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FEMALE CONDOMS AS A MEANS TO REDUCE THE TRANSMISSION OF HIV AMONG MAASAI WOMEN

by

Lisa R. Boeger

Associate of Science in Nursing, Hibbing Community College, 2003

An Independent Study

Submitted to the Graduate Faculty

of the

University of North Dakota

in partial fulfillment of the requirements

for the degree of

Master of Science

Grand Forks, North Dakota

May

2013

PERMISSION

Title

Female Condoms as a Means to Reduce the Transmission of HIV Among Maasai

Women

Department

Nursing

Degree

Master of Science

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Date 16 January 201

Cover Letter:

The following article has been prepared for the *African Journal of Primary Health Care & Family Medicine*

Article Title: Female Condoms to Reduce HIV Among Maasai Women

Significance of Work: AIDS is a major threat to the health and well-being of the Maasai. Female condoms are the only female-initiated means of preventing sexually transmitted infections such as HIV, and pregnancy. Empowering women with an option of self-protection increases their negotiation power in the debate over condom use, thus increasing the use of both female and male condoms, leading to the ultimate positive effect of increased *protected* sex.

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Summary: Article is 4,408 words, 23 pages, and contains three tables.

1 Abstract

- 2 Background: HIV/AIDS continues to present a serious threat to the health of Maasai
- 3 women. Many confounding factors including: the subservient status of women, practice
- 4 of polygamy, and wife-lending place Maasai women at high risk for AIDS. Female
- 5 condoms are the only female-initiated measure for preventing sexually transmitted
- 6 infections, offering negotiating power in the debate over condom use.
- 7 **Objectives**: The scope of this article is to examine the efficacy and practicality of female
- 8 condoms as a barrier method for HIV prevention among Maasai women.
- 9 Method: The following electronic reference databases were searched using both text
- words and subject headings: CINAHL, Cochrane Library, PubMed, TRIP, U.S.
- 11 Preventative Services Task Force, National Guideline Clearinghouse and Europa World
- 12 Plus. Search terms included: female condom, female and male condom, female barrier,
- 13 and Maasai.
- 14 Results: A review of the literature indicates that female condoms are cost effective, an
- effective barrier method for both contraception and STI protection, and generally
- accepted. Current barriers that have prevented the uptake of the female condom use
- include: a lack of systematic introduction, a lack of knowledge in the general population
- concerning female condoms, and cost. Further research on female condoms utilizing
- 19 standardized failure mode definitions and failure rates would be beneficial.
- 20 Conclusion: Female condoms are effective, and need to be introduced in conjunction
- 21 with education for maximal effectiveness. Women in subservient status would greatly
- 22 benefit from the systematic introduction of female condoms, in particular to decrease
- 23 the transmission of HIV among the Maasai.
- 24 How to cite this article: Boeger, L.R., Ralph, J. Female condoms to reduce the
- 25 transmission of HIV among Maasai Women. Afr J Prm Health Care & Fam Med.

Introduction

AIDS and the Maasai

In 2010 sub-Saharan Africa represented 70% of all people who acquired HIV infections globally, but only accounts for only 12% of the world's population.¹ Surveillance among the Maasai is limited, making it difficult to establish the actual prevalence of the disease, though its known to be extremely common.² In areas where testing centers are accessible, HIV rates were found to be as high as 21% in regions of Tanzania where Maasai dwell.² HIV/AIDS is a major threat to the health and well-being of the Maasai.

At least 90% of people infected with HIV/AIDS in Africa do not know they are HIV positive, primarily because of the expense and scarcity of testing.³ The prevalence of HIV among the Maasai has significantly impacted their mortality and quality of life, making it a critical concern for healthcare professionals providing care to that population.

Maasai Women are at High Risk for STIs

Several independent factors exist that contribute to young Maasai women being a high risk population in the AIDS epidemic.

Young Women: The predominant mode of transmission of HIV in Africa is heterosexual intercourse.³ Women are particularly vulnerable to the AIDS epidemic in sub-Saharan Africa. Women in sub-Saharan Africa aged 15-24 years are 3.4 times more likely to become infected with HIV than young men.⁴ Two contributing factors for this increased risk seen among young women in sub-Saharan Africa include gender norms and forced sex.⁵ Cultural gender norms encourage: males to have multiple, often much

younger sexual partners, limited education among females, and limited access to healthcare.^{5,6}

Biological, sociocultural, economic, and political factors are also seen as contributing factors.⁶ According to Mavedzenge, Doyle, Phil, and Ross [7] there are several considerations that contribute to the high risk status of adolescents living in sub-Saharan Africa: "lack of knowledge, poorly developed life skills, lack of parental mentoring, lack of financial autonomy, early sexual debut, sexual coercion, and limited access to health facilities" (p. 568).

Maasai: Maasai are in a particularly high-risk group. The Maasai are fully nomadic pastoralists who reside in Kenya and Tanzania.⁸ Because of their nomadic lifestyle in extremely rural areas, the Maasai have limited and sporadic access to healthcare and condoms, and knowledge about HIV/AIDS is low.⁹ An independent individual risk factor for acquisition of HIV in a wide range of settings is migration.¹⁰ Most migrant Maasai who travel to urban areas for work are not having sex in town, but HIV is seen as a town problem while rural areas are mistakenly seen as "clean" and disease free.¹⁰

Maasai Women Specifically: Polygyny, wife-lending, and the tendency for girls to lose their virginity before puberty all contribute to their high risk.⁸ As among the Maasai, "the subordinate status of women in many countries makes negotiating male condom use with partners especially difficult" (p. 2).¹¹ In sub-Saharan Africa, an estimated 60-80% of HIV positive women contracted the virus from their husband.⁶ Some Maasai women lack control over their sexual decisions because of culturally associated gender inequalities which make abstinence and male condom use difficult.⁶

Sexually transmitted infections (STIs) are a major cause of morbidity among the Maasai, however there is little social stigma associated with them. A Maasai specific study revealed that knowledge of HIV/AIDS was high; however, understanding prevention methods was low, particularly condoms and their correct use. Another confounding factor is the ambiguity of the language surrounding HIV/AIDS among the Maasai. The ambiguity leads to the assumption by some Maasai that "HIV is no different from other diseases that cause weight loss" (p. 1002).

Literature Review

The following electronic reference databases were searched using both text words and subject headings: CINAHL, Cochrane Library, PubMed, TRIP, U.S. Preventative Services Task Force, National Guideline Clearinghouse and Europa World Plus. Search terms included: female condom, female and male condom, female barrier, and Maasai. Additionally, references from relevant studies were examined for supplementary relevant citations.

The Strength of Recommendation Taxonomy (SORT) tool criteria were used to grade levels of evidence for utilizing the study in practice and determining the strength of a recommendation based on a body of evidence. SORT utilizes an algorithm for assessing levels of evidence that assigns a value to individual studies. This level of evidence is reflected by the numeric score assigned. Table 1 illustrates how recommendations are graded for strength and Table 2 illustrates how individual studies are rated for quality.

Table 1. How recommendations are graded for strength using the Strength of Recommendation Taxonomy Tool.

Strength of	Definition
recommendation	
A	Recommendation based on consistent and good-quality patient-
*	oriented evidence.*
В	Recommendation based on inconsistent or limited-quality patient
	oriented evidence.*
С	Recommendation based on consensus, usual practice, opinion,
	disease-oriented evidence, or case series of diagnosis, treatment,
	prevention, or screening.*

^{*} Patient-oriented evidence measures outcomes that matter to patients: morbidity, mortality, symptom improvement, cost reduction, and quality of life. Disease-oriented evidence measures intermediate, physiologic, or surrogate end points that may or may not reflect improvements in patient outcomes.(Adapted from Ebell et al, 2004).¹²

Table 2. How recommendations are graded for strength.

Study Quality	Diagnosis	Treatment/prevention/screen	Prognosis
Study Quanty	Diagnosis	Treatment/prevention/screen	110g110515
		ing	N.
Level 1: Good quality patient-oriented	Validated clinical decision rule	Systematic review (SR) /meta-analysis of RCTs with consistent findings	SR/meta-analysis of good-quality cohort studies
evidence	SR/meta- analysis of high- quality studies	High-quality individual RCT	Prospective cohort study with good follow-up.
	High-quality diagnostic cohort study	All-or-none study	
Level 2:	Unvalidated	SR/Meta-analysis lower-	SR/meta-analysis of
Limited-quality	clinical decision	quality clinical trials or of	lower-quality
patient-	rule	studies with inconsistent	cohort studies or
oriented		findings	with inconsistent
evidence	SR/meta-		results
	analysis of		
	lower-quality	Lower-quality clinical trial	Retrospective
	studies or	or prospective cohort study	cohort study with

	studies with inconsistent findings	Cohort study	poor follow-up
	Lower-quality diagnostic cohort study or diagnostic case-control study	Case-control study	Case-control study Case series
Level 3: Other evidence	practice, opinion, (intermediate or p	lines, extrapolations from bench other evidence disease-oriented ohysiologic outcomes only), or o tment, prevention, or screening	d evidence case series for studies

104 (Adapted from Ebell et al, 2004).¹²

How female condoms address the risk

Female condoms are defined by the World Health Organization (WHO) as

A device that is designed to be used by the woman to prevent pregnancy and/or sexually transmitted infections during vaginal intercourse. It is distinguished from a male condom by being retained in the vagina after insertion. The external component of the device usually provides some protection to the external female genitalia. (p. 4)¹⁴

Female condoms are the only female-initiated means of preventing pregnancy and STIs such as HIV.¹⁵⁻¹⁷ Female condoms offer several advantages over male condoms. The most significant advantage is empowering women with an option of self-protection increases the negotiation power of women in the debate over condom use, thus increasing the use of both female and male condoms with the positive effect of increased *protected* sex.^{18, 19} This accomplishes the ultimate goal of decreased transmission of HIV. It offers women the right to protect themselves from STIs instead

of merely relying on males to initiate protective measures. This especially benefits women in subservient statuses, as seen among the Maasai. The first generation of female condoms are made of polyurethane plastic which is stronger than the latex used in male condoms and isn't weakened by oil-based lubricants.²⁰ The second generation of the female condom is made of nitrile and contains no seams and is produced at a lower cost.²¹ Nitrile is similar to the material used in synthetic latex surgical gloves used for people who have latex allergies.²¹ Furthermore, total clinical failures decreased among the second generation of female condoms.¹⁷

The female condom offers several advantages over the male condom. They can be inserted up to eight hours before sexual contact occurs. ²² They are designed for single use only, as with male condom. ^{20,22} The female condom doesn't require an erect penis and can increase the spontaneity of sex. The design of female condoms offers more physical coverage to both the female and male partners. ^{11, 14} No serious local side effects or allergies have been reported from use of the female condom. ^{11,20} The female condom has been shown to not: alter the vaginal flora, cause significant skin irritation, or result in allergic reactions or vaginal trauma. ^{22,23} In a study using the presence of Prostate Specific Antigen in vaginal fluid as a measure for exposure to semen, male and female condoms were found to be equally effective barriers. ²⁴ Female condoms are generally accepted by male partners, some citing the novelty factor as a motivation for their use. ^{22,25}

Though some feel female condoms are ineffective, male and female condoms have been found to be almost equally effective barriers to semen exposure. 4,24,26 The female condom covers internal and part of the external female genitalia which may provide additional protect against STIs spread by skin or mucosal surface contact such as herpes, syphilis, chancroid, and HPV.6,20,27

Drawbacks of female condoms

While there are many advantages to the female condom there are also limitations. They are more expensive than male condoms, female condom failure and mechanical problems can result from their improper use, and women report being hesitant to using them. Complaints concerning the female condom include: feeling the outer and inner ring of the female condom and discomfort during sex which may be overcome with practice on use. After use, 59.5% of participants reported that female condoms were acceptable and 65.3% of participants reported that they would recommend the female condom to others. Discomfort with insertion and use of the female condom decreased with increased experience with the female condom. The noise associated with the use of first generation female condoms has been reduced with the second generation because of the different material used.

Education has proven to diminish the limitations of improper use and hesitancy in utilizing the device. Studies find that with education sessions, an improvement in the acceptability and proper use of female condoms increased.^{15, 18}

Female condoms are more expensive than male condoms. The Joint United Nations Programme on HIV/AIDS negotiated a public sector price of \$0.58 USD per condom for the first generation of female condoms. Male condoms cost \$0.03 USD per unit. The price difference has decreased with the production of the second generation of female condoms. Holtgrave et al [28] found that the second generation female condom has retained its effectiveness but is much lower in cost. With the production of the second generation of female condoms, cost decreased to \$0.22 USD per unit when purchased in bulk, reducing the price gap between male and female condoms.

Several factors have been implicated for the poor uptake of female condoms: lack of systematic introduction, lack of support from policy makers, less information on the product and high production costs.^{6, 28,29} Two themes emerge as critical barriers: availability and awareness. Information and knowledge concerning female condoms among the general population is limited.^{25, 28} This leads to misinformation concerning the female condom. Gynecologic healthcare products for women have historically taken time to gain popularity. For example, almost three decades passed between the first major marketing campaign and widespread use of the tampon.⁶

Efficacy

The WHO has recognized the lack international standardization for studying the effectiveness and safety of the female condom. A technical review committee convened to address this issue and compile definitions of failure modes associated with the female condom as outlined in *Table 3*.30

Table 3. Failure Modes of Female Condoms Defined by the World Health Organization.

Failure Modes	Definition
Slippage	A female condom that slips completely out of the vagina during intercourse.
Misdirection	Vaginal penetration whereby the penis is inserted between the female condom and vaginal wall.
Invagination	Part or the entire external component of the female condom being pushed into the vagina during intercourse.
Total Breakage	Female condom breakage at any time before, during or after intercourse. Includes both clinical and non-clinical breakage.

Non-Clinical Breakage	Breakage without adverse clinical consequences: breakage noticed before intercourse or occurring after withdrawal of the condom from the vagina.
Clinical Breakage	Breakage with potential adverse clinical consequences: breakage during intercourse or withdrawal of the female condom from the vagina.
Total Clinical Failure	The number of female condoms that clinically break or slip, or are associated with misdirection or invagination, during intercourse or any additional failure mode(s) identified in the risk assessment.
A Condom Failure	A condom for which a non-clinical breakage, a clinical breakage or a slippage occurs, or is associated with misdirection or invagination or any additional failure mode(s) identified in the risk assessment.

(Adapted from World Health Organization, 2007). 30

There is no international standard for testing female condoms. Two methods currently exist for study: patients reporting failure modes of the female condom and the use of Prostate Specific Antigen (PSA) in vaginal fluid. PSA in vaginal fluid is a method for testing whether semen exposure has occurred and has been used to assess male condom effectiveness. Macaluso et al [24] found 14% of male condom uses and 17% of female condom uses were positive for PSA, indicating that semen exposure had occurred. Macaluso et al [24] indicated that self-reported problems associated with the female condom included: breakage, misrouting, invagination, slippage and "other mechanical problems" (p. 90). The study found that breakage among female condoms is rare, but mechanical problems are more common than among male condoms. Incorrect use of the female condom was common in the study, including not holding the rim while removing the penis from the vagina, which could be mitigated with education. Macaluso et al [24] found male and female condoms to be similarly effective in

preventing semen exposure. Semen exposure decreased as experience increased with the use of female condoms.^{6, 24}

The WHO standard for male condoms is breakage rates less than 5%.¹⁷ Breakage rates for male condoms range from 2.4 - 6%.¹⁷ Breakage rates in Bekisinska et al's study [17] for the first generation of female condoms was 0.7% and 0.9% for the second generation of female condoms, which are both lower than breakage rates for male condoms. Fewer women using the second generation of female condoms reported that it was uncomfortable to use when compared to the first generation.¹⁷ Additionally, total clinical failures decreased from 5.2% with the first generation of female condoms to 4.3% among the second generation of female condoms.¹⁷ Failure modes between the first and second generation of female condoms are functionally equivalent when used effectively.^{17,30}

Invagination was found to be the most common type of female condom failure by Beksinska et al [31] and generally occurs during first female condom use. With education and experience, invagination of the condom significantly decreases. Breakage, slippage, misdirection, spilling of ejaculate after removal, and pulling out of the vagina, thus acting like a male condom are other failures of the female condom studied by Beksinska et al.³¹ Each of these types of failures decreased significantly with experience (after 3 uses) and education.³¹ Practice on a pelvic model and insertion with feedback from a nurse decreased insertion difficulty from 25% to 3 %.²⁹ Mantell et al [29] also found that breakage and slippage rates fell from 20% to 1.2 % from the first to fifteenth use. In another study that assessed trichomoniasis re-infection among women who used female condoms and found no participants had been reinfected after 45 days.¹⁹ A controlled study in Thailand showed that when both male and female

condoms were available, the rate of STI transmission was reduced by one-third when compared to the rate of a similar group that solely had access to male condoms.²²

A study in Zambia found couples reporting unprotected sex decreased from 42 to 10% after the introduction of the female condom.⁴ In the US an increase from 38-76% of protected sex acts was reported with the introduction of female.⁴ Studies in both the US and Thailand found a higher proportion of protected sex acts and a decrease of STI incidents were found in the study arms that included female condoms.⁴

Results from in vitro testing conducted before FDA approval of the female condom showed the female condom to be impermeable to both the cytomegalovirus and HIV.¹⁵ A study by French et al [15] suggested that participants in the female condom arm of the study were better protected from STIs than the male condom arm. Beksinska et al [31] recommends that education and follow-up counseling after five uses of the female condom drastically decreases improper use and acceptability of the condom.

How female condoms increase negotiating power

The female condom offers a key advantage over the male condom: it can be used at the initiative of the woman, giving women the ability to take control of their health.

It is critical for a woman to have a method to protect herself from STIs and pregnancy.

Female condoms are entirely under the control of a woman, and eliminate the need for protection negotiation in consensual intercourse. They also increase the negotiating power of women who have access to them, increasing the likelihood of protected sex, whether it is with a male or female condom. Provision of and access to the female condom decreases the number of unprotected sex acts in the population.

4

Measures of effectiveness

In Washington D.C.'s female condom program, an economic evaluation was conducted. The evaluation indicated that "the provision and promotion of female condoms in Washington DC is a highly productive use of public health investment" (p. 1119).²⁸ From an economic standpoint, female condoms have been shown to be costeffective by decreasing STI transmission, including HIV.²⁸

The female condom is more expensive than the male condom, but can be cost-effective because of its ability to increase the number of protected sexual acts.²² The female condom becomes more cost effective and even cost-saving as the level of risk for STIs/HIV increases among users and their partners.²² The female condom also expands barrier protection and contraception options. A systematic review showed that female condoms could prove to be cost-effective in rural South Africa but requires that they be promoted well and targeted effectively.⁴

Programs

Many programs exist that aim to prevent the spread of HIV, however prevalence remains high. "Most HIV/AIDS prevention programs in Africa have largely failed because the research behind them is focused primarily on risk groups, behavioral change models, and flawed understandings of cultural practices and economic conditions" (p. 585).³² A systematic review found strong evidence supporting HIV prevention strategies including: providing information, HIV testing and counseling, and providing and teaching on use of condoms.⁷ Furthermore, "Community involvement and engagement has great potential for improving health, including changing established norms, values, and traditions that may impede HIV prevention and care, increasing the support young people need, and improving access to necessary information and services" (p. 575).⁷

27.0

In 2004, the Kenyan government followed the example of several countries and agreed to support the distribution of female condoms along with male condoms. After education on and access to free female condoms in voluntary counseling and testing services centers in Kenya, a steady increase in uptake was noted.²⁵ In the Kenyan clinics that participated in education on female condoms, males as well as females reacted enthusiastically.²⁵

Discussion

Female condoms and education can greatly reduce the incidence and prevalence of HIV in the Maasai's patriarchal society. The male condom has, and will probably continue to be the key contraceptive and barrier method utilized.²⁴ Female condoms offer an additional choice in preventative health. They are effective because of their ability to increase the negotiating power of women in the debate over protected sex, thus increasing the overall likelihood of protected sex. The female condom offers a key advantage over the male condom: it can be used at the initiative of the woman, giving women increased ability to take control of their health.¹⁵

Many studies involving the comparison of male and female condoms may be inherently biased as male condoms are used much more often and they are more familiar to the general population.^{4, 6, 24} Even with this bias, studies continue to show the effectiveness of the female condom as an effective barrier method for both pregnancy and STIs. When experience with the female condom is gained, failure modes decrease and acceptability increases.²⁴

Practical Implications

The WHO [22] outlines a planning process for introducing the female condom: 1)

Develop a national team to co-ordinate activities, 2) Organize a stakeholders' meeting to put the female condom on the public health agenda and gain a mandate for developing a strategic plan, assess user needs and service capabilities and currently available methods and services. 3) Outline the context for the introduction of the female condom.

4) Draft a strategic document. Use the document to gain consensus from all stakeholders. 5) Implement pilot intervention with monitoring and evaluation. 6)

Feedback, revision and going to scale. This offers a structured, organized approach to the female condom's introduction amongst Maasai females.

An HIV prevention program directed at female Maasai should include: educational sessions concerning the correct use of the female condom incorporating female pelvic anatomy models, motivational interviewing, and supply of female condoms to Maasai women during sexually active years. Education increases the female condom acceptability and its use. Mash, Mash and de Villers [33] suggested incorporating motivational interviewing into the educational sessions would be beneficial. Implementation would occur in several phases. Pre-change activates include: securing an adequate supply of female condoms and training pelvic models, training local health care providers on proper use and instruction, arrangements for an appropriate area to conduct the educational sessions, the use of word of mouth to advertise, and the transportation of female condoms and pelvic models to remote areas.

Implementation would require that the health care providers be proficient in Maasai language and culture. The Rapid Assessment Response and Evaluation (RARE) model was adapted by Birks et al [32] utilizing community engagement to examine the impact of HIV/AIDS among the Maasai at Ngorongoro. Their findings echoed Coast's study [10] identifying cultural awareness and consideration of cultural practices are

imperative for a successful HIV prevention program. As the WHO [22] suggests, some populations may benefit by introducing and promoting the female condom as a contraceptive method. It is important to incorporate local understanding and culturally appropriate HIV interventions for a program to be successful.¹⁰

Education on both HIV and the use of female condoms is important. "Correct knowledge about HIV is strongly associated with reported behavior change" (p. 1005). 10 Coast [9,10] has shown that language surrounding HIV/AIDs is ambiguous and knowledge about the disease process is limited. With implementation of these practice recommendations, women in this high risk population are enabled to practice preventive care and protect their health and well-being.

Limitations

More research is needed using the standardized definitions of failure modes outlined by the WHO and comparing the effectiveness of the female condom to the male condom. Established guidelines and standards for testing and evaluation of female condoms are also necessary to fully test their efficacy in a standardized way. ^{17,30} Surveillance data in rural areas of sub-Saharan Africa is limited. It is difficult to measuring the impact of an intervention in sub-Saharan Africa because accurate epidemiological data is currently lacking.

Recommendations

- The SORT tool will be used as a basis for assigning the strength of each recommendation.
 - 1. Implement two provider-led educational sessions concerning the correct use of the female condom and general information on HIV including transmission

modes. These sessions will incorporate the use of a female pelvic anatomy crosssection model and female condom model. (Level A).

There are both positive and possible negative implications associated with this practice recommendation. Increasing awareness of an additional protective measure from HIV/AIDS among providers and the target audience is crucial. Education has been shown to decrease the failure rate of female condoms. ^{17,18,31} This form of protection may have ethical implications among some providers and participants depending on their religious and cultural beliefs concerning contraception.

2. Supply female condoms to Maasai women during sexually active years. (Level B).

The implication of this recommendation is an additional prevention strategy for women to protect themselves. The mere act of having a female condom increases a woman's negotiating power of protective methods with their partner. 11, 15,19 HIV/AIDS incidence can be decreased among the Maasai with the consistent and correct use of female condoms.

Conclusion

The objective of this article was to examine the efficacy and practicality of female condoms as a barrier method for HIV prevention among Maasai women. Available research indicates female condoms are effective barrier methods, acceptable, and cost-effective. Introduction of female condoms needs to be systematic and include education for maximal effectiveness. Women in subservient status, such as Maasai women, could greatly benefit from the introduction of female condoms in conjunction with HIV

education. Female condoms offer women the opportunity to take increased control of their reproductive health. Further HIV surveillance in rural areas of sub-Saharan Africa is needed to determine effectiveness of interventions introduced among this population. Future research of female condoms should incorporate the standardized definitions of failure modes as presented by the World Health Organization.

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Room: CRSC 103

Location: Thesis/Independent Study

Cabinet

Female Condoms Reduce HIV Maasai

Women



CSC11535