Recommendation 3

The expert panel suggests a strategy of screen with an HPV test 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) (conditional recommendation, ⊕⊝⊝⊝ evidence)

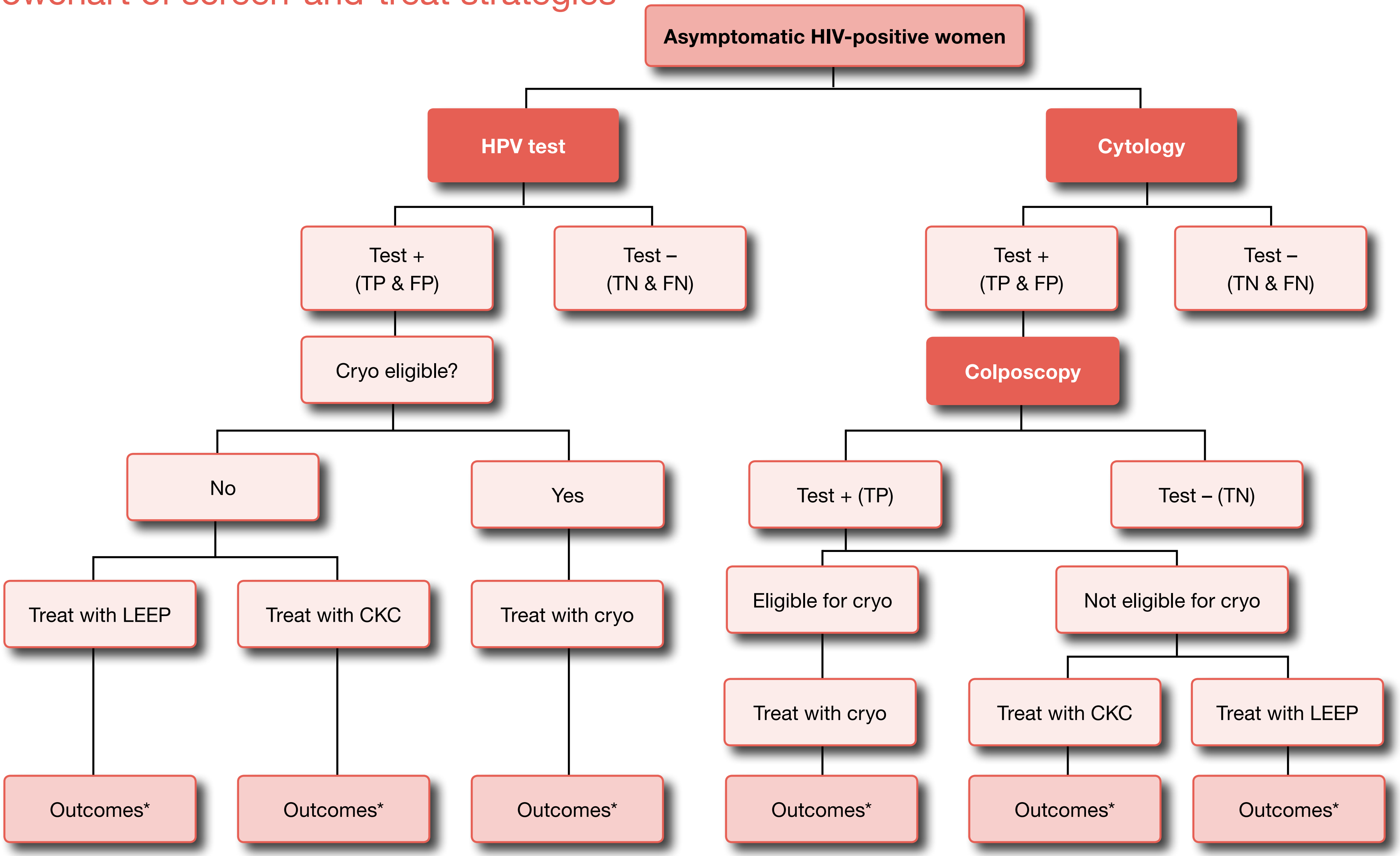
Remarks: The reductions in cancer and related mortality were slightly greater with an HPV test only compared to cytology followed by colposcopy. Although there may be overtreatment of populations with high HPV prevalence and consequently more harms, as well as fewer cancers seen at first-time screening with an HPV test, there are greater resources required in cytology programmes due to quality control, training, and waiting time. The addition of colposcopy also requires a second visit. However, in countries where an appropriate/high-quality screening strategy with cytology (referring women with ASCUS or greater results) followed by colposcopy already exists, either an HPV test or cytology followed by colposcopy could be used.

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 data for cytology followed by colposcopy compared to HPV test 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. 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 HPV test alone were greater than with cytology followed by colposcopy. However, there may be greater harms with HPV test alone (due to overtreatment with HPV test alone) and fewer cancers detected with HPV test.
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 ☐	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. However, in countries where an appropriate/high-quality screening strategy with cytology exists, resources would be required to change over to HPV test.

Evidence for an HPV test 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: HPV test compared to cytology (ASCUS) and colposcopic impression

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

Pooled sensitivity HPV test	94% (95% CI: 89 to 97)	Pooled sensitivity cytology (ASCUS)	70% (95% CI: 57 to 81)	Pooled sensitivity colposcopic impresssion	95% (95% CI: 86 to 98)
Pooled specificity HPV test	90% (95% CI: 86 to 93)	Pooled specificity cytology (ASCUS)	95% (95% CI: 92 to 97)	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: HPV test compared to cytology (ASCUS) and 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		HPV test	Cytology followed by colposcopic impression	
True positives (patients with CIN2+)	11 studies (39 050 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊝⊝ low	94 (89 to 97)	67	CRITICAL
TP absolute difference									27 more		
True negatives (patients without CIN2+)	11 studies (39 050 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊝⊝ low	810 (774 to 837)	874	CRITICAL
TP absolute difference									64 fewer		
False positives (patients incorrectly classified as having CIN2+)	11 studies (39 050 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊝⊝ low	90 (63 to 126)	26	CRITICAL
FP absolute difference									64 more		
False negatives (patients incorrectly classified as not having CIN2+)	11 studies (39 050 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊝⊝ low	6 (3 to 11)	34	CRITICAL
FP absolute difference									28 fewer		

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 HPV test, 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: HPV test compared to cytology (ASCUS) and colposcopic impression

Outcomes	Events in the screen-and-treat strategies for patient-important outcomes (numbers presented per 1 000 000 patients)						
	HPV +/– CKC	HPV +/– LEEP	HPV +/– cryo	Cyto→colp imp +/– CKC	Cyto→colp imp +/– LEEP	Cyto→colp imp +/– cryo	No screen[10]
Mortality from cervical cancer[1]	360	501	501	1524	1624	1624	4350
Cervical cancer incidence[2]	504	701	701	2134	2273	2273	6075
CIN2+ recurrence[3]	6843	9757	9757	28 124	30 186	30 186	79 575
Undetected CIN2+ (FN)	6000			34 000			–
Major bleeding[4]	1580	415	62	795	209	31	0
Premature delivery[5]	722	578	615	612	539	558	500
Infertility[6]	–	–	–	–	–	–	–
Major infections[7]	163	235	25	82	118	13	0
Minor infections[8]	1724	1109	1191	867	558	599	0
Unnecessarily treated (FP)	90 000			26 000			–
Cancer found at first-time screening[9]	2454			4794			–

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% of women of HIV-positive status (Denny et al., 2008; De Vuyst et al., 2012; Joshi et al., 2012; Zhang et al., 2012)
- HPV test: pooled sensitivity 94% (95% CI: 89 to 97), pooled specificity 90% (95% CI: 86 to 93)
- Cytology (ASCUS): pooled sensitivity 70% (95% CI: 57 to 81), pooled specificity 95% (95% CI: 92 to 97)
- 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: HPV test compared to cytology (ASCUS) and colposcopic impression with biopsy when indicated

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

Pooled sensitivity HPV test	94% (95% CI: 89 to 97)	Pooled sensitivity cytology (ASCUS)	70% (95% CI: 57 to 81)
Pooled specificity HPV test	90% (95% CI: 86 to 93)	Pooled specificity cytology (ASCUS)	95% (95% CI: 92 to 97)

(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		HPV test	Cytology followed by colposcopy with biopsy	
True positives (patients with CIN2+)	11 studies (39 050 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊝⊝ low	94 (89 to 97)	70	CRITICAL
TP absolute difference									24 more		
True negatives (patients without CIN2+)	11 studies (39 050 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊝⊝ low	810 (774 to 837)	900	CRITICAL
TP absolute difference									90 fewer		
False positives (patients incorrectly classified as having CIN2+)	11 studies (39 050 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊝⊝ low	90 (63 to 126)	0	CRITICAL
FP absolute difference									90 more		
False negatives (patients incorrectly classified as not having CIN2+)	11 studies (39 050 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊝⊝ low	6 (3 to 11)	30	CRITICAL
FP absolute difference									24 fewer		

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.

[c] Data for cytology followed by colposcopy +/– biopsy 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.

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Undetected CIN2+ (FN)	6000			30 000			–
Major bleeding[4]	1580	415	62	601	158	24	0
Premature delivery[5]	722	578	615	584	530	544	500
Infertility[6]	–	–	–	–	–	–	–
Major infections[7]	163	235	25	62	90	9	0
Minor infections[8]	1724	1109	1191	656	422	453	0
Unnecessarily treated (FP)	90 000			0			–
Cancer found at first-time screening[9]	2454			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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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.

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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.

4. References

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

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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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4.2 References to studies included for diagnostic test accuracy of colposcopic impression

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4.3 References to studies included for diagnostic test accuracy of colposcopic impression

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