

# HIV, Human Papillomavirus and Related Pre-Cancerous and Cancerous Lesions in Men Who Have Sex with Men in the area North West of Pretoria

MSM Study Progress Report  
Fulufhelo Matshonyonge

Supervisor: <sup>1</sup>Dr L Lebelo  
Co-supervisor: <sup>1</sup>Prof SG Selabe



<sup>1</sup>HHRU, Department of Virology, School of Pathology and Pre-clinical Sciences, Faculty of Health Sciences, Sefako Makgatho Health Sciences University, MEDUNSA, Pretoria, South Africa

# Background of the study

- HPV is one of the most common causes of sexually transmitted disease in both men and women around the world
- HPV infect basal epithelial cells of the skin or inner-lining tissues
- HPV infection may results in benign lesions and pre-cancerous lesions which may progress to cancerous lesions
- Several co-factors have been reported to contribute to disease progression

- Based on the literature, Hr HPV types have been regularly detected in 16% to 33% in oral cavity
- Hr HPV prevalence is reported at 27.9 percent for HIV negative MSM and 38.5 percent for HIV positive MSM
- Data on the prevalence of HPV types in MSM from South Africa especially in the area, North West of Pretoria is limited
- Studies internationally show that HPV infection amongst MSM is much higher than in men sleeping with women
- There is lack of consistence in standardizing the prevalence of HPV given that there are such varying populations and methods of sampling for the HPV specimens resulting in some studies reporting 25 to 44 times higher rates in MSM

# Problem statement

- The healthcare needs of MSM have been under-researched and under-resourced in South Africa
- Despite evidence of increased risk of HIV and HPV infection and HPV-related malignancies in the MSM population
- There is evidence of increased risk of HPV infection and HPV-related malignancies in the MSM population
- Data is needed to better understand the epidemiology of HPV infection; HPV related benign, precancerous and cancerous lesions and factors associated
- Establishing prevention strategies and vaccine implementation among MSM, as well as adding significant information to the body of knowledge thus documenting baseline data that may be significant to inform future intervention strategies.

➤ **Research aim:**

- To determine the prevalence HPV types and factors associated with HPV related precancerous and cancerous lesions in the MSM population residing in the North Western area of Pretoria.

# Research questions

- What is the prevalence of HPV infection in the ano-rectal and oral areas of the MSM population in the North West area of Pretoria
- What is the prevalence of ano-rectal and oropharyngeal HPV associated lesions in MSM population in the North West area of Pretoria
- Which HPV types are associated with ano-rectal and oropharyngeal precancerous and cancerous lesions in MSM population in the North West area of Pretoria
- What is the concordance of HPV types in the oral cavity and ano-rectal region
- What are the factors associated with acquisition of HPV infection in MSM population in the North West area of Pretoria

# Specific objectives

- To determine the prevalence of HPV types circulating amongst MSM population in the North West area of Pretoria.
- To determine the prevalence of HPV infection in the MSM population in the North West area of Pretoria.
- To determine the prevalence of ano-rectal HPV associated lesions in MSM population in the North West area of Pretoria.
- To determine the HPV types associated with ano-rectal precancerous and cancerous in MSM population in the North West area of Pretoria.
- To investigate the factors associated with acquisition of HPV infection in MSM population in the North West area of Pretoria.

## Hypothesis to be tested:

- There is a high prevalence of HPV infection in the ano-rectal and oropharyngeal mucosa and HPV-related precancerous and cancerous lesions in a group of MSM residing in the North Western area of Pretoria.



# Research strategy and methods

## ➤ Study design:

- This study is cross sectional descriptive and quantitative. A follow on qualitative study will be submitted in due course to complete the socio-behavioural inquiry into the sexual practices and choices of MSM.

## ➤ Study setting:

- The study is being conducted at Medunsa Clinical Research Unit (MeCRU) in the Sefako Makgatho Health Sciences University which is situated in the North West of Pretoria
- The study involve finding the MSM in the communities and recruiting them to visit MeCRU for participation in the study
- The site formed partnership with South African gay rights organisation for guidance, consultation and support as we implement this research project

# Study Population and sample size:

- The total population of the catchment area is 1.2 million people (Census 2011)
- Using EPI info 7 a sample size of 123 participants at a power of 80% with a 5% confidence limit was calculated at an expected frequency of 25%.
- A sample size of 200 is presumed
- The MSM are being recruited to come to the research unit and participate in the study
- The study include all adult men who are 18 years and older
- Thus far we have managed to collect 88 Samples

- **Inclusion criteria:**
- Any men self-declaring to be MSM; willingness to sign an informed consent to participate in the study; willingness to undergo clinical examination amongst other investigations
- The individuals should live in the area North West of Pretoria
- **Exclusion criteria:**
- Individuals who do not provide full demographical information and sign consent forms will be excluded in the study

# Study Procedures

- **Data collection:**
- Study procedures are being conducted by the MeCRU staff as per their required discipline
- At the research unit, participant information leaflets will be given to potential participants on arrival followed by informed consent processes with individuals as described in the main study
- All participants will be asked to sign a sample storage consent form as part of their consent
- Should anyone not wish to have their samples stored they shall be told that their samples will be destroyed after testing for this study and the consent form will indicate as such

- After signing the informed consent form at visit 1, the following procedures will be performed:
- Documentation of demographic data
- Completion of a structured participant questionnaire on sexual behaviour/activities
- Bloods for laboratory testing: HIV diversity testing, Hepatitis (A, B), HSV 2 and Syphilis serology.
- For those found to be HIV positive from the rapid test, blood will also be taken for CD4 count and viral diversity studies.
- Medical history and physical examination including specific genital, anal and oropharyngeal examinations


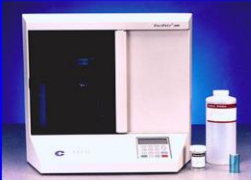
- Two rectal swabs for organisms (Neisseria gonorrhoea, Chlamydia trachomatis, Mycoplasma genitalium, HPV) and cytology (rectal smear).
- Urethral and throat swabs for Neisseria gonorrhoea Chlamydia trachomatis, and Mycoplasma genitalium
- Mouth wash specimen with 5 ml of phosphate buffer saline for HPV studies
- Ano-rectal swab where Ano-rectal brush is insert 2 cm into ano-rectal canal
- Risk reduction counselling
- In the event a biopsy is needed the participants are being referred to the appropriate specialty at the DGM.
- Results are followed up and requested from the hospital for documentation as an output of the study.
- We then follow up participants after 2 months (follow –up visit) to disseminate the results

# Laboratory methods



**Liquid Based Cytology**

- THINPREP™



# Laboratory Progress

	HIV (n=61)		HSV (n=16)		LBC (n=82)		Abbott rtPCR (n=61)		Linear Array (n=3)	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Oral	45	17	4	12	N/A	N/A	2	59		
Rectal									3	0

- Out of the 88 samples collected thus far:
- Cytology was performed on 82 Anorectal and 82 Oral wash samples (164 samples) ➡ Screening of the samples in progress
- Nucleic Acid extraction ➡ 61 Oral wash Samples and 60 Ano-rectal samples
- 73.77 % HIV Pos and only 27.87 % HIV Neg
- 25 % HSV Pos and 75 % HSV Neg
- Only 3.28 % were Pos for HrHPV



# Laboratory results progress

Age Group	18-25 Years	26-35 Years	36-45 Years
Oral Wash Samples	n=18	n=33	n=9
HPV Pos	0/18 (0.0 %)	2/33 (6.0 %)	0/9 (0.0 %)
HPV Neg	18 (100 %)	31/33 (94.0 %)	9/9 (100 %)
Total	18	33	9

Age Group	18-25 Years	26-35 Years	36-45 Years
	N=26	N=38	N=9
HIV Pos	18/26 (69.2 %)	31/38 (81.6 %)	7/9 (77.8 %)
HIV Neg	8/ 26 (30.8 %)	7/38 (18.4 %)	2/9 (22.2 %)
Total	26	38	9

# Data Analysis:

- Currently we are still busy entering data into Microsoft Excel spreadsheets (2013) for those samples already tested
- Once the required sample size have been reached ,then data will be imported into SPSS version 23 and Epi. Info version 3.5.4 for statistical analysis
- Various graphs will be computed and phylogenetic trees computed whilst other data will be described through tables and descriptive statistics

# Ethical consideration

- This study form part of the ongoing overarching study encompassing various departments within the Sefako Makgatho Health Sciences University
- The main study was approved under the SMUREC/P/138/2015 number
- Approval of the sub-studies was also sort from the School of Pathology and Pre-clinical Sciences Research Ethics Committee (SREC) as well as from the Sefako Makgatho Health Sciences University Research Ethics Committee (SMU-REC)
- All participants willing to come to the MeCRU site in response to the recruitment invitation cards given to them will be requested to sign an informed consent for participation in the study
- Patient Identities will be delinked from the samples and only assigned lab descriptions will be used



## Bias:

- MSM include all men who have sex with men whether they self-identify as gay or bisexual
- This may result in the exclusion of a number of potential men who actually have sex with man and are afraid to participate in the study
- This bias is acknowledged and attempts will be made to minimise it by allowing referral by others in the sexual circle, and the word of mouth/snow bawling effect

# Reliability

- Qualitative data is also being collected according to GCP guidelines and the laboratory procedures are according to laboratory SOPs and GCLP standards
- Commercial tests such as Aptima HPV assay on Panther System and Hr HPV assay on Abbott system have been validated
- The assays and systems are calibrated and negative and positive controls are always included in every test run

# Budget

Item	Amount
<b>Collection for Ano-rectal swab and Ora wash</b>	
Combi Brush for Ano-rectal Swabs	R1 750.00
Preservcyt solution kit	R5 375.00
ThinPrep Microscope Slide Kit	R1 915.00
Gyn Filter kit (Clear)	R32 950.00
Universal bottle for mouth wash and Saline	R41 999.60
<b>Extraction and HPV testing in both Oral and Ano-rectal samples</b>	
HPV HR detection kit Panther	R100 000
Abbott extraction kits	R30 000
Bio-Plex Pro™ Flat Bottom Plates	R 23 674.00
Bio-Plex MAGPIX Drive Fluid	R 1 909.00
Bio Plex MAGPIX Calibration Kit	R 11 026.00
Bio-Plex MAGPIX Verification Kit	R 12 355.00
Bio-Plex® Wash Buffer	R 1 242.00
Aptima specimen transfer kit	R2 226.00
Sample collection consumables	R5 000.00
<b>Other tests kits</b>	
Blood tubes: 5 ml PPT tube, 8.5 ml SST, 2ml EDTA	R132 006.47
Universal bottle for mouth wash	
HIV Rapid test kits (Determine alere & Unigold rapid HIV test)	
Immutrep test kit for RPR and TPHA	
Clinic consumables	R 77 993.53
<b>Total</b>	<b>R 559 415.00</b>

# Time lines

	2016												2017											
	January	February	March	April	May	June	July	August	September	October	November	December	January	February	March	April	May	June	July	August	September	October	November	December
Proposal development																								
Funding Application																								
Submission to SRC																								
Submission to SMUREC																								
Community mobilization																								
Start Recruitment																								
Sample collection																								
Data collection																								
Commence Lab work																								
Data analysis																								
Dissertation write-up																								
stakeholders and partners Consultations																								
Article writing																								
Submission of articles																								





Thank you for your attention!  
Questions and comments  
are welcome!



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