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*primary studies - published, non RCT*

## **Maternal and fetal outcomes following elexacaftor-tezacaftor-ivacaftor use during pregnancy and lactation.**

**Code:** PM33762125

**Year:** 2021 **Date:**

**Author:** Taylor-Cousar JL

### **Study design (if review, criteria of inclusion for studies)**

Cross sectional study

### **Participants**

CF Center staff completed an anonymous questionnaire regarding pregnancy and infant outcomes for 45 women who used elexacaftor-tezacaftor-ivacaftor (ETI) during pregnancy and/or lactation.

### **Interventions**

ETI during pregnancy and/or lactation.

### **Outcome measures**

Teratogenicity; unknown fetal impact; complications

### **Main results**

Of 45 ETI-exposed pregnancies reported to date, complications in 2 mothers and in 3 infants (2 born to mothers with poorly controlled diabetes) were rated by clinicians as unknown (possible) or suspected relatedness to ETI use. Two women terminated unplanned pregnancies. Miscarriage rates were consistent with that known in the general U.S. Five of the six women who discontinued ETI out of concern for unknown fetal risk restarted because of clinical deterioration. No infant cataracts were reported though only two infants were formally evaluated.

### **Authors' conclusions**

In the context of the known increased rate of complications in women with CF and their infants, data from this retrospective survey is reassuring for women who choose to continue ETI during pregnancy. However, a large, multi-center prospective study is needed to assess impact of use of ETI in pregnancy.

<http://dx.doi.org/10.1016/j.jcf.2021.03.006>

### **See also**

J Cyst Fibros. 2021 May;20(3):402-406. doi: 10.1016/j.jcf.2021.03.006. Epub 2021 Mar 22.

### **Keywords**

Adult; Aged; CFTR Modulators; Genetic Predisposition to Disease; pharmacological\_intervention; placebo; VX-770; VX-661; ivacaftor; Aminophenols; tezacaftor; VX-445; elexacaftor; Trikafta; Pregnancy;