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Implementation of the automated Leicester Practice Risk Score in two diabetes prevention trials provides a high yield of people with abnormal glucose tolerance

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Abstract

Aims/hypothesis The Leicester Practice Risk Score (LPRS) is a tool for identifying those at high risk of either impaired glucose regulation (IGR), defined as impaired glucose tolerance and/or impaired fasting glucose, or type 2 diabetes from routine primary care data. The aim of this study was to determine the yield from the LPRS when applied in two diabetes prevention trials.

Methods Let's Prevent Diabetes (LPD) and Walking Away from Diabetes (WAD) studies used the LPRS to identify people at risk of IGR or type 2 diabetes from 54 general practices. The top 10% at risk within each practice were invited for screening using a 75 g OGTT. The response rate to the invitation and the prevalence of IGR and/or type 2 diabetes in each study were calculated.

Results Of those invited 19.2% (*n*=3,449) in LPD and 22.1% (*n*=833) in WAD attended. Of those screened for LPD 25.5% (95% CI 24.1, 27.0) had IGR and 4.5% (95% CI 3.8, 5.2) had type 2 diabetes, giving a prevalence of any abnormal glucose tolerance of 30.1% (95% CI 28.5, 31.6). Comparable rates were seen for the WAD study: IGR 26.5%

(95% CI 23.5, 29.5), type 2 diabetes 3.0% (95% CI 1.8, 4.2) and IGR/type 2 diabetes 29.5% (95% CI 26.4, 32.6).

Conclusions/interpretation Using the LPRS identifies a high yield of people with abnormal glucose tolerance, significantly higher than those seen in a population screening programme in the same locality. The LPRS is an inexpensive and simple way of targeting screening programmes at those with the highest risk.

Keywords Impaired glucose regulation · Prevalence · Primary care · Screening · Type 2 diabetes

Abbreviations

ADDITION	Anglo–Danish–Dutch Study of Intensive Treatment in People with Screen Detected Diabetes in Primary Care
GP	General practitioner
IFG	Impaired fasting glucose
IGR	Impaired glucose regulation
IGT	Impaired glucose tolerance
LPD	Let's Prevent Diabetes
LPRS	Leicester Practice Risk Score
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
WAD	Walking Away from Diabetes

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Introduction

Type 2 diabetes is usually preceded by the 'prediabetic' state in which there is impaired glucose regulation (IGR), which includes impaired fasting glucose (IFG) and impaired

glucose tolerance (IGT). Randomised controlled trials have shown that progression from IGR to type 2 diabetes can be prevented through lifestyle or pharmacological intervention [1]. Identification of individuals at high risk of type 2 diabetes is therefore warranted, so that preventive action can be taken. Nevertheless, evidence from the UK is limited despite modelling studies suggesting that screening for IGR followed by appropriate prevention interventions is likely to be cost effective [2].

Risk scores offer a non-invasive way of identifying those at high risk for invitation to screening programmes. A plethora of risk scores have been developed and validated over the past 10 years [3]. Four scores are available for use in the UK. The Cambridge Risk score was designed to identify undiagnosed diabetes [4] and the QDScore predicts 10-year risk of developing diabetes [5]. The Leicester Risk Assessment Score and the Leicester Practice Risk Score (LPRS) are the first scores developed for use in the UK that detect undiagnosed IGR and type 2 diabetes in multi-ethnic populations [6, 7]. The Leicester Risk Assessment score is a questionnaire completed by members of the public without intervention from a heathcare professional or the results of medical tests. The score includes age, sex, ethnicity, BMI, waist circumference, hypertension and family history of diabetes. The LPRS is similar but is for use within primary care databases to rank those listed by risk, this score does not therefore include waist circumference as this is not routinely stored. These risk scores are now recommended by the National Institute for Health and Clinical Excellence (NICE) for risk identification in primary care in the UK [8].

Evidence of the use of risk scores in clinical practice are lacking. Two prevention clinical trials are currently being carried out in the UK that use a risk score for case identification. The aim of this paper is to describe the cohort of 'at risk' people that the score identifies and to report the yield of IGR and type 2 diabetes and compare this with a population-based method of screening.

Methods

LPRS Both the Let's Prevent Diabetes study (LPD) and the Walking Away from Diabetes (WAD) study used a modified version of the LPRS [6] to identify participants at high risk of IGR/diabetes. A higher score reflects higher risk of IGR/type 2 diabetes. The modified score includes the proportion of South Asians within the practice as a proxy for individual ethnicity, reflecting the level of completion of this variable in the electronic medical records at the conception of this project. The score detects IGR or type 2 diabetes based on the OGTT using the WHO 1999 criteria [9]. The score is shown in Fig. 1 with the relative weightings for each variable. A computer programme was written to automate the process.

$$mLPRS = 0.0407 \times age \text{ (years)}$$

$$+ 0.296 \text{ (if male, no change if female)}$$

$$+ 0.934 \text{ (ethnicity, as practice proportion South Asian ethnicity)}$$

$$+ 0.0859 \times BMI \text{ (kg/m}^2\text{)}$$

$$+ 0.440 \text{ (if family history of diabetes, no change otherwise)}$$

$$+ 0.374 \text{ (if on antihypertensive medication, no change otherwise)}$$

Fig. 1 The modified LPRS (mLPRS)

LPD The LPD study has been described in detail elsewhere [10]. Briefly, this was a two-stage project screening for IGR using the risk score followed by a cluster randomised diabetes prevention trial. Forty-four practices were included in the study. The risk score was calculated for all those aged 40–75 years if white European or 25–75 years if South Asian excluding those with known diabetes and terminal illness. The top 10% of patients with the highest scores were invited for screening; in large practices the first 500 were initially invited.

WAD The WAD study screened for those at high risk of diabetes followed by a cluster randomised trial to improve metabolic health and increase physical activity [11]. Ten general practices were included in this study. The risk score was run on the practice database and the top 10% aged 18 years and over (excluding those with known diabetes and those taking steroids) were invited to screening.

Measurements and outcomes Both the LPD and the WAD study used the same standard operating procedures for data collection at the screening visit and the assessment of type 2 diabetes status. All participants received a 75 g OGTT. Participants were categorised according to WHO 1999 criteria [9]. Anyone who had an OGTT result in the diabetes range was recalled for a confirmatory test. In these studies IGR was defined as IFG and/or IGT. IFG was defined as a fasting blood glucose concentration of between 6.1 and 6.9 mmol/l inclusive and IGT as a 2 h blood glucose concentration of between 7.8 and 11 mmol/l inclusive. Those with type 2 diabetes were referred back to their general practitioner (GP) for standard care.

At the screening visit the following data were also collected: HbA_{1c}, cholesterol, BMI, body weight, waist and hip circumference and blood pressure, as well as data on a number of self-reported questionnaires that have been described previously [10, 11].

Statistical methods The primary outcome of the screening phase of both studies was the proportion of people detected with IGR or type 2 diabetes. Although HbA_{1c} was not used for diagnosis in these studies, we also report data on the following categories using HbA_{1c}: 6.0–6.4% (42–47 mmol/mol), ≥6.5% (48 mmol/mol) and ≥6.0% (42 mmol/mol), and those suggested by the ADA: 5.7–6.4% (38–47 mmol/mol) and ≥5.7% (38 mmol/mol) [12]. In addition, we also assessed the yield when using a fasting blood glucose concentration of 5.5–6.9 mmol/l to define IFG, as recommended by NICE [8]. We also assessed the response rate to the invitation to screening.

The response rates and prevalences were compared with those found in the Anglo–Danish–Dutch Study of Intensive Treatment in People with Screen Detected Diabetes in Primary Care (ADDITION)-Leicester study [13]. ADDITION-Leicester used a population-based screening approach in the same locality as LPD and WAD. Random samples of 40- to 75-year-olds (25–75 years for South Asian ethnicity) from 20 general practices were invited for an OGTT [14].

Means (SD) and counts (%) were used to summarise the data. Differences between the studies and screening approaches were assessed using the t test for continuous variables and the χ^2 test for categorical. The prevalence (positive predictive value) of each glucose disorder was calculated for each study. All statistical tests are two-sided and $p < 0.05$ reflects statistical significance throughout.

Results

17,972 people were identified as high risk in the LPD study; 19.2% of those invited attended screening. In the WAD study, 3,769 people were invited and 22.1% attended. No differences in response rates were found between the studies using a risk-score approach and the population-based approach (22.0%, $p=0.88$). In total 4,282 participants were screened (Table 1); 3,449 from LPD and 833 from WAD. The mean age was 63.2 years, 61.4% were male, with the majority being white European (87.0%). LPD and WAD are comparable for the majority of demographic and biomedical characteristics. Those included in the LPD study had a greater waist circumference, systolic blood pressure and antihypertensive use compared with those in the WAD study. Data are not available for those who did not attend screening.

Compared with the participants in the ADDITION-Leicester study, those screened using the risk-score approach were significantly older, more likely to be male, heavier, had higher blood pressure, glucose levels and HbA_{1c} and more likely to be taking lipid-lowering and antihypertensive medications. Higher levels of total cholesterol were observed in the ADDITION-Leicester study, which is probably a reflection of the lower treatment levels (Table 1).

Overall across both studies 30.0% of those screened had abnormal glucose tolerance (Table 2)—30.1% from LPD and 29.5% from WAD. The two studies were similar in the levels of IGR detected, with slightly more type 2 diabetes cases in the LPD study compared with WAD (4.5% vs 3.0%, $p=0.06$). Using a fasting blood glucose range of 5.5–6.9 mmol/l identified around one in three of those at high risk compared with around one in five of those using a population-based approach. Significantly more cases were picked up for each condition compared with the rates found in a study using a population-based screening approach.

Using HbA_{1c} gave higher prevalence across all categories (Table 3). 44.1% had an HbA_{1c} ≥6.0% (42 mmol/mol). Higher levels of both HbA_{1c} 6.0–6.4% (42–47 mmol/mol) and HbA_{1c} ≥6.5% (48 mmol/mol) were seen among participants in the LPD study compared with those screened for WAD. Again significantly higher rates were seen when a two-step approach was used rather than a population-based approach. Using the cut-off points suggested by the ADA [12] significantly increased the yield across all of the studies and screening approaches, for example 75% of those screened using the two-step approach had an HbA_{1c} of ≥5.7% (38 mmol/mol).

Discussion

Finding effective methods to prevent type 2 diabetes is a public health priority and given the unequivocal success of prevention programmes there is an increasing need to develop tools with which to identify high-risk individuals who may benefit from these programmes. This study has shown a higher 'hit rate' when using a two-step screening approach compared with population screening; this is in line with previous studies [15]. This approach has also been shown to be cost effective in modelling studies [16].

Interestingly, although the yield was increased, the uptake to the screening invitation was low and comparable with that found in a population-based screening programme carried out in the same area [14]. This finding suggests that informing people that they are at high risk of diabetes does not increase attendance to screening compared with a generic invitation. This is in contrast to other studies which have shown that risk stratification increases attendance [15]. There are many possible explanations for this. First, the low response rate may be due to people not wanting to take part in the clinical trial, rather than the screening. The National Health Service (NHS) Health Checks Programme, which is not part of a research project, has seen uptake rates of around twice the level we have reported here [17]. Second, everyone received an OGTT. The OGTT is costly, time consuming and inconvenient [18]. Both patients and healthcare professionals have reported that the OGTT is a barrier to attending screening [19]. The ADDITION-Europe study

Table 1 Characteristics of those screened compared with those screened as part of the ADDITION-Leicester study

Characteristic	LPD	WAD	Total	p value (LPD vs WAD)	ADDITION-Leicester	p value (Total vs ADDITION-Leicester)
No. included	3,449	833	4,282		6,479	
Age (years), mean (SD)	63.2 (8.1)	63.1 (8.2)	63.2 (8.1)	0.73	56.1 (10.8)	<0.0001
Sex, male	2,098 (60.8)	529 (63.5)	2,627 (61.4)	0.16	3,221 (49.7)	<0.0001
Ethnicity[a]				0.19		<0.0001
White European	2,989 (86.7)	736 (88.4)	3,725 (87.0)		4,688 (72.4)	
Chinese	2 (0.1)	0 (0)	2 (0.1)		8 (0.1)	
Caribbean/African	72 (2.1)	25 (3.0)	97 (2.3)		129 (2.0)	
South Asian	368 (10.7)	68 (8.2)	436 (10.2)		1,684 (26.0)	
Mixed ethnicity	15 (0.4)	4 (0.5)	19 (0.4)		33 (0.5)	
Weight (kg), mean (SD)	92.3 (17.9)	92.2 (17.6)	92.3 (17.9)	0.85	78.0 (16.1)	<0.0001
BMI (kg/m^2), mean (SD)	32.4 (5.7)	32.5 (5.6)	32.5 (5.7)	0.99	28.1 (5.0)	<0.0001
Waist circumference (cm), mean (SD)	108.8 (12.9)	101.8 (12.4)	107.4 (13.1)	<0.0001	93.9 (13.2)	<0.0001
Men	110.5 (12.1)	103.1 (11.9)	109.0 (12.4)	<0.0001	98.6 (11.5)	<0.0001
Women	106.1 (13.5)	99.6 (13.0)	104.9 (13.7)	<0.0001	89.7 (13.2)	<0.0001
Systolic BP (mmHg), mean (SD)	145.3 (19.1)	142.9 (19.5)	144.8 (19.2)	0.001	137.0 (19.6)	<0.0001
Diastolic BP (mmHg), mean (SD)	86.1 (10.6)	86.6 (10.0)	86.2 (10.5)	0.16	85.4 (10.6)	0.44
Total cholesterol (mmol/l), mean (SD)	5.1 (1.0)	5.1 (1.1)	5.1 (1.0)	0.98	5.5 (1.1)	<0.0001
LDL-cholesterol (mmol/l), mean (SD)	3.0 (0.9)	3.1 (0.9)	3.0 (0.9)	0.31	3.5 (0.9)	<0.0001
HDL-cholesterol (mmol/l), mean (SD)	1.4 (0.4)	1.4 (0.4)	1.4 (0.4)	0.91	1.4 (0.4)	<0.0001
Men	1.3 (0.4)	1.3 (0.4)	1.3 (0.4)	0.58	1.2 (0.3)	<0.0001
Women	1.5 (0.4)	1.5 (0.4)	1.5 (0.4)	0.92	1.5 (0.4)	<0.0001
Fasting glucose (mmol/l), mean (SD)	5.3 (0.8)	5.3 (0.8)	5.3 (0.8)	0.80	5.2 (0.9)	<0.0001
Two-hour glucose (mmol/l), mean (SD)	6.7 (2.7)	6.6 (2.5)	6.7 (2.6)	0.15	6.1 (2.5)	<0.0001
HbA$_{1c}$ (%/mmol/mol), mean (SD)	5.9/40 (0.5)	5.9/40 (0.6)	5.9/40 (0.5)	0.34	5.7/38 (0.6)	<0.0001
Antihypertensive therapy	1,939 (56.2)	430 (51.6)	2,369 (55.3)	0.02	1,532 (23.6)	<0.0001
Statin therapy	1,215 (35.2)	273 (32.8)	1,488 (34.8)	0.01	737 (11.4)	<0.0001
Current smoker	275 (8.0)	76 (9.1)	351 (8.2)	0.28	956 (14.8)	<0.0001

Data are given as n (%) unless otherwise stated

[a] χ^2 tests compare white European with all other ethnicities

used a variety of screening methods to establish a cohort with screen-detected type 2 diabetes [20]. Centres that used a three-step approach, combining a risk score followed by a random blood glucose test followed by an OGTT, had a significantly greater uptake compared with a one-step approach using the OGTT only [15]. Third, both studies have been carried out in Leicester, UK and the ethnic makeup of this locality may have an impact on the response to screening. The area has a high prevalence of ethnic minority groups (ranging from 32% in the city of Leicester to 8% in the county of Leicestershire [according to the 2006 census]).

Lower uptake to screening in those of South Asian ethnicity has consistently been observed [14, 21]. This problem is amplified by the known increased risk of type 2 diabetes in this community [14]. Finally, the method of risk communication used was minimal: potential participants were told that there are risk factors for diabetes, some of which are modifiable and that their medical records suggest they might be at high risk. Informing people of their absolute risk of diabetes and potential benefits of early diagnosis and intervention may have increased uptake to screening. Further investigation into this is warranted

Table 2 Percentage of abnormal glucose tolerance in those screened (positive predictive values) using OGTT

Glycaemic category	LPD	WAD	Total	p value (LPD vs WAD)	ADDITION-Leicester	p value (Total vs ADDITION-Leicester)
Fasting glucose 5.5–6.9 mmol/l [8]	36.4 (34.8, 38.0)	35.9 (32.6, 39.1)	36.3 (34.9, 37.8)	0.76	22.2 (21.2, 23.2)	<0.0001
IFG	7.8 (6.9, 8.7)	9.6 (7.6, 11.6)	8.2 (7.4, 9.0)	0.09	5.0 (4.5, 5.6)	<0.0001
IGT	22.4 (21.0, 23.8)	21.4 (18.6, 24.2)	22.2 (21.0, 23.5)	0.54	13.3 (12.4, 14.1)	<0.0001
IGR	25.5 (24.1, 27.0)	26.5 (23.5, 29.5)	25.7 (24.4, 27.0)	0.58	16.1 (15.2, 17.0)	<0.0001
Type 2 diabetes	4.5 (3.8, 5.2)	3.0 (1.8, 4.2)	4.2 (3.6, 4.8)	0.06	3.2 (2.8, 3.6)	0.01
Any abnormal glucose tolerance	30.1 (28.5, 31.6)	29.5 (26.4, 32.6)	30.0 (28.6, 31.3)	0.74	19.3 (18.3, 20.2)	<0.0001

Data are given as % (95% CI)

Recently the WHO recommended that the diagnostic criteria for type 2 diabetes be revised to include those with an HbA$_{1c}$ of ≥6.5% (48 mmol/mol) [9, 22]. The WHO found insufficient evidence to classify IGR using HbA$_{1c}$ [22]; however, an international expert panel and ADA have suggested that ranges of 6.0–6.4% (42–46 mmol/mol) and 5.7–6.0% (38–42 mmol/mol) can be considered [12]. Based on the ADA criteria, up to two-thirds of the population could fall into this category, which would overwhelm prevention initiatives. Nevertheless, moving away from the OGTT has the potential to increase uptake to screening.

Both studies invited the top 10% at risk within a practice for screening. NICE suggest that the top 50% be invited for further testing [8]. Lowering the cut-point will give potentially lower positive predictive values than seen here as the prevalence of disease will be reduced in a lower risk group. The benefit of using a practice-based risk score for screening is that GP practices can decide where to set the cut-point based on the resources available. The LPRS is the first tool developed for use in GP practices that includes IGR in the conditions detected. Therefore there is limited data with which to compare these results. Alongside the development of the risk score we have also developed a piece of software

that enables integration of this score into routine clinical practice in primary care. Using this tool optimises the high-quality data stored in general practices [23].

There are a number of limitations that must be considered. First, only those at high risk were invited for screening so we are unable to assess sensitivity, specificity and the negative predictive value of the score in this setting. Second, the response rate was low, although this is similar to other studies in similar populations [14]. This reflects the difficulty in recruiting a multi-ethnic urban population with wide variations in social economic status into research studies, which may have affected the representativeness and generalisability of the data. Due to ethical constraints we were not able to collect data on those who were invited but did not attend screening; therefore we are unable to compare the characteristics of those who attended with those who did not. These data were collected in the ADDITION-Leicester study and overall those who attended were older and more likely to be female [14]. Finally, the score used here uses the percentage of South Asians within the practice as a proxy for individual ethnicity. Since the conception of these studies the recording of ethnicity within general practice has improved and the updated version of the LPRS includes an individual's

Table 3 Percentage of abnormal glucose tolerance in those screened (positive predictive values) using HbA$_{1c}$

Glycaemic category	LPD	WAD	Total	p value (LPD vs WAD)	ADDITION-Leicester	p value (Total vs ADDITION-Leicester)
HbA$_{1c}$ 6.0–6.4% (42–47 mmol/mol)	35.0 (33.4, 36.6)	31.9 (28.6, 35.1)	34.4 (33.0, 35.8)	0.09	17.5 (16.6, 18.4)	<0.0001
HbA$_{1c}$ ≥6.5% (48 mmol/mol)	10.0 (8.9, 11.0)	8.9 (6.9, 10.8)	9.7 (8.8, 10.6)	0.34	5.2 (4.7, 5.8)	<0.0001
HbA$_{1c}$ ≥6.0% (42 mmol/mol)	45.0 (43.3, 46.6)	40.7 (37.3, 44.1)	44.1 (42.6, 45.6)	0.03	22.8 (21.8, 23.8)	<0.0001
Cut-points suggested by ADA [12]						
HbA$_{1c}$ 5.7–6.4% (38–47 mmol/mol)	65.0 (63.4, 66.6)	63.5 (60.2, 66.8)	64.7 (63.3, 66.1)	0.41	55.3 (54.1, 56.5)	<0.0001
HbA$_{1c}$ ≥5.7% (38 mmol/mol)	75.0 (73.5, 76.4)	72.3 (69.2, 75.4)	74.5 (73.1, 75.8)	0.12	60.6 (59.4, 61.7)	<0.0001

Data are given as % (95% CI)

ethnicity. Therefore some South Asian participants may have received a falsely reduced score if they belonged to a practice with a high white European population and vice versa.

In summary, using a risk score to identify those at high risk of IGR/type 2 diabetes identifies a high previously undiagnosed yield using either an OGTT (30%) or HbA$_{1c}$ (44%) for diagnosis. Previous population-based screening programmes using universal OGTT have had lower yields of 20%. The LPRS is an inexpensive and simple way of targeting screening programmes at those with the highest risk.

Duality of interest K. Khunti (Chair), M. J. Davies and T. Yates are members of the NICE Public Health Guidance on prevention of type 2 diabetes among people with prediabetes. M. J. Davies and K. Khunti are advisors to the UK Department Health for the NHS Health Checks Programme. M. J. Davies has received funds for research, honoraria for speaking at meetings and has served on Advisory Boards for Lilly, sanofi-aventis, MSD, Novo Nordisk, BMS, BI and Roche. K. Khunti has received funds for research, honoraria for speaking at meetings and or served on Advisory Boards for AstraZeneca, GSK, Lilly, Novartis, Pfizer, Servier and sanofi-aventis. All other authors have no conflicts of interest to declare.

Contribution statement LJG, KK, DW, TY and MJD made substantial contribution to conception and design. CE, SG, JH, DS, SW and TY made substantial contribution to acquisition of data. LJG and DHM analysed and interpreted data. LJG drafted the article and KK, CE, SG, JH, DHM, DS, DW, SW, TY and MJD revised the paper. All authors approved the version to be published.

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