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COMPREHENSIVE STUDY OF ARTIFICIAL WOMB TECHNOLOGY

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ABSTRACT

An artificial womb is an experimental medical device that is designed to create a womb like environment for neonates who are born extremely premature. Emanuel M. Greenberg filed a patent application for the construction of an artificial womb on July 22, 1954. Two drawings of an artificial womb's design were included in the patent. The newborn would float in a transparent "bio bag" surrounded by fluid in the majority of the technologies. Artificial womb technology also referred to as Artificial Amnion and Placenta Technology (AAPT) has various possible advantages such as: higher chances of survival Premature babies can survive longer in artificial wombs because they provide a womb-like environment with dimensions and a form similar to the uterus. By doing this, the chance of consequences including blindness and irreversible lung and brain damage can be decreased. Decreased chance of infection and breathing difficulties Premature newborns who are placed in artificial wombs have a lower chance of infection and respiratory distress. A substitute for newborn critical care for premature babies, artificial wombs may be a more suitable option than neonatal intensive care. The use of artificial wombs may enhance maternal health. Less anxiety for the parents who witness their premature child in intensive care may find less distress while using artificial womb. Improved knowledge of fetal development: Artificial wombs may contribute to our growing comprehension of fetal physiology and development. Artificial wombs do, however, raise certain ethical issues, such as the following: the legality of medical interventions; the influence on mother bonding; the degree of parental autonomy in making decisions; accessibility; and cost-effectiveness. According to two research teams in the

United States and Australia, artificial womb technology (AWT) has proof of principle established. According to both teams, their "artificial womb devices" will completely change how premature newborns are treated. By growing a fetus outside the body of an organism that would typically carry it to term, an artificial womb, also known as an artificial uterus, is a device that would enable extracorporeal pregnancy. As a substitute organ, an artificial uterus would have a variety of uses. It could help both male and female partners with a fetus' development. This might be carried out as a transition from an artificial to a natural uterus, which would push the embryonic viability barrier to a far earlier point in pregnancy. It can be thought of as a neonatal incubator with fairly broad capabilities in this respect. It might also be applied to start fetal development. Additionally, a prosthetic uterus could facilitate fetal surgery. The world saw the closest thing to an Artificial Womb (AW) in 2017 thanks to research conducted by a team in Philadelphia. If the "bio bag" proves to be as effective as preliminary animal research indicates, it will revolutionize the field of neonatal critical care. Premature newborns born before 22 weeks currently have no chance of survival. The mortality rates and frequencies of long-term problems for preterm at the viability threshold have not shown any discernible improvement for a while. Clinical implementation of Artificial Womb Technology (AWT), which could alter these odds, is highly expected. It is imperative that we ascertain whether AWT represents a novel development or merely an expansion of existing critical care. Determining when and how the bio bag should be used on human subjects is largely dependent on this topic.

KEYWORDS: The use of artificial wombs may enhance maternal health.

INTRODUCTION

Two main statements are made and the science supporting AWT is examined in this work. First, AWT and traditional intensive care are conceptually distinct from one another. Determining the reasons behind AWT's particular interpretation highlights the various ethical-legal issues it brings up. Second, language that is intrinsically value-laden should not be used to characterize the "human being growing in the AW" when formulating these questions. The ethical tethers attached to these phrases could lead to further misunderstandings and confusion because the "human being in an AW" is neither a fetus nor a baby. Therefore, this novel byproduct of human reproduction developing human being gestating ex utero should be referred to as "gestate ling." Although it does not aim to address every ethical dilemma related to AWT, this work provides significant explanations. Every year, 15 million preterm

babies are born, and 1 million of those babies pass away from complications, according to the WHO. The creation of artificial amnion and placenta technology, also referred to as the "Artificial Womb," which creates a setting for the fetus to excogitation, is the result of the necessity to lower infant mortality. Since the first artificial womb was created in 1958 by Westin et al. through the cannulation of umbilical arteries, this technology has demonstrated amazing promise for enhancing clinical outcomes in children who are dangerously premature. The Children's Hospital of Philadelphia's Extra-uterine Environment for Neonatal Development (EXTEND), Tohoku University's Ex-Vivo uterine Environment (EVE), and the University of Western Australia now have functional models of the technology. AWT could stop some of these, which could be lethal for both the mother and the kid. Furthermore, it takes on a significant amount of the burden for bearing a child, which is otherwise fully placed on the female. increases gender parity by enabling both parents to assume equal responsibility even before the child is fully born. Women will benefit from this psychologically, physically, and by becoming more self-reliant. Infertile women, same-sex couples, and women who have had hysterectomy can benefit from AWT as an alternative to surrogacy. (Cunningham, F. G & et al.

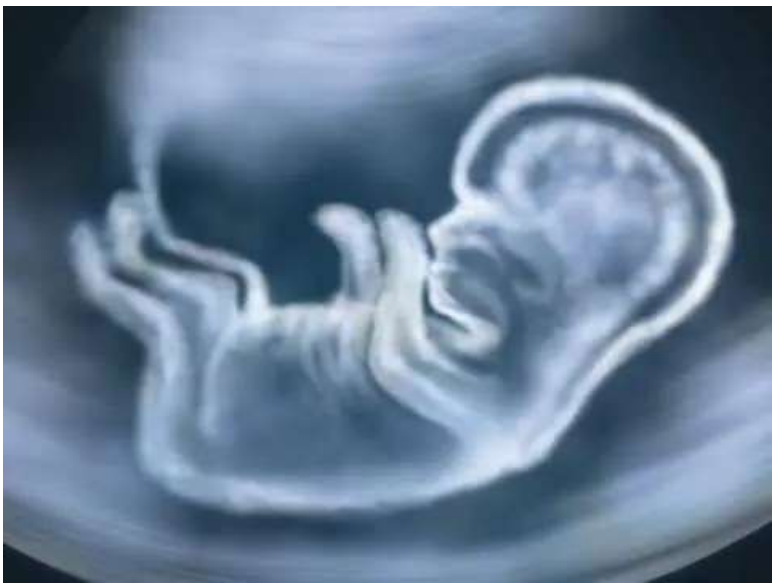

Fig. No. 1: Artificial womb.[1]

2016). Still, there are problems that need to be fixed. Currently, technology only helps the fetus develop from 13 weeks to 38 weeks, which is before full gestation. It will very certainly be preceded by a surgical extraction of the fetus, which could be complicated, because it cannot aid in the growth of the embryo into the fetus. The placenta's innate ability to convert

pulsatile flow from the umbilical artery to laminar flow in the umbilical vein is absent from the models. Furthermore, given the shift in the notion of "giving birth," there is a lack of awareness regarding the long-term psychological and psychological consequences of the womb on parents and future offspring. The AWT raises certain ethical questions given the wide range of potential uses. The primary concerns for parents are the degree of parental autonomy in making decisions on behalf of the child, the effect on mother bonding, cost-effectiveness, and accessibility, while the key concerns for the fetus are the consequentialism of medical interventions and its legal status. Before this technology is released, questions concerning the appropriateness of ectogenesis and the control of abortion should be addressed in society. "Complete ectogenesis," or full gestation outside of the human body, is one possible if not very likely application of the technology. This will have a significant impact on the proven human engagement throughout gestation, turning it into an extracorporeal event and radically changing how people think about pregnancy. (Kumar, V et al 2022).

Artificial Womb Technology (AWT)

Artificial womb technology is a groundbreaking new technology with the potential to transform reproductive health and fertility therapies. This technology aims to make childbirth safer, easier, and more accessible for women all around the world. This novel approach allows embryos to be grown in an artificial environment outside of a woman's body until they are ready for delivery. Using an artificial womb would allow doctors to monitor a baby's development from conception to birth without putting the mother-to-be at risk or making her uncomfortable. It also eliminates many of the hazards associated with traditional childbirth, such as early labor or complications caused by preeclampsia and gestational diabetes, both of which can result in premature or stillbirth. fetus may grow outside of its mother's body in an artificial womb without having to worry about any possible risks or difficulties related to being pregnant or giving birth. Additionally, it might offer a more regulated and pollution-free atmosphere, which could eventually lead to birth abnormalities or other health problems. The two most prevalent medical procedures in contemporary medicine are cesarean sections and preterm deliveries. However, these methods might soon become obsolete thanks to new and creative technologies. Ultrasound waves will be utilized in the future to aid with a fetus's growth outside of the womb. This ground-breaking method has proven to be very successful in minimizing the need for cesarean sections and preventing premature deliveries. Furthermore, the technology gives expectant mothers more autonomy over their own medical choices by enabling them to track their unborn child's development independently of medical

appointments or hospital stays. An artificial womb is a medical experiment designed to provide very preterm babies a womblike environment. The newborn would float in a transparent "biobag" filled with fluid in the majority of the technologies. (Sartorius, A & et al 2017). According to George Michalski, a pediatric surgeon at the University of Michigan, the plan is for preemies to continue developing in this device for a few weeks after birth. This way, "when they're transitioned from the device, they're more capable of surviving and having fewer complications with conventional treatment." Lung development is one of the primary factors limiting survival in newborns born very early. Babies born in an artificial womb would have lab-made amniotic fluid in their lungs instead of air, simulating the amniotic fluid they would have had in gestation. In order for the baby's blood to cycle through an artificial lung and absorb oxygen, neonatologists would place tubes into blood arteries in the umbilical cord. The Extrauterine Environment for Newborn Development, or EXTEND, is the technology that is most close to being prepared for human testing. It encases the infant in a container that contains artificial amniotic fluid. It was created at the Children's Hospital of Philadelphia by Alan Flake and Marcus Davey, and Vitara Biomedical is currently working on its development. Even if they are a little further behind, other researchers are also working on artificial wombs. (Sadlowski, M. & et al 2016). A technology that is quite similar to EXTEND is being developed by scientists in Australia and Japan. The Perinatal Life Support initiative in Europe is developing its own technologies. Additionally, researchers in Canada have been using piglets to test their version of an artificial womb. Similar technology is being developed by researchers at the University of Michigan with the goal of using it with preemies for whom traditional therapies are unlikely to be effective. The infants would only have their lungs full, not floating in fluid. According to Mychaliska, the project manager, "we believe that that has more clinical applicability" because the technology could be utilized in current intensive care units with only minor adjustments.

AN ARTIFICIAL WOMB FACILITY FOR INFERTILE COUPLES BASED ON RENEWABLE ENERGY

Renewable energy sources will power the first artificial womb facility in history. Infertile couples who want to conceive naturally now have the chance thanks to this technology. The artificial womb is an additional alternative for women who have had their uterus removed due to cancer or other potential future issues. The bioreactors used in the artificial womb facility are filled with synthetic amniotic fluid and serve as an incubator for embryos from the time of gestation till delivery. In order for the fetus to grow and develop in the artificial womb that

this device creates in a healthy manner, the fluid is continuously monitored and replaced. No other location in the planet is better for growth! It will also not deplete the planet's resources in any manner because all of the energy needed at this facility will come from renewable sources like wind turbines or solar power. This makes it genuinely eco-friendly and sustainable! With the development of an artificial womb, infertile couples can now conceive naturally without the assistance of third parties. All parents have this dream. Compared to conventional reproductive treatments, this technology does not pose the same health hazards. This makes it a more appealing substitute for people looking for solutions that adhere to the ethical standards for assisted reproduction techniques in use today. They can use these services with confidence that they won't jeopardize their health, safety, or the health of their unborn child. (Sullivan, M. M., et al. 2016).

HOW ARTIFICIAL INTELLIGENCE WILL ADVANCE TECHNOLOGY FOR ARTIFICIAL WOMBS

Artificial intelligence (AI) has enormous potential to contribute to the development of artificial womb technologies. Ectogenesis, or artificial wombs, is a ground-breaking idea that has the potential to completely alter our perception of pregnancy and childbirth. The intricate biological mechanisms involved in establishing an environment outside of a woman's body that promotes healthy fetal growth can be better understood and managed with the help of artificial intelligence. Since artificial intelligence (AI) has already shown useful in medical applications including medication development, diagnostics, and surgical planning, it makes sense that AI may be utilized to further artificial womb technology as well. AI algorithms, for instance, are perfect for vast data analysis since they can do so rapidly and accurately. (Stephenson, J. et al 2018). For instance, AI algorithms are perfect for evaluating fetal health parameters during gestation inside an artificial uterus because they can swiftly and accurately assess vast amounts of data. Furthermore, without any human involvement at all, AI-driven robotics can precisely handle the device's temperature regulation and the nutrition supply systems required to support life in this environment! Our knowledge of how to best create safe environments outside the mother's body where fetuses may develop properly until they are ready for birth will undoubtedly improve thanks to advancements made possible by artificial intelligence. This would genuinely revolutionize reproductive medicine worldwide today! Therefore, it is imperative that this field's research continue in order for us to eventually reap the benefits of its many potential advantages as soon as possible. (Smith, T. E., et al. 2015).

OBJECTIVE OF STUDY

The purpose of this research is to determine what benefits an artificial womb may have for individuals and society as a whole. Artificial wombs are a relatively new technology that will be developed in the future to let infertile couples conceive a baby while also being the infant's biological parents. This novel concept has the potential to revolutionize how our society approaches infertility by providing hope to people who have been unable or unwilling to undergo traditional fertility procedures such as IVF or surrogacy. Furthermore, it may offer choices to women who have had their uterus surgically removed owing to cancer or other difficulties but still want to produce their own genetic offspring. To conclude, the entire potential of artificial wombs will be achieved in the Future. To ensure that artificial wombs are safe to use, we must develop safety guidelines and do additional study into their long-term implications on health. However, if artificial wombs are used correctly, they could bring good improvements not only to individual lives but also to societies around the world by making reproductive technology more accessible to everyone. (Bodenheimer, T & et al 2020).

Advantages

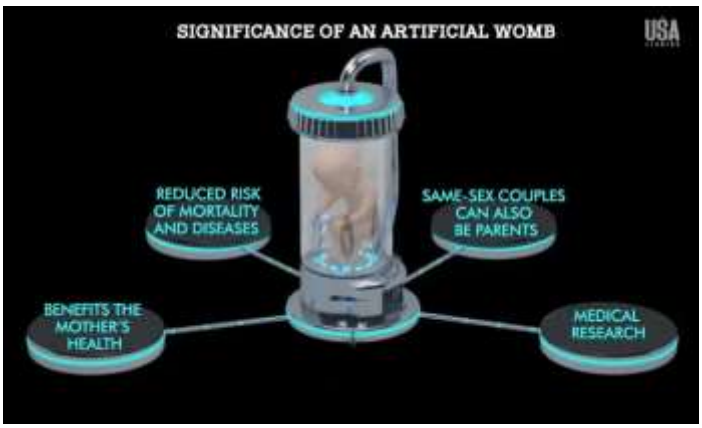

Fig No. 2: Significance of Artificial womb.[2]

Artificial Amnion and Placenta Technology (AAPT), it also referred to as artificial womb technology, offers a number of possible advantages, such as: Better health outcomes for preterm infants Premature newborns may be able to survive and escape serious health issues and impairments with the use of artificial wombs. In incubators, half of babies born at 24 weeks do not survive. A substitute for newborn critical care For premature babies, artificial wombs might be a better option than neonatal intensive care. Decreased fetal death Preterm birth rates and fetal mortality may be decreased via artificial wombs. An alternative to getting pregnant Artificial wombs may offer a different way to conceive without going through the

pregnancy process. Those who desire to lessen the physical labor involved in reproduction or who find pregnancy challenging or unpleasant may find this helpful. Gender equality has increased. If women are no longer viewed as exclusive childbearing, societal expectations for them may shift, which could result in more gender equality. Artificial womb technology is being considered by the FDA, and human trials could begin in the United States. Nourishment, oxygenation, and elimination of waste. If the prosthetic uterus is attached to a woman, she can still provide nourishment and eliminate waste. By transferring IgG antibodies to the developing baby or fetus, she may also offer immunological protection against illnesses. (Swanson, R. H., et al. 2019).

Drawback

There are a number of possible drawbacks to artificial womb technology (AWT), including: Health hazards Blood thinners would be required for premature infants in an artificial womb in order to avoid clots, which could raise the danger of brain hemorrhage. Intracerebral hemorrhage is one of the other short- and long-term physiological effects that AWT may produce. Concerns about ethics Women's access to abortion and reproductive rights may be restricted by AWT. It might also encourage discrimination and inequity. Effects on behavior and psychology Because there is no physical attachment between the mother and the fetus, AWT may have behavioral and psychological repercussions. The placenta is difficult to replicate. The human organ that is least known is the placenta, which is very challenging to reproduce in a laboratory. Due to its potential cost and private nature, access to AWT may be challenging. According to the same stringent standards as other research, experimental AWT should be regarded as medical research. Before it is licensed for broader usage, it must go through a series of clinical trials. One drawback would be that the mother would need to have a Caesarean section. Benefits in terms of cost savings in lowering neonatal comorbidities can be envisioned when examining the technology's potential impact on society as a whole, rather than only the advantages and disadvantages for the parents and the fetus or "gestate ling." (Hamilton, K. A et al 2022).

What would the initial human trials entail?

A meticulously planned transfer is necessary for the procedure. Prior to being placed in the fluid-filled container, the infant must first be delivered by cesarean section and have tubes put into the umbilical cord right away. Since they have few other options, babies born at 22 or 23 weeks would probably be the first to adopt the technology. According to Mychaliska, "you

don't want to put an infant on this device who would otherwise do well with conventional therapy." Babies are little and frequently weigh less than a pound at 22 weeks of gestation. Additionally, their lungs are still growing. Researchers found that 30% of babies delivered between 2013 and 2018 who were resuscitated at 22 weeks survived. At 23 weeks, that percentage increased to about 56%. Additionally, babies born at that stage who do survive are more likely to experience hearing difficulties, mobility issues, cerebral palsy, neurodevelopmental issues, and other disorders. It will be difficult to choose the suitable participants. According to some specialists, gestational age shouldn't be the exclusive factor. As hospitals learn how to care these preemies, the prognosis is better, but it still varies greatly from center to center, which is one aggravating factor. For instance, the University of Iowa Stead Family Children's Hospital has far higher than average survival rates—64 percent for infants born at 22 weeks. They have even successfully kept a few babies alive who were born at 21 weeks. These infants are not without hope. They can definitely survive. "If you are managing them properly, they can definitely thrive," says Brady Thomas, a neonatologist at Stead. "Are you really going to have that much of an impact by incorporating this technology, and what risks might those patients face as you begin testing it?" Depending on a number of variables, the prognosis also differs significantly from infant to newborn. "The girls outperform the lads. According to Yale School of Medicine neonatologist and pediatric bioethicist Mark Mercurio, "the larger ones perform better than the smaller ones." What is the minimum severity of the prognosis required to support the use of an artificial womb with current therapy? Mercurio would like to know the answer to that query. (Thompson, M. & et al 2020).

What dangers exist?

Brain bleeds are a constant worry in the smallest infants. Mychaliska explains, "That's because of a lot of things—a combination of their brain immaturity and partly related to the treatment that we provide." To avoid clotting where the tubes enter the body, babies in an artificial womb would need to be on a blood thinner. According to him, "I think that puts a premature infant at very high risk for brain bleeding." It's not just about the baby, either. Infants must be born by cesarean section in order to qualify for EXTEND, increasing the risk of infection and hemorrhage for the pregnant woman. Future pregnancies may potentially be affected by a C-section delivery.

FOUR MEDICAL SUPPORT AND PRENATAL DEVELOPMENT DOMAINS

The four different categories we have chosen for this manuscript are based on the stages of anatomical and physiological development in humans, as well as the technological assistance that is currently available. Domain I: Implantation and Fertilization (Conception Age: 0–2 Weeks) Louise Brown, the well-known "test tube baby," was born in the United Kingdom in 1978 after the first successful implantation of a human egg outside of the mother's body. Since then, in vitro fertilization (IVF) has emerged as the mainstay of assisted reproductive technologies, accounting for 1.9% of births in the US in 2018, according to data from the Centers for Disease Control and Prevention. The zygote is usually incubated for three to five days after conception before being put in the womb to develop into an embryo. However, ongoing research has optimized culture conditions in an experimental context, enabling the development of human embryos up to 14 days of conceptional age (CA). The cultivation of human embryos after 14 days of development is illegal in the majority of jurisdictions. Although the authors of this experimental effort claim these legal grounds for not going beyond the two-week threshold, their work and findings have been utilized to urge for an extension of these legal and moral constraints. The International Society for Stem Cell Research (ISSCR) revised its guidelines in 2021, suggesting that research projects that aim to cultivate human embryos past the two-week mark be evaluated individually and go through multiple review stages to ascertain when the experiments should end. Domain II: Development of the Embryo and Early Fetus (2 Weeks CA-21 Weeks EGA) Following two weeks of CA, organogenesis and the creation of structures essential to life define embryological development. The embryo develops into a fetus at 11 weeks EGA, and its growth and maturation of organ systems are the main features of its development, which lasts until birth. According to the prospect of survival does not begin to increase until the end of EGA of 22 weeks, which is generally regarded as the lowest threshold of viability, with little chance of survival even if aggressive neonatal resuscitation is initiated at the time of birth. As far as we are aware, there are currently no experimental or clinical extra-uterine life support systems that target domain II intervention. However, it is conceivable that AWT modifications could be utilized in the latter phases of domain II if it is shown to be effective at EGA >22 weeks. Domain III Peri-Viability (22–25 Weeks EGA) In highly developed nations, the majority of professional and governmental standards support palliative comfort care at this point because the survival rate of infants born before 22 weeks EGA is quite low. Due to rising survival rates, recommendations gradually shift over the next three weeks (EGA 22–25 weeks), with the majority of guidelines suggesting active care for infants delivered at

25 weeks EGA. Infants born in this gray zone of viability frequently experience severe somatic morbidity, long-term neurodevelopmental delay, and behavioral disability, even though survival rates have increased as a result of aggressive resuscitation and better clinical neonatal care. Cardio-respiratory resuscitation and, if feasible, minimally invasive mechanical ventilation are the primary goals of the therapeutically accessible technical support now available in domain III. When necessary, tracheal intubation and mechanical ventilation are escalated. In order to guarantee ongoing pulmonary development and enhance overall survival and clinical results, experimental strategies like liquid ventilation and artificial womb technology seek to postpone the first gas exchange in premature lungs until 22–25 weeks. (Wolfe, C. R & et al 2020). Domain IV Prematurity at Risk (26–34 Weeks EGA). Premature babies delivered before 35 weeks of estimated gestation are significantly more likely to have hyaline membrane disease, often known as infant respiratory distress syndrome (IRDS). IRDS was virtually always fatal fifty years ago. Since then, expectations of survival for infants born at earlier EGA have increased due to advancements in neonatal mechanical ventilation technology starting in the 1970s and the introduction of surfactant replacement therapy in the 1980s. As a result, an infant born in the United States at an EGA of 26 weeks currently has an 85% chance of surviving. Accordingly, active supportive care is now typically recommended and provided in highly developed settings since mortality and morbidity significantly improve after 25 weeks EGA. Research is mostly concentrated on enhancing current treatment modalities, and clinical technology to support domain IV viable premature children is comparable to that available for domain III peri-viable infants. However, infants in domain IV continue to experience devastating lung illness and serious catastrophic medical consequences, such as necrotizing enterocolitis or severe intraventricular hemorrhages, with alarming regularity.

The four domains' ethical considerations In conclusion, domain I and IV have well-established and efficient technology support, domain III has clinically extensive but poor assistance, and domain II currently lacks any support at all. Regarding the ethical issues brought up for domains I and IV, there is largely agreement, as evidenced by the existence of applicable institute rules and even laws. Although clinical ethical quandaries are encountered significantly more frequently as a result of the limitations of the current clinical standard of practice, the same is basically true for domain III technology. Guidelines have not yet been developed to summarize or address the ethical issues and concerns that have been brought up for domain II thus far. Under four broad areas, we will outline and go over the ethical issues

for each domain. The "best-interest standard" that directs a large portion of pediatric ethics, the consequentialist idea of balancing the advantages and disadvantages of medical interventions, and the concepts of beneficence and non-maleficence are all taken into account in "Potential Benefits and Harms." The main stakeholders—embryos, fetuses, fetonates, prematurely born newborns, parents, and society—are then the subject of further division under this area. "Decision-Making Authority of Parents" examines the extent to which parents have the power to make decisions about the use of medical technologies and interventions on behalf of the embryo, fetus, fetonate, or prematurely born newborn, as well as any restrictions that may be in place. The legal standing and protections granted to an embryo, fetus, fetonate, or prematurely born infant are particularly referred to as "Legal Status and Protections." Concerns regarding the unequal distribution of advantages provided by the technology or intervention as a result of access inequalities are addressed by "fairness of access."(Fox, N & et al 2017).

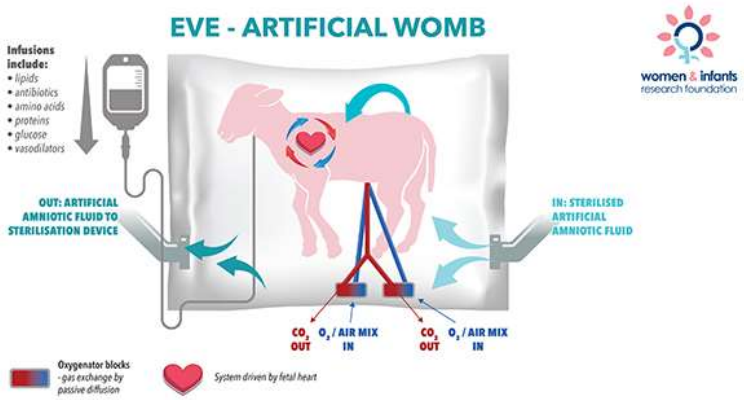

Fig No. 3 EVE (5).

Potential Advantages and Disadvantages

Prematurely Born Infant Active neonatal resuscitation has been linked to better functional outcomes and increased survival for survivors. However, since some infants may survive but have serious comorbidities that significantly lower their quality of life, it is occasionally questioned whether intensive resuscitation at delivery is appropriate for an infant in extremis. Ethicists have debated whether these infants should have been kept alive through resuscitation and continuous invasive procedures, or if they should have been allowed to die at birth or soon after. In the present clinical care system, the parents and the medical team can reduce the amount of resuscitation if the baby is extremely sick at birth or has already experienced severe in utero trauma.

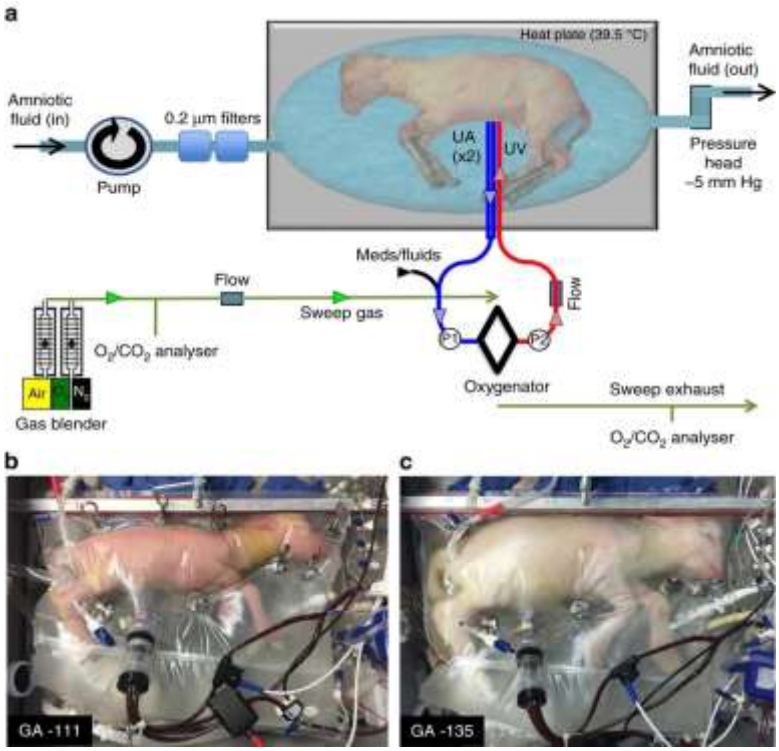

Fig. No. 4: Design of the UA/UV Biobag system.[3]

From: An extrauterine system that supports the extremely preterm lamb physiologically. (a) Components of the circuit and system include an umbilical vascular interface, a closed fluid environment with continuous fluid exchange, and a pumpless, low-resistance oxygenator circuit. (b) A representative lamb was cannulated on day four of support and at 107 days of gestation. (c) The same lamb demonstrating somatic development and maturation on day 28 of support. A premature infant is placed in a biobag and has their umbilical cord connected to a system that eliminates waste and supplies oxygen and nourishment as part of the artificial womb technology (AWT) procedure: Get the biobag ready: A fluid that resembles amniotic fluid is placed inside a biobag made of polyethylene sheet. The biobag can be adjusted to fit the uterus's dimensions. Place the infant in: Carefully, the infant is put inside the biobag. Attach the umbilical cord: Surgeons attach the blood vessels in the baby's umbilical cord to an external oxygenation system. Because the arteries are tiny and constrict after birth, this is a challenging task. Keep an eye on the infant: Vital signs such as blood pressure and heart rate are tracked. (Harrison, A et al 2019). Seal the biobag: To lower the danger of infection, the biobag is sealed. Warmers are placed around the biobag when the infant's vital signs have stabilized. In situations when placental insufficiency can result in preterm labor, AWT may be a good substitute. Additionally, it can lessen respiratory distress in premature infants. It will be difficult to choose the ideal participants for AWT, according to several experts. From

center to center and from infant to baby, the prognosis differs significantly. Advisors from the US Food and Drug Administration convened on September 19 to explore the transition from animal to human artificial womb research. These medical devices are intended to offer very preterm babies a little more time to grow in a womb-like setting before they are released into the world. Although hundreds of lambs (and several piglets) have been used in testing, animal models are not yet able to accurately forecast how the technology would function in humans. At the committee meeting, FDA's lead neonatologist in the Office of Pediatric Therapeutics, An Massaro, stated, "The hardest question to answer is how much unknown is acceptable." As this study progresses from the lab to first-in-human trials, regulators will need to consider that question.

When will humans be used to test this technology?

The EXTEND system's technology has been successfully tested on over 300 lamb fetuses to date. For three or perhaps four weeks, the lambs might live and grow inside the bag. The business needs an FDA investigational device exemption in order to proceed with human testing. Vitara may be prepared to ask for an exemption in September or October, according to Flake, who made the statement at a June meeting. However, Flake refused to respond when asked specifically how far the technology had progressed during the September advisory committee meeting. He added that during the part of the meeting that was closed to the public, he may talk with the advisory committee about time. FDA officials must be persuaded that infants who try EXTEND will likely benefit from the system and perform at least as well as infants who get the existing standard of care in order to approve a trial. (Rothman, B. K. et al (2023).

What would the initial human trials entail?

A meticulously planned transfer is necessary for the procedure. Prior to being placed in the fluid-filled container, the infant must first be delivered by cesarean section and have tubes put into the umbilical cord right away. Since they have few other options, babies born at 22 or 23 weeks would probably be the first to adopt the technology. According to Mychaliska, "you don't want to put an infant on this device who would otherwise do well with conventional therapy." Babies are little and frequently weigh less than a pound at 22 weeks of gestation. Additionally, their lungs are still growing. Researchers found that 30% of babies delivered between 2013 and 2018 who were resuscitated at 22 weeks survived. At 23 weeks, that percentage increased to about 56%. Additionally, babies born at that stage who do survive are

more likely to experience hearing difficulties, mobility issues, cerebral palsy, neurodevelopmental issues, and other disorders. It will be difficult to choose the suitable participants. Gestational age shouldn't be the sole factor, according to some specialists. The fact that the prognosis differs greatly from one center to another and is getting better as hospitals figure out how to manage these preemies is one aggravating element. For instance, the survival rate for kids born at 22 weeks is 64%, which is significantly higher than the norm at the University of Iowa Stead Family Children's Hospital. A few babies born at 21 weeks have even been kept alive by them. "There is yet hope for these babies. They have a good chance of surviving. Brady Thomas, a neonatologist at Stead, adds, "If you are managing them properly, they can definitely thrive." "Will incorporating this technology actually have that much of an impact, and what risks might those patients face as you begin testing it?" Additionally, the prognosis differs greatly from newborn to baby based on a number of variables. "Girls perform better than boys. According to Mark Mercurio, a pediatric bioethicist and neonatologist at the Yale School of Medicine, "the larger ones perform better than the smaller ones." Thus, "how dire must the prognosis be with current treatment to warrant the use of an artificial womb?" That's a query Mercurio wants to see answered. (Chang, E. A & et al 2020).

What dangers exist?

Brain bleeds are a constant worry in the smallest infants. Mychaliska explains, "That's because of a lot of things—a combination of their brain immaturity and partly related to the treatment that we provide." To avoid clotting where the tubes enter the body, babies in an artificial womb would need to be on a blood thinner. According to him, "I think that puts a premature infant at very high risk for brain bleeding." It's not just about the baby, either. Infants must be born by cesarean section in order to qualify for EXTEND, increasing the risk of infection and hemorrhage for the pregnant woman. Future pregnancies may potentially be affected by a C-section delivery. (Partridge, E. A et al 2017).

Could kids be raised completely outside the womb if it is successful?

Not very soon. Perhaps never. This possibility was described as "a technically and developmentally naïve, yet sensationally speculative, pipe dream" by Flake and his colleagues in a 2022 study. There are two issues. First, fetal development is a well planned process that depends on the fetus and the expectant parent's bodies communicating chemically. There is no assurance that researchers could replicate those conditions, even if

they were aware of every element that affects embryonic development, which they are not. Size is the second problem. In order to give oxygenated blood to the developing artificial womb systems, surgeons must introduce a tiny tube into the baby's umbilical chord. This gets more challenging the smaller the umbilical cord. (Miller, F. G & et al 2004).

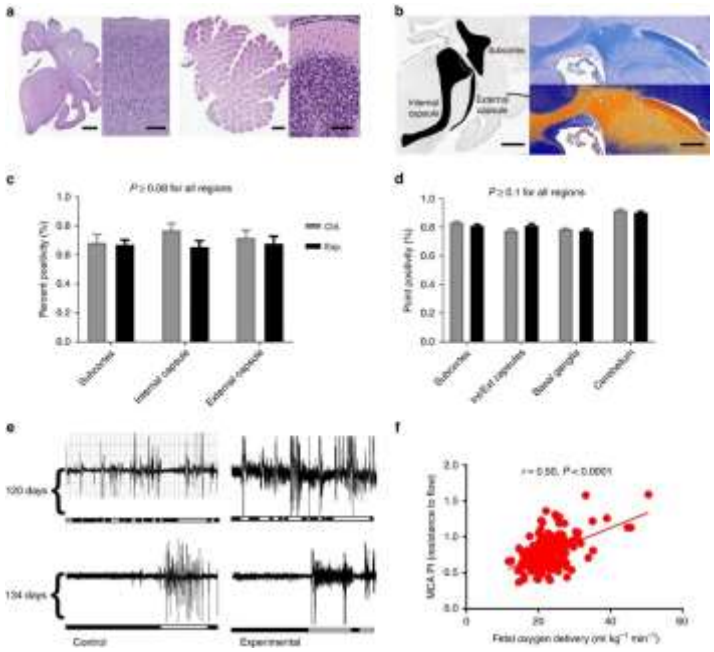

Fig No. 5. Histologic and other parameters of brain development and maturation.[4]

(a) Representative sections of the post-therapy cerebrum/cerebellum and their corresponding cortices stained with hematoxylin and eosin (H&E) show normal brain parenchyma and no signs of damage. (b) Digital pixel identification showing myelin density (orange) and representative Luxol fast blue myelin stain. (c) The percentage of pixels in the chosen regions that are positive. (d) The highest positivity (myelin density) in the chosen areas. (e) Ocular electromyography (EMG) activity in instrumented fetal lambs at 120 days (upper tracing) and 134 and 139 days (lower tracing) respectively. Activity is represented by the white portion of the bar and quiescence by the black portion. (f) Fetal oxygen delivery and the middle cerebral artery pulsatility index (MCA PI) are correlated; the solid line shows the linear best fit. In (c,d), the data are displayed as mainstem. From left to right, the scale bars in (a,b) are 4 mm, 300 μm, 1.5 cm, 150 μm, 4 mm, and 2 mm, in that order. Statistical significance is defined as $P<0.05$. P values in (c,d,f) indicate the difference between the control and experimental groups (student's t-test in c,d, and Pearson's correlation coefficient in f). (Nguyen, C. F & et al 2018).

What moral issues are raised?

In the short run, there are worries about how to make sure that parents who might be in a desperate attempt to rescue their children are giving researchers their informed consent. According to bioethicist Vardit Ravitsky, head of the Hastings Center, a bioethics research institution, "this is an issue that comes up with lots of last-chance therapies." More important questions will be raised if the artificial wombs are successful. According to Ravitsky, "this is obviously potentially a wonderful technology" when these devices are utilized to preserve prematurely born babies. However, like any technology, there may be further applications. Suppose this technique is available and a lady wishes to end her pregnancy at 21 or 22 weeks.

What impact would that have on a woman's autonomy to decide whether to bring a pregnancy to term?

Do we imply the right to physically separate from the fetus when we claim that a woman has the right to terminate? Or are we referring about the freedom to avoid being a biological mother? "What?" asks Ravitsky. That scenario might seem unrealistic given the technology's infancy, but it's important to consider the ramifications now. "An entity undergoing gestation outside the body is a unique human entity," Elizabeth Chloe Romani's, a health-care law and bioethics scholar at Durham University in the UK, contended at the advisory conference, adding that it may have distinct needs and need separate protections. According to Ravitsky, the introduction of an artificial womb prompts a variety of inquiries, including: "What is a fetus, what is a baby, what is a newborn, what is birth, what is viability?" These issues have both legal and ethical ramifications. "There will be a lot of blind spots if we don't start thinking about it now," she says. (Burgess, T. L & et al 2021).

ARTIFICIAL WOMB TECHNICAL PROSPECTS

The results of Partridge et al.'s biobag, an artificial womb-like device intended to prolong gestation outside of the womb, were published in 2017. In addition to facilitating the administration of water and nutrients and the elimination of waste products, catheters mimic umbilical cord access. While ensuring oxygen supply, an oxygenator lets the subject's heartbeat regulate circulation, just like it would in pregnancy. In order to facilitate the delivery of nutrition and prevent infection, the subject is enclosed in (synthetic) amniotic fluid. For 28 days, the biobag was able to support preterm lamb fetuses, which are developmentally comparable to "just-viable" human preterms. Every biobag subject lived and was "delivered" successfully. Every research participant seemed to be in good condition and

to have matured (showing a successfully completed gestation). (Klapper, F et al 2015). The biobag researchers admit that both their findings and the gadget require more testing and improvement. However, they define their probable clinical target population, conclude that their device may soon be ready for human testing, and discuss the rationale behind the use of experimental AWT on people. Usuda et al. released the EVE platform's second trial in 2019. Similar in concept, the EVE device encloses the individual in a sterile plastic bag with a warm bath of amniotic fluid. Circulation is maintained via the subject's heartbeat, an oxygenator, and catheters. According to a 2017 study, the EVE platform had a greater rate of morbidity and death and only kept lamb fetuses alive for a shorter amount of time than the biobag trial. The authors focused their results on redesign and were cautious about the possible clinical use of EVE treatment. They released the findings of a research that used their redesign in 2019. Despite being preliminary, Usuda et al.'s findings "demonstrate the potential clinical utility of a further refined EVE therapy system to improve outcomes for extremely preterm infants" and reported an increased survival rate. Despite their limitations, these investigations are encouraging. Only brief tests with tiny sample sizes have been conducted on the gadgets. Repeated, longer investigations require additional validation of results. Furthermore, without considerable improvement, the results of these experiments shouldn't be regarded as promising enough to permit usage on human beings. Several participants in the EVE research showed early indicators of liver disease, brain damage occurred, and the survival rate was 87.5%. These hazards might not be any more severe than those that frequently arise in NIC. However, it is crucial to recognize the particular dangers and uncertainties. Lastly, the physiology of lambs differs from that of people. As a result, using the gadgets on people might not be as effective. To learn more about the possibility of AWs gestating humans, research must be done on animals with more human-like physiologies, including primates. Before AWs are prepared for human testing, many obstacles need to be removed. Nonetheless, it is evident that scientists think their initial findings validate the hypothesis that their gadgets could extend human gestation ex utero. Given the rapid speed of development in this field, the refining and validation process might not take long. In two years, the EVE team created a revamp. Strong motivations are behind this research: funding is available, and while the main goal is to improve outcomes for preterms and their parents, researchers are equally interested in the bioengineering challenges and the potential prestige of creating the first "artificial womb." The biobag research head, Dr. Flake, hinted in an interview that we may be on the verge of a time "ten years from now" when preterms may be treated with AWT instead of traditional NIC. Prior to evaluating

experimental AWT as a clinical alternative, it is crucial that we begin to take into account some of the ethical and legal concerns that are present. Addressing any ethical concerns in the process requires determining how AWT might be converted into a clinically useful tool. Both research teams state that their device's goal is to enhance clinical results and give human preterms more comprehensive support. However, the research may take different tacks when it comes to eventual clinical translation. The literature makes the assumption that AWT will be applied in ways that go beyond what is now thought to be feasible. However, the biobag research clearly states that the authors do not intend to contest the viability timeline and describes their clinical population as the "just-viable" preterm (23–25 weeks). Their sole goal is to lower the rate of death and morbidity among premature infants who are known to have some capacity to survive. (Floyd, E. B & et al 2021). Experimental AWT would replace the current methodology (traditional NIC), which has yielded inconsistent outcomes, with a strategy that is conceptually sound but has not been tested in humans. Preterms are regularly guaranteed to survive with conventional NIC. However, preterms are still not likely to survive the usual issues linked to prematurity and NIC before 26 weeks. The survival rate for preterm babies born at 22 weeks is only about 9%. According to one study, the survival rate rises to 65% at 24 weeks and 33% at 23 weeks. Heart failure, infection, and ventilation-induced lung injury are among the complications of NIC. Fifty percent of 26-week preterm babies that survive have significant impairments as a result of problems. Among preterms, this rises to 75% at 23 weeks. Over the past 20 years, outcomes for extremely preterm infants (less than 28 weeks) have not altered significantly, even while overall mortality rates in NIC have improved over time. Furthermore, because individual conditions vary widely and it is difficult to predict the outcome in any given situation, standard care does not always result in positive outcomes. The EVE authors state that they envision the EVE platform helping preterms "close to or at the border of viability," however they do not specifically try to identify their clinical group. The gadget was tested on lambs that, according to the study, "approximated the size and weight of a human fetus close to the border of viability (21–24 weeks of gestation)" as much as possible. (Akram, M et al 2021). This suggests that the authors expect EVE to be used experimentally on preterms that are just below that threshold and are not yet deemed viable. This may offer a different approach to clinical translation, whereby AWT is first tested on preterm infants who are born alive but are so functionally underdeveloped that resuscitation would not normally be tried (less than 22 weeks). These two methods (using viable or non-viable preterm) raise distinct moral dilemmas. Methodology Fetal lambs used in the study are put in a plastic bag with synthetic amniotic

fluid inside. An umbilical vascular access, a closed sterile fluid environment, and a pumpless arteriovenous circuit make up the system's three primary parts. In order to most accurately resemble the normal fetal/placental circulation, the pumpless arteriovenous circuit uses a very low resistance oxygenator in conjunction with the fetal heart as the only source of blood flow. To guarantee sterility, the closed sterile fluid environment is crucial. In order to reduce decannulation occurrences and the possibility of mechanical obstruction, researchers devised a method for umbilical cord vascular cannulation that preserves a length of natural umbilical cord (5–10 cm) between the cannula tips and the abdominal wall. The lambs' umbilical cords are connected to a machine outside the bag that functions as a placenta, supplying nourishment and oxygen while also eliminating waste. The equipment was maintained "in a dark, warm room where researchers can play the sounds of the mother's heart for the lamb fetus." For one month, the technique was successful in promoting normal development in the premature lamb fetuses. In fact, eight lambs have been run by scientists while maintaining steady circuit flow levels that are comparable to the placenta's typical flow. Five babies from 105 to 108 days of gestation for 25–28 days and three fetuses from 115 to 120 days of gestation for 20–28 days have been run, specifically. (Patel, R et al 2021). Rather than being unstable, the longest runs ended after 28 days because of restrictions in the animal procedure, indicating that support for these early gestational animals might continue over 4 weeks. Moving testing to premature human fetuses is something Alan Flake, a fetal surgeon at the Children's Hospital of Philadelphia, expects will happen in three to five years. The study's lead, Flake, describes the prospect of their technology being able to replicate a full pregnancy as a "pipe dream at this point" and says he has no plans to develop the technology to do so. Risks consist of: pharmaceutical side effects, such as hypotension and weak or sluggish breathing (respiratory depression). blood loss, which could indicate that a transfusion is necessary. Dehiscence, or thinning or reopening of the uterine scar, increases the likelihood of subsequent pregnancies. the requirement for C-section delivery for ongoing or upcoming pregnancies. The hazards to the fetus include: the potential for premature labor to result after surgery. abruption of the placenta, which may deprive the fetus of the nutrition it requires. separation of the chorioamniotic membrane, which may result in problems. A rare amniotic fluid infection is called chorioamnionitis. (Buchbinder, A & et al 2022). Within ten years, artificial wombs might be accessible, however there are a number of obstacles to be addressed before their widespread adoption: Progress The intricate process of fetal growth depends on the fetus and the expectant parent's bodies communicating chemically. Researchers may not be able to replicate these conditions. Dimensions To supply oxygenated

blood to artificial wombs, a tiny tube must be placed into the baby's umbilical cord. If the umbilical chord is tiny, this may be challenging. Regulatory and ethical considerations In September 2023, the FDA held a meeting to talk about ethical and regulatory issues surrounding human studies. The committee decided that in order to ascertain the long-term health consequences on children, a thorough follow-up would be required. According to others, the initial purpose of artificial wombs will be to supplement infertility medication. Some claim that they could prevent preterm births, which are the world's biggest cause of neonatal mortality. (Cameron, D. D & et al 2019). The following are some possible drawbacks of artificial wombs: Safety: When switching from animal to human trials, there are worries over the safety of artificial wombs. Brain hemorrhage: In order to avoid clots, babies in artificial wombs would have to take blood thinners, which could make them more susceptible to brain bleeding.

Ethical issues: There are numerous ethical issues, such as: Social repercussions: The concept of an artificial womb has social repercussions, including the potential to strengthen prejudice and injustice.

Psychological consequences: The long-term psychological impacts on parents and future children are unknown. Legal status: Concerns have been raised regarding the consequentialism and legal standing of medical procedures. Making decisions: The degree of parental autonomy in making decisions for the baby is a matter of debate. Cost-effectiveness: The affordability of artificial wombs is a topic of debate. Accessibility: Concerns have been raised regarding artificial wombs' accessibility. Development: The goal of attaining full external gestation has reached a standstill.

Uterine simulation: Uterine simulation alone may not be sufficient. There are three main issues in growing children in artificial wombs. In actuality, our knowledge of the placenta is quite limited. Knowing more about the organ we were attempting to reproduce would make the artificial womb concept less implausible. The placenta is that organ, which mediates the exchange of carbon dioxide and other waste products from the fetus with oxygen and nutrition from the mother. (Delgado, A & et al 2023).

1. The issue is that the placenta is "the least understood human organ," according to National Institute of Child Health and Human Development head Alan Guttmacher. That's a big obstacle to building one in the lab that can carry a human embryo to term.

2. A mother's uterus is not all that she is. Our current understanding of pregnancy emphasizes the significant impact that a pregnant woman's actions have on the developing fetus. Janet DiPietro, associate dean for research at the Johns Hopkins Fetal-Development Project, told Don that a mother's posture, speech, food, and sleep patterns all have an impact on the unborn. "The maternal context provides an environment that goes far beyond the direct circulatory-system connection," she stated. In other words, pregnancy is more than just the physical exchange of nutrients and waste that takes place in the womb, even if we were successful in removing the placenta. Humans are complicated enough machines that simply imitating the uterus might not be sufficient, and what a woman accomplishes with the rest of her body is also important. (Lee, M. J et al 2022).

3. In reality, no one is currently working on this. Research by Dr. Helen Liu, who is currently the director of the Reproductive Endocrinology Laboratory at Weill Cornell Medical College, is crucial to the prospect of a human artificial womb. Liu has succeeded in causing cells from the uterine wall, or endometrium, to proliferate outside the body on a framework that resembles a uterus. Don claims that in 2001, she successfully implanted a human embryo on this reconstructed uterine wall, and it lived for ten days when Liu terminated the experiment. (Research on human embryos was prohibited by the US government after 14 days of fertilization.) Liu kept working with mice, and in 2003 she gave birth to a single malformed baby mouse that had a full-term gestation in an external uterus. According to Don, Liu believed that partial gestation within a living animal would be more effective than full external gestation at that point. When Liu attempted to implant mouse embryos that had begun developing in the external uterus into a mouse's abdomen, the outcomes were better than expected; the offspring were smaller than typical but not malformed. Although this seems quite promising, Liu's investigation ended there. She stopped working on the research because of all the attention from medical ethicists, campaigners, and the media. "It turned out to have all of these social implications, and I didn't want to deal with it," Liu stated to Don. Histologic and other measures of brain maturation and development. From: An extrauterine mechanism to sustain the extremely preterm lamb physiologically. (Bitan, S & et al 2022).

CONCLUSION

In summary, there are several potential benefits to the rigorous study of Artificial Womb Technology (AWT), including improved health outcomes for premature infants, a replacement for conventional critical care, a reduction in fetal mortality, and an alternate form

of reproduction. But there are also disadvantages to take into account, including as possible health risks, moral dilemmas, and the difficulties in reproducing the complex fetal development processes outside of the womb. To solve safety issues, advance technology, and resolve the moral and legal conundrums raised by the use of artificial wombs, more study in this area is necessary. Although there are many opportunities to improve infant care and reproductive health, widespread adoption of artificial womb technology will require more thorough research and serious evaluation of the ethical issues.

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Links

1. https://images.app.goo.gl/VEm3pvNWHknyJ2e47
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