HPV test AS primary cervical Screening for women AGED 34 TO 69 years: safe and gradual technology transfer

iPAAC INNOVATIVE PARTNERSHIP FOR ACTION AGAINST CANCER

Co-funded by the Health Programme of the European Union

TYPE	Program for implementation of new technology in cancer screening	LAST UPDATE	May 2021	NORWAY • NATIONAL Screening program
STATUS	Implemented and ongoing			

PROBLEM & OBJECTIVE

PROBLEM

- The knowledge that cervical cancer develops after infection with human papillomavirus (HPV) has led to revolutionary advancements in screening technology and changed cervical cancer prevention strategies. Technical advancements allow now for rapid and easy detection of HPV-infections through molecular testing. HPV tests have higher diagnostic accuracy than traditional Pap-tests in a screening setting. Hence, regular HPV tests allows for safe extension of the screening interval, from 3-years to 5-years, combined with an increased detection of precancers.

- To reduce cervical cancer incidence, substantial investments in establishing nationwide infrastructure has been made to offer an optimal screening program. Replacing the Pap-smear screening test with HPV-testing, requires modifications within the existing infrastructure and new screening protocols. Changes in activity volumes, adjustments in staff training and changes in the data-flow and communication systems for evaluation and reporting are expected.

OBJECTIVE Transferring technology step-wise allows for continuous monitoring and comparative assessment of the old versus new algorithm. This facilitates i) controlled and safe replacement of technology; ii) mitigation of the expected overload of the gynecological and pathological

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KEY COMPONENTS / STEPS

- 2015-2018: Implementation of randomized primary HPV screening pilot in four counties: Rogaland, Hordaland, Sør- and Nord- Trøndelag, including approximately 300,000 women aged 34-69 years. Women were allocated to the HPV-Screening protocol or the standard-of-care traditional LBC-Screening protocol, based on whether their birth date was even or odd number, respectively.
- The implementation of the program was overseen by an Academic Panel, made up of representatives from collaborating laboratories and national and international experts. The Academic Panel was also responsible for reviewing the evidence for relative benefits and harms of the implemented HPV-Screening protocol, as compared to the current standard-of-care (LBC-Screening protocol) in the pilot programme.
- 2019-2021 Step-wise one-by-one county, randomized and controlled roll-out of primary HPV screening.
- Price of test is decided following a national tender and is not publicly available. Within the pilot project we performed about 150,000 tests.
- Age differentiation introduced to prevent harm; Primary HPV screening only offered to women 34-69 years, since incident HPV infection is more common in younger ages.
- Twice a year evaluation of HPV tests used in screening by a working group put in place by the Directorate of Health.
- Substantial modification to screening protocols may in the initial phase require extended funding, to cover laboratory adjustments, staff training and upgrading of the IT infrastructure.

KEY CONTEXTUAL FACTORS

- The organized Norwegian Cervical Cancer Screening Programme NCCSP started in 1995, when national guidelines recommended cytology screening every 3 years for women aged 25 to 69 years. In 2005 HPV testing was introduce as a follow-up of equivocal cytology results.
- The Directorate of Health has the overall responsibility of the cervical cancer screening program and leads the steering group. The Cancer Registry of Norway is responsible for the administration, including the Advisory Board, which brings together national experts and key stakeholders from pathology departments, cytology services, general practitioners, gynecologists and patient representatives throughout the country.
- The aim is to provide an equitable screening program for all Norwegian women.

MAIN IMPACTS / ADDED VALUE

- Implementing HPV-based screening test has prompted an 60% increase in the number of women detected with serious cell abnormalities, prior to development of cancer. Those with negative screening tests will repeat screening in 5 years instead of 3 years.
- HPV-based screening in long run should free-up laboratory capacity and save overall costs due to introduction of a 5-years screening interval instead of 3-years interval.
- Technology transfer is under roll-out, completed in 2024.

LESSONS LEARNED

- A stepwise implementation of new technology in the screening program is important to ensure that the high quality of the program is maintained, and to allow for continuous adjustments throughout the process. However, randomized technology transfer in screening needs to be implemented as broadly as possible, preferably without having a pilot. Emerging results from our pilot indicated significantly improved screening using the HPV test, which in turn, made further randomization ethically difficult.
- The laboratories must have time to adapt to new routines and an increased number of HPV analyzes.
- Specialist health services (gynecologists and pathologists) must have the capacity to receive the women who are referred for further follow-up.
- Integration of IT -systems to handle randomization and assign correct follow-up was a challenge and required nationwide coordination. Initial guidelines for HPV-screening protocols were conservative and resulted in significant increase in colposcopy referrals. These guidelines were changed after evaluation of data from the pilot project.

REFERENCES & DOCUMENTATION

Report from the Norwegian cervical cancer screening 2019
About cervical screening
About HPV screening method
HPV test demands

More over IPAAC Roadmap

This publication was funded by the European Union's Health Programme (2014-2020)