EDITORIALS

Time to question the NHS diabetes prevention programme

Public Health England's focus on individual behaviour change is unlikely to stem the epidemic of type 2 diabetes

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A new Public Health England report on the rising prevalence of type 2 diabetes proposes targeting people with non-diabetic hyperglycaemia (defined as an HbA_{1c} concentration of 42-47 mmol/mol) with behavioural interventions (diet and exercise).[1] Action for this group (10.7% of the adult population) is to be the cornerstone of the NHS Diabetes Prevention Programme, which will be rolled out nationally from 2016.[2]

Such individualised policy is divorced from the multilevel, community-wide, and politically engaged prevention plans recommended by the World Health Organization[3] and Robert Wood Johnson Foundation.[4] In its report on non-communicable disease WHO calls for "multisectoral action that simultaneously addresses different sectors that contribute to the production, distribution and marketing of food, while concurrently shaping an environment that facilitates and promotes adequate levels of physical activity."[3]

Targeting individual behaviour as a preventive strategy rests on five doubtful assumptions: that it is possible, on the basis of a risk score and blood test, accurately to identify a population subgroup with the highest risk of developing diabetes; that individuals thus targeted will behave like participants in research studies; that behaviour changes will be sustained indefinitely; that clinically important improvements in patient relevant outcomes will follow; and that the programme will be affordable and cost effective.

Risk scores and confirmatory tests of hyperglycaemia are imperfect. People excluded on the basis of a risk score (hence, not offered testing) may be falsely reassured.[5-8] For example, few risk scores ask about a history of gestational diabetes, which disproportionately affects Asian women and increases the risk of type 2 diabetes sevenfold.[9] Three systematic reviews (not cited in the Public Health England report) were circumspect about the usefulness of diabetes risk scores and warned that a

score's external validity may be weak if the population on which it is used differs from the one on which it was developed.[5 7 8]

The risk scores were designed to predict type 2 diabetes, but the Public Health England report seems to conflate this with their ability to detect non-diabetic hyperglycaemia. Using HbA_{1c} to identify non-diabetic hyperglycaemia defines twice as many people as "prediabetic" than does the gold standard but impractical oral glucose tolerance test[10]; it may be inaccurate in some groups.[11-14] Substantial underdiagnosis and overdiagnosis is thus likely, with huge workload implications for both primary care and community services.

Public Health England justifies its proposed policy using a new (non-peer reviewed) meta-analysis of behavioural interventions in diabetes prevention,[15] which extends a previous meta-analysis.[16] The 36 primary studies are described—somewhat curiously—as "pragmatic" and "real world." Yet each was limited to a tightly specified individual intervention delivered as part of a research study; half were randomised trials.[15] Average follow-up was one year. All participants met specific inclusion criteria, including willingness to engage and, in most if not all cases, speaking the same language as the researchers. Individuals drawn from an unselected, free living population are unlikely to respond similarly, given their lower health literacy, higher comorbidities, and greater ethnic diversity,[17-19] and changes achieved by short term interventions may not be maintained in the longer term.[20-22]

The pathogenesis of diabetes incorporates genetic, physiological, psychological, sociological, and wider environmental influences that play out differently for different individuals in different settings.[23] Overlooking this complex reality, Public Health England's meta-analysis sought to identify components of behavioural interventions associated with "success," usually measured by surrogate endpoints. For example, it says: "Offering

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13 or more contacts over the first 18 months was associated with a 3.15 kg greater weight loss in intervention arms compared to control arms, than offering less than eight contacts."[15] Statements of this kind were used to build a specification for a complex intervention that would, its architects assumed, be maximally effective across a diverse population. Implicit in this approach is the flawed assumption that particular components of a complex intervention have a transferable effect size whatever else they are combined with, whoever receives the intervention, and in whatever context.[23-26]

The NHS Diabetes Prevention Programme expects a 26% reduction in incidence of diabetes and implies that associated morbidity and mortality will fall. Yet the meta-analysis contains no evidence of any sustained reduction in morbidity or mortality relating to diabetes or cardiovascular disease after lifestyle intervention in prediabetes.[15] Rather, it focuses on changes in surrogate endpoints that were statistically but not clinically significant, such as HbA_{1c} reduction of 0.07%, two hour glucose reduction of 0.28 mmol/l, and weight reduction of 1.57 kg.[15] A newly published evidence synthesis of the effect of lifestyle interventions on overall mortality in prediabetes cites 17 trials that failed to show a significant effect and one that just reached statistical significance.[27] Effects tend to be far smaller in unselected free living populations than in trial participants.[28]

Astonishingly, given that this lifestyle intervention will become national policy, the Public Health England reports offer no formal estimate of the programme's cost or cost effectiveness. The assumption that it will save money is based on speculation that the intervention will produce "optimal effects whilst keeping costs to a minimum."[15] The proposed payment by results model may create perverse incentives to focus on "compliant" populations rather than those at greatest risk of diabetes, which often experience multiple barriers to achieving the desired outcomes.[29 30]

The public consultation on England's proposed NHS Diabetes Prevention Programme runs until 18 September 2015 (www.england.nhs.uk/ourwork/qual-clin-lead/action-for-diabetes/diabetes-prevention). We have serious concerns that the programme consists entirely of a top down, highly standardised behavioural intervention offered to a fraction of the population. Public Health England's estimates suggest that 18.2% of adults in England now have abnormal glucose metabolism (10.7% prediabetic, 7.5% diabetic) and that this figure is rising. This surely necessitates investment in population based strategies such as improving the neighbourhood environments for healthy food choices and physical activity opportunities as well as support for individuals.[10 29 30 31] Readers who share our concerns may wish to contribute their views to the consultation.

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