

Recommendations for the management of birth at the margins of fetal viability- a practical approach for South Africa.

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Abstract

Babies born at the lower limits of viability have a poor prognosis in the South African setting. Neonatal intensive and high care units are overburdened, which leads to outbreaks of resistant organisms. An equitable set of interventions, based on available resources and referral pathways is proposed for each level of care to manage pregnancies and babies around the margins of viability. It is envisaged that this will serve as a basis for each province to develop their own guideline.

Keywords: Limits of viability, comfort care

Introduction

Viability is defined in various ways- on a population scale; viability is usually defined as that gestational age where at least 50% of babies born alive will survive until discharge from neonatal services. Extremely low weight at birth (ELBW) is defined as all babies weighing <1000g at delivery. Due to the dismal outcome of these babies in the South African context, especially those born at home or in rural areas, many babies receive comfort care only.

For deliveries of birth weight 500-999g, where the baby was alive at the time of hospital admission, the main causes of death (according to the PPIP database) is hypertensive conditions of pregnancies or spontaneous preterm delivery. These patients are a particular challenge for clinicians who have to counsel parents when delivery is medically indicated or inevitable at a very early gestation. Parents also have to make a decision between a hands-off obstetric approach or full obstetric intervention with fetal monitoring and possible uterine scarring with the prospect of raising a severely handicapped child.

Long term outcome is determined by more than gestation- the attitude of health care teams, available resources and the willingness of society to put resources into care for damaged babies and the stability of the family all contribute to long term outcomes. In an overburdened health service with limited resources, access to neonatal intensive care should be reserved for those babies who have a reasonable chance of

intact survival.

Survival rates for babies born in tertiary hospitals in SA range between 28% and 38% for birthweights 800-999g.¹ In the Western Cape, where the framework discussed below has been implemented since 2014, most small babies are referred to specialist hospitals intra-uterine. Even these in-born babies, delivered in optimal conditions with access to intensive care, have a poor survival at gestations below 800g- survival without morbidity in the group 701-800g was below 40% in a study from Grootte Schuur hospital.²

There are two types of premature baby- iatrogenic (delivered for medical reasons) and spontaneous. In the spontaneous group, there is usually little opportunity to prevent the delivery of the premature baby. The majority of these babies deliver in the closest facility to the mother, which means that most deliver in community health centres (CHC) and district hospitals (DH). In South Africa a DH on average will deliver eight live babies per year less than 1000g, and almost all will be spontaneous preterm births. The deaths of these neonates cannot be prevented at present.

The second group (iatrogenic) can be treated and managed. This group is mostly the babies of mothers with severe pre-eclampsia. The mothers can be detected and sent to the appropriate level of care; there is also time for appropriate preparation of the fetus (steroids, neuroprotective magnesium sulphate etc). For the discussion on viability that follows, this is the group that should be highlighted. The referral systems are already in place.

For the triennium 2016-2018, from South African PPIP data there were 26 939 babies born that weighed 500-999g. This represents 1.3% of the total deliveries in the country. Of these babies, 14 446 (53%) were born alive. Data from the Western Cape shows that the live born

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distribution in the different weight groups are as follows: 500-599g 6%, 600-699g 11%, 700-799g 26%, 800-899g 30% and 900-901g 27%.

If this same weight distribution is applied to the national data, the numbers born alive can be estimated and compared to the actual numbers of deaths in each group (Table 1).

	Calculated number of live- borns	Actual number of neonatal deaths	Neonatal mortality rate/1000 live births in this weight band	Percentage of survivors beyond 28 days
500-599g	866	760	880/1000	12%
600-699g	1588	1449	910/1000	9%
700-799g	3758	1877	500/1000	50%
800-899g	4335	1973	460/1000	54%
900-999g	3898	1878	481/1000	52%

With the other way, an out-born PPIP database is run from the neonatal unit and includes all neonates transferred in as denominator and the deaths as numerator (e.g. as used in Mpumalanga). When the data is amalgamated for the district there is a correction and the accurate neonatal mortality is found for the district. Thus if there is not an out-born PPIP database the referred neonates are systematically excluded and the neonatal death rate is falsely low. The true mortality rate at primary level of care is shown in Table 2 (courtesy of B Spies, S van Rensburg, M Muller and R Pattinson from the SAMRC/UP Maternal and Infant Health Care Strategies Unit). The data covers the years 2016-2018. A total of 1738 (1,59%) of all neonates were referred to the different levels of care; 25,3% were referred to DH, 12,1% to regional hospitals (RH) and 62,7% to tertiary hospitals (TH). The neonatal death rate per 1000 live births after correcting for referrals for all births (500g+) was 13,5 and for births 1000g or more was 9,4. The neonatal mortality rate for all very low birthweight babies (VLBW) was 416,2/1000 live births and for neonatal referrals 569,5/1000 live births.

Table 2. Mortality of neonates born at the primary level of care

Primary care	Out-born NND (DH+RH+TH) Come from primary level of care	In-born NND (CHC+DH) Death occurred at primary level of care	Total NND Primary level (= in-born and out-born NNDs)	Corrected Inborn survivor = Survivor (CHC+DH) – Out-born NND (DH+RH+TH)	Total births Primary level (= Corrected in-born survivor +Total primary NNDs)	Mortality Per 1000 live births
500g-999g	53	189	242	11	253	956,5
1000g-1499g	64	157	221	339	560	394,6
1500g-1999g	19	72	91	1360	1451	62,7
2000g-2499g	16	71	87	4705	4792	18,2
2500g+	59	189	248	62293	62541	4,0
Total	211	678	889	68708	69597	12,8

In the out-born neonates, the primary cause of neonatal death (NND) for the ELBW babies was spontaneous preterm births (SPTL) (89.8%). Referral of neonates less than 1000g from the primary level of care is currently futile. The most common cause for referral of neonates that died was SPTL in the small neonate and intrapartum asphyxia in the bigger neonate. Ideally the fetus should be transferred in-utero,

but in many cases of spontaneous preterm labour this is not possible. This implies that resources and skills for stabilisation and referral to higher levels for neonates 1000g-1499g needs to be in place. Very few neonates were transferred due to hypertensive disease or antepartum haemorrhage, which implies these neonates were transferred as fetuses *in-utero*.

Based on this data, the following proposal is made for the equitable management of a pregnancy or baby at the limits of viability. The is presented as a discussion document, so the suggestions for each level of care is only a guide. Each province and specialised referral units should discuss what is reasonable in their service so that a consensus document can be created. For each level of care, there are a few categories based on gestation and/or weight.

The following principals guides this proposal:

- All fetuses and babies in these peri-viable groups are considered for some form of active intervention; even it is a palliative intervention.
- *In utero* transfer for delivery of these tiny babies at the appropriate level should be undertaken where appropriate, feasible and safe.
- Babies born <27 weeks of gestation are provided a defined standard level of neonatal care after initial resuscitation, including palliative care where appropriate.
- Wherever they are born, babies with a birth weight equal to or over 1000g should have access to whichever level of care they require.
- For babies born below limits, there are 4 levels of facility care corresponding more or less to designated service levels in the country i.e. MOU/clinic, district hospital, regional hospital or tertiary/central hospital. Within these levels, there should be tiered intervention criteria based on birth weight and/or gestational age appropriate to each level of care.

A. Tertiary/Central Hospital level

Note: All babies in these categories will be inborn because outborn transfers to these units for these groups of babies from MOUs/CHCs, district and regional hospitals will not occur. Outborn babies will be referred in from birth weight of 1000g or more if suitable for NICU care.

CATEGORY 1: Gestational age of 24, 25 or 26 weeks OR an estimated

fetal weight of ≥500g but <650g.

These are either appropriately grown babies <24 weeks or severe IUGR <26 weeks. The estimated weight for gestation is shown in Table 3. At this extremely early gestation, intact survival is rare. This cut-off refers to

pregnancies where delivery is indicated for maternal reasons, or where delivery is imminent and inevitable. **All attempts should otherwise still be made to prolong the gestation to a more advanced gestational age**, if possible and where the maternal condition allows for it.

Gestational age	10 th centile	50 th centile	90 th centile
22 weeks	405g	493g	580g
23 weeks	465g	572g	680g
24 weeks	535g	662g	790g
25 weeks	620g	767g	915g
26 weeks	715g	890g	1065g

OBSTETRIC INTERVENTIONS

Suggested obstetric management:

Corticosteroids can be given if delivery is anticipated within one week, even if no fetal monitoring will be offered, to give the baby the best chance if born alive.

MgSO₄ for neuro-protection can be given after evaluation of the mother and the fetus and if there is imminent delivery (but no fetal monitoring is done).

Fetal monitoring and possible operative delivery will not be offered.

NEONATAL INTERVENTIONS

IV/NG Fluids/feeds, warmth, antibiotics, regulated and monitored oxygen (incl. CANPAP/high flow if available), caffeine, KMC NCO₂/CANPAP, CPAP may be offered only in inborn, well-prepared infants in good condition at birth, depending on bed availability.

No surfactant

No routine blood gas monitoring or blood tests

Palliative measures if failing to respond

Below 24 weeks, attempts at resuscitation will mostly be futile in the current setting; and intact survival is rare; thus the lowest limit of intervention is set at 23 weeks 6 days or less (<24 weeks) OR if the gestation is unknown and ultrasound cannot be done in time, **a birth weight of ≤ 500g**. Babies born <24 weeks/500g will receive comfort care only at birth (if alive).

CATEGORY 2: Certain gestational age ≥27 weeks, but the estimated fetal weight is 650g-799g (intra-uterine growth restriction).

OBSTETRIC INTERVENTIONS

A full fetal evaluation must be done (exclusion of fetal anomalies and evaluation of fetal growth with ultrasound and Doppler) before fetal monitoring is considered. The parents must be fully counselled and accept the risks involved if fetal monitoring is offered.

Corticosteroids can be given if delivery is anticipated within one week

MgSO₄ for neuro-protection can be given after evaluation of the mother and the fetus and if there is imminent delivery (even if no fetal monitoring is done)

Fetal monitoring:

With preterm labour: fetal monitoring can be considered after >48 hours of suppression with formal fetal evaluation (ultrasound and Doppler) AND

discussion with a senior obstetrician/Fetal Medicine subspecialist/neonatal specialist.

Maternal disease: fetal monitoring only after evaluation of fetal growth with ultrasound and Doppler AND opinion of a senior obstetrician/Fetal Medicine subspecialist as well as a neonatal specialist is obtained.

NEONATAL INTERVENTIONS

IV/NG Fluids/feeds, warmth, antibiotics, oxygen (incl. CANPAP/high flow if available), caffeine, KMC

CPAP, and InSure/LISA if indicated (not > 1 instillation)

CATEGORY 3: A sure/certain gestation of 27 weeks AND a minimum estimated fetal weight of at least 800 g

These are babies that are appropriately grown (>10th centile for 27 weeks using Intergrowth)³ as shown in Table 4.

Gestational age	10 th centile	50 th centile	90 th centile
27 weeks	830g	1031g	1230g
28 weeks	965g	1192g	1420g

OBSTETRIC INTERVENTIONS:

This is the gestational age where **all fetuses will receive active obstetric management including:**

Fetal monitoring (CTG) as soon as the mother's condition allows for safe delivery

Antenatal corticosteroids if no contra-indications

Antenatal MgSO₄ for neuroprotection in case of imminent delivery

Suppression of preterm labour where indicated

NEONATAL CARE:

IV/NG Fluids/feeds, warmth, antibiotics, oxygen (incl CANPAP/high flow if available), caffeine, KMC

InSure/LISA, any available respiratory intervention

Must be in an ICU bed if on IPPV or oscillation

B. Regional Hospital

CATEGORY 1: Gestational age <28 weeks OR estimated fetal weight/ birthweight

≥500g-<799g

If feasible, early in-utero transfer of the fetus to a centre with a NICU should take place, wherever successful in-utero transfer is likely.

OBSTETRIC INTERVENTIONS

Corticosteroids can be given if delivery is anticipated within one week, even if no fetal monitoring will be offered, to give the baby the best chance if born alive.

MgSO₄ for neuro-protection can be given after evaluation of the mother and the fetus and if there is imminent delivery (no fetal monitoring is done).

Fetal monitoring and possible operative delivery will not be offered.

NEONATAL INTERVENTIONS

Fluids/feeds, warmth, antibiotics, oxygen (incl CANPAP/ HFHNCO₂ if available), caffeine, KMC

No InSure/LISA, No CPAP, No Blood gas monitoring, no blood tests Access to High Care area only if bed not required for a larger more mature baby, with consultant advice

Palliative measures if failing to respond

CATEGORY 2: ≥28 weeks AND estimated fetal weight/ birthweight >800g-<999g

OBSTETRIC INTERVENTIONS

A full fetal evaluation must be done (exclusion of fetal anomalies and evaluation of fetal growth with ultrasound and Doppler) before fetal monitoring is considered. The parents must be fully counselled and accept the risks involved if fetal monitoring is offered.

Corticosteroids can be given if delivery is anticipated within one week

MgSO₄ for neuro-protection can be given after evaluation of the

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mother and the fetus and if there is imminent delivery (even if no fetal monitoring is done)

Fetal monitoring:

With preterm labour: fetal monitoring can be considered after >48 hours of suppression with formal fetal evaluation (ultrasound and Doppler) AND discussion with a referral hospital.

Maternal disease: mother should preferably be managed at a tertiary hospital, depending on her condition. Fetal monitoring should only be offered after evaluation of fetal growth with ultrasound and Doppler AND an opinion of a senior obstetrician/paediatric specialist is obtained. In an unstable mother, do not do fetal monitoring before transfer.

NEONATAL INTERVENTIONS

Fluids/feeds, warmth, antibiotics, oxygen (incl CANPAP/ HFHNC02 if available), caffeine, KMC InSure/LISA (1 instillation) and CPAP

No transfer to Level 3 service

CATEGORY 3: ≥ 28 weeks AND/OR estimated fetal weight/ birthweight ≥ 1000 g

OBSTETRIC INTERVENTIONS:

This is the gestational age **where all fetuses will receive active obstetric management including:**

Fetal monitoring (CTG) as soon as the mother's condition allows.

Antenatal corticosteroids if no contra-indications.

Antenatal MgSO₄ for neuroprotection in case of imminent delivery.

NEONATAL INTERVENTIONS:

Fluids/feeds, warmth, antibiotics, oxygen (incl. CANPAP/ HFHNC02 if available), caffeine, KMC

InSure/LISA (up to 2 instillations), CPAP or IPPV if available (maximum 48 hours unless improving)

Transfer to tertiary hospital after 48 hours if not improving; transfer sooner if ventilatory requirement is rapidly rising

Must be in a High Care bed if on CPAP or IPPV

C. District hospitals

There is a large range of size and capability of district hospitals. Each district needs to identify what levels of care are reasonable at each hospital or group of hospitals (e.g. a CPAP hub), under the guidance of the regional paediatric service and district paediatricians

CATEGORY 1: Birthweight ≥ 500 g- <1000 g (if gestational age is known, this

category will be for babies 27 weeks or more)

OBSTETRIC INTERVENTIONS:

Corticosteroids can be given if delivery is inevitable (no fetal monitoring is done).

MgSO₄ for neuro-protection can be given after evaluation of the mother and the fetus and if there is imminent delivery (no fetal monitoring is done).

Fetal monitoring:

With preterm labour: fetal monitoring can be considered after >48 hours of suppression after a formal fetal evaluation (ultrasound and Doppler) AND discussion with a referral hospital.

Maternal disease: mother should preferably be managed at a higher level of care, depending on her condition. Fetal monitoring should only be offered after evaluation of fetal growth with ultrasound and Doppler AND opinion of a senior obstetrician/paediatric specialist is obtained. In an unstable mother, do not do fetal monitoring before transfer.

NEONATAL INTERVENTIONS:

Fluids/feeds, warmth, antibiotics, oxygen (incl CANPAP/ HFHNC02 if available), caffeine, KMC

No InSure/LISA, No CPAP, No Blood gas monitoring, no blood tests
Palliative measures if failing to respond

District Hospitals that have Level 2 functionality i.e. CPAP beds and

second level (Paediatrician/experienced Senior Family Physician) cover, may initiate CPAP and InSure/LISA (1 instillation) on local consultant advice in babies ≥ 28 weeks and ≥ 900 - 1000 g. Transfer to Regional/L3 service for IPPV may be considered.

CATEGORY 2: ALL BABIES with birthweight ≥ 1000 g (if gestational age is known, this category will be for babies ≥ 28 weeks)

OBSTETRIC INTERVENTIONS:

This is the estimated fetal weight where all fetuses will receive active obstetric management including:

Fetal monitoring (CTG) as soon as the mother's condition allows.

Antenatal corticosteroids if no contra-indications.

Antenatal MgSO₄ for neuroprotection in case of imminent delivery.

NEONATAL INTERVENTIONS:

All cases: Fluids/feeds, warmth, antibiotics, oxygen (incl. CANPAP/ high flow if available), caffeine, KMC.

Babies requiring higher levels of respiratory support:

If no CPAP or InSure/LISA available - Discuss with Regional hospital.

If Emergency CPAP available - Put on CPAP and Discuss with Regional hospital.

If InSure/LISA and CPAP beds available - InSure/LISA and CPAP. Discuss with Level 2+ or Regional Hospital if not improving within 48 hours or sooner if deteriorating.

Level 2/ Regional Hospital can negotiate transfer to Level 3 NICU if required.

D. MOU/CLINIC

There are two categories of babies with a birth weight less than 1000g born in Midwife Obstetric Units or clinics- those who will be transferred to the referral hospital for continuing care, and those who are so immature or ill that they are very likely to die at the MOU within a short time. At the time of birth, weight is unknown and it may not be clear which category the baby falls into. Figure 1 aims to give direction to midwives and supporting doctors in the initial and subsequent care of these babies. NOTE: gestational age is not a standard part of this decision tree; birthweight is the only criterion.

Management of babies born at the margins of viability who do not qualify for respiratory support interventions (comfort care protocol)

Certain newborn babies at the margins of viability will have a very limited likelihood of surviving. They will thus require care that is not aimed at survival from the time of birth or after initial resuscitative interventions have proved ineffective. Care will concentrate on comfort for the baby and the family (palliative care).

These will largely be babies born below 27 or 28 weeks of gestation, below 800g or extremely low birth weight (ELBW) babies who fail to respond adequately to initial resuscitative interventions at birth.

General principles of care when survival is not expected in perinatal care

Care, Communication, Comfort, and Compassion are the pillars of this approach, in antenatal, labour ward, postnatal and nursery services.

Care: this kind of care is an active process involving empathetic counselling and care interventions that minimise suffering while not aiming to prolong life. It should include admission to a nursery when that is the best place for comfort care to be delivered.

Care: for babies who are surviving for more than a few hours, develop a formal Advance Care Plan.

Communication: Emphasise that ALL babies born alive are given the best care possible: everything done in our service for the extremely small baby is governed by the South African Constitution. Thus all care will be done in "the best interests of the child", irrespective of whether or not the infant qualifies for full ventilator support.

Communication: keep lines of communication between the health care team and family open at all times. Ensure that the messages from the health care team are not conflicting.

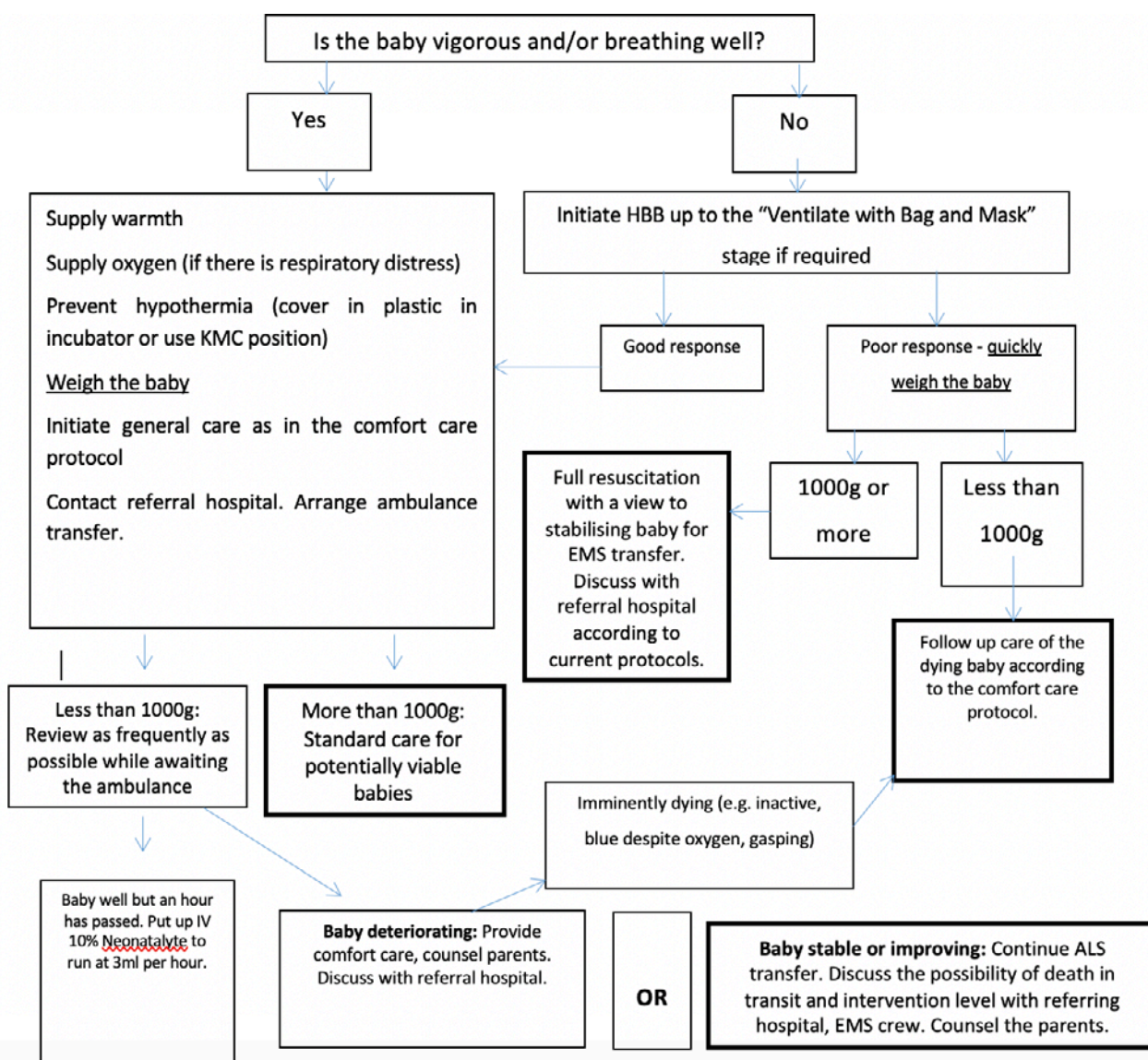


Figure 1. Management of a baby born at the limits of viability in a MOU/CHC

Communication: empathetic communication is important; use the baby’s name if he or she has one; use gentle tones in a private space.

Comfort: comfort is usually required for physical, mental and spiritual pain and distress. In perinatal care, mental and spiritual pain and distress mainly apply to the parents and family.

Comfort: assure the family that the baby’s comfort is important to the health care team. Explain care interventions and their purpose e.g. IV fluids, oxygen.

Comfort: be prepared to offer psychological support and empathetic counselling to the family. Consider the role of spiritual counselling where appropriate for a family.

Compassion: consider how the parents might like a memento of the child.

Compassion: The mother still requires obstetric care. Ensure that this takes place sensitively.

Compassion: give families time and space to deal with their stress and grief.

It is helpful to think of four phases of decision making in this kind of care in caring for a fetus and baby at the margins of viability.

CARE PHASE 1: Anticipate the situation where possible Where delivery of a baby for whom life-sustaining interventions are unlikely to be appropriate seems inevitable, prepare the family for the likely inevitable loss.

Explain the effect of the extreme immaturity on essential organs like

the brain and the lungs.

Listen to their questions and answer them as honestly and clearly as possible. Call in someone more experienced if you are not sure.

Explain that the health care team will examine the baby carefully at birth and make the assessment of likely survival at that point.

Explain that the baby will be kept as comfortable as possible and suffering will be minimised. Let them know that it may be decided that the neonatal ward is the best place for this to happen.

Where there is uncertainty regarding the baby’s viability and extremely premature delivery is inevitable:

Counsel the family honestly about the uncertainty.

Listen to their questions and answer them as honestly and clearly as possible. Call in someone more experienced if you are not sure.

Explain that the health care team will examine the baby carefully at birth and make the assessment of likely survival at that point.

Explain that, whatever the situation, the baby will be kept as comfortable as possible and suffering will be minimised. Let them know that it may be decided that the neonatal ward is the best place for this to happen.

Prepare for immediate care after the delivery.

The delivery room should be warm (minimal temperature of 25°C).

The resuscitator must be kept warm (temperature 37°C).

Check resuscitation equipment.

Ensure that the appropriate staff are present for the delivery.

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CARE PHASE 2: Decide on and implement appropriate resuscitation measures

The intensity of resuscitation efforts must be adjusted according to available and evolving information on likely gestational age and birth weight, and the early response to any resuscitation efforts.

Baby to be covered in plastic as soon as possible after delivery to minimise heat loss

Some babies such as those who are obviously much more immature than anticipated, and those with major congenital anomalies should not be actively given cardio-respiratory support. These babies should receive only comfort care from the start. Parents should be informed and involved as soon as possible.

CARE PHASE 3: Decide where the continuing care of the baby is to take place

A decision on this can usually be made within 10-15 minutes of birth. There are generally two groups of babies at this point with in-facility births

GROUP 1: Babies with good heart rates, regular respiratory patterns, good cry and active movements will be considered for continuing respiratory and other life-saving support measures available at a referral hospital.

the infant should be moved to the neonatal area in the facility or at the referral facility (according to local referral criteria).

for transfers, advice must be sought from the referring hospital to guide the EMS staff on care in transit.

GROUP 2: Babies who do not have these features after initial resuscitation.

Some of these will die within minutes; other may live for hours, even days.

If the child is likely to die in a few minutes, end of life care may take place in a quiet area of the delivery area.

The parents should be informed of the very limited prognosis, and encouraged to have the baby placed in KMC on the mother's or father's chest.

If this is refused or not possible because the mother is too ill, and has no birth companion, the infant should be placed in a warm incubator.

If death within a few minutes seems unlikely or the child is living longer than expected, the child should be moved to the neonatal area for further palliative care if this reasonable.

If transfer to another facility is thought to be appropriate (a journey of a few hours is NOT recommended in this group, in the best interests of the baby and the family),

That death may occur in transit will need to be made clear to the health care teams and the parents.

After delivery, while awaiting transfer: keep the baby as close to mother as possible. Keep parents constantly informed; continue the counselling that was started before delivery.

CARE PHASE 4: Care in the Neonatal area

The infant should be transferred to the Neonatal Unit within 10 minutes of the decision to transfer if possible: either in skin to skin care, or in an incubator set at maximum temperature ≥ 37 degrees Celsius

Humidified high flow air should be administered. An umbilical line or IV line should be inserted, and IV fluid commenced according to protocol.

The mother or parents should be encouraged to name their infant, and absent close family members of the mother's/parents' choice called for counselling together with the mother/parents.

The mother/parents should be encouraged to spend as much time as possible with their infant, doing skin to skin care as much as possible.

The mother should also be encouraged and assisted to express breast milk as the best form of nutrition for her tiny infant.

Ongoing emotional support should be offered by the care team, including doctor, nurse and social worker if available and appropriate.

CARE PHASE 5: After the baby's death

Set up a counselling session with the family

Ensure that the notification of the death and burial paperwork take place as quickly as possible.

Ensure that breast milk suppression takes place.

Consider referral to a perinatal loss clinic

Definitions

CANPAP (NC O2) – Nasal catheter oxygen therapy

HFHNCO2 – High flow humidified nasal cannula oxygen therapy

CPAP – continuous positive airway pressure, usually administered via nasal prongs

ELBW – extremely low birth weight

GA – gestational age

KMC – kangaroo mother care MOU- Midwife Obstetric Unit

InSure - INTubation-SURfactant-Extubation

IPPV – intermittent positive pressure ventilation given via endo-tracheal tube

IVH – intraventricular haemorrhage

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