tained by the postgraduate deans, will keep track of where trainees are in their programmes and will allow the national needs for new consultants to be balanced against the numbers of trainees in each specialty. In the transition period deans will allocate to each eligible trainee a national training number from a quota determined nationally for each specialty. They will then allocate numbers to each newly appointed specialist registrar.

As the Calman report makes clear, specialist training begins at full registration. The guidance notes spell out the process of implementation for the higher, second part of specialist training. An important recommendation of the report, on which advice is still awaited, concerns general professional training—that taken in the senior house officer grade. As progress is made in the higher level programmes, advance is urgently needed on the earlier, foundation part of specialist training.

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Evaluating new surgical procedures

Needs collaboration between surgeons and trialists

Surgery has been slow to take up the challenge of British epidemiologist Archie Cochrane: to prevent the introduction of new therapeutic procedures until randomised trials have shown them to be more effective than existing treatments.[1] For example, laparoscopic cholecystectomy was first performed in 1987 and became the standard treatment for symptomatic gall stones within about seven years. During this period no more than 10 trials comparing laparoscopic with conventional forms of cholecystectomy were published worldwide. Of three peer reviewed randomised trials comparing laparoscopic and minilaparotomy cholecystectomy published in Britain since 1992,[2-4] only one randomised more than 100 patients,[5] justified this with a calculation of sample size, and analysed the results by intention to treat.[6]

Many potential problems have been cited to explain the shortage of rigorous surgical trials.[7] Some are practical—for example, recruiting patients may be difficult. This problem can be resolved by undertaking the trial in many centres. Another potential problem—differences in skills between these centres—can be overcome by stratified sampling.[7] A third practical difficulty is that measuring appropriate outcomes may require years of follow up. This can be overcome if the centre coordinating the trial has long term funding,[8] something that may be easier to achieve in Britain when the new arrangements for funding NHS research facilities are established.[9]

An often cited methodological problem is that patients, when asked for their consent, may refuse to be randomised because they have a definite preference for one procedure rather than another.[7] There are at least three possible solutions to this problem. Firstly, the new procedure could be made available only in a randomised trial.[10] Secondly, it could be part of a patient preference trial, in which patients with a preference for one type of treatment receive their preferred procedure and patients with no preference are randomised.[11] Thirdly, the new procedure could be part of a randomised consent trial, in which only patients randomised to the new procedure are asked for consent.[12]

The fact that surgical trials cannot be double blind or placebo controlled is often seen as a major methodological problem. It is helpful to distinguish here between "explanatory" or "fastidious" trials (which seek to draw conclusions about defined scientific hypotheses) and "pragmatic" trials (which are designed to select the better of two procedures in clinical practice).[13] Fastidious trials define both the alternative procedures and the eligible patients by a rigid protocol that equalises the placebo effect of each procedure; participating surgeons must adhere to the protocol, and patients who fail to comply are excluded from the analysis.[14] In contrast, pragmatic trials define both procedures and patients by a flexible protocol that optimises the placebo effect of each procedure; participating surgeons may exercise clinical judgment, and patients who withdraw from experimental or control groups remain in that group for analysis by intention to treat.[6]

This distinction implies that, while fastidious trials may be helpful in developing a new surgical procedure, pragmatic trials are essential in evaluating its effectiveness in clinical practice. In particular, blinding both the surgeon and the patient to which procedure has been undertaken is not only impractical but also irrelevant since it is not part of the normal practice about which evidence is needed. Instead the real challenge is to ensure that the assessment of outcome is blind or at least unbiased. Use of a placebo or sham operation is equally impractical and irrelevant. Instead the real challenge is to predict the procedures between which commissioners and providers will need to choose.

Probably the most intractable of the methodological problems cited is the need to compare new surgical procedures with established ones.[7] There are two potential solutions to this problem, which are best used in combination. Firstly, analysis should take account of how experienced each surgeon is in performing the new operation. Secondly, and more difficult to achieve, randomisation should begin as soon as is feasible; this enables the researchers to monitor the learning curve and thus evaluate the short term costs, both clinical and economic, of establishing the new procedure. Thereafter the trial should be continued well beyond the end of the learning curve; this enables the researchers to evaluate whether that procedure also brings long term benefits.

In short, the randomised trial is the design of choice for evaluating new surgical procedures. Some of the methodological problems can be overcome by using pragmatic trials, but will need close collaboration between surgeons and trialists.

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Corticosteroids in the management of croup

Nebulised corticosteroids are the treatment of choice

Although croup is one of the commonest childhood complaints, its treatment has been empirical at best. Traditional management at home consists of creating a warm moist atmosphere by placing the child in a steam filled bathroom with the hot water taps running, but there is no objective evidence that this treatment is effective. Nebulised adrenaline is commonly prescribed in North America, and although it is of proved benefit, its effect is short lived.[1] Corticosteroids have been advocated, but until recently their use was contentious because of conflicting reports.[2-4]

Croup, or laryngotracheobronchitis, is most commonly seen in children aged 6 months to 4 years. It is caused by viral infection, usually with parainfluenza virus, although infection with influenza, respiratory syncitial virus, or rhinovirus may cause a similar clinical picture. Croup is characterised by a harsh, barking, seal-like cough, stridor, and hoarse voice, with symptoms usually occurring at night. There is usually a preceding coryzal illness, but fever rarely exceeds 39°C. The three most important differential diagnoses are epiglottitis, bacterial tracheitis, and inhalation of a foreign body. Epiglottitis is rare since the introduction of widespread immunisation against *Haemophilus influenzae*, and it virtually never results in a barking cough. This leaves bacterial tracheitis as the most important differential diagnosis. Although cough is a prominent feature, it is rarely barking, and the child is usually unwell.

The value of corticosteroids in the management of croup has recently been reappraised.[5-7] A meta-analysis of randomised controlled trials suggested that oral corticosteroids reduced the need for endotracheal intubation in children with severe croup,[6] and a prospective study has shown that oral corticosteroids result in earlier extubation and less frequent reintubation in children who have been intubated.[7] More important have been reports of the beneficial effects of nebulised corticosteroids in mild to moderate croup. In a randomised trial in 36 infants admitted with croup Husby *et al* reported significant improvement in those treated with 2 mg of nebulised budesonide compared with those treated with placebo.[8] The researchers graded the severity of croup with a standardised clinical scoring system (maximum score 15) based on the degree of stridor, cough, chest retraction, dyspnoea, and skin discoloration. The croup score decreased significantly from a mean of 8 to 4·5 in the children who received budesonide, while it remained at 8 before and after treatment in the children who received nebulised saline. The fact that significant improvement was evident within two hours suggests more than a simple anti-inflammatory effect.

Using a slightly different croup score, Klassen *et al* measured the effect of nebulised budesonide in 54 children with mild to moderate croup who attended an emergency department.[9] Four hours after treatment the mean croup score was significantly lower in children who received budesonide compared with those who received placebo. More importantly, children who received budesonide were discharged from the emergency department earlier and only one child required admission to hospital, compared with seven of the children who received placebo. In a further comparison of either 2 mg of nebulised budesonide or 0·6 mg/kg of oral dexamethasone versus placebo in children admitted to hospital for croup those who received either nebulised budesonide or oral dexamethasone showed a faster decrease in the croup score and were less likely still to be in hospital 24 hours later.[10]

Croup scores are a relatively crude and subjective measure of severity. Evidence of improvements in more objective physiological measures, such as shift in the phase relation between movement of the ribcage and abdomen, would be welcome. Taken together, however, these studies suggest that corticosteroids are effective in croup. Nebulised corticosteroids probably have fewer side effects than systemic corticosteroids, although there have been no direct comparisons, and they would therefore seem to be the treatment of choice in mild to moderate croup. Although they have been shown to decrease the risk of admission to hospital from an emergency department, there is still a need for controlled studies in the community showing a similar effect. Nevertheless, nebulised budesonide has the potential to decrease hospital admissions for croup, and general practitioners may find it a useful emergency drug to carry. Oral prednisolone may prove to be an alternative. It is essential that the child is reassessed two to four hours after treatment. Failure to respond to treatment should raise the need for alternative diagnoses and admission to hospital.

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