Commentary on the paper by Benninga et al

When the editorial committee discussed whether to accept the paper by Benninga et al for publication, some members raised concerns over the propriety of undertaking rectal manometry on children with abdominal pain. In response, the authors promptly provided their correspondence with the appropriate ethical committee (institutional review board). These revealed that the authors had properly obtained approval for the investigation in constipated children, their siblings (following fully informed consent), and those undergoing endoscopy for other conditions.

We accepted the authors’ explanation that the children with a prime complaint of abdominal pain had been referred to their specialised dysmotility clinic. The inference is that those referring the patients considered their pain might be due to constipation. They wrote: “...in our outpatient clinic, the standard work-up for all children with functional defecation disorders or functional abdominal pain (irritable bowel syndrome or recurrent abdominal pain) includes a thorough medical history and complete physical examination, colonic transit studies, and rectal barostat studies.”

A related issue was raised recently in the correspondence columns of Thorax concerning a paper detailing bronchial biopsies performed, as a research procedure, on children with asthma whose prophylactic medication had been discontinued for the preceding month. Bush and colleagues pointed out that bronchial biopsy would be included among those high risk procedures which the Royal College of Paediatrics & Child Health considers unjustified for research purposes alone. The investigators, who practice far from the guiding light of the RCPCH, responded that informed consent was received from parents (they did not state whether children consented) and that, in any case, they watched the children closely with a view to exclude any disadvantage by cessation of prophylaxis.

So here is the dilemma: research projects require ethical committee approval while standard clinical practice may require only informed consent. In the case of the paper published in this issue, it seems that at some point research had elided seamlessly into routine practice. Once a procedure becomes part of a routine clinic work-up then it is presumably no longer a research project. In the case of the Thorax paper it appears that research regarded in one country as requiring ethical committee approval demands only parental consent in another.

We decided to publish the paper by Benninga et al because it contains valuable information for our readers and we accept there are grey areas, especially in tertiary care, as between research and standard clinical practice. I doubt that we would have published the Thorax paper.

I no longer write as editor, but I know that ADC does not intend to soften its line, but rather strengthen it, when it comes to ethical standards. During 2002, five papers submitted to ADC ended up being reported (after rejection) to the Committee on Publication Ethics (www.publicationethics.org.uk). We have passed on our concerns about four of them to the appropriate head of department or chief executive, asking him or her to mount an enquiry. We are likely to do the same about an alleged attempt at duplicate publication which we are still investigating.

REFERENCES
oxygen with use of an oxygen concentrator. Both provide oxygen with similar (assumed) effects so the economic choice is the therapy that minimises costs.

Costs in most theoretical discussions in economics include costs to all, specifically the value of what is given up to achieve something. There is much theoretical discussion about the use of average or marginal cost, the latter covering the actual change in costs rather than the average across a range of activity. Some things can be free, for example, if there is spare capacity in a system (a spare bed or a vacant and staffed theatre session), and marginal costing tries to take account of this. But marginal costs are often very context specific and there is widespread use of average costs in the practical literature. Also, while costs to citizens and families are theoretically important, practical studies often concentrate on the costs to the health care system alone.

Where outcomes have been measured in some standard units, it is possible to develop a cost effectiveness study. This looks at the cost of achieving each unit of outcome (for example, patient-year free of symptoms, case cured) using each treatment. Here the emphasis is on the incremental cost of achieving an extra unit of outcome by switching from one treatment to another. But cost effectiveness studies of this kind beg the question of whether treatment should be provided. That is, they do not ask the question “Is the health gain worth the cost?”, but only “How much more outcome (in standard units) can we get for our money?”. For example, a case cured may offer little gain relative to a case uncured if a disease is self-limiting and causes little long term health damage.

When outcomes are measured in more detail, typically by assessing the length and quality of life gains achieved by alternative treatments, we have a cost utility study. Utility was originally a definition in economics for the benefits of consumption (of goods and services, not lung disease). Terms such as welfare or wellbeing can be substituted for utility without too much loss of meaning and it is clearly only a short step from welfare to health.

In cost utility studies, changes in health are ideally measured using specialised instruments to assess the changes in individual capacity and the value attached to each element. A range of other techniques have been used to try to elicit values from what usually remain hypothetical choices. It is clearly very difficult to decide whether you would rather have ten years with moderate pain or eight years with no pain until you have had experience of the pain for some time. But equally, we are often assessing potential treatments in advance so the views of what the healthy would spend to avoid something may be more relevant than the views of sufferers, after the event.

In this issue, Ungar and Santos1 have examined the literature reporting health economics studies in paediatrics. They find a much smaller literature than for adults, reflecting, in their view, the greater complexity of research on children. There is no doubt that children face particular problems, but these may be of degree rather than distinction. Of course, children may struggle to value the alternative outcomes from the treatments available explicitly. But this may be less important, in policy terms, if decisions on treatment are made by their parents or other adults. Other factors limiting economic research on children include the reduced level of research by pharmaceutical companies on the smaller market for children’s therapy and perhaps the greater concentration on research in chronic diseases, where expenditure is high and some outcomes rather marginal. There may also be a tendency for children’s health care to gain priority due to the age of those suffering, rather than explicit evaluation of outcomes, so that there is less technical scrutiny of paediatrics (though this explanation is speculative).

Interested readers should see Drummond and colleagues’2 (also available in other languages), and may wish to consider the Distance Learning Course in Health Economics at the University of York (http://www.york.ac.uk/res/herc/distance.htm).

REFERENCE