



PVC/DEHP phase-out is possible anywhere in Europe: Model hospitals show how to succeed

Experience at Karolinska University Hospital (Sweden), the Vienna Hospital Association (Austria), Na Homolce and Olomouc Hospitals (Czech Republic), Kosice Saca Hospital (Slovakia) and Clinique Champeau (France) provide ample evidence for the claim that PVC phase-out is not only possible – it is realistic.

This factsheet describes the common lessons learned from across Europe to show how PVC phase-out is possible, whatever the political and economic climate. It also lists hospitals which are phasing out PVC and the devices with which they are having most success.

For additional information or copies visit the Health Care Without Harm website: www.noharm.org/europe

Introduction

Despite the fact that PVC-free medical devices are readily available on the market, many hospitals are still using PVC medical devices that leach DEHP. This factsheet showcases how many hospitals, and not only those in countries famous for progressive environment policies, have already taken the necessary steps to phase out PVC use.

Who is phasing out PVC?

As a whole, Scandinavian and German-speaking countries have made the most progress in eliminating PVC from hospitals. The programmes were initiated in both cases by regional administrations officially adopting PVC phase-out policies and committing to favour PVC-free products in public procurement contracts.

The Vienna Hospital Association, Austria, committed to phasing-out PVC in 1992. After more than 15 years of this environmental policy, PVC share in medical devices has dropped from approximately 10% of total weight of medical waste in 1992, to 2.5% in 1995, to just 0.6% in 1999. The proportion of PVC packaging material was reduced from 3.6% to 0.04%.

In 2004, Karolinska University Hospital in Stockholm County Council, Sweden, estimated it was using 40 tonnes of phthalates per year just in gloves. By mid-2007, Karolinska Hospital had substituted almost half of its PVC and latex gloves for safer nitrile alternatives.



Because of their small size and intensive treatment, prematurely-born babies can be exposed to particularly high levels of DEHP.

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Although political initiatives are a powerful driver of change, examples from the Czech Republic, Slovakia and France (where political support for such initiatives is entirely absent) show that changes in purchasing policy are occurring at individual hospitals, whatever the economic and political climate is in which they operate.

This strongly suggests that the primary factor determining whether or not hospitals begin PVC phase-out is demand from medical professionals and nurses. The only thing a phase-out projects must have is determination from people who want to prevent health problems and protect the environment by eliminating unnecessary exposure to DEHP and ending the use of PVC.



What are hospitals phasing out?

Hospitals almost always start with PVC devices used in neonatology and paediatric units, and/or with dialysis patients considered at risk from DEHP exposure. Neonates are prioritised because they are most vulnerable to the toxic effects of DEHP and are treated with multiple devices for long periods of time. Their low bodyweight and lengthy treatment results in especially high, prolonged exposure at a critical stage of development.

Unfortunately, safe and reliable PVC-free alternatives are not always available. Na Homolce Hospital and Karolinska University Hospital provide examples of interim solutions.

The health risks of PVC/DEHP

Many medical devices are made from PVC (also known as “polyvinyl chloride” or “vinyl”). Since PVC is naturally rigid, it has to be softened in order to be flexible enough for use in medical applications, such as tubing and IV bags.

Most PVC medical devices are softened with the chemical DEHP (di(2-ethylhexyl)phthalate). The problem with DEHP is that it leaches out of medical devices into the liquids the device contains. These liquids go straight into the patient.

There is increasing evidence that DEHP is harmful, especially to boys exposed in the womb or first few weeks of life. Animal studies have shown genital abnormalities and other developmental disorders. The EU Scientific Committee responsible for investigating new health risks describes DEHP in medical devices as “a concern”.¹

These worries, combined with concerns about the environmental profile of PVC, have led to many hospitals across Europe deciding that it would be irresponsible not to phase-out PVC medical devices and packaging in favour of PVC-free alternatives – so long as the phase-out does not compromise patient safety or care.

For more information about the environmental and health risks of phthalates and PVC, read our factsheet “Why hospitals are moving away from PVC”. You can find out how to eliminate PVC from your hospital in our factsheet “How to survey PVC use in your hospital and begin a successful PVC phase-out programme”.

¹ Scientific Committee on Emerging and Newly-Identified Health Risks SCENIHR preliminary report on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk. EU Commission Health and Consumer Directorate General. October 2007. See http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/scenihhr_cons_05_en.htm

At Na Homolce, the nephrology department switched to DEHP-free haemodialysis sets made with PVC. This measure, combined with substituting IV bags for PVC-free alternatives, reduced haemodialysis patient exposure to DEHP to zero.

As a partial solution, Karolinska initially swapped PVC gloves softened with phthalates for PVC gloves softened with an alternative plasticizer – adipate. Then they began purchasing nitrile gloves, free of all plasticizers and PVC, in increasingly large amounts.

Is it OK to use a different plasticizer to DEHP?

Choosing PVC devices with alternative plasticizers is only a partial solution, since it is probable that alternative plasticizers will also leach from medical devices. Their toxicity has not been investigated to the same extent as DEHP, although some hospitals do consider some alternative plasticizers (such as adipates) to be preferable to using DEHP.

It is also important to note that switching to another softener does not solve the environmental problems related to PVC. Avoiding PVC and phthalates altogether by switching to alternative plastics for medical devices is ultimately the only way to avoid health and environmental problems.

What makes a phase-out programme successful?

1. Determination

HCWH Europe’s experience has been that first impetus for PVC phase-out generally comes from concerned nurses and doctors. Successful PVC phase-out happened in Czech, Slovak and French hospitals after senior departmental employees took the initiative to lead the projects.

At Na Homolce Hospital in Prague, Czech Republic, the head of the nephrology unit was the driving force behind change. Similarly, the Director of the Clinique Champeau in Beziers, France committed his entire hospital to giving preference to PVC-free when purchasing medical devices.

2. Political and executive support

Political support is also important. Long-term plans can only be carried out if there is continuous political support, especially for public hospitals. Vienna Hospital Association and Karolinska University Hospital are prime examples of how the regional governments’ long-standing commitment to PVC phase-out has borne fruit.

3. Know your devices

The first step which all hospitals took to start PVC elimination was to conduct a PVC audit. Each hospital had to identify which devices were PVC, for which suitable alternatives were available on the market.

A PVC audit involves either (a) analysing purchasing statistics in cases where there are data about which products are made of PVC in the purchasing catalogues, or (b) physically examining devices used in the target wards and identifying the materials they are made from.

The Head Nurse of the Olomouc Neonatal Intensive Care Unit performed a medical device audit, collecting information for 106 products used on newborn patients. She asked all manufacturers to provide information on material composition. Out of the 81 most commonly-used products, the nurse was only able to identify the components of 58. 33% of those 58 products were PVC.

More information can be found in our factsheet “How to survey PVC use in your hospital and begin a successful PVC phase-out programme”.

4. Measuring results

Karolinska University Hospital undertook a PVC audit in selected departments to find out what progress had been made in substituting PVC-free alternatives in medical devices and other products it was using.

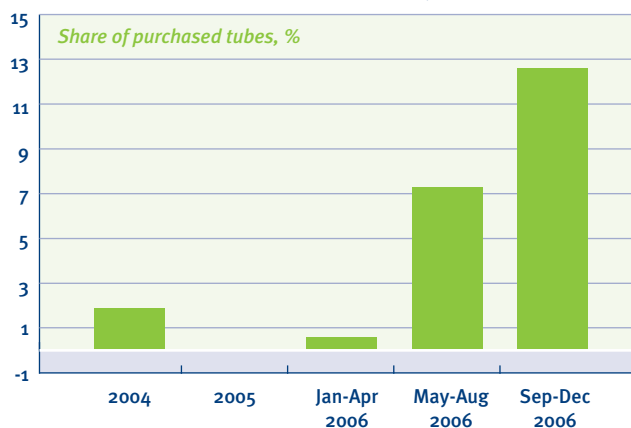
Among the medical devices with long-term DEHP exposure potential, blood bags, tubing and dialysis products were used

	Quantity of products	Phthalate content
Examination gloves*	9.6 mill.	40 tonnes
Blood bags	80 000	6.4 tonnes
Hemo dialysis sets	10 000	Appr. 2 tonnes
Drain tubes	70 000	0.4 tonnes

*before 2004

Table showing phthalate use in selected products at Karolinska University Hospital, Sweden.

Drain tubes free from PVC and phthalates



in the largest quantities. However, the largest amount of phthalates – 40 tonnes per year - came from PVC gloves.

Purchasing statistics obtained from several departments showed that IV sets, catheters and drainage bags are now mostly made from PVC- and phthalate-free materials. Drainage tubes were being substituted for DEHP-free alternatives, before moving in 2006 towards increased use of PVC-free polyolefin alternatives.

5. Communication with manufacturers

The Neonatal Intensive Care Unit at Olomouc Faculty Hospital contacted manufacturers directly. With accurate product information in hand (such as product number and size) and persistence the head nurse obtained material content information from manufacturer representatives. She found that syringes, central venous catheters, ventilation tubing and intravenous cannulae were available in alternative materials such as silicon, polyethylene, polypropylene or rubber.

The NICU then began to negotiate with one of its main medical devices manufacturers, B Braun, who agreed to deliver an entirely PVC-free set for infusion therapy, including the exchange transfusion set. There is now a policy in place to favour non-PVC medical devices if available on the market in the Czech republic.

By 2005, 95% of medical devices in close and regular contact with newborns at Olomouc NICU were replaced with safer alternatives. Alternatives were unavailable for only 5% of the equipment.

But isn't PVC phase-out too expensive?

Hospitals often make the mistake of assuming that PVC phase-out is too costly even to consider – or that only relatively wealthy healthcare systems, such as those in Scandinavia, can afford it.

So it may come as a surprise to some people to find out that hospitals such as Na Homolce in the Czech Republic and Kosice Saca in Slovakia have also carried out successful PVC phase-out programmes.

Na Homolce completely switched over to PVC-free IV bags in 2003, before moving on to PVC-free IV lines. IV bags are a good place to start because they are purchased in large quantities and alternatives are readily available and price-competitive.

A list of PVC-free medical devices available on the European market is available on-line at www.noharm.org/europe

European healthcare institutions and hospitals using PVC-free medical devices

Austria

» Vienna Hospital Association (18 Hospitals, nursing homes, geriatric care centres)

A product catalogue listing approximately 630 alternative PVC-free products is available to the hospitals and geriatric centres associated with the Vienna Hospital Association.

PVC-containing products which are either invasive or have long application periods – such as infusion apparatus, dialysis tube systems, catheters, tubes or drains – are prioritised for substitution.

Glanzing Pediatric Hospital Neonatology Unit has almost completely eliminated PVC & DEHP - almost all invasive devices are now PVC free. They completed most of the work by May 2003. PVC-free devices now being used include:

- » Pacifiers & nipples (cleft lip, cleft palate, sleeping, comforting, wide-mouthed bottle nipples, feeding nipples)
- » IV bags, IV sets, blood filters, respiratory equipment, feeding tubes, other tubes are PVC-free
- » Cannulae
- » Suction tubes
- » Venous catheters
- » Ventilation accessories
- » Probes
- » Perfusion tubes and syringes

- » Connecting tubes
- » Blood filters and infusion bags

The neonatal and paediatric departments in the following facilities are using almost all the same PVC/DEHP-free devices as Glanzing and are in the process of substituting the rest.

Preyer Pediatric Hospital

Vienna General Hospital Neonatology Clinic 1 & 2

Danube Hospital Neonatology Clinic

Hospital Rudolfstiftung

Empress Elisabeth Hospital

Hospital Hietzing

» Styrian Hospital Association (20 Hospitals)

Pilot projects are underway on PVC phase out in three hospitals, one of which has already replaced some PVC medical devices:

Maternity clinic of LKH Deutschlandsberg

- » Female catheter
- » Adult Oxygen Mask
- » Infusion set for pressure or gravity infusion

Denmark

» Sønderborg Hospital Neonatal Department

The following products are examples of devices being used that do not contain DEHP.

- » IV Catheters
- » IV administration sets
- » IV Tubing
- » Guedel Airways

- » Feeding Tubes
- » Nitrile gloves
- » Pacifiers
- » Bandages

» Copenhagen University Hospital Gentofte

- » Catheters
- » IV tubing

Slovakia

» Kosice-Saca Hospital

The hospital has signed a contract for supply of the following PVC/DEHP-free items

- » IV administration sets
- » IV Tubing
- » Enteral feeding tubes
- » Periferal cannulae
- » Intravenous catheters



Sweden

- » **32 Neonatology Units and hospitals in Sweden** use feeding tubes for long-term treatment of babies that are non-PVC. (HCWH has as yet only researched feeding tubes at NICUs.)
- » **Karolinska University Hospital**
 - » PVC examination gloves are being replaced with nitrile gloves (the first step was substitution of DEHP for another plasticizer)
 - » Haemodialysis sets DEHP-free (DEHA)
 - » Urine catheters PVC-free for some uses
 - » Drain Tubes PVC-free / DEHP-free
 - » Blood Transfusion sets PVC-free
 - » IV bags and IV sets PVC-free
 - » Small Urinary bags PVC-free
 - » Identity Bracelets PVC-free
 - » Patient Cards PVC-free
 - » Feeding tubes PVC-free
 - » Catheters PVC-free
- » IV tubes PVC-free For haemodialysis sets, the hospital has a company producing DEHP-free sets
- » **Haemodialysis Clinic Huddinge**
 - » Some PVC-free bags
- » **Peritoneal Dialysis Dept, Huddinge**
 - » some PVC-free bags
- » **Skåne Region (10 Hospitals including Malmö University Hospital):**
 - » 99 % of all packaging is PVC-free
 - » All office supplies: all PVC-free
 - » All syringes: PVC-free
 - » Enteral nutrition: all PVC-free
 - » Infusion: everything is PVC-free
 - » Gloves: All DEHP-free, some pvc-free alternatives
 - » Transfusion: much is PVC-free
 - » Bandages: All PVC-free

Czech Republic

- » **Na Homolce Hospital**
 - » IV bags used for haemodialysis patients – PVC-free (Baxter, multilayer plastic)
 - » DEHP-free haemodialysis sets
- » **Faculty Hospital Olomouc**

The hospital succeeded in replacing about 95% of medical devices that are in direct contact with neonates. These are mainly intravenous and transfusion devices – the entire circuit into the patient's body.

 - » IV bags
 - » Arterial Monitoring Set
 - » Feeding tubes
 - » Extension IV tubes
 - » Central Venous Catheters
 - » Infusion Stopcocks
 - » Umbilical Vessel
 - » Ventilation Circuits
 - » Catheters
 - » Syringes
 - » Bladder (Urine) Catheters
- » **St. Elizabeth Hospital, Louny**

The hospital conducted a PVC audit in 2007. In the first stage they substituted 2 groups of products for the entire hospital

 - » Anaesthesia masks
 - » Syringes
- » **Hospital in Ceske Budejovice**

Ceske Budejovice Hospital. Substituted 90 % of special-use medical devices in intensive care and resuscitation. Devices which have been substituted include:

 - » Venous catheters
 - » Umbilical catheters
 - » Invasive monitoring devices
 - » Respiratory tubing (some substitution with silicon)
 - » IV catheters
 - » Women's catheters
 - » Syringes
 - » Reusable transducers
 - » Oxygen masks
 - » Dialysis catheters
 - » Bags for peritoneal dialysis

A few alternatives to PVC medical devices

For a list of PVC- and DEHP-free medical devices, see our factsheet “Alternatives to Polyvinyl Chloride (PVC) and Di(2-Ethylhexyl) Phthalate Medical Devices on the European Market”



Haemopharm Biobags
(various volumes, multilayer non-PVC plastic)



NeoCare® - Silicone umbilical catheter



B Braun, Redyrob® Trans Plus - Closed wound drainage system for use with Redyrob® Comp



Cryovac® Medical Films



Astra Tech Ltd, LoFric® Plus: PVCfree hydrophilic catheter



Kapitex Healthcare Ltd, Emergency Resuscitation Mask



BD Medical Systems, Connecta Multiflo



Nutri-Cath® feeding tube



B Braun, IV Bag

Disclaimer: The listing of products in this document does not constitute an endorsement of the products nor were the products tested for safety or efficiency by Health Care Without Harm. Products should be tested and evaluated before purchasing to ensure they meet required performance specifications.

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