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Research paper

Uncovering caregiver concerns: 5 key issues that still remain unresolved in administration of oral medicines for children in India

Sushama Talegaonkar^{a,b}, Ayushi Chitlangia^{a,b}, Varsha Pradhan^b, Supriya More^c,
Smita Salunke^{b,d,*}

^a School of Pharmaceutical Sciences, Delhi Pharmaceutical Sciences and Research University (DPSRU), MB Road, New Delhi 110017, India

^b Society for Paediatric Medicines and Healthcare Initiative, Institute of Chemical Technology, Nathalal Parekh Marg, Matunga East, Mumbai 400 019, India

^c Rochiram Thadhani High School for the Hearing Handicapped, Mumbai, India

^d University College London School of Pharmacy, 29-39 Brunswick Square, London WC1N 1AX, United Kingdom



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ABSTRACT

Introduction: Administration devices play a very crucial role in achieving a drug's therapeutic effect. Children are often dosed with oral liquids, but dosing devices don't have the accuracy needed, putting them at risk of inaccurate and suboptimal dosing. The availability and use of administration devices may vary throughout the world. Multiple surveys in UK, Europe and Japan have shown diverging practices by parents/caregivers. The aim of the present investigation was to conduct a larger Pan-India study through a series of workshops to understand the use and challenges of traditional devices and assess the need of innovative administration devices for liquid orals in India.

Methods: The methodology used for the workshop was contextual inquiry and survey questionnaire were used to record the responses. Parents for the workshop were recruited by advertising the survey on various social media platforms. Informed consent was taken from the parents or caregivers for their participation in the survey. Workshops were conducted pan India and both middle class and urban worker families in the occupational category were included in the study. During the workshop, the parents were briefed about the background and purpose of the study. Certain global innovative devices such as oral syringes, syringes with pacifiers were shown to the parents. Their views and opinions were taken through survey questionnaire and via interactive sessions. The questions were themed for the interactive session on 1) challenges faced, 2) willingness to use innovative devices and 3) the factors influencing their decision on the use of innovative devices.

Results: Across the four regions (4 metro cities) involved in the study, 271 caregivers agreed to participate in the workshops. 17.7 % administered solid dosage forms, 81.2 % administered liquid dosage form and the remaining 1.1 % opted for others.

Traditional devices: Caregivers reported the use of measuring cups (41.4 %) followed by household spoons (25.8 %), droppers (15.3 %), measuring spoons (2.6 %), and other dosing devices (5.5 %) for measuring oral liquids. 8.0 % did not use any of the dosing devices as they were administering tablets and/or capsules. The ease-of-use score was the highest for the dropper (2.67 ± 0.68) and the lowest for the measuring spoon (2.00 ± 1.00). The reported challenges were categorised into five categories which also influences the preference of using administration devices. This includes device design, user experience and usability, sociocultural factors, such as beliefs, knowledge and education, regulatory, and market/distribution.

Innovative devices: The majority of the caregivers (86.7 %) were not aware of any of the innovative devices shown to them. 58.7 % were willing to use it if was recommended by the doctor, 1.5 % of caregivers would use it on pharmacists' recommendation and 37.6 % parents would use it if came along with the medicine. The criteria considered by the parents for use of the innovative devices in the descending order were Doctor's recommendation > Quality > Cost > Packed in medicine > Ease of use > Availability/accessibility. There were no differences observed among the low and high socioeconomic status of caregivers regarding the use of traditional

Abbreviations: LMICs, low and medium-income countries; HIC, High Income countries; PMHI, Society of Paediatric Medicines and Healthcare Initiative; EuPFI, European Paediatric Formulation Initiative; DPSRU, School of Pharmaceutical Sciences, Delhi Pharmaceutical Sciences and Research University.

* Corresponding author.

E-mail address: s.salunke@ucl.ac.uk (S. Salunke).

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devices, challenges faced and awareness about innovative devices. Overall, the study revealed heterogeneity in the SES for the use of administration devices in the four zones. The association of SES and opinion on the use of administration devices was demonstrated with no statistically significant interaction between caregiver SES and the use of administration devices.

Conclusion: The workshop revealed the prevalence of traditional dosing devices like measuring cups, household spoons among the caregivers. It highlighted key issues with the use of appropriate administration devices for correct and accurate dosing in children that remain unresolved and prevalent in India. This study reflects on the needs of the target community; thus hope will help facilitate the development of locally sustainable solutions to improve the administration of medicines in children in India.

1. Introduction

The accuracy of the measuring medicines by the patient/caregiver, especially the liquid oral pharmaceutical forms for administration to their children, is crucial to ensure the correct administration of the dose [1]. The potential for dosing errors is greater in children than adults because paediatric doses are dependent upon age, weight, and body surface area. Using the proper administration device is essential for a more accurate dose and a uniform measurement [2]. Hence, it is important that the dosing device is easy and practical to use from the patients' perspective [3]. Results from a survey conducted by European Paediatric Formulation Initiative (EuPFI) in the UK, European and non-European countries provided insights about children's and caregivers' views and experiences regarding oral medicine administration devices [4,5,6]. It highlights that the practices on the use of different devices of administration of liquid oral formulations vary geographically depending on the availability of devices or the dosage form commonly used. However, these studies are skewed toward high income countries (HICs) with disproportionately less research conducted in and relevant to the problems of low and medium-income countries (LMICs). The research conducted in high-income countries fails to adequately address issues related to administration devices prevalent in LMICs. It is postulated that the devices that are commonly used in HIC are often not used in LMICs as a result of differences in dosage forms commonly used, sociocultural factors, lack of availability of administration devices, and awareness of issues associated with improper use of devices. Moreover, the regulatory framework for oral administration devices is globally inconsistent and unclear, hampering new device development. This is not a well-studied topic in many low-and middle-income countries including India. Hence, in collaboration with Delhi Pharmaceutical Sciences and Research University (DPSRU) and Society for Paediatric Medicines and Healthcare Initiative (PMHI), the EuPFI survey was extended to India to assess the Indian perspective in terms of devices used, difficulties experienced by parents and children in using oral and respiratory administration [7]. This study highlighted a need of future studies to assess the differences in the association between socioeconomic status population groups, particularly parents from low-income and ethnically diverse backgrounds. In addition, a need for focus group discussions was recognised to further deep dive into the comments provided by the caregivers and also assess the use and acceptability of innovative devices. Hence a pilot study/remote workshop was conducted in Delhi to collect the caregiver's opinions on the usage and challenges of traditional and innovative administration devices [8]. The use of these devices may vary not only between HICs and LMICs but even within the countries or states. India is a diverse country with substantial variations in demography, socioeconomic transition, disease burden, and health outcomes across the states. Hence, the opinions may vary between and within states. Hence, building on the outcomes of the pilot study, a larger Pan-India study was conducted through a series of workshop-based focus discussions to understand factors (e.g., socioeconomic, environment, design, and technical) that impact the accurate administration of medicines to children. The workshops aimed to foster the active involvement of parents/caregivers from socioeconomic status (SES) in the research and provide them the opportunity to voice their

views on the usage and challenges of administration devices and suggestions for future improvements. This will reflect on the needs of the target community, thus facilitating the development of locally sustainable solutions to improve the administration of medicines in children globally.

2. Method

2.1. Study design and setting

This is a descriptive cross-sectional study based on a survey, delivered through an online self-reported questionnaire [7]. The online questionnaire was circulated via social media platform to parents of children aged 0–12 years in a purposive sample of participants, eliciting information on the actual use of administration devices for oral and respiratory use in India in 2019. Based on findings from this survey, a follow-up interactive Pan India workshop as presented in Fig. 1 was planned. Four workshops were conducted to cover the east, west, north, and south regions of India. The data was collected over 3 months from March 2022 to May 2022. An interpretative description approach [9] was used to understand the users' perceived benefits and challenges of administration devices for children. The interpretative description was considered appropriate for use because it allows for a flexible approach to capturing the experiences of the participants and for researchers to apply research findings to practice.

2.2. Questionnaire design and piloting

The questionnaire designed by EuPFI [5] was adapted for the Indian setting. It was revised in collaboration with EuPFI, DPSRU, and PMHI. Expert opinions and advice were taken from paediatricians and the pharmaceutical industry to ensure its validity. The aims and results of the pilot study and the online survey were assessed, to improve both the questionnaire and data collection method. Additionally, a systematic review literature review was conducted on the use of traditional versus innovative administration for children to further develop the questionnaire for the workshop [10]. The workshop questionnaire was limited to oral administration devices and consisted of 15 questions which took an average of 15–20 min to complete. All responders provided basic demographic information about their youngest child (age) and family (parent education, occupation, and household income). The survey consisted of multiple-choice questions on the following topics: 1) medicines and devices used recently (3 items) 2) experience and opinions on barriers related to the use of administration devices (7 items), 3) willingness and preference to use innovative devices (2 items). Likert style response options were offered for questions corresponding to ease of use of the device (3 options: easy, neither easy nor difficult, difficult). Nominal multiple-choice options were offered for all other questions. Some of the questions were contextual, with one answer prompting a second related response with additional detail. To provide insight into unprecedented opinions, optional general comment boxes were provided in most sections for open-ended responses.

The survey questions were tested with a small sample of parents or caregivers (n = 27) via online zoom sessions. They belonged to an

educated background and some healthcare professionals such as anaesthesiologists, dentists and regulatory affairs professionals also participated in the pilot workshop. The goal of this pilot was to assess whether respondents were able to comprehend questions, summarize information and report an answer. Their views and opinions were taken through polls and interactive one on one discussions via Zoom. Following pilot testing, 5 questions were added, the language used throughout the questionnaire was clarified and simplified and gave respondents an option of replying to open-ended questions in their native language, while the main language of the questionnaire remained English. 27 parents completed the piloting questionnaire from 4 regions, based on which the survey's introductory text was amended and 5-point Likert scale responses were reduced to 3-point Likert scale for some questions. On average, piloting perceived the questionnaire to be "very relevant" and "very clear".

2.3. Study population

Purposive sampling was used. The samples were selected as per the inclusion criteria of parents aged more than 19, who had a child or more aged between 0 months and 12 years, and who agreed to participate in the study. Both the middle class and urban worker parents in the occupational category were included in the study. Parents for the workshop were recruited by advertising the survey via word of mouth and social media platform (WhatsApp). Consent was indicated via a tick box on the hard copy survey. Monetary compensation or gifts were provided as a remuneration to the survey participants for their active engagement in the workshop.

3. Workshop description

The workshops were facilitated by the authors AC and VP. It consisted of the following components – (i) workshop agenda, (ii) feedback from participants (small group activity followed by large group discussion) on traditional and innovative devices, (iii) potential ways to address identified challenges (small group activity followed by large group discussion), and (iv) study questionnaire. On arrival, participants were given an introductory talk about administration devices and the purpose of the study. Basic concepts, such as what are dosing devices, and different administration devices available, the importance of the workshop and why the voices of parent's matter were presented. The problems caused by the inappropriate use of devices were explained, and some examples of the incidents associated with inappropriate use and the need for awareness of the appropriate use of dosing devices were

given. Additionally, a few samples of traditional devices available in the Indian market and innovative devices not available in the Indian market were shown. These samples were acquired from UK from EuPFI. The presentation lasted about 20 min.

Afterward, the group was divided into smaller groups (up to five to six in one group) and the questionnaires were given to each participant in the group (Fig. 2). Each group consisted of at least one facilitator and a mix of participants from different backgrounds. The participants were guided through each question in the questionnaire and asked to provide their responses. Workshop facilitators engaged with participants in their native language and provide clarifications to their queries. Within the small groups, participants were asked to discuss the following questions, in this specific order:

- What do participants think about the availability of dosing devices in the Indian market?
- Were they familiar with the innovative dosing devices?
- What do participants think about the instructions from doctors and nurses on how to use the device?
- Were they aware of the importance of appropriate dosing devices and their appropriate use?
- Do they agree with the need for increased awareness of devices available and how to use them for the proper administration of medicines?

After approximately 10–15 min, participants reconvened as a large group. Facilitators led an open discussion about these questions, asking representatives from each of the small groups to identify key findings. Adhering to best practices for participant-centered learning, the facilitators recorded the shared topics on a PowerPoint slide that was shown



Fig. 2. Workshop focus discussion session.

Pan-India workshop timeline dashboard

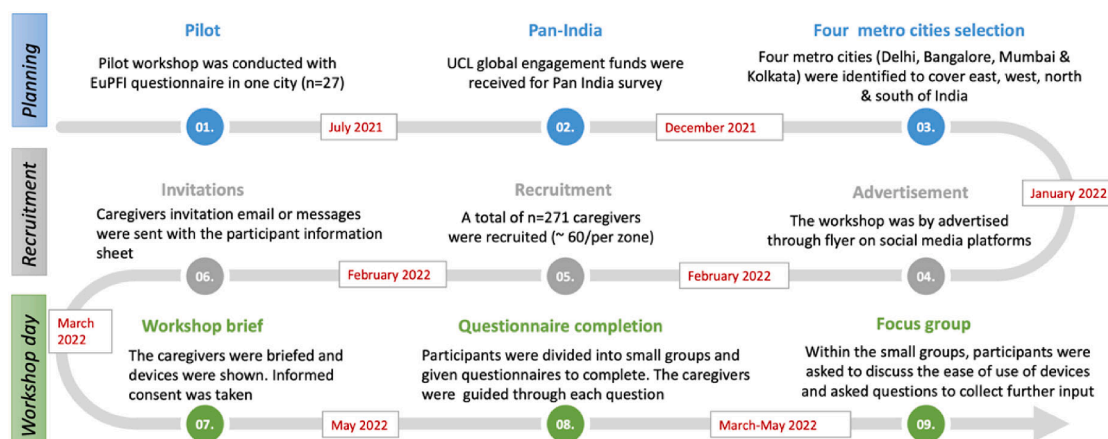


Fig. 1. Workshop methodology and timeline dashboard.

in real-time to allow participants to ensure their thoughts were accurately captured.

4. Data analysis

The responses were collected on hard copy of survey. These responses were then transcribed into Qualtrics [11] platform for further data analysis. A qualitative thematic analysis was conducted on responses to the open-ended questions. This thematic analysis was conducted based on an inductive approach, designed to identify and examine themes from textual data in a way that is transparent and credible [12]. Chapman et al. have outlined four steps in undertaking thematic analysis for applications to healthcare research (i) getting acquainted with data, (ii) recognizing emergent themes, (iii) subdividing/combining and grouping themes into categories, and (iv) conceptualizing the model that interrelates the themes [13]. Three members of the research team (AC, VP, and SS) independently identified key themes emerging from the dataset, then met and defined themes by consensus. Responses to closed questions have been presented as descriptive statistics. For socio-economic stratification, Kuppuswamy's scale was used [14]. It is the most widely used scale for hospital and community-based research in India. It was devised in 1976 and is updated periodically according to the level of education, occupation, and economy of the Indian population. It divides the study population into five groups (lower, upper lower, lower middle, upper middle, and upper) based on the cumulative score of education of the head of the family, occupation, and family income per month.

5. Ethical considerations

Consent from a local Research Ethics Committee was not needed for this type of study. This is per the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants guidelines which exempt the study from ethical review if it is the observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person [15,16]. Consent was indicated via a tick box before the workshop.

6. Results

Across the four regions (4 metro cities) involved in the study, 271 caregivers agreed to participate in the workshops. Region-wise sample distribution showed that 60 caregivers belonged to the Northern region whereas South Indian city contributed 60 caregivers; 91 were from west, and 60 entries belonged to the east. In total, 271 caregivers participated in the workshop and completed the questionnaire. There were statistically significant differences in the frequencies of the different socio-economic classes ($p < 0.001$) (Fig. 3). There was no significant difference in the proportion of the different paediatric age groups (p

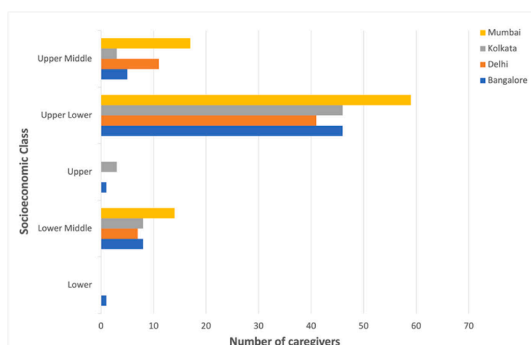


Fig. 3. Socioeconomic status of caregivers.

greater than 0.05) covered in this study (26 % were 0–3 years; 29 % were 4–6 years; 21 % were 7–9 years and 21 % were 10–12 years).

The majority of caregivers were educated to the secondary level. Only a small proportion (9 %) reported post-graduation as their highest level of education. Thirty-three (12.1 %) of the caregivers reported having a professional job, 16 (6.0 %) had a clerical/sales job, 44 (16.2 %) were homemakers, and 15 (11.0 %) had other types of jobs. The detailed characteristics of the caregivers are presented in Table 1.

6.1. Use of traditional devices

Nearly 81.2 % of caregivers were responsible for the administration of liquid medications (including suspensions, drops, and syrups) in their

Table 1
Caregivers (participants) characteristics.

Parameter	n (%)
Age (years) as reported by caregiver	
0 to 3	76 (26.2)
4 to 6	78 (28.8)
7 to 9	58 (21.4)
10 to 12	58 (21.4)
Mean \pm SD	6.09 \pm 3.46
Education of the caregiver	
Illiterate	41 (15.1)
Primary education	46 (16.9)
Secondary education	106 (39.1)
High school	21 (7.8)
Graduate	43 (15.9)
Post Graduate	18 (6.6)
Occupation of the caregiver	
Housewife	44 (16.2)
House help and maids	92 (33.9)
Clerical post	16 (5.9)
Driver, Plumbers	42 (15.5)
Cook	41 (15.1)
Salaried employees	33 (12.2)
Household income	
Upper	4 (1.5)
Upper middle	36(13.3)
Lower middle	37(13.65)
Upper lower	192(70.8)
Lower	01(0.4)
Traditional devices used by the caregiver	
Household spoon	71 (26.2)
Measuring spoon	7 (15.5)
Oral syringe	0 (0)
Dropper	42 (15.5)
Measuring cup	114 (42.1)
Others	15 (5.5)
I do not use one	22 (8.11)
Use of the device	
Easy	179 (66.0)
Difficult	50 (18.4)
Neither easy nor difficult	42 (15.5)
Instructions received on the use of the device by caregiver	
No	36 (13.3)
Yes-Doctor	216 (79.7)
Yes-Nurse	1 (0.4)
Yes-Pharmacist	6 (2.2)
Yes-Other	12 (4.4)
Familiarity regarding innovative devices	
Syringe with pacifier	10 (3.7)
Oral Syringe	6 (2.2)
Spoon syringe	13 (4.8)
Bottle with medication dispenser	0 (0)
X Straw	0 (0)
Mini tablet dispenser	0 (0)
None of these	235 (86.7)
Willingness to use innovative devices	
Yes-on Doctor's recommendation	159 (58.7)
Yes-on Pharmacist's recommendation	4 (1.5)
Yes-if it comes with medicine	102 (37.6)
Don't know	2 (0.7)
No	4 (1.5)

households. These caregivers reported the use of measuring cups (41.4 %) followed by household spoons (25.8 %), droppers (15.3 %), measuring spoons (2.6 %), and other dosing devices (5.5 %) for measuring oral liquids. Few parents noted using an infant feeding device (commonly known as Gokarna/paladai in India) (Fig. 4). They transferred medicines from the spoon into the feeding device and then administered them. 8.0 % did not use any of the dosing devices as they were administering tablets and/or capsules. None of the caregivers reported the use of an oral syringe.

A three-point Likert scale (3: easy, 2: difficult, 1: neither easy nor difficult) was used to rate the ease of use and the mean score of each device is shown in Fig. 5. The results showed that the average ease of use score for the various devices ranged from 2.0 to 2.7, indicating near satisfaction with and no significant difference among the different devices. The ease-of-use score was the highest for the dropper (2.67 ± 0.68) and the lowest for the measuring spoon (2.00 ± 1.00). Most parents (80 %) obtained instructions on the use of devices from their doctors, 2.2 % from pharmacists, 0.3 % from nurses, and 4.4 % from other sources. Whereas 13.3 % ($n = 36$) of the parents reported that they did not receive any instructions on the use of the device.

6.2. Reported challenges in using administration devices

The challenges reported by parents are summarized in Table 2. The reported challenges were categorised into five categories which also influences the preference of using administration devices. This includes device design, user experience and usability, sociocultural factors, such as beliefs, knowledge and education, regulatory, and market/distribution.

The most commonly (43.5 %) reported challenge relates to the device design leading to issues such as measuring the accurate doses, especially small volumes, cleaning the devices after use, and graduation marks which are difficult to read as they were in the same colour as the device. 14.0 % reported difficulties in the practical use of the device. Often the appropriate device was not available with parents had to use their own strategies (e.g., the use of household spoons) to resolve problems. The parents reported difficulties in handling the measuring spoon, specifically filling the spoon and administration without spilling the medicine. Fear and worry were most noticeably associated with the use of measuring spoons as parents thought that spoons sharp edges may cut the lips of their babies during the administration of medicines. The issues reported on users' needs or concerns include use of multiple devices for multiple medications, risk of contamination or infection, and instruction/training on how to use the device.

Quotes from few caregivers highlighting practical issues such as cleaning of the device, measuring issues, spilling are listed below:

“One unfortunate thing that happened with the dropper a few months back one of my twins bit the dropper. Basically, all the plastic came into his mouth luckily, he didn't swallow any”

“Pouring the medicine in the mouth is a bit difficult with the spoon, dropper or cup”.

“Commonly used suspensions are quite thick so when you measure five ml at least point five ml is definitely going to stick, so you have to again reinstate mix it properly, and then administer. So I rinse it with little water and administer it. But I am not sure if I am doing is right”



Fig. 4. Traditional device (gokarna/paladai) used by caregivers.

“Due to leftover medicine in the cup, it becomes difficult to provide exact prescribed dosage to the child”.

“I got introduced to the syringe when I was visiting my sister in the UK. I found it very comfortable to measure and administer medicine. However, I discarded it after some time and then had to use the dosing cups again as similar oral syringe was not available in pharmacies in India”.

For area of improvement the comments received are quoted below.

“Add pictures or QR codes with videos giving instructions on how to use the device and importance of measuring correct dose and using proper devices”

“Display the videos, leaflets in OPD areas so that parents can read or view it while waiting to see the doctor”.

“For parents using the device for first time – healthcare professionals should ask if training is required and provide as necessary”.

“Doctors should advise on the use of innovative devices in order to overcome the challenges currently faced by parents”.

6.3. Use of Innovative devices

For the innovative devices shown to the parents during the workshop. The majority of the caregivers (86.7 %) were not aware of any of the innovative devices shown to them. However, those who had seen or used the devices had outsourced them from western countries. 3.7 % ($n = 10$) of the parents were familiar or had seen the pacifiers, 2.2 % ($n = 6$) had seen a dosing syringe, and 4.8 % ($n = 13$) had seen a spoon syringe. None of the parents had seen or were familiar with a bottle with medication dispensers or X Straw for liquid medicine administration. 48.1 % preferred oral syringes and 25.9 % preferred oral syringes with pacifiers.

The mean score of willingness to use the innovative devices if made available in India was higher. However, the majority (58.7 %) were willing to use it if was recommended by the doctor, 1.5 % of caregivers would use it on pharmacists' recommendation and 37.6 % parents would use it if came along with the medicine. The criteria considered by the parents for use of the innovative devices in the descending order were Doctor's recommendation > Quality > Cost > Packed in medicine > Ease of use > Availability/accessibility mentioned in Fig. 6.

7. Discussion

This pan India study aimed to capture the voice of the caregiver's use and challenges of traditional devices, assess the need for innovative administration devices for liquid orals in India and understand factors (e.g., socioeconomic, environmental, design, and technical) that impact accurate administration of medicines to children in India. The results of this survey challenge the belief that patients are well informed about the appropriate use of administration devices in India. It is basic fact that infants and children should receive the right dose and that parents should be able to easily administer the right dose of medicine to their children without any risk of exposure to undue toxicity. However, the despite knowledge that the appropriate administration of doses is dependent on the measuring device used, the results indicate the use of improper devices, challenges associated with traditional devices, and unavailability of appropriate devices in the Indian market. Use of inappropriate devices or inappropriate use of proper devices is unacceptably commonplace in India [17,18,19]. Many parents during the focus discussion expressed that the healthcare professions prioritise prescription over administration and this is reflected in the lack of assessment or time devoted to the issues faced by parents with the administration of medicines to their children or use of appropriate devices for administering medicines.

This study indicates that the majority of caregivers administered oral liquid dosage form. This could be due to the children in this study had a median age of 6 years, who are generally prescribed liquid dosage forms

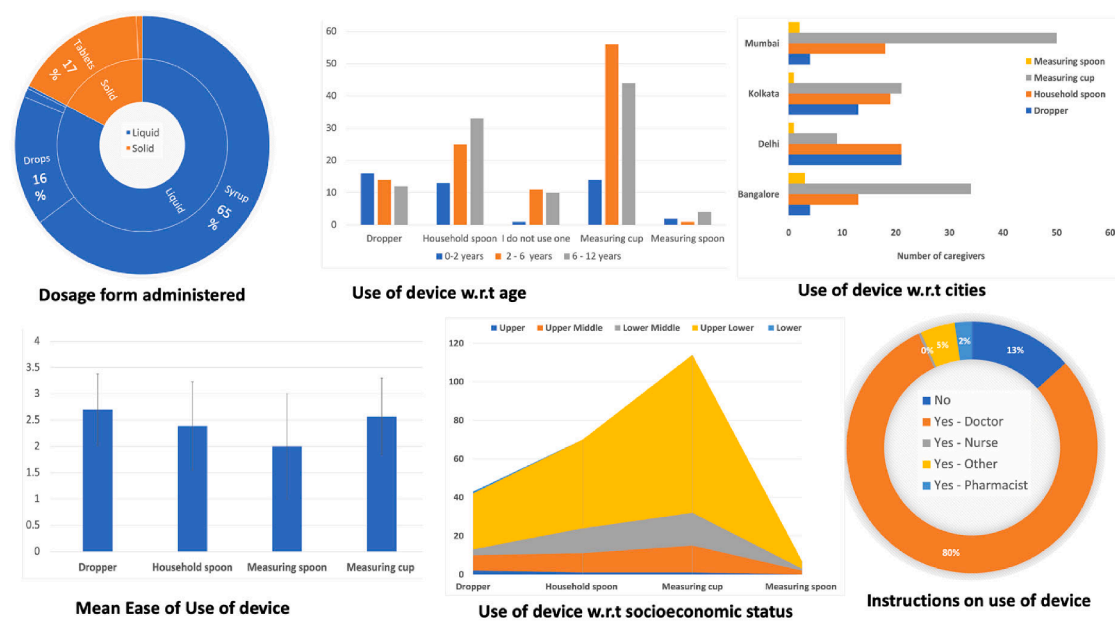


Fig. 5. Use of traditional devices.

Table 2
Problems reported by the caregivers on the use of the administration devices.

Category	Usability Problem
Device design related	Measuring the appropriate doses especially small doses Graduation marks were difficult to read particularly when the marks were same color as the device.
User/Patient related	Cleaning the devices after use Handling the devices was challenging particularly spoon - pouring the liquid from spoon and administration without spillage Fear and worry that the edge of plastic spoon may cut the lips of their babies. One caregiver reported incident of lip cutting with measuring spoon. It's difficult for the child to drink the medicine as it is thick a small amount remains in the dosing cup, sticky medicine. Dropper was not appropriate for large doses and had to use it multiple times to measure and administer large dose. Baby chewed the plastic dropper
Regulatory	Difficult to administer sticky medicines from droppers as the medicines sticks to walls and is difficult to expel No regulations on dosing device provision in packaging of oral liquid medicines
Marketing/ Distribution	Devices such as oral syringes are not available
Sociocultural factors	Device did not come with the medicine Use of traditional device (eg. Paladai) is convenient for babies. Would use the device only if recommended by doctors Very limited knowledge on effect of improper dosing Not hygienic to use it unless they are sterilised for every use. Unaware of innovative devices Measure additional dose to compensate for spilling or sticking in the cup.

in India [20]. The primary caregiver was usually a homemaker (16.2 %) with an education mostly up to high school level (9.5 %); and 13.2 % caregivers were illiterate. Among these caregivers, none reported using an oral syringe and the use of a measuring cups was prevalent at 42.1 % (n = 114/271) followed by household spoons at 26.2 % (n = 71/271). This is consistent with some of the existing evidence on the use of the dosing devices in these settings, which suggests that the measuring cup is the most frequently selected measuring device, but it is the syringe that accounts for the least proportion of inaccurate doses [19,21,22].

The key reason that accounts for use of a measuring cup was that most paediatric liquid formulations in the Indian market come with a measuring cup. If the device did not come with the medicine, then parents opted for household spoons. Hence giving appropriate doses, spillage of medicines during pouring of medicine from the bottle, and administering to child and confusion on the use of tablespoon or teaspoon presented significant issues for caregivers. Mattar et al found that when no dispensing device was given, 71 % of parents used a teaspoon and suggested that this practice can be eliminated through better parent education and by providing labelled measuring devices [23]. Only a minority of caregivers (n = 7/271) used measuring spoons. Caregivers from Delhi (north zone) reported a high prevalence of the use of droppers compared to the other zones. However, there were no statistical differences in the prevalence of the use of devices between four zones (the calculated chi-square value (0.002) is smaller than the critical value (7.815) with 3 df).

Walsh et al reported that the healthcare provider's (HCP) opinions on the age-appropriateness of the oral administration devices reflect the capability of each device type to accurately measure the likely dose volumes required by different ages of children, together with the ability of the child to use the device; oral syringes and droppers were considered particularly appropriate for infants, whilst measuring spoons and dosing cups were considered more appropriate for children aged from 2 to 5 years and 6 to 8 years respectively [24]. This study findings show that the dropper, measuring spoons and dosing cups were used for ages above 8 years as well in India and that there was no preference or prevalence in terms of using devices as per age. Also, caregivers reported using more than one different device for the same medicines and using the devices that came with other medicines as and when required. These practices make it possible to reflect that any device available with the medicine will be used by the caregivers in India, independent of the age of the child. As a consequence, critical reconsideration of regulations on dosing device provision in the packaging of oral liquid preparations is needed in India. Regulatory agencies in western countries have developed guidelines recommending the inclusion of measuring devices in over the counter (OTC) liquid medications, particularly those intended for use in children [25,26]. The regulatory framework for administration devices is described in Article 1(9) MDR [27]. However, there is no such regulation in India. The need for strict regulatory directives on the inclusion of accurate dosing devices in the packaging of oral liquid

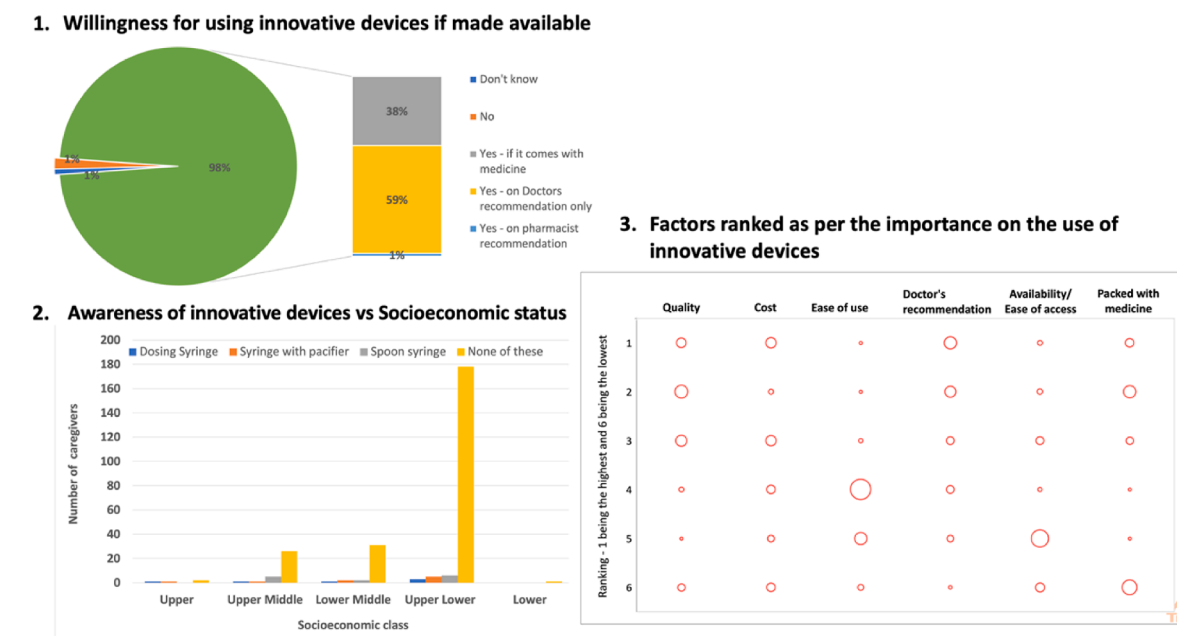


Fig. 6. Awareness and Willingness to use innovative devices.

medicines is needed to reduce the possibility of medication errors. This need is also highlighted by other LMICs [28].

The caregivers' opinions on ease of use did not vary much with the devices. Most of them found it easy to use the device. However, few reported difficulties with household spoons ($n = 16/71$) and measuring cups ($n = 17/114$). Overall, 61 % of caregivers reported experiencing preventable problems in using administration devices recently. However, none perceiving a problem discussed their concern with the HCP. Hence, many patients/caregivers perceived problems remain unknown to doctors. Clearly, clinicians need to be aware of these patient-perceived preventable problems, particularly where there is potential for harm. For instance, the administration of anti-epileptic or potent medications to paediatric patients is an area that requires careful monitoring of doses, and the accurate use of appropriate administrative devices is essential [28]. Thus, improving communication and patient involvement was one of the most frequently suggested solutions for preventing dosing errors, harm, alongside educating caregivers on selection and correct use of appropriate administration devices. Other studies in these settings have documented some of the issues found in this study [5]. However, none have documented if these issues were reported to their doctors.

Problems reported by caregivers were categorised into five dimensions which also influence the preference for using administration devices. This includes device design, user experience and usability, sociocultural factors, such as beliefs, knowledge and education, regulatory, and market/distribution as presented in Table 2. Accurate measuring of medicine was frequently reported followed by difficulty in cleaning. Devices design-related issues included graduation marks on the measuring cups which were difficult to read, and measuring appropriate doses with a dropper whereas the formulation related issue was the viscosity of the medication. Some devices have been reported to be more accurate for runny liquids while others appear more accurate for viscous liquids [29]. The incorporation of air into the dropper could obscure accurate reading of the scale of the dropper [30]. Focus group discussions among caregivers also highlighted their opinion that measuring spoons or household spoons may not be suitable, especially for very young children as the parents were scared that the edges of the spoon would cut the lips of their child. They also informed that the grandparents often used and suggested using the device called gokarna paladia (as shown in Fig. 4). It is a cup-like utensil with a narrow tip that

has been used traditionally to feed babies in India when the mother cannot breastfeed [31,32]. The medicine was measured via spoon or cup and then transferred to gokarna/paladai for administration to children. The spout or narrow tip on this device made it easier to place the device into the baby's mouth. They often administered some water after medicine to ensure a complete dose is administered. It is also easier to clean after use.

The findings indicated that caregivers were more willing to use new devices when they perceive them to be high in relative advantage, low in complexity, and ease of use. The criteria considered by the parents for use of the innovative devices in the descending order were Doctor's recommendation > Quality > Cost > Packed in medicine > Ease of use > Availability/accessibility. The majority of the caregivers (86.7 %) were not aware of any of the innovative devices shown to them. Devices such as oral syringes, which are commonly used in the western population were new to caregivers in India. In general, the Indian healthcare system continues to be impacted by aspects of availability, affordability, and quality of health services. Lack of innovation has resulted in a scarcity of cost-effective products and solutions in the medical industry [33]. At present, there are a limited number of such options available for administration devices, and that too in select pockets of the country. There is a huge gap between the needs of Indian patients and what is available in the market. While there is growing awareness of dosing accuracy and devices related issues around the world, India's population remains ignorant about the latest advancement in administration devices. For example, even though oral dosing syringes have been available in developed countries since 1975, none of the 16 pharmacies surveyed in the Angalakuditi et al study in India were supplying them and local physicians appeared to be unaware of the device [34]. Lack of awareness among pharmacists, healthcare professionals, and caregivers regarding the importance of administration of the right dose of medications and accurate use of dosing devices are the key factors among the others such as regulatory environment, inadequate ecosystem support, limited focus on 'Innovate in India' that impact the use of innovative devices in India. The new administration devices may often reach western populations in a matter of months or years, they rarely reach LMICs at the same pace and quality. The challenge for companies in India is to produce administration devices that are both cost competitive and effective to increase penetration and use. It is in this context that the Make in India initiative becomes significant for the medical devices

industry [35]. The Government plays a critical role in developing the ecosystem (suppliers, buyers, distribution, etc.) of the medical devices industry. In parallel, the industry needs to work with the Government to encourage the development and access to affordable and quality administration devices.

Overall, the study revealed heterogeneity in the SES for the use of administration devices in the four zones. The association of SES and opinion on the use of administration devices was demonstrated with no statistically significant interaction between caregiver SES and the use of administration devices. No association was seen between the profession and the use of administration devices. This study helps in a better understanding of how socioeconomic status influences the use of appropriate devices for the correct dosing of medicines for children. It should thus help policymakers in planning for provision of such devices accordingly. This study's findings, as well as those of the few other mentioned studies, suggest that a large number of caregivers especially those from the lower and middle socio-economic strata, require support (education, training, awareness, and financial) to access proper dosing devices. Essential medical coverage including subsidies for SES management should thus also be extended to administration devices and to the unaided upper lower, lower middle, and upper middle Indian groups, as these strata face maximum challenges in the of paediatric population, and using proper devices play a key role in paediatric treatment.

8. Strengths and weaknesses

The number of caregivers included was not derived through the calculation of the required sample size but determined by the maximum number of caregivers that could be recruited in the given time for each zone. However, we believe that we have comprehensively captured the caregiver perspective by involving members of the public from study design through data acquisition to analysis and reporting. In defining the five categories, we recognize that some measures could plausibly fit within several categories. A further weakness is that the caregivers' suggestions for discussing issues with doctors tended to be non-specific. Collecting patients' suggestions about improving communication with HCP's or understanding HCP's opinions on the use of appropriate administration devices was not the primary aim of this survey but caregivers did engage on this topic during discussion and highlighted that further work in partnership with HCP's is needed to develop this aspect of the survey further. The percentage of the upper lower class was higher and hence the results may be dominated by this class and not representative of all the classes of socioeconomic status. Also, the Kupuswamy scale used for assessing socioeconomic status scale can be used for research purposes only. The income information is retrieved from an individual participating and not necessarily may be the head of the family. There were very limited individuals from lower socioeconomic status in the study. The non-availability of samples from the lower group suggests that this survey would be more appropriate if conducted with other approaches such as a door-to-door interviews. It will help to better assess the problems of inclusion of the lower class but may not be practically possible due to limitations on the expenditure involved and the time consumed.

9. Conclusion

This study provides caregiver's perspectives on the use and challenges of traditional devices, and the need for innovative administration devices for liquid orals in India, and understands factors (e.g., socioeconomic, design and, technical) that impact accurate administration of medicines to children in India. The study findings indicate that five key issues with the use of appropriate administration devices for correct and accurate dosing in children remain unresolved and prevalent in India. This includes 1) awareness of the administration devices and the importance in the administration of the correct dose of medicine to

children 2) appropriate education and training on how to use the administration devices appropriately 3) the need for caregivers, patients, and healthcare professionals to work together to ensure safer administration 4) improving availability and affordability by local production of administration devices, particularly keeping the SES in mind 5) Need of regulatory framework on administration devices in India. The study suggests that socio-economic factors could be one of the roadblocks to the decision on using administration devices in a less developed country like India. Traditional devices such as household spoons are not effective and accurate in administration of medicines for children. The country needs to reorient its use of the administration devices to broader and more reliable options. A multi-dimensional strategy is needed to improve the administration of medicines using the appropriate dosing devices. The process must begin with strengthening the accessibility and availability of devices, awareness of issues associated with improper use of devices, communication between doctors, nurses, pharmacists, and patients, and training and education on proper use of the devices. This study reflects on the needs of the target community, thus hope will help facilitate the development of locally sustainable solutions to improve the administration of medicines in children in India.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

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