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 aspects of perinatal care have not been subjected to a randomized 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 been the subject of adverse publicity, so gaining consent has become increasingly difficult. This problem is compounded when consent is required at or around the time of delivery or when the study involves a child with a life threatening condition. Given that most recruitment and consent are carried out by clinical staff as an “extension” of their normal duties, it is not difficult to understand the recruitment difficulties experienced by most large perinatal trials in the UK over the past five years.

In recognition of this issue, other countries have opted to deal with the problem by establishing formal collaborative networks. Such a model has also worked in the UK for other specialties—for example, the UK children’s cancer study group. Should the UK now establish a perinatal trials network? Around the world such networks use a variety of organisational arrangements. In the USA, in at least one network, collaborating units receive additional funding that is linked to satisfactory recruitment and compliance with trial protocols. In other areas collaborative networks exist on a purely voluntary basis. In the former example entry to the network is limited to a group of highly active hospitals while in the latter essentially all interested perinatal hospitals are free to join. If the UK were to develop a network, what would be the correct approach? The Perinatal Trials Service (PTS) of the National Perinatal Epidemiology Unit (NPEU) already offers advice and support in relation to trials. The missing elements are:

- a mechanism for establishing a national strategy and prioritisation so that competing trials are not taking place at the same time
- an established network of units committed to running randomised trials
- financial support for collaborating units to ensure recruitment and data collection are efficient
- 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.

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- an administrative infrastructure responsible for coordinating protocol development, data management, and follow up

- an established network of units committed to running randomised trials
- financial support for collaborating units to ensure recruitment and data collection are efficient
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