Dangerous experiment in fetal engineering

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(Medical Xpress) -- A new paper just published in the *Journal of Bioethical Inquiry* uses extensive Freedom of Information Act findings to detail an extremely troubling off-label medical intervention employed in the U.S. on pregnant women to intentionally engineer the development of their fetuses for sex normalization purposes.

The paper is authored by Alice Dreger, professor of clinical medical humanities and bioethics at Northwestern University Feinberg School of Medicine and is co-authored by Ellen Feder, associate professor of philosophy and religion at American University, and Anne Tamar-Mattis, executive director of Advocates for Informed Choice.

The pregnant women targeted are at risk for having a child born with the condition congenital adrenal hyperplasia (CAH), an endocrinological condition that can result in female fetuses being born with intersex or more male-typical genitals and brains. Women genetically identified as being at risk are given dexamethasone, a synthetic steroid, off-label starting as early as week five of the first trimester to try to "normalize" the development of those fetuses, which are female and CAH-affected. Because the drug must be administered before doctors can know if the fetus is female or CAH-affected, only one in eight of those exposed are the target type of fetus.

The off-label intervention does not prevent CAH; it aims only at sex normalization. Like Diethylstilbestrol (DES) -- which is now known to have caused major fertility problems and fatal cancers among those exposed in utero -- dexamethasone is a synthetic steroid. Dexamethasone

is known -- and in this case intended -- to cross the placental barrier and change fetal development. Experts estimate the glucocorticoid dose reaching the fetus is 60 to 100 times what the body would normally experience.

The new report provides clear evidence that:

- For more than 10 years, medical societies repeatedly but ultimately impotently expressed high alarm at use of this off-label intervention outside prospective clinical trials, because it is so high risk and because nearly 90 percent of those exposed cannot benefit.
- Mothers offered the intervention have been told it “has been found safe for mother and child” but in fact there has never been any such scientific evidence.
- The U.S. Food and Drug Administration has indicated it cannot stop advertising of this off-label use as “safe for mother and child” because the advertising is done by a clinician not affiliated with the drug maker.
- A just-out report from Sweden in the Journal of Clinical Endocrinology and Metabolism documents a nearly 20 percent “serious adverse event” rate among the children exposed in utero.
- Clinician proponents of the intervention have been interested in whether the intervention can reduce rates of tomboyism, lesbianism and bisexuality, characteristics they have termed “behavioral masculinization.”
- The National Institutes of Health has funded research to see if these attempts to prevent “behavioral masculinization” with prenatal dexamethasone are “successful.”
- The United States’ systems designed to prevent another tragedy like DES and thalidomide -- involving de facto experimentation on pregnant women and their fetuses -- appear to be broken and

ineffectual.

The paper is available for free download at:
www.springerlink.com/content/m … 3l7615744552/?MUD=MP

Provided by Northwestern University