



Children's Hospital - KINDERKLINIK GLANZING
Wilhelminenspital der Stadt Wien
Vienna, Austria

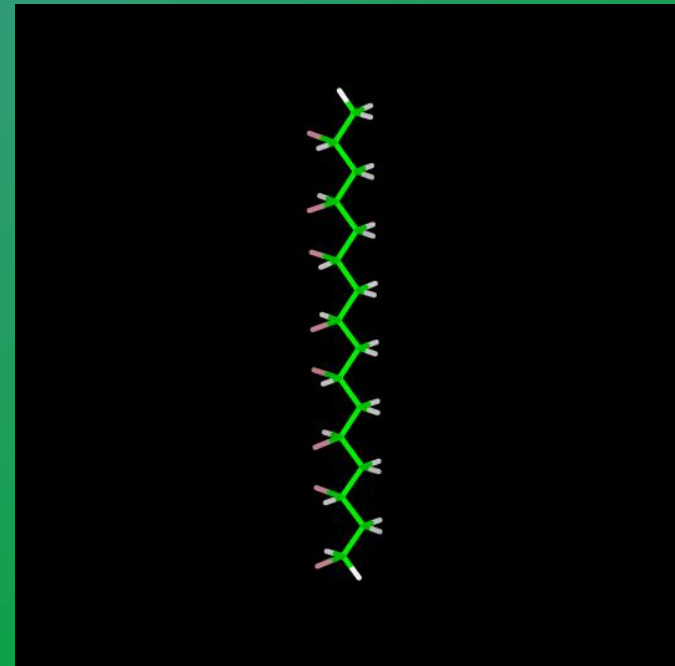
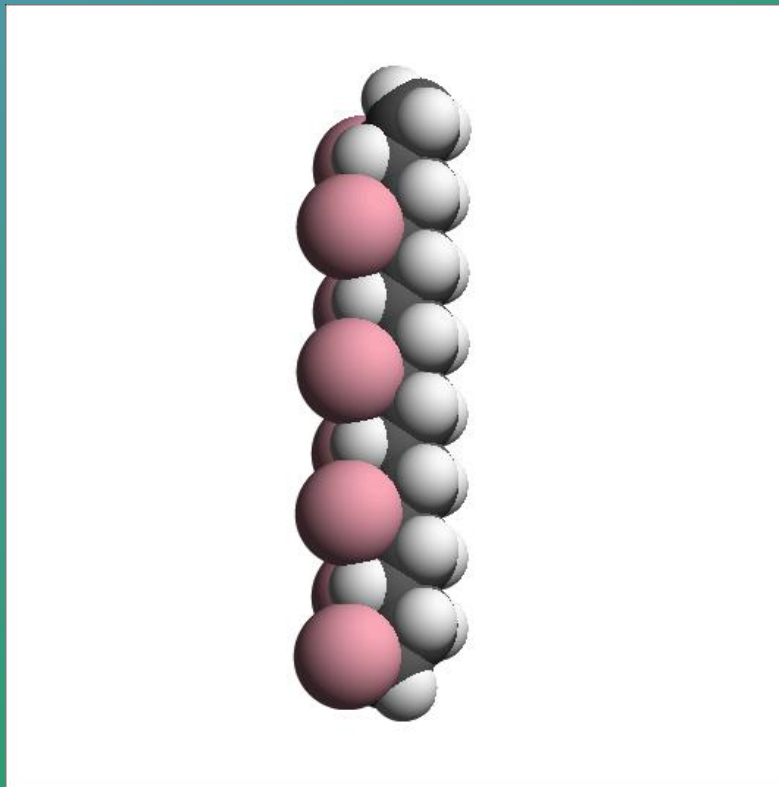
Procuring PVC-free medical devices: The experience of the Vienna Childrens's Hospital Kinderklinik Glanzing

Univ. Prof. Dr. Andreas Lischka, MD
former Head of Kinderklinik Glanzing,
Wilhelminenspital der Stadt Wien, Austria



PVC-

is a synthetic polymer resin



...is free of PVC!





Medical products for invasive treatment in the children's hospital Kinderklinik Glanzing-1

Products free of PVC

Company	Product
Braun	Adapter Luer /Record außen SyringesOmnifix Syringe for pump Spinal (Lumbal)canulas
Bauer Thüriedl	Dummies for soothing teats for bottles- wide dummies teats for bottles with ring teats for CLP- Children teats for cleft lips
Becton Dickinson	three-way mixing valve mandrine for i.v. canula
Benesch	flexiblwe tube set
C.Reiner	flesible tube
Crosstec	venous insertion catheter Medex
Dräger	artificial lung for calibration y- tube for calbration of flow
Duschek	Butterfly





Medical products for invasive treatment in the children's hospital Kinderklinik Glanzing-2

Company	Products free of PVC
Duschek	Butterfly
Ebewe	double umbilical catheter*), Replug tube *) umbilical catheter Vygori*)
Habel	Trach Care connection
Heintel	Suction tube Unoplast*)
Hochwimmer	External ventricular drain system*)
Johnson&Johnson	i.v. canula
Med Care	Pricking needle**), Neonat 4-fold connection*) Pediatric filter for blood**), connection tube/valve mixing bag for infusionsolutions*)
Milupa	teats for bottles- wide
MPÖ Seidel	syringes for tuberculine
Rico	canulas
Rüsch	feeding tubes*) Luerconnections for urethral catheter
Sensormedics	Penrose Drain
Stöhr	Connecting Tube venous canula



*) Free of PVC since 2001.

***) Produced free of PVC by Med Care and successfully tested in Kinderklinik Glanzing.



Medical products for invasive treatment in the children's hospital Kinderklinik Glanzing-3

Products containing PVC

Crosstec	Catheter Neonat v-Cath
Dahlhausen	female urinary catheter (used for enema)
Ebewe	Catheter-trocar
Habel	Trach Care endotrach.suction system
Heintel	endotracheal tube with 2 lumina
Rüsch	Trachealtube
Sensormedics	Cap diaphragma Assay Sensormed
	Flexible Pat Circuit heater Sensor
	Bellows and Watertrap



Produkt Fa. Dahlhausen

At the moment not available free of PVC, but only shorttime use (some minutes)

Produkt Fa. Ebewe not available free of PVC, but used extremely rarely (1x/yr)



Medical products for invasive treatment in the children's hospital Kinderklinik Glanzing-4

Products containing PVC

Products of Fa. Habel und Rüschi

Endotracheal tubes without PVC are available, but they proved to be too soft for Intubation, if containing metals – no MRI possible. The company wants to guarantee medical product free of PVC, if the need is documented.

Products Fa. Sensormedics

It is not planned to produce products free of PVC, the products are used very rarely in Kinderklinik Glanzing

ANNEX:

Nasal oxygen tubes for newborns Fa. Dahlhausen and anesthetic masks Fa. Mallinckrodt are regarded as “semiinvasiv” and still contain PVC

The nasal oxygen tubes: only the prongs insert the nose. Production of tubes free of PVC is possible, would rise the costs to about double the amount as compared to now.

Anesthetic masks Fa. Mallinckrodt are used only for a very short duration of time.





Development of the transit to invasive products free of PVC in Kinderkliniik Glanzing

For quantity delivered/ year

Total quantity in grams (2001):871.069 g

PVC-content 2001 in grams: 40.233 g corresponds to 4,6 %

PVC-content 2003 in grams: 26.368 g corresponds to 3 %

For pieces delivered per year

Total quantity delivered (pieces): 83.176 pieces

PVC-containing products 2001: 13.252 pieces corresponds to 15,9 %

PVC-containing products 2003: 4.341 pieces corresponds to 5,2 %

Data change a little, when semi invasive PVC- containing products are included (oxygen tubes, anesthetic masks)

PVC-content 2003 in grams 31.928 g *corresponds to 3,7 %*

PVC-containing products (pieces) 2003 4421 pieces *corresponds to 5,3 %*

PVC Kinderklinik Glanzing (GLA)

Situation 2010

The values refer to quantities delivered 2001 and waste 2000.

Weighted total amount of the products investigated: 2353 kg

PVC- content of the investigated products 2001	343 kg
PVC- content of the products for 2010	178 kg
PVC- content of the investigated products 2001	14,6 % weight
PVC- content of the products for 2010	7,6 % weight
waste Cat.I und II	73600 kg
PVC- proportion 2001 for Cat.I and II	0,47 % weight
PVC- proportion 2010 for Cat.I and II	0,24 % weight



Including semi invasive products (oxygentubes and anesthetic masks) would change the values to:

<i>PVC- content of the products for 2005</i>	<i>178 kg</i>
<i>PVC- content of the products for 2005</i>	<i>7,6 Gew. %</i>
<i>PVC-Anteil 2005 for cat. I und II</i>	



Reduction of PVC in medical waste

Year	% weight	study in
1990	10	Graz
1995	2,5	FLO
1999	0,6	KHL
2001	0,47	GLA
2005	0,37	GLA
2007	0,36	GLA
2009	0.29	GLA
2010	0.24	GLA



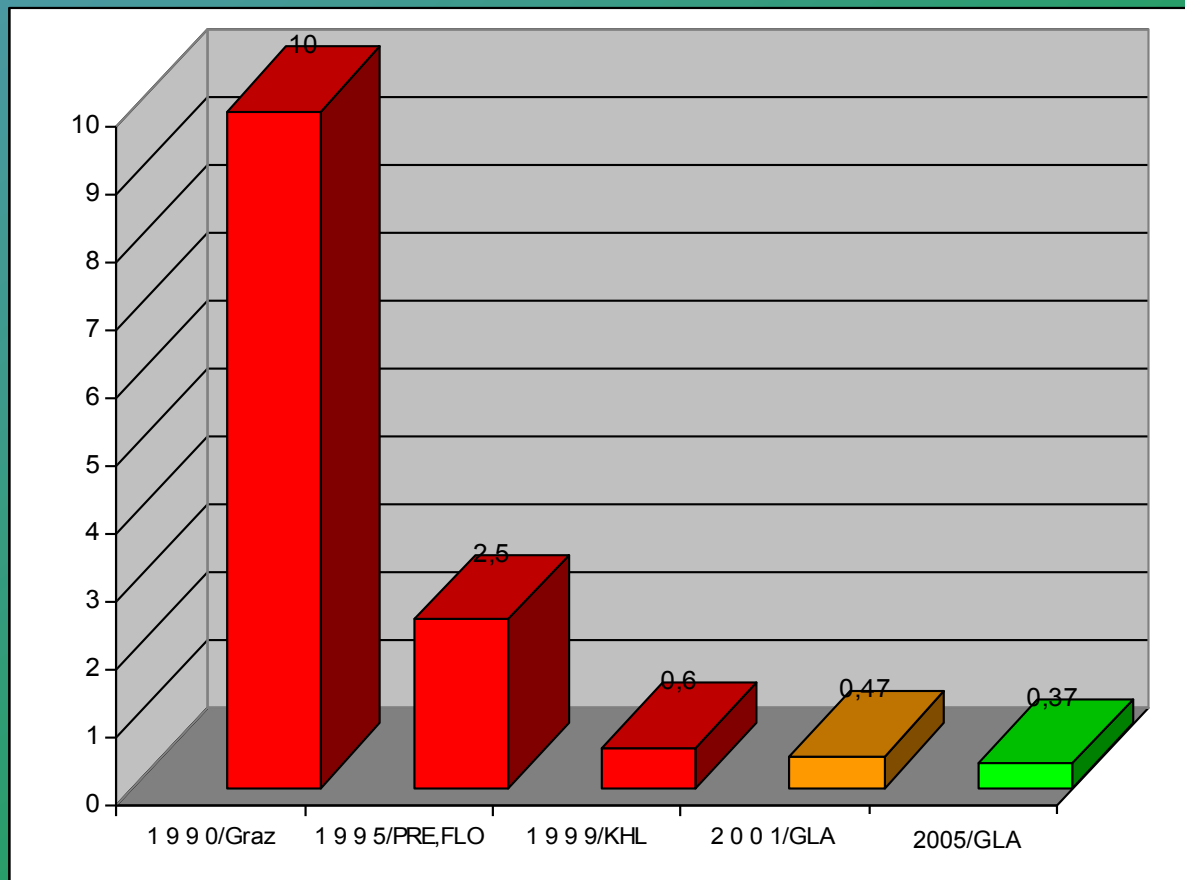
Amount of PVC-containing products delivered and wastage of PVC-containing products used at the NICU of the Kinderklinik Glanzing from 2001 to 2010

Year	Weight (kg)	Weight (% of total waste*)	PVC containing waste (% of total waste Cat.I and II)
2001	343	14.6	0.47
2003	272	11.6	0.37
2007	264	11.2	0.36
2009	212	9.0	0.29
2010	178	7.6	0.24

*The total annual waste at our NICU extrapolated out of the quantity
of waste containers used per year was 2.353 kg.

Reduction of PVC in medical waste

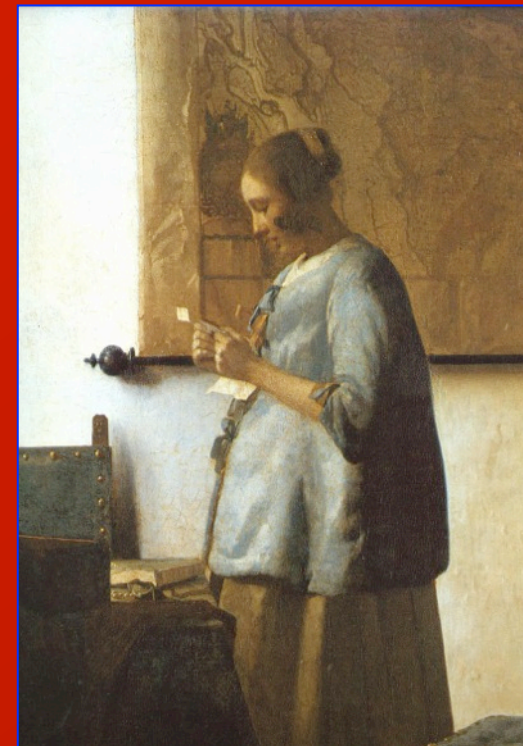
In some Austrian hospitals since 1990 (Graz, Preyer+Floridsdorf, KH Lainz, Glanzing)



Risk assessment for DEHP

At the moment, persons working in laboratories in the EU, get the following safety informations about DEHP:

- R 45: Can be cancerogenous
- R 62: Can probably reduce the reproductive potential
- R 63: Can probably harm the fetus
- R 36/37/38: Irritates eyes, lungs/bronchi and skin



Labelling of DEHP

DEHP and products containing more than 0.5% DEHP, within the EU have to be labelled with the letter T (Toxic) and the toxic symbol, the skull and cross-bones.





Activities of International Bodies

US Food and Drug Administration (US FDA)

Abstain from DEHP- containing products in the therapy of the most vulnerable groups of patients: pretermatures, pregnant women, boys

Now: assessment of alternatives.

Recommendation: elimination of DEHP.



US National Toxicology Programm (US NTP):

DEHP is toxic for human reproduction and teratogenous for animals.

Studies in animals are convincing related to humans.

Three groups of people are subjected to alarming concentrations of DEHP:

- Very sick infants and pretermatures (because of DEHP-containing medical products),
- Healthy infants and children (DEHP-containing toys, nutrition)
- Pregnant and breastfeeding women, because they can endanger the development of their children via their own contamination with DEHP.

Activities of bodies within the EU

European Parliament: Resolution 2000 for a change to medical products free of PVC, establishment of targets for the reduction of the contamination with DEHP

Dutch National Institute of Public Health and Environment:
(RIVM): risk assessment of the most critical medical products containing DEHP - PVC.

Denmark: Taxes for DEHP and PVC (seit 7/2000)

Eight EU- states, including Austria: since 1999 DEHP and five phthalat containing plastizicer (DIDP, DINP, DBP, BBP, DNOP), forbidden in toys for children under three years of age.

EU: 1999 temporary prohibition on the basis of the directive (92/59/EEC), “**Generelle Produktsicherheits- Richtlinie**” edicted.

Actual intention of the PVC-industry

**„Put the rather controversial material
PVC into a better light.“**

„Öko-Kaufprojekt“ of the City of Vienna:
detailed position-paper of the task force
committee

based on latest scientific knowledge

**to avoid chlorinated organic compounds,
especially PVC**

Position Paper

- does not only refer to medical questions,
- but also to the use of plastic in house-building and daily life,
- the release of dioxins and furans in thermic toxic waste incineration
- the use heavy metals, flame retardants and stabilizers,
- as well as properties of PVC in case of fire

HOWEVER

- PVC-Industrie propagates recycling of used PVC-products, but in Europe only 3 % of the PVC are recycled
- Substances like Cadmium and TBT are also recycled and therefore resumed into a new life cycle.

Until today, the problems of the hazardous waste of PVC-products are not solved.

We doubt that there will be a change in the nearer future, because the basic components - vinyl chloride, phtalates and heavy metals - are toxic substances.

Alternatives? DEHP-free Products

ethylene vinyl acetate (**EVA**),

polypropylene (**PP**) polyethylene (**PE**)

polyurethane (**PU**)



Only Solution

**Avoidance of the use of PVC,
even if PVC-industry argues with use
of different, „nontoxic“ softeners,
phase out of Cadmium,
reduced use of lead,
new and better recycling measures**

ABREVIATIONS

- **PCB** **Poly Chlorinated Biphenyls**
- **HCB** **Hexa Chloro Benzene**
5 Chloro, 2 hydroxy benzophenone
- **DDT** **4,4 Dichloro Diphenyl**
1,1,1 Trichloro ethan
- **PBDE** **Poly Brominated Diphenyl Ether**
- **PCDD** **Penta Chloro Dibenzo Dioxin**
- **PCDF** **Poly Chlorinated Dibenzo Furans**