

The English version of Neoventa Medical's statement regarding Blix article in the Norwegian paper: Dagens Medisin

- In this study, Blix and co-authors found that using STAN will drop the use of fetal blood scalp sampling during labour by 41%, the need for operative deliveries with caesarean section or ventouse drops by 8%, and the babies are born healthier because the risk of metabolic acidosis decreases with 36%. This is almost exactly the same results as a meta-analysis with international authors, however the interpretation of the results is quite different to Blix study. In her interpretation of the results of operative deliveries and metabolic acidosis, we argue that Blix and co-authors runs contrary to current international science and proven experience.
- In their arguments, Blix and co-authors report in terms of relative impact is misleading and that the reduction of the frequency of operative deliveries by 8% relative to the total rate is of no practical significance. This is incorrect and suggests that the authors underestimate the reader's own ability to interpret the results. In Sweden in 2014 was the frequency of emergency cesarean section 10% and the frequency of operative vaginal deliveries 6%, ie of approximately 100.000 deliveries annually, with STAN it would be possible to avoid $16000 \times 0,08 = 1280$ operative deliveries. Very few obstetricians and midwives would argue that this is irrelevant.
- Blix and co-authors dismiss the finding that metabolic acidosis decreased by 36% since the great majority of newborn with metabolic acidosis at birth do not develop any neurological disability. It indicates that metabolic acidosis is a poor substitute measure of neurological disability. This is a logical contradiction: it is put beyond any doubt that metabolic acidosis is a consequence that the newborn suffered severe oxygen deficiency during labour. In 70-85% of children who develop neurological disability, the disability is not due to oxygen deficiency during labour, but on other factors affecting the baby before or after birth. It is impossible to misunderstand that STAN can only identify the fetus exposed to oxygen deficiency during labour. It is unscientific by Blix and co-authors to elude a 36% decrease in the frequency of metabolic acidosis in neonates who were monitored with STAN.
- Blix and co-authors have used the GRADE-system for structured assessment of the degree of evidence for or against a method and to develop recommendations for the method how to be used. A significant weakness of the GRADE system is that the recommendations are largely influenced by the researchers' subjective perception and evaluation of the method they are investigating. The team of researchers must therefore be composed of persons that do not in advance have a definite opinion or bias. It is known that two of the authors, Blix and Öian, is against the STAN method and in the article the group of researchers do not present the other three authors' opinion. For this reason, we cannot consider the group of researchers as impartial.
- Recommendations according to the GRADE system is based on the evidence-profile and does not take into account variations in norms, culture, socio-graphic or economic composition of a population. For this reason the Swedish National Board of Health and the evidence-profile of SBU (the Swedish Agency for Health Technology Assessment and Assessment of Social Services) do not use the recommendations of the GRADE system. Therefore it is not valid for us that Blix and co-authors speak out so confident in their recommendations.
- Evidence profile in the GRADE system should not only be based on randomized controlled trials. Clinical trials, case reports, etc. should be considered, but no such studies are included by Blix and co-authors. They admit that if such studies would have been included in their assessment, they might have come to a more valid conclusion. There are several clinical observational studies showing the benefits of STAN, including how the frequency of metabolic acidosis decreases and the child's opportunities for a better health increases. The best studies have been performed in Norway and Sweden, these should be included in the assessment to get the evidence of GRADE to be credible. For a reader to have confidence in a research study requires that the basis for the study is not selected in a way so it may affect the outcome of the study. We find that this is not the case with the study of Blix and co-authors.
- In summary, we find that the interpretations of the results of the meta-analysis did not follow scientific standards and that the conclusions and recommendations are not based on complete data.