

Prevalence and Types of Rectal Douches used for Anal Intercourse: Results from an International Survey

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Introduction

- Concerns about rectal products used for Anal Intercourse (AI)
 - ▣ Potential for rectal products used for AI to facilitate transmission of STIs/HIV
 - ▣ Evidence for the potential increased risk of STIs/HIV based on
 - *In vitro* and animal studies of commercial lubricants
 - Rectal application of N9 associated with rectal tissue damage
 - Epidemiologic study

Rectal douching/enemas may affect rectal epithelium

- Colonic irritation, colitis, and rectal epithelial damage noted with commonly used enemas
- Epidemiologic studies have noted an association with rectal douching and
 - ▣ HIV, LGV, and HBV
 - ▣ Limited data on other STIs

Prevalence of rectal douching

- Rectal douching with AI is a common practice
- Findings from a survey in the US
 - ▣ 44-53% of men reported rectal douching with last AI
 - ▣ 64% in the past 6 months
- Findings from a survey in Peru
 - ▣ 27% reported history of rectal douching
- However, little known about content and type of rectal douches used

Study objectives

- Examine specific content and types of products used for rectal douching
- Examine practices and factors associated with rectal douching

Methods

- Internet based survey on rectal douching practices including products used
- Respondents were eligible to complete the survey if
 - Men and women
 - 18 years of age
 - Reported receptive AI in the past 3 months
 - Douchers and non-douchers
- Respondents recruited through

Data collection

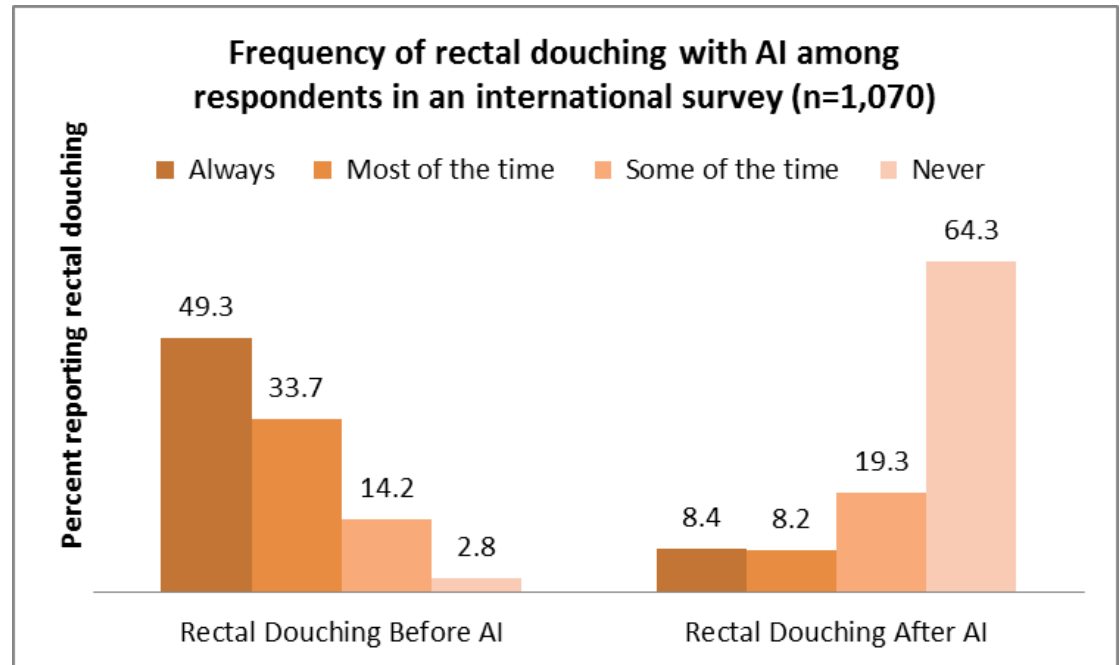
- Survey conducted from August 2011 – May 2012
- Self-administered, 10-15 minute web-based survey offered in English, French, German, Mandarin, Portuguese, Russian, Spanish, and Thai
- Information collected
 - ▣ Demographics
 - ▣ Sexual behaviors
 - ▣ History of STIs
 - ▣ Practices surrounding AI, including douching

Results

- 2,436 respondents attempted the survey
 - ▣ 1,725 (71%) eligible and included in the analysis
- Respondents represented 112 countries
 - ▣ 55% N. America; 22% Europe; 14% Latin America; 5% Asia; 3% Africa
- Majority were male (88%) and < 40 years of age (mean age 36.5 years, range: 18-87 years)

Prevalence of rectal douching

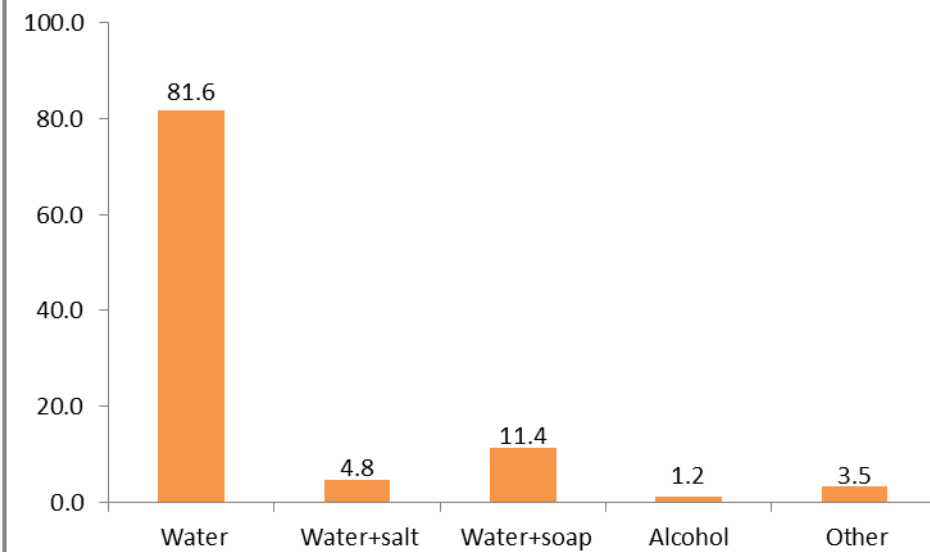
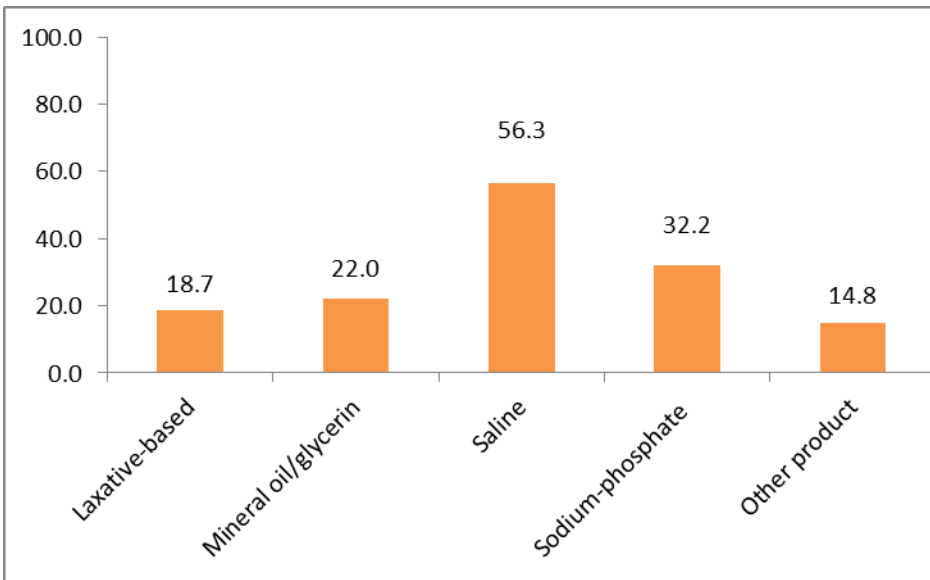
- 62% (n=1,070) reported rectal douching before or after AI
 - ▣ 83% before AI (always/most of time)
 - ▣ 16% after AI (always/most of time)



Types of rectal douches used

□ 31% reported commercial products (332/1,070)

□ 93% reported non-commercial, home-made products (990/1,070)



Prevalence of rectal douching by demographics (n=1,725)

	Rectal Douche/enema use		
	n	%	p value
Age, years*			<.01
Douchers	38.1 (11.7)		
Non-Douchers	34.0 (10.8)		
Gender			<.01
Male	1,258	70.4	
Female	81	32.4	
Region			<.01
Africa	37	61.8	
Asia	58	52.7	
Europe	328	71.9	
Latin America/Caribbean	107	39.9	
North America	773	70.7	

Prevalence of rectal douching by sexual behaviors and STI/HIV status (n=1,725)

	Rectal Douche/enema use		
	n	%	p value
No. of times, RAI, past 3 months			<.01
Douchers	6 (3-15)		
Non-Douchers	4 (2-10)		
Always use condoms for RAI, past 3 months			0.08
Yes	414	63.8	
No	817	67.9	
Lubricant use for RAI, past 3 months			<.01
Yes	1,159	67.8	
No	71	50.0	
Substance use, with sexual activity			<.01
Yes	499	73.6	
No	365	46.1	
STI, past 12 months			<.01
Yes	170	69.4	
No	688	57.1	
HIV-positive			<.01
Yes	352	72.4	
No	499	52.5	

Factors associated with rectal douching

- In multivariable analyses, adjusting for age, gender, region, condom use, and number of RAI events, factors associated with rectal douching included:
 - Lubricant use (AOR=1.77; 95% CI 1.10-2.85)
 - Substance use (AOR=1.93; 95% CI 1.50-2.49)
 - HIV-positive (AOR=1.68; 95% CI 1.26-2.24)
 - Self-reported history of STI in past 12-months (AOR=1.74; 95% CI 1.01-3.00)

Discussion

- Substantial number of respondents reported rectal douching
 - ▣ majority before AI
 - ▣ non-trivial proportion after AI
- Water enemas were most commonly reported product
 - ▣ Hypotonic solution – fewer complications compared to hyperosmolar enemas
 - ▣ Has been associated with rectal epithelial loss when compared to isotonic solutions

Discussion

- Other products including water and soap, sodium phosphate and laxative-based enemas also associated with colonic irritation, colitis, and rectal epithelium damage

Discussion

- Prevalence of rectal douching varied by
 - Region
 - Substance use
 - STI/HIV status

Implications for rectal microbicides

- Findings support promise of acceptability of rectal douches as delivery method for rectal microbicides
 - ▣ Commonly practiced behavior before receptive AI
 - ▣ HIV prevention via rectal douches may fit into the repertoire of those at most risk
 - ▣ Potential for improved safety profile of rectal microbicide compared to commonly used products

Conclusion

- Rectal douching with AI is a common practice and because associated with other risk behaviors, the contribution to transmission and acquisition of STIs/HIV may be important
- Further longitudinal studies may help to further delineate associations between STIs/HIV

Questions ?

Are Rectal Douches Ripe for Further RM Exploration?

*Qualitative data from MSM and TGW in
Lima and Iquitos, Peru and
Guayaquil, Ecuador*

Jerome Galea, PhD, MSW



Peruvian MSM and TGW could benefit from Rectal Microbicides

Group	HIV Prevalence % [95% CI]
General population aged 15-49 ^a	0.40 [0.20-1.10]
MSM ^b	12.4 [*]
MSM Sex Workers ^b	14.6 [*]
TGW ^b	20.8 [*]

^aUNAIDS, Peru fact sheet, <http://www.unaids.org/en/regionscountries/countries/peru/>

^bMinisterio de Salud del Peru, *Informe nacional sobre los progresos realizados en el país período enero 2010-diciembre 2011.*

*Confidence interval not reported

In other words....HIV prevalence is:

- 31 times greater in MSM
- 36.5 times greater in MSM-SW
- 52 times greater in TGW

*Compared to the
general Peruvian population*

Peruvian MSM/TGW would find RMs acceptable: there's a market!

Acceptability of Oral versus Rectal HIV Preexposure Prophylaxis among Men Who Have Sex with Men and Transgender Women in Peru

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ORIGINAL RESEARCH ARTICLE

Lubricant use among men who have sex with men reporting receptive anal intercourse in Peru: implications for rectal microbicides as an HIV prevention strategy

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Summary: This study assessed lubricant use during receptive anal intercourse (RAI) among Peruvian men who have sex with men (MSM) and willingness to use a hypothetical rectal microbicide (RM) formulated as a lubricant to prevent HIV infection. Data were collected from 643 Peruvian MSM for the 2008 HIV Sentinel Surveillance using a computerized self-interview. Half of the participants reported using a lubricant with their last sex partner during RAI, while 77% were willing to use a lubricant to prevent HIV transmission. Lubricant use with last sex partner was significantly associated with unprotected RAI (odds ratio [OR] 1.59, 95% confidence interval [CI], 1.23, 2.06, $P < 0.001$) and willingness to use a future lubricant RM (OR 1.56, 95% CI: 1.26, 1.96, $P < 0.001$). This study provides information on the behaviors associated with lubricant use and non-use among MSM practicing RAI in Peru that should inform future RM studies in Peru and other Latin American countries.

Keywords: lubricant, HIV prevention, rectal microbicides, MSM, South America

INTRODUCTION

Microbicides are substances under development that could be used vaginally or rectally to prevent HIV infection. The bulk of research to date has focused on vaginal microbicides; however, rectal microbicides (RM) – products designed specifically for use during anal intercourse (AI) – is a rapidly expanding research field that has grown considerably over the past five years.¹ While AI is not an exclusively homosexual behavior, globally, men who have sex with men (MSM) are 19 times more likely to be infected with HIV than the general population² and a single act of unprotected receptive anal intercourse (USAI) is 3–80 times riskier for HIV transmission compared with unprotected vaginal intercourse.³ Thus, a safe and effective RM could play an important role in preventing new HIV infections in countries with epidemic control among MSM.

Phase I clinical trials assessing the safety of RM candidates are currently underway in the USA,^{4,5} and a number of studies have examined the use and acceptability of potential RM presentations, including lubricants,^{6,7} suppositories⁸ and candles/rectal doecakes,^{9,10} as well as willingness to participate as RM clinical trials among MSM.^{11–14} While these studies found that MSM responded positively to hypothetical RM

and would be willing to participate in future RM clinical trials, equivalent data in MSM from non-USA populations are virtually non-existent. This need for data on RM acceptability from non-USA populations has already been called for by 894 experts who recognize the potential for differences due to cultural, social, economic and other factors.^{11,12} A key finding in USA-based investigations on lubricant use is that an RM formulated as a sexual lubricant would likely face few barriers to use by MSM since sexual lubricants are already widely used by this population for AI. For example, a household probability study of 679 MSM in San Francisco found that while approximately 50% practiced unprotected AI, lubricant was used by 89% of MSM.¹⁵ Another study among 307 MSM in New York showed that 116 used lubricant use was 94%.¹⁶

This study explores lubricant use in a sample of non-USA (Peruvian) MSM, focusing specifically on those most likely to use an RM: the receptive partner for AI since these men constitute the primary target population for an RM. Peru was chosen to investigate this issue for multiple reasons. First, it is a country experiencing a concentrated HIV epidemic in MSM (prevalence = 18–22%)¹⁷ versus ~1% in the general population¹⁸ and therefore could benefit from an effective RM. Second, Peru has a highly developed HIV research infrastructure and has conducted or is currently conducting clinical trials on a range of biomedical HIV prevention strategies including pre-exposure prophylaxis and vaccine studies.¹⁹ Thus, clinical trials of candidate RM could be feasible in terms of logistical capacity and access to research settings. Finally,

Preparing for Rectal Microbicides: Sociocultural Factors Affecting Product Uptake Among Potential South American Users

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The first phase 2 clinical trial of a rectal microbicide (RM) candidate – a uretrofoam-based, rectally-inserted variant of the vaginal gel evaluated in CAPRISA-004 – is under way in men who have sex with men (MSM) and transgender women (TGW) at 5 international sites.¹ This product is found to be safe and acceptable; efficacy trials could begin by 2015,² leading to a new prevention option for people at risk for HIV infection during unprotected receptive anal intercourse. Especially for MSM and TGW, an HIV prevention option specifically for this type of intercourse is urgently needed. Despite a worldwide decrease in new HIV infections,³ the epidemic continues to expand in MSM across all income levels globally,⁴ and a recent meta-analysis placed the odds ratio for TGW being infected with HIV relative to all other populations at 68.⁵

Overall, acceptability research has demonstrated mixed to a safe and effective RM among MSM and TGW;^{6–15} however, knowledge gaps remain particularly important to understand to help potentially users use themselves interacting with RM, including social, cultural and political factors, all of which may affect the adoption of an HIV prevention technology.¹⁶ We examined views of RMs among potential users in 3 South American cities to understand the sociocultural issues that could affect their uptake.

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Frequency, patterns, and preferences of lubricant use during anal intercourse within male sexual partnerships in Lima, Peru: Implications for a rectal microbicide HIV prevention intervention
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Current practices of lubricant use during anal intercourse can help to assess the context for topical rectal microbicides as an HIV prevention tool for men who have sex with men (MSM). Five qualitative methods to assess current patterns of lubricant use, preferred characteristics, brand formulations, and social and behavioral context of lubricant use within male sexual uni-

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ORIGINAL PAPER

Using Conjoint Analysis to Measure the Acceptability of Rectal Microbicides Among Men Who Have Sex with Men in Four South American Cities

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Abstract Conjoint Analysis (CIA), a statistical market-based technique that assesses the value consumers place on product characteristics, may be used to predict acceptability of hypothetical products. Rectal Microbicides (RM) – substances that would prevent HIV infection during receptive anal intercourse – will require acceptability data from potential users in multiple settings to inform the development process by providing valuable information on desirable product characteristics and issues surrounding potential barriers to product use. This study applied CIA to explore the acceptability of eight different hypothetical RM among 128 MSM in Lima and Iquitos, Peru; Guayaquil, Ecuador; and Rio de Janeiro, Brazil. Overall RM acceptability was highest in Guayaquil and lowest in Rio. Product effectiveness had the greatest impact on acceptability in all four cities, but the impact of other product characteristics varied by city. This study demonstrates that MSM from the same region but from different cities place different values

on RM characteristics that could impact uptake of an actual RM. Understanding specific consumer preferences is crucial during RM product development, clinical trials and eventual product dissemination.

Keywords: HIV · MSM · Rectal microbicides · Acceptability · Conjoint analysis

Resumen El Análisis Conjointe (CIA por sus siglas en inglés) es una técnica estadística de mercadotecnia que sirve para evaluar la valoración que los consumidores otorgan a las características de un producto, y que puede ser usada para predecir la aceptabilidad de productos hipotéticos. Para el desarrollo de microbicidas rectales (MR) – sustancias que podrían prevenir la infección por VIH durante el coito anal receptivo – es necesario contar con datos de aceptabilidad, características deseadas y posibles barreras para el empleo de MR por usuarios potenciales, en múltiples escenarios.

15.10% among MSM and TGW separate HIV prevalence data specific to TGW were not available for Ecuador and 0.31% in the general population.²⁰

Recruitment and Data Collection

Four outreach workers personally recruited participants at venues that MSM and TGW frequented, including parks, beauty salons, volleyball courts, community organizations, bars, saunas, and nightclubs. Previous research studies conducted among the target populations in Peru and Ecuador informed the choice of these recruitment venues.^{21–23} The outreach workers were MSM or TGW and thus had ready networks of potential participants from which to recruit. We screened interested persons for inclusion criteria (age ≥ 18 years, sexual intercourse with men during the previous 12 months) and, if eligible, randomly assigned them to either a focus group or in-depth interview, but not both.

We sought a heterogeneous sample of MSM and TGW. Therefore, the MSM sample comprised men who identified as openly gay (e.g.,

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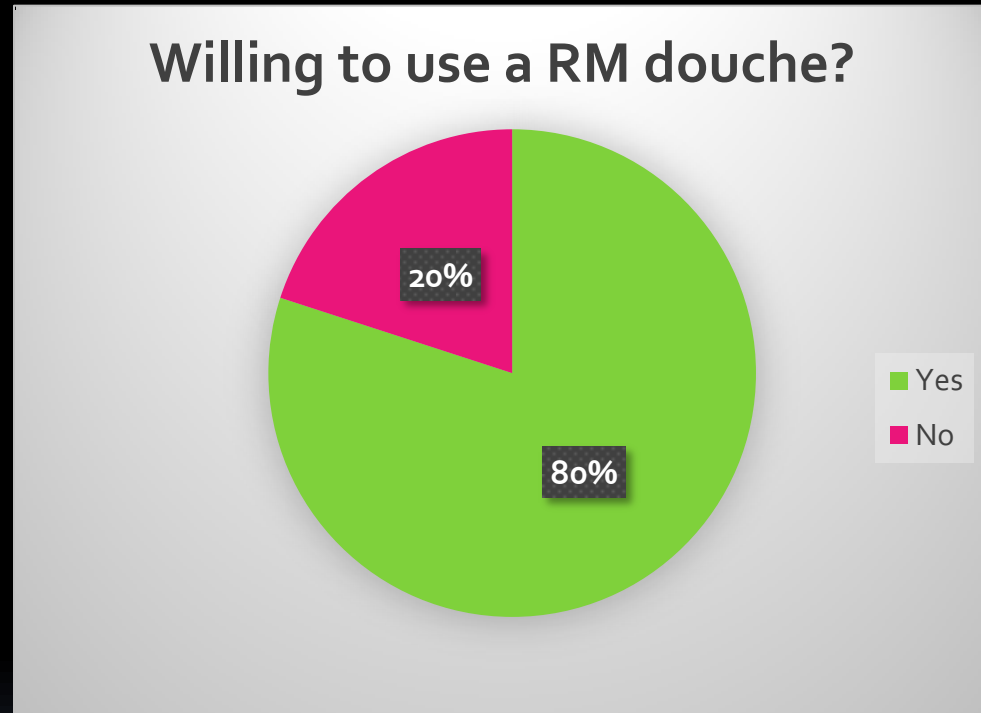
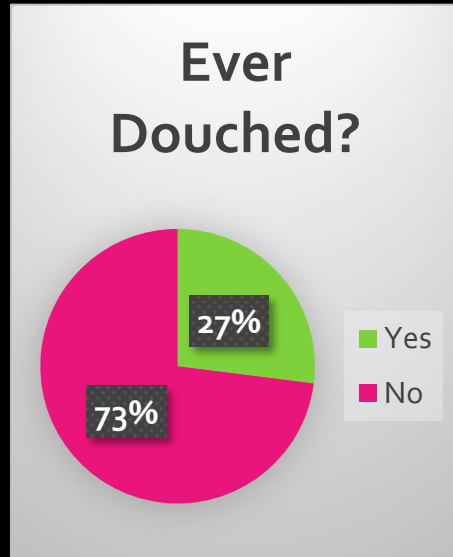
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Among 824 Peruvian MSM/TGW



Positive association between a history of rectal douching and willingness to use an RM formulated as a rectal douche.

Kinsler JJ, Galea JT, Lama JR, Segura P, Peinado J, Casapia M, et al. Rectal douching among Peruvian men who have sex with men, and acceptability of a douche-formulated rectal microbicide to prevent HIV infection. Sexually transmitted infections. 2013;89(1):62.

Study sites - Quali Study



Qualitative methods used

In-depth Interviews



x 36 (12 per study city)

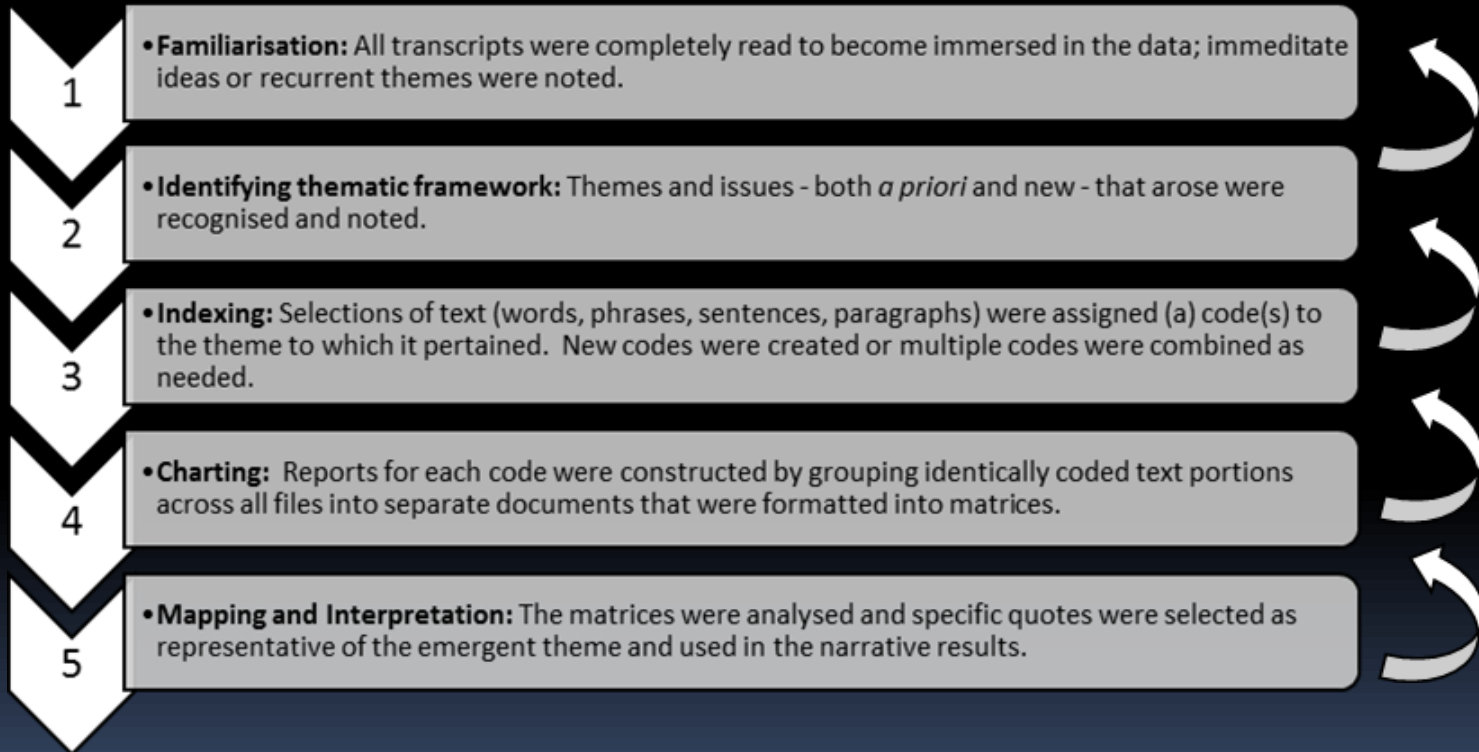
Focus Groups



x 12 (4 groups per study city)

N = 140 participants: Gay out, not gay, sex worker, and TGW

Framework Analysis (using ATLAS.ti)



Participant characteristics

Table 1: Sociodemographics of MSM and TGW (N=140)

Characteristics	All (Total N = 140) N (%)	Lima (Total N = 51) N (%)	Iquitos (Total N = 44) N (%)	Guayaquil (Total N = 45) N (%)
Race/ethnicity				
<i>Mestiza</i>	94 (68)	29 (58)	29 (67)	36 (80)
White	26 (19)	13 (26)	8 (19)	5 (11)
Indigenous	4 (3)	4 (8)	0 (0)	0 (0)
Other	14 (10)	4 (8)	6 (14)	4 (9)
Age				
18-29	107 (80)	29 (62)	38 (88)	40 (90)
30-39	17 (13)	10 (21)	5 (12)	2 (5)
40+	10 (7)	8 (17)	0 (0)	2 (5)
Education				
Less than high school	8 (6)	3 (6)	2 (4)	3 (7)
High school	71 (53)	17 (35)	25 (60)	29 (66)
Greater than high school	56 (41)	29 (59)	15 (36)	12 (27)
Employment				
Employed	81 (64)	33 (72)	23 (58)	25 (61)
Unemployed	23 (18)	11 (24)	3 (7)	9 (22)
Student	23 (18)	2 (4)	14 (35)	7 (17)

Due to missing data, variables do not sum to total N's.

Pros: Hygiene, practical, better

“It could be accepted due to hygiene.” (*Interview, MSM*)

“...it kills two birds with one stone, because I take care of the hygiene and it's for [protecting oneself]” (*Interview, TGW*)

“The ideal would be a type of enema, something like that, because this is going to have more effect, that is, it is going to go deeper [inside your body]” (*Focus Group, MSM*).

Cons: Dryness, impractical

“More than leaving you cleansed you end up really dry, you don't have anything from your body to lubricate, and in the end your partner is going to be uncomfortable” (*Focus Group, MSM*)

“Sometimes there's no time to put on a condom, much less apply an enema” (*Focus Group, MSM*)

Cons: Portability, Risks


“You're going to have to have a huge tube,
you're going to have to carry it around, aren't you?
On the other hand, you carry condoms in your
pocket or a lubricant, as well.” *(Focus Group, MSM)*

“[Douching is] forcing something
into our anus with force. Because when
you do that thing, you flush, the flushing,
you use the enema forcefully so that [it
does] the cleansing, right? And this is
extremely harmful to our health”

(Focus Group, TGW)



Liquids used

- lemon juice
 - tap water
 - soap and water
 - camphor
 - vinegar
 - mixture of soap, bleach and isopropyl alcohol
 - chamomile water
 - detergent
 - shampoo
 - (consumable) alcohol
- 

Apparatuses used

- “telephone” style showerheads
- plastic soda bottles
- hair dye bottles
- store-bought enema kits
- syringes

What do we make of this?

- Interest in RM douches with some caveats
 - To whom would RM douches best be targeted?
 - Range of product presentations?
- Regardless of RMs, douching should be further explored
 - Acidic, corrosive and surfactant products named
 - Practice may be causing more harm than good


Douchers wanted to be “clean and disinfected”

- ...but why?
 - Partner's request?
 - “Indigenous” RM use?
 - Alcohol for cleansing or inebriation?

Need to better understand the context of rectal douching to know how it would fit into an HIV prevention strategy.



Should also note that:

- Small qualitative study embedded in a much larger study
 - Small sample, urban areas
 - Young, educated participants
- 



So...

**Are douches ripe for
further exploration?**

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