Volume marker inaccuracies: a cross sectional survey of infant feeding bottles

ABSTRACT

A cross sectional examination of the accuracy of volume markers on infant feeding bottles available for sale in NSW, Australia between December 2013 and February 2014 was carried out. Ninety-one bottles representing 28 different brands were examined. Volumes were marked in a combination of millilitres and ounces. Forty-two (46%) markings were embossed; 47 (52%) were printed on the bottle; 2 (2%) had both. Forty-seven (54%) bottles had no standard claim; 36 (41%) noted compliance with the European standard EN14350; 5 (6%) with non-existent Australian standards. Nineteen bottles (22%) had at least one measured marking outside the tolerance of EN14350. Markings both over and under-estimated true volume: mean tendency was to slightly over-estimate. Bottles claiming compliance with EN14350 were more likely to have inaccurate (10/36 versus 9/52). More expensive bottles did not have more accurate markings. Three bottles were disposable liner systems; these bottles had particularly large volume inaccuracies. Inaccurate volume markers on infant feeding bottles are a previously neglected but potentially important source of error in the reconstitution of infant formula. Over-concentrated and under-concentrated infant formula can cause serious illness or malnutrition. Over concentrated infant formula may contribute to obesity. Bottles with inaccurate volume markers are unfit for purpose; disposable liner bottles are particularly poor in this regard and should be prohibited from having volume markers on the bottle casing. To avoid individual or public harms, well-enforced standards are needed. Guidance for parents, carers and health professionals is needed to ensure infant formula is accurately reconstituted.

Key Words:

Infant; Infant Feeding; Bottle Feeding; Artificial Feeding; Standards

INTRODUCTION

Infants have special dietary needs. It is recommended that they be fed nothing but breastmilk for the first 6 months of life and continue to be breastfed until around 2 years of age (WHO and UNICEF, 2003). However, substantial proportions of infants in developed nations, and increasingly in developing nations, are exclusively or partially weaned from breastmilk in early infancy (McAndrew et al., 2012; Australian Institute for Health and Welfare, 2011; Tang et al., 2014; Lee Mendoza, 2010). When breastmilk is not available, infants should be fed an infant formula that conforms to the relevant provisions of the *Codex Alimentarius* (WHO and UNICEF, 2003; Fomon, 2001). Because Infant formula is a substitute for a human tissue and may be the sole source of nutrition for infants for up to six months, strict regulation of its composition is necessary (Cohen et al., 2010; Shaw, 2008). Variations in the nutritional profile of infant formula can have significant implications for infant health (Fattal-Valevski et al., 2005; Centers for Disease Control and Prevention, 1996; Skinner et al., 2010; Taitz and Byers, 1972; Chambers and Steel, 1975; Keating et al., 1991).

Where infant formula is manufactured in powdered form, the provision of the intended nutrition is dependent upon accurate reconstitution. Errors in the measurement of powdered milk for reconstitution of infant formula, are common in a variety of contexts (Wise, 1979; Jacob, 1985; Plaster and Bergman, 1995; Jeffs, 1989; Chambers and Steel, 1975; Paxson et al., 1977). However, the measurement of an accurate volume of water is just as critical to the proper reconstitution of infant formula. Parents using infant formula are routinely instructed to reconstitute the product in infant feeding bottles using the volume markers on the bottles to measure water (World Health Organization and Food and Agriculture Organization, 2007). Such advice assumes that bottle volume markers are accurate.

The only comprehensive standard for infant feeding bottles in the world is EN14350 produced by the European Committee for Standardization (European Committee for Standardization, 2004). In relation to accuracy of measurement, EN14350 requires the validation of 3 volume markings. Where these volume markers are less than 100mL they must be accurate to within 5mL of the nominated value. Volume markers of 100mL or more must be accurate to within 5% of the nominated value. Although EN14350 is only enforceable within the European Community, conformity with this standard used as a quality claim for infant feeding bottles sold elsewhere. This study aimed to document the accuracy of volume markings displayed on infant feeding bottles for sale in Australia using the tolerance in the provisions of EN14350 as a benchmark.

MATERIALS AND METHODS

Study design and setting

A cross sectional examination of infant feeding bottles available for sale in NSW, Australia between December 2013 and February 2014.

Inclusion and exclusions criteria

Purposive sampling: one sample of each and every bottle found available for sale was purchased. All brands, volumes and shapes of infant feeding bottles were eligible for inclusion. The search for bottles ceased when saturation was reached and no additional bottle types could be found.

Variables

Deionised water was used to fill each bottle to its graduated markings so that the base of the meniscus was level with the midpoint of markings at 50 mL, 60 mL, 90 mL, 100 mL, 120 mL and 150 mL. These volumes were chosen because they are specified in instructions for reconstitution for infant formula in Australia for infants 2 months of age and less (those most vulnerable in the event of reconstitution error). The mass of the water to 0.1g was measured at each individual graduation mark at 25^{o}C. Bottles and water were weighed using an A&D FX-400 balance (calibrated a week prior) and each measurement was checked by two investigators and recorded. Duplicate measurements were made for disposable liner bottles (bottle systems that had a rigid outer casing with a disposable liner for holding liquid). Notes were made about the ease of measurement and anomalies in markings.

Data and statistical methods

Data were entered in Excel 2013 (Microsoft, USA). Basic calculations of visually observed volume vs volume by mass and percent difference between the two measurements were also carried out in Excel. Data were then transferred to

Stata using StatTransfer v.13 (Circle Systems, USA). Data for results tables and the figures were produced in Stata Intercooled v.13.1 (StataCorp LP, USA). Sub-group analysis of bottles that claimed vs those that did not claim compliance with the existing regulatory standard was made. Since this was a descriptive study rather than one testing an a-priori hypothesis, a formal sample size calculation was not needed.

RESULTS

A total of 91 different infant feeding bottles were purchased, representing 28 brands (mode 3 bottles per brand). These came from 19 different outlets including department stores, discount stores, chemists, supermarkets, hospital supply stores, online stores and convenience stores. Ninety-one of these bottles were hard-sided and 3 were disposable liner bottles. Table 1 summarizes the key characteristics of the 88 hard-sided bottles explored in the main analysis.

Table 1 Main characteristics of hard-sided bottles included in study (n=88)

Variable	N	%
Brands (n=27)	mode 3 per brand (min 1, max 10)	
Volume		
250 mL	25	28%
240 mL	13	15%
150 mL	11	13%
125 mL	12	13%
other <250mL	11	14%
other >250mL	16	18%
Price ($, USD)*	median $4.83 (IQR 2.23 to 8.90), min $0.89, max $26.71	
Marked in		
mL only	8	9%

mL and unspecified ounce	54	61%
mL and unspecified fluid ounce (fl. oz)	18	20%
mL and US fl. oz. †	2	2%
mL and UK fl. oz. †	3	3%
mL US AND UK oz	3	3%
Printed or embossed		
Embossed	40	45%
Printed	45	51%
Both (not aligned)	3	3%
Standards claim		
None	47	54%
European standards label	36	40%
"Australian approved safety standards"	5	6%

*Purchased in Australian Dollars between Dec 2013 and Feb 2014. US Dollar price calculated at midpoint exchange rate, 15th Jan 2014. US$1=AUS$1.123
†UK (Imperial) fluid oz = 28mL; US fluid oz = 30mL

The commonest total volume of hard-sided bottles was 250mL (25 bottles, 28% of sample); 47 (53%) were <250mL; and 16 (18%) were >250mL in volume. Median price was $4.83 USD per bottle, though there was a wide range ($0.89-$26.71). Markings on some bottles were hard to read or ambiguous; for example, one had a marking that was not horizontal but angled. Observers noted that measuring water was easier in narrow bottles than in wide bottles. Most bottles displayed markings in both millilitres and ounces, though often (54 bottles, 61% of sample) the type of ounce was not specified. Forty bottles (45%) had embossed markings, some of which were difficult to read; 45 (51%) had printed markings. Three bottles (3%) had both printed and embossed markings but these markings were not aligned with one another. The manufacturers of 36 (41%) bottles claimed that their product met EN14350.(European Committee for Standardization, 2004) Five (6%) of bottles claimed adherence to "Australian

Approved Safety Standards" despite the absence of any Australian standard for infant feeding bottles.

We found markings on nineteen bottles (22%) (range 1-5) that were outside the accuracy requirement of EN14350. Thirty-nine bottles (44%) had at least one missing marking (range 1- 3) for volumes specified in instructions for reconstitution of infant formula available in Australia for infants 2 months of age and younger (range 1-6). In total, 50 (57%) had either inaccurate or missing markings. A summary of the frequency of inaccurate and missing markings is presented in Table 2.

Table 2 Frequency of inaccurate and missing volume markings on bottles

Volume	Inaccurate*		Missing	
	N	%	N	%
50	9	11	11	13
60	6	9	26	30
90	7	10	22	25
100	9	12	5	6
120	3	5	27	31
150	3	4	1	1
Total	**37**	**9**	**92**	

*Inaccurate is defined as being outside the tolerance levels provided by standard EN14350 of plus or minus 5mls for volumes under 100mL and plus or minus 5% for volumes over 100mL.

Bottles with inaccurate markings were produced or distributed by companies based in Australia, China, New Zealand, UK and the USA and manufactured in Bulgaria, China, Germany, New Zealand, Thailand, and the UK. Bottles with missing markings were produced or distributed by companies based in Australia, China, Malaysia, New Zealand, Singapore, UK and the USA and manufactured in Australia, Austria, China, Hungary, Germany, Thailand, UK, and the USA.

As shown in Figure 1 histograms and Table 3, markings slightly overestimated the actual volume of water present in the bottle: on average by 0.43mL at the 50mL mark; 0.50mL at the 60mL mark; 0.57mL at the 90mL mark; 0.77mL at the 100mL mark; 0.93mL at the 120mL mark; and 0.94mL at the 150mL mark. As illustrated by similar discrepancies and overlapping confidence intervals, mean accuracy was similar for embossed and printed markings. Mean volumes on bottles that claimed compliance with EN14350 were similar to those that did not. However, markings that were outside the tolerance requirements of EN14350 were more commonly found in bottles that claimed to meet this standard (10/36; 28%) compared with those that did not (9/52; 17%). There was no relationship between bottle price and overall accuracy of volume markings (Figure 2).

Table 3 Volume differences according to key characteristics

Mean mL "off" (95% CI)	**All bottles**	**Standard claim**		**Marking type**	
		None	**European standard**	**Embossed**	**Printed**
At 50mL mark (n=80)	-0.43 (-1.1, 0.3)	-0.42 (-1.3, 0.4)	-0.31 (-1.6, 1.0)	-0.53 (-1.5, 0.4)	-0.7 (-1.6, 0.1)
At 60mL mark (n=65)	-0.50 (-1.2, 0.2)	-0.60 (-1.5, 0.3)	-0.17 (-1.3, 1.0)	-0.73 (-1.8, 0.4)	-0.34 (-1.2, 0.5)
At 90mL mark (n=68)	-0.57 (-1.4, 0.2)	-0.69 (-1.47, 0.1)	-0.34 (-1.8, 1.2)	-1.05 (-2.2, 0.1)	-0.67 (-1.6, 0.2)
At 100mL	-0.77	-1.11	-0.23	-1.28	

mark (n=84)	(-1.5, -0.1)	(-2.0, -0.2)	(-1.4, 1.1)	(-2.3, -0.2)	-0.35 (-1.3, 0.6)
At 120 mL mark (n=62)	-0.93 (-1.6, -0.3)	-0.99 (-1.7, 0.2)	-0.81 (-2.0, 0.4)	-1.23 (-2.1, -0.3)	-0.70 (-1.6-0.2)
At 150 mL mark (n=72)	-0.94 (-1.8, -0.1)	-1.42 (-2.6, -0.3)	-0.38 (-1.9, 1.2)	-1.67 (-2.8, -0.5)	-0.76 (-1.8, 0.3)

The disposable liner bottles were made by two manufacturers. Total volumes of the liners were 300mL, 120mL and an unspecified maximum >150mL. Volume markers printed on the rigid casings of these products underestimated water volume to the extent that they were outside the requirements of EN14350 in all but one case. Wide variations were observed when repeat measurements were taken; expansion of the plastic liners with the addition of water was observed to influence volume. Thus, second measurements in the same plastic liner resulted in smaller discrepancies (not reported). Markings were both printed on the bottle casing and embossed on the liners however, measurements could only be made using the markings on bottle casings as the observers were unable to read those printed on the plastic liners once they were filled with water. Table 4 shows volume discrepancies for the three disposable bottle systems in the sample.

Table 4 Volume discrepancies of the disposable liner bottles

Disposable bottle	**Actual Volume at**					
	50mL (% off stated volume)	**60mL** (% off)	**90mL** (% off)	**100mL** (%off)	**120mL** (% off)	**150mL** (%off)
Brand A	31.4 (-37%)	38.8 (-21%)	51.3 (43%)	70.1 (-30%)	86.8 (-28%)	138.5 (-8%)
Brand B – 300mls	56.6 (13%)	-	-	120.9 (21%)	-	184.0 (23%)

Brand B – 120mls	45.3 (9%)	-	-	93.7 (6%)	-

- No mark at this volume

DISCUSSION

This study reveals volume markings on infant feeding bottles are commonly inaccurate and may make it difficult for infant formula to be properly reconstituted. An appreciable proportion of volume markings on the bottles purchased were outside tolerances required by standard EN13450. Factors that consumers might consider to indicate quality, such as claims of compliance with EN13450 or price, were not associated with greater accuracy.

The “bottle marker” problem adds to an already long list of factors responsible for error in infant formula reconstitution, including variation in composition of powdered milk(Paxson et al., 1977); errors in measurement of powdered infant formula due to addition of too few or too many scoops of powder(Lilburne et al., 1988); under-filling, packing or using heaped scoops of infant formula(Lilburne et al., 1988); and adding water or powdered infant formula in the incorrect order.(Daly et al., 1998) Errors in infant formula reconstitution may neutralise one another. However, it has been found that the parents, caregivers and health professionals tend to add more powdered infant formula than is instructed, resulting in over-concentration.(Lilburne et al., 1988; Chambers and Steel, 1975; Jacob, 1985; McJunkin et al., 1987; Jeffs, 1989; Daly et al., 1998) The risk of over-concentration is likely to be compounded by the tendency identified in this study, of bottles to over-represent volumes.

Over-concentrated infant formula has implications for infant health. The most extreme of these is hypernatraemia, a life threatening form of dehydration.(Taitz and Byers, 1972; Chambers and Steel, 1975; Lilburne et al., 1988) Risks are greatest in very small/premature infants whose renal function has least capacity to deal with over-concentration and in young infants with diarrhoea. (Khuffash and Majeed, 1984; Rhodin et al., 2009)

Less dramatic, but more significant for public health, over-concentrated infant formula may contribute to excessive weight gain in infancy. Lucas et al (Lucas et al., 1992) found that infants fed a powdered infant formula gained more weight and were more likely to be overweight at 6 months of age than infants fed the same volume of a comparable ready-to-use liquid infant formula. Over-concentration of powdered infant formula resulted in consumption of an additional 209 kJ/day.(Lucas et al., 1992) Other research indicates that infants can self regulate energy intake, suggesting growth may not be affected by errors in formula concentration. (Fomon et al., 1975; Adair, 1984) However, carer-driven feeding may override compensatory mechanisms. (Bartok and Ventura, 2009)

Over-concentrated infant formula can also exacerbate constipation in formula fed infants (Vandenplas et al., 2013; Nevo et al., 2007) and increase the severity of gastro-oesophageal reflux disease.(Vandenplas et al., 2013; Salvia et al., 2001; Carroll et al., 2002)

Under-concentrated infant formula also has health implications. Sustained suboptimal nutrient intake could result in poor growth and development. (David and David, 1984)

Regulatory Framework

Greater attention to the regulation of the manufacture of infant feeding bottles is necessary to ensure that volume markers are accurate and adequate. Comprehensive standards should require testing of all volume markers as bottles can have a mixture of accurate and inaccurate volume markers. In addition, standards should require that markings are present for the volumes of water specified for infant formula reconstitution on the packaging of infant formula products sold in corresponding markets. Missing markings are potentially just as problematic as inaccurate ones as caregivers may seek to estimate water volume using the available markers. Consideration might be given to standardising the volumes of water required for reconstitution of infant formula products.

This study suggests that volume markers on disposable liner bottles are grossly inaccurate and that this problem is inherent to the design of these bottles. Thus, disposable liner bottles should be prohibited from displaying volume markers so that they cannot be used for measuring water. Although the study included only bottles for sale within Australia, inaccurate bottles originated in a large number of countries. This suggests that the problem of inaccurate volume markers is unlikely to be limited to Australia and that international standards should be developed.

This study also identified that active external monitoring and enforcement of compliance with standards of manufacture is required. A number of bottles claiming compliance with EN14350 had volume markers that were outside the tolerance of the standard. As it currently stands, manufacturers are responsible for monitoring compliance with EN14350 and there is no provision for testing frequency within the standard.

Advising on choice of infant feeding bottle

Caregivers should be encouraged to choose infant feeding bottles that display clear volume markings commensurate with the instructions printed on the infant formula product they are using and to test the volume markers of purchased bottles using a scale accurate to 1g. These are generally available in pharmacies (where many parents purchase infant formula and bottles) and hospitals. In the process of measuring water in bottles for the study it was noted that measurement of water was easier in tall, thin bottles rather than squat and wide ones. It is known that the narrower the container within which liquid is measured, the more accurate the measurement. Hence, measuring cylinders and pipettes are the instruments of choice in laboratories, and for applications where accurate measurement of liquid volumes is crucial.(Ansel, 2012) Caregivers should therefore be advised that narrow bottles will make accurate measurement of water easier.

Those using powdered infant formula require instruction in the accurate measurement of water. Providing parents with education can reduce adverse consequences associated with dilution errors.(Sunderland and Emery, 1979) However, despite requirements for individualised instruction for parents using infant formula in schemes such as the Baby Friendly Hospital Initiative, there is evidence that many parents do not receive such education.(Tarrant et al., 2012; Wirihana and Barnard, 2012) Given the vulnerability of formula fed infants to a variety of avoidable risks, including those associated with reconstitution errors but also poor hygiene, cleaning and over feeding, this is alarming. Education and support of parents and caregivers who are using infant formula by health providers should be considered essential.

Limitations

There are a number of limitations to this research. One of each bottle type was sampled. It may be that different production batches, or even different bottles within the same batch, have greater or fewer accurate markings and that accuracy would vary over time. It is also possible that that bottles for sale in countries other than Australia may be less or more accurate. Indeed an investigation by the New Zealand Ministry of Consumer Affairs found that even when only a single volume marking was measured on bottles purchase in New Zealand, 42% of bottles measured were inaccurately marked.(Ministry of Health, 2013)

The consequences of the inaccuracies we observed in “real life” settings, at individual or population levels have not been studied. Further research is necessary to ascertain how common the problems identified are and to determine how inaccurate volume markers impact infant formula reconstitution in practice.

CONCLUSIONS

Inaccurate volume markers on infant feeding bottles are a previously neglected but potentially important source of error in the reconstitution of infant formula. This study found a tendency of volume markers to over-estimate actual volume of water: this predisposes to over-concentrated infant formula and potential problems like hypernatreamia, obesity and constipation. Other markers under-estimate actual volumes and thus over-dilute the end product, predisposing to under-nutrition. Infant feeding bottles with inaccurate volume markers should be considered unfit for purpose: disposable bottle systems are particularly poor in this regard. To avoid either individual or public harms, well-enforced standards are needed, as is better guidance to both carers and health professionals to accurately measure water volume when reconstituting powdered infant formula.

Key messages

- Volume marker on infant feeding bottles can be inaccurate even where compliance the European Standard EN14350 is claimed.

- Disposable liner bottle systems are particularly inaccurate and volume markings on them should be prohibited to prevent them being used to measure water.
- The health of formula fed infants is likely to adversely impacted by inaccurate volume markers on infant feeding bottles leading to infant formula reconstitution errors.

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Figure 1 Histograms of mL difference between stated volume and measured volume at 50, 60, 90, 100, 120 and 150mL markings (if present, n=80, 65, 68, 84, 62, 72)

Figure 2 Scatterplot of bottle price in USD (x-axis) vs mL difference at 50mL marking

Table 1 Main characteristics of hard-sided bottles included in study (n=88)

Table 2 Frequency of inaccurate and missing volume markings on bottles

Table 3 Volume differences according to key characteristics

Table 4 Volume discrepancies of the disposable liner bottles