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## Debate and Analysis - Pre-diabetes

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## 25 **Introduction**

26 Pre-diabetes is a term used to describe the state where blood glucose levels are above normal but  
27 below the threshold for diagnosis of diabetes. An estimated 1 in 3 of the adult population of the UK  
28 fall into this group.<sup>1</sup> The addition of a coded entry for pre-diabetes to aid adherence to NICE  
29 guidance on follow up of 'at risk' groups is embedding this label within increasing numbers of  
30 patients' lifelong medical records. This article discusses the meaning and significance of this new  
31 'diagnosis' at individual and societal level, the controversy that surrounds it and implications for  
32 policy, practice and research.

33

## 34 **Identification of pre-diabetes**

35 In the UK pre-diabetes is usually diagnosed on the basis of an HbA1c level of 42-47mmol/mol.<sup>2</sup> The  
36 term is also used to encompass people identified as being at high risk of diabetes by other testing  
37 strategies such as fasting glucose or the OGTT. The groups identified as abnormal by different testing  
38 strategies do not entirely overlap and there is on-going debate about which diagnostic test is most  
39 appropriate and what the cut offs should be.<sup>3</sup> Despite the limitations of HbA1c in certain groups and  
40 its poor sensitivity and specificity if the OGTT is taken as the gold standard,<sup>4</sup> its ease of use makes it  
41 the most commonly used diagnostic test.

42 It is estimated that 5-10% of pre-diabetic people will become diabetic each year with a similar  
43 proportion reverting back to normoglycaemia.<sup>5</sup> Those with a family history, certain ethnic groups  
44 and women with polycystic ovarian disease or previous gestational diabetes are at higher risk of  
45 progression to diabetes.

46 NICE guidance on preventing type 2 diabetes encourages individual risk assessment for diabetes and  
47 advises offering fasting glucose or HbA1c testing to those deemed to be at high risk.<sup>2</sup> For those that  
48 have a high risk score and an abnormal result the guideline advises offering a quality assured  
49 intensive lifestyle change programme and re-measuring weight, BMI and a blood test at least once  
50 per year. This has significant workload implications for general practice and exposes large numbers  
51 of the population to investigations and possible intervention.

52

## 53 **Diabetes prevention programmes**

54 The rationale for identifying those at higher than average risk for developing diabetes is to be able to  
55 intervene to prevent this progression. Internationally, large-scale lifestyle modification programmes  
56 have been developed to try to reduce the rate of development of diabetes, most notably in Finland<sup>6</sup>  
57 and USA.<sup>7</sup> The 'Healthier You' Diabetes Prevention Programme (DPP) was introduced in England in  
58 2016 and is due to be rolled-out nationwide by 2020. Those referred to the DPP are offered 'tailored,  
59 personalised lifestyle behaviour change support over at least thirteen face to face sessions, lasting 1-  
60 2 hours and providing a minimum of 16 hours of contact time, over at least 9 months, aiming to  
61 reduce their risk of type 2 diabetes'.<sup>8</sup>

62 The ability to offer individuals referral to such a lifestyle intervention programme, potentially  
63 avoiding the need for medication and the development of complications of diabetes is appealing.  
64 However, evidence for the real world efficacy of such programmes is sparse.

65 A recent meta-analysis of interventions to prevent diabetes in screen detected pre-diabetes  
66 concluded that individually targeted lifestyle interventions have some efficacy in preventing or  
67 delaying the onset of diabetes but the study quality was often low and the effect attenuated with  
68 time from the intervention.<sup>4</sup> The authors also commented that due to the large number of people  
69 who do not meet the eligibility criteria or decline or fail to complete the intervention, it is not  
70 possible to extrapolate percentage risk reductions seen in trials to a reduction in incidence of  
71 diabetes across an entire community.

72 A recent large scale randomised controlled trial to evaluate the effect of a type 2 diabetes  
73 prevention lifestyle intervention (Let's Prevent) in a UK community setting failed to show a  
74 statistically significant reduction in progression to type 2 diabetes at 3 years compared to normal  
75 care<sup>9</sup> i.e. it failed to do the thing that it was supposed to do. Retrospective re-analysis of the data did  
76 show a significant reduction in progression to diabetes in the sub-group of patients who engaged  
77 and then attended subsequent sessions, with the greatest benefit seen for the 29.1% of patients  
78 randomised to the intervention who attended all sessions. Patients were less likely to engage or  
79 attend follow up if they were male, socio-economically deprived, smokers or physically inactive.<sup>10</sup>  
80 These patient groups are at higher risk of developing diabetes than the background population,  
81 therefore failure to reach them with a lifestyle intervention programme has the potential  
82 unintended consequence of increasing health inequity.

83 To reduce diabetes incidence in the whole population, adequately resourced and integrated public  
84 health, primary care and policy strategies to reduce obesity, reduce sugar intake and increase  
85 physical activity are needed. Targeting individuals to change their lifestyle is by comparison  
86 expensive and likely to be minimally effective for the health of the population as a whole. The  
87 groups of people most likely to be able to engage with such lifestyle change programmes are those  
88 with the least barriers to change (income, education levels, an expectation of healthy years lived),  
89 not those that are most at risk of progression to type 2 diabetes and poorer outcomes. These  
90 psychosocial, cultural and demographic barriers need to be considered and addressed if the  
91 programmes are to be effective.

92

### 93 **Overdiagnosis?**

94 Expanding the definition of what is an 'abnormal' blood sugar result and attaching a new label to this  
95 has consequences both for the individual and for society.

96 Labelling a person as having a 'pre-disease' may have unintended consequences such as health  
97 anxiety and stigma even though it may never cause them to become unwell. With some comparable  
98 conditions, such as CKD 3, where the distinction between 'risk factor', 'biochemical abnormality' or  
99 'disease' can be blurred, explicit discussions are not always had with patients about these labels  
100 (rightly or wrongly).<sup>11</sup> However, the existence of a diagnosis and referral pathway for those with pre-  
101 diabetes attributes significance to the condition as something which requires intervention and  
102 follow up. In an ever increasingly stretched primary care service, the opportunity costs of identifying  
103 and managing a new 'condition' also need to be considered.

104 The term 'pre-diabetes' is already familiar to healthcare practitioners (medical specialists, nurses,  
105 GPs, allied health professionals) and administrators and is likely to gradually be normalised in lay  
106 conversations. More widespread acceptance that this pre-diabetic state can be 'treated' may  
107 contribute to an emergent expectation of prescribed medication, with all of the harms that this may  
108 entail. Pharmaceutical companies may see the potential of a huge and growing market for oral  
109 hypoglycaemics and anti-obesity medications linked to more widespread medicalization and public  
110 fears.

111

### 112 **Conclusions**

113 Guidelines and policy dictate that the term pre-diabetes is here to stay and the nationwide rollout of  
114 the Diabetes Prevention Programme means that GPs, practice nurses and healthcare assistants  
115 across England will be having frequent conversations with patients about this acquired health status.  
116 It is therefore incumbent upon us to maximise the benefits and minimise the harms of these  
117 conversations, perhaps creating an opportunity to take ownership of the label as a motivator for  
118 change before it is fixed in the nation's psyche as a 'disease'.

119

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