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# Caution! Diagnosis creep

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#### Key words

conflict of interest, drug industry, guidelines, overdiagnosis

Aust Prescr 2016;39:30-1 http://dx.doi.org/10.18773/ austprescr.2016.021 Twenty years ago British GP Iona Heath observed that one of the key roles of the GP was to help protect people from the unnecessary diagnosis of disease.¹ Perhaps the biggest challenge for doctors who take that role seriously comes from expanding disease definitions. The current definition of 'chronic kidney disease' labels 10% of the adult population as having the condition.² New criteria almost triple the number of pregnant women labelled as having gestational diabetes.³ Thresholds defining attention deficit hyperactivity disorder continue to fall, meaning more children and adults will be diagnosed.⁴

We are labelling more and more healthy people as sick and building bigger potential markets for those selling medicines. For some of the newly labelled patients there will no doubt be benefits, but for others with mild problems or at very low risk of illness, a diagnosis can bring more harm than good, leading to overtreatment and wasting precious resources that could be better directed to those in genuine need.

The process of broadening definitions can be described as 'diagnosis creep' and often results from guidelines prepared by expert panels. In 2013

colleagues and I analysed recent changes made by expert panels to the definitions of 14 common conditions, including hypertension, depression and Alzheimer's disease.5 Of 16 publications from the panels, only one proposed a narrower definition, for five the impacts were unclear, and 10 proposed an expanded definition - pre-diseases were created, thresholds were lowered, or diagnostic processes changed to enable earlier diagnosis. In no case did a panel rigorously investigate and report on the potential danger that some people may be caught unnecessarily by the newly widened definitions. Among the panels that disclosed competing interests, 75% of panel members had multiple financial ties to a median of seven drug companies each. These members were paid by companies for activities like speaking, consulting, advising or researching. This is in direct contrast to recommendations from organisations like the US Institute of Medicine for more independence among those who write guidelines.6

For instance, among the blood pressure guideline panel that in 2003 created 'pre-hypertension', 80% of members disclosed ties to 12 companies each.<sup>5</sup> Eight of the 11 members had financial ties to pharmaceutical companies that sold drugs for hypertension.

Over half of the members of the 2011 joint US National Institute on Aging – Alzheimer's Association panel that described 'pre-dementia' and defined 'pre-clinical' Alzheimer's disease had financial ties to a median of five companies. Similarly for the 2012 psychiatric panels, which widened the definitions of depression and attention deficit hyperactivity disorder, over half disclosed links to companies, including those that could directly benefit from expanded patient populations.

The decisions made by these heavily conflicted panels are not abstract academic exercises. They ultimately influence whether or not an individual is labelled as 'diseased', changing their life's narrative. Moreover, decisions that expand patient populations profoundly affect where we spend our health resources.

Health professionals should be more aware, and patients and the public better informed, about the controversy surrounding many contemporary definitions of disease. Diagnostic criteria are not set in stone – they are regularly changed, often with the best of intentions, but are also often rigorously challenged because of the potential for unintended

## From the Editor



NPS MedicineWise, the publisher of *Australian Prescriber*, has decided to cease publication of the journal in print. In addition, the journal's website australianprescriber.com, established in 1996, will be replaced by a new website hosted by NPS MedicineWise. The *Australian Prescriber* team would like to thank Greg Buchberger (GBI Creative) who has been the journal's webmaster for over a decade. In future, health professionals who wish to continue to

read Australian Prescriber need to register at nps.org.au/australianprescriber.

This penultimate issue of the printed *Australian Prescriber* has a focus on osteoporosis. Angela Sheu and Terry Diamond discuss diagnosis, while Akhil Gupta and Lyn March review its management. Chris Daly describes the dental problems that can result from the treatment of osteoporosis.

While relatively few patients with minimal trauma fractures are investigated for osteoporosis, in other conditions there is overdiagnosis. Ray Moynihan discusses this diagnosis creep.

Borderline personality disorder is often undetected. While management can be challenging, Andrew Chanen and Katherine Thompson tell us that drugs are not first-line therapy.

Managing menstrual problems in women with intellectual disability may also seem challenging, but Jane Tracy, Sonia Grover and Sandra Macgibbon provide helpful advice. The approach to management should be the same as it is in other women.

harms. A peer-reviewed series in the BMJ is currently examining expanding disease definitions and the risk of overdiagnosis. The series has included articles on the evidence underpinning the controversy over gestational diabetes,<sup>3</sup> attention deficit hyperactivity disorder,<sup>4</sup> chronic kidney disease,<sup>7</sup> pre-dementia,<sup>8</sup> mild hypertension<sup>9</sup> and pulmonary embolism.<sup>10</sup>

With gestational diabetes for example, proposals to lower diagnostic thresholds and dramatically expand the patient population have generated ongoing criticism that too many women will be labelled unnecessarily.<sup>11</sup> The proposals have been rejected by an independent panel constituted under the US National Institutes of Health consensus development conference series.<sup>12</sup>

Health professionals can help to expose and challenge diagnosis creep, and improve disease definitions. A group of doctors in the UK has successfully lobbied the Royal College of General Practitioners to set up a standing committee to address overdiagnosis, <sup>13</sup> and similar moves are afoot in Australia. Across Europe the new 'quaternary prevention' movement is also gathering strength within primary care. This doctor-led movement is aimed at preventing people receiving diagnoses that may bring them more harm than good. <sup>14</sup>

Globally, efforts are underway from a range of organisations including the Guidelines International Network, to produce new guidelines for guidelines, to encourage expert panels to rigorously examine both benefits and harms before they shift diagnostic thresholds. In line with the Institute of Medicine's recommendations for more independence in guideline panels,<sup>6</sup> a new approach must surely also mean an end to panel members being speakers or consultants for companies that directly benefit from their deliberations on diagnosis. While it is more difficult to find unconflicted experts, practical models do exist, including the National Institutes of Health consensus development panels.<sup>12</sup>

These efforts to reform the way diseases and diagnostic thresholds are set are happening concurrently with related initiatives to combat medical excess, like the Choosing Wisely Australia campaign. This aims to reduce use of unnecessary tests and treatments.<sup>15</sup>

Finally, in the interest of protecting people from the dangers of diagnosis creep, one might take the provocative advice of Dr Iona Heath. Addressing a symposium about the problem of too much medicine in Canada in 2014, Dr Heath prescribed this solution: 'Whenever I see the sort of guidelines that are, right now, driving overdiagnosis and overtreatment, I think of this: our responsibility not to follow the rules.' 16

Conflict of interest: Ray Moynihan is a member of the scientific committee that is organising the international scientific conference Preventing Overdiagnosis. He is also a member of the planning committee for the Australian Preventing Overdiagnosis and Overuse meetings.

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