

OPEN LETTER TO US Consumer Product Safety Commission

RE: Report #20161012-1150D-214741287

Claim: <https://www.saferproducts.gov/ViewIncident/1600450>

Christy Jo Hendricks, IBCLC, RLC, CLE, CCCE, CD(DONA)
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US Consumer Product Safety Commission
Attn: Clearinghouse
4330 East West Highway
Bethesda, MD 20814-4408

January 29, 2017

Dear US Consumer Product Safety Commission and Reviewers:

I appreciate and respect the authority of your office and understand the gravity used in evaluating the safety of products. I recently received a notification that an invention I manufacture and market, the Lactation Lanyard, has been mentioned in a complaint. I am writing to clarify the utility of the product, the evidence that supports its use, and the fallacious nature of the accusations launched against this important teaching tool.

I understand that the complaint has been published and a response from myself or my company is not required, but I would be remiss if I did not respond to the false accusations directed at my product. I assure you that this is not an anonymous complaint by a "concerned citizen" but rather a spiteful person searching for an outlet for her anger and frustration. I feel compelled to address the complaint and expose the misleading (and selective) information that the author of the submission provided on your form.

The individual who submitted the claim against my product has suffered a personal tragedy (as documented in her submission and on social media) and is trying desperately to find someone or something to blame for her circumstances.

She has gone to great lengths to skew information, and now I fear she has stooped to using your office to submit a frivolous complaint in an effort to execute a personal vendetta against lactation professionals. She has been making these claims on social media and appears frustrated that they have not been taken seriously by a wide audience.

Allow me to share some background information. The person who submitted the claim is part of an organization called "Fed is Best." Her counterpart wrote a blog post attempting to discredit my lanyards and the established research that validates their utility. This new complaint issued to the Safety Commission appears to be yet another effort to grow an audience for their blog which recently featured complaints about the Lactation Lanyard. The picture of the Lactation Lanyard was removed from the editorial when I threatened a cease and desist letter. Even in the poorly written narrative, the author admits that the stomach capacity of a newborn is unknown, which is not entirely accurate. I am frustrated that this individual continues to spout misleading information in hopes of winning people over to her cause. In this case, the means definitely do not justify the ends.

The Myth of the Newborn Stomach Size: Where Did it Come From?

I started my research with my non-clinical hat on and turned to Google, since this is where my patients typically go first. When I did a Google search for newborn stomach sizes there were over 868 thousand links! I was led to a plethora of visual images depicting newborn stomach size. Some of the most popular images were the **belly ball models** that lactation consultants wear on their lanyards so they can visually educate new mothers how big their **newborn's stomach size "is."**



Via Pinterest - Tiny Tummies Teaching Tool

Clinical hat back on, I dug into the science behind these belly balls. In the 2008 Journal of Human Lactation I found a **published article that revealed a completely different utility** for belly ball models. Marble/ball models are often used to represent newborn stomach capacity; **however, their accuracy has not been determined:**

*"Measurement of infant stomach capacity has been attempted for over **100 years**. Exact volumes cannot be standardized, but data suggest that anatomic stomach capacity and physiologic stomach capacity vary widely" and also, "it is important to note that because a wide range of feeding volumes on day 1(1.1-20.4 mL) and day 3 (13.1-103.3 ml) has been reported, and the reasons for these variances are unclear, **it may be best to***



30 Sep

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Fed is Best
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Infant belly size models: What's fact and what's fiction?
@Momivist explains:

themomivist.com/2016/10/10/the...



The Newborn Stomach Size ...
Written by Jody Segrave-Daly, ...
themomivist.com

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Blog by Jody Segrave-Daly, RN, IBCLC

Allow me to address each aspect of her accusations systematically. I believe once the scientific evidence is reviewed, it will be clear that there is absolutely no basis for her claims, and her complaint to the Commission will be disregarded.

First, the **Product Detail** section on the US Consumer Product Safety Commission report contains false information. The submitter states,

"The lactation lanyard and keychain are visual tools used to convince mothers that their newborns are not in need of supplemental feeding. It claims a newborn stomach size of 5-7 mL when in fact the scientific data has shown it is 20 mL. This is leading to dangerous newborn starvation and brain injury..."

My product is indeed a visual tool that shows the approximate intake of a newborn at day one and at day three, based on the anatomy and physiology of human newborns. The card attached to the lanyard also states that a newborn should be fed frequently and that the stomach grows as milk supply increases. The product comes with an instruction card and website address where we offer additional resources. **The lanyard in no way communicates that a mother should never supplement; that is a medical decision to be undertaken by the patient and her medical, nursing and lactation team. In reference to the last statement in the Product Detail, a visual aid cannot lead to starvation or brain injury; neglect and withholding nourishment can, and we would never condone anything remotely associated with that advice.**

The complaint stresses the stomach size on day one. Immediately following birth, families are usually followed by a health professional whether a physician or medical staff in a hospital, or a midwife at a home birth or birth center.

Families are cared for and educated by qualified staff who assess a baby for anything out of the ordinary. Knowing many hospitals and birth centers utilize the lanyards encourages me that these professionals share in the belief that breastmilk is the appropriate and sufficient nutrition for newborns, and will advise a family if supplementation becomes necessary. Dyads are closely monitored by health professionals during the postpartum stay, and surveys include tracking weight and output regularly.

The first 24 hours postpartum is mostly about rest and recovery. Newborns take in small quantities of milk during each feed. The exact amount measurable in milliliters is a moot point. When a mother is feeding from her breast, there is no need to use a feeding device and measure intake. Health care professionals have many ways to assess milk transfer, including documenting diaper count. Even though I will share references for the approximate capacity of a newborn on day one, the reality is we are not actually measuring 5-7 mL and feeding with a syringe, but rather feeding at the breast and ensuring milk transfer is occurring. The measurement of 5-7 mL thus reflects the stomach size and not the exact amount of milk transferred.

I am completely bewildered by the author's paragraph on the Incident Details of the report. It is highly concerning that a Health Care Professional (stated in the submitters report and on her bio), would draw such utterly unscientific conclusions regarding a simple product. The author states:

Lanyards "...prevent them from supplementing newborns who are crying inconsolably for milk when there is not enough. The most recent scientific data shows that in fact, the newborn stomach size is 20 mL using ultrasound and autopsy...these...are leading to accidental newborn starvation and its complications, namely severe dehydration, hypernatremia, hypoglycemia and excessive jaundice which are all know causes of brain injury and permanent disability"

Again, there is not now, nor would there ever be a recommendation to "prevent them from supplementing newborns who are crying inconsolably for milk when there is not enough." That would not only be barbaric, but unprofessional and dangerous. I will not justify the author's accusation with further answers.

To address the author's assertion about the newborn's stomach capacity, there have been numerous studies performed a variety of ways that give approximations of a newborn's stomach capacity, but all offer margins of error. There are no perfect studies, and each resource reiterates that the capacity is an estimate.

I will address the three resources the author cited as her evidence of the dangers of the Lactation Lanyard. I believe it will shed light on the situation and reveal the nature of her complaint.

The author confidently states that the "most recent scientific data shows that in fact..." But she neglects to mention that the "new" scientific data is a review of six previous studies. The studies cited were from 1920, 1987, 1988, 1992, 1997, 2000, 2001. Thus, even though the article was written in 2013, it was based on research from as early as 1920. Dr. Nils Bergman, the author of the article cited as documentation for the 20 mL stomach capacity, arrived at that volume based on an average. It is also important to mention that not all stomachs were measured right at birth. The author's conclusion stated the need for shorter intervals in feeding since a newborn has a small stomach capacity. I do not believe Dr. Bergman would approve of his research being used to justify a greater volume of feeds since his research centers on promoting frequent feeding, skin-to-skin and Kangaroo Mother Care. The point made in the article is regarding feeding intervals, it is not focusing on stomach capacity.

The abstract clearly proclaims, "There is insufficient evidence on optimal neonatal feeding intervals, with a wide range of practices. The stomach capacity could determine feeding frequency. A literature search was conducted for studies reporting volumes or dimensions of stomach capacity before or after birth. Six articles were found, suggesting a stomach capacity of 20 mL at birth."

Dr. Nils Bergman's brilliant work is worth reviewing Bergman, Nils J. "Neonatal Stomach Volume and Physiology Suggest Feeding at 1-h Intervals." *Acta Paediatrica* 102.8 (2013): 773-77. Web.

The following studies suggest a stomach capacity of approximately 5-7 mL.

Hanson, L., Korotkonva, M., The Importance of Colostrum, Breastfeeding May Boost baby's Own Immune System. (2002). Pediatric Infectious Disease Jour; 21:816-821

Silverman, W.A.: Dunham's Premature infants 3rd Edition. Paul B. Hoeber, Inc., Medical Division of Harper and Brothers. New York. 1961. Pp. 143-144

Scammon, R.E. and Doyle, L.O.: Observations on the capacity of the stomach in the first ten days of postnatal life. Am. J. Dis. Child. 20:516-538, 1920

Spangler, A., Randenberg, A., Brenner, M., Howette, M., (2008). Belly Models as Teaching Tools: What is Their Utility? Journal of Human Lactation. May 2008, vol 24; no 2

These studies demonstrate that there is plenty of scientific research that can be found supporting the 5-7 mL stomach capacity reference. There are also many studies that suggest that a newborn can hold a larger volume of fluid. I concur that this is certainly a possibility. **What a newborn *can* consume and what a newborn *should* consume is also worth mentioning. Newborns, along with the general population, have physiological capacity and an anatomical capacity.**

Even if a newborn's stomach can hold more (as in the case of the autopsied newborns where the procedure to measure stomach capacity took a measurement when the stomachs began to bulge), it does not necessarily mean it SHOULD hold more. Nutritionists promote small, frequent meals as the ideal eating pattern for humans, a practice that seems to naturally begin at birth.

It also stands to reason that if women have small amounts of colostrum on day one, the baby must need small amounts of colostrum on day one. All of the emphasis on research and science laboratory studies is important, but it is equally important to consider the anthropology and biological norm of infant feeding.

The Lactation Lanyards have many uses, including supporting the evidence that newborns consume small amounts of colostrum. This information empowers mothers and gives them a more accurate consumption goal than the 2 oz. formula bottles distributed in many hospitals. If families are not shown the volume for an average feed on day one, they are apt to consider the formula bottle as the standard of feeding rather than the anatomy of the infant.

Even though research has validated the small stomach capacity of a newborn, perhaps the most compelling argument for educating families on the infant's stomach capacity is corroboration by the most trusted health care agencies and organizations in the United States. The following agencies accept the information shared on the Lactation Lanyards.

The Academy of Breastfeeding Medicine documents infant's intake in the first 24 hours to be between 2-10 mL per feed. BREASTFEEDING MEDICINE Volume 4, Number 3, 2009 © Mary Ann Liebert, Inc. DOI: 10.1089/bfm.2009.9991

American Academy of Pediatrics Section on Breastfeeding documents a newborns intake on days 1-2 will be between 5-10 mL

American Nurses Association <http://www.nursingworld.org/MainMenuCategories/Policy-Advocacy/Positions-and-Resolutions/Issue-Briefs/Breastfeeding.pdf>

American Pregnancy Association: "It is normal to make only 1-4 teaspoons of colostrum per day."
<http://americanpregnancy.org/breastfeeding/colostrum-the-superfood-for-your-newborn/>

The Office of Women's Health <https://www.womenshealth.gov/breastfeeding/learning-to-breastfeed.html>

La Leche League <http://www.la lecheleague.org/faq/colostrum.html>

The support of professional organizations and well-documented research has spawned the development and spread of this valuable teaching tool. Many pharmaceutical companies have similar products to our Lactation Lanyard (see below),

yet I did not see any reports on these products. I am surprised to be personally targeted; it appears that the author's complaint may be with me personally rather than truly concerned about a product I created. Why have none of these other teaching tools been reported?

The first picture is of the Lactation Lanyard, the following pictures are samples of other very similar items.



The Lactation Lanyard is a portable teaching tool used by health professionals, perinatal professionals, public health educators and breastfeeding advocates. Lactation Lanyards come equipped with double-sided colostrum card and informational card. It also displays the website which provides additional education and resources.

www.Birthingandbreastfeeding.com

Belly Beads
Meg Beard MPH, MCHES, RD, IBCLC
P.O. Box 60213, Santa Barbara, CA 93160-0213
(805)448-4115 • megrtd@cox.net

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Belly Bead Info

User Tips

A newborn's stomach is very small at birth. Nature intended it to stretch out and enlarge gradually as mother's milk increases in volume throughout the first week. This is why large volumes given early on can cause baby to spit milk back up, give him a stomachache, or cause him to sleep unnaturally long and not nurse often enough to stimulate mothers' production well. Also, babies who are routinely given larger amounts of milk at a feeding (via bottle) than nature intended may stretch out their stomachs too far and then think they need more than they really do, making mother feel like she must not be producing enough.

[Click here to View Larger](#)

Colors may Vary

- Show the approximate size of a normal newborn baby's stomach the first few days and weeks of life.
- Help parents of newborns visualize how little milk baby actually needs per feeding and why babies need to eat often.
- Teach formula feeding mothers appropriate amounts to feed by bottle.
- Reassure pumping mothers that they are making enough milk.

Breastmilk is a Gift!

Belly Beads <http://www.sbbreastfeedingcoalition.org/about-us>

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HOME > BABY BELLIES POCKET MODEL KEY CHAIN

Baby Bellies Pocket Model Key Chain

★★★★★ (0) SKU: #53526

\$15.00

Quantity:

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Details

Help breastfeeding mothers understand their newborns' nutritional needs. Handy key chain fits easily in your pocket and features three plastic models that represent the small amounts of breastmilk newborns need per feeding on the first, third, and tenth days of life. The color of each model represents a breastfed baby's healthy stool color on the corresponding day. Includes informative laminated plastic key card.

Baby Bellies Pocket Keychain

<http://www.healthedco.com/53526-Baby-Bellies-Pocket-Model>

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Item Number: 53526x25

Baby Bellies Pocket Model (Pack of 25)

£420.00 inc VAT £350.00 exc VAT

Be the first to review this product

Pack of 25 Baby Bellies Keyrings that show newborn baby stomach sizes on the first, third and tenth days, and the colour of corresponding stools for each day.

Delivery Estimate

✓ Available, 3 - 5 working days

Qty: **ADD TO BASKET**

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Many items are also sold internationally

<http://www.anatomystuff.co.uk/baby-bellies-pocket-model-pack-of-25.html>

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Hospital Products

- Carum Hospital Grade Breastpump
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- Carum Battery Hospital Grade Breastpump
- Calypso Compact
- Amaryll Start
- Clinicare Pumpset
- One Mum Topsets
- Clinic Pumpset (non sterile)
- One Mum Pumpset (Sterile)
- Clinistore Disposable Bottles
- Belly Balls**
- Belly Balls and Demo Breast

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Visual teaching aid for midwives and feeding experts

Belly Balls



The supportive teaching aid for nursing mothers. In the first few days after their baby's birth, mothers produce the right amount of breast milk for their baby. To help mothers better to understand this concept, Ardo has designed Belly Balls.

Each size of Ardo Belly Balls corresponds to the estimated average size of a new-born's elastic stomach. The average size of a new-born baby's stomach will be:

- on the first day: 5-7 ml
- on the third day: 22-27 ml
- on the fifth day: approx. 57 ml

[Buy Belly Balls](#)

References: Wang, Y et al: Preliminary Study on the Blood Glucose Level in the Exclusively Breastfed Newborn; J Trop Peds 1994, 40:187-88. Saint L, Smith M, Hartmann P.E: The yield and nutrient content of colostrum and milk of women form giving birth to 1 month post-partum; British Journal of Nutrition 1984, 52, 87-95. Scammon, R, Doyle L: Observations on the capacity of the stomach in the first ten days of postnatal life. Am J Dis Child 1920; 20:516-38

Newsletter

E-mail address

Belly Balls <http://www.premierhh.co.uk/ardo-belly-balls.html>

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Home / Educational Materials / BREASTFEEDING MATERIALS / BREASTFEEDING TEACHING AIDS / Baby Bellies Display

Baby Bellies Display

Baby Bellies Display for Breastfeeding Education

SKU: 1847
Manufacturer part number: 79077

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The Baby Bellies Display addresses the question: "Is my baby getting enough breastmilk?" Use this reassuring display to help new mothers visualize their babies' small stomach sizes during the first 10 days of life and how much milk it can hold. Models come in a plastic bag and includes a two sided card with additional information.

Baby Bellies Display

Cascade Health Care Products <https://www.1cascade.com/baby-bellies-display>

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Belly Beads Lactation Tool

2 customer reviews ★★★★★ Average rating 5/5
\$20.00 USD

Ease new mothers' minds

Snugabell's Belly Beads are an effective and beautiful visual teaching tool for lactation professionals, suitable for both a group and individual setting. The three beads represent a newborn's stomach size on day one, day three, and day ten, as referenced on the attached belly disc.

This tool makes it easy for new parents to visualize how little milk baby actually needs, as well as why newborns eat so frequently. This reinforces that supplements are not needed and that colostrum, the first milk, is more than enough to meet a newborn's needs. Belly Beads are also effective in showing pumping and formula-feeding moms the appropriate amount to feed by bottle.

IN STOCK

1 ADD TO CART

Product Details

Belly Beads Lactation Tool <https://snugabell.com/products/belly-beads-lactation-tool/>

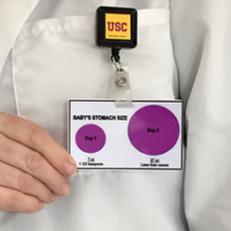
 **Geddes Productions, LLC**

Breastfeeding Techniques That Work™
By **Kittie Frantz, RN, CPNP-PC**

"Remember you are not managing an inconvenience, you are raising a human being" ... **Kittie Frantz**

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STOMACH SIZE BADGE ATTACHMENTS

 Want that perfect addition to your work badge? These Stomach Size Badge attachments, just under 3 1/2" by 2 1/4", are perfect for anyone helping Mom with lactation. Made from a durable plastic, these badge cards aren't a flimsy laminate. They will last forever. Clearly showing Baby's actual stomach size on day one and day three you can reassure parents they don't need to supplement their breastfeeding or over feed the formula fed infant.

Based on the study by Scammon & Doyle that involved 16,000 test weights of breastfed infants, the Day One is a marble size that would hold 7cc with Day Three a ping pong ball size. We tried it and ping pong balls hold 27cc!

These cards are a perfect gift for the staff on the mother-baby unit. Especially after they have completed the training to work towards the Baby Friendly designation. And they make marvelous Holiday gifts or gifts of appreciation also!

badge (c) 2012 Geddes Productions, LLC

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Protecting, supporting and promoting midwifery

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Colostrum The Gold Standard Visual Aid

\$45.36

Convenient, pocket-sized visual makes it easy to understand the small amount of colostrum a newborn baby needs at each feeding. Use as an effective way to teach the importance of early and often feeding as new mums provide this perfect first nutrition. Real spoon filled with simulated colostrum comes with informative plastic key card.

SKU: TA035

Categories: What's New, Models

Tags: Breastfeeding, Childbirth Preparation

Colostrum the Gold Standard Visual Aid

<http://www.childbirthgraphics.com/85156-Colostrum-The-Gold-Standard-Display>

Many educational pamphlets and posters are available from companies that support health facilities. A few examples are provided below.

Nurturing healthy babies, growing healthy families. [My Account](#) [Register](#)  [0 Items](#)


[Shop by Subject](#) | [Shop by Type](#) | [Sale](#)

HOME > **BABY BELLIES TEAR PAD**



Baby Bellies Tear Pad

★★★★★ (0) SKU: #52069

\$27.23

Quantity:

Details
Baby Bellies Tear Pad

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Encourage breastfeeding moms who have questions about how much breastmilk newborns need. Circles on this informative handout correspond to the approximate sizes of a baby's stomach on days 1, 3 and 10. Viewers can see just how small a newborn's tummy is to help them understand that young babies only need a small amount of breastmilk at a time. Also covers how often newborns need to be fed and provides reassuring guidelines for knowing whether they are getting enough breastmilk. English on one side and Spanish on the other. 100 sheets per pad.

©2016, www.childbirthgraphics.com

<http://www.childbirthgraphics.com/52069-Baby-Bellies-Tear-Pad-English-Spanish>

Breastfeeding Around the Clock

Two important facts for every new parent to know:

First, babies don't come with instruction manuals and will rarely follow the "textbook" advice from pediatricians, friends and family members.

Second, babies can't tell time! This is especially important in relation to breastfeeding. A newborn's stomach is very small when born (about the size of a small marble on day 1, the size of a ping pong ball on day 3, and the size of a large egg on day 10) so they need to be fed – and they need to be fed often.



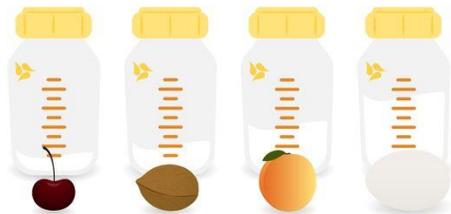
It is totally normal for baby to breastfeed at least 8-12 times in a 24 hour period. That can be exhausting! You may find yourself thinking they will never sleep longer than an hour, but they will. It may be a rough few months, but try not to worry too much about your milk supply. Feeding baby on cue not only makes sure baby is getting plenty to eat, but also teaches your body how much milk it needs to make to satisfy baby's needs.

Your well-meaning partner or other family member may offer to feed the baby during the night. While that may be a tempting offer, skipping a feeding can hurt your supply and can be uncomfortable for you as your milk will build up and your breasts will get swollen. If someone does feed the baby, it is important to pump or hand express during that feeding time to provide the physical cue to your body. This is how the cycle of breastmilk production works. Many moms find that it helps to have baby nearby in a bassinet or a co-sleeper for nighttime feedings. Nursing in the lying down position is also a great way to get some rest in at the same time.

<https://www.lansinoh.com/en/help-advice/breastfeeding-around-the-clock>

Newborn Stomach Size

Your breastmilk is all your baby needs!



Day	Stomach Size	Comparison
Day One	5 to 7 ml .5 tsp	size of a cherry
Day Three	22 to 27 ml .75 to 1 oz	size of a walnut
One Week	45 to 60 ml 1.5 to 2 oz	size of an apricot
One Month	80 to 150 ml 2.5 to 5 oz	size of a large egg

medela

More info at <http://bit.ly/breastfeeding>
Source: <http://www.ill.org/babycenter.com>

<http://blog.medelabreastfeedingus.com/2015/04/the-size-of-your-babys-stomach-breastfeeding-in-the-early-days/>

Belly Balls

Lactation Education Tool

907904

This tool makes it easy for new parents to visualize the size of their newborn's stomach and how much milk it can hold at birth. This reinforces that supplements are not needed and that colostrum, the early milk, is more than enough to meet a newborn's needs.

But there is more. Researchers have found that on **Day 1**, the newborn's small stomach does not stretch to hold more, as it will even a day or two later. This explains the experience of countless hospital nurses who have learned the hard way that when newborns are fed an ounce or two by bottle during the first day of life, most of it tends to come right back up. The walls of the newborn stomach stay firm, expelling extra milk rather than stretching to hold it. On **Day 1**, a newborn's stomach capacity is about one-sixth to one-quarter of an ounce (5 to 7 ml) per feeding. Not surprisingly, this amount of colostrum is ready and waiting in the breast. By **Day 3**, as the baby ideally gets more of these small, frequent feedings, his stomach expands to about the size of a ping pong ball to hold more milk. By **Day 10**, it is the size of an extra-large chicken egg.

Is it a good idea to give a newborn more milk at each feeding to try to stretch out the stomach sooner?

No. This is NOT a case of more is better. Why not?

Small, frequent feedings set up a healthy eating pattern right from the start. Adults are now advised by experts that it is healthier to eat smaller amounts more often and the same is true for babies and children. Coaxing a baby to take more milk leads to overfeeding. If feeling overfull at feedings becomes the norm for a baby, this may lead to unhealthy eating habits that contribute to childhood obesity later.



WARNING

Belly Balls may present a **CHOKING HAZARD** and are for adult use only. Keep out of reach of children. Belly Balls are intended to be used and rearranged within the supplied bag. Accordingly, please do not remove Belly Balls from the bag.

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Belly Balls

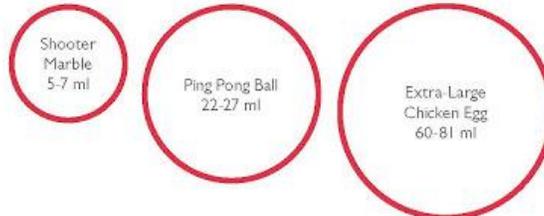
Lactation Education Tool

Shooter Marble = Approximate stomach capacity of a newborn on Day 1

Ping Pong Ball = Approximate stomach capacity on Day 3

Extra-Large Chicken Egg = Approximate stomach capacity on Day 10

Softball = Approximate stomach capacity of an adult



Silverman MA, ed. *Dunstan's Premature Infants*, 3rd edition, New York: Paul B. Hoeber, Inc., Medical Division of Harper and Brothers, 1961, p. 143-144.
Sommner R and L Doyle. Observations on the capacity of the stomach in the first ten days of postnatal life. *Am J Dis Child* 1920; 205:6-38.
Zangen S, C, Di Lorenzo T, Zangen H, Pertz L, Schwabkowsky, and F Heman. Rapid maturation of gastric relaxation in newborn infants. *Pediatr Res* 2001; 50(5): 629-32.
Adapted from Linda J. Smith's, *Coach's Notebook: Games and Strategies for Lactation Education* Boston, Jones and Bartlett, 2002.



HOPE INSPIRED. HOSPITAL TRUSTED.

<https://www.ameda.com/milk-101-article/breastfeeding-guide-for-the-first-12-months/>

These complaints seems to stem from the offense the author takes regarding breastfeeding promotion and public health advocacy in regards to breastfeeding supporter. I am assuming that she is unaware that **the formula companies also use the same research to educate families about the infant's small stomach.**

A large formula manufacturer, Gerber, states:

“Your baby’s tummy is tiny at birth—the size of a marble—and grows to the size of an egg around day 10. Many babies eat a lot quickly, so spit-up is common, and often the result of overeating or air entering the stomach during feeding. ‘Happy spitters’ spit up one to two mouthfuls during, or shortly after, each feeding and show no sign of discomfort.

As your baby’s stomach grows and her digestive system matures, the rate and frequency of spit-up will decrease. Your baby will likely outgrow spitting up around the time he can sit up, but it can continue through the first year in some babies.” (www.Gerber.com)

Below are two samples of parent education provided by Similac, one of the top three formula manufacturers in the United States.

FeedingExpert
from Similac

24/7 live help.
Nurses & lactation
consultants available
800-986-8800
FeedingExpert.com

Expert feeding help.
To comfort both you
and your little one.

Similac

*Lactation consultants provided by LifeCare, Inc.

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Abbott
A Division of

Little tummies take time to grow

Your baby's tummy is about the size of a small marble at birth. After 3 days, it's about the size of a ping-pong ball, but still can't hold much!

Baby's tummy size

Day 1
Marble

Day 3
Ping-pong ball

Until she's about 4 months old, your baby's tummy can only hold small amounts of milk at a time. Too much milk during feedings can lead to things like fussiness or spit-up.

† These models may be useful only as a representation of the average breast milk intake during the early newborn period.
1. Spangler AK, et al. J Hum Lact. 2008; 24(2):199-205.

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If the author desires to take on the Lactation Lanyards, she must also work to discredit the American Nurses Association, Department of Women's Health, AAP, ABM, Public Health Agencies, WIC, La Leche League, hospitals, formula companies and many educational institutions. There are a plethora of products and information sheets that she will need to prove provide "unsafe information." We believe we are in good company and do not feel threatened by the baseless rhetoric being directed at our teaching tool.

In addition to Dr. Nils Bergman's research, the author of the complaint offered two additional pieces to justify her submission to the Product Safety Commission. One such documentation, I will not address as it is her own blog about her story—hardly evidence-based research. The second is equally subjective, but I will address it as I feel it may be the main reason for her witch hunt.

The submitter shares a story about her son. It appears that she experienced a personal tragedy. The narrative on the report to Commission mirrors the story she shares across social media. Her story clearly states that she was followed by a lactation consultant and a pediatrician following the hospital birth of her son. She explains the feelings she encountered on day four, when she realized she had been starving her baby. There is not one mention of my lanyard in

her story. There is not one reference to its use in leading to dehydration. The second part of her story reveals that she was diagnosed with retained placenta, a condition that results in inhibiting milk production (along with other complications). It is pertinent to note that it would not matter if her baby's stomach capacity was 5 mL or 30 mL, the newborn was experiencing weight loss and dehydration due to little or no milk transfer, not because he had a small stomach. There is absolutely no parallel that can be drawn between our product and her baby's consequences. I can only speculate how she must have felt allowing her child to go hungry. She may have been failed by her medical team and may have ignored her own instincts—but whatever led to her withholding food from her newborn is in no way associated with a lanyard. She will have to come to grips with her own feelings and emotions. As a doctor, she is no doubt aware that complications and poor outcomes occur in spite of the best available care. Sometimes, there is not one to blame. <https://fedisbest.org/2015/04/letter-to-doctors-and-parents-about-the-dangers-of-insufficient-exclusive-breastfeeding/>

I can respect the concerns this individual shares. As a medical doctor working in an emergency room, she undoubtedly faces many difficult situations and hopes to avoid others going through what she experienced. I only hope she channels her energy in a positive, honest way. I question her lack of scientific evidence and knee-jerk reaction to attack those she perceives led to his condition—the science just does not back up her accusations.

According to the **About Section** on the Fed is Best Foundation's Facebook page, "Christie del Castillo-Hegy, M.D investigates the real-life breastfeeding stories of mothers through social media and holds the largest collection of breastfeeding stories in existence on her Facebook page." I have no idea if her claims are true, but I do know she solicits stories from her followers that include "unacceptable outcomes" from breastfeeding and requests they sign her petition to "Protect Newborns from Brain Injury Caused by Insufficient Breast Milk Intake."

Her hobby of collecting stories has apparently caused her to put metaphoric rhetoric above science. She is creating her own truth—a very dangerous practice.

I believe I have done due diligence in refuting the complaint issued against the Lactation Lanyard. Not only did the submitter not prove the lanyards to be a safety concern, she used your organization and submission process to pursue a vendetta as publicly as possible. She has wasted everyone's time engaging in this dispute.

I personally feel that Dr. Castillo-Hegy acted irresponsibly in abusing the Public Safety Commission Office by submitting an unfounded, frivolous complaint. She has selfishly added to the demands of your office and consumed a considerable amount of my time in her efforts at self-promotion. I understand from the description on your website that this complaint should have never reached your office.

The U.S. Consumer Product Safety Commission (CPSC) is an independent federal regulatory agency that was created in 1972 by Congress in the [Consumer Product Safety Act](#). In that law, Congress directed the Commission to "protect the public against unreasonable risks of injuries and deaths associated with consumer products."

From the statement on the complaint form, the submission was regarding information and how one individual was able to twist it to her perception. Your office handles complaints about a product. If your office is now in the business of handling complaints about information shared, then perhaps it is time for me to issue a counter-complaint about Dr. Castillo-Hegy who apparently is offering fear-based education and is negligent in respecting the policy statements of her medical professional associations that recommend exclusive breastfeeding for the first six months as the optimal feeding advice.

In closing, I realize the US Consumer Product Safety Commission receives numerous complaints and must take each one seriously. However, I was disappointed that there does not seem to be an independent investigation prior to publishing complaints. A quick Internet search would have verified our tool has not been responsible for any harm and promotes the same information shared by our US health agencies.

I can sympathize with the doctor's predicament, and her desire to find a cause for her son's condition, but I do not respect her accusations against a product that promotes breastfeeding and supports every major health organization's recommendations (WHO, CDC, AAP, ACOG and many more).

While the physician submitting a complaint was undoubtedly beside herself when her child became ill, my Lanyards cannot be faulted.

The author of the complaint shares her personal story as validation that the Lactation Lanyards caused dehydration in her infant. Let me reiterate: **the Lanyards come equipped with a double-sided instruction card that explains that an infant's stomach grows rapidly and babies must be fed frequently.**

The size of the infant's stomach is a moot point. No matter how small a newborn's stomach size is, if a mother is not producing any milk due to retained placenta, the baby will become dehydrated. It is my professional opinion as an International Board Certified Lactation Consultant (IBCLC), that this scenario occurred due to insufficient milk transfer due to low milk supply. The diagnosis of retained placenta is of utmost concern. I am perplexed that a family doctor would try to blame a three dimensional teaching tool on her child's condition. She shares the rest of her story (most likely what lead to low milk supply) here: <https://fedisbest.org/2016/10/the-rest-of-my-breastfeeding-story/>

This complaint appears to be an attempt to promote her blog and discredit science for personal gain and notoriety using the US Consumer Product Safety Commission platform. I am sorry your office was summoned for this purpose.

Thank you for your diligence in accepting complaints and rebuttals in an effort to improve safety for everyone.

Normalizing Breastfeeding through Education and Support,



Christy Jo Hendricks, IBCLC, RLC, CLE, CCCE, CD(DONA)

<https://www.ncbi.nlm.nih.gov/pubmed/19783000>

<http://californiabreastfeeding.org/wp-content/uploads/2015/02/CBC-Hypoglycemia-2015.pdf>

http://www.thevisualmd.com/visualizations/result/infant_stomach_capacity_as_compared_to_various_foods

<http://online.liebertpub.com/doi/abs/10.1089/bfm.2010.9986>

<https://www.aap.org/en-us/about-the-aap/aap-press-room/pages/AAP-Reaffirms-Breastfeeding-Guidelines.aspx>

<http://www.nursingworld.org/MainMenuCategories/Policy-Advocacy/Positions-and-Resolutions/Issue-Briefs/Breastfeeding.pdf>

<http://hosppeds.aappublications.org/content/5/9>

<http://www.la lecheleague.org/fag/colostrum.html>