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Creating Clinical Research Protocols in Advanced Practice: Part III, Building Blocks of Study Design

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Protocol development to formalize an approach for clinical inquiry in the practice setting is challenging. In this series, we identify 3 challenges that often beset advanced practice nurses (APNs) in the research protocol development phase. These 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, APNs are often stymied by limited peer support, rudimentary experience in designing study methods, and the need to negotiate funded time to conduct research as a part of their clinical practice. In this series on research protocol development by APNs, we address these challenges and provide solutions for the various steps of protocol development, with more specific guidance for some individual components of the protocol itself.

Overview, Part I and Part II

In part I, we began with topic selection and addressed broad issues associated with identification of the problem for the background section.[1] As a brief review, in part I of this series, topic identification and project selection were discussed as the initial starting points for quality improvement (QI) and research protocol development. Solutions for some of the challenges that often derail APNs from developing QI or research projects, such as the need for a network of clinical peers, analytical expertise, and time constraints, were described.

In part II of the series, we addressed the next step of protocol development, evaluating the clinical feasibility, by presenting a case example that explored practical steps for considering the implementation processes for a study, including key decision points for evaluating the feasibility of carrying out the protocol.[2] A case example was used to describe critical steps in research protocol development, including (1) assessment of operational feasibility of the project, (2) ascertainment of the approval of key stakeholders, and (3) development of

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a communication plan to ensure long-term engagement of staff and stakeholders throughout the entire phase of research protocol development. A checklist for operational feasibility was provided to guide the process, using the cardiac surgery advanced life support (CALS) case study to give APNs an example of how to evaluate protocol feasibility in a logical sequence. Analogous to the "head to toe" assessment in a history and physical, the checklist prevents omissions and oversights in project evaluation by reminding the APN to think through the more granular details of project feasibility. For example, within the broader headings of the protocol, such as the study population, the aims, outcomes measures and metrics, procedures, analysis plan, time line, and the plan for dissemination of results, are the initial and ongoing resource requirements really feasible, not only from a financial perspective but from a logistical and operational perspective? The checklist addresses these questions and provides a tool for determining the practicality of a protocol.

In part III of this series, we address selecting a method. This section builds on the others by differentiating clinical questions that are best suited for QI from clinical questions that demand a research-based approach. The same example, CALS, will be used to show how to think through key decision points in study design and apply these tools in the practice setting. To recap, the CALS protocol is designed for managing cardiac arrest in adult patients after cardiac surgery by maximizing the use of early defibrillation and pacing and by following a protocol to organize key personnel for early resternotomy.[3]

The purpose of part III of this series is to address the next step in protocol development by describing a process that can be used to determine and plan for study design. In this article, we will provide one tool for distinguishing whether a project is best suited for a QI or research study design, and a second tool for planning a QI design. We will use the CALS case again to provide an example for how to apply these tools in the practice setting.

Considerations in Design

The choice of methodological approach and the subsequent study design, be it QI or research, is dependent on the nature of the clinical question, the presence or absence of existing evidence for practice in published reports, and the state of the baseline data at your local facility, hospital, or health system. In the simplest terms, if evidence for practice exists and yet is not well implemented at your hospital, the quality of patient care suffers and quality metrics are low. An example of this is the evidence for rapid rhythm recovery and cardiac output following cardiopulmonary arrest. If a hospital does not have a system in place to deliver effective advanced cardiac life support (ACLS) for patients who suffer cardiac arrest, patients' outcomes are poor (high mortality rate), quality metrics for in-hospital survival are low, and publicly reported hospital quality scores are subsequently compromised. In this example, the scientific evidence for the link between effective perfusion and patient outcome (mortality rate) is clear. What is less clear, both in our case example and in hospitals around the country, is whether care processes in place for in-hospital cardiopulmonary resuscitation in adult cardiac surgery patients are optimal and whether implementation of a new evidence-based protocol provides improved patient outcomes and process metrics.

Similar to the project feasibility checklist, a tool to address the key decision-points in determining project design (QI versus research) can be used. We will refer to this logical sequence of questions as the Project Design Tool (Table 1).

In the following sections, we describe how the CALS project team used the Project Design Tool to identify the appropriate study design to improve processes for response to cardiac arrest in the cardiothoracic intensive care unit (CTICU). Of particular interest and focus in this example are the role of APNs on the response team and the opportunity to improve processes of care by optimizing the APNs' scope of practice.

The Question: QI or Research?

After feasibility of the project topic or idea is assessed and appears favorable, the next step in protocol development is to determine protocol design. First, one must determine whether the clinical inquiry project should be approached by using QI or research methods. Quality improvement projects are easily confused with research. Both QI and research projects involve systematic collection of data, analysis of data, and tabular reporting and graphic interpretation of the data, and the

Table 1: Project Design Tool Using the CALS Case Example

Key Decision Points and Questions to Ask[a]	Yes (Protocol Is Quality Improvement)	No (Protocol Is Research)
Purpose		
Is the activity intended to improve the process/delivery of care while decreasing inefficiencies within a specific health care setting?	CALS is intended to improve the process of resuscitation of adult cardiac surgery patients in the CTICU by maximizing the use of early defibrillation and pacing and by following an organized protocol for resternotomy if other measures are not successful in resolving cardiac arrest. By assigning and defining roles involved in resternotomy and educating staff on the process, CALS is designed to decrease inefficiencies in the reopening process.	
Scope		
Is the activity intended to evaluate current practice and/or attempt to improve it based on existing knowledge?	CALS is an attempt to improve practice using existing evidence by use of early defibrillation and pacing in cardiac arrest after cardiac surgery. Resternotomy was already being performed in the CTICU, although the unit had no formal protocol; CALS is intended to improve this process using a standard protocol.	
Evidence		
Is there sufficient existing evidence to support implementing this activity to create practice change?	Evidence is summarized in a key paper by Dunning et al,[3] formally outlining the steps for resuscitation of adult cardiac surgery patients after cardiac arrest.	
Clinicians/Staff		
Is the activity conducted by clinicians and staff who are responsible for the practice change in the institution where the practice change will take place?	All key personnel involved in implementation of the protocol work clinically in the CTICU.	
Methods		
Are the methods for the activity feasible and do they include approaches to evaluate rapid and incremental changes?	Education for nurses, NPs, PAs, and surgical fellows was provided by the 3 key implementation personnel. All codes would continue to be documented in the standard fashion and exist in the code blue database. An additional CALS data sheet was created to track CALS specific metrics including time to resternotomy, equipment availability, and opportunities for improvement.	
Sample/Population		
Will the activity involve a sample of the population (patients/participants) ordinarily seen in the institution where the activity will take place?	The CALS population will include a portion of the CTICU adult cardiac surgery patients as identified in the protocol as eligible for CALS and will be recognized by an active order for CALS resuscitation and bedside signage.	
Consent		
Will the activity only require consent that is already obtained in clinical practice, and will that activity be considered part of the usual care?	Resuscitation following cardiac arrest, including resternotomy, is part of the usual care for cardiac surgery patients who have a cardiac arrest postoperatively. Surgical consent for the initial operation is gained preoperatively and covers usual postoperative care.	

Continued

Table 1: Project Design Tool Using the CALS Case Example (*Continued*)

Key Decision Points and Questions to Ask[a]	Yes (Protocol Is Quality Improvement)	No (Protocol Is Research)
Benefits		
Will future patients/participants at the institution where the planned activity will be implemented potentially benefit from the project?	Future patients who require resuscitation for cardiac arrest following cardiac surgery may benefit from improved process efficiency. Possible harmful effects from chest compressions on a fresh sternotomy and hypertension from standard ACLS dose epinephrine administration will potentially be avoided.	
Risk		
Is the risk to the patients/participants no greater than what is involved in the care they are already receiving OR can participating in the activity be considered acceptable or ordinarily expected when practice changes are implemented in a health care environment?	No additional risks to the patients are present.	

Abbreviations: ACLS, Advanced Cardiac Life Support; CALS, Cardiac Surgery Advanced Life Support; CTICU, cardiothoracic intensive care unit; NPs, nurse practitioners; PAs, physician assistants.
[a] Adapted with permission from Duke University's institutional review board (IRB).[4] Developed by Dr M. Hockenberry, IRB Chair, Duke University School of Nursing, Durham, North Carolina.

primary goal of both types of projects is the improvement of patient care.[5] However, the degree of risk to which participants are exposed is a key distinguishing factor. Determining the presence and degree of risk can be simplified by using the Project Design Tool (Table 1).[6]

The Project Design Tool is a sequence of 9 questions used to determine if the protocol falls under the realm of QI or research. The questions embedded in the tool address the risk posed by the activity (project) to study participants in 9 specific domains: purpose, scope, evidence, staff, methods, sample, consent, benefits, and overall (summative) risk. For each question, the investigator is asked to consider domain-specific aspects of the study activities. For example, the question to assess purpose asks specifically about the underlying intentions of the study, focusing on intentions related to process efficiencies "Is the activity intended to improve the process/delivery of care while decreasing inefficiencies within a specific health care setting?" This question, if answered affirmatively, distinguishes the project from one that intends to compare a new treatment to an existing one, or discover new knowledge through experimental design, such as randomly assigning a therapy. A positive answer to the first question in the sequence is indicated by a check mark in the QI column. Questions in each subsequent domain are then answered in this same way. Because the tool is yes-no item response, the degree of risk is not specifically ascertained, rather, the tool enables assessment of the presence or absence of any risk across these 9 domains. Each question should be considered and answered independently of the others, recognizing that responses may be positive (yes) for more than one. If responses to all 9 questions are "yes," then the project should be done by using a QI design. If any of the questions are answered "no," then the project most likely requires a research design.[6]

Using the answers from the Project Design Tool (Table 1), the CALS protocol falls in the QI realm, since the purpose, scope, evidence, staff, methods, population, consent, benefits, and risk questions can all be answered in the "Yes" column. In the CALS example in Table 1, we have explained how the protocol met the "yes" across all 9 domains. Alternatively, if the project activities resulted in 1 or more "no" responses, the institutional review board (IRB) would most likely determine that the proposed project required a research design. These designs will be described in more detail in the next issue. Yet, in short, if the CALS protocol had not been supported by existing evidence, or had been intended to create new evidence, such as determining whether one approach worked better than another, then the design would have been created to accommodate a research question, and a research design would have been specified for the protocol. Likewise, if patients were randomized into different types or methods of resuscitation or were exposed to new risks as a result of the protocol, or if the protocol was applied to populations outside of those it was developed to treat, then a research protocol would have been developed. Importantly, if any responses to the Project Design Tool are "no," a review of the project by the local IRB is instrumental in arriving at a final determination. In our case study, the CALS project was determined by the IRB to be a QI initiative and exempt from IRB review.

Selecting an Approach for Improvement

Selection of a formal QI framework or process is an important consideration for designing and implementing a new protocol. Many different approaches for QI have been reported,[7-9] and some are typically better suited than others for clinical inquiry and problem solving in health care. All of these approaches recognize and prioritize the underlying importance of the Institute of Medicine's (IOM's) "Safe, Timely, Effective, Efficient, Equitable, and Patient-centric" (STEEEP) framework.[10-12] This framework establishes the underlying principles for quality improvement and is helpful to use alongside the specific QI framework and tools that are chosen. For most teams, the STEEEP framework provides a set of metrics that keep any project aligned with the national goals for quality and patient safety. In addition, STEEEP can be used to ensure that the process improvement project is measurable and that improvements made can be additive, eventually building on one another like blocks, leading to quality improvements that also achieve improved clinical outcomes for patients.

Factors to consider in selection of a QI framework should focus on the project fit; for example, whether the project is exploratory, diagnostic, prescriptive, or comparative. An overview of these designs and key indicators for selecting the best approach to fit your clinical question are listed and described in Tables 2 and 3. We limit our discussion here to the example of the CALS case study; however, further information on others in the table is easily obtained from a cursory literature review.

Table 2: Common Quality Improvement Design Frameworks

Quality Improvement Design Frameworks	Indications for Use
1. DMAIC[7]	A method to guide quality evaluation using a data-driven cycle for assessing improvement: Define, Measure, Analyze, Improve, Control
2. PDSA[13]	A method for quality evaluation; a systematic series of steps for gaining valuable learning and knowledge for the continual improvement of a product or process: Plan, Do, Study, Act
3. Lean[14]	A method or analytical technique to improve quality that focuses on reduction of defects in a process
4. Driver diagram[15]	A method to plan quality intervention by laying out aspects of an improvement project so they can be discussed and agreed upon

At our organization, the DMAIC (define, measure, analyze, improve, and control) framework is one of the most commonly used tools for QI initiatives.[7] The advantage of DMAIC over the PDSA (plan, do, study, act), another tool commonly used in health care, is the ongoing, long-term monitoring of sustained success that is afforded in DMAIC by the "C" control phase. This framework reminds users to select a quality metric that can be measured over time to monitor sustained quality.

As illustrated in Table 4, we used the DMAIC process as a guide in the design and protocol development for the CALS project. In a stepwise fashion, we defined the opportunity to optimize our approach for resuscitation in adult cardiac surgery patients; measured or gathered baseline data around our existing cardiac arrest response times, time to resternotomy, initial survival rates, and survival to discharge rates, as well as staff comfort with open chest resuscitation; and analyzed the data to determine the root causes in any delays in resuscitation after cardiac surgery and opportunities to improve and standardize the resuscitation process for adult patients

Table 3: Common Quality Improvement Tools

Quality Improvement Tools	Type	Description
Process diagrams	Cause and effect diagram	
	Process map	A graphic representation of the processes associated with an identified problem within a system.
	Fishbone	A type of cause and effect diagram that identifies possible causes for a problem.
	Swimlane	A graphic representation used in process flow diagrams, or flowcharts, that visually distinguishes job sharing and job responsibilities.
	Stacey matrix	A graphic representation used to identify management decisions on 2 dimensions: (1) the degree of certainty and (2) the level of agreement.
Bar charts	Histogram	A graphic representation of the processes associated with an identified problem within a system.
	Pareto charts	A graphic representation of cause, showing the frequency with which different categories of events take place, ordered with the most common to the left, and the least common to the right.
Plot charts	Box plot	A graphic depiction of groups of numerical data shown in quartiles.
	Box and whiskers plot	A type of box plot with the addition of lines extending vertically from the boxes (whiskers) indicating the variability outside the upper and lower quartiles.
	Scatterplots	A diagram using dots to the value of individual data points. One variable determines the position of the dot on the horizontal (X) axis and the value of the other variable determining the position on the vertical (Y) axis.
Trend charts	Run charts	A graphic display of data showing observed data points, usually connected by a line, and depicting change over time (also called a line chart).
	Shewhart control chart	A type of control chart used to monitor data from a process; important to use when subgroups are not practical.

with cardiac arrest after cardiac surgery. The evidence-based CALS guidelines were adopted and implemented as an improvement process after careful evaluation of existing evidence, local stakeholder approval and buy-in, and systematic communication and planning. Finally in the control phase, we monitored long-term outcomes, including sustained achievement of identified milestones, established review intervals for predetermined metrics and outcomes, and identified a mechanism to leverage lessons learned through ongoing dissemination of our processes. Through the "C" control phase, a QI project is never simply "one and done," as it is an ongoing process of evaluating clinical outcomes associated with the improvement achieved in rapid response to cardiothoracic surgery advanced life support processes.

The Baseline Data: High Quality or Opportunity to Improve?

A critical step in the "M" measurement phase of the DMAIC-based protocol design is evaluation of "current state" or the local baseline data associated with the processes in question. In the CALS example, clinical performance data for cardiac arrest are evaluated by the Code Blue Committee via the code blue database. Nurses became aware of new evidence for a cardiac surgery arrest protocol that more clearly addressed resuscitation for cardiac surgery patients, including emergency resternotomy. In addition, following episodes of emergency resternotomy on the unit, structured code blue debriefing meetings were held in which staff reported that the comfort level and teamwork during open chest codes was suboptimal. As a result, the CALS project

Table 4: Duke DMAIC Problem-Solving Grid Using the CALS Example[a]

Phase	Step	Primary Activities	Tools to Consider (Not Limited to These)	Change Management Considerations	Primary Output
Define	**Identify the opportunity:** Change to evidence-based resuscitation[3] guideline for patients following cardiac surgery.	**Review initial project charter:** Published guideline[3] **Form the team:** Key members from nursing, education, advanced practice, Code Blue Committee **Identify and describe the performance gap:** The CALS protocol maximizes the use of early defibrillation and pacing for cardiac arrest in cardiac surgery patients. If initial attempts at resuscitation fail, follow a standard protocol for resternotomy. **Identify stakeholders:** Surgeons, hospital administration, risk management, education, credentialing, and Code Blue Committee **Finalize and approve project charter:** Hospital protocol for CALS approved	**SIPOC** **CTQs** **Project Charter**	**Understand your team** **Everyone on the team understands the problem and agrees it should be explored—identify change leaders and change resistors:** Surgeons in agreement with implementation of protocol and the need to change practice; emergency resternotomy is not new to the CTICU, an organized protocol is new. Main job of the team was to convince resistors that practice was not changing, just timing and standardization under the new protocol. A new skill was added for NPs/PAs, who were trained to perform resternotomy when surgeon not present. This was needed in order to provide the same standard of care 24/7.	**Project objective defined and charter approved:** Approval of CALS protocol by medical director, Code Blue Committee, and Hospital Clinical Practice Committee
Measure	**Gather the facts:** Review data in code blue database and pre-CALS staff survey on comfort with resternotomy.	**View/map the current process:** Follow ACLS protocol for codes in CTICU. If initial interventions do not result in resolution of cardiac arrest, call attending surgeon to discuss emergency resternotomy and obtain order to proceed. **Gather data on the current process steps:** Ongoing data in code blue database **Brainstorm on initial approaches:** Enlisted support of cardiac surgery fellow. A patient in ICU had cardiac arrest while walking in hall in ICU within a week of introduction of CALS to cardiac surgery fellow. Patient had early resternotomy and was neurologically intact after > 30 min of internal massage and survived to discharge.	**Fishbone diagram** **Value Stream Map** **Swimlane Charts** **SPC Current Process:** Provide clarification of goals of protocol and the need for change. Build consensus for change by centering on the goal of improved patient care by better response to cardiac arrest following cardiac surgery.	**Challenge your team** **Team must agree on current process steps and performance—begin to challenge your team to think differently and get excited about change:** Use success stories about patients who have survived codes to help focus on patients instead of processes. Enlist staff to assist with implementation of CALS in the ICU.	**Map of current process, potential solutions/strategies and measures:** Components of the project that needed to be completed: • Standardize emergency carts • Develop small resternotomy tray • Develop education appropriate for each discipline involved in practice change (staff meeting update vs all-day training)

Continued

Table 4: Duke DMAIC Problem-Solving Grid Using the CALS Example (*Continued*)

Phase	Step	Primary Activities	Tools to Consider (Not Limited to These)	Change Management Considerations	Primary Output
Analyze	**Develop solutions**	**Look for root cause and variation in process** **Use data to verify root causes and non–value-adding activities** **Brainstorm possible actions to address:** Identify all changes in practice with the new protocol and enlist key people in each discipline.	**Swimlane Process** **Pareto Charts** **Cause and Effect**	**Support your team** **Change leaders may start to worry and change resistors may get excited:** Share information with the team, especially the benefits of change. Hear all concerns and answer questions.	**Root causes and 3-5 potential solutions that are easy to explain:** Possible improvements in care: • Maximum use of defibrillation and epicardial pacing in a cardiac arrest could potentially avoid external compressions on a fresh sternotomy • An organized process for resternotomy • Initial arrest survival and survival to discharge
Improve	**Implement solutions**	**Select actions to take:** Develop new protocol with standardized process. Follow steps of approval process for implementation of new practice guideline. **Develop action plans and map new process:** CALS process mapped and staff trained **Implement actions on a small scale:** Not applicable **Study the results/modify action plans:** Review code blue data and CALS debrief sheets.	**5S** **Rapid Improvement** **Affinity Diagrams**	**Empower your team** **Empower the team to take the improvements implemented, test them, and become change leaders:** As unit leaders, charge nurses were the focus of early education and updates; first group to be trained among staff.	**Map of new process, action plans:** Education module developed that summarized protocol Module required for all staff, including float pool

Continued

Table 4: Duke DMAIC Problem-Solving Grid Using the CALS Example (*Continued*)

Phase	Step	Primary Activities	Tools to Consider (Not Limited to These)	Change Management Considerations	Primary Output
Control	**Monitor, sustain, and share:** Debrief after each code and review CALS code data at 6 months, 1 y, and 2 y and ongoing. Results shared in poster and oral presentations at national conferences. Data shared with staff at training sessions.	**Implement actions on a large scale** **Standardize successful actions** **Identify best practices and lessons learned** **Discuss next steps and implement control plan:** Make changes as needed—eg, new sternal closure device required training for staff, equipment and supplies modified as requested by surgical teams for resternotomy, and addition of CTOR charge nurse to emergency pager list.	**Project abstract** **Control plan**	**Celebrate your team** **Celebrate wins and begin to think about how to share best practices and next opportunities:** Publish results. Define process for review and training for new and experienced staff. Provide opportunities for training outside hospitals and staff.	**Project results and control plan (updated policies, documents, schedules). Project abstract posted to website.** Annual CALS protocol review by staff and scheduled simulation Annual review and update as needed for CALS policy

Abbreviations: 5S, sort, set in order, shine, standardize, sustain; ACLS, advanced cardiac life support; CALS, cardiac surgery advanced life support ; CTICU, cardiothoracic intensive care unit; CTOR, cardiothoracic operating room; CTQs, critical quality parameters; DMAIC, define, measure, analyze, improve, control; ICU, intensive care unit; NPs, nurse practitioners; PAs, physician assistants; SIPOC, suppliers, input, process, output, customers; SPC, statistical process control.
[a] Developed by Ashley Holroyd, Manager, Performance Excellence, Duke University Medical Center, Durham, North Carolina.

was proposed, the major aim of which was to improve staff comfort and teamwork with resuscitation of adult cardiac surgery patients through implementation of an evidence-based protocol.

Baseline data on resternotomy times was not routinely captured before implementation of the CALS, but the existing data showed a mean time to reopening the chest of 22 minutes. At the end of the first year of the CALS project, the mean time to reopening was 15.5 minutes, and it was 8.6 minutes at the end of year 2.

Clinical outcome metrics included baseline data for the 18-month period before the CALS initiation and showed an overall cardiac arrest survival rate of 91% (20/22) with 64% (14/22) survival to discharge. These numbers were within the upper limits of averages reported in the literature, and these metrics would be tracked with the CALS project.[3] Two years after CALS implementation, code survival was 96% (26/27) with 59% (16/27) survival to discharge. Importantly, 7 cardiac arrests were corrected with defibrillation or pacing only, preventing the possible untoward consequences of compressions on a fresh sternotomy.

Before initiation of CALS, perception of knowledge and comfort regarding open-chest resuscitation by nurses, nurse practitioners, and physician assistants was measured, although there was not a benchmark against which to compare. Data were collected at 6 and 12 months after the initial CALS training and analyzed by using repeated-measures analysis of variance in Microsoft Excel. Staff perception of knowledge and comfort regarding the standardized process increased between 6 and 12 months. Perception of teamwork with CALS resuscitation during chest reopening increased over time, although the findings were not statistically significant.

Conclusion

As health care delivery system leaders and stewards of high-quality care, APNs recognize the importance of the IOM's STEEEP framework. Regardless of whether a clinical inquiry project is deemed "research" or "QI," the principles inherent in the STEEEP framework resonate across our practice arenas, causing each one of us to strive for the best care for patients. The pressure to achieve high-performing health care systems is synonymous with the 6 domains of quality spelled out more than

15 years ago, and appropriate study design will help us ensure that selected, high-priority initiatives are safe, timely, effective, efficient, equitable, and patient-centered as the ultimate goal of good project design.

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