Comparison of HPV positivity, sensitivity and viral load between four vaginal self collection devices and urine

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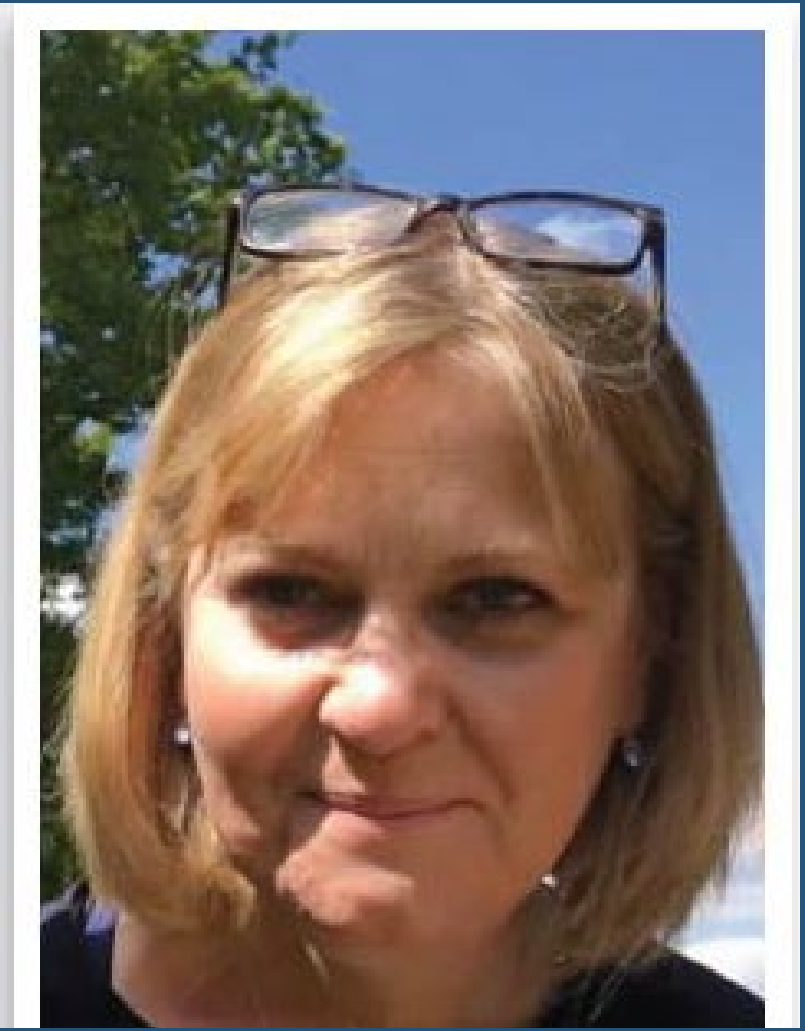
1965 - 2020

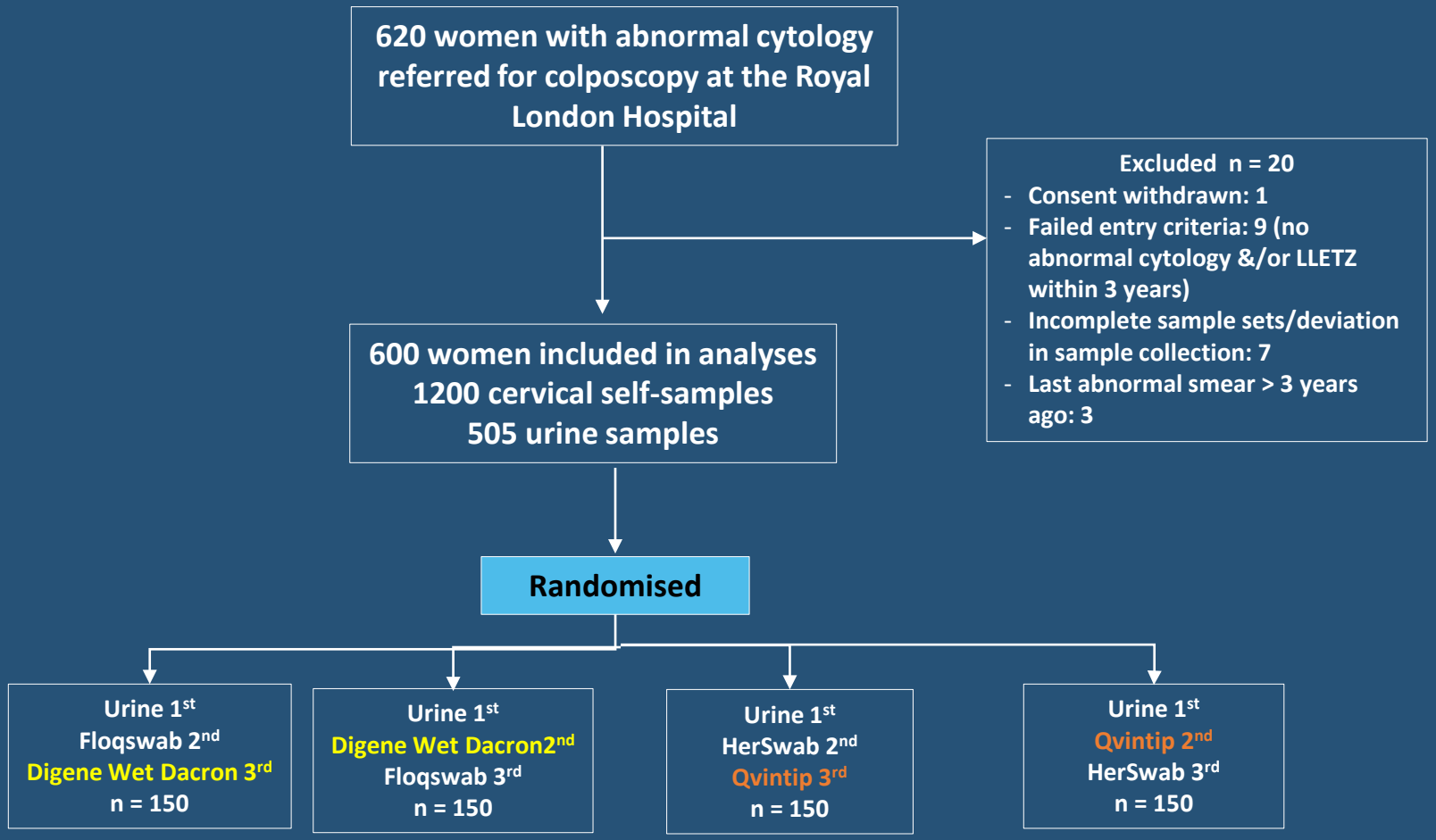


Disclosures

- Becton Dickinson – Travel expenses, Research support to Institution
- Qiagen – Research support to Institution

- Aprovix AB (donated Qvintips)
- eve MEDICAL (donated HerSwabs)
- Novosanis (donated Colli-Pee™devices)

Flowchart



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Devices

Digene swab
(WD, Transported wet)

FLOQswab (FS)

HerSwab (HS)

Qvintip (QT)

Colli-Pee (Urine)

hrHPV positivity rates by sample order

	hrHPV Positivity (%)		
Device	First sample	Second Sample	P-value
Digene STM	69	72	0.61
FLOQswab dry	69	71	0.90
Qvintip dry	67	63	0.52
Herswab dry	58	64	0.43

- **No impact of sample order**

hrHPV positivity rates and sensitivity by device Combined samples – no adjustment for cellularity

HPV positive: Ct ≤ 34.2

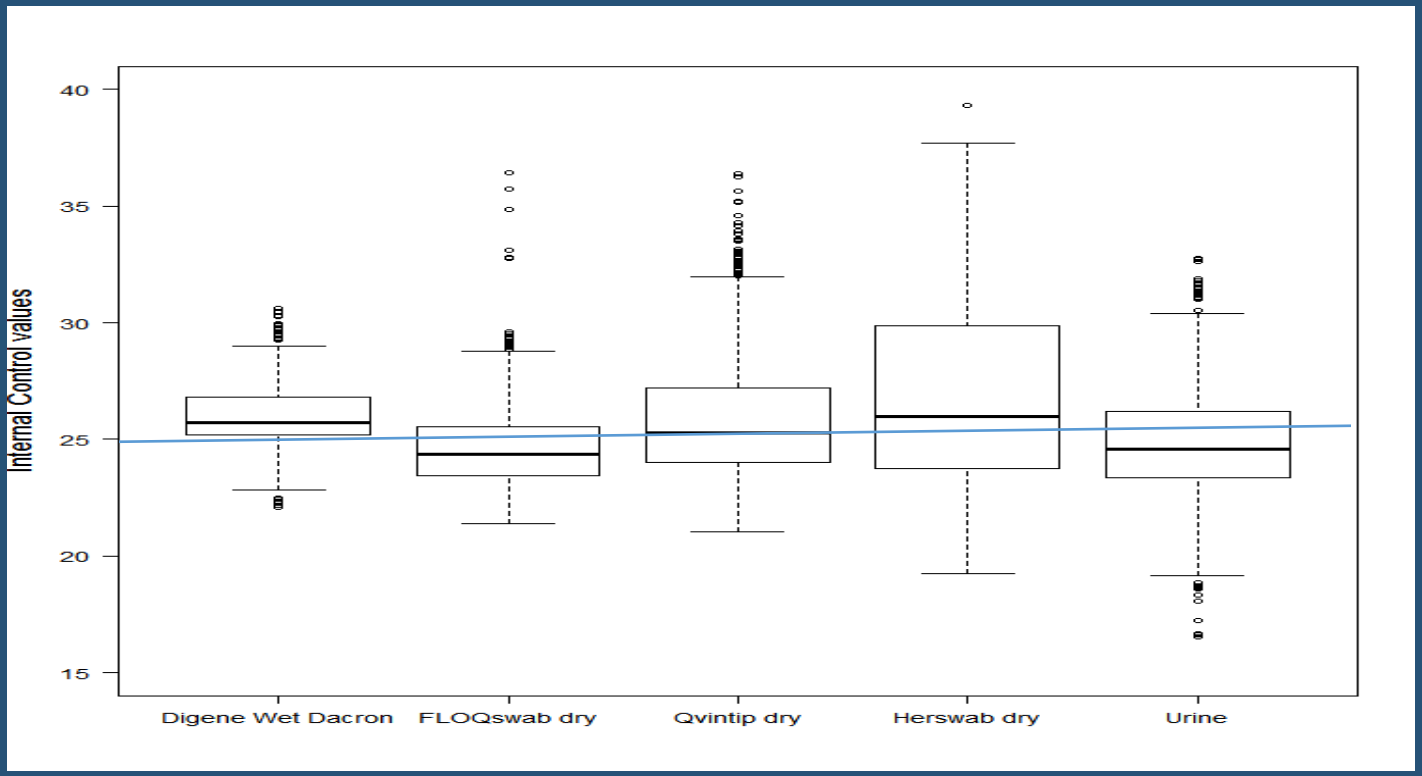
	All samples			CIN2+		
Device	N	Positive (%) (95% CI)	P-value vs WD	N	Positive (%) (95% CI)	P-value vs WD
Wet Digene Dacron (WD)	300	70.3 (64.8, 75.4)	-	69	85.5 (75.0, 92.8)	-
FLOQswab dry (FS)	300	70.0 (64.5, 75.1)	0.99	69	84.1 (73.3, 91.8)	0.99
Qvintip dry (QT)	296	65.2 (59.5, 70.6)	0.19	62	77.4 (65.0, 87.1)	0.26
Herswab dry (HS)	284	60.9 (55.0, 66.6)	**0.019**	60	68.3 (55.0, 79.7)	**0.033**
Urine	504	72.2 (68.1, 76.1)	0.57	114	77.2 (68.4, 84.5)	0.19

Agreement between paired devices

	N	+/+	+/-	-/+	-/-	Agreement (%) (95% CI)
WD v DF	300	198	13	12	77	91.7 (87.9, 94.5)
QT v HS	280	163	22	10	85	88.6 (84.3, 92.1)
Urine v WD	249	155	22	17	55	84.3 (79.2, 88.6)
Urine v FS	249	156	21	16	56	85.1 (80.1, 89.3)
Urine v QT	252	157	29	10	56	84.5 (79.5, 88.8)
Urine v HS	240	143	36	9	52	81.3 (75.7, 86.0)

Internal (cellularity) control values, by device

Ct values



Device	Median (Ct, IQR)
Wet Dacron	25.7 (1.6)
Dry Flocked	24.3 (2.1)
Qvintip	25.3 (3.2)
HerSwab	26.0 (6.1)
Urine	24.6 (2.8)

hrHPV positivity rates by device

- Adjusted for cellularity (and unadjusted)

	All samples			CIN2+		
Device		Positive (%) (95% CI)	P-value vs WD	N	Positive (%) (95% CI)	P-value vs WD
Digene Wet Dacron	300	70.3 (70.3) (64.8, 75.4)		69	84.1 (73.3, 91.7)	
FLOQswab dry	300	62.7 (70.0) (56.9, 68.2)	0.057	69	79.7 (68.3, 88.4)	0.66
Qvintip dry	295	65.1 (65.5) (59.3, 70.5)	0.19	62	80.6 (68.6, 89.6)	0.65
Herswab dry	283	67.5 (60.9) (61.7, 72.9)	0.47	60	83.3 (71.5, 91.7)	1

Higher Ct cutoff for HPV16 - unadjusted

Device	HPV 16 Positive defined as ≤ 34.2				HPV 16 Positive defined as ≤ 38.3			
	CIN2+	Sensitivity	<CIN2	Specificity	CIN2+	Sensitivity	<CIN2	Specificity
Wet Dacron	59/69	85.5	150/229	34.5	62	89.9	151	34.1
FLOQswab	58/69	84.1	150/229	34.5	61	88.4	152	33.6
Qvintip	48/62	77.4	145/234	38.0	51	82.3	154	34.2
Herswab	41/60	68.3	132/224	41.1	49	81.7	136	39.3
Urine	88/114	77.2	274/388	29.4	99	86.8	282	27.3

Ease of Use

Device	N	Very easy	Quite easy	Neither easy nor difficult	Quite difficult	Very difficult	Excluded	Total
WD	247	128 (51.8%)	91 (36.8%)	19 (7.7%)	9 (3.6%)	0 (0.0%)	2	249
DF	247	155 (62.8%)	71 (28.7%)	12 (4.9%)	8 (3.2%)	1 (0.4%)	2	249
QT	254	119 (46.9%)	87 (34.3%)	35 (13.8%)	13 (5.1%)	0 (0.0%)	1	255
HS	254	108 (42.5%)	89 (35.0%)	25 (9.8%)	29 (11.4%)	3 (1.2%)	1	255
Urine	501	304 (60.7%)	146 (29.1%)	29 (5.8%)	17 (3.4%)	5 (1.0%)	3	504

Confidence in correctly using device

	N	Very confident	Fairly confident	Not confident	Excluded	Overall Total
WD	247	97 (39.3%)	132 (53.4%)	18 (7.3%)	2	249
DF	247	109 (44.1%)	113 (45.7%)	25 (10.1%)	2	249
QT	254	88 (34.6%)	146 (57.5%)	20 (7.9%)	1	255
HS	253	92 (36.4%)	125 (49.4%)	36 (14.2%)	2	255
Urine	500	308 (61.6%)	170 (34.0%)	22 (4.4%)	4	504

Conclusions

- Positivity rates for CIN2+ are lower than for clinically taken samples
  - Improved by higher C_t cutoff for HPV16
- Highest cellular yields for urine and FloQswab
  - Largest variation for HerSwab
- Digene Wet Dacron and FLOQswab produced similar and better results than Qvintip, Herswab and urine for raw values
  - More similar after adjustment for cell volume
- Referral population - with high HPV positivity
  - Comparison with clinical samples and use in screening samples needed
- Less stringent cutoffs needed for self sampling (esp for HPV16)
  - consequences of false negatives more serious than false positives
  - eg base cutoff on 95% sensitivity for CIN2+