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From the Other Side: Nurses' Perception on the use of Negative Pressure Wound Therapy in Clinical Setting

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Under the mentorship of Wilma C. Matti RN, MSN, Ph.D.

November 2022

Abstract

Negative Pressure Wound Therapy (NPWT) is a revolutionary technology being used more frequently in clinical settings across the United States. Though there has been extensive research on the efficacy of NPWT medically and otherwise, there has been little research regarding the healthcare providers' perception of use of "wound-vacs," the device used for NPWT. As new techniques and/or devices are made available for use in a clinical setting, the burden to educate staff falls upon patient care providers. The administration of NPWT is wholly reliant on a nurse as they are the ones to apply the dressing, change it and document the progress; therefore, the burden of application and monitoring of NPWT rests predominantly on nurses. A study was conducted on the nurses at East Georgia Regional Medical Center in Statesboro, Georgia exploring the time, skill and educational restraints related to learning a new technique and successfully administering it. Using a mixed-methodology approach, 5 voluntary participating nurses completed a self-paced survey answering questions about the use of NPWT in their respective unit. Despite the small sample size, the answers provided valuable insight into how nurses perceive their workload and the efficacy of NPWT in practice. The results suggest that NPWT is effective for patients as proven by previous quantitative studies but it does increase the burden on healthcare providers, though the workers do not have grievances as they are willing to be flexible for the sake of the patients' wellbeing. It is important as we move forward to recognize the increasing skill load in healthcare nowadays, and increase awareness of moderating workload and appreciating healthcare workers.

Keywords: negative pressure wound therapy, registered nurses, perception of efficacy, healthcare workers' workload

Acknowledgement

I would like to extend my deepest gratitude to the Georgia Southern School of Nursing and Honors College. My path to being a successful student and registered nurse was lit by the staff & faculty of the university that are committed to supporting and encouraging a generation of excellence. The opportunities presented to me through this school have made me the tenacious student and worker I am today.

I would also like to thank my mentor and personal cheerleader, Dr. Wilma Matti, for not only her abettance in my academic work, but also for encouraging me to be my best self in all pursuits in my life. Her personal investment in my scholarly advancement has been my inspiration since the start of this journey.

I would like to express my gratitude to East Georgia Regional Medical Center for cooperating with me on this project and making my vision a reality. The nurses at this facility have been the foundation of my search for answers.

This project would not have been possible without the support of my family and friends through my years in college. Specifically, my parents and brother who have played a vital role in shaping my view of the world and my grit. Without them, I would not be the person I am and neither would I be in such a fortunate position, to be able to share my work with my peers.

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From the Other Side: Nurses' Perception on the use of Negative Pressure Wound Therapy in Clinical Setting

When discussing any and all medical interventions, research heavily focuses on how it impacts the recipient of the intervention and its impact on alleviating burden from the patient. Wound care is an integral part of nursing care as nurses are on the forefront of daily wound care in clinical settings. With the radical changes in wound care technology, Registered nurses (RNs) and licensed practical nurses (LPNs) are required to stay current with education and application of wound care devices. Negative wound pressure therapy (NPWT) is one of the new applications that has very successful results. It is a vacuum assisted technique of closing wounds and has yielded very successful results, making it an evidence based practice in nursing care currently. Though the efficacy of negative pressure wound therapy has been tested, its application, which is solely reliant on the administering nurses' ability, is rarely addressed.

An abundant amount of research exists on the quantitative data pertaining to NPWT, but there is very little qualitative exploration on the efficacy & its administration, especially through the lens of a licensed nurse. This study will address topics such as nurses' opinions on NPWT staff education, dressing administration education, patient success rate with NPWT. The study is focused on a nurse's experience with NPWT because as technology is revolutionized for the supposed better of medicine and for patients, its impact on healthcare providers is sometimes neglected in research. Current research in the realm of wound healing and negative pressure therapy is predominantly, if not entirely, focused on the scientific findings and patient experience. This study proposes an alternative approach that is relatively unprecedented as researchers are often not focused on the caregiver's perspective when new medical devices are introduced.

Literature Review

Before engaging in any form of experimentation or designing a study, it is critical to learn from precedent and determine the strengths that can be learned from other research, as well as limitations that can be avoided. Reviewing sources on the research topic provides direction and guides a clinician or researcher through any gaps of knowledge or weaknesses in implementation. However, due to the focus of this study being a relatively unexplored perspective in clinical research, sources were limited. A search was conducted on electronic databases provided through Georgia Southern University's online forum. Most of the literature was retrieved from CINHAL, Pubmed and EBSCO, and were quantitative in nature. Due to the limited information available on the qualitative aspect of negative pressure wound therapy (NPWT) and its impact on healthcare workers, the search was broadened to include the efficacy of NPWT and stressors related to clinical workers.

Negative pressure wound therapy - Wound VAC

Negative pressure wound therapy is often referred to as vacuum assisted wound closure (Wound VAC). NPWT can be used for a variety of wound types, including stage 2 or higher decubitus ulcers, chronic wounds, recent traumatic wounds, and skin grafts (Johns Hopkins, 2022). Wound VACs function incredibly well thanks to the technology underlying the device. The gasses in the atmosphere constantly exert pressure on a person's body. The pressure exerted on one's body when a wound is healing affects how quickly the skin fuses and new skin is produced. With the use of a wound VAC, this pressure is released from the affected area, aiding in the healing of the wound. The term "negative pressure" refers to the reduced internal pressure within the wound. The device pulls the cutaneous layer together and simultaneously eliminates

bacteria- and fluid-filled fluid from the wound site, keeping the region cleaner and drier than a conventional dressing.

There are several parts to the dressing, and all of the pieces serve to create a seal around the wound. First off, there is a foam or gauze dressing that covers the open area, an adhesive film that goes on top to seal the wound and create a barrier between the pressure outside and around the wound. A drainage tube will be placed under the sticky cover of the dressing that connects to a portable vacuum outside. The vacuum suctions the wound either in cycles or consistently, depending on the setting prescribed. Typically, the dressings need to be changed every 24 to 72 hours, varying on the acuity of the wound and whether it is an inpatient or outpatient procedure.

NPWT has revolutionized wound healing in a lot of ways. Since its first prototype in the 1990s, wound VACs have evolved and become increasingly effective. There are several settings for the pressure on the VACs now, which diversify the types and acuities of wounds that can be treated. Despite the growing array of wounds that are treatable with NPWT, some conditions are still untreatable with this technology. Examples include anastomosis sites, exposed vessels, nerves or organs, malignant wounds, untreated osteomyelitis, necrotic tissue with eschar and non enteric fistulas (Pertea et al., 2018).

The evidence is overwhelmingly positive for the use of wound vacs and in a way, it has revolutionized wound care. A research study conducted by Pariza et al. in 2021 followed a randomized group of 17 patients with varying types and sizes of wounds through their healing process in the hospital treated with the use of negative pressure wound therapy. The purpose of the study was to understand the efficacy of NPWT. The study yielded a favorable outcome for 10 patients. 7 patients' wounds did not heal within a healthy amount of time and the length of stay was almost doubled in this group. There were several patient factors such as comorbidities, age,

overall health status that exacerbated the wound healing time but such factors were present also in the group with a favorable outcome. Despite wound vacs being an excellent therapeutic option, they are not beneficial for all wounds.

Nurses' Workload & Burnout

Though it is well documented in nursing literature that nurses feel overworked and unable to meet daily patient demands, nursing research is rarely done to shine a light on the increasing burden of responsibility that falls upon nurses with new technology being introduced to patient care. Burnout has been on the rise in the nursing field due to increasingly demanding work conditions and migration of workers out of bedside nursing. Burnout is defined as "a syndrome comprising emotional exhaustion, depersonalization and a reduced sense of personal accomplishment" (Zhang et al., 2018). It is caused by prolonged exposure to chronic stress in a workplace. Typically, the worker feels inundated and experiences a detachment from work due to the stress. Nursing is a profession with a reputation for high stress, high demand environments. Role demands in a hospital from a nurse are described as "excessive" and workload holds a key link between burnout and satisfaction (Dwinijanti et al., 2020). While there may be multiple factors influencing an individual's satisfaction in a job, it is important to acknowledge and advocate for the nurse in a consistently dynamic field. Even within the confines of healthcare professionals, nurses have a higher rate of burnout than other roles. This begs an explanation for why and demands change in the healthcare industry.

A nurse's workload is generally reliant on a multitude of factors, some controlled by the nurse, some by the facility and even some dictated by the law. Griffiths et al., (2020) performed a systematic scoping review and discussed nursing workload in relation to staffing methodologies and discovered that many tools used by states and facilities to determine staffing averages have

high discrepancies and do not accurately reflect needs for units. When nurses are consistently assigned more patients than what is considered safe according to a unit or state's guidelines, not only is the provider's mental health jeopardized, there is also a trend of worse patient outcomes and declining standard of care provided.

Technological changes in nursing

The use of technology in healthcare is on a steep incline, and likely will continue to trend upwards with time. The implementation of electronic health records was a turning point for caregivers as it moved the industry to the digital era. Information technology in hospitals is a growing field as an increasing amount of equipment utilized on a patient is digitalized and requires re-learning for nurses that have been in the field for more than 10 years. The median age of a registered nurse in 2020 according to NCSBN was 52 years old, and hospitals employed 54.8% of the workforce. A cross-sectional study performed in 2020 by Ozan and Duman highlighted that novice nurses had a negative perception of technology due to the lack of clinical guidance and expressed an increased need for learning in technology. Ages above 35 included in the survey had concerns regarding the dehumanizing of care provided due to the use of technology and the time-consuming process of learning new systems. The study showcased that while nurses may hold a positive perception towards technology implementation in healthcare, problems exist on both ends of the spectrum, with novice and experienced nurses.

Methods

Setting

This study was conducted at the wound healing center of East Georgia Regional Medical Center (EGRMC). EGRMC has a special unit dedicated to caring for patients with wounds that require specialized care. The unit is committed to safely handling wound dressings, wound-related devices and implementing practices to decrease healing times and hospital stays. The wound healing center has an outpatient facility as well where patients with chronic wounds can receive flexible care. The nurses in this unit provide care with NPWT and are experts in wound care.

Research Design

A mixed-method research design was employed for this study. It is a combination of qualitative and quantitative data, which allows for a more comprehensive view of the research question. As the healthcare sector demands a multifaceted approach, this research design allows such a complex problem to be approached in the most holistic manner (Smajic et al., 2018). A focus group interview was considered at the beginning of the research process but due to obstacles such as COVID-19 restrictions and monetary and time constraints, a voluntary survey was deduced as a more feasible method.

Population and Sampling

The research was aimed at licensed and registered nurses that administer negative pressure wound therapy. Any nurse that handles negative pressure therapy devices, also known as wound-vacs, could have participated in the research. East Georgia Regional Medical Center works closely with Georgia Southern University, therefore it was a convenient choice for conducting the study. There are over 200 registered nurses employed at EGRMC, not all of

whom work with wound-vacs. Typically, the wound care team is assigned to apply, change and maintain wound-vac dressings. This narrowed the number of viable candidates for the study and further limited the study's scope in the area.

Upon IRB approval, a flier was developed to encourage survey responses from nurses at the wound care center. The flier was distributed through the education liaison to the wound care nursing staff at EGRMC. No incentives were provided, and participation was voluntary. A total of 6 total responses were collected. The small sample size, 2.9%, can be considered a limitation for this study. The survey revealed a clearly positive attitude towards NPWT. Most participants agreed that the labor burden of the therapy was worth the results for the patient. However, due to the sample size, no broad claims can be made about the nursing staff's views on NPWT.

Data collection method and process

The data was collected through an online questionnaire built using Qualtrics to ensure proper data collection and storage. Through discussion with peers, research about NPWT and conferring with faculty members, a questionnaire was designed. Literature relating to concepts such as workload delegation, burnout and time management pertaining to the field of nursing aided the line of questioning in the survey. The draft was then distributed to two mentors, who provided insightful feedback and criticism. The recommended changes were implemented to create a more credible survey.

The process of collecting the data was straightforward as the researcher did not have any direct contact with any participants. The final survey's link was embedded in a QR code on the flier, and the flier was emailed to the hospital liaison who circulated it on the floor. When an individual scanned the QR code on the flier, the first page of the survey presented is a consent form and the rights of the participant. If the individual did not consent, the survey immediately

ended. The online survey was the only form of data collection, no other forms of manipulation or experimentation were implemented. Data collection began promptly after IRB approval and the survey was kept open for one month thereafter.

Results

To explore nurses' perceptions of the clinical use of negative pressure therapy, nurses at EGRMC were asked a series of 13 questions in an online survey that was a mix of multiple choice and open text answers as seen in Appendix A. The survey asked the participants about their current role at EGRMC. Out of the five participants, 4 of them were RNs, and all of them provided wound care services. This validated the information collected by the survey and ensured that the questionnaire was reaching its target audience. Much of the data collected was quantitative in nature and provided a statistical perspective of the situation. The data surfaced some standard revelations that are to be expected in a profession that heavily circles the patient.

On average, the nurses reported having to change/assess 4.4 dressings a day, with a minimum of 2 and maximum of 10. Applying a new device took 15 minutes on average and changing dressing took 13.75 minutes. 2 nurses reported having experience in wound care before the use of NPWT. In elaborating on the difference in workload due to wound vacs, one of the nurses wrote "takes more time to prepare dressing changes, more care" and another responded "wound [vacs] normally cut the healing time by half". When asked about comparing the wound healing times exclusively based on experience, the nurses replied that there were too many variables to accurately reply.

At EGRMC, there was no specialized certification required to handle wound vacs but floor nurses typically did not administer NPWT as there is a dedicated wound care team. The wound care team did receive on the job training for the wound vacs, and also had company representatives that educated nurses if a new device was introduced.

Not all of the questions were answered by every participant, which gave a skewed outlook on the data but it was important to provide autonomy and voluntarism to the recipients.

Out of the collected data, all of the nurses reported that ultimately, the introduction of NPWT was beneficial to the patient, and more effective in treating wounds than before its implementation. On the flip side, 100% of the respondents also agreed that wound vacs took longer to prepare and implement than regular dressings. The nurses justified it by comments such as "if it is beneficial to the patient, it is worth adjusting" and "it's helpful to those who are helped by it, we adjust". There were no additional comments by the participants at the end of the survey.

Discussion

The results of the study allude to an expected conclusion. A myriad of medical technology is present on hospital floors nowadays, which mandates an inflation of skilled nursing care. NPWT is one of the many treatments that has been lengthened by the introduction of technology and machinery in healthcare. All of the nurses surveyed agreed NPWT increased the workload and took more skilled labor than a conventional dressing change. Implementation of negative pressure wound therapy is reliant on trained medical personnel, and while the initial insertion in most cases occurs in an OR by a surgeon or experienced scrub nurse, the subsequent burden falls on a wound care nurse (Zaver & Kankanalu, 2022). Wound care provisions account for 66% of a nurse's time according to a survey commissioned by Fletcher and Wasek in 2016. This is a statistically significant value when considering effective nursing care and how to provide the best experience for the patient and the nurse.

The data collected from EGRMC showed that on average, nurses changed/applied 4 dressings per day, which correlates closely with the average of 3-5 dressings per day provided by Fletcher and Wasek (2016). The act of the dressing change or application on average does not take longer than 15 minutes, though the multitude of variables surrounding the dressing change can typically take longer than 30 minutes for each patient. Taking the following factors into

consideration and accounting for the amount of patients a wound care nurse provides for in one day, the nurse's workload grows exponentially.

Data collected about specialized training required for NPWT was inconclusive. Open text answers varied from needing no training to requiring on-the-job training and also continuing education training.

Two participants who had experience in wound care before the introduction of NPWT reported an increase in time spent on dressing change after the new treatment protocol but also that healing times were "cut in half". This speaks to the efficacy of wound vacs from a subjective perspective. The question about comparing healing times also yielded no conclusive results, which could be implying an improper phrasing of questions in the survey, or a lack of instruction in what the question meant.

The final questions were in relation to the opinions of respective participants about the use of NPWT and the workload precipitated by it. The answers of these questions were thought provoking and revealing of what it means to be a nurse. All of the participants were in agreement that while wound vacs take longer to implement, the patient is benefiting from its effects and therefore, it is worth adjusting for. The nurses at EGRMC showcased regardful and supportive traits that are integral to what makes a "good nurse" as researched by Lee and Kim in 2019. The vernacular utilized in the open responses suggests that nurses feel a sense of sacrifice when caring for patients that require additional time. This further encourages the idea that nursing is a selfless profession, and in caring for the patients, nurses often overlook self-care.

Limitations

The study's restricted sample size is likely the most notable downfall. Only having data from five nurses limits the generalizability and reliability of the results. More participants could

not be recruited due to the proximity of available hospitals with wound care centers in the area, and the size of EGRMC. Moreover, the survey was fully online and voluntary. There was no incentive to participate, which could have further limited the amount of responses gathered.

There also were 2 questions in the survey that provided no remarkable answers from all participants. This could have been due to the phrasing of the questions and begs for the reliability of the survey as it is a significant amount relative to the number of questions asked. The researcher should have conducted a preliminary study to assess the fluency of the survey before launching it.

Moreover, there could have been additional questions in the survey that may have provided a better insight to how a nurse perceives the time spent on NPWT. Questions such as "how much time does the nurse spend preparing, traveling, assessing and debriding wounds before applying or changing a wound vac?" would have further validated the study and modeled a more thorough investigation of the research question.

Conclusion

Important conclusions were drawn from studying nurses' perspective on the use of negative pressure wound therapy in the clinical setting. Particularly, recommendations were drawn from the results of the survey. Although generalizations cannot be made due to the limitations of the study, recent research and the results from the study can be used to modify policies and make appropriate changes to avoid overworking the bedside nursing population. While technological advances are critical to the success of medicine and patient care, the burden of care should be distributed more evenly among clinical personnel. Nurses are known to put the patient first and that is the ideology nursing school promotes. It is important to cultivate an environment of self-care and voicing opinions for nurses because research rarely focuses on the clinician's perspective. Introducing more staff to reduce the work demand on a single nurse will also aid in balancing the workload of advanced treatments such as NPWT. The overarching goal of introducing these changes is to provide a better experience for the provider and in turn, better care for the patient as the caregiver functions as patient-oriented rather than task-oriented. Through using a research based approach, there is hope for reforming research in healthcare from a subjective perspective.

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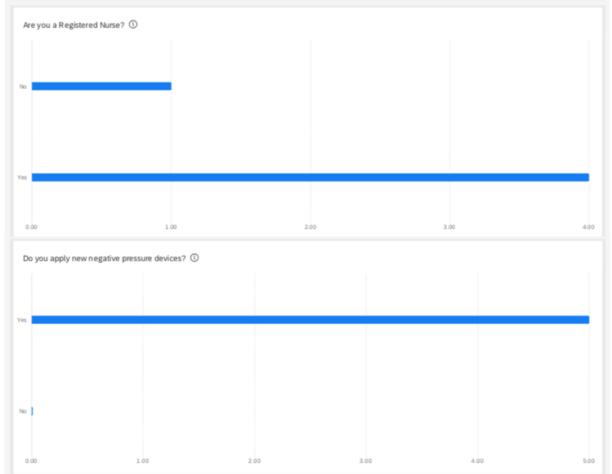
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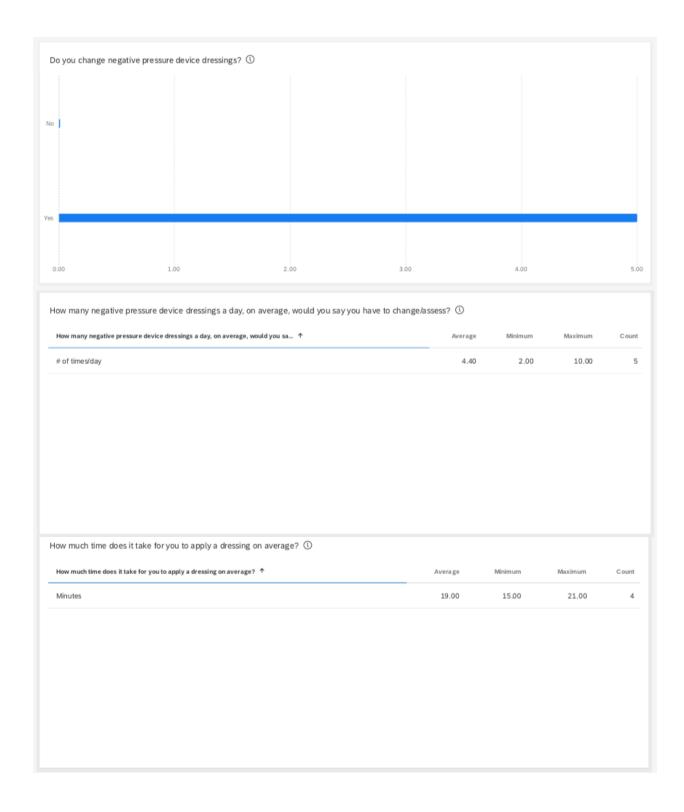
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Appendix A

Informed Consent for Nurses' Perception on Negative Pressure Wound Therapy in a Clinical Setting My name is Chinal Patel and I am a senior year student at Georgia Southern University studying to complete my Bachelor's degree in Nursing. This research is part of my membership in the Honors College at Georgia Southern University. The purpose of this research is to explore the time, skill and educational restraints related to learning and successfully administering negative pressure wound therapy in a typical clinical setting. The study focuses on how the use of a revolutionary technique for wound healing impacts nurses in their job and offers a new perspective on how medical advances impact the healthcare community. Participation in this research will include providing informed consent to take a survey and completion of said survey to the best of your ability. The risks involved with participation in this study are comparable to risks experienced on a daily basis. No identifying information will be asked. The study is about the opinions of nurses; therefore, honesty is crucial and to encourage it, the survey has been made a nonymous. The raw data from the surveys will only be made available to me as the primary investigator during the data gathering phase. After the study is complete, the data will be stored in a password protected on a cloud database, accessible only by me, for probable further studies or validation for the next three years. During this time, your identification will be kept confidential, and after three years, the data will be destroyed. Deidentified or coded data from this study may be placed in a publically available repository for study validation and further research. You will not be identified by name in the data set or any reports using information obtained from this study, and your confidentiality as a participant in this study will remain secure. Subsequent uses of records and data will be subject to standard data use policies which protect the anonymity of individuals and institutions. The benefits to you as a participant include a chance to voice your opinion on the restraints or advantages that you experience on the job with increasing radicalization of medicine. Nurses are very rarely asked their opinions in a clinical setting, so this is a way for you to be heard by a large audience and have your voice matter. The benefits to society include a unique and rare opportunity to look into the workload of a nurse, their grievances but also, their understanding of timeload versus benefit analysis. Though this research may be a local undertaking, I strongly believe it is about time that society became cognizant of the healthcare workers' perspectives. The surview will take annowimately 10 minutes to complete. Participants have the right to ask questions and have those questions answered. If you have question





w much time does it take f	or you to change a dressing on a	average? ①				
How much time does it take for yo	u to change a dressing on average? ↑		Average	Minimum	Maximum	Coun
Minutes			13.75	5.00	20.00	4
ave you treated wounds be	fore the technology of negative	pressure therapy? ①				
00	0.50	1.00		1.50		
	efore the use of negative pressur		e for an open wound to clo	ose properly witho	out wound VACs?	lf you
pends on size of wound and de	epth, usually longer than without vacs					•••
many variables to say						•••
d to say. It varies on type and s	size of wound					•••
		No more results to show				

If you have treated wounds before the use of negative pressure therapy, can you elaborate on how a wound VAC has altered your workload in wound care you have not treated wounds prior to the new technology, please put NA.	? If
Takes more time to prepare dressing changes, more care	•••
Wound vas normally cut healing time by half.	
NA .	
It's not new.	•••
No more results to show	
Do you have to receive specialized training to handle negative pressure devices? If so, how long does it take? ①	
No, standard care	•••
Usually get education from the company representatives, along with in the job training.	
Not specialized training, Just orientation. Watched a nurse do 2 vac changes and then was on my own	
You have to be taught, how many you observe depends on your individual ability to learn and the type of vac. It's OJT	
No more results to show	
How much time do you have to dedicate for achieving and thereafter, keeping up with negative pressure wound therapy certifications? Do you find it to be the time you put in? ①	worth
N/A	•••
You do not have to be certified.	
Certification not necessary	
None	
No more results to show	

What is your opinion on the implementation of negative pressure wound therapy and its impact on your work schedule? ①	
Takes longer than regular dressing change but results are more beneficial	
Wound vac therapy is beneficial to many patients. If it is beneficial for the patient, it is worth adjusting.	
Takes longer than an average dressing. But the wound heals much faster	••
It's helpful for those who are helped by it, we adjust.	••
No more results to show	
Do you have any grievances or alleviations about the use of negative pressure therapy devices, and how it fits into a typical nurse's work shift, that might have not been asked in this survey?	9
not been asked in this survey? ①	•
not been asked in this survey? ① N/A	
N/A Na	••
N/A Na No	
N/A Na No	

Appendix B



Nurses' Perceptions on Negative Pressure Wound Therapy

My name is Chinal Patel and I am a student nurse from Georgia Southern University. I am performing research for my Honors program currently about RNs opinions on the implementation of Negative Pressure wound therapy and its impact on a healthcare worker's workload.

If you are a Registered Nurse and willing to participate in my research, please scan the QR code below with your camera and take this quick 5-to-10-minute survey.

Your participation will give you a chance to voice your opinion to a perceptive audience and allow you the opportunity to be heard about changes that can aid healthcare workers not just here, but anywhere this research is read.

Thank you so much for your time.



Appendix C



Institutional Review Board (IRB)

Veazey Hall 3000 PO Box 8005 • STATESBORO, GA 30460 Phone: 912-478-5465 Fax: 912-478-0719

IRB@GeorgiaSouthern.edu

RESEARCH INTEGRITY

To: Patel, Chinal; Matti, Wilma

From: Eleanor Haynes, Director, Research Integrity

Approval Date: 2/25/2022

Subject: Approval with Conditions from the Georgia Southern University Institutional Review Board –

Exempt/Limited Review

After a review of your proposed research project numbered: "H22232" titled: "Nurses' Perception on Negative Pressure
Wound Therapy in Clinical Setting," it appears that (1) the research subjects are at minimal risk, (2) appropriate safeguards
are planned, and (3) the research activities involve only procedures which are allowable.

Therefore, as authorized in the Federal Policy for the Protection of Human Subjects, I am pleased to notify you that the Institutional Review Board has approved your proposed research with the understanding that you will abide by the following conditions:

You are approved to conduct research at the following locations for which you have obtained letters of cooperation:

- East Georgia Regional Medical Center

Additional locations may be added to this study by submitting additional letters of cooperation.

According to the Code of Federal Regulations Title 45 Part 46, your research protocol is determined to be exempt from full review under the following exemption category(s):

Exemption 2 Research involving only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, if: Information obtained is recorded in such a manner that human participants cannot be identified, directly or through identifiers linked to them. Please visit our FAQ's for more information on anonymous survey platforms; Any disclosure of the human participant's responses outside the research could not reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employ-ability or reputation; Survey or interview research does not involve children; The research project does not include any form of intervention.

Any alteration in the terms or conditions of your involvement may alter this approval. Therefore, as authorized in the Federal Policy for the Protection of Human Subjects, I am pleased to notify you that your research, as submitted, is exempt from IRB approval. You will be asked to notify the IRB upon project completion. If you alter the project, it is your responsibility to notify the IRB and acquire a new determination of exemption.