

How does the development of the biobag influence the legal issues surrounding a fetus?

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Introduction

The biobag is an artificial substitute for a uterus. The concept, alluded to in Huxley's 'Brave New World' [1], has undergone much development and human clinical trials of the biobag are expected within the next 10 years. The term 'gestateling', coined by Romanis [2], is used to describe the individual in the biobag. 'Ectogenesis' is the use of artificial wombs in pregnancy and was coined by Haldane in 1924 [3]. This paper focuses on partial ectogenesis and complete ectogenesis is outside the scope. In complete ectogenesis the entirety of gestation occurs within the biobag, but partial ectogenesis involves part of gestation occurring in a human uterus. The aim of partial ectogenesis is to allow a premature fetus to continue developing extra-corporeally. Prematurity is the biggest cause of infant mortality and morbidity in the developed world, associated with immature physiological development. Thus a treatment for prematurity is an appealing concept. The biobag influences many legal issues surrounding a fetus, such as fetal personhood, parental rights, abortion and clinical trials. These are important to discuss before it is used clinically.

The development of the biobag

The current model of the biobag is an arteriovenous extracorporeal system. It comprises a pumpless oxygenator circuit connected to the fetus via its umbilical cord for gas exchange and nutrition. The fetus lies in a sealed container of circulating synthetic amniotic fluid. Behind this model lies a history of experimentation using animals chosen at an age to represent the stage of development of a 23-week premature human.

A forerunner in investigating the use of an artificial womb for the care of premature fetuses was Emanuel Greenberg in 1954 [4]. He demonstrated the successful transplacental passage and fetal absorption of ions outside of the uterus in rats, indicating the validity of an artificial uterus. He filed a patent for his design [5], which incorporated an amniotic fluid-filled tank, blood pumps, an artificial kidney and a water heater. (Figure 1).

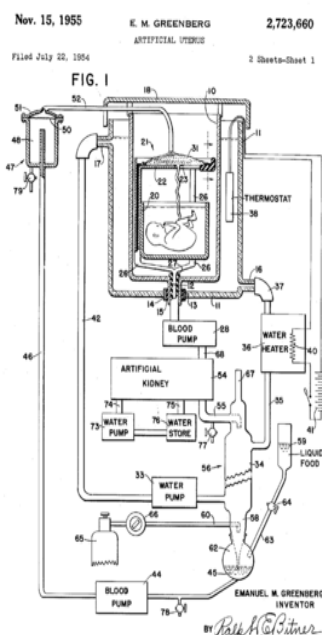


Figure 1: Greenberg, E (1955). Early Apparatus

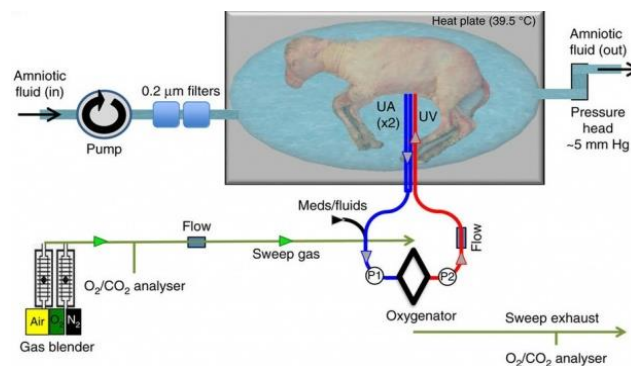


Figure 2: Partridge, E (2017). Current Apparatus

Further experimentation by Westin and Nyberg [6], Callaghan [7] and Lawn and McCance [8] showed limited success in the 1950s-1960s. Improvements in neonatal intensive care put a halt to research on the artificial uterus because interventions such as ventilators and exogenous surfactant administration were favoured as simpler methods for treating prematurity. Kuwabara et al [9]

restarted efforts. Their apparatus, involving a roller pump, membrane oxygenator and arterial reservoir into which blood drained by pump action the fetus heart, kept previable fetuses alive for up to 165 hours. A common reason for deterioration was obstruction in catheters by fetal movement, and oedema due to fetal swallowing. Unno [10] administered muscle relaxant pancuronium bromide to minimise fetal movement and swallowing and reported previable goat fetus survival of 543 hours.

The most impressive results to date come from Partridge et al [11] (figure 2). Importantly, their arteriovenous circuit contained a near-zero resistance oxygenator, and short cannulae to reduce irritation of vasculature and turbulence which can induce vascular spasm. They reported sustaining premature lamb fetuses for up to 4 weeks, with normal growth, lung maturation and haemodynamics. Partridge also added features to the biobag that would make it more suitable for clinical use, such as a darkfield camera to allow the parents to visualise the fetus and a speaker to play maternal heart and abdominal sounds to the fetus. These remarkable results indicate that the artificial womb has potential to sustaining both late premature fetuses and extremely premature ones. This necessitates discussion on the implications of its use, particularly in relation to the legal issues surrounding a fetus.

Distinction between neonatal intensive care and the biobag

Although the objective of both the biobag and neonatal intensive care (NIC) is to treat prematurity, their inherent differences must not be overlooked. Differentiating between them will ensure that the biobag is seen as independent of, rather than an extension of, NIC. Making this distinction allows the specific ethical and legal consequences of the biobag to be analysed, and alternate laws formed. Work by Romanis [12, 13] is central to this discussion.

NIC supports whatever capacity for life the new-born is already exercising. There is some onus on the neonate to sustain itself, for example through performing gas exchange in the lungs with the aid of a ventilator. If the ventilator was turned off, the neonate might survive for a short while. In contrast, the biobag does not aim to rescue whatever function the neonate has. Instead, it replaces this function, such as by gas exchange occurring at the membranous oxygenator of the biobag. The gestating is passive and exercising no independent capacity for life, regardless of its capabilities. If the biobag was switched off, the gestating would die. Additionally, greater caution is needed because the biobag is more experimental and invasive than NIC. Consequently, I argue it is neither logical nor safe to extend the laws that regulate the treatment of the neonate to treatment of the gestating due to conceptual differences between the individual being treated, and the type of treatment.

Fetal personhood

Under current English law, a fetus must be *born alive* to gain legal personhood. The development of the biobag challenges our definition of being both born and alive. I argue that the gestating should be considered alive but not born. However, this would afford it no legal personhood, and thus no rights. The existence of an individual *ex utero* with no rights is dangerous as it is not protected from harm. Thus, the development of the biobag necessitates a change in legislation to protect gestatings, along a similar vein to those afforded to a fetus beyond 24 weeks *in utero* (see later discussion on abortion). Protection should include safety from being killed in most circumstances.

The reason the gestating should not be considered born, despite existing *ex utero*, is because the biobag treats it *as if it had never been born* by continuing the processes of gestation. Furthermore, considering a gestating as unborn ensures that it is not afforded more rights than an fetus *in utero*

of the same age undergoing identical processes, simply because of its different physical location. Therefore, the definition of birth as expulsion from the uterus is inadequate and redundant. Other definitions of birth should be considered. I suggest Greasley's definition to be most suitable [in 13]. She proposes that birth should be defined by the significant biological adaptations that occur in the process, such as clearing of fluid from the lungs to enable inflation. Simple existence *ex utero* does not equate to being born. Birth relates to the emergence from the processes of gestation, rather than the emergence from the uterus. As such, a gestateling is not considered born, and would only be considered so when it exits the biobag having completed the processes of gestation. Then can it be afforded legal personhood.

The fetus must also be born *alive* to gain legal personhood. For the sake of completeness I will ignore the conclusion above and instead assume that a fetus placed into a biobag has been born. This allows brief discussion on whether it is 'alive'. I argue that the gestateling is not dead, as it is showing some signs of life, and so must be alive. Although it does not breathe, the gestateling displays a beating heart, pulsation of umbilical cord and definitive movement of voluntary muscle. These are signs of life given in the WHO's definition of live birth [14]. Additionally, the gestateling has the *potential* to breathe. Further, fetoscope technology can image the fetus within the uterus, or gestateling within the biobag and listen for a heartbeat, thereby proving that it is alive before birth. This questions whether the born alive rule should be abandoned.

Thus, the development of the biobag highlights that current concepts of birth and being born alive are inadequate and require refinement in order to assign legal personhood.

Parental rights

The development of the biobag forces us to dissect how we determine parental rights over a fetus. Current UK law holds that the father has no decision-making power over a fetus developing *in utero* but has equal rights to the mother over a child *ex utero*. The fundamental reasoning behind this is that the mother's right over her body supersedes a father's right to reproduce. Using this, a gestateling in the biobag does not compromise a mother's bodily autonomy and so parental rights should be equal. Consequently, the father acquires more rights over the gestateling than he would have over a fetus *in utero* at the same stage of development.

However, the Human Tissue Authority Code of Practice [15] maintains that fetal tissue of less than 24 weeks of gestation is regarded as the mother's tissue. It could be inferred from this that a fetus transferred to a biobag before the age of 24 weeks is the mother's tissue and so she has total rights to it. Whether the location of the fetal tissue, either *in utero* or *ex utero*, matters is not stated, demonstrating that the development of the biobag necessitates refinement of parental rights over a fetus.

Abortion

The abortion limit, set in the Abortion Act [16] is 24 weeks of pregnancy (except in extenuating circumstances). This limit reflects the viability threshold, which is when a fetus is considered capable of being born alive with the help of medical technology. The biobag has the potential to reduce the viability limit further as it allows a very premature neonate to develop to functional maturity. This questions whether a biobag-induced reduction in the viability limit should translate to a change in the abortion limit.

Furthermore, the development of the biobag questions the ethics of abortion. The justification for abortion typically centres around a woman's right to bodily autonomy. The biobag, however,

presents a woman who does not want the baby with an alternative that does not impinge on her bodily autonomy: transfer the fetus to a biobag for later adoption or paternal care. Severance theory [17] holds that a woman has a right to remove a fetus from her body, but she does not have the right to kill it. While this was previously synonymous with fetal death, the development of the biobag means that a woman could terminate her pregnancy and remove the fetus from her body without killing it. This suggests that abortion could no longer be morally justifiable, which in turn can influence legality.

I believe, however, that forcing women who do not want the child to transfer it to a biobag still compromises her autonomy. It contests the right not to reproduce, and the right to refuse treatment (as fetal extraction will be an invasive process). Instead, I propose that the biobag should increase, rather than restrict woman's options. A previously binary decision could actually be ternary - carry the pregnancy to term, abort (perhaps at an earlier date) or use a biobag.

Clinical Trials

Extensive trials, including human trials, are needed to ensure the safety and efficacy of the biobag before it enters clinical use. Who should it be tested on? Singer and Wells [18] believed that a 'catch 22' situation arises, where it is unethical to attempt ectogenesis in humans until we can be reasonably sure it is safe but we can only be reasonably sure by attempting it. I propose navigating this 'catch 22' by testing the biobag on neonates so premature they are unlikely to survive, based on the view that the outcome is unlikely to be worse than no treatment. For example, babies born at 22 weeks have a 10% survival rate [19].

Conclusion

As the use of the biobag in clinical practice becomes more realistic, it is necessary to examine the implications. This paper looks at how the biobag will influence legal issues surrounding the fetus, particularly in relation to what it means to be born and to be alive, parental rights and abortion. It exposes the need for refinement of terms and implementation of new laws.

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