Community Dental Health (2007) **24,** 75-81
Received 8 June 2004; Accepted 15 November 2005

The cost-effectiveness of adding fluorides to milk-products distributed by the National Food Supplement Programme (PNAC) in rural areas of Chile

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Objective: This paper assesses the cost-effectiveness of a community dental caries prevention programme, targeting pre-school children living in non-fluoridated rural areas of Chile. ***Basic research design:*** The results of a community trial to measure the effects of using fluoridated powdered milk and milk-cereal to prevent dental caries, together with the cost of running the programmeme, were used to determine its cost-effectiveness when compared to the status-quo alternative. In the experimental community, fluoridated milk products were given to approximately 1,000 children aged between six months and six years, using the standard National Complementary Feeding Programme available in Chile. The control group received the milk products only. Dental caries status was recorded at the beginning and end of the programme in both communities using WHO criteria. The costs that would be incurred by such a programme, using a societal perspective, were identified and measured. ***Results***: Children who received fluoridated products had significantly lower mean levels of dental caries than those who had not. This improvement was achieved with a yearly cost of RCH (1999) $1,839.75 per child (1 US$ = RCH (1999) $527.70). On average, this programme resulted in a net societal savings of RCH (1999) $2,695.61 per diseased tooth averted after four years when compared to the control group. ***Conclusions***: While the analysis has inherent limitations as a result of its reliance on a range of assumptions, the findings suggest that there are important health and economic benefits to be gained from the use of fluoridated milk products in non-fluoridated rural communities in Chile.

Key words: Chile, cost-effectiveness, dental caries, milk-fluoridation, prevention programme.

Introduction

In Chile, water fluoridation has been a cornerstone strategy for the prevention and control of dental caries (Ministerio de Salud, 1998a). However, circumstances prevent the benefits of water fluoridation from reaching 100 percent of the population. In particular, populations living in small rural localities, are left with no reliable mechanism of continuous fluoride exposure. This population represents the target group for the implementation of an alternative mechanism of fluoridation of proved effectiveness for the prevention of dental caries. Milk fluoridation has long been recognised as an effective public health intervention and represents an ideal method for children living in communities where water fluoridation or other forms of systemic fluoride are not feasible (Mariño *et al.* 2001).

Economic evaluation is an integral component of the process of decision-making about any preventive programme (Crowley *et al.* 1996). Such an analysis would assist decision makers to determine which dental intervention (or mix of interventions) to use. Cost-effectiveness analysis (CEA) is the form of economic evaluation most commonly adopted by decision makers in the health sector to investigate whether a programme has been efficient in achieving its objective (Drummond *et al.* 1997). Despite this, with the exception of water fluoridation, the use and application of CEA in dentistry remains limited (Burt, 1989). Thus, the empirical evidence from programmes focussing on the economic evaluation of milk fluoridation is sparse. With the exception of one study undertaken in the UK (Calvert & Thomas, 2000), there have been few attempts to assess its cost-effectiveness. Paradoxically, and despite an obvious lack of economic evaluation studies, reports in the literature cite high costs and poor cost-effectiveness as being the main disadvantages of milk-fluoridation as a public health measure.

An economic evaluation of the Chilean milk fluoridation programme would yield data and a model on cost effectiveness of extreme value to agencies in Chile as well as in other countries, which are either implementing or considering implementation of milk fluoridation programmes. This paper aims to estimate the cost-effectiveness, from a societal viewpoint, of adding fluoride to milk products distributed as part of a National Complementary Feeding Programme (PNAC) to prevent dental caries in the primary dentition of children from six months to six years old as compared to a non-intervention (or status-quo) in two rural areas of the 6th Region of Chile with low levels of fluoride in their drinking water.

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Methods

This paper reports on an evaluation based on secondary analysis of outcome data collected as part of a 4-year community trial to test the feasibility and effectiveness of using powdered milk as the vehicle for delivering fluoride to a rural community in Chile (Mariño *et al.* 2001).

Intervention design

In the 1995-1999 milk-fluoridation scheme, two communities from the Chilean 6th region were selected following a matching scheme based on geographic proximity, community size and similarity of the prevalence of dental caries. Codegua, the test community, is an inland municipality, some 100 km to the south of Santiago, the Chilean capital city, with a population of 10,796 in 2002. La Punta, the control community, is located some 10 km north of Codegua. Administratively, La Punta is dependent on the Municipality of San Francisco de Mostazal, where the Community Health Centre (CHC) is located. Despite the difference in distance from the CHC of the two communities, children from both Codegua and La Punta go to the Regional capital (Rancagua) for the majority of their dental treatments.

Milk products and fluoride dosage

In Chile, the National Complementary Feeding Programme (PNAC) is a 50 year-old government programme, under which, every child is entitled to receive, at no charge, two kilos of powdered cow's milk (Purita™) per month, from birth until 2-years-old. Thereafter, until the child reaches six years of age, he/she is entitled to one kilo of a milk derivative (Purita Cereal™) per month. The national coverage of PNAC is about 90% (Ministerio de Salud de Chile, 1998a). Participation in rural communities approaches 100% (Villa *et al.* 1996).

Milk distribution is the responsibility of the nutritionist at the local CHCs. Fluoridated powdered milk and milk-cereal were prepared for distribution in the test community by Loncoleche S.A., a dairy company under contract to the Regional Health Authority, by adding Disodium monofluorophosphate[1] (MFP) to partially evaporated whole milk prior to the final drying process and concurrently with the incorporation of other additives such as vitamins and minerals. The control community (La Punta) consumed the same type of products, but without MFP added.

Following the 1984 dietary fluoride supplementation (American Dietician Association. 1994), the average daily F ingestion from fluoridated milk products was estimated at 0.25 mg F/day among children 0 to 23 months old; 0.5 mg F/day for children 2-3 years old; and 0.75 mg F/day among 3-6 year olds.

Sample

The sample size was determined using Cohen's criteria (Cohen, 1988) to obtain an effect size of five-tenths (0.5) [(raw control group mean - raw test group mean)/standard deviation] at the significance criterion of 0.05, and a power of 0.80. Following these criteria, the minimum sample size was 50 participants in both the control and test groups, for each age group, representing about one quarter of the population in each age group and community.

Convenience samples of children (3 to 6 years) living in Codegua and La Punta were examined from public kindergartens and primary schools. Base-line clinical examinations in the test community were carried out in October 1994 and follow-up examinations were undertaken every consecutive year. The study used repeated cross-sectional samples, consisting of a fresh sample of individuals from each community at each of the examinations (Koepsell *et al.* 1992).

Programme effectiveness

Dental caries experience was assessed using the dmft index. Thus, the primary outcome measure used in this economic evaluation was intervention effectiveness based on the 4-year difference in total dmft between the intervention and control group from baseline to the completion of the trial. Dental status data was collected by two calibrated examiners (SG, RM) using natural light, dental mirrors and sickle probes. Caries diagnostic criteria followed those of the World Health Organization (1997) and the National Institute of Dental Research (1991). Radiographic examination was not performed.

In 1994, as well as in 1999, the levels of inter-examiner reproducibility achieved in the duplicate examinations of 25 children, using kappa coefficient of reliability, were higher than 0.90. Intra-examiner reliability, assessed by the repetition of exams in 25 children, showed kappa statistics higher than 0.90.

Cost analysis.

The estimate of resource use associated with the milk-fluoridation programme for the purposes of the economic evaluation was restricted to those costs likely to vary between study groups, which would not be expected to occur under 'usual' PNAC operating conditions. For example, capital cost and PNAC operating cost and milk product storage were not included in this analysis. Thus, the only operating cost associated with this project was that of buying and adding MFP. This was because the PNAC's costs would have been incurred whether or not F was included in the milk product. This analysis also excluded resource use associated with protocol driven activities.

The cost used in the economic evaluation was a combination of retrospective analysis of resource use associated with implementing and operating the milk-fluoridation intervention and an estimate of the difference in dental treatment costs associated with the differential oral health outcomes between the intervention and control groups over the four-years of the scheme. Judgements on which cost categories to include were made by the research team in consultation with the oral health programme of the National Board of Students Assistance and Scholarships [Junta Nacional de Auxilio Escolar y Becas (JUNAEB)]. JUNAEB, at the time of this analysis was running a milk-fluoridation programmeme in rural public schools from the IX Region of the country (Weitz and Villa, 2004).

The cost of treatment for both study groups was estimated by multiplying the annual incremental change (which occurred throughout the four-years) in the individual component of the dmft index by the average charge for each procedure based on the Ministry of Health fee 1999. These fees tend to be lower than other dental fee schemes in Chile. However, the majority of people in small rural areas have no access to dental care other than from public clinics. Under this scheme, there are no out-of-pocket expenses for dental treatments, as those costs are financed by the central government, which pays providers a fee for services.

To calculate family resources used in dental treatments (i.e., transport and productivity losses), we assumed that the duration of a dental visit was 1.5 hours and that one trip was necessary for each treatment. This time included public transportation time to and from the CHC and the dental treatment. Work productivity losses were calculated for the adult accompanying the child by multiplying the number of dental visits required for each group by the minimum hourly salary in 1999. Time loss for children was not calculated. Transportation costs were calculated for the accompanying adult by multiplying the number of trips by the number of dental visits required for each group.

Total costs for the control group were those associated with dental care only. Total costs in the intervention group included the cost of dental care of the children in this group plus the resource expenditures associated with the milk-fluoridation operation. These included: the salary of the programme field coordinator; the difference in cost of 1 kg fluoridated Purita-cereal given to children aged 3-6 years every month; office rental, office furniture and overhead costs, such as electricity, rent, shared space costs, etc, were estimated based on the usual cost for office rental in Codegua, and cost of power, telephone, cleaning and others services were also based on those for the region.

In addition, Ministry of Health epidemiologic surveillance guidelines for community fluoridation protocols determine that a dental examination should be conducted once every five years (Ministerio de Salud, 1998b) and the urine excretion monitoring should be undertaken. The Chilean National Guidelines for sampling establishes that 20 samples should be taken every 6 months (Instituto Nacional de Normalización, 1994).

When necessary, the consumer price index (CPI) was used to index all cost from April 1995 to April 1999, when the milk-fluoridation finished. Therefore, all costs and savings referred to in this paper are calculated at the level of 1999 Chilean pesos (RCH$) (1 US$ = RCH (1999) $ 527.70).

Form of economic evaluation.

The form of economic evaluation used in this study was Cost-effectiveness Analysis (CEA). In CEA, costs (or inputs) of alternative programmes were measured as economic costs and outcomes were valued in units of effectiveness (dmft) (Drummond, et al, 1997). The comparator was the intervention groups (milk-fluoridation) and the control (or 'status-quo') group. It was considered that comparing costs and benefits with other vehicles of fluoride was less important than comparing with the status-quo for policy developing purposes. Under Chilean conditions, small, rural localities, such as the one considered in this study would not be expected to adopt water fluoridation.

To estimate the incremental cost-effectiveness ratio, the study assumed that on average 1,000 children 3-6 years of age were in the scheme in Codegua programme and another 1,000 children in La Punta. To provide an estimate of the programme's effectiveness, these results were assumed to be applicable for the whole 3-6 year-old population in both communities. CEA was performed as a primary analysis with the following assumptions:

a) that increases in the decayed and missing components of the dmft occurred at the same rate in each year of the study
b) that the treatment costs associated with increases in the decayed and missing components of the dmft score occurred in the year of the increment
c) that the field coordinator's duties could be carried out with a 0.10 full time equivalent appointment
d) Year 2, Year 3 and Year 4 costs were discounted to their present value using an annual discount rate of 3% (Drummond & Jefferson, 1996). Outcomes were not discounted
e) children in both the intervention and control communities were assumed to incur the same mean dmft increment for which data was available
f) that the benefits accrued to age six years, the age at which PNAC ceases
g) all decayed teeth will always receive a one-surface restoration. This is because in the public sector fee scheme there is no difference by number of tooth surfaces affected
h) one dental session is necessary to fill a decayed tooth, and
i) no need to replace deciduous teeth restorations

Sensitivity analysis

A one-way sensitivity analysis was undertaken to test the robustness of the results to estimated parameter values (Drummond *et al.* 1997). Parameters were varied one a time. For the sensitivity analysis the following assumptions included in the primary analysis were varied:

a) dmft outcome at the high and low boundaries of the 95% confidence limits,
b) social discounting varied from 0% and 5%, and
c) paying a coordinator 0.05 and 0.15 FTE for a full period.

Results

The outcome after four years indicates that children aged 3-6-years from Codegua (the test community) who had access to milk fluoridation during the eruption of their deciduous teeth showed a decline in dental caries experience from 4.83 in 1994 to 2.08 in 1999, a reduction of 57% (Mariño *et al.* 2001). In contrast, among children living in La Punta, the non-fluoridated community, the mean dmft index was 3.49 in 1999 and did not vary significantly from baseline (3.53; p=0.90) (Data collected in 1997 were considered baseline data for this locality). The difference of 1.41 dmft in 1999 between the two communities was statistically significant (p<0.01). Table 1 summarises the 1999 dental data for deciduous teeth.

A summary of the estimated cost of operating the milk-fluoridation programme for 1,000 (i.e., 250 for each age cohort) children in Codegua is presented in Table 2. A total value of 1999 RCH$ 7,358,292 was estimated for the four-year programme. This estimate is equivalent to approximately RCH$ 1,839.75 per annum per child.

The estimated cost of dental treatment over the four years for the intervention and control groups, using a discount rate of 3%, is shown in Table 3. Costs were about 70% higher in the control group (RCH$ 28,351,391 or RCH$ 7,087.85 per child per annum) compared with the intervention group (RCH$ 16,709,620 or RCH$ 4,177.40 per child per annum).

Table 1. Effectiveness of the milk-fluoridation programme as measured by the decayed, missing and filled tooth index (dmft) and standard deviations in children 3 to 6 year-old living in Codegua and La Punta at the end of the programme (1999) and increment in 1999.

	1999		
	Codegua	*La Punta*	*Increment*
Decayed teeth	1.91 (2.75)	3.26 (3.26)	1.35
Missing teeth	0.06 (0.30)	0.03 (0.14)	- 0.03
Filled teeth	0.11 (0.56)	0.20 (0.87)	0.09
Decayed, missing and filled teeth	2.08 (2.85) (95% CI=1.72-2.44)	3.49 (3.42) (95% CI=3.02-3.96)	1.41 (95% CI=1.34-1.48)

Table 2. Summary of total programme costs over four-years associated with the milk-fluoridation programme.

Cost category	*Amount (RCH$1999)*	*% of Total*
Salaries		
Programme co-ordinator (Part time 0.10 Full time equivalent)[a]	1,398,746	19.03
Dentist examiner (6 weeks @RCH$ 488,710 FTE per month)[b]	676,675	9.21
Dental assistant (6 weeks @RCH$ 156,034 FTE per month)[b]	216,047	2.94
Data analysis (40 hrs. @RCH$ 4,040 per hour)[c]	161,600	2.20
Laboratory services:		
Urine excretion analysis (50 samples)[d]	200,000	2.72
Milk analysis (80 samples)[e]	463,458	6.31
Consumables		
Programme co-ordinator office rent[f]	834,225	11.35
Programme co-ordinator office expenses[g]	210,000	2.86
Dental instruments[h]	356,700	4.85
Examination expenses[i]	91,981	1.25
Programme consumables[j]	2,497,819	33.99
Overheads	251,041	3.29
Programme co-ordinator office's services[k]		
Total	7,358,292 (US $ 13,944.08)	100.00

[a] Programme co-ordinator wages were based on oral health programme of JUNAEB; RCH$ 301,807 FTE per month

[b] Dentist, chair side dental assistant salaries were based on the public sector monthly wage.

[c] Standard cost charged by the Institute of Nutrition and Food Technology, University of Chile.

[d] Epidemiologic surveillance based on Ministry of Health guidelines for community fluoridation protocols. Standard cost charged by the Institute of Nutrition and Food Technology, University of Chile: RCH$(1999) 4,000 per sample of urinary analysis.

[e] Standard norms for sampling applied in Chile indicate that 20 samples of year of fluoridated milk would be acceptable (Instituto Nacional de Normalización, 1994). Cost charged by the Institute of Nutrition and Food Technology, University of Chile per sample milk analysis RCH $(1999) 6,000.

[f] Renting of office space calculated under standard commercial rates at a 10% use time.

[g] Includes furniture, computers, etc. at a 10% use time.

[h] Includes 100 dental mirrors and probes.

[i] Includes gloves, masks, paper towel, and other disposable equipment and materials.

[j] Difference in cost of 1 kg fluoridated Purita-cereal given to children aged 3-6 years every month in the test community. RCH$57.00 per kilo.

[k] Includes power, phone, post, stationary and other expenses associated with the programme.

Table 3. Summary of costs of dental treatments in the intervention and control communities after four-years of programme.

Treatment item	*Total test community (RCH $)[d]*	*Total control community (RCH $)[d]*
Restorations[a]	12,491,536.08	20,796,577.28
Extractions[a]	96,438.42	46,867.25
Cost travel to CHC[b]	1,653,004.70	2,695,787.33
Cost of productivity losses [c]	2,950,610.58	4,812,159.72
Total costs	17,191,589.78	28,351,391.58

[a] The cost of restorations was based on public sector's fees. RCH$ 6,225 per restoration. Extractions are based on the cost of simple procedures. RCH$ 1,618 per extraction. Both procedures include the costs of the dental examinations.

[b] Cost estimates for child and parent travel. RCH$ 800 per trip.

[c] Calculated at the value of minimum monthly salary in 1999 (RCH$ 110,000). Cost of time in travelling plus treatment time. RCH $952 per hour.

[d] Cost estimates calculated by multiplying dmft component increment by average 1999 dental charges.

Table 4. Total costs, total benefits and cost-effectiveness ratio for the overall milk-fluoridation programme.

A	Total cost test community	24,550,583.00
B	Total cost control community	28,351,391.00
C	Net cost (or saving)	(3,800,808)
D	Incremental benefits (dmft avoided)	1,410
E	Incremental cost (or savings) RCH(1999) per dmft avoided	(2,695.61)

[a] The cost in the intervention community is the sum of the cost of the programme, table 2, plus the overall treatment cost table 3.

[b] The cost in the control community is the cost treatment from table 3.

[c] the incremental benefits are estimated multiplying the annual dmft difference in increment between the test and the control community (from table 1) by the 1000 population.

Combining the costs of the operation of the preventive programme with dental treatment costs and comparing them with the costs in the control group resulted in an overall net saving of RCH$(1999) 3,800,808 (or RCH$ 3,800.81 per child) [i.e. (RCH$ 28,351,391 - RCH$ 24,550,583/1000)] attributable to the preventive programme over the four year study period. Thus, a public investment of RCH$ 1,839.75 per annum per child resulted in an approximate RCH$ 673.90 reduction in dental treatment costs per child per annum [i.e. (RCH$ 28,351,391 - RCH$ 24,550,583/1000/4)].

Table 4 (Row E) summarises the incremental cost-effectiveness ratio for the intervention group compared to the control group for the overall programme. The overall ratio was estimated to be saving RCH$ 2,695.61 per dmft [i.e. (RCH$ 28,351,391 - RCH$ 24,550,583)/1,410 = 2,695.61]. Thus, an investment of RCH$ 1,839.75 per annum per child resulted in a net saving of RCH$ 2,695.61per dmft prevented not only a reduction in disease but a net saving to the community.

Sensitivity analysis resulted in incremental cost–effectiveness ratio ranging from a net saving of RCH$ 5,006.26 to a net cost of RCH $ 3,822.57 per dmft avoided. This range of variability of the cost-effectiveness ratio was produced by uncertainties of the effectiveness of the milk-fluoridation scheme. The most favourable result was gained by using the lower boundary of the effectiveness assumption, that is, using the lower extreme in the test community and the upper boundary in the control community. Conversely, the least favourable result was found using the lower extreme in the control community and the higher boundary in the test community.

The analysis was also sensitive to assumptions with regard to the cost of field coordinators. For example, reducing the employment basis of a coordinator in our model programme would substantially decrease the cost per dmft averted and further increase the estimated savings.

Discussion

Our primary analysis estimated that if a dental caries prevention programme using milk products from the PNAC was available for 1,000 children from 3-6 years, the net saving from a societal perspective would total RCH$ 2,695.61 per dmft avoided over 4 years when compared to the control (or status-quo) group. These societal savings would be achieved at an annual cost of RCH$ 1,839.75 per child. On average, this programme would result in a return to society in dental treatment costs of RCH$ 673.90 per child per annum.

The cost-effectiveness ratio of the programme remained positive even with more stringent and pessimistic assumptions than those projected for a typical case. The exception was the assumption on the effectiveness of the milk-fluoridation scheme. However, in this study we were working with real communities with a sample size that represented about one quarter of the total population in each age group in each community. Thus, it is argued that results on the mean dental caries experience of these children reflect the real pattern of dental caries in those communities. In addition, the design of the study reflects the usual practice setting of an on-going milk-fluoridation programme. No attempt was made in the test community to interfere in the normal operation of the PNAC programme. This is particularly important, because in a fluoridated PNAC, or PNAC equivalent, there are minimal operating costs associated with a milk-fluoridation programme beyond the cost of MFP, the programme coordinator and those associated with epidemiological surveillance of any dental caries prevention programme.

The cost-effectiveness ratios presented in this analysis can be considered conservative estimates. For example, only the cost of the initial treatment was considered. However, it is not unusual that dental restorative work has to be replaced. Additional costs due to potentially costlier treatments were also not considered (e.g., cost of space retainers, necessary after an early extraction of deciduous teeth, or pulpal therapies). More importantly, all restorations were considered as single fillings. This was because under the Chilean public health fee schedule, the cost of a restoration is independent of the number of tooth surfaces involved and the complexity of treatment. This, and the fee schedule used in this evaluation, would have resulted in an underestimation of the averted cost in dental treatments.

Additionally, other non-dental benefits associated with reduction in dental caries and improvements of tooth survival were not included in this analysis (Drummond *et al.* 1997). For example, improvement in quality of life associated with the reduction of dental caries, and discomfort associated with dental treatments (Crowley *et al.* 1996). Also, the positive effects in the permanent dentition of a healthy primary dentition were not been included in the analysis. Had these non-monetary benefits been included, the analysis of the impact would have been even more positive.

On the other hand, the study assumed that the decay component of the dmft index was restored in the year of the increment. There is no guarantee that the necessary treatment will be undertaken. Interestingly, the test community had higher costs of dental extractions than the control community (0.06 teeth vs. 0.03 teeth, respectively). The difference, while marginal compared to the total cost of treatment and statistically non-significant ($p=0.10$), is difficult to explain.

The current study is only the first step in determining whether or not a specific oral health care programme is an efficient use of resources. Although appropriate data sources were available for the majority of assumptions required by the analysis, follow-up studies are required to define some characteristics more precisely to avoid assumptions. Thus, future studies need to be done under more generalizable conditions and it would also be appropriate to prospectively collect information regarding actual treatment costs along with those of the intervention, reducing the need for sensitivity analyses (Drummond *et al.* 1997).

This study is one of few economic evaluations of any oral health prevention programme in Chile, highlighting the need for further economic evaluation studies that systematically evaluate the costs and consequences of alternative means of achieving improvements in the community's oral health, such as water fluoridation and publicly-funded dental health care programmes. The setting and treatment provided in those studies would reflect usual Chilean practices.

Preventive measures and treatment services are extremely limited for rural areas. The data presented here provide additional evidence to make informed decisions about alternative vehicles for fluoride and the overall value of milk-fluoridation in areas where other mechanisms of community fluoridation are not possible or available.

Findings suggest that milk-fluoridation is effective in reducing dental disease and appeared to dominate the alternative, leading to a reduction (that is savings) in total costs. Thus, for situations equivalent to those in Chile, implementation of a milk-fluoridation programme would save valuable community resources as well as generate the best possible dental health outcome in the primary dentition of rural pre-school children without additional burden to an existing distribution programme of milk and milk derivates. Expansion of milk-fluoridation programmes targeted to these groups has the potential to provide an effective strategy for improving the oral health of these groups in a manner consistent with the policies and strategies recommended by the Chilean Ministry of Health (Ministerio de Salud, 2002).

Acknowledgments

This study was funded by a grant received from the Borrow Foundation. The authors would like to acknowledge the support and co-operation received from the Regional Health Service (6th Region), and Dr Olaya Fernández Chief Dental Officer, Ministry of Health, Chile. In particular, we would like to acknowledge the Community Health Center and the Municipality of Codegua, the staff of the day care centres and schools involved in this project for their assistance during the collection of the data. We are also indebted to the educational authorities of the Municipalities of Codegua and San Francisco de Mostazal.

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