NATIONAL DRUG SURVEY 2014 - 2016

Chapter 5

Pilot Study

PILOT STUDY

The pilot study is conducted to validate study design, predict an appropriate sample size, statistical method, identify possible gaps and difficulties which may be encountered in the full scale study. The feedback from the pilot study is used to improve the main study design, data collection forms and digital technology tools.

SCOPE

Pilot study was conducted in the National Capital Region (NCR) for four days from January 6th to 9th, 2015. Drugs Inspectors from UP, Punjab, Haryana, Delhi and Central Drugs Standards Control Organisation (CDSCO) were deployed as Sample Drawing Officers (SDOs) to draw Drug samples as per the methodology designed by ISI, Hyderabad.

OBJECTIVES

- To explain the methodology and assess the understanding of the participants.
- To identify and address possible gaps in the implementation of the proposed sampling procedure.
- To assess the effort that may be required for sample drawing in terms of locating the Source, time and number of visits to be made.
- To train participants in using AKS software for posting sample data online and plug in any glitches in the software or improvise the software.
- To assess the possible success rate of obtaining samples from a predetermined sample size.
- To analyse the laboratory test/analysis data of the Drug samples and to estimate the NSQ and Spurious percentage of the samples collected during pilot study.

METHODOLOGY

The Pilot study was conducted with teams comprising of SDOs and representatives

of Civil Society /Pharmacy Council of India. The study was divided into following three parts:

Part one of the study was training. On January 6th,2015 the methodology of sampling was explained to all teams and they were familiarised with the AKS software for entering data after collecting samples.

Second part of the study was sample collection. Eighty Outlets were randomly selected from the listed population of Outlets in the NCR. These eighty Outlets were distributed among 20 teams so that each team got four Outlets. On 7th and 8th January, 2015 the teams went out in the field and made efforts to collect the samples from assigned Outlets.

Part three was sharing of anecdotal experiences and feedback. On 9th January, 2015 the Core Expert Committee met all team members to understand their experiences and receive feedback to plug in any gaps or improve the Survey methodology.

Training

20 Drugs Inspectors from the CDSCO, UP, Punjab and Haryana were designated as SDOs. These 20 SDOs were divided into 4 Groups based on the area. These areas were:

- Delhi
- Haryana
- UP-I and
- UP-II.

Each group was divided into 5 sub-groups (teams) as A, B, C, D & E. Each team consisted of one Sample Drawing Officer, one representative of Civil Society / Pharmacy Council of India and one observer from Drugs Control department. Training was imparted to teams on 6th January 2015 at the training centre of the National Institute of Biologicals (NIB). The Members of the Drugs Survey - Core Expert Committee made presentations on the following topics concerning (Exhibit 5.1):

- Brief of Drug Survey
- Statistical Sampling Plan
- Packaging of samples
- AKS Software

Exhibit 5.1
Training of participants during pilot study

Training of participants on use of AKS Software

Training of participants on statistical design and sampling methodology

After the class room presentations, a mock practical training for drawing of samples was given to the SDOs and the observers from the dummy pharmacy outlets set up at NIB.

Sample size

Total 80 selected outlets were distributed among 20 teams with 4 outlets assigned to each team. Each team was asked to collect samples from 2 of the 4 outlets. The purpose of assigning 4 outlets to each team was to give them option for cases where the outlet listed didn't exist at the specified address or was closed at the time of visit. Each team was to draw 6 samples from each retail outlet thus making 240 samples for the pilot study (6 samples X 2 outlets X 20 teams).

Sampling methodology

The sampling methodology was developed to provide equal coverage to all the molecules in the list. The list of all 224 molecules selected for the survey was arranged in random order. This random order was independently generated for each outlet. As a result, the representation chance was equal for each of the 224 molecules. According to the sampling design, the Sample Drawing Officers (SDOs) were to obtain 6 samples from each Source as follows:

Starting with the first molecule, going sequentially as per the random order of the molecules for the Source, the SDOs were to go on checking availability of adequate quantity of formulations under six distinct molecules.

Sampling was to be stopped as soon as formulations with adequate quantities for six distinct molecules were obtained or in the case wherein all the 224 molecules in the list was exhausted and less than six samples were drawn.

This procedure was designed to save the sampling effort and also enable the estimation of possible number of molecules available at the Source.

Further, it was decided that for the pilot study, the complete list of 224 molecules would be explored by SDOs at each outlet to gather information about availability of these molecules in the random order and also to assess the time it takes for exploring all 224 molecules.

Teams had to fill the sample drawing data form and other information form which was to be followed by packing and sealing of the Drug samples.

After sample collection, the teams had to feed the sampling details in the Drug Survey AKS software at NIB, Noida. All the 20 teams were directed to complete

the exercise of the sample and data collection procedure including feeding in the AKS software during 7th and 8th of January, 2015.

After drawl, Drug samples were handed over to NIB, Noida, the National Coordinating Centre for the Survey. Each sample was then physically examined by the experts and these samples were thereafter sent to Indian Pharmacopoeia Commission (IPC) in Ghaziabad for laboratory test/analysis.

MAJOR OBSERVATIONS OF THE PILOT STUDY

On 9th January, 2015, the teams made Power Point presentations on the following aspects:

- Design for selection of Retail shops
- Design for selection of samples
- Feeding the data in the software
- Logistics
- Any other suggestion

General observations

- Entire sampling procedure was quiet time consuming
- The functioning of AKS software was appreciated by all the participants who, however, suggested that the Drugs sampling data forms needed to be simplified

Anecdotal experiences

- Few Retail owners showed reluctance in sharing license details
- Few Retail owners did not charge for the samples
- Few Retail owners were unfamiliar with Generic names and reported non-availability

Sourcing the Retail Outlets

- Reduce travel time by allotting nearby areas to one team

Collection of samples

- Standard Operating Procedure (SOP) should be developed on procedure of drawing, packing and dispatch of samples including instructions for processing of forms

Packaging of samples

- Bigger size boxes should be provided for packing of bulky samples like LVPs
- Compact size kit package should be provided for ease of handling
- Provide magnifying glass
- Provide better quality candles
- Provide smaller size brass seal

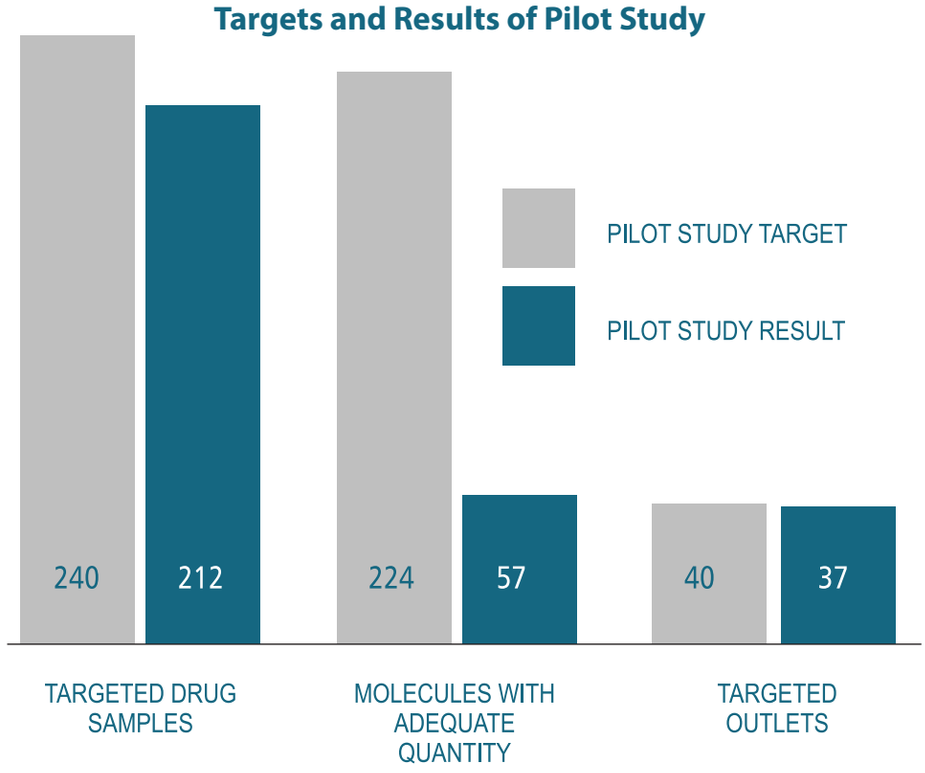
Documentation

- Instead of 6 forms for each Source, only one form should be designed having common details like Source details, bank account details, etc.
- Single invoice for all six samples
- One acknowledgement for each Source

Training

Animated video for easy recall of processes of Source selection, sample selection, documentation, packaging and dispatch should be prepared.

Exhibit 5.2
Targets and Results of Pilot Study



RESULTS OF THE SAMPLE COLLECTION

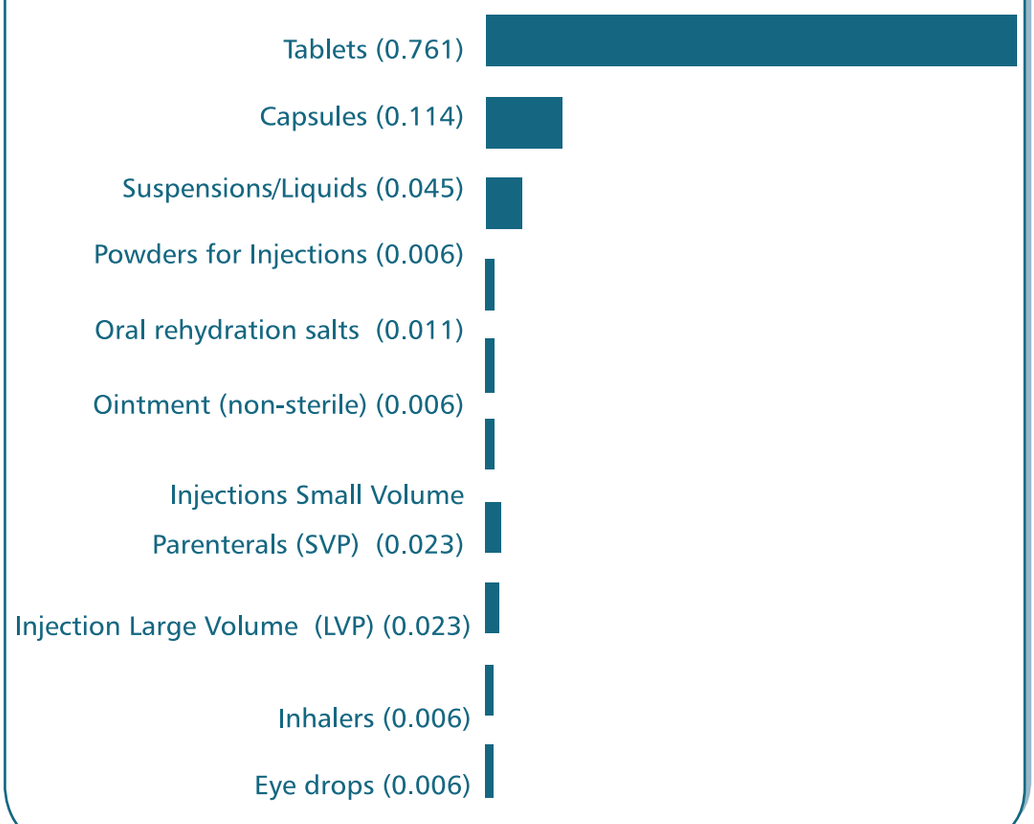
As per the study design, 240 samples were to be collected from 40 Outlets by 20 teams, whereas samples were successfully drawn from 37 Outlets. Samples of 6 distinct molecules were collected from each of 37 Outlets (total 222 samples).

These samples were received by the NIB along with sample drawing forms, acknowledgements and invoices. The payments for the samples were sent to the concerned retail outlets through electronic money transfer.

Nineteen of 20 teams did not fill details of Drug samples in Part B of the form, so details about the store, and most importantly, the approximate number of molecules stored in the Outlet were not available. Some teams did not mention the size of the samples taken. Some teams collected samples from the top six molecules in the lists given to them regardless of whether the top six had

Exhibit 5.3

Targets Proportions of Dosage Forms Among Drug Samples With Adequate Quantities



adequate quantities or not. This resulted in samples with quantities inadequate for all tests in some cases though there was an opportunity to collect samples with adequate quantities. In some cases, the quantities collected were more than the required quantities.

The 222 samples were subjected to visual inspection by the Drugs Inspectors of CDSCO. It was observed that 2 samples were out of the selected list of Drugs. Remaining 220 samples were sent to IPC, Ghaziabad for laboratory test/ analysis. Of these 220 samples, 8 samples were not tested for various reasons such as non-availability of reference substances/impurity profiles/methods of analysis /facilities at IPC Laboratory.

Of the remaining 212 samples belonging to 63 molecules, 176 samples belonging to 57 molecules had adequate quantity. Of the 176 molecules obtained in adequate quantity, 13 were obtained 5 times or more, showing that these molecules had a higher chance of being sampled in the Survey (Exhibit 5.2). Of the 57 molecules obtained in adequate quantity, 29 were obtained only once.

It may be noted that Drug samples were obtained in different dosage forms such as tablets, capsules, suspensions and so on. 76.1% of the samples were in the form of tablets, 11.4% were capsules and 4.5% were liquids and suspensions (Exhibit 5.3).

212 samples were analysed by IPC. A total of 36 tests were performed on the Drug samples as applicable. Criteria for pronouncing a Drug sample as Spurious or NSQ was ascribed. The reports of laboratory test/analysis were submitted to NIB.

RESULTS OF THE LABORATORY TESTS

No Drug was found to be Spurious. Two samples were found to be date expired. Four samples were found to be NSQ (see Exhibit 5.4 for details). From this data the estimated percentage of NSQ Drugs was 1.92%. The percentage of NSQ for not complying with respect to uniformity of weight was 0.83%. The percentage of NSQ for not complying with respect to dissolution was 0.83%. Using the statistical principles, the percentage of NSQ can be anywhere between 0.5% to 4.85% (the approximate 95% confidence interval). The estimate here was based on a very small sample size.

Exhibit 5.4
Samples found to be Not of Standard Quality in pilot study*

Generic Name	Therapeutic Category	State where Drug was manufactured	District where sample was collected	Reason(s) for NSQ
Azithromycin	Anti- infective	Uttarakhand	Ghaziabad	• Assay (64.3%)
Ofloxacin	Anti- infective	Uttarakhand	Ghaziabad	• Assay (85.75%) • Uniformity of Weight
Pantoprazole	Gastrointestinal medicine	Delhi	North West Delhi	• Assay (84.15%) • Dissolution
Dexamethasone	Anti-allergic and used in anaphylaxis	Himachal Pradesh	North West Delhi	• Assay (84%)

Conclusion

The pilot study was carried out to understand and validate the Drug Survey methodology. The pilot study helped in improvising the data formats and corrections in the AKS software for posting the data. It was also ascertained that the Survey can achieve the target of 42,000 samples as reflected in the project report. The AKS software was found to be user friendly and no difficulty was observed in feeding the details of samples drawn. The pilot study therefore had a very definite contribution to the success of the final programme.

Exhibit 5.5
Group photograph of participants of pilot study