How much is a 'pea-sized amount'? A study of dentifrice dosing by parents in three countries

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To provide optimal fluoride effectiveness against caries while minimising risk of negative effects from excessive ingestion from toothbrushing, the fluoride dose delivered at each occasion is critical. This is particularly important for young children, so using a 'pea-sized amount' is generally recommended. However, there appears little guidance regarding what this means in practice, although it has been indicated to be 0.25 g. This study investigated, using conventional toothpastes and toothbrushes in Germany, the USA and the UK, how much toothpaste parents dispense for their 3- to 6 year-old children, and their interpretation of a 'pea-sized' amount of toothpaste. When asked to dispense the amount they would normally for their child, the majority of parents dosed substantially more than 0.25 g; in Germany, all parents over-dispensed. The amount dispensed varied widely: those parents at the 75th centile dispense a pea-sized amount, the mean amount dosed decreased significantly in all countries. In the USA, electric toothbrush users dispensed about 0.1 g more than manual toothbrush users. While over-dispensing of fluoride toothpaste remains a cause for concern, it may be argued that the general recommendation to use a pea-sized amount of toothpaste generally works well in practice to balance the conflicting demands of risk and benefit from toothbrushing with fluoride toothpaste in young children.

Key words: Toothpaste, fluoride, dose, toothbrushing, children, dental caries

INTRODUCTION

Deciduous teeth are particularly vulnerable to damage from caries. They are physically more vulnerable in that they have thinner enamel than permanent dentition, and the enamel is more porous¹. Decay has been shown to penetrate through the enamel to the dentine at approximately twice the rate in deciduous teeth as in permanent teeth². Deciduous teeth are also more vulnerable in that they are present when children are very young and, consequently, likely to be less able and less motivated to clean plaque and food residues from their teeth effectively.

On a population basis, brushing with fluoride dentifrice is the single most important treatment to reduce the incidence of decay³. Fluoride applied topically in this way reduces enamel demineralisation in the presence of plaque bacterial acid, and enhances natural remineralisation processes in the presence of salivary minerals post-challenge⁴. In children and adolescents, fluoride dentifrice typically provides a 25% reduction in caries over a 3-year period³, which is likely to increase with prolonged use over many years⁵. Fluoride can also have negative effects on the body. Excessive exposure to fluoride as a young child can result in fluorosis of the teeth; this is normally visible as white mottling on the permanent dentition, but it may appear as brown mottling in more severe cases, with skeletal damage possible in cases of very high exposure⁶. Young children are particularly vulnerable because the permanent dentition is developing under the gum surface while the deciduous dentition is present, and fluoride exposure can interfere with the developmental process⁷. The risk of fluorosis is also exacerbated by young children's poor coordination and understanding relative to adults, resulting in a much larger proportion of the applied dentifrice being swallowed rather than expectorated after brushing⁸.

With regard to caries prevention via toothbrushing in young children, therefore, the aim of brushing is to get sufficient exposure for topical fluoride to function effectively, without too much exposure that may risk widespread instances of even mild fluorosis in vulnerable populations.

Many studies have been performed to understand how much is 'too much exposure', to support regulation Creeth et al.

of F concentration in oral care products and dosing recommendations. The literature on the potential adverse effects of fluoride from oral care regimens and treatments has been reviewed⁹. Fluoride in oral care products has been identified as a significant factor in the incidence of enamel fluorosis¹⁰. This research has also frequently investigated consumer dosing behaviour. Estimates in different populations of the average amount of toothpaste dispensed for toothbrushing have ranged widely, from 0.25 g to 1.38 g⁸. It should also be noted that some of these dispensing studies may not reflect current practice (many are now several decades old), and recent influences that may have changed behaviour include the introduction of modern toothbrushes (which may have smaller heads), and more modern professional advice for parents to supervise brushing and control toothpaste dose.

While understanding population exposure to fluoride from toothbrushing is a complex task, one very relevant observation is that, in a study subpopulation of over 400 children who claimed to use no more than a pea-sized amount of 1,000 ppm F dentifrice no more than twice per day, as the sole source of fluoride, none developed fluorosis in the anterior permanent dentition¹¹.

Many studies have also been performed to determine the concentration of fluoride in a dentifrice required for 'sufficient exposure'. The relationship between dentifrice fluoride concentration and caries protection has been reviewed¹². The fluoride concentration at which anticaries benefits become clear is between 500 and 1,000 ppm F ions¹², and the protective effect seems to rise with concentration to at least 5,000 ppm F ion¹³.

These studies on the risks and benefits of brushing with fluoride dentifrice have resulted in tight regulation of fluoride concentration in dentifrices in countries around the world, with $1,500 \ \mu g$ F per g of dentifrice the maximum any country regulation allows. There is also a near-universal requirement for dentifrice pack labels to provide advice that young children should use 'a pea-sized amount', typically for twice-daily toothbrushing.

The missing link in this situation is the evidence regarding the relationship between how much dentifrice is used (rather than fluoride concentration) and the degree of therapeutic benefit obtained. What information there is appears contradictory. Three separate caries clinical studies that recorded subjects' use of dentifrice found no evidence for a link with the incidence of caries^{14–16}, although in none of the clinical studies was the quantity of dentifrice controlled, or measured on more than one occasion. In contrast, studies of the effect of dentifrice quantity on fluoride delivery and remineralisation potential, in which quantity was prospectively controlled or carefully monitored, have consistently shown strong positive relationships^{17–20}.

Pendrys *et al.*¹¹ investigated the relationship between reported toothbrushing behaviour and both incidence of fluorosis and decay in young children. The proportion dispensing half a brush head-length or more (i.e. probably at least a gram, judging from the quantities shown in *Figure 1*) was very small (12 individuals), but was still found to have significantly higher levels of fluorosis. However, there was no meaningful difference in caries incidence. A larger, well-designed study is needed to determine if there is a significant relation between quantity of dentifrice and incidence of caries.

Given that the fluoride toxicity from oral care products is relatively well-characterised, and the likelihood that toothpaste dispensing practice at home has evolved in recent years, two outstanding questions regarding the risk-benefit balance for young children brushing with fluoride dentifrice arise:

- How much is a 'pea sized' amount? More specifically, do parents or carers in practice interpret a 'pea-sized' amount to be close to the 0.25 g anticipated in regulatory authority guidance^{20,21}?
- Is a 'pea-sized' amount of dentifrice likely to be enough to deliver the desired therapeutic effects of fluoride?

Addressing the first question is the aim of this article (the second is addressed in the accompanying article by Creeth *et al.* 2013). The approach taken was to survey a population of parents in three developed countries to understand their interpretation of a 'peasized' amount, and to measure how much dentifrice they actually dose for their young children.

The hypotheses underpinning this work were that in the 'real world' of individual practice, (1) there is a very wide range of dentifrice doses given by parents to their children, and (2) the quantity that regulatory authorities define as a target 'pea-sized' amount is quite different from the average amount actually dosed by parents.

Together with the investigation of the effect of quantity of dentifrice used on fluoride performance¹⁷, these findings may have important implications for the caries benefits and fluorosis risk from fluoride dentifrices in the general population.

MATERIALS AND METHODS

Parent population sample and study design

No actual human-use of products was undertaken during this study: samples were dispensed by the participants, weighed by study staff and then safely disposed of.



Figure 1. Images of study toothpaste dispensed in different quantities: (a) 0.25 g, (b) 0.50 g, (c) 1.00 g and (d) 1.50 g of study silica dentifrice with density approximately 1.3 g/ml.

Six hundred individuals who were parents or carers (described as 'parents' for simplicity in this article) of children aged between 3 years and 6 years were recruited into the study between October and December 2010 in the UK, USA and Germany. There were 200 participants in each country, recruited countrywide, and representing a wide range of socioeconomic status. They each gave voluntary, informed consent before participation in the study. The parents characterised themselves as being primarily responsible for dispensing their child's dentifrice for toothbrushing.

In a 'hall-test' (commercial shopping centre) environment, the parents were asked to choose a toothbrush that was similar to the one they currently used for their child at home, from the selection provided. This selection was a broad range, sourced from local supermarkets, and included electric toothbrushes. They were then asked to dispense on to the brush the amount they normally would for their child ('Normal' dispensing). This was repeated three times with an unstriped silica-based children's dentifrice, and three times with a silica-based striped dentifrice with a very similar formulation and density. The order of use of these two dentifrices was randomised.

It was then explained to the parents that dental authorities in their country recommend children aged under 6 years should use a pea-sized amount of dentifrice, and they were then asked to dispense what they understood to be a pea-sized amount onto the same brush ('Pea-sized' dispensing). Again, this was repeated three times with each of the striped and unstriped products (order of use was again randomised). General questions concerning knowledge of and attitudes towards oral care were also investigated by providing advisory or factual statements and asking whether the subjects were aware of the statement before the research.

Products used

Two toothpaste products were used in this study:

- Aquafresh[®] Milk Teeth toothpaste: a white, unstriped, silica dentifrice
- Aquafresh[®] Little Teeth toothpaste: a striped silica dentifrice consisting of two red stripes and two blue stripes alternating with white stripes.

The density of each was about 1.3 g/ml, so 0.25 g is just under 0.2 ml of these toothpastes. For visual reference, the striped paste was carefully dispensed to 0.25, 0.5, 1.0 and 1.5 g quantities on a conventional adult toothbrush and photographed, as shown in *Figure 1*.

RESULTS

The dispensing data are presented in *Tables 1* and 2. There was no evidence of an effect of toothpaste striping on dispensing, either for 'normal' or 'pea-sized' amounts, so data were pooled for all subsequent analyses.

'Normal' dispensing

Almost all parents, irrespective of nationality, dispensed more than the recommended 0.25 g (*Table 1*) when asked to dispense their normal amount of paste for their 3- to 6 year-old child. German parents disCreeth et al.

Parameter	USA		UK		Germany	
	Unstriped	Striped	Unstriped	Striped	Unstriped	Striped
Mean	0.52	0.52	0.58	0.57	1.16	1.19
Median	0.50	0.47	0.48	0.50	1.16	1.18
Standard deviation	0.264	0.267	0.553	0.387	0.456	0.455
25th centile	0.36	0.32	0.34	0.33	0.81	0.76
75th centile	0.64	0.63	0.68	0.71	1.56	1.56

Table 1 Quantity of toothpaste (g) dispensed under 'normal' dispensing regimen

Table 2 Quantity of toothpaste dispensed (g) under 'pea-sized' dispensing regimen

Parameter	USA		UK		Germany	
	Unstriped	Striped	Unstriped	Striped	Unstriped	Striped
Mean	0.41	0.42	0.50	0.48	0.61	0.60
Median	0.38	0.37	0.49	0.43	0.61	0.60
Standard deviation	0.206	0.207	0.263	0.24	0.075	0.074
25th centile	0.29	0.28	0.32	0.35	0.55	0.55
75th centile	0.53	0.51	0.60	0.63	0.66	0.65

pensed on average 1.18 g – considerably more than parents in the UK or USA, who dispensed an average of 0.57 and 0.52 g, respectively. None of the German parents dispensed the recommended 0.25 g amount or less. In the UK and Germany, about 80% of parents dispensed more than 0.25 g. The amount dispensed varied substantially: the standard deviation of the mean approached 0.5 g in UK and Germany and 0.3 g in the USA. Dispensing in the UK was numerically most variable.

There was a significant though modest positive relationship between the age of the child and the amount of toothpaste parents dispensed in the USA and Germany (see *Figure 2*), but not in the UK.

'Pea-sized' dispensing

When asked to dispense a 'pea-sized' amount, German parents dispensed barely half the amount they did when asked to dispense their 'normal' amount: 0.60 g *versus* 1.18 g. In contrast, for UK and US parents, the amount dispensed was reduced by approximately 20%.

The variability of dispensing was less than for 'normal' dispensing (SD 0.075–0.25 g across countries). There was no evidence of a relation to the child's age when dispensing a pea-sized amount of toothpaste.

The weights dispensed are summarised in Table 2.

Dispensing on electric brushes

Only in the USA were there sufficient electric toothbrush users to allow meaningful statistical analysis. This group dispensed about 0.1 g (\sim 20%) more paste, on average, than those using manual brushes.



Figure 2. Effect of age of child on amount of toothpaste dispensed by the parent in Germany, UK and USA. In (a) parents were asked to dispense the amount they normally would to their child; in (b) they were asked to dispense what they understood to be a pea-sized amount.

Oral care knowledge and attitudes

The responses to questions concerning oral care and their attitudes are provided in *Table 3*.

When provided with the statements 'Children should not drink sugary drinks before bedtime', 'Children under the age of 6 should be supervised when brushing', 'Proper use of fluoride toothpaste will help protect your children's teeth against decay', 'Children should visit the dentist regularly', the claimed awareness was uniformly 85% or greater

Table 3 Responses of parents regarding their awareness of statements concerning dental advice and facts for children

Question	USA (%)	UK (%)	Germany (%)
Children under the age of 6 years should be supervised when brushing	97	96	96
Children should not drink sugary drinks before bedtime	95	91	95
Proper use of fluoride toothpaste will help protect your childrens' teeth against decay	94	94	85
The recommended serving of toothpaste for your child is a pea-sized amount	91	79	73
If a young child uses a large amount of fluoride toothpaste when brushing, and tends to swallow, there is a risk of white spots appearing on their permanent teeth	31	51	58
Children should visit the dentist regularly	100	95	85

across all countries. Numerically, awareness of these statements was similar in USA and UK and (other than the question on supervision of brushing) lowest in Germany.

Parents in the UK claimed the highest awareness of the pea-sized recommendation (91% of UK parents claimed to be aware, compared with 79% of US parents and 73% of German parents).

Claimed awareness of the link between children ingesting fluoride toothpaste and visible signs of fluorosis (white spots on permanent teeth) was much lower – under 60% in Germany and the US, and barely 30% in the UK.

DISCUSSION

The concentration of fluoride in a dentifrice can be carefully regulated by Governments but the amount individuals dispense in everyday use cannot. Understanding how much dentifrice is dispensed to young children by their parents or carers is therefore critical to understanding their exposure to fluoride, for both positive and negative effects.

In the present study, performed out-of-home, the question arises whether the sampling method truly represents normal bathroom behaviour. This question is relevant to some extent in all studies of toothbrushing behaviour, whether in-home or not. We attempted to minimise this issue by providing a wide range of toothbrushes to allow individuals to choose one close (or identical) in design to their home toothbrush, by sampling a large number of individuals in each country, and by multiple sampling on each dispensing occasion.

'Normal' *versus* 'pea-sized' parental dosing was investigated in a small pre-school-based study in 3-year-olds by Levy²². 'Normal' dosing was found to be very close to 0.25 g, whereas 'pea-sized' dosing was slightly greater (0.31 g). The authors recognised that the 'normal' dosing quantity was low in comparison to previous studies, and proposed it resulted from the small toothbrush head used, and high awareness in that population of the risk of fluorosis from excessive ingestion of fluoride.

In this study, the average amounts dispensed by parents in the UK and the USA were similar and close to the mean of previous published studies (approximately 0.5 g)¹¹, suggesting that dispensing practice in these countries has not changed greatly in recent years. In contrast, the average amount dispensed in Germany (1.18 g) was at the upper end of previous estimates for this agegroup, with only one study in Canada in 1972²³, soon after fluoride toothpaste became widely available, estimating a higher value (1.38 g). The authors are not aware of an obvious explanation for this difference.

The fact that the 'pea-sized' amount was widely overestimated by the participants in this study (vs. advice that it be taken as 0.25 g)^{20,21} is perhaps unsurprising, given how small a volume this weight of conventional toothpaste actually comprises. *Figure 1* shows 0.25 g of one of the dentifrices used in this study, when dispensed on an adult toothbrush; peas are generally larger. This issue may be even more extreme in toothpastes using other abrasive systems, such as chalk or dicalcium phosphate dihydrate, which typically have a density of approximately 1.5 g/ml.

It is important to consider not only the average but also the range of dosed quantities to understand fully the dispensing practices of different populations^{11,24}. The range of 'normal' dispensing practice is apparent from the fact that those at the 75th centile dispensed approximately twice the amount as those at the 25th centile, irrespective of country of origin. The potential for overdosing appears greatest in Germany, where 25% of parents dispense more than six times the recommended amount of toothpaste.

Many parents appeared to consider the age of their child in their 'normal' dispensing of dentifrice, even within the narrow age range of the study: in the USA and Germany, those with younger children (aged 3-4 years) dispensed less than those with children aged 5-6 years.

The USA group who chose electric toothbrushes confounded accepted wisdom that electric toothbrush users use less toothpaste by dispensing more toothpaste than those choosing manual toothbrushes. This may reflect the fact that the expectation that less toothpaste is used on electric toothbrushes relates to adult practice, and possibly also that electric toothbrush users may have higher disposable income and therefore may be less cautious about how much toothpaste they use.

In summary, the results of this study indicate that, in three developed countries, the large majority of Creeth et al.

parents of 3- to 6 year-old children dispense considerably more toothpaste in the course of their child's normal oral hygiene routine than the recommended 0.25 g. When asked to dispense a 'pea-sized' amount of toothpaste, parents dispensed approximately 20% less than their normal amount in the USA and the UK, and almost 50% less in Germany. This was despite the high claimed awareness of the professional recommendation that their children should be using a pea-sized amount (at least 85% across each population). Awareness of key oral health messages among parents appeared high, but by no means universal, across all countries.

Should we be concerned that so many children are using considerably more fluoride toothpaste than is recommended by oral health-care professionals? Evidence is building that caries protection increases meaningfully if young children use more than the recommended 0.25 g of toothpaste, particularly from studies of salivary fluoride levels post-brushing^{17–20}. Given the evidence that children using a self-assessed pea-sized amount of toothpaste as sole source of fluoride do not suffer from fluorosis¹¹, it may be argued that a recommendation to use a pea-sized amount of toothpaste generally works well in practice, in balancing the conflicting demands of risk and benefit from fluoride in young children.

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Conflict of interest

Authors Creeth, Bosma and Govier are employed by GlaxoSmithKline Consumer Healthcare.

REFERENCES

- 1. van Beek GC. Dental Morphology: an Illustrated Guide (p11). Bristol: Wright; 1983.
- 2. Mejare I, Stenlund H. Caries rates for the mesial surface of the first permanent molar and the distal surface of the second primary molar from 6 to 12 years of age in Sweden. *Caries Res* 2000 34: 454–461.
- 3. Walsh T, Worthington HV, Glenny AM *et al.* Fluoride toothpastes of different concentrations for preventing dental caries in children and adolescents. *Cochrane Database Syst Rev* 2010 Jan 20 (1): CD007868.
- 4. ten Cate JM. Current concepts on the theories of the mechanism of action of fluoride. *Acta Odontol Scand* 1999 57: 325–329.
- 5. Kingman A. Methods of projecting long-term relative efficacy of products exhibiting small short-term efficacy. *Caries Res* 1993 27: 322–327.

- 6. Warren JJ, Levy SM. A review of fluoride dentifrice related to dental fluorosis. *Pediatr Dent* 1999 21: 265–271.
- 7. Warren JJ, Levy SM. Systemic fluoride. Sources, amounts, and effects of ingestion. *Dent Clin North Am* 1999 43: 695–711.
- 8. Levy SM. A review of fluoride intake from fluoride dentifrice. ASDC J Dent Child 1993 60: 115-124.
- 9. Levy SM. An update on fluorides and fluorosis. J Can Dent Assoc 2003 69: 286–291.
- 10. Pendrys DG, Stamm JW. Relationship of total fluoride intake to beneficial effects and enamel fluorosis. *J Dent Res* 1990 69 (Spec Iss): 529–538.
- 11. Pendrys DG, Haugejorden O, Bardsen A *et al.* The risk of enamel fluorosis and caries among Norwegian children: implications for Norway and the United States. *J Am Dent Assoc* 2010 141: 401–414.
- 12. Wong MC, Clarkson J, Glenny AM *et al.* Cochrane reviews on the benefits/risks of fluoride toothpastes. *J Dent Res* 2011 90: 573–579.
- 13. Nordstrom A, Birkhed D. Preventive effect of high-fluoride dentifrice (5,000 ppm) in caries-active adolescents: a 2-year clinical trial. *Caries Res* 2010 44: 323–331.
- 14. Ashley PF, Attrill DC, Ellwood RP et al. Toothbrushing habits and caries experience. Caries Res 1999 33: 401-402.
- 15. Duckworth RM, Morgan SN, Burchell CK. Fluoride in plaque following use of dentifrices containing sodium monofluorophosphate. *J Dent Res* 1989 68: 130–133.
- Sjogren K, Birkhed D. Factors related to fluoride retention after toothbrushing and possible connection to caries activity. *Caries Res* 1993 27: 474–477.
- 17. Creeth J, Zero D, Mau M, Bosma ML *et al.* The effect of dentifrice quantity and toothbrushing behaviour on oral delivery and retention of fluoride in vivo. *Int Dent J* 2013 63 (Suppl 2): 14– 24.
- Reintsema H, Arends J. Fluoridating efficiency of several fluoride-containing dentifrice systems *in vivo*. *Caries Res* 1987 21: 22–28.
- 19. Zero DT, Creeth JE, Bosma ML *et al.* The effect of brushing time and dentifrice quantity on fluoride delivery *in vivo* and enamel surface microhardness *in situ*. *Caries Res* 2010 44: 90–100.
- 20. Denbesten P, Ko HS. Fluoride levels in whole saliva of preschool children after brushing with 0.25 g (pea-sized) as compared to 1.0 g (full-brush) of a fluoride dentifrice. *Pediatr Dent* 1996 18: 277–280.
- 21. SCCNFP. The safety of fluorine compounds in oral hygiene products for children under the age of 6 years. Opinion of The Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers, 13. 24-6-2003. 21-2-2013.
- 22. Levy SM, McGrady JA, Bhuridej P *et al.* Factors affecting dentifrice use and ingestion among a sample of U.S. preschoolers. *Pediatr Dent* 2000 22: 389–394.
- 23. Hargreaves JA, Ingram GS, Wagg BJ. A gravimetric study of the ingestion of toothpaste by children. *Caries Res* 1972 6: 237–243.
- 24. Levy SM. Review of fluoride exposures and ingestion. Community Dent Oral Epidemiol 1994 22: 173-180.

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