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Compliance with school F-milk and non-F milk intake in 3 to 4 and 6 to 7 year old children

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Background: Fluoridated (F) milk schemes are employed in six countries to reduce dental caries in children. To maximise their benefits considerable uptake is required. Measuring compliance and understanding contributing factors is important in evaluating the effectiveness of schemes since it can be unclear whether reported sub-optimal fluoride (F) intakes, measured through urinary F excretion, are due to sub-optimal F contents of milks or lack of compliance with consumption. ***Objectives:*** To determine compliance with milk consumption for children receiving non-F or F milk (containing 0.5 or 0.9mgF per 189ml carton) and rationalise the use of compliance data for clinical observational or intervention studies involving F milk schemes. ***Research design:*** Partially randomised, partial cross-over study. ***Participants:*** 50 children aged 3-4 and 6-7y consuming non-F (n=50) and F milk (0.5mgF; n=15 children; 0.9mg F; n=16 children) at school. ***Results:*** Mean compliance for both non-F and F milk was ≥90% in each of the groups studied and showed no statistically significant difference for children using both milks. The 95% central range of proportions of milk consumed for groups of individuals was wider for 0.9mgF milk (25% to 100%) than for 0.5mgF milk (81% to 100%) although the greatest range of variation in compliance for within individual observations was seen for non-F milk consumption and in older children. ***Conclusion:*** Assessment of compliance with consumption should be included when dental efficacy of F milk consumption is being investigated or evaluated to quantify F exposure from milk. This is important, particularly if a change in the F dose of F milk might be under consideration.

Key words: *fluoridation, milk, child, preschool, schools*

Introduction

Milk has been recommended for all age groups as a nutritious food to achieve optimum growth, development and health (World Health Organization (WHO) 2003; WHO and UNICEF 2007). The consumption of milk has increased from 74 kg/person/year in 1964-66 to 78 kg/person/year in 1997-99 and is predicted to rise to 90 kg/person/year by 2030 (WHO, 2003). Free milk was provided to school children in the UK between 1944 and 1971 under the provisions of the School Milk Act in 1946 (Her Majesty's Government 1998). Currently free school milk is provided for children under five years of age, while for children over 5 years it is currently subsidised by the European Union through the School Milk Scheme, with any difference in cost often being met by the parents of participating children. However, the payment process is quite complicated and varies between local authorities. Provision of free school milk was included in a list of nine evidence-based public health interventions recommended to reduce inequalities in health by the NHS Centre for Reviews and Dissemination (Smith *et al*., 1997).

The use of milk as a vehicle for automatic population-directed administration of fluoride (F) for caries prevention began in Switzerland in the 1950s; the first community scheme was introduced in Bulgaria in 1988 (Pakhomov *et al*., 1995). The first trial of school milk as a vehicle for systemic F in the UK was reported in Scotland in 1984 (Stephen *et al* 1984) following a 5 year double-blind study in four state primary schools. Coverage of F milk schemes had expanded to four local authority districts by 2000 (Woodward *et al*., 2001) and by 2005, F milk schemes included more than 40,000 children aged between 3 and 11 years (Riley *et al*., 2005; WHO 2009).

The WHO's (1999) guidelines for implementation and monitoring of F milk programmes recommends that total F exposure is routinely monitored through measurement of renal F excretion.

School milk schemes can improve child nutrition and F milk schemes can improve dental health (Banoczy *et al*., 1985; Marino *et al*., 2001), but for their benefits to be far reaching they require maximum uptake by participants. Previous reports have highlighted a number of issues surrounding school milk quality which may affect the perception of milk offered in schools and hence the uptake by children (Foster *et al*., 2011; Woodward *et al*., 2001). Factors affecting milk quality, including microbial quality and milk temperature are of particular importance. Quality issues surrounding the delivery of school milk schemes have been assessed in participating schools in Manchester, UK, (Duxbury *et al*., 2005) through an audit of the accuracy of delivery and milk freshness, as well as quality of packaging and temperature of milks on delivery and at consumption. The audit process proved to be a

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useful tool to identify any shortcomings in the delivery of a successful scheme and highlight those which were easily remedied compared with those requiring multi-stakeholder action.

Monitoring compliance with milk consumption can facilitate the evaluation of schemes. For fluoridated milk schemes, compliance data may explain the outcome of observational and intervention studies since uptake of milk from school milk schemes and compliance may differ considerably. At present there are only limited data explicitly demonstrating compliance with milk consumption for children participating in school F milk schemes (Foster *et al*., 2011).

The aims of the present work were to determine the compliance with milk consumption for children receiving non-fluoridated or fluoridated milk (containing 0.5 or 0.9mg F per carton). In addition, an attempt has been made to rationalise the use of compliance data in future observational or intervention studies, in particular those assessing F exposure through fluoridated milk schemes.

Materials and Methods

Data reported were recorded as part of a larger F intake and excretion study amongst school children aged 3-4 years and 6-7 years consuming either 0.5mg or 0.9mg F added to 189ml semi-skimmed (1.8% fat) milk each school day during the study, reported elsewhere. Ethical approval was obtained from the County Durham and Tees Valley Research Ethics Committee. Children were recruited through schools and contacted via their head teachers and parents. The study took place in a deprived area of County Durham in north-east England between October 2009 and January 2010. Recruitment was through an invitation letter to the parents of children attending schools in this area which had agreed to take part. Informed written consent was provided by the parents for children's participation.

In the first phase of this study (baseline), non-fluoridated pasteurised semi-skimmed (1.8% fat) milk consumed at school was monitored over four consecutive days for all children. Fluoridated semi-skimmed milk was then provided for a subset of the children taking part and attending schools in areas where the water supply was not fluoridated. Prior to milk distribution, the thirty-two 6-7 year olds taking part in the fluoridated milk arm were randomised into two groups by the study statistician. Children in this arm received milk containing either 0.5mg or 0.9mg F per carton during four days of the second phase of the study.

Semi-skimmed milk (in 200ml or 189ml cartons depending on the source dairy) was provided via local dairies delivering to schools directly. Milk containing 0.5mg F in 189ml cartons was obtained from a commercial dairy which routinely produces F milk in cartons for F milk schemes in north-west England. Milk containing 0.9mg F per 189ml was produced in collaboration with a dairy production facility at a higher education institution and distributed in white plastic containers with sealed foil lids. The milk containing 0.5mg F was delivered by chilled courier to schools on either the day before or the first day of milk monitoring. All F milk was refrigerated immediately on delivery and labelled for distribution to children by researchers. The 0.9mg F-containing milk, similarly labelled, was delivered to schools by chilled courier on the first day of milk monitoring.

Researchers attended participating schools before the school's milk break to observe and monitor the F milk provision. Each school followed its usual system for provision and distribution of F or non-F milk to children, which usually took place in a classroom just after morning break with the children sitting down quietly together. The cartons, which had been labelled with the subject's reference code, were collected after the children had consumed as much or as little of the milk as was their usual habit. Some children drank the milk with a piece of fruit provided at the same time but usually it was consumed on its own through a straw. Any milk remaining in a carton was measured to the nearest ml using a plastic measuring cylinder (Kartell, Italy) and, by subtraction, the milk consumption by the child was recorded. When one of the four consecutive milk collection days fell on a weekend, the milk carton was collected by the child's parent from school for consumption at home with any remaining milk or empty milk cartons collected from the child's home by study researchers. If it was not practicable for a researcher to be present at school during the milk break, any left-over milk and empty cartons were stored in a fridge by the class teacher until collected by a researcher later that day.

The daily amount of milk consumed was recorded. Compliance with fluoridated milk consumption was calculated as the percentage of the milk provided, which was consumed, with a Coefficient of Variation (%) used to describe the individual variation in daily compliance with milk consumption over each four-day study period. In the event of a child's absence from school or no milk being available, these data were not included in the calculation of average consumption for a child. One-way ANOVA was used to compare consumption of milk across study groups and age ranges. Paired t-tests were carried out to determine any changes in milk consumption for children receiving both non-fluoridated and fluoridated milk. Data analysis was carried out using SPSS Statistics v17.0.

Results

Fifteen children were allocated to the 0.5mg F group and 17 to the 0.9mg F group. One of the latter dropped out of the study following the first round of (non-F) milk monitoring; therefore data for the second phase were not collected for that child.

A total of 311 observations for milk consumption out of a possible 324 were made. Just 13 observations (4%) could not be made due to a child's absence from school during the milk break or a lack of milk available due to supply reasons. Twelve of these missed observations were during the first (non-F milk) phase and 1 was during the F milk monitoring phase.

Observed mean compliance with school-milk intake for all children was generally very high (Table 1). Compliance with milk consumption did not differ significantly between the 3-4 year olds and 6-7 year olds. For the 31 children drinking both non-F and F milks, the mean (95% CI) change in compliance from non-F to F milk

Table 1. Intake of semi-skimmed milk (F or non-F) for children aged 3-4 and 6-7 years receiving non-F milk only (n=18) and both Non-F and F milk (n=32).

					Compliance (%)			Daily individual variation in compliance
Group	*No. of children*	*No. of observations*	*Type of Milk*	*Week number*	*Mean (sd)**	*Median*	*(95% Central Range)**	*95% Central Range*
a) Control group: children receiving only non-F milk								
Age 3-4y	5	20	Non-F	1	99 (4)	100	88-100	0-7
Age 6-7y	13	47	Non-F	1	92 (19)	100	30-100	0-45
b) Study group: children receiving non-F and F milk								
Age 6-7y	15	57	Non-F	1	96 (10)	100	65-100	0-45
	15	59	F (0.5mg)	2	96 (10)	100	81-100	0-28
Age 6-7y	17	64	Non-F	1	96 (14)	100	62-100	0-44
	16	64	F (0.9mg)	2	95 (19)	100	25-100	0-20

* calculated based on the number of observations made.

Table 2. Mean and 95% Confidence Interval for differences in compliance between non-F and F milk consumption.

Group according to the F content of F milk	*n*	*Differences (non-F milk vs F milk) in compliance (%)*		
		Mean	*95% Confidence Interval*	*p value*
0.5mg	15	-2.1	-8.7, +4.4	0.50
0.9mg	16	+1.0	-4.9, +7.0	0.72
All	31	-0.5	-4.7, +3.7	0.81

use was -2.1% (-8.7, +4.4) for 0.5mgF milk and +1.0% (-4.9, +7.0) for the 0.9mgF milk ($p>0.05$)(Table 2). For these children, the 95% central range of proportions of milk consumed was widest when 0.9mgF milk was provided (62% to 100% for non-F milk; 25% to 100% for 0.9mgF milk; 81% to 100% for 0.5mgF milk) although the median proportions of milk consumed were similar (100%) (Table 1).

Although the 95% central range for the variation in compliance within observations made for individuals was greatest for non-F milk consumption (0, 45%) and lowest in the younger children drinking non-F milk (0, 7%) (Table 1), the daily variation in compliance was lower for F milk consumption for individuals using both types of milk (F and non-F).

Discussion

Previous studies have included assessment of the uptake of milk schemes by children and resulted in recommendations to ensure this is maximised (Duxbury *et al*., 2005; Foster *et al.,* 2011, Woodward *et al*., 2001). In order for the reported benefits of milk consumption to have the greatest impact, a high level of compliance with consumption by those participating is required. Ensuring this may be challenging, especially when uptake by children is high. With age, children develop their own personality and therefore ensuring their compliance with food and drink regimes imposed by others may be an added challenge (Waisbren, 1999). Information on food and drink compliance is important for evaluating any dietary-related intervention, such as F milk schemes, for quality assurance in production, distribution and delivery of milks to schools as well as in influencing the logistics of milk supply/distribution including portion size and serving methods.

This study took place in an area of north east England where the overall health of the population is poor and health inequalities remain persistent and pervasive (Durham County Council and NHS County Durham, 2010). Dental caries has been a long-standing and significant health issue for the children of the area (Beal and Pepper, 2002; Landes *et al.*, 2001). A school-based F milk scheme was proposed to address this problem and it was originally targeted at those schools in which more than two-thirds of 5-year-olds had caries experience, plus their feeder nurseries and pre-schools. The programme was introduced and rolled out in 2004, initially providing whole milk, however, when the School Food Trust (Department of Food, Education and Science, 2006) guidelines recommended that children over 5 years of age should receive semi-skimmed milk or skimmed milk at school, the programme switched to semi-skimmed F milk (Whiston, 2008).

In the UK, the effectiveness of F milk in preventing dental caries has been termed "moderate". It has been postulated that this may be due to sub-optimal levels of F in F milk or due to non-compliance with F milk consumption. When the Sheffield Fluoridated Milk Scheme, implemented in 2001, was reviewed and evaluated through a project commissioned by the local Director of Dental Public Health, focus group work undertaken with parents highlighted that some children refused to drink the milk due to its taste (Gibson and Shah, 2001). The report concluded that the success of a scheme is dependent on whether children drink the milk. Compliance with milk consumption in the present study was generally high and this was, in no doubt, due to its high profile in the schools involved although Foster *et al*., (2011) estimated a similar high compliance of 87.8% with F milk consumption in their sample of 5y olds in 15 schools. No statistically significant differences in mean compliance were found between F- and non-F milk consumption, but there was a wider range in compliance with 0.9 mgF milk consumption based on observations compared with 0.5mgF- and non-F milk, although the variation in compliance within individuals was lower for F milk consumption. The wider range between individuals may have been due to a number of reasons. The F milk was provided in packaging unfamiliar to some of the children which may have reduced the usual compliance of more cautious individuals, while attracting others. Non-F and F milks were commonly provided as tetra-packs (0.5mgF per carton and non-F) or small plastic bottles (non-F milk only), while the 0.9mgF milk was provided in white plastic cups sealed with a foil lid. Milk for participating children was stored in school fridges ensuring its distribution to children at chilled temperatures, but information on habitual milk temperatures and conditions on delivery to schools was not recorded in the present study. The participating schools frequently commented on previous experiences of disappointment with the quality of milks delivered and problems encountered with ensuring a consistent and plentiful supply of suitably packaged milk.

Milk is an important source of nutrients for children and F milk offers the added dental health benefits of caries reduction through F supplementation. It is important to be able to quantify the dose-response effect from the use of F milk as well as its contribution to total F exposure. In this regard the topical effect of F milk, which relates primarily to its F concentration and frequency of use, is an important consideration alongside the systemic effect of F milk. The daily F dose (volume of milk consumed x F concentration) in F milk provided to children, in addition to the number of days of use, are key factors which could influence its effectiveness with regard to oral health (WHO, 2009). The interplay between the topical and systemic effects of F milk remain unclear although studies which have demonstrated that fluoride ingested with milk is excreted through the salivary glands indicate that F bioavailability in F milk equals that of other F vehicles (Twetman *et al*., 1998).

The monitoring of F intake from F milk has not previously been routinely reported in many investigations despite being a key factor for efficacy. This may be because compliance has been recorded but not reported, not recorded, or has been assumed to be sufficient. Where compliance is observed and monitored by study researchers but not recorded this may have little relevance to the reported outcome. However, the results of studies which have reported the health effects of F milk schemes or those which have assumed compliance with F milk consumption may be confounded by this lack of information. A urinary F excretion study carried out by Ketley and colleagues (2002) in Knowsley, UK and Cork, Ireland, suggested that total F exposure by children provided with F milk at school, measured through urinary excretion, may not have been optimal. However, no data were reported to indicate whether this might have been due to lack of compliance with milk consumption. The milk schemes audit by Duxbury and colleagues (2005) highlighted how shortfalls in milk delivery can affect the distribution and availability of F milk. To ensure continuous and optimal uptake of school milks by children, their quality and distribution should be routinely assessed. The Manchester audit reported problems faced by many schools including incorrect deliveries, leaking cartons and sub-optimal temperatures of milks on delivery. In particular, the temperature at which milk is served may influence acceptability and should not be overlooked (Woodward *et al*., 2001).

In conclusion, compliance with milk consumption for both non-F and F milk was high at >90% in each of the groups studied. To enable quantification of F exposure from milk, assessment of compliance with F milk consumption should be included when the dental efficacy of F milk consumption in UK school milk schemes is being investigated or evaluated, particularly if a change in the F dose of F milk might be under consideration.

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Letter to Editor CDH June 2012

BASCD members who read the BDJ of 10th March will be aware that the Association has written to the Secretary of State for Health reflecting the concerns of the wider public health community about the impact of the Health & Social Care Act on the NHS and it's implications for health improvement and inequalities. The same issue carried an Editorial by Paul Batchelor, a past president of BASCD, setting out these concerns in more detail and describing a future NHS that may resemble the system in the USA, with all its costs and shortcomings.

Those readers who have experienced previous English NHS re-organisations may see the latest one as the final step in a sequence aimed at creating a real market for health services in England, with a supporting bureaucracy that includes procurement, commissioning, contracting and performance management. Much of the increased cost of the NHS in recent years could be explained by the creation of this chain of processes.

My reason for writing is to point out a significant omission from our BASCD letter and the BDJ editorial, which is that the Act has much to commend it from a dental point of view. The irony is that the Act goes a long way to remedying the problems of a dental market, especially since the 2006 GDS contract but condemning the NHS to a similar learning process.

Dental Services have always operated in a real market, albeit with one major purchaser. Dental practices are all private businesses and we have seen the emergence of national dental companies with significant market share. The lessons learnt from the 2006 contract were set out in the Steele report and the Department of Health (DH) has done a great deal to address these problems and create the conditions where dentists can work within a public health approach to dental disease. It has the potential to create a better future for dental services by a single, consistent commissioning model, an emphasis on oral health outcomes and the opportunity for GDPs to practice prevention in practice, without the perverse incentives of the current (2006) contract. We have learnt the lessons of a private market in dental services and the 'commodification' of treatment and dental access with a heavy emphasis on activity and intervention where clinical decisions are influenced by the reward system.

The wider NHS can learn a great deal from the dental services' experiences of a real market. However they seem likely to go through the same learning process whilst we are moving back from 'marketisation' where dental treatment, oral health and previously registration, became commodities, often in short supply.

The last time BASCD expressed serious concerns about DH policy on dental services was in 2005, with a reversal of direction and the introduction of Units of Dental Activity (UDAs) as the contract currency. BASCD wrote to the Minister at the time setting out their concerns about the effects of the new contract on access to services, oral health and the lost opportunity to move to a preventive approach. The outcome was an agreement to work together. 'Delivering Better Oral Health' was the result and it has become a major component of preventive practice.

I hope that once again BASCD will be able to work with the Dental Division of the Department of Health on developing the preventive potential of a new dental contract.

John Green
BASCD President 2005-2006