

# Vaginal self sampling in the defaulter population in Dumfries and Galloway

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# History of self sampling research in Dumfries and Galloway

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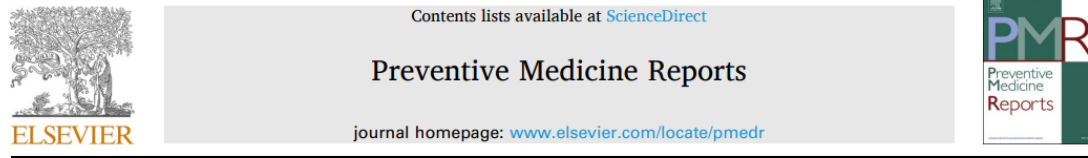
CANCER THERAPY AND PREVENTION

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## Self-sampling as the principal modality for population based cervical screening: Five-year follow-up of the PaVDAg study

Longitudinal follow up on the performance of self sampling in the attender population

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Gwendoline Baxter<sup>4</sup> | James Lawrence<sup>1</sup> | Allan Wilson<sup>5</sup> | Timothy Palmer<sup>6</sup> |  
Marc Arbyn<sup>7,8</sup> | Kate Cuschieri<sup>3</sup>



## The impact of offering multiple cervical screening options to women whose screening was overdue in Dumfries and Galloway, Scotland

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Attitudes and engagement around self sampling as a way to support women who default

Research Article

## Defining Optimal Triage Strategies for hrHPV Screen-Positive Women—An Evaluation of HPV 16/18 Genotyping, Cytology, and p16/Ki-67 Cytoimmunochemistry

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Cancer Epidemiology, Biomarkers & Prevention



Assessment of triage options for primary HPV infection

## HR-HPV testing in self-taken vaginal samples in women who default from Cervical Screening: Lessons from NHS Dumfries and Galloway

### Study objectives:

- To offer something to women whose screening was overdue

### Present Analysis

- Response rate & time taken to return self-taken swabs
- HPV prevalence and sample validity
- Clinical performance of HPV test for detection of CIN2+

## HR-HPV testing in self-taken vaginal samples in women who default from Cervical Screening: Lessons from NHS Dumfries and Galloway

Map showing the position of  
Dumfries  
within the United Kingdom



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### NHS D&G

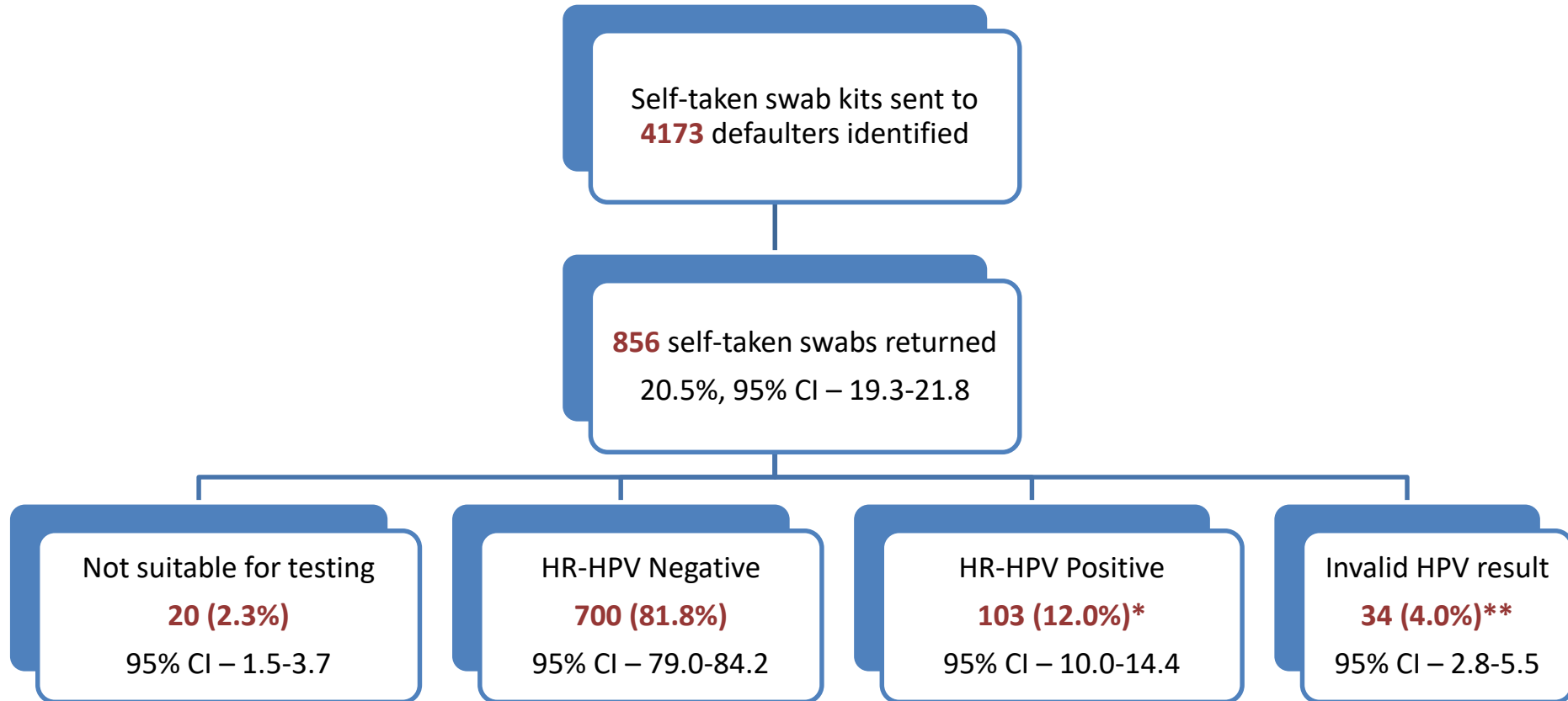
- health board in Scotland
- covers population of 148,000

### Participants

- Defaulters from Scottish Cervical Screening Programme
- aged 25-64
- never attended screening OR
- had defaulted for an invitation  $\geq 6$  months

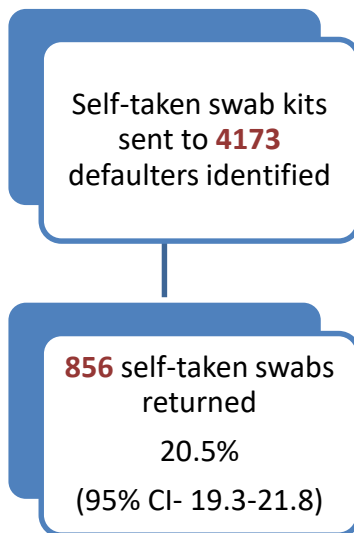
### Methodology

- Multiswab kit (Hologic) & consent forms mailed to address
- Samples returned to D&G by post
- Aptima HPV test performed centrally in Edinburgh
- Results sent back to individual and GP
- If **HPV positive**- Invited to Colposcopy
- If **HPV Negative**- Recommended to attend future screening invitations & 10% invited to Colposcopy as control
- At colposcopy
  - managed according to National Guidelines
  - Vaginal sample and cervical samples (LBC) taken for HPV test

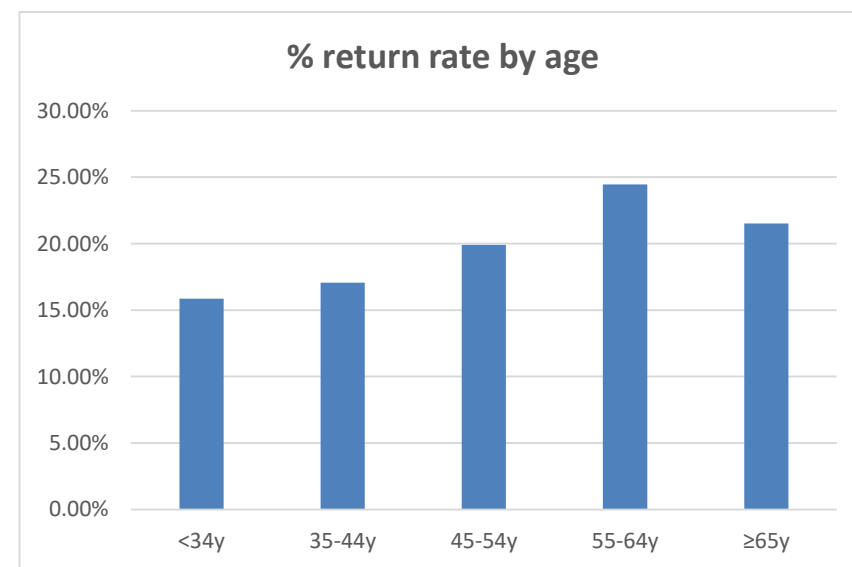


*\*includes one sample positive on repeat swab*

*\*\*includes one sample invalid on repeat swab*

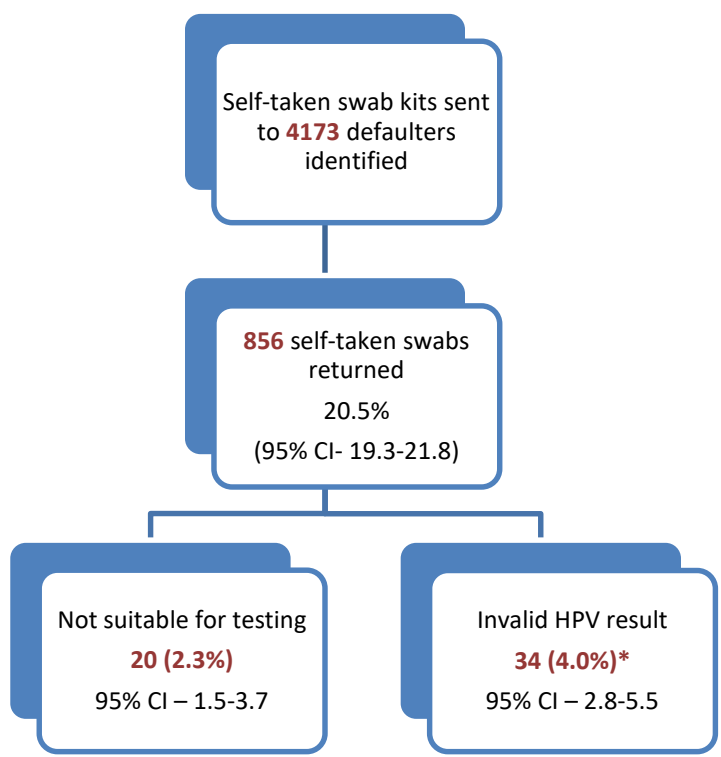


Age Range	Number of self-samples returned	Number of invitations sent	% Return rate	95% CI	P value compared to <34y
<34	102	643	15.9%	13.2-19.0	-
35-44	127	744	17.1%	14.5-20.0	0.55
45-54	216	1085	19.9%	17.6-22.4	0.04
55-64	374	1529	24.5%	22.3-26.7	<0.001
>65	37	172	21.5%	15.8-28.6	0.08
<b>Total</b>	<b>856</b>	<b>4173</b>	<b>20.5%</b>	<b>19.3-21.8</b>	<b>-</b>



### Time to sample return (*Dates available only for 442 samples*)

	N	%
N Samples returned within 14 days	175	39.59%
N Samples returned within 28 days	301	68.10%
N Samples returned within 40 days	349	78.96%
N Samples returned within 60 days	382	86.43%



*\*includes one sample invalid on repeat swab*

## Samples unsuitable for testing

**N = 20 (2.3%, 95% CI – 1.5-3.7)**

Empty tube / insufficient media in tube – 10

No swab in tube – 4

Different swab sent back -1

No consent but sample sent back - 5

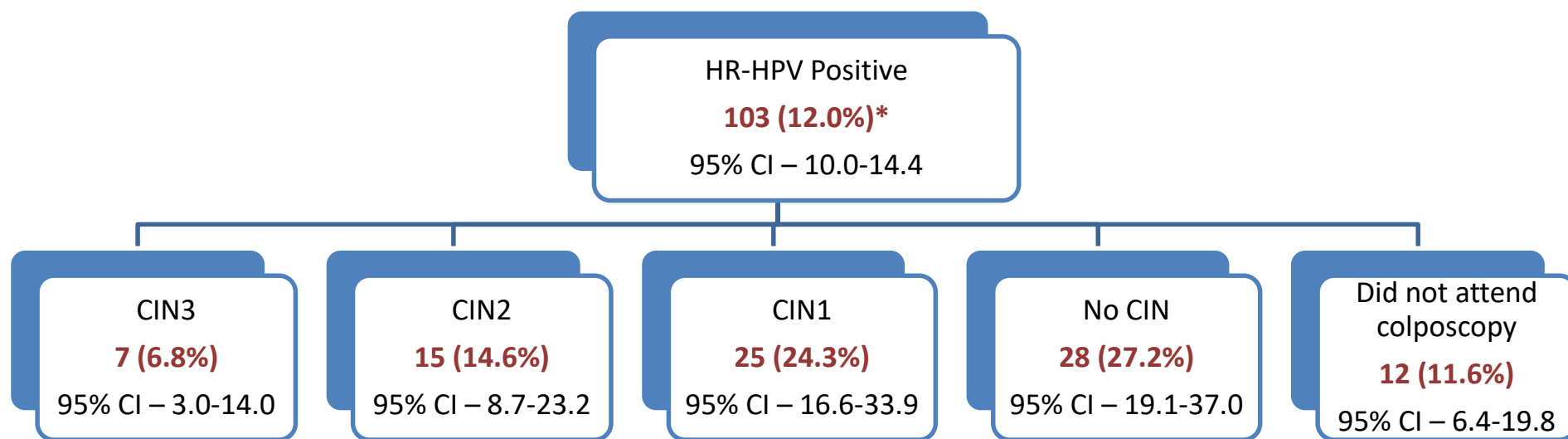
## Samples invalid x 2 times

**N = 34 (4.0%, 95% CI – 2.8-5.5)**

Women were invited to provide a second sample

### 10 repeat swabs received

- 1 positive
- 8 Negative
- 1 Invalid



*\*includes one sample positive on repeat swab*

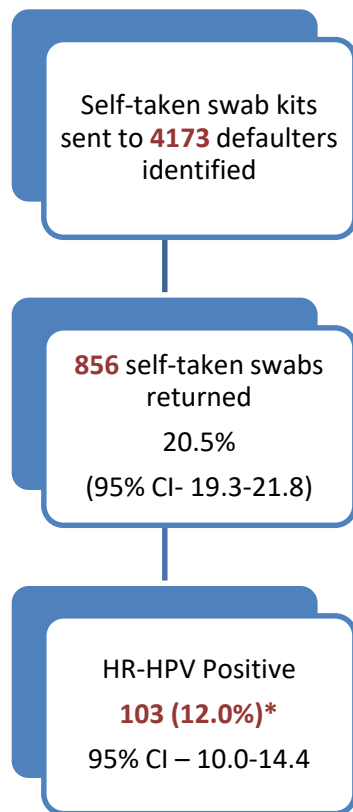
*No biopsy was needed in 11 women*

*2 women categorised as "inadequate for analysis"*

*2 women had VAIN so were excluded*

*1 woman had unsatisfactory colposcopy visit*





*\*includes one sample positive on repeat swab*

## Attendance at Colposcopy (n=101)

*\*2 women had VAIN, so were excluded from analyses*

	N	%
Attended colposcopy	89	<b>88.1%</b>
Did not attend colposcopy	12	11.9%

**88.1% women attended Colposcopy following an HPV positive result**

## Pathology outcomes of HPV positive women who attended colposcopy (n=89)

	N	%
CIN3	7	7.9%
CIN2	15	16.9%
CIN1	25	28.1%
No CIN	28	31.5%
No biopsy needed	11	12.4%
Inadequate for analysis	2	2.3%
Unsatisfactory colposcopy visit	1	1.1%

**PPV for detection of CIN2+ = 24.7% (16.5-35.2)**



# Concordance original vs follow up samples

HPV (+/-/INVALID)	SELF-TAKEN SWAB	+	+	+	+	+	-	-	-
	COLP. VISIT SWAB	+	+	-	-	INVALID	-	+	+
	COLP. VISIT LBC	+	-	+	-	-	-	-	+
CYTOLOGY (N)	+	16	1	-	-	-	1	-	1
	-	7	27	1	21	2	23	6	-
	UNSATISFACTORY/ INSUFFICIENT CELL MATERIAL	2	5	-	5	-	3	-	1
HISTOLOGY (N)	CIN2+	13	5	-	3	1	-	-	-
	CIN1/NO CIN/NO BIOPSY REQUIRED	12	28	1	23	1	27	6	2

White cells= HPV Positive cohort: (n=87). Grey cells= HPV Negative (control) cohort (n=35).

Figures in red are where HPV result was consistent in swab and subsequent LBC sample

Interestingly repeatability of HPV status on subsequent LBC samples (after initial vaginal sample) relatively low. Although higher in samples associated with CIN2+. This reconciles with observations of other studies (BSCCP 2023)

**TABLE 1** Clinical performance of Hr-HPV testing on *self-taken* vaginal samples for the detection of CIN2+ over one to two screening rounds representing up to 69 months of follow-up on a cohort of 4617 women recruited to the PaVDAg study

Test	Sensitivity % (95% CI)		Specificity % (95% CI)		PPV %		cNPV %	
	First round	Second round	First round	Second round	First round	Second round	First round	Second round
<b>CIN2+</b>								
Hr-HPV (any)+	91.4 (85.5-95.2)	88.0 (82.2-92.1)	85.9 (84.8-86.8)	86.1 (85.1-87.1)	16.5	20.7	0.3	0.6
HPV 16/18+	59.9 (51.6-67.6)	55.2 (47.7-62.5)	96.2 (95.6-96.7)	96.2 (95.6-96.8)	32.5	37.5	1.3	1.9
LBC ≥ BNA	73.7 (65.8-80.3)	62.8 (55.4-69.8)	97.3 (96.8-97.8)	97.0 (96.5-97.5)	45.5	46.4	0.8	1.6
<b>CIN3+</b>								
Hr-HPV (any)+	95.2 (87.5-98.4)	93.1 (85.9-97.0)	84.9 (83.8-85.8)	85.1 (84.1-86.1)	9.4	11.3	0.1	0.2
HPV 16/18+	63.9 (52.5-73.9)	58.8 (48.6-68.3)	95.5 (94.9-96.1)	95.4 (94.7-96.0)	18.9	22.3	0.6	1.0
LBC ≥ BNA	77.1 (66.3-85.3)	64.7 (54.6-73.7)	96.4 (95.9-96.9)	96.0 (95.4-96.5)	26.0	26.6	0.4	0.8

Note: Data represent absolute sensitivity and specificity for CIN2+ and CIN3+ (and 95% CI), the computed PPV (positive predictive value) and cNPV (complement of the negative predictive value, 1-NPV). Hr-HPV results are stratified according to “any” Hr-HPV detected in addition to the detection of HPV 16 and/or 18 only. The performance of liquid-based cytology (LBC) at the level of borderline nuclear abnormality and above (≥BNA) is provided as context.

Above table summarises performance of HPV testing in self samples in “attender population”; taken from Stanczuk et al IJC 2022

PPV of HPV+ self sample for CIN2+ slightly lower (16.5%) in attender population vs defaulter population (24.7%) as may be expected

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# What next?

- Follow up-
- 42 treatments—all CIN 2/3 and some CIN 1
- 19 have had TOC smear follow up
- 23 overdue follow up
- Further work-
- Numbers attending for screening after receiving pack

Overwhelmingly positive  
“Defaulter” name seen negatively  
Fantastic option  
Would always prefer this option  
Fear of discomfort  
Convenience



- Self sampling as an offer to the defaulter population in Dumfries and Galloway was associated with ~20% engagement
- Future work to assess subsequent screening behaviours in those who did engage in will be important
- Invalidity rate <5% but still higher than clinician taken samples. Further technical optimisation of sampling/testing on self taken samples is worthwhile.
- Increasing number of countries offering self-sampling as an option for defaulter population or as a routine offer
- Let Scotland be the next!!