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DEVELOPMENT OF INNOVATIVE MEDICAL DEVICES IN NEONATOLOGY: LITERATURE REVIEW

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ABSTRACT

This study aims to review the development of medical devices in neonatology, exploring technological advances, identifying innovations and challenges, and proposing recommendations for future research. The methodology involved a narrative review of the literature, with a search in databases such as PubMed, EBSCO, Cochrane, and IEEE Xplore, focusing on studies from the last ten years on medical devices for neonatology. The results highlight that technologies such as artificial intelligence and machine learning have improved the monitoring and prognosis of neonatal conditions, allowing for more accurate and personalized interventions. 3D printing emerges as a promising tool for creating personalized medical devices, meeting the specific needs of each patient. Wearable devices for continuous monitoring of vital signs and advanced enteral and parenteral feeding devices have demonstrated a positive impact on neonatal health. Mechanical ventilators with gentler and smarter modes reduced serious complications, and catheters with antimicrobial coatings helped decrease the incidence of neonatal sepsis. The findings indicate that technological innovations are key to improving neonatal care. The integration of artificial intelligence, 3D printing, and continuous monitoring has the potential to transform neonatology, improving clinical outcomes and quality of life for newborns. However, challenges such as the variability of neonatal pathologies, the cost and accessibility of devices, and the need for adequate training of health professionals need to be addressed. It is recommended to invest in continuous research, clinical validation, and

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interdisciplinary training to ensure the effective adoption of these innovative technologies in daily clinical practices.

Keywords: Technological Innovations. Intensive Care. Prematurity. Personalization of Treatments.

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INTRODUCTION

The development of medical devices for neonatal care is an area in which intense progress has been made in recent decades, reflecting advances in technology and biomedicine (Biban et al., 2021). Neonatal Intensive Care Units (NICUs) have benefited from innovations targeting newborns, especially premature infants and those with complex medical conditions, as they are the most vulnerable to clinical complications (O'Callaghan et al., 2019).

Technologies such as non-invasive ventilation, wearable sensors for continuous monitoring of vital signs, infection control, and advanced nutrition devices have contributed to improvements in the health of the neonatal population (Boel et al., 2018; Katheria et al., 2015; Polin et al., 2012; Soh et al., 2015; Van Kaam et al., 2010; Were & Bwibo, 2007).

The integration of artificial intelligence (AI) and machine learning (ML) in the development of medical devices has also enhanced the accuracy of diagnoses and the personalization of treatments. These technologies allow for more rigorous monitoring and more effective interventions, resulting in better prognoses for neonates (Beam et al., 2024; McAdams et al., 2022). In addition, the use of 3D printing and tissue engineering is opening up new possibilities for the creation of personalized medical devices and the development of artificial organs, offering innovative solutions to the challenges faced by neonatal care (Chia & Wu, 2015; Murphy & Atala, 2014; Ventola, 2014).

However, despite these advances, many challenges still persist in the development and implementation of new medical devices in neonatology. The variability of neonatal medical pathologies demands highly specialized solutions, many of which have not yet been sufficiently explored or validated. In addition, the accessibility and cost of these devices are limiting factors, especially in resource-scarce regions (Blencowe et al., 2012; Fenton & Kim, 2013; Howson et al., 2013; Rahmani, 2015; Slater et al., 2004).

In this context, some questions arise: How is the development of medical devices in neonatology done? What are the most innovative medical devices currently available for neonatal care?

This narrative review aims to describe the development of the devices, explore technological advances in neonatology, highlighting the most recent devices and their contributions to clinical practice. In addition, it seeks to identify gaps in current research and propose recommendations for future investigations and the development of technologies.

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This study offers contributions to the field of neonatology by providing an overview of the technological innovations that are shaping the future of neonatal care. By identifying key barriers and enablers to the implementation of these innovations, the work can guide health policy, clinical practices, and future research, promoting better health outcomes for newborns around the world.

THEORETICAL FRAMEWORK

Neonatology is a subspecialty or area of expertise which belongs to the medical specialty of pediatrics, and is dedicated to the care of newborns from birth to the first 28 days of life. It also encompasses neonatal intensive care in premature patients, newborns with low birth weight, and those with congenital malformations or other clinical conditions that require neonatal intensive care (Jobe & Bancalari, 2001; Miall, 2015; Sankar et al., 2016; Stoll et al., 2010).

HISTORICAL EVOLUTION OF NEONATAL DEVICES

The history of neonatal care began in the late nineteenth and early twentieth centuries with the introduction of the first incubators, leading to continued progress in life support, monitoring, and treatment technologies (Baker, 2000). Devices such as neonatal ventilators, vital signs monitoring systems, infusion pumps, and phototherapy equipment have become essential in NICUs (S. K. Sinha & Donn, 1996). Initially, neonatal devices were adaptations of pediatric equipment and, in turn, adult devices. Recently, there has been a development specifically targeting the neonatal population, resulting in more precise and effective interventions (Stark, 2004). Innovations such as exogenous surfactant and noninvasive ventilation techniques have improved clinical outcomes, highlighting the importance of technological advancement for improving survival rates and reducing long-term complications in preterm infants (Goldsmith et al., 2016; Jobe & Ikegami, 1998; Sammour & Karnati, 2020; Urschitz et al., 2004).

The development of innovative medical devices has taken a leap forward in neonatal care, which allows for more precise, safer, and more effective interventions, resulting in better clinical outcomes for newborns (Katheria et al., 2015; Van Kaam et al., 2010).

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CLINICAL NEEDS AND CHALLENGES

Newborns, especially premature infants, have unique clinical needs due to the immaturity of their systems. Its characteristics demand specific medical devices, which creates a complex environment for the introduction of new technologies. In addition, minimizing the physical and psychological impact on newborns and their families is a constant challenge in the development of new devices. These devices should consider the small size of patients and the need for minimal, less invasive interventions. The integration of miniaturized sensors, wireless technology, and biocompatible materials is are emerging trend to meet these needs. These innovations can improve neonatal care and clinical outcomes (Ramezani et al., 2014; Te Pas, 2017).

DEVELOPMENT OF MEDICAL DEVICES

The development of medical devices is a process that involves several steps. It is similar to the development process of non-medical products, however, it has its particularities. Each step is informed by rigorous scientific research and interdisciplinary collaboration. This multidisciplinary field integrates knowledge from medicine, engineering, biotechnology, and materials science to create life-saving solutions that improve the prognosis of vulnerable infants (Griffin & Moorman, 2001).

IDENTIFICATION OF CLINICAL NEEDS

The first step in the development of medical devices in neonatology is the identification of clinical needs, using various methods (MacLeod, 2017).

Initially, interviews and consultations are conducted with neonatologists and NICU professionals, including physicians, nurses, and other health care professionals, to identify specific problems in the care of newborns (Turrill, 2003). This approach allows for the collection of detailed data directly from those who work with patients on a daily basis (Beam et al., 2023).

In addition to the interviews, direct observations of clinical routines in NICUs are made to identify areas that could benefit from new technologies. Researchers follow daily activities, providing a practical view of the challenges faced and opportunities for innovations (Alfred et al., 2022; Kitzmiller et al., 2019). Feedback from caregivers, including parents and guardians, is also important, as it reveals needs not perceived by health professionals, but which impact the well-being of neonates and the quality of life of families.

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These strategies ensure a comprehensive understanding of clinical needs, forming the basis for the development of devices that effectively meet the demands of patients and professionals (Cuttini et al., 1999; Kinshella et al., 2022).

RESEARCH AND DEVELOPMENT (R&D)

Conceptualization and Ideation

Once the clinical needs have been identified, the Research and Development (R&D) phase begins, which is essential to transform these needs into innovative solutions. The process begins with brainstorming sessions, in which multidisciplinary teams, including biomedical engineers, physicians, product designers, and regulatory experts, generate and refine ideas for new devices (Alagumalai et al., 2019; Eberhardt et al., 2016; Miller et al., 2021).

During these sessions, ideas are discussed considering the technical, clinical, and operational challenges. Interdisciplinary collaboration allows for the creation of robust and innovative solutions, leveraging the specialized knowledge of each team member (Ulrich & Eppinger, 2016). In parallel, an extensive review of the scientific literature is conducted to identify emerging technologies applicable to neonatology, aligning device development with the latest advances and avoiding duplication of efforts (Batey et al., 2022). The combination of creative brainstorming and rigorous literature review provides a solid foundation for the development of technically feasible and clinically relevant medical devices (Marešová et al., 2020; Roma & de Vilhena Garcia, 2020).

Prototype Development

The prototype development stage is important in the creation of medical devices since it transforms ideas into physical and functional models. Three main methods are used: computer modeling (CAD), 3D printing and rapid prototyping, and computer simulations (Hieu et al., 2005).

CAD modeling allows you to create detailed designs of the devices, facilitating adjustments and improvements before physical construction (Bibb et al., 2014). After modeling, 3D printing and rapid prototyping produce physical models that simulate the final components, allowing for multiple iterations for testing and refinements (Chia & Wu, 2015; Giannatsis & Dedoussis, 2009; Ventola, 2014).

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Simultaneously, computer simulations test the device's performance in real-world conditions, using patient data and mathematical models. These simulations help identify flaws and optimize design by evaluating durability, efficiency, and safety prior to clinical trials (Rengier et al., 2010).

Testing and Validation

Device development requires rigorous preclinical and clinical testing to ensure safety and efficacy (Makower et al., 2010).

In preclinical studies, tests are used in animal models, such as rodents and pigs, to evaluate the safety and functionality of the device, identifying potential adverse effects and biocompatibility. In addition, trials in simulated models, which use neonatal mannequins and virtual reality, replicate clinical conditions to test the device's performance without risk to human patients (10993-1, 2018; Murphy & Atala, 2014; Swindle et al., 1994).

In clinical trials, Phase I focuses on the safety of the device by evaluating it in a small group of neonates and monitoring for immediate adverse effects (Van Norman, 2016). Phase II tests the effectiveness of the device in a larger group of patients, comparing the results with standard treatments or placebo to verify clinical improvements (Moher et al., 2010). Finally, Phase III involves multicenter trials in a diverse population, confirming the safety and efficacy of the device, which are essential for regulatory approval and commercialization (Friedman et al., 2010).

Regulatory Approval

This process involves preparing a regulatory dossier and interacting with regulatory agencies to obtain approval for marketing and clinical use (Ashter, 2022; Umapathi et al., 2024).

Regulatory dossier preparation includes compiling all necessary documentation, such as preclinical test data, clinical trial results, device description, manufacturing processes, and risk analysis. These documents are submitted to regulatory agencies such as the FDA (*Food and Drug Administration*) in the USA and ANVISA (National Health Surveillance Agency) in Brazil, complying with the specific requirements of each agency (Kramer et al., 2020; Van Norman, 2016).

After submission, agencies conduct a rigorous review of the dossier, which may include technical evaluation, request for additional information, facility inspection, and

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labeling review. Approval is granted only when the device meets all the required criteria, ensuring that only safe and effective devices are made available for clinical use (Graves & Maddern, 2012).

Production and Marketing

In the manufacturing phase, the establishment of efficient processes ensures quality and consistency. This is achieved through standard operating procedures (SOPs) and automation technologies (Chao et al., 2009). Adherence to international standards, such as good manufacturing practices, ensures that devices meet safety and efficacy requirements. Rigorous quality control systems, including regular inspections and sample testing, are put in place to ensure compliance with current standards (Bos, 2022; Lavi et al., 2016).

For commercialization, educational materials, such as user manuals, explanatory videos, and training guides, are developed to instruct health professionals on the correct use of the device (Ramaiah et al., 2014). In addition, practical training sessions are offered to doctors and nurses through workshops, online seminars, and e-learning modules. Efficient distribution networks are established to ensure the timely delivery of devices to neonatal intensive care units, maintaining the integrity of the devices during transport and storage (Scott, 2013).

Post-Market Monitoring and Continuous Innovations

Post-market monitoring and continuous innovations are important phases in the medical device lifecycle. These steps ensure that devices continue to be safe and effective after they are introduced to the market and allow for adaptations to new discoveries and emerging needs (Burland & Chevallier, 2022; Cioeta et al., 2022; Feng et al., 2023; Pokvić et al., 2021).

For post-market monitoring, it is essential to have an effective adverse event surveillance system (Parrella, 2014). This system must quickly identify and respond to security issues by collecting and analyzing data reported generally by healthcare professionals. Effective surveillance can prevent serious complications through early interventions. In addition, it is important to obtain continuous feedback from healthcare professionals to identify safety issues and opportunities for functional and operational improvements (Coloma et al., 2013; Moses et al., 2013; Wood, 1991; Woodcock et al., 2011).

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Continuous innovations are based on user feedback and technological advancements. Improved versions of the devices can be developed, including improvements in design, adding new functionality, or incorporating emerging technologies that increase the effectiveness and security of the device. This cycle of continuous improvement ensures that medical devices remain relevant and effective over time. Continuous research is also important for incorporating new scientific and technological discoveries. This involves conducting additional studies to explore new applications of the device, test new materials or technologies, and develop more effective methods of use. In this way, medical device manufacturers can be at the forefront of innovation and respond quickly to changing clinical needs and regulations (Bhuyan et al., 2021; Escayola et al., 2009; Turner & Jones, 2007).

Challenges

Device development faces several key challenges. First, rigorous regulatory and approval processes are key to ensuring the safety and efficacy of devices, but they can delay the introduction of new technologies to the market (Health et al., 2011; Makower et al., 2010; Van Norman, 2016). Second, the high costs associated with the development and implementation of advanced technologies can limit accessibility, especially in regions with fewer resources (DiMasi et al., 2003; Gebbie et al., 2007; Pronovost et al., 2008). Finally, the introduction of new devices requires adequate training of health professionals and adaptations to protocols and clinical routines, which can be a challenging and time-consuming process (Cook & West, 2012; Greenhalgh et al., 2004).

RESEARCH METHODS

The narrative review developed in this manuscript aims to synthesize the existing knowledge on the development of innovative medical devices in neonatology, highlighting the main trends, challenges, and innovations in the field. Below, we describe the methodological procedures adopted.

The main objective of this review is to explore and describe the state of the art in the development of medical devices for neonatology. Among the specific objectives, the following stand out: to identify the main innovations, product development methodologies, and challenges faced in the design and implementation of these devices.

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The following inclusion criteria were established: Studies published in peer-reviewed scientific journals, articles addressing the development of medical devices for neonatology, publications in English and Portuguese, and studies from the last 10 years to ensure the timeliness of the information.

The following exclusion criteria were established: opinion articles, letters to the editor, and non-systematic reviews, studies that do not focus specifically on neonatology or product development, publications without access to the full text.

The search was carried out in the following databases: PubMed, EBSCO, Cochrane, and IEEE Xplore, using specific keywords and search terms. The search was complemented by reviewing the references of the selected studies in order to identify additional relevant publications.

Search strategies were developed using combinations of keywords and MeSH (Medical Subject Headings) terms. The search resulted in a total of 71 articles. The following descriptors were used: "medical devices" OR "medical technology" OR "biomedical engineering" AND (neonatology OR "neonatal care") AND "innovation". In the PubMed database, 27 articles were found. The Cochrane Library returned 1 article. The EBSCO search resulted in 33 articles. Finally, in IEEE Xplore, 10 articles were found.

The screening of articles involved the initial review of titles and abstracts to identify potentially relevant studies, followed by the thorough reading of the selected articles to confirm their relevance and quality.

Data extraction consisted of collecting relevant information from each study, including the type of medical device, the population studied, stages of product development, and technological and clinical challenges. The synthesis of the data was carried out through a narrative synthesis, characterizing the included studies and highlighting the main innovations and results.

The discussion of the findings involved a critical evaluation, highlighting the main contributions to the field of neonatology and the practical implications for the development of new devices. The findings summarized key insights and offered recommendations for future research and innovation.

Finally, the results were analyzed to identify gaps in the research and emerging trends. Gaps were identified in areas with a lack of data or need for more research, while trends highlighted promising technologies and areas of innovation.

RESULTS

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In recent decades, technological innovations have increased exponentially. Artificial intelligence and machine learning are increasingly being used for the monitoring and prognosis of neonatal conditions (Aryanto et al., 2023; Zhang et al., 2023).

3D printing has proven to be a tool in the creation of personalized devices, adapted to the specific needs of each patient. From molds for respiratory support devices to biocompatible implants, 3D printing offers vast possibilities for the customization and improvement of neonatal devices (Ventola, 2014).

Continuous assessment of vital signs can detect early clinical problems in newborns. Wearable devices incorporate non-invasive or minimally invasive monitoring technologies and use wireless communication sensors to assess vital data such as heart rate, oxygen saturation and temperature continuously, remotely and in real time, improving accuracy, care safety and baby comfort. Advances in monitoring technologies have been associated with a significant reduction in neonatal mortality and serious complications (Babar & Rahman, 2021; Cay et al., 2021; Nantume et al., 2023; Schnitzler et al., 2024; Wu et al., 2022).

Enteral and parenteral feeding devices with advanced technology, such as enteral feeding pumps with precise, less invasive controls and sensors to monitor the volume and rate of infusion, ensure accurate and safe administration of nutrients for the development of premature newborns. The implementation of these technologies has been associated with improved nutritional outcomes and neonatal growth (Karpen & Poindexter, 2024; Walsh et al., 2020).

Mechanical ventilation is a common intervention in neonatal intensive care units. Recent advances include ventilators that utilize gentler ventilation modes, such as high-frequency oscillatory ventilation and continuous positive airway pressure ventilation, and have shown improved clinical outcomes, including lower incidence of bronchopulmonary dysplasia and better survival rates. In addition, smart ventilators use artificial intelligence algorithms to automatically adjust ventilation parameters based on the neonate's individual needs (Baldan et al., 2022; Hibberd et al., 2023; Phatigomet et al., 2023).

Hospital-acquired infections pose a potentially fatal threat to newborns. Among the innovations are intravenous access systems with antimicrobial coatings and catheters equipped with sensors capable of detecting early signs of infection, contributing to the reduction of the incidence of neonatal sepsis. The introduction of these catheters has been shown to be effective in decreasing neonatal sepsis rates, without increasing treatment

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costs (Balain et al., 2015; Gilbert et al., 2020; Lai et al., 2016; Paredes et al., 2014; A. K. Sinha et al., 2016). Some advanced infection prevention technologies, including antimicrobial coatings and disinfection systems, are being integrated into incubators and other neonatal equipment (Dunne et al., 2017; Ghosh et al., 2022; Oves et al., 2023; Rtimi, 2021; van Gent et al., 2021).

Systems that use artificial intelligence to predict and prevent neonatal complications, such as sepsis or respiratory crises, can enable early and more effective interventions. Studies show that artificial intelligence can help predict adverse events, such as neonatal sepsis, with greater accuracy than traditional methods (Kaliappan et al., 2023; Rallis et al., 2024; Robi & Sitote, 2023).

Telemedicine is being incorporated into neonatal care, allowing remote consultations with specialists and remote monitoring. Digital health management systems enable more effective integration of patient data and personalization of treatment (Bhat et al., 2024; Joshi et al., 2022; Padovani et al., 2023; Rtimi, 2021; van Gent et al., 2021).

FINAL CONSIDERATIONS

The aim of this research was to describe the development of medical devices, explore technological advances in neonatology, and highlight the latest devices and their contributions to clinical practice. In addition, it sought to identify gaps in current research and propose recommendations for future investigations and development of technologies.

The main results of this review indicate that technological innovations, such as artificial intelligence and machine learning, have been fundamental for the monitoring and prognosis of neonatal conditions. These technologies have allowed important improvements in the precision and personalization of treatments, resulting in better prognoses for neonates. 3D printing has emerged as a promising tool for creating personalized devices, from molds for respiratory support devices to biocompatible implants, offering vast possibilities for personalization and improvement of neonatal care.

In addition, the implementation of wearable devices for continuous monitoring of vital signs and advanced enteral and parenteral feeding devices have demonstrated a positive impact on neonatal health. Advanced mechanical ventilation, with gentler modes and smart ventilators, has improved clinical outcomes and reduced the incidence of serious complications. Infection prevention systems, such as catheters with antimicrobial coatings

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and sensors for early detection of infections, have contributed to the reduction of neonatal sepsis.

The theoretical implications of this research are significant as they provide a deeper understanding of how technological innovations are shaping clinical practice in neonatology. The integration of artificial intelligence and machine learning, 3D printing, and advanced sensors represents a theoretical advance in the approach to neonatal care, enabling more precise and personalized medicine. These advances not only improve clinical outcomes, but also expand knowledge about the specific needs of neonates and how to meet them more effectively.

In practical implications, the technological advances described have the potential to revolutionize clinical practice in neonatal intensive care units. The use of customized devices and continuous non-invasive monitoring improves the accuracy and safety of care, increasing the effectiveness of interventions. The implementation of these technologies can reduce neonatal mortality and long-term complications, promoting a healthy development of newborns. In addition, the adoption of artificial intelligence systems for predicting complications allows for faster and more effective interventions that improve clinical outcomes.

However, this research also identified limitations, such as the variability of neonatal medical pathologies that require highly specialized solutions, many of which have not yet been sufficiently explored or validated. In addition, the accessibility and cost of these devices are limiting factors, especially in resource-scarce regions. The need for adequate training of health professionals for the effective use of these new technologies is also a barrier to be considered.

For the continuity of this research, it is recommended to explore new applications of artificial intelligence and 3D printing in the development of neonatal medical devices, as well as to investigate ways to make these technologies more accessible and economically viable. Future studies should also focus on the clinical validation of new emerging technologies and the continuous training of health professionals, ensuring the effective adoption of these innovations in daily clinical practices. In addition, interdisciplinary collaboration is important for the creation of innovative and comprehensive solutions that meet the complex needs of neonates and their families.

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