Couveuse 2.0

Summary

Centrum voor Ethiek en Gezondheid

The shorter the duration of the pregnancy, the greater the risk that a child may die shortly after birth or survive with minor or serious disabilities. In the Netherlands, two to four babies out of 1000 are born prematurely each year, after 22 to 26 weeks of pregnancy. Extremely premature infants born after at least 24 weeks of pregnancy are cared for in the neonatal intensive care unit in an incubator. When treating such infants, the risk of the development of chronic lung disease (bronchopulmonary dysplasia) is a major concern. This is expected to change with the introduction of technology that mimics the situation in the womb, therefore allowing the lungs to mature longer.

Among the general public, this technology is known as an artificial uterus. This name is rather unfortunate because it creates unrealistic expectations. The technology does not actually mimic the complex function of the uterus but rather the situation inside the uterus. It takes over the function of the amniotic membranes, amniotic fluid (amnion) and placenta, and not that of the entire uterus. It is an alternative to the current incubator. But for implantation and the early development of the embryo, a human uterus is still necessary. The complete development of an embryo into a child outside the womb is very unlikely in the near future.

Studies carried out on the effectiveness and safety of artificial amniotic fluid and placenta (artificial amnion and placenta technology (kunstamnion- en placentatechnologie, hereafter: the KAPT) using animal models have been promising. A Dutch research group has recently received a subsidy to optimise and adapt the technology for receiving the first human premature infant. While the KAPT offers opportunities to improve the treatment of premature babies during their most vulnerable period, at the same time it raises new ethical, legal and social questions in relation to the care currently provided in the neonatal intensive care unit. In this report, the Centre for Ethics and Health (CEG) identifies these questions for the purpose of informing the Minister and policymakers. Moreover, via this report, the CEG wants to initiate a discussion on the desirability and consequences of this technology.

Laboratory studies with simulation models and animal experiments can provide insight into the safety and effectiveness of the KAPT. But the KAPT also gives rise to other questions. It is unclear, for example, what the short- and long-term consequences of a stay in the KAPT would be for the child. Also, in the KAPT, direct contact between the parents and child will most likely be impossible. It is unknown what effect this may have on the bond between parents and child and on the child's socio-emotional development. The CEG recommends further research.

Another dilemma is that parents may feel pressure to take advantage of the potential for survival offered by technologies such as the KAPT, without properly weighing these up against the potential disadvantages and other alternatives relating to treatment or other care. Partly for this reason, parents need proper and intensive counselling to help them make the right decisions about whether or not to use the KAPT.

There are also questions regarding the moral and legal status of the premature baby in the KAPT. There is a debate in the literature on whether a premature infant in the KAPT should be given a different moral or legal status than a premature infant in an incubator. The CEG is of the opinion that there is currently no decisive argument to do so.

Even after preclinical studies with animal and simulation models, some uncertainties will remain, which can only be removed with clinical research. The risks to pregnant women and extremely premature infants must be minimised as far as possible. Also, the risks and burden must be proportionate to the potential benefits of the KAPT. Based on current scientific knowledge, a caesarean section is necessary for transferring the child to the KAPT. This places an additional

burden on the woman and puts her at risk. Women with pre-eclampsia seem to be a suitable group for the first-in-human studies. In many cases, this involves a problem relating to the placenta with growth retardation of the foetus, and this group of pregnant women have often already undergone a C-section.

The CEG also recommends that, before or during the further development of the KAPT, a debate on the social value and desirability of this technology should be carried out with a wide group of stakeholders, such as parents and patient organisations, paediatrics and other doctors, perinatologists, midwives, public health experts, health economists and medical and tech ethicists. For example, there are questions regarding the justification for investing in this technology instead of in research on improving existing forms of prenatal care. Indeed, at present, a relatively small, specific group may benefit from the further development of this technology. An important prerequisite for the debate is that scientists and policymakers must draw up a realistic description of the technology, so that the general public can base its opinion on accurate information and real expectations rather than on science fiction-like ideas about the KAPT.