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Artificial Womb Technology: Advancements, Challenges, and Ethical Considerations

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Abstract: Artificial womb technology (AWT) seeks to mimic the intrauterine environment to facilitate the growth of premature babies, with the potential to close the gap between existing neonatal care and natural gestation. In the last sixty years, developments such as the Extra-uterine Environment for Neonatal Development (EXT). These systems employ extracorporeal membrane oxygenation and sterile biobags to simulate the amniotic cavity, creating a controlled environment for fetal growth. AWT can potentially decrease complications of extreme prematurity, including respiratory distress and infection, by creating a more physiologically suitable environment for growth. Moreover, AWT may be an option in instances of placental insufficiency, which can potentially enhance infant and maternal outcomes by reducing the risks of high-risk pregnancies.

Nevertheless, the use of AWT poses ethical and societal concerns, such as the legal rights of the fetus in an artificial womb, parental autonomy in decision-making, effects on maternal-fetal bonding, and accessibility and cost-effectiveness. In addition, the possibility of full ectogenesis - gestation outside the human body altogether compromises conventional definitions of pregnancy. It may have far-reaching effects on societal attitudes toward reproduction and parenthood. Continued research and interdisciplinarity are necessary to address these challenges and ensure that AWT is incorporated into clinical practice in a way that is both scientifically valid and ethically sound.

Keywords: *Artificial Womb Technology, Ectogenesis, Neonatal Care, Prematurity, Bioethics, Clinical Translation.*

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I. INTRODUCTION

The latest developments in reproductive medicine namely, the discovery of in vitro fertilization (IVF) and the advances in neonatal intensive care have made it possible to pursue ectogenesis: the idea of raising a human fetus in whole or in part ex-utero. Ectogenesis, then, as defined by Bullleti et al., is the employment of an artificial womb that will sustain embryonic growth to the viability point, with potentially game-changing advantages in individuals with uterine factor infertility, not to mention the treatment of very premature babies born below the viability threshold around 24 weeks gestation (Bulletti et al. 2011).

An artificial womb, in its envisioned form, replicates the essential functions of the natural uterus by providing a fetal environment with a supply of oxygen and nutrients and evacuation of metabolic waste via an artificial placenta. Such an extracorporeal device would be used both for reproductive and neonatal care applications, maintaining fetal implantation and development in those who cannot carry a pregnancy and decreasing mortality and morbidity in preterm neonates. Early experiments during the 1980s and 1990s, such as isolated uterine perfusion models, laid the foundation for a rudimentary understanding of uterine physiology and the technicality of extrinsic fetal support, although these experiments were met with strong ethical resistance that stopped human embryo implantation research (Bulletti et al. 2011).

More recently, artificial placenta and artificial womb technologies are about to enter clinical trials, and two different systems are under development: a pump-based veno-venous extracorporeal life support (VV-ECLS) "artificial placenta" and a pumpless arterio-venous extracorporeal life support (AV-ECLS) "artificial womb." These technologies will mimic intrauterine physiology in very premature infants, differing radically in design, use, and accompanying ethical issues (Kukora, Mychaliska, and Weiss 2023). The artificial placenta provides delayed cannulation and ongoing evaluation after delivery, whereas the artificial womb needs immediate cannulation at the time of cesarean delivery to sustain fetal perfusion, thus positioning maternal operative risk.

The medical application of such systems raises sophisticated bioethical issues. Scientists have struggled with the legality and morality of fetuses produced by these

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technologies, how to define what (e.g., "gestatelings"), patient selection criteria, withdrawal procedures, and societal undertones. Lacking is specific ethical direction on how to design first-in-human trials, in particular within a framework of competing technical avenues and resultant risk profiles for each system (Kukora, Mychaliska, and Weiss 2023). This chapter will critically explore the scientific and ethical aspects of ectogenesis, emphasizing the technological advance, clinical promise, and ethical model required to inform future research and practice.

II. HISTORY OF ARTIFICIAL WOMB TECHNOLOGY (AWT)

The idea of carrying human life in vitro, or outside the mother's body - termed ectogenesis - dates back almost a century and has gone through various stages of philosophical, literary, and early scientific periods way before its present technological advances. The first official expression of this concept was made by British geneticist J.B.S. Haldane in his 1924 speech Daedalus: or, Science and the Future, where he used the term "ectogenesis" to refer to the potential for full fetal development in a man-made environment. Haldane pictured this not merely as a technical achievement but as a social upheaval that could transform reproduction and free women from the biological stigma of pregnancy (Dharmapalan 2024).

During the early to mid-20th century, ectogenesis was a speculative idea in scientific and literary thought. Authors like Vera Brittain and Aldous Huxley considered the moral and social implications of artificial birth. In Huxley's Brave New World (1932), reproductive technology obliterates natural pregnancy as a possibility, incubating human beings in mechanical hatcheries and establishing strict class systems from infancy.

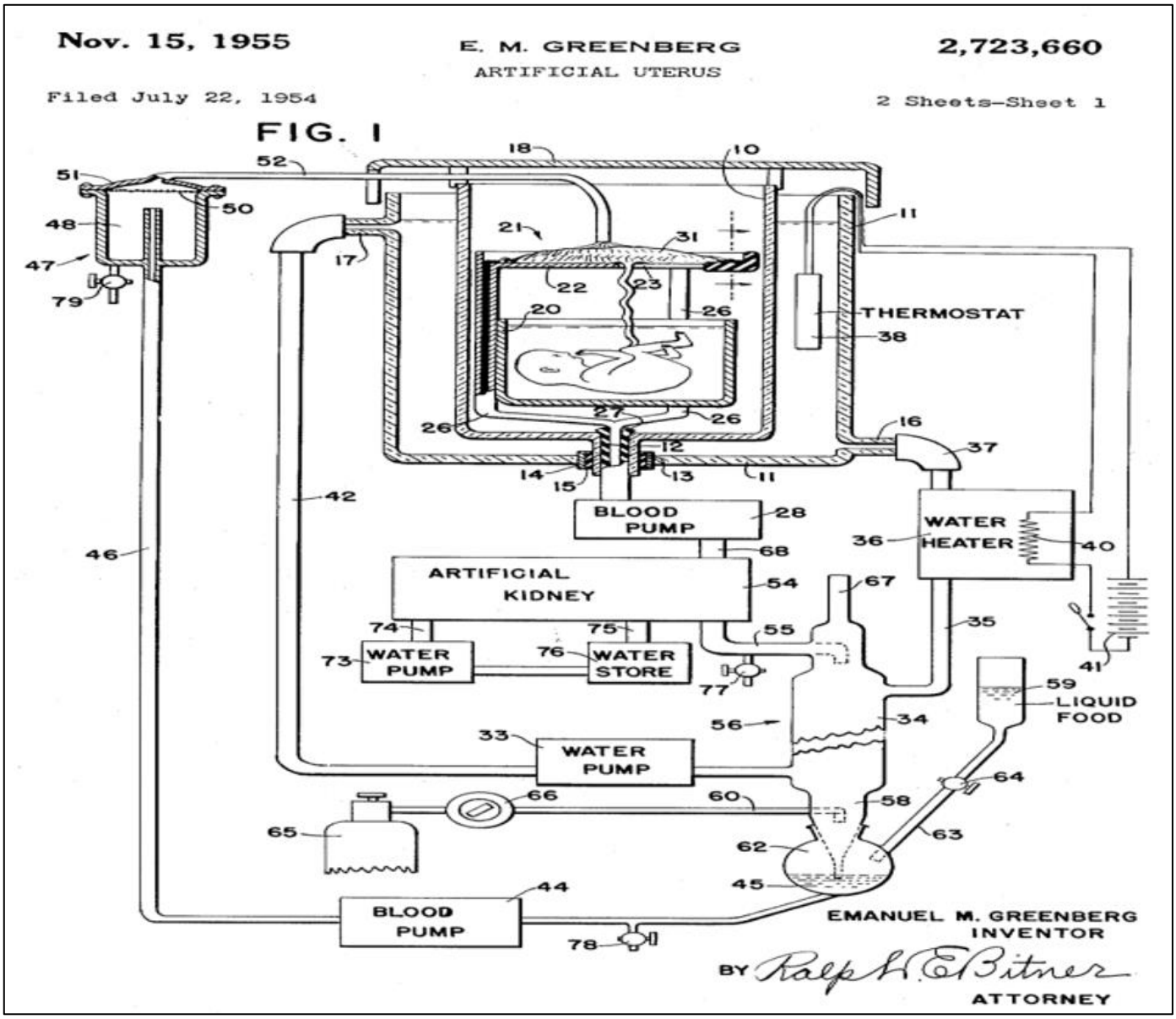

Fig 1 Diagram of Emanuel M. Greenberg's Artificial Uterus (1955).

Source- ARTIFICIAL WOMB A Revolutionary Reproductive Technology for Next-Gen Humans (Biju Dharmapalan)

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This schematic, filed under U.S. Patent No. 2,723,660, illustrates one of the earliest engineered designs for an artificial womb. The system includes a fluid-filled chamber simulating the amniotic sac, an artificial kidney for waste filtration, blood and water pumps for circulation, and a thermostatically controlled environment. Greenberg's invention represents a foundational vision in the history of ectogenesis and artificial gestation, though it was never constructed or tested.

The earliest recorded scientific effort to make artificial womb technology formal was in 1954 when Emanuel M. Greenberg applied for a U.S. patent for a device consisting of an artificial uterus. The device contained features like a reservoir for fluid, injectors for nutrients, a waste elimination system, and a temperature regulation system. Though Greenberg's design was never built, it was the first instance of an engineered design for human ectogenesis (Dharmapalan 2024).

During the 1950s and 1960s, initial experiments-initiated studies on characteristics of technical feasibility in maintaining fetal life ex-utero. For example, characteristics of successful maintenance of fetal circulation for a few hours in human specimens were described by Westin (1958) using perfusion and oxygenation methods. Likewise, Callaghan researched lamb fetuses, creating perfused chambers that were designed to mimic amniotic and placental functions. These experiments, although primitive by today's standards, provided the first knowledge of fetal physiology that would guide subsequent work on artificial gestation (De Bie et al. 2020).

However, research efforts slackened during the 1970s and 1980s as advances in neonatal intensive care, including mechanical ventilation, surfactant therapy, and corticosteroids, substantially improved the survival of premature babies. As neonatal medicine developed, the imperative to create an artificial womb became less pressing, and the idea of ectogenesis fell back into theoretical and academic debate.

The early days of artificial womb technology are marked by prophetic vision and early scientific curiosity. From philosophical prophecy to early animal experiments and failed patents, the earliest efforts during the 20th century reflect both the persistence of the desire and the technological obstacle of growing life outside the womb.

III. WORKING PRINCIPLE OF ARTIFICIAL WOMBS

Artificial Womb Technology (AWT), also referred to as ectogenesis systems, aims to replicate intrauterine conditions and allow fetal development outside of the biological uterus. Essentially, AWT is designed to bridge the vital gap between gestation in utero and viability in the neonatal period by providing a controlled, life-sustaining environment for extremely premature infants, particularly those born before 28 weeks of gestation whose survival and development remain challenging in routine neonatal intensive care. The most extensively debated and experimentally tested system is the "biobag" model, created by investigators at the Children's Hospital of Philadelphia. This system, technically referred to as EXTEND (EXTrauterine Environment for Neonatal Development), consists of two principal components that work in harmony: a fluidic chamber and a modified extracorporeal life support system (Partridge et al. 2017). The fluidic chamber is a clear, sealed polyethylene bag containing circulating and filtered synthetic amniotic fluid. This fluid mimics the amniotic sac of the natural womb by providing buoyancy, cushioning, and thermal control to the developing fetus. It also supports skin integrity and the musculoskeletal system, which would otherwise be compromised within a dry, open-air NICU environment.

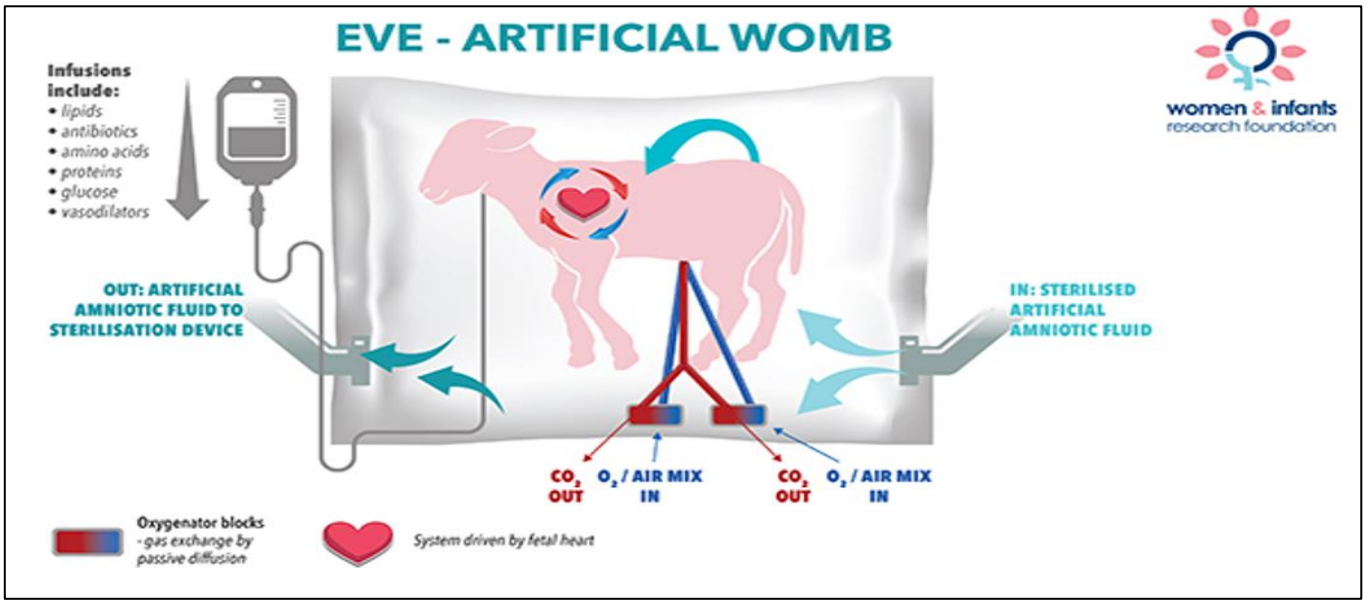

Fig 2 The EVE Artificial Womb System Developed by the Women & Infants Research Foundation.

Source- TOHOKU UNIVERSITY CREATING GLOBAL EXCELLENCE

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The second key component is the vascular interface, which mimics the action of the placenta. In this model, the fetus is surgically joined via its vessels in the umbilical cord to a uniquely constructed pumpless oxygenator and delivery system for nutrients. The arterio-venous circuit is based on the fetal heart's pumping blood in the circuit, skipping the complexities of an external pump. The oxygenator facilitates the exchange of gases, introducing oxygen and removing carbon dioxide, and can facilitate the introduction of drugs, electrolytes, and nutrients (Usuda et al. 2019). This functional replacement of the placenta maintains fetal circulation in a way that avoids ventilation-induced damage, one of the preeminent dangers to preterm neonates with conventional treatment.

The system is monitored for pressure, temperature, oxygenation, and waste levels to maintain homeostasis. Continuous real-time data is obtained, and in more advanced installations, artificial intelligence (AI) systems are proposed to assist in controlling the environment and recognizing deviations (Dharmapalan 2024). Of utmost importance, this closed-loop feedback system is intended to support fetal physiological development, that is, of lungs, brain, and gastrointestinal tract organs most vulnerable to damage in extreme prematurity.

While animal trials, particularly in sheep, have been promising with good fetal growth up to 28 days, human use is still under close regulation. Products such as the biobag have been designated as breakthrough medical devices by the U.S. Food and Drug Administration according to their potential for innovation and requirement for careful advancement to human trials.

Overall, AWT operation involves an advanced integration of fluidics, neonatal physiology, and bioengineering, all aimed at replicating uterine conditions. The technology is more than a mechanical device, a responsive environment designed to facilitate continuous gestation in an external environment.

- *Recent Advances in Artificial Womb Technology*

Artificial womb technology (AWT) has progressed from theoretical investigation to concrete systems with proven efficacy in large animal models at a very fast pace. These technological advances, especially in the support of extremely premature infant's ex utero, hold the promise to revolutionize perinatal medicine by enhancing survival and development in infants born at the margins of viability.

- *The EXTEND System and Long-Term Lamb Support*

A major turning point in AWT occurred in 2017 when researchers at the Children's Hospital of Philadelphia introduced the EXTEND (EXTrauterine Environment for Neonatal Development) system. This artificial womb employs a pumpless, low-resistance extracorporeal circuit driven by the fetal heart. Blood flows through a highly efficient oxygenator through a simplified arterio-venous (AV) loop using either carotid artery/jugular vein (CA/JV) or umbilical artery/umbilical vein (UA/UV) cannulation. The fetus is placed in a sterile, liquid-filled polyethylene bag that replicates the amniotic sac, allowing normal breathing and swallowing movements essential to lung and gut development (Partridge et al. 2017).

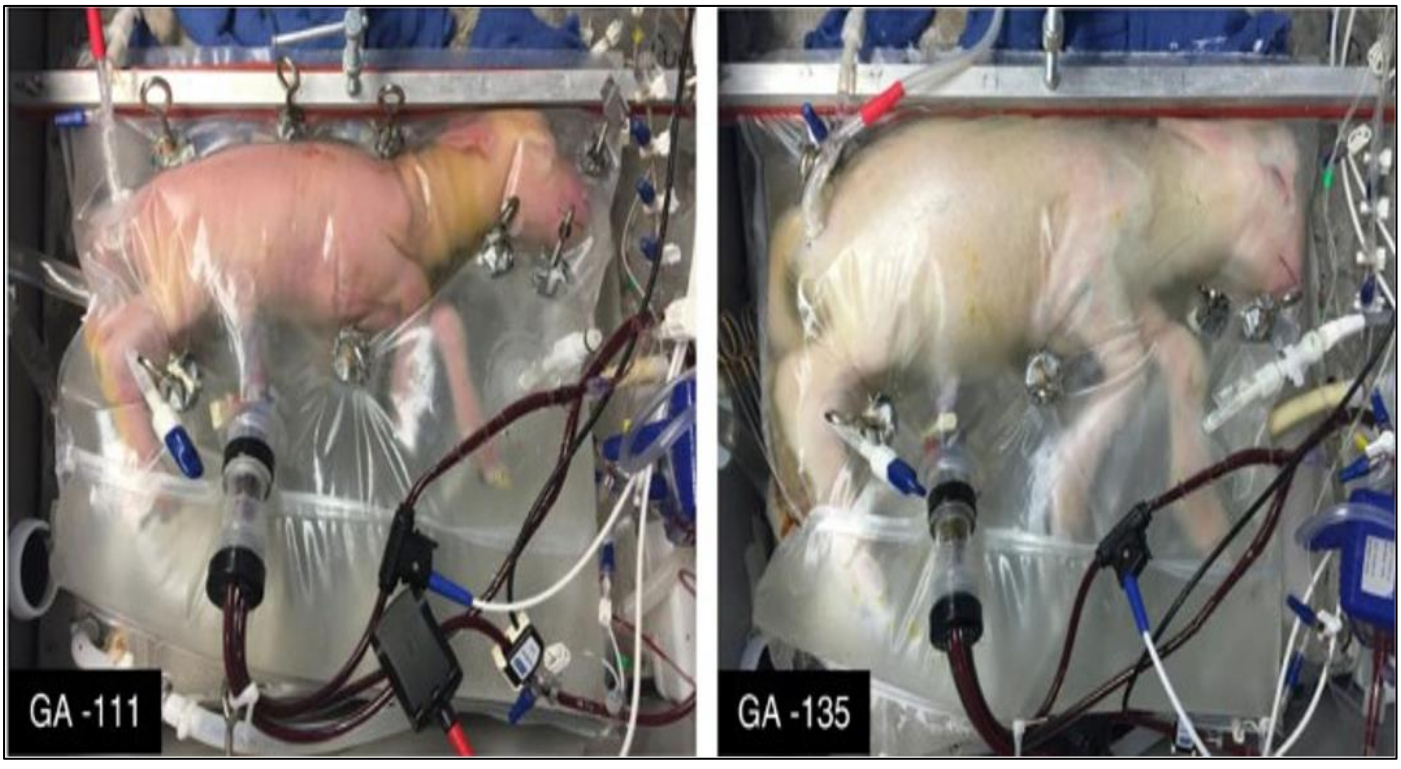

Fig 3 A Lamb Cannulated at 107 Days' Gestation, On Day Four in A Biobag

Source- https://www.nature.com/articles/ncomms15112/figures/1

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Early experiments with near-term lambs showed excellent hemodynamic stability with no evidence of heart failure. Early complications, including fluid contamination and sepsis, were avoided by reconfiguring the incubator to permit total daily fluid exchange, simulating in utero amniotic fluid exchange. This modification provided sustained assistance for up to four weeks, even with extremely preterm lambs (105–110 days' gestation), comparable to 22–24 weeks in human gestation (Kilby, Johnson, and Oepkes 2020).

The change from CA/JV to UA/UV cannulation was decisive, enabling more physiological placental perfusion, improved pressure control, and fewer mechanical issues. These advances produced circuit flow rates of around 170 mL/min/kg, which were very close to in-utero fetal physiology. The application of modified pediatric and neonatal oxygenators, primed at as low as 38 mL, was well matched to placental blood volume characteristics in preterm lambs (Kilby, Johnson, and Oepkes 2020).

Preliminary experiments with near-term lambs were found to display excellent hemodynamic stability with no signs of heart failure. Initial challenges, such as contamination of fluids and sepsis, were overcome by reorganizing the incubator to allow for whole daily fluid exchange, which replicates natural amniotic fluid exchange inside the uterus. This improvement allowed for uninterrupted care for up to four weeks even in very preterm lambs (105–110 days gestation), which is the human equivalent of 22–24 weeks gestation (Kilby, Johnson, and Oepkes 2020).

The switch from CA/JV to UA/UV cannulation was definitive, allowing for more physiological placental blood flow, better pressure control, and fewer mechanical issues. These improvements allowed for circuit flow rates of approximately 170 mL/min/kg, very close to in-utero fetal physiology. The use of modified pediatric and neonatal oxygenators with priming volumes as low as 38 mL was under placental blood volume parameters for preterm lambs (Kilby, Johnson, and Oepkes 2020).

Throughout the four weeks of incubation, lambs exhibited normal physical growth, increased activity, opening of eyes, and wool development. Measurements of function confirmed steady fetal cardiac output, preservation of the ductus arteriosus, and normal cerebral and pulmonary growth. Histological study revealed no brain hemorrhage, infarction, or white matter injury. Daily echocardiography and neurophysiologic monitoring of EEG and EOG evidenced maturation of sleep-wake patterns, in agreement with developmentally oriented trends of in-utero age-matched controls (Kilby, Johnson, and Oepkes 2020).

Anemia, most likely a product of enhanced post-membrane oxygenation levels that suppress fetal erythropoietin synthesis, was treated and diminished recombinant erythropoietin significantly to transfusion demands (Partridge et al. 2017).

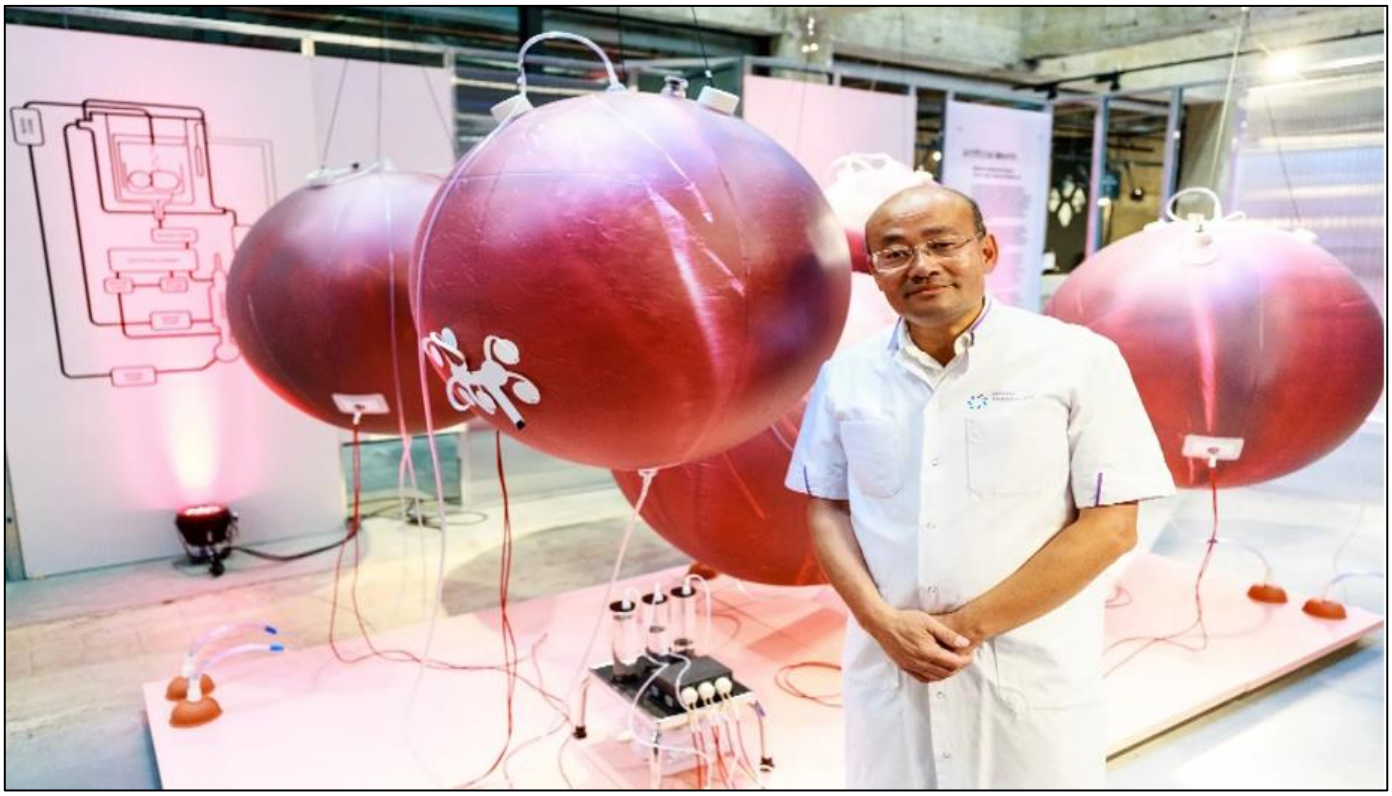

Fig 4 Prof. Dr Guid Oei with the Prototype of the Artificial Womb for Humans

Source- NextNature.Net

Towards Human Translation and Device Improvement

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Following successful preclinical outcomes, the EXTEND system is now being readied for first-in-human trials under the FDA's Breakthrough Devices Program, in collaboration with Vitara Biomedical (Dharmapalan 2024). Advancements in biomaterials, umbilical cannulation techniques, and fluid composition continue to refine the system's safety and adaptability.

There have been recent developments to the literature with the introduction of volume-controllable artificial womb platforms that dynamically scale with fetal growth, having high-level filtration systems to manage waste and sterility (Zhao et al. 2024). These innovations render more feasible extended gestation ex -utero with lower intervention and optimized physiological simulation.

IV. MEDICAL APPLICATIONS AND CLINICAL POTENTIAL

The advent of artificial womb technology (AWT) has sparked intense controversy regarding its categorization whether as a natural evolution of neonatal intensive care (NIC) or a fundamentally different medical model. Traditional NIC has long been characterized as a type of partial ectogenesis, with its use of incubators to sustain increasingly premature neonates. Scholars like Singer and Wells argued way back in 1984 that modern medicine's power to prolong the lives of preterm infants already counts as a partial form of ectogenesis. They and a host of others have proposed that complete ectogenesis will develop not as a deliberate endeavor but as a spin-off of medical striving to minimize neonatal mortality and morbidity by advancing NIC technologies (Singer and Wells 1984). However, this analogy between incubator-based NIC and AWT is mistaken. The key conceptual difference is in the functional aim: NIC aims to salvage preterm neonates who are initiating independent life functions, while AWT aims to extend gestation ex utero by mimicking the natural intrauterine setting. In traditional NIC, for example, the neonate's lungs need to be functional to provide pulmonary gas exchange. AWT systems are created to sidestep this need by duplicating placental gas exchange, keeping the baby in a liquid environment that approximates the uterus, and circumvents the physiological adversity of early use of the lungs (Romanis 2019). This change from supporting nascent autonomy to facilitating ongoing dependence discloses that AWT is not just a refinement of already available technology but a conceptual and physiological innovation in neonatal support (Romanis 2018).

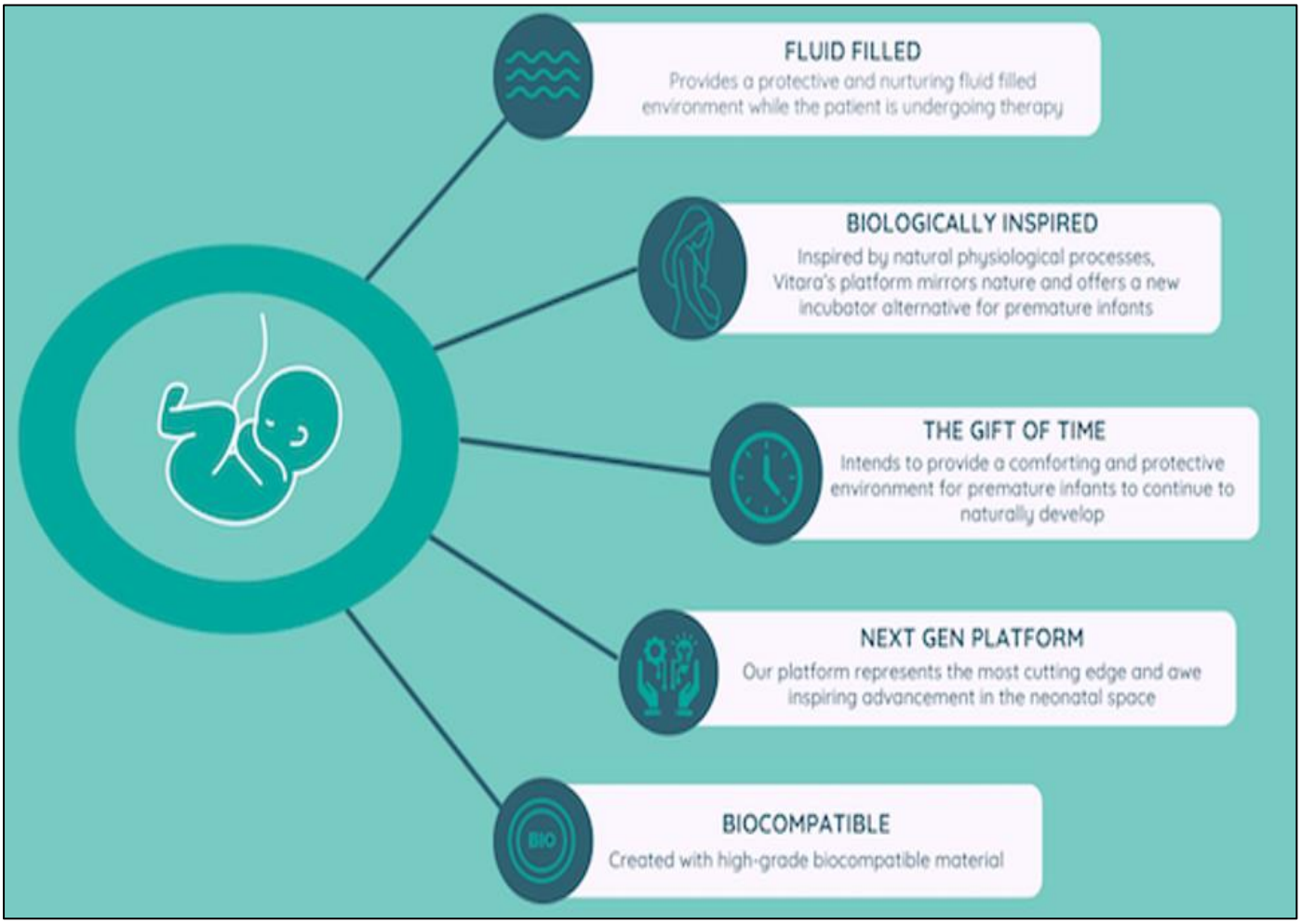

Fig 5 Key Features of an Artificial Womb Platform.

Source-https://www.techtarget.com/pharmalifesciences/feature/Understanding-artificial-womb-technology-for-preterminfants.

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Against this background, AWT is definitional experimentation. It proposes a new mode of care with the intent to mimic biological gestation over augmenting postnatal care. The standard clinical practice currently sustains viable neonates at 23 to 24 weeks with survival rates consistently rising to as high as 81% at 25 weeks (Kukora, Mychaliska, and Weiss 2023). But AWT is designed to sustain neonates at or even under the 22-week mark, where traditional NIC is extremely unreliable. This can appear reasonable considering the dismal results with standard treatment at those extremes, but the lack of clinical data in humans, the large physiological variations from animal models, and unknown short- and long-term harms to patients reinforce its role as a study, not therapy (Kukora, Mychaliska, and Weiss 2023).

Clinical goals for AWT are to prolong the boundaries of viability and decrease the frequency of such complications as bronchopulmonary dysplasia, intraventricular hemorrhage, and neurodevelopmental disability. However, there are still very considerable technical and biological challenges. The most prolonged successful exsanguination support of fetal lambs in a nonphysiologic setting has been around four weeks, and the consequences of protracted support in human subjects are unknown (Kukora, Mychaliska, and Weiss 2023). Hazards like circuit failure, imbalance of nutrients, cardiac overload, and organ damage underscore the fine balance involved in AWT systems (Kukora, Mychaliska, and Weiss 2023). These difficulties imply that although AWT is promising, its clinical application will have to adhere to strict research protocols, such as phased human trials sanctioned by institutional and federal regulatory agencies (Kukora, Mychaliska, and Weiss 2023).

In addition, effective implementation of AWT might change the moral climate of neonatal practice. If AWT is able to safely support development from increasingly early gestational ages, doctors could feel ethically compelled to act, just like they do for 24 to 28-week neonates (Lantos 2001). This might exert pressure to advance viability thresholds further, with potential unforeseen consequences like increased rates of morbidity in younger, more vulnerable fetuses, or reshaping societal norms surrounding birth and reproductive autonomy (Kukora, Mychaliska, and Weiss 2023).

In conclusion, although AWT has life-altering clinical promise both for survival in very preterm infants and for those who cannot become pregnant the application of this technology in medicine must be placed within its experimental basis. Only with rigorous, ethically defensible, and well-designed clinical trials can its safety, effectiveness, and long-term consequences responsibly be determined (Kukora, Mychaliska, and Weiss 2023).

➢ *Ethical Covenants and the Artificial Womb: Balancing Promise and Responsibility*

As artificial womb technology (AWT) transitions from science fiction to clinical fact, the ethical paradigms that direct its development and deployment must do the same. The concept of an ethical covenant a formal moral agreement among stakeholders can serve as a unifying principle for navigating the complex terrain of fetal, maternal, and societal interests created by AWT.

Artificial wombs have the potential to transform neonatal care, increase reproductive autonomy, and even redefine human gestation. But they are accompanied by profound ethical responsibilities. Yuko (2012) draws attention to the fact that the value of the technology is not only in what it enables premature baby care, surrogacy alternatives, or abortion choices but in whether one can manage ethically the dangers it presents. The concept of a moral covenant, in this case, is consciously establishing reciprocal agreements among researchers, clinicians, parents, and society to ensure that the dignity and rights of all parties involved are upheld throughout.

The center of this covenant is the moral standing of the fetus. Veres (2021) offers a dualistic framework placing secular utilitarian standpoints, equating personhood with functionality, against theological grounds arguing inherent human dignity from the moment of conception. An ethical covenant would need to transcend such divisions by acknowledging the preborn as worthy of protective concern, quite independent of philosophical stance, particularly as they become "fetonates" (De Bie et al. 2023), a new class of human beings sustained alive ex utero.

One more pillar of such a covenant has to address informed consent and fairness in research. Kukora et al. (2023) identify ethical threats of preclinical first-in-human trials like parental coercion, therapeutic misconception, and differential access to experimental intervention. The covenant of ethics has to ensure proper supervision, risk communication in the open, and equitable choice of trial participants.

Importantly, the covenant must not be a procedural to-do list but a dynamic agreement that changes to engage new realities, such as the commodification of gestation, impacts on abortion rights, or sociopolitical tensions on parenthood (Yuko 2012). It must also recognize the international disparities in access to new reproductive technologies and try to reduce not reinforce inequities.

In summary, an ethical agreement on artificial womb technology must be built on root bioethical principles autonomy, justice, beneficence, and nonmaleficence without being absolute or elitist. Asking ourselves whether or not we should create AWT is not enough; we must ask if we should, and under what ethical responsibilities.

➢ *Research Challenges in Artificial Womb Technology*

- *Replicating Complex Biological Processes*

The mother's womb is a dynamic, complex setting for fetal development, with hormonal, immunological, and physiological interactions between mother and fetus. Replicating this properly in an artificial system is a huge scientific challenge.

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- *Simulating Placental Function*

The placenta performs essential functions like gas exchange, nutrient delivery, and waste removal. Developing an artificial placenta capable of performing these functions safely and reliably is a major challenge.

- *Functional Circulatory and Fluid System Development*

Artificial wombs must facilitate fetal circulation and transfer oxygen and nutrients effectively. Replicating the fluid flow and regulation of blood circulation poses a major technical challenge.

- *Providing a Sterile Environment*

The normal womb isolates the fetus from external germs. The creation of sterility within an artificial environment so that infection is prevented is both essential and technically demanding.

- *Facilitating Appropriate Organ Development*

Fetal organ systems - most notably the lungs, brain, and immune system are developed in close synchrony with maternal signals. The simulation of the environment necessary for normal organogenesis is an essential research problem.

- *Cost-Effectiveness and Scalability*

Building an artificial womb that is not only feasible but also affordable and scalable for use in mass clinical trials is the condition for applicability. Equilibrium between innovation and affordability remains an underlying priority.

- *I Logistical Sophistication of Clinical Translation*

Clinical trials involving human subjects will involve complex operations, including delivery, vascular access via the umbilical cord, and transfer to the artificial environment safely. All steps have risks and require precise coordination.

V. CONCLUSION

Artificial Womb Technology (AWT) is on the cutting edge of biomedical innovation, poised to redefine the boundaries of fetal viability and transform the neonatal and reproductive health paradigm. With the ability to replicate intrauterine existence through advanced extracorporeal systems, AWT offers a lifeline for very preterm infants already carrying high likelihoods of morbidity and mortality and a future possibility for those plagued by uterine factor infertility. With its clinical potential, AWT has the capacity to revolutionize other areas such as fertility preservation, surrogacy choices, and even reproductive freedom.

And with the advent of such revolutionizing technology comes the complex ethics, law, and social dynamic. Questions of the moral rights of the fetus in an artificial womb, management of parental decision-making, equal access, and long-term effects are yet unanswered. The establishment of a new category of being referred to as "gestatelings" or "fetonates" upends conventional definitions of birth, life, and personhood, requiring new ethical instruments and legal definitions. The risk of over-medicalization, commodification of pregnancy, and further global health disparities also must be addressed with urgency and alarm.

In addition, while the outcome from animal tests is promising, human applications must proceed with cautious optimism. Complete preclinical assessment phased human trials, and constant surveillance by regulatory and ethics committees are a requirement. Multidisciplinary considerations involving bioengineering, obstetrics, neonatology, ethics, and law will be necessary for counseling prudent development.

For all its scientific importance, AWT is not merely a technological breakthrough but a social one as well. Its destiny is not solely in technical feasibility but also in our shared capacity to ask difficult questions, construct equitable policy, and uphold the integrity of autonomy, justice, and compassion. The task is to realize the promise of the artificial womb without sacrificing the dignity of the human person and equity of care.

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