Therapeutic Environment for Esketamine a Policy

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Abstract

This project aimed to develop a structured policy surrounding the therapeutic environment of esketamine to provide continuity of care and maximize therapeutic benefits while mitigating possible side effects of esketamine. A literature review for the most relevant and up-to-date evidence-based knowledge helped to develop recommendations for the following categories: environment, therapeutic techniques, anxiety, dissociation, nausea, temperature control, happiness, excitement, hypertension, and respiratory depression. CDC's Policy Analytical Framework was used to guide the development of a written policy that the organization accepted. Furniture, monitoring equipment, cranial electrotherapy stimulation devices, temperature control devices, music and meditation listening devices, and creative activities were sourced and purchased, giving special consideration to color, safety, and comfort. Given these recommendations, treatment rooms began the process of being redesigned to help support a standardized therapeutic environment in which esketamine is administered to remove inconsistencies and establish consistency for staff and patients.

Keywords: policy, esketamine, side effects, therapeutic environment, cranial electrotherapy stimulation device

Problem Description

History and Background

The specific organization discussed in this paper specializes in treating depression and anxiety for children, adolescents and adults in Oregon, California, and Alaska. Services offered by this outpatient site include pharmacotherapy, Transcranial Magnetic Stimulation, and esketamine. Currently this organization is expanding to become more widely available. With expansion comes a rapid onboarding of new providers and staff.

With the rapid hiring and new locations comes a variety of individuals making judgment calls on what is available for patients. There is no policy for the therapeutic environment in which esketamine is administered. Without a policy to guide staff in setting up treatment rooms, a variety of objects, aesthetics, and materials are available to a patient simply depending on location. This variety results in no guarantee of continuity and a lack of resources available to patients that could maximize the therapeutic effects or mitigate the side effects of treatment.

A policy ensures continuity of care, maximizes therapeutic effects, retains employees, decreases turnover, and supports knowledge growth (Ragsdale and Mueller, 2005). Varying standards of practice lead to inconsistency in the care provided. Specifically, without policies, providers are left to navigate the new setting and make varying judgments on standards of practice. This inherently leads to different standards depending on the individual or the office's location. Addressing the lack of continuity in the treatment environment will promote quality standards and help providers navigate the practice setting, put together treatment rooms that patients can benefit from, and rely on consistency no matter which location they are provided care.

Purpose of policy project

This project aims to develop a structured policy surrounding the therapeutic environment of esketamine for providers at an outpatient psychiatric organization to provide continuity of care and maximize therapeutic benefits while mitigating possible side effects of esketamine. The project aims to develop a policy applicable to all providers, staff, and locations within this organization. A standardized policy will provide a concrete understanding of the best way to design the therapeutic environment in which esketamine is administered to remove inconsistencies and establish consistency for staff and patients. The project will begin in the Portland, Oregon location and be considered for distribution to other sites.

Evidence

Literature Review

An electronic database search was completed to examine treatment research and policies. Preference was given to articles published in the last five years; articles were not excluded based on publishing date but included if deemed to have relevant guidance. Search terms were selected due to the relation to the problem identified. Search terms included: *provider, role transition, policy, therapeutic response, ketamine, esketamine, psychotherapy, and side effects*.

The search strategy and assessment of the quality of the studies were based on publishing dates, the strength of evidence, and relevance. Literature with Levels of Evidence 3, 4, and 5 was used. Inclusion and exclusion were determined by reading abstracts to assess relevancy. Additionally, articles on ketamine were included given the lack of research done specifically on esketamine due to its newness and the chemical similarity between ketamine and esketamine.

Available Knowledge

Transitioning into a professional role at a new facility is difficult. Many new providers change jobs within the first year of employment due to job dissatisfaction (Horner, 2017). One of

the main contributors to decreased job satisfaction is feelings of incompetence (Yeager, 2010). New providers require support and commitment from their employer to maintain job satisfaction and desire to stay within an organization. The organization can provide this support by providing and ensuring adequate and appropriate policies for administering treatments.

Retention is essential as providers are difficult and expensive to replace. In addition, turnover is disruptive to the patient and continuity of care (Horner, 2017). Role ambiguity and insufficient preparation for the setting in which provider practices significantly negatively impact patient care outcomes (Faraz, 2016).

Many new providers feel as if they are heavily scrutinized in their first couple of months of being hired. This actual or perceived scrutiny increases the likelihood that the provider will experience self-doubt and feelings of inadequacy (Yeager, 2010). New providers may be hesitant to make changes that could be beneficial or be quick to change things that could unwittingly negatively impact patient care. Regardless, the organization's goal should be to ensure that providers can provide safe patient care by giving evidence-based policies.

Esketamine. Esketamine is the S-enantiomer of ketamine approved by the FDA in the United States in 2019 for treating depression that has failed to respond to trials of two or more antidepressants (Office of the Commissioner, 2019) and acute suicidality. In contrast to ketamine, which is administered by intravenous injection, esketamine is administered as a nasal spray. Ketamine is a racemic mixture consisting of two molecular forms that are enantiomers, R and S ketamine. In esketamine, the more potent (Jelen, Young & Stone, 2020) active isomer of ketamine (S-enantiomer) is isolated and acts as an *N*-methyl-d-aspartate receptor antagonist (Jalloh, 2020). Although the exact mechanism for the antidepressant effects is unknown, a potential mechanism of action is ketamine blocking NMDA receptors and inhibiting calcium

influx; these affect the release of GABA inhibition, causing a glutamate surge and reversing suppression of protein translation. Reversing protein suppression increases BDNF translation in the hippocampus, which enhances neuroplasticity and synaptic growth, improving depression symptoms (Lent, Arrendondo, Pugh, and Austin, 2019).

For acute management of treatment-resistant depression, the recommended dose of esketamine nasal spray is twice weekly for four weeks during induction, reduced to once weekly for another four weeks. Beyond eight weeks, once weekly or alternating once weekly doses are recommended for ongoing maintenance (Salahudeen & Peterson, 2020).

Esketamine has many notable side effects, including increased blood and intracranial pressure (Vallerand & Sanoski, 2021), dissociation, dizziness, nausea, sedation, spinning sensation, feelings of numbness, anxiety, vomiting, feeling of body temperature change, feeling intoxicated, and feelings of excitement. Due to the high incidence of dissociation and sedation associated with esketamine, the FDA label has a boxed warning and recommends that patients be monitored for at least two hours after administration (Salahudeen & Peterson, 2020) and can't drive themselves for the rest of the day (Office of the Commissioner, 2019).

Treatment Environment. Environmental design should be mindful of the two-hour requirement to remain in the room and the potential perceptual changes. The Johns Hopkins hallucinogen research projects (2022) suggest a living room-like setting with furniture comfortable for sitting or lying down. A clinical environment with an antiseptic look increases anxiety (Johnson, Richards, & Griffiths, 2008). While an aesthetically pleasing environment decreases psychological distress. In terms of aesthetics, subjective feelings of relaxation are higher with the colors green, blue, yellow, and white (Rodrigues & Deuskar, 2016). Red, violet, and orange evoke feelings of mystery, fear, and pain (Rodrigues & Deuskar, 2016). Any potentially

dangerous objects including sharp corners and things made from easily broken materials should be removed (TripSafe, 2017, Johnson, Richards, & Griffiths, 2008). Additionally, the room should not have a telephone as incoming or outgoing communications can be distracting or alarming (Johnson, Richards, & Griffiths, 2008) and capitalize on potential side effects.

Therapy Techniques. Ketamine promotes a break from patterns in the mind, relief from negativity, and provides access to one's inner self. These effects enhance the ability to engage in psychotherapy (Dore et al., 2019). Therapeutic techniques from psychotherapy and cognitive behavioral therapy (CBT) have significantly enhanced therapeutic outcomes when used alongside ketamine. CBT has been shown to sustain the antidepressant effects of ketamine (Wilkinson et al., 2021), increase engagement and reduce anxiety and depression rapidly and significantly (Drozdz et al., 2022). Therapy techniques can be provided through audio meditations and worksheets to identify maladaptive behaviors and thoughts and facilitate the adoption of therapy principles (Wilkinson et al., 2021). Providing worksheets and guided mindfulness meditation recordings as an option for patients to engage and direct their experiences while undergoing treatment will maximize the therapeutic effect of their treatment.

Mitigating Side Effects

Anxiety and Dissociation. Therapeutic effects and experiences can be supported using eyeshades, earplugs, or headphones (through which music is played) by reducing the distractions of environmental stimuli and allowing the patient to focus and reflect (Johnson, Richards, & Griffiths, 2008). Johns Hopkins (2022) crafted a playlist specifically for treatment that alters the perceptual experience. Encouraging patients to listen to music following esketamine administration results in improvement in managing confusion and anxiety associated with dissociation (Pereira et al., 2021). Another way to decrease anxiety and improve mood is through

scents such as bergamot, lemon, clary sage, lavender, chamomile, geranium, rose, sandalwood, and jasmine (Butje, Repede, & Shattell, 2008).

Nausea. Providing flavored candy and beverages in the treatment room for after administration manages and prevents vomiting (Bossaller & Shelton, 2020). Specifically, fruit punch and ginger decrease nausea (Bossaller & Shelton, 2020, Zhu, Dai, Huang, & Li, 2021).

Thermocontrol. Allowing alteration of the room's temperature will address feelings of body temperature change. Patients who feel cold after the administration, offer space heaters, hot packs, and blankets to increase comfort. Those who feel hot need access to cold packs and fans.

Happiness and Excitement. Equipping the rooms with various tactile projects such as coloring pages, markers, puzzles, and fidget toys allows those with extra energy to focus on things that are not disruptive enough to take them out of the therapeutic experiences.

Hypertension and Respiratory Depression. Vital sign monitoring equipment needed include an automatic blood pressure monitor with cuffs in all sizes and a pulse oximeter. For treatment of anxiety related hypertension use of cranial electrotherapy stimulation through the Alpha-Stim device (Kang et al., 2020)[2].

Rationale

The goal of this project was to develop and implement a structured policy to assist and support providers through the delivery and monitoring of esketamine to produce the best therapeutic outcome as possible. The use of CDC's Policy Analytical Framework served as the policy's framework (Centers for Disease Control and Prevention, 2022)[3].

Goals or Objectives

The plan included writing a new policy that encompasses the design of the esketamine treatment rooms to ensure that patients can access all tools to help them during their treatment no

matter their location. Additionally, this policy aimed to increase provider comfort and understanding around administering esketamine by putting a standardized process into place.

Implementation

Rooms were redesigned and modified, items removed and added. These items and design changes were guided by evidence in the literature. Items were purchased and made available for patients in all treatment rooms. These changes were written into a policy for use at all locations to standardize treatment rooms.

Feasibility/Utility

The likelihood of adoption is high; there is buy-in from the Portland, Oregon location and excitement for future application to other locations. Stakeholders are the Techs who will be implementing the policy, the providers as they oversee the treatment, and the organization, which will be providing a monetary budget for items needed.

Anticipated benefits and outcomes are a standardized room that will provide consistency for patients, giving them options to manage side effects of the medication. This will be useful as patients have become attached to certain rooms and often do not want to undergo treatment if they cannot be in a particular room due to its amenities. Ensuring that each room has everything they need will put them more at ease.

The risk of this policy is that all treatment rooms will change in some way. Change can be difficult for people accustomed to a particular experience. This policy will disrupt their experience initially but will hopefully expand upon it as more tools become available.

Outcome Measures

The central measure for this project is determining if the policy developed works to remove inconsistencies and establish consistency for staff and patients. This was measured by

determining first the impact. Specifically, if the policy was implemented and rooms were standardized. Second, feasibility or how likely it is to be adopted and enacted at other locations. Finally, economic and budget, examining the costs relative to the benefits. These will be obtained through qualitative means, specifically, through a retrospective review of the policy and changes made.

Ethical Considerations

This project was reviewed by the OHSU internal review board and determined not to be research. There are no conflicts of interest. The only potential harm is psychological as changes were made to treatment rooms and change has the potential to produce anxiety for those involved.

Achievement and Challenges

The objectives of this project have been partially met at this time. A standardized policy was created and provides a concrete understanding of the best way to design the therapeutic environment in which esketamine is administered[1]. While change is slow and takes time, the policy has been implemented in stages to make changes to each treatment room to establish consistency for staff and patients. Stages included, first, taking inventory of each room and noting where guidelines are met and where there needs to be an improvement. The second stage was to source and obtain items needed for each room. The third stage was to physically make changes to the rooms to align them with policy recommendations. While these stages are sequential, operating in them can move in any direction.

Details of the measures used to determine success are still to be determined. The final economic cost will not be known until each room is updated. As each room needs different updates and additions, an estimated cost cannot be calculated. Current benefits noted at the start

of the project are feedback from staff and patients on how additions have been helpful. Challenges faced during implementation are the amount of time needed to implement changes. No single individual is responsible for enacting changes, and staff members make changes as their schedules allow. Budget is another challenge; there is a budget allotted to making changes in the esketamine treatment rooms, which limits selections and paces changes more slowly depending upon needs.

Recommendations and Conclusions

Recommendations to proceed with this policy project are to continue setting up treatment rooms to align with the guidelines given in the clinical policy to achieve standardization. Next, to reflect on the overall cost to update rooms and the relative added benefit to patients.

Key stakeholders are providers, esketamine technicians, and the company. These stakeholders need to remain engaged and supportive of the policy. Engagement can be maintained by sharing information, resources, and evidenced-based literature that supports changes that need to be made and clarifying any operational issues that arise. A record of changes made and improvements that are still needed for easy access for all those involved will also promote engagement. Potential barriers are the level of investment to update policy in the future, enforce changes as guidelines evolve, and continuously provide education on the importance of maintaining standardization in treatment rooms.

Standardization was needed in treatment rooms to provide a consistent experience for patients and staff. A policy with evidence-based guidelines was created to address this. However, evidence is continuously updated, and this policy needs to remain a living document as new studies are published. As a living document, this policy can be altered, updated, and amended as needed to ensure that guidelines are as up to date as possible.

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Appendix

Clinical Policy

Therapeutic Environment for esketamine Administration

Purpose: A standardized policy that will provide a concrete understanding of the evidence-based way to design the therapeutic environment in which esketamine is administered to remove inconsistencies and establish consistency for staff and patients.

Persons Effected: This policy applies to all members of the healthcare workforce at the Portland, OR and Beaverton, OR locations.

Responsibilities: Providers including MD, DO, PMHNP and esketamine administration technicians

Policy Requirements:

Treatment Factors & Side Effects	**Evidence Based Recommendations**
Treatment Environment	*What to expect from my Spravato Therapy Sessions?* – Info sheet in each room for easy reference Living room-like setting with furniture comfortable for sitting or lying down Reclining chair that has a locking feature when fully reclined, large enough to accommodate all clients Eliminate as much clutter or disorganization as possible Pillows and cushions able to be used to aid in comfortable positioning Color palette: green, blue, yellow, and white Nature inspired art and plants Any potentially dangerous objects including sharp corners and things made from easily broken materials should be removed or modified for safety Room able to limit outside noise either through placement of treatment room, sound proofing, or offering a white noise machine
Anxiety and Dissociation	Ability to cover windows, dim or turn off lights Eyeshades, earplugs Headphones and device for music Johns Hopkins playlist recommended. Music with words recommended to be avoided Scents such as bergamot, lemon, clary sage, lavender, chamomile, geranium, rose, sandalwood, and jasmine Alpha Stim device: 20 minutes is usually enough time if the current is set to at least 250 μA. 40 minutes to 1 hour is recommended if the current is at or below 200 μA.
Nausea	Flavored candies and beverages readily available Fruit punch and ginger flavors are recommended
Thermocontrol	Space heater, blankets, hot packs Fans, ice packs
Happiness and Excitement	Coloring pages, markers, nature puzzles, and fidget toys
Therapy Techniques	CBT therapy techniques, meditations and guided mindfulness provided through recorded audio with headphones, and device CBT Worksheets Guided and free form journals Self-help or improvement literature
Hypertension and Respiratory Depression Monitoring Equipment	Blood Pressure cuffs in size small, medium, large, and extra large Automatic blood pressure monitor For anxiety related hypertension use of cranial electrotherapy stimulation through the Alpha-Stim device can help ease anxiety and reduce blood pressure* Pulse oximeter for blood oxygen saturation monitoring

*Refer to Clinical Policy Cranial Electrotherapy Stimulation Use in Anxiety Related Hypertension Before / During esketamine Treatment

Figure 1. Clinical policy developed for the standardization of the therapeutic environment for esketamine administration from evidence-based recommendations

Clinical Policy

Cranial Electrotherapy Stimulation

Use in Anxiety Related Hypertension Before / During esketamine Treatment

Purpose: A standardized policy that will provide a concrete understanding of the evidence-based way to use an Alpha-Stim device during esketamine treatment to target anxiety related hypertension before and during treatment.

Persons Effected: This policy applies to all members of the healthcare workforce at the Portland, OR and Beaverton, OR locations.

Responsibilities: Providers including MD, DO, PMHNP and esketamine administration technicians

Important Information:

Esketamine causes increases in systolic and/or diastolic blood pressure (BP) at all recommended doses. Increases in BP peak approximately 40 minutes after administration and last approximately 4 hours.

A substantial increase in blood pressure could occur after any dose administered even if smaller BP effects were observed with previous administrations.

Assess BP prior to administration. In patients whose BP is elevated prior to administration (as a general guide: >140/90 mmHg) a decision to delay therapy should be considered depending on benefit and risk in individual patients.

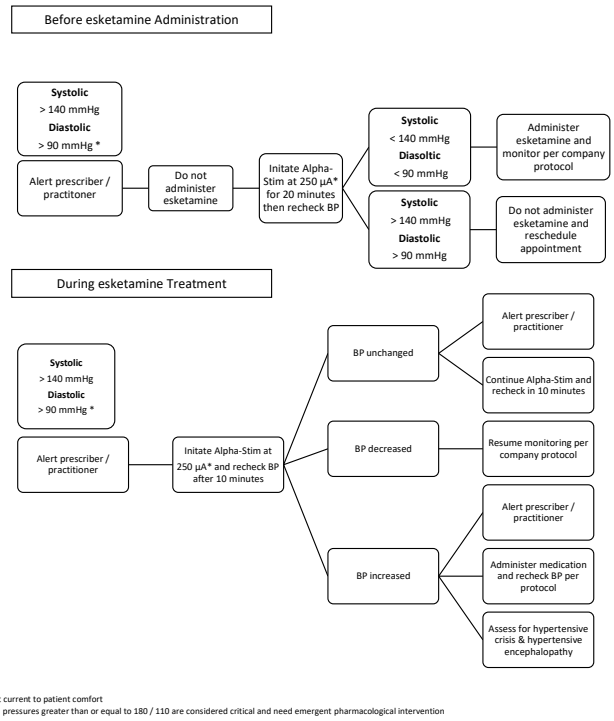
BP should be monitored for at least 2 hours after administration. Measure BP around 40 minutes post-dose and subsequently as clinically warranted until values decline. If BP remains high, promptly seek assistance from practitioners experienced in BP management.

Refer patients experiencing symptoms of a hypertensive crisis (chest pain, shortness of breath) or hypertensive encephalopathy (sudden severe headache, visual disturbances, seizures, diminished consciousness, or focal neurological deficits) immediately for emergency care.

Use of Device:

1. Use clean and dry ear clips and attach 4 new ear clip electrode pads (EEP)
2. Saturate EEPs thoroughly with several drops of conducting solution.
3. Apply one ear clip to each ear lobe. Power on the device.
4. Adjust the current carefully until the patient does not experience tingling, light dizziness, or nausea.
5. Set Timer. 20 minutes is usually enough time if the current is set to at least 250 µA. 40 minutes to 1 hour is recommended if the current is at or below 200 µA.

Decision Guidelines:



*Adjust current to patient comfort
* Blood pressures greater than or equal to 180 / 110 are considered critical and need emergent pharmacological intervention

Figure 2: Clinical policy for the use of cranial electrotherapy stimulation in anxiety related hypertension

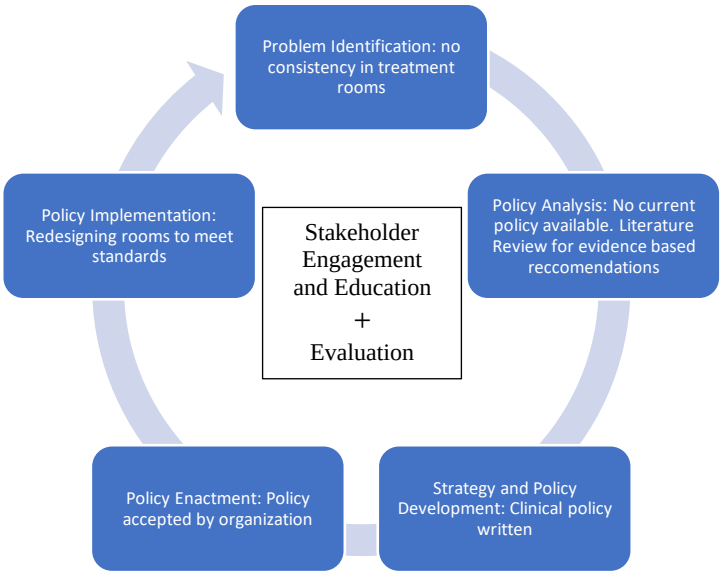


Figure 3: CDC's Policy Analytical Framework applied to project