

# CERVICAL CANCER SCREENING

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## 3. PARTICIPATION IN SCREENING FOR CERVICAL CANCER

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### 3.1 Negative and positive determinants of participation

Achieving high participation is an important element of any screening programme. There are many reasons why women do not use preventive services ([Table 3.1](#)). To capture this multidimensional causal pathway, the Social Determinants of Health Framework ([Solar & Irwin, 2010](#); [Fig. 3.1](#)) considers health outcomes to be the result of interactions between contextual and policy factors, structural factors related to women's socioeconomic conditions, and intermediate factors, which include determinants at the individual level and at the health system level (programme and provider levels). When analysing variables that are negatively or positively related to screening participation in a specific setting, it is important to understand the levels at which factors are operating and how they are interconnected.

#### 3.1.1 Health policy determinants

Contextual aspects, including education, employment, and social protection policies, act as modifiers or buffers that influence the effects of socioeconomic status on health outcomes and well-being in social groups ([Solar & Irwin, 2010](#)). An analysis of data from 15 low-income countries that participated in the 2003 World

Health Survey ([Akinyemiju, 2012](#)) found that a country's health expenditure (as a percentage of gross domestic product) was a significant determinant of participation in cervical cancer and breast cancer screening. This finding suggests that irrespective of individual and neighbourhood factors, investment in health infrastructure has the potential to significantly improve cancer screening rates within a country, for example through better equipment and trained personnel in hospitals.

In their analysis of the effect on cancer care outcomes of disruptions in health insurance coverage in the USA, [Yabroff et al. \(2020\)](#) highlighted how changes in broader policies can exacerbate disruptions in insurance coverage and can increase disparities. For example, the emergence of work requirements for some state Medicaid programmes may increase the prevalence of coverage disruptions. Also, broader employment trends, such as the increased prevalence of gig workers (independent contractors) and associated income fluctuations, may increase disruptions in coverage in a population that faces frequent changes in eligibility for subsidies and coverage affordability. In Mexico, the health-care reform implemented in 2003 to provide universal health coverage resulted in a substantial increase in cervical cancer screening coverage, from 30.0% in 2000 to 48.5% in 2012 ([Goss et al., 2013](#)). Competing health priorities

**Table 3.1 Positive and negative determinants of screening participation**

Positive determinants	Negative determinants
<i>Health policy determinants</i>	
Higher national health expenditure Investments in health infrastructure Universal health coverage	Lack of universal health coverage Fee-paid services
<i>Structural determinants</i>	
Higher socioeconomic status; gender equity (participation in household decisions) Higher levels of education Being employed Younger age Being married Longer time spent in destination country (for immigrants) Health insurance Urban residence	Low socioeconomic status; gender inequality (low control over household decisions; gender violence) Low education level Unemployment Older age Single relationship status Immigrant status; member of disadvantaged racial or ethnic group Lack of health insurance Rural residence Being transgender, non-binary, or lesbian
<i>Intermediate determinants at the individual level</i>	
Health literacy; cervical cancer knowledge; awareness of perceived benefits of screening Previous use of health-care or preventive services; engagement with health-care services; history of ever having had a gynaecological examination History of using contraception Being unconcerned with regard to the sex of the health-care provider Able to talk with family and/or friends about cervical screening; family support; childcare options	Lack of knowledge about cervical cancer; low self-assessed risk of cervical cancer Lack of recent contact with health-care services; long time elapsed since last screening or no history of cervical cancer screening No use of contraception Rejection of gynaecological examination by male health-care providers Lack of social support; lack of childcare Having experienced sexual assault Female genital mutilation Being incarcerated Having a disability Discomfort or previous negative experience with gynaecological examination; negative attitude towards cervical cancer screening Feelings of shame or embarrassment Fear of cancer
<i>Intermediate determinants at the health system level</i>	
Organized screening programmes Adequate availability and distribution of primary health-care and gynaecology services High adherence by health-care providers to programmatic guidelines and recommendations Good-quality services, with adequate infrastructure, supply provision, and trained health-care workforce Use of HPV self-sampling as screening strategy Screening, diagnosis, and/or treatment included as part of a health insurance package Use of screening information systems	Opportunistic screening Low availability of primary health-care or gynaecology centres Low adherence by health-care providers to programmatic guidelines and recommendations Lack of supplies and screening or treatment infrastructure; lack of trained health-care workforce Screening only through gynaecological examination Fee-paid services Lack of screening information systems

**Table 3.1 (continued)**

Positive determinants	Negative determinants
<i>Intermediate determinants at the health provider level</i>	
Encouragement from health-care providers to get screened Use of communication strategies and tools between health-care providers and women; navigation services Option to choose male or female health-care provider Women and health-care providers having the same social and cultural background; screening offered by community health workers	Lack of encouragement from health-care providers Screening services that do not meet women's needs (appointment days and hours, etc.); lack of communication or navigation strategies Male health-care provider only Lack of community health workers or promoters

HPV, human papillomavirus.

Table compiled by the Working Group.

and a lack of emphasis on preventive health have also been shown to be barriers to the implementation of effective population-based cervical cancer screening programmes in low- and middle-income countries (LMICs) ([Mandal & Basu, 2018](#)).

### 3.1.2 Structural determinants

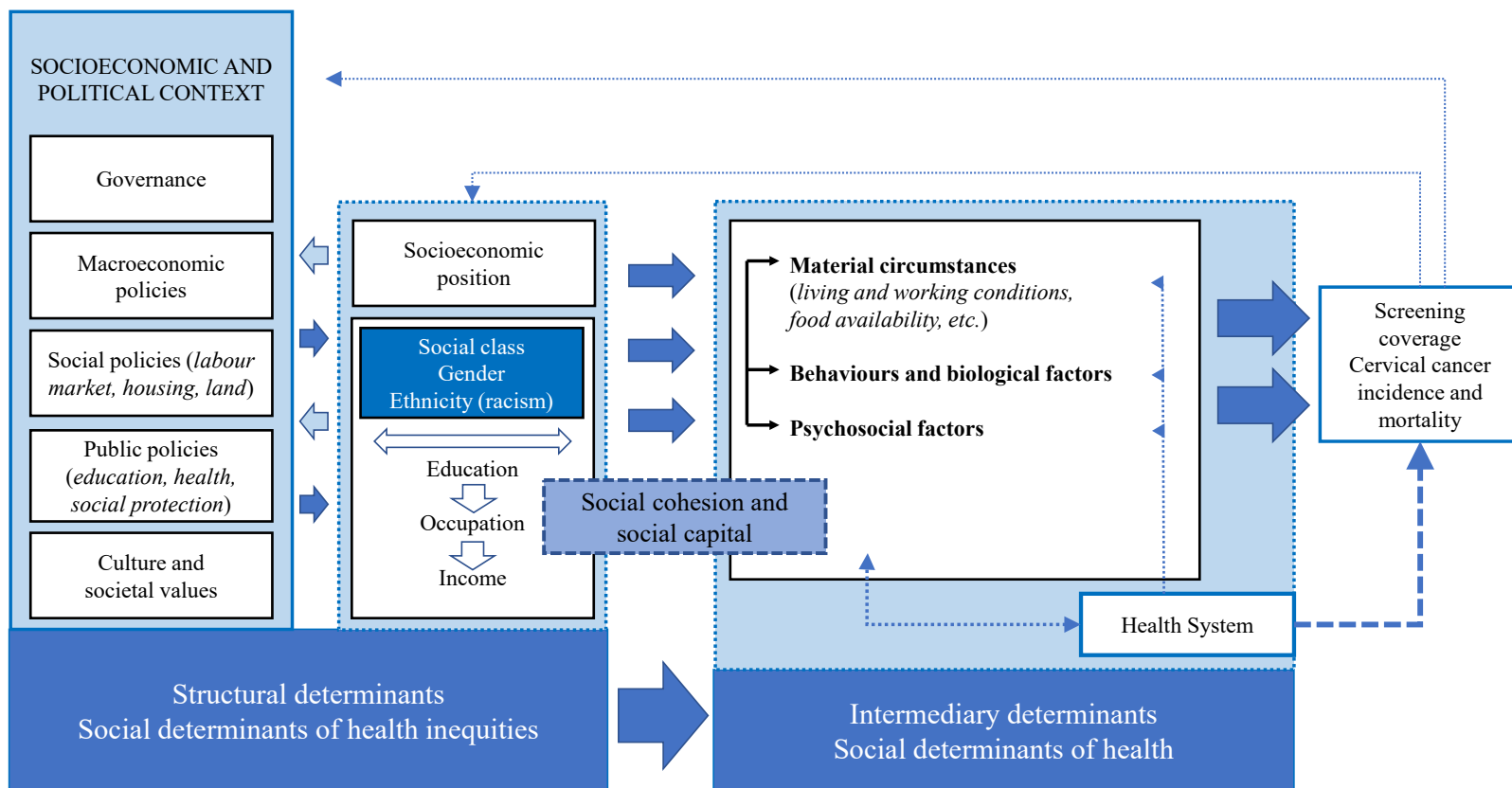
The main structural determinant of screening participation in women is social inequality ([Table 3.1](#)). Women with low socioeconomic status and education level, without health insurance, and with reduced access to health care tend to have lower rates of screening ([IARC, 2005](#)). These main determinants were also identified by reviews of studies in LMICs ([Williams-Brennan et al., 2012](#)) and specific to Latin America ([Nuche-Berenguer & Sakellariou, 2019](#)). Most of this evidence was produced in contexts in which cytology-based screening is the standard of care, but evidence from studies in which screening was carried out with human papillomavirus (HPV)-based testing or visual inspection with acetic acid (VIA)-based testing showed a similar impact of these structural socioeconomic inequalities ([Harder et al., 2018b](#); [Brandão et al., 2019](#)).

An analysis of data from World Health Surveys from 57 countries showed that only 31% of women in the poorest global wealth decile have ever had a pelvic examination, compared

with 91% of women in the richest global wealth decile. Effective cervical cancer screening (the proportion of eligible women who report that they have had a pelvic examination and Pap test in the previous 3 years) was 9% in the poorest decile and 64% in the richest decile ([Gakidou et al., 2008](#)). Being younger ([Barbadoro et al., 2015](#); [Giorgi Rossi et al., 2015](#); [Broberg et al., 2018](#); [Buehler et al., 2019](#)) and living in an urban area ([Akinyemiju, 2012](#)) have been reported to be important positive determinants of participation. Belonging to an ethnic minority group (an indicator of social inequity) ([Soneji & Fukui, 2013](#)) and being a migrant ([Harder et al., 2018a, b](#); [Adunlin et al., 2019](#); [Bacal et al., 2019](#)) have been reported to be negative determinants of participation.

There is much less empirical evidence about how gender inequality, such as the differential access of women to structural resources, power, authority, and control ([WHO, 2007](#)), affects access to screening services. An analysis of knowledge about cervical cancer and screening using the 2014 Kenya Demographic and Health Survey reported that women who face gender inequality (i.e. have no control over decision-making about their own health care and/or household money) and gendered norms on intimate partner violence were less likely to be knowledgeable about cervical cancer screening and to

**Fig. 3.1 Social Determinants of Health Framework**



undergo screening compared with women who did not face these challenges ([Kangmennaang et al., 2018](#)).

Sexual orientation is also a main determinant of participation; transgender men, lesbians, and non-binary people are less likely to be screened ([Connolly et al., 2020](#)). Potential barriers to routine cervical cancer screening for lesbians include the perception that they have a lower risk of cervical cancer, discrimination and homophobia in the health-care system, and a lack of awareness in health-care providers about the disease risk in this population ([Tracy et al., 2013](#)). Barriers to screening in transgender men ([Weyers et al., 2021](#)) include female-only waiting rooms, woman-centred and heteronormative patient education materials, the use of language that is not gender-neutral by health-care providers during the screening examination, and stigma and discrimination by health-care providers and insurance providers, which can lead to postponement of care.

### 3.1.3 *Intermediate determinants at the individual level*

Having had previous contacts with the health-care system is an important determinant of screening participation ([IARC, 2005](#); [Williams-Brennan et al., 2012](#)) through several mechanisms, one of which is increased health literacy. Knowledge and awareness about cervical cancer and the role of screening in disease prevention, as well as knowing another person who has already been screened, are positive determinants of participation ([IARC, 2005](#); [Nwobodo & Ba-Break, 2015](#); [Visanuyothin et al., 2015](#); [Idowu et al., 2016](#); [Bou-Orm et al., 2018](#)). Awareness of risk has also been shown to have an impact on a woman's decision to be screened ([Dhendup & Tshering, 2014](#); [Morema et al., 2014](#)).

“Lack of time” is a negative determinant of participation ([Szarewski et al., 2011](#); [Arrossi et al., 2016](#); [Restivo et al., 2018](#)). Gender inequality

may mean that women have to deal with work demands while having major responsibilities for domestic activities and childcare. In addition, socially disadvantaged women tend to have precarious jobs, without social protection or the flexibility to attend health services. In a study that analysed women's preference for HPV self-sampling in Argentina, the main reasons for choosing self-sampling at home were related to time saved; this method of screening does not interfere with a woman's family and domestic responsibilities, which prevent them from attending a health centre, and avoids barriers to accessing health services, such as a shortage of appointments and physician absenteeism ([Arrossi et al., 2016](#)). Furthermore, in low-income settings, where many women live in areas with poor public transportation and road infrastructure, the “lack of time” variable may reflect not only a woman's difficulty in finding the time to go to the health centre, but also greater difficulty accessing health services because of the barriers associated with the transportation infrastructure and non-responsive health services ([Osingada et al., 2015](#)).

Feelings of shame or embarrassment ([Szarewski et al., 2011](#); [Darlin et al., 2013](#); [Restivo et al., 2018](#)) have been reported to be barriers to screening in many different world regions and settings ([Chorley et al., 2017](#); [Lim & Ojo., 2017](#); [Liebermann, et al., 2018](#); [Marlow et al., 2019](#)), mainly linked to the gynaecological examination and stigma associated with being diagnosed with a reproductive health problem or with a disease that is perceived as being caused by poor hygiene or promiscuous behaviour. A systematic review summarized reported barriers that prevented women from using cervical cancer screening services in sub-Saharan Africa ([Lim & Ojo, 2017](#)); it found that women experienced stigmatization and embarrassment when accessing cervical screening services. The authors reported that because clinician-collected screening involves pelvic examination and may be combined with screening and treatment of a



reproductive or sexually transmitted infection, it can have a negative connotation for a woman. In a systematic review of qualitative literature about women's perceptions and experiences of cervical screening and a thematic analysis of barriers to cervical screening participation in organized programmes, some women perceived cervical cancer screening as a social threat, because a positive test result would cause anxiety and fear of stigma and could result in them being labelled as promiscuous ([Chorley et al., 2017](#)). Previous experiences of sexual assault or female genital mutilation have also been found to be barriers to participation ([Marques et al., 2020](#)).

Fear of cancer and anxiety are other key barriers to screening ([IARC, 2005](#); [Szarewski et al., 2011](#); [Williams-Brennan et al., 2012](#); [Arrossi et al., 2016](#); [Restivo et al., 2018](#)). [Liebermann et al. \(2018\)](#) pointed out that fear has several layers, including fear or perceived pain of the Pap procedure, fear of the results of the Pap test, and fear of cancer, which is seen as an incurable disease. Similarly, [Chorley et al. \(2017\)](#) found that fear and anxiety were linked to fear of cancer through anticipation of pain, suffering, and death, and to concerns in younger women about the impact on fertility. A study to measure the psychosocial impact of HPV testing in 163 HPV-positive women in Argentina reported that worries about cancer and associated treatment had the greatest negative psychosocial impact ([Arrossi et al., 2020](#)). Several studies in Latin America reported similar findings ([Smith et al., 2014](#); [León-Maldonado et al., 2016](#)). The quality of care and the information provided or omitted by physicians have also been shown to contribute to fear and anxiety ([Schoenberg et al., 2010](#)).

Encouragement and social support from a woman's family, friends, or spouse have been found to be positive determinants of participation ([Williams-Brennan et al., 2012](#)). Being in a partnership also increases the probability of being screened ([Williams-Brennan et al., 2012](#);

[Visanuyothin et al., 2015](#); [Hanske et al., 2016](#); [Bou-Orm et al., 2018](#); [Harder et al., 2018a](#)).

Little information is available about screening rates in women in prison; studies have shown both increased and decreased participation in this group of women ([Brousseau et al., 2019](#)). A study that analysed female prisoners' perceptions of screening ([Magee et al., 2005](#)) reported that uncomfortable examination was the main issue; this related to the use of inappropriately sized speculums and the rough manner of health-care providers. The prison infrastructure was also cited as problematic, because of a lack of privacy, poorly maintained facilities, no standard process for scheduling, long delays, inconsistency for costs to the inmate, and the lack of a method to report results.

Women with a disability underuse preventive cervical cancer screening services compared with the general population ([Ramjan et al., 2016](#)). These women not only have lower levels of health insurance, which affects their access to screening, but they also face health-care provider barriers, including physicians' attitudes, poor knowledge, misconceptions, and lack of understanding of the disability. Physical barriers are also an important problem for women with a disability, especially those related to access to health-care facilities and inadequate equipment, such as examination tables for Pap tests.

### *3.1.4 Intermediate determinants at the programme or service organization level*

Health system characteristics and the way screening programmes are organized are intermediate variables that can moderate the impact of social and gender inequalities; they are therefore major determinants of coverage. A systematic review describing the implementation of decentralized cervical cancer prevention services in rural Africa reported that health workforce shortages and lack of outreach were among the

most common supply-side barriers to cervical screening ([Rahman et al., 2019](#)). The availability and distribution of primary health-care and gynaecology services according to urban or rural settings and population density are also determinants of screening participation. A study of 3380 women in France, where universal health care is provided, showed that after individual characteristics were taken into account, women in settings with poor access to a gynaecologist had lower rates of screening participation ([Araujo et al., 2017](#)).

Another important set of considerations are the funding mechanisms for cervical cancer screening and treatment. Whether screening is included as part of a health insurance package or has to be paid for out-of-pocket is a significant determinant of screening participation. Lack of health insurance is an indicator of how health services are funded ([WHO, 2008](#)), and women who are not insured or who have disruptions in health insurance coverage are less likely to participate in screening ([Williams-Brennan et al., 2012](#); [Yabroff et al., 2020](#)). An analysis in Argentina found that providing the HPV test free of charge to women with no health insurance was a key factor for improved screening participation ([Arrossi et al., 2017](#)).

How screening programmes are set up (organized vs opportunistic screening) is another important consideration. An organized screening programme implies that there is an active strategy to reach out to all women defined as eligible in a population at a defined frequency, and that a prioritized programme is in place with adequate funding, a system to ensure follow-up and treatment, an information and monitoring system and quality assurance procedures, and mechanisms to ensure compliance with norms and regulations by health-care providers and institutions. In general, opportunistic screening tends to increase health and social inequalities, whereas organized programmes with active invitation procedures tend to increase access for

socially disadvantaged women ([Palència et al., 2010](#)). The use of screening information systems also facilitates screening participation at the health system level ([Arrossi et al., 2015a](#)).

### *3.1.5 Intermediate determinants at the health provider level*

Good-quality service delivery and good patient-provider relationships and communication are important facilitators of screening. Studies have shown that women are more likely to participate in screening if they have a good relationship with their health-care provider, they feel they are treated well, and they receive adequate information and responses to their questions ([IARC, 2005](#); [Darlin et al., 2013](#); [Restivo et al., 2018](#)). The use of counselling strategies to provide women with information about the screening and treatment process is also a facilitator of screening ([León-Maldonado et al., 2014](#)). In contrast, previous negative experiences with gynaecological examinations and health service delivery are barriers to screening ([Szarewski et al., 2011](#); [Darlin et al., 2013](#)).

Factors related to the way in which health-care services are organized have also been found to affect screening participation. Systems for booking appointments, appointment hours and days, and waiting times can be barriers or facilitators, depending on whether health-care delivery is organized to respond to the needs of women ([Nwobodo & Ba-Break, 2015](#); [Visanuyothin et al., 2015](#); [Restivo et al., 2018](#); [Ryan et al., 2019](#)). In a qualitative study of 3049 women in Jujuy, Argentina, the main reasons for choosing HPV self-sampling for cervical cancer screening were related to health-care organization challenges, such as a shortage of appointments and physician absenteeism ([Arrossi et al., 2016](#)). Other determinants of screening include the high turnover of trained professionals ([Rahman et al., 2019](#)), adherence by health-care providers to programme guidelines



and recommendations ([Arrossi et al., 2010](#)), and the socioeconomic level of the area in which the health-care provider office is situated ([Serman et al., 2020](#)). A significant negative determinant of screening participation at the health-care provider level in low-resource settings is the lack of supplies or infrastructure needed for screening or treatment ([Rahman et al., 2019](#)). This includes the lack of anaesthesia to provide treatment, the lack of reliable electricity, and difficulties in travelling to rural locations.

Screening performed by male health-care providers is a major barrier to screening participation in a variety of settings and countries ([IARC, 2005](#); [Dhendup & Tshering, 2014](#)); in contrast, screening provided by health-care workers of the same social and cultural background as their patients acts as a positive determinant ([Arrossi et al., 2015a](#); [Thompson et al., 2017](#); [Kobetz et al., 2018](#)).

The screening technology used is an important component of the health system dimension; whether cytology-based screening, HPV testing, or VIA is used will affect women's participation in preventive and treatment services. The effect of the use of HPV self-sampling kits on screening participation rates is discussed in Section 3.2.2.

### 3.1.6 Informed decision-making

An informed choice is one that is based on relevant knowledge, that is consistent with the decision-maker's values, and that is implemented behaviourally ([Marlow & Waller, 2014](#)). Informed choices give patients the opportunity to receive their preferred health-care options by choosing from among specified alternatives ([McCaffery et al., 2011](#)). In 2006, the International Patient Decision Aid Standards Collaboration established a checklist of quality criteria for decision aids, which includes categories focusing on essential content (providing balanced information, presenting probabilities, clarifying values, and guiding deliberation and communication),

development (systematic methods, balanced presentation, up-to-date and transparent evidence, and plain language), and evaluation (informed and values-based decisions) ([Elwyn et al., 2006](#)). Two studies in Australia showed that when women were offered evidence-based information, they selected a course of management appropriate to their practical, health, or psychological circumstances ([McCaffery et al., 2008, 2011](#)).

However, in spite of the importance of providing women with information so they can make an informed choice about whether to be screened, little evidence exists about how this affects participation in screening, especially in LMICs. A study in Norway evaluated whether women's stated intention to participate in screening and pursue treatment changed when additional information on screening-related harms was provided; it was found that additional information did not significantly alter women's stated intentions to screen ([Iyer et al., 2019](#)). A study in Australia found that a large proportion of women preferred to be involved in decision-making for both routine Pap tests (87%) and follow-up for abnormal results (89%). Most women wanted information on screening benefits (77%) and risks (70%); of these, 85% wanted this information before screening ([Dieng et al., 2013](#)). [Kim et al. \(2017\)](#) analysed how Korean immigrant women living in the USA made decisions about Pap tests according to three prototypes of shared decision-making in medical encounters: (i) a hierarchical model, in which the decision is made by health-care providers; (ii) an informed model, in which the decision is made by patients after reviewing alternative options; and (iii) a shared decision-making model, in which the decision is made collaboratively by health-care providers and patients on the basis of shared information. They found that for most women in the study, their preferred roles in decision-making were autonomous, but that for some they were hierarchical, collaborative (with the

physician for some participants and with their spouse for others), and peer-influenced. Barriers to informed decision-making are low education level, lack of knowledge, and differences between women and health-care providers in culture, social values, and language ([Suurmond & Seeleman, 2006](#)).

## 3.2 Interventions to increase screening participation

Cytology-based screening has been the standard of care for more than 70 years (see Section 4.3.1), but achieving high coverage is a challenge, especially in women of low socioeconomic status and/or in low-resource settings. One issue is that Pap tests are done through a gynaecological examination by health-care providers. This is also the case for VIA, which is proposed for settings where the development of cytology-based screening programmes is hampered by a lack of resources ([WHO, 2013](#)). The development of HPV testing has changed the scenario, because self-collection of samples for HPV testing has the potential to reduce barriers to access and increase screening participation. This section provides separate analyses of strategies to increase participation of women in cytology-based screening (Pap tests with clinician-collected samples) ([Table 3.2](#)) and strategies to increase participation of women in screening using HPV self-sampling ([Table 3.3](#)).

### 3.2.1 Interventions to increase participation in cytology-based screening

The 2005 *IARC Handbook* ([IARC, 2005](#)) reported that invitation strategies based on telephone invitations, person-to-person approaches, community campaigns, and educational interventions were effective in increasing participation in screening, depending on the context and settings. A review of studies published since 2005 is presented in the following sections.

#### (a) Invitation strategies

Based on a systematic review ([Musa et al., 2017](#)), measures such as invitation letters (with or without a follow-up telephone contact), making appointments, and sending reminders to patients who are due or overdue for screening all have a significant effect on improving participation and cervical cancer screening rates in populations at risk. An earlier meta-analysis of 12 randomized controlled trials (RCTs) of interventions to increase participation or informed participation in cervical cancer screening, which included 99 651 participants, found that screening participation in women who received invitation letters to attend cervical screening was significantly higher than that in women who received usual care or no invitation (relative risk [RR], 1.44; 95% confidence interval [CI], 1.24–1.52) ([Everett et al., 2011](#)).

The evidence from selected cytology-based RCTs using invitation strategies carried out in the general population since 2005 is presented in [Table 3.2](#). Studies were conducted in Europe ( $n = 5$ ), Asia ( $n = 2$ ), Australia ( $n = 2$ ), Africa ( $n = 1$ ), and the USA ( $n = 1$ ). Study participants were mainly adult women, most often non-respondents in organized screening programmes (studies in Australia, Denmark, and Sweden) or women from population groups with low screening participation in settings where screening is opportunistic.

The formats of the invitations are very varied. Invitations may be extended through telephone calls ([Dietrich et al., 2006](#)), mailed letters with or without leaflets or telephone call reminders ([Morrell et al., 2005](#); [Chumworathayi et al., 2007](#); [de Jonge et al., 2008](#); [Jensen et al., 2009](#); [Mullins, 2009](#); [Rashid et al., 2013](#); [Radde et al., 2016](#); [Acera et al., 2017](#)), emails ([Adonis et al., 2017](#)), or text messages ([Rashid et al., 2013](#); [Firmino-Machado et al., 2018](#)). Even with the same strategy (e.g. an invitation by letter), it is not possible to control for all the variables that may have an influence on

**Table 3.2 Studies on strategies to increase participation of women in cytology-based screening**

Reference Country or territory	Study type Intervention	Control group	Key outcomes
<i>Invitation strategies</i>			
<a href="#">Morrell et al. (2005)</a> Australia	RCT Reminder letter to have a Pap test	No letter	Pap test rates in the intervention group were significantly higher than those in the control group (HR, 1.54; 95% CI, 1.43–1.67)
<a href="#">Dietrich et al. (2006)</a> USA	RCT Telephone calls from prevention care managers to address screening barriers and assist with booking appointments, communicating with clinicians, and ensuring women had transportation to their appointments	Preventive health education guide + one telephone call to answer their questions and direct them to their primary care clinician for preventive care	7% (95% CI, 3–11%) increase from baseline for the intervention group. No significant change in the control group
<a href="#">Chumworathayi et al. (2007)</a> Thailand	Quasi-RCT Appointment invitation letter offering dates for Pap testing in the near future	Baseline interviews in their homes + health education	At follow-up, 44.7% of women in the intervention group and 25.9% of women in the control group had been screened ( $P = 0.001$ )
<a href="#">de Jonge et al. (2008)</a> Belgium	Quasi-RCT Invitation letter for cervical cancer screening	No invitation letter	6.4% (95% CI, 5.9–6.9%) increase in the proportion of women reporting for Pap testing, compared with the control group
<a href="#">Jensen et al. (2009)</a> Denmark	Cluster RCT Normal invitation plus targeted letter signed by their GP plus GP intervention: GPs were visited by a facilitator who identified avenues for quality improvement related to cervical cancer screening and offered help with sending screening reminders to patients	Usual care. Women received a normal invitation letter that is sent to all women every 3 yr	Overall, women in the intervention group were 1.17 (95% CI, 1.04–1.30) times as likely to report for Pap testing during the study period as those in the control group
<a href="#">Mullins (2009)</a> Australia	RCT Group 1: A targeted reminder letter, focusing on the heightened risks of cervical cancer later in life and the importance of continuing Pap test screening until age 70 yr Group 2: A general reminder letter, including general information about the importance of Pap test screening, but with no mention of specifics related to Pap test screening later in life	No letter	After 11 wk, 4.3% (95% CI, 3.7–4.9%) of women in the targeted letter group, 4.7% (95% CI, 4.1–5.3%) of women in the general letter group, and 1.6% (95% CI, 1.2–1.9%) of women in the control group had reported for Pap testing

**Table 3.2 (continued)**

Reference Country or territory	Study type Intervention	Control group	Key outcomes
<a href="#">Rashid et al. (2013)</a> Malaysia	RCT 4-arm intervention: Group 1: Invitation letter Group 2: Registered letter Group 3: Text message Group 4: Telephone call In all 4 groups, women received the same information: that they would have to attend for a repeat Pap test within 1 mo from the date the letter was received	Not available	The participation rates of Pap testing in women who received recall by letter, registered letter, text message, and telephone call were 23.86%, 23.04%, 32.93%, and 50.89%, respectively Compared with women who received the standard letter, those who received the invitation through a telephone call were more likely to attend for a repeat Pap test (OR, 2.38; 95% CI, 1.56–3.62)
<a href="#">Radde et al. (2016)</a> Germany	Randomized population-based cohort study Group A: Invitation letter Group B: Invitation letter and information brochure	No invitation	The cervical cancer screening participation rate was 91.8% in the intervention groups, compared with 85.3% in the control group ( $P < 0.001$ ), with a 6.6% increase in participation and an adjusted OR of 2.69 (95% CI, 2.15–3.37). There was no significant difference between intervention groups A and B
<a href="#">Acera et al. (2017)</a> Spain	Community-based RCT Group 1: Personalized invitation letter Group 2: Personalized invitation letter and informative leaflet Group 3: Personalized invitation letter + informative leaflet + personalized telephone call	Spontaneous request for cervical cancer screening	Screening participation attributed to the intervention was 18.6%, 17.4%, and 23.0% in groups 1, 2, and 3, respectively. The total increase in participation was 20% in the 3 intervention groups combined and 9.1% in the control group ( $P < 0.001$ ) Participation was significantly higher in intervention group 3 (84.4%) than in the other intervention groups ( $P < 0.001$ )

**Table 3.2 (continued)**

Reference Country or territory	Study type Intervention	Control group	Key outcomes
<a href="#">Adonis et al. (2017)</a> South Africa	Prospective longitudinal RCT Group 1 (loss-framed): Email messages highlighting the risk of cervical cancer and the danger associated with not participating in Pap test screening Group 2 (gain-framed): Email messages highlighting the health-promoting role of routine Pap test screening and that this is a way to ensure good long-term health outcomes Group 3 (neutral message): Email message outlining Pap test screening recommendation In the 3 groups, messages were accompanied by encouragement to contact their medical practitioner to discuss Pap test screening	Not available	No statistically significant differences were found in the Pap test screening participation rates between the 3 groups
<a href="#">Firmino-Machado et al. (2018)</a> Portugal	RCT Two-arm intervention: Invitation through automated or customized text messages and telephone calls, followed by text message reminders of the appointments Participants were randomly assigned to two models of invitation, used both in text messages and in automated telephone calls: (i) neutral – formal writing to inform women that a screening appointment was scheduled (standard communication style in primary care); (ii) positive – motivational communication style	Letter of invitation	39.0% of women in the intervention group were screened vs 25.7% in the control group ( $P < 0.001$ )
<i>Educational interventions</i>			
<a href="#">Mock et al. (2007)</a> USA	RCT Lay health worker outreach plus media education campaign consisting of Vietnamese-language television, radio, and newspaper advertisement announcements about cervical cancer and Pap test screening. In addition, booklets, reminder cards, posters, and calendars with messaging about Pap test screening were distributed at strategic points in the community	Media education campaign	At baseline, 65.8% of women in the intervention group reported having had at least one Pap test. After the study period, this increased to 81.8%, an increase of 16.0% ( $P < 0.001$ ). In the control group, the percentage of women ever screened increased by 5.4% ( $P < 0.001$ )



Table 3.2 (continued)

Reference Country or territory	Study type Intervention	Control group	Key outcomes
<a href="#">Hiatt et al. (2008)</a> USA	Quasi-experimental controlled trial Outreach strategy to educate participants in small groups and one-on-one settings using lay health workers	Inreach strategies included updates for providers on screening guidelines, the use of patient models to improve skills in breast and pelvic examination, and the institution of computer reminders	Reports of Pap test in the previous 3 yr did not differ significantly in pre-test and post-test surveys
<a href="#">Mishra et al. (2009)</a> American Samoa	RCT An educational programme comprising a cervical cancer education booklet, skill-building and behavioural exercises, and group discussion sessions. The content was culturally tailored and focused on the community's role in addressing cervical cancer. Women received a US\$ 5 payment for each educational session they attended	Opportunistic screening	Women in the intervention group were found to be twice as likely to report for screening (OR, 2.0; 95% CI, 1.3–3.2)
<a href="#">Taylor et al. (2010)</a> USA	RCT Lay health workers (who were bilingual Vietnamese women) attempted to visit the homes of participants to share with them a culturally tailored educational DVD and pamphlet that had information about cervical cancer and screening. They also used visual aids in the home visit to highlight the importance of screening. Lay health workers also provided follow-up calls 1 mo after their visit. If women could not be contacted at home or did not permit home visits, they were sent the DVD and pamphlet	Participants received mailed educational material about physical activity and a pedometer	Ever-screened women in the intervention group were significantly more likely to report Pap testing ( $P < 0.2$ ) than were ever-screened women in the control group (31% vs 13%; OR, 3.15; 95% CI, 1.20–8.27) There were no significant differences between the groups for women who had never been screened
<a href="#">O'Brien et al. (2010)</a> USA	RCT Cervical cancer educational intervention led by community health workers ( <i>promotoras</i> ). Women participated in two 3-h group sessions led by <i>promotoras</i> that focused on cervical cancer and screening. Participants were also given relevant reading materials	Usual care (unspecified)	The Pap test participation rate was higher in the intervention group than in the control group (71% vs 22%; $P = 0.004$ )

**Table 3.2 (continued)**

Reference Country or territory	Study type Intervention	Control group	Key outcomes
<a href="#">Nuño et al. (2011)</a> USA	RCT A <i>promotora</i> -led educational intervention consisting of a 2-h group session focused on addressing common gaps in knowledge relating to breast and cervical cancer. Women were invited to attend an initial class and were also invited to attend a refresher class 1 yr later if they wished	Usual care. Women received a mailed reminder and a telephone call about breast and cervical cancer screening	Women in the intervention group were more likely to report having had a Pap test within the past 2 yr (OR, 2.8; 95% CI, 1.3–6.0). No significant differences were reported for having had a Pap test within the past 1 yr
<a href="#">Paskett et al. (2011)</a> USA	RCT Women received 2 in-person home visits, 2 telephone calls, and 4 postcards from lay health advisors to educate them about cervical cancer, Pap test screening, and treatment, to provide individualized counselling, and to remind women to report for screening	Usual care. Women received a brochure and a letter from their physician	More women in the intervention group had had a Pap test by the end of the study compared with those randomized to usual care (51.1% vs 42.0%; OR, 1.44; 95% CI, 0.89–2.33). Self-report results were more pronounced (71.3% vs 54.2%; OR, 2.10; 95% CI, 1.22–3.61)
<a href="#">Byrd et al. (2013)</a> USA	RCT Individual delivery of the AMIGAS programme consisted of a video novella and flip chart to inform women about barriers and facilitators to cervical cancer screening. Games and activities were also used, and <i>promotoras</i> were used to gauge women's interest in being screened and to help them move towards screening in a culturally tailored manner Three versions of the AMIGAS programme were tested: (i) the entire programme as described above, (ii) the programme without the video, and (iii) the programme without the flip chart	Usual care. No <i>promotora</i> education, but women might have been exposed to some education in clinics or in the media	52.3% of those in the full AMIGAS programme group and 24.8% of those in the control group reported being screened ( $P < 0.0001$ ). There was no statistically significant difference in screening participation among the 3 intervention groups
<a href="#">Abiodun et al. (2014)</a> Nigeria	Quasi-RCT Group health education on cervical cancer and screening (didactic lectures, movie, and participatory discussions)	Education on breast cancer and screening	The proportion of women who had undergone cervical screening increased from 4.3% to 8.3% ( $P = 0.038$ )
<a href="#">Dehdari et al. (2014)</a> Islamic Republic of Iran	Quasi-RCT Weekly 60-min educational sessions provided to women in small groups for 4 wk	Usual care	Participation in screening increased from 0% to 61.9% in the intervention group vs from 0% to 10% in the control group ( $P < 0.05$ ) 3 mo after intervention

**Table 3.2 (continued)**

Reference Country or territory	Study type Intervention	Control group	Key outcomes
<a href="#">Braun et al. (2015)</a> USA	RCT Navigation services including outreach, education, making appointments, sending reminders, providing transportation to appointments, communicating with providers, and completing paperwork	Nutrition education and relevant cancer education materials from another health-care entity	57.0% of women in the intervention group and 36.4% of women in the control group had had a Pap test in the past 24 mo ( $P = 0.001$ )
<a href="#">Thompson et al. (2017)</a> USA	RCT Group 1 (low-intensity): Participants were mailed a culturally appropriate, Spanish-language video about cervical cancer screening and how to access screening in their area Group 2 (high-intensity): Participants were visited at home by a <i>promotora</i> who showed them the education video, informed them of resources to reduce barriers to screening, answered questions, and helped them to make an appointment	Usual care. Participants had access to information about cervical cancer and Pap testing available from their health centre	7 mo after randomization, significantly more women in the high-intensity intervention group had had a Pap test (53.4%) than women in the low-intensity group (38.7%; $P < 0.001$ ) and the control group (34.0%; $P < 0.01$ ) The difference in participation between the control group and the low-intensity group was not significant ( $P = 0.40$ )

CI, confidence interval; GP, general practitioner; h, hour or hours; HR, hazard ratio; min, minute or minutes; mo, month or months; OR, odds ratio; RCT, randomized controlled trial; vs, versus; wk, week or weeks; yr, year or years.

women's participation, such as the style and tone of the letter, the actual service being offered, and who signs the letter. It is important to be aware that similar strategies can differ in ways that might affect participation, including the broader health and social policy environment, the health organization characteristics, and the specifics of the intervention. For example, in a cluster RCT in Denmark ([Jensen et al., 2009](#)), women in the intervention group received the usual invitation letter to the screening programme as well as a more targeted letter signed by their general practitioner (GP); this contributed to an increase in screening participation in the intervention group compared with the group who received only the usual invitation letter as standard of care (odds ratio [OR], 1.17; 95% CI, 1.04–1.30). In addition, the GPs of the women in the intervention group were visited by a facilitator who identified avenues for quality improvement and offered help with sending screening reminders to patients.

All the invitation strategies presented in [Table 3.2](#) were found to increase screening participation in the intervention groups compared with the control groups, with the exception of the strategies used in the study by [Adonis et al. \(2017\)](#) in South Africa. Two studies evaluated the effect of using text messages to increase screening participation, with contradictory findings ([Rashid et al., 2013](#); [Firmino-Machado et al., 2018](#)).

#### (b) Educational interventions

A meta-analysis of five RCTs in 1609 women evaluated the effect of educational interventions on participation in cervical cancer screening ([Musa et al., 2017](#)); it found that the use of theory-based educational interventions resulted in a more than 2-fold (OR, 2.46; 95% CI, 1.88–3.21) increase in screening participation in women who received cervical cancer education compared with women in the comparison group. Similarly, a systematic review of 17 RCTs and non-randomized studies ([Agide et al., 2018](#)) concluded that

health education interventions were effective in increasing participation rates after implementation, although the effectiveness varied with study setting, population characteristics, and mode of delivery.

[Table 3.2](#) summarizes 12 RCTs that have evaluated the effect of educational interventions on cervical screening participation in non-attenders published since 2005 and conducted in the USA ( $n = 9$ ), American Samoa ( $n = 1$ ), the Islamic Republic of Iran ( $n = 1$ ), and Nigeria ( $n = 1$ ). Most studies reported an increase in screening participation in the intervention group compared with the control group, despite a wide variation in the educational modality evaluated: lay health worker outreach plus media education campaign ([Mock et al., 2007](#)), lay health worker outreach plus different forms of audiovisual support ([Taylor et al., 2010](#); [Byrd et al., 2013](#); [Thompson et al., 2017](#)), home visits by lay health workers plus invitation letters and postcards ([Paskett et al., 2011](#)), group education in different settings ([Hiatt et al., 2008](#); [Mishra et al., 2009](#); [O'Brien et al., 2010](#); [Nuño et al., 2011](#); [Abiodun et al., 2014](#); [Dehdari et al., 2014](#)), and help with navigating the health service, including outreach, education, making appointments, sending reminders, providing transportation to appointments, communicating with health-care providers, and completing paperwork on services ([Braun et al., 2015](#)).

Only one study ([Hiatt et al., 2008](#)), which was conducted in multiethnic, underserved women in the San Francisco Bay Area, reported no difference in screening participation between the intervention group (which used an outreach strategy in which racially and ethnically diverse lay health workers were used to engage women) and the control group. [The authors noted that the high baseline screening participation of these women (> 85%) may have contributed to the difficulty of assessing the value of the intervention.]

(c) *Strategies targeting health-care providers*

Evidence presented in the 2005 *IARC Handbook* ([IARC, 2005](#)) was inconclusive with regard to the effect of strategies targeting health-care providers. An update of the evidence from studies in high-income countries published by the Community Preventive Services Task Force in the USA ([Sabatino et al., 2012](#)) concluded that there was sufficient evidence that provider assessment (evaluating provider performance in offering and/or delivering screening to clients) and feedback (presenting health-care providers with information about their performance in providing screening services) were effective in increasing cervical screening participation, and that there was insufficient evidence to determine the effectiveness of provider incentives in increasing cervical screening participation.

3.2.2 *Interventions to increase participation in screening by HPV testing*

This section summarizes evidence from studies that have evaluated participation in screening using self-collection of samples for HPV testing compared with Pap testing or with VIA. In addition, evidence is summarized from studies comparing screening participation in women with self-collected samples versus clinician-collected samples for HPV DNA-based testing.

(a) *Self-collection of samples for HPV testing versus cytology-based screening*

[Table 3.3](#) lists 28 studies that have evaluated the effect of using HPV self-sampling versus cytology-based screening as a strategy to increase participation in women who do not attend screening. These studies were carried out in Europe ( $n = 21$ ), the USA ( $n = 3$ ), Canada ( $n = 2$ ), Australia ( $n = 1$ ), and Mexico ( $n = 1$ ). Most of the studies analysed the effect of mailing an invitation to use self-sampling (using opt-in or opt-out strategies), accompanied by different

educational materials and support activities that were part of the invitation strategy. [Therefore, it cannot be ruled out that any positive effect on screening participation reported in those studies could be due in part to the effect of the accompanying materials.]

(i) *Opt-in strategies*

Under opt-in strategies, women request a self-sampling kit through some mechanism (a letter, a telephone call, or by picking it up at a specific location).

In a meta-analysis of 25 RCTs aiming to determine whether offering self-sampling kits to underscreened women generated higher participation rates compared with invitation or reminder letters, [Arbyn et al. \(2018\)](#) found that opt-in strategies in which women had to request a self-sampling kit were not more effective than invitation letters (relative participation, 1.22; 95% CI, 0.93–1.61). A separate meta-analysis by [Yeh et al. \(2019\)](#) similarly reported a non-significant increase in screening participation in women who requested an HPV self-sampling kit compared with women in the control group (cervical screening by cytology, VIA testing services, or clinician-collected primary HPV testing) (RR, 1.28; 95% CI, 0.90–1.82).

Seven of the studies included in [Table 3.3](#) evaluated the opt-in option ([Giorgi Rossi et al., 2011, 2015](#); [Broberg et al., 2014](#); [Ivanus et al., 2018](#); [Kellen et al., 2018](#); [Kitchener et al., 2018](#); [Tranberg et al., 2018](#)), and four of them showed increased screening participation in the intervention group compared with the control group. One study in Sweden found that an opt-in self-sampling strategy was more effective than the standard invitation protocol in increasing participation in women who do not attend screening, in the context of a national population-based screening programme, but only after a reminder was sent ([Broberg et al., 2014](#)) (RR, 2.32; 95% CI, 2.00–2.70). In the study by [Kellen et al. \(2018\)](#), women in the intervention group had the choice



**Table 3.3 Studies on interventions to increase participation of women in screening using HPV self-sampling (2005–present)**

Reference Country	Study type Intervention	Control group	Outcomes
<i>Compared with cytology-based screening</i>			
<a href="#">Bais et al. (2007)</a> Netherlands	RCT An HPV self-sampling kit was mailed with written and illustrated instructions for use and a return envelope A telephone line for women who had questions about HPV and cervical cancer was made available to all women throughout the study	Women received a recall letter, inviting them for conventional cytology	Total screening participation in the intervention group was 34.2%. Screening participation in the control group was 17.6%. Participation in the intervention group was significantly higher ( $P < 0.001$ )
<a href="#">Gök et al. (2010)</a> Netherlands	RCT Women received a cervicovaginal material collection kit	Women received a reminder to report for conventional cytology	The participation rate in the self-sampling group was significantly higher than that in the control group (crude, 26.6% vs 16.4%; $P < 0.001$ ; adjusted, 27.5% vs 16.6%; $P < 0.001$ ); 10.9% difference (95% CI, 6.5–15.3%; $P < 0.001$ )
<a href="#">Giorgi Rossi et al. (2011)</a> Italy	RCT (4 arms) Group 1: Women were offered the option of an HPV self-sampling kit (the sample to be sent back by mail or delivered to a clinic). The women had to call a toll-free telephone number to opt in Group 2: An HPV self-sampling kit was directly mailed to women. The package included an instruction package, background information on HPV and cervical cancer, the self-sampling device, and a prepaid pack to send the sample back	Invitation letter to (a) a Pap test or (b) an HPV test at a clinic	Inviting women through the standard recall letter had the same participation rate in both control groups (13.9% in Pap test group and 14.9% in HPV test group) Compared with standard recall (Pap test), intervention 2 increased participation (RR, 1.41; 95% CI, 1.10–1.82), but intervention 1 decreased participation (RR, 0.62; 95% CI, 0.45–0.86)
<a href="#">Lazcano-Ponce et al. (2011)</a> Mexico	RCT HPV DNA self-sampling at home. Nurses visited women at home to provide them with HPV self-sampling kits and give instructions on how to use them. Women who could not be reached at home were reassigned to the cytology group	Referral to local clinic for Pap test	98% of women in the self-sampling group were screened vs 87% who attended a clinic for a Pap test ( $P = 0.001$ )
<a href="#">Virtanen et al. (2011)</a> Finland	RCT Women were sent an HPV self-sampling kit, instructions, a brochure about HPV and cervical cancer, and a questionnaire. An information letter was sent to all women in this group a few weeks before the kits were sent	Women were sent a new letter inviting them for cervical screening as well as a brochure about HPV and cervical cancer	31.5% of women in the intervention group were screened vs 25.9% in the control group. Adjusted RR, 1.21 (95% CI, 1.13–1.30)

Table 3.3 (continued)

Reference Country	Study type Intervention	Control group	Outcomes
<a href="#">Wikström et al. (2011)</a> Sweden	RCT Women were sent an information letter, followed a few days later by an HPV self-sampling kit, instructions for use, and a prepaid return envelope. This was provided free of charge. Women were given a reminder if they did not respond	Standard recall. Women were invited again for Pap test screening as part of the existing Pap test screening regime. These women had to pay 100 SEK (~€10) for the Pap test	39% of women in the intervention group were screened vs 9% in the control group ( $P < 0.001$ )
<a href="#">Piana et al. (2011)</a> France	RCT Women were sent an information letter, followed 1 mo later by an HPV self-sampling kit (if they did not opt out), instructions for use, and a prepaid return envelope	Second invitation to cytology-based screening	Response to the second invitation to Pap testing was significantly lower (7.2%) than response to the self-sampling kit (26.4%) ( $P < 0.001$ )
<a href="#">Szarewski et al. (2011)</a> England	RCT Women were sent a package with a contact letter, an information leaflet on HPV, an HPV self-sampling kit with instructions for use, and a prepaid return envelope	Standard recall. Women were sent a normal letter from their primary care trust inviting them for cervical cytology	Participation was 10.2% in the intervention group vs 4.5% in the control group ( $P < 0.0001$ )
<a href="#">Darlin et al. (2013)</a> Sweden	RCT Women were sent an HPV self-sampling kit with instructions for use, a questionnaire, and a prepaid return envelope. If a woman did not respond within 1 mo, a second complete kit was sent	Flexible no-fee cytology screening appointments. If women did not respond, a second letter was sent with additional possible appointment times	In the intervention group, 14.7% of women returned a self-collected sample. In the control group, 4.2% were screened ( $P < 0.0001$ )
<a href="#">Sancho-Garnier et al. (2013)</a> France	RCT Women were sent an initial letter outlining information about HPV and cervical cancer and explaining that an HPV self-sampling kit would soon be sent. The kit included the self-sampling device, instructions with illustrations, and a prepaid return envelope	Invitation for Pap test. Women were sent an invitation for Pap testing with a list of centres that perform screening	18.3% of women in the intervention group were screened vs 2.0% of women in the control group ( $P < 0.001$ )
<a href="#">Broberg et al. (2014)</a> Sweden	RCT Group 1: Women were sent a letter inviting them to order an HPV self-sampling kit. The letter included information about HPV and screening. The women were also told the test kit would cost them €11. Those who agreed were sent a self-sampling kit and prepaid return envelope. Those who ordered a kit and did not return it were sent a reminder Group 2: Telephone contact by midwives, offering women appointments for Pap testing	Standard care. Women received annual invitations for Pap test screening	Participation was 24.5% in the HPV self-sampling group vs 18.0% in the telephone contact group vs 10.6% in the control group. RR compared with control group, 2.32 (95% CI, 2.00–2.70) and compared with telephone contact group, 1.36 (95% CI, 1.19–1.57)

**Table 3.3 (continued)**

Reference Country	Study type Intervention	Control group	Outcomes
<a href="#">Haguenoer et al. (2014)</a> France	RCT Group 1: Women were sent an HPV self-sampling kit, an invitation letter to provide a specimen, an information leaflet, a questionnaire, and a prepaid return envelope Group 2: Women were sent a recall letter, inviting them for Pap testing	No intervention	22.5% of women in the self-sampling group, 11.7% in the recall letter group, and 9.9% in the control group were screened. Participation in the self-sampling group was significantly higher compared with both the recall letter group (OR, 2.20; 95% CI, 1.85–2.62) and the control group (OR, 2.64; 95% CI, 2.21–3.17). There was no significant difference between the recall and control groups (OR, 1.20; 95% CI, 0.98–1.47)
<a href="#">Sewali et al. (2015)</a> USA	Pilot RCT Women were given an HPV self-sampling kit during information sessions, along with instructions that were translated and tailored for the Somali community. Participants were given a telephone number to call with questions they may have had related to self-sampling. Participants were requested to return their specimen to a CHW within 3 mo of receiving the self-sampling kit	Standard of care. Women were asked to attend their usual clinic for Pap test screening	65.6% of women in the intervention group were screened vs 19.4% of women in the control group (OR, 14.18; 95% CI, 2.73–73.51; $P = 0.002$ )
<a href="#">Giorgi Rossi et al. (2015)</a> Italy	RCT Group 1: HPV self-sampling kit mailed to women at home. This kit included the sampler, instructions, information on cervical cancer and prevention, and a return envelope. Women were sent an explanatory letter 1 wk before the kits were sent Group 2: Women were sent a letter inviting them to pick up an HPV self-sampling kit at a designated pharmacy in their area. This letter was accompanied by information on cervical cancer and prevention	Standard recall letter inviting women for Pap test and/or HPV screening in a clinic. Choice of screening was dependent on the local health authority	21.6% of women in the intervention group were screened vs 11.9% in the control group (RR, 2.01; 95% CI, 1.3–3.1). The pharmacy pickup group (12.0% participation) had a participation similar to that of the control group (RR, 1.01; 95% CI, 0.62–1.66)
<a href="#">Cadman et al. (2015)</a> England	Pragmatic RCT Mailed HPV self-sampling kit, with instructions	Women received an invitation letter inviting them for standard cervical cytology screening	13% of women in the intervention group underwent some form of screening (8% returned a self-collected sample, and 5% attended for cytology); 6% of women in the control group responded to a further invitation for cervical screening (RR, 2.25; 95% CI, 1.90–2.65)

Table 3.3 (continued)

Reference Country	Study type Intervention	Control group	Outcomes
<a href="#">Enerly et al. (2016)</a> Norway	RCT Women were sent an explanatory letter; 3 wk later they were sent an HPV self-sampling kit with instructions for use and a prepaid return envelope	Standard of care; a second reminder letter was sent	Total participation was 33.4% in the intervention group vs 23.2% in the control group (RR, 1.44; 95% CI, 1.28–1.62)
<a href="#">Zehbe et al. (2016)</a> Canada	Community RCT Women were offered HPV self-sampling by community-based research assistants after an educational event and other recruitment efforts. The initial 3-mo phase of the trial was followed by a 1–2-mo break. Women in both groups were then offered the alternative screening strategy	Women were offered Pap testing by community-based research assistants after an educational event and other recruitment efforts	In the initial phase of the trial, HPV self-sampling participation in the intervention group was 20.0%. In the control group, Pap testing participation was 14.3%. This is a non-significant difference After the second phase in which the alternative screening method was offered, the cumulative participation in screening was 20.6% in the intervention group and 16.0% in the control group. This is a non-significant difference
<a href="#">Racey et al. (2016)</a> Canada	Pragmatic randomized intervention study Group 1: Women were sent an explanatory letter from their clinic, which was followed 2 wk later (if they did not opt out) by an HPV self-sampling kit, information on HPV and cervical cancer, instructions for self-sampling, and a prepaid return envelope. Those who did not respond within 1 mo of receiving the self-sampling kit received a reminder telephone call Group 2: Women were sent an invitation letter for scheduling a Pap test plus information on HPV and cervical cancer. If no response was recorded within 1 mo, a reminder telephone call was made	Standard of care opportunistic screening	In the control group, 8.6% of women underwent opportunistic Pap test screening; 32% of women in the intervention 1 group were screened and 15.4% of women in the intervention 2 group. Compared with the control group, women who received the self-sampling kit (intervention 1) were 3.7 (95% CI, 2.2–6.4) times as likely to undergo screening; women in the cytology group (intervention 2) were 1.8 (95% CI, 1.0–3.2) times as likely to undergo screening
<a href="#">Sultana et al. (2016)</a> Australia	RCT Women were sent a pre-invitation letter, allowing them 3 wk to opt out of receiving a self-sampling kit. After 3 wk, women were sent an HPV self-sampling kit, instructions for its use, information on HPV and cervical cancer, a personal information form, and a prepaid return envelope for their specimen and form	Standard invitation letter. Women received a letter inviting them for Pap test screening, a personal information form, and a return envelope to return their information form	20.3% of women in the intervention group participated in screening vs 6.0% of those in the control group ( $P < 0.001$ ) Participation was 11.5% vs 6.4% for never-screened women ( $P < 0.001$ )

**Table 3.3 (continued)**

Reference Country	Study type Intervention	Control group	Outcomes
<a href="#">Viviano et al. (2017)</a> Switzerland	RCT Women received a self-sampling kit, instructions for use at home, and a prepaid return envelope	Women received an invitation letter for cytology-based screening	92.7% of women in the control group underwent screening and 94.3% in the intervention group. Differences in screening participation were not statistically significant
<a href="#">Carrasquillo et al. (2018)</a> USA	Single-blind randomized pragmatic clinical trial Group 1 (outreach): Women were provided with a brochure in their preferred language about cervical cancer and how they can get screened in their local community Group 2 (navigation): Outreach as in the intervention 1 group, plus they were scheduled a 30-min one-on-one session with a CHW to help with appointments, navigate challenges, and follow up Group 3 (self-sampling): Same as groups 1 and 2, but during their educational session with the CHW women were given the option of HPV self-sampling	NA	At 6 mo, women in the self-sampling option group were significantly more likely to report having had screening than women in the outreach group (77.3% vs 31.3%, OR, 7.47; 95% CI, 4.75–11.73). Women in the navigation group were also significantly more likely to report having had screening compared with women in the outreach group (42.5% vs 31.3%; OR, 1.62; 95% CI, 1.07–2.45). The proportion of women screened in the self-sampling group was also significantly higher than the proportion screened in the navigation group (OR, 4.61; 95% CI, 3.02–7.05)
<a href="#">Gustavsson et al. (2018)</a> Sweden	Randomized study Mailed HPV self-sampling kit. Women were sent an invitation, a sampling brush, an FTA card, instructions for use, and a prepaid return envelope. Women who did not respond within 3 wk were sent a reminder	Standard of care. Invitation to the regional cervical cancer screening programme, which involves Pap testing conducted by a midwife	The screening participation in the intervention group was higher than that in the control group (47% vs 39%; $P < 2.2 \times 10^{-16}$ )
<a href="#">Ivanus et al. (2018)</a> Slovenia	Open-label, multiarm study with a randomized design Group 1 (opt-in HPV self-collection): Women were sent a package informing them they were late for screening and inviting them to order a self-sampling kit or schedule an appointment with their gynaecologist for cytology screening Group 2 (opt-out): Women were mailed a note that they were late for screening and that a self-sampling device would be sent directly to them in the next 2 wk if they did not opt out	Women were sent an information package, informing them that they were late for screening and inviting them to make an appointment with their gynaecologist	Compared with the control group (18.4%), the opt-out group had the highest participation (37.7%) (RR, 2.0; 95% CI, 1.9–2.2), followed by the opt-in group (34.0%) (RR, 1.8; 95% CI, 1.7–2.0)



**Table 3.3 (continued)**

Reference Country	Study type Intervention	Control group	Outcomes
<a href="#">Kellen et al. (2018)</a> Belgium	Parallel, RCT (4 arms) Group 1 (opt-out): Women were sent a package by mail including information, a self-sampling kit, instructions, and a prepaid return envelope Group 2 (opt-in): Women were mailed an information package and a letter offering the opportunity to order a self-sampling kit	Control 1: Women were sent the standard recall letter, inviting them to attend for a Pap test with their GP or gynaecologist Control 2: No intervention	25.8% of the women in the opt-out group (OR, 3.2; 95% CI, 3.0–3.5) and 18.7% of the women in the opt-in group (RR, 2.3; 95% CI, 2.2–2.5) were screened within 1 yr In the control groups, 10.5% of the women who received a standard recall letter and 8% of those who received no intervention had a Pap test within 1 yr
<a href="#">Kitchener et al. (2018)</a> United Kingdom	Cluster RCT Group 1: Mailed HPV self-sampling kit Group 2: Opt-in for HPV self-sampling Group 3: Choice between nurse navigator assistance and HPV self-sampling	Standard care; invitation for first cervical screening	Compared with standard care, mailed self-sampling kits resulted in an increase in screening participation over 12 mo (OR, 1.51; 95% CI, 1.20–1.91), but the opt-in approach had no effect (OR, 1.07; 95% CI, 0.87–1.33)
<a href="#">Tranberg et al. (2018)</a> Denmark	Randomized, controlled-effectiveness, population-based trial Group 1 (opt-out): Women were directly mailed a reminder, an information package, an HPV self-sampling kit, and a prepaid return envelope. They could report to a clinic for standard cytology Group 2 (opt-in): Women received the same package as the opt-out group except for the self-sampling kit. They were also given information about how to order a self-sampling kit by email, text message, telephone, or through a webpage	Standard reminder letter inviting women for screening with their GP	Compared with participation in the control group (25.2%), participation was significantly higher in the directly mailed group (38.0%; RR, 1.51; 95% CI, 1.40–1.62) and in the opt-in group (30.9%; RR, 1.23; 95% CI, 1.13–1.32)
<a href="#">Winer et al. (2019)</a> USA	RCT Women received usual care plus a mailed HPV self-sampling kit with self-sampler, instructions, information letter, and prepaid return envelope. If a woman did not return a sample or opt out within 3 wk, staff delivered up to 3 reminder telephone calls. Because HPV self-sampling is not the standard of care in the USA, the information letter advised women to report for Pap test screening even if they participated in self-sampling	Usual care. Outreach to women to attend for screening, and clinicians were issued alerts that women were overdue for screening	26.3% of women in the intervention group received screening vs 17.4% in the control group (RR, 1.51; 95% CI, 1.43–1.60)

**Table 3.3 (continued)**

Reference Country	Study type Intervention	Control group	Outcomes
<a href="#">Peeters et al. (2020)</a> Belgium	RCT Women were offered an HPV self-sampling kit at their GP practice along with instructions for use. They could collect the sample at home and mail it using a prepaid envelope or return it to their GP	Women were encouraged by their GP to make an appointment for Pap testing	Screening participation was 78% in the intervention group and 51% in the control group. Adjusted OR, 3.41 (95% CI, 1.31–8.87)
<i>Compared with VIA</i>			
<a href="#">Moses et al. (2015)</a> Uganda	Pilot RCT Group 1 (HPV self-sampling): Outreach workers visited women at home or their place of work and provided them with a Dacron swab and instructions and asked them to provide self-collected samples for carcinogenic HPV DNA testing. Women were asked to take the sample immediately and return it to the outreach worker Group 2 (VIA): Outreach workers visited women at home or at their place of work and invited them to attend a clinic for a scheduled appointment for VIA using a see-and-treat approach		48.4% of women in the VIA group were screened vs 99.2% in the HPV self-collection group ( $P < 0.001$ )
<a href="#">Gizaw et al. (2019)</a> Ethiopia	Cluster RCT HPV self-sampling after a sensitization programme that provided information about cervical cancer and screening. Women were offered an HPV self-sampling kit and performed self-collection under the supervision of a trained health professional at a health facility	Hospital-based VIA after a sensitization programme that provided information about cervical cancer and screening and support to schedule an appointment by a trained nurse	84.1% of women in the HPV self-sampling group were screened vs 50.5% in the VIA group ( $P < 0.0001$ )
<i>Compared with HPV testing (clinician-collected HPV testing or alternative offer of self-collection)</i>			
<a href="#">Arrossi et al. (2015b)</a> Argentina	Cluster RCT CHWs offered women HPV self-sampling testing during a routine home visit. Women were provided with education on HPV self-sampling	CHWs encouraged women to seek HPV testing at any provincial health centre	86% of women in the intervention group had any HPV test within 6 mo of the CHW visit, compared with 20% in the control group (RR, 4.02; 95% CI, 3.44–4.71)
<a href="#">Modibbo et al. (2017)</a> Nigeria	Community-based RCT Women were given dry flocced swabs for HPV DNA self-sampling and prepaid return envelopes. They had the option to mail the envelope, drop it off at certain points in the community, or return it to the central hospital	Women were given appointments for hospital-based HPV DNA testing	92.5% of women in the intervention group completed screening vs 56.5% in the control group ( $P < 0.001$ )

**Table 3.3 (continued)**

Reference Country	Study type Intervention	Control group	Outcomes
<a href="#">Huchko et al. (2018)</a> Kenya	Two-phase cluster RCT HPV self-sampling offered through periodic community health campaigns; outreach and mobilization were included	HPV self-sampling offered at government health facilities. Women were provided with the same information and instructions as those in the intervention	60.0% of women in the intervention group self-collected a sample vs 37.0% of women in the control group ( $P < 0.001$ )
<a href="#">Kobetz et al. (2018)</a> USA	Randomized pragmatic trial A CHW provided women with education about cervical cancer and instructions on how to perform self-sampling at a community location in-person. Women had the option to give the self-collected sample directly to the CHW or to mail their sample later	Women were sent a self-sampling kit that included a prepaid return envelope and instructions for how to use the kit. CHWs telephoned women to ensure they had received their kit and to provide health education about cervical cancer	In the mailed HPV self-sampling kit groups, 71.6% of women returned a sample; in the CHW-provided self-sampling group, 81.0% of women returned a sample ( $P < 0.01$ )

CHW, community health worker; CI, confidence interval; FTA, Flinders Technology Associates; GP, general practitioner; HPV, human papillomavirus; mo, month or months; NA, not applicable; OR, odds ratio; RCT, randomized controlled trial; RR, relative risk; VIA, visual inspection with acetic acid; vs, versus; wk, week or weeks; yr, year or years.

between either self-sampling or attending for screening with the Pap test at a health clinic. The opt-in self-sampling strategy significantly increased screening participation compared with an invitation letter for Pap-based screening, but only when total participation (self-sampling and cytology screening) was computed in the intervention arm, which suggests that factors related to the invitation strategy might have prompted women to get screened irrespective of the chosen method.

(ii) *Mailed with opt-out option*

A meta-analysis performed in 2018 showed that mailing self-sampling kits to women at their home address generated higher response rates compared with invitations or reminder letters to attend conventional cytology screening or HPV testing, or both, with the sample collected by a clinician (pooled relative participation, 2.33; 95% CI, 1.86–2.91) (Arbyn et al., 2018). Similar results were found in the meta-analysis by Yeh et al. (2019), which reported greater screening participation in HPV self-sampling when self-sampling kits were mailed directly to women at their home address (RR, 2.27; 95% CI, 1.89–2.71) compared with women in the control group (cervical screening by cytology, VIA testing services, or clinician-collected primary HPV testing). This increased participation was reported by both meta-analyses, despite significant heterogeneity across the studies in terms of the strategy offered and the population characteristics.

Studies in Table 3.3 that evaluated the opt-out approach included: written or illustrated instructions for use and a return envelope or packaging (Bais et al., 2007; Cadman et al., 2015; Viviano et al., 2017; Kitchener et al., 2018), written instructions and background information on HPV and cervical cancer and a return envelope (Giorgi Rossi et al., 2011; Szarewski et al., 2011; Haguenoer et al., 2014; Kellen et al., 2018; Tranberg et al., 2018), instructions and information about HPV and cervical cancer

and an information letter before sending of the self-sampling kits (Gök et al., 2010; Piana et al., 2011; Virtanen et al., 2011; Wikström et al., 2011; Sancho-Garnier et al., 2013; Giorgi Rossi et al., 2015; Enerly et al., 2016; Sultana et al., 2016; Ivanus et al., 2018), all of the above and a second complete kit sent to non-responders (Darlin et al., 2013) or a reminder telephone call or letter (Racey et al., 2016; Gustavsson et al., 2018; Winer et al., 2019) or a telephone call by community health workers to ensure the women received their kits and to provide health education about cervical cancer (Kobetz et al., 2018).

(iii) *HPV self-sampling kits offered by GPs*

In one study in Belgium (Peeters et al., 2020), HPV self-sampling kits offered to women by their GP, along with instructions for their use at home, increased screening participation compared with encouragement by the GP to make an appointment for cytology-based screening by a GP of the practice or a gynaecologist of choice (RR, 3.41; 95% CI, 1.31–8.87). Women collected the sample at home and could either mail it to the laboratory using a prepaid envelope or return it to their GP's practice.

(iv) *HPV self-sampling kits offered through outreach strategies*

Studies comparing screening with HPV self-sampling offered through outreach strategies versus clinic-based Pap testing (control group) included one study in Canada (Zehbe et al., 2016), one in Mexico (Lazcano-Ponce et al., 2011), and two in the USA (Sewali et al., 2015; Carrasquillo et al., 2018; Table 3.3). In both studies in the USA, women in the intervention (self-sampling) group were significantly more likely to have been screened compared with those in the control group (Sewali et al., 2015: OR, 14.18; 95% CI, 2.73–73.51; Carrasquillo et al., 2018: OR, 7.47; 95% CI, 4.75–11.73). In the study by Carrasquillo et al. (2018), screening participation was higher in the self-sampling group

than in the outreach and navigation groups, suggesting that when compared with cytology-based screening, HPV self-sampling has an impact on screening participation even when the effects of outreach activities have been controlled for.

In the study in Mexico ([Lazcano-Ponce et al., 2011](#)), a small difference in screening participation was observed (98% in the intervention group vs 87% in the control group;  $P = 0.001$ ). [Because the main objective of the study was to evaluate the effectiveness of self-sampling to diagnose cervical intraepithelial neoplasia, it is possible that additional outreach might have been carried out in the cytology-based screening arm, with potential underestimation of the impact of self-sampling.]

(b) *Self-collection of samples for HPV testing versus VIA*

Two studies in sub-Saharan Africa compared screening participation in women using HPV self-sampling and in women attending a clinic for VIA ([Moses et al., 2015](#); [Gizaw et al., 2019](#); [Table 3.3](#)). In a study in Uganda ([Moses et al., 2015](#)), women in one group performed self-sampling at home or at their workplace, and women in the other group were invited to attend a health clinic to undergo VIA and were reminded by telephone the day before their scheduled visit. In a study in Ethiopia ([Gizaw et al., 2019](#)), women were either offered self-sampling at home or given a choice of appointment days to attend for VIA. In both studies, women in the VIA arm had lower screening participation: 48.4% in the VIA arm and 99.2% in the HPV self-sampling arm ([Moses et al., 2015](#)) and 50.5% in the VIA arm and 84.1% in the HPV self-sampling arm ([Gizaw et al., 2019](#)).

(c) *Self-collected versus clinician-collected samples for HPV testing*

Three studies evaluated screening participation in women using HPV self-sampling compared with women who had samples collected by a clinician for HPV testing ([Arrossi et al., 2015b](#); [Giorgi Rossi et al., 2015](#); [Modibbo et al., 2017](#); [Table 3.3](#)). In a community-based randomized trial involving 400 women in a semi-urban district of Abuja, Nigeria, participation in screening was higher in those offered HPV self-sampling during a community gathering compared with those offered clinician-collected HPV testing (92.5% vs 56.5%;  $P < 0.001$ ) ([Modibbo et al., 2017](#)). In a population-based cluster-randomized trial in 6013 women in the province of Jujuy, Argentina, involving community health worker outreach, screening participation in the self-sampling arm was significantly higher than for clinician-collected HPV samples (RR, 4.02; 95% CI, 3.44–4.71) ([Arrossi et al., 2015b](#)). A multicentre RCT in six local health authorities in Italy involving 14 041 women ([Giorgi Rossi et al., 2015](#)) compared mailing of self-sampling kits, pharmacy pick-up of self-sampling kits, and standard recall at health clinics using HPV-based screening (clinician-collected sampling, in four centres) or cytology-based screening (in three centres). Compared with participation rates in women who were mailed self-sampling kits, screening participation was lower in three of the clinician-collected HPV-testing sites; no difference in screening participation was observed at a fourth centre. [The heterogeneity among centres suggests that there are strong effect modifiers not only at cultural and social levels, but also linked to the logistics and organization of the intervention and clinics.] A quasi-experimental before-and-after analysis comparing two periods – a cytology-based screening period (2010–2011) and an HPV-based screening period (2012–2014) ([Arrossi et al., 2019](#)) – showed similar screening participation in the periods (52.7% for the



cytology period and 53.2% for the HPV period) only when both self-collected and clinician-collected samples were included.

(d) *Comparison between self-sampling offered through health centres and in community settings*

Two studies evaluated the effectiveness of various programmes using different methods to offer HPV self-sampling (Table 3.3). In a cluster-randomized trial conducted in 12 communities in western Kenya and involving 4944 women (Huchko et al., 2018), HPV self-sampling offered through periodic community health campaigns yielded higher screening participation rates compared with HPV self-sampling offered at government health facilities (60.0% vs 37.0%;  $P < 0.001$ ). A study in Florida, USA, in 600 women found that HPV self-sampling offered in-person by community health workers in community settings resulted in higher screening participation compared with self-sampling delivered by mail (81.0% vs 71.6%;  $P < 0.01$ ) (Kobetz et al., 2018).

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