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PAKISTAN TRIP REPORT

May 27 to June 9, 1992

Voraya Srisamang
Program for Appropriate Technology in Health
(PATH)

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PAKISTAN TRIP REPORT

Draft Trip Report

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Associate Technical Officer
PATH

I. SUMMARY

The purpose of this trip was to evaluate the condom quality assurance testing laboratory at the National Research Institute for Fertility Control (NRIFC) and to provide upgrades as needed to the condom test equipment and procedures. NRIFC had requested technical assistance in December 1990 (see Attachment 1), but the Persian Gulf War did not allow for a visit at that time. A second request for assistance arrived in April 1992 (see Attachment 1). The resulting laboratory visit included a review of test reports and documents related to equipment calibration and maintenance. It also included the training of NRIFC laboratory personnel on the new test procedures recently approved by the International Organization for Standardization (ISO) as detailed in the 1991 edition of PATH's Condom Testing Handbook.

The condom test equipment is located in the contraceptive testing laboratory at NRIFC. Although the equipment is properly installed and pieces such as the dimensions test kit are operational, the laboratory was established in 1985 and maintenance over years of operation has been minimal. During a technical assistance visit in 1988, the air flow on the air inflation machine was validated. However, the move of NRIFC contributed to subsequent problems with the air inflation and water testing equipment. In this 1992 visit, the air inflation test system was completely upgraded and the water machine leak problem was repaired. Replacement of the auxiliary parts for the air inflation system is recommended. The training on equipment maintenance and the new ISO condom test procedures were conducted for the laboratory staff. All laboratory training was completed successfully.

Because of the significant modifications required on the equipment, the time available for meeting with officials and discussion on programmatic issues related to condom quality management was limited. The author appreciates all of the trainees participating in the training during this visit, but is especially grateful to Dr. Talat Khan, Director of NRIFC; Dr. Razia Kazim Ali, Deputy Director of NRIFC; and Jesse Brandt, consultant to USAID/Islamabad.

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The NRIFC condom laboratory tests condoms upon request from the Pakistan Ministry of Public Welfare. The condoms are used primarily in the family planning program. A review of the test reports indicates that approximately 60 sets of samples were tested between 1988 and 1991.

II. BACKGROUND

In 1985, the laboratory was established with funds from the USAID Mission in Pakistan. A set of PATH-developed equipment for carrying out monitoring tests on condoms used in the Pakistan family planning program was installed at NRIFC in Karachi. In 1988, an audit visit was carried out in order to review the test reports, check the equipment calibration, and provide a refresher training course in test procedures and data reporting.

Since the 1988 visit, there have been refinements to PATH's testing equipment and changes in the ISO standards and test procedures. Since NRIFC has for some time indicated a need for equipment replacement, this visit was designed both to evaluate and ensure proper function and modification of the equipment and to train NRIFC staff in adherence to updated procedures.

III. ACTIVITIES AND FINDINGS

Ms. Voraya Srisamang, PATH associate technical officer, visited Pakistan May 27-June 9, 1992. The scope of work for this visit follows:

- evaluate the existing equipment
- modify, upgrade, repair all equipment as needed
- train laboratory staff in new ISO test procedures
- review test procedures and equipment maintenance
- evaluate and train, if necessary, on record-keeping procedures

Following are the individuals who participated in the training:

Dr. Razia Kazim Ali
Mr. Ehsan M. Syed
Mr. G.M. Khan
Mr. Intisar Ahmad Burney
Mr. Faheem Tahir
Mr. Jawaid Alohte (Electrician)
Mr. Aftal

The training started with all trainees listing their expectations for the course. In general, trainees expected to be able to conduct condom testing and operate equipment properly, to prepare test reports correctly, and to interpret or evaluate test results accordingly. The trainees were also interested in permeability testing for viruses, the possibility of training abroad, and logistics issues. Trainees were advised that these issues were well beyond the scope of this training. Each trainee was given a pre-test prior to the training (see Attachment 2).

Dimensions test kit: The length measuring mandrel was examined for any sign of bending or distortion due to aging. The mandrel was in good condition and no replacement was needed. The ruler used for width measurement was replaced with one showing increments of 0.1 mm. The thickness gauge and micrometer were in good condition. The micrometer was calibrated using the standard feeler gauge and the accuracy was in an acceptable range.

Package seal test apparatus: The chamber seal was tested and was operational. A rack for holding condom samples in the vacuum desiccator was provided. Although the vacuum pump was operational, it was covered with grease since it is not an oil-less type pump. Also, the pump is too large to place on the counter and, therefore, the operator has to check the pressure gauge underneath the bench. Since there is no on-off switch on the pump, operators must activate the pump by placing the plug

into the outlet and turn off the pump by unplugging it. The existing set up, though functional, is inconvenient for the operator to conduct package seal testing.

Water test machine: The exterior of the water machine was clean and had no rust. The overflow drainage channels were cracked but did not leak water. The interior plastic tubings were slightly discolored but showed no ill effects from containing water. One leak was found and fixed at the left T connector (facing the back side of the machine) where the water supply enters the unit.

Air inflation test system: The air inflation machine was completely renovated during this visit. The most important element of the upgrade was replacement of the condom clamp units. Since the initial NRIFC installation, PATH has redesigned and developed a new version of the mechanical clamp used for mounting condoms on the air inflation equipment. The new clamp allows the condom sample to hang freely without stretching and provides a consistently gentle but firm grip that prevents the condoms from slipping. The diameter of the sphere on top of the length limiting rod is larger to increase precision and repeatability among testers.

A major equipment modification was replacement of the pressure regulator screw with an adjustable handle screw. This change was made to allow operators to adjust the true volume flow rate within the ISO specified limit of 24 to 30 liters per minute, with a correction for temperature and barometric pressure at the time of testing.

Another air inflation alteration was the replacement of all tubing for the machine. Color-coded tubes were installed to allow easy reference.

The remaining components, including the pressure regulator, air filter, on-off valves, and connectors were thoroughly inspected. The air filter and pressure regulator were disassembled and cleaned. The staff acknowledged that they have not implemented procedures for cleaning or maintaining these components. Therefore, the components had never been examined since their installation.

Due to the malfunction of one of the on/off valves, the air flow rate was found to be higher on the right side (when facing the front of the machine) than the left side. Since these types of valves are not available locally, the units will be shipped from the USA for replacement. It was advised that testing be conducted using one port until the valves are replaced. (New valves were subsequently sent on July 23.)

New calibration procedures, using a variable area flowmeter (rotameter), were introduced. Previously, the flow calibration was carried out periodically by authorized PATH personnel using a portable electronic mass flowmeter. The new calibration procedure, using a rotameter, is a direct measurement of the volume of air flow and is easier to understand and simpler to calibrate. NRIFC laboratory staff can perform calibrations as frequently as ambient conditions in the laboratory change, to ensure that true volumetric flow rate is within the specified limit.

The training session made heavy use of PATH's revised Condom Testing Handbook which contains relevant information on compliance and monitoring testing, lot and rational lot definitions, sampling procedures, test procedures, and all test data sheets required for testing. The most critical changes in procedures are in the air inflation test protocol. In the current procedure, burst volume limit is a dependent parameter of average condom width in the lot. The rounding of the burst volume limit is to the nearest 0.5 rather than 1.0 liters. The burst pressure limit is constant for all sizes and ages of condoms.

The need for an equipment maintenance program was another major topic discussed during this visit. It was emphasized that periodic maintenance of the equipment is essential, especially for the air inflation system. The compressor needs to be drained and the filter cleaned on a weekly basis when in heavy use. Laboratory staff should work closely with the electrician/technician to ensure routine equipment maintenance is carried out. In addition to the schedule given in the Condom Testing Handbook, a maintenance log was provided for documenting the record of the equipment.

After all the equipment was modified, Mr. G.M. Khan, Mr. Tahir, and Mr. Burney were given some condom samples with which to perform testing and to determine testing efficiency. Each person was able to follow the proper procedures for testing of dimensions, package seal, water leakage, and air inflation. On an average, each person can complete air inflation testing of 25 condoms in one hour.

To review the test procedures, a complete series of tests were conducted. At the end of the training, a post-test was given to each trainee. A comparison of correct responses between pre- and post-training is given in Attachment 2.

To improve laboratory efficiency, a systematic work flow for receiving samples, sampling, testing, and reporting was designed and implemented during this visit. Several containers were obtained to keep samples organized and easily identifiable for each required test.

The record-keeping system at NRIFC was examined and found to be acceptable. NRIFC has an organization-wide procedure for documenting samples received at their institution and the contraceptive testing laboratory has adopted this procedure. The traceability record indicates that a total of 150 sets of samples have been tested since equipment installation. In 1991, NRIFC tested 30 lots of samples.

Several aspects of Good Laboratory Practices, including proper procedures for test validation, sample handling, documenting, changing, and correcting records were discussed. The NRIFC staff was unfamiliar with these procedures and suggested that further training would be an extremely useful means for them to understand the operation of laboratories in the United States.

At the conclusion of the training, NRIFC staff were given an evaluation form to fill out. Responses from the evaluation appear in Attachment 3.

The visit concluded with a discussion with Mr. Jesse Brandt, Private Sector Advisor to USAID/Islamabad, and a visit to the central warehouse and the warehouse rented for social marketing. More than 100 million condoms are stored at the central warehouse. The inventory is stacked 9 layers high with more than 20 cartons in each row and in each column. Mr. Brandt explained that these condoms have been recently moved to this location. The warehouse is planning to organize the inventory and will attempt to separate the condoms by production lot number.

According to Mr. Brandt, this quantity of condoms is equivalent to a 5- to 8-year supply at the current use rate. Furthermore, USAID is planning to phase out aid to Pakistan by July 1993. This situation points to an urgent need for an appropriate quality monitoring program, to ensure that condoms are suitable for distribution in the coming years and that good condoms are not unnecessarily wasted. Discussion with Mr. Brandt covered several other issues relating to condom quality monitoring, including sampling plans, sampling intervals and responsibilities among institutions, and NRIFC capacity and involvement. Mr. Brandt was very keen on implementing the monitoring program as soon as the warehouse is adequately organized. He encouraged an additional visit to develop and implement the monitoring program and to integrate routine testing into logistics.

has
GAP
agreed
to this
plan?

IV. RECOMMENDATIONS

1. Since the installation of the laboratory in 1985, there have been changes in the ISO standard on condom testing. Equipment has been specified in detail to improve reproducibility among laboratories. With constant use and changes in the standard, the existing air compressor and vacuum pump, which are not oil-less types, will prove inadequate for testing. It is strongly recommended that the air compressor and vacuum pump be replaced with oil-less types to eliminate the possibility of oil entering the air supply.
2. Although the test reports are kept in order, there is no proper storage currently available at NRIFC. A lockable file cabinet should be purchased and placed in the laboratory or the supervisor's office for storage of all confidential test reports. Only authorized personnel, including the director and the laboratory supervisor, should have access to the test reports. The existing cabinets in the laboratory should be organized and designated for samples received for testing and archival samples.
3. The condom testing area is located in the general contraceptive testing laboratory which is spacious and has a high ceiling. The building has a central air conditioning system, but under normal testing conditions, the air conditioning is not turned on in order to minimize utility costs. Thus, the room can be very warm during the summer months. A ceiling fan should be installed for ventilation and keeping the room cool without operating the central air conditioning system.
4. Upon request from the Ministry of Public Welfare, NRIFC has tested condoms for compliance with the ISO condom standards (1984 version) to determine whether the condoms are satisfactory for distribution. For the condoms currently stored in the warehouse, it is more appropriate to conduct monitoring testing than compliance testing. Monitoring testing includes only package seal and air inflation tests, the tests most revealing of condom deterioration over time. It is recommended that NRIFC follow the monitoring testing procedures in the Condom Testing Handbook to determine sample sizes and tests required and use the Condom Quality Index (CQI) as the basis for recommendations on the condition of condom batches.
5. Given the large quantity of condoms in the current reserve, it is strongly recommended that a comprehensive plan for quality monitoring be implemented immediately after the warehouse is organized. The plan should be designed based on NRIFC testing capacity and the quantity of condoms in the warehouse. In order

who is responsible here? Can NRIFC do this? I thought we wanted PATH to organize & assist w/ this??

8

to integrate quality assurance testing into the logistics system, NRIFC and other institutions responsible for condom supply and distribution will need to be involved in monitoring activities. The plan should be developed in conjunction with relevant agencies and should be clear as to which agency has the responsibility to request testing, collect samples, test, and authorize the distribution of condoms. All agencies should have a clear understanding of their level of commitment required for a successful monitoring program.

6. The NRIFC laboratory staff expressed interest in international training. They believe that opportunities to visit other model laboratories such as the United States Food and Drug Administration would enable them to evaluate and better improve their routine laboratory procedures. This may be an area for further A.I.D. consideration.



Government of Pakistan
National Research Institute of Fertility Control
Ministry of Population Welfare

Karachi, Dec. 17, 1990.

Attachment 1

Ms. Jane Hutchings,
Program Officer
Technology Management Department,
PROGRAM FOR APPROPRIATE TECHNOLOGY IN HEALTH
4 Nickerson Street
Seattle, WA 98109
U.S.A.

Dear Ms. Hutchings,

As you know that condom testing apparatus was installed in NRIFC in early 1985 and since then it is in continuous use. We feel it needs some adjustment and re-calibration of the air flow system. We do not have a manual of maintenance or an expert to do the job, I would like to have your advice and assistance in this direction.

I am glad that you have received the condoms and data lodger from the last sampling procedure (Sept. 1990). I am in possession of Custom fee receipt but receipt from U.S. Embassy for the APO postage is still awaited. As soon as I receive it, I will mail both receipts.

Yours sincerely,

(DR. TALAT KHAN)
Director



DIRECTOR

Government of Pakistan
National Research Institute of Fertility Control
Ministry of Population Welfare
Karachi. April 20, 1992

No.F 20-1/88-NRIFC

Ms. Jane Hutchings,
path (Program for Appropriate Technology in Health)
4-Nickerson Street, Seattle,
WA 98109-1699,
J. S. A.

Dear Ms. Hutchings,

NRIFC has acquired a condom testing facility in 1985 with the help of PIACT. The equipment set installed included 3 pieces of testing apparatus, Pin hole testing, Air inflation testing and Dimension measuring equipment.

It is nearly seven years since its installation and due to its constant use Air inflation testing apparatus needs replacement. I would be obliged, if you can help me in finding out the approximate cost of this apparatus.

Sincerely yours,

(DR. TALAT KHAN)
Director
N.R.I.F.C.

Condom Testing Pre-test/Post-test

1. What are the parameters measured in the air inflation test?
2. Which tests are conducted for quality monitoring?
3. What is the CQI?
4. What measurement do we take when conducting a dimensions test?
5. How much water is required to fill a condom subjected to water pinhole testing?
6. When should compliance testing be carried out?
7. If a package inflates and remains inflated during package seal testing, do you pass or fail that package?
8. Give an example of a test code.
9. How often do you perform the following:
Leak check _____
Flow rate calibration _____
Water pinhole equipment calibration _____
Clean or change compressor filter _____
Drain compressor storage tank _____
10. Who reviews and signs the test report when completed?

Comparison of correct responses between pre-test and post-test

Question#	Pre-test	Post-test
1	4	4
2	0	4
3	0	4
4	2	4
5	4	4
6	0	4
7	1	4
8	0	4
9	2	4
10	3	4

Training Evaluation

1. The period of training was

1	2	3	4	5
too short	----->			too long

2. The information presented was

1	2	3	4	5
too basic	----->			too difficult

3. The sequence of topics presented was

1	2	3	4	5
confusing	----->			appropriate

4. The presentation indicates that the trainer was

1	2	3	4	5
ill-prepared	----->			well-prepared

5. How comfortable are you in conducting or recommending sampling?
 - a. I can conduct sampling on my own.
 - b. I can conduct sampling with reference to the handbook.
 - c. I can conduct sampling with someone who knows sampling.

6. How comfortable are you to perform condom testing?
 - a. I can perform condom testing on my own.
 - b. I can perform condom testing with reference to the handbook.
 - c. I can perform condom testing with someone who knows how.

7. The overall training was

1	2	3	4	5
a waste of time	----->			very worthwhile

8. Comments:

Responses to the Training Evaluation

Comments:

This training is very useful and necessary. We learn a lot from this training and by only handbook we were not very much confident in evaluation of results. It will be much better if the trainees also get chance to visit other laboratories so as to compare with other and improve ourselves.

Prefer to have the same trainer to visit our lab. If the trainer happens to visit our country or passing by our country, to check and help us if we come across any problems regarding the apparatus or whatever other problems regarding the testing of the condoms we come across. The training was very fundamental and conducted in a well designed manner.

The training was excellent. It has served all the aspects of condom testing with regard to family planning. It would be better if NRIFC was also assigned the task of evaluating condoms with regard to health safety. It would be beneficial for us if the same trainer was to visit us again and re-evaluate us to see what aspects of the training we have been able to grasp and to determine any weakness on our part, if any, in the long run.

There is increase in my knowledge. We should be given the chance to get training of instruments and management, record keeping etc. in other countries such as USA and this training should be done after six months or in a year or two. Either the trainer should come or our NRIFC staff should be training according to new changes, techniques, and the better inventions to conduct the testing of the contraceptives such as condoms, IUDs, tablets, etc. A lab person should be sent to USA at once or twice in his service life.