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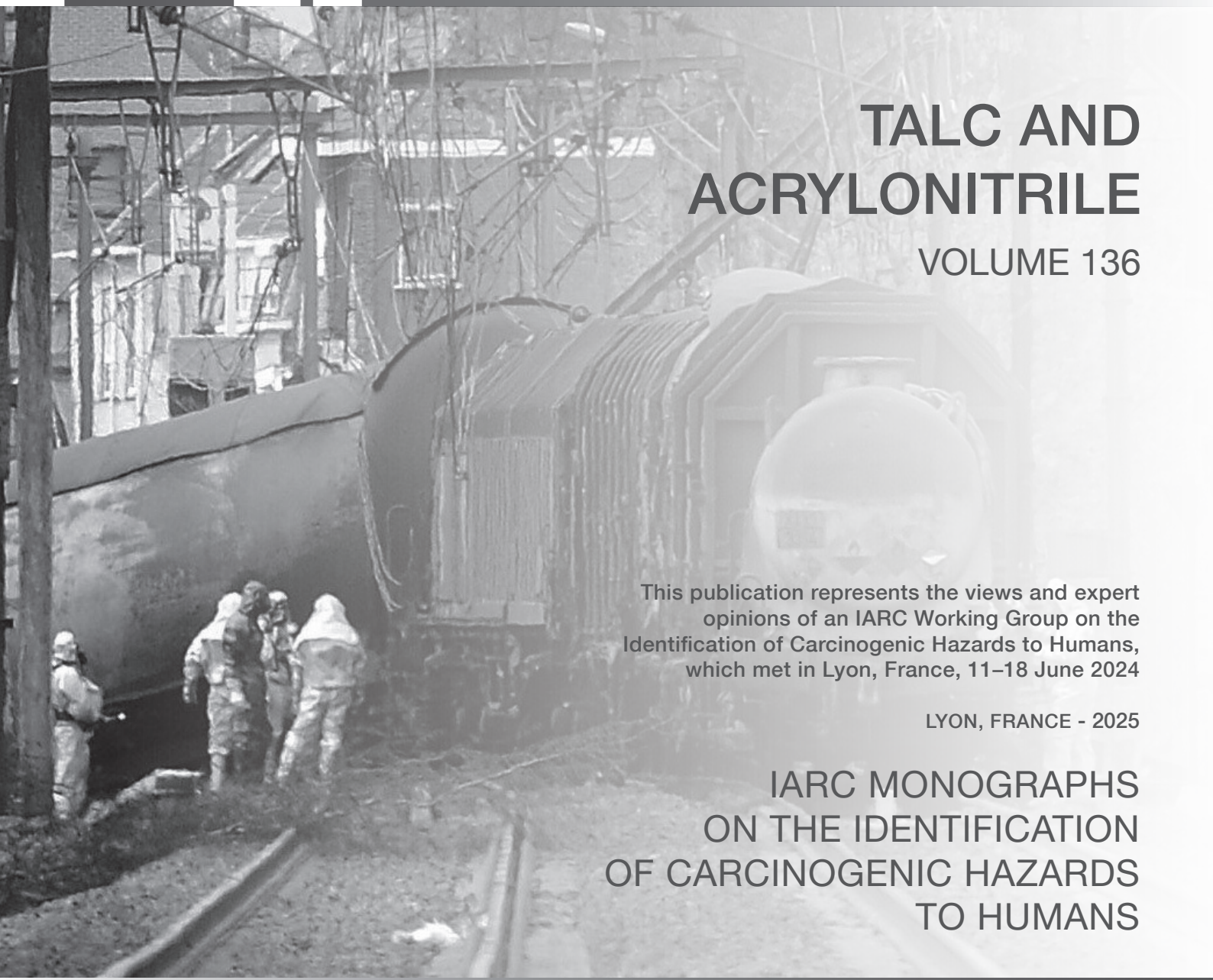

TALC AND ACRYLONITRILE

VOLUME 136

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International Agency for Research on Cancer

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ANNEX 2. QUANTITATIVE BIAS ANALYSIS FOR EXPOSURE MISCLASSIFICATION FOR THE EFFECTS OF EVER VERSUS NEVER USE OF TALC ON OVARIAN CANCER

In studies on talc powder personal use and ovarian cancer, exposure has been assessed on the basis of participant recall, leading to concern about exposure misclassification. Cohort studies, which assess talc exposure before disease occurrence, have the potential for non-differential exposure misclassification, whereas case–control studies, which assess exposure after disease status is known, have the potential for both differential and non-differential exposure misclassification. In the present annex, the Working Group examined the potential bias resulting from misclassification of talc exposure when assessing its effects on ovarian cancer. We limited our analysis to ever versus never use of talc (including body powder) and to the studies included in the pooled analyses of cohort studies (O'Brien et al., 2020) and case–control studies (Terry et al., 2013; Davis et al., 2021). When evaluating cohort studies, we included all women, regardless of whether their reproductive tracts were patent or not.

The extent of bias caused by misclassification is determined by the sensitivity and specificity of exposure classification. No validation studies on the self-reporting of talc use were identified by the Working Group. To quantify sensitivity and specificity, we relied on the expert opinion of Working Group members, particularly the exposure scientists and epidemiologists who had studied perineal use of talc. We conducted an iterative procedure to estimate sensitivity and specificity. First, the purpose of a bias analysis and the process involved were described to the Working Group experts participating in the bias assessment. Next, the experts were asked to quantify their beliefs about the sensitivity and specificity of misclassification, providing a best guess for the sensitivity and specificity values associated with cohort studies and an interval within which they were 95% certain about these estimates (Table A2.1). For case–control studies, these experts were asked to provide separate sensitivity and specificity estimates for cases and controls (Table A2.1).

The experts then met to compare their estimates of sensitivity and specificity and agreed on a range of sensitivities and specificities (separately for cohort and case–control studies) that encompassed the minimum and maximum values that they jointly agreed were plausible. Finally, the members were given the opportunity to review their personal best guesses and 95% certainty intervals and revise them.

Table A2.1 Experts' best guesses for the sensitivity and specificity values

Expert identity	Cohort studies			Case–control studies		
		Best guess (%)	95% Range (%)		Best guess (%)	95% Range (%)
Expert 1	Sens	90	85–95	Sens cases	96	94–98
	Spec	90	85–95	Spec cases	85	80–90
				Sens controls	90	85–95
				Spec controls	90	85–95
Expert 2	Sens	80	75–85	Sens cases	75	65–85
	Spec	90	85–95	Spec cases	90	85–95
				Sens controls	65	60–70
				Spec controls	90	85–95
Expert 3	Sens	80	75–85	Sens cases	90	85–95
	Spec	80	78–82	Spec cases	85	80–90
				Sens controls	80	75–85
				Spec controls	90	85–95

sens, sensitivity; spec, specificity.

This process resulted in the following ranges of values for cohort studies:

- Sensitivity: 0.80–0.95;
- Specificity: 0.80–0.94.

The following ranges were specified for case–control studies:

Cases:

- Sensitivity: 0.80–0.95;
- Specificity: 0.75–0.90.

Controls (the same values as for participants in cohort studies):

- Sensitivity: 0.80–0.95;
- Specificity: 0.80–0.94.

In addition, the experts agreed on the following constraints for the sensitivities and specificities:

A: The sensitivity for cases is greater than or equal to the sensitivity for the controls;

B: The specificity for cases is less than or equal to the specificity for the controls;

C: The extent of differential misclassification does not exceed 10%; that is (sensitivity for cases minus sensitivity for controls) is less than or equal to 10%, and (specificity for controls minus specificity for cases) is less than or equal to 10%.

In addition to these ranges, three experts in subgroups 1 and 2 provided their personal estimates and 95% certainty ranges for the sensitivity and specificity parameters, as follows.

We used the ranges and expert specifications in two sets of analyses:

1. A multidimensional bias analysis to quantify the extent to which the misclassification-adjusted effects change over a range of sensitivity/specificity values;
2. Three separate expert-specific bias analyses that used the bias parameters provided by three experts in the Working Group.

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Analysis

We chose six evenly spaced points between the lower and upper boundaries of the estimates and conducted a bias analysis on each of the 15 cohort and case–control studies indicated in Table A2.2, for every permutation of the sensitivity and specificity values. We always kept the cohort sensitivity and specificity equal to the control sensitivity and specificity in the multidimensional bias analyses (i.e. the misclassification was always non-differential for cohort studies). We only considered permutations of sensitivity and specificity that were consistent with constraints A, B, and C listed above, and this resulted in 306 permutations, on which we conducted bias analyses. Below, we also provide the results of bias analyses for the lowest, midpoint, and highest values for each range (consistent with the constraints) for ease of interpretation.

Each permutation of sensitivity and specificity was used to conduct a bias analysis in the following manner. First, we extracted the observed contingency data for each of the 15 studies (4 cohort and 11 case–control studies), then adjusted the observed data from each study for misclassification. Misclassification-adjusted effects were calculated using formulae from Greenland (1988). These formulae differ according to study design and the desired effect. They also incorporate uncertainty in the sensitivity and specificity parameters in the final interval estimates. For the multidimensional bias analysis, we assumed that there was no uncertainty in the sensitivity and specificity estimates. For the expert-specific bias analyses, we used the variance around the sensitivity and specificity parameters specified by the experts.

Second, the misclassification-adjusted data were adjusted for the impact of confounding. The results from step 1, above, could have been confounded, because unadjusted crude cell counts were used. However, a set of confounders was adjusted-for in each study. We estimated the extent of confounding in each study by computing the ratio of the confounding-adjusted effect to the crude effect for each study, both of which were misclassified. Next, we multiplied the misclassification-adjusted results in step 1 by this factor to produce results adjusted for both misclassification and confounding.

These two steps were repeated for each individual study (4 cohort and 11 case–control), resulting in 15 misclassification- and confounding-adjusted effect estimates and associated variances. These study-specific effects were then combined in a random effects meta-analysis.

For the multidimensional meta-analysis, this procedure was repeated for all 306 sensitivity and specificity permutations. For the expert-specific bias analysis, this procedure was repeated for each expert.

The data abstracted from the 15 studies included in this quantitative bias analysis are shown in Table A2.2, along with the study design and main (identified as "confounder-adjusted") effects. The results of the multidimensional bias analysis for 15 scenarios that represent the extremes of each range and the midpoint (and satisfy constraints A, B, and C above) are presented in Table A2.3. The effects presented in this analysis have been adjusted for both misclassification and confounding. The summary estimates (meta-relative risks, meta-RRs) obtained from meta-analyses for the 15 scenarios ranged from 1.00 to 1.22. The largest meta-RR, of 1.22, is the result that would have been obtained if the sensitivities in cohort and case–control studies were 80%, the specificity in cohort studies was 80%, and the specificity in case–control studies was 75%. The results shown in Table A2.3 are a subset of the 306 analyses that were conducted, which generated meta-RRs ranging from 0.81 to 1.30. The smallest adjusted effects, such as a meta-RR of 0.81, were associated with a large amount of differential misclassification. There was little between-study heterogeneity in any

Table A2.2 Characteristics of the studies included in the quantitative bias analysis for talc and ovarian cancer

Study (reference)	Case-exposed	Case-unexposed	Control-exposed	Control-unexposed	Study design	Effect measure (RR or OR)	Lower limit of 95% CI	Upper limit of 95% CI
NHS-I (O'Brien et al., 2020)	514.08	709.92	32 412.55	46 642.45	Cohort	1.07	0.95	1.20
NHS-II (O'Brien et al., 2020)	18.24	57.76	15 720.64	44 743.36	Cohort	0.81	0.47	1.38
SIS (O'Brien et al., 2020)	63.51	155.49	10 852.11	29 340.89	Cohort	1.02	0.76	1.38
WHI-OS (O'Brien et al., 2020)	363.44	285.56	37 558.45	33 306.55	Cohort	1.11	0.95	1.30
AUS (Terry et al., 2013)	705	300	658	305	CC	1.13	0.92	1.38
DOV (Terry et al., 2013)	272	1293	297	1544	CC	1.13	0.93	1.36
HAW (Terry et al., 2013)	74	326	112	489	CC	0.99	0.7	1.41
HOP (Terry et al., 2013)	194	439	316	989	CC	1.34	1.07	1.67
NCO (Terry et al., 2013)	195	469	122	391	CC	1.37	1.05	1.8
NEC (Terry et al., 2013)	755	1129	636	1239	CC	1.28	1.12	1.47
SON (Terry et al., 2013)	197	252	200	364	CC	1.35	1.03	1.76
USC (Terry et al., 2013)	208	435	170	494	CC	1.36	1.06	1.74
AACES_B (Davis et al., 2021)	119	196	202	394	CC	1.16	0.85	1.57
CCCS_B (Davis et al., 2021)	14	30	15	65	CC	1.51	0.52	4.4
CCCS_W (Davis et al., 2021)	53	180	75	346	CC	1.19	0.77	1.84

AACES, African American Cancer Epidemiology Study; AUS, Australia Ovarian Cancer Study and Australian Cancer Study (Ovarian Cancer); _B, in Black women; CC, case–control; CCCS, Cook County Case Study; CI, confidence interval; DOV, Diseases of the Ovary and their Evaluation; HAW, Hawaiian Ovarian Cancer Study; HOP, Hormones and Ovarian Cancer Prediction; NCO, North Carolina Ovarian Cancer Study; NEC, New England Case–Control Study of Ovarian Cancer; NHS-I, Nurses' Health Study; NHS-II, Nurses' Health Study II; OR, odds ratio; RR, relative risk; SIS, Sister Study; SON, Southern Ontario Ovarian Cancer Study; USC, University of Southern California Study of Lifestyle and Women's Health; _W, in White women; WHI-OS, Women's Health Initiative Observational Study.

of the meta-analyses reported in Table A2.3. Of note, not every set of sensitivity and specificity values was compatible with every study, and therefore studies with data that were not compatible were excluded from the analyses. The total number of studies included is shown in the table.

Table A2.4 presents the results of the three expert-specific bias analyses. The estimate generated in the crude analysis, which was adjusted for confounding but subject to misclassification, was a meta-RR of 1.17 (95% confidence interval, CI, 1.10–1.25). The adjusted estimates (meta-RRs) provided by the three experts were all attenuated and ranged from 1.04 to 1.12. Little heterogeneity was noted between studies after adjusting for misclassification. Figs A2.1, A2.2, A2.3, and A2.4 present forest plots for the meta-analyses, based on the reported effects (adjusted for confounding but subject to misclassification), as well as the results provided by the three experts. Table A2.5 presents study-specific point estimates of the misclassification-adjusted effects calculated using the sensitivity and specificity parameters provided by each expert. Table A2.6 presents study-specific point estimates of the misclassification- and confounding-adjusted effects from

Table A2.3 Multidimensional quantitative bias analysis conducted at the extremes and midpoint of the sensitivity and specificity ranges

Cohort studies or controls[a]		Cases		Meta-RR[b]	*P*[c]	N[d]
Sens	Spec	Sens	Spec			
0.8	0.8	0.8	0.75	1.22	0.77	14
0.8	0.8	0.875	0.75	1.1	0.29	14
0.8	0.87	0.8	0.825	1.17	0.99	14
0.8	0.87	0.875	0.825	1.05	0.71	14
0.8	0.94	0.8	0.9	1.13	0.53	15
0.8	0.94	0.875	0.9	1	0.23	15
0.875	0.8	0.875	0.75	1.19	0.74	14
0.875	0.8	0.95	0.75	1.1	0.28	14
0.875	0.87	0.875	0.825	1.14	0.99	14
0.875	0.87	0.95	0.825	1.04	0.74	14
0.875	0.94	0.875	0.9	1.11	0.58	15
0.875	0.94	0.95	0.9	1	0.26	15
0.95	0.8	0.95	0.75	1.16	0.69	14
0.95	0.87	0.95	0.825	1.13	0.99	14
0.95	0.94	0.95	0.9	1.1	0.61	15

RR, relative risk; sens, sensitivity; spec, specificity.
[a] The sensitivity and specificity for the cohort studies are the same as for the controls in the case–control studies.
[b] Meta-analysis relative risk (meta-RR) estimate obtained from the misclassification- and confounding-adjusted estimates.
[c] Heterogeneity *P* value.
[d] Number of studies included in the meta-analysis. The number is < 15 because not all of the sensitivity/specificity values were compatible with the data for each study.

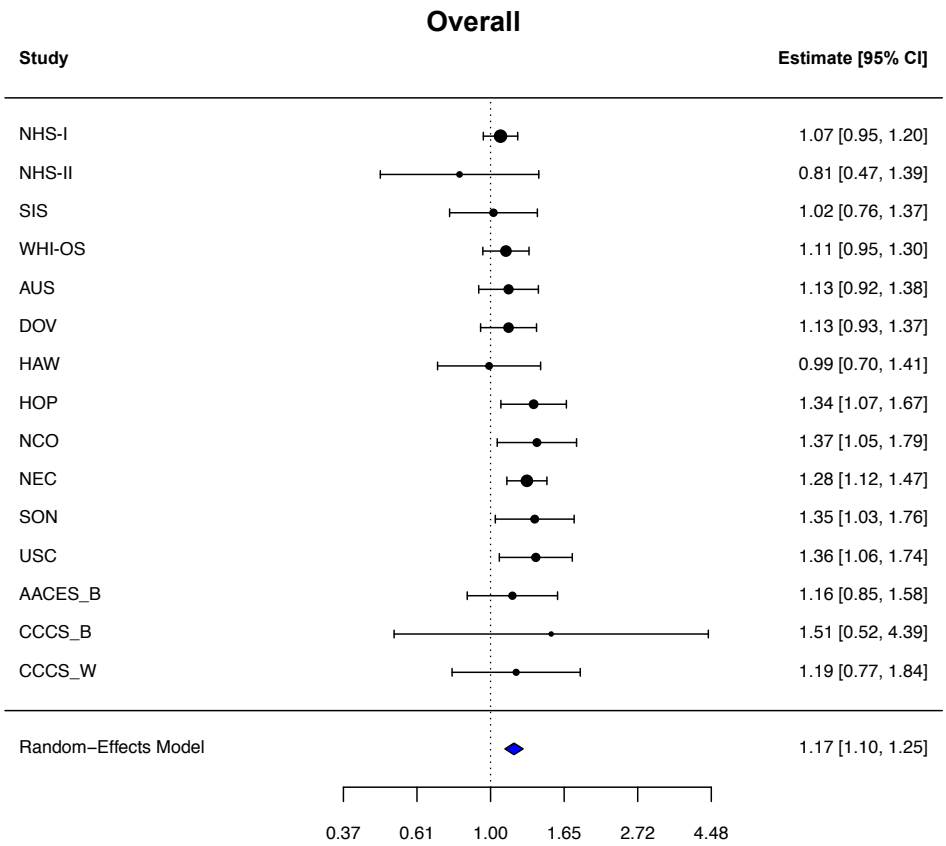
Table A2.4 Quantitative bias analysis using the best guesses by three experts for the sensitivity and specificity, incorporating uncertainty in the sensitivity and specificity estimates

Expert	Meta-RR[b]	Lower limit of 95% CI	Upper limit of 95% CI	*P*[c]
Crude[a]	1.17	1.1	1.25	0.48
Expert 1	1.06	0.97	1.16	0.97
Expert 2	1.12	1	1.25	1
Expert 3	1.04	0.92	1.18	0.85

CI, confidence interval; RR, relative risk.
[a] Assumes perfect sensitivity and specificity.
[b] Meta-analysis of the bias-adjusted estimates, except for the "crude" estimate, which is a meta-analysis of the reported effects from each study.
[c] *P*-value for the heterogeneity of the effects in the meta-analysis.

Fig. A2.1 Forest plots of the confounding-adjusted, but not misclassification-adjusted, study effects using estimates from the original paper

(A) Cohort and case–control studies



AACES, African American Cancer Epidemiology Study; AUS, Australia Ovarian Cancer Study and Australian Cancer Study (Ovarian Cancer); _B, in Black women; CCCS, Cook County Case Study; CI, confidence interval; DOV, Diseases of the Ovary and their Evaluation; HAW, Hawaiian Ovarian Cancer Study; HOP, Hormones and Ovarian Cancer Prediction; NCO, North Carolina Ovarian Cancer Study; NEC, New England Case–Control Study of Ovarian Cancer; NHS-I, Nurses' Health Study; NHS-II, Nurses' Health Study II; RE, random effect; SIS, Sister Study; SON, Southern Ontario Ovarian Cancer Study; USC, University of Southern California Study of Lifestyle and Women's Health; _W in White women; WHI-OS, Women's Health Initiative Observational Study.

each expert. Of note, there is little difference between the results in Table A2.5 and Table A2.6, indicating that there is relatively little observed confounding in the published studies.

We note several limitations of these analyses. First, quantitative bias analysis relies on sensitivity and specificity parameters, and the results of these bias analyses are only as valid as these parameters. Second, the adjustment for confounding is an approximation, rather than an exact result. However, given the very modest levels of confounding, this approximation is likely to be very good. Third, this approach does not incorporate the additional variance caused by the incorporation of confounding. This could result in final interval estimates that are too narrow. Fourth, the misclassification adjustments do not incorporate correlations between the sensitivities and specificities associated with case–control studies. This would probably result in interval estimates that are too wide.

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Fig. A2.1(B) Cohort studies only

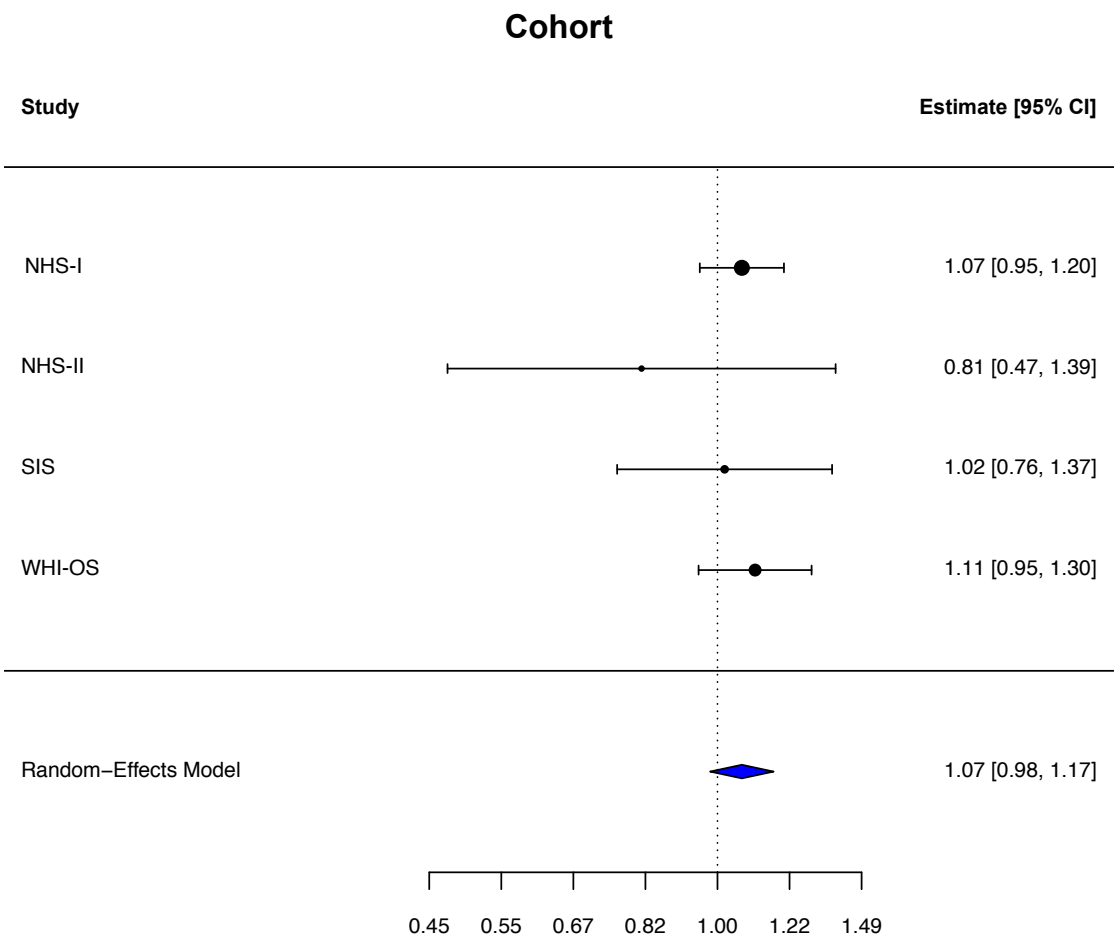

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Fig. A2.1(C) Case–control studies only

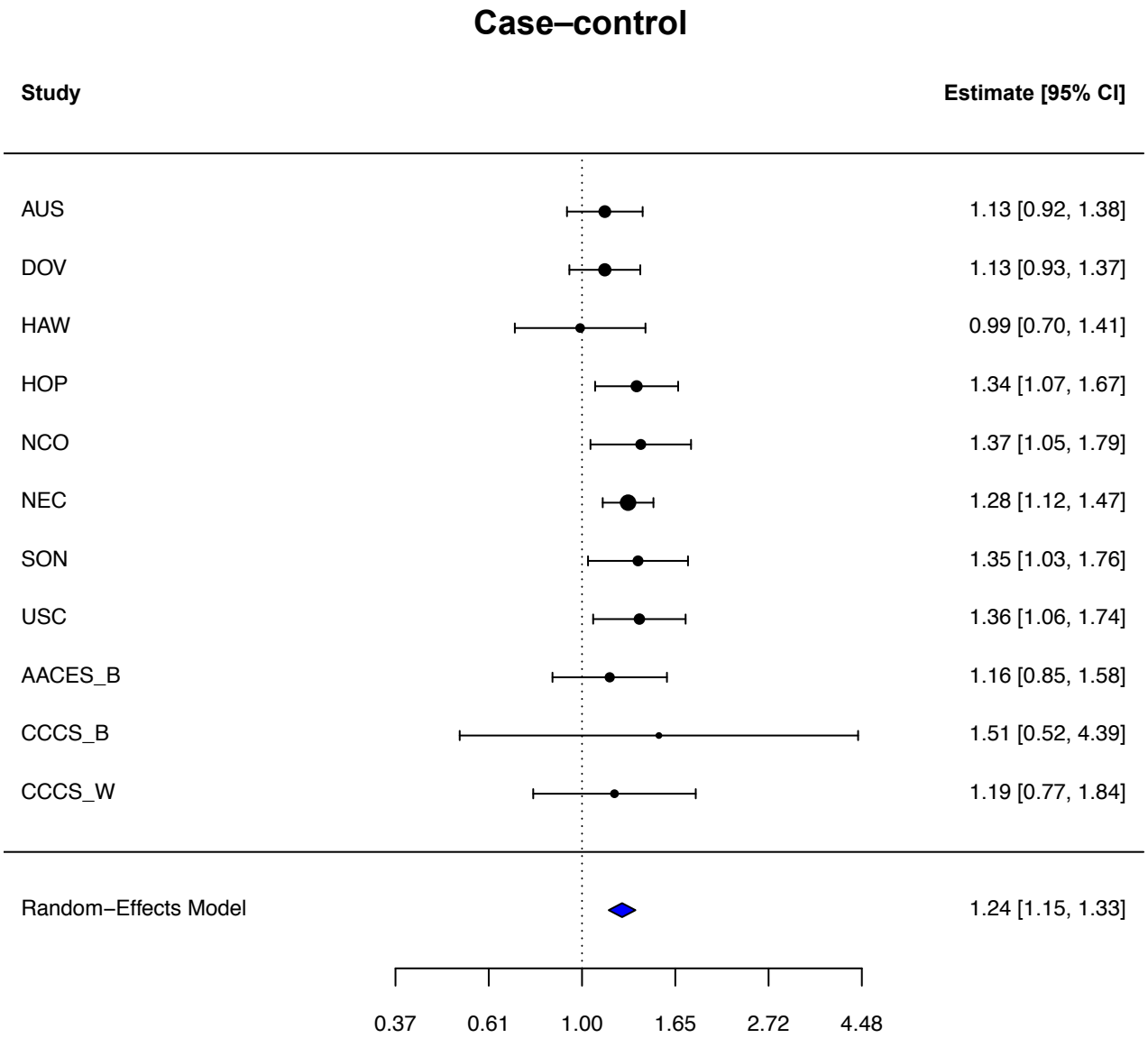

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Fig. A2.2 Forest plot of misclassification- and confounding-adjusted study effects, using the estimates from Expert 1

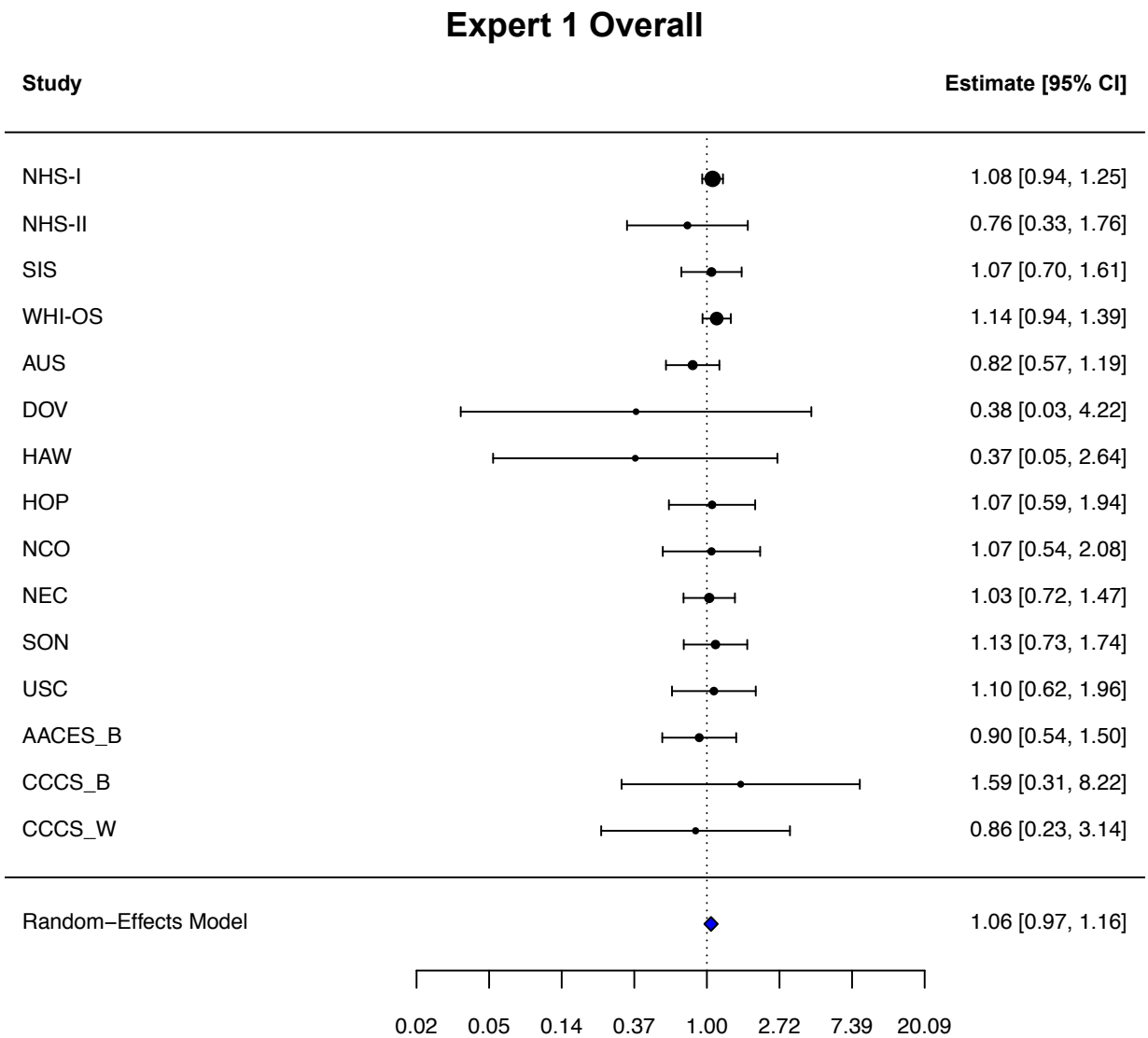

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Fig. A2.3 Forest plot of the misclassification- and confounding-adjusted study effects, using the estimates from Expert 2

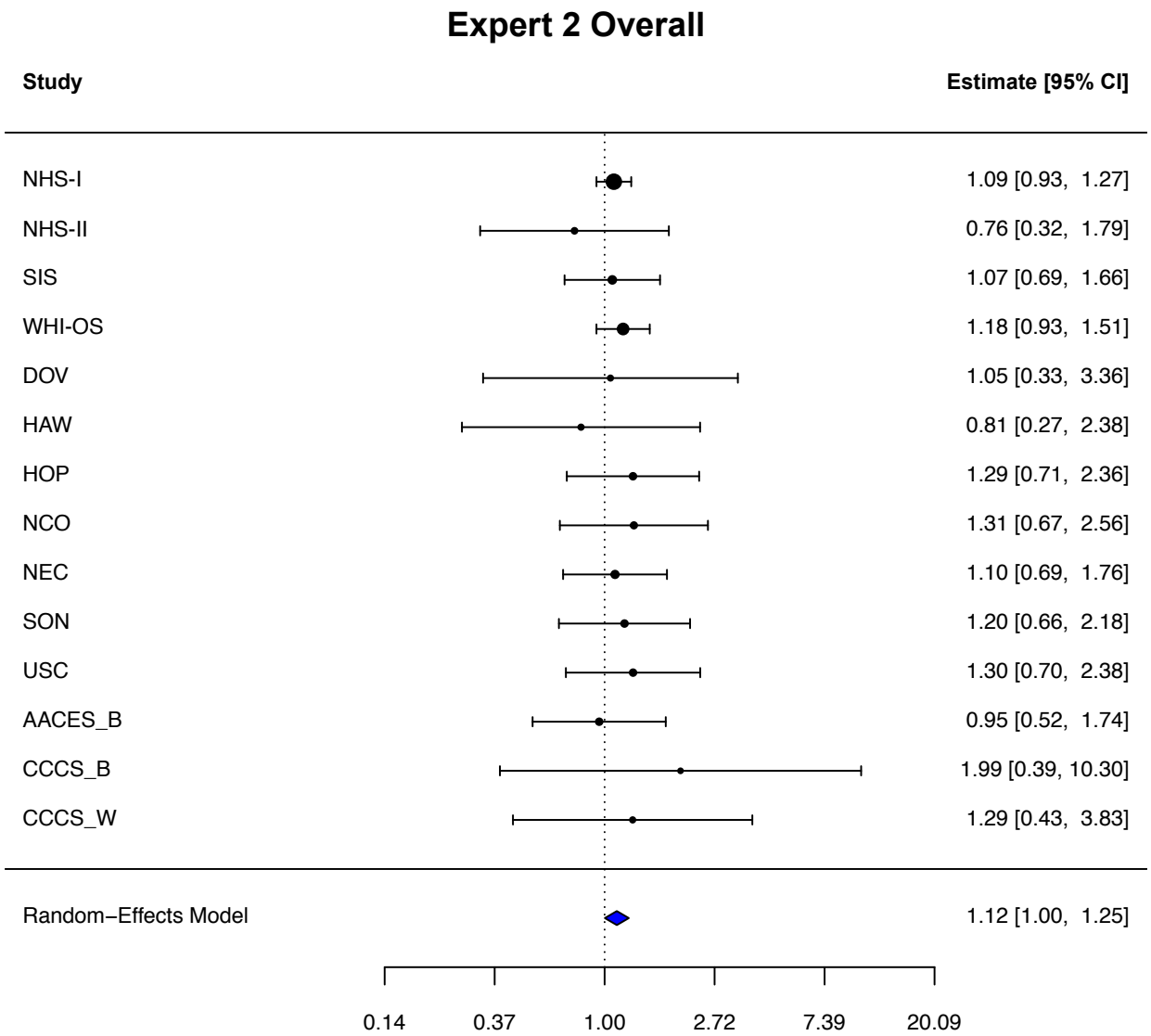

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Fig. A2.4 Forest plot of the misclassification- and confounding-adjusted study effects, using the estimates from Expert 3

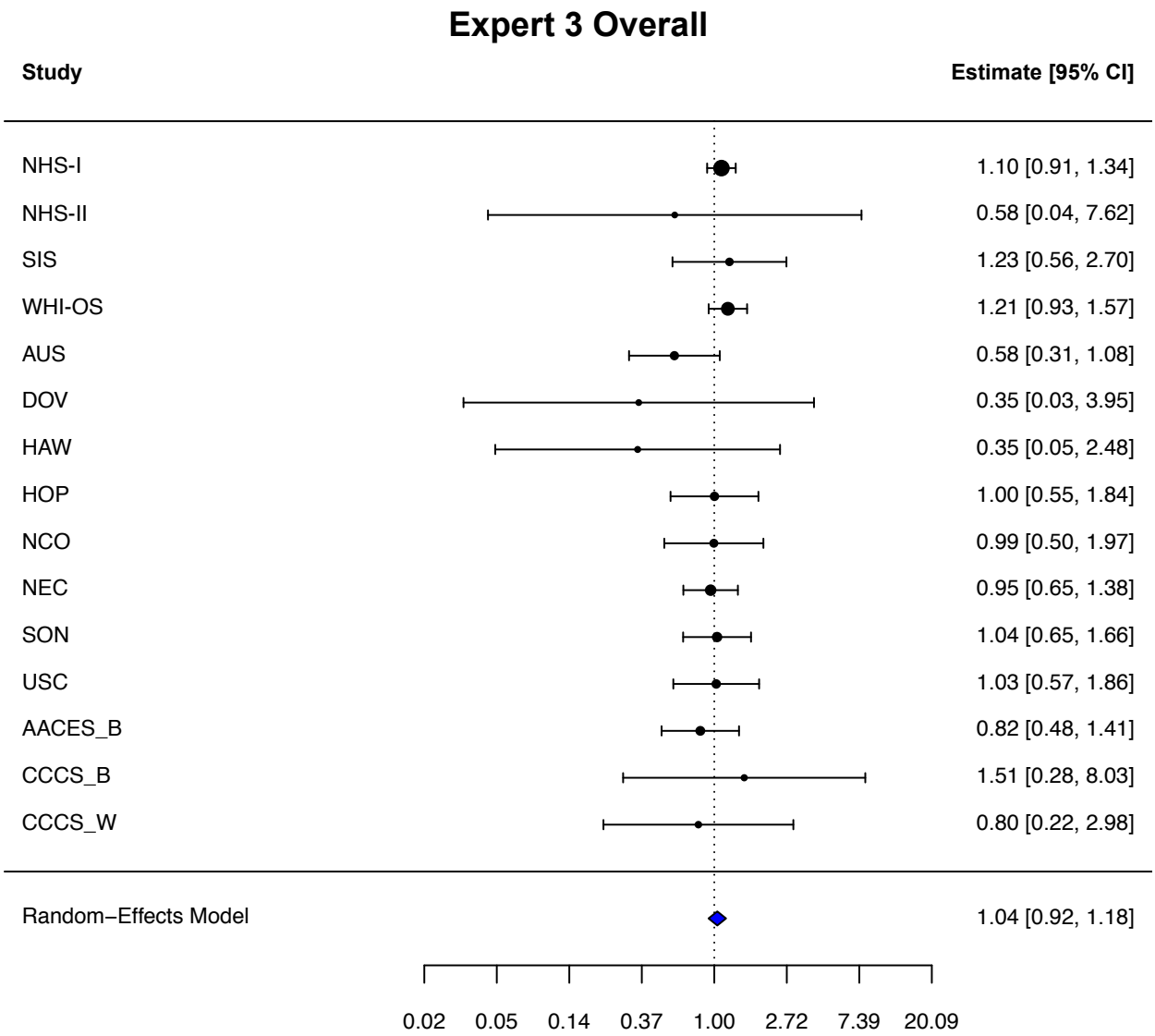

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Table A2.5 Misclassification-adjusted effects, based on the sensitivity and specificity values posited by the three experts, compared with the crude effect assuming perfect sensitivity and specificity

Study	Crude[a]	Expert 1	Expert 2	Expert 3
NHS-I	1.04	1.05	1.06	1.07
NHSII	0.9	0.85	0.84	0.64
SIS	1.1	1.15	1.16	1.33
WHI-OS	1.13	1.16	1.2	1.23
AUS	1.09	0.79	NA[b]	0.56
DOV	1.09	0.36	1.02	0.34
HAW	0.99	0.37	0.81	0.35
HOP	1.38	1.11	1.34	1.03
NCO	1.33	1.04	1.27	0.97
NEC	1.3	1.05	1.12	0.97
SON	1.42	1.19	1.26	1.1
USC	1.39	1.12	1.32	1.05
AACES_B	1.18	0.92	0.97	0.84
CCCS_B	2.02	2.13	2.67	2.02
CCCS_W	1.36	0.98	1.47	0.92

AACES, African American Cancer Epidemiology Study; AUS, Australia Ovarian Cancer Study and Australian Cancer Study (Ovarian Cancer); _B, in Black women; CCCS, Cook County Case Study; DOV, Diseases of the Ovary and their Evaluation; HAW, Hawaiian Ovarian Cancer Study; HOP, Hormones and Ovarian Cancer Prediction; NCO, North Carolina Ovarian Cancer Study; NEC, New England Case–Control Study of Ovarian Cancer; NHS-I, Nurses' Health Study; NHS-II, Nurses' Health Study II; SIS, Sister Study; SON, Southern Ontario Ovarian Cancer Study; USC, University of Southern California Study of Lifestyle and Women's Health; _W in White women; WHI-OS, Women's Health Initiative Observational Study.

[a] Crude analysis, assuming no misclassification of the data and not involving adjustment for confounding.

[b] NA indicates that the ranges of sensitivity and specificity were not compatible with these data.

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Table A2.6 Misclassification- and confounding-adjusted effects, based on the sensitivity and specificity values posited by the three experts, compared with the crude effect, in which perfect sensitivity and specificity was assumed

Study	Crude[a]	Expert 1	Expert 2	Expert 3
NHS-I	1.04	1.08	1.09	1.1
NHS-II	0.9	0.76	0.76	0.58
SIS	1.1	1.07	1.07	1.23
WHI-OS	1.13	1.14	1.18	1.21
AUS	1.09	0.82	NA[b]	0.58
DOV	1.09	0.38	1.05	0.35
HAW	0.99	0.37	0.81	0.35
HOP	1.38	1.07	1.29	1
NCO	1.33	1.07	1.31	0.99
NEC	1.3	1.03	1.1	0.95
SON	1.42	1.13	1.2	1.04
USC	1.39	1.1	1.3	1.03
AACES_B	1.18	0.9	0.95	0.82
CCCS_B	2.02	1.59	1.99	1.51
CCCS_W	1.36	0.86	1.29	0.8

AACES, African American Cancer Epidemiology Study; AUS, Australia Ovarian Cancer Study and Australian Cancer Study (Ovarian Cancer); _B, in Black women; CCCS, Cook County Case Study; DOV, Diseases of the Ovary and their Evaluation; HAW, Hawaiian Ovarian Cancer Study; HOP, Hormones and Ovarian Cancer Prediction; NCO, North Carolina Ovarian Cancer Study; NEC, New England Case–Control Study of Ovarian Cancer; NHS-I, Nurses' Health Study; NHS-II, Nurses' Health Study II; SIS, Sister Study; SON, Southern Ontario Ovarian Cancer Study; USC, University of Southern California Study of Lifestyle and Women's Health; _W in White women; WHI-OS, Women's Health Initiative Observational Study.

[a] Crude analysis, assuming no misclassification of the data and not involving adjustment for confounding.

[b] NA indicates that the ranges of sensitivity and specificity were not compatible with these data.