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Improving Postoperative Outcomes in Lower Extremity Amputees Utilizing a Quality Improvement Approach

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This project focused on adult lower extremity amputees from March 2017 through March 2019. The aim was to improve 30-day surgical site infection (SSI) rates by 10% in two orthopaedic populations. Subaims focused on 30-day readmission rates, length of stay, and 30-day mortality rates. The primary intervention of incisional negative pressure wound vac therapy (iNPWT) device application was instituted. This was supported by World Health Organization recommendations, meta-analyses, and consensus statements advising the utilization of iNPWT devices. Plan–Do–Study–Act cycles were aimed at education, operation efficiency, and patient engagement. By March 2019, goals were met for SSI and 30-day readmission rates in each division. Cost analysis showed a savings of $38,500. Improved clinical significance was noted in SSI rates, 30-day readmission rates, and cost in lower extremity amputees. It is unclear whether the innovation led to improvement in the other subaims; however, this revealed areas for additional areas for improvement.

Introduction

Problem Description

It is estimated that 2 million people live with major limb loss in the United States. Astoundingly, amputation proves to be costly to the United States healthcare system, with over $8 billion per year spent on the care of this population (Amputee Coalition, n.d.).

Between 2012 and early 2018, UCHealth surgeons had performed approximately 650 limb amputations, with a steady increase in number due to the initiation of the Limb Restoration Program, a novel multidisciplinary group that cares for patients at high risk for limb loss from a variety of etiologies. Despite the program's goal of limb salvage, limbs often are unable to be saved and must be amputated. Due to the increased amputation frequency in this institution, the importance of creating quality-driven projects aimed at this population, while aligning with the overall organization's goals, was paramount.

The Orthopedic Trauma division at UCHealth had an anecdotal concern for postoperative complications in lower extremity amputees due to frequent readmissions and surgical site complications. Therefore, a review of the postoperative outcomes of lower extremities was assessed over a 12-month period leading into the initiation of this project. Outcomes in lower extremity amputees were evaluated from March 2017 to February 2018 within the Orthopedic Trauma and Foot and Ankle (F&A) divisions. Of concern was a 10.7% surgical site infection (SSI) rate in the Orthopedic Trauma division and nearly 7.4% SSI rate in the Foot and Ankle division. Readmission rates were found to be 11% in the Trauma division and even higher, 26.9% in the Foot and Ankle division. These readmission rates were found to be much higher than the hospital's quality goals of 10.9% for fiscal year 2018. Complete baseline data are found in Table 1.

Available Knowledge

Patients undergoing amputation are at high risk for postoperative complications due to the medical comorbidities that often accompany amputees. For instance, lower extremity amputation incisions have SSIs rates as high as 13.2%–15.6% (Saeed et al., 2015). This population is at risk for repeat surgical procedures with conversion rates as high as 9.4%–19% from a below-knee amputation to an above-knee amputation due to postsurgical complications (Belmont et al., 2011). The American College of Surgeons National Surgical Quality Improvement Program describes that lower extremity amputees have a 43% complication rate, with 79% of these due to wound complications leading to reoperation and wound complications alone accounting for 49% of causality for readmission (Curran et al., 2014).

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Table 1. Baseline Outcome Data From March 2017 to February 2018[a]

Outcomes	Foot and Ankle Division	Trauma Division
Number of patients	27	31
Surgical site infection	7.4%	11.5%
30-day readmission rates	28%	12.5%
Length of stay	7 days	7.46 days
Mortality	0%	10.3%
Use of iNPWT device	44.4%	25.8%

Note. iNPWT = incisional negative pressure wound vac therapy.
[a]Key for patients who were excluded in data: "surgical site infection" excludes those who died, lost to follow-up; "readmission" excludes those who died, lost to follow-up or remained in the hospital >30 days; "length of stay" excludes those who remained in the hospital >30 days or died in initial hospitalization; "mortality" excludes those lost to follow-up. Quantity of patients excluded: Foot/ankle: surgical site infection, none excluded in predata, one excluded in post data; readmit, two excluded in predata, two excluded in postdata; length of stay, two excluded in predata, two excluded in postdata; mortality, none excluded in pre- or postdata. Length of stay trauma: surgical site infection, five patients either died or lost to follow-up in the pregroup, excluded three in postgroup; readmit, excluded seven in the pregroup, excluding four in the postgroup; length of stay, excluded five in the pregroup, excluded one in the postgroup; mortality, excluded two in the pregroup, excluded three in the postgroup.

Amputations are fraught with risks of mortality, with a reported incidence of 30-day mortality rates between 3.6% and 7% (Belmont et al., 2011).

One well-supported intervention to minimize surgical site complications is the use of incisional negative pressure wound vac therapy (iNPWT) devices. In 2016, the World Health Organization (WHO) provided recommendations for use of iNPWT on closed surgical incisions to minimize risk of SSI (Allegranzi et al., 2016). In addition to these recommendations, two large meta-analyses have been published supporting the WHO endorsement of such products. A 2016 meta-analysis assessed 1,311 surgical incisions and found statistically significant rates of reduced wound infections (Hyldig et al., 2016). Furthermore, a 2017 meta-analysis, evaluating 16 studies, found when iNPWT is used in a prophylactic manner to prevent surgical site complications there were again significant reductions in SSI, wound dehiscence, and length of stay (Strugala & Martin, 2017). In 2017, formal international multidisciplinary consensus recommendations were made to include utilization of iNPWT on patients who are at high risk for surgical site complications and specifically were advised in those undergoing amputation (Willy et al., 2017).

To align with Institute for Healthcare Improvement's (2018) Triple Aim of lower costs of care, cost implications for iNPWT continue to be closely evaluated in current literature; however, early support is shown for cost-efficiency of these devices. A 2017 randomized control trial evaluating 220 joint arthroplasty patients found a cost saving of approximately $1,607 in favor of single-use negative pressure wound therapy versus standard dressings and that even more savings could be found in high-risk patient groups (Nherera et al., 2017). Industry data suggest savings up to $11,277 in dysvascular populations such as amputees (Prevena Incisional Management System, 2016).

Over the past year, iNPWT has only been used in 24.2% of the lower extremity amputee population in the Trauma division and 44.4% of the lower extremity amputee population in the F&A division proving slower adoption of this supported intervention. Given the known wound complications seen in amputees as a causative factor in SSIs and readmissions, use of an iNPWT creates an opportunity for improvement in these factors as well length of stay and potential mortality associated with surgery. This project will focus on transitioning all postoperative dressings to iNPWT devices for all lower extremity amputations performed by the Orthopedic Trauma and F&A divisions at UCHealth.

Rationale

Implementation of the new surgical dressings within these divisions was guided by Roger's Diffusion of Innovation Theory as a well-known process used in healthcare systems to aid in the adoption of a new clinical behavior (Sanson-Fisher, 2004). In order to be consistent with this theory, dissemination of this new innovation was not effective merely by providing evidence to support the change, but required the assistance of clinical role models, attainable change, alignment with the values of this organization, and the adaptability of the new innovation within the organization (Sanson-Fisher, 2004). The use of iNPWT at UCHealth had not been fully developed despite its physical presence and known scientific support within the organization to improve surgical site outcomes. Lack of a clinical champion, as well as the seamless obtainment of the device, stood as barriers in its adoption.

Nola Pender's Health Promotion Model (HPM) regards the multidimensional aspects of a patient's previous health-related behaviors, interpersonal and physical environments, perceptions of change, barriers to change, self-efficacy, and the association to eventual achievement of health-promoting behaviors (Murdaugh et al., 2019). The HPM served as a guide for Plan–Do-Study-Act (PDSA) series aimed at patient teaching and involvement for use of incisional wound VAC (vacuum-assisted closure) devices as a tool to improve postoperative wellness. While not all amputees experience poor previous health-related behaviors, many amputations are the late effect of prior self-neglect, and underlying depression, which leads to lack of health-promoting behaviors, as in the case of poorly controlled diabetes (Bhuvaneswar et al., 2007).

Specific Aims

The primary aim of this project was to improve SSI rates in lower extremity amputees by 10% in both the Orthopedic Trauma and Foot and Ankle (F&A) divisions by March 1, 2019—from 11.5% to 10.4% in the Trauma division and from 7.4% to 6.6% in the F&A division. Subaims included the following in the postoperative lower extremity amputee:

- Improve 30-day readmission rates by 5% by March 1, 2019—from 12.5% to 11.8% in the Trauma

division and from 28% to 26.6% in the F&A division.
- Decrease inpatient length of stay following surgery by 1 day by March 1, 2019—from 7.46 to 6.46 days in the Trauma division and from 7 to 6 days in the F&A division.
- Improve 30-day mortality rates by 10% by March 1, 2019, in the Orthopedic Trauma division only (the F&A division had no mortalities in baseline data). Trauma division goals will be to decrease from 10.3% to 9.3% and the F&A division will remain at 0%.

Description of Team Members

Interprofessional team members collaborating on this project include: project lead nurse practitioner, four orthopaedic surgeons, orthopaedic residents, operating room staff to include the orthopaedic service specialists in the outpatient and inpatient operating rooms, professional research assistants, clinic and administrative staff in the outpatient clinics, industry device representative, hospital supply chain staff, electronic health record staff, wound care nursing, and data collection support from Health Data Compass.

Methods

Context

This project was conducted at UCHealth an academic hospital, located in Aurora, Colorado, with over 600 beds (University of Colorado Denver, 2016). UCHealth was accredited as a level 1 trauma center in 2018 with a focus on limb restorative care. The interventions of this project were conducted in coordination with surgeons and staff in the Limb Restoration Program, a multidisciplinary group caring for individuals with limbs at risk of amputation. Four surgeons affiliated with the Department of Orthopedics' Foot and Ankle and Trauma Division were chosen to participate in this project due to their volume of amputations completed in the prior year.

Interventions

The primary intervention for this project was determined following a thorough literature review, discussions with the quality improvement team, and financial approval from the supporting institution to carry the needed devices. The intervention consisted of the intraoperative application of PREVENA iNPWT devices on adult lower extremity amputees, transmetatarsal up to the level of a hip disarticulation. A detailed description of the protocol for iNPWT application and use can be found in Appendix A.

Several evaluative PDSA cycles occurred prior to the initiation of the intervention to ensure its success to include surgeon, resident, advanced practice provider, and staff education about the device and the project. With influence from Roger's Diffusion of Innovation Theory, multiple education sessions were performed to further emphasize the use of the product and goals of the project. Secondary PDSA series focused on organizational efficiency issues dedicated to streamlining obtainment of the device seamlessly throughout the institution. Approval was required from UCHealth's finance department to obtain the correct sizes of the device in all necessary locations including the operating room supply chain, central supply, and outpatient clinics. Electronic medical record order sets were created with the assistance of health information technology staff and department administrators to improve efficiency in obtaining the device in all needed locales. Further education of staff was required once these interventions were completed. A detailed review of the PDSA cycles is highlighted in Appendix B.

In October of 2018, due to concerns for an increase in 30-day readmissions, a final PDSA series was conducted to engage patients through additional postoperative teaching with a wound ostomy certified nurse (WOCN). The WOCN was consulted to perform patient teaching in the Trauma division alone due to surgeon preference to initiate the intervention. The WOCN instructed patients on further incisional care and signs and symptoms of SSI when the incisional VAC was discontinued. The protocol for WOCN teaching was approved by the surgical teams, WOCNs involved, and clinical staff (see Appendix C).

Study of the Intervention

Preintervention data were gathered from March 2017 to February 2018 to compare to postintervention data, which were collected March 2018 to February 2019. Pre- and postintervention data were compared using simple before-and-after percentages, run charts, and Fisher's exact testing as described in the Analysis subsection The intervention began on June 1, 2018; however, surgeons were already using iNPWT intermittently prior to this time frame. Data from March, April, and May 2018 were included in the run charts to improve transparency, internal validity, and minimize bias as the surgeons had already been educated about the devices and the literature that supported their use. However, the results from these months were not included in the final results.

Measures

The primary objective for all outcomes was to further assess postoperative outcomes in this population. Other drivers including alignment with hospital quality goals were included. Descriptions of the outcome measures are listed including rationale for choosing them and operational definitions.

Surgical site infection within 30 days of surgery was defined as an incisional infection, superficial or deep, with one of the following documented signs or symptoms to include pain, drainage, swelling, redness, heat, fever, evidence of abscess on imaging that requires either topical, oral, or intravenous antibiotics. Surgical site infection was chosen by the quality improvement team due to anecdotal concerns, known literature supporting SSI as a complication in the lower extremity amputee, efforts to align with hospital quality indicators, and growing focus on pay-for-performance in reimbursement.

Thirty-day readmission rates were assessed and defined as readmission to UCHealth or any other hospital, for any medical reason, within 30 days of discharge following lower extremity amputation. Thirty-day readmission rates were chosen as an outcome due to concerns for hospital capacity issues, efforts to align with an annual hospital quality goal, and paramount concerns to continue to improve patient outcomes and better quantify how to prevent these in the future.

Length of stay was assessed and defined as time of stay during a single inpatient hospitalization beginning with the first day following surgery for lower limb amputation. This measure was initially chosen due to concerns for capacity issues within the hospital. Supporting literature also described that incisional negative pressure wound VACs may improve pain and therefore minimize length of stay (Strugula & Martin, 2017).

Mortality was assessed and defined as an occurrence of death within 30 days of lower extremity amputation. Surgeons in the Trauma division were interested in measuring and comprehending causation for mortality in this population due to three patient deaths in the preintervention group.

Additionally, process measures included the frequency of the iNPWT device application with a goal to improve adherence to applying the device in 100% of lower extremity amputees at the time of surgery with a baseline adherence rate of 44.4% in the Foot and Ankle division and 25.8% in the Trauma division. Identification of postoperative discontinuation date of the device was tracked to ensure compliance with manufacturer recommendations to ensure devices were being left on the surgical site for 2–7 days. The third process measure evaluated was malfunction of the iNPWT device to include loss of vacuum seal, battery failure, or patient self-discontinuation with a goal of having this documented in 50% of the postoperative clinical notes.

Balancing measures included the evaluation of skin-related complications, as defined as blistering or contact dermatitis with the application of the device. The goal was to have fewer than 10% of patients have these complications. Second, the cost of the iNPWT devices was evaluated to determine the purchase price of the device compared with the cost of a readmission for SSI.

To ensure completeness of data, patients eligible were identified through retrospective chart review utilizing three approaches. The first was through collecting Common Procedure Terminology codes specific to lower extremity amputations as well as the involved surgeons and date of procedure. This algorithm was developed with a third-party company, Health Data Compass. Reports with the above criteria were developed monthly indicating deidentified patients eligible for retrospective review. This data was checked against Epic's (UCHealth's electronic medical record) SlicerDicer application in the same manner. Lastly, billing reports for each participating surgeon were reviewed again using the listed criteria. These reports were run monthly by the project lead. Once chart reviews were completed, outcomes were categorized by individual patient through deidentified means and were categorically entered into REDCap, a secure web application for managing databases.

Analysis

Due to the small sample size, this project was underpowered for statistical analysis. Simple before-and-after comparisons of percentages and rates were utilized. Run charts were used to track the progress of outcomes. Fisher's exact tests were used for the variables of SSI, readmission, and mortality as well as the process measure evaluating frequency of use of the incisional wound VAC device. Fisher's exact tests fall in the category of nonparametric tests, meaning a normal distribution is not necessary, and are best applied in situations where a sample size is small (as in this project with fewer than 50 patients in each category).

Ethics

Initial ethical considerations for this project included assurance that the iNPWT devices followed compliance with the Food and Drug Administration standards for patient use. A thorough literature review of systematic reviews and meta-analyses supported their use with minimal chance of harm to patients. The devices had already been used within the institution and deemed appropriate standard of care for other surgical populations. No monetary, nor nonmonetary, compensation was obtained from the hospital nor iNPWT device company apart from trial devices provided for free and used for surgeon education. Prior to initiation of this quality improvement project, formal approval was obtained through the University of Colorado's College of Nursing Bridge Committee with members representing the Colorado Multiple Institutional Review Board, to verify that no human subjects research was being completed. The author has no competing interests to acknowledge and would like acknowledge surgeons and staff at UCHealth for their assistance in this project.

Results

Figure 1 represents the timeline of events that transpired over the 2 years of project completion. In addition to the system-level phases that were occurring, PDSA cycles were running through the course of the project from April 2018 to November 2018. Again, these centered on staff education, operation efficiency, and patient engagement through education.

Outcome Measure Results

- *Surgical site infection rates.* The project goal was a 10% reduction in each division by March 2019. The Trauma division saw a 33.04% decrease (p = 1.00); the Foot and Ankle division saw a 100% decrease (p = 1.00).
- *30-day readmission rates.* The project goal was a 5% reduction in each division by March 2019. The Trauma division saw a 36% decrease (p = .66); the Foot and Ankle division saw a 70.36% decrease (p = .23).
- *Length of stay.* The project goal was to decrease length of stay by 1 day in each division. The Trauma division decreased by 0.22 days; the Foot and Ankle division increased by 1.75 days.

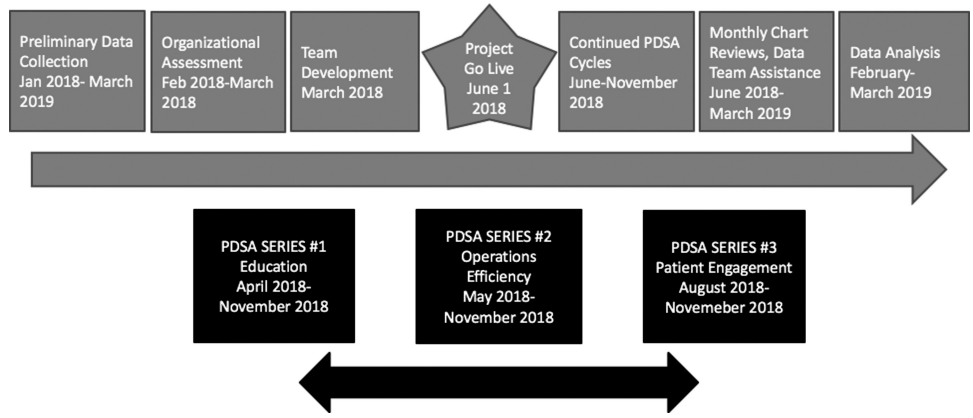

Figure 1. Project timeline.

- *30-day mortality rates*. The project goal was to decrease 30-day mortality rates by 5% in the Trauma division (the Foot and Ankle had no mortalities in the baseline data). The Trauma division saw a 100% decrease ($p = .235$); of note, the Foot and Ankle division saw an increase to 7% in the postintervention group ($p = .3415$).

Process Measure Results

- *Frequency of use*. The goal was to improve application rates of the iNPWT device to 100% by project completion in both divisions. The Trauma division improved compliance from 25.8% to 100% ($p = .0001$); the Foot and Ankle division improved compliance from 44.4% to 92.8% ($p = 0.0028$).
- *Date of discontinuation*. The goal was that each division documented the date of discontinuation of the device in 50% of the postoperative notes. This was documented 90% of the time in the postintervention analysis.
- *Device malfunction*. The goal was that device malfunction(s) be documented in the clinical record 50% of the time. By project completion, two devices were known to have malfunctioned with only one of these being documented in the medical record meeting the 50% goal.

Balancing Measure Results

- *Skin-related complications*. The project goal was to have skin complications less than 10% of the time, as one patient in the baseline data collection had mild blistering with the device. By project completion, 6.9% of the patients had skin complications, all of which were minor and only required local wound care.
- *Cost*. Forty-three devices were utilized at approximately $500 per device for a total of $21,500. There were three fewer SSI rates in the postintervention group, which could have led to a cost savings for the hospital of approximately $60,000 (Ban et al., 2017). Between the costs acquired by using the devices and the potential amount saved in SSI complications, this represents a total cost savings of approximately $38,500. However, due to costs associated with the increased length of stay observed in the Foot and Ankle division, it is likely this is number is inflated.

It is evident that PDSA cycles focused on education sessions among staff and improved acquisition of the device within the institution led to improved utilization of the device, as represented by the statistically significant improvement seen in device use by both divisions. In further evaluation of skin-related complications, it does not appear that the device application led to any significant harm. It is unknown whether discharge teaching led to any patient distress or further confusion, as this was not assessed at the time of administration. To the knowledge of the project lead, the use of several data collection methods ensured there were no known missing data points. All results are depicted in Table 2.

Table 2. Postintervention Outcome Data From June 2018 to March 2019[a]

Outcomes	Foot and Ankle Division	Trauma Division
Number of patients	14	29
Surgical site infection	0%	7.7%
30-day readmission rates	8.3%	8%
Length of stay	8.75 days	7.24 days
Mortality	7.1%	0%
Use of iNPWT device	92.8%	100%

Note. iNPWT = incisional negative pressure wound vac therapy.
[a]Key for patients who were excluded in data: "surgical site infection," excludes those who died, lost to follow-up; "readmission" excludes those who died, lost to follow-up or remained in the hospital > 30 days; "length of stay" excludes those who remained in the hospital >30 days or died in initial hospitalization; "mortality" excludes those lost to follow-up. Data do not include from March 2018 to May 2018. Quantity of patients excluded: Foot/ankle, surgical site infection, none excluded in predata, one excluded in postdata; readmit, two excluded in predata, two excluded in postdata; length of stay, two excluded in predata, two excluded in postdata; mortality, none excluded in pre- or postdata. Length of stay trauma: surgical site infection, five patients either died or lost to follow-up in the pregroup, excluded three in the postgroup; readmit, excluded seven in the pregroup, excluding 4 in the postgroup; length of stay, excluded five in the pregroup, excluded one in the postgroup; mortality, excluded two in the pregroup, excluded three in the postgroup.

Discussion

Summary and Interpretation

An improvement in the primary aim of SSI rates, and subaim of 30-day readmission rates, was noted in this population in both divisions; although not found to be statistically significant both outcomes are of clinical relevance. Length of stay and mortality rates were improved in the Trauma division but not within the Foot and Ankle (F&A) division. Likely length of stay goals were not met within the F&A division due to patient comorbidities and social issue, such as lack of insurance funding for discharge placement. Due to these issues, it is possible that earlier intervention with hospitalists, glucose management teams, or social work would have been helpful. The one patient mortality that occurred was secondary to chronic kidney disease and unlikely related to the surgery or the device, again highlighting the need for more involvement with the hospitalists. There were also population-level differences within the two divisions. The F&A division population was composed of those with complex comorbidities, versus that of the Trauma division's younger, healthier patient population. Perhaps this led to poorer outcomes.

One strength of this project was identification of nuances within an orthopaedic amputee population. This is of importance due to limited literature published on this population versus that of a vascular population. This project also further stratified those differences amongst specific orthopaedic populations. Also, no known published trials are found with utilization of iNPWT in an amputee population.

These findings were comparable to the available literature in that they highlight the complexities of this patient population, such as the multiple risk factors that make them at much higher risk for complications. Overall, the outcomes are difficult to compare, as there is not much literature specific to an orthopaedic population; however, when comparing these findings to dysvascular populations previously studied, these outcomes were better than those described for SSIs, readmission rates, and mortality (Belmont et al., 2011; Coulston et al., 2012; Curran et al., 2014). Length-of-stay data were not found to be comparable due to lack of literature for this outcome in amputees.

A team survey conducted at the completion of the project demonstrated an improved sense of knowledge regarding the intervention, improved efficiency at device obtainment, and agreement to continue utilizing the devices on this high-risk population. One of the six survey respondents was not in agreement with the above consensus; however, further information for discussion was not provided by this team member. Overall, this demonstrates a system-level improvement in the use of these devices however demonstrates that further improvements may need to occur.

Limitations

There were several limitations with this project including the small sample size, which prohibited statistical significance. Also, due to the short timeframe of study, it is unclear whether the results are suggestive of association given the short interval of time captured. There was the potential for bias, as the project lead was employed by the Trauma division and had more interaction with this team and group of patients. This may have led to improved communication and adherence to the protocol. In terms of generalizability, this project was population specific and may not show these findings in other populations. Lastly, not all institutions, particularly those with lower thresholds for financial spending, may not support the monetary upfront costs of purchasing the incisional negative pressure wound VAC devices, limiting the generalizability in other settings.

Conclusions

This project revealed clinically significant results for decreased SSI rates and 30-day readmission rates in each division demonstrating utility of this device across this population. It is unclear whether the interventions conducted had any impact on the other subaims. These outcomes aside, there was statistical significance in adherence to an evidenced-based practice within the institution, which highlights success of the PDSA cycles on diffusion of the device into the institution. In efforts to maintain sustainability of these interventions within this institution, iNPWTs are now accessible in all needed areas of the hospital with greater staff understanding of the device and integrated order sets within the electronic medical record. Literature supporting these devices is now included in preoperative patient education packets. Three of the four surgeons have adopted the device as a routine part of their postoperative protocol, and two of the four surgeons have adopted wound care nursing as routine discharge teaching for these patients highlighting success in change.

Further needs for this project include improved integration with our hospitalists and social work colleagues to continue improvements. This team is interested in submitting institutional review board approval for a randomized control trial looking further at this device within this population and other vascular amputee populations versus standard surgical dressings, as there are no published articles in this population at the time this text was written. Other considerations would include qualitative evaluation of the patient experience with device application and discharge teaching.

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Appendix A. Protocol for Application and Use of Incisional Negative Pressure Wound Vac Therapy Devices

iNPWT Device Application and User Protocol

Updated on March 5, 2018, by Kristin Loker

- Device sizes are determined by the surgical team and are to be placed by the trained surgical team, under sterile conditions at the time of incisional closure in the operating room.
- The use of the device is to be documented in the operative report and billed according to Common Procedural Terminology codes in the surgical log.
- The device is to be placed directly onto a closed surgical incision and remain in place for 2–7 days per manufacturer recommendations with the opportunity to place another device at the surgeon's discretion for an additional 1–2 weeks (Prevena Incisional Management System, 2016).
- The device is portable and follows the patient to the inpatient unit during the period of convalescence.
- If the patient is discharged with the device in place, it is to be removed in the outpatient setting at a maximum of postoperative day 7.
- If the patient remains in the hospital at the time of removal, the surgical team removes the device while inpatient.
- The surgical team is to document in the electronic medical record, the day of discontinuation of the device, the state of the incision and if the device malfunctioned during its use or can report this to the project lead.
- Patients are to be followed up at regular intervals postoperatively to include daily rounding while inpatient while the device is in place.
- If the patient discharges to a subacute rehabilitation facility with the device in place, they are to be seen weekly while the device is in use to assess the incision.
- If the patient is outpatient with the device, they are to be seen postoperatively on weekly intervals for a nursing visit.
- If the device was discontinued and another device was not placed back on, the patient is to be seen week 3 or week 3 after surgery for provider evaluation for suture removal and then at determined intervals based on the appearance of the incision.

Appendix B. Detailed Examination of PDSA Cycles

PDSA Series	Aim	Measure of Success	Number of Cycles	Cycle Dates	Major Cycle Activity (Bulleted Discussion)	Results/Plan
A	Educate team members to improve adherence of incision negative pressure wound vac therapy (iNPWT) application in the operating room setting	Improve application rates of iNPWT in the Orthopedic Trauma Division to 80%, from 23%, and improve application in the Foot/Ankle Division from 48% to 100% by July 15, 2018	2 3 2 1	April 15–30 May 20 to June 11 June 18–22 October 15 to November 15	• Interventions of education began with sessions provided to all involved surgeons and residents • Education sessions were then provided to all staff in the operative settings in the outpatient operating rooms and inpatient operating rooms regarding project and outcomes being evaluated • Trial of workflow began in May • Extended education sessions were required for operative personnel along with product representative to show how products worked and various sizes due to confusion about how the devices worked and what they were compatible with • Full implementation of project began in June 1 • Education sessions were required for outpatient staff due to patient calls with questions about the device • Education reiterated with new staff members in clinic and residents on the Trauma and Foot/Ankle Services	• Interventions began with the surgical staff placing the devices and then were disseminated at their request to the appropriate teams involved • Foot & Ankle Division increased their compliance to 100% by end of June. July data are still pending for their division • Trauma division improved their compliance of application to 100% through July. A decrease in compliance to 75% was seen in May because it was discovered that the inpatient operating room did not have full stock of the appropriate size and therefore one patient did not receive the device. This prompted the second PDSA series • See Appendix A for PDSA Series Run Chart for Foot/Ankle Division, see Appendix B for Trauma division outcomes • Overall improvement seen in both divisions from baseline adherence to application with education series.

Appendix B. Detailed Examination of PDSA Cycles (*Continued*)

PDSA Series	Aim	Measure of Success	Number of Cycles	Cycle Dates	Major Cycle Activity (Bulleted Discussion)	Results/Plan
B	Operations and efficiency improvement to ensure iNPWT stocked appropriately in outpatient operating room, inpatient operating room outpatient clinics and central supply to ensure seamless delivery and adherence to use	Have correct sizes of device in all four locations required with electronic medical record orders to correlate with each device by July 28, 2018	2 2 3 4	May 1–31 June 1–30 June 15 to July 15 July 15 to July 20 July 31 to August 15 November 10–30	• Intervention began with assessment of current stock in all locations • First cycles focused on outpatient clinics. Foot and Ankle Clinic had no supply and required "free product evaluation" forms to be filled out so free product could be provided. Orthopedic Clinic was fully stocked from the beginning • Second cycles focused on inpatient/outpatient operating rooms. Incomplete stock found in both settings. Requires obtaining approval from Finance to order needed sizes of dressings and devices, meeting with central supply managers, Orthopedic service leads • Final cycles focused on Central Supply including staff education in those sessions. Second and third cycles required as the wrong sizes were ordered and the staff had to be reeducated • Fourth cycles included electronic medical records requests placed for unique orders for each size or the device to improve flow of delivery • Email education communication sent to all residents/NPs/PAs/MDs who would be ordering the device about the new electronic medical record orders • August follow-up with central supply and residents to obtain feedback about any issues • Noted that operating room central supply had again run out of the product. Reeducation performed about importance of keeping the shelves stocked in operating room. Continued weekly check-ins to central supply to ensure stock being maintained • Product device recalled due to defective battery. All shelves in all locations check for faulty devices and replaced appropriately with the assistance of the representative from PREVENA	• In April, the only location in the hospital with consistent and proper sizes of iNPWT devices to conduct the project was the outpatient Orthopedic Clinic. This accounted for one of the five locations needed • By May, the Foot and Ankle Clinic had obtained the proper supply accounting for two of the five locations • By June 1, 2018, both the inpatient and outpatient operating rooms had the required supply. Accounting for four of the needed locations. • By July 1, 2018, central supply had ordered the iNPWT device but had ordered the incorrect size. By July 24, 2018, this had been corrected. By July 24, 2018, all five locations. • By July 15, 2018, electronic medical records (EMR) orders were approved and placed into the "live" EMR for each size needed. Email communications had also been sent to surgeons and residents with an update about the new orders as well the location for all stock of iNPWT devices in the hospital • Overall, it took three months to ensure all five departments within the hospital carried the correct sizes of devices for the project with correlating electronic medical record orders in place to ease barriers to implementation • Continued barriers to keeping the shelves stocked, which required frequent check-ins with central supply and operating room. Improved from summer cycles. Only noted that device was not available once

Appendix B. Detailed Examination of PDSA Cycles (*Continued*)

PDSA Series	Aim	Measure of Success	Number of Cycles	Cycle Dates	Major Cycle Activity (Bulleted Discussion)	Results/Plan
C	Ensure that process measures to include percentage of iNPWT use were being accurately tracked and all patients were being logged who fit project criteria	Perform verification checks with surgical logs, Health Data Compass and Epic's Slicer Dicer each month to ensure 100% patients are being captured for data collection by October 1, 2018	1 3 2	July 1–30 August 1–30 September 1–30	• Met with Health Data Compass due to concerns with not obtaining recurrent reports for logging patient data • In August, realized that only two patients were identified by Health Data Compass. Cross-checked with Epic's Slicer Dicer, realized four patients were missing from data • Slicer Dicer access went down with Epic Upgrade. Trouble shot with Epic help desk • Obtained all case logs from billing department for all Common Procedure Terminology codes of interest to perform a third verification to ensure all patients were accurately captured. • Continued meetings with Health Data Compass to ensure algorithm was flagging all needed patients • Cross-checking of Health Data Compass, billing reports and Epic's SlicerDicer was begun	• Obtained new point of contact for Health Data Compass with reprograming of report. Discussed programming error on their end. Report recurred appropriately for August. • Learned that I could obtain case logs from billing to triple check that all patients were being captured based upon Common Procedure Terminology codes. • By October, and through December, data logs were all comparable to all three locations of data collection methods

Appendix B. Detailed Examination of PDSA Cycles (*Continued*)

PDSA Series	Aim	Measure of Success	Number of Cycles	Cycle Dates	Major Cycle Activity (Bulleted Discussion)	Results/Plan
D	Begin engagement of patient participation in health promotion through postoperative incisional teaching to minimize surgical site complications	Perform postoperative incisional care education in 50% of patients at two separate intervals by December 31, 2018	4 2 2 1	August 15–31 September 1–30 October 1–30 November 1–30	• Met with faculty and clinical advisor to discuss plans for fall PDSA cycles due to continued concerns for readmissions • Began discussions with outpatient clinical staff about feasibility of standardized incisional teaching at the patients' first postoperative visit • Met with "skin care champion" physician who advised collaboration with inpatient wound care team to perform postoperative teaching about incisional care during to inpatient postoperative period • Met with inpatient wound care to discuss project and plans for collaboration with fall PDSA cycles • Followed up with inpatient wound RNs/team and provided teaching and developed script and protocol for postoperative teaching • Obtained approval from Trauma surgeons for use of the new protocol • Began implementation of teaching in Trauma patients only in October • November discussed protocol with Foot/Ankle surgeons following use in the Trauma patients as a pilot • Followed back up with wound care team and patients to determine if questions arose or barriers to education	• • Obtained buy-in from clinic RN, athletic trainer to perform standardized incisional teaching in clinic postoperatively • Inpatient wound care team helped to develop protocol and assigned two dedicated RNs to work with the Trauma team patients to perform teaching. • Ultimately the Foot/Ankle Division declined patient teaching by the wound care team due to concerns for concerns about potential for communication errors • Through December 8, three out of four patients received discharge teaching prior to discharge from the hospital. Two of the patients also received additional reinforcement of education postoperatively in the outpatient Trauma Clinic

Appendix C. Protocol for Discharge Teaching

Wound Care Discharge Teaching for Amputees

1. Day of closure, inpatient wound care consult placed requesting postoperative discharge teaching.
2. WOCN RN will perform discharge teaching.
3. Surgical team will discontinue the PREVENA anywhere between postoperative days 2 and 7. If incision is concerning, they may put another one on.
4. If patient is going home with the PREVENA, teaching will be done to include PREVENA basics/troubleshooting and instructions for the incision when the PREVENA comes off (see # 5 below).
5. If wound is without complication and PREVENA is off, recommendations are the following:
   a. Wash hands with soap and water
   b. Clean incision daily with 1/2 capful of HIBICLENS mixed in warm water, rinse well and pat dry (HIBICLENS will go home with the patient)
   c. Cover any open areas with gauze and skin-friendly tape
   d. Place ace wrap, compressive sock and rigid removable dressing back on
   e. OK to shower following removal of PREVENA but no soaking the incision in a pool, bath, hot tub
6. WOCN will also provide education for concerning incision findings (i.e., redness, increasing drainage, dressing changes that need to be more than once/day due to drainage) and will instruct patients to call the Orthopedic Clinic with these findings.
7. WOCN will discuss smoking cessation briefly in those patients who are smoking.
8. If wound looks concerning, WOCN will provide additional recommendations in Epic and notify the surgical team.
9. They will be available as a clinic resource as well for nurse visits if there are issues with wounds at the 1 week postoperative nurse visit.