

# The Clinician's Role in Greening Healthcare

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# OBJECTIVES

- DESCRIBE THE ISSUES RELATED TO PVC AND DEHP AS IT EFFECT NEWBORNS
- DESCRIBE THE PROCESS TO REDUCE THE RISK OF EXPOSURE IN THE NICU
- IDENTIFY WAYS TO “GREEN” THE NICU

# What We Know

- Every one of us is carrying a body burden of toxic chemicals
- Children are more susceptible to environmental exposures than adults
- The fetus can be harmed by amounts of chemicals that do not effect adults
- Already sick patients or the elderly may be less able to deal with the environmental exposures

# Let's look at PVC and DEHP

- Neonatal exposure



# Polyvinyl chloride (PVC)

- Vinyl chloride polymer
- Most widely used plastic in medical products – 27% of all plastic used in 1996
- 445 million pounds in bags, tubing, gloves, trays, catheters, etc.; also in non-medical supplies, flooring, pipes, and wall coverings
- Produced with fillers, stabilizers, pigments, plasticizers, lubricants, anti-oxidants, flame retardants (dependent on application)



# ADVANTAGES OF PVC

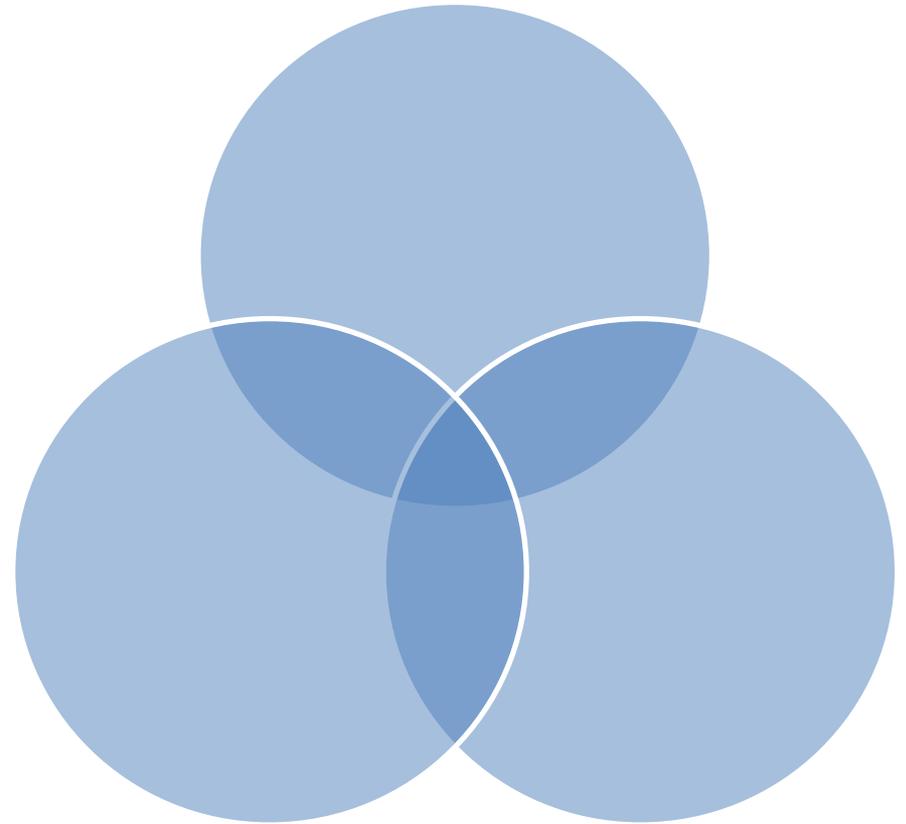
- Cost
- Flexibility
- Transparency
- Resistance to breakage



How do we make PVC "soft" ..

- DEHP

- And why should we worry.....



# Importance of route of exposure; species differences

- DEHP converted to MEHP by intestinal lipases; less rapid conversion after IV administration
- DEHP converted to MEHP in all species
- Adult non-human primates less sensitive than adult humans but impacts in fetuses and infants never examined in non-human primates
- MEHP eliminated largely by glucuronidation (primates); further hydrolyzed by humans before glucuronidation,

# Metabolic age-related differences impacting toxicity of DEHP

- Human fetus and infant have reduced glucuronidation capacity compared to adults
- Infants have higher gastric lipase activity than older children/adults
- Children absorb more DEHP from the intestinal tract than adults



# National Toxicology Program of the US Department of Health 2000

- In animal studies DEHP had various adverse effects
  - Developing male reproductive system and production of normal sperm
  - Interferes with testosterone synthesis
- Animal studies are relevant to humans

# NTP panel – Center for the Evaluation of Risks to Human Reproduction

- "serious concern" for the possibility of adverse effects on the developing reproductive tract of male infants exposed to very high levels of DEHP that might be associated with intensive medical procedures such as those used in critically ill infants.
- "concern" that DEHP exposure can adversely affect reproductive development in infants less than 1 year old because of their greater susceptibility and uncertainties regarding exposure.

# Other effects, DEHP

(FDA report, annex D)

- DEHP causes platelet aggregation and complement activation
- Microemboli during ECMO or cardio-pulmonary bypass may be related to DEHP
- Drug loss by binding to surface of PVC tubing or bags

# FDA Notification 2002

- Recommended that for some medical procedures PVC devices that do not contain DEHP be substituted or devices made of other materials be used if available
- Recommended using these alternatives for
  - Male neonates
  - Pregnant women who are carrying male fetuses
  - Prepubertal males

# FDA safety assessment of DEHP

- Considered species differences, pharmacokinetics, route of exposure
- Developed a “tolerable intake” (TI) for oral and parenteral exposure, below which no adverse effects expected
- TI based only on developing testes as the most sensitive endpoint

# Problem of DEHP Exposure for the Critically Ill Newborn

- Ill newborn at greatest risk
  - Patient sensitivity
    - Developing reproductive system and immature liver glucoronidation pathway for excretion
  - Dose of DEHP
    - Cumulative effect of long term or repetitive therapies



# DEHP EXPOSURE RISKS IN NICU ENVIRONMENT

- High Risk Procedures:
  - Exchange transfusion
  - ECMO
  - TPN with Lipids with PVC bags
  - Multiple procedures
  - Enteral nutrition
  - Ventilator tubing
- Low Risk Procedures:
  - PVC IV bags during infusion of crystalloids, drug storage



# ISSUES

- Liver toxicity (rodent studies document carcinogenic effects)
- Potential relationship to cholestasis in infants receiving TPN or undergoing ECMO
- Potential lung toxicity and respiratory failure in infants on ventilators with PVC
- ? Relationship between BPD/chronic lung disease and PVC
- Renal toxicity
- Potential for decreased renal function and cysts-rodent studies



# Magnitude of Neonatal Exposure

(General population exposure: 0.003 – 0.030 mg/kg/day)

- Neonatal Exchange Transfusion
  - 1.8 mg/kg/exch (0.84 – 3.3) DEHP
- Replacement Transfusion
  - 0.3 mg/kg/tx (0.14-0.72) DEHP
- ECMO (depending on circuit and assumptions)
  - 0.0 – 140 mg/kg DEHP



Sjoberg, 1985. Eur J Clin Invest 15:430

Sjoberg, 1985. Transfusion 25:424

Karle, 1997. Crit Care Med 25:696

**Levels in children with these exposures exceed the NOAEL in animal studies**

# Additional concerns

- Breast milk infusion from non-PVC bag or syringe through DEHP-containing tubing



# FDA public health notification and guidance

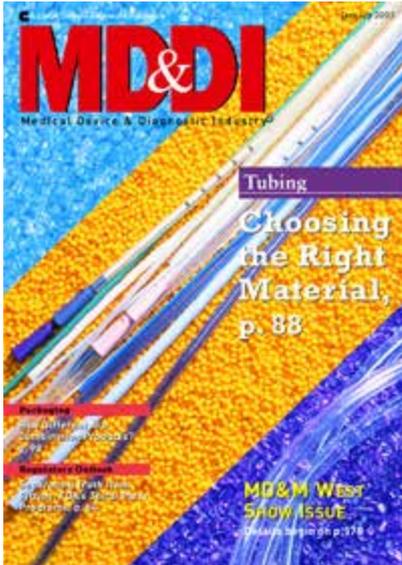
- Recommends the use of alternatives to DEHP-containing products for those procedures where exposures may be excessive
- Recommends reformulation of products to decrease/eliminate DEHP exposures
- Recommends labeling of DEHP-containing products

FDA Public Health Notification: PVC Devices Containing the Plasticizer DEHP, July 2002.

# Performance of PVC-free Alternatives

## Safety

- PVC-free plastics inherently flexible – no plasticizers
- Chlorine-free w/exception of neoprene gloves
- PVC-free plastics compatible with broader range of drugs



## Performance

- ▶ Clear, flexible, often steam sterilizable

## Costs

- ▶ Bags: cost-competitive due to “downgauging”
- ▶ Tubing: can cost more, but may have longer use life
- ▶ Gloves: cost-competitive at large volume

# HCWH's PVC-free Alternatives List

## Products detailed in this publication include:

Ambulatory Products

Bedding Products

Blood Bags:

- fresh frozen plasma
- packed red blood cells
- platelets
- platelet rich plasma

Body Bags

Breast Pump Collection Kits

- tubing

Central Line Catheters and PICC

- central venous catheters
- introcan safety catheters
- midline catheters
- percutaneous catheter introducer
- peripherally-inserted central ca (PICC)

Dialysis Pe

- Cruz ca
- rigid dia
- peritone

Enteral Fe

- bags and
- extensio

Enteral Fe

- gastrost
- nasocent
- nasogas
- nasojej
- pediatri
- PEG tu

Irrigation/Drainage

- drains
- irrigation containers
- mediastinal catheter
- nephrostomy catheters
- surgical and wound drains
- thoracic catheters

Patient ID Bracelets

Plastic Wrap

Respiratory Therapy Products

- Berman airways
- Cricothyrotomy kits
- endotracheal tubes
- epistaxis catheters
- intubation sets
- laryngectomy tubes
- masks, aerosol and oxygen
- nasal and turbinate stents
- oxygen hoods
- Replogle suction catheter
- sleep apnea tubes
- tracheostomy tubes

## Alternatives\* to Polyvinyl Chloride (PVC) and Di(2-Ethylhexyl) Phthalate (DEHP) Medical Devices

### Central Line Catheters and PICC Lines

B. Braun	800.227.2862	www.bbraunusa.com	Polyurethane or Teflon	Percutaneous catheter introducers, Central venous catheter, Introcan safety catheter
Becton Dickinson	201.847.6800	www.bd.com	Silicone, Polyurethane or Teflon	Peripherally-inserted central catheter, Midline catheter
Horizon Medical Products	800.472.5221	www.hmpvascular.com	Silicone	Central venous catheter, Peripherally-inserted central catheter
Klein-Baker Medical	210.696.4061	www.neocare.com	Silicone	Peripherally-inserted central catheter - neonates
Utah Medical Products, Inc.	800.533.4984	www.utahmed.com	Silicone	Peripherally-inserted central catheter - neonates (PICC-Nate)
Vygon	800.544.4907	www.vygonusa.com	Polyurethane or Silicone	Peripherally inserted central catheter - adults and neonates

# Actions at Sparrow

- Pledged to reduce the use when possible-sent pledge to HCWH-signed by VP Nursing and Facilities
- All equipment is evaluated first for the presence of PVC/DEHP
- Changed type of indwelling feeding tubes used
- Not using IV tubing with PVC ports
- Changed type of non-sterile gloves used and evaluated non-latex sterile gloves
- Held discussions with other departments to change practice-Nursery, Respiratory Support and Blood Bank



# What Can Hospitals Do?

## Pledge

for Hospitals and Health Systems in Support of Reducing Polyvinyl Chloride (PVC) and Di-2-ethylhexyl phthalate (DEHP) from Neonatal Intensive Care Units NICUs.

Hospital or NICU pledges to:

- § Conduct a PVC/DEHP audit
- § Commit to eliminate PVC/DEHP
- § Communicate the commitment reduce use in hospital
- § Collaborate hospital wide
- § GPO purchases

## A Pledge

for Hospitals and Health Systems in Support of Reducing Polyvinyl Chloride (PVC) and Di-2-ethylhexyl phthalate (DEHP) from Neonatal Intensive Care Units (NICUs)

■ **The Pledge**  
As a responsible provider of health care services, (your NICU and/or hospital) is committed to the health of our patients, our staff, and our communities. We are committed to the reduction of DEHP-containing devices in our Neonatal Intensive Care Unit (NICU). Specifically, we are committed to the following measures to make our NICU, and hopefully our institution, a model of environmental responsibility by phasing out DEHP and PVC containing products. We pledge to:

■ **Background material**  
DEHP is a plasticizer used to soften and impart flexibility in polyvinyl chloride products (PVC) and has been found to cause reproductive and developmental effects in animal studies. These studies have identified male neonates as especially susceptible to reproductive system damage from DEHP. A recent study out of Harvard University found that neonates receiving intensive therapy with PVC medical devices were exposed to DEHP at much higher levels than the general population - 25 times higher on average and up to 50 times higher for the most exposed. The sick infants were exposed to progressively higher exposures of DEHP as their medical treatments intensified. The FDA released a Public Health Notification in July 2002, which advises hospitals to look for alternatives to DEHP-free containing products for certain patient populations.

PVC is a chlorinated plastic that produces dioxin during manufacture and when incinerated. Dioxin is a known human carcinogen and has a variety of other adverse health effects. Dioxin represents a threat to public health as current environmental levels in part because it is persistent and bioaccumulates.

■ **Conduct a PVC/DEHP audit** to identify all uses and sources of DEHP in our NICU.

■ **Commit to eliminate** the use of PVC/DEHP-containing products in our NICU, unless no reasonable alternatives are available as determined by our neonatologist responsible for care in the unit. If continued use of PVC/DEHP-containing products is necessary, we will take measures to reduce the amount and duration of neonatal contact with PVC products where possible and dispose of PVC in a manner that it will not be incinerated. We will regularly monitor the availability of safe and effective alternatives.

■ **Communicate the commitment** to PVC/DEHP-free purchasing to the entire hospital system, to staff, contractors, subcontractors, and vendors. We will include language in contracts and requests for proposals that express our commitment to minimize PVC and DEHP use in the NICU and our preference for PVC/DEHP-free products. Where appropriate, we will identify deadlines for transition to PVC/DEHP-free products and share those deadlines with vendors, manufacturers, and others.

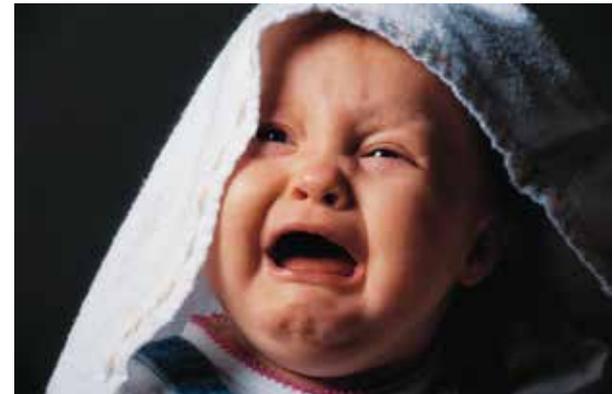
■ **Collaborate hospital wide** to urge support for hospital-wide implementation of PVC and DEHP reduction measures.

**LEARN MORE:**  
2002 FDA Public Health Notification on PVC devices containing DEHP (PDF) - <http://www.fda.gov/cdrh/safety/dehp.pdf>  
PVC/DEHP-free alternatives - <http://www.noharm.org/details.cfm?type=document&id=591>  
Case studies - <http://www.noharm.org/tycdehp/tycdehpPVC#case>  
PVC and DEHP: Guidelines for an Audit - [http://www.noharm.org/library/docs/Guidelines\\_document44-741](http://www.noharm.org/library/docs/Guidelines_document44-741)  
Weight of the Evidence on DEHP - [http://www.noharm.org/library/docs/Guidelines\\_03-11\\_The\\_Weight\\_of\\_Evidence\\_on\\_DEHP.pdf](http://www.noharm.org/library/docs/Guidelines_03-11_The_Weight_of_Evidence_on_DEHP.pdf)

(Go to: [www.noharm.org/details.cfm?type=document&id=1101](http://www.noharm.org/details.cfm?type=document&id=1101))

# CHANGE THE CULTURE: SUPPORT

- LABELING OF DEHP CONTAINING PRODUCTS
- PURCHASING POLICIES FOR PRODUCTS DEHP FREE WHEN AVAILABLE
- DEVELOPMENT OF MORE DEHP PRODUCTS
- HEPARIN COATED TUBING REDUCING PLATELET AGGREGATION AND COMPLEMENT ACTIVATION
- MINIMIZE BLOOD STORAGE TIME IN PVC BAGS
- MINIMIZE SOLUTION AGITATION AND WARMING



# We've Changed Over the Years SO.....



- Turn of the century incubator

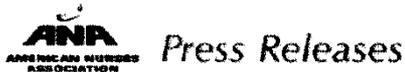


- Incubators of the 21<sup>st</sup> century



# PROFESSIONAL ORGANIZATIONS-ANA

ANA And Health Care Without Harm Urge Hospitals And Health Care Professionals To ... Page 1 of 2



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FOR IMMEDIATE RELEASE

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## **ANA And Health Care Without Harm Urge Hospitals And Health Care Professionals To Switch To DEHP-Free Medical Devices**

*--Concerns Over Potential Health Risks Prompt Warning--*

**Silver Spring, MD** - The American Nurses Association (ANA) joins with Health Care Without Harm (HCWH), a coalition for environmentally responsible health care, in urging hospitals, manufacturers and health care professionals to switch to DEHP-free medical devices in order to protect sick infants and other at-risk patients from phthalates, in light of a new report by the National Toxicology Program (NTP).

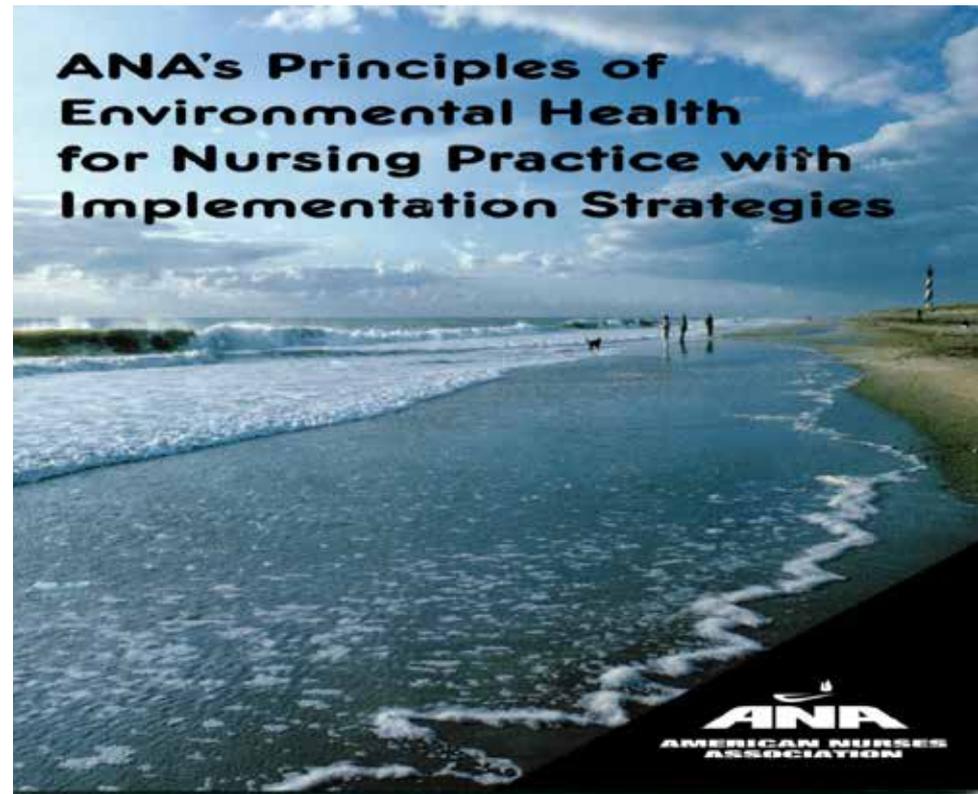
In a new report posted in December, NTP expressed "serious concern" that diethylhexyl-phthalate (DEHP), a chemical that leaches out of PVC plastic medical devices, may harm infant males undergoing intensive medical treatments. The NTP scientists are also concerned that DEHP exposure may specifically harm the sons of pregnant and breastfeeding women receiving medical treatments. Animal testing that is generally agreed to be relevant to humans shows that DEHP can cause testicular damage, reduced fertility, abnormal sperm counts, miscarriage and birth defects.

"The American Nurses Association is an advocate for environmental health and safety in the workplace," remarked President Rebecca M. Patton, MSN, RN, CNOR. "We support any effort to educate nurses about the potentially harmful chemicals used in health care settings. The ANA will work to ensure nurses have full access to information about the potentially hazardous chemicals to which nurses, other health care workers, patients and communities in general are exposed."

In 2006, the American Nurses Association's House of Delegates passed a resolution concerning nursing practice, chemical exposure and right-to-know. The ANA resolved to work locally, nationally and globally to reduce the use of toxic chemicals and to demand adequate information on the health effects of chemicals.

"There is no reason that pregnant women and parents of sick infants should have to worry about toxic chemicals leaching out of medical devices," said Anna Gilmore Hall, RN, executive director, Health Care Without Harm. "As an immediate first step, the FDA should require direct labeling of every DEHP-containing device so that health care providers will know which ones to avoid."

The American Nurses Association and HCWH urge health professional associations to notify their members of the risks of DEHP products, and recommend that doctors and nurses treating neonates,



# Advise as you move forward

- Read what's out there and at least increase your knowledge base about it.
- Don't always trust people - when you ask, "is it that way?" keep going - don't just accept the answers you're given.
- Just because you don't see the difference you're making while you're providing care, doesn't mean it doesn't happen down the road.

“Desire is the starting point of all achievement, not a hope, not a wish, but a keen pulsating desire which transcends everything”

- HCWH: [www.noharm.org](http://www.noharm.org)
- The Luminary Project: [www.theluminaryproject.org](http://www.theluminaryproject.org)
- H2E: [www.H2E-online.org](http://www.H2E-online.org)
- CHE: [www.CHEfor](http://www.CHEforhealth.org) health.org
- Hospitals: [www.sustainablehospitals.org](http://www.sustainablehospitals.org)
- enviRN@ son.unmaryland.edu
- ANA: [www.nursingworld.org](http://www.nursingworld.org)

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