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Utilization of the Nurse Practitioner Skillset in Partnership with the Medical Device Industry

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Abstract

BACKGROUND: Millions of nurse practitioners (NP), physician assistants (PA), and registered nurses (RN) are optimistic that their current employers will help them reach their full potential. One area that can add value to the hospital and empower employees to work to the full scope of their practice, and utilize the skillsets like that of an NP, is to train these providers to support medical device equipment in the operating room instead of relying on medical device representatives (MDRs) of medical device companies.

METHODS: Training NPs, PAs, or RNs how to support neurological medical device equipment will better utilize the skillset of these providers, ensure patient safety, and allow operating rooms to reduce spending and function autonomously. Literature review for evidence was performed focusing on the impact MDRs have on the operating room and implications for patient care and hospital efficiency. A pilot neurological medical device support training program for NPs, PAs and RNs was developed and evaluated.

INTERVENTION: Medical device training was developed utilizing literature on best practices. Offsite medical device training commenced at corporate headquarters followed by onsite training in the operating room at Swedish Cherry Hill in Seattle, WA. At two intervals, post-offsite and post-onsite training, a 5-point Likert survey was e-mailed to the trained staff at SCH evaluating the effectiveness of the training and each trainees confidence level to support the neurological medical device equipment.

RESULTS: Three SCH employees were trained to support neurological navigation medical devices (2 PAs, 1 RN). All trainees reported positive Likert responses, > 4 (agree), regarding their confidence and independence level supporting the neurological medical device technology for spine surgery following offsite training.

CONCLUSION: This project provides a successful example for future trainings of a hospital and medical device company aligned to support the training of healthcare professionals. Additionally, it informs hospital administrators of a new avenue to save money while simultaneously developing and empowering their employees.

The Problem: Hospital Dependence Upon the Medical Device Industry

Medical device representatives (MDR) are medically untrained college graduates, utilized for their medical device product expertise that the hospital or clinic is not able to independently support. According to the American Medical Association (AMA) Code of Medical Ethics (2022), medical device representatives can pose challenges to patient safety, autonomy and professionalism but play an important role in healthcare – providing medical device expertise to medical providers in clinics and operating rooms throughout the country.

Furthermore, a study by Moed and Israel (2017) found that, from a survey of 127 orthopedic surgeons, over 70% agreed that an MDR should be present for surgery. Currently, it is standard operating room procedure to have an MDR in the room for most medical device procedures. As trained experts, if there is no MDR present to expertly walk surgeons or clinic staff through the technology, the potential for adverse events and poorer patient outcomes increase (O'Connor et al., 2016).

From the perspective of this doctor of nursing practice (DNP), family nurse practitioner (FNP) student who is concurrently employed in the medical device industry, we MDRs will happily support the medical device equipment the hospital has purchased from our company. We enjoy being the experts on our particular technology and medical instruments which can include dozens of sterile trays, hundreds of screws and attachment hardware, or sophisticated computer software.

Furthermore, accepting hospital invitations to support surgeries generates a new revenue stream – surgical support service fees. This surgical support service fee often becomes a lucrative area of revenue for medical device companies and adds to the already substantially

large profit for the medical device industry. In 2020 alone, the medical device industry hauled in $150 billion dollars in medical device sales in the United States (Boodman, 2020).

As the relationships between hospitals, surgeons, and MDRs continue to mature, conflicts of interest have an increasing opportunity to develop. Conflicts of interest consist of transfers of value and include activities such as: consulting, gifts, entertainment, meals, travel, grants, or funding physician research (S.301 – 111th Congress 2009-2010). This was such a public concern, that along with the Affordable Care Act (ACA) of 2010, the Physician Payments Sunshine Act (PPSA) was established (S.301 – 111th Congress 2009-2010). Under the PPSA, this healthcare law mandated that all pharmaceutical and medical device companies become transparent and report all financial relationships with surgeons and hospitals.

In an alternative model without an MDR, where the NP, PA, or RN is trained on medical device support, the medical facility would save time, money, reduce conflict of interest, and provide a higher quality of patient centered care. Hospital systems and patients would greatly benefit from a shift away from the transactional relationships MDRs have with hospitals and towards supporting NPs, PAs, and RNs to assume autonomy in medical device support, which would span from surgery to ambulatory care. Doing so allows patients to receive medical care from medical providers as MDRs do not have a medical license nor fully understand disease progression and diagnosis and treatment within the patient population undergoing surgery.

This problem of clinician and hospital dependency on support from the medical device industry is due to a lack of foresight or communication between hospitals and the medical industry regarding training, education, and fee for support while medical device equipment is being negotiated for purchase. Most hospitals will accept the fee for support from a MDR company to assure surgeries are scheduled at maximum capacity, as they have underdeveloped

infrastructure to support the medical device in house nor do they believe they can support it in the first place.

This clinician and hospital dependency is what benefits the medical device industry the most (Grundy et al., 2018). Many hospitals are investing in this MDR coverage through service support contracts or paying per surgery. This overspending by hospitals is ultimately passed on to the consumer and the inability for the hospital to take complete ownership of their medical device equipment keeps them from actualizing the Future of Nursing goals, to lead change, and advance health (Institute of Medicine, 2010).

Project AIM

The objective of this DNP project is to enhance patient centered care practices among surgical patients through optimization of nursing medical device competencies within the established internal hospital workforce. This will decrease costs incurred by having a MDR present, increase operating room efficiency, utilize the skillsets of the medical providers and help develop professional acumen and promote autonomy among the staff of a hospital operating room.

A GANTT chart, work breakdown structure, and GAP analysis were created to identify areas of improvement and to ensure specific deliverables were attained and addressed throughout the project. These graphical representations can be viewed in Appendix G (GAP), H (Work Breakdown Structure), and J (GANTT).

Available Knowledge

The PICOT question for this DNP project is: Among operating room NP, PA, and RN providers (P), can medical device industry training (I), compared to standard dependence from MDRs for surgical coverage of medical device equipment (C), enhance and strengthen provider

scope of practice autonomy, reduce patient and hospital support costs, and improve patient safety (O) within 150 days (T)?

A comprehensive electronic search for available literature was performed using PubMed, Cumulative Index to Nursing & Allied Health Literature (CINAHL), and Scopus databases. The following keywords and phrases were used: *nurse practitioner, registered nurse, medical device representatives, sales rep, vendor and patient safety*. Journal articles were then selected based on the following additional search criteria: articles from peer reviewed academic journals which were published within the past 20 years.

The search produced a combined total of 735 non-duplicated articles and the Johns Hopkins Nursing Evidenced-Based Practice Appraisal Tool, through the Johns Hopkins University School of Nursing (JHUSN), was utilized to analyze the research (Dang & Dearholt, 2017). This rating scale examines the strength of the evidence (e.g., Level I-V) and the quality of the evidence (e.g., high, good, or low). Articles chosen for final review had to focus on the impact the medical device industry and MDRs have on the operating room *and* NP or RN training provided by a MDR.

However, this type of specific combined evidence was not found in the databases queried. This DNP project is a novel approach to enhancing and expanding the NP skillset while promoting autonomy within the operating room. Studies examined and reviewed herein solely focus on the relationships MDRs have in the operating room with surgeons and staff, their expertise and why they are a critical player, and ethical considerations surrounding patient safety involving MDRs. A complete summary of the literature can be found in the Evidence Evaluation Table in Appendix A.

Research by Moed and Isreal (2017), confirmed surgeons prefer MDRs in the operating room. This study utilized a quantitative 5-point Likert response scale (5 = strongly agree, 4 = agree, 3 = neutral, 2 = disagree, 1 = strongly disagree) related to the preference of a MDR in the operating room according to the generational age of orthopedic surgeons. Descriptive statistics, *t* test, and McNemar tests were used to investigate the difference between two groups of surgeons: Generation X and Baby Boomers. Having an MDR present for all cases was more agreeable within the Generation X group ($p = .001$) as the younger surgeon is more accustomed to MDRs through recent residency training programs (Moed & Isreal, 2017). This study was of good quality and level II according to the JHUSN appraisal tool.

Additionally, Moed and Isreal (2017) wanted to note that most surgeons prefer that the MDR be present during surgery to assist in the learning curve that accompanies the medical device product as surgeons and nurses may lack the appropriate training required to use the device. Over the past few decades, MDR use in hospitals has steadily increased -- and will continue to increase as the medical device industry continues to release more advanced devices used during surgery (O'Conner et al., 2016). With the continual advent of new technology, the necessity for MDRs in the operating room is widely accepted among the surgeons and nurses (Plonien & Williams, 2014).

A study by Gagliardi et al. (2017) sought to explore the relationship between surgeons and MDRs and identify opportunities for conflict of interest among this relationship that may influence patient safety. A descriptive qualitative approach was used to help determine the relationship and according to the JHUSN appraisal tool, this study was of good quality with level III evidence.

This study involved phone interviews with 22 of the 561 participants that were invited: 10 cardiovascular and 12 orthopedic surgeons. Participant surgeons within this study characterized the relationship as symbiotic but realized patient safety could be jeopardized by a failure of the MDR to report device defects (Gagliardi et al., 2017). The study's main highlight was that having MDRs in the operating room to support the advanced technology gave surgeons a sense of relief and peace of mind knowing the difficult medical device technology was handled by a professional -- leaving them to focus entirely on the procedure and not on how to use the technology but realized the opportunity for the conflict of interest in the MDR not reporting a recall or device defect is present (Gagliardi et al., 2017).

Researchers Mueller et al. (2011) aimed to identify themes associated with role conflicts and moral distress experienced by implantable cardiac device (ICD) and pacemaker MDRs in the clinical setting. The researchers were concerned with the ever-growing need for MDRs in the clinical setting as each task the MDR performs directly affects patient care (Mueller et al., 2011). Through the use of focus groups, the researchers used a semi-structured discussion guide to probe and draw out the actual experiences of cardiac MDRs in the clinical setting. This qualitative study design was of good quality and level III according to the JHUSN appraisal tool.

Overall, 17 MDRs took part in the focus group discussion where each MDR shared their clinical setting experiences. Through principles of grounded theory and purposive sampling, the results from the focus groups revealed five common themes from the MDRs associated with moral distress and role conflicts they experience. These included: 1) Relationships with patients, 2) Relationships with clinicians; 3) Role ambiguity with clinicians; 4) Customer service; and 5) Experiences with ICD deactivation. One of the biggest concerns to the researchers was that patients often misinterpreted MDRs as licensed clinicians and often sought healthcare advice

from and asked questions and offered up their own health information that is typically reserved for the medical personnel to make clinical decisions (Mueller et al., 2011).

Additional evidence available for discussion revolved around how NPs and RNs historically learn new medical device technology when it is introduced on the medical surgical floor or operating room. Training for providers typically focused on simple operating use for straightforward technology like that of an automatic blood pressure monitor, glucometer, pulse oximetry or transcutaneous unit from a provider who already knew how to operate the device or the new employee figured it out on the job through trial and error (Douglas et al., 2001).

However, when it comes to supporting and running large sophisticated medical device capital equipment in the operating room, much more attention to detail and proper standardized training is required. One option to assure sufficient training to ensure confidence in practice and reduce risk of serious mistakes includes off-site medical device company training and on-site MDR training during surgery. This DNP project hoped to achieve adequate SCH employees confidence and competence in running medical device technology, autonomous from the medical device company. An actionable SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis was conducted in order to help implement this DNP project and can be viewed in Appendix F.

Rationale

The conceptual frameworks that guided this DNP project was Kurt Lewin's Change Model and Jeff Hiatt's, now Prosci's, Awareness, Desire, Knowledge, Ability, and Reinforcement (ADKAR) model (Lewin, 1951; Prosci, 2021). These models provide the necessary conceptual foundation for those that will take on the task of supporting professionals to practice to the full extent of their scope of practice. Visual representation of each model can be viewed in Appendix D (Kurt Lewin) and Appendix E (Prosci).

Kurt Lewin's change model theorizes a three-stage model for change known as unfreezing-change-refreezing that requires prior learning to be rejected and replaced (Lewin, 1951). Kurt Lewin views behavior as a dynamic balance of forces working in opposing directions. This theory will help explain the restraining and driving forces of change between the NP and RN staff (e.g., new role of supporting medical device technology), the MDR role (technical expertise and reliance of), and the improvement on institutional spending, as well as NP professional development and autonomy (e.g., outcome).

The ADKAR model was developed by Jeff Hiatt in 2006 as a way to organize and systematically manage the people aspect of change. The ADKAR model outlines five major goals an individual, unit, or organization must achieve to change successfully: awareness of the need to change, desire to participate and support the change, knowledge on how to change, ability to implement change, and reinforcement to sustain the change (Prosci, 2021). This will help develop and expand the skillset of NP and RNs to practice to the full extent of their scope of practice and provide the structure needed to sustain the change from dependence to independence of medical institutions from medical device companies.

Kurt Lewin's Change Model

Driving forces to change are fourfold under Kurt Lewin's Change model. First, members of senior leadership have chosen to invest in and develop their staff to support advanced medical device technology and not rely on outside help like that from an MDR. Second, by choosing to believe in their staff, leadership created the environment and built the proper morale that fosters growth and belief in their employees that leadership would like to further utilize their staffs critical thinking and provider skills to enhance the patients overall safe experience and develop their careers further. Third, individual RNs, NPs, and PAs who yearn to develop and add to their

repertoire of advanced skills to become more independent as providers, assisting not only their co-workers but also the patients they help on a daily basis, will help drive the change to autonomy for the operating room. Fourth, and final driving force of change, is the expensive fees for surgical support from the MDR if the staff at SCH does not learn to run the technology. Each case the MDR covers will cost SCH thousands of dollars.

Restraining forces that could hinder change and driving forces include the mental state of each individual NP to be trained. Senior nursing leaders and myself needed to convey the importance of change to the staff – that a new direction of medical device support is needed to improve costs and enhance NP utilization and development. However, being that medical device technology support is currently not in their job description, staff members may be unwilling or question leadership regarding the added work to an already full plate of responsibilities and scope of NP practice within the state of WA.

The final restraining force was a major hurdle to overcome. The COVID-19 pandemic hindered progress to change as available elective surgeries to train on plummeted due to surging COVID-19 cases among the staff and citizens of WA. Today, the SCH operating room is only operating and staffing three of their 18 operating rooms for emergent surgeries. Just recently, Washington Governor Jay Inslee initiated a mandate to temporarily halt all elective surgical procedures until February 17th, 2022 in order to help control the outbreak of cases (Governor Jay Inslee, 2022).

For SCH to be successful in the implementation of change, the first step in successfully changing an environment is building the perception that a change is needed (Groves et al., 2011). This is known as the unfreezing stage. Since most people will naturally resist change, the goal was to create an awareness of the problem we needed to solve (Mitchell, 2013). Once you have

created the awareness, discussed the unacceptable status quo, and communicated to the NPs and RNs of the imminent change, the staff can then be motivated to change.

During Lewin's change stage, NPs and RNs have been unfrozen and will now be free to move in to a new state of operation having learned how to operate the medical device equipment. This is the implementation of change and where the introduction of medical device support within their scope of practice will be fostered among the employees that hold a license to provide care. Nursing and nurse practitioner staff at this stage begin to learn new behaviors, processes, and ways of thinking in contributing to the organizational change (Mitchell, 2013).

The final stage of Lewin's change theory is to then refreeze their new behavior and responsibilities that have just been learned. The refreezing stage establishes the change as the new protocol or equilibrium so that it becomes the standard operation moving forward. Without the refreeze process, the nursing staff could fall back in to old protocols and once again rely on the MDR for operating room support. This will also lead to unnecessary expenses incurred by the hospital for that MDR surgical support.

Prosci's ADKAR Model

The ADKAR model was developed as a way to organize and systematically manage the people aspect of change (Hiatt, 2006). The ADKAR model outlines five major goals an individual, unit, or organization must achieve to change successfully: awareness of the need to change, desire to participate and support the change, knowledge on how to change, ability to implement change, and reinforcement to sustain the change (Hiatt, 2006).

At the beginning, the nurse management team communicated the perceived benefits of owning the medical device support inhouse instead of relying on the MDR to support the procedure or clinic check. This will help develop and expand the NP and RN scope of practice

and skillset. This will bring on awareness and personal ownership to the nursing staff that there is in fact a need to change and that this change will benefit them individual and professionally but also the patient and the organization once the change has occurred. The belief message of change will foster the desire to participate and support the change the organization is looking to implement. Medical device knowledge and skills provided by the local MDR team will give them the ability to change. Reinforcement will come with continued onsite education and surgical case handoff over a specific time period to enforce the learning and independence from an MDR being present for the case as the NP or RN take over full responsibility of operating room support.

Ethical and Policy Considerations

Overall, this project meets approved guidelines set out by the University of San Francisco (USF) School of Nursing and Health Professions, for an evidenced-based change in practice. Approval from USF and SCH was granted in October 2021 for a non-research-based project exempt from Institutional Review Board (IRB) approval with non-research statement of determination located in Appendix L. All participant data will be de-identified. Employee participation, or non-participation, will not affect employee performance evaluations.

This DNP project echoes provision three and seven of the American Nurses Association (ANA) Code of Ethics. Provision three states, “the nurse promotes, advocates for, and strives to protect the health, safety, and rights of the patient” (ANA, 2021). Additionally, provision seven states, “the nurse participates in the advancement of the profession through contributions to practice, education, administration, and knowledge development” (ANA, 2021).

Similarly, the codes of ethics from the ANA parallel those from the Jesuits. In particular, the foundational value of reflection within the Jesuit education (Jesuits, 2021). For example,

using work and educational experiences, reflecting and pausing to consider those and the world around us, and then acting on educational instincts by applying the knowledge. An example of health justice, a Jesuit foundational value, is that when you are agreeing to surgery, you know who is in the operating room and you get the best care from the best trained medical providers the hospital has to offer. This is a value not met when institutions are using MDRs, but would be met with exceptional care when institutions support training for NPs, PAs and RNs.

Interventions/Implementation

Objectives

Specific, measurable, achievable, realistic, and timely (SMART) objectives for this DNP project are listed below:

1. Train one (1) NP/PA/RN operating room provider to support medical device neurological navigation technology for the brain and spine service line by the end of March 2022
2. The trained provider will independently support the medical device neurological navigation system by the end of May 2022
3. Reduce or save hospital spending on surgical coverage fees from the medical device industry by May 2022

Outcome measures of success for the SMART objectives were determined by the number of employees trained and the amount of live surgical case coverages the newly trained employee covers in each specialty. With each incremental case supported by a trained SCH employee – the success of the DNP project will increase as the employee builds confidence and comfort with the technology to move through independence progression. This will ultimately be expressed by high Likert score responses post on-site training.

Within the scope of brain surgery, with a MDR present, the SCH employee is to cover three of the following surgeries to demonstrate adequate understanding of the material supporting the medical device equipment independently. The list includes: brain tumor excision or craniotomy, needle brain biopsy, or frame based deep brain stimulation.

Within the scope of spine surgery, with an MDR present, the SCH employee is to cover three of the following surgeries to demonstrate adequate understanding of the material to support the medical device equipment independently. The list includes: posterolateral spinal fusion (PSF), transforaminal lateral interbody fusion (TLIF), or posterior cervical fusion (PCF). The count of employees trained and the count and type of procedures covered by each SCH trainee is listed in Appendix K.

Cost Avoidance

The final and third objective of this DNP project was focused on saving money. Training medical providers how to support neurological medical device equipment would help eliminate or substantially reduce overspending on medical device surgical support.

This DNP project required little financial investment upfront. The budget set aside for this project was $5,000. Swedish Cherry Hill currently has their neurological medical device equipment under contract and thus have hotel rooms and meals from the medical device company for hospital employee training already paid for. Swedish Cherry Hill chose not to take advantage of their already paid for off-site corporate training in the past or this was lost in translation during their previous purchase of medical device equipment. Transportation costs were the only expense to SCH for this DNP project.

For SCH, this expensive medical device equipment sat unused for years as they were unable to fully utilize its capabilities due to the lack of a neurological service line coordinator

and lack of trained personnel. Since they used it so infrequently, SCH had to pay an MDR to come support the equipment the prior year or just did not use it – more so the latter. This charge for MDR support averages $2,500 per surgery and can exceed $10,000. Now that a neuro service line coordinator is employed at SCH, and this DNP project was presented to them, they jumped at the chance to become independent and develop training of their providers in medical device support.

Travel to official off-site corporate headquarter training was $300 for airfare. Three providers attended the March 2022 training and it cost SCH $900 dollars plus snacks for the entire trip. Three days of normal salary was accounted for each employee and broken down in detail within the cost avoidance summary and budget spreadsheet located in Appendix C.

Following off-site training, on-site training in the SCH operating room occurred focusing on supporting live surgeries while a MDR was present for one month due to COVID-19 restrictions in Seattle, WA. By training with an MDR or supporting the surgery independently, SCH will save around $25,000 a month (assuming 10 surgical cases a month at an average MDR coverage fee of $2,500 per surgery).

Outcome Measures

The official outcome measures of the DNP project include the following:

- The number of trained employees at SCH: This will be measured by counting the number of employees at SCH who have completed off-site and on-site training
- Rating trained employees confidence and independence level supporting the medical device technology in surgery among different software platforms: This will be measured by a 5-point Likert scale questionnaire after off-site and on-site training. Likert questions are located in Appendix B.

- Cost avoidance: This will be measured by totaling the amount of current costs to SCH that help prevent SCH from spending unnecessary money in the future. Cost avoidance statement is located in Appendix C.

Results

Following off-site corporate training in Colorado (CO), a quantitative 5-point Likert response scale (5 = strongly agree, 4 = agree, 3 = neutral, 2 = disagree, 1 = strongly disagree) was emailed to each trained SCH employee assessing how each trainee viewed their confidence and independence level in regards to specific surgical procedures (Spine, Cranial, and Frame based procedures). Similarly, once the trainees returned from CO, and following a month of on-site live operating room surgical training and case support with and without a MDR present, the same quantitative 5-point Likert response scale questionnaire was emailed to each trainee asking them to evaluate their new confidence and independence level.

After off-site training had come to an end, trainee confidence results for spinal procedures were all rated a 4 (agree). Following this Likert question, 100% of trainees agreed that they could independently and confidently support spinal procedures using the neurological navigation system at SCH. Regarding the cranial platform, the results were spread across the board. One trainee rated their confidence level as 3 (neutral), another 4 (agree), and the last 5 (strongly agree). Only 66% of trainees agreed they could immediately cover cranial procedures when they returned to the SCH operating room. When it came to frame based procedures, the most difficult technology platform to master, there was a drop in the confidence and independence level. One trainee rated their confidence level as a 2 (disagree) and the other two rated their confidence level as a 4 (agree), as being able to independently and confidently cover frame based procedures on their own following off-site training. Similar to the cranial software,

only 2 of the 3 trainees (66%) felt confident in covering frame surgeries when they returned to the SCH operating room.

Following some hands-on on-site operating room training, the same 5-point Likert questionnaire was emailed to them in early May 2022. Due to employee turnover at both SCH and the local medical device company, post on-site training Likert responses are still pending. It would be expected, that following off-site training with on-site hands-on operating room training, all trainees would indicate an increase in confidence and independence levels as they gained more hands-on experience with the neurological navigation system during surgery.

Recently, trained SCH employees moved through the application and evaluation phase of the work breakdown structure (Appendix H) and into the independence and intervention phase. Due to the unforeseen employee turnover, this DNP project was unable to move the providers to the final phase of completion and evaluation. Similarly, within Kurt Lewin's change theory, the SCH operating room and trained employees were not able to refreeze the new norms they just learned nor are they able to sustain new outcomes according to Prosci's ADKAR model. The potential for SCH and the trained employees to revert back to their old norms is very high. This includes paying for case support from the medical device industry just after training their employees.

Despite the employee turnover and open evaluation results, the DNP project at SCH has been well received. Additional conversations about sending additional employees off-site for training are occurring as well as discussions to hire a dedicated neurological navigation technologist full-time. This position would be separate from the medical provider team and have more of an equipment technician title and would focus on a larger line of medical device maintenance and surgical support.

Conclusion

Let me be clear, I love the medical device industry and what it has to offer and how it can alleviate pain and improve lives. We all know someone that has benefitted from lifesaving medical technology. However, as this project demonstrated, there is a more patient centered and cost effective manner to deliver the same, if not improved care. There are undoubtedly, incredibly advanced technologies that only a MDR is fully trained to support – we will always need them and we are lucky to have them. On the other hand, there is a good large handful of technologies and products that do not require a MDR to be present but the status quo has hospitals dependent on their support regardless of the fee for that support. This project helped prove that a provider can assume the role of the MDR in surgery with standardized training and support from hospital leadership.

Any patient entering the operating room should receive the best possible care. So it is important to know who is in your operating room and what their roles are at that very moment and in the future. This is where we should all pause and ask if reliance on a MDR is always a good thing or should we train and develop the advanced practitioners that are already involved in the patients care? These providers will already know your medical history and understand the disease process you are having surgery for. I believe this is the better direction to take and thus the basis for the project for hospitals to emulate.

With standardized medical device training for the right providers, and a change in mentality through a proper change model, the hospital culture and operating room can make the switch. The switch from MDR reliance for surgical support to in-house support for medical device technology by professionally developing and enhancing the skillset that is already within

the advanced provider. This will ultimately lead to full autonomy in operating rooms across America and a decrease in adverse events by outside visitors.

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Appendix A: Evidence Evaluation Table

Citation	Purpose	Research Design	Methodology	Findings	Conclusion	Critical Appraisal
Bedard, J., Moore, C. D., and Shelton, W. (2014)	Determine the type and amount of involvement MDRs have in surgery	The researchers conducted a qualitative study through an anonymous web based survey on medical device industry forums	The researchers posted the anonymous survey on a professional medical device forum and two medical device industry healthcare provider LinkedIn groups were asked to participate	It was found that of the 43 MDRs that participated in the survey, 38 had provided direct verbal instruction to surgeons and nursing staff on how to use their products effectively leading to successful surgery. Additionally, it was also discovered that 9 of the 43 MDRs had direct physical contact with the patient without being a medically trained professional	This study raises ethical questions about the reliance of surgeons on medical device reps and device companies for education and surgical assistance as well as practical concerns regarding existing levels of competence among operating room personnel	Good quality, level III

Moed, B. R., and Israel, H. A. (2017)	Determine, based on generation, Orthopedic surgeons need or reliance on medical device representatives in their operating room and whether their need for a MDR impacted their decision on what company's product to use	The researchers conducted a quantitative study to explore relationships and conflict of interest between surgeons and medical device representatives	The researches created a survey using a 5-point Likert response scale, related to conflict of interest, and attitudes toward MDRs. Participants were solicited from the Orthopedic Trauma Association database of 384 active members and 127 (33%) completed the survey. Respondents were divided into two subcategories (Generation X vs. Baby Boomers).	Respondents viewed their DSRs favorably without any perception of conflict of interest. However, they perceived their peers as being at risk for conflict of interest (P <= 0.004). Generation X responders feel that DSRs should be in the OR for all cases, whereas Baby Boomers do not (P , 0.01).	With one generational difference, most orthopaedic trauma surgeons feel that they need MDRs in the operating room. Similar to other physician groups, they also feel that they are not subject to COI from salesman contact that affects their peers	Good quality, level III

Gagliardi, A. R et al. (2017)	This study explored interactions with device industry representatives among physicians who use implantable cardiovascular and orthopedic devices to identify whether conflict of interest (COI) is a concern and how it is managed	A descriptive qualitative approach was used. Physicians who implant orthopedic and cardiovascular devices were identified in publicly available directories and web sites, and interviewed about their relationships with device industry representatives	Twenty-two physicians (10 cardiovascular, 12 orthopedic) were interviewed. Ten distinct representative roles were identified: purchasing, training, trouble-shooting, supplying devices, assisting with device assembly and insertion, supporting operating room staff, mitigating liability, conveying information about recalls, and providing direct and indirect financial support.	Participants recognized the potential for conflict of interest but representatives were present for the majority of implantations. Participants revealed a tension between physicians and representatives that was characterized as symbiotic, but required physicians to be vigilant about conflict of interest and patient safety	Participants described a concurrent tension between hospitals, whose policies and business practices were focused on cost-control, and physicians who were required to comply with those policies. further research is needed to establish the clinical implications of the role of, and relationship with device industry representatives; and whether and how hospitals do and should govern interaction with representatives, or support their staff in this regard	Good quality, level III

Mueller, Ottenberg, Hayes, and Koenig (2011),	This study explored interactions with device industry representatives in the clinical setting with a focus on determining conflicts of interest and feelings of moral dilemmas as employees of a medical device company walk the fine line patient care	The researchers conducted a qualitative study design with an emphasis on focus group interviews	This study involved one large focus group during a national Heart Rhythm Society meeting. It involved 17 currently employed MDRs which discussed their day to day activities, actual experiences, involvement in patient care, and attempted to find any conflicts of interest at clinical sites.	The researchers determined five main themes which encompass the MDR position and their impact on the clinical setting. These included: 1) Relationship with patient: 2) relationship with physician: 3) Role ambiguity with clinician: 4) Customer service: and 5) Experiences with ICD deactivation.	The MDR role is ever expanding in to the clinical setting, so much more, that they are becoming defacto clinicians that patient's often do not know the difference and often view MDRs as healthcare providers.	Good quality, level III

Appendix B

Likert Questionnaire

Post off-site training in Colorado (CO):

Please rank the below questions 1 through 5. 1 strongly disagree, 2 disagree, 3 neutral, 4 agree, 5 strongly agree. Your feedback is crucial to the success of this DNP project, thank you.

1. The off-site training in CO prepared me to confidently and independently support **SPINE** navigated procedures when I returned to the OR.

2. The off-site training in CO prepared me to confidently and independently support **CRANIAL** navigated procedures when I returned to the OR.

3. The off-site training in CO prepared me to confidently and independently support **FRAME/DBS** navigated procedures when I returned to the OR.

Post on-site training at SCH:

Please rank the below questions 1 through 5. 1 strongly disagree, 2 disagree, 3 neutral, 4 agree, 5 strongly agree. Your feedback is crucial to the success of this DNP project, thank you.

1. The on-site training in CO prepared me to confidently and independently support **SPINE** navigated procedures when I returned to the OR.

2. The on-site training in CO prepared me to confidently and independently support **CRANIAL** navigated procedures when I returned to the OR.

3. The on-site training in CO prepared me to confidently and independently support **FRAME/DBS** navigated procedures when I returned to the OR.

Appendix C

Cost Avoidance Summary and Budget

Cost Avoidance Summary			
Plane ticket per employee	$ 300.00		
MA salary for three days	$ 432.00		
PA salary for three days	$ 1,392.00		
Trainee initials	Total cost for three days of training	Cost for future cases (year)*	Cost Avoidance
A	$ 732.00	$ 100,000.00	$ 99,268.00
B	$ 1,692.00	$ 100,000.00	$ 98,308.00
C	$ 1,692.00	$ 100,000.00	$ 98,308.00
		$ 300,000.00	
		*Assumes 10 cases a month for 12 months at $2,500 per case	

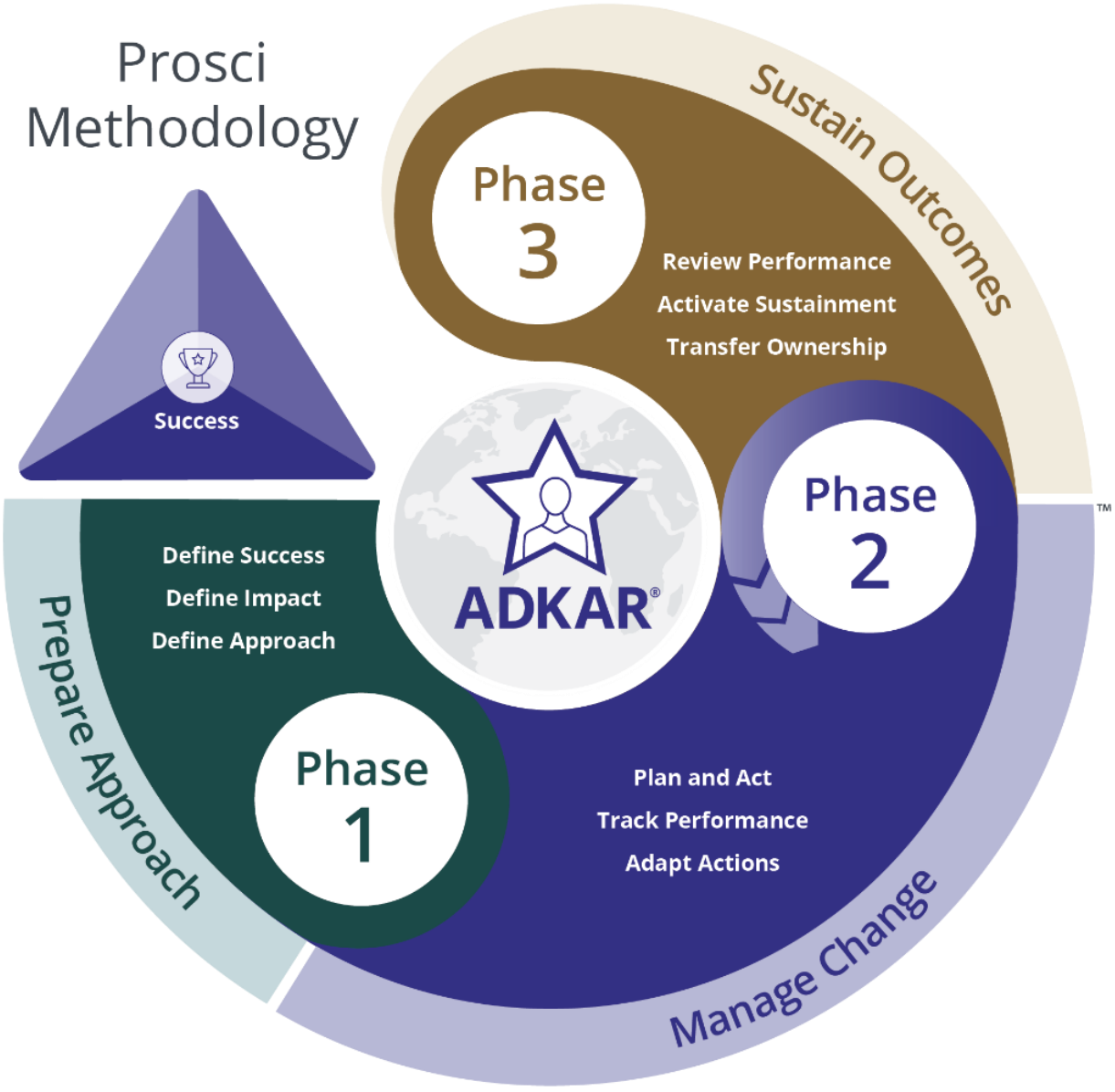
Budget $5,000 for 3 months	
Income	**Amount**
Unknown	Unknown
Total Income	Unknown
Expenses	**Amount**
Airfaire for 3 employees	$900
Taxi (Airport and Hotel)	$120
Snacks during travel	$200
Total Expenses	$1,220

Appendix D

Kurt Lewin's Change Model

Appendix E

Prosci ADKAR Model



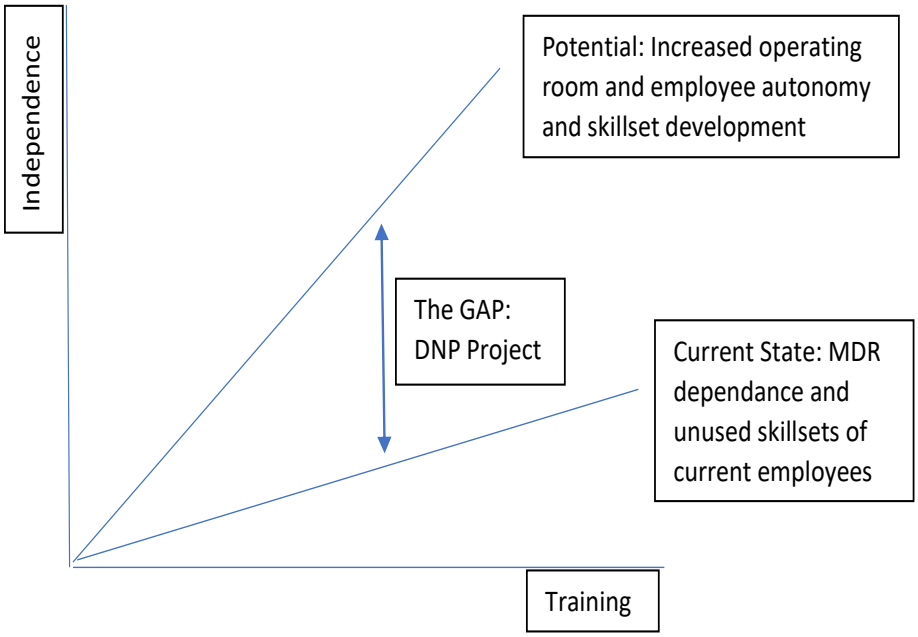
Appendix F

SWOT Analysis

Strengths: • Action has been taken – decision to train current staff or hire new staff to support medical devices has been made • Leadership is ready to make the change from dependance to independence • Physician backing has been achieved • Established and experienced operating room	**Weaknesses:** • Deciding whether to hire internal or external candidate • Training staff on medical device technology is untested • Staff time and availability is limited • Staff training would need to be prior to shift or after shift leading to overtime • Current employees may not be interested in also supporting medical devices on top of their current role responsibilities
Opportunities: • Pilot MDR training program – this project can help other sister hospitals • External candidates seeking higher autonomy from other hospital positions • Development of skillsets for those wanting next level responsibilities	**Threats:** • Ability to control MDR nature • Turnover among the staff due to competitive packages at surrounding hospitals • Lack of qualified candidates to hire from outside the organization

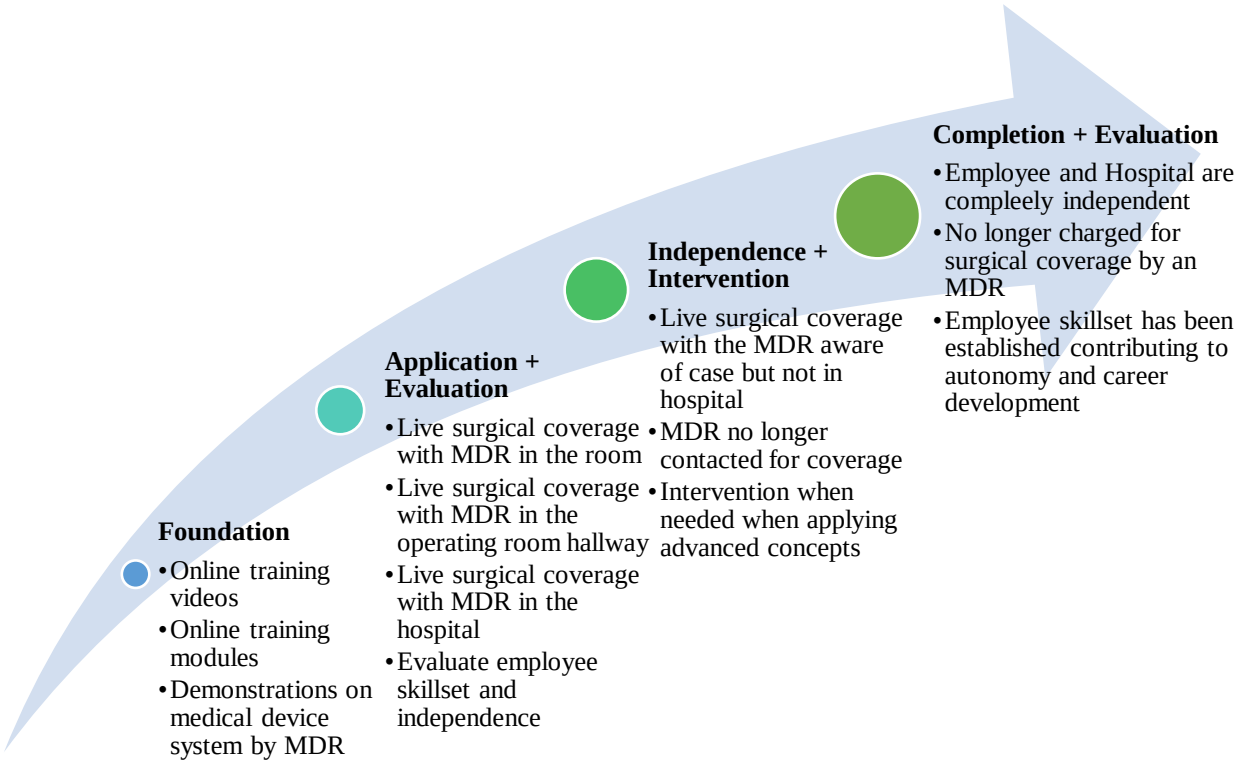
Appendix G

GAP Analysis



Appendix H

Work Breakdown Structure



Appendix I

Communication Matrix

Personel at SCH	Information Discussed	Timing	Method	Month
OR Manager, Neuro/Spine Service Lead	DNP Project Approval	Once	Phone call	October, 2021
Neuro Service Coordinator	Scope of Project, Goals, Outcomes	Once a week	Phone calls, texts	October, 2021
Neuro Service Coordinator	Type of Hire, Pay	Once, ongoing	Phone calls, texts	November, 2021
Neuro Service Coordinator	Training Start Date	Once	Phone call	February, 2022
Neuro Service Coordinator	Foundation: Surgical Training Curriculum	Once a week	Phone calls, texts	March, 2022
Neuro Service Coordinator	Application: Onsite Demonstrations, Live Surgery Coverage Training	Multiple weeks	Onsite	April, 2022
Neuro Service Coordinator and Trained SCH employees	Independence: Live Surgery Hand-off Coverage	Multiple weeks	Onsite	April, 2022
Neuro Service Coordinator and Trained SCH employees	Completion and Evaluation	Once a week	Phone calls, texts	April and May, 2022
Neuro Service Coordinator and Trained SCH employees	Check-ins, cases, independence, confidence, additional trainings	As needed	Phone calls, texts	October 2021 - May 2022
DNP Co-Char	Check-ins, Likert data, research, editing, analysis of data	As needed	Phone calls, emails	January 2022 - May 2022
DNP Co-Chair and Advisor	Check-ins, paper edits, project direction, framework	As needed	Phone calls, emails	October 2021 - May 2022

Appendix J

GANTT Chart

Activity	2021					2022				
	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY
Finalize decision for DNP Project										
Conduct hospital readiness for DNP Project Idea										
Finalize hospital willing to embark on DNP Project										
Decide to hire a medical device technician										
Finalize prospectus										
Train the chosen staff										
Send chosen staff to CO for offsite training										
Transition the employee to independence at SCH										
Finalize DNP project and paper										

Appendix K

Count and Procedure Tally

Procedural Support Count April to Early May 2022

		Procedures						
Trainee Initials (3 Total)	**Title**	**PSF**	**PCF**	**TLIF**	**Crani**	**Biopsy**	**Frame**	**Total Cases Supported**
A	Registered Nurse		1		1		1	3
B	Physician Assistant	3	1			1		5
C	Physician Assistant	2	2		2		1	7

Appendix L

Statement of Non-Research Determination

UNIVERSITY OF SAN FRANCISCO | School of Nursing and Health Professions

Doctor of Nursing Practice

Statement of Non-Research Determination (SOD) Form

The SOD should be completed in NURS 7005 and NURS 791E/P or NURS 749/A/E

General Information

Last Name:	Rowland	**First Name:**	Daniel
CWID Number:	20501195	**Semester/Year:**	Summer 2021
Course Name & Number:	NURS 749A		
Chairperson Name:	Dr. Alexa Curtis	**Advisor Name:**	Dr. Alexa Curtis

Project Description

1. ***Title of Project***

Utilization of the Nurse Practitioner Skillset in Partnership with the Medical Device Industry

2. ***Brief Description of Project***

Clearly state the purpose of the project and the problem statement in 250 words or less.

Enhancing and promoting autonomy for the professional NP in the perioperative and clinical space. Reducing the need for medical device support from the medical device industry by training the NPs on the medical device technology they come across in their respective fields. NP skillset can be broadened and developed to incorporate such tasks like checking a pacemaker, diabetic pump or pain pump in clinic without relying on the medical device rep to visit as well as support for medical device equipment in the operating room thus reducing medical device rep visits and surgical support fees.

3. **AIM Statement: What are you trying to accomplish?**

- What do you hope to accomplish with this project? Aims should be SMART, specific, clear, well-defined, and at a minimum describe the target population, the desired improvement, and the targeted timeframe.
- To improve (your process) from (baseline)% to (target)%, by (timeframe), among (your specific population)

Complete this statement:

To increase / decrease: ____increase medical device NP skillsets_____ (process/outcome)

from: _____minimal NP involvement (0%) _____ (baseline %, rate, #, etc.)

to: _____acceptable NP involvement (50%)_____ (goal/target %, rate, #, etc.)

by: _____6 months_____ (date, 3 - 6-month timeframe)

in: _____new graduate NPs and NPs with heavy medical device patient populations ___ (population impacted)

4 Brief Description of Intervention (150 words).

NP skillset development: train NPs and medical providers alike to support medical devices in the operating room. Training will happen at corporate headquarters and onsite in the operating room.

4a. How will this intervention be implemented?

- Where will you implement the project?
- Attach a letter from the agency with approval of your project.
- Who is the focus of the intervention?
- How will you inform stakeholders/participants about the project and the intervention?

Swedish Cherry Hill, Seattle, WA. NPs and medical providers within the operating room are the focus. Post DNP review with the neurological service line coordinator.

5. Outcome measurements: How will you know that a change is an improvement?

- Measurement over time is essential to QI. Measures can be outcome, process, or balancing measures. Baseline or benchmark data are needed to show improvement.
- Align your measure with your problem statement and aim.
- Try to define your measure as a numerator/denominator.
    - What is the reliability and validity of the measure? Provide any tools that you will use as appendices.
    - Describe how you will protect participant confidentiality.

Outcome:

Measurement of success will be if NP's can take on the responsibilities that the medical device reps currently are responsible for at SCH. These responsibilities supporting certain medical device capital equipment in the operating room within the neuro and spine service line. Utilizing the NP skillset, enhancing it with new medical device skills, then allowing full autonomy of the NP to support and adjust patient outcomes**.**

UNIVERSITY OF SAN FRANCISCO | School of Nursing and Health Professions

DNP Statement of Determination

Evidence-Based Change of Practice Project Checklist*

The SOD should be completed in NURS 7005 and NURS 791E/P or NURS 749/A/E

Project Title:

Utilization of the Nurse Practitioner Skillset in Partnership with the Medical Device Industry

Mark an "X" under "Yes" or "No" for each of the following statements:	**Yes**	**No**
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.	X	
The specific aim is to improve performance on a specific service or program and **is a part of usual care**. <u>All</u> participants will receive standard of care.	X	
The project is **<u>not</u>** 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 **<u>not</u>** follow a protocol that overrides clinical decision-making.	X	
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 **<u>not</u>** develop paradigms or untested methods or new untested standards.	X	
The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does **<u>not</u>** seek to test an intervention that is beyond current science and experience.	X	
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.	X	
The project has **<u>no</u>** funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.	X	
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., **<u>not</u>** a personal research project that is dependent upon the voluntary participation of colleagues, students and/ or patients.	X	
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."*	X	

<u>Answer Key</u>:

- If the answer to <u>all</u> of these items is "Yes", the project can be considered an evidence-based activity that does <u>not</u> meet the definition of research. IRB review is not required. Keep a copy of this checklist in your files.
- If the answer to <u>any</u> of these questions is "No", you must submit for IRB approval.

*Adapted with permission of Elizabeth L. Hohmann, MD, Director and Chair, Partners Human Research Committee, Partners Health System, Boston, MA. To qualify as an Evidence-based Change in Practice Project, rather than a Research Project, the criteria outlined in federal guidelines will be used:

<u>http://answers.hhs.gov/ohrp/categories/1569</u>

UNIVERSITY OF SAN FRANCISCO | School of Nursing and Health Professions

DNP Statement of Determination

Evidence-Based Change of Practice Project Checklist Outcome

Project Title:

Utilization of the Nurse Practitioner Skillset in Partnership with the Medical Device Industry

☒ This project meets the guidelines for an Evidence-based Change in Practice Project as outlined in the Project Checklist (attached). **Student may proceed with implementation.**

☐ This project involves research with human subjects and **must be submitted for IRB approval before project activity can commence.**

Student Last Name:	Rowland	**Student First Name:**	Daniel
CWID Number:	20501195	**Semester/ Year:**	Summer 2021
Student Signature:	Daniel Rowland	**Date:**	6/28/2021

Chairperson Name: Dr. Alexa Curtis

Chairperson Signature: _____ **Date:** _____

DNP SOD Review Committee Member Name: Dr. Trinette Radasa

DNP SOD Review Committee Member Signature: _____ **Date:** _____

Appendix M

Letter of Approval from Agency

DNP Project Approval Email

From: Aissa, Youbirt <youbirt.aissa@providence.org>
Sent: Tuesday, October 26, 2021 10:47 AM
To: Rowland, Daniel <daniel.c.rowland@medtronic.com>
Subject: Re: [EXTERNAL] DNP Project

Hi Dan,

I would be delighted to help work on this project with you. Please let me know how I can assist.

Regards,
Youbirt Aissa CSTIII
Neuro and Spine Service Lead
Swedish Hospital-Cherry Hill Campus
C 480-540-9868

From: Rowland, Daniel <daniel.c.rowland@medtronic.com>
Sent: Monday, October 25, 2021 6:37 PM
To: Aissa, Youbirt <youbirt.aissa@providence.org>
Subject: [EXTERNAL] DNP Project

Hi Youbie,
Great to catch up with you. Glad to hear all the updates!
Thank you for working with me on my DNP project for school, I greatly appreciate it. Please reply with your confirmation regarding my DNP project at Providence Cherry Hill Campus. I can't wait to get started.

Thank you,
Dan