

Appendix 1 (as submitted by the authors): Summary of Articles

Author/ Date	Study Method	Aim of Study	Timeline	Sample Description/ Selection Criteria	Total Sample Size of Study		Sample Size relevant to current analysis		Histologic/ Cytologic Diagnosis	Results	Author(s) inference regarding adequacy of EC cells
					# of wom en	# of smea rs	# of wom en	# of smea rs			
Elias et al., 1983 (5)	Cross-sectional	Evaluate the relationship of endocervical columnar cells to the cytologic identification of abnormality in the cervix	3 years: 1976-1979	· Women aged 35-54 participating in a cancer screening program in the region of Nijmegen, the Netherlands	62,735	63,479	-	55,854	· Atypical squamous cells/ atypical squamous metaplasia · Slight dysplasia/ moderate dysplasia · Severe dysplasia <i>in situ</i> /micro-invasive carcinoma	Abnormal cytology: EC+: 15.8% EC-: 10.5% (squamous metaplastic cells); 4.3% (squamous cells only) Relative risk: 2.2 (slight and moderate abnormality) 4.4 (severe abnormality) P<0.05	“When endocervical cells are not present, a repeat smear should be taken unless the absence of endocervical columnar cells can be explained satisfactorily.”
Kivlahan & Ingram, 1985 (6)	Prospective cohort	Evaluated Papanicolaou smears to compare the frequency of cervical atypia in women without endocervical columnar cells in their smears	4 years: 1980-1984	· Women aged 18-65 who had at least two Papanicolaou smears performed during 4 yr period	18,914	-	-	10,979	Atypia	Abnormal cytology: Group 1 (2 smears) EC+: 3.3% EC-: 3.0% Group 2 (3 smears) EC+: 2.7% EC-: 3.2% Group 3 (4 smears) EC+: 4.4% EC-: 0% NS*	“It may remain in the best interest of the patient to continue to consider Papanicolaou smears without endocervical columnar cells as less than optimal.”
Vooijis et al., 1985 (7)	Cohort	Examine data on the presence of endocervical columnar cells in cervical smears and its	6 years	· Women 35-54 years of age agreeing to participate in study in Nijmegen, the Netherlands	85,782	-	30,555	-	· Minimal atypia · Slight and moderate dysplasia · Severe	Negative cytology: First screening EC+: 85.2% EC-:92.4%	“The chance of missing an abnormal epithelial change is increased in smears without endocervical columnar cells. When endocervical columnar cells are absent, the smear should be considered to be of unreliable quality and a repeat smear

Appendix to: Elumir-Tanner L, Doraty M, for the Southern Alberta Primary Care Research Network (SAPCRN). Management of Papanicolaou test results that lack endocervical cells. *CMAJ* 2011. DOI:10.1503/cmaj.101156.

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		relation to the finding of epithelial abnormalities from a group of women in a mass-screening program							dysplasia, CIS, (micro-) invasive carcinoma	<p>Second screening EC+: 77.8% EC-:82.2%</p> <p>Abnormal cytology:</p> <p>First screening EC+: 14.4% (minimal atypia), 0.40% (slight and moderate dysplasia), 1.1% (severe dysplasia, CIN [micro-] invasive carcinoma) EC-: 7.4% (minimal atypia), 0.23% (slight and moderate dysplasia)</p> <p>Second screening EC+: 21.1% (minimal atypia), 0.89% (slight and moderate dysplasia), 0.16% (severe dysplasia, CIN [micro-] invasive carcinoma) EC-: 17.0% (minimal atypia), 0.79% (slight and moderate dysplasia) , 0.05% (severe dysplasia, CIN [micro-] invasive carcinoma)</p>	should be taken after a short interval, unless the absence of columnar cells can be satisfactorily explained.”
Kristensen et al., 1990 (8)	Retrospective	Evaluate occurrence of and possible reasons for negative and undercalled smears in women developing invasive cervical	4 years: 1979 - 1983	<ul style="list-style-type: none"> Women living in the county of Funen with a diagnosis of invasive cervical cancer Smears with original or review cytodiagnosis of less than cancer 	376	-	202	320	<ul style="list-style-type: none"> Atypia CIN 	<p>Negative cytology: EC+: 55.5% EC-: 45.5%</p> <p>Abnormal cytology: EC+: 84.4% (atypia); 97.8% (CIN) EC-: 15.6% (atypia); 2.2% (CIN)</p> <p>P<0.00001</p>	“Smears without endocervical cells should be considered inadequate and should be repeated.”

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		cancer									
Kwikkel, Quaak & de With, 1986 (15)	Retrospective	Evaluate the validity and performance of the Pap smear, as a diagnostic test	18 years: 1965-1983	<ul style="list-style-type: none"> Women with at least one abnormal Pap smear registered at the Gynaecological Clinic, Vrije Universiteit, Amsterdam Excluded patients referred for clinically overt invasive carcinoma without previous Pap smears 	806	620	806	620	<ul style="list-style-type: none"> Class IIIa (mild or moderate dysplasia) Class IIIb (severe dysplasia) Class IV (carcinoma <i>in situ</i>) Class V (suspicious of invasive cancer) 	Abnormal cytology/histology: Before 1979 - at 6 mnths EC+: 4% EC-: 9% - at 12 mnths EC+: 4% EC-: 9% After 1979 - at 6 mnths EC+: 3% EC-: 7% - at 12 mnths EC+: 3% EC-: 7% - - -	"We are inclined to agree with previous workers who concluded that the presence or absence of identifiable endocervical cells did not appear to have a major bearing on the adequacy of the sample."
Laverty et al., 1989 (9)	Controlled trial	Evaluating the reliability of smears that were made with the Cervex Sampler compared to those taken with a conventional modified Ayre spatula	1 year: 1987 (Ayre spatula) 3 months: 1988 (Cervex Sampler)	<ul style="list-style-type: none"> Smears collected by 119 doctors by the Ayre spatula Smears collected by 10 doctors selected to sample the Cervex Sampler 				962	<ul style="list-style-type: none"> Atypia 	Spearman's rank correlation: EC+ and cytological atypia=0.379 P<0.001	"Our study confirms these findings [positive correlation between presence of endocervical cells and the detection of squamous-cell atypia]...smears which lack endocervical cells offer no opportunity for the detection of endocervical or columnar atypias (glandular intraepithelial neoplasia)."
Mauney, Eide & Sotham,	Retrospective cross-	Assess the effect of the presence or	½ year: 1988	<ul style="list-style-type: none"> Women age 14-85 Smears from private physicians 	-	36,853	-	33,785	<ul style="list-style-type: none"> Condyloma acuminatum CIN I 	Abnormal cytology: EC+: 3.02% EC-: 1.32%	"We found a significantly higher rate of dysplasia in smears with endocervical cells than in those without... We do not,

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1989 (10)	section	absence of endocervical cells on the detection rate of condyloma and dysplasia		and large institutions with specific diagnoses of condyloma acuminatum, CIN I, CIN II, and CIN III					· CIN II · CIN III	P< 0.0001	however, suggest that the presence of endocervical cells alone constitutes an adequate or satisfactory smear. Nor do we feel that those smears lacking endocervical cells should necessarily be reported as unsatisfactory. However, presence or absence of these cells should be routinely reported so that the clinician may weigh clinical factors in deciding appropriate follow-up."
Woodm an et al., 1989 (11)	Case control	Assess whether inadequate smears can be distinguished by the absence of columnar cells of endocervical origin and immature metaplastic cells	10 years	· Women attending the Birmingham and Midland Hospital for Women for investigation of abnormal cytology over a 20 year period with 3 smears over an 18 month period with CIN · The initial and final smears suggested presence of histological abnormality, however, the intermediate smear did not	20	60	18	54	· CIN I · CIN II · CIN III	Abnormal cytology: RR=0.41 (endocervical cells) (95% CI 0.11-1.5) RR=0.04 (immature metaplastic cells) (95% CI 0.01-0.21) RR=0.05 (endocervical and immature metaplastic cells) (95% CI 0.01-0.26)	"Endocervical cells alone were less likely to be found in inadequate than in adequate smears, but this association was not statistically significant."
Mitchell & Medley, 1991 (16)	Longitudin al	Report the results of a longitudinal study of abnormality rates, according	3 years: 1987- 1989	· Women with negative cytology report during 1987 (entry smear) and a later smear (exit smear) from the	22,2 11	22,2 11	20,2 22	20,2 22	· CIN	Abnormal cytology at follow up : Definite/equivocal CIN EC+:4.0% EC-:1.4% $\chi^2=128.9$, p<0.001	"Our study demonstrates that the subsequent incidence of CIN is not substantially higher in women whose smears are negative but lack an endocervical component than in women whose smears are reported as negative

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		to endocervical status, among women who have received negative cytology reports to investigate the assumption underlying the recommendation for an early repeat test for smears that lack an endocervical component		database of all women whose smears are reported by the Victorian Cytology Service						Definite EC+: 1.6% EC-: 0.4% $\chi^2=89.6, p<0.001$	with an endocervical component. Thus there appears to be no scientific basis for recommending an immediate or early repeat test for women whose cytology report is negative but whose smears lack an endocervical component."
Mitchell & Medley, 1992 (17)	Case control	Replicate previous case-control studies indicating that there is no significant difference in endocervical cell status for prediction of CIN	8 years: 1982-1990	<ul style="list-style-type: none"> Women with a chronologic cytological report of CIN, a cytologic report of no abnormality, and a histologic report of CIN Smears entered into the computerized files of the Victorian Cytology Service 	134	134	119	119	· CIN	Negative histology: EC+:71% EC-:29% Abnormal histology: EC+: 84% EC-:14% OR: 2.45 (95% CI, 1.22-4.95, P<0.05)	"...Should negative smears that lack an endocervical component be repeated early? No. The rationale for an early repeat test would be that a higher rate of abnormality was evident on the repeat tests, indicating that important abnormalities were being missed on the negative smears that lacked an endocervical component."
Mitchell & Medley, 1993 (18)	Case control	Detail the proportion of smears reported as including an endocervical component	4 years: 1987-1991	<ul style="list-style-type: none"> Smears reported as including an endocervical component from computerized records Excluded smears 	-	-	-	Over 1,000,000	<ul style="list-style-type: none"> Severe dysplasia Moderate/severe dysplasia Moderate dysplasia 	Abnormal cytology: Rate per 10,000 between 1897-1991 of all abnormalities (lowest to highest): EC+: 55.2-102.6 EC-:13.2-24.7	"The declining ration of reported abnormalities in smears with an endocervical component indicates a weakening of the relationship between endocervical status and the probability of an abnormality being reported."

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		which correlate with the detection rate of high-grade intraepithelial lesions and with the reporting of abnormalities of the endocervix		that were technically unsatisfactory or taken post-hysterectomy							
Sidawy, Tabarra & Silverberg, 1992 (19)	Retrospective	Assess the effect of the presence or absence of the endocervical component on the detection rate of condyloma and dysplasia	1 year: 1989-1990	<ul style="list-style-type: none"> Women referred to The George Washington University Medical Center whose biopsies revealed histologic evidence of condyloma/dysplasia or carcinoma Ages 15-50 years 	84	168	82	166	<ul style="list-style-type: none"> LSIL HSIL 	Negative histology: EC+: 18.4% EC-: 20% Abnormal histology: EC+: 81.6% EC-: 80.0% P=0.84	“Although the presence or absence of an endocervical component should be documented in the cytology report, its absence should not be an indication to report the cervical smears as unsatisfactory.”
Beeby et al., 1993 (12)	Retrospective case control	Evaluate the relationship between various epidemiological, cytological, colposcopic, and histological factors and negative cytology	2 years: 1989-1991	<ul style="list-style-type: none"> Women diagnosed by colposcopic biopsy referred from practitioners and clinics with 2 smears prior to colposcopic examination 	1000	1000	624	624	<ul style="list-style-type: none"> CIN 	Negative histology: EC+: 63% EC-: 37% Abnormal histology: EC+: 75% EC-: 25% $\chi^2=6.6$, df=1, P<0.05	“There is a need either to consider alternative methods of assessing smear quality or to recognize that false negatives can occur despite apparently adequate sampling of the transformation zone.”
Roberts & Woodend, 1993	Retrospective	Identify the causes of failure in the screening process related	24 years: 1965-1989	<ul style="list-style-type: none"> Women aged 27-74 years in Northern Ireland Diagnosed with 	103	140	102	139	<ul style="list-style-type: none"> Dysplasia 	Negative cytology: EC+: 36% EC-: 64%	“Smears lacking an endocervical component are unreliable.”

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(13)		to present laboratory practice		invasive cervical cancer over previous 12 years with initial negative diagnosis or containing smears with few dysplasia cells · Excluded patients with microinvasive disease						Abnormal cytology: EC+: 31% EC-: 69%	
O'Sullivan et al., 1998 (20)	Case control	Investigate if there is a type of severely dyskaryotic smear that is likely to be missed in a normal screening situation	Unknown	· Smears from 5 major cytopathology departments with biopsy-proven CIN III	-	150	-	150	· CIN III	Negative histology: EC+: 57% EC-: 43% Abnormal histology: EC+: 56% EC-: 44% NS*	"[No] significant difference in the proportions of true positives and false negative smears showing endocervical or metaplastic cells."
Bos et al., 2001 (21)	Retrospective	Compare the incidence of invasive cervical cancer and the incidence of preinvasive lesions after negative smears with and without endocervical cells	8.25 years: 1990/1991-1998	· Smears from the Dutch Network and National Database for Pathology · Excluded smears obtained for medical indications and unknown reasons · Excluded smears that followed a positive smear within 4 years · Comparison included	-	1,272,558	-	448,983	· CIN I · CIN II · CIN III · Invasive cervical cancer	Odds ratio (Invasive cervical cancer): 1.01(EC+ to EC-) (95% CI 0.68-1.49)	"These data suggest there is no reason to advise women with negative smears without endocervical cells to undergo an additional smear."

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				preventive negative smears only							
Mitchell , 2001 (22)	Cohort	Determine the incidence of histologically confirmed high- grade cervical disease after a negative Pap smear report according to the endocervical status of the negative smear	3 years: 1996- 1999	· Women with a negative Pap smear report issued during the study time period and a further Pap smear during the next 36 months from the Victorian Cervical Cytology Registry	60,1 44	60,1 44	60,1 44	60,1 44	· High grade abnormality · Low grade abnormality · Abnormal cytology report	Abnormal histology at follow up : Standardized incidence ratio (high-grade disease): EC+ (Cohort A and B respectively): 1.00, 0.89 (95% CI 0.67-1.12, P>0.05) EC- (Cohort C and D, respectively): 0.24 (95% CI 0.13- 0.36, P<0.001), 0.26 (95% CI 0.07- 0.45, P<0.001) Standardized incidence ration (low-grade disease): EC+ (Cohort A and B respectively): 1.00, 0.67 (95% CI 0.49-0.85, P<0.01) EC- (Cohort C and D, respectively): 0.32 (95% CI 0.20- 0.44, P<0.001), 0.32 (95% CI 0.12- 0.51, P<0.001)	“These findings suggest that the extent to which Pap smears without an endocervical component are considered ‘limited’ should be reviewed.”
Selvaggi & Guidos, 2001(23)	Retrospect ive	Assess the effect of the presence or absence of an endocervical component on the detection rate of cervical intraepithelial neoplasia (CIN) II/III	2 years: 1999- 2000	· Asymptomatic women from Loyola University Medical Center · Received yearly routine gynecological exams · Previous atypical smears or previously treated	151	151	151	151	· CIN II · CIN III · HSIL · LSIL	Abnormal histology: EC+: 27% EC-: 23% P>0.5	“The issue of the lack of an endocervical component as a determinant of cervical specimen adequacy should be revisited.”

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				for genital malignancies							
Siebers et al., 2003 (24)	Retrospect ive	Determine the prevalence rate ratio of squamous lesions in women with recent smears without endocervical component versus women having a smear with endocervical component	3 years: 1997- 1999	<ul style="list-style-type: none"> Initial smears diagnosed in east Netherlands and follow-up smears from the National Pathology Database Excluded smears with epithelial atrophy 	-	195, 285	-	167, 604	<ul style="list-style-type: none"> ASCUS+ LSIL+ HSIL+ 	Negative cytology: EC+: 5.0% EC-: 1.4% Abnormal cytology: EC+:95.0% EC-: 98.6%	“These findings lent support to the decision to abolish the repeat of endocervical component negative smears in the Dutch population screening program.”
Pajtler and Audy- Jurkovic, 2002 (25)	Prospectiv e case control	To analyze the association between the presence of endocervical cells and 1) prevalence of abnormal cells, 2) prevalence of histological diagnosed lesions, and 3) sensitivity and negative predictive value of Pap smear	2 years	<ul style="list-style-type: none"> Non-pregnant women between the age of 20 and 50 from whom a vaginal, cervical, endocervical smear was taken during a clinical exam 	1,00 0	1,00 0	1,00 0	1,00 0	<ul style="list-style-type: none"> Cervical lesions CIN II – CIN III 	Abnormal histology: EC+: 20% EC-: 11% P<0.05	“...negative smears without endocervical cells which, in accordance with the applied classification, are ‘less than optimal,’ do not need to be repeated earlier than those with endocervical cells.”
Tacken et al.,	Prospectiv e cross	Investigate efficacy of the	4 years: 1998-	<ul style="list-style-type: none"> Women eligible for population-based 	1,00 7	1,00 7	296	296	<ul style="list-style-type: none"> Abnormalities 	Abnormal cytology at 6 month follow-up:	“Our study demonstrates that the effect [6 month follow up for women with EC- pap

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2005 (26)	sectional	six month recommended follow-up after mass screening of Pap smears because of the absence of endocervical columnar cells	2001	cervical screening with a 6-month follow up recommendation from the National Information Network of General Practices in the Netherlands						EC-: 15.9% Negative cytology at 6 month follow-up: EC-: 84.1%	smears] for the women is negligible, because in most of the EC- cases no abnormalities were found in the subsequent Pap smear taken after 36 weeks."
Ribeiro et al., 2006 (14)	Comparative cross-sectional	Correlate the number of endocervical cells and the number of atypical cells in cervical smears with cytological abnormalities	Unknown	· Conventional cervical smears including LSILs and HSILs	-	294	-	294	· LSIL · HSIL	Odds ratio: 2.87 (endocervical cells to squamous atypical cells) (95% CI 1.54-5.35)	"A higher number of endocervical cells were significantly associated with the detection of a higher number of squamous atypical cells... it would be possible to consider that 10 endocervical or metaplastic cells as defined by Bethesda System may be insufficient to adequate transformation zone component."
Rossi et al., 2010 (27)	Prospective (noncurrent)	Measure the risk of CIN2+ in the 4.5 years following a negative Pap smear with adequate endocervical cells or absent/scarce endocervical cells	11 years: 1980-2001	· 24-50 year old women with a first negative pap smear from the archives of 11 Italian population-based screening programs · Women from the sample with a follow-up smear within 4.5 years of first negative smear	-	490, 290	-	490, 290	· CIN II+	Abnormal cytology: Incidence: EC+: 2.06 per 1,000 (95% CI 0.51-2.3) EC-: 1.09 per 1,000 (95% CI 1.08-3.91) Relative risk (unadjusted): 0.55 (95% CI 0.28-1.06)	"A lower risk of CIN II+ in the 4.5 years following the first negative Pap smear is associated with EC- compared to EC+ status. According to these findings, women with a negative Pap test lacking EC should be referred for retesting at normal screening intervals... independent of age."

*NS: Not significant

CIS : Carcinoma in situ

CIN: Cervical intraepithelial neoplasia

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P: Significance
 χ^2 : Chi square
df : Degrees of freedom
CI: Confidence interval

CIN I: Cervical intraepithelial neoplasia – mild dysplasia
CIN II: Cervical intraepithelial neoplasia – moderate dysplasia
CIN II+: Cervical intraepithelial neoplasia – moderate dysplasia or higher (grade 2 or higher)
CIN III: Cervical intraepithelial neoplasia – severe dysplasia, carcinoma in situ
LSIL: low grade squamous intraepithelial lesion
LSIL+: low grade squamous intraepithelial lesion
HSIL: high grade squamous intraepithelial lesion
HSIL+: high grade squamous intraepithelial lesion
ASCUS+: Abnormal cervical cells