

# Significance of Documentation in Research - Experience of Drug Proving Project

**ABSTRACT:** Documentation in research comprises of recording of all the events, observations and method of observations. In any research study, the entire documentation plan is done prospectively. A large section of the protocol is usually devoted to the method. Documentation process is very challenging especially when trials are conducted on human being. When we try to understand about documentation process one must know few general facts.

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Research in any field keeps that field growing. Clinical Research has played a major role in the development of medicine. Homoeopathy since its inception, is based on the scientific principles. They are derived by unprejudiced observations and recording it accurately, proper analysis of what has been recorded and then finally making proper conclusions and reconfirming them again. So this is a very scientific way of Research. Though all the steps are important, what is the most crucial first basic step is documentation.

## WHY DOCUMENTATION IS IMPORTANT?

### FOR INTEGRITY OF RESEARCH:

Research data, including detailed experimental protocols, all primary data, and procedures of reduction and analysis are the essential components of scientific progress. Integrity requires meticulous attention to the acquisition and maintenance of research data. When questions about the integrity of the research arise, then they are often answered by inspecting and reanalyzing the primary data.

### INTELLECTUAL PROPERTY PROTECTION

Research data are legal documents for purposes of establishing patent rights. Proprietary issues can also drive data access and sharing practices.

### ENSURING CONFIDENTIALITY

Regulations to protect human subjects may require data to be kept confidential. When human trials

are involved confidentiality concerns will dictate how data is collected, retained and shared.

## SOURCE OF DATA

Data is obtained from various sources. Broadly, they can be classified into two groups such as subjective data and objective data.

- Subjective Data can be obtained from
  - Interviews
  - Questionnaires
  - Diaries
- Objective Data can be obtained from
  - Test procedures
  - Laboratory data, and
  - Physical assessments

These data can be obtained either retrospectively from records or prospectively from specially designed case records

### Examples of Source Documents

- Previous medical records
- Procedure and lab reports
- Progress notes in a medical record
- Informed consent form
- Drug disposition records
- Pictures, documentaries are also part of

qualitative data

## EXPERIENCE OF DRUG PROVING PROJECT

To understand the importance of documentation in a homoeopathic research, drug-proving project

is the best example. Drug proving method has undergone a sea change from pre-Hahnemannian era to Hahnemannian drug proving till current modern drug proving.

Post Graduate students of Dr M L Dhawale Memorial Homoeopathic Institute had undertaken drug-proving project for their dissertation work. It was a dissertation topic hence it was a time bound project. Experience of the project speaks about how the documentation process of homoeopathic drug proving is scientific and ups and downs in fulfilling all the steps.

**STEP 1: PROTOCOL WRITING**

Detailed synopsis was already written prior to the study elaborating the guidelines of Hahnemannian and Modern drug proving.

**STEP 2: TEAM FORMATION**

This was very important as when you have experts guiding you, then lot of the unseen difficulties can be avoided. Naturally the most knowledgeable person is none other than Dr K P Mazumdar. He not only gave his consent but also decided the medicine which was to be proven. He gave most importantly guidelines for the documentation.

**TEAM: PG STUDENTS:**

Dr Dilip Nandha, Dr Sachin Junagade, Dr Aquilla Sayyed, Dr Leena Naik, Dr Shatrugna Tiwari, Dr Bhavik Parikh,

**PROJECT DIRECTOR:** Dr C B Jain

**PROJECT CONSULTANT:** Dr K P Mazumdar, Dr Bipin Jain

**RESEARCH COORDINATOR:** Dr Prashant Tamboli

**PRINCIPAL:** Dr K M Dhawale

**STEP 3: SELECTION OF PROVER**

This was the first batch of PG course. MLDMHI is only a PG college. Hence, there are no homoeopathic students to prove the drugs. Now it became mandatory to search for prover outside the college.

**CRITERIA FOR PROVER:**

Inclusive Criteria:

- Relatively healthy human being
- Both Sexes

- Age group: 18 – 45 years
- Honest
- Intelligent to understand symptoms and can record as it expressed

**Exclusion Criteria:**

- Poor state of health
- Advanced structural change
- Hysterical persons,
- Overt anxieties and emotionally disturbed state
- Skin, respiratory, GIT or any other allergies

**SAMPLE SIZE:**

At least 30 cases were required. Additionally 15 cases were needed for taking care of dropouts. Now it was Herculean task to get people relatively free from any disease. Again, there was difficulty in getting all of them at one time. Finally, we approached Commerce College and the Principal of that college gave his consent.

**SCREENING TO SELECT PROVER:**

The next hurdle was how to select a final provers of 45 students out of 440 volunteered candidates. Here some amount of clear documentation was needed. Hence, screening form was designed.

**SCREENING FORM:**

Dr M L Dhawale Memorial Homoeopathic Institute, Palghar

Drug- Proving Project

Date: \_\_\_\_\_ Screening Physician: \_\_\_\_\_

Reg. No: \_\_\_\_\_ Name: \_\_\_\_\_

Age: \_\_\_\_\_ Sex: M / F.

Education, Class and Roll No: \_\_\_\_\_

Mother Tongue: \_\_\_\_\_ Status: S / M / D / W

Caste and Religion: \_\_\_\_\_

Diet: Veg / Non – Veg / Eggs.

Occupation: \_\_\_\_\_ Address: \_\_\_\_\_

**Presently Having Complaints:** Yes / No If Yes?

Hypertension / Diabetes / skin complaints / allergic Disorder / any other than specify

**Past Illness:** Yes / No. If Yes, describe: \_\_\_\_\_

**Allergic to drugs / any other substances**

**Voluntarily** : Yes / No

**Ability to describe symptoms:** Grade I / II / III

**Availability for weekly follow up in Hospital:**

Yes / No

Expectation: \_\_\_\_\_

#### ANALYSIS OF THE SCREENING DATA:

For final selection, first it was examined if candidate fulfills the criteria or not. The last four parameters were important as prover must be able to express clearly his complaints. Therefore grading was used to assess this ability. Expectation criteria also gave a fair idea of the candidates. Some had joined as their friends had joined. Some wanted homoeopathic treatment for their complaints. So documenting all these helped to select only sincere candidates. This process helped in selecting 100 probable candidates.

#### STEP 4: ORIENTATION OF PROBABLE PROVERS AND TAKING THEIR CONSENT

In any scientific project one must note down all the procedure and facts of the trial. This is called investigation brochure. This is another important part of documentation process. Many legal, ethical issues can be answered based on this investigation brochure.

For this project, explanatory note was prepared and given to all the candidates.

- ✦ Homoeopathy and Drug Proving
- ✦ What is a Drug Proving?
- ✦ Need of Drug Proving
- ✦ Drug Proving Method
- ✦ Drug Proving: Dangers?
- ✦ Steps of Drug proving
- ✦ Do's and Don'ts of drug proving

During the orientation, the team answered all their questions, cleared all types of doubts. Finally 60 volunteers were selected through this process and their consent was taken.

#### STEP 5: PRE-TRIAL CHECK UP

Case taking of provers was a new experience for most of our PG students. Normally we take cases of patients having lot of symptoms. But, in this project all were healthy having no symptoms. Therefore, it was necessary to take a lot of expressions of the patient as a person like craving- aversion, their reaction to environmental factors, temperaments. Following system was followed to get all expressions

1. History form and notes on how to write history form: this allowed them to express freely
2. Case taking and physical examination
3. Investigation:
  1. CBC
  2. Urine routine
  3. Stool routine
  4. Fasting Blood Sugar
  5. Lipid profile
  6. Serum Creatinine
  7. USG abdomen
  8. X - Ray Chest - PA View
  9. ECG

All these were recorded in ICR Standardized case Record, published by Dr M L Dhawale Memorial Trust<sup>®</sup> CCRH has accepted this as a standard documentation format. From the documentation point of view this is another important aspect.

#### ANALYSIS OF PRECLINICAL DATA

Each prover's data was analyzed in the following format

1. Location, Sensation, Modalities and Concomitants.
2. Symptoms Classification
3. Forming Conceptual Image

#### STEP 6: ADMINISTRATION OF CODED DRUG

This was double blind study. Drug was coded and administered as per the protocol.

1. Environmental changes and conditions at the time of administration of each of the coded drugs during different rounds in different potency have been noted down to understand its effect on the provers.
2. 3 globules of coded drug, dry on tongue, 4 times a day had been administered for 7 days in 1st round of Placebo, for 14 days in 2nd round of 200th potency and 3rd round of 30th potency.
3. Mother tincture in 4th round had been administered for 14 days.
4. Prover were ask to take 5 drops of mother tincture for initial 3 days once per day, for next 4 days 5 drops twice a day and for last 7 days 10 drops twice a day. The drops of mother tincture had been advised to mix in ¼ glass of water.

5. Drug administration had been suspended at the earliest indication of any change in state of health
6. Drug administration remained suspended till the symptoms disappeared followed by a rest

period of 7 days in first round, for 14 days in 2nd, 3rd, and 4th round.

The drug administration had been resumed in a different potency like 200th in 2nd round, 30th in 3rd round and mother tincture in 4th round and followed the same procedure as mentioned above

**STEP 7: RECORDING BY PROVER IN DAY BOOK**

Prover were oriented about how to record in Day book. Following format was used.

Date	Time of intake of the drug or test substance	Symptoms experienced in order of their appearance	Any change in normal routine by the prover in respect of daily habits pertaining to diet, living conditions etc.

**NOTE:** Ordinary habits of life must be observed, and ordinary work maintained. Changes from routine might cause deviation from the normal balance. In case any change is effected it must be reported under column 4 above.

**PROVER'S SIGNATURE**

Prover used one form for each day. They recorded minutest details. Each column had a special significance. Third column record the changes in the prover. Last column records the change in the environment. This allowed understanding if the symptom was because of drug or because of environmental factor.

**STEP 8: VERIFICATION OF DATA**

Periodically follow ups were taken and following changes were documented.

Follow ups

1. Once / week, if required daily or in between
2. In Day book to look for:
  - ¥ Time of the coded drug taken
  - ¥ Time of commencement of symptoms
  - ¥ Period of duration of change in health
  - ¥ Any change in diet and daily routine,
  - ¥ Any unusual mental and physical stress
3. Prover who gave incomplete expression of their experiences in the day book was given direc-

tion to express the experiences completely.

4. Precaution had been maintained strictly not to ask direct or leading question, not to probe in collecting their experiences.
5. Physical examination has been carried out once / week, if required in between to arrive at a clinical understanding of the symptoms produced by the prover.
6. Examination of Urine sample of every prover was done after completion of proving of 200th dilution of both coded drugs to establish the effect of the drug on the kidney and sugar renal threshold level.
7. Post-trial investigation and Medical report had been prepared along the lines similar to the pre-trial report.
8. Weekly team meeting were conducted to understand the progress of the project.

**STEP 9: TAKING CARE OF DROP OUTS**

In spite of regular orientation there was always a

possibility that few prover may not report regularly. Following ways were decided in the protocol to maintain the pace of the project. This is also important aspect of documentation.

**CONTACTING PROVER THROUGH:**

1. Telephonic call: at their residence phone number, mobile number.
2. Letter: writing letter at their residence or at contact address.

3. Personal contact: in college, at their residence address.

**STEP 10: POST- TRIAL ANALYSIS**

- ⊕ Symptom Elaboration Proforma: was prepared
  - ⊕ Post-trial symptoms and the laboratory finding were compared with the pre-trial data.
- This allowed to distinguish between the symptoms of the drug and of the prover.

**SYMPTOMS ELABORATION PERFORMA**

Date	
Time of administration of the drug or test substance	
Symptoms Observed in order of their Appearance	
Symptoms Appearance Time	
Symptoms Disappearance Time	
Location	
Sensation	
Extension / Direction Radiation of symptoms	
Causation	
Concomitants	
Clinico-pathological finding, if any	
Remarks	

SAMPLE OF ONE PROVER'S SYMPTOMS

A / 2 - Comparison of Follow Ups -				1 Round	2	3	4	
L	S	M	C		200	30	Q	T
Mind	Sadness +++			0	0	1	1	2
Mind	Mood decreased +++			0	0	1	1	2
Mind	No desire to do any work +++, sadness during			0	0	1	1	2
Mind	Laziness ++			0	0	1	1	2
Sleep	Sleepy feeling +++	<+++ 2:30 pm		0	0	1	1	2
General	Body ache ++ Heaviness ++			0	0	1	1	2
Sleep	Sleepy feeling +++			1	0	1	1	3
<b>MIND SYMTOMS</b>				<b>0</b>	<b>0</b>	<b>25</b>	<b>7</b>	<b>32</b>
<b>PHYSICAL SYMPTOMS</b>				<b>2</b>	<b>0</b>	<b>23</b>	<b>58</b>	<b>83</b>
<b>TOTAL SYMPTOMS</b>				<b>2</b>	<b>0</b>	<b>48</b>	<b>65</b>	<b>115</b>

THEN DATA / SYMPTOMS OF ALL THE PROVERS WERE COMBINED

Example:

**Combined - 2nd Round Symptoms of all provers -**

L	S	M	C	A/ 2	A/ 4	A/ 6	A/8	A/ 10	A/13	A/ 15	A/18	T
Mind	Laziness ++			0	0	1	1	0	0	0	0	2

Mind	Doesn't like to work ++			0	0	1	1	0	0	0	0	2
General	Appetite increased ++			0	0	1	0	0	1	0	0	2
General	Hunger increased ++			0	0	1	0	0	1	0	0	2
Head	Heaviness++			0	0	1	0	0	1	0	0	2

**FINAL OUTCOME OF THIS METICULOUS DOCUMENTATION**

There were many outcome of this project. The data was analyzed in different ways to achieve the objectives. Following is just one example for the purpose of demonstration.

OBJECTIVE: To incorporate the ELEMENT OF TIME by representing in sequence of their appearance to have better understanding of evolutionary drug picture.

Time is most important concept Boger had used in describing Materia Medica. The question was how to understand that through drug proving. For this the meticulously done documentation was helpful.

Following is the demonstration of how data was analyzed.

PROVER CODE A2:

**ROUND II**

DAY 1, AFTERNOON: Feeling of sadness, did not like to do anything, but felt better<sup>3</sup> after sleep

5 – 5:30 pm: Memory weakness, forgot to take medicine in the evening; Tiredness

Day 2 to Day 4

No Symptoms

DAY 5, 1:00 pm: There was confusion of mind<sup>2</sup> whether to take medicine before lunch or after

lunch; Laziness<sup>2</sup>

5:00 pm: Mood decreased<sup>3</sup>, did not like to do anything<sup>3</sup>, just wanted to sit, no mood even to sleep; Sadness<sup>3</sup> lasted for 1-1½ hours, with lachrymation from both eyes and heaviness of the body, which was better<sup>3</sup> after roaming out with friends.

Day 6 At 1:00 pm. Felt that mood will be disturbed after taking medicine. Sad<sup>3</sup> mood, with dull headache; No desire to talk with anybody, desire to be alone<sup>3</sup>; No interest in anything which was better<sup>3</sup> after roaming out with friends.

Day 7 12:00 midnight: Experienced bodyache<sup>2</sup>  
2 – 2:30 am – 3:00 a.m : Sleep disturbed<sup>2</sup> at. due to sudden onset of chest pain<sup>2</sup> and heavyness<sup>2</sup>, lasting for 20 – 25 minutes accompanied by bilateral thigh pain, epigastric pain with perspiration and anxiety what will happen to me and fear of death<sup>2</sup>; Chest pain with heaviness > pressure, > stool after<sup>3</sup>.

10 am to 2:30 pm: Had headache bilateral, parietal and occipital region < thinking about it.

10 am – 11 am: Had chest heaviness.

10 am to 7 pm: Sad mood<sup>2</sup> (observed by physician on prover's face).

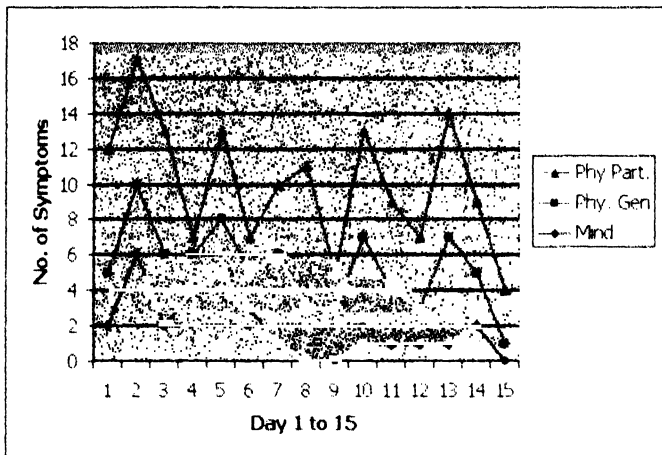
12 noon to 7 pm: Felt uneasiness.

2:30 pm to 7 pm: Tiredness<sup>2</sup> and weak<sup>2</sup> feeling,

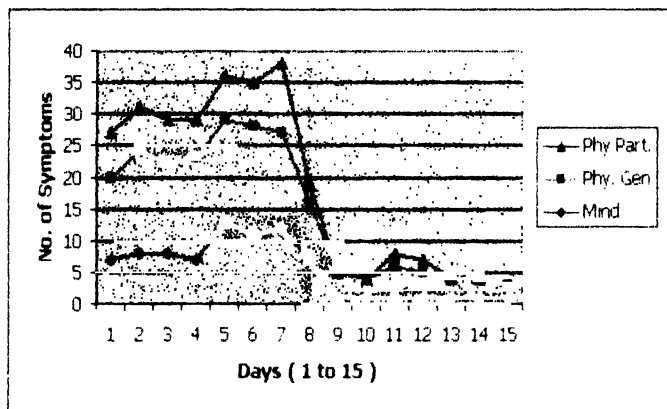
as if he has done hard work  
 2:30 pm to 5:15 pm: Had sleepy feeling<sup>3</sup>; felt sadness<sup>3</sup>.  
 5:15 pm to 7 pm: No interest in anything or any work with lachrymation<sup>2</sup> from both Eyes felt better<sup>2</sup> after roaming out with friends;  
 Then all the symptoms produced by the provers with the specific potency were integrated in an evolutionary manner - Day Wise  
 Day 1: Urge for stool 10 minutes after each dose on day 1 only.  
 Sleepy<sup>2</sup>, Drowsy<sup>2</sup> feeling, 10-15 minutes after each dose lasting for 15 minutes to 1 ½ hours, lasted for almost 15 days.  
 11:00 am: Complaints of cutting pain in the epigastrium, > by pressure.  
 6:15 pm: Hungry<sup>2</sup>  
 7:30 pm: Sensation of mild chilliness > covering<sup>2</sup>  
 9:00 pm: Felt extremely sleepy<sup>2</sup>  
 Had headache in the frontal region which lasted for 30- 45 min accompanied by difficulty in concentration and irritability<sup>2</sup> Calf pains  
 10.20 pm: Burning sensation in abdomen  
 Day 2: 3:45 am and 5:30 am. Increased frequency of urine, woke up from sleep to pass urine.  
 Sneezing in the morning on waking  
 8:15 am: Hunger increased<sup>2</sup>, insatiable hunger  
 6 am: Lumbo-sacral backache and heaviness, after getting up in morning lasting for one hour – lasted for 3 days  
 7:30 am – 9:30 am: Feeling of Laziness<sup>2</sup>, decreased mood<sup>2</sup>, and not feeling like doing any work<sup>2</sup> in morning from daily lasting for 4 days  
 Morning on walking pain<sup>2</sup> in Extremities and stiffness<sup>2</sup> with sensation as if walking on soft surface<sup>2</sup>, and Tingling numbness  
 11:00 am.: Bored sensation<sup>2</sup> > taking tea<sup>3</sup>, laziness and no desire to work<sup>2</sup>  
 2:00 pm and 11:00 pm. Appetite increased<sup>2</sup>  
 Had an argument with aunt which caused frontal headache which was better by going out to a birthday party which is a usual complaint after anger

7.00 pm: Burning sensation in abdomen  
 Day 3  
 4:15 am: Urine frequency increased, had to wake up in the night to pass urine.  
 Heavyness<sup>2</sup> of head, 10 minutes after taking each dose, ie frequency 4 times per day lasting for 30 minutes each time, lasting for 13 days  
 4:00 am to 8:30 am: Throat pain and sensation of catch in the throat, ><sup>2</sup> drinking water, <<sup>2</sup> swallowing  
 6:30 am: Bleeding per rectum, during stool in drops<sup>2</sup>, profuse<sup>2</sup>, bright red<sup>2</sup>, painless<sup>2</sup>, for 1 day only  
 10 am and 4 pm: Appetite increased  
 12.30 pm: Thirst increased  
 2:00 pm: Headache, watery coryza and feverish feeling with extremities pain < from exertion; Evening Laziness<sup>2</sup>, no desire to go out<sup>2</sup> and appetite decreased<sup>2</sup>  
 Sleepy feeling<sup>2</sup>, had to sleep  
 Mild headache  
 3:00 pm: Ineffectual urge for stool.  
 Day 4:  
 2 pm and 7pm: Appetite increased, had to eat something  
 Refreshed feeling, no fatigue inspite of exertion  
 11.00 pm: Chilliness<sup>2</sup>  
 Day 5  
 4.00 am Throat- catching sensation  
 11:50 am - Thirsty, desire for cold drink  
 2:00 pm – appetite increased<sup>2</sup> – but could not eat enough  
 Evening – watering<sup>3</sup> of nose with pain in Extremities  
 Anger, Weepy, didn't attend college  
 5:00 pm to 6:30 pm Feeling of being bored with body ache and no desire to do any work. Right leg pain with increased frequency of urine  
 In this way proving in all potencies of all provers were analyzed.  
 Following graphs gives the comparative aspects of how symptoms were produced. It glaringly shows the changes because of change in the potency.

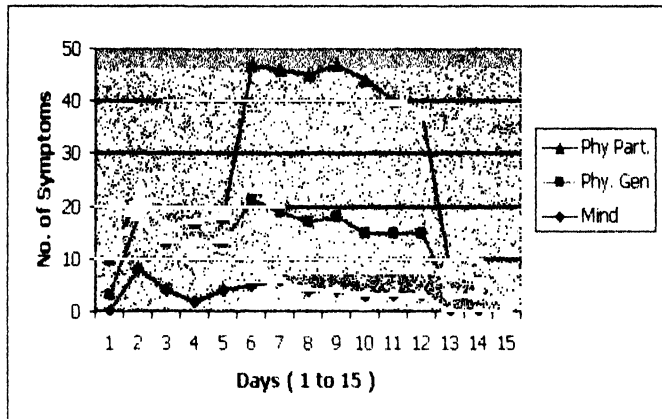
**200 POTENCY: SYMPTOMS EXPRESSED AS PER TIME EVOLUTION**



**30 POTENCY: SYMPTOMS EXPRESSED AS PER TIME EVOLUTION**



**MOTHER TINCTURE: SYMPTOMS EXPRESSED AS PER TIME EVOLUTION**



**CONCLUSIONS**

- Documentation is most important aspect of research process
- Homoeopathic drug proving documentation is very superior way of documentation
- Proper documentation helps in the process of analysis and gives validity to our conclusions.
- Documentation helps in taking care of all legal and ethical issues.
- Proper documentation helps in timely completion of the project.
- Documentation helps in better planning of research as in research one needs to write in advance, what is to be done and then follow what has been written.

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once santa saw a very soni kudi in the market & thought..  
 .....kash k ye meri maa hondi to main v inna sona Honda..



Once someone sent a SMS to a Santa : Bhejanewala mahan padhanewala gadha.  
 Santa got angry and replied : Bhejanewala gadha padhanewala mahan!