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QUALITY CONTROL OF NON-ETHICAL CONTRACEPTIVE PRODUCTS 1/

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SUMMARY

The International Planned Parenthood Federation test for the efficacy of spermicides is described together with the various tests and national specifications for condoms. The difficulty of comparing the results from the different standards is discussed and the need for an international standard pointed out.

The problem of quality control in the field of non-ethical (not medically supervised) contraceptives increases with the increase in users, methods available and manufacturers, particularly as new or potential users need to be convinced of the efficacy of the methods.

For the last six years there has been a test for the efficacy of spermicides which has been recognized internationally by the member organizations of the IPPF. This test is known as "The IPPF Agreed Test For Total Spermicidal Power (1965)" and was the direct result of the work of Harris (1962) who combined the principles of the then accepted tests, those of Baker (1935) in the U.K. and Sander and Cramer (1941) in the U.S.A., into a simple yes-no test. This test requires that 1 ml. of a 1:11 solution of the spermicide in 0.9% saline kill all the spermatozoa in 0.2 ml. of normal human semen in 40 seconds. By maintaining a laboratory to carry out this test at the request of member organizations, regional offices or manufacturers the IPPF has been able to compile a list of tested spermicides which may be referred to, to see if a particular product has been tested, and if so, when and with what result.

The simplicity and common sense of a single test applied throughout the world is obvious and it seems a pity that in the other, much larger, field of non-ethical contraceptives, namely condoms, that there is no internationally recognized test or standard. It is true that there are standards but each requires different tests or the same tests carried out to a different level, in much the same way as the various spermicidal tests prior to the acceptance of the IPPF test.

The differences in the requirements of the various standards makes it extremely difficult to compare the quality of different condoms obtained from different countries and manufactured to different specifications.

At this point it would be as well to differentiate between electronic testing, carried out by most manufacturers, and the batch testing techniques laid down by most of the national standards. Electronic testing is 100%, that is every condom made can be submitted to the test, whereas in the batch testing procedures this is not so since some of the tests demand that the condom be destroyed during the test.

Electronic testing may be wet or dry. In the wet test the condom is placed on a metal electrode which is then passed through a bath of electrlyte. During this passage through the bath a voltage is applied to the electrode inside the condom and if the flow of current through the electrlyte exceeds a certain predetermined level the condom is rejected as faulty. In the dry testing the condom is again placed on an electrode but this time the condom containing the electrode is rolled against another electrode and a voltage usually in excess of 1000 volts is applied. This test actually measures the dielectric strength of the rubber film, and any weakness, including holes, will allow a discharge to occur between the two electrodes which will in turn cause the condom to be rejected as defective. In both wet and dry electronic techniques the pass/fail rate may be varied at will by varying the level of current tolerated in the wet method, and the voltage applied in the dry method. It would be possible to adjust these values so that every condom made passed the test, although in practice the failure rate is of the order of 10%.

Most manufacturers destroy this 10% but it would seem that some sell the condoms intact as scrap rubber, possibly to be packaged and sold as condoms by the unscrupulous. A test which could be applied internationally and which would have some degree of international acceptance would prevent this type of thing as well as bringing at least some degree of rationality to the confused picture of national condom standards.

There are in fact eight national condom standards originating in Denmark, Hungary, India, Israel, Japan, Sweden, U.K., and U.S.A.

Each of these standards requires that the condoms be tested for holes in some way, although only the Hungarian standard stipulates that this test be carried out by an electronic method. The Japanese standard describes an electrical test in which the electrical resistance of the condom must exceed 700,000 ohms, when it is tested between two electrodes in 1% saline. All the other standards stipulate that the condoms should be filled with 300 ml.of water, but hereafter the technique of assessing the holes present diverges. The Israeli standard requires that a visual inspection be made one minute after the water is poured into the condom, the Indian standard, in common with the British standard of 1964, requires that a piece of absorbent paper be wrapped around the condom, while the other standards,

including the British standard of 1972, require that the condom be closed by twisting and that it be rolled onto absorbent paper in order to detect any holes present. It is interesting to note that this last described method is both the most stringent and the most reproduceable in different laboratories of all the water-hole tests.

The other parameter measured is the mechanical strength of the rubber film. This may be done by inflation of the condom with air or water, or by assessing its tensile properties (tensile strength and elongation at break). The air inflation technique is favoured by the Swedish standard, which requires that the mean bursting volume of 100 condoms from each batch be above 25 litres with a relative standard deviation of 25%. The Danish standard requires that 115 condoms from each batch must have a mean bursting volume 1.625 standard deviations greater than 20 litres, while the American standard requires that 8 condoms from a batch have a bursting volume greater than 28.3 litres (1 cu. ft.) before and after accelerated ageing.

The Indian standard requires that a condom be inflated with 5 litres of air, then tested for holes as described already and then that the same condom be filled with 3 litres of water without breaking. The 1964 British standard also required the condom to hold 3 litres of water without breaking, but this has been abandoned in the 1972 standard in favour of a tensile strength requirement. The Hungarian and Japanese standards also incorporate a tensile strength requirement comparable to that of the 1972 British standard (200 $kg.cm.^{-2}$), and all have a minimum elongation at break within the range of 600-700%.

The dimensions of condoms are also mentioned in all standards except the Danish, all laying down a minimum length, but only two, the Hungarian and the American, giving a maximum. The need for some rationalization of the various standards becomes obvious if one considers these last two standards and their stipulations about the length of condoms, where the shortest permissible teat-ended condom in the American standard is at least 1 cm. longer than the longest permissible Hungarian teat-ended condom.

With problems such as this size differential and the difficulty of comparing the strength of the rubber film measured by different methods, and the difficulty experienced concerning the reproduceability of the various techniques for assessing the presence of holes in condoms, there is a need for a standard method of test run on similar lines to that for spermicides so that the relative qualities of various condoms can be assessed.

Finally I would like to thank my colleague, Mr. Philip Kestelman, for supplying me with a draft of a paper on condom testing from which I have taken many of my facts.

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