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CONDOMS

Lab tests reveal some flaws

In a small sample, two brands failed to meet some government standards

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A laboratory test of a small sample has turned up flaws in some brands of condoms currently available at many of Canada's colleges and universities.

The Star commissioned a research firm to test five condom brands – Ramses Sensitol, Trojan-enz, Protex, Beyond and LifeStyles – to see how they stacked up under the requirements of Health and Welfare Canada.

In a critical test of the point at which they burst, a significant number of Protex and Ramses Sensitol failed to meet federal standards. In tests for leakage, the Protex brand showed some flaws.

It was not an exhaustive study; it was a laboratory analysis of 10 to 15 of each of the brands, purchased much as a consumer might buy them. Under federal testing procedures, a greater number would have to be tested before any conclusions could be drawn.

Protex is sold in vending machines at many universities and colleges across Canada as well as in bars and strip clubs; Ramses is one of the best-selling brands in drug stores. Protex is also one of the main brands being considered for use in the new vending machines in Toronto public schools.

The 14 Protex condoms used in the Star tests were purchased in a women's washroom at Ryerson Polytechnical Institute. The Ramses were bought in a Toronto drug store.

In tests performed by Retail Research Laboratories, Protex was the only one that did not conform to length requirements under the federal government's Medical Devices Regulations; this was the only time in two years of testing that testers recall a condom did not meet the length requirement (at least 16 centimetres, or 6.3 inches). Protex was the only one tested that leaked; and one of two not to comply with the bursting volume requirement.

One lot of Ramses – two lots were tested to provide a sufficient number – had a high number of condoms that did not pass the bursting volume requirement, which put them in a borderline situation, and lab technicians say that if more were tested that lot possibly would have failed federal standards. And one Trojan condom of a group that was mechanically aged, as if bought some time ago, did not meet the bursting requirement.

The remaining brands all complied with the federal government's requirements.

Heinz Bolender, president of HYCO Products Ltd., which distributes the Protex condoms in Canada, said in a telephone interview that the samples tested may have failed because they were old or because the vending machine was located too close to the blow-dryers in the washroom.

Because The Star was seeking to simulate the random condom purchases of consumers, and researchers were asked to test only a small sample, these results do not conform to the standard Acceptable Quality Level sampling. It was simply luck of the draw, which is what consumers face.

The tests also showed that when the condoms were lubricated with Vaseline Intensive Care lotion – using an oil-based lubricant is a fairly common practice, according to experts – they *all* failed to a significant degree, according to the researchers.

At one time health officials recommended lubrication to lessen the chances of breakage, but the tests showed that, unlike water-based lubricants, oil-based lubricants such as Vaseline reduced the condoms to less than half the bursting volume allowed by the federal government.

The tests were similar to those carried out periodically by Health and Welfare Canada to ensure that condoms in Canada are reliable.

Under government regulations, every condom must:

- Have an integral rim, located at the open end of the condom in the form of a smooth, uniformly narrow, thickened ring constructed of the same material as the condom.
- Have a length of not less than 16 centimetres (6.3 inches).
- Have a width of not less than 4.5 centimetres (1.8 inches) and not more than 5.5 centimetres (2.2 inches) in the area from the rim to the measuring point (8 centimetres, or 3.1 inches, from the closed end of the condom).
- Have a width of not more than 7 centimetres (2.8 inches) in the region from the measuring point to the closed end on the condom, including the reservoir.
- Not show evidence of leakage when filled with 300 millilitres (10 fluid ounces) of water. (The regulations allow for a margin of error: It is permissible that 0.4 per cent of condoms tested in a batch fail to meet this requirement.)
- Have a bursting volume of not less than 25 litres (5.5 gallons). (It is permissible that 6.5 per cent of the condoms do not meet this requirement.)
- Have a bursting pressure of not less than 1 kilopascal. (It is permissible that 6.5 per cent of the condoms do not meet this requirement.)

The condoms are also required to pass the leakage and bursting tests after being mechanically aged, as if they had been purchased some time ago. And the condoms cannot contain or release any harmful or irritating substances.

To test for leaks, condoms are filled with 300 millilitres (10 fluid ounces) of water, dried, then rolled on a blotter. For bursting tests, they are blown up on a special machine until they burst.

As long as condom packaging is preserved, proximity to the expiry date on the package doesn't seem to weaken or deteriorate the condoms. However, the aluminum foil packaging used on Trojan-enz and LifeStyles, and the individual double packaging on Protex, probably provide better protection than the polyethylene plastic film used to package Ramses Sensitol and Beyond brands, according to researchers.

The Protex results were "the biggest failure I've ever seen here," said Rocco Melito, mechanical technologist with Retail Research Laboratories, a private lab that has tested condoms for clients, such as importers.

"I've never had any that didn't meet the minimum length, and I've never had so many bursting volume problems in the first set of 10. Since we did have so few failures in the past, I consider it a failure of that production lot," said Melito.

The article EM9021 reprinted overleaf and above is used in Figure 11.7b of the STAT 221 Course Materials.