

Clinical Inquiry

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Creating Clinical Research Protocols in Advanced Practice: Part I, Identifying the Fit and the Aim

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The term “advanced practice nurse” (APN) encompasses nurses with graduate level preparation typically focused on direct patient care, or oversight of direct patient care, in a clinical practice setting.¹ Examples include the certified nurse-midwife (CNM), certified registered nurse anesthetist (CRNA), clinical nurse specialist (CNS), and most commonly, nurse practitioners (NPs). The versatility and independence represented by these very different practice arenas is one of the most valuable assets of advanced practice nursing. Yet, the same virtue can become a vice for APNs interested in research or clinical inquiry as an integral component of their everyday practice. Three common and often unanticipated challenges include (1) clinical practice isolation, (2) limited preparation for independent research or improvement science design, and (3) time constraints, either to pursue funding or to engage in unfunded clinical inquiry. As a result, nurses with the most experience and exposure to patients’ problems are often the least likely to have critically needed peer support, methodological skills (eg, study design), or funded time to develop a protocol (eg, nonacademic roles). The purpose of this series is to creatively explore considerations in protocol development and to propose approaches that may be particularly well suited to clinical inquiry projects for APNs. Part 1 in this 3-part series addresses the initial steps of protocol development and presents solutions for the challenges uniquely associated with *clinical practice isolation*.

Protocol Development Framework

A protocol, regardless of the intent for research or improvement science, is a document describing in detail how a study is to be conducted in an actual practice environment. The protocol includes the overall purpose or aim, methods, a plan for analyzing the results, and a plan to protect the rights of people and patients as participants. An overview of the full scope of protocol development is shown in Table 1. Getting started can be challenging. A Google search for “creating a research protocol” yields 3 880 000 results—hardly helpful in narrowing the options for how to begin.

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Table 1: Components of a Protocol

Components of Protocol	Description
Protocol title	Includes the patient population, primary research question, and the approach or comparison being made.
Purpose of the study (Aim)	Is a broad statement of the problem or the specific aim, and is followed by the PICO or research question.
Background and significance	Establishes the argument or need for doing the study.
Methods	
Design	Describes the statistical design and the timing of the intervention sequencing (eg, this study will be a prospective, cross-sectional, controlled intervention study to evaluate colonization of surface contaminants on telemetry boxes and lead wires).
Selection of study participants	States the sampling strategy (eg, consecutive, randomized) and the targeted patient population or cohort definition.
Procedures	Describes the exact sequence of events, time relationships, and individuals involved during the data collection. State what, when, how, and who will collect the data.
Measures	Describes the independent and dependent variables to be measured, including surveys, physiological measures, and metrics to be used.
Recruitment and compensation of participants	Describe methods for identifying the potential participants.
Consent process	Describes how, who will obtain, and when the study consent will be obtained, including site-specific institutional review board requirements for informed (or waived) consent.
Study interventions	Describes research or quality improvement activities that will be done to/for participants for participating in the study.
Risk/benefit assessment	Describes potential risks and benefits that might occur during the project.
Costs to participants	Describes whether the project will incur any costs from the participant.
Data analysis and statistical considerations	Describes preliminary plans for data analysis and specifically states the statistical tests to be used.
Data and safety monitoring	Describes how the data will be monitored to keep the participants safe.
Privacy, data storage, and confidentiality	Describes how the data will be kept confidential.

Abbreviation: PICO, problem, intervention, comparison, and outcome.

The practical aspects of getting started in creating a clinical research protocol depend on teamwork for identification of the overall purpose or aim. To embark on this initial step requires discussion, camaraderie, and collaboration, which is especially daunting in a socially “sparse” environment. That is, by definition, *advanced practice* implies a nursing role as an independent care provider or as a leader of direct care providers. Either circumstance creates a practice environment in which groups of peers with common clinical questions, practice priorities, and concerns are not in close proximity or easily accessible in everyday work. In this isolated scenario, the practical

aspects of creating a clinical research protocol are made more difficult by the absence of a sounding board. Creative solutions for protocol development in the context of professional isolation are possible and in fact highly rewarding, and yet they require focused attention and purposeful planning for opportunities to collaborate at each step in the process.

Focus on Fit: Align Clinical Inquiry Question With Clinical Practice Priorities

To begin protocol development, establishing the *scope of the problem* and stating a *specific aim* are requisite first steps. These are

Table 2: Align Priorities—Partnerships Between Research and Practice Provide Opportunities for Protocol Development^a

Examples of Academic Research Center Priorities	Examples of Patient/Health System Priorities
Science of quality and patient safety	Quality improvement initiatives; patient satisfaction studies
Optimal care delivery models	Health system population management programs; nurse-rounding models of care delivery to improve communication and patient-centeredness of care
Science of self-management	Tele-health and home-based monitoring studies; educational models of information delivery and patient learning
Symptom management	Nurse-managed clinics for anticoagulation, atrial fibrillation, diabetes, and heart failure
Chronic condition management	Palliative care/end-of-life care; community-based care (office care, retail care, home care)
Informatics (emerging)	Patient engagement with electronic health records and patient portals

^a Based on information from Enders et al.⁶

followed closely by the next step, identifying and narrowing a clinical question to fit institutional or independent practice priorities. The skills needed to identify a clinical question are covered in many nursing programs and have been well described in the literature.²⁻⁵ Yet, in an advanced practice role, the practice priorities may be difficult to identify, narrow, evaluate, and prioritize. Lack of an immediately available peer group for discussion makes the task even more challenging.

A strong protocol demonstrates a focus on the fit of the project with the broader, contextual health system priorities and the specific, often more narrow patient care priorities (Table 2). For example, the Institute of Medicine (IOM), in its 2010 report⁷ on the future of nursing, noted the important role of nurses in data capture for quality, care delivery, and patient outcomes, as well as the critical role of nursing input into data entry interface designs, such as electronic health records, to improve data capture of care delivery metrics that reflect “quality” of care.

Another example of *fitting* the protocol aim to the broader context of health system priorities is from the Patient Protection and Affordable Care Act.⁸ The value-based model prioritizes and rewards providers for increased efficiency, improved health outcomes, proactive management of chronic conditions, and prevention efforts that avert unnecessary hospitalizations.⁹ APNs play a key role in evaluation of quality of care, patients’

outcomes, and the processes of care that contribute to and drive high-quality outcomes. In addition, patient-focused care delivery models and outcomes are the focus underlying the IOM recommendations in *Crossing the Quality Chasm: A New Health System for the 21st Century*.¹⁰ Throughout this transformational document are opportunities for nurses to take a key role in providing care that is respectful of and responsive to individual patients’ preferences, needs, and values and to give voice to patients’ values as the driving force behind all clinical decisions.

These examples offer many opportunities for research protocol development to align with priorities on the broader landscape of health care delivery. Particularly challenging, however, are the subsequent initial steps of defining and narrowing the clinical question and developing study aims that fit the roles and role responsibilities of APNs. The everyday life of APNs involves providing interventions that influence patients and health care outcomes, either through direct care of individual patients or through the management of care for populations, health systems, or organizations.¹¹ The broad scope of practice and the degree to which APNs have responsibility for independent decision-making regarding treatment options that directly affect patients’ outcomes, and have opportunities to choose among a host of intervention strategies, make the challenge of defining and narrowing the clinical question difficult.

Table 3: Criteria for Prioritizing Potential Research Topics and Questions^a

Criteria	Question 1	Question 2	Question 3
Large number of potential participants eligible for study			
Sample size required is feasible given clinical volume seen (mean <75 patients)			
Topic builds on clinical expertise of staff participants and investigators			
Important to clinical practice priorities			
Important to patients' outcomes for the clinical area			
Within the nursing scope of practice and realm of control			
Recognizes organizational priorities			
Addresses national patient safety and quality goals			
Data collection could be easily performed in short periods of time with available equipment			
Topic interesting to staff			
Methods are already available for measurement of dependent variable			
Avoids politically charged areas of practice			
Could be done as a replication study			
Requires no additional funds to do study			

^a Based on information from Granger and Chulay.¹²

The task is more feasible if a tool can be used to evaluate options and discuss priorities among a smaller group of peers. One example of a tool for critically evaluating and prioritizing research topics and clinical questions is shown in Table 3. Many such tools exist, but the benefit of using a tool is to give comprehensive coverage and weight to the many factors that affect a decision to proceed with a particular focus for the protocol, particularly in potentially more isolated clinical practice scenarios where buy-in will be key to the success of the project.

Establish Partnerships: Align Project Aims With Health System Partners

A second unique challenge for protocol development for APNs is that of defining a team. Because the research or project team will most likely not be a team of peers (multiple APNs from varied areas of practice), the need to connect with other disciplines, care nurses, and administrative and academic partners will also be key to the success of the project. Defining the team broadly, but keeping the broader team closely aligned with the

clinical problem and focus of the protocol is a necessary skill. Partnerships both within and outside of nursing are a central strength of the role of advanced practice nursing. As noted by the IOM, “Nurses’ regular, close proximity to patients and scientific understanding of care process across the continuum of care give them a unique ability to act as partners with other health professionals and to lead in the improvement and redesign of the health-care system and its many practice environments, including hospitals, schools, homes, retail health clinics, long-term care facilities, battlefields, and community and public health centers.”⁷

In addition, the American Association of Colleges of Nursing’s *Advancing Healthcare Transformation* report⁶ highlights the importance of nursing partnerships as a means to advance the science on integrated systems of health care, achieve improved health outcomes, and foster new models for innovation. Of the 6 priority recommendations in the report, 2 (recommendations 4 and 5) are pertinent to nursing partnerships in protocol development to advance the science of care for patients and their families, developing linkages between acute care and postacute, home-based and

Table 4: Partnerships Between Health Systems and Academic Centers Through Alignment of Study Questions^a**Imperatives for Health Care Systems**

Priority focus on quality, patient safety, and outcomes within the delivery system to meet both a national imperative on quality but also an internal imperative to lower the overall health center cost structure to compete with lower-cost community systems, particularly for less-acute care.

Innovation with patient-oriented research that connects basic science discovery to new clinical interventions, drugs, therapies, and procedures and broader population/public health interventions.

Intersection with Academic Nursing Priorities

Studies related to health care quality, population and disease management (eg, clinical outcomes within and across care delivery settings), patient safety indicators and outcome

Studies related to adoption and implementation science (eg, the study of the effectiveness of quality and safety initiatives implemented in the clinical system and in community-based settings)

Studies related to cost-effectiveness and benefit

Evaluation of new approaches to patient-focused research (eg, participative action research)

Evaluation of nursing roles and approaches to leadership in patient-centered and community-based research

Evaluation of transdisciplinary research teams and new models for team-based care in population health interventions (eg, nurse-led clinics, group visit models, and nursing–community health worker partnership models)

^a Based on information from Enders et al.⁶

long-term care services, and expanding nurse-led community programs under the leadership of academic nursing faculty in partnership with health system leaders and clinicians (Table 4). Examples of partnership opportunities in priority recommendation 4 include partnering across health system and academic or university-based schools of nursing to evaluate the implementation of accountable care. As health systems implement value-based reimbursement programs and assume responsibilities for populations of patients, health system leaders should look to nurses to lead and support prevention and wellness programs, new models of care delivery, continuity across transitions in care settings, and integration with home and community-based services. Strategies to develop such partnerships include forming collaborative protocol development teams around ongoing clinical planning initiatives, or working to form shared responsibility and leadership in clinical practice councils with nurses from both advanced practice and academic settings.

Examples of partnership opportunities in priority recommendation 5 include further developing nursing research programs that are based in the clinical setting and that include members from both the hospital or clinic and the academic setting.¹³ An evidence-based nursing service, based on existing research

and with a mission and vision to produce new knowledge through collaborative protocol development with academic partners, will not only benefit the local project teams and health system, but also patients, patients' families, communities, and the broader scientific national agenda. Strategies for establishing these partnerships include collaborating on jointly sponsored research projects, serving as APN investigators in research and quality improvement work that includes both academic nurses and health system nurse-scientists, and participating in training and mentoring programs for clinical trial coordinators and clinical research nurses.⁶ In each of these cases, the opportunity to collaborate alleviates the barrier of clinical practice isolation for APNs and establishes a community of peers with whom a research protocol might be developed and carried out.

Conclusion

Creating a research protocol that can be practicably executed in clinical practice is challenging for anyone, but common challenges can be particularly vexing for advanced practice nurses, often working in isolated roles in health care delivery settings. Establishing the fit, that is, alignment of the project with practice priorities, and developing partnerships for carrying out the study are 2

solutions for getting started and generating institutional momentum for the project.

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