RSC Pharmaceutics

ROYAL SOCIETY OF CHEMISTRY

PAPER

View Article Online
View Journal

Cite this: DOI: 10.1039/d5pm00133a

Accelerating safer administration of medicines to children in low resource settings – bridging stakeholder viewpoints

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Received 8th May 2025,
Accepted 4th July 2025

DOI: 10.1039/d5pm00133a

rsc.li/RSCPharma

Accurate medicine administration *via* the appropriate route is crucial, with oral liquids requiring dosing devices for precision and inhalation therapy depending on well-designed devices to ensure proper drug delivery. Hence, a workshop was held to understand the uptake of already existing administration devices for oral and respiratory medicines in low- and middle-income countries (LMICs), and to assess the level of awareness of issues associated with use of administration devices as well as the need for innovative devices. Discussions and knowledge shared during this event showed the effectiveness of the workshop in fostering a deeper understanding of the issues regarding use and development of administration devices in low resource settings.

1. Introduction

Dosing errors are among the most common types of medication error, occurring more frequently in children due to their unique physiological conditions, which often necessitate the administration of small volumes.[1,2] Children under the age of 2 years and paediatric intensive care unit patients are at highest risk.[3] It has been reported that tenfold dosing errors in children can easily occur due to a misplaced decimal point or a trailing zero.[4] To achieve optimal clinical outcomes, it is essential to administer the correct dose *via* the appropriate route, which often requires the use of specialized dosing devices.

Among the various routes of drug administration, the oral route is commonly used for children and oral liquids are widely preferred across the whole paediatric age range (birth to 18 years).[5] While oral liquids offer dosing flexibility and ease of swallowing, ensuring accurate dose requires the use of appropriate administration devices. Inhalation, another important route of drug delivery, is particularly effective for the local treatment of respiratory diseases and, due to its ability to bypass first-pass metabolism, can also be used for systemic drug administration.[6] However, the successful delivery of inhaled drugs depends on the type and design of the administration device. Improper use or suboptimal device design can lead to dosing inaccuracies, resulting in over- or under-dosing, underscoring the importance of well-designed, user-friendly administration devices.

Despite the critical role of well-designed administration devices, access to suitable options is not uniform across all regions. Research has highlighted a disparity in the usage and acceptability of administration devices for oral and respiratory medicines between high income countries (HICs) and, middle- and low-income countries (LMICs).[7–11] Addressing this challenge requires a thorough understanding of the pharmacotherapy needs of children in low-resource regions to find solutions that accelerate the development and adoption of easily accessible and user-friendly devices that administer the required dose.

Hence, a workshop was held to promote safe and effective usage of administration devices for children in low resource settings. In the workshop, experts from various stakeholder groups (academic researchers, healthcare professionals (HCPs), representatives of industry and regulatory bodies) were invited to share and review current practices and challenges associated with the development, control, and supply of oral and respiratory administration devices. The purposes of the workshop were to understand the acceptance of already existing administration devices in low- and middle-income countries, and to assess the level of awareness of concerns

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associated with the use of administration devices as well as the need for innovative devices.

2. Workshop structure

The workshop was organised in partnership with the Indian Pharmaceutical Association (IPA), the European Paediatric Formulation Initiative (EuPFI), the Society of Paediatric Medicines and Healthcare Initiative (PMHI), and Thetabeta Analgorithm Pvt Ltd (TBA) at Scitech Centre in Mumbai, India on 4th March 2024.[12] Details of the workshop were disseminated through EuPFI contacts, PMHI website, social media (LinkedIn) and professional bodies (Associated Capsule Group (ACG), IPA, Indian universities) to call for submissions of interest from healthcare professionals, pharmaceutical industry experts as well as the public. Participants of the key stakeholder groups were invited to register *via* submission of an online Expression of Interest Form. Participants were further screened based on their relevant experiences and reasons for their interest to determine if they aligned with the objectives of the workshop. To ensure focused and productive interactions throughout the event, only participants with experience in using, designing, testing, supplying, or assessing administration devices for oral and respiratory medicines were formally invited to the workshop. Additional information including the workshop flyer, workshop agenda, and pre-reading material were shared with participants before the event *via* email. In-person attendance was expected at the workshop, although international attendees were given virtual access if necessary.

The first half of the workshop consisted of two plenary sessions. The first session included presentations on the global landscape of the use of administration devices for paediatric medicines with a panel of representatives from India (PMHI), Japan (National Centre for Child Health and Development), China (China Medical University-Queen's University of Belfast Joint College), Nigeria (Nnamdi Azikiwe University), and Europe (University College London). The second session comprised of presentations on administration device challenges and potential solutions given by a healthcare professional (paediatrician from India), and representatives from the pharmaceutical industry (Johnson & Johnson Innovative Medicine, Merck, Aptar Pharma).

In the second half of the workshop, participants were engaged in forum discussions to brainstorm, present and assess innovative solutions for improving the development and adoption of oral and respiratory administration devices for children in India. Participants were divided into 5 groups, each of which had a balanced representation from the key stakeholder groups (academia, regulatory, industry and hospital) to discuss the procedural and operational challenges in relation to the administration of medicinal products to the paediatric population in both a hospital and domiciliary setting (dosing devices, dosing accuracy *etc.*) and propose constructive solutions. Potential solutions that could facilitate the development of an optimal path towards the correct dosing of paediatric patients and meet the requirements of all stakeholders involved were then drawn up onto flip charts to be presented back to the other teams. At the end of the discussion solution proposals from all groups were summarized into a table on a single flip chart. To ascertain the participants' preferences for the proposed solutions, the attendees were instructed to vote next to their preferred solution under their stakeholder groups.

Following the interactive activity, the last session brought speakers from the European Medicines Agency (EMA) and the Indian regulatory agency (The Central Drugs Standard Control Organisation (CDSCO)) who provided an overview of regulatory guidance in Europe and India. The workshop was closed with a summary of the day's discussions and the initial conclusions drawn from the voting process.

3. Global landscape on the usability of administration devices

A total of forty-two participants, including the speakers and organisers, from seven countries (Belgium, China, India, Japan, Nigeria, UK and USA) attended the workshop. Among them thirty-three attended in-person. Seven international speakers and two international registered participants joined the workshop virtually. Approximately a third of participants were from the pharmaceutical industry (n = 13, 31%). There were five healthcare professionals (n = 5, 12%) and three regulatory officers (n = 3, 7%), whilst the remaining participants were researchers and postgraduate students (n = 21, 50%) (Fig. 1). The majority of the attendees came from LMICs.

A EuPFI survey study revealed that caregivers' and paediatric patients' difficulties in using oral and respiratory administration devices is a perceived challenge, and HCPs do not always explain correct device use, highlighting the need to gain a better understanding of children and caregivers' experiences about the use of these devices.[13] During the first session of the workshop, findings from oral and respiratory administration device usability surveys conducted in multiple HICs and LMICs, were presented and discussed. The data showed

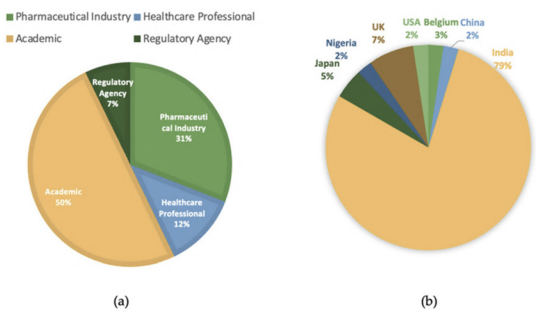

Fig. 1 Workshop participants demographics: (a) participants by job sector (%); (b) participants by country (%).

country-dependent usage of devices for administration of oral and inhaled paediatric medicines. Overall, oral syringes are often used in the United States and Europe, but less common in India, China and Japan.

A multinational survey conducted in European countries (Albania, Spain, Romania, Italy, United Kingdom, Netherlands), Israel and United States to understand caregivers' and children's perspectives on the usability of oral and respiratory administration devices showed a clear preference for liquid dosage forms (*e.g.*, syrups/suspensions) compared to solid dosage forms.[11] Oral devices most frequently used were oral syringes, followed by measuring spoons and household spoons. Respiratory devices were used less frequently, with pressurised metered-dose inhalers (pMDIs) being the most used inhalation device. It was reported that for self-administration, children were usually instructed by their parents or caregivers rather than HCPs on the use of both oral and inhaled devices. All oral and respiratory devices were deemed easy to use, and participants found instructions clear. However, provision of simpler instructions, in the form of images or pictograms as well as key summaries and adequate training on device use were suggested.

A cross-sectional pan-India study showed that oral medicines are much more frequently used than inhaled medicines.[9] The use of measuring cups was most prevalent followed by household spoons. Reported difficulties in using these devices were related to a lack of user instructions and measuring. The respondents who had received clear instructions from HCPs found the oral devices easy to use. Inhalation devices had limited usage. However, nebulisers with facemasks were most frequently used followed by manually actuated metered dose inhalers (MDI). The nebulisers with facemask were reported to be difficult to use by most of the respondents despite receiving clear instructions from HCPs.

Oral medications were used more frequently than inhaled medicines in China.[7] The top three commonly used oral dosage forms were granules, syrups and tablets. The most used devices were measuring cups and household spoons, both of which were well accepted by children and considered easy to use. The most used inhalation device was a nebuliser with facemask; more instructions and demonstrations were provided to inhalation device users by the HCPs as they reported difficulties with device use.

A survey on administration of oral medications in Japan showed that powders were most frequently given to children, followed by liquids.[8] Droppers were most frequently used for children less than 12 months old, while household spoons were most frequently used for older children. Oral syringes were perceived as easy to use.

4. Healthcare professional perspectives

While therapeutic need remains the primary consideration, HCPs in India often have to take access, availability and affordability into account when prescribing medicines to children. Formulations commonly given to children include liquid syrups, tablets, pastilles injectables and capsules. To ensure safe and effective administration of medication, HCPs not only have to inform dosing instructions based on the child's age and weight but also need to check whether excipients in the formulation are suitable for paediatric treatment. Some of these formulations require bedside manipulation, such as extemporaneous compounding of solid dosage forms. In such cases, it is crucial to assess the feasibility of administration of the preparations by evaluating the uniformity, texture, taste, and vehicle compatibility of the final medicine.

A range of devices for administering oral liquid formulations are available and prevalent in India. Frequently used devices are droppers, measuring cups, household spoons and syringes, among which little spoons appear to be the most favoured tools by parents and caregivers due to practical simplicity and acceptability by children. In some parts of India, delivering medicines with the paladai, a traditional silver or brass cup-shaped vessel with a long narrow spout, is also a common practice. However, accuracy of such traditional devices in measuring and administering medicines is generally overlooked by both caregivers and HCPs. Both awareness of the importance of accurate dosing as well as instructions to ensure correct measurements are lacking. Furthermore, medication is often measured using a separate device such as a measuring cup then transferred to a spoon for feeding, and residuals left in the device are simply rinsed off and the rinsings are then re-administered. Nebulizers are the most frequently used devices for administration of pulmonary medicines. When using nebulizers, caregivers and children often encounter mask interface-related compatibility issues due to limited mask size and shape.

5. Pharmaceutical industry perspectives

Considerations for developing oral liquid paediatric products in Europe have expanded significantly due to adoption of a patient-centred approach to product development and heightened regulatory requirements surrounding dose accuracy, dose markings, and product labelling. In addition to drug product characteristics and ease of use which were the main selection components influencing product development in the past, patient and caregiver engagement is comprehensively assessed for new products as it is regarded as critical as safety and efficacy to achieving successful health outcomes. Design of the device requires validation through user feedback to ensure it aligns with user expectations and preferences so that patients adhere to the therapy consistently. Moreover, since the implementation of the European Medical Device regulation in 2017 (EU 2017/745), additional requirements aiming to reduce dosing errors have come into effect. These stricter accuracy requirements imply dosing cups cannot be used for volumes less than 2.5 mL, while dosing spoons lack dose flexi-

bility, accounting for the increased selection of more accurate dosing syringes over time. Additionally, manufacturers and suppliers in Europe must complete human factor studies and risk assessments to demonstrate compliance to usability requirements (ISO 62366), quality management (ISO 13485), and risk management (ISO 14971).

In Europe and the United States, development of inhalation devices for the paediatric population takes into considerations the therapeutic need, drug characteristics, age appropriateness and device usability. Common devices currently available on the market are dry powder inhalers (DPI), MDI and nebulizers. Inhalation products are required to meet several regulatory requirements to demonstrate safety and efficacy. MDIs and DPIs are drug-device combination products by FDA (21 CFR 3.2e) and EU (2017/745) definition and therefore must demonstrate conformance to design controls per FDA (21 CFR 820.30) and EU-MDR (ISO 13485, ISO 14971) guidance. Moreover, all inhalation devices are regulated on drug aerosolization performance (USP<601>, Ph Eur 2.9.18), biocompatibility (ISO 10993), compatibility and stability of the drug product in devices (E&L assessment) and usability (IEC 62366-1:2015). In Europe, inhalers need a CE mark or a Notified Body Opinion prior to registration.

Innovation of paediatric medicinal products in India takes into consideration the problems encountered by children and parents when a medication is given to children. For the child, runny nose, mucous draining down the throat causing cough and difficulty in swallowing are some common factors contributing to their reluctance to take oral medicines. This means the parents and caregivers often must deal with uncomfortable or clingy children, which increases the chance of spilling and makes the process of measuring and administering medication more challenging. To tackle these problems, pharmaceutical developers in India prioritize the need to simplify the dosing and administration process. Advancement in oral liquid medicinal products is therefore driven by the aims to achieve accurate dosing and clean dispensing, exemplified by special leak-proof, no-mess packaging technology for continuous and clean dispensing of liquid or viscous products (*e.g.*, SimpliSqueezeTM and Bag-On-Valve Technology Platform) by Aptar Pharma (India).

6. Regulators perspectives

UK regulatory perspectives on devices used with paediatric medicines focused on issues regarding accuracy of measuring small doses and small volumes, and variable doses with respect to patient age, weight and surface area. The guideline on pharmaceutical development of medicines for paediatric use (EMA/CHMP/QWP/805880/2012 Rev.2) emphasises that liquid paediatric medicines should be supplied with a measuring device unless otherwise justified. Usage of the measuring device must consider the criticality of the dose. For drugs considered to have a narrow therapeutic window such as domperidone-containing medicines, using an adapted graduated oral syringe to accurately measure the dose is required. The suitability of the device for different age groups should also be evaluated and the volume graduations should be appropriate. In general, graduation in 'ml' is the preferred approach, and the minimum volume of a liquid measured should not be lower than 10% of the maximum capacity of the device. To ensure suitable and accurate dosing of small volumes to younger paediatric patients from birth to 12 years, small-size syringes such as 1 ml syringe with 0.01 ml graduations and 5 ml syringe with 0.1 ml graduations must be used. Regulatory guidance aims to encourage the licensing of medicines that are supplied with devices meeting these requirements, ac-companied by suitable instructions for use.

Indian regulatory perspectives were given through an overview of present regulations and steps taken by the Government to promote innovation. The import, manufacture and sale or distribution of drugs in India are regulated by the Drugs and Cosmetics Act 1940. Under this Act, the Medical Devices rules 2017 have been published in line with international practices. The complete regulatory provisions for regulation of medical devices were established when the Ministry of Health and Family Welfare (MOH&FW) released notification for phase-wise regulation of medical devices which were not in licensing dated in 2020. According to the policies, medical devices which do not have a predicate device will undergo through a clinical investigation to establish safety. It was noted that in LMICs, patient safety is challenged by frequent adverse events. Various governmental organisations exist in HICs to safeguard patients, whereas in India no chain of organisations has been established to investigate medication errors at national capacity. To improve medication safety, it was recommended that the country enhance information sharing, strengthen pharmacovigilance, capture patient experience of medication-related harms, build on the expanded roles of pharmacists to promote good prescribing practices, and evaluate implementation of new medication safety strategies.

The Indian pharmaceutical industry is driven by an ambition to expand into innovative drug development and a global market. There is a strong focus on improving healthcare accessibility and embracing digital technologies to enhance drug development, manufacturing, and supply chain management. The government of India aims to provide accessible healthcare to rural populations and digitalize healthcare delivery by introducing the National Rural Health Mission (NRHM) and eHealth Initiatives. Efforts have been made to meet the needs of children and young people. Areas in which medical devices have been developed include 3D printing and new materials for paediatric medical devices, accurate dosing and effective delivery of paediatric formulations, and diagnostic imaging devices. There is a clear need for the life sciences industry and public sector organizations to support advances in paediatric healthcare by specifically focusing on medical devices developed to accommodate the pharmacotherapy needs of paediatric patients.

6.1. Forum discussion – challenges and solutions

Various challenges associated with the usage of oral and respiratory medication administration devices were identified during team discussions, as shown in Table 1. Suggestions for

addressing the issues were then proposed. Voting results according to stakeholder group on potential solutions are presented in Table 2.

7. Discussion

The workshop provided an opportunity for direct conversation and active exchange of ideas between researchers, HCPs, regulators, and industry (device developers and manufacturers) from both high- and low-to-middle income countries. While the workshop was held in India and attended by mostly Indian participants, its objective was to explore perspectives relevant to a broader range of LMICs. The presentations and discussions were structured to incorporate experiences, challenges and insights from various LMICs, as shared by stakeholders representing different regions. Participants converged to share current practices and challenges associated with the administration of oral and respiratory medicines to the paediatric population in their respective culture and were encouraged to learn about other stakeholders' perspectives. The insights gained from these multi-stakeholder discussions are expected to inform future policy decisions and stimulate development and adoption of well-designed administration devices, thereby contributing to the broader goal of accelerating safer medication administration to children in low-resource settings.

The voting results highlighted variability in the scoring of potential solutions according to stakeholder group (Table 2). Overall, the highest scoring solutions were device innovation and regulation harmonisation, with votes from all stakeholder groups. Regulators additionally favoured customisation of existing devices. Patient counselling/dissemination/awareness raising and Instructions in different languages/QR code video scored highly among researchers, indicating their priority to improving health education and the public's access to healthcare information. Both researchers and industry advocated regulations on device materials and packaging and were strongly interested in employing the extensive resources available, especially digital technologies like websites, mobile apps, and artificial intelligence. Industry also found it helpful to engage end-user perspectives while developing a product.

Table 1 Challenges associated with medication administration to children using oral administration and inhalation devices identified during team discussions

Administration of oral medicines	Administration of pulmonary medicines
■ Accuracy in dosing small volumes	■ Restriction in mask size
■ Spillage	■ Acceptance is less in children
■ Loss during transfer	■ Longer administration time
■ Cleaning	■ Stigma that such device should only be used for serious illness
■ Mishandling	
■ Fear induced by syringe shapes	
■ Imprecise graduation interval	
■ Hold up volume in dispenser	

Table 2 List of potential solutions proposed during team discussions and stakeholder voting results

	Number of stakeholder votes		
Proposed solutions	Industry	Academic	Regulatory
Awareness raising and education			
• Patient counselling • Dissemination • Instructions in different languages • QR code video instructions		6	
Device innovation			
• Customisation of existing devices • AI assisted/digital device • Patient engagement/end-user perspective during development	3	5	2
Regulations			
• Regulation harmonisation • Regulations on material of device/packaging	3	3	2

7.1. Uptake of existing devices

As discussed in the presentations, oral formulations given to children in India are generally administered using calibrated caps on medicine bottles, droppers, kitchen spoons, or paladai, and such practices are widely approved by HCPs for their accessibility and affordability (Fig. 2). The HCPs focus more on the practical ease to administer the medications, whereas the importance of dosing accuracy is overlooked, highlighting the limited awareness on using appropriate administration devices for accurate drug delivery. Therefore, it is essential to educate caregivers about the importance of dose quantity and time of medicine administration. In hospitals, especially in neonatal settings, calibrated syringes are being used for drug delivery but their acceptance in households is low.[10,14] As per an observational study conducted in a hospital in India, 69.95% of the participants chose the measuring cup when given a choice to select any of the measuring devices (stainless steel spoon, disposable plastic syringe, dosing cup with etched markings) to measure 5 ml paracetamol syrup.[15] For pulmonary drug delivery, nebulizers are widely accepted in India.[16] The child breathes an aerosol through a facemask or preferably, a mouthpiece. Use of spacers with inhalers is encouraged.[17] Most caregivers from rural India visit nearby clinics to use nebulizers as they do not understand how to use the device properly. A cross-sectional pan-India study recommended providing instructional pamphlets and/or audio-visual assistance, such as video instructions on setting up, operating, cleaning, disinfecting, and maintaining nebulizers.[9]

7.2. Device innovation

Stakeholders' presentations highlighted that higher manufacturing standards in HICs have led to innovation of precision

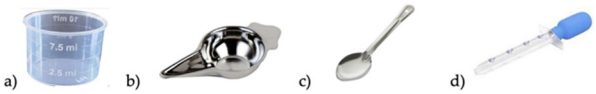

Fig. 2 Commonly used devices for administration of oral medications in India: (a) measuring cup; (b) paladai; (c) household spoon; (d) dropper.

administration devices following strict guidelines and quality control measures, such as small-size oral dosing syringes suitable for accurate measurement of volumes less than 1 mL. Hence, oral syringes are the most used administration device in Europe and the United States as development and adoption of such precision dosing devices are required by health authorities. In India, development and manufacturing of administration devices do not yet meet the same stringent standards. Innovation of medicinal products is thus limited due to lower regulatory reliance, and the research priority is tailored to patients' and caregivers' need for device designs that simplify the administration of medication to children. Moreover, a high level of user engagement during device development phase was noted in HICs. It was recommended that device developers design the product in tandem with the medicine and take the condition (age, disease *etc.*) of the patients into account to have disease and age-appropriate treatments.

In the group discussion, accuracy in dosing small volumes and imprecise graduation intervals were identified as challenges associated with administration of oral medicines (Table 1), suggesting there is some level of awareness on issues around dosing accuracy for younger patients among the stakeholders, particularly device developers. However, these issues are insufficiently addressed in device development in comparison with other challenges regarding spillage, cleaning and mishandling, which are the primary concerns of parents and caregivers. On the other hand, challenges around administration of pulmonary medicines *via* nebulizers such low acceptance due to face mask size restriction, stigma of associated serious illness and long administration time have been approached with smaller, portable user-friendly inhaler designs, exemplified by various pMDIs available on the market. However, despite of the advancement, pulmonary devices were reported by workshop participants to be used much less commonly India, and their scale of adoption and acceptability in children were insufficiently discussed in the workshop.

7.3. Awareness raising and education

Sometimes people have strong beliefs in their traditional knowledge. Hence, it may be difficult to accept novel devices. Feeding cups and oral syringes are available in India now, but more people prefer household items over any novel drug delivery device. Cost and affordability are major factors leading to the reliance on the simpler, traditional method. However, it is also a complex issue rooted in social, cultural, and psychological factors. Culturally, traditional methods are passed down through generations and have earned trust within the community. Social influence such as approval or disapproval from elders, who are highly respected in Indian culture, may also impact acceptance of new administration devices. It was reported in the workshop that there is fear of using innovative products as people relate the more sophisticated designs to serious illness. The possible solutions to increase acceptance of existing devices (*e.g.* oral syringes) or the use of novel devices by Indian caregivers will be to raise public awareness of medication safety not only among parents and caregivers but also HCPs. The proposition by the participants was to develop devices similar to household items but with better quality and feasible cost. It should also be noted that India is a country of diverse ethnicities and languages. For health information to reach all people, participants found it helpful to translate instructions and warnings about administration devices into multiple languages. The participants also suggested digital visual aids to simplify instructions for medication administration. However, their effectiveness is dependent on access to digital infrastructure and user familiarity with technology – both of which may be limited in rural areas. This highlights a significant disparity between sub-populations within the same country, a challenge that may be relevant to other regions with similar socio-economic and digital divides.

7.4. Regulatory oversight

High-income countries have robust regulatory bodies (*e.g.*, FDA in the US and EMA in Europe) that enforce strict regulations and guidelines for the approval and monitoring of medical devices, including those intended for use in the paediatric population. High safety and efficacy standards are ensured *via* regulatory harmonisation, demonstrated by product compliance to the EU medical device regulation (2017/745), usability requirements (ISO 62366), quality management (ISO 13485), and risk management (ISO 14971). In comparison, in India, although all the medical devices are regulated under the Medical Devices Rules 2017 and subsequent amendment made in 2020, there is a need for specific guidelines for regulations of paediatric administration devices. To stimulate paediatric administration device innovation in India, it is crucial to reform certain regulatory policies, develop a supportive ecosystem, create novel incentives, and advocate for legislative changes, and ultimately to actively engage organizations and stakeholders in these strategies. Regulatory bodies also need to keep pace with the rapidly expanding industry, ensuring a patient-centric approach that safeguards paediatric patients.

The government needs to develop strict regulations regarding dose administration to the paediatric population and ensure that these are followed both in hospitals and domestic settings. An example of the efforts made is the Medical Device Adverse Event Reporting form by the Indian Pharmacopoeia Commission in 2019, which is used to collect information on Medical Devices Adverse Events. Non-governmental organizations (NGOs) frequently work directly with local communities, gaining a deep awareness of the distinct difficulties encountered by rural areas. To ensure proper usage of medical devices for paediatric patients, established governmental telemedicine programs such as Digital India may be useful in educating

healthcare professionals and caregivers both from urban and rural areas.

8. Limitations

The results of the workshop are potentially biased as academic representatives formed the largest voting group. A key limitation of the voting exercise is that all participants were from India, which may limit the generalizability of the results to other LMIC contexts. Additionally, healthcare professionals were not involved in the voting primarily due to low attendance. While some HCPs were present at earlier stages of the session, many had left before the voting took place, which would have resulted in unbalanced or non-representative input. It was also not possible to determine the exact proportion of participants who voted, as individuals were permitted to vote under more than one stakeholder category and no identifying information was collected. This may have led to either underestimation or duplication in the vote count. Therefore, the voting results are indicative rather than representative. Moreover, all discussions and presentations in the workshop placed more emphasis on administration of oral medicines than pulmonary medicines. Even though devices for administration of pulmonary medicines appear to be more advanced, information on the adoption and acceptability of these devices was not adequately discussed in the workshop. Another limitation is the absence of direct input from patients and caregivers. While their perspectives are critical to understanding the lived experiences of medication administration, the scope of the workshop was specifically designed to gather insights from key healthcare system stakeholders, including healthcare professionals, device developers, policy makers, and researchers. This focus aimed to identify system-level challenges and opportunities that could inform broader strategies for improving paediatric medication safety. Future work may incorporate patient and caregiver perspectives to complement these findings and provide a more comprehensive understanding of barriers and facilitators to safe medication use in children.

9. Conclusion

The discussions and evidence shared during the workshop highlighted the value of such forums in improving understanding of the challenges surrounding the development, regulation, and availability of medication administration devices in low-resource settings. Participants gained a stronger appreciation of issues such as accurate dosing and the practical barriers to effective medication use in paediatric care. Organising similar events in the future could contribute meaningfully to knowledge exchange, stakeholder engagement, and informed decision-making in LMIC contexts.

Abbreviations

HCP	Healthcare professional
HICs	High income countries
EuPFI	European Paediatric Formulation Initiative
IPA	Indian Pharmaceutical Association
LMICs	Low- and middle-income countries
PMHI	Society of Paediatric Medicines and Healthcare Initiative
TBA	Thetabeta Analgorithm Pvt Ltd
ACG	Associated Capsule Group
CDSCO	Central Drugs Standard Control Organisation
UK	The United Kingdom
USA	The United States of America
EMA	European Medicines Agency
FDA	Food and Drug Administration
pMDI	Pressurized metered dose inhaler
MDI	Metered dose inhaler
DPI	Dry powder inhaler
MRHM	National Rural Health Mission
EU	The European Union
NGOs	Non-governmental organisations

Author contributions

Sifan Hu: conceptualisation, methodology, project administration, writing – original draft, visualisation. Alka Mukne: project administration, writing – review & editing. Vandana Patravale: project administration, writing – review & editing. Pradeep Behera: project administration, writing – review & editing. K. Bangarurajan: writing – review & editing. Esmerald Hermans: project administration, writing – review & editing. Jennifer Walsh: project administration, writing – review & editing. Smita Salunke: conceptualisation, funding acquisition, methodology, project administration, writing – review & editing.

Conflicts of interest

There are no conflicts to declare.

Data availability

All data generated and analysed during this study, including workshop vote counts and participant demographics, are included in the article. No additional data are available.

Acknowledgements

This research was funded by UCL Knowledge Exchange and Innovation Fund award number KEI2023-02-68. The authors would like to acknowledge Preeya Nagi and Emmanuel Chukwuebuka Umeyor for reviewing the manuscript. Also, the

EuPFI Devices workstream members and Society of Paediatric Medicine Healthcare Initiative (PMHI) members for their insightful comments to workshop programme development that enhanced the quality of the delivered workshop. The authors would like to extend sincere gratitude to the speakers for their enlightening presentations. Lastly, to Suhel Khan, whose exceptional planning, dedication, and unwavering support were crucial to the organization of this event.

References

1 A. Mulac, K. Taxis, E. Hagesaether, *et al.*, Severe and fatal medication errors in hospitals: findings from the Norwegian Incident Reporting System, *Eur. J. Hosp. Pharm.*, 2021, **28**, e56–e61, DOI: **10.1136/ejhpharm-2020-002298**.

2 S. D'Errico, M. Zanon, D. Radaelli, M. Padovano, A. Santurro, M. Scopetti, P. Frati and V. Fineschi, Medication Errors in Pediatrics: Proposals to Improve the Quality and Safety of Care Through Clinical Risk Management, *Front. Med.*, 2022, **8**, 814100, DOI: **10.3389/fmed.2021.814100**, PMID: 35096903; PMCID: PMC8795662.

3 H. McPhillips, C. Stille and D. Smith, *et al.*, *Methodological Challenges in Describing Medication Dosing Errors in Children*, in *Advances in Patient Safety: From Research to Implementation (Volume 2: Concepts and Methodology)*, ed. K. Henriksen, J. B. Battles and E. S. Marks, *et al.*, Agency for Healthcare Research and Quality (US), Rockville, MD, 2005. Available from: **https://www.ncbi.nlm.nih.gov/books/NBK20505/**.

4 G. Koren, Z. Barzilay and M. Greenwald, Tenfold errors in administration of drug doses: a neglected iatrogenic disease in pediatrics, *Pediatrics*, 1986, **77**(6), 848–849.

5 Guideline on pharmaceutical development of medicines for paediatric use, 1 august 2023. **https://www.ema.europa.eu/system/files/documents/scientific-guideline/wc500147002_en.pdf**.

6 European Medicines Agency, Reflection Paper: Formulations of Choice for the Paediatric Population, London, 28 July 2016. **https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-formulations-choice-paediatric-population_en.pdf**.

7 S. Lian, Y. Liu, L. Xu, *et al.*, Survey-based investigation into the current use of paediatric medicines and administration devices in China, *Eur. J. Pharm. Biopharm.*, 2023, **191**, 290–302, DOI: **10.1016/j.ejpb.2023.09.006**.

8 J. Saito, H. Nakamura, J. Walsh, A. Yamatani and S. Salunke, A Survey to Understand Parent/Caregiver and Children's Views on Devices Used for the Administration of Oral Paediatric Medicines in Japan, *Children*, 2022, **9**, 196, DOI: **10.3390/children9020196**.

9 S. Abidi, S. Talegaonkar, S. Notani, *et al.*, Stepping into small shoes: Gaining user perspective on appropriate administration devices for paediatric medication in India, *Eur. J. Pharm. Biopharm.*, 2023, **191**, 247–258, DOI: **10.1016/j.ejpb.2023.09.005**.

10 S. Talegaonkar, A. Chitlangia, V. Pradhan, S. More and S. Salunke, Uncovering caregiver concerns: 5 key issues that still remain unresolved in administration of oral medicines for children in India, *Eur. J. Pharm. Biopharm.*, 2023, **187**, 166–174, DOI: **10.1016/j.ejpb.2023.03.009**.

11 E. Alessandrini, J. Walsh, E. Hermans and S. Salunke, Putting children first: Understanding caregivers' and children's perspectives on the usability of oral and respiratory administration devices for paediatric medication, *Eur. J. Pharm. Biopharm.*, 2023, **190**, 35–46, DOI: **10.1016/j.ejpb.2023.07.006**.

12 Accelerating Safer Administration of Medicines to Children in Low Resource Settings, 8 May 2024. **https://www.ucl.ac.uk/pharmacy/news/2024/may/accelerating-safer-administration-medicines-children-low-resource-settings**.

13 J. Walsh, M. C. Math, J. Breitkreutz, T. Zerback and H. Wachtel, European Paediatric Formulation Initiative (EuPFI). Devices for oral and respiratory paediatric medicines: What do healthcare professionals think?, *Int. J. Pharm.*, 2015, **492**(1–2), 304–315, DOI: **10.1016/j.ijpharm.2015.05.041**.

14 D. Thandaveshwara, S. Ganeshan, S. M. Doreswamy and S. Krishnegowda, Comparison of Efficacy Between Paladai and Syringe Feeding in Stable Preterm Neonates-A Randomized Control Trial, *Breastfeed. Med.*, 2022, **17**(3), 247–251, DOI: **10.1089/bfm.2021.0203**.

15 P. Joshi and S. B. Bavdekar, Liquid Drug Dosage Measurement Errors with Different Dosing Devices, *Indian J. Pediatr.*, 2019, **86**(4), 382–385, DOI: **10.1007/s12098-019-02894-8**.

16 R. J. Guleria and K. M. Thakkar, Nebulizer practices among paramedics in India, *Lung India*, 2019, **36**(1), 80–81, DOI: **10.4103/lungindia.lungindia_147_18**.

17 S. K. Katiyar, S. N. Gaur, R. N. Solanki, N. Sarangdhar, J. C. Suri, R. Kumar, *et al.*, Indian Guidelines on Nebulization Therapy, *Indian J. Tuberc.*, 2022, **69**(Suppl 1), S1–S191, DOI: **10.1016/j.ijtb.2022.06.004**.