PVC in medical devices

An inventory of PVC and phthalates containing devices used in health care

Final report

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Contents

1 Assignment

In 1997 the Stockholm County Council (SLL) decided to phase out the use of PVC in health care. It is currently an overall environmental goal of Karolinska University Hospital to reduce the use of chemical products that are harmful to health and the environment, and to reduce the environmental impact of goods and services. The hospital also has a consistent policy of setting environmental requirements during purchasing.

In 2003 Karolinska University Hospital and SLL began a joint project with the organization Health Care Without Harm to carry out an inventory of the use of soft PVC products in its departments. The main goal of the project was to phase out the use of PVC and phthalates wherever suitable alternatives are available. In this phasing-out process, first priority is given to eliminating soft PVC in products that are used over long periods by the most vulnerable groups of patients, such as children and dialysis patients.

A secondary goal was to increase our understanding of the health and environmental effects of chemicals in disposable items, and to identify the information needs of personnel who buy and work with such products. Another secondary goal was to assess how SLL's decision has affected the use of health care articles that contain PVC.

2 The problem of PVC in medical devices

2.1 What is PVC?

Polyvinyl chloride or vinyl (PVC) is a polymer in which more than half of the content by weight consists of chlorine. Plasticizers are added to PVC to make the plastics soft and pliable, which are the most desirable properties for medical products.

2.2 What are phthalates?

Phthalates are the most commonly used softeners or plasticizers in PVC plastic. Medical devices made from PVC normally contain 20–40 percent of plasticizer by weight. The content can be as high as 80 percent in feeding tubes. There are at least 15 different phthalates, all with similar properties. The most widely used phthalate is DEHP (di-ethyl-hexyl-phthalate).

2.3 What's the problem with using PVC in medical items?

Chlorinated pollutants such as dioxins and PCB[i] can be formed during the manufacture and disposal of PVC and other materials containing chlorine. These pollutants can be found in people's bodies, and in breast milk, all over the world.

Another reason for phasing out the use of PVC in health care at global level was the finding by the US Environment Protection Agency (EPA) that incinerators destroying health care waste were among the largest single sources of dioxins in 1997[ii]. Health care authorities in Stockholm do not run their own incinerator plants. This means that the PVC content from health care waste is relatively low in relation to other products that are processed at municipal waste plants.

There are specific areas where the use of PVC is particularly unsuitable from the disposal viewpoint. A number of radioactive substances are used in health care. Radioactive waste is handled separately and sent for special processing. The process of decontaminating radioactive waste is sensitive to chlorine, so products that could become contaminated during the handling of radioactive substances should be kept free from PVC.

Most of the phthalates that are used as plasticizers in PVC have chemical properties that mimic the behaviour of our natural hormones. This means that phthalates can disrupt the human hormone system. DEHP causes a reduction in the testicular weight of laboratory animals and is classified as a reproductive toxicant and teratogen[iii]. Because the disruption affects hormonal development, the risk of harmful health effects is greatest among children and patients who have experienced long-term exposure[iv].

Researchers at Lund University have found a link between the levels of phthalates in the body and reduced sperm production in Swedish men at enlistment age[v]. Other research indicates that human fertility may be more sensitive to phthalate exposure than that of other animals. The results of US studies do not agree with the Swedish research, which has meant that the available research results have so far been inadequate to draw a conclusion on whether phthalates represent a risk to human reproduction or not.

When used indoors, phthalates can give rise to allergies and respiratory problems in children[vi]. This was shown by a Swedish-Danish study presented in 2004. The normal concentration of phthalates in the indoor environment in Swedish homes is sufficient to cause children allergy problems. The study also showed there were differences between the various phthalates. High exposure to DEHP led primarily to an increase in asthma and respiratory problems. BBP was more likely to give problems such as allergic rhinitis and eczema.

A significant part of the population is believed to be exposed to levels of DEHP high enough to exceed the tolerable daily intake (TDI) limit[vii]. Children have higher levels of exposure than adults[viii]. Patients can also be exposed to higher levels of DEHP from medical devices that are used internally, since the phthalates are not bound to the polymer.

2.4 Why is PVC permitted in medical items if it is so hazardous?

Chemical preparations containing DEHP must be labelled with the “skull and crossbones” symbol within the EU[ix]. Medical products are not regarded as “chemical preparations” according to chemicals legislation and are therefore not covered by the general restrictions, despite the likelihood of high exposure.

There is specific regulation of the use of phthalates in toys[x]. Toys that can be placed in the mouth by children under the age of three must not contain six specific phthalates. (Recently, the legislation was updated: phthalates classified as reproductive toxins – DEHP, DBP and BBP are prohibited in all children products. The other three phthalates – DINP, DODP and DIDP are banned from products intended for children under the age of three). DEHP is prohibited for use in cosmetics[xi], adhesives, paint and other consumer products[xii].

Several different PVC products that contain DEHP plasticizer are used in health care. Common products include feeding tubes, tubes and catheters, as well as infusion bags for nutrients or dialysis fluids.

Under the EU’s risk assessment process[xiii] the risks of different types of DEHP exposure have been evaluated. In the case of medical devices, the conclusion is drawn that risk reduction measures are necessary to decrease the exposure of patients who come into contact with DEHP

via medical equipment. A proposal for risk reduction is currently being considered by the European Parliament and Commission.

3 Analysis of materials and risks

3.1 Which are the most widely used products?

Of the total amount of PVC that is produced globally, it is estimated that just 1 percent is used in medical devices. The phasing out of PVC from medical use can therefore not be regarded as critical to the PVC market as a whole.

According to HCWH, bags and tubes account for the largest single amounts of PVC. At SLL, however, the largest single use is gloves.

The investigation carried out prior to the 1997 decision concluded that the largest amounts of PVC were used by the city council in the property and transport sectors. A quick examination of the data shows that the amount of PVC in health care products was probably underestimated. The amount of PVC in gloves alone exceeds the estimated annual amount used for construction and renovation of Locum (Department, responsible for the buildings) properties by 70 percent.

Under the 1997 decision, office supplies should have been PVC-free by the start of 1998. The office supplies range that was lunched in spring 2005 still includes articles that contain PVC.

Table 1. Survey of amount of PVC supplied each year to SLL in 1997 and 2004.

	Buildings	**Transport**	**Office materials**	**Health care**[i]
Flooring	50 tonnes	30 tonnes		
Wiring	35 tonnes			
Gloves				170 tonnes (18.8 million items)
Infusion devices				15–20 tonnes (580,000 items)
Urine bags				13 tonnes (450,000 items)
Total	100 tonnes	No data	No data	> 200 tonnes

[i] Values for health care are based on purchasing inventory for 2004.

3.2 Which products pose the greatest potential risk?

Products that expose patients to long-term or repeated direct (invasive) exposure to DEHP or other harmful substances, and are used for sensitive groups of patients, such as premature babies, infants and children, are likely to have the most significant effect on the health of individuals. Steps should therefore be taken to remove these products first. The category of sensitive patients also includes women of fertile age, since they can transfer toxins to their children during pregnancy and breastfeeding. Many studies have been carried out that show the actual exposure to DEHP[xiv].

4 The Stockholm County Council's action plan

In 1997 Stockholm County Council adopted a plan of action to phase out products that contain PVC[xv]. The report covered all types of PVC-containing products and was very concrete and clear about the groups of products that should be replaced relatively quickly. The largest amounts were found in the property sector (Locum) and transport sector (SL). The initial report said that it would be possible to replace 80–90 percent of the PVC content at an added cost of SEK 10–20 million as soon as the opportunity arose for renovation or extension.

Four years later a follow-up report was produced[xvi]. The results were mixed. On the positive side, 181 tonnes of electrical and telephone cables had been replaced with halogen-free alternatives and some of the promised information initiatives had been taken. But on the other hand there was very little follow-up information in the annual environmental reports of the companies and administrations. Similarly, the product catalogues for MediCarrier and the National Dental Service failed to give consistent information about the types of plastic used, even though this had been specifically pointed out in the programme of action. Now, seven years later, we can report that MediCarrier's catalogues still lack adequate information. See below.

The results for property and transport were not followed up in the study carried out by Karolinska University Hospital in 2004–2005.

5 What has the project led to?

5.1 Analysis of DEHP in medical products in the European market

Karolinska University Hospital has taken part in a study, along with six other European countries, in which selected health care products were analyzed for DEHP content. The study, which was led by HCWH, covered 48 products from 27 different manufacturers. When choosing the test subjects priority was given to products for transporting oxygen, medical fluids and nutrient solutions. Thirty-nine of the PVC products contained between 17 and 41 percent by weight of DEHP. No detectable concentration of DEHP was found in the PVC-free products, with one exception.

5.2 Survey of PVC and phthalate content at Karolinska University Hospital

Statistics regarding purchases of medical devices in the years 2003 and 2004 have been compiled and evaluated. In the case of large amounts of materials that are not bought under SLL's collective purchasing arrangements, direct interviews were carried out with representatives of the departments involved. This applies primarily to blood donation and dialysis.

The aim was to convert product quantities into weights of products and phthalates. Where specific product data was lacking, the plasticizer content was estimated as 30 percent of the total weight of the product. It is unusual for the particular type of plasticizer to be stated. Unless known otherwise, it is assumed that the product contains DEHP. In the case of blood bags, we know for certain that they contain DEHP.

Examination gloves account for the largest supply of PVC in health care. In 2004 SSL introduced a collective purchasing arrangement to buy gloves that are free from phthalates. This purchasing arrangement eliminated the environmental impact of 100 tonnes of phthalates per year.

Among the products with which patients have longer contact, those for blood donation and dialysis are used in the largest quantities. These are bought under the hospitals' local agreements. The next largest quantities are urinary catheters and urinary bags. The replacement of urinary catheters should be straightforward, since some facilities already use mainly PVC-free urine catheters. In the case of dialysis and blood donation, it may take longer to find replacements. A great deal of effort has already been put into finding alternatives, particularly where the handling of blood is involved, but it is often difficult to find solutions that will work reliably in health care.

Table 2. Summary of purchased quantities of consumables at Karolinska University Hospital 2004

Product type	Unknown content	PVC-free	Containing PVC	Phthalate	Remarks
Gloves	1.0 million	7.7 million	10.4 million	41 tonnes DINP[ii]	All gloves are phthalate-free from June 2004
Blood bags		0	80,000	6,4 tonnes DEHP	Only PVC
Haemodialysis devices			Approx. 10,000 Approx. 4 tonnes	1–2 tonnes DEHP	Only PVC
Peritoneal fluid in bags	Approx. 1.9 tonnes total: with PVC and PVC-free			0.5–2 tonnes DEHP	Approx. 20–30% PVC-free
Urine catheters	7,600	100,000	530,000, approx. 5 tonnes	1.6 tonnes DEHP	16% PVC-free
Urine bags	60,000	20,000	150,000 4–5 tonnes	1.3 tonnes DEHP	26% PVC-free
Feed tubes	5,000	5,600	23,000 approx. 1.4 tonnes	0.2 tonnes DEHP	17% PVC-free 0.2% DEHP-free PVC
Catheters	42,000	127,000	14,000		70% PVC-free
Drain tube	11,000	0	70,000 approx. 1.4 tonnes	0.4 tonnes DEHP	Only PVC
Drain bag	21,000	33,000	0		>61% PVC-free
Infusion tube	20,000	400,000	80,000	0.7 tonnes DEHP	80% PVC-free 0.2% DEHP-free PVC
Identity bracelet		43,250	1,250		99% PVC-free
Patient card		500	42 000	Hard PVC No plasticizer	1% PVC-free

[ii] Calculated as if gloves containing phthalates were used for whole year.

5.3 Specially examined departments

The following places of work were chosen because they handle groups of patients who are at particular risk, such as children and dialysis patients who are likely to have prolonged exposure to DEHP if PVC products are used. Another factor that these departments often have in common is that they buy in many articles that are specific to their needs outside the collective purchasing agreements. Local purchasing is carried out by each hospital's purchasing department. An inventory of stock rooms was carried out for a couple of hours together with the staff in charge. The examinations were not exhaustive and should rather be seen as random samples.

Table 3. Random sample of departments with groups of patients at particular risk

Department	Result	Comments
Neonatal clinics in Huddinge and Solna	Mostly PVC-free , particularly in the case of products for invasive use.	High level of awareness among staff and active steps taken to avoid PVC products.
Haemodialysis department in Huddinge	All tubes for haemodialysis were made from PVC. PVC-free bags are most common.	High level of awareness among staff and managers. Active steps being taken to find alternatives to PVC products.
Peritoneal dialysis department in Huddinge	Both PVC bags and PVC-free bags are used. PVC dominates.	Department staff did not take part in inventory.

5.4 Comparison with council assessment when phasing out was agreed in 1997

Patient tags, surgical drapes, overshoes and office materials were already PVC-free from by 1997 according to the investigation by SLL.

Statistics from our study show that if patient tags containing PVC had been phased out in 1997 then they have been reintroduced. Patient tags containing PVC were used at the Karolinska University Hospital in Huddinge in 2003 and were reintroduced at the Karolinska University Hospital in Solna in 2004.

In the case of medical products, SLL stated in 1997 that the replacement of PVC products should take place "within the next year in the case of infusion devices, drain sets, etc., where equivalent PVC-free alternatives can already be purchased". An immediate changeover to PVC-free alternatives was therefore recommended for drain sets, drain tubes and feeding tubes for children. It was also stated that PVC products would only be purchased in special circumstances[xvii]. Those circumstances are probably documented by SLL's purchasing office, but if so, this information is not readily available to staff who have to use the products.

Phasing out was then to be followed up in the annual environmental reports of the municipal companies and administrations.

Purchasing statistics from our study show that infusion items are mostly made from materials that are PVC- and phthalates-free. Drain tubes are generally always made from plasticized PVC. No suitable alternative has been found. Random samples in neonatal departments show that no PVC feeding tubes are bought in for children.

One major practical problem in the task of mapping out and phasing out PVC is the difficulty in identifying which of the collectively purchased products contain PVC and which are made of other materials.

Office products are not yet entirely PVC-free. In the catalogue of office supplies that was issued in 2005 there are still a number of products made from PVC.

5.5 Medicarrier's catalogues

An examination was made of the information given in Medicarrier's catalogues on the materials present in purchased products. The following six catalogues were studied in more depth:

- Feeding tube items
- Surgical items
- Gloves, syringes and cannulas
- Health care items
- Incontinence items
- Anaesthesiology and infusion items

Information on the material content of these products was divided into the categories PVC, PVC-free and not known. Not known refers to products where it has not been possible to identify the materials they contain. Only products made from plastic and rubber were checked. All gloves, feeding tubes, tubes, catheters and bags were checked. Plugs, hard connectors and combined surgical sets were generally excluded.

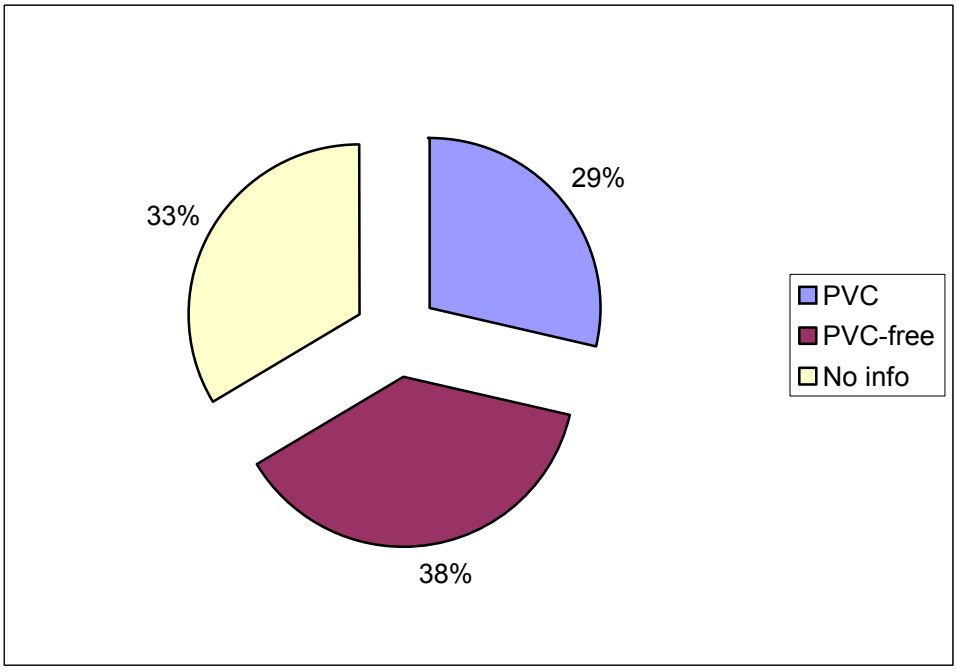

Figure 2. Summary of how information on material content is distributed between common types of collectively purchased disposable products in Medicarrier's catalogues.

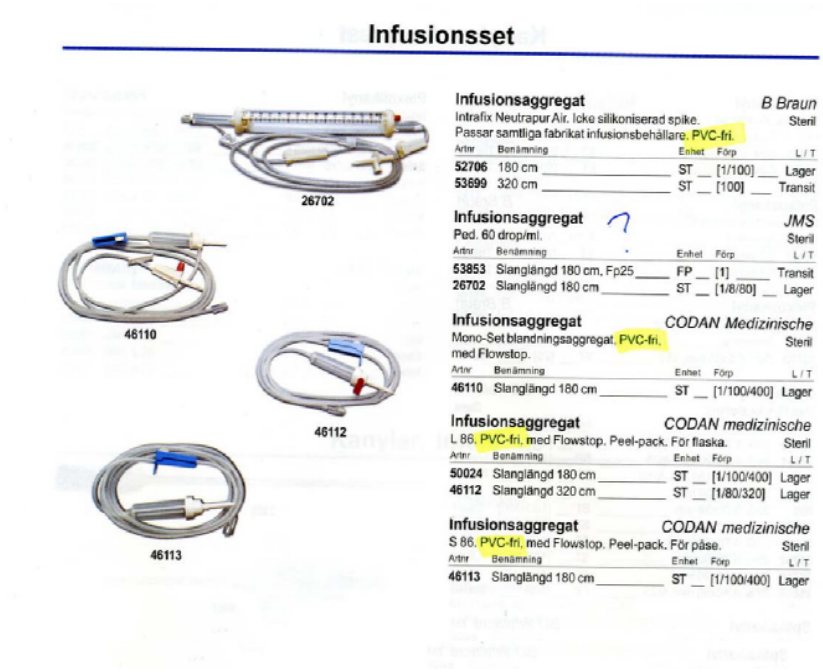

Figure 3: Extract from a MediCarrier catalogue

The figure above shows information on the PVC content of four products, but for the fifth product there is no information at all:

Conclusion: The information on items in the product catalogues needs to be improved to provide adequate environmental information to the departments that buy the products. If the product catalogues are replaced with an electronic purchasing system the same type of information should be added to this system.

6 Recommended future action

6.1 Prioritization is needed

The goal should be a health care system free from PVC. At the same time it makes good sense to proceed in stages, making those changes that are easiest of all and prioritizing risks in order to encourage progress towards the goal. Prioritizing risks mainly entails minimizing the exposure of sensitive groups of patients such as children, women of fertile age and patients who are exposed repeatedly or for extended periods to DEHP. For the sake of caution, other phthalates or additives that can be transferred to patients should also be included in the prioritization of risks.

The easiest changes to make involve items that can be replaced fairly easily in terms of cost and function. In some cases it may make sense to switch to phthalate-free PVC as a temporary solution if the cost of totally PVC-free alternatives is relatively high. Such compromises can be made if the risk of transfer to the patient is reduced, as in the case of examination gloves, for example. However, we should not take the long route via phthalate-free alternatives if there are PVC-free alternatives available at reasonable cost.

The order of prioritization for materials should generally be:

- Eliminate DEHP and other phthalates that have been classified as hazardous
- Eliminate phthalates that have not been classified as hazardous
- Evaluate other additives that are not classified as hazardous
- Choose only PVC-free materials

The order of prioritization for types of materials and applications should be:

- Invasive long-term use
- Invasive use for children and women
- Invasive use for other groups of patients
- Large quantities of items purchased
- Easy to replace in terms of price and function.

Points can be given to each aspect in such a way that high points indicate a high priority. The following table should be seen as a draft suggestion and the allocation of points can naturally be discussed to decide which factor should be given the greatest weight.

Table 4. Order of prioritization for phasing out PVC products

Material	Exposure	Patient group	Quantity	Replaceability
DEHP and other phthalates classed as hazardous – 4p Phthalates not classed as hazardous – 3p Other additive – 2p PVC regardless of additives – 1p	Invasive – 4p Other patient exposure – 3p Other – 1p	Children, fertile women, dialysis patients – 4p Other groups of patients with repeated exposure – 2p Other patients – 1p	Large quantity - 2p Smaller quantity -1p	Max. 10% added cost - 4p Max. 50% added cost -3p More than 50% added cost -2p Not available on market yet. -1p

6.2 Prioritizing vulnerable groups of patients

For clinics or departments treating vulnerable patient groups there may be a need for additional training for one or more members of staff, or even an entire group. It may also be appropriate to give someone special responsibility for monitoring the use of PVC items and testing new products that are developed.

6.3 Working at department level

Responsibility for phasing out PVC should be delegated to departmental level. Each department should be given the opportunity to set its own target deadlines, as circumstances vary from department to department. Technical developments and the risk to patients relative to effects on price should determine each clinic's targets. This approach could work well with the point scoring system outlined above. To increase motivation a chart showing the variation in key figures over the year could be posted on notice boards.

6.4 Training and information

There is a lack of knowledge about which products contain harmful or environmentally hazardous substances. This is because the environmental issues have not been given high priority and because information on purchased items is not readily available. The lack of information is not limited to Karolinska University Hospital; it reflects the state of awareness in the rest of society.

There is a need to increase awareness of the products that are bought by the individual departments and what environmental effects these products have. This information can be passed on in the form of general environmental training, department-specific feedback from purchasing and information on the different types of consumable items and their chemical content.

6.5 Medicarrier's catalogues

MediCarrier's catalogues should present consistent information on material content, such as whether products "contain PVC" or are "PVC-free". They should also give information on the type, i.e. "DEHP-free PVC" or "phthalate-free PVC", where appropriate. Suppliers should be required to identify materials and any additives in a consistent manner in order to become approved suppliers. All materials should be automatically classed as containing PVC unless the supplier has given clear information to the contrary. It will be easier to keep track of the phasing out of PVC and make a good environmental choice if the catalogues contain clear information.

6.6 Exclude PVC if collectively purchased alternatives are available?

In cases where PVC-free or phthalate-free materials meet the user needs, materials that contain PVC or phthalates should be excluded completely from purchasing. This approach will mean that phasing out occurs fully in line with the substitution principle laid down in the Environmental Code. This allows the progress of the phasing-out process to be clearly followed for each application. It would also give a clear signal to suppliers that they need to develop their products.

6.7 Opportunities

A suggested list of high-priority product groups has been drawn up by HCWH: The groups are given in table form in Appendix 1.

6.8 International work

Steps are being taken to phase out PVC primarily at clinics in Austria, Denmark, the Czech Republic and USA through Health Care Without Harm. Because the problems are largely the same and the market for medical products is global, there is a lot to be gained from international collaboration. This can include swapping experiences of alternative materials and exploring opportunities for coordinating purchasing requirements.

6.9 Decisions must be followed up

One of the most important results of this report is that the political policy decisions that are taken must be followed up. There is a need to ensure that someone is appointed with collective responsibility for implementing decisions. Resources are also needed in various parts of the organization to implement the initiatives that follow on from decisions. Unfortunately this does not generally happen in the case of environmental decisions, which often receive less attention under the heading of "other issues". When environmental issues are dealt with as seriously as financial audits, there will be good reason to believe in the future.

7 Conclusions

There has been no systematic follow up to the county council's decision to phase out PVC. For example no one has been put in charge of the phasing-out process.

There are still large amounts of PVC present in medical devices, although clear progress has been made regarding infusion items and products used by neonatal clinics. Several of the improvements that were thought to be easy to implement eight years ago have still not been made. In some cases we can even see a return to phased-out products made from PVC.

The significance of the total quantity of PVC in health care was underestimated in the county council's investigation in 1997. In particular the quantity of examination gloves was incorrectly estimated in relation to building materials and the transport sector.

Individual initiatives within the organization have resulted in the elimination of the county council's largest single source of phthalates. Continued commitment to alternatives to vinyl gloves is still important, however.

The issue of phasing out PVC is more relevant than ever before. The most commonly used plasticizer in PVC – DEHP – has now been more thoroughly investigated and is classed as harmful to reproduction. More data has been gathered which indicates that the phasing out of PVC and phthalates should be more urgent today than it was eight years ago.

Information on the items listed in Medicarrier's product catalogues needs to be improved to provide adequate environmental information to the departments that buy the products.

It is desirable to increase information initiatives concerning the hazardous chemicals in products, by means of internal training and good written information.

The report recommends priorities and working methods for a successful phasing-out process. There are also clear alternatives on the market for applications such as peritoneal dialysis, urology and tube feeding, which ought to be able to replace the entire conventional product range today.

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[ix] Council Directive (67/548/EEC)

[x] Product Safety Directive (92/59/EEC)

[xi] The Directive on Cosmetic Products (76/768/EEC)

[xii] The Directive on Restrictions on the Marketing and Use of Certain Substances and Preparations (76/769/EEC)

[xiii] Chemicals Regulation (793/93/EEC)

[xiv] Table 2 from Preventing Harm from Phthalates, Avoiding PVC in Hospitals, Health Care Without Harm, June 2004.
See www.noharm.org

[xv] Memo, Stockholm County Council, 30 September 1997, project manager: Almerfors

[xvi] Jenny Forsberg, PVC in Health Care – following up the phasing out of PVC by the county council, thesis project Stockholm Environmental Centre, 1 August 2001.

[xvii] Environmental policy action programme for Stockholm County Council 2002–2006, Environment step 4

Appendix 1

Table B1.Summary of available alternatives to PVC products in health care (compiled by Health Care Without Harm)

Product type	Alternative materials available on the market
Blood bags: plasma, whole blood or concentrated red blood cells	Polyolefin works for thrombocytes and frozen fresh plasma. For whole blood there is currently no alternative to PVC apart from glass.
Peritoneal dialysis and haemodialysis	PUR, silicone, laminate
Central venous catheters (invasive)	PUR, Teflon, silicone
Peripheral venous catheters/infusion cannulas	PUR, Teflon, silicone
Infusion sets, infusion pumps and devices + PEG	EVA, polythene
IV (Infusion) sets, IV (infusion) pumps and devices	EVA, polythene
IV (Infusion) bags	Three-ply laminate EVA or PET
IV (Infusion) tubes	PUR, EVA, polythene
Total Parenteral Nutrition sets (TPN sets)	EVA, glass, PUR, laminate
Feeding Tubes	EVA, polythene
Feeding bags/bottles	Glass, polythene
Umbilical vessel catheters	PUR, silicone, Tekoflex
Urinary catheters	Silicone, polypropylene, etc.
Drain sets	Silicone, polypropylene, etc.
Oxygen tubes	Rubber, silicone
(Endo)Tracheal tubes (respirator)	Rubber, silicone, etc.

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