Abstract

Objective. The purpose of this paper is to describe the design and methodology of the Morelos HPV Study. The main objective of this study is to examine the use of two different methods for obtaining HPV DNA specimens, self-collected vaginal and clinician-collected cervical, to detect pre-invasive cervical lesions and cancer. Material and Methods. This study was conducted within the regular population-based framework of the Mexican Institute of Social Security (IMSS) cervical cancer screening program in Morelos. A total of 7,868 women were recruited between May and October 1999 and are representative of the population of women attending cervical cancer screening services at the 23 IMSS clinics in the state of Morelos in 1999. Women were provided with a detailed description of the study before signing an informed consent form. Basic data were obtained from all participants using a standard IMSS registration form. During the initial recruitment visit, a randomly selected subsample of 1,069 participants were interviewed to collect additional information about cervical cancer risk factors, acceptability of the HPV and Pap tests, as well as patient costs. Before the pelvic exam, participants were asked to provide a self-collected vaginal specimen for HPV testing. All participants underwent a pelvic examination that involved collecting a cervical sample for the Pap smear and a clinician-collected HPV specimen. Data were evaluated from 7,732 women with complete information for the three tests. The 1,147 women who received at least one positive result (Pap, self- and/or clinician-HPV tests) were invited to return for a colposcopic examination. During colposcopy, biopsies were taken as appropriate, to histologically confirm a diagnosis of cervical intraepithelial neoplasia (CIN) 2/3 or invasive cancer. A total of 1,015 women attended colposcopy, and 101 women received a histologically-confirmed CIN 2/3 or cervical cancer diagnosis. Conclusions. The initial enrollment activities of the Morelos HPV study are the basis for a prevalent case-control study and a prospective cohort study that will investigate the natural history of HPV infections and determine if an HPV-based screening strategy is a safe and cost-effective alternative to Pap screening. The English version of this paper is available too at: http://www.insp.mx/salud/index.html

Keywords

Key words: HPV; cervical cancer; screening; Papanicolaou; México