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# LETTERS

## HOW SHOULD WE DEFINE HEALTH?

### Proposal for new definition

Huber and colleagues rightly challenge the validity, in the 21st century, of the World Health Organization’s definition of health.<sup>1</sup>

Adaptation and self management are important qualities, but a contemporary definition should include health being a human right protected by certain entitlements and a resource for life that is affected by social, political, economic, and environmental factors.<sup>2</sup>

Public health has always worked on the premise that changes to these types of environment result in greater health gains than any individual action.<sup>3</sup> Because of inequities, many of the current problems that drive ill health in low and middle income countries are outside the control of the dispossessed, the poor, and the disenfranchised. Although we can see the therapeutic approach in which adaptation and self management are desirable, particularly in wealthy developed countries, we fail to see how this approach offers much hope to less advantaged populations. Any definition of health must recognise the effects of this fundamental and growing inequity.

To make meaningful differences for those who need them most, we need systems approaches to policy, legislation, and environments—not just individual approaches to behaviours. A new definition should highlight underlying determinants that are less amenable to self management and consider change to policies and environments.<sup>4 5</sup> This is the purview of policy decision makers rather than consumers.

An alternative definition might be: health is created when individuals, families, and communities are afforded the income, education, and power to control their lives; and their needs and rights are supported by systems, environments, and policies that are enabling and conducive to better health.

We draw your attention to an IUHPE document that outlines health promotion approaches to non-communicable diseases ([www.iuhpe.org/uploaded/Activities/Advocacy/IUHPE\\_KeyMessagesNCDs\\_WEB.pdf](http://www.iuhpe.org/uploaded/Activities/Advocacy/IUHPE_KeyMessagesNCDs_WEB.pdf)).

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Competing interests: None declared.

- 1 Huber M, Knottnerus JA, Green L, van der Horst H, Jadad AR, Kromhout D, et al. How should we define health? *BMJ* 2011;343:d4163. (26 July.)
- 2 WHO. Ottawa charter for health promotion. 1986. [www.who.int/hpr/NPH/docs/ottawa\\_charter\\_hp.pdf](http://www.who.int/hpr/NPH/docs/ottawa_charter_hp.pdf).
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### WHO definition is still valid

I was surprised by Huber and colleagues’ arguments for denouncing the World Health Organization’s definition of health, which has stood for more than 60 years.<sup>1</sup>

It made me wonder why anyone would question this definition, especially with so many

people living with chronic disease. It struck me that the authors wished to diminish the suffering that is associated with many chronic conditions because the patient may on the surface be functioning well.

Someone is healthy or not, in my opinion. There is no shame in having a chronic condition, and society should not turn its gaze from the truth—that many people are not well. Many people have chronic conditions. Many people suffer, often behind closed doors.

In my experience, most people with chronic conditions aspire to physical, mental, and social wellbeing. Most of them acknowledge that they may never again attain such a state of health. Acceptance of this fact is part of the process of moving on with their lives. However, they will never be healthy.

It is wrong to dismiss ill health in the way Huber

and colleagues propose because people with ill health deserve our support, if not sympathy. We are all vulnerable. There is no shame in being unwell or unhealthy, and this article does nothing to increase understanding of what it is like to live with a chronic condition.

The 1948 WHO definition of health is therefore as valid today as it was when it was published: “Health is a state of complete physical, mental, and social wellbeing and not merely the absence of disease or infirmity.”

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- 1 Huber M, Knottnerus JA, Green L, van der Horst H, Jadad AR, Kromhout D, et al. How should we define health? *BMJ* 2011;343: d4163. (26 July.)

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### Health is state of wellbeing

Huber and colleagues define survival, not health. Theirs is a reductionist approach, which perhaps tries to mitigate healthcare’s mission creep and the inflated expectations laid at its door.<sup>1</sup>

The 1948 World Health Organization definition is an aspiration, but just because it is difficult to achieve, do we have to abandon it?

Far reaching as complete wellbeing may be, it calls on spheres other than healthcare to help deliver this definition of health. It calls on political and economic domains to contribute in more innovative and imaginative ways, rather than to delegate and pass the buck.

The components of “wellbeing” vary between people, societies, cultures, and eras. Maslow’s “hierarchy of needs” encapsulates many of the headings,<sup>2</sup> even if the pyramidal order in which they are arranged is questionable. Freedom from fear, including fear of ill health, is another component. Balance and perspective are also key foundations, while the central fulcrum is the ability to love.

Wellbeing is a concept shared across all human boundaries and is the final common pathway to which all these varying components lead. To paraphrase the original definition, health is the state of physical, mental, and social wellbeing, which gives a sense of completeness.

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Competing interests: None declared.



- 1 Huber M, Knottnerus JA, Green L, van der Horst H, Jadam AR, Kromhout D, et al. How should we define health? *BMJ* 2011;343:d4163. (26 July.)
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## A working definition of health

For general use I think a useful working definition is: “the ability to work, love, and sleep” (interpreting the words fairly broadly).<sup>1</sup>

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Competing interests: None declared.

- 1 Huber M, Knottnerus JA, Green L, van der Horst H, Jadam AR, Kromhout D, et al. How should we define health? *BMJ* 2011;343:d4163. (26 July.)

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## PAIN AND AGITATION IN DEMENTIA

### What is agitation?

Husebo and colleagues present their study of the effect of analgesia on agitation as part of the important drive to reduce prescription of antipsychotics to nursing home patients with dementia.<sup>1</sup> However, more than a quarter of the patients were also taking antipsychotics, and their study was not placebo controlled, unlike the antipsychotic studies with which they compare their results. The implication—that analgesia is as effective as antipsychotics—is therefore an oversimplification. Both have their place, but where?

High dose paracetamol is probably a safe first step, and this is an important advance. We also know that a short course of antipsychotics can help if the patient is angry, hostile, or suspicious.<sup>2</sup> But which symptoms should we target with opiates?

Agitation is a complex entity. Study reports should detail the symptom response profile of its components as well as the summative scores. Otherwise we risk promoting a single reaction to a complex problem.

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Competing interests: None declared.

- 1 Husebo BS, Ballard C, Sandvik R, Nilsen OB, Aarsland D. Efficacy of treating pain to reduce behavioural disturbances in residents of nursing homes with dementia: cluster randomised clinical trial. *BMJ* 2011;343:d4065. (15 July.)
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### Pain is not sole cause

When someone with severe communication difficulties is agitated and distressed, it is tempting to try analgesia on the assumption that pain is common,<sup>1</sup> but this approach is flawed.

Firstly, behavioural disturbances can have many different causes; causes such as constipation will be worsened by opioid analgesia.

Secondly, there is no convincing evidence that pain produces unique signs and behaviours.<sup>2</sup>

Thirdly, pain tools in people with severe communication difficulties have poor validity.<sup>3</sup> Tools such as PAINAD detect causes of distress that are not pain,<sup>4</sup> creating mistakenly high estimates for the prevalence of pain in dementia.

The approach recommended by Husebo and colleagues exposes patients and clinicians to risks.<sup>1</sup> Distress behaviours will be assumed to be pain and analgesia started—an approach that would be considered poor practice in any pain or palliative care service. In addition, 22% of the patients with dementia in their study were receiving buprenorphine; the temptation to apply strong opioid transdermal patches to distressed patients with dementia and who refuse oral drug treatment risks replacing adverse effects from antipsychotic drugs with adverse effects from opioids, including increased agitation.

Effective dementia care has always prided itself on careful assessment and multi-modal approaches to supporting distressed patients. Documenting signs and behaviours is only the start to identifying the cause.<sup>5</sup> Analgesia should be at the end of that process, not the beginning.

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- 1 Husebo BS, Ballard C, Sandvik R, Nilsen OB, Aarsland D. Efficacy of treating pain to reduce behavioural disturbances in residents of nursing homes with dementia: cluster randomised clinical trial. *BMJ* 2011;343:d4065. (15 July.)
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## Authors' reply

The absence of a placebo group is an obvious and acknowledged consideration in the interpretation of our results. Our point is that the effect size compared with the control condition of treatment as usual was within the magnitude reported by others with antipsychotic drugs,<sup>1</sup> and thus analgesics may represent an alternative to antipsychotics for some patients. We also agree that identifying the specific symptoms that are most likely to benefit from analgesics, or from antipsychotics, is an important



question. We are currently performing detailed secondary analyses, although we also emphasise the importance of not over-interpreting exploratory data.

We agree with Regnard that careful assessment and a multi-modal approach to treating people with dementia is crucial. Indeed, in partnership with the Alzheimer's Society and Department of Health in the UK we have developed a treatment pathway which considers pain as well as other multifactorial elements.<sup>2</sup> We emphasise that most analgesia in our study was with paracetamol.

Identifying painful medical conditions is a key part in evaluating people with dementia, and analgesia should be considered to be one of several potential management strategies for behavioural and psychiatric symptoms. Our results do suggest, however, that analgesia is potentially beneficial even in people without severe or overt pain and may be an additional potential treatment option even for them.

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Competing interests: None declared.

- 1 Ballard CG, Gauthier S, Cummings JL, Brodaty H, Grossberg GT, Robert P, et al. Management of agitation and aggression associated with Alzheimer disease. *Nature Rev Neurol* 2009;5:245-55.
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## WORKING DURING SHORT ILLNESSES

### Study should be seen in perspective

Dew highlights presenteeism, the pressure to work during short term sickness.<sup>1</sup> This important phenomenon must be kept in perspective.

All workers face health issues at times during their careers. Employers should invest in the health of their workforce to enhance performance and productivity. To cure presenteeism, first encourage action that enables employees to continue their activities when health issues arise by making adjustments and providing effective occupational health support.

Dew cites studies that indicate a high prevalence of presenteeism—for example, over four weeks a third of doctors and nurses worked when they should have taken sick leave.<sup>2</sup> This is a bold claim and will not match many people's experience. It is based on a study of only 32 doctors in Finland. In contrast, only 1% of more than 150 000 NHS staff responding to the 2010 NHS staff survey in the UK indicated that they had not been able to do their daily work for either a physical or psychological reason during the previous four weeks.<sup>3</sup>

Dew also suggests that women may attend work more when ill. The higher rates of sickness absence among female workers are well known.<sup>4</sup> The suggestion that work related factors have a bigger effect on presenteeism than personal circumstances is based on one study of 32 doctors and 137 nurses.<sup>2</sup> Only limited evidence suggests that presenteeism leads to significant morbidity (especially when health issues at work are effectively managed).

Workers have health issues. Employers need to take action and provide suitable occupational health support. Healthcare workers have particular needs, and NHS occupational health services should be suitably commissioned and configured to meet them.<sup>5</sup>

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Competing interests: None declared.

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## AGE RELATED MACULAR DEGENERATION

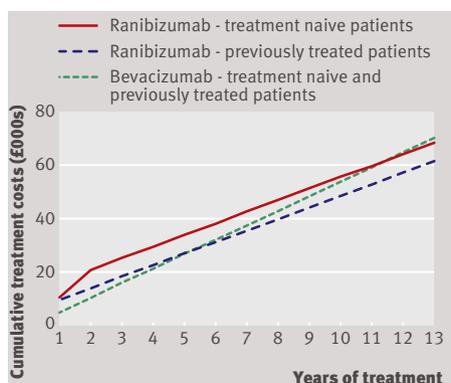
### Ranibizumab and bevacizumab cost comparison

Wet age related macular degeneration (AMD) is the leading cause of blindness in the UK.<sup>1</sup> Most UK patients are treated with ranibizumab (Lucentis, Novartis), according to National Institute for Health

and Clinical Excellence (NICE) guidance. The NHS pays for the first 14 injections; thereafter, the cost is reimbursed by Novartis, but the NHS still spent £138m (€159m; \$225m) on ranibizumab in 2010.<sup>2</sup>

The CATT trial reported that bevacizumab produced an equivalent visual outcome but cost \$385 per patient per year compared with \$13 800 for ranibizumab.<sup>3</sup> Although ranibizumab is licensed for the treatment of wet AMD, bevacizumab is not. Both drugs are owned by Genentech. Many UK healthcare commissioners are requesting that ophthalmologists prescribe bevacizumab instead of ranibizumab to reduce costs.<sup>4</sup>

We undertook an economic evaluation that included a UK comparison of ranibizumab and bevacizumab.<sup>5</sup> The figure shows our projection extended to 13 years, the average life expectancy of someone diagnosed with wet AMD.



**Per patient cumulative treatment costs for bevacizumab and ranibizumab. Projections include NHS drug costs, outpatient charges, and cost of giving intravitreal injections. Costs are for treatment naive patients and those who have had eight previous injections of ranibizumab**

Over a three year projection, the cost of ranibizumab would need to be reduced to £235 (from £913), with retention of the reimbursement scheme, to give equivalent costs in treatment naive patients. In previously treated patients this figure is £550. If drug costs remained unaltered the NHS could save £190m over three years, using bevacizumab to treat 26 000 new cases each year. It is estimated that 414 561 patients have wet AMD.<sup>6</sup> Assuming NICE's estimate of 80% eligibility, eight previous injections of ranibizumab,<sup>5</sup> and an annual death rate of 7.7%,<sup>7</sup> then a switch to bevacizumab would save £556m over three years.

These projections involve several assumptions and caveats, detailed in our report.<sup>5</sup> They do not consider any potential differences in safety, medicolegal risk, treatment burden, or patient preference, and neither do they recognise commercial drug development costs. Nonetheless, there seems to be an economic argument for adopting bevacizumab in treatment naive patients or renegotiating the cost of ranibizumab.

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**Competing interests:** No competing interests related to this work itself. TLJ has received research funding from NeoVista, Novartis, Oraya, and Thrombogenics; he has worked as a consultant to, or is on the advisory board of, DORC, Thrombogenics, Bausch & Lomb, NicOx, and Merck. LK has received funding from NeoVista.

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## TIOTROPIUM MIST INHALER

### Manufacturer's reply

Seed and colleagues suggest that the excipient benzalkonium chloride in the Respimat mist inhaler might partly explain the differences seen between placebo and the Respimat inhaler.<sup>1</sup> The hypothesis is unfounded for three reasons.

Firstly, the placebo in clinical trials with tiotropium Respimat was identical to the active treatment except for the lack of the active chemical entity. All treatment groups therefore received the excipients.

Secondly, the concentration of benzalkonium chloride in Respimat solutions (100 µg/mL) is within the range typically used in nebuliser solutions. However, the nebulised volume of about 20 µL per clinical dose is much smaller than that used with nebulisers, and the delivered dose of 2 µg benzalkonium chloride is 20-200 times lower. European Commission guidelines require a label statement "may cause bronchospasm" for a respiratory product once a threshold of 10 µg for the delivered dose of benzalkonium chloride is reached.<sup>2</sup>

Thirdly, in clinical trials of bronchodilators via Respimat inhaler in asthma and chronic obstructive pulmonary disease the incidence of events possibly indicative of administration related bronchoconstriction, such as an asymptomatic decrease in FEV<sub>1</sub> (forced expiratory

volume in one second), was low and similar to pressurised metered dose inhalers in a similar population.<sup>3,4</sup>

The chemical term benzalkonium chloride encompasses a variety of quaternary ammonium compounds. Case reports of occupational asthma after exposure to a technical detergent quality product are not predictive for the tolerability and safety of a pharmaceutical grade quality one.<sup>1</sup>

There is no rational basis to assume that the small dose of benzalkonium chloride delivered via the Respimat inhaler may adversely affect tolerability and safety.

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- 1 Seed MJ, Cullinan P, Agius R. Tiotropium mist inhaler. Another plausible explanation for mist inhaler's toxicity. *BMJ* 2011;343:d4483. (25 July.)
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## ANIMAL PRODUCTS IN MEDICINE

### Formularies should list animal derived excipients of drugs

Shiwani reminds us that patients are not always aware that surgical implants may originate from animal tissue.<sup>1</sup> Doctors may also be unaware that they are prescribing drugs with excipients derived from animals.<sup>2</sup>

For example, many oral vitamin D or calcium supplements contain porcine or bovine products, as shown in the Electronic Medicines Compendium (www.medicines.org.uk). This is a potential prescribing hazard, given that vitamin D supplements are often used to treat deficiencies arising from cultural or dietary abstention.<sup>3</sup> The *British National Formulary* does not list gelatin as an excipient of vitamin supplements.<sup>4</sup> Its presence can be confirmed in the summary of product characteristics of the various types of preparations.

Clearer listing of excipients is needed in formularies to aid prescribers in informing patients.<sup>2</sup>

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- 1 Shiwani MH. Surgical meshes containing animal products should be labelled. *BMJ* 2011;343:d4625. (27 July.)
- 2 Sattar SP. Patient and physician attitudes to using medications with religiously forbidden ingredients. *Ann Pharmacotherapy* 2004;38:1830-5.
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## CALORIE LABELLING ON HIGH STREET

### Let them eat cake

I wonder how many of the 15% of customers who used the information on calorie content to make healthier choices actually needed to reduce their calorie intake.<sup>1</sup>

My own observational study in a local supermarket cafe indicates that only my patients with a body mass index greater than 30, established coronary heart disease, or diabetes seem to consume the fried breakfast, whereas those I have referred with eating disorders cradle a black coffee or skinny latte. Would calorie labelling encourage these people to change for the better? I doubt it.

I appreciate that obesity and its associated morbidity is increasing, but so are eating disorders. I do not wish my impressionable intelligent 8 year old daughter to be bombarded with "calorie consciousness" when we go out for a hot chocolate after swimming club. Food labelling in supermarket aisles is one thing; but eating out is supposed to be a pleasure, and part of mental wellbeing and healthy eating should be to enjoy "treats" in moderation without being made to feel guilty.

I personally shall boycott establishments with calorie labelling; how can my local supermarket be proud to sign up to this initiative yet on the website of a leading eating disorders charity claim to be a supporter?

This seems to be nanny state taken too far without evidence of appropriate benefit. Thankfully I am too old now to hold up supermarket queues while the assistant verifies my age when buying alcohol. Perhaps in the future I can look forward to being weighed before they allow me to buy cake.

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**Competing interests:** None declared.

- 1 Jebb SA. Calorie labelling on the high street. *BMJ* 2011;343:d4502. (26 July.)

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## A parallel with patient choice



Just as hungry consumers are in the worst position to be making "informed" choices about which foods are best for them,<sup>1</sup> so too are unwell patients in a poor position to be using hospital performance data to make choices about where they wish to be treated. The results of the study by Dumanovsky and colleagues echo findings from the US that patients do not use outcome data to choose a hospital any more than they use calorie counts to choose their food,<sup>2</sup> with anecdotal reports of hospital performance having more influence on choice than risk adjusted mortality data.<sup>3,4</sup> Disclosing information may have an effect on quality from the supply side, but let us not pretend that the mechanism for improvement is informed choice.

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**Competing interests:** None declared.

- 1 Jebb SA. Calorie labelling on the high street. *BMJ* 2011;343:d4502. (26 July.)
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## TUBERCULOSIS IN THE UK

### Consumption and aggression

Looking at the map of tuberculosis prevalence in the UK,<sup>1</sup> the hot spots coincide well with the current outbreaks of violence and looting. Hackney, Brent, and Clapham all have a high prevalence of tuberculosis. Outside the capital, the same pattern is seen in Liverpool, Bristol, and central Birmingham. This probably is a correlation with deprivation, but it is not an excuse.

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- 1 Abubakar I, Lipman M, Anderson C, Davies P, Zumla A. Tuberculosis in the UK—time to regain control. *BMJ* 2011;343:d4281. (29 July.)

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