Chapter 32

ROLE OF THE PHYSICIAN ASSISTANT IN RESEARCH

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Introduction

Army physician assistants (PAs) conduct research in both academic and clinical settings. PAs hold official research positions at the US Army Research Institute of Environmental Medicine, and they also drive investigations at other institutions, hospitals, and clinics. Regardless of setting, Army PAs should attempt to align research interests with the lines of effort designated by the Army Medical Specialist Corps (AMSC) with the intent of better serving Army soldiers. Current lines of research include:

- illness and injury prevention,
- disease and nonbattle injury management and rehabilitation,
- combat trauma management and rehabilitation, and
- health and performance optimization and reintegration.

A complete list of lines of research and their subcomponents can be obtained from the AMSC Research Committee. This committee provides support, advice, and guidance on research directly to the AMSC chief, who typically appoints the committee's head (Figure 32-1).

The onset of any research project should entail a search for similar, previously published literature. Generally, research requires a degree of originality and innovation that adds something to the current

Figure 32-1. Colonel Renee Cole (left) presents the 2019 Mary Lipscomb Hamrick Research Course Lifetime Research Award to Major Seth Holland at JBSA-Fort Sam Houston, TX. Colonel Cole is currently the AMSC Research Committee lead. Major Holland is a graduate of the US Army/Baylor Doctor of Science in Physician Assistant Studies in General Surgery.
Photograph courtesy of Major Robin Cushing.

body of literature. Prior to starting any research, PAs should search online publication depositories (such as PubMed, the Army Medical Department Virtual Library, and the specific academic institution the PA is enrolled in) to ensure their idea meets this criteria.

Evaluating and Conducting Research

Evaluating and conducting research is vital to the growth and development of medical knowledge and practice, for both individual PAs and the medical community as a whole. While isolated laboratory tests provide foundational knowledge in medicine, clinical studies evaluate diagnostic and treatment hypotheses in human subjects for a more direct application to practice. When evaluating existing research and planning future research, PAs must understand the different types of studies and the hierarchy of their evidence. The levels of evidence for clinical studies and examples are provided by Elsevier at: https://www.elsevier.com/__data/promis_misc/Levels_of_Evidence.pdf.[1]

The "PICO" Approach

In developing and evaluating clinical studies and research, PA researchers should understand the goals and applications of each. Integral to this approach is the use of the "PICO" model:

P: patient or population
I: intervention (or exposure)
C: comparison (or control)
O: outcome

An example of utilizing the PICO model is a study of adult patients 18 to 65 years old complaining of a migraine headache (P), receiving 1 g of intravenous acetaminophen (I), compared to those receiving 975 mg of oral Tylenol (C), for a decrease in reported pain based on a visual rating scale (O).

A refined PICO model can be translated into a specific research question, which should include each of these four aspects. Having established these elements, PAs can start to develop and refine a research hypothesis and begin to organize a clinical study. It is important to note that, with the exception of individual case studies, case series,

and expert opinions, all clinical studies require a formal submission to the institutional review board (IRB) for review and approval prior to conducting research.

Types of Studies

The different types of analytic and descriptive studies vary in strength based on the scientific rigor of their respective designs, as outlined in Exhibit 32-1. They are briefly described below.

Metaanalyses

- Metaanalyses systematically group multiple clinical trials, generally with similar characteristics, to test for a shared hypothesis with a larger sample population.
- A popular meta-analysis resource is the Cochrane Reviews database, which contains over 7,500 systematic reviews of literature.
- Strengths: establish a larger sample population for enhanced testing power; draw more diverse populations for enhanced comparison and broader application.
- Weaknesses: strength of evidence depends on strength of sampled

Exhibit 32-1. Study types, from strongest to weakest, based on the scientific rigor of their respective designs.

1. Analytic studies
    a. metaanalysis
    b. experimental: randomized clinical controlled trial
    c. observational
        i. cohort study
        ii. case-control study
        iii. cross-sectional study
2. Descriptive studies
    a. aggregate: ecologic study
    b. individual
        i. cross-sectional study
        ii. case series
        iii. case report
3. Other: expert opinions

trials; time consuming; heterogeneity of sampled studies may confound results; possible selection bias in choice of studies included.

Randomized Clinical Controlled Trials

- In clinical trials, the exposure is determined by the investigator.
- "Randomized" means that differential confounding factors are removed by randomly assigning the exposure.
- Strengths: provide strongest evidence for causality because of clear temporality, cause and effect, and control for unknown confounding factors.
- Weaknesses: expensive; time consuming; possibility of selection bias; potential lack of generalizability to the population of interest.

Cohort Studies

- Cohort studies are prospective studies in which individuals with an exposure are identified and compared to individuals without the exposure with respect to future outcomes of interest. They are longitudinal studies (conducted over time) in which outcome incidence is compared between exposed and unexposed groups.
- Yields: cumulative incidence relative risk ratios and incidence density relative risk ratios.
- Strengths: clearly defined temporality because the exposure occurred before the outcome.
- Weaknesses: time consuming; costly; loss to follow-up is common.

Case-Control Studies

- Case-control studies are retrospective studies in which individuals with a condition (cases) are identified and compared to individuals without the condition (controls) with respect to prior exposures.
- Yields: odds ratios and prevalence ratios.
- Strengths: efficient use of time; less costly; can study rare diseases; statistically efficient.
- Weaknesses: temporal ambiguity; recall bias; selection bias.

Cross-Sectional Studies

- Cross-sectional studies can be seen as "snapshots" in which individuals are selected without regard to outcome or exposure status. Data is collected at one point in time at the individual level. Often these are the first analytic studies to be conducted, because if a causal relationship is not identified, no further studies are needed.
- Yields: odds ratios and prevalence ratios.
- Strengths: relatively inexpensive and efficient.
- Weakness: temporality (because data on exposure and outcome is captured at one point in time, the exposure could have occurred after the outcome of interest).

Ecologic Studies

- In ecologic studies, the units of measurement are captured at the population level (as opposed to the individual level). These studies use group data to describe correlations between conditions and exposures in various populations.
- Yields: correlation ratios.
- Strengths: quick; efficient; yields multinational and multiorganizational comparisons.
- Weaknesses: no direct linkage between exposures and outcomes at the individual level; risk of ecologic fallacy (the correlation identified at the population level does not necessarily represent a relationship at the individual level).

Case Series

- Case series consist of multiple patients who have a similar pattern of presentation, evaluation, or diagnoses, providing a theme for reader learning. These studies are essential for the early identification of problematic exposures, but are not analytic in nature like the studies listed above.
- Yields: illness characteristic and treatment themes.
- Strengths: provide insight into patient populations too small, diverse, or dispersed (in time or place) to effectively conduct proper trials.
- Weaknesses: largely retrospective in nature; small populations; no explicit comparison group.

Case Reports

- Case reports (Figure 32-2) consist of a single patient who has a unique presentation, evaluation, or diagnoses, providing notable insight into an illness. They are essential for reference of rare cases, but are not analytic in nature and cannot establish definitive trends for diagnosis and treatment.
- Yields: illness characteristics and anecdotal treatments.
- Strengths: provide insight into patient populations that are too small, diverse, or dispersed (in time or place) to effectively conduct proper trials.
- Weaknesses: retrospective in nature; isolated cases; no explicit comparison group.

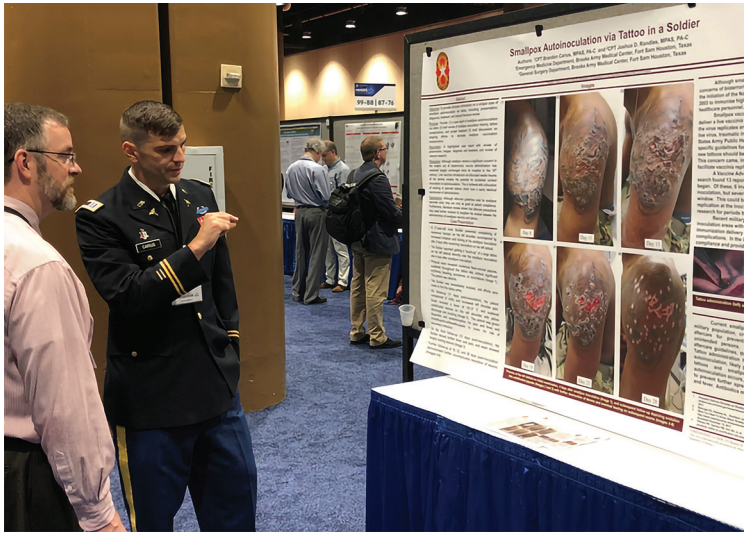

Figure 32-2. Then-Captain Brandon Carius presents a poster on a case report during the Military Health System Research Symposium in Kissimmee, Florida, in August 2018. Major Carius is a graduate of the US Army/Baylor Doctor of Science in Physician Assistant Studies in Emergency Medicine program. Photograph courtesy of Major Brandon Carius.

Expert Opinions

- Expert opinions are statements on the diagnoses or treatment of illness by a prominent member or several members of a specific or overlapping medical specialties, who may or may not refer to published studies for support of their position.
- Yield: an opinion.
- Strengths: provide guidance and insight into the diagnosis and treatment of conditions in the absence of published literature.
- Weaknesses: largely uncited/otherwise unsupported positions.

Collaboration

Current scientific research is expected to include complexity and in-depth analysis. It follows that a substantial range of resources must be marshaled to conduct a research project, particularly in terms of individual talents. Collaboration has therefore been seen as integral to modern research, ensuring that each project is a productive endeavor, with input from multiple perspectives.[1] Research collaboration represents more than the simple involvement of many people, however. Collaboration is a complex process that is not easily defined or assessed,[2] although the presence of differing talents and perspectives is a key component. Collaborations can be established among individuals, departments, or institutions. As providers accustomed to practicing in and leading collaborative medical teams, PAs are well suited to lead this process. In this era of evidence-based medicine, their foundation in clinical science ensures the critical perspective needed for productive medical research.

The recognized benefits of collaboration in research[3] each apply to PAs. Collaboration promotes the effective use of individual talents, while providing PAs an opportunity to employ clinical experience in addition to research-related training (Figure 32-3). Research allows the transference of knowledge. PAs may therefore find that collaboration provides a new mechanism to impart wisdom, both to partner researchers and to readers of publications. Their involvement in collaborative research allows critical experiences and lessons learned to be incorporated into evidence-based practice standards. Collaboration is also a source of intellectual stimulation and companionship as well

Figure 32-3. Major Meghan Joyce (left) and Lieutenant Colonel Amelia Duran-Stanton (right) validate goniometer elbow measurements on Captain David Korb (center), a physician assistant student during his orthopedics rotation at the Brooke Army Medical Center in March 2020. Lieutenant Colonel Duran-Stanton and Major Joyce are graduates of the US Army/Baylor Doctor of Science in Physician Assistant Studies in Clinical Orthopedics program. Lieutenant Colonel Duran-Stanton also earned a Doctor of Philosophy in Postsecondary and Adult Education through Capella University.
Photograph courtesy of Lieutenant Colonel Amelia Duran-Stanton.

as professional networking. PAs may find these benefits refreshing after prior clinical experience involving relatively limited interaction with other professionals.

Balancing Research with Clinical Duties

Research is detail-oriented and requires a significant time investment. While interactions with subjects may occur in the course of normal clinic duty, work for research is often completed outside of these times. It is important to establish a schedule and remain disciplined throughout the research process, which will allow for effective management of multiple requirements. In the beginning of the research process, it is

important to identify the primary and associate investigators (PI and AI, respectively). Assigned roles and responsibilities should be determined at project initiation so all investigators can appropriately balance their clinical responsibilities with the research requirements.

The PI should devise a project timeline and routinely schedule team meetings, whether virtual or face-to-face, to establish accountability. A realistic schedule must be developed to minimize conflict with clinical duties. Backward planning from an agreed-upon end goal is key. Incremental goals and metrics should be established and divided among the research team. Setbacks are inevitable, making it imperative for team members to remain flexible. Time management is a cornerstone to successful research, particularly for those who have clinical duties, required professional development, or travel.

Programs Requiring Research

Currently, the Doctor of Science (DSc) in emergency medicine, general surgery, and orthopedics residency programs, as well as the Doctor of Medical Science (DMSc) degree, require Army PAs to complete a research project. The research may include primary data collection and analysis, secondary data analysis, or metaanalysis. Army PA residents should choose a topic that interests them and solicit feedback from staff along the way. Army PA residents are also required to choose a staff advisor for their topic and routinely meet with the advisor to discuss progress. It is also important to get explicit guidance from the program director on all research requirements. Residencies are generally 18-month programs, and residents must dedicate adequate time to completing their research while managing clinical and didactic responsibilities. All DSc residents are required to defend their research project at the end of the program to university and residency faculty.

When an Army PA is selected for funding to pursue a PhD at a civilian school of choice, they must meet the research requirements of the selected program. Earning a PhD requires completing a dissertation project, which usually includes primary data collection and analysis. Most military schools also require research skills, so it is important to hone research skills as early as possible. During the Interservice Physician Assistant Program, for example, students are required to conduct a literature review for their master's paper.

Captains Career Course students must research and write an analysis of command principles applied to a historical battle. The Command and General Staff College requires students to submit defense papers that include research. The Senior Service College requires students to complete, at minimum, a strategy paper and a research project. The earlier a PA learns how to conduct research, finds out how to format papers depending on the academic or publication requirements, and understands the basics of technological research tools and resources, the better the quality of their work will be as they progress throughout their career.

Institutional Review Board Process

Most types of research involve review and oversight by a third party in order to ensure safe conduct and protections for participants. Military and civilian institutions utilize an IRB as an impartial third party to assess the safety of proposed research prior to its initiation. Before starting an IRB submission, potential investigators should familiarize themselves with the latest requirements, although several have remained consistent. These include an updated curriculum vitae (CV) and completion of Collaborative Institutional Training Initiative (CITI) instruction. CITI course certification, which is good for 3 years, provides potential investigators with a thorough background on the Human Research Protections Office, its purpose, and the paramount need for human protection and safety in conducting scientific research. In the military, IRB organization is generally aligned with the regional health command structure. Using templates, prospective research is submitted to the IRB, where it is first administratively reviewed for proper packet completion, and then categorized for one of three stratified levels of review:

Exempt

- Studies that are deemed to have less than minimal risk to participants, and fit into one of several categories, such as being conducted in an educational setting.
- Examples include anonymous surveys, laboratory studies not involving human samples, or comparing two different educational curricula.

Expedited

- Studies that involve only minimal risk to participants, defined as not being "greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests"[4]; that do not involve vulnerable populations (such as prisoners or military trainees); and that fit into one of several categories, such as data obtained through noninvasive means routinely employed in clinical practice (such as radiographic imaging), or blood samples collected by venipuncture from healthy volunteers.
- Examples include examination of human specimens (such as a blood sample study) or a records review of identifiable patient information.

Full Board Review

- Studies deemed to involve more than minimal risk to participants, or that involve certain categories such as vulnerable populations (eg, persons under age 18, prisoners, military trainees); procedures that might cause physical harm; or collection of information that could seriously harm the participant legally, socially, or financially if other people could identify them.
- Examples include physical exertion testing after blood donation; comparing ketamine to acetaminophen for intravenous pain relief; testing a new type of endotracheal tube for emergent intubation.

Potential investigators must maintain perspective and patience when approaching their local IRB for review and approval of a study. While exempt studies can be returned with approval within weeks, those involving full review, or even expedited review, can take many months or even over a year for approval. IRB panels generally meet on a monthly basis to conduct reviews, and often require multiple revisions and additional input (generally referred to as "stipulations") prior to approval.

Upon approval, investigators should ensure that they understand future requirements from the IRB, including potential ongoing reviews on a scheduled basis (such as annually). Deviations from the approved protocol necessitates notification to IRB office personnel and potentially halting study execution until further review. This is generally outlined in the IRB approval packet.

Upon completion of data collection, IRB procedures must be followed to successfully "close" a study. After a study is closed, investigators must either maintain or destroy paper copies of data as specified in their protocol. Investigators should work with a statistician, either local or easily accessible through electronic communication, to verify their data for statistical analysis. Upon completion of data analysis, investigators create a draft manuscript, presentation, or both, which must be submitted to the IRB public affairs office prior to submission to any conference or journal.

Writing and Publishing

Research is conducted for the primary purpose of increasing medical knowledge, but its effect is limited if not effectively disseminated. Publishing research is the best method to reach the greater medical community. Journal themes range from general practice (eg, the *Journal of the American Academy of Physician Assistants*) to various medical specialties. It is important that PAs have target journals in mind from the outset to ensure compliance with the publisher's requirements (see a partial list of journals under Tools and Resources at the end of this chapter). Formatting guidelines are found on most journals' websites. Strictly following these guidelines, in addition to striving for effective writing (keeping the article as short and succinct as possible), will ensure the best chance of a smooth submission process and, ultimately, article acceptance. Additionally, when conducting a literature review, Army PAs should consult local and online resources available through the military prior to purchasing any references. These are most easily accessed by consulting the local hospital or regional medical center librarian.

The AMSC has recently added publications, presentations, and civilian organization involvement as part of the requirements to earn the 9A proficiency designation (discussed in the attachment to Chapter 1 of this handbook). Additionally, PAs should attend the AMSC's annual Mary Lipscomb Hamrick (MLH) Research Course, taught by subject matter experts, even when they are not in academic programs (Figure 32-4). The earlier PAs attend this course, the earlier they can learn the basics of research and begin networking and collaborating with fellow researchers, while earning continuing medical education and military school credit. (Additional details about the MLH course are available

Figure 32-4. Army Medical Specialist Corps faculty and attendees during the 2019 Mary Lipscomb Hamrick Research Course.
Photograph courtesy of Major Robin Cushing.

on the AMSC's MilSuite page at https://www.milsuite.mil/book/groups/army-medical-specialist-corps. See other chapters in this handbook for additional course listings, as well as information on PAs who have earned MLH research awards.)

Mentoring in Research

There are many opportunities for mentorship within the research community, both supervisor-subordinate and peer-to-peer.

Academic Settings

Army PAs pursuing an advanced graduate degree benefit from mentorship, not only by their academic advisors, but also by fellow Army PAs who have previously earned an advanced degree. Particularly when studying in a civilian school, guidance on how to maneuver through the program in a timely fashion as an active duty PA is imperative. Earning a PhD requires planning and execution of very specific steps, including didactic studies, comprehensive exams, research proposals, and dissertation defense. Similar key events may be present in master's-level programs as well. Failing to complete or meet the standards at every step can result in significant delays or failure to complete the program. Army PA mentors can help provide the guidance necessary to stay on track throughout these programs.

Research Institutes

Army PAs may serve in a research institute, including the US Army Research Institute of Environmental Medicine, where the focus of their duties is to plan, execute, and analyze research (Figure 32-5). These positions may or may not require an advanced or specific degree. Peer-to-peer mentorship while working in these settings can be very useful: learning the steps to getting a research protocol approved by an IRB,

Figure 32-5a. Major Bradley Warr, research physician assistant and chief of the Military Performance Branch of the US Army Research Institute of Environmental Medicine in Natick, Massachusetts, prepares a soldier for measurement of oxygen consumption while carrying 25-mm ammunition cans at Fort Hood, Texas, as part of the Training and Doctrine Command Physical Demands Study in December 2013. Major Warr earned his Doctor of Philosophy in Physical Activity, Nutrition and Wellness from Arizona State University. Photograph courtesy of Major Bradley Warr.

Figure 32-5b. Major Robin Cushing and Sergeant First Class Eileen Tavarez discuss drug research protocols with human volunteers. This double-blind experimental study evaluated the effects of cocoa flavonoids on blood circulation in February 2020. Major Robin Cushing earned her Doctor of Philosophy in Public Health from the University of Hawaii.
Photograph courtesy of Major Robin Cushing.

evaluating the scientific rigor of a proposal, efficiently using available resources, and reviewing manuscripts are all topics that can be discussed among peers. Finding a mentor with significant experience in these processes is appropriate and will contribute to successful research.

Lessons Learned

The following lessons learned will help PAs in navigating the world of research as well as in pursuing other endeavors. PAs should:

- begin with the end in mind—determine when a product or project is due and backwards plan from that goal;
- collaborate early and often—it is important for a researcher to identify their resources and network;
- discuss projects frequently with mentors, especially those who can assist in moving them forward; and
- involve statisticians early in the project, not just when needed.

Tips for Success

Along with lessons learned, the following tips for success will help PAs maximize their opportunities in research. PAs should:

- maintain an updated CV for all authors and collaborators;
- review the IRB requirements and follow them (when in doubt, ask for clarification);
- meet with a senior researcher or researchers in the beginning of the research endeavor, which will save a lot of time and missed steps, especially for junior researchers;
- utilize all the research platforms available in streamlining the project (see Tools and Resources at the end of this chapter);
- attend a research course at the earliest possible time and before it is required, particularly if planning to attend a long-term health education and training program;
- manage time wisely and know all the deadlines required to complete a project; and
- take the time to identify past and current literature that supports the project. A strong literature review is the foundation of the research project.

Conclusion

The ability to conduct research is important for all PAs. Conducting research helps PAs improve their clinical practice while contributing to the body of existing medical literature. All PAs, regardless of educational background, can learn new skills and use them in their current environment. PAs do not need doctorate-level education to conduct research; they require only willingness, fortitude, and interest; time-management skills; and eagerness to learn, especially from senior researchers.

References

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3. Katz JS, Martin BR. What is research collaboration? *Res Policy.* 1997;26(3). Accessed March 19, 2020. https://doi.org/10.1016/S0048-7333(96)00917-1
4. Loan-Clarke J, Preston D. Tensions and benefits in collaborative research involving a university and another organization. *Stud Higher Ed.* 2002;27(2):169–185. Accessed March 1, 2020. http://www.tandfonline.com/doi/pdf/10.1080/03075070220120001

Tools and Resources

Reference Management Tools

- EndNote: https://endnote.com/
- Mendeley: http://www.mendeley.com (also a collaboration tool)
- Microsoft Word: https://support.office.com/en-us/article/create-a-bibliography-citations-and-references-17686589-4824-4940-9c69-342c289fa2a5

- Paperpile: http://www.paperpile.com
- RefWorks: https://www.refworks.com
- Zotero: http://www.zotero.org (also a collaboration tool)

File Sharing

- DoD SAFE: https://safe.apps.mil/
- Box: http://www.box.com
- Google Drive: https://www.google.com/drive
- Dropbox: https://www.dropbox.com

Statistical Tools

- Power and Sample Size Calculator: http://powerandsamplesize.com/
- Statistical Package for the Social Sciences: https://www.ibm.com/analytics/spss-statistics-software
- MiniTab https://www.minitab.com
- Survey Monkey
- Poll Everywhere

Online Publication Depositories

- PubMed: https://www.ncbi.nlm.nih.gov/pubmed
- AMEDD Virtual Library: https://medlinet.amedd.army.mil/
- Research Gate: https://www.researchgate.net/
- Army Public Health Center: https://phc.amedd.army.mil/topics/discond/ptsaip/Pages/References.aspx
- ProQuest: https://www.proquest.com

Collaboration Tools

- Skype
- Zoom
- Facebook Messenger
- Google
- MilSuite
- Trello
- Blackboard Collaborate
- Adobe Connect

Journals

- *American Journal of Emergency Medicine*
- *Cureus*
- *Journal of the American Academy of Physician Assistants*
- *The Medical Journal* (US Army Medical Center of Excellence)
- *Journal of Orthopaedics for Physician Assistants*
- *Journal of Special Operations Medicine*
- *Journal of Trauma and Acute Care Surgery*
- *Military Medicine*
- *Prehospital Emergency Care*
- *Transfusion*
- *Visual Journal of Emergency Medicine*

Research Resources

- Army Human Resource Protection Office
- Army Medical Research Development Command: https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/irbo
- Brooke Army Medical Center Department of Clinical Investigation: https://www.bamc.health.mil/staff/research/dci/
- Collaborative Institutional Training Initiative: https://www.citiprogram.org