



The Capital Region  
of Denmark

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DENMARK

# HPV Self-sampling

Current situation and evolution in the future



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BD Diagnostics  
Genomica  
Hologic  
Self-Screen

## SELF-SAMPLING

A cervical screening sample taken by the woman either without medical staff assistance or with supervision; in the privacy of own home, or at clinic.

Self samples for cervical cancer screening are suitable for HPV tests

Self-sample material types include:

Self-sampling utensils (brush)

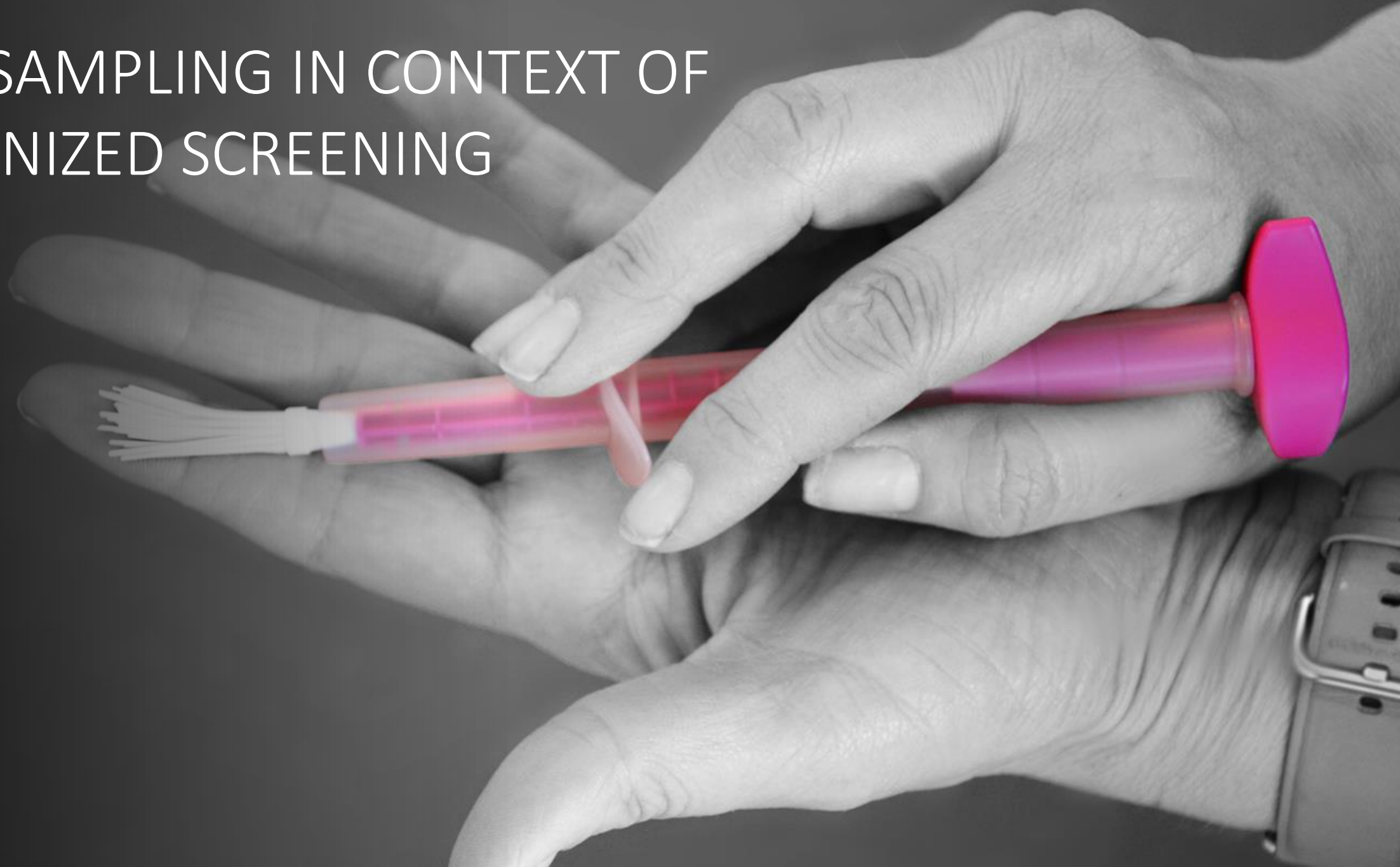
Urine collection devices







# SELF-SAMPLING IN CONTEXT OF ORGANIZED SCREENING



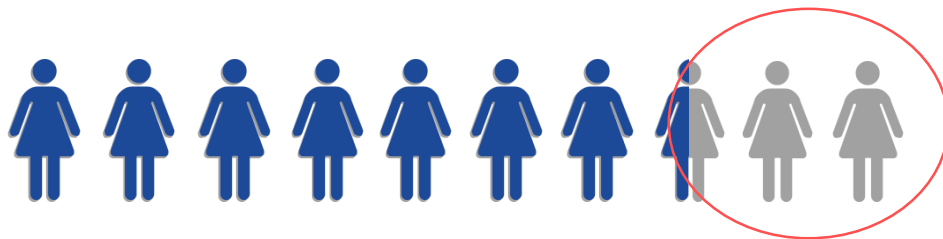
## ORGANISED CERVICAL SCREENING IS CHALLENGED BY DECLINING PARTICIPATION RATES

In Denmark, women between 23-65 years are recommended to attend cervical cancer screening at their own general practitioner (GP)

Screening coverage: 75% (~25% do not attend screening)

~45% of all newly diagnosed cancer cases are found women, who do not attend screening (non-attenders)<sup>1</sup>

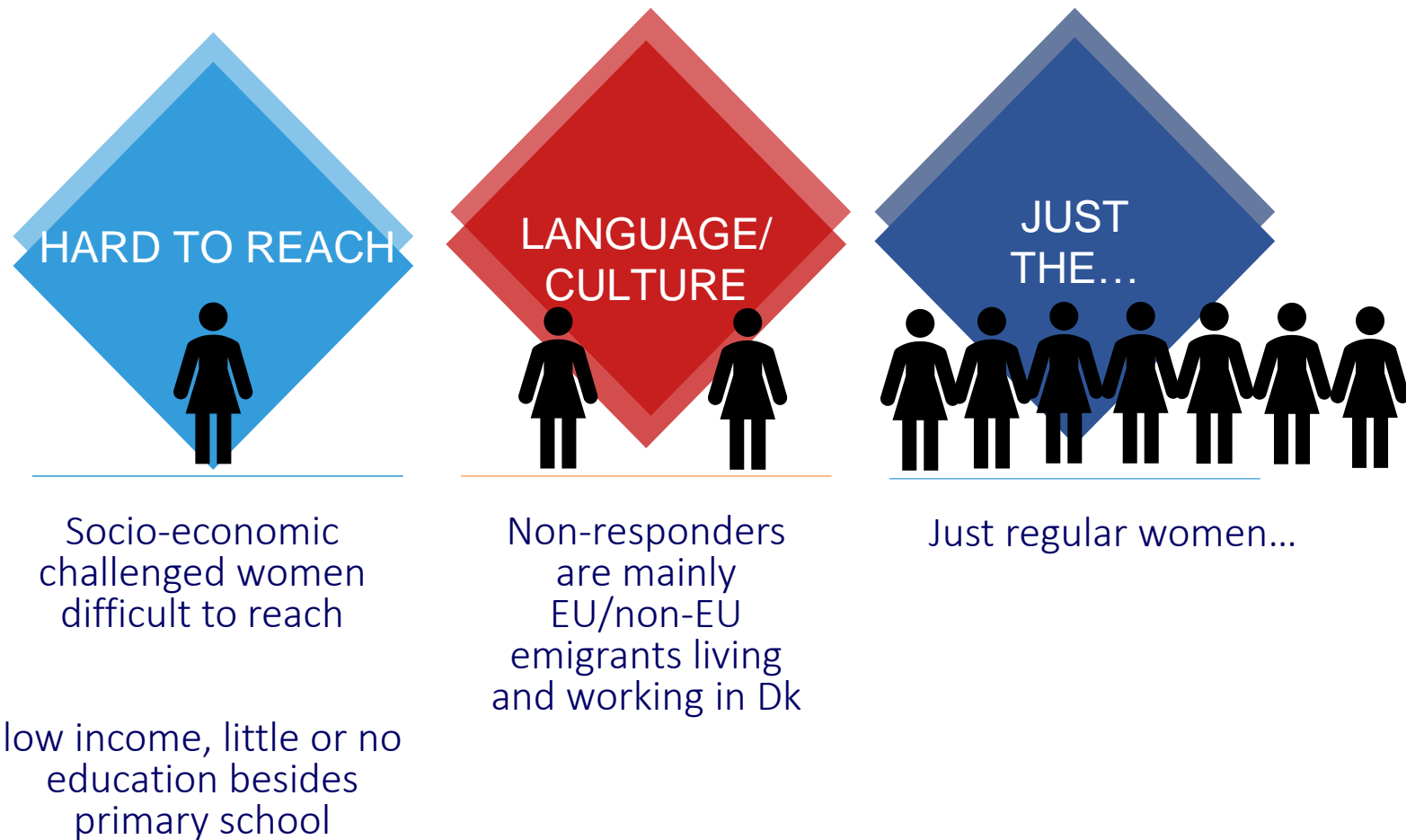
Similar situation in all countries with organized screening



~ **75%** are covered by screening ( by invitation or opportunistic)

~ **45% cancers in non-attenders**<sup>1,2</sup>

## SCREENING NON-ATTENDERS



# CREATING A USER FOCUSED VALUE-CHAIN

Availability of service is paramount to recruitment of non-attenders!

1

SIMPLE

**Women don't go for screening because..**

- Embarrassment
- Fear of examination
- Dont believe its relevant for them
- Thinks vaccination gives full cover
- Procrastinating..

2

EASY

**Adding to the value-chain**

- In privacy of own home
- Multi-language information material
- On-line ordering
- No paperwork to fill out
- Ease of use
- Web/App portal
- E-Mail contact address
- Call-in Hot-line
- No cost

3

SAFE

**Quality Assurance for the Lab**

- Validated stability of device
- Validated performance of the HPV diagnostic test
- Safe patient identification



# SELF-SAMPLING INVITATION STRATEGIES & OUTCOMES

## OPT-IN:

Women are invited and actively accepts

## OPT-OUT:

Women are invited and must actively decline to not receive self-sample

## DIRECT-MAIL/MAIL-TO-ALL:

Women are mailed self-sampling kit directly

Invitation strategy	Country & Study design	Study size	Target age (years)	Participation Rate	Reference
Opt-in	Denmark Cross sectional	N=4874	27-64	20% by self- sampling+ 10% by clinician taken samples after invitation	Lam JUH et al., 2017 (1)
	Sweden Cross sectional	N=369	35-50	32.0%	Stenvall et al., 2007
	Sweden Cross sectional	N=3000	30-58	39.0%	Sanner K et al., 2009
	Sweden RCT	N=800	30-62	16.0%	Broberg et al., 2013
Opt-in & mail-to-all	Italy RCT	Opt in: N=622 Mail-to-all: N=622	35-65	Opt-In : 8.7% Mail-to-all: 19.6%	Giorgi Rossi et al., 2011
	Italy RCT	Opt in: 4513 Mail-to-all: 4516	30-64	Opt-In: 10.5% Opt-out: 19.6%	Giorgi Rossi et al., 2015
Opt-out	Netherlands RCT	N= 2546	30-50	28.9%	Bais et al., 2007
	Netherlands Cohort	N=27,792	30-60	26.6%	Gök et al., 2010
	Sweden Cross sectional	N=8000	30-65	39.0%	Gyllensten et al., 2011
	UK RCT	N=1500	NR	6.4%	Szarewski et al., 2011
	Finland RCT	N=2,397	30-60	27.7%	Virtanen et al., 2011
	Sweden RCT	N=2000	39-60	34.0%	Wikström et al., 2011
	Netherlands RCT	N=26,145	26-63	30.8%	Gök et al., 2012
	Sweden RCT	N=1000	32-65	14.7%	Darlin et al., 2013
	France RCT	N=8,829	35-69	18.4%	Sancho-Garnier et al., 2013
	UK RCT	N=3,000	25-65	13.0%	Cadman et al., 2014

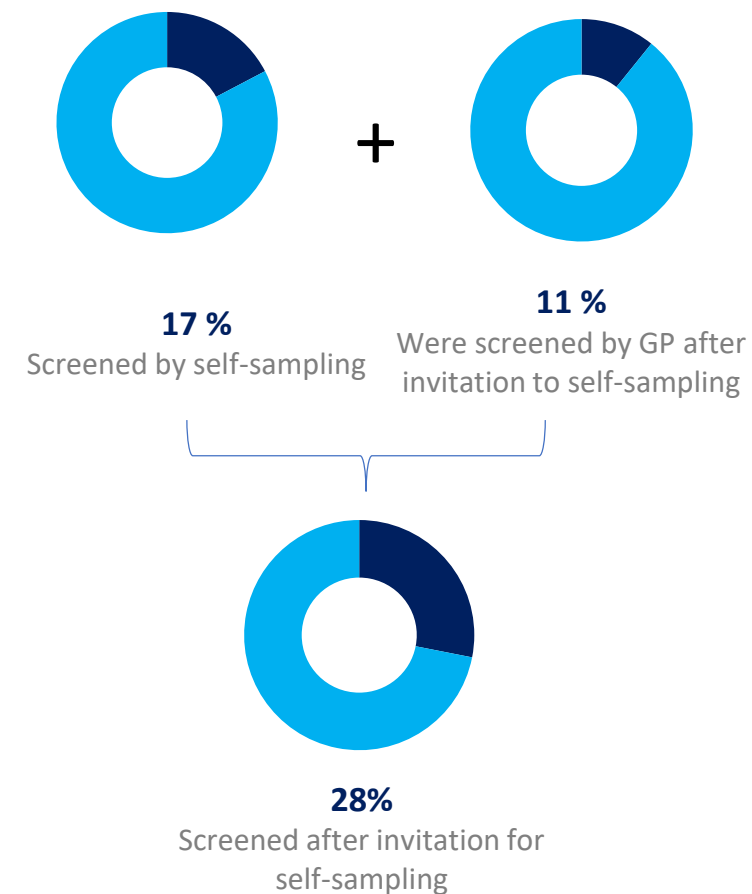
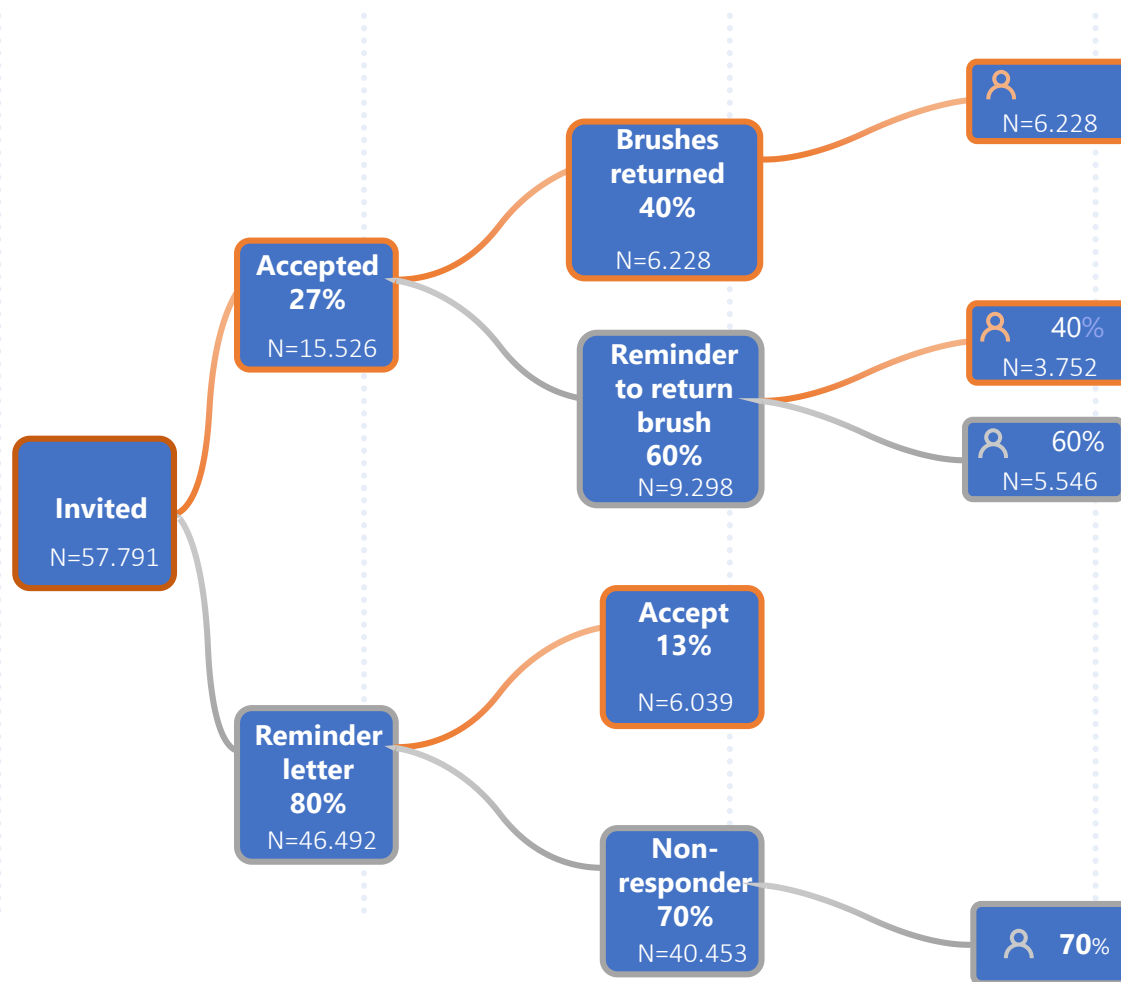
# SELF-SAMPLING UPTAKE AND RETURN RATES IN CAPITAL REGION OF DENMARK IMPLEMENTATION 2017-2019

## Self-sampling Flow

The flow of activities from invitation to end-of-algorithm

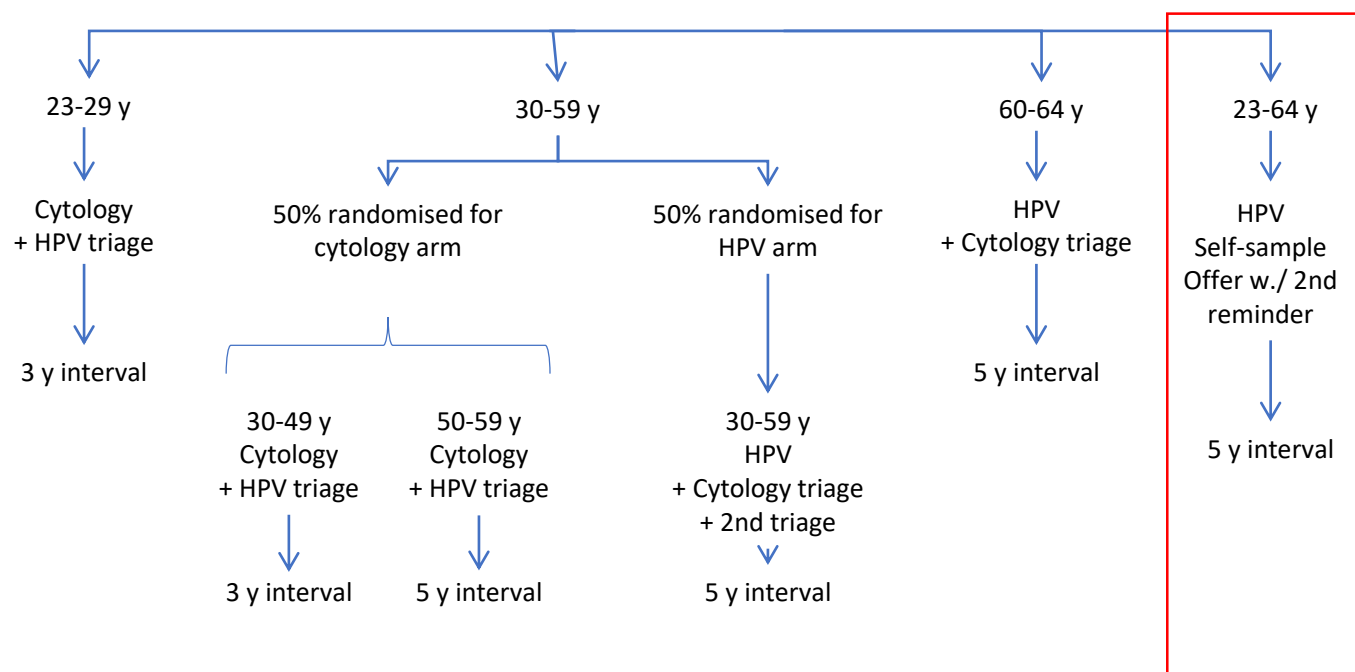
Screened by self-sampling  
17.3%  
of all invited

82.7%  
Non-responders  
of all invited



# SELF-SAMPLING IN CONTEXT OF ORGANIZED SCREENING – DENMARK 2020

[ Implementation date 1<sup>st</sup> September 2020]



[ Implementation date undecided but 1<sup>st</sup> January 2021 suggested]

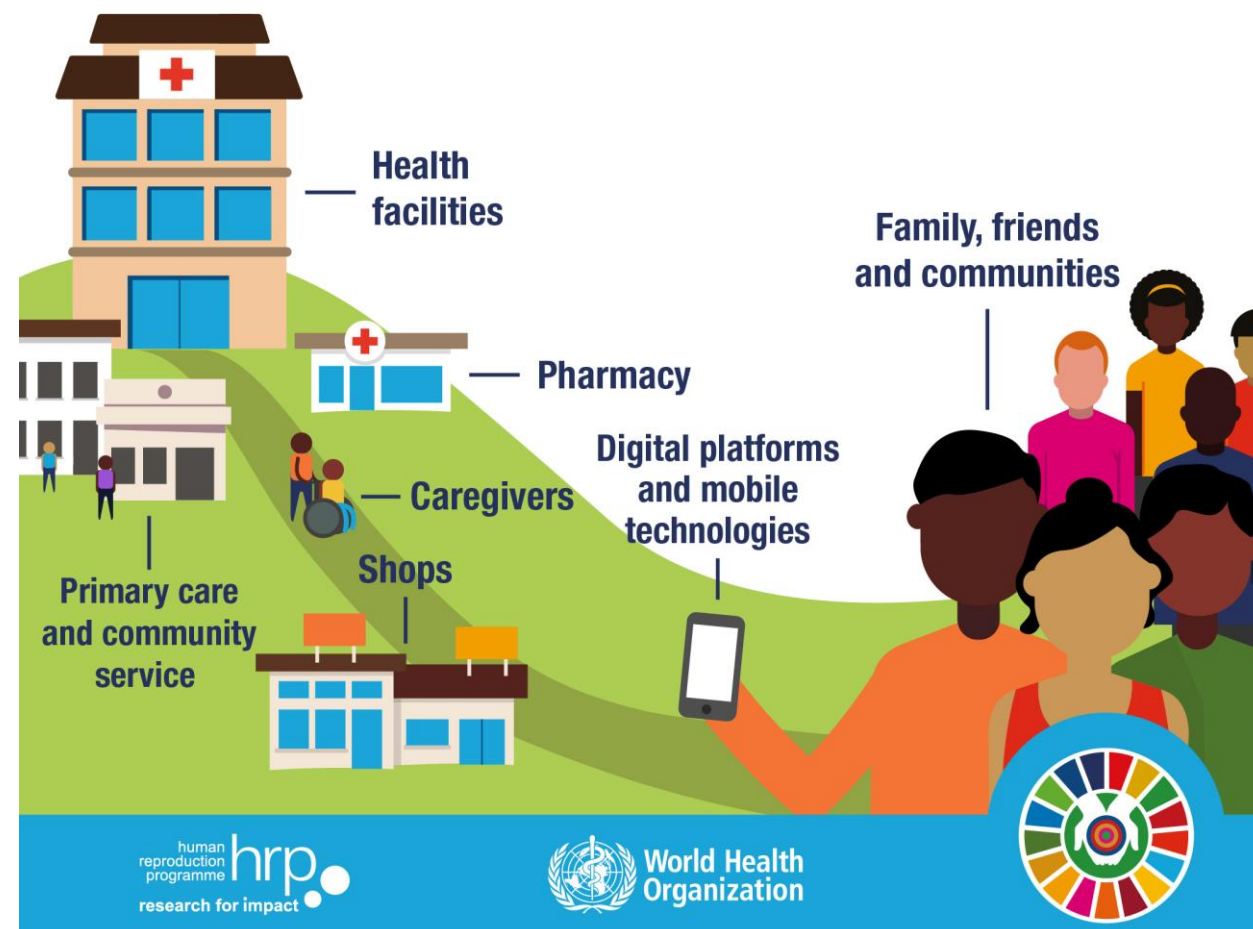
SELF-SAMPLING IN COUNTRIES  
WITHOUT ORGANIZED  
SCREENING

AND

LOW- AND MIDDLE INCOME  
COUNTRIES

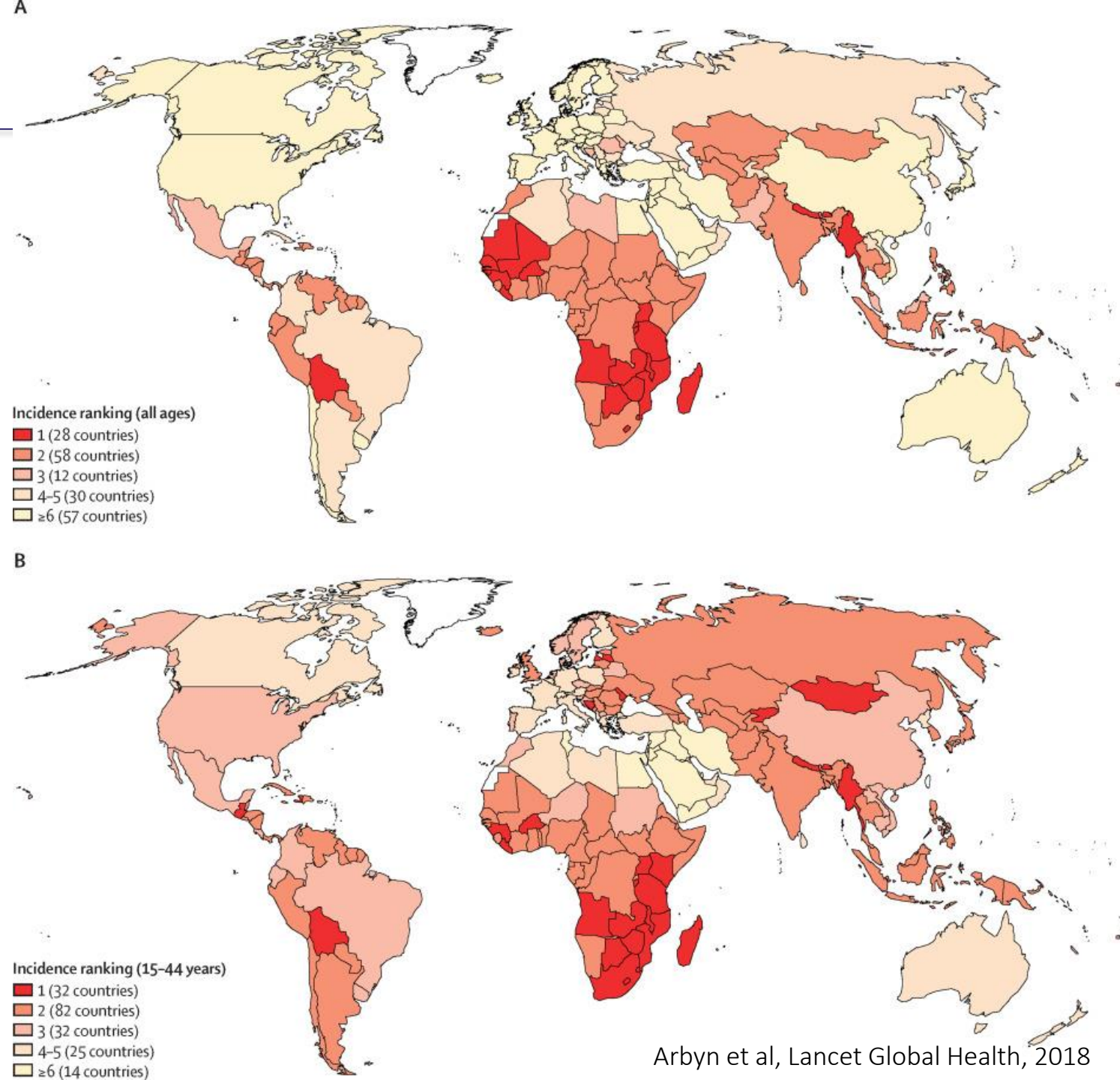
## ACCESS TO SELF-CARE INTERVENTIONS IMPROVE PEOPLE'S AUTONOMY

SELF CARE CAN BE ACCESSED THROUGH:



## SELF-SAMPLING IN CONTEXT OF COUNTRIES WITHOUT ORGANIZED SCREENING

Ranking of cervical cancer incidence burden in 2018 relative to all other cancer sites in women of all ages (A) and aged 15–44 years (B)





# ANALYTICAL STABILITY OF COLLECTED HPV SELF-SAMPLES ALLOWS FOR ADAPTION TO LOCAL HEALTH CARE INFRASTRUCTURE AND GEOGRAPHICAL CHALLENGES

Contents lists available at ScienceDirect

**Papillomavirus Research**

Journal homepage: [www.elsevier.com/locate/plyr](http://www.elsevier.com/locate/plyr)

### Time and temperature dependent analytical stability of dry-collected Evalyn HPV self-sampling brush for cervical cancer screening

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Dry self-sampling brushes  
Analytical stability  
HPV  
Cervical cancer screening

**ABSTRACT**

As a new initiative, HPV self-sampling to non-attenders using the dry Evalyn self-sampling brush is offered in the Capital Region of Denmark. The use of a dry brush is largely uncharted territory in terms of analytical stability. In this study we aim to provide evidence on the analytical quality of dry HPV self-sampling brushes as a function of time and temperature.

We assessed the analytical stability of dry stored Evalyn brushes at three different temperatures, (4 °C, room temperature, 30 °C) and five different storage time points; T = 0 (baseline), 2, 4, 8, 16, and 32 weeks prior to HPV analysis using the BD Oncoarray HPV assay.

Mean Ct value of the Oncoarray internal control was used as a comparator of cellularity across time and temperatures, with no or only borderline statistical differences observed. HPV detection was stable throughout the five time points. In addition, analytically amplifiable DNA copy numbers and DNA fragmentation was assessed using the Agilent PlexE Exome QC assay, with no or only borderline statistical differences observed.

In conclusion, the Evalyn brush is analytically stable with respect to human genomic material and HPV detection for up to 32 weeks at temperatures ranging from 4 °C to 30 °C.

**1. Introduction**

Human papillomavirus (HPV) based cervical cancer screening [1–7] in combination with self-collected samples is increasingly being investigated as an alternative to clinician collected samples aiming at increasing the coverage of cervical screening worldwide [8–12]. In organized screening programs, HPV self-sampling is considered as a potential alternative to screening non-attending women [13–15]. In Denmark, women aged 23–65 years are invited for screening for cervical cancer free of charge as a public cancer prevention program. In Denmark approximately 50% of all cervical cancers are diagnosed amongst the 25% women who do not participate in screening after being invited [16,17], as also observed in similar North European countries with nationwide cervical cancer screening programs [18,19]. In qualitative studies evaluating women's preferences in screening the main reasons for non-participation are reported as a combination between the discomfort/embarrassment of the associated gynecological examination and the general inconvenience of the doctor's visit [20–22]. To address the reasons for non-attendance, the Capital Region of Denmark launched a pilot implementation program in 2014, the

Copenhagen Self-sampling initiative (CSI), offering HPV self-sampling brushes to approx. 24,000 screening non-attenders [9,14,23]. In CSI, we distributed the Evalyn self-sampling brush to invited women who actively opted in after invitation using a purpose designed and developed self-sampling kit [9]. After sampling in the privacy of the woman's own home, the women returned the brush in a dry state to the laboratory for HPV analysis using a postage pre-paid envelope.

Multiple approaches to self-sampling have been described but two types of self-sampling devices have predominantly been used for larger self-sampling initiatives; a "wet" brush that requires the woman to re-suspend the brush in a supplied media (immediately after sampling) or a "dry" brush, shipped directly to the laboratory after sampling without further interaction by the woman. Comparing these two approaches, the use of a dry shipped self-sampling brush in our opinion holds a number of logistical and safety related advantages independently of the self-sampling device. Firstly, a dry brush can be transported by mail between the women and the laboratory without the potential for spillage and leakage during collection and transport. Secondly, any risk of potential skin irritation and harm by accidental consumption e.g. by a child in the household, is eliminated. Thirdly, shipment of liquid



Hvidovre Hospital

Welcome to the HPV self-sample site

ENGLISH

Please type in your ID number from your letter in the area on your right →

Your ID code (Tast Selv Kode)

1234 5678

Next Step

INFORMATION ABOUT HPV SCREENING AND SELF-SAMPLING TEST

- Guidance for HPV self-sampling
- HPV self-sample for women with disabilities
- Do you want to know more about HPV and cervical cancer?
- Frequently asked questions and answers
- Get your test result on Sundhed.dk

DID YOU KNOW...  
Insert here

*Every year approximately 15,000 Danish women are diagnosed with cell changes and annually 350 Danish women are diagnosed with cervical cancer - more than half are below the age of 50 years.*

VIDEO: THIS IS HOW YOU USE THE KIT

Se på dansk

View in english

If you have any questions you can contact us on mail [hvh-mpl@regionh.dk](mailto:hvh-mpl@regionh.dk) or Phone 20 3124 64

# WEB & TELECOMMUNICATION INFRASTRUCTURE ALLOWS FOR “EASY” ADMINISTRATION OF SERVICE

## SELF-SAMPLING IN THE FUTURE

### Organized screening programs

Self-sampling will become a free-of-choice offer along with clinician collected samples, allowing for resource re-allocation in the primary health care sector, making cervical screening more accessible, cheaper, convenient

### Without organized screening programs

Self-sampling enables cervical cancer screening outside the classical restraints of health care infrastructure; cheap, effective, mobile, community engaging