Introducing the Delphi Screener:

Understanding the intention to use a self-sampling method for cervical cancer screening among Italian women in Milan according to the Health Belief Model

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Samenvatting
Achtergrond: In Italië verschilt de georganiseerde screening van baarmoederhalskanker per regio; In sommige regio's functioneren deze programma's vrij goed, terwijl in andere regio's de dekking van de programma's te wensen over laat. In deze regio's wordt gestreefd om door middel van nieuwe screenmethodes de grote groep vrouwen te bereiken die niet- of nauwelijks gescreend zijn (de onder-gescreend). Door te testen op de oorzaak van baarmoederhalskanker - hoogrisicotypes van het Humaan Papillomavirus (HPV) – kunnen voorstadia van baarmoederhalskanker eerder opgespoord worden. Door dit type test aan te bieden, kunnen vrouwen zelf hun monster afnemen, waardoor mogelijk meer vrouwen aan screening van baarmoederhalskanker meedoen. Het doel van deze studie was om te bepalen in hoeverre de psychologische factoren van het Health Belief Model (HBM), en socio-demografische factoren van invloed zijn op de intentie van vrouwen om een instrument van zelfafname te gebruiken, de Delphi ® Screener. Tevens werd onderzocht of deze intentie tot zelfafname varieert tussen vrouwen die ander screengedrag vertonen (onder-gescreend, regelmatig gescreend en over-gescreened).

Methode: Een telefonische enquête werd uitgevoerd onder vrouwen tussen de 25 en 64 jaar oud, woonachtig in de regio Milaan, Italië (N=193). De verbanden tussen de factoren van het HBM zijn met correlatieberekeningen, F-testen en hiërarchische meervoudige lineaire regressieanalyses nagegaan. Zo werd gekeken welke onderdelen van het Health Belief Model hebben bijgedragen aan het voornemen van de vrouwen om de Screener te gebruiken, ook rekening houdend met hun verschillen in screenfrequentie.

Resultaten: Door middel van een vergelijking van de zelfafname met de twee huidige screenings-mogelijkheden voor de vrouw (publieke gezondheidszorg of de privé gynaecoloog), werden waargenomen voordelen en barrières onderzocht. De meeste vrouwen beschouwden zelfafname als de snelste en meest handige methode, terwijl de privé gynaecoloog werd waargenomen als de meest betrouwbare, geruststellende en eenvoudige optie. Bovendien vond het merendeel van de vrouwen de zelfafname het meest risicovol, terwijl de privé gynaecoloog als de duurste optie werd gekenmerkt. Daarnaast lieten vrouwen over het algemeen blijken dat zij hun vatbaarheid op baarmoederhalskanker als gemiddeld beschouwen. Verder waren de meeste vrouwen ofwel erg geïnteresseerd in het gebruik van de Screener of juist helemaal niet (resulterend in een neutraal gemiddelde).
De resultaten hebben uitgewezen dat de factoren van het HBM bijna 40% van de variantie van de intentie van vrouwen verklaren met waargenomen voordelen van zelfafname en opleidingsniveau als significante verklarende voorspellers. Waargenomen vatbaarheid was niet van invloed op intentie.
De intentie van regelmatig gescreende vrouwen was gerelateerd aan waargenomen voordelen van zelfafname en waargenomen voordelen van de privé gynaecoloog, terwijl de intentie van de over-gescreende ook werd verklaard door kennis van het uitstrijkje. De intentie van niet- en onder-gescreende vrouwen was verder gerelateerd aan de plek waar het uitstrijkje word gedaan. Toch werden in alle drie regressiemodellen alleen waargenomen voordelen van zelfafname als significante verklarende variabele teruggevonden met een positieve invloed op intentie.

Conclusie: Bevindingen tonen aan dat zowel de waargenomen voordelen en ervaren barrières een belangrijke rol spelen in de intentie tot zelfafname. Het is van belang in de communicatie naar de vrouw de waargenomen voordelen van zelfafname te benadrukken, omdat het de acceptatie van deze methode kan beïnvloeden. Vooral beter opgeleide vrouwen zijn dan vooral geneigd de Screener te gebruiken. Al met al heeft het aanbieden van de Delphi Screener de potentie om meer vrouwen te betrekken bij screening op baarmoederhalskanker, met als gevolg dat (sterf)gevallen van baarmoederhalskanker kunnen worden voorkomen.

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ABSTRACT

Background: In Italy, organized cervical cancer screening differs in its extension and coverage per region. Where in some regions the organized programs function relatively well, in others screening coverage is not as successful with a big portion of women who are un- or under-screened. Testing on the cause of cervical cancer, carcinogenic high risk types of the human Papillomavirus (HPV), allows for self sampling in cervical cancer screening. In order to improve cervical cancer screening coverage, this study utilizes the Health Belief Model (HBM) to explore beliefs and socio-demographic factors related to the intention to using a novel self sampling method for high risk HPV testing for cervical cancer screening, the Delphi ® Screener. Lastly, it was examined whether this intention towards self-sampling varies among women who have demonstrated different screening attendance behavior (under-screened, regularly screened and over-screened).

Method: A telephone survey was performed to women between 25 and 64 years old, living in the Milan area (*N* = 193). The relationships between several Health Belief Model variables and the intention towards using the self-sampling method was examined by Spearman's rank correlation and F-tests. Hierarchical multiple regression analyses were used to determine which components of the Health Belief Model contributed to the women's intention to use the Screener, also whilst taking into account their differences in Pap screening frequency.

Results: By comparing self-sampling with the private gynecologist and the public health services, perceived benefits and barriers were examined. Most women considered self-sampling to be the quickest and most convenient method, whereas the private gynecologist was perceived most trustworthy, reassuring and easy. Furthermore, the majority of the women found self-sampling the most risky, while the private gynecologist was believed the most expensive option. In addition, women reported a medium level of perceived susceptibility to cervical cancer.

With respect to intention, most women were either definitely interested in using the Screener or definitely not interested (resulting in a neutral mean score). Results show that the psychological factors of the HBM could account for almost 40% of the variance in intention, with perceived benefits towards self-sampling and education being the significant positive predictors. Perceived susceptibility had no influence on the intention of women.

The intention of regularly screened women was related to perceived benefits of self-sampling and the private gynecologist, whereas the intention of the over-screened was also explained by actual knowledge of the Pap test. The intention of under-screened women was further related to Pap test structure. Nevertheless, only perceived benefits towards self-sampling was found to be the significant explanatory variable in all regression models.

Conclusion: Findings suggest that both perceived benefits and educational level play an important role in intention towards self-sampling. It is of interest to highlight the perceived benefits of self-sampling (i.e. quick and convenient) in communication to the women, since it might influence the acceptance towards this method. Offering the Delphi Screener can consequently contribute to an increased coverage of cervical cancer screening, thereby decreasing cervical cancer incidence and mortality.

Keywords: Health Belief Model, perceived benefits, perceived barriers, cervical cancer screening, Pap test, private gynecologist, self-sampling, Human Papillomavirus, women, Italy

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Introduction

In the whole of Europe, there are about 60.000 new cases and 30.000 deaths from cervical cancer every year (Ferlay, Bray, Pisani & Parkin, 2004), making it the seventh most frequent cancer among women in Europe, and the second most common among women between 25 and 44 years of age (Castellsagué *et al.*, 2007). In Italy, the average incidence is approximately

10 cases per 100.000 women per year, meaning that each year about 3.500 women are diagnosed with this type of tumor (Zappa, Naldoni, Paci, Segnan & Vettorrazzi, 2008). This incidence rate makes cervical cancer the 10th most frequent cancer in women in Italy, and the 3rd most common among women between 25 and 44 years of age (Ferlay, Bray, Pisani & Parkin, 2004). An estimated 1.200 women in Italy die of cervical cancer every year (Castellsagué *et al.,* 2007).

Cervical cancer however is one of the most preventable and curable forms of cancer (Bosch, Lorincz, Munoz, Meijer & Shah, 2002; Bosch *et al.,* 2006). It may take at least 10 years for precancerous cells to grow into invasive cervical cancer, during which abnormal cells can be detected by a Papanicolaou (Pap) test (Anttila *et al.,* 2009). Secondary prevention through screening has so far been the single most effective tool in reducing mortality rates in cervical cancer (Walboomers *et al.,* 1999; Bosch, Lorincz, Munoz, Meijer & Shah, 2002). It is estimated that regular cervical screening can prevent more than 90 percent of cervical cancers (Fiebig, Haas, Hossain, Street & Viney, 2009). Since all secondary prevention activities are aimed at early disease detection, screening is a necessary tool to distinguish individuals 'at risk' and possibly detect the disease process early so that medical treatment can be started (Howlett *et al.,* 2009). As a result, many countries have implemented cervical screening programs.

Organized cervical screening in Italy

Since reductions of incidence and mortality of cervical cancer seems to be proportional to the intensity of screening efforts (Walsh, 2006), it is recommended that women between 25 and 64 years old get invited to get a Pap test every three years (European Commission, 2003; Anttila *et al.*, 2004). The European Union (EU) currently recommends that population-based high quality organized cervical screening be offered in all member states (Arbyn, Raifu, Autier & Ferlay, 2007; Arbyn *et al.*, 2010). Since 1996, Italian national guidelines have recommended to its regions the implementation of organized screening programs for cervical cancer, even though the type of organized screening is currently determined by regional legislation and differs per region (Segnan, Ronco & Ciatto, 2000; Ronco *et al.* 2009; Giorgio-Rossi *et al.*, 2009).

Since 1998, annual surveys aim to show the extension of organized screening programs and participation of cervical screening per Italian region (Ronco *et al.,* 2009). In 2008, the total number of women between 25 and 64 years of age eligible for screening was approximately 17 million women, but only 78.4 percent of these women resident in area's with organized screening (ISTAT, 2006; Zappa *et al.*, 2008). Of the women who have access to organized screening, 60.3 percent receives an invitation letter and a mere 39.7 percent of them actually participate in organized screening (Ronco *et al.,* 2010). Participation in organized cervical screening differs per geographical area, with a lower compliance to invitation in the South and the Islands (27.7 percent) as compared to Central and Northern Italy, 40.2 percent and 47.7 percent respectively (Ronco *et al.,* 2009).

Even though participation to organized screening is relatively low (with only 1.6 million women attending annually), data from the Italian Statistics Institute show that an estimated 5.8 million women aged 25–69 years have a Pap test every year (ISTAT, 2006). The remaining 4.2 million women are assumed to be screened at their own initiatives, outside organized programs, indicating that the majority of Pap tests are performed in the so-called opportunistic or spontaneous screening (ISTAT, 2006; Zappa *et al.*, 2008; Giorgio-Rossi *et al.*, 2009).

Pap screening frequency

Since annual statistics tend to give an incomplete image of cervical cancer screening coverage – not taking into consideration the participation rates within the recommended three-year interval – the Italian risk factor surveillance system (PASSI) conducted a study among women between 25 and 64 years old (N=16 064) on their cervical screening behavior over three years time (PASSI, 2009). In 2009, among the Italian local health units that participated, about three in four of the 25 – 64 years old women had a preventive Pap test done in the preceding three years (73

percent), of which about half participated in organized screening settings (36 percent) and half was screened opportunistically (37 percent) in a three-year interval (PASSI, 2009). The remaining one in four of the 25 – 64 years old women never had a Pap test done nor had a preventive Pap test done more than three years ago, 16 percent and 11 percent respectively (PASSI, 2009).

Women who are not screened in the recommended three-year interval or never have had been screened before – mostly referred to as under- and un-screened women – are considered at risk; with an estimated 50 percent of the cervical cancers occurring in this group in countries with well organized screening programs (Makuc, Freid & Kleinman, 1989; Sasieni, Cuzick & Lynch-Farmery, 1996; Crum, Abbott & Quade, 2003). These under-screened women often make no use or no sufficient use of screening possibilities and for some reason do not visit their gynecologist for a preventive check-up (Giorgio-Rossi *et al.,* 2009).

Furthermore, a large portion of the opportunistically screened women are assumed to be over-screened; in Italy, 52 percent of screened women reported having a test every year (Mancini *et al.*, 2004). Over-screened women are screened more frequently than the recommended interval and have a Pap test done at their own initiative. In a study among the participants of the cervical cancer program in Turin (Italy) the interaction between organized and spontaneous screening was examined. 20–25 percent of the women invited to participate in the study – independently of previous testing – joined the program and had tests outside the protocol (Ronco *et al.*, 1997), these women are considered over-screened.

To sum up, while the coverage of cervical screening in a three year interval seems relatively successful, but there still remains a considerable challenge for health behavior research. One of the biggest challenges is increasing the participation rates among under-screened women, also reducing unnecessary over-testing remains a challenge as well. Since screening is necessary to decrease mortality and identify the women at risk, the last challenge involves around improving the accuracy and confidence of cervical screening tests.

Primary screening through Pap testing

Organised screening programs for cervical cancer have been mainly using Pap tests, and have been shown to be effective in decreasing mortality and incidence from the disease (Läärä, Day & Hakama, 1987). A Pap test (Pap smear or smear test) is a way to examine cells collected from the cervix with speculum and brush and its aim is to detect cancer by looking at the composition and abnormality of the cells, also referred to as cytology, that may lead to cancer (Anttila *et al.,* 2009; Howlett *et al.,* 2009).

However, there are multiple problems related to the Pap test. Firstly, evidence suggests that the traditional Pap test requiring a pelvic examination may be a barrier for some women to get screened as it requires time, is invasive and can be negatively perceived by women (Matin & LeBaron, 2004). Pap tests have been associated with barriers such as finding a smear uncomfortable (Hill, Gardner & Rassaby, 1985) and embarrassing (Cockburn, Redman, Hill & Henry, 1992). Secondly, since no test is 100 percent accurate, primary screening using the Pap test requires regular screening to compensate for incorrect false-negative results (Fiebig, Haas, Hossain, Street & Viney, 2009). A false-negative Pap test result means that a woman is told her cells are normal, but she actually has a significant abnormality that was not detected. Using the Pap test for cervical screening thus requires re-testing to compensate for incorrect results, can cause anxiety and can affect a woman's health (Rogstad, 2002).

Cervical cancer and HPV

While manual reading of a Pap test is the current recommended screening technology in most countries, there have been recent technological developments which aim to increase the effectiveness of screening by improving the accuracy of detecting abnormalities in cervical cells (Fahey, Irwig & Macaskill, 1995; Cuzick *et al.*, 2000). A new DNA testing method has been developed, based on virology, to identify infection with the Human Papillomavirus (HPV), the

cancer-causing sexually-transmitted virus near the cervix (Clifford, Smith, Plummer, Muñoz & Franceschi, 2003). Out of the more than 100 types of HPV that have been identified, only fifteen high-risk HPVs are carcinogenic and may cause the cells of the cervix to become abnormal and eventually develop into cervical cancer by integrating to the host cell's chromosomes (Ferenczy *et al.,* 1996; Muñoz *et al.*, 2003; Petry *et al.*, 2003). Even more, only persistent infection with the high-risk types of the Human Papillomavirus can result in developing cervical cancer (Walboomers *et al.*, 1999; Muñoz, 2000; Bosch, Lorincz, Munoz, Meijer & Shah, 2002; Clifford *et al.*, 2005).

Since approximately 80 percent of the sexual active population will get infected with HPV at some point in their lives, HPV is considered one of the most common sexually transmitted infections in the world (Ferenczy *et al.*, 1996; Franco, 1997; Frazer *et al.*, 2006). Nevertheless, only a small percentage of the women develop a persistent infection and only a small percentage of the persistent infections advance into precancerous cells (Zappa *et al.,* 2008). Most HPV infections (70-90 percent) in young women are transient and simply regress in less than 4 to 5 years without causing disease (Petry *et al.*, 2003; Arbyn *et al.*, 2007).

Primary screening through HPV testing

Instead of looking at early changes or abnormalities in cervical cells (Pap test), an HPV DNA test analyzes the DNA on a persistent infection with the high-risk types of HPV *before* it develops into precancerous cells or invasive cervical cancer (Fiebig, Haas, Hossain, Street & Viney, 2009). Primary screening through HPV testing is a more sensitive approach than cytology-based screening programs alone, since it enables the identification of women with high-risk HPV, who were diagnosed with normal cytology (Clifford *et al.*, 2005), thereby overcoming false-negative Pap test results.

An HPV DNA test, however, also has limitations. Since an HPV infection is very common and might be only transient, it is possible that a woman receives a positive HPV test result, but is HPV negative in the next screening round (Arbyn *et al.*, 2007). This chance is higher in young women, who have a higher risk on HPV but a better chance to overcome the infection (Ronco *et al.*, 2010). Moreover, even though the HPV DNA test will give less false-positive results than the Pap test, being HPV positive occurs more often with a chance of 80% to get HPV at some point in life (Verdon, 1997). Having an HPV positive test result only means an increased risk of future pre-cancer or cancer and does not guarantee that a woman has, or will ever get, pre-cancerous cells or cervical cancer (Petry *et al.*, 2003).

Fortunately, by using HPV DNA testing the same sample can be used for both HPV testing and cytology (Naucler *et al.*, 2009). When a woman is diagnosed to be HPV positive, a confirmatory HPV test and cytology can be performed, leading to more exact screening[1], fewer gynecological referrals, reduced over-treatment and possibly a better cost-benefit ratio for screening (Meijer *et al.*, 2000). Furthermore, since high-risk HPV DNA screening means switching to automated diagnostic tests with lower error margins, it will also reduce the amount of time required for consultations and for laboratory analysis and reduce treatment costs (Cuzick *et al.*, 2000; Arbyn *et al.*, 2007). Taking into account the advantages and disadvantages of both cytology and virology, HPV DNA testing is recommended for women who are 35 years or older, but only for primary screening (and if necessary followed by cytology and repeat screening; Ronco *et al.,* 2010).

In a study by Ronco and colleagues, a large randomized trial (n=94 370 women) demonstrated the effectiveness of HPV testing in terms of higher sensitivity and earlier detection of high-grade cervical lesions. In the first phase of the trial, invasive cancers were found in both the group screened with cytology and the HPV screened group (respectively n=9 and n=7). In the second part of the trial, however, 9 cancers were found in the cytology group and none in the HPV group,

[1] If cytology is normal, the woman is recommended to be tested again within a year. If cytology is abnormal, the woman is referred to the gynecologist for colposcopy. These recommendations are country-specific

indicating that testing on high-risk HPV is more sensitive than cytology alone. Since HPV testing however is less specific than cytology for detecting high-grade cervical lesions, for younger women who are HPV-positive (5-15 percent) the recommendation is to use HPV testing only in combination with cytology; young women, who may have only a transient HPV infection, are likely to get an over-diagnosis of high-risk HPV (Ronco *et al.*, 2010).

In a recent publication of the Dutch Health council, advice is given to the Minister of Health, Welfare and Sport on reshaping the screening program. In this report, high-risk HPV testing is recommended as the test to be used for primary cervical cancer screening, since it detects pre-stages of cancer earlier and better protects the woman from cancer than cytology (Health Council of the Netherlands, 2011).

Self-sampling

Another advantage of HPV DNA testing is the possibility to use specimens obtained by self sampling. Since self-sampling allows for screening without the need for gynecological examination, it has the potential to greatly increase participation in cervical cancer screening programs and the overall coverage of screening (Gravitt *et al.*, 2001). Self-sampling can thus be a more effective screening tool for the un- and under-screened women, who rarely attend medical clinics, reaching women who may be reluctant to undergo this exam (Petignat *et al.,* 2007; Barata, Stewart, Howlett, Gagliardi & Mai, 2008). Furthermore, self-sampling is a less costly collection procedure in terms of money and time, allowing samples to be more easily obtained in settings with limited resources or in populations difficult to reach (Nobbenhuis *et al.*, 2002; Petignat *et al.*, 2007). To further improve the clinical reliability of self-sampling, a combination of a high-risk HPV test with a cytological test is considerably more sensitive in comparison with a cytological examination alone (Petignat *et al.,* 2007). This means an analytical method that is as reliable as the clinically obtained smear to identify women with an increased risk to develop cervical cancer (as a result of a persistent high-risk HPV infection; Mosciski, Widdice & Ma, 2010).

Nowadays the accessibility of self-tests to the public has substantially increased with the advanced technologies to design and manufacture these tests and the multitude of buying channels available to the consumer (Ryan, Greenfield & Wilson, 2006). A study by Wilson and colleagues (2008) examined the prevalence of cancer-related self-test use and found that more than a third (36 percent) of the population would consider using a cancer related self-test, though actual action will most likely be prompted by the onset of symptoms, experiences (i.e. diagnosis of cancer in friends or relatives) and the perceived acceptability of cancer self-testing (Wilson *et al.*, 2008). People may use self-tests because of benefits (more convenient and private at home) of being tested outside a conventional setting, but a variety of studies also show potential harms from being tested in this way (Ryan, Greenfield & Wilson, 2006; Ryan *et al.*, 2006), for example, the possible delay of the patient to seek treatment.

In the report of the Dutch Health Council (2011), however, screening coverage is thought to improve by sending non-responders to the population-based organized screening program a self-sampling method for HPV testing, like the Delphi Screener. Nevertheless, further research is needed to examine the influence of such an offering on the current screened population (Health Council of the Netherlands, 2011).

The Delphi Screener

As can be seen in Figure 1, the Delphi Screener allows women to self-collect a cervico-vaginal sample through a deep vaginal lavage with buffered saline (Delphi Bioscience, 2011). Once collected and send to the laboratory, the sample is tested on the high-risk HPV types through an automated DNA test[2]. Women with a negative HPV test result (i.e. normal) are instructed to continue with their cervical screening and have another test within five years. Since the HPV infection may be transient, the laboratory will advise women who are HPV positive (i.e. abnormal)

[2] Automated DNA testing on high risk HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68.

to visit their gynecologist, being at an increased risk for cervical cancer. Similar to all screening tests, only a follow-up test (with confirmatory HPV test and cytology) can determine if the woman indeed has (pre-)cancer (Delphi Bioscience, 2011).

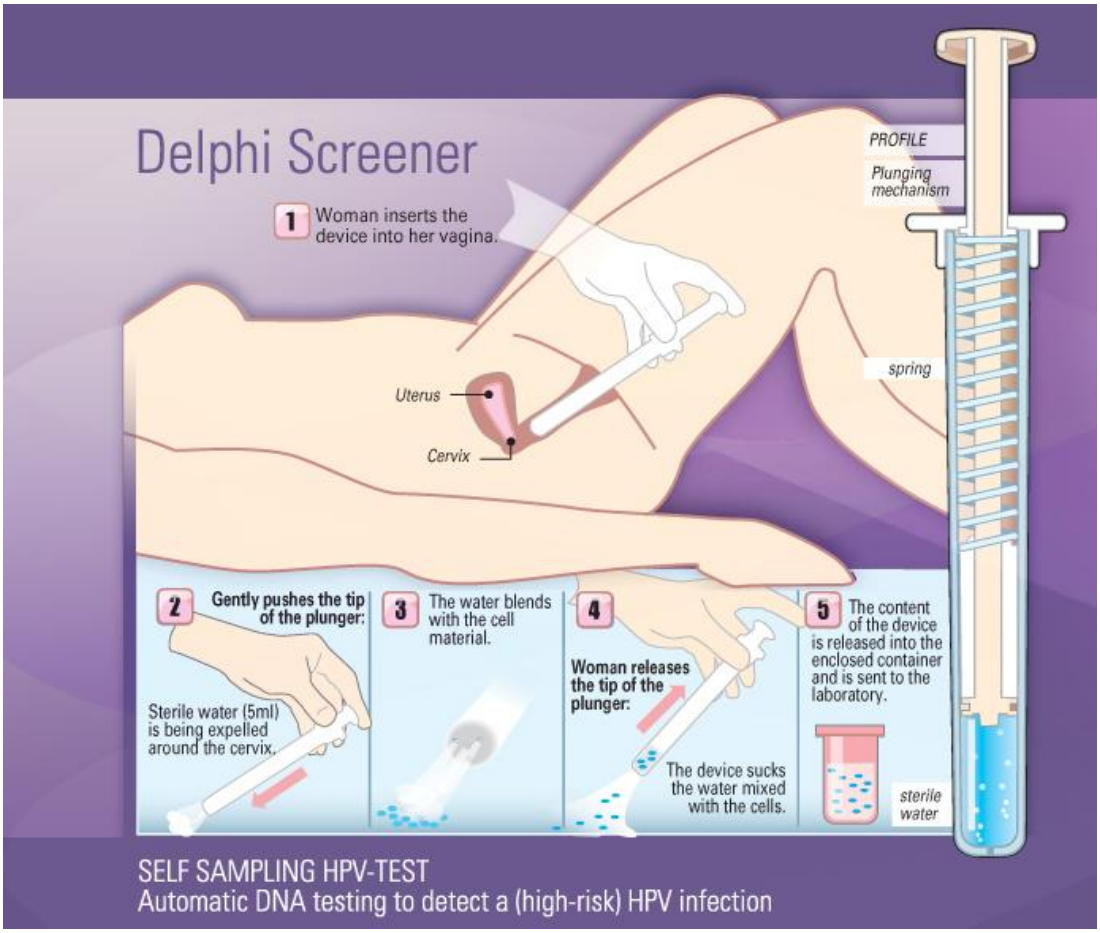

Figure 1: The Delphi Screener

Various studies show the validity of the sample collected with the Screener compared to the clinician-obtained sample, in combination with a high-risk HPV test (Ogilvie *et al.*, 2005; Brink *et al.*, 2006; Petignat *et al.*, 2007; Jones *et al.*, 2009; Virtanen *et al.*, 2010; Gök *et al.*, 2010, Giorgio-Rossi *et al.*, 2011; Igidbashian *et al.*, 2011). Moreover, the effect of self-sampling on non-attendees screening has already been researched in the Netherlands (Gök *et al.*, 2010) and in Italy (Giorgio-Rossi *et al.*, 2011).

In the Netherlands, a cohort study among non-attendees in the nationwide program, called PROHTECT (protection by offering HPV testing on cervicovaginal specimens trial), was used to assess the feasibility and efficacy of offering the Delphi Screener as compared to a standard recall for a Pap test. These non-attendees, women aged 30-60, who had not responded to the previous screening invitation and the standard reminder letter, living in the counties of Noord-Holland or Flevoland (N = 28 073) were selected from the regional health council registry. In this randomized controlled trial, the non-eligible non-attendees (i.e. women who have had a hysterectomy) were excluded from the study. The remaining non-attendees were randomly assigned to either the self sampling group (n = 26 886) who received the Delphi Screener at home or to the recall control group (n = 277) who got a second recall reminder letter for a Pap

test at home (ratio 99:1[3]). Of all women who received the Screener, 27.5 percent returned their self sampled specimen for HPV testing, and 0.2 percent visited their doctor for a Pap test. In the recall control group, 16.6 percent of the women visited their doctor for cervical cytology. This demonstrates a significant difference in compliance rates of 10.9 percent between the self-sampling group and the recall control group, thereby indicating a higher acceptability of the Screener as compared to the Pap test among non-attendees (Gök *et al.*, 2010). Women in the self-sampling group who were HPV-positive (10.3 percent) were advised to visit the general practitioner for a conventional Pap test and a second high-risk HPV test collected by the doctor. Of these women, 82 percent complied and had the recommended follow-up. Both screening history and age did not have an effect on participation of the self-sampling group. Similar to the findings of other studies (Makuc, Freid and Kleinman, 1989; Sasieni, Cuzick and Lynch-Farmery, 1996; Crum, Abbott and Quade, 2003), women who had not attended the previous round had a higher risk of cervical cancer; since more cervical lesions were found in this group.

In Italy, Giorgio-Rossi and colleagues (2011) did a similar study among non-attendees to measure the effect on test compliance of introducing the Screener using different strategies of mailing. Within the settings of three organized screening programs from three different Italian regions (Florence in Tuscany, Rome in Lazio and Terramo in Abruzzo), women aged 35-64, who had not responded to the previous screening invitation and the standard reminder letter, were selected from the screening databases. Sample sizes differed per center; in Rome the sample size was exactly as planned (n = 800), in Florence it was slightly increased (n=951), in Abruzzo slightly decreased (n = 729), with a total of 2 480 participants. In this randomized controlled trial, the non-attendees (N = 2 480) were randomly divided in four arms. Two control groups received recall letters; the first standard recall Pap group (n = 619), received a standard reminder letter for a Pap test, and the second standard recall HPV group (n = 617), was sent letters for an HPV DNA test. The two intervention arms consisted of a self-sampling request group (n = 622), in which women received letters in which the Screener could be requested by telephone, and a direct mailing self sampling group (n = 622), where women directly received the Screener at home. As expected, there was a difference in compliance between the four groups; the highest rate of compliance was achieved in the direct mailing self-sampling group (19.6 percent), followed by the standard recall HPV group (14.9 percent), the standard recall Pap group (13.9 percent) and the self-sampling request group (8.7 percent) with no differences among centers. By offering both the Pap test and the HPV test, potential influence of both tests on compliance could be demonstrated with this study; however, no significant differences between the two recall groups were found. The positive effect on screening coverage was only observed in Florence and Rome. When comparing the standard recall group with the direct mailing self-sampling group, the difference in response rates was lower as compared to the study of Gök *et al.* (2010), respectively 5.7 percent (Giorgio-Rossi *et al.*, 2011). All women who used the Screener were asked to fill in a survey to determine reasons for non-attendance and acceptability towards using the Screener (n = 147, with a 84.4 percent response rate). Having had a Pap test turned out to be the main reason of failing to comply, explained by the authors as a confirmed influence of opportunistic screening outside screening programs. Regarding self-sampling, most women said using the Screener was easy (88.3 percent), and appreciated because they got to do the sampling themselves (57.6 percent) and for privacy motives (49.3 percent).

Considering that self-sampling for HPV testing has shown to be acceptable to women, using the Screener for non-responders may increase cervical screening compliance as compared to women who currently receive standard reminder letters for a Pap test (Gök *et al.*, 2010, Giorgio-Rossi *et al.*, 2011). In a recent publication of the Dutch Health council, advice is given to the Minister of Health, Welfare and Sport on reshaping the screening program. In this report, high-risk HPV testing is suggested as the test to be used for primary cervical cancer screening, since it detects pre-stages of cancer earlier and better protects the woman from cancer than cytology (Health

[3] This ratio was chosen to "provide sufficient power to detect differences in compliance and to maximise the yield of cervical lesions in the self sampling cohort." Gök et al., 2010

Council of the Netherlands, 2011). In order to improve screening coverage, it is recommended that non-responders to the population-based organized screening program are sent a self-sampling method, though further research is needed to examine the influence of such an offering on the current screened population (Health Council of the Netherlands, 2011).

Theoretical framework

Behavioral scientists have always been interested in better understanding why and how people practice or not practice healthy behaviors. Health behavior theories such as the Health Belief Model (HBM; Hochbaum, 1958; Janz & Becker, 1984; Strecher & Rosenstock, 1997) are designed to identify sets of factors that allow for an optimal explanation and prediction of health behavior. Models of health behavior change suppose a pattern of factors that may improve motivation and would eventually lead to continued behavior change.

The Health Belief Model

In terms of health behavior, people tend to engage in a health behavior when they believe doing so can diminish a threat that is likely to have serious consequences if it occurred (Hochbaum, 1958). The HBM is an expectancy-value model and hypothesizes that human behavior is a function of the value placed by an individual on a particular goal (i.e. the desire to avoid illness and to get well), and of the subjective probability, or expectation, that a given action will achieve that goal (i.e. the belief that specific health action will prevent or ameliorate illness; Bartholomew, Parcel, Kok & Gottlieb,2001). In other words, one is more inclined to perform a certain health behavior when one thinks doing so can reduce a threat that is likely and would have severe consequences if it occurred (Champion & Skinner, 2008).

Janz and Becker (1984) explained that if individuals regard themselves at risk of contracting a particular condition or illness (*perceived susceptibility*), believe that condition would have potentially serious consequences (*perceived severity*), believe that various actions available to them would be effective in reducing the threat of a disease (*perceived benefits*), and believe the expected benefits of taking action will dominate the potential negative aspects of a particular health action (*perceived barriers*), they are more likely to participate in preventive health behavior. The individual's perception in terms of capability (*perceived self-efficacy*) is assumed to influence one's behavior as well.

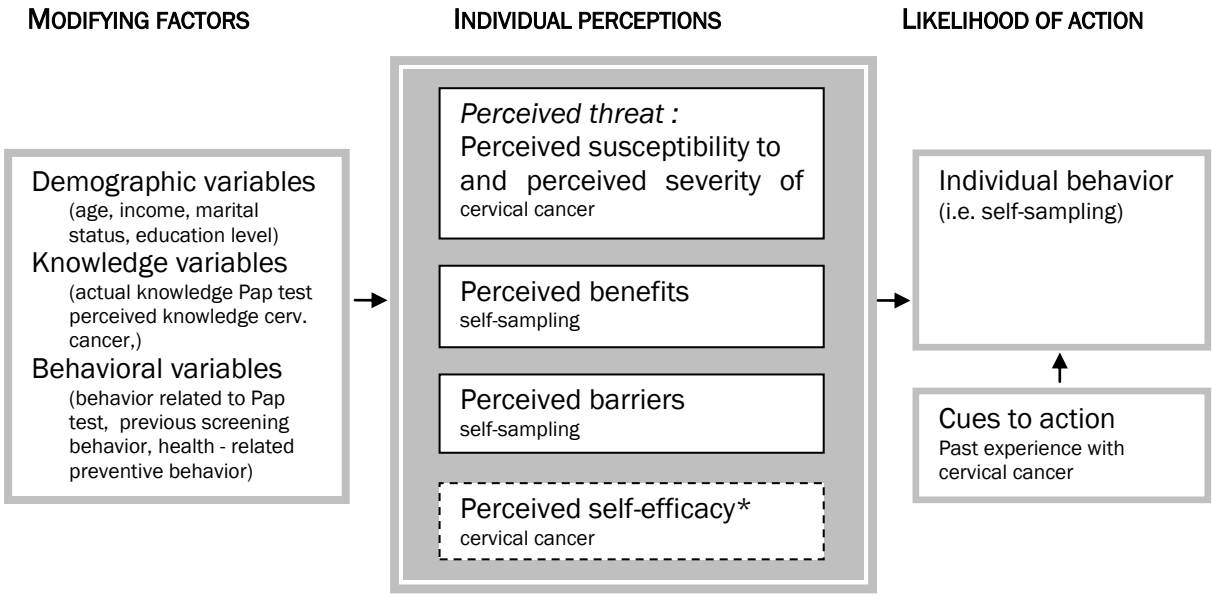

Figure 2: Health Belief Model applied to this study. * Please note that perceived self-efficacy has not been investigated in this study. *Source:* Champion & Skinner in Glanz *et al.*, 2008

As displayed in Figure 2, the relationship between these perception constructs and the likelihood of taking action depends on the mediating or moderating modifying factors, such as demographic and structural variables (Tanners-Smith & Brown, 2010). According to HBM, this decision-making process is triggered by certain cues to action, which may be internal or external (Champion & Skinner, 2008). All previously named constructs should lead to action that people believe will reduce their risks.

The HBM and cervical cancer screening

The Health Belief Model has been used extensively with respect to cervical cancer screening (Tanner-Smith & Brown, 2010), allowing for assumptions to be made regarding the relationship of the HBM predictor variables and intention towards using a self-sampling method, such as the Delphi Screener. Since more studies have been published on the relation between the variables of the HBM with cervical cancer screening using the Pap test, these findings will first be discussed, followed by the relevant studies on self-sampling using the HBM.

Encouraging the belief that preventive action can minimize the likelihood to develop invasive cervical cancer and informing women of their susceptibility to cervical cancer, has shown to be effective in increasing attendance to cervical cancer screening programs; overall, women with higher perceived susceptibility and severity showed a higher probability of having had a Pap test in the previous year (Ingledue, Cottrell & Bernard, 2004). It is even assumed that perceived susceptibility is one of the more powerful perceptions in persuading people to perform health-related preventive behavior, such as pap screening (Norman & Conner, 1993; Fylan, 1998). Perceived barriers were found to be negatively related to past pap screening behavior and future intention of performing a pap test (Tanner-Smith & Brown, 2010). When speaking of perceived barriers, a distinction is made between *emotional* issues, such as embarrassment, discomfort, inconvenience (Cockburn, Redman, Hill & Henry, 1992; Matin & LeBaron, 2004), fear of what the test might find, fear of pain and having had a bad experience of smear test in the past (Waller, Bartoszek, Marlow & Wardle, 2009), and *practical* issues, such as lack of time and money (Hill, Gardner & Rassaby, 1985; Norman & Conner, 1993), not getting around to attending and perceived difficulties in arranging a convenient appointment (Waller, Bartoszek, Marlow & Wardle, 2009). Uptake was especially predicted by the afore-mentioned practical barriers (Waller, Bartoszek, Marlow & Wardle, 2009). Perceived benefits of cervical screening behavior, such as peace of mind when the results are negative, and being in control of their health were reported as well, though these did not predict pap test behavior (Agurto, Bishop, Sánchez, Betancourt & Robles, 2004).

Regarding demographic factors, uptake of cervical cancer screening turned out to be lowest among single women and highest among married and separated women, with age as a significant curvilinear effect on having had a Pap test (Sutton & Rutherford, 2005). Cervical cancer statistics in Italy demonstrate similar effects; at age 25–34 27 percent of the women participated in cervical screening, at age 35–44 over 50 percent, and at age 55–64 the percentage decreased to 43 percent (Mancini *et al.*, 2004). Also in the study of Passi, coverage of cervical screening showed to be greater in women 35 – 49 years old (79 percent), and women who cohabit and are married (77 percent; PASSI, 2009). Furthermore, higher levels of income have shown to be associated with higher uptake of screening (Dzuba *et al.*, 2002; Stewart, Gagliardi & Johnston, 2007). Moreover, since education raises awareness of the significance of regularly screening, several studies showed that cervical screening was more frequent among higher educated women (Sutton & Rutherford, 2005). Lastly, Pap screening has shown to be positively related to knowledge of cervical cancer; more specifically when women know that they can get cervical cancer and that screening helps to diminish that risk, they are more likely to take preventive action (Ingledue, Cottrell & Bernard, 2004; Champion & Skinner, 2008).

When looking at the role of the cues to action construct, screening participation is in most countries stimulated by sending reminders or phone non-attenders of cervical screening programs. In countries with organized screening programs, policy recommends women to be

invited in a certain interval and often studies have looked at the reasons for non-attendance (Tanner-Smith & Brown, 2010), though few have looked at what prompted attendance. Past experience with cervical cancer diagnosis might function as a cue to action as well, leading understandably to a higher intention towards cervical screening (Champion & Skinner, 2008); if someone in the direct environment has been diagnosed with cervical cancer before, the woman herself might have a heightened perceived susceptibility and be therefore more conscious of the necessity of screening.

Concerning the Screener, women have shown to appreciate using the method mainly because it was perceived as very easy to do, because they welcomed the opportunity to do the sampling by themselves, and for privacy reasons (Giorgio-Rossi *et al.,* 2011). In addition, several studies show that self-collection of vaginal samples for HPV testing was well-accepted and perceived as more convenient when compared to 'regular' pelvic speculum examinations collected by the physician (Nobbenhuis *et al.*, 2002; Gök *et al.*, 2010; Jones *et al.*, 2010; Giorgio-Rossi *et al.*, 2011). Furthermore, compliance of un- and under-screened women to cervical cancer screening is encouraged by using different strategies of reminders, such as standard recall letters for a Pap test in comparison to direct mailing of the Screener (Gök *et al.,* 2010; Giorgio-Rossi *et al.,* 2011), assuming a potential influence of the cues to action construct. Although these studies have *not* used the HBM to explain and predict the intention of self-sampling, findings suggest that the opportunity of a home, self-collected sample with the Screener, seems to lower and remove some of the emotional and practical barriers that may discourage women from participating in screening programs or performing a Pap test (Gök *et al.*., 2010; Giorgio-Rossi *et al.*, 2011).

Only few studies on self-sampling using the HBM have been published so far, but results show nevertheless that the variables of the HBM are significantly related to intention. Self-sampling was perceived as an acceptable and more convenient method when compared to the physician-collected Pap test (Dzuba *et al.*, 2002; Flores *et al.*, 2003; Waller *et al.*, 2006; Stewart, Gagliardi & Johnston, 2007). Perceived barriers to self-sampling have been reported as well, such as not having confidence in doing the test correctly (Stewart, Gagliardi & Johnston, 2007). Moreover, perceived susceptibility has shown to predict intention to perform preventive health behaviors (Norman & Conner, 1993). Concerning demographic variables, only education has found to be related: Better educated women were found to feel more comfortable performing self-sampling (Tisci *et al.*, 2003).

Since perceived benefits need to outweigh the perceived barriers in order for action to be performed, previous experience or attending cervical screening is assumed to be related to intention towards using the Screener. It has never been investigated however, to what extent women who differ in their screening behavior (more specific Pap screening frequency) also differ in their intention to use a novel method like the Screener. The assumption that under-screened, regularly screened and over-screened vary in their intention, is twofold. Over-screened women, being more likely to perform preventive action (Cummings, Whetstone, Shende & Weismiller, 2000), are assumed to demonstrate a higher intention to use the Screener. Furthermore, based on the assumptions made by Giorgio-Rossi *et al.* (2011) given the higher compliance of women in the self-sampling group, the under-screened are thought to be interested in using the Screener, since perceived barriers regarding the Pap test (both practical, such as not being able to organize a visit and emotional issues such as embarrassment and discomfort), should be overcome by offering this self-sampling alternative.

Research question

Following the Health Belief Model, likelihood of self-sampling is predicted to be related directly to perceived threat, perceived benefits and perceived barriers. Modifying factors shown to be related to cervical cancer screening, including cues to action, structural variables (such as perceived knowledge of cervical cancer, health-related preventive behavior, previous screening behavior and Pap test behavior) and demographic variables that (such as age, marital status,

income and education level) are predicted to be related to intention towards using a self-sampling method as well.

Where most studies with the Screener suggest that women perceive using a self-sampling method as acceptable (Jones *et al.*, 2009; Gök *et al.*, 2010, Giorgio-Rossi *et al.*, 2011), it is yet unknown which HBM variables best predict intention to use the Screener. Moreover, acceptability was only examined after the women used the Screener, experience with the Screener might have possibly influenced the women's beliefs. This study is first in exploring the factors related to attitudes, beliefs and intention, without the women being exposed to the instrument itself or any experience with it.

Furthermore, considering that previous research on HBM and cervical screening focused mostly on increasing compliance of non-attenders to organized cervical screening, this research is first to examine the beliefs of all women in the target audience (under-screened, regularly screened and overscreened). Taking into account these assumed differences in beliefs and perceptions of these three groups of women, it is researched to what extent intention towards using the Screener actually differs.

Considering the fact that the Screener has not yet been commercialized in Italy, the primary aim of this study is to identify the (mediating) factors that are related to a woman's intention to make use of the product. These factors will be included in communication to the women to ensure acceptance of the concept and potentially influence their intention to use this self-sampling method for cervical cancer screening.

This study will contribute to the existing literature by answering the following research questions:

1. *How is the intention towards self-sampling, using the Delphi Screener for cervical cancer screening, among women in Milan and what are their beliefs on perceived threat of cervical cancer and perceived benefits and barriers of self-sampling?*
2. *How are the variables of the Health Belief Model, behavioral variables and socio-demographic variables related to intention to use the Delphi Screener?*
3. *To what extent do women who have shown different Pap test frequencies (more specifically the under-screened, the regularly screened and the over-screened) vary in their intention to use the Delphi Screener?*

Method

In a telephone survey, 200 women were approached by telephone to participate in a study concerning health. They were informed the interview will last approximately 15 minutes and are guaranteed anonymity. Upon consent the survey started. The aim of the telephone survey was to answer the above-mentioned research questions.

Sample and procedure

Considering the desired medium effect and the maximum of 10 predictors, the sample size required in analysis for regression has a minimum acceptable sample size of 150 women for the telephone survey (Miles & Shevlin, 2001). To be on the safe side, the choice was made to approach 200 women from an existing database (of 10.000 unique contacts) of Criterion, a market research company chosen to implement the survey. Computer-assisted telephone interviewing software (CATI) from Conversoft contacted 50 women per age group (with a distinction made from 25 – 34, 35 – 44, 45 – 54 and 55 – 64 years old). Women under 25 years old and over 64 years old could not participate in this survey.

Following the components of the Health Belief Model, the telephone survey included items measuring health-related preventive behavior, previous screening behavior, perceived susceptibility, perceived benefits, perceived barriers and intention towards using the self-sampling device as compared to two other screening options (being the private gynecologist and the public health services). Modifying factors are measured by looking at both demographic and

structural variables. All survey items were translated from English into Italian by a collaborator of the market research company and back-translated by both the researcher and a second assessor to evaluate correctness of the translation.

Measures

In order to provide input for the telephone survey, four qualitative interviews were performed to structure the items to be used in the final survey. Open-ended questions were used to illicit perceived benefits and barriers to self-sampling.

Variables of the Health Belief Model

The variables of the Health Belief Model were measured with various items. Perceived threat was intended to be examined in terms of perceived susceptibility and severity. Perceived severity however turned out to be a redundant question in the formative stages of this research, since having cancer is assumed to be perceived as severe. Perceived susceptibility was measured with one item measuring the relative perceived risk ('How likely do you think it is that a woman of your age will get cervical cancer?' with answer categories 1=Low, 2=In between low and medium, 3=Medium, 4=In between medium and high, 5=High).

Perceived benefits towards self-sampling, the private gynecologist and public health services were measured by five items ('Between these three possibilities, which one is for you [quickest/most trustworthy/most convenient/easiest/most reassuring]', with response options 1=Self-sampling, 2=Private gynecologist, 3=Public health services). Three new variables were computed to scale perceived benefits by counting the number of times one of the three options was given, resulting in Perceived Benefits Self-Sampling, Perceived Benefits Private Gynecologist, Perceived Benefits Public Health Services, with reliability scores of the scales being respectively α=0.66, α=0.77 and α=0.84. All scales varied from 0=Least positive to 5=Most positive.

Perceived barriers towards self-sampling, the private gynecologist and public health services were measured by two items ('Between these three possibilities, which one is for you [most expensive/most risky]', with response options 1=Self-sampling, 2=Private gynecologist, 3=Public health services). Since the two variables showed not to be significantly associated with each other (r = 0.12, DF = 191, p = 0.07), they were therefore separately included in the analysis. New variables were computed by counting the number of times one of the three options were mentioned (six new variables in total: perceived barrier 'Risky' and perceived barrier 'Expensive' for every option). All variables could vary from 0=Not mentioned to 1=Mentioned.

Intention was operationalized by 'Do you intend to use this self-sampling method?' with a five-point response scale (1=Definitely not; 5=Definitely yes). Higher scores thus indicated a higher willingness to use the Screener.

Knowledge variables

Knowledge factors in the survey were measured by asking what women knew about cervical cancer and the Pap test. In order to measure 'perceived knowledge of cervical cancer', a direct question evaluated the respondent's perceived level of knowledge on cervical cancer ('How do you personally evaluate your level of knowledge and information about this cancer?', with four response-items; 1='Nonexistent' to 4='Good').

Actual knowledge on Pap test was measured by an open-ended question 'What do you know about the Pap test?'. The construct was quantified by counting the number of correct components in the answer. Both the research and a second assessor had three components to count. The first component was 'diagnosis', with other accepted words such as 'control', 'sample' or 'identify'/'identification'. The second component was 'prevention', and the last 'cancer' (in relation to 'vaginal' or 'cervical'). Other accepted words for 'cancer' were 'tumor(s)' and 'abnormal cells'. The counts vary from 1='Nonexistent', i.e. no correct components given to 4='Good', i.e. all

components given. Differences in counting between the researcher and second assessor were examined and when consensus was reached the counted items were used for analysis.

Behavioral factors

Behavioral factors assumed to be related to Pap screening and using a self-sampling device include health-related preventive behavior, previous testing behavior, Pap test structure, and Pap screening frequency.

'Health-related preventive behavior' was examined with eight statements (varying from 'I regularly visit my doctor for preventive check-ups' to 'I do regular blood-tests' and a two-point response; 1='I agree', 2='I don't agree'). These statements were derived from the qualitative interviews. A concise statistical analysis of the eight items showed a higher reliability after deleting three items. The remaining items of this scale are 'I regularly check my blood pressure', 'I do regular blood-tests', 'I undergo other clinical trials (feces, urine etc.)', 'I regularly visit my doctor for preventive check-ups' and 'I visit medical specialists for preventive check-ups'. This new variable 'Health-related preventive behavior' (with α=0.71) was computed by counting the number of times the woman agreed upon the remaining health-related preventive behavior statements (with the scale varying from 0 to 5).

'Previous testing behavior' measured the number of different examinations the woman had undergone (seven items varying from mammography and colonoscopy to Pap test and HPV test, with response items 0=No; 1=Yes). A reliability analysis showed the highest reliability after deleting the HPV test, Uterus ultrasound and the colonoscopy (with α=0.65). The remaining items (the mammography, breast ultrasound, Pap test, and BMD; a test for bone density) were computed in a new 'Previous testing behavior' scale, by counting the number of tests done (0 meaning no test done, until 4 'all tests done').

Feedback from the qualitative interviews showed the need to distinguish the type of Pap test structure a woman uses for cervical cancer screening (opportunistic screening at private gynecologists and organized screening using public health services). One direct item measured the type of structure used by the woman for her cervical cancer screening (response options: 0='no Pap test done yet', 1='private gynecologist' and 2='public health services'). Furthermore, the interviewed women indicated the need to categorize the women based on their Pap screening frequency. Taking into account under-screened and over-screened women, 'Pap screening frequency' was measured by one direct question 'How often have you done a Pap test in the past three years?', with three answer categories 1='Less than once in the past three years' i.e. un- and under-screened, 2='Once in the past three years' i.e. regularly screened, 3='Twice or more often in the past three years' i.e. over-screened.

Modifying factors

Demographic factors were assessed through questions on age, marital status, (not) having children, level of education, income compared to average. Age was asked in the beginning of the survey to avoid interviewing women younger than 25, or older than 64 years old (response items 1=25-34, 2=35-44, 3=45-54, 4=55-64). In order for age to be part of the correlation analysis, an extra variable was computed to make age binary (with 0=25-44 and 1=45-64). Marital status had two response items, with 0 being single and 1 as married/living together. Having children was also a dichotomous variable with 0=No and 1=Yes. Level of education was an ordinal variable with five response items (1=Elementary school, 2=High school, 3=College, 4=University (graduate), 5=Master). Average yearly income was assessed with five response items, with answer categories 1=Low, 2=In between low and medium, 3=Medium, 4=In between medium and high, 5=High.

Personal experience with the disease – may be perceived as a cue to action – was initially assessed with three items. Taking into account the desired length of the survey, one question was thought to cover the intended three items (i.e. personal diagnosis / someone in your family

diagnosed / someone in your direct environment diagnosed) by reformulating the question into 'Do you have a personal history of cervical cancer within your direct environment?'; 0=No, 1=Yes).

Analysis

All data were coded and analyzed using SPSS version 16.0 for Windows.

Firstly, tests for normality were carried out for all scale variables (values of skew and kurtosis, Kolmogorov-Smirnov test). The three perceived benefits variables turned out not to be normally distributed. Therefore, in order to gain insight in which factors of the HBM and other variables are related to intention, Spearman's rank correlation was used to examine significant associations between the variables. Distinction was made between statistical significance at the .01 level and .05 level (both 2-tailed). To determine the potential relation between Pap screening frequency and intention, Spearman's rank correlation was used on the intention of the three different groups as well (under-screened, regularly screened and over-screened).

Hierarchical multiple regression analysis was used to assess the most important predictors of the woman's intention to use the Screener. Finally, additional regression analyses examined to what extent the three groups of women who differ in their screening frequency might also differ in the combination of variables predicting their intention to use the Screener.

As a final step in analysis, the residuals of the regression model were checked for normality. The Durbin-Watson was checked to be close to 2 (i.e. errors in regression are independent), the average of the VIF was checked to be close to 1 (i.e. no multicollinearity), and a close examination of the case summaries indicated no cases influencing the regression model (less than 5 percent of the standardized residuals values > 2).

Results

Of the 265 women who were approached, 200 women agreed to participate in this study, a response rate of 75.5 percent. Women who had a hysterectomy were excluded post hoc from the research, thus reducing the total sample to 193.

Table 1. Characteristics of the participants (*N*=193, no missing values)

Variable	Response items	n	%
Age group	25 – 34 years old	50	25.9
	35 – 44 years old	50	25.9
	45 – 54 years old	48	24.9
	55 – 64 years old	45	23.3
Marital status	Married, living together	131	67.9
	Single	62	32.1
Average income per year	Mean (SD)*	2.9	(0.8)
Education level	Elementary school	5	2.6
	High school	36	18.7
	College	109	56.5
	University	43	22.3
Previous experience CC	No	172	89.1
	Yes	21	10.9
Pap screening frequency	Un- and under-screened	49	25.4
	Regularly screened	72	37.3
	Over-screened	72	37.3
Pap test structure	No Pap test	28	14.5
	Public health services	89	46.1
	Private gynecologist	76	39.4

Note: CC is an abbreviation for cervical cancer. * Given are n and %, unless otherwise indicated.

As can be seen in Table 1,the majority of the respondents are married or living together, have children and an average yearly income. Over half of the respondents are employed and have a high educational level; 56.5 percent attended college and 22.3 percent are university graduates. Only one-tenth of the respondents had a personal history with cervical cancer within their direct environment. Most women were either regularly screened or over-screened (both groups 37.3 percent). The other women were under-screened; 14.5 percent never even had a Pap test before. Lastly, slightly half of the women go to the private structure, the rest goes to the public health services for their Pap screening.

Intention towards self-sampling

Overall, women were quite neutral in their intention towards using the self-sampling method. When examining Table 2, however, it can be seen that women most women are either definitely not interested in using the screener (23.3 percent) or definitely interested (21.8 percent).

When taking into account the Pap screening frequency, the mean scores differed slightly. From the three groups, the regularly screened are most likely to use the Screener, followed by the under-screened and the over-screened. A close examination of Table 2 shows that regularly screened are mostly neutral, whereas most over-screened women are (probably and definitely) not interested in using the Screener. Most under-screened women are either definitely interested in using the Screener or definitely not. It should be noted, however, that these differences between the groups turned out not to be significant.

Table 2. Descriptive statistics and frequency distribution of intention by Pap screening frequency

Variable	Total (N=193)		Pap screening frequency					
			Under-screened (n=49)		*Regular screened* (n=72)		*Over-screened (n=72)*	
	N	*%*	*n*	*%*	*n*	*%*	*n*	*%*
Intention								
Definitely not	45	23.3	16	32.6	13	18.1	16	22.2
Probably not	38	19.7	8	16.3	13	18.1	17	23.6
Neutral	33	17.1	3	6.1	18	25.0	12	16.7
Probably yes	35	18.1	7	14.3	14	19.4	14	19.4
Definitely yes	42	21.8	15	30.7	14	19.4	13	18.1
Mean (SD)	3,0	(1,5)	2,9	(1,7)	3,0	(1,4)	2,9	(1,4)

Note: * Given are n and %, unless otherwise indicated.

Variables of the Health Belief Model

Based on first-choice, women were asked to choose which option (self-sampling, private gynecologist and public health services) they considered most relevant. Looking at the frequency scores in Table 3, it can be seen that most women considered self-sampling to be the quickest method, and most convenient. The opposite could be said for the public health services; only few women believed public health services to be the quickest, most convenient and easiest method.
With respect to self-sampling, only few women estimated the method as trustworthy and reassuring. Instead, the private gynecologist was believed as the most reassuring and trustworthy option. Almost half of the women considered the private gynecologist as the most easy method as well.

Concerning perceived barriers, almost three quarters of the women believed that self-sampling was the most risky method when compared to the private gynecologist and public health services. Furthermore, almost all women said the private gynecologist was the most expensive option, with self-sampling and the public health services considered not expensive. For both perceived benefits and barriers, no significant differences in means were found for the under-screened, regular screened and over-screened women.

Table 3. Frequency distribution of perceived benefits towards self-sampling, the private gynecologist and public health services.

Variable	Towards Self-sampling		Towards the Private gynecologist		Towards the Public health services	
	N	*%*	*n*	*%*	*n*	*%*
*Perceived benefits (0-5)**	1.5	(1.3)	2.6	(1.7)	0.9	(1.4)
Quickest	110	57.0	65	33.7	18	9.3
Trustworthy	14	7.3	126	65.3	53	27.5
Convenient	85	44.0	83	43.0	25	13.0
Easiest	73	37.8	96	49.7	24	12.4
Reassuring	11	5.7	138	71.5	44	22.8
Perceived barriers						
Expensive	0	0.0	192	99.5	1	0.5
Risky	143	74.1	10	5.2	40	20.7

Note: * Given are n and %, unless otherwise indicated.

Since the perceived benefits and barriers have already been discussed, only the means of the perceived susceptibility, knowledge variables and behavioral factors are displayed in table 4. When examining the table, it can be seen that women reported a medium level of perceived susceptibility. Half of the women perceived their personal risk as medium (50.8 percent). An analysis of variance showed an overall significant effect for Pap screening frequency on perceived susceptibility. Scheffé's range test[a] found that the under-screened women differed significantly (at the 0.05 level) as compared to the regularly screened group, showing that under-screened women perceived a smaller personal risk than the regularly screened. No other significant differences were found between the groups.

Table 4. Means of HBM variables and modifying factors per Pap screening frequency

Variable	Total (N=193)	Under-screened (n=49)	Regular screened (n=72)	Over-screened (n=72)		
	M (SD)	*M (SD)*	*M (SD)*	*M (SD)*	*F*	*Sign.*
Perceived susceptibility (1-5)	3.0 (0.9)	2.7 (1.0)[a]	3.0 (0.9)[a]	3.2 (0.9)	4.94	< .01
Knowledge variables						
• Actual knowledge Pap (1-4)	2.6 (0.9)	2.3 (0.9)[b]	2.8 (0.7)[b]	2.5 (0.9)	6.43	< .01
• Perceived knowledge CC (1-4)	2.1 (0.8)	2.4 (0.8)[c]	2.0 (0.6)[c]	1.9 (0.8)[c]	7.09	< .01
Behavioral variables						
• Health preventive behavior (0-5)	2.9 (0.4)	1.8 (0.5)	1.7 (0.4)	2.0 (0.4)	1.18	Ns
• Previous testing behavior (0-4)	2.4 (1.3)	1.5 (1.5)[d]	2.6 (1.0)[d]	2.8 (1.0)[d]	22.35	< .01

Note: Ns is an abbreviation for not significant. CC is an abbreviation of cervical cancer. Gyn. is an abbreviation of gynecologist. [abcd] Scheffé range tests were found significant for these groups.

Overall, actual knowledge of the Pap test was between sufficient and good. Scheffé's range test[b] found that under-screened women differed significantly in their knowledge of the Pap test from regularly screened women; under-screened women mainly had a sufficient knowledge of the Pap test, regularly screened primarily had a good knowledge of the Pap test. Knowledge of cervical cancer was in general perceived as sufficient. A significant effect for Pap screening frequency on perceived knowledge was found; Scheffé's range test[c] showed that under-screened women had a higher self-reported knowledge of cervical cancer than the regularly screened women and the over-screened women. No other significant differences were found between the groups.

On average, the women agreed with three (out of five) health-related preventive behavior statements. When examining the frequency distribution, 52 out of the 193 women said to agree with three statements (26.9 percent). In comparison with all statements, most women agreed with the statement 'I visit medical specialists for preventive check-ups' (84.5 percent). With

respect to previous testing behavior, women had done about two out of the four exams. When examining the frequency distribution, most women, 66 out of the 193, said to have done three exams (34.2 percent). The Pap test was the exam performed on most women; 85.0 percent had done a Pap test in the past. Where no differences were found among the three groups for health-related preventive behavior, previous testing behavior did differ per Pap screening frequency. Scheffé's range test[d] found that under-screened women had less exams done than the regularly screened women and the over-screened women. This difference could have been expected, since under-screened are assumed to have less examinations done than regularly screened women.

Relation between intention towards using the Screener and variables of the HBM

As can be seen in Table 5, overall intention showed to have a significant positive relationship with perceived benefits of self-sampling as well as a significant negative relationship with perceived benefits of the private gynecologist. Thus, women who perceived more benefits of self-sampling had a higher intention to use the Screener, whereas women with higher scores on perceived benefits of the private gynecologist tend to have a lower intention. Furthermore, perceived barriers self-sampling being risky and public health services being risky were found to negatively correlate with intention. This means that women who perceived self-sampling and public health services as risky, were less intended to use the Screener.

Table 5. Correlations between all predictor variables and intention per Pap screening frequency

Variable	Intention			
	Total (N=193)	Under-screened (n=49)	Regular screened (n=72)	Over-screened (n=72)
Variables of HBM				
Perceived susceptibility	--	--	--	--
Perceived benefits:				
• Self-sampling	.59**	.56**	.61**	.56**
• Private gynecologist	-.35**	-.42**	-.34**	-.42**
• Public health services	--	--	--	--
Perceived barriers:				
• Self-sampling as risky	-.26**	--	-.49**	--
• Self-sampling as expensive	--	--	--	--
• Private gyn. as risky	--	--	--	-.29*
• Private gyn. as expensive	--	--	--	--
• Public health as risky	-.31**	--	.42**	.25*
• Public health as expensive	--	--	--	--
Knowledge variables				
• Actual knowledge Pap test	--	-.30*	--	-.30*
• Perceived knowledge CC	--	--	--	--
Behavioral variables				
• Health preventive behavior	--	--	--	--
• Previous testing behavior	--	--	--	--
• PHS as Pap test structure	.17*	.32*	--	--
• PG as Pap test structure	--	-.28*	--	--
• Past experience with CC	--	--	-.22†	--
Demographic variables				
• (Higher) age	--	--	--	--
• Marital status	--	--	--	--
• Average yearly income	--	--	--	--
• Education level	.15*	--	--	--

Note: † $p < .10$; * $p < .05$; ** $p < .01$. CC is an abbreviation of cervical cancer. PHS is an abbreviation of public health services. PG is an abbreviation of private gynecologist.

Opposite to what was assumed by the HBM, perceived susceptibility turned out not to be significantly related to intention. Among the behavioral variables and the knowledge variables, only the dummy variable of Public Health Services as the Pap test structure was found to be related. A similar small positive relationship was found for education level. This means that women with a higher intention are more likely to turn to the public health services for their Pap test and have a higher education level.

As shown in Table 5, it turned out that the strength of the relationship between perceived benefits of self-sampling and the private gynecologist differed slightly per Pap screening frequency. In general, however, higher scores of intention were related to more perceived benefits on self-sampling and lower scores of intention were found to be related to more perceived benefits of the private gynecologist. Most interestingly, among the under-screened perceived barriers showed not to be related to intention. The intention of regularly screened women was correlated with the perceived barriers self-sampling being risky and public health services being risky, with women who perceived self-sampling as risky showing lower scores of intention, whereas women who perceived public health services as risky showing a higher intention. The intention of over-screened women showed to be related to perceived barriers private gynecologist being risky and public health services being risky, indicating that over-screened women show a higher intention when they perceive the public health services as risky, and lower intention when the private gynecologist is perceived as being risky.

Furthermore, there was small but significant positive relationship of intention among under-screened with actual knowledge of the Pap test. This indicates that the under-screened women who had higher scores of intention knew less about the Pap test. Furthermore, the intention of under-screened women was found to be significantly positively related with the public health services as the Pap test structure, and negatively related to the public health services as the Pap test structure. This means that under-screened women who went to the private gynecologist for their Pap test had a lower intention to use the Screener, whereas the under-screened who went to the public health services had a higher intention towards using the self-sampling.

Among the regularly screened women, perceived benefits towards self-sampling and the private gynecologist showed to be related with intention (Cues to action showed to be only marginally related). The intention of over-screened women was related to the perceived benefits of self-sampling and the private gynecologist, as well as a negative relationship with the actual knowledge of the Pap test. Similar to the under-screened women, over-screened women who had higher scores of intention knew less about the Pap test.

The relationship of the over-screened women with the perceived barrier private gynecologist being risky is quite interesting. When examining the frequency distribution, only 4.2 percent of the over-screened said the private gynecologist was risky. The assumption here is that the negative relationship between the variables is actually an indication of the lack of the private gynecologist perceived as risky. This assumption however, cannot be confirmed.

Predicting intention to self-sampling

Following the Health Belief Model, the modifying factors are assumed to have an indirect effect on intention, whereas the perception variables are thought to directly predict intention. In a hierarchical regression model (enter method), only variables that correlated significantly with intention were entered as potential predictors of intention. The potential predictors were entered in blocks, allowing for the assumptions of the HBM to be assessed (i.e. indirect effect of modifying factors and direct effect of perception variables).

In the hierarchical regression model of overall intention, education level and the public health services as the Pap test structure were entered first, representing the modifying factors significantly correlating with intention. Both perceived benefits variables, perceived benefits of self-sampling and of the private gynecologist, and two perceived barriers (self-sampling being

risky and public health services being risky) were added to the second block, representing the perception variables which were found to correlate significantly with intention. Table 6 shows the outcome of this regression analysis.

Table 6: Hierarchical multiple regression of predictors of intention

Variable	Δ R^2	*B*	*SE*	*β*	*T*
Step 1	0.05**				
Constant		1.77	0.46		3.86**
Education level		0.33	0.15	.16	2.25*
PHS as Pap test structure		0.53	0.21	.18	2.49*
Step 2	0.33**				
Constant		1.11	0.52		2.13*
Education level		0.26	0.12	.13	2.09*
PHS as Pap test structure		0.31	0.18	.10	1.73
Perceived barrier: SS as risky		0.04	0.39	.01	0.10
Perceived barrier: PHS as risky		0.46	0.43	.13	1.08
Perceived benefits self-sampling		0.57	0.08	.52	6.84**
Perceived benefits PG		-0.02	0.06	-.02	-0.25

Note: N = 193; R^2 = 0.38 final model. * $p < 0.05$; ** $p < 0.01$. PHS is an abbreviation of public health services, PG is an abbreviation of private gynecologist, SS is an abbreviation of self-sampling.

As shown in Table 6, the first regression model, with the significant positive predictor education level and public health services as the Pap test structure, explained 5.4 percent of the variance ($F_{2,190} = 5.39$, $p < 0.01$). In the final model perceived benefits of self-sampling, perceived benefits of the private gynecologist, perceived barrier self-sampling being risky and perceived barrier public health services being risky were added, with 38.3 percent in intention explained ($F_{6,186} = 19.22$, $p < 0.01$). In this final model, the predictors that contributed significantly to intention were found to be two positive predictors: education level (β = .13) and perceived benefits of self-sampling (β = .52). As a final stage of the analysis, the assumptions of the model were checked.

Under-screened, regularly screened and over-screened

In three separate hierarchical multiple regression analysis, the potential predictors of intention were computed for the under-screened, regular screened and over-screened. The variables related to intention for each group were entered in blocks; in the first block modifying factors were entered, in the second block only the HBM that were found to correlate with intention were added.

Table 7: Hierarchical multiple regression of predictors of intention for under-screened (N=49)

Variable	Δ R^2	*B*	*SE*	*β*	*T*
Intention of under-screened					
Step 1	0.19*				
Constant		3.82	0.72		5.28**
Actual knowledge Pap test		-0.49	0.26	-.26	-1.88
PHS as Pap test structure		0.91	0.65	.26	1.40
PG as Pap test structure		-0.23	0.65	-.07	-0.35
Step 2	0.24**				
Constant		2.96	1.03		2.87**
Actual knowledge Pap test		-0.32	0.23	-.17	-1.41
PHS as Pap test structure		0.42	0.58	.12	0.73
PG as Pap test structure		-0.53	0.56	-.16	-0.96
Perceived benefits self-sampling		0.64	0.21	.47	3.03**
Perceived benefits PG		-0.07	0.16	-.07	-0.42

Note: N = 49; R^2 = 0.43 final model. * $p < .05$; ** $p < .01$. PHS is an abbreviation of public health services, PG is an abbreviation of private gynecologist.

Intention among under-screened was found to correlate significantly with the variables perceived benefits of self-sampling and perceived benefits of the private gynecologist, and modifying factors actual knowledge of the Pap test, public health services as the Pap test structure and the private gynecologist as the Pap test structure. As can be seen in Table 7, the first regression model, with the nonsignificant negative predictors actual knowledge and private gynecologist as the Pap test structure, and nonsignificant positive predictor public health services as the Pap test structure, explained 18.5 percent of the variance ($F_{3,45}$ = 3.41, p < 0.05). When the significant positive predictor perceived benefits of self-sampling and the nonsignificant negative predictor perceived benefits of the private gynecologist were added, the final model explained 42.8 percent in intention ($F_{2,43}$ = 9.10, p < 0.01). In this final model the predictor that contributed significantly to intention among under-screened was the positive predictor perceived benefits of self-sampling (β = .47). As a final stage of the analysis, the assumptions of the model were checked.

Table 8: Hierarchical multiple regression of predictors of intention for regularly screened (N=72)

Variable	Δ R^2	*B*	*SE*	*β*	*T*
Intention of regularly screened					
Step 1	0.39*				
Constant		2.70	0.82		3.28*
Perceived barrier: SS as risky		-0.71	0.70	-.24	-1.02
Perceived barrier: PHS as risky		-0.22	0.69	-.07	-0.32
Perceived benefits self-sampling		0.53	0.15	.54	3.50*
Perceived benefits PG		0.04	0.10	.06	0.46

Note: N = 72; * p < .01. PG is an abbreviation of private gynecologist.

Intention among regularly screened was found to correlate significantly with the variables perceived benefits of self-sampling and perceived benefits of the private gynecologist, perceived barrier self-sampling as risky and perceived barrier public health services as risky. There were no modifying factors that correlated significantly with intention. Table 8 demonstrates that the final model explained 39.5 percent in intention ($F_{4,67}$ = 10.96, p < 0.01). The predictor that contributed significantly to intention among regularly screened women was the positive predictor perceived benefits of self-sampling (β = .54). As a final stage of the analysis, the assumptions of the model were checked.

Table 9: Hierarchical multiple regression of predictors of intention for over-screened (N=72)

Variable	Δ R^2	*B*	*SE*	*β*	*T*
Intention of over-screened					
Step 1	0.03				
Constant		2.21	0.50		4.45*
Actual knowledge Pap test		0.27	0.19	.17	1.43
Step 2	0.41*				
Constant		1.49	0.52		2.87*
Actual knowledge Pap test		0.20	0.15	.12	1.32
Perceived barrier: PG as risky		-1.08	0.67	-.15	-1.61
Perceived barrier: PHS as risky		0.71	0.36	.19	1.97
Perceived benefits self-sampling		0.56	0.12	.53	4.83*
Perceived benefits PG		-0.02	0.09	-.02	-0.21

Note: N = 72; R^2 = 0.44 final model.* p < .01.
PHS is an abbreviation of public health services, PG is an abbreviation of private gynecologist.

Intention among over-screened women was found to correlate significantly with the perception variables perceived benefits of self-sampling and perceived benefits of the private gynecologist, perceived barrier private gynecologist being risky, public health services being risky and modifying factor actual knowledge of the Pap test. The first regression model, with the nonsignificant positive predictor actual knowledge of the Pap test, explained 2.8 percent of the variance ($F_{1,70}$ =

2.05, ns). When the perceived barrier and benefit variables were added, the final model explained 43.7 percent in intention ($F_{5,66}$ = 10.23, p < 0.01). In this final model, shown in table 9, the predictor that contributed significantly to intention was the positive predictor perceived benefits of self-sampling (β = .56). As a final stage of the analysis, the assumptions of the model were checked.

When looking at the regression models of the under-screened, regularly screened and over-screened, the results show only one significant positive predictor in all models varying in strength; perceived benefits of self-sampling among under-screened β = .47, regularly screened β = .54 and over-screened β = .53.

Conclusion

Many studies have used the Health Belief Model to predict the likelihood of preventive health behaviors in cervical cancer screening. Most of these studies focused on either previous and future (Pap) screening behavior (Hill, Gardner & Rassaby, 1985; Norman & Conner, 1993; Fylan, 1998; Agurto *et al.,* 2004; Ingledue, Cottrell & Bernard, 2004; Sutton & Rutherford, 2005; Champion & Skinner, 2008; Waller, Bartoszek, Marlow & Wardle, 2009; Tanner-Smith & Brown, 2010), but more recently, studies have been using the HBM to examine the likelihood of self-sampling (Dzuba *et al.,* 2002; Flores *et al.,* 2003; Waller *et al.,* 2006, Stewart, Gagliardi & Johnston, 2007). The psychological factors which have shown to be directly related to intention are perceived threat to cervical cancer and the perceived barriers and perceived benefits of self-sampling.

This study analyzed beliefs related to cervical cancer and screening, and other socio-demographic factors from the Health Belief Model to understand the intention towards self-sampling for cervical cancer screening among a sample of the Italian female population. In terms of intention to use the Screener, this study revealed that most women showed to be either definitely interested or definitely not interested in self-sampling and were overall quite neutral in their intention to use a method like the Screener. When looking at perceived susceptibility, most women reported a medium level of personal risk. With respect to perceived benefits, most women found self-sampling the quickest and most convenient method in comparison with the private gynecologist and public health services. Only few women estimated self-sampling as trustworthy and reassuring. Instead, the private gynecologist was believed as the most reassuring, easiest and trustworthy option. Concerning perceived barriers, almost three quarters of the women believed that self-sampling was the most risky method compared to the other two options. Moreover, almost all women said the private gynecologist was the most expensive option, with self-sampling and the public health services considered not expensive.

Similar to previous studies (Dzuba *et al.,* 2002; Flores *et al.,* 2003; Waller *et al.,* 2006, Stewart, Gagliardi & Johnston, 2007), this study found that intention towards self-sampling was related to both perceived benefits and barriers. More specifically, women who perceived more benefits of self-sampling had a higher intention to use the Screener, whereas women with higher scores on perceived benefits of the private gynecologist showed a lower intention. Furthermore, women who perceived self-sampling and public health services as risky, were less intended to use the Screener. Opposite to what was expected (following Norman & Conner, 1993), perceived susceptibility turned out not to be significantly related to intention. In line with other studies that showed a significant relation between education and intention towards using the Pap test (Sutton & Rutherford, 2005), and a self-sampling method (Tisci *et al.,* 2003), education level was found to be related to the intention to self-sampling as well, indicating that better educated women showed a higher intention towards using the Screener.

A hierarchical regression analysis was used to assess the most important predictors of the woman's intention to use the Screener. The final model, including perceived benefits towards self-sampling, perceived benefits of the private gynecologist, perceived barriers self-sampling being risky and public health services being risky, education level and turning to the public health

services for Pap screening, explained almost 40 percent of the variance in intention towards self-sampling. Nevertheless, only perceived benefits towards self-sampling and education level were significant predictors of intention.

Considering that previous research on HBM and cervical screening focused mostly on increasing compliance of non-attenders to organized cervical screening, this study assessed to what extent women who show a different Pap screening behavior (under-screened, regularly screened and over-screened) vary in their intention to use the Delphi Screener. When examining the intention towards self-sampling among these three groups, regularly screened were found to be most interested in using a self-sampling method, followed by the under-screened and over-screened. The overall intention, however, was for all groups mostly neutral, and the observed differences were not significant. Though the factors related to intention differed among the three groups, perceived benefits of self-sampling turned out to be the only significant explanatory variable in all three regression models.

Discussion

This study provides a number of contributions to the existing body of research. First, this study provides a possible explanation *why* women intend to use a self-sampling method such as the Delphi Screener, assessing both the variables of the HBM and other potential factors like Pap screening behavior in terms of frequency and structure. No other published studies examined the relation of intention towards self-sampling with Pap screening behavior, taking into account women who are screened on a regular basis, at a more frequent interval and at an insufficient interval, nor the influence of the screening structure. The regression models on the intention of these groups of women show indeed that different factors explain and predict the likelihood to self-sampling. Even though the regression models are of limited use because of the relative small number of women in each calculation, these differences have implications for future communication to the women. Especially in the regions in Italy where cervical cancer screening is not well functioning and where the portion of both under-screened and over-screened women are significant, the communication towards the women regarding the Screener and the concept of self-sampling should be tailored. Furthermore, when looking at the behavioral variables and the knowledge variables, women who are likely to turn to the public health services for their Pap test show a higher intention towards self-sampling. Even though cervical cancer screening is organized differently from country to country (and in Italy even from region to region), examining the Pap test structure and screening frequency in relation to the use of a screening method is suggested for further research.

Various studies already showed a higher response rate of under-screened women to participate in organized screening when using a self-sampling method as compared to the standard recall letters (Gök *et al.,* 2010; Giorgio-Rossi *et al.,* 2011). These post-use studies showed that women preferred the Screener over the pelvic examination (or traditional Pap test). This study was different in assessing the intention to use a self-sampling HPV method for cervical cancer, without women actually using the device. It examined women's perceptions of benefits and barriers and their relation to intention, taking into account both women who do not intend to use the Screener and those who are willing to perform self-sampling. In that sense, direct experience with the Screener is assumed not to have influenced the beliefs towards self-sampling. Nevertheless, when looking at the neutral reactions of the women towards the Screener, it could be that providing the women with too limited information had a negative effect on intention. When comparing results of this study with the positive reactions of the women post-use in other studies (Jones *et al.,* 2008), further research should determine if a better explanation of the concept and a more in-depth description of the product and its functioning might influence women's beliefs.

Since the perceived benefits and barriers relied on a first-choice approach between self-sampling and two known institutions – being the private gynecologist and the public health services – the results of this study are of limited use. Moreover, the perceived benefits and barriers mentioned in the survey were predetermined in the formative stages of the study. This approach towards the

perceived benefits and barriers, was chosen because of the desired length of the survey, but its potential impact should be further investigated.

In order to provide women with an alternative to receiving the Screener at home or going to the doctor for cervical screening, and reduce the high costs of loss in direct mailing, i.e. Screeners who are send home but consequently not used (Gök *et al.,* 2010; Giorgio-Rossi *et al.,* 2011), the pharmacy is suggested as an alternative distribution point in the future. Given the fact that in Italy the pharmacy is highly accessible (with in urban areas situated at virtually every corner), that pharmacies since recently are obliged by law to contribute actively in preventive screening efforts and that women visit the pharmacy on a frequent basis, commercializing the product in the pharmacy is assumed to improve screening coverage as well (Delphi Bioscience, 2011). This study was first to examine if women intend to use the Screener outside a screening program, if it were to be available in the pharmacy. However, since this study primarily examined the intention towards self-sampling as an alternative method for the Pap test, further research should determine the potential influence of offering the Delphi Screener as a total service in the pharmacy. Only women's beliefs to the concept of self-sampling were assessed, thereby not allowing other related factors to be analyzed. These factors may include for example the self-sampling method being the Screener, the process of getting the Screener in the pharmacy, the beliefs of women receiving results of a medical test at home, the responsibility of the women taking action when follow-up is necessary. Furthermore, this study measured only behavioral intentions, with no verification if women would have actually bought the product. Further research should determine to what extent these aspect and others might be related to the intention towards self-sampling and the actual behavior of women.

This study also had several limitations. Firstly, although the response rate was quite high (75.5 percent), we had no information about non-responders. We therefore cannot rule out the possibility of selection bias. Those who participated in this study may have been more interested in cervical cancer screening than the non-responders. In addition, data was collected over the telephone, which may have resulted in sample selection bias. Furthermore, people have shown to overestimate self-reported cancer screening (Caplan *et al.,* 2003), allowing for a measurement error to be introduced in the self-reported information about cancer screening in this study.

Considering the relatively small amount of variance explained, the biggest limitation of this study is not taking into account alternative factors suggested to predict health behavior, such as outcome expectancy, i.e. the women's perception she will be healthier as a result of the action (Boer & Seydel, 1996). Especially not including 'perceived self-efficacy' (in which the woman should believe herself capable enough to perform a preventive health behavior such as self-sampling before taking action) is suggested as one of the reasons only a small amount of variance was explained (Schwarzer & Fuchs, 1996). Taking into consideration the desired length of the survey and in order to avoid different interpretations among respondents, only a limited amount of information on the Screener was mentioned during the study; the Screener was said to be a 'preventive risk assessment tool for cervical cancer screening'. Given the limited information communicated to the women, it was assumed the woman could not form self-efficacy beliefs regarding the subject and it was therefore decided not to include perceived self-efficacy in this study. Since other studies have reported the influence of practical barriers of self-sampling (such as not having confidence in doing the test correctly) similar to the concept of perceived self-efficacy (Stewart, Gagliardi & Johnston, 2007), further research is suggested to determine if indeed perceived self-efficacy is related to intention to using the Screener.

Despite its limitations, this study has several important implications for improving cervical cancer screening. A close examination of the perceived benefits frequencies shows that the main advantage of the private gynecologist involves around matters of trust (it was considered most reassuring and trustworthy). Considering that the perceived benefits of the private gynecologist had a negative relationship with intention, a focus on trust in the Screener could potentially overcome one of the barriers towards the intention to use. Given the fact that the Screener was

mentioned only a few times as being trustworthy and reassuring, and very frequently as being risky, it is suggested that future communication on the Delphi Screener should focus on improving the perceived trust of the woman regarding the method. During the survey, no information was given about the validity and reliability of the Screener, so further research in the construct trust should determine if this alternative factor will be able to explain a higher amount of variance in intention.

Briefly worded, the use of the HBM framework resulted in important information regarding the women's beliefs. Both perceived benefits and perceived barriers were found to explain approximately 40 percent of intention among women in Milan towards self-sampling. There were differences in the factors explaining intention among the under-screened, regularly screened and over-screened, suggesting that communication should be tailored in order to reach all women within the target audience. Overall, in communication to the women, demonstrating the perceived benefits of self-sampling (i.e. quick and convenient) should ensure acceptance of the concept and might influence their intention to use this self-sampling method for cervical cancer screening. As a result, even women who are at a higher risk and are not screened in the recommended interval might be reached with this novel self-sampling method and interested in using the Screener, thereby decreasing cervical cancer incidence and mortality. Self-sampling with the Delphi Screener might improve screening coverage by overcoming perceived barriers and highlighting perceived benefits women to participate in cervical cancer screening.

Personal reflection

Starting as a translator Italian to English, English to Italian for Delphi Bioscience in December 2009, I soon began discussing with the CEO, René Hol, about writing my master's thesis for the company. Since only research on the clinical performance of the Screener has been published, it was considered important to investigate the women's beliefs towards cervical cancer, cervical screening and using a self-sampling tool for cervical cancer screening. End of May 2010, I moved to Milan to start my internship for Delphi Bioscience, assisting the project leader to prepare a pilot project to commercialize the Screener in the Italian pharmacy, working as a translator for the company and, last but not least, performing my research!

My first survey format included variables from various health behavior models (both cognition models and stage models). Unfortunately, it turned out to be impossible to get enough women to fill in that version of the survey (ten pages long). Even when shortening the survey to three pages, using a few hairdresser's salons to distribute the survey, and using only the Health Belief Model variables, my efforts didn't give me enough respondents (a response rate of less than 10%). After more than half a year of little success in increasing the number of respondents, it was decided to contact a market research company in Milan to provide me with a database for a telephone survey. Making use of their database, I finally finished collecting all data in little over a month. Once I moved back to the Netherlands having lived in Milan for about a year, I started completing the document that you just finished reading.

This research, however, could not have been completed without the help of a number of people. I want to thank first and far most Rene Hol and my fellow colleagues from Delphi Bioscience for this opportunity to create, implement and perform a research on such an interesting subject in the beautiful city of Milan, Italy. I also want to thank my first and second reader from the University Twente, Erik Taal and Stans Drossaert, for their guidance and being strict but fair with their advise. I also want to thank the people who were there for me whenever I had an off-day with my research; Clunys, Marieke, Elise, Mom, Dad, family and friends, I couldn't have done it without your support and your weekend visits to Milan! I want to thank Pietro, Simona and Ariana from Criterion for assisting me with performing the telephone surveys. I also want to thank the IEO (Istituto Europea di Oncology: European Institute of Oncology), dr Giorgio-Rossi and dr. Angeloni for providing me with relevant information for my thesis. Last but not least, I want to thank my dear Italian colleague – the project leader of Delphi Bioscience in Milan – from whom I learned to be patient with the Italian way of working; Patrizia Franchini, ti ringrazio per tutto!

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Appendix 1: The telephone survey - Script

Good day / good evening,
we are conducting a research on the opinions of women regarding their health. Can I ask you some questions? I remind you that this interview is anonymous and that the information you give us will be used without referring in any way to the interviewed person, like the law 196a concerning privacy requests.

1. What is your age?
- Less than 25, over 64 → Close
- 25 – 34 1
- 35 – 44 2
- 45 – 54 3
- 55 – 64 4

2. Now let's talk about how you organize yourself when it comes to prevention regarding health. I will read out loud some situations and behaviors. Please tell me with what frequency this occurs.

	Never	*Sometimes*	*Often*
- I regularly check my blood pressure	1	2	3
- I do regular blood-tests	1	2	3
- I undergo other clinical trials (feces, urine etc.)	1	2	3
- I regularly visit my doctor for preventive check-ups	1	2	3
- I visit medical specialists for preventive check-ups	1	2	3

3. Have you had any of the following exams?	*No*	*Yes*
- Mammography	0	1
- Breast ultrasound	0	1
- Pap test	0	1
- BMD	0	1

4. Can you tell me everything you know about the Pap test?

_____

In reality, the Pap test is a preventive diagnosis of cervical cancer.

5. How often did you have a Pap test in the past three-years?
- Less than once in the past three years 1
- Once in the past three years 2
- Twice or more often in the past three years 3

6. To which type of structure did you turn to the last time you did the Pap test?
- I have not had a Pap test before 0
- To the private structure (private clinic, gynecologist) 1
- To the public structure (public clinic, medical consult, hospital) 2

Like we said, the Pap test serves for the prevention of cervical cancer.

Imagine that, instead of the traditional Pap test at a clinic, you are given the opportunity to buy an kit in the pharmacy that allows you to do a preventive check-up on cervical cancer at your own house. The sampling can easily be done by yourself, after that you can deliver the sample to the pharmacy and receive the results after a few days.

7. If this kit were to be available, do you intend to use it?
   - Definitely not 1
   - Probably not 2
   - Neutral 3
   - Probably yes 4
   - Definitely yes 5

   13.1 Why (not)?_____

Imagine now to do such a self-sampling test.

8. Between these three possibilities, which one is for you …

	Self-sampling	Private gyn.	Public health
…quickest?	1	2	3
…most expensive?	1	2	3
…most trustworthy?	1	2	3
…most convenient?	1	2	3
…easiest?	1	2	3
…most risky?	1	2	3
…most reassuring?	1	2	3

Finally I would like your opinion on cervical cancer.

9. How do you personally evaluate your level of knowledge about this cancer?
   - Nonexistent 1
   - Scarce 2
   - Sufficient 3
   - Good 4

10. How likely do you think it is that a woman of your age will get cervical cancer?
   - Low 1
   - In between low and medium 2
   - Medium 3
   - In between medium and high 4
   - High 5

Background data

a) You are…
   - Single 0
   - Married, living together 1

b) Do you have children?
   - No 0
   - Yes 1

c) What is your highest level of education?
   - Elementary school 1
   - High school (diploma) 2
   - College 3
   - University (graduate) 4
   - Master 5

d) According to ISTAT Italian Statistics of 2010, the average income per year (reddito medio) for the region Lombardy is €24.540,- . Compared to these statistics, how do you rate your income?

- Low 1
- In between low and medium 2
- Medium 3
- In between medium and high 4
- High 5

f) Do you have a personal history of cervical cancer within your family?

- No 0
- Yes 1