Reducing risk by improving standards of intrapartum fetal care

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SUMMARY

Confidential Enquiries into Stillbirths and Deaths in Infancy (CESDI) have pointed to a high frequency of suboptimal intrapartum fetal care of a kind that, in the event of an adverse outcome, is hard to defend in court. In an effort to minimize liability, various strategies were applied in a district hospital labour ward—guidelines, cyclical audit, monthly feedback meetings and training sessions in cardiotocography (CTG). The effects of these interventions on quality of care was assessed by use of the CESDI system in all babies born with an Apgar score of 4 or less at 1 min and/or 7 or less at 5 min.

540 babies (4.3%) had low Apgar scores, and neither the percentage nor gestational age differed significantly between audit periods. In the baseline audit, care was judged suboptimal (grade II/III) in 14 (74%) of 19 cases, and in the next four periods it was 23%, 27%, 27% and 32%. In the latest audit period, after further educational interventions, it was 9%. Many of the failures to recognize or act on abnormal events were related to CTG interpretation. After the interventions there was a significant increase in cord blood pH measurement. There were no differences between audit periods in the proportion of babies with cord pH < 7.2.

These results indicate that substantial improvements in quality of intrapartum care can be achieved by a programme of clinical risk management.

INTRODUCTION

In 1992, the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) was set up to collect information on stillbirths and deaths in infancy in England, Wales and Northern Ireland and to identify ways in which these deaths might be prevented. The initial CESDI reports consistently found high levels of suboptimal intrapartum care, which might have contributed to the adverse outcome and which would be difficult to defend in court. In particular, the third annual CESDI report (for 1993) highlighted deficiencies in care relating to cardiotocography (CTG) interpretation and made firm recommendations regarding training and audit¹. The specific shortcomings identified were either a failure to recognize a problem or a failure to act appropriately when a problem had been recognized. Clearly, failure to act may lead to long delays between the onset of fetal compromise and delivery, which in turn may contribute

substantially to the risk of death². In a recent regional perinatal audit, 70% of intrapartum deaths were deemed to have had avoidable factors, most notably a lack of understanding of CTG interpretation³. It is not surprising that there is public concern when 'at least one new born baby a day dies because of a mistake made by doctors and midwives', reinforced by comments such as 'nights and weekends are the killing fields when consultants are not there'⁴.

Although intrapartum death is undoubtedly a calamity, brain damage has more far-reaching consequences for the family and for the health professions⁵. The evidence linking brain damage to intrapartum care remains uncertain^{5,6–8} but this has become the dominant litigation theme internationally. Where liability and causation are both conceded, awards in court to a litigant may be in excess of £3 million. Currently obstetric cases are costing the National Health Service (NHS) £160–200 million/year, constituting 60% of litigation pay-outs (Towns D, personal communication). In terms of contingent liability, the figures facing the NHS are even greater. This has been estimated at nearly £3 billion, against the total NHS annual budget of £37 billion⁹. Although the scoring system used by CESDI assessors has not been formally applied to

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assessments of care of brain-damaged babies, it is clearly relevant given that suboptimal care is very likely to be considered indefensible in court.

Because both intrapartum death and intrapartum brain injury are rare events, an alternative outcome is required for monitoring quality of care. One approach is to identify 'near-miss' cases¹⁰. Currently no single outcome measure can identify such a group⁶. However, the Apgar score is a convenient tool used by all maternity professional groups as a broad measure of immediate fetal wellbeing, and a very low Apgar score is known to be associated with an increased risk of cerebral palsy⁶. Although most babies born with low Apgar scores have good outcomes, they constitute a convenient group in which to establish regular monitoring of quality of care in labour¹¹. In 1994, we had our first multidisciplinary democratic prioritization audit planning day (ASQUAM: Achieving Sustainable Quality in Maternity). This process, described elsewhere 12, resulted in the choice of ten topics per year. Improving the quality of intrapartum fetal care (and therefore minimizing liability) was one of the topics chosen for audit at this first meeting. Subsequently, a further audit standard in relation to measuring cord gases in all 'at risk' infants was included. If normal cord gas results can be presented, the suggestion of a damaging intrapartum hypoxic event is more easily countered⁶. Very few centres in the UK systematically undertake cord-blood sampling⁸.

METHODS

The aim of the audit was to establish whether there was evidence of suboptimal antepartum or intrapartum care for an arbitrarily selected group of babies born in our unit. We chose to look at a manageable cohort of babies each month. The selection was based on low Apgar scores at 1 or 5 minutes. The Apgar scores initially chosen for cut-off were ≤ 5 at 1 minute ≤ 7 at 5 minutes but the 1-minute cut-off was amended to ≤4 from audit period 3 (December 1997) onwards. Other risk criteria could equally have been chosen to identify a group for closer audit, such as low birthweight or preterm gestation. We wished to identify the main areas of suboptimal care and the level of person responsible. In those cases which might have been medicolegally indefensible (CESDI grade II/III), we wished to categorize the main shortcoming in care and note the level at which deficiencies occurred, so as to allow educational feedback to medical and midwifery staff. We also wished to examine in more detail the nature of CTG problems in CESDI grade II/III cases and the rate of cord gas analysis in this cohort. The audit team consisted of the clinical governance support officer (CR), a senior labour ward midwifery sister (MM), an obstetric senior registrar with a perinatal interest (RH, SH and PY) and a

senior lecturer in perinatology (RJ). Our audit standard was that 'No babies born with low Apgar scores should have had suboptimal (CESDI grade II/III) care'.

Audit method

The audit was a critical retrospective analysis of case notes by the team and consensus between authors on whether there was evidence of suboptimal care. Certain cases (usually difficult or controversial) were chosen for discussion in greater detail at the 'low Apgar' meeting. The purpose of the meeting was not to lay blame but to learn jointly from mistakes¹³. Details that could have identified patients and staff were withheld to allow objectivity. Final CESDI grading was agreed democratically, along with judgments about principal areas of deficiency and the level at which deficient care occurred (in some cases more than one level):

- CESDI 0: No suboptimal care (no risk)
- CESDI I: Suboptimal care but different management would have made no difference to the outcome (defendable risk)
- CESDI II: Suboptimal care where different management might have made a difference to the outcome — an avoidable factor of uncertain clarity or influence on outcome (possibly defendable risk)
- CESDI III: Different management would reasonably be expected to have made a difference to the outcome. A clearly avoidable factor implying that the adverse outcome could have been prevented (undefendable risk).

The baseline audit was undertaken in October 1994. The initial interventions thereafter consisted of an open feedback meeting and reinforcement of current labour ward guidance on CTG interpretation and on communication. A follow-up audit was undertaken in October and November 1995. Thereafter, the audit consisted of a series of interventions linked to cyclical review.

Long-term interventions and cyclical audit

Local guidelines

Recommendations from the third CESDI report, findings from the Cochrane Database of Systematic Reviews¹⁴ and evidence from published observational work were incorporated in local guidelines. The guidelines include examples of abnormal CTGs from the 'Crimson File' (a collection of case studies, mainly of intrapartum death, drawn from the West Midlands region)¹⁵. These guidelines were available in full on the labour ward and on the antenatal and postnatal wards as well as in the antenatal clinics, and in the midwifery and medical libraries. A

Table 1 Number of low-Apgar cases and CESDI classification

	Oct 1994	Oct-Nov 1995	Dec 1995-Sept 1996	Aug-Dec 1997	Jan-July 1998	Aug 1998-Jan 1999	
	Baseline	Audit 1	Audit 2	Audit 3	Audit 4	Audit 5	
No. of deliveries	451	852	4220	1981	2467	2494	
Low Apgar scores at 1 min	19 (4.2%)	29 (3%)	189 (4.5%)	101 (5%)	69 (3%)	80 (3%)	
Low Apgar scores at 5 min	9 (1.9%)	11 (1.29%)	81 (2%)	43 (2%)	35 (1%)	46 (2%)	
No. of cases	19 (4%)	31 (4%)	204 (5%)	108 (5.5%)	82 (3%)	96 (4%)	
37-42 wk gestation	17 (89.5%)	20 (64.5%)	131 (64%)	71 (66%)	47 (57%)	61 (63.5%)	
<37 wk gestation	2 (10.5%)	11 (35%)	73 (36%)	37 (34%)	35 (43%)	35 (36.5%)	
Grade III	10 (53%)	4 (13%)	11 (5.5%)	10 (9%)	7 (8.5%)	5 (5.25%)	
Grade II	4 (21%)	3 (10%)	43 (21%)	19 (18%)	19 (23%)	4 (4%)	
Grade I	1 (4%)	4 (13%)	39 (19%)	29 (27%)	11 (13.5%)	9 (9.5%)	
Grade 0	4 (21%)	20 (64%)	111 (54.5%)	50 (46%)	45 (55%)	78 (81.25%)	
Cord pH measured	10 (53%)	17 (55%)	119 (58%)	65 (60%)	57 (69.5%)	70 (73%)	
pH <7.20	2 (20%)	7 (41%)	43 (36%)	22 (34%)	14 (25%)	25 (26%)	
Term babies with low Apgar scores admitted to neonatal unit (% total deliveries)	8 (1.77%)	6 (0.7%)	30 (0.7%)	23 (1.17%)	12 (0.48%)	15 (0.6%)	

CESDI=Confidential Enquiries into Stillbirths and Deaths in Infancy.

shortened version of the guideline was included in the hospital pocket handbook used by all staff on labour ward.

Regular monthly audit

This began at the end of November 1995. All case records of babies who had low Apgar scores 2 months previously were reviewed.

Feedback meetings

Regular low-Apgar meetings began in November 1995. All staff, obstetricians, anaesthetists, paediatricians and hospital and community midwives were invited. The cases with low Apgar scores from 2 months previously were discussed with an increased focus on cases where CESDI grading was considered to be II/III. However, we took pains to discuss not only cases where care might have been poor but also those where care was of a high standard, enabling some positive feedback. The sessions were also used for continuing CTG education, as an adjunct to the CTG training programme introduced in our unit. Where serious deficiencies in care were identified, individual educational feedback was sensitively undertaken before the meeting, enabling the individuals to gain maximum benefit from the meeting.

Teaching programme

RH initiated the first six-session CTG training course. These have been repeated on several occasions, the format having evolved over the intervening 4 years, currently taking two half days every six months (for both midwives and doctors). To date, about 130 midwives have attended for training, with nearly 100 of them attending all sessions; however, only a minority of doctors have participated.

Feedback from conference presentations

Presentations of the low-Apgar audit made at national and international conferences were given locally as well. Posters shown at these conferences were also displayed in various locations within the maternity block.

Statistical methods

To assess the change in distribution of different outcome variables over the six audit periods we used the Kruskal—Wallis test. Armitage's trend test¹⁶ was also used, for example, to compare grade 0 with grades I/II/III and grade III with grades II/I/0 over the six periods. The software was StatXac Turbo (CYTEL), Cambridge, Massachusetts.

RESULTS

During the period of our study 12 465 babies were born in North Staffordshire Hospital. Of these 540 had low Apgar scores (4.3%). Overall 193 of the low-Apgar babies were born at < 37 weeks (36%) but the proportions of preterm babies in each audit period did not differ (trend χ_1^2 =0.0012,

Table 2 Main areas of suboptimal care (grades II/III cases)

	Oct 1994 Baseline (N=14)	Oct-Nov 1995 ——————————————————————————————————	Dec 1995- Sept 1996 Audit 2 (N=54)	Aug-Dec 1997 ——————————————————————————————————	Jan–July 1998 (excl Apr) Audit 4 (N=26)	Aug 1998– Jan 1999 Audit 5 (N=9)
Failure to recognize	4	1	15	4	6	2
Failure to act	7	5	20	20	9	2
Failure in communication	1	0	5	0	2	0
Other	2	1	14	5	9	5
Most senior person responsible						
Consultant Senior registrar/staff grade	1	1	12	8	5	0
Registrar, acting-up SHO, SHO	5	5	23	15	10	4
Midwifery sister, community midwife	2	1	11	2	3	2
Staff midwife, student midwife	4	0	6	4	2	2
Other	2	0	2	0	6	1

SHO=senior house officer

P=0.97); nor did the proportion of low-Apgar cases differ significantly between audits.

Of the 19 cases in the baseline audit period, 14 (74%) had grade II/III suboptimal care (Table 1). Following the initial interventions, the proportions of grade II/III cases fell significantly and this improvement was sustained over the next four periods of the audit programme (23%, 27%, and 32%). After CTG training was made 'compulsory' for all staff involved in intrapartum care¹⁷, the proportion of II/III cases fell to 9.25%. The differences seen in overall distribution of CESDI scores were highly significant according to the Kruskal-Wallis statistic (based on χ_5^2 =46.23). The trend test comparing grade 0 with I/II/ III was also significant (trend $\chi_1^2=18.45$, P<0.001), as was the trend test comparing grade III with II/I/0. However, during the four periods, the proportion of babies requiring admission to the neonatal unit did not change significantly, nor did the number of babies with a cord pH < 7.2 change over the audit periods. The proportion of cases where cord pH was taken and documented did increase significantly over the period (trend $\chi_1^2 = 7.76$, P = 0.0053).

The main areas of suboptimal care and the levels of responsibility are shown in Table 2. The scope for improvement is in the first two items—failure to recognize and failure to act. Other areas identified were failure in communication, paediatric problems, failure of equipment and patient responsibility. The group most frequently implicated is that of the junior medical staff.

Closer examination of CTGs for the CESDI II/II cases (n=139 over the six periods) showed that most of the problems relate to failure to act on recognized

abnormalities (62/139, 45%). However, failure to recognize an abnormality was also common (32/139, 23%). Poor-quality CTGs (18/139, 13%) and delayed response to recognized abnormalities were also important (33/139, 24%).

DISCUSSION

Our findings in relation to poor-quality care closely resemble those of the West Midlands Perinatal Audit Group¹⁸ and those in the third CESDI report¹⁹. Although the initial audit was in small numbers, the figure of over 70% for CESDI II/III was comparable with that recorded in a large survey in the same territory³. Over the period of nearly 5 years since conducting the baseline audit we have addressed the identified problems by a series of interventions. We regard the audit feedback meetings²⁰ as key to the improvements, and suspect that the fall in cases attributable to midwifery error is due to the high midwifery attendance at CTG training courses. Although extensive local guidelines have been available for over 2 years, evidence from other audits within the ASQUAM programme suggests that busy clinicians tend not to consult them. Guidelines need to be linked to audit to be effective²¹.

Whilst the implementation of recommendations from the West Midlands Perinatal Audit, Crimson File and CESDI can be expected to reduce perinatal mortality, there is little evidence that better intrapartum care has much to contribute in terms of brain injury and long-term adverse outcomes⁶. Within the 5 years of the study,

although our efforts to improve quality have been rewarded by a fall in 'indefensible' care, the proportions of babies with low Apgar scores and low cord pH have not changed, nor are any fewer being admitted for neonatal intensive care. This is entirely in keeping with the growing opinion that better fetal monitoring and earlier recourse to caesarean section are unlikely to reduce cerebral palsy^{22,23}. Nevertheless, improving the standards of intrapartum care is fundamental to minimizing medicolegal risk^{24,25}. Were it possible to reduce 'indefensible' care from 70% to less than 30%, the savings could run into many millions. Our system for monitoring and learning from mistakes is endorsed by recommendations in the key CESDI reports^{19,26}.

NHS organizations are now charged with 'continuously improving the quality of their services and safeguarding high standards of care....'²⁷. Scally and Donaldson highlighted some of the deficiencies of clinical audit and emphasized the importance of learning from mistakes and of adverse incident reporting. Clinical risk management is therefore a key component of clinical governance²⁸. Secker-Walker explains that introduction of clinical risk management takes many months and is only really successful when accompanied by a change in culture. All staff need to feel comfortable with the process. Our project has confirmed the need to be patient in terms of achieving improvements.

We are aware of further improvements required in training and risk management. One approach is the development of a series of videos to train midwives and doctors in various aspects of intrapartum care^{29–31}. We hope that this will increase the uptake of 'training' by the doctors in our team. Additionally, as recommended by CESDI²⁶, we have made a computerized CTG training system available on labour ward³². Finally, the low-Apgar cases are now being considered at daily partogram audit and weekly adverse incidence meetings, to allow earlier feedback.

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REFERENCES

1 Department of Health. Report of the Confidential Enquiry into Stillbirths and Deaths in Infancy. Annual Report for 1993 Parts 1 & 2. London: DOH, 1995

- 2 Alessandri LM, Stanley FJ, Read AW. A case–control study of intrapartum stillbirths. Br J Obstet Gynaecol 1992;99:719–23
- 3 West Midlands Perinatal Audit. The Crimson File. CTGS Guidance for Interpretation. Keele: West Midlands Perinatal Audit, 1995
- 4 Macdonald V, Cole E. Doctor vanishes on eve of stillbirth enquiry. Daily Telegraph 30 November 1997
- 5 Clements RV, Simanowitz A. Cerebral palsy the international consensus statement [editorial]. Clin Risk 2000;6:135–6
- 6 MacLennan A. A template for defining a causal relation between acute intrapartum events and cerebral palsy: international consensus statement. BMJ 1999;319:1054—9
- 7 Pickering J. Legal comment on the international consensus statement on causation of cerebral palsy. Clin Risk 2000;6:143–4
- 8 Dear P, Rennie J, Newell S, Rosenbloom L. Response to the proposal of a template for defining a causal relation between acute intrapartum events and cerebral palsy. Clin Risk 2000;6:137–42
- 9 Toynbee P. Shellshocked by cost of complaints. BMA News Rev July 1999:28
- 10 Barach P, Small PS. Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. BMJ 2000;320: 759–63
- 11 Helmreich RL. On error management: lessons from aviation. BMJ 2000;320:781–5
- 12 Johanson RB, Rigby C. Clinical governance in practice. J Clin Excellence 1999;1:19–22
- 13 Reason J. Human error: models and management. BMJ 2000;320:770
- 14 Thacker SB, Stroup DF. Continuous electronic heart rate monitoring versus intermittent auscultation for assessment during labor. (Cochrane Review). In: *The Cochrane Library, Issue 2, 2000*. Oxford: Update Software, 2000
- 15 Tan KH, Wyldes MP, Settatree R, Mitchell T. Confidential regional enquiry into mature stillbirths and neonatal deaths — a multidisciplinary peer panel perspective of the perinatal care of 238 deaths. Singapore Med J 1999;40:251—5
- 16 Altman DG. Practical Statistics for Medical Research. London: Chapman & Hall, 1991
- 17 Clinical Negligence Scheme for Trusts (CNST). Clinical Risk Management Standards: Additional Standards Effective from 1.10.99. London: NHS Litigation Authority, 1999
- 18 West Midlands Perinatal Audit. Stillbirth and Neonatal Death 1991– 1994. Report of National, Regional, District and Unit Mortality Rates. Keele: West Midlands Perinatal Audit, 1996
- 19 Department of Health. Report of the Confidential Enquiry into Stillbirths and Deaths in Infancy. Annual report for 1995 Parts 1 & 2. London: DoH, 1997
- 20 Barach P, Small SD. How the NHS can improve safety and learning. By learning free lessons from near misses. BMJ 2000;320:1683–4
- 21 NHS Centre for Reviews and Dissemination. *Effective Health Care Bull* 1999;**5**:1–16
- 22 Anonymous. The origins of cerebral palsy: a consensus statement, the Australia and New Zealand Perinatal Societies. Med J Aust 1995; 162:85–9
- 23 Anonymous. Cerebral palsy, intrapartum care, and a shot in the foot. Lancet 1989;ii:1251–2
- 24 Umstad MP, Permezel M, Pepperell RJ. Intrapartum cardiotocography and the expert witness. Aust NZ J Obstet Gynaecol 1994;34:20–3
- 25 Action for Victims of Medical Accidents. Fetal distress—failure of midwife to call for assistance—spastic quadriplegia. Inman v Cambridge Health Authority. AVMA Med Legal J 1998;4: 89–100
- 26 Maternal and Child Health Research Consortium. Confidential Enquiry into Stillbirths and Deaths in Infancy. 7th Annual Report. London: MCHRC, 2000

- 27 Scally G, Donaldson LJ. Clinical governance and drive for quality improvement in the new NHS in England. BMJ 1998;317:61–5
- 28 Secker-Walker J. Clinical risk management. In: Lugon M, Secker-Walker J, eds. Clinical Governance: Making it Happen. London: RSM Press, 1999:77–91
- 29 Gibb D, Johanson RB, Lucking P. Fetal wellbeing: Dealing with Aspects of Fetal Monitoring. Coventry: Baby Lifeline Trading Ltd (video recording), 2000
- 30 Arulkumaran S, Gibb D, Lucking PA. Clinical Applications of CTG Monitoring. Coventry: Baby Lifeline Trading Ltd (video recording), 2000
- 31 Young PF, Johanson RB, Lucking P. The Crimson File: Lessons from CTG Disasters. Coventry: Baby Lifeline Trading Ltd (video recording), 2000
- 32 Beckley S, Stenhouse E, Greene KR. The development and evaluation of a computer-based teaching package for intrapartum fetal monitoring. Br J Obstet Gynaecol (in press)