Recommendation 5

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 an HPV test followed by colposcopy (with or without biopsy) and treat with cryotherapy (or LEEP when not eligible) (conditional recommendation, ⊕⊖⊖⊖ evidence)

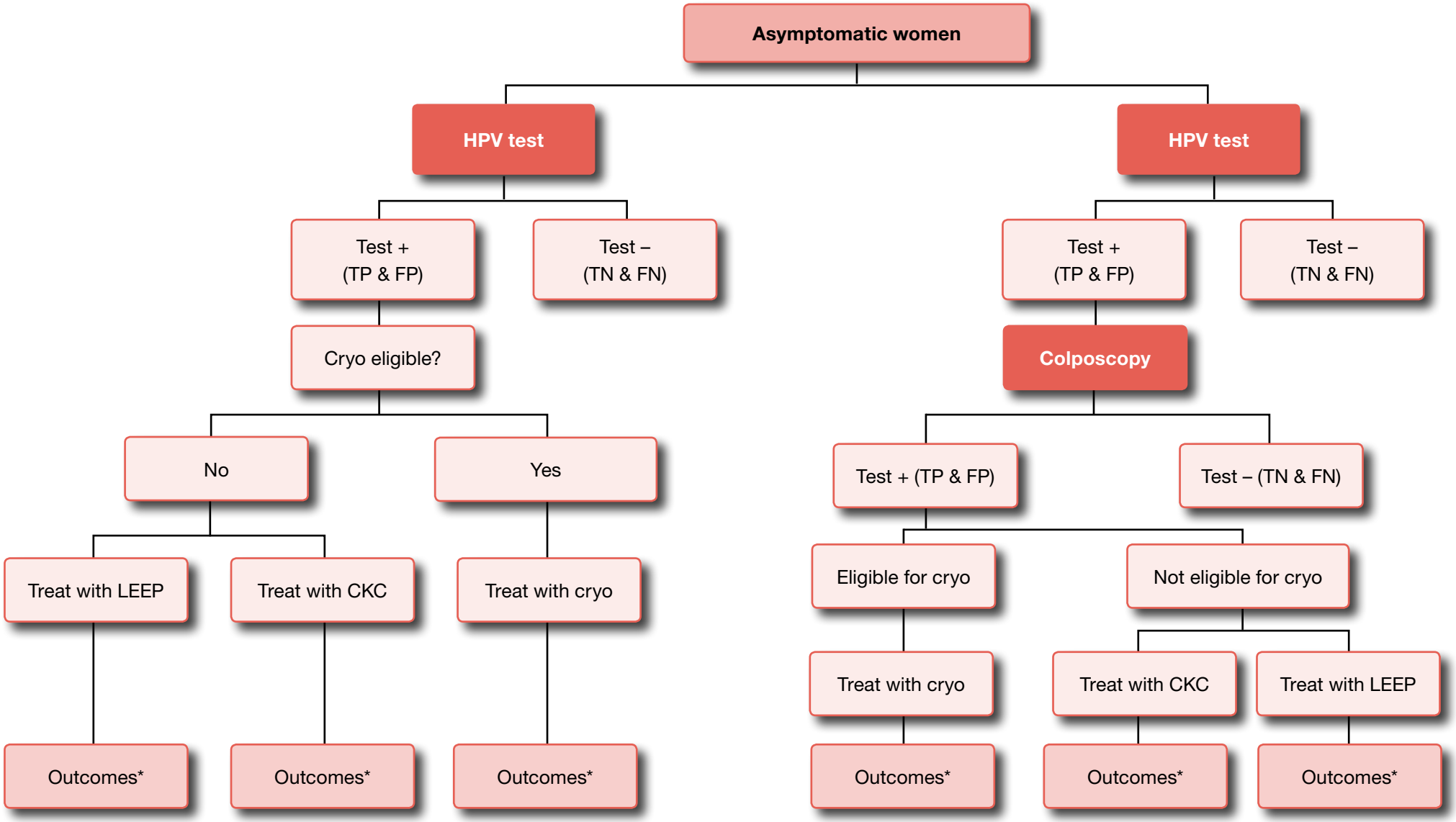
Remarks: The reductions in cancer and related mortality with either strategy outweigh the harms and costs of no screening, and were similar between the two strategies. Although overtreatment and, consequently, harms are reduced with the addition of colposcopy (with or without biopsy), there are more resource implications with colposcopy due to increased training of providers, quality control, waiting time, and the potential for more women to be lost to follow-up. The addition of colposcopy to an HPV test would also require a second visit. In countries without an existing screening strategy, an HPV test followed by colposcopy is not recommended. 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 HPV test followed by colposcopy and we did not have a direct comparison of this triage test 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 followed by colposcopy and HPV test alone may be similar. However, there were greater harms with HPV test alone (due to overtreatment with HPV test alone). There may also be slightly fewer cancers detected with HPV test followed by colposcopy.
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 with the addition of colposcopy (with or without biopsy), there are more resource implications with colposcopy due to increased training of providers, quality control, waiting time, and potential for more women lost to follow up. The addition of colposcopy to HPV test would also require a second visit.

Evidence for HPV test compared to HPV test followed by colposcopy to screen for CIN2+

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 HPV test followed by colposcopic impression

Diagnostic test accuracy

Pooled sensitivity HPV test	93% (95% CI: 87 to 96)	Pooled sensitivity colposcopic impression	95% (95% CI: 86 to 98)
Pooled specificity HPV test	88% (95% CI: 82 to 91)	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 HPV test 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 2%		Importance
			Limitations	Indirectness	Inconsistency	Imprecision	Publication bias		HPV test	HPV test followed by colposcopic impression	
True positives (patients with CIN2+)	15 studies (45 783 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊖⊖ low	19 (17 to 19)	18	CRITICAL
TP absolute difference									1 more		
True negatives (patients without CIN2+)	15 studies (45 783 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊖⊖ low	862 (813 to 892)	911	CRITICAL
TN absolute difference									49 fewer		
False positives (patients incorrectly classified as having CIN2+)	15 studies (45 783 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊖⊖ low	118 (88 to 167)	68	CRITICAL
FP absolute difference									50 more		
False negatives (patients incorrectly classified as not having CIN2+)	15 studies (45 783 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊖⊖ low	1 (1 to 3)	2	CRITICAL
FN absolute difference									1 fewer		

Footnotes:

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

[b] We used QUADAS to assess risk of bias. Many studies only performed one biopsy of an abnormal lesion. 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 HPV test followed by colposcopy were calculated based on sensitivity and specificity of the two tests. Direct data were not available.

[d] Estimates of HPV test and VIA sensitivity and specificity were variable despite similar cut-off values; inconsistency could not be explained by quality of studies. This was downgraded. This judgement was considered in the context of other factors, in particular imprecision.

[e] Few participants contributed to colposcopy data. Therefore there are wide confidence intervals for colposcopy specificity, which 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 HPV test followed by 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	HPV→colp imp +/– CKC	HPV→colp imp +/–LEEP	HPV→colp imp +/– cryo	No screen[10]
Mortality from cervical cancer[1]	20	30	30	31	41	41	250
Cervical cancer incidence[2]	28	43	43	44	58	58	350
CIN2+ recurrence[3]	1088	1677	1677	1704	2263	2263	13 400
Undetected CIN2+ (FN)	1000			2000			–
Major bleeding[4]	1176	309	46	743	195	29	0
Premature delivery[5]	665	558	586	604	537	554	500
Infertility[6]	–	–	–	–	–	–	–
Major infections[7]	122	175	18	77	111	12	0
Minor infections[8]	1283	826	887	810	521	560	0
Unnecessarily treated (FP)	118 000			68 000			–
Cancer found at first-time screening[9]	2454			3545			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 2%
- HPV test: pooled sensitivity 93% (95% CI: 87 to 96), pooled specificity 88% (95% CI: 82 to 91)
- Colposcopic impression: pooled sensitivity 95% (95% CI: 82 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, we assumed 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. To calculate cervical cancer incidence in women with persistent CIN2+, 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 70% natural persistence of CIN2+ with no treatment (30% regression) in FN. The incidence of cervical cancer and mortality are also subtracted from the CIN2+ in FN (see above for calculations). 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 tests 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 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.

2.3 GRADE evidence table for patient-important outcomes following different screen-and-treat strategies by age

	HPV +/– CKC	HPV +/– LEEP	HPV +/– cryo	HPV→colp imp +/– CKC	HPV→colp imp +/–LEEP	HPV→colp imp +/– cryo	No screen[10]
15–39 years[a]							
Mortality from cervical cancer	6	9	9	9	12	12	71
Cervical cancer incidence	8	13	12	12	17	17	100
CIN2+ recurrence	1109	1745	1698	1698	2305	2305	13 829
40–49 years[a]							
Mortality from cervical cancer	37	58	57	57	77	77	464
Cervical cancer incidence	52	82	79	79	108	108	650
CIN2+ recurrence	1062	1653	1651	1651	2213	2213	12 886
50–74 years[a]							
Mortality from cervical cancer	68	108	105	105	142	142	857
Cervical cancer incidence	96	199	151	146	146	199	1200
CIN2+ recurrence	1015	1604	1604	1562	2121	2121	11 943
Complications (same across all groups)							
Major bleeding[4]	1176	309	46	743	195	29	0
Premature delivery[5]	665	558	586	604	537	554	500
Infertility[6]	–	–	–	–	–	–	–
Major infections[7]	122	175	18	77	111	12	0
Minor infections[8]	1283	826	887	810	521	560	0

Footnotes:

[a] Events were calculated similar to Table 2.2. However, events for cervical cancer are based on incidence of cervical cancer in Eastern Africa of 100/1 000 000 cervical cancers per year in women age 15–39 years; 650 for age 40–49 years; and 1200 for age 50–74 years, provided by WHO (http://globocan.iarc.fr/, accessed 30 October 2012). It is assumed that the recurrence of CIN is constant across age groups but the incidence of cervical cancer and associated mortality increases, thus reducing the overall recurrence of CIN (a proportion of those with CIN will develop cancer or die). These data should be used primarily to make comparisons across screen-and-treat strategies, not within columns for different age groups.

[4,5,6,7,8,10] See footnotes for Table 2.2.

3. Evidence used for decision-making: HPV test compared to HPV test followed by colposcopic impression

Diagnostic test accuracy

Pooled sensitivity HPV test	93% (95% CI: 87 to 96)	Pooled specificity HPV test	88% (95% CI: 82 to 91)

(Reference standard: colposcopy with biopsy when indicated)

3.1 Diagnostic test accuracy (DTA) evidence profile: HPV test compared to HPV test 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 2%		Importance
			Limitations	Indirectness	Inconsistency	Imprecision	Publication bias		HPV test	HPV test followed by colposcopy with biopsy	
True positives (patients with CIN2+)	15 studies (45 783 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊖⊖ low	19 (17 to 19)	19	CRITICAL
TP absolute difference									0 more		
True negatives (patients without CIN2+)	15 studies (45 783 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊖⊖ low	862 (804 to 892)	980	CRITICAL
TN absolute difference									118 fewer		
False positives (patients incorrectly classified as having CIN2+)	15 studies (45 783 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊖⊖ low	118 (88 to 176)	0	CRITICAL
FP absolute difference									118 more		
False negatives (patients incorrectly classified as not having CIN2+)	15 studies (45 783 patients)	Cross-sectional and cohort studies	Serious[b]	None[c]	Serious[d]	None[e]	Undetected	⊕⊕⊖⊖ low	1 (1 to 3)	1	CRITICAL
FN absolute difference									0		

Footnotes:

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

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

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Mortality from cervical cancer[1]	20	30	30	20	30	30	250
Cervical cancer incidence[2]	28	43	43	28	43	43	350
CIN2+ recurrence[3]	1088	1677	1677	1088	1677	1677	13 400
Undetected CIN2+ (FN)	1000			1000			–
Major bleeding[4]	1176	309	46	163	43	6	0
Premature delivery[5]	665	558	586	523	508	512	500
Infertility[6]	–	–	–	–	–	–	–
Major infections[7]	122	175	18	17	24	3	0
Minor infections[8]	1283	826	887	178	115	123	0
Unnecessarily treated (FP)	118 000			0			–
Cancer found at first-time screening[9]	2454			3545			0

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[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 tests 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 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.

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	HPV +/– CKC	HPV +/– LEEP	HPV +/– Cryo	HPV→colp biopsy +/– CKC	HPV→colp biopsy +/–LEEP	HPV→colp biopsy +/– cryo	No screen[10]
15–39 years[a]							
Mortality from cervical cancer	6	9	9	6	9	9	71
Cervical cancer incidence	8	12	12	8	12	12	100
CIN2+ recurrence	1109	1698	1698	1109	1698	1698	13 829
40–49 years[a]							
Mortality from cervical cancer	37	57	57	37	57	57	464
Cervical cancer incidence	52	79	79	52	79	79	650
CIN2+ recurrence	1062	1651	1651	1062	1651	1651	12 886
50–74 years[a]							
Mortality from cervical cancer	68	105	105	68	105	105	857
Cervical cancer incidence	96	146	146	96	146	146	1200
CIN2+ recurrence	1015	1604	1604	1015	1604	1604	11 943
Complications (same across all groups)							
Major bleeding[4]	1176	309	46	163	43	6	0
Premature delivery[5]	665	558	586	523	508	512	500
Infertility[6]	–	–	–	–	–	–	–
Major infections[7]	122	175	18	17	24	3	0
Minor infections[8]	1283	826	887	178	115	123	0

Footnotes:

[a] Events were calculated similar to Table 3.2. However, events for cervical cancer are based on incidence of cervical cancer in Eastern Africa of 100/1 000 000 cervical cancers per year in women age 15–39 years; 650 for age 40–49 years; and 1200 for age 50–74 years, provided by WHO (http://globocan.iarc.fr/, accessed 30 October 2012). It is assumed that the recurrence of CIN is constant across age groups but the incidence of cervical cancer and associated mortality increases, thus reducing the overall recurrence of CIN (a proportion of those with CIN will develop cancer or die). These data should be used primarily to make comparisons across screen-and-treat strategies, not within columns for different age groups.

[4,5,6,7,8,10] See footnotes for Table 3.2.

4. References

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

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

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