Recommendation 4

The expert panel recommends a strategy of screen with VIA and treat with cryotherapy (or LEEP when not eligible for cryotherapy) over a strategy of screen with cytology followed by colposcopy (with or without biopsy) and treat with cryotherapy (or LEEP when not eligible) (strong recommendation, ⊕⊖⊖⊖ evidence)

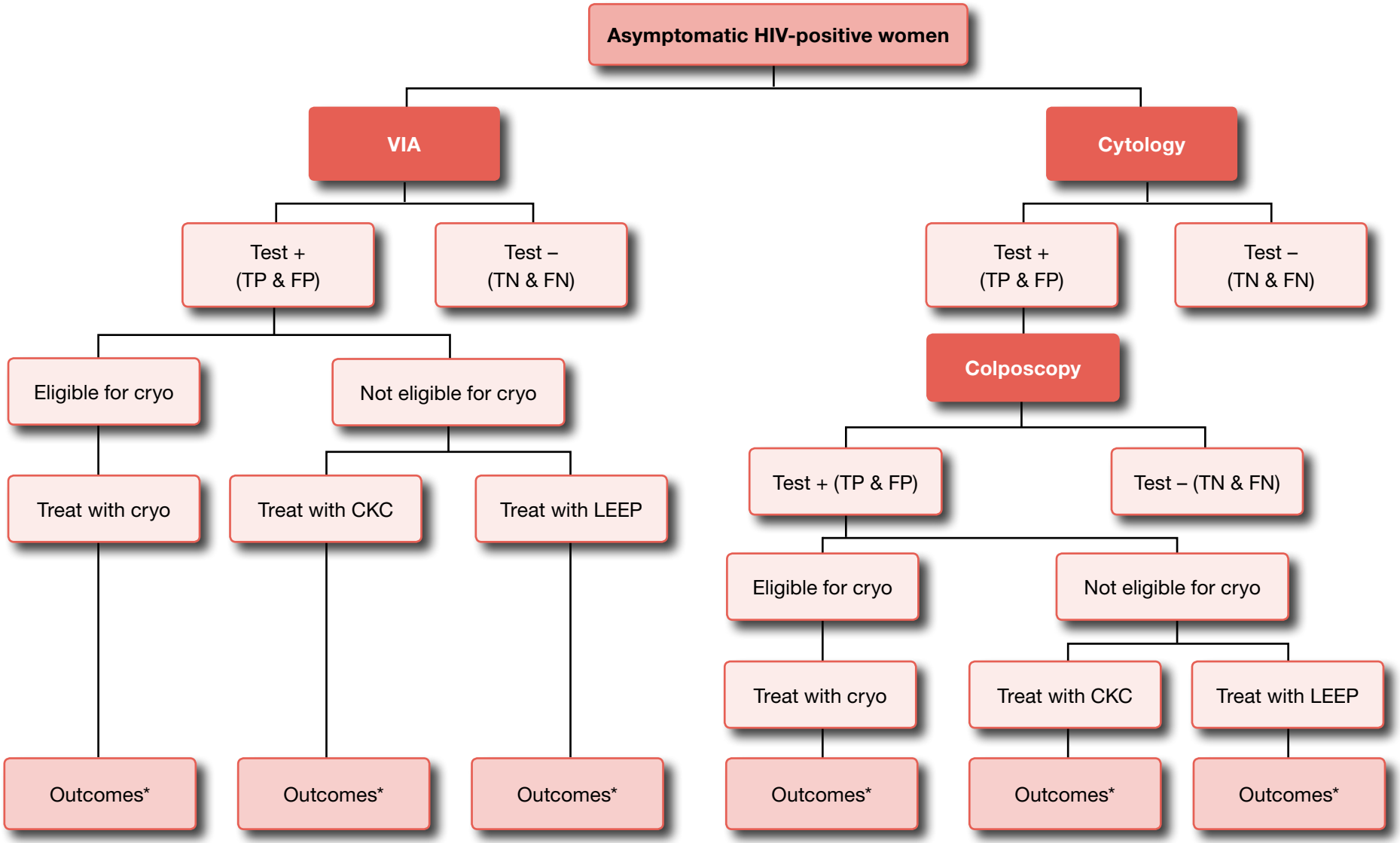
Remarks: The benefits and harms of the two screen-and-treat strategies are similar, but there are fewer harms with cytology followed by colposcopy with biopsy when indicated. Despite overtreatment with VIA and fewer cancers detected at first-time screening, more resources are required for cytology programmes with colposcopy (with or without biopsy) due to quality control, training, and waiting time, as well as a second visit. The recommendation for VIA over cytology followed by colposcopy can be applied in countries that are currently considering either strategy or countries that currently have both strategies available. This recommendation applies to women regardless of HIV status.

Evidence-to-recommendation table

Decision domain	Judgement	Summary of reason for judgement
Quality of evidence *Is there high- or moderate-quality evidence?*	Yes ☐ / No ☒	There is low-quality evidence for the diagnostic test accuracy of cytology followed by colposcopy compared to VIA alone. There is low- to very-low-quality evidence for the effects of treatment and the natural progression of CIN from observational studies often with inconsistent results across studies. Also the link between test accuracy data and treatment effects is very uncertain.
Balance of benefits versus harms and burdens *Are you confident that the benefits outweigh the harms and burdens for the recommended strategy?*	Yes ☐ / No ☒	The benefits of cytology followed by colposcopy and VIA alone may be similar. However, there may be slightly greater harms with VIA alone (due to overtreatment with HPV test alone) and slightly fewer cancers detected with VIA.
Values and preferences *Are you confident about the assumed or identified relative values and are they similar across the target population?*	Yes ☒ / No ☐	High value was placed on a screen-and-treat strategy versus no screening, since qualitative studies have shown that once women decide to be screened they find the screening tests and immediate treatment acceptable. High value was placed on the resources required and lower value on the harms.
Resource implications *Is the cost small relative to the net benefits for the recommended strategy?*	Yes ☒ / No ☐	Fewer resources are required for VIA. There may be additional resources required in cytology programmes due to increased training of providers, quality control, and waiting time. Colposcopy following cytology also requires a second visit.

Evidence for VIA compared to cytology followed by colposcopy to screen for CIN2+ in women of HIV-positive status

1. Flowchart of screen-and-treat strategies



* Outcomes are: mortality from cervical cancer, rate of cervical cancer detection, rate of CIN2+ detection, major bleeding, premature delivery, infertility, STI detection, major infections, and minor infections.

2. Evidence used for decision-making: VIA compared to cytology (ASCUS) followed by colposcopic impression

Diagnostic test accuracy (data based on women with unknown HIV status)

Pooled sensitivity VIA	77% (95% CI: 65 to 85)	Pooled sensitivity cytology (ASCUS)	84% (95% CI: 76 to 90)	Pooled sensitivity colposcopic impression	95% (95% CI: 86 to 98)
Pooled specificity VIA	82% (95% CI: 67 to 91)	Pooled specificity cytology (ASCUS)	88% (95% CI: 79 to 93)	Pooled specificity colposcopic impression	42% (95% CI: 26 to 61)

(Reference standard: colposcopy with biopsy when indicated)

2.1 Diagnostic Test Accuracy (DTA) evidence profile: VIA compared to cytology (ASCUS) followed by colposcopic impression

Outcome	No. of studies (No. of patients) [a]	Study design	Factors that may decrease quality of evidence					DTA QoE	Effect per 1000 patients/year for pretest probability of 10%		Importance
			Limitations	Indirectness	Inconsistency	Imprecision	Publication bias		VIA	Cytology followed by colposcopic impression	
True positives (patients with CIN2+)	11 studies (12 089 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊖⊖ low	77 (65 to 85)	80	CRITICAL
TP absolute difference									3 fewer		
True negatives (patients without CIN2+)	11 studies (12 089 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊖⊖ low	738 (603 to 819)	837	CRITICAL
TN absolute difference									99 fewer		
False positives (patients incorrectly classified as having CIN2+)	11 studies (12 089 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊖⊖ low	162 (81 to 297)	63	CRITICAL
FP absolute difference									99 more		
False negatives (patients incorrectly classified as not having CIN2+)	11 studies (12 089 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊖⊖ low	23 (15 to 35)	20	CRITICAL
FN absolute difference									3 more		

Footnotes:

[a] This is the number of studies that assessed data for HPV test and cytology.

[b] We used QUADAS to assess risk of bias. Half of studies only performed one biopsy of an abnormal lesion and had unclear blinding of tests. Colposcopy studies had unclear blinding of index test results. This was downgraded one level in the context of other factors, in particular indirectness.

[c] Data for cytology followed by colposcopy were calculated based on sensitivity and specificity of the two tests. Direct data were not available. Diagnostic test accuracy data were based on women of unknown HIV status; the data were not considered indirect and so the quality of evidence was not downgraded.

[d] Estimates of VIA, cytology (ASCUS) and colposcopy sensitivity and specificity were variable despite similar cut-off values; inconsistency was not explained by quality of studies. This was downgraded one level in the context of other factors, in particular imprecision.

[e] Wide CI for sensitivity and specificity of cytology followed by colposcopy and therefore wide CI for TP, TN, FP, FN, may lead to different decisions depending on which confidence limits are assumed.

2.2 GRADE evidence table for patient-important outcomes following different screen-and-treat strategies: VIA compared to cytology (ASCUS) followed by colposcopic impression

Outcomes	Events in the screen-and-treat strategies for patient-important outcomes (numbers presented per 1 000 000 patients)						
	VIA +/– CKC	VIA +/– LEEP	VIA +/– cryo	Cyto→colp imp +/– CKC	Cyto→colp imp +/–LEEP	Cyto→colp imp +/– cryo	No screen[10]
Mortality from cervical cancer[1]	1080	1195	1195	961	1080	1080	4350
Cervical cancer incidence[2]	1512	1673	1673	1346	1513	1513	6075
CIN2+ recurrence[3]	19 999	22 386	22 386	17832	20 306	20 306	79 575
Undetected CIN2+ (FN)	23 000			20 000			–
Major bleeding[4]	2052	539	81	1223	321	48	0
Premature delivery[5]	788	602	649	672	561	589	500
Infertility[6]	–	–	–	–	–	–	–
Major infections[7]	212	306	32	126	182	19	0
Minor infections[8]	2239	1440	1547	1334	858	922	0
Unnecessarily treated (FP)	162 000			63 000			–
Cancer found at first-time screening[9]	3168			4794			0

Footnotes:

The colours in the table: In each GRADE evidence table, colour-coding is used to highlight the 'desirability' of the effects for that outcome relative to other outcomes. The continuum runs from dark gray (desirable) through light gray and light pink to dark pink (least desirable).

The numbers in the table are based on

- CIN2+ pretest probability 10% in women of HIV-positive status (Denny et al., 2008; De Vuyst et al., 2012; Joshi et al., 2012; Zhang et al., 2012)
- VIA: pooled sensitivity 77% (95% CI: 66 to 85), pooled specificity 82% (95% CI: 67 to 91)
- Cytology (ASCUS): Pooled sensitivity 84% (95% CI: 76 to 90), pooled specificity 88% (95% CI: 79 to 93)
- Colposcopic impression: Pooled sensitivity 95% (95% CI: 86 to 98), pooled specificity 42% (95% CI: 26 to 61)
- The overall QoE for each of these outcomes is very low ⊕⊖⊖⊖. Our lack of confidence in these effect estimates stems mainly from very-low-quality evidence for treatment effects and natural progression/history data.

[1] We assume no mortality from cervical cancer in TN and FP. To calculate the mortality from cervical cancer in women of HIV-positive status, we assumed the same risk of mortality in women of unknown HIV status: 250 deaths per 350 women with cervical cancer. These numbers are based on Eastern Africa age-standardized rates of cervical cancer and mortality provided by WHO (http://globocan.iarc.fr/, accessed 30 October 2012).

[2] We assume no cervical cancer in TN or FP. The calculations for cervical cancer incidence in women of HIV-positive status with persistent CIN2+ are based on a 2.7 standardized Risk Ratio of cancer when compared to women with unknown HIV status (De Vuyst et al., 2008). For women of unknown status, we assumed 350 cervical cancers per 14 000 women who have persistent CIN2+ (i.e. FN). This incidence is based on Eastern Africa age-standardized rate of cervical cancer of 350 cervical cancers per 1 000 000 women, of whom 2% have CIN2+ (20 000 women with CIN2+, and a subsequent 30% regression for a total of 14 000 with persistent CIN2+). These data are available from WHO (http://globocan.iarc.fr/, accessed 30 October 2012).

[3] We assume no CIN2+ in TN and FP. Our calculations in the model are based on 90% natural persistence of CIN2+ with no treatment (10% regression) in FN. TP are treated and recurrence rates of CIN2+ are 5.3% in cryotherapy and LEEP, and 2.2% in CKC.

[4] We assumed major bleed would be 0 in TN and FN as they were not treated. We assumed 0.000339 of the population treated with cryotherapy, 0.002257 with LEEP, and 0.001705 with CKC, based on pooled proportions in observational studies with no independent controls, will have major bleeding.

[5] We assumed 5% population risk of premature delivery in 1% of women who become pregnant. Based on pooled meta-analysis of controlled observational studies, 0.001125 of the population treated with cryotherapy, 0.000925 with LEEP, and 0.001705 of the population treated with CKC will have premature delivery.

[6] We did not identify any data about the risk of infertility after treatment for CIN2+.

[7] We assumed major infection would be 0 in TN and FN as they were not treated. Based on pooled proportions from studies with no independent control, 0.000135 of the population treated with cryotherapy, 0.001279 with LEEP, and 0.000888 with CKC will have major infection.

[8] We assumed minor infection would be 0 in TN and FN as they were not treated. Based on pooled proportions from studies with no independent control, 0.006473 of the population treated with cryotherapy, 0.006027 with LEEP, and 0.009368 with CKC will have minor infection.

[9] Cancers detected at first-time screening calculated from Sankaranarayanan et al. (2005). Numbers for single screening tests were calculated as 'screen-detected' cancers in women who participated in the screening programme; and numbers for test with colposcopy were calculated as 'screen-detected' plus 'clinically detected' cancers. For a sequence of tests (e.g. HPV test followed by VIA), the greater number of cancers detected between tests was used. No cancers would be found in the 'no screen' group. This is not the annual incidence of cervical cancer (which is shown in a row above). It represents the cumulative rate of cancer development before screening started (i.e. the prevalence of cancer at the time when screening is first conducted).

[10] 'No screen' numbers were calculated using the same assumptions above for FN, with the exception of premature delivery which was baseline risk in the population.

3. Evidence used for decision-making: VIA compared to cytology (ASCUS) followed by colposcopic impression and biopsy when indicated

Diagnostic test accuracy (data based on women of unknown HIV status)

Pooled sensitivity VIA	77% (95% CI: 66 to 85)	Pooled sensitivity cytology (ASCUS)	84% (95% CI: 76 to 90)
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(Reference standard: colposcopy with biopsy when indicated)

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Outcome	No. of studies (No. of patients) [a]	Study design	Factors that may decrease quality of evidence					DTA QoE	Effect per 1000 patients/year for pretest probability of 10%		Importance
			Limitations	Indirectness	Inconsistency	Imprecision	Publication bias		VIA	Cytology followed by colposcopy with biopsy	
True positives (patients with CIN2+)	11 studies (12 089 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊖⊖ low	77 (65 to 85)	84	CRITICAL
TP absolute difference									7 fewer		
True negatives (patients without CIN2+)	11 studies (12 089 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊖⊖ low	738 (603 to 819)	900	CRITICAL
TN absolute difference									162 fewer		
False positives (patients incorrectly classified as having CIN2+)	11 studies (12 089 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊖⊖ low	162 (81 to 297)	0	CRITICAL
FP absolute difference									162 more		
False negatives (patients incorrectly classified as not having CIN2+)	11 studies (12 089 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊖⊖ low	23 (15 to 35)	16	CRITICAL
FN absolute difference									7 more		

Footnotes:

[a] This is the number of studies that assessed data for HPV test and cytology.

[b] We used QUADAS to assess risk of bias. Half of studies only performed one biopsy of an abnormal lesion and had unclear blinding of tests. This was downgraded one level in the context of other factors, in particular indirectness.

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Undetected CIN2+ (FN)	23 000			16 000			–
Major bleeding[4]	2052	539	81	721	190	28	0
Premature delivery[5]	788	602	649	601	536	553	500
Infertility[6]	–	–	–	–	–	–	–
Major infections[7]	212	306	32	75	107	11	0
Minor infections[8]	2239	1440	1547	787	506	544	0
Unnecessarily treated (FP)	162 000			0			–
Cancer found at first-time screening[9]	3168			4794			0

Footnotes:

The colours in the table: In each GRADE evidence table, colour-coding is used to highlight the 'desirability' of the effects for that outcome relative to other outcomes. The continuum runs from dark gray (desirable) through light gray and light pink to dark pink (least desirable).

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[10] 'No screen' numbers were calculated using the same assumptions above for FN, with the exception of premature delivery which was baseline risk in the population.

4. References

4.1 References to studies included in meta-analysis of diagnostic test accuracy

Belinson J et al. Shanxi Province Cervical Cancer Screening Study: a cross-sectional comparative trial of multiple techniques to detect cervical neoplasia. *Gynecologic Oncology*, 2001, 83(2):439–444.

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4.3 Additional references

Denny L et al. Human papillomavirus infection and cervical disease in human immunodeficiency virus-1-infected women. *Obstetrics & Gynecology*, 2008, 111(6):1380–1387.

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