

are small: 90% of obesity in the United States could be abolished by walking an extra 2000 steps a day (equivalent to using up 0.418MJ) and reducing intake by 0.418MJ per day. These changes are well within the range of day to day variability in activity and diet and are potentially achievable and sustainable by large numbers.<sup>6</sup> People will need better education about activity and diet, but a sustainable reduction in obesity will also require the food and exercise industries to work with consumers towards small changes in the environment.

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## A middle way for rationing healthcare resources

*Technical analysis is indispensable but only the start*

The great rationing debate has gone into one of its quiet phases. The occasionally angry controversies of the past decade or so on have ended in something remarkably like a truce between those who saw the future in terms of improved technical analysis and those who wanted better processes for decision making.<sup>1</sup> It is becoming increasingly apparent—and accepted—that these are complementary rather than alternative ways of tackling rationing within whole systems of health care. The technocrats and the political realists are finding common ground in the realisation that, while more information and better analysis are indeed essential, there is no once-and-for-all formula or technical fix for resolving the question of how best to allocate scarce healthcare resources. The result seems to be less interest in the theology of rationing and more emphasis on developing the methodologies of analysis and decision making.

The focus of most of this activity is explicit decision making for whole systems on, for example, the use of specific drugs or procedures in a national service such as the NHS or in individual insurance schemes. At this level, there is a dual requirement for rationing.<sup>2</sup> Firstly, decisions should be seen as legitimate by the actors—the medical profession and others—within the delivery system as well as by the public at large. Secondly, the two requirements point in different directions, and this presents the challenge of how to devise processes that satisfy both conditions. And this leaves aside, for the moment, how explicit rationing decisions are translated into usually implicit rationing decisions affecting individual patients.

The legitimacy of rationing within the healthcare system depends on better, more evidence based methods of analysis. The paper by Camidge et al in this issue (p 1382) documents both the controversies which continue to haunt the conventional methods of economic analysis that underpin most rationing decisions and

suggests a new way forward.<sup>3</sup> To attain legitimacy in the wider sense rationing processes need to command the confidence of a public who do not know, or care, about the profusion of acronyms generated by the technical literature—and cannot tell a LIG from a QALY or a Pily—but do want some assurance that decisions reflect social values and are taken in ways that are transparent.

The evolution of the United Kingdom's National Institute for Clinical Excellence (NICE), now transformed into the National Institute for Health and Clinical Excellence, illustrates the challenge of meeting both requirements. When first set up, NICE was widely seen as an attempt to depoliticise rationing decisions.<sup>4</sup> Science, in the shape of cost effectiveness analysis, would guide its decisions and command assent. But this did not happen. Much of NICE's guidance was concerned not with rationing but with promoting good practice, which often meant extra spending. Many of the institute's decisions were contested and some were reversed, seemingly under pressure from politicians and the pharmaceutical industry. To build a basis for legitimacy in the wider sense NICE set up a Citizens Council, a body of 30 lay people representing a cross section of the population, to inform its decisions.

Most recently, in April 2005, the institute published a consultative paper that acknowledged the limitations of the technical criteria used in its cost effectiveness analyses and restated the importance of incorporating social value judgments.<sup>5</sup> The institute conceded that "there is no empirical basis for assigning a particular value (or values) to the cut-off between cost effectiveness and cost ineffectiveness." In other words, a limit of £20 000 per QALY (quality adjusted life year) for the cost effectiveness of new drugs or procedures—or any other figure—is essentially arbitrary. More crucially still, NICE accepted that there were conflicting theories of distributive justice leading

*Education and debate*  
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to different ways of framing decisions on rationing. From this flowed recognition of the importance of “ensuring that the processes by which decisions are reached have legitimacy” and that there should be “accountability for reasonableness.”<sup>6</sup>

It remains to be seen how this new strategic emphasis will work out. There remains, however, the problem—already touched on—of how macrodecisions about rationing are translated into microdecisions at the delivery end of health care. Economic analysis depends on information about effectiveness produced by clinical trials. And the limitation of most clinical trials is that “they fail to reveal the potentially complex mixture of substantial benefits for some, little benefit for many, and harm for a few.”<sup>7</sup> This is why systems level rationing decisions almost invariably—across different healthcare systems—allow for clinical discretion in the interpretation of such guidance. But this leaves us with the so far unanswered question of how, and to whom,

individual clinicians should be held accountable for “reasonableness” in the exercise of their discretion.

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## Highly active antiretroviral therapy

### *Cardiovascular risk needs to be assessed before starting treatment*

In the industrialised world the availability of highly active antiretroviral treatment (HAART) for advanced HIV-1 disease has dramatically improved patients' life expectancy.<sup>1</sup> However, an unflinching lifelong commitment to antiviral drugs is expected. Furthermore, recent evidence is mounting that cardiovascular and cerebrovascular accidents might seriously impair the health of infected individuals,<sup>2</sup> and the resulting morbidity and mortality have put an end to the unlimited optimism that was associated with the beginning of the HAART era. Here we look at the importance of assessing and targeting the risk of cardiovascular disease before starting HAART and consider what effect this risk has on determining the best time to start treatment.

For people infected with HIV-1, HAART may substantially increase the risk of cardiovascular mortality compared with non-infected individuals or with people infected with HIV who are not yet taking HAART.<sup>3</sup> HAART is associated with known cardiovascular risk factors such as increased plasma concentrations of triglycerides, total cholesterol, possibly hypertension,<sup>4</sup> and increased insulin resistance. In addition, HAART induces endothelial dysfunction, which is known to increase the risk of coronary heart disease.<sup>5</sup>

The medical management of cardiovascular risk factors in patients on HAART gives rise to other problems related to HIV and HAART, such as an additional pill burden, which may impair adherence and lead to increased resistance.<sup>6</sup> This highlights the importance for such patients of reducing risk through changes in lifestyle, such as smoking cessation, salt restriction, and physical activity.

A proper assessment of current cardiovascular risk factors in HIV-1 infected individuals is of critical importance in order to implement strategies to reduce risk. Someone with HIV-1 infection should receive a cardiovascular risk profile as soon as possible and certainly before treatment is started, to inform timing and choice of regimen for HAART. The score most

applicable for this purpose is the Framingham risk score corresponding to known cardiovascular risk factors.<sup>7</sup> HAART may increase this score<sup>8</sup> through alterations in triglycerides, total cholesterol, high density lipoprotein, and possibly through the emergence of hypertension.<sup>4</sup> Currently the decision to start HAART is based on CD4T lymphocyte cell counts. Antiretroviral treatment will be started if the cell count drops below  $350 \times 10^9$  cells (Yeni P, keynote lecture, 7th International Congress on Drug Therapy and HIV Infection, Glasgow, 14-18 November 2004).

A concentration of  $200 \times 10^9$  cells is considered as the lower limit for starting HAART, since below this threshold the chances of developing an AIDS defining illness increase dramatically.<sup>9</sup> Potentially, however, a considerable time span exists between  $350 \times 10^9$  cells and  $200 \times 10^9$  cells—given an average viral load, this could easily be two to five years.<sup>10</sup>

Strong efforts need to be made during the individual's pre-HAART period to reduce cardiovascular risk factors, whereby selecting the patients most likely to benefit from risk reduction strategies is essential. When the Framingham risk scale is used, a score of 23 for women and 15 for men corresponds with a 20% risk over 10 years of developing coronary heart disease.<sup>7 11</sup> In this particular population, lifestyle changes (and eventually lipid lowering drugs) could substantially reduce the risk of coronary heart disease,<sup>11 12</sup> but it has to be borne in mind that the cumulative risk of acquiring an AIDS defining event does not increase if HAART is postponed until a CD4T lymphocyte cell count of  $200 \times 10^9$  is reached.<sup>13</sup> Furthermore, during the years of delay, new treatment options might come into life that carry less risk for cardiovascular disease.

The start of a HAART regimen remains a decision that implies an individual and a holistic approach. A high cardiovascular risk score warrants that treatment is delayed if needed until the lower threshold of  $200 \times 10^9$  CD4T lymphocyte cells is reached. Imple-