



Perinatal MATTERS

REGION 1
North Coast Perinatal Access System
415 / 476-3868

REGION 2
Northeastern California
Perinatal Outreach Program
916 / 733-1750

REGION 3
Perinatal Network of
Alameda / Contra Costa

REGION 4
Mid-Coastal California
Perinatal Outreach Program
650 / 723-5763

REGION 5
San Joaquin / Sierra
Regional Perinatal Program
559 / 221-6315

REGION 6
Perinatal Advisory Council of
Los Angeles Communities
818 / 382-3956

REGION 6.1
Perinatal Outreach
Education Program
562 / 595-6459

REGION 6.2
South Bay Perinatal Access
Project
310 / 222-3651

REGION 6.7
Community Perinatal Network
323 / 725-0199

REGION 7
Inland Counties
Regional Perinatal Program
909 / 558-3970

REGION 8
Orange County
Regional Perinatal Program
714 / 456-6706

REGION 9
San Diego/Imperial Counties
Regional Perinatal System
858 / 467-4990

REGION 10
Kaiser Permanente Regional
Perinatal Program (North)
510 / 987-3430

REGION 11
Kaiser Permanente Regional
Perinatal Program (South)
626 / 405-6052

A Publication of the Regional Perinatal Programs of California

Winter 2001

DEHP Poses Risk to Sick Newborns

Newborn babies are exceptionally delicate, especially if they are preterm. Their lungs, heart, and other vital organs are still developing and vulnerable. Neonatal intensive care physicians and nurses go to great lengths to protect these fragile babies from infection and disease. However, what efforts are made to address chemical contamination?

Recent reports from the National Toxicology Program (NTP) and the Food and Drug Administration (FDA) affirm that babies undergoing certain types of treatments, such as Extracorporeal Membrane Oxygenation (ECMO), exchange transfusions, enteral and total parenteral nutrition feeding, may be at risk of developing additional health complications due to exposure to a chemical called di-2-ethylhexyl phthalate (DEHP).

What is DEHP?

DEHP is a phthalate plasticizer added to polyvinyl chloride (PVC) plastic medical devices to make them soft and flexible. It is also a developmental and reproductive toxin.

By weight, flexible PVC plastic is typically 20% to 40% DEHP, and can reach 80% in applications where flexibility is critical. DEHP is the only phthalate certified by the FDA for use in medical products, so its production volume is tremendous—approximately two million tons are manufactured annually. Respiratory therapy tubing, masks and oxygen reservoir bags, IV products, ECMO tubing, mattress covers, examination gloves and wall coverings are examples of products which may be made of DEHP-added PVC plastic.

Since DEHP is not bound to the PVC polymer, it readily leaches from bags and tubing and into feeding solutions, blood, or directly into the patients' system. Leaching rates increase dramatically if the solution is high in fat since DEHP is lipophilic, meaning it has an affinity for fat.

Potential Risks Associated with DEHP

Studies by the NTP and the FDA have found that doses of DEHP, equivalent to what babies receive with certain critical care procedures, may have adverse effects

on their health. Of particular concern are effects on the developing male reproductive tract. Monoethylhexyl phthalate (MEHP), the toxic monoester metabolite of DEHP, targets the Sertoli cells, which provide nourishment for developing sperm cells. The NTP cited "serious concern" that DEHP exposure may adversely affect male reproductive tract development. Conversion of DEHP to MEHP is substantial if the DEHP is administered via the gastrointestinal tract, where it is converted to MEHP by intestinal lipases.

Toxic effects of DEHP are also evident in the lungs, liver and kidneys. Infants undergoing artificial ventilation with DEHP-added products can develop respiratory distress symptoms and pathological changes resembling hyaline membrane disease (Roth, 1998). Some children undergoing ECMO can develop cholestasis, or an arrest in the normal flow of bile (Plonait, 1993; Shneider, 1991). Reductions in liver function in rhesus monkeys have also been demonstrated (Kevy and Jacobson, 1982), and some studies detected decreased renal function and cysts (Ward, 1998; Crocker, 1988; Kevy and Jacobson, 1982).

Infants undergoing multiple intensive care procedures can receive between 5 and 20 times the tolerable dose, according to the FDA. The NTP Center for the Evaluation of Risks to Human Reproduction concluded that the lowest observable adverse effect level (LOAEL) for DEHP in rodents ranges between 38 and 144 mg/kg per day. Infants receive between 42-140 mg/kg during ECMO therapy alone. Multiple exposures from different treatments can raise exposure substantially, exceeding the LOAEL cited.

DEHP Exposure

Unfortunately, exposure does not end after an infant is released from intensive care. Nor does it begin there. Pregnant women are exposed to DEHP every day. Vinyl products made with DEHP are so ubiquitous that phthalate is a regular contaminant in food products, ambient air, and drinking water. Fatty foods such as oils, milk, cheese, meats and fish typically contain higher

(continued on page 2)

(DEHP continued from page 1)

DEHP residues than other foods. According to the US Department of Agriculture a survey of food intake by individuals shows, pregnant women eat more fatty foods than other women. DEHP also concentrates in breast milk due to its lipophilic properties. Breast pumps and feeding tubes are often made of DEHP-added plastic, increasing the toxin's presence in breast milk. The FDA reported nursing infants of mothers receiving hemodialysis could receive large doses of DEHP.

DEHP is pervasive in medical supplies and can result in a myriad of health effects, particularly in certain vulnerable populations. Only recently has its potentially toxic properties come to light as manufacturers were only required to conduct limited safety testing after the mid-1970's, when the FDA began to regulate medical devices. Material formulations which were used previously were not as rigorously tested as new products after May, 1976. With recent reports from the NTP and FDA demonstrating otherwise, the vinyl industry has embarked on a campaign to prove their products do no harm.

Alternative Products

Donald Marlowe, Director of the FDA's Office of Science and Technology, acknowledges, "We are being specific here, suggesting to clinicians and the users of these devices that they consider devices that are made of alternate materials." Alternatives to DEHP products are readily available. Polyurethane, polypropylene, silicone, and ethylene vinyl acetate are examples of the medical-grade polymers that may replace DEHP-added PVC. There are a number of manufacturers of these products, so health care facilities have flexibility in their purchasing contracts.

First, Do No Harm

Primum non nocere. First, do no harm. An oath physicians take upon graduation from medical school, and a charge to all health care providers. While nurses and doctors diligently work to heal those who are ill, they are also obligated to prevent avoidable harm. Eliminating DEHP-added products from the workplace is one way providers can adhere to this oath while ensuring infants are receiving the safest, best possible care.

For more information on DEHP, or for information on phasing DEHP out of your health care facility, contact Johanna Congleton, Public Health Organizer for Physicians for Social Responsibility-Los Angeles, congleton@psr.org. (213) 386-4901 or your Regional Perinatal Program.

*Supported in part by grants from the
State of California Department of Health Services,
Maternal & Child Health Branch*

Postpartum Depression

For most people the birth of a baby is a special time of joy and excitement. However, it can also be a time when women are susceptible to clinical depression. Two types of postpartum depression (PPD) have been described: 1) postpartum "blues" —a mild mood problem of short duration and 2) postpartum major depression, a severe and potentially life-threatening illness.

Although up to 70% of women report experiencing negative mood symptoms during pregnancy, the prevalence of pregnant women who actually meet the diagnostic criteria for major depression is between 10% and 16%. Some of the risk factors for PPD include a history of depression (not necessarily related to pregnancy), poor social support, adverse life events, marital instability, and ambivalence toward the pregnancy.

There are a number of rating scales for depression, one which has been validated in the postpartum population is the Edinburgh Postnatal Depression Scale. The newer Postpartum Depression Screening Scale also shows promise as a screening tool. It is generally advised that screening for postpartum affective disorders should become routine, ideally at the standard postpartum medical visit at 6 weeks, and subsequent pediatric visits.

Treatment of PPD generally depends on the type and severity of the symptoms. With postpartum blues, additional emotional support or extra help caring for the newborn may be the only intervention needed. If symptoms persist or become more severe, professional treatment may be warranted. In mild cases, psychotherapy may be of benefit. If severe major depression is diagnosed, carefully selected antidepressant medication may be needed and should be combined with counseling and support.

Tricyclic antidepressants (TCA) and fluoxetine (Prozac) are the most widely studied of all the anti-depressants. Early case reports of limb reduction associated with TCA ingestion were concerning, but no statistical association has been documented. Nor does in utero exposure to these drugs appear to impact neurodevelopment or behavior by preschool. SSRIs (selective serotonin reuptake inhibitors) including Prozac, Luvox, Paxil, Celexa, and Zoloft, are being studied more extensively during pregnancy and lactation, with increasing confidence in the safety of their use. In a small number of studies, congenital anomalies and neurobehavioral problems in children have not been found. Monoamine oxidase inhibitors (MAOI's) have been shown to be teratogenic and are not recommended for use during pregnancy.

In general, there are too few studies on the most effective treatment of PPD, and there is a tendency to treat women with PPD less intensely than those with non-pregnancy related affective episodes. Women who are breastfeeding must be informed that all psychotropic medications, including antidepressants, are ex

(continued on page 4)

Zung Self- Rating Depression Scale

The Zung Self-Rating Depression Scale, available from Eli Lilly and Company, is used by diabetes health care providers to help assess the psychosocial status of nonpregnant clients.

In looking for a tool to use with pregnant women with diabetes, the staff at Mt. Diablo Center for Diabetes began utilizing the screening tool in their Sweet Success California Diabetes and Pregnancy Program in July, 1999. The genesis for using such a tool was the staff's increasing concern regarding clients who seemed to be struggling with various facets of their lives, often affecting management of their diabetes.

The Zung Scale (below) quantitatively measures symptoms of depression, comprising a list of 20 items, each relating to a specific characteristic of depression. Together, these 20 items comprehensively delineate the symptoms of depression as they are widely recognized. Opposite the 20 statements are four columns, each with a numerical weight. When the client's responses are

added, they provide the raw score. Individual items indicate what specific sign or symptom the client is manifesting; aggregate scores of several items indicate what areas the client is having the most difficulty. Items 1 and 3 refer to affect; items 2 and 4 through 10 measure physiologic disturbances; items 12 and 13 measure psychomotor disturbance; and items 11 and 14 through 20 measure psychologic disturbances.

High scores are not in themselves diagnostic but indicate the presence of symptoms that may be of clinical significance. The Zung Scale is only a screening tool, not a diagnostic device. Careful review of the client's responses should be completed immediately by a health care professional. Clients indicating frequent or multiple signs of depression should receive follow-up care and counseling. Close attention should be paid to the response to item 19 which may require immediate intervention and referral to a social worker or psychologist. In conclusion, the Sweet Success Program at Mt. Diablo Center for Diabetes found that this self-rating scale has proved to be a useful tool.

ZUNG SELF RATING DEPRESSION SCALE

Please check a Response for each of the 20 items.	None or a little of the time	Some of the time	Good part of the time	Most of the time
1. I feel downhearted, blue and sad				
2. Morning is when I feel the best				
3. I have crying spells or feel like it				
4. I have trouble sleeping through the night				
5. I eat as much as I used to				
6. I enjoy looking at, talking to, attractive women/men				
7. I notice that I am losing weight				
8. I have trouble with constipation				
9. My heart beats faster than usual				
10. I get tired for no reason				
11. My mind is as clear as it used to be				
12. I find it easy to do the things I used to do				
13. I am restless and can't keep still				
14. I feel hopeful about the future				
15. I am more irritable than usual				
16. I find it easy to make decisions				
17. I feel that I am useful and needed				
18. My life is pretty full				
19. I feel that others would be better off if I were dead				
20. I still enjoy the things I used to				



Selected Maternal and Child Health Related Legislation

AB 1147 - County Maternal and Child Health Services

This bill would restore the \$2.6 million from the General Fund to the State Department of Health Services to support County MCH efforts.

Status: Vetoed by the Governor

While this bill was vetoed, the veto message indicated that the bill is no longer needed as the Governor has already directed DHS to restore \$2 Million directed to the Counties.

SB 1027 - Employment Overtime: Nurses and Health Care Workers (Romero)

This bill provides that a registered nurse may not be compelled to work more than 40 hours in a workweek. If the nurse is working under an alternative workweek schedule, he or she may not be required to work in excess of the workday hours provided in the alternative workweek schedule, he or she may not be required to work more than 8 hours in a workday. The bill allows overtime in the case of federal, state, or county emergencies, providing that the nurse's employer makes reasonable efforts to fill staffing needs through alternative means. The bill also prohibits employers from coercing registered nurses into working overtime or from retaliating or discriminating against nurses for refusing to work overtime. The bill specifically exempts nurse midwives, nurse anesthetists and nurse practitioners.

Status: Senate Unfinished Business

SB 101 - Abandonment of Newborns (Brulte)

This bill allocates \$1 million from the General Fund to the State Department of Social Services to develop and implement a social marketing campaign to determine populations likely to abandon their newborn infants and to determine what options are available to them.

Status: Vetoed by the Governor

SB 130 - Family PACT Program (Cardenas)

This bill was SB 500 last legislative term and was vetoed by the Governor. This year's version seeks to do many of the same expansions to the Family PACT program, including covering specified STD screening services for men and preventive health services to low-income women less than 65 years of age.

Status: Senate Committee on Health and Human Services

AB 59 - Health Programs: Eligibility (Cedillo)

This bill provides that any child eligible for food stamps, WIC, Federal Head Start or the school lunch program be automatically considered to have met the income eligibility requirements for Healthy Families and Medi-Cal. The bill would expand Medi-Cal eligibility, however, the necessary funds to expand Healthy Families would only be available when specifically designated in the Budget Act for a specific fiscal year.

Status: Chaptered into Law

AB 1025 Lactation Accommodation (Frommer)

This bill would require employers to provide a reasonable amount of break time to employees desiring to express breast milk. Employers would also be required to provide the use of a room or other location other than a toilet stall in close proximity to the employees work area. The employer would be exempt from this requirement if providing break time to employees desiring to express breast milk would seriously disrupt operations.

Status: Chaptered into Law

Perinatal Statistics and Information

www.perinatal.org

The Perinatal Dispatch Centers of California maintain a website that offers real time information on bed availability for NICU, PICU and high risk maternal care. This website also contains electronic versions of this newsletter.

PeriStats

The March of Dimes has launched a new and exciting interactive perinatal resource data center called *PeriStats*. It allows you to view county, state and national data on a variety of perinatal health indicators. This great new tool has the ability to convert information to custom graphs and charts and compare local data to other countries, states and national statistics, as well as Healthy People 2010 goals. Additionally, *PeriStats* can assist in creating individual needs assessment, grants and so much more. The best part of this great resource is that it is FREE! Visit www.modimes.org. click on *PeriStats* and enter a new realm of perinatal resource data!

Improved Perinatal Outcome Data Reports (IPODR)

IPODR is the result of a collaboration of the California Department of Health Services, Maternal and Child Health Branch, and the School of Public Health at the University of California, Berkeley. The IPODR provides zip code level data from Birth / Death Vital Statistics, US Census data and hospital discharge data. The data is web based with graphical user interface that gives provides access to this rich database on mortality, morbidity, perinatal risk factors, program, demographic, and socio-economic basic and advanced statistical analysis. Visit <http://datamch.berkeley.edu> and find a wealth of information.

(Postpartum Depression continued from page 2)

creted into the breastmilk in varying concentrations. Awareness of the impact of PPD is only the beginning, and attention needs to be focused on prevention. Women with high-risk factors require education and monitoring by their physician and health care professionals. Prophylactic treatments such as psychotherapy, counseling, and support groups do make a difference in the well being of the mother, the child, and the family.