BELIEFS AND PERCEPTIONS REGARDING CERVICAL CANCER AND SCREENING ASSOCIATED WITH PAP SMEAR UPTAKE IN JOHANNESBURG

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of Masters in Medicine (in the speciality of Public Health Medicine)

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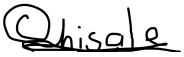
DECLARATION

I, Mantwa Chisale Mabotja; hereby declare that this Research report is my own, unaided work. It is being submitted for the Degree of Masters in Medicine (Public Health Medicine) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

M. Chisale Mabotja

(Signature of candidate)



7th day of October 2019 in Johannesburg

MMED SUBMISSION FORMAT

This MMED research report is submitted in the format of a submissible research article entitled Beliefs and perceptions regarding cervical cancer and screening associated with Pap smear uptake in Johannesburg: A cross-sectional study. The article will be submitted to the BioMed Central (BMC) Public Health journal. This is to certify that the article conforms to the author guidelines for the BMC Public Health journal. The author guidelines are attached (Appendix 4). The research protocol for this MMED research- which was approved by the Faculty of Health Sciences Postgraduate Research Committee on the 26th April 2017 is also attached (Appendix 5).

DECLARATION: Student's contribution to article and agreement of co-authors

We, the co-authors, certify that **Mantwa Chisale Mabotja**, student number **0600025X**, is the first author of this paper. She is responsible for the content of the paper and worked on the following areas regarding the research execution and writing of the article:

- Protocol writing
- Data collection
- Data analysis
- Manuscript write up

Agreement by co-authors:

By signing this declaration, the co-authors listed below agree to the use of the article by the student as part of her Research Report.

Signature of Student: M.Chisale Mabotja Date 07/10/2019

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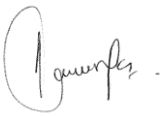
Signature  Date 07/10/2019

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Date: 07/10/2019

PRESENTATIONS ARISING FROM THIS STUDY

	Presentation 1	**Presentation 2**	**Presentation 3**
Conference	Johannesburg district PHC cluster meeting	Faculty of Health Sciences Research Day and Postgraduate Expo	PHASA (Public Health Association of South Africa)
Date	13 August 2018	06 September 2018	11 September 2018
Venue	Hillbrow CHC 1st floor boardroom	University of Witwatersrand	Parys, South Africa
Type	Oral presentation	Oral presentation	Poster presentation
Theme	Research result dissemination	Education, Policy & Systems	Health Systems as a Determinant of Health

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MMED SUBMISSIBLE FORMAT

Beliefs and perceptions regarding cervical cancer and screening associated with Pap smear uptake in Johannesburg: A cross-sectional study

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ABSTRACT

Background: Cervical cancer is a major global public health concern, with 85% of cases occurring in low- and middle-income countries. In South Africa, it is the second most common cancer amongst women. Screening and treatment of cervical cancer precursor lesions is associated with a lower incidence and mortality. This research determines the associations between women's beliefs about cervical cancer and screening and the uptake of Papanicolaou (Pap) smears in Johannesburg, where cervical screening uptake is suboptimal.

Methods: This cross-sectional analytical study applied a validated measurement scale based on the Health Belief Model (HBM), to describe health beliefs regarding cervical cancer and screening uptake using an interviewer-administered questionnaire among 280 women aged 30 years and older attending Johannesburg primary healthcare facilities in 2017. Logistic regression models with robust estimation of variance were fitted to identify health beliefs associated with ever having had a Pap smear (screening uptake), while controlling for potential confounders.

Results: Of the 280 women, 177 (63.2%) had ever been screened, 180 (64.3%) were never married, 199 (71.1%) attained secondary education and 133 (47.5%) were employed full time. The multivariable logistic regression showed that the health beliefs associated with Pap smear uptake were perceived severity and perceived barriers. Women of older age (AOR=1.6 for a 5-year increase in age; CI: 1.3-1.9, P<0.001), with higher knowledge scores (AOR=2.5 for a 5-point increase in knowledge score; 95% CI:1.0-6.3 ;P=0.051), with lower perceived barriers scores (AOR =0.4 for a 5-point increase in barriers score; 95% CI:0.3-0.5; P<0.001) and higher perceived severity scores (AOR=1.3 for a 5-point increase in severity score; 95% CI:1.0-1.6; P=0.017) were more likely to have had a Pap smear.

Conclusions: This study shows that women who take up screening are older, knowledgeable regarding cervical cancer and screening, less likely to perceive screening barriers, and more likely to perceive cervical cancer as a severe disease. This highlights that for public health interventions to increase screening uptake, the focus should include tailored behaviour change communication strategies that addresses women's beliefs regarding screening barriers and emphasize the severity of cervical cancer.

Keywords: Cervical cancer screening, cervical cancer, Pap smear uptake, Beliefs, Perceptions, South Africa

BACKGROUND

Cervical cancer is a major public health concern globally and a significant cause of mortality and morbidity in women (1). It is the 4th most common cancer amongst women globally, with an estimated 311,000 deaths and 570,000 new cases reported worldwide in 2018, with about 85% of these cases occurring in low- to middle-income countries (LMICs) (1).

Cervical cancer is preventable by early detection through screening, early diagnosis and effective treatment of precancerous lesions (2). At a population level, prevention through screening is realised only if high screening coverage is achieved, which means a high proportion of eligible women receiving the available screening tests (2). The World Health Organization (WHO) has identified high cervical screening coverage as the most important measure in achieving reductions in incidence and mortality (3). Screening coverage of eligible women is an average of 19% in low- to middle-income countries (LMICs), and 63% in high income countries (HICs) (4). The successful reductions in mortality and morbidity noted in HICs are mainly attributed to an increased uptake of Papanicolaou (Pap) smears, due to greater access to healthcare and high level of awareness of screening among women (2).

In South Africa, cervical cancer is ranked the second most common cancer amongst women (1). Approximately 12,983 new cases and 5,595 deaths were reported in 2018 (1). The South African National Department of Health (NDoH) implemented a national screening policy in 2000 which states that every woman should have three free Pap smears in her lifetime, done at 10 year intervals from the age of 30 (5). In view of research evidence that cervical cancer incidence rates are significantly higher in HIV infected than HIV negative women (6), and availability of new screening technologies, the national policy was revised in 2017 to include earlier screening (at the time of HIV diagnosis) and a shorter screening interval (three yearly)

for HIV positive women, as well as recommendation for using screening tests other than Pap smears – including the HPV DNA test (7). In South Africa, where screening tests (Pap smears) are available in the public sector, the cervical screening coverage is reportedly lower than expected targets (8). At inception of the policy in 2000, the target was to screen at least 70% of women in the target age group, nationally, within 10 years of initiating the programme (5), however by 2010, only 52.2% of eligible women had been screened (9).

Cervical screening coverage

The literature identifies many factors associated with poor coverage of cervical screening, categorised as healthcare provider, health system and personal factors (9). Health system factors contributing to low screening coverage in LMICs include low investment in screening mainly due to competing healthcare priorities, weak health systems, insufficient financial resources, and limited number of health providers (3). In South Africa, health system and health provider factors include: lack of leadership and good stewardship of the health system, poor monitoring and evaluation, competing health priorities, poor accessibility and quality of screening services, insufficient human and material resources to perform Pap smears (9-12), poor health provider's knowledge of, and negative attitudes regarding cervical screening policy requirements (12, 13).

Personal factors refer to issues such as knowledge, beliefs, and attitudes, which may impact on women's uptake of available health services. Research available in South Africa on personal factors mostly explores women's knowledge and attitudes (14-16). For example, in rural South Africa, Hoque et al (16) showed that low uptake of screening is associated with low level of knowledge of risk factors and prevention of cervical cancer. Qualitative studies conducted in SA (17, 18) highlight that women hold beliefs such as fear of cancer and misconceptions that

Pap smears are associated with "cleaning of the womb" that may influence their decisions to use Pap smear services. However, there is a dearth of research exploring the influence of personal factors such as women's health beliefs on cervical screening uptake in South Africa. Such research is useful to inform demand generation strategies to promote appropriate health seeking behaviour amongst eligible women.

Health Belief Model

The Health Belief Model (HBM) is one of the most widely utilized and oldest models, wherein theory from behavioural sciences is applied to understand health problems (19). It is "a psychological health behaviour change model suggesting that people's beliefs, perceptions and attitudes about a disease determines their willingness to use preventative interventions such as screening for disease" (20) (p25). This model was introduced in the 1950s initially by Hochbaum et al, and consisted of four main constructs: perceived susceptibility, barriers, severity and benefits (21-23). The HBM describes an individual's beliefs regarding the likelihood of experiencing a condition or disease that could adversely affect their health (perceived susceptibility) (24); an individual's interpretation of the degree of severity of a disease (perceived severity) (24), one's beliefs that using the prevention service will benefit the individual, e.g. by preventing disease (perceived benefit) (22, 23); and factors perceived to hinder one's adoption of healthy behaviours, for example, cost or convenience of the service (perceived barriers) (22, 23). Two other constructs were added later to the HBM (22, 23) - cues to action (a cue or trigger that prompts one's engagement in health-promoting behaviours (25), for example, information from health care providers, the media, or close others) and self-efficacy (perceived confidence in one's capability to adopt behaviour that leads to desired favourable outcome) (22, 23, 26).

The HBM is however a cognitive based model that attempts to predict health-related behaviours by accounting for individual differences in beliefs and attitudes, and so does not account for other factors that may influence health behaviours. For example, in South Africa contextual factors such as a high HIV/AIDS prevalence and stigma as well as gender norms wherein men control women's decisions about using health services do influence women's choice to use screening services (18). However, the HBM is a universally recognized theoretical framework of health behaviour and a useful tool for exploring beliefs and perceptions associated with uptake of health services.

Measurement scales based on the HBM have been used to understand various health-seeking behaviours. For example, Champion developed HBM instruments to explore breast cancer screening uptake (22, 27, 28). Champion's Health Belief Model (CHBM) and Champion's Self-efficacy (CSE) scales have been translated, adapted and found to be reliable and valid for use in various cultures and settings (29-33), and have been adapted and used, though not validated, in the Africa context in countries such as Botswana and South Africa (34, 35). The CHBM scale measures all HBM constructs, except self-efficacy, which is measured by the CSE. The CHBM scale has been validated for cervical cancer screening in a study in Turkey, with Cronbach alpha coefficients ranging from 0.62 to 0.86 (24), and the CSE scale was validated in a study in Mexico with a Cronbach alpha coefficient of 0.95 (34). Few studies have explored the association between HBM constructs and the uptake of cancer screening using the CHBM and CSE scales (24, 28, 33, 36-38).

This study applies the HBM to describe the beliefs regarding cervical cancer and screening amongst women attending primary healthcare clinics in the Johannesburg district, South Africa, and determine the associations between their beliefs and uptake of Pap smears. The study was guided by the hypothesis that health beliefs regarding Pap smears differed between women who had ever had a Pap smear (uptake) and those who had not.

METHODS

Study design and setting

This cross-sectional study with an analytical component was conducted in Johannesburg, one of the wealthiest districts in South Africa (39). The Johannesburg district is divided into seven health sub-districts named from A to G. Within sub-districts, the public sector health facilities at primary healthcare level include clinics, community healthcare centres (CHCs) and district hospitals. Clinics and CHCs are administered by either local or provincial government health authorities. Free cervical screening services are provided in public sector primary healthcare facilities for HIV positive women of any age at diagnosis and HIV negative women from age 30. The cervical screening coverage for health districts in South Africa is measured by the number of cervical smears taken in women 30 years and older as a proportion of the female population 30 years and older factored for one smear every 10 years (40). In this district (study site) it was 47,4% during 2016 to 2017 (8, 40) significantly lower than the district (55%), provincial (55%) and national (62%) targets.

Sample size and power considerations

The sample size, calculated using STATA statistical software version 13.0 (41), was 280 women. The effect of clustering of women within clinics, was taken into account. Statistically this effect can be summarised by the design effect or deff. We assumed a moderate clustering effect, with a deff of 1.5, in which case our effective sample size was 190. The proportion of women who have ever had a Pap smear in their lifetime was then estimated with a precision of ± 7.3%. We powered the study to detect an absolute difference of 20% in the proportion of women who have had a Pap smear, between those with a high HBM score and those with a low

HBM score. We conceptualised a high HBM score as above the median and a low HBM score as below the median score. Assuming that among those with a high HBM score, 50% of women have had a Pap smear (using the district cervical screening coverage) compared to 30% among those with a low HBM score, then the study had over 80% power to detect this difference as statistically significant at the 5% level. In the analysis we used the actual score for each woman on each HBM construct rather than a dichotomised (high/low) variable, thus the study had a greater power to detect an association between the HBM scores and having had a Pap smear.

Sampling procedure

A two-stage sampling procedure was used. At the first stage, in each sub-district two clinics were randomly selected by sampling with probability proportional to clinic size. We used, the clinic weekly headcount (number of adult attendees presenting to the clinic for any services) as a measure of clinic size. Only clinics were eligible, to ensure the selection of the same facility type, since not all sub-districts have a CHC or district hospital. In the second stage of sampling we selected 20 participants from each of the 14 sampled clinics. This was done by systematically sampling the first participant from a random starting point in the queue, and the 4th eligible woman was approached until the required sample of 20 women was reached. The study had a 100% response rate. Within each sampled clinic, eligible participants were women aged 30 or older, attending the clinic on the day of the study for any health service (including Pap smear) in 2017. The age restriction was consistent with the target age group for screening as stated in the national cervical cancer prevention and control policy (7). Women with the history of cervical cancer were not excluded from participating in the study.

Data collection and variables

Following a pilot study, data were collected from June to August 2017, using an interviewer-administered structured questionnaire (Appendix 3).

The questionnaire was in English and the interviewer translated it to Isizulu or Sesotho during the interview where the responded could not understand English. Participant responses were captured directly onto REDCap software (42) during the interview. Participant data were collected in each clinic, returning every day until the required number of participants had been interviewed, before moving to the next clinic. The questionnaire measured the six HBM constructs (explanatory variables) from question 13 to 18, and the outcome variable, a binary variable recording whether (yes = 1) or not (no = 0) the respondent had ever had a Pap smear (question 8). The HBM constructs were measured using the adapted and modified CHBM and CSE scales (24, 33). Items in each construct were measured using five-point Likert scales ranging from strongly disagree (1 point) to strongly agree (5 points) (Figure 1, Appendix 3).

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Insert Figure 1

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The HBM refers to modifying factors including age, socio-economic status and general knowledge about cervical cancer and screening (25). Questions on age, marital status, employment status, highest level of education attained were therefore included in our questionnaire (question 1 to 5) as were questions on level of knowledge about screening and cervical cancer (question 6 to 12) . The latter were adapted and modified from an existing validated tool which measures knowledge of screening and cervical cancer (43), however this tool has not been validated in the African context. During the interview, following the

knowledge questions, the researcher explained the concepts of cervical cancer and Pap smear before continuing with the HBM construct section of the questionnaire.

Data management and analysis

The data were captured in REDCap database and analysed in STATA release 13.0 (41) for analysis. All analyses took the clustering of women within clinics and sub-district strata into account, using the survey data analysis commands in Stata. Within each scale (six HBM and one knowledge scale), item scores were summed to create six HBM and one knowledge score. The knowledge score was calculated as the sum of knowledge regarding cervical cancer (question 6, 9 and 10) and knowledge regarding Pap smears (question 7, 11 and 12). Continuous variables (age, knowledge score and HBM construct scores) were summarised with means and 95% confidence intervals and categorical variables were described with proportions. The student t-test was used to assess for significant differences in mean HBM score, age and knowledge scores between women who had a pap smear and those who had not Unadjusted (univariable) models were fitted with "ever had a pap smear" as the outcome variable and each of the explanatory variables in turn while adjusting for age. Thereafter a multivariable model was fitted with "ever had a pap smear" as the outcome variable, significant variables from the univariable analysis and all explanatory variables considered (all six HB M constructs, age and knowledge). Explanatory variables were sequentially removed from the model using a backward elimination algorithm if they were not significant at the 5% level. Significant variables (age, barriers score, severity score and knowledge score) were scaled up to an arbitrary 5-point increase in the scores and age, as we considered 5-points to be meaningful for ease of interpretation. Interactions were investigated one by one between the HBM constructs

in the model and the modifying factors that remained in the model, and age was the only proven confounder.

RESULTS

As shown in Table 1, of the 280 women in the study, 177 (63.2%) had ever had at least one Pap smear in their lifetime, 180 (64.3%) were never married and 199 (71.1%) attained a secondary education. The mean age of participants was 40.4 [39.3-41.4]. Compared to women who had never been screened, those who had ever had a Pap smear had a higher mean age (43.1 [41.8-44.4] vs 35.7 [33.7-37.7]), higher mean knowledge score (13.9 [13.6-14.3] vs 12.5 [11.7-13.3]) and were more likely to be employed full time (96 (54.24%) vs 37 (35.9%)). These cervical cancer knowledge questions include knowing what cervical cancer is, its risk factors, sign and symptoms and treatment. The Pap smear knowledge questions include knowing what Pap smear is, how it is performed, whether they know the existing South African screening policy and the recommended age to start cervical screening test. Of the 280 women, 111 (42.1%) gave a correct response on what cervical cancer is (question 6.1) and 173 (61.8%) gave a correct response on what Pap smear is (question 7.1). Majority of women who had ever had a Pap smear had correct knowledge regarding Pap smears (135 (76.3%) vs 38 (36.9%)) but incorrect knowledge regarding cervical cancer (101 (57.1%) vs 61 (59.2%)). There were no differences observed between the two groups with regards to marital status and education level (Table 1).

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Insert Table 1

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Table 2 shows that women who had ever had a Pap smear had lower mean HBM scores with non-overlapping 95% confidence interval compared to those who had never had a Pap smear for perceived barriers (19.6 [18.5-20.7]; vs 25.9 [23.9-28.1]). The high-scoring perceived barriers include fear of negative results, socio-cultural reasons such as being ashamed to open legs and show private parts, expectations of female health providers performing the test not being met and perceptions such as the test being painful and taking long to perform. However, the two groups of women had relatively similar mean HBM scores for perceived susceptibility (10.5 [9.3-11.6] vs 11.1 [9.7-12.5]), perceived severity (23 [20.7-25.3] vs 21.8 [19.9-23.8]), perceived benefits (41.7 [41.2-42.3] vs 41.3 [39.9-42.6]), cues to action (8.4 [7.5-9.3] vs 7.5 [6.4-8.7]) and self- efficacy (49.4 [49.0-49.8] vs 48.2 [46.8-49.6]).

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Insert Table 2

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The univariable analysis found that knowledge score, perceived barriers score, age and perceived self-efficacy score were associated with uptake of Pap smears (Table 3).

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Insert Table 3

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When controlling for the modifying variables which were statistically significant at the 5% level, the multivariable logistic regression showed that independent factors associated with Pap smear uptake were age, perceived severity score and perceived barriers score, while knowledge score was marginally significant. Women with higher knowledge scores (AOR=2.5 for a 5-

point increase in knowledge score; 95% CI:1.0-6.3 ;P=0.051), older age (AOR=1.6 for a 5-year increase in age; 95% CI: 1.3-1.9; P<0.001), lower perceived barriers scores (AOR =0.4 for a 5-point increase in barriers score; 95% CI:0.3-0.5; P<0.001) and higher perceived severity scores (AOR=1.3 for a 5-point increase in severity score; 95% CI:1.0-1.6; P=0.017) were more likely to have had a Pap smear (see Table 3). Interactions between barrier, knowledge, severity scores and age were investigated but none were significant at the 5% level.

DISCUSSION

This study used the HBM to describe an association between women's beliefs and perceptions regarding cervical cancer and screening and uptake of Pap smears in Johannesburg. A significant association was shown between uptake of Pap smear and perceived severity and perceived barriers scores, independent of other HBM scores and modifying variables. The higher the perceived barriers and perceived severity score, the higher the likelihood of having had a Pap smear. Other HBM constructs (perceived susceptibility, cues to action, benefits and self-efficacy) had no significant association with Pap smear uptake.

Our study shows that women who perceive barriers in accessing Pap smear tests were less likely to have had a Pap smear than those who did not perceive barriers to screening. This finding reveals women's negative perceptions of the test and the health services as well as socio-cultural beliefs regarding women's bodies that influence screening uptake. It was beyond the scope of this study to explore these socio-cultural barriers, but further qualitative studies are recommended to explore these barriers in Johannesburg.

The findings of this study are consistent with a study conducted amongst university students in South Africa which showed perceived barriers to cervical screening include fear of a bad result,

partner resisting cervical screening, the test is too painful, cost barriers and lack of information about the disease (44). Perceived barriers highlighted in other studies include concerns about pain and embarrassment of screening, long distance to screening services, preference regarding the sex of health provider, providers' negative attitudes, fear of cancer, linguistic barriers, and embarrassment that is culturally based (36, 45, 46). A study conducted in Mexico showed that factors increasing uptake of screening include community outreach programs by Hispanic lay health workers, materials printed in Spanish and use of culturally-sensitive media (46). The findings on perceived barriers highlighted in our study suggest the need for public health interventions that include tailored behaviour change communication strategies which are sensitive to socio-cultural beliefs and aim to clear misconceptions about the screening test, as well as health providers changing how they provide care to meet women's expectations. Women are more likely to uptake Pap smears if they perceive the cost and barriers to such behaviour to be reasonable (44).

Our study shows that women who perceived cervical cancer to be a severe disease were more likely to have had a Pap smear. Women who agreed that cervical cancer is a terminal illness they are scared of, admitted the thought of cervical cancer scares them, were afraid of developing and living with cervical cancer, and believed death from cervical cancer is not rare, were more likely to have had a Pap smear than those who scored lower on these beliefs. This finding is consistent with a study conducted in Botswana (45), with a significant number of women strongly agreeing that cervical cancer is as severe as other cancers, makes a woman's life difficult, and causes infertility (45). Findings from our study suggest that increasing screening uptake requires public health interventions that focus on changing women's perceptions regarding the severity of cervical cancer. As the HBM postulates, the likelihood of a person engaging in a health-seeking behaviour is based on their own understanding of the degree of severity of a disease (21).

Our study showed that having a higher level of knowledge regarding cervical cancer and screening increases the likelihood of having had a Pap smear. Lack of knowledge about cervical cancer and screening has been shown to hinder the uptake of screening programmes in South Africa (47). Low knowledge and awareness of cervical cancer signs and symptoms, causes, risk factors, prevention and treatment options as well as low knowledge on screening have been reported in studies conducted in South Africa (44, 48). Our findings suggest there is a need to identify appropriate interventions that enable women in Johannesburg to internalise the belief that cervical cancer is a severe condition. A study conducted in urban areas of Lagos (49) shows that a community-based educational campaign disseminating language-appropriate and culturally sensitive educational information can reach high risk women and increase their knowledge of cervical cancer and screening. This study however did not assess change in screening behaviour. Research evidence from other settings indicates various educational interventions that are effective at increasing awareness and screening uptake, including home-based provision of educational information one-on-one by lay health workers (49) and media-based messaging combined with community outreach by lay health providers (50). A 2018 systematic review identified various health education methods effective at changing women's cervical screening behaviour (including pamphlets, mailed messages, group discussions, amongst others) (51). This review however did not include studies assessing the effectiveness of population-based health education programmes, and did not find any studies in Sub-Saharan Africa (51).

Social and behaviour change communication edutainment interventions such as 'Soul City' in South Africa, a successful mass media intervention that utilises radio, photo-comics and television dramas, has been extensively evaluated and shown to facilitate supportive change or maintain safe sexual behavioural practices (52-54). Such behaviour change interventions require high levels of exposure to reach high numbers of at risk women. Research conducted

in a South African peri-urban community that evaluated the effectiveness of two media interventions (radio-drama and photo-comic) in increasing cervical screening uptake, found that only the radio-drama was effective; and its effectiveness was limited by low levels of exposure (55). This implies that health authorities implementing mass media interventions to increase uptake of cervical screening must concentrate on achieving high levels of exposure to the health messages. Research in South Africa evaluating methods for successfully changing women's health beliefs and cervical cancer screening behaviors are lacking but needed to inform the design and content of behavior change strategies relevant for this context.

As far as the authors are aware, this is the only study describing women's beliefs regarding cervical cancer and Pap smears using the HBM in Johannesburg district where cervical screening coverage is low. Our research identifies health beliefs that are potential targets for interventions to improve screening uptake amongst women over 30 years of age in the district. There are however some limitations related to our study. The participants were women attending clinics; hence it is difficult to generalize the findings to women in the community who are not attending clinics, and women attending health services at other levels of care in the district such as community health centres and district hospitals. The cross-sectional study design means that temporality cannot be determined (whether women's beliefs and perceptions preceded the uptake of screening). The study did not collect medical history data and did not exclude women with history of cervical cancer, this is a potential selection bias as women with cervical cancer might have different perceptions regarding cervical cancer and screening, as compared to women who have no history of cervical cancer. The questionnaire used in this research was interviewer-administered, which could have resulted in socially desirable responses considering the interviewer's presence (information bias), however, a self-administered questionnaire could have resulted in incomplete responses

and might have been difficult for respondents who are unable to read or write in English to complete.

The scales (CHBM, CSE) and cervical cancer awareness tool adapted to compile the questionnaire for this study have been widely utilized and though validated in various settings, have not been validated in the African context. This may have an impact on the interpretation of the results in the context of South Africa. The questionnaire was written in English and where necessary questions were translated on the spot, which could have led to measurement error – inconsistent interviewer interpretations of responses given in other local languages. Finally, a question on HIV status was not included in the questionnaire as this is not addressed in the existing HBM scales. In the context of South Africa where there is a high HIV prevalence, this omission could have resulted in a potential selection bias as HIV positive women are screened more regularly and earlier than age 30. However, including HIV status and medical history (history of cervical cancer) in the questionnaire could have resulted in participants not being willing to participate.

CONCLUSION

Cervical cancer remains a significant cause of mortality among women in South Africa, yet it is preventable through screening. Our study has shown that independent factors that were associated with whether or not a woman had had a Pap smear were two HBM constructs (perceived severity of cervical cancer and perceived barriers to cervical screening), as well as age and knowledge regarding cervical cancer and screening. The findings of this study imply that to increase the screening uptake in Johannesburg district, health authorities should implement tailored behaviour change communication strategies that: target women below age

forty; include messages that are sensitive to socio-cultural beliefs, emphasize the severity of cervical cancer, aim to clear misconceptions about the screening test; and enable health providers changing how they provide care to meet women's expectations. Further qualitative studies are recommended to explore barriers to cervical cancer screening amongst women in Johannesburg.

LIST OF ABBREVIATIONS

CHBM	Champion's Health Belief Model scale
CHC	Community Health Centre
CSE	Champion's Self-efficacy scale
DHB	District Health Barometer
HBM	Health Belief Model
HICs	High Income Countries
HIV	Human Immunodeficiency Virus
HPV	Human papilloma virus
Johannesburg District	Johannesburg Metropolitan Health District
LMICs	Low to Middle Income Countries
NDoH	National Department of Health
Pap smear	Papanicolaou smear
PHC	Primary Health Care
SA	South Africa
VIA	Visual inspection with acetic acid
WHO	World Health Organization

DECLARATIONS

Ethics approval and consent to participate

This research was approved by the University of Witwatersrand Human Research Ethics Committee (Medical), clearance certificate number: M170243 and the Johannesburg District Heath Research Committee prior to conducting the study.

Consent for publication

Not applicable

Availability of data and materials

The Stata dataset used and analysed during the study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

MCM collected primary data, performed the analysis and wrote the manuscript. MK supported the research from conception, contributed by revising the manuscript, and supervised the research process. JL contributed to methodology, results, data analysis and edited the manuscript. All authors read and approved the final manuscript.

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FIGURES

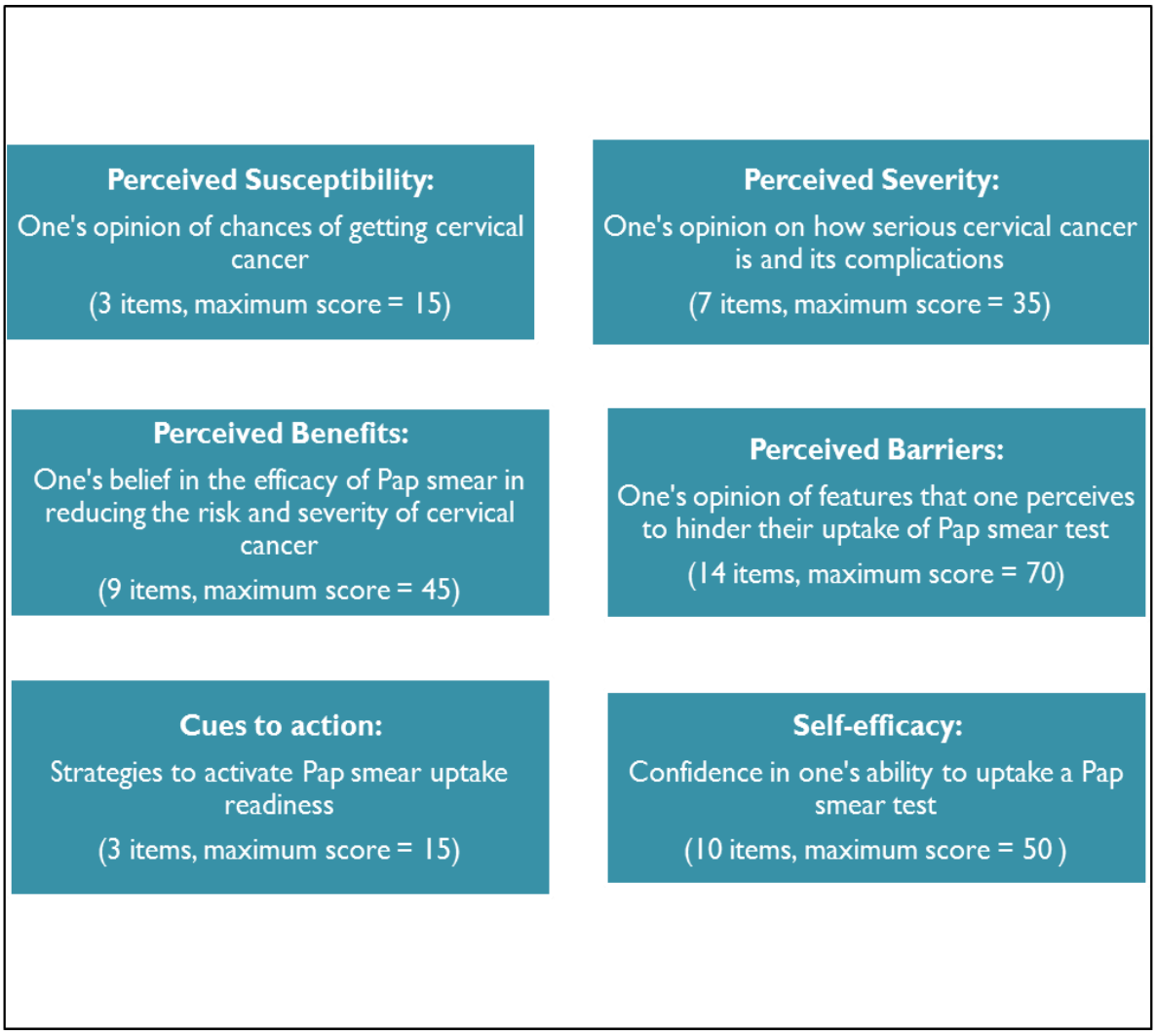


Figure 1: Health Belief Model constructs measured in the study

TABLES

Table 1: Socio-demographic factors and knowledge scores by Pap smear history

Variables	**All women (N=280)**	**Ever had a pap smear *(N=177)***	**Never had a pap smear *(N=103)***
	n (%)	***n (%)***	***n (%)***
Marital status			
Single/never married	180 (64.3)	112 (63.3)	68 (66.0)
Married/living with a partner	80 (28.6)	51 (28.8)	29 (28.2)
Divorced/Separated/widowed	20 (7.1)	14 (7.9)	6 (5.8)
Education level			
≤Primary school	32 (11.4)	19 (10.7)	13 (12.6)
Secondary school	199 (71.1)	132 (74.6)	67 (65.1)
Tertiary education	49 (17.5)	26 (14.7)	23 (22.3)
Employment status			
Employed full-time	133 (47.5)	96 (54.2)	37 (35.9)
Employed part-time	32 (11.4)	19 (10.7)	13 (12.6)
Self-employed	8 (2.9)	2 (1.1)	6 (5.8)
Unemployed	107 (38.2)	60 (33.9)	47 (45.6)
Age			
Mean [95% CI]	40.4 [39.3-41.4]	43.1 [41.8-44.4]	35.7 [33.7-37.7]
Total knowledge score			
Mean [95% CI]	13.4 [12.9-13.9]	13.9 [13.6-14.3]	12.5 [11.7-13.3]

Table 2: Health Belief Model construct scores according to Pap smear history

Characteristics	Total (N=280) Mean [95% CI]	Ever had a pap smear *(N=177)* Mean [95% CI]	Never had a pap smear *(N=103)* Mean [95% CI]	P-value
Susceptibility score	10.7 [9.5-11.9]	10.5 [9.3-11.6]	11.1 [9.7-12.5]	0.130
Severity score	22.6 [20.6-24.5]	23 [20.7-25.3]	21.8 [19.9-23.8]	0.235
Benefits score	41.6 [40.9-42.2]	41.7 [41.2-42.3]	41.3 [39.9-42.6]	0.141
Barriers score	21.9 [20.2-23.7]	19.6 [18.5-20.7]	25.9 [23.9-28.1]	0.000*
Cues to action score	8.1 [7.2-9.0]	8.4 [7.5-9.3]	7.5 [6.4-8.7]	0.091
Self-efficacy score	48.9 [48.2-49.7]	49.4 [49.0-49.8]	48.2 [46.8-49.6]	0.051**

***Significant p value <0.05**
**** Marginally significant 0.05**
-P value: calculated using the student t-test

Table 3: Association between HBM constructs and Pap smear uptake, adjusting for modifying variables

Characteristics	*Crude OR [95% CI]*	*p-value*	*Adjusted OR [95% CI]*	*p-value*
Marital status				
Single/never married (reference)	Ref			
Married/living with a partner	0.8 [0.3-1.7]	0.757		
Divorced/Separated/Widowed	0.6 [0.1-3.8]			
Education level				
≤Primary school (reference)	Ref			
Secondary school	3.9 [0.8-20.4]	0.242		
Tertiary education	3.2 [0.6-16.6]			
Employment status				
Employed full-time (reference)	Ref			
Employed part-time	0.4 [0.2-1.1]			
Self-employed	0.1 [0.03-0.6]	0.138		
Unemployed	0.5 [0.2-1.0]			
Age	1.7 [1.3-2.1]	<0.001*	1.6 [1.3-1.9]	<0.001*
Knowledge score	3.9 [1.3-11.5]	0.019*	2.5 [1.0-6.3]	0.051**
Susceptibility score	0.9 [0.6-1.2]	0.389	0.7 [0.4-1.1]	0.1787
Severity score	1.2 [0.9-1.5]	0.199	1.3 [1.0-1.6]	0.017*
Benefits score	1.2 [0.6-2.3]	0.509	1.0 [0.7-1.6]	0.899
Barriers score	0.4 [0.3-0.6]	<0.001*	0.4 [0.3-0.5]	<0.001*
Cues to action score	1.3 [0.8-2.3]	0.266	1.3 [0.7-2.2]	0.415
Self-efficacy score	2.1 [1.3-3.3]	0.009*	1.2 [0.7-2.1]	0.572

***Significant p value <0.05**
**** Marginally significant 0.05**
-Crude Odds Ratio/unadjusted OR - univariable models were fitted with "ever had had a pap smear" as the outcome variable and each of the explanatory variables one at a time adjusted for age
- Adjusted OR-multivariable model was fitted with "ever had had a pap smear" as the outcome variable and all explanatory variables considered. Explanatory variables were sequentially removed from the model using a backward elimination algorithm if they were not significant

APPENDICES

APPENDIX 1: Plagiarism declaration

PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

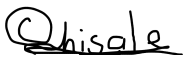
SENATE PLAGIARISM POLICY: APPENDIX ONE

I MANTWA CHISALE MABOTJA (Student number: (0600025X) am a student registered for the degree of MMED in Public Health Medicine in the academic year 2019.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.

Signature: M. Chisale Mabotja Date: 30/08/2019



APPENDIX 2: Ethics clearance certificate

R14/49 Dr Mantwa Chisale Mabotja

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M170243

NAME: (Principal Investigator)	Dr Mantwa Chisale Mabotja
DEPARTMENT:	Community Health School of Public Health Johannesburg Metropolitan Health District
PROJECT TITLE:	Beliefs and Perceptions Regarding Cervical Cancer and Screening Associated with Uptake of Pap Smears in Johannesburg
DATE CONSIDERED:	24/02/2017
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Mary Kawonga
APPROVED BY:	Professor P. Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	26/04/2017

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary 3rd floor, Philip Tobias Building, Parktown, University of the Witwatersrand. I/We fully understand the the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated,from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. in this case, the study was initially review in February and will therefore be due in the month of February each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Chisale — Principal Investigator Signature

26/04/2017 — Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX 3: Questionnaire

Beliefs and perceptions regarding cervical cancer and screening associated with Pap smear uptake in Johannesburg

Thank you for taking part in this interview, we appreciate your time and valuable input. There is no right or wrong answer, and please do not feel shy or embarassed to give us your honest answers. This questionnaire will not be longer than 30 minutes.

Today's date: _____

Clinic name: _____

We would like to ask you a few questions about yourself. This will help us to analyse the results of the study. The data collected will help us to identify specific age or demographic groups of people who participated in the study. You will not be asked your name and all of your answers will be kept strictly confidential.

	Yes	No
Did you receive the information sheet for this study?	○	○
Did you sign the consent form?	○	○

1. What is your age?

_____
(only age 30 and older)

2. What is your marital status?

- ○ Single/never married
- ○ Married/living with partner
- ○ Divorced/separated
- ○ Widowed
- ○ Prefer not to say

3. What is the highest level of education obtained?

- ○ No formal education
- ○ Primary school
- ○ Secondary school
- ○ Tertiary education
- ○ Prefer not to say
- ○ Other

Please specify _____

4. Are you currently:

- ○ Employed full-time
- ○ Employed part-time
- ○ Unemployed
- ○ Self-employed
- ○ Retired
- ○ Still studying
- ○ Prefer not to say
- ○ Other

Please specify _____

5. Have you, your family, or close friends had cancer?

- ○ No one
- ○ You
- ○ Partner
- ○ Close family member
- ○ Other family member
- ○ Close friend
- ○ Other friend
- ○ Prefer not to say

6. I would like to know what people know about cervical cancer.

6.1 Briefly explain what is cervical cancer _____

6.2 Where did you learn about cervical cancer?

- ◯ Media (TV,radio, newspaper, internet)
- ◯ Friend
- ◯ Community member
- ◯ Posters
- ◯ Pamphlets
- ◯ Health educator
- ◯ Health professional
- ◯ Never learnt about it
- ◯ Other

please specify _____

7. I would like to know what people know about Pap smears

7.1 Briefly explain what is a Pap smear _____

7.2 Where did you learn about Pap smears?

- ◯ Media (TV, radio, newspapers, internet)
- ◯ A friend
- ◯ A community member
- ◯ Health professional
- ◯ Health educator
- ◯ Poster
- ◯ Pamphlet
- ◯ Never learnt about it
- ◯ Other

Please specify _____

8. The following questions are all about cervical cancer, which is cancer of the cervix (sometimes called the opening of the womb). Some questions are about Pap smear test which is a test done for cervical cancer to test for presence of abnormal cells on the opening of the womb.

	Yes	No
Have you had a Pap smear test done in your lifetime?	○	○

9. The following may or may not be true regarding cervical cancer. We are interested in your opinion

	True	False	Don't know
Cervical cancer is one of the most common cancers among women	○	○	○
Cervical cancer is preventable	○	○	○
Sexual transmitted infections increase the risk of cervical cancer among women.	○	○	○
Bleeding and spotting after menopause may be associated with cervical cancer	○	○	○
Cervical cancer may be without sign in early stages.	○	○	○

10. The following may or may not increase a woman's chance of developing cervical cancer. How much do you agree that each of these can increase a woman's chance of developing cervical cancer?

	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
Infection with HPV (human papillomavirus)	○	○	○	○	○
Having many sexual partners	○	○	○	○	○
Having a weakened immune system (e.g because of HIV/AIDS, immunosuppressant drugs or having a transplant)	○	○	○	○	○
Smoking any cigarette at all	○	○	○	○	○
Not going for regular Pap smear tests	○	○	○	○	○

11. As far as you are aware, is the department of health providing Pap smear services in South Africa?

○ Yes
○ No
○ I don't know

11.1 If yes, at what age are the women suppose to start screening for cervical cancer in South Africa? _____

Confidential

12. The following may or may not be true regarding Pap smear test. We are interested in your opinion

	True	False	I don't know
Pap smear test before symptomatic cervical cancer, may help detect cervical cancer earlier	○	○	○
Pap smear test is only necessary after age 65	○	○	○
Pap smear test is recommended only for older women.	○	○	○
Pap smear test should be performed only if infection and bleeding was seen	○	○	○

13. PERCEIVED SUSCEPTIBILITY

You may agree or disagree with any of the following statements. Please do state how much do you agree with each of these statements, from strongly agree to strongly disagree.

	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
It is likely that I will get cervical cancer in the future	○	○	○	○	○
My chances of getting cervical cancer in the next few years are high	○	○	○	○	○
I feel I will get cervical cancer some time during my life	○	○	○	○	○

14. PERCEIVED SEVERITY/SERIOUSNESS

You may agree or disagree with any of the following statements. Please do state how much do you agree with each of these statements, from strongly agree to strongly disagree.

	Strongly disagree'	Disagree	Not sure	Agree	Strongly agree
The thought of cervical cancer scares me	○	○	○	○	○
When I think about cervical cancer, my heart beats faster	○	○	○	○	○
I am afraid to think about cervical cancer	○	○	○	○	○
Problems I would experience with cervical cancer would last a long time	○	○	○	○	○
Cervical cancer would threaten a relationship with my boyfriend, husband, or partner	○	○	○	○	○
If I had cervical cancer my whole life would change	○	○	○	○	○
If I developed cervical cancer, I would not live longer than 5 years	○	○	○	○	○

15. PERCEIVED BENEFITS AND HEALTH MOTIVATION

You may agree or disagree with any of the following statements. Please do state how much do you agree with each of these statements, from strongly agree to strongly disagree.

	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
I want to discover health problems early	○	○	○	○	○
Maintaining good health is extremely important to me	○	○	○	○	○
I look for new information to improve my health	○	○	○	○	○
I feel it is important to carry out activities which will improve my health	○	○	○	○	○
If I have a Pap smear test regularly and the result is good, I don't need to worry too much about cervical cancer	○	○	○	○	○
Having regular Pap Smear Tests will help to find changes to the cervix, before they turn into cancer	○	○	○	○	○
If cervical cancer was found at a regular Pap Smear Test its treatment would not be so bad	○	○	○	○	○
I think that having a regular Pap Smear Test is the best way for cervical cancer to be diagnosed early	○	○	○	○	○
Having regular Pap Smear Tests will decrease my chances of dying from cervical cancer	○	○	○	○	○

16. PERCEIVED BARRIERS

You may agree or disagree with any of the following statements. Please do state how much do you agree with each of these statements, from strongly agree to strongly disagree.

	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
I am afraid to have a Pap Smear Test for fear of a bad result	○	○	○	○	○
I am afraid to have a Pap Smear Test because I don't know what will happen	○	○	○	○	○
I cannot remember to have a Pap Smear Test regularly	○	○	○	○	○
I don't know where to go for a Pap Smear Test	○	○	○	○	○
Having a Pap Smear Test takes too much time	○	○	○	○	○
I have other problems more important than having a Pap Smear Test in my life	○	○	○	○	○
I would be ashamed to lie on a examination bed and show my private parts to have a Pap Smear Test	○	○	○	○	○
I am too old to have a Pap Smear Test regularly	○	○	○	○	○
There is no health centre close to my house to have a Pap Smear Test	○	○	○	○	○
Having a Pap Smear Test is too painful	○	○	○	○	○
If there is cervical cancer development in my destiny, having a Pap Smear Test cannot prevent it	○	○	○	○	○
Health professionals doing Pap Smear Test are rude to women	○	○	○	○	○
I prefer a female doctor or nurse to conduct a Pap Smear Test	○	○	○	○	○
I will never have a Pap Smear Test if I have to pay for it	○	○	○	○	○

17. CUES TO ACTION/HEALTH MOTIVATION

You may agree or disagree with any of the following statements. Please do state how much do you agree with each of these statements, from strongly agree to strongly disagree.

	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
I eat well balanced meals for my health	○	○	○	○	○
I exercise at least 3 times a week for my health	○	○	○	○	○
I have regular health check-ups even when I am not sick	○	○	○	○	○

18. SELF-EFFICACY

You may agree or disagree with any of the following statements. Please do state how much do you agree with each of these statements, from strongly agree to strongly disagree.

	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
I can arrange transportation to get a Pap Smear Test	○	○	○	○	○
I can arrange other things in my life to have a Pap Smear Test	○	○	○	○	○
I can talk to people at the Pap Smear centre about my concerns	○	○	○	○	○
I can get a Pap Smear done even if I am worried	○	○	○	○	○
I can get a Pap Smear done even if I don't know what to expect	○	○	○	○	○
I can find a way to pay for a Pap Smear Test	○	○	○	○	○
I can make an appointment for a Pap Smear Test	○	○	○	○	○
I know for sure I can get a Pap Smear Test done if I really want to	○	○	○	○	○
I know how to go about getting a Pap Smear Test	○	○	○	○	○
I can find a place to have a Pap Smear Test	○	○	○	○	○

Cervical cancer is the abnormal growth of cells in the cervix (sometimes called the opening of the womb). The primary cause of cervical pre-cancer and cancer is persistent infection with one or more of the high-risk types of human papillomavirus (HPV).HPV is the most common infection acquired during sexual relations, usually early in sexual life. In most women and men who become infected with HPV, these infections will
resolve spontaneously. A minority of HPV infections persist; this may lead to cervical pre-cancer, which, if not treated, may progress to cancer 10 to 20 years later. Women living with HIV are more likely to develop persistent HPV infections at an earlier age and to develop cancer sooner.

Cervical pre-cancer can be diagnosed early through regular screening (Pap smear) test. A Pap smear test is a procedure where cells from your cervix are gently scraped away and then examined for abnormal growth in the laboratory. The procedure may be mildly uncomfortable, but does not cause any long-term pain.

The department of health in South Africa provides Pap smears in clinics and community health centers. The current policy states that women can have a Pap smear from the age of 30, and every 10 years provided the results are normal, however for HIV positive women the tests are done earlier than the age of 30.

For more information, please read the pamphlet given to you and feel free to visit your local clinic.

Thank you for participating in this study. We greatly appreciate your time

APPENDIX 4: BioMed Central (BMC) Public Health Journal- Authors guidelines

BMC public health

Research article

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Research articles should report on original primary research, but may report on systematic reviews of published research provided they adhere to the appropriate reporting guidelines which are detailed in our editorial policies. Please note that non-commissioned pooled analyses of selected published research will not be considered.

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The information below details the section headings that you should include in your manuscript and what information should be within each section.

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The title page should:

- present a title that includes, if appropriate, the study design e.g.:
    - "A versus B in the treatment of C: a randomized controlled trial", "X is a risk factor for Y: a case control study", "What is the impact of factor X on subject Y: A systematic review"
    - or for non-clinical or non-research studies a description of what the article reports
- list the full names, institutional addresses and email addresses for all authors

    - If a collaboration group should be listed as an author, please list the Group name as an author. If you would like the names of the individual members of the Group to be searchable through their individual PubMed records, please include this information in the "Acknowledgements" section in accordance with the instructions below
- indicate the corresponding author

Abstract

The Abstract should not exceed 350 words. Please minimize the use of abbreviations and do not cite references in the abstract. Reports of randomized controlled trials should follow the CONSORT extension for abstracts. The abstract must include the following separate sections:

- **Background:** the context and purpose of the study
- **Methods:** how the study was performed and statistical tests used
- **Results:** the main findings
- **Conclusions:** brief summary and potential implications
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Keywords

Three to ten keywords representing the main content of the article.

Background

The Background section should explain the background to the study, its aims, a summary of the existing literature and why this study was necessary or its contribution to the field.

Methods

The methods section should include:

- the aim, design and setting of the study

- the characteristics of participants or description of materials
- a clear description of all processes, interventions and comparisons. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses
- the type of statistical analysis used, including a power calculation if appropriate

Results

This should include the findings of the study including, if appropriate, results of statistical analysis which must be included either in the text or as tables and figures.

- ### Discussion

This section should discuss the implications of the findings in context of existing research and highlight limitations of the study.

- ### Conclusions

This should state clearly the main conclusions and provide an explanation of the importance and relevance of the study reported.

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All manuscripts must contain the following sections under the heading 'Declarations':

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- Consent for publication
- Availability of data and material
- Competing interests
- Funding
- Authors' contributions
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Manuscripts reporting studies involving human participants, human data or human tissue must:

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If your manuscript contains any individual person's data in any form (including individual details, images or videos), consent for publication must be obtained from that person, or in the case of children, their parent or legal guardian. All presentations of case reports must have consent for publication.

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All manuscripts must include an 'Availability of data and materials' statement. Data availability statements should include information on where data supporting the results reported in the article can be found including, where applicable, hyperlinks to publicly archived datasets analysed or generated during the study. By data we mean the minimal dataset that would be necessary to interpret, replicate and build upon the findings reported in the article. We recognise it is not always possible to share research data publicly, for instance when individual privacy could be compromised, and in such instances data availability should still be stated in the manuscript along with any conditions for access.

Data availability statements can take one of the following forms (or a combination of more than one if required for multiple datasets):

- The datasets generated and/or analysed during the current study are available in the [NAME] repository, [PERSISTENT WEB LINK TO DATASETS]
- The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.
- All data generated or analysed during this study are included in this published article [and its supplementary information files].
- The datasets generated and/or analysed during the current study are not publicly available due [REASON WHY DATA ARE NOT PUBLIC] but are available from the corresponding author on reasonable request.
- Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.
- The data that support the findings of this study are available from [third party name] but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of [third party name].
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More examples of template data availability statements, which include examples of openly available and restricted access datasets, are available here.

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Hao Z, AghaKouchak A, Nakhjiri N, Farahmand A. Global integrated drought monitoring and prediction system (GIDMaPS) data sets. figshare. 2014. http://dx.doi.org/10.6084/m9.figshare.853801

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Authors' contributions

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was a major contributor in writing the manuscript. All authors read and approved the final manuscript."

Acknowledgements

Please acknowledge anyone who contributed towards the article who does not meet the criteria for authorship including anyone who provided professional writing services or materials.

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- Tabular data provided as additional files can be uploaded as an Excel spreadsheet (.xls) or comma separated values (.csv). Please use the standard file extensions.
- Table titles (max 15 words) should be included above the table, and legends (max 300 words) should be included underneath the table.
- Tables should not be embedded as figures or spreadsheet files, but should be formatted using 'Table object' function in your word processing program.
- Color and shading may not be used. Parts of the table can be highlighted using superscript, numbering, lettering, symbols or bold text, the meaning of which should be explained in a table legend.
- Commas should not be used to indicate numerical values.

If you have any questions or are experiencing a problem with tables, please contact the customer service team at info@biomedcentral.com.

APPENDIX 5: Approved Research Protocol

TABLE OF CONTENT

ANNEXURE

GLOSSARY OF TERMS

Cervical cancer screening: It's a method of identifying abnormal cervical cells (precancerous lesions) early to prevent cervical cancer. There are three types of screening tests that are currently available, namely the convention cytology (Pap smear) and liquid based cytology, Human Papillomavirus (HPV) DNA tests for specific high risk types visual inspection of the cervix with acetic acid (VIA). In this study, screening refers to a Pap smear test.

Primary prevention: Primary prevention of cervical cancer entails preventing the acquisition of HPV infection and the development of cellular changes in the cervix. Good general immunity, prevention of smoking, vaccine against HPV, improved nutrition and sexual health all impact on the risk of incident and persistent HPV infection, and the risk to develop precursor lesions on the cervix.

Secondary prevention: Secondary prevention on cervical cancer refers to early diagnosis of cervical precancerous lesions through screening (Pap smear), followed by adequate treatment.

Knowledge: having the correct understanding regarding cervical cancer prevention, diagnosis and treatment options offered.

Perception: A belief or opinion in which cervical cancer and pap smear is regarded, interpreted or understood.

Health education: a process of exchanging information with the aim of raising awareness and increasing knowledge regarding prevention of cervical cancer, resources that are available in Johannesburg and accessing Pap smear services available.

Risk factor: Any attribute, characteristic or exposure of an individual that increases the likelihood of developing cervical cancer.

Coverage: refers to a proportion of women aged 30 and above who screen for cervical cancer at a specific period.

Screening coverage rate: In South Africa, the rate is measured by calculating the annual total number of Pap smears taken in women aged 30 and older as a proportion of all females aged 30 and above in the population, factored for one Pap smear every ten years.

1. INTRODUCTION

Cervical cancer is a major public health concern globally and a significant cause of mortality and morbidity in women (1). It is preventable by screening (2), however prevention through screening can only be realised if high screening coverage is achieved. A high coverage requires tests to be made available and for a high proportion of eligible women to uptake the tests (2). In South Africa (SA), where screening tests are widely available in the public sector, the cervical screening coverage is reportedly lower than the expected targets (3). There are many factors associated with poor uptake of cervical screening, divided into healthcare provider, health system and personal factors (4). There is more research done in SA to explore the health system and health provider factors, but less on personal factors contributing to low Papanicolaou (Pap) smear uptake in the country.

There are various models that are used in research aiming to understand personal factors such as beliefs and attitude related to health behaviours such as uptake of health services in individuals. The Health Belief Model (HBM) is one of the most widely utilized and oldest models where theory is adapted to health problems from behavioural sciences (5). It is a universally recognized theoretical framework of health behaviour (5). This research will use the HBM framework to explore some of the personal factors that may influence the uptake of Pap smear tests by eligible women in Johannesburg, South Africa.

1.1 BACKGROUND

CERVICAL CANCER BURDEN

Cervical cancer is the 4th common cancer amongst women globally, with an estimated 265,672 deaths and 527,624 new cases reported worldwide in 2012, with about 85% of cases occurring in low- to middle income countries (LMICs) (1). In SA, it is ranked the second most cause of cancer amongst women following breast cancer (1), but the most common cancer amongst women aged 15-44 (1). There were about 7,735 new cases and 4,248 deaths estimated in 2012 only (1).

CERVICAL CANCER PREVENTION

Cervical cancer is a preventable disease, and most deaths could be prevented through access to prevention programmes with a potential to reach all women at risk. It can be prevented through early detection and treatment of precancerous lesions (2). Cervical cancer can be prevented primarily by giving vaccine against HPV and secondary prevention through early detection of precancerous of the cervix followed by adequate treatment. The impact of HPV vaccine will not be known for the next two decades and many women are already exposed to HPV, thus in the interim, attention should focus on secondary prevention through screening (performing Pap smears on all eligible women) (3). There is a difference in cervical cancer mortality and incidence rates between high-income countries (HICs), low- and middle-income countries, largely because of differences in access to cervical screening (6). Almost 9 out of 10 cervical cancer deaths globally occurred in LMICs (6). These disparities are related to gender inequalities and culturally determined factors, socio-economic conditions and poor health services and systems that can all hinder access to cervical cancer preventative services

(2). As such, cervical cancer is usually detected late at an advanced stage, when it is often too late for treatment (2). Cervical cancer can be successfully treated at the precancerous stage, and Pap smear can detect precancerous lesions early (2)

CERVICAL CANCER SCREENING COVERAGE

The World Health Organization (WHO) has identified cervical screening coverage as an important component in providing successful prevention (6).Research shows that coverage of screening in LMICs is an average of 19%, and 63% in HICs (7). Cervical cancer detection has an observed impact on the incidence and mortality in most HICs such as Australia, United States and United Kingdom (8).

SOUTH AFRICAN CONTEXT

The South African Department of Health (NDoH) implemented a national screening policy in 2000 which states that every women should have three free Pap smears in her lifetime, done at 10 year intervals from the age of 30 (9). One of the important components of the national program is the monitoring of screening coverage and follow-up of women after a screening test (10). However, research done in South Africa (SA) has shown that cervical cancer incidence rates are significantly higher in HIV infected women than in HIV negative women (11). This has significant implications for screening and so the current practise is Pap smears in HIV positive women of any age from diagnosis and every three years (12). The cervical cancer screening coverage is however not satisfactory (3) despite the policy and wide availability of screening services at primary healthcare facilities. In 2014 to 2015, the overall cervical screening coverage in SA was 54,5% nationally, which was lower than the NDoH coverage target of 60% (3) and also lower that the policy target of 70% coverage by 2010 (9).

Research is needed to understand reasons for the low cervical screening coverage in order to develop appropriate strategies.

1.2 LITERATURE REVIEW

This section reviews literature on factors associated with Pap smear uptake, with a focus on beliefs and perceptions of women. A literature search was done using various search engines and databases. Only articles written in English were reviewed.

FACTORS ASSOCIATED WITH PAP SMEAR UPTAKE

The successful reductions in mortality and morbidity noted in HICs are mainly attributed to an increased uptake of Pap smears, due to greater access to healthcare and a high level of awareness of screening among women (2) . The WHO highlights factors resulting in low screening coverage in most LMICs such as competing healthcare priorities, weak health systems, insufficient financial resources, and limited number of health providers (6). Research that has been done in various settings globally shows that the factors that are associated with the uptake of Pap smears can be divided into healthcare provider, health system and personal factors (13). There has been extensive research done in SA to show the health system and health provider factors contributing to low Pap smear uptake in the country. Identified health system barriers include lack of leadership and good stewardship, poor health system strengthening including monitoring and evaluation, competing health priorities, poor access to screening service, poor service delivery, and insufficient resources (4, 14-16). Kawonga and Fonn (14) further discuss the health provider factors that influence low Pap smear uptake which includes shortage of trained staff to perform smears, rising

demands on a shrinking workforce, attrition of nursing staff from public sector and inadequate attention to health provider's knowledge, skills and attitude.

There is research done in different countries to explore personal factors. Research done in Tanzania identified factors including women's concerns about pain and embarrassment of screening, approval of cervical cancer screening by the husband, women's knowledge of the disease and prevention, level of education, awareness of and distance to screening services and preference regarding the sex of health provider are all associated with uptake of screening (17). A study conducted in Jamaica showed predicators of uptake of Pap smear were parity, being married, age, perception of the consequences of not having a Pap smear, discussing cancer with a health provider and knowing someone with cervical cancer (18). Another study done in Mexico amongst Hispanic women showed screening barriers include fear of cancer, linguistic barriers, fatalistic views on cancer, feeling less at risk to develop cancer, and embarrassment that is culturally based (19). This study showed that factors increasing uptake of screening include community outreach programs by Hispanic lay health workers, materials printed in Spanish and use of culturally-sensitive media (19).

Though this research focuses on personal factors, it is acknowledged that contextual factors in South Africa do influence women's decisions to use screening services. For example, in this context of a high HIV prevalence, fear of stigmatization affects use of screening services (20). Furthermore, gender norms such as men having control over women's decisions about using health services may hamper screening uptake (20).

Research available in South Africa that focuses on personal factors explores mostly women's knowledge, attitude and awareness (21-23) and shows that inadequate awareness and knowledge of cervical cancer and screening amongst women influences Pap smear uptake. For example, in rural South Africa, Hoque et al (23) showed that low uptake of screening is

associated with low level of knowledge on risk factors and prevention of cervical cancer. A qualitative study in SA (24) highlights that some of the personal factors that influence uptake of Pap smears includes emotional /psychological factors such as fear of cancer and unwillingness to undergo a pelvic examination due to previous bad obstetric history, as well as misconceptions that Pap smears are associated with "cleaning of the womb". Less research has been done to explore the influence of women's beliefs regarding cervical cancer and Pap smears on screening uptake. There are theories available that explain the relationships between beliefs and health behaviour. This study applies the health belief model (HBM).

THE HEALTH BELIEF MODEL FOR EXPLORING BELIEFS AND PERCEPTIONS

The HBM is defined as "a psychological health behaviour change model that was developed to predict and explain health-related behaviours, particularly regarding the uptake of health services" (25). The HBM suggests that people's beliefs, perceptions and attitudes about a disease determines their willingness to use preventative interventions such as screening for disease (25). This model was introduced in the 1950s initially by Hochbaum et al, and consisted of four main constructs: susceptibility, barriers, seriousness and benefits (26-28).

Perceived susceptibility describes an individual's own beliefs regarding the likelihood of experiencing a condition or disease that could adversely affect their health (29). Perceived seriousness also known as perceived severity, refers to an individual's interpretation of the degree of severity of a disease (29). Perceived benefits refers to one's beliefs that taking up the prevention service will benefit the individual to prevent disease occurrence (27, 28). Perceived barriers are features that one perceives may hinder or enable the adoption of healthy behaviours, for example, it may be perceived as expensive, inconvenient, painful, upsetting or unpleasant (27, 28). Confidence and general health motivation were added later

to the framework (27, 28). Cues to action, also known as health motivation refers to a cue, or trigger that prompts one's engagement in health-promoting behaviours (30), for example events or information from close others, the media, or health care providers promoting engagement in health-related behaviours. Confidence also known as self-efficacy refers to perceived confidence in one's ability to adopt behaviour that leads to a rise in the desired favourable outcome (27, 28, 31).

The HBM however has limitations. It is a cognitively based model and attempts to predict health-related behaviours by accounting for individual differences in beliefs and attitudes. However, it does not account for other factors that influence health behaviours such as habitual health-related behaviours, individuals engage in some health-related behaviour for reasons unrelated to health, emotions and environmental factors outside an individual's control that may prevent engagement in desired behaviours (32). Furthermore, The theoretical constructs are broadly defined, and so operationalization of the constructs may be context-specific and not comparable across studies (5, 32). Finally, there is no clear defined relationship between the different constructs, leading to a weak predictive power in most areas of health related behaviour (32).

Research applying the HBM has identified various other inter-personal factors that may interact with or modify the relationship between the HBM constructs and health-seeking behaviour (30). These modifying factors include age, socio-economic status and general knowledge about cervical cancer and Pap smear, which are all derived from related literature.

The HBM has been used to understand beliefs regarding numerous behaviours such as Tuberculosis or cancer screening uptake and risky sexual behaviour. For example, Champion developed HBM instruments in relation to breast cancer screening behaviour (27, 33, 34). In numerous studies, Champion's Health Belief Model (CHBM) scales and Champion's Self-

efficacy (CSE) scales have been translated, adapted and found to be reliable and valid for use in other cultures and countries including Sub-Saharan Africa (35-38). The CHBM scale measures all constructs, except self-efficacy, while CSE measures only the self-efficacy construct. Numerous studies have explored the association between HBM constructs and cancer screening using the CHBM and CSE scales (29, 34, 39-41). A few studies have explored the association between HBM constructs and cervical cancer screening (40-42), but none have applied this model in the South African context. (See Annexure A for a diagram depicting the HBM)

1.3 PROBLEM STATEMENT

The Johannesburg Metropolitan Health District is one of the wealthiest districts in South Africa, and offers free cervical screening services in its primary healthcare facilities. The screening coverage (measured as percentage of eligible women screened) in the district was 45,7% during 2014 to 2015 (3). This indicator remains inappropriately low when compared with the district (55%), provincial (55%) and national (60%) targets. The low coverage also highlights that improvement strategies are urgently needed to increase Pap smear uptake in the Johannesburg Metropolitan Health District (referred to as Johannesburg District from here on). The low cervical screening coverage further raises the question why the proportion of women who had a Pap smear remains low despite the service being offered at a primary healthcare level. This research explores the role of women's beliefs and perceptions regarding cervical cancer and Pap smear tests in the uptake of Pap smears.

1.4 JUSTIFICATION FOR RESEARCH

There has been no research done in the Johannesburg District to understand beliefs and perceptions that influence women's uptake of cervical screening, and to determine the role of other factors such as women's knowledge regarding cervical cancer and Pap smears. The information generated by this research will be crucial and could assist programme managers, health providers and health promoters in this district in providing appropriate and focused client-centred behaviour change interventions that can subsequently improve cervical screening uptake.

1.5 AIMS AND OBJECTIVES

1.5.1 AIM

To apply the Health Belief Model (HBM) to describe the beliefs and perceptions regarding cervical cancer and screening of women attending primary healthcare clinics in the Johannesburg District in 2017 and to determine the association of these beliefs with the uptake of pap smears.

1.5.2 STUDY OBJECTIVES

1. To determine the proportion of women attending clinics for any service in the Johannesburg District over a 4 month period who have ever had a Pap smear in their lifetime.
2. To describe the socio-demographic characteristics and knowledge regarding cervical cancer and Pap smears amongst women attending clinics for any service in the Johannesburg District over a 4 month period.
3. To describe the beliefs and perceptions (six HBM constructs) regarding cervical cancer and Pap smears amongst women attending clinics for any service in the Johannesburg District over a 4 month period.

4. To determine the association between beliefs and perceptions regarding cervical cancer and Pap smears and the uptake of cervical cancer screening amongst women attending clinics for any service in the Johannesburg District over a 4 month period, while controlling for socio-demographics characteristics and knowledge of cervical cancer and screening.

2. METHODOLOGY

2.1 STUDY DESIGN

This is a cross-sectional study with an analytical component. The choice of study design was based on feasibility and resource availability. The analytical component allows one to measure the association between the exposure (women's beliefs and perceptions) and the outcome (uptake of Pap smears) at one point in time.

2.2 STUDY SETTING

The study will take place in the Johannesburg District PHC clinics. The site was purposively selected because the researcher is familiar with the health service organisation in the district, and has offered public health services there as a Public Health Medicine registrar, and the proximity of the site. The district is divided into seven health sub-districts (or regions) named from A to G. Within sub-districts, the health facilities at PHC level include: clinics, community healthcare centres (CHCs) and district hospitals. Clinics and CHCs are administered by either local or provincial government. Only clinics will be selected for this study to ensure selection of the same facility type, because not all sub-districts have a CHC or District hospital.

2.3 STUDY POPULATION

The study population will be women aged 30 and above, presenting to PHC clinics for any service, in the Johannesburg District in 2017. The age restriction is consistent with the age as stated in the national cervical screening policy.

2.4 SAMPLING

Eligibility criteria: Any woman of age 30 and above, attending the clinic on the day of the study for any health service (including Pap smear) during a selected 3 month period.

In each sub-district, two clinics will be selected through simple random sampling by sampling with probability proportion to size, where the measure of size is the clinic weekly headcounts. The sample size of study participants was calculated using STATA statistical software version 13.0 (43)with assistance from a statistician. Suppose we take 20 women per clinic, then the overall sample size is 280. The sample size calculation took into consideration the effect of clustering of women within clinics. The effect of clustering is measured by the design effect (deff). We assumed there is moderate clustering effect, and so use a deff of 1.5. A deff of 1.5 is equivalent to an effective sample size of 190 women. The proportion of participants who have had a Pap smear in their lifetime can be estimated with a precision of ±7.3% for a deff of 1.5. To detect whether the proportion of women who have had a Pap smear differs between women who have low HBM scores (below the median) than those with high HBM scores (above the median), we assume the following:

a) Among women with low HBM scores, 50% will have had a Pap smear done

b) Among women with high HBM scores, this proportion will increase to 70% (absolute increase of 20%)

If moderate clustering effect (deff of 1.5), effective sample size of 190 (95 women per group) will have 84% power to detect the assumed differences as statistically significant at the 5%

level. Thus the study with a sample size of 280 will have sufficient power to detect a significant difference in the uptake of Pap smears between the two groups of women. (See Annexure B for detailed sample size considerations).

Sampling methods will be at two levels. The first level will be the selection of the facilities and the second level will be the selection of participants.

- **Selection of facilities:**

Study clinics will be selected through simple random sampling. Two clinics per Sub-district will be selected. Sub-district A, B, C, D, E; F and G have 12, 7, 7, 31, 10, 14 and 21 clinics respectively.

- **Selection of the participants**

The participants at the facilities will be selected using systematic sampling methods. In each clinic a sample of 20 eligible women will be selected. During data collection, each clinic will be visited daily for five days and the sample proportion of 20 women will be spread across five days. On each day, the first participant will be sampled from a random starting point in the queue, and the nth woman in the queue will be approached systematically. In cases where the approached woman is not an eligible participant, the next eligible woman on the queue will be approached.

2.5 DATA COLLECTION AND VARIABLES

Primary data will be collected using an interviewer-administered structured questionnaire. Participants' responses will be captured onto REDCap software (44). Data will be collected over a 3 month period from each sampled clinic sequentially starting from one clinic, and go there every day until the required number of participants have been interviewed, then move to the next clinic. The interview will be done in a private room at the clinic, following permission from the facility manager. Participants will be taken off the queue and return back

to their position in the queue after the interview. The researcher will have one research assistant who has experience in research and also fluent in English and other local languages to assist with the interviews.

The questionnaire will be compiled using the HBM as a framework to measure three main categories of variables: exposure (beliefs and perceptions), outcome (whether one has ever had a Pap smear done) and possible confounder variables (socio-demographic characteristics and knowledge). The exposure variables will be measured using the adapted and modified CHBM and CSE scales, both tools are validated to ensure internal consistency, content and construct validity. The adapted CHBM scale for cervical cancer screening has five subscales with 35 items and a Cronbach's alpha reliability coefficients ranging from 0.62 to 0.86 (29). The adapted CSE scale with a Cronbach's alpha correlation coefficient of 0.87 will be used to measure the self-efficacy subscale which contains 10 items (39). The items in each subscale are measured using five-point Likert-type response choices ranging from strongly disagree (1 point) to strongly agree (5 points). The outcome variable will be measured by asking each woman whether she has ever had a Pap smear done. The other explanatory variables (possible confounders) include: age, marital status, highest level of education obtained, employment status and general knowledge about cervical cancer and Pap smears, which are all derived from related literature. (See annexure C for data collection tool - questionnaire) Survey link: https://redcap.core.wits.ac.za/redcap/surveys/?s=WFWMELRCCD

2.6 PILOT TEST

The pilot study will be done a month prior to commencing the study to refine and improve the questionnaire and the quality of the interviews, to address any logistical challenges and to assess the cost and timeliness of the interviews. The pilot test will be at a randomly selected clinic in the Johannesburg District which is not part of the selected sample, and ten participants will be interviewed. Final changes to the tool will be made based on the pilot

findings. The research assistant will be trained before and during the pilot study to ensure that the questionnaire is well understood and to standardize the data collection process.

2.7 DATA MANAGEMENT AND ANALYSIS

The database from REDCap software will be exported to STATA statistical software version 13.0 (43) for data analysis. Descriptive statistics will be used to describe the data (means/median, SD/range for numerical and proportions for categorical variables). Items for each HMB subscale and for knowledge will be summed and expressed as total scores (numerical variables) for each subscale. The skewness test will be done to determine if scores are normally distributed, then means and standard deviations calculated, otherwise median and interquartile ranges will be used. Bivariate analysis using the student t-test will be used to determine if there are differences in mean scores for each HBM subscale between women who have had a Pap smear and those who have not, and a reported p value < 0.05 will be regarded as statistically significant. A multivariate analysis will be done using multiple logistic regression to determine whether there is an association between the individual HBM subscales and the uptake of Pap smears. The measure of association to be used is an odds ratio (both crude and adjusted) and reports 95% confidence intervals. (See annexure D for data analysis plan)

2.8 LIMITATIONS AND BIAS

The study is a cross-sectional design, it cannot determine temporality (whether beliefs and perceptions preceded uptake of screening). The study will be conducted in clinics, thus excluding women in the community who are not attending clinics and introducing a potential selection bias. HIV/AIDS as a context issue in South Africa is not addressed in the existing HBM scales that I am applying in my research. The participant's age is also a potential selection bias, because women who are infected with HIV/AIDS are screened for cervical

cancer more regularly earlier than age 30. The questionnaire is interviewer-administered, which could result in socially-desirable responses considering the interviewer's presence (information bias). However, a self-administered questionnaire could result in incomplete responses and might be difficult for respondents who are unable to read or write in English. The questionnaire is in English, so the interviewers may have different interpretation to responses given in other languages.

3. ETHICAL CONSIDERATIONS

This protocol will be submitted to the medical Wits Human Research Ethics Committee and the Johannesburg District Heath Research Committee for approval. No personal identifying information will be collected (no names, only study ID), and the collected data will be confidential for use in this research only. Only the researcher and the research supervisor will have access to the REDCap database which will be stored on the researcher's laptop in a password-protected file. The database will be kept for five years or as long as required by the ethics committee. All participants will be given a full explanation of what the study entails and the purpose in simple English, and clarifications in a local language where possible. Participants will be reassured that choosing to or not to participate in the study will not have an effect in the service they will receive at the clinic. The study poses no harm to the participants and no incentives will be offered for participating. (See Annexure E for participant information sheet and consent form)

4. PROJECT MANAGEMENT

4.1 WORK PLAN

ACTIVITY	Nov'16	Dec	Jan'17	Feb	Mar	Apr	May	Jun	July	Aug	Sept	Oct
Protocol Submission to Postgrad committee												
Protocol Submission to Ethics Committee												
Submission to District Research Committee												
Data collection and capturing												
Data analysis	October to December 2017											
Report writing	January to March 2018- For report submission first semester of 2018											

4.2 BUDGET

Activity	**Estimated Expenditure**	**Total cost**
Printing consent forms and information sheets	R0.40 X 580	R232
Laptop/tablet	R5000	R 5000 (Self-funding)
Employing an extra fieldworker and training	R3000 monthly X 3 Months	R9000
Travelling to cost (petrol to drive to facilities)	R100 per return trip X 28 days	R2800
Total cost		R12032

Application for funding will be submitted to the Wits Faculty of Health Sciences, Cancer Association of South Africa (CANSA) and the Discovery Foundation following ethical clearance of the study.

4.3 RESULT DISSEMINATION PLAN

This research is conducted for a Wits MMed qualification. The study results will be presented as a report to the City of Johannesburg District managers meeting which consists of the sub-district managers and the programme managers and the different stakeholders supporting the district. The results will also be shared with the facility managers of all the clinics that were part of the study. The results will also be presented at conferences and possibly in a scientific publication.

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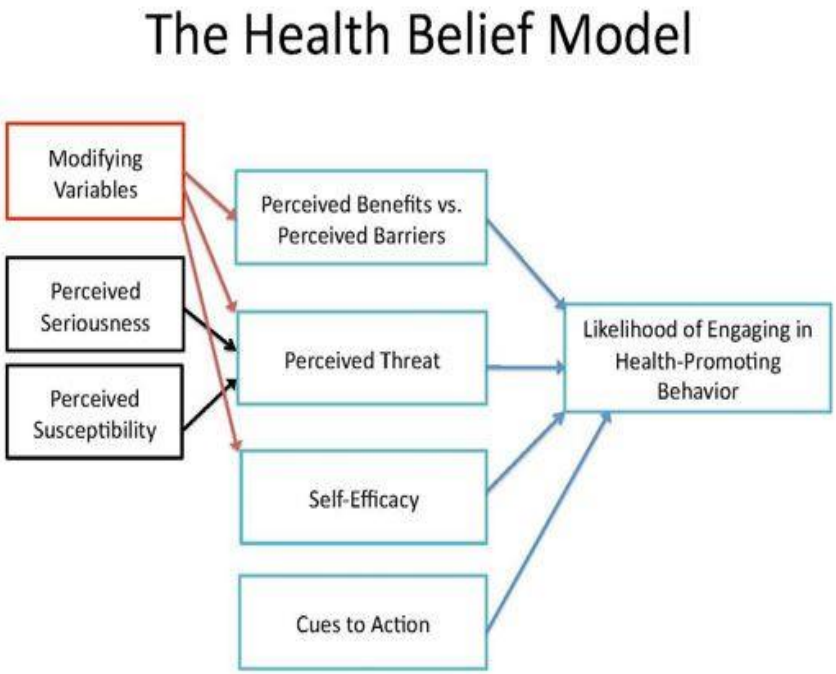
APPENDIX A: Health belief model diagram

ANNEXURE A- Health Belief Model diagram



Concept	Definition	Application
Perceived Susceptibility	One's opinion of chances of getting a condition	Define population(s) at risk, risk levels; personalize risk based on a person's features or behavior; heighten perceived susceptibility if too low.
Perceived Severity	One's opinion of how serious a condition is and what its consequences are	Specify consequences of the risk and the condition
Perceived Benefits	One's belief in the efficacy of the advised action to reduce risk or seriousness of impact	Define action to take; how, where, when; clarify the positive effects to be expected.
Perceived Barriers	One's opinion of the tangible and psychological costs of the advised action	Identify and reduce barriers through reassurance, incentives, assistance.
Cues to Action	Strategies to activate "readiness"	Provide how-to information, promote awareness, reminders.
Self-Efficacy	Confidence in one's ability to take action	Provide training, guidance in performing action.

Source: Google images, retrieved (28/06/2016) https://www.google.co.za/images

APPENDIX B: Sample size considerations

ANNEXURE B- Sample size considerations

In each sub-district a sample of two clinics will be selected with probability proportional size where the measure of size is the clinic weekly headcounts. In each clinic a systematic sample of 20 eligible women will be selected. Suppose we take 20 women per clinic, then the overall sample size is 280. However, one has to take into consideration the clustering of women within clinics. This effect is measured by the deff (design effect). With a deff of 1.5, this is equivalent to an effective sample size of about 190. A deff of 2 is equivalent to an effective sample size of 140.

1. The proportion of participants who have had Pap smears can be estimated with the following precision:
   a) If no clustering, precision will be ±6%
   b) For a deff of 1.5, precision will be ±7.3%
   c) For a deff of 2, precision will be ±8.6%

Thus we will be able to estimate the proportion of women who have had a Pap smear with sufficient precision.

2. To detect whether the proportion differs between women with negative beliefs regarding cervical screening and those with positive beliefs, we assume the following:
   a) Among women with negative beliefs, 40% will have had a Pap smear done in their lifetime
   b) Among women with posItive beliefs, this proportion will increase to 70% (absolute increase of 30%)

3. Approximately equal numbers of women will have negative and positive beliefs regarding cervical cancer and screening
   a) If no clustering, then the total sample size of 280 (140 negative beliefs and 140 positive beliefs) will have 95% power to detect the assumed difference (40% vs 70%) as statistically significant at the 5% level.
   b) If moderate clustering effect (deff = 1.5), then effective sample of 190 (95 per group) will have 84% power to detect as significant.
   c) If strong clustering effect (deff = 2), then effective sample size of 140 (70 per group) will have 72% power.

So the study will have sufficient power to detect a significant difference in the uptake of screening amongst the two groups, provided the clustering effects are moderate. Note that in practice, health belief model scales for beliefs and perceptions regarding cervical screening will be used, which will make it easier to detect a relationship between uptake of Pap smears and beliefs than to one of the two groups namely negative beliefs regarding Pap smears or positive beliefs regarding Pap smears.

SUB-DISTRICT	FACILITY RANDOMLY SELECTED	NUMBER OF PARTICIPANTS TO BE RECRUITED	Adress	Suburb	Tel number
A	Diepsloot South Clinic	20	STAND 5355, DIEPSLOOT X5	DIEPSLOOT EXT 5	011 464 7182
A	Halfway house clinic	20	C/O MARKET & WEST STREET	HALFWAY HOUSE	0118053112
B	Randburg Clinic	20	C/O HENDRIK VERWOERD DRIVE AND SELKIRK AVENUE	RANDBURG	011 686-2144
B	Claremont Clinic	20	96 PRINCESS STREET	CLAREMONT	011 477-9936
C	Helderkruin Clinic	20	PHEASANT STREET	HELDERKRUIN	011 764-5403
C	Zandspruit Clinic	20	ADMINISTRATION HOUSE, DF MALAN DRIVE	ZANDSPRUIT	011 794-2210
D	Jabavu Clinic	20	3123 TUMAHOLE STREET	WHITE CITY JABAVU	011 984-4422
D	Protea Glen clinic	20			0824679385
E	Wendywood clinic	20	C/O WENDY AND BOWLING STREET	WENDYWOOD	011 802 1095
E	Thoko Mngoma Clinic	20	C/O 6TH AVENUE AND 3RD STREETS	MARLBORO	011 448-1402
F	Glenanda clinic	20	C/O SURMON & VOSTER	GLENANDA	0114323546
F	Crown Gardens Clinic	20	C/O ULSTER MOURNE STREET, RECREATION CENTRE	CROWN GARDENS	011 680-4258
G	Orange Farm Ext7 Clinic	20	12481 EXT7	ORANGE FARM	011 850 3527 Sr Nomafu
G	Lenasia South Civic Center Clinic	20	C/O WELLINGTON AND WIMBLEDON STREETS	LENASIA EXT 4	011 855-1617- sister Lindi/any sister available
TOTAL	280				

APPENDIX C: Data collection tool - Questionnaire

https://redcap.core.wits.ac.za/redcap/surveys/?s=WFWMELRCCD

APPENDIX D: Data analysis plan

ANNEXURE D: Table for Data Analysis Plan

OBJECTIVE	VARIABLES	TYPE OF VARIABLE	ANALYSIS
1. To determine the proportion of women attending clinics for any services in the Johannesburg District in 2017 who have ever had a pap smear in their lifetime.	Outcome variable: • Pap smear uptake (yes/no)	• Categorical	a) Descriptive analysis-Proportions
2. To determine the demographic characteristics and knowledge regarding cervical cancer.	Possible Confounder variables: • Age • Education level • Marital status • Employment • Knowledge of screening	• Numerical • Categorical • Categorical • Categorical • Numerical (score)	Descriptive analysis: a) Mean/median & SD/IQR (age and knowledge) b) Proportions (categorical variables)
3. To describe the beliefs and perceptions (six HBM constructs) regarding cervical cancer and Pap smears	Exposure variables: • Susceptibility • Severity • Benefits • Barriers • Cues to action • Self-efficacy	• All numerical (scores)	a) Descriptive analysis-Mean/median &SD/IQR
4. To determine the association between beliefs and perceptions regarding cervical cancer and Pap smears and the uptake of cervical cancer screening, while controlling for demographics characteristics and knowledge	a) For bivariate analysis- student t-test to determine if there are differences in mean scores of the HBM sub-scales between women who have had a pap smear and those who have not. A p-value of <0.05 will be regarded as statistically significant. b) For multivariate analysis – multiple logistic regression analysis to determine association between the HBM sub-scales and uptake of screening. Measure of association: odds ratio (both crude and adjusted odds ratio) and 95% confidence intervals.		

APPENDIX E: Participant information sheet and Consent form

ANNEXURE E- Information sheet and consent form

PARTICIPANT INFORMATION SHEET FOR WOMEN IN THE JOHANNESBURG METROPOLITAN HEALTH DISTRICT

Study title: Beliefs and perceptions regarding cervical cancer and screening associated with uptake of Pap smears in Johannesburg.

Greeting: Good day, my name is Dr Mantwa Chisale Mabotja; I am a Public Health Medicine registrar at University of the Witwatersrand employed by the Gauteng Department of Health. I would like to invite you to consider participating in a research study. Research is a process to learn the answer to a question. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Do not hesitate to ask if you have any questions

Introduction: I am carrying out a research study. In my research I want to learn about women's beliefs and what they think about cervical cancer and the prevention of cervical cancer with Pap smears. I will interview women of age 30 and above who are attending this clinic and the other clinics in Johannesburg. The results will be used to help the health authorities in this district to develop interventions to improve the prevention of cervical cancer.

Invitation to participate: We are asking women aged 30 and above to participate in the research study. We are selecting individuals to participate, and you have been randomly selected to take part in an interview.

What is involved in the study – If you decide to take part, the interview will take approximately 30 minutes to complete. I will use a questionnaire to ask you some questions and I will write down your answers on the questionnaire.

Risks: There are no risks involved in taking part in this study. I will not use your names or personal identifying information in the research.

Benefits: All participants will be given pertinent information on the study while involved in the project. After the study is finished, the results will be made available to clinic managers and district managers in a form of a report.

Participation is voluntary: It is up to you to decide whether or not to take part, taking part is voluntary. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Refusal to participate will involve no penalty or loss of services in the clinic.

Reimbursements: There will be no form of reimbursement for the participants.

Confidentiality: Efforts will be made to keep personal information confidential. All the information that is collected will be kept strictly confidential. No identifying data (name, ID number, phone number, address) will be collected. All the information collected in this interview, will be stored in the REDCap database, which is a secure and only accessible to the researcher. The researcher will be able to download the information from the database and analyse it in new ways.

Thank you for taking the time to read this information sheet.

Contact details of researcher – for further information contact:

Dr Mantwa Chisale Mabotja

Department of Public Health Medicine (Wits)

Cell phone: 0736542355 or Email: mc.chisale@gmail.com

Contact details of REC administrator and chair – for reporting of complaints / problems please contact:

The secretary, Wits Human Research Ethics Committee on (011) 717 1234 or at their physical address: Third Floor, Philip Tobias Building, Jubilee Street, Parktown.

INFORMED CONSENT:

Study title: Beliefs and perceptions regarding cervical cancer and screening associated with uptake of Pap smears in Johannesburg.

- I hereby confirm that I have been informed by the study doctor, Dr Mantwa Chisale Mabotja, about the purpose, conduct, benefits and risks of this research study entitled beliefs and perceptions regarding cervical cancer and screening and associated uptake of Pap smears amongst women in Johannesburg.
- I have also received, read and understood the above written information sheet regarding the research study.
- I am aware that the results of the study, including personal details regarding my age will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by Dr Mantwa Chisale Mabotja or on their behalf.
- I may, at any stage, without reasons, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and declare myself prepared to participate in the study.

PARTICIPANT:

Signature / Mark or Thumbprint **Date and Time**

I, Dr Mantwa Chisale Mabotja, herewith confirm that the above participant has been fully informed about the nature, conduct and purpose of the above study.

STUDY DOCTOR:

Printed Name **Signature** **Date and Time**

TRANSLATOR / OTHER PERSON EXPLAINING INFORMED CONSENT

Printed Name **Signature** **Date and Time**

Source: Version Control No: HREC version August 2011

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