CHAPTER 2.

Methodology

2.1 Advocacy and project planning

The preparatory phase of the Care-4Afrique project began in September 2017 with meetings organized in each focus country between representatives of IARC, the LSF, the MoH, WHO country offices, academic institutions, and civil society organizations. At these meetings, several topics were discussed at length, including the need to improve cervical cancer screening, the objectives of the project, the implementation plan, and the support required from the different stakeholders. The national stakeholders in each focus country identified one project leader (principal investigator) for their country. After extensive discussions with the national stakeholders, the project protocol was customized for each country, taking into consideration the existing national screening guidelines (if any) and the local needs, feasibility, and expectations.

In each country, the services were planned to be delivered through a maximum of five PHCs (to provide VIA and thermal ablation services)

Official launch of the Care4Afrique project in Dakar, Senegal, on 28 November 2017.

and one secondary care facility (to provide colposcopy, cervical biopsy, and LLETZ services). It was decided that the nurses, midwives, and GPs providing routine care at the PHCs would be trained to perform VIA and thermal ablation, and the gynaecologists at the secondary care facilities would be trained to perform colposcopy and LLETZ. The master trainers were identified from the departments of gynaecology at the academic institutions. The data collection tools were designed and finalized after discussion with the stakeholders and were used to develop an electronic database. A data manager was identified in each country to collect the paper records from the screening and colposcopy centres and enter the data into the electronic database regularly. A country-specific final project plan was drafted and approved by the respective national team.

The screening and treatment protocol and the project implementation plans were approved by the national ethics committee in each country as well as by the IARC Ethics Committee. The project was registered in the International Standard Randomized Controlled Trial Number (ISRCTN) trials registry (registration number: ISRCTN21518741; https://doi.org/10.1186/ISRCTN21518741).

The project activities started at different times in different countries, because the time taken to finalize the project plan and obtain the regulatory approvals varied.

2.2 Site selection and assessment of site readiness

The project was designed to screen at least 5000 women per country in the target age group within 18 months from the start of the project and to manage the screen-positive women appropriately. In each country, the project implementation sites and the service delivery sites were identified in consultation with the MoH and other national stakeholders. On the basis of their suggestions, four or five PHCs were selected in each country to provide VIA-based screen-and-treat services, and one secondary-level facility was selected for the referral of the screen-positive women who were not eligible for thermal ablation. The MoH also provided the required regulatory clearances and approvals to use the designated health facilities for the project and to release the staff members for training. A focal point for the project was identified within the MoH to liaise with the principal investigator and other national stakeholders.

The screening facilities were set up at five PHCs in Benin, four PHCs in Côte d'Ivoire, and four PHCs in Senegal. In each country, the nearest district hospital was identified as the secondary-level facility to provide colposcopy services (Table 1).

The principal investigators visited the designated facilities together with the representatives of IARC and the LSF and completed a checklist to assess the site readiness. Lists were made of the staff members to be trained to provide various services, and of the equipment and consumables that were available and those that had to be procured to start services. Equipment and consumables, including vaginal specula, punch biopsy forceps, electro-diathermy machines for loop excision, and thermal ablation devices, were provided to the project sites according to their requirements, to enable the screening and management of at least 5000 women.

2.3 Training of service providers

An assessment of training needs was performed for each country, and a training plan was prepared accordingly. Two master trainers (gynaecologists) to be trained in cervical cancer prevention, early detection, and management were identified in each country.

The training of trainers course was organized by IARC in February 2018 in collaboration with the Nargis Dutt Memorial Cancer Hospital

Ethics approval

1. Approval date 17 October 2017, IARC Ethics Committee (150 cours Albert Thomas, 69372 Lyon Cedex 08, France; Tel: +33 (0)4 72 73 83 41; Email: iec-secretariat@iarc.fr), Ref. Project No. 17-33.
2. Approval date 7 September 2018, National Ethics Committee for Health Research of Benin (BP 01-882 Benin, Cotonou, 01882, Benin; Tel: +229 (0)21 33 2178; Email: info@sante.gouv.bi), Ref. N_58/MS/DC/SGM/DRFMAT/CNERS/SA.
3. Approval date 21 June 2018, National Ethics Committee of Life and Health Sciences (16ème Étage-Tour C Cité Administrative Abidjan-Plateau, Abidjan, 00225, Côte d'Ivoire; Email: ministere.sante@egouv.ci), Ref. 078-18/MSHP/CNESVS-km.
4. Approval date 18 December 2017, Health Research of Senegal (Rue Aimé Césaire – Fann Résidence, Dakar, 12500, Senegal; Tel: +221 (0)869 42 42; Email: informatique@sante.gouv.sn), Ref. Protocol SEN 17/65.

Master trainers were trained in cervical cancer prevention, early detection, and treatment at the Nargis Dutt Memorial Cancer Hospital, Barshi, India.

Table 1. Facilities and categories and numbers of health professionals providing screening, colposcopy, and treatment services in the three focus countries

Country	Sites providing screening services	Screening performed by	Site providing colposcopy services	Colposcopy performed by
Benin	CHU MEL, Cotonou	Midwives (*n* = 4) GP (*n* = 1)	CHU MEL, Cotonou	Gynaecologists (*n* = 2)
	Surulere General Hospital, Cotonou	Nurse (*n* = 1) Midwives (*n* = 4)		
	PHC Missessin, Cotonou	Midwives (*n* = 4)		
	PHC Gbégamey, Cotonou	Nurse (*n* = 1) Midwives (*n* = 3)		
	PHC Ahouansori, Cotonou	Nurse (*n* = 1) Midwives (*n* = 4)		
Côte d'Ivoire	Service de SMI/NIPH, Abidjan	Midwives (*n* = 4) Gynaecologist (*n* = 1)	NIPH, Abidjan	Gynaecologists (*n* = 2)
	CSU 220 Logements, Abidjan	Midwives (*n* = 4) Gynaecologist (*n* = 1)		
	FSU COM Edmond Basque, Abidjan	Midwives (*n* = 4) Gynaecologist (*n* = 1)		
	Hôpital Général d'Abobo-Sud, Abidjan	Midwives (*n* = 4) Gynaecologist (*n* = 1)		
Senegal	Gaspard Kamara District Hospital, Dakar	Nurses (*n* = 2) Midwives (*n* = 15) GPs (*n* = 4)	Gaspard Kamara District Hospital, Dakar	Gynaecologists (*n* = 2)
	PHC HLM, Dakar	Nurses (*n* = 2) Midwives (*n* = 4) GP (*n* = 1)		
	PHC Liberté VI, Dakar	Nurse (*n* = 1) Midwives (*n* = 5) GP (*n* = 1)		
	PHC Maristes, Dakar	Nurses (*n* = 5) Midwives (*n* = 4) GPs (*n* = 2)		

CHU MEL, Centre Hospitalier et Universitaire de la Mère et de l'Enfant Lagune; FSU COM, Formation Sanitaire Urbaine à Base Communautaire; GP, general practitioner; HLM, Habitations à Loyer Modéré; PHC, primary health centre; SMI/NIPH, Santé Maternelle et Infantile/National Institute of Public Health.

Providers were trained in visual inspection with acetic acid (VIA) and thermal ablation in Côte d'Ivoire.

Providers were trained in Benin.

Nurses and midwives were trained in visual inspection with acetic acid (VIA) and thermal ablation in Benin.

(NDMCH), India, and the LSF. The course used a hybrid approach, in which each trainee completed a self-paced online learning module made available on the IARC website before they attended the 1-week practical hands-on training at NDMCH. The French-speaking faculty members included two master trainers from Morocco and two from France. The master trainers from Benin were not able to attend the training of trainers course in India. A separate training course was organized for them in Dakar, Senegal.

Local training courses were conducted for the nurses, midwives, GPs, and gynaecologists who participated in the project at each site. These courses were led by the master trainers in each country. The training included both theoretical knowledge and activities to develop practical skills. An assessment of competency was performed for each trainee, after which a certificate was issued. Continuing supportive supervision and at least one refresher training within a year was provided by the master trainers in each country. Training in data management with the electronic database developed with Research Electronic Data Capture (REDCap) software was conducted in each country by an IARC staff member.

The training sessions held in the three focus countries are listed in Table 2.

Table 2. Training sessions in the three focus countries

Country	Details of the training sessions
Benin	• Primary training course: conducted on 28–31 May 2019 at the Claudine Talon Foundation • Total number of trainees: 27 • Virtual refresher training courses for midwives: conducted on 15 October 2020 and 19 November 2020
Côte d'Ivoire	• Primary training course: conducted on 16–19 July 2018 at the National Institute of Public Health (Institut National de Santé Publique), Abidjan • Total number of trainees: 20
Senegal	• Primary training course: conducted in two sessions (9–12 April 2018 and 16–19 April 2018) at Gaspard Kamara District Hospital, Dakar • Total number of trainees: 45 • Refresher training: conducted independently at each primary health centre (PHC) involved in the project on 19–21 December 2018 • Training course and refresher training on colposcopy and management of cervical precancers: conducted on 14 and 15 January 2019 at Gaspard Kamara District Hospital to train gynaecologists from Senegal and Benin

2.4 Protocol for screening and treatment services

Target age ranges for cervical cancer screening vary between countries. According to the national recommendations, the recommended target age range was 25–49 years in Benin and Côte d'Ivoire and 30–49 years in Senegal. Screening was performed with the VIA test, and VIA-positive women were immediately assessed for eligibility for ablative treatment using the standard criteria. The criteria used to determine eligibility for ablative treatment were as follows: the squamocolumnar junction is fully visible and is on the ectocervix, the lesion is ectocervical and occupies less than 75% of the ectocervix, and there is no suspicion of invasive cancer. The women who were eligible for thermal ablation were offered treatment on the same day. The women who were not eligible for thermal ablation were referred for colposcopy and further investigation. Women with suspected invasive cancer were also referred to the colposcopy facility. Screen-negative women were advised to attend for repeat VIA after 3 years in Benin and Côte d'Ivoire and after 5 years in Senegal. In Senegal, women living with HIV were advised to attend for screening more frequently (every 3 years).

Cervical cancer screening was performed by trained nurses, midwives, or GPs at the designated screening clinics. All women aged 25–49 years (in Benin and Côte d'Ivoire) or 30–49 years (in Senegal) who attended the clinics for various reasons and provided informed consent were offered VIA opportunistically. Women with debilitating illnesses, those with a diagnosis of cervical cancer, and those who had been screened for cervical cancer within the previous 36 months were excluded. The women were counselled either individually or in groups.

Women who required referral for colposcopy were adequately counselled and provided with the details of the colposcopy clinic. At the colposcopy clinic, most of the women with suspected high-grade lesions on colposcopy were offered LLETZ treatment on the same day without waiting for histopathological verification. Women with suspected cancer had cervical biopsies taken at the colposcopy clinic and were managed on the basis of the histopathology report (Fig. 4).

Examination rooms in primary health centres (PHCs) providing visual inspection with acetic acid (VIA) and thermal ablation services in Côte d'Ivoire and Senegal.

2.5 Follow-up of women after treatment

After treatment, women were advised to attend the screening centre for follow-up after 12 months. The VIA test was repeated at follow-up. Women with persistent lesions after thermal ablation were referred to the colposcopy clinic. Women with a normal cervix at follow-up were advised to attend for routine screening after 3 years in Benin and Côte d'Ivoire and after 5 years (or after 3 years for women living with HIV) in Senegal.

2.6 Operational framework and project monitoring

The operational framework of the Care4Afrique project is shown in Fig. 5. At the community level, project activities included creating awareness through communication and education targeting women in the age group 25–49 years (in Benin and Côte d'Ivoire) or 30–49 years (in Senegal). At the primary care level, VIA was performed. Women with a positive VIA result received immediate treatment with thermal ablation or, if the lesion did not meet the criteria for thermal ablation, were referred to the secondary level, where further evaluation could be provided (colposcopy, LLETZ, or biopsy). Healthcare providers were trained and services were monitored and evaluated at all levels.

The principal investigator in each country and the facility in charge were responsible for regular monitoring of the project activities. From time to time, IARC shared the analysed data on screening performance with them.

Periodic discussions were held with all the service providers to track the progress of the work and to receive feedback from them. During the course of the project, at least one supportive supervision visit was held, and the specific activities listed in Table 3 were reviewed to track the progress of the project in each of the three countries. The supportive supervision visit was conducted jointly by IARC and the LSF, and recommendations were made for improvement. The facilities in charge were actively involved in all the supportive supervision visits.

Fig. 4. Flow chart of cervical cancer screening and management. LLETZ, large loop excision of the transformation zone; PHC, primary health centre; VIA, visual inspection with acetic acid.

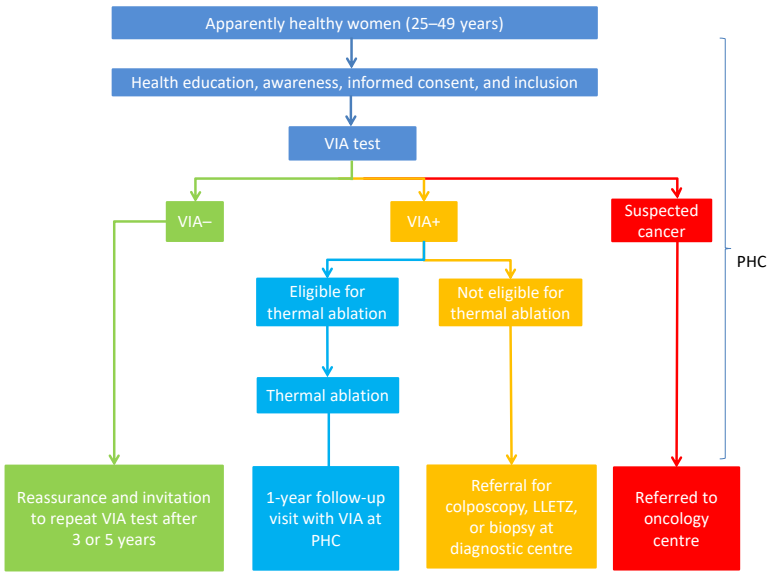

Fig. 5. Operational framework of the Care4Afrique project. IARC, International Agency for Research on Cancer; LLETZ, large loop excision of the transformation zone; LSF, Lalla Salma Foundation for Cancer Prevention and Treatment; MoH, ministry of health; PHC, primary health centre; TA, thermal ablation; VIA, visual inspection with acetic acid.

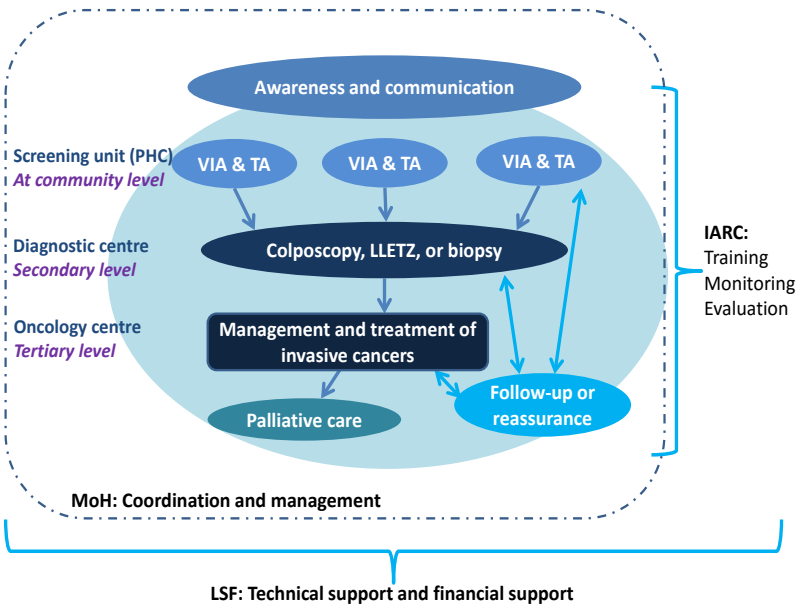

Table 3. Activities included in the supportive supervision visit

1. Assessing the infrastructure of the clinic, the adequacy of privacy and cleanliness, the condition of the equipment, and the supply of consumables
2. Assessing the performance of the service providers for screening, treatment, and other procedures, using a performance checklist
3. Reviewing the infection prevention protocol and the adherence to this protocol by the staff members in the clinic
4. Assessing the quality and completeness of record-keeping
5. Receiving feedback from the different categories of service providers
6. The following key performance indicators were estimated from the records maintained at the clinics and monitored: a. Number of women screened per month b. Proportion of the women screened beyond age 25–49 years (in Benin and Côte d'Ivoire) or 30–49 years (in Senegal) c. VIA positivity rate d. Proportion of VIA-positive women referred to a diagnostic and treatment clinic (secondary care facility) e. Proportion of VIA-positive women eligible for ablative treatment who received treatment f. Proportion of VIA-positive women eligible for ablative treatment who received same-day treatment g. Proportion of women who attended a diagnostic and treatment clinic for positive VIA results who underwent colposcopy (for diagnostic and treatment clinic only) h. Proportion of women with suspected high-grade lesions on colposcopy who were treated (for diagnostic and treatment clinic only)

2.7 Awareness campaign

The screening services in the project were opportunistic, and women who attended the PHCs for various reasons were counselled to undergo screening. Where feasible, community mobilization was done by the community health workers and/or through public awareness campaigns in the newspaper, on the radio, on television, or on the Internet with the help of local nongovernmental organizations, established supportive foundations, and the MoH. The women who underwent screening were asked to spread the word by telling their relatives and friends about the screening service.

2.8 Data collection and data management

Every woman who underwent screening received a registration card with a unique identity number. The outcomes of VIA, colposcopy, treatment of precancerous lesions, and follow-up assessments were entered on paper case record forms and were later entered into REDCap, an electronic data capture tool hosted at IARC [12, 13]. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing (i) an intuitive interface for validated data capture, (ii) audit trails for tracking data manipulation and export procedures, (iii) automated export procedures for seamless data downloads to common statistical packages, and (iv) procedures for data integration and interoperability with external sources. Data were regularly monitored locally and by IARC, to assess the progress of the project and to estimate the key performance indicators.

Supportive supervision visit in Senegal.

(a) The installation of a banner at the entrance to Gaspard Kamara District Hospital in Dakar, Senegal, at the launch of the project, announcing free-of-charge cervical cancer screening and treatment services. (b) Awareness messages delivered to women waiting for cervical cancer screening at a facility in Benin. (c) Face-to-face discussion with participants to explain the screening procedures in Côte d'Ivoire.

(a) The records of each woman who underwent screening were entered in a primary health centre (PHC) register. (b) Data from paper case record forms were entered into the electronic database developed with REDCap software.