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Challenges and Progress of Policies on Cervical Cancer in South Africa

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Abstract

Cervical cancer is the second most common cancer in South African women but the most frequently encountered cancer in black women. In 2000, the South African Department of Health launched a national cervical screening program. However, this has not been fully implemented because of the chronic shortage of health care workers and a lack of essential medical equipment. In addition, there is also a high burden of infectious diseases in this country. South Africa has the largest expanding HIV burden in the world and it is estimated that 6.3 million people in South Africa were living with HIV in 2013, representing 18% of all people living with HIV worldwide.

The high prevalence of HIV complicates the situation as HIV-infected women have greater rates of pre-invasive and invasive cervical cancer rates. In April 2011 the South African government launched the HIV Counseling and Testing (HCT) campaign, a new national drive to encourage people to know their HIV status and access counseling and treatment, including cervical screening. A universal test and treat (UTT) strategy was adopted in September 2016 after research showed that this type of program will reduce the chance of HIV transmission. The South African National Department of Health will soon announce and implement a new cervical cancer control policy. Over the past few years, the South African Department of Health has introduced several new policies regarding HIV testing and care, and plans to introduce a new cervical screening policy shortly. This overview discusses the progress as well as challenges the South African department of health has with the various programs.

Introduction

Cervical cancer is one of the most common causes of cancer deaths in South African women, and as such an important public health issue. Cervical cancer is a largely preventable disease. However, in South Africa, an average of 7735 new cases is diagnosed per annum and about 4248 women succumb to this cancer annually [1]. Currently, no effective, well implemented population-wide screening program is available in South Africa. Opportunistic cervical cancer screening has been available to all South African women for the last 50 years. The aim of this publication is to portray the effects of the various programs implemented by the South African Department of Health

Background of South African Health Services

In March 2012, 165 371 qualified health practitioners in both public and private sectors were registered with the Health Professions Council of South Africa (HPCSA), the health practitioner watchdog body. This includes 38 236 doctors and 5 560 dentists. The doctor-topopulation ratio is estimated to be 0.77 per 1 000. As the vast majority of General practitioners - 73% - work in the private sector, there is just one practicing doctor for every 4 219 people in the public sector [2]. Patients in rural areas suffer due to these shortages as South Africa struggles to attract and retain enough medical staff to provide health services not only in the urban areas, but particularly in remote locations. In South Africa, 43.6% of the population lives in rural areas, but only 12% of the country's doctors work in rural healthcare facilities [3]. The doctors in the public sector are mainly involved with the treatment and management of preinvasive and invasive cervical carcinoma. Almost all screening cervical smears are taken by nurses. The records of the human resources of public health indicates that 51 966 (45.1%) of the 115 244 nurses registered in South Africa work in the public sector and the other 63 278 (54.9%) work in the private sector. The 45.1% of nurses are responsible for primary health care of more than 80% of the South African population. Apart from a chronic shortage of qualified doctors, nurses and other healthcare workers, poor management, a lack of much needed medicines as well as essential medical equipment, there is additionally a high burden of infectious disease in South Africa [4].

In a cervical screening program, be it cytology, HPV or visual inspection based, qualified medical personnel and adequate equipment, is required. There are more than 80 cytology laboratories in South Africa. Twelve well-equipped cytology laboratories are coordinated by the National Health laboratory services (NHLS) which serves predominantly the public sector (between 80-90% of the national population). These 12 laboratories are currently responsible for the support of the national screening program.

Prevention of Cervical Carcinoma

Numerous studies have proven the efficacy of a multipronged approach involving primary, secondary and tertiary prevention to curtail the incidence of, and mortality from, cervical cancer [5]. Primary prevention includes safe sex practices and HPV vaccination. Secondary prevention of cervical cancer includes screening for preinvasive lesions as well as early diagnosis of invasive carcinoma followed by adequate treatment and management [6]. The success of secondary prevention will be determined by the population coverage and the efficacy of the screening technique utilized. Current screening techniques in use in South Africa include mainly conventional cytology while most private laboratories (serving the private health care sector) offer liquid based cytology in addition to conventional cytology as well as HPV testing (DNA or mRNA). VIA or VILI (visual inspection using acetic acid or

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Lugol's iodine) also forms part of secondary prevention. The current national cancer control policy does not endorse VIA or VILI, but NGO's are offering this service in various parts of the country. Tertiary prevention of cervical cancer involves the diagnosis and treatment of confirmed cases of cancer. Treatment is through surgery, radiotherapy and sometimes chemotherapy. Palliative care in the public sector is usually provided to patients when the disease has already reached an incurable stage.

Secondary Prevention in South Africa: A Cervical Cancer Screening Program

Research shows that well implemented and non-opportunistic National Cervical Screening Programs can significantly reduce the morbidity and mortality rates attributed to cervical cancer [7]. According to the WHO, successful screening programs require > 80% coverage, appropriate follow-up and management of patients with positive tests, effective links between screening diagnosis and treatment services, high quality care and adequate resources [8]. Several proposals for cervical screening offered and submitted by academics and professional societies were rejected by policy making authorities of South Africa, mostly on the basis of perceived high cost [9].

Opportunistic cervical cancer screening has been available to all South African women for the last five decades, which is commonly practiced in the private sector. In several regions partial screening takes place, however, currently, there is still no effective population-wide screening program in South Africa.

National Cancer Control Program (NCCP) 2000

A step forward towards an effective South African cervical cancer screening program was made in 1999. At that time, the National Department of Health approved the National Cancer Control Program (NCCP) as a South African health policy. The aim of this policy was to reduce the incidence of carcinoma of the cervix, primarily by detecting and treating the pre-invasive stage of the disease; to reduce the morbidity and mortality associated with cervical cancer; and to ultimately reduce the excessive expenditure of scarce health funds spent on the treatment of invasive cancer of the cervix [9]. The National Guidelines for a Cervical Cancer Screening Program was then launched in 2000. This policy indicated that every asymptomatic woman over the age of 30 should have 3 free conventional cervical smears during her lifetime, with a 10 year interval between the cervical smears - should this patient remain asymptomatic. The goal of the national program for Cervical Cancer Screening was to screen at least 70% of women nationally, within the target age group, within ten years of initiating the program [9].

A national meeting in 2004, however, indicated that the various provinces were not reaching their targets. The Minister of Health announced that the cervical cancer policy would start afresh in 2005 and would end in 2014 [10]. Targets were set for every facility and training of health care workers was intensified. Churches, non-government organizations (NGOs) as well as the Department of Health intensified awareness programs indicating the importance of preventing cervical carcinoma throughout the various regions and districts of South Africa. The target population (70% of all women, 30 years and older) was calculated as 6 866 222. In order to reach this target in 10 years, the annual national target was set at an average of 686 622 Pap smears from asymptomatic women (Figure 1).

Unfortunately no reliable national cytology statistics are available for

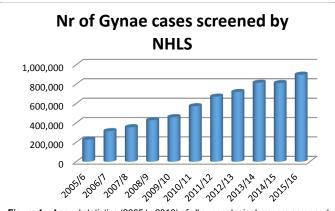


Figure 1: Annual statistics (2005 to 2016) of all gynecological smears screened at the National Health Laboratory Service (NHLS), the South African public sector laboratory (12).

the totals of smears screened during the screening program from 2000 to 2004. The central data warehouse (CDW) of the NHLS commenced at the beginning of 2005 with the implementation of various data programs to assist the cytology program coordinators with the relevant management and evaluation tools for the cytology programs. The total of gynecological cases demonstrated in graph 1 includes smears taken from all asymptomatic and symptomatic women regardless of their HIV status, repeat smears, unsuitable smears and unsatisfactory smears. The NHLS national statistics shows an average of 2% unsuitable smears received between 2005 and 2014. Unfortunately the health care workers do not always complete the request forms properly and fail to indicate whether the woman is asymptomatic or not, except for many of the health care workers from the Western Cape Province. When interrogating the data of the Western Cape, it appears that about 40% of the smears taken by them were from asymptomatic women. It can therefore be assumed that only a maximum of 40% of the annual total demonstrated in Graph 1 represents the totals of smears taken from asymptomatic women as per the national screening program. Following intense training of a large portion of the health care workers, updated statistics for 2015/16 show 26,7% of all cervical smears were taken from HIV+ women; 11,7% were taken from symptomatic women and 50,1% of the total smears were taken from asymptomatic women. The outstanding percentage of smears indicates that 11, 5% of the request forms were still not completed in full.

(Figure 1) demonstrates a steady increase in the number of cervical smears from 2005 up to 2016. However, it clearly indicates that the targets of 686 622 smears per annum for the 2005-2014 cervical cancer control policy were not met, as was the case for the previous program launched in 2000. The shortage of health care workers; lack of equipment, loss to follow-up of patients with abnormal cytology and lack of ample awareness programs (amongst others) are all some of the reasons for the failure of this screening program. Integration of cervical health screening into other women's health services at primary health care level, as well as motivation and training of health care providers, proved to be essential factors for the success of the cervical screening program [11, 12]. Even more alarming is the fact that most of the patients with an abnormal cervical smear result, referred for colposcopy or LLETZ, are placed on very long waiting lists, some as long as 18 months, due to insufficient number of health care facilities that undertake colposcopy and excision [13]. There is no value in rendering a diagnosis for any patient if treatment for that patient is delayed or not available.

Cervical cancer diagnosed cytologically is demonstrated in Figure

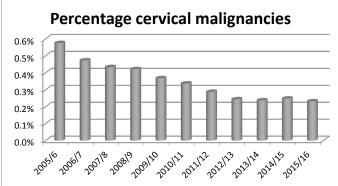


Figure 2: Annual statistics of percentage of gynecological cases diagnosed as cervical carcinoma cytologically-screened at the National Health Laboratory Service (NHLS), the South African public sector laboratory (12).

2. Although the statistics in this graph indicates that the percentage pick-up rate dropped from about 0.6% (2005/6) and stabilized at about 0.2% (2012/13 to 2015/16), it must be noted that cervical smears are not usually taken from women with obvious cervical carcinoma. A cervical biopsy, rather than a smear, is usually recommended. The statistics in Figure 2 may also demonstrate that the correct section of the population may possibly not be screened e.g. predominantly low-risk women are screened. The percentages documented in graph 2 were calculated as a percentage of invasive cervical malignancies divided by the total number of Pap smears screened during that year. All cytology reports are reported as per the 2012 Bethesda reporting system [14].

HIV Counseling and Testing (HCT) Program 2011

Another flaw in the 2005-2014 cervical cancer policy is that it did not account for HIV status and the need to screen more frequently in patients that are HIV-positive. In April 2011, the South African government launched the HIV Counseling and Testing (HCT) campaign, a new national drive to encourage people to know their HIV status and access counseling and treatment, including cervical screening. The HCT policy indicates that a cervical smear must be taken at diagnosis of HIV positivity (if the patient has a CD4 count ≤ 250/µl) and, if normal, the cervical smear should be repeated every three years, irrespective of antiretroviral treatment (ART) status. The policy also indicated that women with abnormal smears require a repeat smear within a year if no other intervention is indicated [15]. According to the HCT program, all the women diagnosed positive for HIV with a CD4 count of $\leq 250/\mu l$ as demonstrated in Table 1 should have had cervical smears taken [15]. The statistics in Figure 1 demonstrates that the annual total of cervical smears screened at the NHLS did not reach this target (Figure 3). Demonstrates the annual totals of women tested HIV positive with a CD4 count \leq 250/ μl, from 10-15 year to over 90 year age groups. The distinct high number of HIV positive women under the age of 30 with this particular CD4 count is significant, noting that the cervical cancer screening program commences only from the age of 30. During 2014, the Minister of Health announced that all women tested positive for HIV with a CD4 count ≤ 500/µl, will be placed on ART and will also need a cervical smear taken [16]. According to the statistics from the central data warehouse at the NHLS, during 2015/2016 a total of 1 332 672 women were tested positive for HIV with a CD4 count $\leq 500/\mu l$ (Figure 4).

Figure 4 demonstrates a similar curve as Figure 3. The peak of both the curves starts at women ages 26 to 30, but the women with a CD4 count \leq 250/µl in this age group equals about 130 000 women compared to 245 000 women with a CD4 count \leq 500/µl. The 2015/2016

target of 686 622 smears for the screening program plus the 1 332 672 women tested positive for HIV (CD4 count \leq 500/µl) who should all have had cervical smears taken, were clearly not met as the NHLS only received a total number of cervical smears of 900 000 pap smears within this year (Figure 1).

Universal Test and Treat (UTT) Strategy 2016

In September 2016, the HCT program was replaced by a universal test and treat (UTT) strategy, after research showed that this type of program will reduce the chance of HIV transmission. This new strategy indicates that all women tested positive for HIV should receive ART and have a cervical smear taken regardless of their CD4 counts [17]. Table 2 demonstrates the annual totals of women tested positive for HIV

| | HIV+ women with CD4 count ≤ 250/μI | | | | | | |
|-----------|------------------------------------|-----------|-----------|-----------|--|--|--|
| 2010/2011 | 2011/2012 | 2012/2013 | 2013/2014 | 2014/2015 | | | |
| 685,911 | 683,913 | 573,275 | 536,921 | 516,287 | | | |

Table 1: Statistics from the Central data warehouse of the NHLS indicating the number of female patients tested HIV viral load positive with CD4 counts $\leq 250/\mu l$ at the laboratory (2010-2016).

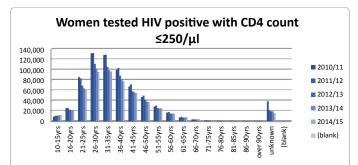


Figure 3: Statistics of women tested HIV positive with a CD4 count $\leq 250/\mu$ I, per 5 years age groups (10-90+ years), from 2010 up to 2015 - screened at the National Health Laboratory Service (NHLS), the South African public sector laboratory (12).

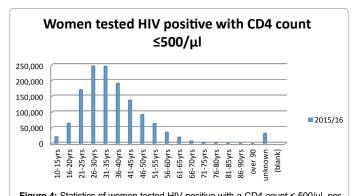


Figure 4: Statistics of women tested HIV positive with a CD4 count ≤ $500/\mu$ l, per 5 years age groups, (10-90+ year), 2015-2016 - screened at the National Health Laboratory Service (NHLS), the South African public sector laboratory (12).

| | Women tested HIV Viral load positive at the NHLS laboratory | | | | | | |
|--|---|-----------|-----------|-----------|-----------|-----------|--|
| | 2010/2011 | 2011/2012 | 2012/2013 | 2013/2014 | 2014/2015 | 2015/2016 | |
| | 462,339 | 838,461 | 851,991 | 918,560 | 895,749 | 1,012,053 | |

Table 2: Statistics from the Central data warehouse of the NHLS indicating the number of female patients tested HIV viral load positive at the laboratory (2010-2016).

at the NHLS laboratories. This increased from 462 339 during 2010/11 to 1 012 053 during 2015/2016. Table 2 demonstrates the annual totals of women tested positive for HIV at the NHLS laboratories. This increased from 462 339 during 2010/11 to 1 012 053 during 2015/16. Unfortunately no statistics is available for point of care testing done at the various facilities. The point of care testing would include onsite testing for HIV. Despite this policy changes in 2011, 2014 as well as 2016, there was no rapid escalation in the number of cervical smears received at the NHLS.

The Impact of the HCT As Well as UTT Program on the Cervical Cancer Screening Program in South Africa

With the implementation of both HCT and UTT programs, a dramatic increase of cervical smears was expected. However, this effect was not noted with the implementation of previous programs. The lack of well- trained and motivated health care workers and facilities as well as all relevant equipment within the HIV facilities, poses a major challenge to reach these targets. Should these programs have the desired effect, the exponential increase in the numbers of cervicalsmears to be taken as well as reported on, the impact of HIV on the occurrence of cervical cancer and its precursors must be noted. The numbers of patients requiring treatment will increase dramatically. Treatment facilities are already overburdened with long waiting lists for women needing treatment. Provision must also be made to follow up women who have received the appropriate therapy as the regression or recurrence of the lesion must be ascertained and managed.

HIV-infected women have greater incidence rates of pre-invasive and invasive cervical cancer. The large variance in the percentage of cytologic lesions in HIV-negative, compared to HIV-infected, women within the same age ranges is documented in Table 3. These women will require management, a further burden on the under-resourced South African public health sector (Table 3). The percentages of women diagnosed cytologically with ASC-US, LSIL, HSIL /ASC-H as well as cervical malignancy, per 5y age groups (20-61+ years) - both HIV negative and HIV positive - was calculated as totals of women per 5y age groups (20-61+ years) divided by the total women screened per age group for the period 2013 to 2016. The expected influx of cervical smears of women diagnosed with ASC-US as well as LSIL as demonstrated in Table 1 may overwhelm the screening laboratories. Options of doing HPV triaging on these patients will have to be considered. The very high percentage variances of HIV negative women to HIV positive women diagnosed with HSIL as well as cervical carcinoma (as per table 3) is enormous. These women will all need treatment which is already a big challenge in South Africa. Figure (5,6,7 and 8) demonstrate the

| | ASC-US | | LSIL | | HSIL plus ASC-H | | Malignant | |
|-------|--------|------|------|------|-----------------|------|-----------|------|
| | HIV- | HIV+ | HIV- | HIV+ | HIV- | HIV+ | HIV- | HIV+ |
| 20-25 | 1.8 | 3.8 | 1.8 | 5.2 | 0.4 | 2.2 | 0.0 | 0.1 |
| 26-30 | 2.2 | 6.0 | 1.8 | 8.7 | 1.1 | 6.3 | 0.2 | 0.8 |
| 31-35 | 2.0 | 6.4 | 1.8 | 8.7 | 1.6 | 8.8 | 0.4 | 2.0 |
| 36-40 | 1.6 | 5.5 | 1.3 | 7.3 | 1.3 | 8.7 | 0.6 | 3.5 |
| 41-45 | 1.6 | 3.9 | 1.2 | 4.4 | 1.2 | 5.8 | 0.7 | 3.0 |
| 46-50 | 1.4 | 2.7 | 0.8 | 2.5 | 1.0 | 3.7 | 1.4 | 2.7 |
| 51-55 | 1.0 | 1.5 | 0.4 | 1.2 | 0.9 | 1.9 | 2.8 | 2.7 |
| 56-60 | 0.7 | 0.8 | 0.3 | 0.5 | 0.5 | 1.0 | 2.8 | 1.4 |
| 61+ | 1.6 | 1.2 | 0.6 | 1.0 | 1.2 | 1.5 | 4.1 | 2.1 |

Table 3: Comparison of percentages of women diagnosed with ASC-US, LSIL, HSIL/ASC-H as well as cervical malignancy, per 5 years age groups (20-61+ years) – both HIV negative and HIV positive - screened at the National Health Laboratory Service (NHLS), the South African public sector laboratory (12).

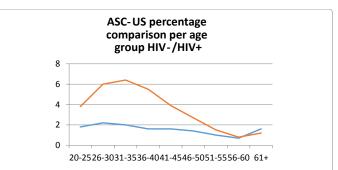


Figure 5: Percentage of women diagnosed with ASC-US per 5 years age groups (20-61+ years) – both HIV negative and HIV positive - screened at the National Health Laboratory Service (NHLS), the South African public sector laboratory (12).

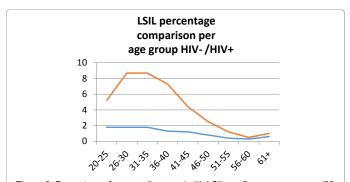


Figure 6: Percentage of women diagnosed with LSIL per 5 years age groups (20-61+ years) – both HIV negative and HIV positive - screened at the National Health Laboratory Service (NHLS), the South African public sector laboratory (12).

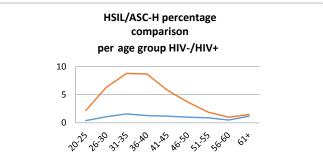


Figure 7: Percentage of women diagnosed with HSIL/ASC-H per 5 years age groups (20-61+ years) – both HIV negative and HIV positive - screened at the National Health Laboratory Service (NHLS), the South African public sector laboratory (12).

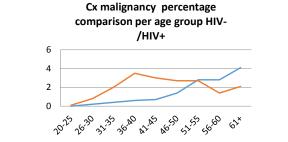


Figure 8: Percentage of women diagnosed with cervical malignancy per 5 years age groups (20-61+ years) – both HIV negative and HIV positive - screened at the National Health Laboratory Service (NHLS), the South African public sector laboratory (12).

variances in percentage of women (HIV negative as opposed to HIV positive) diagnosed with ASC-US, LSIL, HSIL/ASC-H and malignancy respectively. The percentages of women diagnosed cytologically with ASC-US, LSIL, HSIL/ASC-H as well as cervical malignancy, per 5y age groups (20-61+ years) – both HIV negative and HIV positive – was calculated as totals of women per 5y age groups (20-61+ years) divided by the total women screened per age group for the period 2013 to 2016. The massive variances in most of the age groups, underscores the need to screen the women diagnosed positive for HIV. It is very interesting to note in Graph 8 that the percentage of women over the age of 50 who are HIV negative have a higher incidence rate of cervical carcinoma. It is surmised that older, HIV-negative women may not access health facilities as often as younger women e.g. young women bringing small children for vaccination. If older women do visit health facilities, clinic staff may not be sensitized to perform a cervical screen on them.

Conclusion

Though cervical carcinoma is a largely preventable disease, an average of 4 248 women in South Africa die annually from this disease [18]. Research shows that well-implemented, non-opportunistic national cervical screening programs can significantly reduce the morbidity and mortality rates attributed to cervical cancer [19]. Both the cervical cancer screening program as well as the HCT program is not close to reaching the target population. The high prevalence of cervical lesions in HIV+ women in this study underscores the need to implement a well-organized screening program. The UTT program was implemented in September 2016. A new cervical cancer control policy is due to be released soon, combining new technologies with current screening strategies. Staff shortages, the limited availability of medication as well as much needed equipment will have to be addressed by the National Department of Health as a matter of urgency. Training and continual motivation of health care workers is required to ensure that maximal numbers of women undergo cervical screening, appropriate management of cervical abnormalities and follow up of treated women.

This underscores the need to implement the tools already available for the prevention of cervical cancer, notably HPV vaccination, new technologies available, i.e., HPV triaging or co- testing, VIA/VILLI as well as well-organized national programs for both screening and management. The vast rural areas in South Africa as well as the heavy burden of HIV disease, indicates that the diagnosis and management will not be a "one size fits all" for all South African women. Further studies need to confirm whether cytology screening will remain to be the norm in South Africa; whether the same technology, e.g. HPV screening or VIA/VILLI will be more suitable for the rural women and whether the same HPV test will be suitable for both HIV positive as well as HIV negative women.

Ethics Approval and Consent to Participate

This is a review article analyzing several, previously published studies. Therefore no ethics approval was sought.

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Conflict of Interest

The authors declare no conflict of interest.

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