

SWISS SOCIETY OF NEONATOLOGY GUIDELINES

Recommendations for the care of infants born at the limit of viability (gestational age 22-26 weeks)

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Summary

The care of the fetus and preterm infant at the limit of viability (gestational age 22-26 weeks) requires a multidisciplinary approach by an experienced perinatal team. Limited precision in the determination of the gestational age and biological variability may significantly affect the course of action chosen in individual cases.

The decisions that must be made are complex and of long-ranging significance. They are elaborated in a continuing dialogue between all parties involved (physicians, nursing staff and parents) with the primary aim to find solutions that are in the infant's best interest.

The knowledge of current mortality and long-term morbidity data as well as the application of accepted ethical principles form the basis for responsible decision making. Communication between the responsible parties involved plays a central role.

Based on current available mortality and morbidity data, the care of preterm infants with a gestational age of less than 24 weeks should generally be limited to palliative care.

An experienced neonatology team should decide in the delivery room whether initiation of intensive care is appropriate for an infant born at the limit of viability at a gestational age ≥ 24 weeks. It is often reasonable to initiate intensive care measures (provisional intensive care) and evaluate the infant's condition in detail at a later point in time to provide a more solid basis for the decision whether intensive care measures should be continued or aborted.

Life support is continued as long as there is reasonable hope for survival with an acceptable quality of life and the burden of currently used therapies is endurable for the patient.

If, on the other hand, the health care team and the parents have to recognize that the burden of the currently used therapies outweighs the potential benefits, intensive care measures are no longer justified and other aspects of care (e.g., the use of opioids to diminish pain and suffering) become the new priorities (redirection of care to comfort measures).

If a decision is made to withhold (primary non-intervention) or discontinue (withdrawal) life support, comfort care for the dying infant and support of the parents become the main focus for the health care team.

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1. Introduction

These recommendations refer to the care of preterm infants with a gestational age between 22 and 26 weeks of gestation. They have been written for physicians, midwives, nurses and other professionals who are involved in the care of very immature preterm infants. Authored by a task force of the Swiss Society of Neonatology consisting of a group of experienced specialists, they have been approved by the Swiss Society of Obstetrics and Gynecology (SGGG), the Swiss Society of Pediatrics (SGP) and the Swiss Society of Neonatology (SGN).

The Central Ethics Commission of the Swiss Academy of Medical Sciences (SAMW) supports these recommendations.

Recommendations of European, American and Canadian societies were reviewed,¹⁻⁴ and together with the relevant guidelines of the Swiss Academy of Medical Sciences served as the basis for these recommendations.^{5, 6}

2. Background

2.1 Determination of gestational age and biological variability

The *International Classification of Disease (10th revision)* defines the gestational age as the postmenstrual age in weeks and days. The time period between 25 weeks and 0 days and 25 weeks and 6 days, for example, is termed 25 completed weeks of gestation; the fetus has completed 25 weeks and is in the 26th week of gestation.

The calculation of the gestational age is generally based on ultrasound measurements of the crown-rump length at 8-12 weeks of gestation and/or the history of the last menstrual period. It is important to realize that the precision of gestational age determination by early ultrasound is ± 4 days, whereas it is a much wider range of -6 to $+14$ days when the history of the last menstrual period is used. When there is no ultrasound estimate of the gestational age, clinical assessment after delivery may lead to a revision of the gestational age. The parents need to be informed about this possibility to prevent unnecessary worries in such a situation.

Because there is variability in maturity at a given gestational age, preterm infants of identical gestational age may exhibit significantly different biological maturity. Assessment of relative maturity is an appropriate consideration in determining postnatal management and estimating individual risks of mortality and morbidity.

2.2 Current mortality and morbidity rates

With the continuing progress of neonatal intensive care, the limit of viability has continued to shift towards a younger and younger gestational age. For example, survival after only 22 completed weeks of gestation has been described.^{4, 8}

A comparison between published international figures⁸⁻¹⁰ and results of the Swiss Minimal Neonatal Data Set (MNDS) shows that there are considerable differences in mortality rates between different centers (Tab. 1). Recently published international studies have documented that the risk of handicaps clearly increases with decreasing gestational age (Fig. 1); again, considerable inter-institutional differences are obvious.^{8, 9}

The perinatal team should have knowledge of up-to-date mortality and morbidity rates stratified by gestational age. These statistics should include information on the incidence and severity of handicaps at the age of two and more years. Apart from national and international figures, local outcome data regarding preterm infants at the limit of viability is highly relevant.

Table 1. Comparison of different mortality statistics: EPICure Study Group (Great Britain, 1995)⁸, El-Metwally et al. (Rhode Island, 1993-1997)¹⁰, Jacobs et al. (Toronto, 1990-1994)⁹ Swiss Minimal Neonatal Data Set (MNDS, 1996 and 2000)

Study (year of publication)	22 0/7 – 22 6/7 weeks	23 0/7 – 23 6/7 weeks	24 0/7 – 24 6/7 weeks	25 0/7 – 25 6/7 weeks
EPICure Study Group (2000)	136/138 (98%)	216/241 (90%)	284/382 (74%)	241/424 (57%)
El-Metwally et al. (2000)	21/22 (95%)	22/41 (54%)	25/61 (41%)	16/87 (18%)
Jacobs et al. (2000)	-	44/56 (79%)	38/90 (42%)	52/138 (38%)
MNDS 1996 (unpublished data)	-	-	12/14 (86%)	28/54 (52%)
MNDS 2000 (unpublished data)	-	5/5 (100%)	23/28 (82%)	33/62 (53%)

2.3 Ethical considerations

High mortality and morbidity rates (Tab. 1, Fig. 1) have raised ethical concerns in connection with the care of preterm infants at the limit of viability.

In the care of fetuses and preterm infants at the limit of viability the parents and the health care team should decide together which interventions are likely in the best interest of the child. The four ethical principles put forth by Beauchamps and Childress¹¹ (autonomy, non-maleficence, beneficence, and justice) are also valid for preterm infants. However, several conflicts arise when these principles are applied to the situation of preterm infants at the limit of viability.¹²

2.3.1 Physician's duty to preserve life

A first conflict arises from the question of how the physician's duty to preserve life could be modified by thoughts about the achievable quality of life. If it is not permissible to take the quality of life into consideration and human life must be supported with all available means, there is a risk of excessive therapy. On the other hand, to only accept life-prolonging therapies if a high quality of life can be guaranteed to the preterm infant must be regarded as discrimination toward the disabled.

A possible compromise between these two extreme positions might be to always weigh the possible therapeutic benefits for the patient against the suffering imposed on the patient by the various interventions.

The decision to withhold or withdraw therapies (see 3.2.2) is motivated by the desire to protect the preterm infant from undue suffering and not by the wish to prevent survival with handicaps.

2.3.2 Decision maker

Since the preterm infant whose life is directly affected by the treatment decisions cannot communicate his/her preferences, decisions must be made by proxy. Basically, this surrogate role could potentially be played by the health care team, the parents of the infant or by societal body, such as an ethics committee or a court of law.

Ideally, such decisions should not be made by a single party at a particular point in time but should rather be developed in an ongoing dialogue between all parties involved (physicians, nursing staff, parents). A decision will be most acceptable if the parents can understand and support the reasoning behind it; however, they should not feel that they carry the full responsibility for that decision.

2.3.3 Health care resources

Regarding the care of infants at the limit of viability, the question could be raised whether a considerable proportion of available health care resources should be allocated to the treatment of barely viable preterm infants with very limited likelihood of intact survival. If rationing of health care resources is unavoidable, it is designed to accomplish more than simply excluding certain categories of patients (e.g., preterm infants at the limit of viability) from a particular therapy. Rather, this approach should be undertaken to reject certain therapies with a very poor cost-benefit ratio for all patient categories. In this context, cost refers not simply to economic cost but also to the emotional and physical burdens of the indicated therapies.

Such decisions must always be made on a societal level; economic considerations should never interfere with ethical decision making in an individual case.

2.4 Communication

To relay complex information clearly and in a manner adapted to a particular situation and individual set of parents requires communicative competence and great experience. It is therefore essential that these discussions are led by an appropriately trained neonatologist. Continuity, emotional concern, and understanding are of prime importance to parents.

2.4.1 Communication among the members of the perinatal team

The perinatal care of a fetus or a preterm infant at the limit of viability must follow a multidisciplinary approach and requires close cooperation among obstetricians, neonatologists, midwives, nurses and other involved parties. Frequently, decisions have to be made within a short period of time. It is therefore necessary that the members of the perinatal team have previously discussed and agreed upon a standard approach in such situations.

2.4.2 Communication with parents

The possibility to establish a relationship with the parents prior to delivery forms a basis of trust and facilitates later discussions about ethical decision making. The responsible health care team is obligated to continuously inform the parents about the possible consequences of treatment decisions which are made by the health care team and supported by the parents. The communication must be open and the information provided must be complete. In addition, the parents must be given sufficient time to consider the information and their alternatives. Frequently, parents have unrealistic expectations not only of what is medically feasible but also of the prognosis of their child, independent of which therapeutic options are recommended.

3. Recommendations for the care of preterm infants born at the limit of viability

3.1 Prior to delivery

3.1.1 In utero transfer

Criteria for timely transfer of mothers experiencing threatened extremely preterm delivery must be defined clearly and should be evaluated on a regular basis. Maternal transfer to a perinatal center should be considered beginning at 22 completed weeks of gestation. Although no intensive care measures would be initiated at this age should delivery occur (see Tab. 2), transfer of the pregnant women allows for detailed counseling and preparation of the parents (see 3.1.2).

Parents should be informed about the referral in such a way that their expectations are appropriate and remain realistic regarding their individual situation.

Table 2. Management of threatened preterm delivery prior to 26 completed weeks of gestation

Gestational age (completed weeks)	In utero transfer to perinatal center	Cesarean section	Neonatal management
< 22 0/7	not indicated	for maternal indication only	Comfort care
22 0/7 – 23 6/7	possibly indicated	for maternal indication only	Comfort care
24 0/7 – 24 6/7	indicated	rarely for fetal indication	initiation of intensive care measures depending on individual situation*
25 0/7 – 25 6/7	indicated	also for fetal indication	initiation of intensive care measures depending on individual situation*

* To be considered (see also 3.2.1): prenatal factors (gestational age, birth weight, antenatal corticosteroids, intrauterine growth restriction, amnionitis, fetal malformations, multiple gestation), parental preferences, clinical condition of the preterm infant immediately after delivery (asphyxia, heart rate, activity, response to initial resuscitative efforts)

3.1.2 Informing the expectant parents

Prior to the delivery of a preterm infant at the limit of viability, the neonatologist who will be responsible for the care of the infant after delivery should be informed to allow for a first consultation with the parents.

The expectant parents should be informed about the intensive care measures that will likely be used in the first few days of life. Complications that could arise in the context of the medical problems that are expected should be discussed as well. It is important to gain insight into the parental wishes and concerns without expecting any final decisions on their part. This will help to prevent unnecessary parental anxiety and feelings of guilt.

Following detailed discussion of the likely prognosis of their child, some parents prefer that no life support measures be initiated in the delivery room (primary non-intervention). Although parental wishes should be respected, particularly when their infant is likely to be at the limit of viability (gestational age < 26 weeks), they cannot be binding for the health care team in all cases (e.g., more mature infant than estimated prenatally).

3.1.2 Obstetrical interventions

In obstetrical decision making parental wishes have to be included, particularly when the prognosis of the infant is uncertain. There are only very few studies that have evaluated the impact of obstetrical interventions, especially delivery by cesarean section in the context of preterm infants at the limit of viability.¹³ Maternal risks have to be weighed carefully against the potential fetal benefits.

Of course, the delivery of a preterm infant at the limit of viability should be optimized by established obstetrical interventions as long as the associated maternal risks can be justified.

3.2 After delivery

3.2.1 Initial resuscitation in the delivery room

Since the decisions whether intensive care measures should be initiated in the delivery room are very complex and difficult with far reaching consequences, the birth of a preterm infant at the limit of viability should be regarded as an emergency that requires the presence of experienced obstetricians and neonatologists.

The individual interventions will be influenced by prenatal factors (gestational age, birth weight, antenatal corticosteroids, intrauterine growth restriction, chorioamnionitis, fetal malformations, multiple gestation), parental preferences, and the clinical condition of the preterm infant immediately after delivery (asphyxia, heart rate, activity, response to initial resuscitative efforts)

Previously performed obstetrical interventions (e.g., antenatal corticosteroids, delivery by cesarean section) should not bias the decision for or against the initiation of intensive care measures.

3.2.1.1 Resuscitation of an infant with an uncertain gestational age

An experienced neonatology team should attend all deliveries that occur at an estimated gestational age ≥ 23 completed weeks in order to decide whether the initiation of intensive care measures appears to be justified based on the condition of the preterm infant (see 2.1).

In doubtful cases, it is appropriate to initiate intensive care measures and to admit the preterm infant to the neonatal intensive care unit (provisional intensive care) until the clinical course and further discussions with the parents help clarify whether the treatment should be continued or discontinued. If provisional intensive care is initiated in a preterm infant at the limit of viability, the treatment should be optimized to avoid secondary injuries at all cost.

3.2.1.2 Resuscitation of an infant with a certain gestational age

Generally, the care of preterm infants with a gestational age < 24 weeks should be limited to palliative measures (see 3.2.2.3). If a preterm infant appears significantly more mature after delivery (see 2.1) or if previously well-informed parents insist, provisional intensive care can be started until the clinical course helps to decide for or against continuation of intensive care measures.

In the care of preterm infants with a gestational age ≥ 24 weeks, an experienced neonatology team should decide in the delivery room whether initiation of intensive care is appropriate. Provisional intensive care often enables the health care team to more fully evaluate the infant's condition at a later time point; this possibly provides better arguments for continuation or withdrawal of intensive care measures.

The suggested perinatal management of threatened preterm delivery prior to 26 completed weeks of gestation is summarized in table 2.

3.2.2 Further decisions in the neonatal intensive care unit

3.2.2.1 Provisional intensive care

Intensive care interventions that are initiated in the delivery room and continued in the neonatal intensive care unit are based on the primary therapeutic goal of survival of the infant with an acceptable quality of life. To limit intensive care measures only because of a low gestational age is not justified in this situation. Clinically accepted and approved therapies that are likely to provide more benefit than harm should be available to these patients regardless of their gestational age.

As long as there is reasonable hope that the primary goal can be reached and the burden of the used interventions appears justified, the standard indicated therapies are applied. The parents should be informed regularly about the infant's clinical course and the expected prognostic implications of key events.

3.2.2.2 Redirection of care to comfort measures

If, on the other hand, the health care team and the parents have to recognize that the primary goal can no longer be reached, intensive care measures are no longer justified and other aspects of care (e.g., the use of opioids to diminish pain and suffering) become the new priorities (redirection of care to comfort measures).

Decisions regarding withdrawal of intensive care measures should be carefully documented in the patient record. These notes should include a detailed description of the considerations and reasons that have led to a particular decision.

3.2.2.3 Palliative care

Whenever life support measures are withheld (either primarily or secondarily), everything should be done to allow the infant to die peacefully (comfort care). At the same time, the parents should be given the opportunity of close contact with their child to bid farewell.

If necessary for adequate pain control, opiates can be used at doses that might have a life-shortening effect.⁶ In contrast, the use of drugs with the primary intention to end the patient's life is against the law and not consistent with the ethical position described under 2.3.1.

4. Recommendations for quality assessment and improvement

Quality assessment and improvement plays an important role in the care of preterm infants born at the limit of viability. It is indispensable to prospectively collect data on mortality and morbidity that are periodically reviewed both locally and nationally. In addition to perinatal data that is collected in the well established Minimal Neonatal Data Set (MNDS) information on motor and cognitive development of these children should be collected up to school age.

Since decisions made in the care of preterm infants born at the limit of viability can have an impact on the entire family¹⁴ and since only the affected patients and families will ultimately be able to judge whether or not the imposed burden of various intensive care measures can be justified, long-term outcome data on the development of these children should be collected.

The necessary financial resources to realize such projects should be given high priority. As soon as relevant new information regarding the care of preterm infants born at the limit of viability become available, the present recommendations must be reviewed and possibly revised.

Fig. 1a. Mortality and neurological morbidity of preterm infants with a gestational age between 22 0/7 and 23 6/7 weeks (1995). Psychomotor development was assessed at a median age of 30 months. Gray boxes: denominator = *live born infants*, light gray boxes: denominator = *admissions to NICU*, white boxes: denominator = *survivors to discharge* (from the EPICure Study Group, 2000)

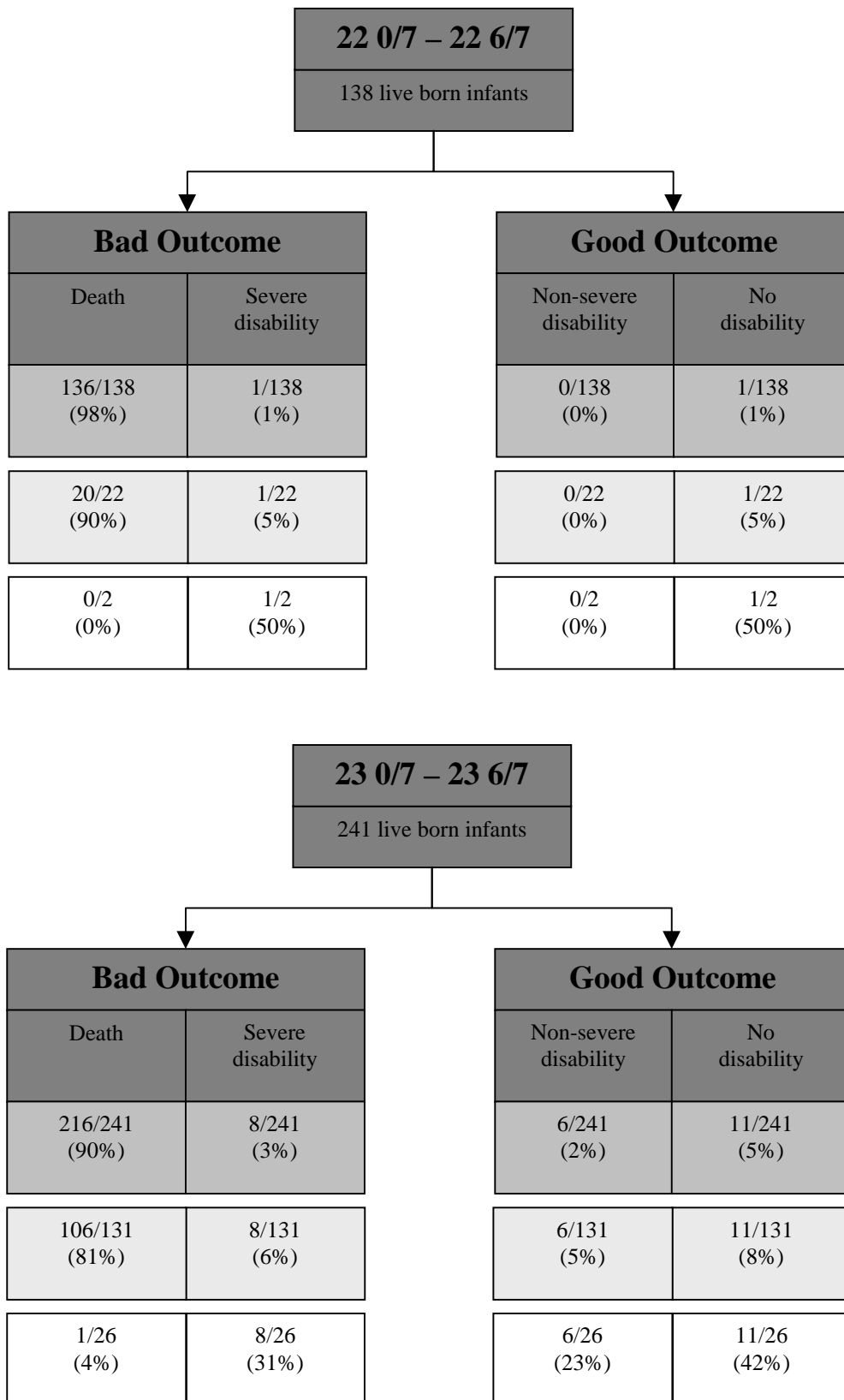
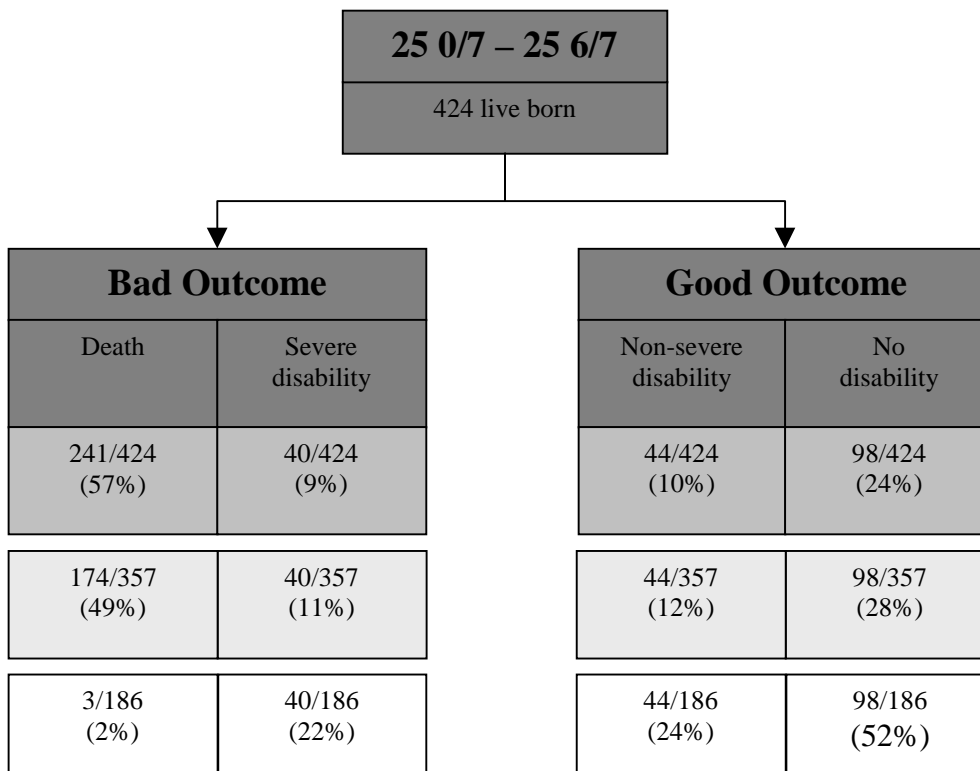
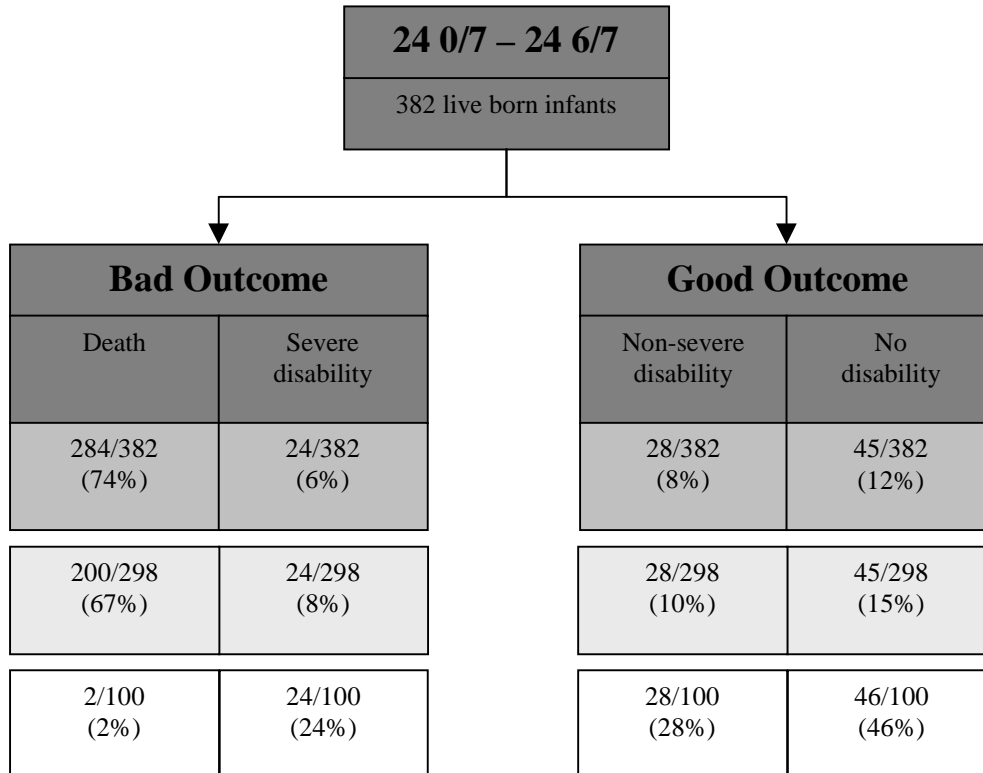


Fig. 1b. Mortality and neurological morbidity of preterm infants with a gestational age between 24 0/7 and 25 6/7 weeks (1995). Psychomotor development was assessed at a median age of 30 months. Gray boxes: denominator = *live born infants*, light gray boxes: denominator = *admissions to NICU*, white boxes: denominator = *survivors to discharge* (from the EPICure Study Group, 2000)



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