***Regulating Assisted Reproductive Technologies – New Horizons*, AMEL ALGHRANI, Cambridge University Press, 2019, 282pp., £63.00, hardback, ISBN 9781107160569**

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Reflecting on the history of the development of regulation surrounding assisted reproductive technologies (ARTs) in the UK, in her introduction to *Regulating Assisted Reproductive Technologies,* Amel Alghrani takes exception to a statement made by Lisa Jardine – then chair of the Human Fertilisation and Embryology Authority (HFEA) – shortly after the Human Fertilisation and Embryology Act 2008 received royal assent. Welcoming this new piece of legislation, Jardine claimed that it 'provided a clear framework for the future and a solid base on which to regulate 21st century practice within 21st century law' (p 5). For Alghrani, however, 'in retaining the architecture of the 1990 legislation', the 2008 Act was an unfortunate and 'missed … opportunity to consider how to equip the regulatory framework for what has been described … as the third era of human reproduction' (pp 5-6). This monograph is Alghrani's attempt to remedy this error, and its 'central purpose… is to advance debate on from the now much-debated issues that arise from the second wave of reproduction and to begin to offer a critical and legal analysis of the regulatory challenges raised by new reproductive technologies in the "third era"' (p 8). Thus, despite a deceptively broad title, Alghrani's interest is not in exploring the regulatory gaps arising from the development of new and emerging ARTs more generally, but a small subset of these technologies: those which fall into this 'third era'.

Yet, what does Alghrani mean when she refers to the 'third era' of reproduction? What are the regulatory challenges it raises, and how do they differ from those raised by ARTs in the 'second era'? The notion that reproduction can be split into eras, and that the 'third era' poses regulatory challenges that were not present during the second era seems to be a key element of the discussions in this monograph. However, what Alghrani means when she refers to the third era of reproduction frustratingly remains somewhat of a mystery throughout the monograph. Initially, her account seems clear as numerous references are made throughout to a 2004 paper by Welin who characterises the third era of reproduction as the point in time at which the foetus may be both conceived and gestated outside of the womb, while in the second era only *in vitro* conception was possible.[1] This understanding, however, does not seem to fit with Alghrani's suggestion that ectogenesis, uterus transplantation, the creation of bioengineered uteri for transplant, and in vitro gametogenesis (IVG) should all be considered third era reproductive technologies (p 8). Provided with no clear definition or explanation, the reader is left to infer her views regarding this central concept. Absent reference to IVG, it could be assumed that Alghrani characterises the third era slightly more broadly than Welin, as one whereby the foetus may theoretically be conceived and gestated outside of the woman. But this does not seem right either. Instead, it *seems* that what Alghrani has in mind when she talks of the third era of reproduction is the development of technologies which seek to (or have the potential to) de-stabilise and alter our ideas concerning the (often sexed, gendered and hetero-normative) roles played, contributions made, and importance of interests held by different stakeholders in reproduction.

[1] See, S Welin, 'Reproductive ectogenesis: The third era of human reproduction and some moral consequences' (2004) 10 *Science and Engineering Ethics* 615.

In Chapter 1, Alghrani proffers an overview of the history of the regulation of the use of ARTs in the UK, and outlines the current role of the HFEA as the licensor and regulator of fertility treatments.[2] Here, a clear, detailed and accessible account of the development of policy in this area is provided. This section adds valuable background and context to later chapters and should prove useful to those without specialised and in-depth knowledge of – as well as a helpful refresher for those already familiar with – this complicated area of regulation. Attention is then directed to the matter of embryo disputes in the UK. The key question explored is whether (and why/why not), as in unassisted reproduction, women ought to retain the decisive say over the fate of their embryos.[3] The chapter begins with an in-depth exploration of two cases of embryo disputes: the now infamous *Evans v. Amicus*,[4] and the more recent *ARB v. Hammersmith*.[5] Alghrani then moves on to explore the question of whether the 'neutral' location of IVF embryos, by this she means outside of the woman's body, should make such a difference to outcomes regarding the claims of gamete progenitors when compared to unassisted reproduction, and discusses a number of alternative models for regulation. Here, she provides an excellent survey of the debate which, although providing no solutions, deftly illustrates the complexity of regulation in this area. The chapter ends with the promise that this complexity is only liable to increase 'when we consider not just embryos growing *in vitro*, but foetuses that can be gestated and maintained in an artificial womb' (p 105).

The focus in the next two chapters is on ectogenesis. Chapter 3 serves primarily as an introduction to ectogenesis research, and briefly covers the major drivers of research into this procedure: its potential benefits for premature babies and prospective reproducers who are unable or unwilling to gestate their future offspring, common objections and worries regarding its development, and how non-human animal and human research into ectogenesis would be governed in the UK.[6] The clarity of Alghrani's explanation of the different ways in which human research into ectogenesis would be treated by existing regulation such as the 1990 and 2008 Human Fertilisation and Embryology Acts, and the Human Tissue Act 2004 (HTA) is commendable. Alghrani then moves, in Chapter 4, to consider a number of more specific questions raised by both 'partial' and 'full'[7] ectogenesis, and, while remaining committed to exploring how existing regulation may apply in these contexts, she also explores a number of normative questions.[8]

In her discussions of partial ectogenesis, Alghrani's major interest lies in how its potential to save the lives of extremely premature infants could be harnessed to both *extend* and *diminish* the reproductive freedoms of women. With regard to the former possibility, she suggests that, if and when it reaches clinical application, ectogenesis could provide additional and meaningful choices for women who need or desire to end a pregnancy but do not wish to end the lives of their foetuses. Alghrani, however, notes that both research into and clinical applications of partial ectogenesis could give rise to criminal liability in the UK if transferal into an ectogenic chamber is considered to constitute 'procuring a miscarriage',[9] imposes

[2] 'Regulation of Assisted Reproduction: Past, Present and Future'.
[3] 'Regulation of Gametes: Resolving Embryo Disputes between Gamete Progenitors', ch 2.
[4] *Evans v Amicus Healthcare Ltd and others* [2004] EWCA Civ 727; [2004] 3 WLR 681.
[5] *ARB v Hammersmith and R* [2018] EWCA Civ 2803; [2019] 2 WLR 1094.
[6] 'In Vitro Gestation I: The Road to Artificial Wombs (Ectogenesis) and Mechanical Reproduction'
[7] Alghrani describes 'partial' ectogenesis as cases 'whereby … at some point during the pregnancy the foetus is transferred into an ectogenic chamber', while in 'full' ectogenesis 'the mother's body is never used in the gestation process': at 145.
[8] 'In Vitro Gestation II: Ectogenesis: A Regulatory Minefield?'
[9] Offences Against The Persons Act 1861, section 58.

significant risks of harm to a viable foetus,[10] and/or causes such significant harms to the foetus that they result in its death post-transfer/birth.[11] Alghrani, however, suggests that it would be 'perverse', seemingly meaning irrational or illogical, 'to allow women to destroy their foetus within the current laws on abortion and yet prohibit a woman the option to end her pregnancy but offer her foetus a chance of survival' (p 149). She thus calls for the government to create guidance specifying the circumstances under which research into partial ectogenesis should be permitted.

In terms of the potential for partial ectogenesis to be used to diminish reproductive freedoms, Alghrani focuses on two questions. First among these is the impact that ectogenesis may have on considerations of foetal viability, given the role that viability has played in the formulation of legislation surrounding abortion for 'social grounds.' Second, is the extent to which a woman's right to abortion should be understood as a right to 'evacuation' rather than the death of her foetus, and, if so, whether ectogenesis might 'end the abortion debate since it provides a middle ground, allowing women to end pregnancies without ending foetal life' (p 157). Alghrani suggests, however, that it is unlikely that pro-choice groups will consider foetal transfer into an ectogenesis device to be an acceptable alternative to abortion given that it will generally be riskier for a woman to have a foetus transferred into an artificial womb, than for her to have an abortion. In England and Wales over 90% of abortions are performed at 12 weeks gestation or less and will generally not involve surgical intervention or anaesthetic.[12] Foetal transfer is, however and as Alghrani notes, likely to require 'invasive surgery akin to a caesarean section' (p 161) *and* for a woman to wait and endure the pain and inconveniences of pregnancy until the foetus is sufficiently developed that foetal transfer is possible (p.162). Furthermore, abortions are generally sought, not just to end a pregnancy, but to avoid parenthood and/or the birth of a child. These points are well-made but would have been enriched by more discussion of the fundamental disagreement underpinning debates surrounding abortion: the moral status of the foetus. After-all, the suggestion that ending foetal life (rather than placing it in an ectogenic chamber after removal from a woman's body) can be justified by appeals to individual desires to avoid parenthood, will only be considered convincing by those who consider foetuses to possess relatively low moral status. For those who hold the foetus to possess high or 'full' moral status, however, such a suggestion is likely to seem monstrous if the foetus could be safely evacuated with comparatively little risk to the pregnant woman's health.

Alghrani's attention is then turned what she considers to be the major regulatory questions posed by 'full' ectogenesis: the legal status accorded to a foetus gestated *ex vivo*, the permissibility of termination of foetal life in this context, and disputes between gamete progenitors regarding the fate of their foetuses. One interesting question she discusses is whether gestational location should make a difference to the status and protections afforded to the human foetus. Alghrani suggests that it should, and that a strong case could be made for extending legal protection to the *ex vivo* foetus. Her reasoning here is clear: in the case of ectogenesis the foetus 'can be protected independently without violating a woman's bodily

[10] *St. George's Healthcare Trust* v *S* [1998] 3 All ER 673, HL.
[11] AG's Reference (No. 3 of 1994) [1997] 3 All ER 936, HL. I refer to 'transfer and/or birth' to acknowledge that there exists some debate regarding whether the foetus should, after transferal into an ectogenic chamber legally be considered a foetus, a newborn or, indeed, a 'gestateling'. For an insight into such discussions see: EC Romanis, 'Challenging the 'Born Alive' Threshold: Fetal Surgery, Artificial Wombs and the English Approach to Legal Personhood' *Medical Law Review* advance access https://doi.org/10.1093/medlaw/fwz014.
[12] Department of Health and Social Care, *Abortion Statistics, England and Wales: 2018* (2019) s. 2.23-2.39. <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/808556/Abortion_Statistics__England_and_Wales_2018__1_.pdf>

autonomy' (p 172). However, while the *ex vivo* foetus could be granted additional protections on this basis, it seems important for the law to remain consistent on the legal status of foetuses because *regardless* of location, they remain relevantly similar in terms of what seems to matter when it comes to moral and legal status - their capacities and potential. What should change depending on context, however, is how such protections are balanced against other competing rights/claims, such as the woman's right to bodily autonomy.

Finally, in Chapters 5 and 6, Alghrani explores the regulatory questions raised by uterus transplantation (UTx), first in cisgender women, and then transgender women and men. This procedure is, of course, no longer 'on the horizon.' With over 60 procedures performed worldwide and 17 live births recorded as of July 2019[13] it is now firmly within our field of vision. In Chapter 5, Alghrani provides an overview of the aims of UTx and the current state of research in this field, both internationally and in the UK.[14] Focusing on the UK context, she explores UTx could be regulated, paying particular attention to matters regarding living and deceased donation, transplantation and the rights and interests of recipients, and the welfare of children who may be born after UTx.

In the context of live donor UTx, Alghrani explores regulation surrounding consent procedures, safeguards to prevent coercion, and undue pressure to donate contained in the HTA 2004, the prospect of retrieval from incapacitated donors, and payment. Appropriate consent procedures for the post-humous donation of uteri are then explored. While Alghrani accurately explains *current* legislation surrounding the donation of reproductive tissues in England, her account of Welsh legislation is incorrect. She suggests that under current 'opt out' organ donation legislation, 'explicit consent [for uterus donation] would be unnecessary … unless a woman communicates that she does not wish to be a uterus donor, this organ can be removed for donation' (p 203). However, current Human Tissue Authority guidance specifies that the uterus falls into the category of 'excluded relevant material',[15] defined in the Human Transplantation (Wales) Act 2013 as material for which 'express consent is required'.[16] It is important that this is recognised because of the impending move in England from a system of explicit consent for organ donation to one of 'deemed' consent, and under the current plans, this will also exclude uteri from the 'opt out' provisions.[17]

With regard to the implications of regulation for recipients and offspring, Alghrani explores consent procedures in the context of UTx, patient refusals to adhere to medical advice, relevant child welfare regulations, the challenges that may result from dual regulation by the HTA 2004 and the Human Fertilisation and Embryology Act 2008, and questions of priority setting. She discusses a number of fascinating questions, such as access to UTx, whether it is likely to be funded in the UK, and 'what legal liability may arise for foetal injury under domestic legislation' (p 213). With respect to public funding, Alghrani suggests that the problem of dual regulation may give rise to anomalies and she questions whether a woman

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[13] See M. Brannstrom et al, 'Global results of human uterus transplantation and strategies for pre-transplantation screening of donors' (2019) 112 *Fertility and Sterility* 3.

[14] 'Regulation of Uterus Transplantation: When Assisted Reproduction and Transplant Medicine Collide'.

[15] Human Tissue Authority (HTA), *Guidance on paragraph 135: HTA's Code of Practice on the Human Transplantation (Wales) Act 2013* (2015) <https://www.hta.gov.uk/policies/guidance-paragraph-135-hta's-code-practice-human-transplantation-wales-act-2013>

[16] Human Transplantation (Wales) Act 2013 ss. 7 (4).

[17] Department of Health and Social Care, *The New Approach to Organ and Tissue Donation in England: Government Response to public consultation* (2018) at 24 <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/731913/govt-response-organ-donation-consent.pdf>.

'could be denied UTx after she has undergone the physical, emotional and financial expenditure of IVF' (p 216). This is unlikely to be the case. Since April 2017, UTx has been included in the NHS's Manual for Prescribed Specialised Services, which states that - due to the small number of individuals likely to seek UTx, the high costs and specialist expertise required by it - 'it is unlikely that CCGs will be the responsible commissioner for any element of the procedure'.[18] As decisions regarding UTx will be made centrally, it is unlikely that the problems articulated by Alghrani, such as acceptance for treatment/the provision of funding for one element of the procedure and not another in a particular patient, would arise. That being said, the provision of UTx could result in inequalities of access for women with different forms of infertility/subfertility, because in areas of the country where IVF funding is not provided or capped at one or two cycles, this would not apply to women with absolute uterine factor infertility accepted for NHS funded uterus transplantation.[19] This possibility must therefore be explored and attempts made to reduce the inequitable implications of decisions to fund centrally *and* through CCGs.

In the final substantive chapter, Alghrani tackles the mammoth question of how current regulation in the UK would apply if UTx became possible for transgender women and men who seek to gestate and give birth to their own future children.[20] After exploring relevant case law and key pieces of legislation - such as the Equality Act 2010, the Gender Recognition Act 2004, the Human Fertilisation and Embryology Act 2008, and the HTA 2004 – she concludes that 'In theory [UTx] should raise no greater regulatory issues than those discussed in the previous chapter' regarding cisgender women (p 239). In the case of UTx in cisgender men, however, Alghrani notes that existing legislation in the UK may pose more significant challenges. The 1990 and 2008 Human Fertilisation and Embryology Acts currently only 'permit provision of fertility treatment services to assist women to become pregnant' (p 248), and thus would need to be amended to include men prior to the performance of UTx in this population. Finally, Alghrani considers the difficulties raised by the current legal definitions of parenthood and the failure of legislation to adequately accommodate transgender persons or men when ascribing parental status. She suggests that definitions of mother and father in UK legislation focuses on biological function, defining mother 'as female who gestates and father as male sperm provider' (p 255). The definitions of father are a little more complex than Alghrani presents,[21] but recent legal cases – such as *Re TT & YY* [2019][22] – illustrate and support her claim that sexed and/or gendered understandings of parenthood are no longer fit for purpose in the so-called 'third era' of reproduction.

In her concluding chapter, Alghrani carefully draws the various threads of her argument together, summarises the book's contents, restates her indictment of current regulation regarding ARTs in the UK, and implores the creation of mechanisms that would allow for the

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[18] For the most recent version see NHS, *Manual for Prescribed Specialised Services 2018/19* (2018) at 389 <https://www.england.nhs.uk/publication/manual-for-prescribed-specialised-services/>

[19] Thanks to my colleague Laura O'Donovan, whose research focuses on this issue, who drew my attention to this document and its implications for Alghrani's work.

[20] 'Uterus Transplantation beyond Cisgender Women: 'O Brave New World, That Hath Such People In It'.

[21] Human Fertilisation and Embryology Act 2008, ss.35-41.

[22] EWHC 2384 (Fam). In this case a transgender man (TT) challenged his registration as 'mother' on the birth certificate of his child (YY) who was gestated and birthed by TT after his gender transition. The court held that TT should remain registered as the child's mother as 'being a "mother" or a "father" with respect to the conception, pregnancy and birth of a child is not necessarily gender specific … and [it is] recognised by the law, for a "mother" to have an acquired gender of male, and for a "father" to have an acquired gender of female' at [280].

creation of proactive rather than reactive regulation. In sum, and despite the important matters noted in this review, this is, on the whole, a fascinating and rigorous treatment of the questions raised and challenges posed by technologies such as UTx and ectogenesis for the regulation of ARTs in the UK. Accessibly written, attractively presented, and generously footnoted, it constitutes an excellent introduction for lawyers, medical professionals, and policy makers with an interest in the development and regulation of ARTs.