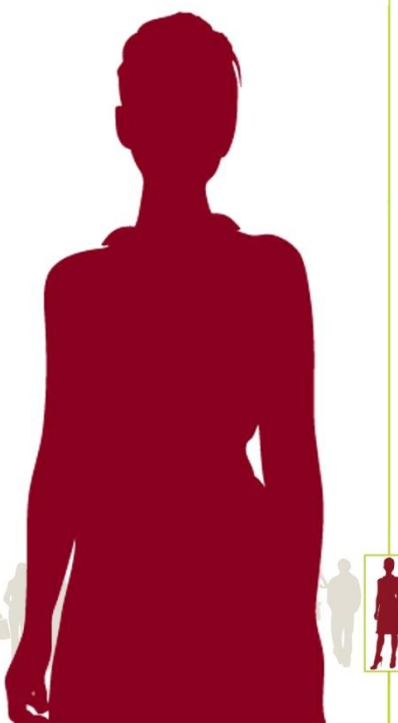
Home sampling for hrHPV testing in Central Denmark Region



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Department of Public Health Programmes
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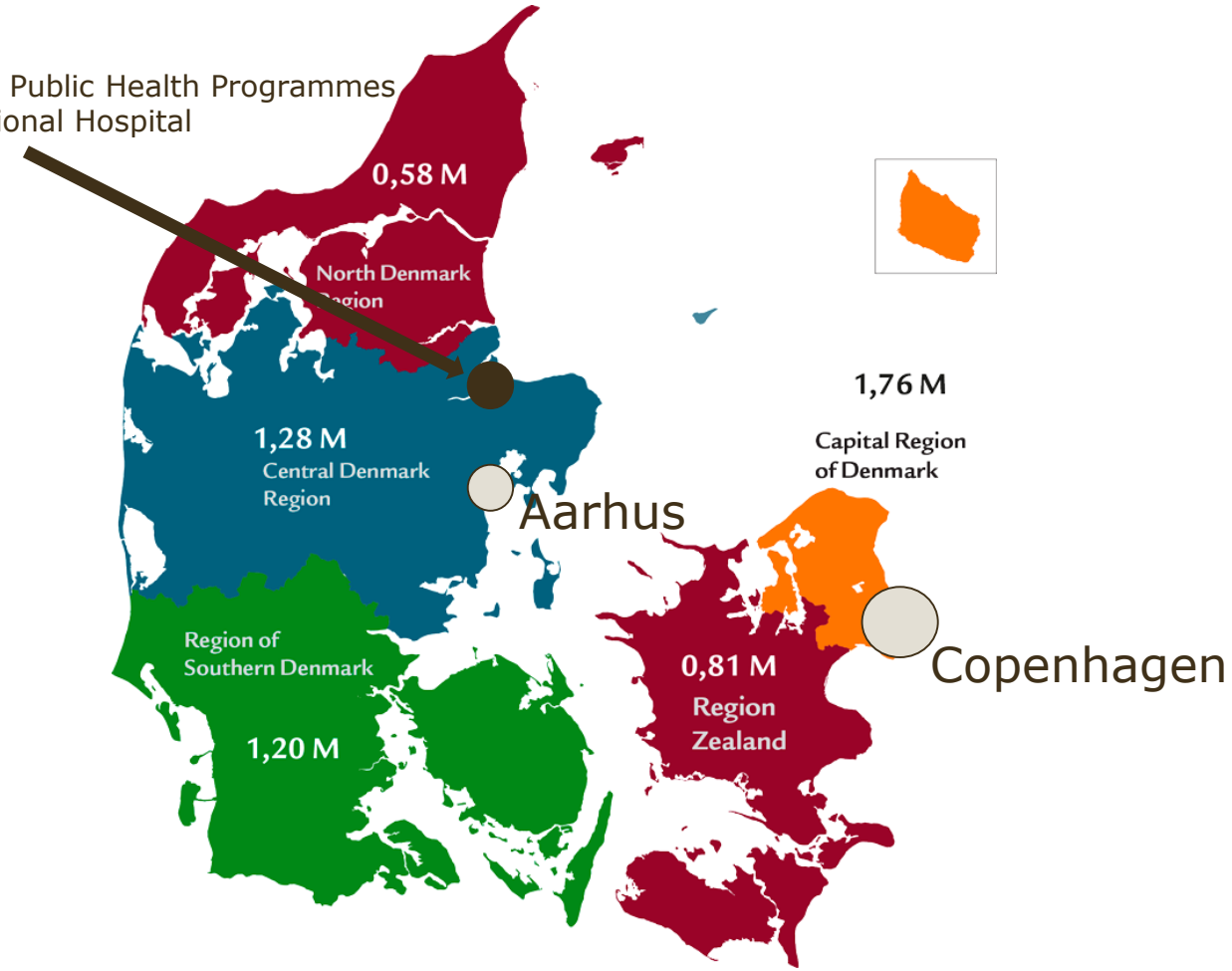


Content

- Introductary remarks
- Initiative to increase up-take in the Danish cervical cancer screening programme
- Patient perspective and laboratory work
- Inequality and inequaty
- Conclusions

Terminology

Sex Transm Infect 2016;**0**:1.
doi:10.1136/sextrans-2016-052841

Self-sampling and self-testing for STIs and HIV: the case for consistent nomenclature

Emma M Harding-Esch,[1,2] Emma Hollis,[1] Hamish Mohammed,[1] John M Saunders[1]

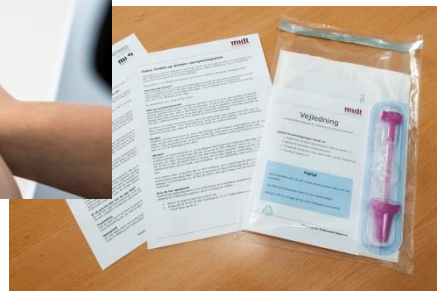
- Home sampling *or* home based self sampling

- *as opposed to:*

- Home testing (Danish ”hjemme-test”)
- Self testing

Home sampling and screening

Colorectal cancer screening programme since 2014



HPV screening project

Cervical cancer screening in DK

- At present
  - 23 to 49 years: Invited every 3rd year
  - 50 to 64 years: Invited every 5th year
- One invitation and up to two reminders
- Women must see a doctor for a gynecological examination
- Opportunistic testing is widespread
- Samples primary analysed by microscopy (<60 years) or hrHPV test (60+)
- All testing and treatment is free of charge

- Participation* in 2014: 65.1%
- Coverage** in 2014: 75.1%**

* Within 365 days after an invitation
** Proportion having a cytology in latest 3 or 5 years (depending on age)

Barrierer for screening for livmoderhalskræft

UGESKR LÆGER 167/46 | 14. NOVEMBER 2005

Cand.comm. Mette Marie Espersen &
overlæge Iben W. Holten

Kræftens Bekæmpelse,
Forebyggelses- og dokumentationsafdelingen

Reasons for non-participation

- Qualitative study among 48 women, 23 to 39 years of age

- Reasons for non-participation:
  - lack of knowledge
  - not feeling at risk
  - fear of getting a cancer diagnosis
  - gynecological examination
  - problems in relation to seeking a doctor
  - practicalities
  - not wanting to participate

ABSTRACT

Objective To obtain large scale and generalisable data on the long term predictive value of cytology and human papillomavirus (HPV) testing for development of cervical intraepithelial neoplasia grade 3 or cancer (CIN3+).

Design Multinational cohort study with joint database analysis.

Setting Seven primary HPV screening studies in six European countries.

Participants 24 295 women attending cervical screening enrolled into HPV screening trials who had at least one cervical cytology or histopathology examination during follow-up.

Main outcome measure Long term cumulative incidence of CIN3+.

Results The cumulative incidence rate of CIN3+ after six years was considerably lower among women negative for HPV at baseline (0.27%, 95% confidence interval 0.12% to 0.45%) than among women with negative results on cytology (0.97%, 0.53% to 1.34%)). By comparison, the cumulative incidence rate for women with negative cytology results at the most commonly recommended screening interval in Europe (three years) was 0.51% (0.23% to 0.77%). The cumulative incidence rate among women with negative cytology results who were positive for HPV increased continuously over time, reaching 10% at six years, whereas the rate among women with positive cytology results who were negative for HPV remained below 3%.

Conclusions A consistently low six year cumulative incidence rate of CIN3+ among women negative for HPV suggests that cervical screening strategies in which women are screened for HPV every six years are safe and effective.

BMJ

RESEARCH

Long term predictive values of cytology and human papillomavirus testing in cervical cancer screening: joint European cohort study

Joakim Dillner, professor,[1] Matejka Rebolj, researcher,[2] Philippe Birembaut, professor and head of department,[3] Karl-Ulrich Petry, professor,[4] Anne Szarewski, clinical consultant and honorary senior lecturer,[5] Christian Munk, researcher ,[6] Silvia de Sanjose, researcher,[7,9] Pontus Naucler, research fellow,[1] Belen Lloveras, researcher,[7] Susanne Kjaer, professor,[6,8] Jack Cuzick, professor and head of department,[5] Marjolein van Ballegooijen, professor,[2] Christine Clavel, professor,[3] Thomas Iftner, professor and head of section[10]

Cite this as: *BMJ* 2008;377:a1754
doi:10.1136/bmj.a1754

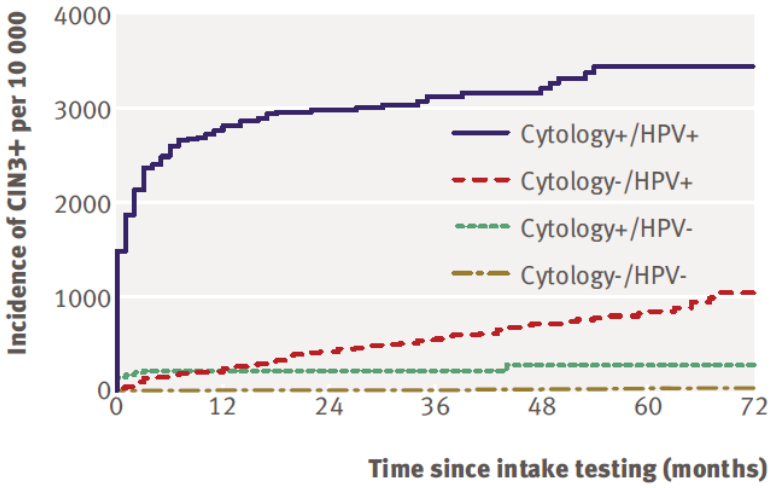
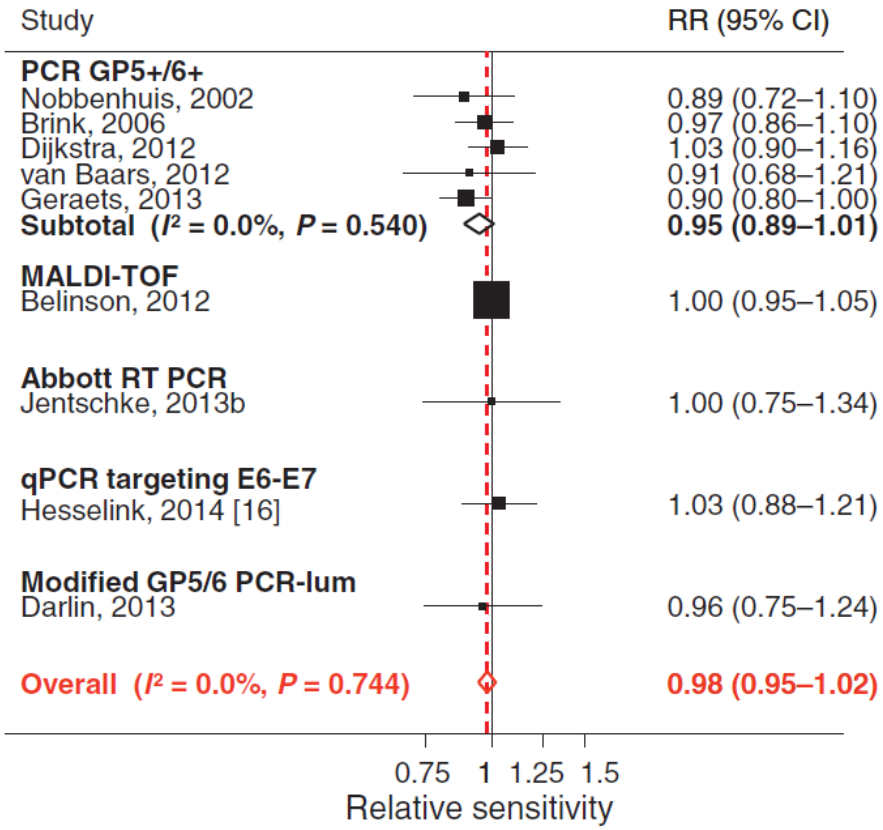
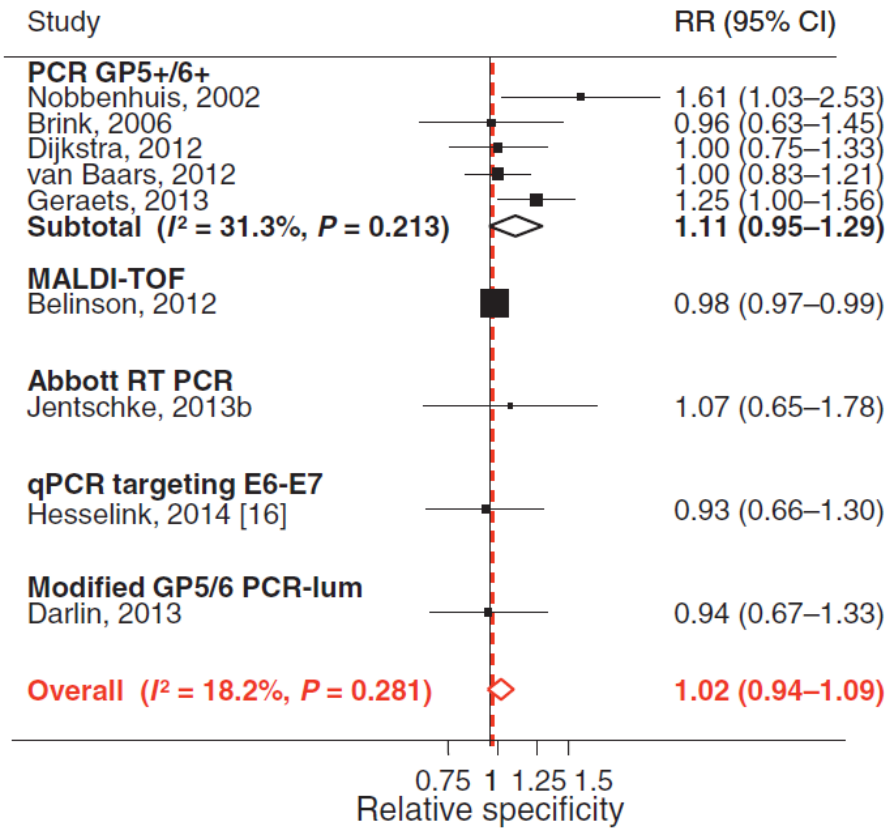
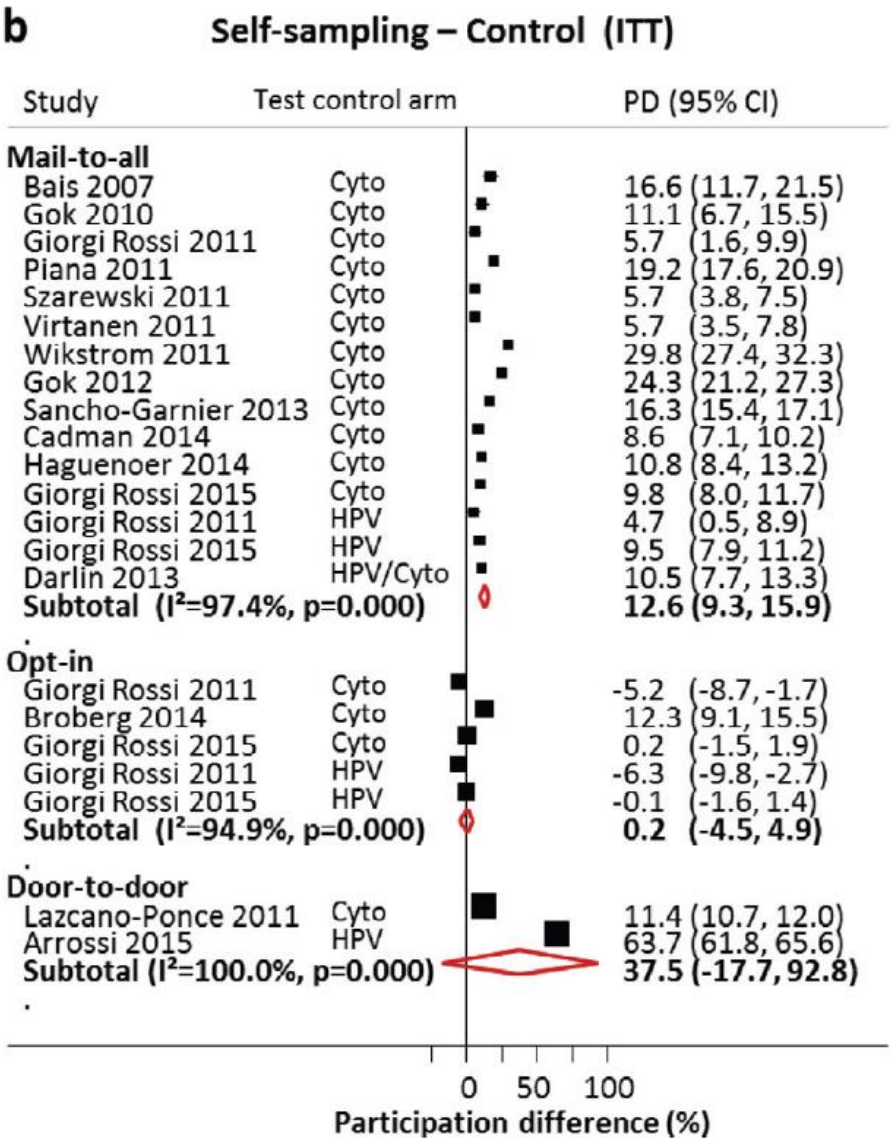


Fig 1 | Kaplan-Meier plots of cumulative incidence rate for CIN3+ for women according to baseline test results in the first 72 months of follow-up in all seven countries


Study
RR (95% CI)
PCR GP5+/6+
Nobbenhuis, 2002 0.89 (0.72–1.10)
Brink, 2006 0.97 (0.86–1.10)
Dijkstra, 2012 1.03 (0.90–1.16)
van Baars, 2012 0.91 (0.68–1.21)
Geraets, 2013 0.90 (0.80–1.00)
Subtotal (I^2 = 0.0%, P = 0.540) 0.95 (0.89–1.01)
MALDI-TOF
Belinson, 2012 1.00 (0.95–1.05)
Abbott RT PCR
Jentschke, 2013b 1.00 (0.75–1.34)
qPCR targeting E6-E7
Hesselink, 2014 [16] 1.03 (0.88–1.21)
Modified GP5/6 PCR-lum
Darlin, 2013 0.96 (0.75–1.24)
Overall (I^2 = 0.0%, P = 0.744) 0.98 (0.95–1.02)
0.75 1 1.25 1.5
Relative sensitivity


Study
RR (95% CI)
PCR GP5+/6+
Nobbenhuis, 2002 1.61 (1.03–2.53)
Brink, 2006 0.96 (0.63–1.45)
Dijkstra, 2012 1.00 (0.75–1.33)
van Baars, 2012 1.00 (0.83–1.21)
Geraets, 2013 1.25 (1.00–1.56)
Subtotal (I^2 = 31.3%, P = 0.213) 1.11 (0.95–1.29)
MALDI-TOF
Belinson, 2012 0.98 (0.97–0.99)
Abbott RT PCR
Jentschke, 2013b 1.07 (0.65–1.78)
qPCR targeting E6-E7
Hesselink, 2014 [16] 0.93 (0.66–1.30)
Modified GP5/6 PCR-lum
Darlin, 2013 0.94 (0.67–1.33)
Overall (I^2 = 18.2%, P = 0.281) 1.02 (0.94–1.09)
0.75 1 1.25 1.5
Relative specificity


b
Self-sampling – Control (ITT)
Study
Test control arm
PD (95% CI)
Mail-to-all
Bais 2007 Cyto 16.6 (11.7, 21.5)
Gok 2010 Cyto 11.1 (6.7, 15.5)
Giorgi Rossi 2011 Cyto 5.7 (1.6, 9.9)
Piana 2011 Cyto 19.2 (17.6, 20.9)
Szarewski 2011 Cyto 5.7 (3.8, 7.5)
Virtanen 2011 Cyto 5.7 (3.5, 7.8)
Wikstrom 2011 Cyto 29.8 (27.4, 32.3)
Gok 2012 Cyto 24.3 (21.2, 27.3)
Sancho-Garnier 2013 Cyto 16.3 (15.4, 17.1)
Cadman 2014 Cyto 8.6 (7.1, 10.2)
Haguenoer 2014 Cyto 10.8 (8.4, 13.2)
Giorgi Rossi 2015 Cyto 9.8 (8.0, 11.7)
Giorgi Rossi 2011 HPV 4.7 (0.5, 8.9)
Giorgi Rossi 2015 HPV 9.5 (7.9, 11.2)
Darlin 2013 HPV/Cyto 10.5 (7.7, 13.3)
Subtotal (I²=97.4%, p=0.000) 12.6 (9.3, 15.9)
Opt-in
Giorgi Rossi 2011 Cyto -5.2 (-8.7, -1.7)
Broberg 2014 Cyto 12.3 (9.1, 15.5)
Giorgi Rossi 2015 Cyto 0.2 (-1.5, 1.9)
Giorgi Rossi 2011 HPV -6.3 (-9.8, -2.7)
Giorgi Rossi 2015 HPV -0.1 (-1.6, 1.4)
Subtotal (I²=94.9%, p=0.000) 0.2 (-4.5, 4.9)
Door-to-door
Lazcano-Ponce 2011 Cyto 11.4 (10.7, 12.0)
Arrossi 2015 HPV 63.7 (61.8, 65.6)
Subtotal (I²=100.0%, p=0.000) 37.5 (-17.7, 92.8)
0
50
100
Participation difference (%)

STUDY PROTOCOL Open Access

Study protocol of the CHOiCE trial: a three-armed, randomized, controlled trial of home-based HPV self-sampling for non-participants in an organized cervical cancer screening program

Mette Tranberg[1*], Bodil Hammer Bech[2], Jan Blaakær[3], Jørgen Skov Jensen[4], Hans Svanholm[1,5] and Berit Andersen[1,6]

- Primary aim
  - To evaluate the effectiveness (participation) of having an offer to obtain a sample at home and mail it directly to the laboratory – by use of two different approaches.

- Secondary aim
  - To measure the proportion of women with hr-HPV infection who have a cytology taken in general practice

STUDY PROTOCOL Open Access

Study protocol of the CHOiCE trial: a three-armed, randomized, controlled trial of home-based HPV self-sampling for non-participants in an organized cervical cancer screening program

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Women aged 30 – 64 (N=9,327)

Not participating in CCU screening after an invitation and one reminder

Randomised 1:1:1

Usual care

Usual care
PLUS
possibility to order
a test-kit

Usual care
PLUS
a test-kit

- ”Add-on” effectiveness study nested into current Danish strategy

- Outcomes
  - Participation after six months (primary outcome)
  - Follow-up after hrHPV (secondary outcome) within 30, 60 and 90 days
  - Possibility to add cost effectiveness analyses

- Timeline: Inclusion of participants ended August 2016. Still collecting data on participation and follow-up.

Patient perspective and laboratory work

- Primary aim:
  - to compare the diagnostic accuracy of home-based self-collected samples (vaginal swab and first-void urine) and conventional samples obtained by a general practitioner using two different hr-HPV assays
- Secondary aim:
  - measure womens acceptability and preferences

- Inclusion of women:
  - Three samples from 200 women will be included
  - Questionnaire data on acceptability is collected
  - All samples will be analysed with two different assays

- Timeline:
  - Samples have been collected and are now being analysed. Results are expected in 2017.

Cancer Epidemiology 38 (2014) 174–180

Contents lists available at ScienceDirect

Cancer Epidemiology

The International Journal of Cancer Epidemiology, Detection, and Prevention

journal homepage: www.canceepidemiology.net

Predictors of non-participation in cervical screening in Denmark

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Inequality in cervical cancer screening

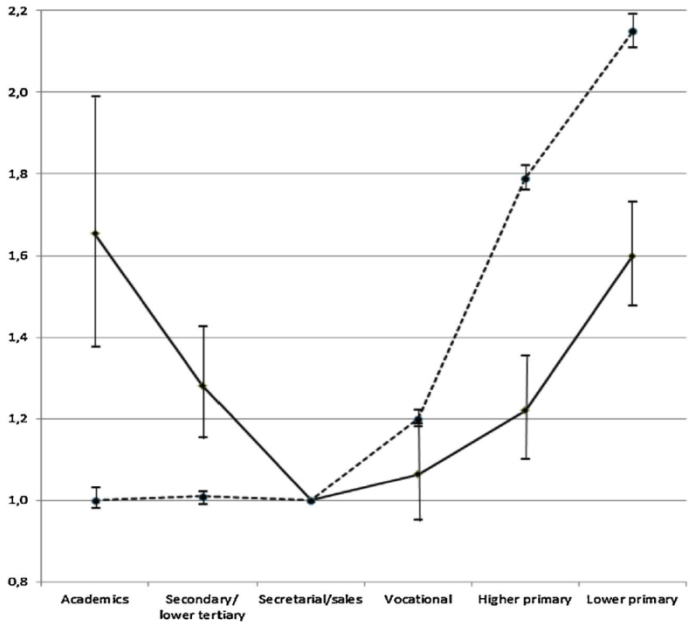
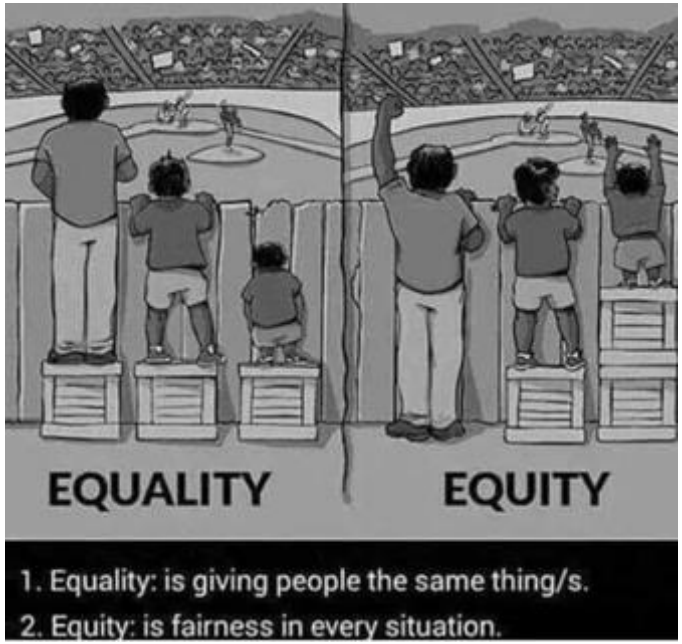


Fig. 1. Age-adjusted odds ratios (ORs) for non-participation in cervical screening in Denmark and mammography screening in Copenhagen, Denmark. Dotted line: cervical screening; solid line: mammography screening.



- Step 1: Can we reduce social inequality by mailing self-sampling kits to non-participants?

- Step 2: Can we reduce social inequality (even more) by introducing home sampling kits in general practices or at social meeting places in underpriviliged areas?

Conclusions

- Home sampling is not yet part of the Danish cervical cancer screening programme
- Results from home-sampling studies in a Danish Context is under way from Central Denmark Region and other regions.
- Home sampling is mentioned in the new Cancer Plan IV, and is expected to be included in the forthcoming revision of cervical cancer screening guidelines

THANK YOU

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