Drug that helps adults addicted to opioid drugs also relieves withdrawal symptoms in newborns

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Thousands of infants each year have exposure to opioids before they are born. Over half of these infants are born with withdrawal symptoms severe enough to require opioid replacement treatment in the nursery. Such treatment is associated with long hospital stays which interferes with maternal/infant bonding. Now, a team of researchers at Thomas Jefferson University has tested a semi-synthetic opioid they say has the potential to improve the treatment of these newborns, which could save hundreds of millions in healthcare costs annually if future tests continue to show benefit.

In the October 6th online issue of *Addiction*, the researchers say that using buprenorphine in a dozen addicted infants was both safe and successful and reduced days of treatment by 40 percent, compared to use of morphine in 12 other infants randomized to this treatment. The difference was 23 days of treatment versus 38 days.

"Given further study, such a beneficial drug could provide a new standard of treatment in a field where a well-defined therapeutic approach doesn't exist," says the study's lead author, Walter Kraft, M.D., associate professor in the Department of Pharmacology and Experimental Therapeutics at Jefferson.

"Not only do we think buprenorphine is an excellent choice to treat neonatal opioid withdrawal, but it may prove to also be cost effective," he says. "There are not good numbers to work with but we estimate up to 16,000 infants each year are at risk for the syndrome. If you assume the costs for this treatment are $2,000 a day over an average 30 days of hospitalization, annual charges for this treatment can be up to $1 billion."

"If we were to reduce hospital stay by just 20 percent, that would save $150 million," Dr. Kraft adds.

The investigative team, which includes experts in neonatology, addictions, clinical pharmacology and pediatric neurology are the first physicians to test buprenorphine in newborns. Buprenorphine is finding increased use in the treatment of adults with opioid dependence.

In infants, the agent was given sublingually - under the tongue - and to keep it there until it is absorbed, the physicians gave the babies pacifiers to suck. "This is the only report of a sublingual drug ever used in infants," Kraft says.

Many of the mothers of the infants receive care at the Family Center, which cares for the majority of pregnant opioid-addicted women in the Philadelphia area, Dr. Kraft says. The program is directed by co-author Karol Kaltenbach, Ph.D., who is a internationally known expert in the treatment of pregnant women with addiction.

In 2008, the research team published results from their first cohort using buprenorphine in infants. In this study, they enrolled 24 infants, half randomized to buprenorphine and half to standard of care oral morphine. The investigators found that infants treated with buprenorphine had a 23-day length of treatment, compared to 38 days for those treated with morphine. Length of hospital stay in the buprenorphine group was 32 days versus 42 in infants treated with morphine.

"They say that to truly know if buprenorphine is a better treatment for these infants, it will be necessary to conduct a double-blind randomized study in which physicians do not know which treatment has been administered. We are not using

buprenorphine in infants who need treatment until we conduct this final step," Dr. Kraft says. "It is important to do the study in the most rigorous way possible, to prove the benefit of the therapy. We are currently in the planning stages of such a study."

Provided by Thomas Jefferson University