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GLOBAL CONSULTATION ON PERSONAL LUBRICANTS

MEETING REPORT

ACKNOWLEDGEMENTS

The Global Consultation on Personal Lubricants was organized under the direction of Bidia Deperthes, Senior HIV Prevention Advisor, and Seloï Mogatle, Technical Specialist, from UNFPA. This work was done in close collaboration with Kent Klindera of USAID, Daniel McCartney of International Planned Parenthood Federation (IPPF), and Mario Philip Festin of WHO/HRP.

The UNFPA team would like to extend special thanks to USAID, which supported attendance costs for members of civil society organizations. Thanks to the more than 80 participants—manufacturers, researchers and technical experts, and members of civil society—who travelled from over 20 countries to attend this productive and ambitious meeting.

We appreciate everyone's commitment to collaborating and reaching a consensus on how to update and revise the 2011 WHO/UNFPA/FHI360 advisory note on additional lubricants, which will ultimately help to ensure safe, acceptable, and affordable lubricants are available to all.

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Executive Summary

As the international community mobilizes to achieve the new UN Sustainable Development Goals and meet ambitious targets to end the AIDS epidemic and eliminate HIV and other sexually transmitted infections (STIs) by 2030, one sexual health tool is receiving special attention: **personal lubricants**.

Lubricants are widely used for sexual intercourse by men, women, and transgender individuals around the world. Some reports suggest that personal lubricant used for rectal sex by men who have sex with men (MSM) is greater than 90% among MSM communities in the USA. Used in combination with condoms, personal lubricants help to reduce friction, improve comfort, and may help to reduce breakage in some situations, providing greater protection against unintended pregnancy, HIV, and other STIs. However, there are concerns about the safety of these products, as research has shown users are experiencing irritation, burning, and damaging effects to vaginal and rectal tissue.

The Global Consultation on Personal Lubricants, held 8–10 November 2016 in Bangkok, Thailand, was convened to study these issues and examine ways to produce, procure, and distribute safer products for all. Hosted by the United Nations Population Fund (UNFPA), the United States Agency for International Development (USAID), the World Health Organization (WHO), and the International Planned Parenthood Federation (IPPF), the meeting brought together more than 80 manufacturers, researchers and technical experts, sexual health advocates and educators, and international organizations that procure lubricants for governments or local organizations.

PURPOSE OF THE MEETING

The purpose of the meeting was to outline broad technical specifications and guidelines for non-toxic, long-lasting, condom-compatible lubricants that are safe and acceptable for all users and sexual practices. These recommendations will help WHO, UNFPA, and Family Health International (FHI360) revise and update the current guidance on personal lubricants (a 2011 advisory note) and, together with manufacturing, research, and civil society partners, formulate robust industry guidelines and clear public health messages.

DISCUSSIONS

The three-day technical consultation was ambitious and productive, with participants working together to reach consensus on what is acceptable to users, safe to use, and affordable to produce.

Researchers and technical experts presented the latest evidence on the safety, efficacy, and acceptability of personal lubricants and reached a common understanding of the science behind the products (osmolality, ingredients, and formulations) and the physiological effects of different types of lubricants.

Manufacturers reported on how they have been applying the current WHO guidance on additional lubricants and what needs to be changed or added to make the specifications more detailed and robust.

Members of civil society and international organizations described the experiences of MSM, sex workers, and transgender individuals with personal lubricants, the availability and demand for personal lubricants in Eastern and Southern Africa, and the local challenges of accessing and distributing lubricant to high-risk populations.

OUTCOMES

The meeting produced three sets of recommendations and action plans—one from manufacturers, one from researchers, and another from community groups—which will guide efforts in 2017 and beyond to produce, research, procure, and distribute quality-assured products that meet the needs of diverse users in a broad range of challenging environments. This report captures the discussions, recommendations, next steps, and action plans of the Global Consultation on Personal Lubricants.

Introduction

The Global Consultation on Personal Lubricants was held in Bangkok, Thailand, 8–10 November 2016. Hosted by the United Nations Population Fund (UNFPA), World Health Organization (WHO), the United States Agency for International Development (USAID), and the International Planned Parenthood Federation (IPPF), this was the first multi-sector meeting on personal lubricants of its kind, attracting tremendous interest from lubricant manufacturers (over 50 companies were in attendance), researchers, sex workers, sexual and reproductive health (and rights) advocates, and international organizations committed to making lubricants safer, more effective, accessible, and affordable for individuals around the world.

Prompted by safety concerns about the damaging effects of personal lubricants on vaginal and rectal tissue and the potential for increased susceptibility to HIV and other sexually transmitted infections (STIs), the meeting was convened to hear the latest research on lubricant safety and risks and develop general guidelines for non-toxic, long-lasting, condom-compatible lubricants that are safe and acceptable for all users and sexual practices.

The meeting featured a combination of presentations, group work, and lively discussions that tackled a variety of questions:

- *What are the health effects of personal lubricants?*
- *Do they increase susceptibility to HIV and other STIs?*
- *What is osmolality and how does it affect vaginal and rectal tissue?*
- *Are manufacturers complying with the current guidance on personal lubricants and what is their experience with these specifications?*
- *Is it feasible to produce a “one size fits all” lubricant that works for both vaginal and rectal intercourse and meets the needs of a variety of users and sexual practices?*
- *Do high-risk populations have access to lubricant and are they using it with condoms?*
- *Are current safety testing methods and standards for personal lubricants stringent enough?*
- *Are lubricants primarily for pleasure or for supporting disease prevention? What is the best message?*

Participants reported that the meeting helped to clarify the science and close other important knowledge gaps about personal lubricants, not only for the manufacturers that produce them, but the international procurers that supply them, and the sexual and reproductive health and advocacy groups that distribute them.

By the end of the meeting, participants had produced thoughtful and detailed recommendations for manufacturing personal lubricants, research needs and priorities, and user preferences and advocacy. These recommendations include an outline of technical specifications for manufacturers, and will help to inform updates to the current guidance on lubricants—a 2011 Advisory Note published by WHO, UNFPA, and Family Health International (FHI360). As these specifications are refined and tested over the next year and more research gets underway, the multi-sector partners who came together at the Global Consultation will work to formulate robust industry guidelines and clear public health messages.

This meeting was the first step in a long-term, ambitious global effort to ensure women, men, and transgender individuals have access to safe, non-toxic, long-lasting, condom-compatible lubricant no matter where they live or how they want to use it. This work will continue throughout 2017 as manufacturers collaborate on technical specifications, researchers seek funding for a new clinical trial, and advocacy organizations form a community task force on lubricants to contribute to this work. At the end of this report are three sets of action plans—one for manufacturers, one for researchers, and another for civil society organizations—with short-term targets for 2017, as well as longer term activities and priorities.

1 WHO, UNFPA, and FHI360 (2011), “Use and procurement of additional lubricants for male and female condoms: WHO/UNFPA/FHI360 – Advisory note”, http://apps.who.int/iris/bitstream/10665/76580/1/WHO_RHR_12.33_eng.pdf

Background

Personal lubricants are used for a variety of reasons: to improve lubrication and enhance sexual pleasure during vaginal or rectal intercourse, reduce pain and the risk of vaginal or rectal tearing, and ameliorate vaginal dryness. However, in recent years there have been growing concerns about the safety of these products, especially their potential to cause irritation and epithelial damage to the rectal or vaginal lining, and perhaps in turn increase susceptibility to transmitting HIV and other STIs.

These concerns about the efficacy and potential toxicity of lubricants (especially water-based ones) are spurring debate about these products. Historically, personal lubricants have been subjected to low levels of regulatory control by most stringent medicines regulatory bodies, and are not subject to extensive safety and toxicity testing. Personal lubricants are now classified as medical devices (Class 2 by the USFDA and Class IIa in Europe) and are required to be evaluated for safety and toxicity. These requirements may not, however, apply in some parts of the world and there may be products on the market that are not yet subjected to full safety testing. Where personal lubricants are classified as medical devices, their manufacture is controlled—for example, manufacturers must be certified to ISO 13485 and are subject to audit.

For manufacturers, lubricants pose two main challenges: maintaining good lubrication during use (a balance of viscosity, i.e. not too runny or too thick, inadequate absorption) and irritation/allergies (in extreme cases people are getting sick). For users, lubricant can be messy, have an unpleasant smell, and cause irritation and pain, particularly for sex workers who may apply it multiple times a day.

There is particular concern about personal lubricants used for rectal intercourse, since epithelium of the rectal region is more delicate than that of the vagina, which has extra layers of cells. Also, unlike the vagina, which secretes lubricating fluids during intercourse, the rectum does not. Yet, most available commercial products were designed for vaginal and not rectal intercourse, creating a higher risk of damage to the rectal epithelium if lubricants cause irritation and related toxicities.

In response to these concerns, the WHO, in collaboration with UNFPA and Family Health International (FHI360), issued an advisory note in 2011 specifying that iso-osmolar products were desirable, but products with an osmolality of <1200 mOsm/kg were acceptable in the interim (WHO, 2012). To provide definitive recommendations on lubricants, the agencies noted the need for a systematic review of the safety of personal lubricants to define both the knowledge and research gaps. This study was commissioned by UNFPA in 2015, and the Global Consultation on Personal Lubricants was convened in part to review the results of this systematic review and develop general guidelines informed by the findings.

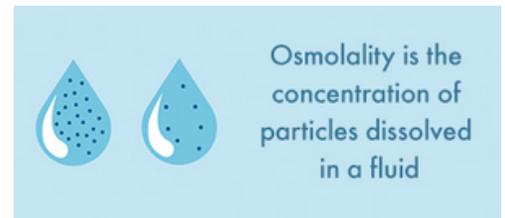
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“It was important to bring these three groups together and get input from different users in the community – manufacturers need to understand what people want and what they’re using. We learned there is no one-size-fits-all lubricant, and understanding the research and learning about anatomy and physiology helped to connect all the issues.”

OSMOLALITY

WHAT IS OSMOLALITY?

In simple terms, osmolality is related to the concentration of dissolved chemicals in a water-based lubricant. In more technical terms, osmolality is the measure of the number of dissolved particles per kg of solvent (water), expressed as mOsm/kg (milliosmoles per kilogram of water).



WHY IS OSMOLALITY IMPORTANT?

Cells in the epithelial layer (the outermost layers of the vagina and rectum) need to maintain an equilibrium of water content. Osmolality determines whether or not water flows into or out of these cells.

Hypo-osmolality

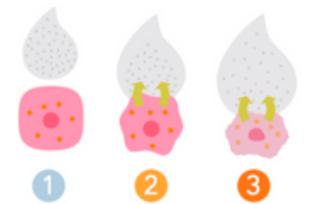
When a lubricant has low osmolality – lower than the inside of the cells, there is an imbalance in osmotic pressure and water is drawn into the cells, causing them to swell and even burst if the lubricant has very low osmolality. This is called **hypo-osmolality**. Hypo-osmotic lubricants can damage epithelium cells and sperm, but there are not many of these types of lubricants on the market.



Hypo-osmolality: swollen, ruptured cells

Hyper-osmolality

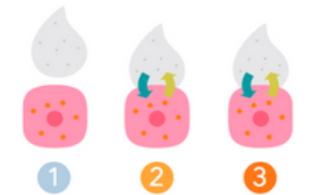
When a lubricant has high osmolality, it draws water out of epithelial cells, and also draws water into the lumen of the vagina or rectum. This is called **hyper-osmolality**. If osmolality is very high, it can cause cells to shrink, die and slough off, leaving the vagina or rectum irritated and more susceptible to infection. The shrunken cells also send out a danger signal to the immune system and initiate inflammation. Many lubricants on the market are hyper-osmolar. They may feel fine, but have toxic effects that do not cause most users any pain (silent toxicity).



Hyper-osmolality: dried out, shrunken cells

Iso-osmolality

When a lubricant has an osmolality similar to that of the body's cells, little water flows into or out of the epithelial cells, and everything remains in balance. This is called **iso-osmolality** and is ideal for a water-based lubricant.



Iso-osmolality: happy cells

WHAT CONTRIBUTES TO HIGH OSMOLALITY IN A LUBRICANT?

Mainly glycols, which are added to modify the lubricity of the lubricants and act as humectants or moisturizers. Glycols help prevent the lubricants from “drying out” during use. Glycerol and propylene glycol are the most commonly used ones. Glycols are relatively small molecules and may be found in quite high concentrations in lubricants. Since the osmolality of a lubricant is almost entirely dependent on small molecules, osmolality can be reduced by reducing the concentrations of glycol.

WHAT IS THE RECOMMENDED OSMOLALITY FOR PERSONAL LUBRICANTS?

To minimize the risk of epithelial damage, the osmolality of a lubricant should be in the same range as the osmolality of body fluids. Vaginal secretions have osmolalities of 260–370 mOsm/kg and semen 250–380 mOsm/kg. Therefore, the osmolality of a personal lubricant should ideally not exceed 380 mOsm/kg. What is considered safe for vaginal use is generally considered safe for rectal use. However, the osmolality of most personal lubricants on the market is much higher: 2,000–6,000 mOsm/kg. Since manufacturers cannot change their formulations overnight, it is not practical to simply impose this limit. For now, the WHO recommends that procurement agencies source lubricant with an osmolality no greater than 1,200 mOsm/kg. There are several products available that meet or only just exceed this recommended limit.

SETTING THE SCENE: THE CURRENT GUIDANCE ON PERSONAL LUBRICANTS

REVIEW OF THE WHO/UNFPA/FHI360 ADVISORY NOTE ON THE USE AND PROCUREMENT OF ADDITIONAL LUBRICANTS FOR MALE AND FEMALE CONDOMS

MARIO FESTIN, WHO

In 2011, the World Health Organization (WHO) Department of Reproductive Health and Research, in collaboration with the United Nations Population Fund (UNFPA) and Family Health International (FHI360), issued an advisory note on the use and procurement of additional lubricants for male and female condoms.

This guidance document included the most recent research on lubricants and condom failure rates, recommendations for the types of lubricants that should be procured, and specifications on osmolality limits for water-based lubricants.

In this session, Mario Festin of WHO summarized the findings and recommendations of the 2011 advisory note, highlighted what has changed since the note was published, and encouraged participants to provide feedback so their concerns and recommendations can be added to the agenda when the Advisory Note is revised in 2017.

OVERVIEW OF 2011 RESEARCH FINDINGS & RECOMMENDATIONS

There is **significant demand for additional lubricants** to be used with condoms, particularly for MSM, female sex workers, and women in menopause and post-menopause.

The correct type of **additional lubricant for male latex and female condoms can be bulk procured with either male or female condoms, if justified by programmatic requirements.** Any additional lubricant that is used must not have a deleterious effect on the properties of the condoms to avoid the risk of breakage or slippage. For example, latex condoms rapidly lose strength if exposed to oil-based lubricants.

When procuring water-based lubricants, iso-osmolar products are desirable, but **products with an osmolality of 1,200 mOsm/kg or less are acceptable in the interim.**

Lubricants containing polyquaternium compounds should be avoided until there is further evidence on the effect of these compounds on HIV replication rates.[2]

When procuring water-based lubricants, a **pH of around 4.5 is recommended** if the primary intended target population will use the product for vaginal intercourse. For lubricants intended primarily for rectal use or where the nature of the intended use cannot be ascertained, a pH of 5.5–7 is recommended. Lubricants with a pH higher than 7 are not recommended.



Five years on, it is time to update the guidance document based on new research and evidence.

[2] Polyquaternium compounds are chemicals that are used as surfactants in shampoos and various hair products. They are cationic polymers that contain quaternary ammonium groups.

The bulk procurement and distribution of lubricants containing spermicides, medicinal, and other active substances is not recommended. Studies have shown that spermicidal additives (predominantly nonoxynol-9) have significant irritant effects.

Water and glycol-based personal lubricants are generally accepted as being compatible with natural rubber latex and safe with latex condoms. Silicone-based lubricants are also compatible with natural rubber latex but are more expensive. Almost any lubricant with proven levels of safety for human use can be used with polyurethane condoms and some other types of synthetic condoms.

For rectal intercourse, research has shown that when additional water-based lubricants are used with condoms, breakage rates were just 3%, but when no additional lubricant was used, it was 21.4%.

For vaginal intercourse, the evidence is less clear. One retrospective study has shown that the use of additional water-based lubrication was associated with lower condom failure rates, while another did not find any difference in breakage and slippage rates when a personal lubricant was used.

The expert group recommended a systematic review of the literature to determine the sum of evidence on which recommendations can be made for the bulk procurement and distribution of personal lubricants that can be safely used as additional lubricant with male and female condoms. This work was commissioned by UNFPA in 2015 and the results were presented at this consultation.

WHAT DO WE KNOW NOW THAT WE DIDN'T KNOW FIVE YEARS AGO?

Osmolality: Ideally, the osmolality of a personal lubricant should not exceed 380 mOsm/kg to minimize any risk of epithelial damage. Most commercial lubricants significantly exceed this value (2,000–6,000 mOsm/kg), but imposing such a limit now could severely limit the options for procurement agencies. So, the WHO still recommends that procurers source lubricant with an osmolality no greater than 1,200 mOsm/kg.

Polyquaternium: The opinion on the safety of polyquaternium compounds has been revised and there is no longer any recommendation to avoid them.

Buffering capacity: We now know it is not just the pH of a lubricant that is important, but its buffering capacity as well. A lubricant with a low buffering capacity will have little effect on the pH of the vagina or rectum, whereas a lubricant with a high buffering capacity will cause a temporary shift in pH. The time it takes for the vagina or rectum to return to its natural pH will depend on the magnitude of the buffering capacity of the lubricant. Lubricants with low buffering capacity are therefore preferred.

WHAT HAS CHANGED SINCE 2011?

Over the last few years, there have been major global commitments to ending the world's worst disease epidemics, improving reproductive and maternal health, and ensuring access to quality, safe, effective and affordable medicines and vaccines for all. The UN Sustainable Development Goals (SDGs) and the UNAIDS Fast-Track Strategy (90-90-90) are two of these commitments.

In 2016, the World Health Assembly adopted three global health sector strategies for 2016-21, which cover HIV, viral hepatitis, and other STIs. These three separate yet interlinked strategies have set ambitious targets to end the AIDS epidemic, STI epidemics (gonorrhoea, syphilis, and HPV are the three priorities), and Hepatitis B&C by 2030.

What role does lubricant play in meeting these targets?

The use of personal lubricant with condoms may help to prevent HIV and other STIs by encouraging condom use and reducing the risk of condom breakage in some circumstances.

EVALUATION OF PERSONAL LUBRICANTS IN GENITAL TISSUES

ELLEN KERSH, CDC

When it comes to the safety of lubricants, there are two main areas of concern: cytotoxicity and the impact on HIV and STI transmission.

In 2011, a lubricant safety working group was formed at the Center for Disease Control (CDC), made up of representatives from domestic and international HIV branches and the STD branch. The task of the working group was to formulate recommendations on lubricant safety and determine whether and how the CDC should act. The working group met until 2014, investigating the different classes of personal and sexual lubricants, behavioural data on prevalence of use, biomedical safety evaluations, and existing public health messages on lubricants and condoms.

In this session, Ellen Kersh of the CDC presented the latest research on the use of personal lubricants, lubricant safety testing, and the implications of lubricant use for the transmission of HIV/SHIV (Simeon Human Immunodeficiency Virus), bacterial vaginosis (BV), and incident rectal STIs (rSTIS).

USE AND SAFETY OF PERSONAL LUBRICANTS

The use of lubricant for rectal and vaginal sexual intercourse is common. A 2012 National Survey of Sexual Health and Behaviour in the US found that 65.5% of women and 70% of men used lubricants to make sex more comfortable, fun, and pleasurable. Men who have sex with men (MSM) in the US use lubricants 20 times more often, with 74% using lubricant in at least 80% of their encounters. Literature reviews have found that physicians usually recommend the use of lubricants for childbirth and fertility clinic procedures to help decrease trauma and micro-abrasions. Most of these lubricants contain high concentrations of glycols to make them feel warmer, dry more slowly, and last longer. However, this makes them “hyperosmolar”, drawing water out of vaginal and rectal tissues and shrinking cells.

RESEARCH ON THE SAFETY OF PERSONAL LUBRICANTS

This presentation focused on safety testing for HIV and other STIs through in vitro, animal, and human studies. Although there are several categories of lubricants—water-based, silicone, natural oil and petroleum-based—the research has focused on water-based lubricants since only soluble types can be studied in vitro.

IN VITRO STUDY

“Is Wetter Better? An Evaluation of Over-the-Counter Personal Lubricants for Safety and Anti-HIV-1 Activity”^[3]

This study used ex vivo mucosal tissue to conduct a tissue viability test (MTT assay) and histology tests (H&E staining) to see if the epithelium kept its integrity in the human body.

RESULTS:

Several lubricants reduced the viability of colorectal and ectocervical tissue (Astroglide and KY Jelly) and one was toxic to mucosal tissue (Gynol II). Gynol II, a hyperosmolar spermicidal gel containing nonoxynol-9, was shown to be very toxic and stripped or disrupted the epithelium. Several aqueous gels were also hyperosmolar and stripped/fractured the epithelium, and two glycerin-free gels also reduced tissue viability. Good Clean Love, PRÉ, FC2, and Wet Platinum had the least amount of tissue changes.

Was there increased risk of HIV/STI acquisition?

No. Ectocervical tissue treated with lubricants showed modest delays in HIV-1 growth, but no overall enhancement of HIV-1 infection. KY Jelly and Sliquid Organic showed reduced HIV-1 infection, but this was likely related to loss of tissue viability.

[3] Dezzutti, C., et al., 2012, “Is Wetter Better? An Evaluation of Over-the-Counter Personal Lubricants for Safety and Anti-HIV-1 Activity”, *PLoS ONE* 7(11): e48328

ANIMAL STUDY

"Rectal Application of a Highly Osmolar Personal Lubricant in a Macaque Model Induces Acute Cytotoxicity but Does Not Increase Risk of SHIV Infection"[4]

This study aimed to determine whether a commercially available lubricant causes rectal cytotoxicity (inflammation, bleeding, tissue damage) and increases HIV/SHIV (Simeon Human Immunodeficiency Virus) risk in a macaque model. One lubricant was used – it had a very high osmolality (8,064) and very low pH (4.4) and polyquarternium (+15).

HUMAN STUDY

Bacterial vaginosis (BV) is a serious concern for women because it is very common, yet usually asymptomatic. There is increased awareness that BV may be linked to the uptake of HIV and other STIs, and unprotected receptive rectal intercourse is one of the highest risk factors.

Various human studies have been conducted to determine whether lubricants alter vaginal and rectal flora and lead to increased incidents of HIV/STI infection.

RESULTS

One hyperosmolar, low pH lubricant induced short-lived rectal cytotoxicity in an animal model (inflammation 30 minutes after lubricant use then subsiding, with no inflammation after two hours). There was no change in pH, no striking changes in bacterial microflora, and biopsies showed healing within seven days.

Was there increased risk of HIV/STI acquisition? Not at the time point (30 min) tested.

These results were surprising. Although Ms. Kersh noted the limitations of the study (only one product was tested, for example), she had expected an increase in HIV uptake/susceptibility. However, the viral inoculum was delivered at the very time that the rectal epithelium was rapidly shedding blood and cells, suggesting that much of the inoculum would have been shed as well. Two hours later, no inflammation was found, implying that rectal epithelium can repair itself very quickly. Thus, the timing of the viral inoculum is critical for the interpretation of this test; had it been applied 45 to 90 minutes later, the results might have been very different, but only the one 30-minute interval was tested.

BV STUDY: 39 women self-collected vaginal swabs and data was combined with a behavioural diary.

RESULTS: BV was linked to lubricant use.

RECTAL STI (rSTI) STUDY: A rectal health and behaviour study of 380 men and women in Los Angeles and Baltimore using “any lubricant”.

RESULTS: rSTI are more common among lubricant users, and the use of any lubricant increases incidents of rSTI. Lubricants appear to modulate vaginal and rectal flora.

SUMMARY OF FINDINGS:

- Most aqueous-based lubricants tested were hyperosmolar.
- Not all glycerin-free lubricants are the same and not all were safe.
- Mucosal tissue toxicity and acute inflammation were noted after lubricant use.
- While current data does not suggest an increased risk for HIV (SHIV), there is an epidemiological association with BV acquisition and incident STI.

CONCLUSIONS

The current research appears to show an association between lubricant use and increased incidence of BV and rSTIs.

Based on the research, the main public health message should be that correct and consistent condom use is recommended to prevent exposure to pathogens.

However, lubricant safety is an extremely difficult area to study. Studies are difficult to design and there are many confounding factors, such as condom use, frequency of sex, how lubricant use is reported, and many other issues.

The studies cited here were small and need to be confirmed and conducted by others. Since more research is needed, the CDC has decided not to produce recommendations just yet.

[4] Viswanathan, S. et al., 2015, “Rectal Application of a Highly Osmolar Personal Lubricant in a Macaque Model Induces Acute Cytotoxicity but Does Not Increase Risk of SHIV Infection”, *PLoS ONE* 10(4): e012002.

MANUFACTURERS' EXPERIENCES WITH CURRENT LUBRICANT SPECIFICATIONS

MODERATED BY SELOI MOGATLE, UNFPA PSB AND BIDIA DEPERTHES, UNFPA HQ

"It is no problem to manufacture based on the Advisory Note, but what does the 1,200 mOsm/kg limit mean? We need a better understanding of how osmolality relates to vaginal irritation."

As the UNFPA Procurement Services Branch (PSB) team has applied the guidance of the 2011 Advisory Note, they have received questions from manufacturers about a variety of technical specifications. As a procurer, UNFPA is seeing lubricants with wide ranges in osmolality, viscosity, and pH. This session heard from manufacturers: their experiences with the guidance and how they are applying it in relation to osmolality and glycol content, viscosity, pH levels, biocompatibility, and stability requirements. Since the Advisory Note did not cover all specifications, such as package seal integrity, they were also invited to provide feedback on this and other parameters. The session followed a Q&A format, which is captured here.

OSMOLALITY: WHY NOT GO LOWER?

Q: If higher osmolality lubricants are causing epithelial damage, why not produce formulations with lower osmolality? How complicated is it to do this?

A: Lubricants need to be long-lasting, but low osmolality lubricants tend to dry out very quickly. It is not difficult to lower the osmolality, but they will not be very effective or meet consumer demand for "wetter" feeling lubricants with high-glycol content. Reformulating is not technically difficult, but not a trivial exercise either. We need to find a balance, taking into consideration how long the lubricant should work, how much glycol is required to work for that period, and what effect this has on osmolality.

PRODUCT TESTING

Q: Is product testing standard across the industry? What safety tests do you conduct?

A: We develop all lubricants as medical devices. We do clinical evaluation testing, standardization testing, and consumer evaluations. Internally, we measure how long-lasting the lubricant is, osmolality, viscosity, and other tests. However, the type of testing can depend on the function of the lubricant (pleasure or health) and consumer preferences (e.g. flavor).

CONSUMER RESEARCH

Q: How do you know what consumers want?

A: We ask them. In focus groups, feedback from consumer complaints about products already on market, etc. The types of lubricants are vast, so the goals differ depending on what you are trying to develop.

How high is too high? How low is too low?

"It is possible to manufacture a lubricant with a maximum osmolality of 1,200 mOsm/kg, but is this the right limit? There was no real science behind this limit – we looked at what osmolality we thought would be safe, what was available, and made a compromise."

– Bill Potter, Stapleford Scientific Services Limited

ADVERSE EFFECTS OF HIGH OSMOLALITY LUBRICANTS: CONFLICTING TEST RESULTS

When testing whether higher osmolality lubricants cause vaginal irritation and other adverse effects, manufacturers are seeing conflicting results.

"When it comes to osmolality, we say that higher is worse, but biocompatibility tests using the ISO 10993 standard are not bearing this out, even very high osmolality lubricants (10,000 mOsmol/kg+). Histology tests are not showing epithelial degradation in the vagina, and condom compatibility and stability testing are not showing adverse effects on the end user either. Some of the literature says it has some impact on the vagina, but the FDA doesn't have enough evidence to say that."

PERSONAL ADDITIONAL LUBRICANTS: REPORT OF THE UNFPA SYSTEMATIC REVIEW

DEXTER TAGWIREYI, AMPELOS INTERNATIONAL CONSULTANCY

As a global procurer of personal lubricants, UNFPA needs to know exactly what it is buying and whether the products it is supplying are safe and effective. In 2015, UNFPA commissioned a systematic review of articles on the safety and toxicity of personal lubricants. Pharmacists and toxicologists Dexter Tagwireyi and Star Khoza of the University of Zimbabwe conducted this independent review, and in this session Mr. Tagwireyi reviewed the findings of the research.

Although only a few countries request personal lubricants, some have reported that users have had irritation and burning from the lubricant UNFPA supplied. This prompted UNFPA to remove the products related to the complaints from the procurement list and invest in a systematic review of the literature on the safety of personal lubricants.

Specifically, UNFPA wanted to learn whether there were studies that had found lubricant damaged rectal and vaginal epithelial tissue, and whether this increased susceptibility to HIV/STIs. At the same time, UNFPA was interested in discovering whether some lubricant ingredients may help to prevent HIV/STI transmission.

DEFINITION OF A PERSONAL LUBRICANT:
ANY FLUID, GEL, CREAM OR LIQUID USED DURING HUMAN SEXUAL ACTS, SUCH AS INTERCOURSE AND MASTURBATION, TO REDUCE FRICTION TO, OR BETWEEN, THE PENIS AND VAGINA, ANUS, OR OTHER BODY PART.

METHODOLOGY OF THE SYSTEMATIC REVIEW

The researchers conducted a computerized and systematic search of PubMed, TOXnet databases and other resources covering the period January 1, 1950 through June 30, 2015, articles reporting on the safety and toxicity of personal lubricants were identified. From the initial 669 studies identified, a total of 25 studies met the inclusion criteria for this review.

Primary research questions:

- What are the effects of personal lubricants on HIV and STI susceptibility?
- How safe are personal lubricants when applied rectally and vaginally?

Secondary research questions:

- What are the effects of personal lubricants on sperm motility and fertility?
- What is the effect of product excipients on lubricant osmolality?

PERSONAL LUBRICANTS AND SUSCEPTIBILITY TO HIV AND STIS

The researchers reviewed human, animal, and in vitro studies. In the human epidemiological studies, the main finding was that **significantly more STIs were found among those who reported consistent use of lubricant than those who reported inconsistent lubricant use.** In the animal studies, it was found that **rectal injury did not result in increase in SHIV transmission, and two personal lubricants significantly increased the risk of infection with HSV-2** compared to the control.

After examining the available literature, several conclusions were reached:

There is a correlation between osmolality and cytotoxicity. The higher the osmolality, the higher the incidence of cytotoxicity.

Hyperosmolar water-based personal lubricants may cause damage to both vaginal and rectal epithelial cells. However, whether this increases susceptibility to HIV/STI infection needs to be studied further.

One study in humans and two animal studies suggest that rectal epithelial damage caused by personal lubricants increases the chances of acquiring STIs. However, more studies are required to confirm this.

Water-based iso-osmolar lubricants appear to be safer than hyperosmotic lubricants, but more studies are needed.

Based on the cytotoxicity osmolality correlation results, a maximum limit of 1,800 mOsm/kg may be acceptable, although **the lower provisional limit of 1,200 mOsm/kg would still be considered safer.**

Data is limited, but suggests that **silicone-based personal lubricants are safe.**

Lubricant osmolality and pH are important determinants of whether a personal lubricant will be toxic to sperms or not, and **hyperosmolar lubricants result in sperm toxicity.** In addition, **lubricants outside the physiological pH range of the vagina are also detrimental to sperms.** However, only in vitro studies have demonstrated a negative effect of personal lubricants on sperm motility.

To reach more definitive conclusions on the above questions and fill in knowledge gaps about the safety of personal lubricants, more systematic studies are needed, ideally clinical studies. The effects of individual excipients or ingredients may also need to be considered, rather than just osmolality and pH.

“I’ve been supplying lubricant to sex workers since 1978, and the issue is the number of times they have sex in a day and the time it takes. The chemistry of the lubricant needs to be completely different if you are applying it 6 or 7 times a day or 100+ times – a drying lubricant will cause burning and other irritations that other populations would not be aware of.

What I think we really need to address is: will hundreds of thousands die because we don’t really know what the STI effects of lubricants are? Especially in Sub-Saharan Africa where there are very few doctors.”

– Paul Whyte, Gel Works

REVIEW OF UNPUBLISHED DATA ON LUBRICANT SPECIFICATIONS

BILL POTTER, STAPLEFORD SCIENTIFIC SERVICES LIMITED

What is the relationship between osmolality and lubricant safety? And what are manufacturers doing to assess the safety of lubricants? Using data provided by manufacturers, Bill Potter of Staple Scientific reported on the types of safety tests manufacturers of personal lubricants are conducting and the results of these tests.

STANDARD SAFETY TESTING REQUIREMENTS

Most lubricant manufacturers carry out testing according to ISO 10993, a series of safety biocompatibility tests developed by international expert groups and used by all regulatory bodies to assess the safety of medical devices. Lubricants are classified as medical devices in the United States (Class II) and Europe (Class IIa). ISO 10993 is an extensive standard including 14 parts. Part 1 has a table that indicates which tests to conduct for a medical device depending on how it is used and the type and degree of exposure it sees. In other words, where the lubricant goes and how long it stays there. Part 1 (10993-1) specifies three types of tests required for lubricants based on the classification table:

- **Cytotoxicity testing** according to ISO 10993-5 (direct contact, elution, or indirect/overlay test. The elution test seems to be the most appropriate one to use.)
- **Irritation testing** according to ISO 10993-10 (Rabbit vaginal test and penile irritation test)
- **Sensitization testing** according to ISO 10993-10 (guinea pig maximization test)

Additional testing may be required depending on where the product will be registered. For example, in the US manufacturers must conduct an acute toxicity test according to ISO 10993-11.

RESULTS

All manufacturers who submitted data for this review conducted the three standard tests listed above (with some variation, for example, some companies conduct dermal irritation tests instead of the rabbit vaginal test).

All of the studies had low toxicity results.

- All the results for irritation testing come out with very low toxicity scores (0 or 1 on a scale of 1 to 4) and fall within the category of non-to mildly irritating.
- All the results from the guinea pig sensitization tests were negative.
- Cytotoxicity testing revealed a variety of results. Why? This was likely because different methods were used (direct contact, elution, overlay) and the results appear to be method sensitive.

“WE NOW KNOW WHAT THE
TRENDS ARE: AS
OSMOLALITY INCREASES,
SO DOES CYTOTOXICITY.
AND WE ARE STILL SEEING
POSITIVE RESULTS BASED
ON THE STANDARD
REQUIRED TESTING.”
– BILL POTTER,
STAPLEFORD SCIENTIFIC
SERVICES LIMITED

MOST OF THE CYTOTOXICITY TESTS WERE NEGATIVE OR MILDLY TOXIC, BUT ONE SET OF DATA STOOD OUT.

One company sent formulations of lubricants and cytotoxicity results from overlay and elution tests. Generally, as glycol content comes down, so does cytotoxicity. However, these tests revealed something quite surprising:

At 94% glycol content, one lubricant had very high osmolality and cytotoxicity scores of 3 and 4, which confirmed it was quite cytotoxic. However, an equivalent lubricant with 60% glycol content had cytotoxicity scores of 3 and 2 and an irritancy score of 0, i.e. it was non-irritant.

Other factors may therefore contribute to toxicity. All the formulations contained preservatives, which by definition are cytotoxic. However, the type and quantity used will vary depending on whether the product is formulated for a single use sachet (lower concentrations), a multi-use bottle (higher concentrations), or a large dispenser jar.

CONCLUSIONS

Manufacturers tend to use standard ISO irritation and sensitization tests and the results are always negative or mild. Cytotoxicity testing is generally resulting in very low scores, but can differ by formulation and the specific test selected from the options given in ISO 10993-5.

Q&A

Q: What is the proper way to measure osmolality?

A: I don't think osmolalities are being calculated or measured properly, especially for higher osmolality lubricants. I've seen units of mOsmol/kg of solution being used as a measure of osmolality, but the unit mOsmol per kg of solution is not a recognised unit and doesn't measure anything.

The correct unit for osmolarity is mOsmols/litre of solution and the correct unit of osmolality is mOsmol/kg of water.

The difference between osmolality and osmolarity becomes irrelevant at low osmolalities/osmolarities. When you get down to around 2,000 mOsmol/kg the osmolality and osmolarity are very similar. When you want to measure the osmolality of your lubricant, you could as a first step use a laboratory that measures blood osmolality. Most of these laboratories can measure up to 4,000 to 5,000 mOsmol/kg directly. Above these values it is necessary to dilute the lubricant.

Q: Can we come up with a standardized measurement at this meeting?

A: The calculation is straightforward, but there is a question about the best method to use for extrapolation if the lubricant has to be diluted before it can be measured. The best method appears to be against the mole fraction of water in the lubricant.

The correct unit for osmolarity is mOsmols/litre of solution and the correct unit of osmolality is mOsmol/kg of water.

NONTOXIC LUBRICANTS FOR VAGINAL AND RECTAL INTERCOURSE: ANATOMY AND PHYSIOLOGY

RICHARD CONE, JOHNS HOPKINS UNIVERSITY

In this session, Richard Cone of Johns Hopkins University gave participants a primer on the anatomy and physiology of the vagina and the penis, explained the toxic effects of hyper-osmolal lubricants on epithelial cells in the vagina and the rectum, and made recommendations for manufacturers to produce nontoxic lubricants for vaginal and rectal intercourse.

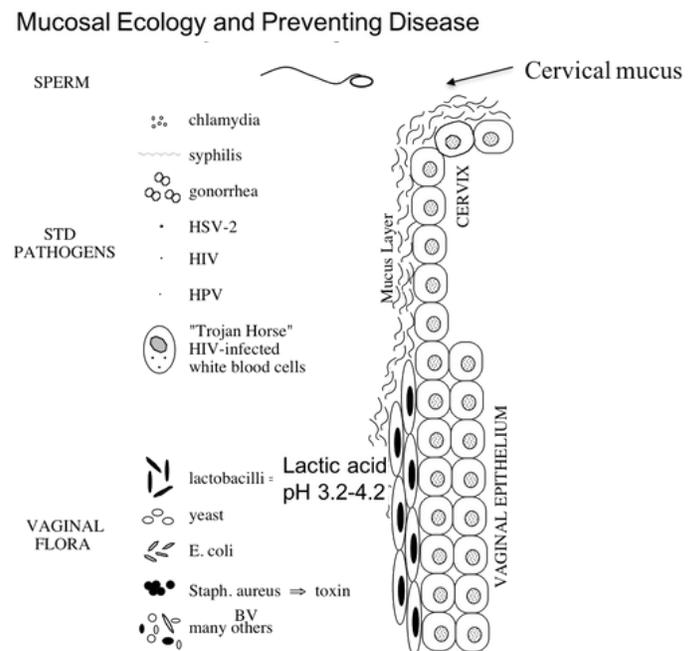
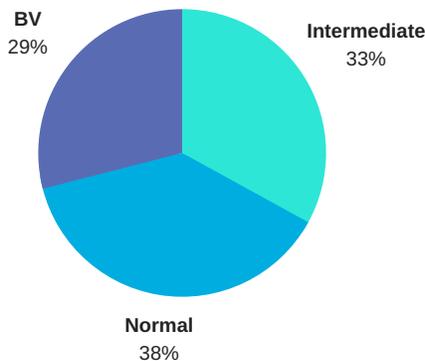
VAGINAL ANATOMY AND DISEASE PREVENTION

From an anatomical point of view, the vagina has evolved to have sexual intercourse fairly often. When a woman is sexually excited, the vulva provides a lot of lubrication and the cervix also secretes mucus, which moves down to the vagina to provide additional lubrication.

The mucosal ecology of the vagina plays an important role in preventing disease. A moist, rich environment, the vagina can harbour STD (STI) pathogens, such as chlamydia, syphilis, gonorrhea, and HIV, as well as different types of vaginal flora: yeast, E. coli, bacterial vaginosis (BV), and others. When there are healthy amounts of lactobacilli in the vagina, the good bacteria battle the bad, killing these pathogens. However, only a minority of women have a 'normal', healthy balance of lactobacilli.

MOST WOMEN IN THE WORLD HAVE POLYMICROBIAL VAGINAL MICROBIOTA, "INTERMEDIATE" AND BACTERIAL VAGINOSIS (BV), WHILE ONLY A MINORITY HAVE HEALTHY AND PROTECTIVE LACTOBACILLI ("NORMAL").

Percentage of US women on any given day:



Using personal lubricants increases the risk of BV, which also makes women more susceptible to STIs. This is why it is so important that personal lubricants do not disrupt lactobacilli.

CONSEQUENCES OF LUBRICANT TONICITY

The vagina is always shedding cells—about four layers a day and even more during the menstrual cycle—which are loaded with glycogen. This glycogen is used by lactobacilli to acidify the vagina and protect it with lactic acid. Young women have a lot of columnar epithelium—these are living cells on the surface of the cervix (“cervical ectopy”) that are very susceptible to the tonicity and osmolality of personal lubricants. Over time, this thin columnar epithelium becomes covered over with more layers of cells, providing more protection as women age.

HOW DOES THE OSMOLALITY OF A LUBRICANT AFFECT EPITHELIAL CELLS?

Hyperosmolar (high osmolality)

lubricants draw water out of cells, squeezing and shrinking them until they slough off the surface. As the cells are squeezed, they send out a pro-inflammatory cytokine (NFAT-5) to the immune system, which calls in immune cells that can target cells for HIV and causes rapid shedding of the outer layer of epithelial cells.

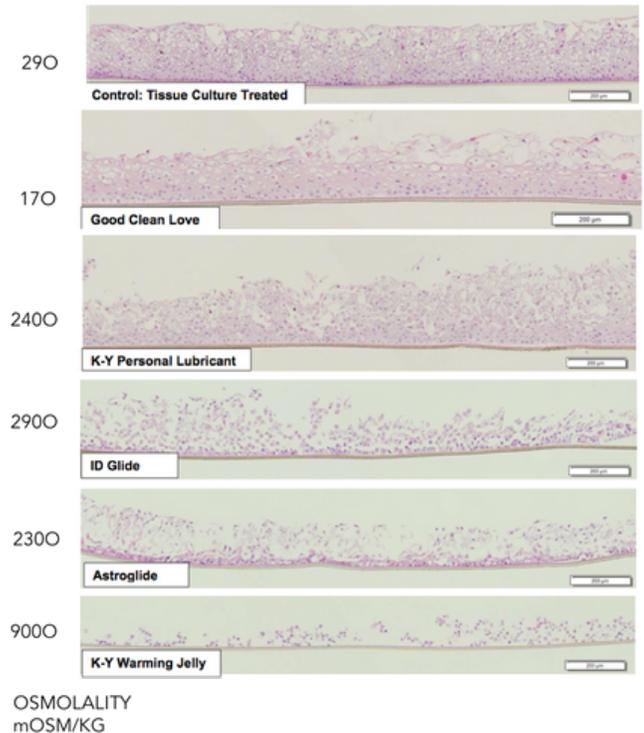
Iso-osmolar lubricants, on the other hand, do not change anything.

When **hypo-osmolar** (low osmolality) lubricants are applied, cells swell and fluid is drawn through the epithelium, concentrating the contents in the lumen of the vagina or rectum.

Histology of EPIVAG 3 dimensional human vaginal epithelium tissue model 24 hours post-exposure (H&E stained)

RANKED BY INCREASING TOXICITY:
Layers of shed cells
Disruptions in basal cell layers

Lubricants with high osmolality are harmful to epithelium and leave women more susceptible to infection.

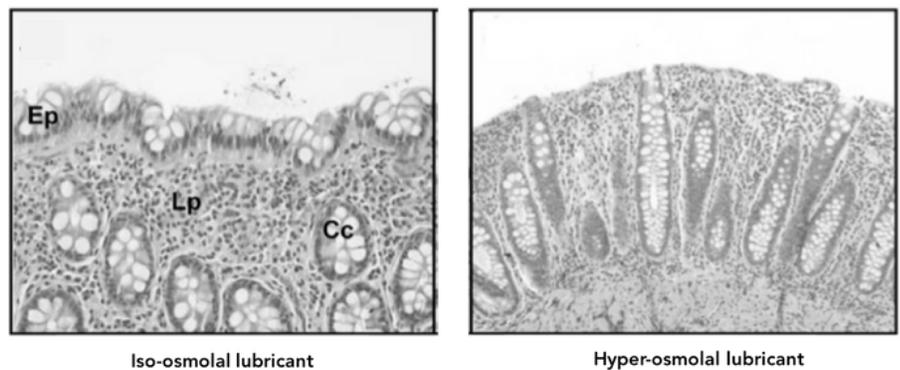


Cone and Ayeahunie, MS in preparation

RECTAL ANATOMY AND THE EFFECT OF HYPEROSMOLAR LUBRICANT

Unlike the vagina, the rectum did not evolve to protect against sexual intercourse. There is no mucus-secreting gland to protect the anus, which is why it is especially important to use lubricants for rectal intercourse. In colonic mucosal biopsy samples (see right), brief exposure to hyper-osmolar lubricant caused the entire layer of epithelial tissue to shed, as well as blood and other fluid.

Hyperosmolar Sexual Lubricant Causes Epithelial Damage in the Distal Colon: Potential Implication for HIV Transmission



Fuchs, Hendrickson et al, JID 2007:195 (1 March)

WHAT IS WRONG WITH HYPEROSMOLAR FLUIDS? A SUMMARY OF THE RESEARCH

- They trigger episodes of BV (Brotman et al, 2008, 2010)
- They trigger the release of pro-inflammatory cytokines (NFAT-5; Neuhofer 2010 Review)
- They cause cell layers to shed and disrupt mucosal integrity in 3D vaginal tissue models (Cone and Seyoum, in prep).
- They cause mucus production and protein secretion by slugs – the more toxic substances they were exposed to, the more mucus they produced (Adreians et al, 2008). (Slugs are a good test model for mucosal epithelia.)
- They increase susceptibility to HIV infection in human mucosal tissue explants (Begay et al, 2011; Dezzutti et al, 2012).
- They cause cellular shedding and disrupt colorectal epithelia in humans (Fuchs, Hendrix et al 2007).
- They increase susceptibility to HSV infections in the mouse vagina (Moench et al, 2010).

In general, the skin that covers the penis, including the foreskin, is tougher than the skin layers in the vagina. So, if a lubricant is safe for the vagina it is generally safe for the penis. However, the smegma or a 'build up' underneath the foreskin can contribute to infection, so hygiene is an important part of disease prevention, and male circumcision can provide a protective effect.

RECOMMENDATIONS FOR LUBRICANTS FOR VAGINAL AND RECTAL INTERCOURSE

- Iso-osmolal – about 300 (100-500) mOsm/kg
- Non-toxic to healthy lactobacilli and vaginal epithelium
- Contain the least toxic preservatives. Sorbic acid at acidic pH seems the best.
- Have good taste, smell, and drying qualities
- Contain no components (oils) that weaken latex condoms
- Have no features that increase HIV infection
- No EDTA calcium chelator – calcium helps hold epithelial cells together, and EDTA, by binding up calcium, opens and weakens the epithelium.

WHAT DO WE NEED TO DO NOW?

1. Solve the drying and stickiness problem for water-based lubricants without resorting to glycol and propylene glycol, which are toxic at high concentrations.
2. Develop and validate more animal models and 3D tissue models. The FDA is working on validating these tissue models – they are increasingly available, and are more affordable than rabbit and monkey tests).
3. Develop a minimum array of lubricants for different users – no one size fits all, but there is a distinct need to develop/identify lubricants that are safe and acceptable for both vaginal and rectal use. For example, low buffer capacity is acceptable for both the vagina and rectum.

Q&A

Q: We know HIV infection for transgender women in Thailand is more than 10 percent. Do you have information or research about the neo-vagina of transgender women and should the lubricants be the same?

A: Across the board, iso-osmolar personal lubricants should be safe for columnar epithelium. Since neo-vaginas tend to be tougher and have no columnar epithelium, they should be safer.

VAGINAL MICROBICIDES: WHAT CAN WE LEARN FROM STUDIES ON LUBRICATION?

MAGS BEKSINSKA, MATCH RESEARCH UNIT,
UNIVERSITY OF THE WITWATERSRAND

Throughout recent history, the idea has persisted that women should practice “vaginal cleansing” for hygiene reasons and for sex. In this session, Mags Beksinska of MatCH reviewed a range of studies on vaginal practices and women’s experiences with vaginal microbicides as they have assumed more agency over HIV prevention.

In Victorian times, there was a preoccupation with women making themselves clean for men, from external genital washing to internal cleansing (douching), topical applications, insertion of substances (sometimes household products), to steaming, smoking, or even cutting their vaginas. A WHO multi-country study of gender, sexuality, and vaginal practices (GSVP) in South Africa, Mozambique, Indonesia and Thailand, found the most common vaginal practices were hygiene related-intravaginal washing (douching), with women reporting they did it to dry or tighten their vagina, but also to lubricate it.

Sensationalist media reports since the late 1980s have popularized the idea that women in Africa and Asia practice, and in fact prefer, unlubricated “dry sex”. Although studies have found that only about 5% of women actually do this, this misconception continues. Even among this 5%, dry sex may not be a preference – a woman may be forced to have sex or to have sex when she is not ready and needs a lubricant.

These various methods and practices have been defined and classified in the research literature (Hilber, 2007), but whether it is called “douching”, “dry sex”, or “vaginal tightening”, the message is the same: vaginal cleansing prior to sexual intercourse increases the pleasure and performance of male sexual partners. A study of urban and rural men from Zimbabwe revealed a cultural preference for “dry sex” and that “wet sex” was not desirable because it reduced friction and sensation during intercourse; prevented the vagina from “heating up”; caused an annoying sound; smelled bad; and was thought to carry germs.

“African and Indonesian women ‘dry’ their vaginas with sand and bleach to make sex more pleasurable for men.”
- *Daily Mail on Sunday, 2014*

HEALTH EFFECTS OF VAGINAL CLEANSING PRACTICES AND UNLUBRICATED SEX

Some studies have reported associations between vaginal practices and STI/HIV acquisition, mediated through the disruption of the vaginal epithelium or increasing bacterial vaginosis (BV). Douching has been found to increase the risk of pelvic inflammatory disease (PID) and even infertility.[6] Other studies report that vaginal practices may result in less condom use and may affect future microbicide use (gel or other formulations that may increase lubrication).[7]

[5] Hilber et al., 2010, “Intravaginal practices, vaginal infections and HIV acquisition: Systematic review and meta-analysis”, *PLoS ONE*, 5e9119.

[6] Ibid.

[7] Allen et al., 2010, “Intravaginal and menstrual practices among women working in food and recreational facilities in Mwanza, Tanzania: Implications for microbicide trials”, *AIDS Behav*, 14: 1169–1181.

VAGINAL MICROBICIDES: WHAT ARE WOMEN AND MEN SAYING?

Vaginal microbicides began to emerge in the early 1990s, giving women more control and agency over HIV prevention. Gels, films, tablets, soft-gel suppositories, creams, and vaginal rings are used to naturally increase lubrication ("wetness"), and studies have been conducted to learn about women's and men's reactions to microbicides and their preferences for lubrication during sex.

THE ACCEPTABILITY OF MICROBICIDE GELS AMONG WOMEN IS OFTEN LINKED TO THE PERCEIVED PROTECTIVE EFFECTS. THIS WAS A TRADE-OFF — THEY DON'T NECESSARILY LIKE THEM, BUT USE THEM ANYWAY BECAUSE THEY ARE BEING PROTECTED.

SEVERAL CONCLUSIONS WERE REACHED:

A woman's ability to use microbicides depends on the kind of relationship she is in. Research has shown that women want to be able to use lubricants covertly, especially with a casual partner. Decisions on whether or not to tell a partner is closely related to whether the partner would notice they were using lubrication and his subsequent reaction.

In areas where dry sex was the stated preference, women feared that men would not like the added lubrication from a microbicide gel since vaginal wetness can lead to sexual promiscuity, infidelity or masturbation, and even the end of a relationship. Forty percent of women involved in a microbicide gel study in South Africa reported experiencing intimate partner violence during the trial and more than half of the incidents were related to participation in the trial - the partner's dissatisfaction with the gel was one issue to be mentioned. Sex workers in Thailand have also reported difficulty with using gel consistently due to difficult clients.

Women have certain preferences for microbicides:

- Neither the partner nor the woman can tell it is there
- Provides extra lubrication and makes the vagina feel "tight"
- Multi-functionality (HIV, STI, pregnancy prevention)
- Short waiting time for it to take effect
- Longer duration of protection (2–3 days)
- Little messiness and leakage
- Clear/translucent colour

Lubrication is reported to enhance sexual pleasure, but this is context specific, especially where "dry sex" is the stated preference. Women often gauge sexual pleasure by how much men are enjoying sex. Generally, increased pleasure from gel lubrication and increased libido from lubricant use had a positive influence on whether women found microbicides acceptable.

In cases where both gel and condoms were used, the increased pleasure from the gel balanced the decreased sexual pleasure from the condom. A US study exploring sexual pleasure and lubricants found that those who experienced an increase in sexual pleasure viewed the gel as a sexual stimulant (rather than as a tool for disease prevention), leading them to want to continue using it after the completion of the trial, regardless of efficacy.

"WHEN YOU MANUFACTURE THIS PRODUCT, MAKE SURE IT DOES NOT PROMOTE WET SEX, BECAUSE THE WOMEN WHO USE IT MIGHT BE THROWN OUT OF THEIR HOMES."
- MALE TAXI DRIVER

Even in contexts where “dry sex” is preferred, there is an awakening that some form of lubrication is good.

A study involving participants from Asia, Africa, South America, and the US found that even in contexts where dry sex was practiced, a certain level of increased lubrication was acceptable to both men and women if they saw it as protecting them against HIV. This same study found that, in general, women are expected to achieve a moderate amount of vaginal lubrication during sex, and that women employ a variety of vaginal practices to achieve this, for example, in Rwanda, using traditional medicines or herbs, inserting Vaseline in the vagina, or drinking alcohol. Women reported there were consequences for not achieving adequate vaginal lubrication, such as experiencing pain during sex, husbands committing adultery, and divorce.

Gel insertion poses challenges, particularly for youth.

Women’s lack of privacy to insert gel before sex and to control the timing of sex interferes with their ability to use microbicide consistently. Timing of gel insertion is especially challenging for adolescent girls, who often report unpredictable, illicit, and rushed sex.

LUBRICANTS & FEMALE CONDOMS

Other than the Women’s Condom, all female condoms are pre-lubricated. The Women’s Condom comes with a water-based lubricant sachet.

Almost all women feel that female condoms are adequately lubricated.

Our studies have shown that almost all women using the Women’s Condom (>95%) added lubricant inside and outside the condom and on the penis.

RESEARCH NEEDS: WHAT DO WE STILL NEED TO LEARN?

A better understanding of “preparation for sex” for both rectal and vaginal sex.

If people are washing and applying lubricant, it may be washed away. We need more information on the volume of lubricant being used, the frequency of use, reapplication, and sites of application in different populations.

Better data on adverse events.

Are they experiencing burning, irritation, or other sensitivities? Adverse events have been collected before, but it is unclear whether they are sex-related (rough sex) or due to condom or lubricant use. We need studies of condom users/non-users in a randomized cross-over design using different lubricant formulations for a defined period.

COMMUNITY-BASED RESEARCH ON LUBRICANT USE FOR RECTAL & VAGINAL SEX: REFLECTIONS OF MSM, SEX WORKER & TRANSGENDER ADVOCATES

DAISY NAKATO, WOMEN'S ORGANISATION NETWORK FOR HUMAN RIGHTS ADVOCACY (WONETHA), UGANDA
PEDRO CARNEIRO, CALLEN-LORDE HEALTH CENTER, NEW YORK CITY
KASIGO OSUPENG, MEN FOR HEALTH AND GENDER JUSTICE, BOTSWANA
THITIYANUN (DOI) NAKPOR, SISTERS, THAILAND
KENNEDY OLANGO, MEN AGAINST AIDS YOUTH GROUP (MAAYGO), KENYA
KENT KLINDERA (MODERATOR), GLAM PROGRAM, USAID

OTHER PARTICIPANTS:

NATT KRAIPET (ASIA PACIFIC TRANSGENDER NETWORK, THAILAND), DERRICIA CASTILLO-SALAZAR (OUR CIRCLE, BELIZE), KYAW ZAYA SWE (JOJO) (ASIA PACIFIC SEX WORKER NETWORK, MYANMAR)

This panel discussion brought together sexual and reproductive health (and rights) advocates from around the world, who shared their experiences in accessing and distributing lubricant, educating key populations about the use of lubricant, and what community members are saying about them. This provided vital feedback for manufacturers and researchers on user needs, behavior, and preferences, since lubricants not only need to be safe, they also need to be liked and accepted by the people who use them.

WHAT KINDS OF LUBRICANTS ARE PEOPLE USING MOST?

Panelists reported that water-based lubricants were the most commonly used commercial lubricants, although availability differed depending on the country. Pedro Carneiro of the Callen-Lorde Health Center in New York City said that the City of New York provides free water-based lubricants with condoms, which the clinic distributes. Water-based lubricants are also provided by Men for Health and Gender Justice in Botswana, while in Uganda, only a small number of organizations have the budget to provide them.

In the absence of commercial lubricant, people are using anything that provides lubrication and is easy to find, from honey to cooking oil, petroleum jelly, and avocado. Daisy Nakato of WONETHA in Uganda pointed out that some people are not receiving enough information about the types of lubricants that are available.

ARE PEOPLE USING CONDOMS WITH LUBRICANT?

In Kenya, access is very difficult in semi-urban and rural areas, but the use and uptake of lubricants is quite high in urban areas where there is a higher concentration of LGBTI organizations. At the same time, MAAYGO's Linkages Project in Kenya is seeing a lot of referrals for STIs, which raises questions about whether people who are taking condoms and lubricants home are actually using them. A New York survey found that condom use for rectal sex is inconsistent (25% reported never using a condom), but 76% of respondents reported using lubricant most times they have sex. In Uganda, condoms are widely used and WONETHA follows up with hospitals on STI referrals, so they know what diseases are in the community.

Among female sex workers, condom use can depend on whether lubricant is available. Since condoms dry out very quickly without lubricant and can break, they may not be used at all if no lubricant is available.

GETTING THE RIGHT MESSAGES OUT

The criminalization of sex work, homophobia, and discrimination against the LGBTI community are serious issues in many parts of the world. Lubricant supplied by the US, for example, has been rejected and returned because governments say it promotes homosexuality. Civil society organizations find themselves walking a fine line between responding to the needs of their community, which use lubricants primarily to enhance sexual pleasure, and their donors, which promote lubricants as a moisturizer to prevent irritation and condom breakage.

Meanwhile, the science is indicating that different lubricants may be needed for rectal and vaginal intercourse, but the economics of supplying and using more than one type of lubricant do not add up. Funding has not been made available for market research with key populations and high-risk communities, nor are their unique sexual and reproductive health needs well understood.

All of this has made it challenging to formulate simple messages about lubricants and speak with one voice. Nevertheless, panelists said there was an urgent need for clear, correct, and consistent messages about lubricant use and safety, and called on manufacturers and researchers to assist in this effort.

PLEASURE

A DIFFICULT MESSAGE FOR GOVERNMENTS & DONORS

Although we know lubricants are a moisturizer and enhance sexual pleasure, this message can backfire with governments that do not want to promote a culture they do not support. In African countries, most sexual health educators and advocates use the HIV pandemic as an entry point and argue that governments should supply lubricant to prevent condom breakage. The CONDOMIZE! campaign also chooses to talk about condoms in terms of HIV prevention since using lubricant with condoms makes them work better (and makes sex more pleasurable).

"No donor agency is going to distribute lubricant for pleasure. There has to be a health component." – Franck DeRose, The Condom Project

Bidia Deperthes of UNFPA pointed out that it is not the role of procurement agencies to talk about pleasure, rather, this is the role of civil society. Franck DeRose suggested that instead of trying to get the perfect messaging on packaging, civil society groups should focus on facilitating better use.

"If we list on a package how the lubricant should be applied to the anus, the product will never reach the end user. Our job is to educate on the ground and we need to be realistic about what we can do. And there will be different messages for sex workers, MSM, and other users."

PACKAGING LUBRICANT & CONDOMS TOGETHER: A POTENTIAL SOLUTION TO DIFFICULT MESSAGING?

SAFETY

Messages about safety and disease prevention must always be based on research and clarify common misconceptions, for example, that lubricant by itself can protect against HIV and other STIs.

No lubricant has ever been shown to protect against HIV and STIs. Lubricants only help to prevent condoms from breaking. Lubricants are not a microbicide and will never protect against HIV or other STIs until there is an anti-HIV microbicide or other chemical barrier to STI available.

Lubricants must be condom compatible. Any product in a bathroom or kitchen should never come close to a condom – they are oil-based and will weaken latex condoms.

"HIV infection is very high among sex workers. After 20 sex acts a day, natural lubrication is not possible and condoms are breaking. For sex workers, this is where the conversation starts. We need lubricants not to promote pleasure, but to ensure the sex we are having with our clients is safe." – Daisy Nakato, WONETHA

"EVERYONE NEEDS CONDOMS AND LUBRICANT. IF THEY COULD BE PACKAGED TOGETHER, THIS WOULD TAKE THE BATTLE AWAY FROM US, AS IT AVOIDS DIFFICULT MESSAGING WITH GOVERNMENTS AND GIVES EVERYONE ACCESS." – DAISY NAKATO, WONETHA

ARE WATER-BASED OR SILICON-BASED LUBRICANTS AFFORDABLE AND ACCESSIBLE?

In Botswana, there is limited availability and free lubricants are only accessible in urban areas. In Uganda, water-based lubricant is not easily accessible and people often bring it back when they travel abroad. However, lubricant may be included in the budget through the Global Fund. In Kenya, the government provides water-based lubricant, normally procured from Malaysia and India, but lubricants are often within 3-4 months of the expiration date and the procurement process is not well understood. In New York City, where lubricant can cost \$12 or more, many rely on city-supplied lubricants. “Transgender women who have to pay \$12 for their estrogen at their clinic will probably choose estrogen over lube,” Pedro Carneiro said.

COMMUNITY NEEDS & RECOMMENDATIONS

We need more information and simple messages.

For sexual health educators, the conversation has moved on from advocating condom use. Now, they need more information, research and straightforward, consistent messages about lubricant to help people make smarter choices about their sexual health. For example, what is lubricant for? Is it to facilitate sex or to reduce the risk of HIV infection? What lubricants are safe to use with condoms and which ones weaken them? It is important, panelists said, to consider the full range of sexual practices and what lubricant will be used for, where, and how long. This will affect messages about comfort, dryness, acceptability, osmolality, and safety. They asked that both manufacturers and researchers play a role in providing this information.

We need more research on lubricants and transgender sexual health. Doi Nakpor expressed frustration that most people do not understand the sexual and reproductive health of transgender people. There is a lack of research and data, he said, on how many trans people in Thailand have undergone surgery, the sexual health issues they are experiencing (elasticity, wounds, bleeding), and the effects of lubricant on neo-vaginas, which do not lubricate naturally.

We need more safety testing. Manufacturers need to go the extra mile to test lubricants for safety and potential adverse effects. Skin irritation tests are not enough. “Rubbing lubricant on your hand does not indicate the safety of putting lubricant in the rectum or vagina.” Daisy Nakato reported that sex workers are reporting itchiness and irritation after using commercial lubricants and when this happens they use other forms of lubrication instead

We need better labelling and more information on ingredients.

In the NYC survey, 21% reported an allergic reaction from lubricants either rarely or sometimes. Although the public is highly educated about condoms and latex allergies, the survey indicated fewer people know what is in their lubricant and how to use them properly. For example, which ones should be used for rectal sex? Can oral sex be performed safely after a lubricant is applied? Should there be safety warnings for the eyes, face, and mouth? Packaging needs to include clear instructions on how much lubricant to use, how many times a day it can be used, where on the body it can be applied, and the potential side effects. Even if the user receives no education about their lubricant, the directions on the package should be sufficient – clear and easy to understand.

“THE ROLE OF COMMUNITY, ESPECIALLY AROUND HIV, IS VITAL. SEVERAL HAVE DONE RESEARCH ON WHAT PEOPLE IN THEIR COMMUNITIES ARE USING, WHAT THEY’RE NOT USING, AND HAVE RECOMMENDATIONS ON HOW TO PUSH THE AGENDA FORWARD.”
– KENT KLINDERA, USAID

“A symbol or other information on a package would be helpful for indicating whether the lubricant is condom compatible, or to explain that it is just a moisturizer. This way, it can be marketed both for pleasure and HIV prevention.”
– Pedro Carneiro, Callen-Lorde Health Center

“It is important to have a list of ingredients on the package: a lot number, batch number, and list of ingredients to make people feel comfortable with the product. In Africa, some communities feel uncomfortable using lubricant as it is. Lubricants should be as traceable as condoms.”
– Franck DeRose, The Condom Project

RAPID ASSESSMENT: PERSONAL LUBRICANT AVAILABILITY, USE, AND FUTURE PLANS IN EAST AND SOUTHERN AFRICA

KANYANTA SUNKUTU, TECHNICAL SPECIALIST,
ESA REGIONAL OFFICE, UNFPA

In this session, Kanyanta Sunkutu of UNFPA's Eastern and Southern Africa (ESA) Regional Office presented the results of the first phase of a rapid assessment study on the availability of personal lubricants in 21 of the 23 ESA countries where UNFPA has a regional office. The objectives of the study were to assess the availability of personal lubricants, barriers to making personal lubricants available, and recommend solutions.

BACKGROUND

Of the 521 million people in ESA, 32% (167 million) are 10 to 24 years old and 31% use contraception – a huge potential market for lubricant manufacturers. Of all Africa's regions, ESA is most affected by HIV. It has been a major contributor to maternal mortality, and young women are particularly affected.



The region faces a number of other challenges:

- Significant widespread gender-based violence
- High pregnancy-related school drop-outs
- High population growth rate and decreased mortality and high fertility in 15 countries

BARRIERS TO MAKING LUBRICANT AVAILABLE IN ESA

- Governments have very negative views toward men having sex with men and it is criminalized in many ESA countries. Since lubricants are associated with MSM and a significant number of governments are resistant to MSM programming, which is seen as aiding and abetting homosexuality.
- Lubricants are not prioritized in procurement plans or planned for as a commodity.
- Supply chain systems do not include lubricants, e.g. in distribution plans.
- Service providers and clients may have low awareness, skills, and demand for lubricants.
- When lubricants are packaged separately from condoms, service providers say they have difficulty linking them .

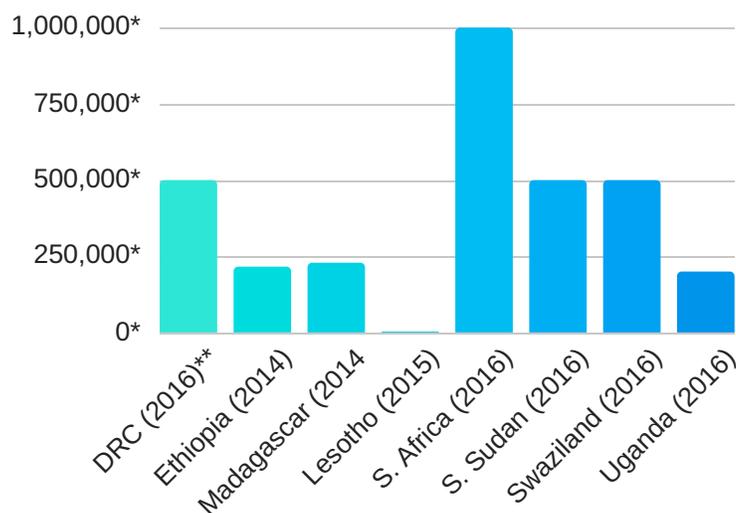
METHODOLOGY OF THE STUDY

The study was conducted using a field-tested questionnaire that was shared with colleagues in ESA country offices via Survey Monkey. The response rate was 15 countries out of 21. Responses were analysed using Survey Monkey and manual comparative analysis.

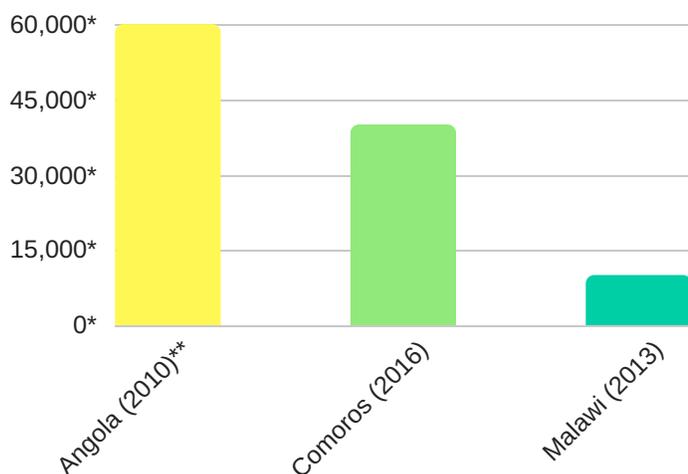
STUDY RESULTS

It was found that just over half of the countries procured and received lubricants (8 out of 15). Lesotho ordered the least (5,000) and South Africa the most (1m). Uganda was a surprise: 200,000 units were ordered in 2016 despite having only recently approved the use of lubricants for public health programs.

COUNTRIES THAT PROCURE LUBRICANTS



COUNTRIES THAT DO NOT PROCURE LUBRICANTS, BUT RECEIVE THEM FROM THE GLOBAL FUND



* Number of sachets ordered

**Year last ordered

COUNTRIES THAT DO NOT PROCURE LUBRICANTS

- Eritrea
- Namibia
- Kenya
- Zimbabwe

Except for a few countries (South Africa, South Sudan, Swaziland, DRC), lubricant orders have been small and inconsistent (Malawi). Lubricants are primarily supplied by UNFPA, the Global Fund, USAID, DFID, and others (governments, such as in Lesotho and South Africa), and generally target female sex workers, MSM, and the general population. But do the people who need lubricant most actually receive it? Five of the eight countries that purchased lubricants had no planned interventions for demand generation.

Seven of the 15 countries did not procure lubricants at all (although some received them from the Global Fund). Zimbabwe does not allow lubricants into the country and the products would require registration. Even when countries have approved lubricants for purchase, this does not necessarily translate into orders. Ministries of Health still have concerns about safety, such as in Swaziland.

OPPORTUNITIES FOR MANUFACTURERS

COUNTRIES THAT DO NOT CURRENTLY HAVE PROGRAMS THAT SUPPORT LUBRICANT, BUT HAVE ORDERED IN THE PAST (E.G. ANGOLA), ARE A MARKET OPPORTUNITY FOR LUBRICANT MANUFACTURERS.

SOUTH AFRICA IS ANOTHER POTENTIAL MARKET SINCE THERE ARE CURRENTLY NOT ENOUGH SUPPLIERS ON THE GOVERNMENT'S TENDER LIST.

RECOMMENDATIONS

A global guidance note on pairing condoms and lubricants

Prepare a global guidance note and subsequent country orientations on packaging condoms and lubricants together. We need to talk about always using condoms and lubricants together and the guidance note would support specific programming needs.

Link procurement and packaging

Operationalize existing UNFPA recommendations to link procurement and packaging in certain cases (e.g. 6 condoms, 1 sachet of lubricant). Could manufacturers routinely package condoms with lubricants? We need to determine how much would this cost.

Conduct operational research

Study the reasons behind public acceptance of lubricant use and the feasibility of selling lubricants in the private sector market in ESA.

Manufacturers should try to get on South Africa's tender list

More lubricant is wanted in South Africa, but there are not enough suppliers on the government's tender list.

Advocate for lubricant with national governments

Prioritize lubricant use in national programs and increase national procurement of lubricants.

Q&A

Q: I see a lot of opportunities for packaging condoms and lubricants together. Did you include social marketing organizations in the survey?

A: We did not – that will be the second phase of the study. We will look at other providers and a whole market approach in all countries. We will also look at community acceptance and the reasons for use or lack of use.

A BIG DEBATE

THREE DAYS OF MEETINGS GENERATED LIVELY DEBATE ON HOW TO PRODUCE LUBRICANTS THAT ARE SAFE AND EFFECTIVE FOR A VARIETY OF USERS AND SEXUAL PRACTICES.

One issue received a great deal of attention: *Is it feasible to produce and market a single, one-size-fits-all lubricant that is acceptable, safe, and appropriate for everyone?*

These are the highlights of those discussions.

“There is a big difference between the “front and the back”. Is it possible to have a different kind of lubricant for different body parts?”

“I have a lot of experience providing products to high-risk populations who cannot use commercial lubricants anymore because it hurts too much. Trying to make a non-toxic lubricant for highly degraded epithelial tissue is completely different from making standard personal lubricant for healthy people, who are happy with anything if they’re not sensitive to the ingredients. It’s all about sexual preferences and practices and whether they’re using it for two minutes or two hours.”

– Paul Whyte, Gel Works

“Saying that lubricant for rectal sex cannot be the same as lubricant for vaginal sex is going to be a difficult message to relay to governments in Africa because they will not purchase separate lubricants. It is also a difficult message to convey to sex workers because it is not practical – they will only use one. If there are lubricants that can serve both purposes, they can at least be safer.”

– Daisy Nakato, WONETHA

“We need lubricants that are safe. And then temper that with ones that are effective in different populations. Couples that have intercourse a few times a week will have a very different experience than those who have high-risk sex several times a day.

One potential differentiation between vaginal and rectal lubricants is pH, but osmolality may also be different. What’s worse? Damage to the rectum or vagina caused by osmolality or damage caused by an ineffective lubricant? This is a balance we need to think through.”

– Bill Potter, Stapleford Scientific Services Limited

“One size not fitting all is true from an academic standpoint, but considering how lubricants are used, especially in resource-limited settings, is this realistic? I don’t think we want to have different types of lube for different types of sex.”

WHAT'S NEXT?

The Global Consultation on Personal Lubricants was an opportunity for lubricant manufacturers, researchers, civil society organizations, and international donors and procurers to develop recommendations and individual and joint actions to move the lubricant agenda forward. Below are the main outcomes of the meeting and next steps.

MAIN OUTCOMES & RECOMMENDATIONS

- 1. Manufacturers will develop detailed technical specifications, standardized definitions for measurement, and formulas for a safe, non-toxic, single product lubricant based on the recommendations of this meeting.**
- 2. Develop and test products** based on these specifications where needed.
- 3. An advocacy meeting will be held in 2017** (although the timing will depend on whether new specifications have been developed). It is hoped that the United Nations, together with civil society, will take the lead on this meeting, inviting government officials from several countries where lubricant is not currently made available. The goal of the meeting will be to educate national governments about lubricant formulations (non-toxic, safe to use), how lubricants help to reduce susceptibility to HIV/STIs when used in combination with condoms and, in turn, have an impact on the AIDS and STIs epidemics and reaching global health targets.
- 4. The next step will be marketing these new products and making them available and affordable to those who need them most.** Perhaps manufacturers can take the lead on discussions about marketing, including packaging, placement, and price.
- 5. The Advisory Note should be updated to include recommendations for national governments on post-shipment testing for lubricant.** The recommendations would be similar for condoms and other medical devices whereby national governments are responsible for ensure the products coming into their country are good quality. Post-shipment testing is based on a risk-based approach (identifying products at risk of not meeting quality standards and performing testing on 50%, 100%, or other proportion of products).

"We're not yet at the advocacy stage, and we still need more research, but we can move forward on developing clear definitions and updating the Advisory Note. The next step after that is to take this to the country level and work with governments to move these products to the users who need them most."
– Peter Godfrey-Fausset, UNAIDS

Manufacturers, researchers, and civil society have important and complementary roles to play in improving the safety, availability, and usage of personal lubricants. The short-term (<year) and long-term (>year) priorities, action points, roles, responsibilities, draft budget, suggested funding sources, and timeframes are outlined on the following pages.

MANUFACTURERS

RECOMMENDATIONS & ACTION PLAN



MAIN TASKS

1. Form a working group to create standardized definitions for measurement, technical specifications, and formulas based on the recommendations of this meeting. Since the manufacturers have established systems already, there will be costs involved in changing them, getting board approval, etc.

2. Develop and test products based on these agreed standards. The products will need to meet market needs, comply with international standards, and be suitable and safe for both vaginal and rectal use (a single product will avoid the problem of stigmatization).

3. Investigate new findings on glycol type. New evidence emerged during the week of the Global Consultation that threw into question whether high osmolality was the sole contributor to cytotoxicity or whether other factors are also at work.

Recent studies found that two lubricants with high glycol content and high osmolalities but different types of glycol gave completely different cytotoxicity results—both lubricants were around 7,500 mOsmol/kg, but one scored 4 on cytotoxicity (highly cytotoxic) whereas the other scored 0 (non-cytotoxic). Meanwhile, two lower osmolality lubricants (ca 1,800 mOsmol/kg) with similar glycol content and the same preservative system were compared; one was found to be highly cytotoxic (score 4) and the other non-toxic (score 0).

How can this be explained? It could be because these formulations contained different glycols, and certain glycols can promote ingress of the preservatives into the cells. The type of glycols used appears to be very important.

TECHNICAL SPECIFICATIONS

Note: This is not a final draft. Manufacturers will invest resources to develop more specific recommendations.

Also note: These recommendations are for water-based lubricants only, since they are the most commonly used, requested, and procured.

1. Labelling – the label should include:

- Manufacturer's name and physical address
- Shelf life after opening for multi-dose products
- Preservatives and potential allergies
- Regulatory labelling requirements
- Manufacturing and expiration dates
- "Not a contraceptive"
- For sachets: "Single use only"
- "Not for the prevention of HIV/STIs"

2. Condom compatibility – Adopt or adapt the ASTM standard for condom compatibility

- No property should change by $> \pm 20\%$
- Naked or lubricated condoms? (ASTM D7661 specified naked condoms, but this is impractical since there is not a source for naked commercial condoms)
- UNFPA to specify condoms to be used in test - criteria to be set, transparency in selection, publicly available information on selection and the final list s be very important.

"THERE'S A LOT MORE TO UNDERSTAND ABOUT THE FORMULATIONS OF THESE LUBRICANTS AND WHAT MAKES THEM TOXIC AND NOT TOXIC, AND MANUFACTURERS ARE GOING TO NEED TO COLLABORATE TO FIND OUT WHAT'S GOING ON. IF TOXICITY IS NOT JUST OSMOLALITY, WE CAN PROBABLY MAKE SAFE LUBRICANTS THAT ARE NOT CYTOTOXIC, BUT HIGHER OSMOLALITIES THAN WE CURRENTLY THINK IS ACCEPTABLE."

– BILL POTTER, STAPLEFORD SCIENTIFIC SERVICES LIMITED



3. Preservatives

- Minimum amount required to provide effective preservation
- Conforms with anti-microbial USP <51>, harmonised

4. Types of glycol

- Leave this up to manufacturers
- State what is used – provide safety data, including name of the monograph if available.

5. **Osmolality** – Keep recommended upper limit at 1,200 mOsm/kg subject to further data. Defining a safe zone or range is difficult without data to support the change. Efforts will be made to explore the existing data and the data from the research proposed at this meeting.

6. **Cytotoxicity** – Use the US FDA-recommended ISO 10993-5 method.

7. Lubrication/Lubricity – How do we determine what is enough?

- A standardized definition is needed.
- Need to explore the different available methods for measuring lubricity and propose acceptance criteria.
- Collaboration – explore other parameters, such as coefficient of friction, viscosity

8. **pH** – Currently the preferred pH for the vagina is 4.5 and for the rectum it is 5.5–7.0. A pH range of 4.5–7 in combination with low buffer capacity, so the pH will adapt to the location it is applied (see 9 below), is acceptable for both vaginal and rectal use.

9. **Buffering capacity** – Set a specification limit for the buffering capacity of lubricants so the lubricant will adapt to the pH of the environment it is in (i.e. the vagina or rectum). A test method and a limit for buffering capacity need to be developed.

10. Stability

- Require stability studies over 30°C to 60°C
- Bio-burden and challenge tests included in assessment
- Preservative content versus effectiveness (preservative effectiveness will need to be monitored during stability studies – it is the most important property)
- Viscosity
- For multi-dose presentations – in-use stability studies, storage when stored inverted
- Reference conditions – Climatic Zone IVb (30°C ± 2°C, 75% RH ± 5% RH)
- Clear requirements – protocol and report

11. Microbial examination at release USP-EP-JP for bioburden

12. Packaging

- Pack for single use in aluminum pack (4ml and 5ml)
– amount based on historical use of aluminum foil, but this can be changed.
- Container/tube for multiple use
- COAs and suitability/compatibility test reports to be submitted by manufacturers

13. Package seal integrity – recommend dry vacuum method (to be published)

14. Shelf life – depends on product but:

- Minimum of 3 years, 3–5 years allowed
- 75% shelf life remaining at port of entry

OTHER RECOMMENDATIONS



1. **Monitor adverse events** – There is a gap and we need to actively seek feedback on all contraceptive devices. We will need to partner with NRAs since they are usually responsible for this.
2. **UNFPA to facilitate acquisition of female condoms for testing of lubricants.**
3. **UNFPA to consider guidance to Member States on testing of lubricants.**
4. **UNFPA to facilitate discussion on follow up work on the impact of glycols on cell toxicity.**

ACTION ITEMS: SHORT TERM (<1 YEAR)

PRIORITY	RESPONSIBILITY	TIMEFRAME
Labeling – not for prevention of HIV/STIs unless used with a condom	Manufacturer (depending on regulatory requirements and UNFPA’s needs)	6 months
FHI360/USAID to facilitate discussion on follow-up work on the impact of glycols on cell toxicity	FHI360	12 months
Preservative, glycol type & osmolality guidance	UNFPA	3 months
Lubrication & lubricity	UNFPA	12 months
Buffering capacity	UNFPA Assistance from Richard Cone, JHU	3 months
Develop standards for stability, packaging, package seal integrity (interrelated but stability is the priority)	UNFPA	3 months
Shelf life studies	Manufacturer	12 months
UNFPA to consider guidance for Member States on testing of lubricants	UNFPA	12 months

ACTION ITEMS: LONG TERM (>1 YEAR)

PRIORITY	RESPONSIBILITY	TIMEFRAME
Condom compatibility	UNFPA	UNFPA will set the standard within 3 months. Manufacturers will complete it within 12 months and submit progress report.
Cytotoxicity	Manufacturer	15 months



PACKAGE SEAL INTEGRITY: A NEW SPECIFICATION FOR THE WHO/UNFPA/FHI360 ADVISORY NOTE

“WHEN WE SHIP CONDOMS AND LUBRICANT IN THE HUNDREDS OF THOUSANDS, THERE IS ALWAYS LEAKAGE. WE CAN’T SEND LUBRICANT THROUGH THE UN SYSTEM ANYMORE BECAUSE OF THE LEAKAGE. THE QUESTION IS HOW MANY BOXES ARE GOING TO LEAK.” (FRANCK DEROSE, THE CONDOM PROJECT)

“Package seal integrity has always been a problem in the condom industry. One leaking condom sachet in a box will cover the rest. We’ve improved it, but we need to get leakage rates down to 1 in 700 to solve this problem. We need to change the sampling, the AQLs, etc. to get to the point where we can ship condoms without leaking. However, if we changed the requirements today, manufacturers probably wouldn’t be able to ship condoms for several years, so we’re doing this progressively.” (Bill Potter, Stapleford Scientific Services Limited)

WHAT IS THE BEST TEST FOR LUBRICANT PACKAGING: THE DRY METHOD OR THE WET METHOD?

“The wet test will not work for lubricant packs. The dry method detects staining and is much more sensitive and reliable. We constrain the pack in a holder with absorbent paper on either side, apply a vacuum, maintain as long as necessary, and look for leakage. This seems like a sensitive and reproducible test. UNFPA will be using this method for condoms.” (Bill Potter, Stapleford Scientific Services Limited)

Package seal integrity has always been a problem in the condom industry. One leaking condom sachet in a box will cover the rest. We’ve improved it, but we need to get leakage rates down to 1 in 700 to solve this problem. We need to change the sampling, the AQLs, etc. to get to the point where we can ship condoms without leaking. However, if we changed the requirements today, manufacturers probably wouldn’t be able to ship condoms for several years, so we’re doing this progressively.” (Bill Potter, Stapleford Scientific Services Limited)

DOES THE PACKAGING MATERIAL (METAL, ALUMINUM, ETC.) IMPACT THE LUBRICANT AND CHANGE THE QUALITY AND THE SHELF LIFE?

“In some regions, these products are exposed to different regulatory requirements, but for UN agencies they are medical devices, so we need to know it is stable throughout the claimed shelf life, backed up with data from stability studies and independently reviewed.” (Seloi Mogatle, UNFPA)

HOW TO REPORT QUALITY ISSUES

There is now a quality complaint form on the UNFPA procurement website: unfpaprocurement.org

Anyone can complete this form and report problems such as leaky packaging.

PACKAGE TESTING IN HIGH-ALTITUDE REGIONS

UNFPA has received reports from high-altitude regions about packages leaking, so it has been working with national regulatory agencies to tighten up the testing and requirements.



RESEARCH PRIORITIES

PRIORITY 1: CLINICAL RANDOMIZED TRIAL WITH SEX WORKERS & MSM

Although money is limited, doing one key trial would allow us to look at safety and behavioural/acceptability issues at the same time. The study would provide baseline behavioural information by analyzing:

- **Lubricant practices** (e.g. acceptability outcomes, volumes used, reapplication, site of application, cleansing practices before and after use, lubricant use with condoms, oral sex exposure, rectal sex (sex workers))
- **Intensity of use** (sub-analysis)
- **Lubricant preferences and use in different populations.**

HOW IT WOULD WORK:

- Participants (sex workers and MSM) would use either water-based lubricant, silicone lubricant, or no lubricant with condoms, for perhaps six months. Participants would have to agree to be in one of the three arms.
- Participants would be counselled on how to use lubricant and condoms – experience using condoms is very variable depending on the types of relationships sex workers have.
- Participants would be tested and treated for STIs/BV at enrollment. (Even in young people, BV rates are high –50% in South Africa—so among sex workers it could be much higher.)
- Look at incident infections of STIs/BV over a defined period and reporting of adverse events (e.g. burning, irritation). Trial could potentially be a three-period randomized cross-over design.
- HIV rates may be high among sex workers and HIV+ women would either be screened out (this wouldn't be an efficient or effective use of resources—in South Africa, 30-40% of women might be screened out) or kept in the study and just look at STIs.
- Participants will be able to use as much water-based lubricant as they want as long as they report the volume and frequency of use.
- Which lubricants to include in the study is to be determined, but perhaps commonly available lubricant with an osmolality of <1200 mOsm and pH that is suitable for both rectal and vaginal sex.
- Propose that a 3D tissue model be developed and different lubricants characterized in parallel with the clinical trial. A working group made up of MatCH, FHI360, and WHO/UNFPA/UNAIDS will develop a concept note for the clinical trial by Q1 of 2017.



PRIORITY 2: BASIC SCIENCE

We need to fund more basic science on lubricants, including:

- Examining silicone lubricants using tissue models
- Reformulating lubricants with lower osmolality and longer drying time
- Ingress and egress of volatile silicones

PRIORITY 3: LITERATURE REVIEWS, OPINION PIECES, AND ADVOCATE FOR FUNDING RESEARCH

Write an opinion piece for a peer-reviewed publication urging the FDA to reconsider the safety testing requirements for lubricants (the rabbit vagina model is inappropriate). Not sure whether this would be enough to change policy.

Write a review of lubricant experience from microbicide trials and vaginal practices studies.

Prepare the UNFPA-commissioned Systematic Review for publication. This will help to inform the Advisory Note because it needs to be based on evidence.

Conduct a review of the silicones manufacturers use (formulations, etc.).

Finalize a review of increased incidence of STIs and BV that may be the result of lubricant use.

ACTION ITEMS: SHORT TERM (<1 YEAR)

PRIORITY	RESPONSIBILITY	FUNDING SOURCE	TIMEFRAME
Concept note for clinical trial	MATCH, FHI360, WHO/UNFPA/UNAIDS	USAID for proposal	Proposed: Q1 2017
Evaluate silicone lubricants in tissue models	Richard Cone, JHU	Part of clinical trial	2017
Opinion piece	Ellen Kersh, CDC	Proposed: UNFPA	TBD
Review of lubrication experience	Mags Beksinska, MATCH	UNFPA	End of Q2 2017
Submit systematic review for publication	UNFPA, University of Zimbabwe	UNFPA	Early 2017

ACTION ITEMS: LONG TERM (>1 YEAR)

PRIORITY	RESPONSIBILITY	FUNDING SOURCE	TIMEFRAME
Lubricants with lower osmolality and longer drying time	Richard Cone, JHU	Ongoing	Ongoing
Ingress and egress of volatile silicones	Paul Whyte, Gelworks	Planned (Australia)	TBD
Review of silicones used by manufacturers	Paul Whyte, Gelworks	Ongoing	Ongoing
Finalize review of increased STI and BV incidence	Paul Whyte, Gelworks Paul Whyte, Gelworks	Ongoing	Ongoing



OTHER SUGGESTIONS FOR RESEARCH

Add a validation test to the clinical trial

Since manufacturers must do a series of safety studies to get regulatory approval for their product, adding a test (e.g. cytotoxicity test using a tissue model) to the clinical trial would give them another way to evaluate safety. This type of trial would be expensive to conduct and they probably wouldn't do it independently. Cross-validation of a human trial would also give us a better way to come up with new formulations.

Conduct a laboratory study to understand how lubricant affects the neo-vagina and new tissues

All our studies are about men and women and original genital parts. Could we try to understand the different kinds of tissues being used for constructed vaginas to determine how safe it is to use lubricants?" Or, if transwomen were included in the sample for the clinical trial, we could still look at adverse events like burning and irritation, but with other tissues.

Create an advocacy and education piece in addition to the opinion piece

An advocacy piece could come out of this meeting and future research that communicates the science of lubricants, how lubricant interacts with new tissues and neo-vaginas, or mixing and matching lubricant with sex toys. We also need to have an education piece for the people we are counselling and this could come out of the research as well.

We could learn from the research on surgical lubricants

The National Institute of Health (NIH) in the US is funding two quite large clinical trials of surgical lubricants where the same issues arise in terms of damage to epithelial tissue. Lubricants are used a lot in surgery and in childbirth (used many times in the process), so this is an opportunity for those interested in personal lubricants to find out what is going on with surgical lubricants.

COMMUNITY

RECOMMENDATIONS & ACTION PLAN



USER PREFERENCES & ADVOCACY

1. Better explain lubricant safety to our communities with correct, consistent messages through community education and effective communication strategies, such as:

- Lubricants do not protect against HIV – they help to prevent condom breakage/failure
- Lubricants must be condom-compatible – certain products should not be used with condoms or when having any kind of penetrative sex.
- Many lubricants are toxic to the vagina and rectum, causing cellular damage.
- Lubricants have various uses – explain how, when, and why lubricant should be used • Other relevant messages (safety of douching and other sexual preparation acts)

2. Use inclusive, non-stigmatizing messages – lubricants are an essential commodity and choice for everyone.

- Include the needs of trans women and other sexual minorities (other uses, sex toys)
- Be careful about messages that are solely about pleasure

3. Support the identification and characterization of various user preferences, such as:

- Quantity/packaging
- Viscosity/long lasting
- Flavoured/scented

WHAT WE NEED FROM RESEARCHERS

1. Clear information about optimal lubricant formulations for vaginal and rectal use and the safest form of lubricant for all. There is a desperate need for this.

2. Evidence for the relative safety of lubricant use:

- Continued understanding/investigation of HIV/STI/RTI susceptibility
- Is it safer to use than not using lubricant? Maybe for certain activities and not others
- Is silicone safer than water-based?
- Is a hybrid safer – silicone/water-based mixed?

3. Inclusive evidence of lubricant safety (and other issues)

- Especially among transgender women (effects with hormones, use with neo-vaginas)
- Both with condoms and without condoms
- Sexual preparation (douching) and other sexual health-related issues



WHAT WE NEED FROM MANUFACTURERS

1. Commitment to providing a safe/safer product

- Meeting community needs and ensuring safety
- Quality assurance needs to recognize evidence related to toxicity (formulations should perhaps be iso-osmotic, optimal pH levels, etc.)
- Support better understanding of regulations (treated as a medical device? Effect of greater regulation)

2. Support development and availability of additional options

- Other formulation possibilities (silicone, hybrid, other); silicone-based not widely used/available in Africa
- Product that combines hormones for transwomen with lubricant possible?

3. Various packaging options and feasibility

- Package condoms and lubricant together (needs to be perforated, single use, have a tube next to the condom, match shelf life of condom) – we'd like more information about these issues
- Need a sachet as small as possible so it is discreet/anonymous – can fit them in your pocket or bra/ use two smaller quantity ones instead of one
- Potential to package condoms with extra lubricant/silicone (non-stigmatizing, would get through government regulation; would need to educate users)
- Recognize how important packaging is (free condoms/lubricant need to look like commercial products)

WHAT WE NEED FROM PROCUREMENT AGENCIES (UN, USAID, CIVIL SOCIETY)

1. Develop and promote an updated advisory note on safe and condom-compatible personal lubricants.

The note should promote lubricants as an essential commodity that is available and accessible to everyone, perhaps linked to global targets like 90-90-90 (could be access to condoms AND lubricant)

2. Develop a more inclusive definition of personal lubricants that includes both pleasure and HIV/STI prevention.

- Inclusive definition (needs of trans people, other sexual minorities, with/without condoms)
- Be careful about pleasure messages (especially working with governments in Africa)
- Avoid stigmatizing lubricants (should be a choice for everyone, rectal use not only MSM)

3. Guidance on optimal procurement

- Information on size/packaging of “standard” sachet – understanding more about quantity
- Guidance/equation for quantities (# of sachets/person, ml per condom – ex. 1 sachet of 5mL per condom?)



ACTION ITEMS: SHORT TERM (<1 YEAR)

#1 Form a Community Lubricant Task Force/ Advisory Group/ Reference Group

Responsibility: Daniel McCartney, IPPF

Timeframe: 2017

- Use Listserv/WhatsApp group to communicate
- Work together to advocate with researchers, manufacturers and procurers for safer lubricant; to inform researchers/manufacturers/procures about various issues/preferences in our communities:
 - Assist manufacturers with labelling, packaging, etc.;
 - Assist researchers in understanding/users
- Utilize the resources we have to reach communities and understand where our communities are at
- Be relevant – continue to advocate the safety agenda on behalf of communities

#2 Develop a survey/assessment for our communities (ask same questions) to gather information on lubricant use, preferences, access, what they know about lubricant safety (are they having reactions, irritation, etc.)

Responsibility: Community Lubricant Task Force

Timeframe: 2017

The survey would include questions such as:

- Do they benefit from lubricant (how they see it)? Did they have problems using it?
- Would you rather condoms with our without? Sachels? Tubes?
- Do you have access to lubricant/if so – how/where? You buy it yourself?
- Start by sending around surveys that have been used in the past
- Focus on effects of using lubricant
- Work on understanding what communities know about safety standards
- Potentially ask providers

Note: Mario Festin of WHO pointed out there are standard questionnaires for this and suggested that the questionnaire for the proposed clinical trial (see Research Priorities) could perhaps be shared or combined.

ACTION ITEMS: LONG TERM (>1 YEAR)

PRIORITY	RESPONSIBILITY	TIMEFRAME
Develop a long-term message about safety and how to market lubricant for communities	Community Lubricant Task Force, IPPF & UNFPA	Beyond 2017
Focus on the development agenda: health promotion/ disease prevention/ family planning	Community Lubricant Task Force, IPPF & UNFPA	Beyond 2017
Focus advocacy on COMFORT – less so on pleasure	Community Lubricant Task Force, IPPF & UNFPA	Beyond 2017
Once we have a safer product, we will advocate for: <ul style="list-style-type: none"> • Including lubricant in national strategic plans • Including lubricant in procurement with condoms 	Community Lubricant Task Force, IPPF & UNFPA	Beyond 2017

GLOSSARY OF TERMS

Additional lubricant – Any lubricant used in conjunction with a condom that is applied to either the condom or the vulva, anus, or inserted into the vagina or rectum.

Buffering capacity – A measure of the efficiency of a lubricant in resisting changes in pH. Conventionally, buffer capacity is expressed as the amount of strong acid or base, in gram-equivalents, that must be added to 1 liter of the solution to change its pH by one unit.

BV – Bacterial vaginosis is a common condition in which the balance of bacteria inside the vagina becomes disrupted.

Cytotoxicity – The degree to which an agent has specific destructive action on certain cells. Cytotoxicity of lubricants can be assessed using a number of standard procedures specified in ISO 10993-5.

Epithelium/Epithelial – The thin tissue that forms the covering of most internal and external surfaces of the body and its organs.

Hyper-osmolality – A solution having an osmolality greater than the cells with which it is in contact.

Hypo-osmolality – A solution having an osmolality less than the cells with which it is in contact.

Iso-osmolality – A solution having an osmolality that is equal to that for the cells with which it is in contact.

Key population – A specific population that is being considered, such as sex workers or MSM.

Microbicide – Substances that kill or reduce the infectivity of viruses or bacteria added to lubricants as preservatives or spermicides. Common microbicides found in lubricants are nonoxynol-9, carrageenan, cellulose sulfate, chlorhexidine gluconate, and sodium dodecyl sulfate.

Osmolality – A measure of the number of dissolved particles per kg of solvent (water).

Osmolarity – A measure of the number of dissolved particles per litre of solution.

Personal lubricant – Any fluid, gel, cream or liquid used during human sexual acts such as intercourse and masturbation, to reduce friction to or between the penis and vagina, anus, or other body part.

pH – The measure of a liquid's basicity or acidity on a scale from 0–14, 0 being most acidic and 14 being most basic (specifically the pH is the negative log₁₀ of the hydrogen ion concentration where the concentration is expressed in moles per litre).

Polyquaternium – A number of polycationic polymers that are used in toiletry and cosmetic formulations.

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GLOBAL CONSULTATION ON PERSONAL LUBRICANTS

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