



TABLE OF CONTENTS

PREFACE

MEMBERS OF THE CESDI ORGANISATION

1. INTRODUCTION

- 1.1 History
- 1.2 The work of CESDI
- 1.3 Enquiry process
- 1.4 Validation of Enquiry findings
- 1.5 Unexpected and unexplained death - Case control studies
 - 1.5.1 Sudden unexpected deaths in infancy (SUDI)
 - 1.5.2 Study of antepartum term stillbirths (SATS)
- 1.6 Rare events - focus group studies
- 1.7 Communications
- 1.8 Changing practice
- 1.9 Views of the National Advisory Body (NAB)

2. RAPID REPORT FORM RETURNS - 1996

- 2.1 Introduction
- 2.2 Notifications to CESDI
 - 2.2.1 Ascertainment
 - 2.2.2 Stillbirth and neonatal death rates
 - 2.2.3 Cause of death
 - 2.2.4 Mortality rates - Regional variation
 - 2.2.5 Late fetal loss rates - Regional variation
 - 2.2.6 Postmortem rates - Regional variation
- 2.3 Summary

3. SECOND PASS PANELS

- 3.1 Introduction
- 3.2 Methods
- 3.3 Results
- 3.4 Discussion
- 3.5 Recommendations

4. SUDDEN UNEXPECTED DEATHS IN INFANCY - THE EXPLAINED GROUP

- 4.1 Introduction
- 4.2 Case control study
- 4.3 Confidential enquiry
- 4.4 Recommendations

5. STUDY OF ANTEPARTUM TERM STILLBIRTHS

- 5.1 Introduction and method
- 5.2 Ascertainment and participation

- 5.3 Results - Clinico-pathological cause of death categorisation
- 5.4 Results - Case control study
- 5.5 Conclusion

6. FOCUS GROUP - PLACE OF DELIVERY

- 6.1 Background
- 6.2 Method
- 6.3 Findings
- 6.4 Discussion
- 6.5 Recommendations for practice

7. FOCUS GROUP - RUPTURED UTERUS

- 7.1 Background
- 7.2 Method
- 7.3 Findings
- 7.4 Discussion
- 7.5 Recommendations for practice

8. FOCUS GROUP - SHOULDER DYSTOCIA

- 8.1 Background
- 8.2 Method
- 8.3 Findings
- 8.4 Conclusions
- 8.5 Recommendations for practice

9. COMMUNICATIONS

10. CHANGING PRACTICE

- 10.1 Implementing the findings
- 10.2 Responses to the recommendations in the 4th Report from:
 - The Royal College of Midwives (RCM)
 - The Royal College of Nursing (RCN)
 - The Royal College of Obstetricians & Gynaecologists (RCOG)
 - The Royal College of Paediatrics & Child Health (RCPCH)
 - The Royal College of Pathologists (RCPATH)
 - United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC)
- 10.3 The future programme
- 10.4 Future research and developments
- 10.5 Future publications

11. CONCLUSION

GLOSSARY

APPENDICES



PREFACE

The 5th Annual Report of the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) is different in format to its predecessors. In those reports the substantive component related to the main confidential enquiry remit of the previous period - intrapartum related deaths (4th Report), and sudden unexpected deaths in infancy (3rd Report). Our current confidential enquiry remit for the years 1996 and 1997 related to a 1 in 10 randomisation of all deaths reported to CESDI. The data from these enquiries are still being collected prior to analysis for planned publication in next year's Annual Report.

The 5th Annual Report focuses on data from a number of specific studies, including analysis of non-SIDS sudden unexpected deaths in infancy, and a case-controlled study of antepartum term stillbirths. Both these reports highlight valuable findings and provide pointers for future research.

The basis of previous reports has been the findings of the regional confidential enquiry panels. The validity of these peer review assessments has been evaluated with the second pass panel study and its findings have led us to develop more structured enquiry assessment forms.

Several issues identified from the intrapartum related death enquiries were selected for in-depth review by 'focus groups'. The reports from three of these - place of delivery, shoulder dystocia and uterine rupture are included. Whilst denominator data is not available to evaluate absolute incidence or risk ratios, the focus group reviews have identified a number of recurring problems enabling the groups to suggest recommendations for practice.

The value of the CESDI process lies not only in the analysis of the data collected, but also in identifying lessons which can be learnt and translated into practice. It is very encouraging to see the responses from the various Royal Colleges and professional bodies in response to last year's report.

The Maternal and Child Health Research Consortium are again indebted to the Regional CESDI Co-ordinators and their staff for their enthusiastic support in collecting the data both rapidly and accurately. The input from the members of the National Advisory Body, the Professionals' Steering Group and the central CESDI Secretariat have ensured satisfactory progress of the Enquiry and their ideas are shaping its future scope along novel and relevant lines.

Professor Robert W Shaw
Vice President, Royal College of Obstetricians & Gynaecologists (RCOG)
Chairman, Executive Steering Group
Maternal and Child Health Research Consortium (MCHRC)



MEMBERS OF THE CESDI ORGANISATION

MEMBERS OF THE CONSORTIUM STEERING GROUP

Professor Robert Shaw (Chair)	Royal College of Obstetricians & Gynaecologists
Dr Keith Dodd	Royal College of Paediatrics & Child Health (until April 1998)
Dr Patricia Hamilton	Royal College of Paediatrics & Child Health (from April 1998)
Dr Steve Gould	Royal College of Pathologists
Miss Catherine McCormick	Royal College of Midwives (until January 1998)
Ms Polly Ferguson	Royal College of Midwives (from March 1998)

MEMBERS OF THE NATIONAL ADVISORY BODY

Lady Littler: Chair	Mrs Linda Lamont Parental Voice
Mrs Vicky Bailey Senior Midwife Nottingham Health Authority	Mrs Gill Mallinson Advisor to Stillbirth and Neonatal Death Society (SANDS) Chair, College of Health
Miss Sue Burr, OBE Advisor on Paediatric Nursing Royal College of Nursing	Mrs Ann Smith Primary Care Manager Southampton Health Commission
Dr Patrick Cartlidge Consultant Neonatal Paediatrician University of Wales College of Medicine	Dr Michael Vaile Director of Public Health West Kent Health Authority
Professor David James Professor of Feto-Maternal Medicine Queens Medical Centre, Nottingham	Professor Andrew Wilkinson Professor of Paediatrics University of Oxford
Mrs Eileen Hutton, OBE Parental Voice	Dr Gavin Young GP Cumbria
Dr Jean Keeling Consultant Paediatric Pathologist Royal Hospital for Sick Children, Edinburgh	

THE CESDI SECRETARIAT

Director (from August 97)
Director (to August 97)
Project Manager
Midwife (to October 97)
Midwife (from November 97)
Data Analyst
IT Specialist
Secretary

Dr Mary Macintosh
Mr Ralph Settatre
Ms Helen Caddy
Mrs Cathy Winter
Mrs Niki Jakeman
Ms Sara McCarthy
Mr Charles Lee
Mrs Mary Humphreys

THE CESDI REGIONAL CO-ORDINATORS

Northern - Ms Marjorie Renwick
Yorkshire - Ms Lesley Anson
Trent - Ms Sue Wood
East Anglia - Ms Jane Baker
North West Thames - Ms Stephanie Roberts
North East Thames - Ms Dawn Saunders
South East Thames - Ms Patricia Hanson
South West Thames - Ms Philippa Cardale
- Ms Julia Chachere
Wessex - Ms Melanie Gompels

Oxford - Ms Irene Boller
South Western - Ms Rosie Thompson
West Midlands - Ms Tessa Mitchell
Mersey - Ms Grace Edwards
North Western - Dr Jean Sands
Wales - Ms Jane Stewart
- Ms Judith Hopkins
Northern Ireland - Dr Maureen Scott

MEMBERS OF THE PROFESSIONALS' STEERING GROUP

Professor Robert Shaw (Chair)
Professor of Obstetrics & Gynaecology
University of Wales College of Medicine

Professor Jem Berry
Professor in Paediatric Pathology
St Michael's Hospital, Bristol

Mrs Sue Botes
Professional Officer
Community Practitioners and
Health Visitors Association

Ms Elizabeth Brandom
(until August 1997)
Midwifery Audit Coordinator
Royal College of Midwives

Dr Jean Chapple
Consultant Perinatal
Epidemiologist
Kensington, Chelsea
& Westminster
Health Commissioning Authority

Dr Graeme Davidson
Consultant Anaesthetist
Manchester Royal Infirmary

Mrs Maxine Dennis
Nurse Manager -
Children's Surgical Services
Leeds General Infirmary

Dr Keith Dodd
Consultant Paediatrician
Derbyshire Children's Hospital
(until April 1998)

Dr Jim Dornan
Consultant Obstetrician
Royal Maternity Hospital, Belfast
(Rep. N. Ireland, DHSS)

Ms Polly Ferguson
Head of Welsh Board
Royal College of Midwives
(from March 1998)

Professor Peter Fleming
Professor of Infant Health &
Developmental Physiology
Royal Hospital for
Sick Children, Bristol

Mr Robert Golding
Consultant in Obstetrics
& Gynaecology
Royal Gwent Hospital, Newport
(Rep. Welsh Office)

Dr Steve Gould
Consultant Paediatric Pathologist
John Radcliffe Hospital, Oxford

Mr Keith Greene
Consultant Obstetrician & Gynaecologist
Nuffield Hospital, Plymouth

Dr Patricia Hamilton
Consultant Paediatrician
St. George's Hospital, London
(from April 1998)

Ms Alison Macfarlane
Reader in Perinatal and Public
Health Statistics, National Perinatal
Epidemiology Unit, Oxford

Dr Roddy Macfaul
Medical Advisor - Paediatric
and Children's Health Services
Department of Health, England

Miss Catherine McCormick
(until January 1998)
Head - External Affairs
Royal College of Midwives

Dr Gillian McIlwaine
(until July 1997)
Consultant in Public Health
(Women's Health), Greater Glasgow
Health Board
(Rep. SHHD)

Dr Gillian Penney
(from August 1997)
Programme Co-ordinator
Scottish Programme for Clinical
Effectiveness in Reproductive Health

Dr Lindsay Smith
GP, Ilchester, Somerset
(Rep. Royal College of General
Practitioners)

In addition to the above named people, we would also like to acknowledge the considerable contribution of the many district co-ordinators and others based throughout England, Wales and Northern Ireland, who, often without recognition and in their own time, undertake work for CESDI.

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 which can be attributed to suboptimal clinical care.

In 1991 the Department of Health directed that the fourteen Regions of England should undertake Perinatal Mortality Surveys. CESDI was subsequently organised on this regional basis with separate arrangements for Wales and Northern Ireland. Each region is autonomous and has a full-time co-ordinator together with varying numbers of support staff. The network of CESDI has remained despite organisational changes in the NHS during 1994-95.

In the first instance, CESDI was funded directly by the Department of Health and supervised by a National Advisory Body (NAB), under the chairmanship of Lady Littler. The NAB included thirteen health professionals, two medical statisticians, one lay person and four observers from the Departments of Health in England, Wales and Northern Ireland. All members were appointed by the Government. 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 & Gynaecologists, the Royal College of Paediatrics & Child Health, the Royal College of Pathology and the Royal College of Midwives, to oversee the running of the Enquiry. The National Advisory Body advise the Consortium. In addition, to involve other key disciplines and professions in the Enquiry, a Professionals' Steering Group (PSG) was established to provide further advice to the Consortium.

In England, Wales and Northern Ireland there are some 10,000 deaths annually occurring between 20 weeks' gestation and 1 year of life. These deaths are notified to the regional co-ordinator, and a sub-set are anonymised and reviewed by a specialist panel within the region. The data is collected by district co-ordinators, using a rapid reporting notification system (RRF). The success of CESDI is highly dependent on the goodwill of these co-ordinators.

Regional data and enquiry findings are collated by the central Secretariat to provide a national overview. Results are published in the CESDI Annual Report.

1.2 THE WORK OF CESDI

This year a variety of studies are reported. Although there is no specific theme, these demonstrate the diversity of work that CESDI undertakes.

CESDI is tasked to provide an overview of the numbers and causes of stillbirth and infant deaths, together with a detailed enquiry into specific sub-sets. Table 1 summarises the enquiry programme to date and the topics highlighted in the various past Reports. The current work of the '1 in 10' sample of all deaths will be covered in the next Annual Report.

Table 1: The Enquiry programme 1993-1997

Designated Sub-Set	Year of Enquiry	Findings Reported
Intrapartum related > 2.5kg	1993	2nd Annual Report
Sudden Unexpected Deaths in Infancy ¹	1993-1994	3rd Annual Report
Intrapartum related > 1.5kg	1994-1995	4th Annual Report
'Explained' Sudden Unexpected Deaths in Infancy ²	1993-1996	5th Annual Report
Antepartum Term Stillbirths ³	1995	5th Annual Report
1 in 10 sample of all deaths >1kg excluding postneonatal deaths and major anomalies	1996-1997	To be reported
All deaths > 4kg	1997	To be reported

¹ - 3 Regions (South Western, Yorkshire, Trent)

² - 5 Regions (South Western, Yorkshire, Trent, Northern, Wessex)

³ - 1 Region (West Midlands)

1.3 ENQUIRY PROCESS

The detailed methodology applied by the multidisciplinary panels was described in the 1st and 2nd Annual Reports. Each panel consists of experts from a number of disciplines including, as a minimum, an obstetrician, paediatrician, midwife, specialist perinatal/paediatric pathologist, general practitioner and an independent chairperson. Other parties with appropriate expertise may also be involved. Panel members are sent anonymised case-notes prior to the meeting. At the meeting itself they produce a summary of the case and complete a standard CESDI form. This includes comments on suboptimal care, each item of which is graded according to the following system:-

- Grade 0 - No suboptimal care.
- Grade 1 - Suboptimal care, but different management would have made no difference to the outcome.
- Grade 2 - Suboptimal care - different management might have made a difference to the outcome.
- Grade 3 - Suboptimal care - different management would reasonably have been expected to have made a difference to the outcome.

The panel assigns an 'Overall Grade' together with comments on the completeness of the record and on the pathological findings (determined by the extended Wigglesworth, fetal/neonatal and obstetric classification).

- 1.4 **VALIDATION OF ENQUIRY FINDINGS**
The exact process followed by a panel varies between regions. A small study in 1993 (2nd Annual Report) concluded that these differences may affect the audit grades. To address the validity of the confidential enquiry process a fifth of all enquiries in 1995 were submitted to a second panel in a different region. The findings of this study are reported in Chapter 3.
- 1.5 **UNEXPECTED AND UNEXPLAINED DEATH - Case Control Studies**
Many of the deaths reported to CESDI are unanticipated and unexplained. For example, sudden unexpected deaths in infancy (SUDI) account for a third of all postneonatal deaths, and antepartum-term deaths account for a quarter of all stillbirths. However, if enquiries are limited to deaths alone, it is not possible to assess aetiology or associated features. Thus, a case-control approach has been adopted for SUDI and antepartum term deaths. In addition to confidential enquiries, data has been sought from medical records, parental interviews and centralised pathology findings.
- 1.5.1 **Sudden unexpected deaths in infancy (SUDI):**
The SUDI acronym includes several causes of death; the studies were conducted between 1993 and 1996. Most cases were babies who died of Sudden Infant Death Syndrome (SIDS), more commonly known as 'cot death'. SIDS is a category of exclusion, limited to those sudden unexpected deaths which cannot be explained either on clinical grounds or by findings at autopsy. Approximately one-fifth of the SUDI deaths were found to have an explanation. These are highlighted in Chapter 4.
- 1.5.2 **Study of Antepartum Term Stillbirths (SATS):**
The unexpected loss of a baby prior to labour at term or weighing more than 2.5 kg attracts less public attention than cot deaths. However, it is a relatively frequent event, the underlying cause of which is usually unknown. In 1994 CESDI commissioned a pilot study of Antepartum Term Stillbirths. The preliminary results of this study are described in Chapter 5.
- 1.6 **RARE EVENTS - Focus Group Studies**
One of the benefits of assembling information on a national scale is to determine whether there are general lessons that can be learned about the management of rare events. Such lessons may not be obvious from enquiry into individual cases. In 1996-97 three conditions were the basis of focus group studies: Planned Home Delivery, Ruptured Uterus and Shoulder Dystocia resulting in an intrapartum death. The findings are reported in Chapters 6, 7 and 8 respectively.

- 1.7 **COMMUNICATIONS**
Good communication is an essential component of the trust that exists between parents and health professionals. It becomes increasingly important in situations leading to a poor outcome. Deficiencies in this area can have wide ranging consequences including the loss of trust in the health system in future pregnancies. Chapter 9 considers the continuing task of improving communications between professionals and between professionals and parents. Good record-keeping is a vital part of this process.
- 1.8 **CHANGING PRACTICE**
The findings of CESDI need to be acted on as well as understood. Chapter 10 describes how the Royal Colleges and other statutory bodies responsible for training and accreditation are responding to the recommendations of the 4th Report which focussed on intrapartum deaths. This chapter also outlines CESDI's future programme.
- 1.9 **VIEWS OF THE NATIONAL ADVISORY BODY**
The NAB have been consulted about this Report and are in general agreement with its findings and recommendations.

ACKNOWLEDGEMENTS

It is the prime responsibility of the Secretariat and the Executive Steering Group to produce the Report, and they gratefully acknowledge the invaluable input of the National Advisory Body to the Report as a whole, as well as the other contributors named in the footnotes to individual chapters.

2

RAPID REPORT FORM RETURNS - 1996

2.1 INTRODUCTION

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

- to obtain a dataset for each death within the CESDI range between 20 weeks' gestation and one year of life
- to provide information as soon as possible after the death on the basis of which subgroups are selected for enquiry

The current form is reproduced in Appendix 4 .

A national collection of mortality statistics is already conducted by the Office for National Statistics (ONS) based on the Death Notification of fetuses from 24 weeks onwards. This is collected from the Registrar of Births and Deaths who also receives the Birth Notification. Notification of death is statutory - thus, these figures are the gold standard of the counting process. However, the Rapid Report Form collects a different set of information. The main features of the two processes are described in Table 2.1.

Table 2.1: A comparison of the two national collections of perinatal and infant mortality

	ONS	CESDI
Notification	Death certificate	Rapid Report Form
Start of collection	24 weeks onwards	20 weeks onwards
Source of data	Parent registering the death	Medical record
Setting of data	Registrar of Births and Deaths	Hospital
Content	Occupation, socio-demographic	Clinical details
Countries covered	England and Wales	England, Wales and N. Ireland
Commenced	1837	1993
Legal requirement	Statutory from 1874	Voluntary

2.2 NOTIFICATIONS TO CESDI

2.2.1 Ascertainment by CESDI and ONS/GRO registration data

Table 2.2 shows the deaths notified by the RRF compared with those collected by ONS in England and Wales and the General Register Office (GRO) in Northern Ireland. Since CESDI started in 1993, the overall difference in the number of cases collected by statutory bodies and RRFs has progressively decreased: CESDI undercounted by 1.3% in 1996,

as against 7.3% in 1993. This reflects improvement in the systems used by CESDI for capturing cases and is due to the determined efforts of CESDI coordinators to improve regional ascertainment.

As in previous years, postneonatal deaths remain the most difficult category of death for CESDI to collect. Nevertheless, the 1996 figures were undercounted by 8.7% compared with 13.9% in 1993. By contrast, there appears to be over-reporting of neonatal deaths: the RRF returns exceed those of ONS. This may be due to differences in classification or to non-reporting to ONS. In the future, CESDI proposes to pursue further examination of the unmatched records.

Table 2.2: Comparison of Rapid Report Form returns 1993-1996 with registration data (ONS & GRO)

Year	England, Wales and Northern Ireland										
	Stillbirths			Neonatal deaths			Postneonatal deaths			Overall difference	
	RRF	Registration	%	RRF	Registration	%	RRF	Registration	%	N	%
1996	3688	3699	-0.3	2785	2755	1.1	1253	1372	-8.7	-100	-1.3
1995	3698	3747	-1.3	2714	2809	-3.4	1156	1328	-13.0	-316	-4.0
1994	3747	3946	-5.0	2749	2817	-2.4	1199	1376	-12.9	-444	-5.5
1993	3726	3966	-6.1	2755	2926	-5.8	1242	1442	-13.9	-611	-7.3

N, %: Difference between the RRF and registration data reports expressed as a number and percentage of the registration data

2.2.2 Stillbirth and neonatal death rates

Table 2.3 shows the number of deaths reported to CESDI via the RRF system between 1993 and 1996. There is a slight increase in death rates in all categories, except for stillbirths. It is not possible to distinguish whether this is due to ascertainment or a rise in actual mortality rates.

Table 2.3: Rapid Report Returns: 1993-1996

	England, Wales and Northern Ireland							
	1993		1994		1995		1996	
	Numbers	Rate	Numbers	Rate	Numbers	Rate	Numbers	Rate
Legal abortions	-	-	-	-	959	-	1102	-
Late fetal loss	1495	-	1573	-	1553	-	1659	-
Stillbirths ¹	3726	5.3	3747	5.4	3698	5.5	3688	5.4
Perinatal deaths ¹	-	-	5897	8.5	5829	8.6	5898	8.7
Neonatal deaths ²	2755	4.0	2749	4.0	2714	4.0	2785	4.1
Postneonatal deaths ²	1242	1.8	1199	1.7	1156	1.7	1253	1.9
Total Reports - RRF	9218		9268		10080		10487	
Total live births	696133		688545		671861		674071	

¹ Rate per 1000 live births+stillbirths

² Rate per 1000 live births

Sources:

Live births: GRO & Child Health System,
N Ireland
ONS, England & Wales

Deaths: RRF 1996

Table 2.4 shows the deaths and mortality rates for singleton and multiple births.

Table 2.4: Stillbirth and neonatal deaths for singleton and multiple births 1993-1996

		England, Wales and Northern Ireland			
		1993	1994	1995	1996
Total live births	Singleton	696133	688545	671861	674071
	Multiple	678676	670734	653278	655834
Stillbirths	Multiple	17457	17811	18583	18237
	Singleton	3422	3390	3340	3329
	Unclassified	297	355	356	350
Neonatal deaths	Unclassified	7	2	2	9
	Singleton	2267	2259	2213	2258
	Multiple	477	477	487	517
Stillbirth rate ¹	Unclassified	11	13	14	10
	Singleton	5.0	5.0	5.1	5.1
	Multiple	16.7	19.5	18.8	18.8
Neonatal mortality rate ²	Singleton	3.3	3.4	3.4	3.4
	Multiple	27.3	26.8	26.2	27.6

¹ per 1000 singleton or multiple total births Sources: GRO & Child Health System, N Ireland,

² per 1000 singleton or multiple live births ONS, England & Wales; RRF 1996

2.2.3 Cause of death

The cause of death, as defined by the extended Wigglesworth classification (see Appendix 3) for stillbirths and neonatal deaths is shown in Figures 2.1, 2.2, 2.3.

For stillbirths the largest group (2666, 72.3%) was unexplained antepartum fetal death; the commonest identifiable causes of death were congenital malformation (373, 10.1%) and intrapartum related (372, 10.1%) (Fig 2.1).

For neonatal deaths the largest group was immaturity (1390, 49.9%), followed by congenital malformation (632, 22.7%) (Fig 2.2).

For postneonatal deaths, the largest group was Sudden Infant Death (390, 31.1%), followed by congenital malformation (364, 29.1%) (Fig 2.3).

Figure 2.1: Stillbirths in England, Wales and Northern Ireland by Wigglesworth classification in 1996

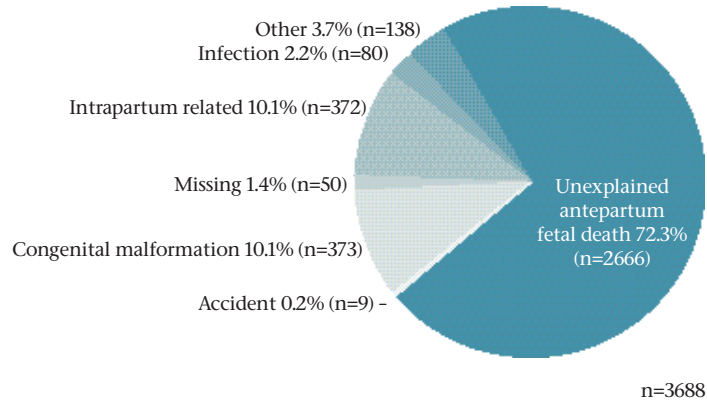


Figure 2.2 Neonatal deaths in England, Wales and N. Ireland by Wigglesworth classification in 1996.

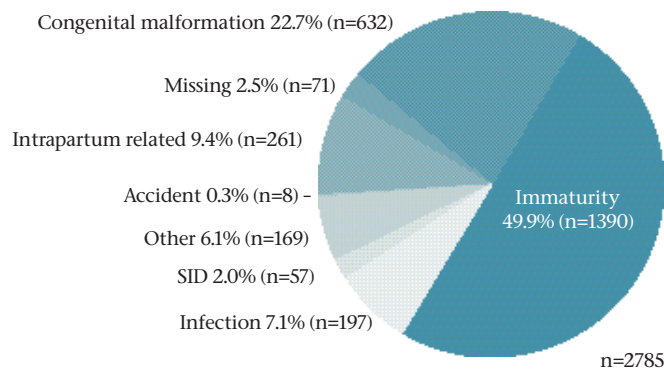
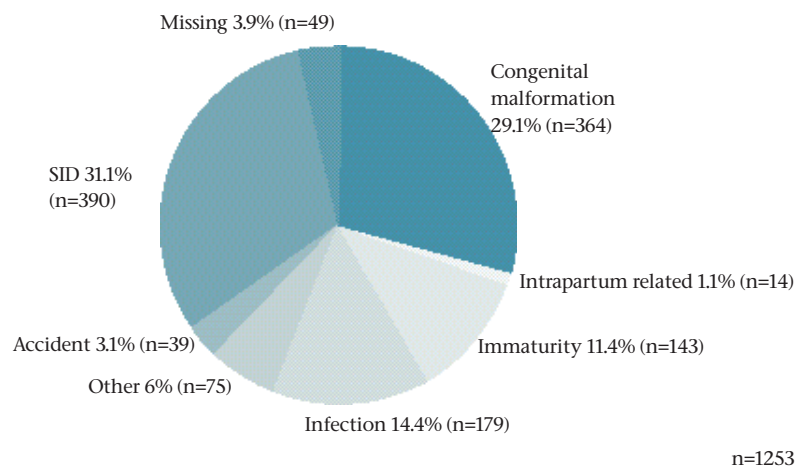


Figure 2.3 Postneonatal deaths in England, Wales and N. Ireland by Wigglesworth Classification in 1996.



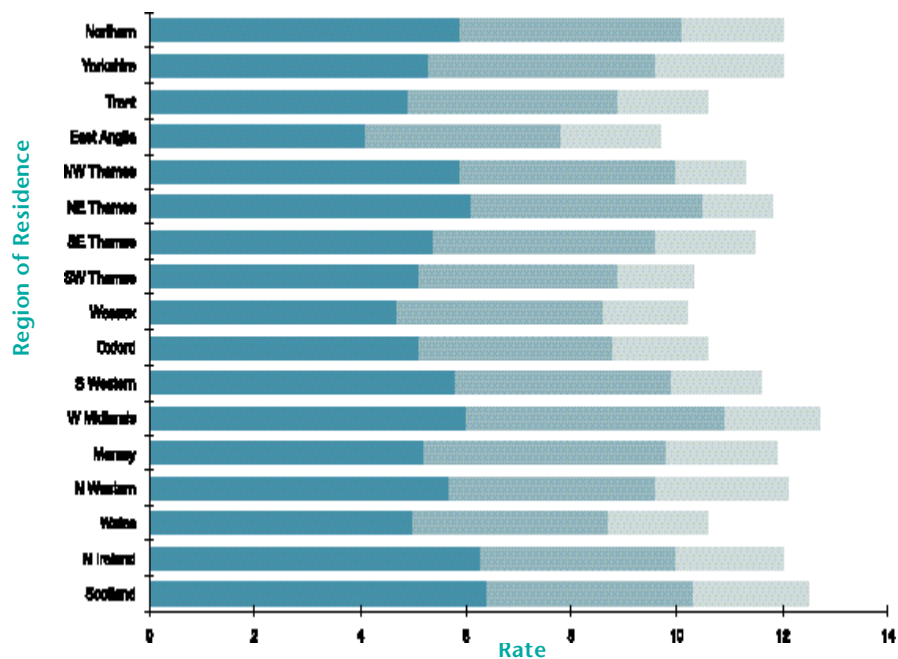
2.2.4 **Mortality rates - Regional variation**

Stillbirth, neonatal and postneonatal mortality rates by the region of residence of the mother in 1996 are shown in Figure 2.4. The 14 Regional Health Authorities (RHA) for England were merged in April 1996 to become eight Regional Offices. CESDI has continued to collect data on deaths within the former RHAs. Wales and Northern Ireland have not been affected by these changes. However, ONS provides denominator data on live births relating to the current eight Regions: this was recategorised to produce mortality rates relevant to CESDI regions. Due to the complex boundary changes in 1996, it has not been possible to define exact numbers of live births in some regions, in particular South Western and Wessex. These crude mortality rates are not indicators of standards of care and should therefore be interpreted with caution.

Mortality rates for stillbirth, neonatal and postneonatal deaths have been combined to obviate bias by differences in regional classification of death (Figure 2.4). The West Midlands region has the highest combined mortality (12.7 per 1000 total births) and East Anglia has the lowest (9.6 per 1000 total births).

For comparison, the figures have been added from the Scottish Stillbirth and Infant Death Report 1996.

Figure 2.4 Stillbirth¹, neonatal², postneonatal² and combined¹ mortality rates by region of residence of mother 1996



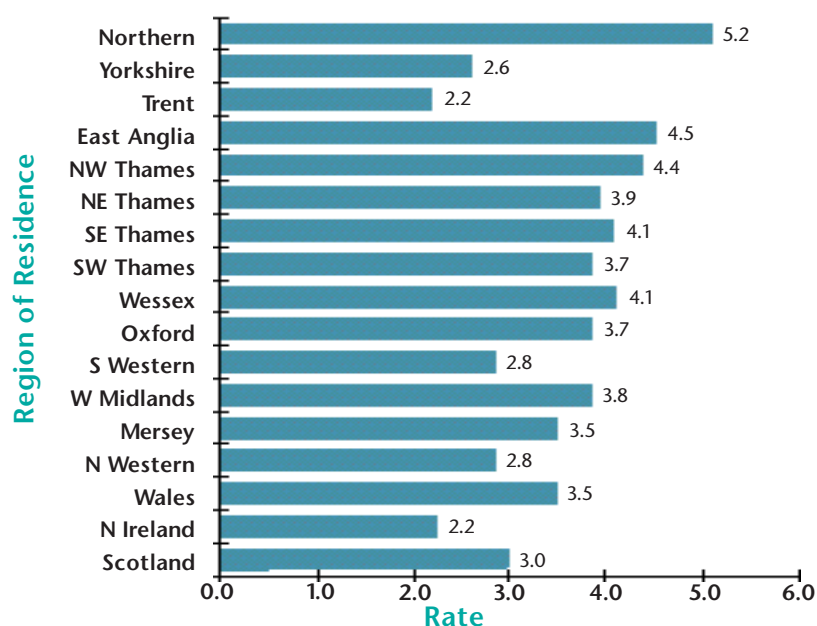
¹ per 1000 live births and stillbirths
² per 1000 live births

Sources:
 RRF 1996
 ONS
 N Ireland and Scotland
 Annual Reports 1996

2.2.5 Late fetal loss rates - Regional variation

Late fetal loss rates (gestation 20+⁰ to 23+⁶ weeks) according to region of residence is shown in Figure 2.5. These figures include terminations of pregnancy in this gestational range. CESDI is the only organisation to collect data in this group at a national level in England, Wales and Northern Ireland. Currently there is no means of validating these figures. The late fetal loss rates show greater regional variation than those at later stages of pregnancy and infancy. These variations may be due to regional ascertainment and will require further exploration.

Figure 2.5 Late fetal loss rates¹ by region of residence of mother 1996



¹ Per 1000 live births + stillbirths + late fetal losses

Sources: RRF 1996, ONS, N Ireland and Scottish Annual Reports 1996.

2.2.6 Postmortem rates - Regional variation

The numbers and rates of postmortem examination for late fetal losses, stillbirths, neonatal and postneonatal deaths according to the RRF returns in 1996 are shown in Table 2.5. The overall average postmortem rate for England, Wales and Northern Ireland was 57% and ranged from 44% in North East Thames to 69% in South Western. Late fetal deaths (64%) were the category most likely to have a postmortem and neonatal deaths the least (44%).

A postmortem examination was carried out on 57% (6,015/10,487) of the deaths notified to CESDI, of which 619 postmortems had been required by a coroner. Postmortem examinations were requested but refused by parents or family in 24% (2,464) of the deaths; postmortems had not been requested in 13% (1,403) of the deaths; in 68 deaths permission had been granted by parents but a postmortem was not carried out. No information about postmortem examination was provided for 5% (537) of the deaths.

Table 2.5 Postmortem of late fetal losses, stillbirths, neonatal and postneonatal deaths by CESDI region 1996.

REGION	Late fetal deaths (inc terminations)		Stillbirths		Neonatal deaths		Postneonatal deaths		All deaths	
	Number with PM	%	Number with PM	%	Number with PM	%	Number with PM	%	Number with PM	%
South Western	127	74.8	201	69.1	136	60.3	62	75.8	526	69.0
Wales	116	81.0	175	70.3	121	48.8	60	68.3	472	67.4
Northern	191	69.1	203	61.6	144	58.3	66	63.6	604	63.4
Oxford	150	75.3	174	67.2	119	44.5	56	58.9	499	63.3
Wessex	144	75.7	159	65.4	131	44.3	56	64.3	490	62.7
Mersey	113	62.8	157	69.4	147	46.3	70	72.9	487	61.4
East Anglia	167	67.7	145	69.0	127	48.8	53	50.9	492	61.4
NW Thames	190	71.6	237	67.9	169	42.6	60	51.7	656	61.0
SW Thames	185	68.6	199	60.3	110	46.4	52	57.7	546	60.1
SE Thames	262	61.1	288	64.6	251	48.2	106	59.4	907	58.4
N. Ireland	69	62.3	156	64.1	93	43.0	39	51.3	357	56.9
Trent	139	62.6	289	64.0	250	41.2	108	63.9	786	56.5
West Midlands	282	60.3	411	62.8	349	42.4	129	39.5	1171	53.5
Yorkshire	173	62.4	238	59.7	185	28.6	108	49.1	704	50.6
North Western	229	41.5	300	55.7	194	43.3	117	61.5	840	49.8
NE Thames	224	45.1	356	50.6	259	33.6	111	47.7	950	44.3
National	2761	63.5	3688	62.8	2785	44.0	1253	57.4	10487	57.4

ACKNOWLEDGEMENTS

Thanks are due to :
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2.3 SUMMARY OF RAPID REPORT FORMS 1996

1. **Total births and deaths:** live and stillbirths in England, Wales and Northern Ireland totalled 677,759 in 1996. A total of 10,487 deaths were notified to CESDI, comprising 1,102 legal abortions, 3,688 stillbirths, 2,785 neonatal deaths, 1,253 postneonatal deaths and 1,659 late fetal deaths. Ascertainment of rapid report forms against registration data is 99% complete.
2. **Stillbirths:** the overall stillbirth rate was 5.4 per 1000 total births.
3. **Neonatal deaths:** the overall neonatal mortality rate was 4.1 per 1000 live births.
4. **Other mortality rates:** perinatal mortality rate, 8.7 per 1000 total births; postneonatal mortality rate, 1.9 per 1000 live births. Both these rates appear stable since the introduction of the Rapid Report Form in 1993.
5. **Singleton births:** the stillbirth rate (5.1 per 1000 total singleton births) and the neonatal mortality rate (3.4 per 1000 singleton live births) remained stable over the past four years.
6. **Multiple births:** The stillbirth rate is 18.8 per 1000 total multiple births and the neonatal mortality rate is 27.6 per 1000 multiple live births.
7. **Regional mortality rates:** The combined (stillbirth, neonatal and postneonatal) mortality rate for England, Wales and Northern Ireland is 11.3 per 1000 total births (range: 9.6 East Anglia to 12.7 West Midlands). The late fetal loss rate for England, Wales and Northern Ireland is 3.5 per 1000 late fetal losses and total births (range: 2.2 Trent to 5.2 Northern.)
8. **Postmortem examinations:** The overall postmortem rate for England, Wales and Northern Ireland was 57% (range: 44% - 69%). Within the various categories of death, the highest rate was 64% for late fetal deaths (range: 42% - 81%); the lowest rate 44% for neonatal deaths (range: 29% - 60%).

3

THE SECOND PASS PANELS

3.1 INTRODUCTION

By definition, confidential enquiry is one of CESDI's core activities. Each case enquiry is a process of peer review in which care is discussed and criticised, and the degree of any suboptimal care graded. In the 4th Annual Report, the results of 1266 confidential enquiries, 873 of which were intrapartum related deaths, were reported in detail. There were a number of important conclusions, including the observation that 40% of all 1266 deaths (52% of the intrapartum related deaths), were subject to suboptimal care such that alternative care might reasonably have been expected to have altered the outcome.

To examine the validity of the confidential enquiry process, a small study was conducted and reported in the 2nd Annual Report (1993). This concluded that each region addressed their task very differently and that this affected the audit grade they reached.

Because this study indicated that, potentially, there was considerable variation in the decisions panels might make when reviewing cases, a larger study on the 1995 cases was undertaken during 1996 to:

- study the levels of agreement and disagreement between panels
- examine the areas in which agreement/disagreement tends to occur
- see if there were ways to improve effectiveness in identifying relevant suboptimal care from which conclusions can be drawn and policies developed to prevent recurrence of avoidable deaths.

3.2 METHODS

In 1995 every fifth enquiry underwent a repeat enquiry in another region. To allow for differences in regional size, the number of cases received for a second review was in proportion to the number of births within that region. In order to allow the second pass panel to compare their own opinions with the first pass panel conclusions, but prevent them being influenced by them, they were given a sealed copy of the first report, but forbidden access to it until their own conclusions were finalised, written and sealed.

Panels assigned overall grades of suboptimal care and comments in their usual manner.

Agreement in the assessment of the grades between two panels was assessed by:

- i observing the percentage of cases for which there was identical agreement
- ii a 'Kappa' statistic which is a measure of agreement between two panels allowing for chance agreement. If kappa =1 there is perfect agreement and if kappa =0 there is no agreement other than that by chance.

In the review of both panels' reports, a subjective assessment of the similarity between the panels was made taking into account:

- whether panel overall grades were **similar** i.e. within one grade of each other
- whether the most serious criticisms made by each panel were in broad agreement
- which aspect of management was criticised. These were classified as: antenatal assessment; CTG assessment; speed of delivery once decision made to deliver; neonatal care including resuscitation; and other.

3.3 RESULTS

A total of 633 cases arising in 1995 were reported in the confidential enquiry results. Just under a fifth (113 sets of notes) were submitted to a different region for a second panel report. Although the selection method was expected to produce a random distribution of the 1995 cases, review of the final returns revealed an excess of cases with grade 3 overall care attributed by the first panel.

3.3.1 Agreement of overall grade

Two cases were not graded by both panels and were excluded in the calculation of kappa. There was agreement in the overall grade for 52 of the 111 (47%) cases (kappa 0.18, p=0.001; Table 3.1).

The overall grades were grouped into two (grade 0 and 1, grade 2 and 3) and there was agreement in this grouping for 84 of the 111 (76%) cases (kappa 0.33, p<0.001; table 3.2).

Table 3.1: Overall Grade assigned by first and second panels.

	Ungraded	Grade 0	Grade 1	Grade 2	Grade 3	Total
	First Panel					
Ungraded					1	1
Grade 0	1	3	5	1	1	11
Grade 1		3	2	4	5	14
Grade 2		6	4	8	13	31
Grade 3			6	11	39	56
Total	1	12	17	24	59	113

Table 3.2: Overall Grade, grouped by (0 and 1) and (2 and 3), assigned by first and second panels.

	Grades 0 + 1	Grades 2 + 3 First Panel	Total
Grade 0 + 1	13	11	24
Grade 2 + 3	16	71	87
Total	29	82	111

3.3.2 Agreement of comments

Each case has an 'overall grade', reflecting the importance of the suboptimal care (if it existed) to the death of the baby. Each comment is also graded. Although the 'overall grade' is usually the same as the worst comment grade, it is possible to be worse. For example, a case may have many comments graded 2, but have a final overall grade of 3. Panels differed in the number of comments per case, often due to style. Some panels made numerous brief comments whereas others provided paragraphs encompassing many points.

There was a variation in panels itemising comments with lesser grades (0 and 1) of suboptimal care. No detailed analysis of these comments was performed unless the other panel had graded it higher (2 or 3). Thus only the cases (97/113) where at least one of the panels had assigned an overall grade 2 or 3 were further reviewed regarding the content of comments.

Grades were described as: **similar** if the grade each panel ascribed was the same or within one grade of the other and **dissimilar** otherwise.

Of the 97 cases with at least one of the two panels classifying suboptimal care grade 2 or 3, 79 (81%) of the panel pairs had a **similar** overall grade and were analysed for agreement in comments between panel pairs.

Agreement of comments was considered present if both panels were referring to the same aspect of management although it was not always possible to cross-check fully because the detail in each comment often differed. E.g. Case 10: Panel 1: Comment 1 - "delay in CS when admitted with a history of fresh bleeding and an abnormal CTG.". Panel 2: Comment 1 - "Failure to recognise an abnormal CTG". Comment 2 - "Delay in emergency CS".

Some agreement between panels was considered present when there was at least one comment that was graded 2 or 3 by both panels, but one panel also had a further comment graded 2 or 3 not mentioned by the other.

There was agreement in the main comments (i.e. those graded 2 or 3), in 54%, some agreement in 20%, and no agreement in 25% (Table 3.3).

Table 3.3: Agreement of comment according to agreement of overall grade in the 97 cases which had a grade 2 or 3 assigned by at least one of the panels.

	Similar overall grade	Dissimilar overall grade	Total
Agreed Reasons	43 (54%)	1 (6%)	44 (45%)
Some Agreement	16 (20%)	3 (17%)	19 (20%)
No Agreement	20 (25%)	14 (78%)	34 (35%)
Total	79 (100%)	18 (100%)	97 (100%)

When a problem relating to CTG interpretation was cited it was likely to be noted by both panels whereas other types of problems (lack of senior staff, ignoring antenatal factors, lack of urgency following recognition of a problem and neonatal care) were not (Table 3.4).

Table 3.4: Citation of aspects of management in the 97 cases which had a grade 2 or 3 assigned by at least one of the panels .

	Cited by either one or both panels	Cited by both panels
CTG interpretation	38	32
Lack of senior staff	19	8
Antenatal factors ignored	23	11
Lack of urgency	19	12
Neonatal care	21	10

3.4 DISCUSSION

The confidential enquiry within CESDI is a peer review process which in common with all enquiries is subject to professional opinion. The results of the second pass panel study assessed the robustness of the current process.

There was modest agreement between the 2 panels on overall grade, but agreement improved if the grade categories were grouped (grade 0 and 1 versus grade 2 and 3), indicating that many differences between panels were only of an order of one grade. It was also notable that of the individual grades, agreement was considerably greater with grade 3 than with lower grades.

The grading system relates to the relationship with fatal outcome and so does not necessarily reflect the quality of management. For example, minor degrees of suboptimal care in the antenatal or early intrapartum period might be considered critical and assigned a grade 3, whereas poor care in the late intrapartum or early neonatal period, in the context of the enquiry, might be deemed unlikely to have altered

outcome and therefore have been graded 1. Despite this, some panels 'over-graded' comments to emphasise the poor quality of care rather than its relationship to outcome. It is also possible that panels come to a different opinion because of applying different standards to a particular aspect of management.

When the panels assigned **similar** overall grades, a comparison of the content of the comments found that the major criticisms were the same half of the time but that different aspects were cited a quarter of times. Where there was no agreement in overall grade, the criticisms made rarely coincided. Only in one case did both panels make the same comment but graded it very differently.

Problems with CTG interpretation was the most frequently mentioned area of suboptimal care for the 1994/95 intrapartum related enquiries. This was more likely to be identified by both panels than other aspects of care.

These findings may reflect differences in the interests of the panel members. It is possible that comments made by both panels were valid despite being different. However, why panels reached different conclusions was not analysed in this exercise, although an earlier study (1993) had noted the chairperson to be influential.

3.5

RECOMMENDATIONS

Agreement between panels is strong evidence of suboptimal management. Three quarters of enquiries had similar grades assigned by the second pass panel but the content of comment was the same only half the time. However, differences in grading and content are not necessarily due to disagreement, but may have arisen from the relatively unstructured approach to the enquiry. In order to increase consistency in the process:-

- (i) Panels should be required to answer as many specific questions as possible to ensure that relevant areas of management will be addressed in a systematic manner.
- (ii) Standards should be predefined to provide guidance to the panel in assessment.
- (iii) The grading system needs modification. It may be more appropriate to grade using letters rather than numbers, the latter implying a continuum where perhaps none may exist.

All these recommendations are being applied to the 1998/1999 Confidential Enquiry Programme study of 27 and 28 week gestation neonatal deaths.

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Thanks for the writing of this chapter are due to:
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4

SUDDEN UNEXPECTED DEATHS IN INFANTS - THE EXPLAINED GROUP

4.1 INTRODUCTION

4.1.1 Outline

The CESDI programme from 1993 to 1996 included special studies on sudden unexpected deaths in infants (SUDI) between the ages of one and 52 completed weeks. These studies, which comprised both a case-control study and a confidential enquiry, began in the South-Western, Trent and Yorkshire (former) Regions in 1993 and were extended to Wessex and Northern Regions in 1995. A full description of the methods, together with the main findings for the first two years, was included in the 3rd Annual Report for CESDI¹, and preliminary results from the case-control study regarding the Sudden Infant Death Syndrome (SIDS) have also been published elsewhere^{2,3,4}. The present report deals with all SUDI other than SIDS occurring throughout the three years of the study.

4.1.2 Categories of unexpected infant death

The majority of SUDI fall into the category of SIDS, in which the death is not adequately explained either by the history or at autopsy. In the remainder the death is again unexpected but a cause is apparent from the history or is revealed at autopsy. These deaths may be termed 'explained SUDI' or 'non-SIDS SUDI'. For the purpose of this study such deaths were taken to include:

- i) those occurring in the course of a sudden acute illness that was not recognised by health professionals as potentially life-threatening.
- ii) those occurring in the course of a sudden acute illness of less than 24 hours duration in a previously healthy baby (plus those occurring after the institution of life support in the first 24 hours).
- iii) those arising from a pre-existing condition that had not been previously recognised by health professionals.
- iv) those arising from any form of accident, trauma or poisoning.

4.1.3 Number and distribution of deaths

Throughout the study period 456 sudden unexpected deaths were identified in the participating regions. 363 (80%) of these deaths were categorised as SIDS while the remaining 93 (20%) were explained.

Extrapolating from the regions of study an approximate estimation can be made that each year throughout England and Wales about 120 infants may be dying in this category of explained SUDI.

4.1.4 Causes of death

Table 4.1 gives the causes of death, under broad headings, for the 93 explained SUDI.

Table 4.1: Causes of death for explained SUDI

Cause of death	Number of cases		Number Interviewed with 4 controls	
		%		%
Infection	35	38	32	44
Suspected maltreatment	21	23	9	13
Accident	15	16	11	15
Congenital abnormality	10	11	10	14
Intestinal obstruction	5	5	5	7
Metabolic disorder	4	4	4	6
Other*	3	3	1	1
Total	93	100	72	100

*broncho-pulmonary dysplasia, cardiac rhabdomyoma, cardiomyopathy.

These figures do not represent the typical pattern of causation for infant mortality as a whole because they do not include deaths in the first week of life, expected deaths and SIDS.

4.2 CASE-CONTROL STUDY

4.2.1 Ascertainment of cases and controls

Full details of the methods used in the case-control study were given in the 3rd Annual Report. In 74 (80%) of the 93 cases of explained SUDI the families were interviewed and data collected by means of a standard questionnaire. Of the 19 families who were not interviewed, 10 were subject to police investigation, six declined an interview, two could not be contacted and one was considered unsuitable because of the mother's psychosis. Basic data for these 19 cases were extracted from other available records.

For each index case four controls aged within two weeks of the index were identified from the same locality and corresponding data were collected. When a family selected as a control proved not to be available, which happened in 19 instances (5%), an equivalent substitution was immediately made. For two index families interviewed, controls could not be found within the required time limit. Data were therefore available for 72 index families and 288 matched controls.

4.2.2 Statistical methodology

For the temporal factors data from all 93 cases were utilised. The remainder of the analysis was limited to the 72 index families

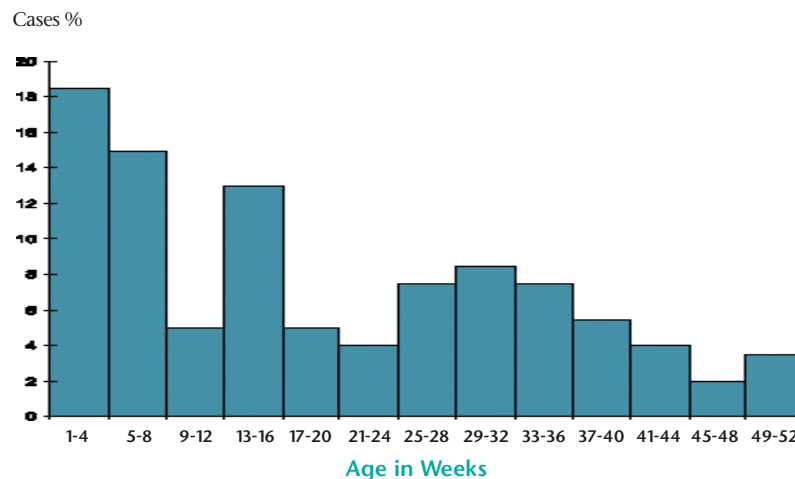
interviewed and the corresponding 288 matched control families. The statistical package SAS⁵, was used to calculate odds ratios and 95% confidence intervals, with allowance for matching.

Results

4.2.3 Temporal factors

Figure 4.1 shows the distribution of explained SUDI deaths by four-week intervals of age. More deaths occurred in the first four weeks than in any later period, despite the fact that this period was a week shorter than the rest because deaths in the first week were excluded. After the first eight weeks there was no obvious pattern to the frequency of deaths. This is in contrast to the characteristic distribution of SIDS deaths, which are uncommon in the first month of life, rise to a peak at 13 weeks and then decline steadily to almost zero by 11 months.

Figure 4.1 Age distribution of explained SUDI deaths



n = 93 Explained SUDI

There was some seasonal variation in the incidence of explained deaths, with most (14/93) occurring in December and fewest (4/93) in April and in August. There was no significant difference between the numbers of deaths occurring on different days of the week.

4.2.4 Factors relating to the infant

More boys than girls proportionally, 44/72 (61%) vs 146/288 (51%), died from explained SUDI but this was not statistically significant (OR=1.57 [0.85 to 2.87]). The birth weight of infants who died was on average 281g less than that of controls, and significantly more 12/70 (17%) vs 15/276 (5%) weighed less than 2500g at birth (OR=3.28 [1.27 to 8.45]). Similarly, the gestational age of babies who died was on average five days less than that of controls, significantly more, 21/68 (31%) vs 21/275 (8%), being born before 38 weeks (OR=6.52 [2.66 to 15.99]). More of the index babies were bottle fed 33/63 (52%) vs 127/288 (44%), the difference not being significant (OR 1.39 [0.72 to 2.66]).

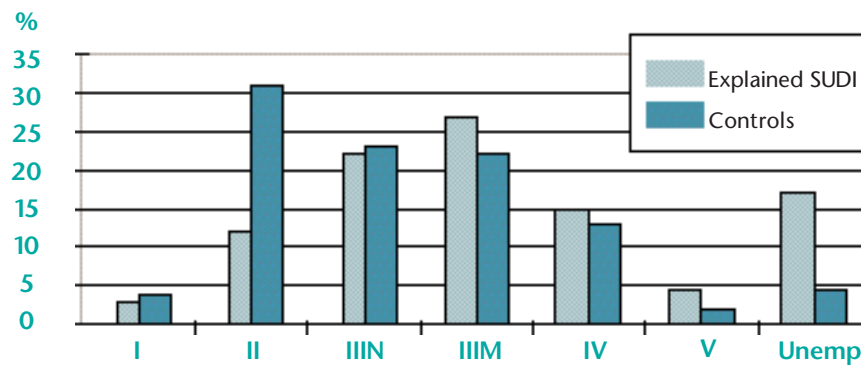
4.2.5 Factors relating to the mother

The mean age of index mothers was 29 months less than that of controls, and significantly more 42/72 (58%) vs 117/288 (41%) were aged under 27 years (OR=2.09 [1.13 to 3.84]). However, index mothers were more likely to have had at least three previous children, but were less likely to have the support of a partner. Significantly more index than control mothers smoked during pregnancy 30/61 (49%) vs 81/288 (28%) : OR=3.54 [1.74 to 7.18], and a dose-response effect was found whereby the association increased with the number of cigarettes smoked. In addition, according to parents' estimates, index babies were exposed to a smoky atmosphere for longer periods each day than were control babies, with significantly more of the index babies (24/58 (41%) vs 76/287 (26%) exposed for at least 1 hour compared to the controls (OR=2.99 [1.44 to 6.21]).

4.2.6 Socio-economic factors

Index parents were more likely to be unemployed at the time of interview 32/67 (48%) vs 44/288 (15%) : OR=5.56 [2.68 to 11.56], and to be receiving Income Support 38/60 (63%) vs 78/288 (27%): OR=3.85 [1.96 to 7.56]. Figure 4.2 shows the occupational classification of index families as compared with controls, using the highest present or previous occupation of either parent. Proportionately more of the index families were classified as social class III manual, IV, V and unemployed compared to the controls, this difference being significant (OR= 2.11 [1.06 to 4.20]). Index parents were also more likely to have no basic educational qualification, to be living in accommodation that was rented and more crowded, and to have no access to a telephone.

Figure 4.2 Occupational classification of index and control families



n = 67 explained SUDI, 283 controls

Based on the Registrar General's Standard Occupation Classification, HMSO 1991.

Class I	Professional occupations
Class II	Intermediate and technical occupations
Class III non-manual	Skilled occupations - non-manual
Class III manual	Skilled occupations - manual
Class IV	Partly skilled occupations
Class V	Unskilled occupations

4.2.7 Recent illness in the baby

The study questionnaire included a number of questions from the Cambridge Baby Check, a system devised to help doctors and carers assess the severity of illness in babies up to six months of age⁶. This system has a list of easily recognised symptoms and signs, each of which is scored, the sum of the scores giving a guide to the severity of the illness. A total score of less than eight indicates that the baby is generally well, while a score between eight and twelve suggests that the baby is unwell but not seriously ill, and the carers are advised to get advice and observe how the baby progresses. A score of more than 12 indicates that the baby is ill and needs a doctor, and if the score is over 19 the baby is seriously ill and needs a doctor straight away. Table 4.2 shows the number of index babies who had a score of more than 12 in the previous 24 hours as compared with controls.

Table 4.2: Health of infant in last 24 hours

Baby Check score	Index cases n=61	Controls n=288	Odds ratio
<12	34 56%	280 97%	1.0 ref. group
>12	27 44%	8 3%	22.02 (6.86 to 70.94)

A striking finding was that, according to retrospective scoring by the Baby Check system, 44% of the index babies had been in need of medical attention in the previous 24 hours as compared with only 3% of controls, a difference that yielded a very high odds ratio. Of the 27 index babies who needed medical attention, 2/27 (7%) had not been seen by any health professional in the week before they died, while 9/25 (36%) of those that had been seen were pronounced to have nothing wrong with them.

4.2.8 Summary of findings of case-control study

The heterogeneity of these explained SUDI deaths means that the findings must be interpreted with caution. The numbers in this study are not great enough to allow the sub-groups to be analysed separately. Perhaps the most striking result was the finding that nearly half the babies showed signs of illness severe enough to need medical attention in the 24 hours before they died. This finding has important implications with regard to the education of parents and health professionals in the recognition of the severity of illness in babies.

In general, the findings paint an epidemiological profile for explained SUDI that is similar in many respects to that seen in SIDS:

The main findings are:

- i) Highest proportion of deaths occurs in first month of life.
- ii) Peak incidence of deaths is in December.
- iii) Babies who die are more likely to be of lower birth weight and gestational age.
- iv) Mothers are more likely to be younger but start families earlier.
- v) Parents are more likely to have poor educational attainment, to be unemployed, or to be in the lower occupation groups.
- vi) Families are more likely to be in receipt of Income Support.
- vii) Accommodation is more likely to be rented and to be overcrowded.
- viii) Babies who die are more likely to show evidence of illness in the previous 24 hours.
- ix) Mothers are more likely to have smoked in pregnancy and babies are more likely to have been regularly exposed to a smoky atmosphere.

Many of these characteristics are similar to those found in SIDS.

4.3 **CONFIDENTIAL ENQUIRY**

4.3.1 **Method of confidential enquiry**

Sixty-seven of the explained SUDI cases were subject to confidential enquiry by regional panels, the procedure for which is described in the 3rd Annual Report. In brief, panels met some weeks after the death and considered all available documentation, including hospital records, notes from general practitioner and health visitor, autopsy report and the questionnaire completed on a home visit by the research interviewer. Panel members included a health visitor, a general practitioner, a paediatric pathologist, a midwife or an obstetrician, a paediatrician and a public health doctor.

As described in the 3rd Annual Report (paragraph 7.4) panels were required to identify notable factors relating to each case following the system pioneered in Exeter. The present report concentrates on the notable factors that involved suboptimal care by either professionals or carers, which in the panel's assessment possibly or probably contributed to the death of the baby.

4.3.2 **Findings - Suboptimal care and notable factors**

Table 4.3 shows the cases according to whether the panels thought there was suboptimal care that may have contributed to the death, and who was involved.

Table 4.3: The 67 cases classified by presence or absence of suboptimal care and person involved.

Who was involved	Number of cases
Professionals alone	12
Carers alone	15
Professional and carer	8
Total with suboptimal care	35
Total with no suboptimal care	<u>32</u>
Total	67

Panels thought that over half (35) of the deaths might have been avoided if those involved had acted differently. Professionals and carers each contributed to approximately a third of the deaths. In most of these 35 cases more than one contributory factor was identified, 105 such factors being cited in all, which suggests that a combination of faults rather than a single error may have led to the death. In several instances both professionals and carers were thought to have been at fault. However, the panels considered that almost half the deaths could not in any way be attributed to poor care either by professionals or by carers.

4.3.3 Suboptimal care involving professionals

Table 4.4 shows the number of cases in which various professional groups delivered care that panels considered to be suboptimal.

Table 4.4: The number of times a professional was involved in the 20 cases with suboptimal care.

	Number of mentions
General practitioner	14
Paediatrician	10
Health Visitor	6
Community midwife	2
Children's nurse	2
Obstetrician	2
Hospital midwife	1
Casualty doctor	1
Ambulance man	1
Total	<u>39</u>

Doctors were implicated much more often than nurses and midwives; this may in part reflect the greater likelihood of a doctor attending a baby who is seriously ill. Panels, expecting specialists to demonstrate appropriate expertise, criticised paediatricians almost as often as they criticised general practitioners. In most cases in which the care given by professionals was deemed to be suboptimal, more than one professional group was implicated, and sometimes the same group was subject to more than one criticism.

4.3.3.1 Suboptimal care by general practitioners

General practitioners were involved in 14 cases with a total of 20 notable factors. The area that most frequently gave rise to concern was failure to recognise the severity of a baby's illness (Table 4.5).

Table 4.5: Notable factors in the 14 cases of suboptimal care involving general practitioners.

	Number of notable factors
Failure to recognise severity of illness	10
Failure to visit during final illness	2
Failure to appreciate social problems	2
Failure to arrange emergency ambulance	1
Inappropriate medication	1
Poor communication	1
Poor management (unspecified)	3
Total	20

EXAMPLE 1

(Note: in this example and those that follow some details have been changed to protect confidentiality, but the essential points remain.)

A young single mother took her three-month-old baby boy to her doctor in the morning because he felt very hot and had a skin temperature of over 40°C, was off his feeds and had sticky eyes. The GP examined the baby briefly and prescribed eye drops. Later in the day the baby started vomiting repeatedly and became very drowsy. The mother called the practice and was told to come at the end of evening surgery. She took the baby straight away nevertheless, but by the time the GP was free to see him he was limp and unresponsive. The mother was told to take him to hospital in her car; she was delayed and when they arrived the baby was dead. Autopsy showed evidence of septicaemia with adrenal haemorrhage.

The panel considered that the GP was at fault for not recognising the severity of the baby's illness when he saw him that morning, and for not arranging an ambulance to take him to hospital when he saw him later.

EXAMPLE 2

A six-month-old baby girl, previously well, happy and plump, became miserable and began to vomit repeatedly. On examining her the family doctor found an inflamed ear drum, for which he prescribed amoxicillin. The vomiting became tinged with green and the stools liquid and blood-stained. The family doctor saw her again and recommended that she be given clear fluids to drink. On the fourth day the parents took her to hospital and soon afterwards she died. At autopsy she was found to have a well-established intussusception and to weigh 15% less than her last live weight.

The panel criticised the GP for not suspecting intussusception despite typical symptoms and signs, and also for not recognising significant dehydration. It was suggested that the second error may have partly resulted from the baby's deceptive plumpness.

4.3.3.2 Suboptimal care by paediatricians

Paediatricians were involved in 10 cases with a total of 15 notable factors (Table 4.6).

Table 4.6 Notable factors in the 10 cases of suboptimal care involving paediatricians

Area of concern	Number of notable factors
Poor clinical management	6
Failure to recognise severity of illness	4
Failure to take account of social background	2
Failure to evaluate baby on arrival	1
Mishandling of hospital transfer	1
Poor communication	1
Total	15

It is notable that in many of the cases factors contributing to the death occurred after specialist referral. The area most commonly highlighted was clinical management.

EXAMPLE 3

A mother who disliked hospitals ruptured her membranes early and was febrile by the time of delivery. A precautionary culture of the baby's blood grew *Streptococcus pyogenes* group B and treatment with intravenous antibiotics was started. However, after 48 hours the mother insisted on taking him home and was required to sign a form acknowledging that she was doing so against medical advice. The baby became unwell over the next few days and the GP visited twice, but he had not been informed of the infection. The baby steadily deteriorated and died, and at autopsy was found to have streptococcal pneumonia.

The panel identified three notable factors that might have contributed to this death. The mother was judged to be at fault for disregarding medical advice, and the consultant paediatrician was criticised for failing to ensure adequate treatment of the baby's infection, and for failing to alert the GP to a potentially dangerous situation.

EXAMPLE 4

A four-month-old baby boy developed vomiting and diarrhoea and was given boiled water to drink. After 48 hours he had a convulsion and was taken to hospital in a comatose state. It took 40 minutes to establish intravenous access, and the blood glucose was never measured. The baby did not recover consciousness and died next day. Postmortem tests established that he had medium-chain acyl-CoA dehydrogenase deficiency.

The panel thought that the baby's convulsion and coma probably resulted from hypoglycaemia, and that he might have responded to prompt treatment with intravenous glucose. The paediatric team was criticised for their failure to take an immediate measurement of blood glucose and for their delay in establishing intravenous access.

4.3.3.3 Suboptimal care by other medical staff

Obstetricians were criticised on two occasions, once for not heeding a family history of infant deaths, and once for poor technique in resuscitating a baby. A casualty doctor was considered at fault for sending back home a baby whose mother had brought him to the casualty department because she was worried. This case illustrates the importance of routinely calling for paediatric assessment whenever a baby is brought direct to hospital.

4.3.3.4 Suboptimal care by health visitors

Health Visitors were involved in 6 cases with a total of 7 notable factors (Table 4.7).

Table 4.7 Notable factors in the 6 cases of suboptimal care involving Health Visitors.

Area of concern	Number of notable factors
Inadequate frequency of visits	2
Failure to recognise severity of baby's condition	4
Inadequate attention to mother's depression	$\frac{1}{7}$
Total	7

As with general practitioners, failure to recognise the severity of the baby's condition was the most frequent factor.

EXAMPLE 5

A six-week-old girl developed a cough and was taken to the general practitioner. He examined the baby and prescribed an antibiotic, and asked the health visitor to visit next day to check her progress. When the health visitor called the mother pointed out that the baby was breathing faster than usual; she was drowsy and had been unable to take her medicine. The health visitor advised that she should be taken back to the surgery next day if there was no improvement. Later that evening the baby abruptly deteriorated and died on the way to hospital. Autopsy revealed widespread staphylococcal pneumonia.

While recognising that staphylococcal pneumonia may progress very quickly, the panel thought that the health visitor had failed to appreciate the severity of the baby's illness at the time of her visit.

4.3.3.5 **Suboptimal care by other health professionals**

Panels identified only one instance of suboptimal care by a hospital midwife, who was thought not to have paid sufficient attention to a mother's psychiatric problems. Community midwives were criticised on three grounds in two cases, inadequate supervision of a baby recovering from neonatal problems, failure to weigh a baby who was feeding poorly, and poor communication.

Children's nurses were also criticised in two cases, once for not recognising significant deterioration in a sick baby, once for incompetent use of a monitor and once for poor technique in resuscitation.

The only other health professional mentioned was an ambulance man who was thought to have used the wrong technique in resuscitating a collapsed baby.

4.3.4 **Notable factors involving carers**

Carers were involved in 23 cases with a total of 51 notable factors. This apparently large number of notable factors arose from panels regarding any item that is known to be associated with increased infant mortality, such as parental smoking, as a factor that might possibly have contributed to the death.

EXAMPLE 8

A 16-year-old single mother who regularly used cannabis was looking after her niece aged 18 months as well as her seven-month-old son. While she was bathing them together she went to answer the phone, and on finishing her conversation came back to find that the smaller baby had become submerged and was drowned.

The panel identified several factors relating to the carer that might have contributed to the baby's death: her young age, her lack of support, her use of cannabis and her lack of attention to the baby in the bath.

EXAMPLE 9

A six-month-old boy with a history of wheezing became chesty and unwell. Both parents were heavy smokers. The mother was depressed, and the father, who was unemployed, took most of the decisions and was averse to anyone in authority. The GP came to see the baby and advised admission to hospital. This was refused, despite a follow-up visit by the health visitor later. Next morning the baby was found dead in his cot. The autopsy showed extensive bronchiolitis and pneumonia.

The panel thought the death could have been avoided if the parents had not refused to allow the baby to go to hospital. It was also thought that their heavy smoking might have contributed to the illness.

4.3.5 **Inadequate resources**

There was one case in which a panel thought inadequate resources probably contributed to the death. This involved a baby with septicaemia who had to be transferred between three hospitals because of a lack of facilities for paediatric intensive care. This shortage has now been officially recognised and is being addressed on a national basis.

4.3.6 **Number of avoidable deaths**

Overall the panels concluded that about half the explained SUDI deaths might possibly have been avoided if professionals and/or carers had behaved differently. Extrapolating this to the number of deaths in this category in England and Wales suggests that each year about 60 deaths might be avoided by better care.

4.4 **RECOMMENDATIONS**

The recommendations are addressed to the Royal Colleges and other statutory bodies responsible for training and accreditation, as well as the NHS Executive and Health Commissioning Authorities.

4.4.1 **Training & Education**

i) **Training for general practice**

Suboptimal care by professionals was most frequently identified as failure by general practitioners to recognise serious illness in babies. At present, GP training does not always include hospital-based paediatric experience; a doctor can practise and provide emergency care for patients of all ages with minimal training or experience in recognising sick babies. This deficiency contributed to some of the 14 deaths in which panels thought that the GP was at fault.

- Before any doctor assumes responsibility for the emergency care of babies, s/he should have had training in the recognition of severe illness in babies.

This is addressed to the Royal Colleges of General Practitioners and of Paediatrics and Child Health.

A similar recommendation was made in the 3rd Annual Report (Paragraph 9.3.3).

ii) **Continuing medical education for consultants**

In most of the 11 cases where care by paediatricians was judged to be suboptimal the fault lay in decisions made or endorsed by the consultant.

- CME for consultant paediatricians should include the best current management of acute severe illness in infancy.

This is addressed to the Royal College of Paediatrics and Child Health.

iii) Resuscitation of infants

An obstetrician, a paediatric nurse and an ambulance man were criticised for faulty resuscitation of a collapsed baby. Usually the fault lay in the use of a technique that is inappropriate for the patient's size.

- All health professionals who have responsibility for the care of sick babies should be trained in emergency cardio-pulmonary resuscitation of infants.

This is addressed to the NHS Executive.

iv) Recognition of intestinal obstruction

In this study there were four deaths from intussusception. Diagnosis may be difficult but is more likely to be made if doctors bear this possibility in mind: in particular, bile-stained vomiting calls for immediate referral to hospital; episodic screaming is suspicious; and the characteristic blood-stained stools may be a late feature.

- All teachers of paediatrics, both undergraduate and postgraduate, should emphasise early diagnosis of intestinal obstruction.

This is addressed to the Royal College of Paediatrics and Child Health.

4.4.2 Targeting Services

i) Provision of health support services

Explained SUDI deaths were more common among disadvantaged families, as is also the case for SIDS. This might be amenable to improvement by health education and by targeted support of families at risk. Some Trusts are already targeting health-visiting services in this way, and this practice is commended.

- Health trusts should give priority to support services for disadvantaged families who have new babies.

This is addressed to Health Commissioning Authorities.

ii) Assessment of sick babies on admission to hospitals

Three babies died after being assessed in hospital by a junior doctor and discharged without the opinion of a more experienced doctor. Any ill baby who is brought to hospital should be assessed by a sufficiently experienced doctor, at least of specialist registrar or equivalent status.

- Paediatric teams and casualty departments should ensure that a baby is always assessed by a doctor of sufficient experience before considering discharge.

This is addressed to the NHS Executive.

iii) Parent Information

Many health visitors find that the parent-held personal child health record is a useful tool for structuring their advice on infant care. The record includes many factors identified in this study: safe sleeping arrangements, reduction of risks such as smoking, avoidance of accidents, and recognition of serious illness.

- Trusts should issue the parent-held personal child health record to all new mothers.

This is addressed to Health Commissioning Authorities.

Four of the cases of accidental death were attributable to inappropriate beds or faulty cots.

- Information for parents should stress that babies should sleep only in a cot that is designed for them, and that the cot should be in a good state of repair.

This is addressed to the Community Practitioners' and Health Visitors' Association, and to all others concerned with the reduction of accidents in childhood.

4.4.3 Further Research

Recognition of illness in babies

Babies dying from explained SUDI often exhibit in the previous 24 hours significant signs of illness that are not recognised or not acted upon by the carers or health professionals. The Baby Check system enables the observer, even if unskilled, to quantify these signs in a structured manner, and to assess the severity of the baby's illness.

- The Baby Check system should be assessed in a wider range of settings and, if its value is confirmed, be used more widely to help both carers and health professionals recognise the severity of a baby's illness.

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STUDY OF ANTEPARTUM TERM STILLBIRTHS

5.1 INTRODUCTION AND METHOD

The unexpected loss of a baby at term or weighing above 2.5kg prior to labour is a relatively common event accounting for nearly an eighth of all fetal deaths reported to CESDI. The underlying cause for these losses is often unknown and there is limited knowledge regarding the potential for prevention of these deaths by improvements in clinical care. As a response to this, CESDI commissioned a regional pilot study of antepartum term stillbirths (SATS). Because of similarities with cot deaths which also are unexplained it was decided to use a similar approach. It was hoped to do the study in two regions (West Midlands and North Thames). Because of organisational difficulties in the preparation phase, North Thames was unable to participate.

5.1.1 Aims of Study

The intention was to evaluate a pilot study investigating losses that occurred prior to labour at term or where the baby weighed at least 2.5kg.

5.1.2 Study Design

The design used a similar approach to that of the SUDI studies. There were three aspects:

- Case control study (case notes, blood tests, parental interviews)
- Confidential enquiries (cases and controls)
- Pathological review (cases only)

5.1.2.1 Case Control Study

Setting of study: One large NHS region (the West Midlands with 68,000 births annually) expecting to recruit 100 cases in 12 months.

Definition of case: A stillbirth after an estimated 37 completed weeks of pregnancy at birth or weighing at least 2.5kg and not having a known life-threatening congenital abnormality.

Selection of cases: All stillbirths meeting the inclusion criteria and occurring between 1st September 1995 and 31st August 1996.

Definition of control: A live birth after an estimated 37 completed weeks of pregnancy or weighing at least 2.5kg and not having a known life-threatening congenital abnormality.

Selection of controls: The two births occurring in the same hospital one week after the case to the nearest time of day that the case had been born. The practicalities of data collection, organising enquiries and parental interviews governed the choice of two controls per case rather than a larger number which would have increased the power of

the study. Multiple pregnancies were not excluded. Controls for cases occurring outside hospital were to be chosen following the death from the unit to which the case was admitted.

Notification: Participating districts contacted the CESDI co-ordinator or one of the study co-ordinators as soon as a case was identified. As a back up measure, a check was made of the Rapid Report Forms which are completed on all fetal losses from 20 weeks gestation onwards and sent to the Regional CESDI office to identify cases that had not been notified to the study team.

Information collected: This comprised: data items from anonymised photocopies of medical records; post-delivery blood and urine samples and parental responses to a structured questionnaire. The process was facilitated in the West Midlands by the universal use of a standard antenatal record. Blood samples were requested and the following measurements taken: full blood count; Kleihauer and estimated size of fetomaternal bleed if positive; Glycated Haemoglobin (HbA1c); Bile acids; Cardiolipin G & M; Alkaline Phosphatase; Alanine Transferase, Aspartate Transferase, Bilirubin; Creatinine; and Urate. Urine samples were requested for Helicobacter Jejuni. All samples were taken within 24 hours of delivery in both the cases and controls. TORCH screens were taken from the cases but not the controls.

Parental interviews:

Advice was sought regarding wording of questions and interview technique from the organisers of the Leicester Perinatal Mortality Survey. This uses a case control design and has included parental interviews for the last twenty years. The interviews were intended to occur within two weeks of the birth. They were undertaken by midwives who had attended a one day training course. The format of the interview followed a structured questionnaire designed to enquire into social and life-style variations, symptoms and events during pregnancy. Explanatory free text was encouraged to expand on answers.

5.1.2.2 Confidential Enquiries

The standard format used for confidential enquiry in the Region was used for both the cases and the controls. There was no attempt to obscure whether the baby was live or stillborn.

The panel recorded relevant comments and then they applied two grades to them. The first related to standard of care and the second related to its relevance to the death, although this was obviously theoretical for the control. Following assessment of the pathology information available, the panel was required to classify the cause of death according to the Wigglesworth, Fetal and Neonatal and Obstetric Classifications. It also assigned an overall grade for the case in order to be compatible with previous CESDI methodology.

5.1.2.3 Pathology

A special consent form and explanatory leaflet describing the autopsy arrangements was designed for the study. Care was taken that nothing

in the protocol should inhibit well organised local practice with regard to stillbirth, but permission was sought for the parents to be interviewed by a researcher whenever possible. Detailed autopsy was undertaken by a perinatal specialist pathologist at a central location subject to parental consent and also that of the responsible clinician. Arrangements made to provide centralised pathology included: a special casket for preservation and transport; a contract with an undertaker to be responsible for both collection and return of the body; an agreed turnaround time from receipt to return by the pathology department performing the autopsy, together with provisional and final reports. If permission for full autopsy was declined, agreement to alternative options was sought. These comprised a detailed external examination, photography, measurements, with or without: whole body radiography and closed (needle) biopsy of selected organs. Detailed examination by a pathologist in the hospital of occurrence was also offered as an option. The placenta was examined in all cases.

5.2. ASCERTAINMENT AND PARTICIPATION

5.2.1 Regional participation - Ethical approval

The West Midlands has 20 maternity units, and ethical consent was gained from 19. The unit declining approval had reservations regarding the centralised autopsy service which reduced opportunities for a local pathologist with a special interest.

5.2.2 Ascertainment Cases

In total, 86 cases entered the study. A further 13 stillbirths fulfilling appropriate criteria according to CESDI Rapid Report Forms during the study period were excluded. Details of the 13 cases not included: delivery outside the region (2); foundlings excluded because of complete absence of clinical detail (2); multiple pregnancies where the fetus had died considerably earlier than 37 weeks but delivery occurred at term (4); delivery at autopsy following maternal death (1); trachea/laryngeal cleft and pulmonary hypoplasia diagnosed at autopsy which was judged a lethal condition (1); uncertainty about the timing of death and considered to be intrapartum (3).

Controls

For the 86 cases 172 controls were identified. After study entry it was realised that there were two babies that weighed less than 2.5kg and were born at less than 37 weeks. These 2 controls were not included in the analysis.

5.2.3 Participation in Interviews Cases

Questionnaires were completed at interview for 73 of the 86 participants. Of the remaining 13, 6 declined, 3 had insufficient English and an interpreter could not be arranged and 4 were not interviewed for other organisational reasons.

Controls

Questionnaires were completed at interview for 139 of the 170 participants. Of the remaining 31, 22 declined to participate in the structured interview and a further 9 were not interviewed for organisational reasons.

5.2.4 Confidential Enquiries

An enquiry occurred on all 86 cases and on 104 controls; these were those associated with the initial 52 cases. The initial intention of the study was to enquire into all 170 controls but the workload involved had a significant impact on the study organisation and goodwill of the assessors. This resulted in a decision to discontinue panel assessment of controls after the first 52 pairs.

5.2.5 Autopsy

The type of autopsy and site of where it was performed is described in Table 5.1.

Table 5.1: Type of autopsy and where performed in the 86 cases

	Centralised	Not Centralised	Total
External only	3	1	4 (5%)
Partial	8	0	8 (9%)
Full	51	8	59 (69%)
No autopsy			15 (17%)
Total			86 (100%)

In summary: 15 (17%) parents declined any kind of postmortem examination; 4 (5%) parents consented to external examination and radiography only; 8 (9%) parents consented to external examination, radiography and tissue biopsy and 59 (69%) consented to full internal and external autopsy examination. A fully funded centralised autopsy service was accepted in 62 (72%) cases.

5.3 RESULTS - Clinico-pathological cause of death categorisation

5.3.1 Pathological Categorisations

Panels categorised cases according to the fetal and neonatal (24 categories) and obstetric (Aberdeen - 22 categories) classifications. Table 5.2 shows the results of the cross-tabulation of the two categorisations for the 86 cases reported by panels.

The fetal and neonatal classification describes the underlying pathological diagnosis that causes death. The obstetric classification categorises cases largely by the underlying clinical obstetric factor leading to death and takes no account of the immediate pathological cause.

Table 5.2: Study of Antepartum Term Stillbirth; Fetal/Neonatal and Obstetric classification categories assigned by panels, n=86

Obstetric Classification and code	Fetal Classification and code					
	Congenital Heart Defect	Antepartum Asphyxia	Intrapartum Asphyxia	Antepartum Infection	Total	
	4	8	9	18		
Non-NTD congenital anomaly	2	1			1	
Placenta Praevia	7				1	
Placental Abruption	8	1			8	
Cord prolapse or compression	10	8	1		2	
Maternal hypertensive disease	14	1			1	
Other maternal disease	15	6			6	
Maternal infection	16			3	3	
Unexplained >=2.5Kg	20	57	1		58	
Unexplained <2.5Kg	21	6			6	
Total		1	80	2	3	86

To maximise pathological information (full postmortem rate 69%) cases were categorised into broad clinico-pathological classification by a single reviewer.

The reviewer used the following approach in prioritising the findings to categorise the case:

- Morbid pathology with histology
- Morbid pathology weights and measurements
- Morbid pathology observation by expert
- Post-delivery maternal serology and biochemistry
- Post-delivery description by expert
- Post-delivery weights and measures
- Pre-delivery clinical observations and events
- Pre-delivery high risk disorders, personal history or family history.

The classification is mutually exclusive and hierarchical.

5.3.2 Details of Categorisation of SATS Special Groups

Group A - Miscellaneous specific fetal conditions or causes of death - 9 cases

This group included those with significant fetal infection (3), congenital anomaly (1), fetal bleeding (3), cord prolapse (1), placenta praevia (1).

Group B - Conditions that are associated with fetal death - 19 cases

This group included impaired glucose tolerance (9), hypertensive disorders (4), generalised pruritis with abnormal biochemical liver function tests (4), others (2).

Impaired glucose tolerance was defined as follows:

- **If full autopsy performed:**
Fetal autopsy features of maternal diabetes and EITHER at least one biochemical abnormality associated with carbohydrate intolerance OR (if no biochemical tests or results normal), at least two substantial clinical markers for carbohydrate intolerance or diabetic pregnancy.
- **In absence of full autopsy:**
Clinical features consistent with diabetic pregnancy including abnormal fetal weight and appearance AND at least one abnormal biochemical marker.

Biochemical markers were as follows:

- Raised Blood Sugar (BS) - generally any fasting BS more than or equal to 5mmol/L or any random BS more than or equal to 8mmol/L
- Glucose Tolerance Test (GTT) - BS more than or equal to 8mmol/L two hours following 75g oral glucose load after fasting
- Glycated Haemoglobin (HbA1c) >6.0%

Clinical markers (at least two required in the absence of a biochemical marker):

- First order relative with diabetes, (two required if the only marker)
- Glycosuria more than once
- Previous macrosomic baby (more than or equal to 4.3kg)
- Clinically macrosomic baby in current pregnancy confirmed following delivery
- Polyhydramnios

Glycated Haemoglobin was >6.0% in 3 of the 106 controls. It should be noted that using this definition there were cases classified as impaired glucose tolerance in which antenatal biochemical tests were in the normal range. When this occurred it was attributed to being performed too early in pregnancy. There were no pre-pregnancy diabetics in this group.

Group C - Placental Abruption - 9 cases

This consisted of cases which did not satisfy criteria for inclusion in A or B, and had constant uterine pain and/or tenderness associated with intrauterine death AND at least two of the following:

- Autopsy findings 'compatible' with abruption
 - Fetal death consistent with acute asphyxia
 - 'Cratering' of placenta at site of placental maternal surface clot
 - Retracted clot adherent to placenta
 - Clot or thrombin between villi
- Antepartum or Intrapartum Haemorrhage (APH or IPH)
- Retro-placental clot

Group D - Intra-Uterine Growth Restriction presumed due to utero-placental insufficiency - 22 cases

This consists of cases which did not satisfy criteria for inclusion in A, B or C and,

- having features of Intra-Uterine Growth Restriction observed by a pathologist on the basis of general appearance and Brain/Liver Ratio greater than 4
- if no autopsy or external examination available then this group included cases where the fetal birth weight was less than the fifth centile corrected for gestation, fetal sex, parity and, when available, maternal height and weight¹.

Group E - Unexplained - 27cases
All other cases were classified as Group E

5.4 RESULTS - Case Control Study

5.4.1 Significant Findings:

From the case notes

There were only two features which occurred more frequently in the cases that were significant. These were: having any antenatal problem noted (OR 2; 95% CI 1.2-3.3) and being a mother of non-white origin (OR 2.6; 95% CI 1.4-4.9).

The ethnic origin of the cases and controls is shown in Table 5.3 The higher number of deaths in the non-white mothers may be real but also may be apparent due to any bias in the recruitment of the controls. There is no accurate distribution of the ethnic origin of the maternity population in the West Midlands available, but unpublished provisional data from the Hospital Episode Statistics (HES) system suggests that the controls were a representative sample. This finding is in keeping with the increased stillbirth rates for mothers whose place of birth is Pakistan, the Caribbean, Bangladesh, New Commonwealth and East Africa².

Table 5.3: - The ethnic origin of the mother in the cases, controls and the West Midlands Maternity population. Unpublished provisional data from the Hospital Episode Statistics (HES) system.

Ethnic Origin of Mother	Cases		Controls		HES data	
White	58	(68%)	141	(85%)	29911	(82%)
Black Caribbean	3	(4%)	6	(4%)	943	(3%)
Black African	0	(0%)	0	(0%)	71	-
Black other	0	(0%)	0	(0%)	222	-
Indian	9	(11%)	4	(2%)	1680	(5%)
Pakistan	10	(12%)	9	(5%)	2452	(7%)
Bangladesh	0	(0%)	4	(2%)	539	(2%)
Chinese	1	(1%)	0	(0%)	101	-
Other	4	(5%)	2	(1%)	520	(1%)
Total	85	(100%)	166	(100%)	36439	100%
Unknown	1	-	4	(2%)	29099	excluding unknown

From the parental interviews

There were only three questions to which there was a significant difference in answers between the cases and the controls:

- Do you remember any change in the way your baby moved at any time during your pregnancy which was different enough for you to consider telling someone else?
- Did you at any time in the 4 weeks before your baby was born have any other (non-CTG) tests?
- Did you have any pain in the abdomen above or below the umbilicus that lasted more than one hour at any time during your pregnancy and which was bad enough for you to tell someone else?

All of these questions are susceptible to recall bias. Even accounting for this, the relatively large proportion of the normal pregnancies that recorded changes in movement (35%) or significant abdominal pain (44%) preclude these questions as having a value in screening prospectively for a high risk group.

From the enquiries

There was a significantly greater proportion of grade 2 and 3's in the cases (Table 5.4). These results show an association between more serious levels of suboptimal care and the loss of a baby. However, it is difficult to assess the effect of the knowledge by the panel of the outcome on the grade given. Using grade 2 and above to reflect at least a moderate degree of suboptimal care then this occurred in 15% of controls in which a good outcome was observed and 62% of the cases. Moderate suboptimal care occurred in all of the presumed impaired glucose tolerance group and in 16 of the 22 cases associated with IUGR.

Table 5.4: The overall grade of suboptimal care in the cases and matched controls Chi Sq.= 47.05, df=3, P<0.0001

Overall grade	Cases		Controls	
0	8	(15.4%)	66	(63.4%)
1	12	(23.1%)	22	(21.2%)
2	19	(36.5%)	15	(14.4%)
3	13	(25.0%)	1	(1.0%)
Total	52	100%	104	100%

5.4.2 **Non-significant Findings:**

From the case records

For all other factors (social class, age, parity, smoking, booking risk assessment) no significant difference was found. Because the study numbers are small it is likely that statistical comparisons on the existing data set will fail to detect a significant difference when a true difference exists (under-powered). For example, if the study is to demonstrate that smokers are twice as likely to have a death as non-smokers, then assuming 15% of the parents who have a healthy baby smoke, then 500 women are required to be in the study to detect this with reasonable confidence. A smaller study will not show the difference when a statistical test is performed. This reservation precludes conclusions being drawn from the limited numbers in the pilot.

	Cases	Controls	Odds Ratio (95% CI)
Smoking at booking	21 (24%)	65 (15%)	1.79 (0.9-3.4)

From the parental interviews:

As with the comparison with the case records no significant difference was found in nearly all the factors enquired.

The parental interviews provided information not in the medical records and sometimes at variance with information in the medical records. For example, of the 55 mothers who admitted smoking during pregnancy at interview, their medical records showed that 17 of this group were classified as non-smokers at booking.

5.5

CONCLUSION

The initial study was intended to take place in two regions and aimed at recruiting 200 cases and 400 controls. The organisational difficulties of approaching all district local research ethical committees in North Thames resulted in the study being under half the original planned size and this limited any conclusions being drawn from case control comparisons.

The methods and processes of the study succeeded in high levels of ascertainment, autopsy consent, centralised pathology providing consistent comparable reports and parental interview. High quality postmortem information and clinical detail permitted an in depth review of the causes of death. No explanation or associated condition for the cause of death was found in 27 out of 86 cases (31%).

Parental interviews provided information not in the medical records and sometimes at variance with information that was present in the medical records. Many of the questions were subject to recall bias affected by the occurrence of stillbirth.

Panel enquiries of 'normal' controls were curtailed because of excessive workload. The cases had an increased frequency of suboptimal care compared to controls. However, the panel assessments were not blind to the outcome and this may have influenced the judgement.

It is important to examine the relationship between ethnic origin and perinatal mortality. Ethnic origin has only been recorded routinely in hospital records since April 1995 and there have been substantial technical problems in collecting the data within the NHS (Hospital Episode Statistics system). Consequently, no appropriate denominator data exists. However, these findings and others suggest significant differences in death rates and underlying causation³. Future work aimed at providing a denominator is essential to clarify these issues.

The difficulty of devising a classification of perinatal mortality that satisfies obstetricians, neonatologists, pathologists and epidemiologists has been described by Wigglesworth⁴. Further work in developing a clinico-pathological classification of this heterogeneous group will aid in understanding the aetiology. The study highlights the high

proportion of deaths amongst fetuses with associated growth restriction. A detailed exploration of the relationship between fetal growth and term stillbirths is ongoing.

Implications for future studies

Priority in a future study should be given to the feasibility of achieving appropriate numbers of cases and controls. The major problem in SATS was the failure to gain ethical consent on a regional basis. The introduction of Multi-Centre Research Ethics Committees (advising on research proposals carried out within five or more Local Research Ethics Committees) will streamline and hasten this process in the future whilst also maintaining the autonomy of the Local Research Ethics Committee.

A case control study is the correct approach for investigating aetiology in unexplained deaths because of the infrequency of the event. A random selection from a population based sample frame may be considered as an alternative to 'matching' the controls⁵. Future studies addressing aetiology are likely to require at least two controls for each case to increase the power. As panel enquiries involving 'normal' controls are deemed to be work intensive and are unlikely to generate new hypotheses they are unlikely to be incorporated in the design.

Parental interviews produce information that is not accurately available from case records and future studies should concentrate on details that are not highly susceptible to recall bias. In addition, alternative approaches such as thematic analysis of transcribed parental interviews should be considered.

Antepartum term stillbirths make a significant contribution to perinatal deaths and, as such, remain a priority area for future investigation.

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6

FOCUS GROUP - PLACE OF DELIVERY

A review of 22 cases of planned home birth associated with the death of the baby

6.1 BACKGROUND

Home birth is a rare event, occurring in only 1.84% of total births in England, Wales and Northern Ireland in 1994 and 1995^{1,2}.

Following the publication of the 4th Annual Report of CESDI, the Maternal and Child Health Research Consortium commissioned a separate in-depth analysis of the data collected on deaths occurring amongst women who either delivered at home or had a significant proportion of their labour at home. It was decided to examine in particular those women whose intention at the onset of labour was to deliver at home.

The aim of the Focus Group was to highlight issues of concern from a review of the casenotes, and to make recommendations about best practice for those involved in providing maternity care in the home.

6.2 METHOD

This was a retrospective casenote review of a very small sample. Data on intended place of delivery are not collected and therefore no denominator could be established for this group of cases. Hence, the matter of relative risk could not appropriately be addressed. (See section 6.4)

The Focus Group comprised 3 obstetricians, 2 General Practitioners, 1 paediatrician, 3 midwives, 1 Public Health specialist and 1 lay representative.

The anonymised casenotes from all the enquiries into stillbirths (SB) and neonatal deaths (NND) in 1994/95, with a birthweight of 2500g or more and excluding malformations, who either delivered at home or had a proportion of their labour supervised at home, were collected from the regions.

The cases were divided equally between the members of the Focus Group. The cases were reviewed independently by two members of the group, who were paired to balance special interests. Answers to a list of questions were compiled.

6.3 FINDINGS

An original group of 38 women was identified. Of these, 6 were excluded because their intended place of delivery was hospital, 2 because they planned to deliver in a GP Unit and 8 who had no record of the intended place of delivery. The group studied was therefore 22. (See Table 6.1).

Table 6.1: Number of intrapartum related stillbirths and neonatal deaths weighing by 2.5kg enquired by CESDI in relationship to planned place of delivery.

	1994	1995	Total
Planned home, delivered at home	4	7	11
Planned home, transferred to hospital during labour	5	6	11
SUB TOTAL	9	13	22
Unplanned home - concealed pregnancy and unattended delivery	2	5	7
Unplanned home - booked for hospital delivery	7	2	9
SUB TOTAL	9	7	16
All other deaths	451	484	915
Total births at domestic addresses(ONS/ GRO data)	11,925	12,559	24,484
All other births not at domestic addresses (ONS/GRO data)	679,943	662,386	1,342,329

The 22 cases were categorised after review into four categories outlined in Table 6.2 in order to identify those women who were considered to be of low obstetric risk.

Table 6.2: Categorisation of cases taking into account obstetric criteria for home birth and degree of support for decision

Category	
A	There were no breaches of low obstetric risk criteria for home birth; midwifery and medical professionals were fully supportive of the chosen place of delivery.
B	There were breaches of low obstetric risk criteria for home birth which were recognised by the professions concerned, but at least one midwife or one doctor agreed willingly to support home birth.
C	No breaches of low obstetric risk criteria for home births, but there was no formal professional agreement to support a home birth. Plans were made for its support in order to comply with a duty of care.
D	There were breaches of low obstetric risk criteria for home birth and there was no formal professional agreement of support. Plans were made for its support in order to comply with a duty of care.

The breakdown of the categories of the 22 cases was: 11 in A, 6 in B, 4 in C and 1 in category D.

In the majority of the category C cases, concerns from the professions were related to the home environment or social circumstances of the mother, rather than obstetric risk factors. (The criteria for assessment of low obstetric risk are set out at Appendix 2).

6.3.1 Outcomes

The cases have been divided into those resulting in a stillbirth and those born with a heartbeat, but who subsequently died as a neonatal death. The salient factors in the cases are summarised in Tables 6.3 and 6.4.

Table 6.3: - Stillbirths

Case No.	Place delivered	Comments	Category at end of pregnancy
1	Home	Woman reluctant to attend ANC. Did not call M/W for 5 hrs. Multip; previous home delivery; cord prolapse. SVD.	C
2	Home	P2; undiagnosed breech; cord prolapse. Fresh SB. Inadequate experience of midwife in conducting breech delivery.	A
3	Home	P1; unable to find midwife when in labour; hospital midwife went out but on arrival cervix fully dilated and no FH heard; delivered fresh SB. Problem in contacting community midwife. Women must have back-up person to contact.	A
4	In transit	P3; on arrival could not identify FH; decision to transfer 2 hrs later; but delivered in transit of fresh SB; delay in seeking help. "Difficulty in hearing FH" is usually an ominous entry in any notes. Confirmation of presence/absence of FH by doppler method advised.	A
5	Hospital	P3; massive abruption during labour, transferred to hospital, absent FH on admission. Poor communication - parents not told for some time that no FH audible after transfer to hospital.	B
6	Hospital	P2; prolonged 2nd stage so transferred to hospital; abnormal CTG on admission (pH 7.05); prompt emergency C/S but fresh SB resulted. Early transfer when problems arise advised.	A
7	Hospital	P3; fetal bradycardia, transferred to hospital; transfer time 2 ¹ / ₂ hrs; 4.38 kg. Delay in contacting delivery suite after difficulty in hearing FH. Sent to A&E, thus delaying arrival at D/S.	A
8	Hospital	P3; previous C/S; FH abnormalities noted at 8 cm dilatation; arrived on labour ward 3 hrs later; C/S performed after some delay in assessment, fresh SB. Delay in decision to transfer, and in making transfer arrangements in high risk woman. Poor care in hospital also a factor.	B
9	Hospital	P5; 2 previous home births; uncertainty about FH from onset; transferred to hospital for delivery. Difficult to contact community midwife, delayed arrival.	A
10	Hospital	P0; fetal bradycardia so transferred to hospital; no FH on admission; transfer time 39 mins.	C
11	Hospital	P2; intrapartum abruption and FH abnormalities at home; transferred to hospital and baby delivered 1 hr later by C/S. Some delay in decision-making and performing C/S in hospital. Delay in calling a paediatrician, further delay in arrival due to split site. Team needs to be available at admission.	A

Table 6.4: - Neonatal deaths

Case No.	Place delivered	Comments	Category at end of pregnancy
12	Home	PO; shoulder dystocia, born in poor condition; transferred to hospital at 28 mins, but started to fit by 9 hrs. No clear record of FH between contractions prior to appearance of meconium. Delay in calling for help.	B
13	Home	P1; previous home delivery; long 2nd stage and baby in poor condition at birth; transferred to hospital at 17 mins; pH on admission 6.50. Failure to transfer multip with prolonged 2nd stage and bradycardia.	B
14	Home	P0; living in remote location; uneventful labour but baby in poor condition at birth - mother declined episiotomy to expedite delivery. No-one able to ventilate at home; transferred to hospital but died in transit.	C
15	Home	P3; uneventful labour but baby in poor condition at birth; transferred to hospital but care withdrawn after 2 days. Prolonged rupture of membranes - midwife not informed.	A
16	Home	Primip; baby born in good condition at home but mother transferred to hospital for PPH; baby collapsed on postnatal ward; congenital pneumonia on postmortem. Presence of meconium not notified to anyone.	A
17	Home	Multiparous client, but insistent on home birth despite many problems and pregnancy complications. Long labour and baby born in poor condition; transferred to hospital but baby died on Day 1.	D
18	Home	P3; uneventful labour but baby born in poor condition; transferred to hospital but died; PM report showed intrapartum anoxia. Inappropriate to maintain as home delivery because of raised B/P, gross obesity.	B
19	Home	P2; unable to find team midwife when in labour so hospital M/W sent out but had difficulty finding house; unattended delivery, baby in poor condition; transferred to hospital but died on Day 2. For clients in remote locations, "dry run" should be done by midwives likely to be on call.	A
20	Hospital	P2; transferred to hospital for delay in first stage of labour but delivered vaginally; went home after 6 hours but baby re-admitted on Day 3 in poor condition and subsequently died; PM showed pyogenic meningitis. Screening issues of early discharge babies.	A
21	Hospital	PO+3 with poor obstetric history; insisted on home delivery against advice. Fetal bradycardia so transferred to hospital; transfer time over 1 hr - waited for GP to arrive and confirm transfer; emergency C/S; baby in poor condition, care withdrawn on Day 5. Delay in notifying bradycardia, GP not best person to call in this circumstance.	C
22	Hospital	Primip; fetal bradycardia; abruption; transferred to hospital; transfer time 3 hrs 10 mins, emergency C/S; born in poor condition, dying at 12 hrs. Transfer delays.	B

6.3.1.1 Stillbirths

Three of the 11 stillbirths were delivered at home, a fourth in transit to hospital. Of the remaining 7 delivered in hospital, in 4 cases (Nos 5, 7, 9, 10) there was no fetal heart rate (FHR) on arrival in hospital. In 2 cases the presence of a FHR was uncertain and despite an emergency caesarean section (C/S), a fresh stillbirth resulted and in the remaining case (No 8) a FHR was present on arrival but delays in expediting delivery resulted in a SB. In this case there had been in addition a prolonged interval in the decision to transfer into hospital despite the presence of fetal distress.

6.3.1.2 Neonatal deaths

Eight of these 11 babies who were subsequent neonatal deaths were delivered at home and then transferred into hospital for varying reasons. The predominant reason for transfer following delivery at home was that in 7 cases a baby was in poor condition and had low Apgar scores at birth. This was either following difficulty at delivery (No 12 - shoulder dystocia), or following a prolonged difficult labour with the woman declining transfer (No 17). However, in most cases delivery occurred following an apparently uncomplicated labour but the babies required resuscitation. In No 19 the baby had already been delivered by the time the hospital midwife arrived, in the absence of the community midwife who could not be contacted.

One baby (No 16) was born in good condition and transferred in with the mother who had suffered a primary PPH. The baby collapsed on the postnatal ward on Day 2 and subsequently died. A postmortem (PM) identified congenital pneumonia. It is noted that there was meconium passed during labour which was not followed up in any specific manner, and the infection is presumed to have been acquired during labour.

The remaining 3 neonatal deaths occurred in babies born in hospital following transfer in labour. In 2 cases (Nos 21 & 22) fetal distress occurred in labour at home, transfer times were prolonged and despite emergency C/S the babies were born in poor condition - one following a placental abruption. In No 20, the mother was transferred in because of prolonged labour, was delivered vaginally in hospital of a healthy baby and discharged home at 6 hours. The baby was re-admitted on Day 3 and died of pyogenic meningitis, thought to have been related to infection contracted during the prolonged labour.

6.3.2 Suboptimal care grades

Table 6.5 shows the distribution of the 'overall' grades given by the panels in 1994-1995 for the 22 cases. The planned home births group were no more likely to have suboptimal care than the other deaths in the enquiries ($p=0.37$).

Table 6.5: Grades of suboptimal care described in the 1994-1995 enquiries for the 22 cases of planned home birth, a subset of the 873 intrapartum related deaths and of the total 1266 enquiries

	Planned home birth	Wigglesworth 3	All enquiries
Total cases (n)	22 (100%)	873 (100%)	1266 (100%)
Ungraded	0	4 (0.5%)	8 (0.5%)
Grade 0 or 1	5 (23%)	195 (22%)	392 (31%)
Grade 2	7 (32%)	219 (25%)	326 (26%)
Grade 3	10 (45%)	455 (52%)	540 (43%)

6.3.3 Suboptimal care issues

6.3.3.1 Identification and management of fetal distress

In a number of cases, there was difficulty in confirming the presence of a fetal heart rate. In addition, there was often substantial delay in seeking further assistance or arranging transfer. In other instances, fetal bradycardia and/or the passage of meconium was recorded but not acted on.

6.3.3.2 Unexpected occurrences in labour

The importance of correctly diagnosing a malpresentation in early labour to facilitate transfer is clearly demonstrated by case No 2, in which the midwife had to deal with a breech delivery in the home setting.

6.3.3.3 Neonatal resuscitation

Inadequate resuscitation is an infrequent cause of death in the intrapartum related studies of hospital births. In the homebirth group, resuscitation equipment and/or skills were mentioned as contributory factors in 4/22 cases. The non-availability of basic resuscitation equipment such as bag and mask demonstrates inadequate preparation for this potential hazard. However, the number of cases that might be rescued by optimal resuscitation is small.

6.3.3.4 Communication issues

A variety of communication problems were identified. These included difficulties in contacting the midwife once labour had commenced (3 cases) and one instance where there was difficulty in finding the community midwife. A hospital-based midwife who was unfamiliar with the remote location of the home was delayed in arrival. In several other instances, there was delay in seeking assistance when problems arose, or failure to contact the appropriate individual on labour ward to inform them of a transfer in advance.

In some cases, poor communication with parents seems to have been an issue, and resulted in delayed consent to transfer. Such issues are not always well documented, so the exact extent of this problem could not be defined.

The availability of a phone in the house, and the provision of a mobile phone to the midwife, should help in promoting quick and easy communications between the mother, her carers and the hospital and ambulance services.

6.3.3.5 **Transport issues**

The group identified two instances of undue delay in response times (more than 1 hour) of the Ambulance Service (Nos 21 and 22). In the other cases transfers occurred within 17 minutes to 1 hour, and the longer times were not necessarily related to remote locations. Distance from a maternity unit may play a part, but traffic conditions in urban areas can also contribute to delays.

6.3.3.6 **Response by hospital following transfer**

The transfer to hospital in labour of a woman booked for home delivery only occurs when a problem arises which has or could compromise the mother or the baby. It is essential, therefore, that the labour ward is forewarned of such transfers, and the most experienced obstetrician and midwife on duty are available for immediate assessment. Confirmation of the presence or absence of the FHR on arrival by doppler or ultrasound is vital. In several instances of emergency C/S with resultant delivery of a stillbirth, it appears that the baby had died prior to the decision being taken to proceed to C/S. In the presence of fetal distress, appropriate assessment of whether to deliver immediately or allow continuation of labour must be made by an experienced obstetrician.

Transfer directly into the labour ward is essential. The woman should not be admitted via the A&E department (No 7). Availability of paediatric and anaesthetic staff on site are desirable for dealing with such transfer cases to enable immediate operative delivery, if indicated (No 11).

6.3.3.7 **Record-keeping**

The lack of adequate recordings of the FHR, maternal vital signs (temperature, pulse, blood pressure) and labour progress was noted in several of these cases. Clear documentation of all these features can be achieved by the use of a partogram, which would also alert the individual when a delay in progress of labour is apparent. The group emphasised the need to record clearly discussions and decisions made with the mother; such records must be timed and signed. This statement refers not only to discussions in relation to management in labour but also to decision-making concerning place of delivery.

6.3.4 **Difficulty in obtaining professional support for home delivery**

In only 1 case (No 17) were there clear breaches of the criteria for home birth. In a further 4 cases professionals were unhappy about providing care for a home birth. These women did not have absolute breaches of obstetric criteria, but concerns were expressed about the facilities available at home, or the social/lifestyle setting. The professionals were providing support in order to comply with a duty of care, and the

quality of rapport may not have been as good as in those cases where professionals were supporting the woman's decision to deliver at home.

Some women insisted on a home birth regardless of the advice they were given, and may have delayed calling the midwife when labour commenced (Nos 1, 15 and 17). Whether they had lost confidence in the professionals because of previous obstetric experiences is uncertain, but the degree of trust the mother has in her carers is an important factor wherever birth occurs.

6.4 **DISCUSSION**

Twenty-five to thirty years ago, many general practitioners would have had experience of managing home births, and community midwives would also have been responsible for significant numbers of home deliveries each year. The centralisation of obstetric services to within hospital maternity units has resulted in the majority of general practitioners now having no experience of home birth, with fewer than 2% of total deliveries occurring at home. In addition, many midwives do not gain experience of home births.

A comprehensive study of home birth in the United Kingdom was recently published³. This suggested that to try and ensure optimal maternal and neonatal outcomes for planned home births, it is essential to have access to and to make appropriate use of secondary care when required.

The enquiry process for these 22 cases identified substandard care of grade 2 or 3 in 77% of planned home births where a death occurred. This is comparable to the 69% in all intrapartum related deaths reviewed in the 1994/1995 Confidential Enquiry process.

Not all problems which arise in labour can be foreseen. It is therefore probable that, even amongst women who are considered by professionals to be of low obstetric risk, serious complications will sometimes occur. It is necessary that all professionals involved in providing community-based maternity services are able to cope with such complications. Their skills and experience will also be vital in providing care to those women who choose home birth despite having some obstetric risk factors identified by professionals.

Where unexpected problems do arise in the community setting, there will be considerable stress and worry for the woman, her family and her carers. Good telephone facilities (both fixed and mobile) will lessen the risk of delay in cases where transfer is required. The inevitable delay in reaching a unit where specialist care is available will be minimized if there is a positive relationship of trust between the woman and her carers, enabling a decision to be taken quickly when needed. Lack of trust may have arisen from previous negative experiences of childbirth. If women are given the opportunity to debrief after such an event, it may contribute to restored trust in

professional carers for future deliveries⁴. This could reduce the number of instances where delay contributes to the loss of or damage to a baby.

We are unable to assess absolute or relative risks between planned home birth and hospital delivery in this study, since denominator data for planned place of delivery are not collected. Amongst those who deliver at home are a variable number booked for hospital delivery, as well as unbooked and concealed pregnancies. Amongst the hospital deliveries, there is a proportion originally booked for home delivery. The proportion of home deliveries actually planned for home delivery varies between 65% and 85% from two studies,^{5,6} but what proportion this is nationally is unknown.

A series of articles in the British Medical Journal in 1996 looked at the outcome of planned home births versus hospital delivery in a variety of differing studies and settings⁷⁻⁹. These reports support the relative safety of home births in women at low risk of obstetric complication, as did a recent meta-analysis¹⁰. However, not all women choosing home delivery will be in the low risk category.

Comparative studies of home versus hospital births, with the exception of a randomised control trial, are likely to suffer from selection bias. Archie Cochrane berated the profession in the 1970s because it had ‘...missed its first opportunity in the sixties ... to randomise the confinement of low risk pregnant women at home and in hospital’¹¹. Now, due to the impracticalities of recruitment in the 1990s, it has probably missed its final opportunity¹².

A precise risk figure for an intrapartum death in a planned home delivery is likely to remain unattainable in the absence of routine data collection on the outcomes of all such deliveries. For example, if the true risk for this event is 1 in 1000, a survey of 11,000 planned home deliveries would provide estimates ranging between 1 in 560 and 1 in 2000, 95% of the time. The meta-analysis of the safety of planned home births combines all existing well designed comparative studies, and has outcomes on 24,092 births¹⁰. Even this number is too small to confidently detect a 2-fold increase in the risk of such a rare outcome as intrapartum death between home and hospital.

However, the difficulty in estimating these risks should not discourage attempts to acquire information on the safety of planned home birth. Meanwhile, it is necessary for health professionals to appreciate the limitations of the interpretation of such risk values when presenting information regarding such rare serious events.

6.5 **RECOMMENDATIONS FOR PRACTICE**

Whilst the number of cases represented in this review is small, there were enough similar scenarios highlighted for the Focus Group to suggest a number of recommendations for consideration by all the professionals involved in providing care to women who deliver at home.

6.5.1 **Informed Choice**

Local evidence-based protocols defining low obstetric risk criteria need to be developed by hospital and community staff, and user groups should also be involved in the process.

Women should have available to them written evidence-based information, such as that contained in the MIDIRS Informed Choice leaflet¹³, to assist them in making their choice concerning place of delivery.

6.5.2 **Communications**

If possible, a woman planning to deliver at home should have a telephone available. If there is no fixed phone in the home, the possibility of hiring a mobile phone could be considered, although there are locations where reception is poor or impossible. Midwives attending home births should have a mobile telephone.

When a home birth is planned, appropriate back-up arrangements should be in place so that the woman knows who to contact if her named midwife is not immediately available. In case of isolated or unusual addresses, a 'dry run' should be undertaken to ensure that staff can locate the woman easily when in labour. Ambulance services should be aware of planned home births in their area.

6.5.3 **Detection of problems arising**

Careful recording of FHR, maternal vital signs and progress in labour should be kept. This is most simply achieved by the use of a partogram.

A fetal doppler should be available to establish the presence of a fetal heart rate when there is any problem identifying the fetal heartbeat or fetal distress is suspected.

6.5.4 **Transfer arrangements**

Arrangements for transfer to hospital should be made at the earliest indication, by whichever professional is present. Where a midwife feels transfer is needed and the woman agrees, this should be done as soon as possible. Waiting for e.g. the GP to arrive and confirm the decision is rarely appropriate.

Hospital staff must be forewarned of the transfer and the reasons for it. Staff of appropriate speciality and seniority should be available to meet the woman/baby in order to assess the situation and decide on further management.

6.5.5 **Resuscitation**

Appropriate equipment for neonatal resuscitation and adequate training in its use should be available to any professional undertaking or sent to conduct a home delivery. Regular updates and practical sessions in the use of bag and mask ventilation should be undertaken.

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13. MIDIRS Informed Choice leaflet No 10 (1997)

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Dr F Alderdice, Health Services Research Fellow, Health and Health Care Research Unit, Belfast

Mrs V Bailey, Senior Midwife, Nottingham Health Authority

Ms L Bennett, Midwife, Bristol

Mr R H Golding, Consultant Obstetrician & Gynaecologist, Newport, S Wales

Mrs N Jakeman, Midwife, CESDI Secretariat (from November 1997)

Dr M Macintosh, Director of CESDI (from August 1997)

Mary Newburn, Head of Policy Research, National Childbirth Trust

Mr R S Settatee, Director of CESDI (until August 1997)

Dr L Smith, General Practitioner, Somerset

Prof A R Wilkinson, Dept of Paediatrics, John Radcliffe Hospital, Oxford

Mrs C Winter, Midwife, CESDI Secretariat (until October 1997)

Dr G Young, General Practitioner, Cumbria

7

FOCUS GROUP - RUPTURED UTERUS

A review of 42 cases of ruptured uterus associated with the death of the baby

7.1 BACKGROUND

7.1.1 Uterine rupture is a rare event resulting in significant morbidity to both the mother and baby. No accurate figures are available for its occurrence in the UK because documentation of this event is not systematically collected. It is estimated to occur in between 1 in 140 and 1 in 300 women who labour with a pre-existing uterine scar^{1,2}.

7.1.2 In 1996 a multidisciplinary group was set up to report on the 42 cases of intrapartum fetal deaths associated with rupture of the uterus that were identified in England, Wales and Northern Ireland during 1994 and 1995. These were a subset of the 873 normally formed babies weighing over 1.5 kg at birth, who were considered to have died as a result of intrapartum events. The Focus Group comprised four obstetricians, a paediatrician, a perinatal pathologist, three midwives and a lay member of the National Advisory Body; the Group met on three occasions.

7.1.3 Table 7.1 shows the distribution of the 'overall' grades given by the panels in 1994-1995 for the 42 cases. For comparison the grade given to the 873 intrapartum related deaths and to the total 1266 enquiries is shown.

Table 7.1: Grades of suboptimal care defined at the 1994-1995 enquiries for the 42 cases of uterine rupture, a subset of the 873 intrapartum related deaths and of the total 1266 enquiries.

	Uterine Rupture		Intrapartum Related Deaths		All Enquiries 1994-1995	
Total cases (n)	42	100%	873	100%	1266	100%
Ungraded	0	0%	4	0.5%	8	0.5%
Grade 0 or 1	2	6%	195	22%	392	31%
Grade 2	8	19%	219	25%	326	26%
Grade 3	32	75%	455	52%	540	43%

The uterine rupture group contained a significantly greater proportion of grade 3s than the other deaths in the enquiries (1266) ($p < 0.001$). Thus, uterine rupture resulting in the death of a baby is regarded as a largely avoidable event.

7.1.4 The ultimate objective of this Focus Group was to provide guidelines for good practice in the anticipation and management of ruptured uterus. These guidelines were to be based on a combination of

published evidence and consensus within the group after studying the 42 cases of intrapartum related death associated with uterine rupture. The group was also asked to make recommendations on areas requiring further research and surveillance.

7.2 **METHOD**

All cases which were associated with a uterine rupture were identified from the 873 intrapartum deaths in 1994-1995 that had passed through a CESDI panel enquiry. The 42 anonymised medical records were divided into sets of 8 or 9; each set was given to a member of the Focus Group for review. A list of relevant data items defined by the Focus Group were extracted from all records and entered into a database. This was summarised and examined for any pattern that may not have been apparent from individual review of these cases. In addition the 1994-1995 panel comments were compiled.

7.3. **FINDINGS**

7.3.1 **Antenatal factors**

7.3.1.1 **Obesity**

The Body Mass Index (BMI) could be calculated in 35 cases; 16 (46%) were considered to be obese (BMI greater than 30). This is considerably greater than the 14% of the whole female population aged 16-54 years who are obese³.

7.3.1.2 **Uterine scar**

Thirty women had a uterine scar resulting from a previous lower segment Caesarean section (CS). All of these were single scars except for one woman who had a scar from three previous Caesarean sections. Of the 12 women with no uterine scar, one was nulliparous, three were para 1, two para 2, three para 3 and three para 4.

7.3.1.3 **Enquiry Comments - antenatal issues**

The enquiry panels made a total of 21 comments pertaining to antenatal management. The most frequent criticisms were:

- the absence of a record of a plan for delivery (5)
- failure to involve 'senior' staff in antenatal management (4)
- inappropriate decision regarding induction or delivery plan (4)

7.3.2 **Labour and Delivery**

All but one scar rupture was confirmed at laparotomy. Nine of these 41 cases required a hysterectomy. There were four cases presenting following delivery, three following collapse of the mother and one where the mother was incontinent of urine and a vesico-uterine fistula was diagnosed thirty six hours following delivery. There were no maternal deaths.

7.3.2.1 **Induction and Augmentation**

The uterine rupture occurred during: spontaneous labour (7), induction of labour (25), and augmentation (10). The relationship of these factors to the presence or absence of a scar is shown in Table 7.2.

Table 7.2: The 42 cases classified by presence of scar, spontaneous labour, augmentation and induction

	Pre-existing scar	No scar	
Spontaneous labour	7	-	7
Augmentation	5	5	10
Induction	18	7	25
Prostaglandin alone	14	5	
Prostaglandin + syntocinon	4	2	

The induction rate for all labours in England, Wales and Northern Ireland is 20%⁴ and is likely to be lower in women with a pre-existing scar. The fact that induction occurred in 18/30 (60%) of these cases suggests that it might be a notable risk factor in this setting. Although details were not always available many inductions involved situations of a 'high head and unfavourable cervix'.

7.3.2.2 Prostaglandin

In the eighteen inductions involving a pre-existing scar prostaglandin was the sole agent used in fourteen. The dose regimes used are shown in Table 7.3; in general these were within the recommended range⁵. The dose of prostaglandin was repeated in 10 of 17 cases. In one case the dose was grossly in excess of that commonly used for induction. In the seven inductions involving multiparous women prostaglandin was the sole agent used in 5 cases. Two cases had doses (2mg) above the recommended initial dose of 1mg gel for this group.

Table 7.3: Prostaglandin regime used in inductions of labour

Dose regime	Numbers
Previous scar	
1mg x 1	1
1mg x 2	7
2mg x 1	1
2mg x 2	1
3mg x 1 (tablet form)	1
3mg x 2 (tablet form)	1
3mg x 2 + 6mg x 1 (tablet form)	1
Regime not known	1
No previous scar	
1mg x 1	2
2mg x 2	2
3mg x 1 (tablet form)	1

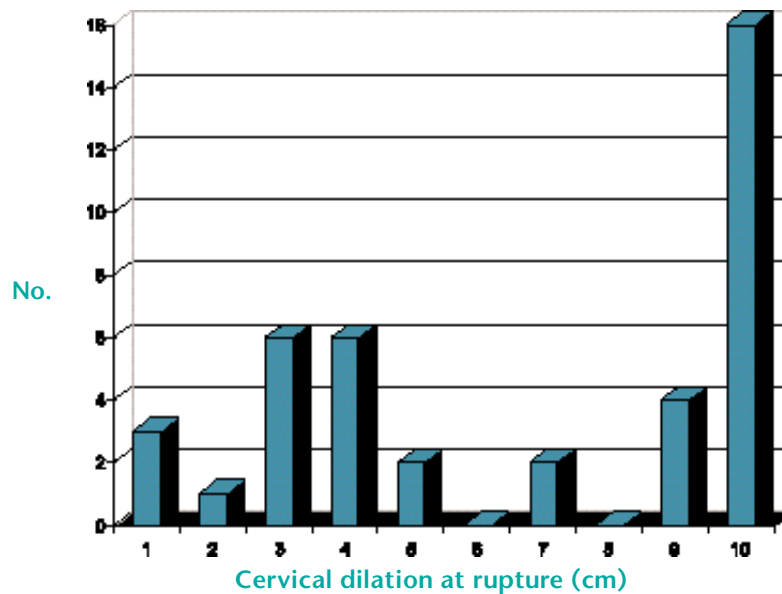
7.3.2.3 Syntocinon

There were 10 cases in which syntocinon was used to augment labour. In 8 of these the indication was slow progress at or near full dilatation (9cm or more) and diminished contractions. This group comprised two breech presentations, two trials of scar and four multiparous labours.

7.3.2.4 Cervical dilatation at time of rupture

This was estimated from the last observation recorded in the notes prior to laparotomy. Most ruptures occurred at (16/40) or close to full dilatation (4/40) (Figure 7.1)

Figure 7.1 Last recorded cervical dilatation at time of rupture



The second stage lasted for more than 2 hours (range 2 hours 4 minutes to 5 hours 30 minutes) in 5 women (1 with a previous scar, 4 with no scar).

7.3.2.5 Presence of warning signs

Scar pain and tenderness (21), vaginal bleeding (5), poor progress in labour (less than 1cm/hour - 10) or fetal heart abnormality (persisting for more than one hour - 17) were the features most commonly described. In most cases there were multiple features.

In 18 of the 42 cases the first diagnosis was made at laparotomy performed for other reasons such as fetal distress or presumed abruption. In three there were no apparent clinical warning signs other than acute fetal distress or maternal collapse.

7.3.2.6 Scar pain

Severe pain is one of the classical features of uterine rupture. In this series there were 8 cases where despite evidence of maternal distress there was a failure to recognise this as a sign. Pain was absent or not recorded in half of the cases. It is always possible that significant pain had existed but was not reported by the women or not observed by the carers or masked by the presence of an epidural analgesia. A retrospective review cannot distinguish between these options.

7.3.2.7 **Progress in labour**

Failure to recognise or act on slow progress occurred in 8 cases. There was an equivalent number where the use of syntocinon was an inappropriate response to slow progress and diminishing contractions at or near full dilatation in multiparous women (4), trials of scar (2) and breech presentation (2).

7.3.2.8 **Fetal heart surveillance**

Some abnormality of the fetal heart in addition to that seen as an acute response at the time of rupture is commonly observed. Failure to recognise or act on this occurred in 11 cases and in 7 cases there was inadequate monitoring.

7.3.2.9 **Pre-term rupture**

There were three occasions on which rupture of the pre-existing scar occurred pre-term (two at 32 weeks and one at 36 weeks). Two cases presented at 32 weeks and had a history of previous Caesarean sections at 26 weeks and 31 weeks respectively. During the current pregnancy both had had admissions for 'threatened' pre-term labour. The third case presented at 36 weeks and had a history of 3 previous Caesarean sections.

7.3.2.10 **Enquiry Comments - Intrapartum issues**

A total of 99 comments were made by the panels pertaining to intrapartum issues. These were as follows:

- Inadequate surveillance and /or interpretation of the fetal heart rate (26)
- Failure to assess and recognise: slow progress (9); abdominal descent/tenderness (3); maternal observations (2); the presence of a previous scar (2); the rupture (11); need for delivery (1)
- Lack of supervision by 'senior' staff (11)
- Inappropriate use of syntocinon (10)
- Inappropriate use of prostaglandin (8)
- Inappropriate location for induction of a trial of scar (6)
- Delay in transfer to operating theatre (5)
- Communication (1)
- Other (4)

7.3.3 **Organisational Factors**

7.3.3.1 **Location of labour and accessibility of skilled staff**

The location of the place of delivery was notable in two cases. One case was a mother who had been accepted for a home delivery despite the presence of a previous uterine scar and who was transferred to hospital in labour. The care given in the home setting was considered appropriate but notable problems arose when she was in the hospital. In the second case the absence of a resident theatre team resulted in delayed delivery.

There was one case where there was no anaesthetist available for 25 minutes.

It was notable that part of the process of induction was carried out distant from the labour ward in 13 of 25 cases. Of these 13, 10 were trials of scar.

7.3.3.2 Experience of supervisory staff

Failure to involve senior staff in decisions regarding induction or delivery were common. Many intrapartum judgements were being made by senior house officers or midwives and were not necessarily communicated to more senior staff. However, there were also several examples of inappropriate decisions made by senior grades.

The panel enquiries had been asked for each comment to state the professional involved and their grade. A review of the 99 grade 2 and 3 comments relating to intrapartum care is shown in Table 7.4. As comments may be attributed to more than one individual, there are a total of 173 persons mentioned. As expected, the registrar or senior registrar was the most likely to be cited, followed by the consultant. Seniority level in midwifery staff was incomplete in 57% of midwife comments.

Table 7.4: The professional and their grade identified by the panel enquiries associated with the 99 grade 2 or 3 intrapartum comments.

Profession	Numbers of mentions
Obstetric staff	
Consultant	34
Registrar or senior registrar	54
Senior House Officer	24
Ungraded	12
Total	124
Midwives	
G grade or 'Sister'	7
Staff midwife	10
Community midwife	1
Ungraded	24
Total	42
Anaesthetists	
Consultant	2
Senior House Officer	1
Ungraded	2
Total	5
Paediatrician	
Ungraded	1
Patient or Family	1

7.3.3.3 Record-keeping

There were 8 cases where record keeping was judged by panels to be of poor quality. In 2 cases it was clear that the notes were non contemporaneous. In 9 cases no cardiotocograph was available. In fourteen cases no partogram was available. Sometimes this was because the presentation necessitated immediate laparotomy, but in 5 there was failure to use the partogram despite information being in the notes. There were several examples where the time intervals used on the partogram were not consistent; a 1cm space was used to represent anything from 10 minutes to 1 hour, all within the same partogram, suggesting misunderstanding of its graphic function. There were several designs of partogram. In particular, symbols used for head descent on some are used for cervical dilatation on others. Descent of the head in the abdomen (fifths palpable) and of the presenting part (the station recorded as distance above or below the ischial spines) are not readily distinguished in most partograms. These factors could contribute to misinterpretation of progress.

7.4

DISCUSSION

The Focus Group did not examine cases of uterine rupture in which the baby survived, nor did it have national data on delivery outcomes of women after Caesarean section. Unfortunately, there are no accurate figures of the occurrence of uterine rupture in the UK or of the proportion of women that have had a previous Caesarean section at booking. This lack of comparative data limits the interpretation of the findings. However, Caesarean section rates in England have risen from 10.4% in 1985 to 15.5% in 1994-95⁶ and the management of women with a previous CS scar is therefore becoming more frequent. The risk of uterine scar rupture has been estimated at 0.3% to 0.7%^{1,2} and the death of the baby has been estimated to occur in approximately a tenth of all uterine ruptures⁷. It is notable that these figures are based on practice that occurred between ten and twenty years ago and may not be relevant today.

Despite the paucity of current information, uterine scar rupture resulting in the death of a baby is a rare event. However, women with a previous uterine scar are considered to be 'high risk' and as such require experienced obstetric involvement in both their antenatal and intrapartum care. This applies particularly to decisions about induction and augmentation. Intensive intrapartum surveillance of mother and fetus is mandatory in all such cases, even though some ruptures may occur without clinical signs.

Substandard Care

Most of the cases had care that was considered to be suboptimal by a CESDI Panel. They appeared not to have been managed as 'high risk' patients. Common failures included: inadequate antenatal recognition of risk; inappropriate decisions regarding induction; inappropriate settings for induction⁷⁵; lack of involvement of senior staff; failure to provide adequate fetal surveillance in labour; and lack of recognition of the overall clinical picture.

All but three of the 42 cases had some impending clinical signs of scar rupture, yet in 18 the diagnosis of ruptured uterus was only made at the time of laparotomy. This suggests a lack of awareness of the clinical scenario leading to this event which is an important reminder for those training staff in intrapartum care.

Prostaglandin

The British National Formulary identifies a previous Caesarean section as a contra-indication to the use of prostaglandin, but nevertheless it is commonly used for this purpose⁸. There is only 1 randomised controlled trial evaluating a single dose of prostaglandin with oxytocin for labour induction in 42 women with a previous Caesarean section⁹ which is too small to evaluate serious rare risks such as scar rupture. The largest prospective series evaluating the benefits and risks in women with a previous scar comprised 482 cases where a single dose was the standard but a repeated dose was given in 43 cases¹⁰. In this study, uterine scar damage occurred in 5 cases (4 dehiscence, 1 rupture), of which three had a second dose of prostaglandin. None of these babies died. There are no formal and substantial reports on the use of repeat doses of prostaglandins in this setting. No conclusion can be made concerning the relationship between repeated prostaglandin and scar rupture as it may have been the poor care that led to this event. However, this is a situation that should be managed with particular vigilance.

7.5 RECOMMENDATIONS FOR PRACTICE

7.5.1 **Women with a uterine scar require:**

- Antenatal management including plans for delivery and induction involving a documented discussion with an experienced obstetrician (ideally a consultant but at least SPR 4 or higher).
- Attentive intrapartum fetal and maternal surveillance in a setting where the baby can be delivered within 30 minutes.
- Involvement of an experienced obstetrician in intrapartum decisions.
- No more than one dose of prostaglandin unless great vigilance is exercised.
- Information about relevant symptoms to be reported to those caring for them in labour.

7.5.2 **Hospital units need to provide:**

- Local guidelines regarding the augmentation of labour.
- Local guidelines regarding the setting and standards of intrapartum fetal and maternal surveillance in women with a uterine scar.
- Whenever uterine rupture occurs it should be the subject of a departmental case review.

7.5.3 **Training issues:**

- All involved in intrapartum care of women must be aware of the factors that may lead to uterine rupture. In particular, they must recognise that women with a uterine scar are 'high risk' and should be managed appropriately.
- All involved in intrapartum care of women should undergo training in the use and interpretation of CTGs.

7.5.4 **Areas for future research:**

- Further evaluation of the risks of prostaglandin, especially repeated doses, in women with a uterine scar.
- A national prospective study of all women labouring with a scarred uterus.
- A review of all uterine ruptures.

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Kate Isherwood, Community Midwife, Dyfed

Mrs N Jakeman, Midwife, CESDI Secretariat (from November 1997)

Dr I Jeffrey, Perinatal Pathologist, St George's Hospital Medical School, London

Mr R Johansson, Consultant Obstetrician, Academic Dept of Obstetrics & Gynaecology, North Staffordshire

Dr M Macintosh, Director of CESDI (from August 1997)

Mr I Z MacKenzie, Reader in Obstetrics & Gynaecology, Nuffield Dept of Obstetrics & Gynaecology, University of Oxford

Mr R S Settatee, Director of CESDI (until August 1997)

Mrs C Winter, Midwife, CESDI Secretariat (until October 1997)

FOCUS GROUP - SHOULDER DYSTOCIA

A review of 56 cases of shoulder dystocia associated with the death of the baby

8.1 BACKGROUND

In 1996, the CESDI Steering Group set up a multidisciplinary Focus Group to report on the 56 cases of fatal shoulder dystocia identified in England, Wales and Northern Ireland during 1994 and 1995. All intrapartum deaths with a birthweight >2500g were subject to Regional Panel reviews in both years, so the anonymised records of all deaths from shoulder dystocia over the 2 year period were available at the CESDI Secretariat.

Learning from one's mistakes or misfortunes is a valuable attribute, and it certainly seems very sensible to use the extensive CESDI database to detect any patterns of risk or adverse aspects of management in specific clinical situations (of which shoulder dystocia and uterine rupture are obvious examples). However, there is also a fundamental problem with trying to produce guidelines for 'best practice' based on a study of those cases of shoulder dystocia who died. The CESDI database did not of course contain any information about those babies who survived shoulder dystocia, nor is there any national denominator data with which to compare the prevalence of risk factors or management strategies in the index group. Some approximate denominators were extrapolated from the large database held by the North West Thames Region.

Since the Focus Group could not provide helpful guidelines based on the management of fatally unsuccessful cases, it decided to accept as best practice the consensus of a variety of clinical reviews. Following this, the Focus Group made a series of common sense recommendations, based on these clinical reviews, and informed by the knowledge of various aspects of care that became apparent in the review of fatal cases.

The Focus Group was composed of 3 midwives, 3 obstetricians, a perinatal pathologist, a paediatrician and a lay member of the National Advisory Body, and met on 3 occasions. The objectives for the Group were laid out in the original terms of reference:

To publish guidelines for good practice for the anticipation and management of shoulder dystocia. The purpose is to reduce the number of deaths in the future for which shoulder dystocia is a cause or strong association.

The guidelines would be based on published evidence or consensus within the Group after studying the case records of all babies that died in 1994 and 1995, either directly from shoulder dystocia, or in cases where shoulder dystocia was a major feature.

The Group might also make recommendations on areas requiring further research and surveillance.

8.2 **METHOD**

At the first meeting of the Group, it was decided to compile a list of all the important details we wished to extract from each set of notes. There was considerable discussion about the definition of shoulder dystocia to be used. The CESDI secretariat had identified all those cases on their database in whom a putative diagnosis of shoulder dystocia had been made at some stage. Many showed a degree of difficulty in delivery of the shoulders, but would not necessarily have fulfilled the strict criteria used by some authors to define 'true' shoulder dystocia. Nevertheless, it was decided to include these cases in the analysis, on the basis that we were aiming to develop a set of guidelines to follow when the problem of shoulder dystocia is perceived at the time of delivery, rather than agreed by retrospective consensus. A dataset for each case was then produced by a Group member, with assistance from other disciplines when appropriate.

Preliminary results were discussed at a second meeting, and an early draft of the Report was produced for the third meeting, when conclusions and recommendations were discussed. Subsequent drafts were produced following postal communications. The Group decided to produce two reports and it is hoped that these will be published in tandem. The first contains details of patient demographics, risk factors and clinical management, and the second is confined to autopsy findings and the quality of postmortem assessments.

8.3 **FINDINGS**

The full results of the Group's review have been submitted for publication to a peer-reviewed journal. Factors affecting antenatal care and risk assessment were examined, as well as aspects of intrapartum management, the events during delivery itself, the postnatal management of the baby, and the findings at autopsy.

8.3.1 **Suboptimal care**

It was not an objective of the Focus Group to replicate the process whereby Regional CESDI panels had already studied all these cases, nor to judge whether care was suboptimal. In fact, although a review of the Panel Comments was available it was not used or referred to in the preparation of the Report. However, for the purposes of this synopsis, it is of considerable concern that 37/56 (66%) of these cases were assigned Grade 3 suboptimal care by the panels i.e. local professional colleagues thought that in two-thirds of these cases there were avoidable factors and that different management could reasonably have been expected to have altered the outcome.

Table 8.1 Grades of suboptimal care defined at the 1994-1995 enquiries for the 56 cases of shoulder dystocia, a subset of the 873 intrapartum related deaths and of the total 1266 enquiries.

	Shoulder Dystocia		Intrapartum Related Deaths		All Enquiries 1994-1995	
Total cases (n)	56	100%	873	100%	1266	100%
Ungraded	0	0%	4	0.5%	8	0.5%
Grade 0 or 1	6	11%	195	22%	392	31%
Grade 2	13	23%	219	25%	326	26%
Grade 3	37	66%	455	52%	540	43%

The shoulder dystocia cases showed a significantly greater proportion of grade 3s than the other deaths in the enquiries ($p < 0.001$).

8.3.2 Antenatal factors

Twenty (20/56, 36%) babies were born to primigravid mothers. Of the 36 multiparous mothers, only one had a history of shoulder dystocia in a previous pregnancy. Body Mass Index (BMI) of the mothers showed a significant tendency towards obesity, with a BMI in excess of 40 being present in 11%, compared to about 1% in pregnant women in NW Thames. Glucose tolerance was impaired during pregnancy in 4 (8%) cases compared to 2% in data from NW Thames.

A large baby was predicted during pregnancy in 22/55 cases (40%), but this information was not always 'flagged up' in the appropriate section of the notes.

While both glucose intolerance and obesity were over-represented, the predictive value of these common risk factors for predicting a rare outcome such as fatal shoulder dystocia remains extremely low. There was no excess of post-maturity in the 56 babies with fatal shoulder dystocia.

8.3.3 Labour and delivery

8.3.3.1 Twenty (36%) of the mothers were induced.

8.3.3.2 Fetal distress prior to delivery of the head was recognised (on the basis of meconium staining of the liquor, abnormal cardiotocogram, or reduced cord pH) in 14/53 of the labours for which adequate information was available. This may indicate a high risk of fetal hypoxia/acidosis during labour in babies who subsequently get stuck. It is more likely to be a reflection of the fatal outcome in our cases, suggesting that preceding hypoxic stress renders a fetus less able to withstand the additional asphyxial insult of shoulder impaction. This interpretation would fit with the fact that some stillborn or unresuscitable babies were born after a remarkably short interval between delivery of the body and the head. In 47% of cases with a recorded head-body delivery interval, the interval was five minutes or less, and one would expect a previously healthy fetus to survive a period of cerebral hypoxia of that duration (see table below). The

reported head-body delivery intervals may, of course, be substantial under-estimates. It is also possible that the combination of insults in shoulder dystocia - cerebral hypoxia-ischaemia, cerebral venous obstruction, trauma, vagal stimulation etc - are more damaging than isolated cerebral hypoxia-ischaemia.

Table 8.2: The head-body delivery interval as reported in 45 of the 56 cases.

Head-body delivery interval (minutes)	No of Cases	%
less than 5	21	47%
5 to 9	15	33%
10 to 14	4	9%
15 or more	5	11%

8.3.3.3 Mode of delivery

Traction alone was used for the delivery of the shoulders in 43% of cases, McRoberts' manoeuvre (hyperflexion of the maternal thighs) with or without suprapubic pressure was used in 32%. Eventual delivery by a procedure involving access to the posterior shoulder and arm was necessary in 36%, and only one mother had a symphysiotomy. The Zavanelli technique (replacement of the head in the birth canal and delivery by Caesarean Section) was never attempted. The lead professional at delivery of the head was a midwife in 65% of cases and in this highly selected population the body was delivered by a midwife in 45% of cases, by an obstetric SHO in 7% and a more senior obstetrician in 47%. It is clear that shoulder dystocia is an obstetric emergency which requires rapid availability of senior obstetric assistance. Resuscitation might well have been more efficient if appropriate paediatric staff had been present at delivery. Given that the difficulty in delivery of the shoulders usually gives labour ward staff some warning of the need for a paediatrician, it is surprising that a paediatrician (usually a single-handed SHO) was only present at delivery in 66% of cases. The majority of the babies (70%) showed no signs of life at delivery, and most proved unresuscitatable. Twenty babies (36%) survived to be admitted to a neonatal unit.

8.3.4 Pathology

The autopsy rate (45%) was disappointingly low, as was the quality of some of the autopsies, the findings of which are the subject of a separate report.

8.3.4.1 As a separate strand of the study, all the available autopsy reports were reviewed by the perinatal pathologist on the Focus Group. The most disappointing feature was the low number of autopsies - only 25 out of 56 cases. This autopsy rate of 45% was well below the target of 75% recommended by the Royal Colleges of Pathology and of Obstetrics and Gynaecology. Only 8 cases were examined by specialists in paediatric or perinatal pathology, and 7 autopsies were judged to be inadequate using an objective scoring system.

- 8.3.4.2 Autopsy revealed evidence of acute hypoxic organ damage in 96% of cases and birth trauma in 24%. Unexpected findings were reported in 6 cases (acute chorio-amnionitis in 2 stillbirths and pneumonia in 4 neonatal deaths), which highlights the importance of autopsy even when the cause of death is apparently clear.
- 8.3.4.3 It was not possible to determine from a retrospective review of case notes why the autopsy rate was so low. Parental refusal was presumably the main reason, and this may reflect unskilled or uncommitted approaches to the parents by members of the clinical team. The parents need to be approached in a sensitive and timely manner by a professional who understands the importance of a careful autopsy, if they are to make a considered and informed decision. Those that do agree to autopsy have the right to expect a complete and well-recorded investigation.

8.4 CONCLUSIONS

Fatal shoulder dystocia is uncommon. There are some acknowledged, very non-specific risk factors, but most cases are unexpected. Midwives are usually attending the mother when the problem becomes apparent, but medical staff are frequently needed to expedite delivery of the body. Fetal or neonatal death may occur even with relatively short (<5 minute) delays in delivery of the body. In a surprising number of cases a paediatrician was not in attendance at delivery.

As shoulder dystocia is uncommon, professionals will be exposed to it relatively infrequently, but urgent action is needed when it does occur. A high level of awareness and training of all birth attendants is therefore necessary.

Middle grade/senior obstetric assistance and the presence of a paediatrician are important. The 'fire-drill' when the problem is identified should include clear instructions for calling the appropriate professionals.

There is reasonable consensus about the sequence of clinical manoeuvres to be undertaken. However, guidelines will vary according to local circumstances, especially with regard to rapid availability of obstetric and paediatric assistance.

8.5 **RECOMMENDATIONS FOR PRACTICE**

Anticipate the possibility of shoulder dystocia if there is evidence of a big baby, especially in association with maternal obesity or glucose intolerance.

If, following delivery of the head, there is immediate head retraction (the 'turtle sign') or restitution does not occur with the next expulsive contraction then immediate action is necessary. Call for assistance. The most senior available obstetrician should be alerted and a paediatrician must be in attendance. Additional midwifery staff may be needed to assist with the delivery. The mother should be given a brief, clear explanation of the problem and the proposed course of action.

McRoberts' manoeuvre should be carried out by flexing the woman's legs right back so that her thighs are on her anterior abdominal wall. Suprapubic pressure should be applied to disimpact the anterior shoulder.

If obstetric assistance is not available and these manoeuvres fail, then it is reasonable to try delivery in a squatting position, or on all fours, using downward traction to release the posterior shoulder.

If a generous episiotomy, McRoberts' manoeuvre and suprapubic pressure have not achieved delivery of the body, an obstetrician or midwife should attempt to get access to the posterior shoulder.

(FUNDAL PRESSURE OR INCREASINGLY FORCEFUL TRACTION ON THE HEAD SHOULD BE AVOIDED.)

By this stage, the first attending paediatrician should have called for assistance from his or her most senior available colleague and, whenever possible, a neonatal nurse experienced in resuscitation.

Complete and accurate clinical notes are essential, especially of the time when help is called for.

Reiteration of delivery ward protocols for shoulder dystocia to labour ward and paediatric staff at regular intervals may be helpful.

Symphysiotomy, deliberate clavicular fracture, or the Zavanelli procedure have not been included in this sequence because they are not widely used in the UK. However, shoulder dystocia is a desperate situation for the fetus, so obstetricians and midwives should be aware of all the possible techniques for effecting delivery.

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Ms Alexandra Lucas, Community Midwife, Chelsea and Westminster Hospital

Dr Denis Martin, Consultant Obstetrician, Altnagelvin Hospital, Londonderry

Dr Isabella Moore, Paediatric Pathologist, Southampton General Hospital

Dr James Pearson, Reader in Obstetrics, University Hospital of Wales

Ms Dawn Saunders, CESDI Regional Co-ordinator

Mr Ralph Settatee, Former Director of CESDI

COMMUNICATIONS

- 9.1 Previous CESDI Reports have drawn attention to the significant contribution to suboptimal care made by deficiencies in communications. Thus, the 2nd and 4th Annual Reports noted that communication failures were cited in some 17% of the comments analysed for the three years of the enquiries into intrapartum related deaths.
- 9.2 The deficiencies noted have ranged from poor and illegible case-notes to poor relations between professionals and parents and between professionals themselves. Criticisms were most often of communications between professionals. However, poor advice to parents, particularly the failure to emphasise adequately the nature and severity of a risk or impending problem, has also been mentioned.
- 9.3 The Reports have noted that communication is a two-way process. The 2nd Report said, for instance: “good communication involves, inter alia: ability to talk and write in terms which the other party, whether parents or professionals, can understand; willingness to hear and understand another’s point of view; and mutual understanding about the outcome at the end of the discussion”. It has also been noted that poor communications are often associated with and exacerbate other failures which have a decisive effect on the outcome, such as failure to recognise or act on a problem, as well as adding to parental grief when the baby has died, as in poor bereavement counselling.
- 9.4 CESDI reports have contained various recommendations designed to improve communications deficiencies, for example:

Need for Training and Guidelines on Communications

- The training and continuing education of all clinical staff involved in maternity and infant care should include skills in clear and sensitive communication between professionals, including those of different disciplines, and with parents (paragraph 6.2.6. of 2nd Report).
- Multidisciplinary guidelines are necessary for:
 - professionals responsible for decision-making when problems are tackled;
 - inter-professional communication and responsibility for hand-over or sharing of care arrangements (paragraph 10.2.6. of 4th Report).

Co-operation between professionals

- All professionals concerned with the care of vulnerable children should make sure that they keep other appropriately interested parties informed, subject to confidentiality safeguards (paragraph 9.3.8. of 3rd Report).

Communication with parents

- Health professionals should ensure that accepted and important messages get across as a matter of routine to all carers and should record that such advice has been given (paragraph 9.3.1. of 3rd Report).
- Advice should be delivered in ways that maximise the chances of its being heard and understood by those least likely to have heard it before or to respond to it (paragraph 9.3.2. of 3rd Report).

Record-keeping

- All professionals should make clear and adequate notes. The standard should be that which enables a colleague coming new to the case to be properly informed (paragraph 9.3.10. of 3rd Report)
- It may be necessary for some departments to review their procedures and proformas for the handling and completion of notes. These should be built on examples of best practice available regionally or nationally (ibid.).
- Purchasers and providers should ensure that the quality of clinical records is included in local perinatal and infant death discussions and is the subject of clinical audit (paragraph 6.2.6. of 2nd Report).
- The relevant professional and statutory bodies should be encouraged and supported in their work to develop standardised case records for maternity and infant care (ibid.).
- 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 (paragraph 10.2.4. of 4th Report).

9.5 CESDI is primarily an audit of professional care, although some criticisms have been made in previous reports of parents/families for their failure to follow advice. Valuable assessments of the social and environmental circumstances of parents and carers have been made in previous CESDI sponsored research studies: for instance, in the case-control studies for the SUDI project reported in the 3rd Annual Report and for the SATS project reported on in Chapter 5 of the present Report. However, parents' views on their care in pregnancy or on the care provided to their babies have not been sought in the confidential enquiries. It is rarely possible therefore to analyse from the available information why parents/families behaved as they did. Paragraph 5.3.5. of the 4th Report noted that: "Future studies on the interactions between professionals and their clients should yield valuable information on discrepancies of expectation and satisfaction".

PROPOSALS

- 9.6 The previous CESDI recommendations on communications and record-keeping described in paragraph 9.4 (above) are still relevant and are endorsed.
- 9.7 CESDI is aware that previous initiatives by the Department of Health and the Royal Colleges and other statutory bodies responsible for professional training have emphasised the importance of good communications and record-keeping. These include:-
- The UK Central Council for Nursing Midwifery and Health Visiting: Standards for Records and Record-Keeping (1993) - (Currently under revision).
- The Royal College of Surgeons of England: Guidelines for Clinicians on Medical Records and Notes (1994)
- The Joint Working Group of the Royal College of Obstetricians & Gynaecologists & the Royal College of Midwives: Communication Standards - Obstetrics (1994)
- Royal College of Physicians Working Party on Communications in Medicine: Improving Communications between Doctors and Patients (1997)
- The Clinical Studies Advisory Group (CSAG) to the Department of Health & NHS Executive: Improving Clinical Communications (1998)
- 9.8 It is considered desirable that the subject of communications should receive further in-depth study in CESDI because of its importance in relation to outcome. This cannot be done by a focus group of the type presently in operation which reviews existing case-notes. The material available to CESDI, even on inter-professional communication, is weak: for instance, paragraph 5.2.5. of the 4th Report noted that in 38% of the comments the status of the professional groups contributing to suboptimal care was 'not stated'. This makes it difficult to assess whether staff of the appropriate seniority and experience were present or available to deal with crises, the relationships between the different professionals dealing with a case, and the quality of management and resources available in hospitals. Moreover, there is no raw material about the parents' view of the relationship. It is not only not possible to assess whether parents understood and accepted the advice they were given: it is not possible to assess whether problems were not identified in pregnancy or labour because health professionals had not listened to and noted what the mother herself said. It is desirable to seek more information about these matters in appropriately designed future projects.
- 9.9 A number of detailed questions designed to elucidate inter-professional relationships are being included in the project now under preparation on premature babies (see paragraph 10.3).

- 9.10 The NAB and the MCHRC have also been exploring what more can be done as regards greater involvement of parents in CESDI. A working group involving clinicians and parental voices on the NAB is being set up to identify communication problems between professionals and parents and vice-versa in the CESDI field. In the first instance it will commission a review of the available literature and experience relevant to CESDI.

ACKNOWLEDGEMENT

Thanks for the writing of this chapter are due to Lady Littler (NAB).

CHANGING PRACTICE

10.1 **Implementing the findings**

How can the findings of CESDI be addressed, and who is responsible for implementing the recommendations? These are questions that the National Advisory Body (NAB) and the Maternal & Child Health Research Consortium (MCHRC) have considered in the last year, since it is of great importance to health professionals, the network of CESDI coordinators who have undertaken an enormous amount of work collecting the data, and not least the parents and their families who have suffered the death of their baby.

At the NAB's request, the MCHRC approached the Royal Colleges and other statutory bodies responsible for training and accreditation to enquire what response they were making to the recommendations in the 4th Report which focused on the enquiries relating to intrapartum deaths.

10.2 **The Royal Colleges have responded as follows:**

The Royal College of Midwives (RCM)

The Royal College of Midwives, together with all other professions within the maternity services, continually strive through research, education & experience to improve standards of clinical care for mothers and babies. The RCM is currently involved with the Royal College of Obstetricians & Gynaecologists in updating guidance for minimum standards of care in labour.

- The findings of the 4th Report were disseminated via the RCM Midwives Journal.
- A conference is planned for June 1998 focusing on the recommendations relating to care in labour. A full conference report will appear in the RCM Midwives Journal.
- The findings have been discussed by RCM networks, including the education forums, to influence pre and post-registration education.
- The RCM has regular meetings with the United Kingdom Central Council for Nursing, Midwifery & Health Visiting (UKCC) and the four National Boards to influence curriculum and design.

The Royal College of Nursing (RCN)

In 1997 a conference entitled Reducing the Risk: A Multidisciplinary Response to CESDI was held at the Royal College of Nursing. This attracted a large number of midwives and the topics included the role of the National Advisory Body, the findings of CESDI, risk management in relation to midwifery practice, interpretation of the CTG trace & record-keeping and communication in relation to stillbirth and infant death. A parent also told her story. These topics were specifically chosen as key areas to be addressed in relation to the recommendations of CESDI.

A regular programme of conferences and educational events is organised for midwives in the UK by the RCN and these are of direct relevance to the aims of CESDI. Regular topics include the interpretation of CTGs and risk management.

The Royal College of Obstetricians & Gynaecologists (RCOG)

The Council of the RCOG discussed at length the 4th CESDI Report and its recommendations. As a direct result of these discussions a number of specific initiatives were instituted.

- The production of a College based guideline entitled Induction of Labour which will outline standards of care with respect to fetal surveillance during induction.
- A working group has been set up, chaired by Professor Martin Whittle, to review the RCOG publication Minimum Standards of Care in Labour in conjunction with the RCM.
- The role of the consultant obstetrician and their involvement in labour ward sessions is being critically appraised by a working group. Consultant cover and training of junior obstetricians is being reviewed as part of its remit.
- The CESDI Executive Summary has been sent to all Fellows and Members of the College along with the President's recent Newsletter. The latter also highlighted the importance of the findings of the 4th Annual Report.

The Royal College of Paediatrics & Child Health (RCPCH)

- The recommendations of the 4th Annual Report have been considered by the RCPCH Research Unit, the Joint Standing Committee RCPCH/RCOG, and by the British Association of Perinatal Medicine (BAPM) which is affiliated to the RCPCH.
- The RCPCH and the Royal College of General Practitioners are considering the possibility of joint training posts in paediatrics and general practice for senior house officers with the aim of improving the recognition of serious illness in babies.
- The Joint Standing Committee RCPCH/RCOG is producing a report on 'The training needs of professionals responsible for resuscitation of babies at birth'. The report, which has been approved by the parent bodies and will be published shortly, describes the training and assessment needs of nurses, midwives, paediatricians, obstetricians, anaesthetists and general practitioners with varying levels of experience and responsibility. It complements the earlier reports from the British Paediatric Association on Neonatal Resuscitation (1993) and of the Joint Standing Committee RCPCH/RCOG on Resuscitation of Babies at Birth (1997).

The Royal College of Pathologists (RCPATH)

- The RCPATH encourages the practice of good autopsy procedure and issued guidelines for perinatal and infant necropsies to all pathologists in 1993.
- The RCPATH supports the development of regional sub-specialist centres and where the problem of local experience or resource

exists, it encourages referral to a regional centre. This may be dependent on the wishes of the local clinical staff and ability of the individual Trust to contract for such referral work.

- Guidelines for purchasers have been issued strongly recommending availability of specialist perinatal and paediatric pathology services. This has been identified as a quality measure of obstetric and paediatric units.
- An ongoing evaluation of the availability and workloads of perinatal and paediatric pathologists, the extent of their involvement in Coroner's work, and the availability of funding for special investigations is being undertaken by the RCPaTh.
- Consideration of the professional performing Coroner's postmortems on childhood or infant deaths is being undertaken by a College working party responding to a Department of Health request. The RCPaTh cannot direct who may or may not perform Coroner's postmortems on child or infant deaths but believes these autopsies should be performed by pathologists with appropriate experience.
- The College has established a new examination in perinatal and paediatric pathology and there is now a Specialist Advisory Committee to deal with paediatric issues.

United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC)

The findings of the CESDI 4th Annual Report were considered by the Midwifery Committee of this Council at its last meeting on 20th January 1998. The findings of this report gave the committee cause for concern, particularly when the recommendations of the previous report were revisited.

Members noted that there were a number of findings very similar to those contained in the report covering 1991-1993. Issues such as substandard care, lack of supervision of junior staff and failure to take action when problems were identified had also been noted in the Report on Confidential Enquiries into Maternal Deaths in the United Kingdom 1991-1993.

Members agreed that the Council should continue to publicise guidance available on matters such as record-keeping and that the importance of the individual practitioner's professional accountability should also continue to be highlighted.

Continuing the momentum

The responses from the Colleges and the Professional Bodies are extremely encouraging. The National Advisory Body and the Maternal and Child Health Research Consortium realise the importance of continuing this momentum and make four general recommendations. The first three relate to training and continuing education of professionals. The fourth relates to the implementation of CESDI findings, and is addressed to the Department of Health and the NHS Executive.

All of the health professionals involved will have undergone their undergraduate or pre-registration training. CESDI and its findings should become an integral part of undergraduate and pre-registration training, with particular emphasis on recurrent themes.

CESDI findings suggest that all grades of seniority of the professions are responsible for suboptimal care and that there is therefore a need for continuing education, with both a practical and theoretical basis, following a professional qualification. The White Paper 'The New NHS' wishes to strengthen the existing systems of professional self-regulation. It is expected that the Royal Colleges and the professional associations will respond positively to this approach. The Royal Colleges and other institutions that regulate educational programmes should consider making the implementation of CESDI recommendations an element of their own educational programme.

One of the recurring CESDI themes is the need for communications between the professional groups. The Royal Colleges should continue to develop multi-professional education and development so that mutual recognition of the relevant professional roles and responsibilities is understood.

Finally, Ministers and the Department of Health clearly lay great importance on the work of CESDI by their ongoing support for the Enquiry. They also stress the importance of clinical audit, clinical effectiveness, and clinical guidelines. Many NHS Executive documents now detail guidance on the above issues. Health Authorities therefore have a duty to place and monitor contracts with providers. Under the White Paper, Health Authorities are to have a strengthened role in monitoring audit and health outcomes. Therefore, it is recommended to the Department of Health and the NHS Executive that CESDI findings become an integral part of the clinical audit contracts with Health Authorities, NHS Trusts, and the new Primary Care Groups.

Summary of general recommendations

- CESDI and its findings should become an integral part of undergraduate training with particular emphasis on recurrent themes.
- The Royal Colleges, statutory bodies and professional associations should consider making the implementation of CESDI recommendations an element of their education programmes.
- The Royal Colleges and professional associations should continue to develop multi-professional education and development
- The Department of Health and the NHS Executive should ensure that CESDI findings become an integral part of clinical audit contracts with Health Authorities, NHS Trusts, and the new Primary Care Groups.

10.3 **THE FUTURE PROGRAMME**

Project 27-28

The findings of an Enquiry Process are sometimes referred to as 'grade C evidence', a pejorative term for material based on subjective opinion

and non comparative data (deaths alone). However, a principle feature of enquiries is the ability to highlight aspects of care that traditional scientific studies have difficulty in eliciting. This is particularly important with rare serious events for which it is impractical to undertake prospective studies because of the large numbers of cases and the time required to accrue accurate answers. Nevertheless, the lack of accurate denominator data has repeatedly limited the interpretation of CESDI data, as demonstrated by the focus studies.

To address these issues, several new developments will be incorporated into the future Enquiry Programme (Project 27-28). This focuses on premature babies born at 27 to 28 weeks' gestation and includes:

- collection of denominator data
- enquiries on a 'control' group
- semi-structured panel enquiry forms
- additional information from the paediatric consultant

The gestational range 27 to 28 weeks was chosen because most of these babies are expected to survive. Variation in care may therefore impact on the outcome. The aim of the enquiry will be to identify this variation.

Gestational 'Denominator' Data

Despite growing professional and public interest in the care given to babies born before 29 weeks, little is known about their epidemiology. Most studies have been hospital-based and data has been analysed in terms of birth weight. Gestational age is not recorded when live births are registered in the United Kingdom. This has precluded the description of national or regional survival rates, or of trends over time. Yet there have been many developments in recent years that are likely to affect survival of these premature infants: for example, the provision of neonatal intensive care and the impact of surfactant. As part of Project 27-28, CESDI will identify all babies born at 27 and 28 weeks. This will be done by the introduction of recording logs in all hospital units.

Enquiries - cases and controls

Enquiries will be held on all neonatal deaths excluding lethal congenital malformations (an estimated 263 cases) together with an equivalent number of survivors (a baby alive at one month, having been born at 27-28 weeks). Survivors will be chosen randomly from the eligible population (estimated to be 1070) in the sample frame constructed from the recording logs.

10.4 **FUTURE RESEARCH AND DEVELOPMENTS**

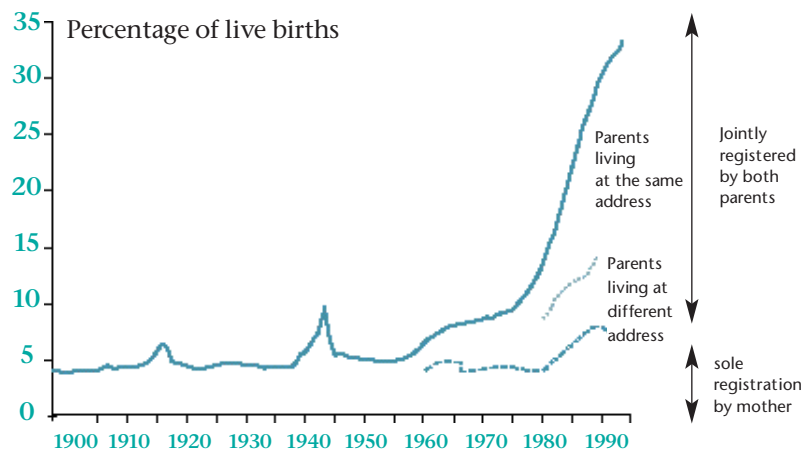
10.4.1 **Socio-economic factors and cause of death - linking RRF to registration data**

Inequalities in health have returned to the national agenda, following the publication of the Office for National Statistics' decennial

supplement 'Health inequalities' and the setting up of the 'Independent enquiry into inequalities in health'. Parents' occupations and other socio-economic characteristics were not included on the Rapid Report Form, because of variations between hospitals in the extent to which such information is recorded.

By contrast, local Registrars of Births, Marriages and Deaths ask parents a standard set of questions when they register a birth or infant death. The most striking trend over the past fifteen years has been the increase in births outside marriage. The proportion of families headed by a lone parent has also increased, but not to the same extent. Most of the increase in births outside marriage has been in births registered jointly by both parents; in nearly three quarters of such cases, they give the same address. The proportion of births registered by mothers on their own has increased much less.

Live births outside marriage, England and Wales, 1900-95



Source: Office for National Statistics, birth statistics, Series FM1

In the past, tabulations of stillbirth and infant mortality rates according to the father's social class were restricted to births within marriage. However, ONS now also publishes these rates for jointly registered births outside marriage. In each social class, mortality rates are slightly higher outside than inside marriage, but the biggest differences are those between the social class groups. It is proposed to link the CESDI Rapid Report Forms to ONS stillbirth and infant death registration data. This will enable CESDI data to be analysed in relation to the socio-economic data collected by ONS.

10.4.2 **Review of the dissemination strategy of CESDI**

The findings of CESDI are important to many individuals and professional bodies. The messages are wide ranging and are appropriate to the entire spectrum of health workers, ranging from doctors, midwives, and health visitors to coroners. At times they are particularly relevant for parents. Professional bodies and institutions also need to be aware of the findings. As the work of CESDI progresses the task of how to publicise the findings effectively has become increasingly complex. CESDI has commissioned a review of the dissemination process which will be completed in 1998.

10.4.3 **'Auditing' the effect of the CESDI process**

CESDI must determine whether its work is effective. Two particular areas have been chosen: the standard of reporting of postmortems and the provision of education for health professionals involved in intrapartum care.

In 1993 CESDI issued guidelines on the Postmortem Examination which were formally endorsed by the Royal College of Pathologists and distributed to all pathologists. An evaluation of the quality of the reports on cases from 1994 and 1995 is being undertaken and the findings will be published in the next annual report.

Many recommendations of the 4th Annual Report centred on training issues within the professions. The strategy for the assessment of the educational programmes for intrapartum care is being developed in collaboration with the Royal College of Obstetricians & Gynaecologists, Royal College of Midwives and the Royal College of Paediatrics & Child Health, and will commence later in 1998.

10.4.4 **Future Research Areas**

The work of CESDI highlights aspects of healthcare with priority for future epidemiological research. This report recommends several specific areas:

10.4.4.1 **Unexplained antepartum stillbirth:**

- recording the ethnic origin of the mother in all births; this will provide the appropriate denominator and quantify any associations.
- development of a clinico-pathological classification of this heterogeneous group as an aid to understanding the aetiology.

10.4.4.2 **Safety of planned home deliveries:**

- recording the place where delivery is intended to occur at the onset of labour for all births; this will provide the appropriate denominator and quantify any associations.

10.4.4.3 **Safety of labour in women with a previous uterine scar:**

- audit of all labours in which there has been a previous uterine scar; further evaluation of repeated doses of prostaglandin in women with a previous uterine scar
- review of all cases of uterine rupture

10.4.4.4 **Assessment of the severity of the baby's illness**

- The Baby Check system should be assessed in a wider range of settings and, if its value can be confirmed, be used more widely to help both carers and health professionals recognise the severity of a baby's illness.

Many of the areas highlighted for research do not lie directly within the remit of CESDI. However, CESDI does undertake additional research activities and two areas have been chosen. The first relates to communication problems, an area especially highlighted in this report. This is a large subject in which qualitative research has an important role. CESDI is commissioning a literature review of relevant topics in this area. This will aid future developments on this complex but highly important topic.

The information CESDI presents does not relate to individual hospital units. Yet it is likely that organisational factors (staffing, facilities, location, size of unit) will have an effect on the outcome of pregnancies. To provide a national overview, CESDI is proposing to develop an anonymised database describing features and outcomes in individual units.

10.5 **FUTURE PUBLICATIONS**

In addition to the annual report there will be:

- a separate publication concentrating on the studies on sudden unexpected deaths in infancy (SUDI). This will be a detailed overview of all SUDI studies from 1993 to 1996. It will also include the findings of the Limerick Report (May 1998) on the 'mattress cover hypothesis', and a review of pathology, with particular reference to various tests and the value of postmortem examination in making a diagnosis of exclusion.
- two new leaflets on Postmortem Examination. The first is an update of the existing leaflet for parents produced by CESDI and the Foundation for the Study of Infant Deaths, and the second is designed to help health professionals in requesting a postmortem examination.

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Alison Macfarlane (PSG) for her contribution to the section on socio-economic factors and cause of death.

CONCLUSION

In the first six years, CESDI has undertaken a wide variety of work all of which has the common aim of improving care and reducing perinatal and infant deaths. The 5th Annual Report reflects the diversity of this work. This chapter summarises many of the important lessons that have emerged. The full recommendations for practice are described within the individual chapters of the Report.

11.1 Epidemiological profiles

The Rapid Report Form system was introduced in 1993; ascertainment has improved yearly. Its usefulness will be further enhanced by linkage to the other national system of collection of deaths, the Office for National Statistics (ONS). Together they will provide a fuller picture of cause of death and the relationship to socio-demographic factors (chapter 10). This is crucial in the assessment of health needs.

The epidemiological profiles of sudden unexpected infant deaths, both unexplained and explained, show that these are more likely to occur to younger mothers and to families in receipt of Income Support. These findings have led to the recommendations to Health Commissioning Authorities regarding the need to provide appropriately targeted health support services (chapter 4).

Classification of death is essential to the work of CESDI, as it allows the development of epidemiological profiles. Unfortunately, none of the numerous classifications is entirely satisfactory for the wide variety of cases that are encountered. CESDI uses three such classifications: extended Wigglesworth; fetal and neonatal; and obstetric. These provide an initial, albeit relatively crude, description of the causes of death.

The pilot study of antepartum term stillbirths found that, despite most cases being 'unexplained', they were far from a homogeneous group. The largest subcategory was associated with growth restriction. The development of a relevant clinico-pathological classification should provide a more refined epidemiological profile. This is necessary in devising clinical strategies for improvements in screening, diagnosis and intervention aimed at preventing fetal death (chapter 5).

11.2 Variation in outcome and practice

Variations in health care undoubtedly exist. The combination of CESDI data with that on all births (ONS) can provide mortality rates on a regional basis (CESDI regions). Although the variations in mortality rates cannot properly be used for comparing standards of care, they do demonstrate differences in outcomes which require explanation.

CESDI provides the only description of late fetal losses (20 to 23 completed weeks' gestation) in England, Wales and Northern Ireland. These appear to show greater regional variation than those at later stages of pregnancy and infancy (chapter 2). This finding could be an artefact of the ascertainment system, but might also be real and require further exploration.

CESDI has also shown considerable regional variations in the uptake of postmortem examinations, not accounted for by the regional patterns of death. Neonatal deaths are those least likely to have postmortem information.

11.3 **Validation of Enquiry findings**

Although the last decade has rightly seen a large shift towards the use of 'Evidence-Based Medicine', reality dictates that much of our clinical activity is based on common sense rather than on what is definitively proven and published. All Enquiry Reports, including those on maternal mortality and peri-operative deaths, are a summary of professional opinion. CESDI is the first to attempt to validate the consistency of opinions in the Panel process (chapter 3). At least three quarters of cases subjected to Panel enquiries were given a similar overall grade when subsequently reviewed by another Panel. Despite this encouraging level of agreement, a more detailed review of the Panel reports found that the subject of the comments was the same in only half of all enquiries. This study has major implications for future Enquiry work, suggesting the need for a more directed and structured approach (chapter 10).

11.4 **Avoidable deaths of at least 60 infants yearly - 'explained' sudden unexpected deaths**

It was an increase in the prevalence of sudden infant death syndrome (SIDS) or 'cot deaths' in the mid-eighties that was the catalyst for the creation of CESDI. Much of the first three years of CESDI work was spent in undertaking the largest study of sudden unexpected deaths in infancy (SUDI). This was carried out in conjunction with the Foundation for the Study of Infant Deaths. Preliminary results were described in the 3rd Annual Report.

Although most (80%) sudden unexpected infant deaths are SIDS, a sizeable proportion (20%) has a specific explanation. There are approximately 120 such 'explained' cases in England and Wales annually. Perhaps the most striking finding was that half of these babies were ill enough to have needed medical attention in the 24 hours before they died. This confirms the Enquiry conclusion that half of these deaths might have been avoided if professionals or carers had behaved differently (chapter 4).

Criticisms inevitably referred most frequently to General Practitioners, the major fault being in failure to recognise the severity of the illness. Current General Practice training does not always include hospital

based paediatric experience, and a doctor can provide emergency care for patients of all ages with minimal experience in recognising sick babies. This report advises that the Royal Colleges of General Practice and of Paediatrics and Child Health review the training requirements of all doctors assuming responsibility for the emergency care of babies (chapter 4).

Frequently, however, the factors contributing to death occurred after specialist referral, the major fault being poor clinical management. This led to the recommendation that Continuing Medical Education for consultant paediatricians should include the best current management of acute severe illnesses in infants (chapter 4).

Carers were as likely as professionals to have contributed to the outcome, highlighting the need for the targeting of health support services to vulnerable populations. These findings reinforce the importance of the provision of appropriate information for parents (chapter 4).

11.5 **Planned home delivery, uterine rupture and shoulder dystocia - associated deaths**

Intrapartum related deaths contribute only a small fraction (5%) to the overall losses in the CESDI range. However, they are perceived to be the equivalent of airline disasters, rare but avoidable in the majority of circumstances. This was substantiated by the findings of the 4th Annual Report which summarised the largest review of such events ever undertaken. It concluded that three quarters of deaths might have been averted if alternative management had occurred. For the parents involved, this must only reinforce their grief. CESDI therefore had a responsibility to review this area in greater detail. Three particular circumstances were selected: planned home delivery, ruptured uterus and shoulder dystocia. Cases of this type occurring in 1994-1995 formed the basis of Focus Group Reports. These could identify patterns of circumstances and care which would not have been obvious from review of individual cases.

In 1960 a third of all deliveries occurred at home but by 1980 this had fallen to less than 2% and has remained at this level. Most reports support the relative safety of home births in women at low risk of obstetric complications, but not all women choosing this option will be in this category. Problems that arise in labour are not always foreseen, and the Focus Group identified areas that contributed to poor management. Recommendations are made concerning the provision of: back-up arrangements of carers; transfer arrangements to hospital; receiving arrangements at the hospital; and the immediate availability of relevant equipment in the home (chapter 6). In addition, the Focus Group drew attention to the need for local protocols drawn up by hospital staff, community staff and user groups, and the availability of printed evidence-based information to assist women in their choice of place of delivery.

Of the three clinical areas, ruptured uterus was singled out as having the largest proportion of cases with suboptimal care. Three quarters of the cases involved women with a pre-existing scar; within this group nearly two thirds were induced, suggesting that this is a particularly high risk combination. Prostaglandin was the most frequently used agent and the dose regimes were generally within those used for uncomplicated inductions. The lack of information on induction using repeated doses of prostaglandin in this setting precluded interpretation of the observations. It may have been the almost universal poor care provided in these cases that resulted in the rupture. However, the Focus Group recommended that decisions about induction should be made by a senior obstetrician and that repeat doses of prostaglandin should only be given with exceptional vigilance. All but three of the 42 cases had some impending clinical signs of scar rupture, yet in 18 the diagnosis was only made at the time of laparotomy. This suggests lack of awareness and inexperience amongst the professional attendants. Consultants were frequently criticised by the Panels, often for the lack of direct input at the relevant and vital times. The need for senior experienced involvement in antenatal and intrapartum management is stressed in the recommendations of the Focus Group (chapter 7).

Shoulder dystocia is a rare and unpredictable event and when it occurs there is a need for urgent skilled action. The review of 56 fatal cases found that the midwife was usually the professional conducting the delivery and on nearly half of these occasions completed the delivery. No paediatrician was present in a third of the cases. The Focus Group emphasise the need for all birth attendants to be trained to manage this event. Recommendations for practice and initiating the 'fire drill' are given in chapter 8.

11.6 Absent denominator - Lack of morbidity data

All three focus groups were limited by the absence of appropriate denominator data. There is a widely held belief and expectation that serious events such as uterine rupture or shoulder dystocia are systematically recorded. This is not the case, and because they are more likely to result in morbidity than death, CESDI has only been able to examine the tip of the iceberg. The lack of routine registering of these events limits the provision of information concerning risk. Best available evidence is sometimes based on out of date practice or findings relating to other countries.

11.7 Tackling communication issues

Good communication is an essential component of health care and becomes increasingly important in situations leading to a poor outcome. Deficiencies in this area have ranged from illegible and incomplete case-notes to poor relations between professionals, and between the professions and parents.

CESDI is uniquely placed to make multi-disciplinary recommendations and recognises the contribution that parents have to make. Every

CESDI report has highlighted communication problems (chapter 9), and this has resulted in the proposed formal review (chapter 10) to guide future developments of this area within CESDI.

11.8 **The future work programme**

The next area of focus by CESDI is babies born at 27 to 28 weeks' gestation. The Office for National Statistics, unfortunately, does not collect gestational age on all live births.

To address this issue, there are several developments in the new programme, Project 27-28, (chapter 10). CESDI aims to identify all babies born between 27 and 28 weeks' gestation by the introduction of recording logs in hospital units to produce the first national picture of these premature babies. Most are expected to survive, and so variation in care may impact on their outcome. To help identify these variations, enquiries will be held on all those that die and also on a randomly selected proportion of the survivors (chapter 10).

Responding to the findings of the second pass panel exercise (chapter 3) a semi-structured panel enquiry form will be introduced and additional information will be sought from the hospital unit concerned with the case.

Following the 4th Report, CESDI has the support of the Department of Health to undertake an audit of the provision of education for health professionals involved in intrapartum care (chapter 10), and work on this is underway.

In addition to the annual report there is going to be a separate publication on the overview of the studies on sudden unexpected deaths in infants (1993 to 1996) and including the findings of the Limerick Report (May 1998) on the 'mattress cover hypothesis'. Two new leaflets on Postmortem Examination are being produced, one updating the existing leaflet for parents produced by CESDI and the Foundation for the Study of Infant Deaths, and the second is designed for health professionals.

As the work of CESDI progresses, the task of how to publicise the findings effectively has become increasingly complex. CESDI has commissioned a review of the dissemination process, which will be completed in 1998.

11.9 **Changing Practice**

Recommendations made by CESDI are often simple and not original. The responses of the Royal Colleges and the other statutory bodies responsible for training and accreditation to the 4th Annual Report are highly encouraging (chapter 10). Guidance on minimum standards of care in labour is being prepared by a multi-professional

working group. The role of consultant obstetricians and their involvement in labour ward management and training of junior obstetricians is under review. Consideration of joint training posts in paediatrics and general practice to enable better recognition of serious illness in babies is under consideration.

The need to continue this progress by integrating the findings in both undergraduate and continuing medical education and also within clinical audit contracts is discussed (chapter 10).

Finally, the findings of CESDI are important to many individuals and professional bodies, but the most important group is the parents and their families who have suffered the death of their baby as expressed in a reply from a mother:

“Your letter held words I really needed to hear. That her postmortem would help and that the results would not just sit on my file - wasted. I am glad some research is being carried out.”

ACKNOWLEDGEMENTS

Particular thanks are due for the considerable contribution of the district co-ordinators and the many others based throughout England, Wales and Northern Ireland, who, often without recognition and in their own time, undertake work for CESDI.



GLOSSARY

AETIOLOGY

The science of causes, especially of disease.

ANONYMISATION

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

ANTEPARTUM STILLBIRTH

Death of a baby before the onset of labour.

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.

CASE CONTROL STUDIES

Case control studies compare exposures in people who have a particular disease or outcome with those who do not.

CONFIDENTIALITY

Information given in confidence may be used only for the purposes for which it is given and may be disclosed for other purposes only in exceptional circumstances. There are legal and ethical duties to maintain confidentiality in the NHS. The principles on which CESDI data are collected are that the identities of the panels, the professionals involved, and the mothers and families of the babies which died will be anonymous within the enquiry. As a result it is not possible to release panel reports to outside agencies on any identifiable or individualised basis.

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 an 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 (CI)

A range of values of a variable, constructed so that the interval has a specified probability of including the population mean or rate for that variable. For example; Perinatal mortality rate in 1994 in district X is 8.9 per 1000 total births (95%CI 6.5 to 11.4).

CONFIDENCE LEVEL

The specified probability at which an observation is regarded as significant and unlikely to have been observed by chance alone. For example; Perinatal mortality is different between district X and district Y at the 1% level, (the probability of them being the same would occur by chance less than once in every 100 observations, ($P < 0.01$)).

CONGENITAL MALFORMATION/ANOMALY

A physical malformation (including biochemical abnormality) which is present at birth.

DENOMINATORS

The population at risk in the calculation of a rate or ratio. Examples relevant to CESDI include number of all live births as denominator for neonatal mortality rate, and birth weight distribution of all live births for birth weight specific mortality calculations.

EARLY NEONATAL DEATH

Death during the first week of life (0-6 completed days inclusive).

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.

GESTATION

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

GRO

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

HOSPITAL EPISODE STATISTICS (HES)

The HES is a national data collection system, introduced in April 1987 to replace the Hospital Inpatient Enquiry. It covers all specialties and is based on consultant episodes (a period of care under one consultant). The HES for maternity includes a 'tail' with maternity data. For a delivery the episode includes data for each baby as well as the mother. CESDI has not yet made use of HES data in a routine way in its enquiries so far.

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.

LATE FETAL LOSS

For CESDI, a late fetal loss is defined as a spontaneous miscarriage occurring between 20 weeks + 0 days and 23 weeks + 6 days. If gestation is not known or not sure, all births of at least 500g are reported, (at least 300g from 1.1.96). 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 birth weight which fulfils these criteria should be registered as a live birth.

MORTALITY RATES

- i) Infant mortality rate
Deaths under the age of 1 year following live birth, per 1000 live births
- ii) Perinatal mortality rate
The number of stillbirths and early neonatal deaths (those occurring in the first week of life) per 1000 live and stillbirths
- iii) Neonatal Death rate
The number of neonatal deaths (ie occurring within the first 28 days of life) per 1000 live births
- iv) Postneonatal mortality rate
Number of infants who die between 28 days and less than 1 year per 1000 live births
- v) Stillbirth rate
Number of stillbirths per 1000 of total births (live births and stillbirths)
- vi) Late fetal loss rate
Number of late fetal losses per 1000 of total births (live births and stillbirths)

NEONATAL DEATH

Death before the age of 28 completed days.

NOTIFICATION OF BIRTH

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

NON REGISTRABLE DEATH

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

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

PERINATAL DEATH

Fetal deaths after 24 completed weeks gestation and death before 7 completed days.

PERINATAL MORTALITY RATE - see Mortality Rates.

POSTNEONATAL INFANT DEATH

Death between 1 month and 1 year of age. (28 days and over, up to 1 year).

POSTNEONATAL MORTALITY RATE - see Mortality Rates.

REGISTRATION OF BIRTH

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

REGISTRATION OF DEATH

Time limit for registration in England, Wales & Northern Ireland is 5 days.

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

- i) 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
- ii) 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 anytime 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.

SUDDEN UNEXPECTED DEATH

A sudden death, unexpected from the previous history. The term is applied to other age groups as well as to a small number of deaths in infancy and early childhood. It includes both explained and unexplained.



APPENDIX 1 - CESDI WORKING GROUPS

MEMBERS OF THE RAPID REPORT FORM WORKING GROUP

Mr Ralph Settatee (Chair)
CESDI - Former Director

Ms Theresa O'Connell
Counselling Sister, St George's
Hospital, London

Dr Patrick Cartlidge
Consultant Neonatal Paediatrician
University of Wales College of Medicine

Dr Michael Vaile
Director of Public Health
West Kent Health Authority

Ms Grace Edwards
CESDI - Regional Co-ordinator

Mrs Cathy Winter (to October 97)
CESDI - Midwife

Ms Sara McCarthy
CESDI -Data Analyst

Miss Alison Macfarlane
Reader in Perinatal and Public Health Statistics
National Perinatal Epidemiological Unit, Oxford

MEMBERS OF THE CTG WORKING GROUP

Professor David James (Chair)
Professor of Feto-Maternal Medicine
Queens Medical Centre, Nottingham

Miss Tessa Mitchell
CESDI - Regional Co-ordinator

Dr Jean Chapple
Consultant Perinatal Epidemiologist
Kensington, Chelsea and Westminster
Health Commissioning Authority

Dr Pat Yudkin
University Research Lecturer,
Division of Public Health and
Primary Health Care
University of Oxford

Professor Keith Greene
Consultant Obstetrician
and Gynaecologist
Nuffield Hospital, Plymouth

Mrs Cathy Winter
CESDI - Midwife

Dr Mary Macintosh
CESDI - Director



APPENDIX 2 - OBSTETRIC RISK FACTORS FOR WOMEN BOOKING FOR HOME BIRTH

(Based on Northern Lakeland Healthcare policy for GP units, with additions from the Glan Hafren NHS Trust Midwifery Led Care protocol. Where these differ from the Lakeland policy, they are marked with an asterisk*.)

1. At First Assessment
 - 1.1 Maternal characteristics:
 - Nullipara age <16 or >35
 - * Primipara or multipara age >40
 - * 4 or more previous births
 - Para 5 or more
 - Multiple pregnancy
 - Maternal diabetes (insulin and non-insulin dependent)
 - Low maternal weight (<50Kg)
 - * Low maternal weight (<45Kg)
 - * High maternal weight (>94Kg)
 - High maternal weight (>100Kg)
 - * Maternal height <152cm
 - Hypertension (systolic >150 and/or diastolic >90mmHg)
 - Significant medical disorders especially cardiac, renal or respiratory
 - Familial/genetic disorders with a high risk of transmission
 - Active Herpes Genitalis infection
 - Known Hepatitis B ag or HIV positive
 - * History of infertility
 - History of sub-fertility
 - * Any medical psychiatric, gynaecological or surgical condition past or present to be discussed with the GP, for advice on suitability of Midwifery Led Care
 - Major gynaecological history
 - Cone biopsy
 - Previous anaesthetic problems
 - Known narcotic abuser
 - * Known alcohol misuse

- 1.2 Past Obstetric History
- Perinatal death
 - Rhesus or other blood group isoimmunisation
 - Eclampsia or severe pre-eclampsia
 - Caesarean Section
 - Shoulder dystocia
 - Severe primary post partum haemorrhage
 - Retained placenta
 - Inversion of uterus
 - Prolonged labour
 - * Previous hysterotomy
 - * Cephalopelvic disproportion
 - * 3 or more spontaneous miscarriages
 - * Previous congenital abnormality
 - * Any known uterine abnormality e.g. bicornuate uterus
 - * Previous IUGR
 - * Previous low birth weight baby (<2.5Kg)
 - * Previous baby with birth weight >4.5Kg
 - * Previous hydatidiform mole
 - Previous difficult forceps delivery
 - * Previous third degree tear (undefined)
 - * Previous premature labour (undefined)
- 2 Conditions arising in pregnancy requiring consultant obstetric opinion
- * Women with concerns arising from screening tests e.g. raised AFP
 - * Abnormal GTT
 - * Isoimmune antibodies
 - Polyhydramnios
 - * Oligohydramnios
 - Malpresentation e.g. breech, transverse lie
 - * Unstable lie after 38 weeks' gestation
 - * Spontaneous rupture of membranes before 37 weeks' gestation
 - Antepartum haemorrhage
 - Pre-term labour (<37 weeks)
 - Suspected IUGR
 - * Suspected large for dates
 - Hypertension (systolic >140, diastolic >90)
 - Proteinuria
 - Excessive weight gain (undefined)
 - Non-engaged head in nullipara near term
 - Prolonged pregnancy (>41 weeks and 3 days)
 - * Haemoglobin <10g/dl at 36 weeks



APPENDIX 3 - 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 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. Due to 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. Due to accident or non-intrapartum trauma: Confirmed non-accidental injury should be coded here. If only suspected code as a sudden unexpected 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 4

Survey Number: XXXXXXXXXX

CESDI (Confidential Enquiry into Stillbirths and Deaths In Infancy) Notification Form - 1998

1. How was this case defined? (tick - it is possible for a case to be both a stillbirth death (stillborn or neonatal death) AND a legal abortion)

1.1 Stillbirth (24+ weeks) 1.2 Early Neonatal Death (age 0 - 6 days) 1.3 Late Neonatal Death (age 7 - 27 days) 1.4 Post Neonatal Death (28 to 366 days) 1.5 Legal Abortion? (Under 1687/92 Abortion Act) **yes**

MOTHER

2. Mother's surname: _____

3. First name: _____ 4. Hospital No.: _____

5. Mother's usual residential address at time of delivery/abortion: of hospital label

6. Postcode: _____

7. Mother's date of birth: _____ or _____ or _____ Tick if N.K.

8. Ethnic group of mother: White Black African Black Caribbean Black other Indian Pakistani Bangladeshi Chinese N.K. OTHER (specify): _____

9. Parity: No. of previous pregnancies of 28 weeks or over: 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100 N.K.

10. What was first day of the Last Menstrual Period (LMP): _____ Day _____ Month _____ Year _____

11. What was the agreed working Estimated Date of Delivery (EDD): _____ Day _____ Month _____ Year _____

12. Gestation at Birth (best estimate): _____ weeks + _____ days

13. Date and Time of delivery / birth: _____ Day _____ Month _____ Year _____ 24 hr clock _____

14. Intended place of delivery at booking: _____ Name of Unit / Place: _____

15. Actual place of delivery: _____ Name of Unit / Place: _____

16. Reason for change between planned and actual place of delivery: No change Change of address during pregnancy Clinical reasons before labour Other reasons before labour Clinical reasons after onset of labour Other reasons after onset of labour Unintentionally after onset of labour Not known

17. Number of fetuses / babies this pregnancy: _____ Tick if N.K.

18. Birth Order This Fetus / Baby (0, 1, 2, 3 etc): _____ Tick if N.K.

19. Maternal result or impaired outcome of pregnancy: Was there any history of maternal diabetes or glucose intolerance? If YES, was this diagnosed during the pregnancy? YES No If YES, was this treated? YES No

20. Presentation just prior to delivery: Cephalic Breech Other

21. Mode of Delivery: Spontaneous Low Forceps Other forceps (see Guidance) Vacuum Assisted Manual N.K. Emergency Caes. Sec. Planned C.S. Other

Please give name or whom to contact for further information: _____ contact address: _____ Telephone number: _____

BABY / INFANT

22. Baby's surname: _____

23. First name: _____ 24. Hospital No.: _____

25. Baby's residential address at time of death if different from Q5: of hospital label

26. Postcode: _____

27. Sex of fetus/baby: MALE FEMALE Indeterminate N.K.

28. Birth Weight (kg) (Estimate possible please): _____ Tick if N.K.

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

30. Date and Time death was FIRST diagnosed (confirming): Live births only _____ Day _____ Month _____ Year _____ 24 hr clock _____

31. Timing of death: before admission, not in labour after admission, still in labour and Late after admission, probably in labour during labour Fetal Losses ONLY after admission but before labour N.K.

32. Signs and symptoms of birth - tick all features observed in the first hour after delivery: Spontaneous breathing Spontaneous heart beat Audible cry Spontaneous body movements Early reactions No reaction Adverse reactions

33. Discharge Home after birth or neonatal care: Live Births ONLY: Was baby ever discharged home after birth? YES No N.K. If YES, date and time of readmission to hospital: _____ Day _____ Month _____ Year _____ 24 hr clock _____

35. CAUSE OF DEATH - CLINICAL DETAILS

a. Any diagnostic condition in clinical notes: _____

b. Other diagnosis or condition in clinical notes: _____

c. Microbiological diagnosis or condition affecting placenta: _____

d. Other relevant diagnostic or condition affecting placenta: _____

e. Other relevant diagnostic or condition affecting placenta: _____

36. EXTENDED WHOLESOME CLASSIFICATION (see guidance): _____

37. FETAL AND INFANT CLASSIFICATION (see guidance): _____

38. DENTISTRY CLASSIFICATION (see guidance): _____

39. POST MORTEM (AUTOPSY): Histology arranged No Requested but not given Requested but not done Parental consent but autopsy not done Other

40. Date CESDI form completed: _____ Day _____ Month _____ Year _____