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Belgian study links DEHP plasticizer in medical devices to attention deficit disorder

There is an urgent need for alternative plastic softeners, says researcher

by: Norbert Sparrow in Medical, Materials on April 11, 2016

There is a significant body of research suggesting that phthalate plasticizers used in PVC could have an effect on human hormones and respiratory functions. The additive has also been linked to symptoms related to attention deficit disorder (ADD) in children. A new study from the Katholieke Universiteit (KU) in Leuven, Belgium, which was presented at the Endocrine Society's 98th annual meeting in Boston earlier this month, claims that children hospitalized in intensive care units are more likely to show signs of ADD later in life. The culprit, according to researchers, are phthalates leaching out of tubing and other medical devices to which the patients are exposed.



"Phthalates have been banned from children's toys because of their potential toxic and hormone-disrupting effects, but they are still used to soften medical devices," said lead researcher Sören Verstraete, MD, a PhD student at KU, in a press release published by the Endocrine Society. "We found a clear match between previously hospitalized children's long-term neurocognitive test results and their individual exposure to the phthalate DEHP during intensive care," said Verstraete, adding that the development

of "alternative plastic softeners for use in indwelling medical devices may be urgently indicated."

The study, as described in the press release, included 100 healthy children and 449 children who received treatment in a pediatric intensive care unit (PICU) and underwent neurocognitive testing four years later. The researchers measured blood levels of DEHP metabolites, or byproducts. Initially they performed the blood tests in the healthy children and 228 of the patients while they were in the PICU. Patients had one to 12 medical tubes in the PICU and ranged in age from newborn to 16 years.

The investigators found that DEHP metabolite levels were not detectable in the blood samples of healthy children. However, at admission to the PICU, the critically ill children, already connected to catheters, had levels that Verstraete called “sky-high.” Although the DEHP levels decreased rapidly, they remained 18 times higher until discharge from the PICU compared with those of healthy children, he said.

Statistical analyses conducted four years after discharge from the PICU reportedly showed a strong association between high exposure to DEHP during the PICU stay and the presence of ADD in the children. The finding was validated with a different group of 221 PICU patients.

“This phthalate exposure explained half of the attention deficit in former PICU patients,” said Verstraete, adding that other factors may account for the other half.

DEHP is typically used in IV bags and tubing, catheters, feeding bags, and respiratory tubing, among other medical devices.

While alternatives to DEHP have existed for some time and new plasticizers have been developed —BASF’s DINCH, for example—industry organizations note that none of them have been tested as extensively as DEHP, which has been used in medical-grade PVC for many decades. Moreover, as stated on the pvc.org website, they may lack the performance attributes of DEHP and can be significantly more costly.

Suppliers of materials to medical device OEMs continue to seek viable alternatives to DEHP for softening PVC, while Melitek in Denmark has developed thermoplastic compounds that can replace PVC in flexible tubing and other medical applications.

In a document titled, “ [DEHP in Plastic Medical Devices](#),” FDA has recommended that “devices made of alternative materials, or that are made of PVC that does not contain DEHP, be used in procedures” involving sensitive patients, notably neonates.

The European Chemicals Agency has classified DEHP as a Substance of Very High Concern.

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