Next month the United Nations will stage its first summit looking at the world epidemic of non-communicable diseases—in particular, cardiovascular disease, cancer, diabetes, and chronic obstructive disease (*BMJ* 2011;342:d3823). This article is part of the *BMJ*'s pre-summit coverage, looking at the risk factors linking these diseases. **See also ANALYSIS, p 402**

CAN RUSSIA START A DRINKING REVOLUTION?

Alcohol misuse accounts for over half of deaths among working aged men in Russia. **Shaun Walker** looks at the reasons for the high rate and government attempts to reduce it

It is 8 in the morning at the square outside Belarus station in central Moscow, but the early hour has not stopped a large number of people from drinking. A man in an ill fitting suit is striding towards the metro entrance, a can of 9% "alcopop" in one hand, briefcase in the other. Several men with heavy luggage, just disembarked from an overnight train, are drinking bottled beers in the morning sunshine around a plastic table, while at an adjacent table a woman smokes a slim cigarette and quaffs a gin and tonic mix from a can. Two bearded tramps are asleep on one of the pavements, an empty vodka bottle by their side, and all around there are kiosks selling beer and shops that sell spirits.

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A man holds a bottle of antiseptic solution on a street in central Moscow. The consumption of surrogate alcohols not originally meant for drinking is one of the most harmful aspects of the Russian drinking culture. Inset: a laboratory assistant checks a liquid for surrogate alcohol in a police laboratory in Pskov

The scene is not unusual in Russia, where alcohol consumption is legendary. Across the country's vast Eurasian landmass, in cities, towns, and villages, millions of Russians engage in dangerous drinking that several studies have shown has an appalling effect on public health and has contributed to the country's demographic crisis. Last year, Prime Minister Vladimir Putin became the latest in a long line of Russian leaders to attempt to tackle the problem, pledging to halve alcohol consumption among Russians by 2020. Measures include cracking down on illegal alcohol, increasing minimum prices for alcohol, and a full ban on advertising. Tighter regulation of beer, previously classed as a soft drink in many respects, has also been announced.

Several studies have suggested that alcohol misuse has contributed hugely to death rates over the past two decades, as Russian male life expectancy took an unprecedented plunge for a country not at war. One study by British, French, and Russian researchers that looked at three industrial towns in western Siberia with typical mortality patterns found that over half of all deaths among working age men between 1990 and 2001 were due to alcohol misuse[1]; this compares with less than 4% of all deaths worldwide.[2] The authors of the report suggested that increased alcohol consumption cost the lives of three million Russians.

Damaging behaviour

What is strange for the observer of drinking in Russia is that according to statistics, while Russians are indeed among the heaviest drinkers in the industrialised world, their consumption does not seem to be as far ahead of that in other European countries as their mortality. According to the World Health Organization's *Global Status Report on Alcohol and Health*, Russia is in fourth place in absolute terms when it comes to

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A villager produces *samogon* (moonshine), a surrogate alcohol that is commonly brewed up in the countryside

per capita alcohol consumption, below Moldova, the Czech Republic, and Hungary, with 15.8 litres of pure alcohol per person a year.[2] The UK, in 17th place, consumes 13.4 litres a year—much less, but not low enough to explain the difference in health problems and death rates caused by alcohol.

Martin McKee, professor of European public health at the London School of Hygiene and Tropical Medicine, is an expert on alcoholism in Russia and has authored several papers and studies on the subject. He highlights two particularly harmful aspects of the Russian drinking culture. One is the consumption of surrogate alcohols not originally meant for drinking, such as perfumes or surgical spirit, which are often more than twice as strong as vodka. The other is *zapoi*, meaning a bender. A *zapoi* is more than just a big night out followed by a sore head the next day, it is an extended drinking binge lasting several days or more, and often planned in advance among friends. During *zapoi* people cease to function properly and essentially withdraw from society for several days. Professor McKee's estimate is that 40% of deaths among men of working age in Russia are caused by harmful drinking—just *zapoi* and surrogate drinking—not including the "ordinary" drinking of vodka. Extrapolated to the whole of Russia, this makes for 170 000 excess male deaths a year, and goes a long way to explaining why the life expectancy for men has hovered around 60 years in the past decade.

"Most Russians don't drink more than most Europeans," says Vadim Drobiz, director of the Centre for Federal and Regional Alcohol Market Studies. "The problem is that we have about 20% of people who drink four or five times the average, and this is the danger group."

What everyone agrees on is the difficulty of finding genuinely reliable statistics on the amount that Russians drink. "We need to exercise considerable care with statistics on consumption as the official data are almost certainly an underestimate," says Professor McKee. "In particular, we need to consider home produced spirits (*samogon*) and alcohol that is, at least officially, not sold for drinking." Mr Drobiz says that, based on his personal research, he estimates that Russians consume about 2.3 billion litres of spirits a year, of which around 800 million litres are legally sold, 700 million are illegally sold, and 800 million are substitutes. The illegally sold spirits tend to be vodka and cognac made legitimately in factories but sold through corrupt schemes without going through the proper taxation channels, he says. The substitutes can be anything, from *samogon*, moonshine brewed up in the countryside, to all sorts of alcohol containing industrial fluids such as de-icers, eau de cologne, and surgical spirit.

"One thing that everybody seems to agree on is that the standard government response of raising prices for alcohol is unlikely to solve the problem"

There are also huge regional fluctuations in how much people drink. "As a general rule, the further north you go, the more people drink, and the further east you go, the more people drink," says Alexander Nemtsov, head of department at the Moscow Research Institute of Psychiatry, putting the regional differences largely down to remoteness and harsher climate. He says that studies of drinking habits and, more importantly, medical interventions are not always calibrated to take into account the specifics of different regions.

Professor McKee says that his research shows that alcohol in Russia is an important cause of cardiac death, a finding that has surprised some others in the profession. "In addition to the usual injuries and liver damage, we see this pattern of drinking causing high rates of sudden cardiac death, probably as a result of abnormal heart rhythms," he says. Although the Russian drinking patterns are unusual, they are replicated in some other areas. "What we see in Russia is also seen in its neighbours, Belarus, Ukraine, and the Baltic states. Although less researched, it is also seen

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Russia is to crack down on sales of alcohol (*BMJ* 2010;341:c4642)
bmj.com/podcasts
Listen to a podcast discussion about alcohol intake in Russia
doc2doc
Is beer alcohol or food? Discuss on BMJ Group's medical community http://bit.ly/oMOaM6

MAURICE JOSEPH/ALAMY


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From 2013 beer, previously classed as a soft drink and commonly drunk in public, will not be available from kiosks or stations nor for sale at night

in some heavy drinking cultures elsewhere, such as Glasgow."

One of the biggest shifts in recent years in Russian drinking habits has been in the consumption of beer. Until the late Soviet period, Russians mainly drank wine and vodka, says Dr Nemtsov. In 1995, when foreign breweries first entered the Russian market en masse, the average Russian consumed 15 litres of beer a year. By 2007, this had risen to 81 litres, a more than fivefold rise in a little more than a decade. "This sort of increase in consumption has never occurred in any society, and will never occur again," says Mr Drobiz.

State intervention

Beer in Russia is not classified as an alcoholic drink, and unlike vodka it is sold in the street kiosks which dot town centres across Russia. Worried by the rapid growth in beer drinking—and egged on, some analysts say, by the power of the vodka lobby—the Russian parliament finally passed a bill earlier this year that brings the laws for beer into line with those for other alcoholic drinks. From 2013, beer will not be available in kiosks, will not be available at stations and other transport hubs, and will not be for sale during night hours.

The night ban could change Russian drinking culture substantially. Currently, the kiosks sell beer and alcopops all through the night. Although sales of spirits are banned after 11 pm, the general availability of alcohol seems a far cry from a complaint made by the alcoholic narrator in Venedikt Yerofeyev's 1970 cult classic novel *Moscow-Petushki*. Skulking around the streets near Moscow's Kursk station, he speaks of the frustrating hours at dawn when it was impossible to buy vodka. "The most powerless and shameful time in the lives of my people is the time between sunrise and when the shops open." There have been no such troubles for citizens of post-Soviet Moscow and other Russian cities, but the ban on all night alcohol sales has been welcomed as likely to reduce drunken and disorderly behaviour on the streets. However, experts say it may not help the real problem drinkers in the Russian provinces. "To get 1 ml of alcohol from beer is much more expensive than to get it from vodka," says Dr Nemtsov. "This means that people who drink because they want to get drunk will not drink beer. The beer drinking phenomenon is mainly a metropolitan thing; in the villages and the small towns, it's too expensive."

Mr Drobiz suggests that in terms of actual amount of beer consumed, the new law could have little effect. He points to neighbouring Belarus, where beer sales were banned in kiosks but consumption did not decrease. "It will leave the kiosks, but there will just be more 24 hour beer bars, to get round it," he says.

One thing that everybody seems to agree on is that the standard government response of raising prices for alcohol is unlikely to solve the problem. The government has promised to double the minimum price of vodka, from 98 roubles (about £2, €2.4, or $3.4) for a half litre to 200 roubles, within the next three years. But while £2 per bottle sounds extraordinarily cheap (buying a coffee in central Moscow can cost three times this), compared to average salaries in the regions, where many people survive on £200 a month or less, it is not. Indeed, for many, the price of alcohol as a ratio of salary is higher than in Western Europe. "If you raise the price, people will just move on to surrogates, and that is more dangerous," says Dr Nemtsov. "Raising the price is the worst thing you can do, in fact. You need to tackle the primary reasons why people drink. If you don't do that, and then take away their ability to buy drink, they will find a way round. The Russian people are very resourceful." A similar dynamic has occurred in recent years among heroin addicts who, faced with rising costs of the drug and decreased access, have turned in their thousands to desomorphine, a lethal analogue cooked up from codeine based painkillers.

"Changing the law can only do so much," says Dr Nemtsov. "The main reasons that people in Russia drink are poverty and a lack of cultural or spiritual satisfaction. Everything else—price, access, the popularity of *samogon*— it's important, but it's all secondary."

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SURROGATES UNDER SCRUTINY

We need a new approach to proxy measures of health, says **Ray Moynihan**

We live in a time when much disease is measured not by symptoms but by numbers, determined by biomarkers in our blood or bone.[1] Transforming a healthy person's risk of disease into a chronic condition has been a key characteristic of modern medicine, creating vast new markets for "preventive" pills designed to reduce suffering and extend life. The annual global spend on cholesterol lowering drugs alone has exceeded £10bn (€11bn; $16bn), while more generally widening definitions and lowering thresholds continue to expand the patient pool.[2] Well funded campaigns urge the public to know their numbers, and professionals are rewarded for treating to target. Yet the grand assumption underpinning this approach—that helping a person's numbers will automatically improve their health—is a delusion as dangerous as it is seductive.

Routinely approving and prescribing therapies on the basis of their effects on someone's numbers, rather than their health, is increasingly seen as irresponsible and dangerous

Use of flecainide to reduce the number of irregular heart beats, for some people also raised their risk of an early death, killing tens of thousands just decades ago.[3 4] Long term hormone replacement therapy lowered "bad" cholesterol and raised "good" cholesterol for generations of women, but it also lifted their chances of heart attacks and strokes.[5] Prescribing pills to aggressively decrease blood sugar in high risk diabetes patients has been increasing their risks of disease and premature death rather than reducing them.[6] Yet decisions to approve and prescribe drugs based on success with surrogate end points continue apace, as do their sometimes deadly consequences.

Since at least the 1950s studies showing correlations like those between high blood pressure and heart disease have led us to believe that if we can modify people's biomarkers, we can lower their risks of disease or early death. While the theory sometimes works, its logical flaw is obvious. Whether we help or harm depends on how we try to lower risks—and long term treatments often carry unintended consequences. Moreover, even when significant clinical benefit is proved, the often minimal risk reductions associated with long term treatment suggest that the current approach may be over-medicalising many for little gain and at great cost.

Unproved benefits

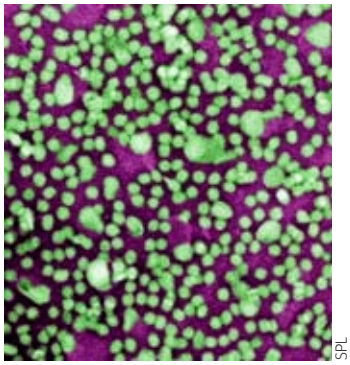
"I think we've been far too cavalier in accepting favourable changes in a biomarker as a perfect proxy for patient benefit," says Yale University public health professor Harlan Krumholz, who helped put together a recent report on surrogates for the United States Institute of Medicine.[7] He says the focus on "knowing your numbers" and "treating to target" seems to play to everyone's best interest—they are easy public health messages, they need only quick visits to doctors' offices, and are a great boon for companies, which don't have to do the larger long term studies of effects on clinically meaningful outcomes. Professor Krumholz believes the evidence shows "simple assumptions" about surrogates are often incorrect, and he argues we need to better inform people about potential dangers. "If a drug is approved only on the evidence of its impacts on a biomarker, there should be big clear warnings saying it has an unproven effect on patient health," he says. "We need to convey the uncertainty."

That recent report from the Institute of Medicine—*Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease*—is sobering reading.[7] It details an often misplaced confidence in relying on surrogates to assess treatment benefits. "Remarkably, the cautionary voices speaking about the risks of using surrogate endpoints have been repeating the same messages for 20 years," says the report. "What has been changing is the continually increasing amount of data supporting their arguments." The report cites examples where treatments have benefited surrogate measures but harmed people, and it urges a far more rigorous evaluation of how these intermediate end points are used.

Even for widely used surrogates there's more uncertainty than we might imagine. Although blood pressure is an extremely reliable proxy, questions arise from the fact that treatments similarly affecting blood pressure can have different effects on heart disease.[7] In the face of the AIDS crisis, researchers discovered HIV-1 RNA was a valuable biomarker, enabling experimental drugs to be assessed quickly. However, in some contexts, short term changes in that biomarker proved to be a poor surrogate because partial suppression of the virus allowed the formation of drug resistant mutations and limited future usefulness of drugs.[7] And although reduction in tumour size is sometimes a useful way to measure the effect of cancer treatment, even major shrinkage does not always represent meaningful improvement because, for example, in some cancers, smaller tumours tend to grow faster than larger ones.[7] There are even doubts about the value of cholesterol, and it serves as a powerful case study of the need for a new way of thinking about surrogate markers.

Caution over cholesterol

Regulators, including the United States Food and Drug Administration, have officially sanctioned low density lipoprotein (LDL) cholesterol as a surrogate end point, allowing many drugs to be approved and marketed if they reduce this "bad cholesterol" without requiring proof they actually improve health. Yet despite the size of the global markets, there are myriad uncertainties surrounding cholesterol. According to the 2010 Institute of Medicine report, although the methods used to determine blood cholesterol are reliable and reproducible, they do not directly measure LDL cholesterol and so have "limitations."[7] In addition, though LDL cholesterol is "hypothesised" to have a causal role in the atherosclerotic disease process, it has "not been conclusively proven."[7] And reinforcing the general point about our overconfidence in surrogates, the report reminds us that lowering LDL cholesterol "does not always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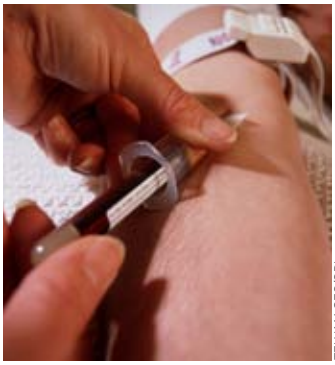
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Cholesterol provides a powerful case study of the need for a new way of thinking about surrogate markers: (from left) LDL cholesterol, testing blood cholesterol, and simvastatin and atorvastatin, two of the most commonly prescribed cholesterol lowering drugs

correlate with improved patient outcome." The report points out there are over 200 coronary risk factors, and that cholesterol, while currently considered by many to be a valuable biomarker for heart disease, is only one of "multiple determinants" and "numerous other mediators."

The benefits of long term preventive therapies like cholesterol lowering drugs are usually portrayed as relative reductions in risk, but when the risks are considered in absolute terms, a different picture emerges. For example, based on a Cochrane review of trials for primary prevention,[8] there has been recent enthusiasm that for people without a history of heart disease statins can reduce premature deaths by 17%, coronary heart disease by 28%, strokes by 22%, and revascularisation by 34%.[9] Yet a close reading of the tables from that systematic review suggests the estimated absolute risk reductions with around four to five years of drug taking are 0.5% for death, 1.9% for coronary heart disease, 0.5% for stroke, and 0.7% for revascularisation.[8] The estimated number needed to treat for four to five years thus ranges from 50 to 200 depending on the outcome measure. So according to this evidence, most people taking long term statins for primary prevention gain no direct benefit.

While there is strong evidence of benefit, reinforced in other recent studies,[10] the magnitude of that benefit in absolute terms is extremely small for those at low risk. There is also a question over the effects of industry funding on this evidence, as even a small amount of bias in the original trials could make the difference between an overall finding of benefit or an overall finding of no effect, in the systematic review's summary. In fact, the Cochrane reviewers' discussion of their results offers cause for great caution in interpreting the existing evidence about statins for primary prevention, and reinforces wider questions about the benefits of long term preventive medicines for otherwise healthy people.

The reviewers said they were unable to disaggregate composite outcome measures reported in the 14 statin trials they reviewed; that one third of those original trials reported outcomes selectively; and a majority did not even report on the drugs' possible harms. Two of the larger cholesterol lowering trials included for review were stopped prematurely because of statistically significant benefits being achieved early, which "may lead to an over-estimation of treatment effects." The Cochrane review also reported that all but one of the original trials had some form of drug company sponsorship, which has been shown to increase the likelihood of bias favouring the sponsor's drug. "In primary prevention where world-wide the numbers of patients eligible for treatment are massive," the reviewers wrote, "there might be motivations to use composite outcomes and early stopping to get results that clearly support intervention." When an independent Canadian group recently reviewed similar evidence, they found that while these drugs undoubtedly lower cholesterol, "the claimed mortality benefit of statins for primary prevention is more likely a measure of bias than a real effect."[11]

Related questions surround other commonly used surrogates which form the basis for profitable markets in drugs for people at risk of future events. A National Institutes of Health consensus conference on hepatitis B found in 2008 that while drugs improved virological or biochemical markers, there was only "low quality evidence" showing correlations between these intermediate outcomes and real world clinical outcomes, and "no conclusive evidence" that treatments reduced the risk of liver disease or death.[12] The surrogate of bone mineral density has been controversial for many years, regarded by some researchers as accounting for only a minor proportion of a person's overall risk of fracture.[13] And while the search continues for reliable biomarkers to enable the prevention of Alzheimer's, a recent conference found, "firm conclusions cannot be drawn about the association of any modifiable risk factor with cognitive decline or Alzheimer's disease."[14] With type 2 diabetes, heavily promoted drug strategies to aggressively reduce blood sugar have raised people's risks of heart disease and death,[15 16] rather than lowered them, despite evidence that lifestyle changes are cheap and effective.[17] Some argue the treatment of type 2 diabetes is a classic example of the medical profession ignoring unfavourable evidence that shows no benefit on meaningful outcomes, while favouring studies that show positive effects on surrogate numbers.[18]

History shows drugs help make diseases

Jeremy Greene, historian of science at Harvard University, has described "a radical restructuring of the normal and the pathological" that emerged in the second half of the 20th century as symptomless people at risk of future disease were increasingly classified as having medical conditions.[1] In *Prescribing by Numbers*, Dr Greene charts how drug companies and their latest products have helped to shape and expand these new risk based conditions—including high blood pressure, type 2 diabetes, and high cholesterol: "Pharmaceuticals played a central and active role in the definition of these categories of illness," he writes. Dr Greene argues this process of expanding categories to include people previously considered healthy can be seen as medicalisation. But rather than a monolithic or concerted strategy driven from the boardrooms of companies or professional medical associations, it demonstrates the "porous relationship between the science and the business of health care," and the process carries benefits as well as risks.

That porous relationship between science and business is still evident in the more recent development of "quality measures," which urge doctors to test for and treat the risk based conditions of the healthy. In the United States one of the main agencies developing quality measures, the National Committee for Quality Assurance, is directly funded by several drug companies, along with other sponsors.[19] In the United Kingdom the process is overseen by a public institution, though there are criticisms of an overly narrow focus on numbers that can be modified by drug treatment.[20] A long term critic of widening boundaries of illness, Iona Heath, president of the Royal

College of General Practitioners, believes many thresholds have been set far too low. She argues quality measures may be encouraging tests that create anxiety and treatments that help surrogates rather than ameliorate the suffering of people.

In recent months we have seen yet more evidence confirming the risks of our over-reliance on surrogate numbers. In May a large trial of niacin was stopped. Though combining niacin with a statin boosted so called "good" cholesterol (high density lipoprotein) high doses were also associated with a small increase in strokes.[21] In June a study in *JAMA* uncovered a pattern of over-estimating the strength of correlations between biomarkers and their respective diseases,[22] highlighting the "thin line between hype and hope."[23]

Shift from numbers to people

A major rethink of the role of surrogates in medicine is timely. Routinely approving and prescribing therapies on the basis of their effects on someone's numbers, rather than their health, is increasingly seen as irresponsible and dangerous. And even when evidence suggests clinical benefits of popular "preventive" medicines for those at lower risks, a rational assessment reveals many people must be treated to prevent one adverse event, so most users gain no direct benefit despite years of treatment. The cost effectiveness of this approach is unsurprisingly in doubt.[24] More disturbing still are the questions about whether some of the suggested clinical benefits are real or simply artefacts of sponsorship bias.

The rigour of the evidence informed approach to medicine has in recent decades helped us all understand the limitations of relying on surrogates, and for one of its key architects—McMaster University professor Gordon Guyatt—this problem is both historical and cultural. He argues that central to putting American medicine on a scientific basis was the assumption that an understanding of biological mechanisms would translate into improved management of patients. And while medical students over a century later are still taught to focus on fixing a person's biological numbers—whether it's cholesterol or bone density—what is urgently required is a new approach that provides genuine improvement for the person.

Understanding biological mechanisms and diagnosing by numbers has undoubtedly brought great benefits. Yet as the definitions of medical conditions relentlessly expand via that porous relationship between the science and business of healthcare, this fragmented reductionist approach is conferring multiple medical labels on vast swathes of healthy people, who are then treated with preventive drugs that won't help most of them and may hurt many.[25] The magic of numbers may help corporate profits and professional pride, but at what cost to the health of ordinary people who mistake a numerical benefit for a genuine one? Surely it's time to ask if there might be a healthier new model for medicine based on far less harmful and costly ways to try to reduce human suffering.

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BMJ.COM BLOGS **Jo Maybin**

Do actions speak louder than words on competition

Last month Andrew Lansley, the health secretary for England, responded to some challenging questions from the House of Commons health select committee about whether the amendments to the Health and Social Care Bill really amount to a significant shift in the role that competition will play in the health system. The government plans not only to keep the principles and rules for cooperation and competition but to give them a new power by enshrining them in law. And the Co-operation and Competition Panel for NHS-Funded Services will no longer be an advisory body but a decision making body situated in the regulator Monitor, whose powers for preventing anticompetitive behaviour remain relatively unscathed by the latest amendments.

If the panel's latest report on the operation of the "any qualified provider" policy (in which a diverse range of providers compete for the custom of NHS patients) in elective care is anything to go by,[1] we can expect the new Monitor to place a lot more emphasis on competition than on cooperation. The report contains some very confident—and evidence light—statements about the benefits to be secured from choice and competition, if only those naughty commissioners would play ball.

The authors believe that willingness to support the policy will improve with time as its benefits are "more widely demonstrated, understood, and accepted . . . with the ongoing enforcement of the principles and rules and other relevant provisions." One recommendation is that authorisation of new clinical commissioning groups ought to be contingent on their abiding by the principles.

The not very deeply buried subtext here is: you are going to learn to like this. And you will have to like it in an increasing number of service areas: last month the health department announced that the "any qualified provider" policy would be extended into community and mental health services.

The tone of the CCP report and the health department's guidance jars with the government's rhetoric, since the "pause" in the bill's progress, concerning the role that competition should have in driving the new system. This casts doubt on whether the amendments to the bill will really translate into a more nuanced approach that supports the use of cooperation as well as competition, recognising that each may be appropriate in particular circumstances.

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1 Cooperation and Competition Panel. Review of the operation of "any willing provider" for the provision of routine elective care: final report. CCP, 2011. http://bit.ly/pYyNo2.

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