

Safer Maternity Care



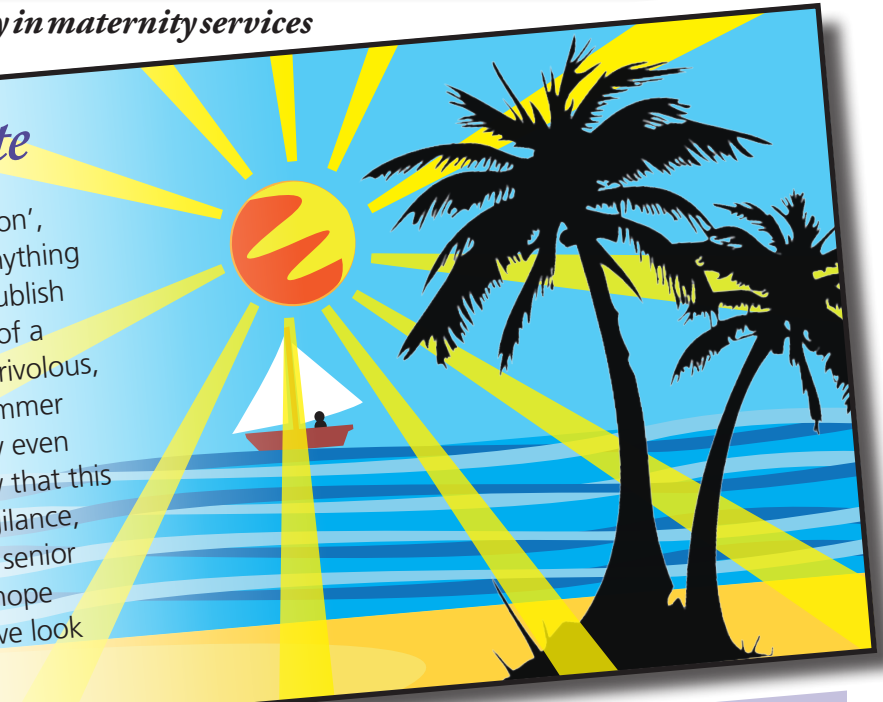
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A quarterly e-magazine promoting safety in maternity services

From the editorial suite

In the media world, this is the 'silly season', the mid-summer weeks when hardly anything newsworthy happens and the media publish frivolous stories to catch the attention of a distracted populace. There is nothing frivolous, however, about the content of this summer issue of SMC. Safety remains a priority even during holidays – indeed studies show that this should be a period for heightened vigilance, as new doctors rotate in whilst many senior colleagues are away on holiday. We hope you find this issue informative, and we look forward to your continuing support.



Latest Perinatal Mortality statistics show improvement

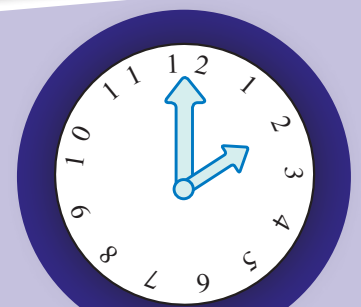
The Centre for Maternal and Child Enquiries (CMACE) has just published its latest perinatal mortality report. The key findings include the following:

- There has been a statistically significant downward trend in the perinatal mortality rate in the United Kingdom, from 8.3 per 1,000 total births in 2000 to 7.5 per 1,000 total births in 2008
- There has also been a statistically significant downward trend in the perinatal mortality rate for twin births in the United Kingdom since 2000
- There are wide regional variations in stillbirth and neonatal mortality rates

- There is also regional variation in the proportion of stillbirths and neonatal deaths with a major congenital anomaly as the primary cause of death
- Mothers of black ethnic origin are 2.3 times more likely to have a stillbirth and 2.3 times more likely to have a neonatal death than mothers of white ethnic origin. Mothers of Asian ethnic origin are 1.8 times more likely to have a stillbirth and 1.7 times more likely to have a neonatal death than mothers of white ethnic origin.

CMACE recommends that all providers of maternity services identified as a perinatal mortality outlier should review their data to ensure that they understand the reasons and take any actions that may be required.

The full report: Centre for Maternal and Child Enquiries (CMACE) Perinatal Mortality 2008: United Kingdom. CMACE: London, 2010.



You always thought so, now it's confirmed

A study using a linkage of Scottish national registries of perinatal deaths and births has shown that delivering an infant outside the normal working week (9 am to 5 pm Monday to Friday) was associated with an increased risk of neonatal death at term ascribed to intrapartum anoxia. Note that although this study was concerned with neonatal deaths, it is probable that similar conclusions also apply to rates of intrapartum-related stillbirth and brain-injury.

See Pasupathy D et al, Time of birth and risk of neonatal death at term: retrospective cohort study. BMJ 2010;341:c3498 doi:10.1136/bmj.c3498, published 15 July 2010.

Home Birth Study Stirs Controversy

Responding, the National Childbirth Trust (NCT) said "this study needs to be looked at in detail... it is important to know whether only good quality studies have been included and those of poor methodological quality have been excluded." The NCT's own detailed review of home birth concluded that although the quality of comparative evidence on safety of homebirth is poor, there is no evidence that women with low risk of complications are any more likely to lose their babies during or after delivery if they plan for a homebirth or hospital delivery.

A spokesperson for the Royal College of Midwives questioned the applicability of this analysis to the UK where services are delivered by midwives who are skilled and experienced at home births and resuscitating newborns, which is 'perhaps in contrast to many of the other countries this research covers.'

A position statement from the American College of Obstetricians and Gynaecologists states that "the hospital, including a birthing center within a hospital complex...or freestanding birthing centers...is the safest setting for labor, delivery, and the immediate postpartum period." The College stated that large comparative studies of the safety of births in different settings are needed, and until the results of such studies are convincing, it strongly opposes home births.

A meta-analysis just published in the *American Journal of Obstetrics and Gynaecology* states that less medical intervention during planned home birth is associated with a tripling of neonatal mortality rates compared with planned hospital births, but the absolute rates were low. The study looked at where the woman had planned to give birth, rather than the actual birthplace. A total of 342,056 planned home and 207,551 planned hospital deliveries were included in the analysis. It found that planned homebirths were associated with lower rates of maternal interventions such as epidural analgesia, electronic fetal heart rate monitoring, episiotomy and operative delivery. Rates of maternal lacerations, haemorrhage, maternal infections, prematurity, low birth weight, and assisted newborn ventilation were also lower. Perinatal mortality rates were similar for planned home and hospital births, but neonatal mortality rates were significantly higher with home births. Planned home births were characterized by a greater proportion of deaths attributed to respiratory distress and failed resuscitation.

The BBC quotes the RCOG president, Professor Sir Sabaratnam Arulkumaran as saying that the finding regarding neonatal mortality needs to be carefully considered by women, policy makers and care providers and that 'the move towards offering women a choice in their place of birth in the UK needs to be weighed against such evidence.' He added that, with a robust selection system which ensured high-risk pregnancies were excluded from homebirths and by making sure all midwives providing the services had good resuscitation skills, risks to the baby could be reduced.

The USA National Association of Certified Professional Midwives said the findings of this study are 'in direct conflict with a growing international body of quality research that demonstrates the safety of home birth for low-risk women and their infants when attended by trained professional midwives'.

The American College of Nurse-Midwives (ACNM) cautioned against over-interpretation of these findings until there has been further review, saying it had methodological concerns with the study. One concern is the inclusion of older studies and studies that did not sufficiently distinguish between planned and unplanned home births.

An editorial in the *Lancet* discusses the findings of this study and says that 'women have the right to choose how and where to give birth, but they do not have the right to put their baby at risk'. The point could have been made with a better choice of words. Advocates of home delivery do not assert a right to put babies at risk; rather they want appropriately selected low risk women to be offered the option of delivering at home, with appropriately qualified attendants and with ready means of transfer to hospital if required for mother or baby.

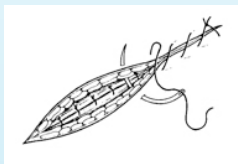
About 1 in 200 women in the US delivers her baby at home, with approximately 75% of these planned in advance as home deliveries. In the UK, 3% of deliveries take place at home. A study is currently being carried out to establish the relative risks of home and hospital births in the UK.

For more information see

- Wax JR, et al. Maternal and newborn outcomes in planned home birth vs planned hospital births: a metaanalysis. doi: 10.1016/j.ajog.2010.05.028
- <http://www.bbc.co.uk/news/10465473>
- The *Lancet* 2010;376:303, doi:10.1016/S0140-6736(10)61165-8, 31 July 2010

For a less controversial discussion of the subject, see Edozien LC, Mellows H, Place of birth. In Mahmood T et al (eds.), *Models of Care in Maternity Services*. London; RCOG Press 2010.

Safety alert: Retained swabs after vaginal birth and perineal suturing



The National Patient Safety Agency (NPSA) has issued a safety alert on reducing the risk of retained swabs after vaginal birth and perineal suturing. Between 1 April 2007 and 31 March 2009, the National

Patient Safety Agency (NPSA) received 99 reported incidents of swabs being left in the vagina following birth. A review of the NHS Litigation Authority (NHSLA) closed claims from 1 April 2007 to 31 March 2009 found 18 relevant cases relating to retained vaginal swabs in maternity services. The safety alerts outlines actions which maternity units should take to address the problem. These include:

- Have written procedures in place for swab counts at all births (including perineal suturing);
- Audit swab count practices in their maternity services;
- Provide education and training about the counting procedure for all midwifery, obstetric and support staff;
- Ensure that midwives and obstetricians are aware of their responsibility for documenting the completed swab count in the woman's health record;

Any "swab" removed from the vagina or brought in by a woman saying she had removed it from the vagina should be examined to confirm it is a swab as there have been reports that retained "swabs" have, in fact, been toilet tissue.

Does your unit have innovative ways of minimising the risk of retained swabs? If yes, share your learning with SMC readers!

Improving Communication

For a video on how to improve communication with your patients, visit: www.youtube.com/user/TheJointCommission#g/p.

Consent for operative vaginal delivery...

The Royal College of Obstetricians and Gynaecologists has just published guidance for obtaining consent for operative vaginal delivery. The document can be found at <http://www.rcog.org.uk/files/rcog-corp/CA11-15072010.pdf>

...And for Repair of Third and Fourth Degree Perineal Tears Following Childbirth

The consent guidance for perineal repair is available at <http://www.rcog.org.uk/files/rcog-corp/CA9-15072010.pdf>

Medical Device Alert: Fetal monitors

The Medicines and Healthcare products Regulatory Agency (MHRA) has updated its alert on fetal monitors, as adverse outcomes are still being reported in the presence of CTG traces that appear normal. The alert advises that clinical staff should not rely solely on the CTG trace for fetal wellbeing and should be aware of limitations and artefacts, such as double maternal heart rate being displayed. Staff should confirm fetal heart rate using independent means (Pinard or hand held Doppler) if there is any clinical uncertainty. Two instructive examples are given, taken from actual incidents which occurred in UK hospitals.

Example 1: In two recently reported incidents the CTG trace showed the FHR was around 160 bpm. The maternal pulse had been noted earlier at around 80 bpm. In one case the baby was stillborn. In the other the baby required extensive resuscitation. It was later suspected that in both cases the trace was showing double maternal rate and was falsely reassuring.

Explanation - The fetus can move out of the ultrasound field or in extreme cases the fetal heart can stop beating. The ultrasound may then pick up the maternal pulse from the aorta, iliac or uterine artery. The FHR displayed will then actually be the maternal heart rate, MHR. Sometimes the maternal artery movement is double counted so MHR x 2 is displayed. This can be within the same range as the expected FHR and can be more difficult to interpret. The resulting trace shows reactivity and variability due to MHR changes and muscle contractions and can be difficult to distinguish from FHR.

Example 2: It has been observed that half the fetal heart rate ($FHR \div 2$) can be displayed. Explanation - This can be due to difficulty in extracting the weak fetal heartbeat Doppler ultrasound signal from the noisy maternal environment.

Ref: MDA/2010/054 Issued: 28 June 2010

Noise – a safety issue

'Close your eyes and think of a hospital. There's the antiseptic smell, the cool, climate-controlled air, the bright lights glinting off linoleum. And then there are the sounds: squeaky-wheeled gurneys, banging doors, ringing phones, the banter of nurses and doctors, the studio audience on the TV above the next bed, the blurting from the overhead PA system as people are paged, and the beeps and buzzes and whirrs and whooshes of the ubiquitous monitors and machinery.....Hospitals walls, floors, and ceilings are traditionally bare and smooth so that they can be washed and kept as sterile as possible. As a result, they reflect sound rather than absorb it.'

The Boston Globe 30 May 2010

Beware of unlawful cord blood collection!



The Human Tissue Authority (HTA) has issued a warning about unlawful collection of umbilical cord blood for donation or storage. The authority had received reports that cord blood collections are being performed by those without any form of training. Also there were reports of parents putting staff under pressure to collect cord blood, and of DIY collection by parents. In at least one case, cord blood was collected in the hospital car park. Collection by untrained staff can increase the risk of contamination, potentially rendering the collected blood useless. Regulations governing the collection of umbilical cord blood came into effect in July 2008. Maternity units must have a licence from the Human Tissue Authority if they wish to collect cord blood at birth for future use. Where the hospital does not hold a licence it may be possible to get a trained specialist to carry out the collection, but this requires planning well in advance. This regulation forms part of the European Union Tissue and Cells Directives (EUTCD) which was transposed into UK law via the Human Tissue (Quality and Safety for Human Application) Regulations on 5 July 2007. The HTA warned that it has the power to prosecute those involved in unregulated collection.

Valproate carries highest risk for major congenital malformations of all antiepileptics.

Sodium valproate exposure during pregnancy more than doubles the risk for major congenital malformations (MCM) in the fetus compared with carbamazepine or lamotrigine. Polytherapy, especially with regimens that include valproate, is linked to an even greater risk than monotherapy. These latest results from the UK Epilepsy and Pregnancy Register and preliminary results from the European and International Registry of Antiepileptic Drugs in Pregnancy (EURAP) were presented at the 9th European Congress on Epileptology. Both studies tracked the incidence and risks for MCMs with antiepileptic drugs (AEDs) during pregnancy.

The UK study found "those exposed to sodium valproate have 2.4 times the risk of a malformation with carbamazepine and 2.7 times the risk (with lamotrigine." Dr Kennedy reported that the lowest risk from available trial data appeared to be exposure to lamotrigine and carbamazepine; however, levetiracetam looks promising. Carbamazepine and lamotrigine were most commonly associated with cardiac and genitourinary MCMs. Valproate was associated with a relatively high rate of neural tube defects (1.2%), facial cleft defects (1.2%) and genitourinary malformations (1.8%). The rates with carbamazepine and lamotrigine were 0.3% for incidence of neural tube defects, 0.4% and 0.1% for facial clefts and 0.6 and 0.7% for genitourinary malformations.

Rates of MCMs in women using polytherapy were higher; when polytherapy contained valproate the malformation rate doubled to 7.77%. Dr Kennedy concluded "for clinical practice, monotherapy is preferable to polytherapy if continuation of drugs in pregnancy is necessary."

Bonfire of quangos



The 'bonfire of quangos' promised by the Conservative party during the elections has been lit - and affects bodies concerned with patient safety. On 26 July 2010 the Health Secretary, Alan Lansley, published his review of the Department of Health's arm's length bodies. An arm's length body (ALB) is a stand-alone organisation working at national level, but at 'arm's length' from the Department. The number of ALBs is to be cut from 18 to between eight and ten, to deliver savings of over £180m by 2014/15. The Care Quality Commission (CQC), Medicines and Healthcare products Regulatory Agency (MHRA) and National Institute for Health and Clinical Excellence (NICE) survived the cull, but the National Patient Safety Agency (NPSA) is to be abolished. Its safety functions will be transferred to the new National Commissioning Board. The Care Quality Commission may inherit some functions from abolished bodies.

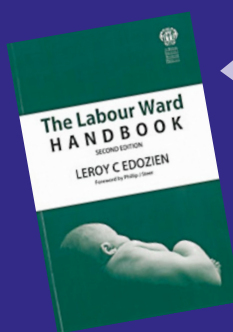
The fate of the NHS Litigation Authority (NHS LA) is not certain: its survival as an arm-length body will depend on the outcome of the proposed further identification of opportunities for commercial involvement.

For details, see *Liberating the NHS: Report of the arms-length bodies review*, London; Department of Health 2010

Books for your patient safety library



Patient Safety. Professor Charles Vincent. Second edition 2010. This book by the UK's leading authority on the subject provides practical guidance on delivering safer care. The first edition was hailed by experts across the globe and, with its emphasis on practice, this edition is poised for greater heights.



The Labour Ward Handbook, second edition has been Highly Commended in the Obstetrics and Gynaecology category of the 2010 BMA Medical Book Awards and short-listed for the first prize in this category. The BMA Medical Book Awards were established in 1996 and aim to encourage and to reward excellence in medical publishing. Prizes are awarded in 21 categories, with an overall BMA Medical book of the year award made from the category winners. 784 books were entered to the Awards this year. The category winners and overall Medical Book of the Year will be announced at a ceremony in London on 14 September 2010.