BEST PRACTICES: Infant Formula Comparisons and Recommendations

Although human breast milk is well known to represent the best option to meet infant nutritional needs,[1] it is important to recognize that there are oftentimes barriers to providing it. Some of the common barriers to breastfeeding include personal choice, concerns for possible risks to exposure to maternal medications, as well as socioeconomic factors. According to the Centers for Disease Control, in 2011 nearly 8 in 10 newborns were initially breastfed. However, by 6 months less than half were breastfeeding, and only 27% were doing so at their 1-year birthday.[2]

Jenifer R. Lightdale, MD, MPH
Division Chief, Pediatric Gastroenterology, Hepatology and Nutrition
UMass Memorial Children's Medical Center
Professor of Pediatrics
University of Massachusetts Medical School
Worcester, MA

Regardless of underlying factors, physicians need to be prepared to counsel many women who cannot or who decide not to breastfeed. When discussing formulas, physicians should also be sensitive to families with limited means, who may be contending with cost of formulas in their household budgets. Such families may benefit from reassurance that Store Brand Infant Formulas present a viable, cost-effective way to nourish infants and are comparable to name brands in providing total infant nutrition.

Food Insecurity and Formula Stretching

One of the areas of great concern in contemplating the needs of disadvantaged families in the United States is the high prevalence of food insecurity. To measure the potential impact of household food insecurity on infants, Burkhardt and colleagues recruited families at urban health centers and surveyed whether respondents were "food secure," "food insecure without hunger," or "food insecure with hunger."[3] The survey also asked about participation in supplemental food programs and ways in which participants may be stretching a limited food supply for their infants.

More than 2 in 10 families surveyed in this study reported themselves to be food insecure without hunger, while nearly 1 in 10 was food insecure with hunger. Results of the survey also suggested that participation in public assistance programs was more likely to be associated with food insecurity than non-participation.

In Burkhardt's study, many of the food insecure families (27%) stated that they stretched formula either by diluting it, using less of it, or increasing the time between feedings. Even food secure families were not immune to the use of stretching strategies, with 9% also reporting using such approaches to conserve formula allotments. More than two-thirds of families who received formula from Women, Infants, and Children (WIC) said they ran out before the end of each month. The study concluded that developing interventions for families with food insecurity are critical.

The need for interventions that reduce costs for infant nutrition has become amplified since 2009, when WIC decreased monthly infant formula allotments in an effort to encourage breastfeeding.[4] Allowances for less formula from a program that was designed to be supplemental—a fact of which not all families and clinicians may be aware—may inadvertently be contributing to widespread use of formula-stretching strategies.[3]

Addressing Food Insecurity's Effects with Store Brand Infant Formula

One way to address food insecurity in families with infants may be to advance the use of Store Brand Infant Formulas, which often cost up to 50% less than national brands, and may save families up to $600 annually, according to a January 2016 price comparison survey.[5] Store Brand Infant Formulas are designed to meet all American Academy of Pediatrics (AAP)-recommended nutrition targets, as well as FDA requirements.[6]

The promise of cost-savings as an intervention to combat food insecurity assumes that families who may be at risk for their WIC-supplemented formula allowance to run out before a month's end will be open to using a less expensive alternative. However, this may not be the case. The Burkhardt study found 76% of respondents said they would not buy Store Brand Infant Formula, and approximately 50% said they believed Store Brand and name brand infant formulas were not nutritionally comparable.[3]

The misperception that name brand formulas provide superior nutrition likely contributes to strategies of diluting infant formula or otherwise stretching it by limiting access to the infant. Such formula stretching is dangerous for infants, and can contribute to poor weight gain and failure to thrive. According to the AAP, watering down formula can cause malnourished infants to develop water intoxication, which can be a cause of neonatal seizures.[7] There have even been reports of infants dying from water intoxication.

The risks posed by formula stretching may serve as the impetus for physicians to use standardized questions to probe for household food insecurity during infant visits. Physicians also can play a crucial role in explaining that the lower cost of Store Brand Infant Formulas is not due to inferior quality. Store Brand Infant Formulas are mandated to meet all requirements of the Infant Nutrition Act, and are highly regulated products by the FDA. Indeed, costs of Store Brand Infant Formulas, as with all generics, are lower in large part because they are not heavily advertised or provided as samples, which allows savings to be passed along to consumers. Of course, the lack of advertising also has meant that Store Brand Infant Formulas may not seem as familiar to families of infants as the more heavily advertised name brands.

Is Switching Formula Safe?

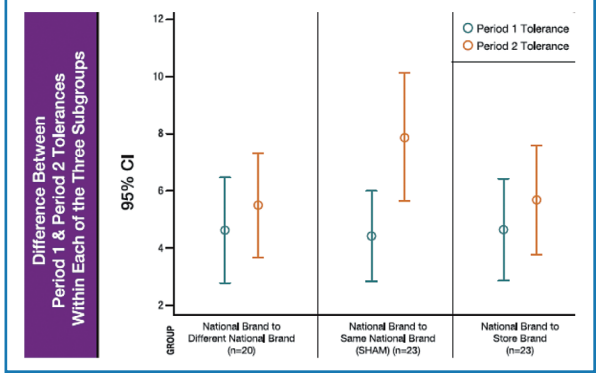
There can be concerns among both clinicians and families about the safety of switching to an equivalent Store Brand from name brand infant formulas. A study by Barber and colleagues looked at switching between the milk-protein based formulas of name brands (Similac® or Enfamil®) and a Store Brand (Parent's Choice®) and symptoms of tolerance (burping, gas, irritability, spit-up).[8] In this study, the investigators randomized 67 infants to switch from the name brand formula they were on to either an alternative formula or a placebo sham, which was their same formula but repackaged.

The infants were observed for 4 days prior to and 4 days after the switch, which took place over a 3-day "transitional period." Caregivers had the option to use the 3 days to switch gradually or immediately, and used a diary to report on tolerance.

In this study, switching from a name brand to either another name brand or to a Store Brand produced no statistically significant increases in burping, gas, crying, and irritability. Meanwhile, the group which remained on the same formula (sham), experienced statistically significant increases in burping, gas, crying, and irritability (but not spit-up).

Further analysis of combined tolerance variables revealed no statistically significant differences across the 3 groups after switching (**Figure**). The authors concluded that switching between different brands of infant formula–including from name brand to Store Brand–is safe. In addition, they found tolerance to be similar, whether the switch occurred gradually over 3 days, or all at once.

FIGURE. Clinical Switch Data Between National and Store Brand Infant Formula



Conclusion

Although breastfeeding is the preferred method of nourishing infants, not all mothers are able or choose to do so from birth, while many others may introduce infant formulas after a few months of exclusive breastfeeding. Research suggests that a substantial number of WIC families may employ stretching strategies to make their monthly allotment of formula last. Families using formula stretching strategies may not be aware of the dangers involved in such practices, and may misperceive lower cost formula as inferior.

Data indicate that switching from a national brand formula to an equivalent Store Brand is well tolerated. Store Brand Infant Formulas are highly regulated by the FDA, and are designed to provide the same nutritional targets as their name brand counterparts. Pediatricians and other clinicians can serve a valuable role in reassuring patients that using less expensive Store Brand Infant Formula is safe, and greatly preferable to engaging in practices of formula stretching.

References

1. Section on Breastfeeding: Breastfeeding and the use of human milk. *Pediatrics*. 2012;129(3):e827-e841.
2. National Center for Chronic Disease Prevention and Health Promotion. Breastfeeding Report Card: United States/2014 . CDC website. http://www.cdc.gov/breastfeeding/pdf/2014breastfeedingreportcard.pdf. Published July 2014. Accessed January 26, 2016.
3. Burkhardt M, Beck A, Kahn R, Klein M. Are our babies hungry? Food insecurity among infants in urban clinics. *Clin Pediatr*. 2012;51(3):238-243.
4. Martinez-Schiferl M. WIC participants and their growing need for coverage. Income and Benefits Policy Center, Urban Institute. April 2012. http://www.urban.org/sites/default/files/alfresco/publication-pdfs/412549-WIC-Participants-and-Their-Growing-Need-for-Coverage.PD. Accessed January 26, 2016.
5. Comparison based on January 2016 survey conducted by Perrigo Nutritionals of Store Brand Infant Formulas versus the leading national brands. Actual prices and savings may vary by store and by location.
6. US Food and Drug Administration. Questions & answers for consumers concerning infant formula. US FDA website. http://www.fda.gov/food/foodborneillnesscontaminants/peopleatrisk/ucm108079.htm#7. Updated June 5, 2015. Accessed January 26, 2016.
7. American Academy of Pediatrics. How to safely prepare formula with water. Healthychildren.org website. https://www.healthychildren.org/English/ages-stages/baby/feeding-nutrition/Pages/How-to-Safely-Prepare-Formula-with-Water.aspx. Updated November 21, 2015. Accessed January 26, 2016.
8. Barber C, Tusing A, Kisamore L, et al. The safety of formula switching for infants. http://www.storebrandformula.com/Switching-Formulas-Store-Brand-Formula-Clinical-Study.pdf. Accessed January 26, 2016.

Copyright © 2016 Frontline Medical Communications Inc. All rights reserved. No part of this publication may be reproduced or transmitted in any form, by any means, without prior written permission of the Publisher. Frontline Medical Communications Inc. will not assume responsibility for damages, loss, or claims of any kind arising from or related to the information contained in this publication, including any claims related to the products, drugs, or services mentioned herein. The opinions expressed in this supplement do not necessarily reflect the views of the Publisher. All other trademarks are property of their respective owners.

Faculty Disclosures: **Dr. Lightdale** reports that she is on the medical advisory board for Perrigo Nutritionals, and is an invited speaker for Mead Johnson & Company, LLC.

A supplement to Pediatric News. This supplement is sponsored by Perrigo Nutritionals.
pediatricnews.com/resources/best-practices.html