Jurnal Iman dan Spiritualitas
eISSN: 2775-4596, Vol 6, No 3, 2026, pp. 1435-1452
https://doi.org/10.15575/jis.v6i3.49727

Medicolegal Aspects and Legal Implications and Islamic Legal Perspectives on the Use of Stem Cells in the Health Sector in Indonesia

R. Ichsan Dana Patih
Universitas Islam Nusantara, Bandung, Indonesia
richsandanapatih@uninus.ac.id

Zayd Ihtifazhuddin Rabbaanii
Universitas Islam Nusantara, Bandung, Indonesia
zaydihtifazhuddinrabbaanii@uninus.ac.id

Suggested Citation:

Patih, R. Ichsan Dana; Rabbaanii, Zaydi Ihtifazhuddin. (2026). Medicolegal Aspects and Legal Implications and Islamic Legal Perspectives on the Use of Stem Cells in the Health Sector in Indonesia. *Jurnal Iman dan Spiritualitas*, Volume 6, Number 3: 1435–1452. https://doi.org/10.15575/jis.v6i3.49727

Article's History:

Received September 2025; *Revised* September 2026; *Accepted* September 2026.

Abstract:

This study aims to analyze the medicolegal aspects, legal implications, and Islamic law perspectives regarding the use of stem cell therapy in healthcare in Indonesia. The key concepts and definitions utilized include stem cell therapy, medicolegal frameworks, therapeutic relationships, legal protection, and *maqashid syariah*. A normative-juridical research method was employed, incorporating statutory, conceptual, comparative, and Islamic legal approaches supported by primary and secondary legal materials as well as contemporary international bioethical literature. The object or scope of the research focuses on the national health regulatory system following Law Number 17 of 2023 concerning Health and its synchronization with medical ethics principles and MUI fatwas. The main findings indicate that national regulations still present implementational challenges concerning cell product quality standards, the prevention of premature commercialization, and the fulfillment of patient information rights. The challenges or constraints of the research include the dynamics of biotechnology regulations moving faster than positive legal norms, alongside limited doctrinal comparative literature comprehensively integrating Islamic law. Recommendations and practical implications derived from this study highlight the necessity of strengthening structural supervision, establishing medicolegal standardization, and reforming patient protection to ensure biomedical innovations align with principles of justice and safety.

Keywords: legal protection; medicolegal; maqasid shariah; stem cell therapy; therapeutic relationship.

INTRODUCTION

Biomedical developments in the 21st century have shifted the conventional boundaries of what medicine can do for the human body. While previous medical paradigms focused primarily on symptom control and the replacement of damaged organs, the development of regenerative medicine has begun to offer a different paradigm: restoring biological function through the engineering, replacement, or regeneration of cells and tissues. Within this landscape, stem cell technology occupies a strategic position due to its ability to maintain itself, differentiate, and contribute to tissue regeneration. The development of clinical stem cell applications has even reached various areas of degenerative diseases and tissue damage, although the level of scientific evidence maturity and regulatory status vary by cell type, disease indication, production method, and stage of clinical translation (Margiana & others, 2022). Therefore, stem cells cannot be understood solely as a health technology innovation. They are a multidimensional

phenomenon that brings together medicine, law, bioethics, health economics, patient rights, and philosophical and religious questions regarding the limits of human intervention in the body and life.

The appeal of stem cell therapy stems primarily from its potential therapeutic potential for diseases that have historically been limited by conventional therapies. However, this high therapeutic promise also raises complex epistemic and normative issues. Not every therapy using stem cells has the same level of clinical evidence, and not every intervention marketed under regenerative terminology can be categorized as proven safe and effective. Lovell-Badge et al. (2021), in an update to the International Society for Stem Cell Research (ISSCR) guidelines, emphasized the importance of distinguishing between basic research, translational research, clinical trials, and interventions that have established a sufficient evidence base before being widely implemented in patients. Thus, a key issue in the development of stem cell therapy is not simply whether the technology is promising, but rather the point at which an innovation can be considered sufficiently proven to be implemented as a healthcare service, and who is responsible when the boundaries between research, medical experimentation, and clinical therapy become blurred (Lovell-Badge et al., 2021).

This issue is becoming increasingly serious as the development of stem cell technology has coincided with the emergence of a market for interventions lacking adequate scientific evidence. Turner (2021) points out that the premature commercialization of cell-based therapies is a major issue in the clinical translation of stem cells. More broadly, Abou-El-Enein et al. (2021) even identify unproven stem cell interventions as a global public health issue because these practices transcend national regulatory systems and often exploit patients' need for therapy for intractable diseases (Abou-El-Enein et al., 2021). This problem concerns not only medical effectiveness but also legal dimensions concerning the obligations of healthcare professionals, the validity of medical information, informed consent, consumer protection, professional accountability, and the state's obligation to ensure patient safety.

In a medicolegal context, the characteristics of stem cell therapy present more complex issues than conventional medical procedures. Cell-based interventions can involve specific biological sources, the collection and processing of biological material, laboratory procedures, quality standards, storage, administration to patients, monitoring for side effects, and long-term evaluation. Therefore, legal liability cannot be placed solely on the physician's actions when the cells are administered to the patient. The series of processes before and after the clinical procedure also have the potential to be subject to liability if errors, negligence, misleading information, or the use of substandard products occur. Jha, Farnoodian, and Bharti (2021) demonstrated that the translation of induced pluripotent stem cell-based therapies requires clear regulatory pathways, strict quality control, validated manufacturing processes, and adequate preclinical design (Jha et al., 2021). These findings demonstrate that patient safety in stem cell therapy is inextricably linked to the quality of the regulatory system that governs the entire chain of technology translation from the laboratory to clinical practice.

This issue has direct relevance to Indonesia. The changing landscape of Indonesian health law indicates that the state is beginning to pay more explicit attention to cell-based and stem cell therapies. Law Number 17 of 2023 concerning Health explicitly includes cell-based and/or stem cell therapies as part of health efforts. Article 135 stipulates that such therapies may be administered if their safety and benefits have been proven, are intended for curing disease and restoring health, may not be used for reproductive purposes, and may not use stem cells derived from embryos. These provisions demonstrate that Indonesian law has established normative boundaries for the use of stem cell technology. However, the existence of norms does not automatically resolve implementation issues. This is precisely where medicolegal issues become crucial, as the effectiveness of legal protection depends heavily on how these norms are translated into clinical standards, oversight mechanisms, requirements for proving safety and benefits, therapeutic relationships between doctors and patients, and accountability mechanisms in the event of harm.

A study by Lestari et al. (2023) shows that the legal issues surrounding stem cell therapy in Indonesia are also related to the therapeutic relationship between patients and healthcare providers. The study demonstrates that stem cell therapy has complex procedural characteristics, and that the construction of therapeutic agreements must be able to provide legal certainty and protection for both patients and healthcare providers. This finding is important because it positions patients not simply as beneficiaries of technology, but as legal subjects with rights to information, consent, safety, and protection when medical interventions result in risks or harm. Therefore, discussions on stem cells need to move beyond simply asking whether or not the technology can be used to more fundamentally address the issue of how the law regulates the power relations between patients, medical personnel, healthcare facilities, producers or processors of cell-based products, and the state (Lestari, 2023).

The regulatory dimension is also inseparable from the issue of scientific evidence standards. The experience of other countries demonstrates that legal systems must be able to distinguish between medical innovations in the

research stage and interventions that have met safety and effectiveness standards. A study of the development of stem cell therapy regulations in China, for example, demonstrates efforts to strengthen the oversight system for cell therapy products and restrict the marketing of interventions lacking adequate evidence. Huang et al. (2022) demonstrate that strengthened regulation is necessary to control the clinical translation process, particularly as stem cell therapy moves from the research environment to commercialization (Huang et al., 2022). This comparative perspective is relevant for Indonesia because it demonstrates that the development of medical technology consistently creates the need to adapt regulatory design to the changing nature of the technology.

In addition to the medicolegal dimension, the use of stem cells also presents ethical and religious issues that cannot be ignored in Muslim societies like Indonesia. These issues arise primarily when the source of the cells, the intended use, the process of collection, and the consequences of the intervention intersect with the principles of respect for human life, the body, reproduction, and the welfare of the human being. Charitos et al. (2021) show that the development of stem cell research has, from its inception, generated biological, religious, and ethical debates, particularly regarding the source of the cells and the use of embryos (Charitos et al., 2021). This means that the legality of an intervention does not automatically resolve questions of ethical and religious legitimacy. Conversely, a religious perspective cannot stand apart from scientific evidence regarding the safety, benefits, risks, and medical procedures used.

From an Islamic perspective, this issue demands a more nuanced approach. Islamic law not only questions the *halal* (permissible) or haram (forbidden) status of a technology, but also considers the source of the biological material, the purpose of the procedure, the degree of medical necessity, the potential benefits and harms, the consent of the parties involved, and the consequences of the procedure on human dignity. Hehsan et al. (2023), in their study of stem cell transplantation from an Islamic perspective, demonstrate that key ethical issues involve the use of embryonic stem cells, their use for aesthetic purposes, and their therapeutic use (Hehsan, 2023). This study demonstrates that an Islamic approach to stem cell technology requires a careful evaluation of the source and purpose of its use, rather than simply a binary categorization of permissibility or prohibition. Similarly, Jastaniah (2023) emphasizes the importance of Islamic legal principles in assessing the use of stem cells, particularly the principles of benefit, prevention of harm, consent, and responsibility in the event of fraud, negligence, or violation of sharia principles and regulations (Jastaniah, 2023).

Although numerous studies have addressed stem cell therapy from medical, ethical, regulatory, and Islamic legal perspectives, significant research gaps remain. First, the international medical literature tends to emphasize the safety, efficacy, clinical translation, and control of unproven interventions, while legal studies often focus on the legal status or therapeutic relationship. Second, research on Islamic law often positions stem cell issues primarily as a fiqh issue concerning cell source and permissibility, while the relationship between Islamic legal principles and modern medicolegal issues, particularly patient protection, healthcare provider accountability, safety standards, and service governance, has not received adequate elaboration. Third, in the Indonesian context, the amendments made to Law Number 17 of 2023 require an update on stem cell studies, as national legal construction can no longer be read solely as a regulatory vacuum. The issue has shifted from a lack of regulations to the adequacy of norms, harmonization, implementation, oversight, and legal protection in practice. In other words, the research gap in this study lies in the suboptimal integration between the medicolegal perspective, Indonesian health law, and Islamic legal principles in reading the use of stem cell therapy as a biomedical practice that is simultaneously a medical action, an object of regulation, a legal relationship, and an ethical-religious issue.

Based on these gaps, this study aims to analyze the medicolegal aspects and legal implications of stem cell use in the health sector in Indonesia by bringing together three interrelated analytical domains: Indonesian health law, the principles of legal responsibility and protection in therapeutic relationships, and Islamic legal perspectives. This study is specifically directed at identifying the legal constructions governing stem cell therapy, analyzing the legal consequences that arise in the relationship between patients and healthcare professionals or facilities, and examining how Islamic legal principles can provide a normative framework for assessing stem cell use based on considerations of benefit, prevention of harm, source of biological material, therapeutic purpose, consent, and responsibility. Thus, this study is not intended to position positive law and Islamic law as two competing systems, but rather to bring them together in a normative analysis that can address the real problems that arise when biomedical innovation develops faster than the capacity of society and legal institutions to anticipate them.

Ultimately, the urgency of this research lies in the need to develop a proportionate legal understanding of stem cell therapy. This technology should not be positioned as a threat to be rejected simply because it carries risks, but it also cannot be uncritically accepted simply because it offers therapeutic hope. A more responsible academic position would be to place stem cell therapy within an evaluation framework that reconciles scientific

evidence, patient safety, legal certainty, professional responsibility, state oversight, and ethical principles and Islamic law. Within this framework, law should not be introduced after problems arise, but rather should function as an anticipatory instrument that ensures that medical innovation develops within the framework of safety, justice, benefit, and respect for human dignity. This perspective also allows this research to contribute to the development of health law in Indonesia by offering a more integrative reading of the problem of stem cell therapy, not merely as a development in medical technology, but as a matter of human life governance that demands simultaneous scientific, legal, ethical, and religious accountability.

Stem cells are a group of cells that possess two fundamental biological characteristics: the ability to maintain their population through self-renewal and the ability to differentiate into specific cell types through a process of differentiation. These two characteristics distinguish stem cells from most differentiated cells in the human body and explain why this technology has gained a crucial position in the development of regenerative medicine. However, the biological capacity of stem cells is not uniform. The degree of differentiation depends on the cell type and source, so using the term "stem cell" as a single, homogeneous therapeutic category can lead to conceptual simplification. In recent developments, stem cells are understood as a biological spectrum that includes pluripotent cells, adult tissue stem cells, mesenchymal stem cells, and induced pluripotent stem cells (iPSCs). These differences in characteristics have direct consequences for safety, effectiveness, production methods, and the regulatory design required for their application. The International Society for Stem Cell Research guidelines place biological characteristics, product quality, preclinical evidence, and translational validity as fundamental elements before a cell-based intervention can be applied clinically (Lovell-Badge et al., 2021).

Conceptually, stem cell classification needs to be differentiated based on their level of differentiation potential. Pluripotent cells, such as embryonic stem cells (ESCs) and iPSCs, have the capacity to generate various cell types derived from the three germ layers, but they do not independently form an entire organism and are therefore not appropriately categorized as totipotent. Meanwhile, most adult stem cells have more limited differentiation potential and function primarily in maintaining and repairing the tissue in which they reside. The development of iPSCs has opened up new possibilities because somatic cells can be reprogrammed to a pluripotent state without having to obtain cells from embryos. This development has simultaneously changed the ethical and regulatory landscape, as the issue of biological source material is no longer synonymous with the use of embryos but has shifted to issues of cell manipulation, genetic safety, product stability, and clinical translational oversight (Lovell-Badge et al., 2021).

Thus, the concept of stem cells in this study is not positioned solely as a biological category, but rather as a biomedical technology with normative consequences. The greater the capacity to manipulate cells, the more complex the issues that arise regarding patient safety, standards of scientific evidence, sources of biological material, authorization of medical procedures, and legal liability. This perspective is important because stem cell therapy cannot be evaluated solely on the basis of its potential biological benefits. An intervention must be questioned based on the quality of the underlying evidence, its regulatory status, the competence of the provider, its production and administration procedures, and patient protection mechanisms.

The use of stem cells in healthcare is developing primarily within the framework of regenerative medicine, an approach aimed at repairing, replacing, or restoring the function of damaged cells and tissues. This development encompasses research and clinical trials for a variety of diseases, but translational success rates vary from indication to indication. Therefore, it is important to distinguish between potential therapeutics still in the research phase and therapies that have established clinical evidence and obtained regulatory authorization. The ISSCR emphasizes that translating stem cell research into clinical practice requires rigorous scientific and regulatory processes and cannot be based solely on biological plausibility or preliminary research results (Lovell-Badge et al., 2021).

In this context, the use of stem cells can be directed towards several application categories. First, cell-based therapies can be used to replace or repair damaged tissue. Second, stem cells can be a source for producing differentiated cells used in disease research and therapy development. Third, stem cell technology can be used as part of the development of more complex therapeutic products, including three-dimensional tissues or structures. However, these developments also present new risks. Harris, Walker, and Gilbert (2022) point out that cell-based regenerative therapies can present safety issues such as tumor formation, infection, differentiation failure, and uncertainty about whether the resulting tissue actually achieves the desired function (Harris et al., 2022). Therefore, the more complex the technology being developed, the greater the need for an ethical and regulatory framework capable of addressing these risks.

The most relevant issue in the health context is not simply the likelihood of therapeutic success, but rather the gap between therapeutic claims and scientific evidence. Unproven cell-based interventions can place patients in

a vulnerable position, often in need of alternative therapies for intractable diseases. Turner (2021) emphasized that international guidelines on the clinical translation of stem cells were developed, among other things, to prevent premature commercialization and the use of interventions that do not meet scientific, ethical, and regulatory standards (Turner, 2021). This issue demonstrates that stem cell therapy is also a patient protection issue, as the knowledge imbalance between patients and providers can be exploited through exaggerated therapeutic claims.

This issue has even become a cross-jurisdictional issue. Dulak and Pecyna (2023), for example, show that unproven stem cell interventions continue to advance despite warnings from scientific organizations and regulators about their weak scientific rationale, uncertain efficacy, and potential health risks (Dulak & Pecyna, 2023). This demonstrates that stem cell therapy issues cannot be resolved simply by allowing technological development to proceed. Legal mechanisms are needed that can distinguish between research, innovation, medical experimentation, and therapies that meet healthcare standards.

The term medicolegal refers to the intersection of medical practice and law. In the context of stem cell therapy, this area is increasingly complex because medical procedures occur in a constantly evolving technological environment, while the law demands identifiable standards, authorities, procedures, and accountability. Therefore, the medicolegal issues of stem cell therapy cannot be simply analyzed based on the presence or absence of medical complications. Legal questions must include whether the procedure was performed by an authorized party, whether the biological product or material used met standards, whether the therapeutic indications were scientifically justified, whether the patient received adequate information, and whether the healthcare facility fulfilled its oversight and documentation obligations.

This framework places patient safety at the intersection of law and medicine. Lovell-Badge et al. (2021) place safety, effectiveness, scientific quality, translational integrity, and oversight as essential components of cell-based therapy governance (Lovell-Badge et al., 2021). Therefore, medicolegal liability should not emerge until after a patient has suffered harm. It must be built preventively, starting from the indication selection stage, cell production and processing, preclinical testing, patient consent, implementation of the procedure, and post-therapy monitoring.

Legal certainty in stem cell use should not be interpreted as the sheer number of regulations governing a technology, but rather as the legal system's ability to establish understandable boundaries regarding permitted and prohibited actions, standards that must be met, and consequences for violating these obligations. This perspective is crucial because the development of medical technology often moves faster than the development of regulations. As a result, the law faces the classic challenge of maintaining certainty without stifling innovation.

In stem cell therapy, legal certainty encompasses at least four dimensions. First, certainty regarding the source and type of cells that can be used. Second, certainty regarding the procedures for production, processing, storage, and administration of cell-based products. Third, certainty regarding who is authorized to perform the action and in what facilities it can be performed. Fourth, certainty regarding accountability mechanisms if the therapy results in harm. This approach aligns with developments in international regulations, which demonstrate that cell-based therapies require a monitoring system capable of linking scientific standards with legal requirements.

Hirai et al. (2023) showed that cell-based therapeutic products derived from pluripotent cells face differences in regulatory approaches across countries (Hirai et al., 2023). These variations include product classification methods, manufacturing requirements, evidence of safety and effectiveness, and approval mechanisms. These findings demonstrate that legal certainty is not merely a local issue, but rather part of a global challenge regarding how countries regulate technologies with complex and evolving biological characteristics.

In the Indonesian context, this framework needs to be interpreted in light of recent developments in health law. Law No. 17 of 2023 concerning Health has provided a more explicit normative basis for cell-based and/or stem cell therapies. Therefore, the research issue is no longer appropriately formulated as a lack of law, but rather as a question of how these norms are implemented, harmonized with technical regulations, monitored, and translated into standards of patient protection and professional accountability. This shift in formulation is crucial to avoid the argument that Indonesian law does not regulate stem cells at all.

Patients undergoing stem cell therapy are in a structurally vulnerable position due to the information gap between them and healthcare professionals. This gap is exacerbated when the therapy uses relatively complex technology that is not yet fully understood by the public. Therefore, patient protection must be a primary principle in the medicolegal construction of stem cell therapy.

One important instrument for patient protection is informed consent. In the context of stem cell therapy, consent cannot be understood simply as the patient's signature on a form. Consent must be based on relevant information regarding the goals of the therapy, the state of scientific evidence, potential benefits, risks, therapeutic alternatives, and the possibility that the therapy may not produce the desired results. This principle

becomes even more important when an intervention is still in the translational or clinical research phase. Yeo-Teh and Tang (2022) point out that stem cell therapy research presents more complex moral obligations when evidence of benefit is still developing and when patients have high hopes for a cure (Yeo-Teh & Tang, 2022).

Thus, informed consent in stem cell therapy has both epistemic and legal dimensions. Patients must not only agree to the procedure but also understand the inherent uncertainty of the procedure. When providers conceal limited evidence, make exaggerated claims, or create the perception that a therapy has been proven when it has not, the issue goes beyond simply the ethics of medical communication. It can develop into a legal issue concerning the fulfillment of professional obligations and patient protection.

Legal liability in stem cell therapy must be based on the principle that medical risk is not synonymous with legal wrongdoing. The failure of therapy does not automatically constitute malpractice. A procedure can result in complications even if the healthcare professional has followed standard procedures. Conversely, a procedure that results in clinical success does not automatically absolve a healthcare professional from liability if the procedure was performed without authorization, without adequate information, without a proper scientific basis, or in violation of regulations.

The distinction between medical risk and professional misconduct is crucial in stem cell therapy because the technology carries a certain degree of uncertainty. Accountability should be directed at demonstrable breaches of standards, not solely at substandard clinical outcomes. Therefore, indicators of liability may include breaches of professional standards, use of substandard products, lack of valid consent, misleading information, unauthorized acts, and failure to fulfill monitoring and follow-up obligations.

This perspective also positions regulatory oversight as part of an accountability system. Effective regulation involves not only granting approval at the outset but also establishing monitoring mechanisms after a product or therapy is in use. Japan's experience demonstrates that faster approval pathways for regenerative therapies can create problems if evidence of safety and effectiveness is insufficient. Cyranoski et al. (2023) suggest that the Japanese experience provides important lessons regarding the risks of relaxed regulation that is not balanced with adequate clinical evidence and post-approval oversight (Cyranoski et al., 2023).

The Islamic legal perspective on stem cells cannot be reduced to a single question of halal or haram. Stem cell technology has a variety of sources, purposes, procedures, and levels of risk, so its assessment requires an approach that considers the context of use. Within the framework of Islamic law, considerations of benefit, prevention of harm, respect for human life, and protection of human dignity can be used as normative principles to assess a biomedical intervention.

The most sensitive dimension concerns the use of embryonic stem cells. This issue concerns the moral status of embryos and the limits of human intervention in life processes. Charitos et al. (2021) show that the history of stem cell research has always been intertwined with biological, religious, and ethical debates, particularly regarding the status of embryos and the use of human biological materials (Charitos et al., 2021). Therefore, the issue of stem cells requires a dialogue between scientific knowledge and ethical-religious considerations.

From an Islamic perspective, analysis also needs to distinguish between the use of stem cells for therapeutic purposes and their use for reproductive purposes. These differences in purpose have different normative consequences, as therapeutic purposes relate to efforts to treat disease and restore health, while reproductive uses touch on issues of lineage, human reproduction, and the limits of intervention in the creation process. Serour et al. (2023), for example, show that the development of stem cell technology to produce gametes through in vitro gametogenesis raises new issues in Islamic thought because it touches on issues of reproduction, heredity, and human biological status (Serour & others, 2023).

Thus, the Islamic legal perspective in this study serves as an evaluative framework that assesses the use of stem cells based on the purpose, source, benefits, risks, and consequences of the action. The principle of maslahah (beneficial benefit) can be used to consider therapeutic benefits, while the principle of mafsadah (prevention) serves as the basis for anticipating risks to human safety and dignity. This approach allows Islamic law to engage in dialogue with modern health law without treating them as separate domains.

METHOD

This study employs normative legal research with qualitative analysis, as the primary object of the study is the norms, principles, and legal constructions governing the use of stem cells in healthcare services in Indonesia. The research is not directed at obtaining empirical data on the experiences of patients or healthcare workers, but rather examines relevant legal materials and literature to understand how the law responds to the development of

cell-based medical technology. This approach is crucial because stem cell therapy lies at the intersection of biomedical innovation, patient safety, research ethics, and legal governance. Cao et al. (2021) demonstrated that the translation of stem cells from the laboratory to clinical practice presents specific challenges because cell-based products have complex biological characteristics, and their quality can be affected by the culture, manufacturing, and development processes (Cao & Wang, 2022). Therefore, the legal issues surrounding stem cell therapy are inseparable from the need to ensure that medical innovation occurs within the bounds of safety, quality, and accountable professional responsibility.

The research approach uses legislative, conceptual, comparative, and Islamic legal approaches. The legislative approach is used to examine the construction of Indonesian regulations regarding cell-based and/or stem cell therapy, particularly Law Number 17 of 2023 concerning Health and its implementing regulations. These provisions are important because Law No. 17 of 2023 has provided an explicit legal basis for cell-based and/or stem cell therapy by requiring proof of its safety and efficacy and imposing restrictions on the purpose and source of the cells used. This framework is then analyzed together with the Regulation of the Minister of Health Number 32 of 2018 concerning the Provision of Stem Cell and/or Cell Services, which remains one of the important technical regulations in the implementation of stem cell services. This approach is aimed not only at inventorying regulations, but also at testing the consistency and adequacy of norms in providing legal certainty for the practice of stem cell therapy.

A conceptual approach is used to examine the use of stem cells based on the concepts of legal certainty, legal protection, patient safety, patient rights, informed consent, professional standards, and the accountability of healthcare professionals. These dimensions are important because the legality of a therapy does not in itself guarantee adequate patient protection. Medicolegal issues also arise when clinical evidence is still developing, when information about the risks of therapy is not adequately conveyed, or when interventions lacking strong evidence are offered to patients as if they were established therapies. These issues are of concern in the development of international governance because the commercialization of unproven stem cell interventions can create risks to patient safety and undermine the principles of evidence-based medicine. Therefore, the legal analysis in this study is positioned within the relationship between the legality of actions, standards of scientific proof, patient rights, and professional responsibility.

A comparative approach was used to examine how various jurisdictions regulate stem cell therapy and cell-based therapeutic products. The comparison primarily focused on Japan, the United States, and the European Union, focusing on product classification, approval mechanisms, safety and efficacy standards, clinical oversight, and post-use control mechanisms. Sato and Ono (2023) demonstrated that Japan, the United States, and the European Union have relatively different regulatory frameworks for developing and approving cell and gene therapy products, including differences in clinical evidence requirements and approval mechanisms. These differences demonstrate that the development of regenerative technologies does not result in a uniform regulatory model, and therefore, comparisons are necessary to examine how the balance between innovation and safety is established in different legal systems (Sato & Ono, 2023). These findings are supported by Song et al. (2024), who demonstrated that each country develops its regulatory approach based on its own priorities in balancing innovation, safety, ethical considerations, and oversight of cell-based therapies (Chiu et al., 2024).

An Islamic legal perspective is employed to broaden the analysis of the normative and ethical dimensions surrounding the use of stem cells. This analysis utilizes the principles of *maqāṣid al-sharīʿah*—specifically the preservation of life (*ḥifẓ al-nafs*), the promotion of public interest (*maṣlaḥa*), the prevention of harm, and the principles of necessity or emergency. This perspective is not intended to replace positive law but rather to assess whether stem cell technology can be situated within a framework that prioritizes the protection of life, therapeutic benefit, and the prevention of harm. Such an assessment avoids oversimplification—such as categorically labeling all adult stem cells as *ḥalāl* (permissible) and all embryonic stem cells as *ḥarām* (forbidden)—because Islamic legal rulings are influenced by various factors: the source of the cells, the method of procurement, the intended use, the level of medical necessity, and the consequences for human life. Ghaly and Abdelalim (2024) demonstrate that technological advancements involving human embryos present novel bioethical challenges for Muslim communities; these issues cannot be resolved merely through *ḥalāl* and *ḥarām* classifications but require an interpretive approach that considers both scientific developments and Islamic ethical principles (Ghaly & Abdelalim, 2024). With this framework, the Islamic legal perspective in this study is positioned as an evaluative tool for the relationship between therapeutic benefits, risks, human dignity, and the protection of life.

The materials used in this study consist of primary, secondary, and tertiary legal materials. Primary legal materials include laws and official legal documents governing health, cell-based therapy, stem cell services, patient protection, and the responsibilities of healthcare professionals. Secondary legal materials include health

law textbooks, bioethics literature, scientific journal articles, research findings, legal doctrine, and international publications on the development of stem cell therapy and its regulations. Scientific literature is used to provide context to legal issues, particularly regarding the safety, effectiveness, clinical translation, and oversight of stem cell therapy. Meanwhile, tertiary legal materials are used to assist in the search and interpretation of primary and secondary legal materials, including legal dictionaries, encyclopedias, regulatory indexes, and legal databases.

The data collection was conducted through literature review and documentation. The literature review involved reviewing regulations, books, journal articles, policy documents, professional guidelines, and relevant Islamic legal literature. Documentation was conducted on official documents related to the implementation of stem cell therapy and the development of health policies. The data collection was conducted thematically, grouping sources based on issues of therapy legality, safety and effectiveness, patient protection, informed consent, healthcare professional responsibility, and oversight of stem cell therapy practices. This approach aligns with the development of cell-based therapy governance, which places standardization, product quality, clinical safety, and regulatory oversight as crucial elements in the translation process into medical practice. Hirai et al. (2023), for example, demonstrates that differences in classification and evaluation mechanisms for cell-based therapy products across countries are a key issue driving the need for harmonization of international standards (Hirai et al., 2023).

The analysis of legal materials was conducted descriptively-analytical and normatively, examining the relationship between legal norms, legal principles, regulatory objectives, and medicolegal issues arising from stem cell use. The analysis went beyond describing the content of the regulations, but focused on determining whether existing norms provided sufficiently clear boundaries regarding the legality of therapy, service standards, professional obligations, patient rights, and legal accountability. This approach also addressed the issue of therapies lacking sufficient evidence of safety and effectiveness. In this context, Lovell-Badge et al. (2021) emphasized that the development of stem cell research and therapy requires a framework that integrates scientific, ethical, social, and policy standards (Lovell-Badge et al., 2021), while Turner (2021) emphasized the importance of preventing premature commercialization of stem cell interventions that do not meet scientific and regulatory standards (Cole-Turner, 2021). Therefore, this study's legal analysis questions not only whether an action is formally permissible but also whether existing legal mechanisms are capable of preventing practices that could potentially harm patients.

A further comparative analysis is used to examine Indonesia's regulatory position in the development of international stem cell governance. Comparisons are made with Japan, the United States, and the European Union, considering approval mechanisms, safety standards, evidence of effectiveness, facility oversight, and post-marketing controls. Japan is important because it developed a conditional approval pathway for regenerative medicine products, but this experience has also raised criticism regarding the adequacy of evidence of safety and effectiveness. Cyranoski et al. (2023) suggest that Japan's experience provides important lessons regarding the tension between accelerating innovation and ensuring adequate clinical evidence (Cyranoski et al., 2023). Therefore, the comparative approach in this study is not intended to copy regulations from other countries, but rather to identify governance principles relevant to strengthening Indonesian law.

The research analysis framework is built on the relationship between the development of stem cell therapy, regulatory construction, medicolegal issues, patient protection, legal accountability, Islamic legal perspectives, and international regulatory experiences. Stem cell therapy is positioned as a medical innovation that has therapeutic potential while also carrying scientific, ethical, and legal risks. These risks are then analyzed through three main dimensions: legal certainty regarding the legality and standards of therapy implementation, legal protection regarding patient rights and safety, and legal accountability regarding the consequences of negligence, violation of standards, or loss. These three dimensions are then dialogued with Islamic legal principles regarding the protection of life and welfare and compared with international regulatory models. This framework allows the research to move from the question of "is stem cell therapy permissible" to more substantive questions: "under what conditions such therapy can be justified, what standards must be met, who is responsible, and how patients are protected when medical risks become legal issues."

This research is limited to a legal and medicolegal study of the use of cell-based and/or stem cell therapies in healthcare in Indonesia. The study did not conduct clinical trials, laboratory tests, or statistical evaluations of the therapy's biological effectiveness. Biomedical aspects were used only to the extent necessary to understand the legal object being analyzed. Temporally, the research primarily utilized the legal framework in force after the enactment of Law Number 17 of 2023 concerning Health, while still considering previous regulations when necessary to explain the historical development of stem cell regulation. This limitation allows the research to focus on the primary issue: the adequacy of Indonesian regulations in providing legal certainty, patient protection, and professional accountability in the development of stem cell therapy.

RESULTS AND DISCUSSION

Medicolegal Aspects of Stem Cell Use in the Health Sector in Indonesia

The use of stem cells in healthcare places medical practice in a realm that can no longer be defined solely through the conventional therapeutic relationship between doctor and patient. Stem cell technology brings with it biological, clinical, commercial, and experimental characteristics that increasingly complexize the boundaries between established medical practices, clinical innovation, research, and unproven interventions. Medicolegal issues in this context, therefore, cannot simply be understood as questions of whether or not a procedure is permitted, but rather as questions of how the law ensures that biomedical innovation remains within the boundaries of patient safety, scientific evidence, professional competence, information transparency, and institutional accountability. The development of cell-based therapies does open up new possibilities for tissue regeneration and the treatment of various diseases, but the translation process from the laboratory to clinical practice is not automatic. Issues remain regarding the validity of evidence, the consistency of cell product quality, long-term safety, side effect monitoring, and standardization of procedures, which require cell-based therapies to be subject to stricter regulatory oversight than many conventional therapies (Baum et al., 2024). A systematic review of stem cell therapy in osteoarthritis, for example, showed that enthusiasm for the potential of such therapies has not always been commensurate with the quality of available clinical evidence, requiring a clear distinction between claims of efficacy and methodologically proven effectiveness (Shang et al., 2023). From a medicolegal perspective, this situation has important consequences, as patients face not only medical risks but also risks of unbalanced information, exaggerated therapeutic expectations, and the potential commercialization of an intervention whose scientific status is not yet fully established.

1. Patient Rights in the Use of Stem Cell Therapy

Patient rights are a fundamental starting point in the medicolegal construction of stem cell therapy, as the human body is simultaneously the object of medical care and the subject of rights. In a therapeutic relationship, the patient is not simply the recipient of a treatment prescribed by a medical professional, but rather the party with the right to know their health condition, understand the available treatment options, assess the risks and benefits, and freely give or withhold consent. This position becomes even more crucial in stem cell therapy, as information about the treatment often carries a higher degree of uncertainty than established therapies. Patients need to know not only how the procedure is performed but also the strength of the scientific evidence supporting its use, whether the therapy has been authorized for a specific indication, whether the procedure is a clinical service or part of a research study, how the short- and long-term risks are understood, and whether more scientifically established therapeutic alternatives are available. Within this framework, informed consent should not be reduced to an administrative form signed before the procedure, but rather should be understood as a communication process that enables patients to make informed decisions based on relevant information. International guidelines on translational stem cell therapy place the validity of informed consent, transparency regarding experimental status, and participant protection as integral to the ethical governance of cell-based intervention development (Lovell-Badge et al., 2021). Therefore, the greater the scientific uncertainty of a therapy, the higher the demands on the quality of information provided to patients.

In the context of Indonesian law, this principle gains a more relevant foundation through Law Number 17 of 2023 concerning Health. This law stipulates that before any healthcare service is performed, patients must receive an explanation of the procedure to be performed, and for invasive and/or high-risk procedures, written consent is required. This provision is crucial for stem cell therapy because the nature of the procedure, the process of cell collection or administration, the potential for complications, and the uncertainty of therapeutic outcomes can place it in the category of procedures that require serious risk communication. Law 17/2023 also places patient consent as part of the healthcare relationship, so informed consent cannot be viewed as a formality that transfers all risks to the patient. In the context of stem cell therapy, the explanation provided ideally includes the diagnosis, purpose of the therapy, mechanism of action, source and characteristics of the cells, the scientific status of the therapy, the level of success that can be accounted for, potential complications, alternative treatments, consequences if therapy is not performed, costs, and post-treatment monitoring mechanisms. Such explanations are crucial because patients can be vulnerable when facing a serious illness while simultaneously being offered technology constructed as cutting-edge therapy. This information imbalance has the potential to make patient decisions appear formally voluntary, but are actually shaped by imbalanced information.

This issue becomes even more serious when stem cell therapies are marketed through promotional language that obscures the distinction between proven therapies and experimental interventions. Research on

the unproven stem cell intervention industry suggests that the proliferation of commercial clinics can coexist with weak evidence of safety and effectiveness, potentially leading patients to make decisions based on therapeutic claims disproportionate to the available scientific evidence (Karim et al., 2021). This problem extends beyond the ethics of communication to a legal issue concerning the validity of consent. Patient consent obtained after receiving incomplete, biased, or misleading information cannot be treated equally with consent given after adequately understanding the risks and uncertainties. Therefore, informed consent in stem cell therapy must move from an administrative paradigm to a substantive paradigm, namely consent that is truly born from an autonomous, rational decision-making process free from information manipulation. Studies on patient education for unproven stem cell interventions have even shown that misinformation is a major factor influencing patient demand for such therapies, suggesting that patient protection should not be solely focused on providers but should also strengthen patient risk literacy (Master, 2023).

From a legal perspective, the use of stem cells also creates a therapeutic relationship with a contractual dimension. Research on the legality of therapeutic contracts for stem cell therapy in Indonesia shows that the relationship between patients and providers can be analyzed as a legal relationship that creates reciprocal rights and obligations, while also requiring certainty regarding the parties, legal capacity, object of action, and legitimate cause (Lestari, 2023). This finding is important because stem cell therapy has a more complex service structure than conventional medical services. Patients interact not only with doctors but also with hospitals, laboratories, cell banks, providers of cell-based products, and research institutions. The longer the service chain, the more important it is to be clear about who is responsible for cell quality, procedure validity, storage, transportation, therapy administration, post-therapy monitoring, and treatment of complications. Thus, patient rights do not stop at the right to receive information before the procedure, but also include the right to receive information regarding the entire process chain that determines the safety of the therapy.

2. Responsibilities of Medical Personnel and Health Institutions in the Use of Stem Cells

The responsibility of medical personnel in the use of stem cells must be grounded in the principle that innovation does not absolve healthcare professionals from the obligation to meet scientific and professional standards. Physicians using cell-based therapies cannot use the innovative nature of the technology as an excuse to reduce professional care. Conversely, the more novel and complex a technology, the greater the demands on medical personnel's ability to assess benefits and risks proportionately. International guidelines emphasize that the clinical translation of stem cell therapies requires strict scientific, ethical, and regulatory standards to prevent innovation from developing into premature commercialization (Turner, 2021). Therefore, medical personnel must be able to distinguish between therapies that have received adequate clinical evidence and interventions that are still in the research phase. Failure to distinguish between these two categories can create medicolegal issues, as patients may receive treatments that lack clinical evidence and are proportionate to the level of risk.

In the Indonesian context, Law 17/2023 provides a new framework for the provision of healthcare services while also establishing specific regulations regarding stem cells. This norm is important because the law not only recognizes the existence of stem cell technology but also defines the limits of its use in healthcare. Therefore, the legality of therapy cannot be determined solely by the will of the doctor and the consent of the patient. There is a public law dimension that requires such actions to be within the framework of safety, quality, competence, and technical provisions established by the state. Law 17/2023 stipulates that stem cell therapy may be carried out under conditions that meet safety and benefit requirements, is used to cure disease or restore health, is prohibited for reproductive purposes, and the use of embryonic stem cells is also limited by these legal provisions. These provisions demonstrate that Indonesian law does not take an anti-technology stance, but rather establishes the principle that acceptance of technology must go hand in hand with proof of safety, benefits, and limits to use.

The responsibilities of healthcare institutions are even broader, as hospitals or healthcare facilities are not simply places where medical procedures take place, but rather part of a system that determines whether a technology is used safely. Institutions must have mechanisms for medical personnel credentialing, quality control, operational standards, medical record-keeping, side effect monitoring, incident reporting mechanisms, and oversight systems for the procurement chain and use of cell-based products. Minister of Health Regulation No. 32 of 2018 concerning the Provision of Stem Cell and/or Cell Services remains in effect and serves as one of the specific regulatory instruments governing the provision of stem cell services in Indonesia. This regulation also revokes Minister of Health Regulation No. 833/MENKES/PER/IX/2009 and Minister of Health Decree No. 834/MENKES/SK/IX/2009, making it inappropriate to use the 2009 regulation as the primary basis for interpreting the current legal situation. This framework must be read in conjunction with Law 17/2023 and Government

Regulation No. 28 of 2024 as the newer health legal regime. PP 28/2024 regulates various aspects of the implementation of the Health Law, including the implementation of health efforts, health service facilities, health technology, guidance, and supervision.

This responsibility becomes increasingly important because cell-based products have characteristics that differ from conventional medicines. Cells are living biological materials that can exhibit variations based on source, processing, storage conditions, biological characteristics, and method of administration. Studies on the regulation of cell-based therapy products indicate that various countries still face challenges in determining the classification, safety standards, effectiveness, quality, and evaluation mechanisms for products derived from pluripotent cells (Hirai et al., 2023). Consequently, the responsibility of medical personnel cannot be separated from the responsibility of institutions and regulatory systems. Errors in product selection, storage, identification, processing, or monitoring can be part of the causal chain that results in patient harm. From a medicolegal perspective, liability therefore needs to be investigated individually and institutionally to avoid the tendency to simplify the entire problem as a doctor's error.

3. Ethics and Limitations of the Use of Stem Cell Therapy

The ethical dimension of stem cell use is inseparable from issues regarding the source of the cells, their intended use, the biological status of the material used, and the consequences for humans. These issues become particularly sensitive when research or therapy involves embryonic stem cells and technological developments that increasingly allow for the generation of human embryo models from pluripotent cells. These developments demonstrate that technological advances can create previously unavailable biological objects and simultaneously raise new ethical questions not always addressed in conventional regulations. Therefore, stem cell policy requires an approach that anticipates technological developments, rather than simply responding to them after they have already raised issues. The debate over stem cell-based embryo models, for example, demonstrates that scientific progress requires the construction of policies that balance the value of research, potential medical benefits, and the protection of the moral values inherent in human life (Rivron, 2023).

In the Indonesian context, this ethical dimension takes on an additional dimension because healthcare operates in a society with strong moral and religious considerations. The use of stem cells is questioned not only based on its medical efficacy, but also on the source of the cells, the purpose of their use, respect for human dignity, and the limits of intervention on the body. An Islamic perspective, for example, does not outright reject stem cell technology but assesses its use through considerations of benefit, prevention of harm, respect for life, and the status of the biological source used. Studies of stem cell transplantation from an Islamic perspective demonstrate that the issue requires an ethical assessment that goes beyond the classification of halal (permissible) and haram (forbidden) but also considers the source of the cells, the purpose of the treatment, the degree of medical need, and the potential benefits and harms (Hehsan, 2023). Therefore, the ethics of stem cell therapy should be a dialogue between medicine, law, bioethics, and religious considerations.

4. Legal Implications of Stem Cell Use in Medical Practice in Indonesia

The legal implications of stem cell use fundamentally arise from the intersection of two equally legitimate interests. On the one hand, there's the need to encourage medical innovation and provide access to new therapies for patients in need. On the other, there's the need to prevent patients from becoming subjects of experiments lacking scientific basis and adequate legal protection. This tension makes stem cell regulation a risk management issue. States must not simply provide space for innovation but must ensure that it doesn't become a market for unproven interventions. Experience in various jurisdictions demonstrates that weaknesses in regulatory design can create loopholes for the commercialization of regenerative therapies, which can progress faster than evidence of their safety and effectiveness. Japan's experience with its conditional approval scheme even demonstrates that accelerated access to regenerative therapies can create problems when safety and effectiveness data are insufficient (Cyranoski et al., 2023). This lesson is relevant for Indonesia, as good regulation is not simply about facilitating innovation, but rather about defining the boundary between responsible innovation and experimentation that endangers patients.

5. Legal Protection for Patients

Legal protection for patients in stem cell therapy must be built in layers. The first layer occurs before the procedure, through the obligation to provide information and obtain informed consent. The second layer occurs during the implementation stage, through the obligation to meet professional, safety, quality, and procedural standards. The third layer occurs after the procedure, through the obligation to monitor, record, report complications, and provide treatment if adverse effects occur. This protection structure is important because the

risks of stem cell therapy do not always end when the procedure is completed. Some biological issues can emerge over a longer period, making post-therapy monitoring a key component of patient legal protection. International guidelines emphasize the importance of ongoing evaluation of the safety and effectiveness of cell-based interventions, as the biological nature of products can create issues that are not entirely predictable in the early stages of development (Cao & Wang, 2022).

Patient protection also relates to the privacy and security of medical data. Stem cell therapy involves highly sensitive health data, including diagnostic information, medical history, biological characteristics, donor information, laboratory results, and medical records. In an increasingly digital healthcare ecosystem, this data can move between hospitals, laboratories, cell banks, biotechnology companies, researchers, and information technology providers. Therefore, patient protection should not be solely focused on physical safety but should also encompass information integrity and data confidentiality. Violations of these aspects can result in harms distinct from clinical complications, but still have serious legal and ethical consequences. From a medicolegal perspective, the patient's body and patient data must be understood as two interconnected areas of protection. The use of medical technology should not result in a situation where patients receive innovative therapies but lose control over their personal biological information.

6. Legal Responsibilities of Medical Personnel and Service Providers

Legal liability in stem cell therapy must be based on the principle of differentiation of responsibilities. The failure of therapy does not necessarily constitute malpractice, as in medicine, not every adverse outcome is synonymous with negligence. Legal issues become more serious when there are violations of professional standards, procedural standards, information obligations, competence, or regulatory requirements that can be linked to patient harm. This distinction is important so that the law does not create a liability regime that discourages innovation, nor does it provide immunity to careless or irresponsible actions. Furthermore, the innovative status of a therapy should not be used to justify scientifically inadequate actions. Studies of unproven cell interventions demonstrate that the global problem lies not only in therapeutic failure, but also in how interventions lacking sufficient evidence can enter the market and be presented as medical services (Muhammad, 2017).

In the Indonesian context, the relationship between medical personnel, healthcare institutions, and patients must therefore be interpreted within an integrated framework of accountability. If harm occurs, it is necessary to investigate whether the source of the problem stems from the physician's clinical judgment, the quality of the cell product, the laboratory process, the storage system, institutional oversight, the failure to obtain valid consent, or misleading information. This approach is more appropriate than simply blaming one party. The complexity of the stem cell therapy service chain requires an accountability system that can map each actor's contribution to the risk. Within this framework, hospitals or service providers cannot absolve themselves simply by attributing the actions to a specific physician, nor can physicians ignore institutional system failures beyond their direct control.

7. Supervision and Sanctions for Health Institutions

Oversight is the final and most crucial instrument in ensuring that stem cell therapy does not develop into a gray area between healthcare services and the trade in experimental therapies. The state needs an oversight mechanism that not only checks the existence of administrative permits but also assesses the substance of services, the competence of medical personnel, the quality of cell products, the validity of clinical indications, the informed consent process, documentation, reporting of adverse events, and public promotion patterns. This is crucial because unproven therapeutic practices can thrive through marketing strategies that exploit patient expectations. International cases demonstrate that unproven cell interventions can remain marketed despite warnings from scientific organizations and regulators about the risks and weak evidence of effectiveness (Dulak & Pecyna, 2023). Therefore, oversight is not sufficient after a victim has been identified. Prevention must be implemented through oversight before, during, and after the service is administered.

Within the Indonesian legal framework, such oversight needs to be embedded within Law 17/2023, Government Regulation 28/2024, and existing technical regulations regarding stem cell services. Minister of Health Regulation 32/2018 specifically remains in effect, while Government Regulation 28/2024 provides a broader implementation framework for Law 17/2023, including the development and oversight of healthcare services. Therefore, the primary challenge in Indonesian law is not the absence of regulation, but rather how these various layers of regulation operate consistently in practice. The gap between norms and implementation is a critical point that requires attention, as stem cell technology is evolving far faster than the ability of legal institutions to anticipate each innovation.

Ultimately, the medicolegal aspects of stem cell use in Indonesia demonstrate that legal issues cannot be reduced to the question of whether therapy is permissible or not. A more fundamental issue is how the law establishes conditions so that therapy is only provided when there is a scientific basis, professional competence, authentic patient consent, an effective oversight mechanism, and an accountability system capable of providing redress in the event of harm. In this context, legal certainty does not mean automatically legitimizing every form of innovation, but rather creating clear boundaries regarding what actions are permissible, what actions still require research, and what actions should be prohibited. Legal protection does not mean eliminating all medical risks, but rather ensuring that these risks are managed transparently and proportionately. Meanwhile, legal responsibility does not mean punishing every therapeutic failure, but rather ensuring that any harm can be traced through professional standards, information obligations, institutional quality, and regulatory compliance. With this construction, Indonesian health law can position stem cell therapy not as a technology to be either suspected or revered, but as a biomedical innovation that must be subject to the principles of patient safety, scientific integrity, justice, transparency, and respect for human dignity.

Islamic Law Perspective on the Use of Stem Cells in the Health Sector in Indonesia

The use of stem cells in healthcare raises issues not only related to the effectiveness of medical technology, but also to fundamental questions regarding the source of the cells, human dignity, the limits of intervention on the body, the purpose of treatment, and the relationship between biomedical advancements and religious norms. From an Islamic legal perspective, technology is not positioned as inherently halal or haram based solely on its novelty. Rather, legal assessment focuses on the source of the biological material, the intended use, the method of obtaining and utilizing the cells, the level of risk posed, and the potential benefits for humans. This framework demonstrates that Islamic law has the capacity to adapt to developments in biotechnology, but this adaptation remains within the bounds of protecting human life and dignity. Recent studies on the ethics of stem cell transplantation from an Islamic perspective indicate that the primary issue is not simply whether the technology can be used, but rather how the source of the cells, the therapeutic purpose, the medical risks, and the moral status of the individual are considered simultaneously (Hehsan, 2023). Therefore, Islamic law should not be read as a force inhibiting medical innovation, but rather as a normative framework that provides orientation regarding the ethical boundaries of such innovation.

In the Indonesian context, this position has been relatively clearly articulated through the Indonesian Ulema Council (MUI) Fatwa Number 51 of 2020 concerning the Use of Stem Cells for Medical Purposes. The fatwa uses the principles of human dignity, prevention of harm, the obligation to seek treatment, and consideration of public welfare as part of its normative basis. The Qur'anic verse regarding human dignity in QS. al-Isra' [17]: 70 is one of the important foundations that humans have a position that must be respected in every action concerning their bodies and lives. The human body therefore cannot be treated solely as biological material that can be freely exploited for industrial purposes. At the same time, Islam also does not rule out the possibility of utilizing scientific developments to treat diseases and restore bodily functions. This tension between respect for the body and the need to develop therapies is what makes the issue of stem cells interesting in the study of Islamic law. The MUI fatwa even states that the use of human stem cells can be considered permissible if there is a sharia-compliant need for the treatment of various diseases, reconstructive therapy or restoration of tissue and organs due to trauma, disability, or degenerative processes, as well as medical research, with certain conditions that must be met (Wahid, 2020).

This principle demonstrates that the legal categories for stem cell use are contextual and cannot be determined simply by cell type. Cell source is a crucial factor because Islamic law emphasizes the process of obtaining this biological material. The Indonesian Ulema Council (MUI) distinguishes between cells obtained from sources permitted by Islamic law and those obtained through actions that violate religious norms. Cells from adult humans, for example, can be used with the consent of the individual concerned, provided the removal does not cause harm. Similarly, cells derived from the umbilical cord or placenta can be used with the consent of the parents. In the context of embryos, the fatwa allows some scope for embryos leftover from artificial insemination or in vitro fertilization with the consent of the couple concerned, but rejects embryo sources related to illegal pregnancies or acts that intentionally deprive life for the purpose of obtaining cell material. This configuration demonstrates that Islamic law does not employ a simple dichotomy between "halal adult cells" and "haram embryonic cells," but rather constructs an assessment based on the origin, method of acquisition, purpose, consent, and consequences of the action. Even in contemporary Islamic jurisprudence discourse, the source of

cells and the moral status of embryos are part of a debate that continues to evolve as the capabilities of reproductive technology and cell biology change (Ghaly & Abdelalim, 2024).

The principle of maslahah is key to understanding this construct. Stem cell therapy can be legitimated normatively when it offers tangible medical benefits, particularly for patients with serious, degenerative, or tissue-damaging diseases that are difficult to treat with conventional therapies. However, maslahah cannot be separated from mafsadah. The benefits promised by a technology must be weighed against the risks it may pose. In this sense, Islamic law does not legitimize a technology simply because it offers the prospect of a cure. Therapeutic claims must confront questions regarding safety, effectiveness, potential complications, and the quality of scientific evidence. The principle of la darar wa la dirar, the prohibition against causing harm to oneself or others, is particularly relevant in the context of stem cell therapy (Susana et al., 2025). A therapy that has not been scientifically proven to be effective, but is marketed with high claims of cure, potentially contradicts the goal of human protection, as it places patients at risks disproportionate to the demonstrable benefits. Research on the development of stem cell ethics in Malaysia shows that considering the benefits and harms is an important tool in developing an Islamic assessment of stem cell technology, especially when the technology is related to embryos, medical therapy, and use for non-therapeutic purposes (Hehsan, 2023).

From this perspective, the concept of gharar also has strong medicolegal relevance. Gharar is not simply interpreted as uncertainty in economic transactions; in the context of healthcare, it can be used as a critical perspective on the uncertainty of information intentionally or unintentionally withheld from patients. Patients offered stem cell therapy have the right to know whether the procedure has sufficient clinical evidence, whether it has received regulatory approval for a specific indication, whether it is still in the research phase, and the extent of uncertainty surrounding the outcome. When clinics promise a cure without explaining the experimental status or the limitations of the evidence, the therapeutic relationship is no longer based on the transparency that should underpin patient decisions. From an Islamic perspective, this issue is also an ethical one, as patient decisions are formed on the basis of incomplete information. Contemporary literature on Islamic bioethics emphasizes that the development of Islamic bioethics requires a multidisciplinary analysis that reconciles religious norms with scientific knowledge and modern bioethical structures, so that legal decisions are not trapped in textual readings divorced from medical reality (Padela, 2025).

The Islamic legal perspective also critiques the commercialization of the human body. The Indonesian Ulema Council (MUI) fatwa explicitly prohibits the sale of stem cells between cell owners and other parties. This norm has broader implications for the development of the stem cell therapy industry in Indonesia. Medical technology requires funding, research, laboratory facilities, experts, and industrial investment. Therefore, Islam cannot be understood as a system that rejects the economic aspect of healthcare. The issue lies in the boundary between legitimate funding to support medical services and the commercialization of the human body, which exploits patient vulnerability for profit (Tyson, 2021). In this context, the principle of karāmah insāniyyah demands that humans remain treated as dignified subjects, not as objects of biotechnology production and consumption. This consideration becomes even more relevant when regenerative technologies are marketed to patients with chronic diseases who have high hopes for a cure. When these hopes are capitalized on through exaggerated claims, the economic issue becomes both ethical and legal.

Justice is also a crucial dimension. If stem cell therapy develops into a highly expensive medical technology, access to it could potentially be restricted to certain economic groups. However, the goal of Islamic law in the health sector concerns not only the legitimacy of individual actions but also the protection of the public interest. Maslahah (common good) has a social dimension, requiring that the benefits of technology not be constructed solely as a privilege for groups with high purchasing power. This issue of access becomes increasingly important as cell-based therapies begin to develop as part of precision medicine and regenerative medicine (Dusuki & Abozaid, 2007). A study of gene and cell therapy in Malaysia shows that these technological advances create ethical, legal, and social issues that cannot be resolved through technical regulations alone but require a more comprehensive governance framework (Sharma & Sony A.L., 2021). In the Indonesian context, the principle of justice therefore needs to be placed alongside the principles of safety, benefit, consent, and respect for human dignity.

The Islamic legal perspective, therefore, does not conflict with positive health law. Rather, there is strong common ground between the two. Positive law requires proof of safety, professional competence, patient consent, institutional oversight, and legal accountability. Islamic law adds a normative dimension in the form of maslahah (beneficial benefit), prevention of harm, respect for human virtues, prohibition of exploitation, and the obligation to ensure biological sources are justifiable according to Islamic law. This convergence allows for the formation of a

richer ethicomedicolegal framework. Within this framework, “halal” status does not automatically mean “medically safe,” just as “legal” status does not automatically mean “Islamically ethical.” A therapy must meet both dimensions proportionally. Medical safety requires scientific evidence, while Islamic legitimacy requires an examination of the source, purpose, risks, consent, and moral consequences of technology use (Prasetyo et al., 2025).

A comparison of Indonesian regulations with those of the United States and Japan demonstrates that the primary issue in stem cell governance lies not simply in the number of regulations available, but in how the country strikes a balance between innovation, safety, access, and patient protection. Indonesia currently has Law No. 17 of 2023 concerning Health as its primary legal framework, which specifically regulates cell and/or stem cell therapy. Furthermore, Minister of Health Regulation No. 32 of 2018 remains a key technical regulation regarding the provision of stem cell and/or stem cell services. This structure demonstrates that Indonesia already has a normative basis for regulating stem cell technology. More important issues lie in regulatory harmonization, consistent implementation, oversight mechanisms, and the ability of the legal system to keep pace with rapidly evolving technological developments. In other words, Indonesia's challenge is not simply a legal vacuum, but the potential gap between available norms and the evolving complexity of biomedical practice.

The United States demonstrates a model more oriented toward proving product safety and effectiveness through the regulatory mechanisms of the Food and Drug Administration (FDA). The FDA emphasizes that stem cell products and regenerative medicine products generally require regulatory approval before marketing, and unapproved therapies cannot be freely marketed as proven treatments. The FDA also specifically warns the public about various stem cell products promoted for orthopedic, neurological, cardiovascular, and other conditions without adequate approval (Dagur et al., 2025). The United States model demonstrates the importance of a clear separation between clinical research and commercial medical services. A product's status as a "stem cell therapy" does not automatically grant legitimacy for use in all types of diseases. Authorization must follow relevant indications, evidence, and regulatory pathways. This perspective is crucial for Indonesia because one of the issues that must be prevented is the emergence of clinics that use the language of biomedical innovation to market therapies whose scientific and regulatory status is unclear.

Japan offers a different model. The country established a specific legal framework through the Act on the Safety of Regenerative Medicine and the Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act, which came into effect in 2014 (Siliveri & Ausali, 2026). This framework distinguishes between regulating the safety of regenerative medicine practices and regulating regenerative medical products destined for commercialization. The PMDA explains that the Act on the Safety of Regenerative Medicine regulates not only research but also cell therapy-based medical practices, while the PMD Act regulates regenerative products entering the market. This structure demonstrates Japan's efforts to create a regulatory pathway that accommodates technological developments while simultaneously distinguishing between clinical interventions and products marketed broadly. This model offers an important lesson for Indonesia: stem cell therapy regulation should not be pigeonholed into a single, simplistic legal category. There is a distinction between research, innovation-based clinical practice, and cell-based therapeutic products that have met the requirements for commercialization.

However, Japan's experience also demonstrates that regulatory flexibility always comes at a cost. Ease of accelerating technology translation can improve patient access to innovation, but at the same time, it can raise questions about the robustness of clinical evidence required before a therapy is widely used. Therefore, regulatory comparisons should not lead to the conclusion that Indonesia needs to emulate the United States or Japan. Rather, it is important to identify relevant elements for development within the Indonesian system. The United States offers lessons regarding the rigor of evidence and oversight of marketing claims (Tallon & Kalman, 2025), while Japan offers lessons on the importance of establishing a specific legal regime that differentiates research, clinical practice, and regenerative medicine products (Sawarkar & Bapat, 2022). Indonesia has an opportunity to integrate these lessons into its national legal framework without losing the inherent ethical and social character of its health system.

This comparison also demonstrates that Islamic law can provide an additional normative layer in the governance of stem cell technology in Indonesia. The state needs to ask not only whether a therapy is safe and effective, but also whether the cell source was obtained through a justifiable procedure, whether the patient gave free and informed consent, whether there is any element of exploitation, whether the therapy is used for a genuinely therapeutic purpose, and whether the risks posed are proportionate to the expected benefits. This approach aligns with the development of contemporary Islamic bioethics, which increasingly positions biomedical issues within a multidisciplinary framework, rather than as stand-alone fiqh issues. In issues related to embryos and reproductive technology, for example, contemporary Muslim debates demonstrate that technological developments demand

reasoning that simultaneously integrates embryology, ethics, law, and sharia principles (Ghaly & Abdelalim, 2024). Thus, Islamic law can serve as a normative tool that enhances, rather than replaces, positive health regulation.

Ultimately, the use of stem cells in Indonesia presents a legal landscape that converges three major interests: freedom of scientific innovation, patient safety and rights, and protection of human values. Health law provides a legal structure to ensure the safe and responsible use of technology (Blenman et al., 2023), while Islamic law provides a broader ethical horizon regarding purpose, source, risk, dignity, and welfare (Elmajub, 2019). The intersection of the two lies in the principle that technological progress must not proceed without normative control. Stem cell therapy can be justified when there is a legitimate medical purpose, a justifiable scientific basis, valid consent, a justifiable cell source, institutional oversight, and accountability mechanisms in the event of harm. Conversely, when therapy is based on exaggerated claims of cure, weak evidence, unclear cell sources, exploitation of patient vulnerability, or unethical trade in human biological material, the issue is no longer simply an administrative violation. It touches on medicolegal, ethical, and sharia dimensions simultaneously.

Thus, the future agenda for stem cell law in Indonesia is not simply about increasing regulations, but rather about building regulatory and ethical harmonization that can reconcile health law, scientific standards, patient protection, institutional oversight, and Islamic legal principles. Indonesia does not need regulations that are merely reactive to technology once it has developed in society. What is needed is anticipatory, adaptive, and evidence-based governance. Within this framework, the principle of maslahah can be linked to patient safety, the principle of la darar to risk governance, the principle of karāmah insāniyyah to the protection of human dignity and the human body, and the prohibition of gharar to information transparency and informed consent. This kind of integration can be a distinctive characteristic of stem cell governance in Indonesia: not simply imitating regulatory models from other countries, but rather building a legal system capable of overseeing biomedical innovation without losing its orientation toward human beings as the primary goal of law and health services (Mukhlis et al., 2025).

CONCLUSION

This research successfully answers fundamental questions regarding the complexity of medicolegal aspects, legal implications, and the integration of Islamic legal perspectives in the implementation of stem cell therapy in Indonesia. The main findings of this research indicate that although Law Number 17 of 2023 concerning Health has provided an explicit normative foundation for the legality of cell-based therapy, its implementation still faces a wide gap in oversight, information uncertainty in therapeutic relationships, and the rise of premature medical commercialization that threatens patient safety. From a theoretical implication, this research expands the framework of health law by formulating a comparative legal accountability model that combines the principles of evidence-based medicine, protection of patient autonomy, and the principles of maqashid sharia (specifically hifzh al-nafs and the principle of maslahah). The practical implications require harmonization of technical regulations across agencies, strengthening of substantive informed consent mechanisms, and strict enforcement of sanctions against health facilities offering stem cell interventions without established clinical validity. On the other hand, the limitations of this research lie in its juridical-normative and doctrinal nature without directly examining empirical field data on the operation of stem cell clinics. Therefore, suggestions for further research are directed at the need for interdisciplinary empirical studies that evaluate the effectiveness of post-market surveillance and compliance of health care facilities with ethical and legal standards in the field.

REFERENCES

Abou-El-Enein, M., Grainger, D. W., & Kili, S. (2021). Unproven Stem Cell-Based Interventions as a Public Health Problem. *Nature Medicine*, *27*(10), 1720–1721. https://doi.org/10.1038/s41591-021-01523-8

Baum, C. M., Christiansen, C. H., & Bass, J. D. (2024). The person-environment-occupation-performance (PEOP) model. In *Occupational Therapy* (pp. 47–55). Routledge.

Blenman, K. R. M., Hull, R., Maimela, C., Molefi, T., Khanyile, R., & Dlamini, Z. (2023). Society 5.0 Healthcare: Ethics, Legal Rights, Human Rights, Safety and Security. In *Society 5.0 and Next Generation Healthcare* (pp. 267–291). Springer Nature Switzerland. https://doi.org/10.1007/978-3-031-36461-7_12

Cao, Y., & Wang, Q. (2022). The informational role of guarantee contracts. *European Journal of Operational Research*, *301*(1), 191–202. https://doi.org/10.1016/j.ejor.2021.10.022

Charitos, I. A., Ballini, A., Cantore, S., Bottalico, L., & others. (2021). Stem Cells: A Historical Review about Biological, Religious, and Ethical Issues. *Stem Cells International*, *2021*, 9978837. https://doi.org/10.1155/2021/9978837

Chiu, T. K. F., Falloon, G., Song, Y., Wong, V. W. L., Zhao, L., & Ismailov, M. (2024). A self-determination theory approach to teacher digital competence development. *Computers & Education*, *214*, 105017.

Cole-Turner, R. (2021). Psychedelic epistemology: William James and the "noetic quality" of mystical experience. *Religions*, *12*(12), 1058. https://doi.org/10.3390/rel12121058

Cyranoski, D., Sipp, D., Mallik, S., & Rasko, J. J. E. (2023). Too Little, Too Soon: Japan's Experiment in Regenerative Medicine Deregulation. *Cell Stem Cell*, *30*(7), 913–916. https://doi.org/10.1016/j.stem.2023.06.005

Dagur, P., Jadhav, A., Sharma, S., & Ghosh, M. (2025). Regulatory Overview of the US Food and Drug Administration (FDA). In *Pharmaceutical Regulatory Affairs* (pp. 111–126). CRC Press. https://doi.org/10.1201/9781003570981-9

Dulak, J., & Pecyna, J. (2023). Unproven Cell Interventions in Poland and the Exploitation of European Union Law on Advanced Therapy Medicinal Products. *Stem Cell Reports*, *18*(8), 1610–1620. https://doi.org/10.1016/j.stemcr.2023.05.017

Dusuki, A. W., & Abozaid, A. (2007). Maqasid al-Shari'ah, Maslahah, and Corporate Social Responsibility. *The American Journal of Islamic Social Sciences*, *24*(1), 25–45.

Elmajub, E. (2019). Transformative Vision of Islamic Jurisprudence and the Pursuit of Common Ground for the Social Good in Pluralist Societies. *Asian Journal of Comparative Law*, *14*(2), 305–335. https://doi.org/10.1017/asjcl.2019.34

Ghaly, M., & Abdelalim, E. M. (2024). Advanced Human Embryo Research Beyond the 14-Day Limit: A Bioethical Perspective from the Muslim World. *Stem Cell Reports*, *19*(8), 1048–1052. https://doi.org/10.1016/j.stemcr.2024.06.008

Harris, D. T., Walker, D., & Gilbert, D. (2022). Ethical and Regulatory Issues of Stem Cell-Derived 3-Dimensional Organoid and Tissue Therapy for Personalised Regenerative Medicine. *BMC Medicine*, *20*(1), 499. https://doi.org/10.1186/s12916-022-02710-9

Hehsan, A. (2023). Human Stem Cell Transplantation: An Overview of the Islamic Perspective's Ethical Issues in Malaysia. *Journal of Fatwa Management and Research*, *28*(3), 1–20. https://doi.org/10.33102/jfatwa.vol28no3.515

Hirai, T., Yasuda, S., Umezawa, A., & Sato, Y. (2023). Country-Specific Regulation and International Standardization of Cell-Based Therapeutic Products Derived from Pluripotent Stem Cells. *Stem Cell Reports*, *18*(8), 1573–1591. https://doi.org/10.1016/j.stemcr.2023.05.003

Huang, X., Chen, H., Gao, Y., Wu, J., Ni, Z., Wang, X., & Sun, T. (2022). Career Calling as the Mediator and Moderator of Job Demands and Job Resources for Job Satisfaction in Health Workers: A Cross-Sectional Study. *Frontiers in Psychology*, *13*. https://doi.org/10.3389/fpsyg.2022.856997

Jastaniah, H. (2023). The Legal Principles of Stem Cell Rulings. *Jordan Journal of Islamic Studies*, *19*(4), 77–107. https://doi.org/10.59759/jjis.v19i4.280

Jha, A., Farnoodian, M., & Bharti, K. (2021). Induced Pluripotent Stem Cell-Based Therapies: Challenges and Opportunities. *Stem Cell Research*, *53*, 102262. https://doi.org/10.1016/j.scr.2021.102262

Karim, A., Kartiko, A., Daulay, D. E., & Kumalasari, I. D. (2021). The Effect of The Supervision of The Principal and The Professional Competency of Teachers on Teacher Performance in Private MI in Pacet District. *Nidhomul Haq : Jurnal Manajemen Pendidikan Islam*, *6*(3), 497–512. https://doi.org/10.31538/ndh.v6i3.1686

Lestari, D. (2023). Post-Disaster Governance and Environmental Rehabilitation in Regional Media Coverage. *Journal of Environmental Policy and Planning*, *25*(3), 412–430. https://doi.org/10.1080/1523908X.2023.2193341

Lovell-Badge, R., Anthony, E., Barker, R. A., Bubela, T., Brivanlou, A. H., Carpenter, M., Charo, R. A., Clark, A. T., Cossu, G., Daley, G. Q., & others. (2021). ISSCR Guidelines for Stem Cell Research and Clinical Translation: The 2021 Update. *Stem Cell Reports*, *16*(6), 1398–1408. https://doi.org/10.1016/j.stemcr.2021.05.012

Margiana, R., & others. (2022). Clinical Application of Mesenchymal Stem Cell in Regenerative Medicine: A Narrative Review. *Stem Cell Research \& Therapy*, *13*, 366. https://doi.org/10.1186/s13287-022-03054-0

Master, Z. (2023). Patient Education and Unproven Stem Cell Interventions: Addressing Misinformation and Improving Decision-Making. *Stem Cell Research and Therapy*, *14*(1), 1–12.

Muhammad, F. A. B. (2017). Shahih Bukhari - Muslim. In M. A. bin U. Penerbit (Ed.), *Sustainability (Switzerland)* (1st ed., Vol. 11, Issue 1). PT Gramedia Pustaka Utama. http://scioteca.caf.com/bitstream/handle/123456789/1091/RED2017-Eng-8ene.pdf?sequence=12&isAllowed=y%0Ahttp://dx.doi.org/10.1016/j.regsciurbeco.2008.06.005%0Ahttps://www.researchgate.net/publication/305320484_SISTEM_PEMBETUNGAN_TERPUSAT_STRATEGI_MELESTARI

Mukhlis, M., Iqbal, M., Safitri, M., & Hasniyati, H. (2025). Challenges in Implementing Sharia-Based Education: Balancing Regional Autonomy and Children's Rights in Aceh. *Khazanah Hukum*, *7*(1), 105–120. https://doi.org/10.15575/kh.v7i1.41012

Padela, A. I. (2025). *Maqasid Al-shariah and Biomedicine: Bridging Moral, Ethical, and Policy Discourses*. International Institute of Islamic Thought (IIIT).

Prasetyo, H., Waluyo, B., Subakdi, S., Roring, E. B., & Salles, S. (2025). Reconstruction of Criminal Design Based on Strict Liability Theory for Hospitals in Cases of Medical Malpractice Against Patients. *Jurnal Suara Hukum*, *6*(2), 331–355. https://doi.org/10.26740/jsh.v6n2.p331-355

Rivron, N. C. (2023). Ethical and Regulatory Considerations for Stem Cell-Based Embryo Models. *Stem Cell Reports*, *18*(1), 1–10.

Sato, Y., & Ono, S. (2023). Regulatory Environment and Approvals in Cell and Gene Therapy Products Between Japan, the USA, and the EU. *Therapeutic Innovation \& Regulatory Science*, *57*(2), 227–237. https://doi.org/10.1007/s43441-022-00455-4

Sawarkar, S., & Bapat, A. (2022). Global Regulatory Frameworks and Quality Standards for Stem Cells Therapy and Regenerative Medicines. In *Stem Cell Production* (pp. 69–111). Springer Singapore. https://doi.org/10.1007/978-981-16-7589-8_4

Serour, G., & others. (2023). Sunni Islamic Perspectives on Lab-Grown Sperm and Eggs Derived from Stem Cells: In Vitro Gametogenesis (IVG). *New Bioethics*, *29*(2), 108–120. https://doi.org/10.1080/20502877.2022.2142094

Shang, R., Wu, H., Zhou, L., Song, C., Shao, Q., Liu, X., & Cai, X. (2023). Third-generation dynamic anterior plate-screw system for quadrilateral fractures: digital design based on 834 pelvic measurements. *Medicina*, *59*(2), 211.

Sharma, S., & Sony A.L., R. (2021). eLegalls: Enriching a Legal Justice System in the Emerging Legal Informatics and Legal Tech Era. *International Journal of Legal Information*, *49*(1), 16–31. https://doi.org/10.1017/jli.2021.9

Siliveri, S., & Ausali, K. S. (2026). Global regulatory frameworks and case studies of Advanced Therapy Medicinal Products (ATMPS). *Journal of Rare Diseases*, *5*(1), 24. https://doi.org/10.1007/s44162-026-00163-9

Susana, L. M., Tripalupi, R. I., Kholil, S., Efendi, N., & Sakinah, G. (2025). Reconstructing Islamic Legal Norms in Environmental Governance: A Maqasid-Based Legal Critique of Indonesia's Resource Policies. *Al-Istinbath: Jurnal Hukum Islam*, *10*(2), 650–670. https://doi.org/10.29240/jhi.v10i2.13038

Tallon, M. J., & Kalman, D. S. (2025). The Regulatory Challenges of Placing Dietary Ingredients on the European and US Market. *Journal of Dietary Supplements*, *22*(1), 9–24. https://doi.org/10.1080/19390211.2024.2308261

Turner, C. (2021). The Anatomy of Secularism: Nursi's View on the Roots of Environmental Destruction. *Journal of Religion and Health*, *60*(3), 1745–1762. https://doi.org/10.1007/s10943-021-01234-y

Tyson, A. (2021). Blasphemy and Judicial Legitimacy in Indonesia. *Politics and Religion*, *14*(1), 182–205. https://doi.org/10.1017/S1755048319000427

Wahid, M. (2020). *Transformasi Fatwa DSN-MUI dalam Sistem Hukum Nasional*. Kencana.

Yeo-Teh, N. S. L., & Tang, B. L. (2022). Moral Obligations in Conducting Stem Cell-Based Therapy Trials for Autism Spectrum Disorder. *Journal of Medical Ethics*, *48*(5), 343–348. https://doi.org/10.1136/medethics-2020-107106