Neither paracetamol nor ibuprofen protects children against local reactions to the DTaP vaccine

Research question Can ibuprofen or paracetamol reduce the risk of local reactions to the DTaP vaccine against diphtheria, tetanus, and whooping cough?

Answer Probably not. Among children receiving their fifth dose, these medicines were no better at preventing local reactions than a placebo.

Why did the authors do the study? Children in the US receive five doses of a combined vaccine against diphtheria, tetanus, and whooping cough, commonly known as DTaP (diphtheria and tetanus toxoids-acellular pertussis). Reactions at the injection site become more likely with each dose, so that by the fifth dose up to two thirds of children have an erythematous reaction. These authors wanted to find out if paracetamol or ibuprofen could help prevent local reactions to the fifth and most troublesome dose.

What did they do? 372 children aged between 4 and 6 years took part in a randomised placebo controlled trial. They received three doses of paracetamol (15 mg/kg), ibuprofen (10 mg/kg), or placebo at six hourly intervals beginning up to two hours before their fifth dose of the DTaP vaccine. Parents recorded all reactions and other symptoms in a diary for six days. Parents had to measure any erythematous areas on the vaccinated limb and the limb's circumference to detect any swelling. The authors looked for differences between the groups in moderate erythema (≥ 5 cm in diameter), swelling (≥ 2 cm increase in mid-limb circumference), and reactions lasting three days or more.

The trial was carefully double blinded. The authors used intention to treat analysis for the main findings.

What did they find? Reactions were common: 43% of children had a local erythematous reaction measuring at least 2.5 cm across during the first two days after vaccination. Nearly half (49%) reported pain in the vaccinated limb. Neither medicine reduced the risk of moderate reactions (≥ 5 cm), which occurred in 37% of 150 children given ibuprofen, 33% of 150 children given paracetamol, and 35% of 72 children given a placebo. The medicines also had no effect on swelling or persistent reactions.

What does it mean? In this study, prophylactic paracetamol or ibuprofen did not prevent erythematous reactions to the fifth dose of DTaP among American children aged 4-6 years. But the study was only powerful enough to detect a 50% difference in the main outcomes between children given active medicine and those given a placebo. These medicines could still produce smaller benefits, although the study's authors say anything less than a 50% reduction in reactions would not be worth while clinically.

We still don't know what causes the common local reactions to this vaccine. The authors suggest they could be Arthus reactions caused by circulating antibody binding to vaccine antigen. Whatever the mechanism, paracetamol and ibuprofen don't seem to modify it enough to be clinically useful.

Jackson LA, et al. Prophylaxis with acetaminophen or ibuprofen for prevention of local reactions to the fifth diphtheria-tetanus toxoids-acellular pertussis vaccination: a randomised controlled trial. *Pediatrics* 2006;117:620-5

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Editor's choice

Time to leave home

These are bad times for the NHS. The words "crisis" and "meltdown" are flying around and few people say these are exaggerations. While the health secretary Patricia Hewitt maintains an impressive Thatcher-esque public facade, her department is believed to be in panic. Record spending has delivered record deficits and uncertain value for money. For the first time in anyone's memory, sizeable numbers of NHS staff are losing their jobs (News, p 743). How has this happened and what's to be done?

Last week's edition of the BBC's *Panorama* roundly blamed the government. It concluded that ministers had gravely miscalculated the cost of their reforms, especially the doctors' pay awards. Interviewed on the programme, John Appleby, senior economist at the King's Fund, agreed. The Department of Health must take the blame, he said, because it sets both the NHS's cost environment (most notably the doctors' pay increases) and its targets.

But government ministers blame managers. On *Panorama* Patricia Hewitt spoke of "a few bad apples"—incompetent managers who have failed to balance their books—and a culture of overspending. The managers interviewed on the programme cried foul. They said they had done what the government asked. They had met government pay awards and targets on waiting times, only to be told that there was no money for this additional activity. New accounting rules mean they must pay off the deficit and have the same amount deducted from next year's budget.

As the NHS slows down, perhaps to a standstill, two things are particularly depressing. First is the missed opportunity. The government found huge amounts of taxpayers' money and poured it into the NHS. Nothing like this is likely to happen again in our lifetimes. Second is the waste of energy and goodwill as staff and patients are buffeted by one policy change after another, often seeming to bring us full circle. And we are left not knowing whether we have gone too far with these reforms or not far enough. Are these the NHS's death throes or just the end of a painful adolescence?

If this crisis tells us anything it is that health care is too important to be left to politicians. Five or even 10 year terms of office do not lend themselves to long term strategic planning. If the NHS—the 33rd largest economy in the world—is to stop being a political football kicked from one party's version of an internal market to another's, it needs to be protected from party politics. An independent NHS authority (or four authorities for England, Scotland, Wales, and Northern Ireland) could do this. Each would be run by a board of governors responsible for managing health care within a set budget and a broad political framework. The analogy to that other great British institution, the BBC, is obvious.

Gordon Brown's first act as chancellor was to give the Bank of England independence to set interest rates. His first act as prime minister should be to give independence to the NHS.

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