6. THE QUALITY GUIDELINE FOR COLPOSCOPY

The quality requirements proposed by the professional group were drawn up by the European Federation of Colposcopy (EFC) as minimal requirements for performing and billing a colposcopic examination:

- Mandatory digitisation: To ensure quality follow-up and enable cooperation between hospitals, interpretable digital images of each colposcopic examination are stored in the electronic medical record.
- Standardised minimal report according to the EFC's minimal requirements for describing the colposcopic examination. The report should include the following information:

° patient's medical history, indicating the presence or absence of risk factors for cervical dysplasia (nicotine abuse, previous HPV vaccination, completeness of previous screening)

- ° desire to become pregnant.
- ° reason for referral for colposcopic examination.
- ° adequacy of examination (interference due to menstruation, cervicitis, etc.).
- ° type of transformation zone (1-2-3).
- ° description of existing lesions, including:
 - aceto-white staining, degree and rate of staining.
 - presence or absence of abnormal vascular patterns.
 - localisation of the lesion.
 - size of the lesion.
 - presence or absence of other high-grade signs according to IFCPC nomenclature.
- Additional training:

An assistant in training in gynaecology in Flanders and Brussels (Dutch-speaking) is required to participate in a colposcopy course organised by the VVOG (Flemish Society for Obstetrics and Gynaecology) to be recognised as a specialist. Furthermore, a minimum number of independently performed colposcopy examinations is required for graduation. The possibility of expert accreditation is being explored. This could complement the existing colposcopy course.

In Wallonia and Brussels (French-speaking), an interuniversity course is being organised for gynaecologists and gynaecologists in training leading to a 'certificat interuniversitaire de colposcopie et de pathologies cervicovaginales et vulvaires.' The intention is to integrate this course into gynaecologist training.

The digital images, the standardised minimal report and the certificate of participation in an accredited colposcopy course must be submitted to the RIZIV control services upon request.

A second reading of the colposcopy image does not contribute significantly to improving the quality of the examination and is therefore not retained as a quality criterion.



STANDARDISED MINIMAL REPORT FOR COLPOSCOPY (template)

1. Relevant Medical History

- Nicotine use (past/present):
- History of Cervical Dysplasia:
- HPV Vaccination Status (vaccin type/number of doses/year of first vaccination):
- Current Method of Contraception:
- Future Pregnancy Desire/Childwish:
- History of Cervical Screening:
- History of immunosuppression :

2. Reason for Colposcopic Referral

3. Colposcopic Findings

- 1. Adequacy of Examination:
 - o Interpretable
 - Not interpretable
 - (Reasons for not interpretable: No visualization of the Cervix, Menstruation/blood loss, Cervicitis, Atrophy, Other)

2. Type of Transformation Zone:

- Type 1: Squamo Columnar Junction (SCJ) completely visible (completely ectocervical)
- \circ $\;$ Type 2: SCJ has endocervical component, but is completely visible
- \circ $\;$ Type 3: SCJ not completely visible, with endocervical component $\;$
- 3. Description of Cervical Lesions:
 - Number of Lesions
 - o Number of Quadrants Involved
 - Surface of the cervix involved:
 - ◊ 0-25 %
 - ◊ 25-50 %
 - ◊ 50-75 %
 - ◊ 75-100
 - Description of Each Lesion:
 - ♦ Clock Position of the lesion:
 - ♦ Acetowhite Staining:
 - Thickness: Thin / dense
 - Transparancy: limpid/Opaque
 - Rapid & persistent appearance of acetowhitening: yes/no
 - surface: regular/irregular
 - Geographic border: Straight/irregular
 - Abnormal Vascular Patterns:
 - Punctuation: (Absent/Fine/Coarse)
 - Mosaicism: (Absent/Fine/Coarse)
 - Other major changes (other signs of major transformation):
 - cuffed crypt (gland) openings
 - inner border sign
 - ridge sign

- ♦ Lugol iodine:
 - Lugol zone negative
 - Lugal zone heterogeneous
- ♦ Suspicion for invasion
 - Fragile vessels,
 - irregular surface
 - exophytic lesion
 - necrosis
 - ulceration
- ♦ Biopsies taken (localization):
- ♦ Endocervical sampling taken:
- 4. Vaginal examination: normal/abnormal (description)/not indicated
- 5. Vulvar examination: normal/abnormal (description)/not indicated
- 6. Colposcopic impression:
 - ♦ Normal
 - ♦ Minor changes
 - ♦ Major changes
 - ♦ Others
- 7. Recommendations (Follow-up/management plan):

Background literature and references

- (1) BCR: <u>https://belgian-cancer-registry.shinyapps.io/data_app/</u>
- (2) Bray F, Laversanne M, Sung H, et al.; Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries; CACancerJClin; 2024 (https://doi.org/10.3322/caac.21834)
- (3) <u>https://vandenbroucke.belgium.be/nl/imc-beslist-over-nieuwe-screening-baarmoederhalskanker</u>
- (4) Arbyn M, Haelens A, Desomer A, et al.; Welke screening voor baarmoederhalskanker?. Health Technology Assessment (HTA). Brussel. Federaal Kenniscentrum voor de Gezondheidszorg (KCE); KCE Reports 238A; 2015 (DOI: 10.57598/R238AS)
- (5) WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, Second edition, 6 July 2021
- (6) 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), 21 December 2021
- (7) Cervical Cancer Screening, IARC Handbooks of Cancer Prevention Volume 18, IARC, 2022 (ISBN-13: 978-92-832-3025-0; ISBN-13: 978-92-832-3024-3)
- (8) Arbyn M; HPV trials update; Cytopathol; 2007 (https://doi.org/10.1111/j.1365-2303.2007.00499_5.x)
- (9) WHO technical guidance and specifications of medical devices for screening and treatment of precancerous lesions in the prevention of cervical cancer. Geneva: World Health Organization; 2020
- (10) Kyrgiou M, Athanasiou A, Paraskevaidis M, et al.; Adverse obstetric outcomes after local treatment for cervical preinvasive and early invasive disease according to cone depth: systematic review and meta-analysis; BMJ; 2016 (doi: 10.1136/bmj.i3633)
- (11) Athanasiou A, Veroniki AA, Efthimiou O, et al.; Comparative effectiveness and risk of preterm birth of local treatments for cervical intraepithelial neoplasia and stage IA1 cervical cancer: a systematic review and network meta-analysis; Lancet Oncol; 2022
- (12) Snijders P, Verhoef V, Arbyn M; High-risk HPV testing on self-sampled versus cliniciancollected specimens: a review on the clinical accuracy and impact on population attendance in cervical cancer screening; Int J Cancer; 2013 (doi: 10.1002/ijc.27790)
- (13) Arbyn M, Buntinx F, Van Ranst M, et al.; Virologic versus cytologic triage of women with equivocal Pap smears: a meta-analysis of the accuracy to detect high-grade intraepithelial neoplasia; J Natl Cancer Inst; 2004 (doi: 10.1093/jnci/djh037)
- (14) Ferris DG, Schiffman M, Litaker MS, for the ALTS Group; Cervicography for triage of women with mildly abnormal cervical cytology results; AJOG; 2001
- (15) Arbyn M, Roelens J, Simoens C, et al.; Human papillomavirus testing versus repeat cytology for triage of minor cytological cervical lesions; Cochrane Database Syst Rev; 2013 (doi: 10.1002/14651858.CD008054.pub2)
- (16) Arbyn M, Antilla A, Jordan J, et al.; European Guidelines for Quality Assurance in Cervical Cancer Screening. Second Edition—Summary Document; Annals of Oncology; 2010
- (17) Hulstaert F, Arbyn M, Huybrechts M, et al.; Baarmoederhalskankerscreening en testen op Human Papillomavirus (HPV). Health Technology Assessment (HTA). Brussel. Federaal Kenniscentrum voor de Gezondheidszorg (KCE). 2006. KCE Reports 38A (DOI: 10.57598/R38A)
- (18) Von Karsa L, Arbyn M, De Vuyst H, et al.; European guidelines for quality assurance in cervical cancer screening. Summary of the supplements on HPV screening and vaccination; Papillomavirus Research; 2015
- (19) Perkins RB, Guido RS, Castle PE, et al.; 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors; Journal of Lower Genital Tract Disease; 2020

- (20) Nayar & Wilbur; The Pap test and Bethesda 2014; First published: 01 May 2015 (https://doi.org/10.1002/cncy.21521)(This article is jointly published in Journal of the American Society of Cytopathology, Cancer Cytopathology, Journal of Lower Genital Tract Disease, and Acta Cytologica by the American Society of Cytopathology, the American Cancer Society, the American Society for Colposcopy and Cervical Pathology, and the International Academy of Cytology)
- (21) New WHO recommendations on screening and treatment to prevent cervical cancer among women living with HIV: policy brief ISBN 978-92-4-003096-1 (electronic version)

References for cervical cancer screening and women with HIV

- (22) Schuman P, Ohmit SE, Klein RS, et al.; HIV Epidemiology Research Study (HERS) Group. Longitudinal study of cervical squamous intraepithelial lesions in human immunodeficiency virus (HIV)-seropositive and at-risk HIV-seronegative women; J Infect Dis.; 2003
- (23) Kuhn L, Wang C, Tsai WY, et al.; Efficacy of human papillomavirus-based screen-and-treat for cervical cancer prevention among HIV-infected women; AIDS; 2010
- (24) Stier EA, Engels E, Horner MJ, et al.; Cervical cancer incidence stratified by age in women with HIV compared with the general population in the United States, 2002-2016; AIDS; 2021 (doi: 10.1097/QAD.00000000002962)
- (25) Massad LS, Xie X, Minkoff H, et al.; Longitudinal assessment of abnormal Papanicolaou test rates among women with HIV; AIDS; 2020
- (26) Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV <u>https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-</u>

opportunistic-infections/human (accessed on October 20th 2024)

- (27) Egemen D, Cheung LC, Chen X, et al.; Risk Estimates Supporting the 2019 ASCCP Risk-Based Management Consensus Guidelines; J Low Genit Tract Dis; 2020 (doi: 10.1097/LGT.00000000000529)
- (28) Arbyn M, Xu L, Verdoodt F, et al.; Genotyping for Human Papillomavirus Types 16 and 18 in Women With Minor Cervical Lesions: A Systematic Review and Meta-analysis; Annals of Internal Med; 2016
- (29) Canadian Partnership against Cancer: https://www.partnershipagainstcancer.ca/
- (30) Australian Guideline: https://www.cancer.org.au/clinical-guidelines/cervicalcancer/cervical-cancer-screening
- (31) Redman CWE, Kesic V, Cruickshank ME, et al. (European Federation for Colposcopy and Pathology of the Lower Genital Tract (EFC) and the European Society of Gynecologic Oncology (ESGO)); European consensus statement on essential colposcopy; Eur J Obstet Gynecol Reprod Biol; 2021 (doi: 10.1016/j.ejogrb.2020.06.029)
- (32) McGee AE, Alibegashvili T, Elfgren K, et al. (European Federation for Colposcopy and Pathology of the Lower Genital Tract (EFC) and the European Society of Gynaecological Oncology (ESGO)); European consensus statement on expert colposcopy; Eur J Obstet Gynecol Reprod Biol; 2023 (doi: 10.1016/j.ejogrb.2023.08.369)

ANNEX 1

INTEGRATED ADVICE – 25-29 AND 30-64 YEAR OLDS

Age range: 25-29 years						
Result cytological examination	Result reflex hrHPV test	(Integrated) advice	Result 2 nd triage (in 12 months)	Result reflex hrHPV test	(integrated) advice	
NILM	NA	Regular screening interval (in 3 calendar years)				
ASC-US		Result of reflex HPV test, with recommendation, will follow				
	> hrHPV negative	Regular screening interval (in 3 calendar years)				
	> hrHPV positive	Repeat cytology in 12 months	> NILM	NA	Regular screening interval (in 3 calendar years)	
			> ASC-US		Result of reflex HPV test, with recommendation, will follow	
				> hrHPV negative	Regular screening interval (in 3 calendar years)	
				> hrHPV positive	Immediate referral for colposcopic examination	
			> ≥ LSIL		Immediate referral for colposcopic examination	
LSIL	NA	Repeat cytology in 12 months	> NILM	NA	Regular screening interval (in 3 calendar years)	
			> ASC-US		Result of reflex HPV test, with recommendation, will follow	
				> hrHPV negative	Regular screening interval (in 3 calendar years)	
				> hrHPV positive	Immediate referral for colposcopic examination	
			> ≥ LSIL		Immediate referral for colposcopic examination	
≥ ASC-H/AGC	NA	Immediate referral for colposcopic examination		NA		
INSU	NA	New sampling after 6 weeks at the earliest		NA		

Age range: 30-64 years								
Result hrHPV test	Result reflex cytology	(Integrated) advice	Result 2 nd triage (in 12 months)	(Result reflex cytology)	Advice			
hrHPV negative	NA	Regular screening interval (in 5 calendar years)						
hrHPV non-16/18 positive		Result of reflex cytology, with recommendation, will follow						
	> ≥ ASC-US	Immediate referral for colposcopic examination						
	> NILM	Repeat hrHPV testing in 12 months	> hrHPV negative		Regular screening interval (in 5 calendar years)			
			> hrHPV positive	(cytology, not as triage)	Immediate referral for colposcopic examination			
					Result of reflex cytology will follow			
HPV 16/18 positive	(cytology, not as triage)	Immediate referral for colposcopic examination						
		Result of reflex cytology will follow						
HPVi		New sampling after 6 weeks at the earliest						

≥ASC-H/AGC = ASC-H or a more severe abnormality (HSIL, SCC, AIS, AC) or AGC

INSU: insufficient cytology, not representative sample (lack of epithelial cells/insufficient cellular material, cell lysis, abundant blood, ..)

HPVi: inconclusive HPV test result

NB: Immediate referral for colposcopic examination is understood within 3 months or faster, according to the severity of the screen-positive result (cfr. 5.3.1)

Cave: If on cytological examination **normal** endometrial cells are found in an entitled person > 45 years, additional advice is given: 'Correlation with clinic is indicated to exclude endometrial pathology in post-menopausal women'.

Cave: If on cytological examination abnormal endometrial cells are found at any age, additional advice is given: 'Exploration to exclude endometrial pathology'.

In **bold**: the actual integrated advice, after samples were send for reflex testing.



ANNEX 2

ADVICE: ≥65y, in case of no reimbursed screening in the last 10 years

Age range: ≥ 65 year, in case of no screening in the last 10 years						
Result hrHPV test and cytology within cotesting	Advice Result repeat HPV testing (in 12 months)		Advice			
HPV 16/18 positive, independant of cytology result	Immediate referral for colposcopic examination					
hrHPV non-16/18 positive	Result of co-test cytology with recommendation will follow					
> cytology ≥ ASC-US	Immediate referral for colposcopic examination					
> cytology NILM	Repeat hrHPV testing in 12 months	-> hrHPV negative	No further follow-up			
		-> hrHPV positive	Immediate referral for colposcopic examination			
			Result of reflex cytology will follow			
hrHPV negative	Result of co-test cytology with recommendation will follow					
-> cytology ≥LSIL	Immediate referral for colposcopic examination					
-> cytology ASC-US	Repeat hrHPV testing in 12 months	-> hrHPV negative	No further folow-up			
		-> hrHPV positive	Immediate referral for colposcopic examination			
			Result of reflex cytology will follow			
-> cytology NILM	No further follow-up					
HPVi	New sampling after 6 weeks at the earliest					

HPVi: inconclusive HPV test result

