CESDI

Confidential Enquiry into Stillbirths and Deaths in Infancy
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8th Annual Report

Focusing on:
Stillbirths
European Comparisons of Perinatal Care
Paediatric Postmortem Issues
Survival Rates of Premature Babies – Project 27/28

CONTENTS

PREFACE

The Maternal and Child Health Research Consortium are pleased to publish the 8th Annual Report of the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI).

As with previous reports, we begin with a general review and analysis of all cases reported to the Enquiry. It is again gratifying to see the extremely high rate of ascertainment of cases – a reflection of the reporting mechanisms developed through the Rapid Report Forms – and the vigilance and hard work of our Regional Co-ordinators and their local networks.

The contents of this report reflect the evolving function and structure of our Confidential Enquiry. The current Enquiry topic – Project 27/28 – has not only collected denominator data but, in addition, is a case-control study. When fully analysed, it will provide vitally important data and pointers to potential improvements in antenatal, intrapartum and neonatal care in this very important group of premature infants.

It is gratifying that the methodology developed by CESDI is being used as a model for use by other European countries. This, in future, will provide the basis for real comparisons across Europe – several countries of which spend far greater percentages of their gross domestic product on health provision.

The messages from previous reports with regard to electronic fetal monitoring and the need for structured training initiatives and appropriate use in labour in high-risk cases is evident from the report in Chapter 8. These key points have been further amplified in the publication in May 2001 of the National Institute of Clinical Excellence (NICE) Clinical Guideline entitled 'The Use of Electronic Fetal Monitoring'. This demonstrates how useful the links between Confidential Enquiry findings and the National Institute for Clinical Excellence could be in the future, particularly if extended further into areas for National Audit identified by the Enquiries.

Implementation of uptake of guidance now becomes of paramount importance to the NHS if we are to make progress in improving standards of care and outcomes – aspects that Clinical Governance Committees in all NHS Trusts should address.

We await the decisions of NICE following their review of all four Confidential Enquiries. CESDI sees advantages in change, but the quality of data and ascertainment of cases has been dependent upon our

excellent Regional Co-ordinators and networks. We thank all concerned for their continued commitment and hard work in the Regions, but most especially the contributions from the members of the Interim Advisory Group and Dr Mary Macintosh and the central CESDI Secretariat for ensuring, once again, that we have produced another timely and educative Annual Report.

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The Confidential Enquiry for Stillbirths and Deaths in Infancy is associated with the National Institute of Clinical Excellence through a funding contract. This arrangement provides the Institute with the ability to secure value for money in the use of NHS funds invested in this organisation's work, and enables NICE to influence topic selection, methodology and dissemination to be of value to the NHS in England and Wales, and recommend that it be used to inform decisions on service organisation and delivery.

This publication represents the views of the authors, and not necessarily the views of the Institute.

1 INTRODUCTION

1.1 HISTORY

The Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) was established in 1992 to improve understanding of how the risks of death in late fetal life and infancy, from 20 weeks of pregnancy to one year after birth, might be reduced. CESDI attempts to identify risks that can be attributed to suboptimal clinical care.

In 1991, the Department of Health directed that the 14 'Regions' of England should undertake Perinatal Mortality Surveys. CESDI was subsequently organised on this regional basis with separate arrangements for Wales and Northern Ireland. The CESDI network has remained despite organisational changes in the NHS during 1994–95 and 1998–99.

In the first instance, CESDI was funded directly by the Department of Health. In April 1996, responsibility for the management of CESDI was assumed by the Maternal and Child Health Research Consortium (MCHRC). This group was established by the Royal College of Obstetricians and Gynaecologists (RCOG), the Royal College of Paediatrics and Child Health, the Royal College of Pathology and the Royal College of Midwives. From 1 April 1999, CESDI has been one of the four National Enquiries under the umbrella of the National Institute for Clinical Excellence (NICE). Administratively, CESDI now reports to NICE rather than directly to the Department of Health.

1.2 THE REVIEW OF ENQUIRIES

NICE commissioned an external review of the National Enquiries which reported in June 2000. The focuses of the other Enquiries are maternal deaths, peri-operative deaths, and suicides and homicides by people with mental illness. Key issues were the purpose of the Enquiries in the new NHS, their past, present and likely future contributions to health, and whether their methods, including the issue of confidentiality, required change. The review acknowledged that the strengths of the Confidential Enquiries are their independence and the support they receive from the professions. However, it highlighted that the Enquiries are largely autonomous with no mandatory link to Government healthcare priorities. The review also commented that the present confidentiality arrangements involved no feedback, either to the clinicians involved or to the responsible trusts or health authorities.

One of the main recommendations of the review was that the four Enquiries should be managed by a single agency with a single

consolidated budget, perhaps as a National Confidential Enquiries Consortium (NCEC). The Consortium should have a detailed service-level contract with NICE to pursue a specific and regularly reviewed programme. The implementation of this is in progress.

1.3 THE ORGANISATIONAL STRUCTURE

CESDI comprises a central Secretariat and a network of Regional Co-ordinators throughout England, Wales and Northern Ireland. An Executive Steering Group, comprising a nominee from each of the four Colleges of the MCHRC oversees the running of the Enquiry. In addition, since its inception CESDI has had a series of three advisory groups: the National Advisory Body (1992–99); the Professional Steering Group (1996–99) and the Interim Advisory Group (1999 to the present date). The Interim Advisory Group was appointed when CESDI transferred into NICE and will continue until the proposed arrangements with NICE are formalised.

The Advisory Group advises on the content of the work programme and reviews the Annual Report. The Secretariat is responsible for the design and implementation of this programme including the preparation and dissemination of the Annual Report.

1.4 THE WORK OF CESDI

CESDI is tasked to provide an overview of the numbers and causes of stillbirth and infant deaths, together with a detailed Enquiry into specific subsets. A notification process (the Rapid Report Form) was introduced in 1993 and identifies some 10 000 deaths annually occurring between 20 weeks' gestation and 1 year of life in England, Wales and Northern Ireland. Validation checks with the Office for National Statistics show this reporting to be around 99% complete. It is not possible to enquire on all deaths, and so from the outset CESDI had a rolling programme with the choice of the subset for Enquiry. The notification process in conjunction with the annual validation check ensures that the subset is representative of the whole population and is not limited or biased by self-reporting.

The Advisory Group has determined the choice of topic for Enquiry; the flexible rolling programme is summarised in Table 1.1. For the future, the NICE review recommended that Enquiry programmes should concur with the health targets of the Government.

In addition to panel enquiries, there are a series of other projects that include: focus groups and central reviews; audits and collaborative projects. These are summarised in Table 1.1.

Until 1998, the enquiries had been restricted to deaths, although information on 'controls' had been collected in the Sudden Unexpected Death in Infants study and in the Antepartum Term Stillbirth study. In general, the absence of controls and denominator information had limited the interpretation of the findings in a wider context. In response to this, collection of the 'denominators' and controls has been introduced into the current programme (Project 27/28) which is evaluating the care of premature babies.

Table 1.1 The work programmes of CESDI

	Year of study	Findings reported
Enquiry topic		
Intrapartum related deaths >2.5 kg	1993	2nd Annual Report
Intrapartum related deaths >1.5 kg	1994–95	4th Annual Report
'Explained' sudden unexpected deaths in infancy	1993–96	5th Annual Report
'1 in 10' sample of all deaths >1 kg	1996–97	6th Annual Report
All deaths 4 kg and over	1997	6th Annual Report
Case control studies		
Sudden unexpected deaths in infancy	1993–96	3rd and 5th Annual Report
Sudden unexpected deaths in infancy	1993–96	The CESDI SUDI studies[1]
Antepartum term stillbirths	1995	5th Annual Report
Project 27/28	1998–2000	8th Annual Report
Focus groups and central reviews		
Shoulder dystocia	1994–95	5th Annual Report
Ruptured uterus	1994–95	5th Annual Report
Planned home delivery	1994–95	5th Annual Report
Anaesthetic complications and delays	1994–95	7th Annual Report
Breech presentation at the onset of labour	1994–95	7th Annual Report
Stillbirths	1996–97	8th Annual Report
Audits and collaborative work		
Postmortem reporting	1994–95	6th Annual Report
Postmortem reporting	1993	2nd Annual Report
CTG education	1999	7th Annual Report
European comparisons of perinatal care	1995–98	8th Annual Report
Use of electronic fetal monitoring	1999	8th Annual Report

1.5 THE ENQUIRY PROCESS

The Enquiry itself has comprised a review of anonymised medical records from an individual case by a multidisciplinary panel independent of the case or hospital. Each panel consists of experts from a number of disciplines including obstetrics, paediatrics, midwifery, specialist perinatal/paediatric pathology and general practice. Other parties with appropriate expertise may also be involved. Panel members are sent anonymised case-notes prior to the meeting. At the meeting itself, the panel produces a summary of the case and completes a standard CESDI form outlining any areas of suboptimal care. The information is given with the understanding that there will be no feedback to the units or

individuals concerned with the case, but that the findings will be published in a report.

This process necessarily involves a large number of assessors, in part because the participation process is educational. This in turn means that consistency of assessment is not easy to achieve. With this in mind, a more structured enquiry form and guidance on the standards of care expected have been introduced into the most recent programme, Project 27/28.

Until 1999, cases were assessed within the Region of care. However because of the difficulties in obtaining an independent neonatologist within Region for Project 27/28, the assessments for the second year of this programme have been held outside Region.

1.6 FUTURE PROGRAMME

1.6.1 Multiple pregnancies

Last year (7th Annual Report[2]) multiple pregnancy was highlighted as the next topic for Enquiry. A consultation exercise was undertaken and it became apparent that this is a particularly complex area for national enquiry work. It has been decided that further time is required to determine the scope and design a programme in this area suitable for implementation at national level.

1.6.2 Diabetic pregnancies – the next Enquiry

Diabetes is the most common pre-existing medical disorder complicating pregnancy in the United Kingdom (approximately 4 per 1000 pregnancies). It was also widely hoped that the goal of the St Vincent Declaration[3] of a near-normal outcome of a diabetic pregnancy could be achieved, but it appears that this may not have been met within the UK. Three population-based surveys[4–6] have shown perinatal mortality rates ranging from 36.1/1000 to 42.8/1000, against a background perinatal mortality rate of 7.9/1000.

There is a wide variation in the type of care that a diabetic patient may expect during her pregnancy. A national survey in 1993–94 showed that the facilities and supervision of pregnant diabetic women appeared to be suboptimal in around half of obstetric units[7].

The Northern Region has piloted a Confidential Enquiry approach in this area successfully[8] and, in view of this, CESDI will introduce an Enquiry into the care of diabetic pregnancies as its next programme. This will include identification of all pregnancies and enquiries into pregnancies associated with losses from 20 weeks' gestation to one month of life, and also into a sample of those that are associated with a good pregnancy outcome.

1.6.3 **Evaluating the enquiry method**

The educational value of multidisciplinary panel assessment has been a key strength of CESDI. Following a Second Pass Panel Exercise (1997) of consistency of panel assessment, CESDI decided to introduce a series of changes to the panel format, many in keeping with the subsequent Review recommendations. These include a structured enquiry form and a standards document. In addition, three other significant changes were introduced in Project 27/28: the use of controls; assessment outside the Region of birth, and collection of denominator data. A formal assessment of these changes is proposed to inform future enquiry methods.

1.7 CONTENTS OF THIS REPORT

1.7.1 **Infant and perinatal mortality – 1999**

CESDI undertakes a national on-going survey of perinatal and infant deaths (between 20 weeks' gestation and 1 year of life). Chapter 2 describes the 1999 national data, and highlights trends from 1993. In particular, it is pleasing to report that, for the first time, there is a significant reduction in the number of deaths of babies weighing over 1 kg attributed to intrapartum events. Care during labour has been one of the key areas of concern for CESDI over recent years. The 4th Annual Report[9] highlighted that at least half of labour-related deaths were considered to have been avoidable. The regular reporting of these deaths since 1993 has made it possible to confirm the fall in the number of deaths.

1.7.2 **Stillbirths – unexplained but not unavoidable**

Recent improvements in intrapartum care have not been echoed in other aspects of antenatal care. Stillbirths are frequently described as unexplained – and as such are often thought to be unavoidable. This was not the conclusion of the CESDI panels, which found suboptimal care in nearly half of all stillbirths in the '1 in 10' programme (6th CESDI Annual Report)[10]. Stillbirths contribute over a third of all deaths reported to CESDI. Because of this, it was recommended that a review of the antenatal and postnatal comments made by the panels should be undertaken, and this is covered in Chapter 3. The review reveals widespread inconsistencies in the definition of good practice in the management of common pregnancy complications. Management of the suspected small baby was a notable area. The problems of identifying and classifying the cause of death in the case of a stillbirth are discussed in the accompanying commentary; in particular, the failure of the current classification to give sufficient emphasis to growth restriction and to identify associated maternal and fetal conditions.

1.7.3 **Use of electronic fetal monitoring – a UK survey**

In the review of the intrapartum-related deaths in 1994–95, the most frequent criticism related to failures in the use and interpretation of cardiotocograph (CTG) tracings. As a result of this, CESDI recommended that every hospital provide a regular training programme

in this area[9]. The Report did not comment on the value of routine use of this technology. The Department of Health commissioned a national evidence-based guideline addressing this question which was undertaken by the Clinical Effectiveness Support Unit of the RCOG. To inform the guideline, the unit carried out a survey of the use of electronic fetal monitoring in a variety of situations. The survey also included the provision and availability of facilities for fetal blood sampling, umbilical cord blood sampling and departmental guidelines. The results are reported in Chapter 6 of this Report.

1.7.4 **Issues related to gaining consent for postmortem**

During the inquiry into the management of the care of children receiving heart surgery at Bristol, it emerged that retention of hearts removed during postmortem examination had been commonplace and in many cases it appears to have taken place without parental consent. It subsequently emerged that a more extreme situation existed at Alder Hey Children's Hospital in Liverpool. These events have resulted in a great deal of public concern. The issues relating to gaining consent for postmortem are discussed in Chapter 5. As a response to the recommendations from these public inquiries, CESDI is updating its information leaflet issued in 1999: *The Fetal and Infant Post-mortem: Brief Notes for the Professional*.

1.7.5 **European comparisons of perinatal care**

Differences in perinatal mortality rates between countries might be associated with the quality of antenatal and perinatal care. This issue has been addressed as part of a large European collaboration, the EuroNatal study, which has investigated the background to differences in perinatal mortality.

Seven of the CESDI Regions contributed to this work on behalf of England. A panel of 12 experts from participating countries reviewed 1619 cases of perinatal death from ten European countries to determine whether or not there were suboptimal factors in antenatal and perinatal care in certain categories of stillbirths and neonatal deaths. The grading of suboptimal care used by CESDI was adopted and the experts addressed explicit criteria based on international consensus and evidence of effectiveness. This was a unique opportunity to compare the quality of care provided within different healthcare systems of Europe and the possible association with perinatal mortality rates. The initial results are given in Chapter 4.

1.7.6 **Premature babies at 27 to 28 weeks' gestation – national and regional survival rates**

Prematurity is the major cause of neonatal deaths. This applies especially in the very low birth weight group (less than 1.5 kg) which accounts for 1–2% of births and approximately half of neonatal deaths. However, despite data on gestational age being routinely recorded on all births, it

is not collected centrally in England or Northern Ireland. Consequently, it has not been possible to provide national data on survival after preterm delivery. One of the key aims of the recent Enquiry programme Project 27/28 was to provide national and regional survival figures for premature babies born between 27 to 28 weeks' gestation in 1998 to 2000. A notification process at birth was introduced by CESDI to provide the relevant denominator. This comprised completion of specially designed logbooks introduced on all delivery suites and neonatal intensive care units. A minimum data set, including all locations for the baby in the first 28 days following birth, was collected by the Regional Co-ordinators and collated centrally. The results provide a two-year snapshot of regional and national survival rates and ex-utero transfers. These are reported in Chapter 7.

1.7.7 **Changing practice – risk management approaches**

Fundamental to the purpose of the Enquiries is that action should be taken on the basis of the findings. Two Reports have included reviews of how the Royal Colleges and other statutory bodies responsible for training and accreditation are responding to the recommendations[10,11]. A Regional response was reported last year[2] (7th Annual Report). This year the Clinical Negligence Scheme for Trusts, which covers all NHS Trusts in England, has reported on how it uses the CESDI findings. This scheme does not exist in Wales or Northern Ireland but commentaries on the relevance of the Enquiry findings to these Regions are included in Chapter 8.

1.8 VIEWS OF THE INTERIM ADVISORY GROUP

The Interim Advisory Group have been consulted about this Report and are in agreement with the contents.

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Members of the Consortium Executive Steering Group, the Secretariat, the Interim Advisory Group and the various working groups are listed in this Report. While it has been the prime responsibility of the Secretariat and the Executive Steering Group to produce the Report, they gratefully acknowledge the invaluable input made by the Interim Advisory Group to the Report as a whole, as well as the other contributors named in Appendix 5.

2

INFANT AND PERINATAL MORTALITY – 1999

2.1 INTRODUCTION

The Rapid Report Form (RRF) is the CESDI notification system first used in 1993. Its purposes are:

- to obtain a data set for each death within the CESDI range between 20 weeks' gestation and one year of life; and
- to provide information as soon as possible after the death in order to support the enquiry process.

The RRF data collection form for 1999 is reproduced in Appendix 1.

Statistics on all infant deaths and stillbirths at 24 or more completed weeks of gestation are also compiled at a national level for England and Wales by the Office for National Statistics (ONS) and for Northern Ireland by the General Register Office (GRO), Northern Ireland. They are based on information recorded when stillbirths and infant deaths are registered with local registrars of births and deaths, and include socio-demographic information, such as details of parents' ages, occupations, countries of birth and marital status. As registration of death is statutory, the ONS and GRO figures can be used as an ascertainment check for the RRF returns. The content of RRF data is predominantly clinical.

2.2 NOTIFICATIONS TO CESDI

2.2.1 Ascertainment and quality of CESDI notifications

Ascertainment of CESDI notifications has improved consistently since 1993 and has levelled out at around 99% of registered stillbirths and infant deaths from 1996 onwards. Identification of post-neonatal deaths has been the most difficult for CESDI but this has continued to improve from 86% in 1993, to 93% in 1999.

The quality of the data items on the RRF is assessed by the response rate to 29 questions considered to be essential. Completion of these questions in 1999 was high – for example, case definition (100%), date delivered (100%), date of death (99.9%), sex (98.7%) and Wigglesworth classification (98.8%). The question answered least often was the first day of the last menstrual period (86.0%).

2.2.2 Stillbirth rate and neonatal mortality rate

Table 2.1 shows the number of deaths reported to CESDI by RRF between 1993 and 1999.

Table 2.1 Rapid Report Form returns 1993–99

	England, Wales and Northern Ireland													
	1993		1994		1995		1996		1997		1998		1999	
	No.	Rate	No.	Rate	No.	Rate	No.	Rate	No.	Rate	No.	Rate	No.	Rate
Legal abortions	–	–	–	–	959	–	1102	–	1299	–	1503	–	**1558**	–
Late fetal loss [a]	1495	–	1573	–	1553	–	1659	–	1774	–	1672	–	**1679**	–
legal abortions									*1062*		*1204*		*1248*	
Stillbirths[a,b]	3726	5.3	3747	5.4	3698	5.5	3688	5.4	3440	5.1	3347	5.0	**3216**	5.0
legal abortions									*179*	*0.3*	*256*	*0.4*	*253*	*0.4*
Perinatal deaths[a,b]	–	–	5897	8.5	5829	8.6	5898	8.7	5503	8.2	5266	7.9	**5115**	7.9
legal abortions									*237*	*0.4*	*299*	*0.5*	*310*	*0.5*
Neonatal deaths[a,c]	2755	4.0	2749	4.0	2714	4.0	2785	4.1	2648	4.0	2493	3.8	**2502**	3.9
legal abortions									*58*	*0.1*	*43*	*0.1*	*57*	*0.1*
Postneonatal deaths[c]	1242	1.8	1199	1.7	1156	1.7	1253	1.9	1257	1.9	1210	1.8	**1184**	1.8
Total reports – RRF	9218		9268		10080		10487		10418		10225		**10139**	
Total live births	696133		688545		671861		674071		666370		659762		**644940**	

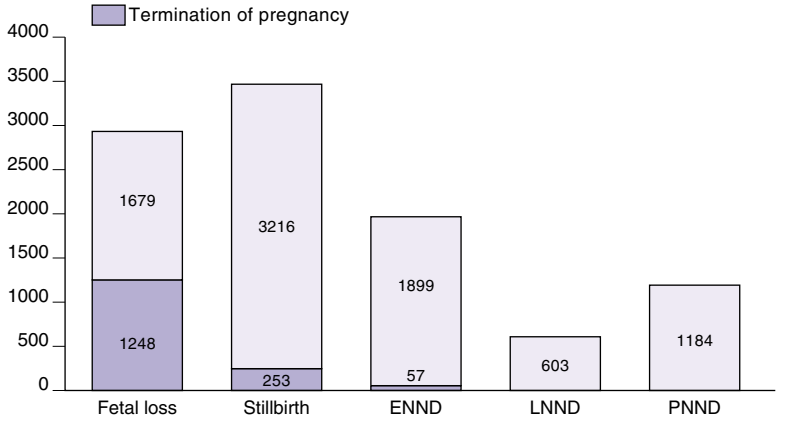
[a]Excluding legal abortions 1997–99
[b]Rate per 1000 live births + stillbirths
[c]Rate per 1000 live births

Sources: Deaths: RRF 1999
Live births ONS 1999
N Ireland GRO 1999

Classification of terminations of pregnancy

Since 1995, CESDI has collected information on terminations of pregnancy in England, Wales and Northern Ireland after 20 weeks or more of gestation. Up to 1996, distinctions were not made between a termination of pregnancy and a spontaneous late fetal loss, stillbirth or early neonatal death. For example, if a late fetal loss was due to termination of pregnancy, it could be reported as a late fetal loss or a termination of pregnancy but not both. In 1997, the question on termination of pregnancy was modified to enable it to be identified independently. Figure 2.1 shows the proportion of terminations of

Figure 2.1 The proportion of terminations of pregnancy for each case definition from RRF returns in 1999. There was a total of 1558 terminations and 10 139 deaths. ENND, Early neonatal death; LNND, late neonatal death; PNND, post-neonatal death



Source: RRF 1999

pregnancy for each case definition in 1999. The effects of these modifications on late fetal loss, stillbirth and early neonatal death rates are shown in Table 2.1. It is seen that 57 terminations of pregnancy were notified as early neonatal deaths. Of these 57 cases, 46 (80.7%) were performed for fetal abnormality and 4 (7.0%) for significant maternal disease (in 7 cases the indication for termination of pregnancy was not given); 43 (75.4%) were carried out at less than 23 weeks' gestation.

The number of live births, number of deaths and the mortality rates for singleton and multiple births in England, Wales and Northern Ireland is shown in Table 2.2.

Table 2.2 Stillbirths and neonatal deaths for singleton and multiple births 1993–99

	England, Wales and Northern Ireland						
	1993	**1994**	**1995**	**1996**	**1997**	**1998**	**1999**
Total live births	696133	688545	671861	674071	666370	659762	644940
Singleton	678676	670734	653278	655834	647279	640781	626269
Multiple	17457	17811	18583	18237	19091	18778	18455
Stillbirths							
Singleton	3422	3390	3340	3329	3251	3230	3073
Multiple	297	355	356	350	358	371	395
Unclassified	7	2	2	9	10	2	1
Neonatal deaths							
Singleton	2267	2259	2213	2258	2228	2071	2085
Multiple	477	477	487	517	472	457	470
Unclassified	11	13	14	10	6	8	4
Stillbirth rate[a]							
Singleton	5.0	5.0	5.1	5.1	5.0	5.0	4.9
Multiple	16.7	19.5	18.8	18.8	18.4	19.4	21.0
Neonatal mortality rate[b]							
Singleton	3.3	3.4	3.4	3.4	3.4	3.2	3.3
Multiple	27.3	26.8	26.2	28.3	24.7	24.3	25.5

[a]Rate per 1000 live births + stillbirths
[b]Rate per 1000 live births

Sources: N Ireland GRO 1999
RRF 1999
ONS 1999

2.2.3 Cause of death

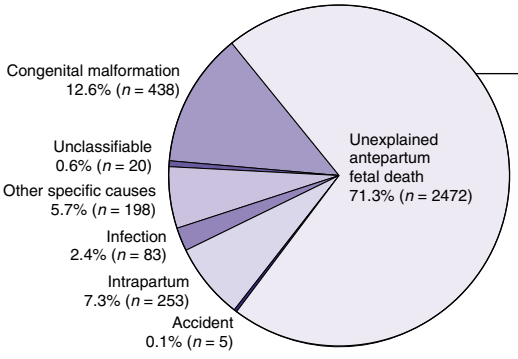
The cause of death grouped according to the three classifications used by CESDI (Extended Wigglesworth; Obstetric Aberdeen; Fetal and Neonatal Factor; see Appendices 2, 3 and 4) for stillbirths, neonatal and post-neonatal deaths in 1999 is shown in Figures 2.2, 2.3 and 2.4.

For stillbirths grouped according to the Wigglesworth classification (Figure 2.2), the largest proportion was unexplained antepartum fetal death (n = 2472, 71.3%). The most common identifiable causes of death were congenital malformation (n = 438, 12.6%) and intrapartum related events (n = 253, 7.3%). The 2472 unexplained antepartum fetal deaths were further described using the Obstetric Aberdeen classification. This analysis indicated that antepartum haemorrhage occurred in 404 cases (11.6% of total stillbirths; 403/3469).

For neonatal deaths grouped according to the Wigglesworth classification (Figure 2.3), the main cause of death was immaturity (*n* = 1209, 47.2%), followed by congenital anomaly (*n* = 625, 24.4%). The 1209 neonatal deaths caused by immaturity were further described using the Fetal and Neonatal Factor classification, and 778 of these deaths were due to asphyxia before birth.

For post-neonatal deaths (Figure 2.4), the three most common causes of death were congenital anomaly (*n* = 338, 28.5%), sudden infant death syndrome (SIDS *n* = 291, 24.6%) and infection (*n* = 233, 19.7%).

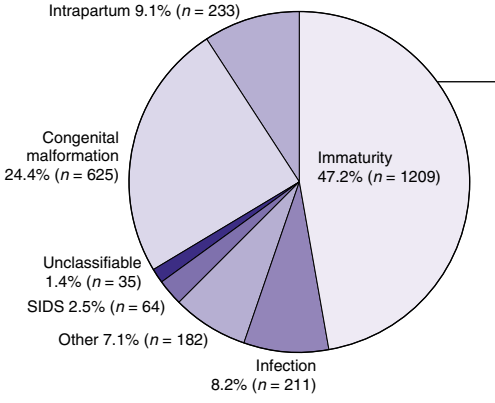
Figure 2.2 Stillbirths in England, Wales and Northern Ireland in 1999 grouped according to the Wigglesworth classification



Obstetric Aberdeen classification	Unexplained deaths Number	(%)
Antepartum haemorrhage	404	16.3
Maternal disorder	162	6.6
Pre-eclampsia	121	4.9
Mechanical	39	1.6
Miscellaneous	11	0.4
Unexplained	1735	70.2
Total	**2472**	**100.0**

n = 3469
Source: RRF 1999

Figure 2.3 Neonatal deaths in England, Wales and Northern Ireland in 1999 grouped according to the Wigglesworth classification



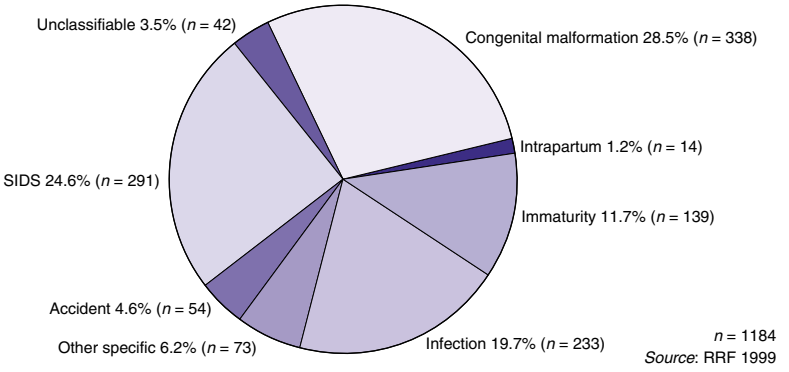
Fetal Neonatal Factor classification	Immaturity deaths Number	(%)
Asphyxia before birth	778	64.4
Hyaline membrane disease	349	28.9
Intraventricular haemorrhage	39	3.2
Infection	34	2.8
Unclassifiable	9	0.7
Total	**1209**	**100.0**

n = 2559
Source: RRF 1999

2.2.4 Variation in mortality rates by CESDI region

Stillbirth rate, neonatal and post-neonatal mortality rates by tabulated region of residence of mother in 1999 are shown in Figure 2.5. Numbers of live births in 1999 were obtained from the ONS and Northern Ireland GRO. The ONS data pertaining to England were initially classified

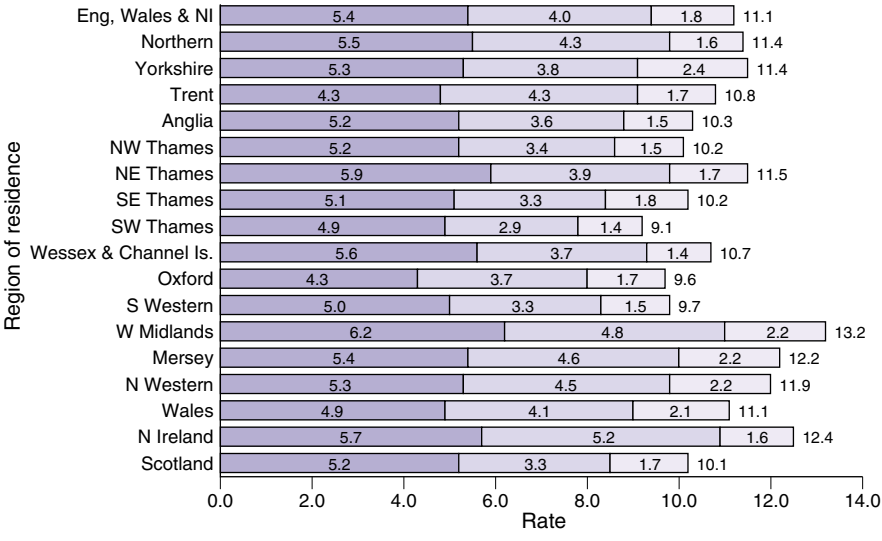
Figure 2.4 Post-neonatal deaths in England, Wales and Northern Ireland in 1999 grouped according to the Wigglesworth classification



according to the eight NHS Executive Regional Office boundaries (1997) and converted to the 14 CESDI regions. Due to boundary changes, however, the conversion for some regions, notably South Western and Wessex and the Channel Islands are not exact. These crude mortality rates are *not* direct indicators of standards of care and should *not* be interpreted as such. There are other factors which can influence outcomes.

The combined mortality rate (stillbirths, neonatal and post-neonatal deaths per 1000 total births, i.e. live births + stillbirths) was calculated

Figure 2.5 Stillbirth rate[a], neonatal[b], post-neonatal[b] and combined[a] mortality rates in 1999 by CESDI region of residence of mother



[a] per 1000 live births and stillbirths.
[b] per 1000 live births.

Source: RRF 1999, ONS 1999, N Ireland GRO 1999, Scotland annual report 1999

for each region (Figure 2.5). This ranged from 9.1 to 13.2 deaths per 1000 total births and overall was 11.1 per 1000 total births. For comparison, figures have been included from the Scottish Stillbirth and Infant Report 1999.

2.2.5 Intrapartum-related mortality rates

An intrapartum-related death refers to category 3 of the Extended Wigglesworth classification (Appendix 2), and is defined 'as any baby who would have survived but for some catastrophe occurring during labour'. Table 2.3 shows the number and rate of intrapartum-related deaths for babies weighing 1 kg and above in England, Wales and Northern Ireland for 1993 to 1999. The Northern Ireland denominator for this rate included all birthweights. This intrapartum-related mortality rate has decreased from 0.77 (1993) to 0.62 (1999) per 1000 live births and stillbirths. This trend was tested using the chi-squared statistical test and was highly significant ($\chi^2 = 21.5, p < 0.001$).

Table 2.3 Comparison of intrapartum mortality rates[a], birthweights 1 kg and over, 1993–99

Year	Intrapartum related deaths Number	Rate[a]	Lower CI	Upper CI	Live births + stillbirths
1993	529	0.77	0.71	0.84	684391
1994	630	0.95	0.88	1.03	660637
1995	530	0.82	0.75	0.90	644584
1996	493	0.76	0.70	0.83	647128
1997	445	0.69	0.63	0.76	640327
1998	486	0.74	0.67	0.81	658254
1999	**398**	**0.62**	**0.56**	**0.68**	**642156**

[a]Rate per 1000 live births + stillbirths
CI = Confidence interval

Sources: RRF 1999
ONS 1999
N Ireland GRO 1999

2.2.6 Postmortem rates

The number and rate of postmortem examination for late fetal losses, stillbirths, neonatal and post-neonatal deaths from the 1999 RRF returns are shown in Table 2.4. The overall postmortem rate for England, Wales and Northern Ireland was 52.8% and ranged from 42.4% to 68.6% within the CESDI regions. Stillbirths were the category most likely to have a postmortem (57.6%), and neonatal deaths the least likely (40.5%).

The rates for previous years are shown in Table 2.5.

Of the 5354 postmortems reported in 1999, 648 had been requested by a coroner. The reasons for failure to perform a postmortem in 4382 cases were: offered but declined by parents or family (2827, 64.5%); not offered (1520, 34.7%); permission granted by parents but not performed (35, 0.8%). In 403 cases (4.0%) there was no information about postmortem.

Table 2.4 Number of late fetal losses, stillbirths, neonatal and post-neonatal deaths 1999, and percentage with postmortem

Region	Late fetal loss (incl. abortions)		Stillbirths		Neonatal deaths		Postneonatal deaths		All deaths	
	No.	% PM	No.	% PM	No.	% PM	No.	% PM	No.	% PM
England, Wales & N Ireland	2927	56.5	3469	57.6	2559	40.5	1184	56.1	10139	52.8
Northern	163	63.8	172	63.4	142	43.7	54	72.2	531	59.1
Yorkshire	161	57.8	208	53.8	146	32.9	91	56.0	606	50.2
Trent	214	54.7	268	60.4	240	44.2	102	65.7	824	54.9
Anglia	153	31.4	162	44.4	116	56.0	45	37.8	476	42.4
NW Thames	218	63.3	226	65.5	143	46.2	75	58.7	662	59.8
NE Thames	332	51.5	336	47.9	220	35.9	109	46.8	997	46.3
SE Thames	248	66.5	275	63.6	176	31.3	94	52.1	793	56.0
SW Thames	224	55.8	192	54.7	104	39.4	50	64.0	570	53.2
Wessex & Channel Isles	131	72.5	190	75.3	132	56.1	45	60.0	498	68.1
Oxford	166	57.2	144	59.0	107	33.6	50	62.0	467	52.9
S Western	162	75.3	183	68.3	120	59.2	54	70.4	519	68.6
W Midlands	297	51.5	407	50.6	314	33.1	141	43.3	1159	45.2
Mersey	125	51.2	147	53.1	136	38.2	70	52.9	478	48.3
N Western	174	39.1	274	48.5	224	34.4	105	59.0	777	43.8
Wales	100	75.0	153	63.4	126	45.2	65	66.2	444	61.3
N Ireland	59	37.3	132	65.9	113	38.9	34	44.1	338	49.7

Source: RRF 1999

Table 2.5 Rate of postmortem performed in England, Wales and Northern Ireland 1993–99

Year	Late fetal loss % PM	Stillbirths % PM	Neonatal deaths % PM	Post-neonatal deaths % PM	All deaths % PM
1993	54.2	66.7	47.6	60.3	58.1
1994	58.7	67.5	46.7	59.5	58.8
1995	57.5	64.1	46.0	57.5	56.6
1996	63.5	62.8	44.0	57.4	57.4
1997	57.5	61.6	40.7	56.2	54.4
1998	60.4	61.5	41.2	52.3	55.1
1999	**56.5**	**57.6**	**40.5**	**56.1**	**52.8**

Source: RRF 1999

2.3 SUMMARY OF RAPID REPORT FORMS 1999

Total births and deaths: Registered live births and stillbirths in England, Wales and Northern Ireland totalled 644 940 in 1999. A total of 10 139 deaths were notified to CESDI, comprising 2927 late fetal losses, 3469 stillbirths, 2559 neonatal deaths and 1184 post-neonatal deaths.

Stillbirths: The stillbirth rate was 5.0 per 1000 total births. This excludes terminations of pregnancy.

Perinatal mortality rate: 7.9 per 1000 total births. This excludes terminations of pregnancy.

Neonatal death rate: 3.9 per 1000 live births. This excludes terminations of pregnancy.

Post-neonatal mortality rate: 1.8 per 1000 live births and remains unchanged.

Singleton births: The stillbirth rate was 4.9 per 1000 total singleton births and the neonatal death rate was 3.3 per 1000 singleton live births.

Multiple births: The stillbirth rate was 21.0 per 1000 multiple total births and the neonatal death rate was 25.5 per 1000 multiple live births.

CESDI regional mortality rates: The combined (stillbirth, neonatal and post-neonatal) mortality rate for England, Wales and Northern Ireland was 11.1 per 1000 total births and ranged from 9.1 to 13.2 within the regions.

Intrapartum-related mortality rate: 0.62 per 1000 total births.

Postmortem examinations: The overall postmortem rate for England, Wales and Northern Ireland was 52.8% (range: 42.4–68.6%). Within the various categories, the highest rate was for stillbirths (57.6%, range 44.4–75.3%) and the lowest rate was for neonatal deaths (40.5%, range 31.3–59.2%).

2.4 CONCLUSION

CESDI's 4th Annual Report summarising enquiry findings of the 873 intrapartum-related deaths in 1994–95 found that 52% had received suboptimal care where 'different management would reasonably have been expected to have made a difference to the outcome'[1]. It stressed the importance of teaching, assessment and supervision of all professionals caring for women in labour – a message that has been reiterated in subsequent Annual Reports.

There have been initiatives nationally and locally in response to CESDI's findings. These have included a RCOG/RCM Working Party report '*Towards Safer Childbirth – Minimum Standards for the Organisation of Labour Wards*'[2] and the development of national evidence-based guidelines on induction of labour and the use and interpretation of electronic fetal monitoring.

It is therefore extremely encouraging to see that intrapartum-related mortality has now decreased significantly from 0.95 (1994) to 0.62 (1999) per 1000 live births and stillbirths. Although it is not possible to predict if this is a continuing downward trend, it is hoped that by maintaining efforts to achieve the highest possible standard of intrapartum care this will prove to be the case.

REFERENCES

1. *Confidential Enquiry into Stillbirths and Deaths in Infancy: 4th Annual Report, 1 January–31 December 1995.* 1997, London: Maternal and Child Health Research Consortium.
2. Royal College of Obstetricians and Gynaecologists and Royal College of Midwives. *Towards Safer Childbirth: Minimum Standards for the Organisation of Labour Wards. Report of a Joint Working Party.* 1999 London: RCOG Press.

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3

ENQUIRY COMMENTS ON 422 STILLBIRTHS OCCURRING 1996–97

3.1 INTRODUCTION

Stillbirths are the commonest notification to CESDI. They are frequently described as being 'unexplained'. However an extensive review of antenatal and postnatal care of over 400 cases by CESDI in 1996–97 found that 45% of stillbirths were associated with suboptimal care. As a result of this, it was recommended that a qualitative review of the panel comments should be undertaken to identify the key areas for improvement in subsequent care.

The stillbirths were a subset (422/573) of the '1 in 10' programme which was a random sample of the deaths reported to CESDI excluding babies weighing less than 1 kg, major congenital malformations and post-neonatal deaths.

In 1996–97, the panels were not provided with any predetermined standards and the comments that are quoted are the views of the panellists. There is not necessarily a consensus view between panels on what constitutes suboptimal care. Some comments which were described as being antepartum in fact refer to intrapartum events. These comments and the ones described as intrapartum have all been excluded as this is an area that has been extensively covered in previous reports. Comments on cases where no suboptimal care was found were not included.

The aim of this study was to identify antenatal suboptimal care factors that might have contributed to the occurrence of stillbirth. It also examined areas of poor care following stillbirth, even though this has no effect on the outcome of death.

3.2 INFORMATION FROM PANEL COMMENTS

3.2.1 Suboptimal care grades

Assessment panels reviewed all aspects of care and recorded instances where they felt care was suboptimal. The proportion of enquiry cases given grade 2 or 3 was similar in the stillbirth group to that in the overall 1 in 10 sample, as reported in the 6th CESDI Annual Report[1].

A total of 720 comments were made on the antenatal and postnatal care given to the 422 women studied. The most frequently cited suboptimal care factors are listed in Table 3.1.

Table 3.1 Suboptimal care factors most frequently cited by assessment panels

Nature of suboptimal care	No. of comments
Risk recognition	
Failure to recognise high-risk woman at booking	30
Growth	
Inadequate monitoring of growth	33
Failure to recognise intra-uterine growth restriction	16
Failure to act on intra-uterine growth restriction	19
Fetal movement	
Failure of professional to act on decreased fetal movements	21
Importance of changes in fetal movement not explained to woman	19
Decreased fetal movements not reported by mother until after delivery	29
Management	
Failure to act on high-risk situation/history	60
Failure to act on raised blood pressure and/or proteinuria	30
No plan of care/management	19
Failure to act on suspicious antenatal cardiotocograph	13
Failure to do or to repeat glucose tolerance test	13
Poor diabetic management	14
Inappropriate grade of staff involved in care	28
Communication	
Poor documentation	62
Poor communication – oral and written	33
Lifestyle	
Maternal smoking	23
Poor attendance for antenatal checks	16
Post-delivery	
Inadequate screening following stillbirth	11
Postmortems – quality issues, failure to send samples	66
Bereavement support	7

3.2.2 Risk recognition/assessment related to booking

There were frequent comments on failures to recognise and/or act on risk factors such as a previous history of pregnancy-induced hypertension (PIH), intra-uterine growth restriction (IUGR) or stillbirth. General Practitioners (GPs) did not always highlight known risk factors in their referral letters. Women with a complicated history were sometimes inappropriately managed at booking by a Senior House Officer (SHO).

'This was a high risk woman. Grande multip. previous blood transfusion @29/40 and she was treated as low risk.'

'High risk pregnancy, late booker, grande multip. with a twin pregnancy. Not treated as high risk.'

'Incorrect assessment as low risk at booking – weight 100 kg, previous LSCS for pre-term baby, sister diabetic.'

3.2.3 Identification of IUGR and action on diagnosed IUGR

Panels frequently highlighted failures to monitor fetal growth adequately during pregnancy.

'Failure to consider woman with past history of 2 × IUGR babies as high risk. No appreciation of need for extra vigilance, e.g. by fetal weight/growth estimations.'

'Booking mentions the need for serial scans, but only one extra one was performed. A previous small-for-dates baby should have reinforced the need for these.'

'Growth-retarded baby – this was an 'at risk pregnancy' – needing serial ultrasound.'

Midwives and doctors also often failed to recognise poor growth.

'Severe IUGR not recognised or acted on despite estimated fetal weight below 3rd centile at 34/40.'

When IUGR was suspected and noted, it was not always acted on. In those women with a previous history of IUGR, this represents particularly poor care.

'Failure to organise proper investigations such as dopplers when found to be clinically small for dates.'

3.2.4 Changes in fetal activity

A concern voiced by many panels was the failure of the mother to report decreased fetal movements to any of her carers.

'Decreased fetal movements for 2 days – only reported by patient after admission following APH.'

However, professionals were also described as having failed to communicate adequately to the mother the need to report changes in fetal activity.

'Apparent lack of communication between professionals and mother regarding fetal movements and relevance of same to fetal well-being. No evidence that mother was given any advice.'

When changes in fetal movement were reported, the professional action taken was often considered inadequate by the panels.

'When the mother complained of reduced fetal movements at 32 weeks, she was given reassurance and a kick chart, but no tests of fetal well-being were carried out.'

3.2.5 Management issues

Failure to act on high-risk situation

Panels were often critical of delay in dealing with risk situations that developed during the course of a pregnancy. Some specific management problems are examined in the following paragraphs. These often involved poor management of bleeding in pregnancy, with carers failing to act appropriately in an emergency situation. When not dealt with promptly, such risks put the fetus, and sometimes the mother, in danger.

'Patient's situation was a classic story of abruption. Inappropriate to allow patient to return home.'

'The panel commented on the delay in proceeding to delivery following the diagnosis of placental abruption. This resulted in a worsening of resultant DIC.'

On other occasions, there were failures to carry out investigations of women who developed signs of infection during pregnancy. The woman was not always examined physically, even when she was pyrexial. Concerns were also expressed about the management of anaemic or rhesus-negative women, of women with recurrent infections, and of women with signs of possible cholestasis of pregnancy.

'Failure to carry out adequate examination of patient complaining of cough at 36 weeks and inappropriate prescription of antibiotics without adequate investigation or diagnosis.'

'Raised liver function test results reported one week before delivery, having been requested by community midwife following history of itching. These were not acted on or followed up.'

Pregnancy-induced hypertension

This well-recognised and potentially lethal complication of pregnancy was often not well managed.

'Antenatal appointment at 34+4 weeks. Raised BP, proteinuria, hypertension. Should have been admitted.'

'Proteinuria at 34 weeks was not followed up. The patient's BP had been slowly rising, yet all the signs and symptoms of potential PIH were ignored.'

Lack of plan

There was often a failure to make a plan for the care of high-risk women – such as increased frequency of antenatal appointments or serial scanning for women with a history of previous IUGR.

'There was no care plan for the pregnancy recorded in the notes (diabetic, smoker, non-attender).'

'Care plan inappropriate for patient with a past obstetric history of stillbirth and IUGR. Should have been considered high risk.'

Failure to act on suspicious antenatal CTG
Abnormal cardiotocograph (CTG) traces were recognised but not acted on.

'The CTG at 32 weeks was not normally reactive with no variability. The mother should not have been allowed to go home on this evidence having had vaginal blood loss.'

Failure to do or repeat glucose tolerance test (GTT)
The presence of recurrent glycosuria in pregnancy was often not acted on. This was despite risk factors for gestational diabetes, such as obesity or a family history of diabetes. Women who failed to attend for glucose tolerance tests were often not diligently followed up.

'She had 5 episodes of glycosuria. No further investigations appear in the notes.'

Poor diabetic management
Some women with pre-pregnancy diabetes did not receive specialist supervision of their pregnancies.

'The antenatal care between the 27/40 admission and the labour at 37/40 was inadequate. Patient was seen at 31 and 36/40 and both times it was noted that diabetic control was inadequate, yet nothing done to correct problem, or see patient more often.'

Inappropriate grade of staff involved in care
Women with known risk factors or recognised complications were sometimes seen by insufficiently experienced carers.

'This was a high-risk pregnancy and the mother should have been seen by more senior obstetricians at each visit – does not appear to have been consultant involvement.'

'Apparently no consultant involvement at all in this case. This led to failure to recognise and act on signs of increasingly severe PET. No-one senior in overall charge of the case.'

'Despite GP identifying a probable intra-uterine fetal death, the admission and initial CTG was performed and handled by an inexperienced midwife.'

3.2.6 Communication issues

Poor documentation
As highlighted in previous Annual Reports, record-keeping was an area of consistently poor performance.

'Entries in both medical and midwifery notes unclear. No records of diagnoses, plan of care, treatment or investigations. Labour records scanty and unclear with unsigned entries.'

'There was a discrepancy in the notes regarding the size of the last baby. It was 4 pounds and 5 ounces, but recorded in notes as 4.5. Panel thought this caused a false sense of security regarding size of baby.'

Poor communication – oral and written
Careless or insensitive communication can make a bad situation worse. There were several instances when poor interpersonal skills detracted from the quality of care the woman received.

'Mother sent for scan by herself. Antenatal clinic did not inform radiology department that they wanted to check for fetal heart presence.'

'The letter to the GP describes the infant as having been live-born. This error should have been spotted.'

'Poor communication between medical staff and patient due to the limited English of the patient, e.g. failure of patient to complete fetal movement chart was probably due to patient's failure to comprehend instructions. A linkworker/interpreter was not called.'

3.2.7 Lifestyle issues

Smoking
Panels commented that many mothers continued to smoke throughout pregnancy, despite being aware of the risks to the fetus. Occasionally, staff were criticised for not having advised women to stop smoking.

'Mother smoked 20 cigarettes per day despite advice.'

'Not advised to stop smoking.'

Smoking was sometimes combined with other forms of substance abuse.

'Mother smoking and taking heroin and methadone during pregnancy.'

Poor attendance at antenatal check–ups
Staff were sometimes criticised for failing to make adequate efforts to contact the woman.

'The mother DNA'd on two occasions late in pregnancy. There is a record in the notes that the community midwfe was to visit, but no record that this happened.'

Some panels highlighted the failure of women to attend for antenatal examination.

'The mother did not attend on 2 occasions for her BP profile.'

'Unco-operative mother, did not attend for antenatal care despite requests on nine occasions. Baby had severe IUGR and mother continued to smoke.'

3.2.8 Post-delivery issues

Investigations following stillbirth

This included failure to carry out glucose tolerance test (GTT), Kleihauer, glycosylated haemoglobin (HbA_1C) etc., particularly when postmortem examination had been declined. In the absence of such investigations, it is difficult to offer the mother meaningful advice about the likely outcome of future pregnancies.

'There was a failure to request maternal acute phase antibodies (IgM) and a test for maternal listeria at the time of the stillbirth – viral screens should be carried out following all unexplained stillbirths.'

'Incomplete investigation following stillbirth even though postmortem declined. HbA, GTT, Kleihauer and fetal Hb should have been done.'

Postmortems

This was the most frequently criticised area of post-delivery care. Staff were criticised for not discussing the possibility of a postmortem at all, or for not presenting adequate information about the different levels of examination that could be carried out. Discussion was sometimes undertaken by junior staff. Occasional problems arose concerning the failure to carry out a postmortem for which consent had been given, or when the body was incorrectly released for burial prior to examination.

Where a postmortem was carried out, the report was most commonly criticised for failing to identify IUGR or its cause. Incompleteness of histological examination and the poor quality of some reports were also commented on. Failure to send the placenta for histology was criticised on several occasions.

'The postmortem examination failed to emphasise the severe IUGR and did not include any discussion regarding the significance of the acute chorioamnionitis.'

'An external clinical examination postmortem was reported but there was no histology on the placenta, which might have shed light on the cause of this unexplained stillbirth.'

Bereavement support
There was no bereavement support in several cases. Letters sent to bereaved parents were sometimes described as insensitive, and counselling included attributing the baby's death to maternal smoking.

'There is no documentation of any post-delivery follow-up of emotional, drug-related or midwifery care.'

'Failure in post-death counselling. GP unaware of patient's case.'

3.3 DISCUSSION

The stillbirth rate in England, Wales and Northern Ireland for 1999 is 5.0 per 1000 total births. This rate has been stable since 1993 when deliveries from 24 weeks' completed gestation were first included in the definition. The majority of such losses are classified as 'unexplained', partly due to the limitations of the current classification systems in use (this is discussed in detail in the Commentary on Chapter 3). Nevertheless, there is an understandable concern on the part of parents and professionals that the possible reasons for these devastating events are identified.

Effective use of maternity resources implies that specialist services should be reserved for women with complicated pregnancies, or those at most risk of developing complications. For this approach to succeed, it is important that risk is appropriately assessed at booking. It should also be remembered that the risk status of a woman may change during the course of her pregnancy. Efficient transfer from low-risk to high-risk care programmes must be effected when complications arise.

The panels were critical of women who failed to attend for antenatal care. However, accessibility of clinics and long waiting times may contribute to non-attendance. Ensuring that antenatal care effectively triages high-risk pregnancies could reduce this problem.

There was strong agreement by panels that there were frequent failures in growth monitoring, although there was a lack of consensus as to the most appropriate screening tools. Variations in opinion regarding fetal growth assessment are due to insufficient evidence to inform best practice[2,3].

Assessing fetal movement as a measure of well-being was the focus of many critcisms by the panels. The most frequently cited criticism concerned mothers who delayed reporting changes in fetal movement. This may have been due to poor understanding of the significance of

decreased movements. The use of kick charts as a tool for assessing fetal movement was advocated by many assessors, although the acceptable level of fetal movement is ill-defined[4]. Formal counting of movements as a routine screening tool has not been proven to decrease antepartum death rates,[5] but it is recognised that informal assessment of fetal movements should not be disregarded.

Even when women did report changes in fetal activity, panels felt that the response was not always appropriate. Again, there was variation in the recommended response by panels, with possible responses including cardiotocography, biophysical profile and doppler studies. However, a normal cardiotocograph (CTG) may give false reassurance and does not alter perinatal outcome[6]. There is also insufficient evidence to determine the exact role of the biophysical profile in high-risk pregnancies[7]. The use of umbilical artery doppler ultrasound shows promise for reducing perinatal mortality[8], and it is likely that further research will establish its role.

From this discussion, and as highlighted in CESDI's 4th Annual Report[9], there is a need for a national multidisciplinary initiative to develop evidence-based guidelines on the assessment of fetal and maternal welfare prior to labour. The differing views of the panels on fetal movement and growth assessment reflect the current lack of consensus and highlights the need for such an initiative.

It is noteworthy that the most common adverse comment related to failure to act on a high-risk situation. This may be due to poor communication, lack of effective training, staffing shortages, poor leadership or inconsistent policies. Formal processes to minimise these problems should be robust and auditable.

The care of women following a stillbirth was another area of criticism, including the issue of postmortem. Postmortem can provide valuable information about the cause of death and future implications, and the parents must be central to any decision for investigation. CESDI has produced two leaflets aimed at improving communication on gaining informed consent, one for parents[10] and the other for the professional[11]. Since publication, issues surrounding the paediatric postmortem examination have been the subject of intense media interest. There have been two public Inquiries (Bristol Royal Infirmary and Alder Hey) and a series of documents issued by the profession in response. These are discussed in more detail in Chapter 5. Poor care at the time of bereavement may not alter the outcome but will affect future encounters of the parent with the health service. Getting this area right in the future is essential to restore the confidence of the public.

Poor record-keeping was high on the list of aspects of care that were criticised by assessment panels. This problem has been highlighted in all previous reports and was reviewed in detail in the 6th Annual Report of CESDI[1]. Standards laid down by national bodies such as the Royal

Colleges, the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC) and the Clinical Negligence Scheme for Trusts (CNST) are widely publicised. However, it seems that much remains to be done by professionals to ensure good standards of record-keeping.

Most of the issues highlighted in the panel comments on cases of stillbirth are not specific to stillbirth as such. Rather, they concern standards of antenatal care in general. Accurate risk assessment at booking and during the antenatal period is essential to good quality antenatal surveillance. Efficient detection and appropriate management of problems that arise during pregnancy might lead to a reduction in the number of stillbirths.

3.4 RECOMMENDATIONS

Risk assessment

- All maternity professionals should have an easily accessible, robust protocol to assist in ascertaining maternal and fetal risk throughout pregnancy.

- Health professionals involved in maternity care should be vigilant in identifying and communicating any possible risk factors to specialist services.

- Plans regarding antenatal management in complicated pregnancies should be made in conjuction with a senior colleague.

- A national evidence-based guideline covering the assessment of fetal and maternal welfare prior to labour should be made available. The Royal College of Obstetricians and Gynaecologists (RCOG) Antenatal Care Guideline, due for publication in Autumn 2001, is a timely initiative that will be welcomed by those providing maternity care.

Postmortem issues

- Parents should be counselled regarding postmortem by a senior professional who can provide honest, objective information to enable a well-informed choice at a time of personal tragedy. Guidelines regarding postmortem issues, investigations and bereavement support[12] should be readily available to all staff.

Record-keeping

- Documentation standards should be audited locally on a regular basis.

- The recommendations of the 4th and 5th CESDI Annual Reports are repeated:

'The quality of maternity records needs to be improved to enable clear identification of risk factors and documentation of management plans for these during both antepartum and intrapartum periods. These would be facilitated by a well-designed, universally used national maternity record.' (paragraphs 10.2.4 of 4th Annual Report[9] and 9.4 of 5th Annual Report[13]).

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COMMENTARY – CLINICAL IMPLICATIONS OF 'UNEXPLAINED' STILLBIRTHS

The 'unexplained' stillbirth remains the biggest problem for all involved in maternity care. The qualitative review of the panel comments have identified a series of areas of concern. The EuroNatal study (Chapter 4) parallels these findings. CESDI invited Dr Jason Gardosi, Director of the West Midlands Perinatal Institute to write a response on how CESDI is best placed to take this topic forwards.

The purpose of counting perinatal mortality rates and conducting confidential enquiries is ultimately to understand contributing factors and trends, and to seek ways of avoiding recurrence. However, the high proportion of stillbirths which are in the 'unexplained' category is not helpful to this endeavour. Surveys on perinatal mortality and reports of the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) consistently find that about 70% of stillbirths are 'unexplained'. This has become the single largest category in perinatal mortality statistics. While analysis of year-on-year trends suggests a gradual decline in perinatal mortality rates overall, the relative proportion of 'unexplained' stillbirths appears to be on the increase[1].

Does 'unexplained' mean unavoidable?
The preponderance of stillbirths in the 'unexplained' category occurs despite the three-tier classification used on CESDI Rapid Report Forms. This classification includes: (1) the pathophysiological classification of Wigglesworth[2], (2) the Fetal and Neonatal Factor classification[3], described by Bound *et al.* in 1956[4] and applied in the 1958 British Mortality Survey[5] and (3) the revised Aberdeen classification[6] described by Baird and Thomson[7] in 1954[8].

In the CESDI '1 in 10' enquiry, 10% of all singleton stillbirths in England and Wales in 1997 were examined, excluding congenital anomaly and weight <1000 g. Despite thorough review of the causes, these deaths were given a category other than 'unexplained' in only 17% of cases according to Wigglesworth, 16% by the Fetal and Neonatal Factor classification and 21% by the Aberdeen classification[9]. Yet in many instances, panel members commented on substandard management and considered that the death was potentially avoidable. Our current

classification system appears to work against the internal review by the clinicians involved in a case, or external, anonymised review by expert panels, seeking to establish what could have led to the loss.

Any classification system that throws up such a high proportion of 'unexplained' cases would appear to be failing to fulfil its purpose and failing to help in the quest to understand and reduce perinatal mortality. There is a danger that 'unexplained' is seen as synonymous with 'unavoidable', resulting in the conclusion that nothing can be done. The main aim of a classification system should be to shed light on the events and to inform on future management. Better understanding is important for counselling the affected parents and establishing a prognosis and a management plan for future pregnancies. There is also a need to link health promotion and death prevention initiatives to clinical observation and epidemiological research.

Studies using other classification systems for perinatal death report substantially lower rates of stillbirth in the 'unexplained' category. Whitfield's study in Glasgow[10] found that only 15/67 (22%) of stillbirths remained unexplained, and a more recent report from Montreal suggested that 27% of antepartum deaths were unexplained[11]. Detailed analysis of cause of death in two Scandinavian studies left only 12% and 9%, unresolved or 'unexplained'[12,13]. All of these studies include a category of small for gestational age (SGA) or fetal growth restriction (FGR).

Fetal weight and stillbirth

The link between perinatal mortality and fetal growth restriction is obscured by definitions such as that by WHO for 'low birth weight' which has served its purpose but is now outdated wherever routine gestation dating by ultrasound is used. It lumps together two conditions, prematurity and growth restriction, with varying combinations of the two. Perinatal mortality statistics are collected in separate weight and gestational age groupings[14], and such categories persist in England and Wales[15] as well as in Scotland[16]. Making comparisons *within* weight categories, i.e. controlling for birthweight[17], can obscure the fact that many in-utero deaths include fetuses that are smaller than they should be at that gestational age. Nevertheless, even within the confines of the current classifications and the use of 'low birth weight' in an extended Aberdeen classification, an inferred category of 'growth retardation' emerges as the single most important component of stillbirth statistics, often occurring in mothers with no obstetric risk[18].

The extent of the link between fetal weight and death becomes most apparent when weight is corrected for gestational age. Williams[19] analysed over 23 000 fetal deaths in California on population-based percentile curves and demonstrated a strong link between fetal weight for gestational age and demise. Analysis of the large Swedish birthweight register also demonstrated the strong links between smallness for

gestational age and fetal death[20]. Closer to home, in the absence of good denominator data, smaller, targeted studies in the Midlands confirmed the importance of a link, for stillbirths at all gestational ages[21] and for unexplained stillbirths at term[22].

Although the exact time of fetal demise may not be known, it can in most instances be derived with sufficient accuracy to calculate a valid weight-for-gestational age percentile. A cessation of fetal activity in the third trimester tends to be reported early by mothers. Furthermore, in many instances labour commences spontaneously soon after fetal death. Many clinicians can recall agonising about an in-utero fetal death which resists attempts at induction of labour, but such cases are relatively infrequent. It is estimated that the average time interval between fetal death and spontaneous or induced delivery is 48 hours[21], which is also consistent with histopathological evidence[23]. A median death-to-delivery interval of two days can be deduced from the gestational age at birth when calculating weight-for-gestational age percentiles for stillbirths[21].

There is no evidence that dead fetuses, even when severely macerated, lose weight in utero. In addition, pathologists often observe that 'dry weight' measured just before postmortem tends to be *lower* than that recorded at delivery, as third space fluid – such as that which accumulated following congestive fetal heart failure – has had opportunity to drain. The weight at postmortem is therefore likely to be an underestimate of actual weight at time of death[21], with weight at time of delivery being the best reflection of true fetal weight.

Diagnosis of growth restriction

Smallness for gestational age (SGA) is not synonymous with fetal growth restriction (FGR) or intrauterine growth retardation (IUGR), as smallness may not be pathological, but the result of physiological/constitutional variation. Evidence of FGR in a stillborn fetus can be established in several ways:

1 Ultrasound imaging has allowed us to get a better understanding of normal growth, which occurs almost linearly in normal pregnancy[24,25]. Serial ultrasound biometry of the fetal abdominal circumference, or biophysical assessment (doppler flow) would establish the diagnosis of restricted growth. However, in most instances this information is not available; if it was, then it is likely that action would have been taken to deliver the fetus before in-utero demise, provided it was considered sufficiently mature.
2 Few would doubt that a higher rate of postmortems is desirable to help throw light on the causes of stillbirth. However, the quality of the postmortem and the standards used are important. There is evidence that, with the current classification, the proportion of 'unexplained' stillbirths is not substantially different in cases that had a postmortem and those that did not[21]. Pathologists have relied

on reference data from other stillborn babies[26] for individual organs as well as for whole body weights. But reference data from cadavers can hardly be regarded as a standard or 'norm', and the association between smallness and death can be missed. Careful histological examination of organs such as the heart and adrenals, and organ weight ratios, can help to determine whether growth restriction was present.

3 Birthweight can be linked to other measurements (e.g. length) to calculate a ratio (e.g. ponderal index). However, the validity and significance of ponderal index at various gestational ages, and for stillborn babies, has not been established.

4 Comparison can be made with a normal weight for gestational age standard; such reference curves have improved by the use of computerised databases and routine pregnancy dating with ultrasound which 'straighten' birthweight curves[27]. If a cohort of stillbirths has a disproportionate number of babies weighing less than, say, the tenth percentile, but is not significantly different in constitutional variables, then it can be reasonably deduced that the difference in size for gestation is due to a higher prevalence of growth restriction in the stillborn compared with the live-born group[21].

5 Smallness of individual babies could still be due to constitutional variation. To avoid this, a lower birth weight ratio or percentile cut-off can be used, as in Montreal, where a definition of '25% underweight' (equivalent to the 2.4 centile) was applied[28]. However, the same group found that a higher centile category (2.5–10th) is also significantly associated with stillbirths[11] and this is confirmed in other studies[29,30]. It has also been argued that the severity of SGA varies with gestational age; stillbirths at earlier gestations are smaller and a lower centile cut-off should apply[31,32]. However for prevention, the recognition of a small baby remains essential, whatever cut-off limit is used. Varying the percentile limits below which a weight is considered small would obscure the observation that preterm babies that die are more severely affected, or, that the more severely affected tend to die more prematurely.

6 A customised or individualised birthweight standard allows inferences to be made about growth status, as constitutional variation in fetal weight due to factors such as maternal height and weight, ethnic group, parity and sex is adjusted for, while pathological factors such as smoking are excluded. Adjustments for such variables create a weight standard which better reflects FGR and its association with neonatal morphometric indices[33], adverse pregnancy events[34] and perinatal mortality[30]. The link between stillbirth and growth failure is seen to be even stronger[30]. Calculation of customised centiles has to be done by computer. The software is freely available on the internet (www.gestation.net).

Detection and avoidability

It is important for the health service and for clinicians in perinatal disciplines to learn from outcome, and to be aware that growth failure is

a substantial contributor to perinatal mortality. The purpose of a classification is to highlight the areas in need of attention to reduce mortality, and clearly a category of 'fetal growth restriction' is required. The majority of growth restriction is currently not detected because it is not looked for and because its importance is not recognised. Analysis of the '1:10' stillbirth enquiries highlights the fact that in many instances, growth screening and assessment was considered inadequate. But even in the general population, routine growth screening strategies are failing – only about 25% of SGA babies are detected antenatally in an unselected population[35]. In a 'low risk' population, this can be as low as 16%[36].

Although there is no in-utero treatment, fetal death following slow growth has to be considered as potentially avoidable. The majority of such deaths occur at mature gestations, and these babies are likely to do well if delivered in good condition. Appropriate surveillance of babies recognised as high risk is possible following the substantial improvements in maternal–fetal medicine, and will allow determination of the best time for delivery from an unfavourable intrauterine environment. The missing link is the screening and detection of which babies are at risk.

The role of antenatal care

An acknowledgement of the importance of fetal growth – and the need for early detection – will define the priorities of antenatal care and question much of current practice. For example, the utility of risk assessment at the beginning of pregnancy must be in doubt in this regard, as most cases of growth failure occur in pregnancies with *no* risk factors. If a designation of 'low risk' at the beginning of pregnancy results in fewer visits, and less vigilance and attention to fetal well-being, then such pregnancies might be at a *higher* risk of fetal demise.

All pregnancies require a minimum standard of antenatal surveillance in the third trimester, with two main components:

- **Maternal perception:** the sensation of fetal movement is an important indicator of fetal well-being. Yet there is often insufficient counselling and emphasis on the need to be seen urgently if a reduction in fetal movements is felt. In addition, the test ordered for 'decreased fetal movements' is usually an antenatal CTG (non-stress test of the fetal heart rate), which is an inappropriate investigation, as it may provide false reassurance[37]. The antenatal CTG is one of the last parameters which becomes abnormal in the sequence of events leading to fetal demise. Ultrasound and doppler is indicated if fetal movements appear reduced[38].

- **Clinical assessment:** first-line screening needs to include the systematic measurement and serial plotting of fundal height. Symphysio-fundal height measurement has had mixed reports in the

literature, but was often used to predict weight or gestational age, rather than to assess fetal growth. The measurement is often not done properly, or with incorrect technique, and is not even taught in many medical and midwifery schools. The (erroneous) expectation – that the measurement in centimetres should be equivalent to the gestational age in weeks – also leads to bias. However, standardised measurement, plotted on customised fundal height charts, and referral according to well-established criteria results in a significant increase in the detection of babies which are too small or too large[39]. Furthermore, this method results in *fewer* referrals for investigations for fetal well-being (such as ultrasound scan and doppler), as midwives are reassured when growth is proceeding normally.

Thus it is likely that the required service development would be cost-neutral, but would require the effort and resources to achieve a shift in emphasis towards a system of antenatal care that acknowledges the importance of this problem. Currently, fetal surveillance does not appear to feature prominently in discussions about the aims of maternity care. Better awareness of fetal growth would not only allow timely intervention to reduce intrauterine death, but in other cases forewarn of diminished reserve to ensure optimum intrapartum and neonatal management. Furthermore, knowledge of the prevalence of fetal growth failure would improve our understanding of the social, physiological and pathological factors affecting growth within a defined population, and provide a basis for future improvements in maternity services.

Summary

Fetal growth failure is a precursor of many instances of 'unexplained' stillbirths. There is an urgent need to alter our current classification system and to raise awareness of the problem of growth restriction – both in the understanding of adverse outcome and in the development of better strategies for prevention.

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4

EUROPEAN COMPARISONS OF PERINATAL CARE – THE EURONATAL STUDY

4.1 INTRODUCTION

Differences in perinatal mortality rates between countries might be associated with the quality of antenatal and perinatal care. The EuroNatal study is part of a large European collaboration that has investigated the background to differences in perinatal mortality[1]. It covers selected regions in ten European countries.

Audit methods have been developed, both nationally and internationally, with the aim of improving perinatal care. In the early 1990s, the European Association of Perinatal Medicine attempted to standardise the methodology used for perinatal audits throughout Europe. Previous international audits compared only pairs of countries, such as Norway and Sweden, and Denmark and Sweden.

For the EuroNatal international audit, the questionnaire incorporated explicit criteria based on international consensus and evidence of effectiveness. A panel of 12 experts from participating countries, the EuroNatal International Audit Panel, reviewed 1619 cases of perinatal death from ten European countries. The experts did not know the origin of the cases. Their aim was to discover any suboptimal factors in antenatal and perinatal care in certain categories of stillbirths and neonatal deaths. The study was a unique opportunity to compare the quality of care provided within different healthcare systems and any possible association with perinatal mortality rates.

This chapter provides a brief description of the EuroNatal international audit, the methods used and the initial results. Detailed reports of the study will be published at a later time.

4.2 AUDIT METHODS

4.2.1 Case recruitment

For each participating country, the EuroNatal Working Group selected a region (or regions) which was expected to have about 400 perinatal deaths over a period of one to two years. As far as possible, the region was representative of the country in terms of urban and rural characteristics, socio-economic characteristics, ethnicity and level of perinatal care. The regions involved in the study are shown in Table 4.2.

The size of region and period of data collection varied but all data was collected between 1995 and 1998. The method of data collection in Greece was quite different from the other regions in that Greece conducted a cross-sectional National Perinatal Survey, based on all consecutive births and perinatal deaths during eight weeks of 1998.

4.2.2 Selection of cases for review

The EuroNatal definition of perinatal death was 'all stillbirths and neonatal deaths in babies born at 28 weeks of completed gestation onwards'. From these perinatal deaths, the EuroNatal Working Group selected three groups of cases: (1) singleton fetal deaths at 28 or more weeks of gestational age, with or without growth restriction; (2) intrapartum deaths at 28 or more weeks of gestational age; and (3) neonatal deaths at 34 or more weeks of gestational age. These groups were chosen on the basis that they would yield information relevant to the quality of antenatal, intrapartum and early neonatal care. Babies with major congenital anomalies were excluded.

This selection corresponds to categories II, III, VI, X and XI of the Nordic–Baltic (N–B) Perinatal Death Classification (Table 4.1)[2]. This classification is based on the recognition that certain categories of perinatal deaths may be more 'potentially avoidable' than others. Categories that are believed to include large proportions of cases that are 'potentially avoidable by improved health care services' are II, VI and VIII (neonatal deaths, after delivery at 28 to 33 weeks of gestation and with an Apgar score over 6 at five minutes).

Group 1 included both the antenatal categories II and III to enable future examinations of the definitions of intra-uterine growth restriction (IUGR). Group 2 comprised category VI, and group 3 was categories X and XI combined. Categories VIII and IX were not included because suboptimal care factors among babies born at 28 to 33 weeks of gestation are more likely to be related to lack of technology, while those beyond that age are more likely to be related to problems in basic maternity and neonatal care. Category I, babies with major congenital anomalies, was also not included.

Because national growth charts were not available for all countries, the standard growth chart used by Denmark and Sweden was adopted[3]. This was based on weight-for-gestational-age for an unselected population including infants still in utero, with weights estimated on the basis of ultrasound measurement. Two standard deviations below the average was defined as the upper limit of severe growth restriction.

4.2.3 Audit criteria

Explicit criteria for standards of care were defined by the EuroNatal Working Group and incorporated into a questionnaire. This was done so that all cases could be evaluated in a comparable way and each case

Table 4.1 Original Nordic–Baltic (N–B) perinatal death classification and modified version used for the EuroNatal study

Original N-B classification

Variables
Time of death in relation to admission and delivery
Fetal malformation
Gestational age
Growth retardation
Apgar score at 5 minutes

Categories

I	Fetal abnormality
II	Antenatal death, single growth-retarded fetus, ≥ 28 weeks of gestation
III	Antenatal death, single fetus, ≥ 28 weeks of gestation
IV	Antenatal death before 28 weeks of gestation
V	Antenatal death, multiple pregnancy
VI	Intrapartum death after admission (≥ 28 weeks of gestation)
VII	Intrapartum death after admission (before 28 weeks of gestation)
VIII	Neonatal death, 28–33 weeks of gestation and Apgar score > 6 after 5 min
IX	Neonatal death, 28–33 weeks of gestation and Apgar score < 7 after 5 min
X	Neonatal death, ≥ 34 weeks of gestation and Apgar score > 6 after 5 min
XI	Neonatal death, ≥ 34 weeks of gestation and Apgar score < 7 after 5 min
XII	Neonatal death before 28 weeks of gestation
XIII	Unclassified

Modified N-B classification

Variables
Time of death in relation to admission and delivery
Fetal malformation
Gestational age
Growth retardation

Categories

I	Fetal abnormality (major anomalies)
II	Antenatal death, single growth-retarded fetus, ≥ 28 weeks of gestation
III	Antenatal death, single fetus, ≥ 28 weeks of gestation
IV	*omitted**
V	Antenatal death, multiple pregnancy
VI	Intrapartum death after admission (≥ 28 weeks of gestation)
VII	*omitted**
VIII/IX	Neonatal death, 28–33 weeks of gestation
X/XI	Neonatal death, ≥ 34 weeks of gestation
XII	*omitted**
XIII	Unclassified

*All deaths < 28 weeks of gestation are omitted

checked by a restricted number of relatively simple questions. The criteria were based on international consensus and evidence of effectiveness, from a study of the literature and discussions of the international panel. Additional information was provided on social or other circumstances, and on the availability of records and documents.

The first step in defining explicit criteria for optimal clinical practice was identifying relevant elements of perinatal care. These elements were formulated for each category of the N–B classification and explicit criteria for optimal clinical care were defined for each element. The criteria, nearly 50 in all, fell into three groups:

1. Criteria based on **clear evidence available from controlled trials**. The source of information was The Cochrane Pregnancy and Childbirth database of 1995 (issue 2)[4].
2. Criteria for which the **evidence is not as firmly established** as in 1. These also originated from The Cochrane Pregnancy and Childbirth database of 1995 (issue 2)[4].
3. Criteria formulated by the EuroNatal International Audit Panel based on consensus about appropriate perinatal practice, and defined primarily for standardisation of the EuroNatal audit.

The Cochrane Pregnancy and Childbirth database of 1995 was used because the criteria were applicable to the whole period of the audit (1995–98).

Initial review of the grading revealed that smoking, growth restriction and delay in reporting the absence of fetal movements were given widely divergent grades by panel members. In-depth discussion led to additional criteria and guidelines to assess the cases involved.

4.2.4 Panel composition

The International Audit Panel consisted of 12 members drawn from all participating countries except Finland. Panel members were nominated by representatives from the various countries in the EuroNatal Working Group and were recognised experts in their field.

Four subpanels were formed to work more effectively in the actual review of the cases by dividing the workload. The complete panel came together to prepare the audit, formulate criteria, discuss difficulties, review particular difficult cases and to supervise the reporting of the audit. The four subpanels comprised: (1) an obstetrician, a pediatrician/perinatal epidemiologist and a midwife; (2) an obstetrician, a neonatologist and a midwife; (3) an obstetrician, a neonatologist and a perinatal epidemiologist; (4) two obstetricians and a perinatal epidemiologist. This last subpanel did not assess neonatal deaths.

4.2.5 Grading of suboptimal care

To define suboptimal care, a grading system from CESDI's 2nd Annual Report[5] was used. Each case was blinded for country and distributed randomly to one subpanel. Each subpanel member received a copy of the questionnaire, the narrative summary and a sheet that identified lack of compliance with the explicit audit criteria. After reviewing these, the panel member decided whether there were instances of suboptimal care.

Any such instances were listed on a standard form. The panel member marked the timing as antenatal, intrapartum or neonatal and whether it was 'maternal/social', 'infrastructure/service organisation' or 'professional care delivery'. They also marked the contribution of each suboptimal factor to the fatal outcome as 'unlikely', 'possibly' or 'likely'. They then allocated a final grade from the following scale:

0: no suboptimal factors identified;
1: suboptimal factor(s) identified but are *unlikely* to have contributed to the fatal outcome;
2: suboptimal factor(s) identified and *might* have contributed to the fatal outcome;
3: suboptimal factor(s) identified and are *likely* to have contributed to the fatal outcome;
X: insufficient information to assign a grade.

4.2.6 Defining consensus

Consensus on a final subpanel grade was reached in an audit procedure that began with a sequence of assessments by correspondence, followed by plenary meetings of the subpanels. When consensus was not reached in the assessment rounds by correspondence, the case was referred for discussion in a plenary meeting. If more than one of the three subpanel members could not assign a grade to a case because of insufficient information, the case was considered 'not-auditable'.

The consensus grade was taken from the three grades determined by the subpanel. Grade 0 was when the grades were X00, X01, 000, 001; grade 1: X11, 011, 111; grade 2: X22, X23, 222, 223; grade 3: 233, 333. The combination X33 was not used. Flowcharts of this audit process are shown in Figures 4.1 and 4.2.

Figure 4.1 Flowchart for the first round of case assessments in the EuroNatal audit

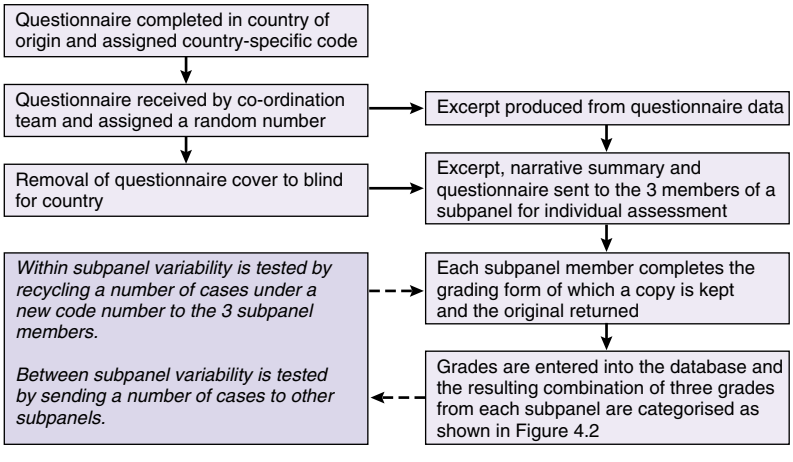
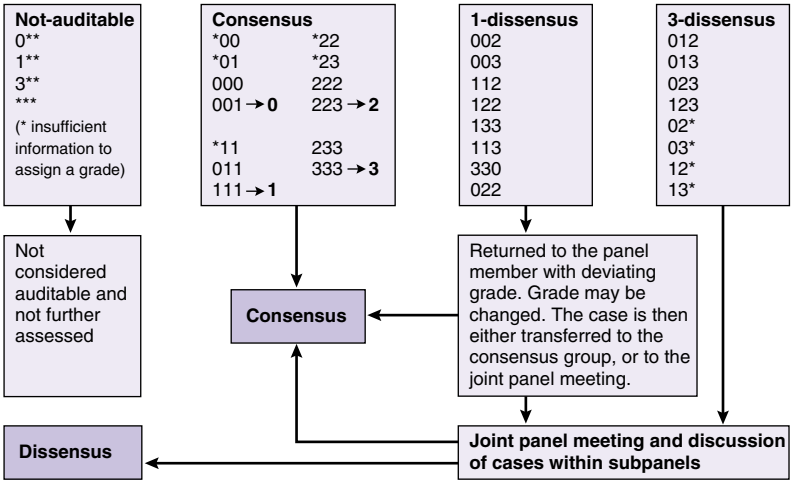


Figure 4.2 Flowchart for reaching consensus in the EuroNatal audit



4.2.7 Identifying suboptimal factors

For each case with a final grade of 2 or 3, the suboptimal factors were identified which had 'possibly' or 'likely' contributed to the fatal outcome. Only factors marked as such by at least two out of three subpanel members were taken into consideration. As a result, one or more suboptimal factors were identified for each case and categorised as explained in section 4.2.5. Thus, a baby who died during labour could have been subjected to both 'maternal/social' and 'professional care delivery' suboptimal factors in the antenatal period, or 'professional care delivery' factors in both the antenatal and intrapartum period.

4.3 OUTCOME OF THE AUDIT

4.3.1 Case identification

The level of completeness of case identification and recruitment was 93% in Flanders, Denmark, England, Finland, Norway, Scotland and Sweden. The level of case identification was high in Norway, but only 85% of cases were included. The levels of completeness were lower in the regions of Spain (20% of cases missing) and The Netherlands (18% missing). Although an extensive effort was made in Greece, using both hospital and civil records to identify all births and perinatal deaths, it was difficult to establish the precise number of missing cases.

4.3.2 Cases audited

A total of 1619 cases were included in the EuroNatal international audit. Because the number of categories was restricted, this represented approximately 60% of all cases of perinatal death in the regions, using the following definition of perinatal mortality: fetal deaths at 28 or more completed weeks of gestation plus (early and late) neonatal deaths among babies born alive after 28 or more completed weeks of gestation,

divided by the total births after 28 or more completed weeks of gestation (× 1000). The number of cases per region ranged from 89 to 269 with an average of 162. In six regions these cases represented over 92% of the known or estimated number of eligible perinatal deaths. In Finland 89% of cases were represented; in Norway 85%; in The Netherlands 80%; and in Valencia 80% because of the difficulty in obtaining information from private clinics.

4.3.3 Reaching consensus

Of the 1619 cases included in the audit, only 65 (4%) were definitely considered by the audit panels to contain insufficient information for grading. There were variations in the completeness of information in the remaining 96% of the cases, which the majority of panel members felt they could grade. The overall results of the EuroNatal international audit in terms of grading are shown in Table 4.2. A total of 1742 cases were circulated to the subpanels. These included 123 cases that were duplicated to assess intra- and inter-panel variability.

Table 4.2 Number and percentage of cases audited, total number graded and the number graded 2 and 3, in the selected Nordic-Baltic categories in regions of ten European countries

Audit region	Total number (%) entered into audit	Number not auditable (% of total audited)	Dissensus (% of total audited)	Total number graded (% of total audited)	Number in grade (% of total graded)				Number (%) graded 2 or 3	95% CI of percentage graded 2 or 3
					0	1	2	3		
Flanders (Belgium)	207 (100)	19 (9.2)	0	188 (90.8)	46 (24.5)	46 (24.5)	72 (38.3)	24 (12.8)	96 (51.1)	43.9–58.2
Whole country (Denmark)	269 (100)	6 (2.2)	3 (1.1)	260 (96.7)	54 (20.8)	73 (28.1)	111 (42.7)	22 (8.5)	133 (51.2)	45.1–57.2
7 former NHS regions (England, UK)	221 (100)	5 (2.3)	1 (0.5)	215 (97.3)	37 (17.2)	63 (29.3)	91 (42.3)	24 (11.2)	115 (53.5)	46.8–60.1
13/22 Hospital districts (Finland)	175 (100)	10 (5.7)	2 (1.1)	163 (93.1)	74 (45.4)	37 (22.7)	41 (25.2)	11 (6.7)	52 (31.9)	25.1–39.4
Whole country (Greece)	110 (100)	4 (3.6)	1 (0.9)	105 (95.5)	20 (19.0)	31 (29.5)	51 (48.6)	3 (2.9)	54 (51.4)	41.9–60.9
Part South-Holland province (The Netherlands)	165 (100)	5 (3.0)	3 (1.8)	157 (95.2)	40 (25.5)	41 (26.1)	54 (34.4)	22 (14.0)	76 (48.4)	40.7–56.2
Four counties (Norway)	142 (100)	2 (1.4)	1 (0.7)	139 (97.9)	38 (27.3)	46 (33.1)	45 (32.4)	10 (7.2)	55 (39.6)	31.7–47.9
Grampian (Scotland, UK)	89 (100)	4 (4.5)	0	85 (95.5)	10 (11.8)	32 (37.6)	40 (47.1)	3 (3.5)	43 (50.6)	40.0–61.1
Valencia province (Spain)	106 (100)	4 (3.8)	0	102 (96.2)	18 (17.6)	39 (38.2)	37 (36.3)	8 (7.8)	45 (44.1)	34.7–53.9
Southern Healthcare Region (Sweden)	135 (100)	6 (4.4)	0	129 (95.6)	32 (24.8)	51 (39.5)	42 (32.6)	4 (3.1)	46 (35.7)	27.8–44.2
Total	**1619 (100)**	**65 (4.0)**	**11 (0.7)**	**1543 (95.3)**	**369 (23.9)**	**459 (29.7)**	**584 (37.8)**	**131 (8.5)**	**715 (46.3)**	**43.9–48.8**

4.3.4 Explicit and implicit criteria

Of all suboptimal factors identified by the subpanels leading to a final grade 2 or 3, approximately 75% were based on the explicit criteria formulated by the audit panel in plenary meetings before and during the study. The remaining 25% of the factors were based on consensus within the subpanels, without reference to the explicit criteria developed for the EuroNatal audit.

4.3.5 Reproducibility of subpanel agreement

Between-subpanel variability

To test variability between panels, 27 cases of antenatal and intrapartum death were assessed by all four panels, and five cases of neonatal death were assessed by three panels (total of 32 cases). The variability of grading (0, 1, 2 or 3) was calculated. In one case no consensus was reached. There was a reasonable measure of agreement in the remaining 31 cases (Kappa coefficient = 0.61 with a standard error of ± 0.08).

Within-subpanel variability

To test variability within panels, a total of 32 cases were presented for a second time to the four subpanels. One case was not included in the final calculation because no consensus was reached in the second assessment. There was a good measure of agreement (Kappa = 0.74 with a standard error of ± 0.12).

Between-panel member variability

This was not calculated because it was inherent in the panel composition. As members with different professional backgrounds were included in the audit panel, a certain degree of variability in grading between the members would be expected.

Within-panel member variability

To test variability of panel members, a total of eight cases were presented for a second time to each of the 12 panel members accounting for 96 cases included in this analysis. There was a good measure of agreement (Kappa coefficient = 0.69 with a standard error of ± 0.07).

4.4 ANALYSIS OF THE AUDIT RESULTS

4.4.1 Grades per region

In the study group, a total of 369 cases (23.9%) were graded as 0, 459 (29.7%) as 1, 584 (37.8%) as 2 and 131 (8.5%) as 3. Table 4.2 shows the distribution of grades across the regions that were audited, together with the number of cases that were not auditable or in which no consensus was reached. A total of 715 cases (46.3%) were graded as 2 or 3, indicating the presence of suboptimal factors that possibly or likely contributed to the fatal outcome. Table 4.2 shows the percentage of grade 2 or 3 per

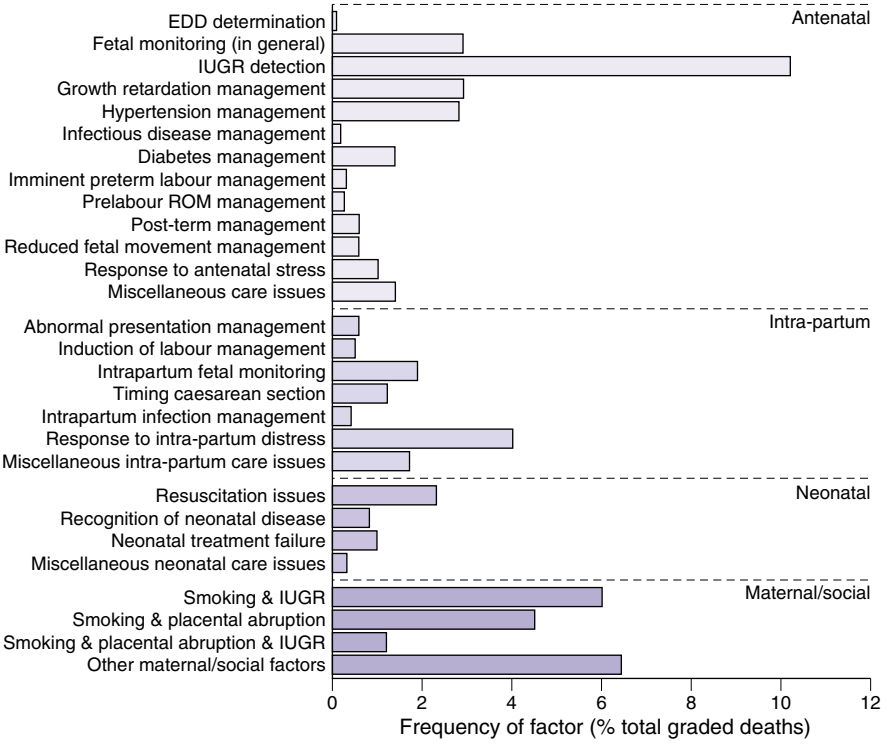
region, with 95% confidence intervals. The 95% confidence limits from most regions overlap, with the exception of the English regions (53.5%) when compared with Finland (31.9%) and Sweden (35.7%).

4.4.2 Distribution of suboptimal factors

Figure 4.3 shows the frequency of suboptimal professional care delivery factors and maternal/social factors identified in all cases classified as grade 2 and 3 in the ten European countries. Suboptimal factors due to problems of infrastructure or service organisation were seen in only 16 cases (1.0%). These are not shown in the figure.

Among the grade 2 and 3 cases with suboptimal professional care delivery factors, 352 (22.8% of all deaths reviewed) were identified in the antenatal period, 148 cases (9.6%) in the intrapartum period, and 64 cases (4.2%) in the neonatal period. Factors related to severe IUGR were most frequent (13.0%), with failure of detection as the most prominent factor (10.2%). There were no marked differences between the regions in the percentage of suboptimal factors related to IUGR (range: 10.3–17.1%).

Figure 4.3 Frequency of suboptimal professional care delivery factors and maternal/social factors in all cases classified as grade 2 and 3 in the ten European countries



The number of grade 2 and 3 cases with suboptimal maternal/social factors was 278 (18.1% of all deaths reviewed). These were most frequently related to maternal smoking (11.7%). The remaining cases (6.4%) included miscellaneous maternal and social problems such as non-attendance for antenatal care, unrecognised pregnancy, drug addiction and psychiatric problems. Differences in suboptimal factors relating to maternal smoking varied between countries from 6.2% in the English regions to 16.2% in Denmark, 18.0% in the Norwegian regions and 21.2% in the Scottish region.

4.5 DISCUSSION AND CONCLUSIONS

The EuroNatal study shows that there are differences between European regions in the proportion of perinatal deaths in which the quality of antenatal and perinatal care was judged suboptimal. As the study addressed only selected subgroups representing approximately 60% of all deaths, the results may not be representative of all perinatal deaths. It should also be emphasised that the quality of perinatal care assessed in this study relates only to deaths: there were no denominator data (data on babies surviving at 28 days after delivery).

Completeness of case identification is an important condition for valid comparison between regions. A high level of case identification was achieved in Flanders, Denmark, England, Finland, Norway, Scotland and Sweden because of the possibility for linkage between medical and civil registrations and other routine case ascertainment procedures. In Greece, The Netherlands and Spain, special studies were necessary to identify all relevant cases of perinatal mortality, with less complete levels of case identification. Differences between regions in the way cases were reviewed could not be completely avoided. In England, for example, the cases had already been audited and narratives produced after multidisciplinary audit. This meant that suboptimal care could be more completely ascertained than in regions where one person from a single discipline reviewed the case notes. It is unclear whether this different procedure in England caused a bias in the audit towards a higher proportion of cases with suboptimal care compared with the other regions.

However, there appears to be an association between the percentage of cases graded 2 and 3 in a region, and the total perinatal mortality rate in that region. In particular, the regions in Finland and Sweden with the lowest percentages of grade 2 and 3 cases also have the lowest total perinatal mortality rates. Thus differences in perinatal mortality rates between countries might be explained, in part, by differences in the quality of antenatal and perinatal care. This might relate to the availability and implementation of clinical practice guidelines for antenatal and perinatal care.

The results from the EuroNatal audit study suggest that stillbirths might be reduced by an improvement in the detection of severe growth restriction and the management of growth-restricted fetuses. An even larger reduction of intrapartum and neonatal deaths may be achieved by improved care, but the absolute numbers of grade 2 and 3 deaths in these categories are low in most regions.

An important factor in perinatal mortality is smoking. A relatively high percentage of smokers were identified in cases of perinatal death in Denmark and the regions in Scotland and Norway; this could explain part of the difference in perinatal mortality between the regions.

The EuroNatal audit study identifies aspects of perinatal care in which improvement might lead to lower perinatal mortality. Participating countries will need to consider the findings of this audit and its applicability at national level.

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COMMENTARY

The EuroNatal study and CESDI have on separate occasions reviewed the maternity and neonatal care of stillbirths and neonatal deaths of babies born in England after 28 weeks' gestation and reached a similar conclusion. Both found that in just over half of the deaths there was evidence of significant suboptimal care.

The EuroNatal study used an enquiry approach to assess the contribution of suboptimal antenatal and perinatal care to mortality rates for babies at 28 weeks' gestation onwards. It reviewed deaths of normally formed babies born after 28 weeks' gestation, whereas CESDI used a weight restriction of babies weighing over 1 kg.

The EuroNatal study shared many similarities with CESDI in the approach used: multidisciplinary and independent panels; the itemising of suboptimal care factors; and applying an overall grade. However, there were two significant differences: (1) the material for review comprised a summary and survey information rather than anonymised case notes and (2) there was a sequential process to establish a consensus of panellists regarding the overall grade.

One of the objectives of the EuroNatal study was to see if the perinatal mortality rates in each of the participating countries were influenced by the quality of care. It was of concern that England contained the greatest proportion of cases receiving significant suboptimal care. However, there are two particular biases that might have influenced this finding.

Firstly, the summaries of the English cases in the European study were compiled from a CESDI report from the '1 in 10' enquiry programme, whereas summaries of cases from other countries were compiled by a EuroNatal researcher abstracting directly from the medical records. It is likely that the CESDI reports had positively identified suboptimal care and that the summary provided to the European panels reflected this.

The second potential bias is the selection process of the perinatal deaths for inclusion into the EuroNatal study. Those from England were from seven of the 14 CESDI regions; the choice to participate was made at Regional level. The participating Regions were geographically widespread throughout England. The cases forwarded had already been the subject of enquiry by CESDI as part of the '1 in 10' programme. Inclusion in the latter was on the basis of a random sample of 1 in 10 relevant perinatal losses reported to CESDI. All such cases from the seven participating Regions were entered into the EuroNatal study. Because of the notification process that CESDI set up in 1992, ascertainment of perinatal deaths can be accurately assessed and it is known that less than 2% of relevant deaths were not identified. This circumstance did not hold in all of the other European countries, and it is

possible that in some countries the sample assessed was not representative and that those not included received poorer care.

The EuroNatal method of defining consensus with respect to the grading of care is a good example for future enquiry programmes. Grading of care is necessarily subjective and the grading system has been a major issue for CESDI. The EuroNatal study introduced a two-stage process with an initial assessment given independently by each assessor. Only cases where there was disagreement were reviewed again. This could prove to be an effective screening process for identifying cases requiring subsequent panel review and it could also overcome the potential for individual opinion to dominate panel assessments.

The EuroNatal study found an association between perinatal mortality rates and the proportion of cases with suboptimal care. This suggested that differences in perinatal mortality rates may be explained in part by differences in the quality of antenatal, perinatal and neonatal care. Comparisons of the different maternity systems may provide insight into future directions.

Regardless of which country is at which extreme of such a league table of suboptimal care, all showed a significant proportion of poor care. The areas of concern are similar to those highlighted in CESDI's review of antenatal panel comments in Chapter 3. There appears to be widespread difficulty with the detection and management of suspected poor fetal growth. The Commentary on Chapter 3 enlarges on this area.

The most frequently noted suboptimal maternal/social factor in the EuroNatal study was maternal smoking (11.7% of cases). Smoking in pregnancy reduces birth weight and is associated with increased perinatal mortality. Interventions aimed at smoking cessation in pregnancy are an important step towards reducing at least one contributory factor to perinatal mortality.

Despite the inherent biases and lack of control data, the EuroNatal study is welcome as an initial attempt to identify reasons for differences in perinatal mortality rates. CESDI looks forward to future collaboration in this very important area.

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5

UPDATE ON ISSUES SURROUNDING THE POSTMORTEM

5.1 INTRODUCTION

One of the first tasks identified and initiated by the CESDI Consortium, was to improve information on the postmortem to parents and professionals. This resulted in an updated *Guide to the Postmortem Examination: Brief Notes for Parents*, which was published in July 1998[1], after consultation with CESDI, the Foundation for the Study of Infant Deaths, the Stillbirth and Neonatal Death Society, and the Royal Colleges.

In addition, it was accepted that, critical to the consent process, was a requirement for a well-informed member of the clinical staff to be available to discuss the postmortem process in more depth. The *Fetal and Infant Postmortem: Brief Notes for the Professional* was published in April 1999[2]. This was never intended to be comprehensive but rather to provide indicators of the issues of which clinicians should be aware.

Since the publication of these notes, however, issues surrounding the paediatric postmortem examination, notably concerning organ retention, have been the subject of intense media attention. This has been associated with the publication of a number of reports (see below). These media reports have added to the stress and confusion of parents who are asked for consent for postmortem on their baby or whose child is subject to postmortem under direction from a Coroner. Further, it may be extremely difficult for professionals to have a full appreciation of the current position.

5.2 BACKGROUND

Following proceedings at the General Medical Council in 1997, a public inquiry was ordered into the paediatric cardiac services at The Bristol Royal Infirmary in 1998. In addition to the quality of the clinical services, the inquiry had, as part of its remit, to examine postmortem practices because it had become apparent that there was a large collection of hearts retained by the pathology department over a period of years. Evidence was heard that such collections were not unique nor was the retention of whole organs at postmortem an unusual practice.

As a direct result of the issues raised by knowledge of this postmortem practice, a series of reports and other documents have been published and include:

- The Royal College of Pathologists (RCPath) guidelines[3], March 2000.
- The Bristol Royal Infirmary Report[4], May 2000.
- Amendment to the Cremation Regulations[5], 2000.
- Interim BMA Guidelines[6], October 2000.
- The Royal Liverpool Children's Hospital Inquiry[7], January 2001.
- Interim Guidance to the NHS on Postmortem Examination[8], March 2000
- The National Summit on Organ Retention[9], January 2001.

The remainder of this chapter gives a summary of these reports. The purpose is not to provide a critique of the above publications but to place them in context and extract some of the essential messages that are likely to inform practice. Because much of the guidance is still in an interim form, it is impossible to provide definitive conclusions.

5.3 THE ROYAL COLLEGE OF PATHOLOGISTS' GUIDELINES

The Royal College of Pathologists' (RCPath) guidelines form the most complete set of practical guidance available to date and were formulated over a fairly prolonged period during 1999 and early 2000 after wide consultation. It is directed towards all pathologists, most of whom perform postmortems on adults.

5.3.1 Summary of Royal College of Pathologists' recommendations

- Medical schools and hospitals should provide training for medical and other appropriate personnel, such as nurses or bereavement counselling officers, in the process of obtaining consent for postmortem examination and advising parents about the examination including tissue and organ retention. This educative process should also be part of induction programmes for all relevant staff.
- Those staff, medical or otherwise, obtaining consent for postmortem should be aware of the need for tissue retention in individual cases, and discuss this with the pathologist, if necessary, before obtaining consent.
- Hospital authorities should provide an information leaflet for parents explaining the purpose of the postmortem examination and their rights to grant or withold consent.
- A copy of the consent form signed by the parents should be available for them to keep, as well as any information received.
- The consent form should offer parents a range of options for which they can separately grant or withold their agreement.
- Parents whose infant or child is subject to a Coroner's postmortem, should be provided with information, including a leaflet, explaining the legal requirements and the need, when appropriate, for tissue and organ retention.
- Coroners' postmortem reports should state clearly what, if any, tissues or organs have been retained in the investigation of death.
- Hospitals should have written standard operating procedures for archiving and disposal of tissues retained from postmortem

examinations. Methods should meet with public expectation, be respectful, safe and lawful.

- If any tissue (or organ) is retained after the infant or baby has been buried or cremated, it should be:
  respectfully disposed of;
  retained for medical education or research (with appropriate consent);
  released, with confirmation of identity, to funeral directors who are acting on behalf of parents and who are able legitimately to dispose of tissue with appropriate regard to health and safety regulations.
- Guidelines should be reviewed periodically and amended in the light of advances in medicine and changes in public attitude or legislation.

5.3.2 **Annexes**

The RCPath document is accompanied by three annexes:

- Annex A, is a leaflet: *Examination of the Body after Death. Information about Postmortem Examination for Relatives.* This has some similarities in format to the CESDI leaflet for parents, but it is more detailed and directed more towards postmortems on adults. It is not suitable for the perinatal and paediatric postmortem.
- Annex B is a model form for consent to postmortem examination. This is far more detailed than previous forms. Although it, or variants, should now be in use, it will almost certainly be changed in the light of subsequent reports.
- Annex C is a form for use in the context of Coroner's postmortems. It obtains information about what 'relatives' wish to happen to tissues or organs retained after a Coroner's postmortem and obtains permission for tissues and/or organs to be retained for medical research and education. However, Coroners might authorise the long-term retention of tissue in some cases depending on the circumstances. There are uncertainties concerning disposal authority in this area and this is likely to be a focus of further discussion.

5.4 THE BRISTOL ROYAL INFIRMARY REPORT

The Bristol Royal Infirmary (BRI) interim report arose from the recognition, during investigation of childhood cardiac services at Bristol, that hearts were commonly retained at postmortem and that a collection of hearts existed for research and education going back over many years. In addition, it became public knowledge that it was routine for tissues to be retained at postmortems for histological diagnosis and these tissues were usually archived (in a wax block). The BRI inquiry remit was expanded to include a review of postmortem practices. It was acknowledged that the practice at Bristol was not necessarily different from practice elsewhere in the country, and indeed that paediatric practice was no different to adult postmortem practice.

The BRI interim report (excluding appendices and annexes) contains 69 recommendations. This chapter can only highlight a few points from the report that supplement the RCPath guidelines or raise further questions on the issue of postmortem practice.

The BRI interim report also criticises the RCPath document. Most notably, it suggests that the RCPath leaflet provides too much information and might be unnecessarily distressing to relatives. Further, while emphasising that the postmortem should be conducted strictly in accordance with the law, the BRI inquiry also recognises that, in the context of a Coroner's postmortem, the law is far from clear on some aspects of tissue retention and the uses to which this tissue can be put. The report recognises that the legal boundaries of the postmortem may limit its scope for documenting all the pathology. It recommends that the law should be clarified and if necessary altered.

The BRI report makes little distinction between the long-term retention, in archive file, of small pieces of tissue that may have been taken for the purposes of histological diagnosis and of whole organs retained for education and research. It recommends that the short-term and long-term retention of any tissue (including slides), should be subject to consent by parents. The various uses to which it can be put should be specified.

5.5 AMENDMENT TO THE CREMATION REGULATIONS

One of the recommendations of the RCPath guidelines is that tissues and organs, if subject to hospital 'disposal', should be disposed of lawfully and respectfully. However, it has not been possible for tissues or organs retained at postmortem to be subject to separate hospital cremation or burial. For many, if not all hospitals, disposal will be via the clinical waste system.

The cremation of bodies and human tissues is governed by the Cremation Act of 1902 and Cremation Regulations 1930. Amendments made in the early part of 2000 were introduced with the intention of allowing tissues removed at postmortem to be cremated at some later date separate to the body. Two main requirements need to be met for such cremation to take place:

1. Parents have granted consent and wish for cremation to take place.
2. The tissues are appropriately identified. This can now be performed by the hospital rather than referring back to parents.

Strictly, regulations do not cover 'non-viable' fetuses of less than 24 weeks of gestation as, within the Act, these are not considered human remains. Cremation of pre-24-week fetuses is therefore at the discretion of the crematorium although, at least anecdotally, most seem to agree that cremation and gestation of the fetus is not an issue.

5.6 INTERIM BRITISH MEDICAL ASSOCIATION GUIDELINES

These were published in October 2000 as further interim guidance. Most of the document reiterates other reports but it raises the point that obtaining consent should be regarded as a process rather than a single event that precedes the postmortem. It emphasises that the postmortem is about investigating uncertainty and that it may not be possible to inform parents fully before the event. This means that further discussions may need to take place after the postmortem and may include consideration of retention and use of tissue for specified research purposes.

5.7 THE ROYAL LIVERPOOL CHILDREN'S HOSPITAL INQUIRY

The release of this report, more than any of the reports above, has altered the current working environment and public perception of postmortem practice. Although the practice at Alder Hey was exceptional and much of the criticism is specific to Liverpool, many of the points are of general importance and of direct relevance to clinicians. Only a few can be highlighted here.

5.7.1 Summary of Liverpool recommendations

- Clinicians shall be aware of the precise terms and provisions of the Coroner's Act and the circumstances in which it is obligatory to report cases to the Coroner. Information given to next of kin when a Coroner's case is to be performed should include:
  - the nature of the examination, including the need to open the body, remove and weigh organs;
  - the need for tissue samples and possible retention of organs.
- Pathologists shall not retain samples and organs beyond those reasonably incidental to establishing the cause of death unless there is also written consent properly obtained under the Human Tissue Act 1961.
- The Department of Health, the Royal Colleges and medical schools should instruct members of the medical profession in the precise terms of the Human Tissue Act and the need for strict compliance.
- The Human Tissue Act should be amended to provide a test of fully informed consent for postmortem and retention of body parts.
- The Act should be amended to impose a criminal penalty for breach of its provisions.
- Guidelines should be drawn up for obtaining fully informed consent with provision made for a breach to result in disciplinary proceedings.

5.7.2 Consent

Fully informed consent means that a person must have all the information required to form a final decision. Next of kin need to understand what is involved in a postmortem examination – no matter how distasteful the giving of this information might be to the clinician

concerned. The consent procedure should be assisted by a bereavement advisor.

5.7.3 **The consent form**

No current consent form was considered adequate. The report does not recommend a particular form but suggests that it should include sections on: patient details; the purpose of the postmortem; the extent of the postmortem, including specifying from where tissue samples can be obtained; organ retention and purpose; tissue retention and purpose; and what will happen to tissues/organ (e.g. archived, returned to body, used in research etc.).

5.8 REPORTS FROM THE CHIEF MEDICAL OFFICER

Two reports have been produced by the Chief Medical Officer and are summarised below. The first was the interim guidance published at the same time as the RCPath guidelines in early 2000 and directed at Trust Chief Executives. The guidance stressed the management responsibilities and systems that Trust Executives should ensure are in place to promote an immediate change in practice and to provide greater transparency.

The second was the result of a National Summit on Organ Retention held in London in January 2001, to obtain views on organ retention from professional, parental and other groups. Although held in advance of the publication of the Liverpool Inquiry, the recommendations took into account its content.

5.8.1 **Interim guidance from the Chief Medical Officer on postmortem examination**

Many of the points reinforce the recommendations of the RCPath guidelines but place them in a wider context. They include the proposals that all NHS Trusts should:

- designate a named individual to provide information and support to families where a hospital or Coroner's postmortem examination may be required (this person should be trained in bereavement but also be able to counsel parents about all aspects of the postmortem including tissue retention);
- provide written information for parents about the postmortem;
- ensure compliance with Trust-agreed arrangements for tissue and organ disposal and ensure that management systems are in place to record postmortem consent, and the fate of tissues and organs retained (archived or means of disposal);
- ensure that best practice is followed, taking specific account of the RCPath guidelines;
- arrange for copies of the postmortem consent form to be a part of the postmortem record, the clinical notes and a copy for parents;

- ensure that parents and appropriate clinicians are fully informed of the results of the hospital or Coroner's postmortem.

5.8.2 **The National Summit on Organ Retention**
This included the following proposals:

- The Human Tissue Act should be amended to clarify that consent must be sought from those with parental responsibility, and a penalty for non-compliance should be introduced.
- The Coroner's rules should be amended to clarify that the pathologist has no independent right to retain, use or dispose of human material once the postmortem is concluded.
- A Code of Practice should be introduced to set out required standards of practice in communications with families about both hospital and Coroner's postmortems.
- A standardised consent form should be introduced throughout the NHS.
- The ultimate disposal of retained tissue, organs, stillborn babies and fetuses should be in accordance with any expressed wishes of the individual or family.
- The Coroner's system, as it relates to hospital deaths and deaths under the care of a General Practitioner, should be reviewed and the concept of a 'medical examiner' system should be explored.
- There should be a programme of education for public and health professionals to ensure that there is a general understanding of what is involved in a postmortem process and its potential value.
- Research should be commissioned into less invasive procedures of postmortem examination.

5.9 CONCLUSION

Even though some aspects of practice had already changed, the paternalistic approach is no longer acceptable. Some aspects of these various reports differ but the central messages are common and cannot be ignored. Firstly, Trusts need to ensure that parents are provided with more information about the postmortem. This will require the professional who discusses the postmortem with parents to be better informed; this will include obstetricians, paediatricians, midwives and neonatal nurses. They should be supported by specifically trained bereavement support staff and more written information. The consent process will need to ensure that the postmortem examination is better explained and that all the various options regarding tissue retention are explored with parents. Secondly, pathologists need to be fully aware of the limits and constraints in the use of tissue imposed by the consent provided by parents or by the authority granted by the Coroner when ordering a postmortem examination. Thirdly, in postmortems required by

law (Coroner's postmortems), parents should be informed of the reasons for requiring a postmortem examination by law, of its location, and of the retention of any tissue or organs having received this information from the pathologist.

Considerable work yet remains and the next couple of years will see further activity which may include a Code of Practice governing the postmortem examination. A consent form specific to infants and children for use throughout the country is also required together with standardised information leaflets. How much information is deemed necessary before consent can be considered 'informed' is likely to require considerable discussion. The law needs to be clarified – notably the 1961 Human Tissues Act. The operation of the Coroner's system will also be the subject of review. This may result in very significant differences in the environment in which the postmortem system operates. With such work yet to be done, the recommendations of the current reports cannot be considered definitive although they do act as authoritative signposts.

Future CESDI Reports will continue to highlight guidance and good practice on the management associated with bereavement as and when it is forthcoming.

KEY POINTS

- Postmortem practice has been the subject of numerous reports over the past two years – either acknowledging deficiencies in or criticising aspects of past practice. All recommend that parents should be better informed about the postmortem.

- Those who discuss postmortems with parents have a responsibility to understand the process so that consent is informed.

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6

THE USE OF INTRAPARTUM ELECTRONIC FETAL MONITORING IN ENGLAND, WALES AND NORTHERN IRELAND – A CROSS-SECTIONAL SURVEY

COMMENTARY – THE USE OF ELECTRONIC FETAL MONITORING

The past four CESDI annual reports have consistently commented on fetal monitoring. The 4th Annual Report showed that failures in the use and interpretation of cardiotocographs (CTGs) were present in more than half of intrapartum-related deaths. The Focus Group on ruptured uterus (5th Annual Report), found that 26 of 99 comments on substandard care were related to fetal monitoring. Likewise, the '4 kg and over' survey (6th Annual Report), confirmed that problems in fetal monitoring accrued the highest number of comments, with CTG interpretation as the basis of the most frequent criticism.

However, while CESDI has recommended that every hospital offering intrapartum care should have in place a regular rolling update/training programme in the use of CTGs for all professionals involved in intrapartum care, it has not commented on the value of the routine use of electronic fetal monitoring (EFM).

The following audit was carried out by the Clinical Effectiveness Support Unit (CESU) of the Royal College of Obstetricians and Gynaecologists (RCOG) in response to the work of CESDI over the last five years. It was also part of a larger piece of work to develop national evidence-based guidelines on the use of EFM commissioned initially by the Department of Health and subsequently by the National Institute of Clinical Excellence (NICE). The audit assesses current UK practice, which has not been surveyed for over ten years.

CESU's literature review does not find any evidence to suggest that EFM has any positive effect on perinatal mortality although there is consistent evidence that maternal intervention rates increase.

This audit is not attempting to deliver the message that EFM should be used routinely, but to pull together existing evidence of current UK practice. The NICE guidelines on the use of EFM were published in May 2001 and are available on the RCOG and NICE websites.

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6.1 INTRODUCTION

The Clinical Effectiveness Support Unit (CESU) at the Royal College of Obstetricians and Gynaecologists (RCOG) was commissioned initially by the Department of Health and subsequently by the National Institute for Clinical Excellence (NICE) to develop a national evidence-based guideline on the use of electronic fetal monitoring (EFM). A systematic search of the literature was performed to look for evidence of current UK practice. This revealed that the last UK survey had been conducted in 1986.

To inform the guideline development group, an audit was therefore undertaken to assess current practice and to compare this with 10 and 20 years ago. Audit standards were developed from a combination of the recommendations made in the 4th and 5th CESDI Annual Reports[1,2], the RCOG/RCM working party report *Towards Safer Childbirth*[3], the report from the Clinical Negligence Scheme for Trusts[4] and recommendations from expert panels[5]. The standards included:

- Basic provision of EFM facilities should be 2–4 machines per 1000 deliveries in each unit.
- A guideline on the use of EFM should be available in every unit.
- Continuous EFM should be used in a selection of high-risk pregnancies.
- If EFM is used, then fetal blood sampling (FBS) should be available.
- In situations of suspected fetal compromise, umbilical cord pH should be measured at delivery.

Both the 4th and 5th Annual Reports[1,2] recommended that all units employing EFM should provide a teaching programme for all professionals. During the development of the CESU survey, CESDI was planning to conduct its own cross-sectional survey on educational provision with regard to EFM. To avoid duplication, therefore, questions relating to this area were omitted from the CESU questionnaire. The results of the CESDI survey have been published in the 7th Annual Report[6].

With regard to the role of EFM, three systematic reviews have been published comparing EFM with intermittent auscultation (IA), and examining the effects on maternal and neonatal outcomes[7–9]. EFM does not reduce perinatal mortality or improve Apgar scores[7–9]. Vintzileos[8] found a significant reduction in perinatal deaths in a subgroup in which death resulted from fetal hypoxia. A reduction in neonatal seizure rates has been shown in two of the reviews[7,9], although in the review by Grant[9] this was restricted to trials with an option for fetal blood sampling (FBS). The consistent finding of all reviews was the increase in maternal intervention rates, including operative vaginal delivery and caesarean section[7–9].

There have been two surveys of EFM practice in the UK[10,11]. The first, conducted in 1978[10], found a bimodal distribution of the proportion of patients monitored in the responding units, with peaks at 20–30% and 80–90%. This was felt to reflect a division in opinion over whether monitoring should be routine or applied selectively to high-risk pregnancies. Only 40% of units used FBS in conjunction with intrapartum fetal monitoring. A second survey[11] by the same group conducted in 1985/86 aimed to assess changes in practice. The number of fetal heart rate (FHR) monitors had increased by 88%. The percentage of monitored pregnancies was no longer bimodal: 63% of units monitored over 60% of patients. However, only 44% of units employed FBS in conjunction with intrapartum monitoring.

The second survey[11] followed the publication of the large randomised controlled trials into EFM[12–19]. These concluded that EFM did not significantly improve outcome when compared with intermittent auscultation, and therefore may have affected the uptake of EFM on a wider scale. A French study[20] published in 1989 showed that EFM was widely used and that only 1% of French obstetricians reserved its use for high-risk pregnancies. The principal reasons cited for this were the earlier detection of fetal distress and the reduction in the number of midwives. An American survey[21] published in 1993 looked at EFM practice in the US between 1980 and 1988. The use of EFM had increased from 44% to 62% over the period. Low-risk women were more likely to be monitored than high-risk women, although this finding must be interpreted with caution as the allocation to each group was made retrospectively using national data rather than individual patient records.

6.2 MATERIALS AND METHODS

A structured questionnaire was sent to the Delivery Suite Managers of 250 NHS delivery suites in the UK. The units were identified from databases at the RCOG and CESDI. The questionnaire was sent out initially in November 1999, and further postal requests for information were made in January 2000. The remaining units were contacted directly by telephone. Inconsistencies in data were clarified via further telephone contact.

The questionnaire asked 11 closed structured questions relating to the use of EFM. Information was requested on the annual delivery rates, the number of cardiotocograph (CTG) machines available and the availability of a departmental guideline on the use of EFM. Other practices surveyed the use of EFM in a variety of high-risk clinical situations, the use of FBS, availability of pH-measuring facilities and additional fetal monitoring modalities. Information was also requested on the frequency and types of umbilical cord blood samples taken.

The questionnaires were pre-coded to allow identification of non-responding units. Returned questionnaires were collated in a database and analysed using SPSS version 10.0.

6.3 RESULTS

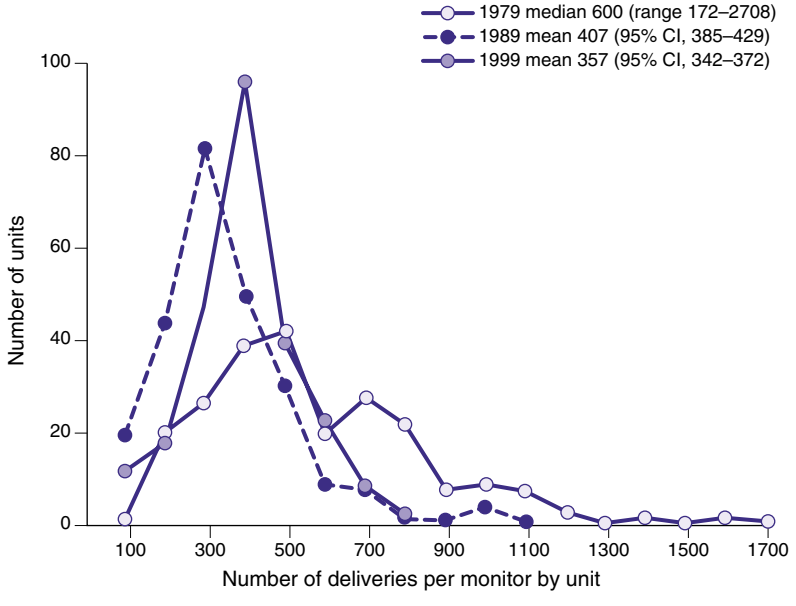
6.3.1 Responses

Of the 250 obstetric units, two no longer offered intrapartum care. Data were sought from the remaining 248 units. Responses were received from 207 (83.5%) on the first mailing, an additional 21 (8.5%) from reminders and the remaining 20 units were contacted directly by telephone. Thus, a complete response rate was achieved. Missing data were minimal with an average of 4.6 (1.6%) missing responses per question.

6.3.2 Provision of EFM facilities

The median delivery rate of the 248 units providing intrapartum care was 2700 per year (range 75–6500), with the median number of CTG machines being seven (range 0–22). The number of deliveries per monitor was calculated for each unit, as in both of the previous surveys, and comparison was made of provision over the 22-year period (see Figure 6.1). This graph shows how the variation in practice has narrowed over the time period. The current mean ratio is 357 deliveries per monitor in each unit (95% CI: 342 to 372).

Figure 6.1 Ratio of number of deliveries per monitor by unit in current and previous EFM surveys



Of the 248 units surveyed, nine units did not use EFM and only provided low risk obstetric care. All subsequent data apply only to the remaining 239 units.

6.3.3 Availability of departmental guideline on EFM

A guideline was available in 177 (74%) of units. The availability of a guideline of EFM use was not related to the delivery rate in that unit (Table 6.1). Of units not having a guideline, 16 (29%) had delivery rates in excess of 3000 deliveries per year.

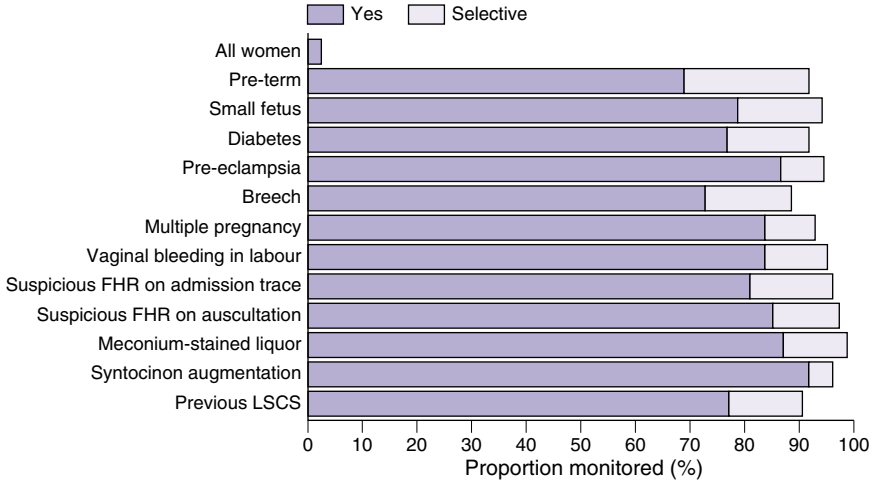
Table 6.1 Availability of a departmental guideline on EFM according to unit delivery rate (in units employing EFM)

	Deliveries per year: number (%)											
	< 1000		< 2000		< 3000		< 4000		< 10000		Total	
Available	12	(6.8)	39	(22.0)	57	(32.2)	44	(24.9)	25	(14.1)	177	(100)
Not available	7	(12.7)	16	(29.1)	16	(29.1)	14	(25.5)	2	(3.6)	55	(100)
Missing data	1	(14.2)	0	(0)	4	(57.1)	1	(14.2)	1	(14.2)	7	(100)
Total	**20**		**55**		**77**		**59**		**28**		**239**	**(100)**

6.3.4 Use of EFM with high-risk pregnancies

The average percentage of patients monitored either routinely or selectively was 93%, with a minimum of 88% for breech presentation in labour and a maximum of 98% in the presence of meconium-stained liquor (Figure 6.2).

Figure 6.2 Monitoring practice in selected high-risk pregnancies



Routine admission traces on all women regardless of risk were employed in 189 (79%) of units (Table 6.2).

Table 6.2 Use of admission traces according to unit delivery rate (in units employing EFM)

	Deliveries per year: number (%)											
	< 1000		< 2000		< 3000		< 4000		< 10000		Total	
Routine	14	(7.4)	46	(24.3)	61	(32.3)	47	(24.9)	21	(11.1)	189	(100)
Never	3	(16.7)	4	(22.2)	2	(11.1)	4	(22.2)	5	(27.8)	18	(100)
Selective	3	(9.7)	5	(16.1)	14	(45.2)	7	(22.6)	2	(6.5)	31	(100)
Missing	0	(0)	0	(0)	0	(0)	1	(100)	0	(0)	1	(100)
Total	**20**		**55**		**77**		**59**		**28**		**239**	**(100)**

6.3.5 Use of fetal blood sampling

FBS was employed in 81% of units using EFM (Table 6.3). Of the 42 units *not* using FBS, 13 (31%) had delivery rates <1000 per year and six had delivery rates >3000 per year. Of the units performing FBS, 189 (98%) used heparinised tubes for specimen collection and 192 (99%) had pH-monitoring facilities on the delivery suite.

Table 6.3 Availability of fetal blood sampling facilities according to unit delivery rate (in units employing EFM)

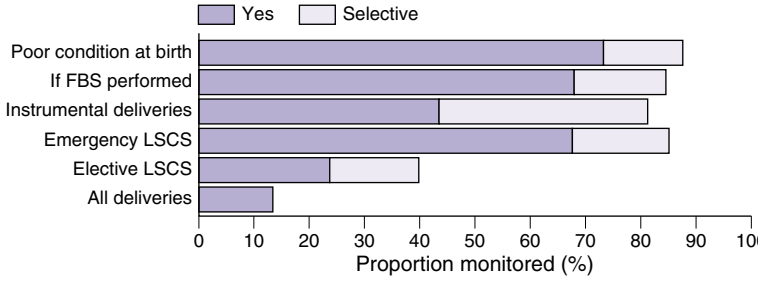
	Deliveries per year: number (%)											
	< 1000		< 2000		< 3000		< 4000		< 10000		Total	
Available	3	(1.6)	43	(22.3)	66	(34.2)	54	(28.0)	27	(14.0)	193	(100)
Not available	13	(31.0)	12	(28.6)	11	(26.2)	5	(11.9)	1	(2.4)	42	(100)
Not applicable*	4	(100)	0	(0)	0	(0)	0	(0)	0	(0)	4	(100)
Total	**20**		**55**		**77**		**59**		**28**		**239**	**(100)**

*Four units that use EFM transfer all women with suspicious traces to larger units.

6.3.6 Frequency and type of umbilical cord sample

The frequency of cord sampling in a variety of situations is shown in Figure 6.3. Only 162 (68%) of units routinely sampled cord blood following emergency caesarean sections. Cord pH samples were performed in 163 (68%) if an FBS had been performed in labour and 105 (44%) of all instrumental deliveries. Of those performing EFM, 14 units (6%) did not perform cord blood analysis.

Figure 6.3 Frequency of umbilical cord blood sampling



6.3.7 Alternative monitoring modalities

Pulse oximetry was used in two units, fetal scalp lactate in two units and fetal electrocardiogram analysis in one unit.

6.4 DISCUSSION

With a 100% response rate, this data presents a complete national picture of the use of EFM in 1999. The percentage of missing data was small.

The provision of monitoring facilities has become increasingly standardised; only 35 (14%) of units were outside the recommendation of 2–4 monitors per 1000 deliveries set by the RCOG[3].

The availability of guidelines on the use of EFM was poor. Perhaps more surprising, the availability of these guidelines was not dependent on unit size. It is recognised that guidelines do not guarantee high quality care – content, quality and compliance must also be considered. It is likely that local implementation protocols will be developed following dissemination of the national evidence-based guideline in 2001.

There was much variation in the use of EFM in high-risk situations. The average of 93% was encouraging but the variation between categories was surprising.

There has been an increase in the availability of facilities for FBS over the past 20 years: from 40% in 1979, to 44% in 1989, to the current value of 81%. This still falls short of the optimum. Despite its problems, FBS is a more specific marker of fetal well-being than EFM alone[7–9].

The frequency of cord blood samples was lower than anticipated. Only 68% of units collected cord pH samples with all emergency caesarean sections; 17% were selective in this category, probably for cases of fetal distress. Although the predictive value of cord blood pH in relation to long-term handicap is limited[22–25], it is predictive of short-term neonatal complications[26–28], and it is reassuring if the value is normal.

The use of alternative techniques is low because most are at the research stage. Fetal ECG analysis has no benefits over EFM[29,30]. The benefits of pulse oximetry over EFM will not be known until the results are available from a direct comparison of the two. The use of fetal scalp lactate as an alternative to FBS is promising, as it is easier to perform, has a lower failure rate and requires a smaller sample of blood[31]. However, implementation is limited by the lack of combined measuring facilities.

KEY POINTS

- The provision of EFM in most delivery suites in England, Wales and Northern Ireland is within recommended levels.
- The availability of EFM guidelines is poor.
- The use of EFM in high-risk labours is variable.
- Fetal blood sampling is available as an adjuvant to EFM in most units.
- The use of umbilical cord blood analysis is variable.

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7

SURVIVAL RATES OF BABIES BORN BETWEEN 27 AND 28 WEEKS' GESTATION IN ENGLAND, WALES AND NORTHERN IRELAND 1998–2000

7.1 BACKGROUND

Prematurity is the major cause of neonatal deaths. This applies especially in the very low birthweight group (less than 1.5 kg) which accounts for 1–2% of births and approximately half of neonatal deaths. However, despite data on gestational age being routinely recorded on all births it is not collected centrally in England or Northern Ireland. Consequently it has not been possible to provide national data on survival after preterm delivery.

One of the key aims of Project 27/28 was to provide national and regional survival figures for preterm babies in the period 1998 to 2000. Because of the work involved in introducing a notification process dependent on manual recording at birth, a restricted gestational range was chosen, 27^{+0} to 28^{+6} weeks. At this gestation, most babies are expected to survive; and differences in standards of care may make a significant contribution to the outcome.

The data from the notifications served two purposes: (1) to provide crude survival rates at day 28; (2) to act as a population frame for the sampling of cases for national enquiry. This chapter is restricted to describing the survival rates. The Enquiry findings from Project 27/28 will be published in the next Annual Report 2002.

7.2 METHOD

Specially designed logbooks were introduced into all labour wards and neonatal units in England, Wales and Northern Ireland. All live-born babies with a clinical gestation between 26^{+0} and 29^{+6} weeks born between 1 September 1998 and 31 August 2000 were entered onto the log by the CESDI Hospital Co-ordinator. The four-week range was chosen to allow for inaccuracies in the estimation of clinical gestation at birth. A minimum basic data set was recorded on every baby entered onto the log (Table 7.1). The various locations for the baby in the first 28 days following birth were noted. Notification from the logs were sent from hospitals to the 16 Regional Co-ordinators and then to the central Secretariat on a monthly basis.

Table 7.1 Labour ward and neonatal unit data set recorded on notification

Topic	Details obtained
Ultrasound scan (USS)	Date of first USS < 20 weeks
	Gestation at first USS < 20 weeks (weeks and days)
Mother	Age
	Last menstrual period (LMP)
Delivery	Presentation
	Mode
Birth	Place of birth
	Clinical gestation at delivery (weeks and days)
	Date and time of delivery
Baby	Sex
	Number of babies in this pregnancy
	Birth order
	Birthweight (grams)
	Life-threatening congenital malformation
Admission to neonatal unit	Name of previous unit or ward
	Date of admission to this unit
Paediatric assessment	Date at which the paediatrician assessed gestation
	Estimated gestation (weeks and days)
Transfer	Place and date of next transfer out of this unit or date of death

7.2.1 Defining gestation

Gestation may be defined on the basis of clinical estimates, ultrasound measurements or menstrual history. For consistency, an algorithm was used on the basic data set recorded in the logs: this was known as the Algorithm Gestation (Figure 7.1).

7.2.2 Describing the hospital units

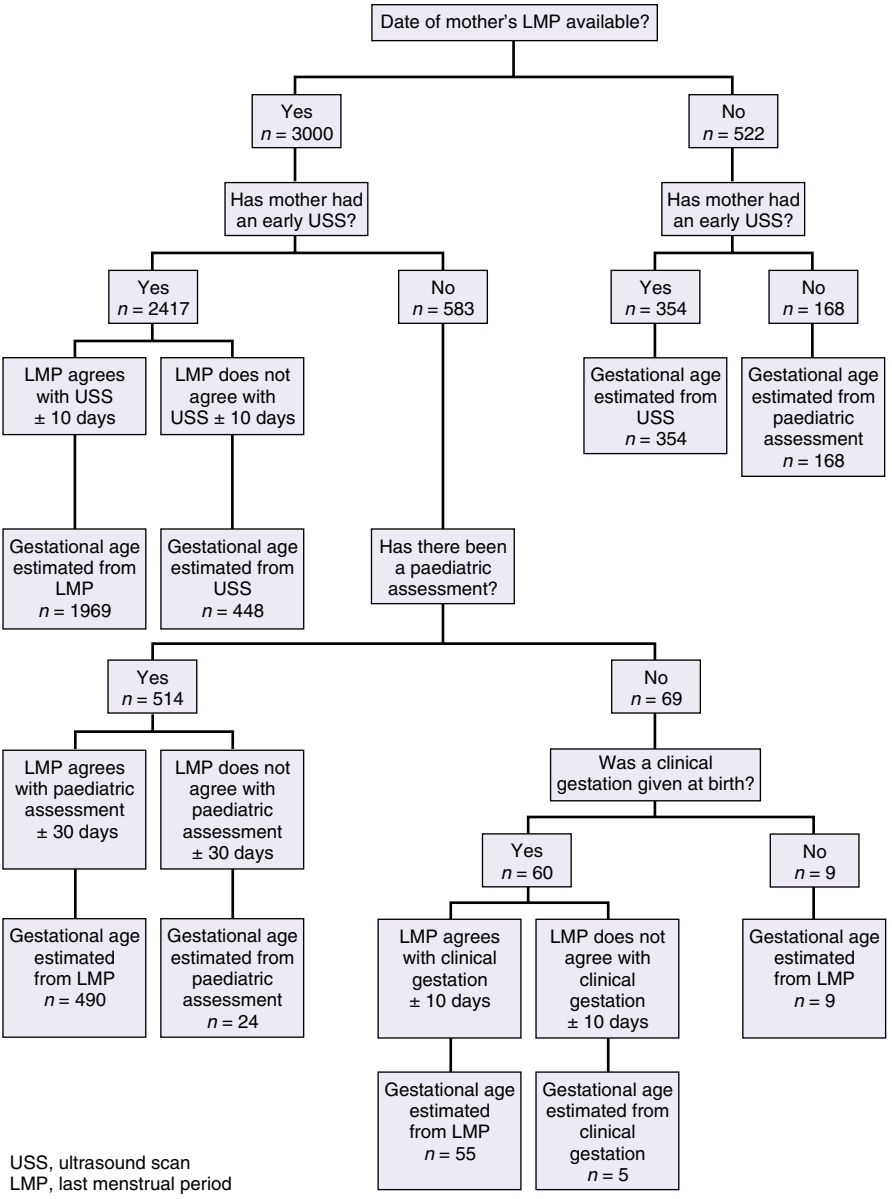
The Regional Co-ordinators were asked to provide a description of the work and facilities at each hospital over the period of the collection of the logs. This included the number of deliveries, the presence of a neonatal intensive care unit, the number of level 1 intensive care days as defined by the British Association of Perinatal Medicine[1] and referral practice for a baby of 27 to 28 weeks' gestation (Table 7.2). A neonatal intensive care

Table 7.2 Category of neonatal unit

Category	Description
NICU routine referrals	A unit with NICU facilities which receives referrals of babies in the 27/28 week gestational range (in-utero or ex-utero) routinely
NICU in-house	A unit with NICU facilities which cares for its in-house babies in the 27/28 week gestational range but is not an acceptor of referrals routinely
No NICU, transfers some	A unit without NICU facilities which stabilises and then transfers some, but not all, babies out
No NICU, transfers all	A unit without NICU facilities which stabilises and then has a policy to transfer all babies out if possible

A NICU (neonatal intensive care unit) is a unit that provides long-term (more than 48 hours) artificial ventilation facilities

Figure 7.1 Dating algorithm for defining gestational age



USS, ultrasound scan
LMP, last menstrual period

unit was defined as a unit providing long-term (more than 48 hours) artificial ventilation.

7.3 RESULTS

7.3.1 Notifications

There were 6693 babies with a clinical gestation between 26^{+0} and 29^{+6}

weeks born between 1 September 1998 and 31 August 2000 whose notifications had been received by the Secretariat by 17 May 2001. These included 3522 babies (Figure 7.1) with an algorithm gestation of 27^{+0} to 28^{+6} weeks born to 3101 mothers.

In total, 253 hospitals completed and returned log data during the study period. The 42 that did not were small maternity units, delivering less than a thousand babies annually. The relevant births in these units were checked by the Regional Co-ordinator by personal contact with the hospital.

The median notification time to the Secretariat for the neonatal deaths was 68 days, and for the babies surviving at day 28 it was 79 days from birth.

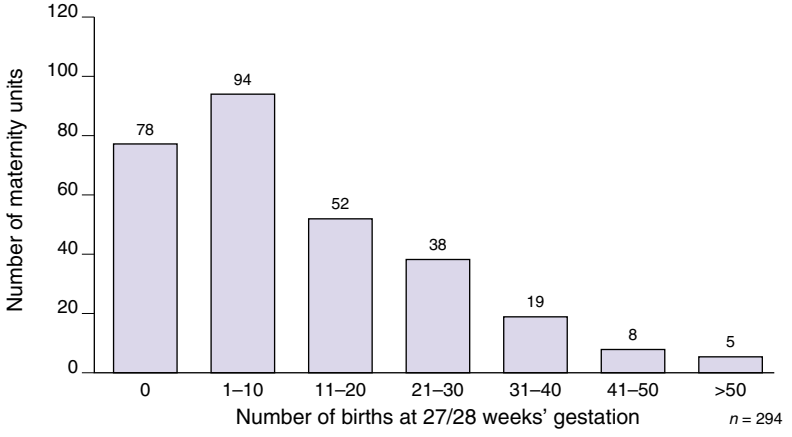
7.3.2 Maternity and neonatal units

On 1 September 1998 there were 293 maternity units and 148 neonatal intensive care units in England, Wales and Northern Ireland. During the study period, two maternity units and two neonatal units closed and one maternity and one neonatal unit opened.

Of the 294 maternity units, 77 had a NICU that received routine referrals, 71 had a NICU that treated its in-house babies, 36 had no NICU and transferred some babies, 110 had no NICU and transferred all babies. One hospital had a NICU that received routine referrals but no maternity unit.

Nearly one-quarter of the maternity units (71, 24%) had less than a thousand deliveries annually and these included 51 midwife-led and eight GP units serving low-risk maternity populations. These 71 hospitals accounted for 2.4% of all deliveries in 1998 regardless of gestation and 0.2% (8/3522) of births at 27 to 28 weeks' gestation during the study period.

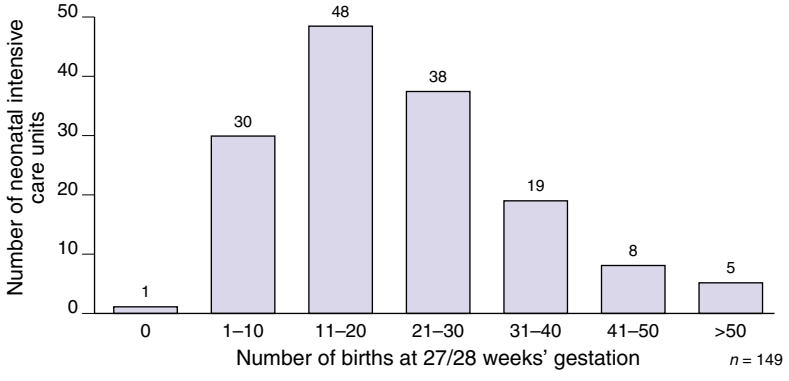
Figure 7.2 Distribution of maternity units according to the number of births at 27/28 weeks' gestation from 1998 to 2000



The distribution of maternity units according to the number of babies born in the study is shown in Figure 7.2. There were 94 units reporting between 1 and 10 babies over 2 years, and 78 reported none.

The distribution of the 149 neonatal intensive care units according to the number of babies born in the study is shown in Figure 7.3. There were 31 neonatal units with less than 11 babies born in the study period of 2 years.

Figure 7.3 Distribution of neonatal intensive care units according to the number of births at 27/28 weeks' gestation from 1998 to 2000



7.3.3 Gestation

Menstrual history was recorded for 2633/3101 (84.9%) mothers. Early scan information (prior to 20 weeks' gestation) was available on 2439/3101 (78.6%) mothers.

Information on scan data varied regionally from 53% to 91% mothers (Table 7.3). Trent, Anglia and West Midlands had the highest rates, and Northern Ireland, North East Thames and North West Thames had the lowest. Reasons for low rates may have included mothers booking late, non-attendance for scan, non-use of scans and scan data not being provided for the notification.

7.3.4 Place of birth

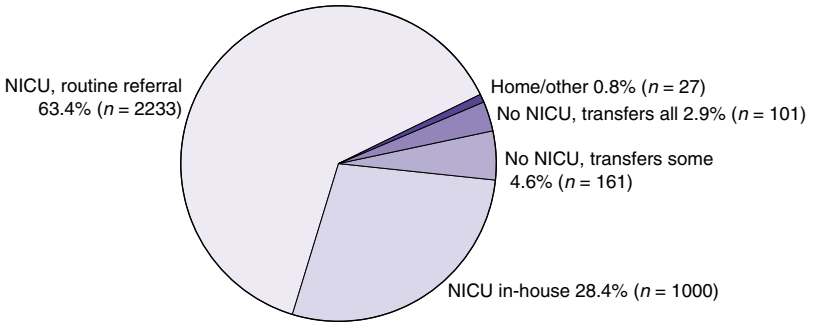
Most babies (3495; 99.2%) were born in a labour ward. Of the 27 who were not: 1 was a planned delivery in a cardiac theatre; 21 were born at home; 3 in transit; 1 in prison and 1 in an accident and emergency department. Of the babies born outside a labour ward, one-third (9) were from the North Western region (1 in prison and 8 at home).

There were 2233 (63%) babies born at a hospital with a neonatal intensive care unit (NICU) that received routine referrals, and 1000 (28%) in a hospital with a NICU that manages in-house babies at this gestation. There were 262 (7%) born in hospitals that do not routinely manage babies at this gestation (Figure 7.4).

Table 7.3 Regional distribution of availability of scan data

CESDI region of birth	Number of mothers with scan data (% of mothers in each region)
Northern	112/133 (84.2)
Yorkshire	136/180 (75.5)
Trent	264/289 (91.3)
Anglia	137/153 (89.5)
North West Thames	131/210 (62.4)
North East Thames	165/275 (60.0)
South East Thames	222/282 (78.7)
South West Thames	112/152 (73.7)
Wessex & Channel Islands	118/152 (77.6)
Oxford	114/148 (77.0)
South Western	99/153 (64.7)
West Midlands	328/362 (90.6)
Mersey	97/122 (79.5)
North Western	220/250 (88.0)
Wales	143/162 (88.3)
Northern Ireland	41/78 (52.6)
Total	**2439/3101 (78.6)**

Figure 7.4 Distribution of place of birth of babies born at 27/28 weeks' gestation from 1998 to 2000 according to neonatal facilities



7.3.5 Characteristics of babies and pregnancies

The mean age of the mothers was 28 years (range 14–49). There were 2675 (86.3%) singleton maternities and 426 (13.7%) multiple maternities (752 twins, 91 triplets and 4 quadruplets). There were 1930 (54.8%) male and 1592 (45.2%) female infants. At birth or shortly after, 63 (1.8%) babies were noted to have life-threatening congenital malformations.

The mode of delivery for the babies was caesarean section (2220; 63.0%); operative vaginal delivery (155; 4.4%); spontaneous vaginal delivery (1076; 30.5%); not known (71; 2.0%).

Table 7.4 gives details concerning place of birth and birthweight.

Table 7.4 Number of births at 27–28 weeks' gestation during the period 1 September 1998 to 31 August 2000 according to various characteristics, together with survival rates

Characteristic	Number of births (%) n = 3522	Number survived to 28 days (%) [95% CI]	χ^2 test p-value
Sex			0.001
Female	1592 (45.2)	1435 (90.1) [88.5–91.5]	
Male	1930 (54.8)	1666 (86.3) [84.7–87.8]	
Plurality			0.44[a]
Singletons	2675 (76.0)	2365 (88.4) [87.1–89.6]	
Twins	752 (21.4)	652 (86.7) [84.0–89.0]	
Triplets	91 (2.6)	80 (87.9) [79.0–93.5]	
Quads	4 (0.1)	4 (100) [39.6–100]	
Presentation			<0.001[b]
Cephalic	2118 (60.1)	1893 (89.4) [88.0–90.6]	
Breech	1029 (29.2)	870 (84.5) [82.2–86.7]	
Other	210 (6.0)	185 (88.1) [82.7–92.0]	
Not known	165 (4.7)	153	
Mode of delivery			0.06[b,c]
Caesarean (emergency + planned)	2220 (63.0)	1937 (87.2) [85.8–88.6]	
Spontaneous vaginal	1076 (30.5)	965 (89.7) [87.7–91.4]	
Assisted manual	90 (2.5)	74 (82.2) [72.4–89.2]	
Forceps	63 (1.8)	57 (90.5) [79.8–96.1]	
Ventouse	2 (0.1)	2 (100) [19.8–100]	
Not known	71 (2.0)	66	
Place of birth			<0.001[d]
Hospital	3495 (99.2)	3084 (88.2) [87.1–89.3]	
Home/in transit/other	27 (0.8)	17 (63.0) [42.5–79.9]	
Hospital type at birth			0.83[e]
NICU – routine referrals	2233 (63.4)	1965 (88.0) [86.6–89.3]	
NICU – in house	1000 (28.4)	889 (88.9) [86.7–90.7]	
No NICU – transfers some	161 (4.6)	140 (87.0) [80.5–91.6]	
No NICU – transfers all	101 (2.9)	90 (89.1) [81.0–94.2]	
Home/in transit/other	27 (0.8)	17	
Number of 27/28 week babies born per hospital (during study period)			0.60[f,g]
≤10	409 (11.6)	361 (88.3) [84.6–91.1]	
11–20	796 (22.6)	703 (88.3) [85.8–90.4]	
21–30	970 (27.5)	863 (89.0) [86.8-90.8]	
31–40	671 (19.0)	588 (87.6) [84.8–90.0]	
41–50	360 (10.2)	316 (87.8) [83.8–90.9]	
>50	289 (8.2)	253 (87.5) [83.0–91.0]	
Number of level 1 intensive care days per hospital (during 1998)			0.44[f,g]
None	139 (4.0)	122 (87.8) [80.9–92.5]	
1–499	843 (24.1)	738 (87.5) [85.1–89.7]	
500–999	673 (19.3)	599 (89.0) [86.3–91.2]	
1000–1499	653 (18.7)	573 (87.7) [84.9–90.1]	
1500–1999	556 (15.9)	486 (87.4) [84.3–90.0]	
≥2000	631 (18.0)	566 (89.7) [87.0–91.9]	
Birthweight (g)			<0.001[b,f]
≤500	35 (1.0)	15 (42.9) [26.8–60.5]	
501–750	389 (11.0)	316 (81.2) [76.9–84.9]	
751–1000	1072 (30.4)	931 (86.8) [84.6–88.8]	
1001–1250	1447 (41.1)	1319 (91.2) [89.5–92.5]	
1251–1500	502 (14.3)	456 (90.8) [87.9–93.1]	
>1500	72 (2.0)	60 (83.3) [72.3–90.7]	
Not known	5	4	
Birthweight centile			<0.001[b,f]
≤5th	174 (4.9)	118 (67.8) [60.3–74.6]	
6th–10th	176 (5.0)	146 (83.0) [76.4–88.0]	
11th–25th	542 (15.4)	461 (85.1) [81.7–87.9]	
26th–50th	890 (25.3)	804 (90.3) [88.2–92.2]	
51st–75th	876 (24.9)	792 (90.4) [88.2–92.2]	
76th–90th	515 (14.6)	473 (91.8) [89.0–94.0]	
91st–95th	176 (5.0)	160 (90.9) [85.4–94.5]	
≥96th	168 (4.8)	143 (85.1) [78.6–90.0]	
Not known	5 (0.1)	4	
Transfers			<0.001[f]
Not transferred	2668 (75.8)	2301 (86.2) [84.9–87.5]	
Transferred within 24 hours	238 (6.8)	209 (87.8) [82.8–91.6]	
Transferred after 24 hours but within 28 days	616 (17.5)	591 (95.9) [94.0–97.3]	

[a]Categories triplets and quads combined for χ^2 test. [b]χ^2 test excludes the category 'not known'. [c]Categories forceps and ventouse combined for χ^2 test. [d]Fisher's exact test. [e]χ^2 test excludes the category 'Home/in transit/other'. [f]χ^2 test for trend. [g]Excludes 27 babies who were born at home or elsewhere.

7.3.6 Transfer details

Following delivery, 854 (24.2%) babies were transferred to another unit at least once within 28 days. Within the first 24 hours of birth, 238 (6.8%) babies were transferred.

Babies in a multiple birth (220/847, 26.0%) were slightly more likely to be transferred than singletons (634/2675, 23.7%). In total, 119 sets of twins or triplets were involved in transfer of a sibling at least once within 28 days of birth. For this group, 39 were separated due to transfer (31/109 sets of twins and 8/10 sets of triplets).

There were 640 babies (18.2%) transferred once, 203 babies (5.8%) transferred twice and 17 babies (0.5%) transferred three times within 28 days of delivery.

There was substantial regional variation in the proportion of babies being transferred within the first 24 hours (0–16%) and within 28 days (4.5–41%) of birth (Table 7.5).

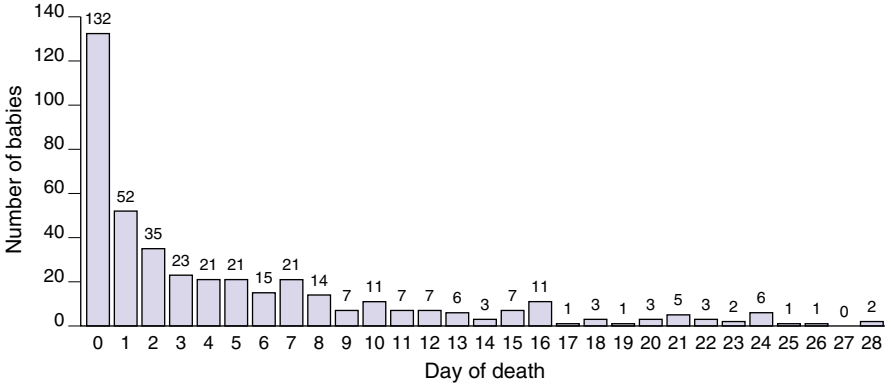
Table 7.5 Regional distribution of proportion of babies transferred within 28 days and 24 hours of birth

CESDI Region	Total number of births in 27/28-week gestation 1998–2000	Number of babies transferred within 28 days (proportion of 27/28-week babies born)	Number of babies transferred within 24 hours (proportion of 27/28-week babies born)
Northern	151	62 (41.1)	24 (15.9)
Yorkshire	203	51 (25.1)	9 (4.4)
Trent	319	105 (32.9)	39 (12.2)
Anglia	178	48 (27.0)	7 (3.9)
North West Thames	236	68 (28.8)	21 (8.9)
North East Thames	316	50 (15.8)	18 (5.7)
South East Thames	327	79 (24.2)	28 (8.6)
South West Thames	168	51 (30.4)	12 (7.1)
Wessex & Channel Isles	169	35 (20.7)	2 (1.2)
Oxford	172	16 (9.3)	3 (1.7)
South Western	169	39 (23.1)	13 (7.7)
West Midlands	414	97 (23.4)	25 (6.0)
Mersey	140	27 (19.3)	10 (7.1)
North Western	286	86 (30.1)	24 (8.4)
Wales	186	36 (19.4)	3 (1.6)
Northern Ireland	88	4 (4.5)	0 (0)
Total	**3522**	**854 (24.2)**	**238 (6.8)**

7.3.7 Deaths

A total of 421 babies (12.0%) died within 28 days. The age at death ranged from 1.2 minutes to 28 days, with a median of 2 days. The overall distribution is shown in Figure 7.5. There were 299 deaths (71%) in the first week, 132 (31%) died in the first 24 hours and 31 (7%) died in the labour ward.

Figure 7.5 Distribution of babies according to day of death



7.3.8 **Survival rates in England, Wales and Northern Ireland 1998–2000**

The overall survival rate at 28 days for the two years was 88.0% (95% CI: 86.9–89.1). For babies born at 27 weeks' gestation it was 86.2% (95% CI: 84.4–87.9) and for babies born at 28 weeks' gestation it was 89.5% (95% CI: 88.0–90.8).

7.3.9 **Regional survival rates**

Regional survival rates ranged from 80.0% to 92.3%. Regional survival rates adjusted for birthweight, gender and gestation were extremely similar to the crude survival rates, and did not alter the pattern of regional variation. The confidence intervals are given in Table 7.6. The overall differences were not statistically different.

7.3.10 **Survival rates according to characteristics of the mother and baby**

Sex of baby

The survival rate of male babies was 86.3%, significantly less than that of females (90.1%), ($p = 0.001$) (Table 7.4).

Birthweight

The survival rate improved significantly as the birthweight for gestation increased (less than 5th centile, 67.8%; 26th–75th centile, 90%; 76th–95th centile, 91%; $p < 0.001$ for trend). The survival rate also improved significantly as birthweight increased (up to 500 grams, 43%; 1–1.5 kg, 91%; $p < 0.001$ for trend) (Table 7.4).

Plurality

Survival rates for singletons (88.4%), twins (86.7%), triplets (87.9%) and quadruplets (100%) were not significantly different (Table 7.4).

Table 7.6 Regional and overall survival rates of babies born between 1 September 1998 to 31 August 2000

CESDI region of birth	No. births (%)	No. survived to 28 days (%) [95%CI]	Adjusted survival rate[a] (%)	No. births (%)	No. survived to 28 days (%) [95%CI]	Adjusted survival rate[a] (%)	No. births (%)	No. survived to 28 days (%) [95%CI]	Adjusted survival rate[a] (%)
	1 September 1998 to 31 August 2000			1 September 1998 to 31 August 1999			1 September 1999 to 31 August 2000		
Northern	151 (4.3)	126 (83.4) [76.3–88.8]	82.4	91 (4.9)	73 (80.2) [70.3–87.5]	78.7	60 (3.6)	53 (88.3) [76.8–94.8]	87.7
Yorkshire	203 (5.8)	184 (90.6) [85.1–94.1]	90.0	112 (6.0)	101 (90.2) [82.7–94.7]	89.2	91 (5.5)	83 (91.2) [82.9–95.8]	91.1
Trent	319 (9.1)	273 (85.6) [81.1–89.1]	85.7	160 (8.6)	138 (86.3) [79.7–91.0]	86.3	159 (9.6)	135 (84.9) [78.2–89.9]	85.2
Anglia	178 (5.0)	154 (86.5) [80.4–91.0]	86.0	104 (5.6)	92 (88.5) [80.3–93.6]	88.3	74 (4.4)	62 (83.8) [73.0–91.0]	82.8
North West Thames	236 (6.7)	214 (90.2) [86.0–93.9]	90.1	121 (6.5)	110 (90.9) [84.0–95.1]	89.6	115 (6.9)	104 (90.4) [83.2–94.9]	90.3
North East Thames	316 (9.0)	285 (90.2) [86.2–93.1]	90.8	173 (9.3)	154 (89.0) [83.1–93.1]	88.9	143 (8.6)	131 (91.6) [85.5–95.4]	93.2
South East Thames	327 (9.3)	292 (89.3) [85.3–92.3]	90.0	188 (10.1)	167 (88.8) [83.2–92.8]	89.7	139 (8.4)	125 (89.9) [83.4–94.2]	90.5
South West Thames	168 (4.8)	155 (92.3) [86.9–95.6]	92.2	79 (4.2)	73 (92.4) [83.6–96.9]	92.0	89 (5.4)	82 (92.1) [83.9–96.5]	92.1
Wessex & Channel Islands	169 (4.8)	149 (88.2) [82.1–92.4]	87.9	88 (4.7)	71 (80.7) [70.6–88.0]	81.2	81 (4.9)	78 (96.3) [88.8–99.0]	95.5
Oxford	172 (4.9)	156 (90.7) [85.1–94.4]	91.7	84 (4.5)	76 (90.5) [81.6–95.5]	90.4	88 (5.3)	80 (90.9) [82.4–95.7]	92.7
South Western	169 (4.7)	145 (85.8) [79.4–90.5]	86.0	91 (4.9)	82 (90.1) [81.6–95.1]	90.6	78 (4.7)	63 (80.8) [70.0–88.5]	80.6
West Midlands	414 (11.8)	364 (87.9) [84.3–90.8]	88.2	218 (11.7)	193 (88.5) [83.4–92.3]	88.4	196 (11.8)	171 (87.2) [81.6–91.4]	87.8
Mersey	140 (4.0)	112 (80.0) [72.2–86.1]	79.8	79 (4.2)	59 (74.7) [63.4–83.5]	75.1	61 (3.7)	53 (86.9) [75.2–93.8]	85.9
North Western	286 (8.1)	250 (87.4) [82.9–90.9]	87.7	134 (7.2)	116 (86.6) [79.3–91.6]	87.7	152 (9.1)	134 (88.2) [81.7–92.6]	88.1
Wales	186 (5.3)	162 (87.1) [81.2–91.4]	86.7	94 (5.0)	81 (86.2) [77.1–92.1]	86.1	92 (5.5)	81 (88.0) [79.2–93.6]	87.3
Northern Ireland	88 (2.5)	80 (90.9) [82.4–95.7]	90.6	45 (2.4)	42 (93.3) [80.7–98.3]	93.2	43 (2.6)	38 (88.4) [74.1–95.6]	88.2
Total	**3522 (100)**	**3101 (88.0) [86.9-89.1]**	**88.1**	**1861 (100)**	**1628 (87.5) [85.9–88.9]**	**87.4**	**1661 (100)**	**1473 (88.7) [87.0–90.1]**	**88.7**

p-values for overall difference in regional survival rates (all p-values relate to χ^2 test): 2 years of study (0.06), first year (0.02), second year (0.26)

[a]Survival rate adjusted for birthweight, gender and gestation

Presentation and mode of delivery

Survival rate was significantly less for babies with breech presentation (84.5%) than for babies with cephalic presentation (89.4%) ($p < 0.001$) (Table 7.4).

Survival rates for babies with cephalic presentation were significantly greater ($p = 0.004$) for those born by spontaneous or assisted vaginal delivery (91.7% and 91.2%) than for those delivered by caesarean section (87.3%) (Table 7.7). Survival for breech presentation was significantly greater ($p = 0.001$) in those delivered by caesarean section (86. 5%) than in those delivered vaginally (77.4%) (Table 7.8).

Table 7.7 Survival rates for cephalic presentations according to mode of delivery

Mode of delivery	Number of births (%)	Number survived to 28 days (%) [95% CI]	χ^2 test[a] p-value
Caesarean section	1124 (53.1)	981 (87.3) [85.1–89.1]	0.004
Spontaneous vaginal	934 (44.1)	857 (91.7) [89.8–93.4]	
Forceps/ventouse	57 (2.7)	52 (91.2) [80.0–96.7]	
Not known	3 (0.1)	3	
Total	**2118 (100)**	**1893 (89.4) [88.0–90.6]**	

[a]χ^2 test excludes the category 'not known'

Table 7.8 Survival rates for breech presentations according to mode of delivery

Mode of delivery	Number of births (%)	Number survived to 28 days (%) [95% CI]	χ^2 test[a] p-value
Caesarean section	807 (78.4)	698 (86.5) [83.9–88.7]	0.001
Vaginal	221 (21.5)	171 (77.4) [71.2–82.6]	
Not known	1 (0.1)	1	
Total	**1029 (100)**	**870 (84.5) [82.2–86.7]**	

[a]χ^2 test excludes the category 'not known'

Transfers

The survival rate for babies who were not transferred within 28 days of birth was 86.2% whereas it was 93.7% for babies who were transferred to another neonatal unit ($p < 0.001$). Trend analysis showed a significant increase in survival rate with a greater number of transfers ($p < 0.001$). Of the babies who were transferred within the first 24 hours, 209 (87.8%) survived to 28 days (Table 7.4).

7.3.11 Survival rates according to place of birth

Individual hospitals

Survival rates in the 216 units where deliveries occurred ranged from 0 to 100%; there were nine units (4.2%) with survival rates of less than 70%, and 67 units (31.0%) had survival rates of 100%. The survival rates by unit were subject to wide confidence intervals and these extreme values are likely to be due to chance.

Type of hospital

There was no significant association between survival and the 'self designated' category of hospital (NICU for routine referrals, 88.0%; NICU for in-house, 88.9%; no NICU, transfers some, 87.0%; no NICU, transfers all, 89.1%) (Table 7.4).

There was no association between survival rates and the number of babies at 27 to 28 weeks' gestation reported by a hospital during the study (units with less than 10 babies, 88.3%; units with more than 50 babies, 87.5%) (Table 7.4).

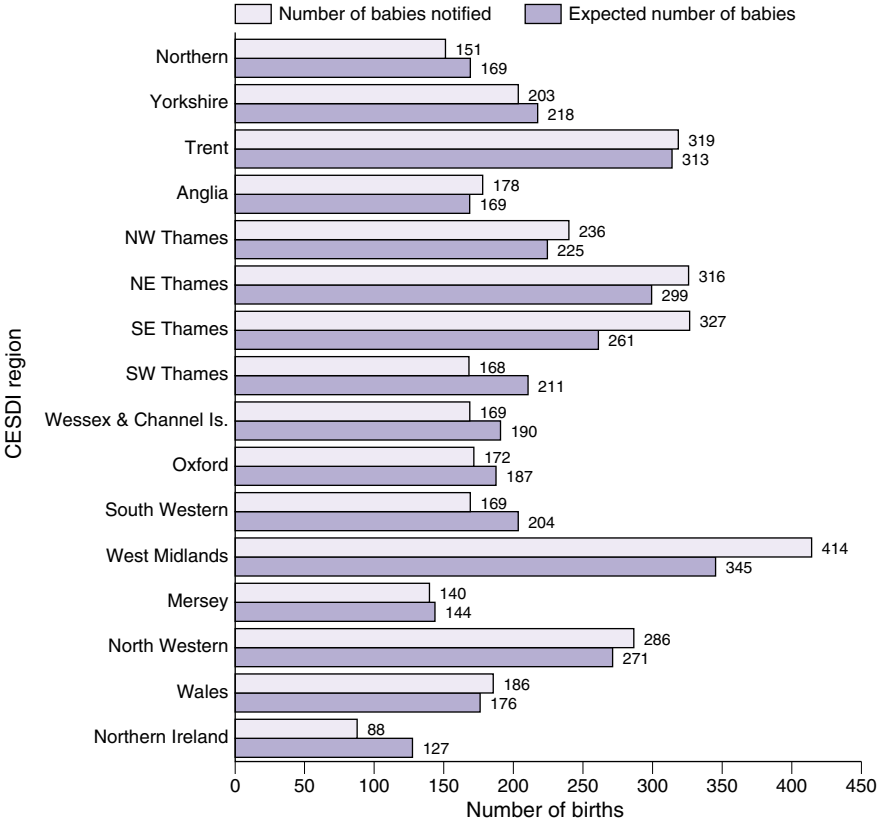
There was no association between survival rates and the number of level 1 intensive care days per hospital (Table 7.4).

7.3.12 Ascertainment

Because there is no routine national collection of gestational data, we cannot directly validate the completeness of our data collection. An alternative approach was used. Expected numbers of notifications per region during the study were estimated from the regional distribution of live births in each CESDI region in 1998 using data provided by the Office for National Statistics (ONS) and the Northern Ireland office (GRO) (Figure 7.6).

The observed and expected notifications in the 16 regions showed a statistically significant difference ($\chi^2 = 67.5$, 15 df, $p < 0.001$). The numbers were less than expected in Northern Ireland, South West Thames and South Western, and greater than expected in South East Thames and West Midlands. It is not possible to determine whether these were true differences in the prevalence of preterm birth or artefacts due to variation in ascertainment.

Figure 7.6 Comparison of observed and expected numbers of 27/28-week babies during the study



7.4 DISCUSSION

7.4.1 Population data

Gestation at birth is not collected centrally in England or Northern Ireland despite being routinely recorded. This has precluded description of national trends in survival rates of preterm babies, although such information is available in Wales and Scotland. The present study is a snapshot of babies born between 27 to 28 weeks during 1998–2000. Survival to day 28 was unexpectedly high (88%). This is a rapid improvement over the last decade: earlier studies found rates of 41% in Trent in 1987[2] (although this included all babies less than 28 weeks); 75% in Trent in 1994–97[3]; and 80% in Wales 1993-94[4].

However, despite these rapid improvements it must be stressed that survival does not necessarily equate with well-being. It remains unknown whether serious morbidity in these preterm babies has become less frequent, in parallel with improved survival. A 5-year follow up of a

cohort of these children would be of great value in addressing this important question.

National trends in these survival figures could be available once allocation of a NHS number at birth is introduced in 2002. The NHS number is currently allocated at the time of registration which is up to 6 weeks following the birth. This change in procedure is part of automating the birth notification process and will include a record of gestation. If this data set at birth is linked to national mortality information, it could provide national survival figures for specific gestations.

7.4.2 Characteristics of mother and baby related to survival

Multiple births are associated with high perinatal mortality rates. This has led to the commonly held belief that the survival rate of a multiple birth is less than that of a singleton birth at a particular gestation. This was not confirmed in our study: survival rates were similar. Other studies have yielded inconsistent findings with similar[5], increased[6] or decreased survival rates[7].

The present study reaffirmed the improved survival for female babies. It also confirmed the increased risk of death for babies weighing less than 500 grams or weight being less than the 5th centile of the range for gestational age.

Caesarean section was associated with reduced survival for cephalic presentations when compared with vaginal delivery and improved survival for breech presentations. Selective delivery of high-risk babies by caesarean section may explain some of the difference in the group with cephalic presentation. Similar allowance for this in the breech group would suggest an even greater protective effect of delivery by caesarean section. However, these observations are not based on a randomised comparison, so firm conclusions regarding the optimum mode of delivery for the breech baby at this gestation cannot be made.

7.4.3 Organisational factors and survival

Transfer

Almost one-quarter of the babies were transferred between hospitals within the first 28 days. In-utero transfers were not recorded, but the ex-utero transfers would include a significant proportion of these babies returning to their original unit. Thus considerable numbers of transfers occurred to ensure that babies were born in hospitals with appropriate and available neonatal intensive care.

An integrated neonatal service should include clear-cut policies for transfer. Excellent survival rates are a measure of the effectiveness but not the efficiency of the current service. Specific indications for transfers were not ascertained but it was notable that in 1 in 3 multiple pregnancies

the siblings required separation. This implies a shortfall of resources within the service. The recent census in the UK[8] highlighted the large numbers of in-utero transfers that were attributed to lack of facilities at the referring unit. The frustrations of the professionals involved are matched by the distress and financial costs to the parents.[9] These acute situations would be better supported by an organised network rather than ad hoc transfers.

Babies who were transferred were more likely to survive than those who were not, independent of when and how many times a transfer occurred. This is particularly reassuring, as at least 1 in 13 babies were born in units without appropriate facilities and 1 in 15 were transferred within the first 24 hours of life. The better survival rates in the transferred group suggest that the more compromised babies are less likely to be transferred. This re-emphasises the importance of transferring such babies *antenatally.*

Type of hospital – distribution of neonatal services

In the last 10 years there has been a steady increase in neonatal intensive care beds in the UK[10]. The distribution of these facilities is the subject of continuing debate, focusing on whether neonatal intensive care should be delivered by large tertiary centres or by smaller local units. The data set in the present study cannot answer this question because it cannot adjust for case mix, clinical risk and illness severity. Mortality rates, adjusted for these factors, have been considered to be a measure of clinical performance of a unit. However most hospitals providing neonatal intensive care in England, Wales and Northern Ireland manage relatively small numbers; therefore neonatal mortality rates for individual hospitals will inevitably be subject to large fluctuations due to chance and this will preclude their usefulness[11].

Mortality rates might be estimated for categories of hospitals[10]. This is difficult when there is no accepted categorisation, although some regions have introduced such schemes. In the present study, a pragmatic classification was used based on the referral pattern for babies at this gestation as reported by the unit. Most (63%) babies were born in units that received routine referrals and a further 28% in units managing in-house births. Only 7% of babies were born in units without intensive care provision on site.

Survival was independent of the type of hospital where the baby was born. These figures did not account for the condition of the baby at the time of birth and it is likely that the referral hospitals dealt with a higher-risk population but still managed to achieve as good results as the non-referring hospitals. This would imply that the units are managing to function effectively as a hierarchical network, which is consistent with findings of the UK Neonatal Staffing Study[12]. However, the question as to whether the system is efficient has not been addressed.

It is commonly believed that preterm babies will do better in large specialist units, although 'large' is ill-defined. In this study, survival rates were independent of the numbers of babies treated or number of level 1 intensive care days undertaken by the unit. Similar observations were made in the EPICure study, which reviewed the outcomes to discharge for infants born at less than 26 weeks' gestation in the United Kingdom in 1995: survival was no greater in centres with large numbers of extremely preterm births[7]. Again, failure to adjust for the condition of the baby at birth may be a factor, with the larger units achieving as good results with sicker babies. The absence of an agreed categorisation may mirror the debate over centralisation of the services. This lack of consensus limits not just statistical comparability[13] but, more importantly, it may hinder the provision of a unified service.

7.5 CONCLUSIONS

Babies born at 27 and 28 weeks' gestation in England, Wales and Northern Ireland during 1998 to 2000 had an equal chance of survival regardless of the type of hospital in which they were born. This suggests that units are functioning effectively in their referral patterns. Only 7% of babies were born in a unit without intensive care facilities. The efficiency of this process was not formally addressed but the large proportion (one-third) of all multiple births requiring to be separated suggests a shortfall in service provision.

The overall survival rate (88%) was significantly improved and has doubled in the last 15 years. It must be highlighted that death is relatively simple to measure but serious morbidity is not, and the latter is an important measure of the quality of life. Morbidity may be associated with referral practice or hospital of birth but this was not addressed. Overall, it is reassuring that extremely good survival rates are being achieved and this has to be a tribute to the current obstetric and neonatal services.

7.6 RECOMMENDATIONS

- Collection of data on gestational age at birth in England and Northern Ireland would allow description of trends in survival rates of preterm babies. The introduction of an NHS number at birth in 2002 as part of automating the birth notification process will include a record of gestation. If this was linked to mortality information it could provide survival figures adjusted for gestation. It is recommended that the Department of Health considers introducing this as a routine data set.

- High-quality population-based morbidity outcome studies of preterm babies should be introduced.

KEY POINTS

- There is no routine central collection of gestational data at birth within England or Northern Ireland. This precludes information on trends in survival rates of preterm babies.
- In 1998–2000, the survival rate to day 28 of a baby born at between 27^{+0} to 28^{+6} weeks' gestation was 88%. This was far better than anticipated and is a measure of the rapid improvements that have occurred since the mid-1980s when survival rates were half this level.
- In 1998–2000, hospital of birth and 'self designated' transfer practice did not affect crude survival rates at 27^{+0} to 28^{+6} weeks' gestation.

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8

CHANGING PRACTICE – A VIEW FROM THE CLINICAL NEGLIGENCE SCHEME FOR TRUSTS

COMMENTARY

Recent Annual Reports have included the response to CESDI recommendations by national bodies such as the Royal Colleges and the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC). Last year, examples of regional and local initiatives were highlighted. This year, CESDI invited the response of the Clinical Negligence Scheme for Trusts (CNST), which has contributed to establishing risk management in the National Health Service (NHS) as another example of how the awareness of CESDI can reduce adverse outcomes.

The cost of clinical negligence claims made against the NHS has been rising year on year. Patients who feel that they have been harmed are now much more inclined to pursue their case in the courts, and the courts are awarding ever larger amounts to successful claimants. In response to this, the NHS Executive established the NHS Litigation Authority to administer the CNST in 1995 with the joint aims of managing and funding the claims and minimising the overall cost of claims through a programme of risk management initiatives. CNST applies to England; Wales, Scotland and Northern Ireland are establishing their own arrangements.

Arrangements in Wales are that each trust or health authority manages its own claims with legal advice, provided in the main by one legal services provider, which is in-house to the NHS in Wales. There is a single compendium of guidance on risk management for the NHS in Wales and it is against those standards which trusts will be assessed in 2001. All trusts in Wales are developing their clinical risk management systems and practices are changing. The National Assembly of Wales is taking an active interest in the promotion of risk management practice in order to reduce the rising costs to the NHS of clinical negligence claims and introducing an adverse clinical incident monitoring system in Wales as part of the clinical governance strategy being developed.

Northern Ireland has established its own arrangements for the funding of clinical negligence claims. Claims are funded by a Central Fund established to finance the cost of all clinical negligence settlements. Health and Social Services bodies manage the process for handling and settling claims and on settlement apply to the Central Fund for reimbursement.

The following chapter highlights the ways in which the findings from CESDI link with other organisations, in particular CNST, and work towards changing future practice.

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8.1 INTRODUCTION

The Clinical Negligence Scheme for Trusts (CNST) is available to all NHS trusts in England and, although voluntary, all but one eligible trust have joined. It is a 'pay as you go' scheme: each year actuaries analyse the available data and predict the total amount to be paid out in the ensuing year in respect of claims, costs and associated expenses. This amount is then apportioned between the member trusts. Individual trust contributions are based on a range of criteria, such as activities, budget, numbers of doctors by discipline, nurses and other professionals.

Effective management of claims will reduce the overall cost, but it would obviously be preferable to reduce the number of incidents that give rise to claims. The CNST therefore promotes a number of clinical risk management standards reflecting good practice. These standards provide a framework that trusts can use to manage their clinical risks effectively. Those trusts that can comply with the standards receive a discount from their contribution to the scheme. For an acute trust with maternity services, this discount can represent a significant and valuable saving. In addition, compliance with the CNST risk management standards is recognised as a component of an effective clinical governance programme.

The standards cover a range of aspects – some organisational, some focusing on clinical practice. Because childbirth involves both the highest number and the highest cost of claims, there is a standard relating solely to maternity services. The standards are drawn from a range of services and, in the case of maternity, include the findings and recommendations of the Confidential Enquiries.

Each standard comprises a number of separate criteria, addressing different aspects of the subject. These are organised into one of three 'levels'. Level 1 criteria represent the basic elements of a clinical risk management framework; levels 2 and 3 are more demanding and concern the implementation and integration into practice of policies and procedures, monitoring, and acting on the results.

The Scheme rules require every trust to be assessed against the standards at least once every three years – initially at level 1, and subsequently at level 2 or 3 when the trust believes it is ready and it has met the standards at the earlier level. The assessment is undertaken by one of a small team of full-time clinically qualified assessors. As well as undertaking the assessments, the assessors provide a valuable service in answering trust queries on risk management issues relating to the standards, and providing 'good practice' contact names from their extensive networks. Assessment takes one day on site at level 1, and two or more days at higher levels. As well as a review of paperwork, the assessor will interview a range of staff – many from within the maternity unit. Equity, consistency and objectivity are considered to be essential features of the assessment.

8.2 CHANGING PRACTICE IN ORGANISATIONS

The standard setting and assessment process of the CNST has long had a symbiotic relationship with CESDI. Creating a standard based on recommendations from the Enquiries, past and present, affords authority and credibility to that standard. In turn, the assessment process will determine if those recommendations are being put into action within trusts.

There are 12 standards covering a range of issues (Table 8.1). Two strong themes which run through all of these standards are: 'communication' and 'learning from experience'. It is by learning that both the individual and the organisation can change practice.

Table 8.1 The 12 standards covered by the CNST

Strategy and Organisation
Clinical Incident Reporting
Response to Major Clinical Incidents
Managing Complaints
Advice and Consent
Health Records
Induction, Training and Competence
Implementation of Clinical Risk Management
Clinical Care
Maternity Care
The Management of Care in Trusts providing Mental Health Services
Ambulance Service

The thread of learning from events, recommending action and evaluating the outcome can be seen in the standards on clinical incident reporting, response to major clinical incidents, managing complaints and effective implementation of clinical risk management. In respect of these, the CNST looks for the features listed in Table 8.2.

Table 8.2 Features of a risk management programme emphasised by CNST. Numbers in parentheses refer to the CNST document[1].

Evidence of management action arising from clinical incident reporting (2.2.2)
A process for the detailed investigation of major clinical incidents (3.2.1)
Demonstration of two changes that reduce risk introduced as a consequence of complaints (4.2.1)
All clinical risk management standards and processes are in place and operational (8.2.1)
The trust applies the advice in the National Confidential Enquiries (9.2.1)

The standards also expect organisations to benefit and learn from the experiences and recommendations of others, such as the Royal Colleges and the General Medical Council, and to implement change as necessary. These outside bodies have significantly influenced the development of the standards especially in the areas of Advice and Consent, and of Induction, Training and Competence.

In addition, there are criteria that apply to specific clinical activities. For example, in the CNST standard on maternity care there is a criterion on training in cardiotocograph (CTG) interpretation which comes directly from the CESDI recommendations.

8.3 CHANGING PRACTICE IN OBSTETRICS

Untoward outcomes in maternity have a huge cost – both in terms of personal suffering to those involved, and in economic costs to the NHS. The experience of the NHS Litigation Authority is that one in five claims relates to obstetrics, while the cost of these claims is 80% of all claims. Obstetric claims can be extremely expensive, with court awards of up to £3.5 million in recent years. Not surprisingly this has resulted in obstetrics receiving special attention from the NHS Litigation Authority and, in particular, the CNST. There has been a specific standard for Maternity Care since the start of the Scheme; in the last 12 months this standard has become more searching and is assessed in greater depth. The ten criteria within this standard fall under two headings: Communication and responsibility (Table 8.3), and Education and learning (Table 8.4).

8.3.1 Communication and responsibility

Communication, or lack of it, is a theme that runs through all the CESDI Reports. All clinical staff and women who use the service should be aware of the professional responsible for delivering care at every stage of the pregnancy. Communication lines between and across professional groups should be clearly defined. The labour ward must have designated lead professionals and sufficient staff of appropriate seniority available to provide safe care at all times.

Table 8.3 Criteria of communication and responsibility

The arrangements are clear concerning which professional is responsible for the woman's care at all times (10.1.1).
There is an agreed mechanism for direct referral to a consultant by a midwife (10.1.3).
There is a personal handover of care when medical shifts change (10.1.4).
There is a labour ward forum or equivalent, to ensure that there is a clear documented system for management and communication throughout the key stages of maternity care (10.1.5).
There is a lead consultant obstetrician and clinical midwife manager for labour ward matters (10.2.1).
The labour ward has sufficient medical leadership and experience to provide a reasonable standard of care at all times (10.2.2).
There is a personal handover to obstetric locums, either by the post-holder or senior member of the team, and vice versa (10.2.3).

Table 8.4 Criteria of education and learning

There are referenced, evidence-based multi-disciplinary policies for the management of all key conditions/situations on the labour ward. These are subject to review at intervals of not more than three years (10.1.2).
All clinicians should attend six-monthly multi-disciplinary in-service education/training sessions, on the management of labour, and CTG interpretation (10.1.6).
Emergency caesarean section can be undertaken rapidly and in a short enough period to eliminate unacceptable delay (10.1.7).

Another area of communication addressed by CNST is that of health records and record keeping standards (Standard 6 of the CNST scheme[1]). The 7th CESDI Annual Report[2] states that 'record keeping is a vital part of care and one of the major problems was a failure to document events adequately'. At all three levels of the CNST assessment, obstetric units are expected to audit the standard of their record keeping. This should range from the basics at level 1 (entries are signed, dated and legible) to the quality of the clinical content at level 2.

8.3.2 Education and learning

In the event of an unexpected situation arising during pregnancy or labour, all staff need guidance on what is expected of them; up-to-date referenced policies should be readily available. The standard on Maternity Care (Standard 10 of the CNST Guidance Manual[1]) identifies 19 specific conditions or situations where a written policy is required. These are based on the 4th, 5th, 6th and 7th CESDI Annual Reports[2–5] as well as on the Confidential Enquiry into Maternal Deaths. The policies should be subject to audit and review and are seen as an educational tool and learning resource for staff.

A key area for audit is the time interval between the decision to perform an emergency caesarean section and the delivery. CNST believes that each trust should set its own standard: if the standard is not met, the trust should review the reasons and take remedial action.

Finally, one of the most important criteria in Standard 10 is training in CTG interpretation (10.1.6). The 4th, 6th and 7th CESDI Annual Reports[2,3,5] have made recommendations on the need for staff to receive formal training and CNST firmly supports this. Training should ideally be multi-disciplinary with participation by all clinicians who provide intrapartum care.

8.4 HAS PRACTICE CHANGED?

When trusts were first assessed against the CNST standards in 1996/7, the concept of clinical risk management was unfamiliar to many organisations. For some, new systems had to be created and implemented. But from an early stage it was evident that some maternity units were already proactive in identifying and managing clinical risks. The assessment process has demonstrated that maternity units in particular recognised the value of standards and have a very positive attitude to achieving them.

As a result, practice has changed. Communication channels have been formalised rather than being left to custom and habit; the quality of written communication is now subject to regular audit. Written policies for managing key conditions can be found in the labour ward and these are now becoming referenced and reviewed at intervals of three years or less.

One of the most important recent changes has been the impetus to ensure that all clinical staff receive formal training in CTG interpretation at frequent intervals. For some trusts, resource issues are an obstacle in achieving this aim (finances and staff availability). Nevertheless the value of such training is recognised and there is a clear intention and drive to accomplish this.

8.5 CONCLUSION

It is not yet possible to state with certainty that any of the changes in practice promoted by the CNST have made an impact on clinical negligence claims. It can be years after an event before a claim is settled. In addition, there are many other contributory factors and it would be over-simplistic to make such a connection at this early stage.

However, the evidence from CESDI provides a firm basis and direction that it would be foolish to ignore. CNST provides a mechanism for encouraging, monitoring and benchmarking progress in the

implementation of the lessons learned. The fundamental objectives of both CESDI and CNST are the same, to reduce the level of untoward outcomes and to improve patient care. To this end CNST will continue to review future CESDI reports as part of the continuing development and evolution of the standards.

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9

CONCLUSIONS – A TIME TO PROGRESS

9.1 THE ENQUIRIES AND NICE

The 8th Annual Report of CESDI comes at a time of change for the organisation. When the National Institute of Clinical Excellence (NICE) was set up in 1999, the four National Enquiries were allocated to its portfolio. The focuses of the other Enquiries are maternal deaths, peri-operative deaths, and suicides and homicides by people with mental illness. Despite the different subjects, they share two core features. First, a common goal of improving future practice by deriving general lessons from past care associated with deaths. Second, accruing the lessons in a confidential and blame-free environment. In 1999, NICE commissioned an external review of the Enquiries to determine how to maximise the benefits from their work in the context of the new arrangements. Since that time a partnership between the Enquiries and NICE has begun to emerge. The future heralds new opportunities for the Enquiries with an increase in remit and scope.

At a time of change it is natural for the work programme to be questioned – what did CESDI do well and what improvements can be made within the organisation? CESDI has produced significant and influential data in three different areas: sudden unexpected deaths in infancy, intrapartum-related deaths and management of premature babies. It has made a particular impact on labour ward management.

The Annual Report is a major tangible product of the work of CESDI. The contents reflect relevant current topics but do not necessarily coincide with the completion of a specific work programme. While the Report makes it possible to highlight major issues regularly, it is difficult to target a multiplicity of messages to a diffuse audience. The ways in which feedback is given, in addition to Reports, is a particular area for future review.

9.2 QUALITY OF INTRAPARTUM AND ANTEPARTUM CARE

This year CESDI demonstrates that, for the first time, intrapartum-related deaths are showing a definite downward trend. Regular reporting of deaths to CESDI since 1993, with ascertainment running at 98% since 1996, has provided the means to confirm this finding. Care during labour has been one of the key areas of concern for CESDI over recent years. The 4th Annual Report highlighted that at least half of labour-related deaths occurring in 1994 and 1995 were associated with suboptimal care that was likely to have contributed to the death. It was therefore

particularly gratifying to see the launch in 2001 of two national guidelines for this specific area; one on induction of labour[1] and the other on the use of electronic fetal monitoring (EFM)[2]. CESDI findings contributed to the successful bid by the Clinical Effectiveness Support Unit at the RCOG to produce these documents. While compiling the EFM guideline, a survey of existing practices was undertaken (Chapter 8) and this demonstrated large variation in the management of high-risk labours. With the release of these guidelines and 'closing of the loop', a further decrease in such deaths may be possible. CESDI, via its Rapid Report Form notification, will be able to describe these trends.

Recent improvements in intrapartum care have not been echoed in other aspects of antenatal care. This year's report includes a summary of enquiries on over 400 stillbirths in England and Wales (Chapter 3). These represented three-quarters of the '1 in 10' Enquiry programme (6th Annual Report). The Report also includes a description of a European programme (Chapter 4) aimed at comparing standards of care and their contribution to the variable perinatal mortality rates. Both the '1 in 10' and the European study addressed a series of stillbirths and neonatal deaths occurring in 1996 and 1997. The European study involved ten countries including seven of the 14 CESDI regions in England. Despite the differing methodology, similar conclusions were reached: that suboptimal care had occurred in approximately half the cases. It was of particular concern that England was at the lower extreme of the league table of ten European countries. Certain biases may have contributed to this positioning, namely that the summary material for the European assessors had been compiled differently for the cases from England compared with other countries. The summary for the English cases was based on findings recorded following a CESDI panel whereas for other countries it was compiled by a research worker from the medical record. It is likely that the CESDI summaries were more critical, as the panel assessors have been specifically tasked to identify suboptimal care. Notwithstanding this, the European assessors made three-quarters of all judgements from explicit criteria rather than by consensus. There were many similarities between countries in the nature of the suboptimal care; failures to recognise extremes in growth and failure to take appropriate action in such cases were especially common.

The CESDI review of the panel comments pertaining to the stillbirths revealed widespread inconsistencies in the definition of good practice in the management of common pregnancy complications. Paralleling the European study's findings, management of a suspected small baby emerged as a notable area for concern. This area, in particular, would benefit from evidence-based guidance.

Record keeping is an essential part of the care and communication process. Good records should provide clear evidence of the care planned, the decisions made and the care delivered. All Reports, including this

one, continue to find significant deficiencies in this area. Improvements here continue to remain a priority.

9.3 QUALITY OF CARE FOLLOWING A STILLBIRTH

This year has witnessed the professional and public anguish which accompanied the Bristol and Alder Hey Inquiries. It will take a long time to rebuild the confidence of the public in the medical profession regarding the practice of postmortem examination. The problem has been underpinned by a series of failed communications. Within the professions there is often a lack of understanding of the purpose and process of postmortem, leading to problems when seeking consent from relatives. The lack of training in how to explain the purpose and how to seek consent for postmortem inevitably results in poor practice. This Report notes several examples of failure to provide adequate support at the time of bereavement (Chapter 5). Relevant investigations were omitted and discussions and follow-up support for the parents was at times inadequate. Poor care at the time of bereavement does not alter the outcome but it will affect future encounters of the parent with the health service.

A frequent concern was the quality and the value of the postmortem report itself. This was consistent with the audit findings reported in the 6th Annual Report[3].

CESDI has had a long history of trying to improve standards in perinatal and paediatric pathology. This has included the issue of seeking consent: in 1999 CESDI distributed a leaflet for professionals and a leaflet for parents written in conjunction with the Stillbirth and Neonatal Death Society (SANDS). These will be updated in the light of recent events and CESDI will strive to restore the confidence of parents in health professionals and the health service.

9.4 LACK OF GESTATIONAL DATA

A major problem for all of the four Enquiries has been the difficulty in acquiring relevant denominator data. The existing sources of routine data are of limited quality, especially in maternity and infant care, and immediate improvements seem unlikely. One of the major strengths of CESDI has been the ability of the network to facilitate alternative means of collecting denominator data. Gestation at birth is routinely recorded but not collected centrally in England or Northern Ireland. The lack of this data item has precluded trends of survival in premature infants. CESDI collected this data for two years to produce survival figures for babies born between 27 and 28 weeks' gestation (Chapter 7). The overall survival rate at day 28 (88%) was much higher than anticipated and demonstrated the large improvements that have occurred in neonatal care in the last 15 years, effectively doubling survival rates. Survival was

unaffected by the type of hospital of birth or whether or not the baby was transferred. However, these figures are not adjusted for case mix. For example, a 'referral' unit might achieve a certain survival figure for a group that included the most compromised infants, whereas a non-referral unit might achieve the same figure for a group at rather lower risk. It was particularly reassuring that transfer was not associated with higher death rates, as a quarter of the babies were transferred at least once in the first 28 days of life. It is not known what proportion of these transfers were medically indicated, but the separation of siblings in a third of all multiple births requiring a transfer suggested a significant shortfall in available services. The application of the NHS number at birth will be implemented from 2002 and this will be linked to a data set including gestation. CESDI proposes that this could form the basis of a maternal and infant data set that could be automatically linked to mortality information to provide regular and good quality information on survival rates.

The NICE Review recommended moving towards objective assessments. This shift is welcome but may restrict evaluation to what is easily measurable and not necessarily to what needs to be assessed. Professional comments may lack total objectivity but will remain part of the CESDI process, and will continue to make a significant contribution to the Enquiry assessment. Next year's Report will summarise the panel reports for Project 27/28 and highlight where there is scope for improvement in the management of premature babies.

9.5 FUTURE DIRECTIONS FOR CESDI

The NICE Review addressed how the future work of the Enquiries would align with the other changes occurring in the NHS. Clinical Governance has become a key activity in all trusts and encourages local responsibility for improvement in the quality of the service. Clinical Governance involves an openness of culture, learning from mistakes by reflecting on local practice. Appraisal of critical incidents, near misses and adverse event auditing are all such exercises. These are similar to the approaches that have been used by CESDI panels over the last nine years. Lessons from local review are of enormous benefit. In addition, the Enquiry findings provide a checklist of issues for internal critique.

The Enquiry findings also contribute to the standards used by the Clinical Negligence Scheme for Trusts (CNST). The standards provide a framework for effective management of clinical risk. The fundamental objectives of both CESDI and CNST are to reduce the level of untoward outcomes and to improve patient care. Progress in changing practice towards this objective from CNST's view is outlined in Chapter 8. It is not yet possible to measure the impact on clinical negligence claims. However the number of instances of litigation in Obstetrics and Gynaecology is one of the four areas for action in the Government's

plans to improve patient safety; a target of a 25% reduction has been set for the end of 2005[4].

Extending the focus of the Enquiries to include near misses will be an important area for NICE to consider.

The NICE Review recommended that Enquiry programmes should be topic-oriented and should concur with the health targets of the Government. An excellent example is the care of diabetic pregnancies: this will be the next subject for the CESDI programme. National Service Frameworks (NSFs) outline standards in priority areas of healthcare. An NSF for children which includes maternity services has recently been announced for development. In addition, the NSF on diabetes is due for release towards the end of 2001. Since 1989, it has been a goal for obstetricians that the 'outcome of diabetic pregnancy should approximate that of the non-diabetic pregnancy'[5]. This goal has not been met. Three population-based studies[6–8] have shown perinatal mortality rates in diabetic mothers ranging from 36.1/1000 to 42.8/1000, against a background perinatal mortality rate of 7.9/1000. CESDI will introduce a notification process to ascertain all pre-gestational diabetic pregnancies in England, Wales and Northern Ireland, and will enquire into the care of a sample of these cases. The aim is to see improvements in health service provision and, ultimately, improvements in outcome for these women and their babies.

Meanwhile, CESDI looks forward to closer collaboration with the other Enquiries. From inception, CESDI has always been required to change its focus on a regular basis, and we look forward to extending our remit and scope. Constructive learning and improving future practice and outcome will remain at its core.

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APPENDIX 1 – RAPID REPORT FORM 1999

CESDI - Confidential Enquiry into Stillbirths and Deaths in Infancy - 1999

Survey Number

One form should be completed for each fetus born after **20 weeks of pregnancy** (or birthweight >300 grams if weeks not known) including legal abortions **and each live birth dying before one year of age.**

1. How was this case defined? *Note:- It is possible for a case to be both a registrable death (stillbirth or neonatal death) AND a legal abortion*

Late fetal loss (20+0-23+6 weeks) 1 | Stillbirth (24+ weeks) 2 | Early Neonatal Death (age 0 - 6 days) 3 | Late Neonatal Death (age 7 - 27 days) 4 | Post Neonatal Death (28 to 364 days) 5

2. Legal Abortion? (Notifiable under 1967/92 Abortion Act) YES 1 NO 2

MOTHER

3. Mother's surname

4. First name 5. Hospital No.

6. Mother's usual residential address at time of delivery/birth

7. Postcode

Q code of Residence — CESDI regional office to complete

8. Mother's date of birth — Day Month Year — or Estimated age — or tick if N.K. 9

9. Ethnic group of mother: White 1 | Black African 2 | Black Carib. 3 | Black other 4 | Indian 5 | Pakistani 6 | Bangladeshi 7 | Chinese 8 | OTHER (specify) 0 | N.K. 9

10 Parity No. of previous pregnancies of 24+ weeks ONLY — tick if N.K. 9

11. What was first day of the Last Menstrual Period (LMP) — Day Month Year — N.K. 9

12. Early ultrasound (less than 20 weeks) — Please answer a) *OR* b)

a) Date of early USS (<20wks) — Day Month Year

OR

b) Estimated Date of Delivery by early USS (<20wks) — Day Month Year

Gestation by early USS (<20wks) — weeks + days — No early USS done 8

13. Gestation at Birth (best estimate) — weeks + days

14. Date and Time of delivery / birth — Day Month Year — 24 hr clock

15. Intended place of delivery at booking

Name of Unit/Place

16. Actual place of delivery

Name of Unit/Place

17. Reason for change between planned and actual place of delivery

No change 1 | Change of address during pregnancy 2 | Clinical reasons before labour 3 | Other reasons before labour 4 | Clinical reasons after onset of labour 5 | Other reasons after onset of labour 6 | Unintentionally after onset of labour 7 | Not known 8

18. Number of fetuses / babies this pregnancy — All identifiable fetuses at delivery, including papyraceous — tick if N.K. 9

19. Birth Order This Fetus / Baby (0, 1, 2, 3 etc) — 0 = Singleton — tick if N.K. 9

20. Presentation just prior to delivery — Cephalic 1 | Breech 2 | Other 3 — tick if N.K. 9

21. Mode of Delivery — Spont. Vaginal 1 | Low Forceps 2 | N.K. | Other forceps (inc. Kiellands) 3 | Ventouse 4 | Assisted Manual 5 | N.K. 9 | Emergency Caesn. Sec. 6 | Planned C.S. 7 | Other 8

Please give name or whom to contact for further information

Name/Position: Contact address:

BABY / INFANT

22. Baby's surname

23. First name 24. Hospital No.

25. Baby's residential address at time of death if different from Q6.

26. Postcode

Region of Residence — CESDI regional office to complete

27. Sex of fetus/baby — MALE 1 | FEMALE 2 | Indeterminate 3 | N.K. 9

28. Birthweight (kg) (Earliest possible please) — Tick if N.K. 9 | Never recorded 0

29. Place of death (LIVEBIRTHS ONLY) — Name of Unit / Place

30. Date and Time death was FIRST diagnosed (confirmed) — Live births only — Day Month Year — 24 hr clock — tick if time estimated

31. Timing of death Stillbirths and Late Fetal Losses ONLY — Death before admission? YES 1 NO 2 — Death before labour? YES 1 NO 2 — N.K. 9

32. Signs/observations at birth: tick all features observed in the *first hour* after delivery — if N.K. 9 — Audible cry 1 | Spontaneous heart beat 4 | Spontaneous breathing effort 2 | No maceration-no signs of life 5 | Active body movements 3 | Maceration 6

33. Discharge Home after birth or neonatal care — Live births ONLY — Was baby ever discharged home after birth? YES 1 NO 2 N.K. 9 — If YES, date and time of readmission to hospital — Day Month Year — 24 hr clock

34. CAUSE OF DEATH - CLINICAL DETAILS

for office use

a. **Main** diseases or conditions in **fetus / infant**

b. **Other** diseases or conditions in **fetus / infant**

c. **Main maternal** diseases or conditions affecting fetus/neonate

d. **Other maternal** diseases or conditions affecting fetus/neonate

e. **Other relevant** causes or comments

35. EXTENDED WIGGLESWORTH CLASSIFICATION (see guidelines) — Text — enter number

36. FETAL AND INFANT CLASSIFICATION (see guidelines) — Text — enter number

37. OBSTETRIC CLASSIFICATION (see guidelines) — Text — enter number

38. POSTMORTEM (AUTOPSY) — Held/being arranged 1 | Not requested 2 | Requested but consent not given 3 | Coroners PM 4 | Parental consent but autopsy not done 5 | office use N.K. 9

39. Date CESDI form completed — Day Month Year

Tel. number:

APPENDIX 2 – EXTENDED WIGGLESWORTH CLASSIFICATION

Category 1 **Congenital defect/malformation (lethal or severe)**: Only **lethal** or potentially lethal congenital malformation should be included here. **Serious biochemical abnormalities** such as **Tay Sach's disease** and any known single gene defects known to have a high risk of death should be included.

Category 2 **Unexplained antepartum fetal death**: Most late fetal losses should be coded here. Where a live-born baby dies due to problems during the antepartum period, code this as 'other specific causes' (category 6).

Category 3 **Death from intrapartum 'asphyxia', 'anoxia' or 'trauma'**: This category covers any baby who would have survived but for some catastrophe occurring during labour. These babies will tend to be normally formed, stillborn or with poor Apgar scores, possible meconium aspiration or evidence of acidosis. Very premature infants (those less than 24 weeks' gestation) may be asphyxiated at birth, but should not be entered in this category as a rule.

Category 4 **Immaturity**: This applies to live births only, who subsequently die from structural pulmonary immaturity, surfactant deficiency, intra-ventricular haemorrhage, or their late consequences – including chronic lung damage.

Category 5 **Infection**: This applies where there is clear microbiological evidence of infection that could have caused death, e.g. maternal infection with Group B streptococci, rubella, parvovirus, syphilis etc; or in the case of a baby dying with overwhelming sepsis.

Category 6 **Other specific causes**: Use this if there is a specific recognisable fetal, neonatal or paediatric condition not covered under the earlier categories. Examples include:

(1) ***fetal*** conditions; twin-to-twin transfusion and hydrops fetalis;

(2) ***neonatal*** conditions; pulmonary haemorrhage, pulmonary hypoplasia due to prolonged loss of liquor (primary hypoplasia being classed as a malformation), persistent transitional circulation (in the absence of infection, aspiration or surfactant deficiency), blood loss unassociated with trauma (e.g. vasa praevia);

(3) ***paediatric*** conditions; malignancy and acute abdominal catastrophe (such as volvulus without antecedent congenital malrotation).

Category 7 **Accident or non-intrapartum trauma**: Confirmed non-accidental injury should be coded here. If only suspected, code as a sudden infant death cause unknown (category 8).

Category 8 **Sudden infant death, cause unknown**: This will include all infants in whom the cause is unknown or unsuspected at the time of death. Modification due to postmortem information should be notified later.

Category 9 **Unclassifiable**: To be used as a last resort. Details must be given if this option is ticked.

APPENDIX 3 – OBSTETRIC (ABERDEEN) CLASSIFICATION

DEFINITION OF THE TERMS USED IN THE OBSTETRIC (Aberdeen) CLASSIFICATION

CONGENITAL ANOMALY. Any genetic or structural defect arising at conception or during embryogenesis incompatible with life or potentially treatable but causing death.

ISOIMMUNISATION. Death ascribable to blood group incompatibility, rhesus (3) or non rhesus (4).

PRE-ECLAMPSIA. Diastolic blood pressure of 90 mmHg or more on two separate days after 20 weeks gestation (140 days) with significant proteinuria in the absence of existing hypertensive disease prior to pregnancy. Without APH (5) or with APH (6).

ANTEPARTUM HAEMORRHAGE (APH), after 20 weeks gestation (140 days) whether revealed or not, excluding antepartum haemorrhage secondary to pre-eclampsia (which is classified under pre-eclampsia). Minor degrees of haemorrhage at the start of labour (a show), and haemorrhage due to a cervical erosion or polyp should be ignored, but significant or recurrent bleeding of uncertain origin that is fairly closely followed by preterm labour should not be ignored.

MECHANICAL. Any death from uterine rupture and those deaths from birth trauma, or intrapartum asphyxia that are associated with problems in labour such as disproportion, malpresentation, cord prolapse, cord compression, or breech delivery in babies of 1000g or more. If there is no evidence of difficulty in labour, deaths from asphyxia or trauma should be classified as unexplained. Antepartum deaths associated with cord entanglement in the absence of strong circumstantial evidence that cord compression caused death (eg, fetal death soon after external version) should also be classified as unexplained.

MATERNAL DISORDER. Include maternal trauma (such as a road traffic accident), diabetes, appendicitis, and cardiac disease etc, if severe enough to jeopardise the baby. Include significant renal disease or essential hypertension known to be present before pregnancy. Also include symptomatic and asymptomatic maternal infection when this resulted in the death of the baby.

MISCELLANEOUS. Specific fetal and neonatal conditions only. Do not include conditions directly ascribable to prematurity or anoxia before birth, because these deaths are attributable to the relevant underlying obstetric disorder or are unexplained (see below). Include, however, specific fetal conditions (eg, twin-to-twin transfusion) or neonatal conditions (eg, inhalation of milk) where these are not directly ascribable to intrapartum anoxia or preterm delivery. Include, also postnatally acquired infection, except in babies of less than 1000g; here the reason for the ventilator dependancy or low birthweight is the codeable factor.

UNEXPLAINED. Deaths with no obstetric explanation, including unexplained antepartum stillbirths, deaths resulting from unexplained preterm delivery (including hyaline membrane disease, intraventricular haemorrhage, etc) and cases of intrapartum anoxia or trauma if the baby weighed less than 1000g at birth or delivery without any obvious associated mechanical problem. Cases should be subclassified into those babies weighing 2500g or more (20) and those of less than 2500g (21) at birth.

UNCLASSIFIABLE. Cases where little or nothing is known about pregnancy or delivery and that cannot be fitted into any of the above categories. Use this category as sparingly as possible.

OBSTETRIC (Aberdeen) CLASSIFICATION

Categories at the head of the list take priority over those lower down. Only ONE answer applies — **it is the lowest numbered category that adequately describes the death.**

Code	Category
	Congenital anomaly:— any structural or genetic defect incompatible with life or potentially treatable but causing death.
1	Neural tube defects
2	Other anomalies
	Isoimmunisation:— death ascribable to blood group incompatibility
3	Due to Rhesus (D) antigen
4	Due to other antigens
	Pre-eclampsia
5	Without APH
6	Complicated by APH
	Antepartum Haemorrhage (APH)
7	With placenta praevia
8	With placental abruption
9	APH of uncertain origin
	Mechanical
10	Cord prolapse or compression with vertex or face presentation
11	Other vertex or face presentation
12	Breech presentation
13	Oblique or compound presentation, uterine rupture etc.
	Maternal disorder
14	Maternal hypertensive disease
15	Other maternal disease
16	Maternal infection
	Miscellaneous
17	Neonatal infection
18	Other neonatal disease
19	Specific fetal conditions
	Unexplained
20	Equal or greater than 2.5kg
21	Less than 2.5kg
22	Unclassifiable

APPENDIX 4 – FETAL AND NEONATAL FACTOR CLASSIFICATION

DEFINITION OF THE TERMS USED WHEN CLASSIFYING THE MAIN FETAL AND NEONATAL FACTORS INVOLVED IN PERINATAL DEATH.

CONGENITAL ANOMALY. Any genetic or structural defect arising at conception or during embryogenesis incompatible with life or protentially treatable but causing death. Separate out deaths associated with a neural tube defect and death caused by chromosomal, cardiac or renal abnormality from deaths due to other miscellaneous or multiple abnormalities.

ISOIMMUNISATION. Death ascribable to blood group incompatibility.

ASPHYXIA BEFORE BIRTH (whether the baby is stillborn or not). Specify whether the insult originated before (8) or during (9) labour. All non-malformed stillborn babies are arbitrarily classified as dying of asphyxia unless death is due to a specific recognisable condition such as idiopathic hydrops fetalis, twin-to-twin transfusion etc, or there is evidence of malformation, isoimmunisation, trauma or infection. It would be assumed that asphyxia developed during labour unless there is reasonable evidence to the contrary if the baby was alive when labour started.

BIRTH TRAUMA. Death during or after birth due to rupture of the liver, splenic avulsion, fracture/dislocation of the occipital bone, or due to serious damage of the falx, tentorium, great cerebral vein or cervical spine during delivery. Where there is clinical or postmortem evidence of both asphyxia and trauma, death should be ascribed to asphyxia before birth (see above) unless it is clear that trauma is the more important factor.

SEVERE PULMONARY IMMATURITY. Babies with structural immaturity of the lung so gross as to render sustained ventilatory support unsatisfactory from the outset. Such babies are almost always less than 27 weeks gestation at birth.

HYALINE MEMBRANE DISEASE (HMD). Death due to pulmonary immaturity or surfactant deficiency or its late consequences. Specify whether there was significant periventricular bleeding (or infarction) (13) or secondary infection (14) as well.

INTRACRANIAL HAEMORRHAGE (or infarction). Exclude intraventricular and periventricular haemorrhage associated with potentially lethal HMD (12-14), and other haemorrhage secondary to trauma (10) or asphyxia before delivery (8 or 9). Separate deaths due to intraventricular or periventricular haemorrhage or infarction (15) including periventricular leukomalacia (conditions that are normally associated with preterm delivery) from other intracerebral haemorrhages (such as subarachnoid or cortical haemorrhage) or cerebrovascular occlusion of the type more normally seen in babies born at term (16).

INFECTION (including necrotising enterocolitis). Include antepartum as well as postpartum infection but exclude infection secondary to treatment for HMD. Separate deaths from necrotising enterocolitis from other deaths, and indicate, in the remaining cases, whether the infection was thought to have been acquired before the onset of labour, during delivery, or after birth. Specify site and organism.

MISCELLANEOUS. Death due to other specific fetal and neonatal conditions. Specific fetal conditions include tumours, isoimmunisation, unexplained hydrops fetalis and death due to the twin-to-twin transfusion syndrome. Specific neonatal conditions include aspiration of milk or gastric contents, unexplained pulmonary haemorrhage, pulmonary hypoplasia due to prolonged loss of liquor (primary hypoplasia being classed as a malformation), persistent transitional circulation (in the absence of underlying aspiration or surfactant deficiency), and blood loss unassociated with trauma.

UNCLASSIFIABLE OR UNKNOWN. Other inadequately documented deaths, unattended deliveries, unexpected and unexplained cot deaths (22) unattended deliveries not otherwise classifiable (23) and other undocumented death (24)

FETAL AND NEONATAL FACTOR CLASSIFICATION

Categories at the head of the list take priority over those lower down. **Only one number can be applied to any one death.**

Code	Category
	Congenital anomaly:— any structural or genetic defect incompatible with life or potentially treatable but causing death.
1	Chromosomal defect
2	Inborn error of metabolism
3	Neural tube defect
4	Congenital heart defect
5	Renal abnormality
6	Other malformation
7	Isoimmunisation
	Asphyxia before birth
8	Antepartum asphyxia
9	Intrapartum asphyxia
10	Birth trauma
11	Severe pulmonary immaturity
	Hyaline Membrane Disease (HMD)
12	Hyaline Membrane Disease
13	HMD with IVH
14	HMD with infection
	Intracranial Haemorrhage (+Infarction)
15	Intraventricular haemorrhage (IVH)
16	Other intracranial bleeding
	Infection
17	Necrotising enterocolitis
18	Antepartum infection
19	Intrapartum infection
20	Post partum infection
21	Miscellaneous
	Unclassifiable or unknown
22	Cot death
23	Unattended delivery
24	Other undocumented death

APPENDIX 5 – REVIEWERS

Thanks are given to all members of the Interim Advisory Group and Executive Steering Group for their input into the writing of this Report. Additional comments on individual chapters were received from:

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GLOSSARY

AETIOLOGY

The science of causes, especially of disease.

ANONYMISATION

The removal of information that would identify babies, family members, professionals and institutions.

ANTEPARTUM DEATH

Death of a baby before the onset of labour.

APGAR SCORE

A system to assess the status of the infant after birth. The Apgar score is based on the following five variables: heart rate, respiratory effort, muscle tone, reflex irritability and colour. Maximum score is 10. It is recorded at one minute and five minutes after birth.

BIAS

Any effect at any stage of investigation that tends to cause results to depart systematically from the true values. Examples include observer bias due to differences among observers recording study results; and selection bias where systematic differences occur between selection of cases and controls.

CARDIOTOCOGRAPH (CTG)

The electronic monitoring of the fetal heart rate and of uterine contractions. The fetal heart rate is recorded by means of either an external ultrasonic abdominal transducer or a fetal scalp electrode. Uterine contractions are recorded by means of an abdominal pressure transducer. The recordings are graphically represented on a continuous paper printout (trace).

CASE CONTROL STUDIES

Case control studies are used to evaluate multiple risk factors associated with a particular disease or outcome. They are particularly useful when the condition is rare (see Control).

CESDI

The Confidential Enquiry into Stillbirths and Deaths in Infancy.

CHI-SQUARED TEST

A χ^2 test is used to test whether there is an association between a number of variables. When the table has only 2 rows and 2 columns this is the equivalent to the comparison of proportions.

CONFIDENTIALITY

Information given in confidence may be used only for the purposes for which it is given. There are legal and ethical duties to maintain confidentiality in the NHS. Panel reports are not released to outside agencies.

CONFIDENTIAL ENQUIRY

Enquiry by peer groups, including experts in the field, into the cause of, and the factors surrounding, a death, where strict confidentiality is observed at all stages of the process. It is a form of clinical audit, with the important difference that the feedback or 'closing of the audit loop' is via reports on the general findings, and not direct feedback to those involved with the individual cases subjected to enquiry.

CONFIDENCE INTERVALS (95% CI)

A range of values about which there is a 95% chance that it includes the true value. For example, if the stillbirth rate is 5.4 per 1000 total births and the 95% confidence intervals are 5.3 to 5.5 per 1000 total births, then there is a 95% chance that the actual stillbirth rate lies between 5.3 and 5.5 per 1000 total births.

CONGENITAL ANOMALY

A physical malformation, chromosomal disorder or metabolic abnormality which is present at birth.

CONTROL

As used in a case control study, 'control' means person(s) in a comparison group that differ only in their experience of the disease or condition in question. If matched controls are used they are selected so that they are similar to the study group, or cases, in specific characteristics, e.g. age, sex, weight.

DENOMINATORS

The population at risk in the calculation of a rate or ratio. An example relevant to CESDI is the number of all live births as the denominator for neonatal mortality rate.

DIC

Disseminated intravascular coagulation is an acquired disorder of clotting characterised by intravascular fibrin formation which occurs in the course of a variety of conditions including sepsis and pre-eclampsia.

EARLY NEONATAL DEATH

Death of a liveborn infant occurring less than 7 completed days (168 hours) from the time of birth.

EFM

Electronic fetal monitoring.

ENQUIRY – SEE CONFIDENTIAL ENQUIRY

FBS

Fetal blood sampling. This is a test performed in labour to obtain a capillary blood sample from the baby to check for well-being.

FETAL DEATH

(based on WHO recommended definition)
Death prior to complete expulsion or extraction from its mother of a recognisable fetus, irrespective of duration of pregnancy. After separation, the fetus does not show any evidence of life.

FHR

Fetal heart rate.

GESTATION

The time from conception to birth. The duration of gestation is measured from the first day of the last normal menstrual period.

GESTATIONAL DIABETES

A carbohydrate intolerance of variable severity with onset, or first recognition during pregnancy.

GRO

General Register Office – the official statistics collection body for Northern Ireland.

GTT

Glucose tolerance test. This is a test for diagnosing diabetes, where blood glucose is measured at specific intervals after a glucose-rich meal is taken.

INFANT DEATH

Death in the first year following live birth; on or before the 365th day of life (366th in a leap year.).

INFANT MORTALITY RATE

see Mortality Rates.

INTERMITTENT AUSCULTATION

Listening to the fetal heart at regular intervals between contractions.

INTRAPARTUM DEATH

Fetal death during labour. If a baby is born without signs of life, but also without maceration (the skin and other changes that occur at varying lengths of time after death in the womb), there is a strong presumption that death occurred during labour. There are exceptions in both directions, which require judgement on the timing of death in relation to the presumed onset of labour.

IUGR

Intra-uterine growth restriction. This is a term often used interchangeably with the term 'small for gestational age' (SGA). IUGR strictly refers to babies that have failed to reach their growth potential during pregnancy. They are frequently but not always SGA. SGA is variably defined as a baby/fetus with measurements less than the 3rd centile/5th centile/10th centile.

LATE FETAL LOSS

For CESDI, a late fetal loss is defined as a death occurring between 20 weeks + 0 days and 23 weeks + 6 days. If gestation is not known or not sure, all births of at least 500 grams are reported, (at least 300 grams from 1 January 1996). Late fetal loss and stillbirth are distinguished by gestational age at the time of delivery, which is not necessarily the time of death.

LIVE BIRTH

Delivery of an infant which, after complete separation from its mother, shows any signs of life. There is no recognised gestation or weight qualifier in UK law on Birth Registration, so that any birth at any gestation or birthweight, which fulfils these criteria, should be registered as a live birth.

MORTALITY RATES

Infant mortality rate
The number of deaths under the age of 1 year following live birth, per 1000 live births.

Perinatal mortality rate
The number of stillbirths and early neonatal deaths (those occurring in the first week of life) per 1000 live and stillbirths.

Neonatal death rate
The number of neonatal deaths (those occurring within the first 28 days of life) per 1000 live births.

Postneonatal mortality rate
The number of infants who die between 28 completed days and less than 1 year following live birth, per 1000 live births.

Stillbirth rate
The number of stillbirths per 1000 live births and stillbirths.

Late fetal loss rate
The number of late fetal losses per 1000 live births and stillbirths.

NEONATAL DEATH

Death before the age of 28 completed days following live birth.

NICE

The National Institute for Clinical Excellence.

NICU

Neonatal intensive care unit.

NON-REGISTRABLE DEATH

A fetus delivered before the end of 24 completed weeks of pregnancy without signs of life.

NOTIFICATION OF BIRTH

By law all births must be notified within 36 hours of their occurrence to the Director of Public Health in England and Wales and the Chief Administrative Medical Officer in Scotland and Northern Ireland.

ODDS RATIO (OR)

This is a measure of the excess risk or degree of protection given by exposure to a certain factor. An odds ratio of greater than one shows an increased risk and less than one shows a protective effect.

ONS (FORMERLY OPCS)

Office for Populations Censuses and Surveys – merged with the National Statistics Office to become the Office for National Statistics on 1 April 1996.

PERINATAL MORTALITY RATE

see Mortality Rates.

POSTNEONATAL INFANT DEATH

Death occurring after 28 completed days up to 1 year following live birth.

POSTNEONATAL MORTALITY RATE

see Mortality Rates.

REGISTRATION OF BIRTH

A statutory requirement for all births in England, Wales and Northern Ireland within 42 days of birth.

REGISTRATION OF DEATH

The time limit for registration of death in England, Wales and Northern Ireland is 5 days.

SGA

Small for gestational age – see IUGR.

SHOULDER DYSTOCIA

Shoulder dystocia is used to describe a range of difficulties encountered in the delivery of the baby's shoulders. Discrepancies in the definition and the use of terms such as 'mild' or 'severe' shoulder dystocia have led to variations in reported incidence.

STILLBIRTH

Legal definition: England and Wales
A child which has issued forth from its mother after the 24th week of pregnancy and which did not at any time after being completely expelled from its mother breathe or show any other signs of life.

Legal definition: Northern Ireland
A stillbirth 'means the complete expulsion from its mother after the 24th week of pregnancy of a child which did not at any time after being completely expelled or extracted breathe or show any other evidence of life'.

SUDDEN INFANT DEATH SYNDROME (SIDS)

(1969 Seattle definition)
The sudden death of an infant or young child, which is unexpected by history, and in which a thorough postmortem examination fails to demonstrate an adequate cause of death.

With few exceptions SIDS occurs in the first year of life. It is also known as cot death.

TERMINATION OF PREGNANCY

This is the term used to describe deliberate ending of a pregnancy, under the provisions of the current law (1967/92 Act of Parliament), with the intention that the fetus will not survive.

TRACE

see Cardiotocograph.

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