

IN THEIR EFFORTS TO IMPROVE THE health outcomes of neonates and infants in the Neonatal Intensive Care Unit (NICU), neonatal nurses should understand the potential for harm that plastic medical devices pose to infants. Di(2-ethylhexyl) phthalate (DEHP) is a plasticizer used to soften polyvinylchloride (PVC) that can leach from the plastic into the fluid or gas being delivered to the neonate. DEHP can harm the developing reproductive system.

The U.S. Food and Drug Administration (FDA) has issued a public health notification recommendation that DEHP-free devices be considered for use in NICU patients.¹ There are alternatives available. The purpose of this column is to inform neonatal nurses of the risk of DEHP exposure among infants and to make it simpler for them to implement change in reducing DEHP in their institution.

BACKGROUND ON DEHP

DEHP is part of the phthalate family of chemicals, used to provide softness and flexibility in medical devices such as intravenous (IV) tubing and blood bags. DEHP is the phthalate of highest concern as it is not covalently bound in the PVC and can be released into the patient.² Moreover, infants in the NICU have a compromised physical condition that may necessitate a multitude of medical interventions, each increasing the patient's exposure levels.

A recent expert panel report from the Center for the Evaluation of Risks to Human Reproduction (CERHR) expressed serious concern that DEHP exposure may adversely affect male reproductive tract development and function.² Phthalates such as DEHP have been shown to be "gender-bending" chemicals that mimic the female hormone estrogen and have the potential to disrupt the development of male infants.³

ANIMAL AND HUMAN STUDIES

According to recent animal studies, adverse effects in the male reproductive system include testicular atrophy, factors that impair sperm maturation (such as a decrease in the diameter of seminiferous tubules), and depletion of germi-

How to Reduce DEHP in Your NICU: A Plan of Simple Steps to Promote Change

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nal cells in the testes.⁴ Damaging effects on the Sertoli cells, which affect spermatogenesis, have previously been observed in rodents.⁵ Female animal models have shown potential adverse effects such as suppression of estradiol production in the ovaries leading to anovulation, which is a common cause of female infertility.⁶

The latest human studies have shown that infusion lines can leach plasticizers in significant amounts and be a contributor to

hepatotoxic effects during long-term total parenteral nutrition (TPN) in infants.⁷ In addition, the release of DEHP is related to its lipophilic nature, which means that DEHP dissolves in lipid-containing fluids such as lipids, plasma, platelets, and blood.^{8,9}

In a recent study, Green and colleagues discovered that NICU infants had high exposure levels through NICU equipment and that as the length of medical treatments using common PVC-DEHP medical devices progressed, neonates were exposed to progressively higher levels of DEHP, as much as 25 times higher than levels measured in the general population.¹⁰

Human studies have begun to reveal the potential for adverse effects. Swan and coworkers were the first to demonstrate subtle developmental effects in humans related to phthalate exposure. These investigators found that phthalate exposure significantly affected the anogenital index (AGI), a sensitive index of masculinization of the male reproductive tract. In their study, women who had a greater exposure to phthalates, such as DEHP during pregnancy, delivered infant boys with a smaller than normal anogenital index. Boys with lower AGIs had smaller penis volumes, were more likely to experience incomplete testicular descent, had lowered sperm count, and were at a greater risk for testicular tumors in adulthood.³

The fact that chemicals such as DEHP are potentially linked to adverse health effects is enough to urge precautionary action to protect NICU infants. As new research and technology emerges, nurses have the responsibility of bringing the most up-to-date, evidence-based care for their patients. The potential adverse health effects of DEHP exposure among vulnerable neonates warrant a change in the types of medical devices used in NICUs. As with latex-reduction strategies in hospitals, it is possible for nurses and other health care professionals to identify DEHP-leaching devices that pose a patient risk and eliminate them as quickly as possible.

Switching to DEHP-free medical equipment can protect NICU patients from avoidable toxic exposure. In 2004,

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25 Years

NEONATAL NETWORK

TABLE 1 ■ Organized List of Medical Equipment in Supply Room

Item Name	Order Number	Manufacturer Name	Does It Contain DEHP?
Transducer	3343	Transpac	Yes
Feeding tube	2563	Portex	Yes

nearly all NICUs in Sweden had phased out PVC/DEHP-containing feeding tubes, and they are in the process of removing other medical equipment since learning of the reproductive toxicities of phthalates.¹¹ NICUs in the U.S. can use Sweden's example and make similar modifications to reduce DEHP exposure among their patients.

CASE STUDY: ROLE OF NURSES IN INITIATING CHANGE

Nurses have the potential to be the most influential motivators to mobilize change in practice patterns associated with the use of medical equipment that contains phthalates such as DEHP. Nurses can choose equipment that dramatically reduces NICU DEHP exposure and enhances patient outcomes. The success of John Muir Medical Center (JMMC) in DEHP reduction is a case in point. In July 2002, the FDA published a Public Health Notification entitled "PVC devices containing the plasticizer DEHP".¹ It identified medical procedures that posed the highest risk of exposure to DEHP in the neonate: exchange transfusion, extracorporeal membrane oxygenation, TPN with lipids in PVC bags, multiple procedures that result in high cumulative exposure, hemodialysis, and enteral nutrition. The FDA recommended considering the use of devices that do not contain DEHP for these procedures. Responding to this notification, Valerie Briscoe, Neonatal Clinical Nurse Specialist at JMMC, helped to organize the elimination of DEHP devices in the NICU at JMMC within 6 months.¹² This accomplishment demonstrates the influence that nurses can have on improving the care and lives of their patients.

INSTITUTING CHANGE IN YOUR NICU

Making the change to DEHP-free devices in the NICU is not as daunting as it seems. Numerous resources have been created to help DEHP-reduction efforts. The following steps incorporate the respective sources:

Four Steps to Reducing DEHP in Your NICU

- Go to your supply room and list the medical equipment that you believe may contain DEHP.
 - Organize a list with the name of the product, order number, and manufacturer; then, by looking at material contents or contacting the manufacturer, document whether or not each product contains DEHP (Table 1). You may need to contact the manufacturer; about 10 percent of the JMMC NICU's products were not labeled with material content.
 - The organization Health Care Without Harm has developed an audit tool to help with this task: <http://www.noharm.org/details.cfm?type=document&id=741>.
 - You may also document the cost savings on your equipment. The JMMC NICU has saved approximately \$700 per year by using DEHP-free equipment. Table 2 provides an example of this documentation.
- Contact the purchasing department of your hospital.
 - The purchasing department may be able to provide a list of devices ordered by your unit. Review the list and examine the items to see if they contain DEHP.
 - Make sure the purchasing department is aware of your plan of reducing DEHP-containing devices from your unit. Any new or replacement supplies being considered for purchase should be DEHP-free.
 - Using the list of devices, determine if they are used in the high-risk procedures outlined by the FDA. Items that are DEHP-free may carry a symbol—a circle around the letters DEHP with a slash across it. If you are unable to determine if the device contains DEHP, you or your purchasing department will need to contact the manufacturer for more information. Most manufacturers list products that are DEHP-free. Examine products such as blood bags, central line catheters, enteral administration sets, enteral feeding tubes, IV administration sets, IV bags, IV tubing, peripherally inserted central catheter lines, TPN kits, umbilical vessel catheters, urinary drainage catheters, and wound/drainage systems.
- Identify alternative devices, and replace DEHP equipment.
 - Health Care Without Harm (<http://www.noharm.org>) provides contact information for dozens of companies that make DEHP-free or PVC-free products. Another source for identifying alternatives is http://www.sustainablehospitals.org/cgi-bin/DB_Index.cgi.

TABLE 2 ■ Documentation of Cost Savings Between DEHP and DEHP-Free Equipment

Old Item: DEHP Equipment	Item Number	Cost per Item	New Item: Non-DEHP Equipment	Item Number	Cost per Item	Number of Items Purchased Annually	Annual Cost Difference
Transducer Transpac	3343	8.69	Transducer Medex	48795	6.88	630	1140
Feeding tube Portex	2531	0.76	Feeding tube Vygon	50013	1.05	2510	-728
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4. Inform other nurses and the health care team in your unit about the toxicity of DEHP to infants.
 - Nurses are in an ideal position to determine the appropriateness of alternative devices. They also have an opportunity to attend conferences in which manufacturers advertise medical products. As consumers of DEHP-free devices, nurses can help to create market demand that encourages manufacturers to increase the supply of DEHP-free devices among NICUs.
 - Have the nurses in your NICU sign a petition based on the DEHP-Free NICU Pledge, available on Health Care Without Harm's website.
 - It is important to attain a consensus, as it will require teamwork to maintain a DEHP-free NICU environment and continued vigilance in monitoring DEHP-free equipment in the supply room.

SUMMARY OF RELATED WEBSITES

1. Health Care Without Harm (<http://www.noharm.org>)
An agency committed to reducing pollution in the health care industry. Its site contains literature about PVC and DEHP, and provides resources for PVC-free alternatives.
2. Sustainable Hospitals (http://www.sustainablehospitals.org/cgi-bin/DB_Index.cgi)
An organization that provides technical support to the health care industry for selecting products and work practices to reduce occupational and environmental hazards, maintain quality patient care, and contain costs.
3. Center for the Evaluation of Risks to Human Reproduction (CERHR) (<http://cerhr.niehs.nih.gov>)
An agency of the National Toxicology Program that provides timely, unbiased, scientifically sound evaluations of phthalate exposure in humans.

SUMMARY

The integration of research into practice can be a challenge; however, the DEHP-reduction steps provided in this column should make the process simpler and faster. DEHP's link to adverse effects makes it crucial for neonatal nurses to do their best to protect their patients using a preventative approach. As critically ill neonates and infants continue to be exposed to DEHP-leaching devices, neonatal nurses can be at the forefront in taking precautionary action to reduce DEHP exposure among their most vulnerable patients.

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