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Research Article

Rational Prescribing of Oral Dosage Forms of Medicines to Children at a Teaching Hospital in Sri Lanka

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ABSTRACT

Purpose: Rational use of medicine includes prescribing practices at all levels. According to the available literature prescribing practices especially in children has been a challenge and poor prescribing practices are seen widely. Hence there is a need to investigate whether oral dosage forms of medicines are prescribed rationally to children. The objective of this study was to describe the rational prescribing practice of oral dosage forms of medicines to children in a teaching hospital in Sri Lanka. **Methods**: A descriptive cross-sectional study was conducted to assess the prescribing practices of 1800 oral dosage forms of medicines prescribed to children under the age of 12 years over a period of one year using validated indicators. Required data were extracted from the prescriptions using a structured pre-tested data extraction sheet. Descriptive statistics was used to analyse the data. **Results:** A total of 2195 medicine were prescribed during the study period and 1800 (82%) were oral dosage forms. Only 24 % of the oral dosage forms were prescribed appropriate to the weight of the child. The majority of the oral dosage forms were liquid and solid dosage forms were prescribed even to children under two years. Capsules were rarely prescribed to children. **Conclusion**: Prescribing practices of oral dosage forms of medicines to children has to be improved in the healthcare setting.

Keywords: Rational use; Oral dosage form; Prescribing; Children; Indicators

BACKGROUND

Rational use of medicine (RUM) is defined as "patients receiving medications appropriate to their needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community".(1) Recognising that the children are not small adults, the World Health Organisation (WHO) further clarified in 2010 that "the ideal children's medicine is one that suits the age, physiological condition, and bodyweight of the child taking them, and is available in a flexible solid oral dosage form.(2)

Prescribers face many unique challenges in rational prescribing of medicines to children.(3) Lack of expertise in paediatric clinical pharmacology, lack of clinical trial data in children, off label use of medicines,

lack of appropriate formulations, lack of medicines in suitable strengths, lack of knowledge of parents about administering medicines to children, lack of resources at the point of care delivery E.g. standard paediatric formularies, weighing scales are some of the key challenges faced by the prescribers.(4) These challenges become significant with oral dosage forms of medicines because they are the commonly prescribed dosage forms in young children and they are unable to swallow tablets and follow administration instructions. Measuring the extent and types of these challenges were also inconsistent as there were no paediatric-specific indicators in the literature. Therefore, as a first step in describing the rational use of oral dosage form of medicines in children, we developed indicators using the RAND/UCLA appropriateness method.(5)

The objective of this paper is to describe the prescribing practice of oral dosage forms (ODFs) of medicines in a cohort of children treated in a tertiary healthcare facility using the recently developed and published indicators.(5)

METHODS

This was a part of a large-scale cross-sectional descriptive study, which investigated the rational use of ODFs of medicines in children in a tertiary healthcare facility which is also a teaching hospital. Data were collected prospectively from three study settings namely outpatient department (OPD), paediatric clinic, and a paediatric ward for a period of one year from January 2017. Children with non-acute short term illnesses like mild respiratory diseases, diarrhoea, and febrile episodes were generally managed at the OPD without referring to ward for admission. Children who required admissions were referred to the paediatric ward. Main diseases treated in the ward include respiratory tract infections, dengue, diarrhoea, cardiac problems, renal diseases, acute asthma, and convulsions. Children on long term treatment for conditions like asthma, epilepsy, nephrotic syndrome, urinary tract infections and anaemia were managed in the clinic.

Study sample: Oral dosage forms of medicine prescribed to children under the age of 12 years in the above three study settings.

Sample size: The WHO methodology on investigating drug use in health facilities recommends (6) that there should be at least 600 encounters ideally collected from 20 health facilities of the same category (at least 30 encounters/facility) for these types of studies. Since we were studying ODFs of medicines given to children under the age of 12 years, we equalized one ODF of medicine as one encounter. In our study, we had three categories of health facilities, OPD, paediatric clinic, and paediatric ward in a teaching hospital but all three were stand-alone health facilities for the entire Province with no possibility of finding 20 facilities in the same category. So we decided to collect data from 30 encounters in 20 different time points over a year from each category (30 X 20 = 600 encounters). Each data collection time point was equalized to one health facility in that category. The total sample size was 1800.

Selection of sample: Depending on the study setting, children were serially numbered according to OPD, clinic or bed head ticket number. In the ward, the first child was identified from the admission register. On the day of the visit of PI, the admission register was checked to find the first child. Admission numbers are given numerically in the register. Therefore the lowest numerical

number in the register who had been prescribed with ODF was selected as the first child. In the OPD and clinic, the first child was according to the clinic or OPD number. Numerical numbers are given to patients of OPD and clinic when they come to the clinic or OPD. On the day of data collection, a child with the lowest numerical number and with an ODF prescribed was taken as the first child. Prescription or drug chart of every other child starting from the first child was screened to identify the ones with at least one ODF of medicine. If an ODF of medicine was not found in the selected prescription or the drug chart, the next in the order which had at least one ODF of medicine prescribed was selected. The process was repeated until 30 ODFs of medicines were surveyed.

Indicators: In the first phase of this study indicators to describe the prescribing practice of ODFs were developed and validated.(5) The indicators are given in Figure 1. These indicators were converted to a data collection tool which was also pre-tested. Inter-rater reliability was also tested.(5)

Figure 1: Prescribing indicators

No	Indicators
1	Average number of oral dosage forms of medicines per child
2	Percentage of oral dosage forms of medicines prescribed in a dose appropriate for the weight of child
3	Percentage of solid oral dosage forms of medicines prescribed
4	Percentage of oral dosage forms of medicines prescribed as tablets
5	Percentage of oral dosage forms of medicines prescribed as capsules
6	Percentage of oral dosage forms of medicines prescribed as a dosage form suitable for age
7	Mean number of tablets prescribed per child
8	Mean number of capsules prescribed per child
9	Mean volume of liquids prescribed per child

Data collection: The principal investigator personally collected the data at 20 time points over a period of one year from all three study settings to reach the required sample size of at least 1800 oral dosage forms of medicines. In the case of OPD and clinic, selection of prescription and extraction of data were done when parents were waiting to get the medicines from the respective pharmacies whereas, in the ward, selection of drug chart and extraction of data were done by screening the bed head tickets. A data extraction sheet was used in extracting the data. Informed written consent from the parents was obtained before data extraction.

Approvals: Ethical approval was obtained from Ethics Review Committee, Faculty of Medicine, University of Colombo, Sri Lanka (EC-15-022). Administrative approval was obtained from the Director/ teaching hospital and all other relevant administrative authorities.

Data analysis: Data were analyzed using the Statistical Package for Social Sciences, SPSS23.0 (IBM Corporation, NY). Descriptive statistics were used to calculate the indicators. Children were categorized based on age as, term newborn (0-27 days), infants and toddlers (1 month to 23 months), pre-school children (2-5 years), and school children (6-11 years).(7) For each ODF prescribed, the dose was calculated based on the weight of the child. Standard formularies like British National Formulary for Children [BNFc] (8), Australian Medicine Handbook (9), WHO model formulary for children (10) were used as standard formularies to check the weight appropriate prescribing. First

BNFc was checked and in the absence of data in the BNFc other formularies were used. The prescribed dose was taken as appropriate when it fell within the dose range given for weight in the formulary. When the range was not given and a single value was given in the formularies, this single value was matched with the calculated value to assess appropriateness. The values other than the standard value were taken as inappropriate. The accuracy of the dose was calculated for 0.1 (one decimal point). Tablets and capsules were considered as not applicable to children under the age of two years.(7) The mean number of tablets/capsules/volume of liquids were calculated from their prescriptions. For the calculation of indicators, only the dosage forms with required data were considered. Few ODFs did not have the required details E.g. the dosage form details, the weight of the child, and for some ODFs, weight based dosing were not given in the formularies. We excluded them when calculating the indicators.

RESULTS

Out of 627 medicines prescribed in the clinic to 253 children, 600 were ODFs (95.7%, 95% CI: 93.8%-97.1%), and out of 655 medicines prescribed to 252 children in the OPD, 600 were ODFs (91.6%, 95% CI: 89.2%-93.6%). Of the 913 medicine prescribed to 244 children in the ward, 600 were ODFs (65.7%, 95% CI: 62.5%-68.8).

Indicator 1: Average number of oral dosage forms of medicines per child

Average number of ODFs per child was 2.4±1.2 with a median of 2.4(1-11). The average number of ODFs prescribed was between 1-2.5 for the age categories and between 2.4-2.5 for the study units. The ward had a higher value than the OPD and clinic (Table 1).

Indicator 2: Percentage of oral dosage forms of medicines prescribed in a dose appropriate for the weight of child

Only 426 ODFs (23.7%, 95% CI: 21.8%-25.7%) were prescribed appropriate to the weight of the child. Out of 1800 ODFs prescribed to children, 2% of ODFs were prescribed without the weight of the child. Weight based doses were not given in the standard formularies for 25% of the ODFs. Weight inappropriate prescribing was seen more in the ward and OPD compared to the clinic (Table 2).

Indicator 3: Percentage of solid oral dosage forms prescribed

Solid oral dosage forms prescribed were 33% (Table 3). Of the 1800 ODFs, 42% (95 % CI: 39%-44%) did not indicate whether it was a solid or liquid dosage form. Of the ODFs which did not indicate details of dosage forms, 12% were from OPD, 39% were from the clinic, and 49% were from the ward.

Indicators 4 and 5: Percentage of oral dosage forms of medicines prescribed as tablets and capsules

Out of 1050 which had the dosage forms details in the prescriptions, 348 were tablets (33%, 95% CI: 30%-36%). This was relatively more in the clinic compared to the other two study settings (Table 3). Infants and toddlers (6%) and preschool children (6%) had been prescribed with tablets. Only five ODFs were prescribed as capsules.

Indicator 6: Percentage of oral dosage forms of medicines prescribed as a dosage form suitable for age

Of the ODFs which had the dosage form details in the prescriptions, 90% (95% CI: 88%-91%) were suitable for the age. As shown in Table 4, even infants and toddlers were prescribed with dosage forms which were not suitable for their age. Out of 1050

ODFs which had the dosage form details, 110 ODFs (10.5%, 95% CI: 8.7%-12.5%) were prescribed in dosage forms not suitable for infants and toddlers. This practice was seen more in the clinic and ward compared to OPD.

Indicator 7: Mean number of tablets prescribed per child

Mean number of tablets prescribed per child for a day was 2.7±2.4 [median of 2(1-3)] with a mean of 2.5±1.75 in the clinic, 2.8± 3.3 in the ward, and 7.6±3.9 in the OPD. The mean number of tablets at a time will vary depending on the frequency. In one instance, an in-ward child had been prescribed 20 tablets on a day.

Indicators 8 and 9: Mean number of capsules and mean volume of liquids prescribed per child

The mean number of capsules prescribed per child was only 1±0.4. Overall mean volume of liquids prescribed per child for a day was 24±14.4 ml [median of 19(10 -31.5) ml]. Mean volume of liquids prescribed per child in the OPD was 26±14.4 ml, in the clinic was 9±6.9 ml, and in the ward was 16±11.6 ml. This may vary for a particular time depending on the frequency.

Table 1: Number of oral dosage forms prescribed to children under the age of 12 years in the three study settings

Setting	Age	Number of children (%)	Number of ODFs prescribed (%)	Average number of ODF per child±SD	Range	Median (LQ,UQ)
Clinic	**Infants and toddlers**	80(31.6)	174(29)	2.2±0.9	1-5	2(2,3)
	Preschool children	88(34.8)	225(37.5)	2.6 ±1.3	1-11	2(2,3)
	School age children	85(14.2)	201(33.5)	2.4±1.6	1-9	2(1,3)
	Total	**253(100)**	**600(100)**	**2.4**±1.3	**1-11**	**2(2,3)**
OPD	**Term new-born**	2(0.8)	3(0.5)	1.5±0.7	1-2	2.5(1)
	Infants and toddlers	101(40.1)	232(38.7)	2.3±0.7	1-4	2(2,3)
	Preschool children	110(43.7)	273(45.5)	2.5±0.7	1-5	3(2,3)
	School age children	39(15.5)	92(15.3)	2.4±0.9	1-5	2(2,3)
	Total	**252(100)**	**600(100)**	**2.4**±0.8	**1-5**	**2(2,3)**
Ward	**Term new-born**	1(0.2)	1(0.2)	1	1	1(1,1)
	Infants and toddlers	105(17.7)	254(42.3)	2.4±1.3	1-8	2(1,3)
	Preschool children	62(28)	158(26.3)	2.5±1.4	1-7	2(2,3)
	School age children	76(40.7)	187(31.2)	2.5±1.4	1-8	2(1,3)
	Total	**244(100)**	**600(100)**	**2.5**±1.4	**1-8**	**2(2,3)**

Table 2: Oral dosage forms (ODFs) prescribed based on the weight of the child

Setting	Age group	ODFs prescribed without weight of the child* (%)	ODFs prescribed without weight based dose in the formulary** (%)	ODFs prescribed appropriate to the weight of the child (%)	ODFs prescribed inappropriate to the weight of the child			Total
					Under dosing (%)	Over D osing (%)	Total (%)	
Clinic	Infants and toddlers	3(0.5)	79(13.2)	29(4.8)	33(5.5)	30(5)	63(10.5)	174(29)
	Preschool children	0(0)	114(19)	40(6.7)	36(6)	35(5.8)	71(11.8)	225(37.5)
	School age children	0(0)	63(10.5)	42(7)	69(11.5)	27(4.5)	96(16)	201(33.5)
	Total	**3(0.5)**	**256(42.6)**	**111(18.5)**	**138(23)**	**92(15.3)**	**230(38.3)**	**600 (100)**
OPD	Term new-born	0(0)	2(0.3)	0(0)	1(0.2)	0(0)	1(0.2)	3(0.5)
	Infants and toddlers	14(2.3)	70(11.7)	58(9.7)	68(11.3)	22(3.7)	90(15)	232(38.7)
	Preschool children	7(1.2)	8(1.3)	67(11.2)	102(17)	89(14.8)	191(31.8)	273(45.5)
	School age children	14(2.3)	11(1.8)	16(2.7)	26(4.3)	25(4.2)	51(8.5)	92(15.3)
	Total	**35(5.8)**	**91(15.2)**	**141(23.5)**	**197(32.8)**	**136(22.7)**	**333(55.5)**	**600(100)**
Ward	Term new-born	0(0)	1(0.2)	0(0)	0(0)	0(0)	0(0)	1(0.2)
	Infants and toddlers	0(0)	44(7.3)	77(12.8)	83(13.8)	50(8.3)	133(22.2)	254(42.3)
	Preschool children	0(0)	26(4.3)	42(0.7)	58(9.7)	32(5.3)	90(15)	158(26.3)
	School age children	0(0)	32(5.3)	55(9.2)	72(12)	28(4.7)	100(16.7)	187(31.2)
	Total	**0(0)**	**103(17.2)**	**174(29)**	**213(35.5)**	**110(18.3)**	**323(53.8)**	**600(100)**
Total***		**38 (2)**	**450 (25)**	**426 (24)**	**548 (30)**	**338 (19)**	**886 (49)**	**1800(100)**

Percentages may not sum up to 100% due to rounding of numbers; * and ** were excluded in calculating the indicator
***The total of ODFs from the three settings; Children were categorized based on age as term new born (0-27 days), infants and toddlers (1 month to 23 months), pre-school children (2-5 years), and school children (6-11 years); ODFs, oral dosage forms

Table 3: Types of dosage forms prescribed in the settings

Setting	Age category	Number of ODFs					
		Solid			Liquid (%)	ODFs without dosage forms details in the prescription* (%)	Total (%)
		Tablets (%)	Capsules (%)	Total (%)			
Clinic	Infants and toddlers	84(14)	0(0)	84(14)	17(2.8)	73(12.2)	174(29)
	Preschool children	112(18.7)	0(0)	112(18.7)	18(3)	95(15.8)	225(37.5)
	School children	70(11.7)	3(0.5)	73(12.2)	2(0.3)	126(21)	201(33.5)
	Total	**266(44.3)**	**3(0.5)**	**269(44.8)**	**37(6.2)**	**294(49)**	**600(100)**
OPD	Term new-born	0(0)	0(0)	0(0)	3(0.5)	0(0)	3(0.5)
	Infants and toddlers	0(0)	0(0)	0(0)	210(35)	22(3.7)	232(38.7)
	Preschool children	3(0.5)	0(0)	3(0.5)	244(40.7)	26(4.3)	273(45.5)
	School children	11(1.8)	0(0)	11(1.8)	40(6.7)	41(6.8)	92(15.3)
	Total	**14(2.3)**	**0(0)**	**14(2.3)**	**497(82.8)**	**89(14.8)**	**600(100)**
Ward	Term new-born	0(0)	0(0)	0(0)	0(0)	1(0.2)	1(0.2)
	Infants and toddlers	26(4.3)	0(0)	26(4.3)	86(14.3)	142(23.7)	254(42.3)
	Preschool children	18(3)	2(0.3)	20(3.3)	53(8.8)	85(14.2)	158(26.3)
	School children	24(4)	0(0)	24(4)	24(4)	139(23.2)	187(31.2)
	Total	**68(11.3)**	**2(0.3)**	**70(11.7)**	**163(27.2)**	**367(1.2)**	**600(100)**
Total**		**348(19.3)**	**5(0.28)**	**353(19.6)**	**697(38.7)**	**750(41.7)**	**1800(100)**

Percentages may not sum up to 100% due to rounding of numbers; * was excluded in calculating the indicator; **The total of ODFs from the three settings; Children were categorized based on age as term new born (0-27 days), infants and toddlers (1 month to 23 months), pre-school children (2-5 years), and school children (6-11 years); ODFs, Oral dosage forms

Table 4: Oral dosage forms (ODFs) prescribed as a dosage form suitable for the age

Setting	Age group	Number of ODFs suitable for the age		Number of ODFs without the details of the dosage forms*	
		N (%)	Yes (%)	(%)	Total (%)
Clinic	Infants and toddlers	84(14)	17(2.8)	73(12.2)	174(29)
	Preschool children	0(0)	130(21.7)	95(15.8)	225(37.5)
	School age children	0(0)	75(12.5)	126(21)	201(33.5)
	Total	**84(14)**	**222(37)**	**294(49)**	**600(100)**
OPD	Term new-born	0(0)	3(0.5)	0(0)	3(0.5)
	Infants and toddlers	0(0)	210(35)	22(3.7)	232(38.7)
	Preschool children	0(0)	247(41.2)	26(43)	273(45.5)
	School age children	0(0)	51(8.5)	41(6.8)	92(15.3)
	Total	**0(0)**	**511(85.2)**	**89(14.8)**	**600(100)**
Ward	Term new-born	0(0)	0(0)	1(0.2)	1(0.2)
	Infants and toddlers	26(4.3)	88(14.7)	142(23.7)	256(42.6)
	Preschool children	0(0)	71(11.8)	85(14.2)	156(26)
	School age children	0(0)	48(8)	139(23.2)	187(31.2)
	Total	**26(4.3)**	**207(34.5)**	**367(61.2)**	**600(100)**
Total**		**110(6.2)**	**940(52.2)**	**750(41.7)**	**1800(100)**

Percentages may not sum up to 100% due to rounding of numbers; *was excluded in calculating the indicator; **The total of ODFs from the three settings; Children were categorized based on age as term new born (0-27 days), infants and toddlers (1 month to 23 months), pre-school children (2-5 years), and school children (6-11 years)

DISCUSSION

Though there are papers in the literature describing irrational use of medicine in children (11, 12), to the best of our knowledge, this is the first paper which specifically describes the paediatric specific challenges in using oral dosage forms rationally by using paediatric specific indicators. It has been reported that the majority of errors in the paediatric age group happens at the level of prescribing. (13)

In this paper, we have documented that rate of inappropriate dose, and unsuitable dosage forms are notable in all three study settings. Most of them appear to be unavoidable as

medicines were not available in child size, and lacked suitable dosage forms. However, there were instances where the weight of the child was not recorded or where the calculations were incorrect. The latter errors are easily correctable. Though dosing based on pharmacokinetics is the emerging recommendation for dose calculation for children, at present the most common method for dose adjustment in paediatric clinical practice is to normalize the adult dose by body weight (i.e. $mgkg^{-1}$), assuming a linear relationship between weight and doses. We have reported in this paper that only 32% of children had been prescribed ODFs appropriate to the dose/weight recommendations. This is far from the ideal. Weight inappropriate dosing was seen more for children under the age of six years. Inappropriate dosing is known to cause dose dependent adverse reactions or toxic effects if the dose is larger than the recommended, or therapeutic failure if it is under dose.(14) Kaushal R et.al (13) also found that dosage error was the most usual type of medication errors in children.

Our study also found that around 2% of the ODFs prescribed did not have weight details in the prescription. This could have been avoided because all three study units had the facility to weigh a child.

Apart from appropriate dose, the other issue in paediatric practice was giving the medicines in inappropriate dosage forms. The WHO has recommended that an ideal dosage form for children should allow minimal dosage and frequency; should have one dosage form to fit all or a full range; should have minimal impact on lifestyle; a minimum of nontoxic excipients, and should have convenient, easy, reliable administration.(15)

With the newly developed indicators, we managed to document many dosage form related issues which have remained undocumented for a long time as children were considered as 'half adults' and problems related to manipulated adult dosage forms were not highlighted. In the recent past, research are being published highlighting the issue of unsuitable dosage forms in children and consequences of giving manipulated adult dosage forms to children.(16) These problems are notable in developing countries where many essential medicines are still not available in dosage forms suitable for children.(17) Parents have no option other than manipulating these unsuitable dosage forms in a way suitable to give the medicine to the child.(18) Swallowing the crushed/broken pill, swallowing the dry powder from crushed pill, and drinking the crushed/dissolved pill mixed with water are few such methods adopted by parents, and sometimes pharmacists when they dispensed medicines.(19)

Manipulated dosage forms are associated with the highest risk of errors since stability data are not available, dose bioavailability is unpredictable, and they are difficult to monitor. Several studies have shown that quality of the manipulated dosage forms is not acceptable.(20-22)

We have documented that tablets had been prescribed even for infants and toddlers. The reason for this may be due to non availability of dosage forms suitable for the age. We feel that the prescribers should be conscious about this problem and take adequate remedial action to prevent such unfortunate situations for example, prescribers can look for an alternative medicine which comes in a suitable dosage form. Subsequently, doctors treating children in this hospital together with

pharmacists and administrators should review the situation of dosage forms of medicines available for children under two years (term new born, and infants and toddlers) and device a standard operational procedure. This may be time consuming, but innocent children will be prevented from getting medicines in unsuitable dosage forms.

The mean number of tablets prescribed per child for a day was 2.7 which is similar to a study done in Tanzania where the total number of tablets per day was 3–6 for those in early years at primary school and 6–9 for older children.(19)

Our study shows that the mean volume prescribed per child per day was only 24 ml. Small volumes are normally better accepted for preparations with known palatability issues, but there are issues in very small volumes of oral liquids for administration in children. The accuracy of dosing relative to the devices available is a concern in very small volumes for oral dosage forms.(23)

The major drawback of the study was the fact that it was limited to only one hospital. Even though our study was done in a single hospital the problems faced in a large tertiary care facility will be similar or less when compared with similar or lower level health facilities as all the hospitals will have similar or worse problems. These problems should be considered as vital problems. Another limitation was that ODFs which did not have the required details were not taken for indicator calculation, but since the sample size was large it will not effect the results drastically. The advantage of these missing details helped us to find values for other irrational practices like prescribing without the weight of the child and the type of dosage form.

Underlying reasons and outcomes of these inappropriate prescribing needs to be investigated further. Paediatric prescribers need to be more attentive towards calculation of doses. Paediatric friendly dosage forms for children under two years (term new born and infants and toddlers) should be made available in hospital settings where these children are treated. Pharmacists should keep the prescribers informed on a daily basis about the available strength and dosage forms of medicines given to children. The regulatory bodies should focus more on suitable paediatric dosage forms.

CONCLUSIONS

Prescribing practices of oral dosage forms of medicines to children has room for improvement. Prescribing weight, inappropriate dose with regards to weight and age, even to children under the age of two years (term new born, and infants and toddlers) were seen in the study population. Preventable practices such as prescribing without the weight, and not mentioning the type of dosage form were also observed in this study. Paediatric prescribers need to be more attentive towards the calculation of doses. They should ensure that the weight and the age of the child are considered when prescribing oral dosage forms. Necessity of age appropriate dosage forms needs to be re-looked by the Authorities.

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