

# Letters to the Editor

## Online-Only Letters to the Editor

### Is Routine Testing of Vitamin B<sub>12</sub> Cost- effective in Workup for Cognitive Impairment?

Matthew W. Warren,  
MD, PhD, and Myron F.  
Weiner, MD, with reply  
by Robert C. Langan,  
MD (<http://www.aafp.org/afp/2012/0415/ol1.html>)

### Electrodesiccation and Curettage for Removal of Non- genital Warts

Jonathan R. Dreazen,  
MD, with reply by  
Elie Mulhem, MD  
(<http://www.aafp.org/afp/2012/0415/ol2.html>)

Send letters to Kenneth W. Lin, MD, Associate Medical Editor for *AFP* Online, e-mail: [afplet@aafp.org](mailto:afplet@aafp.org), or 11400 Tomahawk Creek Pkwy., Leawood, KS 66211-2680.

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## Paroxetine Use Should Be Avoided During Pregnancy

**Original Article:** Antidepressant Use During Pregnancy [FPIN's Clinical Inquiries]

**Issue Date:** May 15, 2011

**Available at:** <http://www.aafp.org/afp/2011/0515/p1211.html>

TO THE EDITOR: In the FPIN's Clinical Inquiries on which antidepressants are safe to use during pregnancy, Dr. Patel and colleagues suggest that paroxetine (Paxil) is safe. Although they note that the American College of Obstetricians and Gynecologists recommends avoiding paroxetine use during pregnancy, they do not provide the evidence supporting the recommendation. Paroxetine actually carries a category D rating from the U.S. Food and Drug Administration (FDA) for safety in pregnancy.

Two studies have found an association between first trimester paroxetine use and congenital malformations, notably cardiac malformations. The first study, completed in 2005, showed "a trend towards a 1.5-fold increased risk for cardiovascular malformations for paroxetine compared to other antidepressants. This study also showed a statistically significant increased overall risk of major congenital malformations (inclusive of the cardiovascular defects) in infants exposed to paroxetine compared to other antidepressants."<sup>1</sup>

In the second study, an analysis of data from the Swedish Medical Birth Register revealed an association between use of paroxetine and cardiovascular congenital defects, most notably ventricular and atrial septal defects.<sup>2</sup> On the basis of these two studies and at the FDA's request, GlaxoSmithKline downgraded their rating of paroxetine safety in pregnancy to category D.<sup>3</sup>

When this information is added to the data presented by the authors, I believe the evidence supports avoiding paroxetine use during pregnancy, especially in the first

trimester. Physicians should also consider this evidence when counseling women of childbearing age about medication choices for depression.

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2. Källén BA, Otterblad Olausson P. Maternal use of selective serotonin re-uptake inhibitors in early pregnancy and infant congenital malformations. *Birth Defects Res A Clin Mol Teratol*. 2007;79(4):301-308.
3. U.S. Food and Drug Administration. Paroxetine HCl—Paxil and generic paroxetine. <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm152062.htm>. Accessed May 30, 2011.

IN REPLY: As Dr. Budenholzer points out, paroxetine received a D rating from the FDA. However, in a 2008 study, paroxetine use in early pregnancy did not appear to be associated with an increased risk of cardiovascular defects in infants; the incidence in more than 3,000 infants was within the population incidence of cardiovascular disease of approximately 1 percent.<sup>1</sup>

Other studies have found an association between maternal paroxetine use and cardiac malformations in infants. A 2005 study reported a 1.5-fold increased risk of cardiovascular malformations with paroxetine use, although the author counted all diagnosed cardiovascular defects, even those that resolved spontaneously.<sup>2</sup> In contrast, the teratology information services groups that produced data for the *American Journal of Psychiatry* study did not include cardiovascular defects that resolved spontaneously.<sup>1</sup> The GlaxoSmithKline results did not specify the severity of the cardiovascular defects, so a number of these cases may have resolved spontaneously.<sup>3</sup>

I agree with Dr. Budenholzer that

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## Letters

paroxetine use during pregnancy should be avoided because of the increased risk of cardiovascular defects in infants, regardless of whether they are categorized as minor, moderate, or severe.

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## Correction

The article, "Hirsutism in Women" (February 15, 2012, page 373) contained an error in *Figure 1* on page 374. The figure should have contained a footnote clarifying that a score of 0 indicates absence of terminal hair. The online version of this article has been corrected.

## Clarification

In the Practice Guidelines, "ACIP Releases 2012 Immunization Schedules," (February 1, 2012, page 281) the accompanying 2012 young children (birth through six years of age) immunization schedule was clarified by the Centers for Disease Control and Prevention after publication. In *Figure 1*, the second bulleted item under footnote 1 now reads: "For infants born to hepatitis B surface antigen (HBsAg)-positive mothers, administer HepB vaccine and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth. These infants should be tested for HBsAg and antibody to HBsAg (anti-HBs) 1 to 2 months after completion of at least 3 doses of the HepB series, at age 9 through 18 months (generally at the next well-child visit)." The online version of this handout has been updated. ■