Community Based Diabetes Prevention

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Outline

- NIHR Programme Grant – proposal and update to progress
- The Vascular Check programme
- HbA1c debate
- Algorithm to detect undiagnosed T2DM and ‘those at high risk’

Background

- There is now unequivocal evidence from large long-term RCTs that effective lifestyle interventions can reduce the risk of diabetes by 40-60%.

- However, tested interventions to date have been resource-intensive and have proven ineffective at promoting long-term behaviour change or improved health in the UK.

- Therefore an effective intervention that is suitable for implementation with the resource and infrastructure limitations of the NHS is needed.

Background: structured education

- Cost-effective method of promoting behaviour change
- Recommended for every individual with T2DM (NICE 2008)
- Has a track record of implementation within primary care for those with newly diagnosed T2DM
- Similar approach to implementation programmes used in Finland, Germany, USA and Australia

Desmond™

Diabetes **E**ducation and **S**elf-**M**anagement for **O**ngoing and **N**ewly **D**iagnosed

A collaborative group in the UK (predominantly England) with a Steering Group of 45+ individuals representing 13+ Diabetes Services, drawn from the whole of the spectrum of professions with an interest in diabetes, and including people with diabetes and patient representatives.

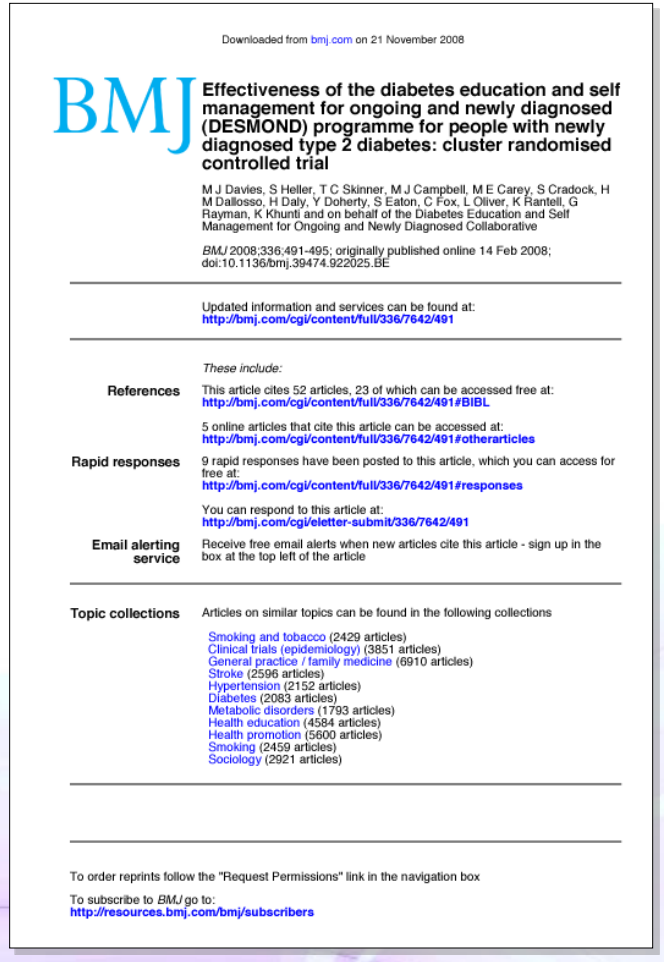
DH Department of Health

Diabetes UK

DESMOND Intervention

Skinner TC et al. Patient Education and Counselling 2006;64:369-377

No difference in HBA1c (-1.5%)
Weight loss 1.1kg
Smoking cessation (OR 3.6)
Changes in health beliefs
Reduced depression scores
Reduced CVD Risk



BMJ

Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised controlled trial

M J Davies, S Heller, T C Skinner, M J Campbell, M E Carey, S Cradock, H M Dallosso, H Daly, Y Doherty, S Eaton, C Fox, L Oliver, K Rantell, G Rayman, K Khunti and on behalf of the Diabetes Education and Self Management for Ongoing and Newly Diagnosed Collaborative

BMJ 2008;336:491-495; originally published online 14 Feb 2008; doi:10.1136/bmj.39474.922025.BE

Davies MJ, et al. Effectiveness of a structured group education programme on individuals newly diagnosed with Type 2 diabetes: a cluster randomised controlled trial of the DESMOND programme. *BMJ* published online 14 Feb 2008; doi:10.1136/bmj.39474.922025.BE.

Cost Effectiveness

Cost Effectiveness of Delivering the DESMOND Intervention (Diabetes Education and Self-Management for Ongoing and Newly Diagnosed) for People Newly Diagnosed with Type 2 diabetes


BMJ

RESEARCH

Delivering the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cost effectiveness analysis

BMJ on line 2010

Analysis using current cost to PCTs of delivering DESMOND

- 'Real world' cost per patient of delivering the DESMOND course for a typical PCT * is £ 76 compared to £ 203 in the trial
- Training costs much lower than during the trial and economies of scale (eg more patients per course)

	Control Mean	Intervention Mean	Adjusted Incremental Mean (95% CI)
Intervention Cost	-	£76	£76
Combined Cost	£16,941	£17,032	£91 (-£321 to £631)
Combined long-term QALYs	10.2166	10.2572	0.0406 (-0.0283 to 0.1050)
Incremental Cost per QALY	-	-	£2,241

M. Gillett, H.M. Dallosso, S. Dixon, A. Brennan, M.E. Carey, M.J. Campbell, S. Heller, K. Khunti, M.J. Davies Diabetologia 2009 O13 and BMJ 2010

National Impact

- Adding to the evidence base for people newly diagnosed with T2D
- Highlighting the importance of HCP training
- Contributing to future developments in self management education

102 PCOs delivering DESMOND

775 Educators

89 Training courses

Ref Source: DESMOND National Programme 2011

NIHR programme grant

Community based primary prevention programme for T2DM integrating identification, lifestyle intervention and community services for prevention.

Melanie J Davies, Kamlesh Khunti, Azhar Farooqi, Marian Carey
Keith Abrams, Chas Skinner, Jaako Tuomilehto, Simon Heller
Nilesh Samani, Bernie Stribling, Alastair Gray, Ken Jones

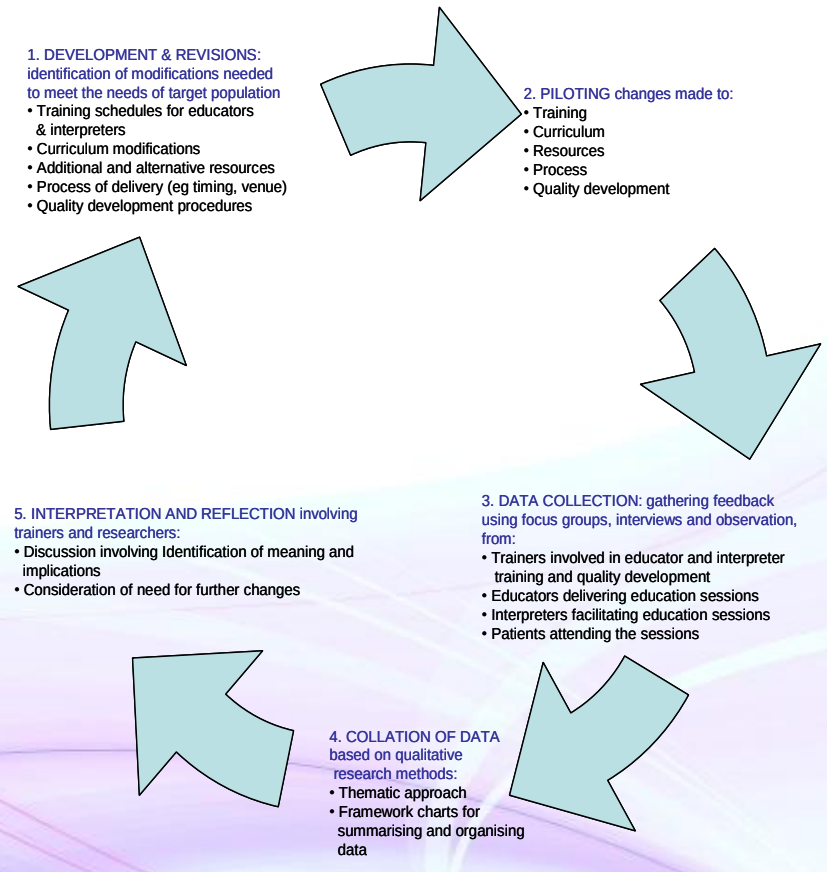
Study aims

- Develop and validate a pathway for detecting those with prediabetes (PDM) based on risk score technology
- Develop and pilot a structured education programme aimed at promoting lifestyle change and reducing the risk of developing diabetes in those with PDM using the MRC's framework for complex interventions
- Evaluate the developed programme using a cluster RCT with progression to diabetes as the primary outcome

Development of a structure education programme

- Based on qualitative research in those with PDM and the PREPARE and DESMOND programmes, a multifactoral 6 hour structured education programme aimed at targeting body weight, diet and physical activity was developed; this included a version specifically tailored to South Asian communities
- The full educator training and quality assurance programme was also developed for both the standard and South Asian programmes.
- The education and educator training and quality assurance programmes were piloted extensively using the cyclical development process shown opposite.
- Pilot data revealed that the programme was effective at targeting illness perceptions, self-efficacy and promoting behaviour change

Programme development cycle

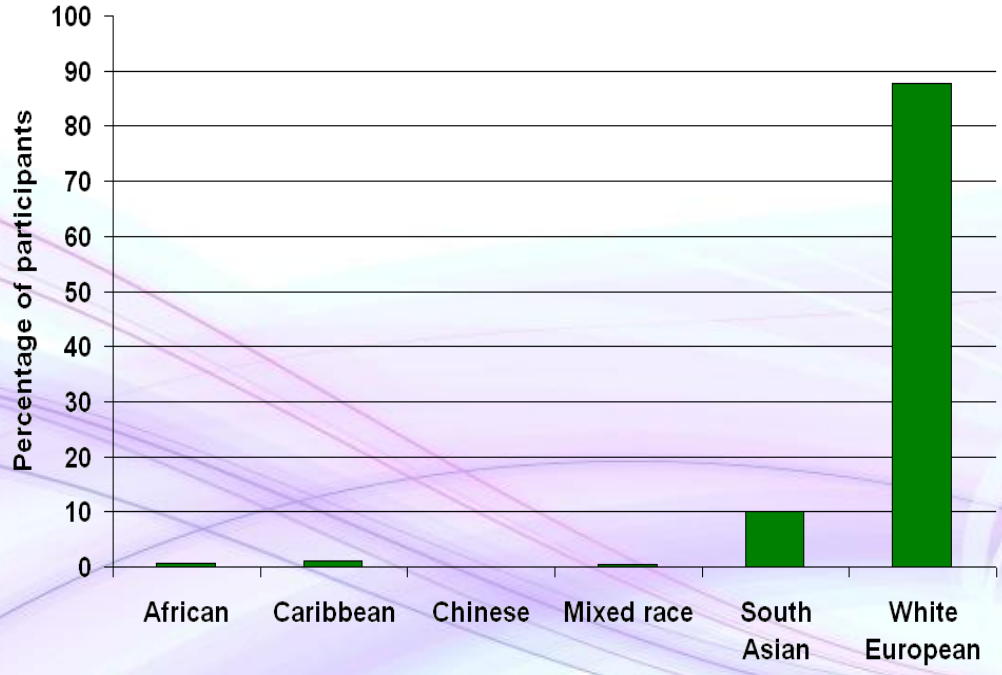


Cluster RCT

- Aims to recruit 44 GP practices, of which 22 will receive intervention conditions
- Aims to screen around 3000 high risk individuals (defined through the automated Leicester Risk Score) to detect a total cohort of 748 with PDM, allowing for a 20% drop-out
- Intervention to consist of a 6-hour structured education programme followed by annual group-based maintenance sessions and 3 telephone counselling sessions per year
- Study designed to detect a 40% reduction in the relative risk of developing diabetes over 3 years

Screening

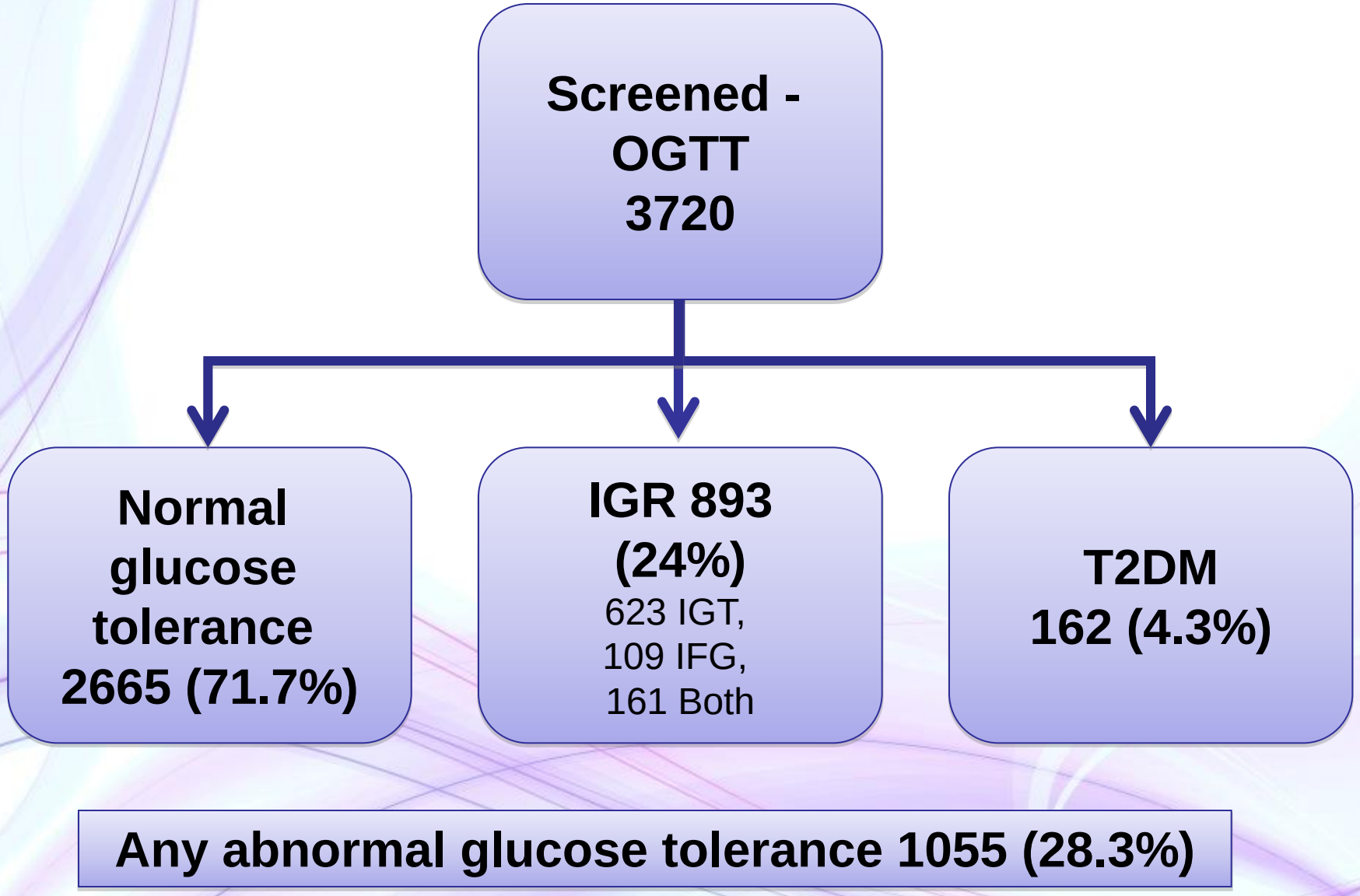
- 3,720 people have been screened from 44 GP practices
- 61% male, mean age 63.6 years (SD 7.8), mean BMI 31.9 kg/m2 (SD 4.9)



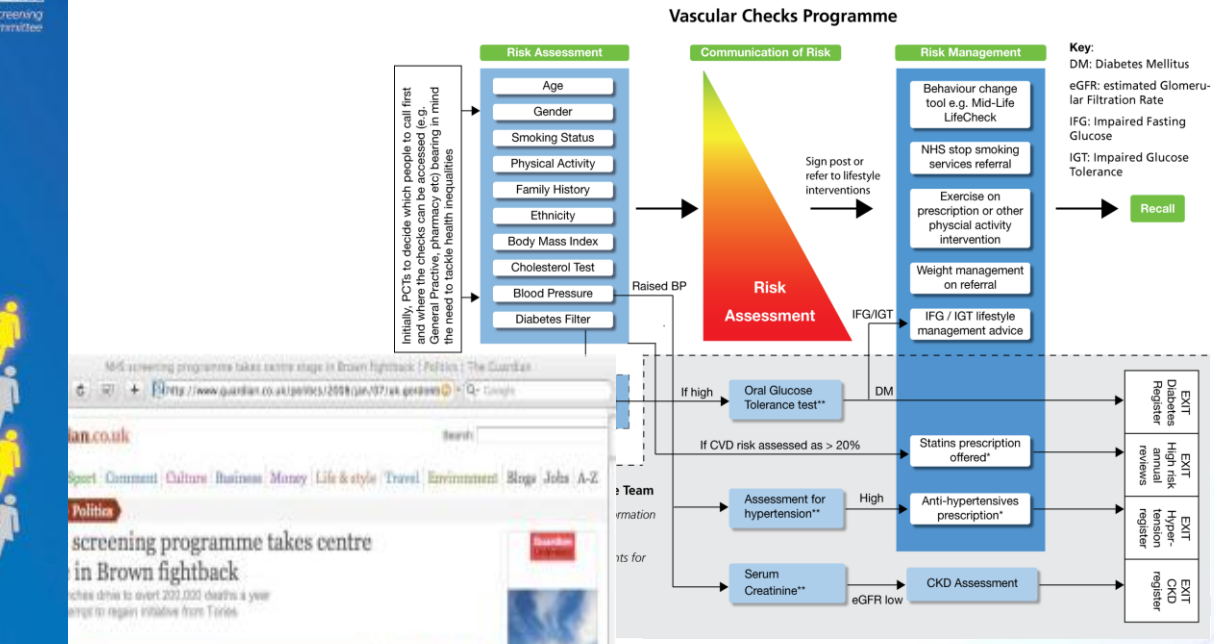
Screening (data from first 2556 subjects)

- 804 (31%) had high blood pressure
  - of which 30% were not taking antihypertensive medication
- 1,407 (55%) had high cholesterol (≥5)
  - of which 77% were not taking lipid lowering medication.
- 202 (8%) were current smokers

Screening - Results



NHS Health Check model



Vascular Check programme – Economic Evaluation

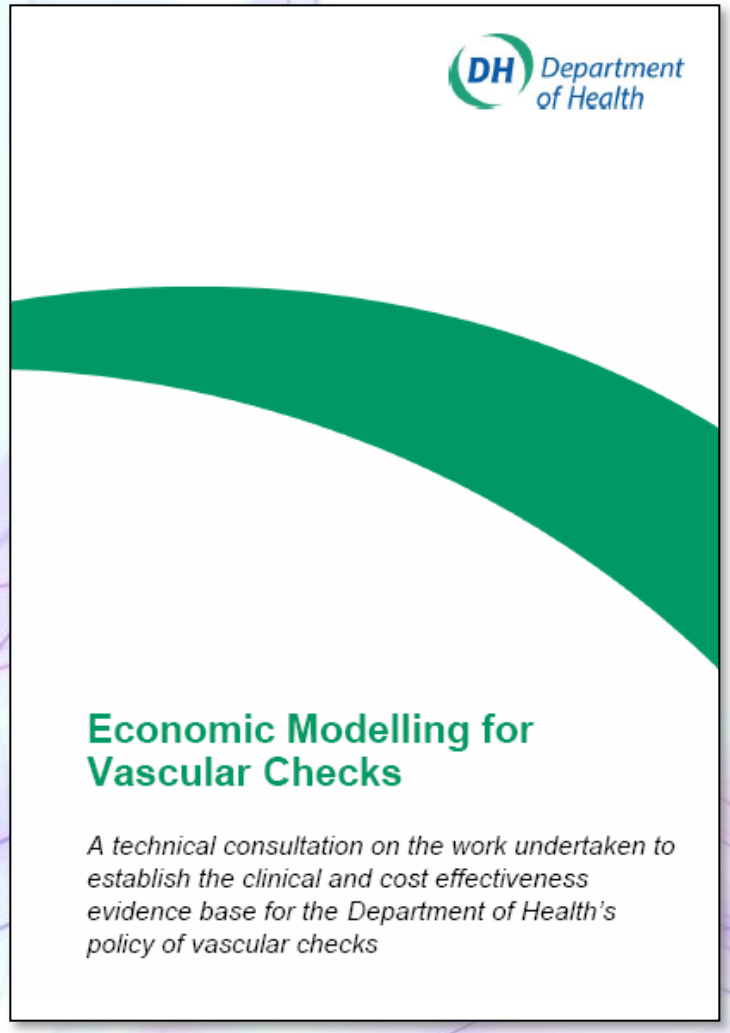
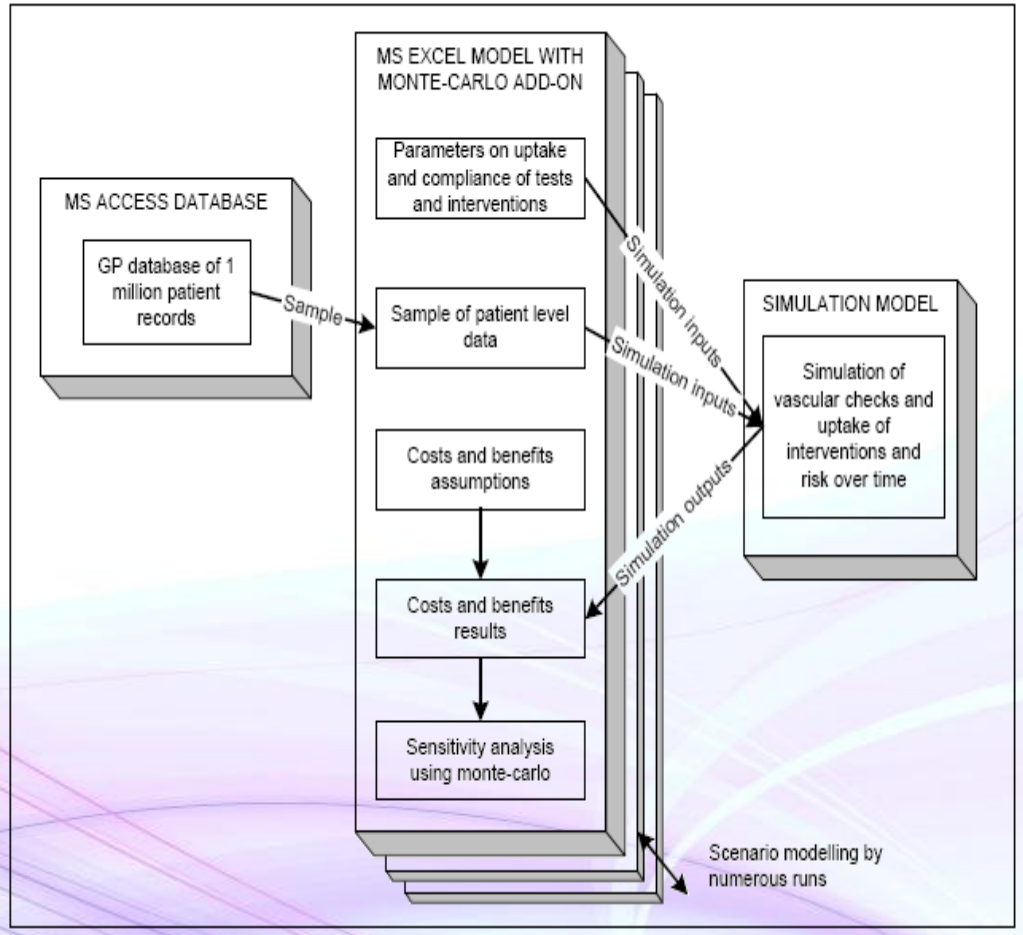


Figure 1: VRA Model Architecture



Vascular Check programme – Economic Evaluation

Table 6 – Lifetime costs and QALYs for each intervention

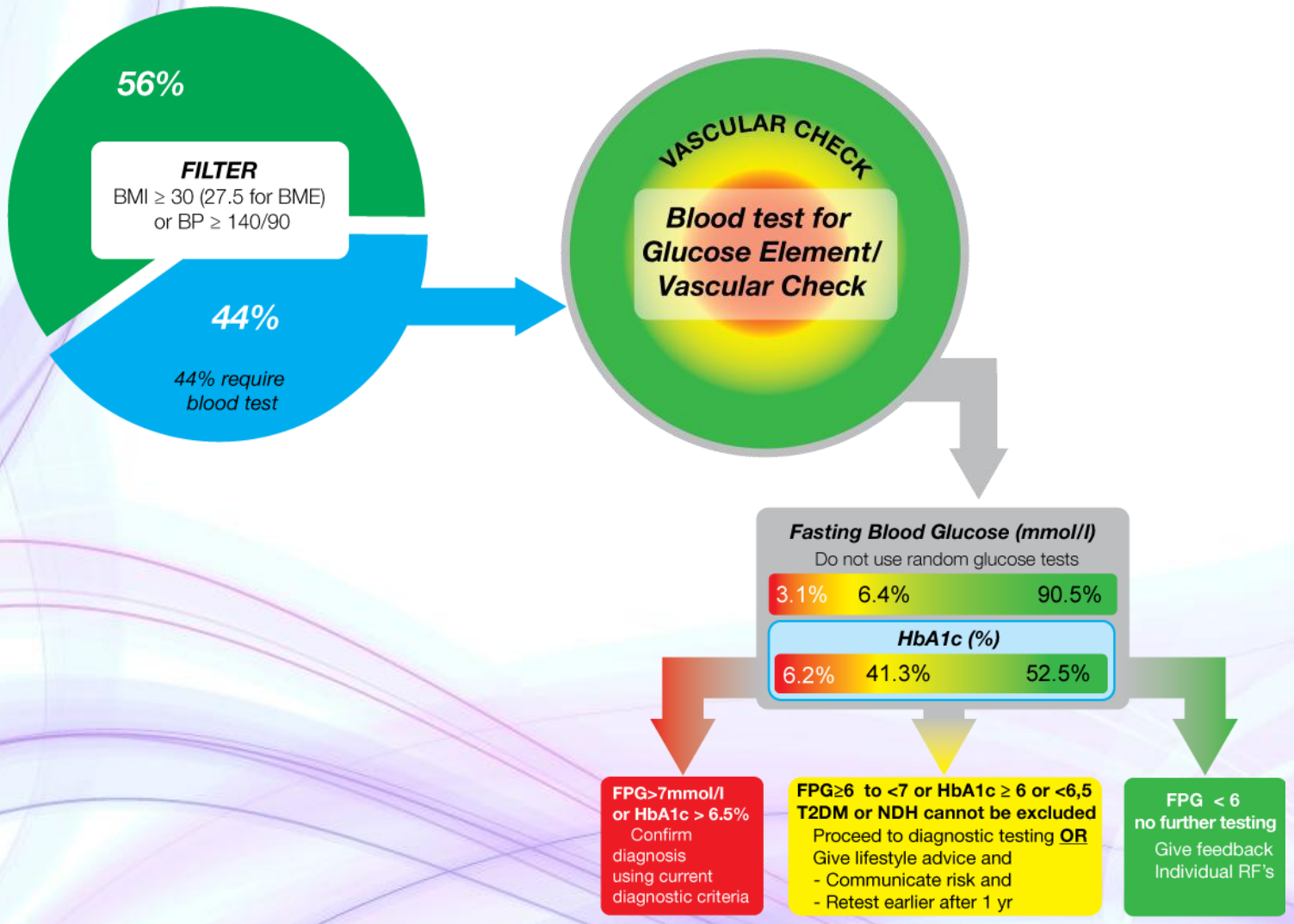
Intervention	Age	Gender	Lifetime cost (£)	Lifetime QALYs
IGR lifestyle intervention	25-44	All	-398	0.63
	45-54	All	493	0.63
	55-64	All	1821	0.53
	65-74	All	2637	0.39
Statins	40-49	Male	2374	0.47
	50-59	Male	2241	0.30
	60-69	Male	2092	0.18
	70-79	Male	1695	0.08

Vascular Check programme – Economic Evaluation

Table 14: Average total costs per annum by intervention

Cost component	£m p.a.	%
IGT lifestyle intervention	67.8	42%
Statins – drugs and lab costs	28.3	18%
Anti-hypertensives – drugs and lab costs	20.9	13%
Exercise chat	4.7	3%
Stop Smoking Services	4.3	3%
Diabetes management	3.4	2%
Weight loss programme	2.1	1%
Intervention costs: nurse time	1.9	1%
Intervention costs: GP time	27.6	17%
Intervention costs: Healthcare Assistant time	0.1	0%
TOTAL	**161.1**	**100%**

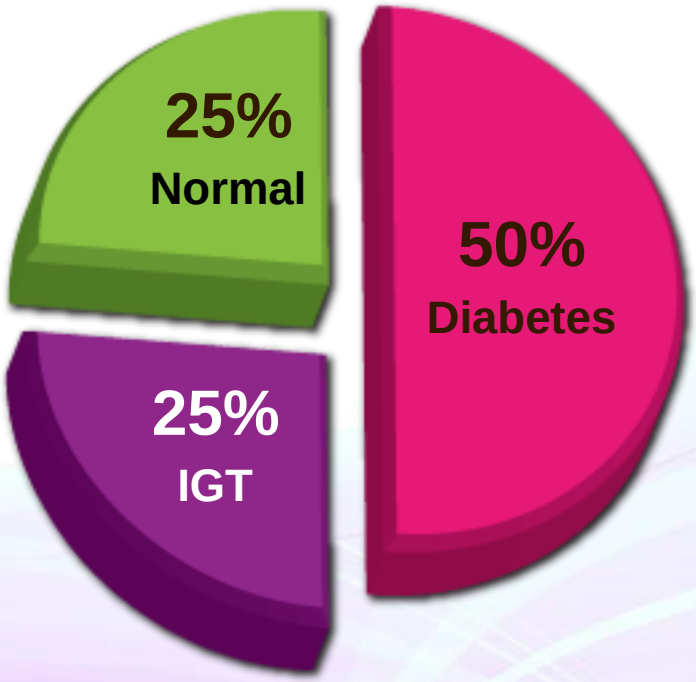
‘Pragmatic Approach’ to ‘glucose’ assessment in the Vascular Check Programme



IGT as a target for Diabetes and CVD Prevention

The prevalence of IGT:
16% of the US subjects aged 40–74 years
13% in the DECODE study
15% in the DECODA study

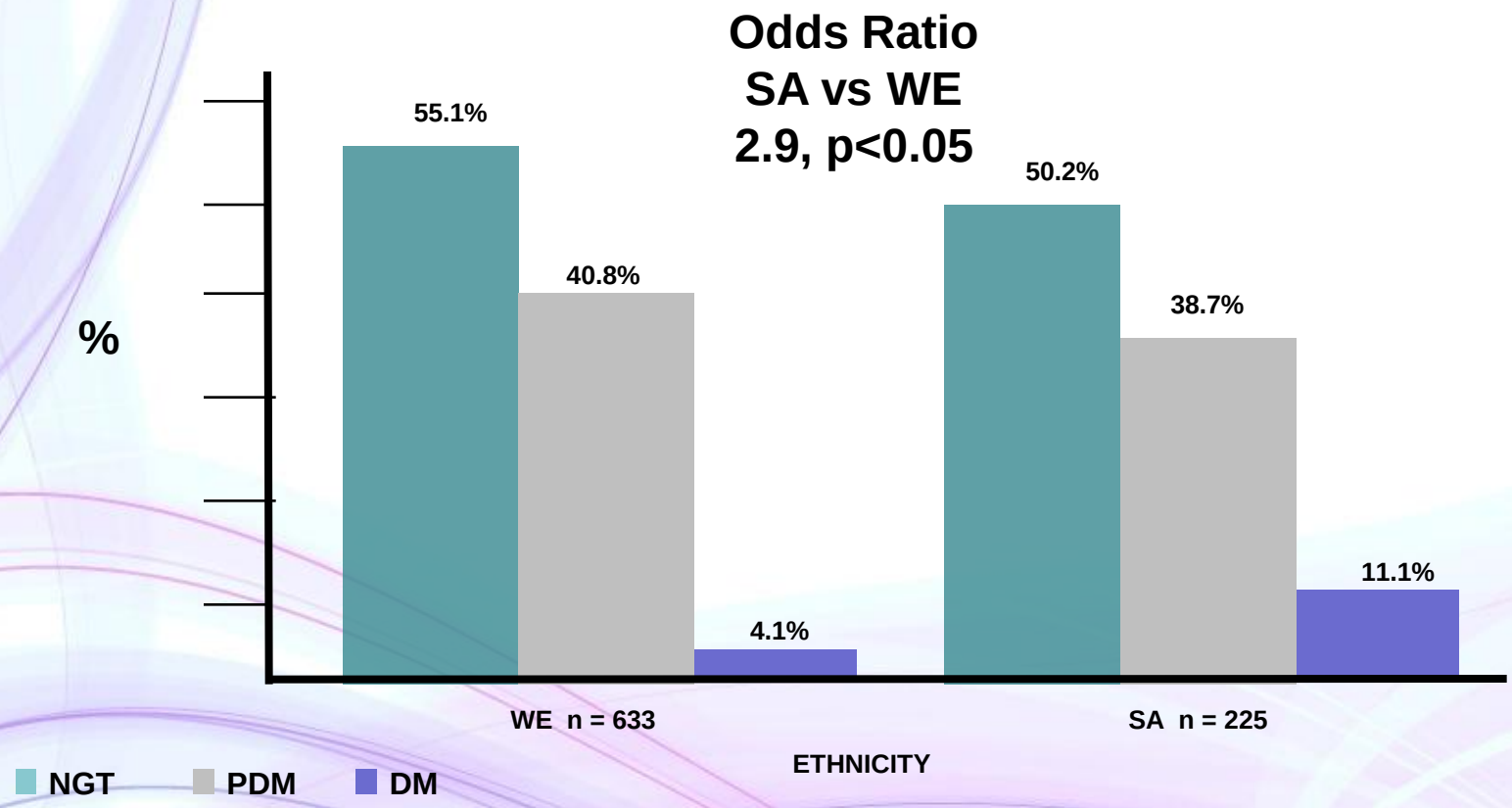
IGT → **After 10 years**



Impaired glucose tolerance and impaired fasting glycaemia: the current status on definition and intervention. Unwin N, Shaw J, Zimmet P, Alberti KG. Diabetic Medicine 19:708-723 2002

Diagnosis, prognosis, and treatment of impaired glucose tolerance and impaired fasting glucose.Santaguida,P.L.; Balion,C.; Hunt,D.; Morrison,K.; Gerstein,H.; Raina,P.; Booker,L.; Yazdi,H. Evidence Report Technology Assessment (Summary) 128 1-11 2005

Progression to diabetes in a multi ethnic population with PDM in the UK



Srinivasan BT, Davies MJ, Webb DR, Gray LJ, Gosai B, Khunti K. Diabetes; Vol 58; S 1; A273; 1033P and University of Leicester MD Thesis 2011 submitted

HBA1c for Diagnosis of diabetes

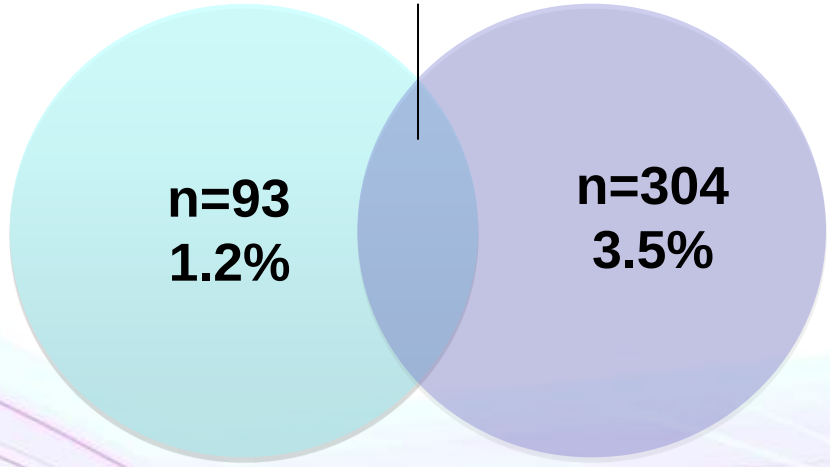
- Cohort size: n = 8696
- Mean cohort age: 57.3 years (SD 9.7)
- Mean cohort HbA1c: 5.71% (SD 0.61)
- White Europeans (WE) 74.7%, South Asians (SA) 22.8%
- Mean HbA1c: WE: 5.66% vs. SA: 5.86%, $p<0.0001$

Mostafa S et al. Diabetic Medicine 2010

Prevalence of HbA1c vs. OGTT

33% of the population remain the same

DM on OGTT & HbA1c≥6.5%
N=198
(2.3%)



DM on OGTT
n=291
(3.3%)

HbA1c≥6.5%
n=502
(5.8%)

Total
n=595, 6.8%

Using HbA1c≥6.5%:

- **Increase in 'T2DM' prevalence: ~ 2 fold**

Detection rates:
SA > WE
p<0.0001

Mostafa S et al. Diabetic Medicine 2010

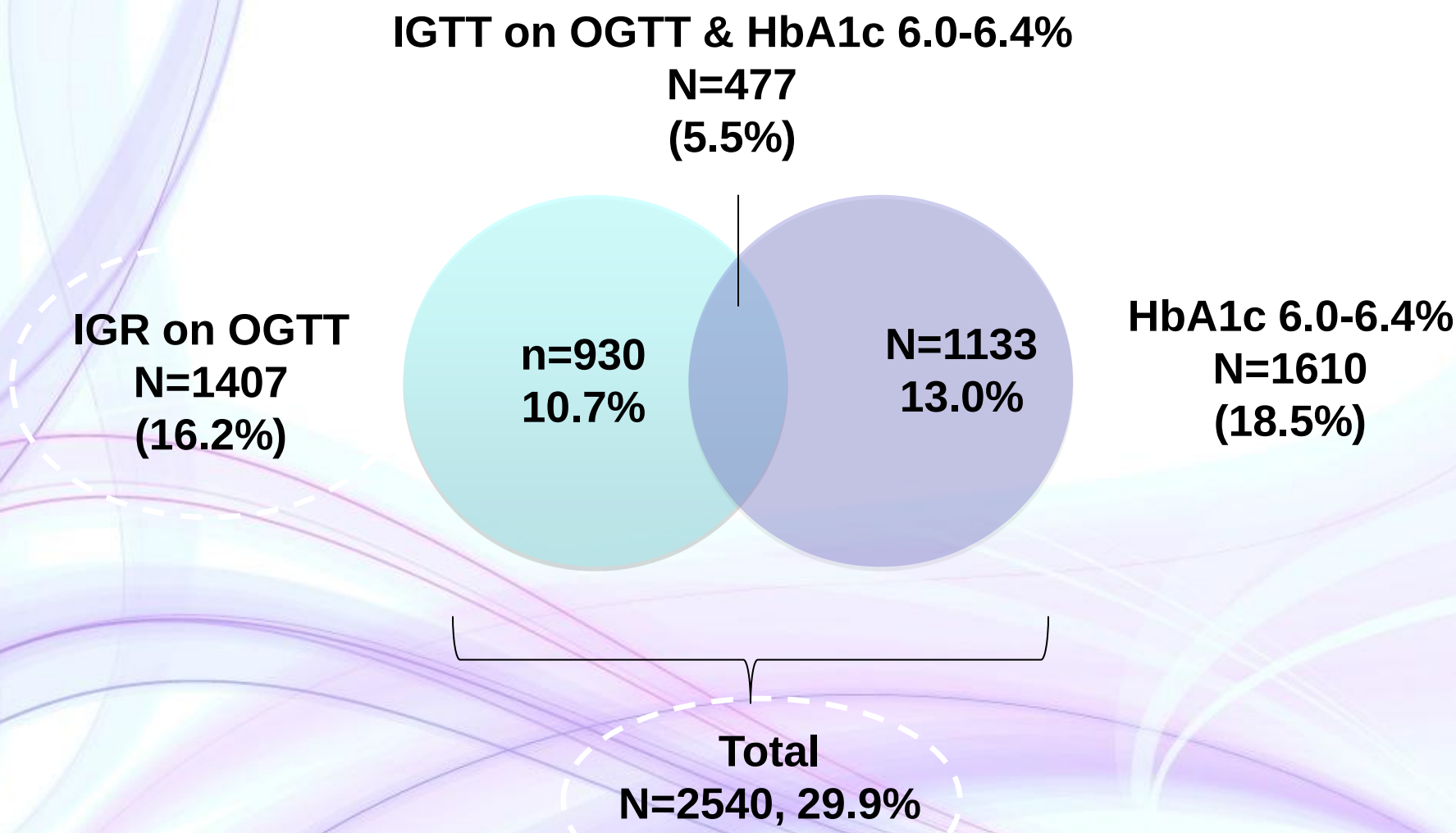
T2DM on OGTT vs. 'Additional people' detected

		DM on OGTT	HbA1c ≥ 6.5%, No DM on OGTT	p
	Age (years)	59.9 (9.3)	59.1 (9.5)	0.248
	% Male	57.0	56.6	0.909
Ethnicity	% White Europeans	63.6	48.6	0.001
	% South Asians	33.2	46.2	-
	Waist Circumference (cm)	103.2 (13.3)	100.7 (14.1)	0.025
	Waist: Hip Ratio	0.943 (0.08)	0.928 (0.09)	0.025
	Systolic BP (mmHg)	148.1 (20.0)	138.9 (19.6)	<0.0001
	Diastolic BP (mmHg)	87.3 (11.8)	84.5 (10.8)	0.004
	Mean Triglycerides (mmol/l)	2.15 (1.57)	1.66 (0.82)	<0.0001
	% Total Cholesterol > 5.0mmol/l	65.4	58.6	0.025
	% Microalbuminuria	17.4	11.3	0.034

Mostafa S et al. Diabetic Medicine 2010

Prevalence of IGR on OGTT vs. HbA1c

18.8% of the population remain the same



Mostafa et al Dia Res Clin Pract 90 (2010) 100-108

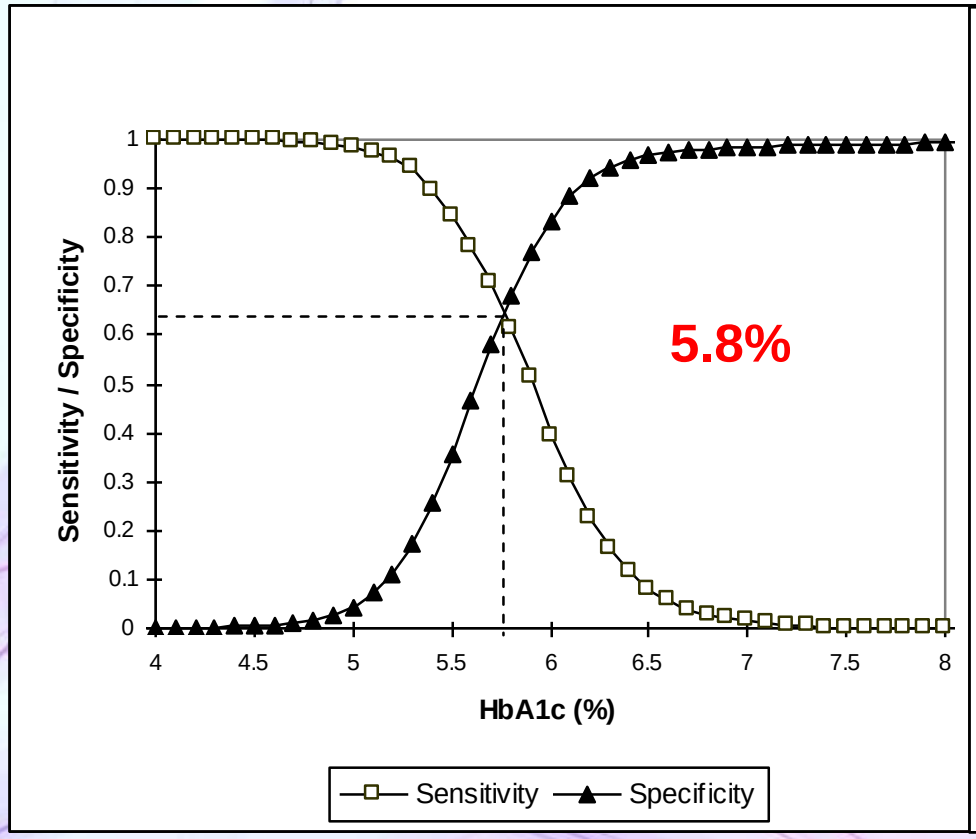
Comparison of clinical characteristics

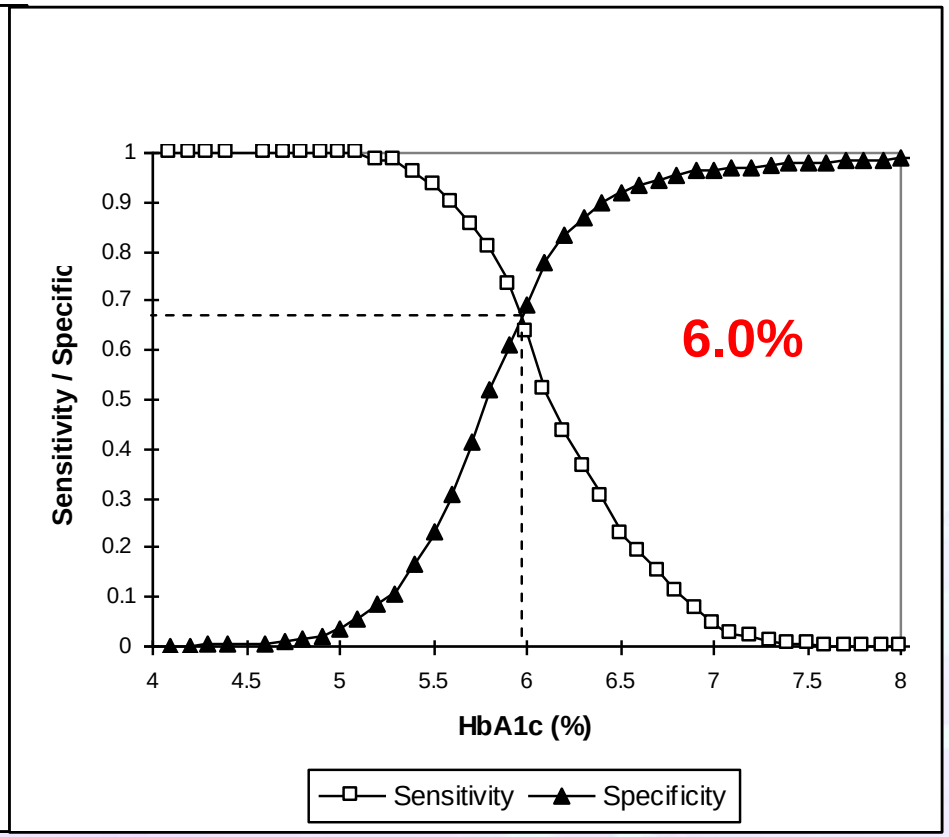
		IGR on OGTT without 6.0-6.4%	HbA1c 6.0-6.4%, No IGR	p
Age (years)		59.9	59.2	0.099
% Female		49.7	51.5	0.421
Ethnicity	% WE	73.0	64.1	<0.0001
	% SA	24.4	32.0	-
Waist Circumference(cm)		98.1	95.9	<0.0001
Mean BMI (kg/m^2)		29.4	28.5	<0.0001
Mean Systolic BP (mmHg)		142.1	137.7	<0.0001
Mean Diastolic BP (mmHg)		85.7	83.7	<0.0001
Mean Triglycerides (mmol/l)		1.6	1.52	0.018

Mutually exclusive groups analysed

Mostafa et al Dia Res Clin Pract 90 (2010) 100-108

The relationship between HbA1c level and sensitivity/specificity for detecting IGR detected using WHO 1999 criteria) in (a) white Europeans and (b) south Asians.





(a) white Europeans

(b) south Asians

The dotted line represents the optimal balance between sensitivity and specificity (HbA1c≥ 5.8% for white Europeans and ≥ 6.0% for south Asians).

Mostafa et al Dia Res Clin Pract 90 (2010) 100-108

Risk Scores

- Pre-existing databases involving over 10,000 patients (ADDITION and STAR) were used to develop and validate two diabetes-specific risk scores.

1) A self-assessment score that can be used as a method of engaging people with their diabetes risk status

   (Gray et al. 2010, Diabetic Medicine)

1) A practice-based automated risk score that uses MIQUEST technology to rank risk status using data routinely coded within primary care

   (Taub et al. Diabetologia. 2009;52[suppl. 1]:S325-6).

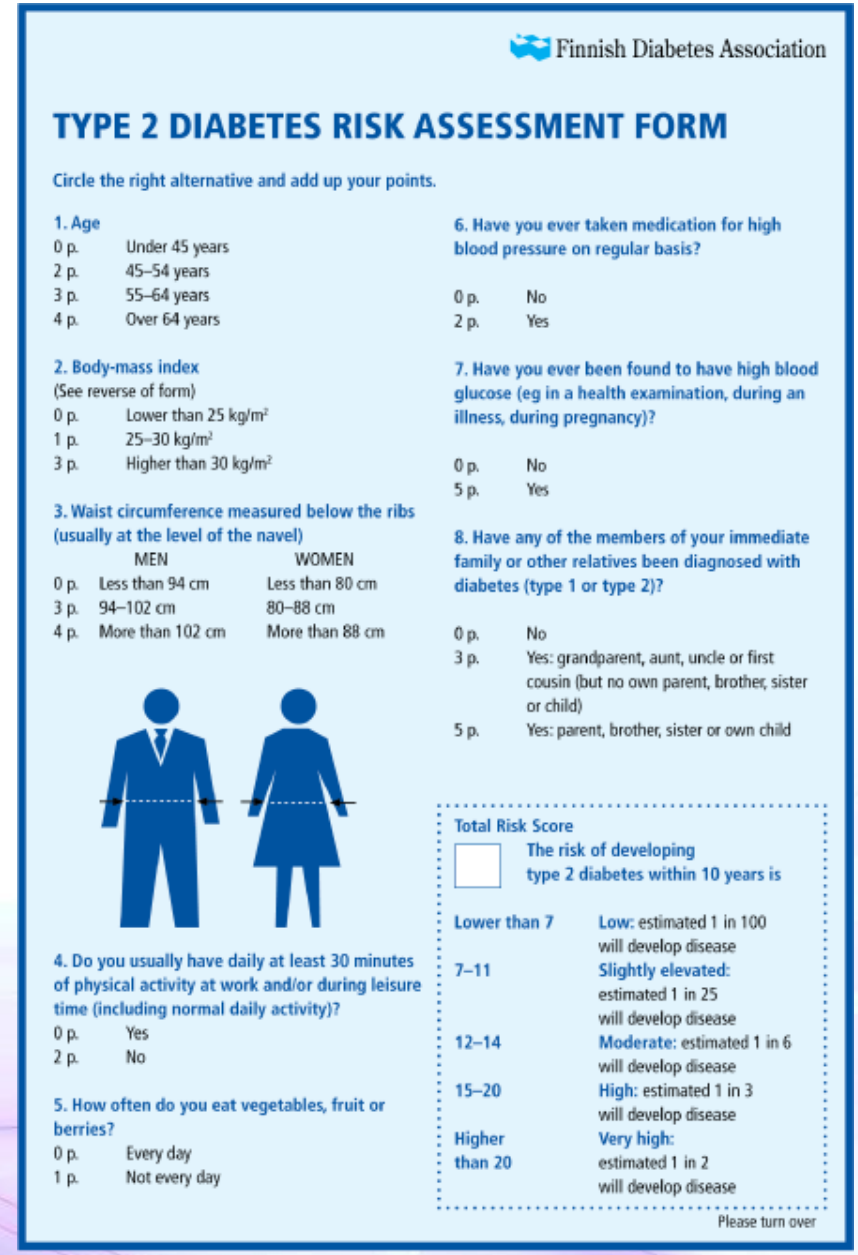
Self-Assessment based Strategies

- To increase individuals' awareness and understanding of how their lifestyles and health behaviour impact upon their quality and length of life.
- To challenge, motivate and empower individuals
- To provide individuals with personalised information, practical advice and signposting to relevant services.

FINDRISC

The original FINDRISC included only 7 questions. Using the original 7 questions showed that the score was reliable in predicting future DM over a 10 year period, in two cohorts
Using this original score with a value of 9 or above was associated with an increased risk of future DM with a sensitivity of 78% and a specificity of 77%

The final FINDRISC has been amended in two ways; the age categories have been changed, with the addition of an age category of >64 years with a score value of 4, and the addition of a question regarding family history.
Not validated in a UK multi-ethnic population



Finnish Diabetes Association

TYPE 2 DIABETES RISK ASSESSMENT FORM

Circle the right alternative and add up your points.

1. Age
0 p. Under 45 years
2 p. 45–54 years
3 p. 55–64 years
4 p. Over 64 years

2. Body-mass index
(See reverse of form)
0 p. Lower than 25 kg/m²
1 p. 25–30 kg/m²
3 p. Higher than 30 kg/m²

3. Waist circumference measured below the ribs (usually at the level of the navel)

	MEN	WOMEN
0 p.	Less than 94 cm	Less than 80 cm
3 p.	94–102 cm	80–88 cm
4 p.	More than 102 cm	More than 88 cm

4. Do you usually have daily at least 30 minutes of physical activity at work and/or during leisure time (including normal daily activity)?
0 p. Yes
2 p. No

5. How often do you eat vegetables, fruit or berries?
0 p. Every day
1 p. Not every day

6. Have you ever taken medication for high blood pressure on regular basis?
0 p. No
2 p. Yes

7. Have you ever been found to have high blood glucose (eg in a health examination, during an illness, during pregnancy)?
0 p. No
5 p. Yes

8. Have any of the members of your immediate family or other relatives been diagnosed with diabetes (type 1 or type 2)?
0 p. No
3 p. Yes: grandparent, aunt, uncle or first cousin (but no own parent, brother, sister or child)
5 p. Yes: parent, brother, sister or own child

Total Risk Score

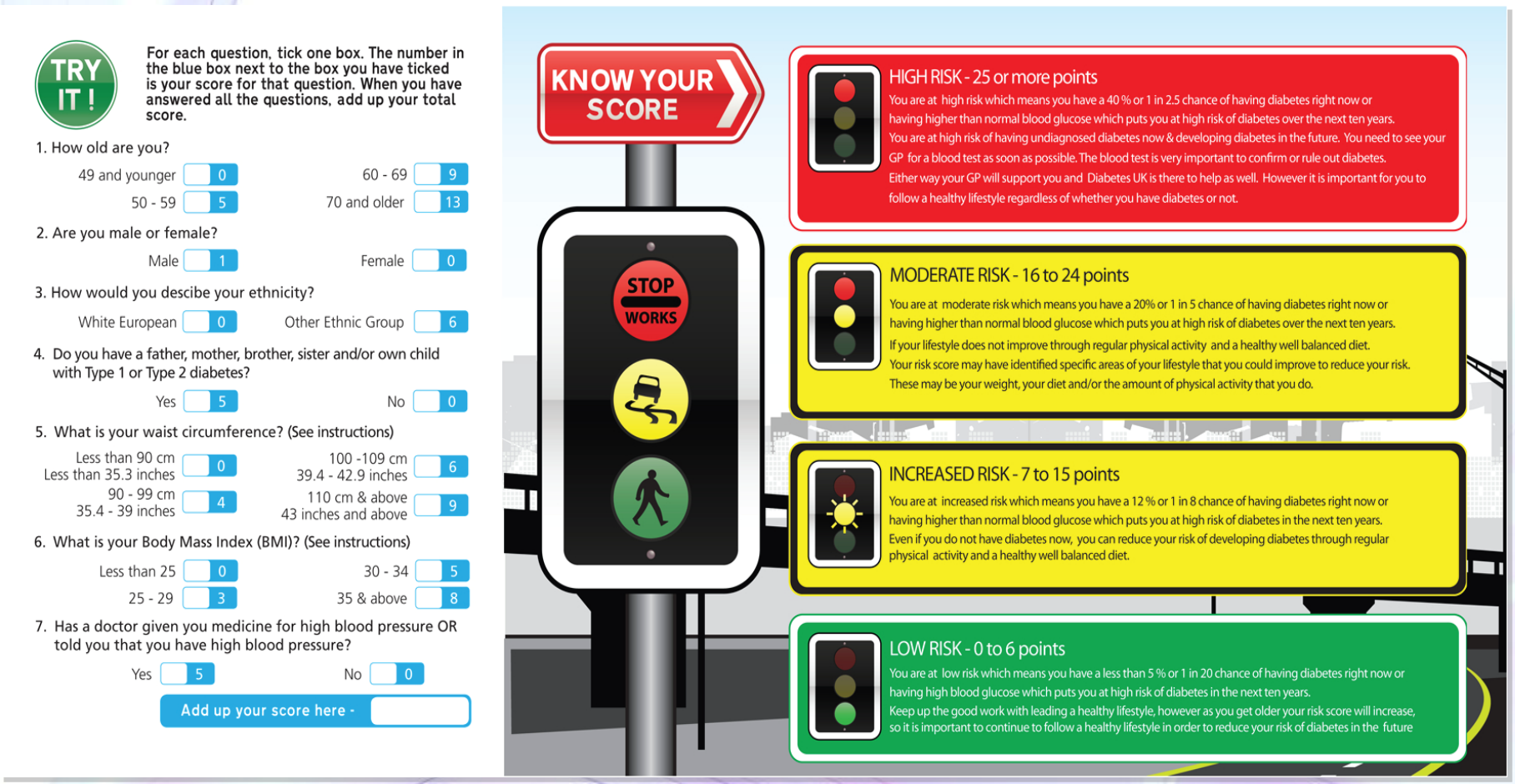
The risk of developing type 2 diabetes within 10 years is

Lower than 7	Low: estimated 1 in 100 will develop disease
7–11	Slightly elevated: estimated 1 in 25 will develop disease
12–14	Moderate: estimated 1 in 6 will develop disease
15–20	High: estimated 1 in 3 will develop disease
Higher than 20	Very high: estimated 1 in 2 will develop disease

Please turn over

Lindstrom J,.Tuomilehto J. The diabetes risk score: a practical tool to predict type 2 diabetes risk. Diabetes Care;26:725-31 2003

Leicester Self Assessment (LSA)



Gray et al. 2010, Diabetic Medicine

Leicester Practice Risk Score

- Automated tool for identifying those at high risk of either IGR or T2DM
- Uses routine data from GP practice databases

The **Leicester Practice Risk Score** is calculated as follows:

LPRS = 0.0407 × age (years)

+ 0.296 (if male, no change if female)

+ 0.934 (ethnicity, as practice proportion SA)

+ 0.0859 × BMI (kg/m2)

+ 0.440 (if family history of DM, no change otherwise)

+ 0.374 (if on antihypertensive medication, no change otherwise)

Taub et al. Diabetologia. 2009;52[suppl. 1]:S325-6

Practice data in GP computers

- Age & Gender
- Body Mass Index
- Ethnicity (as proportion of practice)
- Family History of DM
- Smoking Status
- Use of hypertensives
- Socio-economic status

Taub et al. Diabetologia. 2009;52[suppl. 1]:S325-6

Cost per Case : screening for diabetes and PDM; potential strategies

Strategy 1	All subjects undergo OGTT.
Strategy 2	All subjects undergo fasting glucose. Those above a certain threshold undergo OGTT.
Strategy 3	All subjects undergo HbA1c. Those above a certain threshold for HbA1c undergo OGT.
Strategy 4	All subjects undergo fasting glucose and HBA1c. Those above a certain threshold undergo OGTT.
Strategy 5	All subjects undergo self-assessment using a modified ethnic specific FINDRISK score. Those above a certain threshold undergo OGTT.
Strategy 6	All subjects undergo self-assessment using a modified ethnic specific FINDRISK score. Those above a certain threshold for FINDRISK undergo fasting glucose. Those above a certain threshold for fasting glucose undergo an OGTT.
Strategy 7	All subjects undergo self-assessment using a modified ethnic specific FINDRISK score. Those above a certain threshold for FINDRISK undergo an HbA1c. Those above a certain threshold for HBA1c undergo an OGTT.
Strategy 8	All subjects are invited on basis of a risk cut-off using routine practice data including age, sex, ethnicity and BMI. Those above a certain threshold undergo an OGTT.

Khunti et al Diabetic Medicine 2010

Summary

- Use of glycaemic measures and risk scores allows accurate risk calculation for future diabetes but needs validation in the local population in which they will be used
- Cost effectiveness for the identification of those at risk and interventions and the ‘combined’ pathway have been undertaken but there are gaps in the literature
- Evidence for a more intensive intervention in those at higher risk (> 50% 10 yr future DM risk) is proven lower levels need further evaluation
- Most of the cost lies with the intervention costs and strategies for identification even those confirmed with OGTT are relatively modest
- A stepwise screening strategy using self-assessment or practice routine data followed by HBA1c appears an efficient screening strategy for detecting T2DM and T2DM/IGR in a community setting.
- Remain some questions re the use of HbA1c in those with ’IGR’ for example effectiveness of interventions compared to those with traditional IGT