Chapter 1

THE EVOLUTION OF NEONATAL CARE

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Learning outcomes

After reading this chapter the reader will be expected to be able to:

● Summarise the history of the development of neonatal care
● Explain the influences which have lead to the current model of delivery of neonatal care
● Relate the published mortality rates to the analysis of reproductive health services
● Explain the term ‘evidence based practice’
● Summarise the origin of the best evidence that guides current practice
● Explain the term ‘research governance’

The photo in Figure 1.1 shows an intensive care space at a modern well-designed neonatal unit that allows enough space for parental access as well as for the neonatal nurse and clinical team to provide neonatal intensive care comfortably (Christchurch Women’s Hospital, New Zealand).

Introduction: historical accounts of neonatal care

Throughout history there are records of medical interventions focused on babies. In pre-modern societies, as well as in much of the developing world today, pregnancy and childbirth was the main cause of death for women of childbearing age. Infants have always been born preterm and with the other problems commonly seen on neonatal units, but it is only in the last fifty years that there has been sufficient understanding of these problems for significant effective treatments to be developed.

The problem of how to resuscitate infants at birth is a good example of these developments. It has long been recognised that some newly born infants are unresponsive and apparently lifeless. Many interventions for use in this situation were advocated by people with apparently positive experiences of their use. These included such bizarre treatments as applying onion or mustard to the infant’s mouth and nose, blowing smoke into the infant’s rectum and the use of an inhaled brandy mist1. We now understand that the apparent success of some of these treatments was simply due to the fact that most infants who do not breathe immediately at birth will go on to establish
spontaneous respirations without any help at all; in other words, these historical infants were getting better *despite* what the attendants at the birth did, not *because* of it. As an understanding of the physiology of the establishment of breathing at birth was gained, so it was possible to develop effective tools and procedures to deal with infants who do not breathe immediately, and for these to be incorporated into protocolised teaching programmes that are now widely disseminated to those engaged in newborn care\(^2\).

Similar processes, which could be characterised as a movement away from care that was based on poor understanding of physiology and towards care based on good evidence founded on well-established physiological studies, have occurred in every aspect of the care of sick newborn infants.

**Implications for practice**

The development of neonatal care can be summarised as occurring because of an improved understanding of the physiology of the newborn with well established physiological studies leading to evidence for the practice of effective care.
The development of modern neonatal care

Neonatology and neonatal nursing as specialty areas of work are relatively new, having largely emerged over the period since 1970. Prior to this period sick newborn infants were mostly cared for by obstetricians and midwives and there was scant specialist provision. Most hospitals did not have a dedicated unit for sick infants.

Technology

Starting slowly, clinical care has advanced ever more rapidly during the modern era. The possibility of using warmth from incubators and additional oxygen to breathe as treatments for premature infants were first explored at the end of the nineteenth century but the term ‘neonatology’ wasn’t invented until 1960 and the first newborn ICU didn’t open until 1965.

Innovation and new treatments have followed rapidly since this period. Some, with minor modifications, remain in use to this day. For example, the first observation that light has an effect on bilirubin levels was made in 1956 by Sister Ward, a nurse on the premature baby unit at Rochford General Hospital in Essex and remains the mainstay of treatment. Other treatments have been adopted enthusiastically and subsequently substantially modified, most notably the use of inhaled oxygen for premature infants with respiratory distress. Early work showed that additional oxygen improved the respiratory status of infants with premature lung disease, but it needed the first ever randomised controlled trial in newborns to show that too much oxygen often led to severe visual impairment by the development of retinopathy of prematurity (ROP). Oxygen saturation monitoring for newborns was first described in 1987, and now is ubiquitous in neonatal units. It is of note, however, that the ‘right’ level of blood oxygen saturation for premature newborn infants has yet to be reliably established, and research continues (http://www.npeu.ox.ac.uk/boost).

Nursing

The establishment of neonatal nursing as a specialty occurred in the UK in the 1970s. The need for skilled nurses to staff newly-established neonatal units led to training courses being designed (English National Board Course 405 in Special & Intensive Care of the Newborn, and others). The nurse staffing units at this time started to come together regionally and nationally to discuss common concerns, and this led in 1977 to the formation of the Neonatal Nurses Association, and later of the Scottish Neonatal Nurses Group. While the educational framework for neonatal nursing has changed as higher education has developed, courses in universities which educate nurses in neonatal care remain a cornerstone of care provision. A number of specialist roles for nurses developed subsequently, in areas such as family support and transport.

Advanced neonatal nurse practitioners (ANNPs) have been trained in the UK since 1992, following earlier development of the role in the USA. ANNP training builds on the role of the neonatal nurse to produce a professional able to integrate both nursing and medical aspects of care. Differing approaches have been developed, both to the education programmes and to the subsequent deployment of ANNPs in practice. ANNPs have been evaluated in structured research projects and found to offer equivalent or better care when compared to existing caregivers in doing acute transport, resuscitation at birth and routine neonatal checks. While their ability to provide cohesive and comprehensive care has been a strength, their identity as neither wholly medical nor nursing has hindered group development and recognition.

For nursing careers, the latest development has been the emergence of Neonatal Nurse Consultants. Envisaged as a new group giving nursing increased influence, and with diverse areas of responsibility, from transport to low dependency care, they are a group whose ability to influence quality of care is under some scrutiny and where further evaluation is needed.
Organisation

As clinical care has evolved, so has the organisation of the services in which clinical care is provided. In the UK, important steps in the establishment of neonatal care are marked by Government reports. In 1971 the Sheldon Report recommended that neonatal care be provided in some form wherever infants were being born\textsuperscript{11}. It also recognised that not every unit would be able to provide every treatment, and so a distinction was drawn between intensive and special care units and the report recommended that expert transport facilities would be needed to move sick infants to the place best able to care for them. Subsequently, a variety of influences have helped shape the service in the UK and elsewhere. Initially, it was the enthusiasm of a small number of individuals that led to the formation of a handful of units specialising in the care of sick newborn infants. However pressure from the professions and the public encouraged successive governments in the UK to develop a service with nationwide coverage\textsuperscript{12–17}. The rate of evolution varied around the country but, particularly during the 1980s, there was a steady move towards a three-tier service based on the health regions (populations of 2 to 4 million) that existed at the time. The intention was that each of these geographical areas would be served by three types of neonatal unit:

Level 1

- Hospitals which delivered infants expected to be well; resuscitation could be provided if necessary but no ongoing care. Infants requiring such support were transferred.

Level 2

- Hospitals with higher delivery rates capable of providing resuscitation and limited ongoing care. Infants with more complex problems were transferred.

Level 3

- Regional centres, based largely in teaching hospitals, capable of providing a full range of neonatal services.

The rationale for this approach was:

- Reasonable geographical coverage was ensured
- High throughput for the level 3 units enabled clinical skills to be maintained
- High levels of bed occupancy (in level 3 units) permitted efficient use of expensive resources

The regional centres also had additional responsibilities, including specialist training for nurses and doctors and the provision of a transport service for sick babies born elsewhere. Although this structure, which had been adopted by a number of other high-cost, low-volume specialties, appeared a sensible approach for the delivery of neonatal intensive care it was never fully established across the UK at that time. Concerns that a centralised system of care was not appropriate centred on the following:

- Infants in outlying units were disadvantaged in terms of access and availability
- Shortage of cots, leading to very long distance transfers
- Deskilling in local units
- Disruption to family life following long distance transfers

Reforms of the 1990s

By the beginning of the 1990s rising demand for neonatal intensive care generated increasing public disquiet over access to and availability of neonatal intensive care facilities. Both Government and health authorities were keen to respond to public demands for increased local services. The NHS reforms, introduced for other reasons, and an increase in the personnel with neonatal expertise available in District General Hospitals proved
to be the vehicles for change. By 1992, strategic planning and funding for neonatal care (in fact for virtually all services) was reduced to Health District level (average population 500,000). By 1996 any tendency towards increasing centralisation had ceased and a quarter of neonatal intensive care was delivered in small local units (i.e. less than three intensive care cots) whilst the old regional centres (at least six intensive care cots) retained approximately one half.

The current model of care

The decentralised approach to specialist neonatal care continued until the turn of the century, when a number of factors lead to review of the service. Particularly important considerations were:

- The introduction of the European Working Time Directive, which made the medical staffing of smaller neonatal units particularly costly
- A growing shortage of specialist neonatal nurses
- Increasing complexity of care associated with improved survival of the most immature babies

A review, initiated by the Department of Health, recommended the introduction of managed clinical networks. It was envisaged that these would be based in groups of units, who between them would generally deliver 15000–30000 births, working together. Within any one network units would be designated to a particular role: level 1, level 2 or level 3, exactly in line with the three-tier model of the 1980s described above. The difference here would be that:

- Neonatal care capacity for the population would be planned
- In any one network all complex intensive care would fall to just one or two level 3 units
- Just one intensive care unit would act as the lead and take on wider responsibilities for activities such as guideline development, audit training, transport, training, etc.
- The group of hospitals would work collaboratively

It is too early to assess the success or otherwise of this particular model, but in time it will be important to look at the effectiveness of this model of care in terms of:

- Whether the increased centralisation (described in relation to the three-tier model of the 1980s) is now seen as acceptable to the public at large
- Whether outcomes are at least as good as those prior to the introduction of networks
- Whether there is increased efficiency, with higher rates of occupancy, particularly of the intensive care cots compared to when these were shared over many more units

Implications for practice

The current model of neonatal care has similarities with the three-tier system of the 1980s but involves units of different tiers working together in managed clinical networks. Its development was stimulated by changes in medical working patterns, availability of specialist nursing staff and the survival of infants with increasing complex medical needs.

The development of transport services

In any service that relies to some extent on treatment in a central unit, transport of patients becomes an essential element of the package of care. In general, families do not welcome the prospect of changing hospitals and teams at a time of anxiety and if there are other children the move may cause additional worries and impose significant cost. Referring clinicians are therefore under particular pressure to achieve the best outcome whilst exposing mother and infant to the least possible risk (see also Chapter 13).

In utero transfers

Neonatal intensive care is in the special position of often being able to choose to move the
potential patient either before or after delivery. There is no doubt that it is far easier, and in general safer, to move an infant in utero.

While much attention has been given to the organisation of post-natal transfers (see below) there has been little increase in the sophistication of the organisation of in utero (or antenatal) transfers. The process usually involves a local decision that an impending infant cannot be offered care locally, for reasons of complexity of care or local workload. This decision is followed by telephone calls to obstetric, midwifery and neonatal staff at local units until both an obstetric and a neonatal bed have been found. Some networks have developed cot-finding services that appear effective in coordinating the referring and receiving units, but these are far from universal.

In utero transfer sometimes causes particular problems for the family when after moving to another hospital away from their home delivery is delayed, perhaps for several weeks.

Post-natal transfer

The same individual enthusiasm which marked the initial development of specialist neonatal units in the UK was also responsible for the provision of emergency transfer services. Units often constructed their own equipment for this purpose, with medical and nursing staff chosen ad hoc from those on duty on the neonatal unit when a transport was required. These people were often untrained in the particular constraints and issues involved in safe post-natal transfer. A number of high profile accidents highlighted the inappropriateness of this approach. European standards now exist which specify very precisely the type of equipment that should be used during such transfers and the way in which it should be transported. With regard to staff, regulation of working hours has meant that the old system of ad hoc teams could not continue and there has, since 2000, been a steady move towards the use of transport teams. Nursing and medical staff engaged in neonatal transfers now routinely receive training specifically in transport care. Many of the recently formed neonatal networks have treated getting transport provision right as a priority, and so investment in staff and supporting infrastructure for transport has been considerable in these areas.

Definitions of neonatal care

Traditionally, the work of the neonatal service has been subdivided as follows:

- Normal care – that which could reasonably be expected to be given by the parents
- Special care – for babies requiring some specialist medical or nursing input
- Intensive care (normally divided into intensive care and high dependency care) – for babies requiring continuous medical and nursing support

Within the UK, a number of definitions exist relating to this broad structure and around the world there are further variations. These systems have been developed from clinical interest to allow the work of any one unit to be monitored over time and as an aid to audit.

More recently, consideration has been given to clinical classifications as markers of cost. In the UK, Health Resource Groupings (HRGs) have been developed based on the BAPM 2001 system for describing levels of care. It was envisaged that from 2008, work identified using this system would be the basis of the funding that individual neonatal units in the UK would receive.

Analysis of reproductive health services

The quality of services for mothers and babies are described by measuring particular rates. These are:

- The perinatal mortality rate: this is the number of stillbirths and the number of babies dying in the first week of life divided by the total number of births (alive and dead)
for a given period. In the UK all babies born
dead after 24 weeks of gestation are included
in this number as stillbirths, but figures vary
between countries with some using, for exam-
ple, 28 weeks of gestation as the cut-off with
regard to stillbirths.
• The neonatal mortality rate: this is the num-
ber of live born children dying at or before 28
days of age divided by the number of live
births for a given period.
• The infant mortality rate: this is the number
of live born children dying in the first year of
life divided by the number of live births for a
given period.

Perinatal mortality is heavily influenced by late
stillbirths but all three of the above rates are
heavily influenced by prematurity and congenital
anomalies. In fact these are the major influences
for neonatal and infant mortality.

These rates are typically calculated over a one-
year period so that clusters of small numbers of
deaths do not produce sudden major variations in
the mortality rates. They are normally calculated
for whole geographical population. This means
that rather than looking at the results of a single
hospital it is the results of the whole locality (i.e.
the net effect of all the mother and baby serv-
ices) that are assessed. This is done in order that
some obvious biases are removed. For example,
if one were to compare the perinatal mortality
results of a general hospital that booked all the
women for delivery from the locality considered
high risk and compared the rate to that of the
local midwifery unit that delivered only low-risk
women then inevitably the rate for the general
hospital would be higher than that for the mid-
wifery unit. Therefore these rates are best used
to compare whether the whole service for a com-
munity with all its component parts is working
better or worse than those in other parts of the
country. Figure 1.2 shows trends in two of these
measures over a thirty-year period.

Does this mean that individual hospitals can-
not be compared? It is true that comparing hos-
pitals fairly is complex, but systems have been
developed to allow some aspects of the work
of individual neonatal units to be compared.
A variety of techniques have been developed
which allow the babies admitted at 32 weeks ges-
tation or less to be scored in terms of how ill they
are and how likely they are to die. As a result,
for each unit it is possible to calculate how many
babies one would have expected to die and com-
pare this to how many actually did die. The scor-
ing systems are based on a variety of factors such
as birthweight, gestation, oxygen requirement,
temperature, etc., and the exact combination
and how they are used are unique to each sys-
tem. The most commonly used of these scores in
the UK are CRIB (Clinical Risk Index for Babies)
and CRIB II (see Table 1.1).
Nursing the Neonate

Using evidence – evolution of research methods

Neonatal care can now claim to be one of the most evidence-based areas of medical practice. Most NICUs have guidelines and protocols outlining how care and treatment should be delivered, and these are usually based wholly or substantially on evidence from clinical trials. This is not to suggest that we know everything – many questions remain to be answered and many problems remain unsolved and much more research is needed, but nonetheless there is now a substantial knowledge base underpinning neonatal care.

But as we saw above in the section discussing historical practice in the resuscitation of infants at birth, it is only in the recent past that it has been possible to base clinical practice on good evidence. To understand how we got from a time when there was little evidence, and practice was governed by the beliefs of the practitioner, to the situation now, where discussion of evidence in the clinical setting is commonplace, it is necessary to consider both the regulatory and social contexts in which both care and research were undertaken and also improvements in research methods.

Research methods

The knowledge base is advanced by several distinct types of study. Basic science research is concerned to understand physiological processes. For example, in neonatal care important work was done in 1960s to work out what the problem was in premature infants that caused them to have breathing difficulties. For some time the patent ductus arteriosus was thought to be the cause, and treatment strategies were developed for this. It was the work of Mary Ellen Avery which led to an understanding that the key issue was surfactant deficiency.

Once physiological processes are understood it becomes possible to develop rational treatment strategies. However, simply because a new

### Table 1.1 CRIB scoring system.

<table>
<thead>
<tr>
<th>Physiological variable</th>
<th>Range of values that provided the weighting</th>
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<tbody>
<tr>
<td>Birthweight (g)</td>
<td>&gt; 1350</td>
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<tr>
<td></td>
<td>851–1350</td>
</tr>
<tr>
<td></td>
<td>701–850</td>
</tr>
<tr>
<td></td>
<td>≤ 700</td>
</tr>
<tr>
<td>Gestation (wk)</td>
<td>≥ 24</td>
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<tr>
<td></td>
<td>≤ 24</td>
</tr>
<tr>
<td>Congenital malformation (excluding inevitably lethal malformation)</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Not acutely life-threatening</td>
</tr>
<tr>
<td></td>
<td>Acutely life-threatening</td>
</tr>
<tr>
<td>Maximal base excess in first 12 h (mmol/L)</td>
<td>≥ − 7</td>
</tr>
<tr>
<td></td>
<td>− 7 to − 9.9</td>
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<tr>
<td></td>
<td>− 10 to − 14.9</td>
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<tr>
<td></td>
<td>≤ − 15</td>
</tr>
<tr>
<td>Minimum appropriate FIO₂ in first 12 hours (TcPO₂ or PaO₂ = 6.7–10.7 kPa or SaO₂ = 88–95%)</td>
<td>≤ 0.40</td>
</tr>
<tr>
<td></td>
<td>0.41–0.60</td>
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<tr>
<td></td>
<td>0.61–0.90</td>
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<tr>
<td></td>
<td>0.91–1.00</td>
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<tr>
<td>Maximum appropriate FIO₂ in first 12 hours (TcPO₂ or PaO₂ = 6.7–10.7 kPa or SaO₂ = 88–95%)</td>
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<td>0.41–0.80</td>
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<td>0.81–0.90</td>
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<td>0.91–1.00</td>
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CRIB is one of a number of scores developed to help compare outcomes between units. Every infant less than 32 weeks is given a numerical score based on each of the above criteria in the first 12 hours of life. Babies with higher scores are ‘sicker’ and therefore would be expected to have a higher risk of dying. The score allows adjustment for this fact between units. A subsequent version of this score has used a somewhat more complex approach, whilst others scores tend to be based on many more variables.

Imlications for practice

The perinatal and neonatal mortality rates are used to give information that relates to the neonatal care within a particular geographical population. The use of scoring systems such as the CRIB score can be used to assess the care of a particular hospital.
drug or treatment has been developed from basic science research does not mean that it will be effective. The most important development in clinical research has been the ability to do good randomised controlled trials.

**Randomised controlled trials (RCTs)**

The RCT has become the cornerstone of clinical research. Before RCTs it was common for new treatments to simply be given to a selected group of patients and some simple short-term outcome data collected. These treatments often appeared effective, especially when compared with a selected group of patients given the ‘old’ treatment. Many problems became evident with these methods. Groups of patients given the old and new treatments were not comparable, studies were very small, the researchers knew who had received which treatment so might have been biased in favour of the patients receiving the new one and outcome measures were often very short term. Modern RCTs aim to produce evidence that is as unbiased and as widely applicable as possible. In order to do this, researchers take a number of important steps. First, the study is designed with sufficient numbers of patients to reduce the possibility of an erroneous conclusion. When studies are very small it is possible to achieve apparently strikingly significant results which are actually incorrect because by chance there are a larger than expected number of treatment successes or failures in one of the groups. Larger studies minimise these problems. Second, wherever possible researchers seek to achieve comparability between the two groups of patients in the study, those receiving the new treatment and those not. This is best done by randomly assigning patients to receive one or other treatment. Additionally, in order to reduce bias it is best if none of the team caring for the patient (or family) or the researchers are aware of which treatment group the patient is in. This helps reduce the possibility for any possibly unconscious bias when patients are being assessed. Finally, studies are designed with outcome measures that are important. For example, a new treatment for hypotension could be shown to raise blood pressure when compared to standard treatment. While this finding might be interesting to researchers, what clinical staff and families want to know is whether this results in more infants surviving NICU care and surviving with neurodevelopment that is equal or better than infants treated without the new drug.

**Cochrane**

The most significant recent development in RCTs is the improvements in the methods available for pooling the results of several studies. Each individual study in a particular area has limitations, maybe in the number of infants enrolled or their severity of illness or their ethnic background, etc. The Cochrane Library of Systematic Reviews is a web-based resource comprising meta-analyses of similar studies. A meta-analysis is where several similar studies are analysed together in an attempt to elicit whether the increase in numbers of patients available for analysis by this pooling of data reveals more reliable findings than from the individual studies alone. For example, using these methods established unequivocally the effectiveness of antenatal steroid treatment for maturing the lungs of premature infants.

**Other research methods**

While interventions such as new drugs and treatments may be readily studied using RCTs, other aspects of care require different approaches. Much neonatal nursing research has been directed toward understanding the experience of being a parent of an NICU infant. Qualitative research methods are the appropriate tool to use in this setting, and a diverse range of approaches have been developed.

Rather than try to produce definite results like in a drug trial, qualitative research aims to develop an authentic understanding of the lived experience of the subjects. A number of methods have been developed to both collect and analyse
qualitative data. Some data collection methods aim to reproduce the rigour of quantitative studies, for example by using scales to quantify attitudes and feelings. Others reject attempts at quantification, claiming this area of research is unsuitable for numerical analysis, and use observation, interview and recordings of conversations to collect data.

While these types of research are often criticised for their subjectivity when compared to quantitative studies, it seems unlikely that attitudes and feelings can be reliably reduced to numerical analysis. In fact there is now a large body of nursing research attempting to understand various aspects of the parental experience. The challenge now is to attempt to draw these together and build a greater understanding based on many individual studies.

**Implications for practice**

The evidence for neonatal care was historically based on scientific physiological studies as well as observation. These methods had a number of weaknesses and have been replaced by the use of randomised controlled trials which aim to provide quantitative information of an unbiased nature that provides evidence to advance neonatal care.

**Evolution of research regulation**

The climate in which research is undertaken has changed completely over the period of the evolution of modern neonatal care.

In the early days of neonatal research, projects were usually undertaken entirely at the whim of the academic involved. A new treatment could be developed and tested on sick newborn infants with little external scrutiny of whether it was a sound idea, whether the study was well constructed and likely to yield a result, whether it might result in harm for the patient and certainly without seeking consent for participation from the infant’s family.

In the wider social context of the time, this was not an unusual attitude. All kinds of medical treatments were delivered by paternalistic doctors to passive patients, both parties believing that ‘doctor knows best’. The relationship between the medical professions and the public has altered substantially and hand in hand with that the research climate has evolved too. In particular, widely reported instances of problems with research both in neonates and elsewhere have led to ever greater regulation of how research is done. A substantial legislative and procedural framework (‘research governance’) now exists, which governs every aspect of how research is undertaken. For a research project to proceed now formal applications for approval will have to be made, both locally and possibly nationally, to ethics committees, research and development departments of hospitals, to funding bodies, research coordination networks and others. The process is intensely bureaucratic, repetitive and time-consuming. The days of the amateur researcher, the clinician who dabbles, are largely over. There have been a number of important benefits from the changes in the research climate. Better constructed, larger studies are being done, and because such multicentre studies often need local coordination there are opportunities for nurses and others to get involved in research. Nurse academics with their own research programmes are also established now, both in the UK and elsewhere.

**Implications for practice**

The term ‘research governance’ is a term that encompasses the policies and procedures that now surround the application and delivery of research, which have been brought in to raise standards and protect patients.

**Conclusion**

Nurses have always believed that nursing care makes a difference for babies in intensive care, and while there is some evidence for this the
nature of what constitutes ‘best care’ remains to be elicited in many areas. The challenge in the coming era for both clinical neonatal nurses and for those engaged in research is to strive to make neonatal nursing a speciality that has a sound research base and where the connections between researchers and clinical nurses mean that the care that is delivered is based on this research evidence.

References


