Evidence in perinatal medicine: enough of trial and error?

A philosophy of practice based on evidence is well established in perinatal medicine and several large randomised controlled trials, organised in the UK, have made an important contribution in this regard. However, it is important to realise that, despite the current imperative in relation to evidence based practice, many fundamental aspects of perinatal care have not been subjected to a randomised trial. In the UK setting up studies to address such issues has always been difficult as there is only limited infrastructure available to support the process. Furthermore, important changes during the past few years, both within the service and in the public’s perception of the Health Service and research, mean that previous approaches may no longer be sustainable.

During the past 20 years there has been a major improvement in the survival of preterm infants that is unlikely to be repeated. As a result the primary outcomes of future trials are likely to be based on either very small improvements in survival (requiring large numbers of infants), or improved morbidity rates (requiring extensive follow up arrangements for large numbers of babies). Therefore, having developed a protocol the organisers of each new randomised trial have to compete for collaborating centres and largely re-invent the necessary administrative structure and follow up arrangements—all at a stage when the study is unfunded. The public have not generally understood the nature and role of trials and some have had an important contribution in this regard. However, it is important to realise there is a great deal of waste incurred by the present approach. Large amounts of time go into full protocol development and grant applications that do not succeed; funded trials fail to achieve recruitment targets, leading to failure of the study or requests for grant extensions; follow up arrangements are regularly re-invented and or duplicated. Eliminating these problems would represent a real saving.

There are, of course, many controversial issues that require wider debate. Should any network be exclusive—for example, limited to 20 large centres—or inclusive—open to all? Would membership mean that collaboration in every trial supported by the network was mandatory? Where would the “headquarters” be based and how would it be funded? Would funding for units joining the network be available through Culyer (money from central NHS funds given to Trusts to underpin research)? From the administrative point of view, how would those in the collaboration be viewed by university authorities in relation to grant income and publications, both of which would be “owned” by the network?

Despite these concerns, for the moment the key issue is that of principle. Many individuals involved in perinatal trials are aware of mounting difficulties that could be improved. A collaborative network might allow us to move forwards rapidly and the time is right to consider this option carefully both in relation to if, and how, we might take this step. Everyone involved in perinatal care has a role in that debate. However, if there is support then it must be the Royal Colleges of Paediatrics and Child Health and Obstetrics and Gynaecology who, together, take the lead on discussions with the NHS Executive on the ramifications. Given the government’s commitment to “evidence” and “clinical effectiveness,” it seems inconceivable that the executive would not support such a development if the message from the profession(s) is clearly supportive.

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2 Jones J. Government sets up inquiry into ventilation trial. BMJ 1999;318:553.