

#### INTRODUCTION

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

#### IDENTIFICATION OF PRE-DIABETES

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

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

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

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numbers of the population to investigations and possible intervention.

#### DIABETES PREVENTION PROGRAMMES

The rationale for identifying those at higher than average risk for developing diabetes is to be able to intervene to prevent this progression. Internationally, large-scale lifestyle modification programmes have been developed to try to reduce the rate of development of diabetes, most notably in Finland<sup>6</sup> and the US.<sup>7</sup> The 'Healthier You' Diabetes Prevention Programme (DPP) was introduced in England in 2016 and is due to be rolled out nationwide by 2020. Those referred to the DPP are offered:

*... tailored, personalised lifestyle behaviour change support over at least thirteen face to face sessions, lasting 1–2 hours and providing a minimum of 16 hours of contact time, over at least 9 months, aiming to reduce their risk of type 2 diabetes.<sup>8</sup>*

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

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

A recent large-scale randomised controlled trial to evaluate the effect of a type 2

diabetes prevention lifestyle intervention (Let's Prevent) in a UK community setting failed to show a statistically significant reduction in progression to type 2 diabetes at 3 years compared with normal care,<sup>9</sup> that is, it failed to do the thing that it was supposed to do. Retrospective re-analysis of the data did show a significant reduction in progression to diabetes in the subgroup of patients who engaged and then attended subsequent sessions, with the greatest benefit seen for the 29.1% of patients randomised to the intervention who attended all sessions. Patients were less likely to engage or attend follow-up if they were male, socioeconomically deprived, smokers, or physically inactive.<sup>10</sup> These patient groups are at higher risk of developing diabetes than the background population, therefore failure to reach them with a lifestyle intervention programme has the potential unintended consequence of increasing health inequity.

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

#### OVERDIAGNOSIS?

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

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#### ADDRESS FOR CORRESPONDENCE

##### Helen Twohig

Academic Department of Primary Medical Care, University of Sheffield, Samuel Fox House, Northern General Hospital, Herries Road, Sheffield S5 7AU, UK.

Email: [h.twohig@sheffield.ac.uk](mailto:h.twohig@sheffield.ac.uk)

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

The term ‘pre-diabetes’ is already familiar to healthcare practitioners (medical specialists, nurses, GPs, allied health professionals) and administrators, and is likely to be gradually normalised in lay conversations.

More widespread acceptance that this pre-diabetic state can be ‘treated’ may contribute to an emergent expectation of prescribed medication, with all of the harms that this may entail. Pharmaceutical companies may see the potential of a huge and growing market for oral hypoglycaemics and anti-obesity medications linked to more widespread medicalisation and public fears.

#### CONCLUSIONS

Guidelines and policy dictate that the term pre-diabetes is here to stay and the nationwide roll-out of the DPP means that GPs, practice nurses, and healthcare assistants across England will be having frequent conversations with patients about this acquired health status.

It is therefore incumbent upon us to maximise the benefits and minimise the harms of these conversations, perhaps creating an opportunity to take ownership of the label as a motivator for change before it is fixed in the nation’s psyche as a ‘disease’.

##### Helen Twohig,

GP and Honorary Clinical Fellow, Academic Unit of Primary Medical Care, University of Sheffield, Northern General Hospital, Sheffield.

##### Victoria Hodges,

GP Academic Fellow, Academic Unit of Primary Medical Care, University of Sheffield, Sheffield.

##### Caroline Mitchell,

Senior Clinical Lecturer and GP, Academic Unit of Primary Medical Care, University of Sheffield, Sheffield.

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