



[National Heart, Lung, and  
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**Statement on Oral Contraceptive Study from Barbara Alving, M.D., Director of the Women's Health Initiative and Acting Director of the National Heart, Lung, and Blood Institute**

A Women's Health Initiative (WHI) review of a recent abstract on the effects of oral contraceptive use on cardiovascular disease has found flaws in both the design and interpretation of the WHI data used in the study. The October presentation of the abstract at the annual scientific meeting of the American Society of Reproductive Medicine – and subsequent media coverage – may have created the impression that OC use is linked to lower risk of cardiovascular disease (CVD). However, the WHI review of the abstract shows no evidence that OC use is linked to lower risk of CVD.

The abstract used information provided by WHI participants at baseline when they first joined the study. Such analyses are limited and considered exploratory and they should not be used to reassure women about OC use. There is a large and reputable body of higher scientific evidence linking current OC use to future increases in risk of stroke and heart attack, especially in older women and in smokers. The abstract bears no relationship to the findings from the WHI clinical trials of hormones, which showed that postmenopausal hormone use clearly does not reduce, and in fact may increase the risk for CVD.

The presentation of the abstract was not made on behalf of the Women's Health Initiative (WHI) and it had not been reviewed by WHI or by the National Heart, Lung, and Blood Institute (NHLBI) prior to presentation in Philadelphia. The data in the abstract have now been reviewed by senior statisticians at the WHI Clinical Coordinating Center. They repeated the analysis for OC and CVD in the WHI baseline data. They controlled for age and other factors and could not find a relationship between OC use and cardiovascular disease. The statisticians also doubt the validity of a separate cancer abstract which used WHI baseline data to examine OC cancer risks. They conclude that the cancer analyses

have the same potential for finding misleading results as occurred with the CVD analysis. Therefore, these kinds of data are not suitable for the exploration of any link between OC use and cancer.

In general, randomized controlled clinical trials provide the highest quality evidence to answer scientific questions. Analyses using baseline data, such as the one described in the recent presentation, have biases and errors that raise doubts about the validity of any associations found in the exploratory analyses.

It is important to understand that WHI data come only from postmenopausal women who were 50 to 79 years of age when they joined the study. The recent presentation was based on women's recall of their past OC use and diseases they thought they developed. Because people can forget details, the best studies try to collect these data as close to the event as possible and to confirm any report of disease with hospital records.

For any valid analysis of the effect of OC use on cardiovascular disease it would be important to control adequately for factors such as age, body weight, blood pressure, smoking, high blood cholesterol, and diabetes. All of these factors may be related to whether women used OCs and whether they had CVD. The age of women when they enrolled is particularly important, since OCs were not available to older women and CVD is strongly related to age. For a more complete discussion of these points, see the [WHI study website](http://www.whi.org/news/) (www.whi.org/news/).

Other research studies have found that women who take OCs have a small increased risk for CVD, like blood clots, heart attacks, and stroke. These studies provide better scientific data than the recent analysis because they focused on specific questions about OCs and CVD. Research conducted in the past to answer specific questions about OCs and breast cancer has shown an increased risk of breast cancer in women who have recently used OCs. Past research has also shown a decreased risk of ovarian cancer and a slight decreased risk of endometrial (uterine) cancer in women who use some types of OCs. Information on risks and side effects of OCs is available from the [U.S. Food and Drug Administration](http://www.fda.gov) (www.fda.gov) and from the [National Cancer Institute](http://www.nci.nih.gov) (www.nci.nih.gov).

WHI is funded by the National Heart, Lung, and Blood Institute and conducted in collaboration with the National Institute on Aging, the National Cancer Institute, the National Institute for Arthritis, Musculoskeletal and Skin Disorders, and the NIH Office of Women's Health Research.

NHLBI is part of the National Institutes of Health (NIH), the Federal Government's primary agency for biomedical and behavioral research. NIH is a component of the U.S. Department of Health and Human Services. Additional information on menopausal hormone therapy, including the WHI estrogen-plus-progestin study, can be found on the

[NIH Website](http://www.nih.gov) (www.nih.gov), on the [NHLBI Website](http://www.nhlbi.nih.gov) (www.nhlbi.nih.gov), and on the [FDA Website](http://www.fda.gov) (www.fda.gov).

*For more information:*

- [Press Statement from Wayne State University and the WHI Investigators](http://www.whi.org/news/press_oral_contraceptives.php) (http://www.whi.org/news/press\_oral\_contraceptives.php)
- [FAQs from Wayne State University and the WHI Investigators](http://www.whi.org/news/faq_oral_contraceptives.php) (http://www.whi.org/news/faq\_oral\_contraceptives.php)
- [Women's Health Initiative](http://www.nhlbi.nih.gov/whi) (http://www.nhlbi.nih.gov/whi)
- [Menopausal Hormone Therapy Information \(NIH\)](http://www.nih.gov/PHTindex.htm) (http://www.nih.gov/PHTindex.htm)



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