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Inconsistencies on U.S. Departments of Health Websites Regarding Anal Use of the Female Condom

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Abstract

The female condom (FC) is FDA approved to prevent pregnancy and sexually transmitted infections during vaginal intercourse, but not for use during anal intercourse. Studies suggest that a sizeable proportion of men who have sex with men use the FC for anal intercourse despite lack of safety and efficacy information. We reviewed Department of Health (DOH) websites for U.S. states (n = 50) and major municipalities (population >500,000; n = 29) regarding anal use of the FC. Fortyeight (60.8 %) websites mentioned the FC, of which only 21 (45.8 %) mentioned anal use. Of those that mention anal use, 8 (38.1 %) supported, 13 (61.9 %) were neutral, and 1 (4.8 %) discouraged this use. Ten websites (47.6 %) provided instructions for anal use of the FC-ranging from removal of the inner ring, leaving the inner ring in place, and either option. In the absence of safety and efficacy data, U.S. DOH websites are providing different and often contradictory messages about the FC for anal sex.

Keywords

Female condom;	Anal sex; l	Men who	have sex	with men;	Department of	health	website

Introduction

The female condom (FC) has been evaluated and approved by the Food and Drug Administration (FDA) for pregnancy and disease prevention when used during vaginal intercourse [1], but its safety and efficacy for HIV/STI prevention during anal intercourse have not been demonstrated. Despite the lack of data, a number of studies have documented that a significant proportion of men who have sex with men (MSM) use the FC for anal sex, with prevalence estimates ranging from 13 to 21 % [2–5]. Distinct from the male condom, the FC has two rings, an inner ring that fits over the cervix to hold the condom in place during vaginal intercourse and an outer ring which sits outside of the body [1]. Some may remove the inner ring for improved comfort when using the FC for anal sex, however, the removal of the inner ring may cause it to slide out during use, leading to reduced efficacy [2]. In the absence of safety and efficacy data, the recommendations regarding anal use of the FC are based on anecdote.

Department of Health (DOH) websites are resources that the public often refers to for information about HIV prevention. Given that anal use of the FC is prevalent while safety and efficacy data on this use are lacking, we conducted a comprehensive review of DOH websites to investigate their messages regarding the FC for anal sex.

Methods

Website Search

An independent search of DOH websites for all 50 U.S. states and 29 major U.S. municipalities was conducted by at least two reviewers (KR, CV-D, ML, & EK), with the most recent review occurring January-March, 2014. A major U.S. municipality was defined as an urban area with a population >500,000 based on 2000 census estimates. The search terms used were "female condom," "condom," "HIV prevention," "female condom for anal sex," and "anal sex." In addition, website menus were used to navigate to sections where the FC might be discussed, such as HIV/STI prevention and contraception.

A DOH website was classified as containing relevant information if the webpage itself provided FC information or if it had a posted document with FC information, even if the document was originally published by another source (e.g. an MMWR or CDC report). We did not classify a website as providing pertinent information if it directed the user to an unaffiliated website or a PDF located on another website that was sponsored by an independent organization. In a few cases, DOH websites provided links to information on another website that was sponsored by the DOH (i.e. a DOH affiliated website). In those cases, we counted the information as being provided by the DOH.

Here we report our findings regarding the general mention of the FC on DOH websites, as well as messaging specific to FC use during anal intercourse. Among those websites that do mention anal use of the FC, we also describe whether the messages appeared to be supportive of this use, discourage it, or neutral. In the neutral category, we include messages that specified that the FC can be used for anal sex but the safety and/or efficacy was unknown, as well as websites that included a short statement about using male or FCs for

vaginal and anal sex that one might interpret to mean that the FC can be used for anal sex even if this was not the intention of the website. For example, the Maryland DOH states "It is recommended that people either abstain from sex or protect themselves by using barriers such as latex condoms, dental dams and FCs whenever having oral, anal or vaginal sex [6]." While it is possible that the website did not intend to say that the FC can be used for anal sex by this statement, it could be interpreted that way. Four websites with such general statements are included in the neutral category (Arkansas, Maryland, Illinois, and Milwaukee).

Data Analysis

Summary statistics are presented to describe the percentage of public DOH websites that discuss the FC at all and what they say specifically about its use for anal intercourse overall and stratified by state versus municipality. The Fisher's exact test was used to assess the statistical significance of any differences in information by state versus municipality websites. Statistical significance was set at $\alpha = 0.05$ and all analyses were conducted in SPSS 20.0 (Chicago, IL).

Results

Of the 79 websites searched, 48 (60.8 %) mentioned the FC, and of those, 22 (45.8 %) mentioned use of the FC for anal sex. Of the sites that mentioned the FC for anal sex, 9 (40.9 %) had messages that were supportive of this use, 12 (54.5 %) were neutral, while one (4.5 %) website specifically discouraged use of the FC for anal sex, stating that "Female condoms should not be used for anal sex, as they do not provide adequate protection. Because use of the FC during anal sex requires removal of the inner ring, the FC is unlikely to stay in place during anal intercourse [7]" (Table 1).

Only ten (45.5 %) of the websites that mention anal use of the FC provided instructions regarding the inner ring. Of these ten websites, seven explicitly instructed users to remove the inner ring, one said to leave it in, and two said the user could either leave it in or remove it. Out of the ten websites that also provided instructions regarding how the FC should be inserted when used for anal sex, five sites recommended inserting the FC directly into the anus before sex, two suggested placing the FC on the penis first and then using the penis to insert the FC into the anus, and three suggested that either method could be used (Table 1).

State and municipal DOH websites differed in terms of the information they provided on the FC. More state websites mention the FC (72.0 % state vs 41.4 % municipal, p = 0.009), but of those that mention the FC, more municipal websites mentioned anal use of the FC (33.3 % state vs 83.3 % municipal, p = 0.006). Of the websites that mention anal use of the FC, municipal websites were more likely to provide instructions regarding the inner ring (25.0 % state vs 70.0 % municipal, p = 0.084) and insertion methods (25.0 % state versus 70.0 % municipal, p = 0.084), although the difference was of only borderline significance (Table 1).

Details about each DOH website are presented in Table 2.

Discussion

Of the 48 websites that mention the FC, 45.8 % specifically mention the product for anal use. However, the messaging on the DOH websites about the FC for anal sex is inconsistent, with some providing unwavering support of its use, others somewhat less supportive, and one state strongly discouraging this use. Furthermore, the instructions provided for anal use of the product varied in terms of the inner ring and insertion methods. The information included on a DOH website is likely determined by a number of different factors, including the political climate of the area. In addition, some DOHs may have a policy to follow the precedent of federal health organizations such as the Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (DHHS). At present, the DHHS provides no information regarding the FC for anal use while the CDC states on its website that "some people use FCs for anal sex. However, we do not know how well FCs prevent HIV and other STDs when used for anal sex. But we do know that HIV cannot travel through the nitrile barrier [8]." The varied messaging about anal use of the FC on DOH websites suggests that in the absence of safety and efficacy data, there are different policies being used in deciding what to post on the website. FCs are designated by the FDA as class 3 devices, while male condoms as class 2. This means that any label change for the FC to include anal sex would require more research and evidence than such a change for a male condom [9].

There are a number of limitations to this study. As in any content analysis, the analysis is descriptive and limited by the availability of information on the websites searched. Thus we did not evaluate educational and/or promotional materials that may be available from the DOH but not posted on the website. Additionally, it is possible that some information was overlooked as websites can sometimes be difficult to navigate and search engines do not always work as well as they should.

Despite these limitations, it is clear that the messaging around the FC for anal intercourse varied widely. Such inconsistencies in the recommendations regarding use of the FC for anal sex may lead to confusion, uncertainty, and distrust of the FC among the public. Ultimately, people may be placed at increased risk by either using the device in an unsafe way or by not using the product at all, thus potentially missing an additional opportunity for protection. Safety and efficacy studies are needed in order to assess the FC for anal sex and to determine the optimal method for its use if it is proven safe and effective. In the meantime, efforts should be made to design appropriate and consistent messaging about anal use of the device given the current uncertainty and lack of evidence so that people receive the same information no matter what DOH website they are viewing.

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 $\label{thm:constraint} \textbf{Table 1} \\ \textbf{Summary of number (\%) of public health department websites that discuss the FC} \\ \textbf{overall and for anal intercourse} \\$

	All DOH websites N (%)	State DOH websites N (%)	Municipality DOH websites N (%)	Fisher's exact P-value for difference between state and municipality
Total	79 (100.0)	50 (100.0)	29 (100.0)	NA
Any mention of the FC	48 (60.8)	36 (72.0)	12 (41.4)	0.009
Among those websites mentioning the FC, they include information on anal use	22 (45.8)	12 (33.3)	10 (83.3)	0.006
Tone of message suggests they				
Support this use	9 (40.9)	3 (25.0)	6 (60.0)	
Discourage this use	1 (4.5)	1 (8.3)	0 (0.0)	
Are neutral regarding this use	12 (54.5)	8 (66.7)	4 (40.0)	
Among the websites that mention anal use of the FC, Instructions are provided regarding the inner ring	10 (45.5)	3 (25.0)	7 (70.0)	0.084
Instructions recommend:				
Removing inner ring	7 (70.0)	3 (100.0)	4 (57.1)	
Leaving inner ring in condom	1 (10.0)	0 (0.0)	1 (14.3)	
Either remove the inner ring or leave it in, depending on preference	2 (20.0)	0 (0.0)	2 (28.6)	
Among the websites that mention anal use of the FC, Instructions regarding method of applying the, condom are provided	10 (45.5)	3 (25.0)	7 (70.0)	0.084
Instructions for insertion recommend:				
Inserting it directly into the anus prior to sex	5 (50.0)	2 (66.7)	3 (42.9)	
Placing it on the penis prior sex	2 (20.0)	1 (33.3)	1 (14.3)	
Either inserting it into the anus directly or placing it on the penis prior to sex, depending on preference	3 (30.0)	0 (0.0)	3 (42.8)	

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1/17/2014 Yes Not mentioned \(\times \)	Vermont	1/31/2014		Not mentioned	\ \ \	5	http://healthvermont.gov/	http://healthvermont.gov/prevent/std/faq.aspx
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1/17/2014 Yes Not mentioned ~ ~ ~ http://www.wdhhr.org/ 1/17/2014 No mentioned ~ ~ ~ http://www.dhs.wisconsin.gov/ 1/17/2014 Yes Not mentioned ~ ~ ~ http://www.health.wyo.gov/ 1/12/2014 No ~ ~ ~ http://www.baltimorehealth.org/ http://www.baltimorehealth.org/ 3/14/2014 Yes Support Insert into anus Remove Inner Ring http://www.bphc.org/ 1/12/2014 No ~ ~ ~ ~ ~ ~ http://charmeck.org/mecklenburg/county/HealthDepartment/Pages/Default.aspx?src=ud	Washington	3/14/2014		Not mentioned	ζ		http://www.doh.wa.gov/	http://here.doh.wa.gov/materials/birth-control-choosing-the-n
1/17/2014 Not mentioned ~~~ http://www.dhs.wisconsin.gov/ 1/17/2014 Yes Not mentioned ~~~ http://www.health.wyo.gov/ 1/12/2014 No ~~~ ~~~ http://www.baltimorehealth.org/ 3/14/2014 Yes Support Insert into anus Leave inner ring in thtp://www.baltimorehealth.org/ http://www.baltimorehealth.org/ 1/12/2014 Yes Support Insert into anus Remove Inner Ring http://charmeck.org/mecklenburg/county/HealthDepartment/Pages/Default.aspx?src=ud 1/12/2014 No ~~ ~~ ~	West Virginia	1/17/2014		Not mentioned	5		http://www.wvdhhr.org/	http://www.wvdhhr.org/fp/files/rev_male_guidelines_2009_e
1/17/2014 Yes Not mentioned ~~~ http://www.health.wyo.gov/ ricipalities 1/12/2014 No ~~~ ~~~ ~~~ http://austintexas.gov/department/health 3/14/2014 Yes Support Insert into anus Remove Inner Ring http://www.baltimorehealth.org/ 1/12/2014 No ~~~ ~~ ~~ http://austintexas.gov/department/health 1/12/2014 No ~~~ ~~ ~~ http://www.baltimorehealth.org/ 1/12/2014 No ~~~ ~~ ~~ ~~ http://charmeck.org/mecklenburg/county/HealthDepartment/Pages/Default.aspx?src=ud	Wisconsin	1/17/2014		\ \ \	;	\ \ \	http://www.dhs.wisconsin.gov/	? ? ?
nicipalities 1/12/2014 No ~~~ ~~~ http://austintexas.gov/department/health 3/14/2014 Yes Support Insert into anus Leave inner ring in http://www.baltimorehealth.org/ 3/14/2014 Yes Support Insert into anus Remove Inner Ring http://www.bphc.org/ 1/12/2014 No ~~ ~~ http://charmeck.org/mecklenburg/county/HealthDepartment/Pages/Default.aspx?src=ud	Wyoming	1/17/2014		Not mentioned	5	;	http://www.health.wyo.gov/	http://www.health.wyo.gov/phsd/std/stdphysresources.html
1/12/2014 No ~~~ ~~~ http://austintexas.gov/department/health 3/14/2014 Yes Support Leave inner ring in http://www.baltimorehealth.org/ http://www.bphc.org/ 3/14/2014 Yes Support Insert into anus Remove Inner Ring http://www.bphc.org/ 1/12/2014 No ~~ ~~ http://charmeck.org/mecklenburg/county/HealthDepartment/Pages/Default.aspx?src=ud	Cities and municipo.	ılities						
3/14/2014 Yes Support Insert into anus Leave inner ring in http://www.baltimorehealth.org/ 3/14/2014 Yes Support Insert into anus Remove Inner Ring http://www.bphc.org/ 1/12/2014 No ~~~ http://charmeck.org/mecklenburg/county/HealthDepartment/Pages/Default.aspx?src=ud	Austin, TX	1/12/2014		\ \ \	\ \ \	<pre></pre>	http://austintexas.gov/department/health	\ \ \
3/14/2014 Yes Support Insert into anus Remove Inner Ring http://www.bphc.org/ http://charmeck.org/mccklenburg/county/HealthDepartment/Pages/Default.aspx?src=ud $\sim \sim \sim$	Baltimore, MD	3/14/2014		Support	Insert into anus	Leave inner ring in	http://www.baltimorehealth.org/	http://www.baltimorehealth.org/HB2015 InterimUpdateOct20
$1/12/2014 No \sim \sim \sim \text{http://charmeck.org/mecklenburg/county/HealthDepartment/Pages/Default.aspx?src=ud} \sim \sim \sim \sim \sim \sim \text{http://charmeck.org/mecklenburg/county/HealthDepartment/Pages/Default.aspx?src=ud} \sim \sim \sim \sim \sim \sim \text{http://charmeck.org/mecklenburg/county/HealthDepartment/Pages/Default.aspx?src=ud} \sim \sim \sim \sim \sim \sim \text{http://charmeck.org/mecklenburg/county/HealthDepartment/Pages/Default.aspx?src=ud} \sim \sim \sim \sim \sim \sim \sim \sim \sim \sim \sim \sim \sim \sim \sim \sim $	Boston, MA	3/14/2014		Support	Insert into anus	Remove Inner Ring	http://www.bphc.org/	http://www.mass.gov/eohhs/docs/dph/cdc/factsheets/condom
	Charlotte, NC	1/12/2014		? ?		2	http://charmeck.org/mecklenburg/county/HealthDepartment/Pages/Default.aspx?src=ud	ζ

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Department of Health	Date accessed	FC mentioned	Message regarding	Methods for FC use with	Instructions regarding	DOH homepage	Webpage where FC mentioned
(рон)			FC use for AI	AI	inner- ring		Rodr
Chicago, IL	3/14/2014	Yes	Neutral	Put condom over penis	Either remove or leave in inner ring	http://www.cityofchicago.org/city/en/depts/cdph.html	http://www.cityofchicago.org/city/en/depts/cdph/govdrs/sti_hiv
Columbus, OH	1/12/2014	No	\ \ \	?	? ?	http://publichealth.columbus.gov/	≀ al.
Dallas, TX	1/12/2014	No	?	?	? ? ?	http://www.dallascounty.org/department/hhs/home.html	? ?
Denver, CO	1/12/2014	No	?	?	? ? ?	http://www.denvergov.org/environmentalhealth/EnvironmentalHealth/CommunityHealth/tabid/444617/Default.aspx	2 2
Detroit, MI	1/12/2014	No	?	?	? ? ?	http://www.detroitmi.gov/Departments/HealthWellnessPromotionDepartment/tabid/113/Default.aspx	2 2 2
El Paso, TX	1/12/2014	No	?	?	? ? ?	http://home.elpasotexas.gov/health/	? ?
Fort Worth, TX	1/12/2014	No	?	?	? ? ?	http://fortworthtexas.gov/health/	2 2 2
Houston, TX	1/12/2014	No	\ \ \	?	? ? ?	http://www.houstontx.gov/health/	2 2 2
Indianapolis, IN	1/12/2014	No	\ \ \	\ \ \	\ \ \	http://www.mchd.com	\ \ \ \
Jacksonville, FL	1/12/2014	No	\ \ \	\ \ \	\ \ \	http://www.dchd.net/	\ \ \ \
Los Angeles, CA	3/14/2014	Yes	Support	Insert into anus	Remove Inner Ring	http://publichealth.lacounty.gov/	http://publichealth.lacounty.gov/dhsp/Condoms.htm
Memphis, TN	1/13/2014	Yes	Not mentioned	\ \ \	\ \ \	http://www.shelbycountytn.gov/index.aspx?NID=24	\ \ \ \
Milwaukee, WI	1/13/2014	Yes	Neutral	Not mentioned	Not mentioned	http://city.milwaukee.gov/Health	http://city.milwaukee.gov/Have-safer-sex.htm
Nashville, TN	1/30/2014	No	\ \ \	\ \ \	\ \ \	http://www.nashville.gov/Health-Department.aspx	\ \ \ \
New York City, NY	3/14/2014	Yes	Neutral	Not mentioned	Not mentioned	http://www.nyc.gov/html/doh/	http://www.nyc.gov/html/doh/pregnancy/html/before/birth-contr
Oklahoma City, OK	1/13/2014	No	?	?	? ?	https://www.occhd.org/	2 2 2
Philadelphia, PA	1/30/2014	Yes	Not mentioned	?	? ? ?	http://www.phila.gOv/health/jindex.html	http://takecontrolphilly.org/protect/
Phoenix, AZ	3/14/2014	Yes	Neutral	Not mentioned	Not mentioned	http://www.maricopa.gov/publichealth/	http://www.maricopa.gov/PublicHealth/Services/STD/HIV/faq.a
Portland, OR	1/13/2014	No	\ \ \	\ \ \	\ \ \	https://web.multco.us/health	\ \ \ \
San Antonio, TX	1/30/2014	No	\ \ \	\ \ \	\ \ \	http://www.sanantonio.gov/health	\ \ \ \
San Diego, CA	1/30/2014	No	\ \ \	\ \ \	\ \ \	http://www.sdcounty.ca.gov/hhsa/programs/phs/	\ \ \ \
San Francisco, CA	3/14/2014	Yes	Support	Both- Insert into anus and put FC over penis	Either remove or leave in inner ring	http://www.sfdph.org/dph/default.asp	http://fc2sf.com/wp-content/uploads/2012/07/FC2-Instruction-S
San Jose, CA	1/14/2014	No	\ \ \	\ \ \	\ \ \	http://www.sccgov.org/sites/sccphd/en-us/Pages/phd.aspx	\ \ \ \
Seattle, WA	3/14/2014	Yes	Support	Both- Insert into anus and put FC over penis	Remove Inner Ring	http://www.kingcounty.gov/healthservices/health.aspx	http://www.kingcounty.gov/healthservices/health/communicable
Washington, DC	3/14/2014	Yes	Support	Both- Insert into anus and	Remove Inner Ring	http://doh.dc.gov/	http://doh.dc.gov/node/133972

Rodi	guez	e t al.			
Webpage where FC mentioned					
DOH homepage					
DOH					
Instructions regarding inner- ring					
Methods for FC use with AI	put FC over penis put FC over penis				
Message regarding FC use for AI					
FC I mentioned I					
Date accessed					
Department of Health (DOH)					

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