Development of a Clinical Simulation Protocol for the Transfer of a Premature Fetal Manikin to the Perinatal-Life-Support System

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At present, Perinatal-Life-Support (PLS) research is progressing to offer extreme premature infants (24-28 wks) an extracorporeal environment for extended growth that mimics the natural womb closely. During the early phase development of this novel life-support technology, validation and training could be facilitated by the use of a medical simulation. Within this abstract, the development to realize a well orchestrated clinical simulation protocol is described, tailored to the specific needs of novel procedure(s) regarding the transfer of a premature fetus from the maternal uterus to the PLS system.

Throughout protocol development an iterative approach is used, initiated with a literature analysis and a review of existing obstetrics guidelines for premature births.\(^1\)\(^2\) Co-creation sessions and interviews with medical and engineering experts led to a holistic understanding of fetal physiology, patient and specialist needs, current procedures, task divisions, hospital resources and drug specifications. Expert feedback on drafts, checklists and an explanatory step-by-step video, led to multiple re-designs as unforeseen procedural difficulties arose.

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**Topics of discussion**

**Sterility**
- Avoid exposure to vaginal flora to decrease risk of early onset sepsis\(^4\)
- Prophylactic treatment of candidates
- Non-iodine solutions for vaginal lavage

**Canulation**
- Placental bypass via Seldiger technique
- Intra-uterine via EXIT procedure
- Canulation after UC is cut

**Breathing reflex**
- Suppression through medication
- Type of maternal anesthesia (C-section and vaginal delivery)
- Amnioinfusion in case of PROM

Using medical simulation during the early phase development process of the PLS-system allows us to train and validate novel practices, in particular the transfer procedure. With this approach we aim to establish a simulation protocol by providing a step-by-step plan, informed by literature and expert consultation to ensure the advancement of a safe, hygienic and effective simulation protocol. We expect to offer a realistic simulation training whilst also informing requirements for the future development of PLS-related devices and their validation.

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\(^1\) RegioRichtlijn partus prematurus, 2016


\(^4\) Dong Y, Speer CP. Late-onset neonatal sepsis: Recent developments. Arch Dis Child Fetal Neonatal Ed. 2015;100(3):F257–63.

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