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Screening för livmoderhalscancer med självprovtagning för HPV

Ett vetenskapligt underlag

STATENS BEREDNING FÖR MEDICINSK OCH SOCIAL UTVÄRDERING

Innehåll

1. Inledning

Sedan slutet av 1960-talet har kvinnor i Sverige erbjudits screening för livmoderhalscancer. Verksamheten har varit framgångsrik och insjuknande och död i livmoderhalscancer har sjunkit kraftigt sedan introduktionen. Genom åren har utformning av screeningen justerats efter ökad erfarenhet och tillgänglig kunskap. Socialstyrelsen ser nu över om rekommendationerna behöver uppdateras då ny forskning kan ha tillkommit. SBU fick förfrågan av Socialstyrelsen att ta fram ett vetenskapligt underlag för användning av självprovtagning vid screening för livmoderhalscancer. Underlaget kommer vara ett stöd i Socialstyrelsens översyn av rekommendationerna för ett nationellt screeningprogram för livmoderhalscancer. SBU utvärderar här det vetenskapliga underlaget för självprovtagning av HPV, inklusive HPV som primärt screeningtest för åldersgrupperna 23 till 29 år.

I detta vetenskapliga underlag använder vi ordet kvinnor generellt. Vi är dock väl medvetna om att det finns individer som inte identifierar sig som kvinnor men som kallas till screening för livmoderhalscancer. Vi hoppas att alla som har en livmoderhals, oavsett kön eller könsidentitet, kan känna sig inkluderade i underlaget.

2. Bakgrund

Det har sedan år 2015, då Socialstyrelsens rekommendationer utfärdades, tillkommit ny forskning om HPV-baserad screening, i synnerhet om självprovtagning av HPV som ett enklare sätt att genomföra screening.

2.1 Acceptans av självprovtagning

HPV-självprovtagning innebär att kvinnan förses med provtagningsmaterial och utför provtagningen på egen hand, istället för att en barnmorska eller annan vårdgivare tar provet. Självprovtagningen ger bara svar på om kvinnan bär på HPV, inte om det samtidigt finns en cellförändring.

År 2018 kallades en halv miljon kvinnor till gynekologisk cellprovskontroll i Sverige. Av dessa deltog 61 procent inom 3 månader och 72 procent inom 12 månader (genomsnittet)[1]. Om självprovtagning av HPV ska införas som primär screeningmetod i Sverige är det viktigt att utreda om det kan påverka deltagandet.

[1]. Förebyggande av livmoderhalscancer i Sverige Verksamhetsberättelse och Årsrapport 2020 med data till och med 2019; Nationellt Kvalitetsregister för Cervixcancerprevention (NKCx)

2.2 Diagnostisk tillförlighet för självprovtagning som primär screeningmetod

Socialstyrelsens nationella screeningprogram för livmoderhalscancer rekommenderar att kvinnor i åldern 30 till 70 år ska erbjudas cellprovtagning, med analys för HPV-test med cytologisk triage, av HPV-positiva. Provtagningen ska dessutom göras med vätskebaserad teknik. En fördel med detta är att HPV-positiva kvinnor inte behöver återkomma för ny provtagning med cytologi eftersom denna analys kan göras utifrån det befintliga provet och därmed blir det inget bortfall. Om självprovtagning av HPV ska införas som primär screeningmetod i Sverige kommer HPV-positiva kvinnor behöva kallas för ett vårdgivartaget cellprov.

För att utvärdera den diagnostiska tillförlitligheten för självprovtagning av HPV som primär screeningmetod, och generalisera resultaten till en svensk kontext, bör man utgå från studier med samma diagnostiska förfarande som används i Sverige idag, det vill säga triage av HPV-positiva med cytologiskt prov.

Flertalet publicerade studier om självprovtagning av HPV är utförda på en liten och selekterad population av kvinnor. För att relatera resultaten till svenska förhållanden ska studierna även vara baserade på en screeningpopulation.

2.3 Överrensstämmelse mellan självprovtaget och vårdgivartaget HPV-test

Tidigare systematiska översikter har visat på god överenstämmelse mellan självprovtaget HPV-test och vårdgivartaget HPV-prov för PCR-baserade metoder [1][2]. En systematisk översikt från år 2018 visade i en poolad analys att den relativa sensitiviteten för CIN2+ var 99 procent för självprovtaget jämfört mot vårdgivartaget HPV-test och den relativa specificiteten var 98 procent [1]. Dessa resultat kom från studier som använde en PCR-baserad metod för analys av HPV. För analysmetoder baserade på en äldre metod med signalförstärkning (ej i bruk i Sverige längre) var överrensstämmelsen mellan självprovtaget och vårdgivartaget HPV-test sämre [1].

2.4 HPV som primär screeninganalys för kvinnor mellan 23 och 29 år

I nuvarande rekommendationer från Socialstyrelsen bör hälso- och sjukvården erbjuda cellprovtagning med primäranalys för HPV för kvinnor från 30 år till som lägst 64 år och fortsatt uppföljning till 70 år. För kvinnor i åldern 23 till 29 år rekommenderas cellprovtagning med primär analys med cytologi. Detta på grund av att prevalensen av HPV var högre hos yngre kvinnor. Skyddet mot cancer var heller inte högre. Det är vanligt att kvinnor under 30 får en HPV-infektion, även med HPV av högrisktyp. De flesta av dessa infektioner läker dock ut av sig själva och få blir långvariga. Det kan därför finnas en risk för en överdiagnostik av CIN2+ och onödig stigmatisering om primär HPV-analys används för yngre kvinnor då de flesta av dessa cellförändringar återbildas av sig själva. En behandling av alla skulle därmed innebära en överbehandling.

I SBU:s tidigare vetenskapliga underlag om screening fört livmoderhalscancer från 2014 var specificiteten för HPV-test lägre hos kvinnor under 30 år än hos äldre kvinnor enligt de inkluderade studierna [3]. Litteraturen hade oftast studerat kvinnor i allmänhet och inte specifikt studerat effekt på cancer i denna åldersgrupp. År 2010 infördes vaccination mot HPV för flickor i det svenska barnvaccinationsprogrammet. Detta kompletterades med organiserad catch-up vaccination till artonårsåldern och i vissa regioner upp till tjugosexårsåldern. Från augusti 2020 erbjuds HPV-vaccination till alla barn i årskurs 5. De kvinnor som blivit erbjudna HPV-vaccin är idag upp till 28 år och kallas till screening för livmoderhalscancer. Eftersom antalet HPV-infektioner minskar bland vaccinerade är det relevant att på nytt utvärdera om man bör erbjuda cellprovtagning med analys för HPV även för kvinnor under 30 år. Detta vetenskapliga underlag är delvis en uppdatering på tidigare SBU-underlag [3] men med en smalare frågeställning.

3. Frågeställningar och metod

3.1 Frågeställningar

Självprovtagning

1. Vilken acceptans har självprovtagning av HPV, jämfört med vårdgivartaget prov, som primär screeningmetod för kvinnor som kallas till för livmoderhalscancer?
2. Vilken diagnostisk tillförlitlighet har självprovtagning av HPV, jämfört med vårdgivartaget prov, som primär screeningmetod för att finna CIN2+ hos kvinnor som deltar i screeningprogram för livmoderhalscancer?
3. Vilken överenstämmelse har självprovtagning av HPV, jämfört med vårdgivartaget prov, för att bekräfta HPV-infektion hos kvinnor?

Screeningmetod för kvinnor under 30 år

1. Vilken diagnostisk tillförlitlighet har primär HPV-analys jämfört med cytologi som screeningmetod för kvinnor under 30 år (23 till 29 år)?

3.2 Urvalskriterier

Fråga 1: Acceptans av självprovtagning av HPV som primär screeningmetod

Population
Kvinnor som kallas till screening för livmoderhalscancer
Indextest
Självprovtagning av HPV som primär screeningmetod
Jämförande test
Vårdgivartaget test (HPV, cytologi eller annat)
Utfall
Deltagande och acceptans
Studiedesign
Randomiserade kontrollerade studier
Övrigt

- Endast studier med en population ≥100
- Studier publicerade 2010 och framåt

Fråga 2: Diagnostisk tillförlitlighet av självprovtagning av HPV som primär screeningmetod

Population

Kvinnor som screenas för livmoderhalscancer

Indextest

Självprovtagning av HPV som primär screeningmetod (och triage med cytologi hos HPV-positiva)

Jämförande test

Vårdgivartaget HPV-test som primär screeningmetod (och triage med cytologi hos HPV-positiva)

Referensstandard

Histopatolog

Utfall

Sensitivitet och specificitet för CIN2+

Studiedesign

Tvärsnittsstudier, kohortstudier och kontrollerade studier, med eller utan randomisering

Övrigt

- HPV-testet är begränsat till amplifieringstester såsom PCR, mRNA (ej Hybrid Capture)
- Prov taget i urin eller med tampong exkluderas
- Endast studier med en population ≥100
- Studier publicerade 2010 och framåt

Fråga 3: Överrensstämmelse mellan självprovtaget och vårdgivartaget HPV-prov

Population

Kvinnor

Indextest

Självprovtagning av HPV-test

Jämförande test

Vårdgivartaget HPV-test

Utfall

Överrensstämmelse i onkogen och molekylär HPV-infektion

Studiedesign

Tvärsnittsstudier där samtliga deltagare måste ha tagit båda testerna

Övrigt

- HPV-testet är begränsad till amplifieringstester såsom PCR, mRNA (ej Hybrid Capture)
- Provtaget i urin eller med tampong exkluderas
- Endast studier med en population ≥100
- Studier publicerade 2010 och framåt

Fråga 4: Primär HPV-analys som screeningmetod för kvinnor under

30 år

Population
Kvinnor i åldrarna 23 till 30 års ålder som screenas för livmoderhalscancer
Indextest
Primär HPV-analys som screeningmetod (triage med cytologi hos HPV-positiva)
Jämförande test
Cytologi som screeningmetod (med eller utan triage)
Referensstandard
Histopatologi
Utfall
Sensitivitet och specificitet för CIN2+
Studiedesign
Tvärsnittsstudier, kohortstudier och kontrollerade studier, med eller utan randomisering

Övrigt

- Exkluderar studier som inte särredovisar för denna åldersgrupp
- Prov taget i urin eller med tampong exkluderas
- Endast studier med vätskebaserad cytologi (LBC)
- Analysen och resultatet för det avsedda utfallet ska vara redovisat tydligt i studien
- Endast studier med en population ≥100
- Endast studier som utvärderar båda screeningstrategierna (indextest och jämförande test) ingår

3.3 Process för urval av studier

Underlaget utfördes i enlighet med SBU:s metodbok [4]. Syftet med det vetenskapliga underlaget är att få en objektiv kartläggning av kunskapsläget utifrån genomförd forskning på området. Samtliga vetenskapliga studier som är aktuella för underlagets frågeställningar identifierades och granskades utifrån relevans och risk för systematiska fel.

3.3.1 Litteratursökning

Strukturerade och uttömmande litteratursökningar genomfördes för projektets frågeställningar om screening för livmoderhalscancer med hjälp av självprovtagning av HPV, och screening med HPV-analys. Sökningar efter originalstudier begränsades till de tre databaser som bedömdes som viktigast.

Sökstrategin utformades och beslutades av projektgruppens informationsspecialist, sakkunniga och projektledare. Sökstrategin granskades av ytterligare en informationsspecialist på SBU. Fullständiga sökdokumentationer redovisas i Bilaga 1.

Litteratursökning efter originalstudier och systematiska översikter, metaanalyser och HTA-rapporter gjordes i februari 2021 i följande databaser: Cochrane Library (Wiley), EMBASE (Embase.com) och Medline (Ovid). Sökningar efter systematiska översikter, metaanalyser och HTA-rapporter gjordes också i databaserna: CRD Database (Centre for Reviews and Dissemination), Epistemonikos (Epistemonikos), International HTA Database (INAHTA), KSR Evidence (Kleijnen Systematic Reviews Ltd.), NHS Evidence Search (NICE), Prospero (Centre for Reviews and Dissemination).

3.3.1.1 Avgränsningar

Sökningarna avgränsades till språken engelska, svenska, norska och danska.

Sökningarna för de tre frågeställningarna om självprovtagning avgränsades till litteratur publicerad från och med år 2010 och framåt. Testmetoder som använts dessförinnan är inte relevanta för frågeställningarna, och projektgruppen bedömde därför att den avgränsningen inte medförde någon risk att missa relevanta studier.

3.3.2 Bedömning av relevans

En projektledare vid SBU:s kansli granskade på abstraktsnivå de referenser som identifierades i litteratursökningarna. De referenser som uppfyllde urvalskriterierna, eller där det fanns en osäkerhet om de uppfyllde kriterierna, beställdes i fulltext. Studierna granskades i fulltext av projektledare vid SBU:s kansli och vid osäkerhet gick studien vidare till en sakkunnig som bedömde om studierna uppfyllde de uppställda urvalskriterierna. Studier som inte uppfyllde kriterierna exkluderades och redovisas i Bilaga 2.

3.3.3 Bedömning av risk för bias

Risk för bias i de inkluderade studierna bedömdes med hjälp av SBU:s granskningsmallar. Två projektledare vid SBU:s kansli bedömde varje studie oberoende av varandra. Eventuella oenigheter löstes genom diskussion i hela projektgruppen. Studier där risken för bias bedömdes som hög exkluderades från analysen, men redovisas i Bilaga 2.

3.3.4 Syntes

I de studier som hade låg till måttlig risk för bias extraherades betydelsefulla data och sammanfattades i tabeller och, i de fall det var tillämpligt, metaanalyser.

3.3.5 Bedömning av de sammanvägda resultatens tillförlitlighet

SBU har inte bedömt tillförlitligheten till resultaten men sammanfattar överförbarheten av resultaten i en kommentar.

4. Resultat

4.1 Acceptans för självprovtagning av HPV som primär screeningmetod

4.1.1 Urval av studier

Litteratursökningen för självprovtagning av HPV (Bilaga 1) identifierade 1 542 referenser, varav 235 lästes i fulltext. Av dessa bedömdes 6 studier vara relevanta för frågeställningen. Alla dessa studier bedömdes ha hög risk för bias och redovisas i Bilaga 2.

4.1.2 Kommentar

Det saknas underlag för att bedöma hur självprovtagning påverkar deltagandet i primär livmoderhalscancerscreening. Forskning visar att självprovtagning av HPV ökar deltagandet för de kvinnor som uteblivit från sin ordinarie screeningkallelse. I en systematisk översikt från år 2018 var slutsatsen att om man skickade hem ett HPV- självprovtagningskit till dessa kvinnor ökar sannolikheten för provtagning jämfört med att skicka påminnelser om att få provet taget av vårdgivare på klinik [1]. Det är inte självklart att resultaten från en population som uteblivet från besök kan generaliseras till självprovtagning som primär screeningmetod för alla kvinnor.

Vid litteraturgenomgången fann vi två studier utförda i Uppsala som var relevanta för frågeställningen, men som hade för många faktorer som kunde introducera bias (snedvridning) för att vi skulle kunna vara säkra på resultaten kring deltagande och generalisera dessa till hela Sverige. Dessa två studier kom från samma forskargrupp där kvinnor som deltog i det ordinarie screeningprogrammet av livmoderhalscancer randomiserades till två olika grupper: en självprovtagningsgrupp och en kontrollgrupp. Kvinnorna i självprovtagningsgruppen fick en kallelse med en instruktion, en provtagningsborste, ett FDA-kort samt ett frankerat returkuvert. I den ena studien var studiedeltagarna mellan 30 och 49 år. Kontrollgruppen fick en kallelse och hanterades enligt rutinen för gynekologisk cellprovtagning där en barnmorska tar ett cellprov från livmodertappen för cytologisk analys [5]. I den andra studien var studiedeltagarna över 50 år och i kontrollgruppen tog barnmorskan ett prov från livmoderhalsen enligt ordinarie rutin vid tidpunkten, med skillnaden att provet analyserades för HPV. Även ett positivt vårdgivartaget prov krävde nytt besök för triage [6]. Resultaten från studierna pekar på att screeningdeltagandet för första provtagningstillfället ökar om man skickar ut ett HPV-test för självprovtagning ($p < 0.01$). Det finns dock risk för överskattning av resultaten. I studierna fick deltagarna i självprovtagningsgruppen en påminnelse 3 veckor efter att självprovtagningen skickats, medan deltagarna i kontrollgruppen fick en påminnelse först efter 12 månader. Dessutom var provtagningen gratis för kvinnorna i självprovtagningsgruppen medan de i kontrollgruppen fick betala en avgift. Deltagandet för

livmoderhalscancerscreening i dåvarande Uppsala läns landsting låg under riksgenomsnittet[2] vid den tidpunkt då studierna genomfördes, vilket gör det osäkert att extrapolera de relativa skillnaderna i deltagande till hela landet. Uppföljningstiden för deltagandet i studierna är oklar, men det absoluta deltagandet i självprovtagningsgruppen i studierna (47 [5] och 53 procent [6]) underskrider det nationella deltagandet både för 3 och 12 månader, såväl år 2014, då studien gjordes (57 respektive 70 procent), som i det nuvarande screeningprogrammet.

[2]. Förebyggande av livmoderhalscancer i Sverige Verksamhetsberättelse och Årsrapport 2015 med data till och med 2014; Nationellt Kvalitetsregister för Cervixcancerprevention (NKCx).

Primär HPV-testning kräver triage eftersom inte alla som testats positivt kan remitteras till uppföljning med kolposkopi. Vid vårdgivartagna prover med vätskebaserad cytologi (LBC, liquid-based cytology) som triageras med cytologi kräver detta inte något extra besök vilket däremot behöver ske vid självprovtagning. Deltagandet behöver därför också värderas utifrån det bortfall som kan uppkomma vid triagering då kvinnor som testats positivt behöver uppsöka en mottagning för cellprovtagning.

Det finns svårigheter med att utvärdera deltagande då studier kring populationsbaserad screening begränsas till studiedeltagare, rekryterade med informerat samtycke. Dessa har begränsad generaliserbarhet till en allmän population. Deltagande är också väldigt kontextberoende, där i princip samma strategi kan ge väldigt olika resultat på deltaganden beroende på vilken population de implementeras i. De populationer som överväger implementering bör göra real-life studier med en försöksimplementering som går att utvärdera och med möjlighet till reversibilitet om strategin visar sig vara ineffektiv.

4.2 Diagnostisk tillförlitlighet av självprovtagning av HPV som primär screeningmetod

4.2.1 Urval av studier

Litteratursökningen kring självprovtagning av HPV (Bilaga 1) identifierade 1 542 referenser, varav 235 lästes i fulltext. Endast en studie bedömdes vara relevant för frågeställningen [7]. Studien bedömdes ha måttlig risk för bias och inkluderades i underlaget.

4.2.2 Beskrivning av de ingående studierna

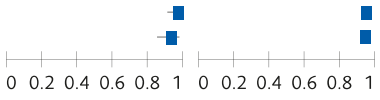
Studien hade en non-inferiority design för att undersöka om självprovtagning av HPV var lika bra på att upptäcka CIN2+ som ett vårdgivartaget HPV-test [7]. Studiedeltagarna var kvinnor som i samband med kallelse till det ordinarie screeningprogrammet för cellprovtagning med cytologisk undersökning erbjöds att delta i en forskningsstudie. De 16 410 kvinnor (motsvarar 8 procent av de tillfrågade) som tackade ja till att ingå i studien randomiserades till två grupper för screening med HPV-test; en självprovtagningsgrupp och en kontrollgrupp. Kvinnorna i självprovtagningsgruppen fick en provtagningsborste tillsammans med instruktioner och ett frankerat returkuvert skickat hem till sig. Kvinnorna i kontrollgruppen fick en kallelse till sin vårdcentral för att ta ett vårdgivartaget HPV-prov. De kvinnorna i självprovtagningsgruppen med ett positivt HPV-prov blev återkallade till sin vårdcentral för att ta ett cellprov med cytologisk analys. För kvinnorna i kontrollgruppen gjordes ett uppföljande triage med cytologi utan att kalla in kvinnan för att ta ett nytt prov. Alla kvinnor (oavsett grupp) med avvikande cytologiskt resultat remitterades till kolposkopi som utfördes enligt de standardiserade procedurerna i Nederländerna, och de histologiska proverna undersöktes enligt riktlinjerna.

4.2.3 Sammanfattning av resultaten

Resultaten från studien visade att detektion av CIN2+ var liknande mellan självprovtagningsgruppen (111 (1,5 %) av 7 643) och kontrollgruppen (92 (1,5 %) av 6 282) med en relativ risk på 0,99 (95 % KI 0,75 till 1,31). Figur 4.1 redovisar den diagnostiska tillförlitligheten för de två provtagningsmetoderna.

Figur 4.1 Diagnostisk tillförlitlighet för CIN2+ för HPV-analys med PCR-baserad teknik och triage med cytologi för HPV positiva.

Sample collection	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Clinician	106	359	4	5831	0.96 (0.91; 0.99)	0.94 (0.94; 0.95)
Self	78	458	6	7074	0.93 (0.85; 0.979	0.94 (0.93; 0.94)



4.2.4 Kommentar

Enligt en studie så var den diagnostiska tillförlitligheten liknande för självprovtagning av HPV som för ett vårdgivartaget HPV-test [7]. Det finns dock metodologiska problem i studien som kan påverka resultaten: (a) Studien har en screeningpositiv design, det vill säga att endast de personer som testade positivt vid indextestet (om HPV+ och sedan cytologi+ och omvänt) gick igenom referensstandarden (CIN2+ i histopatologi). Det finns fördelar med denna design då det kan bli låg följsamhet till att ta ett uppföljande test för de vars första test var negativt. Det är också etiskt tveksamt (och nästintill omöjligt) att ta biopsier på en stor screeningpopulation. Det kan dock introduceras bias för specificiteten då man inte kan fånga några fall av CIN2+ hos de kvinnor som var HPV-negativa (b). Populationen i studien är förselekterad då de gjorde ett aktivt val att delta i studien istället för att gå på den ordinarie kallelsen för screening och endast 8,8 procent (16 410/187 473) tackade ja till studien. Självprovtagning av HPV kan därmed inte riktigt ses som en primär screeningmetod i den enda inkluderade studien, då en önskan att få delta i studien kan ha byggt på en positiv inställning till att testa sig, och på ett annat sätt än den som erbjöds som rutin. Även om grupperna i studien har gjorts jämförbara med randomisering (intern validitet) kan det finnas vissa problem med överförbarhet till en allmän screeningpopulation.

4.3 Överrensstämmelse mellan självprovtaget och vårdgivartaget HPV-prov

4.3.1 Urval av studier

Litteratursökningen kring självprovtagning av HPV (Bilaga 1) identifierade 1 542 referenser, varav 235 lästes i fulltext. Av dessa bedömdes 42 studier vara relevanta för frågeställningen och 4 av dessa studier bedömdes ha hög risk för bias (redovisas i Bilaga 2). Totalt bedömdes 38 studier ha låg eller måttlig risk för bias och inkluderades i underlaget [8-45].

4.3.2 Beskrivning av de ingående studierna

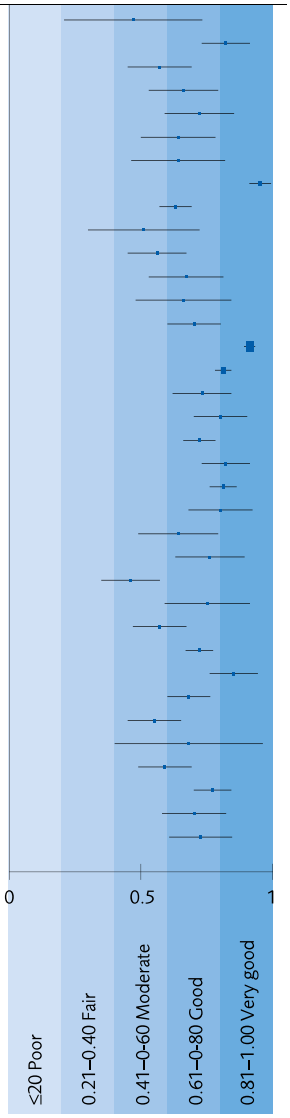
Det var en stor heterogenitet i val av population och designupplägg i de inkluderade studierna (Bilaga 3, för beskrivning av studiernas karakteristiska). De flesta av studierna var utförda på en selekterad population av kvinnor som exempelvis uppsökt en vårdcentral för gynekologiska besvär eller remitterats för positivt screeningtest. Vilken typ av analysmetod av HPV som studierna använde skiljde sig åt och omkring tio olika typer av HPV-tester ingår i underlaget. Vilket typ av prov som togs av vårdgivare skiljde sig också; i vissa studier ett vätskebaserat cellprov och i andra studier enbart ett HPV-test. I de flesta studier utförde kvinnorna självprovtagningen på en klinik, enskilt i ett rum, innan de fick sitt prov taget av vårdgivare. Det var endast i ett fåtal studier där kvinnorna fick självprovtagningen hemskickad och utförde testningen i hemmet.

Överensstämmelsen mellan olika provtagningsmetoder kan sammanfattas på olika sätt och vi valde att använda studiens kappavärde för överensstämmelse i högrisk-HPV mellan självprovtagning och vårdgivartaget test. Det finns tumregler för tolkning av kappavärde där: ≤0,20 är dålig överrensstämmelse; 0,21–0,40 är svag; 0,41–0,60 är måttlig; 0,61–0,80 är bra och 0,81–1,00 är mycket bra överensstämmelse [4]. I Figur 4.2 redovisas resultaten från de inkluderade studierna. Då studierna är så heterogena skulle det vara missvisande att göra en sammanvägning av resultaten. Värt att notera är att de flesta studiers kappavärde hamnar på bra eller mycket bra överrensstämmelse.

Figur 4.2 En forest plot över varje studies kappavärde, tillhörande konfidensintervall samt grad av överrensstämmelse mellan provtagningsmetoderna.

Study, year	Kappa	SE	Weight	Kappa IV, Fixed, 95% CI
Ajenifuja, 2018	0.47	0.1327	0.2%	0.47 (0.21, 0.73)
Asciutto, 2017	0.82	0.0459	1.6%	0.82 (0.73, 0.91)
Asciutto, 2018	0.57	0.0612	0.9%	0.57 (0.45, 0.69)
Bergengren, 2018	0.66	0.0663	0.8%	0.66 (0.53, 0.79)
Campos, 2014	0.72	0.0663	0.8%	0.72 (0.59, 0.85)
Catarino, 2015	0.64	0.0714	0.7%	0.64 (0.50, 0.78)
Catarino, 2017	0.64	0.09	0.4%	0.64 (0.46, 0.82)
Chen, 2016	0.95	0.0204	8.0%	0.95 (0.91, 0.99)
Chernesky, 2014	0.63	0.0306	3.6%	0.63 (0.57, 0.69)
Cho, 2019	0.51	0.1071	0.3%	0.51 (0.30, 0.72)
Cho, 2020	0.56	0.0561	1.1%	0.56 (0.45, 0.67)
Darlin, 2012	0.67	0.0714	0.7%	0.67 (0.53, 0.81)
Des Marais, 2018	0.66	0.0918	0.4%	0.66 (0.48, 0.84)
Dijkstra, 2012	0.7	0.051	1.3%	0.70 (0.60, 0.80)
Du, 2021	0.91	0.0102	32.0%	0.91 (0.89, 0.93)
El-Zein, 2018	0.81	0.0153	14.2%	0.81 (0.78, 0.84)
Geraets, 2013	0.73	0.0561	1.1%	0.73 (0.62, 0.84)
Guan, 2013	0.8	0.051	1.3%	0.80 (0.70, 0.90)
Haguenoer, 2014	0.72	0.0306	3.6%	0.72 (0.66, 0.78)
Jentschke, 2016	0.82	0.0459	1.6%	0.82 (0.73, 0.91)
Ketelaars, 2017	0.81	0.0255	5.1%	0.81 (0.76, 0.86)
Leeman, 2017	0.8	0.0612	0.9%	0.80 (0.68, 0.92)
Leinonen, 2018	0.64	0.0765	0.6%	0.64 (0.49, 0.79)
Onuma, 2020	0.76	0.0663	0.8%	0.76 (0.63, 0.89)
Phoolcharoen, 2018	0.46	0.0561	1.1%	0.46 (0.35, 0.57)
Reisner, 2018	0.75	0.0816	0.5%	0.75 (0.59, 0.91)
Rohner, 2020	0.57	0.051	1.3%	0.57 (0.47, 0.67)
Saidu, 2021	0.72	0.026	4.9%	0.72 (0.67, 0.77)
Satake, 2020	0.85	0.0459	1.6%	0.85 (0.76, 0.94)
Saville, 2020	0.68	0.0408	2.0%	0.68 (0.60, 0.76)
Senkomago, 2018	0.55	0.051	1.3%	0.55 (0.45, 0.65)
Stanczuk, 2015	0.68	0.1423	0.2%	0.68 (0.40, 0.96)
Ting, 2013	0.59	0.051	1.3%	0.59 (0.49, 0.69)
Toliman, 2019	0.77	0.0357	2.6%	0.77 (0.70, 0.84)
Tranberg, 2018	0.7	0.0612	0.9%	0.70 (0.58, 0.82)
van Baar, 2012	0.725	0.0602	0.9%	0.72 (0.61, 0.84)

Heterogeneity: Chi^2=407.13, df=35 (P<0.00001); I^2=91%
Test for overall effect: Z=139.69 (P<0.00001)



4.3.3 Kommentar

Frågan är väl studerad och överenstämmelsen mellan självprovtaget och vårdgivartaget prov bedöms som god. Skillnaderna i resultaten mellan studier kan bero på flera faktorer såsom: typ av provtagningsmaterial, hur provet förvaras, vilken population som ingick i studien samt var självprovtagningen ägde rum (hemma eller på klinik) [1]. Dessa olika faktorer kan även påverka överförbarheten till svensk kontext. Då vi valde att titta på överrensstämmelsen mellan två olika provtagningssätt för ett HPV-test, inkluderades endast studier där alla individer genomgick båda HPV-testerna. Vill man undersöka den diagnostiska tillförlitligheten för respektive testmetod så kan man även inkludera randomiserade, kontrollerade studier [5] [6] [46] [47] [48]. Om två HPV-prover tas samma dag finns det risk att cellprovtagningen kan gynna det först tagna provet som kan fånga ett större cellmaterial. I majoriteten av de studier som ingår i underlaget utfördes självprovtagningen innan ett vårdgivartaget cellprov.

4.4 Primär HPV-analys som screeningmetod för kvinnor under 30 år

4.4.1 Urval av studier

Frågan om primär HPV-analys som screeningmetod har undersökts i ett tidigare vetenskapligt underlag från SBU, där litteratursökning gjordes i april år 2014 [3]. För detta vetenskapliga underlag har vi dels utgått från tidigare underlag, dels kompletterat med en ny litteratursökning från år 2014 och framåt. Litteratursökningen genererade 9 584 referenser, varav 3 800 var publicerade från år 2014 och framåt. Av dessa lästes 169 studier i fulltext och ingen bedömdes vara relevant för frågeställningen. Från det gamla underlaget var en studie relevant för frågeställningen, och har tidigare bedömts ha måttlig risk för bias [3]. Den vanligaste orsaken för exklusion var att studierna inte särredovisade för ålder, inget triage med cytologi för HPV-positiva eller att data för sensitivitet och specificitet för CIN2+ inte rapporterades. Nedan beskrivs den studie som även ingick i underlaget år 2014 [49].

4.4.2 Beskrivning av ingående studie

ARTISTIC är en populationsbaserad randomiserad studie från England som jämför primär HPV-analys som screeningmetod med cytologi [49]. Studien utfördes mellan åren 2001 till 2013 och totalt 25 078 kvinnor i åldrarna 20 till 64 år som kallades till livmoderhalscancerscreening gjorde både ett vätskebaserat cytologiprov och ett HPV-test. Kvinnorna randomiserades till två grupper: en där resultatet för både HPV och cytologi delgavs (och som man agerade på) och en grupp som endast informerades om resultaten för cytologi (resultatet för HPV var dolt och agerades inte på). Kvinnor med höggradiga cellförändringar i cytologi remitterades till kolposkopi. Kvinnorna i interventionsgruppen, där HPV-resultatet delgavs, som var positiva för HPV och hade normal cytologi testades igen efter 12 månader. Om de fortfarande var HPV-positiva så erbjöds de kolposkopi eller upprepad HPV-testning efter 24 månader (om de då fortfarande var positiva utfördes en kolposkopi). Studien inkluderar data från baslinjemätningen och andra screeningomgången som genomfördes tre år senare. Data för åldersgruppen 20 till 29 år särredovisas.

4.4.3 Sammanfattning av resultaten

Resultaten visade små skillnader både beträffande hur många som remitterades till kolposkopi och hur många CIN2+ som upptäcktes/missades. I Tabell 4.1 redovisas den diagnostiska tillförlitligheten för de olika screeningstrategierna och resultaten uppvisar inte någon betydande skillnad mellan jämförelserna. Data är från interventionsgruppen, det vill säga de kvinnor där resultat för både HPV och cytologi delgavs, för åldrarna 20 till 29 år (n=3 879, med 236 fall av CIN2+ vid andra screeningomgången).

Tabell 4.1 Relativ* sensitivitet och specificitet för CIN2+.

	CIN2+ som inte upptäcktes n (%)	Sensitivitet (%, 95 % KI)	Remitterade till kolposkopi n (%)	Specificitet (%, 95 % KI)
HPV med cytologi triage	31 (13,1)	86,9 (81,9 till 90,9)	645 (16,6)	87,9 (86,8 till 89,0)
Cytologi med HPV triage	27 (11,4)	88,6 (83,8 till 92,3)	696 (17,9)	86,6 (85,5 till 87,7)

*Relativt till den kombinerade testningen med både HPV och cytologi

4.4.4 Studier som inte uppfyllde urvalskriterierna men som har hög relevans för frågeställningen

SBU har inte beräknat sensitivitet och specificitet för de studier som inte själva har redovisat dessa resultat, dessutom fattades det ofta viktiga data i flera av studierna för att kunna göra en egen analys. För att ge vägledning kring frågan om primär HPV-analys som screeningmetod för kvinnor under 30 år sammanfattar vi data från två studier som hade liknande upplägg för screening för livmoderhalscancer som Socialstyrelsens nuvarande rekommendationer. Vi bedömer att dessa studier har hög överförbarhet till svenska förhållanden, eftersom både Kanada och Australien har liknande organiserade program för livmoderhalscancerscreening som Sverige har [50] [51].

4.4.4.1 HPV FOCAL

HPV FOCAL är en randomiserad populationsbaserad screeningstudie från Kanada som jämför primär HPV-analys som screeningmetod (triage med cytologi hos HPV-positiva) med cytologi (triage med HPV hos cytologi-positiva) [51]. Totalt ingår 25 243 kvinnor i studien, varav 2 188 var kvinnor i åldrarna 25 till 29 år. I Tabell 4.2 nedan visas resultat för HPV FOCAL, från första screeningomgången [51] och fyraårsuppföljningen [52]. Studien visar att vid första screeningomgången (baslinjemätning och tolvmånadersuppföljning) så upptäckte primärscreening av HPV fler fall av CIN2+ än cytologi för kvinnor mellan 25 och 29 år. Vid fyraårsuppföljningen var det ingen betydande skillnad i CIN2+ för HPV som primär screeningmetod jämfört med cytologi för samma åldersgrupp. Dessa resultat tyder på att primär HPV-screening tidigarelägger diagnosen av CIN2+. Tyvärr redovisas inga åldersspecifika uppgifter om antal eller andel testpostiva eller testnegativa i någon av artiklarna. Man skulle kunna se antal fall som återkallas till kolposkopi som ett indirekt mått på specificitet. Data från den första screeningomgången visade att HPV som primär screeningmetod hade mer än dubbelt så många remitteringar till kolposkopi jämfört med cytologi för åldrarna 25 till 29 år. Dessvärre särredovisas inte ålderspecifika data för fyraårsuppföljningen. Däremot visade resultaten att bland de kvinnor som vara negativa för HPV eller cytologi vid baslinjemätningen fanns det fler fall av CIN2+ i cytologiarmen än i HPV-armen ($p < .05$).

Tabell 4.2 Resultat för de två olika screeningstrategierna för kvinnor i åldern 25 till 29 år.

	HPV-screening (triage med cytologi) (95 % KI)	Cytologi-screening (triage med HPV) (95 % KI)	Risk Ratio (HPV vs cytologi) (95 % KI)
CIN2+ detektion vid första screeningomgången Antal/1 000	54,5 (41,0 till 72,1)	31,4 (21,5 till 45,6)	1,73 (1,08 till 2,78)
CIN2+ detektion upp till 48 månaders uppföljning incidens/1 000	71,4 (55,8 till 91,0)	64,0 (49,3 till 82,8)	1,11 (0,78 till 1,60)
PPV för CIN2+ vid första screeningomgången	32,0 (26,7 till 37,8	40,0 (29,1 till 52,0)	-
CIN2+ detektion vid 48 månaders uppföljning för negativt resultat vid baslinjemätningen Incidens/1 000	15,7 (8,6 till 28,7)	33,0 (22,4 till 48,3)	0,48 (0,23 till 0,99)
Remitterad till kolposkopi vid första screeningomgången Antal/1 000	199,0 (178,5 till 221,1)	80,9 (64,2 till 101,5)	-
Remitterad till kolposkopi vid 48 månaders uppföljning Antal/1 000	Finns inga särredovisade data	Finns inga särredovisade data	-

4.4.4.2 Compass

Compass är en randomiserad populationsbaserad screeningstudie (med informerat samtycke från deltagarna) som jämför bland annat primär HPV-analys som screeningmetod (triage med cytologi hos HPV-positiva) med cytologi (triage med HPV hos cytologi-positiva) [50]. Totalt ingick 4 994 kvinnor i studien, varav 1 078 var kvinnor i åldrarna 25 till 33 år. Studien är utförd i Australien, det första landet att introducera ett nationellt vaccinationsprogram för HPV, med syfte att undersöka HPV som primär screeningmetod i en vaccinerad population. Kvinnorna i studien benämnd som ”den vaccinerade kohorten” är mellan 25 till 33 år gamla och har tidigare blivit erbjudna HPV-vaccinering, med ett upptag av 50 till 70 procent. Data om varje enskild studiedeltagares vaccinationsstatus saknas. I Tabell 4.3 redovisas resultatet från Compass-studien. I HPV-armen upptäcktes fler fall av CIN2+ och fler kvinnor remitterades till kolposkopi än i cytologiarmen, även i denna vaccinerade ålderskohort. Även om skillnaden i upptäckta CIN2+ kan framstå som stor (5 gånger) så är skillnaden inte statistiskt signifikant då utfallen är få (11 respektive 1).

Tabell 4.3 Resultat för primär screening med HPV (n=418) eller cytologi (n=211) för kvinnor i HPV-vaccinerade ålderskohorter.

	HPV-screening (triage med cytologi) (95 % KI)	Cytologi-screening (triage med HPV) (95 % KI)
CIN2+ detektion	2,6 (1,3 till 4,7)	0,5 (0,0 till 2,6)
Remittering till kolposkopi	8,1 (5,7 till 11,2)	4,7 (2,3 till 8,5)

4.4.5 Kommentar

Den inkluderade studien ARTISTIC har hög validitet för aktuella svenska förhållanden, med det väsentliga undantaget att den aktuella populationen inte var vaccinerad [49]. Testningen gjordes med metoder som idag inte betraktas som helt moderna. Detta torde inte ha påverkat resultaten på något avgörande sätt. Studien analyserade bland annat sensitivitet och specificitet för CIN2+ mellan primär screening med cytologi (med HPV triage) och HPV (med cytologi triage) och fann ingen betydande skillnad. Analysen av resultaten för HPV-screening av kvinnor mellan 23 och 29 år hittar inte någon betydande skillnad beträffande vad som tidigare är känt för kvinnor över 30 år [3].

I studien från HPV FOCAL är screeningintervallen inte helt överensstämmande med svenska förhållanden och en kolposkopisk utredning sker av grupper som inte utreds direkt i Sverige. Emellertid är flera förhållanden likartade och studiens huvudresultat bedöms ha god relevans för Sverige.

Den australienska Compass-studien har också validitet för Sverige eftersom den genomförs i ett välorganiserat screeningprogram, även om uppföljning och utredning av HPV-positiva är mer aggressiv än här. Dess stora tillgång är att den redovisar data för en till stor del vaccinerad population. Studien är liten så stora skillnader i punktestimat (CIN2+ och kolposkopiremitteringar) är inte statistiskt signifikanta.

Tillgängliga forskningsresultat för primär HPV-screening i denna åldersgrupp är alltså mycket sparsamma och det är anmärkningsvärt att den enda studien med god relevans och överförbarhet är 12 år gammal. En rimlig slutsats av ofullständiga forskningsdata är att primär HPV-analys i åldrarna 23–30, a) kan leda till tidigareläggning av upptäckt av CIN2+, b) kan leda till ökat behov av kolposkopi initialt.

Konsekvenserna av tidigareläggande av CIN2+ är svåra att bedöma. De kan möjligen bidra till att sänka cancerincidensen i denna åldersgrupp med få cancerfall, men där har incidensen inte minskat sedan screening introducerats i Sverige – till skillnad från alla äldre åldersgrupper.[3] Samtidigt ökar risken för detektion av självläkande CIN2-förändringar och kommer att ställa krav på vårdprogram och kolposkopi för att undvika skadlig överbehandling i en känslig åldersgrupp. Ökning av kolposkopibehov får betraktas som initial eftersom

erfarenhet från många studier i andra ålderspopulationer visar att det följs av en sänkning efter första screeningomgången. Kolposkopi är en belastad resurs som kan ha svårigheter att klara även en initial volymökning. Det kan också ge problem med överdiagnostik när kolposkopier ökar i en population där andelen med CIN2+ kan förväntas att succesivt minska som en följd av vaccinationerna.

3. https://www.socialstyrelsen.se/statistik-och-data/register/alla-register/cancerregistret/.

En möjlig hypotes är att primärscreening med HPV för kvinnor under 30 år kan ge färre positiva screeningresultat i denna alltmer vaccinerade kohort, än tidigare. I åldersgrupperna över 30 år får 9 procent av svenska deltagare besked om ett positivt prov i HPV-screening.[4] Motsvarande svenska data för åldersgruppen 23 till 29 år saknas naturligt nog men kan förväntas vara 2 till 3 gånger högre hos ovaccinerade [53]. Förekomsten av vaccintyper av HPV (bland annat 16 och 18) sjunker i vaccinerade åldersgrupper så problemen med hög överdiagnostik hos yngre kvinnor minskar [54].

4. Förebyggande av livmoderhalscancer i Sverige Verksamhetsberättelse och Årsrapport 2020 med data till och med 2019; Nationellt Kvalitetsregister för Cervixcancerprevention (NKCx)

5. Medverkande

5.1 Projektgrupp

5.1.1 Sakkunniga

- Joakim Dillner, professor i infektionsepidemiologi, Institutionen för laboratoriemedicin, Karolinska institutet
- Björn Strander, docent, specialist i obstetrik och gynekologi, Avdelningen för obstetrik och gynekologi, Göteborgs universitet, Sahlgrenska Akademin

5.1.2 Kansli

- Margareta Hedner, projektledare
- Naama Keenan Moden, biträdande projektledare
- Maja Kärrman Fredriksson, informationsspecialist
- Emma Wernersson, projektadministratör
- Jenny Odeberg, projektansvarig chef

5.1.3 Bindningar och jäv

Sakkunniga har i enlighet med SBU:s krav lämnat deklarationer om bindningar och jäv. SBU har bedömt att de förhållanden som redovisats där är förenliga med myndighetens krav på saklighet och opartiskhet.

6. Ordförklaringar och förkortningar

Cellprov i livmoderhalscancerscreening
Hela proceduren kring provtagning och analys. Analysen kan antingen vara en cytologi eller ett HPV-test

CIN
Cervical Intraepitelial Neoplasia, histologisk diagnos som kräver ett vävnadsprov (biopsi) eller vävnad från till exempel en operation för att kunna fastställas. CIN1 är lindrig, CIN2 måttlig och CIN3 grav atypi eller dysplasi i cellerna

Cytologi
Mikroskopisk undersökning av ett cellutstryk

HPV
Humant papillomvirus (HPV) är en grupp virus som omfattar mer än 200 olika typer. HPV är en mycket smittsam sexuellt överförbar infektion och de flesta människor infekteras med en eller flera olika typer av viruset någon gång i livet

Högrisk HPV
Tretton HPV-typer klassificeras som högriskvirus och kan orsaka olika typer av cancer. HPV-typerna 16 och 18 är de vanligast förekommande högrisktyperna och orsakar omkring 70 procent av alla fall av livmoderhalscancer

Incidens

- Antalet fall av en viss sjukdom som uppträder i en befolkning under en viss tid; anges till exempel som antalet diagnoser per 1 000 invånare per år
- Antalet av en viss studerad händelse i en klinisk prövning eller kohortundersökning, dividerat med antalet deltagare i gruppen. Graden av skillnad mellan två gruppers incidenstal kan uttryckas genom att det ena divideras med det andra till en incidenskvot

Kolposkopi
Undersökning av livmodermunnen med syfte att ge närmare information om avvikande celler som upptäckts i cellprov

Non-inferiority design
Studiedesign för att visa att ny behandling åtminstone inte är sämre än annan, ofta standardbehandling. Man sätter i förväg upp en marginal för hur mycket sämre effekt vi kan tänka oss att acceptera och ändå anse att den nya behandlingen är kliniskt likvärdigt med jämförande behandling

Relativ sensitivitet
Sensitiviteten av ett screeningtest där referensen är ett jämförande test

Relativ specificitet
Specificiteten av ett screeningtest där referensen är ett jämförande test

Sensitivitet
Egenskap hos diagnosmetod: andelen av sjuka som metoden identifierar korrekt genom att utfalla positivt, det vill säga ge onormalt resultat

Specificitet
Egenskap hos diagnosmetod: andelen av friska som metoden identifierar korrekt (genom att utfalla negativt, det vill säga ge normalt resultat)

Triage
Kategorisering för vidare omhändertagande. I denna rapport avses den undersökning som vid ett avvikande screeningtest görs för att ytterligare utreda vilka som ska undersökas vidare

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Bilaga till rapport

Screening för livmoderhalscancer, rapport 338, (2021)

Bilaga 1, Sökdokumentation

Innehåll

Självtester

Cochrane Library via Wiley February 10th, 2021
Title: Screening livmoderhalscancer – Självprovtagning av HPV

Search terms		Items found
Population: Cervical cancer		
1.	MeSH descriptor: [Uterine Cervical Neoplasms] explode all trees	2092
2.	MeSH descriptor: [Cervical Intraepithelial Neoplasia] explode all trees	561
3.	MeSH descriptor: [Papillomavirus Infections] explode all trees	755
4.	MeSH descriptor: [Uterine Cervical Dysplasia] explode all trees	203
5.	(((cervic* or cervix*) NEAR/1 (canc* or neoplas* or carcinom* or dysplas*))):ti,ab,kw OR ((HPV* or papillomavir*)):ti,ab,kw	7440
6.	*1-5 (OR)*	*7472*
Index test: Self test		
7.	MeSH descriptor: [Self-Examination] explode all trees	208
8.	MeSH descriptor: [Self Care] explode all trees	5677
9.	(((Self or home) NEAR/5 (collect* or samp* or test* or obtain* or HPV*))):ti,ab,kw	9647
10.	*7-9 (OR)*	*15061*
Combined sets		
11.	*6 AND 10*	*344*
Final result		
12.	**11**	**CDSR/1 Cochrane Protocols/0 CENTRAL/ 343**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

:au = Author; MeSH = Term from the Medline controlled vocabulary, including terms found below this term in the MeSH hierarchy; **this term only** = Does not include terms found below this term in the MeSH hierarchy; **:ti** = Title; **:ab** = Abstract; **:kw** = Keyword; ***** = Truncation; **" "** = Citation Marks; searches for an exact phrase; **CDSR** = Cochrane Database of Systematic Review; **Cochrane Protocols** = Protocols of systematic reviews registered in Cochrane Library; **CENTRAL** = Cochrane Central Register of Controlled Trials, "trials"

CRD Database via Centre for Reviews and Dissemination February 22nd, 2021
Title: Screening livmoderhalscancer – Självprovtagning av HPV

Search terms		Items found
Population: Cervical cancer		
13.	MeSH DESCRIPTOR uterine cervical neoplasms EXPLODE ALL TREES	541
14.	MeSH DESCRIPTOR Papillomavirus Infections EXPLODE ALL TREES	283
15.	MeSH DESCRIPTOR Uterine Cervical Dysplasia EXPLODE ALL TREES	22
16.	(((cervic* OR cervix) AND (cancer* OR carcinom* OR precancer* OR neoplas* OR dysplas*))) OR ((papillomavir* OR hpv* OR hrhpv*))	863
17.	*1-4 (OR)*	*890*
Index test: Self test		
18.	MeSH DESCRIPTOR self care EXPLODE ALL TREES	633
19.	MeSH DESCRIPTOR self-examination	7
20.	("self test*" or "self taken" or "self collect*" or "self samp*" or "self obtain*" or "self HPV*" or "home test*" or "home taken" or "home collect*" or "home samp*" or "home obtain*" or "home HPV*" or "self-test*" or "self-taken" or "self-collect*" or "self-samp*" or "self-obtain*" or "self-HPV*" or "home-test*" or "home-taken" or "home-collect*" or "home-samp*" or "home-obtain*" or "home-HPV*")	56
21.	*6-8 (OR)*	*669*
Final result		
22.	**5 AND 9**	**19**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

[MeSH] = Term from the Medline controlled vocabulary, including terms found below this term in the MeSH hierarchy; [MeSH:NoExp] = Does not include terms found below this term in the MeSH hierarchy; **[MAJR]** = MeSH Major Topic; **[TIAB]** = Title or abstract; **[TI]** = Title; **[AU]** = Author; **[OT]** = Other term; **[TW]** = Text word; **Systematic[SB]** = Filter for retrieving systematic reviews; ***** = Truncation

Embase via Elsevier February 10th, September 2021
Title: Screening livmoderhalscancer – Självprovtagning av HPV

	Search terms	Items found
Population: Cervical cancer		
23.	'uterine cervix carcinoma'/exp OR 'papillomavirus infection'/de OR 'uterine cervix dysplasia'/exp OR 'uterine cervix carcinoma in situ'/exp OR 'cervical intraepithelial neoplasia 2'/exp OR 'cervical intraepithelial neoplasia 3'/exp OR 'cervical intraepithelial neoplasia grade 2'/exp	60,390
24.	((cervic* OR cervix*) NEAR/1 (canc* OR neoplas* OR carcinom* OR dysplas*)):ti,ab	85776
25.	hpv*:ti,ab OR papillomavir*:ti,ab	72,740
26.	*1-3 (OR)*	*154,483*
Index test: Self test		
27.	'self care'/exp OR 'self examination'/de	89,659
28.	((self OR home) NEAR/5 (collect* OR samp* OR test* OR obtain* OR hpv*)):ti,ab	62,086
29.	*5 OR 6*	*148,408*
Study types: randomised controlled trials and other trials		
30.	'systematic review'/de	281,791
31.	'meta analysis'/de	205,549
32.	[cochrane review]/lim	21,856
33.	((systematic* NEXT/3 (review* OR overview)):ti,ab) OR ((systematic* NEXT/3 bibliographic*):ti,ab) OR ((systematic* NEXT/3 literature):ti,ab) OR 'meta analy*':ti,ab OR metaanaly*:ti,ab	402,623
34.	*8-11 (OR)*	*505,663*
Limits: language, publication year, publication type		
35.	([danish]/lim OR [english]/lim OR [norwegian]/lim OR [swedish]/lim) AND [2010-2021]/py	
36.	([conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [data papers]/lim)	
Combined sets		
37.	*4 AND 7*	*1,989*
Final result		
38.	**(15 AND 13) NOT 14**	**1,204**
39.	**11 AND 16**	**47**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

/de = Term from the EMTREE controlled vocabulary; **/exp** = Includes terms found below this term in the EMTREE hierarchy

/mj = Major Topic; **:ab** = Abstract; **:au** = Author; **:ti** = Article Title; **:ti,ab** = Title or abstract; ***** = Truncation; **' '** = Citation Marks; searches for an exact phrase; **NEAR/n** = Requests terms that are within 'n' words of each other in either direction; **NEXT/n** = Requests terms that are within 'n' words of each other in the order specified

Epistemonikos via Epistemonikos February 22 th, 2021
Title: Screening livmoderhalscancer – Självprovtagning av HPV

Search terms		Items found
Population: Cervical cancer		
40.	(title:((cervic* OR cervix) AND (cancer* OR carcinom* OR precancer OR neoplas* OR dysplas*)) OR abstract:((cervic* OR cervix) AND (cancer* OR carcinom* OR precancer OR neoplas* OR dysplas*))) OR (title:(papillomavir* OR hpv* OR hrhpv* OR CIN*) OR abstract:(papillomavir* OR hpv* OR hrhpv* OR CIN*))	38,549
Index test: Self test		
41.	(title:("self-test*" OR "self-taken" OR "self-collect*" OR "self-samp*" OR "self-obtain*" OR "self-HPV*" OR "home-test*" OR "home-taken" OR "home-collect*" OR "home-samp*" OR "home-obtain*" OR "home-HPV*") OR abstract:("self-test*" OR "self-taken" OR "self-collect*" OR "self-samp*" OR "self-obtain*" OR "self-HPV*" OR "home-test*" OR "home-taken" OR "home-collect*" OR "home-samp*" OR "home-obtain*" OR "home-HPV*")) or (title:("self test*" OR "self taken" OR "self collect*" OR "self samp*" OR "self obtain*" OR "self HPV*" OR "home test*" OR "home taken" OR "home collect*" OR "home samp*" OR "home obtain*" OR "home HPV*") OR abstract:("self test*" OR "self taken" OR "self collect*" OR "self samp*" OR "self obtain*" OR "self HPV*" OR "home test*" OR "home taken" OR "home collect*" OR "home samp*" OR "home obtain*" OR "home HPV*"))	81
Final result		
42.	**1 AND 2**	**16**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

:au = Author; MeSH = Term from the Medline controlled vocabulary, including terms found below this term in the MeSH hierarchy; **this term only** = Does not include terms found below this term in the MeSH hierarchy; **:ti** = Title; **:ab** = Abstract; **:kw** = Keyword; ***** = Truncation; **" "** = Citation Marks; searches for an exact phrase; **CDSR** = Cochrane Database of Systematic Review; **Cochrane Protocols** = Protocols of systematic reviews registered in Cochrane Library; **CENTRAL** = Cochrane Central Register of Controlled Trials, "trials"

International HTA Database via INAHTA February 22th, 2021
Title: Screening livmoderhalscancer – Självprovtagning av HPV

Search terms		Items found
Population: Cervical cancer		
43.	((cervic* OR cervix) AND (cancer* OR carcinom* OR precancer* OR neoplas* OR dysplas*))[Title] OR (papillomavir* OR hpv* OR hrhpv* OR CIN*)[Title] OR ((cervic* OR cervix) AND (cancer* OR carcinom* OR precancer* OR neoplas* OR dysplas*))[abs] OR (papillomavir* OR hpv* OR hrhpv* OR CIN*)[abs]	172
Index test: Self test		
44.	(("self test*" or "self taken" or "self collect*" or "self samp*" or "self obtain*" or "self HPV*" or "home test*" or "home taken" or "home collect*" or "home samp*" or "home obtain*" or "home HPV*")) OR ("self-test" or "self-tests" or "self-testing" or "self-taken" or "self-collected" or "self-collecting" or "self-collection" or "self-sample" or "self-samples" or "self-sampling" or "self-obtained" or "self-HPV" or "home-test" or "home-tests" or "home-testing" or "home-taken" or "home-collected" or "home-collecting" or "home-collection" or "home-sample" or "home-samples" or "home-sampling" or "home-obtained" or "home-HPV")	17
Final result		
45.	**1 AND 2**	**4**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

/de = Term from the EMTREE controlled vocabulary; **/exp** = Includes terms found below this term in the EMTREE hierarchy **/mj** = Major Topic; **:ab** = Abstract; **:au** = Author; **:ti** = Article Title; **:ti,ab** = Title or abstract; ***** = Truncation; **' '** = Citation Marks; searches for an exact phrase; **NEAR/n** = Requests terms that are within 'n' words of each other in either direction; **NEXT/n** = Requests terms that are within 'n' words of each other in the order specified

KSR Evidence via Kleijnen Systematic Reviews February 22th, 2021
Title: Screening livmoderhalscancer – Självprovtagning av HPV

Search terms		Items found
Population: Cervical cancer		
46.	(cervic* or cervix) AND (cancer* or carcinoma* or precancer* or neoplas* or dysplas*) in Title or Abstract	794
47.	papillomavir* or hpv* or hrhpv* in Title or Abstract	623
48.	*1 OR 2*	*1190*
Index test: Self test		
49.	"self test*" or "self taken" or "self collect*" or "self samp*" or "self obtain*" or "self HPV*" or "home test*" or "home taken" or "home collect*" or "home samp*" or "home obtain*" or "home HPV*" in All text	65
Final result		
50.	**3 AND 4**	**16**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

AB = Abstract; **AU** = Author; **DE** = Term from the thesaurus; **MH**= Exact Subject Heading from CINAHL Subject Headings; **MM** = Major Concept; **TI** = Title; **TX** = All Text. Performs a keyword search of all the database's searchable fields; **ZC** = Methodology Index; ***** = Truncation; **" "** = Citation Marks; searches for an exact phrase; **N** = Near Operator (N) finds the words if they are a maximum of x words apart from one another, regardless of the order in which they appear.; **W** = Within Operator (W) finds the words if they are within x words of one another, in the order in which you entered them.

Medline via OvidSP February 10th, 2021
Title: Screening livmoderhalscancer – Självprovtagning av HPV

Search terms		Items found
Population: Cervical cancer		
51.	Uterine Cervical Neoplasms/	76147
52.	Cervical Intraepithelial Neoplasia/	10140
53.	Papillomavirus Infections/	26867
54.	exp Uterine Cervical Dysplasia/	4499
55.	((cervic* or cervix*) adj1 (canc* or neoplas* or carcinom* or dysplas*)).ab,ti.	63*109*
56.	(HPV* or papillomavir*).ab,ti.	55*340*
57.	*1-6 (OR)*	*132158*
Index test: Self test		
58.	Self-Examination/	1148
59.	exp Self Care/	55808
60.	((Self or home) adj5 (collect* or samp* or test* or obtain* or HPV*)).ab,ti.	47506
61.	*8-10 (OR)*	*101062*
Study types: systematic reviews, meta analysis		
62.	(systematic reviews pre 2019 or systematic reviews or meta analysis)	
Limits: Publication year, language		
63.	(yr="2010 -Current" and (danish or english or norwegian or swedish)	
Final result		
64.	**7 AND 11 AND 13**	**1203**
65.	**12 AND 14**	**49**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

.ab. = Abstract; .**ab,ti.** = Abstract or title; **.af.** = All fields; **Exp** = Term from the Medline controlled vocabulary, including terms found below this term in the MeSH hierarchy; **.sh.** = Term from the Medline controlled vocabulary; **.ti.** = Title; **/** = Term from the Medline controlled vocabulary, but does not include terms found below this term in the MeSH hierarchy; ***** = Focus (if found in front of a MeSH-term); *** or $** = Truncation (if found at the end of a free text term); **.mp** = Text, heading word, subject area node, title; **" "** = Citation Marks; searches for an exact phrase; *ADJn* = Positional operator that lets you retrieve records that contain your terms (in any order) within a specified number (n) of words of each other.
exact phrase; **?** = Wildcard, used to replace any single character either inside or at the right end of a word

NICE Evidence Search via National Institute for Health and Care Excellence 22 February 2021
Title: Screening livmoderhalscancer – Självprovtagning av HPV

Search terms		Items found
Population: Cervical cancer/Index test: Self test		
66.	("self test*" or "self taken" or "self collect*" or "self samp*" or "self obtain*" or "self HPV*" or "home test*" or "home taken" or "home collect*" or "home samp*" or "home obtain*" or "home HPV*") (HPV or hrHPV or cervical or cervix or papillomavir* or CIN*)	70
Study types: systematic reviews, HTA-reports		
67.	Evidence type: Systematic Reviews filter Evidence type: Health Technology Assessments	
Final result		
68.	**1 AND 2**	**12**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

.ab. = Abstract; .**ab,ti.** = Abstract or title; **.af.** = All fields; **Exp** = Term from the Medline controlled vocabulary, including terms found below this term in the MeSH hierarchy; **.sh.** = Term from the Medline controlled vocabulary; **.ti.** = Title; **/** = Term from the Medline controlled vocabulary, but does not include terms found below this term in the MeSH hierarchy; ***** = Focus (if found in front of a MeSH-term); *** or $** = Truncation (if found at the end of a free text term); **.mp** = Text, heading word, subject area node, title; **" "** = Citation Marks; searches for an exact phrase; *ADJn* = Positional operator that lets you retrieve records that contain your terms (in any order) within a specified number (n) of words of each other.

Prospero via Centre for Reviews and Dissemination February 21 th,2021
Title: Screening livmoderhalscancer – Självprovtagning av HPV

Search terms		Items found
Population: Cervical cancer/Index test: Self test		
69.	("self test*" or "self taken" or "self collect*" or "self samp*" or "self obtain*" or "self HPV*" or "home test*" or "home taken" or "home collect*" or "home samp*" or "home obtain*" or "home HPV*" or "self-test*" or "self-taken" or "self-collect*" or "self-samp*" or "self-obtain*" or "self-HPV*" or "home-test*" or "home-taken" or "home-collect*" or "home-samp*" or "home-obtain*" or "home-HPV*") AND (HPV* or papilloma* or cervic* or cervix)	**37**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

TITLE-ABS-KEY = Title or abstract or keywords; **ALL =** All fields; **PRE/n =** "precedes by". The first term in the search must precede the second by a specified number of terms (n).; **W/n =** "Within". The terms in the search must be within a specified number of terms (n) in any order.; ***** = Truncation; **" "** = Citation Marks; searches for an exact phrase; **LIMIT-TO (SRCTYPE, "j"** = Limit to source type journal; **LIMIT-TO (DOCTYPE, "ar"** = Limit to document type article; **LIMIT-TO (DOCTYPE, "re"** = Limit to document type review

Primär screeninganalys: Cytologi vs HPV

Cochrane Library via Wiley February 26th, 2021 (CDSR, Cochrane Protocols & CENTRAL)
Title: Screening livmoderhalscancer - Primär HPV-analys som screeningmetod

Search terms		Items found
Population: Cervical cancer		
70.	MeSH descriptor: [Uterine Cervical Neoplasms] explode all trees	2108
71.	MeSH descriptor: [Cervical Intraepithelial Neoplasia] explode all trees	568
72.	MeSH descriptor: [Papillomavirus Infections] explode all trees	1109
73.	MeSH descriptor: [Uterine Cervical Dysplasia] explode all trees	206
74.	MeSH descriptor: [Papillomaviridae] this term only	389
75.	MeSH descriptor: [Alphapapillomavirus] explode all trees	229
76.	(((cervic* or cervix*) NEAR/3 (canc* or precanc* or neoplas* or adenocarcinom* or carcinom* or dysplas*))):ti,ab,kw	6121
77.	((HPV* or hrHPV* or hr-HPV* or papillomavir* or CIN*)):ti,ab,kw	17036
78.	*1-8 (OR)*	*21679*
Index test: HPV-analysis		
79.	MeSH descriptor: [Human Papillomavirus DNA Tests] explode all trees	10
80.	MeSH descriptor: [Uterine Cervical Dysplasia] explode all trees and with qualifier(s): [virology - VI]	27
81.	MeSH descriptor: [Cervical Intraepithelial Neoplasia] explode all trees and with qualifier(s): [virology - VI]	170
82.	MeSH descriptor: [Papillomavirus Infections] explode all trees and with qualifier(s): [virology - VI]	237
83.	MeSH descriptor: [Polymerase Chain Reaction] explode all trees	2076
84.	(((HPV* or papilloma*)NEAR/3 (analy* or DNA or test* or smear* or assay*))):ti,ab,kw	1119
85.	((PCR or "polymerase chain reaction" or virology)):ti,ab,kw	25216
86.	*10-16 (OR)*	25921
Reference test: Cytology		
87.	MeSH descriptor: [Cell Biology] explode all trees	3
88.	MeSH descriptor: [Papanicolaou Test] explode all trees	238
89.	(cytodiagn* OR cytolog* OR papanicolau OR papanicolaou):ti,ab,kw OR (pap NEAR/1 (test* OR smear* OR swab* OR scrap*)):ti,ab,kw	11029
90.	*18-20 (OR)*	11030
Final result		
91.	**9 AND 17 AND 21**	**CDSR/4 Cochrane Protocols/1 Central/681**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

:au = Author; MeSH = Term from the Medline controlled vocabulary, including terms found below this term in the MeSH hierarchy; **this term only** = Does not include terms found below this term in the MeSH hierarchy; **:ti** = Title; **:ab** = Abstract; **:kw** = Keyword; ***** = Truncation; **" "** = Citation Marks; searches for an exact phrase; **CDSR** = Cochrane Database of Systematic Review; **Cochrane Protocols** = Protocols of systematic reviews registered in Cochrane Library; **CENTRAL** = Cochrane Central Register of Controlled Trials, "trials"

CRD Database via Centre for Reviews and Dissemination March 4th,2021
Title: Screening livmoderhalscancer - Primär HPV-analys som screeningmetod

	Search terms	Items found
Population: Cervical cancer		
92.	("cervical cancer" OR "cervical neoplas*" OR "cervical carcinom*" OR "cervical adenocarcinom*" OR "cervical dysplas*" OR "cervical intraepithelial" OR "cervix cancer" OR "cervix neoplas*" OR "cervix carcinom*" OR "cervix adenocarcinom*" OR "cervix dysplas*" OR "cervix intraepithelial" OR "HPV-infection*" OR hrHPV* OR "hr-HPV*" OR "papillomavirus-infect*")) AND ("HPV analys*" or "HPV DNA-analys*" or "HPV-test*" or "papillomavirus-analys*" or "papillomavirus DNA-analys*" or "papillomavirus-test" or PCR or "polymerase chain reaction" or virology) AND (cytodiagn* or cytolog* or papanicolau or papanicolaou or "pap test*" or "pap smear" or "pap swab" or "pap scrap")	**102**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

AB = Abstract; AF = Author affiliation; **All** = Performs a keyword search in most of the database's searchable fields, except full text; **AU** = Author; **MAINSUBJECT** = Term from the thesaurus; **TI** = Title; ***** = Truncation; **" "** = Citation Marks; searches for an exact phrase; **?** = Wildcard, used to replace any single character either inside or at the right end of a word

Embase via Elsevier February 26th, 2021
Title: Screening livmoderhalscancer - Primär HPV-analys som screeningmetod

	Search terms	Items found
Population: Cervical cancer		
93.	'uterine cervix tumor'/exp OR 'uterine cervix carcinoma in situ'/exp OR 'cervical intraepithelial neoplasia 2'/exp OR 'cervical intraepithelial neoplasia 3'/exp OR 'cervical intraepithelial neoplasia grade 2'/exp OR 'papillomavirus infection'/exp OR 'uterine cervix dysplasia'/exp OR 'papillomaviridae'/de OR 'alphapapillomavirus'/exp	167,239
94.	((cervic* OR cervix*) NEAR/3 (canc* OR precanc* OR neoplas* OR adenocarcinom* OR carcinom* OR dysplas*)):ti,ab,kw	111,961
95.	hpv*:ti,ab,kw OR hrhpv*:ti,ab,kw OR 'hr hpv*':ti,ab,kw OR papillomavir*:ti,ab,kw OR cin*:ti,ab,kw	244,679
96.	*1-3 (OR)*	*373,639*
Index test: HPV-analysis		
97.	'human papillomavirus dna test'/exp OR 'virology'/exp OR 'human papillomavirus test'/exp OR 'human papillomavirus testing'/exp OR 'polymerase chain reaction'/exp OR 'pcr'/exp	1,045,937
98.	((hpv* OR papilloma*) NEAR/3 (analy* OR dna OR test* OR smear* OR assay*)):ti,ab,kw	22,812
99.	pcr:ti,ab,kw OR 'polymerase chain reaction':ti,ab,kw OR virology:ti,ab,kw	922,195
100.	*5-7 (OR)*	*1,317,025*
Reference test: Cytology		
101.	'cytology'/exp OR 'papanicolaou test'/exp	911,172

102.	cytodiagn*:ti,ab,kw OR cytolog*:ti,ab,kw OR papanicolau:ti,ab,kw OR papanicolaou:ti,ab,kw	139,078
103.	(pap NEAR/1 (test* OR smear* OR swab* OR scrap*)):ti,ab,kw	12,779
104.	*9-11 (OR)*	*968,774*
Study types: diagnostic studies		
105.	'sensitivity and specificity'/exp OR 'predictive value'/exp OR 'receiver operating characteristic'/exp OR 'area under the curve'/exp	683,017
106.	(accuracy OR diagnostic OR diagnosis OR detect* OR predict* OR probabil* OR performance OR sensitiv* OR specific* OR ppv OR npv OR roc OR auroc)	11,776,782
107.	*13-14 (OR)*	*11,902,946*
Study types: systematic reviews, meta analysis		
108.	'systematic review'/de OR 'meta analysis'/de	384,963
109.	[cochrane review]/lim	21,865
110.	((systematic* NEXT/3 (review* OR overview)):ti,ab) OR ((systematic* NEXT/3 bibliographic*):ti,ab) OR ((systematic* NEXT/3 literature):ti,ab)	268,195
111.	'meta analy*':ti,ab OR metaanaly*:ti,ab	252,015
112.	*16-19 (OR)*	*508,999*
Limits: language, publication type		
113.	([danish]/lim OR [english]/lim OR [norwegian]/lim OR [swedish]/lim)	
114.	([conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [short survey]/lim)	
Final result		
115.	**4 AND 8 AND 12 AND 15 AND 20 AND 21**	**198**
116.	**(4 AND 8 AND 12 AND 15 AND 21) NOT 22**	**6,527**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

/de = Term from the EMTREE controlled vocabulary; **/exp** = Includes terms found below this term in the EMTREE hierarchy **/mj** = Major Topic; **:ab** = Abstract; **:au** = Author; **:ti** = Article Title; **:ti,ab** = Title or abstract; ***** = Truncation; **' '** = Citation Marks; searches for an exact phrase; **NEAR/n** = Requests terms that are within 'n' words of each other in either direction; **NEXT/n** = Requests terms that are within 'n' words of each other in the order specified

Epistemonikos via Epistemonikos March 4th, 2021
Title: Screening livmoderhalscancer - Primär HPV-analys som screeningmetod

Search terms		Items found
Population: Cervical cancer		
117.	(title:("cervical cancer" OR "cervical neoplas*" OR "cervical carcinom*" OR "cervical adenocarcinom*" OR "cervical dysplas*" OR "cervical intraepithelial" OR "cervix cancer" OR "cervix neoplas*" OR "cervix carcinom*" OR "cervix adenocarcinom*" OR "cervix dysplas*" OR "cervix intraepithelial" OR "HPV-infection*" OR hrHPV* OR "hr-HPV*" OR "papillomavirus-infect*") OR abstract:("cervical cancer" OR "cervical neoplas*" OR "cervical carcinom*" OR "cervical adenocarcinom*" OR "cervical dysplas*" OR "cervical intraepithelial" OR "cervix cancer" OR "cervix neoplas*" OR "cervix carcinom*" OR "cervix adenocarcinom*" OR "cervix dysplas*" OR "cervix intraepithelial" OR "HPV-infection*" OR hrHPV* OR "hr-HPV*" OR "papillomavirus-infect*"))	3,770

Index test: HPV-analysis		
118.	(title:("HPV analys*" or "HPV DNA-analys*" or "HPV-test*" or "papillomavirus-analys*" or "papillomavirus DNA-analys*" or "papillomavirus-test" or PCR or "polymerase chain reaction" or virology))	13,082
Reference test: Cytology		
119.	(title:(cytodiagn* or cytolog* or papanicolau or papanicolaou or "pap test*" or "pap smear" or "pap swab" or "pap scrap"))	3,924
Final result		
120.	**1 AND 2 AND 3**	**75**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

TITLE-ABS-KEY = Title or abstract or keywords; **ALL =** All fields; **PRE/n =** "precedes by". The first term in the search must precede the second by a specified number of terms (n).; **W/n =** "Within". The terms in the search must be within a specified number of terms (n) in any order.; ***** = Truncation; **" "** = Citation Marks; searches for an exact phrase; **LIMIT-TO (SRCTYPE, "j"** = Limit to source type journal; **LIMIT-TO (DOCTYPE, "ar"** = Limit to document type article; **LIMIT-TO (DOCTYPE, "re"** = Limit to document type review

International HTA Database via INAHTA March 4th, 2021

Title: Screening livmoderhalscancer - Primär HPV-analys som screeningmetod

Search terms		Items found
Population: Cervical cancer		
121.	("cervical cancer" OR "cervical neoplas*" OR "cervical carcinom*" OR "cervical adenocarcinom*" OR "cervical dysplas*" OR "cervical intraepithelial" OR "cervix cancer" OR "cervix neoplas*" OR "cervix carcinom*" OR "cervix adenocarcinom*" OR "cervix dysplas*" OR "cervix intraepithelial" OR "HPV-infection*" OR hrHPV* OR "hr-HPV*" OR "papillomavirus-infect*")) AND ("HPV analys*" or "HPV DNA-analys*" or "HPV-test*" or "papillomavirus-analys*" or "papillomavirus DNA-analys*" or "papillomavirus-test" or PCR or "polymerase chain reaction" or virology) AND (cytodiagn* or cytolog* or papanicolau or papanicolaou or "pap test*" or "pap smear" or "pap swab" or "pap scrap")	**3**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

AB = Abstract; AF = Author affiliation; **All** = Performs a keyword search in most of the database's searchable fields, except full text; **AU** = Author; **MAINSUBJECT** = Term from the thesaurus; **TI** = Title; ***** = Truncation; **" "** = Citation Marks; searches for an exact phrase; **?** = Wildcard, used to replace any single character either inside or at the right end of a word

KSR Evidence via Kleijnen Systematic Reviews March 4th, 2021

Title: Screening livmoderhalscancer - Primär HPV-analys som screeningmetod

Search terms		Items found
Population: Cervical cancer		
122.	"cervical cancer" or "cervical neoplas*" or "cervical carcinom*" or "cervical adenocarcinom*" or "cervical dysplas*" or "cervical intraepithelial" or "cervix cancer" or "cervix neoplas*" or "cervix carcinom*" or "cervix adenocarcinom*" or "cervix dysplas*" or "cervix intraepithelial" or "HPV-infection*" or hrHPV* or "hr-HPV*" or "papillomavirus-infect*" in All text	904

Index test: HPV-analysis		
123.	"HPV analys*" or "HPV DNA-analys*" or "HPV-test*" or "papillomavirus-analys*" or "papillomavirus DNA-analys*" or "papillomavirus-test" or PCR or "polymerase chain reaction" or virology in All text	1391
Reference test: Cytology		
124.	cytodiagn* or cytolog* or papanicolau or papanicolaou or "pap test*" or "pap smear" or "pap swab" or "pap scrap" in All text	535
Final result		
125.	**1 AND 2 AND 3**	**38**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

[MeSH] = Term from the Medline controlled vocabulary, including terms found below this term in the MeSH hierarchy; [MeSH:NoExp] = Does not include terms found below this term in the MeSH hierarchy; **[MAJR]** = MeSH Major Topic; **[TIAB]** = Title or abstract; **[TI]** = Title; **[AU]** = Author; **[OT]** = Other term; **[TW]** = Text word; **Systematic[SB]** = Filter for retrieving systematic reviews; ***** = Truncation

Medline via OvidSP February 26th, 2021
Title: Screening livmoderhalscancer - Primär HPV-analys som screeningmetod

Search terms		Items found
Population: Cervical cancer		
126.	Uterine Cervical Neoplasms/	76294
127.	Cervical Intraepithelial Neoplasia/	15961
128.	Papillomavirus Infections/	26985
129.	exp Uterine Cervical Dysplasia/	4505
130.	papillomaviridae/ or exp alphapapillomavirus/	32528
131.	((cervic* or cervix*) adj3 (canc* or precanc* or neoplas* or adenocarcinom* or carcinom* or dysplas*)).ab,kf,ti.	85186
132.	(HPV* or hrHPV* or hr-HPV* or papillomavir* or CIN*).ab,kf,ti.	184499
133.	*1-7 (OR)*	*266541*
Index test: HPV-analysis		
134.	Human Papillomavirus DNA Tests/	533
135.	Uterine Cervical Dysplasia/vi [Virology]	523
136.	Cervical Intraepithelial Neoplasia/vi [Virology]	3918
137.	Papillomavirus Infections/vi [Virology]	9661
138.	exp Polymerase Chain Reaction/	453117
139.	((HPV* or papilloma*) adj3 (analy* or DNA or test* or smear* or assay*)).ab,kf,ti.	17254
140.	(PCR or "polymerase chain reaction" or virology).ab,kf,ti.	675233
141.	*9-15 (OR)*	*885288*
Reference test: Cytology		
142.	exp Cytological Techniques/	1508654
143.	Papillomaviridae/cy [Cytology]	4
144.	Papanicolaou Test/	6747
145.	(cytodiagn* or cytolog* or papanicolau or papanicolaou or (pap adj1 (test* or smear* or swab* or scrap*))).ab,kf,ti.	110896
146.	*17-20 (OR)*	*1565948*

Study types: diagnostic studies		
147.	exp "Sensitivity and Specificity"/	599851
148.	(accuracy or diagnostic or diagnosis or detect* or predict* or probabil* or performance or sensitiv* or specific* or PPV or NPV or ROC or AUROC).ab,kf,ti.	9198777
149.	*22-23 (OR)*	*9311384*
Study types: systematic reviews, meta analysis		
150.	(systematic reviews pre 2019 or systematic reviews)	
Limits: language		
151.	(danish or english or norwegian or swedish)	
Final result		
152.	**8 AND 16 AND 21 AND 24 AND 25 AND 26**	**199**
153.	**8 AND 16 AND 21 AND 24 AND 26**	**8381**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

.ab. = Abstract; .**ab,ti.** = Abstract or title; **.af.** = All fields; **Exp** = Term from the Medline controlled vocabulary, including terms found below this term in the MeSH hierarchy; **.sh.** = Term from the Medline controlled vocabulary; **.ti.** = Title; **/** = Term from the Medline controlled vocabulary, but does not include terms found below this term in the MeSH hierarchy; ***** = Focus (if found in front of a MeSH-term); *** or $** = Truncation (if found at the end of a free text term); **.mp** = Text, heading word, subject area node, title; **" "** = Citation Marks; searches for an exact phrase; *ADJn* = Positional operator that lets you retrieve records that contain your terms (in any order) within a specified number (n) of words of each other.

NICE Evidence Search via National Institute for Health and Care Excellence March 4th, 2021
Title: Screening livmoderhalscancer - Primär HPV-analys som screeningmetod

Search terms		Items found
Population: Cervical cancer		
154.	("cervical cancer" OR "cervical neoplas*" OR "cervical carcinom*" OR "cervical adenocarcinom*" OR "cervical dysplas*" OR "cervical intraepithelial" OR "cervix cancer" OR "cervix neoplas*" OR "cervix carcinom*" OR "cervix adenocarcinom*" OR "cervix dysplas*" OR "cervix intraepithelial" OR "HPV infection*" OR hrHPV* OR "hr HPV*" or "papillomavirus infect*") AND ("HPV analys*" or "HPV DNA analys*" or "HPV test*" or "papillomavirus analys*" or "DNA analys*" or "papillomavirus test" or PCR) Evidence type: Systematic Reviews, Health Technology Assessments	**70**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

AB = Abstract; AF = Author affiliation; **All** = Performs a keyword search in most of the database's searchable fields, except full text; **AU** = Author; **MAINSUBJECT** = Term from the thesaurus; **TI** = Title; ***** = Truncation; **" "** = Citation Marks; searches for an exact phrase; **?** = Wildcard, used to replace any single character either inside or at the right end of a word

Prospero via Centre for Reviews and Dissemination March 4th, 2021
Title: Screening livmoderhalscancer - Primär HPV-analys som screeningmetod

	Search terms	Items found
Population: Cervical cancer		
155.	(cervical or cervix) AND ("HPV analys*" or "HPV DNA-analys*" or "HPV-test*" or "papillomavirus-analys*" or "papillomavirus DNA-analys*" or "papillomavirus-test")	**57**

The final search result, usually found at the end of the documentation, forms the list of abstracts.

AB = Abstract; AF = Author affiliation; **All** = Performs a keyword search in most of the database's searchable fields, except full text; **AU** = Author; **MAINSUBJECT** = Term from the thesaurus; **TI** = Title; ***** = Truncation; **" "** = Citation Marks; searches for an exact phrase; **?** = Wildcard, used to replace any single character either inside or at the right end of a word

Bilaga till rapport

Screening för livmoderhalscancer rapport 338, (2021)

Bilaga 2 Exkluderade studier och studier med hög risk för snedvridning

Innehållsförteckning

Självprovtagning (frågeställning 1,2 och 3)

Exkluderade studier på grund av relevans

Denna del består av artiklar som ansågs relevanta i abstraktgallringen, men som vid fulltextgranskning inte besvarade frågeställningen och uppfyllde inklusionskriterierna. För frågeställningarna 1 till 3 kan en studie kan ha olika skäl till exklusion beroende frågeställning, dock är bara en av skälen angiven i listan.

Studie	**Exklusionsorsak**
Aarnio R, Isacson I, Sanner K, Gustavsson I, Gyllensten U, Olovsson M. Comparison of vaginal self-sampling and cervical sampling by medical professionals for the detection of HPV and CIN2+: a randomized study. International Journal of Cancer, 2021; 2626.	Fel population
Aarnio R, Ostensson E, Olovsson M, Gustavsson I, Gyllensten U. Cost-effectiveness analysis of repeated self-sampling for HPV testing in primary cervical screening: a randomized study. BMC Cancer, 2020; 20 (1): 645.	Fel studiedesign
Adamson PC, Huchko MJ, Moss AM, Kinkel HF, Medina-Marino A. Acceptability and Accuracy of Cervical Cancer Screening Using a Self-Collected Tampon for HPV Messenger-RNA Testing among HIV-Infected Women in South Africa. PLoS ONE [Electronic Resource], 2015; 10 (9): e0137299.	Fel population
Adler DH, Almudevar A, Gray GE, Allan B, Williamson AL. High level of agreement between clinician-collected and self-collected samples for HPV detection among South African adolescents. Journal of Pediatric & Adolescent Gynecology, 2012; 25 (4): 280-1.	Fel studiedesign
Adler DH, Laher F, Lazarus E, Grzesik K, Gray GE, Allan B, et al. A Viable and Simple Self-Sampling Method for Human Papillomavirus Detection among South African Adolescents. Journal Of Immunological Techniques In Infectious Diseases, 2013; 2 (3): 18.	Fel population
Aiko KY, Yoko M, Saito OM, Ryoko A, Yasuyo M, Mikiko AS, et al. Accuracy of self-collected human papillomavirus samples from Japanese women with abnormal cervical cytology. J Obstet Gynaecol Res, 2017; 43 (4): 710-17.	Fel utfall
Aitken CA, van Agt HME, Siebers AG, van Kemenade FJ, Niesters HGM, Melchers WJG, et al. Introduction of primary screening using high-risk HPV DNA detection in the Dutch cervical cancer screening programme: a population-based cohort study. BMC Medicine, 2019; 17 (1): 228.	Fel population
Allende G, Surriabre P, Ovando N, Calle P, Torrico A, Villarroel J, et al. Evaluation of the effectiveness of high-risk human papilloma self-sampling test for cervical cancer screening in Bolivia. BMC Infectious Diseases, 2020; 20 (1): 259.	Fel indextest
Arbyn M, de Sanjose S, Weiderpass E. HPV-based cervical cancer screening, including self-sampling, versus screening with cytology in Argentina. The Lancet Global Health, 2019; 7 (6): e688-e89.	Fel indextest
Arbyn M, Verdoodt F, Snijders PJ, Verhoef VM, Suonio E, Dillner L, et al. Accuracy of human papillomavirus testing on self-collected versus clinician-collected samples: a meta-analysis. Lancet Oncology, 2014; 15 (2): 172-83.	Fel utfall

Arrossi S, Paolino M, Laudi R, Gago J, Campanera A, Marin O, et al. Programmatic human papillomavirus testing in cervical cancer prevention in the Jujuy Demonstration Project in Argentina: a population-based, before-and-after retrospective cohort study. The Lancet Global Health, 2019; 7 (6): e772-e83.	Fel studiedesign
Arrossi S, Thouyaret L, Herrero R, Campanera A, Magdaleno A, Cuberli M, et al. Effect of self-collection of HPV DNA offered by community health workers at home visits on uptake of screening for cervical cancer (the EMA study): a population-based cluster-randomised trial. The Lancet Global Health, 2015; 3 (2): e85-94.	Fel indextest
Batmunkh T, Dalmau MT, Munkhsaikhan ME, Khorolsuren T, Namjil N, Surenjav U, et al. A single dose of quadrivalent human papillomavirus (HPV) vaccine is immunogenic and reduces HPV detection rates in young women in Mongolia, six years after vaccination. Vaccine, 2020; 38 (27): 4316-24.	Fel indextest
Belinson JL, Du H, Yang B, Wu R, Belinson SE, Qu X, et al. Improved sensitivity of vaginal self-collection and high-risk human papillomavirus testing. Int J Cancer, 2012; 130 (8): 1855-60.	Fel utfall
Berggrund M, Gustavsson I, Aarnio R, Hedlund-Lindberg J, Sanner K, Wikstrom I, et al. HPV viral load in self-collected vaginal fluid samples as predictor for presence of cervical intraepithelial neoplasia. Virology Journal, 2019; 16 (1): 146.	Fel jämförande test
Berner A, Hassel SB, Tebeu PM, Untiet S, Kengne-Fosso G, Navarria I, et al. Human papillomavirus self-sampling in Cameroon: women's uncertainties over the reliability of the method are barriers to acceptance. Journal of Lower Genital Tract Disease, 2013; 17 (3): 235-41.	Fel indextest
Bertucci M, Dambroise C, Satger L, Boulle N. Self-collection for HPV testing: a new strategy to improve cervical screening coverage? Revue Francophone des Laboratoires, 2018; 2018 (503): 50-57.	Fel studiedesign
Bhatla N, Puri K, Kriplani A, Iyer VK, Mathur SR, Mani K, et al. Adjunctive testing for cervical cancer screening in low resource settings. Australian & New Zealand Journal of Obstetrics & Gynaecology, 2012; 52 (2): 133-9.	Fel indextest
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Zhang S, Kang L, Liu B, Cui J, Chen F, Liu X, et al. [Evaluation of screening performance of HPV DNA test on specimens from different sites of the female genital tract]. Zhonghua Zhong Liu Za Zhi, 2014; 36 (5): 389-93.	Fel indextest
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Zhao FH, Jeronimo J, Qiao YL, Schweizer J, Chen W, Valdez M, et al. An evaluation of novel, lower-cost molecular screening tests for human papillomavirus in rural China. Cancer Prev Res (Phila), 2013; 6 (9): 938-48.	Fel jämförande test
Zhao FH, Lewkowitz AK, Chen F, Lin MJ, Hu SY, Zhang X, et al. Pooled analysis of a self-sampling HPV DNA Test as a cervical cancer primary screening method. Journal of the National Cancer Institute, 2012; 104 (3): 178-88.	Fel studiedesign
Zhao XL, Xu XQ, Duan XZ, Rezhake R, Hu SY, Wang Y, et al. Comparative performance evaluation of different HPV tests and triaging strategies using self-samples and feasibility assessment of thermal ablation in 'colposcopy and treat' approach: A population-based study in rural China. International Journal of Cancer, 2020; 147 (5): 1275-85.	Fel jämförande test

Exkluderade studier på grund av hög risk för bias

Denna del består av artiklar som ansågs relevanta i abstraktgallringen och vid fulltextgranskning, men bedömdes ha hög risk för bias vid kvalitetsgranskningen

Studie
Carrasquillo O, Seay J, Amofah A, Pierre L, Alonzo Y, McCann S, et al. HPV Self-Sampling for Cervical Cancer Screening Among Ethnic Minority Women in South Florida: a Randomized Trial. J Gen Intern Med. 2018;33(7):1077-83.
Esber A, Norris A, Jumbe E, Kandodo J, Nampandeni P, Reese PC, et al. Feasibility, validity and acceptability of self-collected samples for human papillomavirus (HPV) testing in rural Malawi. Malawi Med J. 2018;30(2):61-6. Available from: https://doi.org/https://dx.doi.org/10.4314/mmj.v30i2.2.
Gustavsson I, Aarnio R, Berggrund M, Hedlund-Lindberg J, Sanner K, Wikstrom I, et al. Randomised study of HPV prevalence and detection of CIN2+ in vaginal self-sampling compared to cervical specimens collected by medical personnel. Int J Cancer. 2019;144(1):89-97.
Gustavsson I, Aarnio R, Berggrund M, Hedlund-Lindberg J, Strand AS, Sanner K, et al. Randomised study shows that repeated self-sampling and HPV test has more than two-fold higher detection rate of women with CIN2+ histology than Pap smear cytology. Br J Cancer. 2018;118(6):896-904.
Modibbo F, Iregbu KC, Okuma J, Leeman A, Kasius A, de Koning M, et al. Randomized trial evaluating self-sampling for HPV DNA based tests for cervical cancer screening in Nigeria. Infect Agent Cancer. 2017; 12:11. Available from: https://doi.org/10.1186/s13027-017-0123-z.
Porras C, Hildesheim A, Gonzalez P, Schiffman M, Rodriguez AC, Wacholder S, et al. Performance of self-collected cervical samples in screening for future precancer using human papillomavirus DNA testing. J Natl Cancer Inst. 2015;107(1):400. Available from: https://doi.org/10.1093/jnci/dju400.
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Surriabre P, Allende G, Prado M, Caceres L, Bellot D, Torrico A, et al. Self-sampling for human papillomavirus DNA detection: a preliminary study of compliance and feasibility in BOLIVIA. BMC Womens Health. 2017;17(1):135.
Zehbe I, Jackson R, Wood B, Weaver B, Escott N, Severini A, et al. Community-randomised controlled trial embedded in the Anishinaabek Cervical Cancer Screening Study: human papillomavirus self-sampling versus Papanicolaou cytology. BMJ Open. 2016;6(10):e011754. Available from: https://doi.org/10.1136/bmjopen-2016-011754.

Primär screeninganalys: Cytologi vs HPV (Frågeställning 4)

Denna del består av artiklar som ansågs relevanta i abstraktgallringen, men som vid fulltextgranskning inte besvarade frågeställningen och uppfyllde inklusionskriterierna. En studie kan ha olika skäl till exklusion, dock är bara en av skälen angiven i listan.

Exkluderade studier på grund av relevans

Studie	Exklusionsorsak
Acuti Martellucci C, Nomura S, Yoneoka D, Ueda P, Brotherton J, Canfell K, et al. Human papillomavirus vaccine effectiveness within a cervical cancer screening programme: cohort study. BJOG: An International Journal of Obstetrics & Gynaecology, 2021; 128 (3): 532-39.	Fel indextest
Adcock R, Cuzick J, Hunt WC, McDonald RM, Wheeler CM. Role of HPV genotype, multiple infections, and viral load on the risk of high-grade cervical neoplasia. Cancer Epidemiology Biomarkers and Prevention, 2019; 28 (11): 1816-24.	Fel indextest
Agorastos T, Chatzistamatiou K, Katsamagkas T, Koliopoulos G, Daponte A, Constantinidis T, et al. Primary screening for cervical cancer based on high-risk human papillomavirus (HPV) detection and HPV 16 and HPV 18 genotyping, in comparison to cytology. PLoS ONE, 2015; 10 (3).	Fel jämförande test
Ahmadi M, Jalilian FA, Dokhani N, Golparian M, Moradi Y. Evaluation of the prevalence of human papillomavirus in asymptomatic patients at the women's clinic in hamadan and comparing the 2 methods of pap smear and PCR in detecting the virus. International Journal of Women's Health and Reproduction Sciences, 2020; 8 (2): 232-35.	Fel referensstandard
Ali MAM, Bedair RN, Abd El Atti RM. Cervical high-risk human papillomavirus infection among women residing in the Gulf Cooperation Council countries: Prevalence, type-specific distribution, and correlation with cervical cytology. Cancer Cytopathology, 2019; 127 (9): 567-77.	Fel jämförande test
Almonte M, Murillo R, Sanchez GI, Gonzalez P, Ferrera A, Picconi MA, et al. Multicentric study of cervical cancer screening with human papillomavirus testing and assessment of triage methods in Latin America: the ESTAMPA screening study protocol. BMJ Open, 2020; 10 (5): e035796.	Fel population
Altobelli E, Scarselli G, Lattanzi A, Fortunato C, Profeta VF. A comparison between Pap and HPV screening tests and screening methods. Molecular & Clinical Oncology, 2016; 5 (2): 348-54.	Fel population
Andrews J. Combining HPV genotypes and cytology results to predict risk and guide management in cervical cancer screening. European Journal of Obstetrics Gynecology and Reproductive Biology, 2019; 234e77.	Fel studiedesign
Andrews J. Reducing unnecessary colposcopy by risk discrimination. HPV genotyping & NILM & low-grade cytology: Systematic review. Journal of Lower Genital Tract Disease, 2018; 22 (2): S21.	Fel studiedesign
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Aoyama-Kikawa S, Fujita H, Hanley SJB, Kasamo M, Kikuchi K, Torigoe T, et al. Comparison of human papillomavirus genotyping and cytology triage,	Fel indextest

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Ara R, Khatun S, Pervin S, Jahan M, Shahera U, Ferdous J, et al. Role of molecular biomarker human papilloma virus (HPV) E6 oncoprotein in cervical cancer screening. Gynecologic Oncology, 2020; 158 (3): 590-96.	Fel population
Arbyn M, Ronco G, Anttila A, Meijer CJ, Poljak M, Ogilvie G, et al. Evidence regarding human papillomavirus testing in secondary prevention of cervical cancer. Vaccine, 2012; 30 Suppl 5F88-99.	Fel population
Arbyn M, Smith SB, Temin S, Sultana F, Castle P, Collaboration on S-S, et al. Detecting cervical precancer and reaching underscreened women by using HPV testing on self samples: updated meta-analyses. BMJ, 2018; 363k4823.	Fel population
Arbyn M, Xu L, Verdoodt F, Cuzick J, Szarewski A, Belinson JL, et al. Genotyping for Human Papillomavirus Types 16 and 18 in Women With Minor Cervical Lesions: A Systematic Review and Meta-analysis. Annals of Internal Medicine, 2017; 166 (2): 118-27.	Fel population
Asthana S, Labani S. Adjunct screening of cervical or vaginal samples using careHPV testing with Pap and aided visual inspection for detecting high-grade cervical intraepithelial neoplasia. Cancer Epidemiology, 2015; 39 (1): 104-8.	Fel population
Atkinson AE, Mandujano CAM, Bejarano S, Kennedy LS, Tsongalis GJ. Screening for Human Papillomavirus in a Low- and Middle-Income Country. Journal of Global Oncology, 2019; 5JGO1800233.	Fel indextest
Aydogan Kirmizi D, Baser E, Demir Caltekin M, Onat T, Sahin S, Yalvac ES. Concordance of HPV, conventional smear, colposcopy, and conization results in cervical dysplasia. Diagnostic Cytopathology, 2021; 49 (1): 132-39.	Fel population
Barodawala SM, Chadha K, Kavishwar V, Murthy A, Shetye S. Cervical cancer screening by molecular Pap-transformation of gynecologic cytology. Diagnostic Cytopathology, 2019; 47 (5): 374-81.	Fel population
Bedell SL, Goldstein LS, Goldstein AR, Goldstein AT. Cervical Cancer Screening: Past, Present, and Future. Sexual Medicine Reviews, 2020; 8 (1): 28-37.	Fel studiedesign
Belinson J, Qiao YL, Pretorius R, Zhang WH, Elson P, Li L, et al. Shanxi Province Cervical Cancer Screening Study: a cross-sectional comparative trial of multiple techniques to detect cervical neoplasia. Gynecol Oncol, 2001; 83 (2): 439-44.	Fel population
Bhattacharya A, Sen S, Mandal P, Sharma Saha S, Sarkar S, Pathak OP, et al. Prevalence and age-wise distribution of Human Papillomavirus type 16/18 infections among hospital screened women of a peri-urban area in West Bengal: Impact of socio-demographic factors. Cancer Epidemiology, 2018; 5431-37.	Fel referensstandard
Bigras G, de Marval F. The probability for a Pap test to be abnormal is directly proportional to HPV viral load: results from a Swiss study comparing HPV testing and liquid-based cytology to detect cervical cancer precursors in 13 842 women. British Journal of Cancer, 2005; 93 (5): 575-81.	Fel population
Bouchard-Fortier G, Hajifathalian K, McKnight MD, Zacharias DG, Gonzalez-Gonzalez LA. Co-testing for detection of high-grade cervical intraepithelial neoplasia and cancer compared with cytology alone: a meta-analysis of randomized controlled trials. J Public Health (Oxf), 2014; 36 (1): 46-55.	Fel studiedesign
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Bilaga till rapport

Screening för livmoderhalscancer, rapport 338, (2021)

Bilaga 3, Tabeller över inkluderade studier

Innehållsförteckning

Frågeställning 2

Polman 2019

Clinical setting and study design	**Design: Randomised control study** **Inclusion/exclusion:** Exclusion criteria were previous hysterectomy and childbirth less than 6 months ago, as well as current pregnancy. **Allocation:** Women were randomly assigned (1:1) to the intervention group (HPV self-sampling) or the control group (clinician-based sampling).
Patient characteristics	**Population:** Women aged 29–61 years; (mean age 45,5 years in self-sampling group and 45,7 years in the clinician-based sampling group) **Sample size:** Self-sampling group: n=7643, Clinician-based sampling group n=6282 **Setting:** Women were invited to participate in the study as part of their regular screening invitation for the organised screening programme in the Netherlands
Index and comparator tests	**Index test (self-collected sample):** Women received a package including a brush-based self-sampling device (Evalyn Brush), and written and graphical user instructions about the device. Women were requested to self-collect a cervicovaginal sample and return the dry brush to the laboratory in a freepost return envelope. **Comparator text (clinician collected sample):** Women were invited to

	their general practitioner's practice to provide a clinician collected sample. These samples were obtained with the Cervex-Brush, a brush device used for cervical sampling by a physician during internal examination and were collected in a vial with 10 mL ThinPrep PreservCyt media. **Triage test (cytology):** Women in the self-sample group with a positive HPV test were referred to their general practitioner to give a liquid-based cytology sample for cytological assessment. In the clinicial-sample group, reflex cytology was done for women with a positive HPV test result based on the available clinician-collected sample. Women with abnormal cytology (borderline or mild dyskaryosis or worse were referred for colposcopy.
Reference standard	**Histologically confirmed CIN2+:** At the colposcopy visit, biopsies were taken from suspected areas according to standard procedures in the Netherlands
Screening pathway	
Outcomes	**Absolute sensitivity*:** n/N (% [95% CI]) Self-sampling: 78/84 (92.9% [87.3–98.4]) Clinician-based sampling: 106/110 (96.4% [92.9–99.9]) **Absolute specificity*:** n/N (% [95% CI]) Self-sampling 7074/7532 (93.9% [93.4–94.5]) Clinician-based sampling 5831/6190 (94.2% [93.6–94.8]) **Relative accuracy** (self-sampling vs clinician-based sampling) % (95% CI) Sensitivity: 0.96 (0.90–1.03) Specificity: 1.00 (0.99–1.01) * Sensitivity was estimated by the number of positive HPV cross-test results among women with detected disease. Specificity was estimated by the number of negative HPV test results among women without detected disease.
Risk of bias	Unclear
Notes	The proportion of women providing informed consent in our opt-in study was 8.8%, which raises concerns about the generalisability of the results beyond the study population. There are some caveats to the analysis: the sensitivity of HPV-self test could have been biased by the non-attendance of hrHPV+ women for a follow-up of the cytology test.

Frågeställning 3

Ajenifuja 2018

Patient sampling	**Design**: Cross-sectional study **Inclusion/exclusion**: No further details given
Patient characteristics and setting	**Population**: Women presenting for cervical cancer screening **Sample size**: 194 **Setting**: A community-based clinic for screening of cervical cancer as well as other diseases of the female genital tract, Nigeria
Index tests	Self-sampled test: HPV DNA (HPV GenoArray test kits by Hybribio Biochemical Company Limited, China) **Instructions**: The respondents were taught how to perform the procedure for sampling the upper vagina according to the instructions on the sample collection kit **Sample collection**: Patients stratified into two groups. Respondents in group A underwent provider sampling before self-sampling, while respondents in group B had self-sampling before undergoing provider sampling **Sampling device and storage medium**: Cytobrush (cervexR) cervical cell sampler and Hybribio HPV DNA collection kit
Comparator test	Clinician-sampled HPV tests: HPV DNA (HPV GenoArray test kits by Hybribio Biochemical Company Limited, China) **Sample collection:** Patients stratified into two groups by a systematic random sampling technique. Respondents in group A underwent provider sampling before self-sampling, while respondents in group B had self-sampling before undergoing provider sampling. **Sampling device and storage medium**: Cytobrush (cervexR) cervical cell sampler and Hybribio HPV DNA collection kit
Flow and timing	Time interval between index and comparator test: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** provider sampling: 12/194 (6.2%) self-sampling: 14/194 (7.2%)

	HR-HPV detection agreement: Kappa (95% CI) Provider sampling vs self-sampling: 0.47 (21.3 to 72.3%)
Risk of bias	Unclear

Asciutto 2017

Patient sampling	**Design**: Cross-sectional study **Inclusion/exclusion**: Not stated
Patient characteristics and setting	**Population**: Women aged 19 to 71 years with an abnormal cervical smear in the screening program or with symptoms were invited to the Outpatient Colposcopy Clinic at regional hospitals in Kristianstad and Helsingborg **Sample size**: 218 **Setting**: Outpatient Colposcopy Clinic at regional hospitals
Index tests	Self-sampled test: Cobas® 4800 HPV test (Roche Molecular Diagnostics, Pleasanton, CA, USA) **Instructions**: The women were asked to place a swab 6–10 cm into the vagina and rotate it 360 degrees 3–4 times before putting the swab into the tube provided. **Sample collection**: All vaginal self-samples were performed by the participating women at the clinic before undergoing a gynaecological examination **Sampling device and storage medium**: Cobas® PCR Female Swab Sample Kit
Comparator test	Clinician-sampled HPV tests: Cobas® 4800 HPV test (Roche Molecular Diagnostics, Pleasanton, CA, USA) **Sample collection:** The gynaecologist collected a cervical sample [Cobas® PCR Female Swab Sample Kit] and a liquid-based cytology (LBC) specimen from the cervix **Sampling device and storage medium**: no further details given
Flow and timing	Time interval between index and comparator test: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives**

	clinician-collected cervical sample: 166/213 (77.9%) self-collected vaginal sample: 167/213 (78.4%) **HR-HPV detection agreement: Kappa (95% CI)** clinician-collected sample vs self-collected dry swab: 0.82 (0.73–0.91)
Risk of bias	Unclear

Asciutto 2018

Patient sampling	**Design**: Cross-sectional study **Inclusion/exclusion**: Exclusion criteria were status after hysterectomy, history of earlier gynecological cancer, or current oncological treatment
Patient characteristics and setting	**Population**: Women attending the women's clinic because of a referral for colposcopy due to the presence of abnormal findings in their screening results **Sample size**: 205 **Setting**: A women's clinic, Sweden
Index tests	Self-sampled test: HPV mRNA (Aptima Vaginal Swab Specimen Collection Kit, Hologic Inc, MA, USA) **Instructions**: All participating women received oral and written instructions on how to use the self-sampling kit (placing a swab 3–4 cm up into the vagina and rotating it 360°, two or three times) **Sample collection**: All vaginal self-samples were performed by the participating women at the clinic before undergoing a gynecological examination **Sampling device and storage medium**: Cotton swab in a test tube containing transport media
Comparator test	Clinician-sampled HPV tests: HPV mRNA (Aptima Vaginal Swab Specimen Collection Kit, Hologic Inc, MA, USA) **Sample collection:** Prior to colposcopy, a clinician-taken HPV sample was collected from the cervix with a swab **Sampling device and storage medium**: no further details given
Flow and timing	Time interval between index and comparator test: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests

	Detection of HR-HPV positives clinician-collected cervical sample: 136/205 (66.3%) self-collected vaginal sample: 132/205 (64.4%) **Correlation between vaginal HPV mRNA and cervical HPV mRNA analyses (Spearman rho correlations)** Rs=0.565 ($p < 0.01$) **HR-HPV detection agreement: Kappa (95% CI)** Kappa not stated
Risk of bias	Unclear

Bergengren 2018

Patient sampling	**Design**: Cross-sectional study **Inclusion/exclusion**: Eligible if they were 55–60 years old with a positive HR-HPV and normal cytology result at their exit screening (performed between January 1, 2012, and December 31, 2014). Women who had undergone hysterectomy after their exit sample was collected were excluded.
Patient characteristics and setting	**Population**: Women who were initially recruited from an age-specific prevalence study of HPV, and then invited to attend a follow-up visit at the Women's Health Department Clinic **Sample size**: 119 **Setting**: A women's Health Department at a University Hospital, Sweden.
Index tests	Self-sampled test: HPV using a DNA-based assay (CLART HPV2; Genomica, Madrid, Spain) **Instructions**: No other than the manufacturer's written and illustrated leaflet on how to perform a self-sample, which was included in the kit **Sample collection**: The sample was taken at home and sent in by mail **Sampling device and storage medium**: A dry brush (Evalyn; Rover, Oss, Netherlands)
Comparator test	Clinician-sampled HPV tests: HPV using a DNA-based assay (CLART HPV2; Genomica, Madrid, Spain) **Sample collection:** Professional sampling was performed by one experienced midwife **Sampling device and storage medium**: Liquid-based sampling (Hologic, Marlborough, MA, USA)

Flow and timing	Time interval between index and comparator test: within one week after comparator sample was taken.
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** clinician-collected sample: 54/119 (45.4 %) self-collected dry swab: 54/722 (45.4 %) **HR-HPV detection agreement: Kappa (95% CI)** clinician-collected sample vs self-collected dry swab: 0.66 (0.53–0.80)
Risk of bias	Unclear

Campos 2014

Patient sampling	**Design**: Cross-sectional study **Inclusion/exclusion**: ≥ 18 years of age and had not undergone a hysterectomy
Patient characteristics and setting	**Population**: Women who were forwarded to gynaecological exams **Sample size**: 170 **Setting**: The public health system. Brazil
Index tests	Self-sampled test: HPV DNA (Wizard® Genomic DNA Purification Kit, Promega, Corporation, Madison, WI, USA) **Instructions**: After verbal and diagrammatic instruction the women self-collected a vaginal specimen **Sample collection**: The women performed the self-collections in the clinician's office or near the clinician's office prior to the clinical examination and collection **Sampling device and storage medium**: No further details given
Comparator test	Clinician-sampled HPV tests: HPV DNA (Wizard® Genomic DNA Purification Kit, Promega, Corporation, Madison, WI, USA) **Sample collection:** A health professional used a speculum and collected an endocervical specimen **Sampling device and storage medium**: No further details given
Flow and timing	Time interval between index and comparator test: consecutive

Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** (HPV16, 18, 31, 33, 45) clinician-collected sample: 39/170 (22.9%) self-collected sample: 45/170 (26.5%) **HPV detection agreement: Kappa (95% CI)** clinician-collected sample vs self-collected sample: 0.72 (CI not stated)
Risk of bias	Unclear

Catarino 2015

Patient sampling	**Design**: Cross-sectional study **Inclusion/exclusion**: Women were eligible if they were over 30 years old, not pregnant women, no history of hysterectomy, and if they understood the study procedures and voluntarily agreed to participate by signing a written informed consent form.
Patient characteristics and setting	**Population**: Women from the colposcopy clinic **Sample size**: 150 **Setting**: The colposcopy clinic of Geneva University Hospitals
Index tests	Self-sampled test: the Anyplex II HPV28 (H28) Detection test (Seegene, Seoul, South Korea) **Instructions**: A research nurse gave oral instructions to participants, who were instructed to wash their hands before the specimen collection procedure. Each participant received a package containing a specimen collection kit. **Sample collection**: At the clinic **Sampling device and storage medium**: The Rovers Viba-Brush (RoversMedical Devices B.V., Oss, The Netherlands) was used for self-collection with the FTA cartridge, and the mid-turbinate flocked vaginal swab (FLOQSwabs™; COPAN Italia) used for self-collection with the s-DRY method
Comparator test	Clinician-sampled HPV tests: the Anyplex II HPV28 (H28) Detection test (Seegene, Seoul, South Korea) **Sample collection:** During the subsequent colposcopy consultation, a physician also collected a cervical sample for HPV testing. **Sampling device and storage medium**: a swab immersed in a collection medium (ESwab™; COPAN Italia, Brescia, Italy)

Flow and timing	Time interval between index and comparator test: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** clinician-collected sample: 56.2 % self-collected dry swab: 62.3% self-collected cytobrush FTA: 54.6% **HR-HPV detection agreement: Kappa (95% CI)** clinician-collected sample vs self-collected dry swab: 0.64 (0.50–0.78) clinician-collected sample vs self-collected cytobrush FTA: 0.64 (0.50–0.77)
Risk of bias	Unclear

Catarino 2017

Patient sampling	**Design**: Cross-sectional study **Inclusion/exclusion**: Women were eligible if they were at least years old, not pregnant women, no history of hysterectomy, and if they understood the study procedures and voluntarily agreed to participate by signing a written informed consent form.
Patient characteristics and setting	**Population**: Women from the colposcopy clinic **Sample size**: 150 **Setting**: The colposcopy clinic of Geneva University Hospitals
Index tests	Self-sampled test: not stated, analyzed with the Xpert HPV Assay **Instructions**: Each participant received a package containing a specimen collection cotton swab in a plastic tube and instructions for use. **Sample collection**: At the clinic **Sampling device and storage medium**: a dry swab
Comparator test	Clinician-sampled HPV tests: cobas HPV Test (Roche Diagnostics, Basel, Switzerland), analyzed with the Xpert HPV Assay **Sample collection:** A physician collected a cervical specimen **Sampling device and storage medium**: Cervex brush (Rovers Medical Devices B.V., Oss, Netherlands), which was immediately placed in PreservCyt
Flow and timing	Time interval between index and comparator test: consecutive

Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** clinician-collected sample (cobas): 67/146 (46.2%) clinician-collected wet sample: 61/146 (46.2%) self-collected dry swab 56/114 (49.1%) **HR-HPV detection agreement: Kappa (95% CI)** clinician-collected wet sample vs self-collected dry swab: 0.64 (0.50–0.78)
Risk of bias	Unclear

Chen 2016

Patient sampling	**Design**: Cross-sectional study **Inclusion/exclusion**: Women aged 18 years and over
Patient characteristics and setting	**Population**: Half of the study population was recruited from women with both negative cytology and histopathology, according to general cervical screening findings. The other participants, with abnormal cytology or pathology results were selected from the cervical disease outpatient clinic. **Sample size**: 202 (101 patients with cervical lesions and 101 patients without cervical lesions or with non-specific cervicitis) **Setting**: A large gynecological outpatient clinic. China
Index tests	Self-sampled test: HPV DNA (Abbott RealTime High-Risk HPV Test) **Instructions**: Written instructions with illustrations provided by the manufacturer and translated into Chinese were given to each potential participant before enrollment **Sample collection**: After enrollment all women collected a cervicovaginal specimen in a separate room at the clinic **Sampling device and storage medium**: Dry self-sampling device, the Evalyn Brush. The samples were transferred to 20 ml of ThinPrep medium about 16–18 weeks after collection.
Comparator test	Clinician-sampled HPV tests: HPV DNA (Abbott RealTime High-Risk HPV Test)

	Sample collection: After self-sampling, all women underwent their scheduled colposcopy examination, by a physician, during which a cervical specimen was collected **Sampling device and storage medium**: cervical brusch (The Digene Female Swab Specimen Collection Kit) and 1ml of Specimen Transport Medium (STM) for storage. After 16–18 weeks the samples were transferred to ThinPrep medium before testing.
Flow and timing	Time interval between index and comparator test: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** physician-collected sample: 93/202 (46.0%) self-collected dry swab: 92/202 (45.5%) **HR-HPV detection agreement: Kappa, weighted (95% CI)** physician-collected sample vs self-collected dry swab: 0.95 (0.91–0.99)
Risk of bias	Unclear

Chernesky 2014

Patient sampling	**Design**: Cross-sectional study **Inclusion/exclusion**: no further details given
Patient characteristics and setting	**Population**: Women between 18 and 63 years of age (mean, 39 years) referred for colposcopy due to previous abnormal cytology and/or positive HPV results **Sample size**: 580 **Setting**: Women's health colposcopy clinic. Canada
Index tests	Self-sampled test: HPV mRNA (AHPV assay, Hologic/Gen-Probe Inc) **Instructions**: Each woman followed an illustrated set of instructions to self-collect a vaginal sample **Sample collection**: The women performed the self-collections in the clinician's office or near the clinician's office before seeing the physician **Sampling device and storage medium**: Tapered round brush on the end of a round plastic stick and a tube of transportation media (APTIMAi SCT kit, Hologic/Gen-Probe Inc)

Comparator test	Clinician-sampled HPV tests: HPV mRNA (AHPV assay, Hologic/Gen-Probe Inc) **Sample collection:** A physician first collected a vaginal sample, and after insertion of a speculum three cervical samples were collected **Sampling device and storage medium**: Vaginal sample collected with tapered round brush on the end of a round plastic stick and a tube of transportation media (APTIMAi SCT kit, Hologic/Gen-Probe Inc) Cervical samples collected in the following order: L-Pap into PreservCyt with a cervex broom; APTIMA cervical SCT; L-Pap into SurePath with a cervix broom.
Flow and timing	Time interval between index and comparator tests: consecutive
Outcomes	Agreement between self-collected HPV tests and physician-collected HPV tests **Detection of HR-HPV positives** physician-collected cervical sample: 241/554 (43.5%) physician-collected vaginal sample: 195/569 (34.3%) self-collected vaginal sample: 242/569 (42.5%) **HR-HPV detection agreement: Kappa (95% CI)** physician-collected vaginal sample vs self-collected vaginal sample: 0.68 (0.62–0.74) physician-collected cervical sample vs self-collected vaginal sample: 0.63 (0.57–0.70)
Risk of bias	Unclear

Cho 2019

Patient sampling	**Design**: Multicenter cross-sectional study **Inclusion/exclusion**: Exclusion criteria were: previous treatment for cervical disease (including the loop electrosurgical excision procedure, cold knife conization, cryotherapy, and laser therapy), previous hysterectomy, prior chemotherapy, or radiation treatment for cervical neoplasia or another concurrent cancer, HIV infection or AIDS, or pregnant at the time of the study.
Patient characteristics and setting	**Population**: Women aged 20–50 years, admitted for surgical treatment of high grade squamous intraepithelial lesions (HSIL) or ovarian disease. **Sample size**: 101

	Setting: Four medical centers. Korea.
Index tests	Self-sampled test: HPV DNA (three different assays) Anyplex II HPV (Seegene, Seoul, South Korea) RealTime HR-S HPV assays (Sejong Medical Co., Ltd., Paju, South Korea) Roche Cobas HPV (Roche Molecular Diagnostics, Pleasanton, CA, USA) **Instructions**: Each participant was provided with a self-sampling kit with illustrated instructions. Participants were instructed to collect a vaginal sample by inserting the plastic brush one inch into the vagina, rotating the swab for 15 seconds, and then remove it. **Sample collection**: The women performed the self-collections in the clinician's office or near the clinician's office before the clinical examination and sample collection. **Sampling device and storage medium**: Plastic brush (Flocked Swab, manufactured by Noble Biosciences, Inc., Gyeonggi-Do, South Korea) and PreservCyt Solution (ThinPrep, manufactured by Hologic, Marlborough, MA, USA))
Comparator test	Clinician-sampled HPV tests: HPV DNA (three different assays) Anyplex II HPV (Seegene, Seoul, South Korea) RealTime HR-S HPV assays (Sejong Medical Co., Ltd., Paju, South Korea) Roche Cobas HPV (Roche Molecular Diagnostics, Pleasanton, CA, USA) **Sample collection:** Participants underwent a pelvic exam during which the clinician-collected a cervical sample using a cervical brush **Sampling device and storage medium**: Cervical Brush (Noble Biosciences, Inc., Gyeonggi-Do, South Korea) and ThinPrep, PreservCyt Solution (Hologic, Marlborough, MA)
Flow and timing	Time interval between index and comparator test: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** Realtime HR-S HPV: clinician-collected cervical sample: 87/101 (86.1%) self-collected vaginal sample: 84/101 (83.2%) Anyplex II HPV: clinician-collected cervical sample: 89/101 (88.1%) self-collected vaginal sample: 81/101 (80.2%) Cobas HPV:

	clinician-collected cervical sample: 89/101 (88.1%) self-collected vaginal sample: 79/101 (78.2%) **HR-HPV detection agreement: Kappa (95% CI)** Realtime HR-S HPV: self-collected vaginal sample vs clinician-collected cervical sample: 0.58 (0.36–0.80) Anyplex II HPV: self-collected vaginal sample vs clinician-collected cervical sample: 0.49 (0.26–0.71) Cobas HPV: self-collected vaginal sample vs clinician-collected cervical sample: 0.51 (0.30–0.73)
Risk of bias	Unclear

Cho 2020

Patient sampling	**Design**: Multicenter cross-sectional study **Inclusion/exclusion**: Eligible if they were between the ages of 20 and 60, not pregnant at the time of the study, and have had none of the following: previous treatment for cervical disease (including the loop electrosurgical excision procedure, cold knife conization, cryotherapy, and laser therapy), previous hysterectomy, prior chemotherapy, radiation treatment for cervical neoplasia or another concurrent cancer, and human immunodeficiency virus infection or acquired immune deficiency syndrome
Patient characteristics and setting	**Population**: Women referred for colposcopy following abnormal cytology **Sample size**: 314 **Setting**: Three medical centers. Korea
Index tests	Self-sampled test: HPV DNA (two different assays): Realtime HR-S HPV (Sejong Medical Co., Ltd., Paju, South Korea) Anyplex II HPV (Seegene, Seoul, South Korea)) **Instructions**: Each participant was provided with a self-sampling kit with illustrated instructions. Participants were instructed to collect a vaginal sample by inserting the plastic brush one inch into the vagina, rotating the swab for 15 seconds, and then remove it. **Sample collection**: The women performed the self-collections in the clinician's office or near the clinician's office before the clinical examination

	Sampling device and storage medium: Plastic brush (Flocked Swab Noble Biosciences, Inc., Hwaseong, Korea) and ThinPrep, PreservCyt Solution (Hologic, Marlborough, MA, USA)
Comparator test	Clinician-sampled HPV tests: HPV DNA (two different assays: Realtime HR-S HPV (Sejong Medical Co., Ltd., Paju, South Korea), and Anyplex II HPV (Seegene, Seoul, South Korea)) **Sample collection:** Participants underwent a pelvic exam during which the clinician-collected a cervical sample using a cervical brush **Sampling device and storage medium**: Cervical Brush (Noble Biosciences, Inc.) and ThinPrep, PreservCyt Solution (Hologic, Marlborough, MA)
Flow and timing	Time interval between index and comparator test: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** Realtime HR-S HPV: clinician-collected cervical sample: 247/314 (78.7%) self-collected vaginal sample: 234/314 (74.5%) Anyplex II HPV: clinician-collected cervical sample: 230/314 (70.7%) self-collected vaginal sample: 222/314 (73.2%) **HR-HPV detection agreement: % (95% CI)** Realtime HR-S HPV: clinician-collected cervical sample vs self-collected vaginal sample: 85.03% (80.60– 88.79) Anyplex II HPV: clinician-collected cervical sample vs self-collected vaginal sample: 82.17% (77.47–86.24) **HR-HPV detection agreement: Two-tailed McNemar's test** Realtime HR-S HPV: clinician-collected cervical sample vs self-collected vaginal sample: McNemar p = 0.079 Anyplex II HPV: clinician-collected cervical sample vs self-collected vaginal sample: McNemar p = 0.350

	HR-HPV detection agreement: Kappa (95% CI) Kappa not stated.
Risk of bias	Unclear

Darlin 2012

Patient sampling	**Design**: Cross-sectional study **Inclusion/exclusion**: -
Patient characteristics and setting	**Population**: Women, aged 18–65, who had been found to have an abnormal cervical smear in the organized screening program, **Sample size**: 108 **Setting**: The outpatient colposcopy clinic at Lund University Hospital, Sweden.
Index tests	Self-sampled test: Luminex-based HPV genotyping **Instructions**: Oral and written instructions were given to the study persons before taking the self-collected vaginal sample. **Sample collection**: At the clinic **Sampling device and storage medium**: A cotton swab
Comparator test	Clinician-sampled HPV tests: Luminex-based HPV genotyping **Sample collection:** A consultant collected the standard liquid-based cytology (LBC) for HPV detection. **Sampling device and storage medium**: The LBC was collected by a plastic device Rovers® Cervex- Brush® Combi scraping cells from portion and put into a "Thin Prep preservCyt Solution".
Flow and timing	Time interval between index and comparator test: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** clinician-collected sample: 65/108 (60%) self-collected dry swab: 64/108 (59%) **HR-HPV detection agreement: Kappa (95% CI)** clinician-collected sample vs self-collected dry swab: 0.67 (0.53–0.81),
Risk of bias	Unclear

Des Marais 2018

Patient sampling	**Design**: Cross-sectional study

	Inclusion/exclusion: Eligible if they were 30 to 64 years of age; reported no history of Pap testing in the past 4 years (overdue for screening by national guidelines at the start of the study); had a household income below 250% of the poverty level; were not pregnant; had not had a hysterectomy; and were uninsured, underinsured, or had Medicaid insurance. Eligibility measures were assessed by self-report. Income and insurance criteria were defined to ensure eligibility for free cervical cancer screening services through collaborating safety net clinics and programs.
Patient characteristics and setting	**Population**: Women at elevated risk of cervical cancer due to underscreening **Sample size**: 193 **Setting**: Clinic not specified. USA.
Index tests	Self-sampled test: HPV DNA (Aptima HPV assay (Hologic, Inc.) **Instructions**: Participants received self-collection kit by mail and were instructed to introduce the brush into the vagina as far as it could comfortably go and rotate 5 times, remove the brush head and place it into a collection tube. An incentive of $35 USD was given for returning the self-home sample and attending an appointment for self-clinic and clinician collected samples. Instructions were slightly revised during project implementation to emphasize that vials should be closed tightly, which resolved an emergent issue of several samples leaking in transit. At the study clinic appointment, participants self-collected a second vaginal sample using the same brush, preservation solution, and instructions used for at-home self-collection. **Sample collection**: Two self-samples taken: A cervical-vaginal sample self-collected at home and returned by mail A cervical-vaginal sample self-collected in a clinic and handed to a nurse **Sampling device and storage medium**: Viba brush (Rovers Medical Devices B.V., The Netherlands) and Aptima sample transport media (Hologic, Inc., Marlborough, Mass.)
Comparator test	Clinician-sampled HPV tests: HPV DNA (Aptima HPV assay (Hologic, Inc.)) **Sample collection:** The clinician performed a standard pelvic examination during which a cervical sample was collected

	Sampling device and storage medium: Endocervical brush (Cytobrush Plus GT) and spatula (Pap-Perfect), preserved in PreservCyt media (Hologic, Inc.)
Flow and timing	**Time interval between index and comparator test:** Home self-collected samples were returned an average of 15 days before clinic appointment. Time interval between self-clinic sample and comparator test: consecutive.
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** clinician-collected sample: 22/193 (11.4%) self-collected home sample: 24/193 (12.4%) self-collected clinical sample: 30/193 (15.5%) **HR-HPV detection agreement: Kappa (95% CI)** self-home sample vs clinician collected sample: 0.66 (0.46–0.80) self-clinic sample vs clinician collected sample: 0.56 (0.36–0.73) self-home sample vs self-clinic sample: 0.86 (0.71–0.96)
Risk of bias	Low

Dijkstraa 2012

Patient sampling	**Design**: Cross-sectional study **Inclusion/exclusion:** No further details given
Patient characteristics and setting	**Population**: 105 women referred for colposcopy-directed biopsy because of a cervical smear with moderate dyskaryosis or worse, or repeated equivocal Pap smear results, 30 women were referred for post-coital bleeding and had normal cytology **Sample size**: 135 **Setting**: Outpatient clinic. The Netherlands.
Index tests	Self-sampled test: HPV DNA (GP5+/6+-PCR EIA and subsequent reverse line blot (RLB) assay) **Instructions**: All women were given an illustrated instruction leaflet **Sample collection**: The women were instructed to collect a vaginal self-sample at home one week before the visit to the outpatient clinic **Sampling device and storage medium**: Viba-brush® (Rovers Medical Devices B.V.) and Thinprep® vial PreservCyt®, Hologic Inc.)

Comparator test	Clinician-sampled HPV tests: HPV DNA (GP5+/6+-PCR EIA and subsequent reverse line blot (RLB) assay) **Sample collection:** A gynaecologist first took a vaginal sample whereafter a vaginal speculum was inserted to take a regular cervical scrape **Sampling device and storage medium**: Vaginal sample taken with Viba-brush® (Rovers Medical Devices B.V.), cervical sample taken with Rovers® Cervex-brush, both stored in Thinprep® vial PreservCyt®, Hologic Inc.)
Flow and timing	Time interval between index and comparator tests: one week
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** clinician-collected cervical sample: 84/135 (62.2%) self-collected vaginal sample: 85/135 (63.0%) **HPV detection agreement: Kappa (95% CI)** clinician-collected cervical sample vs self-collected vaginal sample: 0.70 (0.60–0.78)
Risk of bias	Unclear

Du 2021

Patient sampling	**Design**: Multicenter cross-sectional study **Inclusion/exclusion**: Women were eligible if they were 30–59 years of age, sex experienced but not pregnant, no prior hysterectomy, and no prior pelvic radiation.
Patient characteristics and setting	**Population**: Women who had not done cervical cancer screening for at least 3 years. **Sample size**: 10399 **Setting**: Hospital. China
Index tests	Self-sampled test: HPV DNA (Cobas 4800 HPV assay and SeqHPV) **Instructions**: Self-sampling instructions were provided by poster diagrams and personal instruction. **Sample collection**: The women performed the self-collections in a private room at the hospital. **Sampling device and storage medium**: Liquid stored swab –

	"JustForMe" brush, CE-marked, (Preventive Oncology International, Inc, Cleveland Heights, OH), agitated in 6 mL of ThinPrep PreservCyt Solution (TCT, Hologic)
Comparator test	Clinician-sampled HPV tests: HPV DNA (Cobas 4800 HPV assay and SeqHPV) **Sample collection:** The physician placed a vaginal speculum and collected an endocervical sample from each of the participants using a "broom" sampler. **Sampling device and storage medium**: "broom" sampler in liquid - (Rovers Medical Devices, Oss, the Netherlands). Sample was placed in 20 mL of ThinPrep PreservCyt Solution (TCT, Hologic)
Flow and timing	Time interval between index and comparator tests: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** clinician-collected sample Cobas 4800: 1 121/10 399, 10.8% self-collected liquid swab Cobas 4800: 1 433/10 399, 13.8% clinician-collected sample SeqHPV: 1 133/10 399, 10.9% self-collected liquid SeqHPV: 1 211/10 399, 11.6% **HPV detection agreement: Kappa (95% CI)** clinician-collected Cobas 4800 vs self-collected Cobas 4800: 0.77 (0.76–0.79) clinician-collected Cobas 4800 vs clinician-collected SeqHPV: 0.83 (0.81–0.85) clinician-collected Cobas 4800 vs self-collected SeqHPV: 0.83 (0.81–0.85) clinician-collected SeqHPV vs self-collected SeqHPV: 0.91 (0.89–0.92)
Risk of bias	Unclear

El-Zein 2018

Patient sampling	**Design**: 3-arm cross-sectional study **Inclusion/exclusion**: Women aged 21–74 were eligible to participate if they had been referred to the participating colposcopy clinic because of an abnormal cervical cancer screening result or for initial treatment of a cervical lesion.
Patient characteristics and setting	**Population:** Women attending the colposcopy clinic. **Sample size**: 1217

	Setting: In colposcopy clinics at three University affiliated hospitals. Canada.
Index tests	Self-sampled test: HPV DNA (cobas®4800 HPV Test) **Instructions**: Each participant was verbally instructed on how to perform the cervicovaginal self-sampling techniques using bilingual, illustrated instructions. These were also posted in designated areas in which the self-sampling was performed. **Sample collection**: The women performed the unsupervised self-collections in the hospital (restroom, changing area or examination room) before the clinical examination and collection. **Sampling device and storage medium**: Liquid stored swab - 1. HerSwab™ (Eve Medical, Toronto, ON) – suspended in 20 ml of PreservCyt solution 2. cobas® PCR Female swab - cobas® PCR media
Comparator test	Clinician-sampled HPV tests: HPV DNA (cobas®4800 HPV Test) **Sample collection:** The clinician collected a cervical sample with the use of a speculum. **Sampling device and storage medium**: Not specified sample device in liquid – suspended in 20 ml of PreservCyt solution
Flow and timing	Time interval between index and comparator tests: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** clinician-collected sample: 554/1217, 45.5% self-collected HerSwab: 560/1217, 46.0% self-collected Cobas: 593/1217, 48.7% **HPV detection agreement: Kappa (95% CI)** clinician-collected sample vs self-collected HerSwab: 0.87 (0.81–0.87) clinician-collected sample vs self-collected Cobas: 0.81 (0.78–0.85) self-collected HerSwab vs self-collected Cobas: 0.87 (0.84–0.90)
Risk of bias	Unclear

Geraets 2013

Patient sampling	**Design**: Cross-sectional study **Inclusion/exclusion**: Women referred to a gynecological outpatient clinic because of an abnormal Pap smear (ASC-US+)

Patient characteristics and setting	**Population**: High risk population. All women had been referred because of an abnormal Pap smear (ASC-US+) detected at local health centers on average 3 months prior to the study visit (range: 1.5–6 months) **Sample size**: 182 **Setting**: the gynecological outpatient clinic of the Hospital Clinic in Barcelona, Spain
Index tests	Self-sampled test: HPV DNA (Rovers Viba-Brush (dry storage) / 2 detection methods: SPF10 PCR hybridization, GP5+/6+-PCR and sequencing) **Instructions:** Women received verbal instructions from the physician **Sample collection**: details not reported **Sampling device and storage medium**: Sampled with Rovers Viba-Brush (Rovers Medical Devices, Oss, The Netherlands), and subsequently applied to an Indicating FTA-elute cartridge (GE Healthcare, Buckinghamshire, United Kingdom) and air-dried.
Comparator test	Physician-sampled HPV tests: HPV DNA (Rovers Cervex-Brush (liquid storage) / 2 detection methods: SPF10 PCR hybridization, GP5+/6+-PCR and sequencing) **Sample collection:** A gynecologist obtained a cervical scrape before colposcopy was performed. **Sampling device and storage medium**: Sampling with the Rovers Cervex-Brush (Rovers Medical Devices). The brush was collected in 20 ml PreservCyt medium (Cytyc Corp., Boxborough, MA, USA)
Flow and timing	**Time interval between index and comparator tests:** Consecutive, self-collected samples were taken prior to colposcopy examination. Self-collected samples were stored for 2–15 months (median: 4 months) and transported at room temperature. Detection assays: All samples were tested with two HPV assays at DDL Diagnostic Laboratory, Rijswijk, The Netherlands: (1) the HPV SPF10 PCR-DEIA-LiPA25 version 1 (Labo Bio-medical Products BV, Rijswijk, The Netherlands); and (2) GP5+/6+-EIA kit (Diassay BV, Rijswijk, The Netherlands). Positive samples were sequenced using digene HPV Genotyping LQ Test (Q Test; Qiagen).
Outcomes	Agreement between self-sampled HPV tests and Physician-sampled HPV tests

	Detection of HR-HPV positives SPF_{10} detection Physician-collected cervical sample (liquid storage): 137/182 (75.3%) Self-collected vaginal samples (dry storage): 123/182 (67.6%) GP5+/6+ detection Physician-collected cervical sample (liquid storage): 117/182 (64.3%) Self-collected vaginal samples (dry storage): 97/182 (53.3%) **HR-HPV detection agreement: Kappa (95% CI)** Self-collected vs. clinician-collected samples: SPF_{10} detection Kappa 0.733 (0.625–0.841) Agreement 89.0% GP5+/6+ detection Kappa 0,642 (0.532–0.751) Agreement 82.4%
Risk of bias	Unclear

Guan 2013

Patient sampling	**Design**: cross-sectional study **Inclusion/exclusion**: Eligible women were not pregnant and have not had a hysterectomy. Between the ages of 30 and 59.
Patient characteristics and setting	**Population**: Women between the ages of 30 and 59 who underwent initial screening in the local clinics, which consisted of gynecologic exam with visual inspection with acetic acid and Lugol's iodine (VIA/VILI). **Sample size**: 174 **Setting**: Maternal and Child Health Hospital. China.
Index tests	Self-sampled test: HPV DNA. Qiagen cervical sampler brush (Qiagen, Gaithersburg, MD, USA) and a Whatman indicating FTA elute cartridge (GE Healthcare, Buckinghamshire, UK) **Instructions**: Participants were given written and verbal instructions for self-collection. The instructions were given in Chinese and each step was also supplemented with descriptive figures. Instructions were also posted in the self-collection room for reference. **Sample collection**: The women performed the self-collections in a private room near the clinician's office before the clinical examination and collection. **Sampling device and storage medium**: Cervical sampler brush and dry stored swab - Qiagen cervical sampler brush (Qiagen, Gaithersburg,

	MD, USA) and a Whatman indicating FTA elute cartridge (GE Healthcare, Buckinghamshire, UK)
Comparator test	Clinician-sampled HPV tests: HPV DNA, Qiagen cervical sampler brush (Qiagen, Gaithersburg, MD, USA) and a Whatman indicating FTA elute cartridge (GE Healthcare, Buckinghamshire, UK) **Sample collection:** The clinician performed a sample collection using a speculum and cervical sampler brush. **Sampling device and storage medium**: Cervical sampler brush and dry stored swab - Qiagen cervical sampler brush (Qiagen, Gaithersburg, MD, USA) and a Whatman indicating FTA elute cartridge (GE Healthcare, Buckinghamshire, UK)
Flow and timing	Time interval between index and comparator tests: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives (13 carcinogenic HPV-variants)** clinician-collected sample: 44/174 (25.3%) self-collected dry swab: 42/174 (24.1%) **HPV detection agreement: Kappa (95% CI)** clinician-collected sample vs self-collected dry swab: 0.75 (0.64–0.87)
Risk of bias	Unclear

Haguenoer 2014

Patient sampling	**Design**: Multicentre cross-sectional study **Inclusion/exclusion**: Eligible if they were 20 to 65 years old, self-reported not a virgin, not pregnant, not vaccinated against HPV, not menstruating, had had no Pap smear for at least 2 years and had no prior hysterectomy
Patient characteristics and setting	**Population**: Women who were due for a routine screening Pap smear. **Sample size**: 722 **Setting**: A family-planning clinic and a gynaecology consultation centre in the University Hospital, France.
Index tests	Self-sampled test: HPV DNA **Instructions**: Women were given a self-collection kit that included 1) a leaflet designed in collaboration with a medical illustrator with written

	and cartoon instructions detailing how to perform the 2 vaginal self-collections **Sample collection**: The women performed the self-collections in the clinician's office or near the clinician's office before the clinical examination and collection. **Sampling device and storage medium**: for DRY samples, an envelope containing a nylon flocked swab in a non-breakable sterile tube (53080C, Copan, Brescia, Italy); and for Liqiud samples, an envelope containing a nylon flocked swab with a molded breakpoint on the swab shaft that was enclosed in a sterile peel pouch (509CS01, Copan, Brescia, Italy) and a 12 × 80-mmscrew cap tube containing 2 mL transport and preservation liquid medium (610C, CyMol, Copan, Brescia, Italy).
Comparator test	Clinician-sampled HPV tests: HPV DNA **Sample collection:** The clinician performed a pelvic and speculum examination during which a cervical specimen was collected **Sampling device and storage medium**: Ectocervical and endocervical cells were collected with use of a Cervexbrush (Rovers Medical Devices B.V., Oss, The Netherlands) and were resuspended in a specimen transport liquid medium (Thinprep Paptest, Presercyt solution, Hologic, Bedford, MA, USA).
Flow and timing	Time interval between index and comparator tests: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives n/N (%)** clinician-collected sample: 177/722 (24.5%) self-collected dry swab: 151/722 (20.9%) self-collected swab in a transport liquid medium: 184/722 (25.5%) **HPV detection agreement: Kappa (95% CI)** clinician-collected sample vs self-collected dry swab: 0.76 (0.71–0.82) clinician-collected sample vs self-collected swab in a transport liquid medium: 0.72 (0.66–0.78)
Risk of bias	Low

Jentschke 2016

Patient sampling	**Design:** Pilot cross-sectional **Inclusion/exclusion**: Not pregnant and no history of hysterectomy. Women aged 17 to 78 years.
Patient characteristics and setting	**Population**: Study participants were recruited among the patients referred for abnormal cervical screening results or general gynecological diseases.

	Sample size: 146 **Setting**: At a colposcopy clinic and the gynecological outpatient clinic of a medical school. Germany.
Index tests	Self-sampled test: HPV DNA, Abbott RealTime High Risk HPV test **Instructions**: At first, all participants were given the two sampling devices (alternating order in every patient), written and illustrated instructions as provided by the manufacturers (translated to German). **Sample collection**: The women performed the self-collections in a separate room at the clinic, without assistance by hospital staff, before the clinical examination and collection. **Sampling device and storage medium**: Dry stored swab – 1. Evalyn Brush (Rovers Medical Devices) 2. Qvintip (Aprovix)
Comparator test	Clinician-sampled HPV tests: HPV DNA, Abbott RealTime High Risk HPV test **Sample collection:** The clinician performed a pelvic and speculum examination during which a liquid-based cervical cytology smear was taken with a broom-like device. **Sampling device and storage medium**: Broom-like device in liquid – (Hologic, Marlborough, MA)
Flow and timing	Time interval between index and comparator tests: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** clinician-collected sample: 75/136 self-collected dry swab, Evalyn: 73/136 self-collected dry swab, Qvintip: 68/136 **HPV detection agreement: Kappa (95% CI)** clinician-collected sample vs self-collected dry swab Evalyn: 0.822 (0.726–0.918) clinician-collected sample vs self-collected dry swab Qvintip: 0.779 (0.674–0.885)
Risk of bias	Unclear

Ketelaars 2017

Patient sampling	**Design**: Cross-sectional study

	Inclusion/exclusion: Women aged 30-60 years
Patient characteristics and setting	**Population**: Women invited at 5-year intervals for a cervical smear, generally taken by their physician. **Sample size**: 2049 **Setting**: A family-planning clinic and a gynecology consultation center in the University Hospital, France.
Index tests	Self-sampled test: Cobas 4800 HPV test **Instructions**: The participants received a self-sampling kit including a self-sampling device, an explanatory letter, an informed consent form, user instructions (written and drawn), and a return envelope with the address of the laboratory. **Sample collection**: Women self-collected a cervicovaginal sample at home or in the physician's practice, in either case after the physician collected sample was taken **Sampling device and storage medium**: A dry brush: the Evalyn Brush, Rovers Medical Devices B.V., Oss, Netherlands
Comparator test	Clinician-sampled HPV tests: Cobas 4800 HPV test **Sample collection:** A regular cervical smear taken by their physician as part of the nationwide program. **Sampling device and storage medium**: liquid-based cytology sample using a Rovers Cervex-Brush (Rovers Medical Devices B.V., Oss, Netherlands). The Cervex-Brush was rinsed in ThinPrep medium (Hologic, Marlborough, MA) in the Nijmegen region and in SurePath medium (Klinipath BV, Duiven, Netherlands)
Flow and timing	Time interval between index and comparator tests: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives n/N (%)** clinician-collected sample: 163/2046 (8.0%) self-collected: 204/2046 (10.0%) **HPV detection agreement: %** clinician-collected vs self-collected sample: 96.8%
Risk of bias	Unclear

Leeman 2017

Patient sampling	**Design**: Cross-sectional single-center study. **Inclusion/exclusion**: Women included were aged 18 years or older and had been referred for colposcopy to the Hospital Clinic because of abnormal cervical cytology.
Patient characteristics and setting	**Population**: A cohort of 113 women referred for colposcopy after an abnormal Pap smear. **Sample size**: 113 **Setting**: A colposcopy outpatient clinic in Spain.
Index tests	Self-sampled test: HPV DNA (SPF10-DEIA-LiPA25 assay and GP5+/6+-EIA-LMNX.) **Instructions**: Not described **Sample collection**: At the outpatient clinic, women were asked to perform a brush-based self-sample of cervicovaginal cells **Sampling device and storage medium**: Dry stored swab Evalyn brush™ (Rovers Medical Devices B.V., Oss, the Netherlands).
Comparator test	Clinician-sampled HPV tests: HPV DNA (SPF10-DEIA-LiPA25 assay and GP5+/6+-EIA-LMNX.) **Sample collection:** The clinician performed a pelvic and speculum examination during which a cervical specimen was collected. **Sampling device and storage medium**: Cervex-brush in liquid - Cervex-Brush (Rovers Medical Devices B.V., Oss, the Netherlands) in PreservCyt solution (Hologic Corp, Marlborough, MA, USA).
Flow and timing	Time interval between index and comparator tests: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** SPF10 clinician-collected sample: 68/91 self-collected dry swab: 66/91 GP5+/6+ clinician-collected sample: 62/91 self-collected dry swab: 59/91 **HPV detection agreement: Kappa (95% CI)** SPF10

	clinician-collected sample vs self-collected dry swab: 0.92 (0.822–1.01) GP5+/6+ clinician-collected sample vs self-collected dry swab: 0.80 (0.68–0.93)
Risk of bias	Unclear

Leinonen 2018

Patient sampling	**Design**: Multicenter cross-sectional study **Inclusion/exclusion**: They contacted patients referred for treatment for premalignant lesions to Østfold Hospital Trust (ØHT) or Oslo University Hospital (OUH), Ullevål, and patients with confirmed cervical carcinoma or carcinoma suspicion starting treatment at the Norwegian Radium Hospital. They assessed samples that were returned with informed consent.
Patient characteristics and setting	**Population**: High risk population. The recruited study population consisted of 249 patients with cervical premalignant lesions and 61 women with carcinoma diagnosis or carcinoma suspicion. Patients referred for treatment of premalignant lesions were recruited from the Østfold Hospital Trust (ØHT) and Oslo University Hospital (OUH), Ullevål. Patients with confirmed cervical carcinoma or carcinoma suspicion were recruited at the Norwegian Radium Hospital. **Sample size**: 310 (232 had complete data for all detection tests) **Setting**: Self-collection was done at home, and physician-collection was done in conjunction with normally scheduled consultations, presumably at the clinics where the women were recruited
Index tests	Self-sampled test: HPV DNA (Evalyn dry brush and FLOQSwabs dry swabs /3 real-time PCR assays: Anyplex™ II HPV28, Cobas® 4800 HP, and Xpert HPV) **Instructions:** The women received self-collection devices with written instructions by mail. **Sample collection**: Participants performed self-collection at home using two sampling devices the day before their appointment. **Sampling device and storage medium**: Sampling done with (1) dry brush (Evalyn®Brush, Rovers Medical Devices, Lekstraat, The Netherlands) and (2) a dry swab (FLOQSwabs™, COPAN, Brescia, Italy). The brushes were stored dry until they were processed.
Comparator test	Physician-sampled HPV tests: HPV DNA (a brush / 3 real-time PCR assay: Anyplex™ II HPV28, Cobas® 4800 HP, and Xpert HPV)

	Sample collection: Before the gynecologic procedure, a physician took a cervical specimen using a brush. **Sampling device and storage medium**: Sampling with a brush. The specimen was rinsed directly into PreservCyt® buffer (Hologic, Inc., Marlborough, MA)
Flow and timing	**Time interval between index and comparator tests:** Self-collected samples were taken first at home the day before their scheduled appointment. The order of the device use was randomized, and clearly indicated on the study instructions. Women brought self-collected specimens to their appointment from where they were transported to the CRN. The devices were then re-labelled and sent dry to the laboratory of ØHT at room temperature. The time interval between specimen-collection and shipment to the laboratory ranged from four to 194 days, median time being 23 days. At the laboratory, Evalyn®Brush and FLOQSwabs™ heads were suspended with 4.6 ml ThinPrep medium. Aliquots of 1 ml were refrigerated or stored at -20 °C until analysis. No details provided on how the physician-collected samples were handled after the specimens were rinsed into the buffer. 3 real-time PCR tests used for detection: Anyplex™ II HPV28 Detection (Seegene Inc., Seoul, Korea) simultaneously detects and sequences 28 HPV types. The 14 hrHPV types plus 14 possibly carcinogenic or non-cancer-causing types. Cobas® 4800 HPV Test simultaneously detects and sequences the 14 hrHPV types. Xpert®HPV simultaneously detects and sequences the 14 hrHPV types,
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** <u>Anyplex II HPV28</u> Clinician-collected cervical specimen: 207/232 (89%) Self-collected with **Evalyn Brush**: 209/232 (90%) Self-collected with **FLOQSwabs**: 193/232 (83%) <u>Cobas 4800</u> Clinician-collected cervical specimen: 200/232 (86%) Self-collected with **Evalyn Brush**: 196/232 (84%) Self-collected with **FLOQSwabs**: 185/232 (80%) <u>Xpert HPV</u> Clinician-collected cervical specimen: 199/232 (86%) Self-collected with **Evalyn Brush**: 197/232 (85%) Self-collected with **FLOQSwabs**: 188/232 (81%)

	HR-HPV detection agreement: Kappa (95% CI) Self-collected vs. clinician-collected samples: Anyplex™ II HPV28 Self-collected with **Evalyn Brush** vs. Clinician-collected sample Kappa 0.68 (0.52–0.83) Agreement 94.0% Self-collected with **FLOQSwabs** vs. Clinician-collected sample Kappa 0.50 (0.33–0.64) Agreement 87.9% Cobas 4800 Self-collected with **Evalyn Brush** vs. Clinician-collected sample Kappa 0.64 (0.49–0.77) Agreement 91.0% Self-collected with **FLOQSwabs** vs. Clinician-collected sample Kappa 0.60 (0.44–0.73) 0.60 Agreement 88.4% Xpert HPV Self-collected with **Evalyn Brush** vs. Clinician-collected sample Kappa 0.66 (0.52–0.80) 0.66 Agreement 91.4% Self-collected with **FLOQSwabs** vs. Clinician-collected sample Kappa 0.60 (0.45–0.73) 0.60 Agreement 88.8%
Risk of bias	Unclear

Onuma 2020

Patient sampling	**Design**: Cross-sectional study **Inclusion/exclusion**: Patients who had previously tested negative for intraepithelial lesions or malignancy/HPV-positive, and patients with atypical squamous cells of undetermined significance or worse (ASCUS+) cytology were eligible. Exclusion criteria included patients who had undergone hysterectomy, were pregnant, or who had received chemotherapy.
Patient characteristics and setting	**Population**: Selected population (1) outpatients with abnormal cytology and requiring colposcopy and biopsy and (2) NILM/HPV-positive patients in the Fukui Cervical Cancer Study (FCCS – investigated combined screening with liquid-based cytology; women who had tested NILM/HPV-positive in the baseline phase were followed up for 3 years; yearly physician-collected HPV testing, cytology, and colposcopy) **Sample size**: 100 (number with both tests) **Setting**: University of Fukui Hospital from January 2019 to July 2019

Index tests	Self-sampled test: HPV DNA (Evalyn brush /Cobas 4800 PCR-based HPV testing) **Instructions**: Participants received instruction on how to submit samples after HPV self-sampling but not details concerning use of the Evalyn brush for sample collection. Participants were instructed to read the instructions describing use of the Evalyn brush before self-sampling, with these instructions created under supervision of the Japan Cancer Society. These instructions were verified that Japanese people could read and understand before this study. **Sample collection**: Participants performed HPV self-sampling in the bathroom at the hospital, immediately placing the brushes in provided ThinPrep vials. HPV infection was confirmed using a PCR-based Cobas 4800 HPV DNA test. **Sampling device and storage medium**: The Evalyn brush heads were stored at room temperature in ThinPrep vials (Hologic, Marlborough, MA, USA). The samples were stored at room temperature and transferred to the Fukui Health Care Association on a fixed day of the week.
Comparator test	Clinician-sampled HPV tests: HPV DNA (Rovers Cervex brush, Rovers Medical Devices, Oss, The Netherlands / Cobas 4800 PCR-based HPV testing) **Sample collection:** The physician performed HPV and cell sampling using an endocervical brush and immediately stored the brush heads in ThinPrep vials. HPV infection was confirmed using a PCR-based Cobas 4800 HPV DNA test. **Sampling device and storage medium**: The Cervex brush was immediately placed in ThinPrep vials. The samples were stored at room temperature and transferred to the Fukui Health Care Association on a fixed day of the week.
Flow and timing	Time interval between index and comparator tests: consecutive, self-sampling first, physician sampling immediately after
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** Physician-collected sample: HPV all types: 51/100 (51%) Self-collected sample:

	HPV all types: 50/100 (50%) **HR-HPV detection agreement: Kappa (95% CI)** Self-collected compared to clinician-collected samples HPV perfect match[2] all types concordance: kappa 0.76 [0.63–0.89) Agreement: 88%
Risk of bias	Unclear

Phoolcharoen 2018

Patient sampling	**Design**: Cross-sectional study **Inclusion/exclusion**: Eligible women were aged 30–70 years, had no history of cervical cancer, had not undergone a hysterectomy, and were currently not pregnant.
Patient characteristics and setting	**Population**: Selected population. Women who visited a colposcopy Clinic for any indication (e.g. abnormal cytology, screened positive for HPV). **Sample size**: 247 **Setting**: colposcopy clinic at Chulabhorn Hospital, Bangkok, Thailand
Index tests	Self-sampled test: HPV DNA (Evalyn Brush dry vaginal brush from Rovers Medical Devices B.V., Oss, The Netherlands / Cobas4800 HPV PCR test) **Instructions**: The women received instructions by video made by research project's staffs to explain how to use the vaginal self-sampling brush, verbal and illustrations for vaginal self-sampling. **Sample collection**: presumably at the clinic, samples were analysed with Cobas4800 HPV test (Roche Molecular Diagnostics, Pleasanton, CA, USA) within 1 week after collection. **Sampling device and storage medium**: Evalyn Brush (dry vaginal brush, Rovers Medical Devices B.V., Oss, The Netherlands), stored in 10 ml transport medium, SurePath Preservative Fluid (Becton, Dickinson and Company, USA).
Comparator test	Clinician-sampled HPV tests: HPV DNA (Cervex-Brush from Rovers Medical Devices / Cobas4800 HPV PCR test) **Sample collection:** endocervical sample collected by a gynecological oncologist, Samples were analyzed with Cobas4800 HPV test (Roche Molecular Diagnostics, Pleasanton, CA, USA) within 1 week after collection.

	Sampling device and storage medium: Cervex-Brush (Rovers Medical Devices) 10 ml transport medium, SurePath Preservative Fluid (Becton, Dickinson and Company, USA)
Flow and timing	Time interval between index and comparator tests: consecutive, self-sampling first
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests (in a transport liquid medium) **Detection of HR-HPV positives** Physician-collected sample: 89/247 (36%) Self-collected sample: 102/247 (41.3%) **HR-HPV detection agreement: Kappa (95% CI)** Self-collected vs. physician-collected samples: Kappa[1] 0.46 (hrHPV) Agreement 74.5%
Risk of bias	Unclear

Reisner 2018

Patient sampling	**Design**: cross-sectional study **Inclusion/exclusion**: Trans masculine people (i.e. people were assigned female sex at birth and now have a masculine spectrum gender identity) between 21 and 64 years old, have a cervix, have been sexually active within the past 3 years (sexual partner(s) of any gender); (5) able to speak and understand English; (6) willing and able to provide informed consent. Prior HPV vaccination was not grounds for exclusion from the study.
Patient characteristics and setting	**Population**: Screening of a sub-population: trans masculine volunteers recruited broadly from the community. **Sample size**: 131 **Setting**: a federally qualified community health center that serves the LGBT community in Boston, Massachusetts (Fenway Health)
Index tests	Self-sampled test: HPV DNA (Polyester-tipped swab from Puritan Medical Products Company / DNA Hybridization Assay) **Instructions**: Trained study staff provided all participants with a written instruction sheet and detailed verbal instructions on self-collection and packaging of specimens. **Sample collection**: Participants were provided with a hand mirror and latex gloves. Self-collection of vaginal specimens occurred alone in a private exam room or single-stall bathroom, based on participant preference. Sterile polyester-tipped swabs were inserted approximately two inches into the vaginal canal and rotated in a circular motion for 10±30 seconds.

	Samples were tested for hrHPV by Quest Diagnostics, Marlborough, MA, USA using DNA Hybridization Assay via digene Hybrid Capture II technology (Qiagen, Gaithersburg, Inc., Gaithersburg, MD, USA). **Sampling device and storage medium**: Polyester-tipped swab from Puritan Medical Products Company LLC, Guilford, ME, USA, stored in a Cytyc ThinPrep solution canister directly after sampling.
Comparator test	Clinician-sampled HPV tests: HPV DNA (Cytobrush Plus from Cooper Surgical, Trumbull, CT, USA / DNA Hybridization Assay) **Sample collection:** Cervical samples were collected from all participants. A physician or nurse practitioner collected cervical specimens using a Medscand Pap-Perfect Spatula and Cytobrush Plus A vaginal sample was also collected from the last 53 participants. A clinician collected vaginal specimens using a fresh sterile polyester-tipped swab from inserted approximately two inches into the vaginal canal and rotated in a circular motion for 10±30 seconds (the same equipment and instructions as used in self-testing); this specimen was collected with the speculum in place. Samples were tested for hrHPV by Quest Diagnostics, Marlborough, MA, USA using DNA Hybridization Assay via digene Hybrid Capture II technology (Qiagen, Gaithersburg, Inc., Gaithersburg, MD, USA). **Sampling device and storage medium**: All participants: Cytobrush Plus (Cooper Surgical, Trumbull, CT, USA) that were deposited into a Cytyc ThinPrep solution. Last 53 participants: Cytobrush Plus as above plus polyester-tipped swab from Puritan Medical Products Company LLC, Guilford, ME, USA). Both samples were stored in a Cytyc ThinPrep solution canister.
Flow and timing	Time interval between index and comparator tests: All specimens were collected at the single study visit. The order of specimen collection (self- or provider-collected first) was randomized. For participants self-collecting after provider collection, providers removed excess lubricant using an additional cotton swab with ring forceps while withdrawing the speculum.
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** Clinician-collected sample (cervical sample with Cytobrush): 21/131 (16.0%) Self-collected sample (vaginal sample with Puritan swab): 17/131 (13.0%)

	HR-HPV detection agreement: Kappa (95% CI) Self-collected vs clinician collected sample (cervical sample with Cytobrush): 0.75 (0.59 to 0.92)
Risk of bias	Unclear

Rohner 2020

Patient sampling	**Design**: Multicenter cross-sectional study **Inclusion/exclusion**: Recruited women ages 25–65 years attending colposcopy clinics at either the University of North Carolina (UNC) Women's Hospital (Chapel Hill, NC) or Duke University Hospital (Durham, NC) for one of the following reasons: (i) abnormal cytology results, (ii) infection with HPV-16 or 18, (iii) persistent infection with other hr-HPV genotypes, or (iv) treatment for CIN2þ. In addition, we invited women to participate in the study if they were NILM on cytology, but positive for hr-HPV genotypes other than 16 or 18 at their routine screening ("research only" group). Women were excluded from participation if they were pregnant or had their cervix removed; additionally, women in the "research only" group were excluded if they were taking blood thinners or if the enrollment date was not within 3 months of their original hr-HPV diagnosis. Women were not asked to abstain from sexual intercourse before the study visit.
Patient characteristics and setting	**Population**: Selected[1]. Women attending colposcopy clinics to follow-up test results indicating an increased risk for HPV infections (see inclusion criteria). **Sample size**: 314 **Setting**: Colposcopy clinics at either the University of North Carolina (UNC) Women's Hospital (Chapel Hill, NC) or Duke University Hospital (Durham, NC)
Index tests	Self-sampled test: HPV DNA (Viba-Brush / PCR and nucleic acid hybridization testing, Onclarity Assay) Instructions: participating women received detailed verbal and written instructions concerning the study procedures in either English or Spanish. **Sample collection**: Women self-collected a cervico-vaginal sample at the clinic by inserting a Viba-Brush to the top of the vaginal canal, rotating five times, removing it, and releasing the brush head into a vial prefilled with 6 mL of preservative liquid–based Cytology Media.

	Sampling device and storage medium: Sampling with Viba-Brush (Rovers Medical Devices BV); stored in vial prefilled with 6 mL of preservative liquid–based Cytology Media (ThinPrep, Hologic Inc.). Samples were stored in a cooler within 10 minutes of collection, processed same day, and then stored at -20° in HPV diluent buffer until it was shipped to BD (Becton Dickinson) for hr-HPV[1] testing with the Onclarity Assay (BD).
Comparator test	Clinician-sampled HPV tests: HPV DNA (Wallach Papette / PCR and nucleic acid hybridization testing, Onclarity Assay) **Sample collection:** During a pelvic examination, the clinician collected a cervical scraping with two 360° turns in a clockwise fashion of a brush-like cervical cell collector. The clinician-collected cervical sample was preserved in a standard 20 mL vial of ThinPrep media for subsequent hr-HPV testing. Immediately stored in a cooler, processed same day then stored at -20° until it was shipped to BD (Becton Dickinson) for hr-HPV testing. **Sampling device and storage medium**: Sampling with a brush-like cervical cell collector (Wallach Papette, Wallach Surgical Devices); stored in a standard 20 mL vial of ThinPrep media (ThinPrep, Hologic Inc.). Samples were stored in a cooler within 10 minutes of collection, processed same day, and then stored at -20° in HPV diluent buffer until it was shipped to BD (Becton Dickinson) for hr-HPV[2] testing with the Onclarity Assay (BD).
Flow and timing	Time interval between index and comparator tests: consecutive during a visit to the clinic, self-collection first
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of any HR-HPV positives** Clinician-collected cervical sample: 220/314 (70%) Self-collected cervical-vaginal brush: 239/314 (76%) **HR-HPV detection agreement: Kappa (95% CI)** self-collected vs. clinician-collected samples: Kappa = 0.57 (0.47 to 0.67) 83% agreement
Risk of bias	Unclear

Saidu 2021

Patient sampling	**Design**: Cross-sectional study (prospective observational study) **Inclusion/exclusion**: not reported Half of each group was HIV-positive by design, no details on selection provided.

	Screening: Any woman who wanted to be tested for HRP and had proof of HIV status (HIV testing was available at the clinic for those who did not have it) was eligible. Referral: Presumably any woman who had been referred for abnormal HPV results
Patient characteristics and setting	**Population**: Both screening and selected populations included. Half of the study population was HIV-positive (n=535). Most (80%) of the HIV-positive women were on antiretroviral therapy. Screening: Women from the general population seeking primary screening. Recruited through a large public clinic that serves a disadvantaged population. Referral: Women referred to the clinic because of abnormal screening results. Recruited through the routine colposcopy services at a university hospital. **Sample size**: 1121 Screening: 715 (HIV-positive: N=330; HIV-negative: N=375) Referral: 406 (HIV-positive: N=200; HIV-negative: N=202) **Setting**: Screening: Samples were collected at Khayelitsha Site B Primary Health Care Clinic, a large public clinic serving a disadvantaged population resident in this community on the outskirts of Cape Town, South Africa. Referral: No information provided
Index tests	Self-sampled test: HPV DNA (Puritan swab / PCR-based Xpert HPV (CE-IVD) test) **Instructions:** "Instructions were given to them by a community health worker." **Sample collection**: Women performed the self-collection in a private clinical examination room (vaginal sample) **Sampling device and storage medium**: Sampled with a standard flock tip swab (Puritan, Guilford, ME) Stored in 5-mL vial (Globe Scientific, Paramus, NJ) containing 4 mL of PreservCyt solution (Hologic, Bedford, MA)
Comparator test	Physician-sampled HPV tests: HPV DNA (2 cervical samples taken with plastic spatula and endocervical cytobrush / PCR-based Xpert HPV (CE-IVD) test) **Sample collection:** Two cervical samples were collected during a pelvic exam, after visualization of the cervix with a speculum. **Sampling device and storage medium**: 2 samples were taken from each woman 1- Extended tip plastic spatula (Medscand, Berlin, Germany)

	2- Endocervical cytobrush (Medscand, Berlin, Germany) The cervical samples were placed in 2 separate ThinPrep vials (Hologic) each filled with 20 mL of PreservCyt solution. Both clinician-collected samples and self-collected samples were tested with the PCR-based Xpert HPV (CE-IVD) test using the GeneXpert instrument system (Cepheid, Sunnyvale, CA) at the Khayelitsha site. The test detects the presence of HR-HPV variants in 5 subgroups: HPV 16; HPV 18 and/or 45; HPV 31, 33, 35, 52, and/or 58; HPV 51 and/or 59; and HPV 39, 56, 66, and/or 68.
Flow and timing	**Time interval between index and comparator tests:** Consecutive, self-collected samples were taken first
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** Screening: Clinician-collected cervical sample: 220/705 (31%) Self-collected vaginal samples: 297/705 (42%) Referral: Clinician-collected cervical sample: data not provided Self-collected vaginal samples: data not provided **HR-HPV detection agreement: Kappa (95% CI)** Screening: Self-collected vs. clinician-collected samples: Kappa 0.72 (0.669 to 0.771) Agreement 86.8% Referral: Self-collected vs. clinician-collected samples: Kappa 0.62 (0.476 to 0.726) Agreement 89.3%
Risk of bias	Unclear

Satake 2020

Patient sampling	**Design**: Single center cross-sectional study **Inclusion/exclusion**: Women signing an informed consent at the study clinics.
Patient characteristics and setting	**Population**: Women visiting the study clinics. **Sample size**: 300 **Setting**: Three private obstetrics/gynecology clinics and hospitals in Sapporo city, Japan.

Index tests	Self-sampled test: HPV DNA Cobas® 4800 HPV system (Roche Diagnostics GmbH, Mannheim, Germany) **Instructions**: Women received complete instructions on how to use the self-sampling tool from a gynecologist/ obstetrician or a nurse, and then a self-sampling kit was handed over to them. (A cell sampling tool, Home Smear Set®, is a cylindrical and partially conical stick of approximately 20 cm in length, with a 7-cm-long tip portion that is purple in color to mark the insertion depth into the vagina. After the tip of the Home Smear Set® is inserted into the vagina, its white handle at the other end of the stick is inserted into the stick. Then, the spongy part is pushed out from the tip of the stick inserted into the vagina. Cervicovaginal cells are collected by rotating the spongy part. After collection of the cells, the white handle is pulled back so that the spongy part is put back into the stick, and the stick is drawn out of the vagina. Then, the spongy part is rinsed well in a tube (cell fixation container) containing the fixation fluid so that the cells are washed off into the fixation fluid in the tube.) **Sample collection**: Women collected cervicovaginal cells by themselves in a treatment room or a restroom prior to physician sampling. Specimens collected were temporally stored at ambient temperature together with a request form according to their routine procedures, and then specimens were retrieved on-site. **Sampling device and storage medium**: Home Smear Set® (ISK Co., Ltd., Tokyo, Japan). In this kit, both the self-sampling tool and the cell fixation container were enclosed, and cells collected by the self-sampling procedure were transferred into a cell fixation container (principal component is ethanol).
Comparator test	Clinician-sampled HPV tests: HPV DNA Cobas® 4800 HPV system (Roche Diagnostics GmbH, Mannheim, Germany) **Sample collection:** A vaginal speculum was inserted to visualize the cervix uteri and the sample was collected. Specimens collected were temporally stored at ambient temperature together with a request form according to their routine procedures, and then specimens were retrieved on-site. **Sampling device and storage medium**: Cervex-Brush® (Rovers Medical Devices B.V., The Netherlands) was used as the sampling tool, and a SurePathTM vial (principal component is ethanol; Becton, Dickinson and Company, Franklin Lakes, NJ, USA) was used as the cell fixation container.
Flow and timing	Time interval between index and comparator tests: consecutive

Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** clinician-collected sample: 41/300 13.7% self-collected sample: 44/300 14.7% **HR-HPV detection agreement: % (95% CI)** 96.3% (94–98%) **HPV detection agreement: Kappa (95% CI)** Not stated
Risk of bias	Unclear

Saville 2020

Patient sampling	**Design**: Single center cross-sectional study **Inclusion/exclusion**: Not stated
Patient characteristics and setting	**Population**: Women 18 years of age or older scheduled to undergo a colposcopy examination. **Sample size**: 303 (ranging from 291-302 depending on HPV assay) **Setting**: A tertiary referral centre – a Dysplasia Clinic at the Royal Women's Hospital in Melbourne, Australia.
Index tests	Self-sampled test: HPV DNA, 6 assays used: cobas 4800 and cobas (Roche Diagnostics, Basel, Switzerland), BD Onclarity HPV assay (BD Diagnostics, Sparks, MD, USA), Xpert HPV test (Cepheid, Inc., Sunnyvale, CA, USA), Anyplex II HPV HR Detection test (Seegene, Seoul, Korea) and Abbott Realtime HPV (Abbott Laboratories, Abbott Park, IL, USA). This study was conducted by VCS Pathology (VCS) **Instructions**: Participants were given written instructions on how to obtain a self-collected vaginal specimen using a flocked swab. **Sample collection**: In the clinic. After self-collection, participants returned the swab to the health practitioner. Self-collected flocked swabs were stored at ambient room temperature for a week before placing into 5 ml of PreservCyt solution (Hologic Marlborough, MA, USA), swirling for 20 seconds, before removing the swab. **Sampling device and storage medium**: Flocked swab (FLOQSwab 552C, Copan, Brescia, Italy). PreservCyt solution (Hologic Marlborough, MA, USA)

Comparator test	Clinician-sampled HPV tests: HPV DNA, 6 assays used: cobas 4800 and cobas (Roche Diagnostics, Basel, Switzerland), BD Onclarity HPV assay (BD Diagnostics, Sparks, MD, USA), Xpert HPV test (Cepheid, Inc., Sunnyvale, CA, USA), Anyplex II HPV HR Detection test (Seegene, Seoul, Korea) and Abbott Realtime HPV (Abbott Laboratories, Abbott Park, IL, USA). This study was conducted by VCS Pathology (VCS) **Sample collection:** A cervical specimen was collected by a practitioner as per usual practice, as part of a scheduled, colposcopic examination. Practitioner-collected samples were also stored at ambient temperature for one week before testing. **Sampling device and storage medium**: (Cervex-Brush, Rovers Medical Devices, Lekstraat, The Netherlands). Rinsed in 20 ml of PreservCyt solution (Hologic, Marlborough, MA, USA).
Flow and timing	Time interval between index and comparator tests: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** clinician-collected sample: cobas 4800: 162/299 54.2% (48.3-59.9) cobas: 170/302 56.3% (50.5-62.0) Onclarity: 141/299 47.2% (41.4-53.0) Xpert: 149/302 49.3% (43.6-55.1) Anyplex II: 177/302 58.6% (52.8-64.2) Abbott: 151/299 50.5% (44.7-56.3) self-collected sample: cobas 4800: 195/295 66.1% (60.4-71.5) cobas: 194/293 66.2% (60.5-71.6) Onclarity: 162/300 54.0% (48.2-59.7) Xpert: 172/291 59.1% (53.2-64.8) Anyplex II: 186/296 62.8% (57.1-68.4) Abbott: 162/296 54.7% (48.9-60.5) **HR-HPV detection agreement: % (95% CI)** Cobas 4800: 242/292 82.9% (78.1-87.0) cobas: 248/292 84.9% (80.3-88.8) Onclarity: 240/296 81.1% (76.1-85.4) Xpert: 242/291 83.2% (78.4-87.3) Anyplex II: 257/296 86.8% (82.4-90.5) Abbott: 250/296 84.5% (79.8-88.4) **HPV detection agreement: Kappa (95% CI)** Not stated – calculated Gwet's AC1 coefficient instead

Risk of bias	Unclear

Senkomago 2018

Patient sampling	**Design**: Prospective longitudinal study **Inclusion/exclusion**: 18–50 years. Women were at least 18 years, were not in the second or third trimester of pregnancy and had an intact cervix.
Patient characteristics and setting	**Population**: Female sex workers **Sample size**: 350 (344 complete samples at baseline) **Setting**: Study-associated clinic in Korogocho, Nairobi, Kenya.
Index tests	Self-sampled test: Aptima HPV assay (Hologic, USA) **Instructions**: Participating women self-collected a cervico-vaginal specimen for hrHPV-RNA testing in accordance with simple pictorial instructions. **Sample collection**: In the clinic. **Sampling device and storage medium**: Aptima Cervical Specimen Collection and Transport cytobrush (Hologic, Marlborough, MA, USA).
Comparator test	Clinician-sampled HPV tests: Aptima HPV assay (Hologic, USA) **Sample collection:** The physician collected one cervical specimen for a conventional cervical smear test and a second cervical specimen for hrHPV-RNA testing. **Sampling device and storage medium**: Cervex-Brush (Rovers Medical Devices, Oss, The Netherlands) in PreservCyt medium (Hologic).
Flow and timing	Time interval between index and comparator tests: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** clinician-collected sample: Baseline: 103/344 3 months: 84/300 6 months: 74/269 9 months: 58/258 12 months: 70/273

	15 months: 68/267 18 months: 56/254 21 months: 56/257 24 months: 53/218 self-collected sample: Baseline: 98/344 3 months: 94/300 6 months: 92/269 9 months: 76/258 12 months: 91/273 15 months: 78/267 18 months: 62/254 21 months: 57/257 24 months: 53/218 **HR-HPV detection agreement: % (95% CI)** Baseline: 82.8 (78.9–86.8) 3 months: 81.3 (76.9–85.7) 6 months: 82.2 (77.6–86.7) 9 months: 82.9 (78.4–87.5) 12 months: 86.4 (82.4–90.5) 15 months: 85.0 (80.7–89.3) 18 months: 85.0 (80.7–89.4) 21 months: 92.6 (89.4–95.) 24 months: 93.6 (90.3–96.8) **HPV detection agreement: Kappa (95% CI)** Baseline: 0.55 (0.45–0.65) 3 months: 0.55 (0.45–0.66) 6 months: 0.57 (0.47–0.68) 9 months: 0.56 (0.45–0.67) 12 months: 0.68 (0.59–0.77) 15 months: 0.62 (0.53–0.73) 18 months: 0.60 (0.48–0.69) 21 months: 0.78 (0.69–0.88) 24 months: 0.83 (0.74–0.91)
Risk of bias	Unclear

Stanczuk 2015

Patient sampling	**Design**: Single centre cross-sectional study **Inclusion/exclusion**: Not stated
Patient characteristics and setting	**Population**: Women with abnormal cytology referred to Colposcopy Clinic **Sample size**: 109 enrolled (100 complete samples)

	Setting: National Health Service (NHS) Colposcopy Clinic (Dumfries and Galloway Royal Infirmary), Scotland, UK.
Index tests	Self-sampled test: HPV DNA, Cobas 4800 HPV Test (Roche Molecular Systems, California, USA) **Instructions**: Women were advised to insert the brush into the vagina and slowly rotate it a few times. **Sample collection**: In the clinic. **Sampling device and storage medium**: Rovers Cervex-Brush (Oss, The Netherlands). The brush was subsequently suspended in 5 mL of ThinPrep, PreservCyt Solution (Hologic, UK).
Comparator test	Clinician-sampled HPV tests: HPV DNA, Cobas 4800 HPV Test (Roche Molecular Systems, California, USA) **Sample collection:** Prior to undertaking colposcopy, the clinician collected an LBC sample. **Sampling device and storage medium**: Cervexbrush in liquid, liquid based cytology (LBC).
Flow and timing	Time interval between index and comparator tests: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** clinician-collected sample: 92/100 self-collected sample: 91/100 **HR-HPV detection agreement: % (95% CI)** 94% (87 to 98) **HPV detection agreement: Kappa (95% CI)** Not stated
Risk of bias	Unclear

Stanczuk 2016

Patient sampling	**Design**: Multicenter cross-sectional study **Inclusion/exclusion**: All women, 20-60 years, other than those previously diagnosed with CIN2+, presenting for routine cervical screening.

Patient characteristics and setting	**Population**: Women attending routine cervical screening in primary care. **Sample size**: 5318 enrolled (5299 clinician-collected samples, 5208 self-collected samples) **Setting**: 40 general practice clinics serving 160 000 inhabitants in the region of Dumfries and Galloway in Scotland, UK.
Index tests	Self-sampled test: HPV DNA. Cobas 4800 DNA HPV test. **Instructions**: Women were advised to follow instructions printed on the collection kit. **Sample collection**: Women self-collected a vaginal sample prior to a routine cervical sample being collected by the clinician. **Sampling device and storage medium**: Cobas PCR female swab sample packets (Roche Molecular Systems), validated for chlamydia/gonorrhea (CT/NG) self-vaginal sampling. Liquid stored swab. Swabs were immediately immersed in tubes containing Roche PCR media. In an early pilot phase, 200 patients used two swabs together for sampling, one immersed immediately in buffer as above, the other left dry for 28 days before immersion in the laboratory immediately prior to assay.
Comparator test	Clinician-sampled HPV tests: HPV DNA. Cobas 4800 DNA HPV test. **Sample collection:** Cervical liquid-based cytology (LBC) samples were clinician collected. Three milliliter of LBC sample was aliquoted into a separate tube for HPV testing. **Sampling device and storage medium**: Rovers Cervex-Brush (Oss, the Netherlands) and suspended in 20ml of ThinPrep solution (PreservCyt Solution, Hologic, UK).
Flow and timing	Time interval between index and comparator tests: consecutive
Outcomes	Agreement between self-sampled HPV tests and clinician-sampled HPV tests **Detection of HR-HPV positives** clinician-collected cervical sample: 787/5299 self-collected vaginal sample: 867/5208 **HR-HPV detection agreement: % (95% CI)** Not stated **HPV detection agreement: Kappa (95% CI) N**ot stated

Risk of bias	Unclear

Ting 2013

Patient sampling	**Design**: Single centre cross-sectional study **Inclusion/exclusion:** Women were excluded if they had undergone hysterectomy or were in the second trimester of pregnancy or later.
Patient characteristics and setting	**Population**: Female sex workers, aged 18 to 49 **Sample size**: 344; 350 originally enrolled **Setting**: Clinic in Nairobi slum area
Index tests	Self-sampled HPV test: Aptima hrHPV mRNA (AHPV; Hologic/Gen-Probe Incorporated, San Diego, CA, USA) **Instructions**: Pictoral instructions **Sample collection**: Self-collected cervicovaginal specimen. Collected at clinic, exact location not specified. **Sampling device and storage medium**: Aptima Cervical Specimen Collection and Transport cytobrush (Hologic/Gen-Probe Incorporated, San Diego, CA, USA). Brush swirled in Aptima specimen transport medium.
Comparator test	Clinician-sampled HPV tests: Aptima hrHPV mRNA (AHPV; Hologic/Gen-Probe Incorporated, San Diego, CA, USA) **Sample collection:** Physician collected two cervical samples; one for Aptima test, one for conventional Pap test. **Sampling device and storage medium**: Cervex-Brush (Rovers Medical Devices, Oss, the Netherlands). Brush swirled in PreservCyt (Hologic Corporation, Marlborough, MA, USA).
Flow and timing	Time interval between index and comparator tests: consecutive
Outcomes	Agreement between AHPV physician testing and self-testing **hrHPV positive rate, AHPV** Physician collection: 103/344 (29.9%) Self-collection: 98/344 (28.5%) **AHPV detection agreement: Kappa (95% CI)**

	Physician collected vs self-testing: 0.59 (0.49-0.68)
Risk of bias	Unclear

Toliman 2019

Patient sampling	**Design**: Multicentre cross-sectional study **Inclusion/exclusion**: Women in target age group for cervical screening.
Patient characteristics and setting	**Population**: Women aged 30-54 years (target age group for cervical screening in Papua New Guinea). **Sample size**: 1 005 women enrolled. Total 985 vaginal + cervical samples tested for any hrHPV using Xpert, Cobas 4800 and Aptima. **Setting**: Two clinics for women located in the Highlands region of Papua New Guinea.
Index tests	Self-sampled HPV test: Xpert HPV; Cobas 4800; Aptima **Instructions**: Oral instructions and pictoral guide. **Sample collection**: Vaginal sample. Self-collection was conducted in a private room in each participating clinic, device then returned to laboratory technician. **Sampling device and storage medium**: Cytobrush, placed by laboratory technician in ThinPrep PreservCyt (Hologic, Marlborough, MA, USA)
Comparator test	Clinician-sampled HPV tests: Xpert HPV; Cobas 4800; Aptima **Sample collection:** Endocervical sample collected by clinician during gynecological examination. **Sampling device and storage medium**: Cytobrush, same type as self-sample. Immediately placed in PreservCyt.
Flow and timing	Time interval between index and comparator tests: Consecutive
Outcomes	Agreement between Self-collected samples and clinician-collected samples **hrHPV positive rate** Self-samples: 14.4% (clinic 1) / 15.5% (clinic 2) Clinician-collected samples: 10.8% (clinic 1) / 12.9% (clinic 2) **hrHPV detection agreement: Kappa (95% CI)**

	Self-sample (vaginal) Xpert vs clinician-collected (cervical) Xpert: 0.74 (0.70-0.79) Self-sample (vaginal) Xpert vs clinician-collected (cervical) Cobas 4800: 0.73 (0.70-0.76) Self-sample (vaginal) Xpert vs clinician-collected (cervical) Aptima: 0.59 (0.53-0.65) Self-sample (vaginal) Cobas 4800 vs clinician-collected (cervical) Xpert: 0.76 (0.70-0.82) Self-sample (vaginal) Cobas 4800 vs clinician-collected (cervical) Cobas 4800: 0.77 (0.70-0.83) Self-sample (vaginal) Cobas 4800 vs clinician-collected (cervical) Aptima: 0.61 (0.55-0.67) Self-sample (vaginal) Aptima vs clinician-collected (cervical) Xpert: 0.65 (0.59-0.71) Self-sample (vaginal) Aptima vs clinician-collected (cervical) Cobas 4800: 0.69 (0.63-0.75) Self-sample (vaginal) Aptima vs clinician-collected (cervical) Aptima: 0.63 (0.57-0.69) Most comparisons demonstrated that V (vaginal) specimen results had substantial (kappa 0.6 – 0.8) to almost perfect (kappa 0.8 – 1.0) agreement with C (cervical) specimens, particularly for the detection of HPV 16.
Risk of bias	Unclear

Tranberg 2018

Patient sampling	**Design**: Multicentre cross-sectional study **Inclusion/exclusion**:
Patient characteristics and setting	**Population**: 30 to 59-year-old women diagnosed with low-grade cytological lesions within the screening program. **Sample size**: 213. 1110 women were eligible, 216 returned a self-sample. Three self-samples excluded. **Setting**: Home / GP clinic
Index tests	Self-sampled HPV test: HPV DNA Cobas 4800 (Roche Diagnostics, Switzerland) **Instructions**: Written and picture-based user instructions sent together with sampling device. **Sample collection**: Self-sample at home

	Sampling device and storage medium: Dry-stored brush - Evalyn brush (Rovers Medical Devices B.V., Oss, Netherlands). Resuspended in SurePath medium (BD Diagnostics, Burlington, NC) upon arrival in laboratory.
Comparator test	Clinician-sampled HPV tests: HPV DNA Cobas 4800 (Roche Diagnostics, Switzerland) **Sample collection:** Physician took sample from cervix. **Sampling device and storage medium**: Cervical brush. Brush head placed in SurePath medium (BD Diagnostics, Burlington, NC) and mailed to laboratory.
Flow and timing	Time interval between index and comparator tests: Median number of days between samples: 43 days (IQR: 34-53 days, range: 13-95 days)
Outcomes	Agreement between Self-collected samples and GP-collected samples **hrHPV positive rate, HPV DNA** Self-samples: 52/213 (24.4%) GP-collected samples: 47/213 (22.1%) **hrHPV detection agreement: Kappa (95% CI)** Self-sample vs GP-collected samples: 0.70 (0.58-0.81)
Risk of bias	Unclear

Twu 2010

Patient sampling	**Design**: Multicenter cross-sectional study **Inclusion/exclusion**: Women who had not received a Pap smear in the previous three years were included in this study. Exclusion criteria included acute cervicitis or vaginitis, pregnancy, menstruating period, or sexual intercourse within two days before the study.
Patient characteristics and setting	**Population**: Women due for Pap smear test, screening **Sample size**: 1 717 **Setting**: Clinic
Index tests	Self-sampled HPV test: HPV Blot test (EasyChip, King Car, YiLan, Taiwan) **Instructions**: Not specified, probably oral instructions by physicians. **Sample collection**: Vagina sample. The patients were instructed to introduce the cytobrush into the vagina till they met with resistance, and

	then rotate the brush 3-5 times to take specimens for HPV typing. The women performed the self-collections at clinic before the clinical collection. Exact location not specified. **Sampling device and storage medium**: Cytobrush. Specimens smeared onto clear slides, cells remaining on cell sampling instruments placed in tube containing 10 mM Tris-HCl, 1mM EDTA, pH7.5 solution.
Comparator test	Clinician-sampled HPV tests: HPV Blot test (EasyChip, King Car, YiLan, Taiwan) **Sample collection:** Physician took sample from cervix and the endocervical canal. **Sampling device and storage medium**: Ayre's spatula and endocervical cytobrush. Specimens smeared onto clear slides, cells remaining on cell sampling instruments placed in tube containing 10 mM Tris-HCl, 1mM EDTA, pH7.5 solution.
Flow and timing	Time interval between index and comparator tests: consecutive
Outcomes	Agreement between vaginal samples and cervical samples **hrHPV positive rate, HPV Blot** Vaginal samples: 15.9% Cervical samples: 23.8% **HPV detection agreement: Kappa (95% CI)** Vaginal vs Cervical specimens: 0.37 (0.25-0.50)
Risk of bias	Unclear

Van Baars 2012

Patient sampling	**Design**: Multicentre cross-sectional study **Inclusion/exclusion**: Women were included if they visited one of two participating gynecological outpatient clinics for colposcopic evaluation due to an abnormal Pap smear or for a follow-up visit after an abnormal Pap smear.
Patient characteristics and setting	**Population**: Women 18 years and above visiting gynecological outpatient clinics due to abnormal Pap smear. **Sample size**: 134 **Setting**: Gynecological outpatient clinics, Netherlands.

Index tests	Self-sampled test: HPV DNA (HPV SPF10-LiPA25, version 1; Labo Bio-medical Products B.V., Rijswijk, Netherlands / GP5/6 primer-mediated PCR assay; Diassay, Rijswijk, Netherlands). **Instructions**: Women were given verbal and written instructions with illustrations. **Sample collection**: The women performed the self-collections at clinic before the clinical collection. Exact location not specified. **Sampling device and storage medium**: Dry-stored brush - Evalyn brush (Rovers Medical Devices B.V., Oss, Netherlands). Resuspended in Thinprep (Hologic, Marlborough MA, USA) upon arrival in laboratory.
Comparator test	Clinician-sampled HPV tests: HPV DNA (HPV SPF10-LiPA25, version 1; Labo Bio-medical Products B.V., Rijswijk, Netherlands / GP5/6 primer-mediated PCR assay; Diassay, Rijswijk, Netherlands). **Sample collection:** The physician obtained a liquid-based cytology sample. **Sampling device and storage medium**: Cervexbrush in liquid (Rovers medical Devices B.V., Oss, Netherlands). ThinPrep medium (Hologic, Marlborough, MA, USA) or SurePath medium (Klinipath BV, Duiven, Netherlands).
Flow and timing	Time interval between index and comparator tests: consecutive
Outcomes	Agreement between self-sampled dry brush and physician-sampled liquid-based sample. **Detection of hrHPV positives, SPF10 PCR-DEIA-LiPA25 system** Physician-collected sample: 72/134 (54%) Dry brush self-collected sample: 71/134 (53%) **Detection of hrHPV positives, GP5+/6+-LQ** Physician-collected sample: 58/134 (43%) Dry brush self-collected sample: 56/134 (42%) **HPV detection agreement: Kappa (95% CI)** Clinician-collected sample vs self-collected sample, SPF10 PCR-DEIA-LiPA25: 0.691 (0.617-0.766) Clinician-collected sample vs self-collected sample, GP5+/6+-LQ: 0.725 (0.607–0.843)
Risk of bias	Unclear

Frågeställning 4

Kitchener 2009

Clinical setting and study design	**Design: Randomized control study** **Trial name:** ARTISTIC **Inclusion/exclusion:** not stated **Allocation:** All women had both cytology and HPV testing and were randomly assigned at a ratio of 3:1 to have the HPV result reported and acted on (revealed group) or concealed from the woman and her doctor (concealed group).
Patient characteristics	**Population**: Women aged 20 to 64 years **Sample size**: 24 510 eligible women at entry (18 386 in the revealed group), For 20 to 29 years in the revealed group, n=3879. **Setting**: Women attending after receiving a routine invitation for screening within the National Health Service Cervical Screening Programme (NHSCSP) were recruited in general practice and family-planning clinics in Greater Manchester.
Index and comparator tests	**Index test (self-collected sample):** Testing for high-risk HPV DNA was done according to manufacturer's instructions using the Digene Hybrid Capture 2 (HC2, Qiagen; Crawley, UK) test. **Comparator text (clinician collected sample):** Slides were prepared from LBC samples on a ThinPrep T3000 processor (Hologic; Crawley, UK). Cytolgy was reported using the classification of the British Society of Cervical Cytology.
Reference standard	**Histologically confirmed CIN2+:** Colposcopy was done for women with a single high-grade (moderate or severe) cytological abnormality. Women with a low-grade (borderline or mild) cytological abnormality were referred for colposcopy after two consecutives mild dyskaryosis or three consecutive borderline results. Biopsy samples were taken in the presence of an abnormality; random punch biopsy samples were not taken in cases of negative, satisfactory colposcopy. High-grade cytology required a biopsy, and if not a punch biopsy, a loop excision of the transformation zone was done.
Screening pathway	
Outcomes	Women aged 20–29 years (n=3879; 236 CIN2+) **Relative[1] sensitivity:** (% [95% CI]) Cytology with HPV triage of borderline lesions: 88.6% (83.8–92.3) HPV with cytology triage: 86.9 (81.9–90.9) **Relative1 specificity:** (% [95% CI])

	Cytology with HPV triage of borderline lesions: 86.9 (81.9–90.9) HPV with cytology triage: 87.9 (86.8–89.0) [1]From the revealed group, we have analysed different combinations of cytology and HPV testing in primary screening and triage with respect to their sensitivities and specificities (relative to the combined testing of the revealed group).
Risk of bias	Unclear
Notes	