A Quality Improvement DNP Project to Increase Adherence to an Adult Hypersensitivity Protocol in the Non-Hospital Based Infusion Center

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A Project Report Submitted to
The Faculty of The School of Nursing at
The University of North Carolina at Greensboro
in Partial Fulfillment
of the Requirements for the
Doctorate in Nursing Practice

Greensboro, NC

May 2023

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Dedication

This DNP project is dedicated to all who supported me tirelessly throughout this educational endeavor. Through your endless encouragement and support, this project was feasible and attainable. My thanks to you will be forever just as endless.

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Abstract

Background: The use of therapeutic intravenous immunomodulatory agents in the past decade has increased incrementally in the Infusion Center setting. Similarly, adverse drug events (ADE) related to infusion-related reactions (IRR) are rising. This can lead to adverse patient outcomes, such as increased morbidity, reduction in treatment modality and efficacy, and the possible need for escalation in care management. The burden of costs associated with ADE exceeds $30-130 billion dollars per annum in the United States. While IRRs comprise only a fraction of ADE events, efforts to decrease their occurrence and effective clinical management should be made in all Infusion Centers.

Purpose: This DNP student project aims to ascertain whether a concentrated educational effort amongst Infusion staff increases the use and adherence to an established Adult Hypersensitivity protocol (AHP), thereby optimizing patient care outcomes.

Methods: A five-question survey regarding the AHP was administered to staff prior to the multidimensional education intervention to determine baseline knowledge. Similarly, chart audits were conducted to deduct the staff's current use and adherence to the AHP in the Infusion Center during an ADR. Using the Plan-Study-Do-Act translational framework, a multimodal educational intervention was conducted that entailed a concentrated recorded presentation regarding the AHP, the use of visual cues at the bedside, and one on one staff education and real-time verbal feedback. A three-month postimplementation chart review and repeat survey were conducted to determine whether increased protocol knowledge, use and adherence by staff had been accomplished.

Results: Protocol use and adherence increased percentages. However, it was determined to be statistically non-significant. The data represent inconclusive conclusions based on project implementation inference errors, sample power, and effect size. This

Recommendations and Conclusion: The unexpected finding that staff use and adherence to the AHP protocol did not increase following a concentrated educational effort represents the need for further research and exploration in this clinical area. Future recommendations include a site-specific review of the protocol and a more comprehensive institutional effort to assess protocol use and adherence amongst all related Infusion Centers.

Keywords: Adverse drug reaction (ADR); Anaphylaxis; Clinical practice guidelines (CPG); Hypersensitivity reaction (HSR); Infusion-related reaction (IRR); Quality improvement (QI).

Background and Significance

Infusion-related reactions are on the rise. This is evidenced by the dramatic increase in the use of biologic therapy to treat oncologic and autoimmune diseases worldwide (Akarsu et al., 2020; Bonamichi-Santos & Castells, 2018; Checkley et al., 2019). While this directly reflects our nation's population living longer with chronic diseases, much of this is attributed to biologic agent efficacy profiles (Akarsu et al., 2020; Cáceres et al., 2019). The use of monoclonal antibodies, one of the most common biologic agents, is anticipated to expand further over the next few decades.

With the rapidly growing arsenal of therapeutic agents, there is also an expanding occurrence and risk of patients experiencing drug hypersensitivity reactions (DHR) or an adverse drug event (ADE). Untoward adverse drug reactions (ADRs) remain a clinical challenge in Infusion Centers that administer such agents (LaCasce, et al., 2021; Pintea et al., 2021). The World Health Organization (WHO) defines adverse drug reactions as "any noxious, unintended, and undesired effect of a drug that occurs at doses used for prevention, diagnosis, or treatment" (Bonamichi-Santos & Castells, 2018; Cox et al., 2017).

Biologic therapy, especially with specific monoclonal antibodies (mAbs), carries an inherent risk for infusion-related reactions (IRRs) (Bonamichi-Santos & Castells, 2018; Cáceres et al., 2019; Roselló et al., 2017). IRRs are defined as any signs or symptoms experienced by patients during the infusion of a biologic agent, including any event occurring on the first day of administration. While most IRRs arise after the first or second administration, IRRs are rarely predictable (Roselló et al., 2017) and may progress to anaphylaxis. In addition, the exact

mechanism of these reactions is currently unknown (Akarsu et al., 2020). This, in turn, has incrementally increased the number of observed adverse drug reactions (ADR) in all infusion treatment settings (Cáceres et al., 2019; Pintea et al., 2021; de las Vecillas Sánchez et al., 2017). According to the National Action Plan for Adverse Drug Event (ADE) Prevention by the U.S. Department of Health and Human Services (2019), the burden of costs for ADE per annum in the U.S. exceeds anywhere from $30 to $130 billion per year. While ADRs only comprise a small percentage of ADEs, they can cause increased morbidity and mortality in affected persons, given the extensive physiologic nature of the event.

Furthermore, ADRs also comprise those reactions that include overt anaphylaxis. According to the Common Terminology Criteria for Adverse Events (CTCAE), adverse drug reactions are graded based on symptom severity. ADRs and related IRRs are graded on a scale from I-5, with I being no intervention necessitated and 5 equaling death. This applies to all ADRs and all infusion clinical settings, regardless of specialty or affiliation. It is imperative that when a patient experiences an ADR/IRR, they are treated immediately and effectively to ensure the best clinical outcome (Pirschal, Chris, 2017). Therefore, adherence to ADR/IRR clinical protocols and guidelines is essential when caring for patients at risk for an ADR, such as in the infusion clinical setting.

It is well known that protocol-based care incorporates the best available evidence to provide concise instructions on how clinical care should be delivered, intending to standardize care and improve patient outcomes (Boal & Corkin, 2019). However, definitive gaps in the literature became salient to the author while reviewing the state of current knowledge. Such as, no article was found in the literature review that specifically addressed adult hypersensitivity

protocols related to infusion therapy. Conclusively, substantial gaps in the literature were identified in that the author could ascertain no studies to date that systematically reviewed the impact of AHP adherence "as a prognosis factor" (Ricci-Cabello et al., 2020, p. 1). According to Pirschel (2017), "creating guidelines and an existing protocol for HSR prevention and management will help to provide a standard of care when emergencies arise," and "safely addressing HSRs means being proactive in practice" (p.38). This statement is consistent with the primary goal of this quality improvement project.

Purpose

This DNP QI project aims to improve adherence to an established institution-specific Adult Hypersensitivity Protocol (AHP) in the outpatient Infusion setting (Appendix B). The PI plans to achieve this by identifying barriers to protocol implementation and disseminating a concentrated staff education intervention utilizing the rapid cycle Plan-Do-Study-Act framework.

Aims:

1. Determine existing perceived or tangible barriers to Infusion staff utilizing the AHP during an adverse drug reaction.
2. Determine the Infusion staff's baseline knowledge of and compliance with the existing AHP.
3. Determine if increasing awareness of the AHP through a concentrated education intervention also increases staff knowledge and implementation of the AHP.
4. Demonstrate that increased compliance with the AHP subsequently improves patient care outcomes.

Review of Current Evidence

An exponentially growing number of biologic and monoclonal antibodies are administered yearly to manage chronic (autoimmune) diseases. Given cost management primarily directed by commercial payers and the U.S. Centers for Medicare & Medicaid Services (CMS) guidelines, the drive for cost-effective care is tangible in infusion therapy. Therefore, the expansion and use of non-hospital-based infusion clinics have grown exponentially over the past decade (Pirschal, Chris, 2017). However, this does not mean the acuity of the infusion patient and their medical necessity needs are conversely reduced. Likewise, with the redirection of care outside of the immediate hospital setting, it is even more crucial that the care team act quickly, cohesively, and effectively should an emergent situation arise, such as an ADR.

While any biologic therapy may induce an HSR in a patient, the three most common reactive agents administered in the non-oncology patient population are the monoclonal antibodies ocrelizumab, rituximab, and infliximab. These agents' therapeutic benefits must be "balanced with a substantial risk of infusional reactions" (Levin et al., 2017, p. 108). Such as, a patient receiving treatment with rituximab has a 77% chance of experiencing an HSR. Likewise, patients receiving treatment with infliximab have a 3-34% chance of an HSR during the induction phase of treatment. Therefore, while statistics demonstrate a 5% life-long chance of experiencing an ADR to the individual, a patient who receives treatment with a biologic/mAb therapy, whether it be for oncologic or non-oncologic purposes, has anywhere from a 3% to 77% chance of experiencing an ADR (Levin et al., 2017).

Our current institution-wide adult (AHP) is embedded within a Smart Set in EPIC (electronic health record/EHR) to manage entity-wide ADRs. This protocol was most recently updated in February 2022 following a core clinical team's review and synthesis of evidence-based best practices to manage adult anaphylactic and hypersensitivity reactions. The protocol is intended for the entity-wide management of all adverse drug reactions, regardless of the agent. Implementation of this protocol is inconsistent at our two non-HBC Infusion sites. This is consistent with Boal & Corkin (2019), who report that "despite benefits of using protocols for decision-making, evidence suggests that they are not always used" (p.25).

Our key-stakeholder steering committee is comprised of both clinical and operational team members. The committee identified notable inconsistencies in practice regarding the adherence and application of our institution-wide AHP within our Infusion Centers. Literature has demonstrated that "suboptimal adherence" to healthcare guidelines, recommendations, and protocols have the potential to "negatively affect patient outcomes and on overall healthcare costs" (Ricci-Cabello et al., 2020, p. 1). Such as, patients who experienced an ADR were found to have inconsistent AHP guideline management and, therefore, unpredictable and occasionally suboptimal clinical outcomes, such as avoidable transfer to the ED and failure of drug re-challenge.

Conceptual Framework

Given this DNP project's quality improvement (QI) aim, the principles of two of the most well-known quality improvement theorists, Kurt Lewin and W. Edwards Deming, will serve as the theoretical framework upon which the project is comprised and postulated. Current thinking about

continuous quality improvement (CQI) in healthcare draws heavily on these ideas and has demonstrated reliability in their translation to QI movements. Therefore, this project will fuse these principles of CQI to show that to be effective; this process is continual, purposeful, and systematic.

Lewin's theory of change includes three incremental phases. The first phase is to unfreeze or identify any processes that hinder change. In contrast, the second phase is one of "change," in which key stakeholders "transition into a new reality" and develop the change action plan (Huang et al., 2020). The third phase establishes the change as a new "standard operating procedure." This DNP project is hopeful of unfreezing barriers to the effective implementation of the institution's established adult hypersensitivity protocol (AHP), demonstrating change by increasing adherence to the AHP, which then enhances patient outcomes and refreeze this practice as the newly accepted standard operating procedure and standard work.

Critics of Lewin's theory of change related to healthcare posture that it is linear, somewhat simplistic, and therefore does not account for the dynamic healthcare environment (Wojchiechowsi et al., 2016). Therefore, this project also considers Deming's quality management theory, which builds on his theory of profound knowledge. Deming's theory of profound knowledge is based on the principle that an organization, such as healthcare, comprises a complex system of interrelated processes and people that make up the system's components (Peralta Rodriguez et al., 2019). Each person and process that comprises the system is integral to its success, including any quality improvement endeavors undertaken.

In addition, the ability of key stakeholders and management to orchestrate effective change is critical when considering overall quality improvement. Deming's theoretical

framework of quality management, also known as total quality management (TQM), focuses on quality improvement as a continuous cycle. This philosophy of change supports continual adjustment and refinement in the (change) plan. The aim of this DNP project is consistent with these philosophical principles in hopes of improving patient care outcomes through increasing adherence to an existing clinical practice protocol.

Methods

Translational Model

This DNP project utilized the Plan-Do-Study-Act (PDSA) model, one of the most familiar and commonly used Rapid Cycle Performance Improvement (RCPI) approaches, as its roadmap (White, Kathleen et al., 2021). PDSA, also known as the Deming cycle is one of the most applied approaches in healthcare to enhance performance by reducing medical errors and deviations in practice that lead to less-than-optimal outcomes for the patient (Martin et al., 2020). The PDSA template allows for a "logical cycle of improvement that supports ongoing adjustment and refinement in the plan" (White, Kathleen et al., 2021). In addition, this cylindrical process allows for real-time refinement of the project aims and continual analysis of improvement. Therefore, the iterative nature of the PDSA cycle allowed for minor changes to be implemented with minimal hopeful resistance. This increased confidence in the change through incremental modifications and adjustments (Crowfoot & Prasad, 2017; Martin et al., 2020). The PDSA cycle served as the blueprint for the following translational DNP project.

PLAN= The PI and critical stakeholders implemented a rapid cycle quality improvement project within the outpatient infusion settings. The aim was to increase adherence to an existing evidence-based adult hypersensitivity.

DO= The PI performed a multi-factorial education intervention with staff. The PI first implemented an in-person update of the AHP utilizing a PowerPoint™ Presentation. For participants unable to attend the in-service, a recording was made available to all staff on the entity's Infusion Wiki page and stored electronically. This ensured ease and continuity of staff accessibility. The PI also posted a copy of the AHP in the provider workroom and at the nurses' station for increased visibility and availability, especially during an ADR.

STUDY= Utilizing a mixed-methods approach with quantitative and qualitative data, the PI ascertained staff adherence to the AHP baseline and post-intervention. The Pearson Chi-square and Fisher's exact test were conducted with a p-value of <0.5. Patient care outcomes will be deduced from the SRS system and quantified based on same-day re-challenge within the AHP guidelines.

ACT= Based on statistical data, measurements, and outcomes, further practice modifications will be made to demonstrate hopeful change in quality improvement, clinical practice, and patient outcomes.

The theories of Lewin and Deming were the foundation upon which this project is postulated. At the same time, the Plan-Do-Study-Act model will serve as the project's constructive foundation. A pretest was administered employing the institution's approved Qualtrics survey platform to all infusion nurses and covering providers to ascertain baseline knowledge. Group-

specific presentations, dissemination of supporting written materials, and individual education were then conducted regarding the AHP. A 3-month post-implementation chart audit and educational post-test were also conducted to determine if increased protocol adherence and competence were achieved. Pre and post-tests will be comprised of twelve questions. The first six questions were aimed at participant demographics, and the following five questions assessed the participant's level of knowledge of the AHP. The final question was an open-ended one that inquired participants to describe any barriers that may contribute to decreased compliance with implementing the institution's Adult Hypersensitivity Protocol in the Infusion Center.

Chart audit analyses utilized the institution's Safety Reporting System (SRS). All patients who experienced a reportable ADR within our two non-HBC infusion centers were identified. Clinical management of the ADR was reviewed in relation to adherence to the AHP guidelines. This was a defined categorical variable with a YES/NO response by chart audit. Additional variables of interest were the medication management tactics, such as type of drug, dosage, and sequence of administration. This was compared to the institution's established AHP.

Setting

The setting for this project was two non-hospital-based Infusion Centers affiliated with an extensive quaternary-tertiary academic health system located in the southeastern United States. The two clinics are strategically located to serve two adjacent state counties. The combined clinics treat approximately 6,000 patients per year. The patient population consisted of adults aged 18 years or older with diseases necessitating immunomodulatory treatment. The focus of care was benign diseases encompassing all specialty service lines within the entity's health system. The

healthcare system is a well-known referral site for rare diseases; therefore, the Infusion Centers also administer orphan drugs and medications following immediate FDA approval. The infusion sites were selected by convenience/accidental as they directly reflect the area of interest in which the PI practices as an advanced practice provider (APP).

Sample

The sample was cross-sectional, population, and convenience-based. Patient inclusion criteria entailed patients who experienced an ADR during infusion therapy within the studies' identified time frame and subsequently reported to the SRS system. Staff inclusion criteria entailed healthcare members overseeing the direct medical management of a patient experiencing an ADR within the study's designated Infusion Centers. Staff included registered nurses (RNs) dedicated to the infusion suite who deliver direct patient care and the attesting covering providers, consisting of physicians and APPs. Participants were recruited on a voluntary basis only. Participants were informed that there were no associated employment consequences to choosing not to participate in the study. Participants were also informed that they might choose to decline further participation in the project.

Instruments & Measurements

The questionnaire pre-test/post-test tool created was not an established one. However, the device was specific to the target population and consistently applied to all participants regardless of role. Pre and post-test surveys mirrored one another, and each subject served as their control to minimize internal bias and increase intra-rater reliability.

Questions 1-6 of the survey are demographic and were compiled using qualitative metrics and descriptive statistics.

Questions 7-11 assessed participants' knowledge and confidence in implementing the existing AHP. Scores were calculated as either correct or incorrect.

Question 12 was an open-ended response to any barriers the participant may perceive or experience implementing the AHP during an ADR in the Infusion Suite (Appendix D).

Budget and Time

This project was managed solely by the PI and not funded by any outside sources. The PI incurred and maintained all associated costs with the production of this DNP project. The intervention timeline for completing this DNP project was six months. Staff subject participation was strictly voluntary and neither incentivized nor compensated monetarily.

Permissions

Permission to copy, disseminate, and utilize the institution's Standing Order Protocol: Order Set for Adult Chemotherapy/Biotherapy Hypersensitivity and Anaphylactic Reactions was obtained by the site's Policy Committee. Permission was also granted by the Institute for Healthcare Improvement for the PI to utilize the QI Essentials Toolkit and PDSA worksheet.

Ethical Considerations

This QI project met all the requirements of the student's academic institution and the clinical sites of implementation. The project was submitted to both Institutional Review Boards for approval before its execution. All participants were recruited voluntarily with no compensatory measure nor employer admonishment for non-participation. Participant surveys were disseminated using a de-identified link through the institution's password-protected Qualtrics platform. Patient-sensitive data and protected health information (PHI) was maintained on the PI's employer's cloud-based secure Box site. Access to all data was both password and duo-authentication protected. Data were de-identified before conducting statistical analyses utilizing SPSS software.

IRB Approval

IRB approval was obtained by both the educational and project site-specific institutions. All ethical principles for subject protection, including respect for persons, beneficence, and justice, were strictly adhered to. This DNP project was deemed dually exempt as there was no risk to subjects in this pilot QI project.

Data Collection

The data collected during this study was reviewed utilizing a mixed-methods analysis. The first analysis was an initial survey disseminated anonymously to participants to ascertain baseline knowledge regarding the Adult Hypersensitivity protocol (AHP). Demographics related to participant Infusion-related role, length of service, and ability to locate the order set within the electronic medical record (EMR) were determined. Five questions about the AHP were included

to deduce the participant's baseline level of knowledge. The final question was open-ended to allow participants to express any perceived barriers to implementing and adhering to the AHP.

A three-month retrospective and a three-month prospective EMR chart review on all patients experiencing an ADE during the pre-implementation and post-implementation phase of the study design was then conducted. The AHP is to be released by staff immediately should a patient begin to display signs and symptoms of an adverse drug event (ADE) in the Infusion Center. Clinical staff initiates this protocol by executing an order set within the EMR that automatically releases medication orders to the patient's medication administration record (MAR). The medications released and the administration sequence depend on the ADE's clinical severity. ADEs are classified as mild, moderate, and severe based on clinical symptomatology and gradation of hypersensitivity reaction according to the Common Terminology Criteria for Adverse Events (CTCAE). Both functions of the staff releasing the protocol to the patient's MAR and the sequence of medications administered during an ADE were reviewed by the PI to determine use and adherence to the AHP. The files submitted to the entity's Safety Reporting System were reviewed simultaneously to determine staff use and adherence to the AHP.

Three months following the AHP staff educational intervention, a second survey was disseminated anonymously to participants. This survey mirrored the first one sent to participants at the study's inception, except for the final question. The last question was open-ended to allow participants to express how they perceived the initiatives of this QI project and the possible relevance to their clinical practice.

Data Analysis

The demographic data of participants were analyzed utilizing descriptive statistics. The number and percent of participant roles, years employed with the Infusion Center, ACLS certification status, and the ability to locate the AHP order set in the EMR were calculated (Table 1). The baseline and post-intervention level of knowledge was determined by calculating the number of accurate responses to the five questions regarding the adult hypersensitivity protocol. The mean and standard deviation of the aggregate correct responses were then calculated (Table 2; Table 3).

The use and adherence to the AHP by staff were analyzed utilizing statistical comparisons and cross-tabulations. The number of ADEs was reviewed three months retrospectively and three months prospectively to the educational intervention regarding the AHP. The totals and percentages of the staff use and adherence to the AHP were then calculated. The Chi-square and Fisher's exact test in SPSS was conducted to determine statistical significance with a set p-value of 0.05%. Fisher's exact test was performed given the violation of assumptions of the minimum expected count of n=17.61 occurrences.

Results

Participant responses to the pre-intervention survey were reviewed for demographic data and baseline level of knowledge (Table 1; Table 2). The sample (n=18) consisted of 8 RNs (44.4%), four advanced practice providers (22.2%), and six physicians (33.4%). Most participants had 2-5 years of experience (55.6%) within the Infusion Center(s). In addition, 88.9% of participants, regardless of role, were Advanced Cardiac Life Support (ACLS) certified. Only

55.6% of participants reported receiving educational material regarding the AHP upon becoming affiliated with the Infusion Center. Eleven of the seven participants (61.11%) reported difficulty locating the AHP order set in the EMR.

The baseline level of knowledge was determined by asking participants to answer five questions regarding the AHP. Table 2 demonstrates the five knowledge-based questions asked of participants. The number and percentage of correct responses were then calculated. The aggregate median rate of accurate responses was 71.3%, with a standard deviation of 21.28%. Following the multifaceted educational intervention, participants were asked the same five knowledge-level questions in a second survey. The mean percentage of accurate responses was 79.98%, with a standard deviation of 12.88% (Table 3). Statistical analyses with the Pearson Chi-square test utilizing SPSS demonstrated a p-value of 0.091, indicating no significant increase in participant knowledge of the AHP post-intervention. The null hypothesis was, therefore, not rejected by the PI.

The open-ended question in the initial survey was one in which participants were asked to identify perceived barriers to their use and adherence to the AHP protocol. Responses encompassed two identified barriers by participants: awareness and prior education regarding the AHP and how to locate the order set within the EHR platform. Specific participant responses included “did not know it existed,” “Lack of awareness of this protocol, limited training on this subject matter,” “ difficult in finding it in the system; unable to keep it on the EMR toolbar.” and “didn’t know its location.” A few staff members requested a one-on-one session with the PI to further discuss the protocol. They also engaged the PI's assistance in populating the AHP order set as a personal orderable favorite in the EHR to facilitate accessibility.

Data were then extrapolated from the entity's EHR and the Safety Reporting System (SRS) to determine the number of ADEs that occurred and the use and adherence to the AHP by Infusion staff. A total of 24 patient charts were reviewed three months before and three months post the multidimensional educational intervention. Each patient chart reviewed represented a single ADE occurrence. Interestingly, there were 12 patient ADEs before and 12 ADEs post-intervention. Before the educational implementation, the staff utilized the AHP 50% of the time. During the three months following the performance, the AHP was used at 92%. Despite an increase in the utilization of the AHP by Infusion staff during an ADE by an absolute percent of 42%, this was not found to be statistically significant by Fisher's exact test in SPSS. Fisher's exact two-sided p-value was calculated at 0.069.

Similarly, adherence to the AHP was evaluated for pre- and post-intervention periods. Adherence to the AHP by staff before the educational intervention was calculated at a rate of 58%. Adherence post-intervention was estimated at a rate of 83%. Despite an increase in adherence by staff in the post-intervention period of 25%, this was not found to be statistically significant with a Fisher's exact 2-sided p-value of 0.371.

The post-intervention survey's final question allowed participants to express any open-ended feedback regarding the intervention, including interest, efficacy, and possible changes in clinical practice. Responses included, "it would be good to have this training on an annual basis," "excellent project," and "having an easily accessible protocol is key for reference." Similarly, multiple participants reported that the visual cues of having laminated hard copies of the AHP protocol readily available in the nurse's station, and the provider workroom proved beneficial in effectively managing an ADE in the Infusion Suite.

Discussion

Summarization of Project Aims & Results

This DNP quality improvement project examined the knowledge and clinical practice regarding using an existing Adult Hypersensitivity Protocol (AHP) in two non-hospital-based Infusion Centers affiliated with an academic quaternary hospital on the eastern seaboard. The fundamental goal was to improve adherence to the entities' established AHP. An initial survey containing knowledge-based questions regarding the AHP was disseminated to participants at the study's inception. This demonstrated a gap in the staff's awareness of and subsequent clinical practice and application of the AHP in the Infusion Centers during an ADR.

The staff's baseline knowledge regarding the AHP was averaged at 71.3%. More importantly, on average, only 55.6% of staff reported ever receiving any education regarding the existence and application of the AHP within the Infusion arena. Similarly, staff identified additional barriers to their successful implementation of the AHP in that the order set was difficult to locate within the EMR and, even when located, did not understand its application in the Infusion suite when a patient was experiencing an ADR. The result was not an anticipated one, with the overall outcome being non-significant. The null hypothesis that staff's baseline knowledge would not change following a multi-factorial educational effort concerning the AHP was accepted as the Pearson Chi-square test demonstrated a p-value of 0.091.

The staff's baseline utilization of the AHP protocol was also analyzed through an EMR chart review and the use of the entities' Safety Reporting System. The initial chart review demonstrated that staff utilized the AHP 50% of the time during an ADR. Following the

concentrated educational effort, staff implementation of the AHP increased to 92%. This was, however, interestingly found to be a non-significant finding by Fisher's exact test in SPSS. This finding will be further discussed and expounded upon in this DNP effort's interpretation and limitations sections.

In addition to utilization, staff adherence to the AHP was also examined. Initial adherence to the AHP protocol was at a rate of 58%. Following the concentrated educational effort, compliance increased to 83%. This as well, was not found to be statistically significant.

Interpretation of Results

In summation, the aims of this DNP project to improve both utilization and adherence to an existing evidence-based AHP among Infusion staff through a multi-factorial educational effort were found to be statistically non-significant. Not only was this surprising to the PI, but it was also found to be discordant with prior studies conducted on the use of clinical protocol guidelines and education to increase staff awareness and thereby improve patient care outcomes ((Boal & Corkin, 2019; Ricci-Cabello et al., 2020; Yan et al., 2019). This DNP project's overall insignificant statistical results are discordant with prior studies conducted on the use, application, and improving adherence to clinical best-practice protocols.

However, as (Makin & Orban de Xivry, 2019) report:

> "There is currently an ongoing debate about the validity of null hypothesis significance testing and the ups of significance thresholds. We agree that no single *p-value* can reveal the plausibility, presence, truth, or importance of an association or effect" (p. 10).

The PI below further discusses the violations of assumptions that primarily led to statistically insignificant results.

Limitations

This DNP QI project had many limitations and delimitations that could have affected the generalizability to other Infusion Centers. The research study design was found to have confounding variables, such as sample size, the internal and external validity of instruments utilized, and the overall interpretation of the results, including the non-significance of outcomes.

The most significant limitation was the sample population studied and its relative number. Initial Infusion staff participation revealed an N-value of 18, whereas the post-survey conducted demonstrated an attrition rate of 33.3%, with a final N-value of 12. This lack of engagement by staff could have skewed the results to represent non-significant outcomes based on participation alone. Participant data was also unpaired. Both factors inherently reduced the studies' internal and external validity and generalizability. The study also included only two of the entities' seven Infusion Centers. Should the PI have included such clinical sites, the number of participants would have increased exponentially and most likely contributed to a more statistically significant value.

Secondly, the instruments utilized were constructed based on the PI's deductions and the direct population being studied, as no previously established tools were available. This could have significantly impacted the validity and reliability of the pre-test and post-test surveys administered to participants. Also, the educational effort was unilaterally driven by the PI with no collaborative team effort to ensure the accuracy of the information disseminated and therefore has inherent bias and questionable validity.

In addition, given that only one PI performed the project's data analyses, triangulation of qualitative data to generate thematic data with more robust validity and reliability was not possible. Similarly, the PI could have also incorporated Bayesian statistics to analyze further the probability of inferences and potential statistical significance in the relationship between variables.

Lastly, the data was obtained on a limited timeline, consisting of three months pre-intervention and three months post-intervention. This did not allow sufficient time for the PI to measure additional variables that could have contributed to increased protocol adherence and patient care outcomes. It did, however, eliminated the need for interrater reliability and increased data collection consistency and validity. A three-month period is likely insufficient time to thoroughly analyze the rate of hypersensitivity reactions in the Infusion setting, along with staff use and adherence to the AHP protocol. A longer pre- and post-assessment period would be more beneficial in generating more generalizable and sustainable results.

The limitations of this DNP pilot project become future research implications.

Recommendations for Future Study and Clinical Practice

It is clear from the conclusions of this DNP project that future studies and work need to be conducted surrounding Adult Hypersensitivity Protocols in the Infusion Treatment arena, regardless of affiliation or treatment base. The PI intends to enlist the help of colleagues within this study's institution of interest to extend the educational effort and hopefully elicit further implementation of best practice managing ADRs within the Infusion Center sites. This is directly related to this current project's failure to generate a sample value that would most likely lead to statistically significant results and more generalizable conclusions.

First, future quality improvement endeavors necessitate a larger sample size (n-value). By increasing the sample size, statistical power and the chances of rejecting the null hypothesis will also increase. This project only included two of the seven Infusion Centers within the healthcare system. Had the project included all Infusion sites, the sample size would have been exponentially larger and entailed a more global assessment of the overall institution's adherence to the AHP protocol.

Secondly, to enhance applicability and sustainability, subsequent steps must be taken within the current institution to further the educational intervention platform. During the initial implementation phase, a rapid cycle PDSA analysis revealed that staff participation in the educational presentation was initially surprisingly low despite favorable attendance response rates. The PI then adjusted the educational presentation to a recorded online module that participants on their timetable could easily access. The presentation could also be accessed multiple times and downloaded as a portable document format for reference. Another suggestion for a more consistent and concrete educational platform is using an institution's Learning Management System (LMS). Creating a learning module in LMS would ensure accessibility and ease of participant use while affording aggregate data for key stakeholders and PIs.

Conclusion

While this DNP project did not generate statistically significant results, it effectively established the importance of staff education and training regarding using the AHP protocol in the Infusion Clinic setting. Infusion staff expressed global concerns about the lack of training when onboarding to the Infusion Clinic. They set the precedence that a more formalized education

platform be developed to facilitate their knowledge and enhance their clinical practice and patient care outcomes. This DNP project serves as a foundation upon which further quality improvement projects may be expanded to increase adherence to hypersensitivity protocols in the Infusion setting and enhance patient care outcomes and safety.

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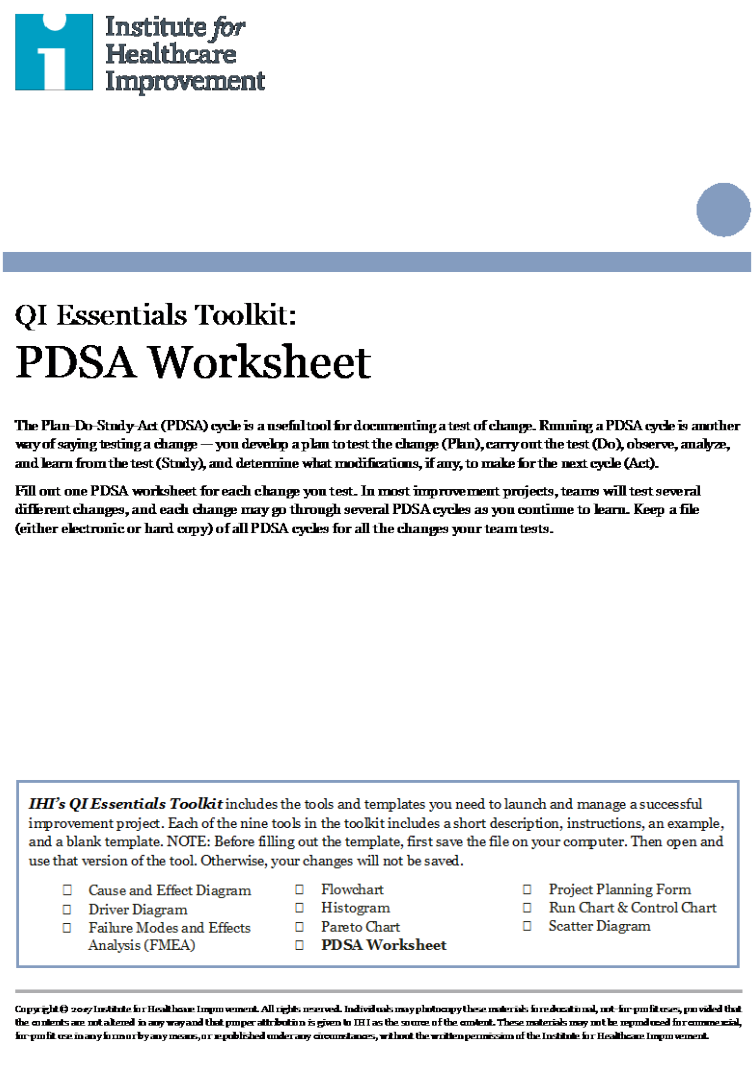
Appendix A: Plan-Do-Study-Act Template

The Institute for Healthcare Improvement granted explicit permission to PI from the online resource link via an academic (@uncg) email request.

Source: http://www.ihi.org/resources/Pages/Tools/PlanDoStudyActWorksheet.aspx



Institute for Healthcare Improvement

QI Essentials Toolkit:

PDSA Worksheet

The Plan-Do-Study-Act (PDSA) cycle is a useful tool for documenting a test of change. Running a PDSA cycle is another way of saying testing a change — you develop a plan to test the change (Plan), carry out the test (Do), observe, analyze, and learn from the test (Study), and determine what modifications, if any, to make for the next cycle (Act).

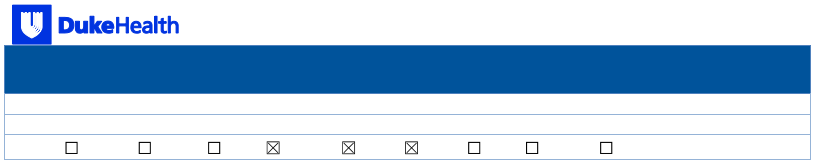
Fill out one PDSA worksheet for each change you test. In most improvement projects, teams will test several different changes, and each change may go through several PDSA cycles as you continue to learn. Keep a file (either electronic or hard copy) of all PDSA cycles for all the changes your team tests.

IHI's QI Essentials Toolkit includes the tools and templates you need to launch and manage a successful improvement project. Each of the nine tools in the toolkit includes a short description, instructions, an example, and a blank template. NOTE: Before filling out the template, first save the file on your computer. Then open and use that version of the tool. Otherwise, your changes will not be saved.

- ☐ Cause and Effect Diagram
- ☐ Driver Diagram
- ☐ Failure Modes and Effects Analysis (FMEA)
- ☐ Flowchart
- ☐ Histogram
- ☐ Pareto Chart
- ☐ **PDSA Worksheet**
- ☐ Project Planning Form
- ☐ Run Chart & Control Chart
- ☐ Scatter Diagram

Appendix B: Standing Order/Protocol: DUHS Order Set for Adult Chemotherapy/Biotherapy Hypersensitivity and Anaphylactic Reactions

PI obtained explicit permission from the affiliated Health System Policy Center to replicate and distribute the AHS Protocol.



1.
2.
3.

4.
5.

6.
7.

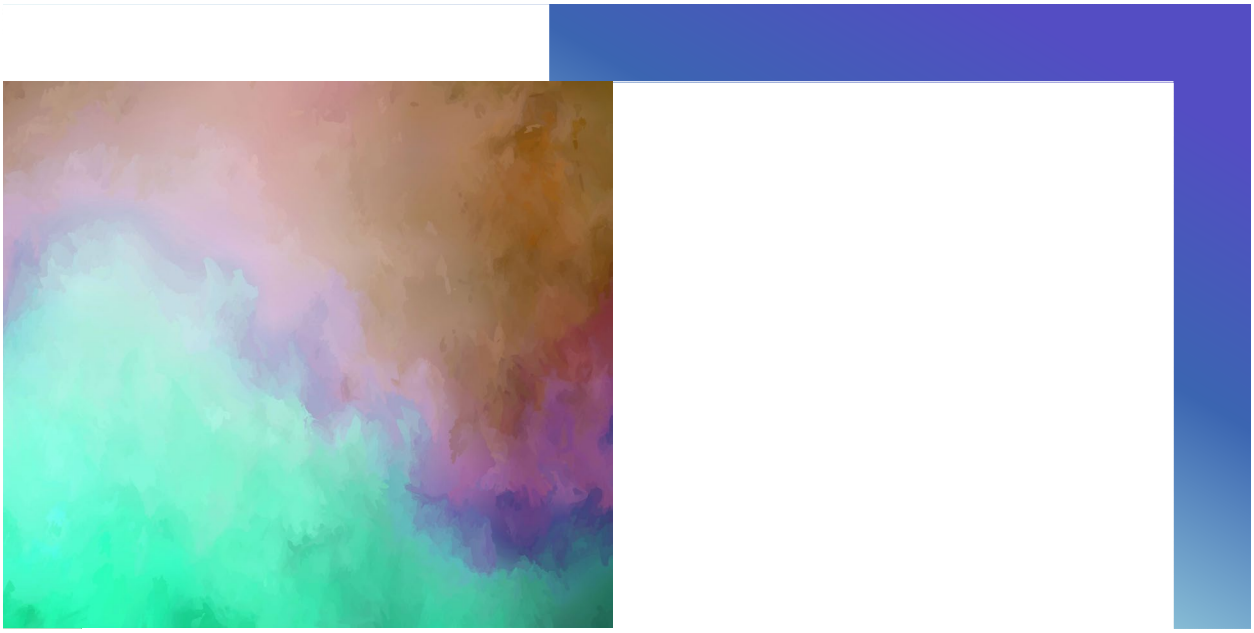
1.
2.
3.

4. Give epinephrine 0.3mg IM (preferred) or SQ x 1 (may repeat x 1 in 5 minutes)†† (If given IM, then the

5.
6.

7. standby should patient's respiratory status
8.
9.

Appendix C: PowerPoint™ presentation to participants



Appendix D:

Qualtrics Survey Pre-Post-Test Participant Questionnaire

I AM A:

- MD
- APP
- RN

I HAVE BEEN ASSOCIATED WITH THE INFUSION CENTER FOR:

- less than one year
- 1-4 years
- more than 5 years

I AM ACLS CERTIFIED:

- True
- False

UPON BECOMING ASSOCIATED WITH THE INFUSION CENTER, I WAS GIVEN EDUCATION AND MATERIAL REGARDING THE INSTITUTION'S ADULT HYPERSENSITIVITY PROTOCOL.

- True
- False

I AM COMFORTABLE MANAGING ADVERSE DRUG REACTIONS IN THE INFUSION CENTER

- Strongly Agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

I KNOW HOW TO EASILY FIND THE ADULT HYPERSENSITIVITY PROTOCOL IN EPIC:

- True
- False

NURSING MAY ADJUST MEDICATION DOSES IN THE ADULT HYPERSENSITIVITY PROTOCOL BASED ON THE SEVERITY OF THE ADVERSE DRUG REACTION:

- True
- False

FOLLOWING A GRADE II REACTION, PATIENTS SHOULD NOT BE RE-CHALLENGED SAME DAY:

- True
- False

IN ORDER TO PREVENT SECONDARY, DELAYED HYPERSENSITIVITY REACTIONS, IT IS BEST PRACTICE TO ADMINISTER METHYLPREDNISOLONE FOLLOWING ANY TYPE OF ADVERSE DRUG EVENT:

- True
- False

IF A PATIENT NECESSITATES EPINEPHRINE DURING AN ADVERSE REACTION THAT IS GRADE 3 OR LESS, IT IS BEST PRACTICE TO NOT RESUME TREATMENT THE SAME DAY:

- True
- False

SHOULD THE CARE TEAM DECIDE TO RESUME TREATMENT FOLLOWING AN ADVERSE REACTION, IT IS WITHIN THE SCOPE OF PRACTICE FOR NURSING TO DETERMINE AT WHAT RATE OF MEDICATION ADMINISTRATION TO RE-CHALLENGE THE PATIENT:

- True
- False

PLEASE DESCRIBE ANY BARRIERS THAT HAVE CONTRIBUTED TO POSSIBLE DECREASED COMPLIANCE TO THE IMPLEMENTATION OF THE INSTITUTION'S ADULT HYPERSENSITIVITY PROTOCOL IN THE INFUSION CENTER:

Appendix E:

Participant Demographic Results (N=18)

TABLE 1

Variable	n (%)
Provider type	
Nurse (RN)	8 (44.4)
Advanced Practice Provider (APP)	4 (22.2)
Physician (MD)	6 (33.4)
Years associated with Infusion Center	
< 2 years	4 (22.2)
2-5 years	10 (55.6)
5 or more years	4 (22.2)
ACLS certified	
True	16 (88.9)
False	2 (11.1)
Previously given education/material regarding AHP	
True	10 (55.6)
False	8 (44.4)
Able to easily locate the AHP in EPIC/Orders	
True	7 (38.89)
False	11 (61.11)

Appendix F: Participant Pre- Intervention Level of Knowledge Survey Results

TABLE 2

Question	n (%) With Correct Response
1. Nursing may adjust medication doses in the Adult Hypersensitivity Protocol based on the severity of the adverse drug reaction	10 (58.8)
2. Following a Grade II reaction, patient should not be re-challenged the same day	16 (100.0%)
3. To prevent secondary, delayed hypersensitivity reactions, it is best practice to administer high dose (125 mg) IV methylprednisolone following any gradation of adverse drug event	10 (58.8)
4. If a patient necessitates epinephrine during an adverse drug reaction that is Grade III of less, it is best practice not to resume treatment same day	9 (50.0)
5. Should the care team decide to resume treatment following an adverse reaction, it is within the scope of practice for nursing to determine at what rate of medication administration to re-challenge	16 (88.9)
	Average percent of correct response
	71.3%
	Standard deviation
	+/- of 21.28%

Appendix G: Participant Post- Intervention Level of Knowledge Survey Results

TABLE 3

Question	n (%) With Correct Response
1. Nursing may adjust medication doses in the Adult Hypersensitivity Protocol based on the severity of the adverse drug reaction	8 (61.5)
2. Following a Grade II reaction, patient should not be re-challenged the same day	12 (92.3)
3. To prevent secondary, delayed hypersensitivity reactions, it is best practice to administer high dose (125 mg) IV methylprednisolone following any gradation of adverse drug event	10 (76.9)
4. If a patient necessitates epinephrine during an adverse drug reaction that is Grade III of less, it is best practice not to resume treatment same day	10 (76.9)
5. Should the care team decide to resume treatment following an adverse reaction, it is within the scope of practice for nursing to determine at what rate of medication administration to re-challenge	12 (92.3)
	Average percent of correct response
	79.98%
	Standard deviation
	+/- 12.88%

Appendix H: Summary of Data Analysis

TABLE 4

KNOWLEDGE

Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Outcome * Intervention	155	100.0%	0	0.0%	155	100.0%

Outcome * Intervention Crosstabulation

Count

		Intervention		
		1_Pre	2_Post	Total
Outcome	Correct	61	52	113
	Incorrect	29	13	42
Total		90	65	155

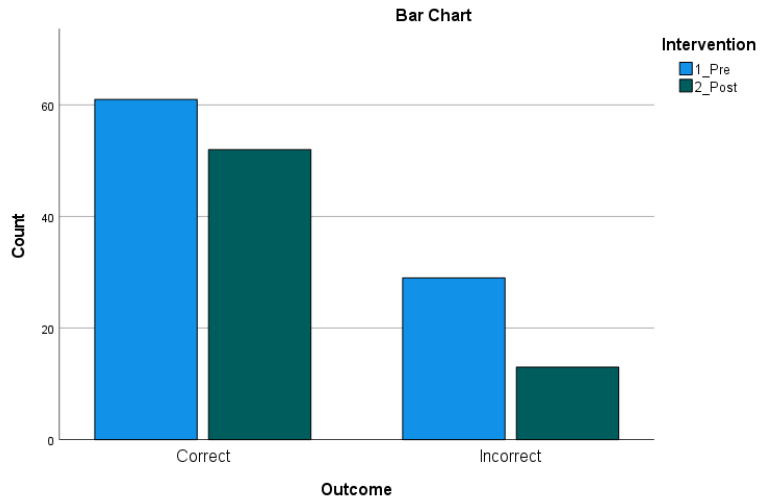
Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	2.854[a]	1	.091		

Continuity Correction[b]	2.269	1	.132		
Likelihood Ratio	2.920	1	.088		
Fisher's Exact Test				.102	.065
N of Valid Cases	155				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 17.61.

b. Computed only for a 2x2 table



AHP UTILIZATION

Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
AHP_utilized * Intervention_1	24	100.0%	0	0.0%	24	100.0%

AHP_utilized * Intervention_1 Crosstabulation

Count

		Intervention_1		
		1_Pre	2_Post	Total
AHP_utilized	No	6	1	7
	Yes	6	11	17
Total		12	12	24

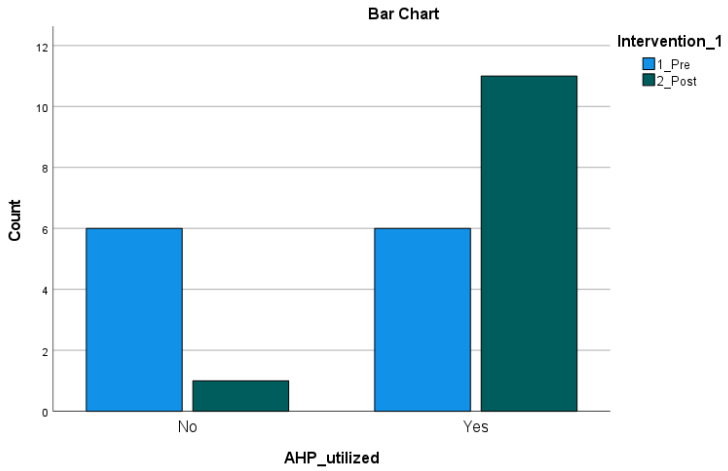
Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	5.042[a]	1	.025		
Continuity Correction[b]	3.227	1	.072		
Likelihood Ratio	5.455	1	.020		

Fisher's Exact Test				.069	.034
N of Valid Cases	24				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 3.50.

b. Computed only for a 2x2 table



AHP ADHERENCE

Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
AHP_adhered * Intervention_2	24	100.0%	0	0.0%	24	100.0%

AHP_adhered * Intervention_2 Crosstabulation

Count

		Intervention_2		
		1_Pre	2_Post	Total
AHP_adhered	No	5	2	7
	Yes	7	10	17
Total		12	12	24

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.815[a]	1	.178		
Continuity Correction[b]	.807	1	.369		

Likelihood Ratio	1.860	1	.173		
Fisher's Exact Test				.371	.185
N of Valid Cases	24				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 3.50.

b. Computed only for a 2x2 table