MBRRACE-UK Signs of Life Guidance Consultation

The MBRRACE-UK Signs of Life working group has launched a consultation relating to the development of UK guidance to support health professionals in the assessment of signs of life for spontaneous births before 24^{+0} weeks of gestational age where active survival-focused care is not appropriate.

This guidance aims to reduce the confusion and distress experienced by parents by helping doctors and midwives with the assessment of newborn babies who are born before 24 weeks of pregnancy. The guidance also aims to increase the consistency of the registration of births and deaths. This is a distressing and sensitive topic and may be upsetting, particularly for those affected by the loss of a baby.

The draft guidance was developed by consensus by a multi-disciplinary UK working group comprising representatives from all of the relevant UK clinical organisations, Government health departments, Northern Ireland Public Health Agency, academic experts in extremely preterm birth, medical law and medical ethics and third sector stakeholders. The group is led by MBRRACE-UK who are commissioned by the Healthcare Quality Improvement Partnership (HQIP) to undertake the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP) on behalf of NHS England, the Welsh Government, the Scottish Government Health and Social Care Directorate, the Northern Ireland Department of Health, the States of Guernsey, the States of Jersey, and the Isle of Man Government. The aims of the MNI-CORP are to collect, analyse and report national surveillance data and conduct national confidential enquiries in order to stimulate and evaluate improvements in health care for mothers and babies.

The draft guidance is intended for health professionals but may also be of interest to other stakeholders. It will complement guidance on decision making around obstetric interventions and initiation of neonatal intensive care at extreme preterm gestations by the British Association of Perinatal Medicine.

This consultation seeks views on the content of the draft guidance. We want to ensure that the guidance is clear, comprehensive and useful for its intended readers. We wish to hear from a wide range of people, including but not limited to: health professionals, government representatives, charities and organisations that work with women and parents. We would be grateful if you would share this email with anyone you think may be interested. We are interested in individual views but due to the distressing topic area, we will be consulting parents through parent advocacy groups. Parents who have been affected by this issue may be interested in sharing their views but may find it upsetting and support is available from the stillbirth and neonatal death charity, Sands, the Miscarriage Association, and Antenatal Results and Choices.

In the pursuit of openness and transparency, we will publish non-confidential versions of responses on the MBRRACE-UK webpages. Please indicate any responses that contain information that you regard as sensitive and would like to be omitted from publication on our webpages with an explanation of the reasons for omission.

MBRRACE-UK
Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK

Draft national clinical guidance for the assessment of signs of life for spontaneous births before 24^{+0} weeks of gestational age where active survival-focused care is not appropriate

Background

Research has highlighted substantial variation across the UK and internationally as to whether deaths of babies born before 24^{+0} weeks of gestational age (the legal gestational age limit in the UK for stillbirth registration – Box 1) are reported as a miscarriage (or where relevant, as a termination of pregnancy) or registered as a live birth and subsequent neonatal death [1,2].

Box 1: Registration of birth, death and stillbirth in the UK

Live birth registration: If a baby is born alive regardless of gestation, it is a UK legal requirement that the birth must be certified and subsequently registered.
Neonatal death registration: It is a UK requirement to certify and register deaths of all babies born alive, regardless of the gestational age at which the birth occurred.
In England, Wales and Northern Ireland: Legal certification that a baby lived and died requires a doctor to witness the baby prior to death. Where a doctor does not witness the baby showing signs of life, but signs of life are observed by the midwife and/or parents, a doctor must notify the coroner before issuing a neonatal death certificate to confirm that coronial review of the death is not necessary.
In Scotland: Legal certification that a baby lived and died requires a doctor to witness signs of life or *based on documented history be professionally accountable in certifying to the best of their knowledge and belief* the baby showed signs of life.
Stillbirth registration: In the UK if a baby is born showing no signs of life at or after 24^{+0} weeks of gestational age there is a legal requirement to register the death as a stillbirth. If a baby is born showing no signs of life before 24^{+0} weeks of gestational age there is no legal certification or registration of the death in the UK.

In a study of healthcare organisations in England, the percentage of births at 22^{+0} to 23^{+6} weeks of gestational age registered as live births ranged from 20% to 80%[1]; a range which is unlikely to reflect real variation in live births between areas. This variation has consequences for birth and death certification and the reliability of data regarding neonatal deaths at extremely preterm gestations. Such variation in the reporting of births before 24^{+0} weeks of gestational age has been shown to influence strongly perinatal mortality rates. This prevents fair comparisons of rates between healthcare organisations and also between countries[1,3,4]. In the UK, this variation in practice also has significant financial and emotional impacts on many parents. Only when the baby is born alive before 24^{+0} weeks of gestational age do parents receive official recognition of their baby's life and become eligible for maternity and paternity leave and benefits. The latter includes financial benefits

as well as permitted time off work for parents to grieve. These inequalities can further exacerbate the distress experienced by parents following the death of their baby.
In the UK, the World Health Organization (WHO) definition of live birth is commonly used by clinicians when determining signs of life (Box 2).

Box 2. World Health Organisation (WHO[8]) definitions of live birth and fetal death

Live birth is the complete expulsion or extraction from its mother of a product of conception+, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached; each product of such a birth is considered live born.

Fetal death is death prior to the complete expulsion or extraction from its mother of a product of conception+, irrespective of the duration of pregnancy; the death is indicated by the fact that after such separation the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.

+Although this is the WHO definition many people find product of conception an insensitive term in the context of a wanted pregnancy

Variation in practice across the UK suggests that interpretation of the WHO definition of live birth is difficult and varies between health care professionals in the judgement about "beating of the heart", "definite movements of voluntary muscles", and "breathing" when these signs are very short lived. Healthcare professionals also vary in the extent to which they feel that transient signs of life should be actively sought before 24^{+0} weeks of gestational age. These variations may arise from individual level differences in practice[5] or organisational-level policy[1,3,6].

This variation in practice is of particular relevance to spontaneous births where, following discussion and agreement with parents, a decision has been made to provide palliative care for the baby and not to initiate active survival-focused neonatal care due to an extremely high chance of death or survival with unacceptably severe morbidity. These births occur in a variety of clinical settings and may be attended by persons with varying levels of maternity care experience. Only around 1 in 800 births occurs between 22^{+0} and 23^{+6} weeks of gestational age[7]. Consequently, health care professionals working in maternity services may be involved in very few, if any, such births and experience difficulty in distinguishing between true signs of life and fleeting reflex activity that can occur after death.

Evidence and existing guidance

The BAPM has developed Frameworks for Practice to assist health care professionals in the perinatal management of extremely preterm birth[8,9] but there is currently no national guidance to help health care professionals present at births at or before the threshold of survival to interpret transient signs of life consistently.

A scoping review was performed for the purpose of developing this guidance regarding the assessment of signs of life in births at or before the threshold of survival. Online electronic databases Medline, Midirs, Web of Science and Cinahl were searched for peer-reviewed articles available in English with no year restriction. A manual search of reference lists and citations of included studies was conducted to identify any additional relevant studies that may have been missed. This review did not identify any published studies directly reporting the reliability of signs of life at birth at the threshold of survival or comparing different approaches to this question. A relevant US study showed that, despite the lack of reference to gestational age in the official definition of live birth, a third of neonatologists and obstetricians included gestational age criteria in their decision as to whether a birth should

be recorded as live born[10]. A further relevant study reported recorded observations and signs of life at 20^{+0} to 23^{+6} weeks of gestational age between 1995 and 2000 in a single UK health region[11]. Approximately one third died before labour, one third died during labour, and one third showed some signs of life after birth. The largest group of those births where signs of life were present had a heartbeat detected, but no respiratory effort or active body movement. For births at 20^{+0} to 21^{+6} weeks of gestational age signs of life were observed in between 12% and 20% of births and of those live born, 50% died within one hour and 94% within 4 hours[11]. Similar survival times have been seen elsewhere [12-14].
Online searches and requests for local guidelines from the UK Bereavement Midwives Forum identified locally developed guidance around the assessment of signs of life with significant inconsistencies, which supports the need for a national guideline to create consistency across the UK.

Ethical and legal considerations

Within the UK, there is no statutory definition of live birth. In England and Wales Section 41 of the Births and Deaths Registration Act 1953 (as amended by the Stillbirth (Definition) Act 1992, s1[15]) defines stillbirth as "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." Similar definitions apply in Scotland and Northern Ireland. However, there is no further definition or explanation of what constitutes 'signs of life'. Similarly, there is no statutory definition of death in the UK. The courts have endorsed professional (clinical) standards for determination of death in adults and children by circulatory or neurological criteria[16-18] but such standards were developed for a very different population and cannot necessarily be extrapolated to newborn babies born at the threshold of survival.

For the babies covered by this guidance, "signs of life" may be subtle and ambiguous. Fleeting movements of the limbs or chest might constitute signs of a live born baby but these could also represent brain stem reflex movements in the final phase of terminal apnoea[19]. In experimental models, newborns who have entered the phase of secondary apnoea do not recover in the absence of resuscitation[19]. Furthermore, some movements observed transiently after birth could represent spinal reflexes in babies who have died shortly before birth. Finger or toe movement, extension at arms and shoulders and flexion of arms and feet have been observed in brain dead adult patients spontaneously and in response to stimuli such as touch[20,21].

In newborn babies for whom resuscitation, stabilisation and initiation of neonatal care are potentially beneficial, identification of signs of life are important in directing and guiding the care of the newborn baby. Evidence of vital activity at one minute after birth, including respiratory effort, heart rate and movement are routinely recorded[22-24]. In such babies, resuscitation guidelines encourage active efforts to seek signs of life, including the use of a stethoscope to listen for a heartbeat and palpation of the umbilical cord, with or without the support of pulse oximetry and electrocardiography[24].

In newborn babies born before the threshold of survival, or for those babies where following conversation and agreement with the parents, there has been a prior decision not to provide active survival-focused care, it is important that incorrect identification of transient or fleeting physiological responses as signs of life do not lead to inappropriate attempts to resuscitate, and therefore change an agreed pathway of care.

During the process of the writing of the guidance, the working group identified some areas where existing law regarding birth and death registration appears to create significant challenges for health professionals, women and bereaved parents:

- *Regarding birth and death registration when a baby is born alive but dies shortly after birth with no doctor present* –It was reported by multiple sources to the working group that the requirement in England, Wales and Northern Ireland for a doctor to inform the coroner of the death in order to allow a death certificate to be issued (See Box 1), often leads to unhelpful delays and difficult situations for healthcare professionals and parents. The group saw considerable merit in the process in Scotland whereby a doctor is able to rely on the history with which they have been provided by the attending midwife or other health care professional in order to verify the live birth and issue a birth notification and death certificate.
- *Registration of live birth following termination of pregnancy* - Based on evidence collected during the development of the guidance in the context of selective abortion, the legal requirement for a woman to register the birth and death is likely to cause unnecessary distress and be detrimental to the provision of women-centred care.

Purpose of the guidance

When a baby is born before 24^{+0} weeks gestational age, in some instances it would be considered in the best interests of the baby, and standard practice, not to offer neonatal intensive care because the baby is unlikely to survive. This draft guidance is to support health professionals in this situation with the assessment of signs of life for spontaneous births before 24^{+0} weeks of gestational age where active survival-focused care is not appropriate. This guidance complements other guidance that supports decision making around obstetric interventions, or initiation of neonatal intensive care at extreme preterm gestations by the British Association of Perinatal Medicine.

The terms “parents” and “baby” are predominantly used in this guidance because this is how many people choose to describe their situation in the context of a wanted pregnancy ending in spontaneous birth before 24^{+0} weeks of gestational age. However each situation is unique and there are those who would find this upsetting and would prefer to be addressed as people rather than parents, for the birth to be referred to as “the end of the pregnancy” or as a “miscarriage”, and for the baby to be described as a “fetus”. This guidance recommends that health care professionals actively listen and take the lead from the woman and her partner regarding preferred language.

Target users of the guidance

The draft guidance is for health professionals present at births before 24^{+0} weeks of gestational age in hospital settings including midwives, obstetricians, gynaecologists, neonatologists and nurses. The guidance may also be useful in assessing signs of life where birth has occurred outside the hospital setting.

Aims of the guidance

The guidance is to support doctors and midwives with the assessment of signs of life. This guidance is for spontaneous births before 24 weeks of pregnancy where active survival-focused care is not appropriate and has the following aims:

- To reduce confusion and distress experienced by parents
- To support health care professionals in their conversations with parents at this difficult time
- To offer guidance to health care professionals for whom assessment of the newborn at these extreme preterm gestations is unfamiliar
- To increase consistency in birth and death certification and registration practice including official reporting to the coroner or procurator fiscal
- To ensure appropriate comparisons of perinatal mortality rates between organisations to aid assessment of the quality of perinatal care provision

Births included in this guidance

The guidance is intended for use in hospital settings by health care professionals present at the birth including midwives, obstetricians, gynaecologists, neonatologists and nurses and relates to the following births:

- Spontaneous births at 22^{+0} to 23^{+6} weeks of gestational age where, following conversation and agreement with parents, active survival-focused care is not appropriate.
- Spontaneous births before 22^{+0} weeks of gestational age. Few babies born before 22^{+0} weeks of gestational age survive labour and birth and active survival-focused care is not appropriate. Signs of life are relatively unlikely at this gestation.

There are additional births where the **same principles may be applicable**:

- Spontaneous births at or after 24^{+0} weeks of gestational age where palliative care is planned because of the presence of severe life-limiting conditions
- Spontaneous births before 22^{+0} weeks of gestational age in pre-hospital settings

Births where active survival-focused treatment may be appropriate are **excluded** from this guidance:

- Spontaneous births of uncertain gestational age

Spontaneous births at 22^{+0} to 23^{+6} weeks of gestational age where initiation of active (survival-focused) neonatal care is planned or there is uncertainty regarding initiation of active neonatal care. In these cases, the guidance is only applicable if, following birth, active survival-focused care is not considered appropriate

Assessment of signs of life

In the absence of evidence to form a basis for practice, the guidance presented here is informed by general agreement based on clinical practice and represents the consensus view of a multi-disciplinary working group informed by wider consultation. The working group endorsed a pragmatic approach to this challenging situation. The principles for assessing signs of life are detailed below.

The aim of the process is to assess signs of life at birth while ensuring that care following birth is respectful and that the individual needs of the woman and her partner are prioritised at this difficult time. The midwife or other attending health care professional may observe for visible signs of life while drying the baby and handing them to the parents (if the parents wish to hold the baby). Subsequent observation for signs of life should be discreet and respectful.

Assessment should be based on persistent, readily evident visible physiological responses. Listening for a heartbeat with a stethoscope or palpation of the umbilical cord is not necessary.

Evident signs of life after birth would include at least one of the following

- easily visible heartbeat seen through the chest wall
- visible pulsation of the cord
- breathing or sustained gasps
- definite movement of arms and legs

Short-lived fleeting reflex activity including transient gasps, brief visible pulsation of the chest wall or brief twitches or involuntary muscle movement can be observed in babies that have died shortly before birth and so the multi-disciplinary working group recommends that such fleeting reflex activity observed only in the first minute after birth does not warrant classification as signs of life.

Confirmation and documentation of signs of life

Where active survival-focused care for the baby might be indicated or there is significant uncertainty, a paediatrician or neonatologist should be called to attend the birth. This guidance is only applicable if, following birth, active survival-focused care is not considered appropriate.

In situations where there are visible signs of life and, following conversation and agreement with parents, active survival-focused care is not appropriate, a doctor (usually the attending obstetrician) should be called to confirm the presence of signs of life and enable completion of a neonatal death certificate. The role of the doctor in this circumstance is not to provide active survival-focused care but to have a role in supporting palliative care.

The certification and notification procedures required in the UK differ for a live birth ending in a neonatal death compared to births where signs of life are not present:

No signs of life observed: For births before 24^{+0} weeks of gestational age where no signs of life are observed, birth notification and birth and death certification are not required. For

babies born showing no signs of life at or after 24^{+0} weeks of gestational age a stillbirth certificate should be issued and where appropriate a cremation form.
Signs of life observed: For births at any gestational age, if signs of life have been witnessed by the attending doctor, that doctor must complete a neonatal death certificate and where appropriate a cremation form. A member of the care team must also complete a birth notification for all confirmed live births and the family must register the birth. If a doctor has not been present to witness signs of life, the legal requirements for death certification differ between Scotland and the rest of the UK and practice should proceed as follows:

- In England, Wales and Northern Ireland if a doctor has not been present to witness signs of life, the attending midwife or other health care professional and the doctor should discuss and decide if signs of life were present. They should communicate with the parents in a sensitive way and include the parents' observations (if they would like to share them) in these discussions. If following these discussions it is confirmed that there were persistent evident signs of life after birth, the doctor must inform the coroner to allow a death certificate to be issued.
- In Scotland the process is different and *does not depend on a doctor personally witnessing signs of life*; the doctor can rely on the history with which they have been provided by the attending midwife or other health care professional in order to verify the live birth and they can then issue a birth notification and death certificate without having been present prior to the death. There is no requirement for a doctor to discuss this scenario with the procurator fiscal unless the death falls within one of the categories of reportable deaths.

Where appropriate palliative care should be provided following a palliative care perinatal pathway such as "Together for Short Lives. A Perinatal Pathway for Babies with Palliative Care Needs").
Any doctor who has concerns about interpretation of this guidance or whether it should be followed in any clinical situation should discuss the matter with professional colleagues, seek advice from their employer's ethics committee or legal advisors, or contact their Medical Defence Organisation.

Communication, counselling and emotional support for parents

Spontaneous birth before 24 weeks of gestational age is generally a very distressing time for parents and they are likely to be unsure what to expect. The individual needs of the pregnant woman and (where appropriate) their partner should be central to the provision of care and any communication with them. As described earlier it is important that healthcare professionals actively listen and take the lead from the woman and her partner regarding preferred language. Recommendations for conversations with parents about perinatal management of births before 27 weeks of gestational age are provided in the British Association of Perinatal Medicine Framework for Practice.
For births encompassed by this guidance sensitive communication with parents needs to take place including explanation of the following aspects:

- Babies born before 22^{+0} weeks of gestational age are so small and fragile that few survive labour and birth. Active survival-focused neonatal care is not appropriate. Around half of babies born at 22^{+0} to 22^{+6} weeks of gestational age are likely to show signs of life and the likelihood of this increases at 23^{+0} to 23^{+6} weeks of gestational age.

- Babies who have died a few minutes before birth may show some fleeting transient reflex movements after birth; these do not constitute signs of life.
- Following birth, some babies may show persistent evident signs of life such as an easily visible heartbeat seen through chest wall, breathing or sustained gasps, or definite movement. Women should be told that if this is the case:
    - a doctor will attend to confirm signs of life
    - the time their baby will live is hard to predict and may be only a few minutes but may be longer (up to several hours
    - where appropriate comfort care will be provided (for example following Together for Short Lives: A Perinatal Pathway for Babies with Palliative Care Needs) and parents will be offered choices around spending time with the baby
    - there will be a legal requirement to register the birth and death

It is important to include parents' observations (if they would like to share them) in discussions about the presence of signs of life. Where potential disagreement occurs between parents and health care professionals about the assessment, guidance endorsed by the Royal College of Pediatrics and Child Health should be followed (Linney et al. *Arch Dis Child* 2019; **104**(5): 413-6). This includes a focus on communication between families and healthcare staff and an understanding of differing perspectives, appropriate involvement of parents in discussions and timely use of effective resolution.

All parents, irrespective of whether their baby is born showing signs of life or not, should (if they wish) be provided with time and privacy with their baby and opportunities to make memories. Referral to community postnatal care, GP and mental health teams should follow established local protocols. A parent-led bereavement care plan should be put in place for the family. In England and Scotland, this should follow the guidance outlined in the relevant National Bereavement Care Pathway and locally developed bereavement pathways should be followed in Wales and Northern Ireland. Parents should be informed about and, where requested, referred for emotional support.

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