Reducing Vascular Access Complications Through Precise Cannulation Plan Implementation

Rosemarie Quicho
rosemarie.quicho@gmail.com

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Reducing Vascular Access Complications Through Precise Cannulation Plan Implementation

Rosemarie Quicho

University of San Francisco

November 16, 2019
Abstract

Aneurysm, which is the dilatation of the arteriovenous fistula (AVF), and pseudo-aneurysm, which is caused by leaking of blood outside the arteriovenous graft (AVG), pose a threat to the vascular access (VA) and the patient (Mudoni et al., 2015). Uneven vein penetration by dialysis needles and subsequent skin scarring lead to the development of inflammatory changes in the VA area. Scab formation masks the signs of ongoing inflammation. Damage to and tearing of the scab can then lead to lethal exsanguination from the VA (Handlos, Marecová, Smatanová, Dvořáček, & Dobiáš, 2018). Dialysis staff members are trained to use the entire length of the VA for cannulation; this rope-ladder cannulation method relies on changing the puncture sites for each dialysis treatment (Twardowski, 2015). However, in daily clinical practice, often the same area of the fistula or graft is cannulated for reasons of comfort and ease (Verhallen, Kooistra, & Jaarsveld, 2007). An engaged outpatient in-center hemodialysis (HD) team adopts the use of a disposable measuring tool of their choice to create a VA-specific cannulation plan to achieve the aim of reducing aneurysm or pseudoaneurysm formation in new VA by 50% within one year. Weekly audits of Chairside VA assessment monitor adherence to cannulation plan. The monthly quality score VA-in-use percentage reflects VA longevity. Continuous assessment of patients’ care experience and the team’s adherence to the cannulation plan will identify opportunities for improvement, and determine the successful adoption of evidence-based practice (EBP).
Reducing Vascular Access Complications Through Precise Cannulation Plan

Implementation

End-Stage Renal Disease Quality Incentive Program (ESRD QIP) promotes patient health by providing a financial incentive for renal dialysis facilities to deliver high-quality patient care. ESRD QIP allows the Centers for Medicare & Medicaid Services (CMS) to apply an appropriate payment percentage reduction, of up to two percent, to facilities that do not meet or exceed established total performance scores. Preserving the longevity of the vascular access (VA) through VA complication prevention will positively impact all of the ESRD domains: dialysis adequacy, and VA measure under the clinical care domain; National Healthcare Safety Network (NHSN) blood stream infection, and dialysis event reporting measure under the safety domain; In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) under the patient and family engagement domain; Standardized Readmission Ratio (SRR), Standardized Hospitalization Ratio (SHR) under the care coordination domain (CMS, 2019).

Problem Description

Vascular access (VA) is considered as both the lifeline and the Achilles’ heel of hemodialysis therapy. The ultimate quality indicator is the effect of the access on patient mortality and morbidity. Complications associated with the VA constitute the most common cause of patient hospitalization. In addition to choosing the best access type, prevention of access complications has high priority in dialysis therapy. Cannulation practice particulars positively and negatively influence the VA survival (Parisotto et al., 2014).
Available Knowledge

In outpatient hemodialysis patients, does site rotation cannulation preserve the longevity of the vascular access compared with same area cannulation? The National Kidney Foundation (NKF) produces clinical practice guidelines through the NKF Kidney Disease Outcomes Quality Initiative (NKF KDOQI). This program has provided evidence-based guidelines for all stages of chronic kidney disease (CKD) and related complications since 1997. Rotation of cannulation sites, also known as rope ladder cannulation, was included in the list of guidelines in 2006 to avoid pseudoaneurysm formation, and again in 2018 based on moderate quality of evidence.

A search of the PUBMED database was conducted using the keywords dialysis, access, fistula, complications, site rotation cannulation, and exsanguination. The search yielded a sufficient number of relevant articles. Seven articles with dates ranging from 2011 to 2018 were found that supported the evidence, and thus selected for review. The articles included in the literature review describe how the various cannulation methods influence the development of vascular access complications, and the longevity of vascular access survival. Table 1 provides a summary of the characteristics of the reviewed articles.

Table 1

<table>
<thead>
<tr>
<th>Author(s), Year and Country</th>
<th>Area of Study</th>
<th>Sample</th>
<th>Study Design</th>
<th>Results Outcomes of Cannulation</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handlos Marecová Smananová Dvořáček &amp; Dobiáš (2018)</td>
<td>Lethal hemorrhage from arteriovenous fistula.</td>
<td>n = 2 cases of sudden deaths of people with ESRD.</td>
<td>Case report.</td>
<td>One death was due to exsanguination from an ulcerated arteriovenous fistula.</td>
<td>Examination found a brachio-cephalic AVF near the defect that had bulged into an aneurysm.</td>
</tr>
<tr>
<td>Author(s), Year and Country</td>
<td>Area of Study</td>
<td>Sample</td>
<td>Study Design</td>
<td>Results Outcomes of Cannulation</td>
<td>Conclusions</td>
</tr>
<tr>
<td>-----------------------------</td>
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</tr>
<tr>
<td>Stolic et al. (2017) Serbia</td>
<td>Impact of cannulation technique on the functioning of arteriovenous fistula (AVF) in older adult patients.</td>
<td>n = 110 patients.</td>
<td>Retrospective study.</td>
<td>No consensus about optimal cannulation techniques in the older adult population.</td>
<td>Rope ladder is proposed to allow the healing of stab wounds and to avoid possible complications.</td>
</tr>
<tr>
<td>Parisotto, Pelliccia, Grassmann &amp; Marcelli (2016) Europe, Middle East &amp; Africa</td>
<td>Vascular access (VA) cannulation practices and complications.</td>
<td>n = 10,807 cannulation procedures observed; 171 dialysis units surveyed.</td>
<td>Cross-sectional survey.</td>
<td>Same area cannulation lowers the risk for unsuccessful cannulation. Rope-ladder cannulation is associated with better fistula survival.</td>
<td>Staff training reduces acute VA complications which could potentially prolong VA life.</td>
</tr>
<tr>
<td>Inston et al. (2015) London</td>
<td>Aneurysms of vascular access (AVA) and pseudoaneurysm of vascular access (pAVA).</td>
<td>Experts and active audience.</td>
<td>The Charing Cross Vascular Symposium master class.</td>
<td>Pain and/or rapid expansion, thin shiny or necrotic skin overlying the AVA, scabs, ulceration, or signs of infection are all harbingers of imminent rupture and mandate urgent intervention.</td>
<td>Avoidance of pAVA and AVA at cannulation sites is essential as rupture is a life-threatening emergency.</td>
</tr>
<tr>
<td>Parisotto et al. (2014) Portugal, United Kingdom,</td>
<td>Cannulation effect on VA longevity.</td>
<td>n = 7,058 patients.</td>
<td>Cox regression model.</td>
<td>Rope-ladder may have the initial advantage of favoring progressive</td>
<td>Same area cannulation is associated with a significantly</td>
</tr>
<tr>
<td>Author(s), Year and Country</td>
<td>Area of Study</td>
<td>Sample</td>
<td>Study Design</td>
<td>Results Outcomes of Cannulation</td>
<td>Conclusions</td>
</tr>
<tr>
<td>-----------------------------</td>
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</tr>
<tr>
<td>Ireland, Italy, Turkey, Romania, Slovenia, Poland, &amp; Spain.</td>
<td>Maturation along the entire length of the fistula, but it requires fistula with sufficiently long segments suitable for cannulation.</td>
<td>n = 88 patients from January 2000 to July 2007 at 58 different dialysis facilities.</td>
<td>Case–control study.</td>
<td>higher risk of access failure.</td>
<td></td>
</tr>
<tr>
<td>Ellingson et al. (2012) District of Columbia, Maryland, and Virginia</td>
<td>The epidemiology of fatal vascular access hemorrhages (FVAH).</td>
<td>n = 88 patients from January 2000 to July 2007 at 58 different dialysis facilities.</td>
<td>Case–control study.</td>
<td>FVAH events were likely related to complications affecting the mechanical integrity of the fistula or graft. 72% (n=18) of the 25 AV graft and fistula cases had evidence of access erosion.</td>
<td></td>
</tr>
<tr>
<td>Gill, Storck &amp; Kelly (2011) New York City</td>
<td>Exsanguination from VA sites may cause a rapid death.</td>
<td>n = 100 deaths</td>
<td>Review of the medical examiner records.</td>
<td>Most patients died at home or on the way to the hospital thus reflecting the rapidity of these deaths.</td>
<td>Exsanguination is a mechanism of death caused by treatment-related blood loss due to repetitive needle sticks.</td>
</tr>
</tbody>
</table>

**Rationale**

For hemodialysis access, repeated puncture is inevitable. Each puncture is a mechanical injury to the vascular walls. (Hsiao et al., 2010). Repeated punctures in a clustered area, or same area cannulation technique, can weaken the vascular access wall and cause aneurysm formation. Aneurysms generally require surgical repair if there is evidence of loss of skin
integrity or ulceration. Left untreated, aneurysms are at risk of rupture and exsanguination, as well as limiting the available sites for cannulation (Al-Jaishi, Liu, Lok, Zhang, & Moist, 2017).

In the site rotation or rope-ladder technique, the cannulator changes the needle placement sites for each dialysis, choosing sites at a defined distance along the vascular access line from the previous puncture sites (Parisotto et al., 2014). A ruler or tape measure is an instrument that can be used for measuring distances. Using a disposable paper ruler or tape measure can ensure adequate distance from the previous puncture sites to prevent repeated punctures in a clustered area, or same area cannulation technique.

**Specific Project Aim**

The aim is to reduce the prevalence of aneurysm or pseudoaneurysm formation in a new vascular access by 50% within one year through the implementation of a VA site-specific cannulation plan. Aneurysm and pseudoaneurysm formation have been misconstrued as “normal” or “common” by staff members. If aneurysms or pseudoaneurysms form, staff members may not be leaving a proper distance between cannulation sites, or the cannulation segment of the access is too short for site rotation. Too short a segment for cannulation should be discussed with the surgeon (Ball, 2013). Using a disposable ruler or tape measure to measure the VA as opposed to “eyeballing” the VA to estimate its length provides the precision required to design an appropriate cannulation plan.

**Context**

The local outpatient in-center hemodialysis facility has an average of 20 chairs and run three shifts per day. One patient care technician (PCT) is assigned a pod of four patients per shift for a total of 12 patients a day. The PCT works under the supervision of the dialysis registered nurse (RN) who is assigned ten patients per shift for a total of 30 patients a day. Normal direct
patient care (DPC) staffing for the facility would be one charge RN, three dialysis RNs, and eight PCTs.

An engaged medical director, supportive management, and self-motivated teammates create and sustain a patient-centered culture of high performance as evidenced by the team’s ability to meet or exceed established total performance scores. This type of culture consistently earns the facility a 5-start rating from the Dialysis Facility Compare which provides information on more than 7,000 facilities throughout the country. This culture also fosters the team’s willingness to adhere to the Conditions for Coverage (CfC) for ESRD facilities § 494.90 Condition: Patient plan of care (POC) which mandates vascular access monitoring and surveillance for early detection of failure, and the § 494.110 Condition: QAPI which includes the preservation of fistulas, and provides the reminder that fistula survival may be affected by cannulation technique problems (CMS, 2008).

DPC staff members are trained to use the entire length of an AVF or AVG for cannulation in order to prevent aneurysm or pseudo-aneurysm formation; this rope-ladder cannulation method relies on changing the puncture sites for each dialysis treatment (Twardowski, 2015). However, in daily clinical practice, often the same area of the fistula or graft is cannulated for reasons of comfort and ease (Verhallen, Kooistra, & Jaarsveld, 2007). Cannulating the same area ensures a “sure shot” thus avoiding any potential need to “fix a needle” which takes time. DPC staff members consider time as the primary barrier to adequate VA assessment and plan of care (POC).

Introduction of the disposable ruler or tape measure to improve VA assessment and needle site selection to the DPC team can be added to the huddle meeting agenda upon approval by management. Communication, collaboration, and coordination among CNL, management and
DPC team is crucial to launch the project, and sustain the momentum for adopting the disposable measuring tool into the team’s clinical practice. CNL visibility and accessibility provide opportunities to support the DPC team through coaching and positive reinforcement.

**Intervention**

Harwood, Wilson, & Oudshoorn, (2016) determined patient-centered care, teamwork, opportunity and skill, and nurse self-awareness, contribute to successful fistula cannulation. The results of this qualitative study can be applied to interventions to promote change and skill development in DPC team members. The CNL educator can augment the team’s efforts to identify strategies to preserve vascular access longevity by introducing the disposable measuring tool after receiving management approval to communicate, collaborate, and coordinate with the teammates. Including a disposable ruler or measuring tape in the cannulation set-up kit provides a measuring tool which can be used to evaluate both VA characteristics and cannulator factors in the same patient and their combined impact on preserving VA longevity (Besarab & Kumbar, 2014).

The CNL educator, during clinic visits, can also review with the team the basic premise that in the system approach, humans are fallible and errors are to be expected, even in the best organizations (Reason, 2000). The routine nature of dialysis work potentially breeds complacency, which may lead to "mind not on task" vascular access assessment and POC oversights (Wilson, 2010). The CNL can remind the PCTs and RNs that mindfulness is about what people do with what they notice as it is about the activity of noticing itself (Weick, Sutcliffe, & Obstfeld, 2008).
Measures

The quality assessment and performance improvement (QAPI) software program will monitor the project’s outcome through tracking and trending of the monthly VA usage rates, monthly VA intervention referrals, and monthly adverse events. Appendix A details the measure and values. Reviewing the electronic chairside VA assessment documentation weekly will measure compliance with using the measuring tool.

Ethical Considerations

Dialysis is a team sport. Collaboration between the patient, who is on the receiving end of the fistula needle, and the RN or PCT wielding the needle fosters success. One person should not give orders to another person, but both should agree to take their orders from the situation. If orders are simply part of the situation, the question of someone giving and someone receiving does not come up. Both accept the orders given by the situation (Follett, 1925).

The demands of day-to-day practice inevitably shift the logic of action from one based primarily on evidence-based practice (EBP) to one driven more tightly by the cannulation task—the ever-present demands of minute-to-minute practice. Over time, the seductive persistence of pragmatic practice loosens the grip of even the most rational and well-designed EBP (Snook, 2000). The theory of shared leadership can mitigate the impact the theory of practical drift from EBP has on VA complication creation. Engaging the patient through patient education, POC meeting, and cannulation plan designing prior to the first cannulation increases the project’s success. Shared leadership supports the dialysis care team’s volley ball team feature of their work culture.
Results

Introducing the ruler/tape measure intervention was made with the experience the DPC team already had. The team’s experience generated the demand for the formation of a plan to change; experience also dictated how best to incorporate the ruler/intervention into clinical practice. The theory of experience fosters team ownership of the intervention thereby minimizing the occasions in which the CNL has to exercise authority. When it is necessary to speak and act firmly, it is done in behalf of the team’s interest (Dewey, 1938).

In keeping with the microsystem’s process, the charge nurse rolled out the intervention to the DPC team. Instead of a disposable paper ruler, the charge nurse opted to utilize a measuring tool which happened to be plentifully in stock: disposable tape measure. In the interest of time, and for ease of implementation, a huddle meeting was held in lieu of a POC and in-service training. The huddle meeting hosted by the charge nurse at a dialysis station provided an opportunity to introduce the intervention to both patient and DPC team concurrently while providing a demonstration of the intervention in real time on an actual new VA.

One month after the implementation (see Appendix B for Gantt chart), the distance between puncture sites was assessed by measuring the distance between all the puncture sites. The distance measured one quarter of an inch which is the distance stated in the policy. At this point, approval from management was requested and granted to include the distance of one centimeter between puncture sites for AVG per recommendation from the AVG manufacturer (Gore, 2013). The distance between puncture sites for AVF remains one quarter of an inch.

The charge nurse empowered the DPC team to extend the application of the disposable tape measure intervention to existing vascular accesses (VAs). The success of the tape measure intervention on promoting rope ladder cannulation on new VAs makes it easier to “market” for
use on existing VAs. Appendix C details the team’s journey to process improvement. The positive nature of the team’s previous experience with adding a disposable tape measure to cannulation packs for new VAs allows the PCTs to seamlessly incorporate this same practice for existing VAs.

**Discussion**

The starting place for designing or redesigning of dialysis microsystems is to evaluate the four P’s: the ESRD patient population, the people who work together in the microsystem, the processes the microsystem uses to provide services, and the patterns that characterize the microsystem’s functioning (Godfrey, Nelson, Wasson, Mohr, & Batalden, 2003). System mapping serves as the “blueprint” upon which all changes (procedural and/or physical) are designed and analyzed before testing and implementation (see Appendix D for microsystem assessment). It is also a “marketing” tool that facilitates “selling” the necessary changes to other teams and stakeholders. Internal marketing of change elements and process are often overlooked. Without local championship of change, system changes often fail. The importance of this cannot be overstated; the buy-in of local team system members is directly proportional to the local leadership provided by the microsystem champion (Barach & Johnson, 2006).

The dialysis microsystem selected for the measuring tool intervention roll-out featured cooperative patients, willing professionals, and a charge nurse comfortable in the role of change champion. The charge nurse successfully influenced the DPC team to welcome and adopt the change to their daily practice. Practical issues, such as saving clinical time, cost-effectiveness and ease of use (Mathieson, Grande, & Luker, 2018) were resolved by replacing POC meetings and in-service training sessions with huddle meetings, and by opting to use the measuring tool
which the facility secretary keeps in stock for the purpose of measuring the height of patients who are not able to stand.

The CNL educator introduced the precise cannulation plan concept to the microsystem champion through facilitation. Genuine mutual respect; a partnership in learning; a dynamic, goal-orientated process; and critical reflection make for an effective facilitation. Genuine mutual respect is achieved by creating an open learning environment which involves sharing tentative opinions, acknowledging good points and limitations, and expressing uncertainty or sudden insight. The partnership includes the facilitator as a co-learner which creates capacity for the facilitator to take or delegate leadership. Responsibility, however, is shared through a process of negotiation. A dynamic goal-orientated process goes beyond stepping back and simply providing resources to include goal identification, encouraging investigation, giving meaning to activities and indicating appropriate resources. Critical reflection enable growth, enhance significant learning and promote self-direction (Burrows, 1997).

**Conclusion**

The precise cannulation plan implementation concept does not reinvent the wheel. What the project does is invite the clinical team to consider using a tool, such as a disposable ruler or tape measure, to measure the access and distance between puncture sites. Using a measuring tool offers the team an opportunity to align their daily cannulation practice to the evidence-based guideline of evaluating the efficacy of a puncture site (Gore, 2013).

Attempts to introduce the precise cannulation plan implementation to other microsystems were made using the same change process (see Appendix E for change process map). While the lack of sufficient time to implement the plan was quoted by one microsystem to be the barrier to change the patterns of VA care (Bahadori, Raadabadi, Ravangard, & Mahaki, 2016), the
flexibility and the autonomy to adapt the innovation encouraged another microsystem to place an order for disposable tape measure (Mathieson, Grande, & Luker, 2018). Appendix F details the benefit of investing in disposable tape measure.
References


## Appendix A

### Quality Assessment and Performance Improvement Measures Assessment Tool

<table>
<thead>
<tr>
<th>Standard</th>
<th>Measure</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascular access (VA) Evaluation of VA problems, causes, solutions</td>
<td>Arteriovenous fistulas for dialysis using 2 needles</td>
<td>↑ to ≥65% or ≥66%</td>
</tr>
<tr>
<td></td>
<td>Infections per use-life of accesses</td>
<td>↓ to &lt;1% (fistula); &lt;10% (graft)</td>
</tr>
<tr>
<td></td>
<td>VA patency</td>
<td>↑ % with fistula &gt;3 years &amp; graft &gt;2 years</td>
</tr>
</tbody>
</table>

(CMS, n.d.)
Appendix B

Gantt Chart

<table>
<thead>
<tr>
<th>Activity</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduce Measuring Tool Intervention to Management</td>
<td><strong>Y</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Select Measuring Tool of Choice</td>
<td></td>
<td><strong>Y</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Select Patient with New Access</td>
<td></td>
<td></td>
<td><strong>Y</strong></td>
<td></td>
</tr>
<tr>
<td>Huddle Meeting at Selected Patient’s Dialysis Station</td>
<td></td>
<td></td>
<td></td>
<td><strong>Y</strong></td>
</tr>
<tr>
<td>Measure Length of Access</td>
<td></td>
<td></td>
<td></td>
<td><strong>Y</strong></td>
</tr>
<tr>
<td>Plot Cannulation Sites at One Quarter Inch Intervals</td>
<td><strong>Y</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Include Disposable Tape Measure in Cannulation Packs</td>
<td></td>
<td><strong>Y</strong></td>
<td><strong>Y</strong></td>
<td><strong>Y</strong></td>
</tr>
<tr>
<td>Cannulate Next Site One Quarter Inch Away from Previous Puncture Sites</td>
<td></td>
<td></td>
<td><strong>Y</strong></td>
<td><strong>Y</strong></td>
</tr>
<tr>
<td>Assess Efficacy of the Measuring Tool Intervention by Measuring the Distance Between Puncture Sites</td>
<td></td>
<td></td>
<td></td>
<td><strong>Y</strong></td>
</tr>
</tbody>
</table>
Appendix C

PDSA (Plan-Do-Study-Act) Process Map

- **PLAN**
  - Use Tape Measure on Existing Access; graft 1cm distance
  - Huddle Meeting; Patient Education; Tape Measure

- **DO**
  - Used Disposable Tape Measure to Select Site on New Access
  - ¼" Distance Between Puncture Sites After One Month

- **STUDY**
  - Huddle Meeting; Patient Education; Tape Measure
  - Used Disposable Tape Measure to Select Site on New Access

- **ACT**
  - Use Tape Measure on Existing Access; graft 1cm distance
  - ¼" Distance Between Puncture Sites After One Month
Appendix D

Microsystem Assessment

- Purpose: Safe Dialysis, Quality Care
- Professionals: Manager, Nurses, Technicians, Secretary
- Process: Shared Leadership, Huddles, Access Management
- Patterns: Quality Assessment, Performance Improvement
- Patients: With New Access
Appendix E

Change Process Map

- Theory of Experience
- Facilitation
- Situational Leadership
Appendix F

Cost Benefit Analysis

<table>
<thead>
<tr>
<th>COSTS</th>
<th>BENEFITS DERIVED FROM SAVINGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper Tape Measure, 24&quot;, Heavyweight Disposable,</td>
<td></td>
</tr>
<tr>
<td>Blue Markings, 1000/box</td>
<td>Annual Cost per Patient with a Failed Vascular Access (USRDS, 2018)</td>
</tr>
<tr>
<td>Sales Tax</td>
<td>Median Award from Fatal Vascular Access Hemorrhages</td>
</tr>
<tr>
<td>Shipping (MedOfficeDirect)</td>
<td>(Phair, Carnevale, Wilson, &amp; Koleilat, (2019))</td>
</tr>
<tr>
<td>Total Costs</td>
<td>Total Benefits Derived from Savings</td>
</tr>
</tbody>
</table>
IRB Non-Research Determination Form

STUDENT NAME: Rosemarie Quicho

DATE: 11/16/2019

SUPERVISING FACULTY: Robin Jackson MSN RN CNL

Instructions: Answer YES or NO to each of the following statements:

<table>
<thead>
<tr>
<th>Project Title:</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>The aim of the project is to improve the process or delivery of care with established/accepted standards, or to implement evidence-based change. There is no intention of using the data for research purposes.</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>The specific aim is to improve performance on a specific service or program and is a part of usual care. ALL participants will receive standard of care.</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>The project is NOT designed to follow a research design, e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case control). The project does NOT follow a protocol that overrides clinical decision-making.</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does NOT develop paradigms or untested methods or new untested standards.</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does NOT seek to test an intervention that is beyond current science and experience.</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>The project is conducted by staff where the project will take place and involves staff who are working at an agency that has an agreement with USF SONHP.</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>The project has NO funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>The agency or clinical practice unit agrees that this is a project that will be implemented to improve the process or delivery of care, i.e., not a personal research project that is dependent upon the voluntary participation of colleagues, students and/or patients.</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>If there is an intent to, or possibility of publishing your work, you and supervising faculty and the agency oversight committee are comfortable with the following statement in your methods section: “This project was undertaken as an Evidence-based change of practice project at X hospital or agency and as such was not formally supervised by the Institutional Review Board.”</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

**ANSWER KEY:** If the answer to **ALL** of these items is **yes**, the project can be considered an Evidence-based activity that does NOT meet the definition of research. IRB review is **not** required. Keep a copy of this checklist in your files. If the answer to **ANY** of these questions is **NO**, you must submit for IRB approval.