APPENDIX III

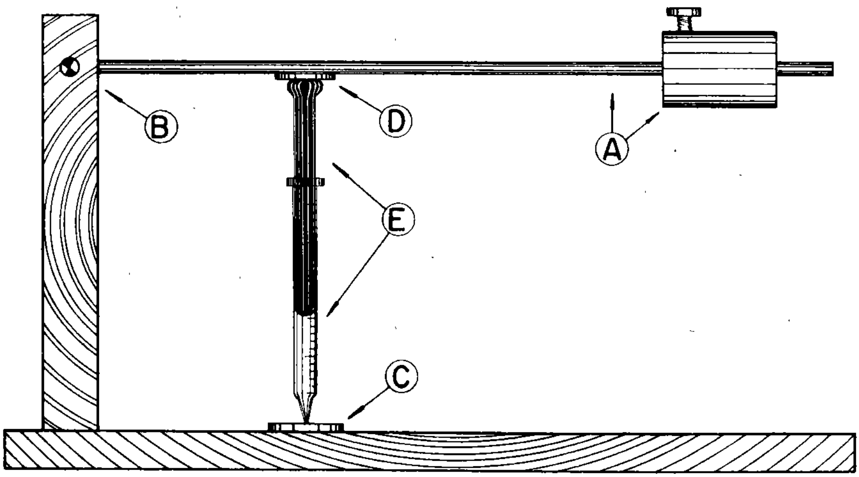
MEASUREMENT OF LEAKAGE OF TUBERCULIN SYRINGES *

Many of the syringes used for intracutaneous injections tend to leak between plunger and barrel, often to such an extent that reading from the graduated scale may be grossly misleading. In practice the quantity of liquid actually injected is therefore usually estimated by measuring the size of the wheal produced at the site of injection. For scientific work, however, where accurately measured dosage is required, unsatisfactory syringes must be detected and eliminated before use.

Description of Apparatus

A simple, easily constructed apparatus for accurate measurement of leakage in syringes is illustrated in fig. 1. The syringe (E), when filled with distilled water, is placed vertically in the apparatus. The tip, with no needle attached, is pressed against the soft smooth rubber disc (C), and the lever with a certain weight (A) is brought down upon the plunger. This lever, while holding the syringe steady, subjects the plunger and

FIG. 1. DIAGRAM OF APPARATUS FOR MEASURING LEAKAGE OF SYRINGES



A	Lever with adjustable weight	C, D	Rubber discs
B	Joint for vertical rotation of lever	E	Syringe

consequently the contents of the syringe to a constant pressure. As the tip is embedded in the rubber disc, the contents can only escape by leaking out between plunger and barrel, and the rate of decrease of the contents thus becomes a measure of the rate of

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leakage. The pressure is correct only if the lever is nearly horizontal, so when testing short or partly filled syringes the distance between the lower rubber disc and the lever must be correspondingly reduced by placing the rubber disc on a box of appropriate height.

If the diameter of the plunger is about 4.5 mm (as in most all-glass tuberculin syringes), an external pressure of about 1 kg is used, corresponding to a pressure inside the syringe of 5 to 6 kg/cm^2. (This pressure corresponds roughly to what was found in the following experiment : several experienced testers were asked to exert, by hand, on a tight, air-filled syringe, a pressure estimated to correspond to that used for an ordinary Mantoux test. By this procedure the air volume was reduced to between 1/5 and 1/8, corresponding to an internal pressure of 5 to 8 atmospheres.)

If the diameter of the plunger exceeds 4.5 mm (as in most record syringes), the external pressure must be correspondingly increased in order to keep the internal pressure constant.

Experiments

A series of experiments, designed to furnish data on the leakage rate of syringes—as measured by the apparatus—have been carried out.

Twelve new all-glass 1-ml tuberculin syringes of the type used for field studies reported in this monograph were filled with distilled water to a certain level and subjected to constant pressure in the apparatus.

Each syringe was tested for leakage at five different levels of filling, namely, filled to the 1.0, 0.8, 0.6, 0.4, and 0.2 ml marks. Starting from each of these levels, the decrease in the contents of the syringe was measured by reading the scale every minute for a period of five minutes. All tests were repeated once, then the syringes were boiled in distilled water for 30 minutes and tested again at two different levels of filling, 1.0 and 0.4 ml. When the tests were repeated, the person reading the scale had no knowledge of previous results. The findings were plotted on a graph, the time during which the fluid in the syringe was kept under pressure being indicated on the horizontal scale, and the contents of the syringe during the testing period on the vertical scale, as illustrated in fig. 2 for four of the twelve syringes tested.

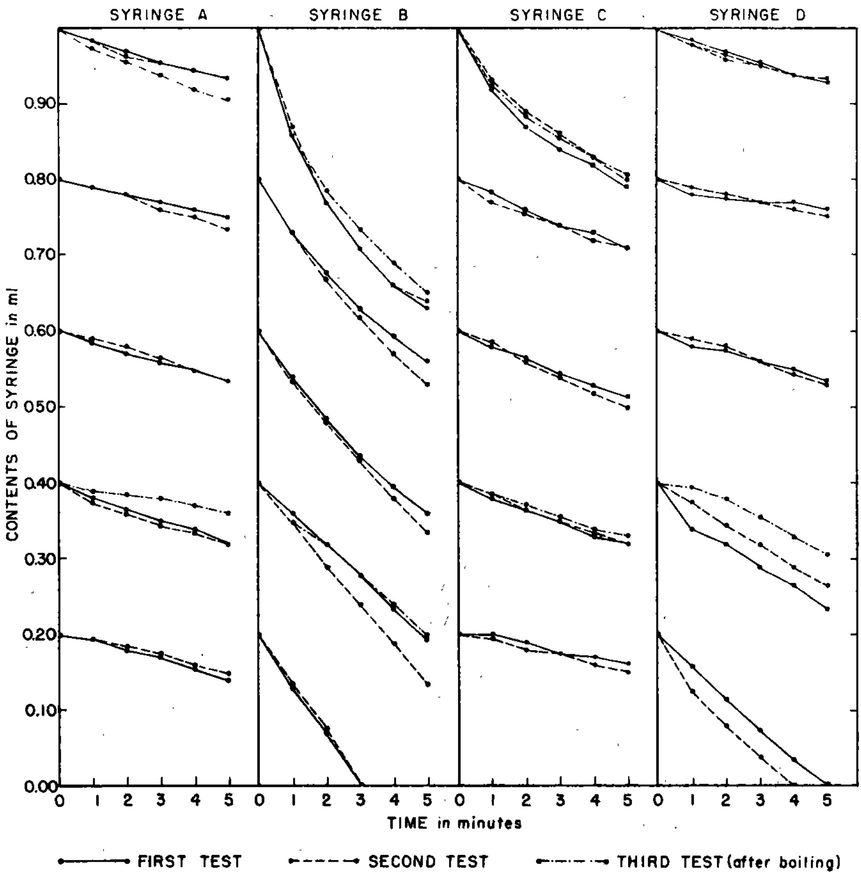
The leakage rate varied to a surprising extent from syringe to syringe, ranging from 0.06 ml to more than 0.4 ml in five minutes. In some instances the leakage rate showed considerable variations from level to level in the same syringe. There was good agreement between the results of the first and the second series of tests. Boiling in distilled water for 30 minutes did not appear to alter the leakage rate.

Practical Application

Syringes to be used for research by our field teams are now pretested for a period of *six* minutes with an internal pressure of 5-6 kg/cm^2. As leakage may be different in different parts of the syringe, each syringe is tested for two different degrees of filling, namely, completely and two-fifths filled. The results are expressed in units of 0.01 ml per six minutes (0.1 ml per hour). When a syringe is said to have a leakage of 15, for example, it means that the leakage in six minutes (average of the two trials) amounts to 0.15 ml.

From such information it is also possible to estimate the percentage of fluid lost in injecting 0.1 ml. If it is assumed that the injection is made in five seconds, and that the internal pressure in the syringe is 5-8 atmospheres, a leakage rate of 10 corresponds to a loss of 2% or less of the 0.1-ml dose. A leakage rate of 20 corresponds to a 3-4% loss, and a rate of 30 to a loss of 5-6%.

FIG. 2. RESULTS OF EXPERIMENTS CARRIED OUT ON FOUR SYRINGES

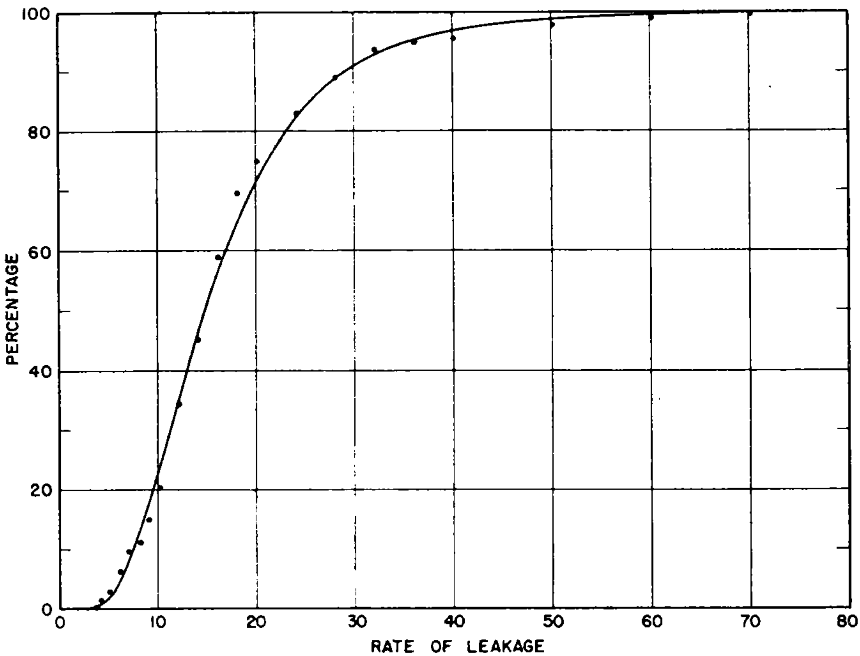


Each curve shows the decrease in contents with time, under fixed pressure.

Tests have been made on 387 new syringes of the particular brand we have found to be most satisfactory; the results are given in fig. 3, presented as a cumulative distribution. The leakage rate varies from 4 to 70 and is less than 15 in half of the total sample of syringes. The distribution is thus skew but will be nearly normal when the arithmetic value of the leakage rate is replaced by its logarithm, as can be seen when comparing the actual findings (represented by the points) with the hypothetical curve that represents the logarithmically normal distribution.

It appears from fig. 3 that the maximum leakage may be lowered from 70 to 25 by rejecting 15% of the syringes. To have a maximum leakage of 20 means rejecting 25% of the syringes and a maximum leakage of 15 means rejecting half of the syringes. Information from a curve of this kind is thus a good guide when a compromise is sought between economy and low maximum leakage.

FIG. 3. CUMULATIVE DISTRIBUTION OF THE LEAKAGE IN 387 NEW SYRINGES



The abscissa represents the rate of leakage expressed in units of 0.01 ml per 6 minutes, under a pressure of approximately 5 kg cm^2. The ordinate gives the cumulative percentage of the total number of syringes. Each point represents the proportion of syringes with leakage below the specified rate. The continuous curve shows the normal distribution function of the logarithms of the rate of leakage (with the observed mean and standard deviation).

It should be understood, of course, that the particular curve shown here applies to a rather expensive brand of syringes selected as one of the best from a number of different products available in large quantities. As an example of the results obtained with other brands, we found leakage rates ranging from 19 to 144 with one sample of 24 new record syringes of the type selected for a mass programme as having comparatively low leakage. Half of this sample of syringes had rates above 52.

New syringes with a leakage rate below 20 are seldom found to show any apparent leakage when first used in the field. Only the sides of the plunger become moist, evaporation evidently keeping pace with minimal leakage. After 1,000 to 1,500 injections, however, syringes usually begin to leak, one or two drops for every 10 to 20 injections. Both the syringe and the tester's hand then begin to get wet, and further increase in leakage (or leakage from between the needle and the tip of the syringe) can no longer be detected. Thus it is not difficult in the field to know when a syringe is leaking, but it is difficult to estimate how much fluid is lost.

We have adopted the plan of testing all new syringes before they are sent to the field, rejecting those with leakage rates above 20. The moment a syringe begins to leak steadily in the field, we ask that it be returned for retesting in the apparatus (to control gross error in the tester's judgment). Leakage rates between 20 and 30 are usually found; if above 20, the syringes are rejected for further field use.

The expenses involved by such strict criteria may seem prohibitive, even for research work, but the cost of leakage cannot be disregarded. For example, the leakage rates for a sample of 55 syringes, discarded because of leakage in a mass BCG-campaign where " some " leakage was tolerated, was found to vary from 20 to 540, with half of the sample tested having a rate above 90. A rate of 90 probably corresponds to a loss of 15% or perhaps 20% of the amount of fluid actually injected—a net loss of 15 ml of tuberculin or vaccine for one thousand injections, at a cost which cannot be considered negligible when compared with the cost of a new syringe. Workers from some of the mass campaigns maintain that occasionally they have used 1-ml syringes yielding only one or two vaccinations for each refilling—a very costly procedure indeed, in terms of both time and money.

Summary

A home-made apparatus is described for measuring leakage between the plunger and barrel of tuberculin syringes. Even with the brand of syringes which has been found the most satisfactory, about one out of every four new syringes leaks to a greater extent than is compatible with accurate work. After being used for 1,000 to 1,500 intracutaneous injections, many syringes begin to show obvious signs of leakage and, when retested, fail to meet the criteria adopted for acceptability. Unless new syringes are first tested before use and a plan for periodic retesting is followed, it is unreasonable to expect field workers to be able to measure accurately the amount of fluid given in intracutaneous injections or to avoid wasting a considerable amount of tuberculin or vaccine.