Safer Chemicals

Polyvinyl chloride in health care

A rationale for choosing alternatives

Ted Schettler MD, MPH

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Health Care Without Harm

INTRODUCTION

Polyvinyl chloride (PVC) is a versatile, high-volume, synthetic material with many different formulations and configurations. Globally PVC is the fifth most highly manufactured plastic at 61 million metric tons annually. Construction materials account for approximately 75% of all PVC use. The material is commonly used in building materials, including flooring, pipes, carpet backing, and wall coverings. Office furniture, supplies, and packaging can be made of PVC. Health care-specific uses include PVC-based IV bags, blood bags, urine bags, tubing, oxygen masks, catheters, and disposable gloves.

Polyvinyl chloride is a particularly problematic plastic because of the toxicity of chlorine production as well as the toxicity of the monomers required to make the polymer and the generation and release of hazardous compounds during manufacture and disposal. It also generally requires more additives, many with their own toxic properties (such as diethylhexyl phthalate [DEHP]), when compared to other polymers. The material is also challenging to recycle.

A problematic plastic

Concerns about the hazards of PVC chemicals are associated with its entire life cycle – from production to disposal – including additives required to impart various performance characteristics.

Chlorine production

Polyvinyl chloride production is associated with the use and generation of chemicals of concern. The final product is nearly 60% chlorine by weight. The chlorine is obtained through an energy-intensive process that splits sodium chloride (NaCl) from seawater or brackish underground water into chlorine gas and caustic soda (sodium hydroxide, NaOH). This is accomplished through one of several technologies.

Mercury

The oldest technology uses a mercury-cell to separate the sodium from chlorine. During the process, a significant amount of mercury can be released into the environment. Two mercury cell plants continue to operate in the United States, one of which is converting to membrane technology. From 1987 to 2016, these two plants combined reported releasing over 28 tons of mercury into the air, 742 kilograms of mercury into water, and 23 tons of mercury into landfills. Mercury is a toxic metal that bioaccumulates in the food chain, particularly in fish, and can damage the developing brain at fairly low levels of exposure. Mercury readily crosses the placenta, exposing the developing fetus in pregnant women. An estimated 6.5% of women of reproductive age in the United States have blood mercury levels higher than what is considered safe, although levels vary by region and ethnicity. Both the Food and Drug Administration and the European Food Safety Authority recommend avoiding the consumption of some kinds of fish because of excessive mercury levels.

Asbestos

Another technology uses an asbestos diaphragm, which is then disposed of at the end of its useful life. Chlorine manufacturers are the largest importers of asbestos in the United States. The U.S. Geological Survey estimates that chlor-alkali plants are using 340 tons of asbestos annually. Twelve plants in the United States and Canada use an asbestos diaphragm technology. Asbestos is a known carcinogen. Chlorine manufacturers point out that the asbestos is wet when used and, therefore, opportunities for inhalation exposure are minimal during the use-phase of the life cycle. However, at the end of their useful life, asbestos diaphragms are ultimately disposed of in landfills from which asbestos can be released. There are also potential exposures to workers and communities in countries where asbestos is mined.

Fluorinated substances

Two other technologies use per- and poly-fluorinated alkyl substances (PFAS) to coat a membrane or diaphragm, which separates the chlorine. These substances are highly persistent in the environment. Some PFAS bioaccumulate. Some are carcinogens and reproductive and immune system toxicants. Two widely distributed PFAS, perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA), are so hazardous that they were included in an international treaty – the Stockholm Convention – to phase out persistent organic pollutants (commonly referred to as the POPs Treaty). The toxicity profile of many others is poorly studied. PFAS membrane technology is sometimes combined with asbestos.

Feedstock chemicals

Polyvinyl chloride is produced by combining chlorine with a carbon source. In most of the world, the PVC production process combines ethylene – obtained from cracking naphtha or natural gas – and chlorine to produce ethylene dichloride (EDC). This is then converted to vinyl chloride monomer (VCM), which is polymerized into PVC.

Another process for making VCM uses coal as its carbon source, rather than gas or naphtha. In this process, acetylene is obtained from calcium carbide, which comes from coal and limestone. Acetylene and hydrogen chloride are reacted over a mercuric chloride catalyst to yield vinyl chloride. Some of the mercury is released into the environment. This practice, which was once nearly obsolete, is again widespread due to its use in new PVC plants in China. This industry is one of the top two sources of mercury pollution in the world. Healthy Building Network estimates that China produces more than one-third of the world's PVC.

Toxic releases during production

Varying amounts of VCM, EDC, and vinylidene chloride are released to the environment from production facilities, although EPA regulates levels that are legally allowed. Vinyl chloride is a known human carcinogen. According to the National Cancer Institute, vinyl chloride exposure is associated with an increased risk of a rare form of liver cancer (hepatic angiosarcoma), as well as brain and lung cancers, lymphoma, and leukemia. The link between VCM and angiosarcoma of the liver in VCM workers led the U.S. Occupational and Safety Administration (OSHA) and the European Union to set permanent standards to limit the exposure of plant workers to VCM. Low levels of unreacted VCM also leach out of PVC storage containers and tubing, potentially directly exposing patients receiving therapy from those products.

The Environmental Protection Agency classifies EDC as a probable human carcinogen and the International Agency for Research on Cancer (IARC) classifies EDC as possibly carcinogenic to humans. The EU has recommended EDC as a Substance of Very High Concern (SVHC) in the candidate list for authorization. Both EDC and vinylidene chloride also have non-cancer health effects.

Historically people living adjacent to EDC/VCM/PVC manufacturing facilities have experienced excessive exposures to EDC and VCM as a result of environmental releases. Improvements in chemical management and production practices have reduced VCM releases per unit of PVC produced over the past twenty years. However, PVC production has increased substantially over that timeframe, and total VCM releases to air have only marginally improved. According to the EPA's Toxics Release Inventory Program over the past four years, VCM releases – mostly to air – have been relatively constant at about 600,000 pounds annually from U.S. facilities.

Various stages in the production of PVC generate small amounts of highly hazardous dioxins, furans, and other chlorinated byproducts. [1, 2] This mainly occurs during ethylene oxychlorination, which is one of the process steps leading to the production of VCM. Government and voluntary regulations have reduced dioxin/furan generation and environmental releases from well-quantified sources in recent years but their effectiveness in curbing releases from poorly-studied sources, including smaller industries and landfill or building fires, is unknown.

Dioxins and furans

Chlorinated dioxins and furans are highly hazardous compounds that can have a range of adverse health impacts, even at very low levels of exposure. The most potent dioxin compound (TCDD) is a known human carcinogen, reproductive and developmental toxicant, and alters function of the immune and endocrine systems. Low level exposures are particularly hazardous for the developing fetus and infant. Dioxins and related organochlorines are also persistent and bioaccumulative. As a result, they contaminate the food chain through which all humans are exposed. These widely acknowledged hazards and exposure pathways led to the inclusion of dioxins and furans in the Stockholm Convention.

Factory worker (James Mcdermott/Flickr)

Additives

Polyvinyl chloride is typically blended with other ingredients to confer durability, stability, color, and flexibility as needed. Combinations of additives give formulations the characteristics needed for a wide range of PVC products. The final mix of additives depends not only on the intended application but also on regulatory considerations and pressures to replace hazardous chemicals with those that are safer.

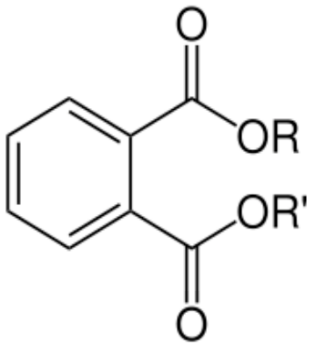
Heat stabilizers are generally required. Historically, lead and cadmium were used, but these two toxic heavy metals are largely being phased out and replaced with alternatives, including zinc-calcium formulations. Lubricants, antioxidants (including bisphenol A in some applications), and impact modifiers are added in various proportions. Some PVC products also contain significant amounts of flame retardants.

A joint project by the European Chemical Agency and industry created a list of over 400 functional additives or pigments used in plastics, including information on the polymers where they are most commonly found and the typical concentration ranges. Plasticizers added to PVC provide varying amounts of flexibility, necessary for many applications since, without them, PVC is rigid. Ortho-phthalates (phthalates) are a group of compounds long used as plasticizers to soften PVC and add flexibility.

Concerns about phthalates in health care

Diethylhexyl phthalate (DEHP) is the phthalate most commonly used in medical products. Some medical products such as IV bags and tubing can contain up to 40% DEHP by weight. Other phthalate-containing PVC products include wall coverings, tablecloths, floor tiles, furniture upholstery, shower curtains, garden hoses, swimming pool liners, rainwear, plastic diaper covers, dolls, some toys, shoes, automobile upholstery, packaging film and sheets, and sheathing for wire and cable. DEHP or other phthalates have commonly been used in these applications, although alternatives are increasingly being substituted because of toxicity concerns. For example, the Consumer Product Safety Commission has restricted eight phthalates, including DEHP, from children's toys because ingestion can cause harmful health effects. Similarly, the European Commission recently adopted a decision to restrict the use of several phthalates in consumer products on the EU market, including DEHP, benzyl butyl phthalate (BBP), dibutyl phthalate (DBP), and diisobutyl phthalate (DIBP).

This phthalate leaches to varying degrees from medical devices during certain medical procedures, directly exposing the patient. Concerns about DEHP exposure center primarily around findings from extensive laboratory animal testing showing that exposures during critical periods of development can interfere with testosterone production and disrupt normal male reproductive



General chemical structure of orthophthalates; R varies from short to longer linear or branched carbon chains

tract development. This literature was reviewed by an expert committee convened at the National Toxicology Program's National Institute of Environment Health Sciences. In their final report, the committee expressed concern about the potential impacts of DEHP on the developing reproductive tract of infant boys.

Subsequently, FDA conducted a safety assessment of DEHP. In a 2002 Public Health Notification, the agency advised health care professionals to switch to devices made of alternative materials, or made of PVC that does not contain DEHP when possible, when treating patients who may be particularly vulnerable, including male neonates, pregnant women who are carrying male fetuses, and peripubertal males. Subsequently, scientists from the Endocrine Society concluded that DEHP has the potential to act as an androgen disruptor and, in fact, does so under a number of conditions.

More recent studies in human populations confirm some of the adverse impacts of DEHP on male reproductive tract development first identified in many experimental animal studies. A systematic review also finds that higher exposures to DEHP are associated with sperm abnormalities and lower testosterone levels.

Recent studies also show that prenatal exposure to phthalates is associated with adverse impacts on neurodevelopment, including lower IQ, and problems with attention and hyperactivity, and poorer social communication.

Exposures to DEHP during critical periods of development can interfere with testosterone production and disrupt normal male reproductive tract development. This phthalate leaches to varying degrees from medical devices during certain medical procedures, directly exposing the patient. (Randy Cox/Flickr)

EU directives on medical devices (Regulation (EU) 2017/745) will go into effect in May 2020. The regulation MDR 745/2017 - Annex I.II.10.4 introduces provisions that would help phase out endocrine-disrupting chemicals, carcinogenic, mutagenic and reproductive/developmental toxic substances (CMRs), and particular phthalates in medical devices if safer alternatives are available and technically feasible.

The European Union has determined that DEHP is a reproductive toxicant and endocrine disruptor. The State of California has determined that DEHP is a reproductive and developmental toxicant and a carcinogen.

Alternative plasticizers

With growing concerns about DEHP toxicity, some product manufacturers are substituting alternative plasticizers for DEHP in various medical products rather than switching to alternative, non-PVC polymers that do not require plasticizers at all. The toxicity of other plasticizers and their tendency to leach out of the PVC product can vary from DEHP. Some are less hazardous and have no-effect levels higher than DEHP. However, many have not been as extensively studied as DEHP and related phthalates, particularly with regard to reproductive toxicity and endocrine disruption.

Alternative PVC plasticizers include:

- ASE - Alkylsulfonic acid esters
- ATBC - tributyl O-acetylcitrate
- BTHC - butyryl trihexyl citrate
- COMGHA - glycerides, castor-oil-mono-, hydrogenated, acetates
- DEHT - bis(2-ethylhexyl) terephthalate
- DINA - diisononyl adipate
- DINCH - Diisononyl cyclohexanedicarboxylate
- DOA/DEHA - Bis(2-Ethylhexyl) Adipate
- ESBO - Epoxidized soybean oil
- TOTM/TEHTM - trioctyl trimellitate/tri-(2-ethylhexyl)-trimellitate)

Four of these alternative PVC plasticizers (DINCH, BTHC, TEHTM, DEHT) were recently included in the European Pharmacopoeia, Europe's legal and scientific benchmark for pharmacopoeial standards, in order to provide manufacturers with alternatives to DEHP in medical applications.

End of life

Similar to other kinds of plastics, when PVC products reach the end of their useful life they must be disposed of or recycled.

Disposal

Waste incineration or landfilling are the prominent disposal options. When PVC is burned in waste incinerators, highly hazardous dioxins and furans are formed and released directly into the environment or sequestered in ash that must be disposed of. The synthesis of highly hazardous dioxins, furans, and/or related organochlorines requires the presence of chlorine and organic compounds, often in association with metal catalysts, heated within a range of temperatures that fosters the formation of these molecules from precursors or *de novo*. The extent to which combustion in waste incinerators produces dioxins, furans, and related compounds depends on incinerator design, operating conditions, and fuel composition. Under certain combustion conditions, higher PVC concentrations in the fuel mix result in higher dioxin formation. PVC is an important contributor to dioxin/furan formation in poorly controlled incineration and building or landfill fires.

In the United States, federal regulation of waste incinerator emissions and incinerator closures have significantly reduced dioxin and furan releases to the air from those sources in recent years, although incinerator ash containing these compounds remains. Emissions from backyard burning, landfill fires, and accidental fires cannot be controlled.

Recycling

Opportunities for recycling plastics vary, depending on the nature of the polymer and additives in the original product.

In general, materials in plastics can be recovered and reused by:

1. Mechanical technologies, including separation of polymer types, decontamination, re-melting, and re-making into similar or different products; or
2. Chemical technologies that use hydrolysis, high heat, gasification, or other means to produce basic feedstock compounds that can be reused. [3, 4, 5, 6] Chemical technologies typically require economic subsidies because of the relatively low prices of virgin feedstock materials compared with plant and processing costs incurred by breaking down the plastics.

Burning plastics as fuel in waste-to-energy plants designed to produce heat, steam, or electricity is sometimes called “recycling” but it’s a misuse of the term and the technologies carry risks similar to waste incineration.

Governmental commentary and policy on DEHP

A number of agencies and authoritative government bodies have reviewed the toxicity of DEHP.

- FDA conducted a Safety Assessment of DEHP Released from PVC Medical Devices and concluded that some patients may be at risk of harm from DEHP leaching from PVC medical devices.
- FDA issued a public health notification on DEHP warning health care providers to reduce DEHP exposure for certain vulnerable populations, including infants and other patients receiving multiple medical treatments.
- The U.S. National Toxicology Program Expert Panel expressed concern that the phthalate DEHP may pose a risk to human development and fertility.
- The California Office of Environmental Health Hazard Assessment concluded that DEHP is a reproductive toxicant under Proposition 65.
- The European Commission Scientific Committee identified premature neonates and patients undergoing hemodialysis as being at high-risk populations to DEHP exposure via medical devices.
- In France, legal provisions prohibiting the use of certain medical devices containing DEHP were adopted to minimize exposures to certain patient populations. Since 2015, the use of DEHP-containing tubing in pediatric, neonatology, and maternity wards is prohibited in France.
- The EU Directives on medical devices (Regulation (EU) 2017/745) will go into effect in May, 2020. The MDR 745/2017 - Annex I.II.10.4 resolution introduces provisions that would help phase out endocrine disrupting chemicals, carcinogenic, mutagenic and reproductive/developmental toxic substances, and particular phthalates in medical devices if safer alternatives are available and technically feasible.

In general, plastics recycling is preferable to single-use and disposal, although without proper safeguards, recycling technologies can pose occupational, public and environmental health risks. For example, mechanical recycling is often a labor-intensive activity in which workers hand-sort waste streams and disassemble products, resulting in their exposure to hazardous chemicals if they are not properly protected. Emissions from poorly-operated recycling facilities can also contaminate air, water, and soil.

Among the various plastic polymers, very little post-consumer PVC is recycled. It is challenging for several reasons:

- When waste streams of various kinds of plastic are mixed without sorting and separation, PVC content of more than 10-15% can make them much less useful and sometimes destroy their value completely. Recycling facilities must therefore rigorously separate PVC from mixed plastic through hand sorting or automated systems. [7, 8, 9, 10]
- PVC can be difficult to recycle in part because of additives. [11, 12] Moreover, recycled PVC often contains hazardous additives including metals, phthalates, and other toxicants that make their way from the recycled source into new consumer products. For successful recycling, PVC products need to be "super-separated" by product type to keep them from going to an incinerator or landfill.
- The costs of PVC recycling can be particularly high. [13, 14, 15] In 2018, a specialized PVC recycling facility in Italy was closed after 15 years of losses and collapsing demand for their product.

Alternatives to PVC products

Among the alternative plastics that can be used for various medical products and devices are polyolefins, including polyethylene and polypropylene; polyethylene terephthalate, a polyester; multi-layer laminate plastics; polyurethane; silicone; ethylene-vinyl acetate; polycarbonate; and polystyrene. Some of these plastics are also used for food packaging and office supplies. For building products, there are a wide range of substitutes, including wood, linoleum, rubber, and a variety of other polymers suitable for various applications.

Each of these polymers also requires various additives depending on the intended application but at far lower levels than plasticizers used in flexible PVC. Life-cycle evaluations of the hazards of alternative plastics also vary, with some inherently safer than others. For example, polyurethane is one of the more problematic polymers. It is produced by combining an isocyanate with a polyol.

Health professional associations commentary on PVC and DEHP

A number of medical and nursing professional associations have expressed concern about the health risks associated with PVC medical devices and DEHP including:

- The American Academy of Pediatrics warned about pediatric exposure and potential toxicity of phthalate plasticizers in a technical report. They also issued a policy statement, reaffirmed the policy, and addressed phthalates in the Green Book.
- An American Medical Association resolution encouraging alternatives to both PVC and DEHP products was passed and reaffirmed.
- The American Public Health Association issued a policy statement.
- The California Association of Neonatologists issued a statement.
- The Chicago Medical Society issued a resolution to encourage the study and evaluation of alternative products and practices.
- The California Medical Association issued resolutions on DEHP use in neonatal intensive care units, and dioxins and medical waste incineration.
- The Illinois State Medical Society issued a resolution.
- The International Society of Doctors for the Environment issue a resolution.

Currently, chlorine chemistry is fundamental to the process because most isocyanates are formed when phosgene is reacted with the appropriate amine, and phosgene is made by reacting chlorine with carbon monoxide. Isocyanates are also potent asthmagens and an important cause of occupational asthma. And, polyurethane recycling options are limited.

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Health Care Without Harm seeks to transform health care worldwide so the sector reduces its environmental footprint and becomes a leader in the global movement for environmental health and justice.

Health Care Without Harm's Safer Chemicals program collaborates with health care leaders to leverage markets to reduce harmful exposures by engaging the supply chain, driving the reformulation of products through model environmental health criteria and institutional policies, and advancing state and national policies.

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