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## FEATURE ARTICLE

### **Chemical Contamination Found In Human Milk**

Human milk is without question the best source of nutrition for infants and young children. In addition to meeting nutritional needs, human milk provides immunologic, developmental, psychological, economic, and practical advantages. A recent report (February 2005) of perchlorate (a chemical found in rocket fuel) contamination in the breastmilk of thirty-six California mothers has caused parents and health care professionals to question the safety of human milk and breastfeeding.

Perchlorate is both manmade and occurs naturally in the environment. It is used to make rubber, paint, fireworks, highway flares, and rocket fuel. Food and water are the primary sources of human contamination. Perchlorate interferes with iodine uptake in the thyroid gland and can inhibit thyroid function. Impaired thyroid function in expectant mothers can cause delayed development and decreased learning capacity in the newborn. Studies of perchlorate contamination in expectant mothers have produced conflicting data. Currently there are no reports of adverse effects in breastfed infants.

In February 2004, Northwest Environmental Watch reported high levels of polybrominated diphenyl ethers (PBDEs) in the breastmilk of

### *Caught In The Web* **State Breastfeeding and Maternity Leave Legislation**

The United States Breastfeeding Committee has released a detailed analysis of state breastfeeding legislation. *State Legislation that Protects, Promotes and Supports Breastfeeding* is available online at [www.usbreastfeeding.org](http://www.usbreastfeeding.org)

nine Puget Sound women. PBDEs are flame retardant chemicals that are used in the production of computer plastics, furniture foam, textiles, and other products. In laboratory studies, PBDEs cause learning, memory, and behavior problems. PBDEs have been banned in Sweden and environmental, public health, and consumer advocacy groups are seeking a ban on the use of PBDEs in Washington State.

### **Human Milk a Biomonitoring Tool**

Environmental chemicals are found in air, water, food, soil, and dust. Biomonitoring is the direct measurement of environmental chemicals in people—usually in blood or urine specimens but also in human milk. Human milk has

## Ask Amy

### Q. How long can I store my breastmilk?

Treat your breastmilk the same way you treat other foods. Place your milk in any container made for food. Store your milk in a cool place, place it in the refrigerator as soon as possible, and freeze it for later use. Recommended storage times vary from study to study. To be safe, store your milk in a cool room for up to 5 hours, in the refrigerator for up to 5 days, in the freezer section of a refrigerator/freezer for up to 5 months, or in an upright or chest freezer for 5 months to 1 year.

been used as a biomonitoring tool for approximately 50 years. Because human milk is easily accessible and has a high fat content, it is well-suited for this purpose. The level of chemicals in human milk is a measure of the exposure of the population at large, particularly women and children.

The presence of environmental chemicals in human tissues has been documented since the 1950s. But only recently has public awareness increased. The term “environmental chemicals” refers to pharmaceutical agents, alcohol, heavy metals, and organic compounds. Recent research has focused on a specific group of environmental chemicals known as persistent, bioaccumulative, and toxic (PBT) chemicals. Widely used, PBTs are fat-loving (lipophilic) and persistent. As such, they can accumulate in human body fat including the breast and subsequently in human milk.

The amount of fat in human milk varies from month to month, week to week, day to day, and from the beginning to the end of a feeding. Therefore the concentration of PBTs in human milk will vary depending upon when the sample is collected. In addition, there are number of study limitations that make interpretation of the

perchlorate data and guidance difficult. These include:

- differences in study design
- incomplete reporting of sampling techniques and characteristics of the mother
- use of participant samples that are not representative of the general population
- timing of sampling

### Study Design

Because the composition of human milk changes over the course of a day, differences in the way human milk samples are collected can affect the usefulness of the data. Some researchers collect human milk from two or more mothers and combine or pool the milk prior to analysis. Pooling results in loss of information on ranges of concentrations and makes it impossible to examine the impact of lifestyle and other factors on the level of environmental contamination.

### Incomplete Data

Certain types of information can aid interpretation of the data. But quite often, this information is not collected or is not included in the published results. Useful information includes the method(s) used to collect the human milk samples, the timing of sample collection, demographic and lifestyle information, and maternal age, parity, dietary information and occupational

exposures. A particular concern is the absence of data regarding whether the infants in the sample were exclusively or partially breastfed.

### **Sample size**

While some large-scale studies have been conducted, most study samples were small numbers of women from specific geographic areas, as opposed to large samples representative of the general population.

### **Timing of Sampling**

The concentration of some environmental chemicals in human milk decreases over time. When samples are collected at different times, it limits the ability of the researcher to explore trends and reach conclusions about infant exposure and the impact on infant health.

### **What's a mother to do?**

Recent reports of environmental contamination represent small samples of women in very specific geographic areas. While further investigation is warranted, parents and professionals may find it useful to know that, (1) levels of most PBTs in human milk appear to decline over the course of lactation; (2) most women appear to have lower levels of PBTs with successive lactation; (3) levels of PBTs in milk increase with the age of the mother; and (4) consumption of large amounts of fish and marine mammals caught in polluted waters is associated with higher levels of some PBTs in human milk.

## *Did You Know?*

### **2003 U.S. Breastfeeding Initiation Rates Decline 4%**

In-hospital breastfeeding rates during 2003 declined by four percentage points following a decade of increases. Breastfeeding at six months of age declined marginally compared to 2002. According to the Ross Mothers Survey, declines occurred predominantly in black and Hispanic mothers, mothers under 24 years of age, those with a grade school education, and mothers with low-birth weight infants. A substantial gap still exists between WIC and non-WIC participants. Full-time employment is also associated with decreased breastfeeding rates.

### **Don't Shoot the Messenger**

While the presence of toxic chemicals in human milk signals an urgent need to reduce environmental contamination, human milk remains the optimal choice for mothers and babies. Although human milk substitutes have not been shown to contain PBTs, human milk substitutes lack the many ingredients known to contribute to infant health. In addition, human milk substitutes contain other environmental chemicals including those found in the water used to reconstitute artificial formula.

### **Are Infants at Risk?**

The mere presence of environmental chemicals in blood, urine or milk specimens does not equate with disease. Small amounts may have no health risks while larger amounts may be cause for concern. A thorough risk

## *It's the Law*

February 2, 2005; a bill (HB302) prohibiting the promotion of infant formula by health care providers was read for the first time in the Texas House of Representatives and referred to the Committee on Public Health. A companion bill was also introduced in the Texas Senate (SB113).

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subchapter A, Chapter 165, Health and Safety Code, is amended by adding Section 165.005 to read as follows:

Sec. 165.005. INFANT FORMULA PROMOTION PROHIBITION.

(a) A hospital, birthing center, physician, or other health care provider that provides services to mothers and infants may not promote the use of infant formula, including by:

(1) distributing without charge an infant formula or any item containing the name of an infant formula; and

(2) advertising an infant formula.

(b) The executive commissioner of the Health and Human Services Commission shall adopt rules to implement this section.

SECTION 2. This Act takes effect September 1, 2005.

For additional information and to track the progress of the bill visit [www.capitol.state.tx.us](http://www.capitol.state.tx.us)

assessment must be done, so that evidence-based health guidance can be developed, but much more information is needed.

### **Comprehensive Monitoring System**

Contamination of human milk is a consequence of decades of environmental pollution. A comprehensive human milk monitoring system using

standardized protocols for collection and analysis of specimens is needed. Reliable data on time trends and global patterns of contamination would provide a sound basis for evidence-based public health policies. Without such data, it is difficult to provide advice to health care professionals and to mothers on the potential risks and benefits of breastfeeding.

### **National Children's Study**

To assess the effects of contaminants in human milk on child health and development, it will be necessary to examine children prospectively over many years in longitudinal epidemiologic studies that use standardized examination protocols and that specifically assess exposures to environmental contaminants via breastmilk. This is the study design envisioned for the National Children's Study now being planned under the direction of the National Institute of Child Health and Human Development. The goal of this study will be to examine the influences of multiple exposures, environmental, behavioral, socioeconomic, and genetic on child and adult health. As many as 100,000 children representing all regions of the United States will participate. Children will be followed from conception to 21 years of age.

### **Breastfeeding the Best Choice in a Polluted World**

Until more data is available, breastfeeding remains the best way to feed infants and young children. Restricting breastfeeding does not eliminate a ba-

by's exposure to environmental chemicals; it only eliminates the protection breastfeeding provides. As long as the known benefits of breastfeeding outweigh the potential risks associated with the presence of environmental chemicals in human milk, mothers should be encouraged to breastfeed. Data may one day show that human milk provides protection against environmental chemicals as well. Perhaps not surprising, given the extent to which human milk changes to meet the needs of babies.

LaKind JS et al. Environmental chemicals in human milk: a review of level, infant exposures and health, and guidance for future research. *Toxicology and Applied Pharmacology* 2004;198:184-208.

Landrigan PJ et al. Chemical Contaminants in Breast Milk and Their Impacts on Children's Health: An Overview. *Environmental Health Perspect* 2002;110:A313-A315.

## ***SCIENCE OR SCIENCE FICTION*** ***Evidence Based Care: How Good is the Evidence?***

Authors Steinberg and Luce in a recent article titled, "Evidence Based? Caveat Emptor!" discuss the history of evidence-based medicine. They explore the methods used to rate strength of evidence, and identify additional issues that need to be considered when rating evidence underlying a clinical practice guideline or performance measure.

The term "evidence-based medicine" first appeared in publication in the early 1990s. Early methods of evaluation were strongly influenced by expert opinion, but more recently, methods

for evaluating published data have strengthened. A measure of the quality of a study is the extent to which the study's design and conduct can be shown to protect against systematic bias, non-systematic bias, and inferential error.

There is general agreement that susceptibility to bias is lowest in well-designed and executed randomized controlled trials (RCTs), followed by nonrandomized controlled trials, prospective or retrospective cohort studies, cross-sectional studies, case registries and case reports. But even well designed studies can be poorly executed and therefore be susceptible to bias.

"Direct" versus "indirect" evidence is always preferred. Direct evidence is produced when both the use of the treatment and the occurrence of the outcomes are observed in the same study. In contrast, evidence is indirect when two or more sets of data are needed to relate the treatment to the outcomes. According to the authors, "Many, if not most, evidence-based clinical practice guidelines are based on indirect evidence because they rely on a chain of reasoning that is based on several distinct bodies of evidence."

While data from more than one study is always preferred, the obvious benefit being an increased sample size, it is more difficult to rate the quality of a body of evidence than to evaluate the quality of an individual study. The RTI International-University of North Carolina Evidence-based Practice Center (EPC) recently completed a comprehensive review of approaches used to grade the strength of evidence that emerges when an entire body of re-

search on a particular topic is reviewed. Forty approaches were identified, but only eight met EPC standards.

When a body of evidence is evaluated, there are key considerations.

- Was the approach used to identify pertinent literature comprehensive and unbiased?
- Was bias avoided in evaluating, synthesizing, and interpreting available evidence?
- Was the data derived from a narrowly or broadly defined group?
- What is the likelihood of error (Type I or II)?
- What are the relevant cost considerations?

When a clinical practice guideline is developed, evaluating the strength of evidence is even more difficult and complicated. Firstly, much or all of the evidence is indirect and linked only by reasoning; secondly, opinion often fills in gaps in the evidence base.

It's important to note that the absence of evidence, either direct or indirect, does not mean that an intervention is not safe or effective. It is estimated that 50-85 percent of all medical treatments have never been validated by clinical trials. According to the Institute of Medicine, only about 4 percent of all treatments have strong evidence and more than half have very weak or no evidence.

Data derived from a narrowly defined group may not be clinically significant when applied to a much broader group thus the distinction between "efficacy" and "effectiveness." An intervention is efficacious when there is evidence that the intervention is beneficial when administered by experts in a research setting. It is not considered effective until it is administered by a representative sample of physicians in routine practice settings to the full spectrum of patients

to whom the technology is likely to be provided in real life. Subsequently every effort should be made to define the inclusion criteria for clinical trials as broadly as possible and the exclusion criteria as narrowly as possible to ensure that the findings are relevant to the greatest proportion of patients.

There are two types of errors: Type I- concluding that there is a distinct difference between two interventions when in fact the observed difference was caused by chance and Type II- concluding that there is no difference when in fact there is a difference.

Last but not least there are cost considerations i.e. the cost of the intervention, the magnitude of the health outcome relative to the cost, and who is paying for the intervention.

Given all of these considerations, real world health decisions are difficult at best. For example, the Food and Drug Administration (FDA) requires companies to prove that the benefits of a product outweigh the harms. Traditionally, RCTs are performed on narrowly defined patient populations. Manufacturers are not required to show that their product is more efficacious than another product, only that their product produces a biological effect when compared to a placebo. The FDA does not permit a company to market a product for off-label use, but once a product is commercially available, the FDA does not regulate how physicians use the product. In most cases there is no economic incentive for manufacturers, providers or insurers to pursue off-label studies. Because the number of patients enrolled in RCTs is small, most adverse effects do not appear until the

product reaches the marketplace i.e. Cox-2 inhibitors. If the FDA has lingering concerns about a product, it may require post-market surveillance but most often reporting of adverse events is entirely voluntary and therefore unreliable. These considerations highlight the fact that approval of a product by the FDA does not ensure that the product is safe and effective when used in routine clinical practice.

More recently, individuals have called for "evidence-and outcomes-based criteria" to ensure that treatments are backed by sufficient evidence and will impact outcomes that people care about including death, pain, suffering, and disability; and that a comparison of the outcomes should show that the treatment is effective, beneficial, and cost-effective. But this model would preclude "investigational" interventions that have been in use for a long time but have not been formally evaluated. While data is desirable, there may be no practical way of obtaining the data.

There are many mechanisms for evaluating the quality of care, but because the methods are often applied inconsistently and/or improperly interpreted, one should not blindly assume that by labeling an intervention as "evidence-based" the label is truly deserved. Health Aff 2005;24(1): 80-92

## **WHAT'S NEW**

### **Nutritional Support of the Very Low Birth Weight Infant: Part II**

The California Perinatal Quality Care Collaborative (CPQCC) has recently released its seventh

CPQCC Quality Improvement Toolkit titled Nutritional Support of the Very Low Birth Weight Infant: Part II. This second part of a two part series is designed to provide information on practices to optimize parenteral nutrition as well as transition to enteral feedings. For information about how to download a copy of the toolkit please visit [www.cpqcc.org](http://www.cpqcc.org).

## **EDUCATIONAL EVENTS**

\*An asterisk indicates those events where Amy Spangler will be speaking.

April 28-May 1, 2005\*  
CAPPA Conference  
Orlando, Florida USA  
[www.CAPPA.net](http://www.CAPPA.net)

May 1-3, 2005\*  
Florida/Georgia AWHONN Section Conference  
St. Simon's Island, Georgia USA  
Ellen Zottoli  
[ellenzottoli@comcast.net](mailto:ellenzottoli@comcast.net)

May 12-13, 2005\*  
Breastfeeding Coalition of Placer County  
Sacramento, California USA  
Cynthia Bastian  
[Bastian@SacCounty.net](mailto:Bastian@SacCounty.net)

July 8-12, 2005\*  
ILCA Conference  
Chicago, Illinois USA  
[www.ilca.org](http://www.ilca.org)

September 16, 2005\*  
San Joaquin Breastfeeding Coalition

Stockton, California USA  
Susan Pirie  
[spirie@chw.edu](mailto:spirie@chw.edu)

September 18, 2005\*  
Nursing Mothers Council  
San Mateo/San Francisco  
Laura Steuer  
[laurafs@juno.com](mailto:laurafs@juno.com)

October 12-16, 2005\*  
CAPPA Conference  
Anaheim, California USA  
[www.CAPPA.net](http://www.CAPPA.net)

October 18, 2005\*  
Overlook Hospital Professional Education Conference  
Summit, New Jersey USA  
Fran Drigun  
[Fran.drigun@ahsys.org](mailto:Fran.drigun@ahsys.org)

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