Patterns of Dietary Fluoride Supplement Use in Children from Birth to 96 Months of Age

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Abstract

***Objective**: This paper reports on fluoride supplement use from birth to age 96 months. **Methods**: As part of the Iowa Fluoride Study, questionnaires were mailed at 3 to 6- month intervals assessing use of supplements. Estimated fluoride intake from supplements was calculated as a daily fluoride intake in mg. Analyses include descriptive statistics of supplements use for individual periods, area-under-the-curve (AUC) for combined periods, and associations between fluoride supplement use and demographic covariates. **Results**: Participants (n=1,388) were mostly white, with about two-thirds of parents having some college education. Percentages using fluoride supplements were 11.2% (12 months), 6.3% to 6.8% (24, 36, 48 and 60 months) and 3.6% to 4.7% (72, 84 and 96 months). Physicians prescribed most supplements until age three. The mean supplement dosage when used gradually increased from 0.25 mg (12 months) to 0.82 mg (84 months) and 0.75 mg (96 months). The effective mean daily fluoride supplement quantities ingested among users for the successive age groups from 12 to 96 months old were 0.14, 0.14, 0.25, 0.34, 0.37, 0.43, 0.48, and 0.37mg, respectively. Estimated daily average fluoride ingested from supplements increased from 0.06 mg (birth-12 months) to 0.07 mg (12-60 months) to 0.18 mg (60-96 months). **Conclusion**: Fluoride supplement use patterns varied substantially among individuals; however, average use within the intervals birth-12 months, 12-60 months, and 60-96 months was fairly consistent.*

Key Words: fluoride, dietary fluoride supplements, children, and patterns of use.

Introduction

A significant decline in the prevalence of dental caries in children has been reported in the United States and other industrialized countries (1,2), due largely to the widespread use of fluoride in many forms (1). There also has been an increase in dental fluorosis prevalence (3) due to combined fluoride ingestion from fluoridated water, dietary supplements, dentifrice, infant formulas and other sources (4). However, relatively few studies have investigated in detail these sources of fluoride intake.

Dietary fluoride supplements have been used as an alternative to water fluoridation for more than 50 years (5), based on evidence of caries preventive benefits from a number of small clinical trials (6) that recently have been criticized for flaws in study design and the way conclusions were drawn (7,8).

Several clinical trials reported poor patient compliance with supplement use (9,10). "Regular" patients probably will have poorer compliance with their provider-based supplement regimen than research subjects, especially over time. This would result in an ingestion of lower amounts of fluoride than prescribed (10). Further, there is substantial evidence that use of supplements has contributed to dental fluorosis, (8,11,12), even among children without fluoridated water (13). Dietary fluoride supplements are an important source of fluoride ingestion in children using them. About 15% of U.S. children younger than age four years used supplements (14), and 54% of U.S. schoolchildren (in 1986-87) had used supplements sometime (15).

Authorities in several countries recently modified the recommended schedule for fluoride supplements, with focus for high-risk caries children because of doubt about caries-preventive efficacy and/or concern about contribution to dental fluorosis (16-19).

Studies have not comprehensively reported fluoride supplement use by children longitudinally. Detailed patterns of supplement use from birth to 12 months have been reported (10). The purpose of this paper is to report on fluoride supplement use longitudinally until the age of eight years among a cohort of children studied from birth.

Methods

The group followed as part of the Iowa Fluoride Study (IFS) (10,20,21) was a birth cohort recruited from eight hospitals' postpartum units in eastern Iowa from 1992-95. The newborns of the eight hospitals comprised about 20% of all new Iowa births (10). The University of Iowa Institutional Review Board approved this study and parents provided informed consent. Detailed information regarding age, family demographics and water sources was obtained at baseline. Pretested questionnaires were mailed to the participants' homes when the children were ages 1.5, 3, 6, 9, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 66, 72, 78, 84, 90, and 96 months with nonrespondents mailings after three and six weeks, if necessary. Therefore,

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the response ages generally vary several days to weeks from the ages of each initial mailing.

Mothers were asked questions assessing their children's use of dietary fluoride supplements (10): whether supplements were used and, if so, the number of weeks of use during the time interval, number of days per week, product's brand and dosage or quantity. For each period, an estimate of fluoride intake from supplements was calculated as a daily fluoride intake in mg using information from those questions, and intake was also reported per kg of the body weight (mgF/kg bw).

Reliability of the responses concerning use of dietary fluoride supplements (yes/no) was assessed by matching 504 answers from questionnaires for ages 1.5 to 28 months with those obtained by phone calls to the same mothers 7-10 days later. The kappa statistic was 0.967, with 99.6% agreement.

Data were reviewed, and double entered. Statistical analyses were generated using The SAS System for Windows 9.0 (22). The average daily amount of fluoride ingested from supplements was calculated by (the proportion of weeks supplements were used) x (the proportion of days supplemented during those weeks) x (the dosage per day when supplements were used).

Three types of analyses were descriptive tabulations, establishment of an area-under-the-curve (AUC) for combined periods, and assessment of the relationships between the outcome variables and the covariates of interest. In descriptive summaries, responses were categorized discretely as occurring closest to one of the individual time periods of assessment, so each observation is considered to have occurred at only one time. Summary statistics (mean, standard error, selected percentiles) were computed for each time period.

The second analyses assessed the proportion of days of fluoride supplement use and the average daily amount of fluoride ingested from supplements over combined time periods (ages) by collapsing the 22 time periods into 3 intervals: birth to 12 months; 12 to 60 months; and 60 to 96 months. The proportion of days of fluoride supplement use and the average daily supplement over the whole time interval (mgF) was calculated separately for these three time intervals by calculating AUC for both variables. Subjects who used fluoride supplements at any time period during an interval were included in that interval's analysis. Any missing values of responses at any time period inside each interval were considered missing. Conversely, responses of those who did not use any fluoride supplements at all in that interval were assigned zeros. If the endpoints for these three time intervals were missing, then these values were replaced by the results for their closest timepoints. For example, if age 60 months is missing, then the time interval of 12 to 56 months would be used instead of 12-60 months. Descriptive analyses including mean, standard deviation, and percentiles of the proportion of days of fluoride supplement use and the average daily amount of fluoride ingested from supplements were calculated for AUC estimates.

The third analyses used one-way analysis of variance to compare average daily fluoride ingested from supplements across demographic covariates, both with and without adjustment for subject-specific combined fluoride levels. Regression analysis models were established to estimate the effect of these demographic variables on the average daily amount of fluoride ingested from supplements used during a specified time interval. These analyses were conducted separately for the three time intervals.

Results

The study sample's demographic characteristics at recruitment are presented in Table 1. About 60% of the mothers were under age 30 years (mean age 28.1) compared to 40% of the fathers (mean age 30.8). Mothers and fathers were similarly educated, with about two-thirds having some college education. About 40% of families had annual income of at least

Table 1
Demographic characteristics of respondents (n=1,388*)

Variable	Category	Percentage
Mother's age (years)	<20	7.4
	20-24	20.6
	25-29	31.0
	30-34	27.2
	≥35	13.8
Father's age (years)	<20	1.2
	20-24	11.9
	25-29	29.8
	30-34	32.2
	≥35	24.8
Mother's education	Up to high school	30.5
	Some college	32.3
	College graduate or more	37.2
Father's education	Up to high school	34.5
	Some college	27.8
	College graduate or more	37.7
Family income	<$20,000	23.8
	$20,000 - $39,999	35.7
	≥$40,000	40.5
Race	White	95.3
	Other	4.7
First child	Yes	44.2
	No	55.8

* Among the 1,388 recruited who provided at least one response other than baseline recruitment.

Table 2
Number and percentage of fluoride supplement users and combined water fluoride level (weighted combination of home, childcare, bottled & school water sources) by age

Age	Sample size	Users		Combined fluoride level		
		N	%	<0.3 ppm	0.3-0.6 ppm	>0.6 ppm
12 months	801	90	11.2	50.6%	26.5%	22.9%
24 months	663	42	6.3	61.5%	23.1%	15.4%
36 months	631	42	6.7	58.5%	34.1%	7.3%
48 months	613	41	6.7	56.8%	29.7%	13.5%
60 months	636	43	6.8	48.8%	36.6%	14.6%
72 months	613	22	3.6	52.4%	38.1%	9.5%
84 months	570	27	4.7	55.0%	35.0%	10.0%
96 months	422	15	3.6	45.5%	36.4%	18.2%

$40,000. Most children were white (95%), and 44% were first children.

Table 2 presents numbers and percentages of fluoride supplement users and water fluoride levels as weighted averages of home, childcare, bottled and school water sources. Fluoride supplements were reported used by 11% of the subjects at age 12 months, 6.3% to 6.8% at 36, 48, and 60 months, and 3.6% to 4.7% at 72, 84 and 96 months. At ages 24 to 60, supplement use was about 40% lower (proportionally) than at age 12 months, with continued decline at ages 72 to 96 months. Combined water source level categories (<0.3, 0.3-0.6 or >0.6 ppm) were generally consistent across age groups. Since children with water fluoride levels more than 0.6 ppm are not recommended to receive dietary supplements, our data suggest that 7-23% are probably receiving supplements inappropriately.

About 48% of all fluoride supplements from 12 to 36 months were prescribed by pediatricians, 33% by family physicians, 11% by general dentists, and 7% by pediatric dentists (Table 3). Thus, most supplements (63-97%) were prescribed by physicians to age three, while about 71% were prescribed by dentists at 48 months.

Table 4 presents user's information on proportion of weeks supplements were used, days per week, dosage, and average daily amount of fluoride ingested from supplements for the eight study periods. About 62-78% of subjects receiving supplements from 12 to 96 months received them more than 75% of weeks. The means proportions of weeks are stable over time at 0.73-0.81. Approximately one-third to one-half (33-52%) receiving supplements at each age received them seven days per week, with 1-4 days per week for 33-47%. The means are stable at 4.3-5.0 days a week. Approximately 74%-81% receiving supplements at ages 12-24 months reportedly received a dosage of 0.25 mg fluoride per day. For ages 36-60 months, the doses of 0.25, 0.5 and 1.0 mg fluoride supplements were each received by about 23-42% of subjects and about 83-95% of subjects aged 72-96 months received supplements of 0.5 and 1.0 mg. The mean dosages when supplements were used increased gradually from 0.25 mg (12 months) to 0.82 mg (84 months) and 0.75mg (96 months).

The amount of ingested fluoride from supplements among users during that whole time interval (mgF) is presented in the last section of Table 4. This was calculated by multiplying the proportion of weeks supplements were used, number of days per week received, and dosage per day when received. For 12 and 24 months, about one-fifth of subjects received supplements in the amount of 0.01-0.05, 0.051-0.1 and 0.1-0.15 mg, respectively, and about one-quarter received 0.25-0.375 mg. By 36 and 48 months, about one-quarter received an estimated 0.376-0.5 mg of fluoride. At 60 and 72 months, about 19-28% received estimated doses 0.376-0.5 mg and 0.501-1.0 mg, while 38-47% at 84-96 months received an estimated dose of 0.376-0.5 mg. The effective mean daily dosage of fluoride supplement among users for the successive age groups from 12 to 96 months old were 0.14, 0.14, 0.25, 0.34, 0.37, 0.43, 0.48, and 0.37 mg, respectively.

An estimate of the number of days of fluoride supplement use over the three time intervals was determined using AUC technique. Among those children using supplements, about 28-42% used them up to half day/week, 13-21% more used them up to one day/week, 13-17% more used supplements up to 2 days/week, and 25-44% used them more than two days/week for the entire time intervals (birth-12, 12-60, and 60-96 months). The number of days of fluoride supplement use averaged 1.7

Table 3
Distribution of professionals who prescribed dietary fluoride supplements (percentages)*

Prescriber	Age in months				Total
	12 months	24 months	36 months	48 months	
General dentist	1.1	9.8	21.9	47.1	11.1
Pediatric dentist	1.1	7.3	12.5	23.5	6.7
Family physician	38.9	36.6	25.0	11.8	33.3
Pediatrician	57.8	46.3	37.5	17.6	47.8
Others	1.1	0.0	3.1	0.0	1.1

* Among the 180 subjects who provided responses to this question.

Table 4
Patterns of fluoride supplement use by age (percentages)*

Variable	Category	Age of subjects in months: 12 (n=89)	24 (n=42)	36 (n=42)	48 (n=40)	60 (n=43)	72 (n=22)	84 (n=27)	96 (n=15)
Proportion of weeks	<0.25	10.1	16.7	19.0	12.5	18.6	0.0	7.4	6.7
	0.25-0.50	7.9	11.9	7.1	7.5	11.6	13.6	11.1	13.3
	0.51-0.75	12.4	2.4	11.9	5.0	4.7	13.6	3.7	6.7
	0.76-1.00	69.7	69.0	61.9	75.0	65.1	72.7	77.8	73.3
Mean		0.79	0.76	0.73	0.81	0.73	0.81	0.78	0.78
SE		0.03	0.05	0.05	0.05	0.05	0.05	0.05	0.07
Number of days per week	<1	7.9	4.8	4.8	2.4	7.0	4.5	7.4	6.7
	1-2	13.5	26.2	19.0	19.5	9.3	13.6	11.1	20.0
	3-4	21.3	14.3	19.0	19.5	23.3	27.3	33.3	26.7
	5-6	6.7	14.3	4.8	19.5	14.0	4.5	11.1	13.3
	7	50.6	40.5	52.4	39.0	46.5	50.0	37.0	33.3
Mean		4.9	4.5	4.9	4.8	5.0	4.9	4.6	4.3
SE		0.25	0.38	0.37	0.35	0.34	0.49	0.44	0.62
Dosage per day when supplements received	0.063	2.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	0.125	14.0	15.8	11.8	3.0	0.0	0.0	0.0	0.0
	0.250	81.4	73.7	41.2	33.3	22.6	16.7	4.8	6.7
	0.500	0.0	5.3	23.5	33.3	41.9	38.9	28.6	40.0
	1.000	2.3	5.3	23.5	30.3	35.5	44.4	66.7	53.3
Mean		0.25	0.28	0.47	0.56	0.62	0.68	0.82	0.75
SE		0.01	0.03	0.06	0.06	0.05	0.07	0.06	0.07
Average daily amount of flouride ingested from supplements over whole time interval (mgF)	<0.01	3.5	5.3	2.9	3.1	3.2	0.0	0.0	0.0
	0.01-0.051	18.6	15.8	14.7	6.3	25.8	5.6	4.8	13.3
	0.051-0.100	18.6	28.9	14.7	12.5	3.2	16.7	0.0	13.3
	0.101-0.150	14.0	18.4	14.7	15.6	3.2	0.0	4.8	6.7
	0.151-0.200	14.0	5.3	8.8	3.1	6.5	0.0	9.5	0.0
	0.201-0.250	4.7	0.0	2.9	6.3	3.2	0.0	4.8	6.7
	0.251-0.375	25.6	23.7	11.8	12.5	12.9	27.8	14.3	0.0
	0.376-0.500	1.2	0.0	23.5	25.0	19.4	22.2	38.1	46.7
	0.501-1.000	0.0	2.6	5.9	15.6	22.6	27.8	23.8	13.3
Mean		0.14	0.14	0.25	0.34	0.37	0.43	0.48	0.37
SE		0.01	0.03	0.04	0.05	0.06	0.07	0.06	0.07

* among supplement users.

days/week for the first time interval, 1.4 days/week for the second time interval and 2.1 days/week for the third time interval.

Table 5 presents patterns of average daily supplement use over the three intervals among users stratified by combined fluoride level (home, childcare, bottled, and school water sources) using the AUC technique. Approximately 66% to 93% of users were using 0.1 mg or less of fluoride daily in the time intervals birth-12 months and 12-60 months, vs. 42-80% in the 60-96 months time interval. An average of 21% and 12% of the subjects, respectively, were using an average amount of 0.1 to 0.20 mg of fluoride for the intervals birth-12 months and 12-60 months. Average amounts of 0.21- 0.25 mg were used by 1-11% of subjects over the three time intervals. The subjects who had more than 0.25 mg increased from 1% (first interval) to 9% (second interval) to 35% (third interval). The mean, median, standard deviation and maximum values of the average daily fluoride supplement amounts are also in Table 5. Estimated mean (median) daily supplement amount ingested increased from 0.06 (0.04) mg (birth-12 months) to 0.07 (0.02) mg (12-60 months) to 0.18 (0.07) mg (60-96 months), respectively. The mean and median values of average daily fluoride supplement use demonstrate a consistent trend of lower supplement amount per day with higher combined water source of fluoride.

The distribution of average daily supplement amount (mgF) over the three time intervals stratified by the independent demographic variables was explored. The bivariate analyses revealed significant associations for mother's education and race with amount of supplement ingested from birth to 12 months of age. Also mother's education was significantly associated with amount of daily

Table 5
Patterns of the average daily supplement dosage over designated time intervals (mgF) among users stratified by a weighted combination of home, childcare, bottled & school water sources of fluoride level (ppm)†

Time intervals (in months)	Combined water fluoride level (ppm)	Percentage distribution of AUC fluoride supplement use per day supplement use categories (mg F) †				Summary measures of supplements use in mg per day			
		0.01-0.10	0.11-0.20	0.21-0.25	0.25+	Mean	SD	Median	Max.
Birth-12 (n=192)*	<0.3 (n=62)	72.6%	17.7%	8.1%	1.6%	0.08	0.08	0.06	0.43
	0.3-0.6 (n=44)	65.9%	31.8%	2.3%	-	0.06	0.06	0.04	0.21
	>0.6 (n=86)	80.2%	17.4%	1.2%	1.2%	0.05	0.05	0.03	0.26
	Total	74.5%	20.8%	3.6%	1.0%	0.06	0.06	0.04	0.43
12-60 (n=90)**	<0.3 (n=24)	70.8%	16.7%	-	12.2%	0.10	0.15	0.04	0.59
	0.3-0.6 (n=39)	71.8%	12.8%	2.6%	12.8%	0.08	0.11	0.02	0.48
	>0.6 (n=27)	92.6%	7.4%	-	-	0.03	0.04	0.01	0.15
	Total	77.8%	12.2%	1.1%	8.9%	0.07	0.02	0.02	0.59
60-96 (n=26)***									
	<0.3 (n=12)	41.7%	-	8.3%	50.0%	0.28	0.29	0.24	0.98
	0.3-0.6 (n=9)	55.6%	-	11.1%	33.3%	0.14	0.12	0.08	0.3
	>0.6 (n=5)	80.0%	20.0%	-	-	0.03	0.05	0.02	0.13
	Total	53.8%	3.8%	7.7%	34.6%	0.18	0.23	0.07	0.98

* F= 4.5, p value = 0.013

** F= 3.2, p value = 0.045

*** F= 2.6, p value = 0.097

† Dosage determined by AUC for the entire time interval among those using supplements during at least one questionnaire period.

supplement ingested from 12-60 months. No consistent significant associations of average daily fluoride supplement use with other demographic variables, both with and without adjustment for weighted water fluoride level were found. Multiple regression analysis for the average daily supplement amount (mgF) over whole time interval (12-96 months) revealed no significant association of supplemental fluoride with any of the demographic variables.

Discussion

The approach used here is different from other studies that assessed past dietary fluoride supplement use only generally (no specific ages or time periods), or at a single time point. This study assessed supplement use longitudinally, near the times of exposure, thus reducing recall bias.

The sample size at recruitment was large, 1,388 completing the baseline questionnaire and one or more subsequent responses. The number of time periods from birth to 96 months with responses was 15,470 for the whole sample. Of those, fluoride supplements were used only during 1,312 time periods (8.5%). The study sample was not fully representative of any defined population group, and was disproportionately white with high education.

Other limitations include that data were collected by parent self-report without direct validation. There are variable numbers of measurements per individual due to missing data and the measurements are not always collected exactly as scheduled. Since not all children participated for the full duration of the study (8 years), there is the possibility of bias due to the fact that the relationship between fluoride intake and demographic covariates may not be the same for individuals who responded at every survey as for individuals who dropped out or who otherwise had intermittent missing values.

There are no previously published reports of longitudinal patterns of supplement use during early childhood. However, the supplement data covering infancy had been previously published (10). In the earlier report (10), the mean daily fluoride supplement for the interval 1.5-12 months was 0.07 mg fluoride, with 75% having <= 0.10 mg. The previous results are similar to those here for the interval birth to 12 months of age, even though the earlier sample size was smaller and simple weighted averages statistics were used (10).

The proportion of subjects using fluoride supplements were lower than that reported by Pendrys and Morse in Connecticut in 1995 (4). Their retrospective data indicated a gradual decline in the proportion of users with age (21.3% at 12 months to 7.5% at 96 months). In the present study, three general ranges of fluoride supplement use by age were noticed: 11.2% at 12 months, 6.3% to 6.8% at 24-60 months, and 3.6% to 4.7% at 60-96 months. In another retrospective study from Norway (11), 38% of children used fluoride supplements sometime from 0.5 to <4 years of age, and

65% sometime from 6-8 years. Both studies were based on questions answered by parents about fluoride supplement use for the previous 8 years of their children's life, suggesting greater potential for recall bias.

The dosage of fluoride supplement increased with age from being predominantly 0.25 mg for the first two years of life, to 0.25, 0.5, or 0.1 mg for age 3-6 years, to predominantly 0.5 and 1.0 mg for ages 7-8 years. This indicates general compliance of the study sample with the recommended dosages of fluoride supplements (18). The present data reported that 7-23% of the children receiving supplements had water fluoride levels more than 0.6 ppm, which indicates that they were probably receiving supplements inappropriately. These results are generally consistent with those reported by Pendrys and Morse (4).

As mentioned in the introduction, authorities revised fluoride supplement dosage schedule to become smaller doses, to older age groups and to be limited to targeted high risk groups (17-19). When the number of days and average amounts of fluoride ingested from supplements was investigated, the effective average daily fluoride ingestion from supplement (considering all days and not just those when supplements were received) was much less than the currently recommended daily dosages for children 6 months to 3 years, 3-6 years, and 6+ years of age who are without fluoridated water. Most supplement users received much less than 0.25mg, 0.25-0.5mg, and 0.25-0.1mg for the three age intervals. Approximately 59-73% of the subjects received an average daily supplement dosage 0.25 mg fluoride or less in the first three years of life. Also, 72-78% received an average daily supplement dosage 0.5 mg or less in years 4-6, whereas 23% and 13% received an average daily supplement dosage of 0.5-1.0 mg for years 7 and 8, respectively.

While fluoride supplements contributed to the total fluoride intake of those who used them, there are relatively few children who used them. Among users, they generally averaged much less per day than the prescribed dosage. Therefore, fluoride supplements by themselves are likely to play an important role in fluorosis risk for only few individuals, with other sources also very important for many. It is difficult to draw specific conclusions about the appropriateness of the fluoride supplement dosages received due to various changes in dosage schedule recommendations (ADA, 1994) and indications based on caries risk (CDC, 2001). The majority of our sample (62%-70%) at different ages had access to optimally fluoridated home water (above 0.6ppm) vs. 21%-31% with less than 0.3 ppm fluoride and 6%-11% with 0.3-0.6 ppm fluoride, so that only 30%-38% should potentially have been prescribed supplements based on home water fluoride levels. Recently, the U.S. Preventive Services Task Force (2004) recommended supplements for all children without fluoridated water, due in part to inadequate evidence showing caries risk assessment by physicians to be effective. However, our data suggest that supplements were not always prescribed when indicated based on home water fluoride levels. Supplements were meant to be a "substitute" for fluoridated water. However, with substantial compliance issues, it seems unlikely in actual practice that supplements could produce the level of benefit of water fluoridation. Therefore, caution is necessary in recommending extensive Dental Public Health fluoride supplement programs due to the question of benefit versus extensive resources needed for such a program, as well as increased dental fluorosis risk.

We also used AUC analyses with interpolation of several different time points to summarize fluoride intake and describe patterns from supplements over three defined intervals of time. This enhances understanding about the amounts of fluoride supplement ingested over the whole time interval. This will also enhance understanding of the distribution of fluoride supplement users among different dosage categories in the three time intervals.

The regression model used to assess associations of fluoride supplement intake with other demographic covariates did not reveal significant associations. However, there were significant associations for mother's education and from birth to 12 months of age, and mother's education from 12 to 60 months. Results are consistent with Pendrys and Morse's (4) study, where no significant differences in fluoride supplementation with age, sex, education and income were found. However, mother's education was inversely associated with fluoride supplement use in another study (11). The results reveal a substantial individual variation in the actual pattern of supplement use.

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