Original Article

A study of knowledge, attitude and practice regarding administration of pediatric dosage forms and allied health literacy of caregivers for children

Amrita Sil[1], Chaitali Sengupta[1], Alak Kumar Das[1], Puspita Das Sil[2], Supratim Datta[3], Avijit Hazra[1]

Departments of [1]Pharmacology and [3]Pediatrics, Institute of Postgraduate Education and Research, Kolkata, [2]Department of Zoology, Tamralipta Mahavidyalaya, Tamluk, Purba Medinipur, West Bengal, India

Abstract

Context: Caregivers of sick children have to be careful with medicine dosing and giving medicines to a reluctant child can be challenging. **Aim:** To assess the knowledge, attitude, and practices of caregivers regarding pediatric medicine administration and health literacy allied to this task. **Settings and Design:** This cross-sectional study was carried out on outpatient and inpatient basis in the pediatrics department of a teaching hospital over 6 months. **Subjects and Methods:** Data regarding sociodemographic profile of patient and caregiver, idea regarding pediatric dosage forms, dosing of medicines, and medication errors during administration were recorded from 377 caregivers. Reconstitution of dry powder and measurement of 5 mL liquid medicine using measuring cup of the medicine phial was demonstrated by the caregivers. **Statistical Analysis:** Association assessed by point biserial correlation and Spearman's rank correlation. **Results:** Majority of the primary caregivers surveyed were young, educated, homemaker mothers. Liquid medicines were used maximally (88.9%). Majority (87.3%) of the caregivers used standardized dosing instruments to measure liquids and reconstitution (85.9%), and teaspoon measurement task (91%) was performed satisfactorily by most. Some potentially wrong practices (e.g., adding medicine to milk, redilution of reconstituted medicine, and storing beyond the recommended period) were recorded. Medication errors were reported by 44.5% caregivers, significantly more in the outpatient setting. Although the statistical correlation was weak, the chance of medication error was less, and the precision of measurement was better with increasing education of the caregiver. **Conclusions:** Physicians need to be aware of the limitations of knowledge and the possibility of wrong administration practices among caregivers of children. Remedial measures in this regard can reduce the risk of medication errors.

Keywords: Children, knowledge-attitude-practice, medication errors, medicine dosing, medicine safety

Introduction

Administration of pediatric medicines varies from typical adult medicine dosing.[1,2] Children have to depend on their caregivers for their medication. In addition, they are often fed liquid medicines, the dosing of which requires more time and care than the administration of tablets or capsules. Proper dosage forms for children, keeping in mind quality, palatability, and ease of administration are often lacking. Where they do exist, inability on the part of caregivers to exercise due diligence may lead to imprecise dosing and medication errors.[3,4] The World Health Organization's Promoting Safety for Children booklet in 2007 and the launch of the United Nations Commission on Life-Saving Commodities for Women and Children in 2012 have recommended establishing standards and guidelines for pediatric formulations and improving supply chains.[5,6] However, caregivers often do not realize the precision of pediatric formulations, and it is quite likely that medication errors occur

Address for correspondence: Dr. Amrita Sil, Department of Pharmacology, Institute of Postgraduate Education and Research, Kolkata - 700 020, West Bengal, India.
E-mail: drsilamrita@gmail.com

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in pediatric practice, which may contribute toward treatment failure, development of antimicrobial resistance, or even harm to the child.

We undertook this study to assess the knowledge, attitude, and practices, regarding medicine administration and literacy in allied matters, of caregivers of children attending our teaching hospital. This should contribute toward formulating counseling needs and implementing measures to improve pediatric medicine administration practice.

Subjects and Methods

This cross-sectional study was conducted in an urban teaching hospital of Eastern India which serves as a large tertiary care referral hospital. All consenting caregivers of patients attending the pediatric outpatients' department (OPD) or admitted to the pediatric ward were included over a 6 months period. The OPD was visited twice weekly, rotating the days of visit every week, and indoor patients were surveyed once weekly also on a rotating day basis. The Institutional Ethics Committee permission was obtained beforehand.

Demographic data of patient and caregiver, information regarding medicines used in the last 12 months (apart from vaccines), knowledge, and practice regarding liquid medicine dosing and some general concepts regarding medicine use were recorded at face-to-face interview using a structured questionnaire. Medication errors possible at the time of administration, such as wrong drug, wrong dose, or wrong time of administration, were recorded by questioning the mothers carefully about their practices in the last 12 months.

The questionnaire underwent face and construct validation by two pediatricians unrelated to the study. Quantitative intrarater validation was done by piloting on 30 primary caregivers in the pediatric ward. The correlation between the answers given by caregivers on two instances of questioning, at an interval of 2 days, was very high (intraclass correlation coefficient or kappa coefficient >0.9) for all items indicating that the questionnaire was sufficiently valid and reliable for our purpose.

Caregivers were asked to demonstrate the reconstitution of oral liquids from dry powders on medicine samples (physician samples) supplied to them. In addition, they were asked to measure out 1 teaspoon (5 mL) of liquid medicine with a dose marked plastic cup (supplied with the medicine phial). The amount measured was pipetted out using a micropipette and volume recorded using a 10 mL measuring cylinder. Similar measuring cups, pipettes, and measuring cylinders were used in all these practical assessments that were undertaken by the same investigator in every case. The measurement was deemed to be correct if the volume measured was in the range 5 ± 0.5 mL.

The sample size was determined on the basis of the proportion of mothers who would be able to demonstrate correctly the measuring out of 1 teaspoon (5 mL) of liquid medicine. It was calculated that 380 caregivers would need to be assessed to determine this proportion with 5% margin of error at 95% confidence level. In the absence of prior data, a response distribution of 50% on this issue was assumed in the calculation of sample size.

Numerical data were summarized as mean and standard deviation (SD), when normally distributed, and as median and interquartile range (IQR) when skewed. Subgroup comparisons were done using Student's independent samples *t*-test and Mann–Whitney U-test for parametric and nonparametric variables, respectively, and by Fisher's exact test or Chi-square test for categorical variables. Association between number of years of formal education and medication error was explored by calculating point biserial correlation coefficient (r_{pb}), while that between literacy status and accuracy of liquid medicine measurement by Spearman's rank correlation coefficient (rho). MedCalc version 10.2 (MedCalc Software, 2011, Mariakerke, Belgium) and Vassarstats online statistical calculators (http://vassarstats.net/) were used for statistical analysis. The cutoff for statistical significance was $P < 0.05$.

Results

Of the 380 subjects approached over a 6-month period, 377 (99.21%; 197 outpatient caregivers) consented to participate. The median age of the children involved was 4 years. About 62% were males and 84% resided in rural areas.

The sociodemographic profile of the study participants is summarized in Table 1. The primary caregiver was the mother in 89.7% cases followed by grandmother, aunt, or father in the rest 10.4%. There was no significant difference in the primary caregiver status between the children admitted and those who were OPD attendees ($P = 0.090$). The primary caregiver was usually young (mean age 28; SD 7.52 years), homemaker (83.6%) with an education mostly up to high school level (71%); and 17.8% caregivers were illiterate. Most (84.6%) families were below the official poverty line.

Table 2 provides a breakup of the various dosage forms reported to be used. Oral liquids were being used in the majority (88.9%), followed by topical formulations (87%), and then tablets and capsules (24.4%). The experience of conventional tablet use in children was reported by 66.1% caregivers while the rest reported only dispersible tablet use. Intravenous injections were used in 59.2% patients; significantly more ($P < 0.001$) in admitted cases. Inhalational medicines were used in 20.2%; again significantly more in ($P = 0.003$) indoor cases.

As seen from Table 3, the accepted measurement of one teaspoon (5 mL) was correctly reported by 61.8% caregivers, whereas one tablespoon (15 mL) was correctly interpreted by only 53.1%. Household measurers such as spoon (29 persons) or paladai (19 persons) were used to measure out the medicine

Table 1: Sociodemographic profile of study participants

Parameter	Overall *n*=377 (%)	Outdoor patients *n*=197 (%)	Indoor patients *n*=180 (%)	*P*
Child				
Age (months)				
Mean±SD	58.3±41.04	52.6±35.03	64.5±46.06	0.005
Median (IQR)	48 (24-84)	48 (24-72)	47 (24-108)	
Gender				
Male: female	235:142 (62.3:37.7)	119:78 (60.4:39.6)	116:64 (65.4:34.6)	0.457
Residence				
Rural: urban	317:60 (84.1:15.9)	157:40 (79.7:20.3)	160:20 (88.9:11.1)	0.017
Primary caregiver				
Age (years)				
Mean±SD	28.0±7.52	27.5±6.62	28.5±8.38	0.192
Median (IQR)	26 (23-31)	26 (23-30)	26 (22-33)	
Gender				
Male: female	25:232 (6.6:93.4)	21:176 (10.7:89.3)	4:176 (2.2:97.8)	0.001
Relation with child				
Mother	338 (89.7)	182 (92.4)	156 (86.7)	0.090
Others (grandmother, father, Aunt)	39 (10.4)	15 (7.6)	24 (13.3)	
Occupation				0.005
Homemaker	315 (83.6)	175 (88.8)	140 (77.8)	
Working	62 (16.4)	22 (11.2)	40 (22.2)	
Formal education				0.107
Illiterate/informal	67 (17.8)	27 (13.7)	40 (22.2)	
Up to 4 years	39 (10.3)	26 (13.2)	13 (7.2)	
4-10 years	229 (60.7)	122 (61.9)	107 (59.4)	
10-12 years	19 (5.0)	11 (5.6)	8 (4.4)	
>12 years	23 (6.1)	11 (5.6)	12 (6.8)	
Average monthly income of family (Rs.)				0.003
<5000	319 (84.6)	155 (78.7)	164 (91.1)	
5000-10,000	42 (11.1)	30 (15.2)	12 (6.7)	
10,000-15,000	9 (2.4)	5 (2.5)	4 (2.2)	
>15,000	7 (1.9)	7 (3.6)	0	

P value in the last column is from intergroup (outdoor vs. indoor) comparison by Mann–Whitney U-test for age and Fisher's exact test or Chi-square test for the categorical variables. IQR: Interquartile range; SD: Standard deviation

Table 2: Frequency of use of various dosage forms in study children

Parameter	Overall *n*=377 (%)	Outdoor patients *n*=197 (%)	Indoor patients *n*=180 (%)	*P*
Tablets	92 (24.4)	52 (26.4)	40 (22.2)	0.401
Type of tablet				
Dispersible	128 (33.9)	58 (29.4)	70 (38.9)	0.064
Swallowed	249 (66.1)	139 (70.6)	110 (61.1)	
Oral liquids	335 (88.9)	167 (84.8)	168 (93.3)	0.009
Inhalations	76 (20.2)	28 (14.2)	48 (26.7)	0.003
Intravenous injections	223 (59.2)	34 (17.3)	120 (66.7)	<0.001
Topical preparations	328 (87)	172 (87.3)	156 (86.7)	0.879

P value in the last column is from intergroup (outdoor vs. indoor) comparison by Fisher's exact test.

by 48 (12.7%) care-providers whereas 329 (87.3%) preferred using the measuring device supplied by the manufacturer, such as plastic measuring cup (368) and dropper (43). Separately purchased oral syringes were used in 4 instances by caregivers of seriously ill admitted children. In the test of measuring, out liquid medicine in front of the investigators, using the dosing cup supplied, majority (91%) successfully accomplished the task and the mean volume recorded was 4.98 mL (SD 1.01 mL). The measured amount was not significantly different between OPD and indoor cases.

Shaking the liquid medicine bottle before use was correctly demonstrated by 330 (87.5%) care providers. Satisfactory demonstration of dry powder reconstitution was provided by 324 (85.9%) persons, significantly more in the outdoor setting ($P = 0.002$). The reconstituting fluid used was boiled and cooled water in 80.6%, reconstituting fluid supplied with the medicine in 8.2%, and drinking water in 7.4% cases. The reconstituted medicine was kept for 7 days by 231 (61.3%) caregivers, kept until the phial was exhausted by 38 (10.1%) and kept for 15 days or more by 37 (9.81%) caregivers; 18.8% caregivers were ignorant of the duration of time to keep the reconstituted medicine. The residual quantity of liquid medicine in the measuring device was fed to the child after washing the device in 44.6% cases, scooped by finger and fed in another 13.3%, not fed in 42.2% cases. Most persons (97.6%) washed the feeding device after use.

Table 3: Knowledge, attitude, and practice of liquid medicine use among caregivers

Parameter	Overall *n*=377 (%)	Overal *n*=377 (%)	Outdoor patients *n*=197 (%)	Indoor patients *n*=180 (%)	*P*
Knowledge of liquid dosage form being more precise					
Yes: no	356:21 (94.4:5.6)	356:21 (94.4:5.6)	184:13 (93.4:6.6)	172:8 (95.6:4.4)	0.380
Knowledge about one teaspoon measurement					
Yes: no	233:144 (61.8:38.2)	233:144 (61.8:38.2)	129:68 (65.5:34.5)	104:76 (57.8:42.2)	0.138
Measurement of teaspoon (among those who know)					
Knowing correctly	128 (54.9)	128 (54.9)	72 (55.8)	56 (53.8)	0.792
Not knowing correctly	105 (45.1)	105 (45.1)	57 (44.2)	48 (46.2)	
Knowledge about one tablespoon measurement					
Yes: no	200:177 (53.1:46.9)	200:177 (53.1:46.9)	104:93 (52.8:47.2)	96:84 (53.5:46.7)	1.000
Measurement of tablespoon (among those who know)					
Knowing correctly	23 (11.5)	23 (11.5)	15 (14.4)	8 (8.3)	0.192
Not knowing correctly	177 (88.5)	177 (88.5)	89 (85.6)	88 (91.7)	
Method of shaking bottle proper					
Yes: no	330:47 (87.5:12.5)	330:47 (87.5:12.5)	178:19 (90.4:9.6)	152:28 (85.4:14.6)	0.088
Satisfactory demonstration of reconstitution					
Yes: no	324:53 (85.9:14.1)	324:53 (85.9:14.1)	180:17 (91.4:8.6)	144:36 (80.0:20.0)	0.002
Reconstitution fluid					
Boiled and cooled water	304 (80.6)	304 (80.6)	170 (86.3)	134 (74.4)	0.001
Drinking water	28 (7.5)	28 (7.5)	10 (5.1)	18 (10.0)	
Reconstituting fluid supplied	31 (8.3)	31 (8.3)	16 (8.1)	15 (8.3)	
Uncertain	40 (10.6)	40 (10.6)	8 (4.1)	32 (17.8)	
Time of keeping reconstituted fluid					
Kept for 7 days	231 (61.3)	231 (61.3)	151 (76.7)	80 (44.4)	<0.001
Kept for 15 days or more	37 (9.8)	37 (9.8)	13 (6.6)	24 (13.3)	
Kept till phial exhausted	38 (10.1)	38 (10.1)	18 (9.1)	20 (11.1)	
Uncertain	71 (18.8)	71 (18.8)	15 (7.6)	56 (31.1)	
Device for administration					
Household measures	48 (12.7)	48 (12.7)	20 (10.2)	28 (15.6)	0.124
Devices supplied with medicine	329 (87.3)	329 (87.3)	177 (89.8)	152 (84.4)	
Residual quantity of liquid dose in feeding device					
Fed after washing the device	168 (44.6)	168 (44.6)	64 (32.5)	104 (57.8)	<0.001
Scooped by finger and fed	50 (13.3)	50 (13.3)	30 (15.2)	20 (11.1)	
Not fed	159 (42.2)	159 (42.2)	103 (52.3)	56 (31.1)	
Whether feeding device washed after use					
Yes: no	368:9 (97.6:2.4)	368:9 (97.6:2.4)	189:8 (95.9:4.1)	179:1 (99.4:0.6)	0.039

P value in the last column is from intergroup (outdoor vs. indoor) comparison by Fisher's exact test or Chi-square test

Regarding knowledge of allied issues as listed in Table 4, 275 (72.9%) caregivers had satisfactory knowledge about expiry date of medicines, and this seemed to be better in the OPD attendees ($P < 0.001$). About half the caregivers usually gave the medicines to the child for the duration stipulated by the prescribing physician; the rest stopped the medicine when the child got better. If the child vomited the medicine, most caregivers (44.8%) skipped the present dose and fed the next dose as scheduled; others waited for some time and then tried again (36.3%). Satisfactory idea about "BD" dosage interval (12 ± 2 h) was present in 42.7% caregivers. "Before meal" meant a median of 30 min (range 5–60 min; IQR 10–30 min), whereas "after meal" again meant a median of 30 min (range 5–60 min, IQR 10–30 min) for the caregivers; 39.3% mothers knew correctly that "before meal" implied at least 30–60 min before; 6.63% mothers incorrectly knew "after meal" meant an hour after the last meal. If the child vomited following medicine dosing, most caregivers (44.8%) skipped the present dose and fed the next dose as scheduled. Others waited for some time and then fed the medicine (36.3%) while a substantial proportion (15.4%) preferred skipping the medicine altogether. In the event of a child refusing to take medicine, 31.3% mothers force fed the medicine, 24.9% fed it after some time while 28.9% skipped the dose altogether. Some mothers preferred to add the medicine to milk (4.8%) and then feed the child or diluted the medicine further (2.1%) and then administered it to the child.

Medication administration errors within the past 1 year were reported significantly more ($P < 0.001$) in OPD attendees (128) than in indoor (40) patients. Wrong timing was the most common problem among outpatient caregivers while wrong dose was the most common fault among indoor caregivers. [Table 5]. There was, however, no significant difference in error frequency between mothers and other individuals as primary caregivers.

There was weak negative correlation (r_{pb} – 0.09) between primary caregiver literacy (in terms of years of formal

Table 4: General concepts about medication use among caregivers of sick children

Parameter	Overall *n*=377 (%)	Outdoor patients *n*=197 (%)	Indoor patients *n*=180 (%)	*P*
Satisfactory knowledge about expiry date				
Yes: no	275:102 (72.9:27.1)	175:22 (88.8:11.2)	100:80 (55.6:44.4)	<0.001
How long medicine given if duration of therapy is 5 days				
5 days	200 (53.1)	136 (69.0)	64 (35.6)	1.000
Until child gets better	177 (46.9)	61 (31.0)	116 (64.4)	
What is done if child vomits medicine?				
Medicine given again immediately	3 (0.8)	3 (1.5)	0	<0.001
Wait for some time, then try again	137 (36.3)	73 (37.1)	64 (35.6)	
Medicine stopped	58 (15.4)	54 (27.4)	4 (2.2)	
Dose skipped, next dose given	169 (44.8)	61 (31.0)	108 (60.0)	
Others	2 (0.5)	2 (1.0)	0	
Variable	8 (2.1)	4 (2.0)	4 (2.2)	
Satisfactory idea about BD dosage interval (12±2 h)				
Present	161 (42.7)	85 (43.1)	76 (42.2)	1.000
Absent	216 (57.3)	112 (56.9)	104 (57.8)	
Idea about "before meal" duration (min)				
Mean±SD	32.5±51.46	32.1±61.25	32.9±37.39	0.874
Median (IQR)	30 (10-30)	30 (10-30)	20 (10-30)	
Idea about "after meal" duration (min)				
Mean±SD	31.5±51.10	30.5±60.57	32.6±37.58	0.698
Median (IQR)	30 (10-30)	30 (10-30)	20 (10-30)	
Course of action in case of refusal to take medicine				
Added to milk and fed	18 (4.8)	8 (4.1)	10 (5.6)	<0.001
Further dilution of dose done	8 (2.1)	6 (3.0)	2 (1.1)	
Kept for next dose	109 (28.9)	57 (28.9)	52 (28.9)	
Fed forcefully	118 (31.3)	86 (43.7)	32 (17.8)	
Fed after some time	94 (24.9)	34 (17.3)	60 (33.3)	
Variable	30 (8)	6 (3.0)	24 (13.3)	

P value in the last column is from intergroup (outdoor vs. indoor) comparison by Mann-Whitney U-test for time variables and Fisher's exact test or Chi-square test for the categorical variables. IQR: Interquartile range; SD: Standard deviation

Table 5: Medication error profile

Parameter	Overall *n*=377 (%)	Outdoor patients n=197 (%)	Indoor patients *n*=180 (%)	*P*
Medication error committed				
Yes: no	168:209 (44.6:55.4)	128:69 (65.0:35.0)	40:140 (22.2:77.8)	<0.001
Type of error				
Wrong medicine	14 (3.7)	6 (3.1)	8 (4.4)	<0.001
Wrong dose	35 (9.3)	11 (5.6)	24 (13.3)	
Wrong time	119 (31.6)	111 (56.3)	8 (4.4)	

P value in the last column is from intergroup (outdoor vs. indoor) comparison by Fisher's exact test or Chi-square test

education) and medication error. The correlation between literacy and the accuracy of liquid medicine dosing was also negligible (rho = 0.031).

Discussion

Most of the caregivers in our study were young homemakers with at least high school education, although they came from less privileged backgrounds. This demographic profile is similar to a South Korean study by Ryu and Lee[7] where 85.7% were female caregivers, with 95.3% having at least a high school education and were either the parent or grandparent of the child in 94% cases. Oral liquids were the most frequently used medicine dosage form, given the fact that the children in the study had median age 4 years. At this age, swallowing liquids are preferable to swallowing tablets. However, dispersible tablets were also used by the care providers. In admitted cases, intravenous and inhalational dosage forms were used given the nature and severity of the illnesses that necessitated admission. A study in Tanzania has also reported the preference for liquid medicines in case of young children and swallowed or water-dispersible tablets for others. A fondness for sweet-tasting medicine was also revealed in that study.[8]

Our study found that many caregivers lacked proper knowledge of the quantity implied in one teaspoon and one tablespoon. Since most pediatric liquid formulations in the Indian market now come with a measuring cup or spoon, a better practice would be to mention the exact volume of the liquid medicine, and if necessary, demonstrate the measuring out process using the cup or spoon supplied by the manufacturer. Household measures were used by some care providers, but encouragingly, the bulk of them used the standardized measuring devices. The accuracy of 5 mL measurement using the dosing cup provided by the investigators was achieved by the majority. This is in contrast to Yin *et al.*,[9] who reported that nearly 23.3% caregivers (double that in our study) used nonstandardized liquid dosing instruments, and 67.8% were unaware of weight-based dosing.[9] However, Ryu and Lee[7] have reported that the error committed in dosing measurement was only 11.3% and etched calibrated dosing cup, printed calibrated dosing cup, dosing spoon, dispensing bottle or spoon with bottle adapter were used by caregivers to measure out liquid medicines. Most of the caregivers properly reconstituted dry powder and used appropriate fluids for reconstitution. They also washed the dosing devices before storing. These are also encouraging practices we encountered.

However, knowledge regarding the duration of storage of reconstituted medicine was not optimum, although most caregivers being literate could read and understand the expiry date on the medicine labels and others could rely on their literate partners or family members. Nearly, half the study subjects stopped the medicines once the child got better, instead of following the advice of the physician. This practice can compromise therapeutic outcome and in case of antibiotics, foster resistance. This also implies inadequate counseling of the parents or guardians by doctors and other caregivers. It was often found that if children vomited medicines, the mothers resorted to skipping the present dose or feeding the medicine after some time. In an online survey to identify the practices and opinion of pediatricians about redosing of medicines after vomiting,[10] it was found that the time between ingestion and vomiting was the most important factor to redose the medicine. This time was stated as 30 min by 60% doctors and 15 min by 32% care providers. Thus, guiding the mother to redose only if the time gap between ingestion and vomiting was within 30 min would be essential information to avoid overdosing.

Pediatric patients are susceptible to medication error due to lack of appropriate pediatric formulations, liquid nature of pediatric dosage forms, availability of nonstandardized devices for measurement, dose calculation mistakes, ignorance of caregivers, and inadequate information and counseling by physicians.[11,12] Our study found that under supervised conditions of indoor wards, medications errors are less frequent than in the OPD setting. Most errors were wrong timing of the dose or the amount of dose fed, committed by the mother or other primary caregiver. An Australian study[13] has documented that regarding medication errors in children, incorrect or double dosing accounted for 58% and 26% cases, respectively, were made at home in 98%, occurred via the oral route in 98.4%, and close family members were responsible in 83.1% instances. Literacy status improvement leads to better understanding of the measurement of liquid medicines, proper comprehension of physician's instructions, and less frequent medication error.[9] In addition, demonstration of measurement can decrease the rate of medication error.[14] We encountered similar trends. Thus, such errors can be minimized by appropriate demonstration of dose measurement by the physician or nursing staff, the use of more accurate devices for measurement and improvement of the information given to parents and caregivers on the prescribed medicines.

Our study has the limitations of being only hospital based and of relatively short duration. Despite this, in conclusion, we can say that clinicians should be aware that many caregivers still continue potentially wrong practices in measuring and administering liquid medicines to children. Once the knowledge gaps and wrong practices can be identified by spending time over these issues, remedial measures can be implemented, beginning with rapport building between the treating physicians and the caregivers who look after these children and continuing with counseling at every opportunity. This would contribute to making medicines safer and more effective for sick children.

Conclusion

Physicians need to be aware of the limitations of knowledge and the possibility of wrong administration practices among caregivers of children. Remedial measures in this regard can reduce the risk of medication errors.

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Conflicts of interest

There are no conflicts of interest.

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