

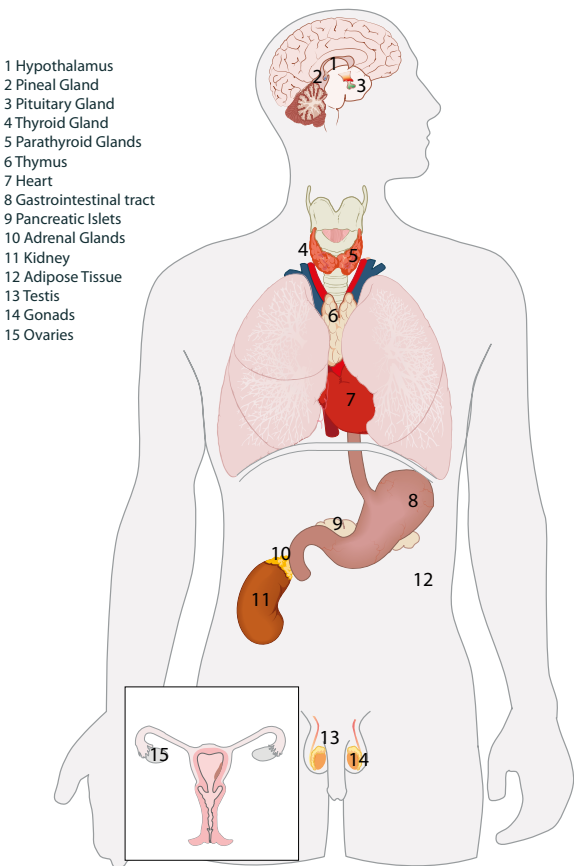
# Endocrine disruptors in the healthcare sector

Are there reasons for concern?



# WHAT ARE ENDOCRINE DISRUPTING CHEMICALS?

Endocrine disrupting chemicals (EDCs) are exogenous substances or mixtures that interfere with the function(s) of the endocrine system and can cause adverse effects to human health and wildlife<sup>1</sup>. **More than 800 substances have been pointed as possible EDCs.** Although some medications intentionally cause these effects, the majority of these substances are poorly studied and their effects are unintended.



The Endocrine System

EDCs can affect the endocrine system by:

**“Interfering with the synthesis, secretion, transport, metabolism, binding action, or elimination of natural blood-borne hormones that are responsible for homeostasis, reproduction, and development process.”<sup>2</sup>**

EDCs can be commonly found in food, food containers, medical devices, pharmaceuticals, plastic materials, cosmetics, cleaning products and building materials, to name just a few.

## WHY SHOULD WE BE CONCERNED?

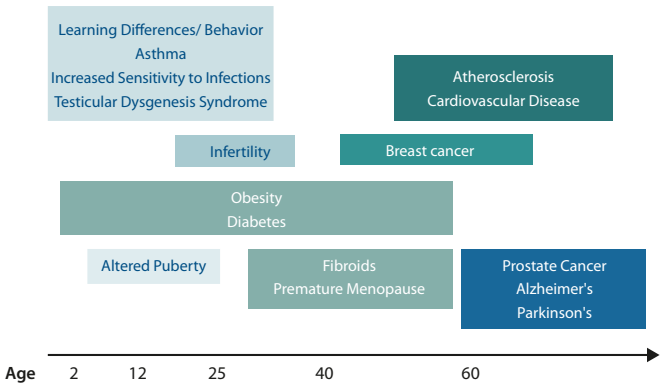
Human biomonitoring studies have detected chemicals with endocrine disrupting properties in almost every individual analysed and in a variety of human tissues and fluids such as placental tissue, breast milk, urine, blood and saliva<sup>1</sup>.



Human exposure to endocrine disrupting chemicals

Human exposure to EDCs may be difficult to estimate because of other confounding factors, genetic variability and the amount of time and difficulty involved to perform an epidemiological study when these chemicals are ubiquitous and we are being exposed to them constantly.

An increase in the incidence of hormone-related diseases and illnesses in humans at different stages of life, from neonatal and infancy to adulthood, has been associated with exposure to EDCs<sup>3</sup>. For example, prenatal exposure to EDCs has been linked to shortened gestational time and effects on the development of the foetus, including impaired brain development and diminished ano-genital distance<sup>1</sup>.



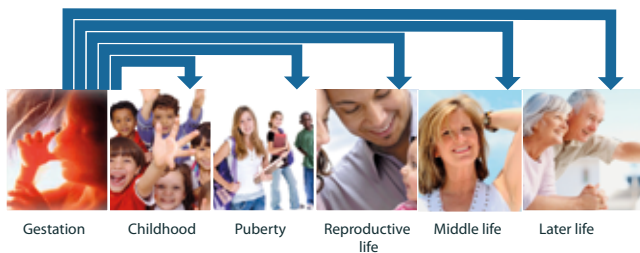
**Developmental origins of health and disease**

(Based on Birnbaum 2012, Endocrine Disruption: Where do we go from here? - Endocrine Disruptors: Current challenges in science and policy, Brussels, 11-12 June)

Scientific evidence from animal studies suggest that EDCs can affect a wide range of health endpoints, causing effects at different levels of exposure, including at very low doses. This contradicts the common assumption behind safety regulatory testing, which assumes that effects are dose dependent, and can lead to an underestimation of the hazardousness of the substances and weak safety standards for human health. Moreover, EDCs have also been shown to have additive and even synergistic properties that are likely to have unexpected and unpredictable effects on human health<sup>4</sup>.

## WHO IS AT RISK?

Nursing women, foetuses, babies and children are subjects of great concern because of their vulnerability to the effects of hazardous chemicals. Unborn children and infants are not able to process chemical substances in the same way adults do due to the on-going development of their organs and maturation of their endocrine system<sup>5</sup>. The susceptibility to EDC exposure in early life-stages has been related with the occurrence of developmental diseases later in life<sup>1</sup>.



### Developmental stressors lead to disease throughout life

(Based on Birnbaum 2012, Endocrine Disruption: Where do we go from here? - Endocrine Disruptors: Current challenges in science and policy, Brussels, 11-12 June)

The exposure of premature babies to EDCs in Neonatal Intensive Care Units (NICUs) has been the focus of several studies. **Researchers and healthcare professionals are especially concerned with the risks that may arise due to premature babies' low weight and insufficient organ development, allied with the fact that they require many medical interventions:**

- Levels of DEHP metabolites in urine were related with the number of DEHP-containing medical devices<sup>6</sup>. Within 6 hours, neonates receiving lipid-base infusates through a PVC infusion line, received a DEHP dose exceeding the lower limit of the total daily intake (TDI)<sup>7</sup>.



- Premature infants undergoing intensive therapeutic medical interventions had mean urinary concentrations of DEHP one order of magnitude higher than the general population<sup>8</sup>.
- BPA was found in urine samples of all premature babies in two NICUs. On average, infants requiring naso-gastric or respiratory tubes had significant higher concentrations than babies not requiring these devices<sup>9</sup>.

## WHERE ARE EDCS HIDDEN IN HEALTHCARE?

The potential health risks of EDC exposure, as a result of the presence of these chemicals in the healthcare sector, have generated considerable concern among the scientific community, healthcare professionals and advocacy groups.

### The past case of Diethylstilbestrol (DES): A pharmaceutical agent used to prevent miscarriage

Prescribed between the 1950s and 1960s, DES was found to cause adverse effects in daughters of women who had taken it during pregnancy to prevent miscarriage. Effects included increased risks of reproductive tract abnormalities and of breast and ovarian cancer<sup>10</sup>. DES was banned in the 1970s, but its effects are still showing up today in the granddaughters and grandsons of the women that were treated. The DES case gave the first alarm to the effects of EDCs on human health.



## The current cases of Phthalates, Bisphenol A and PVC

### *What are Phthalates?*

Phthalates are a group of chemical substances, primarily used as plasticisers (softeners) in plastics. They are abundant in polyvinyl-chloride (PVC) based medical devices such as blood bags, nutrition pockets, tubing, umbilical venous catheters or disposable gloves, where they can account for up to 40% of the final product.

Phthalates are also commonly used as medicine excipients to make coatings for oral medications and in flooring, among many other uses. Phthalates can easily be released, transferred or leached into the air, water or body fluids during their production, use and disposal.

**Numerous phthalates are documented or suspected EDCs, which act by inhibiting the production of testosterone in the testes<sup>11</sup>, and are classified as toxic to reproduction according to European legislation.**

### *What is BPA?*

Bisphenol A (BPA) is a chemical substance that can be polymerised to produce polycarbonate plastic and other plastic products, or used as an additive in PVC plastic. Applications in the health sector include, among others, medical tubing, hemodialysers, newborn incubators, syringes and nebulizers. **BPA is a strong endocrine disrupting chemical able to interfere with the action of estrogen and the estradiol hormone.** BPA has been shown to leach from medical devices containing PVC (similarly to phthalates) or other polymerized plastics and from dental sealants<sup>12,13,14</sup>.



## WHY ARE HARMFUL CHEMICAL SUBSTANCES ALLOWED IN THE HEALTHCARE SECTOR?

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Despite the increasing awareness of the health effects of EDCs in the European sphere, thorough legislative action has not been taken to reduce the presence of EDCs in the healthcare sector.

### The EU medical device legislation

The existing Directives on Medical Devices require that devices containing specific phthalates (DEHP, DBP, DIBP and BBP) that are classified as carcinogenic, mutagenic or toxic to reproduction (CMRs), need to be labelled. It also specifies that if such devices are intended to treat children and pregnant and nursing women, the manufacturer should justify the use of such substances.

Currently, a new proposal is being discussed at the European level requiring substances with endocrine disrupting properties and probable health effects to be reduced in medical devices. The proposal does not however include concrete mechanisms to phase them out within specific deadlines or enforce the development of safer alternatives. Several Members of the European Parliament are looking into the possibility of introducing a phase-out of harmful chemicals in medical devices, whenever safer alternatives are available.

One could wonder why these harmful substances are still allowed in medical devices without restrictions when, for instance, different phthalates have already been banned in toys intended for infants up to three years old.

Despite, the weak EU's stance on this matter, different countries are already taking national actions to restrict the use of EDCs, particularly phthalates in medical devices due to concerns with their endocrine disrupting abilities.



## France's ban on DEHP in tubing

In December 2012, France passed a law that bans, for the first time, the use of tubes containing DEHP in paediatric, neonatology and maternity wards. The ban, which will enter into force from July 2015, foresees the possibility to also prohibit the use of other phthalates like DBP and BBP in all medical devices in the near future.

## Denmark paving the way

The Danish Health Minister has recently supported the phasing out of phthalates in medical devices, pushing for the creation of partnerships between industry, authorities and experts to call for a European phase-out within a reasonable time frame.

## MOVING TOWARDS AN EDC-FREE HEALTHCARE

Healthcare professionals are also extremely apprehensive with patients being exposed to EDCs and with the possible adverse health effects for vulnerable and chronically ill patient groups. Several hospitals throughout Europe have implemented practices to reduce the risks of exposure to hazardous substances.



## The Austrian PVC-free neonatal care experience

To avoid unnecessary health burdens for premature babies, the Vienna Hospitals Association adopted a PVC-free policy in their Neonatal Intensive Care Units. The criteria cover invasive consumables and products that come into contact with the skin of babies. In the Neonatology Unit of the Glanzing Children's Hospital, the phase-out of PVC started in 2000 and the PVC content of invasive medical products was halved by 2010, with an estimated increase in prices of less than 15%<sup>16</sup>.

## The Stockholm County Council phase out

The Stockholm County Council (SLL) also decided to phase out PVC and phthalates from its hospitals as early as 1997. In 2004, the SLL introduced a collective purchasing arrangement to buy phthalate-free gloves, eliminating the environmental impact of 100 tonnes of phthalates per year<sup>16</sup>. To date, the neonatal unit of the Karolinska University Hospital is completely PVC-free.

The termination of PVC products is also taking place in neonatal units in other countries - Czech Republic (Na Homolce and Olomouc Hospitals), Slovakia (Kosice Saca Hospital (Slovakia) and France (Clinique Champeau) - providing extensive evidence that a PVC phase-out is not only possible but realistic.

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### Do you want to know more?

<sup>1</sup> Bergman et al., "State of the science of endocrine disrupting chemicals - 2012", UNEP/WHO, 2013, 260 pp.

<sup>2</sup> Diamanti-Kandarakis et al., 2009, "Endocrine-Disrupting Chemicals: An endocrine society scientific statement", Endocrine Society, 50 pp.

<sup>3</sup> Birnbaum, 2013, Trends Endocrinol Metab 24: 321-323

<sup>4</sup> Zoeller et al., 2012, Endocr Rev 33: 1-78

<sup>5</sup> Fischer et al, 2013, J Paediatr Child Health 49: 413-419

<sup>6</sup> Hu et al, 2005, Environ Health Perspect 113: 1222-1225

<sup>7</sup> Rose et al., 2012, Anaesthesia 67: 514-520

# WHAT CAN YOU DO?

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As a medical doctor or nurse, you can facilitate the transition to innovative and sustainable processes in the healthcare sector – to lessen the use of hazardous chemicals such as EDCs and contribute to limit their adverse effects on patient health.

## Doctors and nurses as champions of change: what are the steps?

- Focus on how the vision of an EDC-free healthcare system will help improve your patients' health.
- Find a small group of people within your hospital that share the vision of an EDC-free healthcare system and that can communicate it and spread it to colleagues around the hospital.
- Turn your vision into concrete steps. Talk to the management of your hospital and define a plan for acquiring and using alternative products that do not contain EDCs, when feasible.
- Provide positive feedback to other hospitals, and share your best practices.

Changes like these could force a major shift in the provision of healthcare and, in the long-run, lead to **healthier hospitals, healthier people and a healthier planet.**

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<sup>8</sup> Calafat et al., 2004, *Pediatrics* 113: e429–e434

<sup>9</sup> Duty et al., 2013, *Pediatrics* 131: 483–489

<sup>10</sup> Titus-Ernstoff et al., 2001, *Brit J Cancer* 84: 126–133

<sup>11</sup> Martino-Andrade et al., 2010, *Mol Nutr Food Res* 54: 148–157

<sup>12</sup> Vandentorren et al., 2011, *Environ Res* 111: 761–764

<sup>13</sup> Murakami et al., 2007, *Blood Purif* 25: 290–294

<sup>14</sup> Fleisch et al., 2010, *Pediatrics* 126: 780–788

<sup>15</sup> Lischka et al., 2011, *J Environ Sci Eng* 5: 1162–1166

<sup>16</sup> Vesterber et al., 2005, "An inventory of PVC and phthalates containing devices used in healthcare", Karolinska University Hospital, 18 pp.



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