

income have been added to the direct costs of medical care for varicella illness.<sup>4</sup>

If developed country governments are truly committed to the cause of global social justice,<sup>5</sup> they should be willing to forego the marginal benefits offered by vaccines such as the varicella vaccines and redirect these resources to ensuring that children in developing countries have greater access to an expanded range of life-saving vaccines.

I declare that I have no conflict of interest.

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## Payments for health care in India

Eddy van Doorslaer and colleagues (Oct 14, p 1357)<sup>1</sup> recognise the impoverishing effect of out-of-pocket (OOP) expenditure on Asian households. However, they do not explore an important element: the role of the providers, especially in the private sector, in contributing to high OOP payments. We take the example of India to highlight this issue.

India has the highest number of poor in the world; it is also one of the countries with the highest proportion of OOP payments for health care. However, most of these payments are in the private sector. Peters and colleagues<sup>2</sup> have shown that, even in poor Indian families, 79% of all

ambulatory care and 40% of all hospital admissions are in the private sector. Moreover, most of these OOP payments are made at the time of illness and the providers charge on a fee-for-service basis.<sup>3</sup> A tremendous burden is placed on families because they have to mobilise resources when they are most vulnerable.

This situation is further compounded by the poor quality of health care in the unregulated private sector<sup>4</sup> that results in unnecessary interventions and overprescriptions. We have found that more than 10% of all women between 18 and 45 years admitted to private hospitals in rural India had a hysterectomy, usually for dubious indications such as “pelvic inflammatory disease” or “white discharge per vagina” (unpublished data).

The government of India has proposed the introduction of health insurance. However, although this might protect households from direct OOP, it will still expose them to poor quality care and might even result in cost escalation.<sup>5</sup> So risk pooling needs to be accompanied by regulation of the private sector and quality assurance mechanisms.

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## Safety and immunogenicity of H5N1 vaccine

Jean-Louis Bresson and colleagues (May 20, p 1657)<sup>1</sup> report a phase I randomised trial of an inactivated H5N1 influenza vaccine. This work provides convincing evidence for the efficacy and short-term safety of this vaccine. However, we have some concerns about the long-term safety of this adjuvant-containing formulation.

The manufacturer chose aluminium hydroxide, a long-used adjuvant known to potentiate immune response through strong Th2 immunostimulatory effects.<sup>2</sup> It was regarded as safe and devoid of any severe adverse effects, but the emergence of macrophagic myofasciitis should lead vaccinologists to revisit this view.<sup>3</sup> Macrophagic myofasciitis is characterised by focal accumulation of aluminium-hydroxide-loaded macrophages at the site of previous intramuscular vaccination, representing unexpected long-term persistence of aluminium hydroxide after injection (median 53 months, range 3 months to 8 years).<sup>3</sup> Macrophagic myofasciitis lesions were associated with myalgias and fatigue, most patients fulfilling diagnostic criteria for chronic fatigue syndrome.<sup>3</sup>

Thus it seems clear that aluminium hydroxide does not fulfil the need for adjuvants to be “biodegradable and easily removed from the body”<sup>4</sup> and that the possible long-term adverse effects induced by this compound should be assessed.<sup>5</sup> We believe that trials assessing new vaccines containing aluminium hydroxide adjuvant should include long-term follow-up of enrolled participants.

We declare that we have no conflict of interest.

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