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Each Baby Counts: National Quality improvement programme to reduce intrapartum related deaths and brain injuries in term babies

Louise Robertson (MBChB, MRCOG, louiserobertson5@nhs.net, Centre for Women's Health Research, University of Liverpool, Crown Street, Liverpool, L8 7SS, telephone 07702222118)

Hannah Knight (BA, MSc, HKnight@rcog.org.uk, Royal College of Obstetricians and Gynaecologists, 27 Sussex Place, London, NW1 4RG)

Edward Prosser-Snelling (BA (Hons), MBBS, MRCOG, edwardprosser-snelling@doctors.org.uk, Norfolk and Norwich University Hospital, Colney Lane, Norwich, NR47UY)

Emily Petch (BA, epetch@rcog.org.uk, Royal College of Obstetricians and Gynaecologists, 27 Sussex Place, London, NW1 4RG)

Marian Knight (MA, MBChB, MPH, DPhil, FFPH, FRCPE, marian.knight@npeu.ox.ac.uk, Professor of Fetal and Child Population Health, University of Oxford Maternal and Infant Health, University of Oxford, Old Road Campus, Headington, Oxford, OX3 7LF)

Alan Cameron (MD, FRCOG, FRCP (Glas), ACameron@rcog.org.uk, Professor Obstetrics and Gynaecology, Southern General Hospital, 1345 Govan Rd, Govan, Glasgow G51 4TF)

Zarko Alfirevic (MD, FRCOG, zarko@liverpool.ac.uk, Professor of Fetal and Maternal Medicine Women's and Children's Health, Centre for Women's Health Research, University of Liverpool, Crown Street, Liverpool, L8 7SS)

Abstract

Although the most recent MBRRACE – UK perinatal mortality report has shown a downward trend in perinatal mortality, the UK still lags behind the best performing countries in Europe.

The burden of perinatal morbidity and mortality is wide reaching and devastating for the families and care providers involved. The aim of the Each Baby Counts project is to reduce intrapartum term stillbirths, early neonatal deaths and severe brain injuries by 50% by 2020.

Every maternity care provider has been asked to report their intrapartum term stillbirths, early neonatal deaths and severe brain injuries to the EBC project and provide a copy of the local review. The local reviews are assessed by two trained EBC reviewers in order to establish if the reviews are of adequate quality. The EBC reviewers are asked independently to assess if there is sufficient clinical information to make a clinical judgement about care, and if different care could have had a positive impact on the outcome. The reviewers are asked to indicate in what areas care could be improved.

The analysis of the local reports will be two fold. Initially quantitative analysis will provide us with information about the scale of the problem, the quality of the local review process into adverse events and who is involved in such reviews. Qualitative analysis of the themes highlighted in the reviews will enable us to develop care bundles or other tools to drive local quality improvement.

Key Points

- Each Baby Counts Project is a UK-wide initiative aiming to reduce intrapartum stillbirth, early neonatal death and severe brain injury in term infants by 50% by 2020

- The process collates local reviews in order to establish an ongoing UK-wide surveillance of term intrapartum stillbirth, early neonatal death or severe brain injury in normally formed infants
- The first report highlighted the need for more robust local reviews using a standardised perinatal mortality tool that is expected in the near future
- Parental involvement in local reviews needs to be improved and encouraged
- Reviews should be multidisciplinary and there are significant benefits to including an professional member of the review panel from outside the investigating organisation
- The next challenge is to look at the themes that arise from the local reviews and develop recommendations and drive improvement in maternity services

Introduction

The most recent MBRRACE- UK perinatal mortality report shows a downward trend in perinatal mortality, nevertheless, the UK¹ still lags behind the best performing countries in Europe². Experiencing a stillbirth, neonatal death or severe brain injury in their newborn is associated with significant emotional, psychological, social and economic costs to parents, their families and friends³. Caring for parents and children through such events also has a significant impact upon the healthcare professionals involved. Claims concerning negligence in maternity care reported to the National Health Service Litigation Authority (NHSLA) represent the highest value of claims and second highest frequency of claims⁴. The highest value claims are Cerebral Palsy (40.52%), CTG interpretation (14.95%) and management of labour (13.6%) according to a report in 2012⁴. The total value of all claims in this 10-year period was £3.1 Billion. Of this amount stillbirth claims amounted to just 0.5%. Current

expenditure in maternity claims has risen to nearly £500 million per year⁵, making clear the potential financial savings from these two groups alone. In addition to this financial cost is the unquantifiable social, psychological and emotional cost to the families and staff involved.

Epidemiology of Intrapartum Related Stillbirth and Perinatal Death

More than a million stillbirths are estimated to occur in labour each year⁶. Unfortunately, over 130 countries do not have available data on intrapartum stillbirths⁶. In the UK, 1 in 12 stillbirths occur intrapartum at any gestation¹, and the incidence is likely to be much higher in Low and Middle Income Countries (LMICs)⁶. There is considerable variation in overall stillbirth rates across High Income Countries (HICs) ranging from 1.3 per 1000 births in Iceland to 8.8 per 1000 births in the Ukraine². The UK sits in the middle of the rankings with a rate of 2.9 stillbirths per 1000 births². Direct comparison between countries continues to be hindered by variation in data capture and reporting methods, including variable inclusion of termination of pregnancies or the use of lower gestations to define stillbirth, however real epidemiological variation in rates is present with potential for reduction².

Identifying the causes of intrapartum events and formulating solutions

Maternity care in the UK has a strong association with risk management as is evident through the achievements in reduction of maternal mortality associated with pregnancy through the national level confidential enquiries dating back to 1952⁷. The 1997 Confidential Enquiries into Stillbirths and Deaths in Infancy (CESDI) report included a chapter that looked at intrapartum related deaths of normally formed babies weighing > 1.5kg in 1994-1995. The report found that 660 (75.6%) of the 873 intrapartum fetal deaths were associated with suboptimal intrapartum care⁸. Errors in fetal heart rate monitoring, CTG interpretation, risk

assessment, management of labour and delivery were identified as the common themes in these cases⁹.

In 2003, a retrospective audit of 10 regions in Europe examined perinatal deaths between 1993 and 1998. The English region consisted of seven former NHS regions in England. In the English region, 53.5% of cases involved suboptimal care that had either possibly or likely contributed to the fatal outcome⁹. When this was compared to the 9 other regions, England had the highest percentage of cases that involved suboptimal care¹⁰.

Seven years later a regional confidential enquiry found that 21 of 25 or 84% of the intrapartum fetal deaths could have been avoided if better care was provided and identified CTG interpretation, risk assessment, management of labour and delay in labour as causes¹⁰. Therefore, we know that there is a problem and that common themes have previously been identified but there has been very little change in these themes over the last 19 years. The Each Baby Counts (EBC) project has established an infrastructure that brings together the results of local investigations into these events to understand the bigger picture and share the lessons learned to improve future care.

Rationale for the Each Baby Counts (EBC) Project

The overall aim of the EBC project is to achieve a 50% reduction in the incidents during term labour that lead to stillbirth, early neonatal death and severe brain injury in normally formed infants by 2020. However, the evidence base for effective actions to reduce stillbirths and neonatal deaths is still developing¹¹, and that due to the relative infrequency of these events randomised controlled trials are unlikely to be feasible. By bringing together data from all local investigations of the care of babies who die or have a severe brain injury, contemporary common themes can be identified that can be used to formulate

recommendations for improvements in the provision of maternity care. This EBC goal will be achieved through the following four objectives:

1. To set up an ongoing UK-wide surveillance of term intrapartum stillbirth, early neonatal death or severe brain injury in normally formed infants
2. To undertake ongoing analysis of local governance/risk management investigations of these babies
3. To use the results of this analysis to encourage local improvement the quality of maternity services. Some of the issues identified will be national, but the focus of the project is on local quality improvement initiatives.
4. To use the data we collect to drive continuous improvement in services, measuring our stated outcomes over the period of our project and reporting trends.

Inclusion criteria

The Each Baby Counts project focuses upon normally-formed term babies including multiple pregnancies. Notifiable babies include those born at term (≥ 37 completed weeks of gestation) following labour that resulted in one of the following outcomes:

- Intrapartum stillbirth: when the baby was thought to be alive at the start of labour but was born with no signs of life.
- Early neonatal death: when the baby died within the first week of life (i.e. days 0-6) of any cause.
- Severe brain injury diagnosed in the first seven days of life, when the baby:
 - Was diagnosed with grade III hypoxic ischaemic encephalopathy (HIE) OR
 - Was therapeutically cooled (active cooling only) OR

- Had decreased central tone AND was comatose AND had seizures of any kind

This is a pragmatic definition which is a composite of defined populations such as the TOBY (Total Body HYpothemia) trial¹² as well as data that we are able to capture from neonatal information systems. The definition is deliberately wide in order to maximise the learning that is possible.

In order to capture as many 'intrapartum' events as possible the definition of labour includes:

- Any labour diagnosed by a health professional, including the latent phase of labour at less than 4cm cervical dilatation
- When the woman called the unit to report any concerns of being in labour, for example (but not limited to), abdominal pains, contractions or suspected ruptured membranes
- When the baby was thought to be alive at induction of labour
- When the baby was thought to be alive following suspected or confirmed pre-labour rupture of membranes

Although intrapartum care at term is a narrow focus, we believe that such an emphasis will allow us to target the most preventable causes of perinatal death and injury, as these women are under medical and midwifery care, when the events occur. Limiting the project to intrapartum events also reduces overlap with other work that is being undertaken aiming to reduce antenatal stillbirths.

By including women in the latent phase of labour the EBC project is adopting an inclusive approach and thus potentially capturing causes of death and severe injury that are not investigated systematically elsewhere. It was felt that the learning from these early labour

events could be significant and this warrants their inclusion. Management in the latent phase is varied and at present there is no national guidance. By including these babies we may identify an area that could benefit from further research to improve care in the latent phase.

Rather than restricting the project only to stillbirths, the inclusion criteria includes early neonatal deaths and severe brain injury associated with term labour. The importance of including these babies is that the events that there is overlap between the causative events which lead to such injuries, and that they may be avoided by similar changes in care. There is little information on children who are born with severe perinatal asphyxia that is likely to lead to life-long disability, therefore, including these babies in the study will allow more information to be gleaned that can be turned into learning.

Collection of the data

From January 2015, all maternity care providers in the UK were asked to nominate a Lead Reporter who would have responsibility for completing the online registration form for all eligible babies born in their unit. Data collection started in February 2015 and by April 2015 100% of the NHS trusts and health boards in the UK had agreed to participate in the Each Baby Count Project. Private maternity hospitals and independent midwives have also been invited to participate in the project to ensure improvements in all aspects of intrapartum care can be identified.

Initially Lead Reporters are requested to complete some basic information within 5 working days of the baby's birth or death. This information confirms the eligibility of the baby and the delivery characteristics using data available in the maternal and/or baby case records

and discharge summary. No identifiable data are collected as part of the programme. Data collection is via a secure online platform¹³.

Once the local review of the baby's care has been completed Lead Reporters are asked to upload an anonymised copy of the report for further analysis. The anonymised report from the local review is then sent to two Each Baby Counts trained reviewers, a midwife and an obstetrician. The reviewers do not have access to the case notes or statements from the staff involved therefore the process is reliant upon the quality of the local reviews. The reviewers are required to answer the following questions

- In your opinion, taking into account the information presented, is this review of sufficient quality to make a judgement on the care provided?
- According to the information presented, would different clinical care have resulted in a different outcome?
- What were the critical contributory factors that, if done differently, could have changed the outcome?¹⁴

The reviewers have the option of further analysis by an additional expert if they feel it is warranted, for example a neonatologist or anaesthetist. Reviewers are not asked to assess the care of babies from their own or neighbouring regions to reduce the possibility of recognition of individuals and for the protection of the confidentiality of both patients and staff involved.

Case ascertainment

At periodic intervals the data that are submitted to the EBC project are cross-checked with national sources of data to ensure that all eligible babies are identified. Intrapartum

stillbirths and early neonatal deaths are cross-checked against MBRRACE-UK data which are themselves cross-checked with the Office for National Statistics, National Records for Scotland and hospital data in Northern Ireland birth and death registration data.

Severe neonatal brain injury cases are identified through the National Neonatal Research Database (NNRD) that encompasses 98% of neonatal units in England and Wales and some units in Scotland¹⁵. Northern Irish neonatal units use the Badger.net database¹⁶ and this is also used to check case ascertainment against these data.

The group that may be difficult to fully ascertain are the babies who are thought to be alive at the onset of labour by their mother, but are found to have died when she attends the hospital. These babies are nevertheless included as far as possible in order to learn messages from their care.

Around four times a year, Lead Reporters are sent lists of potentially eligible babies that have been born in their unit and they will be asked to confirm their eligibility via the online reporting system. The Clinical Director of Obstetrics (also known as Chief of Service) in each maternity unit is held ultimately responsible for ensuring that data are submitted in a timely fashion and that each eligible baby is reported.

It is anticipated that the project will be able to identify all cases of intrapartum stillbirth and early neonatal death as these are reportable events through MBRRACE-UK and the Office of National Statistics but babies with severe brain injury may prove more difficult to fully identify. One of the objectives of the EBC project is to develop UK-wide surveillance of these babies and therefore to provide more reliable data, accepting that it may take some time to perfect case ascertainment.

Preliminary results from 2015 (January-December)¹⁷

Of the over 777,000¹⁸ babies that were born in the UK in 2015, provisional data suggests that 921 were eligible for EBC. 119 (13%) were intrapartum stillbirths, 147 (16%) babies died at less than 7 days of age and 655 babies (71%) had severe brain injuries. Of the babies who were stillborn intrapartum, 77 were confirmed to be alive at the onset of care in labour by a health professional, 42 were thought to have been alive at the start of labour but this was not verified by a health professional.

Initially, we estimated between 500 and 900 babies would be eligible for the EBC project each year, equating to approximately 1 per 1,000 births. This estimate is made up of

- 168-226 intrapartum stillbirths
- 163 – 373 early neonatal deaths
- 170-300 infants with severe brain injury

These figures were based on calculations performed on the rates of stillbirth, early neonatal death and severe brain injury found in the MBRRACE-UK 2015 report¹, CMACE 2011 report¹⁹, Office for National Statistics (ONS) 2012 data²⁰, National Neonatal Audit

Programme 2011 Report²¹, Welsh HIE study²² and The Neonatal Data Analysis unit data from 2014²³. There were limitations with the estimations as term intrapartum events are often not separated out of the data and there is a significant overlap between severe brain injury and early neonatal death that is difficult to extract from the data.

The number of babies eligible for EBC was higher than the estimate. This is largely due to a higher number of babies than we expected that suffered severe brain injury and reflects the likelihood that these babies have probably not been fully acknowledged in other perinatal audits or research studies. Although the definition of brain injury is limited to the information we have in the first 7 days of the child's life these babies are undergoing intensive treatments via therapeutic cooling or have obvious gross neurological dysfunction and so they represent a group of babies that have been significantly affected. A majority of the infants meeting the criteria for severe brain injury (96%) were actively cooled. This is an intensive intervention requiring sedation and admission to the neonatal unit and at times transfer to another unit which reflects the seriousness of these babies condition at birth. Evidence from the TOBY Children Study shows that 22% of the children who survive and are cooled for birth asphyxia are at risk of moderate or severe disability²⁴.

Of the 921 eligible babies, at the time of analysis in May 2016, 610 reports (66%) had been fully completed by the Lead Reporter. The remaining 34% were incomplete either because the report had not been completed or because further information had been requested. Of the 610 reports had been fully completed, 599 (98%) had undergone some kind of local review.

Figure 1 Tool or methodology used in local reviews, demonstrating little consistency in local practices

From the initial reviews, only 52% used a specific tool or methodology to conduct the review (Figure 1). While 96% of the local reviews were carried out by a multidisciplinary team, only 62% involved a neonatologist. Considering that 87% of the eligible EBC babies are babies that were born alive and either died in the neonatal period or had severe brain injury neonatal specialist input would be crucial to a review identifying causes or solutions. Seven percent of panels included an external panel member (Figure 2).

Figure 2 Composition of local review panels

Parents were invited to be part of the review in only 25% of cases; a further 50% of parents were made aware of the review but were not invited to contribute. Excluding parents from the reviews risks missing vital information about what happened, as they are first hand witnesses to the care they received and may have valuable information for future care. In light of our duty of candour, that we as clinicians must be open and honest with a patient when something goes wrong²⁵, the transparency strived for in such investigations and the respect that should be afforded to the parents, it is imperative that they are invited to be part of this review process. The involvement of parents and relatives in the review process formed part of the recommendations in the Kirkup report on the investigation of Morecambe bay NHS Foundation Trust in 2015²⁶. The report also recommended that clear standards for incident reporting and investigation should be drawn up and it is hoped that the EBC project will help facilitate improvement and standardisation in incident reporting and investigation.

Two hundred and four of the 599 local reviews have been assessed by the two EBC Reviewers; in 27% both reviewers agreed that the report did not contain sufficient information to allow the care to be classified and in a further 10% one of the reviewers felt there should be more information.

The lack of consistency in using a recognised tool and insufficient evidence included in the reviews echo the problems found in Confidential Enquires and the Kirkup Report. Failure to undertake a robust investigation into these events prevents learning and leaves a risk of repeating the mistakes again and again. This is evident in the recommendations among the local reviews that have been evaluated. Of the 150 local reviews with sufficient information for full evaluation, 32 (21%) contained no actions or recommendations, 27(18%) contained recommendations that focused solely on individual members of staff, in 11(7%) it was not clear if the recommendations were individual or systems based and the final 80 (53%) did involve recommendations that were systems based. In 2000 the Department of Health report *An Organisation with a Memory* stated the importance of identifying the causes of serious failures that are likely to stretch far wider than one or two individuals involved in care²⁷ yet this is evidence that local reviews undertaken still focus on individual rather than system errors.

Each case is assessed as to whether different management could have changed the outcome. If different management would have had a positive impact on the outcome the reviewers are asked to indicate in what areas different management would have altered the outcome under the following categories;

- CTG interpretation and fetal blood sampling
- Intermittent auscultation

- Risk recognition
- Team communication
- Individual human factors
- Education/training issues
- Management of labour
- Management of delivery
- Management of neonatal care
- Patient factors

The EBC team will then analyse the frequency of certain factors and identify themes that will be subjected to further qualitative analysis. Identifying these themes, which, are likely to be multifactorial, will facilitate the development of recommendations for changes in care or services that we hope will lead to a reduction in the number of babies who die or who are seriously injured as a result of intrapartum events. There is no way, however, to re-invent the current system of regulation and clinical governance that exists in the UK. Trusts, Units and Providers will all have to take responsibility for improving the quality of their own care. The Each Baby Counts reports and quality improvement recommendations will provide useful perspectives and ideas for identifying gaps in patient safety. The training gap in quality improvement skills is something which has been addressed by the Academy of Medical Royal Colleges, who have made recommendations as to how to deliver the quality improvement training that is needed²⁸. Illustrative vignettes will highlight particular aspects of care in order to encourage individual health professionals to think beyond their current practice and to give meaning to the figures presented²⁹.

This analysis is qualitative in nature, subject to the quality of local incident reviews and must be carefully considered; it is not evidence from a randomised controlled trial, but these are unlikely to be feasible. Therefore, it represents the best opportunity to generate learning to improve care, as it is conducted by pairs of independent multidisciplinary reviewers. It will bring together the results of many hours of work completed by multidisciplinary review teams and share the learning that lies within the reports with the aim of driving improvement by seeing the results of these analyses translated into actions for frontline NHS staff.

There may be some events that we cannot predict or influence the outcome with different care such as sudden placental abruption or cord prolapse. It is, however, important to know how many of these babies there are in order to appreciate the true scale of improvements in care needed.

Next steps

Our intention is to undertake both a quantitative analysis of the numbers of cases from year to year and to produce in depth reports into specific areas that have been highlighted through the incident reports. These will be used to develop care bundles or other tools to drive local quality improvement.

The EBC project is supporting the development of a new standardised perinatal mortality tool to facilitate a robust and comprehensive review of the care of each baby. The aspiration should be that all reviews of the care of babies who die or have a severe brain injury are truly multidisciplinary with the inclusion of external reviewers and engagement with the parents tailored to their wishes¹⁸.

Conflict of Interest Statement

None declared

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