# Challenges in preventative care and research in primary healthcare facilities: information obtained during implementation of a cervical cancer screening project in the Tshwane Health District

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#### Abstract

**Objectives**: The aim was to identify challenges to conducting research and obstacles to successful cervical cancer screening in public sector primary healthcare clinics (PHCs).

Design: Qualitative research was conducted, using semi-structured interviews.

**Setting and subjects**: Study staff and healthcare workers involved in the implementation of a large screening study conducted in existing primary healthcare facilities were interviewed during the study period.

**Outcome measures**: The outcome measure was qualitative data on problems and obstacles to research and cervical cancer screening in public health facilities.

**Results**: Twenty-one participants were interviewed at intervals over three years. It was found that clinical research could only be conducted in PHC facilities if no additional burden was placed on the staff or facilities. Preventative care was not found to be part of the focus of the clinics, which rather concentrated on disease. The need for gynaecological examinations was identified as an important obstacle to screening at PHC clinics. Self-sampling was widely accepted, as was cervical sampling for human papillomavirus. Reporting of screening results to patients presented a huge challenge to PHC facilities. Ineffective communication of the results was identified as another major obstacle to effective screening.

**Conclusion**: Future cervical cancer screening methods should include sampling, without the need for an intimate examination. Finding new ways of calling women in for structured screening at regular intervals and reporting the results to them requires urgent attention.

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# Introduction

Approximately 80% of cervical cancer cases worldwide occur in developing countries, where it is still the most common cancer in women and survival of the disease remains poor.<sup>1</sup> The disease is mostly diagnosed in the late stages in South Africa, resulting in poor survival. The result is that interventions to prevent the disease in our country are predicted to be very cost-effective.<sup>2</sup> The high prevalence and late diagnosis are widely attributed to socio-economic factors, but imperfect access to screening and health care also play an important role. The success of cytology screening is strongly based on repetitive testing by trained healthcare workers in a well equipped facility, combined with effective communication. It is no surprise that the effective implementation of such programmes in developing settings is uncommon.<sup>3</sup> Testing for high-risk human papillomavirus (HPV), the well established causative agent of cervical intraepithelial and invasive neoplasm, provides an exciting alternative screening method, with proven sensitivity and cost-effectiveness. Furthermore, its use for primary screening has been advocated by South African experts since 2009.<sup>4-6</sup>

In addition, the availability of HPV vaccines provide the opportunity to prevent cervical cancer, primarily in future generations, by providing immunity to HPV types responsible for oncogenesis.<sup>7,8</sup> Decisions on the use of HPV vaccines and HPV-based screening must be based on accurate and up-to-date data on HPV types associated with disease. Although infection with a limited range of oncogenic HPV types causes cervical cancer, the geographical variation in prevalence and type distribution is reported to exist between regions. Changes also occur over time.<sup>9</sup> Most of the available data on the epidemiology of HPV-associated disease has been collected in the developed world. Limited data exist from the northern part of South Africa.<sup>10</sup>

A large prospective, cross-sectional study was performed on urban and peri-urban South African women from 2009-2012 to describe the current local epidemiology of high-risk HPV-associated cervical disease. In addition, this study also aimed to identify and address challenges to cervical cancer screening in primary healthcare facilities. The results of prevalence, type and distribution of HPV infection and cervical cytology were recently published.<sup>11</sup> The outcomes of self-sampling, and details and historical context of cytology and HPV-type distribution in women with normal and abnormal cytology are reported elsewhere in this issue.<sup>12-15</sup> The aim of this report was to describe the background and methodology of this study, and to report identified obstacles and challenges to the implementation of cervical cancer screening in primary healthcare clinics, and to propose potential solutions to these problems.

### Method

The research was conducted in Tshwane Health District, in collaboration with municipal primary healthcare clinics. Approval for this screening study was obtained from the Faculty of Health Sciences Research Ethics Committee, University of Pretoria Ethics Board (Protocol No: 210/2008). The research ethics and the decision to conduct the study on municipal primary healthcare clinics was also approved by the Tshwane Metropolitan Municipality health authority. Investigators identified suitable clinics that serve a variety of social and patient populations, namely the Olievenhoutbosch, Atteridgeville, Sammy Marks, Eastlynn, Lyttelton, Pomolong and Winterveld clinics. These study sites are situated in the inner city, townships and peri-urban area (up to 50 km from the city centre). Numerous economic groups attend these facilities, and reside in informal settlements, high-density housing and relatively affluent formal townships. The clinics were visited by the research staff and invited to participate in the study. Suitable areas were identified for counselling and speculum examination. Study staff members were trained to perform conventional cervical cytology and cervical dry swab collection for HPV testing, and to instruct patients to self-test.

One study day per week was identified which suited the clinic routine. An on-site study contact person was appointed for communication purposes, usually the nurse manager. Participants were provided with written and explained information and asked to sign consent. A speculum examination was performed to collect conventional cervical cytology. HPV testing was carried out on a dry swab from the cervix, or from a selfinserted tampon left in the vagina for approximately two hours. Laboratory testing and reporting of cervical cytology and HPV specimens was conducted according to standard protocol, and as previously described.<sup>16</sup> Testing was performed at the Departments of Anatomical Pathology and Medical Virology, National Health Laboratory Service, Tshwane Laboratory, the University of Pretoria. Referral for further treatment was guided only by the cytology result, using standard government referral routes. Patients were asked to return for their results and telephonically traced if the results were abnormal. The study interventions were performed by specially appointed research nurses.

Data collection included an audit of sites, as well as interviews with healthcare and study personnel, to assess challenges to clinical research and cervical cancer screening in the PHC facilities. During the initial pilot phase, pre-study screening audit data, patient load and staffing were assessed, as well as facilities, equipment and the environment. During the study phases, individual interviews were conducted with administrative and healthcare personnel involved in the different aspects of the project, as described. Two site coordinators frequently visited the sites to collect information on obstacles and challenges, and to seek solutions that involved the local staff. Administrative support and data collection was centralised and was considered to be invaluable to the success of the project. Administrative personnel also provided unique viewpoints during interviews. Participants in the interviews were selected on the basis of their involvement in the screening project, and/or in the PHC system of the area. Over a period of three years, participants included seven nurses in charge of the selected clinics, three junior nurses, eight research nurses, two site coordinators and three municipal and regional healthcare managers.

Challenges were reported by participants with regard to aspects of research, and aspects that related to the implementation of cervical cancer screening in existing primary healthcare clinics. Data from these interviews were collected over time, structured and analysed. In addition, the methods employed by staff to solve these problems and which were reported during the interviews were investigated further. Solutions that were tested, confirmed and implemented during the current trial are reported.

#### Results

Some problems were unique to the conduct of a

research project in a busy and understaffed primary healthcare clinic, but it is likely that many of the encountered problems were linked to the underlying causes for the partial failure of the cervical cytology screening. Usually, aspects of suboptimal care are linked to "malfunctioning" segments of the health system, including facilities, staff, communication and equipment. However, the problems that were identified in this study question the role of the general or "mixed" primary healthcare clinic in a developing country with regard to traditional cervical cancer screening. Therefore, obstructions and solutions that were identified are discussed according to the underlying principle of care.

### Research in the primary healthcare facilities

Clinical research in a primary healthcare clinic in the developing world presents investigators with unique challenges. The most prominent encountered obstacles during this project were low staffing levels, conflict between clinical needs and study objectives, and limited or no experience of clinical research. Staff capacity problems were only resolved by supplying extra project personnel for the research steps, including those that usually belong to clinical care. A shortage of basic equipment, like stationery, was easily resolved by supplying more than the needs of the study. Excellent relations and communication were essential in order to share the limited space available and the burden created by the need to obtain written informed consent, as well as the need to collect data, which was carried out completely by the study personnel. In this study, clinical research was welcomed, provided that benefits were added without any extra burden to an already overstretched healthcare system.

# Preventive care at the primary healthcare facilities

Major differences in cervical cancer screening habits were detected before the intervention between the facilities from the screening audit data. Most clinics had very low screening statistics before the start of the project, although adult women comprised the largest patient group. Screening represents testing for possible asymptomatic or future disease. In the current study, it did not compare favourably with the attention that disease demands. Risk detection is inherently at a disadvantage when competing with existing illness. Women who attended the facilities during the study period usually suffered from an illness, or were accompanied by another patient, making them a poor target for the current and ineffective system of opportunistic screening. Another prominent finding from the interviews was that preventive care only received attention when capacity existed and when targets were set and outcomes awarded.

# Gynaecological care at the primary healthcare facilities

Traditional cervical cancer screening requires that speculum examination, a light source and sterilising equipment (or disposables) are available in the clinic. A standard examination couch is adequate, but trained staff is needed, and privacy must be guaranteed. These requirements demand a separate room with an area in which to undress. The initial investigation of the selected clinics for this study revealed that many facilities did not have an existing private separate room. It had to be created for the duration of the study by using dividers. This room or area usually had to be shared, even on screening days, because of the patient load. Light sources were primitive, but sufficient. Sterilising equipment and limited gynaecological instruments were available. More instruments were needed to meet the relatively low numbers set as study targets (approximately five patients per screening day). These were provided and donated to the sites after the study.

# Novel technologies at the primary healthcare facilities

During this study, two sampling methods for molecular screening were introduced into the existing clinics. Study nurses were only provided with brief oral instructions on how to collect the HPV samples, using a study protocol document. Cervical swabs were taken at the time of the speculum examination. This method demands less accuracy and less training than cytology, but is still reliant on an invasive and intimate gynaecological examination. The nursing staff reported no problems in collecting these samples. The patients were not aware of the additional sampling. Patient-collected tampon sampling demanded that an explanation was given to the patient, but this was not reported to be a burden by the nurses. This study did not evaluate patient perceptions of tampon sampling, but study participants reported that patients were interested in, and even excited about, an alternative to a speculum examination. Uptake was close to 100%. Self-sampling requires a small private area only, such as a toilet, although the examination room was usually used during this study. Dry swabs were easier to store and transport than tampon specimens, mainly because of volume and some reported leakage of the medium.

# Communication to patients at the primary healthcare facilities

Laboratory results are traditionally reported to the health facility, which then has to communicate the results to the patient. The communication of results followed the routine method in this study, and thus the process could be studied. The effective communication

of results required many successful steps, including results from the laboratory, reading and correctly interpreting them, identifying abnormal results, locating contact details, making contact with the patient and successfully interpreting the results and the necessary action to patients. It is clear from this process that reporting often failed. Multiple difficulties were reported by the study participants. Participants reported that PHC clinics were generally poorly equipped and had a budget with regard to storing and retrieving files and patient details, as well as calling patients. Most patients who needed treatment were contacted using the research facilities. Referral for treatment was usually performed via the PHC clinic. Participants reported well developed referral pathways at most of the clinics.

### Discussion

Clinical research in the PHC system is possible and was conducted successfully. It is believed that the project added value to the community and the permanent staff, who was exposed to research methods and new screening technologies. The many challenges to research in this setting were mostly overcome by providing extra resources, including equipment and staff.

Staff members at primary healthcare facilities do not focus on preventive care because of the conflicting priority of disease, inadequate capacity and motivation, and an inappropriate patient population. This finding is in accordance with many recent reports on ineffective preventive care and the inability of primary care facilities to implement guidelines for prevention.<sup>17,18</sup> Lack of capacity highlights the need to involve women in a screening programme in a totally new way that does not rely on opportunistic screening. Call-recall of patients for repetitive structured cytology screening using the existing PHC system requires enormous investment in facilities, staff and data systems, and is not considered to be a realistic option.<sup>19</sup>

During interviews with study participants who were involved in the clinics, it was reported that an intimate examination was difficult for staff and patients at primary health facilities. The main problem was a suitable private area, rather than the availability of instruments. Gynaecological instruments are available on a limited basis, but clinics struggle to provide a dedicated private area in which intimate examinations can be conducted. Health planners need to take note of this finding as women have been identified as an important target for primary health care. Various aspects of reproductive health care necessitate gynaecological examinations.

The need for a gynaecological examination was identified as an important obstacle to screening at

the PHC clinics in this study. Even if the facilities were improved, this obstacle would remain, and would probably prevent many women from being screened for the reasons mentioned. Molecular screening has been successfully piloted in other countries.<sup>20-22</sup> Based on the results from this study, it is proposed that our country implements molecular primary screening with self-sampling as soon as possible. Areas without existing facilities should be targeted first.

The reporting of screening results presents a huge challenge to PHC facilities. Ineffective communication of the results was identified as a major obstacle to effective screening. Identifying the obstacles to successfully trace patients for treatment, confirmed this as a major weakness in the programme. It is proposed that results should be communicated electronically, directly to the patient. Participants were not optimistic about interventions to drastically improve the percentage of patients reached via existing communication systems.

## Limitations

Limitations of this study included the relatively small number of participants in the interviews, the restricted geographical distribution of the clinics, and limitations inherent to the study methodology. The results may not be representative of other regions, and the interpretation of the results may not be reproducible. Individual interviews ensured anonymity, and ample and equal opportunity for each participant to express her views. Participation by staff of different seniority and involvement in the health system enriched the findings.

### Conclusion

Currently, healthcare facilities are too overburdened by treatment needs to optimally attend to screening for asymptomatic conditions. Conducting intimate gynaecological examinations is problematic in many existing clinics. Dedicated clinics may be more suited to attend to women's reproductive health needs. HPVbased technology can assist to improve cervical cancer screening because self-screening is possible. Selfsampling was widely accepted by women participating in this project and is proposed for facilities that are not equipped nor staffed to conduct gynaecological examinations.

The results from this study suggest that primary healthcare facilities need strengthening to enable preventive interventions. In addition, novel technologies, including self-screening and direct reporting to the patient, could relieve the burden on PHCs remarkably, while creating the opportunity to up-scale screening. The role of the primary healthcare clinic remains crucial in interpreting results and supporting and referring patients for treatment. This study was conducted in an urban setting, but the results could be very useful in rural areas, where facilities and staffing are under even more stress.

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#### Declaration

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