ASHP Guidelines for Pharmaceutical Research in Organized Health-Care Settings

The promotion of research in the health and pharmaceutical sciences and in pharmaceutical services is a purpose of the American Society of Hospital Pharmacists, as stated in its Charter.[1] In keeping with this purpose, pharmacists in organized health-care settings should understand the (1) basic need for research and systematic problem solving in pharmacy practice; (2) fundamental scientific approach; (3) basic components of a research plan; (4) process of documenting and reporting findings; and (5) responsibilities of investigators with respect to patients, employers, grantors, and science in general.

In its purest form, scientific research is the systematic, controlled, empirical, and critical investigation of hypothetical propositions (theories) about presumed relationships among natural phenomena.[2] Aspects of the research process (e.g., problem definition, systematic data gathering, interpretation, and reporting), however, are also applicable to resolving specific practice problems. Independent, intraprofessional, and interdisciplinary collaborative research and problem solving are encouraged.

Need

Since pharmacy is based on the theories of the pharmaceutical, medical, and social sciences, pharmacy's advancement is linked to advancement in those sciences. Scientific inquiry, through formal research and systematic problem solving, leads to an expansion of knowledge and thus to advancement. Both research and systematic problem solving in organized health-care settings are needed for developing knowledge in pharmaceutics and drug therapy and for evaluation, modification, and justification of specific practices. Therefore, an understanding of the research process is important to pharmacists in such settings.

Primary areas for research by pharmacists in organized health-care settings are those in which pharmacists possess special expertise or unique knowledge. These areas include drug therapy, pharmaceutics, bioavailability, pharmacy practice administration, sociobehavioral aspects of pharmaceutical service systems, and application of information handling and computer technology to pharmacy practice.

The Scientific Approach

Aspects of the scientific approach may be applied to formal research and systematic problem solving. The scientific approach consists of four basic steps:

1. ***Problem—Obstacle—Idea***.[3] The scientist experiences an obstacle to understanding or curiosity as to why something is as it is. The scientist's first step is to express the idea in some reasonably manageable form, even if it is ill defined and tentative.
2. ***Hypothesis.*** The scientist looks back on experience for possible solutions—personal experience, the literature, and contacts with other scientists. A tentative proposition (hypothesis) is formulated about the relationship between two or more variables in the problem; for example, "If such and such occurs, then so and so results."
3. ***Reasoning—Deduction.*** The scientist deduces the consequences of the formulated hypothesis. The scientist may find that the deductions reveal a new problem that is quite different from the original one. On the other hand, deductions may lead to the conclusion that the problem cannot be solved with existing technical tools. Such reasoning can help lead to wider, more basic, and more significant problems as well as to more narrow (testable) implications of the original hypothesis.
4. ***Observation—Test—Experiment.*** If the problem has been well stated, the hypotheses have been adequately formulated, and the implications of the hypotheses have been carefully deduced, the next step is to test the relationships expressed by the hypotheses, that is, the relationships among the variables. All testing is for one purpose: putting the relationships among the variables to an empirical test. It is not the hypotheses that are tested but the deduced implications of the hypotheses. On the basis of the research evidence, each hypothesis is either accepted or rejected.

Components of a Research Plan

Formal research frequently requires the development of a written plan (protocol or proposal). In funded research, the plan may take the form of a grant application. A typical plan might include

1. A problem statement.
2. A review of available literature on the subject.
3. The objectives for the project, including the hypotheses and the to-be-tested relationships among variables.
4. A description of the methodology to be used.
5. A description of statistical analyses to be applied to the data collected.
6. A budget and time frame for the project (where applicable).
7. The expected applicability of the research findings.

Documentation and Reporting

The structure of a research report is similar to the structure of a research plan. A typical outline is as follows:

1. Problem.
   - **a.** Theories, hypotheses, and definitions.
   - **b.** Previous research: the literature.
2. Methodology.
   - **a.** Sample and sampling method.
   - **b.** Experimental procedures and instrumentation.
   - **c.** Measurement of variables.
   - **d.** Statistical methods of analysis.
   - **e.** Pretesting and pilot studies.
3. Results, interpretation, and conclusions.

The statement of the problem sets the general stage for the reader and may be in question form. A common

practice is to state the broader, general problem and then to state the hypotheses, both general and specific. All important variables should be defined, both in general and in operational terms, giving a justification for the definitions used, if needed.

The general and research literature related to the problem is discussed to explain the theoretical rationale of the problem, to tell the reader what research has and has not been carried out on the problem, and to show that this particular investigation has not been conducted before (except in the case of validating research).

The methodology section should meticulously describe what was done so as to enable another investigator to reproduce the research, reanalyze the data, and arrive at unambiguous conclusions about the adequacy of the methods. This section should tell what samples were used, how they were selected, and why they were selected. The means of measurement of the variables should be described. The data analysis methods should be outlined and justified. Where pilot studies and pretesting were used, they should be described.

Results and data should be condensed and expressed in concise form. Limitations and weaknesses of the study should be discussed. The question of whether the data support the hypotheses must be foremost in the mind of the report writer. Everything written should relate the results and data to the problem and the hypotheses.

Investigators' Responsibilities

Investigators bear a general responsibility to be scientifically objective in their research inquiries, conclusions, and reports. They bear a responsibility for being methodical and meticulous in the gathering of research data. They also bear both a fiduciary and a reporting responsibility to employers and grantors. In general, employee investigators are at least partially responsible to their employer organizations in the choice of research topics. Research funded from sources outside an investigator's organization may impose additional contractual obligations on the investigator and the organization.

In research involving patients, investigators are responsible for protecting patients from harm while the patients are participating in the research. All research involving patients should be reviewed and approved, before initiation, by an institutional review board. Written, informed consent should be obtained from every patient participating in each research project.[4] Meticulous recordkeeping is required regarding the clinical experience of patients participating in research projects.

Employee investigators bear responsibility for helping their organizations differentiate true, objective research from product marketing trials and promotions that may purport to be research projects. Grants for bona fide research typically bear a direct cost-recovery relationship to projects and typically involve the direct transfer of grant funds from grantors to the employee investigator's employer organization. Specific institutional policies vary widely, but employee investigators can generally better fulfill their fiduciary responsibilities when funds are not distributed directly from grantors to investigators. In keeping with their fiduciary responsibilities and their responsibility to be scientifically objective, investigators should be wary of arrangements in which prospective grantors offer inducements of value (gifts, trips, experiences, publicity, publications, etc.) to investigators, institutions, or patients before, during, or after the completion of proposed projects.

Investigators should make legitimate efforts to document publicly the findings of research in scientific, objectively refereed publications.

References

1. American Society of Hospital Pharmacists. Governing documents of the American Society of Hospital Pharmacists. Bethesda, MD: American Society of Hospital Pharmacists; 1984.
2. Kerlinger F. Foundations of behavioral research. New York: Holt, Rinehart and Winston; 1964:13.
3. Dewey J. How we think. Boston: Heath; 1933:106–18, as adapted to the scientific framework by Kerlinger, op cit., p 13–5.
4. American Society of Hospital Pharmacists. ASHP guidelines for the use of investigational drugs in institutions. *Am J Hosp Pharm.* 1983; 40:449–51.

Approved by the ASHP Board of Directors, September 30, 1988. Developed by the Council on Professional Affairs. Supersedes the "ASHP Guidelines for Scientific Research in Institutional Pharmacy" approved on November 15, 1977.

The bibliographic citation for this document is as follows: American Society of Hospital Pharmacists. ASHP guidelines for pharmaceutical research in organized health-care settings. *Am J Hosp Pharm.* 1989; 46:129–30.