A Research Primer: Basic Guidelines for the Novice Researcher

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Research can achieve many objectives, primarily by establishing a supportable, verifiable basis for clinical decisions. An evidence-based practice can streamline patient care, improving safety through consistency of care and making health care more affordable for patients. By cultivating research skills, osteopathic physicians and trainees can begin to forge a reciprocal relationship with medical literature and current findings, approaching research as active contributors as well as consumers. Many challenges, however, potentially hinder osteopathic physicians, residents, or medical students who wish to develop research skills. In the present article, the authors summarize research concepts and terminology that will enable novice researchers to interact effectively with more experienced researchers, statisticians, and methodologists.

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The word *research* continues to draw mixed reactions from osteopathic physicians, residents, and medical students. Although the landscape in the osteopathic field continues to change,[1] most research is still conducted by nonphysicians such as basic scientists. From our experience, the lack of a strong research culture denies many clinicians and trainees the chance to develop skills in research, and they come to regard research as not important to their current or future practice objectives. A pervasive mindset in the osteopathic medical profession is that an osteopathic physician (ie, DO) is patient centered and not research oriented.[2] To quote Andrew Taylor Still, MD, DO: "If we wish to be governed by reason, we must take a position that is founded on truth and capable of presenting facts, to prove the validity of all truths we present. A truth is only a hopeful supposition if it is not supported by results."[3(p22)] Dr Still supported evidence-based practice. It can be argued that patient-centered practice does constitute a kind of research, one that complements evidence-based medicine.[4]

Research and scholarly involvement aims to achieve many objectives, the first of which is to establish a supportable, verifiable basis for clinical decisions. Research should be treated as a tool or approach to answering many health care–related questions. A common misperception is that a physician needs a master's or doctorate degree to engage in research and scholarly activity.[5] This is, however, far from the truth. There is more than 1 way to become involved in research, gain valuable experience, and contribute to the medical literature.

An evidence-based practice can impact patient care and safety through quality improvement efforts and may make health care more affordable for patients.[6,7] Physicians and trainees forge a reciprocal relationship with medical literature and current findings, approaching research as active contributors as well as consumers. Osteopathic physicians are in a position to contribute tremendously to clinical research because their bedside focus is inherently patient centered. Research that is not published, however, is research that benefits few. Researchers can support their institutions by applying for research funding. Residents and students who engage in research gain a valuable advantage for future fellowships and jobs.

Two major challenges potentially hinder DOs or student DOs who wish to develop research skills: lack of clinical mentors and lack of protected time. (In addition, the allopathic medical field is facing rising student debt as a critical constraint to physicians pursuing a career in research, which contributes to a decrease in number of mentors.[8])

To the authors' knowledge, the majority of current osteopathic clinical faculty and preceptors were never trained for or engaged in research. As a result, faculty are uncomfortable with the prospect of participating in or mentoring students in research. Therefore we propose—bolstered by our experience working with hundreds of physicians, residents, and medical students—that cultivating a more robust research culture in the osteopathic medical field requires buy-in from current clinical faculty.

In our experience, many osteopathic residency programs do not offer protected time for research activity, and this can deter potential resident-researchers. Bhattacharya et al[9] reported, in a study of general surgery training programs in allopathic institutions, that protected time allows research efforts to flourish and provides a pathway to careers in research beyond residency. A survey of orthopedic residents[10] indicated protected time was an incentive to engage in research during residency.

Undergraduate medical schools, too, may or may not offer students opportunities for protected time. Some schools, such as the Ohio University Heritage College of Osteopathic Medicine, offer research elective rotation time to students. This protected time has paved the way for more research opportunities for medical students during third-year and fourth-year clinical rotations. Many osteopathic medical schools offer summer research programs. Several other osteopathic medical schools also offer similar research programs during the school year and the summer.

Osteopathic physicians enter the medical field with varying levels of research or scholarly experience. Most start their medical education with a bachelor's degree, and a few hold a graduate degree, such as a master's or a doctorate.[5]

Our goal with the current article is to provide guidance to novice researchers and to focus on simple studies that are feasible within a limited time constraint. We introduce research concepts and terminology that will enable novice researchers to interact effectively with statisticians and other research design experts.

The Research Process

Figure 1 encapsulates the research process. We will discuss each of the steps listed therein for remainder of the current article.

Figure 2 offers a novice researcher additional practical ideas for undertaking a research project.

Develop an Idea

A novice researcher, if he or she is a student or resident, may find it difficult to generate an idea because of limited experience with patients. As students and residents see more patients and practice longer, ideas for research projects will occur more easily. Ideally, researchers should choose a topic that they are passionate about, but this cannot always be the case. Nevertheless, every opportunity to engage in research is valuable, even if it does

1. Develop an idea
2. Formulate the research question
3. Review the literature
4. Set the objectives and hypotheses
5. Construct a methodology
6. Create a proposal
7. Secure funding
8. Seek approval from the institutional review board
9. Collect the data
10. Analyze and interpret the data
11. Prepare the data for publication

Figure 1.
Steps of the research process.

not spring from passion, because there is so much to gain by familiarity with the research process and its requirements.

The following actions will help researchers get started:

- **Enlist established clinical or research mentors as collaborators.** Ask others at your college, hospital, or institution. Identify those who are active in research and contact them. Explain your desire to gain research experience, and offer them assistance. It always helps to read a researcher's publications, grants, and research focus before meeting with him or her. This knowledge will allow you to be conversant on the topic, have a clear direction and outcome, show motivation and genuine interest, and not waste your intended mentor's time. (See the section "Formulate the Research Question" for more suggestions about mentors.)
- **Reach out to researchers in other disciplines, such as psychologists, basic scientists, and quality of life researchers.** Journal articles for original research almost always have authors from interprofessional fields.
- **Continue an in-progress study started by a student or resident.** A first-time researcher may prefer to join an ongoing project. Residents and students may need collaborators to help with data collection. Some studies continue for multiple years before enough participants become available. The research may require an additional study site to be used. There are many ways to become involved: recruiting participants; collecting, entering, analyzing, or interpreting data; writing a portion or all of the manuscript; or creating a poster or oral presentation.
- **Generate ideas from observations made during clinical rotations.** For example, one student developed an idea during a rotation when her preceptor did not adhere to certain guidelines indicated for a patient they were seeing. She asked how many physicians adhere to such guidelines and then conducted a survey based on the responses she received.
- **Consult the published literature.** The literature can function to confirm that an idea, or some aspect of an idea, has not been studied. Look for gaps in the literature, recommendations, and limitations, which are often called out in the comment or discussion section of an article. Do not duplicate a previous study unless an article about the study indicated that a larger sample size is needed or that the data are invalid or outdated. It is also possible that a study looked at 1 section of the population but was not able to study others because of funding. Authors who investigated an urban population may recommend that rural populations be investigated as well. Check for subsequent commentary (eg, letters to the editor) on articles. The US Library of Medicine's PubMed database may link to commentary pertaining to the original article

1. Design your research so that it can be completed within a manageable time frame.
2. Write a proposal and then fill out an Institutional Review Board (IRB) application, not the other way around. They share many elements but are structured differently: a proposal builds on an idea and progresses into a methodology and list of references, whereas an IRB application provides a format for easy review of human subjects protection plan. Start with a proposal that allows you to detect gaps in your design before submitting to an IRB. A well-written proposal serves as a foundation for a complete IRB form.
3. If this is your first experience with clinical research, join an existing project, conduct a simple survey or chart review, or use secondary data to ensure that you will finish within a specified time frame.
4. For trainees, research is a very engaging process and should be done with careful planning so it does not interfere with their education.
5. Collaborate. Enlisting other researchers lightens the workload, but could also present challenges. At the beginning of a project, it can help to do the following: (a) identify a leader, (b) set clear goals and expectations for each collaborator, (c) distribute tasks and responsibilities equitably, (d) set dates for periodic reviews to keep everyone on schedule, and (e) commit to identifying and solving problems in a timely manner.
6. Understand how a contribution to a study is ranked. Author order is determined by how much each author contributed to the study. Most seasoned researchers are willing to provide poster authorship to novice collaborators who may have helped with some areas of the project but not in an intellectually substantial manner (for example, collecting some of the data, editing and formatting the manuscript, or creating a poster). It is unethical, however, to confer authorship to people who neither made a substantial intellectual contribution to a study nor had an extensive involvement in the project.
7. Surveys involving students, faculty, residents, and practicing physicians may be easier to conduct than surveys involving patients. Check with schools, hospitals, and professional organizations to determine if these institutions would enlist others to distribute the surveys to their respective constituencies.

Figure 2.
Additional tips for the novice researcher.

in subsequent journal volumes. Postpublication commentary can provide an idea of whether the original research is in dispute or has an error and correction related to it. Validating and updating the study may be necessary.

- **Attend lectures and conferences.** Ideas from research paper or poster presentations may lead to additional questions.
- **Use secondary databases.** Secondary databases can be accessed by following the institution's request process. Note that approval from the institutional review board (IRB) is required to use this service. Two examples of available secondary databases are the Central Ohio Trauma System Regional Trauma Registry (http://goodhealthcolumbus.org/cots/trauma-registry), which began collecting data from 23 participating hospitals in 1999, and the Centers for Disease Control and Prevention's National Center for Health Statistics (http://www.cdc.gov/nchs/data_access.htm).

Formulate the Research Question

An initial research question is defined by gaps in the literature. Background and context serve to establish the research question as a credible issue to explore or problem to address. Once an initial idea is identified, confirm the feasibility of the idea by considering the FINER acronym: Is it "Feasible, Interesting, Novel, Ethical, and Relevant"?[11] This acronym will help the researcher fine-tune the idea.

Novice researchers should consult at least 2 mentors at this point. The optimal combination is composed of an experienced clinician and a research design expert (eg, a statistician or an experienced researcher). A clinician provides medical expertise and helps to determine if an idea is relevant, valuable to the field, and feasible. A statistician or methodologist advises on research design, methods, feasibility, statistical analysis, and data interpretation. A statistician ensures that research questions and objectives are answerable and the correct data or information will be gathered to answer the research questions.

Throughout the remainder of the current article, we will use a study by Coglianese et al[12] titled "Usefulness of the Blood Hematocrit Level to Predict Development of Heart Failure in a Community" to provide examples that illustrate our research guidelines.

First, the authors[12] identified how the existing medical literature regarded the connection between heart failure and higher levels of hemoglobin:

> Current data suggest that increases in hemoglobin may decrease nitric oxide and adversely affect vascular function. In the preclinical setting, these changes could precipitate the development of heart failure.

This connection led the authors to their study's research question: Would higher hematocrit levels be associated with an increased incidence of new-onset heart failure in the community?

Review the Literature

As a research question is formulated, a thorough literature search helps researchers to (1) determine the originality of the idea, namely, by identifying a gap in the literature that the research will address and (2) establish a framework and justification for a proposed study, which researchers will address in the introduction or the review of the literature when their findings are published.

The most frequent starting point for accessing citations to life science and biomedical literature is MEDLINE (Medical Literature Analysis and Retrieval System Online), a database compiled by the US National Library of Medicine and accessible at PubMed (http://www.ncbi.nlm.nih.gov/pubmed/). The PubMed database provides researchers with a powerful means of searching through the literature.

In addition to such publicly available websites as PubMed, resources for novice researchers include subscription-only peer-reviewed journals or databases, which are accessible at colleges and teaching hospitals. Searching and obtaining the literature is efficient and relatively easy. The process is not as onerous as it was 2 decades ago, when a literature search meant walking to a library to borrow a physical copy of a journal or, worse, waiting many weeks to receive a copy requested through an interlibrary loan. Any researcher with a computer and an Internet connection is now able to search databases that were previously accessible solely through a library.

A combined effort or partnership between a novice researcher and a medical librarian is optimal. Librarians have experience in searching clinical publications and other reliable resources, some of which may be unknown to a novice researcher. Librarians can suggest journals and techniques to refine a search. Handing a set of key words to librarians may be a good start but may not cover the depth needed in an extensive literature review. A researcher may be better able to sift through search results and align them with the aim of a research question. For example, when PubMed lists related articles, only a researcher might be able to detect nuances that make the search results more relevant to the research question.

It is possible that no specific literature exists pertaining to a proposed research question. Although this could prove beneficial to a study by revealing a gap that needs to be addressed, a novice researcher should still attempt to tie the existing literature to his or her own subject. This may entail investigating topics that are

similar but may have been applied to different aspects of the problem or other field. If a search for these more obliquely related articles proves fruitless, you can indicate, for example, that "no study, to our knowledge, exists to address this gap" and cite only the most closely aligned results.

Set the Objectives and Hypotheses

An objective states the precise purpose or intention of a research question. The objective can be 1 or multiple statements and can be in the form of an overall objective, specific objectives, or both.

A hypothesis transforms an objective into a statistical expression declaring significance or no significance. A null (H_0) hypothesis states no significance, and an alternative hypothesis (H_1) states statistical significance and is the idea that a researcher seeks to prove. Statistical significance is the level of confidence a researcher wants to assume for the data set. Usually, statistical significance is set at the 5% probability level ($P = .05$). The P value is an indicator a statistician uses to determine if a study's results have real effects.

For example, Coglianese et al[12] stated their hypothesis as follows:

> We hypothesized that high [hematocrit levels], even within the "normal range," would be associated with a greater risk of new-onset [heart failure].

Construct a Methodology

The methodology is a detailed description of how the research will be implemented in a study. This description includes the following details: population description, performance sites, sample size, research design, variables, data collection procedure, statistical tests, and statistical analysis. The methodology section should have all the necessary details to enable other researchers to duplicate or repeat the study. If there is a plan to submit the research for publication, use the target journal's style and format from the beginning to minimize future formatting efforts.

Consult with a statistician or methodologist often to avoid cluttered data. Use the KISS principle ("Keep It Simple, Stupid") when designing a study. An overcomplicated study design adds substantial time to the entire process, from the IRB's evaluation to conducting the study.

The literature abounds with information about validated surveys, also called *measures* or *instruments*. The authors will gladly share them for free in many cases. Using validated measures will save time and effort and greatly enhance the credibility of your results.

Researchers should list as many details as possible to enable readers to replicate the study under the same conditions.

Create a Proposal

A proposal is the blueprint or map of your research, combining all steps of the research process we have covered thus far. It is prepared for review by the research team and forms the basis for the subsequent proposal to the IRB. A proposal is composed of an introduction (literature review, justification, research question, and objectives), methodology (all the details necessary to implement the study), and references. To facilitate formatting of references, use RefWorks or other bibliographic databases. These databases are especially helpful as a proposal is worked out through multiple drafts and if the proposal is resubmitted.

As with the methodology, if the findings of a study are intended for publication, write the proposal in the target journal's style and format from the beginning to minimize future reformatting. To increase success in navigating the IRB, complete the proposal before submitting to the IRB.

Secure Funding

Some research, such as medical record reviews, require little or no funding. For more complex projects, financial support may be necessary. We intend to discuss this topic in detail in a future article.

Seek Approval From the IRB

For some researchers, the very mention of an IRB is cause for concern. This should not be the case because individuals in the IRB office are available to discuss review requirements and recommend modifications if necessary to facilitate the IRB process.

Each institution conducting research has an IRB committee or is linked to another entity's IRB. The IRB is tasked with ensuring that research is conducted in a manner that protects human participants' privacy and safeguards the use of participants' data or information.

There are 2 levels of IRB approval that researchers must meet before conducting studies involving human participants: federal and institutional.

Per federal regulation, researchers must gain IRB approval in writing before any form of research can begin. The timeline until approval depends on study design, but in our experience the average from submission to approval to begin the research is 3 months. As part of the requirements, researchers will need to participate in a training program with either the Collaborative Institutional Training Initiative (https://www.citiprogram.org) or the National Institutes of Health (http://phrp.nihtraining.com/users/login.php). Federal regulations, as dictated by the US Department of Health and Human Services, require research studies to be approved by an IRB. Institutions vary in their requirements. Some institutions require that they review research that is approved by another institution. Others avoid this by having an interinstitutional agreement in place to streamline the process. Novice researchers should always verify their institution's requirements.

An overview of the US Department of Health and Human Services policies and regulations pertaining to human subjects research can be found at the department's regulations website (http://www.hhs.gov/ohrp/humansubjects/index.html). For studies involving animals, researchers should consult with a parallel committee called the Office of Laboratory Animal Welfare (http://grants.nih.gov/grants/policy/air/policy.htm).

Collect the Data

Methods of data collection must be standardized, especially if multiple data collectors are involved. A researcher's methodology should be detailed enough that other researchers are able to follow the instructions precisely. Any proposed changes to the methodology must be documented and reported to the IRB for approval before a study is undertaken.

New challenges arise at the data collection stage. One challenge is the potential for unreliable data. If they have not already done so, researchers should consult a statistician before creating a data collection form and data entry file in a statistically analyzable format. Another challenge is the recruitment of participants or subjects, which can be challenging. When possible, a multisite study can potentially increase access to relevant target populations. Any change in study methodology after a study begins, however, will require multiple IRB approvals. Adding investigators also will help with recruitment. Again, it is standard procedure to train all investigators and recruiters so that errors are not introduced in the recruitment and research process.

For more advanced studies, such as clinical trials, another possible recruitment approach is registering the project at http://www.clinicaltrials.gov. Registration is now a requirement for clinical trials. This website provides a central source of the study's information and access to potential participants, researchers, or health care workers.

Analyze and Interpret the Data

Researchers can perform simple analyses such as percentages and means using Microsoft Excel or other spreadsheet programs. We intend to discuss statistical analyses in a future article.

Prepare the Data for Publication

Publication is an elaborate process, but there are techniques to help novice researchers get started. Novice researchers may exhibit their findings as posters or oral

presentations at conferences. Researchers are strongly encouraged to submit to peer-reviewed journals. Even if an article is rejected, a novice researcher may nevertheless benefit from the external reviewers' comments.

Conclusion

Research is not solely the province of medical scientists. Osteopathic physicians, residents, and medical students can benefit from conducting research and making a contribution to the medical literature.

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