UK government likely to miss its target to reduce childhood obesity

Andrew Cole *London*

Confusion among local professionals over the best way to tackle child obesity is threatening the UK government's target of halting the increase in the condition by 2010, a report by three influential public watchdogs has warned.

A joint study by the Audit Commission, the Healthcare Commission, and the National Audit Office notes that two years after the announcement of the target, to stop the rise in obesity in children under 11, there has been little action on the ground.

Obesity in 2-10 year olds in the United Kingdom rose from 9.9% to 13.7% between 1995 and 2003, said the Audit Commission's chief executive, Steve Bundred. If present trends continue, the next generation will have a shorter life expectancy than their parents.

The government's plans to

tackle the problem were "very complex and ambitious," involving changing the behaviour and lifestyle of about a million children and their parents as well as close coordination between many different departments. But so far, says the report, little evidence indicates that the 20 different programmes to improve children's health and nutrition will encourage obese children to eat more healthily or exercise more.

The report is particularly critical of the lack of central guidance, which has meant that organisations have been unclear about their roles and that staff on the ground "may be wasting resources on ineffective or inappropriate interventions that fail to target those children most at risk."

The Department of Health produced guidance in early January on how schoolchildren should be measured and

weighed, with the aim of producing reliable baseline data as well as identifying where resources need to be targeted. Further advice on helping obese children is due later in the year.

Mark Davis, the director of cross government studies at the National Audit Office, said that the big question was whether

existing initiatives could really identify and target the children who were most at risk: "For instance, having more playing fields may just appeal to the children who like sport rather than the overweight ones."

Tackling Child Obesity: First Steps is available at www.nao.org.uk.

NEJM stands by its criticism of Vioxx study

Janice Hopkins Tanne *New York*

The *New England Journal of Medicine* last week reaffirmed the expression of concern that it made last December, about the omission of three heart attacks from a study of rofecoxib (Vioxx) published in 2000. The online editorial was published on 22 February 2006 (<http://content.nejm.org>, doi: 10.1056/NEJMe068054).

The journal also published responses from 11 authors of the study who are not employed by Merck, the drug's manufacturer, and from two authors who are (doi: 10.1056/NEJMc066096).

The controversy concerns the VIGOR (Vioxx gastrointestinal outcomes research) study, which compared upper gastrointestinal toxicity of rofecoxib with naproxen and was published in the journal in 2000 (*New England Journal of Medicine* 2000;343:1520-8).

Last year, the journal editors reviewed electronic documents

relating to the study when the journal's executive editor, Gregory Curfman, was preparing to testify at a trial in which a man's wife charged that rofecoxib caused his fatal heart attack. Merck won the case last month (*BMJ* 2006;332:440).

The editors said that they discovered that three patients had had heart attacks but had not been included in the published study. The journal then published its expression of concern (*New England Journal of Medicine* 2005;353:26, *BMJ* 2005;331:1423).

In the journal's reaffirmation of its original criticism, its editors say, "More than four months before the article was published, at least two of its authors were aware of critical data on an array of adverse cardiovascular events that were not included in the VIGOR article. These data, which should have raised concern about potential cardiovascular toxicity of rofecoxib, are part of an internal Merck memorandum."

"Although the information... was reported to the [Food and Drug Administration] and posted on its website three months after publication of the VIGOR article, it was not made available

to the journal editors during the manuscript review process. Because these data were not included in the published article, conclusions regarding the safety of rofecoxib were misleading."

The 11 non-Merck authors say that they approved the study termination date of 10 February 2000 and the cut-off date of 9 March 2000 for reporting gastrointestinal events.

Analysis of cardiovascular events, they write, was not part of the original study. Shortly before completion of the study, however, the independent data safety and monitoring board recommended to Merck that information on serious cardiovascular events be included. Merck decided to use the study termination date, 10 February 2000, as the cut-off date for reporting cardiovascular events, a month earlier than the cut-off date for reporting gastrointestinal events.

The non-Merck authors say that they did not know of the cut-off date for reporting cardiovascular events.

The three heart attacks were reported between 16 and 20 February 2000. The authors say that they did not know about them during the review process.

Even if they been included, assessment of the relative risks and widely overlapping 95% confidence intervals "does not suggest a difference in the conclusions," they write.

The two Merck authors also say that it was appropriate to exclude the three heart attacks because they occurred after the cut-off date. The authors deny a suggestion that information on the three heart attacks had been deleted from the manuscript before its submission, and say they did not know about these cases at the time of submission. If they had been included they would not have meaningfully changed the relative risk.

Furthermore, they say, "Merck consistently made full and appropriate disclosures of the cardiovascular results from VIGOR."

But the *New England Journal of Medicine*'s editors write that because the published article "did not contain relevant safety data available to the authors more than four months before publication, [it] did not accurately reflect the potential for serious cardiovascular toxicity with rofecoxib. We therefore reaffirm our expression of concern."