Community Based Diabetes Prevention

Melanie Davies

Professor of Diabetes Medicine
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
Diabetes Education and Self-Management for Ongoing and Newly Diagnosed

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

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

National Impact

• 102 PCOs delivering DESMOND

• 775 Educators

• 85 Training courses

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

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

1. DEVELOPMENT & REVISIONS: identification of modifications needed to meet the needs of target population
   - Training schedules for educators & interpreters
   - Curriculum modifications
   - Additional and alternative resources
   - Process of delivery (eg timing, venue)
   - Quality development procedures

2. PILOTING changes made to:
   - Training
   - Curriculum
   - Resources
   - Process
   - Quality development

3. DATA COLLECTION: gathering feedback using focus groups, interviews and observation, from:
   - Trainers involved in educator and interpreter training and quality development
   - Educators delivering education sessions
   - Interpreters facilitating education sessions
   - Patients attending the sessions

4. COLLATION OF DATA based on qualitative research methods:
   - Thematic approach
   - Framework charts for summarising and organising data

5. INTERPRETATION AND REFLECTION involving trainers and researchers:
   - Discussion involving identification of meaning and implications
   - Consideration of need for further changes
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

Screened - OGTT 3720

- Normal glucose tolerance 2665 (71.7%)
- IGR 893 (24%)
  - 623 IGT,
  - 109 IFG,
  - 161 Both
- T2DM 162 (4.3%)

Any abnormal glucose tolerance 1055 (28.3%)
Vascular Check programme – Economic Evaluation

Economic Modelling for Vascular Checks

A technical consultation on the work undertaken to establish the clinical and cost effectiveness evidence base for the Department of Health’s policy of vascular checks.
## Vascular Check programme – Economic Evaluation

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

### Table 6 – Lifetime costs and QALYs for each intervention
## Vascular Check programme – Economic Evaluation

### Table 14: Average total costs per annum by intervention

<table>
<thead>
<tr>
<th>Cost component</th>
<th>£m p.a.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>IGT lifestyle intervention</td>
<td>67.8</td>
<td>42%</td>
</tr>
<tr>
<td>Statins – drugs and lab costs</td>
<td>28.3</td>
<td>18%</td>
</tr>
<tr>
<td>Anti-hypertensives – drugs and lab costs</td>
<td>20.9</td>
<td>13%</td>
</tr>
<tr>
<td>Exercise chat</td>
<td>4.7</td>
<td>3%</td>
</tr>
<tr>
<td>Stop Smoking Services</td>
<td>4.3</td>
<td>3%</td>
</tr>
<tr>
<td>Diabetes management</td>
<td>3.4</td>
<td>2%</td>
</tr>
<tr>
<td>Weight loss programme</td>
<td>2.1</td>
<td>1%</td>
</tr>
<tr>
<td>Intervention costs: nurse time</td>
<td>1.9</td>
<td>1%</td>
</tr>
<tr>
<td>Intervention costs: GP time</td>
<td>27.6</td>
<td>17%</td>
</tr>
<tr>
<td>Intervention costs: Healthcare Assistant time</td>
<td>0.1</td>
<td>0%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>161.1</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>
‘Pragmatic Approach’ to ‘glucose’ assessment in the Vascular Check Programme

56%
FILTER
BMI ≥ 30 (27.5 for BME) or BP ≥ 140/90

44%
44% require blood test

VASCULAR CHECK

Blood test for Glucose Element/Vascular Check

Fasting Blood Glucose (mmol/l)
Do not use random glucose tests
3.1% 6.4% 90.5%

HbA1c (%)
6.2% 41.3% 52.5%

FPG > 7 mmol/l or HbA1c > 6.5%
Confirm diagnosis using current diagnostic criteria

FPG ≥ 6 to <7 or HbA1c ≥ 6 or <6.5
T2DM or NDH cannot be excluded
Proceed to diagnostic testing OR
Give lifestyle advice and
- Communicate risk and
- Retest earlier after 1 yr

FPG < 6
no further testing
Give feedback individual RF’s
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

25% Normal
50% Diabetes
25% IGT


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; S1; A273; 1033P and University of Leicester MD Thesis 2011 submitted

Odds Ratio
SA vs WE
2.9, p<0.05

<table>
<thead>
<tr>
<th>ETHNICITY</th>
<th>NGT</th>
<th>PDM</th>
<th>DM</th>
</tr>
</thead>
<tbody>
<tr>
<td>WE n = 633</td>
<td>55.1%</td>
<td>40.8%</td>
<td>4.1%</td>
</tr>
<tr>
<td>SA n = 225</td>
<td>50.2%</td>
<td>38.7%</td>
<td>11.1%</td>
</tr>
</tbody>
</table>
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
33% of the population remain the same

Using HbA1c ≥ 6.5%:

- Increase in ‘T2DM’ prevalence: ~ 2 fold

DM on OGTT & HbA1c ≥ 6.5%
N = 198
(2.3%)

DM on OGTT
n = 291
(3.3%)

n = 93
1.2%

n = 304
3.5%

HbA1c ≥ 6.5%
n = 502
(5.8%)

Total
n = 595, 6.8%

Detection rates:
SA > WE
p < 0.0001

Mostafa S et al. Diabetic Medicine 2010
**T2DM on OGTT vs. ‘Additional people’ detected**

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

Mostafa S et al. Diabetic Medicine 2010
Prevalence of IGR on OGTT vs. HbA1c

18.8% of the population remain the same

IGTT on OGTT & HbA1c 6.0-6.4%
N=477 (5.5%)

IGR on OGTT
N=1407 (16.2%)

n=930 10.7%

HbA1c 6.0-6.4%
N=1610 (18.5%)

N=1133 13.0%

Total
N=2540, 29.9%

## Comparison of clinical characteristics

<table>
<thead>
<tr>
<th></th>
<th>IGR on OGTT without 6.0-6.4%</th>
<th>HbA1c 6.0-6.4%, No IGR</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td>59.9</td>
<td>59.2</td>
<td>0.099</td>
</tr>
<tr>
<td>% Female</td>
<td>49.7</td>
<td>51.5</td>
<td>0.421</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% WE</td>
<td>73.0</td>
<td>64.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>% SA</td>
<td>24.4</td>
<td>32.0</td>
<td>-</td>
</tr>
<tr>
<td><strong>Waist Circumference(cm)</strong></td>
<td>98.1</td>
<td>95.9</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Mean BMI (kg/m²)</strong></td>
<td>29.4</td>
<td>28.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Mean Systolic BP (mmHg)</strong></td>
<td>142.1</td>
<td>137.7</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Mean Diastolic BP (mmHg)</strong></td>
<td>85.7</td>
<td>83.7</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Mean Triglycerides (mmol/l)</strong></td>
<td>1.6</td>
<td>1.52</td>
<td>0.018</td>
</tr>
</tbody>
</table>

*Mutually exclusive groups analysed*

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).

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.
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.
Leicester Self Assessment (LSA)

For each question, tick one box. The number in the blue box next to the box you have ticked is your score for that question. When you have answered all the questions, add up your total score.

1. How old are you?
   - 49 and younger: 0
   - 50 - 59: 5
   - 60 - 69: 9
   - 70 and older: 13

2. Are you male or female?
   - Male: 1
   - Female: 0

3. How would you describe your ethnicity?
   - White European: 0
   - Other Ethnic Group: 6

4. Do you have a father, mother, brother, sister and/or own child with Type 1 or Type 2 diabetes?
   - Yes: 5
   - No: 0

5. What is your waist circumference? (See instructions)
   - Less than 90 cm: 0
   - 90 - 99 cm: 4
   - 100 - 109 cm: 6
   - 39.4 - 42.9 inches: 4
   - 110 cm & above: 9
   - 43 inches and above: 9

6. What is your Body Mass Index (BMI)? (See instructions)
   - Less than 25: 0
   - 25 - 29: 3
   - 30 - 34: 5
   - 35 & above: 8

7. Has a doctor given you medicine for high blood pressure OR told you that you have high blood pressure?
   - Yes: 5
   - No: 0

Add up your score here - 

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:

\[
LPRS = 0.0407 \times \text{age (years)} \\
+ 0.296 \text{ (if male, no change if female)} \\
+ 0.934 \text{ (ethnicity, as practice proportion SA)} \\
+ 0.0859 \times \text{BMI (kg/m2)} \\
+ 0.440 \text{ (if family history of DM, no change otherwise)} \\
+ 0.374 \text{ (if on antihypertensive medication, no change otherwise)}
\]

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

<table>
<thead>
<tr>
<th>Strategy 1</th>
<th>All subjects undergo OGTT.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strategy 2</td>
<td>All subjects undergo fasting glucose. Those above a certain threshold undergo OGTT.</td>
</tr>
<tr>
<td>Strategy 3</td>
<td>All subjects undergo HbA1c. Those above a certain threshold for HbA1c undergo OGTT.</td>
</tr>
<tr>
<td>Strategy 4</td>
<td>All subjects undergo fasting glucose and HbA1c. Those above a certain threshold undergo OGTT.</td>
</tr>
<tr>
<td>Strategy 5</td>
<td>All subjects undergo self-assessment using a modified ethnic specific FINDRISK score. Those above a certain threshold undergo OGTT.</td>
</tr>
<tr>
<td>Strategy 6</td>
<td>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.</td>
</tr>
<tr>
<td>Strategy 7</td>
<td>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.</td>
</tr>
<tr>
<td>Strategy 8</td>
<td>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.</td>
</tr>
</tbody>
</table>
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.