



Country Meeting

HPV Prevention and Control Landscape and the Way Forward

Warsaw, Poland

23 - 24 November 2023

Standardization of procedures according to the PSCCP



Robert Jach







European Federation for Colposcopy



PSCCP – Polish Society for Colposcopy and Cervical Pathology



<u>COLPOSCOPY 2020 Project</u> started – the first guidelines in Poland standardized all ccs procedures in HPV-related strategy



Secondary prevention of the cervical cancer in the HPV-related strategy – PSCCP Statement <u>POLISHPV 2023</u> (in Progress)

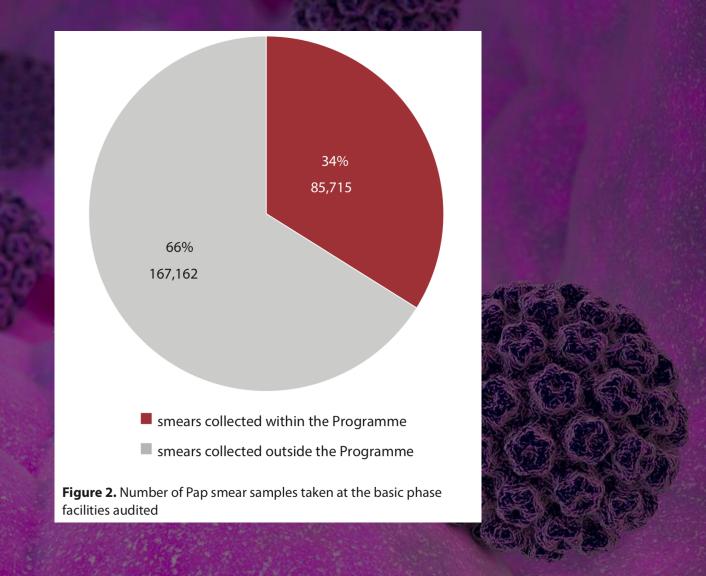




- opportunistic public funds-based model (cc every 3 y 25-64) with registry, without standardization for HPV-related strategy (coverage 11,61% 01/10/2023)
 LOW ACCEPTANCE – LOW TRUST
- opportunistic private funds-based model (various approaches, heterogeneous) no registry, standardization ongoing (coverage? up to 60%)
 TRADITION ACCEPTANCE TRUST
- history: organized population-based program 2006-2016 (coverage up to 26,8%)

The role of opportunistic private funds-based screening in Poland









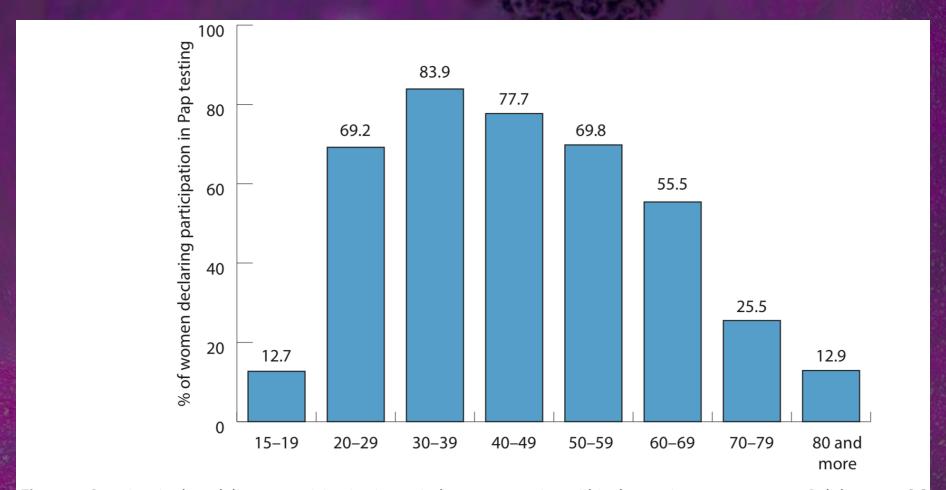
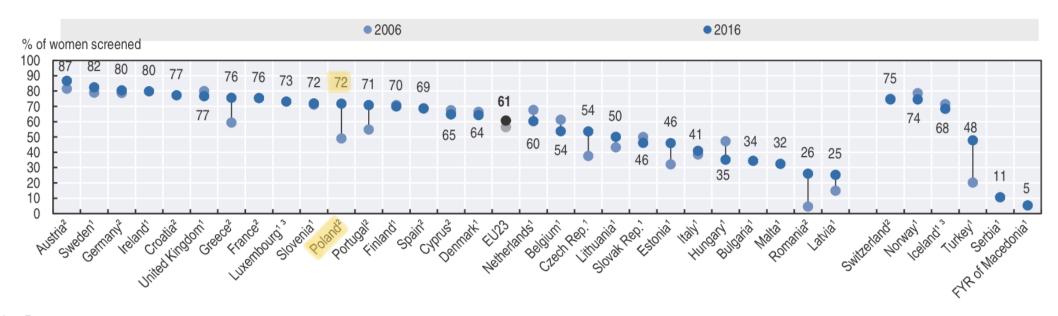


Figure 1. Questionaire-based data on participation in cervical cancer screening within the previous 3-years among Polish women [7]

The role of opportunistic private funds-based screening in Poland



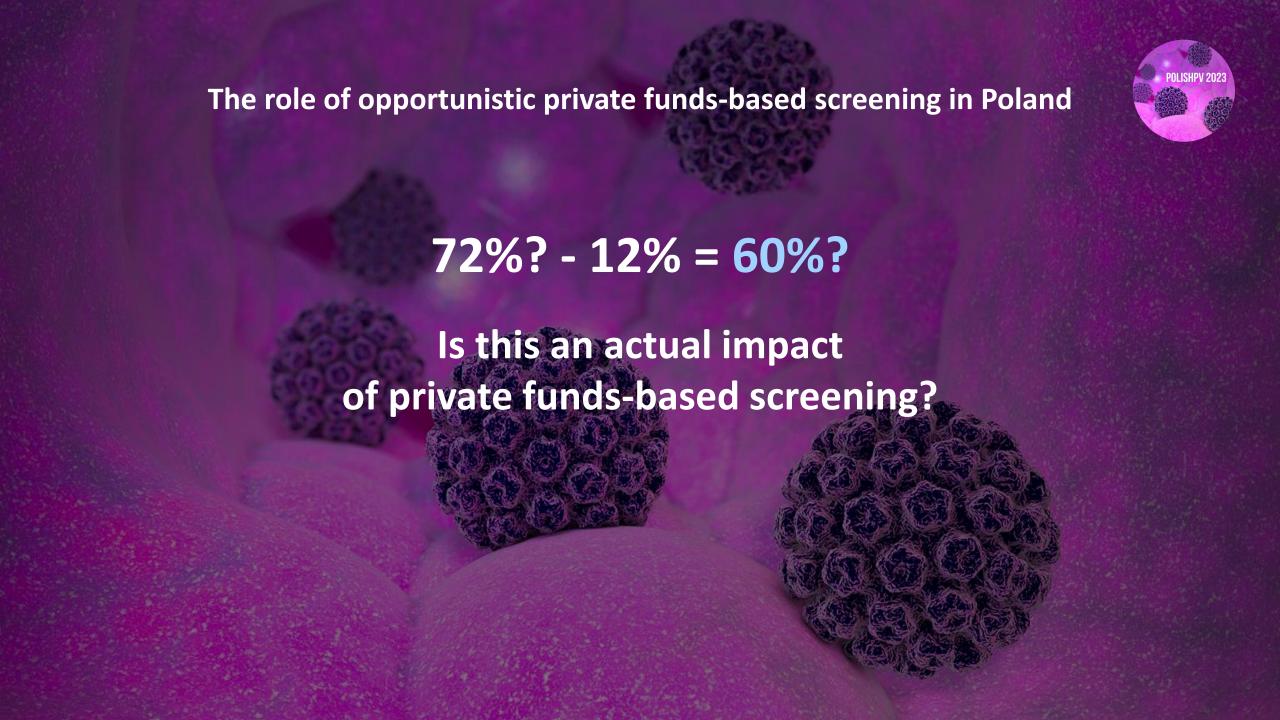
6.16. Cervical cancer screening in women aged 20-69 within the past 3 years, around 2006 and around 2016



- Programme.
- 2. Survey.
- 3. Three-year average.

Note: The EU average is unweighted and only includes countries with data covering the whole time period.

Source: OECD Health Statistics 2018, https://doi.org/10.1787/health-data-en.



COLPOSCOPY 2020 CCS Standardization Project

- Polish response to the WHO Call for Action 2020

The Cervical Cancer Screening Continuous Quality Improvement Project (CQI "SKY" Project)





COLPOSCOPY 2020 CCS Standardization Project



The first and only comprehensive multi-level project for the standardization of diagnostic and therapeutic procedures in the secondary prevention of CCS in Poland, introducing new screening paradigms.



COLPOSCOPY 2020 CCS Standardization Project

Continuous Quality Improvement Project

of introducing and updating recommendations for Polish opportunistic screening model outside public financing with the possibility of implementation (including partial) into a model financed from public funds.









Standardization of all ccs secondary prevention procedures

- Pre-Colposcopy stage (pre-colposcopic procedures)
- Colposcopy stage (standardized colposcopy and expedited treatment)
- Post-Colposcopy stage (excisional or ablative treatment, active observation, follow-up)

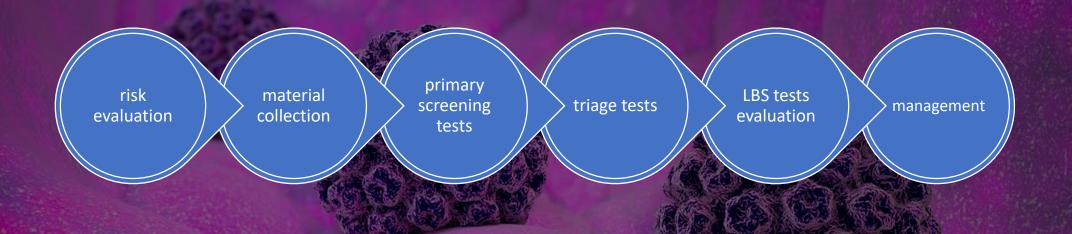






PSCCP standardization of all ccs secondary prevention procedures

Pre-Colposcopy stage





Jach R, Mazurec M, Trzeszcz M et al. Ginekol Pol. 2020;91(6):362371.

Jach R, Mazurec M, Trzeszcz M et al. Med. Prakt. Ginekol. Położ., 2022; 6: 67–80

www.kolposkopia.info POLISHPV 2023 Statement (in Progress)

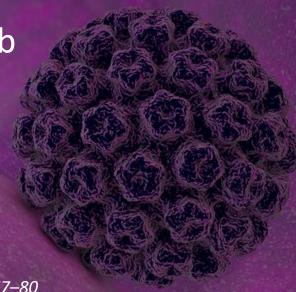
COLPOSCOPY 2020 Project – POLISHPV 2023 Statement Material collection PSCCP standardization



Methods of material collection - standardization:



- medical staff collected samples by physicians
 (gynecologists!) or midwives
- self-sampling vaginal swab





Jach R, Mazurec M, Trzeszcz M et al. Ginekol Pol. 2020;91(6):362371.

Jach R, Mazurec M, Trzeszcz M et al. Med. Prakt. Ginekol. Położ., 2022; 6: 67–80

www.kolposkopia.info POLISHPV 2023 Statement (in Progress)



Methods of material preparation – standardization & validation:

material collection

- SurePath
- PreservCyt/ThinPrep





Jach R, Mazurec M, Trzeszcz M et al. Ginekol Pol. 2020;91(6):362371.

Jach R, Mazurec M, Trzeszcz M et al. Med. Prakt. Ginekol. Położ., 2022; 6: 67–80

www.kolposkopia.info POLISHPV 2023 Statement (in Progress)



Multiparameter HPV-based and HPV-related LBS

Liquid-Based Screening/LBS

Jach R, Mazurec M, Trzeszcz M et al. TR 2021. Ginekol Pol 2021;92(2):165-173.

Jach R, Mazurec M, Trzeszcz M et al. Stanowisko PTKiPSM 08/2022. Med. Prakt. Ginekol. Położ., 2022; 6: 67–80

www.kolposkopia.info POLISHPV 2023 Statement (in Progress)

Mazurec M, Trzeszcz M. Część 1. Etap przedkolposkopowy. GpD 04/2022.





The Project recommends the use of a liquid medium as a medium for material collected from the cervix, which, after dedicated laboratory preparation, allows the necessary diagnostic tests to be performed in one collection.

Liquid-based screening (LBS) based on the primary molecular HRHPV14 DNA detection test (optionally RNA – based on WHO 2021 guideline) with limited (16/18) genotyping, is recommended as the diagnostic optimum.



Jach R, Mazurec M, Trzeszcz M et al. TR 2021. Ginekol Pol 2021;92(2):165-173.

Jach R, Mazurec M, Trzeszcz M et al. Stanowisko PTKiPSM 08/2022. Med. Prakt. Ginekol. Położ., 2022; 6: 67–80

www.kolpaskopia.info POLISHPV 2023 Statement (in Progress)

Mazurec M, Trzeszcz M. Część 1. Etap przedkolposkopowy. GpD 04/2022.



Single material collection (one patient visit) = all screening tests:

- HRHPV14 with limited (16/18) genotyping
- LBC
- p16/Ki67 DS



Jach R, Mazurec M, Trzeszcz M et al. TR 2021. Ginekol Pol 2021;92(2):165-173.

Jach R, Mazurec M, Trzeszcz M et al. Stanowisko PTKiPSM 08/2022. Med. Prakt. Ginekol. Położ., 2022; 6: 67–80

www.kolposkopia.info POLISHPV 2023 Statement (in Progress)

Mazurec M, Trzeszcz M. Część 1. Etap przedkolposkopowy. GpD 04/2022.

COLPOSCOPY 2020 Project – POLISHPV 2023 Statement Clinically validated HRHPV14 tests PSCCP standardization based on FDA Approval



Validated HRHPV14 DNA tests (for primary HPV testing alone in USA) with limited (16/18) genotyping:

primary screening tests

- Cobas HPV assay
- Onclarity HPV assay

FDA PMA No: P100020/S008, 04/2014 FDA PMA No: P160037, 02/2018

COLPOSCOPY 2020 Project – POLISHPV 2023 Statement Clinically validated HRHPV14 tests PSCCP standardization based on ESGO 2020 list



Validated HRHPV14 DNA tests (for primary HPV testing alone ESGO 2020) with limited (16/18) genotyping:

primary screening tests

- Alinity m HR HPV Assay (Abbott)
- Anyplex II HPV HR Detection (Seegene)
- Cobas 4800 HPV test (Roche)
- HPV-Risk Assay (Self-Screen BV)
- Onclarity HPV Assay (BD)
- Papillo-Check HPV-Screening Test (Greiner Bio-One)
- RealTime High Risk HPV Test (Abbott)
- Xpert HPV (Cepheid)

COLPOSCOPY 2020 Project – POLISHPV 2023 Statement Clinically validated HRHPV14 tests PSCCP standardization based on WHO 2021 Guideline



HRHPV14 mRNA tests may also be used (for primary HPV testing) with limited (16/18/45) genotyping using samples taken by the health-care provider:

primary screening tests

APTIMA HPV Test (Hologic)

Note: No recommendation was made for using HPV mRNA in women living with HIV because evidence on the outcomes of using HPV mRNA detection applicable to this population was not identified.

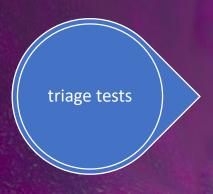
Web Annex. Evidence-to-decision framework for mRNA testing for HPV. In: WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, second edition; use of mRNA tests for human papillomavirus (HPV). Geneva:

Weste Health Operation, 2021, Headton GC RV NC 54-2-0-100.

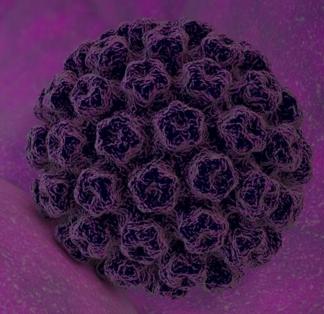
COLPOSCOPY 2020 Project – POLISHPV 2023 Statement Triage tests PSCCP standardization



Recommended HSIL triage tests for HPV HR12+:



- reflex cytology
- reflex p16/Ki67 test



PMA P190024: FDA Summary of Safety and Effectiveness Data.

Jach R, Mazurec M, Trzeszcz M et al. Ginekol Pol 2021,92(2):165-173

www.kolposkopia.info POLISHPV 2023 Statement (in Progress)

COLPOSCOPY 2020 Project – POLISHPV 2023 Statement Triage tests PSCCP standardization





p16/Ki67 DS

The future of HSIL risk triage?

PMA P190024: FDA Summary of Safety and Effectiveness Data.

Jach R, Mazurec M, Trzeszcz M et al. Ginekol Pol 2021,92(2):165-173

www.kolposkopia.info POLISHPV 2023 Statement (in Progress)



Polish LBS validation for opportunistic private funds-based model

(large data studies)



Trzeszcz M, Mazurec M, Jach R, et al. Liquid-Based Screening Tests Results: HPV, Liquid-Based Cytology, and p16/Ki67 Dual-Staining in Private-Based Opportunistic Cervical Cancer Screening. *Diagnostics* (Basel). 2021 – *IF 3,9*



Trzeszcz M, Mazurec M, Jach R, et al. Is Primary HPV with Secondary p16/Ki67 Dual-Stain an Alternative HSIL-Risk Detection Strategy in Cervical Cancer Screening for Women under 30 Years? *Diagnostics* (Basel). 2021 – *IF 3,9*



Mazurec K, Trzeszcz M, Mazurec M, et al. Triage Strategies for Non-16/Non-18 HPV-Positive Women in Primary HPV-Based Cervical Cancer Screening: p16/Ki67 Dual Stain vs. Cytology. *Cancers* (Basel). 2023 – *IF 5,2*

Preprint (accepted 15/11/2023)

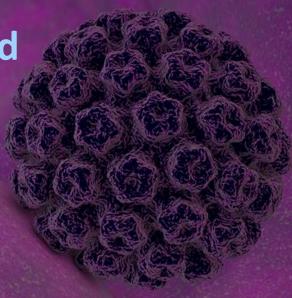
JMV: IF 12.7

Martyna Trzeszcz, Maciej Mazurec, Robert Jach, et al. p16/Ki67 dual stain triage versus cytology in primary human papillomavirus-based cervical cancer screening with limited genotyping. *Authorea*. August 11, 2023. **DOI:** 10.22541/au.169173724.46140403/v1 – *J Med Virol IF* 12,7



It really works in opportunistic private funds-based

model in Poland



COLPOSCOPY 2020 Project – POLISHPV 2023 Statement Gynecological cytopathology PSCCP standardization HPV Cytologist Academy



PSCCP & PTDL

(Polish Society of Laboratory Diagnostics)

Educational Project with Certification

in gynecological cytopathology for Polish cytotechs

COLPOSCOPY 2020 Project – POLISHPV 2023 Statement Gynecological cytopathology PSCCP standardization



HPV Cytologist Academy

Courses levels of certification in liquid-based preparation (LBC & DS) in HPV-related strategy:

LBS tests evaluation

- Level 0 basics in gynecological cytopathology (online) is just starting
- Level 1 LBC as a triage test in HPV-related strategy (on-site)
- Level 2 DS as a triage test in HPV-related strategy (on-site)

COLPOSCOPY 2020 Project – POLISHPV 2023 Statement

Gynecological cytopathology PSCCP standardization

HPV Cytologist Academy



LBS quality assessment and control standardization:

LBS tests evaluation

- LBC reporting rates
- cytologic-virologic correlations (CVC)
- virologic/cytologic- histologic correlations (V/CHC)
- immunocytologic-histologic correlations (IHCHC)
- PPV in gynae cytopathology

COLPOSCOPY 2020 Project – POLISHPV 2023 Statement Management PSCCP standardization



Management strategies:



- tests results-based (classic)
- risk-based (progressive) open for new tools
 (e.g. DS, extended genotyping, vaccination status)

COLPOSCOPY 2020 Project – POLISHPV 2023 Statement

Management PSCCP standardization

HPV-based & HPV-related screening







- HPV HR12+ to triage
- safer for patients
- unknown (probably low) quality Polish gynae cytopathology



COLPOSCOPY 2020 Project – POLISHPV 2023 Statement

Test results-based management PSCCP standardization

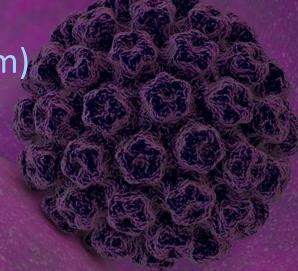
FLOWCHARTS



Primary test standardization:

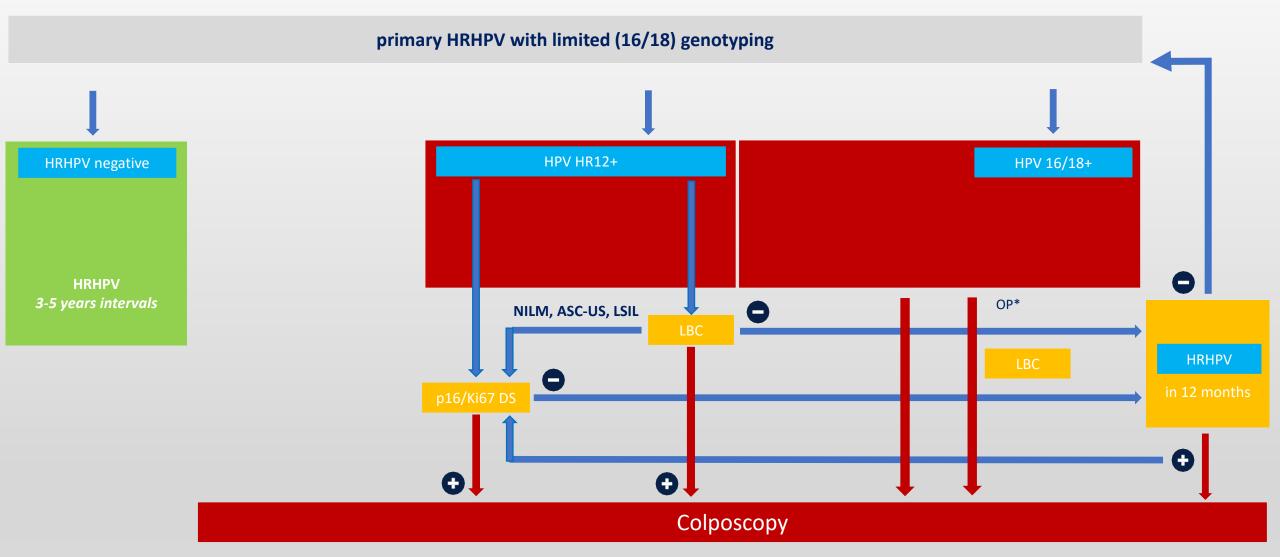


- primary HPV with limited (16/18) genotyping
- primary cotesting
- age range 25-74y (minimum)
- intervals 3-5y





25 to 74 YEARS (minimum)

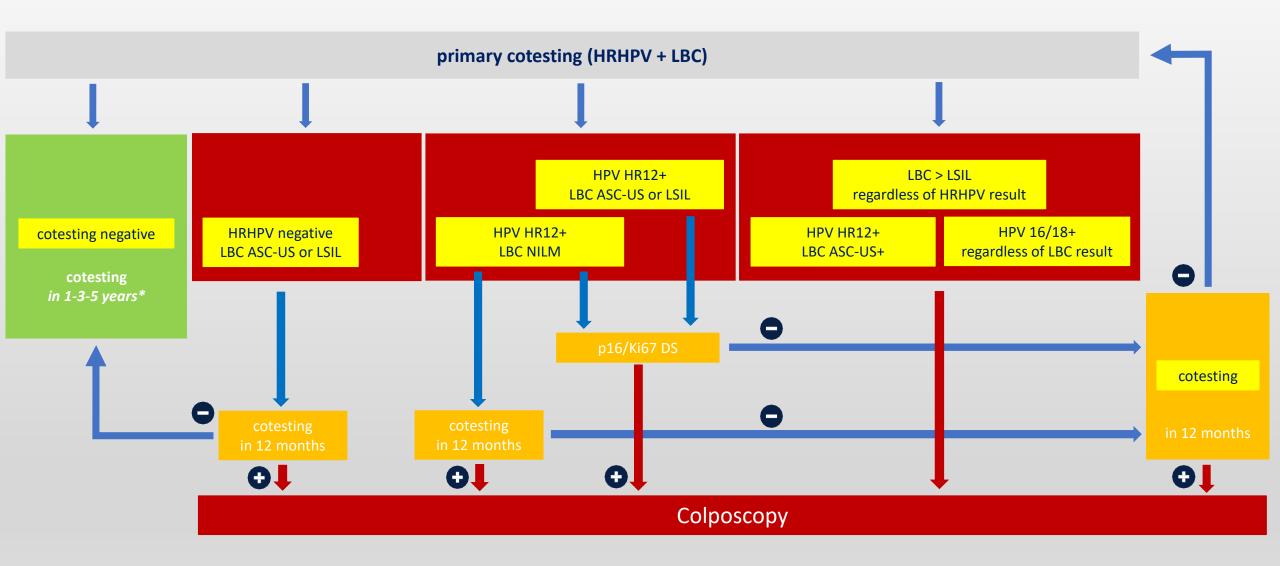


screening model:

primary HRHPV



25 to 74 YEARS (minimum)



COLPOSCOPY 2020 Project—POLISHPV 2023 Statement

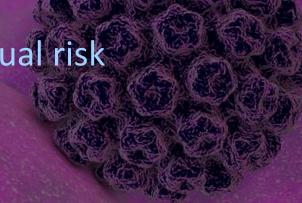
Risk-based management PSCCP standardization based on ASCCP 2019 Guidelines and mobile App



Management standardization based on:



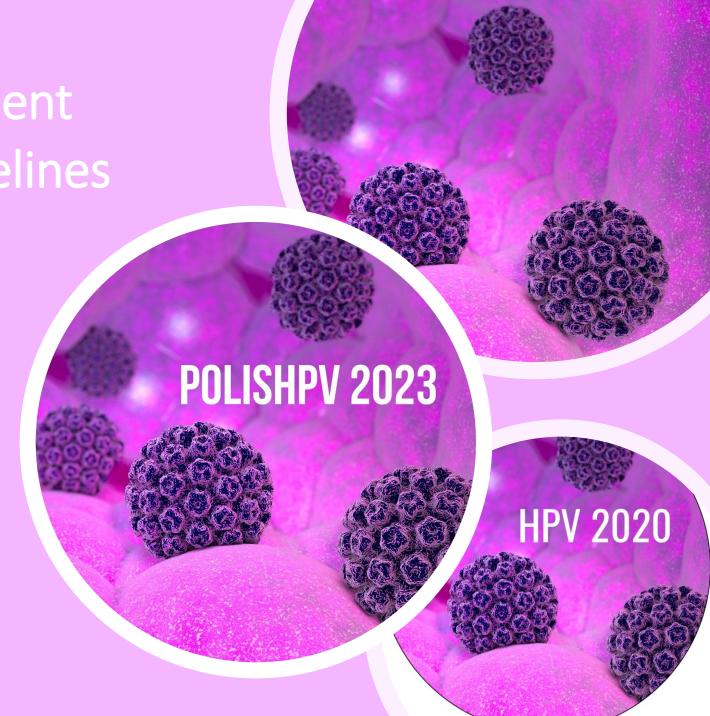
- immediate HSIL/CIN3+ risk
- 3 Years HSIL/CIN3+ risk
- 5 Years HSIL/CIN3+ risk
- equal management for equal risk



Why can we implement the ASCCP 2019 Guidelines

in Poland?

?







"Patients with similar test results and screening history combinations have largely similar CIN 3+ risk, regardless of their geographic location, race, ethnicity, or socioeconomic status"





PSCCP standardization of all ccs secondary prevention procedures

Colposcopy & post-Colposcopy stages

Courses levels of certification in colposcopy (PSCCP & EFC) in HPV-related strategy:

- Level 1 in colposcopy
- Level 2 in excisional & ablative procedures



Jach R, Mazurec M, Trzeszcz M et al. Ginekol Pol. 2020;91(6):362371.

Jach R, Mazurec M, Trzeszcz M et al. Med. Prakt. Ginekol. Położ., 2022; 6: 67–80

www.kolposkopia.info POLISHPV 2023 Statement (in Progress)



Performance of standardised colposcopy to detect cervical precancer and cancer for triage of women testing positive for human papillomavirus: results from the ESTAMPA multicentric screening study



Joan Valls, Armando Baena, Gino Venegas, Marcela Celis, Mauricio González, Carlos Sosa, Jorge Luis Santin, Marina Ortega, Ana Soilán, Elmer Turcios, Jacqueline Fiqueroa, Margarita Rodríquez de la Peña, Alicia Fiqueredo, Andrea Verónica Beracochea, Natalia Pérez, Josefina Martínez-Better, Oscar Lora, Julio Yamil Jiménez, Diana Giménez, Laura Fleider, Yuly Salgado, Sandra Martínez, Yenny Bellido-Fuentes, Bettsy Flores, Silvio Tatti, Verónica Villagra, Aurelio Cruz-Valdez, Carolina Terán, Gloria Inés Sánchez, Guillermo Rodríquez, Maria Alejandra Picconi, Annabelle Ferrera, Laura Mendoza, Alejandro Calderón, Raul Murillo, Carolina Wiesner, Nathalie Broutet, Silvana Luciani, Carlos Pérez,

Teresa M Darragh, José Jerónimo, Rolando Herrero, Maribel Almonte, on behalf of the ESTAMPA study group*

Background Colposcopy, currently included in WHO recommendations as an option to triage human papillomavirus Lancet Glob Health 2023; (HPV)-positive women, remains as the reference standard to guide both biopsy for confirmation of cervical precancer 11: e350-60 and cancer and treatment approaches. We aim to evaluate the performance of colposcopy to detect cervical precancer and cancer for triage in HPV-positive women.

Methods This cross-sectional, multicentric screening study was conducted at 12 centres (including primary and secondary care centres, hospitals, laboratories, and universities) in Latin America (Argentina, Bolivia, Colombia, Costa Rica, Honduras, Mexico, Paraguay, Peru, and Uruguay). Eligible women were aged 30-64 years, sexually active, Research on Cancer, Lyon did not have a history of cervical cancer or treatment for cervical precancer or a hysterectomy, and were not planning to move outside of the study area. Women were screened with HPV DNA testing and cytology. HPV-positive women were referred to colposcopy using a standardised protocol, including biopsy collection of observed lesions, endocervical sampling for transformation zone (TZ) type 3, and treatment as needed. Women with initial normal colposcopy or no ReddeCáncer (CIBERONC). high-grade cervical lesions on histology (less than cervical intraepithelial neoplasia [CIN] grade 2) were recalled after Madrid, Spain () Valls); Clinica 18 months for another HPV test to complete disease ascertainment; HPV-positive women were referred for a second colposcopy with biopsy and treatment as needed. Diagnostic accuracy of colposcopy was assessed by considering a positive test result when the colposcopic impression at the initial colposcopy was positive minor, positive major, or de Piura, Lima, Peru suspected cancer, and was considered negative otherwise. The main study outcome was histologically confirmed CIN3+ (defined as grade 3 or worse) detected at the initial visit or 18-month visit.

Findings Between Dec 12, 2012, and Dec 3, 2021, 42502 women were recruited, and 5985 (14-1%) tested positive for SMartings SBN. RMurillo HPV. 4499 participants with complete disease ascertainment and follow-up were included in the analysis, with a median age of 40 · 6 years (IQR 34 · 7-49 · 9). CIN3+ was detected in 669 (14 · 9%) of 4499 women at the initial visit or 18-month visit (3530 (78 · 5%) negative or CIN1, 300 [6 · 7%] CIN2, 616 [13 · 7%] CIN3, and 53 [1 · 2%] cancers). Sensitivity was 91 · 2% puntaments, costa Rica (95% CI 88·9–93·2) for CIN3+, whereas specificity was 50·1% (48·5–51·8) for less than CIN2 and 47·1% (45·5–48·7) (C Sosa MD, JL Santin MD); for less than CIN3. Sensitivity for CIN3+ significantly decreased in older women (93.5% [95% CI 91.3-95.3] in those aged 30-49 years vs 77.6% [68.6-85.0] in those aged 50-65 years; p<0.0001), whereas specificity for less than CIN2 significantly increased (45 · 7% [43 · 8 – 47 · 6] vs 61 · 8% [58 · 7 – 64 · 8]; p<0 · 0001). Sensitivity for CIN3+ was also significantly (M Ortega MD, A Soilán MD). lower in women with negative cytology than in those with abnormal cytology (p<0.0001).

Interpretation Colposcopy is accurate for CIN3+ detection in HPV-positive women. These results reflect ESTAMPA efforts in an 18-month follow-up strategy to maximise disease detection with an internationally validated clinical management protocol and regular training, including quality improvement practices. We showed that colposcopy can Lorenzo, Ministerio de Salud be optimised with proper standardisation to be used as triage in HPV-positive women.

Funding WHO; Pan American Health Organization; Union for International Cancer Control; National Cancer Institute (NCI); NCI Center for Global Health; National Agency for the Promotion of Research, Technological Development, and Innovation; NCI of Argentina and Colombia; Caja Costarricense de Seguro Social; National Council for Science and Technology of Paraguay; International Agency for Research on Cancer; and all local collaborative institutions.

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ESTAMPA

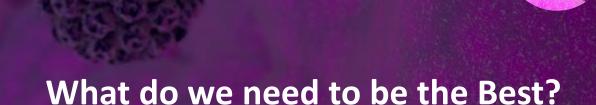
standardized colposcopy protocol

Sensitivity for HSIL/CIN2+

90,4% (95% CI: 88,4-92,2)

Specificity for less than HSIL/CIN2

50,1% (95% CI: 48,5-51,9)



Colposcopy procedure standardization

ESTAMPA Study 2023

what can we achieve?





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DOI: 10.5603/GP2020.0075



COLPOSCOPY 2020 — COLPOSCOPY PROTOCOLS A Summary of the Clinical Experts Consensus Guidelines of the Polish Society of Colposcopy and Cervical Pathophysiology and the Polish Society of Gynecologists and Obstetricians

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OOI: 10 5603/GP2020 007

COLPOSCOPY 2020 — COLPOSCOPY PROTOCOLS

BASIC PROTOCOL — minimal colposcopy approach

According to the main goal of the guidelines a minimal colposcopy scope is recommended — the basic protocol should therefore be treated as an obligatory minimum colposcopy approach, which includes:

- ECC (minimum) and/or ECB (optional) in the case of:
 - TZ3 (obligatory) and TZ2 (optional) (VI-A)
 - positive status of HRHPV 16 and/or 18 (VI-B)
 - ASC-H+ (ASC-H and higher) cytologic results (VI-A)
 - positive p16/Ki67 test result (VI-B)
 - abnormal colposcopic findings or suspicious for invasion (VI-A)
 - all major screening abnormalities of precolposcopic stage when any colposcopic abnormalities were found (VI-B)
 - considering the subsequent ablation treatment (cryo- or laser ablation) (VI-A)
 [1, 3, 13, 16, 25, 29–33, 35, 44, 75, 76].
- Targeted biopsy (in particular, from lesions assessed as abnormal colposcopic findings, suspicious for invasion, suspicious metaplasia and from other suspected areas) (VI-A)





RECOMMENDATIONS

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DOI: 10.5603/GP.2020.007

COLPOSCOPY 2020 — COLPOSCOPY PROTOCOLS
A Summary of the Clinical Experts Consensus
Guidelines of the Polish Society of Colposcopy and
Cervical Pathophysiology and the Polish Society of
Gynecologists and Obstetricians

OPTIMAL PROTOCOL — recommended colposcopy approach

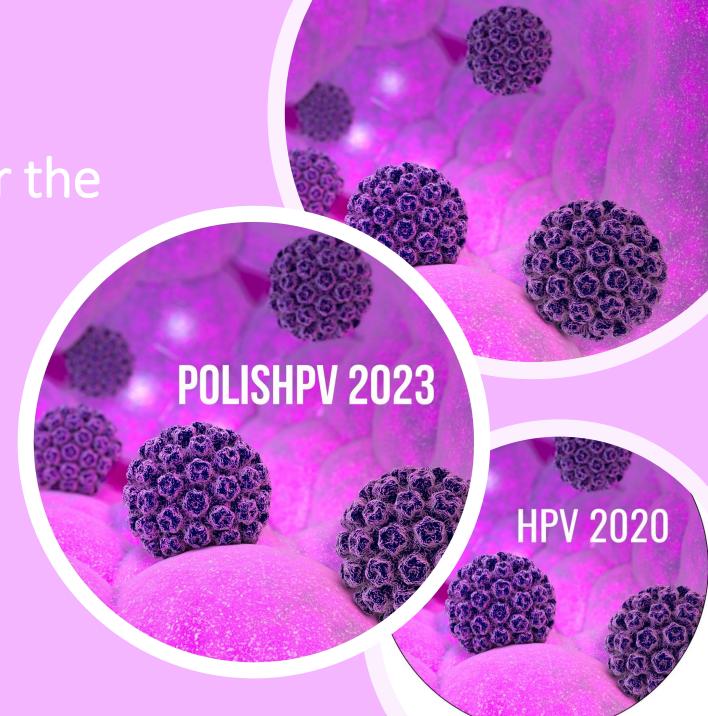
always ECC and/or ECB (VI-B)





What do we need for the future?

?



The Future



- original hybrid model
 - organized public funds-based ?
 - opportunistic private funds-based HRHPV with limited (16/18) genotyping and triage tests for HPV HR12+ with standardized colposcopy

Secondary prevention of the cervical cancer in the HPV-related strategy PSCCP Statement *POLISHPV* 2023



