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

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Abstract
A cross-sectional examination of the accuracy of volume markers on infant feeding bottles available for sale in Australia between December 2013 and February 2014 was carried out. Ninety-one bottles representing 28 different brands were examined. Eighty-eight bottles were hard sided. Volumes in these bottles were marked in a combination of milliliters and ounces. Thirty-six (41%) bottles claimed compliance with the European standard EN14350, five (6%) with non-existent Australian standards, and forty-seven (54%) bottles had no standard claim. Nineteen bottles (22%) had at least one measured marking outside the tolerance of EN14350. Bottles claiming compliance with EN14350 were not less likely to have inaccurate markings than those that made no claim. More expensive bottles did not have fewer inaccurate markings. Three bottles were disposable liner systems and had particularly large volume inaccuracies (up to 43% outside the marked volume). 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 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 that infant formula is accurately reconstituted.

KEYWORDS
artificial feeding, bottle feeding, infant, infant feeding, standards

1  |  INTRODUCTION

Infants have special dietary needs. It is recommended that they be fed nothing but breast milk for the first 6 months of life and continue to be breastfed up until 2 years of age or longer (WHO and UNICEF, 2003). However, substantial proportions of infants in developed nations, and increasingly in developing nations, are exclusively or partially weaned from breast milk in early infancy (McAndrew et al., 2012; Australian Institute for Health and Welfare, 2011; Tang et al., 2014; Lee Mendoza, 2010). When breast milk 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 6 months, strict regulation of its composition is necessary (Cohen, Xiong, & Sakamoto, 2010; Shaw, 2008). This is because variations in the nutritional profile of infant formula can have significant and adverse impacts on infant health (Fattal-Valevski et al., 2005; Centers for Disease Control and Prevention, 1996; Skinner, Thomas, & Osterloh, 2010; Taitz & Byers, 1972; Chambers & Steel, 1975; Keating, Schears, & Dodge, 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 & Bergman, 1995; Jeffs, 1989; Chambers & Steel, 1975; Paxson, Adcock, & Morris, 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. Inaccurate volume markers
may result in improper reconstitution of infant formula to the detriment of infant health.

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 the accuracy of measurement, EN14350 requires the validation of three volume markings. Where these volume markers are less than 100 ml, they must be accurate to within 5 ml of the nominated value. Volume markers of 100 ml 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 is used as a quality claim for infant feeding bottles sold elsewhere. This study aimed to determine whether volume markings displayed on infant feeding bottles for sale in Australia are accurate using the tolerance in the provisions of EN14350 as a benchmark.

2 MATERIALS AND METHODS

2.1 Study design and setting

A cross-sectional examination of infant feeding bottles available for sale in Australia between December 2013 and February 2014 is used in this study.

2.2 Inclusion and exclusions criteria

Purposive sampling: one sample of each and every bottle found available for sale. Bottles were primarily purchased in New South Wales by the first author; however, requests for bottle searchers were also made via social media sites supporting mothers who bottle feed their babies and the Australian Breastfeeding Association in order to obtain bottles from throughout Australia. 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.

2.3 Variables

Deionized 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, 60, 90, 100, 120, and 150 ml. These are the volumes specified in manufacturers’ instructions for reconstituting infant formula for infants 2 months of age or less (those most vulnerable in the event of reconstitution error) in Australia. The mass of the water to 0.1 g was measured at each of these graduations at 25°C, by placing each bottle empty on an FX-400 balance (A&D Company Ltd, Japan) and using the “tare” function to account for the mass of the empty bottle and reading the weight of water filled to the relevant volume markers. The balance had been calibrated a week prior to data collection, and each measurement was taken by two investigators and was 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.

2.4 Data and statistical methods

Data were recorded in Excel 2013 (Microsoft, USA) to facilitate calculation of differences between visually observed volume and volume by mass, which were then expressed as percent difference between the two measurements. These data were used to identify bottles that failed to achieve the relevant European Standard (EN14350). Failure to achieve the requirements of the standard was recorded as a categorical variable (inaccuracy), where 1 indicated that the bottle contained at least one volume mark that did not fall within the tolerance specified in EN14350. Data for results tables and the figure were produced in Stata Intercooled v.13.1 (StataCorp LP, USA). Chi-square tests (with Yates Continuity Correction) were conducted using IBM SPSS Statistics Package 24 (IBM, USA) to determine whether bottles that displayed one or more inaccurate volume marker (as defined by EN14350) were more likely to cost more than US$5 (price), bear the European Standard mark, or display embossed (in lieu of or as well as printed) volume markers.

3 RESULTS

Niney-one different infant feeding bottles were purchased, representing 28 brands (mode three 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 three were disposable liner bottles. Table 1 summarizes the key characteristics of the 88 hard-sided bottles explored in the main analysis.

The commonest total volume of hard-sided bottles was 250 ml (25 bottles, 28% of sample); 47 (53%) were <250 ml; and 16 (18%) were >250 ml in volume. Median price was US$4.83 per bottle, although there was a wide range ($0.89–$26.71). Markings on some

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.
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 milliliters and ounces, although often (54 bottles, 61% of sample) the type of ounce was not specified.

As shown in Figure 1, volume markings are both underestimated and overestimated actual volumes. Thirty-seven markings on 19 bottles (22%) (range 1–5) were found to be so inaccurate that they were outside the requirements of EN14350. Twenty-one of these markings overestimated the volume, and 16 underestimated the volume. Furthermore, 39 bottles (44%) had at least one missing marking (range 1–3) for volumes specified in manufacturers’ instructions for reconstitution of infant formula available in Australia for infants 2 months of age and younger (range 1–6). In total, 50 bottles (57%) had either inaccurate or missing markings. A summary of the frequency of inaccurate and missing markings is presented in Table 2.

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

The disposable liner bottles were made by two manufacturers. Total volumes of the liners were 300, 120 ml, and an unspecified maximum >150 ml. 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 3 shows volume discrepancies for the three disposable bottle systems in the sample.

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. Bottles with only embossed markings were no more likely to be inaccurate than bottles with only printed markings ($p = .78$).

The manufacturers of 36 (41%) bottles claimed that their product met EN14350. Five (6%) bottles claimed adherence to “Australian Approved Safety Standards” despite the absence of any Australian standard for infant feeding bottles. Ten of the 36 bottles (28%) that

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

<table>
<thead>
<tr>
<th>Variable</th>
<th>$N$</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brands ($n = 27$)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Volume (ml)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>250</td>
<td>25</td>
<td>28</td>
</tr>
<tr>
<td>240</td>
<td>13</td>
<td>15</td>
</tr>
<tr>
<td>150</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>125</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>Other &lt;250</td>
<td>11</td>
<td>14</td>
</tr>
<tr>
<td>Other &gt;250</td>
<td>16</td>
<td>18</td>
</tr>
<tr>
<td>Price (US$)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marked in</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ml only</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>ml and unspecified ounce</td>
<td>54</td>
<td>61</td>
</tr>
<tr>
<td>ml and unspecified fluid ounce (fl. oz)</td>
<td>18</td>
<td>20</td>
</tr>
<tr>
<td>ml and US fl. oz.†</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>ml and UK fl. oz.†</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>ml US and UK oz.†</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Printed or embossed</td>
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<td></td>
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<td>Embossed</td>
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<td>45</td>
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<tr>
<td>Printed</td>
<td>45</td>
<td>51</td>
</tr>
<tr>
<td>Both (not aligned)</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Standards claim</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>47</td>
<td>54</td>
</tr>
<tr>
<td>European standards label</td>
<td>36</td>
<td>40</td>
</tr>
<tr>
<td>“Australian approved safety standards”*</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>


†UK (Imperial) fluid oz. = 28 ml; US fluid oz. = 30 ml.
claimed compliance with EN14350 and nine of the 52 bottles (17%) that made no such claim had markings that were outside the tolerance requirements of EN14350. Bottles that claimed to comply with EN14350 were no less likely to be inaccurate than those that did not make a compliance claim (p = .23).

Nine of 53 bottles priced >$5 (17%) were found to be inaccurate, and 12 of 38 bottles priced <$5 (32%) were inaccurate. No statistically significant association between price category and inaccuracy was detected (p = .13).

### DISCUSSION

This study reveals that 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

![Histograms of milliliters difference between stated volume and measured volume at 50, 60, 90, 100, 120, and 150 ml markings (if present, n = 80, 65, 68, 84, 62, and 72)]

![Table 2](image)
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, Oates, Thompson, & Tong, 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, MacDonald, & Booth, 1998). Errors in infant formula reconstitution may neutralize 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 & Steel, 1975; Jacob, 1985; McJunkin, Bithoney, & McCormick, 1987; Jeffs, 1989; Daly et al., 1998). The risk of over-concentration is likely to be compounded in cases where bottles over-represent volumes.

Over-concentrated infant formula has implications for infant health. The most extreme of these is hypernatremia, a life-threatening form of dehydration (Taitz & Byers, 1972; Chambers & 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 diarrhea (Khuffash & 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, Lockton, and Davies (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 that growth may not be affected by errors in formula concentration (Fomon, Filmer, Thomas, Anderson, & Nelson, 1975; Adair, 1984). However, carer-driven feeding may override compensatory mechanisms (Bartok & Ventura, 2009).

Over-concentrated infant formula can also exacerbate constipation in formula-fed infants (Vandenplas et al., 2013; Nevo, Rubin, Tamir, Levine, & Shaoul, 2007) and increase the severity of gastroesophageal reflux disease (Vandenplas et al., 2013; Salvia et al., 2001; Carroll, Garrison, & Christakis, 2002).

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

### 4.1 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 standardizing 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.

### 4.2 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 that they are using and to test the volume markers of purchased bottles using a scale accurate to 1 g. Such scales 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 & Emery, 1979). However, despite requirements for individualized 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, Sheridan-Pereira, McCarthy, Younger, & Kearney, 2012; Wirihana & 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 overfeeding, this is alarming. Education and support of parents and caregivers who are using infant formula by health providers should be considered essential.

4.3 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 purchased in New Zealand, 42% of bottles measured were inaccurately marked (Ministry of Health, 2013).

The consequences of the inaccuracies that 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.

5 CONCLUSIONS

Inaccurate volume markers on infant feeding bottles are a previously neglected but potentially important source of error in the reconstitution of infant formula. Markers were identified that overestimate actual volume predisposing to over-concentrated infant formula and potential problems like hypernatremia, obesity, and constipation. Other markers underestimate actual volumes and thus over-dilute the end product, predisposing to undernutrition. 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.

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CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

CONTRIBUTIONS

KG conceived and designed the study, purchased infant feeding bottles, collected data, and wrote and revised the manuscript. NB conceived and designed the study, collected data, and wrote and revised the manuscript. MK conducted the statistical analysis and critically revised the manuscript. MC assisted in study design, collected data, and critically revised the manuscript. All authors contributed to and approve the final manuscript.

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