)
5-9.99	43,687 (20.4)	114,706 (7.8)
10-14.99	32,452 (15.1)	55,306 (3.8)
15-19.99	22,639 (10.6)	31,356 (2.1)
20+	24,869 (11.6)	27,902 (1.9)
Framingham score recorded	33,260 (15.5)	76,051 (5.2)

not recorded	181,035 (84.5)	1,388,679 (94.8)
Framingham score		
<5%	7152 (3.3)	20,532 (1.4)
5-9.99	10,196 (4.8)	25,898 (1.8)
10-14.99	6896 (3.2)	15,286 (1.0)
15-19.99	4283 (2.0)	7787 (0.5)
20+	4733 (2.2)	6547 (0.4)
20+ QRisk2 or Framingham	**27,624 (12.9)**	**32,481 (2.2)**

Table 4

Outcomes for people who did and did not have an NHS Health Check (number, %)

Recorded at NHS Health Check, relevant index date or in 12 months following these dates

	NHS Health Check No. (%)	No NHS Health Check No. (%)
Total patients	**214,295**	**1,464,729**
New diagnoses		
Chronic kidney disease (eGFR <60ml/min/)	807 (0.4)	2310 (0.2)
Type 2 diabetes	1934 (0.9)	5647 (0.4)
Hypertension	7844 (3.7)	16,184 (1.1)
Risk factor recording		
Body mass index recorded	151,480 (70.7)	144,756 (9.9)
Positive family history of premature CHD recorded	14,760 (6.9)	4720 (0.3)
Blood pressure recorded	140,995 (65.8)	242,928 (16.6)
eGFR recorded	59,021 (27.5)	160,843 (11.0)
Fasting glucose	35,801 (16.7)	78,934 (5.4)
Random glucose	64,439 (30.1)	102,568 (7.0)
Total cholesterol recorded	123,342 (57.6)	137,207 (9.4)
Cholesterol/HDL ratio recorded	118,930 (55.5)	115,011 (7.9)
Smoking status recorded	188,282 (87.9)	410,301 (28.0)
Risk factors identified (as % recorded)		
Fasting glucose≥7mmol/L	954 (2.7)	2983 (3.7)
Random glucose≥ 11mmol/L	421 (0.6)	1291 (1.3)
Raised BP SBP ≥ 140mmHg or DBP ≥ 90mmHg	26,126 (18.5)	52,236 (21.5)
Obesity BMI≥ 30 kg/m^2	32,133 (21.2)	39,774 (27.5)
New referrals (as % recorded)		
Current smokers referred to smoking cessation clinic	2571 (6.8)	9944 (3.2)
Weight referrals: BMI ≥ 30 kg/m^2	12,430 (38.7)	4441 (11.2)
Exercise referrals: BMI ≥ 30 kg/m^2	13,309 (41.4)	4082 (10.3)
Alcohol referrals: > 6 units/day	1823 (33.9)	1459 (5.1)
New medication		
2+ prescriptions for statins	10,900 (5.1)	15,086 (1.0)
2+ prescriptions for anti-hypertensives	8457 (3.9)	26,178 (1.8)

Table 5

Characteristics of people at high CVD risk who attended an NHS Health Check 1 April 2009 to 31 March 2013

Recorded at or prior to the date of the NHS Health Check

	NHS Health Check risk ≥20% No. (%)
Total patients all CVD risks	**214,295**
Total with CVD risk ≥20%	**27,624**
Females	5992 (21.7)
Males	21632 (78.3)
Age band (years)	
40-49	778 (2.8)
50-59	4475 (16.2)
60-74	22,371 (81.0)
Townsend quintile	
1 (most affluent)	5135 (18.6)
2	5356 (19.4)
3	5301 (19.2)
4	5284 (19.1)
5 (most deprived)	6539 (23.7)
Ethnicity	
Ethnicity recorded	26,392 (95.5)
White	25,037 (90.6)
Indian	376 (1.4)
Pakistani	264 (1.0)
Bangladeshi	276 (1.0)
Other Asian	135 (0.5)
Caribbean	89 (0.3)
Black African	27 (0.1)
Chinese	17 (0.1)
Other	171 (0.6)
Not recorded	1232 (4.5)
Smoking status recorded	27,611 (100.0)
Non smoker	10,517 (38.1)
Ex-smoker	9351 (33.9)
Light smoker (1-9/day)	4024 (14.6)
Moderate smoker (10-19/day)	2199 (8.0)
Heavy smoker (20+/day)	1520 (5.5)
Alcohol intake prior to or at NHS Health Check	
Alcohol status recorded	26,765 (96.9)

Non drinker	6897	(25.0)
Trivial <1 units/day	7919	(28.7)
Light 1-2 units/day	4684	(17.0)
Moderate 3-6 units/day	6322	(22.9)
Heavy 7-9 units/day	601	(2.2)
Very Heavy >9 units/day	304	(1.1)
Drinker: amount not recorded	38	(0.1)
Risk factor recording prior to or at NHS Health Check		
Body Mass Index recorded	27,243	(98.6)
Systolic blood pressure recorded	27,600	(99.9)
Cholesterol recorded	26,241	(95.0)
Positive family history of premature CHD	9503	(34.4)
Mean body mass index (SD)	27.6	(4.2)

Table 6

Outcome of NHS Check for people at high CVD risk (10 year risk ≥20%)

Recorded at NHS Health Check or in 12 months following this date

	NHS Health Check risk ≥20% No. (%)	
Total CVD risk ≥20%	**27,624**	
New diagnoses		
CKD (wider definition)	235	(0.9)
Type 2 diabetes	489	(1.8)
Hypertension	2195	(7.9)
Cardiovascular disease	337	(1.2)
Coronary heart disease	206	(0.7)
Stroke	140	(0.5)
Risk factors identified		
Fasting glucose ≥7	256	(0.9)
Random glucose≥ 11	84	(0.3)
Raised BP SBP≥ 140 or DBP ≥ 90	4772	(17.3)
Obesity BMI≥ 30	4222	(15.3)
New referrals		
Smokers referred to smoking cessation clinic	439	(1.6)
Weight referrals in patients with BMI ≥30	1691	(6.1)
Physical activity referrals in patients with BMI ≥30	1780	(6.4)
Alcohol referrals in patients drinking > 6u/day	300	(1.1)
New medication		
2+ prescriptions for statins	5325	(19.3)
2+ prescriptions for antihypertensives	2438	(8.8)
Risk factor recording		
Body mass index recorded	18,203	(65.9)
Positive Family history CHD recorded	2660	(9.6)
Blood pressure recorded	15,905	(57.6)
eGFR recorded	8229	(29.8)
Fasting glucose	5694	(20.6)
Random glucose	8392	(30.4)
Total cholesterol recorded	14,876	(53.9)
Cholesterol/HDL ratio recorded	14,974	(54.2)

Figure 1

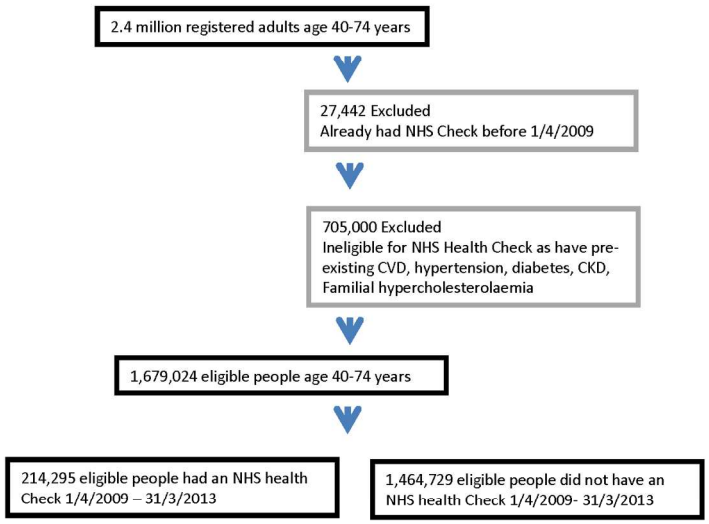

Figure 1
215x279mm (200 x 200 DPI)

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

Title **The NHS Health Check in England: an evaluation of the first four years.**

	Item No	Recommendation	Pg #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	3-4
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4-5
Bias	9	Describe any efforts to address potential sources of bias	5-6
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4-6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	5-6
		(*b*) Describe any methods used to examine subgroups and interactions	5-6
		(*c*) Explain how missing data were addressed	5-6
		(*d*) If applicable, explain how loss to follow-up was addressed	5-6
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6 & 22
		(b) Give reasons for non-participation at each stage	6 & 22
		(c) Consider use of a flow diagram	22
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6 Tables 1,2
		(b) Indicate number of participants with missing data for each	ditto

		variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	Report numbers of outcome events or summary measures over time	6-9, Tables 3-5
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6-9 Tables 3-5
		(*b*) Report category boundaries when continuous variables were categorized	5
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	9-10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10-11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	11-12
Generalisability	21	Discuss the generalisability (external validity) of the study results	11-12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.