The Mississauga Halton Palliative Sedation Therapy (PST) Sample Policy

Sample Policy for Palliative Sedation Therapy (PST) Development Committee

- Tracey Human, Toronto Palliative Pain and Symptom Management Consultant
- Julia Johnston, Mississauga Halton Advanced Practice Nurse, Palliative Care
- Jennifer Land, Toronto Palliative Pain and Symptom Management Consultant
- Wendy May, Palliative Care Consultation Program, Consultant
- Sue Shipley, Palliative Care Consultation Program, Consultant
- Cindy Shobbrook, Mississauga Halton Advanced Practice Nurse, Palliative Care
- Carol Sloan, Palliative Care Consultation Program, Manager/Consultant
- Mickey Turner, Palliative Care Consultation Program, Consultant

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Development of this sample policy was significantly influenced by rigorous work undertaken by the Champlain Region, Ontario [1] and Capital Health, Alberta. [2]

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Background

The community of palliative care professionals in Mississauga Halton Region recognizes the need for a consistent evidence-informed approach to the provision of palliative sedation therapy (PST). The use of sedation to control intractable symptoms has been recognized in the literature since 1990 however, terminology and definitions continue to be inconsistent. Previously described as sedation, terminal sedation and palliative sedation, PST is the most recognized terminology within the international palliative care community and will therefore be the term used throughout this document.

Use of this Document

This sample policy may be adapted by organizations and teams to support the assessment, planning, implementation and ongoing evaluation of palliative sedation therapy in diverse settings.

For the purpose of this sample policy, PST is distinct from the following:

- Temporary use of sedation (sometimes known as intermittent or respite sedation) whereby the individual is rendered unconscious for a period of time to allow for management of refractory symptoms until the underlying causes have been reversed and sedation is withdrawn. [3]
- Sedation as an unintended adverse effect of treatment (e.g. opioid-related sedation, sedation from the use of adjuvant analgesics, anxiolytics or anticonvulsants).
- Procedure-related sedation (e.g. sedation for dressing changes).
- Sedation intended to hasten death (this is euthanasia).

Definitions

- **Euthanasia** is the intentional putting to death of a terminally-ill or severely debilitated individual by the commission of an act (active euthanasia) or intentionally withholding a life-saving medical procedure (passive euthanasia). This should not be confused with refusal of treatment which competent individuals have the right to do. [4]

- **Palliative Sedation Therapy (PST)** is the intentional continuous induction of a reduced level of consciousness in order to relieve an intractable symptom or symptoms in an individual who is at the end of life (i.e. last days and hours). The intent is to relieve suffering and not to hasten death. *PST is therefore not euthanasia.*

- **Intractable Symptom** is a symptom for which there is no effective treatment available within the given time frame that the individual can tolerate; or for which the risk-benefit ratio is not acceptable to the individual. Symptoms are defined as

intractable if all other possible treatments have failed, or it is estimated by team consensus after repeated assessments by skilled experts, that no methods are available for alleviation within the time frame.

- **Existential Distress** at end of life has been defined as feelings of hopelessness, burden to others, loss of sense of dignity, desire for death, loss of will to live [5] and threats to self identity. [6] Existential loneliness is the actualization of the sense of self as a separate human being and the feeling of intolerable loneliness, emptiness, longing and sadness that may occur as a result. [7]

- **Psychological Distress** at the end of life can prevent individuals from experiencing pleasure and reduces their capacity for meaning and connection. Such distress may reduce quality of life, and increase the experience of pain and other symptoms. Depression, anxiety and fear are psychological symptoms that can be experienced at end of life. [8]

Ethical Validity of PST

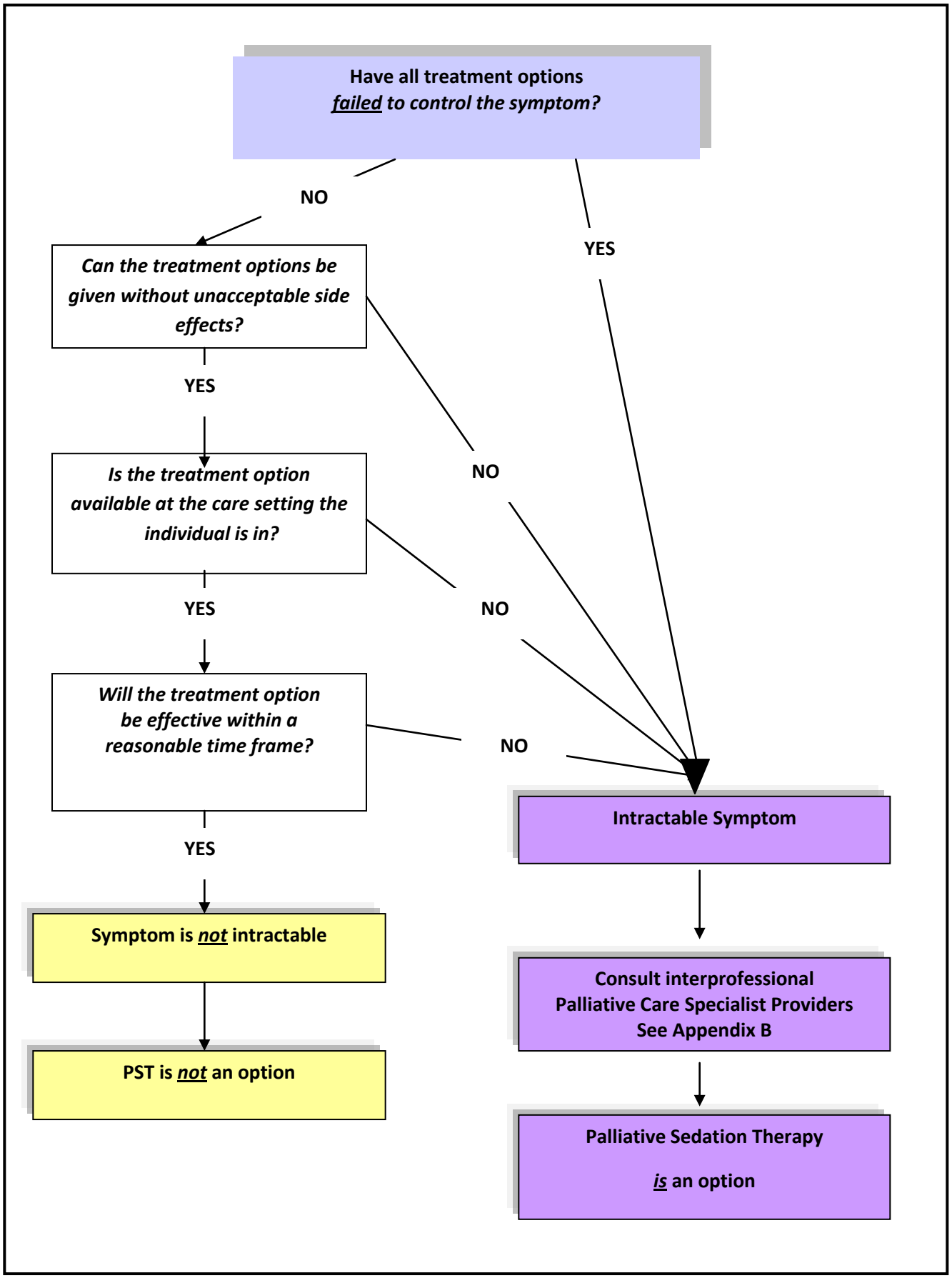
When applied appropriately according to evidence informed guidelines PST is an ethically justified therapeutic option. The intent is to alleviate the suffering caused by an intractable symptom(s) in the last days and hours of life.

Recent studies show that PST does not shorten life. PST will not suspend the disease progression or the natural process of dying. It should be emphasized that the intention of this practice is exclusively to relieve intractable symptoms. If the intent is to shorten life it would be considered euthanasia not PST. [9, 10, 11]. Euthanasia is illegal in Canada.

Every clinician involved in the initiation or monitoring of a person receiving palliative sedation therapy is urged to be familiar with their professional Code of Ethics.

The following algorithm should be used to determine if symptoms are intractable and whether PST is a treatment option.

Intractable Symptom / PST Decision Making Process



Criteria

The following criteria need to be in place prior to considering PST:

1. A progressive, incurable illness is present with a limited life expectancy. Death must be imminent within days to hours.
2. The presence of an intractable symptom or symptoms. Based on current available evidence PST is not recommended as a means to alleviate psychological or existential distress at end of life. An interprofessional approach is recommended to optimize symptom relief.
3. All attempts have been made to control symptoms using other interventions. This may include accessing additional resources outside of the care setting.
4. Informed consent of the individual or his/her surrogate decision maker must be obtained and documented.
5. A Do Not Resuscitate (DNR) or Allow Natural Death (AND) directive from the individual or their Substitute Decision Maker (SDM) is in effect. This must be clearly documented.

See **Appendix A** for a sample PST Criteria and Process Checklist.

Process

The presence of an intractable symptom is a core requirement for initiating PST.
In addition to the above criteria, the team must undertake the following critical process steps before PST is initiated:

1. All criteria are met.
2. The primary attending care team will ensure that a palliative care specialist is consulted to review the case and ensure that all other interventions have been considered. Open dialogue amongst the primary care team is encouraged to explore team member comfort and concerns about providing PST.
3. The criteria and rationale for considering and/or initiating PST are documented in the health record.
4. In addition to discussing PST and explaining what it is, a discussion also occurs with the person or his/her SDM regarding hydration and nutrition. Where death is imminent, artificial nutrition and hydration may be withdrawn or withheld. This decision should be addressed on a case-by-case basis.
5. Explore family member expectations, comfort and concerns with PST. This may involve collaboration with the primary team and a palliative specialist team.

See **Appendix B** for a list of palliative care specialist providers who may be consulted by the primary care team regarding the use of PST as a therapeutic option.

Documentation

Documentation of all steps, medication changes, and assessments will be entered in the health record. Documentation includes the indications for initiating PST, consultations by a palliative care specialist and any discussions with the person or substitute decision maker and the family (with permission).

Monitoring

Parameters and monitoring frequency is influenced by the setting, circumstances and the availability of clinical staff. Staffing assignments may need to be adjusted or supplemented. Some parameters should be monitored routinely, while others are on a case-by-case basis, (see **Appendix C**). The parameters being assessed may also change over time.

1. Level of sedation
   Various clinical assessment instruments to assess the level of sedation are used in palliative care programs across the world i.e. the Richmond Agitation Sedation Scale (RASS -- see **Appendix D**). The use of such a clinical instrument standardizes the assessment method and provides the interprofessional team with a standardized method of communicating about PST, assessing the effectiveness of treatments and setting treatment goals.

2. Airway patency and air entry
   Assess airway patency. Observe for stridor, excessive oral secretions, emesis and evidence of airway obstruction. Reposition the person and/or suction the oral cavity only as required. Deep suctioning is not recommended because it causes an increase in secretion production.

3. Respiratory rate
   Changes in respiratory patterns and sounds, as well as reduced oxygen saturation are normal end-of-life changes and will occur whether or not the individual is receiving PST. Ongoing monitoring of oxygen saturation is not necessary.

4. Bladder fullness
   Urinary retention can cause significant distress. Assess for urinary retention and consider an indwelling urinary catheter.

Continue medications to treat other symptoms for example opioids for pain and anticholinergics for upper respiratory secretions.

Palliative Sedation Therapy: Sample Medication Protocols

Although PST is usually associated with deep levels of sedation, some individuals may find relief of their intractable symptom at light or moderate levels of sedation. The principle of proportionality in using the lowest dose to achieve optimal symptom relief is emphasized.

This section relates specifically to the medications used for achieving palliative sedation therapy. Midazolam and methotrimeprazine are the most commonly used across care settings. Some of these medications may be used in palliative care for indications other than PST such as methotrimeprazine for delirium and midazolam for agitation. In the context of PST, they are used with the intent of inducing sedation where the symptom is assessed to be intractable. The practicality of different care settings (e.g. a palliative care unit versus individual's home) influences the medications and protocols used. Other medications such as phenobarbital and propofol are sometimes used but are not addressed in this sample policy due to their limited application.

Other Considerations:

Drug Interactions
Midazolam is a major substrate of cytochrome P450-3A4. Concomitant medications that are CYP-3A4 inducers may result in rapid increment of dosage of midazolam in a short period, whereas CYP-3A4 inhibitors may cause heavy sedation with a relatively low dose of midazolam. Medication review by the pharmacist prior to initiation of palliative sedation with Midazolam is encouraged. This may result in discontinuation of the inducer or inhibitor. Vigilant assessment is required when the drug cannot be discontinued. An alternate palliative sedation medication may be necessary.

Artificial Hydration and/or Nutrition
Gradual cessation of voluntary intake of fluids is often an indication of approaching death. The vast majority of people have virtually ceased eating and drinking by the time PST is considered. In individuals who are imminently dying, artificial hydration or nutrition may be considered a burden rather than benefit.

If the person is able to take fluids and food orally, the team must discuss with the individual and family the consequences of initiating continuous sedation on the ability of the person to take oral fluids or food. In this situation, artificial hydration by hypodermoclysis may be considered. If an individual already has a feeding tube in place, hydration or feeding may be considered. However, it would not be appropriate to insert a feeding tube to provide artificial feeding or hydration in an individual requiring PST.

Bladder Catheterization
Individuals may require an indwelling catheter once they are sedated. Non catheterized individuals must be regularly assessed for urinary retention.

Other Medications
Continue an individual's current analgesic regimen while receiving PST. If an individual was receiving oral analgesics prior to the PST, switch it to a parenteral route.
Review the individual's medications and discontinue any unnecessary medications (e.g. vitamins and minerals, statins) if the individual is receiving moderate to deep sedation.

Introduction to Medication Protocol

Goal:

To identify the lowest possible dose of medication and lightest level of sedation that achieves comfort. In some cases comfort may be achieved with light to moderate sedation while others will require deeper levels of sedation. The dosage required to achieve these various levels of sedation may vary considerably between individuals. An individual may achieve a light level of sedation with a lower dose of midazolam, while another may become deeply sedated with a lower dose of the same drug.

Medications Used for Palliative Sedation Therapy

Midazolam (Versed™) is the drug of choice for PST because of its potency, short half-life and the ability to titrate the dose up or down fairly rapidly. It also has amnesic properties. The subcutaneous route (s/c) is usually preferred, although the intravenous route may be considered if an individual already has a central line. For PST, midazolam is usually administered by a continuous subcutaneous or intravenous infusion particularly if sedation is expected to continue for more than one or two days. However, it is recognized that in some settings, where access to a pump for continuous infusion is not readily available, midazolam may be administered on an hourly basis.

Methotrimeprazine (Nozinan™) is another medication that is often used for PST. It may be used as the first line agent (at high doses- see below) or as an adjuvant added to midazolam if midazolam alone is not optimally effective.

Phenobarbital is usually not considered a first-line medication for initiating PST. However, it may be considered as first line, if the individual has been experiencing seizures. It may also be considered first line if there is no access to midazolam and the individual has a history of extrapyramidal side effects to methotrimeprazine. Otherwise, phenobarbital may be considered as a second line, added to midazolam, if midazolam is not effective.

The use of opioids should never be considered as palliative sedation therapy. They are ineffective in this role. Opioids pose a high risk of neurotoxicity and/or respiratory depression and cannot be titrated rapidly.

MEDICATION PROTOCOLS FOR PST

Option 1: Midazolam (Versed™) by continuous infusion. This is the preferred option.

1. Administer a loading dose of Midazolam: 2.5 mg or 5mg subcutaneously or IV.
2. Initiate a continuous infusion of Midazolam at 0.5 or 1 mg/hour subcutaneously or IV infusion via an infusion pump. Titrate up (or down) by 1 mg/hr every 30 minutes if needed until the goal is achieved. The usual dose required to achieve PST is between 1 - 6mg/hr.
   The initial titration may need to be rapid (i.e. dose adjusted by 1mg/hr every 30 minutes until the individual is sedated).
3. Titrate dose as needed to maintain sedation.
4. Maintain the hourly dose once the goal is achieved.
5. Consider adding Methotrimeprazine where doses greater than 10mg /hr are required.

Intermittent Midazolam Subcutaneous Injection

1. Intermittent injections are to be considered only as a temporary solution while waiting for infusion pump delivery. The expectation is for the infusion pump to arrive within 24 hours. Continuous infusion is the preferred delivery method to maintain the desired level of sedation. Administer Midazolam 2.5 -5mg subcutaneously q30-60 minutes
2. Titrate dose as needed to maintain sedation.

Option 2: Methotrimeprazine (Nozinan™)

1. Administer a stat dose of methotrimeprazine 25 mg s/c (12.5 mg in a very small, frail individual)
2. Follow up with methotrimeprazine 12.5-25 mg s/c q 8hrs and methotrimeprazine 12.5-25 mg s/c q1hr PRN
   - In most cases, the higher dose (25mg) is required if PST is the intent
3. The dose may be increased to a maximum of 25mg s/c q6 hrs to achieve the goal of PST
   - If higher doses than 25 mg s/c q6 hrs are required, consider switching to midazolam

Appendix A PST Criteria & Process Checklist

	Criteria
	Progressive, incurable illness is present
	Death is expected within days to hours
	Presence of intractable symptom(s)
	All interventions to control symptoms have been exhausted
	Psycho-existential distress is *not* the solitary intractable symptom
	Informed consent for PST has been obtained and documented from individual/substitute decision maker (SDM)
	"Do Not Resuscitate" (DNR) order is in effect *or* clearly documented wishes to "Allow Natural Death" (AND)
	Process
	All above criteria have been met
	Consultation with interprofessional palliative care team expert(s)
	Criteria and rationale for initiating PST are documented in the health care record
	The goals of care have been established through discussions with the individual/SDM, communicated with the care team, and have been documented in the health record. Including: ☐ Expected changes in level of consciousness ☐ Expected changes in oral intake and hydration ☐ Expected respiratory patterns and sounds changes ☐ Artificial hydration burden/benefit ratio ☐ Artificial nutrition burden/benefit ratio ☐ Medications used in PST ☐ Subcutaneous medication administration ☐ Continuous infusion medication delivery ☐ Rationale for discontinuing non-essential medication ☐ Alternate route of administration for essential medications ☐ Pain management will be continued ☐ Ongoing monitoring of: ☐ Pain ☐ Sedation/LOC ☐ Agitation ☐ Other ☐ Family informed of signs of imminent death ☐ The need for: ☐ Indwelling bladder catheter ☐ Oral, eye, skin care ☐ Special bed surfaces ☐ Other

Appendix B Palliative Care Specialist Providers

When considering the use of PST an interprofessional palliative team of one or more of the following palliative care specialists should be consulted:

Ethicist
Palliative Care Advanced Practice Nurse
Palliative Pain and Symptom Management Consultant (PPSMC)
Pharmacist with palliative care expertise
Physician with palliative care expertise
Psychologist with palliative care expertise
Social Worker with palliative care expertise
Spiritual/Religious Advisor with palliative care expertise

Appendix C PST Monitoring

Frequency of Monitoring			
A team member must be available to respond immediately to any requests for reassessment			
		Midazolam	Methotrimeprazine **
PST initiation		<u>Monitor:</u> q15 min. during dose titration to PST goal is achieved (comfort). Once individual remains comfortable without requiring additional bolus/ PRN dose titrations up or down continue monitoring q 15 min x 1 hour <u>Then monitor:</u> q 4 hrs.	<u>Monitor:</u> q1 hr. during dose titration to PST goal is achieved (comfort). <u>Then monitor:</u> q 4 hrs.
Maintaining PST		<u>Monitor</u>: q 4 hrs.	<u>Monitor</u>: q 4 hrs.
All dose adjustment or bolus/ PRN doses given		<u>Restart monitoring:</u> As above for initiation through to maintaining PST	<u>Restart monitoring:</u> As above for initiation through to maintaining PST
***** When Methotrimeprazine in conjunction with Midazolam is used the monitoring in the "Midazolam" column applies.***			

Appendix D Richmond Agitation Scale

Richmond Agitation Sedation Scale (RASS) *

Score	Term	Description
+4	Combative	Overtly combative, violent, immediate danger to staff
+3	Very agitated	Pulls or removes tube(s) or catheter(s); aggressive
+2	Agitated	Frequent non-purposeful movement, fights ventilator
+1	Restless	Anxious but movements not aggressive vigorous
0	Alert and calm	
-1	Drowsy	Not fully alert, but has sustained awakening (eye-opening/eye contact) to *voice* **(>10 seconds)**
-2	Light sedation	Briefly awakens with eye contact to *voice* **(<10 seconds)**
-3	Moderate sedation	Movement or eye opening to *voice* **(but no eye contact)**
-4	Deep sedation	No response to voice, but movement or eye opening to *physical* stimulation
-5	Unarousable	No response to *voice or physical* stimulation

Procedure for RASS Assessment

1. Observe patient
   a. Patient is alert, restless, or agitated. **(score 0 to +4)**
2. If not alert, state patient's name and *say* to open eyes and look at speaker.
   b. Patient awakens with sustained eye opening and eye contact. **(score –1)**
   c. Patient awakens with eye opening and eye contact, but not sustained. **(score –2)**
   d. Patient has any movement in response to voice but no eye contact. **(score –3)**
3. When no response to verbal stimulation, physically stimulate patient by shaking shoulder and/or rubbing sternum.
   e. Patient has any movement to physical stimulation. **(score –4)**
   f. Patient has no response to any stimulation. **(score –5)**

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