



[\[Reporting of adverse drug reactions to the Norwegian Drug Control Agency\].](#)

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Abstract: This article reports on a retrospective study in two major Norwegian hospitals of spontaneous reporting to the Adverse Drug Reaction Committee of the Norwegian Medicines Control Agency of adverse reactions from the use of oral contraceptives (OCs) among patients with a diagnosis of venous thromboembolism. In these two hospitals, 168 women between 15 and 44 were diagnosed with a first event of venous thromboembolism during the ten-year period up to the end of 1997; 69 of them were OC users at the time of diagnosis. Three medical records (4%) kept at the hospital contained information on a report of adverse drug reaction to the Norwegian Medicines Control Agency. The Agency's database of all spontaneous reports on adverse drug reactions contains 112 reports of venous thromboembolism in the context of OC use. These reports came from all over Norway during the ten-year period of our study; four of the reports came from the study hospitals. We conclude that venous thromboembolism during the use of OCs was underreported by more than 90%. This corresponds to estimates of underreporting of other adverse drug reactions from the use of various compounds, in Norway as well as in other countries.

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