VAPOTHERM®

The Importance of Early Ambulation

Rehabilitation as a Philosophy of Care to Improve Clinical and Economic Outcomes

WITH NANCY NATHENSON, RRT,
POPULATION HEALTH MANAGEMENT

Adapted with Credit to Nancy Nathenson.
Nancy Nathenson is a paid consultant of Vapotherm.

Bio: Nancy A. Nathenson, RRT, is a registered respiratory therapist and educator with more than 35 years of experience, ranging from ICU to rehabilitation. Her experience has included direct patient care across the healthcare continuum. Nancy served in leadership roles in the ICU as the RT Clinical Critical Care Specialist and as Pulmonary Program Manager in the rehabilitation setting. In her current role as Respiratory Therapy Education Coordinator at Madonna Rehabilitation Hospital in Lincoln, NE, Nancy develops programs, provides continuing education, training and competencies for respiratory therapists and the interdisciplinary team. In her experience she has noted the gaps between levels of care. Bridging those gaps with an early mobility model can bring about a more enriching experience for clinicians and enhance the experience for patients and families while improving patient and financial outcomes. A pioneer and leader in population health management, Nancy develops strategies that are evidence based, community led, and linked across professional domains. She specializes in addressing key clinical outcomes and providing tools for safe, culturally competent, socially and economically equitable care.

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Table of Contents

Introduction

Rehabilitation Not as a Place, but as a Philosophy of Care

Almost anyone in healthcare can likely agree that early mobilization benefits our patients, whether or not they are mechanically ventilated. However, the development of pharmaceuticals for sedation, technological advancements in life support as well as the higher acuity of patients in our Intensive Care Units (ICU) over the years, all present us with challenges as to how to get our patients up and possibly ambulating.[1] The first step toward addressing this challenge is to begin thinking of rehabilitation, not as something confined to a specific location, or hospital department, but as a philosophy of care.

REHABILITATION IS NOT TIED TO A SPECIFIC SETTING—IT CAN AND SHOULD OCCUR IN THE ICU, STEP DOWN UNITS, LTACH, ACUTE REHAB, SUB ACUTE, NURSING HOME, ASSISTED LIVING, AS WELL AS THE HOME.

Rehabilitation is not tied to a specific setting—it can and should occur in the ICU, Step Down Units, LTACH, Acute Rehab, Sub Acute, Nursing home, Assisted Living, as well as the home. All of these settings present caregivers with a continuum of care where they have an opportunity at each step to help patients achieve their cognitive and physical function. The philosophy underlying this approach is one that **views the patient holistically and aims to maximize their independence, their chance of returning to life's roles, and chance to resume their place in their community**. To achieve this end, rehabilitation early on in the continuum of care—also known as pre-habilitation—is crucial in helping to prevent impairments that can lead to barriers to recovery later on.

As mentioned above, there of course are challenges in the way of rehabilitating patients at every step. We are now in perhaps the most technologically advanced era in medical care. From pharmaceutical interventions to high tech tools, healthcare is changing rapidly, and clinicians face challenges from many angles: more complex patients, escalating costs, and a pressing need to improve patient outcomes.[2] However, the argument can be made that amidst the complexities of healthcare systems, there are interventions that address these challenges

[1] Stauffer, J. L., Olson, D. E., & Petty, T. L. (1981). Complications and consequences of endotracheal intubation and tracheotomy: a prospective study of 150 critically ill adult patients. The American Journal of Medicine, 70(1), 65-76.
[2] Lajoie, S. P., Naismith, L., Poitras, E., Hong, Y. J., Cruz-Panesso, I., Ranellucci, J., ... & Wiseman, J. (2013). Technology-rich tools to support self-regulated learning and performance in medicine. In International handbook of metacognition and learning technologies (pp. 229-242). Springer, New York, NY.

Introduction

in ways that benefit both the patient and the clinician. Early mobility is one such intervention. It is a simple, relatively low-cost option that can drastically improve the patient experience and outcomes of care.

Historical Roots of Early Mobilization and the ICU

Early mobilization was identified as being important as early as 1889, though it was not seriously introduced until late during World War II.[3] Medical staff was using early ambulation in an attempt to speed up recovery of injured soldiers in order to return them to the battlefield as soon as possible. The first conference on bed rest was published in 1944 and there was also an international journal titled *The Evil Sequelae of Complete Bed Rest*.[4] A quote from the journal reads as such: "First morale is improved, ... general health and strength are better maintained, and convalescence more rapid."

All these bits of history give indication that we, as a medical community, have known of the importance of early mobilization for generations.

The specialty of Intensive Care Medicine, and with it the ICU, is a little bit younger and originated as a consequence of the poliomyelitis epidemic (1950's and 60's). To combat the disease, widespread mechanical ventilation was needed and the tool of the day was the iron lung, depicted in the reference image here. Patients ventilated via the iron lung could not get up and ambulate.

However, despite these beginnings, technology has evolved and there is precedence of early ambulation and rehabilitation in the ICU. Physician Thomas L. Petty, a renowned pulmonologist, contrasted ICU patients in the 1960s vs today, claiming that decades ago ventilator-dependent patients were awake, aware, and often sitting in a chair where they could interact with others and feel human. Today, on the other hand, they are often sentenced to forced bed rest; lying without motion, and appearing to be dead, except for the monitors that

[3] Morris, P. E., Goad, A., Thompson, C., Taylor, K., Harry, B., Passmore, L., ... & Penley, L. (2008). Early intensive care unit mobility therapy in the treatment of acute respiratory failure. Critical Care Medicine, 36(8), 2238-2243.

[4] Dock W. The Evil Sequelae of Complete Bed Rest. JAMA. 1944;125(16):1083–1085. doi:10.1001/jama.1944.02850340009004

Introduction

provide the telltale signs through beeps and waveforms that indicate life. It is possible for ICU patients to receive holistic and humane care even in today's higher acuity environment.

The ICU Today

According to the Society of Critical Care Medicine more than 5.7 million patients are admitted to ICUs across the United States each year.[5] While this patient population is not a monolith, all ICU patients require increased monitoring. The five most common diagnoses of admitted patients include:

- Respiratory insufficiency/failure
- Postoperative management
- Ischemic heart disorder
- Sepsis
- Heart failure

Thomas Petty also noted that ICU patients are anxious and depressed and required a greater amount of interaction from their care team. Paradoxically many present-day ICUs are not providing this attention. Although the ICU is designed as an important setting of emergency care and recovery, from a patient perspective, the ICU can be a hostile environment. Noise, ambient light, social isolation, and restriction of mobility lead to delirium, sleep deprivation, and imbalances in hormone regulation. Adverse emotional problems can result, leading to loss of sense of self, self-esteem, and social functioning, which can compound the effects of other issues.[6]

80-90% of patients survive their ICU stay[7], but even the accomplishment of medical care of long-term survival of chronically ill patients is dampened by the negative effects of prolonged ICU stays.

To understand the role that early ambulation of ICU patients—whether or not they're mechanically ventilated—can play in improving patient outcomes, it is first important to understand some of the ways in which bed rest adversely impacts a patient's disposition.

FROM A PATIENT PERSPECTIVE, THE ICU CAN BE A HOSTILE ENVIRONMENT. NOISE, AMBIENT LIGHT, SOCIAL ISOLATION, AND RESTRICTION OF MOBILITY LEAD TO DELIRIUM, SLEEP DEPRIVATION, AND IMBALANCES IN HORMONE REGULATION.

[5] Critical Care Statistics, retrieved on February 7, 2019 from https://www.sccm.org/Communications/Critical-Care-Statistics

[6] Walker,J.et al (2007) Psychology of Nurses and the Caring Professions.Maidenhead:McGraw Hill/Open Press.

[7] Critical Care Statistics. Ibid.

The Risks of Bed Rest and Immobility

The Impact on the Body

It is difficult to understate the harmful effects of prolonged bed rest. Even in healthy subjects, for example a young skier who broke her leg, the effects of bed rest are very profound and of course worse in elderly and ill subjects. Here are some of the consequences:

Muscle Wasting[8]: After one week of bed rest, muscle strength may decrease as much as 20%, with an additional 20% loss of remaining strength each subsequent week. After three to five weeks of bed rest almost half the normal strength of a muscle is lost. This is problematic because weakened muscles generate increased oxygen demand. Even high intensity exercises done in bed do not counteract the adverse effects of bed rest.

EVEN HIGH INTENSITY EXERCISES DONE IN BED DO NOT COUNTERACT THE ADVERSE EFFECTS OF BEDREST.

Allostatic Response to Critical Illness[9 10 11 12]: During critical illness, homeostasis is compromised and during the body's allostatic response, chemicals persist in the body without restoration of stability. Consequences of this include:

- Persistent protein tissue breakdown
- Organ and tissue deterioration
- Persistent inflammatory response
- High and difficult-to-control blood sugars even if patients have never been diabetic, which in turn increase the patient's risk for renal failure due to advanced glycation end products (AGE)

Ventilator Induced Diaphragm Dysfunction (VIDD) in Mechanically Ventilated Patients[13]**:** Due to the lowered neuro-stimulation and muscle loading of the diaphragm in mechanically ventilated patients, the diaphragm atrophies. In the process Myosin Isoforms convert fatigue-resistant slow twitch muscle fibers into fast twitch fibers, which are not fatigue resistant. In general muscle length and blood flow decrease. Additionally, the lungs experience a decrease in the residual volume which increases the risk of lung collapse if the patient is off the ventilator.

[8] English KI, Paddon-Jones D. Protecting muscle mass and function in older adults during bed rest. Curr Opin Clin Nutr Metab Care 2010;13(1):34-39
[9] Shlomo, M. (2001). Series introduction: The immuno-neuroendocrine interface. Journal of Clinical Investigation, 108(11), 1563–1566.
[10] Mechanick, J. I., & Brett, E. M. (2002). Endocrine and metabolic issues in the management of the chronically critically ill patient. Critical Care Clinics, 183, 619–642.
[11] Van den Berghe, G. (2002). Nueroendocrine pathobiology of chronic critical illness. Critical Care Clinics, 18(3), 509–528.
[12] Vanhorebeek, I., & Van den Berghe, G. (2006). The neuroendocrine response to critical illness is a dynamic process. Critical Care Clinics, 22(1), 1–15.
[13] Babb, T., Levine, B., & Philley, J. (2012). ICU-acquired weakness: an extension of the effects of bed rest. American Journal of Respiratory and Critical Care Medicine, 185(2), 230-231.
Robinson GV. Pulmonary embolism in hospital practice. BMJ. 2006;332(7534):156-60.

The Risks of Bed Rest and Immobility

Cardiac Complications: Patients who are prone in bed and have not been sitting up or standing develop postural hypotension, which is associated with fluid losses. Patients can develop an increased heartrate, decreased stroke volume, decreased cardiac output, and decreased peak oxygen uptake. It's important to note that these cardiac complications have been observed in healthy volunteers undergoing bed rest with a long recovery period.

CARDIAC COMPLICATIONS HAVE BEEN OBSERVED IN HEALTHY VOLUNTEERS UNDERGOING BED REST WITH A LONG RECOVERY PERIOD.

Hematological Effects: Due to the water loss during bed rest, the blood thickens, which decreases the patient's oxygen demand as well as the availability of hemoglobin—the oxygen carrying protein. Additionally, because the patient is immobile, venous blood pools, leading to venous stasis. All these factors combined increase the risk of en embolism. Embolisms are particularly dangerous as they can lead to:

- Stroke
- Myocardial Infarction (MI)
- Deep Vein Thrombosis (DVT)
- Pulmonary Embolism
    - The latter is the most common cause of sudden, unexpected death in hospitals, after elective surgeries[14]

Bone Loss: Weightbearing activities contribute to the development and maintenance of bone mass. On the other hand, weightlessness and immobility result in bone loss, which is why it is very commonly seen in patients undergoing bed rest.

ICU Delirium: As mentioned earlier, the ICU is a hostile environment from a patient perspective. The noise, ambient light, restriction of mobility, and social isolation all can lead to ICU delirium. The negative effects of delirium include:

- Peripheral vasoconstriction
- Increased arterial pressure
- Increased epinephrine release
- Increased muscle tension

All of these symptoms in turn can contributes to an increased length of stay as well as mortality.

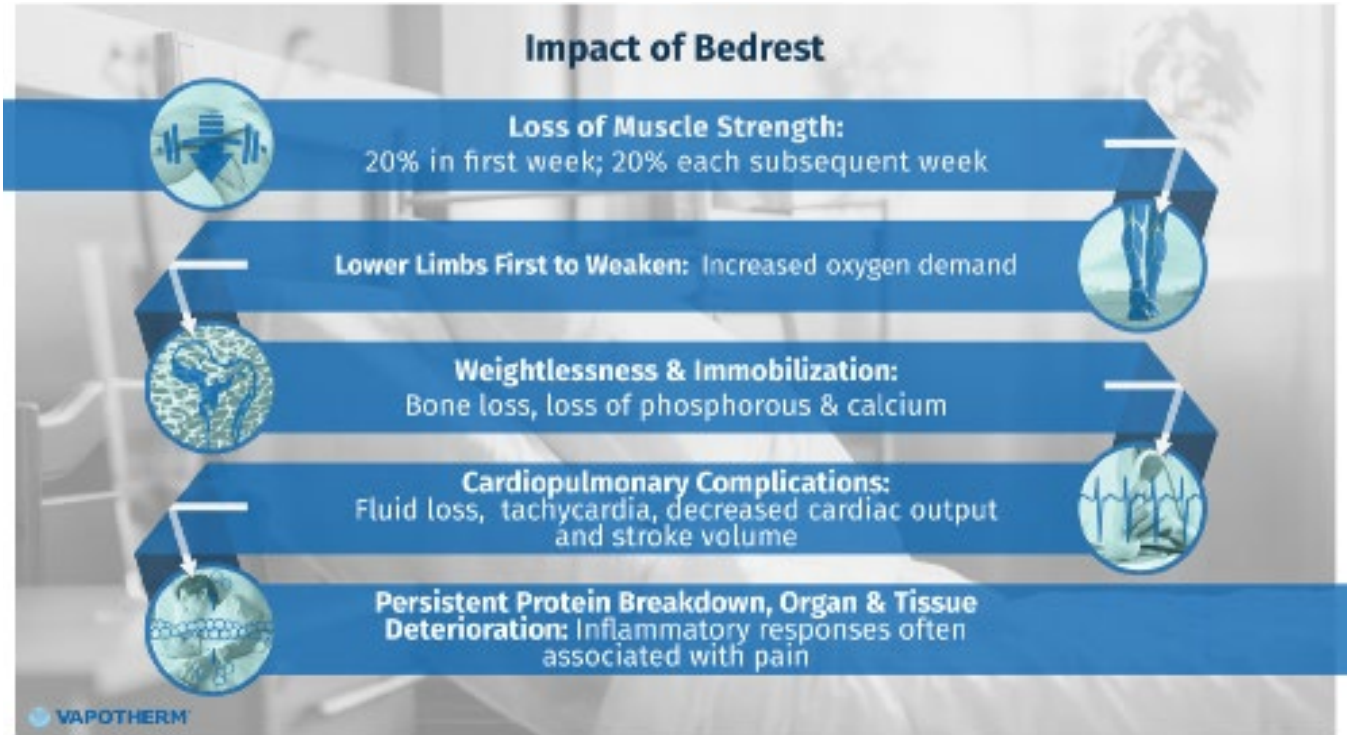
[14] Robinson GV. Pulmonary embolism in hospital practice. BMJ. 2006;332(7534):156-60.

The Risks of Bed Rest and Immobility

Immune Suppression: Although the ICU was conceived as a place of rehabilitation and healing, it paradoxically doesn't allow most patients to sleep. Due to all the stressors and stimuli patients encounter in the ICU, sleep deprivation is a common occurrence in ICUs. This leads to a host of adverse reactions as sleep is one of the key ways our bodies repair themselves. During the early stages of sleep, certain immune cells peak in concentration which enhances our body's ability to form an initial response to pathogens. However, sleep deprivation depresses this response to invading organisms and compromises the patient's natural immune response, which is exacerbated by the fact that there of course are plenty invading organisms and pathogens in hospital settings.

Each one of these adverse consequences of bed rest in general, and bed rest in the ICU particularly, only further complicates eventual rehabilitation and return to life's roles for the patient.

The below graphic illustrates this list in summary.



The Risks of Bed Rest and Immobility

The Impact on the Mind

It should come as no surprise that the patients' mental health and psychological well-being also suffer in the ICU especially with prolonged bed rest. As addressed previously sleep deprivation is a serious problem in the ICU. In addition to the negative physiological effects, it also has a direct impact on the patient's experience.

Sleep deprivation will negatively impact:

- Attention
- Awareness
- Reaction time
- Memory
- Reasoning skills
- Creative thinking

All these factors combined with the experience of illness ultimately impact the patient's sense of self. Self-concept—the stable set of beliefs about one's qualities and attributes[15] —along with self-esteem—the feeling of self-worth[16] —make up a person's body image, achievement, social functioning and self-identification. All of these are severely impacted by prolonged bedrest, as it causes a decrease in body function and an altered appearance. Ultimately the achieving self, the social self, and the private self are all negatively affected.

This is why emotional problems are a common symptom in the ICU patient's recovery. Around 25% of ICU survivors experience adverse emotional outcomes during the months and years after being released from the ICU.[17] These survivors struggle with everyday activities, including working and interacting with friends and family. Predictors of these adverse emotional outcomes are linked to ICU length of stay, prolonged mechanical ventilation, female gender, alcohol use, and smoking.[18]

[15] Baumeister, R. F. (Ed.) (1999). The self in social psychology. Philadelphia, PA: Psychology Press (Taylor & Francis).
[16] Walker,J.et al (2007) Psychology of Nurses and the Caring Professions.Maidenhead:McGraw Hill/Open Press.
[17] Dimitry S. Davydow, Jeneen M. Gifford, Sanjay V. Desai, O. Joseph Bienvenu, Dale M. Needham. Intensive Care Medicine, 2009, Volume 35, Number 5, Page 796
[18] Hopkins RO, Key CW, Suchyta MR, Weaver LK, Orme JF Jr. Gen Hosp Psychiatry. 2010 Mar-Apr;32(2):147-55. doi: 10.1016/j.genhosppsych.2009.11.003. Epub 2009 Dec 14.

Early Mobility Intervention Strategies and the Clinical Benefits

Early Interventions and Developing an Interdisciplinary Mobility Team

There are strategies, philosophies, and protocols to address the problems associated with bed rest, and to enhance the overall outcome of the patient. An evidence-based protocol known as the early mobility bundle is comprised of awakening and breathing coordination; delirium monitoring/management and early mobility.[19] The early mobility ABCDEF bundle resulted in a 12% increase in patient survival rate.[20] The early use of speaking valves with ventilator patients is also incorporated to facilitate communication and shorten ventilator weaning times.

THE EARLY MOBILITY ABCDEF BUNDLE RESULTED IN A 12% INCREASE IN PATIENT SURVIVAL RATE.

Successful programs develop a multi-disciplinary quality improvement team, identify clinical champions, and establish inclusion and exclusion criteria for early mobility; most establish an algorithm or structured protocol. The interdisciplinary mobility team needs to **have buy-in from and includes the physician, nurse, physical therapist, physical therapy aid, respiratory therapist, occupational therapist, neuropsychologist, and pastoral care.**

Early intervention strategies should also include:

- Good communication
- Assisting patients with goal setting
- Scheduling patient/family meetings within 24-48 hours of ICU admission
- Being proactive with patient and family communication
- Ongoing assessments
- Early implementation of activity (3-5 days after admission)

[19] Balas, M. C., Burke, W. J., Gannon, D., Cohen, M. Z., Colburn, L., Bevil, C., ... & Vasilevskis, E. E. (2013). Implementing the awakening and breathing coordination, delirium monitoring/management, and early exercise/mobility bundle into everyday care: opportunities, challenges, and lessons learned for implementing the ICU Pain, Agitation, and Delirium Guidelines. Critical Care Medicine, 41(9 Suppl 1), S116-27.

[20] Schweickert, W. D., Pohlman, M. C., Pohlman, A. S., Nigos, C., Pawlik, A. J., Esbrook, C. L., ... & Schmidt, G. A. (2009). Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomized controlled trial. Lancet373(9678), 1874-1882.

Early Mobility Intervention Strategies and the Clinical Benefits

Clinical Benefits of Early Mobilization:

As discussed in a previous section, bed rest is deleterious to the patient. Some of the clinical benefits of early mobility include:

- Prevention of muscle and muscle strength loss to facilitate the patient's eventual return to life's roles
- Prevention of bone loss as weightbearing is the best treatment
- Decreased risk of immobilization associated pain
- Decrease of serum glucose to normal levels, which can mitigate the risk of heart and renal failure
- Prevention of pressure ulcers and hospital acquired injuries
- Possible reduction of risk for gastrointestinal problems, including the development of gastrointestinal reflux (GERD) that puts mechanically ventilated patients at risk of aspiration and pneumonia
- Decreased risk of hematological adverse effects, including embolisms

Helping the Mobility Team Structure the Philosophy of Care:

Given these overwhelmingly beneficial outcomes of early mobility, it is often not difficult to receive buy-in from the medical and clinical mobility team. While there are barriers to implementation, they often come from the hospital administration and we'll address them in the next section. Even though the mobility team may fully understand the benefits their patient is receiving, it is helpful to have a unified vision for the rehabilitation approach. One such approach comes from Myra Estrine Levine, a nurse and theorist who developed **Levine's Four Conservation Principles**.[21]

Conservation of **personal integrity**:
- Recognize the patient as an individual needing respect, self-awareness, self-determination

Conservation of **social integrity**:
- Reconnect patient to their loved ones

Conservation of **structural integrity**:
- Restore and maintain structure of the body (skin, brain, muscles, nerves) to prevent physical breakdown

Conservation of **energy**:
- Save energy for the healing process, balance input and output to avoid excessive fatigue, provide adequaterest, sleep and adequate nutrition

[21] Levine ME. The conservation principles: a model for health. In: Schaefer KM, Pond JB (eds). Levine's Conservation Model: A Framework for Nursing Practice. Philadelphia, Pa: F.A. Davis Company;1991

Early Mobility Intervention Strategies and the Clinical Benefits

The Three Phases of Mobility in the ICU

When assessing whether a patient is a candidate for early an early mobility intervention, the clinicians should determine medical stability. The suggested guidelines are:

- HR < 110/min at rest
- Mean arterial blood pressure between 60 and 110 mmHg
- FiO_2 < 0.6

Major contraindications of early mobility include:

- Pulmonary instability
- Cardiovascular instability
- Musculoskeletal instability

If the patient is determined to be medically stable and no contraindications are present, the clinicians can use the following phases to ease the patient into mobility rehabilitation:

Phase 1:

This phase constitutes initial interventions to help counteract the negative impact of bed rest, such as:

- Range of Motion exercises (passive as well as active)
- Stretching
- Resistance exercises
- Breathing exercises

Phase 2:

Here we can incorporate standing activities:

- In standing frame
- With walker
- With assistance
- Weight shifts
- Steps in place
- Side Steps
- Walking re-education as tolerated

Phase 3:

Finally, in this phase we can introduce limited walking with a walker as well as with assistance in order to increase the patient's transfer and endurance. Be sure to meet the patient's oxygenation and ventilation needs for increased exertion.

Vapotherm does not practice medicine or provide medical services or advice. These guidelines are based on an assessment of peer-reviewed published literature and Nan Nathenson's experience. Providers should refer to the full indications for use and operating instructions of any products referenced before use.

Early Mobility Intervention Strategies and the Clinical Benefits

Technologies That Can Help

Although advancements in technology have contributed to the long-term survival of ICU patients, and thereby paradoxically to all the complications that result from long-term ICU stays, technologies also must be a part of the solution.

Some of the tools in our modern toolbox include the following:

- Portable mechanical ventilators
- Wireless monitoring devices
- Mobile Mask-Free NIV™ for spontaneously breathing patients via High Velocity Nasal Insufflation (HVNI) system
- Neuromuscular Electrical Stimulation (NEMS) devices which use low-level electrical pulses to create passive muscle contractions through electrodes. This helps to mimic mild exercise.
- Cycle ergometers that can help preserve muscular architecture
- Custom transport carts with shelves for ventilators, IV poles, hooks as needed, and a seat for patients
- Specialty beds that can transform into a chair

To ensure that the right strategy is implemented and smoothly executed, it is crucial to have multi-disciplinary education for the whole mobility team. It can sometimes happen that nurses don't want respiratory therapists touching their patient and the respiratory therapists don't want the nurses touching their ventilators. To have an effective approach that is in the best interest of the patient, teams must work together.

The following competencies are recommended for each team member:

- Ventilator Modes, Levels of Support and Troubleshooting
- Endo-tracheal Tube and Tracheostomy
- Management and Troubleshooting
- Speaking Valve Use
- Airway Emergencies
- Work of Breathing
- Safe Patient Handling
- Patient Monitoring

The Economic Benefits of Early Mobility Intervention Strategies

Making the Business Case to the Administration

As the patient's strength and endurance improve, their quality of life improves as well. But there are also economic benefits to early ambulation. Ultimately if the patient is rehabilitating better sooner, their length of stay in the ICU may decrease and the cost of care may ultimately decrease as well.

Despite the relative simplicity of these strategies one of the barriers is often lack of administrative support. The clinicians providing direct care to the patient will tell you they lack the time, personnel, equipment, and knowledge to implement early ambulation activities.

However, this barrier can be overcome, too. Administrative buy-in is achieved with the development of a business model to demonstrate that financial investments in additional staff reap rewards in cost savings through decreased critical care patient days, decreased over-all hospital stay, and fewer complications.

ADMINISTRATIVE BUY-IN IS ACHIEVED WITH THE DEVELOPMENT OF A BUSINESS MODEL TO DEMONSTRATE THAT FINANCIAL INVESTMENTS IN ADDITIONAL STAFF REAP REWARDS IN COST SAVINGS THROUGH DECREASED CRITICAL CARE PATIENT DAYS, DECREASED OVER-ALL HOSPITAL STAY, AND FEWER COMPLICATIONS.

For example, the early mobility clinical trial completed at Wake Forest University Medical Center resulted in a savings of $504,789 for patients enrolled in an early mobilization group as compared to patients receiving the usual care.[22] A study from Duke University decreased periods of delirium by 50%. A Johns Hopkins study demonstrated the beneficial effects of the 4 E's approach; Engage, Educate, Execute, Evaluate. This pilot study resulted in 2.1 fewer average ICU days and 3.1 fewer overall hospital days.[23]

[22] Engel HJ, Needham DM, Morris PE, Gropper MA. Crit Care Med. 2013 Sep;41(9 Suppl 1):S69-80. doi: 10.1097/CCM.0b013e3182a240d5.

[23] Lord, R. K., Mayhew, C. R., Korupolu, R., Mantheiy, E. C., Friedman, M. A., Palmer, J. B., & Needham, D. M. (2013). ICU early physical rehabilitation programs: financial modeling of cost savings. Critical Care Medicine, 41(3), 717-724.

The Vapotherm Transfer Unit as an Option for Early Ambulation

Hi-VNI® Technology on the Go

Hi-VNI Technology is Mask-Free NIV for spontaneously breathing patients and has comparable outcomes to non-invasive positive pressure ventilation (NiPPV).[24] As discussed, clinicians have several options when it comes to rehabilitating their patients through mobilization and ambulation. Hi-VNI Technology is a good solution for clinicians looking to ambulate even moderate-acuity patients without a mask interface.

Hi-VNI Technology is effective at providing ventilatory support and treating spontaneously breathing patients in undifferentiated respiratory distress, including those with hypercapnia and acute decompensated heart failure. Hi-VNI Technology requires spontaneous breathing and cannot meet the full ventilatory requirements for mechanically ventilated patients.

The Vapotherm Transfer Unit (VTU) is a mobile option for providing Hi-VNI Technology while mobilizing patients or transferring them within a hospital. The unit has a light-weight, medical-grade power supply that lasts up to 60 minutes and delivers a comfortable, easy to tolerate therapy. In this way clinicians can maintain the integrity of the respiratory support on the go.

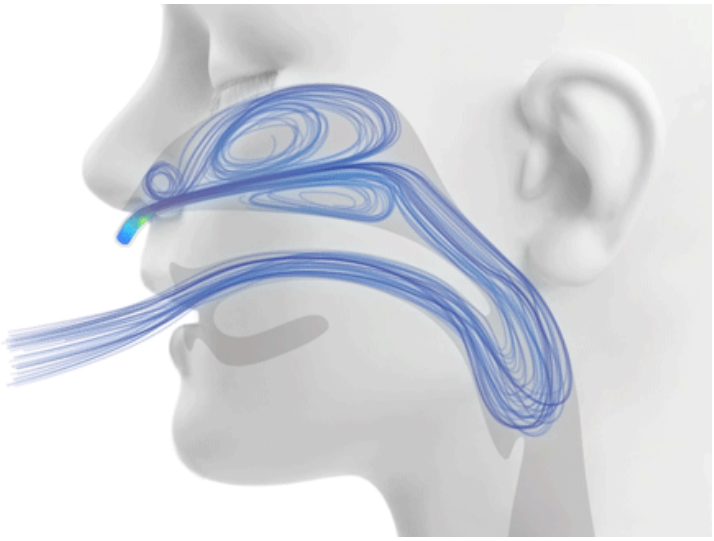
Additionally, the mask-free interface allows patients to take oral medications, eat, drink, and talk with their caregivers and thereby helps to combat some of the isolation that ICU patients can often experience.

So, how does this technology work?

[24] Doshi, Pratik et al. High-Velocity Nasal Insufflation in the Treatment of Respiratory Failure: A Randomized Clinical Trial. Annals of Emergency Medicine, 2018, 2018; 72:73-83 e5.

The Vapotherm Transfer Unit as an Option for Early Ambulation

Mechanisms of Action



The primary mechanism of action of HVNI delivered by Vapotherm's Hi-VNI Technology, is the flushing of end-expiratory CO_2 from the upper airway between breaths. This is accomplished rapidly and efficiently with a high velocity stream of optimally conditioned breathing gas. Because Hi-VNI Technology is an open system, the fresh gas is insufflated through the nares and the end-expiratory CO_2 is flushed out through the mouth. This reduces the CO_2 content of the next inspiration and fills the nasopharyngeal cavity with fresh gas. **Like a tracheostomy that mechanically bypasses the dead space, the high velocity purge functionally minimizes it by changing the dead space to a fresh gas reservoir.**

Although the flush of end-expiratory CO_2 is the primary mechanism of action, Hi-VNI Technology also achieves its efficacy in part through the following[25]:

- Some distending airway pressure
  - Primarily during exhalation against the high velocity flow
- Warming gas flow (typically 33-37°C)
  - Which decreases inspiratory resistance
- Humidification
  - Optimal humidity preserves mucociliary function and aids in mucus clearance from airways

[25] Dysart K, Miller TL, Wolfson MR, Shaffer TH. Research in high flow therapy: Mechanisms of action. Respir Med 2009; 103:1400-1405

The Vapotherm Transfer Unit as an Option for Early Ambulation

Difference between Hi-VNI Technology and NiPPV

Clinicians used to NiPPV as the gold standard treatment for patients with hypercapnia may be skeptical about how a mask-free device that does not deliver pressure as a primary mechanism of action could achieve alveolar ventilation in patients. In reality NiPPV and Hi-VNI Technology are just two different approaches toward the same goal. Let's look at the basics:

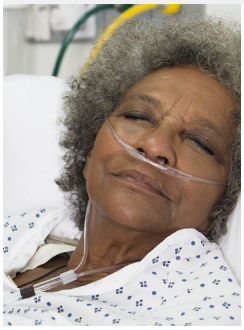
Ventilation with NiPPV

Alveolar Ventilation = (**Tidal Volume** — Dead Space) x Respiratory Rate

In order to achieve ventilation, NiPPV most greatly affects the Tidal Volume aspect of the above equation.[26] The machine ensures ventilation by using positive pressure to deliver target Tidal Volume. Because there is a risk of over-pressurization, clinicians generally start low and adjust up for effect to stabilize a patient.

Ventilation with Hi-VNI Technology

Alveolar Ventilation = (Tidal Volume — **Dead Space**) x Respiratory Rate



However, it is also possible to achieve alveolar ventilation by affecting the other parameter in the equation: Dead Space.

The rapid flushing out of the upper airway Dead Space is the mechanism of action by which Hi-VNI Technology facilitates alveolar ventilation.[27] [28]

Unlike NiPPV, Hi-VNI Technology is an open system de-escalation therapy—it is safe to turn on high and stabilize the patient fast. The clinician can then titrate down upon patient response.

[26] Mehta, Sangeeta and Nicholas S. Hill. Noninvasive Ventilation. American Journal of Respiratory and Critical Care Medicine 163(2).

[27] Dysart K, Miller TL, Wolfson MR, Shaffer TH. Research in high flow therapy: Mechanisms of action. Respir Med 2009; 103:1400-1405

[28] Miller TL, Saberi B, Saberi S (2016) Computational Fluid Dynamics Modeling of Extrathoracic Airway Flush: Evaluation of High Flow Nasal Cannula Design Elements. J Pulm Respir Med 6:376. doi: 10.4172/2161-105X.1000376

The Vapotherm Transfer Unit as an Option for Early Ambulation

Difference between Hi-VNI Technology and Commodity High Flow Oxygen Systems

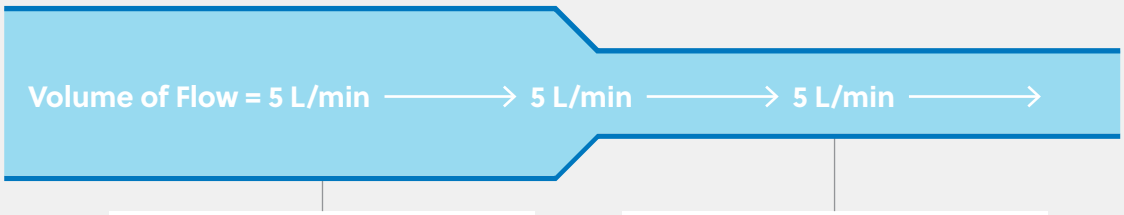
Hi-VNI Technology is frequently confused with commodity high flow oxygen systems, also commonly known as high flow nasal cannula (HFNC). This comparison is understandable at first glance—both deliver high liter flows of conditioned gas though a cannula interface. However, there are some significant differences between these devices and the likely explanation for the difference in clinical outcomes. Hi-VNI Technology has been clinically demonstrated to be comparable to NiPPV in treating patients in undifferentiated respiratory distress.

Why Velocity Matters

Hi-VNI Technology is designed to deliver High Velocity Nasal Insufflation, and as the name suggests, velocity is a key component of the efficacy of this therapy. Unlike most conventional large-bore HFNC, Hi-VNI Technology uses small-bore cannulas. This matters because velocity, at a constant volume of flow, varies inversely with the cross sectional area of a tube, as depicted below.

A HELPFUL WAY TO THINK ABOUT IT IS TO ENVISION A GARDEN HOSE WITH WATER FLOWING OUT. IF YOU PLACE YOUR THUMB TO NARROW THE DIAMETER OF THE HOSE, THE WATER INSTANTLY MOVES FASTER.

In other words, the smaller the diameter of the cannula, the faster the gas will travel so long as the volume remains constant. The Precision Flow system is specifically designed to withstand the back pressure high velocity creates.



From Kacmarek, Robert M., James K. Stoller, Albert J. Heuer, and Donald F. Egan. Egan's Fundamentals of Respiratory Care. St. Louis, MO: Elsevier/Mosby, 2013.

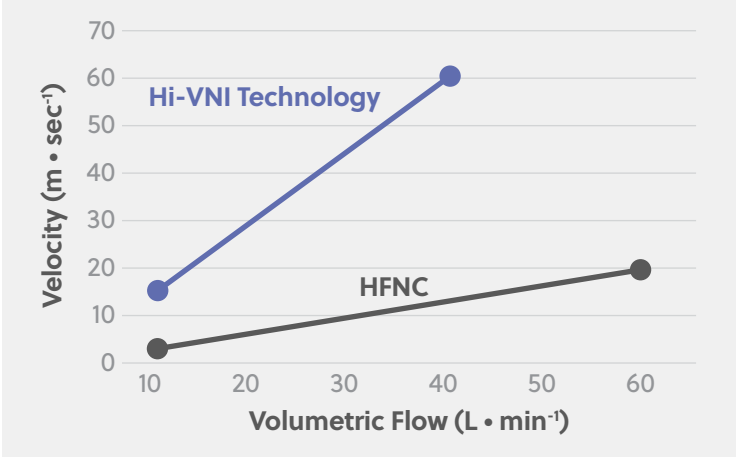
The Vapotherm Transfer Unit as an Option for Early Ambulation

The Greater the Velocity, The Faster the Flush

In the 2016 study "Computational Fluid Dynamics Modeling of Extrathoracic Airway Flush: Evaluation of High Flow Nasal Cannula Design Elements" Miller and colleagues demonstrated that small-bore cannula prongs flush the upper airway dead space faster than large-bore cannulas. More precisely, the Hi-VNI small-bore cannula achieves a flush in 2.2 seconds while the large-bore cannulas flush in 3.6 seconds. The time to flush is important because the time between breaths is small in patients with high respiratory rate.

This is clinically meaningful because with the velocity the small-bore cannulas generate, a lower flow rate is needed to achieve an effective flush. Figure 1 illustrates how Hi-VNI Technology compares to commodity high flow oxygen systems when generating velocity. For example, Hi-VNI Technology achieves the same velocity at approximately 15 L/min that HFNC systems require 60 L/min to achieve.

Figure 1: Hi-VNI Technology



We are sometimes asked why Hi-VNI Technology only goes up to 40 L/min in its settings when some commodity high flow oxygen systems require higher flow rates. As illustrated, the answer is that Hi-VNI Technology is clinically effective below 40 LPM.

Flush Time is Crucial for Patients in Respiratory Distress

Ultimately this differentiator wouldn't matter if it didn't have real-life impact on the treatment of patients. So, the bottom line is that the more tachypneic a patient, the more important it is that their end-expiratory CO_2 be flushed out fast – before they take their next breath in. The patient breathes in more oxygenated gas, reducing the work of breathing and augmenting alveolar ventilation.

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Why Humidification Matters

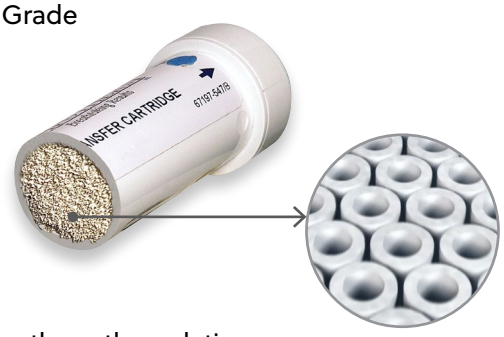
Although velocity is a salient difference between Hi-VNI Technology and systems that don't deliver HVNI, it is not the only difference. Humidification is another key component.

As we know, optimal humidification is crucial for maintaining airway health and mucociliary transport of secretions. Inspired gas at core temperature and optimal humidity is moisture neutral and preserves maximum mucociliary function.[29] At lower levels of inspired humidity, water is removed from the mucus and periciliary fluid by evaporation, causing increased viscosity of mucus and loss of periciliary fluid depth. This in turn leads to negative consequences from thickening of secretions to atelectasis. This is why any system with high flows of gas offers some kind of humidification.

Membrane Humidification vs. Passover Humidification

The difference between Hi-VNI Technology humidification and the pass over humidification used by most ventilators and commodity high flow oxygen systems is that the temperature in the system never exceeds the gas delivery temperature in order to create or maintain humidification. High flow oxygen products use higher than set temperatures in both the creation and maintenance of humidification.

While Hi-VNI technology uses membrane humidification, high flow oxygen humidifiers use a pass-over humidification system. With pass-over humidification, breathing gas passes over highly heated water to add moisture and humidify the gas. Hi-VNI Technology, on the other hand, uses a vapor transfer cartridge to deliver water molecules to the gas path across a membrane to create Medical Grade Vapor™ without high heat.



When we look at a cross section of the Vapor Transfer Cartridge in Hi-VNI Technology, we see hundreds of tiny, semi-permeable "straws". The straws are surrounded by water and as gas flows down these fibers, it becomes optimally humidified[30]. This method is quite different from pass-over humidification. Water molecules enter the gas pathway through tiny .05 micron pores in the fibers by osmotic pressure.

[29] Williams, RB. Respir Care Clin N Am 1998 Jun; 4 (2): 215-28

[30] Waugh J, Granger W. An evaluation of 2 new devices for nasal high-flow gas therapy. Respiratory Care. 2004 Aug; 49(8): 902-906.

The Vapotherm Transfer Unit as an Option for Early Ambulation

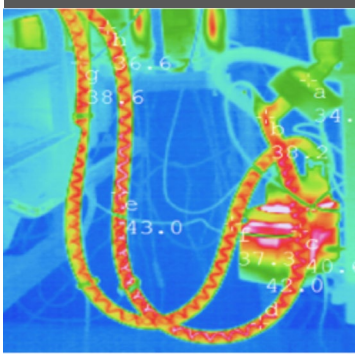
Delivering Optimally Conditioned Gas to the Patient

Generating optimally conditioned gas is just the first step. To be clinically effective, the gas also needs to be delivered in its humidified state all the way to the patient.

Most commodity oxygen products and ventilators use a heated wire circuit for dewpoint control as they deliver the gas. As the heat mapping image in Figure 2 illustrates, the wire circuit does not provide uniform heating and leaves parts of the tubing cooler. Each time the humidified gas hits a cold spot in the tubing, there is an opportunity for water to condense out and create rainout. The patient may receive less than optimally humidified breathing gas, and may also experience the discomfort of water droplets being delivered through the cannula.

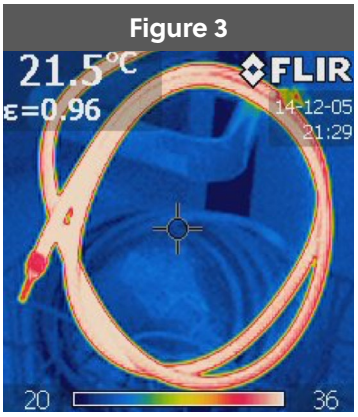
In contrast, Hi-VNI Technology ensures that the delivery tubing is uniformly heated and thereby reduces the chance of rainout, as shown in Figure 3. This is accomplished through a triple-lumen—or three-channel—delivery tube. In essence, the tube creates a warm-water jacket that keeps the Medical Grade Vapor energetically stable all the way from the Vapor Transfer Cartridge to the Hi-VNI® Cannula, where the short supply tubing continues to ensure that the possibility of rainout is further reduced.

Figure 2

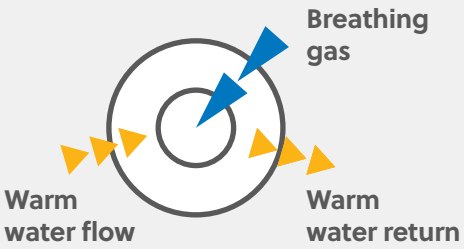


Heated wire circuit of commodity high flow oxygen systems.

Figure 3



Triple lumen delivery tube of Hi-VNI Technology.



AN ADDED BENEFIT TO THE TRIPLE LUMEN DELIVERY TUBE IS THAT IT'S SAFE TO THE TOUCH AND WILL NOT CAUSE BURNS

The Vapotherm Transfer Unit as an Option for Early Ambulation

Hi-VNI Cannula Selection and Application

Now that we've covered why Hi-VNI Technology could be a great treatment for patients in undifferentiated distress and how it works, we'll address how to apply the therapy.

Maintaining an Open System

Given that the primary mechanism of action in Hi-VNI Technology is not pressure, but flush, it is important to maintain an open system at the patient. This is why the **Hi-VNI Cannula prongs should never occlude more than 50% of the diameter of the nare**. It allows gas flow out around the cannula as well as through the patient's mouth helping to create the turbulence that efficiently clears CO_2. Vapotherm manufactures 8 different Hi-VNI Cannula sizes to accommodate all patient populations from premature neonate to adult.

HI-VNI TECHNOLOGY PARAMETERS (FLOW RATE AND FIO_2) CAN BE CONTROLLED INDEPENDENTLY OF EACH OTHER. ADJUSTMENT IN FIO_2 GENERALLY TARGETS OXYGENATION STATUS OF THE PATIENT (E.G., SPO_2), AND FLOW RATE (L/MIN) TARGETS VENTILATORY WORK (WORK OF BREATHING).

Maintaining an open system not only provides an exit path for the purging of end-expiratory CO_2, but it also ensures that no inadvertent pressure is built up.

Vapotherm recommends applying the cannula to the patient while the Precision Flow system comes to temperature. This allows the cannula tubing to warm to body temperature. When the system is warmed up and primed (usually less than 5 minutes) it is time to start delivering respiratory support.

Starting Settings Across Patient Populations

Once the proper interface has been selected and applied, it is time to select the starting parameters of the therapy.

Flow is independent of FiO_2. FiO_2 starting settings should be chosen to achieve target SpO_2.

Typical L/min Recommendations

Adults: 25 – 35 L/min[31]
It is also okay to start at 40 L/min, then titrate down based on the clinical response from the patient.

Pediatrics: Approximately 2 L/min/kg[32] of ideal bodyweight.

Neonates: 4 – 8 L/min[33]

Vapotherm does not practice medicine. These guidelines are based on published literature and physiologic modeling. Providers should refer to the full indications for use and operating instructions before using Precision Flow®.

[31] Doshi, Pratik et al. High-Velocity Nasal Insufflation in the Treatment of Respiratory Failure: A Randomized Clinical Trial. Annals of Emergency Medicine, 2018, 2018; 72:73-83 e5.

[32] Weiler, Thomas MD, Asavari Kamerkar DO, Justin Hotz RRT, Patrick A.Ross MD, Christopher J.L.Newth MD, FRCPC, Robinder G.Khemani MD, MsCI. The Relationship between High Flow Nasal Cannula Flow Rate and Effort of Breathing in Children. The Journal of Pediatrics Volume 189, October 2017, Pages 66-71.e3.

[33] Yoder BA, B Manley, C Collins, K Ives, A Kugelman, A Lavizzari, and M McQueen. "Consensus approach to nasal high-flow therapy in neonates." Journal of Perinatology (2017) 00, 1–5.

Summary

Facing the Future

The fastest growing age population in the US are people 65 years and older. According to the National Institute on Aging, roughly 10, 000 baby boomers will turn 65 today, and about that same number will do so every day for the next 19 years. This continuous increase in the age of our population will be reflected in our ICUs.

Looking ahead, it is time to embrace early rehabilitation as a humane and holistic philosophy of care at every step. Although there are and will be barriers to implementation, a focused and dedicated team can communicate to the hospital staff that the complications of immobility are preventable. Support daily in and out of bed activities, incorporate physical and occupational therapy, minimize sedation, preserve functional capacity, promote patient/family participation in care, and balance rest and activity.

The barriers to early mobilization can be overcome and it is in the best interest of the patient as well as possibly in the hospital's best economic interest to implement early mobility intervention strategies.

If you would like to learn more and access further in-depth material presented by Nancy Nathenson, please go to www.vapotherm.com and watch Nan's "The Importance of Early Ambulation" webinar.

If you are interested in learning more about the Vapotherm Transfer Unit or Hi-VNI Technology in general to determine whether it would be the right fit for your hospital:

Our expert field team is always available to demonstrate Hi-VNI technology, provide education, technical support, or answer questions. Vapotherm provides 24/7 technical support 365 days per year.
Contact **855-557-8276** or reach us through the website **www.vapotherm.com**