# ORAL SEDATION WITH INCREMENTAL ADMINISTRATION

#### **Definition**

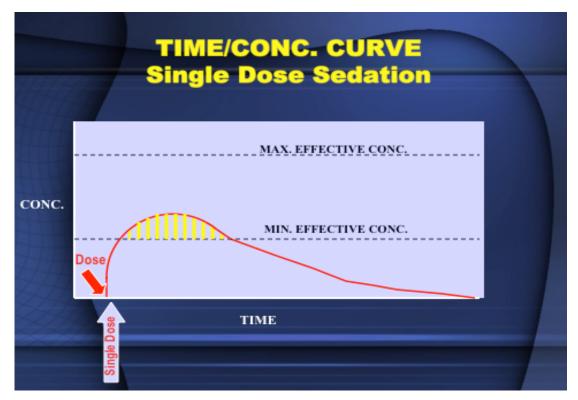
The administration of small doses of an oral sedative at appropriate intervals to achieve and maintain sedation.

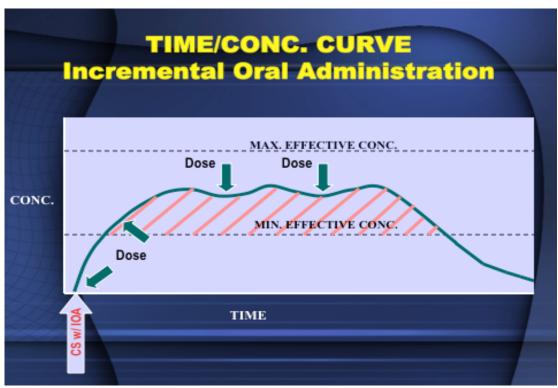
#### Rationale

The Time/Concentration Curve for Incremental Oral Administration differs from that of the Single-Dose Protocols in that additional sedative medication doses are given incrementally ("Dosing To Effect" – Not Titration\*) to keep the patient at a "steady state" of sedation. This allows for better control of depth and length of sedation while maintaining the lowest total dose of a medication. Remember to use the lowest effective dose of any sedative.

Along with the ability to readily extend the depth and length of the sedation, incremental dosing affords the clinician the opportunity to administer smaller doses initially as well as throughout the appointment). This allows for an extra degree of safety not always possible with bolus dosing. In addition, the ability to administer additional doses allows for fewer sedation failures due to the high degree of individual variability.

\*Titration is not a meaningful term when used to describe the actions of oral medications – in this case the desired action of sedation in the dental setting. As stated above, "Incremental Oral Administration is defined as the administration of small doses of an oral sedative at appropriate intervals to achieve and maintain conscious sedation". In this definition, "small doses" refer to dosage amounts that would normally not produce a moderate level of sedation (conscious sedation) by itself. "Appropriate intervals" in this definition refers to two aspects of the incremental approach. The first is the technique of timing the assessment of an individual's response susceptibly to a previous dose, not the mean peak concentration, so that appropriate additional medications may be administered if necessary (with the understanding that additional sedative action will continue to occur from the previous dose). The second aspect that "appropriate intervals" refers to is the timing of additional small doses during an extended visit to maintain a comfort level for the patient. "Achieving...conscious sedation" refers to a minimally depressed level of consciousness whereby the patient retains their protective reflexes, can maintain there own airway, and responds to physical and verbal stimuli. "Maintaining conscious sedation" refers to the readministration of small doses at appropriate intervals (usually tied to the halflife of the medication) to continue the comfort of the patient with the understanding that the appropriate amount of time be allotted after the last dose for the patient to recover and be dismissed safely.





### **Indications**

- Moderate to high fear patients
- Longer Appointments (2-9 hrs.)

### State Board Restrictions

No state requires a permit when the practitioners' intent is anxiolysis and a single dose of an oral anxiolytic agent is administered the day of the appointment. Most states require a permit, usually tied to additional continuing education for minimal sedation using an incremental approach, or conscious sedation (or moderate sedation). Due to the ability of individual state board regulations to change from time to time, it is important to check with your state licensing authority to insure proper compliance with current regulations. DOCS members may also check with DOCS regulatory department's attorney for guidance regarding your individual state.

## **Drug List for Protocols**

The drugs recommended for minimal sedation are the same drugs recommended for anxiolysis. These drugs all have a long track record of performance and safety for minimal sedation in dentistry. The clinical difference between their use for single dose and incremental oral minimal sedation involves the total dosage given and the time of administration. The other important difference between the use of these drugs for anxiolysis and conscious sedation lies in your intent as a practitioner for its use.

Drug (Generic Name)
Diazepam
Triazolam
Drug (Brand Name)
Valium
Halcion

Hydroxyzine Atarax or Vistaril

Lorazepam Ativan

Nitrous Oxide Laughing Gas

## **Protocols**

The protocol for single dose and incremental oral minimal sedation is similar; the exception is the incremental dosing technique. Therefore, patient assessment, pre- post-operative instructions, airway management, monitoring, record keeping and documentation, what to say and not to say, as well as patient dismissal are all the same.

The patient's perception of anxiolysis or minimal sedation is the same. Most will not remember the visit and assume they slept through the appointment.

The difference between the techniques is the assessment for additional medication at appropriate intervals during the appointment. The administration of additional medication is based on patient's individual needs and is largely governed by inter-patient variability.

As with the anxiolysis and single-dose protocols, the incremental dose protocol utilizes an appropriate dose of a long-acting benzodiazepine, diazepam, the night before the appointment at bedtime. This dose serves two primary purposes:

- **1.** The highly anxious patient is allowed to rest better the night before the appointment making for a more pleasant pre-operative experience.
- 2. The highly anxious patient has a sedative/hypnotic agent on board when they present the next day for their appointment making them not only more relaxed, but more susceptible to lower doses of preoperative sedation prior to their appointment. This occurs through a synergistic effect between the two benzodiazepines, as well as obtunding the patient's anxiety resulting in better absorption from the gastrointestinal tract.

There are three categories of drug administration during the day of the appointment for the incremental dose protocol:

- One hour prior to the appointment The medication of choice is taken by the patient one hour before the appointment. The medication is taken at the patient's home or while on their way with a companion driving them to the office.
- 2. At initial assessment When the patient presents to the office, having taken the pre-operative dose as instructed, they are seated in the operatory. Physiologic monitoring begins at this time and is constant throughout the appointment. At the appropriate time interval, based on half-life kinetics, the patient's level of sedation is assessed. Based on this determination, additional medication may be administered in appropriate doses to maintain sedation. No additional medication is required at this point if the patient is sedated properly. Remember, the patient is NEVER left unattended.
- 3. At subsequent assessments during the appointment Depending on susceptibility to a medication, the patient may require additional medication prior to or during treatment. After initial assessment, if additional medication is administered, the patient should be reassessed in 30-60 minutes. If the patient is at the proper level of sedation (a comfortable patient that fulfills the definition of minimal sedation), then dental procedures can be initiated as your schedule permits. If at this

assessment it is determined that the patient is not yet properly sedated, additional doses of medication should be considered. It should be noted that the peak clinical effect of the original dose may not have occurred yet. Therefore, the dose of any additional medication should be considered judiciously. Absorption time may differ from individual to individual. This is why the protocol suggests NPO for 6 hours to improve absorption predictability.

One may question the 30-60minute assessment interval when considering the pharmacological characteristics of the drugs involved. How can a proper assessment be obtained when the peak concentration of an orally administered drug does not occur for more than an hour?

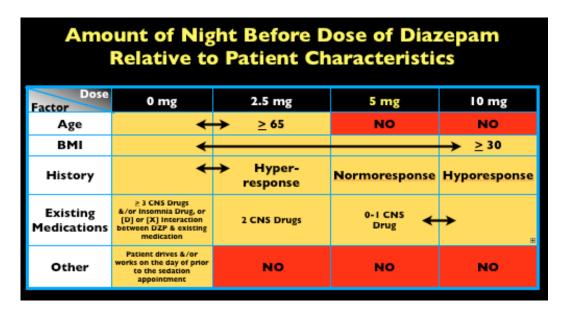
The 30-60 minute assessment interval is explained through the inactivation, redistribution, and elimination that are constantly taking place at receptor sites in the central nervous system. Even though the peak concentration has not occurred, a realistic assessment of the patient's susceptibility to that dose can be determined especially when administered sublingually.

Once dentistry has begun, reassessment should occur every two to three hours until the appointment is completed. It should be emphasized that this two to three hour interval is an average for triazolam and lorazepam respectively, and each patient should be evaluated individually. Some patients will not need additional medication after dentistry has begun. Others will show signs of diminished sedation before the average two hour interval requiring more frequent assessment, and if appropriate, more frequent dosing. In all cases, additional medication should <u>not</u> be administered 2-4 hours prior to dismissal to allow for drug elimination.

# Incremental Protocol #1 ASA I & II Adults

- **Diazepam –** Night before at bedtime, 0 10 mg, swallowed
- Triazolam 1 hr. prior to appointment 0.125 0.25mg, swallowed
- Triazolam At initial assessment and reassessment, 0 0.5mg, sublingual
- Nitrous in office, during delivery of local, titrate to effect with appropriate protocol

### At Bedtime night before appointment - Diazepam



## Day of the appointment

	Initial Dose (1 hr. prior to appoint- ment)	Initial assessment (1 hr. after initial dose)	Reassessment (q0.5hr until dentistry begun, and q2h thereafter)
Elderly/Debilitated/	0.125 mg	0 - 0.125 mg	None to 0.125 mg Triazolam¹
CNS depressants*	Triazolam	Triazolam¹	
All others*	0.25 mg	0 - 0.5 mg	None to 0.5mg
	Triazolam	Triazolam¹	Triazolam¹

<sup>\*</sup>Nitrous Oxide titrated to effect during administration of local anesthesia

<sup>&</sup>lt;sup>1</sup> See Assessment and Reassessment section of this chapter.

### THE "GOLDEN STANDARD" PROTOCOL

(For an 8 a.m. appointment where dentistry is planned to begin at 9 a.m.)

- 1. The patient (Adult ASA I or II) has received prior to their appointment a single dose of 0.25 mg of triazolam (for elderly, debilitated, or patients with a history of hyperreactivity, 0.125mg would be appropriate). They have also received a single dose of 5 mg of diazepam unless they are characteristics that would cause them to hyporespond (10 mg), or hyper-respond (0 2.5 mg).
- 2. Night Before Appointment at Bedtime: The patient swallows a single dose of diazepam (if appropriate).
- 3. 7 AM: The patient takes a single dose of triazolam on an empty stomach (6 hours) one hour before appointed time at the office. A responsible companion escorts patient.
- 4. 8 AM: The patient arrives at the office with a companion, (one hour before dental appointment time). The patient's compliance with medications is obtained and they are then escorted to the bathroom.
- 5. 8:03 AM: The patient is seated in the operatory and has wristwatch and glasses removed and given to their companion.
- 6. 8:04 AM: Continuous monitoring of vital signs (BP every 5 minutes, Heart Rate, and SaO<sub>2</sub>) via pulse oximeter is initiated. Remember that the patients level of consciousness is assessed at each BP reading.
- 7. 8:05 AM: The patient is assessed for additional medications. This assessment is a measure of patient susceptibility, not maximum clinical effect. If necessary, additional medication is provided sublingually.
- 8. 8:35 AM: After 30-60 minutes the patient is reassessed as to their sedation state. If additional medication is deemed necessary, it should be delivered sublingually. The purpose of the incremental system is to achieve the lowest appropriate dose for a comfortable visit.
- 9. 8:54 AM: Six minutes prior to dental appointment time, oxygen is introduced with the appropriate protocol!
- 10.8:57 AM: Nitrous oxide is introduced with appropriate protocol.
- 11.9:00 AM: Local anesthesia is administered.

- 12. Nitrous oxide is removed with the appropriate protocol.
- 13. Begin dentistry.
- 14. Continuous monitoring and checking patient every 5 minutes for appropriate verbal responses.
- 15. When temporary patient cooperation is needed (bite adjustments, bathroom breaks or x-rays) 2 oz. of a clear juice drink with a straw is provided. This should improve cooperation for approximately 5 minutes. The mechanism here is not pharmacological reversal of sedation but physiological stimulation through minor hypoglycemic reversal (the patient has been npo for >8hours.)
- 16. When dentistry is completed, the patient consumes at least 10 ounces of a clear sugar drink. Gatorade type drinks work well.
- 17. The patient will arouse and must be completely conscious to be able to make the journey home safely with their responsible companion.
- 18. Ask the patient to tell you where they are? What day is it? What is their name? This will give you a psychological assessment of orientation X3. Make sure the patient is responding appropriately and is ambulatory.
- 19. Record all appropriate information in the chart... "Patient tolerated treatment well and was ambulatory and oriented X3 when they left".
- 20. The patient and their companion are given written postoperative instructions. Remember to have the companion sign a copy of these instructions.
- 21. Call all patients that night (remind them to hydrate!).

Incremental Protocol #1 is the "golden standard". Although there is limited scientific research at present to support its use, the protocol has an extensive clinical record. It has been effective for 75-90% of all patients requiring minimal sedation.

Additional protocols (Protocols #2-4) are provided for situations where protocol #1 is less effective or not indicated. These protocols are not supported by any scientific research at present, however based upon the pharmacological characteristics of the medications, and clinical experience, they are viable alternatives. These additional protocols are indicated in the

following situations: sedation resistant patients, smokers, or instances where triazolam is contraindicated (ie complex medical conditions or potential drug reactions). Lorazepam has a metabolic pathway that is more resistant to the effects of cirrhosis and hepatic failure. As a result Lorazepam may be preferable to triazolam in a patient with liver failure. The metabolism of lorazepam differs from that of triazolam. This characteristic may make lorazepam an acceptable alternative to triazolam when contraindications to triazolam exist.

### Modifications to the Golden Protocol for the afternoon appointment:

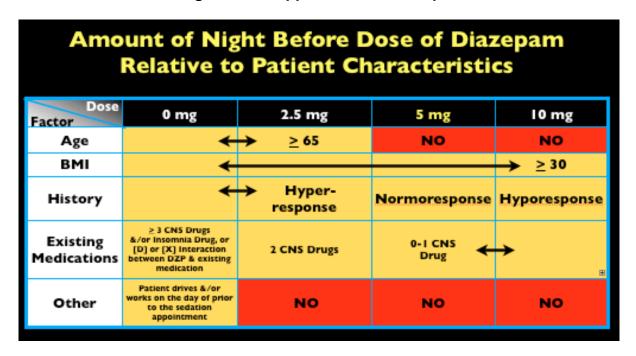
Occasionally, a patient will need to be scheduled in the afternoon to accommodate the needs of the office or the patient. When this occurs, the following needs to be kept in mind:

- The patient still needs to be NPO for six hours prior to the appointment. If their appointment time is 1 p.m., for instance, then they must be NPO since 7 a.m.. To deprive a patient of any nourishment since the night before for such an appointment increases the likelihood of hypoglycemia. All other preoperative instructions remain the same, except for #2 below.
- 2. The preoperative dose of valium the night before should be eliminated and taken instead on the morning of the appointment. If taken at the time of their morning meal, consideration should be given to a larger dose. Once the valium is taken, the patient cannot work or drive, or participate in any other activity forbidden on the day of a sedation appointment.

# Incremental Protocol #2 ASA I & II Adults

- **Diazepam –** Night before at bedtime, 0-10 mg, swallowed
- Triazolam 1 hr. prior to appointment 0.125 0.25 mg, swallowed
- Hydroxyzine At initial assessment 0 100 mg, slurry drink swallowed
- Triazolam At initial assessment and reassessment 0 0.5 mg sublingual
- Nitrous in office, during delivery of local, titrate to effect with appropriate protocol

## At Bedtime night before appointment - Diazepam



### Day of the appointment

	Initial Dose (1 hr. prior to appoint- ment)	Initial assessment (1 hr. after initial dose)	Reassess- ment (q0.5hr until dentistry begun, and q2h thereafter)
Elderly/Debilitated/ CNS depressants*	0.125 mg Triazolam	0 - 0.125 mg Triazolam¹ 25 mg – 50 mg Hydroxyzine	0 - 0.125 mg Triazolam¹
All others*	0.25 mg Triazolam	0 - 0.5 mg Triazolam¹ 50 mg – 100 mg Hydroxyzine	0 - 0.5 mg Triazolam¹

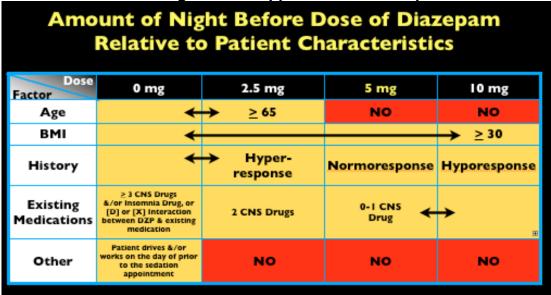
<sup>\*</sup>Nitrous Oxide titrated to effect during administration of local anesthesia

<sup>&</sup>lt;sup>1</sup> See Assessment and Reassessment section of this chapter

# Incremental Protocol #3 ASA I & II Adults

- •Diazepam Night before at bedtime, 0-10 mg, swallowed
- ●Lorazepam 1 hr. prior to appointment 1 -2 mg, swallowed
- **●Lorazepam –** At initial assessment and reassessment 0 3 mg, sublingual
- Nitrous in office, during delivery of local, titrate to effect with appropriate protocol

At Bedtime night before appointment – Diazepam



Day of the appointment

	Initial Dose (1 hr. prior to appoint- ment)	Initial assessment (1 hr. after initial dose)	Reassess- ment (q0.5hr until dentistry begun)
Elderly/Debilitated/ CNS depressants*	1 mg Lorazepam	None to 2 mg Lorazepam¹	None to 2 mg Lorazepam¹
All others*	2 mg Lorazepam	None to 3 mg Lorazepam¹	None to 3 mg Lorazepam¹

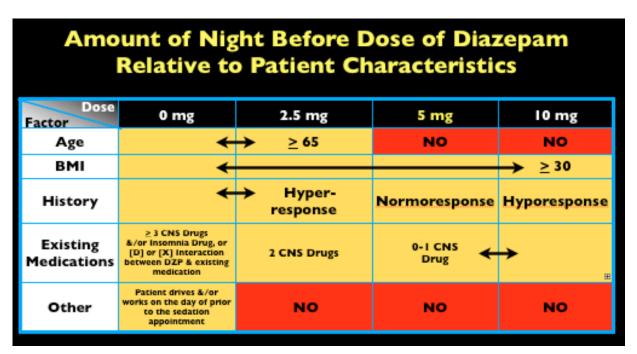
<sup>\*</sup>Nitrous Oxide titrated to effect during administration of local anesthesia

<sup>&</sup>lt;sup>1</sup> See Assessment and Reassessment section of this chapter

# Incremental Protocol #4 ASA I & II Adults

- Diazepam Night before at bedtime, 0-10 mg, swallowed
- Lorazepam 1 hr. prior to appointment 1 2 mg, swallowed
- Hydroxyzine At initial assessment 0 100 mg, slurry drink swallowed
- Lorazepam At initial assessment and reassessment 0 3 mg sublingual
- Nitrous in office, during delivery of local, titrate to effect with appropriate protocol

At Bedtime night before appointment – Diazepam



### Day of the appointment

	Initial Dose (1 hr. prior to appointment)	Initial assessment (1 hr. after initial dose)	Reassess- ment (q0.5hr until dentistry begun)
Elderly/Debilitated/ CNS depressants*	1 mg Lorazepam	0 - 2 mg Lorazepam¹ 25 mg – 50 mg Hydroxyzine	0 - 2 mg Lorazepam¹
All others*	2 mg Lorazepam	0 - 3 mg Lorazepam¹ 50 mg – 100 mg Hydroxyzine	0 - 3 mg Lorazepam¹

<sup>\*</sup>Nitrous Oxide titrated to effect during administration of local anesthesia

# ASSESSMENT FOR ADDITIONAL MEDICATION (See Protocol 8:05AM)

- 1. Sit at eye level with the patient.
- 2. Ask the patient to rate their level of sedation. "Mary, on a scale from 1 to 10, where 1 is that you are totally relaxed (like don't bother me please!) and 10 is your totally awake (like you are ready to go Christmas shopping), where are you on that scale?" Using the individual patient's social history, construct the above questions to best relate examples of a relaxed or excited state.
- 3. Observe the following:
  - **a.** Patient's ability to make eye contact. Good eye contact indicates a low level of sedation. Poor eye contact is indicative of a deeper level of sedation.
  - **b.** Patient's speed of answering. Appropriate response time indicates less sedation; a delay in response indicates a deeper level of sedation.
  - **c.** Patient's language
    - i. Slurred speech. Clear annunciation indicates less sedation; slurred speech, a deeper level of sedation.

<sup>&</sup>lt;sup>1</sup> See Assessment and Reassessment section of this chapter

- ii. Use of "ums" and pauses. Clearly timed speech indicates less sedation; ums and pauses indicate a deeper level of sedation.
- iii. Volume of speech is it hard to hear them? Appropriate volume indicates less sedation; decreased volume indicates a deeper level of sedation.
- d. Did the patient give you a number in response to the "scale" question? You cannot rely on the number given as the primary indication of the level of sedation. You must take into consideration all the listed observation factors before making a determination. If you must insist on a numbered response from the patient, this also indicates a deeper level of sedation.
- **e.** Did the patient ask you to repeat the scale? This indicates confusion and a deeper level of sedation.
- **f.** Patient's physical posture. If the patient is sitting upright and erect this indicates a lighter level of sedation. If the patient leaning or seeking a supine position, this indicates a deeper level of sedation.
- 4. Based on your observations of the patient, determine if additional medication is required.
- 5. Before administering additional medication, ask the patient if they would like to be more sedated. If the patient says "no", do not deliver additional medication. The patient may be comfortable at this lighter level. As always, we must ensure the use of the lowest dosage possible.
- 6. If you have determined that additional medication is required (and the patient said "yes"), then you must determine the appropriate dose according to the following:
  - a. 0.5 mg Triazolam would be appropriate when the patient responded clearly, quickly and appropriately to the "scale" question with a 9 or 10. Eye contact was good and posture is erect. There is no evidence of confusion (substitute 3 mg Lorazepam for protocols #3 & 4 and add 50mg Hydroxyzine for protocols #2 & 4).
  - b. 0.25 mg Triazolam would be appropriate when the patient's response is clear but slightly delayed. They have moderate eye contact and their volume may be slightly decreased and may respond to the "scale" question without using numbers. The patient's posture is relaxed but self-supporting (substitute 2 mg Lorazepam for protocols #3& 4 and add 50mg Hydroxyzine for protocols #2 & 4).
  - c. 0.125 mg Triazolam would be appropriate when the patient's response is slightly slurred and delayed. They may ask you to repeat the "scale" question. Eye contact may be inconsistent and the patient may begin to lean (substitute 1 mg Lorazepam for protocols #3& 4 and add 50mg Hydroxyzine for protocols #2 & 4).

d. No additional medication would be appropriate when the patient's response is slurred and delayed. The patient may be very quiet and use "ums". Confusion is evident. No eye contact is made and the patient leans and seeks a supine position.

# REASSESSMENT <u>AFTER</u> ADDITIONAL MEDICATION (See Protocol 8:35AM)

- 1. Sit at eye level with the patient.
- 2. Ask the patient to rate their level of sedation by turning the scale upside down to test for confusion. "Mary, on a scale from 1 to 10, where 1 is your totally awake (like you are ready to go Christmas shopping), and 10 is that you are totally relaxed (like don't bother me please!), where are you on that scale?" Using the individual patient's social history, construct the above questions to best relate examples of a relaxed or excited state.

### 3. Observe the following:

- **a.** Patient's ability to make eye contact. Good eye contact indicates a low level of sedation. Poor eye contact is indicative of a deeper level of sedation.
- **b.** Patient's speed of answering. Appropriate response time indicates less sedation; a delay in response indicates a deeper level of sedation.
- **c.** Patient's language:
  - I. Slurred speech. Clear annunciation indicates less sedation; slurred speech, a deeper level of sedation.
  - II. Use of "ums" and pauses. Clearly timed speech indicates less sedation; ums and pauses indicate a deeper level of sedation.
  - III. Volume of speech is it hard to hear them? Appropriate volume indicates less sedation; decreased volume indicates deeper level of sedation.
- d. Did the patient give you a number in response to the "scale"? question? You cannot rely on the number given as the primary indication of the level of sedation. You must take into consideration all the observation factors before making a determination. If you must insist on a numbered response from the patient, or they did not catch the scale being switch around, this also indicates a deeper level of sedation.
- **e.** Did the patient ask you to repeat the scale? This indicates confusion and a deeper level of sedation.
- **f.** Patient's physical posture. If the patient is sitting upright and erect this indicates a lighter level of sedation. If the patient

leaning or seeking a supine position, this indicates a deeper level of sedation.

- 4. Based on your observations of the patient, determine if additional medication is required.
- 5. Before administering additional medication, ask the patient if they would like to be more sedated. If the patient says "no", do not deliver additional medication. The patient may be comfortable at this lighter level. As always, we must ensure the use of the lowest dosage possible.
- 6. If you have determined that additional medication is required, you must determine the appropriate dose.
  - **a.** 0.5 mg would be appropriate when the patient responded clearly, quickly and appropriately to the "scale" question with a 9 or 10. Eye contact was good and posture is erect. There is no evidence of confusion (substitute 3 mg Lorazepam for protocols #3 & 4).
  - **b.** 0.25 mg would be appropriate when the patient's response is clear but slightly delayed. They have moderate eye contact and their volume may be slightly decreased and may respond to the "scale" question without using numbers. The patient's posture is relaxed but self-supporting (substitute 2 mg Lorazepam for protocols #3 & 4).
  - c. 0.125 mg would be appropriate when the patient's response is slightly slurred and delayed. They may ask you to repeat the "scale" question. Eye contact may be inconsistent and the patient may begin to lean (substitute 1 mg Lorazepam for protocols #3 & 4).
  - d. No additional medication would be appropriate when the patient's response is slurred and delayed. The patient may be very quiet and use "ums". Confusion is evident. No eye contact is made and the patient leans and seeks a supine position.

### **Patient Dismissal**

Important note: all patients should be fully conscious, ambulatory and psychologically oriented before considering dismissing them in the care of a responsible companion.

- Make sure they are oriented X3
- Do not be afraid to use Flumazenil (Romazicon or Anexate) if you are having trouble getting them to respond to verbal commands or the constant physiological monitoring indicates a trend towards nonmanageable oxygen desaturation.

- Review postoperative instructions with the responsible companion (see New Patient Packet). Remember to have the companion sign a copy of these instructions.
- Review dental procedures with the patient (when they are completely recovered)
- Have the companion walk with their hand on the patient's elbow for balance
- Remind them to rehydrate
- Have companion drive patient <u>directly</u> home and contact the office as soon as they arrive
- Always be encouraging
- Schedule hygiene instructions appointment the next day

### Do Not Dismiss When:

- Patient is sleepy and not ambulatory
- Patient is unable to answer correctly when asked: where they are, what day it is and what is their name (ambulatory x 3)
- Patient is nauseous or vomiting
- Patient is experiencing excessive bleeding
- Patient's vital signs are not stable
- No responsible companion is available to take patient home and attend to their needs.