HAZARDOUS CHEMICALS IN MEDICAL DEVICES: BISPHENOL A (BPA)

Due to the extensive presence of Bisphenol A (BPA) in the environment, the large amount of scientific data showing human exposure to BPA via different routes and the fact that safety thresholds of no effect cannot be set for endocrine disrupting chemicals like BPA, it is of paramount importance to try to avoid all possible sources of exposure to BPA, particularly for vulnerable groups. In the healthcare sector, this can be achieved by phasing out hazardous chemicals in medical devices and using products that do not contain BPA and other harmful chemicals, whilst keeping high quality medical care.

Some examples of BPA applications in Medical Devices

Polycarbonate

Eye lenses, tubing, blood oxygenators, dialysers, intravenous administration sets, syringes, catheters

Polysulfone

Surgical trays, nebulizers, humidifiers, haemodialysis membranes

Polyacrylates

Dental composite resins, dental sealants, coating for medical devices

Polyetherimide

Sterilisation trays, dentist devices, pipettes

Additive for PVC

Autotransfusion apparatus, intravenous fluid bags, nasogastric and enteral feeding tubes, respiratory masks, endotracheal tubes, umbilical catheters

Bisphenol A can be polymerized to produce polycarbonate plastic and other plastic products, or used as an additive in polyvinyl chloride (PVC) plastic. Applications in medical devices include among others, medical tubing, hemodialysers, newborn incubators and dental composite resins[1,2]. Several studies have shown that BPA is a strong endocrine disrupting chemical (EDC), able to interfere with the action of estrogen and the estradiol hormone. Relating high and low levels of BPA exposure with an increase in the rate of developmental cancers, reproductive impairments (lower sperm counts, hormonal changes, enlarged prostate glands, early onset of puberty), neurological and behavioural disorders, cardiovascular diseases, obesity and diabetes[3,4,5,6,7].

BPA has been shown to leach from medical devices containing PVC (similarly to phthalates), from polymerized plastics in devices by diffusion of residual BPA left behind after the manufacturing process and from dental sealants in normal conditions of use[8,9,10]. The scientific community has considered leaching from medical devices as an important source of exposure to BPA in humans[7]. BPA has been found in a variety of human tissues and fluids such as placental tissue, breast milk, urine, blood, and saliva[7]. Once in the body, most BPA is believed to be quickly transformed by the liver and intestines from "free BPA" (active molecule) to "conjugated BPA" (not active and less likely to have health effects) and eliminated in the urine. However, BPA transformation is not fully efficient, and different bio-monitoring studies have shown

that the general human population is exposed to BPA, including significant internal body exposure to free BPA[7]. Moreover, free BPA can be stored in body fat and slowly released into the blood stream. Moreover, a recent study has also suggested that MBP, a metabolite of BPA, can actually interfere more strongly with estrogen than BPA[11].

Healthcare professionals are concerned about patients potentially experiencing increased exposure to BPA as a result of the use of this chemical in medical devices and with the possible adverse health effects for vulnerable and chronically ill patient groups, who can be exposed for long and critical periods of time.

Haemodialysis patients can be exposed to substantial amounts of BPA due to the use of polycarbonate in dialysers, polysulfones in haemodialysis membranes and PVC in tubing[9]. Impaired kidney functions have been associated with a decrease in excretion[12] of urinary BPA. Hence, the use of BPA-containing haemodialysis equipment can put patients at higher risk and due to their renal disease, lead to an increase of BPA in their blood.

A recent study found that newborns receiving medical treatment using four or more devices had a level of BPA in their urine three times higher than babies treated with three or fewer medical devices[13]. Premature infants that receive intensive care treatment are both developmentally and physiologically immature and are therefore at a higher risk of exposure to BPA. Early life exposure is of high concern. Different studies have suggested that young animals have inefficient abilities to transform chemical substances.

Moving towards PVC free healthcare

Different studies have found an association between BPA and phthalates (used as plasticizers to soften PVC, e.g. DEHP) concentrations, suggesting common exposure sources[13,14,15]. One study further demonstrated that the intensity of use of PVC medical devices containing DEHP was proportional to the exposure to BPA, with levels of BPA increasing when four or more PVC medical devices were in use[14]. Several local authorities and hospitals throughout Europe have already recognised the need to avoid harmful chemicals in their medical devices and started to phase out medical devices containing PVC. To avoid unnecessary health burdens for premature babies, the Vienna Hospitals Association started reducing PVC-containing medical devices in the nineties and has since implemented a PVC-free policy for their neonatal intensive care units. The criteria cover invasive medical consumables, as well as products that come into contact with the skin of premature babies. In the Neonatology Unit of the Children's Hospital Glanzing, the phase-out of PVC started in 2000 and the PVC content of invasive medical products was reduced from 343 kg and 14.6% weight in 2001, to 178 kg and 7.6% weight in 2010. The estimated increase in price was only 9 to 15%[16].

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