by valency of the vaccine and the outcomes by type of vaccine, population, or settings. None of six reviews found a statistically significant effect of pneumococcal polysaccharide vaccines on mortality in industrialised countries or on pneumoccoccal pneumonia in high risk and immunocompromised patients. Five of the six reviews reported a statistically significant reduction in pneumococcal pneumonia and bacteraemia among immunocompetent adults who were not otherwise at increased risk. The review by Watson et al reported a significant reduction in mortality (relative risk 0.79, 95% confidence interval 0.63 to 0.99) and all cause pneumonia (0.67, 0.52 to 0.87) in trials done in less industrialised countries.[1] A Cochrane review of eight trials of the effects of pneumococcal polysaccharide vaccines in children found an average protective efficacy of 10% against acute otitis media.[6] The Cochrane review by Sheikh et al found limited evidence of the effectiveness of pneumococcal polysaccharide vaccines in children and adults with asthma.[7]

The safety profile of pneumococcal polysaccharide vaccine is good, with transient erythema and induration appearing in up to 50% of recipients[4] and, very rarely, high fever.[1] Outcome data about safety were, however, seldom collected or reported in the trials.[1 4]

The acceptability of pneumococcal polysaccharide vaccines in elderly people seems good, especially if combined with influenza vaccines. Pneumococcal polysaccharide vaccines require revaccination, probably every five years, whereas the influenza vaccine needs to be administered every year.

The economic profile of pneumococcal polysaccharide vaccines is affected by the uncertainties underlying the epidemiology of the disease, the effectiveness of pneumococcal polysaccharide vaccines, and the economic methods used.[8] These problems are not specific to pneumococcal polysaccharide vaccines but affect a broad range of interventions and procedures that have been the subject of economic evaluations.[w8] Although several economic evaluations have concluded in favour of vaccination, a systematic review of the evidence has found that the evaluations used optimistic estimates of effectiveness.[8]

Given the diversity of epidemiological profiles of pneumococcal disease in different settings and populations and the consequent different vaccine performance, we believe that there is no generalisable answer to the question of whether and how to employ pneumococcal vaccine. It may be that protein conjugate pneumococcal vaccines show clearer effectiveness.[w9]

Each decision making body must make it own evaluation based on known epidemiology of the disease, likely effectiveness and safety, cost, and fit with the existing immunisation programme. We are struck, however, by the apparent conflict between evidence of effectiveness of pneumococcal polysaccharide vaccines and existing recommendations for their use. Enhanced surveillance of pneumococcal disease and a systematic review of all comparative studies assessing the effects of pneumococcal polysaccharide vaccines may allow us to glimpse the stars through clearer skies.

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Extending choice in the NHS

Implications for national sovereignty and trade rules have not been realised

The NHS white paper *Delivering the NHS Plan* continues the British government's commitment to "engage more constructively with the private sector" by giving patients a choice among public and private providers.[1] Building on the concordat between the private sector and the NHS, and the discussion document *Extending Choice*,[2] the white paper pledges that from July 2002 patients waiting six months for a heart operation can choose an alternative provider, "be they public or private." *Extending Choice* promised that by 2005 all hospital patients should be able to opt for treatment in "local NHS hospitals, NHS hospitals or diagnostic and treatment centres elsewhere, private hospitals, private diagnostic and treatment centres, or even hospitals overseas."

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The use of patient choice as a means of involving the private sector in the delivery of NHS care follows a series of rulings of the European Court of Justice. In the landmark Kohll case about patients' freedom to go to other European countries to get publicly funded health care,[3] the court ruled that patients can cross borders to get publicly funded "indispensable" treatment in the event of "undue delay." Indispensable treatment, according to the European Court of Justice, is treatment "sufficiently tried and tested by international medical science." Undue delay, however, has not been defined.

These rulings have serious implications for national control over health policy since they move decisions about healthcare policy from national

governments to the European Commission. The judgment gives the European Court of Justice licence to define "medical necessity" and "undue delay," and members of the European Union will be bound by this decision. For example, under a European Court of Justice definition of "undue delay" patients could challenge the United Kingdom government's qualification period of six months before patients with cardiac illness get access to providers outside the United Kingdom.

But patient choice among competing providers is a market reform that has wider repercussions under international trade law. Although the European Union's role has attracted growing attention,[3] little consideration has been given to the way in which consumer choice and the use of the private sector for NHS care will trigger the powers of the World Trade Organisation.

In 1994 the United Kingdom made commitments to liberalise hospital services under the rules of the World Trade Organisation. The rules governing multilateral trade agreements in services are set out in the General Agreement on Trade in Services. When services are supplied on a commercial basis the rules that protect the economic freedoms of private providers are triggered. The General Agreement on Trade in Services treaty is notoriously ill defined, and there is no coherent use of "commercial" in publications by the World Trade Organisation.[4] But the organisation has said that only a monopoly provider in the public sector is excluded from coverage by the General Agreement on Trade in Services. Additionally, a service is commercial when patients have a choice of hospitals—that is, when hospitals are effectively in competition regardless of whether ownership is in public or private hands.[5]

According to this interpretation, the market oriented reforms of the NHS Plan redefine the NHS as a commercial service subject to trade rules.[6] At the very least, final determination of the status of the NHS under the General Agreement on Trade in Services rules will be dependent on a disputes settlement panel of the World Trade Organisation and not on the British government. The determination is crucial because the government has already made commitments for commercial hospital services that leave the NHS vulnerable.

Under the rules of the General Agreement on Trade in Services, countries may opt to open markets (liberalise) in public services using any one of four modes of supply: crossborder supply (selling services abroad), consumption abroad (effectively the free movement of patients), commercial presence (foreign investment in health services) and presence of natural persons (free movement of medical personnel). In 1994 the United Kingdom's government agreed to open hospital services to foreign investors and to the free movement of patients (modes 2 and 3 liberalisation).[7] The commitment applied only to commercial hospital services (in those days, the United Kingdom's small private hospital sector). But the British government's involvement of the private sector in the provision of NHS hospital core services means that the NHS as a whole can now be considered commercial and subject to rules of the General Agreement on Trade in Services.

More seriously, in 1994 the United Kingdom failed to protect its policy making powers or right to regulate commercial hospital services. By contrast, seven of the 11 other European signatories to the European Commission commitment on hospital services (Belgium, France, Italy, Luxembourg, Portugal, the Netherlands, and Spain) placed restrictions on the private sector to ensure their involvement met with public healthcare objectives. For example, Spain requires that private suppliers seek prior authorisation from public authorities before setting up business, whereas Belgium, France, Italy, the Netherlands, and Luxembourg use healthcare planning to restrict private supply.

The United Kingdom's failure to protect its health policy making powers by using market access and national limitations of treatment in its schedule of commitments could have profound effects on the hospital system, creating uncertainty about the determination of key policy areas such as licensing and qualification requirements, service volume and quality, and the "necessity" of public policy (Organisation for Economic Cooperation and Development, services experts meeting. OECD, Paris, 4-5 March 2002).

It is far from evident that the British government has taken the necessary steps to protect the right to regulate NHS funded hospital services under its United Kingdom's General Agreement on Trade in Services commitments. The policy implications of opening up NHS services to private for profit providers are quite different under the World Trade Organisation than under the European integration process. In Europe decisions over necessary care and waiting times are now vested in the hands of the European Court of Justice pending a Europe wide health policy. In the World Trade Organisation's business friendly environment, granting the private sector a bigger role in the NHS has the potential to move control over health policy not simply out of the United Kingdom but out of the European public domain.[8 9] There is no sign yet that the Department of Trade and Industry has discussed the implications of introducing private sector providers into the NHS with the Department of Health and the Treasury.

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