to ensure effective transfer of information and continuity of care. Care pathways with defined roles and competencies for all professional groups are also required. A systematic review found that care pathways can improve the effectiveness of treatment for depression compared with usual care for people with mild to moderate depression for up to 12 months. These care pathways included interdisciplinary collaboration, intensive patient education, case management, and telephone support. Only by overcoming the barriers to treatment, providing comprehensive screening programmes, and ensuring the delivery of appropriate and timely care will we effectively prevent and treat postnatal depression.


Rationing new medicines in the UK

A fair and consistent process is needed for dealing with absence of evidence

In England and Wales the National Institute for Health and Clinical Excellence (NICE) issues guidance on the appropriate use of medicines that is based on an assessment of evidence submitted by the manufacturer. The scope of the assessment depends on whether the appraisal concerned is a single technology appraisal or a multiple technology appraisal (box). NICE recently terminated four single technology appraisals of cancer drugs because it did not receive submissions from drug companies that met the institute’s specification of evidence. As a result, NICE was unable to recommend the use of the products for the clinical indications for which they were licensed, but it stated that, after considering the reasons for the lack of guidance, NHS organisations could still use the drugs. In contrast, the Scottish Medicines Consortium approves medicines only if drug companies submit evidence, so non-submission results in a recommendation not to use the drugs concerned in the Scottish NHS.

This situation is one consequence of NICE’s switch to undertaking more single technology appraisals, the main advantage of which is a shorter time between the drug’s marketing approval and a preliminary decision. However, in shortening the time allowed for the appraisal, NICE is largely reliant on information provided by the manufacturer, whereas under the original (multiple) technology appraisal process, the independent review group contracted by NICE also undertook an analysis.

One concern is that, in the future, companies could terminate an appraisal by failing to submit data if they thought the chance of a positive NICE recommendation was small. Clinicians or patient organisations could then bring pressure to bear on local decision makers, whereas this would not be possible after a negative NICE appraisal. In most jurisdictions that use an evidence based approach to drug use, this situation cannot arise because a formal application must be made by the manufacturer for inclusion on the national formulary or “positive list.” In the United Kingdom, however, most licensed drugs are automatically available for prescribing on the NHS, unless guidance from NICE, the Scottish Medicines Consortium, or the All Wales Medicines Strategy Group limits their use. If terminated appraisals effectively delegate decisions to the local level, this could exacerbate the “postcode lottery” that NICE was created to tackle.

So what could be done? Moving towards a comprehensive approach for evaluating the clinical effectiveness and cost effectiveness of all new drugs, linked to listing for reimbursement, raises a wide range of questions, not least that of whether NICE could cope with the workload. Certainly, without substantial extra resources it would have to simplify its procedures greatly. In particular, it would need to limit stakeholder involvement and perhaps be less rigorous with its reviews, thereby increasing its reliance on manufacturers’ submissions.

Single technology appraisal
One drug or technology for a single indication where assessment is based on submission of data from the manufacturer alone.

Multiple technology appraisal
More than one drug or technology where data submitted from the manufacturer are supplemented by independent analysis by NICE.
Alternatively, NICE could follow the approach used by the Scottish Medicines Consortium and, in the absence of a submission, rule that the drug is not recommended for use. This approach would remove the incentive not to submit. However, this equates absence of evidence with evidence of absence (of clinical effectiveness and cost effectiveness), and it may deny patients access to drugs that might be cost effective. A third option would be for NICE to negotiate a “coverage with evidence” agreement with the manufacturer. Under this scenario, the drug would be available for use in NHS patients, but access would be conditional on a commitment by the manufacturer to provide evidence on outcomes and costs at a set date in the future when the NICE decision would be reviewed. This approach may be useful if non-submission reflects an absence of evidence for the relevant patient group (for example, the terminated appraisals on carmustine implants for recurrent glioma [TA149] and cetuximab for colorectal cancer [TA150]). However, it would be of little use if the drug company chose not to submit because the limited available evidence indicates that the drug is unlikely to be cost effective when assessed against NICE’s cost per quality adjusted life year threshold (for example, bevacizumab for breast cancer [TA147]). In such situations a coverage with evidence approach could provide a perverse incentive for companies to claim that no data exist, to increase the chances of market access for their product.

A fourth possibility, arguably more in keeping with NICE’s ethos, would be to commit to convert a single technology appraisal to a multiple technology appraisal if and when it becomes clear that the manufacturer is not intending to make a submission in accordance with the institute’s specification. This might lengthen the appraisal process and may be unsatisfactory if the manufacturer fails to give access to unpublished data. However, it is more likely to encourage submissions from manufacturers wherever possible, because the incentive to the manufacturer would be to ensure that its point of view was adequately reflected in the appraisal.

None of these strategies is without its drawbacks. Nevertheless, simply terminating appraisals runs the risk that the NHS in England and Wales will have to make difficult decisions in the context of an absence of evidence. The fourth option, of converting single technology appraisals to multiple technology appraisals when the manufacturer fails to make a submission, would be the best way forward.

Climate change kills at least 150,000 people each year, and the suffering it causes will increase as we continue to pollute the atmosphere.\(^1\) The effects of climate change on health will continue to be concentrated in the poorest parts of the world and will mainly affect children.\(^2\) The NHS is responsible for 25% of England’s public sector emissions—more than 18 million tonnes of carbon dioxide a year. The NHS carbon reduction strategy for England, “Saving Carbon, Improving Health,” was published this week; it sets out how the NHS aims to lead the way to a low carbon world.\(^3\)

The strategy builds on a strong evidence base—the groundbreaking NHS carbon footprinting exercise published in 2008.\(^4\) However, the strategy quickly runs into its first obstacle. The largest part (60%) of the NHS carbon footprint is from procurement—the manufacture and transport of goods and services purchased by the NHS from other organisations. Pharmaceuticals contribute most to procurement emissions, being responsible for four million tonnes of carbon dioxide a year. The strategy is weak in this area, saying that “research will be undertaken into the carbon footprint of pharmaceuticals within the NHS to better understand this and to inform actions to produce significant reductions.” This sounds like a dodge.

The NHS could reduce drug related carbon emissions either by reducing the carbon intensity of drug production or by reducing drug use. The NHS already pays a high price for drugs—much of the basic research that underpins drug development is funded by the public, which enables the drug industry to cream off the profitable part.\(^5,6\) Because the global atmosphere also bears some of the costs, the real cost of drugs is even higher than the monetary cost. The NHS can and should use its purchasing power to press the drug industry to decarbonise.

The Department of Health should also give the prevention of disease the priority that it deserves but currently lacks. For example, the United Kingdom is predicted to be a predominantly obese society by 2050.\(^7\) If we want to avoid a situation where more than half of the population is taking carbon intensive drugs to suppress their appetite or to prevent their bodies from absorbing fat, then we will need to do much better than Change4Life, the new “lifestyle revolution” recently launched by the Department of Health to stem rising obesity.\(^8\)