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The impact of decentralising colposcopy services from a busy tertiary hospital to a primary care clinic in inner-city Johannesburg, South Africa

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Manuscripts

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3 **Title:** The impact of decentralising colposcopy services from a busy tertiary hospital to a
4 primary care clinic in inner-city Johannesburg, South Africa
5

6
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3 **Abstract (max 300 words)**
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5 **Objective:** To assess whether decentralising colposcopy services to a primary care facility in
6 inner-city Johannesburg, South Africa raises access to colposcopy.
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9 **Design:** Before-after study comparing two years before and two after decentralisation, using
10 clinical records, and laboratory data on cervical cytology and histology.
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13 **Primary outcome:** The proportion of all women attending HCHC with an abnormal Pap
14 smear who had a colposcopy post-decentralisation.
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16
17 **Setting:** Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) has provided
18 colposcopy services for several decades. The Hillbrow Community Health Centre (HCHC),
19 located about 3km away, began colposcopy services in 2014.
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23 **Participants:** Women, aged above 18 years, who had a colposcopy for diagnosis and
24 treatment of precancerous cervical lesions following a Pap smear, from 2012-2016 at
25 CMJAH or HCHC.
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29 **Results:** Pre-decentralisation at CMJAH, 910 women had colposcopy (2012-2014). Post-
30 decentralisation (2014-2016), 721 had colposcopy at CMJAH and 399 at HCHC, the
31 decentralised facility. The number who had a Pap smear at HCHC and then a colposcopy
32 rose three-fold post-decentralisation (114 versus 350). Post-decentralisation, 43 women at
33 HCHC were referred from to CMJAH for colposcopy, compared to 114 pre-decentralisation.
34 Post-decentralisation, 47.3% of women at CMJAH waited >6 months for colposcopy, while
35 35.5% did at HCHC ($p < 0.001$). Across all three groups, 26.9-30.3% of women had CIN III
36 lesions or carcinoma on colposcopy. The proportion of invalid specimens was similar at
37 CMJAH and HCHC (1.8-2.8%). Of 401 women who had an abnormal Pap smear at HCHC post-
38 decentralisation, 267 had colposcopy (66.6%).
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47 **Conclusion:** Decentralisation can decrease the time to colposcopy and reduce the workload
48 of tertiary hospitals. Overall, more women accessed services. Colposcopy coverage at HCHC
49 is higher than other sites, but could be further improved. Decentralisation did not appear to
50 affect the quality of services and this model could be extended to similar settings in South
51 Africa and elsewhere.
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55 **Key words:** South Africa, colposcopy, cervical cancer, primary health care, decentralisation
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Article Summary

Strengths and limitations of this study

- Data were collected for the purposes of patient care, and not specifically for research, potentially reducing data quality.
- The limited data collected meant that the study could not fully investigate several important questions, such as reasons for delays in colposcopy, and whether these delays relate to limited human resources for performing colposcopy or deficiencies in laboratory capacity, for example.
- Given that the study only covered the first two years after decentralisation, we are unable to ascertain the intervention's sustainability in the long-run.
- The study strengths include a relatively large number of women in all study groups, allowing us to detect differences between the time periods

Introduction

Though cervical cancer is a largely preventable disease, it is the second most common cancer among women aged 15 to 44 years in the world (1). In South Africa, it is the commonest cancer in that age group, and mortality rates are high (2, 3). About 3% of women in South Africa harbour cervical human papilloma virus (HPV)-16/18, which is responsible for the majority of cases of cervical cancer in the country (3). Rates of cervical cancer in South Africa can partly be attributed to the high HIV prevalence rate (4). Women with HIV infection have a seven fold higher rate of persistence of high-risk HPV compared to HIV uninfected women (5), heightening their risk for incident and progressive precancerous lesions. While antiretroviral therapy reduces the risk of cervical cancer and its precursors, the risk remains much higher than for HIV-negative women (6).

Cervical screening is used for the early identification and treatment of pre-cancerous lesions of the cervix. Screening methods include HPV screening, visual inspection with acetic acid, or cytology through Papanicolaou (Pap) smear, with referral of atypical findings for colposcopy to establish a definitive diagnosis. During colposcopy, the view of the cervix is magnified and, where required, a biopsy is taken or a large loop excision of the transformation zone (LLETZ) is conducted. WHO recommends that women who are older than 30 years have repeat cervical cancer screening every 3-5 years, and more frequently if HIV infected (7).

A range of health systems and patient factors influence access to colposcopy. System barriers include a limited number of colposcopy services, which are mostly centralised within tertiary-level facilities, with long waiting times for patients and few opportunities for non-specialist health workers to develop requisite skills (8). There are limited numbers of specialist gynaecologists within the public sector, and the high demands on these doctors for emergency and curative obstetric and gynaecology services may reduce the time available for diagnostic or preventive interventions, such as colposcopy. Another key factor is the complexity of providing Pap and other results to patients and then scheduling colposcopy appointments across the disjointed systems that often exist between a tertiary hospital and primary care centres (9-11). Patient-related factors linked with low uptake of colposcopy include low education levels, being single, fear of HIV testing and disclosure, a low CD4 count in HIV-infected women and transport costs for the additional visits (10, 12,

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3 13). Patient demand for colposcopy is also undermined by a general fear of cancer, and lack
4 of awareness or knowledge about cervical cancer (9, 14). Poor patient-provider interactions
5 restrict access, whilst a longstanding relationship with a primary clinician can optimise
6 uptake (14).
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10 In South Africa, patients who require colposcopy are generally referred to a tertiary-level
11 facility where the procedure is rendered by specialist gynaecology oncologists and trainee
12 gynaecologists under supervision. While there may be benefits to decentralising colposcopy
13 services to lower levels of care, these need to be balanced by the advantages of
14 centralization of cancer services, such as concentrating clinical expertise, with a higher
15 quality of care, and the rationalisation of expensive specialist equipment. Thus, in this
16 before- and after-study, we assessed whether access to colposcopy would be raised by
17 decentralising colposcopy services from a tertiary-level hospital to a primary care facility in
18 inner-city Johannesburg, South Africa.
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26 **Methods**

27 **Study participants and setting**

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30 Women, aged 18 years and older, who accessed colposcopy services at either Charlotte
31 Maxeke Johannesburg Academic Hospital (CMJAH) or Hillbrow Community Health Centre
32 (HCHC) between October 2012 and September 2016 were included in the study. Both
33 facilities are in sub-district F of the Johannesburg Health District (JHD).
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38 The Colposcopy clinic at CMJAH is part of the Gynaecology-Oncology Department at CMJAH,
39 which has two colposcopy machines operated by specialist gynaecology-oncologists.

40 Women attending a facility in JHD who have an abnormal Pap smear are referred to the
41 facility, where they are provided with an appointment date for colposcopy.
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45 Hillbrow Community Health Centre (HCHC) is situated in the densely populated inner-city
46 area of Hillbrow, about 3km from CMJAH. HCHC provides primary level care, including a 24
47 hour casualty and a midwife obstetrics unit. The facility is run predominantly by nursing
48 staff, with support from non-specialist medical doctors.
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53 **Implementation of decentralised services**

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3 In 2013, a review of patient files at HCHC found that a large proportion of women attending
4 the HIV clinic had high-risk lesions on Pap smear (15). Moreover, there were some reports
5 from patients and health workers at HCHC of prolonged waiting times for colposcopy
6 services at CMJAH. The Wits Reproductive Health and HIV Institute (Wits RHI) thus set about
7 establishing colposcopy services at the facility. A private sector company donated a
8 colposcopy machine. Two district medical officers were trained by specialist gynaecology
9 oncologists at CMJAH to provide the service. CMJAH staff provided ongoing support and
10 established referral processes between the two facilities. The services, which began in
11 October 2014, were provided twice a week by the medical officers, with assistance from the
12 nurse who takes Pap smears at the facility. Patients attending HCHC and some surrounding
13 clinics were given an appointment for colposcopy if they had an abnormal Pap smear result,
14 defined as: high-grade squamous intraepithelial lesion (HSIL), atypical squamous cell and
15 HSIL cannot be excluded (ASC-H), or squamous cell carcinoma (SCC) (16). A few patients
16 with Pap smear results other than those defined as abnormal smears were also referred for
17 colposcopy. Patients with complex lesions, such as abnormal cervical anatomy or a high
18 suspicion of cancer on Pap smear were referred to CMJAH, as were those with a failed
19 colposcopy. Colposcopy procedures included visual inspection only, or visual inspection
20 together with either a Lletz or biopsy. After colposcopy, patients were given a date to return
21 for results, where decisions on further tests and clinical management were made. Histology
22 specimens from both sites were processed at the National Health Laboratory Service (NHLS).

37 38 **Data sources and collection**

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40 For the purpose of this evaluation, women who accessed colposcopy services at CMJAH and
41 HCHC were divided into three groups, according to when and where colposcopy took place:
42 1) pre-decentralisation at CMJAH between October 2012 and September 2014; 2) post-
43 decentralisation at CMJAH between October 2014 and September 2016; and 3) post-
44 decentralisation at HCHC between October 2014 and September 2016.

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46 At CMJAH, we extracted data from paper-based records at the colposcopy clinic, including
47 on patients' age, HIV status, antiretroviral treatment, date of Pap smear, Pap smear result,
48 date of colposcopy, colposcopy procedure performed and histology results. Data were
49 entered into a REDCap electronic database (REDCap Software, Version 4.14.5, Vanderbilt
50 University) (17). At HCHC, demographic and clinical data on women who accessed
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3 colposcopy services were entered into an MS Excel spreadsheet after each patient visit.
4 Data were also obtained from the NHLS on Pap smear cytology for women attending HCHC
5 who had a Pap smear and for the whole JHD.
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8 **Study variables and statistical analysis**

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10 Patient characteristics and colposcopy procedures were compared between HCHC and
11 CMJAH post-decentralisation, and within CMJAH before and after decentralisation. Time to
12 colposcopy was calculated as the number of months from date of Pap smear to colposcopy
13 and was categorised as optimal (under 3 months), acceptable (3-6 months) and delayed
14 (greater than 6 months). Histology results were classified as normal (includes benign
15 endocervical polyp, atrophic ectocervical mucosa, koilocytosis and metaplasia), Cervical
16 Intraepithelial Neoplasia (CIN) I, CIN II, CIN III, carcinoma, other (includes infections such as
17 cervicitis, inflammation and dysplasia) and invalid specimens (includes absent results). The
18 coverage of colposcopy services at HCHC, the primary outcome, was estimated by
19 calculating the proportion of all women at HCHC with an abnormal Pap smear who had a
20 colposcopy.
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30 Data were presented as proportions, medians and inter-quartile ranges, and differences
31 between groups were assessed using a chi-square test or a Wilcoxon rank-sum test, as
32 appropriate. All data were analysed using STATA version 13.0.
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36 **Ethical considerations**

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38 Ethical approval was obtained from Human Research Ethics Committee of the University of
39 the Witwatersrand (Certificate number: M151184). Permission for use of the CMJAH data
40 was granted by the hospital's Chief Executive Officer and the head of the Department of
41 Obstetrics and Gynaecology at CMJAH. The NHLS Academic Affairs and Research Office gave
42 permission for use of their data.
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47 **Patient Involvement**

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49 The study utilised data that had already been collected as part of routine patient care, and
50 thus patients were not directly involved in the study. The findings will be used to further
51 optimise their care and extend the intervention to other sites. We aim to include patients in
52 those activities.
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Results

Of all Pap smears done in the JHD in the two years after decentralisation (114,983), 1.9% were done at HCHC (2227; Table 2). Of these, 18.0% had abnormal cytology and required colposcopy (n=401), compared to only 8.2% of other women in JHD as a whole (n=1826; $p<0.001$).

In total, 910 women accessed colposcopy at CMJAH between October 2012 and September 2014. In the subsequent two years, 1120 women had a colposcopy: 399 at HCHC (35.6%) and 721 at CMJAH (64.4%; Table 1 and Figure 1a). The estimated colposcopy coverage among women who had a Pap smear at HCHC was 66.6% (267/401; 95%CI=61.7-71.2%).

The median age women at CMJAH was 37.1 years pre-decentralisation and 39.4 years post-decentralisation ($p<0.001$), and was 37.5 years at HCHC. In the post-decentralisation period, more women at CMJAH were older than 45 years than women at HCHC (30.6% versus 21.9%; $p=0.002$). At CMJAH, more women had a known HIV status pre-decentralisation than post-decentralisation (71.4% versus 59.5%, $p<0.001$). All women at HCHC had a documented HIV status. Around 85% of women with a known HIV status were HIV positive in all three groups. The proportion of positive women receiving ART rose in the second period at CMJAH from 78.7% to 87.6% ($p<0.001$), and almost all positive women were on ART at HCHC (99.7%; $p<0.001$).

In both periods, the large majority of women who had a colposcopy at CMJAH had had a Pap smear elsewhere, while three quarters of women who had a colposcopy at HCHC also had their Pap smear at the facility. The percentage of women at CMJAH who had had a Pap smear at HCHC halved post-decentralisation ($p<0.001$) and the absolute number decreased from 113 to 43. Post-decentralisation, the number of women who had a Pap smear at HCHC and then a colposcopy at either facility rose three-fold (from 113 to 350). At HCHC, post-decentralisation, 24.2% of women who had a colposcopy at HCHC, had a Negative for intraepithelial lesion or malignancy NILM or LSIL result on their Pap smear, compared with 18.5% in CMJAH in the same time period ($p=0.02$). Overall, across all three time periods, 17 women had a suspected carcinoma on Pap smear (0.8%).

Almost half of the women at CMJAH had a delay in receiving colposcopy (>6 months between Pap smear and colposcopy) post-decentralisation, compared to about a third pre-

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3 decentralisation (47.3% versus 36.2%, $p < 0.001$; Figure 1b). At HCHC, 21.7% of women had a
4 colposcopy within three months of a Pap smear being taken (versus 11.8% at CMJAH pre-
5 and 15.4% post-decentralisation, $p < 0.001$).
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9 At CMJAH, in both periods, nearly 60% of women had a biopsy at colposcopy (58.2%), while
10 the same proportion had a Lletz at HCHC (58.2%). Women at HCHC were 3.6 fold more likely
11 to have visual inspection only during colposcopy than women at CMJAH (95%CI odds ratio
12 [OR]=2.3-5.4). Three women who had a colposcopy at HCHC were referred to CMJAH due to
13 an unsuccessful procedure.
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17 Women at HCHC were 3.5 fold more likely to have a normal result on histology than women
18 at CMJAH (95%CI OR=2.1-5.7). Post-decentralisation, 29.0% of women at CMJAH and 26.3%
19 at HCHC had CIN III lesions ($p = 0.37$; Figure 1c). Post-decentralisation, 11 women had a
20 diagnosis of carcinoma on histology (1.1%), compared to 3 before decentralisation (0.4%;
21 $p = 0.06$). The proportion of invalid specimens was similar across the three groups, ranging
22 from 1.8 to 2.8%.
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31 Discussion

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33 In this study we determined whether decentralisation to primary care level improved access
34 to colposcopy services by reviewing the number of women attending the service before and
35 after decentralisation, and the coverage of colposcopy among women at HCHC. We found
36 that the cumulative number of colposcopies across the two facilities rose following
37 decentralisation, and after only two years, HCHC was responsible for a third of all
38 colposcopies in the sub-district, even though it performs a negligible number of Pap smears
39 relative to other sites. Overall, following decentralisation, three fold more women who had
40 a Pap smear at HCHC had a colposcopy, and at CMJAH, the proportion of women from HCHC
41 also reduced almost threefold. The marked increase in number of women from HCHC who
42 had a colposcopy indicates that prior to decentralisation there may have been a large unmet
43 need for the service, which was now being addressed, at least in part. The coverage reached
44 66.6%, considerably higher than figures in other settings.
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54 Decentralisation of colposcopy services to primary level care has several potential benefits.
55 Firstly, with adequate training, tasks that had been performed by highly specialised staff can
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3 be shifted to lower health worker cadres, allowing specialists to focus on more complex
4 cases (18). Also, decentralisation may alleviate patient barriers to access, by bringing
5 services closer to them – in settings they are familiar with – and reducing their transport and
6 other costs (9, 18). Decentralisation has long been central to the provision of HIV services in
7 this setting through, for example, task shifting, providing antiretroviral treatment in primary
8 health care and the dispensing of drugs from local pharmacies, rather than clinics (19).

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14 Decentralisation of colposcopy can take several forms, including telecolposcopy from
15 distant sites, outreach portable colposcopy, shifting of services to nurse practitioners or
16 medical officers, and decentralisation to lower level facilities, as in this study (20). In other
17 settings, shifting services to lower care levels was found to be cost-effective, acceptable to
18 patients and to increase rates of attendance for colposcopy (12, 20, 21). In the Western
19 Cape, South Africa, for example, colposcopy services were decentralised to a district
20 hospital and provided by a gynaecologist (18). This raised uptake of the service and reduced
21 time to procedure. Also, a study in the United Kingdom found that colposcopy could be
22 performed by nurse practitioners, but they were restricted to only examining cases of post-
23 coital bleeding (22). In high-income countries, services have been successfully decentralised
24 to community health centres and portable outreach programmes in Alaska, the United
25 States, and parts of Canada and Australia, targeting immigrant, Inuit and other vulnerable
26 women (12, 13, 21, 23, 24).

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37 Women attending HCHC colposcopy were at lower risk than those at CMJAH, as shown by
38 their younger age and lower grades of abnormalities on Pap smear and histology. This may
39 suggest that, as the programme had envisaged, higher-risk patients are being referred to
40 CMJAH. Overall, services at HCHC appear to be performing well, with all women tested for
41 HIV and almost all those positive were receiving ART. In addition, colposcopy services were
42 now integrated into their care, which was previously off-site, complex to access and marked
43 by lengthy delays. HIV-positive women made up the large majority of patients in all groups,
44 reflecting the higher levels of risk for cervical cancer in this population. Clearly it remains a
45 priority to integrate screening for cervical cancer within all clinics providing antiretroviral
46 treatment.

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55 The similar number of invalid histology samples and the isolated cases of failed colposcopy
56 suggests that the quality of colposcopy services at HCHC may have been comparable to

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3 CMJAH. Unlike at CMJAH, however, Lletz was the commonest procedure at HCHC, in
4 keeping with evidence that Lletz is better suited to lower level facilities and staff (7). With
5 decentralisation, it is critical to ensure that staff are adequately trained and service quality is
6 closely monitored. The hesitancy to decentralise colposcopy to date, may reflect underlying
7 concerns that cases of cancer may go undetected by lower-level staff. In some settings,
8 lower-level health workers undergo a process of certification and have to perform a certain
9 number of colposcopies per year to remain registered. While this approach may hold
10 advantages, onerous processes around certification and recertification may lead to staff
11 discontinuing colposcopy (22).

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19 The decline in number of colposcopies at CMJAH is concerning, and may reflect factors
20 other than a reduction in demand that accompanies decentralisation. Fewer women at the
21 site had a known HIV status and waiting times for colposcopy lengthened. Thus, though
22 decentralisation can reduce the patient burden at referral centres, this does not necessarily
23 translate into improved services at that site. Other patient and systems factors may play a
24 larger influence, for example, coinciding with the period after decentralisation, CMJAH lost a
25 number of senior specialists.

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Delays in colposcopy vary considerably between settings, from an average of 39 days from
referral to colposcopy in one study in KwaZulu Natal, South Africa (8), to around 5-6 months
in both our study and another in the Western Cape (18). It is concerning that time from Pap
smear to colposcopy is greater than six months for half the women at CMJAH, and a third at
HCHC. Reducing these delays is clearly a priority at both sites. We were unable, however, to
discern reasons for these delays, which could be caused by delays in providing the results of
Pap smears to patients, patient delays in making or attending appointments, or shortages of
specialist staff. We could also not investigate which group of patients required referral to
higher levels of care, and future studies might attempt to define criteria for referral.

Moreover, given the relatively short period of the review, we are unable to assess
sustainability of the services in the long-run, a pressing question. Lastly, the study evaluated
the use of colposcopy following cytological screening with Pap smears and these findings
may not be generalizable to screening with HPV testing, which is increasingly being used in
many countries (25). HPV testing has a considerably higher sensitivity for detecting

precursor lesions of cervical cancer compared to cytology, and thus may alter the number of patients requiring colposcopy and types of lesions identified (26, 27).

Conclusion

In conclusion, decentralisation of colposcopy services can improve access to colposcopy, resulting in faster diagnoses of precancerous lesions of the cervix, more lesions being treated with LLETZ and a reduction in the burden of patients in tertiary hospitals. Most importantly, increasing the number of colposcopies and treatments of precancerous lesions could reduce the incidence of cervical cancer. This is particularly important among HIV-positive women who now live longer with ART, and the treatment of their co-morbidities is rapidly gaining in importance. Though coverage of colposcopy reached two thirds at HCHC, it is important to identify interventions to raise coverage levels. Decentralisation is unlikely to affect the quality of services if medical officers are appropriately trained, supervised and supported by clear up-referral guidelines. The approach presented here could be extended to other primary- or secondary-level facilities in South Africa, and perhaps encompass the use of portable colposcopes or telecolposcopy, under close supervision. If done correctly and at scale, decentralisation of colposcopy services, could shore up cervical cancer prevention and finally decrease the public health burden and mortality due to the cancer.

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Competing Interests

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3 All authors listed in this study do not have competing interests to declare.
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5 **Data sharing statement**
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7 There's no additional unpublished data from the study.
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14 **Author Contributions**
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17 **Manuscript title:** Decentralising colposcopy services raises access to treatment of abnormal
18 cervical smears: a pilot in an inner-city clinic in Johannesburg, South Africa
19

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21 *All persons who meet authorship criteria are listed as authors, and all authors certify that*
22 *they have participated sufficiently in the work to take public responsibility for the content,*
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34 *Authorship contributions Please indicate the specific contributions made by each author (list*
35 *the authors' initials followed by their surnames, e.g., Y.L. Cheung). The name of each author*
36 *must appear at least once in each of the three categories below.*
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10
11 **Category 2**
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Table 1: Patient characteristics and colposcopy outcomes at a community clinic, and a tertiary-level facility before and after decentralisation

Variables		Before versus after decentralisation at CMJAH			HCHC versus CMJAH after decentralisation	
		A) Pre-decentralisation (2012-2014) N=910	B) Post-decentralisation (2014-2016) N=721	P (A versus B)	C) Hillbrow CHC (2014-2016) N=399	P (B versus C)
Characteristics	Age groups in years					
	<20	7 (0.8)	6 (0.8)		0 (0)	
	20-34	351 (39.8)	209 (30.2)		150 (37.6)	
	35-44	342 (38.8)	266 (38.4)		156 (39.1)	
	45-59	161 (18.3)	187 (27.0)		79 (19.8)	
>60	20 (2.3)	25 (3.6)	0.001	7 (1.8)	0.003	
	HIV status known	650 (71.4)	429 (59.5)	<0.001	399 (100)	<0.001
	HIV status [^]					
	Negative	105 (16.2)	59 (13.8)		62 (15.5)	
	Positive	545 (83.9)	370 (86.3)	0.28	337 (84.5)	0.47
	On ART [%]	428/544 (78.7)	324/370 (87.6)	<0.001	336/337 (99.7)	<0.001
Cervical	Facility where Pap smear done					
	CMJAH	115 (12.8)	124 (17.5)		0 (0.0)	
	HCHC	114 (12.7)	43 (6.1)		307 (76.9)	
	Other clinic or hospital	671 (74.6)	540 (76.4)	<0.001	92 (23.1)	<0.001

	Pap smear results					
	NILM	6 (0.7)	8 (1.1)		17 (4.3)	
	LSIL	141 (15.5)	125 (17.4)		79 (20.0)	
	ASCUS	19 (2.1)	34 (4.7)		4 (1.0)	
	HSIL	678 (74.7)	478 (66.4)		263 (66.4)	
	ASC-H	63 (6.9)	65 (9.0)		27 (6.8)	
	Carcinoma	1 (0.1)	10 (1.4)	<0.001	6 (1.5)	<0.001
	Pap smear risk categories					
	NILM, LSIL or ACSUS	166 (18.3)	167 (23.2)		100 (25.3)	
	HSIL, ASC-H or carcinoma	742 (81.7)	553 (76.8)	0.015	296 (74.8)	0.44
Cervical cancer diagnosis	Procedure during colposcopy					
	Visual inspection only	37 (4.1)	37 (5.2)		63 (15.9)	
	Lletz	337 (37.2)	258 (35.9)		231 (58.2)	
	Biopsy	526 (58.0)	420 (58.4)		90 (22.7)	
	Other	7 (0.8)	4 (0.6)	0.69	13 (3.3)	<0.001
	Histology result ^{&}					
	Normal	27 (3.1)	30 (4.4)		45 (13.8)	
	CIN I	254 (29.3)	200 (29.3)		84 (25.7)	
	CIN II	298 (34.3)	209 (30.7)		99 (30.3)	
	CIN III	236 (27.2)	198 (29.0)		86 (26.3)	
Carcinoma	3 (0.4)	9 (1.3)		2 (0.6)		
Other [*]	34 (3.9)	19 (2.8)		2 (0.6)		
Invalid specimen	16 (1.8)	17 (2.5)	0.10	9 (2.8)	<0.001	

χ^2 test for categorical variables or Wilcoxon Rank-sum test for continuous variables. [&]Of those with a known HIV status. [%]Of those HIV positive. [&]Of those with a histology specimen taken at biopsy, Lletz or other procedure. Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). Hillbrow Community Health Centre (HCHC). ^{*}Other includes infections such as cervicitis, inflammation and dysplasia

Table 2: Cytology results in the City of Johannesburg in 2014-2016

Variable n (%)	Johannesburg health district* (n=114,983)	Hillbrow Community Health Centre (n=2227)	P
Pap smear results			
NILM	74,969 (65.2)	852 (38.3)	
LSIL	23,212 (20.2)	790 (35.5)	
ASCUS	7391 (6.4)	184 (8.3)	
HSIL	7808 (6.8)	364 (16.3)	
ASC-H	1221 (1.1)	28 (1.3)	
Carcinoma	382 (0.3)	9 (0.4)	<0.001
Number requiring colposcopy			
No (NILM, LSIL or ASCUS)	105,572 (91.8)	9411 (82.0)	<0.001
Yes (HSIL, ASC-H or carcinoma)	1826 (8.2)	401 (18.0)	

Data from the National Health Laboratory Service. Excludes invalid or missing specimens, and other Pap smear results (n=2446). *District total excludes HCHC

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Invalid specimen	16 (1.8)	17 (2.5)	0.10	9 (2.8)	<0.001	

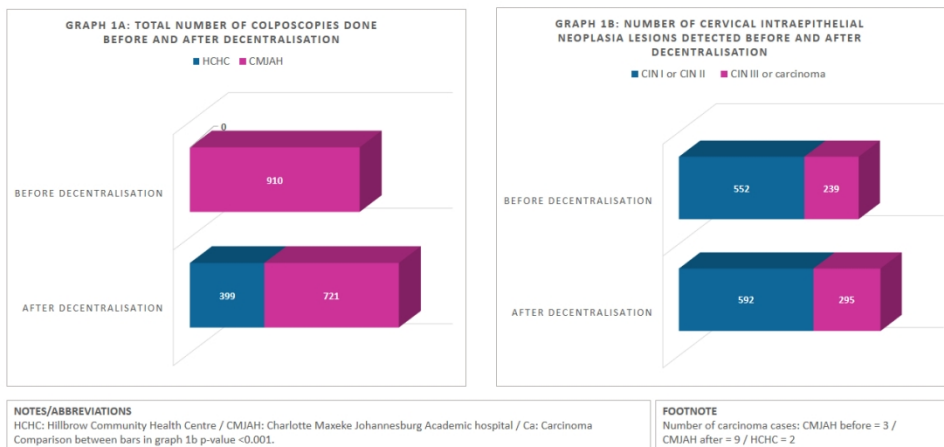
χ^2 test for categorical variables or Wilcoxon Rank-sum test for continuous variables. [^]Of those with a known HIV status. [%]Of those HIV positive. [&]Of those with a histology specimen taken at biopsy, Lletz or other procedure. Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). Hillbrow Community Health Centre (HCHC). ^{*}Other includes infections such as cervicitis, inflammation and dysplasia

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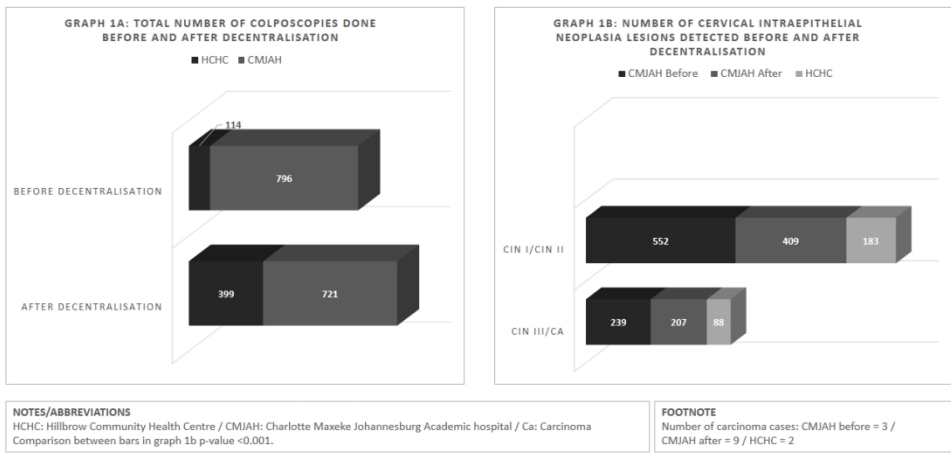
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BMJ Open

The impact of decentralising colposcopy services from tertiary- to primary-level care in inner-city Johannesburg, South Africa: a before and after study

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Manuscript ID	bmjopen-2018-024726.R1
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Secondary Subject Heading:	Diagnostics, Obstetrics and gynaecology, Oncology, Reproductive medicine
Keywords:	Colposcopy < GYNAECOLOGY, Community gynaecology < GYNAECOLOGY, Gynaecological oncology < GYNAECOLOGY, Minimally invasive surgery < GYNAECOLOGY, PRIMARY CARE, Decentralised Care

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4 **Title:** The impact of decentralising colposcopy services from tertiary- to
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ABSTRACT

Objective: To assess whether decentralising colposcopy services to a primary care facility in inner-city Johannesburg, South Africa raises access to colposcopy.

Design: Before-after study comparing two years before and two after decentralisation, using clinical records, and laboratory data on cervical cytology and histology.

Primary outcome: The proportion of all women attending Hillbrow Community Health Centre (HCHC) with an abnormal Pap smear who had a colposcopy post-decentralisation.

Setting: Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) has provided colposcopy services for several decades. HCHC, located about 3km away, began colposcopy services in 2014.

Participants: Women, aged above 18 years, who had a colposcopy for diagnosis and treatment of precancerous cervical lesions following a Pap smear, from 2012-2016 at CMJAH or HCHC.

Results: Pre-decentralisation at CMJAH, 910 women had colposcopy (2012-2014). Post-decentralisation (2014-2016), 721 had colposcopy at CMJAH and 399 at HCHC, the decentralised facility. The number who had a Pap smear at

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4 HCHC and then a colposcopy rose three-fold post-decentralisation (114
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6 versus 350). Post-decentralisation, 43 women at HCHC were referred from
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9 CMJAH for colposcopy, compared to 114 pre-decentralisation. Post-
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11 decentralisation, 47.3% of women at CMJAH waited >6 months for
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13 colposcopy, while 35.5% did at HCHC ($p<0.001$). Across all three groups,
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15 26.9-30.3% of women had CIN III lesions or carcinoma on colposcopy. The
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17 proportion of invalid specimens was similar at CMJAH and HCHC (1.8-2.8%).
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19 Of 401 women who had an abnormal Pap smear at HCHC post-
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21 decentralisation, 267 had colposcopy (66.6%).
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30 **Conclusion:** Decentralisation can decrease the time to colposcopy and reduce
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32 the workload of tertiary hospitals. Overall, more women accessed services.
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34 Colposcopy coverage at HCHC is higher than other sites, but could be further
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36 improved. Decentralisation did not appear to affect the quality of services and
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38 this model could be extended to similar settings in South Africa and
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41 elsewhere.
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46 **Key words:** South Africa, colposcopy, cervical cancer, primary health care,
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57 STRENGTHS AND LIMITATIONS OF THIS STUDY

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- Data were collected for the purposes of patient care, and not specifically for research, potentially reducing data quality.
 - The limited data available meant that the study could not fully investigate several important questions, such as reasons for delays in colposcopy or a detailed assessment of the quality of decentralised services. Additionally, the absence of baseline data at the primary care site does not allow us to directly compare changes in access among women at the primary care site over time.
 - As the study only included a single primary care centre, we are unable to fully assess the potential impact of a broader decentralisation strategy. The findings of this study may thus not be generalizable to a larger initiative that, for example, adopted a hub and spoke approach encompassing several primary care centres.
 - Given that the study only covered the first two years after decentralisation, we are unable to ascertain the intervention's long-term sustainability.
 - The study strengths include a relatively large number of women in all study groups, allowing us to detect differences between the time periods

INTRODUCTION

Cervical cancer is a largely preventable disease and WHO has recently launched an initiative aimed at eliminating the condition.[1] At present, cervical cancer is the second most common cancer among women aged 15 to 44 years in the world.[2] In South Africa, it is the commonest cancer in that age group, and mortality rates are high.[3, 4] About 3% of women in South Africa harbour cervical human papilloma virus (HPV)-16/18, which is responsible for the majority of cases of cervical cancer in the country.[4] Rates of cervical cancer in South Africa can partly be attributed to the high level of HIV.[5] Women with HIV infection have a seven-fold higher rate of persistence of high-risk HPV compared to HIV uninfected women,[6] heightening their risk for incident and progressive precancerous lesions. While antiretroviral therapy reduces the risk of cervical cancer and its precursors, the risk remains much higher than for HIV-negative women.[7]

In South Africa, the policy for cervical cancer screening was introduced in 2001 and updated in 2017.[8] The policy recommends that low-risk women have three Pap smears in a lifetime at the ages of 30, 40 and 50 years, while women with HIV-infection are to be screened every three years, regardless of age. Screening is predominately based on cytology using Papanikolaou (Pap) smears, although there are plans to introduce liquid-based cytology which

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3 offers the potential to do HPV screening. Women with atypical findings on
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6 cytology are referred for colposcopy to establish a definitive diagnosis. During
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9 colposcopy, the view of the cervix is magnified and, where required, a biopsy
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12 is taken or a large loop excision of the transformation zone (LLETZ) is
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15 conducted.[9]
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18 A range of health systems and patient factors influence access to colposcopy.
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21 System barriers include a limited number of colposcopy services, which are
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24 mostly centralised within tertiary-level facilities, with long waiting times for
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27 patients and few opportunities for non-specialist health workers to develop
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30 requisite skills.[10] There are limited numbers of specialist gynaecologists
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33 within the public sector, and the high demands on these doctors for
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36 emergency and curative obstetric and gynaecology services may reduce their
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39 time available for diagnostic or preventive interventions, such as colposcopy.
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42 Another key factor is the complexity of providing Pap and other results to
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45 patients and then scheduling colposcopy appointments across the disjointed
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48 systems that often exist between a tertiary hospital and primary care
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51 centres.[11-13] Patient-related factors linked with low uptake of colposcopy
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54 include low education levels, being single, fear of HIV testing and disclosure, a
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57 low CD4 count in HIV-infected women and transport costs for the additional
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60 visits.[12, 14, 15] Patient demand for colposcopy is also undermined by a

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4 general fear of cancer, and lack of awareness or knowledge about cervical
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6 cancer.[11, 16] Poor patient-provider interactions restrict access, whilst a
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8 longstanding relationship with a primary clinician can optimise uptake.[16]
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12 In South Africa, colposcopy procedures are generally done at tertiary-level
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14 facilities, by specialist gynaecology oncologists and trainee gynaecologists
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16 under supervision. While there may be benefits to decentralising colposcopy
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18 services to lower levels of care, these need to be balanced by the advantages
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20 of centralization of cancer services, such as concentrating clinical expertise,
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22 with a higher quality of care, and the rationalisation of expensive specialist
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24 equipment. Thus, in this before- and after-study, we aimed to determine if
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26 access to colposcopy increased following the decentralisation of colposcopy
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28 services from a tertiary-level hospital to a primary care facility in inner-city
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30 Johannesburg, South Africa. We compare the total number of colposcopies
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32 done and the coverage of colposcopy services in the primary-level facility after
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34 decentralisation. We also compare the two sites, specifically, the patient profile
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36 and cervical cancer risks, colposcopy procedures, quality of the services and
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38 histology outcomes.
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51 52 53 **METHODS**

54 55 56 **Study participants and setting** 57 58 59 60

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4 Women, aged 18 years and older, who accessed colposcopy services at either
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6 Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) or Hillbrow
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8 Community Health Centre (HCHC) between October 2012 and September
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10 2016 were included in the study. Both facilities are in sub-district F of the
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12 Johannesburg Health District (JHD).
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18 The colposcopy clinic at CMJAH is part of the Gynaecology-Oncology
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20 Department at CMJAH, which has two colposcopy machines. Women
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22 attending a facility in JHD who have an abnormal Pap smear are referred to
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24 the facility, where they are provided with an appointment date for colposcopy.
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31 Hillbrow Community Health Centre (HCHC) is situated in the densely
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33 populated inner-city area of Hillbrow, about 3km from CMJAH.[17] HCHC
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35 provides primary level care, including a 24 hour casualty and a midwife
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37 obstetrics unit. The facility is run predominantly by nursing staff, with support
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39 from non-specialist medical doctors.
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45 **Implementation of decentralised services**

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49 In 2013, a review of patient files at HCHC found that a large proportion of
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51 women attending the HIV clinic had high-risk lesions on Pap smear.[18]
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55 Moreover, there were reports from patients and health workers at HCHC of
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57 prolonged waiting times for colposcopy services at CMJAH. The Wits
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4 Reproductive Health and HIV Institute (Wits RHI) thus set about establishing
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6 decentralised colposcopy services at HCHC. A private sector company
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8 donated a colposcopy machine. Two district medical officers were trained by
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10 specialist gynaecology oncologists at CMJAH to provide the service. CMJAH
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12 staff provided ongoing support and established referral processes between the
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14 two facilities. Monthly meetings were held between staff at the two facilities,
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16 where concerns and difficult cases could be discussed.
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24 The services, which began in October 2014, were provided twice a week by
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26 the medical officers, with assistance from the nurse who takes Pap smears at
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28 the facility. Patients attending HCHC and some referred from surrounding
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30 clinics were given an appointment for colposcopy if they had an abnormal Pap
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32 smear result, defined as: high-grade squamous intraepithelial lesion (HSIL),
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34 atypical squamous cell and HSIL cannot be excluded (ASC-H), or squamous
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36 cell carcinoma (SCC).[19] A few patients with Pap smear results other than
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38 those defined as abnormal smears were also referred for colposcopy. Patients
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40 with complex lesions, such as abnormal cervical anatomy or a high suspicion
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42 of cancer on Pap smear were referred to CMJAH, as were those with a failed
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44 colposcopy. Colposcopy procedures included colposcopic assessment only, or
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46 colposcopic assessment together with either a Lletz or biopsy. Histology
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48 specimens were processed at the National Health Laboratory Service (NHLS).
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Data sources and collection

For the purpose of this evaluation, women who accessed colposcopy services at CMJAH and HCHC were divided into three groups: 1) pre-decentralisation at CMJAH between October 2012 and September 2014; 2) post-decentralisation at CMJAH between October 2014 and September 2016; and 3) post-decentralisation at HCHC between October 2014 and September 2016.

At CMJAH, we extracted data from paper-based records at the colposcopy clinic, including on patients' age, HIV status, antiretroviral treatment, date of Pap smear, Pap smear result, date of colposcopy, colposcopy procedure performed and histology results. Data were entered into a REDCap electronic database (REDCap Software, Version 4.14.5, Vanderbilt University).[20]. At HCHC, demographic and clinical data on women who accessed colposcopy services were entered into an MS Excel spreadsheet after each patient visit. Data were obtained from the NHLS on Pap smear cytology for women attending HCHC who had a Pap smear and for the whole of JHD.

Study variables and statistical analysis

Patient characteristics and colposcopy procedures were compared between the three groups. Time to colposcopy was calculated as the number of months from date of Pap smear to colposcopy and was categorised as optimal (under

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4 3 months), acceptable (3-6 months) and delayed (greater than 6 months).

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6 Histology results were classified as normal (includes benign endocervical
7 polyp, atrophic ectocervical mucosa, koilocytosis and metaplasia), Cervical
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9 Intraepithelial Neoplasia (CIN) I, CIN II, CIN III, carcinoma, other (includes
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11 infections such as cervicitis, inflammation and dysplasia) and invalid
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13 specimens (includes absent results). We used the proportion of invalid
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15 specimens and number of failed colposcopies as proxy markers of the quality
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17 of services. The coverage of colposcopy services at HCHC, the primary
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19 outcome, was estimated by calculating the proportion of all women at HCHC
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21 with an abnormal Pap smear who had a colposcopy. Differences between the
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23 three study groups were assessed using a chi-square test or a Wilcoxon rank-
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25 sum test, as appropriate. All data were analysed using STATA version 13.0.
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38 **Ethical considerations**

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41 Ethical approval was obtained from Human Research Ethics Committee of the
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43 University of the Witwatersrand (Certificate number: M151184). Permission for
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45 use of the CMJAH data was granted by the hospital's Chief Executive Officer,
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47 and the head of the Department of Obstetrics and Gynaecology at CMJAH.

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50 The NHLS Academic Affairs and Research Office gave permission for use of
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52 their data.
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59 **Patient involvement**

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The study utilised data that had already been collected as part of routine patient care, and thus patients were not directly involved in the study. We did, however, attempt to contact patients who had abnormal lesions on histology and had not attended follow-up visits.

RESULTS

Access to colposcopy and timeliness of services

In total, 910 women accessed colposcopy at CMJAH between October 2012 and September 2014. In the subsequent two years, 1120 women had a colposcopy: 399 at HCHC (35.6%) and 721 at CMJAH (64.4%; Table 1 and Figure 1).

One quarter of women who had a colposcopy at HCHC had had their Pap smear at another facility. The percentage of women at CMJAH who had had a Pap smear at HCHC halved post-decentralisation ($p < 0.001$) and the absolute number decreased from 113 to 43. The number of women who had a Pap smear at HCHC and then a colposcopy at either facility was three-fold higher post-decentralisation than pre-decentralisation (from 113 to 350) (Table 1).

Table 1: Patient characteristics and colposcopy outcomes at a community clinic, and a tertiary-level facility before and after decentralisation

Variables	Before versus after decentralisation at CMJAH	HCHC versus CMJAH after decentralisation
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		A) Pre-decentralisation (2012-2014) N=910	B) Post-decentralisation (2014-2016) N=721	P (A vs B)	C) Hillbrow CHC (2014-2016) N=399	P (B vs C)
Characteristics	Age groups in years					
	<20	7 (0.8)	6 (0.8)		0 (0)	
	20-34	351 (39.8)	209 (30.2)		150 (37.6)	
	35-44	342 (38.8)	266 (38.4)		156 (39.1)	
	45-59	161 (18.3)	187 (27.0)		79 (19.8)	
>60	20 (2.3)	25 (3.6)	0.001	7 (1.8)	0.003	
	HIV status known	650 (71.4)	429 (59.5)	<0.001	399 (100)	<0.001
	HIV status[^]					
	Negative	105 (16.2)	59 (13.8)		62 (15.5)	
	Positive	545 (83.9)	370 (86.3)	0.28	337 (84.5)	0.47
	On ART[%]	428/544 (78.7)	324/370 (87.6)	<0.001	336/337 (99.7)	<0.001
Cervical cancer Screening	Facility where Pap smear done					
	CMJAH	115 (12.8)	124 (17.5)		0 (0.0)	
	HCHC	114 (12.7)	43 (6.1)		307 (76.9)	
	Other clinic or hospital	671 (74.6)	540 (76.4)	<0.001	92 (23.1)	<0.001
	Pap smear results					
	NILM	6 (0.7)	8 (1.1)		17 (4.3)	
	LSIL	141 (15.5)	125 (17.4)		79 (20.0)	
	ASCUS	19 (2.1)	34 (4.7)		4 (1.0)	
	HSIL	678 (74.7)	478 (66.4)		263 (66.4)	
	ASC-H	63 (6.9)	65 (9.0)		27 (6.8)	
Carcinoma	1 (0.1)	10 (1.4)	<0.001	6 (1.5)	<0.001	
	Pap smear risk categories					
	NILM, LSIL or ACSUS	166 (18.3)	167 (23.2)		100 (25.3)	
	HSIL, ASC-H or carcinoma	742 (81.7)	553 (76.8)	0.015	296 (74.8)	0.44

Cervical cancer diagnosis	Procedure during colposcopy					
	Visual inspection only	37 (4.1)	37 (5.2)		63 (15.9)	
	Lletz	337 (37.2)	258 (35.9)		231 (58.2)	
	Biopsy	526 (58.0)	420 (58.4)		90 (22.7)	
	Other	7 (0.8)	4 (0.6)	0.69	13 (3.3)	<0.001
	Histology result^{&}					
	Normal	27 (3.1)	30 (4.4)		45 (13.8)	
	CIN I	254 (29.3)	200 (29.3)		84 (25.7)	
	CIN II	298 (34.3)	209 (30.7)		99 (30.3)	
	CIN III	236 (27.2)	198 (29.0)		86 (26.3)	
	Carcinoma	3 (0.4)	9 (1.3)		2 (0.6)	
	Other [*]	34 (3.9)	19 (2.8)		2 (0.6)	
	Invalid specimen	16 (1.8)	17 (2.5)	0.10	9 (2.8)	<0.001

χ^2 test for categorical variables or Wilcoxon Rank-sum test for continuous variables. [†]Of those with a known HIV status. [%]Of those HIV positive. [&]Of those with a histology specimen taken at biopsy, Lletz or other procedure. Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). Hillbrow Community Health Centre (HCHC). ^{*}Other includes infections such as cervicitis, inflammation and dysplasia

Almost half of the women at CMJAH had a delay in receiving colposcopy (>6 months between Pap smear and colposcopy) post-decentralisation, compared to about a third pre-decentralisation (47.3% versus 36.2%, $p < 0.001$; Figure 1: Graph 1A). At HCHC, 21.7% of women had a colposcopy within three months of a Pap smear being taken (versus 11.8% at CMJAH pre- and 15.4% post-decentralisation, $p < 0.001$).

Of all Pap smears done in the JHD in the two years after decentralisation (114,983), 1.9% were done at HCHC (2227). Overall, 18.0% Pap smears done at HCHC had abnormal cytology and required colposcopy ($n = 401$), compared to only 8.2% of other women in JHD as a whole ($n = 1826$; $p < 0.001$) (Table 2).

The estimated colposcopy coverage among women who had an abnormal Pap smear at HCHC was 66.6% (267/401; 95%CI=61.7-71.2%).

Table 2: Cytology results in the City of Johannesburg in 2014-2016

Variable n (%)	Johannesburg health district* (n=114,983)	Hillbrow Community Health Centre (n=2227)	<i>P</i>
Pap smear results			
NILM	74,969 (65.2)	852 (38.3)	
LSIL	23,212 (20.2)	790 (35.5)	
ASCUS	7391 (6.4)	184 (8.3)	
HSIL	7808 (6.8)	364 (16.3)	
ASC-H	1221 (1.1)	28 (1.3)	
Carcinoma	382 (0.3)	9 (0.4)	<0.001
Number requiring colposcopy			
No (NILM, LSIL or ASCUS)	105,572 (91.8)	9411 (82.0)	
Yes (HSIL, ASC-H or carcinoma)	1826 (8.2)	401 (18.0)	<0.001

Data from the National Health Laboratory Service. Excludes invalid or missing specimens, and other Pap smear results (n=2446).

*District total excludes HCHC

Characteristics of women in the three groups

The proportion of women older than 45 years pre-decentralisation at CMJAH was 20.5%, post-decentralisation at CMJAH 30.6% and at HCHC 21.9% ($p < 0.001$). At CMJAH, more women had a known HIV status pre-decentralisation than post-decentralisation (71.4% versus 59.5%, $p < 0.001$). All women at HCHC had a documented HIV status. Around 85% of women with a

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4 known HIV status were HIV positive in all three groups. The proportion of
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6 positive women receiving ART rose in the second period at CMJAH from
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8 78.7% to 87.6% ($p < 0.001$), and almost all positive women were on ART at
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10 HCHC (99.7%; $p < 0.001$). (Table 1)
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15 **Description of colposcopy procedures and histology findings**

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18 At CMJAH, in both periods, nearly 60% of women had a biopsy at colposcopy
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20 (58.2%), while the same proportion had a Lletz at HCHC (58.2%). Three
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22 women who had a colposcopy at HCHC were referred to CMJAH due to an
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24 unsuccessful procedure.
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31 Women at HCHC were 3.5 fold more likely to have a normal result on
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33 histology than women at CMJAH (95% CI OR=2.1-5.7). Post-decentralisation,
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35 29.0% of women at CMJAH and 26.3% at HCHC had CIN III lesions ($p = 0.37$;
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37 Figure 1: Graph1B). Post-decentralisation, 11 women had a diagnosis of
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39 carcinoma on histology (1.1%), compared to 3 before decentralisation (0.4%;
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41 $p = 0.06$). The proportion of invalid specimens was similar across the three
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43 groups, ranging from 1.8 to 2.8%.
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50 **DISCUSSION**

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53 In this study we determined whether decentralisation to primary care level
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55 improved access to colposcopy services by reviewing the number of women
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4 attending the service before and after decentralisation, and the coverage of
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6 colposcopy among women at HCHC. We found that the cumulative number of
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8 colposcopies across the two facilities rose following decentralisation, and after
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10 only two years, HCHC was responsible for a third of all colposcopies in the
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12 sub-district, even though it performs a negligible number of Pap smears
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14 relative to other sites. Overall, following decentralisation, three fold more
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16 women who had a Pap smear at HCHC had a colposcopy, and at CMJAH, the
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18 proportion of women from HCHC reduced almost threefold. The marked
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20 increase in number of women from HCHC who had a colposcopy indicates
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22 that prior to decentralisation there may have been a large unmet need for the
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24 service, which was now being addressed, at least in part. The coverage
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26 reached 66.6%, considerably higher than figures in other settings.
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38 Decentralisation of colposcopy services to primary level care has several
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40 potential benefits. Firstly, with adequate training, tasks that had been
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42 performed by highly specialised staff can be shifted to lower health worker
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44 cadres, allowing specialists to focus on more complex cases.[21] Also,
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46 decentralisation may alleviate patient barriers to access, by bringing services
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48 closer to them – in settings they are familiar with – and reducing their transport
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50 and other costs.[11, 21] Decentralisation has long been central to the provision
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52 of HIV services in this setting through, for example, task shifting, providing
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4 antiretroviral treatment in primary care services and the dispensing of drugs
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6 from local pharmacies, rather than clinics.[22] Integration with HIV and ART
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8 services is beneficial to women as it reduces opportunity costs associated with
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10 multiple visits to the clinic and lowers the risk of loss to follow up.
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15 Decentralisation of colposcopy can take several forms, including
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17 telecolposcopy from distant sites, outreach portable colposcopy, shifting of
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19 services to nurse practitioners or medical officers, and decentralisation to
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21 lower level facilities, as in this study.[23] In other settings, shifting services to
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23 lower care levels was found to be cost-effective, acceptable to patients and to
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25 increase rates of attendance for colposcopy.[14, 23, 24] In the Western Cape,
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27 South Africa, for example, colposcopy services were decentralised to a district
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29 hospital and provided by a gynaecologist.[21] This raised uptake of the service
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31 and reduced time to procedure. In high-income countries, services have been
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33 successfully decentralised to community health centres and portable outreach
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35 programmes in Alaska, the United States, and parts of Canada and Australia,
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37 targeting immigrant, Inuit and other vulnerable women.[14, 15, 24-26] The
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39 National Health Service in United Kingdom has gone a step further and
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41 colposcopy is often performed by nurse practitioners once they have
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43 completed certification procedures.[27]
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4 Women attending HCHC colposcopy were at lower risk than those at CMJAH,
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6 as shown by their lower grades of abnormalities on Pap smear and histology.
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9 Women at HCHC were also younger than those at CMJAH, important as risk
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11 for cervical cancer rises considerably with age (the mean age at diagnosis of
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13 cervical cancer is 52.3 in South Africa).[28] These findings may suggest that,
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15 as the programme had envisaged, higher-risk patients are being referred to
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17 CMJAH. Overall, services at HCHC appear to be performing well, with all
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19 women tested for HIV and almost all those positive were receiving ART. In
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21 addition, colposcopy services were now integrated into their care, which was
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23 previously off-site, complex to access and marked by lengthy delays. HIV-
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25 positive women made up the large majority of patients in all groups, reflecting
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27 the higher levels of risk for cervical cancer in this population. Clearly it remains
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29 a priority to integrate screening for cervical cancer within all clinics providing
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31 antiretroviral treatment.
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44 The similar number of invalid histology samples and the isolated cases of
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46 failed colposcopy suggests that the quality of colposcopy services at HCHC
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48 may have been comparable to CMJAH. Unlike at CMJAH, however, Lletz was
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50 the commonest procedure at HCHC, in keeping with evidence that Lletz is
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52 better suited to lower level facilities and staff.[9] With decentralisation, it is
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54 critical to ensure that staff are adequately trained and service quality is closely
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3 monitored. The hesitancy to decentralise colposcopy to date, may reflect
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6 underlying concerns that cases of cancer may go undetected by lower-level
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9 staff. In some settings, lower-level health workers undergo a process of
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12 certification and have to perform a certain number of colposcopies per year to
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15 remain registered.[27] While this approach may hold advantages, onerous
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18 processes around certification and recertification may lead to staff
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21 discontinuing colposcopy.[29]

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24 The decline in number of colposcopies at CMJAH is concerning, and may
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27 reflect factors other than a reduction in demand that accompanies
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30 decentralisation. Fewer women at the site had a known HIV status and waiting
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33 times for colposcopy lengthened. Thus, though decentralisation can reduce
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36 the patient burden at referral centres, this does not necessarily translate into
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39 improved services at that site. Other factors may play a larger influence, for
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42 example, coinciding with the period after decentralisation, CMJAH lost a
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45 number of senior specialists.

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48 Delays in colposcopy vary considerably between settings, from an average of
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51 39 days from referral to colposcopy in one study in KwaZulu Natal, South
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54 Africa,[10] to around 5-6 months in both our study and another in the Western
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57 Cape.[21] It is concerning that time from Pap smear to colposcopy is greater
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60 than six months for half the women at CMJAH, and a third at HCHC. Reducing

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4 these delays is clearly a priority at both sites. We were unable, however, to
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6 discern reasons for these delays, which could be caused by delays in
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8 providing the results of Pap smears to patients, patient delays in making or
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10 attending appointments, or shortages of specialist staff. We could also not
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12 investigate which group of patients required referral to higher levels of care,
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14 and future studies might attempt to define criteria for referral. Moreover, given
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16 the relatively short period of the review, we are unable to assess sustainability
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18 of the services in the long-run, a pressing question. Lastly, the study evaluated
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20 the use of colposcopy following cytological screening with Pap smears and
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22 these findings may not be generalizable to screening with HPV testing, which
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24 is increasingly being used in many countries.[30] HPV testing has a
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26 considerably higher sensitivity for detecting precursor lesions of cervical
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28 cancer compared to cytology, and thus may alter the number of patients
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30 requiring colposcopy and types of lesions identified.[31, 32]
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47 CONCLUSION

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51 In conclusion, decentralisation of colposcopy services can improve access to
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53 colposcopy, resulting in faster diagnoses of precancerous lesions of the cervix,
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55 more lesions being treated with LLETZ and a reduction in the burden of patients
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57 in tertiary hospitals. Most importantly, increasing the number of colposcopies
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4 and treatments of precancerous lesions could reduce the incidence of cervical
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6 cancer. This is particularly important among HIV-positive women who now live
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8 longer with ART, and the treatment of their co-morbidities is rapidly gaining in
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10 importance. Though coverage of colposcopy reached two thirds at HCHC, it is
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12 important to identify interventions to further raise coverage levels.
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18 Decentralisation is unlikely to affect the quality of services if medical officers
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20 are appropriately trained, supervised and supported by clear referral
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22 guidelines. The approach presented here could be extended to other primary-
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24 or secondary-level facilities in South Africa, and perhaps encompass the use
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26 of portable colposcopes or telecolposcopy, under close supervision. If done
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28 correctly and at scale, decentralisation of colposcopy services, could shore up
29
30 cervical cancer prevention and finally decrease the public health burden and
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32 mortality due to the cancer.
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38 used if there are more than 10 authors):
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FIGURE LEGENDS

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Figure 1:

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Graph 1A: Total number of colposcopies done before and after
decentralisation

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Graph 1B: Number of cervical intraepithelial neoplasia lesions detected before
and after decentralisation

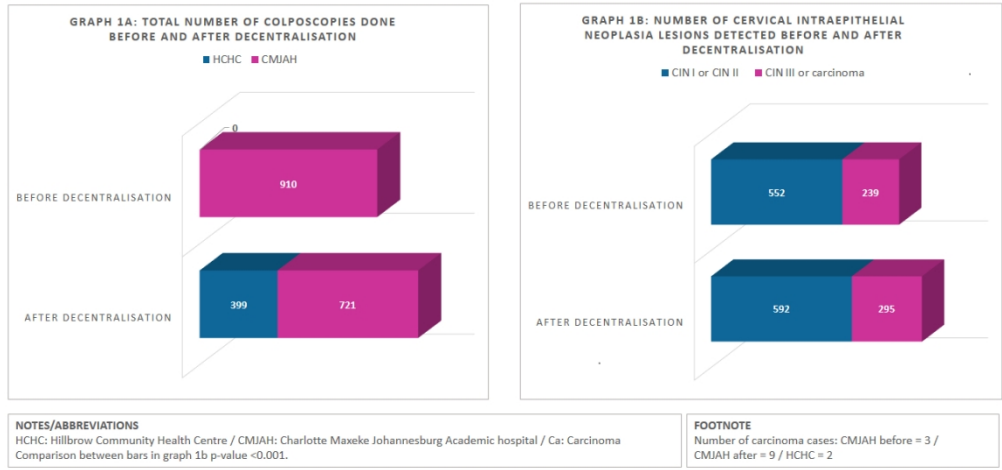


Figure 1:
Graph 1A: Total number of colposcopies done before and after decentralisation
Graph 1B: Number of cervical intraepithelial neoplasia lesions detected before and after decentralisation

271x128mm (120 x 120 DPI)

BMJ Open

The impact of decentralising colposcopy services from tertiary- to primary-level care in inner-city Johannesburg, South Africa: a before and after study

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4 **Title:** The impact of decentralising colposcopy services from tertiary- to
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6 primary-level care in inner-city Johannesburg, South Africa: a before and after
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8 study
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ABSTRACT

Objective: To assess whether decentralising colposcopy services to a primary care facility in inner-city Johannesburg, South Africa raises access to colposcopy.

Design: Before-after study comparing two years before and two after decentralisation, using clinical records, and laboratory data on cervical cytology and histology.

Primary outcome: The proportion of all women attending Hillbrow Community Health Centre (HCHC) with an abnormal Pap smear who had a colposcopy post-decentralisation.

Setting: Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) has provided colposcopy services for several decades. HCHC, located about 3km away, began colposcopy services in 2014.

Participants: Women, aged above 18 years, who had a colposcopy for diagnosis and treatment of precancerous cervical lesions following a Pap smear, from 2012-2016 at CMJAH or HCHC.

Results: Pre-decentralisation at CMJAH, 910 women had colposcopy (2012-2014). Post-decentralisation (2014-2016), 721 had colposcopy at CMJAH and 399 at HCHC, the decentralised facility. The number who had a Pap smear at

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4 HCHC and then a colposcopy rose three-fold post-decentralisation (114
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6 versus 350). Post-decentralisation, 43 women at HCHC were referred from
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9 CMJAH for colposcopy, compared to 114 pre-decentralisation. Post-
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12 decentralisation, 47.3% of women at CMJAH waited >6 months for
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15 colposcopy, while 35.5% did at HCHC ($p<0.001$). Across all three groups,
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18 26.9-30.3% of women had CIN III lesions or carcinoma on colposcopy. The
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21 proportion of invalid specimens was similar at CMJAH and HCHC (1.8-2.8%).
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24 Of 401 women who had an abnormal Pap smear at HCHC post-
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27 decentralisation, 267 had colposcopy (66.6%).
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30 **Conclusion:** Decentralisation can decrease the time to colposcopy and reduce
31
32 the workload of tertiary hospitals. Overall, more women accessed services.
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35 Colposcopy coverage at HCHC is higher than other sites, but could be further
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38 improved. Decentralisation did not appear to undermine the quality of services
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41 and this model could be extended to similar settings in South Africa and
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43
44 elsewhere.
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46 **Key words:** South Africa, colposcopy, cervical cancer, primary health care,
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ARTICLE SUMMARY

Strengths and limitations of this study

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4 • Data were collected for the purposes of patient care, and not specifically
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6 for research, potentially reducing data quality.
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9 • The limited data available meant that the study could not fully investigate
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11 several important questions, such as reasons for delays in colposcopy or a
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13 detailed assessment of the quality of decentralised services. Additionally,
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15 the absence of baseline data at the primary care site does not allow us to
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17 directly compare changes in access among women at the primary care site
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19 over time.
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26 • As the study only included a single primary care centre, we are unable to
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28 fully assess the potential impact of a broader decentralisation strategy. The
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30 findings of this study may thus not be generalizable to a larger initiative
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32 that, for example, adopted a hub and spoke approach encompassing
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34 several primary care centres.
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40 • Given that the study only covered the first two years after decentralisation,
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42 we are unable to ascertain the intervention's long-term sustainability.
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46 • The study strengths include a relatively large number of women in all study
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48 groups, allowing us to detect differences between the time periods.
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51 Additionally, the hub and spoke approach has been used for several other
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53 health services that similarly require an integrated tiered health care and
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55 laboratory system, such as TB care and colorectal cancer screening. The
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4 successful application of this approach elsewhere supports the
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6 generalizability of the study findings and assertions about the validity of the
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8 results reported.
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22 INTRODUCTION

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24 Cervical cancer is a largely preventable disease and WHO has recently
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26 launched an initiative aimed at eliminating the condition.[1] At present, cervical
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28 cancer is the second most common cancer among women aged 15 to 44
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30 years in the world.[2] In South Africa, it is the commonest cancer in that age
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32 group, and mortality rates are high.[3, 4] About 3% of women in South Africa
33
34 harbour cervical human papilloma virus (HPV)-16/18, which is responsible for
35
36 the majority of cases of cervical cancer in the country.[4] Rates of cervical
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38 cancer in South Africa can partly be attributed to the high level of HIV.[5]
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40 Women with HIV infection have a seven-fold higher rate of persistence of
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42 high-risk HPV compared to HIV uninfected women,[6] heightening their risk for
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44 incident and progressive precancerous lesions. While antiretroviral therapy
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46 reduces the risk of cervical cancer and its precursors, the risk remains much
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48 higher than for HIV-negative women.[7]
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4 In South Africa, the policy for cervical cancer screening was introduced in
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6 2001 and updated in 2017.[8] The policy recommends that low-risk women
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8 have three Pap smears in a lifetime at the ages of 30, 40 and 50 years, while
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10 women with HIV-infection are to be screened every three years, regardless of
11
12 age. About 60% of women aged 30 to 49 years have had cervical cancer
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14 screening.[9] Screening is predominately based on cytology using
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16 Papanikolaou (Pap) smears, although there are plans to introduce liquid-
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18 based cytology which offers the potential to do HPV screening. Women with
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20 atypical findings on cytology are referred for colposcopy to establish a
21
22 definitive diagnosis. During colposcopy, the view of the cervix is magnified
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24 and, where required, a biopsy is taken or a large loop excision of the
25
26 transformation zone (LLETZ) is conducted.[10]
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38 The gap between screening for cervical cancer and treatment of high-risk
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40 lesions is believed to be very high in South Africa.[11] Although there are few
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42 published data to support this assertion, the fact that the number of cervical
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44 cancer cases remains high despite the large number of cervical cancer
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46 screening procedures suggest this is the case. A range of health systems and
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48 patient factors influence access to colposcopy. System barriers include a
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50 limited number of colposcopy services, which are mostly centralised within
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52 tertiary-level facilities, with long waiting times for patients and few
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3 opportunities for non-specialist health workers to develop requisite skills.[12]
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6 There are limited numbers of specialist gynaecologists within the public
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8 sector, and the high demands on these doctors for emergency and curative
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10 obstetric and gynaecology services may reduce their time available for
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12 diagnostic or preventive interventions, such as colposcopy. Another key factor
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14 is the complexity of providing Pap and other results to patients and then
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16 scheduling colposcopy appointments across the disjointed systems that often
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18 exist between a tertiary hospital and primary care centres.[13-15] Patient-
19
20 related factors linked with low uptake of colposcopy include low education
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22 levels, being single, fear of HIV testing and disclosure, a low CD4 count in
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24 HIV-infected women and transport costs for the additional visits.[14, 16, 17]
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26 Patient demand for colposcopy is also undermined by a general fear of
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28 cancer, and lack of awareness or knowledge about cervical cancer.[13, 18]
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31 Poor patient-provider interactions restrict access, whilst a longstanding
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33 relationship with a primary clinician can optimise uptake.[18]
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In South Africa, colposcopy procedures are generally done at tertiary-level facility, by specialist gynaecology oncologists and trainee gynaecologists under supervision. While there may be benefits to decentralising colposcopy services to lower levels of care, these need to be balanced by the advantages of centralization of cancer services, such as concentrating clinical expertise,

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4 with a higher quality of care, and the rationalisation of expensive specialist
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6 equipment. Thus, in this before- and after-study, we aimed to determine if
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8 access to colposcopy increased following the decentralisation of colposcopy
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10 services from a tertiary-level hospital to a primary care facility in inner-city
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12 Johannesburg, South Africa. We compare the total number of colposcopies
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14 done and the coverage of colposcopy services in the primary-level facility after
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16 decentralisation. We also compare the two sites, specifically, the patient
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18 profile and cervical cancer risks, colposcopy procedures, quality of the
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20 services and histology outcomes.
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29 30 **METHODS**

31 32 **Study participants and setting**

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36 Women, aged 18 years and older, who accessed colposcopy services at
37
38 either Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) or
39
40 Hillbrow Community Health Centre (HCHC) between October 2012 and
41
42 September 2016 were included in the study. Both facilities are in sub-district F
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44 of the Johannesburg Health District (JHD).
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51 The colposcopy clinic at CMJAH is part of the Gynaecology-Oncology
52
53 Department at CMJAH, which has two colposcopy machines. Women
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55 attending a facility in JHD who have an abnormal Pap smear are referred to
56
57 the facility, where they are provided with an appointment date for colposcopy.
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4 Hillbrow Community Health Centre (HCHC) is situated in the densely
5
6 populated inner-city area of Hillbrow, about 3km from CMJAH.[19] HCHC
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8 provides primary level care, including a 24 hour casualty and a midwife
9
10 obstetrics unit. The facility is run predominantly by nursing staff, with support
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12 from non-specialist medical doctors.
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18 **Implementation of decentralised services**

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22 In 2013, a review of patient files at HCHC found that a large proportion of
23
24 women attending the HIV clinic had high-risk lesions on Pap smear.[20]
25
26 Moreover, there were reports from patients and health workers at HCHC of
27
28 prolonged waiting times for colposcopy services at CMJAH. The Wits
29
30 Reproductive Health and HIV Institute (Wits RHI) thus set about establishing
31
32 decentralised colposcopy services at HCHC. A private sector company
33
34 donated a colposcopy machine. Two district medical officers were trained by
35
36 specialist gynaecology oncologists at CMJAH to provide the service. CMJAH
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38 staff provided ongoing support and established referral processes between
39
40 the two facilities. Monthly meetings were held between staff at the two
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42 facilities, where concerns and difficult cases could be discussed.
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54 The services, which began in October 2014, were provided twice a week by
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56 the medical officers, with assistance from the nurse who takes Pap smears at
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58 the facility. Patients attending HCHC and some referred from surrounding
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4 clinics were given an appointment for colposcopy if they had an abnormal Pap
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6 smear result, defined as: high-grade squamous intraepithelial lesion (HSIL),
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8 atypical squamous cell and HSIL cannot be excluded (ASC-H), or squamous
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10 cell carcinoma (SCC).[21] A few patients with Pap smear results other than
11
12 those defined as abnormal smears were also referred for colposcopy. Patients
13
14 with complex lesions, such as abnormal cervical anatomy or a high suspicion
15
16 of cancer on Pap smear were referred to CMJAH, as were those with a failed
17
18 colposcopy. Colposcopy procedures included colposcopic assessment only,
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20 or colposcopic assessment together with either a Lletz or biopsy. Histology
21
22 specimens were processed at the National Health Laboratory Service (NHLS).
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31 32 **Data sources and collection**

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36 For the purpose of this evaluation, women who accessed colposcopy services
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38 at CMJAH and HCHC were divided into three groups: 1) pre-decentralisation
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40 at CMJAH between October 2012 and September 2014; 2) post-
41
42 decentralisation at CMJAH between October 2014 and September 2016; and
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45 3) post-decentralisation at HCHC between October 2014 and September
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48 2016.
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53 At CMJAH, we extracted data from paper-based records at the colposcopy
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55 clinic, including on patients' age, HIV status, antiretroviral treatment, date of
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57 Pap smear, Pap smear result, date of colposcopy, colposcopy procedure
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3 performed and histology results. Data were entered into a REDCap electronic
4 database (REDCap Software, Version 4.14.5, Vanderbilt University).[22] At
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6 HCHC, demographic and clinical data on women who accessed colposcopy
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8 services were entered into an MS Excel spreadsheet after each patient visit.
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15 Data were obtained from the NHLS on Pap smear cytology for women
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17 attending HCHC who had a Pap smear and for the whole of JHD.
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21 **Study variables and statistical analysis**

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24 Access to colposcopy was measured by the total number of colposcopies
25
26 done across the two facilities and the colposcopy coverage at HCHC, the
27
28 primary study outcome. Coverage was estimated by calculating the proportion
29
30 of all women at HCHC with an abnormal Pap smear who had a colposcopy.
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35 Time to colposcopy was calculated as the number of months from date of Pap
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37 smear to colposcopy and was categorised as optimal (under 3 months),
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39 acceptable (3-6 months) and delayed (greater than 6 months). We also
40
41 examined changes in referral patterns of women who had an abnormal Pap
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43 smear at HCHC.
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50 Patient characteristics were compared between the three groups, as well as
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52 level of integration of HIV services (provision of HIV testing and antiretroviral
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54 treatment).
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4 We also compared the types of colposcopy procedures performed in the
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6 different periods and histology findings. Histology results were classified as
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8 normal (includes benign endocervical polyp, atrophic ectocervical mucosa,
9
10 koilocytosis and metaplasia), Cervical Intraepithelial Neoplasia (CIN) I, CIN
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12 II, CIN III, carcinoma, other (includes infections such as cervicitis,
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14 inflammation and dysplasia) and invalid specimens (includes absent results).
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Quality of services was evaluated using proxy markers, specifically the proportion of invalid specimens and number of unsuccessful colposcopy procedures. Differences between the three study groups were assessed using a chi-square test or a Wilcoxon rank-sum test, as appropriate. All data were analysed using STATA version 13.0.

Ethical considerations

Ethical approval was obtained from Human Research Ethics Committee of the University of the Witwatersrand (Certificate number: M151184). Permission for use of the CMJAH data was granted by the hospital's Chief Executive Officer, and the head of the Department of Obstetrics and Gynaecology at CMJAH.

The NHLS Academic Affairs and Research Office gave permission for use of their data.

Patient involvement

The study utilised data that had already been collected as part of routine patient care, and thus patients were not directly involved in the study. We did, however, attempt to contact patients who had abnormal lesions on histology and had not attended follow-up visits.

RESULTS

Access to colposcopy and timeliness of services

In total, 910 women accessed colposcopy at CMJAH between October 2012 and September 2014. In the subsequent two years, 1120 women had a colposcopy: 399 at HCHC (35.6%) and 721 at CMJAH (64.4%; Table 1 and Figure 1).

Table 1: Patient characteristics and colposcopy outcomes at a community clinic, and a tertiary-level facility before and after decentralisation

Variables		Before versus after decentralisation at CMJAH			HCHC versus CMJAH after decentralisation	
		A) Pre-decentralisation (2012-2014) N=910	B) Post-decentralisation (2014-2016) N=721	P (A vs B)	C) Hillbrow CHC (2014-2016) N=399	P (B vs C)
Characteristics	Age groups in years					
	<20	7 (0.8)	6 (0.8)		0 (0)	
	20-34	351 (39.8)	209 (30.2)		150 (37.6)	
	35-44	342 (38.8)	266 (38.4)		156 (39.1)	
	45-59	161 (18.3)	187 (27.0)		79 (19.8)	
	>60	20 (2.3)	25 (3.6)	0.001	7 (1.8)	0.003
	HIV status known	650 (71.4)	429 (59.5)	<0.001	399 (100)	<0.001

	HIV status[^]					
	Negative	105 (16.2)	59 (13.8)		62 (15.5)	
	Positive	545 (83.9)	370 (86.3)	0.28	337 (84.5)	0.47
	On ART[%]	428/544 (78.7)	324/370 (87.6)	<0.001	336/337 (99.7)	<0.001
Cervical cancer Screening	Facility where Pap smear done					
	CMJAH	115 (12.8)	124 (17.5)		0 (0.0)	
	HCHC	114 (12.7)	43 (6.1)		307 (76.9)	
	Other clinic or hospital	671 (74.6)	540 (76.4)	<0.001	92 (23.1)	<0.001
	Pap smear results					
	NILM	6 (0.7)	8 (1.1)		17 (4.3)	
	LSIL	141 (15.5)	125 (17.4)		79 (20.0)	
	ASCUS	19 (2.1)	34 (4.7)		4 (1.0)	
	HSIL	678 (74.7)	478 (66.4)		263 (66.4)	
	ASC-H	63 (6.9)	65 (9.0)		27 (6.8)	
Carcinoma	1 (0.1)	10 (1.4)	<0.001	6 (1.5)	<0.001	
Cervical cancer Screening	Pap smear risk categories					
	NILM, LSIL or ACSUS	166 (18.3)	167 (23.2)		100 (25.3)	
	HSIL, ASC-H or carcinoma	742 (81.7)	553 (76.8)	0.015	296 (74.8)	0.44
Cervical cancer diagnosis	Procedure during colposcopy					
	Visual inspection only	37 (4.1)	37 (5.2)		63 (15.9)	
	Lletz	337 (37.2)	258 (35.9)		231 (58.2)	
	Biopsy	526 (58.0)	420 (58.4)		90 (22.7)	
	Other	7 (0.8)	4 (0.6)	0.69	13 (3.3)	<0.001
	Histology result^{&}					
	Normal	27 (3.1)	30 (4.4)		45 (13.8)	
	CIN I	254 (29.3)	200 (29.3)		84 (25.7)	
	CIN II	298 (34.3)	209 (30.7)		99 (30.3)	
	CIN III	236 (27.2)	198 (29.0)		86 (26.3)	
Carcinoma	3 (0.4)	9 (1.3)		2 (0.6)		
Other [†]	34 (3.9)	19 (2.8)		2 (0.6)		
Invalid specimen	16 (1.8)	17 (2.5)	0.10	9 (2.8)	<0.001	

χ^2 test for categorical variables or Wilcoxon Rank-sum test for continuous variables. [^]Of those with a known HIV status. [%]Of those HIV positive. [&]Of those with a histology specimen taken at biopsy, Lletz or other procedure. Charlotte Maxeke

Johannesburg Academic Hospital (CMJAH). Hillbrow Community Health Centre (HCHC). *Other includes infections such as cervicitis, inflammation and dysplasia

Of all Pap smears done in the JHD in the two years after decentralisation (114,983), 1.9% were done at HCHC (2227; Table 2). Overall, 18.0% of Pap smears done at HCHC had abnormal cytology and required colposcopy (n=401), compared to only 8.2% of other women in JHD as a whole (n=1826; $p<0.001$). The estimated colposcopy coverage among women who had an abnormal Pap smear at HCHC was 66.6% (267/401; 95%CI=61.7-71.2%).

The number of women who had a Pap smear at HCHC and then a colposcopy at either facility was three-fold higher post-decentralisation than pre-decentralisation (from 113 to 350) (Table 1).

Table 2: Cytology results in the City of Johannesburg in 2014-2016

Variable n (%)	Johannesburg health district* (n=114,983)	Hillbrow Community Health Centre (n=2227)	<i>P</i>
Pap smear results			
NILM	74,969 (65.2)	852 (38.3)	
LSIL	23,212 (20.2)	790 (35.5)	
ASCUS	7391 (6.4)	184 (8.3)	
HSIL	7808 (6.8)	364 (16.3)	
ASC-H	1221 (1.1)	28 (1.3)	
Carcinoma	382 (0.3)	9 (0.4)	<0.001
Number requiring colposcopy			
No (NILM, LSIL or ASCUS)	105,572 (91.8)	9411 (82.0)	

Yes (HSIL, ASC-H or carcinoma)	1826 (8.2)	401 (18.0)	<0.001
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Data from the National Health Laboratory Service. Excludes invalid or missing specimens, and other Pap smear results (n=2446).

*District total excludes HCHC

Almost half of the women at CMJAH had a delay in receiving colposcopy (>6 months between Pap smear and colposcopy) post-decentralisation, compared to about a third pre-decentralisation (47.3% versus 36.2%, $p<0.001$; Figure 1: Graph 1A). At HCHC, 21.7% of women had a colposcopy within three months of a Pap smear being taken (versus 11.8% at CMJAH pre- and 15.4% post-decentralisation, $p<0.001$).

The absolute number of women at CMJAH who had had a Pap smear at HCHC decreased from 113 to 43 in the second period. One quarter of women who had a colposcopy at HCHC had had their Pap smear at another facility.

Characteristics of women in the three groups and HIV service integration

The proportion of women older than 45 years pre-decentralisation at CMJAH was 20.6%, post-decentralisation at CMJAH 30.6% and at HCHC 21.9% ($p<0.001$). At CMJAH, more women had a known HIV status pre-decentralisation than post-decentralisation (71.4% versus 59.5%, $p<0.001$). All women at HCHC had a documented HIV status. Around 85% of women with a known HIV status were HIV positive in all three groups. The proportion of

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4 positive women receiving ART rose in the second period at CMJAH from
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6 78.7% to 87.6% ($p<0.001$), and almost all positive women were on ART at
7
8 HCHC (99.7%; $p<0.001$) (Table 1).
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23 **Description of colposcopy procedures, histology findings and colposcopy** 24 **quality** 25 26 27 28

29 At CMJAH, in both periods, nearly 60% of women had a biopsy at colposcopy
30 (58.2%), while the same proportion had a Lletz at HCHC (58.2%). Three
31 women who had a colposcopy at HCHC were referred to CMJAH due to an
32 unsuccessful procedure.
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41 Women at HCHC were 3.5 fold more likely to have a normal result on
42 histology than women at CMJAH (95%CI OR=2.1-5.7). Post-decentralisation,
43 29.0% of women at CMJAH and 26.3% at HCHC had CIN III lesions ($p=0.37$;
44 Figure 1; Graph1B). Post-decentralisation, 11 women had a diagnosis of
45 carcinoma on histology (1.1%), compared to 3 before decentralisation (0.4%;
46 $p=0.06$). The proportion of invalid specimens was similar across the three
47 groups, ranging from 1.8 to 2.8% (Table 1).
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DISCUSSION

In this study we determined whether decentralisation to primary care level improved access to colposcopy services by reviewing the number of women attending the service before and after decentralisation, and the coverage of colposcopy among women at HCHC. We found that the cumulative number of colposcopies across the two facilities rose following decentralisation, and after only two years, HCHC was responsible for a third of all colposcopies in the sub-district, even though it performs a negligible number of Pap smears relative to other sites. Overall, following decentralisation, three fold more women who had a Pap smear at HCHC had a colposcopy, and equally, at CMJAH, the proportion of women referred from HCHC reduced almost threefold. The marked increase in number of women from HCHC who had a colposcopy indicates that prior to decentralisation there may have been a large unmet need for the service, which was now being addressed, at least in part. The coverage reached 66.6%, considerably higher than figures in other settings.

Decentralisation of colposcopy services to primary level care has several potential benefits. Firstly, with adequate training, tasks that had been performed by highly specialised staff can be shifted to lower health worker cadres, allowing specialists to focus on more complex cases.[23] Additionally,

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4 decentralisation may alleviate patient barriers to access, by bringing services
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6 closer to them – in settings they are familiar with – and reducing their transport
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8 and other costs.[13, 23] Decentralisation has long been central to the
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10 provision of HIV services in this setting through, for example, task shifting,
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12 providing antiretroviral treatment in primary care services and the dispensing
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14 of drugs from local pharmacies, rather than clinics.[24]
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21 Decentralisation of colposcopy can take several forms, including
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23 telecolposcopy from distant sites, outreach portable colposcopy, shifting of
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25 services to nurse practitioners or medical officers, and decentralisation to
26
27 lower level facilities, as in this study.[25] In other settings, shifting services to
28
29 lower care levels was found to be cost-effective, acceptable to patients and to
30
31 increase rates of attendance for colposcopy.[16, 25, 26] In the Western Cape,
32
33 South Africa, for example, colposcopy services were decentralised to a district
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35 hospital and provided by a gynaecologist.[23] This raised uptake of the service
36
37 and reduced time to procedure. In high-income countries, services have been
38
39 successfully decentralised to community health centres and portable outreach
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41 programmes in Alaska, the United States, and parts of Canada and Australia,
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43 targeting immigrant, Inuit and other vulnerable women.[16, 17, 26-28] The
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45 National Health Service in United Kingdom has gone a step further and
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4 colposcopy is often performed by nurse practitioners once they have
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6 completed certification procedures.[29]
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10 Women attending HCHC colposcopy were at lower risk than those at CMJAH,
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12 as shown by their lower grades of abnormalities on Pap smear and histology.
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15 Women at HCHC were also younger than those at CMJAH, important as risk
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17 for cervical cancer is higher in rises considerably with age (the mean age at
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19 diagnosis of cervical cancer is 52.3 in South Africa).[30] These findings may
20
21 suggest that, as the programme had envisaged, higher-risk patients are being
22
23 referred to CMJAH. Overall, services at HCHC appear to be performing well,
24
25 with all women tested for HIV and almost all those positive were receiving
26
27 ART. In addition, colposcopy services were now integrated into their care,
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29 which was previously off-site, complex to access and marked by lengthy
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31 delays. HIV-positive women made up the large majority of patients in all
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33 groups, reflecting the higher levels of risk for cervical cancer in this population.
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Clearly it remains a priority to integrate screening for cervical cancer within all
clinics providing antiretroviral treatment. Equally, ART and services such as
screening and treatment for sexually transmitted infections could be integrated
within colposcopy clinics, reducing the opportunity costs associated with
multiple visits to the clinic and lowering the risk of loss to follow up.

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4 The similar number of invalid histology samples and the isolated cases of
5
6 failed colposcopy suggests that the quality of colposcopy services at HCHC
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8 may have been comparable to CMJAH. Unlike at CMJAH, however, Lletz was
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10 the commonest procedure at HCHC, in keeping with evidence that Lletz is
11
12 better suited to lower level facilities and staff.[10] With decentralisation, it is
13
14 critical to ensure that staff are adequately trained and service quality is closely
15
16 monitored. The hesitancy to decentralise colposcopy to date, may reflect
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18 underlying concerns that cases of cancer may go undetected by lower-level
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20 staff. In some settings, lower-level health workers undergo a process of
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22 certification and have to perform a certain number of colposcopies per year to
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24 remain registered.[29] While this approach may hold advantages, onerous
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26 processes around certification and recertification may lead to staff
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28 discontinuing colposcopy.[31]

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41 The decline in number of colposcopies at CMJAH is concerning, and may
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43 reflect factors other than a reduction in demand that accompanies
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45 decentralisation. Fewer women at the site had a known HIV status and waiting
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47 times for colposcopy lengthened. Thus, though decentralisation can reduce
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49 the patient burden at referral centres, this does not necessarily translate into
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51 improved services at that site. Other factors may play a larger influence, for
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4 example, coinciding with the period after decentralisation, CMJAH lost a
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6 number of senior specialists.
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10 Delays in colposcopy vary considerably between settings, from an average of
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12 39 days from referral to colposcopy in one study in KwaZulu Natal, South
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14 Africa,[12] to around 5-6 months in both our study and another in the Western
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16 Cape.[23] It is concerning that time from Pap smear to colposcopy is greater
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18 than six months for half the women at CMJAH, and a third at HCHC. Reducing
19
20 these delays is clearly a priority at both sites. We were unable, however, to
21
22 discern reasons for these delays, which could be caused by delays in
23
24 providing the results of Pap smears to patients, patient delays in making or
25
26 attending appointments, or shortages of specialist staff. We could also not
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28 investigate which group of patients required referral to higher levels of care,
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30 and future studies might attempt to define criteria for referral. Moreover, given
31
32 the relatively short period of the review, we are unable to assess sustainability
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34 of the services in the long-run, a pressing question. Lastly, the study
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36 evaluated the use of colposcopy following cytological screening with Pap
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38 smears and these findings may not be generalizable to screening with HPV
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40 testing.[29] HPV testing has a considerably higher sensitivity for detecting
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42 precursor lesions of cervical cancer compared to cytology, and thus may alter
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4 the number of patients requiring colposcopy and types of lesions
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6 identified.[32, 33]
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9 10 **CONCLUSION**

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13 In conclusion, decentralisation of colposcopy services can improve access to
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15 colposcopy, resulting in faster diagnoses of precancerous lesions of the
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17 cervix, more lesions being treated with LLETZ and a reduction in the burden of
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19 patients in tertiary hospitals. Most importantly, increasing the number of
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21 colposcopies and treatments of precancerous lesions could reduce the
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23 incidence of cervical cancer. This is particularly important among HIV-positive
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25 women who now live longer with ART, and the treatment of their co-
26
27 morbidities is rapidly gaining in importance. Though coverage of colposcopy
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29 reached two thirds at HCHC, it is important to identify interventions to further
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31 raise coverage levels. Decentralisation is unlikely to affect the quality of
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33 services if medical officers are appropriately trained, supervised and
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35 supported by clear referral guidelines. The approach presented here could be
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37 extended to other primary- or secondary-level facilities in South Africa, and
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39 perhaps encompass the use of portable colposcopes or telecolposcopy, under
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41 close supervision. If done correctly and at scale, decentralisation of
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43 colposcopy services, could shore up cervical cancer prevention and finally
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45 decrease the public health burden and mortality due to the cancer.
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COMPETING INTERESTS

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4 All authors listed in this study do not have competing interests to declare.
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10 DATA SHARING STATEMENT

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12
13
14 There's no additional unpublished data from the study.
15
16

17 AUTHOR CONTRIBUTIONS

18
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20
21 **Manuscript title:** The impact of decentralising colposcopy services from
22 tertiary- to primary-level care in inner-city Johannesburg, South Africa: a
23 before and after study
24
25
26

27 Category 1

28
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56 Category 3

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59 **Approval of the version of the manuscript to be published:**
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39 used if there are more than 10 authors):
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23 **FIGURE LEGENDS**
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27 Figure 1:
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30 Graph 1A: Total number of colposcopies done before and after
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32 decentralisation
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36 Graph 1B: Number of cervical intraepithelial neoplasia lesions detected before
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38 and after decentralisation
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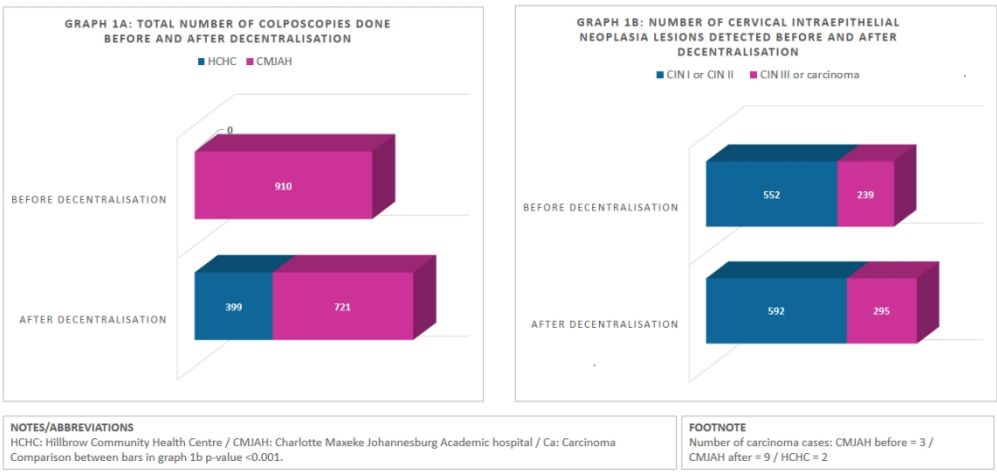


Figure 1:
Graph 1A: Total number of colposcopies done before and after decentralisation
Graph 1B: Number of cervical intraepithelial neoplasia lesions detected before and after decentralisation

271x128mm (120 x 120 DPI)

BMJ Open

The impact of decentralising colposcopy services from tertiary- to primary-level care in inner-city Johannesburg, South Africa: a before and after study

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4 **Title:** The impact of decentralising colposcopy services from tertiary- to
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6 primary-level care in inner-city Johannesburg, South Africa: a before and after
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8 study
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ABSTRACT

Objective: To assess whether decentralising colposcopy services to a primary care facility in inner-city Johannesburg, South Africa raises access to colposcopy.

Design: Before-after study comparing two years before and two after decentralisation, using clinical records, and laboratory data on cervical cytology and histology.

Primary outcome: The proportion of all women attending Hillbrow Community Health Centre (HCHC) with an abnormal Pap smear who had a colposcopy post-decentralisation.

Setting: Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) has provided colposcopy services for several decades. HCHC, located about 3km away, began colposcopy services in 2014.

Participants: Women, aged above 18 years, who had a colposcopy for diagnosis and treatment of precancerous cervical lesions following a Pap smear, from 2012-2016 at CMJAH or HCHC.

Results: Pre-decentralisation at CMJAH, 910 women had colposcopy (2012-2014). Post-decentralisation (2014-2016), 721 had colposcopy at CMJAH and 399 at HCHC, the decentralised facility. The number who had a Pap smear at

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4 HCHC and then a colposcopy rose three-fold post-decentralisation (114
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6 versus 350). Post-decentralisation, 43 women at HCHC were referred from
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9 CMJAH for colposcopy, compared to 114 pre-decentralisation. Post-
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12 decentralisation, 47.3% of women at CMJAH waited >6 months for
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15 colposcopy, while 35.5% did at HCHC ($p<0.001$). Across all three groups,
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18 26.9-30.3% of women had CIN III lesions or carcinoma on colposcopy. The
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21 proportion of invalid specimens was similar at CMJAH and HCHC (1.8-2.8%).
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24 Of 401 women who had an abnormal Pap smear at HCHC post-
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26
27 decentralisation, 267 had colposcopy (66.6%).
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30 **Conclusion:** Decentralisation can decrease the time to colposcopy and reduce
31
32 the workload of tertiary hospitals. Overall, more women accessed services.
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35 Colposcopy coverage at HCHC is higher than other sites, but could be further
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37
38 improved. Decentralisation did not appear to undermine the quality of services
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41 and this model could be extended to similar settings in South Africa and
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44 elsewhere.
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46 **Key words:** South Africa, colposcopy, cervical cancer, primary health care,
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ARTICLE SUMMARY

Strengths and limitations of this study

- The study included a relatively large number of women from high-volume facilities in all study groups, allowing us to detect differences between the time periods
- As the study assessed only one primary care centre in the first two years after decentralisation, we were unable ascertain the intervention's long-term sustainability, or to assess the impact of a broader decentralisation strategy, such as a hub and spoke approach encompassing several primary care centres
- A hub and spoke approach has been successfully applied to other similar health services that require an integrated, tiered health care and laboratory system (such as TB care and colorectal cancer screening), supporting the generalizability of the study findings to similar settings, and assertions about the validity of the results reported.
- The limited number of variables collected meant that the study could not investigate several important questions in detail, such as reasons for delays in colposcopy, the quality of decentralised services or comparisons of changes in access among women at the primary care site over time.
- Data were collected for the purposes of patient care, and not specifically for research, potentially reducing data quality.

INTRODUCTION

Cervical cancer is a largely preventable disease and WHO has recently launched an initiative aimed at eliminating the condition.[1] At present, cervical cancer is the second most common cancer among women aged 15 to 44 years in the world.[2] In South Africa, it is the commonest cancer in that age group, and mortality rates are high.[3, 4] About 3% of women in South Africa harbour cervical human papilloma virus (HPV)-16/18, which is responsible for the majority of cases of cervical cancer in the country.[4] Rates of cervical cancer in South Africa can partly be attributed to the high level of HIV.[5] Women with HIV infection have a seven-fold higher rate of persistence of high-risk HPV compared to HIV uninfected women,[6] heightening their risk for incident and progressive precancerous lesions. While antiretroviral therapy

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4 reduces the risk of cervical cancer and its precursors, the risk remains much
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6 higher than for HIV-negative women.[7]
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10 In South Africa, the policy for cervical cancer screening was introduced in
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12 2001 and updated in 2017.[8] The policy recommends that low-risk women
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14 have three Pap smears in a lifetime at the ages of 30, 40 and 50 years, while
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16 women with HIV-infection are to be screened every three years, regardless of
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18 age. About 60% of women aged 30 to 49 years have had cervical cancer
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20 screening.[9] Screening is predominately based on cytology using
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22 Papanikolaou (Pap) smears, although there are plans to introduce liquid-
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24 based cytology which offers the potential to do HPV screening. Women with
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26 atypical findings on cytology are referred for colposcopy to establish a
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28 definitive diagnosis. During colposcopy, the view of the cervix is magnified
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30 and, where required, a biopsy is taken or a large loop excision of the
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32 transformation zone (LLETZ) is conducted.[10]
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45 The gap between screening for cervical cancer and treatment of high-risk
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47 lesions is believed to be very high in South Africa.[11] Although there are few
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49 published data to support this assertion, the fact that the number of cervical
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51 cancer cases remains high despite the large number of cervical cancer
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53 screening procedures suggest this is the case. A range of health systems and
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55 patient factors influence access to colposcopy. System barriers include a
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4 limited number of colposcopy services, which are mostly centralised within
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6 tertiary-level facilities, with long waiting times for patients and few
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8 opportunities for non-specialist health workers to develop requisite skills.[12]
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12 There are limited numbers of specialist gynaecologists within the public
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14 sector, and the high demands on these doctors for emergency and curative
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16 obstetric and gynaecology services may reduce their time available for
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18 diagnostic or preventive interventions, such as colposcopy. Another key factor
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20 is the complexity of providing Pap and other results to patients and then
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22 scheduling colposcopy appointments across the disjointed systems that often
23
24 exist between a tertiary hospital and primary care centres.[13-15] Patient-
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26 related factors linked with low uptake of colposcopy include low education
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28 levels, being single, fear of HIV testing and disclosure, a low CD4 count in
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30 HIV-infected women and transport costs for the additional visits.[14, 16, 17]
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34 Patient demand for colposcopy is also undermined by a general fear of
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36 cancer, and lack of awareness or knowledge about cervical cancer.[13, 18]
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40 Poor patient-provider interactions restrict access, whilst a longstanding
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42 relationship with a primary clinician can optimise uptake.[18]
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47 In South Africa, colposcopy procedures are generally done at tertiary-level
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49 facility, by specialist gynaecology oncologists and trainee gynaecologists
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51 under supervision. While there may be benefits to decentralising colposcopy
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4 services to lower levels of care, these need to be balanced by the advantages
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6 of centralization of cancer services, such as concentrating clinical expertise,
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8 with a higher quality of care, and the rationalisation of expensive specialist
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10 equipment. Thus, in this before- and after-study, we aimed to determine if
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12 access to colposcopy increased following the decentralisation of colposcopy
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14 services from a tertiary-level hospital to a primary care facility in inner-city
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16 Johannesburg, South Africa. We compare the total number of colposcopies
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18 done and the coverage of colposcopy services in the primary-level facility after
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20 decentralisation. We also compare the two sites, specifically, the patient
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22 profile and cervical cancer risks, colposcopy procedures, quality of the
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24 services and histology outcomes.
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35 **METHODS**

36 **Study participants and setting**

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38 Women, aged 18 years and older, who accessed colposcopy services at
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40 either Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) or
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42 Hillbrow Community Health Centre (HCHC) between October 2012 and
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44 September 2016 were included in the study. Both facilities are in sub-district F
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46 of the Johannesburg Health District (JHD).
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56 The colposcopy clinic at CMJAH is part of the Gynaecology-Oncology
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58 Department at CMJAH, which has two colposcopy machines. Women
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3 attending a facility in JHD who have an abnormal Pap smear are referred to
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5
6 the facility, where they are provided with an appointment date for colposcopy.
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10 Hillbrow Community Health Centre (HCHC) is situated in the densely
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12 populated inner-city area of Hillbrow, about 3km from CMJAH.[19] HCHC
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14 provides primary level care, including a 24 hour casualty and a midwife
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16 obstetrics unit. The facility is run predominantly by nursing staff, with support
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18 from non-specialist medical doctors.
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23 24 25 **Implementation of decentralised services**

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28 In 2013, a review of patient files at HCHC found that a large proportion of
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30 women attending the HIV clinic had high-risk lesions on Pap smear.[20]
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33 Moreover, there were reports from patients and health workers at HCHC of
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35 prolonged waiting times for colposcopy services at CMJAH. The Wits
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37 Reproductive Health and HIV Institute (Wits RHI) thus set about establishing
38
39 decentralised colposcopy services at HCHC. A private sector company
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41 donated a colposcopy machine. Two district medical officers were trained by
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43 specialist gynaecology oncologists at CMJAH to provide the service. CMJAH
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45 staff provided ongoing support and established referral processes between
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47 the two facilities. Monthly meetings were held between staff at the two
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49 facilities, where concerns and difficult cases could be discussed.
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4 The services, which began in October 2014, were provided twice a week by
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6 the medical officers, with assistance from the nurse who takes Pap smears at
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8 the facility. Patients attending HCHC and some referred from surrounding
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10 clinics were given an appointment for colposcopy if they had an abnormal Pap
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12 smear result, defined as: high-grade squamous intraepithelial lesion (HSIL),
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14 atypical squamous cell and HSIL cannot be excluded (ASC-H), or squamous
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16 cell carcinoma (SCC).[21] A few patients with Pap smear results other than
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18 those defined as abnormal smears were also referred for colposcopy. Patients
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20 with complex lesions, such as abnormal cervical anatomy or a high suspicion
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22 of cancer on Pap smear were referred to CMJAH, as were those with a failed
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24 colposcopy. Colposcopy procedures included colposcopic assessment only,
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26 or colposcopic assessment together with either a Lletz or biopsy. Histology
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28 specimens were processed at the National Health Laboratory Service (NHLS).
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41 **Data sources and collection**

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44 For the purpose of this evaluation, women who accessed colposcopy services
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46 at CMJAH and HCHC were divided into three groups: 1) pre-decentralisation
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48 at CMJAH between October 2012 and September 2014; 2) post-
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50 decentralisation at CMJAH between October 2014 and September 2016; and
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56 3) post-decentralisation at HCHC between October 2014 and September
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4 At CMJAH, we extracted data from paper-based records at the colposcopy
5
6 clinic, including on patients' age, HIV status, antiretroviral treatment, date of
7
8 Pap smear, Pap smear result, date of colposcopy, colposcopy procedure
9
10 performed and histology results. Data were entered into a REDCap electronic
11
12 database (REDCap Software, Version 4.14.5, Vanderbilt University).[22] At
13
14 HCHC, demographic and clinical data on women who accessed colposcopy
15
16 services were entered into an MS Excel spreadsheet after each patient visit.
17
18 Data were obtained from the NHLS on Pap smear cytology for women
19
20 attending HCHC who had a Pap smear and for the whole of JHD.
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30 **Study variables and statistical analysis**

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32 Access to colposcopy was measured by the total number of colposcopies
33
34 done across the two facilities and the colposcopy coverage at HCHC, the
35
36 primary study outcome. Coverage was estimated by calculating the proportion
37
38 of all women at HCHC with an abnormal Pap smear who had a colposcopy.
39
40
41 Time to colposcopy was calculated as the number of months from date of Pap
42
43 smear to colposcopy and was categorised as optimal (under 3 months),
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45 acceptable (3-6 months) and delayed (greater than 6 months). We also
46
47 examined changes in referral patterns of women who had an abnormal Pap
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49 smear at HCHC.
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4 Patient characteristics were compared between the three groups, as well as
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6 level of integration of HIV services (provision of HIV testing and antiretroviral
7
8 treatment).
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12 We also compared the types of colposcopy procedures performed in the
13
14 different periods and histology findings. Histology results were classified as
15
16 normal (includes benign endocervical polyp, atrophic ectocervical mucosa,
17
18 koilocytosis and metaplasia), Cervical Intraepithelial Neoplasia (CIN) I, CIN
19
20 II, CIN III, carcinoma, other (includes infections such as cervicitis,
21
22 inflammation and dysplasia) and invalid specimens (includes absent results).
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30 Quality of services was evaluated using proxy markers, specifically the
31
32 proportion of invalid specimens and number of unsuccessful colposcopy
33
34 procedures. Differences between the three study groups were assessed using
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36 a chi-square test or a Wilcoxon rank-sum test, as appropriate. All data were
37
38 analysed using STATA version 13.0.
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44 **Ethical considerations**

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46
47
48 Ethical approval was obtained from Human Research Ethics Committee of the
49
50 University of the Witwatersrand (Certificate number: M151184). Permission for
51
52 use of the CMJAH data was granted by the hospital's Chief Executive Officer,
53
54 and the head of the Department of Obstetrics and Gynaecology at CMJAH.
55
56
57
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The NHLS Academic Affairs and Research Office gave permission for use of their data.

Patient involvement

The study utilised data that had already been collected as part of routine patient care, and thus patients were not directly involved in the study. We did, however, attempt to contact patients who had abnormal lesions on histology and had not attended follow-up visits.

RESULTS

Access to colposcopy and timeliness of services

In total, 910 women accessed colposcopy at CMJAH between October 2012 and September 2014. In the subsequent two years, 1120 women had a colposcopy: 399 at HCHC (35.6%) and 721 at CMJAH (64.4%; Table 1 and Figure 1).

Table 1: Patient characteristics and colposcopy outcomes at a community clinic, and a tertiary-level facility before and after decentralisation

Variables	Before versus after decentralisation at CMJAH			HCHC versus CMJAH after decentralisation	
	A) Pre-decentralisation (2012-2014) N=910	B) Post-decentralisation (2014-2016) N=721	P (A vs B)	C) Hillbrow CHC (2014-2016) N=399	P (B vs C)

Characteristics	Age groups in years					
	<20	7 (0.8)	6 (0.8)		0 (0)	
	20–34	351 (39.8)	209 (30.2)		150 (37.6)	
	35–44	342 (38.8)	266 (38.4)		156 (39.1)	
	45–59	161 (18.3)	187 (27.0)		79 (19.8)	
	>60	20 (2.3)	25 (3.6)	0.001	7 (1.8)	0.003
	HIV status known	650 (71.4)	429 (59.5)	<0.001	399 (100)	<0.001
	HIV status[^]					
	Negative	105 (16.2)	59 (13.8)		62 (15.5)	
	Positive	545 (83.9)	370 (86.3)	0.28	337 (84.5)	0.47
	On ART[%]	428/544 (78.7)	324/370 (87.6)	<0.001	336/337 (99.7)	<0.001
Cervical cancer Screening	Facility where Pap smear done					
	CMJAH	115 (12.8)	124 (17.5)		0 (0.0)	
	HCHC	114 (12.7)	43 (6.1)		307 (76.9)	
	Other clinic or hospital	671 (74.6)	540 (76.4)	<0.001	92 (23.1)	<0.001
	Pap smear results					
	NILM	6 (0.7)	8 (1.1)		17 (4.3)	
	LSIL	141 (15.5)	125 (17.4)		79 (20.0)	
	ASCUS	19 (2.1)	34 (4.7)		4 (1.0)	
	HSIL	678 (74.7)	478 (66.4)		263 (66.4)	
	ASC-H	63 (6.9)	65 (9.0)		27 (6.8)	
Carcinoma	1 (0.1)	10 (1.4)	<0.001	6 (1.5)	<0.001	
	Pap smear risk categories					
	NILM, LSIL or ACSUS	166 (18.3)	167 (23.2)		100 (25.3)	
	HSIL, ASC-H or carcinoma	742 (81.7)	553 (76.8)	0.015	296 (74.8)	0.44
Cervical cancer	Procedure during colposcopy					
	Visual inspection only	37 (4.1)	37 (5.2)		63 (15.9)	
	Lletz	337 (37.2)	258 (35.9)		231 (58.2)	
	Biopsy	526 (58.0)	420 (58.4)		90 (22.7)	
	Other	7 (0.8)	4 (0.6)	0.69	13 (3.3)	<0.001

	Histology result ^{&}					
	Normal	27 (3.1)	30 (4.4)		45 (13.8)	
	CIN I	254 (29.3)	200 (29.3)		84 (25.7)	
	CIN II	298 (34.3)	209 (30.7)		99 (30.3)	
	CIN III	236 (27.2)	198 (29.0)		86 (26.3)	
	Carcinoma	3 (0.4)	9 (1.3)		2 (0.6)	
	Other [*]	34 (3.9)	19 (2.8)		2 (0.6)	
	Invalid specimen	16 (1.8)	17 (2.5)	0.10	9 (2.8)	<0.001

χ^2 test for categorical variables or Wilcoxon Rank-sum test for continuous variables. [^]Of those with a known HIV status. [%]Of those HIV positive. [&]Of those with a histology specimen taken at biopsy, Lletz or other procedure. Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). Hillbrow Community Health Centre (HCHC). ^{*}Other includes infections such as cervicitis, inflammation and dysplasia

Of all Pap smears done in the JHD in the two years after decentralisation (114,983), 1.9% were done at HCHC (2227; Table 2). Overall, 18.0% of Pap smears done at HCHC had abnormal cytology and required colposcopy (n=401), compared to only 8.2% of other women in JHD as a whole (n=1826; p<0.001). The estimated colposcopy coverage among women who had an abnormal Pap smear at HCHC was 66.6% (267/401; 95%CI=61.7-71.2%). The number of women who had a Pap smear at HCHC and then a colposcopy at either facility was three-fold higher post-decentralisation than pre-decentralisation (from 113 to 350) (Table 1).

Table 2: Cytology results in the City of Johannesburg in 2014-2016

Variable n (%)	Johannesburg health district* (n=114,983)	Hillbrow Community Health Centre (n=2227)	P
Pap smear results			

NILM	74,969 (65.2)	852 (38.3)	
LSIL	23,212 (20.2)	790 (35.5)	
ASCUS	7391 (6.4)	184 (8.3)	
HSIL	7808 (6.8)	364 (16.3)	
ASC-H	1221 (1.1)	28 (1.3)	
Carcinoma	382 (0.3)	9 (0.4)	
			<0.001
Number requiring colposcopy			
No (NILM, LSIL or ASCUS)	105,572 (91.8)	9411 (82.0)	
Yes (HSIL, ASC-H or carcinoma)	1826 (8.2)	401 (18.0)	<0.001

Data from the National Health Laboratory Service. Excludes invalid or missing specimens, and other Pap smear results (n=2446).

*District total excludes HCHC

Almost half of the women at CMJAH had a delay in receiving colposcopy (>6 months between Pap smear and colposcopy) post-decentralisation, compared to about a third pre-decentralisation (47.3% versus 36.2%, $p<0.001$; Figure 1: Graph 1A). At HCHC, 21.7% of women had a colposcopy within three months of a Pap smear being taken (versus 11.8% at CMJAH pre- and 15.4% post-decentralisation, $p<0.001$).

The absolute number of women at CMJAH who had had a Pap smear at HCHC decreased from 113 to 43 in the second period. One quarter of women who had a colposcopy at HCHC had had their Pap smear at another facility.

Characteristics of women in the three groups and HIV service integration

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4 The proportion of women older than 45 years pre-decentralisation at CMJAH
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6 was 20.6%, post-decentralisation at CMJAH 30.6% and at HCHC 21.9%
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8 (p<0.001). At CMJAH, more women had a known HIV status pre-
9
10 decentralisation than post-decentralisation (71.4% versus 59.5%, p<0.001). All
11
12 women at HCHC had a documented HIV status. Around 85% of women with a
13
14 known HIV status were HIV positive in all three groups. The proportion of
15
16 positive women receiving ART rose in the second period at CMJAH from
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18 78.7% to 87.6% (p<0.001), and almost all positive women were on ART at
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20 HCHC (99.7%; p<0.001) (Table 1).
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40 **Description of colposcopy procedures, histology findings and colposcopy** 41 **quality** 42 43 44

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46 At CMJAH, in both periods, nearly 60% of women had a biopsy at colposcopy
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48 (58.2%), while the same proportion had a Lletz at HCHC (58.2%). Three
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50 women who had a colposcopy at HCHC were referred to CMJAH due to an
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52 unsuccessful procedure.
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4 Women at HCHC were 3.5 fold more likely to have a normal result on
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6 histology than women at CMJAH (95%CI OR=2.1-5.7). Post-decentralisation,
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8 29.0% of women at CMJAH and 26.3% at HCHC had CIN III lesions (p=0.37;
9
10 Figure 1; Graph1B). Post-decentralisation, 11 women had a diagnosis of
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12 carcinoma on histology (1.1%), compared to 3 before decentralisation (0.4%;
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14 p=0.06). The proportion of invalid specimens was similar across the three
15
16 groups, ranging from 1.8 to 2.8% (Table 1).
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23 24 DISCUSSION

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27 In this study we determined whether decentralisation to primary care level
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29 improved access to colposcopy services by reviewing the number of women
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31 attending the service before and after decentralisation, and the coverage of
32
33 colposcopy among women at HCHC. We found that the cumulative number of
34
35 colposcopies across the two facilities rose following decentralisation, and after
36
37 only two years, HCHC was responsible for a third of all colposcopies in the
38
39 sub-district, even though it performs a negligible number of Pap smears
40
41 relative to other sites. Overall, following decentralisation, three fold more
42
43 women who had a Pap smear at HCHC had a colposcopy, and equally, at
44
45 CMJAH, the proportion of women referred from HCHC reduced almost
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47 threefold. The marked increase in number of women from HCHC who had a
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49 colposcopy indicates that prior to decentralisation there may have been a
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3 large unmet need for the service, which was now being addressed, at least in
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6 part. The coverage reached 66.6%, considerably higher than figures in other
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9 settings.

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12 Decentralisation of colposcopy services to primary level care has several
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14
15 potential benefits. Firstly, with adequate training, tasks that had been
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18 performed by highly specialised staff can be shifted to lower health worker
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21 cadres, allowing specialists to focus on more complex cases.[23] Additionally,
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23
24 decentralisation may alleviate patient barriers to access, by bringing services
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27 closer to them – in settings they are familiar with – and reducing their transport
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29
30 and other costs.[13, 23] Decentralisation has long been central to the
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33 provision of HIV services in this setting through, for example, task shifting,
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36 providing antiretroviral treatment in primary care services and the dispensing
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39 of drugs from local pharmacies, rather than clinics.[24]

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41
42 Decentralisation of colposcopy can take several forms, including
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45 telecolposcopy from distant sites, outreach portable colposcopy, shifting of
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48 services to nurse practitioners or medical officers, and decentralisation to
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51 lower level facilities, as in this study.[25] In other settings, shifting services to
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54 lower care levels was found to be cost-effective, acceptable to patients and to
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57 increase rates of attendance for colposcopy.[16, 25, 26] In the Western Cape,
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59
60 South Africa, for example, colposcopy services were decentralised to a district

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4 hospital and provided by a gynaecologist.[23] This raised uptake of the service
5
6 and reduced time to procedure. In high-income countries, services have been
7
8 successfully decentralised to community health centres and portable outreach
9
10 programmes in Alaska, the United States, and parts of Canada and Australia,
11
12 targeting immigrant, Inuit and other vulnerable women.[16, 17, 26-28] The
13
14 National Health Service in United Kingdom has gone a step further and
15
16 colposcopy is often performed by nurse practitioners once they have
17
18 completed certification procedures.[29]

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27 Women attending HCHC colposcopy were at lower risk than those at CMJAH,
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29 as shown by their lower grades of abnormalities on Pap smear and histology.
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31
32 Women at HCHC were also younger than those at CMJAH, important as risk
33
34 for cervical cancer is higher in rises considerably with age (the mean age at
35
36 diagnosis of cervical cancer is 52.3 in South Africa).[30] These findings may
37
38 suggest that, as the programme had envisaged, higher-risk patients are being
39
40 referred to CMJAH. Overall, services at HCHC appear to be performing well,
41
42
43 with all women tested for HIV and almost all those positive were receiving
44
45 ART. In addition, colposcopy services were now integrated into their care,
46
47 which was previously off-site, complex to access and marked by lengthy
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49 delays. HIV-positive women made up the large majority of patients in all
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58 groups, reflecting the higher levels of risk for cervical cancer in this population.
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4 Clearly it remains a priority to integrate screening for cervical cancer within all
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6
7 clinics providing antiretroviral treatment. Equally, ART and services such as
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9
10 screening and treatment for sexually transmitted infections could be integrated
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13 within colposcopy clinics, reducing the opportunity costs associated with
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15
16 multiple visits to the clinic and lowering the risk of loss to follow up.

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18 The similar number of invalid histology samples and the isolated cases of
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20
21 failed colposcopy suggests that the quality of colposcopy services at HCHC
22
23
24 may have been comparable to CMJAH. Unlike at CMJAH, however, Lletz was
25
26
27 the commonest procedure at HCHC, in keeping with evidence that Lletz is
28
29
30 better suited to lower level facilities and staff.[10] With decentralisation, it is
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32
33 critical to ensure that staff are adequately trained and service quality is closely
34
35
36 monitored. The hesitancy to decentralise colposcopy to date, may reflect
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38
39 underlying concerns that cases of cancer may go undetected by lower-level
40
41
42 staff. In some settings, lower-level health workers undergo a process of
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45 certification and have to perform a certain number of colposcopies per year to
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47
48 remain registered.[29] While this approach may hold advantages, onerous
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50
51 processes around certification and recertification may lead to staff
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53
54 discontinuing colposcopy.[31]

55
56 The decline in number of colposcopies at CMJAH is concerning, and may
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58
59 reflect factors other than a reduction in demand that accompanies
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3 decentralisation. Fewer women at the site had a known HIV status and waiting
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6 times for colposcopy lengthened. Thus, though decentralisation can reduce
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8
9 the patient burden at referral centres, this does not necessarily translate into
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11
12 improved services at that site. Other factors may play a larger influence, for
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14
15 example, coinciding with the period after decentralisation, CMJAH lost a
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17
18 number of senior specialists.
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21 Delays in colposcopy vary considerably between settings, from an average of
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23
24 39 days from referral to colposcopy in one study in KwaZulu Natal, South
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26
27 Africa,[12] to around 5-6 months in both our study and another in the Western
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29
30 Cape.[23] It is concerning that time from Pap smear to colposcopy is greater
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32
33 than six months for half the women at CMJAH, and a third at HCHC. Reducing
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35
36 these delays is clearly a priority at both sites. We were unable, however, to
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38
39 discern reasons for these delays, which could be caused by delays in
40
41
42 providing the results of Pap smears to patients, patient delays in making or
43
44
45 attending appointments, or shortages of specialist staff. We could also not
46
47
48 investigate which group of patients required referral to higher levels of care,
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50
51 and future studies might attempt to define criteria for referral. Moreover, given
52
53
54 the relatively short period of the review, we are unable to assess sustainability
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56
57 of the services in the long-run, a pressing question. Lastly, the study
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59
60 evaluated the use of colposcopy following cytological screening with Pap

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4 smears and these findings may not be generalizable to screening with HPV
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6 testing.[29] HPV testing has a considerably higher sensitivity for detecting
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8 precursor lesions of cervical cancer compared to cytology, and thus may alter
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10 the number of patients requiring colposcopy and types of lesions
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15 identified.[32, 33]
16

17 18 **CONCLUSION**

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20
21 In conclusion, decentralisation of colposcopy services can improve access to
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23 colposcopy, resulting in faster diagnoses of precancerous lesions of the
24
25 cervix, more lesions being treated with LLETZ and a reduction in the burden of
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27 patients in tertiary hospitals. Most importantly, increasing the number of
28
29 colposcopies and treatments of precancerous lesions could reduce the
30
31 incidence of cervical cancer. This is particularly important among HIV-positive
32
33 women who now live longer with ART, and the treatment of their co-
34
35 morbidities is rapidly gaining in importance. Though coverage of colposcopy
36
37 reached two thirds at HCHC, it is important to identify interventions to further
38
39 raise coverage levels. Decentralisation is unlikely to affect the quality of
40
41 services if medical officers are appropriately trained, supervised and
42
43 supported by clear referral guidelines. The approach presented here could be
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45 extended to other similar primary- or secondary-level facilities in South Africa,
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47 and perhaps encompass the use of portable colposcopes or telecolposcopy,
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4 under close supervision. If done correctly and at scale, decentralisation of
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6 colposcopy services, could shore up cervical cancer prevention and finally
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8 decrease the public health burden and mortality due to the cancer.
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15

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8
9

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14
15
16
17 All authors listed in this study do not have competing interests to declare.
18
19

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24
25
26
27 There's no additional unpublished data from the study.
28
29

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34
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38
39

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48
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53 This statement is signed by all the authors (a photocopy of this form may be
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55 used if there are more than 10 authors):

56 57 58 **REFERENCES**

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FIGURE LEGENDS

Figure 1:

Graph 1A: Total number of colposcopies done before and after
decentralisation

Graph 1B: Number of cervical intraepithelial neoplasia lesions detected before
and after decentralisation

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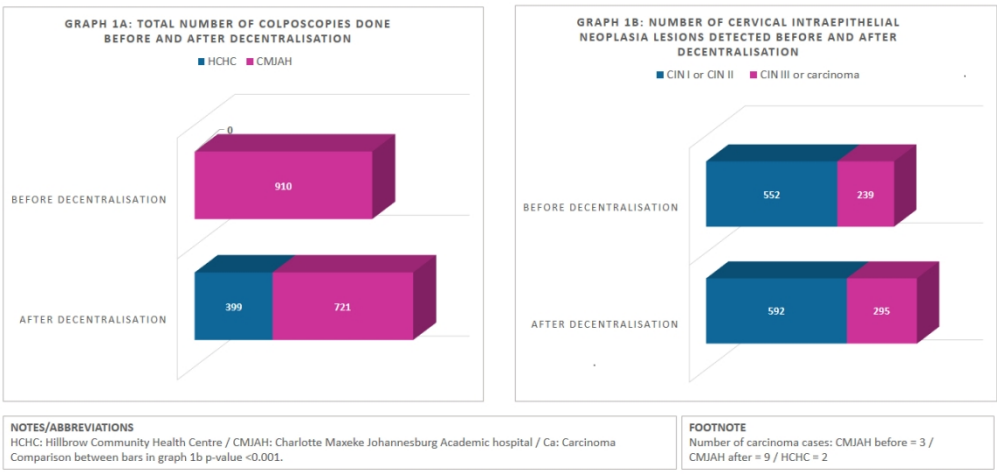


Figure 1:
Graph 1A: Total number of colposcopies done before and after decentralisation
Graph 1B: Number of cervical intraepithelial neoplasia lesions detected before and after decentralisation

271x128mm (120 x 120 DPI)