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The Use of Artificial Intelligence (AI) in Assisted Reproductive Technology (ART): Examining the Legal and Ethical Implications.

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# THE USE OF ARTIFICIAL INTELLIGENCE (AI) IN ASSISTED REPRODUCTIVE TECHNOLOGY (ART): EXAMINING THE LEGAL AND ETHICAL IMPLICATIONS.

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### Abstract

*In a world where Artificial Intelligence (AI) is rapidly gaining prominence, its potential application in the field of Assisted Reproductive Technology (ART) cannot be overlooked. AI in ART has revolutionized the field of reproductive medicine, promising enhanced efficiency and outcomes. This article delves into the legal and ethical considerations surrounding this burgeoning intersection. AI algorithms are increasingly utilized in ART procedures such as in vitro fertilization (IVF), embryo selection, and gamete screening, optimizing success rates, and minimizing risks. AI holds promise. This study explores the intersection of AI and ART, investigating the legal challenges arising from their integration. It scrutinizes the implications of employing AI in reproductive technologies, delving into concerns such as data privacy, consent, liability, and the potential necessity for novel regulatory frameworks. The research provides a comprehensive overview of the evolving legal and ethical landscape in this domain. Employing a doctrinal methodology, which involves analyzing legal principles and doctrines, the study aims to contribute to the ongoing discourse on the ethical and legal framework essential for ensuring the responsible and equitable utilization of AI in ART. Despite the numerous challenges, the amalgamation of AI and ART is poised to significantly influence the trajectory of medical advancement in the future.*

**Keywords:** Artificial Intelligence, Assisted Reproductive Technology, Legal Issues, Infertility, Ethical Issues, Health Law

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## 1.0 Introduction

The intersection of Artificial Intelligence (AI) and Assisted Reproductive Technology (ART) marks a profound shift in the landscape of reproductive medicine, reshaping the possibilities and ethical considerations surrounding human reproduction. This convergence brings together cutting-edge technologies to address infertility, genetic disorders, and embryo selection, offering both promises of improved outcomes and potential pitfalls. As AI continues to advance, its integration into ART introduces a wide array of legal and ethical inquiries that extend beyond the confines of the laboratory and clinical settings. From questions of autonomy, consent, and the commodification of human life to broader societal implications such as equity, access, and the redefinition of parenthood. The collaboration between AI and ART forces us to confront complex moral dilemmas and navigate uncharted legal territories. In this paper, we embark on an exploration of the multifaceted landscape of legal and ethical issues arising from the amalgamation of AI and ART, aiming to foster a comprehensive understanding of the implications for individuals, families, and society at large.

## 2.0 Conceptual Clarification

### 2.1 Artificial Intelligence

AI encompasses the capacity of machines to learn and exhibit intelligence, distinct from the innate intelligence exhibited by humans.<sup>1</sup> It is the ability of a digital computer or computer-controlled robot to perform tasks commonly associated with intelligent beings. The term is frequently applied to the project of developing systems endowed with the intellectual processes

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<sup>1</sup> R. Wang, W. Pan, L. Jin, Y. Geng, C. Gao, & S. Liao. Artificial Intelligence in Reproductive Medicine. *Reproduction*, 2019. 158(4), R139-R154.

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characteristic of humans, such as the ability to reason, discover meaning, generalize, or learn from experience.<sup>2</sup>

John McCarthy first introduced the term "Artificial Intelligence" (AI) during the Dartmouth Summer Research Project on Artificial Intelligence in 1955.<sup>3</sup> Since its inception, AI has experienced rapid evolution and has progressively integrated into various aspects of our personal and societal realms. In recent years, advancements in computer processing power, memory capacity, data storage capabilities, and the availability of vast datasets have propelled computers to tackle increasingly intricate learning tasks with remarkable efficacy. Specific applications of AI include expert systems, natural language processing, speech recognition and machine vision.<sup>4</sup> AI systems work by ingesting large amounts of labeled training data, analyzing the data for correlations and patterns, and using these patterns to predict future states.<sup>5</sup>

The world-renowned Artificial Reproductive Technology Specialist, Professor Oladapo Ashiru, has submitted that technology will radically change how the subject of Medicine is taught and practiced in the coming years.<sup>6</sup> He declared that Artificial Intelligence (AI), among other digital innovations, will play a defining role in that invasion.<sup>7</sup>

AI is gaining ground in human reproduction and embryology. Advances in AI applications are constantly promoted by the increasing amount of data available in reproductive medicine. Despite some potential pitfalls, making decisions for infertility patients based on the analysis of

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<sup>2</sup> B.J. Copeland, Britannica; *Artificial Intelligence.*, Available At: <https://www.britannica.com/technology/artificial-intelligence> Assessed December 2<sup>nd</sup>, 2023.

<sup>3</sup> R. Wang, W. Pan, L. Jin, Y. Geng, C. Gao, & S. Liao. Artificial Intelligence in Reproductive Medicine. *Reproduction*, 2019. 158(4), R139-R154.

<sup>4</sup> N. Laskowski, 'A Guide To Artificial Intelligence In The Enterprise' Retrieved At: <https://www.techtarget.com/searchenterpriseai/definition/Ai-Artificial-Intelligence> Accessed On 12<sup>th</sup> December 2023

<sup>5</sup> Ibid

<sup>6</sup> LexisNexis, "In the Next Five Years, Medicine Will Not Be Taught as We Currently Do", Says Renowned IVF Specialist, Daily Independent (Nigeria) October 28, 2023, Saturday

<sup>7</sup> Ibid

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medical data is the optimal clinical approach. To reduce the gap between research and clinical practice, we need to focus on combining Assisted Reproductive Technology (ART) and AI development.<sup>8</sup>

## 2.2 Assisted Reproductive Technology

Assisted Reproductive Technology (ART) encompasses medical procedures and technologies designed to assist individuals or couples in achieving pregnancy when conventional methods are unsuccessful. ART includes all fertility treatments in which either eggs or embryos are handled. In general, ART procedures involve surgically removing eggs from a woman's ovaries, combining them with sperm in the laboratory, and returning them to the woman's body or donating them to another woman.<sup>9</sup> They do not include treatments in which only sperm are handled (i.e., intrauterine or artificial insemination) or procedures in which a woman takes medicine only to stimulate egg production without the intention of having eggs retrieved.<sup>10</sup>

ART involves various techniques such as in vitro fertilization (IVF), intracytoplasmic sperm injection (ICSI), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), embryo cryopreservation, and the use of donor eggs or sperm. Surrogacy can also be considered a form of ART. These methods aim to address infertility issues caused by factors such as blocked fallopian tubes, low sperm count, ovulation disorders, or unexplained infertility. ART procedures are conducted under medical supervision and involve assisted manipulation of eggs, sperm, or

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<sup>8</sup> J.M. Raimundo, & P. Cabrita. Artificial Intelligence at Assisted Reproductive Technology. *Procedia Computer Science*, 2021 181, 442-447.

<sup>9</sup> C. Farquhar, & J. Marjoribanks, J. Assisted Reproductive Technology: An Overview of Cochrane Reviews. 2018 *Cochrane Database of Systematic Reviews*, (8).

<sup>10</sup> Centres For Disease Control and Prevention (CDC), 'Assisted Reproductive Technology' Available At: <https://www.cdc.gov/art/whatis.html> Accessed On 12th December 2023

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embryos to facilitate fertilization and implantation, ultimately helping individuals or couples achieve their desired pregnancies.<sup>11</sup>

### 2.2.1 Types of Assisted Reproductive Technology

Assisted Reproductive Technology (ART) encompasses a range of techniques aimed at assisting individuals or couples in achieving pregnancy when conventional methods fail. Here are the main types of ART:

- a) **In Vitro Fertilization (IVF):** IVF is the most widely known and commonly used form of ART. This is a procedure that allows for the fertilization to happen outside the woman's body. Sperm and eggs are combined in a special dish to make embryos (fertilized eggs). The resulting embryos are then cultured for a few days before one or more are transferred to the woman's uterus. IVF may be used in cases of fallopian tube blockages, endometriosis, or unexplained infertility.<sup>12</sup>
- b) **Intracytoplasmic Sperm Injection (ICSI):** ICSI is a specialized form of IVF used in cases of severe male infertility, where sperm quality or quantity is low. It involves the direct injection of a single sperm into an egg to facilitate fertilization. ICSI can overcome issues such as low sperm count, poor sperm motility, or abnormal sperm morphology.<sup>13</sup>
- c) **Gamete Intrafallopian Transfer (GIFT):** GIFT involves the transfer of both eggs and sperm into the fallopian tubes, where fertilization occurs naturally within the woman's body. Unlike IVF, fertilization takes place inside the fallopian tubes rather than in a laboratory

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<sup>11</sup> M.J. Faddy, M.D, Gosden, & R.G. Gosden, A Demographic Projection of The Contribution of Assisted Reproductive Technologies To World Population Growth. 2018 *Reproductive Biomedicine Online*, 36(4), 455-458.

<sup>12</sup> V.M. Wolff, & T. Haaf, In Vitro Fertilization Technology and Child Health: Risks, Mechanisms and Possible Consequences. *Deutsches Ärzteblatt International*, 117(3), 23.

<sup>13</sup> S.C. Esteves, M. Roque, G. Bedoschi, T. Haahr, & P. Humaidan, Intracytoplasmic Sperm Injection for Male Infertility and Consequences for Offspring. 2018 *Nature Reviews Urology*, 15(9), 535-562.

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dish. GIFT requires at least one patent fallopian tube and is less commonly performed compared to IVF.<sup>14</sup>

- d) **Zygote Intrafallopian Transfer (ZIFT):** ZIFT is similar to IVF but involves the transfer of fertilized embryos (zygotes) into the woman's fallopian tubes rather than her uterus. The embryos are transferred within 24 hours after fertilization to ensure they are at the zygote stage. ZIFT may be recommended when there are concerns about embryo development or uterine factors affecting implantation.<sup>15</sup>
- e) **Surrogacy:** Surrogacy involves a woman (surrogate) carrying a pregnancy for another individual or couple (intended parents). Depending on the arrangement, the surrogate may be genetically related to the child (traditional surrogacy) or not (gestational surrogacy), using either her own eggs or those of a donor. Surrogacy arrangements can involve ART procedures such as IVF to facilitate embryo transfer to the surrogate's uterus.<sup>16</sup>

These types of ART offer various options for individuals and couples facing infertility, allowing them to pursue their goal of starting or expanding their families. Each technique has its own indications, success rates, and considerations, and the choice of ART method depends on individual circumstances and medical recommendations.

### 3.0 The Use of Artificial Intelligence in Assisted Reproductive Technology

Artificial intelligence (AI) is finding applications across various sectors, including healthcare, particularly in the field of medicine. In reproductive medicine, there is exploration into new AI-based methods. Individuals or couples facing infertility often experience significant emotional

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<sup>14</sup> R.T. Hull, Gamete Intrafallopian Transfer (Gift). 2019 In *Encyclopedia of Reproductive Technologies* (Pp. 251-254). Routledge.

<sup>15</sup> S.F. Jongh, *Gift and Zift: Is There a Place for These Procedures in a New Era Of Assisted Reproduction?* (Doctoral Dissertation)

<sup>16</sup> N.H. Patel, Y.D. Jadeja, H.K. Bhadarka, &N.R. Sodagar, Insight into Different Aspects of Surrogacy Practices. 2018 *Journal of Human Reproductive Sciences*, 11(3), 212.

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distress and a diminished quality of life.<sup>17</sup> The inability to conceive may challenge their existential outlook, as reproduction is a fundamental aspect of many people's life visions.<sup>18</sup> Despite advancements in reproductive technologies, infertility still affects millions worldwide. The drive behind AI development in reproductive medicine is to enhance patient treatment and prognosis by leveraging large datasets for meaningful insights.<sup>19</sup>

Artificial Intelligence (AI) is increasingly playing a pivotal role in advancing Assisted Reproductive Technology (ART), offering a range of benefits that encompass improved clinical outcomes, enhanced patient care, and more efficient treatment protocols. One significant application of AI in ART is its capacity to analyze extensive datasets comprising patient demographics, medical histories, genetic profiles, and reproductive parameters.<sup>20</sup> Through sophisticated algorithms, AI can identify patterns, correlations, and predictive markers that aid clinicians in tailoring personalized treatment plans for individuals undergoing fertility treatment.<sup>21</sup> By leveraging AI-driven data analysis, ART practitioners can optimize treatment strategies to maximize success rates while minimizing risks and complications associated with procedures such as in vitro fertilization (IVF).<sup>22</sup>

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<sup>17</sup>G. Briganti, & O. Le Moine, Artificial Intelligence in Medicine: Today and Tomorrow.2020 *Frontiers in Medicine*, 7, 27.

<sup>18</sup>K.Y. Chu, D.E. Nassau, H. Arora, S.D. Lokeshwar, V. Madhusudhana, & R. Ramasamy, Artificial Intelligence in Reproductive Urology. 2019 *Current Urology Reports*, 20, 1-6.

<sup>19</sup> C. Lovis, Unlocking the Power of Artificial Intelligence and Big Data in Medicine. 2019, *Journal of Medical Internet Research*, 21(11), e16607.

<sup>20</sup> Ibid

<sup>21</sup> M.K. Santos, J.R. Ferreira Júnior, D.T. Wada, A.P. Tenório, M.H. Nogueira-Barbosa, & P.M. Marques, Artificial Intelligence, Machine Learning, Computer-Aided Diagnosis, and Radiomics: Advances in Imaging Towards to Precision Medicine. 2019, *Radiologia Brasileira*, 52, 387-396.

<sup>22</sup> N. Zaninovic, & Z. Rosenwaks, Artificial Intelligence in Human In Vitro Fertilization and Embryology.2020, *Fertility and Sterility*, 114(5), 914-920.

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Another area where AI demonstrates substantial potential in ART is in image recognition and analysis.<sup>23</sup> Embryo selection is a critical aspect of IVF, and traditionally, embryologists visually assess embryo quality based on morphological characteristics.<sup>24</sup> However, this process is subjective and prone to variability among practitioners. AI-powered algorithms can automate and standardize embryo assessment by analyzing images captured during the fertilization process.<sup>25</sup> By employing machine learning techniques, AI can accurately evaluate embryo quality, leading to more precise selection for implantation and ultimately improving the chances of successful pregnancy outcomes.<sup>26</sup>

Furthermore, AI facilitates the development of predictive models that forecast the likelihood of successful pregnancy outcomes based on various patient-specific factors.<sup>27</sup> These predictive models take into account factors such as age, fertility history, hormonal profiles, and genetic predispositions to generate personalized prognoses for patients undergoing ART.<sup>28</sup> By providing clinicians with actionable insights derived from AI-driven predictive modeling, healthcare providers can offer more informed counseling and decision-making support to patients, thus optimizing treatment plans and improving overall patient satisfaction.

In addition to its clinical applications, AI in ART holds promise for streamlining administrative processes and enhancing operational efficiency within fertility clinics. AI-driven systems can automate routine tasks such as appointment scheduling, patient communication, and medical record management, allowing healthcare providers to allocate more time and resources to direct

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<sup>23</sup> L. Drukker, J.A. Noble & A.T. Papageorghiou, Introduction to Artificial Intelligence in Ultrasound Imaging in Obstetrics and Gynecology. 2020, *Ultrasound in Obstetrics & Gynecology*, 56(4), 498-505.

<sup>24</sup> M.F. Kragh, & H. Karstoft, Embryo Selection with Artificial Intelligence: How to Evaluate and Compare Methods? 2021, *Journal of Assisted Reproduction and Genetics*, 38(7), 1675-1689.

<sup>25</sup> Ibid

<sup>26</sup> Ibid

<sup>27</sup> P. Vogiatzi, A. Pouliakis, & C. Siristatidis, An Artificial Neural Network for The Prediction of Assisted Reproduction Outcome. 2019, *Journal of Assisted Reproduction and Genetics*, 36, 1441-1448.

<sup>28</sup> Ibid



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patient care.<sup>29</sup> Moreover, AI-enabled decision support systems can assist clinicians in interpreting complex datasets and guiding treatment decisions in real-time, thereby facilitating more efficient and effective delivery of care to patients undergoing fertility treatment.<sup>30</sup>

Despite its tremendous potential, the integration of AI into ART also presents challenges and ethical considerations that warrant careful attention. Issues such as data privacy and security, algorithmic bias, and regulatory oversight must be addressed to ensure responsible and equitable use of AI in reproductive medicine. By addressing these challenges and leveraging the transformative capabilities of AI, the field of ART stands poised to achieve significant advancements in improving fertility outcomes, enhancing patient care, and reshaping the landscape of reproductive healthcare for years to come.

#### **4.0 Legal Framework for Artificial Intelligence and Assisted Reproductive Technology**

In recent times, AI and ART have been a point of legal discussion in the national and international spheres. Where laws regulate health procedures, medical practitioners, patients, and the world are protected. The emergence of various issues in the field of AI and ART has led some countries to enact legislation and regulating guidelines. This section considers the legal frameworks related to AI and ART nationally and internationally. Unfortunately, Nigeria has no specific legal framework regulating Assisted Reproductive Technology (ART). Thus, Medical Facilities providing assisted reproductive technique services have no law regulating their practice.<sup>31</sup>

#### **4.1 National Legal Framework**

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<sup>29</sup> M.A. Riegler & T.B. Haugen, Artificial Intelligence in the Fertility Clinic: Status, Pitfalls and Possibilities. 2021, *Human Reproduction*, 36(9), 2429-2442.

<sup>30</sup> Ibid

<sup>31</sup> I. Tolulope, Conference Paper; Assisted Reproductive Techniques In Nigeria: Imperative For Legal Framework,

[https://www.researchgate.net/publication/335936837\\_assisted\\_reproductive\\_techniques\\_in\\_nigeria\\_imperative\\_for\\_legal\\_framework](https://www.researchgate.net/publication/335936837_assisted_reproductive_techniques_in_nigeria_imperative_for_legal_framework) Assessed December 4<sup>th</sup>, 2023

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Nigeria does not have comprehensive legislation specifically addressing assisted reproductive technology (ART). However, some legal frameworks and regulations indirectly touch upon certain aspects of ART such as The Nigerian Constitution and the National Health Act. The absence of specific legislation dedicated to ART poses challenges and uncertainties for individuals and clinics involved in these procedures.

#### **4.1.1 The Constitution of the Federal Republic of Nigeria (1999) as Amended (CFRN)**

Sections 15(3)(c), 17(3)(h), and 37 of the CFRN guarantee the right to privacy in family life and the need for government to promote and protect family. This set of rights embodies the right for consenting adults to establish a family and beget children. The Government must make rules that will preserve the parenthood and family unit. One such law made by the government is the Child's Rights Act.

#### **4.1.2 The National Health Act**

The National Health Act 2014 establishes the framework for regulating, developing, and managing the national health system. Part II of the Act deals with health establishment and technologies. The National Health Act also provides explicit guidelines for doctors on handling tissues and gametes, which are the end products of ART.<sup>32</sup>

Section 50 of the National Health Act 2014 provides that a person shall not: (a) manipulate any genetic material, including genetic material of human gametes, zygotes, or embryos; or (b) engage in any activity, including the nuclear transfer or embryo splitting for the cloning of human beings; (c) Import or export of human zygotes or embryos. It also provides that a person who contravenes or fails to comply with the provision of this section commits an offence and is liable on conviction to imprisonment for a minimum of five years with no option of fine.

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<sup>32</sup> National Health Act 2014 No 145 Federal Republic of Nigeria, Official Gazettes, s 51.

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An attempt was made in 2016 to enact an Act to provide a national framework for regulating and supervising reproductive technology and related matters.<sup>33</sup> However, the said bill did not receive the support of the Senate, nor was it assented to by the President.<sup>34</sup> The Nigerian government needs to enact comprehensive legislation specifically addressing ART. Such legislation would provide clarity on various aspects including the rights and responsibilities of parties involved, regulation of fertility clinics, and the legal status of children born through ART.

Having discussed laws on ART, it should be noted that as of February 2024, there are no specific laws in Nigeria governing the general public's usage of AI.

## **4.2 Legal Framework Regulating Artificial Intelligence and Assisted Reproductive Technology in Other Jurisdictions**

These laws and regulations are established in other countries relevant to rights under Assisted Reproductive Technology.

### **4.2.1 United Kingdom (UK)**

UK enacted comprehensive legislation to regulate ART and related practices, namely the Human Fertilization and Embryology Act of 1990. It was subsequently amended in 2008.<sup>35</sup> Some key features of the Act for ART in the UK have some necessary provisions that cannot be overlooked. The Act provides for the Human Fertilisation and Embryology Authority (HFEA) which is the regulatory body responsible for overseeing the use of ART and human embryo

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<sup>33</sup> The Assisted Reproductive Technology Bill 2016

<sup>34</sup> Ibid

<sup>35</sup> Human Fertilization and Embryology Act 2008, Cap 22.

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research in the UK. It licenses and monitors fertility clinics and research involving human embryos, ensuring compliance with legal and ethical standards.<sup>36</sup>

The HFEA licenses and regulates fertility clinics and laboratories where ART procedures such as in vitro fertilization (IVF), artificial insemination, and embryo storage are carried out. Clinics must adhere to strict standards regarding the quality and safety of procedures and the welfare of patients and any resulting children.<sup>37</sup> The Act prohibits using gamete and embryos that have not been certified or licensed by the Human Fertilization and Embryo Authority.<sup>38</sup> This implies that only permitted embryos can be implanted into the uterus using any technique in ART. The Act also prohibits human cloning.<sup>39</sup> Guidelines also exist for the screening of gamete and embryo donors, as well as the screening of embryos for genetic disorders or chromosomal abnormalities. These guidelines aim to balance the welfare of any resulting children with the reproductive autonomy of individuals and couples.<sup>40</sup>

The Act provides for mandatory counseling of all parties before any fertility service is offered to anyone. Consent and record keeping are also requirements of this Act.<sup>41</sup> Section 33 of the Act defines a mother of the Child as the woman carrying or who carries the pregnancy to term.

There is also a provision for consent and legal parenthood, where HFEA establishes requirements for informed consent from individuals undergoing ART procedures and ensures clarity regarding legal parenthood,<sup>42</sup> particularly in cases involving donated gametes or embryos.<sup>43</sup> The regulatory framework also governs research involving human embryos,

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<sup>36</sup> Human Fertilization and Embryology Act 2008, s. 5-8D

<sup>37</sup> Human Fertilization and Embryology Act 2008, s. 11-21

<sup>38</sup> Human Fertilization and Embryology Act 2008, s 3.

<sup>39</sup> Ibid

<sup>40</sup> Ibid

<sup>41</sup> Ibid

<sup>42</sup> Human Fertilization and Embryology Act 2008, s. 33-47

<sup>43</sup> Human Fertilization and Embryology Act 2008, Schedule 3, para 9-13

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including restrictions on the creation, storage, and use of embryos for research purposes.<sup>44</sup> Research must be conducted by strict ethical guidelines and requires specific authorization from the HFEA.<sup>45</sup>

While the existing legislation and regulatory framework in the UK primarily focus on traditional ART practices, such as IVF and gamete donation, they provide a foundation for addressing emerging technologies and practices, including those involving AI. As technologies evolve, regulatory bodies like the HFEA continue to review and update guidelines to ensure they remain relevant and effective in safeguarding the welfare of patients and any children born as a result of ART procedures.

#### **4.2.2 Australia**

The primary legislation relevant to ART in Australia is the Assisted Reproductive Treatment Act 2008 (ART Act), which is enforced at the state and territory level. Each state and territory in Australia have its regulatory authority responsible for overseeing ART practices and ensuring compliance with the ART Act and associated regulations. For example, in Victoria, the Victorian Assisted Reproductive Treatment Authority (VARTA) oversees the administration and regulation of ART.<sup>46</sup> .<sup>47</sup> Section 1 of the Act sets parameters for the implementation of the statutory provisions of ART. Section 5 provides for the welfare and interests of persons born or to be delivered because of treatment procedures. It stipulates that at no time should the use of the treatment procedures be for exploitation of the reproductive capabilities of men and women.<sup>48</sup>It further states that children born as the result of the use of donated gametes have a right to

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<sup>44</sup> Ibid

<sup>45</sup> Ibid

<sup>46</sup> Assisted Reproductive Treatment Act 2008, part 10, s.99.

<sup>47</sup> State Of Victoria Assisted Reproductive Treatment Act 2008 (No 76 Of 2008).

<sup>48</sup> Ibid Ss 7,11 And 13

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information about their genetic parents.<sup>49</sup>

The qualification to carry out the ART procedure is meant for registered medical doctors.<sup>50</sup> Part 6 of the Act contains comprehensive provisions on the keeping of registers and access to information about the donor, the child born through donor-gamete and parents of the child. Under the Australian Law a woman need not be married or cohabit with a partner to undergo the ART procedure.<sup>51</sup>

The Act ensures that fertility clinics and laboratories offering ART procedures must obtain accreditation and licenses from the relevant regulatory authority. These licenses ensure that clinics meet standards for safety, quality, and ethical practice. The ART Act also sets out requirements for obtaining informed consent from individuals undergoing ART procedures and addresses issues related to legal parenthood, including the rights and responsibilities of donors, recipients, and any resulting children.<sup>52</sup>

Regulations governing the recruitment, screening, and use of gamete donors (sperm and egg donors) are established to ensure the health and welfare of donors, recipients, and any children born because of donor conception.<sup>53</sup> The Act also includes provisions for different types of treatment procedures such as artificial insemination<sup>54</sup>. Fertility clinics are often required to provide counseling and support services to individuals and couples undergoing ART procedures, helping them to navigate the emotional, ethical, and legal aspects of fertility treatment which the Act also provides for.<sup>55</sup>

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<sup>49</sup> *Ibid*, s 16

<sup>50</sup> State Of Victoria Assisted Reproductive Treatment Act 2008, s 46.

<sup>51</sup> *Pearce v South Australian Health Commission* (1996) 66 Sasr 486 Par 23

<sup>52</sup> Assisted Reproductive Treatment Act 2008, s.20-22.

<sup>53</sup> Assisted Reproductive Treatment Act 2008, s.16

<sup>54</sup> Assisted Reproductive Treatment Act 2008, s.8

<sup>55</sup> Assisted Reproductive Treatment Act 2008, s.13-18.

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Overall, the regulatory framework for ART in Australia aims to balance the rights and interests of individuals seeking fertility treatment with considerations for the welfare of any children born because of ART procedures. The regulations are designed to promote safe, ethical, and responsible practices within the field of reproductive medicine.

#### **4.2.3 Universal Declaration on Bioethics and Human Rights (UNESCO, 2005)**

This declaration sets out principles and guidelines for the protection of human dignity, human rights, and fundamental freedoms in the field of life sciences and biomedicine. It emphasizes the importance of obtaining informed consent, protecting the rights of individuals involved in ART procedures, and ensuring equity and justice in accessing ART services.<sup>56</sup>

### **5.0 Legal and Ethical Implications of the Use of Artificial Intelligence in Assisted Reproductive Technology**

#### **5.1 Legal Implications**

AI in ART raises a host of legal implications that touch upon various aspects of patient rights, privacy, liability, and regulatory oversight. One key area of concern is data privacy and security. The use of AI in ART involves the collection and analysis of sensitive patient data, including medical histories, genetic information, and reproductive health records.<sup>57</sup> As such, healthcare providers and fertility clinics must adhere to stringent data protection regulations, to safeguard patient confidentiality and prevent unauthorized access or misuse of personal health information.

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<sup>56</sup> Article 3, 5, 6, 9 and 10 of Universal Declaration on Bioethics and Human Rights (UNESCO, 2005)

<sup>57</sup> D, Schönberger, Artificial Intelligence in Healthcare: A Critical Analysis of The Legal and Ethical Implications. *International Journal of Law and Information Technology*, 27(2), 2019, 171-203.

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The issue of liability presents a significant challenge associated with the utilization of AI in healthcare. As medicine becomes increasingly digitized and algorithms are integrated, new stakeholders are entering the healthcare arena. Among these are tech companies and programmers who play vital roles in the development, training, and testing of these systems. Should AI applications lead to treatment errors or incorrect diagnoses, this will inevitably prompt inquiries into accountability which can lead to a legal battle.<sup>58</sup> The complexity is compounded by the opaque nature of many machine learning (ML) applications, often likened to black boxes. This lack of transparency can erode patients' trust in AI applications pertinent to their care especially on information of liability where issues arise.<sup>59</sup> Moreover, navigating human-machine interactions presents its own set of challenges. Seasoned physicians in their respective fields tend to harbor greater skepticism toward AI systems, while less experienced practitioners may place undue reliance on them.

Furthermore, the development and deployment of AI algorithms in ART necessitate robust measures to address algorithmic bias and fairness. AI systems trained on biased or incomplete datasets may inadvertently perpetuate disparities in access to fertility treatment and healthcare outcomes.<sup>60</sup> Legal frameworks must be established to ensure transparency, accountability, and fairness in the design, validation, and deployment of AI technologies in reproductive medicine. Additionally, healthcare providers may be held liable for the consequences of AI-driven decision-making in ART, highlighting the need for clear guidelines and standards of care to mitigate legal risks and ensure patient safety.<sup>61</sup>

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<sup>58</sup>N. Naik, Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility? *Frontiers In Surgery*, 9, 2022, 266.

<sup>59</sup> Ibid

<sup>60</sup> M.A. Riegler, Artificial Intelligence in The Fertility Clinic: Status, Pitfalls and Possibilities. *Human Reproduction*, 36(9),2021, 2429-2442.

<sup>61</sup> N. Naik, Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility? *Frontiers In Surgery*, 9, 2022, 266.



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Another legal consideration pertains to the regulation of AI-enabled medical devices used in ART procedures. In many jurisdictions, medical devices incorporating AI technologies are subject to rigorous regulatory scrutiny to ensure their safety, efficacy, and quality.<sup>62</sup> Fertility clinics and medical device manufacturers must comply with applicable regulatory requirements, such as obtaining clearance or approval from regulatory agencies before marketing and using AI-driven devices in reproductive medicine. Failure to adhere to regulatory standards could result in legal consequences, including fines, sanctions, or product recalls.<sup>63</sup>

Patients undergoing fertility treatment must be fully informed about the potential risks, benefits, and limitations of AI-driven technologies, as well as their implications for treatment outcomes and reproductive choices.<sup>64</sup> Legal frameworks governing informed consent should encompass provisions for disclosing the use of AI in ART procedures and ensuring patients' understanding and voluntary participation. Furthermore, patients should have the right to opt out of AI-driven interventions if they have concerns about privacy, data security, or algorithmic decision-making.

The use of AI in ART presents a myriad of legal implications that necessitate careful consideration and proactive measures to address. From data privacy and algorithmic bias to regulatory compliance and patient consent, the legal landscape surrounding AI in ART is complex and evolving. Healthcare providers, policymakers, and stakeholders must collaborate to develop robust legal frameworks that balance innovation with patient safety, privacy, and legal principles in the rapidly evolving field of reproductive medicine. Failure to address these legal considerations adequately could undermine public trust, hinder innovation, and pose significant risks to the well-being of individuals seeking fertility treatment.

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<sup>62</sup> A. Haleem, Current Status and Applications of Artificial Intelligence (AI) In Medical Field: An Overview. *Current Medicine Research and Practice*, 9(6), 2019, 231-237.

<sup>63</sup> M.A. Riegler, Artificial Intelligence in The Fertility Clinic: Status, Pitfalls and Possibilities. *Human Reproduction*, 36(9), 2021, 2429-2442.

<sup>64</sup> T. Lysaght, AI-Assisted Decision-Making in Healthcare: The Application of An Ethics Framework for Big Data In Health And Research. *Asian Bioethics Review*, 11, 2019, 299-314.

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## 5.2 Ethical Implications

The use of AI in ART presents a myriad of ethical implications that touch upon issues of autonomy, equity, and the commodification of human life. One prominent concern is the potential for AI-driven decision-making to influence reproductive choices and outcomes. As AI algorithms analyse vast amounts of patient data to predict fertility outcomes and recommend treatment options, questions arise about the extent to which individuals should rely on machine-generated predictions and the impact of AI on patients' autonomy in making informed decisions about their reproductive health.<sup>65</sup> There is a need for transparency and informed consent to ensure that patients understand the role of AI in ART and have agency in determining their treatment preferences.<sup>66</sup>

Developing enhanced approaches for infertility treatment utilizing AI has the potential to elevate the likelihood of successful reproduction, particularly with the advent of novel methodologies requiring experimentation and participation. Nonetheless, there exist certain inherent risks.<sup>67</sup> In all forthcoming investigations regarding AI's integration into ART, the provision of well-considered information to prospective mothers or parents will be paramount. It is imperative to remain mindful of potential pitfalls when disseminating information to prospective mothers or parents; participants in studies may foster misguided hopes or unattainable expectations, especially in the face of contemporary, attention-grabbing innovations under examination.<sup>68</sup>

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<sup>65</sup> Park, C. W., Seo, S. W., Kang, N., Ko, B., Choi, B. W., Park, C. M., ... & Yoon, H. J. (2020). Artificial Intelligence in Health Care: Current Applications and Issues. *Journal Of Korean Medical Science*, 35(42).

<sup>66</sup>D. Schönberger, Artificial Intelligence in Healthcare: A Critical Analysis Of The Legal And Ethical Implications. *International Journal of Law and Information Technology*, 2019 27(2), 171-203.

<sup>67</sup> Kelly, C. J., Karthikesalingam, A., Suleyman, M., Corrado, G., & King, D. (2019). Key Challenges for Delivering Clinical Impact with Artificial Intelligence. *Bmc Medicine*, 17, 1-9.

<sup>68</sup> Ethics Committee of The American Society for Reproductive Medicine. Disparities In Access to Effective Treatment for Infertility in The United States: An Ethics Committee Opinion. *Fertil Steril* 2015; 104: 1104–1110.

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Women or couples enduring prolonged anguish due to infertility should be recognized as a vulnerable demographic. Given that participants in such studies might perceive this as their final opportunity to realize their desire for parenthood, meticulous precautions are essential to ensure voluntary involvement.<sup>69</sup>

Another ethical consideration is the potential for algorithmic bias and discrimination in AI-driven decision-making processes. AI algorithms trained on biased datasets may inadvertently perpetuate disparities in access to fertility treatment and healthcare outcomes, particularly among marginalized communities.<sup>70</sup> Addressing algorithmic bias requires ongoing efforts to diversify training data, develop fair and transparent algorithms, and implement mechanisms for bias detection and mitigation. Additionally, healthcare providers must ensure that AI technologies in ART adhere to principles of fairness, equity, and non-discrimination to uphold the ethical principles of justice and beneficence in reproductive medicine.

Moreover, the use of AI in ART raises broader ethical questions about the commodification of human life and the potential for exploitation in the pursuit of reproductive technologies.<sup>71</sup> As AI-driven interventions become increasingly sophisticated and accessible, there is a risk of prioritizing commercial interests over patients' well-being and autonomy. Ethical frameworks governing the use of AI in ART should prioritize the principles of patient-centered care, respect for human dignity, and the promotion of reproductive justice. This entails ensuring equitable

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<sup>69</sup> Husain W, Imran M. Infertility as Seen by The Infertile Couples from a Collectivistic Culture. *J Community Psychol* 2021; 49: 354–360.

<sup>70</sup>L.A. Celi, J. Cellini, & S. Yao, Sources of Bias in Artificial Intelligence That Perpetuate Healthcare Disparities—A Global Review. *Plos Digital Health*, 1(3), 2022, e0000022.

<sup>71</sup>D. Schönberger, Artificial Intelligence in Healthcare: a Critical Analysis Of The Legal And Ethical Implications. *International Journal of Law and Information Technology*, 2019 27(2), 171-203.

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access to fertility treatment, addressing social determinants of health that contribute to infertility, and prioritizing the holistic well-being of patients over profit-driven motives.<sup>72</sup>

Cultural and religious values play a significant role in shaping attitudes toward the use of AI in ART. Ethical implications arise when the application of AI in ART conflicts with or challenges these values. Different cultures and religions have varying perspectives on reproduction, parenthood, and family. Some may view certain ART procedures, such as in vitro fertilization (IVF) or gamete donation, as morally permissible or even encouraged, while others may have religious or cultural beliefs that prohibit or discourage these practices. Also, cultural, and religious traditions often influence ideals of family structure, lineage, and kinship ties. The use of AI in ART, such as donor conception or surrogacy, may challenge traditional notions of kinship and parental identity, leading to ethical dilemmas regarding the recognition of legal parentage, inheritance rights, and the social and emotional well-being of children born through these methods. Cultural and religious values also emphasize the importance of respecting tradition, customs, and community norms. Ethical implications arise when AI technologies in ART diverge from or conflict with traditional practices or cultural expectations surrounding reproduction, marriage, and family life. Balancing the introduction of new technologies with respect for cultural diversity and heritage requires sensitivity to the values and beliefs of diverse communities.

Finally, the centralization of AI-driven reproductive medicine services in advanced technological centers could lead to an initial rise in the costs of procedures and interventions deemed essential or desirable.<sup>73</sup> While this dynamic response to AI implementation might offer advantages for the reproductive autonomy of certain individuals, it also presents challenges from the perspectives of reproductive justice and the healthcare market economy, where services and expenses are collectively financed. This concentration may disadvantage specific patient groups with limited

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<sup>72</sup> Ibid

<sup>73</sup> P. Iftikhar, M.V. Kuijpers, A. Khayyat, A. Iftikhar, Artificial Intelligence: A New Paradigm In Obstetrics And Gynecology Research And Clinical Practice. *Cureus*, 2020 12(2).

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financial means or mobility.<sup>74</sup> Therefore, in ethical evaluations and considerations of the ramifications of technological advancements, it's imperative to address potential access barriers, availability issues, and the financing of services.

The ethical implications of using AI in ART underscore the need for careful consideration of principles such as autonomy, fairness, and justice in the design, implementation, and regulation of AI-driven interventions. Balancing the potential benefits of AI in improving fertility outcomes with the ethical concerns surrounding patient autonomy and algorithmic bias requires ongoing dialogue, interdisciplinary collaboration, and a commitment to upholding ethical principles in reproductive medicine. By addressing these ethical considerations proactively, stakeholders can harness the transformative potential of AI in ART while ensuring that patient rights, dignity, and well-being remain central priorities in the pursuit of reproductive health equity and justice.

## 6.0 Conclusion

In conclusion, the integration of AI into ART holds immense promise for revolutionizing fertility treatments and enhancing outcomes for individuals and couples struggling with infertility. AI technologies offer the potential to optimize various aspects of ART, from personalized treatment protocols to predictive analytics for embryo selection. However, alongside these opportunities come significant ethical, legal, and practical considerations. Issues such as data privacy, algorithm bias, and the potential exacerbation of healthcare disparities must be carefully addressed to ensure that the benefits of AI in ART are equitably distributed and responsibly implemented.

Moreover, as we navigate the complexities of AI in ART, it is imperative to maintain a patient-centered approach that prioritizes informed consent, transparency, and respect for reproductive autonomy. Ethical frameworks and regulatory guidelines must evolve in tandem with

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<sup>74</sup> M.P, Trolice, C. Curchoe, & A. Quaas, A. Artificial Intelligence—The Future Is Now. *Journal Of Assisted Reproduction and Genetics*, 38, 2021, 1607-1612.

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technological advancements to safeguard the well-being and rights of all individuals involved in fertility treatments. By fostering collaboration between clinicians, researchers, ethicists, and policymakers, we can harness the transformative potential of AI to advance reproductive medicine while upholding fundamental principles of justice, equity, and compassion. Ultimately, the responsible and inclusive integration of AI in ART has the power to redefine possibilities for family-building and empower individuals on their journey towards parenthood.

### **7.0 Recommendation**

Based on the potential benefits and challenges associated with the use of AI in Assisted Reproductive Technology (ART), several recommendations can be made to guide its legal, ethical, and effective implementation. Firstly, there is a critical need for interdisciplinary collaboration between reproductive specialists, AI developers, ethicists, and policymakers to develop robust laws, guidelines, and standards for the use of AI in ART. This collaborative approach can ensure that AI technologies are developed and deployed in a manner that prioritizes patient well-being, autonomy, and safety.

Secondly, transparency and accountability must be central principles in the development and deployment of AI algorithms in ART. This includes transparent reporting of data sources, algorithmic processes, and potential biases to both patients and healthcare providers. Furthermore, mechanisms for ongoing monitoring and evaluation of AI systems should be established to identify and address any unintended consequences or disparities in access and outcomes.

Thirdly, efforts should be made to promote equitable access to AI-driven ART technologies, particularly for marginalized and underserved populations. This may involve initiatives to reduce barriers to access, such as financial assistance programs or telemedicine services that enable remote consultations and monitoring.

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Finally, ongoing research and innovation are essential to continue advancing the field of AI in ART while addressing emerging ethical and practical challenges. Longitudinal studies are needed to evaluate the long-term safety, efficacy, and societal impacts of AI-driven reproductive technologies, ensuring that they remain aligned with evolving ethical standards and patient preferences.

In summary, the responsible integration of AI in ART holds great promise for improving fertility treatments and outcomes, but it requires careful attention to ethical, legal, and social considerations. By following these recommendations, stakeholders can work together to harness the transformative potential of AI while safeguarding the rights and well-being of individuals seeking reproductive assistance.