Objective
To assess the performance of HPV mRNA test in primary screening.

Background
Primary cervical screening using HPV test relative cytology has been advocated because of higher sensitivity for detection of CIN2+. However, HPV DNA testing is not cost-effective in women 20-34 years due to a high positivity rate of HPV infection.

There are no conflicts of interests

Results
5.2% were HPV mRNA positive at screening. The overall cumulative rate of CIN2+ was 1.8% through 81 months of follow-up. For women 20-34 years (n=5085) 9.4% were HPV mRNA positive at baseline and the overall cumulative rate of CIN2+ was 2.9%. For women 35-69 years (n=7873) 2.5% were HPV mRNA positive at baseline and the overall cumulative rate of CIN2+ was 1.1%.

Cumulative rates by baseline status for HPV mRNA positive and HPV mRNA negative in women 20-34 years were 20.7% and 1.0%, respectively 20.1% and 0.6% in women aged 35-69 years. Except for HPV-18, the cumulative incidence rates for CIN2+ were relatively constant for HPV-16 and HPV-31/33/45 by age.

Conclusion
The HPV mRNA test may be used in primary screening for both women 20-34 and 35-69 years. Due to differences in test properties and understanding of oncogenesis of cervical cancer, studies comparing "head-to-head" DNA and mRNA tests in primary screening are warranted.

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Methods
In 2003-2004 18 852 women were tested with HPV mRNA (PreTect HPV-Proofer, NorChip AS) in primary and secondary screening. Women with a history of abnormal PAP-smear, with biopsy with CIN2+ before screening or until 3 months after, were excluded. Eligible were 12 958 women 20-69 years in a situation resembling primary screening. Follow-up through December 2009 were done through national surveillance of CIN2+ in three registries administered by the Norwegian Cancer Registry (CIN treatment registry, CIN biopsy registry, Cancer registry). All analyses were done by survival analysis in SPSS (version 17.0).