

NICE GOES GLOBAL

NICE decisions on NHS drug funding have attracted attention abroad, but can the international interest be turned into profit?

Nigel Hawkes reports

When the National Institute for Health and Clinical Excellence (NICE) first started to flex its muscles in 1999, the drug industry would love to have exported it, preferably somewhere like Mars. Ten years later, the influence of NICE, far from being blunted, is beginning to spread. Its methods and organisational model have become something of a beacon to governments wrestling with the issues of efficacy and fairness in healthcare delivery.

This newfound popularity has inspired NICE to set up a small team to investigate whether NICE-ness can be sold for a profit abroad. Andrew Dillon, NICE's chief executive, said that interest has come from many different places. "It's clear that what we do and how we do it is of interest to healthcare systems around the world, regardless of how they are funded," he said. "It's not related to the wealth of the system. Optimising the way money is spent is our approach, and that is of interest to everybody, rich or poor."

Widened influence

Among rich countries, the United States might be reckoned about as likely as Mars to provide a haven for NICE. But the appointment of former senator Tom Daschle as President Obama's health secretary has changed the picture.

Mr Daschle's big idea, outlined last year in his book *Critical: What We Can Do About the Health Crisis*, is the creation of a federal health board to provide guidelines and maybe also to measure the cost effectiveness

of treatments. "We're paying top dollar for mediocre results," the book claims. By choosing what treatments should be provided and how much they were worth, the new board "would steer providers to the services that are most clinically valuable and cost-effective and dissuade them from wasting money on those that are neither." Sound familiar?

Mr Daschle is not alone. Sean Tunis, who was chief medical officer of the Centers for Medicare and Medicaid Services under George W Bush's administration, told the *New York Times* recently that he spent a lot of his time in government "learning about NICE and trying to adopt the processes and mechanisms they use, and we just couldn't."¹

The industry view is represented by the Center for Medicine in the Public Interest, an advocacy group whose vice president, Robert Goldberg, has likened NICE to a terrorist organisation and declared its decisions morally indefensible. Peter Pitts, its president, writes an entertaining blog on the centre's website. Under the headline "Good Golly Miss QALY," Mr Pitts recently celebrated NICE's partial retreat from the use of quality adjusted life years for assessing end of life drugs: "British citizens with mortal illnesses will finally be treated like human beings," he concludes. But he notes that there is no intention of extending this to all conditions—which would cost, in the words of NICE chairman Michael Rawlins, "hundreds of millions of pounds." Mr Pitts comments: "Well, heaven forbid that the NHS should provide the best care when adequate care is available."

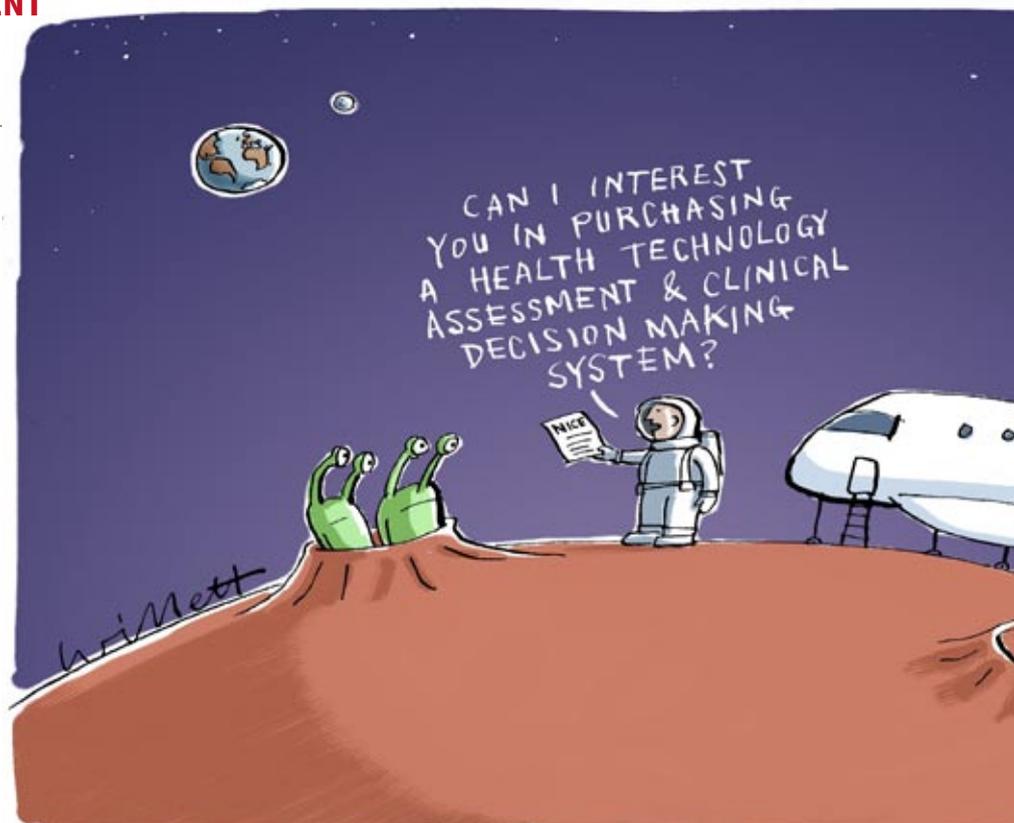
The tone of the centre's public pronounce-

ments suggests that it sees NICE as a serious threat. But what alarms drug companies in the US, where 17 cents in each health dollar are spent on medicines, is music to the ears of governments elsewhere who wish to avoid getting in so deep with the drug industry. These range, said Mr Dillon, from South Korea, through Turkey, to Colombia, a spectrum covering a wide range of income per capita.

"South Korea has a well developed health system but wants to involve us in providing targeted advice," he said. "Turkey is interested in practical clinical guidelines. We've put a proposal in there and we're waiting for a response. With money from the Department for International Development, we have also visited three middle income countries—Jordan, Ghana, and Colombia. And with support from the World Bank, we've also been to Russia."

These direct contacts are probably less of a threat to drug companies than the indirect effects of NICE's constant downward pressure on UK drug prices. In recent deals Johnson & Johnson agreed a risk sharing deal for the multiple myeloma drug bortezomib—charging only if it is shown to be effective—while Novartis agreed to free injections of ranibizumab for patients with wet age related macular degeneration if they needed more than 14 treatments.

Sir Michael Rawlins, who will seek reappointment as NICE chairman when his term of office ends in March, makes no secret of his belief that drug companies are price gouging. He said these risk sharing deals suit the



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companies because they are a way of concealing price cuts. But concealment won't work in the long run, he suggests, because "I can't see that other countries will be so dim as not to notice it."

Acting on results

NICE is not unique in applying the results of health technology assessments to clinical decision making. Indeed, assessment

existed long before NICE was set up and is well established in almost every developed country. There are almost 50 publicly funded health technology assessment agencies around the world, including 31 in Europe. So why has NICE made such a splash when so many others have laboured in relative obscurity?

The reasons are to be found in the nature of the NHS, and the way NICE is organised. In a strict sense, it is not a health technology assessment agency at all. Most of the heavy lifting is done by seven university based groups under contracts issued by the NHS Research and Development Directorate. "We don't do assessments, we commission them," said Mr Dillon. "Then we interpret the results and make a very clear statement of what the NHS should do. In the past, people produced lots of reports that still left you saying 'What should we do?' We filled that gap."

The difference NICE made was to put "a front end" on the evidence produced by health technology assessment and to integrate it with policy. Assessments and appraisals are almost universal in developed countries, but as a recent study by the European Observatory on Health Systems and Policies shows,² only in England and Wales are they integrated with decision making, legally binding, national in scale, and put into practice in a system with a single paymaster. That gives them a sharp cutting edge generally lacking in other countries.

The technique used by NICE is also distinctive, as Michael Drummond of the University of York and Frans Rutten of Erasmus

University in the Netherlands point out in a briefing paper for the Office of Health Economics.³ The use of QALYs makes across the board comparisons possible. The cost of paying for a new drug can be compared directly with a different health intervention—improving maternity care, for example.

In contrast, the German Institute for Quality and Efficiency in Healthcare (IQWiG), which is superficially similar to NICE, has laid down a completely different appraisal system. This uses the results of randomised controlled trials to compare cost against value for drugs within a given therapeutic area. Only if a new drug is superior to the old, and its cost-value figure is comparable, will it be accepted for reimbursement through the German medical insurance system.

This means, say Drummond and Rutten, that less efficient but cheaper drugs (which the NHS welcomes because of their cost effectiveness) are not assessed at all in Germany, where only the best will do. It also means that no comparisons can be made across specialties. IQWiG justifies this by saying that the German healthcare system does not operate within a fixed national budget, so there is no question of robbing Peter to pay Paul. Trade-offs between therapeutic areas are not allowed. This claim of an infinitely expandable budget is "not obvious," the authors remark drily.

Despite IQWiG's generous appraisal system, there have been rows about its decisions. In 2006 it ruled that short acting insulin analogues should not be used in place of human insulin in treating diabetes, provoking anger among patient groups. But this decision was on grounds of efficacy, not cost.

Another difference between the NHS and insurance based systems is in the use of copayments. Patients in insurance based systems are familiar with the concept that not everything is covered. In France, NICE's equivalent is the French National Authority for Health, which decides whether a technology is reimbursable or not under the statutory insurance scheme. Some treatments will qualify for 100% reimbursement, others for 65%, 35%, or none at all. Patients have to pay the difference or take out supplementary insurance to cover it. "For many countries, the idea that there's a copayment is normal," Mr Dillon said. "The NHS is unique in feeling that it has to do everything."

As in Germany, the French system does not use cost per QALY in assessing the value of treatments. To keep costs under control it uses conditional reimbursement, price-volume agreements, and negotiations to drive down the prices of new drugs. These often lead to long delays between licensing and a decision on reimbursement. The National Authority for Health also reviews older treatments and has so far delisted more than 400, which means they are no longer reimbursable.

According to Jill Sanders, president and chief executive officer of the long established Canadian Agency for Drugs and Technologies in Health, the key issue is whether a health technology assessment agency is inside or outside government. Speaking in December 2008 at Health Technology Assessment World, a conference organised by Health Network Communications in London, she said this was a political decision. Agencies inside government, such as NICE, normally produce results that are mandatory but are accused of bias and a lack of transparency. Those outside government, such as hers, must work by persuasion and knowledge transfer rather than diktat but are generally seen as less biased and more transparent.

Which is more effective? NICE has certainly acquired a more macho image than many of its peers around the world, which is why it is currently in favour with some overseas governments. But this owes more to its setting within a single payer health system with a constrained budget than it does to anything unique about its methods. Few other systems are anything like the NHS, which may ultimately set limits on NICE's export potential.

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