34,317 women in these two groups. For reasons explained above, the intrauterine device users could not be included in this prevalence study but will be considered in subsequent incidence studies. There were too few women choosing other methods (condom, foam, etc.) to warrant their inclusion (Dubrow *et al.*, 1969).

Cases with carcinoma or carcinoma in situ

For determination of prevalence rates it was important to identify those patients who could be reasonably assumed to have had carcinoma or carcinoma in situ of the cervix at the time they entered the study. We required that they have (*a*) cytological evidence of carcinoma, or suspicion of it, on initial examination or on repeat examinations carried out within eight months; or (*b*) that in those patients with a significant but non-diagnostic abnormality on initial cytological examination there be definite evidence of the disease on the first repeat cytological specimen.

Cytological specimens reported as unsatisfactory for evaluation were counted as no specimen, and the first satisfactory specimen was regarded as the initial specimen.

The arbitrary eight-month period was selected to include all patients who had repeat cytological examinations for any reason before their routine annual smear. By selecting cases in this manner we were confident that the patients with lesions actually present at the time of first examination, but inadequately represented in the first cytological sample, were included.

Those patients who had cytological evidence of the disease when they entered the study, as defined above, and then had histological diagnoses confirmed by us of carcinoma in situ, carcinoma in situ with microfocal invasion, or invasive carcinoma (one case only) were accepted for determination of prevalence rates. There were some patients with abnormal cytological findings who failed to return or refused biopsy examination. As is shown below, the loss from such cases was random, and did not affect statistical evaluation.

Cases of carcinoma in situ that have subsequently appeared in patients without initial cytological evidence of the disease, as defined above, are not considered in this report. Cases with lesser degrees of epithelial abnormality are also not included, but are being followed, and will be the subject of subsequent communications.

Our criteria for the cytological diagnoses and for the histological diagnoses of carcinoma, carcinoma in situ, and related lesions, based on a long prospective study of this disease, have been described in detail and amply illustrated in previous publications (Koss *et al.*, 1963; Koss, 1968). We are aware that some of the lesions we diagnose as carcinoma in situ may be named "precancerous metaplasia," "anaplasia," "dysplasia," "atypical hyperplasia," "significant epithelial abnormality," "cervical intraepithelial neoplasia," and a variety of other terms by some other pathologists. Any of these lesions may be precursors of invasive cervical carcinoma, and though there is controversy about which particular patient with which particular lesion will develop invasive cervical carcinoma, and when—something we cannot predict—there is evidence that invasive carcinoma can be prevented if all women with these precursor lesions are treated (Marshall, 1965).

All cytological and histological examinations were performed without referral to clinical data collected for statistical evaluation and without knowledge of the contraceptive used or contemplated.

METHODS OF DATA ANALYSIS

The initial data analysis compares prevalence rates of carcinoma in situ (including carcinoma in situ with microfocal invasion and the one case of clinically occult invasive carcinoma) in all of the women choosing and using diaphragms with those choosing and using oral steroids, according to documented minimum duration of use.

Then, for women using these contraceptive methods for at least one year, prevalence rates are compared according to each of the five factors that were selected because of their known influence on the rate of the disease. As previously noted, these are age, ethnic origin, age at first pregnancy, number of children born alive, and net family income.

Finally, in order to eliminate bias which might be introduced by the known association between these five factors and the method of contraceptive chosen (Dubrow *et al.*, 1969), three separate random matching programmes have been