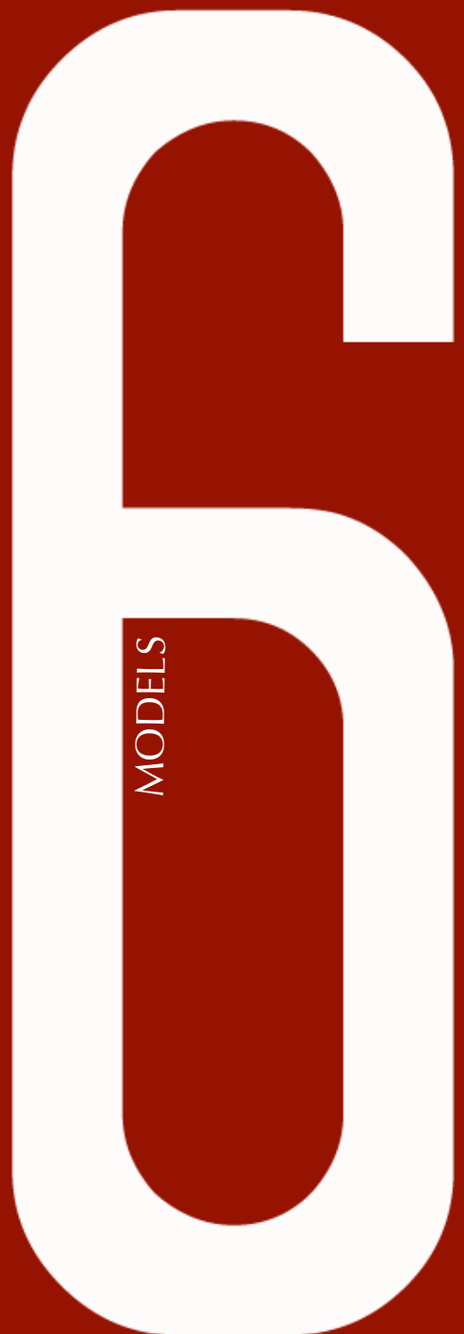
CHAPTER 6: MODELS OF SEX IN CONDOM TESTING



Condoms are made to withstand the rigors of sex. But the models used by governments to test condom durability have nothing to do with sex.

Goals of Condom Manufacture: prevent disease transmission, prevent pregnancy, maintain sensation

Condoms (the male variety) have long been the mainstay of last-second, desperate appeals for contraception, although with the advent of AIDS and hepatitis B virus they have taken on additional prominence in the prevention of sexually-transmitted disease (the only purpose for which they were legally sold in many states just a couple decades ago). In either case, a condom merely serves as a barrier against microbes (sperm or pathogens). And to make sure that condoms indeed function in this capacity, governments of Western countries test condoms to meet minimal standards, to ensure that the condoms don't break or leak when in use.

Any male who has used a condom realizes that disease prevention and contraception are not the only goals in condom design - if they were, the simplest solution would be to avoid sex. An additional goal is to minimize the loss of sensation realized during sex. The goal of sensation is in direct conflict with the goal of preventing disease and sperm transfer, because the way to manufacture a condom to be a faultless barrier is to make it thick, whereas the way to maximize sensation is to make it thin. Manufacturers thus make condoms as thin as possible while maintaining minimum standards for condom strength. And it is precisely this compromise that leads to occasional condom failure.

The material used in condoms is latex (rubber). Advantages of latex are that it can be produced in thin sheets, and it can stretch greatly without breaking. But latex is a biological material, and it is profoundly sensitive to various environmental conditions. Even temperatures as high as body temperature degrade it, albeit slowly, and oils (as in vegetable oil and baby oil) degrade it rapidly. So even if condoms meet reasonable standards in the factory, they may fail under a wide array of conditions experienced in "the field."

There are many models of condom testing. You might ask why. The reason is merely that none of them are useful for each of the many goals we have in using condoms – they all have major limitations. Different models are used to overcome the perceived shortcomings of the other tests.

Human Models

Condoms need to be tested to ensure that they meet certain standards. It is obvious that the truest model of condom performance is sex itself – that humans are the most accurate models. It is otherwise difficult to know how much sensation is being lost, or what the real transmission rate of disease is. Humans as models here have several drawbacks, however. First, they are not convenient. Governments are not about to hire people as condom testers, to have frequent sex with different partners, each with different sexually-transmitted diseases. We let people make their own choices about who to sleep with and whether they are willing to risk HIV, hepatitis, gonorrhea, etc., but we cannot ethically assign them to such risks. Any pregnancies arising from such experiments would raise problems as well.

An alternative to trained human "sex technicians" is human volunteers. This avoids the ethical/convenience complication, but it introduces a new one: lack of uniformity. Untrained people are notoriously inconsistent in how they use condoms, the condoms may be mistreated (e.g., they degrade rapidly when exposed to any kind of oils or Vaseline). So volunteers have their own problems. They are used, however, as we will come back to below.

A drawback of any use of humans to test condoms is time. If a batch of condoms was being tested for disease transmission or blocking pregnancy, it would take weeks to months after sex to determine whether the condom had done its job.

Add up all these problems with humans, and you can begin to understand why condom testing is done with non-human (non-animal) physical models.

Physical Models of Durability

"Empty-condom" tests: There are lots of ways to test condoms that avoid ethical issues while adhering to high standards of uniformity. These kinds of tests are what all governments use. Some tests measure the durability of the entire condom, some measure only part of the condom, and some test for holes. Some of the more common tests involve testing empty condoms (or putting water in them). We might think of these as "dickless" tests, but this is of course not a term that you'll hear used by professionals:

- Electrical conductance test: This is a non-destructive test applied to all condoms. Each condom is tested to see if it blocks electricity. An intact condom should not allow electricity to pass through it.

The next tests are all destructive – a tested condom cannot be sold.

- Water leak test: Used by the Food and Drug Administration, this test involves filling a condom with 10 ounces of water and looking for leaks.
- Tensile test (stretch test): This method involves slicing a band from the shaft of a condom and testing its stretchability.
- Airburst test: A method used by many European countries, Canada, and now the U.S., inflates the condom with air until it bursts; the maximum volume of air tolerated is used as the measure of strength.

Other tests are of the packaging (package integrity test, lubricant test) and a simulated aging test by warming the wrapped condom in an oven at 70° C.

Regardless of which specific test is used, condom testing involves taking a sample of several condoms from a batch and calculating the fraction that pass the test. The condoms tested are thus a sample (sampling model) of the others in the batch. In the US, a batch of condoms cannot be sold if 5 or more condoms per 1000 fail the test.

So you can be relatively confident that any condom sold in the U.S. (and maintained under proper conditions) will survive the water test and airburst test. Should we be comforted with that knowledge? Only to the extent that condom survival in these tests reflects condom survival during sex. That is, only to the extent that a water test or airburst test is a good model of the rigors of sex. Furthermore, the fact that different batches of condoms pass the FDA test does not mean that all of them are equivalent. Consumer Reports has evaluated several brands of condoms using the airburst test and has ranked them accordingly (to be presented in class). Perhaps surprisingly, a few brands had failure rates of 10% or more.

There are several levels at which models apply, beginning with the lowly one in which a few condoms in a batch are treated as a model of the entire batch (otherwise, we would have to test every condom in the batch). At a higher level, we may regard one condom brand as a model of other brands (hence the advice from healthcare workers to "use a condom," which makes no statement about a brand). Then we have the government models of sex that are used to evaluate condom survival, such as the airburst test, the water test, and the stretch tests.

Validation of the “empty-condom” tests. It takes little imagination to understand how these models are limited and may be seriously in error. However, although the airburst test is not anyone's idea of sex, when properly calibrated, it might give us a good idea of whether a condom will hold up during sex. Not surprisingly, people have been interested in this question. The organization Family Health International (see website above) has been involved in several studies and has also evaluated others to determine just how accurately the empty-condom tests predict condom failures in humans. These tests involve (i) evaluating some of the condoms with the airburst test (most commonly), and (ii) using other condoms from the same batch to obtain breakage rates from volunteers. These tests have been the most illuminating when done with aged condoms, because breakage rates are higher with aged condoms. In general, the physical, **empty-condom tests are only mildly good at predicting condom failure rate** experienced by human volunteers.

More Accurate Physical Models: Fake Penises

The foregoing physical models can be objected to on the grounds that they don't mimic realistic forces during sex. Over the last decade or so, there have been a few studies that tested condoms by simulating sex with various types of dildos. None of those studies have inspired widespread acceptance of test. The elaborate system developed a decade ago by the "Mariposa" Foundation of Topanga California (probably now defunct) consisted of a rubber "vagina" through which water (at body temperature) is circulated and into which a dildo (model of a penis) is thrust with a piston device. The condoms are inserted over the dildo and subjected to several "cycles" of piston thrusting. An ejaculation was also simulated. The various parameters have been established by a number of methods (quotes to be read in class). It is clear from the difficulties encountered by that organization (if only in calibrating their model) that creating a more realistic model that could be used as an industry standard would not be easy.

SECTION 5

Models of STD Transmission

Even if the models used to test condoms are reasonable indicators of whether a condom will break during sex, and thus whether they will function adequately in preventing sperm from reaching the female's reproductive system, but they may be rather poor indicators of whether a microscopic pathogen can pass from one partner to the other. For example, the water test can detect holes only as small as 5 mm, but this sized hole is many times the size of sexually-transmitted viruses and even of the bacterium Chylamidia. Similarly, the airburst test is insensitive to small holes. So here we find new limitations of existing methods of testing condoms: these models don't give us a good understanding of the barrier to pathogens afforded by a condom. That is, these models have serious limitations when considering condoms as barriers to infectious disease.

Other models have been tried. Several involve filling a condom with a pathogen (in water, for example) and determining whether the pathogen escapes to the outside - a passive transmission test. .Some tests use the sexually-transmitted pathogen itself, which is the best model of a pathogen. But those tests are expensive because they require special facilities for working with pathogens. So other, simpler tests use the harmless bacterial virus fX174, which is somewhat smaller than the smallest sexually-transmitted pathogen (Hepatitis B Virus) and is easily assayed on bacterial plates. These tests can also be made more realistic by subjecting the condom to various forces, such as might be encountered during sex.

Volunteers. When we want definitive data on how condom use influences disease transmission rates, there is no substitute for accuracy – using sexually active humans known to be exposed to STDs, necessarily volunteers. There have been several studies of this sort in the last decade, mostly with HIV. These studies use “discordant” couples, in which one partner is not infected and the other is infected. Couples were rated (after the fact) as to whether they used condoms consistently or inconsistently (the latter category including those who didn’t use them at all). Overall the studies suggest that condom use greatly decreases the risk of HIV infection.

NUMBER OF COUPLES IN WHICH THE HIV- PARTNER BECAME HIV+ DURING THE STUDY	
CONSISTENT USERS	**INCONSISTENT USERS**
0/123	12/122 (10%)
3/171 (2%)	8/55(12%)
<2%	12% (300 total couples)
0%	10% (250 total couples)

1996 study from Haiti: estimated a conversion rate of 1/100 person years with consistent condom use; 6.8/100 with inconsistent use.

(a higher female to male than male to female infection rate was observed in this study as well)

1994 study from Europe lasting 20 months: 0/124 consistent users converted; conversion rate of 4.8/100 person years among inconsistent users.

In an interesting twist on these and similar data, the CDC (Centers for Disease Control) public position on condom use shifted from emphasizing the benefits of STD prevention afforded by condoms to one that now emphasizes that condoms do not always prevent STD transmission (see the comparison of 'now and then' at http://www.advocatesforyouth.org/PUBLICATIONS/iag/condom.htm). It is suspected that the change in condom advocacy was from political pressure.

Summary of Material in Templates for Models

MODEL	KIND	APPLICATION	LIMITATIONS
Passive transmission test	physical	pathogen passage through condom during sex	neglects wear and tear during sex
Volunteers	physical, sampling	condom integrity and breakage during sex	poor uniformity and compliance by untrained people; time to complete studies; other risk factors
discordant couples	physical, sampling	STD prevention by condoms	poor uniformity and compliance by untrained people; time to complete studies; other risk factors
PhiX174	physical	a sexually-transmitted pathogen	PhiX174 may pass through condoms differently than pathogens
Airburst test	physical	condom integrity and breakage during sex	lacks the complexities of sex; does not test porosity
electrical conductivity	physical	condom integrity and breakage during sex	lacks the complexities of sex; does not test durability of the condom
Stretch test	physical	condom integrity and breakage during sex	tests only part of a condom and lacks the complexities of sex; does not test porosity
A few condoms	physical or sampling	model of entire batch	variation exists between condoms of one batch
One brand	physical	model of other brands	different brands have different properties

GOAL	to provide a barrier against STDs, pregnancy	to provide a barrier against STDs, pregnancy	to provide a barrier against STDs, pregnancy
MODEL	airburst test	volunteers	airburst test
IS A MODEL OF	sex between humans	sex between humans	sex between humans
ACCURACY	+	-	+
CONVENIENCE	+	+/-	+
UNIFORMITY	+	-	+
HOW USEFUL	overall measure of condom integrity, convenient, uniform	accuracy – we can find out whether condoms work for their intended goal	not useful – the poor accuracy of the airburst test is too severe for this goal
LIMITATIONS	not address STD passage, not fully reliable indicator of breakage during sex (both due to poor accuracy)	source of failures unknown, limited sample sizes, slow turnaround (poor on convenience, uniformity)	does not enable assessment of sensitivity (due to poor accuracy)