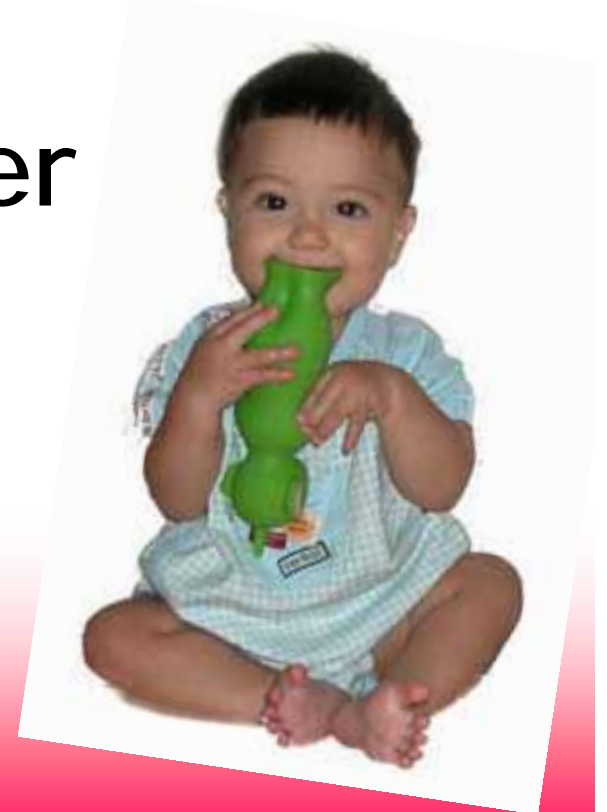


DEHP: Concerns and Alternatives

Patrick Wooliever
Tetra Tech EM Inc.



Take Home Message

1. Increasing Medical Concerns -
FDA Advisory: Minimize DEHP products in high-risk patient populations.
2. Tackle High-Risk Areas & Align Your Focus and Influence.
3. Alternatives Are Readily Available.
4. \$\$ - Additional Cost Is Relatively Low:
~10-20% more, <\$20/patient/day

The Larger Issue...PVC

- Most widely used plastic in medical products
 - Cost
 - Flexibility
 - Transparency
 - Resistance to breakage
- 27% of all plastic used in 1996
- The only common plastic that is chlorinated
- DEHP (di-ethylhexyl phthalate) often used as a plasticizer in medical devices



DEHP

di (2-ethylhexyl) phthalate

- Migrates from PVC when in contact with fluids, air, or heat
- Lipophilic

Leaching increases with...

- Temperature
- Contact (storage time)
- Amount of fluid
- Agitation
- Lipid content



Increasing Medical Concerns

- Reproductive & developmental toxicant
- Infertility, hypospadias spectrum, premature thelarche
- Targets Sertoli cells of the testes
- Liver and pulmonary effects
- ❖ **FDA and NTP issued warnings**



Government Warnings

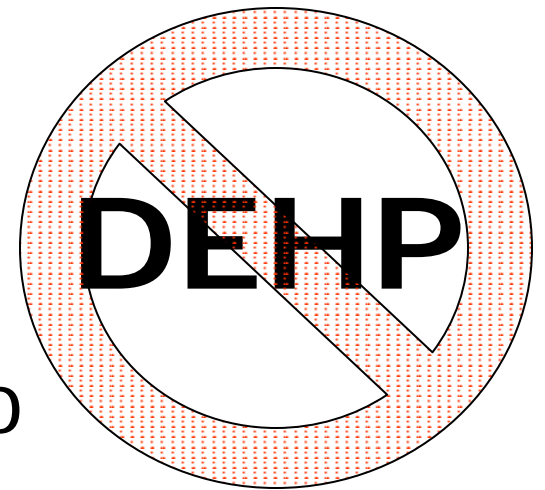
- **October, 2000:** US Department of Health, National Toxicology Program
- **March, 2001:** CA Medical Association Resolution: Eliminate DEHP in Neonatal Intensive Care Units
- **July, 2002:** FDA Public Health Notification



FDA Public Health Notification

Recommends:

- Using alternatives to DEHP-containing products for procedures with excessive exposures
- Reformulation of products to decrease/eliminate DEHP exposures
- Labeling of DEHP-containing products



FDA Safety Assessment

- FDA derived a “tolerable intake” (TI) for DEHP
 - Parenteral: 0.6 mg DEHP/kg/day
 - Oral: 0.04 mg DEHP/kg/day
- TI calculations based on NOAELs and LOAELs from numerous animal studies of testicular toxicity



DEHP Exposures

mg/kg/day	Adult		Neonate	
	DEHP dose	TI/dose	DEHP dose	TI/dose
IV: crystalline	0.005	120	0.03	20
IV drugs w/vehicles	0.15	4	0.03	20
TPN (lipid)	0.13	5	2.5	0.2
Enteral nutrition		< 1.0	0.14	0.3
ECMO	3.0	0.2	14	0.04
Exchange Transfusion			22.6	0.02





Photo: Valerie Briscoe, JMMC

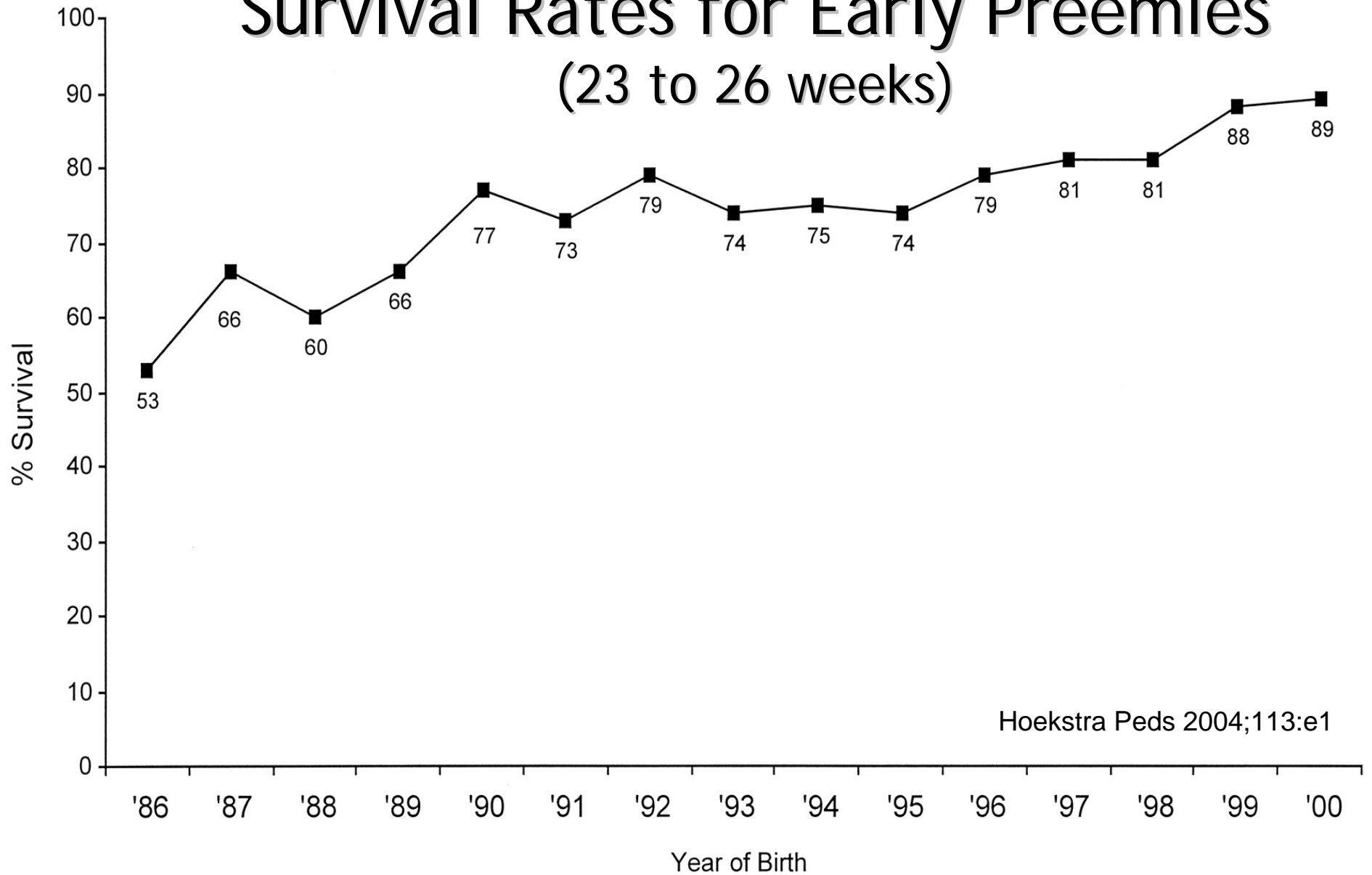
Focus: High Risk Areas

Early Preterm Infants

- Critically ill patient population
 - IV therapy
 - Parenteral and enteral feedings
 - Ventilation
 - Blood transfusion
- Long hospital stay
 - Prolonged therapies



Survival Rates for Early Preemies (23 to 26 weeks)



Hoekstra Peds 2004;113:e1

Most Sensitive System:

Immature Male Reproductive Tract

- MEHP is the toxic metabolite
- Mechanism of Action
 - Decrease testosterone synthesis; interference with Leydig cell differentiation
- Target Tissues
 - Sertoli cells
 - Seminiferous tubules, sperm, epididymis, penis, prostate (fetal exposures)



PVC/DEHP-Containing Products

Gloves

- ✓ Exam
- ✓ Surgery

Bags

- ✓ IV
- ✓ Nutrition
- ✓ Blood

Tubing



Gloves

Low risk: not typically invasive or long-contact



1. Latex
2. Nitrile
3. PVC (usually marketed as latex-free)

❖ Parallel efforts to eliminate latex gloves because of allergies...

...but “latex-free” usually means PVC/DEHP



Gloves - Alternatives

- ✓ Use powder-free latex or nitrile
- ✓ Examine life cycle costs and performance of PVC gloves

...Tufts/1999 Kaiser Studies:

- Failure Rate:
 - PVC 30%
 - Nitrile/Latex 2%
- Staff use "double-gloving" for extra protection
- Nitrile/Latex gloves are cost competitive



Tubing



High-risk: long contact, conveys air and fluids, some high volume

- PVC less prone to kinking
- Becomes more brittle with use as DEHP leaches



Tubing - Alternatives

- ✓ Focus on tubing used to introduce fluids/gases into the patient
- ✓ Examine tubing upstream of equipment: e.g., wall to ventilator



Respiratory Therapy Ventilator



IV Bags

High risk: long contact, some lipid fluids, some high volume

- PVC/DEHP-free alternatives available
- Driven by demand
- 3 Vendors: Baxter, Braun, Hospira (Abbot)



IV Bags - Alternatives



- B Braun is the only current supplier of PVC/DEHP-free bags
- PVC bags:
 - Require an “overwrap” to preserve shelf life
 - Are thicker/heavier than alternatives

B Braun DEHP-free bags are cost competitive;
10-20% more expensive



Nutritional Bags - Alternatives

- Market demand exists:
 - Baxter: EVA (no-PVC)
 - Hospira (Abbot): PVC but w/o DEHP
 - Each has about 40% market share

PVC/DEHP-free alternatives are cost competitive



Blood Bags

- Blood Bank Users:
 - Few PVC/DEHP-free bags available/used
 - DEHP used as a preservative



Tackle other areas first; raise awareness among blood banks/public



JMMC DEHP Reduction Plan

1. Establish DEHP reduction policy for NICU
2. Implement reduction plan
 - a. Get list of all supplies from Purchasing Dept.
 - b. Audit supply room and identify plastics used in “high-risk therapies.”
 - c. Purchasing Dept. contacts manufacturers to determine DEHP content
 - d. Nursing and respiratory therapy staff evaluate alternative based on clinical applicability and efficacy
 - e. Preferred product list sent to Purchasing Dept.
3. Expand program



JMMC Success Factors

- Easily identified “Cause Champion”
- Changes occurred “under the radar”
- Cost not a large factor
- Readily available alternatives for most products
- Effort required:
 - 40 hours primarily by nursing supervisor over 1 year



Problematic Areas

- Premixed IV solutions
 - Parenteral solutions mixed by pharmacy in non-DEHP bags
- Blood Bank
 - Red Cross blood products uses blood bags containing DEHP





JMMC Plastic Products

Item #	Description	Cat#	DEHP?	Manufacturer
9906	Long-life feeding Tube	730709	No	Children's Medical Venture
5420	Dispensing pin with valve	3548441 3500	No	B. Braun
2695	Neonatal catheter	2184-00	No	Vygon



JMMC Plastic Products

Item #	Description	Cat#	DEHP?	Manufacturer
34257	Soluset-Microdrip	00131194802	Yes	Abbott
1843	Butterfly Inf 19 X 7/8 X 12	00134590010 1	Yes	Becton Dickinson
3094	Transducer Transpac	00154256001	Yes	Abbott
13062	Tray Exchange Transfusion	07055004110	Yes	Pharmaseal Allegiance

JMMC Plastic Products

Item #	Description	Cat#	DEHP?	Manufacturer
34257	Soluset-Microdrip	19231-12	No	Abbott-new item
1843	Butterfly Inf 19 X 7/8 X 12	00134590 0101	Yes	Becton Dickinson-use for blood <u>drawing</u> -no risk
48795	Transducer	MX20775	No	Medex-New Item
13062	Tray Exchange Transfusion	07055004 110	Yes	Pharmaseal Allegiance- No alternative. No longer used, change in practice



NICU Replacement Summary

- Survey found:
 - 31 plastic items
 - Only 5 contain PVC/DEHP and are used in exposure scenarios
 - Others are used for extraction procedures
 - One was eliminated procedurally

Only 4 items need to be replaced



+H365MX453HL05

LOT NUMBER

33G210044



+\$33G2100445W

**Non-DEHP T Connector
w/Swivel M.L.L.**

SINGLE USE

STERILE
CONTENTS
AND FLUID PATH NONPYROGENIC UNLESS
PACKAGE IS DAMAGED OR OPENED.

CAUTION: CONNECTORS MAY HAVE LOOSENED DURING
SHIPMENT. MAKE SURE ALL FITTINGS ARE SECURE BEFORE
USING. AVOID OVERTIGHTENING AND STRIPPING.

SLIDE CLAMP IS SPECIFICALLY DESIGNED FOR EASE OF REMOVAL. PREVENT INADVERTENT REMOVAL.

CAUTION: Federal Law (U.S.A) restricts this device to sale by or on the order of a physician.

Latex Free

0618

MADE IN USA

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DEHP Resources

- Sustainable Hospitals:
www.sustainablehospitals.org
- Health Care Without Harm:
www.noharm.org
 - Audit Form:
<http://noharm.org/details.cfm?type=document&id=741> :
 - Alternative List:
<http://www.noharm.org/details.cfm?type=document&id=591>

