

Neonatal Surgery And The Law: Rights, Responsibilities, And Regulations

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ABSTRACT

Neonatal surgery, a field dedicated to addressing congenital anomalies and acquired conditions in newborns, occupies a unique and sensitive position within the broader medical landscape. The patients, neonates, are inherently vulnerable, lacking the capacity for self-determination and reliant entirely on others for their well-being. The interventions, often life-saving, carry significant risks and frequently necessitate complex, life-altering decisions. This intersection of vulnerability and high-stakes decision-making creates a complex web of ethical and legal considerations that demand careful navigation.

This paper delves into the intricate interplay between neonatal surgery and the law, aiming to illuminate the key legal principles that underpin this specialized area of practice. It explores the legal frameworks that govern decision-making, emphasizing the crucial balance between respecting parental autonomy and safeguarding the best interests of the neonate.

1. INTRODUCTION

Neonatal surgery presents a unique set of ethical and legal challenges due to the vulnerable nature of the patient population and the often life-altering decisions involved. This paper explores the intricate interplay between neonatal surgery and the law, examining key legal principles, consent considerations, decision-making processes, liability issues, and the impact of emerging technologies. It delves into the specific legal frameworks governing neonatal surgical practice, emphasizing the importance of balancing parental autonomy with the best interests of the neonate.

2. KEY LEGAL PRINCIPLES

The foundation of legal practice in neonatal surgery rests upon several fundamental principles, including:

- **The Best Interests Standard:** This principle dictates that all decisions made on behalf of the neonate must prioritize their well-being. It requires a comprehensive assessment of the potential benefits and burdens of any intervention, taking into account the child's current and future quality of life.
- **Parental Autonomy:** Parents, as the natural guardians of their child, possess the right to make decisions regarding their child's medical care. However, this autonomy is not absolute and is subject to limitations when it conflicts with the child's best interests.
- **Informed Consent:** Obtaining informed consent from parents is a critical legal and ethical requirement. This process involves providing parents with comprehensive information about the proposed surgical procedure, including its risks, benefits, and alternatives, to enable them to make an informed and voluntary decision.
- **Child Protection:** In situations where parental decisions are deemed to be harmful to the child, the state has a duty to intervene and protect the child's welfare. This may involve seeking court orders to override parental decisions or appointing a guardian ad litem to represent the child's interests.

FUNDAMENTAL LEGAL PRINCIPLES GOVERNING NEONATAL CARE

- **Best Interests Standard-** The "Best Interests Standard" stands as a cornerstone principle guiding medical decision-making for neonates, particularly in the context of surgical interventions. This standard mandates that all actions undertaken on behalf of a newborn must prioritize their overall well-being. It necessitates a comprehensive and nuanced evaluation that extends beyond merely addressing the immediate medical condition. Healthcare providers must consider the potential long-term implications of treatment options, including the impact on the child's physical, emotional, and developmental trajectory. This evaluation requires a multidisciplinary approach, drawing upon the expertise of neonatologists, surgeons, nurses, social workers, and ethicists to ensure a holistic understanding of the

neonate's unique circumstances. The Best Interests Standard compels clinicians to weigh the potential benefits of a proposed intervention against its associated risks and burdens, always keeping the child's future quality of life at the forefront of their deliberations. In situations where the long-term prognosis is uncertain or the potential for significant disability exists, the Best Interests Standard demands a particularly rigorous and thoughtful analysis, often involving extensive discussions with parents and, when appropriate, consultation with ethics committees.

Furthermore, the application of the Best Interests Standard is not static. It requires ongoing reassessment as the neonate's condition evolves and new information becomes available. The dynamic nature of neonatal care necessitates a flexible approach, allowing for adjustments to the treatment plan in response to the child's changing needs. This may involve modifying surgical strategies, altering medication regimens, or providing additional supportive care. The Best Interests Standard also recognizes the importance of parental involvement in decision-making, acknowledging their role as the primary advocates for their child.

- **Parental Autonomy and Decision-Making-** Parental autonomy, the right of parents to make decisions concerning their child's health and well-being, is a fundamental principle in medical ethics. It acknowledges the unique bond between parent and child and recognizes parents as the primary advocates for their offspring. In the context of neonatal care, this principle is particularly salient, as newborns are inherently incapable of making decisions for themselves. Parents are entrusted with the responsibility of acting in their child's best interests, making choices that align with their values, beliefs, and understanding of their child's needs. This autonomy extends to decisions regarding medical treatment, including surgical interventions, medication administration, and end-of-life care. However, it is crucial to recognize that parental autonomy is not absolute. It is subject to limitations when parental decisions are deemed to be harmful to the child or when they conflict with established medical standards of care. In such instances, the state may intervene to protect the child's welfare, overriding parental preferences in favor of what is considered to be in the child's best interests. This delicate balance between respecting parental autonomy and safeguarding the child's well-being requires careful consideration of the specific circumstances of each case, often involving collaboration between medical professionals, ethicists, and legal experts. The process of parental decision-making in neonatal care is often fraught with emotional complexity. Parents may be grappling with shock, grief, and uncertainty, particularly when faced with unexpected diagnoses or life-threatening conditions.
- **The Rights of the Child-** The rights of the child, particularly in the context of neonatal care, are paramount and form the ethical and legal foundation for all decision-making. These rights, enshrined in documents like the United Nations Convention on the Rights of the Child, emphasize the inherent dignity and worth of every child, regardless of their age or medical condition. In the neonatal setting, where infants are entirely dependent on others, these rights translate into the right to life, the right to the highest attainable standard of health, and the right to protection from harm. Healthcare professionals are ethically and legally bound to uphold these rights, ensuring that all interventions are guided by the child's best interests.

3. CONSENT AND DECISION-MAKING IN NEONATAL SURGERY

- A. **Challenges and Nuances-** In the realm of neonatal surgery, the legal imperative of informed consent presents unique challenges and nuances. Unlike adult patients who possess the capacity for autonomous decision-making, neonates rely entirely on their parents or legal guardians to act on their behalf. The legal framework necessitates that these surrogates receive comprehensive information regarding the proposed surgical intervention, encompassing potential risks, benefits, and alternative treatment options. This information must be presented in a manner that is both understandable and culturally sensitive, acknowledging the emotional distress often experienced by parents facing critical decisions for their newborn. Legally, the informed consent process must be documented meticulously, demonstrating that the parents understood the information provided and made a voluntary decision, free from coercion. Furthermore, the law recognizes the potential for conflicts of interest and requires that any deviation from standard medical practice or experimental procedures undergo rigorous ethical review and, in some jurisdictions, judicial oversight.
- B. **Surrogate Decision-Making:** neonatal surgery, surrogate decision-making, primarily by parents or legal guardians, is governed by principles that prioritize the child's best interests while acknowledging parental rights. Parents are generally presumed to be the appropriate surrogates, possessing the inherent right to make medical decisions for their minor children.¹ However, this right is not absolute and is subject to legal limitations. Courts may intervene when parental decisions are deemed to be harmful or neglectful, or when there is a conflict of interest. The legal framework often mandates a "substituted judgment" standard, requiring surrogates to make decisions that align with what the child would want if they were capable of expressing their own wishes. In the absence of such knowledge, the "best interests" standard prevails, demanding decisions that maximize the child's well-being.
- C. **Conflict Resolution:** In the complex landscape of neonatal surgery, conflicts can arise between medical professionals, parents, and even within the healthcare team regarding the most appropriate course of action. To

navigate these ethically and legally challenging situations, conflict resolution mechanisms play a crucial role. Ethical committees, composed of medical experts, ethicists, and legal professionals, provide a forum for discussing complex cases, offering guidance on ethical dilemmas, and facilitating consensus-building. They often employ a multidisciplinary approach, ensuring that all relevant perspectives are considered. However, when conflicts persist or when parental decisions are deemed to be harmful to the neonate, court intervention may be necessary. Courts, acting as the ultimate arbiters, can issue orders to override parental decisions, appoint guardians ad litem to represent the child's interests, or mandate specific medical treatments.

4. SPECIFIC LEGAL CONSIDERATIONS IN COMMON NEONATAL SURGICAL CONDITIONS

The legal landscape surrounding neonatal surgery is a complex tapestry woven with threads of ethical considerations, parental rights, and the overarching principle of the child's best interests. Congenital anomalies, for instance, often necessitate weighing the potential benefits of invasive surgical interventions against the risks of long-term disability and diminished quality of life. Legal frameworks across jurisdictions grapple with defining the boundaries of parental autonomy in such cases, often requiring judicial oversight when parental decisions appear to deviate from established medical norms. Prematurity, with its inherent fragility and heightened risk of complications, raises questions regarding the standard of care, resource allocation, and the legal implications of adverse outcomes. The delicate balance between aggressive intervention and palliative care becomes a legal tightrope, demanding meticulous documentation and a clear articulation of the medical rationale behind each decision.

Cardiac defects, frequently requiring complex and staged surgical procedures, introduce legal complexities related to informed consent and the long-term management of chronic conditions. Parents, often overwhelmed by the emotional weight of their child's condition, must be provided with comprehensive information regarding the risks and benefits of each intervention, including the potential for complications and the impact on the child's future quality of life. The legal emphasis on informed consent in these scenarios underscores the importance of clear communication and a thorough understanding of the medical complexities involved. Neurological conditions, particularly those diagnosed in the neonatal period, pose unique challenges related to long-term prognostication and the potential for developmental disabilities. Legal frameworks must address the need for early intervention while acknowledging the inherent uncertainty surrounding long-term outcomes. The legal implications of decisions made during the neonatal period can extend far into the child's future, necessitating a careful consideration of the potential for future litigation and the need to ensure that all interventions are grounded in sound medical practice and a thorough understanding of the legal principles involved.

5. LIABILITY AND NEGLIGENCE IN NEONATAL SURGERY

The specter of liability and negligence looms large in the field of neonatal surgery, demanding meticulous adherence to legal standards and ethical principles. The "standard of care," a cornerstone of medical malpractice law, dictates the level of skill and care that a reasonably competent medical professional would exercise in similar circumstances. In neonatal surgery, this standard is often highly specialized, requiring expert testimony from physicians with extensive experience in this subspecialty to establish what constitutes acceptable practice. Expert witnesses play a crucial role in elucidating the complexities of neonatal surgical procedures, the risks associated with various interventions, and the prevailing medical consensus on appropriate treatment strategies. Their testimony can significantly influence the outcome of medical malpractice claims, highlighting the importance of selecting experts with impeccable credentials and a thorough understanding of the unique challenges of neonatal care.

Medical malpractice claims in neonatal surgery often hinge on proving causation and damages. Plaintiffs must demonstrate that the healthcare provider's negligence directly caused the neonate's injuries and that these injuries resulted in quantifiable damages, such as medical expenses, lost future earnings, and pain and suffering. Establishing a direct causal link between the alleged negligence and the resulting harm can be particularly challenging in neonates, given their inherent vulnerability and the potential for pre-existing conditions or complications. Furthermore, quantifying damages in cases involving infants can be complex, requiring expert testimony from economists and life care planners to project future medical needs and the impact of the injuries on the child's quality of life. The legal burden of proof in these cases is substantial, demanding meticulous documentation and a compelling narrative that connects the alleged negligence to the resulting harm.

Documentation and record-keeping assume paramount importance in mitigating the risk of liability in neonatal surgery. Detailed and accurate medical records serve as crucial evidence in medical malpractice claims, providing a chronological account of the neonate's medical history, the interventions performed, and the rationale behind treatment decisions. Any discrepancies or omissions in medical records can be interpreted as evidence of negligence, potentially undermining the healthcare provider's defense. Legal standards mandate that medical records be comprehensive, legible, and maintained in accordance with established guidelines. Electronic health records, while offering numerous advantages, also introduce new challenges related to data security, privacy, and the potential for inadvertent alterations. Healthcare providers must implement robust record-keeping systems and ensure that all staff members are trained in proper documentation practices to minimize the risk of legal liability.

The fear of litigation can lead to the practice of "defensive medicine," wherein healthcare providers order excessive tests, procedures, and consultations primarily to protect themselves from potential lawsuits, rather than to benefit the patient.

Legal reforms, such as caps on non-economic damages and the implementation of alternative dispute resolution mechanisms, may help to mitigate the fear of litigation and encourage healthcare providers to prioritize patient-centered care. Ultimately, fostering a culture of transparency, open communication, and a commitment to patient safety is essential for minimizing the risk of liability and ensuring the provision of high-quality neonatal surgical care.

6. THE ROLE OF LEGISLATION AND REGULATORY BODIES

- **National and International Guidelines-** The bedrock of ethical and legally sound neonatal surgical practice rests upon a framework of legislation and regulatory oversight. National and international guidelines serve as crucial instruments in shaping standards of care, ensuring patient safety, and promoting accountability. These guidelines, often developed through collaborative efforts of medical experts, legal professionals, and ethicists, provide a comprehensive framework for navigating the complex ethical and legal dilemmas inherent in neonatal surgery. At the national level, legislation may address issues such as informed consent, parental rights, child protection, and medical malpractice, establishing clear legal boundaries for healthcare providers and ensuring that the rights of vulnerable neonates are safeguarded.

International guidelines, such as those promulgated by the World Health Organization (WHO) and professional medical societies, contribute to the harmonization of neonatal surgical practice across borders. These guidelines often address issues such as access to care, resource allocation, and the ethical considerations surrounding emerging technologies. While not legally binding in all jurisdictions, international guidelines can serve as persuasive authority in legal proceedings, influencing judicial interpretations of national laws and shaping the development of best practices. The legal framework must adapt to the evolving landscape of medical technology and the increasing globalization of healthcare, ensuring that national laws are consistent with international norms and that neonates receive equitable and high-quality care regardless of their location.

The role of legislation and regulatory bodies extends beyond setting standards of care to encompass the protection of vulnerable populations and the prevention of medical errors. Laws may mandate the reporting of suspected child abuse or neglect, ensuring that neonates at risk receive timely intervention and protection. These initiatives often involve collaboration between healthcare providers, legal experts, and patient advocacy groups, fostering a culture of transparency and accountability. The legal framework must strike a balance between promoting innovation and ensuring patient safety, encouraging the development of new technologies while safeguarding against potential risks.

- **Hospital Policies and Protocols-** Hospital policies and protocols play a crucial role in shaping the legal landscape of neonatal surgery, serving as internal guidelines that translate broader legal principles into actionable procedures. These policies are not merely advisory; they often carry significant legal weight, particularly in medical malpractice litigation. Courts may consider a hospital's failure to adhere to its own established protocols as evidence of negligence, demonstrating a deviation from the standard of care that the institution itself deemed appropriate.

Furthermore, hospital policies often address specific legal requirements related to informed consent, documentation, and patient confidentiality. For example, policies may outline the process for obtaining informed consent in emergency situations, the requirements for documenting surgical procedures and post-operative care, and the protocols for safeguarding patient privacy in accordance with HIPAA and other applicable laws.

Hospital policies also play a crucial role in risk management and quality improvement. They may establish protocols for reporting adverse events, conducting root cause analyses, and implementing corrective actions to prevent future errors. These policies often align with national patient safety goals and accreditation standards, demonstrating the hospital's commitment to providing high-quality care and minimizing the risk of medical malpractice.

7. NEONATAL SURGERY IN INDIA

Neonatal surgery in India is a field of medicine that is constantly evolving. The Indian Constitution guarantees the right to life and personal liberty, which includes the right to access healthcare. This right is particularly important for newborns, who are often vulnerable to a variety of medical conditions.

Neonatal surgery is a complex and challenging field of medicine. It requires a high degree of skill and expertise. Neonatal surgeons in India are highly trained and experienced. They are able to provide a wide range of surgical services to newborns, including complex procedures such as heart surgery and brain surgery.

The Indian Government is committed to improving the quality of neonatal care in the country

The Indian government has taken a number of steps to improve the quality of neonatal care in the country. These steps include:

- Increasing the number of neonatal intensive care units (NICUs)

- Training more neonatal surgeons
- Providing financial assistance to families of newborns who need surgery

There are a number of challenges that neonatal surgeons in India face

One of the biggest challenges is the lack of access to quality healthcare. This is especially true for newborns in rural areas. Another challenge is the high cost of neonatal surgery. This can be a financial burden for families.

Despite these challenges, neonatal surgery in India is a growing field

The number of neonatal surgeries performed in India is increasing each year. This is due to a number of factors, including:

- Increased awareness of the importance of neonatal surgery
- Improved access to healthcare
- Advances in medical technology

The future of neonatal surgery in India is bright

With the continued support of the government and the medical community, neonatal surgery in India is poised to make significant progress in the years to come.

8. JUDICIAL APPROACH

Delving into Indian jurisprudence concerning "Neonatal Surgery and the Law: Rights, Responsibilities, and Regulations" reveals a legal landscape where specific, isolated judgments dedicated solely to neonatal surgery are scarce. However, the principles governing medical negligence, consumer protection, and constitutional rights, as interpreted by Indian courts, provide a robust framework for understanding the legal implications in this specialized field.

1. Landmark Judgments on Medical Negligence:

- The *Jacob Mathew v. State of Punjab & Anr. (2005) 6 SCC 1* case is a cornerstone in Indian medical negligence jurisprudence. The Supreme Court laid down guidelines for determining negligence, emphasizing that a mere error of judgment does not constitute negligence. The court stressed the need to differentiate between medical negligence and medical mishap. This judgment significantly impacts how courts assess liability in complex surgical cases, including those involving neonates.
- In *Laxman Balkrishna Joshi (Dr.) v. Trimbak Babu Godbole and Anr. (1969) 1 SCR 206*, the Supreme Court established the duty of care owed by medical professionals. This case, though not specifically about neonates, sets the precedent that medical practitioners are expected to exercise reasonable care and skill in their practice, which is directly applicable to neonatal surgical procedures.

2. Consumer Protection and Medical Services:

- The *Indian Medical Association v. V.P. Shantha and Ors. (1995) 6 SCC 651* case brought medical services under the purview of the Consumer Protection Act. This decision enables aggrieved parties, including parents of neonates, to seek redressal for deficient medical services. Consumer courts have since adjudicated numerous cases involving medical negligence, awarding compensation for damages. These judgments provide a mechanism for holding hospitals and doctors accountable for substandard care in neonatal surgery.
- The **Consumer Protection Act, 2019** further strengthened consumer rights, and its implications extend to medical negligence cases concerning neonatal surgery.

3. Constitutional Rights and the Right to Health:

- Article 21 of the Indian Constitution, which guarantees the right to life and personal liberty, has been interpreted by the Supreme Court to include the right to¹ health. In cases where neonates are denied necessary medical care, courts can invoke Article 21 to ensure their right to health is protected.

9. EMERGING TECHNOLOGIES AND LEGAL IMPLICATIONS

The rapid advancement of emerging technologies in neonatal surgery presents a complex and evolving legal landscape. Fetal surgery and prenatal diagnosis, for instance, raise profound legal and ethical questions regarding maternal autonomy, fetal personhood, and the potential for wrongful birth or wrongful life claims. The ability to diagnose and treat fetal conditions in utero introduces new considerations regarding informed consent, the allocation of scarce medical resources, and the long-term implications for both mother and child. Legal frameworks must adapt to these technological advancements, balancing the potential benefits of early intervention with the need to protect the rights and interests of all parties involved. Furthermore, the increasing use of prenatal genetic testing necessitates careful consideration of privacy concerns, the potential for genetic

discrimination, and the legal implications of genetic counseling and selective termination of pregnancy.

Genetic testing and personalized medicine hold the promise of tailoring neonatal surgical interventions to the individual patient's genetic profile. However, this also raises legal concerns regarding the privacy and security of genetic data, the potential for genetic discrimination in insurance or employment, and the ethical implications of using genetic information to make treatment decisions. Legal frameworks must address these concerns, ensuring that genetic testing is conducted in a responsible and ethical manner, and that patient privacy is protected. Furthermore, the use of genetic information in decision-making requires careful consideration of the potential for bias and the need to ensure equitable access to personalized medicine for all neonates, regardless of their socioeconomic background.

10. COMPARATIVE ANALYSIS ON INDIAN AND INTERNATIONAL LAWS

Area of Focus	Indian Context	International Context	Key Considerations
Informed Consent	Consent required from parents/legal guardians. Emphasis on providing information about procedure, risks, benefits. Legal framework: Indian Contract Act, relevant court decisions.	Similar principle of parental/guardian consent. Varying levels of detail required in information disclosure (e.g., specific risks). Legal framework: Varies by country (e.g., common law, civil law).	Capacity to consent is a key issue. Emergency situations and the "best interests" principle. Cultural variations in decision-making.
Medical Negligence/Malpractice	Doctors held to a standard of care. Consumer Protection Act, Indian Penal Code. Medical Council of India (National Medical Commission) plays a role.	Similar principle of professional duty of care. Legal frameworks vary widely (e.g., tort law). Standards of care may be influenced by international guidelines.	Defining "reasonable" standard of care in neonatal surgery. Burden of proof in legal cases. Availability and access to legal recourse.
Child Rights and Protection	Constitution of India, Juvenile Justice (Care and Protection of Children) Act. Focus on the child's best interests.	UN Convention on the Rights of the Child (UNCRC) is a key international treaty. Emphasis on the child's right to life, health, and well-being.	Balancing parental autonomy with the child's rights. Decision-making in cases of conflicting medical opinions. Ethical dilemmas in neonatal surgery (e.g., end-of-life care).
Ethical Principles	Medical ethics principles (beneficence, non-maleficence, autonomy, justice) are generally accepted. Indian Medical Council Code of Ethics.	Similar ethical principles are universally recognized. International guidelines (e.g., WHO) influence ethical practice.	Ethical dilemmas in neonatal surgery can be complex (e.g., resource allocation, experimental treatments). Cultural and religious values can influence ethical decision-making.
Specific Regulations	Regulations may exist for specific procedures or technologies (e.g., organ transplantation). Hospital regulations and guidelines.	Detailed regulations vary significantly by country (e.g., on research involving neonates, assisted reproductive technologies). Professional medical associations often set standards.	Keeping up with rapid advances in neonatal surgery. Ensuring quality and safety of care. Addressing disparities in access to care.

11. ETHICAL CONSIDERATIONS AND FUTURE DIRECTIONS

The evolving role of the neonatal surgeon, encompassing not only surgical expertise but also ethical leadership and advocacy for vulnerable patients, necessitates a re-evaluation of legal standards for professional conduct. Legal frameworks must address the increasing complexity of medical decision-making, the need for interdisciplinary collaboration, and the importance of open communication with families. Courts may be called upon to adjudicate disputes regarding the scope of professional responsibility, the duty to disclose medical errors, and the ethical obligations of surgeons in complex cases. Furthermore, legal standards must address the potential for conflicts of interest, ensuring that surgeons prioritize the best interests of their patients above all other considerations. The legal framework must adapt to the changing landscape of medical practice, ensuring that neonatal surgeons are held to the highest ethical and professional standards.

Courts may be called upon to adjudicate disputes regarding the adequacy of state and federal funding for neonatal care, the implementation of public health initiatives to address health disparities, and the enforcement of anti-discrimination laws in healthcare settings. Furthermore, legal standards must address the potential for implicit bias in medical research and clinical trials, ensuring that all neonates are represented in the development of new treatments and technologies. The legal framework must adopt a holistic approach to addressing disparities in neonatal surgical outcomes, recognizing the interconnectedness of social, economic, and environmental factors.

12. CONCLUSION

In conclusion, the legal and ethical landscape of neonatal surgery is a complex and evolving domain, demanding a delicate balance between parental autonomy and the paramount principle of the neonate's best interests. From the intricacies of informed consent and surrogate decision-making to the challenges posed by emerging technologies and the ever-present specter of liability, legal frameworks must adapt to the unique vulnerabilities of this patient population. The imperative to uphold the rights of the child, coupled with the need for equitable access to care and the mitigation of disparities, necessitates a robust system of legislation, regulation, and hospital protocols. As medical advancements continue to push the boundaries of neonatal intervention, legal and ethical considerations must remain at the forefront, ensuring that the most vulnerable members of society receive compassionate, just, and high-quality care.

REFERENCES

- [1] Andreoletti Mattia, Teira David. Rules versus Standards: What Are the Costs of Epistemic Norms in Drug Regulation? *Science, Technology, & Human Values*. 2019;44:1093–1115.
- [2] Sacks Chana A, Avorn Jerry, Kesselheim Aaron S. The Failure of Solanezumab — How the FDA Saved Taxpayers Billions. *New England Journal of Medicine*. 2017;376:1706–1708.
- [3] K.I. Paraskevas et al. Why randomized controlled trials do not always reflect reality *J Vasc Surg* (2019)
- [4] J. He, S. L. Baxter, J. Xu, J. Xu, X. Zhou, and K. Zhang, “The practical implementation of artificial intelligence technologies in medicine,” *Nature Med.*, vol. 25, no. 1, pp. 30–36, Jan. 2019.
- [5] C. Zhang and Y. Lu, “Study on artificial intelligence: The state of the art and future prospects,” *J. Ind. Inf. Integr.*, vol. 23, Sep. 2021, Art. no. 100224.
- [6] A. Rawal, J. McCoy, D. B. Rawat, B. M. Sadler, and R. S. Amant, “Recent advances in trustworthy explainable artificial intelligence: Status, challenges, and perspectives,” *IEEE Trans. Artif. Intell.*, vol. 3, no. 6, pp. 852–866, Dec. 2022.
- [7] Farrokhyar Forough, Karanicolas Paul J, Thoma Achilleas, Simunovic Marko, Bhandari Mohit, Devereaux PJ, Anvari Mehran, Adili Anthony. Randomized Controlled Trials of Surgical Interventions. *Annals of Surgery*. 2010;251:409–416.
- [8] Blencowe NS, Mills N, Cook JA, Donovan JL, Rogers CA, Whiting P, Blazeby JM. Standardizing and monitoring the delivery of surgical interventions in randomized clinical trials. *British Journal of Surgery*. 2016;103:1377–1384.
- [9] Wartolowska Karolina, Collins Gary S, Hopewell Sally, Judge Andrew, Dean Benjamin JF, Rombach Ines, Beard David J, Carr Andrew J. Feasibility of surgical randomised controlled trials with a placebo arm: a systematic review. *British Medical Journal Open*. 2016;6:e010194.
- [10] Savulescu Julian, Wartolowska Karolina, Carr Andy. Randomised placebo-controlled trials of surgery: ethical analysis and guidelines. *Journal of Medical Ethics*. 2016;42:776–783.
- [11] Pereira Tiago V, Ralph I, Horwitz, John PA Ioannidis. Empirical evaluation of very large treatment effects of medical interventions. *JAMA*. 2012;308:1676–1684.
- [12] Hayes Michael J, Kaestner Victoria, Mailankody Sham, Prasad Vinay. Most medical practices are not parachutes: a citation analysis of practices felt by biomedical authors to be analogous to parachutes. *CMAJ*

Open. 2018;6:E31–E38.

- [13] B. Speich Adequate reporting of the sample size calculation in surgical randomized controlled trials *Surgery* (2020)
 - [14] C. Hegde, “Anomaly detection in time series data using data-centric AI,” in *Proc. IEEE Int. Conf. Electron., Comput. Commun. Technol. (CONECCT)*, Jul. 2022, pp. 1–6.
 - [15] M. Batty, “Planning data,” *Environ. Planning B, Urban Anal. City Sci.*, vol. 49, pp. 1588–1592, Jan. 2022.
 - [16] C. Ré, F. Niu, P. Gudipati, and C. Srisuwananukorn, “Overton: A data system for monitoring and improving machine-learned products,” in *Proc. 10th Conf. Innov. Data Syst. Res.*, Amsterdam, The Netherlands, Jan. 2020.
 - [17] Holzinger A. Human-Computer Interaction and Knowledge Discovery (HCI-KDD): what is the benefit of bringing those two fields to work together? In: A Cuzzocrea, C Kittl, DE Simos, et al., eds. *Multidisciplinary Research and Practice for Information Systems*, Springer Lecture Notes in Computer Science LNCS 8127. Heidelberg, Berlin, New York: Springer; 2013: 319-328.
 - [18] Kircher K, Larsson A, Hultgren JA. Tactical driving behavior with different levels of automation. *IEEE Transactions on Intelligent Transportation Systems*. 2014; 15(1): 158-167.
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