



HUMAN RIGHTS MINING: ARTIFICIAL INTELLIGENCE AND REPRODUCTIVE AUTONOMY

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Abstract:

Using fully automated deep learning models to predict the probability of pregnancy i.e. effective and standardized embryo selection could be promising improvement of the safety and efficacy of reproductive services. However, this aspect of artificial intelligence (AI) application in clinical decision making tasks might be the most disputable since it interferes within complex ethical and legal issues related to reproductive choice. Together with advancement of new reproductive technologies like partial or full ectogenesis that implies AI application through the whole process, increasing role of AI in preimplantation reproductive choice could challenge the very paradigm of reproductive autonomy. Herein we are going to see how existing and forthcoming EU legislation assess the role or capacity of AI in reproductive choice at both preimplantation and ectogestation stages. The results of this inquiry might be useful for health regulatory bodies and HTA bodies since it could provide insight into eventually normativised social values requiring consideration before placing suchlike AI at the EU market. In this research, we are not going to discuss the most suitable concept of reproductive autonomy for the digital environment. Rather, it is going to be indicated if the concept of reproductive autonomy as we know it extends to this environment as it should.

Key words: AI, reproductive choice, ectogenesis, ecto-technologies, human rights mining

1. Introduction

Promising potential of artificial intelligence (AI) to improve healthcare services initiated broad quest for its application in decision making tasks across all four categories of its potential application in medicine: basic science, clinical, logistics, and policy-making,¹ regardless to certain legal uncertainties.² As to the application of AI in clinical decisioning, it is expected from it to contribute in improvement of ‘patient outcomes, increase the efficiency of healthcare diagnosis and treatment, and lower the cost of care’³ which needs to be in conformity to the ethical principles such as respect for autonomy, beneficence, non maleficence, and justice.⁴ Thus, the application of AI in clinical decision making process should satisfy legal as well as ethical requirements both of which are not always so clear. Application of AI in the field of reproductive services might be especially sensitive from both aspects.⁵ Still, AI will be applied in their provision⁶ which calls for human rights analysis.

¹ Artificial Intelligence in Medicine (Eds. Niklas Lidströmer, Hutan Ashrafian), Springer, 2022.

² [Identification and assessment of existing and \(europa.eu\)](#), 45

³ Lehmann L.S. (2022) Ethical Challenges of Integrating AI into Healthcare. In: Lidströmer N., Ashrafian H. (eds) Artificial Intelligence in Medicine. Springer, Cham. https://doi.org/10.1007/978-3-030-64573-1_337

⁴ *Ibid.*

⁵ See Alghrani, A. (2018). Regulating Assisted Reproductive Technologies: New Horizons (Cambridge Bioethics and Law). Cambridge: Cambridge University Press. doi:10.1017/9781316675823

In parallel with introduction of AI in embryo selection procedures^{7,8} which supported its increasing role in reproductive choice as well, scientists are culturing embryos within *in vitro* systems⁹ without maternal tissue,¹⁰ and continuously developing artificial wombs or ‘biobag’ (ecto-technologies).¹¹ The aim of those technologies is to substitute natural gestation with the process called ectogenesis,¹² for medical and non-medical purposes. Those ecto-technologies tend to transform biological-corporal process of gestation into non-bodily procedure conducted in artificial environment, controlled by AI, where algorithms and protocols are taking precedence over the biological role of progenitors be it through whole process of gestation be it in its part.

Even though it can improve neonatal care as well as reproductive services, suchlike developments are challenging very paradigm of reproductive autonomy. In whole Europe, human rights paradigm of reproductive autonomy predominantly rests upon the bodily concept of autonomy. Consequently, decisioning powers in reproductive sphere are decided by: (1a) gestational interconnection (it conferred woman with greater control over reproduction as compared to man,¹³ as she is the person ‘primarily concerned by the pregnancy and its continuation or termination’,¹⁴ and ‘made it impossible to isolate life of unborn from that of mother’¹⁵); (1b) viability-in-future (in Europe abortion is temporally limited with the child’s viability mostly regardless of indications)¹⁶; (1c) protection of the interests in life and health (The institutions of the European Convention had indicated that in the event of the conflict between mother’s interests from the ambit of Article 2 and proportional interests of the unborn in initial stages of pregnancy the precedence shall be given to ‘protecting the life and health of the woman’).

When ecto-technologies once enable (2a) temporal and physical separation between procreation and gestation, gestation and progenitor(s); (2b) instantaneous emergence of viability at the beginning of gestation; (2c) preclusion of the conflict in life and physical health; essentials of reproductive choice will be terminated. For, this inquiry dominantly intends to investigate if the forthcoming EU legislation such as the Artificial Intelligence Act,¹⁷ could provide legal determinants to define the role or capacity of AI in reproductive choice. The results could be applicable for the process of health technology assessment for the purpose of its authorisation in the EU market.

⁶ See Romanis EC. *J Med Ethics* 2018;0:1–5. doi:10.1136/medethics-2018-104910, 3.

⁷ Tran D, Cooke S, Illingworth PJ, Gardner DK. Deep learning as a predictive tool for fetal heart pregnancy following time-lapse incubation and blastocyst transfer. *Hum Reprod.* 2019 Jun 4;34(6):1011-1018. doi: 10.1093/humrep/dez064. PMID: 31111884; PMCID: PMC6554189.

⁸ <https://www.newscientist.com/article/2231591-ai-is-being-used-to-select-embryos-for-women-undergoing-ivf/>

⁹ Reardon, Sara. ‘Human embryos grown in lab for longer than ever before’ *Nature* (2016) Retrieved from: <https://www.nature.com/news/human-embryos-grown-in-lab-for-longer-than-ever-before-1.19847>

¹⁰ Shahbazi, N. Marta, ‘Self-organization of the human embryo in the absence of maternal tissues’ *Nature Cell Biology* 18, 700–708 (2016) doi:10.1038/ncb3347

¹¹ Segers, S. The path toward ectogenesis: looking beyond the technical challenges. *BMC Med Ethics* 22, 59 (2021). <https://doi.org/10.1186/s12910-021-00630-6>

¹² Partridge, A. Emily. and others ‘An extra-uterine system to physiologically support the extreme premature lamb’ *Nature Communications* (2017) DOI: 10.1038/ncomms15112

¹³ See Sally Sheldon, ‘Gender Equality and Reproductive Decision-Making’ (2004) 12 *Feminist Legal Studies* 303-316, 312.

¹⁴ *Boso v Italy*, no. 50490/99, 5 September 2002. § 4.

¹⁵ *Paton v The United Kingdom*, Application No. 8416/78, Decision of the Commission 1980, § 19.

¹⁶ See Report of the Library of Congress *Abortion Legislation in Europe* available at <http://www.loc.gov/law/help/abortion-legislation/europe.php>.

¹⁷ Proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts [EUR-Lex - 52021PC0206 - EN - EUR-Lex \(europa.eu\)](https://eur-lex.europa.eu/eur-lex.do?uri=CELEX:52021PC0206:EN:EUR-Lex)

2. Application of AI at different stages of reproduction

Software such as IVY, operates in preimplantation stage of reproductive process enabling effective and standardized embryo selection,¹⁸ i.e. autonomously makes reproductive decisions to a certain extent. In technological sense, this particular software is using fully automated system in order to predict the probability of fetal heart pregnancy based on raw time-lapse videos directly obtained.¹⁹ Basic legal rules governing assessment process of the medical devices,²⁰ including software²¹ that operates at this stage of reproduction were introduced through the Directive 98/79/EC of the European Parliament and of the Council,²² i.e. Regulation (EU) 2017/745 of the European Parliament and of the Council,²³ and Regulation (EU) 2017/746 of the European Parliament and of the Council.²⁴ Still, since embryo selection process itself is decided by non-exhaustive list of implantation data,²⁵ whole process might be legally²⁶ and ethically disputable,²⁷ either because of parameters used and their impact on reproductive autonomy,²⁸ either because of the lack of explainability.²⁹ But even so, the main consideration at this stage of reproduction remains respect for genetic progenitor's (patients) rights and interests since that of *in vitro* embryos received no recognition at regional level.

Situation, however, could essentially differ in the event of the similar AI application in the ecto-technologies since there is a new patient at healthcare. As results in previous inquiry showed³⁰ the obtainment of viability and the exclusion of the conflict between competitive rights (genetic progenitors vs. embryos/fetuses) requires autonomous recognition of the artificially gestated human entity under the European Convention on Human Rights and

¹⁸ Tran D, *et al.*, *op. cit.*

¹⁹ Tran D, *et al.*, *op. cit.*

²⁰ Forthcoming changes listed at Factsheet for Authorities in non-EU/EEA States on Medical Devices and in vitro Diagnostic Medical Devices available at <https://ec.europa.eu/docsroom/documents/33863>

²¹ Guidance on Classification Rules for in-vitro Diagnostic Medical Devices for Regulation (EU) 2017/746, Medical Device Coordination Group Document 2022. Retrieved from https://ec.europa.eu/health/system/files/2022-01/md_mdcg_2020_guidance_classification_ivd-md_en.pdf

²² Directive 98/79/EC of the European Parliament and of the Council <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A01998L0079-20120111>

²³ Regulation (EU) 2017/745 on medical devices (MDR)

²⁴ Regulation (EU) 2017/746 of the European Parliament and of the Council <https://eur-lex.europa.eu/eli/reg/2017/746/oj>

²⁵ Berntsen J, Rimestad J, Lassen JT, Tran D, Kragh MF (2022) Robust and generalizable embryo selection based on artificial intelligence and time-lapse image sequences. PLOS ONE 17(2): e0262661. <https://doi.org/10.1371/journal.pone.0262661>

²⁶ European Union Agency for Fundamental Rights, *Getting the future right : artificial intelligence and fundamental rights : report*, Publications Office, 2020, <https://data.europa.eu/doi/10.2811/774118>

²⁷ Carolyn Riley Chapman, Kripa Sanjay Mehta, Brendan Parent, Arthur L Caplan, Genetic discrimination: emerging ethical challenges in the context of advancing technology, *Journal of Law and the Biosciences*, Volume 7, Issue 1, January-June 2020, Isz016, <https://doi.org/10.1093/jlb/Isz016>

²⁸ Siermann M, Claesen Z, Pasquier L, Raivio T, Tšuiiko O, Vermeesch JR, Borry P. A systematic review of the views of healthcare professionals on the scope of preimplantation genetic testing. *J Community Genet.* 2022 Feb;13(1):1-11. doi: 10.1007/s12687-021-00573-w. Epub 2022 Jan 14. PMID: 35028914; PMCID: PMC8799829.

²⁹ Amann, J., Blasimme, A., Vayena, E. *et al.* Explainability for artificial intelligence in healthcare: a multidisciplinary perspective. *BMC Med Inform Decis Mak* 20, 310 (2020). <https://doi.org/10.1186/s12911-020-01332-6>

³⁰ Dragan Dakić, The Scope of Reproductive Choice and Ectogenesis: A Comparison of European Regional Frameworks and Canadian Constitutional Standards, *ELTE Law Journal* 2017/2, ISSN: 2064 4965 pp.127-145.B <https://eltelawjournal.hu/the-scope-of-reproductive-choice-and-ectogenesis-a-comparison-of-european-regional-frameworks-and-canadian-constitutional-standards/>

Fundamental Freedoms (the European Convention).³¹ It is so even in respect to genetic progenitors whose eventual the demand to abort the ectogestation would be disconnected from the guarantees they enjoy under the European Convention.³² Their reproductive autonomy herein is also intruded by potentially broadened margin of appreciation that derives out of the public interest.³³

All of this could pose significant obstacles to regulatory as well as to health technology assessment bodies in the near future. Even though traditional legal working method implies application of existing legal frameworks to new circumstances i.e. extension of the abovementioned rules covering medical devices/software intended for preimplantation stage of reproduction to medical devices/software deployed to ectogestation, it is useful to conduct quick scan, limited by the length of the contribution, of the forthcoming EU legislation. Promising feature of new AI-specific EU legislation in the context of this research is its compliance to current AI-related legislation that is predominantly centered around individuals and their rights. Recently the European Commission published a proposal for the so-called Artificial Intelligence Act,³⁴ which is among other purposes, designed to safeguard fundamental rights against AI's adverse effects.³⁵ In this regard a number of fundamental rights enshrined in the EU Charter of Fundamental Rights³⁶ (the Charter) were recognized as AI-affected including the right to human dignity (Article 1), respect for private life and protection of personal data (Articles 7 and 8), non-discrimination (Article 21) and equality between women and men (Article 23).

Therefore, it could be considered that fundamental rights are required parameters or accepted 'class labels'³⁷ herein. This claim is firmly supported through Title II and Title III of the Artificial Intelligence Act that labeled violation of fundamental rights as prohibited AI practices. Furthermore, Title III is addressing high-risk AI systems and identifies its two main categories one of which is stand-alone AI systems with mainly fundamental rights implications. Among AI's listed in Annex III that contains a limited but not final number of AI systems whose risks have already materialised or are likely to materialise in the near future, Artificial Intelligence Act enumerates 'Access to and enjoyment of essential private services and public services and benefits' covering AI systems intended to be used for medical aid. But even so, the Artificial Intelligence Act is not immune to critique from the fundamental/human rights perspective. The main shortcomings in this regard is its omission to clearly ensure application of necessity and proportionality tests as well as to 'consistently allocate legal responsibility for the wrongs and harms of AI.'³⁸ Necessity and proportionality tests are fundamentals in human rights reasoning essential for reproductive choice. Legal responsibility is important aspect of decision making competences in any area including reproduction. All of this makes vague role and competences of AI in reproductive choice and potentially leaves rights and interests of all patients inappropriately protected. Hence, AI with

³¹ European Convention on Human Rights and Fundamental Freedoms <https://www.echr.coe.int/Pages/home.aspx?p=basictexts&c>

³² Dakić, *Op. cit.*

³³ *Ibid.*

³⁴ [EUR-Lex - 52021PC0206 - EN - EUR-Lex \(europa.eu\)](https://eur-lex.europa.eu/eur-lex.do?uri=CELEX:52021PC0206:EN)

³⁵ Smuha, Nathalie A., Beyond the Individual: Governing AI's Societal Harm (September 2021). Internet Policy Review, 10(3). <https://doi.org/10.14763/2021.3.1574>, Available at SSRN: <https://ssrn.com/abstract=3941956>

³⁶ EU Charter of Fundamental Rights <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXT>

³⁷ European Union Agency for Fundamental Rights, *Getting the future right : artificial intelligence and fundamental rights : report*, Publications Office, 2020, <https://data.europa.eu/doi/10.2811/774118>

³⁸ Smuha, Nathalie A. and Ahmed-Rengers, Emma and Harkens, Adam and Li, Wenlong and MacLaren, James and Piselli, Riccardo and Yeung, Karen, How the EU Can Achieve Legally Trustworthy AI: A Response to the European Commission's Proposal for an Artificial Intelligence Act (August 5, 2021). Available at SSRN: <https://ssrn.com/abstract=3899991> or <http://dx.doi.org/10.2139/ssrn.3899991>

decision powers (to select the best fetus for the completion of the ectogestation or to terminate/proceed the process if the malformation develops) might fail to meet the fundamental/human rights standards as required in the Artificial Intelligence Act.

3. Conclusions

Application of AI in medicine, including clinical decisioning, was already regulated at EU level. Existing AI-related EU regulation could well cover described application of AI in preimplantation stage of reproduction. This only implies obtainment of informed consent from patients' i.e. genetic progenitors.

Basic legal source on AI and its application in EU is forthcoming Artificial Intelligence Act. This Act is considered to be relevant for the assessment of AI application in (future) ecto-technologies. Due to significance conferred to them in the Artificial Intelligence Act, fundamental rights as enshrined in the Charter are identified as normativised social values requiring consideration by health regulatory bodies and HTA bodies. It was concluded that AI with decision powers in ectogestation might fail to meet required fundamental/human rights standards since it has no defined role and competences in reproductive decisioning. It is so because it lacks fundamentals of human rights reasoning as well as legally important aspect of decision making competences.

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