LIFE AND FAMILY INITIATIVE

Fact Sheet
Excluded Adverse Events in Real-World Study of Mifepristone

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Overview

In the most comprehensive U.S. study to date of abortion pill safety, the Ethics and Public Policy Center (EPPC) analyzed insurance claims data from 865,727 mifepristone abortions (2017–2023). The study identified a serious adverse event rate of **10.93%**, but notably **excluded a majority of emergency room visits** to avoid overstating risks. This ensures a conservative, accurate estimate of harm.

The emergency room visits **included in the report are only those related to the chemical abortion**, based on the diagnosis and procedure codes in the insurance records, and are counted only if treatment for a serious complication related to the chemical abortion took place. Thus, if a woman took the chemical abortion pill and then got into a car accident or broke a bone, that did not count. Likewise, if a woman took the chemical abortion pill and had mild cramping related to the chemical abortion, that also did not count.

What was excluded?

We excluded pregnancy-related non-serious or unrelated to chemical abortion ER visits:

- 72% of emergency room (ER) encounters within 45 days of abortion were excluded from the analysis.
- These 98,483 ER visits involved diagnoses not clearly related to the chemical abortion or not medically serious, including but not limited to:
  - Shortness of breath
  - Nausea with vomiting
  - Unspecified lower abdominal pain
  - COVID-19 exposure
  - Nicotine dependence
  - Asthma
  - Anxiety disorder

We excluded mild and moderate adverse events (Grades 1 & 2):

- The study only included severe (Grade 3) and life-threatening (Grade 4) events per NIH's Common Terminology Criteria for Adverse Events (CTCAE).
- **Excluded** non-serious events required minimal or no medical intervention.

We excluded non-life-threatening mental health codes:

- In order to provide a conservative estimate, we only included life-threatening mental health codes. Of which only two codes met this criterion: homicidal and suicidal ideation

We excluded women being treated for a miscarriage:

- We only included mifepristone only abortions if the encounter was accompanied by a Z332 code (an encounter for elective termination of pregnancy) to intentionally capture only chemical abortions rather than miscarriages

We excluded non-serious bleeding:

- Only codes related to hemorrhage or serious bleeding (according to the FDA definition) were included. "Typical expected bleeding" as a known and expected side-effect of the pill is not captured in our serious adverse events.

Why This Matters

Rigorous methodology:

This rigorous approach, excluding 72 percent of ER visits, represents a floor for serious adverse events, and it is cautious to avoid artificially inflating serious adverse event rates.

Benchmarking against FDA data:

The Mifeprex label reports abortion-related ER visits of up to 4.6%, and this study identified a nearly identical rate of 4.7%.

Conclusion

The EPPC study presents a careful and conservative assessment of abortion pill safety, excluding a vast number of irrelevant or minor events. Even with these exclusions, it finds a **22x higher** rate of serious complications than reported by the FDA and drug manufacturers. These findings suggest an urgent need for stronger safety protocols and regulatory oversight.