DESIGN, ETHICAL AND STATISTICAL CHALLENGES WHEN STUDYING THE PERFORMANCE OF NEW SCREENING TESTS FOR CERVICAL CANCER

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Screening for cervical cancer with the Pap smear has contributed to a 90% decrease in mortality from this cancer in settings where quality screening is carried out. However, in recent years there has been a leveling of those rates, and even an increase in certain groups. For this reason, much work is being carried out to improve cervical cancer screening activities. Testing for the presence of Human Papillomaviruses (HPV), the causal agent of cervical cancer, alone or in combination with the Pap smear, appears to be the most promising avenue to improve screening in resource-rich settings. Trials attempting to measure and compare the diagnostic performance of those screening tests face a number of challenges. We discuss the design and analytical avenues we have chosen when carrying out an RCT comparing HPV to Pap testing in screening for cervical cancer precursors in Canada. At the design stage, the presence/absence of cancer was determined by biopsy in those women in whom at least one test was positive, and in a random sub-sample of those with double-negative tests. We describe how we calculated point and interval estimates of the sensitivity and specificity for each test, in the context of incomplete disease ascertainment. We review other studies and evaluate whether the reported point and interval estimates do in fact capture the full uncertainty due to missing data.