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Science, Innovation, and Innovation in the Science of Pharmacy

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The editorial team for the 'Science' section of INNOVATIONS in pharmacy is inviting submissions on a wide range of topics. Before describing the types of manuscripts that we invite in the *Science* section of the journal, we feel that it is necessary to discuss what science, innovation, and the process of scientific inquiry are as these principles have guided us in the process of determining the types of manuscripts we solicit.

I. Science

By definition, science is the undertaking that seeks to understand natural and social phenomena through the application of systematic observation, (sometimes) experimentation, recording of observations, and analysis of these observations.^{1,2} These basic steps (or 'scientific method') allow one to compare intuitions about the state of reality to information on its actual functioning. As such, science is distinguished from other ways of knowing, such as faith and "common sense". Through the iterative application of this process, we are able to refine our understanding of pharmacists, patients, and the medication use process, and eventually develop and test models and theories that are useful for description, prediction and control in the context of pharmacy and pharmaceuticals.

Philosophers of science have suggested that science can be distinguished from other ways of knowing by three general attributes.^{3,4} The first of these is a reliance on one's sense impressions, or experiences, of empirical phenomena. Although this may seem self-evident, many positions once widely accepted as true were later disproved with the aid of careful observation. For example, one influential theory in the eighteenth century regarding the spread of smallpox was that of the 'epidemic constitution', which suggested that a vague constellation of climactic conditions was responsible for the disease's spread.⁵ The second attribute that distinguishes science from other ways of knowing is the application of rigorous analysis to these sense impressions. Quantitative researchers often apply mathematical models in these analyses, while qualitative investigators apply an array of other techniques to the data they collect as a way of understanding the world. The final attribute that distinguishes science from other ways of knowing is its social structure.³ For example, we often rely on scientists working in other fields such as economics, sociology, or consumer research when we search for models or theories (and the variables

they suggest) to guide our own research on the medication use process. We make use of the institutional nature (i.e. annual conferences, academic journals) of our field, as well as informal social networks, to help us 'stand on the shoulders of giants' and improve the knowledge base in our field. It is this final attribute of science that the *Science* section of *Innovations in Pharmacy* hopes to serve in providing a forum for innovative, peer-refereed work in our area.

II. Innovation

What is innovation? What is it that makes anything in general and science in particular, innovative? Within economics, innovation can be defined as the introduction of a new good to a market, the application of a new idea to decrease production costs, the organization of a firm in a novel way, or the opening of a new market for an existing service or product.^{6,7} That is, the essential criterion of an innovation is that of 'newness'. Specifically, innovation is the application of an existing idea to a new situation which is different from invention (the discovery of a new idea or knowledge).⁸ For example, the use of computed tomography (CT) scans to screen for colon cancer would be considered an innovation, but the development of the first CT scanning machine would be termed an invention. In this *Science* section, our focus is on innovation, rather than invention.

Innovations in science are important as they help improve the body of knowledge within each discipline and help move disciplines forward. Oftentimes, to move disciplines forward, researchers and academicians are required to switch from the old to more novel ways of approaching problems. Here, we explain how innovations impact our disciplines by using *The Structure of Scientific Revolutions*⁹ by Kuhn. Kuhn developed a general theory of the history and development of scientific disciplines that has been termed 'historical relativism' by some.¹⁰ Kuhn proposed that scientific endeavors within a given discipline are dominated by a central paradigm, which contains content such as laws, concepts, and standard examples of the types of problems that the current paradigm is able to address as well as a scientific methodology which is used to address the problems. The development of scientific disciplines passes through three stages.³

The first of these is the pre-paradigmatic stage in which there is little agreement among scientists within the discipline regarding the proper methodology to employ and the correct manner in which to interpret a collection of observations.^{3,9} During this stage, a number of schools of thought exist until a single theory comes to the forefront and attracts a number of adherents sufficient that it comes to dominate a field. When this occurs, the second, or 'normal science' stage begins. It is at this point that a single paradigm comes to dominate the conduct of science in a discipline because it is viewed as more successful at addressing problems than other competitors.

However, investigators working within a field eventually begin to note more and more counterexamples, or anomalous observations, that cannot easily be explained using the predominant paradigm.⁹ The existing paradigm is increasingly seen as inadequate to address the questions the with which the discipline is faced. This phenomenon leads to the third or 'scientific revolution' stage, in which scientists search and evaluate competing paradigms for one that does a better job at explaining known phenomena in addition to the anomalous observations. When one of these is found, a 'paradigm shift' occurs. Importantly, it is during this period of recognition by increasing numbers of practitioners within a given field of the inadequacy of a given paradigm during which true innovation in a scientific field is able to occur. Hence, this 'Science' section of the Journal serves as a forum for researchers to communicate novel ways of approaching and solving health care problems which may lead to a shift in paradigm.

III. Innovation in the Science of Pharmacy

A cursory examination of the field of social and administrative pharmacy would suggest to most observers that our discipline is not dominated by any single paradigm. However, our discipline has been fortunate in that it has featured many scientists that have been influential enough to 'change the conversation' among large numbers of us for prolonged periods of time by introducing novel theoretical perspectives, new methodologies, and/or new perspectives from which to view the medication use process. Although these individuals are far too numerous to list and discuss, we provide several examples of these persons below and the innovations they introduced.

For many years, disciplinary perspectives provided by economics, marketing and management held sway in social and administrative pharmacy.¹¹ As a result, a significant amount of study was devoted to dyadic relationships important in the medication use process (e.g. pharmacist – patient, pharmacist – technician). Departing from others who

studied dyadic relationships, Kenneth N. Barker, Ph.D. was one of the first scientists in our field to suggest a shifting of the focus from this micro-level of study to the system level with his pioneering work in the field of medication safety.^{12,13} For example, Dr. Barker introduced and evaluated the unit dose medication dispensing system as well as an accurate observational method for measuring medication errors in institutions. The unit dose system and observation method are still in use and continue to have a positive impact on the practice of pharmacy.

Further, studies of the structure (e.g. how many outpatient pharmacies) and processes (e.g. how patients were counseled) were predominant during the discipline's early years. As such, this made the work of J. Lyle Bootman, Ph.D. quite novel. Dr. Bootman introduced a focus on economic evaluation of outcomes in the medication use process with a number of influential articles on the use of cost-effectiveness and cost-benefit analysis.^{14,15} Interest in the application of these techniques to pharmaceutical interventions in both academia and the pharmaceutical industry has grown steadily, eventually morphing into the discipline known as pharmacoeconomics. Today, the importance of these techniques is attested to by the fact that the majority of U.S. pharmacy schools require significant exposure to pharmacoeconomics principles in their professional curricula.¹⁶

The last investigator whom we would like to mention in this commentary has also made significant contributions in Social and Administrative Pharmacy. Trained as a medical sociologist, Bonnie Svarstad, PhD, brought a unique theoretical perspective to her studies of the medication use process. Although Dr. Svarstad has made numerous contributions to the field throughout her career, she is recognized internationally as an authority on medication adherence. Examples of her contributions include introduction and elaboration of the Health Communication Model^{17,18} which describes the effects of health care providers' use of a collaborative communication style on client knowledge of and beliefs regarding drug treatment regimens and ultimately their satisfaction and adherence to these regimens. Dr. Svarstad also has developed innovative tools used in this work, such as the Brief Medication Questionnaire¹⁹, which is used to screen for medication adherence problems and has been applied widely.

IV. The Process of Scientific Inquiry

Thus far, we have discussed how innovations may change scientific paradigms and we have also given specific examples related to Social and Administrative Pharmacy. In this next

section, we discuss the process of scientific inquiry. Two approaches to inquiry have dominated scientific investigation: these are commonly referred to as *quantitative* and *qualitative* research methodologies. These paradigms differ in the theoretical orientations that guide them, the research questions that are addressed by each, as well as the data collection and analysis methods that dominate each of these areas of scientific inquiry.

Quantitative research methods often are identified with the positivist or empiricist orientations to research, which describes the world as being comprised of “measurable facts”.²⁰ Therefore, researchers using quantitative research methodologies “quantify” or numerically measure elements of interest, often through the use of statistics. *A priori* hypotheses and theory frequently are the drivers of quantitative research.²¹ On the other hand, *qualitative research methods* typically are associated with a constructivist research orientation in which “reality is socially constructed, complex, and ever changing.”²⁰ In the qualitative paradigm, the researcher collects data in a naturalistic setting, often using small groups of subjects whose perceptions are solicited. The researcher is the “key instrument” in the data collection and interpretation/analysis process, which usually focuses on words and patterns, rather than numbers.^{20, 22} Instead of being hypothesis and theory driven, researchers using qualitative approaches often use an inductive approach in data collection and analysis to generate hypotheses and theory which can be tested in future research. Examples of qualitative approaches to scientific inquiry include focus groups, personal interviews, and field research.

A decision to select a quantitative or qualitative method depends on the research question being investigated. That is, the research question should dictate the type of research design employed by the scientist. A researcher using an *exploratory* research design focuses on studying a phenomenon of interest and uncovering “ideas and insights” about the phenomenon.^{22,23} For example, a scientist may conduct an exploratory study in a group of patients to discern which attributes are important when they form professional relationships with pharmacists. *Descriptive* research designs can be guided by preliminary hypotheses and can be used to determine relationships between and among variables of interest, or, to determine the frequency with which an attribute of interest occurs.²³ Using a descriptive research design, a researcher could develop a model of pharmacist-patient relationships and examine the associations among model constructs.

Both exploratory and descriptive research designs can result in data that might be used to generate hypotheses for future research using *experimental* research designs. *Experimental* designs are used to determine hypothesis driven *causal* relationships.²⁴ When this type of design is used, an experiment or intervention is implemented to assess the effect of the manipulation of at least one independent variable on one or more dependent variables. An experimental research design could be used to test the effect of an intervention designed to increase patient participation in the pharmacist-patient relationship and then measure its effect on the relationship quality from the patient’s viewpoint. It is important for researchers to consider the research question(s) and goals of their study and then choose the appropriate design, making sure that their rationale is apparent in manuscripts submitted to *Innovations in Pharmacy*.

Regardless of the type of scientific inquiry used, it is important for authors to address measures of quality or rigor in their research. In this section, we describe measures of quality in both quantitative and qualitative research.

Addressing internal and external validity is critical to assessing the quality of scientific research. In quantitative research the researcher should be concerned with threats to *internal and external validity*. A study has *internal validity* if the relationship between two or more variables is due to the experimental treatment or intervention, and not due to extraneous variables or other conditions of the experiment.⁸ Examples of extraneous variables that could confound the effect of the intervention (or experiment) if not controlled, include the effects of history, maturation, testing, and instrumentation.²⁵ *External validity* in quantitative research refers to the generalizability of the study results to the target population of interest. According to Campbell and Stanley²⁵ factors such as the interaction effect of testing, the interaction effects of selection bias and the experimental variable, and the reactive effects of experimental arrangements can all limit the generalizability of study results.

Quality assessment in qualitative research also is concerned with internal and external validity; however, different terminology is used to address these issues. Based on differences in qualitative techniques, different methods of evaluating quality within this paradigm can be found in the literature. For example, internal validity in qualitative research can be measured by *credibility*.²⁶ Credibility “measures how vivid and faithful the description of the phenomenon is.”²⁷ To evaluate credibility, the research design, as it relates to data collection and analysis, must be

critiqued. *Fittingness* is a term used in the qualitative research paradigm to address external validity. Guba and Lincoln²⁶ state that “fittingness measures how well the working hypotheses or propositions fit into a context other than the one from which they were generated.” Based on this definition, fittingness is analogous to generalizability.

Quality assessment also must focus on the reliability and validity of the instruments used in the data collection process. *Internal-consistency reliability* is defined as consistency of measurement,⁸ and often is used to assess reliability of multi-item, latent constructs. Examples of common methods to determine internal-consistency reliability include Cronbach’s coefficient alpha, Kuder-Richardson-20, and the split-half procedure.²² *Auditability* is the term that is used to assess consistency (reliability) in qualitative research.^{26,27} Specifically, auditability has been defined as “the ability of another investigator to follow the decision or audit trail”. Evaluation of auditability in qualitative research typically focuses on how data were analyzed.²⁷ The *validity* of an instrument refers to whether or not the data collection instrument is accurately measuring what it is intended to measure. Types of validity include content or face validity, construct validity and criterion-related validity.^{22,23}

A detailed description of the threats to internal and external validity is beyond the scope of this paper. However, researchers submitting papers to the *Science* section of *Innovations in Pharmacy* are encouraged to discuss threats to internal and external validity as they apply to their research design and the type of research conducted (quantitative or qualitative). If appropriate, a discussion of the manner in which these threats were minimized (e.g. for quantitative research, randomization, statistical control for certain variables, etc.) should be included in the manuscript to make it clear to the reader that appropriate steps were taken to help ensure the quality of the research. If further threats to internal and/or external validity exist in the study, then the researcher(s) should acknowledge these in the ‘Limitations’ section of their manuscript. Similarly, an author submitting a paper to this journal in which a data collection instrument was developed or used should clearly provide data to support assertions of reliability and validity.

In summary, we encourage journal submissions from researchers who use a quantitative or qualitative approach, or, a combination of both approaches. Regardless of the type of scientific inquiry used, it is important for authors to address measures of quality or rigor in their research. These processes should be transparent and clearly described in manuscript submissions.

V. Innovation Section: Scope and Type of Manuscripts

V. 1 Scope

The aim of the *Science* section is to advance pharmacy practice and health care through empirical investigation and theoretical analysis. The *Science* section provides an international and interdisciplinary forum for the dissemination and discussion of research related to health, health care practitioners, health care institutions, and/or health care systems. We are receptive to research across a broad range of health care and pharmacy practice topics such as implementation and dissemination of advanced patient care services, patient and provider education, patient-provider communications, pharmacy management and leadership, pharmacoeconomics, comparative effectiveness and marketing. Contributions can be grounded in various social science disciplines including economics, communication, psychology, sociology, management sciences and education. All empirical methods are invited including qualitative, quantitative, and mixed methods. A key feature of this journal is a mix of theoretically driven articles, methodology articles, and research articles exploring emerging health care and pharmacy practice topics. It thus addresses an audience of researchers as well as practitioners who seek to advance pharmacy practice and health care.

V. 2 Type of Manuscripts

Manuscripts submitted to our Section can be empirical, conceptual or methodology oriented. Empirical manuscripts should use rigorous research designs to address gaps in existing literature. Well-articulated and strong theoretical foundations in empirical manuscripts are strongly encouraged. Conceptual manuscripts should provide new theoretical insights that can advance our understanding of issues with high importance for pharmacy practice and health care. It should be noted that a review article that simply reports research previously conducted but fails to provide new insights will not be considered. Further, we aim to promote the scientific development of health care and pharmacy practice research. Hence, we invite research articles that focus on examining methodological approaches for more rigorous scientific results in the social sciences. That is, manuscripts that address methodology problems in empirical research, including research design, data collection, measurement, and data analysis are encouraged. Manuscripts that focus on the methodological problems involved in any approach used in empirical research are also appropriate. Finally, we encourage submission of “replication” studies and also the submission of research reports presenting “non-statistically significant findings.” These findings are important for scientific inquiry and for making progress in a field.

VI. A Call for Papers

The editorial team welcomes submissions to the Science section of the INNOVATIONS in pharmacy. We encourage submissions exploring a variety of health care-related topics from all perspectives and all types of scientific inquiry. The significance of the issue of interest, the novelty of the approach used, and the measures of quality and rigor in their research should be transparent and clearly communicated. We are looking forward to receiving your submissions and we thank you for considering INNOVATIONS *in Pharmacy* as a channel for disseminating your work to further advance pharmacy practice and health care systems.

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