



## How to be good at practical procedures?

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## Something is moving in European drug research for children, but a more focused effort concerning all therapeutic needs is necessary

There is a well-recognised lack of suitable paediatric therapies. This is caused by the great difficulty in performing paediatric clinical trials. However, a recent assessment<sup>1</sup> evaluating and comparing ongoing and published paediatric drug-therapy trials found that significant therapeutic research efforts are ongoing.

The analysis examined data from both clinical trials in the Drug Evaluation in Children (DEC-net) European register of paediatric drug therapy trials<sup>2</sup> and published articles, and compared the results with the WHO European Region Top 7 Burden of Disease data for 0–14 year olds (ERBoD) to assess adherence of research to therapeutic needs based on documented disease impact. The main area for which European paediatric research seems to be carried out, neoplasms, is not among the top 7 ERBoD.

The study's data were analysed further. Data from trials representing ongoing research in Europe and published trials of EU research were compared with data from the ERBoD. Only 5% of the ongoing, and 9% of the published, trials addressed one of the three ERBoD areas concerning conditions treatable with drug therapies. The most commonly addressed, by both published and ongoing research, was asthma: the area of lowest burden in the Top 7 list.

Another recent analysis<sup>3</sup> evaluated the published trials more thoroughly and compared the EU trials to the European Medicines Agency (EMA) priority list for studies into off-patent paediatric medicinal products to compare the European research situation with paediatric drug therapy needs. The trials addressed the infectious and parasitic disease area most frequently (21.4%), and only addressed four of the 25 EMA priority conditions, the most common of which were malignant diseases (18% of trials) and asthma (3%). This revealed a lack of overlap between therapeutic needs and research.

Two of the EMA priority areas also appear in the ERBoD: migraine and asthma. However, while several trials (published and ongoing) addressed asthma, only one of the published, and none of the ongoing, addressed migraine. A possible explanation for such prioritisation of asthma research may be market pressure,<sup>4</sup> as is true for infectious disease therapy studies.

The data evaluated show an overall lack of response of research to documented paediatric needs. Published research's main interests involve three conditions (tumours, asthma and infections), which are always characterised by abundant research compared with other recognised therapeutic priorities. Thus, in Europe, children's need

for appropriate, effective medicines often remains neglected. Paediatric Regulation will certainly lead to more, improved, research but close monitoring is fundamental to verify that such research truly reflects children's needs.

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## How to be good at practical procedures?

There has been increasing concerns in the acute admission setting about the quality of lumbar punctures (LP), virtually all of which are undertaken by doctors in training. Traumatic (blood-stained) LP taps often result in diagnostic uncertainty, increased anxiety, the perception of technical incompetence and probably unnecessary treatment and prolonged stay in hospital. An audit of all acute LPs was recently undertaken in our paediatric department, which receives all GP referrals from Newcastle upon Tyne.

Seventy-seven LPs were performed in 15 months (January 2007 to March 2008). 31% were "champagne taps" of zero red cells and 21% were traumatic taps (>1000 red cells/ml). The same standard for defining a traumatic tap was used in a similar but larger survey<sup>1</sup> in which a higher rate of 35% was reported.

We believe that in the brave new world of competency-based training and European Working Time Directive that novel initiatives will need to be introduced to master essential procedures such as LP. Only five LPs per month were performed in our paediatric department, which has seven rostered SHOs. An SHO therefore has the opportunity to do an average of four LPs per SHO per six-month rotation if they are allowed to attempt each one. This is probably insufficient to master new skills. Possible learning opportunities currently

underutilised include regular oncology LP lists performed under general anaesthesia. Doctors in training can no longer rely on "being on the coal face" to learn all their practical procedures.

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## Pneumococcal prophylaxis for children with sickle cell disease in Africa

Penicillin prophylaxis and pneumococcal vaccination are routinely used in the United States and in Europe to prevent invasive pneumococcal diseases (IPD) in children with sickle cell disease (SCD). Their usefulness in African children with SCD has been recently challenged.<sup>1</sup> Indeed, a study of blood cultures in 155 SCD children with temperatures >38°C cared for in one medical centre in Uganda identified *Streptococcus pneumoniae* in only 6% of episodes. We agree with the authors that large, well-constructed studies assessing the risk of IPD in Africa are in order. However, we would like to suggest that their relatively small and monocentric study was perhaps biased by the fact that large numbers of children had succumbed to pneumococcal sepsis before ever reaching medical care. We believe that the available data strongly support the suggestion that *S pneumoniae* infection is a common cause of childhood bacteraemia in Africa. In Bamako, Mali, *S pneumoniae* was identified in 106 (5%) of 2049 children having a fever of 39°C or higher, including 47 children with meningitis and 44 with bacteraemic pneumonia.<sup>2</sup> IPD caused 10% of deaths and their overall fatality rate was 24%. Blood cultures were positive in 1094 (6.6%) of 16 570 children admitted to a rural district hospital in Kenya. *S pneumoniae* was found in 26% of patients 12 to 23 months old, and in 49% of patients more than 5 years old. The predominant isolates among children who died on the day of admission (103 deaths) was *S pneumoniae* (49%).<sup>3</sup> The same group obtained blood cultures from 1093 children who visited their hospital outpatient department over a 6-month period. The incidence of pneumococcal bacteraemia was 597 (416–778) per 100 000 person-year of admission in children younger than 5 years of age. Three-quarters of episodes had a clinical focus or required admission, or both; one in six was