

PVC Medical Devices Containing the Plasticizer DEHP

Guidelines for an Audit

Is it time to reduce your use of PVC medical products?

Many hospitals are reconsidering their use of polyvinyl chloride (PVC or vinyl) medical products. Their concerns with PVC products relate to patient safety or potential environmental health effects. The use of flexible PVC medical devices often exposes patients to the reproductive toxicant, DEHP (di-2-ethylhexyl phthalate). And when incinerated as waste, PVC causes emissions of dioxin, a known human carcinogen that also causes reproductive and developmental disorders.

How can a PVC medical device expose a patient to DEHP?

Manufacturers add DEHP to PVC to make it flexible. But DEHP does not attach to the plastic — it “floats” within the vinyl structure. During certain procedures DEHP leaches from medical devices and exposes patients receiving medications, blood transfusions, and feeding products. In some cases, exposure levels exceed the FDA’s estimated “tolerable intake,” increasing the risk of harmful impacts in certain patients.

Recognizing the potential hazards with DEHP, the FDA issued a Public Health Notification, “PVC Devices Containing the Plasticizer DEHP,” recommending that health care providers move away from these devices. The FDA stated that for some procedures,

“PVC devices that do not contain DEHP can be substituted, or devices made of other materials (such as ethylene vinyl acetate (EVA), silicone, polyethylene, or polyurethane) can be used, if available. ... We recommend considering such alternatives when ... high risk procedures are to be performed on male neonates, pregnant women who are carrying male fetuses, and peripubertal males.”

See, Appendix A for the FDA’s list of high risk procedures.

How can a hospital remove PVC medical devices from its shelves?

To move away from PVC devices containing DEHP, hospitals are

- performing audits to identify PVC and DEHP products;
- identifying and evaluating alternatives;
- purchasing PVC- or DEHP-free products of equivalent quality and performance.

Hospitals are replacing DEHP-containing PVC with either

- PVC-free products – PVC-free products are inherently flexible and do not contain a plasticizer like DEHP; or
- DEHP-free products – A PVC product with a non-DEHP plasticizer.

How to do a PVC/DEHP audit:

In the best of all possible worlds, performing a PVC audit would be relatively simple:

- ask procurement for the list of medical devices purchased by your department;
- review each device label to see if it contains DEHP or is manufactured from PVC; and
- develop a list of products that contain PVC and DEHP.

Unfortunately we don’t live in the best of all possible worlds when it comes to DEHP, PVC, and medical devices. In most situations, purchasing lists are incomplete, the presence of PVC or DEHP is not noted on the label, or manufacturers are reluctant to provide material content data. Here is a strategy to help department managers identify and eliminate DEHP from your unit and facility.

Begin with your purchasing/materials department.

Start the audit with purchasing. Ask your materials manager (procurement officer or resource manager) for a list of medical devices purchased by the department and products on contract with your Group Purchasing Organization (GPO). Purchasing will have a list of many devices used in your department. They may even know of others who completed a similar audit. Note: your department probably uses products not on purchasing's list.

Perform a walk through of your department.

Review all flexible plastic products on your storage room shelves. Any flexible plastic product, clear or opaque, may be made with PVC. PVC is widely used in bags and tubing. See list of common PVC medical devices in Appendix B.

Carefully read the labels. Each manufacturer labels material content differently. The most common situation will be that products are not labeled with material content.

- Keywords for PVC-free products include: "EVA," "Polyurethane," "Silicone," "Polypropylene," "PVC-free."
- Keywords for PVC products made without DEHP include: "DEHP-free" and "TOTM" (non-DEHP plasticizer).
- Keywords for products containing DEHP: "Contains DEHP," "Polyvinyl chloride," "PVC," and "Vinyl." Products labeled as containing PVC, but with no mention of DEHP, typically contain DEHP. Flexible plastic medical devices with no mention of material content may be made with DEHP and PVC.

See Appendix C for a listing of product label examples.

Update purchasing's list by adding material content information for those additional products you found on shelves. Your product list should include the product name, product

number, product size (e.g., 8 FR, 30 cm, 22 inches), and manufacturer name. See Appendix D for a sample list.

Fill in material data.

Unfortunately, you will have no material content for some of the devices. Here are some material data gathering strategies:

- Ask your GPO. With growing concerns over DEHP exposure, GPOs are beginning to label products in their catalogues for DEHP and PVC content.
- Contact manufacturers directly. With accurate product information in hand (e.g., product number, product size) and persistence you can extract material content information from manufacturer representatives.
- Request help from purchasing in collecting material content information. Purchasing works with manufacturer representatives and knows how to get information from them. Tell them that this is a patient care issue.
- Contact Health Care Without Harm (www.noharm.org) or the Sustainable Hospitals Project at the University of Massachusetts, Lowell (www.sustainablehospitals.org) for assistance.

Note: it is always beneficial for manufacturers and GPOs to hear directly from their customers. Many manufacturers state that they do not label material contents because customers do not request it.

Identify alternatives.

- Look for alternative products and manufacturers. Start with the websites of Health Care Without Harm and the Sustainable Hospitals Project.
- Work with your GPO. Review the list of available products offered through your GPO. If you cannot find alternatives, ask your GPO to identify or make DEHP-free alternatives available.
- Contact medical device manufacturers. Ask for PVC- and DEHP-free

products that meet your particular specs for your particular products (for example, some manufacturers may only offer DEHP-free products in their adult product line). Request that they work with you to make more DEHP-free products available for your specific needs.

Further steps

Increasing concerns with DEHP and PVC have led departments and hospitals to develop programs that favor alternative products. See Appendix E for strategies on how to de-select PVC- and DEHP-containing products.

Appendix A: Prioritizing PVC Products for Replacement

Identify highest risk patient populations. For example, the FDA identifies high risk populations as:

- male neonates;
- pregnant women carrying male fetuses; and
- peripubertal males.

Identify highest risk procedures. For example, the FDA identifies high risk procedures as:

- total parenteral nutrition in neonates (with lipids in PVC bag)
- enteral nutrition in neonates and adults
- multiple procedures in sick neonates (high cumulative exposure)
- hemodialysis in peripubertal males or pregnant or lactating women
- exchange transfusion in neonates
- heart transplantation or coronary artery bypass graft surgery (aggregate dose)
- massive infusion of blood into trauma patient
- extracorporeal membrane oxygenation (ECMO) in neonates
- transfusion in adults undergoing ECMO

Appendix B Polyvinyl Chloride (PVC) Products in Hospitals

Disposable Health Care Products

Blood Products and Transfusions

- apheresis circuits
- blood bags and tubing
- extracorporeal membrane oxygenation circuits

Collection of Bodily Fluids

- dialysis, peritoneal: drainage bags
- urinary collection bags, urological catheters, and irrigation sets
- wound drainage systems: bags and tubes

Enteral Feeding Products

- enteral feeding sets (bags and tubing)
- nasogastric tubes
- tubing for breast pumps

Gloves, Examination

Intravenous (IV) Therapy Products

- catheters
- solution bags
- tubing

Kidney (Renal Disease) Therapy Products

- hemodialysis: blood lines (tubing) and catheters
- peritoneal dialysis: dialysate containers (bags) and fill and drain lines (tubing)

Packaging, Medical Products

- film wrap
- thermoformed trays for admission and diagnostic kits, and medical devices

Patient Products

- bedpans
- cold and heat packs and heating pads
- foot orthoses
- inflatable splints and injury support packs
- patient ID cards and bracelets
- sequential compression devices

Disposable Health Care Products (continued)

Respiratory Therapy Products

- aerosol and oxygen masks, tents, and tubing
- endotracheal and tracheostomy tubes
- humidifiers, sterile water bags and tubing
- nasal cannulas and catheters
- resuscitator bags
- suction catheters

Office Supplies

- notebook binders
- plastic dividers in patient charts

Durable Medical Products

- testing and diagnostic equipment, including instrument housings

Furniture Products and Furnishings

- bed casters, rails, and wheels
- floor coverings
- furniture upholstery
- inflatable mattresses and pads
- mattress covers
- pillowcase covers
- shower curtains
- thermal blankets
- wallpaper
- window blinds and shades

Construction Products

- doors
- electrical wire sheathing
- pipes: water and vent
- roofing membranes
- windows

Appendix C: Examples of Product Labels

E.V.A. Mixing Container — interpretation: the bag is made from ethylene vinyl acetate (EVA). Since EVA is not PVC, it is plasticizer-free. It does not contain DEHP or any other plasticizer

Silicone Feeding Tube — interpretation: the tubing is made from silicone, no PVC, no DEHP, no plasticizer

Polyurethane Umbilical Vessel Catheter — interpretation: the tubing is made from polyurethane: no PVC, no DEHP, no plasticizer

0.9% Sodium Chloride Injection USP ... Latex-free; PVC-free; DEHP-free — interpretation: this label is easier to understand. The product does not contain DEHP or PVC, although the label does not specify the material the bag is made from

IV Administration Set ... TOTM (Non-DEHP) PVC Fluid Path — interpretation: tube made with PVC, plasticizer is TOTM, an alternative to DEHP

IV Administration Set, Polyethylene Lined Tubing with PVC Cassette — interpretation: tube made with PVC, plasticizer not specified, probably DEHP, polyethylene coating added to inner tubing surface to reduce DEHP leaching

Extension Set [for lipids] ... Contains DEHP — interpretation: PVC made with DEHP

Oxygen Connecting Tube, Polyvinyl Chloride — interpretation: tube made with PVC, type of plasticizer used is not specified. When plasticizer is not specified, interpret that to mean it contains DEHP

Catheter - 9.6 French ... Latex Free — interpretation: it is not clear what plastic or plasticizer this product contains. Suspect PVC with DEHP, but that can only be verified by contacting the manufacturer

Appendix D: Sample spreadsheet for identifying DEHP-containing products

Product Type	Product Name	Product #	Product size	Manufacturer	Type of Plastic	Does material contain DEHP?
Blood bags (not including packed red blood cells)						
Central line catheters						
Enteral administration sets						
Enteral feeding bags						
Enteral feeding tubes						
IV administration sets						
IV bags						
IV tubing						
PICC lines						
Total parenteral nutrition						
Umbilical vessel catheters						
Urinary drainage catheters						
Wound/drainage systems						

Appendix E: Other PVC/DEHP Reduction Strategies

Hospitals can take further measures to reduce the use of PVC- and DEHP-containing devices in addition to an audit. To eliminate the use of PVC and DEHP:

1. Create a hospital-wide policy that includes a resolution or pledge to reduce PVC- and DEHP-containing medical products.
2. Perform a system-wide audit to determine the presence of PVC- and DEHP-containing medical products throughout the facility. Make sure to ask the following questions:
 - i. Does the audit include an inventory of all PVC/DEHP-containing products?
 - ii. Have you labeled those devices containing PVC/DEHP?
 - iii. Do you have a plan in place to replace those devices that contain PVC/DEHP?
3. Perform departmental audits to determine the presence of PVC/DEHP-containing medical products throughout the department (e.g., NICU, Pediatric, Maternal and Child Health, PICU).
4. Form a committee or make it a priority on a purchasing committee to regularly review PVC/DEHP use for reduction and/or elimination for continuous quality improvement.
5. Replace any products or product lines that contain PVC/DEHP. Prioritize those used to treat the most vulnerable patient populations.
6. Implement a purchasing policy statement that requires the elimination or reduction of PVC/DEHP-containing medical products, where feasible.
7. Require a PVC/DEHP disclosure on all products coming into your facility that contain PVC/DEHP, through GPO contracts and/or vendor contracts.
8. Request information about PVC/DEHP-free products from your GPO.
9. Include language in your GPO and vendor contracts that specifies your preference for PVC/DEHP-free products.
10. Ask your GPO to identify products in their catalogues that contain (or don't contain) PVC/DEHP.



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Without Harm

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