eases listed in Table 1, and for any others in the same low incidence range. The sample size does depend on the prevalence of oral contraceptive usage, however, and requirements are shown for three different levels of use. Numbers are given only for a doubling of the risk of disease; even smaller samples are needed if the risk is greater.

It is clear that retrospective studies require much smaller samples than prospective studies. The hazard of thromboemboli can be studied with 110 cases and 110 controls in a community where oral contraceptives are used by about half of the female population. One hundred and twenty of each would be needed if the usage were less common. This compares with samples of 9,000 for prospective studies of a doubling effect. Only for malformation is there any similarity in sample sizes indicated in Tables 1 and 2.

Just as with prospective studies, the sample sizes listed in Table 2 are minimal. An interest in subgroups, such as particular ages or types of oral contraceptives or durations of use, requires that larger groups be studied.

Summary

Much of the needed information on the longterm medical effects of oral contraceptives will be obtained only by epidemiologic studies. These studies are beset with numerous problems. Users are almost always self-selected and undergo further screening by their physicians on the basis of their medical histories. Patterns of use may be checkered with periods of discontinuance and changes in formulation prescribed. Furthermore, the drugs used, their formulations, and dose schedules are almost always subject to change.

Both prospective and case-control methods can be used for these studies and it may be advantageous to use both for certain problems. The principal difficulties with prospective studies are the large sample sizes required and biases resulting from losses to follow-up. Problems with retrospective studies include potential bias from inappropriate sample selection, difficulties in obtaining histories of illnesses and contraceptive use, and the fact that the procedure does not provide information on the incidence of disease.

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