

Extracting symptoms from homoeopathic drug provings*

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Abstract

There has been a lack of consistency in the way symptoms are extracted from homoeopathic provings. The current situation is discussed and recommendations for a proving protocol laid out.

KEYWORDS: Homoeopathic provings; Protocols; Clinical trials.

Introduction

Background

The process of symptom extraction from homoeopathic drug provings (HDP) has not been analysed or tested in a systematic fashion. This is reflected in the ongoing debate and inconsistencies within homoeopathy regarding the criteria for 'grading' rubrics in homoeopathic repertories. If one studies the provings of Hahnemann, compares the symptoms listed in the final report and cross-references them with the clinical keynotes for the medicine, one notices that many of the symptoms experienced by the subjects in an HDP are not utilized. This raises the following questions.

- Which symptoms experienced by the subjects in an HDP are reliable and which are superfluous?
- Are symptoms experienced by subjects in an HDP which are *not* used in the clinical practice of homoeopathy 'noise' or,
- Are they useful symptoms which have been overlooked?

Hypothesis

- 1 Hahnemann was one of the outstanding research scientists of his day. The methodology for homoeopathic drug provings he initiated can be improved on by incorporating relevant scientific research methods used today.
- 2 The understanding and development of old and new homoeopathic medicines is done by triangulating among homoeopathic drug proving information (current and historical), information from clinical practice, and the toxicological data for medicines

with a toxicological profile.

- 3 Certain criteria for selecting symptoms experienced in a homoeopathic drug proving are more relevant than others for the selection of homoeopathic medicines in clinical practice. The criteria for selecting symptoms experienced in an HDP can be articulated and systematically applied. Using a Bayesian approach, this could result in a probability rating for the likelihood that a symptom is associated with a drug to be developed.

Objectives

- 1 Review the overall methodological considerations which must be addressed by those conducting a proving in order to be able to review and compare the results of one proving with another.
- 2 In order to accomplish the first objective, clear symptom selection criteria must be applied to all symptoms extracted from the subjects' journals in a homoeopathic drug proving.

Proposal and recommendations

Recommendations for homoeopathic drug proving protocols

The research protocol guidelines outlined below are of great importance in assuring a systematic commitment to reliable results. The following guidelines summarize a general framework for conducting high quality homoeopathic drug provings and cover the categories of information that should be included or at least considered. These guidelines are consistent with the homoeopathic drug proving guidelines of the HPUS and the good clinical practice and research guidelines of the EU and the FDA. We have conducted over 50 homoeopathic drug provings using most of these guidelines.

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Principal investigators

The names and addresses of all persons who are in any way responsible for carrying out the homoeopathic drug proving, for example,
 —Proving Director. At least 5 years experience in homoeopathy and 2 years experience in homoeopathic drug provings.
 —Proving Supervisors. Experienced homoeopaths.

Background/Objective

This section defines the objective of the homoeopathic drug proving.

Design

This section should contain information concerning the duration of the homoeopathic drug proving, the location and time of year of the provings, and information regarding the duration of the proving for an individual subject. The homoeopathic drug proving should be described using the following descriptive terms as examples:

- mono-centre/multi-centre
- prospective/retrospective
- randomized/non-randomized/stratified
- open/single-blind/double-blind
- controlled (placebo, active medication)/non-controlled
- parallel/crossover
- run-in phase/pre-observation period
- total number of subjects

Subjects

The number of subjects for the homoeopathic drug provings should be stated. In multi-centre homoeopathic drug provings the total number of subjects, the planned centres and the proposed number of subjects per centre should be stated. Demographic data on all subjects should be available.

Inclusion/exclusion criteria

This section defines the inclusion/exclusion criteria for subjects who are to be included in the homoeopathic drug proving. It should be as specific as possible and should contain information which will allow a subject to be included or excluded from the homoeopathic drug proving.

Other circumstances

All further particulars concerning the selection of subjects, both at the time of recruitment

and during the homoeopathic drug proving, that cannot be classified as inclusion or exclusion criteria should be recorded in this section. Examples would be preference for subjects who have some knowledge of homoeopathy, or education of those who have no knowledge of homoeopathy, etc. Any information that might be relevant to someone who would like to replicate the proving should be noted.

Proving medication

All information concerning the study medication must be listed, such as:

- Name of the medication
- Trade name
- Starting material, manufacturer, preparation method
- Batch numbers
- Manufacturer of study medication
- Potency, dosage information
- Stability of starting material and study medication
- Labelling
- Storage conditions and/or special storage instruction
- Packaging
- Expiration date of starting material and study medication

Proving time-line

All phases of the homoeopathic drug proving and the planned examinations (check-ups, final examination, follow-ups, exit interviews, etc.) should be described in the protocol.

Subject withdrawal and premature study termination

Any reason requiring the withdrawal of an individual subject from a homoeopathic drug proving (dropout) or the premature termination of the homoeopathic drug proving at any time for medical and/or organizational reasons should be clearly described.

Adverse events

Any adverse events should be clearly documented and reported to the appropriate individual or sponsor.

Criteria for symptom selection

The symptom selection criteria should be stated in advance and documented in the final report of the homoeopathic drug proving. Symptom

selection should be on an individual basis prior to any group discussions with the subjects. The symptom selection process is dependent on a careful review of the symptoms each subject experiences during a proving based on a thorough understanding of the individual. We are utilizing the following symptom selection criteria:

- modalities (something which makes a symptom better or worse)
- concomitants (something occurring in conjunction with a symptom)
- timing of the symptom (periodicity, specificity of timing)
- localization (sides, extension)
- unique descriptions of a symptom (descriptive adjectives)
- intensity of the symptom
- a symptom is new or has not been experienced in the past 12 months
- a symptom occurred after taking the medication on at least 2 occasions during the homoeopathic drug proving
- a symptom experienced when the proving started and which disappeared or is significantly ameliorated after the administration of the proving medication, is classified as a cured symptom
- a symptom experienced in more than one subject.

Monitoring

Monitoring of the homoeopathic drug proving by an outside individual or organization, if necessary, should be stated in the protocol.

Biometric evaluation/statistical analysis

The procedures used for data extraction and analysis of the symptoms, for example, qualitative or quantitative methods, and preparation of the final report should be described.

Ethical and legal provisions

All legal provisions, requirements and regulations should be mentioned and discussed.

Informed consent

Prior to the start of the homoeopathic drug proving, each potential subject should be informed by the investigator about the nature, meaning and consequences of the drug proving in a comprehensible and clear manner. Before participating in a homoeopathic drug proving the subject must provide

written informed consent.

Ethics Commission/Institutional Review Board (IRB)

Prior to initiation of the homoeopathic drug proving, the protocol, a blank copy of a subject's diary, and the informed consent form should be submitted to the appropriate committee for approval, if applicable.

Confidentiality

All data recorded should be treated in strict confidence. During documentation and analysis of the homoeopathic drug proving, the individual subjects should only be identified by an identification number.

Subject insurance

All subjects participating in a homoeopathic drug proving sponsored as a research trial with IRB or Ethics Commission approval should have insurance for the subjects. If there is no sponsor, the proving director bears the responsibility for any adverse events.

References

All bibliographical and reference data should be cited.

Conclusions

The systematic application of a consistent scientific methodology for homoeopathic drug provings, with a particular emphasis on the symptom selection process, will improve the quality of homoeopathic drug provings. All data should be ideally entered into a computerized database so that further analyses can be done as indicated and provings can be easily compared. The systematic application of symptom selection criteria creates the possibility for comparison of useful clinical symptoms of a homoeopathic medication and the pattern of symptom selection criteria for those symptoms if they occurred in homoeopathic drug provings. A Bayesian approach might allow for the possibility of developing a probability statement about the likelihood that a symptom occurring in homoeopathic drug proving will be useful clinically.

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