severe hypoglycaemia over a period of between five and 15 years is either mild or negligible. For a few individuals, with vulnerability factors which as yet remain obscure, brain function may be permanently and importantly affected. Strict glycaemic control has the great benefit of reducing target organ damage—delaying the onset and slowing the progress of retinopathy, nephropathy, and neuropathy—but brings with it a threefold increase in severe hypoglycaemia.¹² No one doubts that severe hypoglycaemia should be avoided, but patients and their carers are right in demanding more research to help them make intelligent decisions about the long term trade off between the Scylla of hyperglycaemia and the possible Charybdis of hypoglycaemia.

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New and not so new vaccines

Let's think about evidence based policy making

Calls are being made both at national¹ and international² level, to vaccinate whole populations against hepatitis B. Such exhortations are based on the fact that for the past 15 years safe and effective vaccines have been available to prevent the notable burden of morbidity and mortality from this global disease. But if uncritically accepted and extended to all new vaccines, this apparently humane logic could lead in the future to serious clashes between good intentions and resources. Some clear decision making principles are needed.

Technological advances such as genetic engineering and the advent of monoclonal antibodies have led to an explosion in the number of vaccines currently being developed and tested, many of which may become available in the next few decades. In future vaccines may be available to prevent or control such diverse and important diseases as melanoma,³ salmonellosis, hepatitis C, and cervical cancer.⁴

If the hepatitis B story is repeated it is likely that after each new vaccine has been licensed governments and other policy-makers will face pressure for its introduction firstly in high risk groups and then, if this approach is perceived as failing, in the general population, thus leading to diversion of resources from other health care programmes. Similar pressures may in the long run force a lack of coordination of health policies and may reinforce the concept that intervention on a particular problem is warranted simply because that intervention is available. Clear decision making rules would benefit consumers, governments, and the biomedical industry alike. How can these rules be decided and should they be international or national?

Vaccination programmes have traditionally been a national responsibility, and proposals for coordinated regional (or global) vaccination programmes and scheduling carry the faint whiff of utopia. In the European Union, for instance, virtually every member state has a different policy or reimbursement schedule for vaccinating against influenza.⁵ These differences in policy may be due to historical reasons or practical ones, such as school entry age. Perhaps the best approach would be to propose international criteria for allocating resources to a vaccination programme using either new (not previously licensed) or old vaccines.

Several possible candidate criteria exist. Firstly, the target disease should be important. Importance could be epidemiologically defined by each nation or subcontinent. A further refinement could be the definition of the economic burden avoidable by vaccination—in other words, how many resources could be freed up by an effective intervention. A second candidate criterion would be the quality of evidence of the vaccine's effectiveness, including its ability to achieve its objectives under field conditions, and not just in trials. This would involve an assessment of a vaccine's effectiveness after implementation of the vaccination programme. The third candidate criterion could be safety of the vaccine, perhaps assessed both through reports of adverse effects and large trials. Next we could assess whether the vaccine makes best use of available resources compared with other vaccines or with other interventions competing for the same resources. Other criteria could include the acceptability of the intervention to the general public and its integration into a country's general policies on health care.

Such explicit criteria would promote a wide debate on the necessity of involving policy makers, scientists, and the public in decisions which affect society. It would also stimulate the development of common surveillance policies and new ways of assessing new technologies. Most of all it would diminish the risk of hurried debates on whether to introduce a particular health programme, often conducted by pressure lobbies, who are never the most objective actors.

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