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EDITORIALS

New hypertension guidance risks overdiagnosis and overtreatment

The boundaries of disease should be defined by multidisciplinary panels, including patients

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The UK's National Institute for Health and Care Excellence (NICE) has launched an updated draft guideline for the diagnosis and management of hypertension in adults.[1] The main changes are to recommend drug treatment of stage 1 hypertension for people with a 10% risk of cardiovascular diseases over 10 years—down from a previous threshold of 20%—and to consider treating younger adults with a risk below 10%. NICE presents limited evidence for these recommendations, concluding that "evidence suggested some benefit of treating people with stage 1 hypertension" but "most uncertainty was in treating stage 1 hypertension, particularly for people with a lower cardiovascular risk."[1]

Lowering the threshold for treating hypertension has implications beyond changes to disease definitions, including risks to our wellbeing and shifts in our conceptualisation of health and disease. The new draft NICE guidance has at least three serious problems.

Firstly, the guidance does not benefit from a recently published checklist of eight essential items that must be considered before modifying a disease definition.[2] This checklist has been used to scrutinise the 2017 American College of Cardiology/American Heart Association (ACC/AHA) hypertension guideline,[3] concluding that most new "patients" created by the expanded criteria will not benefit from the label "hypertensive." One item in the checklist (differences between new and previous definitions) is assessed adequately in the NICE guidance; one is assessed inadequately (reasons for modification); and the remaining six items are not assessed at all (box 1).

Box 1: Checklist items for modifying the definition of diseases[2] not assessed in NICE hypertension guidance

Number of people affected—Expected influence of the change on prevalence and incidence of the disease

Prognostic ability—Ability of the new disease definition to accurately predict clinically meaningful outcomes for the patient

Precision and accuracy of disease definition—Repeatability, reproducibility, and accuracy of the new definition

Benefit—Incremental benefit of the change, including non-health outcomes, with an assessment of certainty using validated methods such as GRADE

Harm—Incremental harms of the change, including overdiagnosis, non-health outcomes, and resource implications, for the wider health system

Net benefits and harms—Consideration of the balance between all harms and benefits, reflecting the values and preferences of patients and the wider community, including effect on resources

The only harms mentioned in the new draft guidance are hypotension and "harms, such as injury from falls and acute kidney injury."[1] However, five decades of studies have reported the harms associated with being labelled hypertensive.[4 5] These include increased absenteeism from work, lower self rated health, and psychological and marital harm from, for example, anxiety and depression.[3-5] In addition, the SPRINT trial, to which the guidance refers, found that 1 in 50 patients experienced serious adverse drug effects during 3.3 years of intense treatment.[3] These included hypotension, syncope, electrolyte derangements, acute kidney injury, and acute renal failure.

Secondly, the guidance gives insufficient attention to patients' preferences and values, one of the three fundamental principles of evidence based medicine.[6] NICE highlights "the importance of discussing the person's preferences and encouraging lifestyle changes before starting treatment"[1]; but how should this be done in the face of so much uncertainty (box 1), including limited evidence? Furthermore, robust evidence shows that lifestyle interventions offered after a health check (plus pharmacological primary prevention for some) have no effect on cardiovascular

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mortality or morbidity even among people with identified risk factors or hypertension.[7]

Thirdly, the guidance is not explicit about why a 10% risk of cardiovascular disease over 10 years should be classified as a disease. This is a fundamental question. The ontological status of hypertension is primarily as a risk factor[4]: the higher the blood pressure, the greater the risk of cardiovascular disease, and the better the chance of benefit from drug treatment.[8] Blood pressure is a continuum with no clear boundary between normal (health risk small enough to be accepted) and pathological (health risk unacceptably high). To avoid overmedicalising healthy people, recommendations must be evidence based and follow a detailed consideration of the consequences of any changes for individuals, populations, and health systems. This has not been done for NICE's proposed changes, but use of the 2017 ACC/AHA guidance labels 46% of all US adults[9] and 63% of those aged 45 to 75[10] as having hypertension.

Problematic discourse

The draft NICE guidance represents passive support for a well known and problematic discourse—the illusory aim of modern public health to eliminate any risk, accident, pain, disease, aging, and death.[11] To help change this discourse, diagnostic thresholds and the boundaries of disease should be defined not by disease specialists but by financially independent, people centred panels that are led by primary care[12] and include research methodologists, experts in critical appraisal, healthcare consumers, and health economists.

This approach encourages explicit consideration of the harms of overdiagnosis, which can be physical, psychosocial, societal, cultural, and financial.[13] It also ensures that discussions about the benefits and harms of changes to disease definitions or thresholds for treatment are based on outcomes meaningful to patients and the public rather than surrogate markers.

People centred evaluation changes the viewpoint of proposed guidance from that of the health professional to that of the individual, while multidisciplinary input allows a broad perspective beyond the narrow concerns of treatment. There is still time for NICE to think again, more collaboratively, about the proposed expansion of drug treatment for stage 1 hypertension.

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