perinatal care at the threshold of viability

Note

This guideline provides advice of a general nature. This statewide guideline has been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach. The guideline is based on a review of published evidence and expert opinion.

Information in this statewide guideline is current at the time of publication.

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Health practitioners in the South Australian public health sector are expected to review specific details of each patient and professionally assess the applicability of the relevant guideline to that clinical situation.

If for good clinical reasons, a decision is made to depart from the guideline, the responsible clinician must document in the patient’s medical record, the decision made, by whom, and detailed reasons for the departure from the guideline.

This statewide guideline does not address all the elements of clinical practice and assumes that the individual clinicians are responsible for discussing care with consumers in an environment that is culturally appropriate and which enables respectful confidential discussion. This includes:

- The use of interpreter services where necessary,
- Advising consumers of their choice and ensuring informed consent is obtained,
- Providing care within scope of practice, meeting all legislative requirements and maintaining standards of professional conduct, and
- Documenting all care in accordance with mandatory and local requirements.
Important points

> Infants who are born prematurely at 21 weeks gestation or earlier are not considered viable. Their extreme physical and physiological immaturity means that survival is not possible with current technology and expertise.

> Infants born later, but still extremely early, for example between 22 and 24 weeks gestation, may be able to be supported with intensive care, but have a high risk of dying despite treatment. This period is sometimes referred to as the “threshold of viability”.

> For infants born around the threshold it may be appropriate to provide only comfort measures following delivery, to provide full intensive care support, or to provide a trial of treatment with management adjusted to the response to resuscitation and intensive care.

> Where there is the possibility of preterm delivery around the threshold expert obstetric and neonatal advice should be sought. Where possible and safe, early transfer of the mother should be arranged to a centre with level 6 neonatal care.

> A paediatrician should be present at the delivery of any infant around the threshold of viability whether or not active resuscitation is planned.

> The PAGE* framework provides guidance for appropriate decision-making (*Prognosis for Average Gestation Equivalent infant, see below page 8). It is based on the following principles:

  - Decisions about treatment should be based on the best available evidence about the prognosis for the infant.
  - Decisions should reflect all relevant prognostic factors and should not be based on gestational age alone.
  - Fetuses or infants with similar prognosis should be treated similarly.

> Where there is a high risk for an infant of death or survival with severe morbidity, parents should be sensitively counselled about realistic options and the risks and benefits of those options. Parents’ views about resuscitation and the best interests of the child should be sought, and should be an important factor in decisions. Written information should be provided and opportunities given for parents to reflect before decisions are made.

> If there is doubt about whether or not to provide treatment, resuscitation should be provided in the first instance. If the infant responds poorly to initial treatment, or it subsequently becomes apparent resuscitation is not in the best interests of the infant, there is the option of withdrawing treatment.

> (Note - in this document, reference to a particular gestation refers to the interval of the index week – e.g.: 24 weeks refers to the interval 24\textsuperscript{4} to 24\textsuperscript{6} weeks)
Summary
> Delivery anticipated around the threshold of viability
  1. Seek obstetric/neonatal advice
  2. Arrange antenatal transfer if safe and feasible
  3. Assess prognostic factors for infant (gestation, expected birth weight, gender, singleton/multiple, antenatal steroids, other factors) – determine PAGE* category
  4. Sensitive counsel parents about realistic options, provide written information, and determine parental wishes
  5. Give antenatal steroids if delivery not immediate (PAGE* 23-24 or PAGE* 25, consider if PAGE* 22). Give intravenous magnesium sulphate for neuroprotection if delivery expected within twenty four hours and resuscitation/intensive care planned
  6. Delivery Room management
    > PAGE* 22 – provide comfort care
    > PAGE* 23-24 – provide treatment according to parental wishes
    > PAGE* 25 – provide resuscitation and intensive care – reassess if prognosis subsequently worse than anticipated

PAGE* Framework for decisions

<table>
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> For the purposes of this table, a ‘poor outcome’ refers to either death despite treatment, or survival with profound impairment (Bayley score of < 50 (untestable), or severe cerebral palsy, Gross Motor Classification Score 5) [2]
> PAGE* – refers to “Prognosis for Average Gestation Equivalent infant”
A. Obstetric management

> "Expert obstetric and neonatal advice should be sought for any woman presenting in preterm labour around the threshold of viability, or with delivery anticipated around this time (e.g. prelabour rupture of membranes, evolving pre-eclampsia)

> Transfer of the woman should be considered and arranged if safe and appropriate. This may facilitate counselling, obstetric and neonatal management. There is a substantial increase in mortality and morbidity for extremely premature infants born outside centres with neonatal intensive care capability

> Management during labour will be influenced by the estimated prognosis for the infant, and planned management after birth (see B below)

> "If active resuscitation of the infant after birth is planned (see below), obstetric management should consider measures to improve fetal wellbeing and improve the chances of survival after birth (subject to maternal consent)

> Antenatal corticosteroids should be considered in any mother where delivery is anticipated soon and active resuscitation is planned. They should also be considered even if resuscitation is not currently planned, but where delivery may be delayed long enough that resuscitation would be desired/planned

> Neuroprotection of the fetus (with magnesium sulphate) should be considered in women with active preterm labour where delivery is expected within 24 hours and active resuscitation is planned
B. Assessing prognosis for extremely premature infants

*Where delivery around the borderline of viability is anticipated, the prognosis for the infant should be determined, taking into account all available relevant factors*

**Outcome - Survival**

> The prognosis for infants born extremely prematurely is affected by a number of factors. These include the infant’s gestation, birth weight, gender, whether a singleton or multiple birth, whether or not the mother has received antenatal corticosteroids, the presence of acute chorioamnionitis, the presence of fetal compromise, or of major congenital malformations.\[3,4\] (others)

> Gestational age at birth is strongly correlated with survival.\[5\] Survival rates at a particular gestation represent the average survival for infants born during a particular week e.g. ‘24 week gestation’ represents infants born between 24 weeks and 0 days, and 24 weeks and 6 days.

![Survival rates graph](image-url)

**Figure:** Survival rates – as a proportion of infants mechanically ventilated/admitted to neonatal intensive care from NICHD Neonatal Research Network\[2\] and ANZNN report 2008-11 \[6, 7\]

> In Australian neonatal units over the 4 years 2008-2011, the rate of survival to hospital discharge was 78% for infants born at 25 weeks’ gestation and admitted to intensive care, 65% at 24 weeks’ and 52% at 22/23 weeks’ gestation (Australian and New Zealand Neonatal Network [ANZNN] reports).\[6\] Survival rates at 22 weeks have not been reported separately in ANZNN data because of the very small numbers of infants admitted to intensive care at this gestation. Studies in North America suggest an approximately 20% survival rate to hospital discharge for this group of infants if admitted to intensive care\[3,7\]

> Prenatal steroid exposure, gender, singleton/multiple birth and higher birth weight all have an influence on survival rate that is equivalent to approximately one weeks’ gestation.\[3,7\] Infants born at the same gestation may have a strikingly different prognosis depending on these and other factors.
Outcome - disability

> In population-based studies, approximately ¼ of surviving extremely premature infants are diagnosed with a significant neurosensory disability at follow-up including cerebral palsy, cognitive impairment and sensory deficits.[8] By mid-childhood 2/3 of surviving children had one or more chronic health problems, and increased health care needs compared to 11% of children born at term.

> However, only a small proportion of surviving extremely premature infants have severe impairments affecting activities of daily living.[8,9] In a Victorian population based study, only 3.7% of surviving infants born between 22 and 27 weeks gestation in 2005 had a “severe disability” (cerebral palsy unlikely to walk, severe developmental delay or blindness).[10] In an earlier Victorian cohort (born in 1997) the rates of severe disability at age 8 were 22% at 23 weeks, 8.3% at 24 weeks, and 12.8% at 25 weeks gestation[11].

> To estimate the prognosis for a given infant we recommend using one of the following tools

1. NICHD online calculator
   (http://www.nichd.nih.gov/about/org/der/branches/ppb/programs/epbo/Pages/epbo_case.aspx?start=03:06:33)
   > This calculator provides estimated survival and survival without profound disability based on a large US cohort study. Separate estimates are available as a proportion of live births and as a proportion of infants receiving mechanical ventilation. (“Profound disability” in this calculator– developmental quotient <50 (untestable) at age 2 or severe cerebral palsy (requiring adult assistance to move)

   > Survival rates using this calculator appear close to those seen in a recent Victorian follow-up study, however the rates of profound disability in the Australian study were lower than those estimated from the calculator[12].

   > An estimated fetal weight and fetal sex is required for the calculator. If these are not known the following table may be used

2. Estimation tool for death among extremely premature infants

   | Estimated Mortality Rates of Infants Born at 23-26 weeks Gestation |
   |----------------------|-------------------|-------------------|-------------------|-------------------|
   | Birth Weight Percentile | Prenatal Steroids | Gestational Age (weeks) |
   |                       |                   | 26                | 25                | 24                | 23                |
   | >75th                 | Yes               | 0%                | 17%               | 34%               | 51%               |
   |                       | No                | 22%               | 39%               | 56%               | 73%               |
   | 25-75th               | Yes               | 16%               | 33%               | 50%               | 67%               |
   |                       | No                | 38%               | 55%               | 72%               | 89%               |
   | <25th                 | Yes               | 32%               | 49%               | 66%               | 83%               |
   |                       | No                | 54%               | 71%               | 88%               | 100%              |

   > The Table is from a large Israeli population cohort of preterm babies born between 1995-2006[4].

   > In this study outcome was as a proportion of live births. Survival estimates in this table are lower than published Australian figures (e.g. ANZNN). Figures in the model are likely to have been influenced by decisions not to provide resuscitation.

   > Note this table provides only an estimate of survival.
It is important to recognise that these tools provide a statistical estimate based upon published outcome data. They are a guide to prognosis, but may not incorporate other relevant factors

C. Decision making

Legal principles

- The legal principle that underpins all decisions relating to resuscitation of newborn infants is that of the ‘best interests’ of the child[13]
- There is no statutory definition of viability, nor any legal definition as to when resuscitation should or should not be provided. It is a clinical judgement
- The South Australian Consent to Medical Treatment and Palliative Care Act (1995) indicates that medical practitioners are not required to provide life-sustaining treatment to children in the “terminal phase of a terminal illness” if that would merely prolong life in a moribund state (section 17[2]), in the absence of an express direction to the contrary
- There is no relevant case law in Australia relating to resuscitation of extremely premature infants. In the case of Baby D, the Australian Family Court affirmed that a decision to withdraw life-sustaining treatment could be in the best interests of a newborn infant, and that parents were authorised to consent to such decisions.(Re: Baby D [No. 2] [2011] FamCA 176 [16 March 2011]). Other legal cases and ethical analyses have found no legal or ethical difference between decisions to withhold life-sustaining treatment and decisions to withdraw the same treatment[14]
- Withholding resuscitation from a newborn infant where this treatment is reasonably judged to be not in the best interests of the infant is therefore consistent with existing law

Ethical and practical framework

- Use the PAGE* framework to relate an infant’s prognosis to appropriate obstetric and neonatal management
- Resuscitation of infants born around the borderline of viability has often been called into question because of the relatively high risk of death despite resuscitation and intensive care, the high burden of treatment for infants (prolonged hospitalisation, repeated invasive and painful procedures), and the poor long-term outcome for some survivors
- There are three general principles relating to these decisions
  1. Decisions should be based on the best available evidence about the prognosis for infants born in situations similar to that currently present. They should reflect all relevant prognostic factors
  2. Where there is a high risk for an infant of death or survival with severe morbidity, parents’ wishes about resuscitation should be sought. The views and values of parents are an important factor in determining whether intensive treatment or comfort care is in the infant’s best interests
  3. If there is doubt about whether or not to provide treatment, for example, where gestation is uncertain or there is little or no time to discuss options and ascertain the parents’ views, a paediatrician should be present at delivery and resuscitation provided in the first instance. If the infant responds poorly to initial treatment, or it subsequently becomes apparent that parents do not feel that resuscitation is in the best interests of the infant, there is the option of withdrawing life-sustaining measures and providing comfort care
- The following PAGE* framework provides guidance for appropriate decision-making (Prognosis for Average Gestation Equivalent infant).[5] This framework is based on the following, for which there is broad agreement internationally:
  - Fetuses and infants with similar estimated outcome should be treated similarly.
  - In general at 23-24 weeks’ gestation parents’ views about resuscitation should guide treatment. From the previous section this corresponds to a probability of a poor outcome of more than 50% but less than 90%
  - Decisions should not be based on gestational age alone
Further examples are given below, but as an example, a 24 week female singleton infant with estimated birth weight of 750g, whose mother has received antenatal steroids, has a prognosis that is similar to the ‘average’ 25 week infant, and should be treated in a similar way. Such an infant should usually be provided with active obstetric management, resuscitation and intensive care.

PAGE* Framework for decisions

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PAGE* refers to “Prognosis for Average Gestation Equivalent infant”

PAGE* less than 23 weeks

In some situations, even if full resuscitation and intensive care is provided after birth, the chance of survival without profound impairment is estimated to be less than 10%. In this situation it is often judged to be not in the best interests of the infant to provide resuscitation and intensive care. This would be the case for an average infant born at 21 or 22 weeks gestation. It would also appear to be the case for some more mature infants with adverse prognostic features for example, twins born at 23 weeks gestation in the absence of antenatal corticosteroids.

In this situation it is appropriate to provide comfort care for the infant or infants after birth (see below). Obstetric interventions should usually be limited to those focused on maternal wellbeing. However, if it is possible that delivery will be delayed to a point at which resuscitation would be appropriate and desired by parents, antenatal corticosteroids should be given, since these have been shown to reduce mortality if given prior to delivery even at 22 or 23 weeks gestation. [15] Similarly, transfer of the mother to a tertiary (level 6) obstetric centre should be undertaken primarily for maternal reasons. However, if delivery may be delayed to a point where resuscitation would be planned, antenatal transfer should be seriously considered.

In some situations, for infants with a PAGE* of <23 weeks, it may be appropriate to consider resuscitation as investigational. [1] Despite the apparent low chance of survival without profound impairment a trial of treatment may be offered. For example, this might be offered where there is uncertainty about the actual gestational age of the fetus/infant and consequently about prognosis. Parents should have a clear understanding of the likely outcome of treatment and have consented to it. Parents should be counselled that if the
infant fails to respond to active treatment in the delivery room or following admission to intensive care that care should be redirected to comfort measures

PAGE* 23 to 24 weeks

> For infants who have a more than 50% (but less than 90%) chance of a poor outcome, provision of resuscitation and intensive care is considered to be optional. This would apply to the average infant born at 23 to 24 weeks’ gestation. However, it would also potentially apply to less mature infants with favourable prognostic features, or to more mature infants with adverse prognostic factors (for example major congenital malformations, severe growth restriction, or prelabour preterm rupture of the membranes with anhydramnios)

> If, following counselling, parents judge that it is not in the best interests of their infant to provide resuscitation and intensive care, comfort care should be provided at birth. If parents judge active treatment for their infant after birth to be in the infant’s best interests, resuscitation and intensive care should be provided in the first instance, though parents should also be aware that treatment may need to be reconsidered if the infant fails to respond. For some families a trial of treatment may offer an acceptable way of dealing with uncertainty

> If delivery is likely and parents wish for comfort care only to be provided for their infant, obstetric management should focus on maternal wellbeing. However, if delivery may be delayed such that then resuscitation would be indicated, antenatal corticosteroids and transfer should be considered. For parents who are unsure about decisions, transfer may also facilitate counselling and support if parents change their mind

> If delivery is likely and parents wish for active resuscitation and intensive care for their infant, obstetric management should be guided by both maternal and fetal considerations. This may include antenatal transfer, fetal neuroprotection with magnesium sulphate, electronic fetal monitoring, and expedited delivery in the presence of fetal compromise. There is a high morbidity for extremely preterm infants who require transfer after birth,[16] and consequently antenatal transfer to a tertiary (level 6) obstetric centre should be undertaken if this is feasible and safe. Options for mode of delivery should be discussed with the woman. At present there is insufficient evidence to determine whether planned caesarean section offers any benefit for the baby over vaginal delivery.[17] Caesarean section around the threshold of viability is associated with increased maternal complications, as it may require a vertical rather than transverse incision[18,19]

PAGE** 25 weeks or greater

> Where the chance of a good outcome with resuscitation and intensive care is greater than 50% it would be usual to provide active treatment after birth for the infant. This would be the situation for the average infant born at 25 weeks or later. However, it may also apply to less mature infants with favourable prognostic features

> Obstetric management should be guided by both maternal and fetal considerations (subject to maternal consent). This may include antenatal transfer, fetal neuroprotection with magnesium sulphate, electronic fetal monitoring, and expedited delivery in the presence of fetal compromise. Options for mode of delivery should be discussed with the woman. There is a high morbidity for extremely preterm infants who require transfer after birth,[16] consequently antenatal transfer to a tertiary (level 6) obstetric centre should be undertaken if this is feasible and safe

> Although resuscitation and intensive care will usually be provided initially, this may need to be reconsidered depending on the infant’s response to treatment. For example, prolonged (>5 minutes) cardiopulmonary resuscitation in the delivery room in extremely premature infants has been associated with high rates of mortality and neurodevelopmental impairment,[20] and consequently parents’ wishes about further treatment should be sought

Disagreement

> If there is disagreement within the medical team, or between doctors and parents about what would be best for the infant, a second opinion should be sought. This allows confirmation of prognosis and appropriate treatment options. Where disagreement persists, and where there is time to do so, a staged approach to resolution of disputes may be used. It may be useful to use an independent third party such as a senior health professional, social worker, or other person agreed upon by those involved. The person should have
sufficient seniority to be respected by all parties, and be demonstrably independent of the treating team. Alternatively or additionally, a hospital clinical ethics committee can provide a mechanism for resolving disagreement. Alternatively or additionally, a hospital clinical ethics committee can provide a mechanism for resolving disagreement. As a last resort, legal advice should be sought, and applications may be made to the Supreme Court.

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D. Counselling

> Delivery around the threshold of viability may occur suddenly, without the opportunity for counselling or consideration of treatment options. However, there is often time for counselling to occur.

> Careful counselling is most critical in situations where the risk of adverse outcomes for the infant is high and obstetric and neonatal decisions should be guided by parental wishes (i.e. PAGE* 23-24).

> Parents should be given the opportunity to speak to staff experienced in obstetric and neonatal care and should be given information about the risks and benefits of available treatment options. Parents should be reassured that neither they, nor their baby will be abandoned if they choose the option of comfort care.

> Studies of parents who have been involved in prenatal decision-making suggest that parents wish to be involved in decisions, [21, 22] but that their understanding and recall of information conveyed during counselling varies. The values that parents find most important may not be the same as those of physicians[21]

> Physicians should be sensitive to the needs of individual families, and adapt counselling accordingly [23]. Counselling should avoid overwhelming parents with facts and statistics. Physicians should assess parents’ understanding and recall of the information conveyed, and repeated consultations may be required [24].

> Counsellors should be sensitive to the potential vulnerability of parents, and aware that the way that counsellors present information has an influence on parental decision-making. For example, in one study, participants were more likely to choose resuscitation when mortality statistics were presented as the chance of survival (rather than as the chance of death)[25].

> Where possible, parents should be provided with written information about treatment options, and the risks and benefits of these for extremely premature infants. Provision of written information during counselling has recently been demonstrated to improve recall of factual information and reduce parental anxiety[26].

> The following ‘Too small too soon’ information sheets are available:

  > 20 – 22⁰ weeks

  > 23 – 24⁰ weeks

  > 25+⁰ weeks

#NB: Parents should receive information sheets and counselling relevant to their PAGE* category (see above). This may be different from their actual gestational age.

> Physicians should be sensitive to the needs of parents from different cultural and religious traditions. It may be important for Aboriginal women to include members of their extended family or community in discussions. Indigenous families should be offered support from Aboriginal Liaison Officers or Aboriginal Maternal Infant Care (AMIC) workers where available. Some Aboriginal women may find direct eye contact and questioning offensive. Parents whose first language is not English should be provided with an interpreter if possible.

> Where the death of the infant is expected, counselling should include supportive discussion about the appearance of the infant, and options for care, for example, holding, dressing, bathing, creating mementos and going home with the baby. For further information about bereavement support see the SA Perinatal Practice Guideline “Perinatal loss” at www.sahealth.sa.gov.au.

> A multidisciplinary team approach to counselling and support of parents is strongly encouraged.
A summary of the information provided and parents’ views about treatment should be clearly documented in the woman’s medical record.

If delivery does not occur within a short period (for example 2-3 days) prognosis could have changed and counselling may need to be repeated.

E. Delivery room management

Comfort care

Where comfort care has been planned on the basis of the fetus/infant’s apparent prognosis the aim should be to support the mother and infant and to avoid interventions that may cause discomfort, pain or separation of the infant from the mother.

Ideally, a neonatologist or paediatrician should be present at delivery even if comfort measures have been planned to provide a brief assessment of the infant’s condition at birth, and to support midwifery staff and the family.

If the infant is born unexpectedly in particularly good condition, paediatric staff should consider whether the estimated gestation and prognosis were accurate and whether the planned palliative approach is still appropriate.

Simple measures to support the infant include drying, wrapping, radiant heat and skin-to-skin contact. Supplemental oxygen is not necessary, but could be provided if parents desire.

Parents should be counselled that the infant may breathe after birth, and may develop gasping respiration. On average, newborn infants receiving comfort care in the delivery room after birth live for approximately 60 minutes.[27,28]

Resuscitation and intensive care

See SA Perinatal Practice Guideline “Stabilisation of the newborn” www.sahealth.sa.gov.au for specific issues in delivery room management, including surfactant, thermal management and the use of oxygen/air for resuscitation.

The use of advanced measures for resuscitation including cardiac massage and endotracheal or intravenous adrenaline is controversial in infants around the borderline of viability. There is concern about the lack of evidence of benefit of cardiopulmonary resuscitation (CPR) in this population and possible adverse consequences. [29, 30]

However, the outcome in extremely preterm infants who receive CPR is not necessarily poor. Single-centre studies have reported intact survival in some extremely preterm infants who have received cardiopulmonary resuscitation.[31] Larger studies suggest that approximately 50% of extremely low birth weight infants who receive CPR in the delivery room survive without severe intraventricular haemorrhage.[32] On the other hand, a failure to respond to CPR may indicate a poor prognosis. In a more recent study, only 14% of extremely low birth weight infants who received prolonged resuscitation (as indicated by need for CPR and a 5 minute Apgar score of <2) survived without neurodevelopmental impairment.[20]

Trial of treatment

One approach to decision-making around the threshold of viability is to provide a trial of therapy. This may be an attractive option for families who find it difficult to make decisions in the face of uncertainty. Treatment is provided initially with the expectation that it will be withdrawn if the infant fails to respond, or develops serious complications.

Treatment may be limited in the delivery room if the infant is born in particularly poor condition. However, it is important to recognise that prediction of death or severe impairment in the delivery room may not be accurate. In one study, heart rate and Apgar scores at 1 and 5 minutes were neither sensitive nor specific for subsequent death or severe impairment.[33]

Alternatively, treatment may be withdrawn after the infant has been admitted to intensive care. Recent work suggests that a combination of corroborated clinician intuition (that the infant will die before discharge), and severe abnormalities on cranial ultrasound are highly predictive of a poor outcome for the infant.[34]

There is no ethical difference between decisions to withhold (i.e. not start) treatment and...
decisions to withdraw (i.e. stop) treatment. Decisions to limit treatment in intensive care should be on the same basis as those made to limit treatment at birth (see above). However, caregivers and parents may find it more difficult to stop treatment that has already been commenced. It may be worth discussing this in advance if a trial of treatment is planned.

References


Abbreviations

<table>
<thead>
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<tr>
<td>ANZNN</td>
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