



XIII INTERNATIONAL WORKSHOP ON
LOWER GENITAL TRACT PATHOLOGY
HPV Disease and Cervical Cancer: Summing Up
ROME | APRIL 12-13 2018

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HPV test in triage of ASC-US/LSIL

The risk of CIN3+ in 5-type HPV mRNA negative women - 6 years follow-up

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No conflicts of interests to declare



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Background

- Management of minor cervical lesions is challenging, comprising a high volume of tests
- 14-type HPV DNA tests generate many positive results and a trade-off between benefits (detected CIN2+) and harms (unnecessary colposcopies/biopsies) has to be considered
- A 3-year risk of CIN3+ below 2.0% is considered acceptable for return to screening

The 5-type HPV mRNA (PreTect HPV-Proofer) is used in triage of ASC-US/LSIL by several hospitals in Italy

Objectives

Evaluate performance of a 5-type HPV mRNA test in triage of ASC-US/LSIL for women age 25-69 years attending screening in the two most northern counties Troms and Finnmark

HPV testing for only 5 genotypes has raised questions about safety for the triage negative women

We will compare the risk of CIN3+ among test negative (exposed cohort) with a control group of women who had a normal cytology (non exposed cohort) at study start

Methods

Historical prospective cohort study

The study was initiated by Clinical Pathology, University Hospital of North Norway starting in 2006 with follow up until 2014

Follow-up: Merged Lifetime data on cervical cytology/ histology in four national registries administered by Norwegian Cancer Registry (NCR)

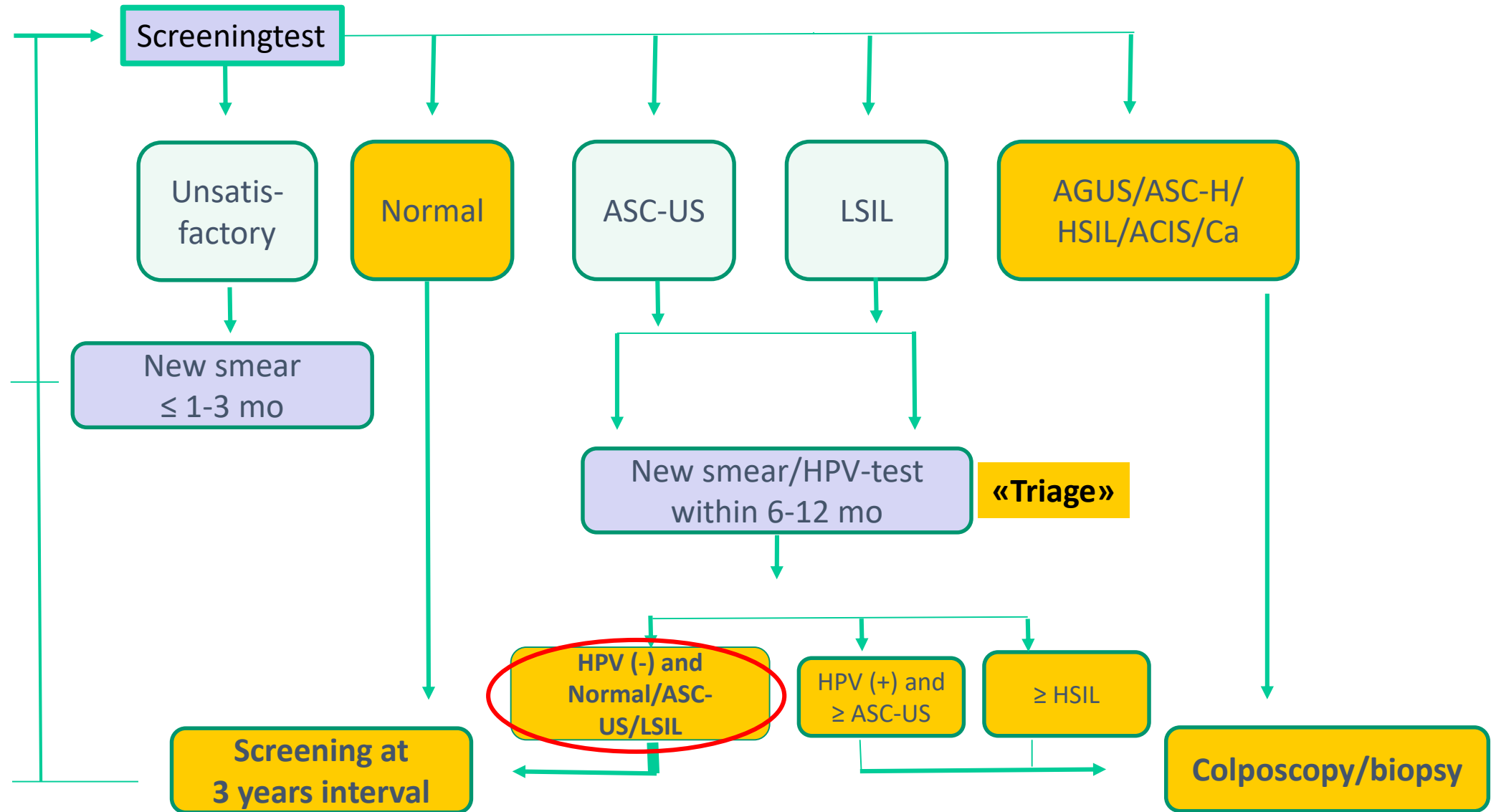
Cytology: Bethesda system PAP/LBC (ThinPrep)

Histology: CIN classification - Outcome CIN3+

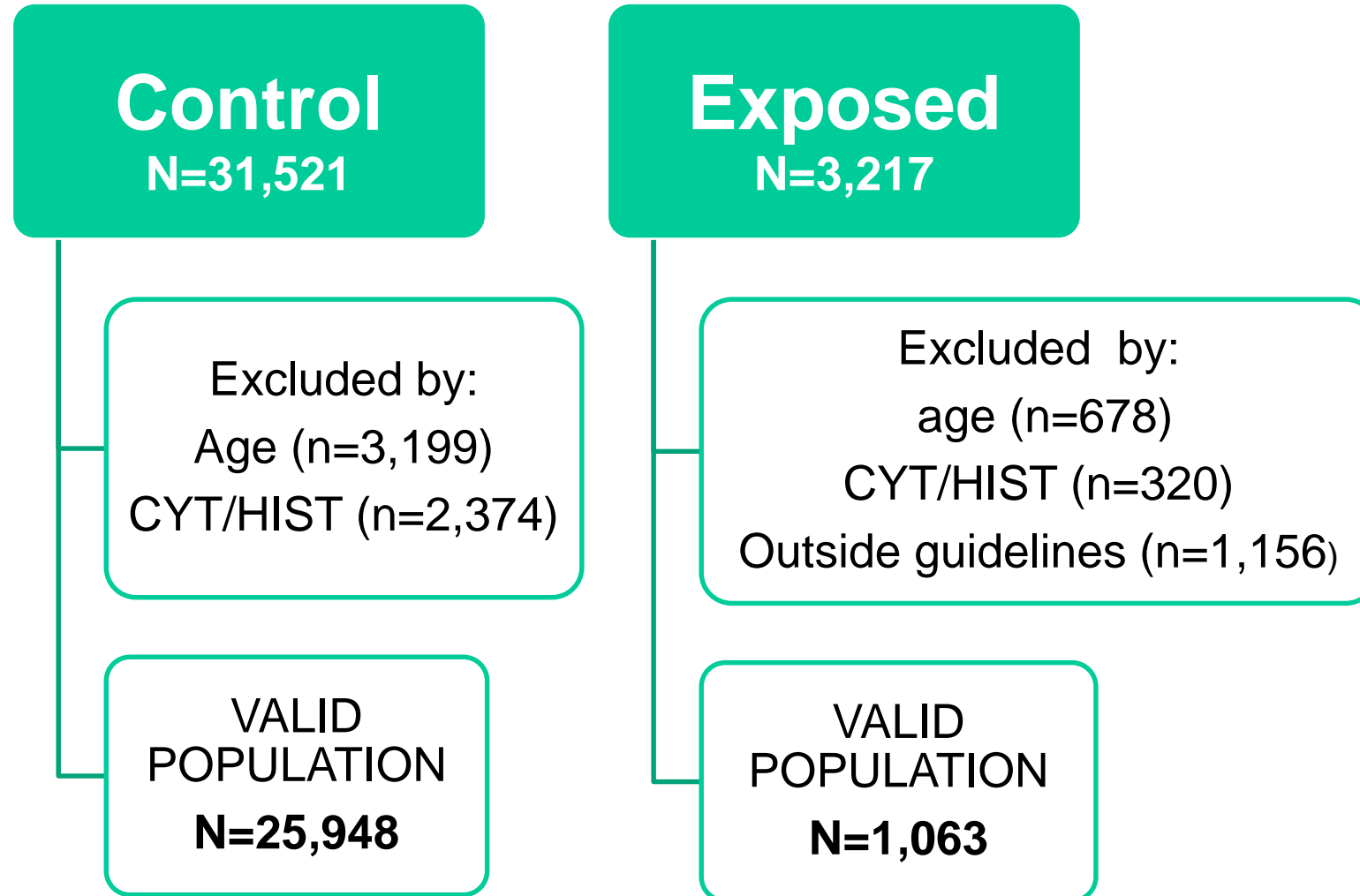
HPV testing: PreTect HPV-Proofer

Individual genotyping of HPV E6/E7 mRNA 16, 18, 31, 33 and 45

Norwegian screening algorithm during the study years 2006-2011



Study population



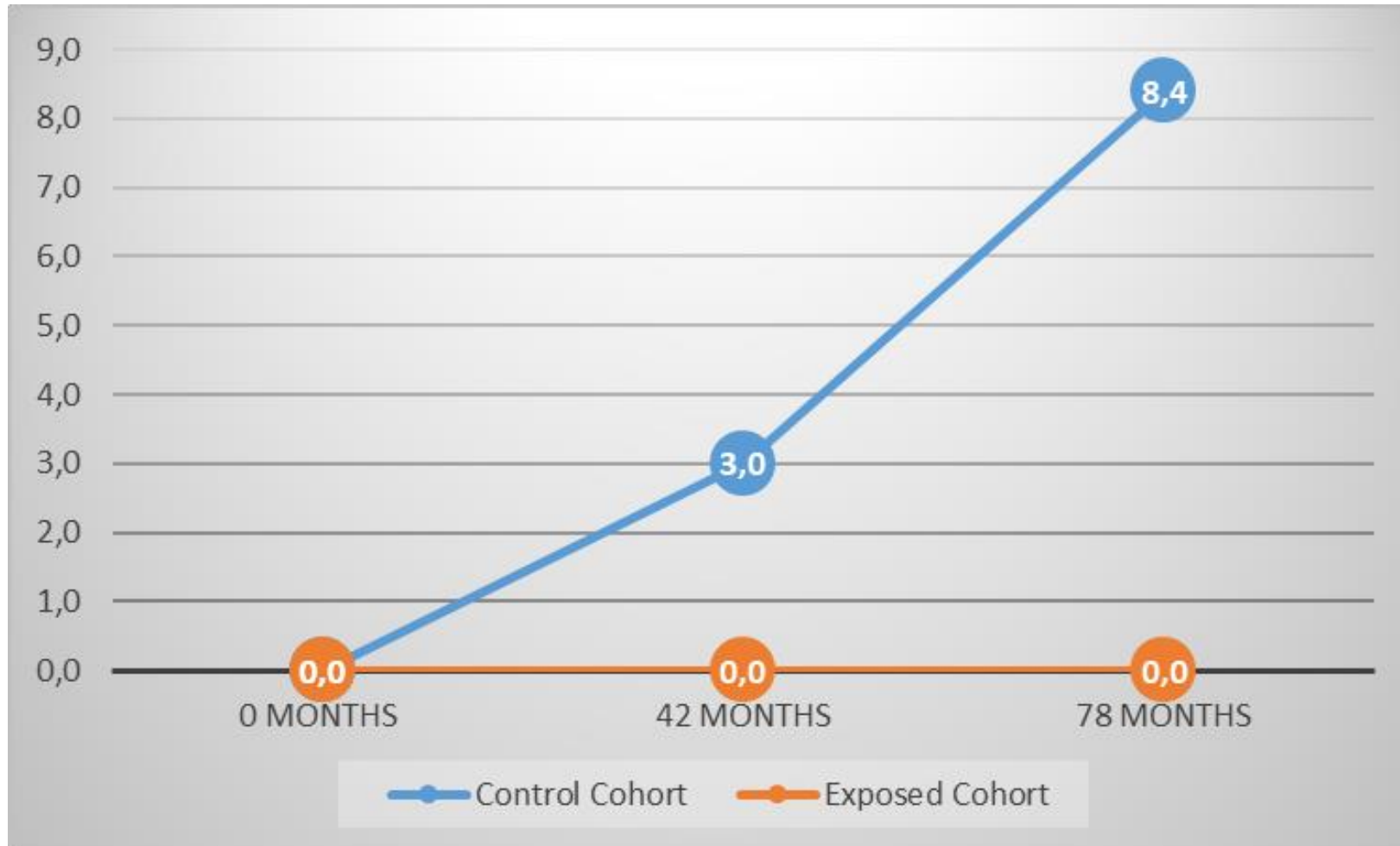
The crude cumulative proportion of CIN3+ at 42 and 78 months of follow-up



*Rescreening at 3 years intervals when CIN3+ risk < 2% is considered acceptable

Castle P et al. Risk assessment to guide prevention of cervical cancer AJOG. 2007; 197(4): 356.e1–356.e6

Cervical cancer incidence per 100,000 women-years



Summary

3-year risk of CIN3+ among women with a negative HPV mRNA test in triage of ASC-US/LSIL is low and within the recommended risk threshold

Risk of CIN3+ over 42 months follow-up:

- ✓ Normal cytology: 0.24%
- ✓ HPV mRNA negative/ASC-US/LSIL: 1.45%

Conclusions

- The 5-type HPV mRNA test provides acceptable safety in triage of ASC-US / LSIL and test negatives may return to screening at 3-year interval
- The PreTect HPV-Proofer test has a high PPV for CIN3+ (41%)* and provides better risk stratification of minor cervical lesions than a 14-type HPV DNA test
- HPV mRNA will be important in triage of HPV DNA positive women entailing a more accurate patient management

*Sørbye SW, Fismen S, Gutteberg T, Mortensen ES (2010) Triage of Women with Minor Cervical Lesions: Data Suggesting a “Test and Treat” Approach for HPV E6/E7 mRNA Testing. PLoS ONE 5(9): e12724. <https://doi.org/10.1371/journal.pone.0012724>