Research Exposes the Risk to Infants from the Chemicals Used in Liquid Medicines

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(PhysOrg.com) -- A team of medical scientists from the University of Leicester has published research which looks into the harmful substances in liquid medicines that premature babies are being exposed to.

Research published today (Jan 20) ahead of print in the *Fetal & Neonatal Edition of Archives of Disease in Childhood* documents the non-drug ingredients (excipients) present in liquid medicines given to premature infants as part of their medical care.

The study led by Dr Hitesh Pandya, Senior Lecturer in Child Health in the Department of Infection, Immunity and Inflammation at the University of Leicester and Consultant Paediatrician at the University Hospitals of Leicester NHS Trust, revealed that the chemicals added to medicines to improve their taste, absorption and to prolong their shelf-life could be potentially harmful to very small babies.

The chemicals generally used are ethanol, sorbitol and Ponceaau 4R (a colouring agent). The study revealed that premature babies are exposed to these potentially harmful excipients in amounts equivalent to over three pints of beer per week.

Dr Pandya said: “This study documents a worldwide problem. It shows that the collection of medicines given to babies may ultimately lead to them being exposed to harmful chemicals with the potential for short and long-term toxic effects. Our research highlighted this, and we are planning further studies on the chemicals to understand exactly what

these effects might be. What our study hasn't done is find any direct evidence on the cause and effect of these chemicals and the medical problems that these babies might be being treated for."

Dr Andrew Currie, Consultant at the University Hospitals of Leicester NHS Trust who was also part of the research team said "Parents should not panic about these findings. These chemicals can be found in foods all around the world. What the study highlighted is that we have a greater understanding of the side-effects of the drugs than we do of the chemicals that many of these drugs are mixed with; there just simply hasn't been enough research done. It is often necessary that these chemicals are added to medications, and in the majority of cases it improves the way the drugs work, but we should be taking more of an interest in them and their effects. It is great news that Dr Pandya and his team will continue their research."

Dr Pandya added: "Babies and older children are often given medicines that have only received formal testing on adults, which means we estimate amounts that should be given to children and babies. There are numerous reasons for this, such as the practical problems in performing studies in very small babies, worries their parents may have about involving their child in drug trials and drug manufacturer's reluctance to tackle the problem. Our study showed that more work needs to be done to tackle this problem and to improve our understanding."

"Both the UK Government and the European Union have recently passed legislation to incentivise drug companies to develop better medicines for children. Our research team is planning to engage with parents to talk about how they can be encouraged to allow their children to participate in drug trials. We are also in close discussions with drug manufacturing companies about overcoming some of the practical hurdles that restrict performing drug trials in very small children. We are hopeful that this world-wide problem can be addressed for the benefit of future

generations by highlighting the issue and through constructive engagement with interested parties."

Dr Pandya concluded by saying "Parents should begin to understand what chemicals are in the medicines being given to their children, but they should not be overly concerned. In many cases there may not be an alternative medicine, and the risk will be balanced in favour of using them in treatment. As a research team we do feel it is important that the [medicines regulators] not only ensure that all manufacturers provide detailed labelling of the excipient content of their products but all lead action to determine whether existing practice constitutes a risk, and if so, how this might be dealt with."

The authors point out that children's medicines have to cater for a wide age range, making it difficult for manufacturers to tailor their products for each age group. The inclusion of some excipients is also a necessity.

Provided by University of Leicester