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Inferior Vena Cava Filters: Aligning Practice with Evidence to Improve Patient Outcomes

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Inferior Vena Cava Filters: Aligning Practice with Evidence to Improve Patient Outcomes

A dissertation in partial satisfaction of the

requirements for the degree Doctor of Nursing Practice

by

Ana Luisa Barajas

2021

ABSTRACT OF THE DISSERTATION

Inferior Vena Cava Filters: Aligning Practice with Evidence

to Improve Patient Outcomes

by

Ana Luisa Barajas

Doctor of Nursing Practice

University of California, Los Angeles, 2021

Professor Wendie A. Robbins, Chair

Background: Retrievable inferior vena cava (IVC) filters were developed for the transient prevention of pulmonary embolisms. Despite indications for removal, many filters are unintentionally left in place indefinitely. Adverse events associated with chronic indwelling retrievable filters have generated increased interest in improving their retrieval rates.

Objective: This DNP scholarly project aimed to determine if a collaborative IVC filter retrieval protocol developed by the researcher and adopted by the Interventional Radiology (IR) clinical team, increased filter retrieval rates and decreased loss to follow-up of patients who had undergone temporary IVC filter placement.

Methods: Seven-step IVC filter retrieval protocol was created and implemented. Following a quasi-experimental comparative design the pilot-study prospectively included all consecutive adult patients who underwent insertion of a retrievable IVC filter for a period of four months.

Data collected included patient demographics, filter outcomes, and documented follow-up. Same data variables were collected using a retrospective review of similar patients who had undergone retrievable IVC filters placement 24-months prior to initiation of the new protocol. Chi-square statistical analysis was performed for all variables.

Results: Total of 101 IVC filters (97 retrievable, 4 permanent) were inserted during the 28-month pilot-study period. Of the 97 retrieval filters placed (85 retrospective, 12 prospective), the retrieval rates of eligible filters increased from 64.15% to 100% and patients lost to follow-up decreased from 35.85% to 0% following implementation of the new protocol (p= 0.3, both outcomes). However, there was a statistically significant positive correlation between IVC filter conversion to permanent status and malignancy ($r(26) = 0.32$; $p < 0.01$). As a consequence, this led to an increase in the number of permanent IVC filters placed in the prospective cohort (1.2% vs. 20%; $p < 0.01$).

Conclusion: Although not statistically significant, adoption of a collaborative IR led process for the management of IVC filters led to improved IVC filter retrieval rates and decreased patient loss to follow-up. Additionally, pre-insertion discussion of type of filter needed, as outlined in the new protocol, helped identify the right filter for the right patient, demonstrating a statically significant change in practice that ultimately transformed the IR department's common practice into best practice.

The dissertation of Ana Luisa Barajas is approved.

Nancy Jo Bush

Mary Cadogan

Janet C. Mentes

Wendie A. Robbins, Committee Chair

University of California, Los Angeles

2021

Dedication

In memory of my grandparents, who helped raise me and filled my world with love, teaching me to be proud of my Mexican heritage and embracing the struggle so that I may appreciate the triumphs.

In memory of my nursing school friend and one of my biggest cheerleaders, Laura E. Chavez, a dedicated intensive care unit nurse who took care of COVID-19 patients at the start of the outbreak and paid the ultimate price. We started this nursing path together and I was expecting to share this accomplishment with you here. I will continue to carry our message of hope and healing to all those I care for.

For my parents, Jose and Maria Barajas, who raised me to be strong and provided me a solid and strong foundation of family and faith, allowing me to find my own path. Thank you for sacrificing so much for our family.

For my nephews and nieces Jose, Adelina, Mateo, Mariana, Felipe, Gerardo, Elina, Esteban and Timothy, you are my heart and happiness and I hope to inspire you all to pursue your goals and dreams.

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List of Frequently Used Acronyms

Name	Acronym
Anticoagulation	AC
Deep Vein Thrombosis	DVT
Doctor of Nursing Practice	DNP
Electronic Health Record	EHR
Evidence-based Practice	EBP
Food and Drug Administration	FDA
Interventional Radiology	IR
Inferior Vena Cava	IVC
Nurse Practitioner	NP
Picture Archiving and Communication System	PACS
Plan, Do, Study, Act cycle	PDSA
Pulmonary Embolism	PE
Quality Improvement	QI
Registered Nurse	RN
Return of Investments	ROI
Society of Interventional Radiology	SIR
Table of Evidence	TOE
Venous Thromboembolism	VTE

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Lastly, I want to thank my interventional radiology team at Keck Hospital of USC, who were supportive and accommodated my school schedule, provided me with great feedback, and enthusiastically participated, leading to the successful implementation of the scholarly project.

VITA

Ana Luisa Barajas

DNPc, RN, ACNP-BC

Ana Barajas is a board-certified acute care nurse practitioner and clinical nurse specialist who specialized in the care of interventional radiology patients, earning both her Bachelor's and Master's degree in the Science of Nursing from the University of California, Los Angeles (UCLA) in 2003 and 2005. She is also set to complete her Doctor of Nursing Practice (DNP) in June of 2021 from UCLA, her scholarly project focused on improving the management of patients who undergo the placement of a retrievable IVC filter under the care of the interventional radiology (IR) service.

Ana Barajas has prior experience as an intensive care unit nurse at LAC-USC Medical Center before becoming a nurse practitioner. As a new nurse practitioner graduate, she was hired at Olive View Medical Center in Sylmar, California, a 370-bed county hospital by the department of internal medicine, diagnosing, and treating adult patient admitted to the hospital for the management of acute medical conditions. In 2007 she helped launch the hospital's first hospitalist service. She divided her time between medicine and radiology. While working under the interventional radiology (IR) service, most of her duties involved providing IR consultation and assisting in IR procedures. She has specialized in the management of IR patients helping to establish a new IR clinic and grew the consultation aspect of the service.

Ana Barajas is currently a faculty member at the University of Southern California (USC) as a clinical instructor of radiology. Working out of both the Keck Medical Center and Norris Cancer Center, she assists her fellow physicians in the direct care of patients undergoing image guided procedures. Again, as the only nurse practitioner for the radiology department she is helping to pave the way for other nurse practitioners to join this specialty.

Ana Barajas has received several awards including being honored on three separate occasions (2014, 2015, & 2017) as Nurse Practitioner of the Year at Olive View Medical Center. In 2014 she received a Certificate of Recognition from the Los Angeles County Department of Health Services.

Chapter One

Introduction

Venous thromboembolism **(**VTE), defined as a deep vein thrombosis (DVT) or a pulmonary embolism (PE), is a potentially deadly diagnosis affecting every 1 to 2 per 1,000 Americans annually (Beckman et al., 2010), and is the third leading vascular diagnosis after heart attack and stroke (American Heart Association [AHA], 2017). Pulmonary embolism is often the primary cause of mortality associated with a DVT and is the leading cause of preventable hospital deaths in the United States, with an estimated incidence of more than 200,000 deaths per year (Guez et al. 2018). Anticoagulation (AC) is the preferred first line treatment of VTE, but in certain cases the use of AC is contraindicated or fails to protect the patient from a PE (Buso et al., 2020; Guez et al., 2018; Klinken et al., 2017). In these cases, it is common practice for patients to undergo percutaneous insertion of an inferior vena cava (IVC) filter for mechanical prevention of a PE.

Types of IVC Filters

There are two categories of IVC filters, permanent or temporary/retrievable, both have been developed in an attempt to reduce the sequela of a PE. An IVC filter that can later be retrieved versus a permanent one is typically placed in patients who require temporary prophylactic PE prevention or are deemed to have short-term contraindications to AC (Salei et al., 2020). Retrievable IVC filters are designed differently than permanent filters and because of that, have been associated with a higher incidence of adverse outcomes with prolonged dwell times. Andreoli et al. (2014) compared the two types of filters and found that chronic indwelling retrievable IVC filters had an adverse outcome rate of 86.8% versus permanent filters at 13.2%. Common adverse events related to prolonged filter dwell times include caval perforation,

iliocaval thrombosis, organ penetration, migration, and fracture of filter strut (Dowell et al., 2017; Salei et al., 2020). Moreover, the longer the retrievable filter remains in place, the more difficult and less likely its successful retrieval will be without advanced techniques (Desai et al., 2017). In response to over 900 reported adverse events, the Food and Drug Administration (FDA) released a formal safety alert in 2010 followed by an amendment in 2014, stating that once the threat of a PE had resolved, the risk of having a filter in place outweighed its benefit. The FDA recommended that implanting physicians follow patients with retrievable IVC filters and remove the filter ideally within 29 to 54 days after its insertion if the risk of having a PE had passed.

Significance of Problem

Despite the FDA's recommendation, Dowell et al. (2017) found a great variance in institutions' IVC filter retrieval rates. In current practice the process of retrieving temporary IVC filters remains a referring physician-led process and retrieval rates remain suboptimal, with studies reporting baseline rates ranging from 7% to 53% (Klinken et al., 2017; Salei et al., 2020). Several barriers to retrieving IVC filters at the patient, provider, and institutional level are noted in the literature (Buso et al., 2020; Klinken et al., 2017; Salei et al., 2020). Desai et al. (2016) found that a lack of structure and the traditional referring physician-led process of having filters retrieved rarely led to the timely removal of the device. In healthcare, new information or an awareness of a gap in care can trigger an opportunity for change. The repeated FDA advisory statements have compelled many services implanting IVC filters to switch the paradigm of care and develop their own formal filter retrieval process in order to improve patient safety outcomes. Indications for IVC filter dwell times vary from weeks to months with the majority of filters placed during patients' acute hospitalization. The challenges health systems face in managing

these filters stem from the complexity of patients transitioning to the outpatient setting with a filter in situ. This gap in continuity of care emphasizes the importance of interprofessional collaboration among providers who are requesting the filter placement, providers who place the devices, and the outpatient providers who have to manage them. There are recent studies reporting that in centers where low retrieval rates were once noted, adoption of an IVC filter retrieval process, especially those that incorporate a collaborative effort, have led to an increase in retrieval rates, with studies reporting rates as high as 54% to 81% (Rottenstreich et al., 2017; Klinken et al., 2017; Lynch, 2011).

Ethical Implications

Patients believe that healthcare providers have their best interest in mind, thus they entrust them with their bodies. This trust necessitates that providers practice at a high ethical standard of care. A proper consent that includes full disclosure of potential risks associated with IVC filters ensures that the patient is making a true autonomous decision about the procedure. It is not enough to only discuss the indications, risks and benefits of the procedure itself. It is the duty of the implanting services to ensure that patients are made aware of the temporary intention of the retrievable filter and the need for follow-up. Populations at high risk of misinformation or not understanding the full implications of undergoing such a procedure such as the elderly, those with disabilities or those that do not speak or understand English require additional support and attention. Understanding that prolonged filter dwell times can lead to increased adverse events can help patients understand the importance of follow-up and provides them with the information needed to be advocates in their own care. This understanding also obligates providers to take measures to improve the system in order to reduce adverse outcomes and comply with ethical principles of beneficence and nonmaleficence. There is an opportunity for a Doctor of Nursing

Practice (DNP) prepared nurse, in this setting, to align the practice with evidence and be a true advocate for their patients, in order to improve the health outcomes of patients undergoing IVC filter placement.

PICOT Question

In patients who have undergone temporary inferior vena cava filter placement, does an interventional radiology led IVC filter retrieval protocol, compared to standard care with no protocol, result in less patients lost to follow-up, and improved filter retrieval rates in four months' time?

Purpose and Objectives

The purpose of this DNP scholarly project was to utilize scientific underpinnings to translate evidenced-based knowledge into clinical practice in an effort to align common practice with best practice. Thereby providing quality of care to a highly specialized targeted population of patients under the care of interventional radiology (IR). The aims were to determine if a collaborative IR led IVC filter retrieval protocol, compared to standard care, decreases loss to follow-up and increases filter retrieval rates in patients who have undergone temporary IVC filter placement under the IR service. Guided by the right theoretical model, and through authentic leadership a project such as this can achieve its goals. The success of the project will help determine if adoption of the systems change is feasible for the institution.

Doctor of Nursing Practice Essentials

The scholarly project largely addresses DNP Essential I: *Scientific Underpinning for Practice* and Essential II: *Organizational and Systems Leadership for Quality Improvement and Systems Thinking* (American Association of Colleges of Nursing [AACN], 2006). It utilizes Essential I which demonstrates how the DNP can translate evidence from the sciences into practice that will benefit patients. The Essential II concepts were used to successfully facilitate a

system change in order to improve patient and healthcare outcomes. As stated by the AACN (2006), successful implementation and sustainability of a change in practice requires a change in organizational arrangements, professional culture and financial stability. This task highlights the importance of leadership skills to mobilize a team and guide the practice change. Here the DNP prepared nurse is in an optimal position to use collaboration, communication and authentic leadership skills to be a bridge among providers as the patient transitions through the systems' different levels of care. Translating evidence-based knowledge into the clinical setting through a change in the system will not only make the change sustainable and improve patient outcomes but it is the fundamental intention of the DNP role.

CHAPTER TWO

Theoretical Framework

The FDA's recommendations as well as recent literature regarding IVC filter management has brought to light a significant clinical problem and has created an opportunity to implement a change in practice. The Iowa Model Revised (see Appendix A) is a process model that can be used to guide clinicians from a knowledge-based or problem-based trigger to a sustainable evidence-based practice (EBP) solution in order to improve patient outcomes (Buckwalter et al., 2017). It was developed at the University of Iowa Hospitals and Clinic in the 1990s and was most recently revised in 2015. The Iowa Model Revised has been successfully utilized and adopted in the health care setting (Buckwalter et al., 2017; Hanrahan et al., 2019; White & Spruce, 2015). It is an application-oriented guide through the EBP process. It guides clinicians who question the current practice and seek an EBP solution. Steps in the Iowa Model include identifying the opportunity, stating the question, forming a team, synthesizing the evidence, designing and piloting the change, implementation of the change if appropriate, and dissemination of findings.

The Iowa Model takes a problem-solving approach, which starts with a trigger (the FDA safety alert), followed by identification of the problem (patients with temporary IVC filters lost to follow-up and low retrieval rates), then forming of the research pilot-study question (will a dedicated radiology-led filter retrieval protocol improve patient quality outcomes?). The identified problem was determined to be a priority for the IR department in a tertiary academic medical health center, and a team made up of IR staff and faculty was assembled. The PICOT question was formed to help guide an appropriate literature search. Synthesis of the literature provided the underpinnings for the interventions applied in the project design. The

implementation of the change was a radiology-led team driven effort. Staff feedback was instrumental and led to modifications of the proposed change in order to ensure the development of an appropriate and feasible workflow. A systematic approach guided by an EBP model is critical to the success and sustainability of the change.

CHAPTER THREE

Review of Literature

Evidence Search

Databases used for literature review included MEDLINE through PubMed, CINAHL, Embase and Cochrane Library. To capture sentinel studies published after the first FDA recommendation the literature search was extended to 2010. Once key initial studies were identified, the search was limited to studies published within the last five years. The process was guided by the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines (see Appendix B). MeSH terms and keywords were based on the PICO question in order to find articles that compared the impact of IVC filter retrieval interventions versus historical referring physician-led processes on filter retrieval rates. Primary MeSH subject headings and Boolean operators included: *inferior vena cava filters* AND *retrieval rates* (AND *radiology* AND *interventions* AND *lost to follow-up)*. Titles were screened, duplicates, commentaries and editorials were removed. Abstracts were screened and the studies selected for full-text review were deemed to have relevance to the systematic review. The final eight studies selected were all peer reviewed studies that recognized the gap in care related to IVC filter management, implemented and tested an intervention using filter retrieval rates as a primary or secondary outcome. Study details are presented in the Table of Evidence (see Appendix C) and includes a summary of study's purpose, sample, setting, methods explaining the intervention, study results specifically the IVC filter retrieval rates and interpretation of findings.

Literature Review

A sentinel study by Lynch (2011), was a pre-post design, performed at a single institution that enrolled 1,127 participants. The study aimed to determine the impact of a formal IR filter

retrieval process on retrieval rates. The intervention included a single IR physician assuming the responsibility for follow-up of the IVC filters inserted under his service. He created a tracking database of patients who had undergone filter placement and based on periodic chart review he contacted, by mail, the patients deemed to be eligible for filter retrieval and their providers. The study demonstrated statistically significant improvement in the probability of patients returning for filter retrieval compared to no formal follow-up process (59% vs. 24%, $p < .001$), with loss to follow-up decreasing from 76% to 16.2%. The researcher then applied the intervention to the pre-intervention group, increasing their baseline retrieval rate of 24 % to 54%, and loss to follow-up decreased to 18.2%. This was the first study implemented that demonstrated a shift in paradigm from referring physician to the implanting physician. Additionally, a new line of communication was created not just between physician-to-physician, but also between implanting physician-to-patient, which was not previously seen in this setting. Subsequent published studies continued to follow this new paradigm of care.

A more recent study from Inagaki et al. (2016) aimed to create a sustainable protocol that would improve the retrieval rate of eligible IVC filters. This study had a pre-post design, conducted at a single institution that enrolled 1,275 participants, data covered an 11-year period. They implemented an interprofessional collaborative intervention created by a multidisciplinary task force of physicians from IR, hematology, cardiology, trauma and vascular surgery. Through this task force an institutional IVC filter protocol for the management of filters was developed and implemented. The protocol included four key elements (1) a patient education pamphlet that was reviewed with patient/family prior to filter insertion (2) an additional procedure form filled out by the IR physician documenting filter indication and estimated duration of filter, (3) an interdepartmental IVC filter registry, and (4) a dedicated nurse coordinator. Analysis of data

demonstrated that IVC filter retrieval rate was statistically significant with pre-intervention removal rates at 11% vs. post-intervention 54% ($p < .001$). Findings demonstrated that a comprehensive team intervention can improve positive patient outcomes.

In an attempt to implement a sustainable process, Sutphin et al. (2015), designed an intervention using the Define, Measure, Analyze, Improve, Control (DMAIC) methodology of the Six Sigma process improvement paradigm for their IVC filter quality improvement (QI) initiative. The study used two separate intervention strategies with a pre-post design. The aim was to increase the retrieval rates of IVC filters in eligible patients in one years' time. It incorporated an interprofessional team that included the IR service along with a nurse coordinator, physician assistant, QI facilitator, pulmonologist and hematologist. Over a period of two years, patients identified through the electronic health record (EHR), who had undergone placement of an IVC filter were separated into three groups based on timing of filter placement. The *base group* was designated as the first eight months and was used to determine baseline retrieval rates. The following eight months made up the *letter* cohort, these patients along with providers were retrospectively contacted by letters to schedule a clinic visit. The last eight months made up the *prospective* cohort, these patients were automatically scheduled for an IR clinic follow-up at time of filter insertion. The researchers found that retrieval rates in the letter group increased from a baseline of 8% to 40% ($p = .03$) and up to 52% ($p=.007$) in the automatically scheduled follow-up group. They concluded that the increased number of IVC filters retrieved was directly associated with the number of patients seen in the clinic. This study also demonstrated a secondary gain, as the increased number of clinic visits led to increased revenue due to reimbursement for the visits as well as the additional filter retrieval procedures.

The Dowell et al. (2017) study further aimed to demonstrate a cost-benefit analysis of establishing a dedicated IVC filter clinic to improve patient care. This study used a pre-post study design and enrolled all consecutive patients over an 18-month period at a tertiary academic medical center. A formal IR clinic was established, along with a comprehensive patient database. During the ten-month period of clinic visits, referring physicians were contacted to facilitate retrieval. Communication was performed via messaging in the EHR or phone calls, starting at four weeks after IVC filter was placed and every four weeks after, until the filter was removed, or decision was made to make it permanent. This was compared to a retrospective review of an eight months pre-IVC filter intervention clinic period. A cost analysis model was created to calculate the average cost and reimbursement of each IVC filter placed and retrieved. This model took the weighted average costs from six major third party payers, subtracting reimbursements from the average costs. It included professional and technical components which were obtained by the institution's financial services and based on Current Procedural Terminology (CPT) codes. The researchers found that IVC filter retrieval rates increased from a baseline of 8.4% to 29% ($p < .0001$). Pre-intervention group was then contacted, and an additional 19.3% filters were removed. The cost-benefit analysis revealed that there was an average net financial loss for temporary IVC filters not retrieved and a net financial gain for each temporary IVC filter that was retrieved. Additionally, they were able to offset the cost of maintaining the filter clinic by removing an additional 3.1 filters per year.

In the Klinken et al. (2017) study, authors aimed to evaluate and implement an intervention to address the number of filter patients lost to follow-up as well as retrieval rates. The study used a pre-post study design and data was collected over a five-year period. They enrolled a total of 254 participants that did not differ in basic demographics and clinical history

($p > .05$), although the post-intervention group had a statistically larger number of prophylactic filters inserted (8.1% vs. 17.8%, $p = 0.02$). The intervention involved multiple IR physicians and a resident medical officer. Review of the pre-intervention group's indication for IVC filter removal was a consensus decision made by the IR team and then collaboratively discussed with the patients referring provider. In the intervention group the retrieval decision was first made after 90-day post filter placement. If there was no documented decision, an alert message would be displayed each time the database was accessed and would continue every three months until final filter status was determined. They found that the number of attempted IVC filter retrievals improved to 72.9% from 52.9% ($p = .001$). More importantly the number of patients lost to follow-up was significantly reduced from 23% to 0% ($p < .001$).

Salei et al. (2020) was an 18-month pre-post comparative study that enrolled 182 participants, both groups of participants were identified through the EHR. The study aimed to demonstrate that an IVC filter retrieval program would improve both the number of IVC filters retrieved as well as decrease the number of patients lost to follow-up. The study's intervention was designed by an IR physician and involved developing a tracking database, scheduling the patients for a retrieval consult, with a physician assistant to review indications for filter removal. The study's findings supported the effectiveness of an IR-driven clinic-based filter retrieval program which not only improved filter rates from 6.6% to 28.3% but also the number of patients lost to follow-up decreased from 55.3% to 16% ($p < .001$ for both findings).

Rottenstreich et al. (2017) set out to evaluate the impact of an institutional IVC filter protocol on patterns of filter use. Study was a pre-post design. They enrolled 493 participants covering five years pre-intervention compare to one-year post-intervention. A multidisciplinary protocol was developed by the IR and hematology services. Protocol included dedicated follow-

up of patients with temporary IVC filters and a physician education program regarding utilization of IVC filters. A dedicated hematologist was tasked with updating the database. At discharge each patient was scheduled for hematology clinic follow-up and filter status evaluation. These efforts were supplemented with a series of in-hospital lectures for referring services at the medical center. The American College of Chest Physicians (ACCP) and American Society of Hematology (ASH) were the recommended indications guidelines used. The study demonstrated a pre-intervention retrieval rate of 16.7% vs. 60.5% post-intervention, and patients lost to follow-up decreased from a pre-intervention 77.1% to post-intervention 0% ($p < .001$ for both findings).

Wang et al. (2016) also aimed to demonstrate the impact of adding a component of physician education regarding current evidence on IVC filter use, and the effect it would have on IVC filter retrieval rates. This study was multicentered, performed at a Kaiser Permanente Northern California regional level which included 14 urban centers, it included community hospitals and large tertiary centers (serving 3.5 million members). The study used a pre-post design and enrolled 520 participants who had undergone IVC filter placement through their electronic database over a period of two years. Permanent IVC filters and patients who expired after 12 weeks of filter placement were excluded from study. A series of IVC filter grand rounds were held at all participating facilities. Researchers found that the rate of filter retrieval increased from pre-intervention group of 38.9% to 54% post-intervention ($p = .0006$). The study revealed that there was a statically significant correlation between an increase in the number of IVC filter retrieval attempts and physician grand rounds participation ($r = 0.51$, $p = .051$). There was also a correlation between ground round participation and a reduction in filters inserted at each facility

22% (r = -0.69, p = .007). Thus, demonstrating that physician education dramatically impacted the utilization of IVC filters.

Synthesis of the Evidence

Eight articles were identified for this review. Studies were similar in that they used a quasi-experimental comparison design and were Evidence Level II (*Libguides: Evidence Based Practice Toolkit for Nursing: Levels of Evidence*, 2020). Among the various interventions examined in the studies, there were overarching themes (a) patient tracking system/database, (b) an engaged/dedicated team following the patient, (c) interprofessional collaboration (d) a mechanism of triggering filter status evaluation, and (e) a multidisciplinary approach.

Every study reviewed established that *patient loss to follow-up* was consistently the underlying cause of poor retrieval rates. Therefore, a fundamental intervention to decrease this gap in care was the development of a patient tracking system, either through a shared database or patient registry which was implemented in every study reviewed. Three studies, Klinken et al. (2017), Rottenstreich et al. (2017) and Wang et al. (2016) were able to achieve 100% follow-up of their post intervention prospective group.

The shift of the IVC filter management paradigm to the implanting provider was evident in all the studies reviewed. Every implanting service took it upon themselves to follow the patient and create a retrieval process. Some studies focused solely on patients for their interventions (Inagaki et al., 2016; Lynch, 2011), by sending letters and making phone calls to patients eligible for filter retrieval, many others took a more comprehensive approach and included interventions targeting providers and institutional systems (Dowell et al., 2017; Klinken et al., 2017; Rottenstreich et al., 2017; Salei et al., 2019; Stuphin et al., 2015; Wang et al., 2016). These system changes included creating new dedicated clinics, initiating automatic scheduling of

patients for follow-up, electronic alerts/reminders, standardized provider documentation in the EHR, protocols defining new workflows, and provider education on IVC filter management.

Researchers found that an interprofessional collaborative decision that involved the referring physician helped determine filter outcomes. The collaboration with referring providers was key in every study, as removal of the filter was always pre-discussed between the providers. These discussions were prompted by an alert mechanism. A method of bringing attention to the filter patient varied, some studies established new clinics, which significantly improved baseline retrieval rates, from 8.4% to 28.9% (Dowell et al., 2017) and from 6.6% to 28.3% (Salei et al., 2020), and although they did require additional institutional resources, Sutphin et al. (2015) and Dowell et al. (2017) were able to demonstrate an overall financial gain to the institution. Klinken et al. (2017) and Wang et al. (2016) used the EHR to send out automatic computer alerts to notify the implanting provider when to reach out to referring providers and have a filter discussion. Dedicated IVC filter clinics and the automated computer alerts were a way of dedicating time to reevaluate patients' indications for continued filter need and provided patients with a safety net to prevent loss to follow-up.

A multidisciplinary approach to finding solutions led to more comprehensive retrieval processes. Interventions that incorporated a multidisciplinary collaboration with services such as hematology, surgery, internal medicine and IR, such as those demonstrated by Inagaki et al. (2016) and Klinken et al. (2017), yielded some of the highest retrieval rates at 66% and 73% respectively. Aside from implementing an institutional multidisciplinary protocol, both Rottenstreich et al. (2017) and Wang et al. (2016) also conducted a physician education program, each study demonstrating increased filter retrieval rates.

Taken together, the literature review demonstrated that a structured process helped improve patient loss to follow-up and filter retrieval rates. There were study limitations that are important to identify and discuss, so that gaps in literature can be acknowledged. The studies were all quasi-experimental comparing a pre- and post-intervention process, with the inherent biases and confounding variables of a retrospective review which relies on the accuracy of documentation. All but one study was conducted at a single center, thus limiting the generalizability of the findings. Sample demographics were not always clearly recorded which may lend itself to internal validity issues.

Understanding factors that contribute to low IVC filter retrieval rates is essential in the implementation of the correct intervention. The DNP prepared nurse must recognize and understand what the implications of study findings are in order to be an effective leader and create impactful changes at their prospective institutions. Review of the literature repeatedly demonstrates gaps in care related to the management of IVC filter patients. The DNP has the skills to recognize those gaps and place themselves in the key position to close them. By bringing evidence-based solutions and collaborating with colleagues through effective communication, systems know-how and leadership charisma, a DNP can be an effective leader in uniting others through a shared goal to improve patient health and safety outcomes.

CHAPTER FOUR

Methods

Study Design

The aims of this DNP scholarly project were to determine if an interventional radiology led IVC filter retrieval protocol, compared to traditional care with no protocol, decreased loss to follow-up and increased rates of filter retrieval in patients who had undergone temporary IVC filter placement. This study used a quasi-experimental, pre-post comparative study design (see Appendix D). The study was conducted in the IR department of an academic tertiary medical center in the greater Los Angeles area. The IR department at this institution covers a 400-bed acute care hospital as well as a 60-bed comprehensive cancer center, and performs approximately 2,200 cases a year, with an average of four IVC filters inserted each month. Currently the "standard care" for patients who undergo IVC filter placement is to have one IR provider, the nurse practitioner (NP), track these patients and expedite the removal of eligible filters. However, due to an unstructured process and limited time and resources, most decisions for IVC filter retrievals remain driven by the referring physicians and compliance is unknown. Therefore, the IR NP, who was the Principal Investigator (PI) for this DNP Scholarly Project formally developed a protocol whereby the IR service as a team assumed primary responsibility for follow-up of patients who underwent IVC filter placement under their service. The new IVC filter retrieval protocol was tested as a pilot-study.

The study was reviewed by the Human Research Subjects Institutional Review Board (IRB) at both the sponsoring educational institution and the medical center in which the study was implemented and was determined to be exempted from full IRB review. Ethical standards of

the IRB and Health Insurance Portability and Accountability Act-compliant (HIPAA) protocols were followed.

The post-intervention group was identified through convenience sampling of all consecutive adult patients who underwent insertion of an IVC filter during the four-month prospective period. Inclusion criteria included adult in- and outpatients undergoing IVC filter placement under the IR service at one institution covering two separate facilities. Patients under the age of 18, and those who had their IVC filter placed at an outside institution were excluded from the study. The same sampling strategy was used to identify participants in the twenty-four-month pre-intervention period which formed the baseline comparative data. A total of 28 months' worth of data was collected between the pre- and post-protocol groups. Reliability of the study was established via inter-rater reliability (two raters, blinded to the other's conclusions), who independently collected a random subset of the data from a random 10% of subjects. Greater than 90% agreement between the two raters established that the electronic medical record data collection was reliable.

The IR team nurses, and technologist were informed about the study's aim, protocol workflow, and their individual roles through a verbal 30-minute presentation during their monthly staff meeting by the champion registered nurse (RN) and the NP. The IR faculty physicians as well as physician trainees received a 60-minute Power-Point presentation, presented by the chair of the radiology department, who is an IR physician and an expert in IVC filter data, along with the NP. Presentation was given during their morning conference and focused on IVC filter education and explanation of the proposed protocol. Algorithm for protocol was created (see Appendix E). Dashboard tracking the number of patients enrolled in the study along with staff responsibilities were on display in the IR suite to serve as a reference for the

staff. This board was updated by the various team members as each additional patient was added to study. There was no change in the technical aspects on how the IVC filter insertion or removal procedures were performed.

Data Collection Instruments

Demographic Data

Patient demographics and clinical data including medical diagnosis, date of filter placement and retrieval, indication and type of filter, referring provider, site that implanted filter, and estimated filter dwell times were collected. The data was extracted from the *IVC Filter Placement Data* form (see Appendix F) that was created specifically for this study, as well as the EHR and the institution's Picture Archiving and Communication System (PACS). The same variables and methods of data collection were used for the retrospective review of the same type of patients who underwent IVC filters placement twenty-four months prior to the initiation of the new protocol.

Demographic data was also collected on the IR faculty, trainees, and staff who utilized the IVC filter retrieval protocol which included age, gender, job title, specialty, certification in specialty, years in practice, and years in IR. Aside from staff nurses, the same NP, physicians and technicians were present during the pre- and post-intervention periods. Clinic staff nurses had a large turnover rate and the majority of the nurses in the prospective period were new to the IR department.

IVC Filter Placement Data Form

The IVC filter Placement data form was developed by the researcher specifically for this protocol and was derived from a synthesis of interventions utilized in the literature. Data from this form was entered into a secure tracking database purchased by the department. The content

validation of this form was performed by the institution's current sitting chair of the department of radiology and published expert in the field (R.K.R) along with two currently practicing IR attendings from the institution with five and eleven years of IR practice.

Staff Satisfaction Questionnaire

Interventional radiology team feedback was collected through the use of a five question *Likert* scale questionnaire (see Appendix G), asking about the ease of the protocol implementation process (which ranged from "strongly agree" to "strongly disagree"). The questionnaire was distributed to the participating IR team members through a quick response (QR) code which was scanned through their mobile phones. Paper form of the questionnaire was also made available. Questionnaires were distributed at weeks six and twelve of the pilot-study. The IR team was allotted five working days in which to take and complete the survey each time. Results of the survey were used to make adjustments to the project in order to promote a more appropriate workflow as determined by the staff. Approximate time to answer the five questions was less than three minutes.

Project Intervention

Filter Outcome Definitions

Collaborative discussions with referring providers during the IVC filter follow-up period served to categorize patients with retrievable IVC filters into one of six groups: (1) those who were deemed candidates for *immediate retrieval*, (2) those who had filter converted to a *permanent* status due to patient developing permanent indications as determined by primary or IR provider, (3) patients who continued to have continued filter indications and thus contraindication for immediate removal and required continued follow-up were deemed *pending,* (4) patients were considered *lost to follow-up* and final letter (see Appendix H) was sent to their

last known address if decision was made to remove filter, but IR service was unable to locate patient after three phone calls in one month's time, and (5) an *expired* filter was a patient with a retrievable filter that died prior to having it removed, and (6) patients who for varied reason chose not to have filter retrieved were categorized as *refused*. Patients categorized as permanent IVC filters at time of filter insertion were not monitored. Final filter outcomes are defined in Appendix I.

IVC Filter Retrieval Protocol

Developed from evidence-based literature findings, a comprehensive IVC filter retrieval protocol was created in order to standardize the IVC filter retrieval process. The goal of the protocol was to create a sustainable systematic change that would improve patient tracking and enhance patient quality outcomes by decreasing patients lost to follow-up and increasing IVC filter retrieval rates. The protocol was initiated by the IR team at time of the initial IVC filter consultation to IR, before the filter was inserted. The study protocol was carried out using seven elements:

(1) *Provider to provider discussion*. Once the inpatient consult order for the filter was received, the IR provider of the day initiated a discussion with the referring service regarding indication, type of IVC filter to be placed, and estimated time for filter retrieval. This discussion took place prior to the filter being inserted. Aspects of this conversation were documented on the IVC Filter Placement Data form. With regard to outpatients, documentation on the IVC Filter Placement Data form was initiated at the time of referral by the NP, this was done to ensure type of filter and its indication by the referring team was documented prior to the scheduling of the outpatient procedure, documentation on the form was not completed until day of filter insertion by the physician performing the procedure.

(2) *IVC Filter Placement Data Form*. Decisions from the provider-to-provider discussion along with study variables were recorded onto a paper form that was located in the IR suite. The forms were completed by the IR physician immediately post filter placement, average time to complete form was five minutes. Both blank and completed forms had a designated location in the IR suite and was picked up by the NP on a weekly or as needed basis. The pre-intervention group did not have this form, thus review of the EHR and PACS was used to obtain similar variables, which were recorded on the same form. All completed forms were kept in a folder in a secured office within the radiology department.

(3) *Documented recommendation of prompt filter retrieval*. The post-procedure notes of every retrievable IVC filter placed included a standardized statement, dictated by the IR physician performing the case which read: "When the patient no longer requires mechanical PE prophylaxis, the filter will be removed. The patient will be followed by the interventional radiology service. Please contact radiology department with any questions (###-####)." Once the IVC filter was successfully placed the NP flagged the patients' charts by adding *Presence of IVC filter* to the patients' list of diagnosis as well as *Insertion of IVC filter with date* into the past procedures section in the EHR, which automatically auto-populates every time a new note is generated in the EHR by any provider, serving as an additional reminder of the filter in situ. Diagnosis was converted to resolved once the filter was retrieved.

(4) *IR shared tracking database*. The NP was responsible for the maintenance of the database. The champion RN also had access for data input purposes. Information from IVC Filter Placement Data form, including patients' demographics were entered into the tracking database by the NP or the champion IR nurse.

(5) *Scheduling of an automatic electronic alert for follow-up*. The IR staff nurse on the case was responsible for notifying the IR scheduler of the need for setting up an electronic alert in the NP's calendar for the initial two-week follow-up.

(6) *Collaboration with referring providers*. The two-week follow-up alert prompted the NP to perform a review of the patients' chart to assess filter outcome and a note was documented in the EHR, titled "IVC Filter Assessment Follow-up" and contained information drawn from the original IVC Filter Data form. Referring physicians were contacted via EHR messaging or telephone to discuss and collaboratively assess for continued filter indications and potential filter removal. This communication continued every four weeks (depending on clinical scenario) until the final filter outcomes were decided. Once the decision was made to remove the filter, the patient was contacted and scheduled for an IR telemedicine/telephone follow-up to discuss the consensus decision to retrieve filter as well as details of the retrieval procedure.

(7) *Patient education material.* During the consent process the patient and/or family member received a patient educational brochure (see Appendix J). This pre-printed patient reminder kit was developed by Argon Medical, Inc., which is the institution's current temporary IVC filter supplier. Along with basic IVC filter information, the contact information for the IR department was included. Providing patients with a way for them to be reminded of the temporary intention of the filter was a way of empowering them to be proactive with their own follow-up.

Implementation Evaluation

The Iowa Model Revised calls for an evaluation plan. Frequent evaluation of the implementation process was key in ensuring vital elements of the protocol were being followed and provided early identification of potential workflow compliance issues. The Institute for

Healthcare Improvement (IHI) (2016) Plan, Do, Study, Act (PDSA) process was the tool used to document a test of change, through frequent and routine evaluations of the short-term goals with the IR team. The PDSA cycle (see Appendix K) is a process that has been utilized and is well established in the healthcare setting (Sutphin et al., 2015).

Frequent meetings and project updates with the champion IR nurse, schedulers and IR physician were conducted during the 4-month period of the pilot study to assess Likert scale results and discuss concerns. Timing of meetings varied pending the groups' schedules. The causes for missed steps, such as the one time the nurses forgot to call the scheduler to set up follow-up alert and when the new resident did not perform the appropriate documentation, were closely evaluated and solutions were identified. These discussions led to changes in workflow as well as identified the need to re-educate the staff on the protocol. A dashboard with project aim, metrics on time, and action items was used to keep the team motivated and focused on the goals. The presence of this dashboard also helped new staff rotating through the department and who were unfamiliar with setting become aware of the department's project.

Statistical Analysis

Data collection was performed using the REDCap platform (Research Electronic Data Capture) software, a secure web application purchased by the institution's radiology department. All data was classified as categorical and were reported as percentages and frequencies. Reliability was established via two-person inter-rater reliability which found 100% agreement. The SAS® 9.4 software was used to perform statistical analysis. Chi-square was used to test for difference between retrieval rates in the pre-intervention group versus post-intervention group and the number of patients who were lost to follow-up in the pre-intervention group compared to the post-intervention group. Statistical significance was set at $p < 0.01$.

CHAPTER FIVE

Results

Inter-rater reliability from the two raters who independently collected a random subset of the data from a random 10.9% (11) subjects resulted in 100% match.

Patient Demographics

A detailed summary of patient demographics is shown in Table 1. There were no statistically significant differences between the pre-intervention and post-intervention group when it came to the age, gender, race/ethnicity, type of medical insurance or diagnosis of active malignancy. What was observed is that both groups' average age was 60s, they were predominately white males of non-Hispanic race/ethnicity having private insurance. The diagnosis of malignancy is an important factor to note when discussing IVC filter management given that it can be a good predictor of the type of filter to be inserted.

Staff Demographics

The IR staff participating in the study included faculty, nursing, radiology technicians and schedulers, characteristics listed in Table 2. Males made up 54.3% (n=19) of staff members, with a mean age 42.3years. Faculty had the largest number of people certified in IR (85.7%). While the nursing staff was the largest group force, only one individual was certified in the radiology specialty. Nursing staff also had the newest members, with some having 0.5 years of IR experience.

Staff Survey of Protocol

There were two anonymous Likert scale surveys conducted on the IR staff questioning the ease of the new protocol. The survey results are shown in Table 3. The first survey conducted at week 6 demonstrated a 32.2% number of responses of "Strongly Agree" to the

question, *the protocol adds significantly to my duties*. It was determined that this answer was predominantly from the trainee physicians who were spending a lot of time filling out the IVC filter data form for outpatients undergoing IVC filter insertion. This prompted a change in the workflow, specifically with the NP now obtaining the necessary information prior to the scheduling of outpatients. Leading to a decrease in the physicians' time spent in trying to obtain the needed information. The second and same survey taken at week 12, that same question's answer demonstrated a statistically significant reduction in the number of staff members who felt the protocol was adding to their work duties ($p < 0.01$). No other statically significant differences in the answers were noted. Although paper versions of the surveys were made readily available, the entire staff chose to enter their responses through a QR scanning feature in the REDCap software used to tract the study data. The QR scanning was performed via the staffs' own smart phones. These responses were automatically recorded into the REDCap software, facilitating the analysis of the results.

Filter Placement

A total of 101 patients (86 pre- and 15 post-intervention) underwent placement of an IVC filter during the 28-month pilot-study period. Four patients (1 in the pre- and 3 in the post-intervention) were excluded due to having a permanent type of filter placed. During the 24-month pre-intervention period from January 2019 to December 2020, 85 retrievable filters were placed at a rate of 3.5 per month. Similar findings were noted in the 4-month post-intervention period of January 2021 to April 2021, where 12 retrievable filters were placed at a rate of 3 per month. There were significantly more IVC filters placed at the institution's 400-bed acute-care hospital versus its affiliated 60-bed cancer center, but not statistically different between the pre- and post-intervention groups ($p = 0.37$). In fact, there was no statistical significance in filter

variables with regard to brand of retrieval filter placed, filter indication, or rate of complications. Summary of filter related variables in the pre- and post-intervention groups are summarized in Table 4.

The top referring services included the intensive care unit, oncology and neurology surgical services (i.e., general surgery, transplant, orthopedics, thoracic, spine, and urology). While the remaining medical services (i.e., internal medicine, cardiology, hematology, hepatology, renal, pulmonary and gynecology-oncology) accounted for the rest.

Filter Outcomes

Comparison of the raw data on filter outcomes pre- and post-intervention are illustrated in Figure 1. Retrieval rates adjusted for patients lost to follow-up and those pending a decision, as illustrated in Figure 2, requires taking into consideration those patients who have expired, have had their filters converted to permanent status, and those who refused to have the filter retrieved. Rates were calculated in the same way for both the pre- and post-intervention patients. Although the pilot met its highest expectation for the primary outcome with 100% IVC filter retrieval rate and 0% of patients lost to follow-up, the sample size was determined to be too small to be statistically significant.

Additional beneficial outcomes of the pilot study were observed, as noted in Figure 3, the improvement in documentation of the type of filter, estimated time of filter need, post-insertion follow-up and IR's recommendation for prompt removal when filter is no longer indicated was statically significant between the pre- and post-intervention group in all four outcomes. This new standardized documentation in the EHR was performed primarily by members of the IR team as outlined in the protocol.

Filter Conversion and Malignancy

In the pre-intervention group, 28 (32.9%) of 85 retrievable IVC filters were inserted in patients with a known active malignancy at time of insertion. Figure 4 demonstrates the statistically significant positive correlation between the number of these patients with malignancy who then had their filters converted to permanent status. ($r(26) = 0.32759$; $p < 0.01$). This was noted early in the pilot-study and provided new knowledge that was unknown to the IR team. This finding led to a change in the post-intervention group's pre-filter insertion discussion regarding what type of filter should be inserted. As noted in Figure 5, this had an influence in the number of permanent IVC filters placed in the post-intervention group, which was statistically higher than in the pre-intervention group ($p < 0.01$). Due to inability to determine the exact timing of patients who had known malignancy and had expired with a filter in place, an accurate correlation between those two groups could not be made.

Table 1

Patient Demographics Before and After Implementation of New Protocol

Patient Variables	Pre-Intervention n (%)	Post-Intervention n (%)	*p* value
Age	61 ± 15	60 ± 16	0.89
Gender			0.53
Female	29 (34.12)	3 (25)	
Male	56 (65.88)	9 (75)	
Race			0.32
Hispanic	26 (30.59)	2 (26.67)	
Non-Hispanic	59 (69.41)	10 (83.33)	
Ethnicity			0.07
Asian	6 (7.06)	1 (8.33)	
Black	8 (9.4)	0 (0)	
White	56 (65.88)	5 (41.67)	
Other	15 (17.65)	6 (60)	
Medical Insurance			0.34
Medicare	18 (21.18)	4 (33.33)	
Medicaid/Medical	7 (8.2)	2 (16.67)	
Private	60 (70.6)	6 (50)	
Malignancy			0.2
Yes	38 (44.71)	3 (25)	
No	47 (55.29)	9 (75)	

Note: There was no statistical significance between the two groups' demographics or characteristics, alpha set at < 0.01.

Table 2

Interventional Radiology Staff Demographics and Professional Characteristics

Job Title	n	Gender (%)	Average Age yrs.	Certified in Specialty n (%)	Average Years in Practice	Average Years in IR (range)
Faculty	7	F 3 (42.8) M 4 (57.2)	50.4	6 (85.7)	17.9	17.9 (4 - 32)
Physician Trainee	3	M 3 (100)	33.7	N/A	0	1
Radiology Technicians	9	F 1 (11.1) M 8 (88.9)	39.1	4 (44.4)	12	8.8 (1 - 19)
Registered Nurse	14	F 9 (64.3) M 5 (35.7)	42.9	1 (7.1)	13.2	9.5 (0.5 - 22)
Scheduler	2	F 2(100)	36	N/A	11.5	2.5 (13 - 10)
Grand Total	35	F = 16 (45.7) M = 19 (54.3)	42.3	11 (31.4)	14.4	12 (0.5 - 32)

Note: F= female; M = male. N/A was applied in job titles that do not have a recognized certification for specialty. IR = Interventional Radiology

Table 3

Results of Interventional Radiology Staff Protocol Survey

Question	Category	Week 6 n = 29 (%)	Week 12 n = 33 (%)	*p* value
The protocol is easy to follow	Agree	9 (32.14)	9 (27.27)	0.68
	Strongly Agree	19 (67.86)	24 (72.73)	
Quality improvement projects are important	Neither Agree nor Disagree	0 (0)	5 (15.15)	0.1
	Agree	8 (28.57)	9 (27.27)	
	Strongly Agree	20 (71.43)	19 (57.58)	
The protocol adds significantly to my duties	Strongly Disagree	11 (39.29)	24 (75)	**<0.01**
	Disagree	5 (17.86)	7 (21.88)	
	Neither Agree nor Disagree	1 (3.57)	0 (0)	
	Agree	2 (7.14)	1 (3.13)	
	Strongly Agree	9 (32.14)	0 (0)	
The protocol is easy to understand	Agree	6 (21.43)	6 (18.18)	0.75
	Strongly Agree	22 (78.57)	27 (81.82)	
I believe the protocol is useful	Neither Agree nor Disagree	2 (7.14)	0 (0)	0.12
	Agree	6 (21.43)	13 (39.39)	
	Strongly Agree	20 (71.43)	20 (60.61)	

Note: Five option *Likert* scale was used, scale ranged from "Strongly disagree" to "Strongly Agree". Survey was an anonymous quick response QR code that was scanned from participants' phone directly to a data program (REDCap). Team members were given one week to respond in each of the two surveys. Significant values bolded, alpha set at < 0.01.

Table 4

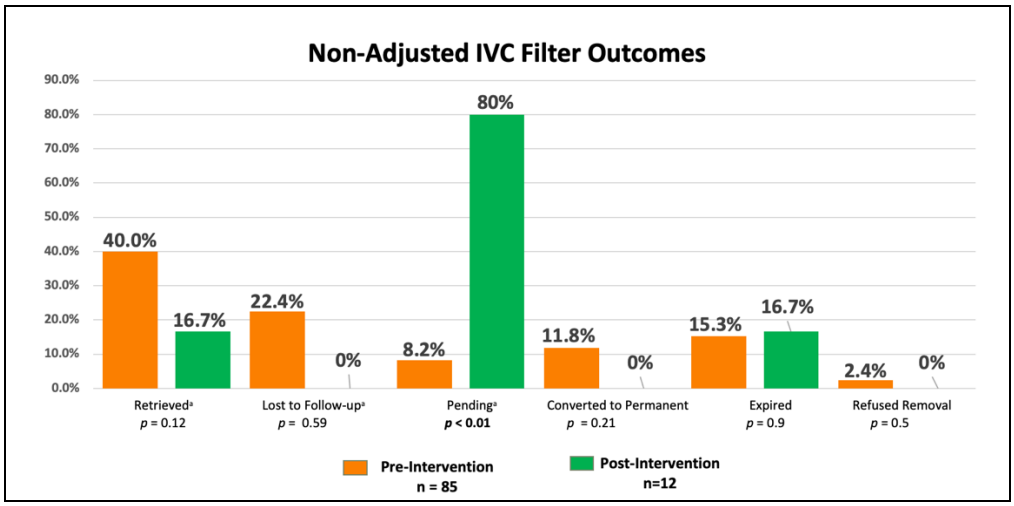
Retrievable IVC Filter Variables before and After Implementation of New Protocol

Filter Variables	Pre-Intervention n (%)	Post-Intervention n (%)	*p* value
Number of retrievable IVC filters placed	85	12	
Site of filter placement			0.37
400-Bed Acute-Care Hospital	69 (81.2)	11 (91.7)	
60-Bed Cancer Center	16 (18.8)	1 (8.3)	
Filter Brand			0.71
Option Elite	84 (98.8)	12 (100)	
Gunther Tulip	1 (1.2)	0 (0)	
Filter Indication			0.47
Absolute	81 (95.3)	11(91.7)	
Relative	2 (2.4)	1(8.3)	
Prophylactic	2 (2.4)	0 (0)	
Complications			0.78
Filter Insertion	0 (0)	0 (0)	
Filter Retrieval	1 (2.9)	0 (0)	
Filter Outcomes			
Retrieved[a]	34 (40)	2 (16.7)	0.12
Lost to Follow-up[a]	19 (22.4)	0 (0)	0.07
Pending[a]	7 (8.2)	8 (80)	**<0.01**
Converted to Permanent	10 (11.8)	0 (0)	0.21
Expired	13 (15.3)	2 (16.67)	0.9
Refused Removal	2 (2.35)	0 (0)	0.59

Note: Total 101 IVC Filters were inserted during the pilot-study period. Permanent filters (1-Retrospective; 3 – Prospective) were excluded.
IVC = Inferior Vena Cava. Significant p-value set at < 0.01. Significant values bolded.
[a] Dummy code variable, number of filters retrieved does not reflect filter retrieval rate of eligible filters; filters adjusted for loss to follow-up or filters pending decision for outcome.

Figure 1

Inferior Vena Cava Filter Outcomes Pre- and Post- Implementation of New Protocol

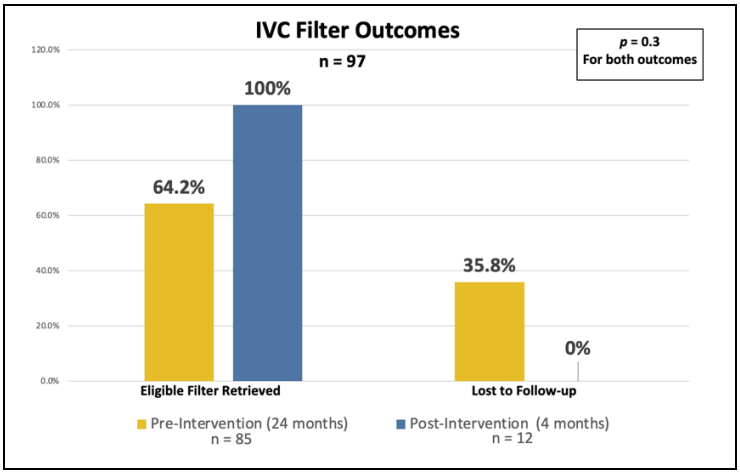


Note: Total of 97 retrievable IVC filters were placed during the 28-month pilot-study period. alpha set at < 0.05.

[a] Number of filters retrieved, lost to follow-up and pending do not reflect adjusted values.

Figure 2

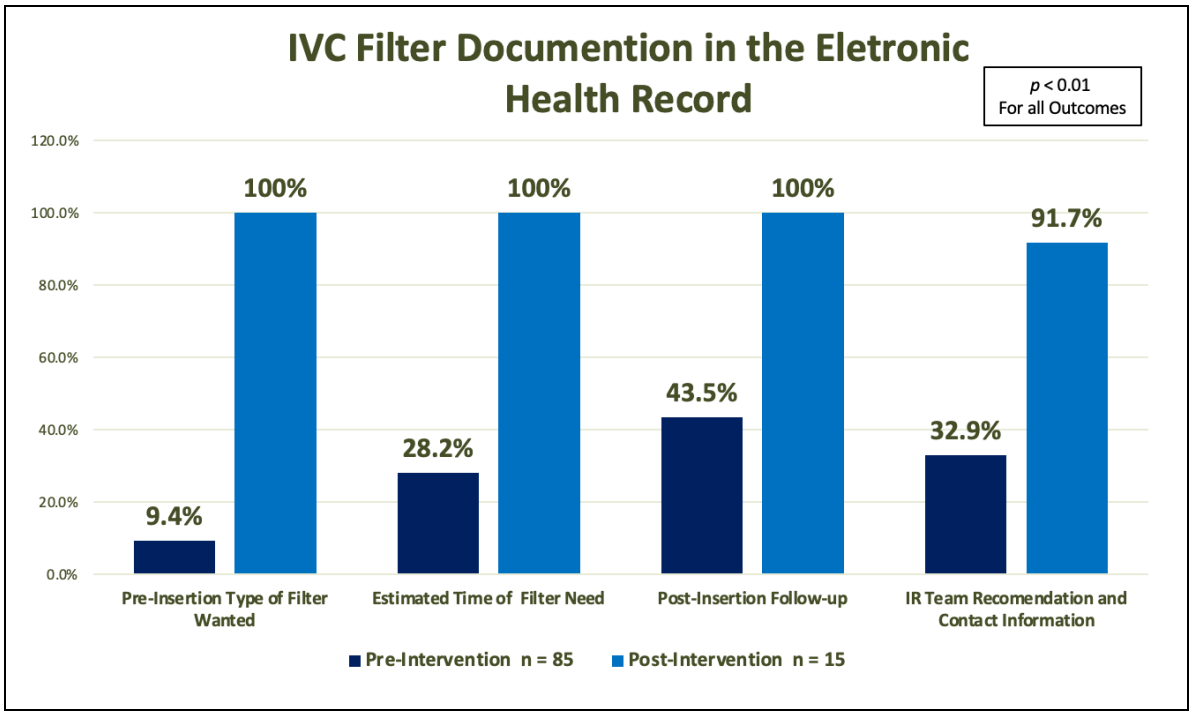
Adjusted IVC Filter Outcomes Pre- and Post- Implementation of New Protocol



Note: Eligible filters determined by subtracting any pending, expired, converted to permanent, and refused filters from total number of filters placed. For the pre-intervention group (85 - 7 -10 - 13 - 2 = 53). Retrieval rate of eligible filters retrieved determined by taking percentage of retrieved filters from remaining filters (number retrieved was 34, thus 34 of 53 = 64.15%). Percentage of remaining filters not retrieved were lost to follow-up (19 of 53 = 35.84%). Same calculation used for the post-intervention group. Despite 100% retrieval rate sample size determined to be too small to be statistically significant.

Figure 3

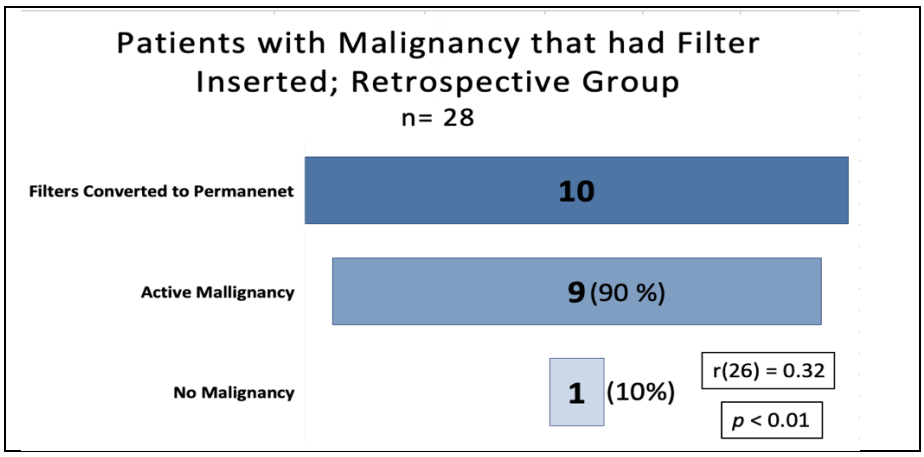
Impact of New IVC Filter Protocol on the Documentation of Filter Management



Note: Statistical difference was noted in all outcomes. Documentation was performed by interventional radiology providers.

Figure 4

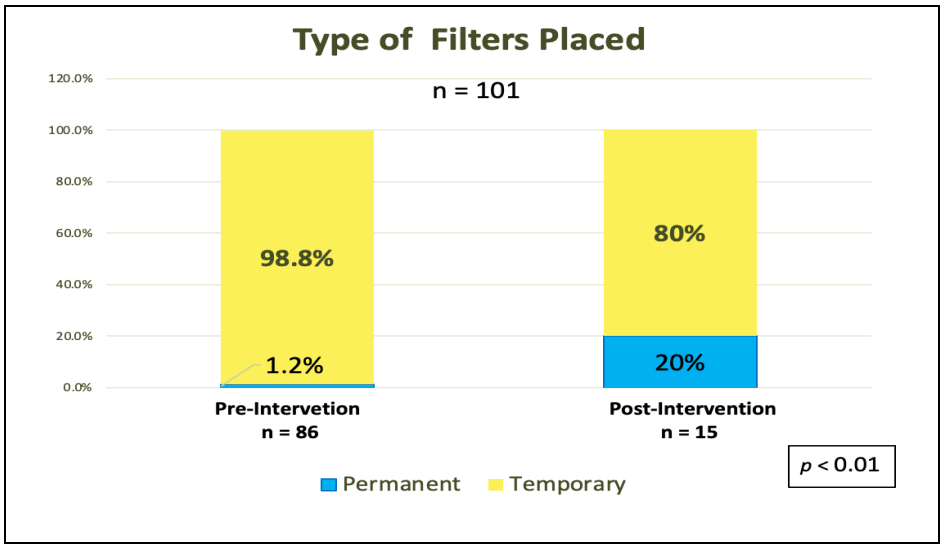
Correlation Between IVC Filter Conversion to Permanent Status and Malignancy



Note: Out of 85 filters inserted in retrospective group 28 had a diagnosis of active malignancy. There was a significant positive relationship between the number of IVC filters inserted in patients with active malignancy and the number of filters converted to permanent. Degrees of freedom (df) = 26. Finding was relevant as it led to a more conscientious approach to evaluation of the type of filter to be inserted in the prospective group.

Figure 5

Type of Filter Placed Pre- and Post- Implementation of New Protocol



Note: Increase in the number of permanent filters placed in the post-intervention group can be attributed to implementation of protocol. Significant p-value set at < .05. Permanente filters did not require monitoring after they were inserted, thus no additional data was collected on them.

CHAPTER SIX

Discussion

The effects of an interventional radiology led IVC filter retrieval protocol on the number IVC filters retrieved and patients lost to follow-up was examined in this DNP scholarly project. In the present pilot-study the IVC filter retrieval rate of 64.15% and the 35.85% of patients lost to follow-up, calculated from the baseline pre-intervention data, matched that of literature which reports that in practices who have incorporated a filter retrieval process, retrieval rates can be as high as 54% to 81% (Rottenstreich et al., 2017; Klinken et al., 2017; Lynch, 2011). The PI of this study sought to improve the current process from an unstructured and less sustainable, single IR provider process which continued to rely heavily on referring providers, to an IR team-led process guided by a protocol developed from evidence-based literature. The aim was to have the IR team use the new protocol to further improve retrieval rates and decrease loss to follow-up of patients who had undergone IVC filter placement under the IR service. The project was driven by the institution's IR NP's determination to improve patient outcomes by aligning the practice with the evidence and to be in accordance with the FDA's recommendation which acknowledged increasing reports of adverse events attributed to IVC filters that were being left in situ beyond their indicated need for PE prevention. The theoretical framework used to guide the QI project was the IOWA Model Revised which takes a problem-solving approach and guides the user to a feasible solution increasing the success and sustainability of the proposed change in practice.

Review of the literature, specifically studies evaluating interventions used to increase filter retrieval rates was instrumental in the creation of the final protocol design. Although there are multiple factors leading to reported low rates of filter retrievals, many previous studies addressing this problem established that patient loss to follow-up was consistently the underlying

cause of poor retrieval rates. Therefore, steps aimed at increasing patient tracking through the creation of a database was a fundamental intervention utilized in the present study. As in all the previous studies, the most substantial component of the new protocol was the establishment of the IR led follow-up. This new ownership of patient outcomes by the implanting service demonstrated higher retrieval rates, largely in part due to the fact that those who insert these devices are in an advantageous position to better recognize indications for continued filter need versus removal. This shift in the paradigm of care also imparted the IR providers with a more active role in the patients care and offered a more deliberate type of follow-up.

The methodology used consisted of early chart review and documentation post filter insertion, within the first two weeks of the filter's implantation, performed by the IR NP. Together with the referring provider the filter outcome was determined. Those patients with continued indication for leaving the filter in place and requiring further monitoring had their charts flagged and with repeated alerts for follow-up, which served as a safety net for patients in order to mitigate the possibility of being lost to follow-up.

In the present study all retrieval filters were inserted with the intent of having them removed once the threat of a PE had passed. The rate of IVC filter retrievals in eligible filters increased to 100% from 64.15%;($p = 0.3$) after the adoption of an IR led IVC filter retrieval protocol. Despite 100% retrieval rate and no patients lost to follow up in the prospective group, the sample size was determined to be too small to achieve statistical significance for either outcome ($p = 0.3$). Although there was no statistical significance in the primary outcomes of the study, there were additional beneficial outcomes that were observed.

In the post-intervention group, the statistically significant increase in the documentation surrounding the placement and follow-up of the IVC filter was vital in determining the patients'

eligibility for IVC filter retrieval. Improved communications between all providers requesting, inserting and managing these patients, either directly or through the EHR was essential to the project meeting its goals. It is believed that the improved documentation and collaborative discussions between providers led to a heightened awareness of the presence of the filter, which in turn led to more diligence in the management and follow-up of these patients. The use of the EHR in this study was instrumental as it permitted quick chart review of the patients, facilitated communications between the providers, simplified the entire process and was invaluable in the documentation of the filter outcomes. It was these essential components that ultimately resulted in 0% loss to follow-up of the patients in the post-intervention group. Of note, the new protocol was then also applied to the retrospective group and an additional two patients previously lost to follow-up were scheduled to have their filters removed by the end of data collection, four previously pending filters have been retrieved and two filters were declared permanent. These results support the findings of Klinken et al. (2017) and Lynch (2011), who also noted significant improvement in their filter retrieval rates (52.9% to 72.9% and 24% to 54%) following retrospective auditing.

Lynch (2011) found that low filter retrieval rates may also be seen in practices where the practice defaults to placing retrievable filters in everyone, even though permanent indications were present from the start. As he noted, this is an appealing strategy for many practices as it promotes physician familiarity with the insertion and removal of the device and makes tracking inventory of the types of filers easier to perform. Post implementation of the new protocol, the first patient who had undergone a retrievable IVC filter placement had known advanced malignancy, the patient was re-hospitalized within a week of undergoing filter placement and expired during that hospitalization. This prompted a closer look at the pre-intervention data

which revealed that this default of placing retrievable filters in all or most patients was observed at the institution. During the pre-intervention 24-month period, one (1.2%) permanent filter and 85 (98.8%) retrievable IVC filters were inserted. However, the retrospective data demonstrated a trend towards having retrievable filters converted to permanent status in patients who had a diagnosis of active malignancy. This positive correlation led to a more conscientious approach to answering the first question on the IVC Filter form; *Type of filter to be inserted*. Determining the right filter for the right patient created an opportunity to educate the IR providers on the importance of pre-filter insertion discussions with referring providers regarding the appropriate filter for each patient's clinical scenario. Moving away from the thought of *one filter fits all* had a significant impact on the remainder of the study. Ultimately the post-intervention group had 3 out of 15 (20%) permanent filters inserted during the 4-month study which was found to be statically significant ($p < 0.01$), but more importantly this demonstrated a change in the way the IR department practices, converting common practice into best practice, thereby improving their patients' outcomes.

Sustainability of the Change

In order to obtain the project's aims, the staff had to learn and implement the new protocol. The use of staff surveys questioning the ease of the protocol provided feedback which ultimately helped develop a protocol that was feasible and sustainable for the team. It was during review of the surveys that changes to the protocol were made. One notable finding from the week 6 survey results was the opinion that the protocol added significantly to the staff's work duties. This finding was discussed at a project meeting and staff were allowed to express any issues. It was identified that outpatients required significantly more time to fill out IVC Filter data form, due to outside providers not being readily available to have the conversation needed to

obtain the information. This was resolved by having the IR NP obtain the information at time of outpatient referral, prior to the scheduling of the procedure. This step alone alleviated much of the burden on the implanting physicians and increased their compliance to the protocol. A team approach to creating and adapting the protocol will increase sustainability. Involving multiple staff members such as nursing, technicians, scheduler and providers ensures that there will be some team members present to facilitate and remind others to carry-on the process.

Financial Considerations

Collaborative pre-filter insertion discussion helped identify the right type of filter for the right patient and provided a cost savings for the department. The currently used retrieval IVC filters cost the department $1,960 each and the permanent IVC filters cost $1,523. There is an extra expenditure of $437.00 for every retrievable filter placed in a patient who may be better served having a permanent filter placed. A more difficult but valuable savings to calculate would be the prevention of lost time and resources needed for the IR department to continue tracking these patients who ultimately will have their filters converted to permanent status. Additionally, having patients come back for a retrieval procedure produced additional income for the department, calculated from three different payers (PPO, Medicare and HMO) there was approximately a net loss of approximately $1,667 for every temporary IVC filter that was not retrieved.

Return of investment (ROI) quantifies a project's value by determining the ratio of dollars invested, compliance with regulation or update in clinical practice (Capella & Nakfoor, 2018). Given that all the necessary resources, IR nurses, physicians, NP, schedulers, and the use of telemedicine were already in place the cost of the project was in kind to the organization. While financial return is important, it does not always reflect strategic importance. For a project such as this, it would be impossible to know the cost the organization is saving by preventing

hospitalization from the future long-term complications of forgotten IVC filters. The financial ROI was not an essential driving force of this particular clinical inquiry of current practice. Instead, this project set out to implement a pilot study, mainly the evaluation of a new clinical protocol to bring the organization up to compliance with FDA's recommendations and ultimately improve patient safety outcomes. However, the intangible ROIs for the organization are the improved brand strength and reputation for providing safe, efficient, timely and high-quality patient care. The IR department can now assure the organization that they are taking steps that are in line with the institution's mission of providing safe high-quality patient care while the added revenue will be looked upon as an additional favorable outcome for the department.

Limitations

Efforts were taken to minimize study limitations, though some were inherent. The baseline comparative data was obtained from a retrospective review, thus accurate historic documentation was not always available. The study was non-randomized, lending itself to selection bias. The project was carried out in one institution working out of two facilities, one facility was an academic acute care setting while the other was a smaller but nationally known cancer center, with the majority of filters placed in the main hospital. This is a unique setting which may limit the generalizability of the findings. The nursing staff was also relatively new to the IR department, thus more likely to adopt a change in practice, which may not represent other IR departments. The urban location of the institution caters to a more affluent population with private insurance plans These demographics may ultimately affect retrieval rates and loss to follow-up at other institutions who serve patients of a different demographic.

Lastly, the pilot-study was conducted during the middle of the COVID-19 global pandemic, as such many non-emergent services were postponed, this indirectly affected the

number of filters ordered. Although in the end, the rate of filters placed per month was not significantly different between the two comparison groups, the majority of the filters placed in the prospective group were inserted later in the study. Enrollment of participants later in the four-month phase of the study limited the number of filters eligible for retrieval given that the mean indicated dwell time of filters estimated by the referring providers was 59 days. Short study period was one of the pilot study's biggest limitations. The effects of the pandemic on the mental and physical well-being of the staff are unclear, one can assume that the motivation to perform a QI project in the middle of a pandemic can seem overbearing in a time when concern for adequate personal protective equipment and anxiety or fear of becoming infected are on the minds of every healthcare worker. Although motivation for the project was slightly dampened the team followed the protocol with minimal missed steps.

Implications for practice

When a project comes to an end, specifically a DNP scholarly project, there is an opportunity to capture lessons learned and best practices, which can then help guide other future projects and will eventually become part of the growing legacy DNPs are making in the healthcare world. This project demonstrated that adoption of an IR led IVC filter retrieval protocol by the IR department can lead to a change in practice and ultimately improve patient outcomes. These findings were limited to one department in an institution where other services such as cardiology and vascular surgery also place these devices, a multidisciplinary team approach involving all these services not only has the potential to bring the institution as a whole in compliance with the FDA's recommendations, but also ensures that when it comes to the management of these devices, all patients receiving care under this institution are receiving quality care.

Since the study by Andreoli et al. (2014), which found an 86.8% adverse outcome associated with prolonged dwell times of retrievable filters, new retrievable IVC filters have been developed. Future research is needed to assess if these newer filters have the same risks of adverse outcomes as their earlier versions. Future research is also needed to determine if any unseen health disparities may be contributing to patients being lost to follow-up, as these may require additional interprofessional collaboration with service sectors, such as social services or other community resources.

CHAPTER SEVEN

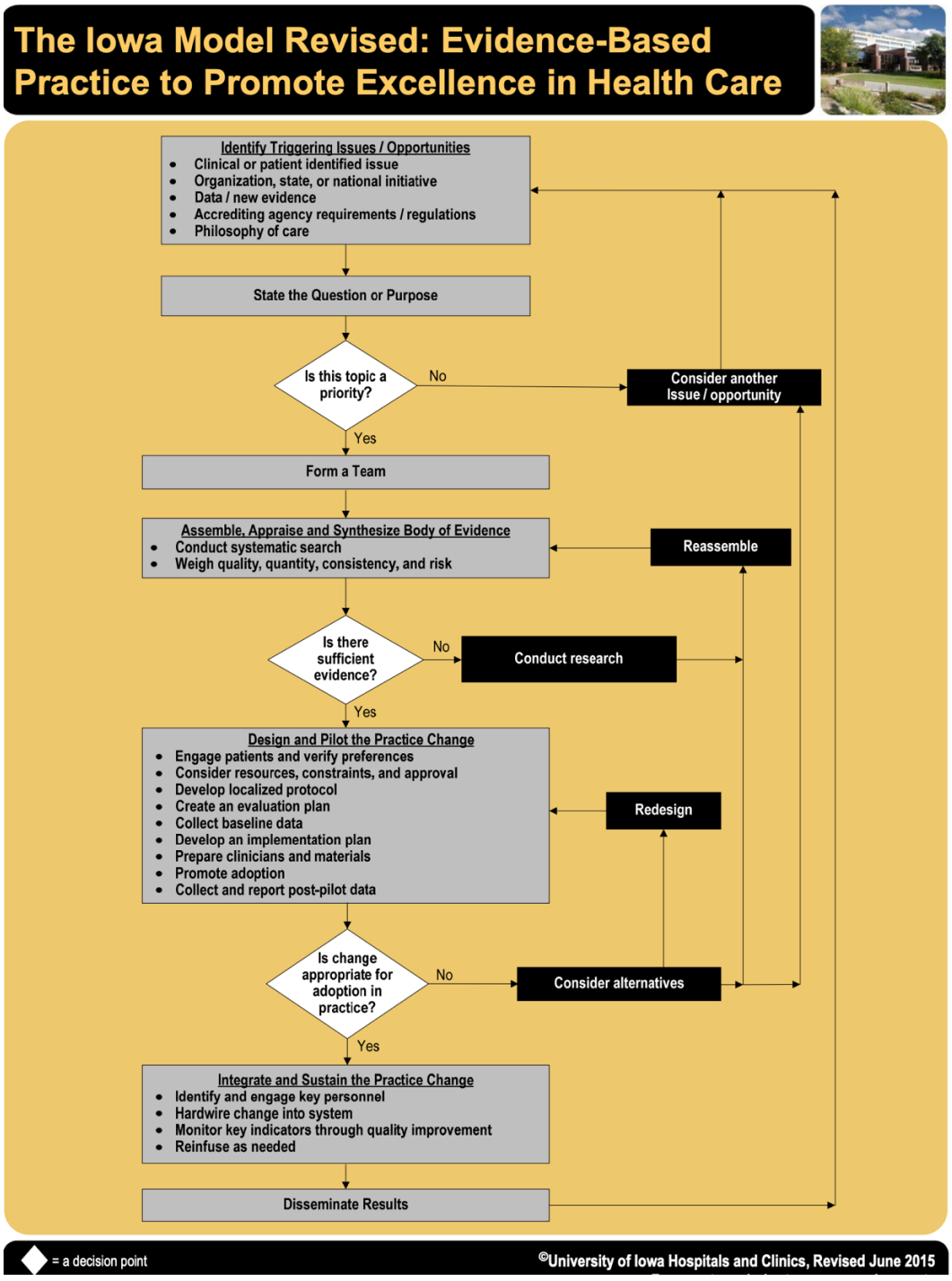
Conclusion

Adoption of an IVC filter retrieval protocol, led by the service that places these devices, seeks to align the organization with the FDA's recommendations and, more importantly, has the potential to improve patient quality outcomes by decreasing the adverse events associated with filters that are unintentionally left in place. A review of the literature showed that despite varied interventions and levels of significance obtained, every study reported some amount of improvement. This was demonstrated also in this pilot-study. Although the primary outcome did not meet statistical significance, post implementation of the intervention the practice did demonstrate a statically significant change in the way it practices by selecting the more appropriate IVC filter for their patients. These findings imply that any act emphasizing the clinical importance of the QI process can transform common practice into best practice. The DNP prepared nurse has the ability to be a pivotal translator of evidence-based knowledge into tangible positive patient outcomes.

APPENDICES

Appendix A

The IOWA Model Revised



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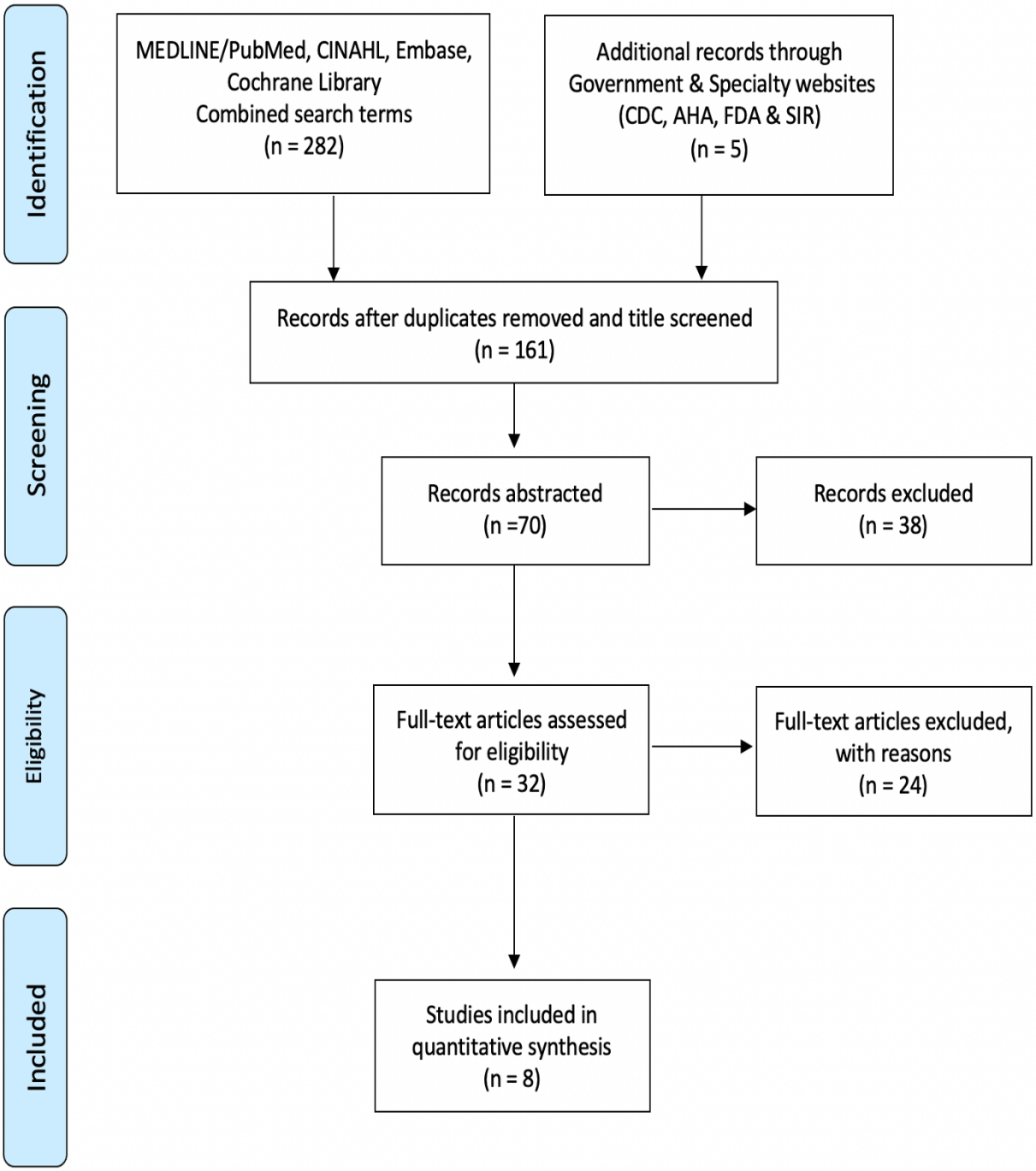
Appendix B

Prisma Flow Diagram



Appendix C

Table of Evidence

Author, Year	Purpose	Sample & Setting	Methods, Design, Interventions, Measures	Results	Discussion, Interpretation, Limitations of Findings, Conclusion.
Dowell, J. D., Shah, S. H., Cooper, K. J., Yildiz, V., & Pan, X. (2017). Cost-benefit analysis of establishing an inferior vena cava filter clinic. *Diagnostic and Interventional Radiology*, *23*(1), 37–42. https://doi.org/10.5152/dir.2016.16007	Aimed to demonstrate the cost-benefits of implementing an IVC filter clinic to improve the quality of care for patients with IVC filters.	Single institution in urban location. **Sample:** n = 335 adults Mean age 59 Females = 176 Males= 159 PRE: 119 POST: 152 **Sampling:** All consecutive patients undergoing IVC filter placement and/or removal	-Intervention Targets: Interventional radiologist **Study design:** Pre vs. Post Retrospective review -Study Time Period: **Pre:** Jan 2012 – Aug 2012 **Post**: Sep. 2012 – June 2013 *Retrospective group also received intervention. **Intervention:** - IVC filter clinic was established - Collaboration with PMD, to determine type of filter to be placed. - After placement, patient data, placed in database, managed by nurse. - Communication via EHR and phone calls with PMD	**Retrieval rates:** **PRE:** 10/119 = 8.4% **POST:** 44/152 = 28.9% **Statical significance:** $p < .0001$ Pre intervention group contacted, additional 13 (19.3%) filters were retrieved - Financial net loss $535/each retrievable filter not removed. -Eligible IVC filter retrieval yielded and	-Establishment of a dedicated IVC filter clinic significantly improved filter retrieval rates. -IVC filter clinic yielded $54,311.85 in revenue over one year above that generated by baseline model. -Resources for clinic was offset by removal of additional 3.1/yr. **Implication:** -Potential financial incentive to implement an IVC filter retrieval process that incorporates a clinic.

			initiated 4 weeks following placement. IVC filter Clinic established for 10 months. - Collaboration with primary provider for removal - Retrospective view: 8 months pre-clinic time Cost-benefit analysis model: determined by average cost and reimbursement for both types of filters. **Stats:** -Two sample t-tests and Chi-square test were used to compare differences in patient demographics and retrievable rates between post and pre-clinic phases. p value set at <.0001	additional $31,102.53 in actual revenue (10 months)	-New process created a way to educate referring providers on the clinic initiative, in addition to improving retrieval rates. **Limitations:** -Cost of products, labor and supply were based on one institution, and likely to vary another institution. -LTF and filter dwell times were not specifically addressed.
Author, Year	**Purpose**	**Sample & Setting**	**Methods, Design, Interventions, Measures**	**Results**	**Discussion, Interpretation, Limitations of Findings, Conclusion.**
Inagaki, E., Farber, A., Eslami, M. H., Siracuse, J. J., Rybin, D. V., Sarosiek, S., Sloan,	To develop an operational sustainable protocol.	Single tertiary hospital, US, Boston Medical Center	- Intervention Targets: Patients **Study design:** Pre vs. Post Retrospective review	**Retrieval rates:** **PRE group =11%** 784 (72%) were	- Implementation of multidisciplinary team approach IVC filter protocol led to a significant increase in

J. M., & Kalish, J. (2016). Improving the retrieval rate of inferior vena cava filters with a multidisciplinary team approach. *Journal of Vascular Surgery Venous and Lymphatic Disorders*, *4*(3), 276–282. https://doi.org/10.1016/j.jvsv.2015.11.002	Hypothesized that the implementation of a new IVC filter retrieval protocol would increase the retrieval rate of eligible filters	**Sample:** n=1,275 underwent IVC filter placement. 36 were excluded d/t incomplete records. **PRE**: 1088 of **784** were temporary filters **POST:** 151of **119** were temporary filters Demographics: Mean age 55 ± 20, no significant difference in both groups. (p = 0.2) **Sampling:** Identified through hospital	- Study Time Period: **Pre:** Sep. 2003 - July 2012 **Post**: Aug 2012 - Sept. 2014 Prospective data using a centralized interdepartmental IVC filter registry from August 2012 to Sept 2014 was collected. **Intervention:** Multidisciplinary task force was established, they developed and implemented a new IVC filter protocol. Multidisciplinary team: Trauma Surgery, Vascular Surgery, IR, Cardiology Protocol Developed**:** 1) Patient education pamphlets 2) An additional IVC filter procedure form 3) Centralized interdepartmental IVC filter registry 4) A dedicated administrator coordinator -Patient education prior to filter placement -IVC filter procedure form, decision:	retrievable filters, of these: 4% died 2% convert to permanent 720 eligible for retrieval, 14% attempted) **POST group=54%** 119 (79%) were retrievable, of these: 9% died 21% convert to permanent 74 eligible for retrieval, 49% (66% attempted) 34% were still being actively followed for removal. **Statical significance:** p < .001 LTF: Not recorded Dwell time: PRE: 119 days POST: 130 days	the retrieval rates of temporary filters **Implication:** Improved retrieval rates are possible with dedicated resources. -Dedicated filter process can potentially lead to in decreased filter adverse outcomes in the future. **Limitations:** -Single center -PRE-group had a higher number of IVC filters placed compared to POST, likely due to Hawthorne effect since vascular surgery participated in development of protocol, thus fewer IVC filters were inserted prophylactically in trauma patients likely due to review of indications for filters

		records using CPT codes. Patients were chronologicall y categorized into pre and post groups and comparisons of outcomes were measured <u>Inclusion:</u> **PRE-** All consecutive patients from Sept 2003 to July 2012 **POST**- All consecutive patients from Aug 2012 to Sept 2014. -Post group significantly more non-trauma (p=.007) and more likely in pts. with VTE	*Permanent* (no retrieval needed) *Immediate* (retrieval in same day hospital of < 1month) *Short term* (retrieval in 1-6 months) *Long term* (retrieval > 6 months) on the basis of clinical judgement of operating physician. Info entered to database, access limited, Excel worksheet, maintained by dedicated coordinator. Follow-up methodology varied among departments- mail, phone, clinic. **<u>Stats:</u>** - Bivariate comparisons of clinical variables and outcome measures used, - X^2 test for categorical variables - Unpaired *t*-test for continuous variables. -Logistic regression and one-way ANOVA for		was discussed in multidisciplinary task force. -Long term complications were not discussed. - LTF numbers not included

		rather than prophylactic.	comparison of outcomes among immediate, short term and long-term filters p value set at <.05		
Author, Year	**Purpose**	**Sample & Setting**	**Methods, Design, Interventions, Measures**	**Results**	**Discussion, Interpretation, Limitations of Findings, Conclusion.**
Klinken, S., Humphries, C., & Ferguson, J. (2017). Establishment of an inferior vena cava database and interventional radiology led follow-up - Retrieval rates and patients lost to follow-up. *Journal of Medical Imaging and Radiation Oncology*, *61*(5), 630–635. https://doi.org/10.1111/1754-9485.12611	To assess the rates of IVC filters retrieved and the percentage of patients lost to follow-up, before and after the establishment of an IR-led process.	Single tertiary medical center, Australia **Sample:** PRE-implementation n= 136 (over 3 years) POST - implementation n=118 (over 2 years) Total data covers 5 years **Sampling:** Demographic obtained from EHR database,	Intervention Targets: Patients **Study Design:** Pre vs. Post Retrospective review -Study Time Period: **Pre:** June 2009 - May 2012 **Post:** June 2012 - May 2014 **Intervention:** IR database established, IR team took responsibility for follow-up Data obtained, both groups: Patient demographics, insertion indications, filter types, retrieval status, documented retrieval decisions, time in situ, trackable events complications	**Results:** **Primary outcomes:** Attempted IVC filter retrieval rate **PRE**: 52.9% **POST:** 72.9% **Statical significance:** P = .001 Secondary outcome: LTF: **PRE:** 23% **POST:** 0% (p < 0.001) Dwell times: **PRE:** 137 days **POST**: 113 (p = 0.159)	Establishing an IR-led follow-up with tracking of patients through a database led to a significant increase in the number of attempted filter retrievals and the number of patient's LTF. **Implication:** -Tracking of patients LTF is as important as tracking retrieval rates by implanting service. **Limitations:** -Single center -Samples varied significantly in filter placement indications.

		No statistical difference in number of patients, or age (p = .225) or gender (p = .85) Data on patients inserted from between June 1, 2009 to May 2012 were retrospectively reviewed	Pre group: Consensus decision to remove or deem permanent Post group: IVC filter placed, after 90 days of placement indications for filter were reviewed by physicians in the IR team and a medical officer. If continued indication automatic alert in system would alert every 3 months until filter status was determined **Stats:** SPSS using X^2 or Fisher's exact test. p value set at < .05		
Author, Year	**Purpose**	**Sample & Setting**	**Methods, Design, Interventions, Measures**	**Results**	**Discussion, Interpretation, Limitations of Findings, Conclusion.**
Lynch, F. C. (2011). A method for following patients with retrievable inferior vena cava filters: Results and lessons learned from the first 1,100 patients. *Journal of*	To determine the efficacy of an IVC filter retrieval process on patient follow-up, where previously no formal process existed.	Single institution, tertiary center, US Hershey Medical Center, Penn State	-Intervention Targets: Provider **Study Design:** Pre-Post Retrospective review -Study Time Period: **Pre:** May 2002 - Oct. 2005 **Post**: Oct 2005 - May 2010	**Results:** **PRE: 24%** 154 placed, 37 retrieved **POST: 59%** 973 placed, 574 removed	-Implementing an IVC filter follow-up method can improve IVC filter retrieval rates. * First to publish change in paradigm of care

Vascular Interventional Radiology, *22*(11), 1507–1512. https://doi.org/10.1016/j.jvir.2011.07.019	Two endpoints: 1)Filter removal or decision to make permanent 2) Continuation of active surveillance for future filter removal	**Sample:** n = 1,127 IVC filter placements **Pre**:154 **Post:** 973 Demographics: 71% male -Largest age group 31-50 years **Sampling:** Pre/Post: All patients having undergone a temporary filter from May 2002 to May 2010 Inclusion: All retrievable filters placed between during study periods Exclusion: IVC filter placed at outside	**Intervention:** Pre-Post an IR formal process, additional follow-up of pre- patients - One IR physician -Starting Oct.13, 2005, IR assumed responsibility for follow-up for all patients receiving temporary filters. Including pre- group -Patients tracked through hospital database. If not removed within 90 days of placement, reviewed and determined if it filter status should be converted to permanent, requiring further follow-up or immediate removal. -If deemed ready for removal, letter was sent to patient and provider. Two additional letters sent to patient if no response. Additionally, effort to contact patient by home were made, but time consuming and switched to 4th and final letter.	**Statical significance:** p< .001 Research then applied intervention to pre-group: **Retrieval rate:** **Pre-group with intervention: 54%** 154 placed, 84 removed -LTF: Pre: NR Post: 16.2% Pre with intervention: 18.2% -Median Dwell time: Pre: 91 days. Post: 306.5 days. Pre with intervention: 436 days	**Implications:** Implanting services need to manage their IVC filter patients **Limitations:** - Complications not discussed - Single institution, affecting generalizability

		institution, although if filter removed at outside facility due to letters, were included.	**Stats:** X^2 used to measure effectiveness of the method. p value set at <.001		
Author, Year	**Purpose**	**Sample & Setting**	**Methods, Design, Interventions, Measures**	**Results**	**Discussion, Interpretation, Limitations of Findings, Conclusion.**
Rottenstreich, A., Arad, A., Lev Cohain, N., Bloom, A. I., Varon, D., Klimov, A., Roth, B., & Kalish, Y. (2017). Implementation of an institutional protocol to improve inferior vena cava utilization and outcomes. *Journal of Thrombosis and Thrombolysis*, *44*(2), 190–196. Retrieved July 14, 2020, from https://doi.org/10.1007/s11239-017-1513-1	To evaluate the impact a multidisciplinary institutional protocol would have on IVC filter retrieval rates and patterns of use. **Secondary aim:** Improving the selection of patients based on evidence-supported guidelines.	Level 1 trauma, single center, Israel **Sample:** Total 493 patients PRE: 455 POST: 38 Mean age 56 59% males 40% were ICU 31.6 %surgical services 28.4% internal med/onc/ortho **Sampling:** PRE group:	Intervention Targeted: Physician -**Study design:** Pre vs. Post -Study Time Period: **Pre:** Jan 2009 – Dec 2014 **Post:** June 2015 – May 2016 **Intervention: (Two part)** 1). Dedicated physician in AC service managed database, coordinated f/u and eval of eligible filter removal -Patients scheduled for AC clinic at time of discharge. In clinic the filter status was determined as either: - permanent - candidate for removal	**Results:** **Filter retrieval:** **PRE:** 16.7% 15.4% died 10.4% ongoing eval **POST:** 60.5% 26.3% died 13.2% ongoing eval **Statical significance:** (p<.0001) LTF: **PRE:** 77.1% **POST:** 0% (p< .0001) Dwell Time: **PRE:** 105 days	-Implementation of an institutional IVC filter protocol can improve both patterns of use and retrieval rates of IVC filter. **Implication:** Stricter guideline will lead to less use of filters, eval of complications needs further evaluation. **Limitations:** -Single center

		identified through EHR, All consecutive patients between Jan 2009-Dec 31, 2014 Compared to POST group: All consecutive patients from June 2015 to May 2016 (Post) Prospective group had data collected during a period of one year. No statistical difference in groups' demographics p =0.40-gender p = 0.20-age	- intermediate – f/u 1-3mos until permanents or removed 2). In-house lectures to referring services were given. Filter indication followed ACCP and ASH guidelines. As well as FDA recommendation for prompt removal **Stats:** Categorical variables; X^2 and Fisher's exact test Continuous variables used Man-Whitney U Two-sided, p value set < .05	**POST:** 50 days (p = .006) Clinic f/u rates: Pre: 22.9% Post:100% **Indication**: Post: 76.3% with e/o VTE and contraindication to AC, 21.1% prophylaxis Pre: 48.4% with e/o VTE with contraindication to AC 40.2 % prophylactic in setting of trauma or perioperative	

Author, Year	Purpose	Sample & Setting	Methods, Design, Interventions, Measures	Results	Discussion, Interpretation, Limitations of Findings, Conclusion.
Salei, A., Raborn, J., Manapragada, P. P., Stoneburner, C. G., Aal, A. K., & Gunn, A. J. (2020). Effects of a dedicated inferior vena cava filter retrieval program on retrieval rates and number of patients lost to follow-up. *Diagnostic and Interventional Radiology*, *26*(1), 40–44. https://doi.org/10.5152/dir.2019.18579	To assess the efficacy of a dedicated IVC filter retrieval process on: 1) retrieval rates patients lost to follow-up	Single tertiary center in US, Alabama **Sample:** PRE: 76 median age 65 45% female POST: 106 median age 60 47% female Ethnicity & diagnosis not presented **Sampling:** PRE: 76 found via electronic medical records 9 months pre-intervention. POST: 106	Intervention Targets: Provider **Study Design:** Pre vs. Post -Study Time Period: **Pre:** Nov 2015 – June 2016 **Post:** July 2016 - April 2017 Total of 18 months (9 vs.9) **Intervention:** -All data collected retrospectively. -Once filter was placed patient data placed in database and scheduled for IR clinic, seen by physician assistant. -Clinic outcomes: 1). Filter no longer needed-scheduled for retrieval. 2). Filter deemed permanent.	**Results:** **Retrieval rates:** PRE: 6.6% POST: 28.3% **Statical significance:** $p < .001$ LTF: PRE: 55.3% 29% died POST: 16% 21.7% died ($p < .001$) Filters deemed permanent Pre: 9.2% Post: 26.4% P=.004 Decision Pending Pre:0% Post:7.5% P=0.15	-Findings supported the effectiveness of a clinic-based, IR driven IVC filter retrieval program in improving retrieval rates and lowering number of patients lost to follow-up. **Implications:** -Improving patients lost to follow-up can lead to improve retrieval rates as well. **Limitations:** -Statistical differences in age and gender of two groups. -Single center -Dwell times not recorded

		All consecutive patients who underwent insertion of a temporary IVC filter by IR service in 9 months' time	3). Continued follow needed -> Repeat clinic visit. If clinic missed 3 times, letter sent to referring MD no response marked LTF. **<u>Stats:</u>** Descriptive statistics for continuous variables, and frequency count. -Percentages were used for categorical variables. Kruskal Wallis test for age between both group because not normally distributed. Fisher's exact test was used for gender. Two proportion-test was used in proportion comparison between groups for variables including the indication for placement, filter brand and filter outcomes. p value set at <0.05	-All patients seen in clinic presented for procedure, only 1 not retrieved due to thrombus	

Author, Year	Purpose	Sample & Setting	Methods, Design, Interventions, Measures	Results	Discussion, Interpretation, Limitations of Findings, Conclusion.
Sutphin, P. D., Reis, S. P., McKune, A., Ravanzo, M., Kalva, S. P., & Pillai, A. K. (2015). Improving inferior vena cava filter retrieval rates with the define, measure, analyze, improve, control methodology. *Journal of Vascular Interventional Radiology*, *26*(4), 491–498.e1. https://doi.org/10.1016/j.jvir.2014.11.030	To utilize a theoretical framework to design a sustainable process to improve optional IVC filter retrieval rates.	Tertiary academic hospital, US, Texas **Sample:** 139 patients 71 men, 68 women Average age 64 Ethnicity & diagnosis not recorded **Sampling:** Participants were all identified through use of electronic health record. All participants were divided into 3 groups	Intervention Targets: Both patients and physicians **Study Design:** Pre vs. Post -Study Time Period: Base: Jan 2012 – Aug 2012 Letter: Sep. 2012 – April 2013 Clinic: May 2013 – Dec 2013 -DMAIC (Six sigma) framework: Define- the problem Measure- the problem Analyze- the process Improve- the process Control- the process **Multidisciplinary team**: Interventional Radiologist IR physician assistant Nurse coordinator Internal medicine nurse coordinator	**Results:** **Retrieval rates** Baseline 8% Letter group: 8% to 40% (p=.03) Prospective group: 8% to 52% (p=.007) Average filter dwell time: Base: 64 days Letter: 137 days Prospective: 59 days LTF: Not recorded But seen in clinic: Base = 0 Letter =19% Prospective= 49% **Process generated revenue:** Estimated revenue per 100 IVC filter	-The study demonstrated between a letter or automatic scheduling intervention, scheduling was statistically more effective in increasing IVC filter retrieval rates, although both interventions were better than baseline. -Retrieval of filters can generate revenue **Implication:** -Using a framework may be helpful in creating sustainable QI project. **Limitations:** -Base group, patients who died were considered ineligible for retrieval without further evaluation of their filter status, which may lead to an underestimation

		depending on time of filter placement.	QI facilitator Hematologist Pulmonologist **<u>Two Workflows</u>** <u>Group 1</u>: Sept 2012-April 2013 -Letter was sent to PMD, patient to schedule for clinic visit with a LE Ults. If no response in 2 weeks, second letter was sent until 3. "No response" was documented in EHR with no further workup. <u>Group 2:</u> May 2013 or later Automatic scheduling of a clinic visits and LE Ults 4 weeks after IVC filter was placed for outpatient or 4-6 weeks for inpatients. *patents who did not keep appointments remained in eligible pool **<u>Intervention:</u>** Database created	placed increased $2,249 to $10,518 with mailing of letters and $17, 022 with the automated clinic scheduling.	retrieval rate in this group. -Letter group was contacted several months after clinic, possibly affecting clinic show-up - Complications not reported -LTF not recorded

			Between Jan 2012 and Dec 2013 139 retrievable IVC filter placed Base group: (n=51) used for comparison Letters group: (n=43) Patients and Physicians were retrospective contacted Prospective group:(n=45) Patients were scheduled for clinic at time of IVC filter placement. **<u>Stats:</u>** IVC filter retrieval rates based on (%) retrieved = IVC filter retrieved/ (total placed – (patients eligible of filter retrieval)) * 100 Statistical comparison between -base & letter -base & clinic Using Fisher exact test p value set at <.05		

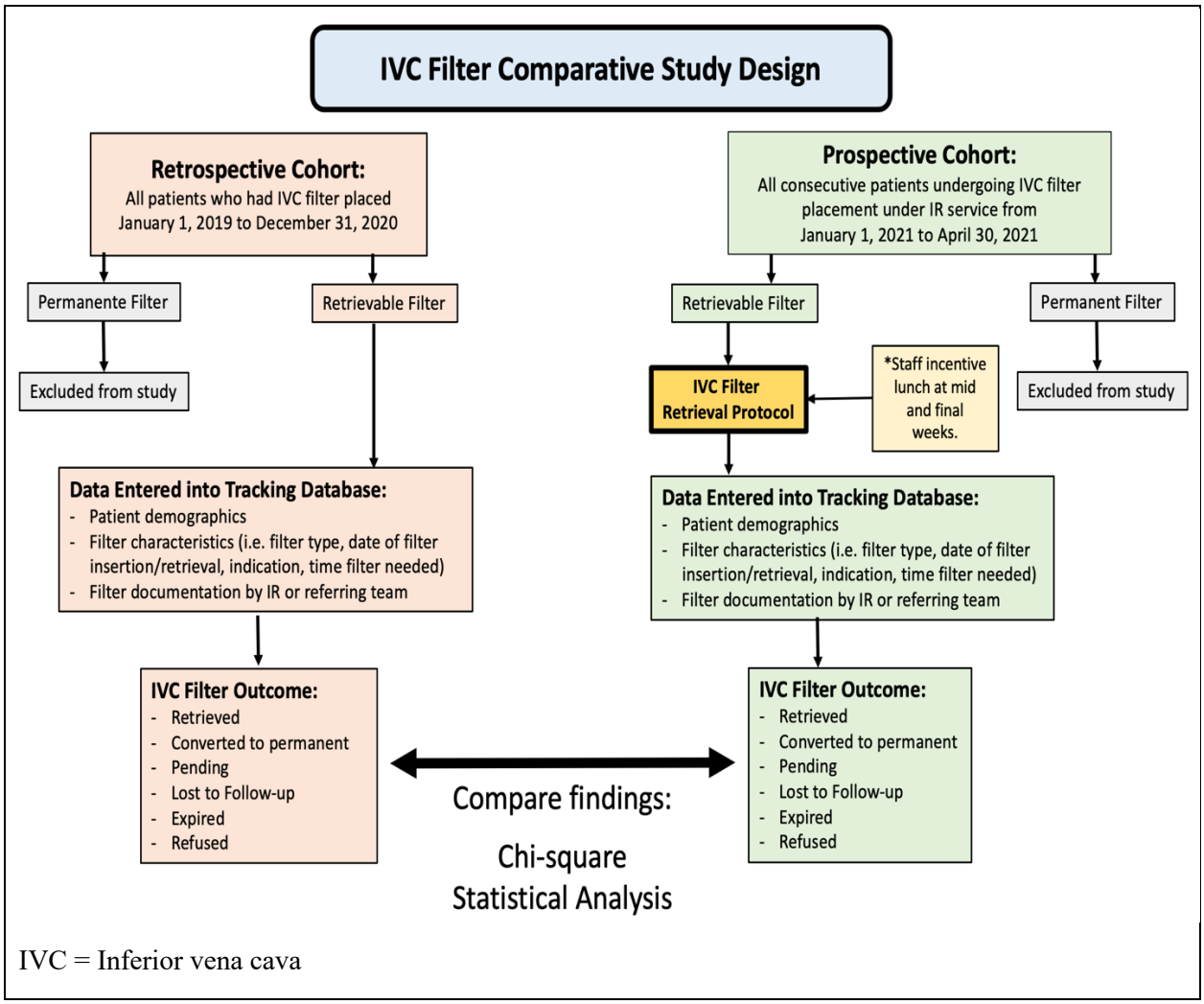
Author, Year	Purpose	Sample & Setting	Methods, Design, Interventions, Measures	Results	Discussion, Interpretation, Limitations of Findings, Conclusion.
Wang, S. L., Cha, H.-H. A., Lin, J. R., Francis, B., Elizabeth, W., Martin, P., & Rajan, S. (2016). Impact of physician education and a dedicated inferior vena cava filter tracking system on inferior vena cava filter use and retrieval rates across a large us health care region. *Journal of Vascular and Interventional Radiology*, *27*(5), 740–748. Retrieved July 12, 2020, from https://doi.org/10.1016/j.jvir.2016.01.130	To assess the impact of adding a component of physician education regarding current evidence on IVC filter use, and the effect it would have on IVC filter retrieval rates.	14 urban centers, US, Northern California, Kaiser Permanente ranged from community hospitals to larger tertiary centers. Serving 3.5 million members **Sample:** n=659 **PRE:** n=369 had temporary filter placed. **POST:** n=290 had temporary filter placed **Sampling:**	Intervention Targets: physicians **Study design:** Pre vs. Post All data collected retrospectively -Study time Period: **Pre:** Dec 2011 – Mar 2013 **Post:** Feb2013 – May 2014 CME ground rounds to participants Recommended conservative ACCP guidelines **Intervention:** IVC filter clinic model and filter tracking were established. Clinic model: 1) The IR department assumed responsibility for filter follow-up 1) A regional computer tracking system tool (Excel) was used, built-in alters	**Results:** **Retrieval rate:** **PRE: 38.9%** 427 filter placed 369 (86.6%) retrievable **POST: 54%** 347 filter placed 290 (83.6%) retrievable **Statical significance:** (p = .0006) Positive correlation between filter retrieval attempts and physician attendance at ground rounds. (r = .51; p = .051)	-Referring physician education and filter tracking led to improved IVC filter retrieval rates. -Use of in-hospital grand rounds on evidenced-based approach to IVC filter management resulted in a reduction in IVC filter use. -Electronic safety net used to prevent lost to follow-up 12 months **Implications:** -Study highlights the need to reduce IVC filter for non- evidence supported indications and represents an opportunity for future interventions to be more comprehensive.

		Participants identified through internal IVC filter registry Patients who died within 12 weeks of filter placement were excluded n=85 (pre), n=56 (post) <u>Excluded:</u> Permanent filters and those who died within 12 weeks of filter placement	notifying user at 9- and 12-week filter dwell time. -One-hour long CME approved Ground Rounds given by a vascular and IR physician. -Clinic deployed same day Grand rounds given -IR and AC collaborated to determine filter status, followed AACP guidelines Electronic safety net used to prevent lost to follow-up 12 months **<u>Stats:</u>** Calculated using Pearson correlation coefficient. p value set at < .05	-Reduction in IVC filter use statistically reduced **22%** (r = -0.69, p = .007) <u>Dwell time</u>: Pre: 10.2 wks Post:10.8 wks	**<u>Limitations:</u>** -Did not account for outside influences - Sample demographic not given - LTF not specifically addressed

- AC = anticoagulation, AACP = American Association of Chest Physicians, ANOVA = analysis of variance, ASH = American Society of Hematology, CME = continued medical education, EHR = electronic health record, FDA = Food and Drug Administration, IR = interventional radiology, IVC = inferior vena cava, LTF = lost to follow-up, PMD = primary care physician, QI = quality improvement, t-test = student's t distribution, VTE – venous thromboembolism, X^2 = Chi square

Appendix D

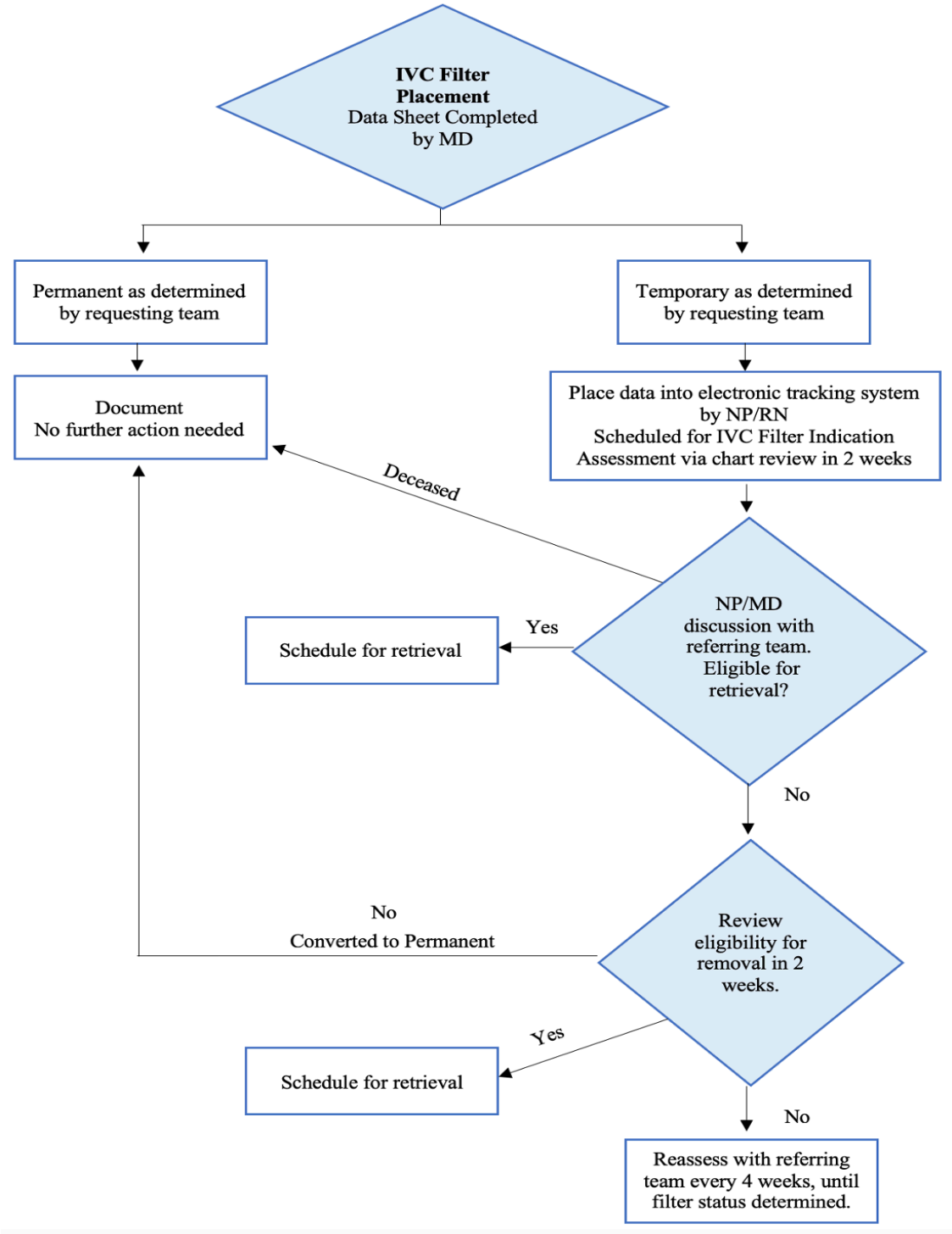
Study Design



IVC = Inferior vena cava

Appendix E

Algorithm for IVC Filter Retrieval Protocol



Appendix F

IVC Filter Placement Data Form

Patient Sticker

IVC Filter Placement Data

IR physician to fill out for every IVC filter inserted

Patient Name & MRN:			
Date of placement:		Removed:	
Filter Intention:	☐ Temporary	☐ Permanent	
Indication for filter: **(SIR Guidelines)**	☐ **Absolute (+VTE)** - Contraindication to anticoagulation - Complication of anticoagulation - Inability to achieve/maintain therapeutic anticoagulation - Documented progression of DVT - Recurrent PE while on anticoagulation	☐ **Relative (+VTE)** - Iliocaval, large, ore free-floating proximal DVT - Difficult establishing therapeutic anticoagulation - Massive PE treated with thrombolysis/thrombectomy - Chronic PE treated with thromboendoarterectomy - Thrombolysis for iliocaval DVT - VTE with limited cardiopulmonary reserve - Recurrent PE with filter in place - Poor compliance with anticoagulation - High risk of complications of anticoagulation (ataxia, frequent falls)	☐ **Prophylactic (no VTE)** - Severe trauma patient - Closed head injury - Spinal cord injury - Multiple long bone or pelvic fracture - Patients at high risk (Immobilized or in ICU).
Referring Provider: (Which attending made the decision to place filter – NO residents/fellows)	**Contact #:**	**Estimated Time of Filter Need:**	
Service: (Circle one)	ICU Orthopedics Hematology Oncology HBS Surgical-Onc ENT Pulmonary Medicine Neuro-Surg Hepatology Urology Other: _____		
Presenting Diagnosis:		**Active Malignancy:** ☐ **Yes** ☐ **No**	
Procedural issues/complications:			

***Standardized Procedure Note Statement:** "When the patient no longer requires mechanical PE prophylaxis, the filter will be removed. The patient will be followed by the interventional radiology service. Please contact Keck-USC Interventional Radiology department with any questions (323) 442-8598".

FOR REVIEWER: Site [] Keck Hospital []Norris Cancer Center
Documentation: IR post-Procedure Note with contact information: []Yes []No
Pre-Procedure; Referring team documenting type of filter wanted: []Yes []No
Post-Procedure documentation of filter outcome [] Referring team: []IR []Both []None

Appendix G

Staff Satisfaction Questionnaire

IVC Filter Retrieval Protocol

For each of the questions below, circle the response that best characterizes how you feel about the statement in regard to the inferior vena cava filter retrieval protocol.

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
1. The protocol is easy to understand.	1	2	3	4	5
2. The protocol is easy to follow.	1	2	3	4	5
3. The protocol adds significantly to my duties.	1	2	3	4	5
4. I believe the protocol is a useful tool.	1	2	3	4	5
5. Quality improvement projects are important.	1	2	3	4	5

Additional Comments:_____

Appendix H

Patient Letter

Date…

Dear Mr./Mrs. XXX,

According to our records, you had a procedure performed in the Interventional Radiology Department at XXX on XXX, at which time an inferior vena cava (IVC) filter was inserted into your body to protect your lungs from blood clots.

This filter should be removed when it is no longer clinically necessary. Normally, the IVC filter is removed whenever a patient can tolerate blood thinning medications at a therapeutic dose or when it is determined by your doctor that you no longer require the filter.

We encourage you to discuss possible IVC filter removal with your primary doctor to determine if you are a candidate for removal.

When you are ready for the filter to be removed, please contact our office by telephone or email.
Our contact information is:
Phone: XXX-XXX-XXXX
Email: _____

Thank you for putting your trust and confidence in us and allowing us to serve your healthcare needs. Please feel free to contact us if you have any questions.

We look forward to hearing from you.

Sincerely,

Interventional Radiology Division

Appendix I

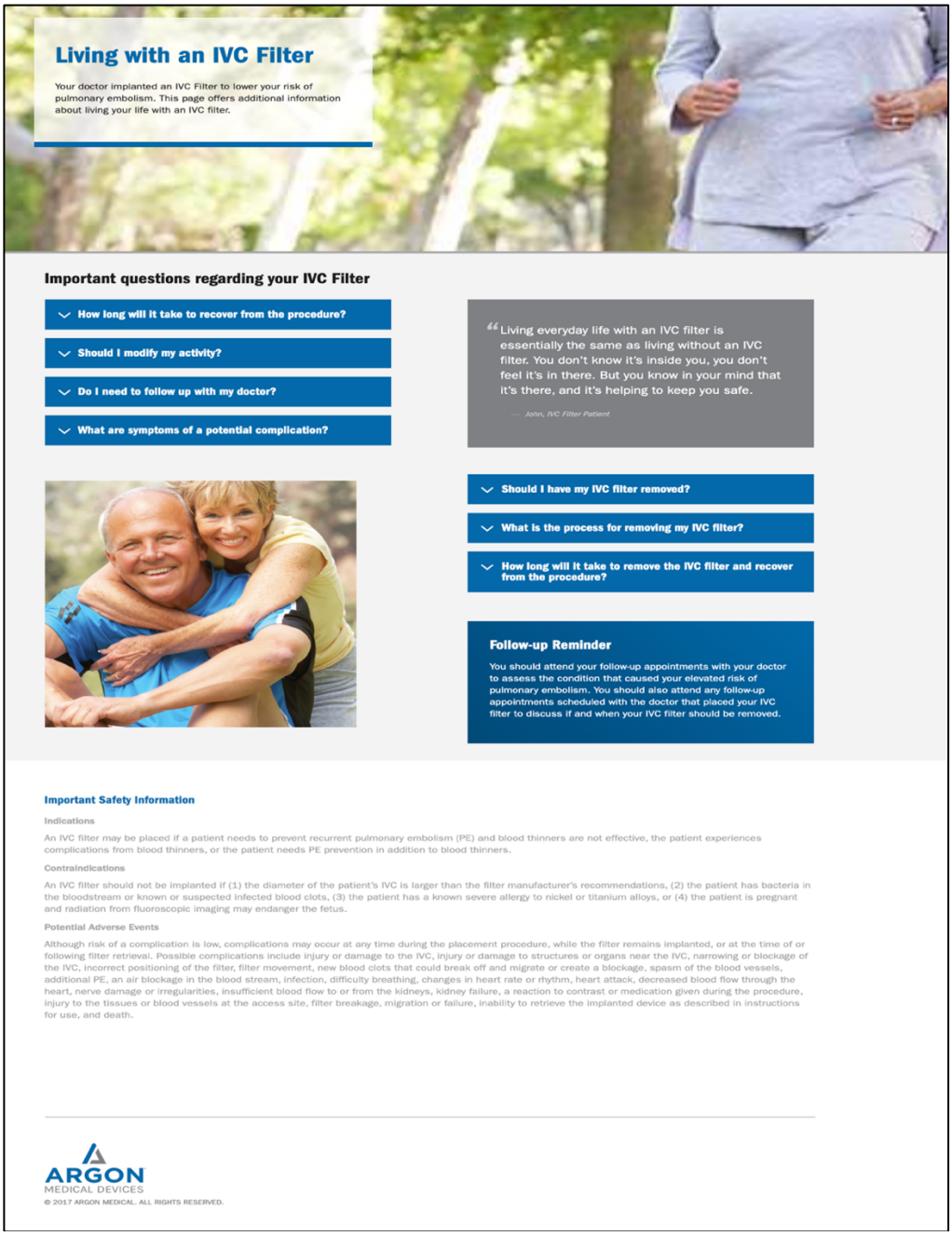
Filter Outcome Definitions

Filter Outcome	Definition
Retrieved	An IVC filter that was successfully retrieved.
Converted to Permanent	A documented decision was taken by a provider to leave IVC filter in place.
Pending Decision	Prior to protocol: Documentation of continue need for filter with IR intent to follow-up. Post protocol: Documentation of continue need for filter with IR intent to follow-up or decision for filter outcome not determined by the time of data collection.
Lost to Follow-up	Prior to protocol: No documentation of decision regarding the filter's continued indication, need for removal, or follow-up with IR noted (90 days after its insertion or 90 days gaps of time). Post protocol: No *IVC Filter Assessment* note in chart within 14 to 30 days post placement and/or IR team unable to reach patient after three documented attempts.
Expired	Patient died prior to decision of filter outcome was determined.
Refused	Patient contact for filter retrieval, but patient deciding not to have filter retrieved.

IVC = Inferior vena cava

Appendix J

Argon Medical; IVC Filter Patient Educational Brochure – Online Version



Living with an IVC Filter

Your doctor implanted an IVC Filter to lower your risk of pulmonary embolism. This page offers additional information about living your life with an IVC filter.

Important questions regarding your IVC Filter

- How long will it take to recover from the procedure?
- Should I modify my activity?
- Do I need to follow up with my doctor?
- What are symptoms of a potential complication?

"Living everyday life with an IVC filter is essentially the same as living without an IVC filter. You don't know it's inside you, you don't feel it's in there. But you know in your mind that it's there, and it's helping to keep you safe.

— John, IVC Filter Patient

- Should I have my IVC filter removed?
- What is the process for removing my IVC filter?
- How long will it take to remove the IVC filter and recover from the procedure?

Follow-up Reminder

You should attend your follow-up appointments with your doctor to assess the condition that caused your elevated risk of pulmonary embolism. You should also attend any follow-up appointments scheduled with the doctor that placed your IVC filter to discuss if and when your IVC filter should be removed.

Important Safety Information

Indications

An IVC filter may be placed if a patient needs to prevent recurrent pulmonary embolism (PE) and blood thinners are not effective, the patient experiences complications from blood thinners, or the patient needs PE prevention in addition to blood thinners.

Contraindications

An IVC filter should not be implanted if (1) the diameter of the patient's IVC is larger than the filter manufacturer's recommendations, (2) the patient has bacteria in the bloodstream or known or suspected infected blood clots, (3) the patient has a known severe allergy to nickel or titanium alloys, or (4) the patient is pregnant and radiation from fluoroscopic imaging may endanger the fetus.

Potential Adverse Events

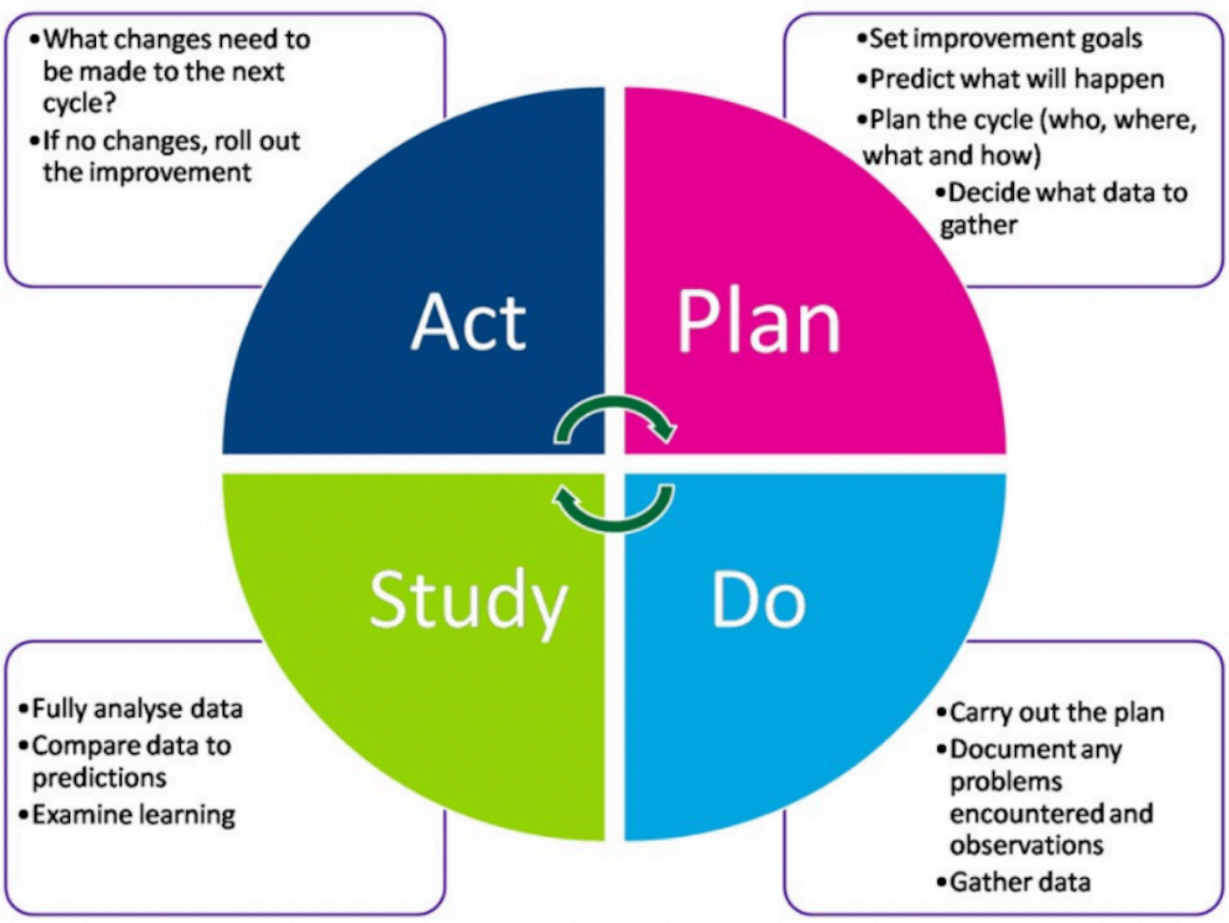
Although risk of a complication is low, complications may occur at any time during the placement procedure, while the filter remains implanted, or at the time of or following filter retrieval. Possible complications include injury or damage to the IVC, injury or damage to structures or organs near the IVC, narrowing or blockage of the IVC, incorrect positioning of the filter, filter movement, new blood clots that could break off and migrate or create a blockage, spasm of the blood vessels, additional PE, an air blockage in the blood stream, infection, difficulty breathing, changes in heart rate or rhythm, heart attack, decreased blood flow through the heart, nerve damage or irregularities, insufficient blood flow to or from the kidneys, kidney failure, a reaction to contrast or medication given during the procedure, injury to the tissues or blood vessels at the access site, filter breakage, migration or failure, inability to retrieve the implanted device as described in instructions for use, and death.

ARGON MEDICAL DEVICES

This pre-printed brochure was developed by the Argon Medical Device, Inc, which is the institution's current retrievable IVC filter supplier. Permission granted for printing.

Appendix K

The PDSA Cycle for Planning and Improving



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