

FOR OUR PATIENTS

Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient

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The summary below is based on a more extensive article that appears in the February 2006 issue of *The Annals of Pharmacotherapy* (volume 40, no. 2, pages 191-197). The full report is entitled “Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient” and is authored by Margaret M Gary, MD and Donna J Harrison, MD. It was first published in *The Annals Online* on December 27, 2005 and can be accessed at <http://dx.doi.org/10.1345/aph.1G481>.

What is mifepristone?

In September 2000, the Food and Drug Administration (FDA) approved mifepristone, a drug used to terminate pregnancy.

Why was this study conducted?

There have been a total of 8 known maternal deaths related to mifepristone, including 5 Americans. Six of the deaths were caused by a life-threatening infection known as sepsis, one died from an ectopic pregnancy, and one died from massive hemorrhage. One of the deaths was a 13-year-old girl. The authors are also concerned that the FDA may be unable to adequately alert people about the serious adverse effects of this drug, because its Adverse Event Reporting System does not require critical information needed for complete case assessment.

How was this study conducted?

The authors reviewed 607 mifepristone Adverse Event Reports submitted to the FDA between September 2000 and September 2004.

What did the authors discover about severe adverse events related to mifepristone use?

Among the adverse event reports women were described as having experienced hemorrhage (39%), infection (11%), and missed diagnosis of ectopic pregnancy (2.8%). Sixteen of these adverse events occurred in teenage girls between the ages of 13 and 17. There were at least 513 surgical procedures performed in the 607 patients with adverse events; 235 were emergency surgeries. At least 40% of the patients were hospitalized for treatment, including 12 to the intensive care unit.

There is no standard for requiring clinics to determine gestational age of the fetus before giving women mifepristone. It has only been approved for use up to 49 days from the last menstrual period, but some clinics routinely advertise mifepristone use up to 63 days from the last menstrual period. Of the 607 cases reviewed, 278 mifepristone abortions failed (21%). Furthermore, a serious concern is the suggested fetal malformation rate of at least 23% if mifepristone fails and a woman chooses to continue her pregnancy.

What were the limitations of this study?

Analysis and coding were based only on the limited contents of the reports. Poor documentation almost certainly resulted in the underestimation of the severity of some adverse events. Also, the reports only indicate associations between the drug and the effects, but do not prove causality.

What do the authors recommend?

Mifepristone presents a significant risk of severe, life-threatening, or even lethal adverse events. The most commonly fatal adverse event is sepsis, an infection that may begin without fever and progress rapidly to death. The choice of mifepristone over a surgical abortion is based mainly on patient perceptions of the drug's safety, convenience, and privacy. These perceptions do not reflect the realities of this choice. Furthermore, the authors believe the FDA must promptly review its Adverse Event Reporting System to determine whether the failures described in this report are peculiar to mifepristone or are present in all of its Adverse Event Reports.

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