

PRIORITY BRIEFING

The purpose of this briefing paper is to aid Stakeholders in prioritising topics to be taken further by PenCLAHRC as the basis for a specific evaluation or implementation project.

QUESTION DETAILS

Question ID: 1

Question type: Intervention

Question: Does the Health Compass Healthy Lifestyle programme promote changes in lifestyle behaviour, in people with obesity who have either (a) greater than 20% risk of cardiovascular disease or (b) impaired glucose regulation, identified through the NHS Health Check initiative?

Population: Adults with obesity aged 40-74 years identified through the NHS Health Check initiative as having a greater than 20% risk of cardiovascular disease or who have impaired glucose tolerance or impaired fasting glycaemia.

Intervention: The Health Compass Healthy Lifestyle programme. This is a moderate-intensity intervention programme which involves a range of established techniques for supporting and maintaining behaviour change and is delivered in a group setting.

The intervention has been developed through evidence based recommendations from a systematic review of reviews conducted by PMS researchers and builds on a psychological process model (Health Action Process Approach) for behaviour change and specific techniques from the Australian Green Triangle Diabetes Prevention Programme. The proposed local approach includes additional techniques based on the systematic review recommendations and material from the 'Health Compass' health promotion book.

Control: Usual care and an information leaflet.

Outcome: Changes in weight, waist circumference, blood pressure, blood based indicators of cardiovascular risk (e.g. lipids, HbA1c) physical activity levels and overall cardiovascular risk.

Note on the Health Compass Healthy Lifestyle programme:

The Health Compass Healthy Lifestyle programme has not yet been implemented anywhere in the UK, although it is based on programmes that have been successfully trialled in Australia and in Finland and has been designed in collaboration with the NHS. Devon PCT has shown interest in piloting the proposed intervention. Training materials for delivery of the programme have been developed by PCMD primary care researchers as part of the IMAGE diabetes prevention project.

Part 1: Research Background

Guidelines: NICE guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children published in 2006 concludes that multi-component interventions should be preferred for the treatment and prevention of obesity.

Research Summary: There have been no previous evaluations of the Health Compass Healthy Lifestyle programme. Our limited literature searching was unable to identify any published systematic reviews of moderate intensity weight loss and physical activity interventions in obese patients with a greater than 20% increase in cardiovascular risk or impaired glucose tolerance.

To help inform the use of diet and activity related interventions in reducing cardiovascular risk a brief search for systematic reviews was conducted. One recent systematic review on the use of dietary interventions in reducing cardiovascular risk⁶ reported some evidence of greater effectiveness in people told that they were at risk of heart disease or cancer. Modest improvements were also shown in blood pressure and total and LD (low density) -cholesterol levels. However, the trials did not have a long enough follow up period to be able to determine if the beneficial changes in cardiovascular risk factors resulted in a reduced incidence of heart disease, stroke, or heart attack. One recent review on the use of physical activity interventions⁷ supported the use of exercise as a weight loss intervention, particularly when combined with dietary change. Exercise is associated with improved cardiovascular disease risk factors even if no weight is lost.

However, the Health Compass Healthy Lifestyle programme has been in-part informed by similar intervention programmes successfully trialled by researchers in Finland and in Australia. The Finnish Diabetes Prevention Study utilised a relatively high intensity lifestyle intervention programme in overweight men and women (n=522) with impaired glucose tolerance, who were randomised to receive the active intervention or control (general written and verbal health advice) for a median of four years with further follow-up for a median of three years. In the seven year follow-up period there was a reduction in the relative risk of incidence of type II diabetes of 43%.¹ The risk reduction was related to the success in achieving the intervention goals of weight loss, reduced intake of total and saturated fat and increased intake of dietary fibre and increased physical activity. Similar results were seen in two further randomised trials of intensive interventions.^{2,3}

There have been several attempts to replicate the results of these high intensity interventions with lower intensity group counselling delivered in a more pragmatic primary care setting e.g. the GOAL intervention study in Finland⁴ and the Greater Green Triangle Diabetes Prevention Project in Australia.⁵ Results of these trials

suggest that lifestyle interventions that involve group counselling in a primary care setting can also produce noticeable reductions in weight, waist circumference, mean fasting glucose, plasma glucose two hours after oral glucose challenge, total cholesterol, low density lipoprotein cholesterol, triglycerides and diastolic blood pressure. Significant improvements were also found in most psychological measures.

There appear to be relatively few examples of the use of moderate intensity (and therefore relatively low cost) lifestyle intervention programmes aimed at more generally reducing the risk of cardiovascular disease.

Ongoing Research:

The US National Heart, Lung, and Blood Institute is conducting a study, due to complete 2011, investigating the effects of worksite wellness interventions on vascular function, insulin sensitivity and high-density lipoprotein in overweight or obese women. The primary outcome measures will be endothelial function determined by brachial artery reactivity to stress, at baseline/following 6m program participation comparison of change between subjects randomised to exercise with weight-loss intervention vs. those randomized to exercise.

Part 2: Prioritisation Information

1. The health problem

Epidemiology:

The World Health Organisation (WHO) defines cardiovascular diseases (CVD) as including coronary heart disease (heart attacks), cerebrovascular disease, raised blood pressure (hypertension), peripheral artery disease, rheumatic heart disease, congenital heart disease and heart failure. The major causes of cardiovascular disease are tobacco use, physical inactivity, and an unhealthy diet.

Globally, the WHO reports that cardiovascular disease is the number one cause of death and is projected to remain so. An estimated 17.5 million people died from cardiovascular disease in 2005, representing 30% of all global deaths. Of these, 7.6 million were due to heart attacks and 5.7 million due to stroke. About 80% of deaths occurred in low- and middle-income countries. If current trends are allowed to continue, by 2015 an estimated 20 million people will die from cardiovascular disease.

CVD remains a leading UK public health problem associated with substantial premature mortality, morbidity and financial cost. In 2004, CVD caused 37% of UK deaths (over 216,000 people) and cost the economy £29 billion. Health care represents 60% of CVD costs, followed by productivity losses (23%) and informal care-related costs (17%). There is a wealth of additional epidemiological evidence on the strong links between weight and physical activity and cardiovascular morbidity /mortality. NICE therefore recommends behavioural interventions, which address both diet and physical activity for all adults with obesity.

Locally, in Devon PCT approximately 36% of all deaths in 2006 resulted from circulatory diseases (Public Health Annual Report, 2007/08). Results from a study 2008⁸ suggest that the prevalence of adults aged 35-74 years with a cardiovascular risk score of more than or equal to 20% is 4.9% and those with Impaired Glucose Regulation (IGR) account for 10-15%⁹ most of whom may benefit from a diet and/or physical activity programme. Therefore, in Devon, which has approximately 326,000 people aged 40-74 (who are also eligible for NHS Health Checks), there may be expected to be 16,000 with high CV risk and at least 32,600 with IGR. The estimated total people eligible for this study might therefore be in the region of 40,000 (which is 12% of those screened and 5.5% of the total Devon population).

A total of 22.8% of adults are classified as obese, only slightly below the national average of 23.6%. Cornwall, Gloucestershire, Plymouth, South Gloucestershire and Swindon have adult obesity levels above the national average.

2. Identification of the topic as a priority:

NICE guidelines on obesity recommend further research, particularly from randomised clinical trials, into effective programmes to prevent or manage obesity in children and adults. There is also interest in the cost effectiveness of those interventions, the elements of an intervention that determine effectiveness and sustainability and the level of training needed to deliver an intervention.

NICE also recommends that managers and health professionals in all primary care settings should ensure that preventing and managing obesity is a priority at both strategic and delivery levels with dedicated resources allocated for action.

Devon PCTs new Healthy Weight Strategy seeks to address this by supporting patients who may benefit, to access referral to a scheme which helps them to become more physically active and providing effective services to people who are already overweight and obese to help them to reduce their Body Mass Index (BMI) and maintain a healthy weight. This is in line with the national NHS strategy to offer personalised advice and support and complementing preventative care with treatment for those who already have weight problems.

The Department of Health's Impact Assessment of the likely benefits from NHS Health Checks predicts a saving across England of £55billion over the next 20 years, but this assumes that the treatments offered in practice, including lifestyle interventions, will be as effective as the research interventions used for the cost-modelling. If this can be achieved, the prize in terms of preventing a large amount of the projected future burden of cardiovascular disease (for both patients and NHS services) is of great value.

SW SHA Priorities framework 2008-11

- Reduce mortality rates from heart disease and stroke and related diseases in people aged under 75 to 65 per 100,000 European standardized population by 2013.
- Improving clinical effectiveness, safety and the user experience
- Ensure that all people with a long-term condition have a personalized care plan that supports their self-management by 31 March 2010.

3. Local perspective

Tractability:

A trial of the Health Compass Programme may be complex and require considerable resources, although local levels of experience and support are high (in both the NHS and PCMD/University).

An overview of the local context:

Lots of local expertise and support for this topic. A significant amount of work has already gone into developing ideas for funding. The NHS Health Check initiative will aim to systematically screen all adults between the ages of 40 and 74 for cardiovascular risk. Devon PCT has been chosen as a pilot site for NHS Health Check with screening due to start in 2009.

References

(1) Lindström J, Ilanne-Parikka P, Peltonen M et al. Sustained reduction in the incidence of type 2 diabetes by lifestyle intervention: follow-up of the Finnish Diabetes Prevention Study. *Lancet*. 2006; 368(9548):1673-9.

BACKGROUND: Lifestyle interventions can prevent the deterioration of impaired glucose tolerance to manifest type 2 diabetes, at least as long as the intervention continues. In the extended follow-up of the Finnish Diabetes Prevention Study, we assessed the extent to which the originally-achieved lifestyle changes and risk reduction remain after discontinuation of active counselling. **METHODS:** Overweight, middle-aged men (n=172) and women (n=350) with impaired glucose tolerance were randomly assigned to intensive lifestyle intervention or control group. After a median of 4 years of active intervention period, participants who were still free of diabetes were further followed up for a median of 3 years, with median total follow-up of 7 years. Diabetes incidence, bodyweight, physical activity, and dietary intakes of fat, saturated fat, and fibre were measured. **FINDINGS:** During the total follow-up, the incidence of type 2 diabetes was 4.3 and 7.4 per 100 person-years in the intervention and control group, respectively (log-rank test $p=0.0001$), indicating 43% reduction in relative risk. The risk reduction was related to the success in achieving the intervention goals of weight loss, reduced intake of total and saturated fat and increased intake of dietary fibre, and increased physical activity. Beneficial lifestyle changes achieved by participants in the intervention group were maintained after the discontinuation of the intervention, and the corresponding incidence rates during the post-intervention follow-up were 4.6 and 7.2 ($p=0.0401$), indicating 36% reduction in relative risk. **INTERPRETATION:** Lifestyle intervention in people at high risk for type 2 diabetes resulted in sustained lifestyle changes and a reduction in diabetes incidence, which remained after the individual lifestyle counselling was stopped.

(2) Pan XR, Li GW, Hu YH et al. Effects of diet and exercise in preventing NIDDM in people with impaired glucose tolerance. The Da Qing IGT and Diabetes Study. *Diabetes Care* 1997; 20(4):537-44.

OBJECTIVE: Individuals with impaired glucose tolerance (IGT) have a high risk of developing NIDDM. The purpose of this study was to determine whether diet and exercise interventions in those with IGT may delay the development of NIDDM, i.e., reduce the incidence of NIDDM, and thereby reduce the overall incidence of diabetic complications, such as cardiovascular, renal, and retinal disease, and the excess mortality attributable to these complications.

RESEARCH DESIGN AND METHODS: In 1986, 110,660 men and women from 33 health care clinics in the city of Da Qing, China, were screened for IGT and NIDDM. Of these individuals, 577 were classified (using World Health Organization criteria) as having IGT. Subjects were randomized by clinic into a clinical trial, either to a control group or to one of three active treatment groups: diet only, exercise only, or diet plus exercise. Follow-up evaluation examinations were conducted at 2-year intervals over a 6-year period to identify subjects who

developed NIDDM. Cox's proportional hazard analysis was used to determine if the incidence of NIDDM varied by treatment assignment. RESULTS: The cumulative incidence of diabetes at 6 years was 67.7% (95% CI, 59.8-75.2) in the control group compared with 43.8% (95% CI, 35.5-52.3) in the diet group, 41.1% (95% CI, 33.4-49.4) in the exercise group, and 46.0% (95% CI, 37.3-54.7) in the diet-plus-exercise group ($P < 0.05$). When analyzed by clinic, each of the active intervention groups differed significantly from the control clinics ($P < 0.05$). The relative decrease in rate of development of diabetes in the active treatment groups was similar when subjects were stratified as lean or overweight (BMI $<$ or $>$ or $= 25$ kg/m²). In a proportional hazards analysis adjusted for differences in baseline BMI and fasting glucose, the diet, exercise, and diet-plus-exercise interventions were associated with 31% ($P < 0.03$), 46% ($P < 0.0005$), and 42% ($P < 0.005$) reductions in risk of developing diabetes, respectively. CONCLUSIONS: Diet and/or exercise interventions led to a significant decrease in the incidence of diabetes over a 6-year period among those with IGT.

(3). Knowler WC, Barrett-Connor E, Fowler SE et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med.* 2002; 346(6):393-403

BACKGROUND: Type 2 diabetes affects approximately 8 percent of adults in the United States. Some risk factors--elevated plasma glucose concentrations in the fasting state and after an oral glucose load, overweight, and a sedentary lifestyle--are potentially reversible. We hypothesized that modifying these factors with a lifestyle-intervention program or the administration of metformin would prevent or delay the development of diabetes. METHODS: We randomly assigned 3234 nondiabetic persons with elevated fasting and post-load plasma glucose concentrations to placebo, metformin (850 mg twice daily), or a lifestyle-modification program with the goals of at least a 7 percent weight loss and at least 150 minutes of physical activity per week. The mean age of the participants was 51 years, and the mean body-mass index (the weight in kilograms divided by the square of the height in meters) was 34.0; 68 percent were women, and 45 percent were members of minority groups. RESULTS: The average follow-up was 2.8 years. The incidence of diabetes was 11.0, 7.8, and 4.8 cases per 100 person-years in the placebo, metformin, and lifestyle groups, respectively. The lifestyle intervention reduced the incidence by 58 percent (95 percent confidence interval, 48 to 66 percent) and metformin by 31 percent (95 percent confidence interval, 17 to 43 percent), as compared with placebo; the lifestyle intervention was significantly more effective than metformin. To prevent one case of diabetes during a period of three years, 6.9 persons would have to participate in the lifestyle-intervention program, and 13.9 would have to receive metformin. CONCLUSIONS: Lifestyle changes and treatment with metformin both reduced the incidence of diabetes in persons at high risk. The lifestyle intervention was more effective than metformin.

(4) Uutela A, Absetz P, Nissinen A et al. Health psychological theory in promoting population health in Päijät-Häme, Finland: first steps toward a type 2 diabetes prevention study. *J Health Psychol.* 2004 Jan;9(1):73-84.

In public health promotion, behavioural science theories and theory-based methods should be translated into practical strategies that fit environmental conditions and are feasible for implementation. In this article, an effort to meet this challenge is presented. As a starting point we describe the conditions for development and success of the previous generation of public health promotion programmes in Finland. However, changes both in the population structure and in the population health bring new demands for programme development. We consider possibilities offered by health psychology and give a practical example of how theories and theory-based methods are applied in a community programme for type 2 diabetes prevention implemented in the Finnish primary health care.

(5) Laatikainen T, Dunbar JA, Chapman A et al. Prevention of type 2 diabetes by lifestyle intervention in an Australian primary health care setting: Greater Green Triangle (GGT) Diabetes Prevention Project *BMC Public Health.* 2007;7:249..

BACKGROUND: Randomised controlled trials demonstrate a 60% reduction in type 2 diabetes incidence through lifestyle modification programmes. The aim of this study is to determine whether such programmes are feasible in primary health care. **METHODS:** An intervention study including 237 individuals 40-75 years of age with moderate or high risk of developing type 2 diabetes. A structured group programme with six 90 minute sessions delivered during an eight month period by trained nurses in Australian primary health care in 2004-2006. Main outcome measures taken at baseline, three, and 12 months included weight, height, waist circumference, fasting plasma glucose and lipids, plasma glucose two hours after oral glucose challenge, blood pressure, measures of psychological distress and general health outcomes. To test differences between baseline and follow-up, paired t-tests and Wilcoxon rank sum tests were performed. **RESULTS:** At twelve months participants' mean weight reduced by 2.52 kg (95% confidence interval 1.85 to 3.19) and waist circumference by 4.17 cm (3.48 to 4.87). Mean fasting glucose reduced by 0.14 mmol/l (0.07 to 0.20), plasma glucose two hours after oral glucose challenge by 0.58 mmol/l (0.36 to 0.79), total cholesterol by 0.29 mmol/l (0.18 to 0.40), low density lipoprotein cholesterol by 0.25 mmol/l (0.16 to 0.34), triglycerides by 0.15 mmol/l (0.05 to 0.24) and diastolic blood pressure by 2.14 mmHg (0.94 to 3.33). Significant improvements were also found in most psychological measures. **CONCLUSION:** This study provides evidence that a type 2 diabetes prevention programme using lifestyle intervention is feasible in primary health care settings, with reductions in risk factors approaching those observed in clinical trials.

(6) Brunner, E., K. Rees, et al. (2007). "Dietary advice for reducing cardiovascular risk." *Cochrane Database of Systematic Reviews* (4).

BACKGROUND: Changes in population diet are likely to reduce cardiovascular disease and cancer, but the effect of dietary advice is uncertain. **OBJECTIVES:**

To assess the effects of providing dietary advice to achieve sustained dietary changes or improved cardiovascular risk profile among healthy adults. **SEARCH STRATEGY:** We searched the Cochrane Central Register of Controlled Trials, DARE and HTA databases on The Cochrane Library (Issue 4 2006), MEDLINE (1966 to December 2000, 2004 to November 2006) and EMBASE (1985 to December 2000, 2005 to November 2006). Additional searches were done on CAB Health (1972 to December 1999), CVRCT registry (2000), CCT (2000) and SIGLE (1980 to 2000). Dissertation abstracts and reference lists of articles were checked and researchers were contacted. **SELECTION CRITERIA:** Randomised studies with no more than 20% loss to follow-up, lasting at least 3 months involving healthy adults comparing dietary advice with no advice or minimal advice. Trials involving children, trials to reduce weight or those involving supplementation were excluded. **DATA COLLECTION AND ANALYSIS:** Two reviewers independently assessed trial quality and extracted data. Study authors were contacted for additional information. **MAIN RESULTS:** Thirty-eight trials with 46 intervention arms (comparisons) comparing dietary advice with no advice were included in the review. 17,871 participants/clusters were randomized. Twenty-six of the 38 included trials were conducted in the USA. Dietary advice reduced total serum cholesterol by 0.16 mmol/L (95% CI 0.06 to 0.25) and LDL cholesterol by 0.18 mmol/L (95% CI 0.1 to 0.27) after 3-24 months. Mean HDL cholesterol levels and triglyceride levels were unchanged. Dietary advice reduced blood pressure by 2.07 mmHg systolic (95% CI 0.95 to 3.19) and 1.15 mmHg diastolic (95% CI 0.48 to 1.85) and 24-hour urinary sodium excretion by 44.2 mmol (95% CI 33.6 to 54.7) after 3-36 months. Three trials reported plasma antioxidants where small increases were seen in lutein and β -cryptoxanthin, but there was heterogeneity in the trial effects. Self-reported dietary intake may be subject to reporting bias, and there was significant heterogeneity in all the following analyses. Compared to no advice, dietary advice increased fruit and vegetable intake by 1.25 servings/day (95% CI 0.7 to 1.81). Dietary fibre intake increased with advice by 5.99 g/day (95% CI 1.12 to 10.86), while total dietary fat as a percentage of total energy intake fell by 4.49 % (95% CI 2.31 to 6.66) with dietary advice and saturated fat intake fell by 2.36 % (95% CI 1.32 to 3.39). **AUTHORS' CONCLUSIONS:** Dietary advice appears to be effective in bringing about modest beneficial changes in diet and cardiovascular risk factors over approximately 10 months but longer term effects are not known. **DIETARY ADVICE FOR REDUCING CARDIOVASCULAR RISK:** Diet is an important determinant of chronic disease risk, particularly heart disease. This review assessed the effects of providing dietary advice to healthy adults in order to produce sustained improvements in their diets. Whether dietary improvement would reduce the risk factors associated with heart disease was also examined. We found 38 trials in which healthy adults were randomly assigned to receive dietary advice or no dietary advice. The dietary improvements recommended to the people in the intervention groups centred largely on the reduction of salt and fat intake and an increase in the intake of fruit, vegetables, and fibre. Advice was delivered in a variety of ways, including one-to-one contact, group sessions, and written materials. There were variations

in intensity of intervention, ranging from one contact per study participant to 50 hours of counselling over 4 years. The duration of the trials ranged from 3 months to 4 years, with a median follow-up period of 10 months. There was some evidence of greater effectiveness in people told that they were at risk of heart disease or cancer. Modest improvements were shown in cardiovascular risk factors, such as blood pressure and total and LD -cholesterol levels. In the trials that separated effects by gender, women tended to make larger reductions in fat intake, but there was insufficient evidence to show whether this translated to a larger reduction in total cholesterol levels. The trials did not last long enough to answer the question of whether the beneficial changes in cardiovascular risk factors resulted in a reduced incidence of heart disease, stroke, or heart attack.

(7) Shaw Kelly, A., C. Gennat Hanni, et al. (2006). "Exercise for overweight or obesity." Cochrane Database of Systematic Reviews (4).

BACKGROUND: Clinical trials have shown that exercise in adults with overweight or obesity can reduce bodyweight. There has been no quantitative systematic review of this in The Cochrane Library. **OBJECTIVES:** To assess exercise as a means of achieving weight loss in people with overweight or obesity, using randomized controlled clinical trials. **SEARCH STRATEGY:** Studies were obtained from computerised searches of multiple electronic bibliographic databases. **SELECTION CRITERIA:** Studies were included if they were randomized controlled trials that examined body weight change using one or more physical activity intervention in adults with overweight or obesity at baseline and loss to follow-up of participants of less than 15%. **DATA COLLECTION AND ANALYSIS:** Two authors independently assessed trial quality and extracted data. **MAIN RESULTS:** The 43 studies included 3476 participants. Although significant heterogeneity in some of the main effects' analyses limited ability to pool effect sizes across some studies, a number of pooled effect sizes were calculated. When compared with no treatment, exercise resulted in small weight losses across studies. Exercise combined with diet resulted in a greater weight reduction than diet alone (WMD - 1.0 kg; 95% confidence interval (CI) -1.3 to -0.7). Increasing exercise intensity increased the magnitude of weight loss (WMD - 1.5 kg; 95% CI -2.3 to -0.7). There were significant differences in other outcome measures such as serum lipids, blood pressure and fasting plasma glucose. Exercise as a sole weight loss intervention resulted in significant reductions in diastolic blood pressure (WMD - 2 mmHg; 95% CI -4 to -1), triglycerides (WMD - 0.2 mmol/L; 95% CI -0.3 to -0.1) and fasting glucose (WMD - 0.2 mmol/L; 95% CI -0.3 to -0.1). Higher intensity exercise resulted in greater reduction in fasting serum glucose than lower intensity exercise (WMD - 0.3 mmol/L; 95% CI -0.5 to -0.2). No data were identified on adverse events, quality of life, morbidity, costs or on mortality. **AUTHORS' CONCLUSIONS:** The results of this review support the use of exercise as a weight loss intervention, particularly when combined with dietary change. Exercise is associated with improved cardiovascular disease risk factors even if no weight is lost. **EXERCISE FOR OVERWEIGHT OR OBESITY:** Overweight and obesity are important public health problems and are associated

with many serious health conditions. The risk of developing overweight and obesity depends on lifestyle factors such as food intake and physical activity levels. Treatment for overweight and obesity therefore commonly involves diet and exercise. We found that exercise has a positive effect on body weight and cardiovascular disease risk factors in people with overweight or obesity, particularly when combined with diet, and that exercise improves health even if no weight is lost. No data were identified on adverse events, quality of life, morbidity, costs or mortality.

(8) Julia Hippisley-Cox, Carol Coupland, Yana Vinogradova, John Robson, RubinMinhas, Aziz Sheikh, Peter Brindle, Predicting cardiovascular risk in England and Wales: prospective derivation and validation of QRISK2 *BMJ* 2008;336

ABSTRACT Objective To develop and validate version two of the QRISK cardiovascular disease risk algorithm (QRISK2) to provide accurate estimates of cardiovascular risk in patients from different ethnic groups in England and Wales and to compare its performance with the modified version of Framingham score recommended by the National Institute for Health and Clinical Excellence (NICE). Design Prospective open cohort study with routinely collected data from general practice, 1 January 1993 to 31 March 2008. Setting 531 practices in England and Wales contributing to the national QRESEARCH database. Participants 2.3 million patients aged 35-74 (over 16 million person years) with 140 000 cardiovascular events. Overall population (derivation and validation cohorts) comprised 2.22 million people who were white or whose ethnic group was not recorded, 22 013 south Asian, 11 595 black African, 10 402 black Caribbean, and 19 792 from Chinese or other Asian or other ethnic groups. Main outcome measures First (incident) diagnosis of cardiovascular disease (coronary heart disease, stroke, and transient ischaemic attack) recorded in general practice records or linked Office for National Statistics death certificates. Risk factors included self assigned ethnicity, age, sex, smoking status, systolic blood pressure, ratio of total serum cholesterol: high density lipoprotein cholesterol, body mass index, family history of coronary heart disease in first degree relative under 60 years, Townsend deprivation score, treated hypertension, type 2 diabetes, renal disease, atrial fibrillation, and rheumatoid arthritis. Results The validation statistics indicated that QRISK2 had improved discrimination and calibration compared with the modified Framingham score. The QRISK2 algorithm explained 43% of the variation in women and 38% in men compared with 39% and 35%, respectively, by the modified Framingham score. Of the 112 156 patients classified as high risk (that is, $\geq 20\%$ risk over 10 years) by the modified Framingham score, 46 094 (41.1%) would be reclassified at low risk with QRISK2. The 10 year observed risk among these reclassified patients was 16.6% (95% confidence interval 16.1% to 17.0%) — that is, below the 20% treatment threshold. Of the 78 024 patients classified at high risk on QRISK2, 11 962 (15.3%) would be reclassified at low risk by the modified Framingham score. The 10 year observed risk among these patients was 23.3% (22.2% to 24.4%) — that is, above the 20% threshold. In the validation cohort, the annual incidence

rate of cardiovascular events among those with a QRISK2 score of $\geq 20\%$ was 30.6 per 1000 person years (29.8 to 31.5) for women and 32.5 per 1000 person years (31.9 to 33.1) for men. The corresponding figures for the modified Framingham equation were 25.7 per 1000 person years (25.0 to 26.3) for women and 26.4 (26.0 to 26.8) for men). At the 20% threshold, the population identified by QRISK2 was at higher risk of a CV event than the population identified by the Framingham score. Conclusions Incorporating ethnicity, deprivation, and other clinical conditions into the QRISK2 algorithm for risk of cardiovascular disease improves the accuracy of identification of those at high risk in a nationally representative population. At the 20% threshold, QRISK2 is likely to be a more efficient and equitable tool for treatment decisions for the primary prevention of cardiovascular disease. As the validation was performed in a similar population to the population from which the algorithm was derived, it potentially has a “home advantage.” Further validation in other populations is therefore advised.

(9) THE DECODE STUDY GROUP. Age- and Sex-Specific Prevalence of Diabetes and Impaired Glucose Regulation in 13 European Cohorts *Diabetes Care* 26:61–69, 2003.

OBJECTIVE— To report the age- and sex-specific prevalence of diabetes and impaired glucose regulation (IGR) according to the revised 1999 World Health Organization criteria for diabetes in Europe. **RESEARCH DESIGN AND METHODS**— A total of 13 studies from nine European countries with 7,680 men and 9,251 women aged 30–89 years were included in the data analysis.

RESULTS— In most of the study populations, the age-specific prevalence of diabetes were 10% in subjects younger than 60 years and between 10 and 20% at 60–79 years of age. Mean 2-h plasma glucose (2hPG) concentration increased linearly with age, but fasting plasma glucose (FPG) concentration did not. The increase in the prevalence of undiagnosed diabetes and IGR in the elderly was mainly a result of the large increase in 2hPG rather than FPG.

Diabetes and impaired fasting glycemia defined by isolated fasting hyperglycemia was more common in men than in women 30–69 years of age, whereas the prevalence of isolated postload hyperglycemia, particularly impaired glucose tolerance, was higher in women than in men, especially in the elderly (individuals ≥ 70 years of age). More than half of the diabetes was undiagnosed in subjects younger than 50 years of age. **CONCLUSIONS**— Most European populations have a moderate to low prevalence of diabetes and IGR. Diabetes and IGR will be underestimated in Europe, particularly in women and in elderly men, if diagnoses are based on fasting glucose determination alone.