

Assessing the implementation fidelity of HPV self-collection offered by Community Health Workers during home visits (the EMA strategy): a case study in a low-middle resource setting in Argentina

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Abstract

Background

In Argentina, HPV self-collection offered by Community Health Workers was demonstrated to be effective to improve cervical cancer screening uptake. Based on these findings, the EMA strategy was scaled-up in nine Argentinian provinces. However, there is no evidence about the degree of fidelity -in relation to the core components proposed by the National Program on Cervical Cancer Prevention- with which this strategy was implemented in the new jurisdictions. We carried out a fidelity evaluation of the EMA strategy scaling-up aimed at evaluating the level of adherence to the core components of the EMA strategy, and how different moderating factors affected the implementation fidelity.

Methods

This descriptive study used a multi-methods approach involving quantitative and qualitative evaluations of the implementation fidelity using the Conceptual Framework for Implementation Fidelity. Evaluation of the degree of adherence to the core components of the EMA strategy was carried out through the analysis of a self-administered survey of health promoters (HPs), observations, and secondary data from the national screening information system. The analysis of moderating factors was carried out through analysis of field notes, and semi-structured interviews with key stakeholders.

Results

Our results showed that the core components with highest fidelity were “Training”, Sample Handling, and Transportation. Regarding the Offer of HPV self-collection, we found some adaptations such as locations in which HPs offered HPV self-collection, and fewer pieces of information provided to women during the offer. In the Follow-up and Treatment core component we found a reduced adherence to triage and colposcopy. Some contextual factors had a negative impact on implementation fidelity, such as urban insecurity and the reduction in the number of HPs that offered HPV self-collection. Moderating factors that contributed to achieve high level of fidelity included a well-defined strategy with clear steps to follow, permanent feedback and high level of engagement among implementers.

Conclusions

Our study shows how the analysis of fidelity and adaptations of HPV self-collection in real-world contexts are key to measure and maximize its effectiveness in Low-middle income settings.

Contributions To The Literature

- Our case study is the first that analyzed the implementation fidelity of an HPV self-collection strategy (EMA strategy) using an implementation science framework (the Conceptual Framework for Implementation Fidelity) in a low-middle resource setting.

- Data showed that core components of the EMA strategy were implemented with different levels of fidelity and adaptation. The use of CFIF allowed us to identify key factors that influenced the implementation process in a real-world context. Our results highlighted the need of context-adapted strategies.

-This case study provides useful evidence about implementation fidelity during a scaling-up process that is key for countries that are considering the incorporation of HPV self-collection into their cervical cancer prevention programs.

Background

Cervical cancer (CC) is one of the leading causes of cancer death among women from low- and middle-income countries (LMIC). The disease is highly preventable with existing knowledge and technologies, and that is why the World Health Organization (WHO) has launched a global initiative to eliminate CC.¹ One key strategy to control the disease is HPV self-collection, which is effective at increasing screening uptake, especially among hard-to-reach women who are at a higher risk of CC.²⁻⁷

However, for HPV self-collection to have an impact in screening coverage and disease detection at population level, it needs to be implemented in programmatic contexts.

In Argentina, HPV self-collection was implemented in the province of Jujuy as part of the EMA study (Self-collection Modality Trial, initials EMA in Spanish), a mixed-methods study that included a cluster-randomized controlled trial to evaluate effectiveness of HPV self-collection offered by community health workers (CHWs) at home visits to increase screening uptake.³ The strategy resulted in a fourfold increase in screening uptake (from 20.2–85.9%), demonstrating that the strategy was effective to improve CC screening.³ In 2014, EMA strategy was scaled-up to the whole province.¹¹ Evaluation of the scaling-up in Jujuy showed that the strategy resulted in a 45% increase in screening of vulnerable population, and allowed the identification of core components of the strategy, which could be implemented in new contexts. Based on these findings, the EMA strategy was scaled to other settings, and at present, nine Argentinian provinces use it to increase screening uptake among vulnerable women. The scaling-up in Argentina was carried out by the provincial programs through joint work with the team of the National Cervical Cancer Prevention Program (NCCPP). Argentina is a federal country, and health system organization varies in each province, which can influence how HPV self-collection is implemented locally.

One main issue of the HPV self-collection scaling-up is the implementation fidelity, this is, the degree to which an intervention is delivered as intended.⁸ This analysis is especially relevant for complex interventions that consist of several core components (i.e., active ingredients that were essential to achieve the intended outcomes).⁹ Otherwise, there is a risk of evaluating effects of an intervention that has been designed as part of a randomized trial, but not fully implemented when scaled-up. Maximizing fidelity to core components will be highly associated with the success in achieving change in targeted outcomes and having long-term public health impact.¹⁰ However, there is no evidence about the degree of

fidelity -in relation to the core components proposed by the NCCPP- with which this strategy was implemented in the new jurisdictions.

We carried out an evaluation of implementation fidelity of the EMA strategy scaling-up in Argentina. The study was carried out in La Matanza, a district in the Metropolitan Area of Buenos Aires, an urban setting very different from Jujuy, the Northern province in the border with Bolivia and Chile (Map 1) where the EMA-study was conducted. Study specific aims were: 1) To evaluate the level of adherence to the core components of the EMA strategy, and 2) to evaluate how different moderating factors affected the implementation fidelity. The Standards for Reporting Implementation Studies (StaRI) Statement were used to guide research reporting (Additional file 1).¹²

Methods

Study design

We carried out a descriptive study using multiple-methods involving quantitative and qualitative evaluations of the implementation fidelity using the Conceptual Framework for Implementation Fidelity (CFIF).⁸ A multiple-method study uses both quantitative and qualitative techniques, as distinctly separate parts of one research program.¹³ Evaluation of the degree of adherence to the core components of the EMA strategy was carried out through the analysis of a self-administered survey of HPs, observations, and secondary data from the national screening information system (SITAM, for its initials in Spanish). The analysis of moderating factors was carried out through semi-structured interviews with key stakeholders, and analysis of field notes that provided complementary information on different factors that affected the fidelity of implementation. Phases of EMA strategy implementation and evaluation are showed in Fig. 1.

Setting

The study was carried out in La Matanza, a district in the Metropolitan Area of Buenos Aires (Map 1). La Matanza has 2 million inhabitants, 50% of which are poor. La Matanza public health system is comprised of a network of hospitals and primary health care centers. For the uninsured population health services are provided free of cost, including screening, diagnosis, and treatment. In La Matanza, programmatic population-based self-collection was initiated in 2017. HPV testing (Hybrid Capture 2; Qiagen, Germantown, MD, USA) was introduced as primary screening for women aged 30 and older attending the public health system. HPV self-collection is offered by health promoters (HPs) during home visits. Unlike CHWs in Jujuy, HPs did not belong to the permanent staff of the health system; they were women from the community who receive social plans (conditional income transfer for protection of families in poverty conditions) provided by the Social Development National Ministry.

Conceptual Framework for Implementation Fidelity

The CFIF⁸ was used as a conceptual model to retrospectively evaluate the implementation fidelity of EMA strategy. We chose the CFIF because it is particularly appropriate to evaluate implementation fidelity of complex interventions -as the EMA strategy- because it allows a comprehensive assessment of different dimensions of implementation fidelity and the moderating factors that may influence it (Fig. 2). This model was integrated in all stages of the research, including conceptualization (e.g., selecting implementation components on which to focus), data collection (e.g., using components of the conceptual model to design interview guides), and analysis.

Several terms have been used interchangeably with fidelity in the literature, including treatment fidelity,¹⁴⁻¹⁷ intervention fidelity,¹⁸⁻¹⁹ implementation fidelity,^{8,9} or fidelity of implementation.²⁰ This variety in terms associated with fidelity is related to the fact that initially, fidelity was mostly referred to the evaluation of what was delivered clinically in randomized trials. At present, it applies to all types of studies, from tightly controlled efficacy trials to implementation studies, although the focus on fidelity varies across each type of study.¹⁰ Following Carroll et al.,⁸ we have chosen the term “implementation fidelity” defined as the degree to which the EMA strategy was implemented as it was intended in the original model. It relates to the process of implementation of core strategy components.²¹ Implementation fidelity is critical to a successful translation of evidence-based strategies into real-contexts, and it is a factor that may influence the relationship between the strategy and its intended outcomes. Evaluation of implementation fidelity is particularly important given the greater potential for inconsistencies in implementation of a strategy in the real world rather than in experimental conditions.⁸

For Carroll et al.,⁸ the measurement of implementation fidelity is the measurement of adherence. Adherence includes the subcategories of content (i.e., 'active ingredients'), frequency, duration, and coverage (i.e., dose). The **content** of the intervention may be seen as its 'active ingredients' or components that are essential to achieve the intended outcomes. In our case study, the content was defined as the core components of the EMA strategy (which are described below). **Coverage** refers to the degree to which women who met inclusion criteria accepted the intervention; and **frequency and duration** refer to whether the intervention/strategy was delivered with the regularity and duration as planned by its designers. In addition, the level of implementation fidelity achieved may be influenced by other variables called moderating factors. The original model described four moderating factors: intervention complexity, facilitation strategies, quality of delivery, and participant responsiveness. The CFIF model used in this study has been modified based on the adaptation made by Hasson et al.^{9,22} for the assessment of fidelity of complex interventions. Following Hasson's model we have included the following moderating factors:

Participant responsiveness

refers to how well participants respond to or are engaged by the intervention. In our case study, responsiveness refers to the engagement of health staff involved in EMA strategy implementation (e.g., HPs that offer SC).

Intervention complexity

refers both to intervention and its implementation strategy characteristics – e.g., number of core components, – and to the way in which they have been described and transmitted to the implementers.⁸

Facilitation strategies

refers to support strategies that may be used both to optimize and to standardize implementation fidelity, i.e., to ensure that everyone is receiving the same training with the aim that the delivery of the intervention is as uniform as possible (e.g., manuals, monitoring and feedback, etc.).⁸

Context

refers to surrounding social systems such as structures and cultures of organizations and groups, inter-organizational linkages, and historical as well as concurrent events.^{9,14}

The CFIF states that different moderating factors might affect, positively or negatively, the implementation process and its fidelity. In addition, factors interact with each other, and the effect of one factor on fidelity might be influenced by another moderating factor.⁸

Description of the EMA strategy

The EMA strategy is a complex evidence-based intervention that was implemented, evaluated and scaled-up nested into the Jujuy Demonstration Project (JDP),²³ -more details about the EMA strategy can be found elsewhere-.^{3,11} It is consisting of several active ingredients that address multifaceted processes within interpersonal, organizational, and community contexts.^{24,25} It is based on the concept of Cancer Care Continuum defined as a process of care consisting of several steps (screening-diagnosis-treatment) and interfaces between patients, providers and organizations. Central to the process of care across the continuum is the transfer of information and responsibility from one institution to another, from one health professional to another and from providers to patients.²⁶ The EMA strategy involves a door-to-door offer to women of HPV self-collection by trained health staff together with provision of information about how to perform self-collection, sampling handling and transport of samples to the HPV laboratory, follow up and treatment of HPV-positive women at health centers (Fig. 3).¹¹ These components are essential to achieve high level of adherence to screening, triage, diagnosis and treatment, the necessary steps to assure the screening program effectiveness to prevent CC. CFIF dimensions applied to the EMA strategy are as follows:

Content

As mentioned above, the EMA strategy included four core components that were defined as the content of the intervention. Table 1 shows specifications for each core component following Proctor et al. model.²⁵

Table 1

Specification of core component of EMA strategy following Proctor model (Cont.)²⁵

Core component: TRAINING	
Actor	National and Local Training team expert in Cervical Cancer Prevention, HPV test and Health Communication. Experts that participated in EMA Study (RCT and Scaling Up in Jujuy province).
Actions	To provide training through different techniques (with expert presentations, discussions in small groups, and role playing) regarding: Cervical cancer prevention and HPV, HPV results. To evaluate knowledge acquired during training (self-administered survey)
Target of the action	Health promoters in charge of Offer of Self Collection, Health supervisors, health professionals involved in EMA strategy implementation in La Matanza.
Temporality	Pre-implementation phase
Dose	Two workshops
Implementation outcome	Adoption and Fidelity
Justification	Health education/training of implementers
Core component: OFFER OF SELF-COLLECTION	
Actor	Trained Health Promoters
Actions	To identify the target population: age, pregnancy, previous screening. To provide information about HPV test and Cervical Cancer To explain on how to perform self-collection
Target of the action	Women aged 30 and over
Temporality	Implementation phase
Dose	10 minutes step by step explanation of how to do self-collection
Implementation outcome	Acceptability and Fidelity
Justification	Door to door offer is effective to increase screening uptake and acceptability of HPV self-collection. ³⁻⁶
Core component: Sample Handling and Transport	
Actor	Health promoters who offer self-collection /Supervisors/ health professionals involved cervical cancer prevention program

Core component: TRAINING	
Actions	<p>To label collectors with the woman's name and the national unique identification number.</p> <p>To fill in sample collection forms.</p> <p>To transport samples at room temperature to primary health care centers.</p> <p>To assure that specimens arrive to HPV laboratory within 14 days after sample collection.</p>
Target of the action	Women aged 30 + who performed HPV Self-collection
Temporality	<p>Implementation phase:</p> <p>Labelling collector: during self-collection offer.</p> <p>Transporting: within 14 days after sample collection.</p>
Dose	Always
Implementation outcome	Fidelity
Justification	Protocol of identification and transport of samples following manufacture instructions.

Training

Self-collection should be offered by trained HPs. Training should include at least: 1) two workshops about CC prevention and HPV test, with expert presentations, discussions in small groups, and role playing to recreate different scenarios during the offer (Box 1), and 2) at the end of the last workshop, inviting HPs to complete a self-administered survey to evaluate knowledge acquired during training.

Box 1: Description of training workshops

Sections	Description
Project background	Provides information about the EMA study and the scaling-up into the programmatic context.
Cervical cancer	Provides scientific information about cervical cancer and its relation with HPV.
HPV-testing	Provides basic information regarding HPV testing as primary screening for cervical cancer prevention.
HPV Self-collection	Provides specific information about HPV self-collection: differences with clinician collected tests, steps of self-collection take-up, understanding results of self-collection and follow-up of HPV+ women.
Communication skills	Provides communication skills to conduct the educational talk (instruct women on how to perform self-collection).
Logistical procedures	Training about how to label and transport samples.

Adapted from Arrossi et al., 2017.¹¹

Box 2. Description of core components, sub-dimension, items and activities included in the checklist

Core component: Offer of self-collection
Sub-dimension: Identification of target population (3 items)
<i>Age</i>
<i>Pregnancy</i>
<i>Previous HPV screening</i>
Sub-dimension: Key information during SC offer (7 items)
<i>Information about HPV test</i>
<i>Information about CC prevention</i>
<i>Information about SC</i>
<i>Information about SC is painless</i>
<i>Information about possible results (HPV positive/negative)</i>
<i>Information about results delivery date</i>
<i>Information about results delivery methods</i>
Sub-dimension: Step-by step explanation on how to perform self-collection (6 items)
<i>Private place to perform SC</i>
<i>Information about different positions to perform self-collection</i>
<i>Explanation about that woman should be careful with the liquid inside the tube</i>
<i>Explanation about that woman had to insert the brush into their vagina until it reaches the bottom</i>
<i>Explanation about that woman had to rotate the brush 3 times.</i>
<i>Use of communication support material</i>
Core component: Sample Handling and Transportation (4 activities)
<i>To Check that the tube was correctly closed</i>
<i>To carry the tube in vertical position</i>
<i>To label collectors</i>
<i>To fill HPV-form</i>

Offer of self-collection

Self-collection offered during home visits by trained HPs should include at least: 1) identifying the target population, 2) the offer of self-collection, 3) providing women with information about CC prevention and HPV self-collection (Box 2), 4) offering women to perform HPV self-collection, and a 10-min step-by-step

explanation on how to perform it using communication support material (Additional file 2), and 5) providing women with the HPV collector to collect the sample.

Sample handling and transportation

Sample handling and transportation should include at least: 1) labelling collectors with the woman's name and the national unique identification number, 2) filling in sample collection forms 3) samples transported at room temperature to primary health care centers and then to the HPV laboratory, 4) assuring that specimens arrive to the HPV laboratory within 14 days after sample collection, and 5) samples without liquid, brush, or identification data discarded at the HPV laboratory.

Follow-up and treatment

Follow-up and treatment should be organized according to national guidelines:²⁷ 1) HPV-positive women should be referred to cytology triage. HPV-positive women with normal cytology should repeat the HPV-test in 18 months 2) Women with abnormal cytology (ASCUS+) should be referred to colposcopy, and biopsy if needed, 3) Identified cases of CIN2 + should be treated according to standard protocols (loop electrosurgical excision procedure -LEEP- or conization and 4) HPV-negative women should be repeat screening in 5 years.

Dose (Duration)

The "dose" of EMA strategy was defined based on the expected duration of the step-by-step explanation on how to perform self-collection (10 minutes).

Coverage (acceptability)

Coverage was defined as the proportion of women who accepted self-collection after the offer of self-collection. The expected acceptability of self-collection was based on results of EMA Study (86%).

Indicators and sources of data used to measure adherence (content, dose, and coverage) to the core components of the EMA strategy are presented in Table 2.

Table 2. Adherence to core component of EMA strategy: Indicators and source of data

ADHERENCE	SUB-DIMENSIONS	INDICATORS	SOURCE OF DATA
Content: core components of the strategy			
TRAINING	Training	Number of planned workshops implemented	Training registries
		Inclusion of expert presentations, role-playing and discussions in small groups	Training material
	Participation in training	% of HPs that participated in the workshops	Training registries
	Level of knowledge about the strategy among HPs	% of HPs with adequate knowledge about the EMA strategy	Self-administered questionnaires after training
OFFER OF HPV SELF-COLLECTION	Place of offering SC	% of SC offered during home visit	Checklist
	Identification of target population		
	Age	% of SC offers in which HPs asked the woman their age	Checklist
	Pregnancy	% of SC offers which HPs asked if the woman was pregnant	Checklist
	Previous screening	% of SC offers in which HPs asked if the woman had a previous HPV test	Checklist
	Key information during SC offer		
	Information about HPV test	% of SC offers in which HPs mentioned information about HPV test	Checklist
	Information about CC prevention	% of SC offers in which HPs mentioned information about CC prevention	Checklist
	Information about HPV SC	% of SC offers in which HPs mentioned information about	Checklist
	Information about SC is painless	% of SC offers in which HPs mentioned that SC is painless?	Checklist
	Information about possible results (HPV positive/negative)	% of SC offers in which HPs mentioned information about possible HPV results	Checklist
Information about results delivery date	% of SC offers in which HPs mentioned information about results delivery date	Checklist	

ADHERENCE	SUB-DIMENSIONS	INDICATORS	SOURCE OF DATA
	Information about results delivery methods	% of SC offers in which HPs mentioned information about results delivery methods	Checklist

Data collection

Quantitative data sources

Observations

To evaluate the implementation fidelity of the core components “Offer of self-collection” and “Sample Handling and Transportation” we conducted observations during routine self-collection offers. Between June 14 and July 23, 2019, four trained observers carried out 74 observations. All the HPs of La Matanza who received training in 2017 and offered self-collection in 2019 were eligible to participate. In total, 78 HPs who were working in the PHC system were eligible. Using a computer-generated random number list, we selected a sample of 20 HPs to be accompanied during a workday. An observation protocol (checklist) was developed based on the competencies and activities carried out by the HPs. We first identified a comprehensive list of planned activities by reviewing programmatic documents and training materials. We then classified this list of activities according to the content of the strategy (Box 2). The list of activities was validated by the training coordinator of the NPCCP. For each planned activity we evaluated whether it was implemented according to the EMA model (Yes/No). In addition, observers registered any adaptation of the offer.

Self-administered questionnaires

An ad-hoc self-administered survey was developed to evaluate knowledge acquired by HPs in training workshops. At the end of the last workshop, HPs were asked to complete an anonymous, self-administered survey. In total 171 HPs completed the survey. The self-administered survey included questions regarding scientific data on CC and its relationship with HPV, basic information on HPV testing, the step-by-step offer of self-collection, and follow-up of HPV + women. Results were registered in a specific database for processing and analysis.

National screening information system (SITAM)

We used data extracted from SITAM to evaluate the core component “Follow up and treatment” We analyzed the SITAM database containing records of all women aged 30 years and older screened in La Matanza using HPV self-collection during 2017–2018, and data recorded until December 2019 for follow-up. Colposcopies, biopsies and treatments not registered in SITAM were considered lost to follow-up. The data were accessed by authorized healthcare workers and researchers.

Qualitative data sources

During April-June 2020 we carried out six semi-structured interviews with key informants to explore their views on the EMA strategy and moderating factors that affect its implementation. Due to COVID-19 pandemics these interviews were carried out online. Online tools for data collection are suitable for different topics and allowed us to solve logistical issues.²⁹ In addition, we analyzed field notes that were taken during observations, and training materials (e.g., power point presentations and training documents).

Data analysis

Quantitative data

Indicators presented in Table 2 were analyzed through frequencies and percentages. The percentage of implemented activities was calculated as follows: Total number of implemented activities /total number of planned activities following EMA model * 100. The percentage of implemented activities represented the degree of fidelity. Based on other studies that evaluate implementation fidelity in community settings³⁰ the following scoring categories were used in this study: 80–100%, high; 79–51%, moderate; and ≤ 50%, low.

We also calculated the percentage of adequate knowledge, defined as percentage of correct answers in the self-administered survey as follows: number of correct answers / total number of answers (adequate knowledge > 70% correct answers).

Qualitative data

Qualitative data were analyzed thematically³¹ using the CFIF dimensions. Two researchers became independently familiar with the data through audios and transcriptions and classified data using an initial codebook, to later compare and generate themes,³² debate, and resolve the inconsistencies with the other team members. We sought quotation examples that adequately graphed each theme and were the most relevant to assess implementation fidelity.

Stakeholder Engagement

Municipal health authorities and professionals actively participated in the planning, implementation, and fidelity evaluation of the strategy. The Director of Training of the Primary Health Care Direction of La Matanza was co-researcher. She participated in the design, implementation, and data analysis. All the staff of the Secretariat of Health helped organize the field work and participated in meetings where several aspects of the project were discussed. The Secretary of Health of La Matanza, health authority in charge of the primary health care centers, gave his support to the project. In addition, NPCCP staff participated in the design, checklist elaboration, field work, and data analysis. Also, Argentina NCI funded the Study.

Results

Adherence to the core components of EMA strategy

The degree of adherence to activities included in the four core components of the EMA strategy is shown in Table 3.

Table 3. Adherence to the core components of EMA strategy and moderating factors

Adherence	INDICATORS	VALUE	Moderating factor that affect level of adherence (+ positive / - negative)	
Content: core components of the strategy				
TRAINING	% of planned workshops implemented in La Mataza	100% (n = 2/2)	Context: Stakeholder engagement, Political will (+)	
	% of HPs that participated in the two workshops	95% (n = 163/171)	Participant responsiveness: motivation of health promoters, active participation of local stakeholders during planning and implementation of training (pre-implementation phase) (+)	
	% of HPs with adequate knowledge about the EMA strategy	92% (n = 157/171)		
OFFER OF HPV SELF-COLLECTION	% of SC offered during home visit (following EMA model)	54% (n = 40/74)	Context: Urban Insecurity (-) / reduction of number of health promoters that were involved in cervical cancer prevention (-) Previous experience in Community work allows for adaptation related place of offer (+)	
	Identification of target population (among all women, n = 74)			
	% of SC offers in which HPs ask the woman age	70% (n = 52/74)	Context: Less time to the offer (-) /reduction of information during the offer	
	% of SC offers which HPs ask if the woman was pregnant	34% (n = 25/74)		
	% of SC offers in which HPs ask if the woman had a previous HPV test	22% (n = 16/74)	Intervention complexity: several pieces of information	
	Key information during SC offer (among women considered eligible, n = 63)			
	% of SC offers in which HPs mentioned information about HPV test	43% (n = 27/63)		
	% of SC offers in which HPs mentioned information about CC prevention	68% (n = 43/63)		
	% of SC offers in which HPs mentioned information about SC	47% (n = 29/63)		

Adherence	INDICATORS	VALUE	Moderating factor that affect level of adherence (+ positive / - negative)
	% of SC offers in which HPs mentioned that SC is painless?	27% (n = 17/63)	
	% of SC offers in which HPs mentioned information about possible HPV results	41% (n = 26/63)	
	% of SC offers in which HPs mentioned information about results delivery date	51% (n = 32/63)	
	% of SC offers in which HPs mentioned information about results delivery methods	82% (52/63)	
	Explanation on how to perform self-collection (among women who accept SC, n = 50)		
	% of SC offers in which HPs suggest a private place to perform SC	78% (n = 39/50)	
	% of SC offers in which HPs mentioned different positions to perform SC.	36% (n = 18/50)	
	% of SC offers in which HPs warned women that should be careful with the liquid inside the tube	54% (n = 27/50)	
	% of SC offers in which HPs explained to the women that they had to insert the brush into their vagina until it reaches the bottom	70% (35/50)	
	% of SC offers in which HPs explained that woman had to rotate the brush 3 times.	90% (45/50)	
	% of SC offers in which HPs used communication support material	48% (n = 24/50)	
SAMPLE HANDLING AND TRANSPORTATION	% of SC offers in which HPs check that the tube was correctly closed	96% (n = 48/50)	Facilitator strategies: Feedback and supervision in different levels of the health system: health care centers – HPV lab– second-level hospitals

Adherence	INDICATORS	VALUE	Participant responsiveness: Moderating factor: Motivation and active participation of health promoters, supervisors and local stakeholder that affect level of adherence (+ positive / - negative)
	% of SC offers in which HPs carried the tube in vertical position	96% (n = 48/50)	
	% of SC offers in which HPs labeled collectors	98% (n = 49/50)	
	% of SC offers in which HPs filled HPV-form	96% (n = 48/50)	
FOLLOW UP AND TREATMENT	% of HPV positive women with triage Pap at 120 days	38% (318/830)	Intervention complexity: different levels of health system involved in screening – triage – diagnosis and treatment (-)
	% of HPV-positive/abnormal Pap women with colposcopy	64% (n = 34/49)	
	% of CIN2 + with treatment	100% (n = 13/13)	
Dose			
Duration	Mean duration of SC offers	8 minutes	
Coverage			
Coverage	% of women who accepted SC	79% (50/63)	

Content

Training

Training was implemented with high level of adherence. In 2017, national and municipal team members led two workshops (100% of planned workshops). These teams planned and carried out the workshops following the EMA strategy model, which included expert presentations, role-playing and discussions in small groups. In total 95% of HPs participated in both workshops. In the last workshop acquired knowledge was evaluated, 91% of HPs had adequate knowledge about the strategy.

Offer of SC

This core component was implemented with adaptations. The level of adherence among the 16 items included in this component were highly variable (from 22 to 82%). 54% (n = 40/74) of SC offers were carried out during home visits and 46% (n = 34/74) were carried out in community health meetings and waiting rooms in primary health care centers. Regarding “Identification of target population”, most HPs (70%; n = 52/74) asked women their age, but previous HPV-testing and pregnancy status were asked less

frequently; in some cases, HPs evaluated the eligibility status without asking women specific information. Observations of information provided about CC prevention and HPV self-collection showed that in 68% (n = 43/63) and 82% (n = 52/63) of SC offers, HPs mentioned the relationship between the test and CC prevention and the result-delivery methods, respectively. However, information about the HPV test characteristics (43%; n = 27/63), SC characteristics (27%; n = 17/63), and HPV results (41%; n = 26/63) was provided to a lesser extent. Four out of the six items included in the “Step-by-step explanation about how to perform SC” were mentioned in more than 54% of observations (range 54%-90%). Communication support materials were used in 48% of the offers (n = 24/50).

Sample handling and transportation

All the activities included in Sample Handling and Transportation were performed with high level of adherence. In 96% (n = 48/50) of observations, HPs carried out the tube in vertical position, labeled collectors and filled in the HPV-form. In 50% of the cases this activity was carried out in the health center with support of the supervisor.

Follow-up and treatment

Between May 2017 and December 2018, 5069 women aged 30 and older were screened with SC (51% of total HPV-tested women, n = 5069/9977). Among them, 16% were HPV-positive. 38% of HPV-positive women had a triage test at 120 days after screening showing a low level of adherence. Adherence to diagnosis and treatment were higher: 64% of women with positive triage performed a colposcopy. In total, 13 CIN2+ were identified and 100% were treated.

Dose

In general, HPs spent less time than stipulated to offer self-collection (mean: 8 minutes; range: 1–17 minutes) therefore, as we mentioned above, fewer pieces of information were provided.

Coverage

During the study, 63 of 74 visited women were considered eligible to perform self-collection. Among them, 79% accepted to perform it.

Moderating factors

Participant responsiveness

We found a high level of engagement among all actors involved in the implementation. Decision makers from the three levels (national, provincial, municipal) were involved since the beginning, with participation in round tables organized by the NPCC to plan the EMA strategy implementation at the local level. As mentioned by one of the interviewees, this involvement of all governmental level was key to integrating and coordinating all the necessary activities:

It requires a lot of will at the level of health policy. I mean, not only from the person who is carrying it out... In other words, it seems to me that this worked at least in [La] Matanza because there were people to make it work in the municipality, and in the nation and in the province, in other words, from the three of them. Not from just one because just one can't achieve this."

(E1. Training Coordinator)

Additionally, all interviewees recognized the active involvement of health professionals, HPV-laboratory staff, and particularly, the HPs. This involvement was related to the EMA strategy, which was considered an innovative and important tool to facilitate the health system to reach a population that is usually out of reach. In agreement with this recognition, data from fieldnotes showed high acceptability and motivation among HPs and their supervisors.

"The SC changed everything... because sometimes many women were reluctant to go to the gynecologist. This was revolutionary, this was bringing health into their homes... so innovative..."

(E3. Supervisor of Primary Health Care Direction)

"... Today, I can't imagine working on CC prevention without the HPV test. I would say it would be like taking 25 steps backwards (...) I think the HPV test and the whole [EMA] strategy to ensure women's access is fundamental. We are fully confident that this is the way forward."

(E2. Navigator)

Perceived complexity

The EMA strategy was defined by the interviewees as a complex intervention due to the several core components that included and the several health system institutions and providers that needed to be involved:

"I think it's a complex process that requires many actors and each of them must carry out their part correctly, because if someone took the sample and doesn't store it properly or if when they go to offer it, they don't explain it well... There are many participants, and they all have to be linked together, it's a gear..."

(E1. Municipal Training Coordinator)

[The most complex issue is] the relation with the second-level hospital, to continue with triage and treatment. But this was worked on and greatly improved.

(E3. Supervisor of Primary Health Care Direction)

In spite of its perceived complexity, stakeholders characterized the EMA strategy as well-planned. All agreed in defining the core components as clear stages to follow, and they mentioned that they had clear and sufficient information on how to proceed during the implementation. The interviewees highlighted the relevance of the training, and they described it as balanced between the use of accurate medical terms and accessible language to laypersons.

"[The strategy] isn't too complex. The key part of it is training the health personnel. Once they're involved and trained, it's very easy.

"[The HP training content] was perfect according to the target audience, it was very well thought out: they didn't talk in technicalities, they went straight to the point but not as if they were children. Everything was said with the correct terminology, but with simple and easy explanations..."

(E1. Municipal Training coordinator)

Facilitator strategies

A key facilitation strategy was the permanent feedback among implementers (e.g., the laboratory team, the navigator, and the supervisors). As the implementation progressed, this allowed them to identify problems in sample handling, transportation or data registration and therefore facilitate their resolution. These activities affected positively implementation fidelity. In fact, Sampling Handling and Transportation was one of the core components with high level of fidelity (Table 3).

"We held a meeting with all the supervisors and HPs on sample issues, as sometimes the samples arrived without the forms and in the meeting, we said, 'But a key person is missing here, the driver who carries the samples is missing'. So, we met with the driver to explain".

(E4. Supervisor of Primary Health Care Direction)

In addition, training organization and education materials were also considered facilitators of the strategy: for example, the meetings held during the pre-implementation phase to plan training activities and adapt training materials to local needs, as well as the use of handbooks and flyers to guide and standardize the delivery of the intervention.

[The HPs] received explanations on how to write the data in clear handwriting... everything was explained. They were given a flip chart with an explanation to be provided to the women, as well as handouts. They could keep the flipchart and that could help them explain everything to the women...everything they had learned....

(E1. Municipal Training Coordinator)

Context

Some contextual factors had a direct impact on implementation fidelity. Financial resources for the employment of HPs fluctuated during the implementation phase. In 2019 there was a change in the national Social Development Ministry policy of HPs. This change resulted in a decrease of the number of HPs, which was reduced from 171 in 2017 to 78 in 2019.

In addition, social insecurity negatively affected implementation fidelity. La Matanza is a complex urban setting. It is a large territory, with social inequality and with high levels of insecurity (i.e., perception of risk as well as lack of safety because of a high level of crime in some suburban areas). Data from semi-

structure interviews and field notes showed that insecurity was an important moderator of the implementation (in fact, one of the observers had to interrupt field work due to a shooting incident).

"[when we were not working on our usual neighborhood] It was very difficult to go into a house because of the safety issue. You know that not everyone opens the door to their house..."

(E1. Municipal Training Coordinator)

Due to insecurity problems and the reduction of HPs, local health staff decided to offer HPV self-collection during community activities carried out in schools, churches, fairs, and squares. This was possible because of the presence of a motivated health system staff that understood the context, and that had a broad experience in primary health care and community work. In addition, the municipality of La Matanza had a health trailer that was used to provide women with a place to perform HPV self-collection when offered at community places. Interviewees evaluated this adaptation as a satisfactory response to guarantee the intervention.

In addition to the door-to-door offer... we implemented what were called "healthy circuits" which is where the mobile hospital went. This was a trailer that had several clinics, where they worked on other issues such as diabetes, hypertension... And there the HPs offered the self-collection test... That same moment, in the trailer bathroom, they would take the self-collection test."

(E3_Supervisor of Primary Health Care Direction)

Discussion

This is, to our knowledge, the first study that analyzed implementation fidelity of an HPV self-collection strategy using implementation science methods. Utilization of the CFIF allowed us to carry out a comprehensive evaluation of adherence to core components of the EMA strategy and to identify key factors that influenced its implementation. Using a multi-methods approach we analyzed the implementation fidelity of the EMA strategy in La Matanza, an urban and low-middle resource setting in Buenos Aires, a different context from Jujuy, in which EMA strategy was designed. Our results showed that the core components with highest fidelity were "Training" and "Sample Handling and Transportation". Regarding the Offer of SC, we found some adaptations such as the locations in which HPs offered SC, and fewer pieces of information provided to women. In "Follow-up and Treatment" we found a reduced adherence to triage. Some contextual factors had a negative impact on implementation fidelity, such as urban insecurity and the reduction in the number of HPs that offered SC. Moderating factors that contributed to achieve high level of fidelity included a well-defined strategy with clear steps to follow, permanent feedback and high level of engagement among implementers.

Our results showed that training was implemented with high level of fidelity. The provision of supportive materials for training may have a direct impact on the quality with which the strategy is delivered, and this may, in turn, affect the fidelity with which a strategy is implemented.⁸ Key stakeholders mentioned that training organization and education materials were facilitators of the strategy. Similar results were

found in Jujuy, where CHWs mentioned that training organization was the main facilitator of the implementation of EMA strategy.³³ Training is a key core component that allows standardization of complex interventions and should be considered as a priority core component in future scaling-up of the EMA strategy.

The core component “Offer of SC” was implemented with adaptations, such as collective rather than individual SC offer and changes relating the place of the offer. These adaptations were carried out due to context factors: urban context, insecurity situations and a reduction in the number of HPs that offered SC. These adaptations emerged during the implementation process and was proposed by health system staff with high motivation and engagement. This result is similar to the result reported by Hassson et al.^{9,22} In their study they observed that staff enthusiasm for the project (responsiveness) was high, and this seemed to be a reason for adapting components to the intervention.²² Wide evidence illustrate how adaptation of evidence-based interventions is the rule rather than the exception when used in real-world practice.³⁴ Although there are studies showing high fidelity to be related to better outcomes than low fidelity^{15,17} other studies suggest that adapted interventions may be more effective than non-adapted ones.³⁵ As Carroll et al., mentioned, the evaluation of implementation fidelity provides a scope for identifying adaptability to local conditions. The adaptations observed during our case study could inform future scaling-up of EMA strategy in other urban settings with a dearth of human resources for the offer of self-collection.

Our results also showed that HPs spent less time during the offer (dose), and consequently the women received fewer pieces of information, especially regarding HPV-testing and its role in CC prevention and results delivery and how to follow-up if positive. Our results suggest that these adaptations did not affect the acceptability of HPV self-collection among women, but it might have an impact on adherence to triage and follow-up (a core component in which we observed low level of fidelity). In addition, not fully understanding the role of self-collection in CC prevention might reduce women capacity to make an informed decision. Strategies to support women with all the information included in the Offer of SC core component might be needed to guarantee this, e.g., an app aimed at providing information and counseling to HPV + women is being developed³⁶ and it might contribute to complement the explanation provided by HPs.

HPV testing is only effective if all the women receive the corresponding follow-up and treatment. In our study, the adherence to triage was 38% at 120 days. Limited compliance to triage has been reported in Argentina,^{11,23,37,38} and other countries.³⁹⁻⁴¹ Studies that analyzed why screen-positive women failed to complete follow-up found that in most cases it was due to problems related to the health services organization⁴²⁻⁴³ (i.e., delays or failures in result delivery, lack of appropriate guidance concerning the steps to follow after receiving a positive test, etc.). The EMA strategy is a complex intervention consisting of several steps that address multifaceted processes within interpersonal, organizational, and community contexts that may affected implementation fidelity. For example, if self-collection is offered during community meetings the delivery of results and referring patients for follow-up is challenging. The use of

mHealth technologies to send reminders to women could be a feasible tool to reduce the time from screening to triage and improve patient- provider communication. In Jujuy, the ATICA project,⁴⁴ an effectiveness-implementation hybrid type-I trial, showed that a multi-component mHealth intervention increased adherence to triage among women with HPV + self-collected tests. This strategy could be scaled up to improve the effectiveness of SC and reduce CC incidence and mortality.

Participant responsiveness refers to how well participants are engaged by an intervention/strategy.²² Several studies showed that higher levels of implementation fidelity could be achieved when those responsible for implementing a strategy are enthusiastic about it.^{8,9} Stakeholders and HPs considered SC as a tool that allowed the health system to reach a population that is usually unreachable and, therefore, produce a real change in the burden of the disease. In addition, high engagement of implementers (responsiveness) could be associated with other important moderator - facilitator strategies- that can contribute to improve the level of implementation fidelity. In our study, permanent feedback among the laboratory team, the navigator, and the supervisors contributed to a high level of fidelity of Sampling Handling and transportation. As Carroll et al.,⁸ mentioned, the more that is done to help implementation through monitoring or feedback the higher the potential level of implementation fidelity achieved. The role of such strategies is even more important in the case of complex interventions, which can be more vulnerable to variation in their implementation in real-world conditions.⁸

Incorporating research into implementation, and political will, have been identified as factors associated with faster diffusion of an innovation and its sustainability.⁴⁵⁻⁴⁶ Our research project was carried out in a programmatic context and run collaboratively between CEDES (an NGO with broad experience in public health research), the NPCCP and municipal health authorities and staff. In La Matanza, stakeholders participated in the plan, implementation and fidelity evaluation of the strategy. Thus, this study can serve as a model of how implementation science can be used to plan, conduct, and evaluate strategies implemented on a large scale in programmatic, real-world contexts. The evaluation of implementation fidelity of complex strategies in real world contexts is crucial to identify factors that limit or facilitate their scaling-up. It is particularly important in low-and middle resources settings, which need to optimize resources to benefit as many people as possible and improve public health.

One strength of our study is multiple data collection methods to assess fidelity, including observations that according to the literature, are one of the most widely used techniques for content evaluation. Stakeholder engagement since inception of the study will facilitate using the results to improve the offer of HPV self-collection. However, our study finalized in 2020 in the midst of the COVID-19 pandemics and therefore, translation of these results into programmatic modifications of the strategy was delayed.

Conclusion

HPV self-collection has great potential for CC prevention, with a concrete possibility of saving thousands of lives in LMIC. Implementation science tools and frameworks are essential to enhance the way HPV-based strategies in CC prevention are implemented and evaluated. Our case study shows how HPV self-

collection in programmatic contexts can be strengthened by using frameworks and tools used by Implementation Science. Specifically, it shows how the analysis of fidelity and adaptations of HPV self-collection in real-world contexts are key to measure and maximize its effectiveness in LMIC.

Abbreviations

ASCUS+: atypical squamous cells of undetermined significance or worse (Include: atypical squamous cells of undetermined significance atypical cells cannot rule out high-grade squamous intraepithelial lesion (ASC-H); low/high-grade squamous intraepithelial lesions (LSIL /HSIL); and cancer).

CC: Cervical cancer

CFIF: Conceptual Framework for Implementation Fidelity

CHWs: Community Health Workers

HPs: Health Promoters

HPV: Human papillomavirus

JDP: Jujuy demonstration project

NCCPP: National Cervical Cancer Prevention Program

SITAM: national screening information system (for its initials in Spanish)

WHO: World Health Organization

Declarations

Ethics approval and consent to participate

This protocol was approved by the COMUBI Review Board. A written informed consent was obtained from all participants in the study.

Consent for publication

Not applicable

Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

MP was the study coordinator, made substantial contributions to the conception and design of the study and the drafting and final editing of the manuscript. VSA was responsible for qualitative component of the research, contributed to the data analysis and interpretation and made a critical revision of the manuscript. MC made substantial contributions to the conception and design of the study, contributed with data analysis, and a critical revision of the manuscript. MC and ALP contributed with data collection and made a critical revision of the manuscript. FB and JDM produced the figures and tables (in consultation with co-authors). BF was local principal investigator, were largely involved with project implementation and contributed with interpretation of findings and a critical revision of the manuscript. SA made a substantial contribution to the conception and design of the study, contributed to the data analysis and interpretation and made a substantively revision of the manuscript. All authors read and approved the final manuscript.

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References

1. Das M. WHO launches strategy to accelerate elimination of cervical cancer. *Lancet Oncol.* 2021;22:20–1. doi: 10.1016/S1470-2045(20)30729–4.

2. Arbyn M, Smith SB, Temin S, Sultana F, Castle P. Collaboration on Self-Sampling and HPV Testing. Detecting cervical precancer and reaching underscreened women by using HPV testing on self samples: updated meta-analyses. *BMJ*. 2018;363:k4823.
3. Arrossi S, Thouyaret L, Herrero R, et al. Effect of self-collection of HPV DNA offered by community health workers at home visits on uptake of screening for cervical cancer (the EMA study): a population-based cluster-randomised trial. *Lancet Glob Health*. 2015;3(2):e85–94.
4. Gök M, Heideman DA, van Kemenade FJ, Berkhof J, Rozendaal L, Spruyt JW, et al. HPV testing on self-collected cervicovaginal lavage specimens as screening method for women who do not attend cervical screening: cohort study. *BMJ*. 2010. doi:10.1136/bmj.c1040.
5. Lazcano-Ponce E, Lorincz AT, Cruz-Valdez A, Salmerón J, Uribe P, Velasco-Mondragón E, et al. Self-collection of vaginal specimens for human papillomavirus testing in cervical cancer prevention (MARCH): a community-based randomised controlled trial. *Lancet*. 2011. doi:10.1016/S0140-6736(11)61522-5.
6. Arbyn M, Verdoodt F, Snijders PJ, Suonio E, Dillner L, et al. Accuracy of human papillomavirus testing on self-collected versus clinician-collected samples: a meta-analysis. *Lancet Oncol*. 2014. doi:10.1016/S1470-2045(13)70570-9.
7. Giorgi Rossi P, Marsili LM, Camilloni L, Iossa A, Lattanzi A, Sani C, et al. The effect of self-sampled HPV testing on participation to cervical cancer screening in Italy: a randomised controlled trial (ISRCTN96071600). *Br J Cancer*. 2011. doi:10.1038/sj.bjc.6606040.
8. Carroll C, Patterson M, Wood S, Booth A, Rick J, Balain S. A conceptual framework for implementation fidelity. *Implement Sci*. 2007;2:40.
9. Hasson H, Blomberg S, Dunér A. Fidelity and moderating factors in complex interventions: a case study of a continuum of care program for frail elderly people in health and social care. *Implement Sci*. 2012;7:23.
10. Allen J, Linnan L, Emmons K. Fidelity and its relationship to implementation effectiveness, adaptation, and dissemination. In: Browson R, Graham C, Proctor E, editors. *Dissemination and Implementation Research in Health*. New York: Oxford University Press; 2012.
11. Arrossi S, Paolino M, Thouyaret L, Laudi R, Campanera A. Evaluation of scaling-up of HPV self-collection offered by community health workers at home visits to increase screening among socially vulnerable under-screened women in Jujuy Province, Argentina. *Implement Sci*. 2017;12(1):1.
12. Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A. Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. *BMJ*. 2017;356:i6795.
13. Morse JM. Principles of mixed methods and multimethod research design. In: Tashakkori A, Teddie C, editors. *Handbook of Mixed Methods in Social & Behavioral Research*. Thousand Oaks: Sage; 2003. pp. 189–208.
14. Hogue A, Henderson CE, Dauber S, Barajas PC, Fried A, Liddle HA. Treatment adherence, competence, and outcome in individual and family therapy for adolescent behavior problems. *J Consult Clin*

- Psychol. 2008 Aug;76(4):544–55. doi: 10.1037/0022-006X.76.4.544.
15. Spillane V, Byrne MC, Byrne M, Leathem CS, O'Malley M, Cupples ME. Monitoring treatment fidelity in a randomized controlled trial of a complex intervention. *J Adv Nurs*. 2007 Nov;60(3):343–52. doi:10.1111/j.1365-2648.2007.04386.x.
 16. Bellg AJ, Borrelli B, Resnick B, Hecht J, Minicucci DS, Ory M, Ogedegbe G, Orwig D, Ernst D, Czajkowski S, Treatment Fidelity Workgroup of the NIH Behavior Change Consortium. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol*. 2004 Sep;23(5):443–51. doi:10.1037/0278-6133.23.5.443.
 17. Cohen DJ, Crabtree BF, Etz RS, Balasubramanian BA, Donahue KE, Leviton LC, Clark EC, Isaacson NF, Stange KC, Green LW. Fidelity versus flexibility: translating evidence-based research into practice. *Am J Prev Med*. 2008 Nov;35(5 Suppl):S381-9. doi: 10.1016/j.amepre.2008.08.005.
 18. Santacroce SJ, Maccarelli LM, Grey M. Intervention fidelity. *Nurs Res*. 2004 Jan-Feb;53(1):63–6. doi:10.1097/00006199-200401000-00010.
 19. Siedlecki SL. Research Intervention Fidelity: Tips to Improve Internal Validity of Your Intervention Studies. *Clin Nurse Spec*. 2018 Jan/Feb;32(1):12–14. doi: 10.1097/NUR.0000000000000342.
 20. Dusenbury L, Brannigan R, Falco M, Hansen W. A review of research on fidelity of implementation: Implications for drug abuse prevention in school settings. *Health Educ Res*. 2003;18:237–56.
 21. Fixen DL, Naon SF, Blase KA, et al. Implementation research: a synthesis of the literature. Tampa: University of South Florida, Louis de la Parte Florida Mental Health Institute, The National Implementation Research Network (FMHI Publication #231); 2005.
 22. Hasson H, Blomberg S, Dunér A. Fidelity and moderating factors in complex interventions: a case study of a continuum of care program for frail elderly people in health and social care. *Implement Sci*. 2012 Mar 22;7:23. doi: 10.1186/1748-5908-7-23.
 23. Arrossi S, Paolino M, Laudi R, Gago J, Campanera A, Marín O, et al. Programmatic human papillomavirus testing in cervical cancer prevention in the Jujuy Demonstration Project in Argentina: a population-based, before-and-after retrospective cohort study. *Lancet Glob Health*. 2019;7:e772–83. doi:10.1016/S2214-109X(19)30048-8.
 24. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Medical Research Council Guidance. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*. 2008 Sep 29;337:a1655. doi: 10.1136/bmj.a1655.
 25. Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations for specifying and reporting. *Implement Sci*. 2013 Dec 1;8:139. doi: 10.1186/1748-5908-8-139.
 26. Taplin SH, Rodgers AB. Toward improving the quality of cancer care: addressing the interfaces of primary and oncology-related subspecialty care. *J Natl Cancer Inst Monogr*. 2010;2010(40):3–10. doi:10.1093/jncimonographs/lgq006.
 27. Arrossi S, Thouyaret L, Paul L. Recomendaciones para el tamizaje, seguimiento y tratamiento de mujeres para la prevención del cáncer cervico-uterino en el marco de la incorporación de la prueba de

- VPH. Buenos Aires: Ministerio de Salud de la Nación; 2015. [cited 2021 September]. Available from: <https://bancos.salud.gov.ar/recurso/recomendaciones-para-el-tamizaje-seguimiento-y-tratamiento-de-mujeres-para-la-prevencion>.
28. Nekhlyudov L, Latosinsky S. The interface of primary and oncology specialty care: from symptoms to diagnosis. *J Natl Cancer Inst Monogr*. 2010;2010(40):11–7. doi:10.1093/jncimonographs/lgq001.
 29. Davies L, LeClair KL, Bagley P, et al. Face-to-Face Compared With Online Collected Accounts of Health and Illness Experiences: A Scoping Review. *Qual Health Res*. 2020;30(13):2092–102.
 30. Pérez MC, Chandra D, Koné G, Singh R, Ridde V, Sylvestre MP, Seth A, Johri M. Implementation fidelity and acceptability of an intervention to improve vaccination uptake and child health in rural India: a mixed methods evaluation of a pilot cluster randomized controlled trial. *Implement Sci Commun*. 2020 Oct 8;1:88. doi: 10.1186/s43058-020-00077-7.
 31. Gale NK, et al. “Using the Framework Method for the Analysis of Qualitative Data in Multi-Disciplinary Health Research.” *BMC Med Res Methodol*, 13, 1, Dec. 2013, 117, doi:10.1186/1471-2288-13-117.
 32. Braun V, Clarke V. Using Thematic Analysis in Psychology. *Qualitative Res Psychol*. Jan. 2006;3(2):77–101. doi:10.1191/1478088706qp063oa. “”, , .
 33. Curotto M, Zalacaín-Colombo J, Paolino M, Arrossi S. Adopción e implementación del ofrecimiento de la autotoma VPH por agentes sanitarios en Jujuy, Argentina [Adoption and implementation of HPV self-collection sampling by CHWs in Jujuy, Argentina]. *Salud Publica Mex*. 2018;60(6):674–82. doi:10.21149/8854. Spanish.
 34. von Thiele Schwarz U, Aarons GA, Hasson H. The Value Equation: Three complementary propositions for reconciling fidelity and adaptation in evidence-based practice implementation. *BMC Health Serv Res*. 2019 Nov 21;19(1):868. doi: 10.1186/s12913-019-4668-y.
 35. Sundell K, Beelmann A, Hasson H, von Thiele Schwarz U. Novel Programs, International Adoptions, or Contextual Adaptations? Meta-Analytical Results From German and Swedish Intervention Research. *J Clin Child Adolesc Psychol*. 2016 Nov-Dec;45(6):784–796. doi: 10.1080/15374416.2015.1020540.
 36. Sanchez Antelo V, Szwarc L, Paolino M, Saimovici D, Massaccesi S, Viswanath K, Arrossi S. Counseling Mobile App to Reduce the Psychosocial Impact of HPV-Testing: Formative research from a user-centered design approach in a low-middle income setting in Argentina *JMIR Formative Research*. 17/11/2021:32610 (forthcoming/in press).
 37. Paolino M, Campanera A, Martiarena S, et al. Adherencia al triaje en contexto de tamizaje con autotoma del test de virus del papiloma humano en la provincia de Jujuy *Rev Argent Salud Pública*. 2019;10(40):7–13. Registro RENIS No: IS001709.
 38. Paolino M, Gago J, Pera AL, Cinto O, Thouyaret L, Arrossi S. Adherence to triage among women with HPV-positive self-collection: a study in a middle-low income population in Argentina. *Ecancermedicalscience*. 2020;14:1138. doi:10.3332/ecancer.2020.1138.
 39. Sancho-Garnier H, Tamalet C, Halfon P, et al (2013) HPV self-sampling or the Pap-smear: a randomized study among cervical screen- ing non-attenders from lower socioeconomic groups in France *Int J Cancer* 133(11) 2681–2687 <https://doi.org/10.1002/ijc.28283> PMID: 23712523.

40. Holme F, Maldonado F, Martinez-Granera OB, et al. HPV-based cervical cancer screening in Nicaragua: from testing to treatment. *BMC Public Health*. 2020;20(1):495.
41. Giorgi Rossi P, Fortunato C, Barbarino P, et al. Self-sampling to increase participation in cervical cancer screening: an RCT comparing home mailing, distribution in pharmacies, and recall letter. *Br J Cancer*. 2015;112(4):667–75.
42. Paolino M, Sankaranarayanan R, Arrossi S. Determinantes sociales del abandono del diagnóstico y el tratamiento de mujeres con Papanicolaou anormal en Buenos Aires. *Argentina Rev Pan de Salud Pública*. 2013;34(6):437–45.
43. Zapka J, Taplin S, Anhang Price R, et al. Factors in quality care—the case of follow-up to abnormal cancer screening tests— problems in the steps and interfaces of care. *J. Natl Cancer Inst Monogr*. 2010;40:58–71. <https://doi.org/10.1093/jncimonographs/lgq009>.
44. Arrossi S, Paolino M, Sanchez Antelo V, Thouyaret L, Kohler E, Cuberli M, Flores L, Serra V, Viswanath K, Orellana L. Effectiveness of an mHealth intervention to increase adherence to triage of HPV DNA positive women who have performed self-collection (the ATICA study): a hybrid type I cluster randomized effectiveness-implementation trial. *Lancet Reg Health-Americas*, 2022: 9: <https://doi.org/10.1016/j.lana.2022.100199>.
45. Khresheh R, Lesley B. Practice–research engagement. Jordanian experience in three Ministry of Health hospitals. *Action Res*. 2007. doi:10.1177/ 1476750307077313.
46. Yamey G. Scaling up global health interventions: a proposed framework for success. *PLoS Med*. 2011. doi:10.1371/journal.pmed.1001049.

Map

Map 1 is available in the Supplementary Files section

Figures

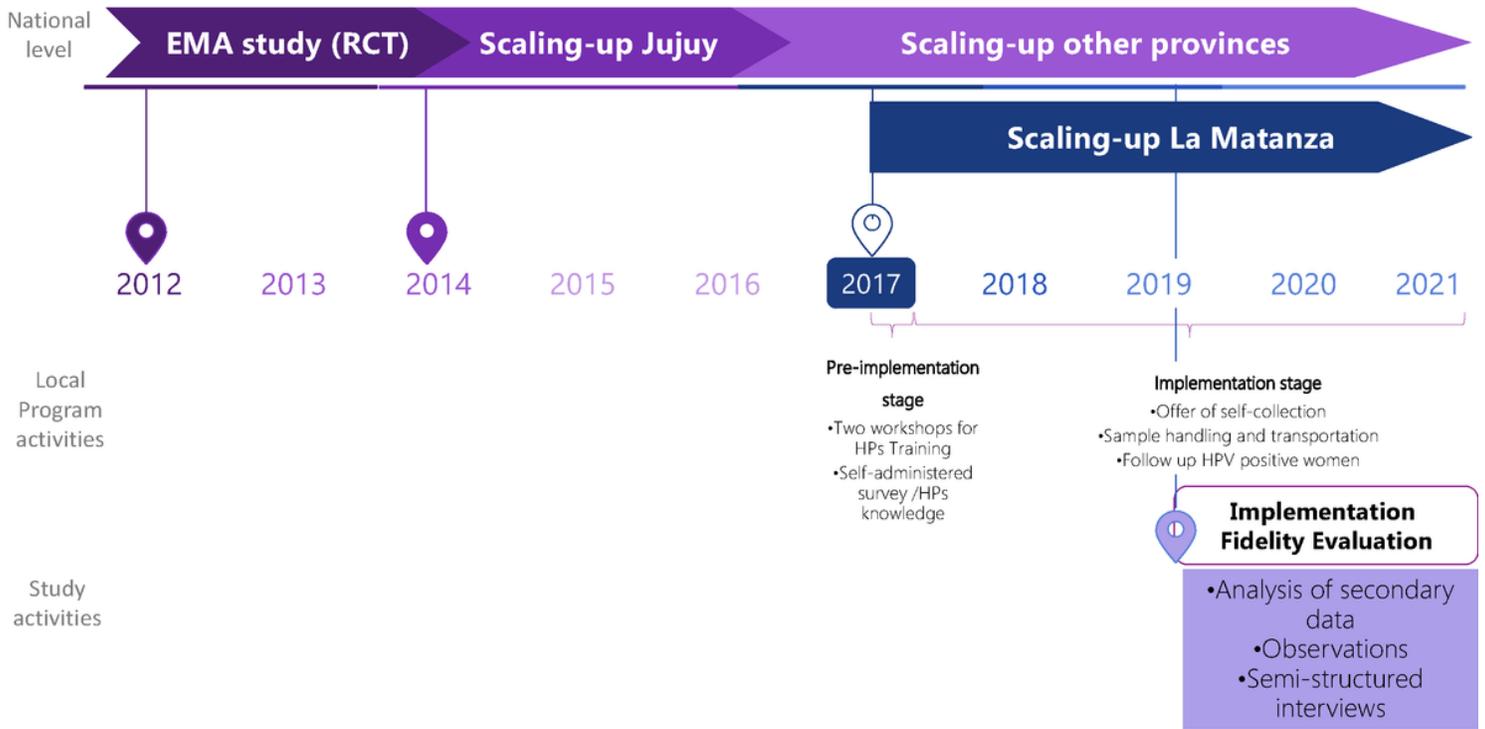


Figure 1

Phases of EMA strategy implementation and evaluation

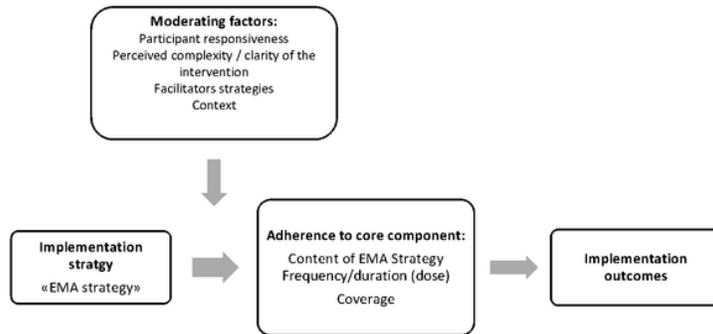


Figure 2

CFIF model adapted to EMA strategy

Adapted from *Caroll et al., 2007; Hasson et al., 2010*

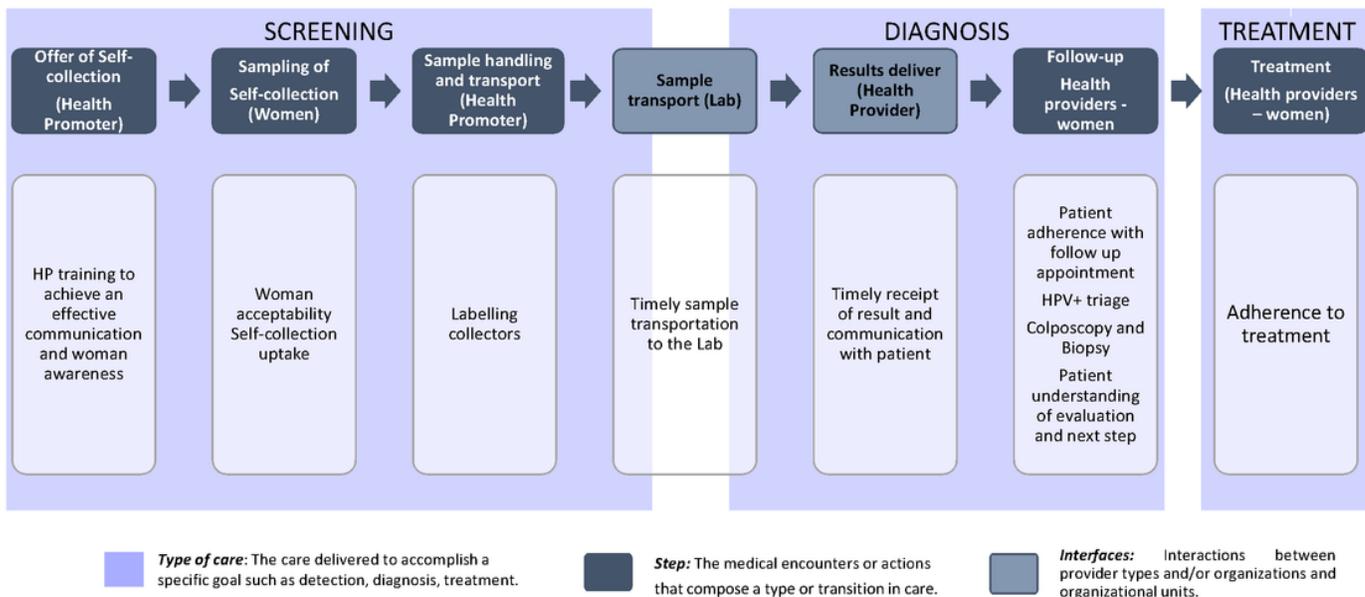


Figure 3

Steps and interfaces in EMA strategy

Adapted from Taplin and Rodgers 2010²⁵ and Nekhlyudov et al., 2010.²⁸

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Map1.pdf](#)
- [Additionalfile1.StaRIchecklistArrossifidelity.docx](#)
- [Additionalfile2Leaflet.pdf](#)
- [Suppl.file1.Submissionexplanation.docx](#)