POSITION PAPER

Digital Tools in Pediatric Chronic Respiratory Disease Management: Technical, Ethical, and Social Challenges – A Position Paper by the Italian Pediatric Respiratory Society (SIMRI/IPRS)

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ABSTRACT

Digital technologies are increasingly integrated into the management of pediatric chronic respiratory diseases, offering new opportunities for monitoring, diagnosis, treatment adherence, and patient engagement. However, their implementation raises important technical, ethical, and social challenges, including issues of interoperability, data protection, equitable access, and clinical validation. This position paper, endorsed by the Italian Pediatric Respiratory Society (SIMRI/IPRS), synthesizes current evidence and expert consensus to provide a structured overview of these challenges. It highlights areas of unmet need, such as the development of standardized guidelines, the promotion of responsible data sharing, and the creation of inclusive digital health policies. By addressing these aspects, the paper aims to inform clinicians, researchers, policymakers, and technology developers, fostering the safe, effective, and equitable integration of digital innovations into pediatric respiratory care.

IMPACT STATEMENT

This position paper synthesizes current evidence to guide the safe, equitable, and effective integration of digital health tools in pediatric respiratory care.

HIGHLIGHTS BOX

What is already known about this topic? Digital tools are increasingly used in pediatric respiratory care, but their adoption is inconsistent and challenged by issues of interoperability, data protection, clinical validation, and health equity. **What does this article add to our knowledge?** This multidisciplinary position paper from the Italian Pediatric Respiratory Society defines technical, ethical, social, and regulatory priorities for the safe, equitable, and sustainable integration of digital technologies into pediatric respiratory medicine. **How does this study impact current management guidelines?** It provides expert-based recommendations supporting the development of standardized guidelines and policies that ensure responsible, child-centered use of digital tools in pediatric chronic respiratory disease management.

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10.56164/PediatrRespirJ.2025.84

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KEY WORDS

Digital health; pediatric respiratory diseases; chronic disease management; telemedicine; digital therapeutics; data sharing; health equity; ethical implications.

INTRODUCTION

Pediatric chronic respiratory diseases, such as asthma, cystic fibrosis (CF), bronchopulmonary dysplasia (BPD), bronchiectasis, and primary ciliary dyskinesia, represent a significant burden for patients, families, and healthcare systems worldwide. These conditions are associated with long-term morbidity, recurrent exacerbations, reduced quality of life, and considerable healthcare costs (1). Early diagnosis, close monitoring, and individualized management are crucial to improving clinical outcomes and preventing disease progression.

Over the past two decades, digital health technologies have progressively reshaped the management of chronic respiratory conditions. These include mobile health (mHealth) applications, wearable sensors, telemonitoring platforms, and artificial intelligence (AI)–driven analytics. These tools offer new ways to track symptoms, promote adherence and enable timely clinical decisions, complementing traditional in-person care (2).

The COVID-19 pandemic acted as a catalyst for the adoption of digital tools (DTs) in pediatric respiratory medicine. Physical distancing measures, combined with the need to maintain continuity of care, accelerated the implementation of telemedicine and remote monitoring systems, demonstrating their potential to complement traditional in-person care. At the same time, this rapid integration has exposed critical gaps. These include limited interoperability, concerns regarding data security, inequalities in access, and insufficient evidence on long-term clinical impact (2).

Despite growing enthusiasm, the use of DTs in pediatrics presents unique challenges. Children and adolescents differ from adults not only in physiology but also in their developmental, cognitive, and psychosocial needs. Digital solutions must therefore be tailored to children's specific needs to ensure usability, safety, and engagement, while preserving their autonomy and well-being.

This position paper, endorsed by the Italian Pediatric Respiratory Society (SIMRI/IPRS), presents a structured analysis of the technical, ethical, and social challenges in adopting DTs for the management of pediatric chronic respiratory diseases. It reviews current evidence, identifies areas of unmet need, and highlights key factors for ensuring their safe, effective, and equitable integration into pediatric respiratory care.

TECHNOLOGICAL OVERVIEW

The term DTs refers to a wide range of technologies designed to perform specific tasks, enhance functions, or facilitate processes through digital means. DTs may be either physical (*e.g.*, electronic devices) or virtual (*e.g.*, software, mobile applications, artificial intelligence (AI) solutions, web-based platforms). These tools can be integrated into electronic devices, allowing for complex functionalities.

In the field of respiratory medicine, DTs are typically categorized by their location and level of portability: home devices, hand-held devices, and portable or wearable devices (2). When properly supported, these devices can collect biometric data and transmit it to mobile applications installed on patients' devices or to web-based platforms accessible to clinicians. Mobile applications may synchronize with third-party devices and offer functionalities such as symptom diaries, educational resources, serious games (3), reminders, and secure communication channels with healthcare professionals.

This integration of DTs facilitates remote patient monitoring or telemonitoring, becoming a vital part of telemedicine workflows. When equipped with AI capabilities, these tools can analyze complex datasets to support disease recognition, risk stratification, exacerbation prediction, and early detection of clinical deterioration (4, 5) (**Table 1**).

Home devices

Home digital devices are advanced medical tools designed for use by patients in their own homes. Examples of these devices include smart home-care ventilators, home respiratory polygraphy systems, long-term oxygen therapy devices, sphygmomanometers, contactless (or "invisible") monitors, and environmental sensors. Smart ventilators, respiratory polygraphy systems, and oxygen therapy devices can continuously measure multiple respiratory parameters. This can be done either directly or indirectly through sensors mounted on the patient, and these measurements are supported by embedded software (6-9). Environmental monitors can detect and report local air pollution levels, alerting patients in cases of hazardous exposure (10). Emerging non-contact systems ("invisible") use fixed-position infrared or standard cameras, microphones, and environmental sensors placed in the patient's home. These systems

Table 1. *Key Elements of the Technological Overview.*

Definition of digital tools (DTs) – Encompass physical and virtual technologies designed to perform specific tasks, enhance functions, or facilitate processes in healthcare, including devices, software, applications, artificial intelligence solutions, and web-based platforms.
Classification by portability – DTs in pediatric respiratory medicine can be categorized as home devices, hand-held devices, and portable/wearable devices, each with distinct functions and integration potential.
Home devices – Include smart home-care ventilators, home respiratory polygraphy, long-term oxygen therapy devices, environmental monitors, and emerging contactless ("invisible") monitoring systems for continuous data collection in domestic settings.
Hand-held devices – Such as digital peak flow meters, portable spirometers, and forced oscillation technique devices, often equipped with Bluetooth connectivity for real-time data transfer and remote monitoring.
Portable and wearable devices – Including smartphones, tablets, smartwatches, activity trackers, and sensor-based wearables capable of tracking respiratory and non-respiratory parameters during daily life.
Clinical integration – DTs support remote monitoring, telemedicine, and AI-assisted decision-making, with current applications primarily in asthma, cystic fibrosis, sleep-disordered breathing, and rare pediatric lung diseases.
Evidence base – Randomized controlled trials (mainly in asthma) suggest benefits for adherence and disease control, although larger, long-term studies are needed to confirm sustained impact.

monitor physiological and environmental parameters without requiring physical interaction (11-13).

Hand-held devices

Hand-held digital devices are small, portable tools designed for manual operation. In pediatric respiratory medicine, these devices include digital peak flow meters, hand-held spirometers, and devices that utilize the forced oscillation technique (FOT). These devices aim to reduce measurement variability and usually come equipped with Bluetooth connectivity, allowing them to integrate with mobile applications (14). FOT devices require minimal patient cooperation and can assess lung mechanical properties without supervision (15). Additionally, inhaler-integrated sensors can record actuation events, which provide indirect measures of adherence and disease control, particularly in asthma management (16).

Portable and wearable devices

Portable and wearable devices are designed for mobility and continuous use. Portable devices, such as smartphones, tablets, and compact hand-held instruments, are lightweight and easy to carry. Wearable devices include smartwatches, activity trackers, chest straps, sensor patches, pulse oximeters, and smart textiles. These devices are worn on the body and often incorporate multiple biosensors (17). These devices can measure both respiratory and non-respiratory parameters, with data typically transmitted to applications held by patients or platforms monitored by clinicians. Additional features may include electronic symptom diaries and automated alerts (18).

Current state of adoption in pediatric pulmonology

The COVID-19 pandemic further accelerated the adoption of DTs in pediatric pulmonology, highlighting the value of remote monitoring and virtual care (19, 20). Most randomized controlled trials (RCTs) in pediatric respiratory medicine have focused on asthma, the most common chronic respiratory disease in children (21, 22). These interventions have included health education for patients and caregivers, behavioral strategies such as serious games and educational apps, electronic adherence monitoring devices linked to mobile applications, and the integration of mobile health into routine care. Evidence indicates that these tools can enhance adherence and improve asthma control; however, there is a need for larger, longer-term RCTs with follow-up after interventions to confirm the sustainability of these benefits (3). For sleep-disordered breathing, no RCT has directly compared telemedicine follow-ups with standard in-hospital care. Nonetheless, existing reports show promising feasibility and acceptance (23-26). In the case of CF, telehealth and remote monitoring have demonstrated good feasibility and reliability, facilitating interactions with patients and their families (27-29). Similar advantages have been observed in other rare pedi-

atric respiratory diseases, including primary ciliary dyskinesia, BPD, and interstitial lung disease (2).

Telemonitoring is becoming increasingly common for children receiving long-term continuous positive airway pressure (CPAP) or non-invasive ventilation (NIV), with data primarily used to assess adherence, leaks, and respiratory parameters (30, 31).

TECHNICAL CHALLENGES

Despite their rapid development, implementing digital technologies in pediatric respiratory medicine still presents several technical challenges. These challenges include system interoperability, data accuracy and reliability, and cybersecurity and data protection. In pediatrics, age-specific physical and psychological challenges underline the importance of user-centered design (**Table 2**).

System Interoperability

System interoperability is defined as "the ability of different information systems, devices and applications to access, exchange, integrate, and cooperatively use data in a coordinated manner, within and across organizational, regional, and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally" (32). Effective interoperability allows secure data sharing across platforms while maintaining data integrity and reducing the need for human intervention. In contrast, a lack of interoperability can compromise the safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity of DTs (33). Clear and shared standards for terminology, data structure and security are essential to achieve seamless interoperability between home-monitoring systems and clinical platforms. Strengthening integration reduces fragmentation and supports more efficient and timely care (2).

Data accuracy and reliability

A key challenge is ensuring the accuracy, reliability, and integrity of data collected by DTs. Inaccurate or incomplete data can result in misdiagnosis, flawed prognostic assessments, and inappropriate clinical decisions. In pediatrics, the variations in age, size, and physiology often require datasets to be divided into smaller cohorts, which negatively impact the performance of digital models. However, advanced data-science techniques, such as model fine-tuning, may help address these limitations in the future (34).

Cybersecurity and data protection

Cybersecurity is a critical concern in safeguarding pediatric patients from privacy breaches, cyberbullying, and exposure to inappropriate content. The European regulatory framework aims to balance technological innovation with the protection of children's rights and sensitive health information (35).

Among the key instruments, the General Data Protection Regulation (GDPR) strengthens transparency, security, and accountability in the collection and processing of personal and health data, introducing specific safe-

***Table 2**. Key Technical Challenges in the Use of Digital Tools for Pediatric Chronic Respiratory Disease Management.*

System interoperability – Need for standardized terminology, content, and security protocols to enable seamless integration between home-monitoring tools and healthcare systems, ensuring timely and coordinated patient care.
Data accuracy and reliability – Ensuring completeness and validity of collected data, avoiding errors that could lead to inappropriate clinical decisions, and addressing pediatric heterogeneity that may impact model performance.
Cybersecurity and data protection – Safeguarding sensitive health and biometric data from breaches, ensuring compliance with European and national regulations, and applying specific protections for minors.
Child-specific physical challenges – Designing devices adapted to children's size and growth, preventing discomfort, pressure injuries, or interference with treatment adherence, and exploring customizable solutions such as 3D-printed interfaces.
Child-specific psychological challenges – Adapting tools to the cognitive and emotional needs of children and adolescents, promoting engagement without fostering screen dependency, and tailoring educational strategies to developmental stages.
User-centered design – Involving children and caregivers in co-development, ensuring devices are safe, affordable, easy to use, and socially compatible, while minimizing physical and environmental risks.

guards for minors, such as the requirement for parental consent when processing the personal information of individuals under 16 years of age, and the obligation to provide age-appropriate explanations regarding the implications of data use (36). The Medical Device Regulation (MDR) establishes minimum safety and security standards for all medical devices, including digital ones (37). Additional legislative initiatives, such as the Data Act, Data Governance Act, Cybersecurity Act, and Artificial Intelligence Act, further regulate fairness, cybersecurity, and innovation in information and communication technologies and AI-driven products (38).

In the healthcare domain, the European Health Data Space (EHDS) represents a pivotal initiative to create a unified framework for cross-border access, sharing, and reuse of electronic health data, enforcing interoperability, privacy, and cybersecurity standards (39). A dedicated extension, the Pediatric Health Data Space (PHDS), is under development to facilitate secure data exchange among pediatric hospitals, ensure compliance with data protection laws, and support AI-driven research and collaborative pediatric care (40). For high-risk data processing involving children's biometric or health information, additional safeguards—such as Data Protection Impact Assessments—are recommended to ensure the highest standards of privacy and security (35, 36).

Child-specific technical challenges

There are specific technical challenges related to children, which can be either physical or psychological in nature. Children often need miniaturized devices or equipment that can adapt as they grow (2). In the context of chronic respiratory care, examples include appropriately sized oxygen saturation (SpO_2) sensors for BPD and well-fitting interfaces for long-term NIV. Bulky or uncomfortable interfaces can lead to reduced data accuracy, increased air leaks, and impaired patient-ventilator synchrony. Additionally, interfaces that are too narrow may cause pressure injuries on the forehead, nasal bridge, cheeks, or chin, which can decrease patient adherence. Customized 3D-printed interfaces have the potential to improve comfort, minimize side effects, and enhance outcomes for home NIV (41).

DTs should be tailored to meet the changing cognitive and emotional needs of children, supporting disease self-management while promoting independence. This is especially important during adolescence, as greater engagement can enhance adherence to treatment (34). DTs must also consider age-related physiological changes and should utilize interactive and engaging strategies, which tend to be more effective than passive education (2). Additionally, it is crucial for digital tools to avoid increasing daily screen time or encouraging digital dependency, such as smartwatch addiction (42). Ideally, device connectivity should be restricted to healthcare-related functions only (34).

User-centered design

A user-centered approach is crucial in pediatrics. Children's needs and caregivers' insights should be actively incorporated into the design and customization of digital technologies to ensure safety, usability, and accessibility. Devices must be affordable, intuitive, and suitable for children of different ages, featuring interfaces that children can use independently, without interfering with their social activities. Instructions should be simple and tailored to developmental stages, using oral guidance for younger children and text-based prompts for adolescents (34). Additionally, devices should be designed to protect children from the devices and vice versa (34). This includes minimizing risks of ingestion or inhalation of small parts, preventing mechanical breakage, and avoiding exposure to harmful materials.

Clinical risks and practical barriers in the use of digital tools

DTs may generate false alarms or low-quality signals, which can contribute to alert fatigue and increase workload for clinicians and caregivers (2). Continuous data streams may also lead to information overload when systems are not well integrated or when algorithms lack pediatric validation (33, 34). These challenges can elevate clinicians' workload and create anxiety for families, particularly when exposed to frequent alerts or continuous surveillance (34). Addressing these barriers requires streamlined workflows, reliable alert management, and appropriate training for both healthcare professionals and families.

ETHICAL CHALLENGES

The integration of DTs into pediatric respiratory care brings important ethical considerations that must be addressed to ensure responsible and equitable use. These chal-

Table 3. Key Ethical Challenges in the Use of Digital Tools for Pediatric Chronic Respiratory Disease Management.

Privacy and informed consent – Protecting children's rights in the collection, storage, and use of health data, with age-appropriate communication to ensure understanding and meaningful participation.
Data security – Safeguarding sensitive pediatric information from breaches, misuse, or unauthorized access while complying with relevant regulations.
Equity of access – Avoiding disparities in availability and use of digital tools caused by socioeconomic status, infrastructure gaps, or low digital literacy, and promoting inclusion through targeted support programs.
Patient and family autonomy – Encouraging shared decision-making and self-management skills while preventing over-reliance on technology or excessive surveillance that may undermine independence.
Child-centered design – Developing digital tools that reflect children's cognitive, emotional, and developmental needs, ensuring usability, safety, and engagement without compromising well-being.

lenges can be grouped into three main domains: privacy and informed consent, equity of access, and impact on patient and family autonomy. Each domain reflects the need to balance technological innovation with the protection of children's rights, well-being, and developmental needs (**Table 3**).

Privacy and informed consent in pediatric patients

Digital technologies have transformed healthcare by enabling personalized treatments, continuous monitoring, and remote care. In pediatrics, however, these advancements raise specific ethical concerns related to privacy, data security, and informed consent. In the digital era, personal and medical data circulate widely. This requires a careful balance between protecting children's rights and ensuring access to appropriate care. Because children may not fully understand the implications of data processing, enhanced safeguards and age-appropriate explanations are essential.

The concept of acting in the "*best interests of the child*", as framed by Beauchamp and Childress (43) through the four principles of biomedical ethics, autonomy, beneficence, non-maleficence, and justice, provides a foundation for ethical decision-making in this context. Parental supervision through DTs may contribute to a surveillance culture in which children's privacy is overlooked in favor of perceived safety. Moreover, children's consent is rarely sought in medical decision-making (44), and insufficient or misleading information may generate anxiety or mistrust toward digital health. To address these concerns, children should receive clear, age-appropriate explanations about how DTs work and their intended purpose (2). Education for both families and healthcare providers on transparent, developmentally appropriate communication can improve acceptance and adherence to digital interventions in pediatric care.

Inequalities in access to digital tools

Digital health offers benefits that extend beyond individual care to population-level health improvements (45). Nevertheless, pediatric DTs remain underrepresented compared with adult-targeted technologies, partly due to lower financial investment (46). Recent regulatory efforts in Europe and the United States have sought to address this gap by encouraging industry to address children's specific health needs (47).

The ethical principle of justice demands equitable access to healthcare. However, DTs may unintentionally widen disparities, particularly among economically disadvantaged families, due to high device costs, inadequate infrastructure, and low digital literacy (34). In addition, self-exclusion from digital health initiatives is more common in lower-income groups, exacerbating the divide between wealthier and poorer families (48). Strategies to mitigate these inequalities include reimbursement programs for eligible households, community-based digital literacy initiatives, and targeted policies ensuring that all children, regardless of socioeconomic background, can benefit from technological innovation in healthcare.

Impact on patient and family autonomy

Autonomy is defined as self-governance in thought and action (49). In pediatric care, children rely on adults for decision-making (34), but a child-centered approach—actively involving young patients in their own care—can foster informed choice, responsibility, and self-management skills (2). Digital technologies may enhance

Table 4. Key Social Challenges in the Use of Digital Tools for Pediatric Chronic Respiratory Disease Management.

Acceptance and usability – Variability in patient, family, and clinician acceptance; potential reduction in in-person interactions; limitations in assessing qualitative and psychological aspects; risk of weakened trust when digital outputs differ from clinical judgment.
Cultural and socioeconomic barriers – Financial constraints, low digital literacy, self-exclusion due to mistrust or unfamiliarity, language barriers, and culturally rooted resistance; influence of parental attitudes and automation bias.
Education and training – Need for tailored programs for children, caregivers, and healthcare providers to ensure correct use, integration into care, and awareness of benefits and limitations.
Community engagement – Importance of collaboration with schools, local organizations, and cultural leaders; provision of multilingual and culturally adapted resources to promote inclusion and trust.

autonomy by enabling self-monitoring and shared decision-making.

However, potential drawbacks exist. Automated digital algorithms can contribute to depersonalization, with children perceived primarily as sources of data (2). Discrepancies between device-generated information and the child's own symptom reports may undermine the child's credibility (50), and caregivers may place greater trust in device outputs than in the patient's experience. Excessive parental monitoring via DTs may also reduce opportunities for independent self-management, increasing anxiety and dependence (2, 34).

Ethically sound practice requires a balance between leveraging digital tools for improved health outcomes and preserving children's mental and emotional well-being. Clinical teams should promote informed participation, respect for autonomy, and guidelines to prevent over-surveillance, ensuring that technology supports rather than diminishes the child's role in their own care.

SOCIAL CHALLENGES

The integration of DTs into pediatric respiratory care also raises important social challenges that can influence their acceptance, accessibility, and effectiveness. These challenges relate primarily to acceptance and usability, cultural and socioeconomic barriers, and education and training for users, each of which has implications for equitable and sustainable adoption (**Table 4**).

Acceptance and usability by patients, families, and healthcare providers

The use of DTs in pediatric care can reshape the physician–child–parent relationship, particularly by reducing the frequency of in-person consultations. Evidence from pediatric asthma research shows that attitudes toward DTs have evolved over time. Before the SARS-CoV-2 pandemic, only 19% of parents preferred DT-based consultations over traditional visits (48); during the pandemic, this figure rose to 43%, with 53% of children expressing a preference for digital health solutions (51).

Despite growing acceptance, DTs may not fully capture the relational and qualitative dimensions of care that emerge during in-person encounters. Emerging digital twin systems (DTS) create a virtual representation of the patient and may weaken the empathic bond between patients, families, and healthcare providers (34). Discrepancies between DTS-generated recommendations and physician advice may also undermine mutual trust (53).

Socioeconomic and cultural barriers

The implementation of DTs in pediatric healthcare can be hindered by financial barriers, as lower-income families may struggle to afford these technologies, exacerbating existing healthcare disparities (53). Limited digital literacy further compounds these inequalities, making effective use of DTs more challenging (34).

Self-exclusion is another concern. Individuals with lower educational attainment or socioeconomic status may be reluctant to engage with digital health initiatives due to mistrust or unfamiliarity. Language barriers and cultural attitudes toward healthcare technology can also contribute to resistance, especially in communities where traditional models of care are deeply rooted (34, 48).

Parental attitudes strongly influence the acceptance of DTs. Some families may be hesitant to grant children greater autonomy in managing their conditions, while automation bias, a tendency to trust digital out-

puts over human judgment, can create conflicts when device-generated results contradict patient-reported symptoms (54). Addressing these cultural and attitudinal factors is essential for equitable and effective DT adoption.

Education and training for use

Targeted education and training programs are key to overcoming these barriers and ensuring that DTs are accessible, user-friendly, and culturally appropriate (55). For parents and caregivers, digital literacy initiatives should explain how DTs function, their benefits, and their limitations. Practical workshops and online resources can bridge knowledge gaps and build confidence in using these tools (55). For children, educational materials should be engaging, interactive, and age-appropriate, with gamified tools, mobile apps, and instructional videos that teach correct device use and symptom reporting, fostering active participation in care.

Healthcare providers also require dedicated training to integrate DTs into practice effectively. Pediatricians should be able to interpret DT-generated data, combine digital insights with clinical judgment, and address family concerns (56). Training should also cover ethical aspects, including data privacy, patient autonomy, and potential biases in digital assessments.

Finally, community engagement is essential to build trust in DTs. Collaboration with schools, local organizations, and cultural leaders can help dispel misconceptions, while multilingual and culturally adapted resources can ensure that diverse populations are informed, included, and empowered to use DTs effectively.

REGULATORY ASPECTS AND CHILDREN'S RIGHTS

DTs used in pediatric respiratory care are regulated within a broad and evolving framework that aims to balance innovation with safety, privacy, and children's rights. Depending on their intended purpose and associated risk, digital tools may qualify as medical devices and must comply with the Medical Device Regulation (MDR) and, when applicable, the In Vitro Diagnostic Regulation (IVDR) (37). Additional guidance from regulatory bodies, such as Medical Device Coordination Group (MDCG) documents and international harmonization initiatives, supports consistent interpretation and implementation of these requirements (57).

Networked or software-based devices must also meet cybersecurity and data-governance obligations, as defined by the GDPR (36) and complemented by recent European initiatives on data governance and interoperability (58, 59). In parallel, emerging frameworks such as the European Health Data Space (EHDS) (39) and the Artificial Intelligence Act (60) establish further standards for data protection, transparency, and the responsible use of AI-enhanced systems in healthcare.

Children require particular protection in the digital environment because they may not fully understand how their personal and health data are collected, shared, and reused. International and European policy instruments - including the Council of Europe Recommenda-

***Table 5**. Key Regulatory Aspects and Children's Rights in Pediatric Digital Tools.*

Regulatory frameworks – DTs must comply with MDR/IVDR and follow MDCG guidance and harmonization initiatives. Networked or software-based devices require GDPR compliance and alignment with emerging EU governance frameworks, including the EHDS and the AI Act.
Device-specific requirements – Regulatory obligations vary by device type, with additional safeguards for connected and AI-driven systems, particularly regarding data governance and transparency.
Children's rights – European and international instruments - Council of Europe Recommendation, UN CRC General Comment No. 25, and relevant Digital Services Act provisions - highlight the best interests of the child, age-appropriate design, and protections for vulnerable groups.
Safety and usability – Devices must minimize physical risks (including PFAS exposure), limit screen time, and support developmental appropriateness while avoiding excessive surveillance or stress for families.
Regulatory incentives – The absence of structured pediatric-specific pathways limits innovation. Strengthened oversight, dedicated routes, and targeted incentives are needed to promote validated and equitable child-centered DTs.

AI Act – Artificial Intelligence Act; EHDS – European Health Data Space; GDPR – General Data Protection Regulation; IVDR – In Vitro Diagnostic Regulation; MDCG – Medical Device Coordination Group; MDR – Medical Device Regulation; PFAS – Per- and Polyfluoroalkyl Substances; UN CRC – United Nations Convention on the Rights of the Child

tion on children's rights in the digital environment (61), the UN Committee on the Rights of the Child General Comment No. 25 (62), and binding provisions of the Digital Services Act - emphasize the best interests of the child, age-appropriate communication, enhanced safeguards for sensitive data processing, and attention to children living in vulnerable circumstances or with disabilities.

Safety, design, and usability requirements are especially relevant for pediatric DTs. Beyond regulatory compliance, devices should minimize physical risks, such as choking, ingestion, or exposure to harmful substances including per- and polyfluoroalkyl substances (PFAS)-containing components (63), and limit unnecessary screen time (42). Interfaces must match children's developmental and cognitive abilities, supporting autonomy without creating excessive surveillance or stress for families (34, 64). Child-centered design and human-factors engineering play a key role in ensuring usability, comfort, and psychological well-being.

Compared with pharmaceuticals, where pediatric investigation plans are mandatory, the medical device sector lacks systematic pediatric-specific evaluation. This gap is particularly relevant for DTs that influence clinical decision-making or daily disease management. Dedicated regulatory pathways, stronger involvement of pediatric expert committees, and targeted incentives could promote child-centered innovation. European initiatives in this field (65) underscore the importance of developing, validating, and equitably implementing digital technologies adapted to children's needs (**Table 5**).

SUSTAINABILITY ASPECTS

DTs offer substantial clinical advantages in pediatric respiratory care but also raise sustainability considerations that must be addressed to ensure responsible long-term implementation (**Table 6**). While telemedicine and remote monitoring can reduce emissions associated with travel and in-person appointments, thereby lowering the overall carbon footprint of healthcare delivery (66, 67), the production, operation, and disposal of digital devices contribute to energy consumption, resource depletion, and electronic waste. Globally, the healthcare sector already represents a significant environmental burden (66), and the growing use of digital tools may further increase this impact if not accompanied by appropriate mitigation strategies.

Electronic waste remains a critical challenge. Medical and consumer-device components, including batteries, sensors, plastics, and circuit boards, generate pollutants that pose risks to ecosystems and human health if not properly managed (68). Energy-intensive infrastructures such as data centers, required to store and process large-scale health data, also contribute to greenhouse gas emissions (69). A sustainability-oriented approach therefore requires assessing the full lifecycle of DTs, from manufacturing to end-of-life disposal, and promoting design principles that extend device lifespan, support repairability, and facilitate recycling.

Several strategies can help minimize environmental impact. These include using energy-efficient cloud services, optimizing software and data-processing sys-

***Table 6**. Key Sustainability Aspects of Digital Tools in Pediatric Chronic Respiratory Disease Management.*

Environmental impact – DTs reduce travel-related emissions and paper use but contribute to e-waste, energy consumption, and environmental degradation from device manufacturing and mineral extraction.
Data center footprint – Large-scale storage of electronic health data consumes significant electricity, often from non-renewable sources, increasing the carbon footprint.
Resource use in manufacturing – Production of smartphones, wearables, and sensors relies on critical minerals and generates waste during the device lifecycle.
E-waste management – Improper disposal of medical electronics and plastics can cause pollution; recycling and safe disposal programs are essential.
Sustainable strategies – Adopt renewable-powered, energy-efficient data centers; use optimized software and AI for energy management; apply lifecycle assessment before implementation.
Circular economy principles – Extend product lifespans through modular upgrades, refurbishing, reusing, and recycling; promote biodegradable materials and eco-friendly packaging.
Policy and awareness – Mandate environmental criteria in procurement, incentivize sustainable design, integrate green principles into healthcare training, and raise awareness among patients and providers.

tems, applying data-minimization principles, and promoting renewable-energy solutions for digital infrastructures (69). Lifecycle assessments and responsible procurement processes can guide healthcare institutions in selecting devices and platforms with lower ecological footprints. In addition, recycling and take-back programs for digital health devices, such as inhalers, sensors, or remote-monitoring equipment, should be encouraged to reduce e-waste generation (68). Educational initiatives for families and clinicians can improve awareness of proper disposal practices and support a more sustainable culture of device use.

Embedding sustainability criteria into digital health strategies, including eco-design, reduced energy consumption and circular-economy approaches, can minimize the environmental footprint of DTs and support long-term responsible adoption (70, 71).

CLINICAL AND RESEARCH PERSPECTIVES

DTs have the potential to become integral components of therapeutic pathways for pediatric chronic respiratory diseases. Effective integration requires a hybrid model that combines in-person clinical care with remote monitoring and virtual consultations. Such models can enable early detection of exacerbations, personalized treatment adjustments, and enhanced patient engagement. The integration process should follow structured protocols, ensuring interoperability between DTs and electronic health records, and establishing clear criteria for clinical action based on device-generated data.

Collaboration between pediatric respiratory specialists, general practitioners, allied health professionals, and technical experts is essential to ensure smooth incorporation into existing care workflows. Additionally, integration should be accompanied by training programs for healthcare providers, as well as educational support for patients and caregivers, to maximize usability and adherence.

Despite significant progress, several unmet needs must be addressed to optimize the use of DTs in pediatric respiratory care. First, there is a lack of evidence-based guidelines specifically focused on the responsible implementation of DTs in children. These guidelines should cover safety, efficacy, ethical considerations, and long-term follow-up. Second, policies are needed to promote equity, ensuring that DT adoption does not exacerbate existing socioeconomic or geographic disparities. This includes supporting infrastructure development in underserved areas, reimbursement schemes, and digital literacy initiatives. Third, sustainability considerations must be embedded in policy and procurement processes, incentivizing eco-friendly design, energy efficiency, and responsible e-waste management. Finally, fostering collaborative approaches among clinicians, researchers, industry stakeholders, patient advocacy groups, and policymakers will be critical to drive innovation, validation, and widespread adoption of high-quality, child-centered digital health solutions.

OPERATIONAL FRAMEWORK AND KEY RECOMMENDATIONS FOR THE INTEGRATION OF DIGITAL TOOLS IN PEDIATRIC RESPIRATORY CARE

The implementation of DTs in pediatric respiratory care benefits from a structured and pragmatic framework that supports clinicians, families, and policymakers in daily practice. Based on current evidence and expert consensus, we propose the following operational recommendations:

- Clinical Assessment and Prioritization: DTs should be selected according to the child's clinical profile, disease severity, and specific monitoring needs. Before implementation, clinicians should assess the potential benefits, risks, and feasibility of integrating each tool into existing care pathways.
- Data Governance, Privacy, and Transparency: Healthcare teams must ensure compliance with data protection regulations and provide families with clear, age-appropriate information about data use, storage, and access. Transparent communication fosters trust and encourages engagement.
- Integration into Clinical Workflows: Digital tools should complement, not replace, clinical evaluation. Clear action thresholds, alert hierarchies, and response workflows are needed to prevent data overload, false alarms, or misinterpretation. Institutions should ensure interoperability with electronic health records and avoid parallel, non-integrated platforms.
- Training and Digital Literacy: Clinicians, patients, and caregivers require tailored training to use digital tools effectively. Educational resources should cover device

functionality, correct data interpretation, and troubleshooting, while promoting realistic expectations and shared decision-making.

- Family Engagement and Psychosocial Support: Digital solutions should empower, but not overburden, families. Monitoring intensity should match the clinical scenario to avoid unintended stress or anxiety. Supportive communication and regular feedback loops help maintain adherence and prevent technology-related fatigue.
- Continuous Evaluation and Quality Improvement: Implementation should include mechanisms for ongoing assessment of usability, clinical impact, safety, and equity. Feedback from children, families, and clinicians should guide iterative refinement of digital systems and institutional policies.
- Equity and Accessibility: To prevent widening health disparities, programs should incorporate strategies to support families with socioeconomic vulnerabilities, limited digital literacy, or technological barriers. Reimbursement policies and institutional lending programs may improve access to essential devices.

CONCLUSIONS

DTs can enhance the management of pediatric chronic respiratory diseases by supporting early detection, treatment adherence and patient engagement. Their integration, however, requires careful attention to safety, equity, interoperability and sustainability.

The successful integration of DTs into pediatric respiratory care requires a careful balance between innovation and responsibility, aligning technological capabilities with the developmental needs, rights, and well-being of children. Clinicians must be supported by clear protocols, robust evidence, and interoperable systems; policymakers must enact regulations and incentives that promote both equity and sustainability; and industry must commit to child-centered design and high safety standards.

Looking ahead, the vision for the future is a digitally empowered, patient-centered healthcare ecosystem in which DTs complement, rather than replace, the human elements of care. Such a model would leverage real-time data, artificial intelligence, and telehealth to provide personalized, proactive, and participatory care, while maintaining empathy, trust, and respect for children's rights. Achieving this vision will require ongoing research, multidisciplinary collaboration, and a shared commitment to ensuring that digital innovation serves the best interests of every child.

ACKNOWLEDGMENTS

The authors wish to thank all members of the IPRS/SIMRI Board for their support in the dissemination of this study. Special appreciation is extended to the PeDiT-Care Study Group members for their substantial contribution to the conceptualization, coordination, and preparation of the manuscript.

COMPLIANCE WITH ETHICAL STANDARDS

Conflict of interest

The authors declare that they have no conflicts of interest relevant to the content of this article.

Financial support

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Authors' contributions

AL and GF conceived the position paper, coordinated the working group, and drafted the initial version of the manuscript. BA, AG, VM, MN, GR, and LV contributed to the literature review, methodology definition, and manuscript writing. DD and SLG critically revised the manuscript for important intellectual content and supervised the overall work. All authors contributed to the study design, reviewed the manuscript critically, and approved the final version. They all agree to be accountable for the integrity and accuracy of the work.

AL and GF contributed equally as co-first authors. DD and SLG contributed equally as co-last authors.

Ethical approval

Not applicable.

Data sharing and data accessibility

The data that support the findings of this review are available from the corresponding author upon reasonable request.

Publication ethics

The authors declare that this manuscript is original, has not been previously published, and is not under consideration for publication elsewhere. All authors have

approved the final version of the manuscript and agree with its submission to this journal.

The authors affirm that the work complies with the highest standards of research integrity. No data have been fabricated, manipulated, or falsified. The manuscript is free from plagiarism, and all sources and contributions have been appropriately acknowledged.

The authors confirm adherence to ethical principles regarding authorship, data transparency, and responsible communication of scientific results.

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