HPV Self-sampling
Current situation and evolution in the future
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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 IS AN EQUALLY GOOD SAMPLE AS A CLINICIAN COLLECTED SAMPLE

META ANALYSIS
COMPARATIVE PERFORMANCE ANALYSIS
CLINICAL IMPLEMENTATION STUDIES
VALIDATION METHODOLOGY
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)\(^1\)

Similar situation in all countries with organized screening

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

\(~45\%\) cancers in non-attenders\(^1,2\)

Kirchner et al. Gynecol Oncol. 2011
Dugue PA et al. Preventive Medicine. 2012;54(3-4)
SCREENING NON-ATTENDERS

**HARD TO REACH**
- Socio-economic challenged women difficult to reach
  - low income, little or no education besides primary school

**LANGUAGE/CULTURE**
- Non-responders are mainly EU/non-EU emigrants living and working in Dk

**JUST THE...**
- Just regular women...
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
   • Don’t believe it’s 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

<table>
<thead>
<tr>
<th>Invitation strategy</th>
<th>Country &amp; Study design</th>
<th>Study size</th>
<th>Target age (years)</th>
<th>Participation Rate</th>
<th>Reference</th>
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<tbody>
<tr>
<td><strong>Opt-in</strong></td>
<td>Denmark Cross sectional</td>
<td>N=4874</td>
<td>27-64</td>
<td>20% by self- sampling+ 10% by clinician taken samples after invitation</td>
<td>Lam JUH et al., 2017 (1)</td>
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<td>Sweden Cross sectional</td>
<td>N=369</td>
<td>35-50</td>
<td>32.0%</td>
<td>Stenvall et al., 2007</td>
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<td>Sweden Cross sectional</td>
<td>N=3000</td>
<td>30-58</td>
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<td>Sanner K et al., 2009</td>
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<td></td>
<td>Sweden RCT</td>
<td>N=800</td>
<td>30-62</td>
<td>16.0%</td>
<td>Broberg et al., 2013</td>
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<td><strong>Opt-in &amp; mail-to-all</strong></td>
<td>Italy RCT</td>
<td>Opt in: N=622 Mail-to-all: N=622</td>
<td>35-65</td>
<td>Opt-In: 8.7% Mail-to-all: 19.6%</td>
<td>Giorgi Rossi et al., 2011</td>
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<td>Opt in: 4513 Mail-to-all: 4516</td>
<td>30-64</td>
<td>Opt-In: 10.5% Opt-out: 19.6%</td>
<td>Giorgi Rossi et al., 2015</td>
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<td>Netherlands RCT</td>
<td>N= 2546</td>
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<td>28.9%</td>
<td>Bais et al., 2007</td>
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<td>Netherlands Cohort</td>
<td>N=27,792</td>
<td>30-60</td>
<td>26.6%</td>
<td>Gök et al., 2010</td>
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<td>UK RCT</td>
<td>N=1500</td>
<td>NR</td>
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<td>Darlin et al., 2013</td>
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<td>France RCT</td>
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<td>25-65</td>
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<td>Cadman et al., 2014</td>
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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

Invited
N=57,791

Screened by self-sampling 17.3% of all invited

Screened by self-sampling
17% Screened by self-sampling
11% Were screened by GP after invitation to self-sampling

Non-responders
82.7% of all invited

Accept 27%
N=15,526

Reminder letter 80%
N=46,492

Accept 13%
N=6,039

Brushes returned 40%
N=6,228

Reminder to return brush 60%
N=5,298

Non-responder 70%
N=40,453

70%

13%
N=5,546

N=6,228

N=3,752

N=46,492

N=6,039

N=5,298

N=40,453

Courtesy of Dr. Ejegod, presented EUROGIN 2019, 6th December, FC16
SELF-SAMPLING IN CONTEXT OF ORGANIZED SCREENING – DENMARK 2020

[Implementation date 1\textsuperscript{st} September 2020]

- **23-29 y**
  - Cytology + HPV triage
  - 3 y interval
  - 30-49 y Cytology + HPV triage
    - 3 y interval

- **30-59 y**
  - 50% randomised for cytology arm
  - 50% randomised for HPV arm
  - 5 y interval
  - 30-59 y HPV
    - Cytology triage + 2nd triage
      - 5 y interval

- **60-64 y**
  - HPV + Cytology triage
  - 5 y interval

- **23-64 y**
  - HPV Self-sample Offer w/ 2nd reminder
  - 5 y interval

[Implementation date undecided but 1\textsuperscript{st} January 2021 suggested]
SELF-SAMPLING IN COUNTRIES WITHOUT ORGANIZED SCREENING

AND

LOW- AND MIDDLE INCOME COUNTRIES
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)

Arbyn et al, Lancet Global Health, 2018
ANALYTICAL STABILITY OF COLLECTED HPV SELF-SAMPLES ALLOWS FOR ADAPTION TO LOCAL HEALTH CARE INFRASTRUCTURE AND GEOGRAPHICAL CHALLENGES

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.