VALUE SENSITIVE DESIGN AND THE ARTIFICIAL PLACENTA

ABSTRACT

Artificial placenta technologies (also termed 'artificial wombs') for use in place of conventional neonatal intensive care are increasingly closer to first-in-human use. There is growing ethical interest in partial ectogestation (the use of an artificial placenta to continue gestation of an underdeveloped human entity extra uterum), however, there has been little reflection on the ethical issues in the design of the technology. While some have noted the importance of such reflection, and others have noted that a 'value sensitive design' approach should be preferred, they have not elaborated on what this means. In this article, we consider what a value sensitive design approach to artificial placenta design might encompass. We believe that applying this framework to the topic at hand raises theoretical and substantive ethical questions that merit further elucidation. Highlighting that there is a careful need to separate preferences from values and that our intervention should be considered only a starting point, we explore some of the values that could be used to make ethical design choices about the artificial placenta: efficacy, compassion, and accessibility.

INTRODUCTION

Several teams of fetal surgeons and medical engineers working worldwide are on the verge of developing the first artificial placenta:[1-3] a machine capable of facilitating the later gestation of human entities with fetal physiology outside the body. There is a heterogeneity of labels to denote this potential technology, but we will use the term 'artificial placenta' ('AP', as a shortening of 'artificial amniotic and placenta technology'), rather than 'artificial womb' – as has been commonplace in the ethical literature, for accuracy per Kingma and Finn.[4] While terminology is rather diffused, there is relative consensus – at least among the research groups studying technical feasibility – that the

primary translational goal should be the procurement of an alternative to conventional neonatal intensive care.[5-6] Artificial placenta technology ('APT') is highly sought after for how it might improve outcomes for prematurely born babies and people experiencing dangerous pregnancies.[5] As research teams work towards this goal, it is imperative to explore the legal and ethical issues in clinical translation.[5-7]

As noted by Verweij and others,[8] one challenge that merits more normative attention, is the AP's design. We agree that it is important to thoroughly interrogate both the advantages and disadvantages to different potential service-users (putative parent(s) and health professionals) in design and research phases of the technology to bolster coherence among ethico-legal considerations, technical feasibility, and expectations of service-users. This includes questions about distributive justice concerns, as the costs of design choices might influence where APs are available and who can access them (e.g., expensive choices mean APs are likely to be available only in high-income economies, thus entrenching existing inequalities in neonatal mortality between low- and high-income economies).[9] While it is difficult to predict how technologies will be used during design stages,[10] it is important that we attempt to do so to best ensure that APT 'is designed *for* and *accessible to* everyone who may need it'.[11] What is meant by a design that works for those who 'need' it, and what is meant by 'accessibility', has thus far not been explored in sufficient depth, and neither have the normative underpinnings of design choices been made explicit.

In this article, we highlight that design requires more ethical deliberation. We explore the importance of making visible the values underlying design choices and what this might mean in practical terms for the AP. What particularly interests us is the statement that the potential impact of APT on societal values and moral perceptions of pregnancy, childbirth, and gestation warrants a so-called 'value-sensitive design approach'.[12] Some research teams have suggested that they plan human testing in the near future (in the next five to ten years).[6] The United States Food and Drug Administration has

begun the process of discussing the ethical considerations for first-in-human use.[13] Other teams across the world are in the design phase of APT before animal experimentation. Consequently, it is timely to explore questions about values-sensitive design (VSD). VSD is a framework for ensuring that moral values are considered and embedded in designing new technologies.[14-15] The approach advocates consideration of values in all stages of design: conceptual, empirical, and technical.[15,16] Van der Hout-van der Jagt and others have suggested that a VSD approach to APT is preferred and gave some indicators of design choices[12] but did not elaborate on what the VSD process encompassed nor the values underpinning the design choices they articulated. While VSD has been described as a "well-developed methodology for the elucidation of values"[17] – a reputation we do not aim to dispute – and which may provide important insights in the context of APT, we believe that applying this framework to the topic at hand does raise theoretical and substantive ethical questions that merit further elucidation[i] if it is to buttress responsible adoption of this technology. Inquiry into the domain of value comes with conceptual and normative challenges, of which questions about what should be understood as values, where they come from, and which values 'count' morally speaking, are only some of the more philosophically intricate points of discussion. Much of this debate belongs to the sphere of axiology and metaethics (at least to that extent that determining what counts as 'value', 'moral' and 'moral value' is part of such second order level analyses). For the sake of the argument, we will side with Friedman and Hendry that 'value', as discussed in the context of VSD, emphasizes "what is important to people in their lives, with a focus on ethics and morality".[15] The question before us derives from the recognition that questioning what 'value' means in the specific context[18] of APT, has direct relevance for problems pertaining to the development of APs. This resonates with van de Poel's understanding of "conceptualization of values",[19] understood as analytical clarification of a value's meaning and applicability. On this reading, inquiring into 'values' throughout the design phase of APT, will require a minimum degree of analytical work.

[i] Or 'problematisation', depending on one's preferences.

In this article, we tentatively broach parts of this analytical task and consider questions of a 'values-sensitive' AP together with some surrounding ethical issues. Our reflections include consideration about how the device functions, but also what it looks like. For those who use it, visual elements will influence their experience. In section I, we introduce the AP and posit that how the technology is conceptualised (as an extension of current forms of conventional neonatal intensive care, or as a paradigmatic shift in approach) will influence the design of the device. In section II, we highlight some of the values that may or should be centred in the design of the AP, including efficacy, compassion, and accessibility. We do not claim this to be an exhaustive list of relevant values – but they are an important starting point. As we primarily want to stimulate the translational debate about the design of AP and how particular design choices have a normative impact, the values considered here are meant to spark the debate and are not meant as 'conditions' which AP design must meet, although from our positionality as designers, and legal and ethical scholars working on AP, we do consider them critically important. For the present purposes these values are rather intended to illustrate how certain design choices may result in a trade-off between different factors people may care about, leading up to moral decision making as part of AP engineering. It is for another occasion, or other groups, to perform a fully normative VSD approach to AP design.

While we emphasise that values guiding design are distinct from preferences in section II, in section III, we reflect on the importance of preference-gathering amongst potential service-users of APs as a means of deliberating between any conflicts in values guiding design. In section IV, we illustrate with images some design ideas that reflect the ethical analysis we have set out.

A general note on terminology: we use the term 'gestateling'[5] to describe the subject of the AP. This term is useful for conceptual clarity and in recognition of the fact that this is a unique human entity that has yet to have ever existed: a human entity gestating outside of the body of a human person.[5,20] We note that this is a contested conclusion, but one that has been well defended in the existing

literature and so we adopt it as our starting point.[4-5, 20, 21-24,] That the entity is unique does mean there is much fascination around how this entity will come to be understood: design choices, as a result of the visuals they create, are likely to play a large role in the broader social implications of gestation outside of the body.

I. THE ARTIFICIAL PLACENTA

How an AP is designed to function and to look depends on what "problem" the technology is designed to solve. Part of this discussion about the scope of intended use ties in with the controversy over the proper naming of this technology. To choose a term is to plead a cause[iiii25]: in this case, by circumscribing ectogestative technology as a 'life support system',[26] the domain of 'appropriate' application is more restricted than when it is named, say, 'artificial womb technology',[iii] which theoretically leaves reproductive applications within the scope of envisioned usage. While there is speculation about future technology capable of facilitating gestation entirely ex utero, APs that are currently in development are envisaged as a solution to prematurity, and a replacement for conventional neonatal intensive care.[6]

Premature birth (delivery before 37 weeks') remains the leading cause of death amongst neonates worldwide.[27iv] Approximately one in ten born worldwide every year are premature.[28] Conventional

[iiii] This phrase is loosely borrowed from Stevenson, but we do not intend to invoke his broader (moral) epistemological views. See: Stevenson C. Ethics and Language. Yale University Press 1958.

[iii] There are multiple models of the technology in development and different research groups use these different terms to delineate some of the differences between models (though the terms are used interchangeably in much of the ethical literature). See Spencer BL, Mychaliska GB. Updates in Neonatal Extracorporeal Membrane Oxygenation and the Artificial Placenta. Clin Perinatol. 2022 Dec;49(4):873-891. doi: 10.1016/j.clp.2022.07.002.

[iv] A reviewer encourages us to clarify that prematurity as the leading cause of neonatal death is skewed by the many deaths in low- and middle- income economies where there is a lack of the same infrastructure to support premature babies. In high-income economies congenital abnormalities have higher mortality rates than prematurity (both have improved vastly with advances in technological and other care practices over the last few decades). As the artificial placental technologies in development are intended for premature human entities at 22-26 weeks' gestation the technology will likely not greatly impact the global problem of neonatal mortality from prematurity given the existing global disparities in access (that are discussed in greater detail later in this article).

neonatal intensive care technologies rely on the premature neonate exerting some life functions and being able to withstand mechanical ventilation.[29] The technology, therefore, has limits; it is unable to support neonates born before 22 weeks because they do not have sufficiently developed lungs.[v] Furthermore, such technologies have considerable risks; mechanical ventilation can damage the (already underdeveloped) lungs and there is a high risk of infection.[29] A non-trivial minority of neonates who receive intensive care do not survive, in addition to those deemed too immature for treatment to be instigated. Of those that do survive, there are often enduring long-term, complex health problems.

Because of the limitations of conventional neonatal intensive care, scientists are seeking to develop an AP capable of gestating human entities outside of the body: allowing continued organ maturation and 'side-stepping' many of the common complications resulting from invasive treatment in conventional neonatal intensive care.[5] Results of prototype APs have been showing significant promise in animal models since 2017.[1,3,30] The prototypes that have been designed and are being tested on animals in the United States, Japan/Western Australia, and Canada, all have similar designs. A further team with a similar design in the Netherlands is being tested using fetal mannequins.[31] The design choices in the present-day proof of principle studies are propelled by the aim of salvaging morbidity and mortality among extremely preterm infants. The physiological approach of the most recent APT models mimics the uterine physiology and fetal umbilical-placental circulation as closely as possible.[1,2,30,32,33] They are sealed systems of warmed artificial amniotic fluid, a pump-less oxygenator circuit, and catheter that act like an 'umbilical cord' delivering oxygen and nutrients. The key feature is that these machines facilitate liquid-based ventilation (to emulate how a fetus obtains oxygen during pregnancy) rather than gas-based.[34] Only some artificial placenta models feature the fluid-filled bag to mimic uterine physiology – which will be pertinent in our discussion later.

[v] This threshold has reduced over the last two decades and so some suggest there is the possibility this could lower again in future. Though, this does depend on the premature human entity having sufficiently solid lungs to tolerate the gas-based therapies available.

II. CRITICAL PRELIMINARIES

It is a well-established theorem that technology, design, and values feed into one another.[15,35] Yet, in the context of ectogestative research it has only recently been made explicit that this endeavour incorporates and propagates value-laden choices worthy of ethical attention.[6] In considering a VSD-approach to APT, minimally four theoretical aspects should be taken into account.

First, in one – rather narrow – sense, openness about the intent to reduce morbidity and mortality for extremely preterm infants may be seen as an explication of the central value this emerging therapy is meant to serve. In another – only slightly broader – sense, one may see that the decision to approach preterm birth (and associated death/comorbidity) by developing an AP, is only one possible way – and indeed: a value-laden one – to address this phenomenon. The observation that some causes of premature birth (and associated morbidity and mortality) may be preventable by addressing socio-economic inequality, could bring into view a different[vi] way to address this reality.[36]Approaching a given phenomenon in one way rather than another – and prioritizing among these options – implies value-laden judgments. On the ethics' side one may speculate whether the greater attention for 'high-tech' solutions over societal approaches may be an effect of bioethics' "concern for 'the neon problems' of high controversy".[37] It may even be discerned that a fundamental value judgment already resides in the view that this phenomenon – morbidity and mortality in case of preterm birth – should be addressed as a "problem" in the first place, a characterisation which we do not wish to challenge – but that is not the point here. The point is that these value-dimensions receive only limited attention in the debate about APT, and VSD would require that these are made explicit and, accordingly, made the subject of moral interrogation.

[vi] Different also in terms of impacts on the pregnant person – which is a morally critical matter.

Second, of the groups currently investigating AP's technical feasibility, the Dutch consortium has been most outspoken in its advocacy for 'a value-sensitive design approach *throughout* the research and development process'.[12] As far as we can tell from published material, this intention mainly follows from the expectation that APT will affect "ethical, legal and societal" norms. What does this mean? On one level, one may wonder whether it will be the material realisation of APT that may affect these norms, or rather (already) the anticipated imaginations surrounding it.[38] APT need not be existent as a present technology to trigger divergent interpretations of norms shaped by dominant paradigms about, say, birth, parental and medical duty, termination of pregnancy. Speculative accounts of technology capture much imagination that shape our expectations (and which might induce social and conceptual disruptions, we return to this below).[39,40] It is, at least partly, the purview of ethics to imagine things other than they are with the appropriate methodological caveats.[41] On another, but related level, the inference that APT will have ethical, legal, and societal implications and *therefore* warrants a VSD approach,[12] needs further unpacking. What is the nature of the reason conveyed by this 'therefore'? One may minimally distinguish between a 'functionalist' and a 'transformational' interpretation of this assumed reason. The transformational interpretation is exemplified by the belief that APT "will highly influence societal values and perceptions regarding e.g., pregnancy, childbirth, women and (unborn) babies, but also the moral and legal status of the perinate".[12] This influence may be regarded as transformative of how we value such phenomena. The functionalist interpretation adds to this that if insufficient attention is paid to how these changes may deviate from what is common and/or valued, societal acceptance of this technology may dwindle.[12] VSD is functional, then, as a strategy for securing support for the technology one is developing. The transformative interpretation primarily focuses on how technological imaginations or realities may transform what is valued. The functionalist interpretation assesses this in function of societal recognition of the benefits for which APT is being researched.[38] It should be noted that what is indicated here, can be enriched by bringing it closer to insights from the burgeoning domain of 'value change' and 'techno moral change' where authors focus on technology's impact on moral and social values, and how this should be understood both descriptively and evaluatively.[39,42-44]

Third, Friedman and Hendry[16] explain that VSD often includes a conceptual investigation (as already mentioned above) in which designers attempt to identify (in)direct stakeholders and values, which may lead to a back-and-forth between analytic and empirical components. In making design choices in the technical design, those involved in this process will have to consider a breadth of interests and values, also leading them to explicate and balance their own assumed value commitments (i.e., designer values).[15] Given the ambition to include a broad scope of stakeholders – including patients, families, caregivers, and health care professionals – in the development of an AP,[8,12] one of the questions will be whether this dialogue will be open-ended, or rather constrained to a pre-selection of values over which there may be some deliberation. This may require a trade-off between securing inclusivity of values versus overseeing the practicability of such an inclusive dialogue. This also means that securing representation of diverse groups in this dialogue will be a point of attention. Relatedly, it may be noted that VSD will often focus on shared, so-called "community values", which may lead into concerns about reifying certain values over less dominant ones.

Finally, it is, in a VSD analysis, critical to avoid conflation of 'preferences' and 'values'. Ideally, 'first-order' preferences about design choices (e.g., a translucent vs. an opaque ectogenic chamber) should be backed by a corresponding 'higher-order' value (e.g., effectiveness measured in morbidity rates) but this is not necessarily so. If design is based on 'what people like', without a 'higher order value-backing', such a practice should rather be regarded as 'preference sensitive design' which opens the normative question whether, why, and to what extent there is an ethical obligation to cater to personal preferences. Indeed, the assumption that some value should be ascribed to people's preferences can already be marked as a value-laden assumption that should come into view during a VSD-procedure. It is an ongoing debate in VSD literature how the relationship between values and preferences should be evaluated, and, relatedly, how from a global set of pro-attitudes a particular segment can be isolated as those values that should figure in a design context. Mander-Huits has made the important point that 'VSD offers no methodological account for distinguishing genuine moral values from mere preferences'.[45] Jacobs and Huldtgren have provided a much needed contribution to

this question by making clear that such a distinction between values and preferences is not a neutral matter, and that making this distinction – at least if it is held that the former have normative priority over the latter – implies a normative intervention that should be backed by ethical theory.[46] We subscribe to both points.

In part, this ties in with the broader question about how empirical data on a population's preferences can inform what the design of this potential technology *should* look like. We leave this for another occasion, but friends of coherentism may want to consider a reflective equilibrium approach in which preferences may be tested as expressions of considered moral judgments, and balanced against more abstract, 'higher level' principles, to reach a coherent account of what an ethically acceptable design and use of AP would look like. We take it that our view closely aligns with the "mid-level" theory espoused by Jacobs and Huldtgren which equally relies on a coherence model of justification and a two-way balancing of considered moral judgments and 'higher level' principles.[46] In accordance with this view, we consider the values discussed here as a way to provide more concrete content to the more abstract principles, to which we will refer throughout our argument. By themselves, moral principles like beneficence, non-maleficence, respect for autonomy and justice[47] are too indeterminate, and therefore require additional content through a constant process of balancing and refinement[46] (a conclusion which advocates of principlism would agree).[47] We consider efficacy, compassion, and accessibility as concrete instantiations of, respectively, the principles of beneficence, non-maleficence, and justice. Vice versa, we consider that said principles provide normative valence to said values.

III. WHAT VALUES

Verweij and others place considerable emphasis on the design choices that need to be made about 'accessibility, visibility and levels and kinds of interaction facilitated between the fetus/baby and caregivers/parents'[8] on the basis that these decisions embody and facilitate particular conceptual framings of the technology. However, they do not explain what they take to be the normative

underpinnings – the 'values' – that drive these design choices. In this section, we offer some analysis of relevant moral considerations that we have provisionally subsumed under three labels that can be understood as 'value labels' (these represent values that we have applied to the context at hand). Whether these labels should be identified as 'value labels' (or as something else: e.g. as characteristics) can evidently be contested, though for our purposes it is most critical that if these elements are stipulated to steer design choices in AP development, they will in effect figure as value-laden interventions, affecting how an AP works and which consequences it has for those affected.

What we explore is neither exhaustive nor conclusive. It is not exhaustive because other important values and morally important considerations will need to be considered. It is important to be reflexive and acknowledge that what we explore as morally relevant considerations are specific to us as researchers and as a group from collaborative conversation. We only discuss three in this article for reasons of space (and those which we decided we did not have the scope to elaborate on in this work we considered to be less immediate). This exploration may be considered a continuous work in progress, not in the least because the epistemic authority of what is presented at any given time as a 'complete' account, may be challenged from different perspectives, given different moral experiences. There will be a difference in the values identified by different thinkers/groups of thinkers, and how these are conceptualised and prioritised, at different stages of the development of this technology. There may be a stark difference between the beginning phases of this technology and more 'near-future' uses of this technology where we know how it works and we are pushing the boundaries of how it could work. For the purposes of our article, we consider the development and 'near-future' uses of the technology, rather than the more remote future (where we could speculate about this technology as being available as an alternative to a complete gestation as some have imagined).[48,49]

What we have explored is not conclusive because there are different ways of interpreting the morally relevant considerations that we raise. We have described and justified what we believe to be morally

relevant considerations and we have illustrated how they can be provisionally subsumed under certain notions of a 'value'. These values are efficacy, compassion, and accessibility. We acknowledge that how we have interpreted what is morally relevant for our purposes may be the subject of further debate. The content of what we have identified as morally relevant considerations (or indeed what considerations become morally relevant because of the values that we are thinking with), and how they guide design questions, only become apparent when applied in a given context, where sometimes they may give contradictory answers. There may, therefore, be different interpretations other than what we have presented that should be afforded further consideration. Future research should interrogate how these values might be interpreted further.

Efficacy

Efficacy is one of – if not *the* most important – value to be taken into consideration in design. This is not to say that efficacy should always be prioritised over other values, but that efficacy is *always* relevant. Often, VSD is considered as a mechanism to move designers to go beyond traditional values – like reliability, efficiency, correctness, and efficacy – and emphasize so-called "moral values".[15] Yet, if 'efficacy' is here interpreted in terms of effectiveness to reduce morbidity and mortality in case of extreme prematurity, it would be rather quaint *not* to consider this a moral value. Efficacy is, in the approach of all research teams, clearly the implicit value that acts as a guiding motivation. Making this explicit in the context of design is important, however, because there is normative force behind these guiding motivations, despite the possibility that efficacy might be interpreted in different ways, and this should be subject to ethical interrogation.

First, foregrounding efficacy as a value will be functional to spell out more clearly on which scale this value is to be measured, and, more concretely, which standard of reference should be the comparator e.g., should it be life expectancy/estimated quality of life among extremely premature neonates or a similar measure among neonates born after full-term gestation? Second, a focus on efficacy highlights

that the design of an AP must have some purported benefit for potential users, otherwise its use would be wholly unethical.[7] The widely shared opinion that the design must have utility in improving morbidity and mortality among extremely preterm infants may be considered a benefit both for the extreme preterm infant but also for its parent(s). In that vein, 'efficacy' and its moral relevance as a value, may be seen as a specification of beneficence, which demands that the best interests of the patient are promoted, and which some[vii] consider the pivotal tenet of the medical relationship.[50] In the context of ectogestation, however, the notion of 'the patient' may rather be an explanandum than an explanans, as it may be subject to debate who should be considered 'the patient'. While effectiveness in reducing morbidity and mortality is mostly interpreted in terms of beneficence towards the future child, it should not be ignored that the (formerly) pregnant person is physically impacted by translocating the fetus to the AP (see below). Exposing the pregnant person to the potential harms of a caesarean section performed at an extremely early gestation[51] also has ethical implications that should feature in discussion about how AP modalities are developed/designed.

The physiological approach of the most recent APT models, where the uterine physiology and the fetal umbilical-placental circulation is mimicked as closely as possible,[1,2,30,33,34] embody the object of efficacy. In terms of technological feasibility and supporting design choices, substantial departures from the uterine physiology must, therefore, be considered suboptimal. The fluid-filled bag design some teams have adopted might better simulate "natural" in utero development than those that do not, but might also hinder care provision in an emergency. A device that was truly trying to mimic the human uterine physiological conditions as closely as possible would be enclosed and mostly dark, but with just the right amount of light exposure.[52] Some teams also reflect on the fact that there should be 'equal sensory input' that replicate that which a fetus is exposed to in a pregnant person's uterus including 'auditory and motion perspective'.[12] It would have a series of noise features that would mimic those noises that would be perceptible constantly in the human womb e.g., those made by the

[vii] Pellegrino and Thomasma (1993) have argued along these lines, though the dominant interpretation of principlist bioethics (Beauchamp and Childress 1994) emphasises that there is a non-hierarchical relationship among beneficence, non-maleficence, respect for autonomy and justice.

pregnant person's digestive system. Van der Hout-van der Jagt assert the importance of sensory stimuli that replicates that which occurs in a pregnant body and from external sources 'should be applied to the perinate using targeted technology'.[12] It would also not be a completely static device; during a gestation sustained by pregnancy there is much movement as the pregnant person goes about their usual activities (these are obviously dependent on the habits and preferences of a particular pregnant person). There is little doubt that a device with the capacity to do all that we have just described could look heavily mechanical. It should be noted, however, that in neonatal intensive care it is known that exposure to movement and bright or loud stimuli has the potential to worsen outcomes – and so there may be some debate about whether, though these devices facilitate gestation rather than incubation, would be more efficacious in integrating sensory inputs at all.[viii]

With respect to some of the aspects of efficacy, it is intelligible that monitoring of optimal settings will be aided by automated alerts, and possibly adjustments, issued by a clinical support system. Depending on the circumstances in which an AP is utilised, there might be questions about what is the most efficacious. For example, to resemble the uterine environment the device must be entirely sealed, with only the canula controlling what enters and leaves the sterile amniotic fluid. However, if an AP is to facilitate so-called "ectogestation-aided prenatal treatment"[6,51] the most efficacious design may include some way of health professionals seeing or accessing the subject for some specific treatments.[12]

Compassion

In conventional medical ethics it is well accepted that in the course of providing care, attention ought to be afforded to the avoidance of further harm. This is often articulated as the principle of 'non-maleficence'.[53] Harm avoidance is mostly characterized as distinct from 'doing good'[54] and, in this context, involves asking questions of how a novel care pathway that is intended to do good may also

[viii] A reviewer raised this important point.

have some unintended harmful consequences. Many writing on ectogestation have advocated that care pathways must be designed with thought for the impact of ectogestation of those others around the gestateling, most notably the formerly pregnant person and any other parent(s).[55,56] Given that non-maleficence is a fundamental principle in bioethical thought, and granting that there are moral reasons to approach AP design in a value sensitive manner, one may infer that AP design should tally with values expressing the principle of non-maleficence. We then must think about what this means in value and design terms. For one thing, it may be found arbitrary to isolate considerations in terms of non-maleficence from efficacy as a value: much will depend on whether one finds it morally reasonable to hold that APT may be very effective in reaching its intending goal, and simultaneously recognize that it may come at a cost considered in terms of harm. It may be nuanced, however, that there is no a priori reason to stipulate that a considered value cannot be subsumed under more than one ethical principle. Indeed, the interpretation of ethical principles and their substantiation is an ongoing moral negotiation.

One value that may be considered to provide more substantive content to the ethical principle of non-maleficence, and which may appear to be relevantly distinct from efficacy, is the value of compassion. In the current body of ethical literature, the relevance of compassion may be found to be (at least implicitly) flagged as morally consequential. For instance, Romanis and Adkins have highlighted that there might be ways in which putative parents may find the use of an AP emotionally challenging – the impact they note is one that primarily impacts on the (formerly) pregnant person.[56] They note how the experience of pregnancy loss (where a person is grieving for their experience of pregnancy) even if their fetus survives the ending of the pregnancy could be something that some struggle with.[56] Taking into account this potential experience of loss might have significant implications for care-pathways and they therefore suggest 'loss-sensitive care' be adopted giving the example of how the language used could exacerbate difficult feelings around pregnancy loss.[56] Similarly, Segers and Romanis consider the adults' psychological perspective of future AP usage, and how this may be informed by data from current NICU practices.[6] What is not explored in these

papers, however, are questions of design. We agree about the importance of centring respect for putative parents (particularly the person who birthed)[ix] and their emotional wellbeing and we think this extends to design and consideration of how design choices could inadvertently cause harm and different choices could be made to minimise this harm. The harm minimisation here is about the importance of making design choices that minimise distress including some of the feelings of guilt and shame that can be experienced during and after premature birth (often because of the operation of patriarchal narratives).[56] Van der Hout-van der Jagt and others acknowledge, without articulating the underlying value motivating their reflections on design, that AP care will have a significant impact on pregnant people and that they 'envision to differentiate carefully between functions of the placenta and the role of the mother'.[12] It is unclear what they mean by this, but perhaps design features that encourage engagement with the device from parents could go some way toward addressing any feelings of loss or guilt surrounding the pregnancy loss.

It is a normative matter whether design features are chosen that emphasise the AP as a gestating machine (potentially to be thought of as a 'replacement' for a complete pregnancy) or those that emphasise the device as an alternative to conventional neonatal intensive care. Those designs that seek to reinforce how the device gestates (rather than incubates) may feel more alien to those first exposed to the technology and in the longer-term could perpetuate the complex feelings surrounding pregnancy loss for formerly pregnant people where an AP device needs to be used.[56] As was noted in our discussion of efficacy, however, the device is likely to be highly mechanical and, if a design is preferred that bares similarities to neonatal intensive care incubators, this is likely to be more familiar to what parents will have seen described in cultural mediums (film, tv, literature).

Another important matter will be to what extent the design allows access to the subject of the AP. There are different features that we could imagine that might allow for more (or less) interaction with

[ix] NB: we are not assuming that every person who birthed will be a parent of the resulting child as we recognise that some people carry a pregnancy intending that someone else parents (e.g., they have undertaken a surrogacy, or they have decided to pursue adoption).

the gestateling. Some of these, might actually be motivated by the value of efficacy, where they are about exposing the gestateling to sounds/voices it might have heard in the duration of a pregnancy. However, there are some that we cannot explain with relation to efficacy – for example, if there were to be extra features that allowed some physical contact between parent and gestateling. This will not be contact like that which is commonplace in contemporary neonatal intensive care (like Kangaroo care) because of the need to keep the gestational environment sterile. There may, however, be other ways to design in aspects that simulate contact for parents e.g., a glove-shaped access point. Or, alternatively, enabling more visual features that increase the visibility of the gestateling for parents may go some way towards addressing the difficulties they may experience in not being able to physically hold or interact with the gestateling.[56] Another suggestion that has been raised is that of enabling the sensory inputs to the AP (voices, maternal digestive system, maternal heartbeat) to be recorded by the formerly pregnant person/parents for their own gestateling.[12] In addition to securing psycho-emotional wellbeing, the moral relevance of these considerations may be said to derive from the importance that should be attached to respecting people's personal preferences regarding pregnancy and gestation. The belief that these preferences should be given due consideration is a value-laden choice – and, arguably, a legitimate one – expressing value not wholly motivated by efficacy, but also by respect, agency, care, self-esteem, and compassion for parents who may want to involve themselves in the process of gestation ex utero in what ways they can.

What parents who have experienced premature birth might think is a compassionate approach to design is a fruitful area for further reflection and empirical inquiry.[x] This will matter in thinking about how compassion-driven design choices are weighed against concerns of efficacy, which we anticipate will be a complex matter. There are many putative parents who would reject the importance of compassion-driven design choices that might negatively affect outcomes for the gestateling, however, this does not mean that compassion-driven design should be entirely dismissed because of the potential psychological impact on parents (particularly a formerly pregnant person). The relevance of

[x] [redacted for review].

'doing no harm' to individuals who are also patients in the process of ectogestation (because the fetus must be extracted from them) means we must take their needs into consideration when thinking about design.

Accessibility

Some concerns have been raised about inequality and inequity in *who* APT will be accessible to and in *what* circumstances.[11] Romanis and Horn have noted the potential for an unfair distribution of the burdens of APT: disadvantaged persons are more likely to be those on whom the technology is tested (because structural health inequalities mean they are more likely to experience premature birth) and then the least likely to be able to access it if/when it becomes offered more routinely in jurisdictions like the US without free at the point of access.[57] These concerns are rooted in a concern for justice, which is taken to be a critical principle in medical ethics.[53] Justice remains the least developed of the critical principles of bioethics.[58] As Beauchamp and Childress observe in their foundational text there are multiple different conceptions and theories of justice, but many have at their heart a concern for equality and like being treated alike[53] – though what equality is (and how we measure what things are alike remains highly contested). There has been a critical move in much bioethics scholarship toward the recognition that we must go beyond concerns of equality towards consideration of *equity* in healthcare.[59] Not all users of healthcare are the same, and consequently do not have equal need, and thus should not always be treated the same to ensure fairness: equity instead recognises that all individuals are not the same and do not have the same needs, and as such affording equal resources to all people may perpetuate existing unfairness.[59] Important context for our understanding of justice in bioethics must be the realities of social determinants of health and their intersectional impacts.[58,59]

As a reflection on the importance that we place on the value of justice in healthcare, we are concerned with *equitable* access to APT. We think about the matter of equitable access amongst important matters of context. Firstly, in high income western economies structural racism has come to

have a huge impact on the incidence of premature birth: prematurity is much more common among Black people and other racialised persons and is linked to systemic racism.[60] Second, in health systems that operate on the basis of private health insurance, such as the US, it is often the case that people most marginalised in society, along the axes of gender, race, socio-economic status and immigration status, are least likely to have health insurance as a reflection of existing social disparities.[61] Among those marginalised by race, class, and socioeconomic status, where they are insured, this will be government-subsidised insurance,[61] which can mean that they do not have access to the same standard of pregnancy care.[62] There might be serious concern, therefore, about access to APT being limited by cost – both where people are responsible for their own health bills or where insurance companies seek to limit costs. This is likely to impact most the group that are, for reasons already indicated, most likely to need the technology. Such concerns about access are not limited to private health systems. Highly technical and specialist health services, for reasons of efficiency because the care is higher cost, are concentrated in public health systems. In the UK, for example, highly specialist neonatal intensive care units (level 3) provide the most specialised care for the most premature and critically ill babies. A map of the UK shows that these units are concentrated in larger cities and in some parts of the UK, especially Scotland, Northern Ireland, and Northwest England, people living outside of larger cities are a long way from these units.[63] The expense and technical skills needed to use and monitor complex technology does limit its accessibility to people in rural and less populated areas. Finally, prematurity is a global problem:[28] not just one impacting the wealthiest economies. Thus, it is important to think about the global dimensions of accessibility of APT and consider how these technologies are/become accessible beyond the global north and in spaces and places that do not have resource-intensive health systems.

The cost of APT can come to limit its accessibility within health systems and across borders. Accessibility, related to cost, is something that we can be mindful of in design decisions. For example, we might centre the value of accessibility in reflecting on what materials should be used to build the AP, how much of these materials are required, how difficult maintenance of the materials

will be over time, and where these materials are sourced from. These reflections should not be limited to the cost of building the device, and thus how much it might cost to purchase the device, but also how much maintenance of the device might cost over time and what additional resources (such as specialist staff) are needed to operate them. The fluid-filled bag type design might be more likely to be prohibitively expensive in low-income settings compared to other models.

There will, of course, be some balance here to be maintained between efficacy (choosing materials that optimise function as much as possible) and accessibility (choosing materials that optimise function sufficiently and are not prohibitively expensive). Design choices that centre accessibility will also need to be balanced against compassion-motivated design features we outlined above, which, while reducing the potential for harm to putative parents might increase cost. We do not make any comment here on how the right balance is to be reached. We note only that if we are to place any value on justice, which we strongly advocate that we should, design choices have to be attentive to matters of cost and consequently accessibility.

It is important to note, however, that accessibility as a value should not be equated with the cost of the device/service. A given treatment may be very costly yet highly subsidized so that it becomes better accessible or affordable to a larger group of people.[64] Making accessibility an explicit dimension in considerations of VSD should push the ethical discussion towards questions of distributive justice and collective responsibility. If one agrees that the importance of enhancing clinical outcomes for extremely premature neonates should not be dependent on personal financial capacity, then conditions of wealth disparity should weigh towards ensuring public access to APT for everyone without excessive burden.

IV. ETHICAL TRADE OFFS

What has become immediately apparent from our research, reflections, and conversations about design choices for the AP is that there will be trade-offs between values and morally relevant considerations. We highlighted in the previous section, while explaining the relevance of each value, some places where there may be conflict. How conflicts between values and morally relevant considerations are resolved is an important part of the normative deliberation in VSD and, as such, is a critical ethical question in need of further reflection. Exactly how these values– efficacy, compassion, and accessibility - intersect and weigh against each other is a matter for further debate.

We have mapped out how we explored these values throughout our discussion as a starting point (see **figure 1**). To translate the underlying values into tangible design choices, an exploratory process was undertaken to examine how these values manifest in design and their potential interactions. Each value was looked at to identify design aspects aligned with it, as well as contrasting aspects. For instance, in the context of compassion, a design might prioritize creating a nurturing and familiar environment for the gestateling, akin to baby-related products such as a baby walker. Conversely, a design that does not prioritize such considerations could appear, consequently, less compassionate and, as one may imagine, may be judged (at least by some) to be less 'gentle' for 'housing' a gestateling. This does not mean that people's reactions to a given design will be homogenous, though the fact that design choices in product development in general are the topic of careful consideration in the first place, does convey that the way in which people react to them can, at least roughly be anticipated.

Subsequently, the inquiry delved into the interplay between the values in the design of the artificial placenta. This involved assessing whether certain values may need to be compromised to accommodate others, or if synergies exist between different design aspects. For instance, a design focused on accessibility might prioritize using few materials, potentially conflicting with the efficacy of the AP's design, as achieving optimal simulation of the "natural womb" might necessitate avoiding

shortcuts. The figure **(figure 1)** illustrates an exploration of how we might integrate these values and consider their relevance into and as part of the design process, making connections between them through various design elements.

Figure 1: Value Map

V. CONSIDERING DESIGN AND VALUES THROUGH VISUALS

Based on this exploration, we have drawn up three distinct designs that we considered might exemplify divergent future scenarios, each prioritizing one of the design values that we highlighted throughout this paper. We have provided visuals in this paper because they help bring to life the ethical reflections we have explored. Part of the relevance of generating these images resides in the theoretical assumption that (speculative) design can be used to open up future possibilities and unpack different values, preferences, fears, hopes, worries, etc.[65] An inspiring example of how this theoretical approach can be put to practice, has been presented by speculative designer Lisa Mandemaker at the Dutch Design Week 2018 in close collaboration with Maxima Medical Centre.[66] Mandemaker also collaborated with the ESDiT team in the study of how ectogestation invites speculative scenarios, which may, in turn, spark philosophical questions of how imaginations of AP may induce conceptual and social disruptions related to structures like family, birth, parenthood and the like. The question when and in what sense technology may induce 'disruption' in ethics, is a separate debate (for some reflections, see: De Proost and Segers, 2023).[67]

The process of creating the images for this study was facilitated by Midjourney (version 6.0).[68] One of the authors led this process – for each image they began with a specific prompt that provided the

general shape and feel we were aiming for, which they then fine-tuned within Midjourney using the 'vary (region)' function until it was sufficiently close to proceed to Photoshop for final adjustments. Different combinations of keywords were entered such as "neonate," "fluid-filled plastic bag," "tubes and cables," "mattress," "artificial lighting," "Neonatal Intensive Care Unit," "medical baby crib," "medical device," etc., along with previously generated images to create images that reflected the decision. Drafts of the images were then discussed and reflected on by all authors in collaboration and edits agreed between the authors were fed into the software to make changes to the images. The visuals we have provided are only three potential designs as ways of imagining our ethical reflections coming to life.

Design 1: Simple

Figure 2: Simple Design

This first hypothetical design **(figure 2)** depicts a simple and cost-effective design for an Artificial Placenta (AP). It features a plastic base capable of regulating temperature and placeable on any flat surface. The AP can be handheld or mounted on a wall, displaying only essential vitals and functionalities crucial for sustaining the gestateling's life. This might be considered the most accessible sort of design because it might be the cheapest way of creating the device. This might entail less attention to some of the finer points of efficacy and compassion in the design.

Design 2: Open

Figure 3: Open Design

This design (**figure 3**), in contrast to the first, showcases a more elaborate and expensive AP design, emphasising a welcoming and comforting aesthetic. Its open design resembles familiar baby-related products, that are likely to resonate with the socio-cultural frames expectant parents will have imagined for their baby. There are features that are designed with facilitating parent-gestateling interaction in mind. Aspects of this may compromises on aspects like safety and the faithful

replication of the "natural womb" environment, for example, because there is greater light exposure. This design might be thought of as the most compassion-focused design, as there is less attention paid to efficacy and accessibility.

Design 3: High-Tech

Figure 4: High-Tech Design

The final design we present (**figure 4**) portrays a highly advanced AP design, nearly unrecognizable in its function. Adorned with an array of interfaces, it offers extensive high-tech features for optimizing gestateling development by simulating the natural womb environment as closely as possible. Thus, the gestateling remains concealed and can only be accessed in case of emergency. This design might be considered the most efficacy focussed, and thus, there might be said to have less accessibility or compassion.

VI. CONCLUSION

APT capable of facilitating partial ectogestation are on the horizon. As testing on animals/with fetal mannequins continues and as regulators begin to debate the ethical issues in first-in-human use ethical issues surrounding the development of the technology need more ethical attention. One such issue is the matter of the design of the AP. VSD, a framework for ensuring that human values are considered and embedded in designing new technologies,[14-15] has been suggested as important in the development of the AP.[12] However, there has been little interrogation of what VSD might encompass in the design of AP nor what values or moral considerations might be relevant in making design choices. In this article, we outlined some important features of a VSD approach to the design of AP devices. We advocated the importance of making explicit the objectives of the AP (what problem are they designed to solve), of speculative reflection on ethical, legal, and societal implications of APs, of *both*

analytic *and* empirical conceptual investigation to identify stakeholders and morally relevant considerations and values, and, finally, of being careful to appropriately delineate between preferences and values.

In this article we also started the conversation about what considerations and values might be morally relevant in making design choices about the AP. We highlighted many moral considerations that we provisionally subsumed under three identified values: efficacy, compassion, and accessibility. These values, we illustrated, will shape various design choices: how much access is there to the gestateling? Of what nature? What does the device look like? What is it made of?

Our reflections, while neither exhaustive nor conclusive, illustrate that VSD involves trade-off between values that, when it comes to design, may be in conflict. Trade-offs are not a purely scientific question, but an ethical one. In deciding such matters, it will be important to listen to various stakeholders, such as parents who have experienced NICU and medical professionals, about their views (which is why we have emphasised the importance of future empirical work). Analytic work following this preference-gathering will be necessary to draw out the important values underlying preferences and figure out how conflicts should be resolved.

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