

# A pilot study of community-based self-sampling for HPV testing among non-attenders of cervical cancer screening programs in El Salvador

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## Abstract

**Objective:** To establish the feasibility and acceptability of home-based HPV self-sampling among women who did not attend screening appointments in rural El Salvador.

**Methods:** In a cross-sectional study, data were collected from May 2015 to January 2016 among 60 women aged 30–59 years who were not pregnant, provided informed consent, had not been screened in 2 years, had no history of pre-cancer treatment, and did not attend a scheduled HPV screening. Participants completed questionnaires and received educational information before being given an opportunity to self-sample with the Hybrid Capture 2 High Risk HPV DNA Test.

**Results:** Self-sampling was accepted by 41 (68%) participants. Almost all women chose to self-sample because the process was easy (40/41, 98%), could be performed at home (40/41, 98%), and saved time (38/41, 93%), and because they felt less embarrassed (33/41, 80%). The most common reason for declining the test was not wanting to be screened (8/19, 42%). The prevalence of high-risk HPV types among women who accepted self-sampling was 17% (7/41).

**Conclusion:** For most women, community-based self-sampling was an acceptable way to participate in a cervical cancer screening program. In low-resource countries, incorporating community-based self-sampling into screening programs might improve coverage of high-risk women.

## KEYWORDS

Cervical cancer; Community-based screening program; Feasibility; HPV; Low-resource countries; Self-sampling

## 1 | INTRODUCTION

Cervical cancer is the fourth most commonly diagnosed cancer among women worldwide, and more than 80% of new cases occur in low- and middle-income countries (LMICs).<sup>1,2</sup> In El Salvador, cervical cancer incidence and mortality are among the highest in the world (respectively, 25 and 11.9 per 100 000 women [age-adjusted]).<sup>3</sup> Current screening

programs reach few women, with estimates ranging from 19% to 47% depending on the survey.<sup>4</sup> Moreover, 40% of women with an abnormal diagnosis do not receive adequate follow-up or treatment.<sup>5</sup>

In high-income countries, cytology-based screening programs have successfully reduced cervical cancer mortality; however, such programs are less feasible in low-income countries.<sup>6</sup> HPV DNA testing, which offers high sensitivity and does not require the multi-step



process needed for cytology-based programs, is thus a promising approach to primary screening in LMICs.

In 2014, El Salvador introduced HPV DNA testing into the public sector through the Cervical Cancer Prevention (CAPE) initiative.<sup>7,8</sup> However, one study<sup>9</sup> showed that 25%–30% of targeted women in rural areas did not attend scheduled provider-based screenings. Self-sampling could increase screening coverage: Rosenbaum et al.<sup>10</sup> reported that more than 60% of women in rural regions of the country accepted the practice. In other low-resource settings, self-collection has also been shown to be an appealing alternative to provider-based screening.<sup>11–16</sup> Therefore, investigating the acceptance of the practice among non-attenders (i.e. women who do not attend provider-based screening appointments) is important and could identify areas where improved patient education is required.

The primary aim of the present pilot study was therefore to establish the feasibility and acceptability of home-based self-sampling for HPV testing among a population of non-attenders in the CAPE program in El Salvador. Secondary aims were to determine factors associated with accepting and declining self-sampling, and differences in barriers and motivations between the two groups.

## 2 | MATERIALS AND METHODS

The present cross-sectional study was undertaken from May 1, 2015, to January 31, 2016, among women who did not attend scheduled appointments for cervical cancer screening. The study was approved by University of Pittsburgh Institutional Review Board and the National Ethical Review Board of El Salvador. All participants provided informed consent (signature or fingerprint).

Women were recruited from patient registries compiled during phases 1 and 2 of the CAPE program.<sup>7,8</sup> These registries included individuals aged 30–49 years with no record of cervical cancer screening in the previous 5 years and who fell within the catchment area of local primary healthcare clinics that had been assigned by the Ministry of Health to take part in CAPE. These communities were located in the Paracentral region of El Salvador and included San Pedro Perulapan, San Sebastian, Apastepeque, San Rafael Cedros, Candelaria, Periferica de San Vicente, Tecoluca, and Suchitoto. Non-attenders were identified from the same registries who attended educational sessions about cervical cancer screening and scheduled a screening but did not attend the appointment, and through community health workers (CHWs) who lived in the same areas. All names were cross-checked against the database of women who were already screened through CAPE to ensure that individuals in the recruitment pool had not been previously screened.

A sample size of 60 was planned on the basis of feasibility, time constraints, and size of the participating communities. Non-attenders were assigned an identification number and a random number generator was used to select 60 potential participants. Two researchers (BL and RF) and at least one CHW from the same community went to the homes of the identified women to determine eligibility. Eligible participants were aged 30–59 years, not pregnant, and capable of providing

informed consent. Women screened within the past 2 years or with a history of cryotherapy, loop electrosurgical excision procedure, or hysterectomy were excluded from the study. If, on the home visit, a woman did not meet the eligibility criteria, the next randomly chosen woman was visited. Recruitment ended when the sample size of 60 participants was reached. No incentive to participate was provided.

After enrollment, the researchers administered an oral questionnaire in a private area of the home chosen by the women. The English survey is shown in Appendix S1, and the Spanish version is shown in Appendix S2. Information about sociodemographic characteristics (age, education, marital status, household size, and number of children), sexual history (age at first intercourse, number of lifetime sexual partners, and birth control method), smoking history, previous cervical cancer screening, knowledge and risk perception of HPV and cervical cancer, and reasons for non-attendance.

Women were then offered the opportunity to self-sample during the visit. They were shown the self-sampling device (hc2 DNA Collection Device; Digene Corporation, Gaithersburg, MD, USA), and given verbal instructions with a visual aid showing how to collect the sample. Women were instructed to insert the brush into the vagina until resistance was felt, and to turn the brush three to five times. They were told to remove the brush, place it into the tube, break the plastic portion of the brush, and close the tube. After receiving these instructions, women who agreed to self-sampling went to a private location in their home and used the device. Researchers and the CHW were available in case the women requested assistance, but only one participant did so. After self-collection, researchers asked additional survey questions focused on reasons for agreeing to self-sampling. Women who participated were advised to attend a retest at a health clinic within 1 year, because self-sampling is not yet an approved cervical cancer screening tool in El Salvador. If a woman declined self-sampling, she was asked her reasons for not participating and advised to schedule provider-based cervical cancer screening.

The samples were analyzed for 13 high-risk HPV genotypes at the José Matías Delgado University, San Salvador, El Salvador. A pooled HPV DNA assay (Hybrid Capture 2 High-Risk HPV DNA Test; Digene Corporation) was used. This test has been used in other self-sampling studies around the world.<sup>17,18</sup>

After the samples were analyzed, the results were collected by the researchers and sent to the women's health centers. Women were informed of the results by providers and health promoters at their assigned clinic through existing systems. Women who tested positive were referred to the regional public hospital for colposcopy, biopsy sampling, and recommended treatment.

Minitab Express version 1.4.0 (Minitab, State College, PA, USA) was used for data analysis. Univariate analyses were used to compare demographic characteristics, sexual and medical history, knowledge and perceived risk of HPV and cervical cancer, reasons for non-attendance at the clinic, and concerns about self-sampling between women who declined and those who accepted self-sampling. These factors were evaluated for their association with acceptance of self-sampling using  $\chi^2$  or Fisher tests of significance.

An association was considered statistically significant if the *P* value was 0.05 or less.

### 3 | RESULTS

The mean age of participants was 40.7 years. Table 1 shows their sociodemographic characteristics. Most women had not received more than an elementary school education, and three-quarters were married, widowed, or partnered. A substantial portion had more than five children. Most were sexually active before 20 years of age, and more than one-quarter were younger than 16 years at first intercourse. Few women reported four or more sexual partners in their lifetime; more than two-fifths reported only one. Cervical cancer knowledge, risk perception, and screening history of the women are presented in Table 2.

Community-based self-sampling was accepted by 41 (68%) of the 60 participants. High-risk strains of HPV were detected in 7 (17%) of these women. Table 3 shows the reasons that women who participated in self-sampling provided and their assessment of the self-sampling experience. Over 90% of the women gave as reasons that self-sampling was an easy process, it could be performed in their own home, it saved time, and they felt less embarrassment (Table 3). Sixty-three percent of these women agreed with the statement "Self-collection made you feel empowered/in control." All but one woman would perform self-sampling again. Overall, the women rated the experience as an average of 9.5 on a scale of 1–10 (10 indicated highest satisfaction), felt confident that they had completed the test accurately, and felt little discomfort (Table 3).

As shown in Table 4, the most common concerns about self-sampling were that the brush would cause pain and they might hurt themselves during the sampling. Disinterest in screening, preference for clinician sampling, lack of privacy at home, discomfort with touching themselves, embarrassment regarding the procedure, or worrying about their partner's opinion were not listed as concerns by women who accepted self-sampling.

Among the 19 women who declined self-sampling, the most common reason was not wanting to be screened at all. The least common reason for declining was concern that the results might not be correct. As compared with those who accepted self-sampling, a higher proportion of women who declined self-sampling expressed concerns about touching themselves, felt embarrassed by self-sampling, preferred not to be screened, preferred that a clinician take the sample, or reported not having the time and/or privacy in their own home (all  $P < 0.001$ ). Notably, 16 (84%) of the 19 women who declined self-sampling chose at least one of these five concerns, but no women who accepted self-sampling chose any of these (Table 4).

As shown in Table 5, women who declined self-sampling were more likely to perceive themselves to be at low risk for cervical cancer and indicate that they did not need to go to clinic because they did not have symptoms. Perceived risk of HPV infection, however, was not statistically associated with declining self-sampling.

**TABLE 1** Sociodemographic characteristics of participants.<sup>a</sup>

Characteristic	Overall (n=60)	Self-sampling		<i>P</i> value <sup>b</sup>
		Accepted (n=41)	Declined (n=19)	
Age, y				0.111
30–40	28 (47)	22 (54)	6 (32)	
>40	32 (53)	19 (46)	13 (68)	
Highest education				0.102
None/elementary	42 (70)	26 (63)	16 (84)	
Middle/high school	18 (30)	15 (37)	3 (16)	
Marital status				0.262
Married/ widowed/ partnered	45 (75)	29 (71)	16 (84)	
Divorced/ separated/single	15 (25)	12 (29)	3 (16)	
Work outside the home				0.570
Yes	22 (37)	16 (39)	6 (32)	
No	38 (63)	25 (61)	13 (68)	
No. of children				0.944
0–2	9 (15)	6 (15)	3 (16)	
3–4	24 (40)	17 (41)	7 (37)	
≥5	27 (45)	18 (44)	9 (47)	
Size of household				0.225
0–4	29 (48)	22 (54)	7 (37)	
≥5	31 (52)	19 (46)	12 (63)	
Smoked >100 cigarettes in life				0.233
Yes	3 (5)	3 (7)	0	
No	57 (95)	38 (93)	19 (100)	
Age of first intercourse, y				0.991
<16	16 (27)	11 (27)	5 (26)	
16–19	31 (52)	21 (51)	10 (53)	
≥20	10 (17)	7 (17)	3 (16)	
Missing	3 (5)	2 (5)	1 (5)	
Lifetime sexual partners				0.317
1	24 (40)	15 (37)	9 (47)	
2–3	27 (45)	19 (46)	8 (42)	
≥4	4 (7)	4 (10)	0	
Missing	5 (8)	3 (7)	2 (11)	
Birth control method (ever, multiple answers per respondent allowed)				0.308
Oral contraceptives	17 (28)	14 (34)	3 (16)	

Table 1 Continued

Characteristic	Overall (n=60)	Self-sampling		P value <sup>b</sup>
		Accepted (n=41)	Declined (n=19)	
Injectable	33 (55)	24 (59)	9 (47)	
Intrauterine device	4 (7)	3 (7)	1 (5)	
Other	17 (28)	10 (24)	7 (37)	
None	14 (23)	7 (17)	7 (37)	

<sup>a</sup>Values are given as number (percentage) unless indicated otherwise.

<sup>b</sup>By  $\chi^2$  or Fisher exact test.

Refusal of self-sampling was associated with the following reasons for non-attendance at scheduled cervical cancer screening: no need to be screened ( $P=0.052$ ), not at risk of cervical cancer ( $P=0.016$ ), and having no symptoms ( $P=0.018$ ) (Table 5).

## 4 | DISCUSSION

The results showed that, for a majority of non-attenders in the Paracentral region of El Salvador, community-based self-sampling might be an acceptable way to participate in a cervical cancer screening program. Consistent with previous findings, women who accepted self-sampling were younger, more educated, and more frequently unmarried, although these associations were not statistically significant. Other studies on community-based self-sampling<sup>12,16,19</sup> found that acceptance of self-sampling was inversely related to age; however, the present pilot study did not confirm this finding.

In the present study, 26% of women who declined self-sampling were likely to perceive themselves as not at risk of cervical cancer; by contrast, only 5% of women who accepted saw themselves as not at risk. These findings indicate that some women might not make the association between lack of screening and cervical cancer risk, highlighting the need for improved education.

The present study corroborates existing studies on acceptability and reasons for choosing self-sampling.<sup>12,20,21</sup> Most women in this study chose self-sampling because of practical reasons: convenience, privacy, and less embarrassment. Most women who accepted self-sampling were satisfied with their experience and would choose it again. Overall, the acceptance of community-based self-sampling was similar to that reported for clinic-based self-sampling.<sup>10</sup> Although many women listed pain and discomfort as concerns regarding self-sampling, most of them felt little or no discomfort during the collection. Almost two-thirds of the women who accepted self-sampling reported that choosing self-sampling made them feel empowered or in control of their health. Testimonials by women satisfied with self-sampling and empowered by the opportunity to be proactive about their health might be incorporated in education and future screening campaigns.

Under-screened women are more likely to be at higher risk of cervical cancer. In the present non-attender population, the prevalence of high-risk HPV was 17%, which is higher than that observed during the

**TABLE 2** Knowledge, risk perception, and screening history of participants.<sup>a</sup>

Variable	Overall (n=60)	Self-sampling		P value <sup>b</sup>
		Accepted (n=41)	Declined (n=19)	
Heard about HPV previously				0.113
Yes	30 (50)	23 (56)	7 (37)	
No	28 (47)	16 (39)	12 (63)	
Missing	2 (3)	2 (5)	0	
History of HPV infection				0.160
Yes	7 (12)	5 (12)	2 (11)	
No	34 (57)	20 (49)	14 (74)	
I don't know/not sure	19 (32)	16 (39)	3 (16)	
Could get HPV				0.386
Yes	42 (70)	30 (73)	12 (63)	
No	10 (17)	5 (12)	5 (26)	
I don't know/not sure	8 (13)	6 (15)	2 (11)	
Seriousness of HPV				0.820
Serious/somewhat serious	11 (18)	8 (20)	3 (16)	
Extremely serious	36 (60)	25 (61)	11 (58)	
I don't know/not sure	13 (22)	8 (20)	5 (26)	
Could get cervical cancer				0.159
Yes	41 (68)	31 (76)	10 (53)	
No	14 (23)	8 (20)	6 (32)	
I don't know/not sure	5 (8)	2 (5)	3 (16)	
Seriousness of cervical cancer				0.350
Serious	2 (3)	2 (5)	0	
Extremely serious	57 (95)	39 (95)	18 (95)	
Missing	1 (2)	0	1 (5)	
Last screen for cervical cancer				0.264
<3 y	25 (42)	17 (41)	8 (42)	
≥3 y	30 (50)	19 (46)	11 (58)	
Never	5 (8)	5 (12)	0	
Previous screen was routine				0.070
Yes	48 (80)	32 (78)	16 (84)	
No	7 (12)	7 (17)	0	
Missing	5 (8)	2 (5)	3 (16)	

<sup>a</sup>Values are given as number (percentage) unless indicated otherwise.

<sup>b</sup>By  $\chi^2$  or Fisher exact test.

**TABLE 3** Factors involved in choosing self-sampling and satisfaction with self-sampling.

Variable	Accepted (n=41)
What factors made you choose self-sampling? <sup>a,b</sup>	
Self-collecting was an easy process	40 (98)
You like that you can perform self-sampling in your own home	40 (98)
You felt the self-collection saved time	38 (93)
You feel less embarrassed with the self-sampling	33 (80)
Self-collecting made you feel empowered/in control	26 (63)
You feel embarrassed/uncomfortable during a pelvic examination (with a physician)	18 (44)
You do not want to be examined by a male physician	16 (39)
You do not want a pelvic/speculum exam	10 (24)
You do not trust physicians	2 (5)
Would you perform self-sampling in home again? <sup>b</sup>	40 (98)
Sampling process <sup>c</sup>	
Satisfaction with kit	9.5 (10)
Overall satisfaction with self-sampling	9.7 (10)
Nervousness (10=most nervous)	2.0 (1)
Amount of discomfort (10=most discomfort)	1.6 (1)
Confidence that you completed the test accurately (10=most confident)	9.4 (10)

<sup>a</sup>Multiple responses allowed.

<sup>b</sup>Values are given as number (percentage).

<sup>c</sup>Scale 1–10; values are given as mean (mode).

CAPE initiative.<sup>7,8</sup> This underscores the importance of extending coverage of the screening program to this population. Women who did not accept community-based self-sampling had a low perceived risk of cervical cancer, did not want to be screened at all, and preferred

provider-based screening. By contrast with previous studies,<sup>12,22</sup> few of these women cited concerns with accuracy of self-sampling or properly executing the collection. Instead, declining was associated with concerns about touching themselves, embarrassment, preference not to be screened, preference for provider-collected sample, and not having time and/or privacy. Most women who declined self-sampling chose at least one of these options, whereas none of the women who accepted chose any of them. These five concerns, in combination with the significant reasons for not attending the original clinic appointment, might be used as criteria to identify women who are less likely to accept self-sampling.

As compared with provider-collected samples, self-collected samples in the clinic have decreased sensitivity and specificity for cervical intraepithelial neoplasia grade 2 or greater, with a meta-analysis indicating a pooled absolute sensitivity and specificity of 74% and 86%, respectively.<sup>23</sup> However, self-sampling is at least as sensitive as cytology and more sensitive than visual inspection with acetic acid,<sup>23,24</sup> both of which are currently standards of care in LMICs. As compared with provider-collected cytology, community-based self-sampling shows higher sensitivity than cytology for detection of cervical intraepithelial neoplasia grade 2 or greater, but has a lower positive predictive value.<sup>25</sup>

The main limitation of the present study is the absence of information on follow-up care. In the future, it will be important to include follow-up methods to address which protocol is most likely to be successful in rural areas of El Salvador. Another limitation is the lack of control over the interview setup. Because the study was conducted in the women's homes, it was sometimes difficult to obtain complete privacy. Although the women consented to have other individuals present, this might have affected their responses, especially for sensitive topics. The identity of the interviewers is another issue. A male researcher and female researcher were present at each interview, but uptake of self-sampling might have been different if only one sex had

**TABLE 4** Concerns about performing self-sampling.<sup>a</sup>

Factor	Overall (n=60)	Self-sampling		P value <sup>b</sup>
		Accepted (n=41)	Declined (n=19)	
You are concerned that the brush will hurt	15 (25)	12 (29)	3 (16)	0.242
You are concerned you will hurt yourself	15 (25)	12 (29)	3 (16)	0.242
You don't want to be screened at all	8 (13)	0	8 (42)	<0.001
You prefer that a clinician take the sample	7 (12)	0	7 (37)	<0.001
You have no time or privacy in your home	6 (10)	0	6 (32)	<0.001
You do not want to touch yourself	6 (10)	0	6 (32)	<0.001
The procedure was embarrassing	5 (8)	0	5 (26)	<0.001
You are afraid that you would do something incorrectly	5 (8)	3 (7)	2 (11)	0.620
You are confused about how to self-sample	4 (7)	2 (5)	2 (11)	0.430
You are concerned about your partner's opinion	3 (5)	0	3 (16)	– <sup>c</sup>
The results might not be correct or exact	3 (5)	2 (5)	1 (5)	– <sup>c</sup>

<sup>a</sup>Multiple responses allowed; values are given as number (percentage) unless indicated otherwise.

<sup>b</sup>By  $\chi^2$  or Fisher exact test.

<sup>c</sup>Sample size too small for comparison.

**TABLE 5** Reasons for non-attendance at the clinic.<sup>a</sup>

Reason	Overall (n=60)	Self-sampling		P value <sup>b</sup>
		Accepted (n=41)	Declined (n=19)	
<b>Practical</b>				
The appointment was at an inconvenient time	11 (18)	9 (22)	2 (11)	0.287
You were not able to get time off work	8 (13)	7 (17)	1 (5)	0.234
You don't need to do the test	6 (10)	2 (5)	4 (21)	0.052
You could not pay for transportation	5 (8)	4 (10)	1 (5)	0.558
You did not have adequate transportation	4 (7)	2 (5)	2 (11)	0.415
You were not able to find adequate childcare	4 (7)	3 (7)	1 (5)	0.767
You do not know what the test is for	4 (7)	2 (5)	2 (11)	0.415
You forgot you had an appointment	3 (5)	2 (5)	1 (5)	-
Your spouse/family member would not let you go	2 (3)	0	2 (11)	-
You had to wait too long at the clinic	1 (2)	0	1 (5)	-
<b>Emotional</b>				
You are embarrassed about being seen by a male physician	30 (50)	19 (46)	11 (58)	0.405
You think the screening will be painful	12 (20)	8 (20)	4 (21)	0.889
You had a bad experience with pelvic examinations in the past	9 (15)	7 (17)	2 (11)	0.509
You are afraid of the test result	6 (10)	3 (7)	3 (16)	0.309
You do not trust the doctors	5 (8)	3 (7)	2 (11)	0.676
You are afraid you will need treatment	4 (7)	2 (5)	2 (11)	0.415
If you believe cancer cannot be cured, why should you get test?	3 (5)	1 (2)	2 (11)	-
You are afraid to lose "part of your uterus" to surgery/biopsy	2 (3)	1 (2)	1 (5)	-
<b>Risk</b>				
You are not at risk for HPV	9 (15)	4 (10)	5 (26)	0.095
You do not have symptoms so you do not need to go to the clinic	7 (12)	2 (5)	5 (26)	0.018
You are not at risk for cervical cancer	7 (12)	2 (5)	5 (26)	0.016
You are not sexually active	6 (10)	3 (7)	3 (16)	0.309

<sup>a</sup>Multiple responses allowed; values are given as number (percentage) unless indicated otherwise.

<sup>b</sup>By  $\chi^2$  or Fisher exact test.

been present. A previous study<sup>19</sup> found that the sex of the CHW did not affect acceptance, but future studies should explore this further.

In the present study, the researchers were accompanied to the women's homes by a CHW; however, the CHW was not present during the interviews. During the home visits, some women revealed that they were comfortable with the self-sampling because the researchers were not part of the healthcare system which they associated with a lack of confidentiality and privacy. Issues related to distrust of the healthcare system had not been anticipated and were not included in the study and deserve further investigation.

Despite these limitations, the present data show that most women accepted community-based self-sampling in a low-resource setting, supporting previous studies on acceptance in low-income countries. This has significant implications in terms of practice and policy. If El Salvador could incorporate community-based self-sampling, it would increase coverage of the current screening programs. Specifically, it would improve coverage for women who would not necessarily travel

to the clinic otherwise—a population that has a higher risk of cervical cancer than does the screened population. The fact that the non-attender population had an increased prevalence of high-risk HPV highlights the necessity and importance of increasing the existing program coverage to include these women. Similar situations might be true of other LMICs that would benefit from the introduction of self-sampling as part of a cervical cancer control program.

In practical terms, the present findings have highlighted ways in which a future study might be improved or in which self-sampling uptake might be improved. If screening and self-sampling were normalized during the explanation of the procedure, uptake might increase. Emphasizing the importance of the test not only for the health of the woman, but also for that of her partner and family might also affect uptake. Additionally, self-sampling offers women the option to perform the collection where and when it is convenient. Use of this patient-controlled approach to screening holds much promise for significantly improving the detection of cervical dysplasia and reducing cervical cancer worldwide.



## AUTHOR CONTRIBUTIONS

BL was responsible for study design and execution, preparation of institutional review board materials, and drafting the manuscript. RF executed the study and revised the manuscript. KMA and MM contributed to study design, preparation of institutional review board materials, and manuscript revisions; KMA also contributed to study execution. ICS was responsible for methods including questionnaire design, and revised the manuscript. EC conducted data analysis, data interpretation, and manuscript revisions. JCC also contributed to methods and manuscript review. MC contributed to study design, data interpretation, and manuscript revision.

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## CONFLICTS OF INTEREST

The authors have no conflicts of interest.

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## SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

**Appendix S1.** English version of the oral questionnaire used.

**Appendix S2.** Spanish version of the oral questionnaire used.