VIRGINIA BOARD OF DENTISTRY

Regulatory Advisory Panel (RAP) Meeting

AGENDA

February 02, 2018

1:45p.m.

Department of Health Professions
Perimeter Center - 9960 Mayland Drive, 2nd Floor Conference Center,
Henrico, Virginia 23233
Board Room #4

TIME		PAGE
1:45 p.m.	**Call to Order – John M. Alexander, D.D.S., Chair**	
	Evacuation Announcement – Ms. Reen	
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	February 2, 2018 Discussion Draft of the Regulations Governing the Practice of Dentistry	**P. 44**
	Dr. Sarrett's Review Comments on Part VI. Controlled Substances, Sedation and Anesthesia	**P. 84**
	Guidelines for Monitoring and Management of Pediatric Patients Before, During and After Sedation.....	**P. 96**
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	Next Steps	
Adjourn		

UNAPPROVED

BOARD OF DENTISTRY
MINUTES OF THE REGULATORY ADVISORY PANEL ON THE CONTROLLED SUBSTANCES, SEDATION AND ANESTHESIA REGULATIONS
Friday, December 1, 2017

TIME AND PLACE: The meeting of the Regulatory Advisory Panel (RAP) of the Board of Dentistry was called to order on December 1, 2017 at 1:45 p.m. at the Department of Health Professions, 9960 Maryland Drive, Suite 201, Training Room 1; Henrico, Virginia.

PRESIDING: John Alexander, D.D.S, Chair

PANEL MEMBERS PRESENT:
David Sarrett, D.D.S.
Malinda Husson, D.D.S.
Jacques Riviere, D.D.S.
Carol Russek, JD

ESTABLISHMENT OF QUORUM: All members of the Panel were present.

STAFF PRESENT:
Sandra K. Reen, Executive Director
Kelley W. Palmatier, Deputy Executive Director
Sheila Beard, Executive Assistant
Elaine Yeatts, DHP Policy Analyst

Ms. Reen gave the instructions for evacuating the building in case of emergency.

OPEN FORUM: Dr. Alexander explained the Forum is an opportunity for speakers to address their questions, concerns and recommendations for the Board of Dentistry's regulations. He noted that speakers have about five minutes to address their concerns. He then called on members of the audience who had signed the attendance sheet to make their comments. Other members of the audience also made comments. The transcript of the comments received are attached to these minutes.

PANEL DISCUSSION: Following a brief break, Dr. Alexander asked the panel how it would like to proceed with its review. Discussion followed about topics that should be considered in addition to the ones identified by the public.

Ms. Yeatts suggested the panel take time to go over the ADA guidelines and our current regulations along with the transcript from the open forum.

After identifying a number of topics of interest, the panel agreed to defer discussion of regulatory changes to a subsequent meeting in order to review all the comments received. In addition, staff was asked to send the full text of the Regulations Governing the Practice of Dentistry, the American Academy of Pediatric Dentistry sedation guidelines and the American Society of Anesthesiologists practice guidelines.

NEXT MEETING: Ms. Reen noted that Friday, February 2, 2018 had been reserved if a second meeting was needed. The Panel agreed to meet that day.

ADJOURNMENT: With all business concluded, Dr. Alexander adjourned the meeting at 3:44 p.m.

John M. Alexander, D.D.S., Chair	Sandra K. Reen, Executive Director
Date	Date

VIRGINIA BOARD OF DENTISTRY
REGULATORY ADVISORY PANEL

OPEN FORUM

ON CONTROLLED SUBSTANCES, SEDATION AND

ANESTHESIA REGULATIONS

Perimeter Center
9960 Mayland Drive
Richmond, Virginia

December 1, 2017

1:45 p.m.

BOARD MEMBERS:

John M. Alexander, DDS

Sandra K. Reen, Executive Director

David Sarrett, DDS

Malinda Husson, DDS

Carol R. Russek, JD

Jacques Riviere, DDS

Elaine J. Yeatts

Shiela M. Beard

TRANSCRIPT OF PROCEEDINGS

MR. ALEXANDER: Good afternoon everyone. Welcome and thank everyone for coming. We're looking forward to input from everyone.

ATTENDEE: Can't hear.

MR. ALEXANDER: Do I have to repeat that again?

Welcome everyone. Thank everyone for coming, and we certainly look forward to all the input from the audience for this forum.

Before we get started, I would like Sandy Reen to read you evacuation notes.

MS. REEN: In the event of a fire or other emergency requiring the evacuation of the building, alarms will sound. When the alarm sounds, leave the room immediately following any instructions given by security staff. To exit this room, go out of either of the two doors -- three doors to my left. Turn to the hallway that goes immediately outside that door and turn left to the emergency exit door and proceed to the back of the parking lot to the fence and wait for instructions from security personnel.

If you need assistance exiting this room, please let me know, and I'll make sure security

personnel are aware of your needs. Thank you.

MR. ALEXANDER: Okay, I would like the people up here in front to introduce themselves starting on the right-hand side.

MS. BEARD: Shiela Beard, Board Staff.

MS. YEATTS: Elaine Yeatts, Policy Analyst for the Department.

MR. RIVIERE: Jacques Riviere, retired oral surgeon.

MS. REEN: Sandy Reen, Executive Director of the Board.

MR. ALEXANDER: John Alexander, board member.

DR. SARRETT: David Sarrett, general dentist, dean of D.C. School of Dentistry.

DR. HUSSON: Malinda Husson, pediatric dentist and anesthesiologist in private practice, Richmond, Virginia.

DR. RUSSEK: Carol Russek, citizen member of the Board of Dentistry.

MR. ALEXANDER: I think we can get started. This is an opportunity for us to hear you and your concerns concerning the Anesthesia Regulations of the Board of Dentistry of Virginia. You can come up here and sit in that chair. You have approximately five

minutes to tell us your concerns. This is not a time for us to discuss with you. We will be discussing what you say at this point a little later on in the afternoon. So Ms. Reen ...

MS. REEN: Ms. Beard is getting the sign-in sheet now.

MR. ALEXANDER: When you come up here, just give us your name, and if you have a specialty or general dentistry or nursing, whatever it is, just let us know what you're speaking for and whether you represent a specific organization or not.

Okay, I'm going to call the first one on the list, and it's Amanda Kerns?

MS. KERNS: And I'm going to waive the right to talk. I'm just going to listen for a while if that's okay, Mr. Alexander.

MR. ALEXANDER: If at the end you feel like you want to say something, you're welcome to.

Jon Shneidman.

MR. SHNEIDMAN: I do have a question, sir. As a general dentist, I do a lot of oral surgery. As a general dentist, I do a fair amount of oral surgery, and I'd like to know what the Board's policy is on giving narcotic pain medication post-op?

Specifically, I've been kind of told

through the grapevine that we are not to give Percocet anymore and we're to limit the amount of Percocet. Well, I don't even give Percocet anymore. I'm giving Vicodin and Norco, but I want the Board's input on what's considered appropriate treatment when you're taking out multiple teeth.

Also, I see a lot of emergency patients who are in pain. And as you know, because of the epidemic, the opioid overdose epidemic, what standard of care does the Board expect us to follow? I want your guidance on what is considered reasonable to give somebody who comes in, has abscess teeth or needs multiple extractions.

Because, like I say, my guidance is I'm not giving out Percocet anymore. I'm going to Norco and Vicodin, and I'm limiting the number that I'm giving. Before I was giving like 20, 20 Percocet out and I'm not doing that anymore. I want your input into what is considered by the Board of Dentistry the standard of care concerning that issue.

MR. ALEXANDER: I appreciate your question. This is a forum so we're not going to be able to discuss that with you, especially this is a forum on anesthesia. We do have new regulations on opioids, and if you read that, it is pretty clear what you

need to do in giving patients medications for postoperative pain and so forth. So I think if you follow those guidelines...

If you have any specific questions, you can contact the Board and we'll be able to discuss that with you.

MR. SHNEIDMAN: Thank you very much, sir.

MR. ALEXANDER: Do you have anything to say about anesthesia?

MR. SHNEIDMAN: No, that was all I wanted to say.

MR. ALEXANDER: Al Stenger.

DR. STENGER: Good afternoon. I'm Al Stenger, as you've heard. I am a general dentist here in Richmond, Virginia, and I practice with two other dentists.

I've come to comment on the implications of the sedation regulations on access to care for people that have disabilities. Some background. Our dental practice has provided care to people with disabilities for some 40 years since James Schrader started this practice in the 1970s. Currently we average over 50 adult special needs patient visits per month. These visits range from preventive care to basic restorative and surgical care.

Some special needs patients can receive care with simple attention to their needs; others need various levels of sedation, as you can imagine. We provide a range of services in this area. Even going to the operating room with general anesthesia is required to complete their needed dental care.

We have concerns in three areas we'd like the Board to consider. They all involve access to care.

No. 1: The current regulations make it difficult to provide cost-effective preventive services under mild sedation if this routine service cannot be provided by a dental hygienist under general supervision. Many of these patients simply need a bump in their routine benzodiazepine medication prior to their visit or maybe need a low dose benzodiazepine to lower their anxiety level.

We'd like clarification from the Board as to whether this is considered mild sedation and whether a dental hygienist can deliver the care under this circumstance under general supervision with a dentist present in the building, not in the room.

As you can imagine, if this is not possible, then the cost of delivering routine preventive care to patients who need a very mild form

of benzolysis will be elevated by raising the cost of accessing this care to a population who generally can least afford it.

As you can imagine, a lot of these people need to come three and four times a year to maintain their health.

No. 2: Regarding monitoring of patients with disabilities undergoing moderate conscious sedation, there are some considerations we'd like the Board to think about. When a special needs patient needs a level of sedation such that monitoring with standard BP pulse ox monitoring equipment is indicated, that doesn't necessarily mean that monitoring is simple or straightforward.

Many times we can provide appropriate dental care with sedation while the patient still moves their hands and arms uncontrollably. Sometimes their head also moves from time to time, but we can still deliver appropriate care.

The problem comes when managing the monitoring takes more efforts than managing the patient or the procedure. We're wondering how many hands it will take to stabilize the patient who is moving a little, stabilize the monitor, thinking in terms of capnography here, and deliver the dental

care. There is only so much room available at the patient's head.

We would ask the Board to consider that the monitoring requirements might make it necessary to take these patients to the operating room where general anesthetic would be required.

It's our opinion this would expose many of these patients to unnecessary medical risk, as well as elevate the cost of care to levels that will limit access to care.

No. 3: Our experience is that many people with disabilities have a very difficult time accessing dental care, especially in a dental office in their local community. We believe this to be the case because of the stories they tell us. We don't have any empirical evidence to share with you all, but we do have a concern that the sedation regulations are not helping.

We believe many special needs patients could safely and appropriately receive most of their dental care, particularly routine dental care, preventive services in the dentist office near their home.

We believe those who need very mild sedation are facing barriers, some of which are due

to regulation, sedation regulations.

In sum, we'd like the Board to consider what impact these regulations have on access to care for people with disabilities. We believe that our society should work to integrate people with disabilities fully into our communities, including being able to receive cost-effective routine preventive dental care at a general dental office nearby.

I thank you all for your consideration of these matters.

MR. ALEXANDER: Thank you very much.

Okay, Stuart Broth.

MR. BROTH: I have no comment at this time.

MR. ALEXANDER: Lisa -- Carl Atkins.

MR. ATKINS: I also have no comment at this time. I reserve the right to talk later.

MR. ALEXANDER: Certainly, if you'd like at the end.

Lisa Turner.

MS. TURNER: I have no comment at this time.

MR. ALEXANDER: Benita Miller.

MS. MILLER: I'll be quick.

MR. ALEXANDER: Take your time.

MS. MILLER: I just want to thank this panel and the Board for having an open forum and working towards making the regulations as clear as they can be, because we as dentists want to do the best we can for our patients and comply with the law as best we can. So thank you for doing that. I just wanted to say that.

I do have a question under the minimal sedation. It's just a little confusing in terms of the role of the hygienist. So it would be on Page 6 18VAC -- well, 280 "Administration of Minimal Sedation", letter C, "Delegation of Administration", and then under that D, "Dental hygienist with the training required only for administration of nitrous oxide/oxygen with the dentist present in the operatory."

So I'm a little unclear, because on Page 5, it allows the hygienist to administer nitrous oxide under indirect supervision. So in other words, the dentist is in the office but not in the operatory. But then on Page 6, it's saying the dentist must be in the operatory. So to me that conflicts with what we already have in place in 5.

And then item -- under C, item or No. 3, it says "If minimal sedation is self-administered by or

to a patient 13 years of age or older before arrival at the dental office or treatment facility, the dentist may only use the personnel listed in Subdivision 1 of this subsection to administer local anesthesia."

So I guess my question is: Can a hygienist give local anesthesia to a minimally sedated patient? I mean, I know you can't answer that but that's just a point of clarity.

And I think that was the main -- the two main points.

MR. ALEXANDER: The question is: Can a hygienist give local anesthesia for minimal sedation?

MS. MILLER: Yes.

And then sort of subsequent to that, you know, is it -- since nitrous oxide can be used as a way to provide minimal sedation and hygienists are allowed to treat a patient under the influence of nitrous oxide, if a patient had taken, say, a very low dose of a Benzodiazepine and, again, they were minimally sedated, is a hygienist allowed to clean that person's teeth, clean that patient's teeth with the dentist in the office but not necessarily in the operatory? I guess my hope would be, yes, that would be the case.

And that's all I have to comment on.

MR. ALEXANDER: Sort of the same question about the dentist having to actually be there?

MS. MILLER: Correct. That's it.

MR. ALEXANDER: Thank you very much.

Tom Padgett.

MR. PADGETT: I'm going to waive my right to speak.

MR. ALEXANDER: Cathy Harrison.

MS. HARRISON: No comment at this time.

MR. ALEXANDER: Michele Satterlund.

MS. SATTERLUND: Good afternoon. Michele Sutherland on behalf of the Virginia Association of Nurse Anesthetists. I'm a lobbyist for McGuireWoods Consulting.

First of all, I want to thank you all for having us here this afternoon. We applaud your efforts to take a look at the Anesthesia regulations and find out if there are opportunities to make them simpler, more efficient and more in compliance with the statutory requirement.

So I have two comments actually, specific to CRNAs in the Anesthesia regulations. The first deals with the terms that are used in describing the relationship between the dentist and the CRNA.

In the regulations, the term is used "medical direction and indirect supervision." I think back when these regulations were written, those were the terms used in the code. Those are no longer the terms used in the code and there's no definition of what those mean. So our comment would first be to eliminate that language.

And because the code already mandates supervision for CRNAs, whether that's via physician, podiatrist or a dentist, we would say it's unnecessary to have any descriptor related to the CRNAs. So just to avoid confusion, eliminate those terms.

MS. BEARD: This is her handout.

MS. SATTERLUND: I'm sorry, I apologize. I know there is an echo. Is this echoing to all of you?

MR. ALEXANDER: That's fine.

MS. SATTERLUND: We have submitted comments, that I don't know if they've been passed around, but I have written detail about the exact regulatory provisions that I'm discussing here.

The second concern I want to bring up, and this is 290, 291 and 301, and I didn't write 301, but each of these sections says that in accordance with

the statutory requirement, and I think the enabling legislation was passed in 2012, that no dentist may administer anesthesia or sedation unless the dentist has a permit.

And then that section of the regulations is in keeping with the code requirement, but what's confusing them is if you go later into those same regulatory requirements, it says that a dentist without a permit may use an anesthesiologist or a qualified dentist in a dental office.

And the code is very precise and unambiguous, and I feel that that allowance, that exception is contrary to what the code allows. The code says, "The Board shall require any dentist who provides or administers sedation or anesthesia in a dental office to obtain either a conscious/moderate sedation permit or a deep general anesthesia permit."

Interestingly, the code makes the distinction between provide and administer. I looked up in the dictionary what provide means. It means to make available. Administer means to apply. So when I read this, the General Assembly intended that that requirement to be served in two different instances and makes no exception for allowing another anesthesia provider to practice in the dental office

unless that dentist has a permit.

So our recommendation, if you read our comments, is just to follow the statutory requirement, use the words that are used in the statute, provide rather than employ, which is what the regulations use, and cause confusion.

Do you have any questions? Was that clear, what we're trying to explain here?

MR. ALEXANDER: I think so, but I think we should read this over and look at that carefully.

MS. SATTERLUND: Thank you. And if you have any questions, I am here to serve as a resource, and I appreciate your time this afternoon.

MR. ALEXANDER: Thank you very much.

That's the end of the list that I have here. You don't have to be on the list if you really need to say something in this, for this. Any input?

MR. GLAZIER: Thank you all for having this open forum today and for your time. My name is Thomas Glazier. I am a periodontist in private practice here in Richmond, Virginia.

I'm asking the Board to provide a little clarification in the language. If you look at Page 3, it should be under the "General Provisions" part under "Pediatric Patients", which is stated in

several areas of this regulation, that "No sedating medication shall be prescribed for or administered to a patient 12 years of age or younger prior to his arrival of the dentist office or treatment facility."

I would like a little clarification in the language. The way I read this, it says, "No sedating medication shall be prescribed for." If you just ignore the administer part, which makes sense to me, but what does not make sense is how you prescribe for a patient 12 years of age, period. The way this reads, it sounds like you can't prescribe to them until they get to the dental office, which just does not make sense the way I'm reading this.

MR. ALEXANDER: This is one of those sentences you have to read a couple times.

MR. GLAZIER: Sure, absolutely.

MR. ALEXANDER: We'll certainly look at that and make it so there's no question.

MR. GLAZIER: On that same note, if you look further on Page 9 under VAC60-21-291 under No. 3, there is a distinction here between the age of 13 years of age or older, which is a clear-cutoff to me that they are 13 years, zero days old. Whereas, under the next part, it again refers to a patient 12 years of age or younger. So what I'm wondering is

where does a person stand if they're 12 and a half years old?

MR. ALEXANDER: Good point.

MR. GLAZIER: Lastly under the administration of nitrous oxide, on Page 6 under "Discharge Requirements" and, again, this is just the administration of nitrous oxide under postoperative instructions, it says that "They shall be given verbally and in writing." Does this apply to routine hygiene appointments with the use of nitrous oxide being administered by a qualified dental hygienist?

DR. SARRETT: Tom, what section is that?

MR. GLAZIER: So it would be under 18VAC60-21-279 "Administration of local and of only inhalational analgesia nitrous oxide." And then that would be under letter G, "Discharge Requirements" No. 2.

So I understand that verbally but in writing is my question for appointments that say or just routine recall appointments utilizing nitrous oxide. Thank you all for your time.

MR. ALEXANDER: Thank you very much.

MR. GLAZIER: Have a great day.

MR. ALEXANDER: Dr. Pirok.

DR. PIROK: Good afternoon. I am a

practicing oral surgeon in Saluda, Virginia, and I'm here to advocate. I am a member of the Community Service Boards and member of the Association of Community Service Boards, and I'm speaking about the CSBs, not for them.

There are approximately 30,000 staff members, and we are by statute commissioned to be concerned about mental health, intellectual and developmental disabilities and substance abuse.

My first advocacy is for the revived program. The revive program is a combination of the Health Department and the Community Service Boards, and this revive program advocates that lay people prepare themselves to deal with overdoses that may or may not occur in the office or near the office. With 3,000 hygienists, approximately, and 6,000 dentists, that could be a formidable force to be available to correct an overdose, particularly with the opioids. Approximately six dental patients die a day in Virginia from overdoses.

Now, you may say how is that, but everybody needs a dentist. It's universal, and so I would visualize the people dying from overdoses of opioids would be dental patients.

I recommend careful and continued

preparation for emergencies in the dental office. And I see this as one aspect of it.

General anesthesia and IV sedation should be used by the provider only if it is the last resort, such as the care of children, and not be a provider moneymaker.

I recommend that the provider attest on the anesthesia record that no other alternative pain control option was available and that active promotion of IV or inhalation treatment did not occur.

Postoperatively, only minimum amounts of opioid medication be prescribed unless the patient clearly has a medical indication for those agents.

I also advocate that the medical history be expanded to include mental health and chemical dependency questions to aid the provider in supporting prevention. 80 percent of the heroin overdoses were first alcoholics, and we as dentists can make, through our inquiries, an assessment as to whether chemical dependency exist in that dental patient. I thank you.

MR. ALEXANDER: Thank you.

Okay, yes.

DR. WONG: Hello, my name is Jonathan Wong.

I am a dentist anesthesiologist, and I want to talk just more in generalities regarding preoperative, perioperative, postoperative vital signs and some of the monitoring techniques that we use.

Really the argument on a national level and local level has been about access to care versus patient safety.

Now, with the latest ADA guidelines that came out in 2016, the ADA has moved much more aggressively to mirror the American Society of Anesthesiologist guidelines, which I think should be applauded, because most anesthesia providers, whether that's a nurse anesthetist, dental anesthesiologist or MD or DO anesthesiologist, use that as the gold standard.

Where there is a lack of those guidelines tends to be in the minimal sedation realm, because that's something that is more or less unique to dentistry.

Having said that, the ADA's guidelines recommend using a maximum recommended dose for oral medications. And those maximum recommended doses are doses that are allowed for patients to take without any monitoring. So with those ADA guidelines, they recommend that pulse ox may be a beneficial

monitoring device for that minimal sedation scenario. And I believe that that's warranted and recommended because one of the major tenets of all of this is that patients may go into a deeper level of sedation than originally intended.

Now, with the new 2016 guidelines, the old terminology of being able to rescue one level deeper than what was intended to be delivered is now gone. And I think that's a good idea because anything that we do, whether it's oral sedation, IV moderate sedation, has the ability even as a single agent to get us as deep as general anesthesia. And that's kind of where that links to the opioid crisis.

For example, someone can use simply just narcotic and get themselves to the point that they are basically in general anesthesia and needing an airway rescue and that's how they overdose.

So having said that, I think that those things are good things. I think the new educational guidelines that require you to be able to rescue deeper levels at all levels is a very important thing to enforce.

So, for example, moderate sedation permits should probably not be obtained as they were in the past with just oral sedation experiences. And that

has been reflected in the new update to the 2016 educational guidelines that show that a practitioner must be able to show IV or IO competency and access.

Having said that, I'm going to focus now more on vital signs, which you guys have been asking about. Capnography is a very important part of what anesthesiologists monitor. And we can argue that will things like --

MR. ALEXANDER: Dr. Wong, we want a clarification of the last statement.

DR. WONG: Okay. I'm sorry, before I went into the vital signs?

MR. ALEXANDER: Yes.

DR. WONG: So in the 2016 educational --

DR. SARRETT: Earlier in your comments you said the requirements to be able to rescue one level deeper were removed but then you said that they are in the educational guidelines. I'm just looking.

DR. WONG: Yes, I'm sorry. One level deep, the old guidelines used to say you had to be able to rescue one level deeper.

DR. SARRETT: Which guidelines?

DR. WONG: The old educational guidelines on sedation from the ADA.

DR. SARRETT: The educational guidelines.

DR. WONG: Educational guidelines, and they have removed that. Now it says that you should be able to rescue from any aspect of complication that might arise from your sedation. So if you're, say, a moderate sedation provider, you should be able to rescue someone who goes into deep sedation or even general anesthesia. So you need to at least have the training to appropriately use a bag mask, an LMA or endotracheal tube to rescue that person.

Before it was, oh, if you're doing minimal sedation, you should be able to rescue someone with basically a jaw thrust in case they went to moderate sedation. So that's where that has changed.

MR. ALEXANDER: That's changed for good.

DR. WONG: It is a good change, and I recommend in my opinion that we mirror that, and the Board has always done that, kind of mirrored what the updates were with the ADA recommendations or guidelines were.

MR. ALEXANDER: Okay.

DR. WONG: Any other questions about that?

MR. ALEXANDER: I'm sorry.

DR. WONG: No, please. I know I covered a lot in that. Any other questions about that?

DR. SARRETT: I just wasn't sure if you

were in favor or not in favor.

DR. WONG: Definitely in favor. Definitely in favor of it. Thank you.

As far as vital signs monitoring, our regulations are a bit nebulous, and people have asked what exactly should we be monitoring for each of the levels of anesthesia or during the perioperative period, the intraoperative period and the postoperative period. And I don't know what the right answer is for that. I think it is very, very patient dependent, but at the same time we need to stress patient safety.

So by prescribing basic things like the standard ASA or American Society of Anesthesiologist monitoring is probably a good thing, which includes capnography. However, the question then really becomes pre-op.

I see a lot of special needs children and adults who are extremely combative, sometimes wouldn't even get out of the car. Are you going to be able to get preoperative vitals signs on them? No. We do a preoperative exam, often in the car, listening to their lungs, trying to look in their mouth. We're not going to get any better than that. I'm not going to get a blood pressure on them.

Oftentimes I can't get a reliable pulse ox reading because the kid is doing this or throwing it across the car or not even letting me touch him. So that would severely hamper our access to care for those patients. However, intraoperatively, absolutely everything should be monitored, including capnography.

One gentleman, not to be disrespectful, said, look, it's more equipment; it's more that you have to have area for. It's really a nasal cannula or a small little gas sampling line that hooks to a nasal hook. It's not that much more difficult. It is an added expense but it is something in our current regulations you have to have available anyway so why not use it.

The next part of things becomes the postoperative period, and this can be rather difficult, because if we say all monitoring must be performed, sometimes blood pressure monitoring on young kids as they're waking up is not very accurate and it's also not very beneficial. The reason being that the kids are moving around so we are not getting an accurate blood pressure; it's making them more agitated by squeezing their arm repeatedly.

And the final thing is that these children,

especially at that age, are very rate dependent, meaning that their blood pressure is based on their current heart rate. So if we're monitoring pulse ox and therefore heart rate and we're monitoring that in the immediate postoperative period, we really don't need to be monitoring those additional criteria once they've met kind of what we call phase one discharge criteria, meaning that they don't need the one-on-one relationship with the anesthesiologist anymore. At that point they go to my RN often. At that point we really don't need quite as much, I hate to say invasive because it is noninvasive, but that type of monitoring still.

The final thing that we have also noticed in here is it also said that those should be monitored until discharge, but it's not clear whether that's discharge criteria being met or the patient actually being discharged from the office. Because sometimes discharge criteria is met.

In my patient population, Medicaid and Medicaid cabs, sometimes we'll wait three hours for the Medicaid cab to show up. That means I have to have my RN sit with them for three hours when I could have, you know, a dental assistant sitting with them after they no longer need any monitoring.

In fact, at this point they are often playing games in the waiting room, eating a Popsicle and everything, yet still I have my RN telling them hold still because I need to get additional vitals and everything. Those things we are not sure.

MR. ALEXANDER: Basically you want us to look at the monitoring and to be sure that it's clear, and obviously when you have a patient that's not cooperative, you know, you are going to have to use your own judgment.

DR. WONG: Absolutely. And I think that a lot of that is just using good judgment from a provider. The problem is that sometimes it's cumbersome. Sometimes people need those regulations in place to make sure that they are doing what's appropriate.

MR. ALEXANDER: Well, thank you very much.

DR. WONG: I appreciate your time.

MR. ALEXANDER: Excellent points.

We have time for anymore input from the --

DR. STENGER: Is it appropriate I can ask the gentleman a question? One of the things we struggle with is the definitions of moderate rate --

MS. REEN: Dr. Stenger, we can't hear you.

DR. STENGER: One of the things that we --

and it's become clear, you know, with the comment I just heard. One of the things we really struggle with is the definition of this mild, moderate deep sedation. And where we're having trouble, you know, is the patient that's moving around that we can still do treatment on. You know, we may consider it moderate sedation because of the medication we gave them but they're still pretty resistive, and we don't necessarily want to bring them any deeper. You know, if we are going to bring them deeper, we are going to take them to the OR. So this is where we have our issues with the capnography and even all the monitoring.

So if the previous gentleman, I understand what he's saying, you know, if you are willing to put that person into a deeper level, a deeper state, then of course monitoring becomes easy. But what we're trying to do is work with the public and with the limitations that they have financially and with our ability to safely treat them at a lower level of sedation. I mean, heck, it may even be considered mild sedation. A lot of these folks are on chronic benzos and they are resistant to medications and they are moving around quite frankly.

So where we're struggling is as the

regulations become more -- you know, I know you're trying to clarify, but as they become a little bit more strict, they are really making it difficult for us to do what we have done for 40 years safely for a large population of disabled folks in our office. Maybe that's the way the state wants us to go and the public. Maybe that's the right way to go, but I don't know. I don't think it's going to improve access to care. And I know the gentleman mentioned that was an issue.

So I don't know if it's better to clarify the -- I mean the bottom line, experienced doctors, we know what we're doing. We've been doing it for a long time. I know you guys see a lot of folks who have had trouble, and it would help to clarify, but I don't want to -- caught in all the clarifications and all the safety, I don't want to see us back to the days where people with disabilities are taking to the operating room routinely for easy basic dental care. Thank you.

MR. ALEXANDER: Appreciate your comments.

DR. WONG: Mind if I reply to that?

MR. ALEXANDER: Sure. This is the last one, though.

DR. WONG: Just as a quick reply to that.

One of the first things is defining those different levels of sedation. And the American Society of Anesthesiologists has defined that very well. And the new ADA guidelines for the use of sedation and general anesthesia by dentists actually does define that very specifically.

So going back to looking at that, I think that we do get some answers there and perhaps it's just a matter of adopting that specifically.

Now, movement itself does not determine the level of sedation. It's purposeful movement. It is actual intent for a behavior. So moderate sedation when it's performed, just repeated verbal stimuli or even just regular verbal stimuli should elicit a response that is purposeful from that patient. So if I say Dr. Alexander, you would say oh, what? And that is moderate sedation.

Now, if I have to tap you multiple times and give you multiple verbal stimuli, that's deep sedation. If you don't respond to tactile stimuli, that's general anesthesia. It's not based on movement. Because even under general anesthesia, if I don't use local and I prick someone's hand and I have not paralyzed them, they will withdraw and move from it, and that will happen as a spinal reflex. So

therefore it is not the movement that determines these things. It's actually as the new ADA guidelines recommend.

Now, in regard to access to care, completely agree, and that's where we were talking about that balance of patient safety and access to care. And oftentimes, yes, people can be treated, especially special needs patients, with either oral sedation, oral conscious sedation or IV moderate sedation. Yet sometimes they don't and aren't able to do that. That doesn't necessarily mean they have to go to the OR.

For example, in my facility, we have this happen all the time. Patients are appointed to go to the OR. Their medical insurance doesn't cover it. They come in and they say I was quoted a $12,000 bill to go in my area CHKD's Ambulatory Surgery Center. They come into us. Our facility is a category one med gas certified facility, so we are allowed to do general anesthesia. We're certified the same as one of these ambulatory surgical centers; yet they pay 1,200 bucks, sometimes less than that if they have insurance.

I mean, one of these patients came in and was quoted yesterday I think $5,000 to do all the

work, went through, had two insurances, and ended up paying I think 300. Same thing with Medicaid. So the access to care is possible. It's there. It's just changing the way we think about things, and sometimes that's, you know, updating standards.

The American Society of Anesthesiologists dealt with this in the '80s and '90s. We, as anesthesiologists, morbidity and mortality from anesthesia was high, and they had to change the way they thought and what the standard should be. And what they did is they went to the airline industry and started looking at safety checks. And those safety checks helped improve anesthesia from being one of the most dangerous procedures in the hospital to one of the safest.

And I think doing the same thing on the dental side of anesthesia is important. And I think that we do have to balance both of them, but patient safety should always be paramount.

MR. ALEXANDER: Absolutely, thank you.

Any other?

MS. CARNEY: Hi, good afternoon. I am Jacqueline Carney. I am a pediatric dentist and also dental anesthesiologist. I also submitted the petition for clarification about the guidelines that

were proposed on sedation and anesthesia.

I think I have the impression that if we have patients that aren't cooperative for the vital signs that are listed to be obtained, that merely documenting that in our records is sufficient representation of our attempt to meet the guidelines that are listed. And I would hope that that would be taken into consideration by all of the practitioners and by all of the people on the Board of Dentistry for a case that were to come forward.

My concerns with the petition that I submitted is that based on the current writings, I can't tell what vital signs you would like for me to obtain during each of the three important parts of a sedation or anesthesia. In my mind, there is a perioperative period before we provide any treatment to the patient -- or a preoperative period before we provide treatment, a perioperative period where we are providing treatment and then a postoperative period.

And in many of the paragraphs that were written about each of the stages, minimal sedation, moderate sedation, deep sedation, and general anesthesia, the criteria changed. And in some of those categories, they aren't even listed. Pre-op

has one set, post-op has a different set and nothing is listed for the perioperative period.

I want to be able to get the vital signs because that helps keep the patient safe, but I also want to meet the criteria, and I can't do that with the way it's currently described.

I have the same concerns that Dr. Wong brought up about the statement of staff remaining with the patient until discharge. It's not uncommon at all in our practice that the patient clinically has met discharge criteria and despite our repeated statements to the parents that they don't leave the office, they're out running errands or they have gone to pick up four other children from school.

And I have an assistant that right now is stuck with the patient who is back to baseline, but because I don't know what the Board is really asking of me and my staff with the current definitions, I don't know whether or not I can allow that staff member to move on to other things.

Additionally, one other point that I haven't heard mentioned today is the vital signs for the blood pressure to be obtained for nitrous oxide before and after, and I haven't been able to find any other state that has that requirement. I can't find

literature either to support the need for that.

Blood pressure tends to be the most unreliable vital sign that you can obtain particularly in a patient that is anxious, which is an indication for the use of the nitrous oxide. So I'm hoping that that can be taken into consideration as well. It is a very difficult vital sign to get on an anxious pediatric patient at any point of the care process.

I appreciate the time you guys are giving to all of this to help us understand better what it is you believe we should be doing so that we can meet those guidelines and criteria. Thank you.

MR. ALEXANDER: Thank you. Appreciate your comments and the material that you submitted to us a while ago.

Any other comments from the audience? Okay, I think at this time if there's nothing further, I think we can take a little break and in a couple minutes we'll come back and begin the portion where the actual RAP or the Regulatory Committee will address some of these issues and discuss this whole change and try to make things a little clearer. And that's mainly what we would like to do.

We would like to let you know that we do

listen to you, and we like to make things easier for you and understandable. Somebody said it, obviously patient safety is paramount. We'll come back in about ten minutes.

(Thereupon, the proceedings concluded at 2:41 p.m.)

CERTIFICATE OF REPORTER

I, Lois B. Boyle, RMR, do hereby certify that I reported verbatim the proceedings for the Public Hearing for the Virginia Board of Dentistry, Regulatory Advisory Panel on December 1, 2017 at Virginia Board of Dentistry, Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Richmond, Virginia.

I further certify that the foregoing is a true, accurate and complete transcript of said proceedings.

Given under my hand this 18th day of December at Newport News, Virginia.

_____

Lois B. Boyle
Notary Registration No. 203748

VANA 1934
Virginia Association of Nurse Anesthetists
CRNA

December 1, 2017

Ms. Sandra Reen
Virginia Board of Dentistry
Dept. of Health Professions
Perimeter Center
9960 Mayland Drive
Richmond, VA 23233-1463

Re: Open Forum Review: Part VI of the Regulations Governing the Practice of Dentistry on Controlled Substances, Sedation and Anesthesia

Dear Ms. Reen,

On behalf of the Virginia Association of Nurse Anesthetists ("VANA") I am pleased to provide comments regarding Part VI of the Regulations Governing the Practice of Dentistry on Controlled Substances, Sedation and Anesthesia ("the Regulations").

VANA represents the more than 1900 certified registered nurse anesthetists ("CRNA") who practice in every setting in which anesthesia is delivered in Virginia, including hospital surgical suites, outpatient surgery centers, and of course, dental offices.

VANA applauds the Board of Dentistry ("Board") for its efforts to ensure the Regulations are in compliance with Virginia's statutory requirements and reflect today's anesthesia practice environment. We look forward to working with you on this important matter.

1. **18VAC60-21-270 and 18VAC60-21-280**

Under Virginia Code §54.1-2900, CRNAs are defined as advanced practice registered nurses who are jointly licensed by the Board of Medicine and Nursing and practice under the supervision of a doctor of medicine, osteopathy, podiatry or dentistry. Neither the Virginia Code, nor the regulations promulgated by the Joint Boards of Nursing and Medicine governing nurse practitioners, require that the supervising physician or dentist be trained in anesthesia delivery, nor do these laws require the supervising provider to be located on-site during the delivery of anesthesia care.

In contrast, 18VAC60-21-270 and 18VAC60-21-280 require the CRNA to practice under the "medical direction and indirect supervision" of the dentist. Because Virginia Code already prohibits CRNAs from

practicing without the supervision of a dentist, the Board's use of "medical direction and indirect supervision" is unnecessary and does not accurately reflect the statutorily mandated relationship between dentists and CRNAs. VANA recommends the Board eliminate the use of the terms "medical direction and indirect supervision."

2. **18VAC60-21-290 and 18VAC60-21-291**

18VAC60-21-290(A) prohibits a dentist from employing or using conscious or moderate sedation in a dental office unless the dentist has been issued a permit. This is in keeping with the enabling statute, Virginia Code §54.1-2709.5, which states (emphasis mine):

> "A. Except as provided in subsection C, the Board shall require *any* dentist who *provides* or *administers* sedation or anesthesia in a dental office to obtain either a conscious/moderate sedation permit or a deep sedation/general anesthesia permit issued by the Board. The Board shall establish by regulation reasonable education, training, and equipment standards for safe administration and monitoring of sedation and anesthesia to patients in a dental office.

The word "provide" is precise and unambiguous and is defined by Collins World English Dictionary as "to put at the disposal of, furnish or supply." Merriam-Webster defines "provide" as "to supply or make available" and further defines "administer" as "to provide or apply" or "to give remedially."

While the statute makes no exception and requires "any dentist who provides or administers sedation or anesthesia in a dental office" to obtain a permit, 18VAC60-21-291(A)(1) goes beyond what is statutorily authorized and allows a dentist who does not hold a permit to use the services of a qualified dentist or an anesthesiologist to administer sedation in a dental office.

So as to avoid confusion and to better ensure compliance with the Virginia Code, VANA recommends the Board amend 18VAC60-21-290(A) and 18VAC60-21-291(A)(1) to reflect the exact words of §54.1-2709.5:

> 18VAC60-21-290(A): "A. ~~After March 31, 2013, no~~ **No** dentist may **provide** ~~employ~~ or **administer** ~~use~~ conscious/moderate sedation in a dental office unless he has been issued a permit by the board...."
>
> 18VAC60-21-291(A)(1) "A dentist who does not hold a permit to administer conscious/moderate sedation shall ~~only use the services of a qualified dentist or an anesthesiologist to~~ **not provide or** administer such sedation in a dental office~~.~~."

VANA 1934
Virginia Association of Nurse Anesthetists
CRNA

3. **18VAC60-21-300 and 18VAC60-21-301**

See comments 1. and 2. above.

Again, we thank the Board for its efforts and we urge your consideration of these amendments.

Sincerely,

/s/ Jerrol Wallace

Jerrol Wallace
President
Virginia Association of Nurse Anesthetists

cc: Michele Satterlund, McGuireWoods Consulting

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Commonwealth of Virginia

2/2/2018 RAP
DISCUSSION DRAFT

REGULATIONS
GOVERNING THE PRACTICE OF DENTISTRY

VIRGINIA BOARD OF DENTISTRY

Title of Regulations: 18 VAC 60-21-10 et seq.

Statutory Authority: § 54.1-2400 and Chapter 27 of Title 54.1 of the *Code of Virginia*

Effective Date: June 14, 2017

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CHAPTER 21
REGULATIONS GOVERNING THE PRACTICE OF DENTISTRY

Part I. General Provisions.

18VAC60-21-10. Definitions.

A. The following words and terms when used in this chapter shall have the meanings ascribed to them in § 54.1-2700 of the Code of Virginia:

"Board"

"Dental hygiene"

"Dental hygienist"

"Dentist"

"Dentistry"

"License"

"Maxillofacial"

"Oral and maxillofacial surgeon"

B. The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"AAOMS" means the American Association of Oral and Maxillofacial Surgeons.

"ADA" means the American Dental Association.

"Advertising" means a representation or other notice given to the public or members thereof, directly or indirectly, by a dentist on behalf of himself, his facility, his partner or associate, or any dentist affiliated with the dentist or his facility by any means or method for the purpose of inducing purchase, sale, or use of dental methods, services, treatments, operations, procedures, or products, or to promote continued or increased use of such dental methods, treatments, operations, procedures, or products.

"CODA" means the Commission on Dental Accreditation of the American Dental Association.

"Code" means the Code of Virginia.

"Dental assistant I" means any unlicensed person under the direction of a dentist or a dental hygienist who renders assistance for services provided to the patient as authorized under this chapter but shall not include an individual serving in purely an administrative, secretarial, or clerical capacity.

"Dental assistant II" means a person under the direction and direct supervision of a dentist who is registered by the board to perform reversible, intraoral procedures as specified in 18VAC60-21-150 and 18VAC60-21-160.

"Mobile dental facility" means a self-contained unit in which dentistry is practiced that is not confined to a single building and can be transported from one location to another.

"Nonsurgical laser" means a laser that is not capable of cutting or removing hard tissue, soft tissue, or tooth structure.

"Portable dental operation" means a nonfacility in which dental equipment used in the practice of dentistry is transported to and utilized on a temporary basis at an out-of-office location, including patients' homes, schools, nursing homes, or other institutions.

"Radiographs" means intraoral and extraoral radiographic images of hard and soft tissues used for purposes of diagnosis.

C. The following words and terms relating to supervision as used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Direct supervision" means that the dentist examines the patient and records diagnostic findings prior to delegating restorative or prosthetic treatment and related services to a dental assistant II for completion the same day or at a later date. The dentist prepares the tooth or teeth to be restored and remains immediately available in the office to the dental assistant II for guidance or assistance during the delivery of treatment and related services. The dentist examines the patient to evaluate the treatment and services before the patient is dismissed.

"Direction" means the level of supervision (i.e., immediate, direct, indirect, or general) that a dentist is required to exercise with a dental hygienist, a dental assistant I, or a dental assistant II or that a dental hygienist is required to exercise with a dental assistant to direct and oversee the delivery of treatment and related services.

"General supervision" means that a dentist completes a periodic comprehensive examination of the patient and issues a written order for hygiene treatment that states the specific services to be provided by a dental hygienist during one or more subsequent appointments when the dentist may or may not be present. Issuance of the order authorizes the dental hygienist to supervise a dental assistant performing duties delegable to dental assistants I.

"Immediate supervision" means the dentist is in the operatory to supervise the administration of sedation or provision of treatment.

"Indirect supervision" means the dentist examines the patient at some point during the appointment and is continuously present in the office to advise and assist a dental hygienist or a dental assistant who is (i) delivering hygiene treatment, (ii) preparing the patient for examination or treatment by the dentist, or (iii) preparing the patient for dismissal following treatment.

"Remote supervision" means that a dentist is accessible and available for communication and consultation with a dental hygienist employed by such dentist during the delivery of dental hygiene services but such dentist may not have conducted an initial examination of the patients who are to be seen and treated by the dental hygienist and may not be present with the dental hygienist when dental hygiene services are being provided. For the purpose of practice by a public health dental hygienist, "remote supervision" means that a public health dentist has regular, periodic communications with a public health dental hygienist regarding patient treatment, but such dentist may not have conducted an initial examination of the patients who are to be seen and treated by the dental hygienist and may not be present with the dental hygienist when dental hygiene services are being provided.

D. The following words and terms relating to sedation or anesthesia as used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Analgesia" means the diminution or elimination of pain.

"Conscious/moderate sedation" or "moderate sedation" means a drug-induced depression of consciousness, during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

"Deep sedation" means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. The ability to

independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

"Enteral" means any technique of administration in which the agent is absorbed through the gastrointestinal tract or oral mucosa (i.e., oral, rectal, sublingual).

"General anesthesia" means a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilator function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

"Inhalation" means a technique of administration in which a gaseous or volatile agent, including nitrous oxide, is introduced into the pulmonary tree and whose primary effect is due to absorption through the pulmonary bed.

"Inhalation analgesia" means the inhalation of nitrous oxide and oxygen to produce a state of reduced sensation of pain with minimal alternation of consciousness.

"Local anesthesia" means the elimination of sensation, especially pain, in one part of the body by the topical application or regional injection of a drug.

"Minimal sedation" means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilator and cardiovascular functions are unaffected. Minimal sedation includes "anxiolysis" (the diminution or elimination of anxiety through the use of pharmacological agents in a dosage that does not cause depression of consciousness) and includes "inhalation analgesia" when used in combination with any anxiolytic agent administered prior to or during a procedure.

"Local anesthesia" means the elimination of sensation, especially pain, in one part of the body by the topical application or regional injection of a drug.

"Minimal sedation" means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilator and cardiovascular functions are unaffected. Minimal sedation includes "anxiolysis" (the diminution or elimination of anxiety through the use of pharmacological agents in a dosage that does not cause depression of consciousness) and includes "inhalation analgesia" (the inhalation of nitrous oxide and oxygen to produce a state of reduced sensibility to pain without the loss of consciousness).

"Moderate sedation" (see the definition of ~~conscious~~/moderate sedation).

"Monitoring" means to observe, interpret, assess, and record appropriate physiologic functions of the body during sedative procedures and general anesthesia appropriate to the level of sedation as provided in Part VI (18VAC60-21-260 et seq.) of this chapter.

"Parenteral" means a technique of administration in which the drug bypasses the gastrointestinal tract (i.e., intramuscular, intravenous, intranasal, submucosal, subcutaneous, or intraocular).

"Titration" means the incremental increase in drug dosage to a level that provides the optimal therapeutic effect of sedation.

"Topical oral anesthestic" means any drug, available in creams, ointments, aerosols, sprays, lotions, or jellies, that can be used orally for the purpose of rendering the oral cavity insensitive to pain without affecting consciousness.

"continual" means repeated regularly and frequently in a steady succession.

"continuous" means prolonged without any interruption at any time.

18VAC60-21-20. Address of record.

Each licensed dentist shall provide the board with a current address of record. All required notices and correspondence mailed by the board to any such licensee shall be validly given when mailed to the address of record on file with the board. Each licensee may also provide a different address to be used as the public address, but if a second address is not provided, the address of record shall be the public address. All changes of address shall be furnished to the board in writing within 30 days of such changes.

18VAC60-21-30. Posting requirements.

A. A dentist who is practicing under a firm name or who is practicing as an employee of another dentist is required by § 54.1-2720 of the Code to conspicuously display his name at the entrance of the office. The employing dentist, firm, or company must enable compliance by designating a space at the entrance of the office for the name to be displayed.
B. In accordance with § 54.1-2721 of the Code a dentist shall display his dental license where it is conspicuous and readable by patients in each dental practice setting. If a licensee practices in more than one office, a duplicate license obtained from the board may be displayed.
C. A dentist who administers, prescribes, or dispenses Schedules II through V controlled substances shall maintain a copy of his current registration with the federal Drug Enforcement Administration in a readily retrievable manner at each practice location.
D. A dentist who administers conscious/moderate sedation, deep sedation, or general anesthesia in a dental office shall display his sedation or anesthesia permit issued by the board or certificate issued by AAOMS.

18VAC60-21-40. Required fees.

A. Application/registration fees.	
1. Dental license by examination	$400
2. Dental license by credentials	$500
3. Dental restricted teaching license	$285
4. Dental faculty license	$400
5. Dental temporary resident's license	$60
6. Restricted volunteer license	$25
7. Volunteer exemption registration	$10
8. Oral maxillofacial surgeon registration	$175
9. Cosmetic procedures certification	$225
10. Mobile clinic/portable operation	$250
11. Conscious/moderate sedation permit	$100
12. Deep sedation/general anesthesia permit	$100
B. Renewal fees.	
1. Dental license - active	$285
2. Dental license - inactive	$145
3. Dental temporary resident's license	$35
4. Restricted volunteer license	$15
5. Oral maxillofacial surgeon registration	$175
6. Cosmetic procedures certification	$100
7. Conscious/moderate sedation permit	$100

8. Deep sedation/general anesthesia permit	$100
C. Late fees.	
1. Dental license - active	$100
2. Dental license - inactive	$50
3. Dental temporary resident's license	$15
4. Oral maxillofacial surgeon registration	$55
5. Cosmetic procedures certification	$35
6. Conscious/moderate sedation permit	$35
7. Deep sedation/general anesthesia permit	$35
D. Reinstatement fees.	
1. Dental license - expired	$500
2. Dental license - suspended	$750
3. Dental license - revoked	$1000
4. Oral maxillofacial surgeon registration	$350
5. Cosmetic procedures certification	$225
E. Document fees.	
1. Duplicate wall certificate	$60
2. Duplicate license	$20
3. License certification	$35
F. Other fees.	
1. Returned check fee	$35
2. Practice inspection fee	$350

G. No fee will be refunded or applied for any purpose other than the purpose for which the fee is submitted.

H. For the renewal of licenses, registrations, certifications, and permits in 2016, the following fees shall be in effect:

1. Dentist - active	$210
2. Dentist - inactive	$105
3. Dental full-time faculty	$210
4. Temporary resident	$25
5. Dental restricted volunteer	$10
6. Oral/maxillofacial surgeon registration	$130
7. Cosmetic procedure certification	$75
8. Conscious/moderate sedation certification	$75
9. Deep sedation/general anesthesia	$75
10. Mobile clinic/portable operation	$110

Part II. Standards of Practice.

18VAC60-21-50. Scope of practice.

A. A dentist shall only treat based on a bona fide dentist-patient relationship for medicinal or therapeutic purposes within the course of his professional practice consistent with the definition of dentistry in § 54.1-2700 of the Code, the provisions for controlled substances in the Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code), and the general provisions for health practitioners in the Code. A bona fide dentist-patient relationship is established when examination and diagnosis of a patient is initiated.

B. For the purpose of prescribing controlled substances, the bona fide dentist-patient relationship shall be established in accordance with § 54.1-3303 of the Code.

18VAC60-21-60. General responsibilities to patients.

A. A dentist is responsible for conducting his practice in a manner that safeguards the safety, health, and welfare of his patients and the public by:

1. Maintaining a safe and sanitary practice, including containing or isolating pets away from the treatment areas of the dental practice. An exception shall be made for a service dog trained to accompany its owner or handler for the purpose of carrying items, retrieving objects, pulling a wheelchair, alerting the owner or handler to medical conditions, or other such activities of service or support necessary to mitigate a disability.

2. Consulting with or referring patients to other practitioners with specialized knowledge, skills, and experience when needed to safeguard and advance the health of the patient.

3. Treating according to the patient's desires only to the extent that such treatment is within the bounds of accepted treatment and only after the patient has been given a treatment recommendation and an explanation of the acceptable alternatives.

4. Only delegating patient care and exposure of dental x-rays to qualified, properly trained and supervised personnel as authorized in Part III (18VAC60-21-110 et seq.) of this chapter.

5. Giving patients at least 30 days written notice of a decision to terminate the dentist-patient relationship.

6. Knowing the signs of abuse and neglect and reporting suspected cases to the proper authorities consistent with state law.

7. Accurately representing to a patient and the public the materials or methods and techniques to be used in treatment.

B. A dentist is responsible for conducting his financial responsibilities to patients and third party payers in an ethical and honest manner by:

1. Maintaining a listing of customary fees and representing all fees being charged clearly and accurately.

2. Making a full and fair disclosure to his patient of all terms and considerations before entering into a payment agreement for services.

3. Not obtaining, attempting to obtain, or cooperating with others in obtaining payment for services by misrepresenting procedures performed, dates of service, or status of treatment.

4. Making a full and fair disclosure to his patient of any financial incentives he received for promoting or selling products.

5. Not exploiting the dentist-patient relationship for personal gain related in nondental transactions.

18VAC60-21-70. Unprofessional practice.

A. A dentist shall not commit any act that violates provisions of the Code that reasonably relate to the practice of dentistry including but not limited to:

1. Delegating any dental service or operation that requires the professional competence or judgment of a dentist to any person who is not a licensed dentist or dental hygienist or a registered dental assistant II.

2. Knowingly or negligently violating any applicable statute or regulation governing ionizing radiation in the Commonwealth of Virginia, including but not limited to current regulations promulgated by the Virginia Department of Health.

3. Unauthorized use or disclosure of confidential information received from the Prescription Monitoring Program.

4. Failing to maintain and dispense scheduled drugs as authorized by the Virginia Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code) and the regulations of the Board of Pharmacy.

5. Failing to cooperate with an employee of the Department of Health Professions in the conduct of an investigation or inspection.

B. Sexual conduct with a patient, employee, or student shall constitute unprofessional conduct if:

1. The sexual conduct is unwanted or nonconsensual or

2. The sexual contact is a result of the exploitation of trust, knowledge, or influence derived from the professional relationship or if the contact has had or is likely to have an adverse effect on patient care.

18VAC60-21-80. Advertising.

A. Practice limitation. A general dentist who limits his practice to a dental specialty or describes his practice by types of treatment shall state in conjunction with his name that he is a general dentist providing certain services (e.g., orthodontic services).

B. Fee disclosures. Any statement specifying a fee for a dental service that does not include the cost of all related procedures, services, and products that, to a substantial likelihood, will be necessary for the completion of the advertised services as it would be understood by an ordinarily prudent person shall be deemed to be deceptive or misleading. Where reasonable disclosure of all relevant variables and considerations is made, a statement of a range of fees for specifically described dental services shall not be deemed to be deceptive or misleading.

C. Discounts and free offers. Discount and free offers for a dental service are permissible for advertising only when the nondiscounted or full fee, if any, and the final discounted fee are also disclosed in the advertisement. In addition, the time period for obtaining the discount or free offer must be stated in the advertisement. The dentist shall maintain documented evidence to substantiate the discounted fee or free offer.

D. Retention of advertising. A prerecorded or archived copy of all advertisements shall be retained for a two-year period following the final appearance of the advertisement. The advertising dentist is responsible for making prerecorded or archived copies of the advertisement available to the board within five days following a request by the board.

E. Routine dental services. Advertising of fees pursuant to this section is limited to procedures that are set forth in the American Dental Association's "Dental Procedures Codes," published in Current Dental Terminology in effect at the time the advertisement is issued.

F. Advertisements. Advertisements, including but not limited to signage, containing descriptions of the type of dentistry practiced or a specific geographic locator are permissible so long as the requirements of §§ 54.1-2718 and 54.1-2720 of the Code are met.

G. False, deceptive, or misleading advertisement. The following practices shall constitute false, deceptive, or misleading advertising within the meaning of subdivision 7 of § 54.1-2706 of the Code:

1. Publishing an advertisement that contains a material misrepresentation or omission of facts that causes an ordinarily prudent person to misunderstand or be deceived, or that fails to contain reasonable warnings or disclaimers necessary to make a representation not deceptive;

2. Publishing an advertisement that fails to include the information and disclaimers required by this section;

3. Publishing an advertisement that contains a false claim of professional superiority, contains a claim to be a specialist, or uses any terms to designate a dental specialty unless he is entitled to such specialty designation under the guidelines or requirements for specialties approved by the American Dental Association (Requirements for Recognition of Dental Specialties and National Certifying Boards for Dental Specialists, November 2013), or such guidelines or requirements as subsequently amended; or

4. Representation by a dentist who does not currently hold specialty certification that his practice is limited to providing services in such specialty area without clearly disclosing that he is a general dentist.

18VAC60-21-90. Patient information and records.

A. A dentist shall maintain complete, legible, and accurate patient records for not less than six years from the last date of service for purposes of review by the board with the following exceptions:

1. Records of a minor child shall be maintained until the child reaches the age of 18 years or becomes emancipated, with a minimum time for record retention of six years from the last patient encounter regardless of the age of the child;

2. Records that have previously been transferred to another practitioner or health care provider or provided to the patient or his personal representative pursuant to § 54.1-2405 of the Code; or

3. Records that are required by contractual obligation or federal law may need to be maintained for a longer period of time.

B. Every patient record shall include the following:

1. Patient's name on each page in the patient record;

2. A health history taken at the initial appointment that is updated (i) when analgesia, sedation, or anesthesia is to be administered; (ii) when medically indicated; and (iii) at least annually;

3. Diagnosis and options discussed, including the risks and benefits of treatment or nontreatment and the estimated cost of treatment options;

4. Consent for treatment obtained and treatment rendered;

5. List of drugs prescribed, administered, or dispensed and the route of administration, quantity, dose, and strength;

6. Radiographs, digital images, and photographs clearly labeled with patient name, date taken, and teeth identified;

7. Notation of each treatment rendered, the date of treatment and of the dentist, dental hygienist, and dental assistant II providing service;

8. Duplicate laboratory work orders that meet the requirements of § 54.1-2719 of the Code including the address and signature of the dentist;

9. Itemized patient financial records as required by § 54.1-2404 of the Code;

10. A notation or documentation of an order required for treatment of a patient by a dental hygienist practicing under general supervision as required in 18VAC60-21-140 B; and

11. The information required for the administration of conscious/moderate sedation, deep sedation, and general anesthesia required in 18VAC60-21-260 D.

C. A licensee shall comply with the patient record confidentiality, release, and disclosure provisions of § 32.1-127.1:03 of the Code and shall only release patient information as authorized by law.

D. Records shall not be withheld because the patient has an outstanding financial obligation.

E. A reasonable cost-based fee may be charged for copying patient records to include the cost of supplies and labor for copying documents, duplication of radiographs and images, and postage if mailing is requested as authorized by § 32.1-127.1:03 of the Code. The charges specified in § 8.01-413 of the Code are permitted when records are subpoenaed as evidence for purposes of civil litigation.
F. When closing, selling, or relocating a practice, the licensee shall meet the requirements of § 54.1-2405 of the Code for giving notice and providing records.
G. Records shall not be abandoned or otherwise left in the care of someone who is not licensed by the board except that, upon the death of a licensee, a trustee or executor of the estate may safeguard the records until they are transferred to a licensed dentist, are sent to the patients of record, or are destroyed.
H. Patient confidentiality must be preserved when records are destroyed.

18VAC60-21-100. Reportable events during or following treatment or the administration of sedation or anesthesia.

The treating dentist shall submit a written report to the board within 15 calendar days following an unexpected patient event that occurred intra-operatively or during the first 24 hours immediately following the patient's departure from his facility, resulting in either a physical injury or a respiratory, cardiovascular, or neurological complication that was related to the dental treatment or service provided and that necessitated admission of the patient to a hospital or in a patient death. Any emergency treatment of a patient by a hospital that is related to sedation anesthesia shall also be reported.

Part III. Direction and Delegation of Duties.

18VAC60-21-110. Utilization of dental hygienists and dental assistants II.

A. A dentist may utilize up to a total of four dental hygienists or dental assistants II in any combination practicing under direction at one and the same time. In addition, a dentist may permit through issuance of written orders for services, additional dental hygienists to practice under general supervision in a free clinic or a public health program, or on a voluntary basis.

B. In accordance with § 54.1-2724 of the Code of Virginia, no dentist shall employ more than two dental hygienists who practice under remote supervision at one time.

18VAC60-21-120. Requirements for direction and general supervision.

A. In all instances and on the basis of his diagnosis, a licensed dentist assumes ultimate responsibility for determining with the patient or his representative the specific treatment the patient will receive, which aspects of treatment will be delegated to qualified personnel, and the direction required for such treatment, in accordance with this chapter and the Code.
B. Dental hygienists shall engage in their respective duties only while in the employment of a licensed dentist or governmental agency or when volunteering services as provided in 18VAC60-21-110.
C. Dental hygienists acting within the scope of a license issued to them by the board under § 54.1-2722 or 54.1-2725 of the Code who teach dental hygiene in a CODA accredited program are exempt from this section.

D. Duties delegated to a dental hygienist under indirect supervision shall only be performed when the dentist is present in the facility and examines the patient during the time services are being provided.

E. Duties that are delegated to a dental hygienist under general supervision shall only be performed if the following requirements are met:

1. The treatment to be provided shall be ordered by a dentist licensed in Virginia and shall be entered in writing in the record. The services noted on the original order shall be rendered within a specific time period, not to exceed 10 months from the date the dentist last performed a periodic examination of the patient. Upon expiration of the order, the dentist shall have examined the patient before writing a new order for treatment under general supervision.

2. The dental hygienist shall consent in writing to providing services under general supervision.

3. The patient or a responsible adult shall be informed prior to the appointment that a dentist may not be present, that only topical oral anesthetics can be administered to manage pain, and that only those services prescribed by the dentist will be provided.

4. Written basic emergency procedures shall be established and in place, and the hygienist shall be capable of implementing those procedures.

F. An order for treatment under general supervision shall not preclude the use of another level of supervision when, in the professional judgment of the dentist, such level of supervision is necessary to meet the individual needs of the patient.

18VAC60-21-130. Nondelegable duties; dentists.

Only licensed dentists shall perform the following duties:

1. Final diagnosis and treatment planning;

2. Performing surgical or cutting procedures on hard or soft tissue except a dental hygienist performing gingival curettage as provided in 18VAC60-21-140;

3. Prescribing or parenterally administering drugs or medicaments, except a dental hygienist, who meets the requirements of 18VAC60-25-100, may parenterally administer Schedule VI local anesthesia to patients 18 years of age or older;

4. Authorization of work orders for any appliance or prosthetic device or restoration that is to be inserted into a patient's mouth;

5. Operation of high speed rotary instruments in the mouth;

6. Administering and monitoring conscious/moderate sedation, deep sedation, or general anesthetics except as provided for in § 54.1-2701 of the Code and Part VI (18VAC60-21-260 et seq.) of this chapter;

7. Condensing, contouring, or adjusting any final, fixed, or removable prosthodontic appliance or restoration in the mouth with the exception of packing and carving amalgam and placing and shaping composite resins by dental assistants II with advanced training as specified in 18VAC60-30-120;

8. Final positioning and attachment of orthodontic bonds and bands; and

9. Final adjustment and fitting of crowns and bridges in preparation for final cementation.

18VAC60-21-140. Delegation to dental hygienists.

A. The following duties shall only be delegated to dental hygienists under direction and may only be performed under indirect supervision:

1. Scaling, root planing, or gingival curettage of natural and restored teeth using hand instruments, slow-speed rotary instruments, ultrasonic devices, and nonsurgical lasers, with any sedation or anesthesia administered.

2. Performing an initial examination of teeth and surrounding tissues including the charting of carious lesions, periodontal pockets, or other abnormal conditions for assisting the dentist in the diagnosis.

3. Administering nitrous oxide or local anesthesia by dental hygienists qualified in accordance with the requirements of 18VAC60-25-100.

B. The following duties shall only be delegated to dental hygienists and may be performed under indirect supervision or may be delegated by written order in accordance with §§ 54.1-2722 D and 54.1-3408 J of the Code to be performed under general supervision:

1. Scaling, root planing, or gingival curettage of natural and restored teeth using hand instruments, slow-speed rotary instruments, ultrasonic devices, and nonsurgical lasers with or without topical oral anesthetics.

2. Polishing of natural and restored teeth using air polishers.

3. Performing a clinical examination of teeth and surrounding tissues including the charting of carious lesions, periodontal pockets, or other abnormal conditions for further evaluation and diagnosis by the dentist.

4. Subgingival irrigation or subgingival application of topical Schedule VI medicinal agents pursuant to § 54.1-3408 J of the Code.

5. Duties appropriate to the education and experience of the dental hygienist and the practice of the supervising dentist, with the exception of those listed as nondelegable in 18VAC60-21-130, those restricted to indirect supervision in subsection A of this section, and those restricted to delegation to dental assistants II in 18VAC60-21-150.

C. Delegation of duties to a dental hygienist practicing under remote supervision shall be in accordance with provisions of § 54.1-2722 F of the Code. However, delegation of duties to a public health dental hygienist practicing under remote supervision shall be in accordance with provisions of § 54.1-2722 E.

18VAC60-21-150. Delegation to dental assistants II.

The following duties may only be delegated under the direction and direct supervision of a dentist to a dental assistant II who has completed the coursework, corresponding module of laboratory training, corresponding module of clinical experience, and examinations specified in 18VAC60-30-120:

1. Performing pulp capping procedures;
2. Packing and carving of amalgam restorations;
3. Placing and shaping composite resin restorations with a slow speed handpiece;
4. Taking final impressions;
5. Use of a non-epinephrine retraction cord; and
6. Final cementation of crowns and bridges after adjustment and fitting by the dentist.

18VAC60-21-160. Delegation to dental assistants I and II.

A. Duties appropriate to the training and experience of the dental assistant and the practice of the supervising dentist may be delegated to a dental assistant I or II under indirect supervision, with the exception of those listed as nondelegable in 18VAC60-21-130, those which may only be delegated to dental hygienists as listed in 18VAC60-21-140, and those which may only be delegated to a dental assistant II as listed in 18VAC60-21-150.

B. Duties delegated to a dental assistant under general supervision shall be performed under the direction and indirect supervision of the dental hygienist who supervises the implementation of the dentist's orders by examining the patient, observing the services rendered by an assistant, and being available for consultation on patient care.

18VAC60-21-170. Radiation certification.

No dentist or dental hygienist shall permit a person not otherwise licensed by this board to place or expose dental x-ray film unless he has one of the following: (i) satisfactory completion of a radiation safety course and examination given by an institution that maintains a program in dental assisting, dental hygiene, or dentistry accredited by CODA; (ii) certification by the American Registry of Radiologic Technologists; or (iii) satisfactory completion of the Radiation Health and Safety Review Course provided by the Dental Assisting National Board or its affiliate and passage of the Radiation Health and Safety Exam given by the Dental Assisting National Board. Any certificate issued pursuant to satisfying the requirements of this section shall be posted in plain view of the patient.

18VAC60-21-180. What does not constitute practice.

The following are not considered the practice of dental hygiene and dentistry:

1. General oral health education.
2. Recording a patient's pulse, blood pressure, temperature, presenting complaint, and medical history.
3. Conducting preliminary dental screenings in free clinics, public health programs, or a voluntary practice.

Part IV. Entry, Licensure, and Registration Requirements.

18VAC60-21-190. General application provisions.

A. Applications for any dental license, registration, or permit issued by the board, other than for a volunteer exemption or for a restricted volunteer license, shall include:

1. A final certified transcript of the grades from the college from which the applicant received the dental degree or post-doctoral degree or certificate as specified in 18VAC60-21-200;
2. An original grade card documenting passage of all parts of the Joint Commission on National Dental Examinations; and
3. A current report from the U.S. Department of Health and Human Services National Practitioner Data Bank (NPDB).

B. All applicants for licensure, other than for a volunteer exemption or for a restricted volunteer license, shall be required to attest that they have read and understand and will remain current with the laws and regulations governing the practice of dentistry, dental hygiene, and dental assisting in Virginia.

C. If a transcript or other documentation required for licensure cannot be produced by the entity from which it is required, the board, in its discretion, may accept other evidence of qualification for licensure.
D. Any application for a dental license, registration, or permit may be denied for any cause specified in § 54.1-111 or 54.1-2706 of the Code.
E. An application must include payment of the appropriate fee as specified in 18VAC60-21-40.

18VAC60-21-200. Education.

An applicant for unrestricted dental licensure shall be a graduate of and a holder of a diploma or a certificate from a dental program accredited by the Commission on Dental Accreditation of the American Dental Association or the Commission on Dental Accreditation of Canada, which consists of either a pre-doctoral dental education program or at least a 12-month post-doctoral advanced general dentistry program or a post-doctoral dental program of at least 24 months in any other specialty that includes a clinical component.

18VAC60-21-210. Qualifications for an unrestricted license.

A. Dental licensure by examination.

1. All applicants for licensure by examination shall have:

a. Successfully completed all parts of the National Board Dental Examination given by the Joint Commission on National Dental Examinations; and

b. Passed a dental clinical competency examination that is accepted by the board.

2. If a candidate has failed any section of a clinical competency examination three times, the candidate shall complete a minimum of 14 hours of additional clinical training in each section of the examination to be retested in order to be approved by the board to sit for the examination a fourth time.

3. Applicants who successfully completed a clinical competency examination five or more years prior to the date of receipt of their applications for licensure by this board may be required to retake an examination or take continuing education that meets the requirements of 18VAC60-21-250 unless they demonstrate that they have maintained clinical, ethical, and legal practice in another jurisdiction of the United States or in federal civil or military service for 48 of the past 60 months immediately prior to submission of an application for licensure.

B. Dental licensure by credentials. All applicants for licensure by credentials shall:

1. Have passed all parts of the National Board Dental Examination given by the Joint Commission on National Dental Examinations;

2. Have successfully completed a clinical competency examination acceptable to the board;

3. Hold a current, unrestricted license to practice dentistry in another jurisdiction of the United States and be certified to be in good standing by each jurisdiction in which a license is currently held or has been held; and

4. Have been in continuous clinical practice in another jurisdiction of the United States or in federal civil or military service for five out of the six years immediately preceding application for

licensure pursuant to this section. Active patient care in another jurisdiction of the United States (i) as a volunteer in a public health clinic, (ii) as an intern, or (iii) in a residency program may be accepted by the board to satisfy this requirement. One year of clinical practice shall consist of a minimum of 600 hours of practice in a calendar year as attested by the applicant.

18VAC60-21-220. Inactive license.

A. Any dentist who holds a current, unrestricted license in Virginia may, upon a request on the renewal application and submission of the required fee, be issued an inactive license. With the exception of practice with a current restricted volunteer license as provided in § 54.1-2712.1 of the Code, the holder of an inactive license shall not be entitled to perform any act requiring a license to practice dentistry in Virginia.

B. An inactive license may be reactivated upon submission of the required application, which includes evidence of continuing competence and payment of the current renewal fee. To evaluate continuing competence the board shall consider (i) hours of continuing education that meet the requirements of 18VAC60-21-250; (ii) evidence of active practice in another state or in federal service; (iii) current specialty board certification; (iv) recent passage of a clinical competency examination that is accepted by the board; or (v) a refresher program offered by a program accredited by the Commission on Dental Accreditation of the American Dental Association.

1. Continuing education hours equal to the requirement for the number of years in which the license has been inactive, not to exceed a total of 45 hours, must be included with the application. Of the required hours, at least 15 must be earned in the most recent 12 months and the remainder within the 36 months immediately preceding the application for activation.

2. The board reserves the right to deny a request for reactivation to any licensee who has been determined to have committed an act in violation of § 54.1-2706 of the Code or who is unable to demonstrate continuing competence.

18VAC60-21-230. Qualifications for a restricted license.

A. Temporary permit for public health settings. A temporary permit shall be issued only for the purpose of allowing dental practice in a dental clinic operated by a state agency or a Virginia charitable organization as limited by § 54.1-2715 of the Code.

1. Passage of a clinical competency examination is not required, but the applicant cannot have failed a clinical competency examination accepted by the board.

2. A temporary permit will not be renewed unless the holder shows that extraordinary circumstances prevented the holder from taking the licensure examination during the term of the temporary permit.

B. Faculty license. A faculty license shall be issued for the purpose of allowing dental practice as a faculty member of an accredited dental program when the applicant meets the entry requirements of § 54.1-2713 of the Code.

1. A faculty license shall remain valid only while the holder is serving on the faculty of an accredited dental program in the Commonwealth. When any such license holder ceases to continue serving on the faculty of the dental school for which the license was issued, the licensee shall surrender the license, which shall be null and void upon termination of employment.

2. The dean of the dental school shall notify the board within five working days of such termination of employment.

C. Restricted license to teach for foreign dentists. The board may issue a restricted license to a foreign dentist to teach in an accredited dental program in the Commonwealth in accordance with provisions of § 54.1-2714 of the Code.

D. Temporary licenses to persons enrolled in advanced dental education programs. A dental intern, resident, or post-doctoral certificate or degree candidate shall obtain a temporary license to practice in Virginia in accordance with provisions of § 54.1-2711.1 of the Code.

1. The applicant shall submit a recommendation from the dean of the dental school or the director of the accredited advanced dental education program specifying the applicant's acceptance as an intern, resident, or post-doctoral certificate or degree candidate. The beginning and ending dates of the internship, residency, or post-doctoral program shall be specified.

2. The temporary license permits the holder to practice only in the hospital or outpatient clinics that are recognized parts of an advanced dental education program.

3. The temporary license may be renewed annually by June 30, for up to five times, upon the recommendation of the dean of the dental school or director of the accredited advanced dental education program.

4. The temporary license holder shall be responsible and accountable at all times to a licensed dentist, who is a member of the staff where the internship, residency, or post-doctoral program is taken. The holder is prohibited from practicing outside of the advanced dental education program.

5. The temporary license holder shall abide by the accrediting requirements for an advanced dental education program as approved by the Commission on Dental Accreditation of the American Dental Association.

E. Restricted volunteer license.

1. In accordance with § 54.1-2712.1 of the Code, the board may issue a restricted volunteer license to a dentist who:

a. Held an unrestricted license in Virginia or another U.S. jurisdiction as a licensee in good standing at the time the license expired or became inactive;

b. Is volunteering for a public health or community free clinic that provides dental services to populations of underserved people;

c. Has fulfilled the board's requirement related to knowledge of the laws and regulations governing the practice of dentistry in Virginia;

d. Has not failed a clinical examination within the past five years; and

e. Has had at least five years of clinical practice.

2. A person holding a restricted volunteer license under this section shall:

a. Only practice in public health or community free clinics that provide dental services to underserved populations;

b. Only treat patients who have been screened by the approved clinic and are eligible for treatment;

c. Attest on a form provided by the board that he will not receive remuneration directly or indirectly for providing dental services; and

d. Not be required to complete continuing education in order to renew such a license.

3. The restricted volunteer license shall specify whether supervision is required, and if not, the date by which it will be required. If a dentist with a restricted volunteer license issued under this section has not held an active, unrestricted license and been engaged in active practice within the past five years, he shall only practice dentistry and perform dental procedures if a dentist with an

unrestricted Virginia license, volunteering at the clinic, reviews the quality of care rendered by the dentist with the restricted volunteer license at least every 30 days. If supervision is required, the supervising dentist shall directly observe patient care being provided by the restricted volunteer dentist and review all patient charts at least quarterly. Such supervision shall be noted in patient charts and maintained in accordance with 18VAC60-21-90.

4. A restricted volunteer license granted pursuant to this section shall expire on June 30 of the second year after its issuance or shall terminate when the supervising dentist withdraws his sponsorship.

5. A dentist holding a restricted volunteer license issued pursuant to this section is subject to the provisions of this chapter and the disciplinary regulations that apply to all licensees practicing in Virginia.

F. Registration for voluntary practice by out-of-state licensees. Any dentist who does not hold a license to practice in Virginia and who seeks registration to practice on a voluntary basis under the auspices of a publicly supported, all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people shall:

1. File a complete application for registration on a form provided by the board at least 15 days prior to engaging in such practice;

2. Provide a complete record of professional licensure in each state in which he has held a license and a copy of any current license;

3. Provide the name of the nonprofit organization, and the dates and location of the voluntary provision of services; and

4. Provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with provisions of subdivision 5 of § 54.1-2701 of the Code.

Part V. Licensure Renewal.

18VAC60-21-240. License renewal and reinstatement.

A. The license or permit of any person who does not return the completed renewal form and fees by the deadline shall automatically expire and become invalid, and his practice of dentistry shall be illegal. With the exception of practice with a current, restricted volunteer license as provided in § 54.1-2712.1 of the Code practicing in Virginia with an expired license or permit may subject the licensee to disciplinary action by the board.

B. Every person holding an active or inactive license and those holding a permit to administer conscious/moderate sedation, deep sedation, or general anesthesia shall annually, on or before March 31, renew his license or permit. Every person holding a faculty license, temporary resident's license, a restricted volunteer license, or a temporary permit shall, on or before June 30, request renewal of his license.

C. Any person who does not return the completed form and fee by the deadline required in subsection B of this section shall be required to pay an additional late fee.

D. The board shall renew a license or permit if the renewal form, renewal fee, and late fee are received within one year of the deadline required in subsection B of this section provided that no grounds exist to deny said renewal pursuant to § 54.1-2706 of the Code and Part II (18VAC60-21-50 et seq.) of this chapter.

E. Reinstatement procedures.

1. Any person whose license or permit has expired for more than one year or whose license or permit has been revoked or suspended and who wishes to reinstate such license or permit shall submit a reinstatement application and the reinstatement fee. The application must include evidence of continuing competence.

2. To evaluate continuing competence, the board shall consider (i) hours of continuing education that meet the requirements of subsection G H of 18VAC60-21-250; (ii) evidence of active practice in another state or in federal service; (iii) current specialty board certification; (iv) recent passage of a clinical competency examination accepted by the board; or (v) a refresher program offered by a program accredited by the Commission on Dental Accreditation of the American Dental Association.

3. The executive director may reinstate such expired license or permit provided that the applicant can demonstrate continuing competence, the applicant has paid the reinstatement fee and any fines or assessments, and no grounds exist to deny said reinstatement pursuant to § 54.1-2706 of the Code and Part II (18VAC60-21-50 et seq.) of this chapter.

18VAC60-21-250. Requirements for continuing education.

A. A dentist shall complete a minimum of 15 hours of continuing education, which meets the requirements for content, sponsorship, and documentation set out in this section, for each annual renewal of licensure except for the first renewal following initial licensure and for any renewal of a restricted volunteer license.

1. All renewal applicants shall attest that they have read and understand and will remain current with the laws and regulations governing the practice of dentistry and dental hygiene in Virginia.

2. A dentist shall maintain current training certification in basic cardiopulmonary resuscitation with hands-on airway training for health care providers or basic life support unless he is required by 18VAC60-21-290 or 18VAC60-21-300 to hold current certification in advanced life support with hands-on simulated airway and megacode training for health care providers.

3. A dentist who administers or monitors patients under general anesthesia, deep sedation, or conscious/moderate sedation shall complete four hours every two years of approved continuing education directly related to administration and monitoring of such anesthesia or sedation as part of the hours required for licensure renewal.

4. Continuing education hours in excess of the number required for renewal may be transferred or credited to the next renewal year for a total of not more than 15 hours.

5. Up to two hours of the 15 hours required for annual renewal may be satisfied through delivery of dental services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic.

B. To be accepted for license renewal, continuing education programs shall be directly relevant to the treatment and care of patients and shall be:

1. Clinical courses in dentistry and dental hygiene; or

2. Nonclinical subjects that relate to the skills necessary to provide dental or dental hygiene services and are supportive of clinical services (i.e., patient management, legal and ethical responsibilities, and stress management). Courses not acceptable for the purpose of this subsection include, but are not limited to, estate planning, financial planning, investments, business management, marketing, and personal health.

C. Continuing education credit may be earned for verifiable attendance at or participation in any course, to include audio and video presentations, that meets the requirements in subsection B of this section and is given by one of the following sponsors:

1. The American Dental Association and the National Dental Association, their constituent and component/branch associations, and approved continuing education providers;

2. The American Dental Hygienists' Association and the National Dental Hygienists Association, and their constituent and component/branch associations;

3. The American Dental Assisting Association and its constituent and component/branch associations;

4. The American Dental Association specialty organizations and their constituent and component/branch associations;

5. A provider accredited by the Accreditation Council for Continuing Medical Education for Category 1 credits;

6. The Academy of General Dentistry, its constituent and component/branch associations, and approved continuing education providers;

7. A college or university that is accredited by an accrediting agency approved by the U.S. Department of Education or a hospital or health care institution accredited by the Joint Commission on Accreditation of Healthcare Organizations;

8. The American Heart Association, the American Red Cross, the American Safety and Health Institute, and the American Cancer Society;

9. A medical school accredited by the American Medical Association's Liaison Committee for Medical Education;

10. A dental, dental hygiene, or dental assisting program or advanced dental education program accredited by the Commission on Dental Accreditation of the American Dental Association;

11. State or federal government agencies (i.e., military dental division, Veteran's Administration, etc.);

12. The Commonwealth Dental Hygienists' Society;

13. The MCV Orthodontic Education and Research Foundation;

14. The Dental Assisting National Board and its affiliate, the Dental Auxiliary Learning and Education Foundation; or

15. A regional testing agency (i.e., Central Regional Dental Testing Service, Northeast Regional Board of Dental Examiners, Southern Regional Testing Agency, Council of Interstate Testing Agencies, or Western Regional Examining Board) when serving as an examiner.

D. The board may grant an exemption for all or part of the continuing education requirements due to circumstances beyond the control of the licensee, such as temporary disability, mandatory military service, or officially declared disasters. A written request with supporting documents must be submitted prior to renewal of the license.

E. The board may grant an extension for up to one year for completion of continuing education upon written request with an explanation to the board prior to the renewal date.

F. A licensee is required to verify compliance with the continuing education requirements in his annual license renewal. Following the renewal period, the board may conduct an audit of licensees to verify compliance. Licensees selected for audit must provide original documents certifying that they have fulfilled their continuing education requirements by the deadline date as specified by the board.

G. All licensees are required to maintain original documents verifying the date and subject of the program or activity, the sponsor, and the amount of time earned. Documentation shall be maintained for a period of four years following renewal.

H. A licensee who has allowed his license to lapse, or who has had his license suspended or revoked, shall submit evidence of completion of continuing education equal to the requirements for the number of years in which his license has not been active, not to exceed a total of 45 hours. Of the required hours, at least 15 must be earned in the most recent 12 months and the remainder within the 36 months preceding an application for reinstatement.

I. Continuing education hours required by board order shall not be used to satisfy the continuing education requirement for license renewal or reinstatement.

J. Failure to comply with continuing education requirements may subject the licensee to disciplinary action by the board.

Part VI. Controlled Substances, Sedation, and Anesthesia.

18VAC60-21-260. General provisions.

A. Application of Part VI. This part applies to prescribing, dispensing, and administering controlled substances in dental offices, mobile dental facilities, and portable dental operations and shall not apply to administration by a dentist practicing in (i) a licensed hospital as defined in § 32.1-123 of the Code, (ii) a state-operated hospital, or (iii) a facility directly maintained or operated by the federal government.

B. Registration required. Any dentist who prescribes, administers, or dispenses Schedules II through V controlled drugs must hold a current registration with the federal Drug Enforcement Administration.

C. Patient evaluation required.

1. The decision to administer controlled drugs for dental treatment must be based on a documented evaluation of the health history and current medical condition of the patient in accordance with the Class I through V risk category classifications of the American Society of Anesthesiologists (ASA) in effect at the time of treatment. The findings of the evaluation, the ASA risk assessment class assigned, and any special considerations must be recorded in the patient's record.

2. Any level of sedation and general anesthesia may be provided for a patient who is ASA Class I and Class II.

3. A patient in ASA Class III shall only be provided minimal sedation, conscious/moderate sedation, deep sedation, or general anesthesia by:

a. A dentist after he has documented a consultation with the patient's primary care physician or other medical specialist regarding potential risks and special monitoring requirements that may be necessary;

b. An oral and maxillofacial surgeon who has performed a physical evaluation and documented the findings and the ASA risk assessment category of the patient and any special monitoring requirements that may be necessary; or

c. A person licensed under Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code who has a specialty in anesthesia.

4. Minimal sedation may only be provided for a patient who is in ASA Class IV by:

a. A dentist after he has documented a consultation with the patient's primary care physician or other medical specialist regarding potential risks and special monitoring requirements that may be necessary; or

b. An oral and maxillofacial surgeon who has performed a physical evaluation and documented the findings and the ASA risk assessment category of the patient and any special monitoring requirements that may be necessary.

5. Conscious/moderate sedation, deep sedation, or general anesthesia shall not be provided in a dental office for patients in ASA Class IV and Class V.

D. Additional requirements for patient information and records. In addition to the record requirements in 18VAC60-21-90, when conscious/moderate sedation, deep sedation, or general anesthesia is administered, the patient record shall also include:

1. Notation of the patient's American Society of Anesthesiologists classification;

2. Review of medical history and current conditions, including the patient's weight and height or, if appropriate, the body mass index;

3. Written informed consent for administration of sedation and anesthesia and for the dental procedure to be performed;

4. Preoperative vital signs;

5. A record of the name, dose, and strength of drugs and route of administration including the administration of local anesthetics with notations of the time sedation and anesthesia were administered;

6. Monitoring records of all required vital signs and physiological measures recorded every five minutes; and

7. A list of staff participating in the administration, treatment, and monitoring including name, position, and assigned duties.

E. Pediatric patients. No sedating medication shall be [~~prescribed for or~~]administered to a patient 12 years of age or younger prior to his arrival at the dentist office or treatment facility.

F. Informed written consent. Prior to administration of any level of sedation or general anesthesia, the dentist shall discuss the nature and objectives of the planned level of sedation or general anesthesia along with the risks, benefits, and alternatives and shall obtain informed, written consent from the patient or other responsible party for the administration and for the treatment to be provided. The written consent must be maintained in the patient record.

G. Level of sedation. The determinant for the application of the rules for any level of sedation or for general anesthesia shall be the degree of sedation or consciousness level of a patient that should reasonably be expected to result from the type, strength, and dosage of medication, the method of administration, and the individual characteristics of the patient as documented in the patient's record. The drugs and techniques used must carry a margin of safety wide enough to render the unintended reduction of or loss of consciousness unlikely, factoring in titration and the patient's age, weight, and ability to metabolize drugs.

H. Emergency management.

1. If a patient enters a deeper level of sedation than the dentist is qualified and prepared to provide, the dentist shall stop the dental procedure until the patient returns to and is stable at the intended level of sedation.

2. A dentist in whose office sedation or anesthesia is administered shall have written basic emergency procedures established and staff trained to carry out such procedures.

**[add Special needs Patients....from page 12 ADA guidelines.

I. Ancillary personnel. Dentists who employ unlicensed, ancillary personnel to assist in the administration and monitoring of any form of minimal sedation, conscious/moderate sedation, deep sedation, or general anesthesia shall maintain documentation that such personnel have:

1. Training and hold current certification in basic resuscitation techniques with hands-on airway training for health care providers, such as Basic Cardiac Life Support for Health Professionals or a clinically oriented course devoted primarily to responding to clinical emergencies offered by an approved provider of continuing education as set forth in 18VAC60-21-250 C; or

2. Current certification as a certified anesthesia assistant (CAA) by the American Association of Oral and Maxillofacial Surgeons or the American Dental Society of Anesthesiology (ADSA).

J. Assisting in administration. A dentist, consistent with the planned level of administration (i.e., local anesthesia, minimal sedation, ~~conscious/~~moderate sedation, deep sedation, or general anesthesia) and appropriate to his education, training, and experience, may utilize the services of a dentist, anesthesiologist, certified registered nurse anesthetist, dental hygienist, dental assistant, or nurse to perform functions appropriate to such practitioner's education, training, and experience and consistent with that practitioner's respective scope of practice.

K. Patient monitoring.

1. A dentist may delegate monitoring of a patient to a dental hygienist, dental assistant, or nurse who is under his direction or to another dentist, anesthesiologist, or certified registered nurse anesthetist. The person assigned to monitor the patient shall be continuously in the presence of the patient in the office, operatory, and recovery area (i) before administration is initiated or immediately upon arrival if the patient self-administered a sedative agent, (ii) throughout the administration of drugs, (iii) throughout the treatment of the patient, and (iv) throughout recovery until the patient is discharged by the dentist.

2. The person monitoring the patient shall:

a. Have the patient's entire body in sight;

b. Be in close proximity so as to speak with the patient;

c. Converse with the patient to assess the patient's ability to respond in order to determine the patient's level of sedation;

d. Closely observe the patient for coloring, breathing, level of physical activity, facial expressions, eye movement, and bodily gestures in order to immediately recognize and bring any changes in the patient's condition to the attention of the treating dentist; and

e. Read, report, and record the patient's vital signs and physiological measures.

L. A dentist who allows the administration of general anesthesia, deep sedation, or conscious/moderate sedation in his dental office is responsible for assuring that:

1. The equipment for administration and monitoring, as required in subsection B of 18VAC60-21-291 or subsection C of 18VAC60-21-301, is readily available and in good working order prior to performing dental treatment with anesthesia or sedation. The equipment shall either be maintained by the dentist in his office or provided by the anesthesia or sedation provider; and

2. The person administering the anesthesia or sedation is appropriately licensed and the staff monitoring the patient is qualified.

M. Special needs patients:

1. Because many patients undergoing deep sedation/general are mentally and/or physically challenged, it is not possible to have a comprehensive physical examination or appropriate laboratory test prior to administrating care. When these situations occur, the dentist responsible for

administrating deep sedation/general anesthesia should document the reasons preventing the recommended preoperative management.

2. In selected circumstances, deep sedation oar general anesthesia maybe utilized without establishing an indwelling intravenous line. These selected circumstances may include very brief procedures or periods of time, which, for example, may occur in some patients; or the establishment of intravenous access *after* deep sedation or general anesthesia has been induced because of poor patient corporation.

18VAC60-21-270. Administration of local anesthesia.

A dentist may administer or use the services of the following personnel to administer local anesthesia:

1. A dentist;

2. An anesthesiologist;

3. A certified registered nurse anesthetist **?[~~under his medical direction and indirect supervision~~];

4. A dental hygienist with the training required by 18VAC60-25-100 C to parenterally administer Schedule VI local anesthesia to persons 18 years of age or older under his indirect supervision;

5. A dental hygienist to administer Schedule VI topical oral anesthetics under indirect supervision or under his order for such treatment under general supervision; or

6. A dental assistant or a registered or licensed practical nurse to administer Schedule VI topical oral anesthetics under indirect supervision.

18VAC60-21-279. Administration of only inhalation analgesia (nitrous oxide).

A. Education and training requirements. A dentist who utilizes nitrous oxide shall have training in and knowledge of:

1. The appropriate use and physiological effects of nitrous oxide, the potential complications of administration, the indicators for complications, and the interventions to address the complications.

2. The use and maintenance of the equipment required in subsection D of this section.

B. No sedating medication shall be prescribed for or administered to a patient 12 years of age or younger prior to his arrival at the dental office or treatment facility.

C. Delegation of administration.

1. A qualified dentist may administer or use the services of the following personnel to administer nitrous oxide:

a. A dentist;

b. An anesthesiologist;

c. A certified registered nurse anesthetist **?[~~under his medical direction and indirect supervision;~~]

d. A dental hygienist with the training required by 18VAC60-25-100 B and under indirect supervision; or

e. A registered nurse upon his direct instruction and under immediate supervision.

2. Preceding the administration of nitrous oxide, a dentist may use the services of the following personnel working under indirect supervision to administer local anesthesia to numb an injection or treatment site:

a. A dental hygienist with the training required by 18VAC60-25-100 C to parenterally administer Schedule VI local anesthesia to persons 18 years of age or older; or

b. A dental hygienist, dental assistant, registered nurse, or licensed practical nurse to administer Schedule VI topical oral anesthetics.

D. Equipment requirements. A dentist who utilizes nitrous oxide only or who directs the administration by another licensed health professional as permitted in subsection C of this section shall maintain the following equipment in working order and immediately available to the areas where patients will be sedated and treated and will recover:

1. Blood pressure monitoring equipment;

2. Source of delivery of oxygen under controlled positive pressure;

3. Mechanical (hand) respiratory bag; and

4. Suction apparatus.

E. Required staffing. When only nitrous oxide/oxygen is administered, a second person in the operatory is not required. Either the dentist or qualified dental hygienist under the indirect supervision of a dentist may administer the nitrous oxide/oxygen and treat and monitor the patient.

F. Monitoring requirements.

1. Baseline vital signs, to include blood pressure and heart rate, shall be taken and recorded prior to administration of nitrous oxide analgesia, during the administration of nitrous oxide and prior to discharge, unless extenuating circumstances exist and are documented in the patient's record.

2. Continual clinical observation of the patient's responsiveness, color, respiratory rate, and depth of ventilation shall be performed.

3. Once the administration of nitrous oxide has begun, the dentist shall ensure that a licensed health care professional or a person qualified in accordance with 18VAC60-21-260 I monitors the patient at all times until discharged as required in subsection G of this section.

4. Monitoring shall include making the proper adjustments of nitrous oxide/oxygen machines at the request of or by the dentist or by another qualified licensed health professional identified in subsection C of this section. Only the dentist or another qualified licensed health professional identified in subsection C of this section may turn the nitrous oxide/oxygen machines on or off.

5. Upon completion of nitrous oxide administration, the patient shall be administered 100% oxygen for a minimum of five minutes to minimize the risk of diffusion hypoxia.

G. Discharge requirements.

1. The dentist shall not discharge a patient until he exhibits baseline responses in a post-operative evaluation of the level of consciousness. Vital signs, to include blood pressure and heart rate, shall be taken and recorded prior to discharge.

2. Post-operative instructions shall be given verbally and in writing. The written instructions shall include a 24-hour emergency telephone number.

3. Pediatric patients shall be discharged with a responsible individual who has been instructed with regard to the patient's care.

18VAC60-21-280. Administration of minimal sedation.

A. Education and training requirements. A dentist who utilizes minimal sedation shall have training in and knowledge of:

1. The medications used, the appropriate dosages, the potential complications of administration, the indicators for complications, and the interventions to address the complications.

2. The physiological effects of minimal sedation, the potential complications of administration, the indicators for complications, and the interventions to address the complications.

3. The use and maintenance of the equipment required in subsection D of this section.

B. No sedating medication shall be prescribed for or administered to a patient 12 years of age or younger prior to his arrival at the dental office or treatment facility.

C. Delegation of administration.

1. A qualified dentist may administer or use the services of the following personnel to administer minimal sedation:

a. A dentist;

b. An anesthesiologist;

c. A certified registered nurse anesthetist **[~~under his medical direction and indirect supervision;~~]

d. A dental hygienist with the training required by 18VAC60-25-100 C only for administration of nitrous oxide/oxygen with the dentist present in the operatory; or

e. A registered nurse upon his direct instruction and under immediate supervision.

2. Preceding the administration of minimal sedation, a dentist may use the services of the following personnel working under indirect supervision to administer local anesthesia to numb an injection or treatment site:

a. A dental hygienist with the training required by 18VAC60-25-100 C to parenterally administer Schedule VI local anesthesia to persons 18 years of age or older; or

b. A ~~dental hygienist~~ [? Repeat of 2.[a], dental assistant, registered nurse, CRNA or licensed practical nurse to administer Schedule VI topical oral anesthetics;

3. If minimal sedation is self-administered by or to a patient 13 years of age or older before arrival at the dental office or treatment facility, the dentist may only use the personnel listed in subdivision 1 of this subsection to administer local anesthesia.

D. Equipment requirements. A dentist who utilizes minimal sedation or who directs the administration by another licensed health professional as permitted in subsection C of this section shall maintain the following equipment in working order and immediately available to the areas where patients will be sedated and treated and will recover:

1. Blood pressure monitoring equipment;

2. Source of delivery of oxygen under controlled positive pressure;

3. Mechanical (hand) respiratory bag;

4. Suction apparatus; and

5. Pulse oximeter.

E. Required staffing. The treatment team for minimal sedation shall consist of the dentist and a second person in the operatory with the patient to assist the dentist and monitor the patient. The second person shall be a licensed health care professional or a person qualified in accordance with 18VAC60-21-260 I.

F. Monitoring requirements.

1. Baseline vital signs to include blood pressure, respiratory rate, and heart rate, and oxygen saturation shall be taken and recorded prior to administration of sedation and prior to discharge.

2. Blood pressure, oxygen saturation, respiratory rate, and pulse shall be monitored ~~continuously~~ continually during the procedure.

3. Once the administration of minimal sedation has begun by any route of administration, the dentist shall ensure that a licensed health care professional or a person qualified in accordance with 18VAC60-21-260 I monitors the patient at all times until discharged as required in subsection G of this section.

4. If nitrous oxide/oxygen is used in addition to any other pharmacological agent, monitoring shall include making the proper adjustments of nitrous oxide/oxygen machines at the request of or by the dentist or by another qualified licensed health professional identified in subsection C of this section. Only the dentist or another qualified licensed health professional identified in subsection C of this section may turn the nitrous oxide/oxygen machines on or off.

5. If any other pharmacological agent is used in addition to nitrous oxide/oxygen and a local anesthetic, requirements for the induced level of sedation must be met.

G. Discharge requirements.

1. The dentist shall not discharge a patient until he exhibits baseline responses in a post-operative evaluation of the level of consciousness. Vital signs, to include blood pressure, respiratory rate, and heart rate and oxygen saturation shall be taken and recorded prior to discharge.

2. Post-operative instructions shall be given verbally and in writing. The written instructions shall include a 24-hour emergency telephone number.

3. Pediatric patients shall be discharged with a responsible individual who has been instructed with regard to the patient's care.

18VAC60-21-290. Requirements for a ~~conscious~~/moderate sedation permit. ? strike out conscious just moderate sedation?

~~A. After March 31, 2013~~, No dentist may provide ~~employ~~ or administer ~~use~~ ~~conscious~~/moderate sedation in a dental office unless he has been issued a permit by the board. The requirement for a permit shall not apply to an oral and maxillofacial surgeon who maintains membership in the American Association of Oral and Maxillofacial Surgeons (AAOMS) and who provides the board with reports that result from the periodic office examinations required by AAOMS. Such an oral and maxillofacial surgeon shall be required to post a certificate issued by AAOMS.

B. Automatic qualification. Dentists who hold a current permit to administer deep sedation and general anesthesia may administer conscious/moderate sedation.

C. To determine eligibility for a conscious/moderate sedation permit, a dentist shall submit the following:

1. A completed application form indicating one of the following permits for which the applicant is qualified:

a. Conscious/moderate sedation by any method;

b. Conscious/moderate sedation by enteral administration only; or

c. Temporary conscious/moderate sedation permit (may be renewed one time);

2. The application fee as specified in 18VAC60-21-40;

3. A copy of a transcript, certification, or other documentation of training content that meets the educational and training qualifications as specified in subsection D of this section, as applicable; and

4. A copy of current certification in advanced cardiac life support (ACLS) or pediatric advanced life support (PALS) as required in subsection E of this section.

D. Education requirements for a permit to administer conscious/moderate sedation.

1. Administration by any method. A dentist may be issued a conscious/moderate sedation permit to administer by any method by meeting one of the following criteria:

a. Completion of training for this treatment modality according to the ADA's Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry in effect at the time the training occurred, while enrolled in an accredited dental program or while enrolled in a post-doctoral university or teaching hospital program; or

b. Completion of a continuing education course that meets the requirements of 18VAC60-21-250 and consists of (i) 60 hours of didactic instruction plus the management of at least 20 patients per participant, (ii) demonstration of competency and clinical experience in conscious/moderate sedation, and (iii) management of a compromised airway. The course content shall be consistent with the ADA's Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry in effect at the time the training occurred.

2. Enteral administration only. A dentist may be issued a ~~conscious/~~moderate sedation permit to administer only by an enteral method if he has completed a continuing education program that meets the requirements of 18VAC60-21-250 and consists of not less than 18 hours of didactic instruction plus 20 clinically oriented experiences in enteral or a combination of enteral and nitrous oxide/oxygen conscious/moderate sedation techniques. The course content shall be consistent with the ADA's Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry in effect at the time the training occurred. The certificate of completion and a detailed description of the course content must be maintained.

3. A dentist who self-certified his qualifications in anesthesia and moderate sedation prior to January 1989 may be issued a temporary conscious/moderate sedation permit to continue to administer only conscious/moderate sedation until May 7, 2015. After May 7, 2015, a dentist shall meet the requirements for and obtain a conscious/moderate sedation permit to administer by any method or by enteral administration only.

E. Additional training required. Dentists who administer conscious/moderate sedation shall:

1. Hold current certification in advanced resuscitation techniques with hands-on simulated airway and megacode training for health care providers, such as ACLS or PALS as evidenced by a certificate of completion posted with the dental license; and

2. Have current training in the use and maintenance of the equipment required in 18VAC60-21-291.

18VAC60-21-291. Requirements for administration of ~~conscious/~~moderate sedation.

A. Delegation of administration.

1. A dentist who does not hold a permit to administer ~~conscious/~~moderate sedation shall only use the services of a qualified dentist or an anesthesiologist to administer such sedation in a dental office. In a licensed outpatient surgery center, a dentist who does not hold a permit to administer conscious/moderate sedation shall use either a qualified dentist, an anesthesiologist, or a certified

registered nurse anesthetist to administer such sedation. [Do not see justification for change suggested by CRNA at fourm and the Virginia Association of Nurse Anesthesist see handout}

2. A dentist who holds a permit may administer or use the services of the following personnel to administer conscious/moderate sedation:

a. A dentist with the training required by 18VAC60-21-290 D 2 to administer by an enteral method;

b. A dentist with the training required by 18VAC60-21-290 D 1 to administer by any method;

c. An anesthesiologist;

d. A certified registered nurse anesthetist ?[under ~~the medical direction and~~ indirect supervision of a dentist who meets the training requirements of 18VAC60-21-290 D 1;] or

e. A registered nurse upon his direct instruction and under the immediate supervision of a dentist who meets the training requirements of 18VAC60-21-290 D 1.

3. If minimal sedation is self-administered by or to a patient 13 years of age or older before arrival at the dental office, the dentist may only use the personnel listed in subdivision 2 of this subsection to administer local anesthesia. No sedating medication shall be [~~prescribed for or~~] administered to a patient 12 years of age or younger prior to his arrival at the dentist office or treatment facility.

4. Preceding the administration of conscious/moderate sedation, a permitted dentist may use the services of the following personnel under indirect supervision to administer local anesthesia to anesthetize the injection or treatment site:

a. A dental hygienist with the training required by 18VAC60-25-100 C to parenterally administer Schedule VI local anesthesia to persons 18 years of age or older; or

b. A dental hygienist, dental assistant, registered nurse, or licensed practical nurse to administer Schedule VI topical oral anesthetics.

5. A dentist who delegates administration of conscious/moderate sedation shall ensure that:

a. All equipment required in subsection B of this section is present, in good working order, and immediately available to the areas where patients will be sedated and treated and will recover; and

b. Qualified staff is on site to monitor patients in accordance with requirements of subsection D of this section.

B. Equipment requirements. A dentist who administers conscious/moderate sedation shall have available the following equipment in sizes for adults or children as appropriate for the patient being treated and shall maintain it in working order and immediately available to the areas where patients will be sedated and treated and will recover:

1. Full face mask or masks;

2. Oral and nasopharyngeal airway management adjuncts;

3. Endotracheal tubes with appropriate connectors or other appropriate airway management adjunct such as a laryngeal mask airway;

4. A laryngoscope with reserve batteries and bulbs and appropriately sized laryngoscope blades;

5. Pulse oximetry;

6. Blood pressure monitoring equipment;

7. Pharmacologic antagonist agents;

8. Source of delivery of oxygen under controlled positive pressure;

9. Mechanical (hand) respiratory bag;

10. Appropriate emergency drugs for patient resuscitation;

11. Electrocardiographic monitor if a patient is receiving parenteral administration of sedation or if the dentist is using titration;

12. Defibrillator;

13. Suction apparatus;

14. Temperature measuring device;

15. Throat pack; and

16. Precordial or pretracheal stethoscope.

17. An end-tidal carbon dioxide monitor (capnograph) [unless preclude.....}

C. Required staffing. At a minimum, there shall be a ~~two-person~~ three person treatment team for ~~conscious~~/moderate sedation. The team shall include the operating dentist and one ~~second~~ person to monitor the patient as provided in 18VAC60-21-260 K and one person to assist the operating dentist as provided in 18VAC60-21-260 J~~, both of whom~~ the three person team shall be in the operatory with the patient throughout the dental procedure. If the second one is a dentist, an anesthesiologist, or a certified registered nurse anesthetist who administers the drugs as permitted in 18VAC60-21-291 A, such person may monitor the patient.

D. Monitoring requirements.

1. Baseline vital signs to include blood pressure, oxygen saturation respiratory rate and heart rate shall be taken and recorded prior to administration of any controlled drug at the facility and prior to discharge.

2. Blood pressure, oxygen saturation, respiratory rate heart rate, ~~end-tidal carbon dioxide, and pulse~~ and end tidal CO2 unless precluded or invalidated by the nature of the patient, procedure or equipment, respiratory rate and shall be monitored *continually [?]* during the administration and recorded every five minutes. ...

3. Monitoring of the patient under conscious/moderate sedation is to begin prior to administration of sedation or, if pre-medication is self-administered by the patient, immediately upon the patient's arrival at the dental facility and shall take place continuously during the dental procedure and recovery from sedation. The person who administers the sedation or another licensed practitioner qualified to administer the same level of sedation must remain on the premises of the dental facility until the patient is evaluated and is discharged.

E. Discharge requirements.

1. The patient shall not be discharged until the responsible licensed practitioner determines that the patient's level of consciousness, oxygenation, ventilation, and ~~circulation~~, blood pressure and heart rate are satisfactory for discharge and vital signs have been taken and recorded.

2. Post-operative instructions shall be given verbally and in writing. The written instructions shall include a 24-hour emergency telephone number.

3. The patient shall be discharged with a responsible individual who has been instructed with regard to the patient's care.

F. Emergency management. The dentist shall be proficient in handling emergencies and complications related to pain control procedures, including the maintenance of respiration and circulation, immediate establishment of an airway, and cardiopulmonary resuscitation.

18VAC60-21-300. Requirements for a deep sedation/general anesthesia permit.

A. After March 31, 2013, no dentist may provide ~~employ~~ or administer ~~use~~ deep sedation or general anesthesia in a dental office unless he has been issued a permit by the board. The requirement for a permit shall not apply to an oral and maxillofacial surgeon who maintains membership in AAOMS and who provides the board with reports that result from the periodic office examinations required by AAOMS. Such an oral and maxillofacial surgeon shall be required to post a certificate issued by AAOMS.

B. To determine eligibility for a deep sedation/general anesthesia permit, a dentist shall submit the following:

1. A completed application form;

2. The application fee as specified in 18VAC60-21-40;

3. A copy of the certificate of completion of a CODA accredited program or other documentation of training content which meets the educational and training qualifications specified in subsection C of this section; and

4. A copy of current certification in Advanced Cardiac Life Support for Health Professionals (ACLS) or Pediatric Advanced Life Support for Health Professionals (PALS) as required in subsection C of this section.

C. Educational and training qualifications for a deep sedation/general anesthesia permit.

1. Completion of a minimum of one calendar year of advanced training in anesthesiology and related academic subjects beyond the undergraduate dental school level in a training program in conformity with the ADA's Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry in effect at the time the training occurred; or

2. Completion of an CODA accredited residency in any dental specialty that incorporates into its curriculum a minimum of one calendar year of full-time training in clinical anesthesia and related clinical medical subjects (i.e., medical evaluation and management of patients) comparable to those set forth in the ADA's Guidelines for Graduate and Postgraduate Training in Anesthesia in effect at the time the training occurred; and

3. Current certification in advanced resuscitative techniques with hands-on simulated airway and megacode training for health care providers, including basic electrocardiographic interpretations, such as courses in ACLS or PALS; and

4. Current training in the use and maintenance of the equipment required in 18VAC60-21-301.

18VAC60-21-301. Requirements for administration of deep sedation or general anesthesia.

A. Preoperative requirements. Prior to the appointment for treatment under deep sedation or general anesthesia the patient shall:

1. Be informed about the personnel and procedures used to deliver the sedative or anesthetic drugs to assure informed consent as required by 18VAC60-21-260 F.

2. Have a physical evaluation as required by 18VAC60-21-260 C.

3. Be given preoperative verbal and written instructions including any dietary or medication restrictions.

B. Delegation of administration.

1. A dentist who does not meet the requirements of 18VAC60-21-300 shall only use the services of a dentist who does meet those requirements or an anesthesiologist to administer deep sedation or general anesthesia in a dental office. In a licensed outpatient surgery center, a dentist shall use either a dentist who meets the requirements of 18VAC60-21-300, an anesthesiologist, or a

certified registered nurse anesthetist to administer deep sedation or general anesthesia. **[same thinking see 18vac-291-A. {1}.

2. A dentist who meets the requirements of 18VAC60-21-300 may administer or use the services of the following personnel to administer deep sedation or general anesthesia:

a. A dentist with the training required by 18VAC60-21-300 C;

b. An anesthesiologist; or

c. A certified registered nurse anesthetist under the ~~medical direction and~~ indirect supervision of a dentist who meets the training requirements of 18VAC60-21-300 C.

3. Preceding the administration of deep sedation or general anesthesia, a dentist who meets the requirements of 18VAC60-21-300 may use the services of the following personnel under indirect supervision to administer local anesthesia to anesthetize the injection or treatment site:

a. A dental hygienist with the training required by 18VAC60-25-100 C to parenterally administer Schedule VI local anesthesia to persons 18 years of age or older; or

b. A dental hygienist, dental assistant, registered nurse, or licensed practical nurse to administer Schedule VI topical oral anesthetics.

C. Equipment requirements. A dentist who administers deep sedation or general anesthesia shall have available the following equipment in sizes appropriate for the patient being treated and shall maintain it in working order and immediately available to the areas where patients will be sedated and treated and will recover:

1. Full face mask or masks;

2. Oral and nasopharyngeal airway management adjuncts;

3. Endotracheal tubes with appropriate connectors or other appropriate airway management adjunct such as a laryngeal mask airway;

4. A laryngoscope with reserve batteries and bulbs and appropriately sized laryngoscope blades;

5. Source of delivery of oxygen under controlled positive pressure;

6. Mechanical (hand) respiratory bag;

7. Pulse oximetry and blood pressure monitoring equipment available and used in the treatment room;

8. Appropriate emergency drugs for patient resuscitation;

9. EKG monitoring equipment;

10. Temperature measuring devices;

11. Pharmacologic antagonist agents;

12. External defibrillator (manual or automatic);

13. An end-tidal carbon dioxide monitor (capnograph); [unless precluded by…]

14. Suction apparatus;

15. Throat pack; and

16. Precordial or pretracheal stethoscope.

D. Required staffing. At a minimum, there shall be a three-person treatment team for deep sedation or general anesthesia. The team shall include the operating dentist, a second person to monitor the patient as provided in 18VAC60-21-260 K, and a third person to assist the operating dentist as provided in 18VAC60-21-260 J, all of whom shall be in the operatory with the patient during the dental procedure. If a second dentist, an anesthesiologist, or a certified registered nurse anesthetist

administers the drugs as permitted in subsection B of this section, such person may serve as the second person to monitor the patient.

E. Monitoring requirements.

1. Baseline vital signs shall be taken and recorded prior to administration of any controlled drug at the facility to include: temperature, blood pressure, pulse, oxygen saturation, EKG, and respiratory rate.

2. The patient's vital signs, end-tidal carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment, EKG readings, blood pressure, pulse, oxygen saturation, temperature, and respiratory rate shall be monitored continually and recorded every five minutes, and reported to the treating dentist throughout the administration of controlled drugs and recovery. When depolarizing medication are administered temperature shall be monitored ~~constantly~~ continuously. ? add EKG to #1. ?

3. Monitoring of the patient undergoing deep sedation or general anesthesia is to begin prior to the administration of any drugs and shall take place ~~continuously~~ continually [?] during administration, the dental procedure, and recovery from anesthesia. The person who administers the anesthesia or another licensed practitioner qualified to administer the same level of anesthesia must remain on the premises of the dental facility until the patient has regained consciousness and is discharged.

F. Emergency management.

1. A secured intravenous line must be established and maintained throughout the procedure.

2. The dentist shall be proficient in handling emergencies and complications related to pain control procedures, including the maintenance of respiration and circulation, immediate establishment of an airway, and cardiopulmonary resuscitation.

** add Special Needs Patients... page 12 ADA Guidelines... *this would satisfy those with concerns of Patient Access*

G. Discharge requirements.

1. The patient shall not be discharged until the responsible licensed practitioner determines that the patient's level of consciousness, oxygenation, ventilation, and circulation are satisfactory for discharge and vital signs have been taken and recorded. ? or use of Alrette score or similar scores?

2. Post-operative instructions shall be given verbally and in writing. The written instructions shall include a 24-hour emergency telephone number for the dental practice.

3. The patient shall be discharged with a responsible individual who has been instructed with regard to the patient's care.

*** continually should be used to mean " very often; at regular or frequent intervals.

And continously to mean "unceasingly; constantly; without interruption.[*these could be added to definitions.]*

Part VII. Oral and Maxillofacial Surgeons.

18VAC60-21-310. Registration of oral and maxillofacial surgeons.

Every licensed dentist who practices as an oral and maxillofacial surgeon, as defined in § 54.1-2700 of the Code, shall register his practice with the board.

1. After initial registration, an oral and maxillofacial surgeon shall renew his registration annually on or before December 31.

2. An oral and maxillofacial surgeon who fails to register or to renew his registration and continues to practice oral and maxillofacial surgery may be subject to disciplinary action by the board.

3. Within one year of the expiration of a registration, an oral and maxillofacial surgeon may renew by payment of the renewal fee and a late fee.

4. After one year from the expiration date, an oral and maxillofacial surgeon who wishes to reinstate his registration shall update his profile and pay the reinstatement fee.

18VAC60-21-320. Profile of information for oral and maxillofacial surgeons.

A. In compliance with requirements of § 54.1-2709.2 of the Code, an oral and maxillofacial surgeon registered with the board shall provide, upon initial request, the following information within 30 days:

1. The address of the primary practice setting and all secondary practice settings with the percentage of time spent at each location;

2. Names of dental or medical schools with dates of graduation;

3. Names of graduate medical or dental education programs attended at an institution approved by the Accreditation Council for Graduate Medical Education, the Commission on Dental Accreditation, and the American Dental Association with dates of completion of training;

4. Names and dates of specialty board certification or board eligibility, if any, as recognized by the Council on Dental Education and Licensure of the American Dental Association;

5. Number of years in active, clinical practice in the United States or Canada, following completion of medical or dental training and the number of years, if any, in active, clinical practice outside the United States or Canada;

6. Names of insurance plans accepted or managed care plans in which the oral and maxillofacial surgeon participates and whether he is accepting new patients under such plans;

7. Names of hospitals with which the oral and maxillofacial surgeon is affiliated;

8. Appointments within the past 10 years to dental school faculties with the years of service and academic rank;

9. Publications, not to exceed 10 in number, in peer-reviewed literature within the most recent five-year period;

10. Whether there is access to translating services for non-English speaking patients at the primary practice setting and which, if any, foreign languages are spoken in the practice; and

11. Whether the oral and maxillofacial surgeon participates in the Virginia Medicaid Program and whether he is accepting new Medicaid patients.

B. The oral and maxillofacial surgeon may provide additional information on hours of continuing education earned, subspecialities obtained, and honors or awards received.

C. Whenever there is a change in the information on record with the profile system, the oral and maxillofacial surgeon shall provide current information in any of the categories in subsection A of this section within 30 days.

18VAC60-21-330. Reporting of malpractice paid claims and disciplinary notices and orders.

A. In compliance with requirements of § 54.1-2709.4 of the Code, a dentist registered with the board as an oral and maxillofacial surgeon shall report in writing to the executive director of the board all malpractice paid claims in the most recent 10-year period. Each report of a settlement or judgment shall indicate:

1. The year the claim was paid;
2. The total amount of the paid claim in United States dollars; and
3. The city, state, and country in which the paid claim occurred.

B. The board shall use the information provided to determine the relative frequency of paid claims described in terms of the percentage who have made malpractice payments within the most recent 10-year period. The statistical methodology used will be calculated on more than 10 paid claims for all dentists reporting, with the top 16% of the paid claims to be displayed as above-average payments, the next 68% of the paid claims to be displayed as average payments, and the last 16% of the paid claims to be displayed as below-average payments.

C. Adjudicated notices and final orders or decision documents, subject to § 54.1-2400.2 G of the Code, shall be made available on the profile. Information shall also be posted indicating the availability of unadjudicated notices and orders that have been vacated.

18VAC60-21-340. Noncompliance or falsification of profile.

A. The failure to provide the information required in 18VAC60-21-320 A may constitute unprofessional conduct and may subject the licensee to disciplinary action by the board.

B. Intentionally providing false information to the board for the profile system shall constitute unprofessional conduct and shall subject the licensee to disciplinary action by the board.

18VAC60-21-350. Certification to perform cosmetic procedures; applicability.

A. In order for an oral and maxillofacial surgeon to perform aesthetic or cosmetic procedures, he shall be certified by the board pursuant to § 54.1-2709.1 of the Code. Such certification shall only entitle the licensee to perform procedures above the clavicle or within the head and neck region of the body.

B. Based on the applicant's education, training, and experience, certification may be granted to perform the following procedures for cosmetic treatment:

1. Rhinoplasty and other treatment of the nose;
2. Blepharoplasty and other treatment of the eyelid;
3. Rhytidectomy and other treatment of facial skin wrinkles and sagging;
4. Submental liposuction and other procedures to remove fat;
5. Laser resurfacing or dermabrasion and other procedures to remove facial skin irregularities;
6. Browlift (either open or endoscopic technique) and other procedures to remove furrows and sagging skin on the upper eyelid or forehead;
7. Platysmal muscle plication and other procedures to correct the angle between the chin and neck;
8. Otoplasty and other procedures to change the appearance of the ear; and
9. Application of injectable medication or material for the purpose of treating extra-oral cosmetic conditions.

18VAC60-21-360. Certification not required.

Certification shall not be required for performance of the following:
1. Treatment of facial diseases and injuries, including maxillofacial structures;
2. Facial fractures, deformity, and wound treatment;
3. Repair of cleft lip and palate deformity;
4. Facial augmentation procedures; and
5. Genioplasty.

18VAC60-21-370. Credentials required for certification.

An applicant for certification shall:

1. Hold an active, unrestricted license from the board;

2. Submit a completed application and fee;

3. Complete an oral and maxillofacial residency program accredited by the Commission on Dental Accreditation;

4. Hold board certification by the American Board of Oral and Maxillofacial Surgery (ABOMS) or board eligibility as defined by ABOMS;

5. Have current privileges on a hospital staff to perform oral and maxillofacial surgery; and

6. If his oral and maxillofacial residency or cosmetic clinical fellowship was completed after July 1, 1996, and training in cosmetic surgery was a part of such residency or fellowship, submit:

a. A letter from the director of the residency or fellowship program documenting the training received in the residency or in the clinical fellowship to substantiate adequate training in the specific procedures for which the applicant is seeking certification; and

b. Documentation of having performed as primary or assistant surgeon at least 10 proctored cases in each of the procedures for which he seeks to be certified.

7. If his oral and maxillofacial residency was completed prior to July 1, 1996, or if his oral and maxillofacial residency was completed after July 1, 1996, and training in cosmetic surgery was not a part of the applicant's residency, submit:

a. Documentation of having completed didactic and clinically approved courses to include the dates attended, the location of the course, and a copy of the certificate of attendance. Courses shall provide sufficient training in the specific procedures requested for certification and shall be offered by:

(1) An advanced specialty education program in oral and maxillofacial surgery accredited by the Commission on Dental Accreditation;

(2) A medical school accredited by the Liaison Committee on Medical Education or other official accrediting body recognized by the American Medical Association;

(3) The American Dental Association or one of its constituent and component societies or other ADA Continuing Education Recognized Programs (CERP) approved for continuing dental education; or

(4) The American Medical Association approved for category 1, continuing medical education; and

b. Documentation of either:

(1) Holding current privileges to perform cosmetic surgical procedures within a hospital accredited by the Joint Commission on Accreditation of Healthcare Organizations; or

(2) Having completed at least 10 cases as primary or secondary surgeon in the specific procedures for which the applicant is seeking certification, of which at least five shall be proctored cases as defined in this chapter.

18VAC60-21-380. Renewal of certification.

In order to renew his certification to perform cosmetic procedures, an oral and maxillofacial surgeon shall possess a current, active, unrestricted license to practice dentistry from the Virginia Board of Dentistry and shall submit the renewal application and fee on or before December 31 of each year. If an oral and maxillofacial surgeon fails to renew his certificate, the certificate is lapsed and performance of cosmetic procedures is not permitted. To renew a lapsed certificate within one year of expiration, the oral and maxillofacial surgeon shall pay the renewal fees and a late fee. Reinstatement of a certification that has been lapsed for more than one year shall require completion of a reinstatement form documenting continued competency in the procedures for which the surgeon is certified and payment of a reinstatement fee.

18VAC60-21-390. Quality assurance review for procedures performed by certificate holders.

A. On a schedule of no less than once every three years, the board shall conduct a random audit of charts for patients receiving cosmetic procedures that are performed by a certificate holder in a facility not accredited by Joint Commission on Accreditation of Healthcare Organizations or other nationally recognized certifying organization as determined by the board.
B. Oral and maxillofacial surgeons certified to perform cosmetic procedures shall maintain separate files, an index, coding, or other system by which such charts can be identified by cosmetic procedure.
C. Cases selected in a random audit shall be reviewed for quality assurance by a person qualified to perform cosmetic procedures according to a methodology determined by the board.

18VAC60-21-400. Complaints against certificate holders for cosmetic procedures.

Complaints arising out of performance of cosmetic procedures by a certified oral and maxillofacial surgeon shall be adjudicated solely by the Board of Dentistry. Upon receipt of the investigation report on such complaints, the Board of Dentistry shall promptly notify the Board of Medicine, and the investigation report shall be reviewed and an opinion rendered by both a physician licensed by the Board of Medicine who actively practices in a related specialty and by an oral and maxillofacial surgeon licensed by the Board of Dentistry. The Board of Medicine shall maintain the confidentiality of the complaint consistent with § 54.1-2400.2 of the Code.

Part VIII. Mobile Dental Clinics.

18VAC60-21-410. Registration of a mobile dental clinic or portable dental operation.

A. An applicant for registration of a mobile dental facility or portable dental operation shall provide:

1. The name and address of the owner of the facility or operation and an official address of record for the facility or operation, which shall not be a post office address. Notice shall be given to the board within 30 days if there is a change in the ownership or the address of record for a mobile dental facility or portable dental operation;

2. The name, address, and license number of each dentist and dental hygienist or the name, address, and registration number of each dental assistant II who will provide dental services in the facility or operation. The identity and license or registration number of any additional dentists, dental hygienists, or dental assistants II providing dental services in a mobile dental facility or portable dental operation shall be provided to the board in writing prior to the provision of such services; and

3. The address or location of each place where the mobile dental facility or portable dental operation will provide dental services and the dates on which such services will be provided. Any additional locations or dates for the provision of dental services in a mobile dental facility or portable dental operation shall be provided to the board in writing prior to the provision of such services.

B. The information provided by an applicant to comply with subsection A of this section shall be made available to the public.

C. An application for registration of a mobile dental facility or portable dental operation shall include:

1. Certification that there is a written agreement for follow-up care for patients to include identification of and arrangements for treatment in a dental office that is permanently established within a reasonable geographic area;

2. Certification that the facility or operation has access to communication facilities that enable the dental personnel to contact assistance in the event of a medical or dental emergency;

3. Certification that the facility has a water supply and all equipment necessary to provide the dental services to be rendered in the facility;

4. Certification that the facility or operation conforms to all applicable federal, state, and local laws, regulations, and ordinances dealing with radiographic equipment, sanitation, zoning, flammability, and construction standards; and

5. Certification that the applicant possesses all applicable city or county licenses or permits to operate the facility or operation.

D. Registration may be denied or revoked for a violation of provisions of § 54.1-2706 of the Code.

18VAC60-21-420. Requirements for a mobile dental clinic or portable dental operation.

A. The registration of the facility or operation and copies of the licenses of the dentists and dental hygienists or registrations of the dental assistants II shall be displayed in plain view of patients.

B. Prior to treatment, the facility or operation shall obtain written consent from the patient or, if the patient is a minor or incapable of consent, his parent, guardian, or authorized representative.

C. Each patient shall be provided with an information sheet, or if the patient, his parent, guardian, or authorized agent has given written consent to an institution or school to have access to the patient's dental health record, the institution or school may be provided a copy of the information. At a minimum, the information sheet shall include:

1. Patient name, date of service, and location where treatment was provided;

2. Name of dentist or dental hygienist who provided services;

3. Description of the treatment rendered and tooth numbers, when appropriate;

4. Billed service codes and fees associated with treatment;

5. Description of any additional dental needs observed or diagnosed;

6. Referral or recommendation to another dentist if the facility or operation is unable to provide follow-up treatment; and

7. Emergency contact information.

D. Patient records shall be maintained, as required by 18VAC60-21-90, in a secure manner within the facility or at the address of record listed on the registration application. Records shall be made available upon request by the patient, his parent, guardian, or authorized representative and shall be available to the board for inspection and copying.

E. The practice of dentistry and dental hygiene in a mobile dental clinic or portable dental operation shall be in accordance with the laws and regulations governing such practice.

18VAC60-21-430. Exemptions from requirement for registration.

The following shall be exempt from requirements for registration as a mobile dental clinic or portable dental operation:

1. All federal, state, or local governmental agencies;

2. Dental treatment that is provided without charge to patients or to any third party payer;

3. Clinics operated by federally qualified health centers with a dental component that provide dental services via mobile model to adults and children within 30 miles of the federally qualified health center;

4. Clinics operated by free health clinics or health safety net clinics that have been granted tax-exempt status pursuant to § 501(c)(3) of the Internal Revenue Code that provide dental services via mobile model to adults and children within 30 miles of the free health clinic or health safety net clinic; and

5. Clinics that provide dental services via mobile model to individuals who are not ambulatory and who reside in long-term care facilities, assisted living facilities, adult care homes, or private homes.

DR. SARRETT'S REVIEW COMMENTS

Part VI. Controlled Substances, Sedation, and Anesthesia.

18VAC60-21-260. General provisions.

A. Application of Part VI. This part applies to prescribing, dispensing, and administering controlled substances in dental offices, mobile dental facilities, and portable dental operations and shall not apply to administration by a dentist practicing in (i) a licensed hospital as defined in § 32.1-123 of the Code, (ii) a state-operated hospital, or (iii) a facility directly maintained or operated by the federal government.

B. Registration required. Any dentist who prescribes, administers, or dispenses Schedules II through V controlled drugs must hold a current registration with the federal Drug Enforcement Administration.

C. Patient evaluation required.

1. The decision to administer controlled drugs for dental treatment must be based on a documented evaluation of the health history and current medical condition of the patient in accordance with the Class I through V risk category classifications of the American Society of Anesthesiologists (ASA) in effect at the time of treatment. The findings of the evaluation, the ASA risk assessment class assigned, and any special considerations must be recorded in the patient's record.

2. Any level of sedation and general anesthesia may be provided for a patient who is ASA Class I and Class II.

3. A patient in ASA Class III shall only be provided minimal sedation, ~~conscious/~~moderate sedation, deep sedation, or general anesthesia by:

a. A dentist after he has documented a consultation with the patient's primary care physician or other medical specialist regarding potential risks and special monitoring requirements that may be necessary;

b. An oral and maxillofacial surgeon who has performed a physical evaluation and documented the findings and the ASA risk assessment category of the patient and any special monitoring requirements that may be necessary; or

c. A person licensed under Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code who has a specialty in anesthesia.

4. Minimal sedation may only be provided for a patient who is in ASA Class IV by:

a. A dentist after he has documented a consultation with the patient's primary care physician or other medical specialist regarding potential risks and special monitoring requirements that may be necessary; or

b. An oral and maxillofacial surgeon who has performed a physical evaluation and documented the findings and the ASA risk assessment category of the patient and any special monitoring requirements that may be necessary.

5. ~~Conscious/m~~Moderate sedation, deep sedation, or general anesthesia shall not be provided in a dental office for patients in ASA Class IV and Class V.

D. Additional requirements for patient information and records. In addition to the record requirements in 18VAC60-21-90, when ~~conscious/m~~moderate sedation, deep sedation, or general anesthesia is administered, the patient record shall also include:

Commented [DCS1]: ADA guidelines have statements regarding ASA II and IV patients that are specific to the levels of sedation. For minimal "may require consultation with primary care physician". For moderate and deep/GA "should require consultation"

Commented [DCS2]: See previous comment.

Commented [DCS3]: See above comment

1

1. Notation of the patient's American Society of Anesthesiologists classification;

2. Review of medical history and current conditions, including the patient's weight and height or, if appropriate, the body mass index;

3. Written informed consent for administration of sedation and anesthesia and for the dental procedure to be performed;

4. Preoperative vital signs;

5. A record of the name, dose, and strength of drugs and route of administration including the administration of local anesthetics with notations of the time sedation and anesthesia were administered;

6. Monitoring records of all required vital signs and physiological measures recorded every five minutes; and

7. A list of staff participating in the administration, treatment, and monitoring including name, position, and assigned duties.

E. Pediatric patients. No sedating medication shall be prescribed for or administered to a patient 12 years of age or younger prior to his arrival at the dentist office or treatment facility.

F. Informed written consent. Prior to administration of any level of sedation or general anesthesia, the dentist shall discuss the nature and objectives of the planned level of sedation or general anesthesia along with the risks, benefits, and alternatives and shall obtain informed, written consent from the patient or other responsible party for the administration and for the treatment to be provided. The written consent must be maintained in the patient record.

G. Level of sedation. The determinant for the application of the rules for any level of sedation or for general anesthesia shall be the degree of sedation or consciousness level of a patient that should reasonably be expected to result from the type, strength, and dosage of medication, the method of administration, and the individual characteristics of the patient as documented in the patient's record. The drugs and techniques used must carry a margin of safety wide enough to render the unintended reduction of or loss of consciousness unlikely, factoring in titration and the patient's age, weight, and ability to metabolize drugs.

H. Emergency management.

1. If a patient enters a deeper level of sedation than the dentist is qualified and prepared to provide, the dentist shall stop the dental procedure until the patient returns to and is stable at the intended level of sedation.

2. A dentist in whose office sedation or anesthesia is administered shall have written basic emergency procedures established and staff trained to carry out such procedures.

I. Ancillary personnel. Dentists who employ unlicensed, ancillary personnel to assist in the administration and monitoring of any form of minimal sedation, conscious/moderate sedation, deep sedation, or general anesthesia shall maintain documentation that such personnel have:

1. Training and hold current certification in basic resuscitation techniques with hands-on airway training for health care providers, such as Basic Cardiac Life Support for Health Professionals or a clinically oriented course devoted primarily to responding to clinical emergencies offered by an approved provider of continuing education as set forth in 18VAC60-21-250 C; or

2. Current certification as a certified anesthesia assistant (CAA) by the American Association of Oral and Maxillofacial Surgeons or the American Dental Society of Anesthesiology (ADSA).

J. Assisting in administration. A dentist, consistent with the planned level of administration (i.e., local anesthesia, minimal sedation, conscious/moderate sedation, deep sedation, or general anesthesia) and appropriate to his education, training, and experience, may utilize the services of a dentist, anesthesiologist, certified registered nurse anesthetist, dental hygienist, dental assistant, or

Commented [DCS4]: ADA does not provide specific time interval but uses the words "continuously" and "continually"

Commented [DCS5]: ADA guidelines are not applicable to children and refer to the AAP/AAPD Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures. These guidelines do not define a child's age but does support not prescribing medication to be administered prior to arriving at the office.

nurse to perform functions appropriate to such practitioner's education, training, and experience and consistent with that practitioner's respective scope of practice.

K. Patient monitoring.

1. A dentist may delegate monitoring of a patient to a dental hygienist, dental assistant, or nurse who is under his direction or to another dentist, anesthesiologist, or certified registered nurse anesthetist. The person assigned to monitor the patient shall be continuously in the presence of the patient in the office, operatory, and recovery area (i) before administration is initiated or immediately upon arrival if the patient self-administered a sedative agent, (ii) throughout the administration of drugs, (iii) throughout the treatment of the patient, and (iv) throughout recovery until the patient is discharged by the dentist.

2. The person monitoring the patient shall:

a. Have the patient's entire body in sight;

b. Be in close proximity so as to speak with the patient;

c. Converse with the patient to assess the patient's ability to respond in order to determine the patient's level of sedation;

d. Closely observe the patient for coloring, breathing, level of physical activity, facial expressions, eye movement, and bodily gestures in order to immediately recognize and bring any changes in the patient's condition to the attention of the treating dentist; and

e. Read, report, and record the patient's vital signs and physiological measures.

L. A dentist who allows the administration of general anesthesia, deep sedation, or ~~conscious~~/moderate sedation in his dental office is responsible for assuring that:

1. The equipment for administration and monitoring, as required in subsection B of 18VAC60-21-291 or subsection C of 18VAC60-21-301, is readily available and in good working order prior to performing dental treatment with anesthesia or sedation. The equipment shall either be maintained by the dentist in his office or provided by the anesthesia or sedation provider; and

2. The person administering the anesthesia or sedation is appropriately licensed and the staff monitoring the patient is qualified.

18VAC60-21-270. Administration of local anesthesia.

A dentist may administer or use the services of the following personnel to administer local anesthesia:

1. A dentist;

2. An anesthesiologist;

3. A certified registered nurse anesthetist under his medical direction and indirect supervision;

4. A dental hygienist with the training required by 18VAC60-25-100 C to parenterally administer Schedule VI local anesthesia to persons 18 years of age or older under his indirect supervision;

5. A dental hygienist to administer Schedule VI topical oral anesthetics under indirect supervision or under his order for such treatment under general supervision; or

6. A dental assistant or a registered or licensed practical nurse to administer Schedule VI topical oral anesthetics under indirect supervision.

18VAC60-21-279. Administration of only inhalation analgesia (nitrous oxide).

A. Education and training requirements. A dentist who utilizes nitrous oxide shall have training in and knowledge of:

1. The appropriate use and physiological effects of nitrous oxide, the potential complications of administration, the indicators for complications, and the interventions to address the complications.

2. The use and maintenance of the equipment required in subsection D of this section.

B. No sedating medication shall be prescribed for or administered to a patient 12 years of age or younger prior to his arrival at the dental office or treatment facility.

Commented [DCS6]: See comment above regarding children.

C. Delegation of administration.

1. A qualified dentist may administer or use the services of the following personnel to administer nitrous oxide:

a. A dentist;

b. An anesthesiologist;

c. A certified registered nurse anesthetist under his medical direction and indirect supervision;

d. A dental hygienist with the training required by 18VAC60-25-100 B and under indirect supervision; or

e. A registered nurse upon his direct instruction and under immediate supervision.

2. Preceding the administration of nitrous oxide, a dentist may use the services of the following personnel working under indirect supervision to administer local anesthesia to numb an injection or treatment site:

a. A dental hygienist with the training required by 18VAC60-25-100 C to parenterally administer Schedule VI local anesthesia to persons 18 years of age or older; or

b. A dental hygienist, dental assistant, registered nurse, or licensed practical nurse to administer Schedule VI topical oral anesthetics.

D. Equipment requirements. A dentist who utilizes nitrous oxide only or who directs the administration by another licensed health professional as permitted in subsection C of this section shall maintain the following equipment in working order and immediately available to the areas where patients will be sedated and treated and will recover:

1. Blood pressure monitoring equipment;

2. Source of delivery of oxygen under controlled positive pressure;

3. Mechanical (hand) respiratory bag; and

4. Suction apparatus.

Commented [DCS7]: ADA Guidelines for minimal sedation which includes nitrous oxide inhalation only states monitoring oxygen saturation with pulse oximeter "may be clinically usefule and should be considered".

E. Required staffing. When only nitrous oxide/oxygen is administered, a second person in the operatory is not required. Either the dentist or qualified dental hygienist under the indirect supervision of a dentist may administer the nitrous oxide/oxygen and treat and monitor the patient.

F. Monitoring requirements.

1. Baseline vital signs, to include blood pressure and heart rate, shall be taken and recorded prior to administration of nitrous oxide analgesia and prior to discharge, unless extenuating circumstances exist and are documented in the patient's record.

2. Continual clinical observation of the patient's responsiveness, color, respiratory rate, and depth of ventilation shall be performed.

3. Once the administration of nitrous oxide has begun, the dentist shall ensure that a licensed health care professional or a person qualified in accordance with 18VAC60-21-260 I monitors the patient at all times until discharged as required in subsection G of this section.

4. Monitoring shall include making the proper adjustments of nitrous oxide/oxygen machines at the request of or by the dentist or by another qualified licensed health professional identified in subsection C of this section. Only the dentist or another qualified licensed health professional identified in subsection C of this section may turn the nitrous oxide/oxygen machines on or off.

5. Upon completion of nitrous oxide administration, the patient shall be administered 100% oxygen for a minimum of five minutes to minimize the risk of diffusion hypoxia.

G. Discharge requirements.

1. The dentist shall not discharge a patient until he exhibits baseline responses in a post-operative evaluation of the level of consciousness. Vital signs, to include blood pressure and heart rate, shall be taken and recorded prior to discharge.

2. Post-operative instructions shall be given verbally and in writing. The written instructions shall include a 24-hour emergency telephone number.

3. Pediatric patients shall be discharged with a responsible individual who has been instructed with regard to the patient's care.

18VAC60-21-280. Administration of minimal sedation.

Commented [DCS8]: ADA guidelines specify that administration of one drug, with our without nitrous oxide, and exceeding the MRD for the drug requires moderate sedation guideance. Using more than one drug also requires moderate sedation guidance. Inhalation of nitrous oxide only is considered minimal sedation in ADA guidelines.

A. Education and training requirements. A dentist who utilizes minimal sedation shall have training in and knowledge of:

1. The medications used, the appropriate dosages, the potential complications of administration, the indicators for complications, and the interventions to address the complications.

2. The physiological effects of minimal sedation, the potential complications of administration, the indicators for complications, and the interventions to address the complications.

3. The use and maintenance of the equipment required in subsection D of this section.

B. No sedating medication shall be prescribed for or administered to a patient 12 years of age or younger prior to his arrival at the dental office or treatment facility.

Commented [DCS9]: See comment above regarding children.

C. Delegation of administration.

1. A qualified dentist may administer or use the services of the following personnel to administer minimal sedation:

a. A dentist;

b. An anesthesiologist;

c. A certified registered nurse anesthetist under his medical direction and indirect supervision;

d. A dental hygienist with the training required by 18VAC60-25-100 C only for administration of nitrous oxide/oxygen with the dentist present in the operatory; or

e. A registered nurse upon his direct instruction and under immediate supervision.

2. Preceding the administration of minimal sedation, a dentist may use the services of the following personnel working under indirect supervision to administer local anesthesia to numb an injection or treatment site:

a. A dental hygienist with the training required by 18VAC60-25-100 C to parenterally administer Schedule VI local anesthesia to persons 18 years of age or older; or

b. A dental hygienist, dental assistant, registered nurse, or licensed practical nurse to administer Schedule VI topical oral anesthetics;

3. If minimal sedation is self-administered by or to a patient 13 years of age or older before arrival at the dental office or treatment facility, the dentist may only use the personnel listed in subdivision 1 of this subsection to administer local anesthesia.

Commented [DCS10]: ADA guidelines and AAP/AAPD do not define an age for children and adults.

D. Equipment requirements. A dentist who utilizes minimal sedation or who directs the administration by another licensed health professional as permitted in subsection C of this section shall maintain the following equipment in working order and immediately available to the areas where patients will be sedated and treated and will recover:

1. Blood pressure monitoring equipment;

2. Source of delivery of oxygen under controlled positive pressure;

3. Mechanical (hand) respiratory bag;

4. Suction apparatus; and

5. Pulse oximeter.

E. Required staffing. The treatment team for minimal sedation shall consist of the dentist and a second person in the operatory with the patient to assist the dentist and monitor the patient. The second person shall be a licensed health care professional or a person qualified in accordance with 18VAC60-21-260 I.

F. Monitoring requirements.

1. Baseline vital signs to include blood pressure, respiratory rate, and heart rate shall be taken and recorded prior to administration of sedation and prior to discharge.

2. Blood pressure, oxygen saturation, respiratory rate, and pulse shall be monitored continuously during the procedure.

3. Once the administration of minimal sedation has begun by any route of administration, the dentist shall ensure that a licensed health care professional or a person qualified in accordance with 18VAC60-21-260 I monitors the patient at all times until discharged as required in subsection G of this section.

4. If nitrous oxide/oxygen is used in addition to any other pharmacological agent, monitoring shall include making the proper adjustments of nitrous oxide/oxygen machines at the request of or by the dentist or by another qualified licensed health professional identified in subsection C of this section. Only the dentist or another qualified licensed health professional identified in subsection C of this section may turn the nitrous oxide/oxygen machines on or off.

5. If any other pharmacological agent is used in addition to nitrous oxide/oxygen and a local anesthetic, requirements for the induced level of sedation must be met.

G. Discharge requirements.

1. The dentist shall not discharge a patient until he exhibits baseline responses in a post-operative evaluation of the level of consciousness. Vital signs, to include blood pressure, respiratory rate, and heart rate shall be taken and recorded prior to discharge.

2. Post-operative instructions shall be given verbally and in writing. The written instructions shall include a 24-hour emergency telephone number.

3. Pediatric patients shall be discharged with a responsible individual who has been instructed with regard to the patient's care.

18VAC60-21-290. Requirements for a ~~conscious~~/moderate sedation permit.

A. After March 31, 2013, no dentist may employ or use ~~conscious~~/moderate sedation in a dental office unless he has been issued a permit by the board. The requirement for a permit shall not apply

to an oral and maxillofacial surgeon who maintains membership in the American Association of Oral and Maxillofacial Surgeons (AAOMS) and who provides the board with reports that result from the periodic office examinations required by AAOMS. Such an oral and maxillofacial surgeon shall be required to post a certificate issued by AAOMS.

B. Automatic qualification. Dentists who hold a current permit to administer deep sedation and general anesthesia may administer ~~conscious/~~moderate sedation.

C. To determine eligibility for a ~~conscious/moderate~~moderate sedation permit, a dentist shall submit the following:

1. A completed application form indicating one of the following permits for which the applicant is qualified:

a. ~~Conscious/moderate~~Moderate sedation by any method;

b. ~~Conscious/moderate~~Moderate sedation by enteral administration only; or

c. Temporary ~~conscious/moderate~~moderate sedation permit (may be renewed one time);

2. The application fee as specified in 18VAC60-21-40;

3. A copy of a transcript, certification, or other documentation of training content that meets the educational and training qualifications as specified in subsection D of this section, as applicable; and

4. A copy of current certification in advanced cardiac life support (ACLS) or pediatric advanced life support (PALS) as required in subsection E of this section.

D. Education requirements for a permit to administer ~~conscious/moderate~~moderate sedation.

1. Administration by any method. A dentist may be issued a ~~conscious/moderate~~moderate sedation permit to administer by any method by meeting one of the following criteria:

a. Completion of training for this treatment modality according to the ADA's Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry in effect at the time the training occurred, while enrolled in an accredited dental program or while enrolled in a post-doctoral university or teaching hospital program; or

b. Completion of a continuing education course that meets the requirements of 18VAC60-21-250 and consists of (i) 60 hours of didactic instruction plus the management of at least 20 patients per participant, (ii) demonstration of competency and clinical experience in ~~conscious/moderate~~moderate sedation, and (iii) management of a compromised airway. The course content shall be consistent with the ADA's Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry in effect at the time the training occurred.

2. Enteral administration only. A dentist may be issued a ~~conscious/moderate~~moderate sedation permit to administer only by an enteral method if he has completed a continuing education program that meets the requirements of 18VAC60-21-250 and consists of not less than 18 hours of didactic instruction plus 20 clinically oriented experiences in enteral or a combination of enteral and nitrous oxide/oxygen ~~conscious/moderate~~moderate sedation techniques. The course content shall be consistent with the ADA's Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry in effect at the time the training occurred. The certificate of completion and a detailed description of the course content must be maintained.

3. A dentist who self-certified his qualifications in anesthesia and moderate sedation prior to January 1989 may be issued a temporary ~~conscious/moderate~~moderate sedation permit to continue to administer only ~~conscious/moderate~~moderate sedation until May 7, 2015. After May 7, 2015, a dentist shall meet the requirements for and obtain a ~~conscious/moderate~~moderate sedation permit to administer by any method or by enteral administration only.

Commented [DCS11]: This is conflict with ADA guidelines since ADA makes no distinction in required training for moderate sedation by route of administration. All moderate sedation, regardless of route of administration requires 60 hours plus 20 supervised cases and demonstration of certain competencies.

Commented [DCS12]: This paragraph seems not needed any longer since the date expired.

E. Additional training required. Dentists who administer ~~conscious/moderate~~moderate sedation shall:

1. Hold current certification in advanced resuscitation techniques with hands-on simulated airway and megacode training for health care providers, such as ACLS or PALS as evidenced by a certificate of completion posted with the dental license; and

2. Have current training in the use and maintenance of the equipment required in 18VAC60-21-291.

18VAC60-21-291. Requirements for administration of ~~conscious/moderate~~moderate sedation.

A. Delegation of administration.

1. A dentist who does not hold a permit to administer ~~conscious/moderate~~moderate sedation shall only use the services of a qualified dentist or an anesthesiologist to administer such sedation in a dental office. In a licensed outpatient surgery center, a dentist who does not hold a permit to administer ~~conscious/moderate~~moderate sedation shall use either a qualified dentist, an anesthesiologist, or a certified registered nurse anesthetist to administer such sedation.

2. A dentist who holds a permit may administer or use the services of the following personnel to administer ~~conscious/moderate~~moderate sedation:

a. A dentist with the training required by 18VAC60-21-290 D 2 to administer by an enteral method;

b. A dentist with the training required by 18VAC60-21-290 D 1 to administer by any method;

c. An anesthesiologist;

d. A certified registered nurse anesthetist under the medical direction and indirect supervision of a dentist who meets the training requirements of 18VAC60-21-290 D 1; or

e. A registered nurse upon his direct instruction and under the immediate supervision of a dentist who meets the training requirements of 18VAC60-21-290 D 1.

3. If minimal sedation is self-administered by or to a patient 13 years of age or older before arrival at the dental office, the dentist may only use the personnel listed in subdivision 2 of this subsection to administer local anesthesia. No sedating medication shall be prescribed for or administered to a patient 12 years of age or younger prior to his arrival at the dentist office or treatment facility.

Commented [DCS13]: See above comments regarding children and lack of age definition in ADA and AAP/AAPD guidelines

4. Preceding the administration of ~~conscious/moderate~~moderate sedation, a permitted dentist may use the services of the following personnel under indirect supervision to administer local anesthesia to anesthetize the injection or treatment site:

a. A dental hygienist with the training required by 18VAC60-25-100 C to parenterally administer Schedule VI local anesthesia to persons 18 years of age or older; or

b. A dental hygienist, dental assistant, registered nurse, or licensed practical nurse to administer Schedule VI topical oral anesthetics.

5. A dentist who delegates administration of ~~conscious/moderate~~moderate sedation shall ensure that:

a. All equipment required in subsection B of this section is present, in good working order, and immediately available to the areas where patients will be sedated and treated and will recover; and

b. Qualified staff is on site to monitor patients in accordance with requirements of subsection D of this section.

B. Equipment requirements. A dentist who administers ~~conscious/moderate~~moderate sedation shall have available the following equipment in sizes for adults or children as appropriate for the patient being treated and shall maintain it in working order and immediately available to the areas where patients will be sedated and treated and will recover:

1. Full face mask or masks;

2. Oral and nasopharyngeal airway management adjuncts;

3. Endotracheal tubes with appropriate connectors or other appropriate airway management adjunct such as a laryngeal mask airway;

4. A laryngoscope with reserve batteries and bulbs and appropriately sized laryngoscope blades;

5. Pulse oximetry;

6. Blood pressure monitoring equipment;

7. Pharmacologic antagonist agents;

8. Source of delivery of oxygen under controlled positive pressure;

9. Mechanical (hand) respiratory bag;

10. Appropriate emergency drugs for patient resuscitation;

11. Electrocardiographic monitor if a patient is receiving parenteral administration of sedation or if the dentist is using titration;

12. Defibrillator;

13. Suction apparatus;

14. Temperature measuring device;

15. Throat pack; and

16. Precordial or pretracheal stethoscope.

17. An end-tidal carbon dioxide monitor (capnograph).

Commented [DCS14]: ADA guidelines require having equipment to "obtain intravascular or intraosseous access" for drugs

C. Required staffing. At a minimum, there shall be a two-person treatment team for ~~conscious/moderate~~moderate sedation. The team shall include the operating dentist and a second person to monitor the patient as provided in 18VAC60-21-260 K and assist the operating dentist as provided in 18VAC60-21-260 J, both of whom shall be in the operatory with the patient throughout the dental procedure. If the second person is a dentist, an anesthesiologist, or a certified registered nurse anesthetist who administers the drugs as permitted in 18VAC60-21-291 A, such person may monitor the patient.

D. Monitoring requirements.

1. Baseline vital signs shall be taken and recorded prior to administration of any controlled drug at the facility and prior to discharge.

2. Blood pressure, oxygen saturation, end-tidal carbon dioxide, and pulse shall be monitored continually during the administration and recorded every five minutes.

Commented [DCS15]: ADA Guidelines state for ventilation monitoring: "The dentist must observe chest excursions continually. The dentist must monitor ventilation and/or breathing by monitoring end-tidal CO2 unless precluded or invalidated by the nature of the patient, procedure or equipment. In addition, ventilation should be monitored by continual observation of qualitative signs, including auscultation of breath sounds with a precordial or pretracheal stethoscope.

3. Monitoring of the patient under ~~conscious/moderate~~moderate sedation is to begin prior to administration of sedation or, if pre-medication is self-administered by the patient, immediately upon the patient's arrival at the dental facility and shall take place continuously during the dental procedure and recovery from sedation. The person who administers the sedation or another licensed practitioner qualified to administer the same level of sedation must remain on the premises of the dental facility until the patient is evaluated and is discharged.

E. Discharge requirements.

1. The patient shall not be discharged until the responsible licensed practitioner determines that the patient's level of consciousness, oxygenation, ventilation, and circulation are satisfactory for discharge and vital signs have been taken and recorded.

2. Post-operative instructions shall be given verbally and in writing. The written instructions shall include a 24-hour emergency telephone number.

3. The patient shall be discharged with a responsible individual who has been instructed with regard to the patient's care.

F. Emergency management. The dentist shall be proficient in handling emergencies and complications related to pain control procedures, including the maintenance of respiration and circulation, immediate establishment of an airway, and cardiopulmonary resuscitation.

18VAC60-21-300. Requirements for a deep sedation/general anesthesia permit.

A. After March 31, 2013, no dentist may employ or use deep sedation or general anesthesia in a dental office unless he has been issued a permit by the board. The requirement for a permit shall not apply to an oral and maxillofacial surgeon who maintains membership in AAOMS and who provides the board with reports that result from the periodic office examinations required by AAOMS. Such an oral and maxillofacial surgeon shall be required to post a certificate issued by AAOMS.

B. To determine eligibility for a deep sedation/general anesthesia permit, a dentist shall submit the following:

1. A completed application form;

2. The application fee as specified in 18VAC60-21-40;

3. A copy of the certificate of completion of a CODA accredited program or other documentation of training content which meets the educational and training qualifications specified in subsection C of this section; and

4. A copy of current certification in Advanced Cardiac Life Support for Health Professionals (ACLS) or Pediatric Advanced Life Support for Health Professionals (PALS) as required in subsection C of this section.

C. Educational and training qualifications for a deep sedation/general anesthesia permit.

1. Completion of a minimum of one calendar year of advanced training in anesthesiology and related academic subjects beyond the undergraduate dental school level in a training program in conformity with the ADA's Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry in effect at the time the training occurred; or

2. Completion of an CODA accredited residency in any dental specialty that incorporates into its curriculum a minimum of one calendar year of full-time training in clinical anesthesia and related clinical medical subjects (i.e., medical evaluation and management of patients) comparable to those set forth in the ADA's Guidelines for Graduate and Postgraduate Training in Anesthesia in effect at the time the training occurred; and

3. Current certification in advanced resuscitative techniques with hands-on simulated airway and megacode training for health care providers, including basic electrocardiographic interpretations, such as courses in ACLS or PALS; and

4. Current training in the use and maintenance of the equipment required in 18VAC60-21-301.

18VAC60-21-301. Requirements for administration of deep sedation or general anesthesia.

A. Preoperative requirements. Prior to the appointment for treatment under deep sedation or general anesthesia the patient shall:

1. Be informed about the personnel and procedures used to deliver the sedative or anesthetic drugs to assure informed consent as required by 18VAC60-21-260 F.

2. Have a physical evaluation as required by 18VAC60-21-260 C.

3. Be given preoperative verbal and written instructions including any dietary or medication restrictions.

B. Delegation of administration.

1. A dentist who does not meet the requirements of 18VAC60-21-300 shall only use the services of a dentist who does meet those requirements or an anesthesiologist to administer deep sedation or general anesthesia in a dental office. In a licensed outpatient surgery center, a dentist shall use either a dentist who meets the requirements of 18VAC60-21-300, an anesthesiologist, or a certified registered nurse anesthetist to administer deep sedation or general anesthesia.

2. A dentist who meets the requirements of 18VAC60-21-300 may administer or use the services of the following personnel to administer deep sedation or general anesthesia:

a. A dentist with the training required by 18VAC60-21-300 C;

b. An anesthesiologist; or

c. A certified registered nurse anesthetist under the medical direction and indirect supervision of a dentist who meets the training requirements of 18VAC60-21-300 C.

3. Preceding the administration of deep sedation or general anesthesia, a dentist who meets the requirements of 18VAC60-21-300 may use the services of the following personnel under indirect supervision to administer local anesthesia to anesthetize the injection or treatment site:

a. A dental hygienist with the training required by 18VAC60-25-100 C to parenterally administer Schedule VI local anesthesia to persons 18 years of age or older; or

b. A dental hygienist, dental assistant, registered nurse, or licensed practical nurse to administer Schedule VI topical oral anesthetics.

C. Equipment requirements. A dentist who administers deep sedation or general anesthesia shall have available the following equipment in sizes appropriate for the patient being treated and shall maintain it in working order and immediately available to the areas where patients will be sedated and treated and will recover:

1. Full face mask or masks;

2. Oral and nasopharyngeal airway management adjuncts;

3. Endotracheal tubes with appropriate connectors or other appropriate airway management adjunct such as a laryngeal mask airway;

4. A laryngoscope with reserve batteries and bulbs and appropriately sized laryngoscope blades;

5. Source of delivery of oxygen under controlled positive pressure;

6. Mechanical (hand) respiratory bag;

7. Pulse oximetry and blood pressure monitoring equipment available and used in the treatment room;

8. Appropriate emergency drugs for patient resuscitation;

9. EKG monitoring equipment;

10. Temperature measuring devices;

11. Pharmacologic antagonist agents;

12. External defibrillator (manual or automatic);

13. An end-tidal carbon dioxide monitor (capnograph);

14. Suction apparatus;

15. Throat pack; and

16. Precordial or pretracheal stethoscope.

D. Required staffing. At a minimum, there shall be a three-person treatment team for deep sedation or general anesthesia. The team shall include the operating dentist, a second person to monitor the patient as provided in 18VAC60-21-260 K, and a third person to assist the operating dentist as provided in 18VAC60-21-260 J, all of whom shall be in the operatory with the patient during the dental procedure. If a second dentist, an anesthesiologist, or a certified registered nurse anesthetist administers the drugs as permitted in subsection B of this section, such person may serve as the second person to monitor the patient.

E. Monitoring requirements.

1. Baseline vital signs shall be taken and recorded prior to administration of any controlled drug at the facility to include: temperature, blood pressure, pulse, oxygen saturation, and respiration.

2. The patient's vital signs, end-tidal carbon dioxide, and EKG readings shall be monitored, recorded every five minutes, and reported to the treating dentist throughout the administration of controlled drugs. When depolarizing medications are administered, temperature shall be monitored constantly.

3. Monitoring of the patient undergoing deep sedation or general anesthesia is to begin prior to the administration of any drugs and shall take place continuously during administration, the dental procedure, and recovery from anesthesia. The person who administers the anesthesia or another licensed practitioner qualified to administer the same level of anesthesia must remain on the premises of the dental facility until the patient has regained consciousness and is discharged.

F. Emergency management.

1. A secured intravenous line must be established and maintained throughout the procedure.

2. The dentist shall be proficient in handling emergencies and complications related to pain control procedures, including the maintenance of respiration and circulation, immediate establishment of an airway, and cardiopulmonary resuscitation.

G. Discharge requirements.

1. The patient shall not be discharged until the responsible licensed practitioner determines that the patient's level of consciousness, oxygenation, ventilation, and circulation are satisfactory for discharge and vital signs have been taken and recorded.

2. Post-operative instructions shall be given verbally and in writing. The written instructions shall include a 24-hour emergency telephone number for the dental practice.

3. The patient shall be discharged with a responsible individual who has been instructed with regard to the patient's care.

Guideline for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016

Developed and Endorsed by
American Academy of Pediatric Dentistry and American Academy of Pediatrics

Latest Revision*
2016

Abstract

The safe sedation of children for procedures requires a systematic approach that includes the following: no administration of sedating medication without the safety net of medical/dental supervision, careful presedation evaluation for underlying medical or surgical conditions that would place the child at increased risk from sedating medications, appropriate fasting for elective procedures and a balance between the depth of sedation and risk for those who are unable to fast because of the urgent nature of the procedure, a focused airway examination for large (kissing) tonsils or anatomic airway abnormalities that might increase thepotential for airway obstruction, a clear understanding of the medication's pharmacokinetic and pharmacodynamic effects and drug interactions, appropriate training and skills in airway management to allow rescue of the patient, age- and size-appropriate equipment for airway management and venous access, appropriate medications and reversal agents, sufficient numbers of staff to both carry out the procedure and monitor the patient, appropriate physiologic monitoring during and after the procedure, a properly equipped and staffed recovery area, recovery to the presedation level of consciousness before discharge from medical/dental supervision, and appropriate discharge instructions. This report was developed through a collaborative effort of the American Academy of Pediatrics and the American Academy of Pediatric Dentistry to offer pediatric providers updated information and guidance in delivering safe sedation to children.

Introduction

The number of diagnostic and minor surgical procedures performed on pediatric patients outside of the traditional operating room setting has increased in the past several decades. As a consequence of this change and the increased awareness of the importance of providing analgesia and anxiolysis, the need for sedation for procedures in physicians' offices, dental offices, subspecialty procedure suites, imaging facilities, emergency departments, other inpatient hospital settings, and ambulatory surgery centers also has increased markedly.[1–52] In recognition of this need for both elective and emergency use of sedation in nontraditional settings, the American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentistry (AAPD) have published a series of guidelines for the monitoring and management of pediatric patients during and after sedation for a procedure.[53–58] The purpose of this updated report is to unify the guidelines for sedation used by medical and dental practitioners; to add clarifications regarding monitoring modalities, particularly regarding continuous expired carbon dioxide measurement; to provide updated information from the medical and dental literature; and to suggest methods for further improvement in safety and outcomes. This document uses the same language to define sedation categories and expected physiologic responses as The Joint Commission, the American Society of Anesthesiologists (ASA), and the AAPD.[56,57,59–61]

This revised statement reflects the current understanding of appropriate monitoring needs of pediatric patients both during and after sedation for a procedure.[3,4,11,18,20,21,23,24,33,39,41,44,47,51,62–73] The monitoring and care outlined may be exceeded at any time on the basis of the judgment of the responsible practitioner. Although intended to encourage high-quality patient care, adherence to the recommendations in this document cannot guarantee a specific patient outcome. However, structured sedation protocols designed to incorporate these safety

ABBREVIATIONS
AAP: American Academy of Pediatrics. **AAPD:** American Academy of Pediatric Dentistry. **ASA:** American Society of Anesthesiologists. **BIS:** Bispectral index. **CPAP:** Continuous positive airway pressure. **ECG:** Electrocardiography. **EEG:** Electroencephalogram/electroencephalography. **EMS:** Emergency medical services. **LMA:** Laryngeal mask airway. **MRI:** Magnetic resonance imaging. **OSA:** Obstructive sleep apnea. **PALS:** Pediatric advanced life support.

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** This guideline was originally adopted in 2006 and reaffirmed in 2011.*

principles have been widely implemented and shown to reduce morbidity.[11,23,24,27, 30-33,35,39,41,44,47,51,74-84] These practice recommendations are proffered with the awareness that, regardless of the intended level of sedation or route of drug administration, the sedation of a pediatric patient represents a continuum and may result in respiratory depression, laryngospasm, impaired airway patency, apnea, loss of the patient's protective airway reflexes, and cardiovascular instability.[38,43,45,47,48,59,62,63,85-112]

Procedural sedation of pediatric patients has serious associated risks.[2,5,38,43,45,47,48,62,63,71,83,85,88-105, 107-138] These adverse responses during and after sedation for a diagnostic or therapeutic procedure may be minimized, but not completely eliminated, by a careful preprocedure review of the patient's underlying medical conditions and consideration of how the sedation process might affect or be affected by these conditions: for example, children with developmental disabilities have been shown to have a threefold increased incidence of desaturation compared with children without developmental disabilities.[74,78,103] Appropriate drug selection for the intended procedure, a clear understanding of the sedating medication's pharmacokinetics and pharmacodynamics and drug interactions, as well as the presence of an individual with the skills needed to rescue a patient from an adverse response are critical.[42, 48,62,63,92,97,99,125-127, 132,133,139-158] Appropriate physiologic monitoring and continuous observation by personnel not directly involved with the procedure allow for the accurate and rapid diagnosis of complications and initiation of appropriate rescue interventions.[44,63, 64,67,68,74,90,96,110,159-174] The work of the Pediatric Sedation Research Consortium has improved the sedation knowledge base, demon-strating the marked safety of sedation by highly motivated and skilled practitioners from a variety of specialties practicing the above modalities and skills that focus on a culture of sedation safety.[45,83,95,128-138] However, these groundbreaking studies also show a low but persistent rate of potential sedation-induced life-threatening events, such as apnea, airway obstruction, laryngospasm, pulmonary aspiration, desaturation, and others, even when the sedation is provided under the direction of a motivated team of specialists.[129] These studies have helped define the skills needed to rescue children experiencing adverse sedation events.

The sedation of children is different from the sedation of adults. Sedation in children is often administered to relieve pain and anxiety as well as to modify behavior (e.g., immobility) so as to allow the safe completion of a procedure. A child's ability to control his or her own behavior to cooperate for a procedure depends both on his or her chronologic age and cognitive/ emotional development. Many brief procedures, such as suture of a minor laceration, may be accomplished with distraction and guided imagery techniques, along with the use of topical/local anesthetics and minimal sedation, if needed.[175-181] However, longer procedures that require immobility involving children younger than 6 years or those with developmental delay often require an increased depth of sedation to gain control of their behavior.[86,87,103] Children younger than 6 years (particularly those younger than 6 months) may be at greatest risk of an adverse event.[129] Children in this age group are particularly vulnerable to the sedating medication's effects on respiratory drive, airway patency, and protective airway reflexes.[62,63] Other modalities, such as careful preparation, parental presence, hypnosis, distraction, topical local anesthetics, electronic devices with age-appropriate games or videos, guided imagery, and the techniques advised by child life specialists, may reduce the need for or the needed depth of pharmacologic sedation.[29,46,49,182-211]

Studies have shown that it is common for children to pass from the intended level of sedation to a deeper, unintended level of sedation,[85,88,212,213] making the concept of rescue essential to safe sedation. Practitioners of sedation must have the skills to rescue the patient from a deeper level than that intended for the procedure. For example, if the intended level of sedation is "minimal," practitioners must be able to rescue from "moderate sedation"; if the intended level of sedation is "moderate," practitioners must have the skills to rescue from "deep sedation"; if the intended level of sedation is "deep," practitioners must have the skills to rescue from a state of "general anesthesia." The ability to rescue means that practitioners must be able to recognize the various levels of sedation and have the skills and age- and size-appropriate equipment necessary to provide appropriate cardiopulmonary support if needed.

These guidelines are intended for all venues in which sedation for a procedure might be performed (hospital, surgical center, freestanding imaging facility, dental facility, or private office). Sedation and anesthesia in a nonhospital environment (e.g., private physician's or dental office, freestanding imaging facility) historically have been associated with an increased incidence of "failure to rescue" from adverse events, because these settings may lack immediately available backup. Immediate activation of emergency medical services (EMS) may be required in such settings, but the practitioner is responsible for life-support measures while awaiting EMS arrival.[63,214] Rescue techniques require specific training and skills.[63,74,215,216] The maintenance of the skills needed to rescue a child with apnea, laryngospasm, and/or airway obstruction include the ability to open the airway, suction secretions, provide continuous positive airway pressure (CPAP), perform successful bag-valve-mask ventilation, insert an oral airway, a nasopharyngeal airway, or a laryngeal mask airway (LMA), and, rarely, perform tracheal intubation. These skills are likely best maintained with frequent simulation and team training for the management of rare events.[128,130,217-220] Competency with emergency airway management procedure algorithms is fundamental for safe sedation practice and successful patient rescue (see Figs. 1, 2, and 3).[215,216,221-223]

Practitioners should have an in-depth knowledge of the agents they intend to use and their potential complications. A number of reviews and handbooks for sedating pediatric patients are available.[30,39,65,75,171,172,201,224-233] There are specific situations that are beyond the scope of this document. Specifically, guidelines for the delivery of general anesthesia and

monitored anesthesia care (sedation or analgesia), outside or within the operating room by anesthesiologists or other practitioners functioning within a department of anesthesiology, are addressed by policies developed by the ASA and by individual departments of anesthesiology.[234] In addition, guidelines for the sedation of patients undergoing mechanical ventilation in a critical care environment or for providing analgesia for patients postoperatively, patients with chronic painful conditions, and patients in hospice care are beyond the scope of this document.

Goals of Sedation

The goals of sedation in the pediatric patient for diagnostic and therapeutic procedures are as follows: (1) to guard the patient's safety and welfare; (2) to minimize physical discomfort and pain; (3) to control anxiety, minimize psychological trauma, and maximize the potential for amnesia; (4) to modify behavior and/or movement so as to allow the safe completion of the procedure; and (5) to return the patient to a state in which discharge from medical/dental supervision is safe, as determined by recognized criteria (Supplemental Appendix 1).

These goals can best be achieved by selecting the lowest dose of drug with the highest therapeutic index for the procedure. It is beyond the scope of this document to specify which drugs are appropriate for which procedures; however, the selection of the fewest number of drugs and matching

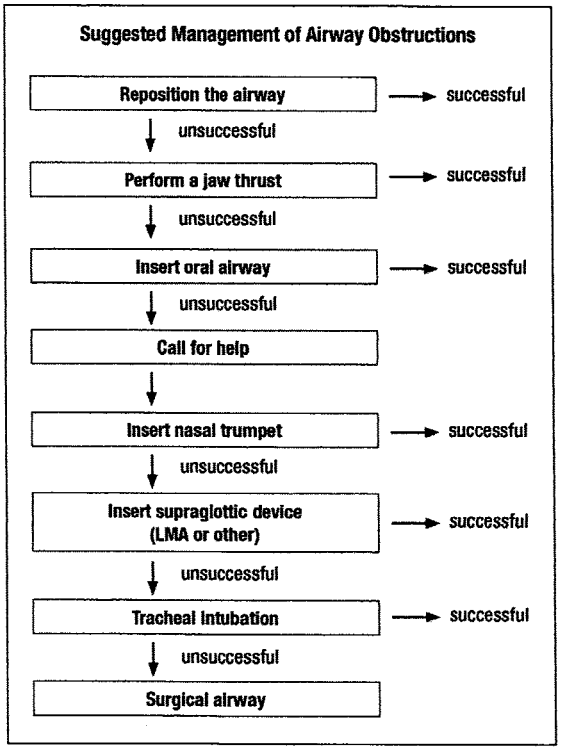

Figure 1. Suggested management of airway obstruction.

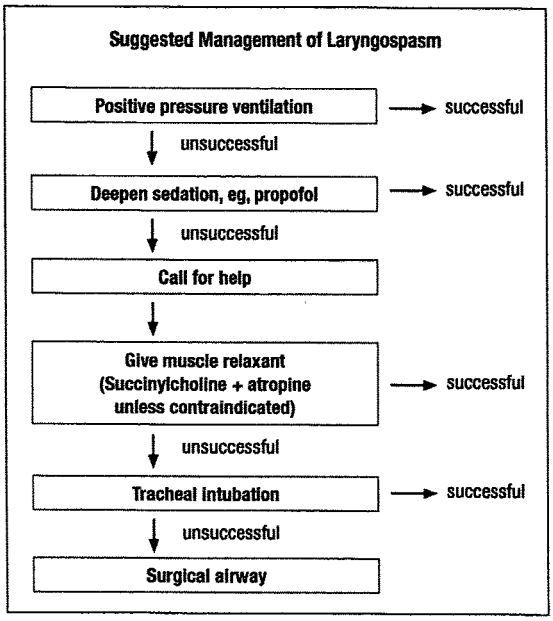

Figure 2. Suggested management of laryngospasm.

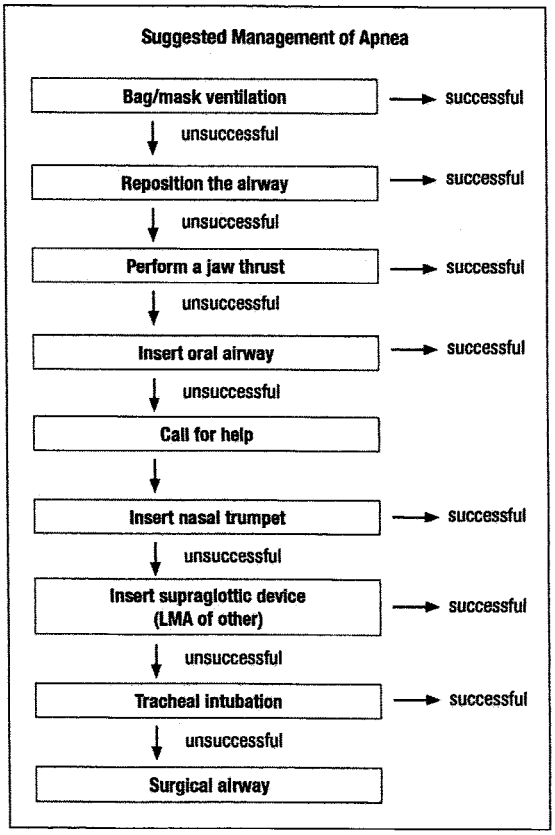

Figure 3. Suggested management of apnea.

drug selection to the type and goals of the procedure are essential for safe practice. For example, analgesic medications, such as opioids or ketamine, are indicated for painful procedures. For nonpainful procedures, such as computed tomography or MRI, sedatives/hypnotics are preferred. When both sedation and analgesia are desirable (e.g., fracture reduction), either single agents with analgesic/sedative properties or combination regimens are commonly used. Anxiolysis and amnesia are additional goals that should be considered in the selection of agents for particular patients. However, the potential for an adverse outcome may be increased when 2 or more sedating medications are administered.[62,127,136,173,235] Recently, there has been renewed interest in noninvasive routes of medication administration, including intranasal and inhaled routes (e.g., nitrous oxide; see below).[236]

Knowledge of each drug's time of onset, peak response, and duration of action is important (e.g., the peak EEG effect of intravenous midazolam occurs at ~ 4.8 minutes, compared with that of diazepam at ~ 1.6 minutes[237–239]). Titration of drug to effect is an important concept; one must know whether the previous dose has taken full effect before administering additional drugs.[237] Drugs that have a long duration of action (e.g., intramuscular pentobarbital, phenothiazines) have fallen out of favor because of unpredictable responses and prolonged recovery. The use of these drugs requires a longer period of observation even after the child achieves currently used recovery and discharge criteria.[62,238–241] This concept is particularly important for infants and toddlers transported in car safety seats; re-sedation after discharge attributable to residual prolonged drug effects may lead to airway obstruction.[62,63,242] In particular, promethazine (Phenergan; Wyeth Pharmaceuticals, Philadelphia, PA) has a "black box warning" regarding fatal respiratory depression in children younger than 2 years.[243] Although the liquid formulation of chloral hydrate is no longer commercially available, some hospital pharmacies now are compounding their own formulations. Low-dose chloral hydrate (10–25 mg/kg), in combination with other sedating medications, is used commonly in pediatric dental practice.

General Guidelines

Candidates

Patients who are in ASA classes I and II are frequently considered appropriate candidates for minimal, moderate, or deep sedation (Supplemental Appendix 2). Children in ASA classes III and IV, children with special needs, and those with anatomic airway abnormalities or moderate to severe tonsillar hypertrophy present issues that require additional and individual consideration, particularly for moderate and deep sedation.[68,244–249] Practitioners are encouraged to consult with appropriate subspecialists and/ or an anesthesiologist for patients at increased risk of experiencing adverse sedation events because of their underlying medical/surgical conditions.

Responsible person

The pediatric patient shall be accompanied to and from the treatment facility by a parent, legal guardian, or other responsible person. It is preferable to have 2 adults accompany children who are still in car safety seats if transportation to and from a treatment facility is provided by 1 of the adults.[250]

Facilities

The practitioner who uses sedation must have immediately available facilities, personnel, and equipment to manage emergency and rescue situations. The most common serious complications of sedation involve compromise of the airway or depressed respirations resulting in airway obstruction, hypoventilation, laryngospasm, hypoxemia, and apnea. Hypotension and cardiopulmonary arrest may occur, usually from the inadequate recognition and treatment of respiratory compromise.[42,48,92,97,99,125,132,139–155] Other rare complications also may include seizures, vomiting, and allergic reactions. Facilities providing pediatric sedation should monitor for, and be prepared to treat, such complications.

Back-up emergency services

A protocol for immediate access to back-up emergency services shall be clearly outlined. For nonhospital facilities, a protocol for the immediate activation of the EMS system for life-threatening complications must be established and maintained.[44] It should be understood that the availability of EMS does not replace the practitioner's responsibility to provide initial rescue for life-threatening complications.

On-site monitoring, rescue drugs, and equipment

An emergency cart or kit must be immediately accessible. This cart or kit must contain the necessary age-and size-appropriate equipment (oral and nasal airways, bag-valve-mask device, LMAs or other supraglottic devices, laryngoscope blades, tracheal tubes, face masks, blood pressure cuffs, intravenous catheters, etc) to resuscitate a nonbreathing and unconscious child. The contents of the kit must allow for the provision of continuous life support while the patient is being transported to a medical/dental facility or to another area within the facility. All equipment and drugs must be checked and maintained on a scheduled basis (see Supplemental Appendices 3 and 4 for suggested drugs and emergency life support equipment to consider before the need for rescue occurs). Monitoring devices, such as electrocardiography (ECG) machines, pulse oximeters with size-appropriate probes, end-tidal carbon dioxide monitors, and defibrillators with size-appropriate patches/ paddles, must have a safety and function check on a regular basis as required by local or state regulation. The use of emergency checklists is recommended, and these should be immediately available at all sedation locations; they can be obtained from *http://www.pedsanesthesia.org/*.

Documentation

Documentation prior to sedation shall include, but not be limited to, the following recommendations:

1. Informed consent: The patient record shall document that appropriate informed consent was obtained according to local, state, and institutional requirements.[251,252]
2. Instructions and information provided to the responsible person: The practitioner shall provide verbal and/or written instructions to the responsible person. Information shall include objectives of the sedation and anticipated changes in behavior during and after sedation.[163,253–255] Special instructions shall be given to the adult responsible for infants and toddlers who will be transported home in a car safety seat regarding the need to carefully observe the child's head position to avoid airway obstruction. Transportation in a car safety seat poses a particular risk for infants who have received medications known to have a long half-life, such as chloral hydrate, intramuscular pentobarbital, or phenothiazine because deaths after procedural sedation have been reported.[62,63,238,242,256,257] Consideration for a longer period of observation shall be given if the responsible person's ability to observe the child is limited (e.g., only 1 adult who also has to drive). Another indication for prolonged observation would be a child with an anatomic airway problem, an underlying medical condition such as significant obstructive sleep apnea (**OSA**), or a former preterm infant younger than 60 weeks' postconceptional age. A 24-hour telephone number for the practitioner or his or her associates shall be provided to all patients and their families. Instructions shall include limitations of activities and appropriate dietary precautions.

Table 1. APPROPRIATE INTAKE OF FOOD AND LIQUIDS BEFORE ELECTIVE SEDATION

Ingested material	Minimum fasting period (h)
Clear liquids: water, fruit juices without pulp, carbonated beverages, clear tea, black coffee	2
Human milk	4
Infant formula	6
Nonhuman milk: because nonhuman milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period	6
Light meal: a light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.	6

Source: American Society of Anesthesiologists. Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures. An updated report by the American Society of Anesthesiologists Committee on Standards and Practice Parameters. Available at: "https://www.asahq.org/For-Members/Practice-Management/Practice-Parameters.aspx". For emergent sedation, the practitioner must balance the depth of sedation versus the risk of possible aspiration; see also Mace et al.[272] and Green et al.[273]

Dietary precautions

Agents used for sedation have the potential to impair protective airway reflexes, particularly during deep sedation. Although a rare occurrence, pulmonary aspiration may occur if the child regurgitates and cannot protect his or her airway.[95,127,258] Therefore, the practitioner should evaluate preceding food and fluid intake before administering sedation. It is likely that the risk of aspiration during procedural sedation differs from that during general anesthesia involving tracheal intubation or other airway manipulations.[259,260] However, the absolute risk of aspiration during elective procedural sedation is not yet known; the reported incidence varies from ~1 in 825 to ~1 in 30037.[95,127,129,173,244,261] Therefore, standard practice for fasting before elective sedation generally follows the same guidelines as for elective general anesthesia; this requirement is particularly important for solids, because aspiration of clear gastric contents causes less pulmonary injury than aspiration of particulate gastric contents.[262,263]

For emergency procedures in children undergoing general anesthesia, the reported incidence of pulmonary aspiration of gastric contents from 1 institution is ~ 1 in 373 compared with ~ 1 in 4544 for elective anesthetics.[262] Because there are few published studies with adequate statistical power to provide guidance to the practitioner regarding the safety or risk of pulmonary aspiration of gastric contents during procedural sedation,[95,127,129,173,244,259-261,264-268] it is unknown whether the risk of aspiration is reduced when airway manipulation is not performed/ anticipated (e.g., moderate sedation). However, if a deeply sedated child requires intervention for airway obstruction, apnea, or laryngospasm, there is concern that these rescue maneuvers could increase the risk of pulmonary aspiration of gastric contents. For children requiring urgent/emergent sedation who do not meet elective fasting guidelines, the risks of sedation and possible aspiration are as-yet unknown and must be balanced against the benefits of performing the procedure promptly. For example, a prudent practitioner would be unlikely to administer deep sedation to a child with a minor condition who just ate a large meal; conversely, it is not justifiable to withhold sedation/analgesia from the child in significant pain from a displaced fracture who had a small snack a few hours earlier. Several emergency department studies have reported a low to zero incidence of pulmonary aspiration despite variable fasting periods[260,264,268]; however, each of these reports have, for the most part, clearly balanced the urgency of the procedure with the need for and depth of sedation.[268,269] Although emergency medicine studies and practice guidelines generally support a less restrictive approach to fasting for brief urgent/ emergent procedures, such as care of wounds, joint dislocation, chest tube placement, etc, in healthy children, further research in many thousands of patients would be desirable to better define the relationships between various fasting intervals and sedation complications.[262–270]

Before elective sedation

Children undergoing sedation for elective procedures generally should follow the same fasting guidelines as those for general anesthesia (Table 1).[271] It is permissible for routine necessary medications (e.g., antiseizure medications) to be taken with a sip of clear liquid or water on the day of the procedure.

For the emergency patient

The practitioner must always balance the possible risks of sedating nonfasted patients with the benefits of and necessity for completing the procedure. In particular, patients with a history of recent oral intake or with other known risk factors, such as trauma, decreased level of consciousness, extreme obesity (BMI ≥95% for age and sex), pregnancy, or bowel motility dysfunction, require careful evaluation before the administration of sedatives. When proper fasting has not been ensured, the increased risks of sedation must be carefully weighed against its benefits, and the lightest effective sedation should be used. In this circumstance, additional techniques for achieving analgesia and patient cooperation, such as distraction, guided imagery, video games, topical and local anesthetics, hematoma block or nerve blocks, and other techniques advised by child life specialists, are particularly helpful and should be considered.[29,49,182–201,274,275] The use of agents with less risk of depressing protective airway reflexes, such as ketamine, or moderate sedation, which would also maintain protective reflexes, may be preferred.[276] Some emergency patients requiring deep sedation (e.g., a trauma patient who just ate a full meal or a child with a bowel obstruction) may need to be intubated to protect their airway before they can be sedated.

Use of immobilization devices (protective stabilization)

Immobilization devices, such as papoose boards, must be applied in such a way as to avoid airway obstruction or chest restriction.[277–281] The child's head position and respiratory excursions should be checked frequently to ensure airway patency. If an immobilization device is used, a hand or foot should be kept exposed, and the child should never be left unattended. If sedating medications are administered in conjunction with an immobilization device, monitoring must be used at a level consistent with the level of sedation achieved.

Documentation at the time of sedation

1. Health evaluation: Before sedation, a health evaluation shall be performed by an appropriately licensed practitioner and reviewed by the sedation team at the time of treatment for possible interval changes.[282] The purpose of this evaluation is not only to document baseline status but also to determine whether the patient has specific risk factors that may warrant additional consultation before sedation. This evaluation also facilitates the identification of patients who will require more advanced airway or cardiovascular management skills or alterations in the doses or types of medications used for procedural sedation.

An important concern for the practitioner is the widespread use of medications that may interfere with drug absorption or metabolism and therefore enhance or shorten the effect time of sedating medications. Herbal medicines (e.g., St. John's wort, ginkgo, ginger, ginseng, garlic) may alter drug pharmacokinetics through inhibition of the cytochrome P450 system, resulting in prolonged drug effect and altered (increased or decreased) blood drug concentrations (midazolam, cyclosporine, tacrolimus).[283–292] Kava may increase the effects of sedatives by potentiating γ-aminobutyric acid inhibitory neurotransmission and may increase acetaminophen-induced liver toxicity.[293–295] Valerian may itself produce sedation that apparently is mediated through the modulation of γ-aminobutyric acid neurotransmission and receptor function.[291,296–299] Drugs such as erythromycin, cimetidine, and others may also inhibit the cytochrome P450 system, resulting in prolonged sedation with midazolam as well as other medications competing for the same enzyme systems.[300–304] Medications used to treat HIV infection, some anticonvulsants, immunosuppressive drugs, and some psychotropic medications (often used to treat children with autism spectrum disorder) may also produce clinically important drug-drug interactions.[305–314] Therefore, a careful drug history is a vital part of the safe sedation of children. The practitioner should consult various sources (a pharmacist, textbooks, online services, or handheld databases) for specific information on drug interactions.[315–319] The U.S. Food and Drug Administration issued a warning in February 2013 regarding the use of codeine for postoperative pain management in children undergoing tonsillectomy, particularly those with OSA. The safety issue is that some children have duplicated cytochromes that allow greater than expected conversion of the prodrug codeine to morphine, thus resulting in potential overdose; codeine should be avoided for postprocedure analgesia.[320–324]

The health evaluation should include the following:

- Age and weight (in kg) and gestational age at birth (preterm infants may have associated sequelae such as apnea of prematurity); and
- Health history, including (1) food and medication allergies and previous allergic or adverse drug reactions; (2) medication/drug history, including dosage, time, route, and site of administration for prescription, over-the-counter, herbal, or illicit drugs; (3) relevant diseases, physical abnormalities (including genetic syndromes), neurologic impairments that might increase the potential for airway obstruction, obesity, a history of snoring or OSA,[325–328] or cervical spine instability in Down syndrome, Marfan syndrome, skeletal dysplasia, and other conditions; (4) pregnancy status (as many as 1% of menarchal females presenting for general anesthesia at children's hospitals are pregnant)[329–331] because of concerns for the potential adverse effects of most sedating and

anesthetic drugs on the fetus[329,332–338]; (5) history of prematurity (may be associated with subglottic stenosis or propensity to apnea after sedation); (6) history of any seizure disorder; (7) summary of previous relevant hospitalizations; (8) history of sedation or general anesthesia and any complications or unexpected responses; and (9) relevant family history, particularly related to anesthesia (e.g., muscular dystrophy, malignant hyperthermia, pseudocholinesterase deficiency).

The review of systems should focus on abnormalities of cardiac, pulmonary, renal, or hepatic function that might alter the child's expected responses to sedating/analgesic medications. A specific query regarding signs and symptoms of sleep-disordered breathing and OSA may be helpful. Children with severe OSA who have experienced repeated episodes of desaturation will likely have altered mu receptors and be analgesic at opioid levels one-third to one-half those of a child without OSA[325–328,339,340]; lower titrated doses of opioids should be used in this population. Such a detailed history will help to determine which patients may benefit from a higher level of care by an appropriately skilled health care provider, such as an anesthesiologist. The health evaluation should also include:

- Vital signs, including heart rate, blood pressure, respiratory rate, room air oxygen saturation, and temperature (for some children who are very upset or noncooperative, this may not be possible and a note should be written to document this circumstance);
- Physical examination, including a focused evaluation of the airway (tonsillar hypertrophy, abnormal anatomy [e.g., mandibular hypoplasia], high Mallampati score [i.e., ability to visualize only the hard palate or tip of the uvula]) to determine whether there is an increased risk of airway obstruction[74,341–344];
- Physical status evaluation (ASA classification [see Appendix 2]); and
- Name, address, and telephone number of the child's home or parent's, or caregiver's cell phone; additional information such as the patient's personal care provider or medical home is also encouraged.

For hospitalized patients, the current hospital record may suffice for adequate documentation of presedation health; however, a note shall be written documenting that the chart was reviewed, positive findings were noted, and a management plan was formulated. If the clinical or emergency condition of the patient precludes acquiring complete information before sedation, this health evaluation should be obtained as soon as feasible.

2. Prescriptions. When prescriptions are used for sedation, a copy of the prescription or a note describing the content of the prescription should be in the patient's chart along with a description of the instructions that were given to the responsible person. Prescription medications intended to accomplish procedural sedation must not be administered without the safety net of direct supervision by trained medical/dental personnel. The administration of sedating medications at home poses an unacceptable risk, particularly for infants and preschool-aged children traveling in car safety seats because deaths as a result of this practice have been reported.[63,257]

Documentation during treatment

The patient's chart shall contain a time-based record that includes the name, route, site, time, dosage/ kilogram, and patient effect of administered drugs. Before sedation, a "time out" should be performed to confirm the patient's name, procedure to be performed, and laterality and site of the procedure.[59] During administration, the inspired concentrations of oxygen and inhalation sedation agents and the duration of their administration shall be documented. Before drug administration, special attention must be paid to the calculation of dosage (i.e., mg/kg); for obese patients, most drug doses should likely be adjusted lower to ideal body weight rather than actual weight.[345] When a programmable pump is used for the infusion of sedating medications, the dose/kilogram per minute or hour and the child's weight in kilograms should be double-checked and confirmed by a separate individual. The patient's chart shall contain documentation at the time of treatment that the patient's level of consciousness and responsiveness, heart rate, blood pressure, respiratory rate, expired carbon dioxide values, and oxygen saturation were monitored. Standard vital signs should be further documented at appropriate intervals during recovery until the patient attains predetermined discharge criteria (Appendix 1). A variety of sedation scoring systems are available that may aid this process.[212,238 346–348] Adverse events and their treatment shall be documented.

Documentation after treatment

A dedicated and properly equipped recovery area is recommended (see Appendices 3 and 4). The time and condition of the child at discharge from the treatment area or facility shall be documented, which should include documentation that the child's level of consciousness and oxygen saturation in room air have returned to a state that is safe for discharge by recognized criteria (see Appendix 1). Patients receiving supplemental oxygen before the procedure should have a similar oxygen need after the procedure. Because some sedation medications are known to have a long half-life and may delay a patient's complete return to baseline or pose the risk of re-sedation[62,104,256, 349,350] and because some patients will have complex multiorgan medical conditions, a longer period of observation in a less intense observation area (e.g., a step-down observation area) before discharge from medical/dental supervision may be indicated.[239] Several scales to evaluate recovery have been devised and validated.[212, 346–348, 351, 352] A simple evaluation tool may be the ability of the infant or child to remain awake for at least 20 minutes when placed in a quiet environment.[238]

Continuous quality improvement

The essence of medical error reduction is a careful examination of index events and root-cause analysis of how the event could be avoided in the future.[353–359] Therefore, each facility should maintain records that track all adverse events and significant interventions, such as desaturation; apnea; laryngospasm; need for airway interventions, including the need for placement of supraglottic devices such as an oral airway, nasal trumpet, or LMA; positive-pressure ventilation; prolonged sedation; unanticipated use of reversal agents; unplanned or prolonged hospital admission; sedation failures; inability to complete the procedure; and unsatisfactory sedation, analgesia, or anxiolysis.[360] Such events can then be examined for the assessment of risk reduction and improvement in patient/family satisfaction.

Preparation for sedation procedures

Part of the safety net of sedation is using a systematic approach so as to not overlook having an important drug, piece of equipment, or monitor immediately available at the time of a developing emergency. To avoid this problem, it is helpful to use an acronym that allows the same setup and checklist for every procedure. A commonly used acronym useful in planning and preparation for a procedure is **SOAPME**, which represents the following:

- **S** = Size-appropriate suction catheters and a functioning suction apparatus (e.g., Yankauer-type suction).
- **O** = an adequate Oxygen supply and functioning flow meters or other devices to allow its delivery.
- **A** = size-appropriate Airway equipment (e.g., bag-valve-mask or equivalent device [functioning]), nasopharyngeal and oropharyngeal airways, LMA, laryngoscope blades (checked and functioning), endotracheal tubes, stylets, face mask.
- **P** = Pharmacy: all the basic drugs needed to support life during an emergency, including antagonists as indicated.
- **M** = Monitors: functioning pulse oximeter with size-appropriate oximeter probes,[361,362] end-tidal carbon dioxide monitor, and other monitors as appropriate for the procedure (e.g., noninvasive blood pressure, ECG, stethoscope).
- **E** = special Equipment or drugs for a particular case (e.g., defibrillator).

Specific guidelines for intended level of sedation

Minimal sedation

Minimal sedation (old terminology, "anxiolysis") is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. Children who have received minimal sedation generally will not require more than observation and intermittent assessment of their level of sedation. Some children will become moderately sedated despite the intended level of minimal sedation; should this occur, then the guidelines for moderate sedation apply.[85,363]

Moderate sedation

Moderate sedation (old terminology, "conscious sedation" or "sedation/analgesia") is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands or after light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. The caveat that loss of consciousness should be unlikely is a particularly important aspect of the definition of moderate sedation; drugs and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Because the patient who receives moderate sedation may progress into a state of deep sedation and obtundation, the practitioner should be prepared to increase the level of vigilance corresponding to what is necessary for deep sedation.[85]

Personnel

The practitioner. The practitioner responsible for the treatment of the patient and/or the administration of drugs for sedation must be competent to use such techniques, to provide the level of monitoring described in these guidelines, and to manage complications of these techniques (i.e., to be able to rescue the patient). Because the level of intended sedation may be exceeded, the practitioner must be sufficiently skilled to rescue a child with apnea, laryngospasm, and/or airway obstruction, including the ability to open the airway, suction secretions, provide CPAP, and perform successful bag-valve-mask ventilation should the child progress to a level of deep sedation. Training in, and maintenance of, advanced pediatric airway skills is required (e.g., pediatric advanced life support [PALS]); regular skills reinforcement with simulation is strongly encouraged.[79,80,128,130,217–220,364]

Support personnel. The use of moderate sedation shall include the provision of a person, in addition to the practitioner, whose responsibility is to monitor appropriate physiologic parameters and to assist in any supportive or resuscitation measures, if required. This individual may also be responsible for assisting with interruptible patient-related tasks of short duration, such as holding an instrument or troubleshooting equipment.[60] This individual should be trained in and capable of providing advanced airway skills (e.g., PALS). The support person shall have specific assignments in the event of an emergency and current knowledge of the emergency cart inventory. The practitioner and all ancillary personnel should participate in periodic reviews, simulation of rare emergencies, and practice drills of the facility's emergency protocol to ensure proper function of the equipment and coordination of staff roles in such emergencies.[133,365–367] It is recommended that at least 1 practitioner be skilled in obtaining vascular access in children.

Monitoring and documentation

Baseline. Before the administration of sedative medications, a baseline determination of vital signs shall be documented. For some children who are very upset or uncooperative, this may

not be possible, and a note should be written to document this circumstance.

During the procedure. The physician/dentist or his or her designee shall document the name, route, site, time of administration, and dosage of all drugs administered. If sedation is being directed by a physician who is not personally administering the medications, then recommended practice is for the qualified health care provider administering the medication to confirm the dose verbally before administration. There shall be continuous monitoring of oxygen saturation and heart rate; when bidirectional verbal communication between the provider and patient is appropriate and possible (i.e., patient is developmentally able and purposefully communicates), monitoring of ventilation by (1) capnography (preferred) or (2) amplified, audible pretracheal stethoscope (e.g., Bluetooth™ technology)[368-371] or precordial stethoscope is strongly recommended. If bi-directional verbal communication is not appropriate or not possible, monitoring of ventilation by capnography (preferred), amplified, audible pretracheal stethoscope, or precordial stethoscope is required. Heart rate, respiratory rate, blood pressure, oxygen saturation, and expired carbon dioxide values should be recorded, at minimum, every 10 minutes in a time-based record. Note that the exact value of expired carbon dioxide is less important than simple assessment of continuous respiratory gas exchange. In some situations in which there is excessive patient agitation or lack of cooperation or during certain procedures such as bronchoscopy, dentistry, or repair of facial lacerations capnography may not be feasible, and this situation should be documented. For uncooperative children, it is often helpful to defer the initiation of capnography until the child becomes sedated. Similarly, the stimulation of blood pressure cuff inflation may cause arousal or agitation; in such cases, blood pressure monitoring may be counterproductive and may be documented at less frequent intervals (e.g., 10-15 minutes, assuming the patient remains stable, well oxygenated, and well perfused). Immobilization devices (protective stabilization) should be checked to prevent airway obstruction or chest restriction. If a restraint device is used, a hand or foot should

Table 2. COMPARISON OF MODERATE AND DEEP SEDATION EQUIPMENT AND PERSONNEL REQUIREMENTS

	Moderate sedation	Deep sedation
Personnel	An observer who will monitor the patient but who may also assist with interruptible tasks; should be trained in PALS	An independent observer whose only responsibility is to continuously monitor the patient; trained in PALS
Responsible practitioner	Skilled to rescue a child with apnea, laryngospasm, and/or airway obstruction including the ability to open the airway, suction secretions, provide CPAP, and perform successful bag-valve-mask ventilation; recommended that at least 1 practitioner should be skilled in obtaining vascular access in children; trained in PALS	Skilled to rescue a child with apnea, laryngspasm, and/or airway obstruction, including the ability to open the airway, suction secretions, provide CPAP, perform successful bag-valve-mask ventilation, tracheal intubation, and cardiopulmonary resuscitation; training in PALS is required; at least 1 practitioner skilled in obtaining vascular access in children immediately available
Monitoring	Pulse oximetry ECG recommended Heart rate Blood pressure Respiration Capnography recommended	Pulse oximetry ECG required Heart rate Blood pressure Respiration Capnography required
Other equipment	Suction equipment, adequate oxygen source/supply	Suction equipment, adequate oxygen source/supply, defibrillator required
Documentation	Name, route, site, time of administration, and dosage of all drugs administered Continuous oxygen saturation, heart rate, and ventilation (capnography recommended); parameters recorded every 10 minutes	Name, route, site, time of administration, and dosage of all drugs administered; continuous oxygen saturation, heart rate, and ventilation (capnography required); parameters recorded at least every 5 minutes
Emergency checklists	Recommended	Recommended
Rescue cart properly stocked with rescue drugs and age- and size-appropriate equipment (see Appendices 3 and 4)	Required	Required
Dedicated recovery area with rescue cart properly stocked with rescue drugs and age- and size-appropriate equipment (see Appendices 3 and 4) and dedicated recovery personnel; adequate oxygen supply	Recommended; initial recording of vital signs may be needed at least every 10 minutes until the child begins to awaken, then recording intervals may be increased	Recommended; initial recording of vital signs may be needed for at least 5-minute intervals until the child begins to awaken, then recording intervals may be increased to 10–15 minutes
Discharge criteria	See Appendix 1	See Appendix 1

be kept exposed. The child's head position should be continuously assessed to ensure airway patency.

After the procedure. The child who has received moderate sedation must be observed in a suitably equipped recovery area, which must have a functioning suction apparatus as well as the capacity to deliver >90% oxygen and positive-pressure ventilation (bag-valve mask) with an adequate oxygen capacity as well as age- and size-appropriate rescue equipment and devices. The patient's vital signs should be recorded at specific intervals (e.g., every 10–15 minutes). If the patient is not fully alert, oxygen saturation and heart rate monitoring shall be used continuously until appropriate discharge criteria are met (see Appendix 1). Because sedation medications with a long half-life may delay the patient's complete return to baseline or pose the risk of re-sedation, some patients might benefit from a longer period of less intense observation (e.g., a step-down observation area where multiple patients can be observed simultaneously) before discharge from medical/dental supervision (see section entitled "Documentation Before Sedation" above).[62,256,349,350] A simple evaluation tool may be the ability of the infant or child to remain awake for at least 20 minutes when placed in a quiet environment.[238] Patients who have received reversal agents, such as flumazenil or naloxone, will require a longer period of observation, because the duration of the drugs administered may exceed the duration of the antagonist, resulting in re-sedation.

Deep sedation/General anesthesia

"Deep sedation" ("deep sedation/ analgesia") is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated verbal or painful stimulation (e.g., purposefully pushing away the noxious stimuli). Reflex withdrawal from a painful stimulus is not considered a purposeful response and is more consistent with a state of general anesthesia. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. A state of deep sedation may be accompanied by partial or complete loss of protective airway reflexes. Patients may pass from a state of deep sedation to the state of general anesthesia. In some situations, such as during MRI, one is not usually able to assess responses to stimulation, because this would defeat the purpose of sedation, and one should assume that such patients are deeply sedated.

"General anesthesia" is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive-pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Table 3. COMMONLY USED LOCAL ANESTHETIC AGENTS FOR NERVE BLOCK OR INFILTRATION: DOSES, DURATION, AND CALCULATIONS

Local anesthetic	Maximum dose with Epinephrine [a] (mg/kg)		Maximum dose without Epinephrine (mg/kg)		Duration of action [b] (min)
	Medical	Dental	Medical	Dental	
Esters					
Procaine	10.0	6	7	6	60-90
Chloroprocaine	20.0	12	15	12	30-60
Tetracaine	1.5	1	1	1	180-600
Amides					
Lidocaine	7.0	4.4	4	4.4	90-200
Mepivacaine	7.0	4.4	5	4.4	120-240
Bupivacaine	3.0	1.3	2.5	1.3	180-600
Levobupivacaine [c]	3.0	2	2	2	180-600
Ropivacaine	3.0	2	2	2	180-600
Articaine [d]	—	7	—	7	60-230

Maximum recommended doses and durations of action are shown. Note that lower doses should be used in very vascular areas.

[a] These are maximum doses of local anesthetics combined with epinephrine; lower doses are recommended when used without epinephrine. Doses of amides should be decreased by 30% in infants younger than 6 mo. When lidocaine is being administered intravascularly (e.g., during intravenous regional anesthesia), the dose should be decreased to 3 to 5 mg/kg; long-acting local anesthetic agents should not be used for intravenous regional anesthesia.

[b] Duration of action is dependent on concentration, total dose, and site of administration; use of epinephrine; and the patient's age.

[c] Levobupivacaine is not available in the United States.

[d] Use in pediatric patients under 4 years of age is not recommended.

Table 4. LOCAL ANESTHETIC CONVERSION CHART

Concentration (%)	mg/mL
4.0	40
3.0	30
2.5	25
2.0	20
1.0	10
0.5	5
0.25	2.5
0.125	1.25

Table 5. TREATMENT OF LOCAL ANESTHETIC TOXICITY

1. Get help. Ventilate with 100% oxygen. Alert nearest facility with cardiopulmonary bypass capability.
2. Resuscitation: airway/ventilatory support, chest compressions, etc. Avoid vasopressin, calcium channel blockers, B-blockers, or additional local anesthetic. Reduce epinephrine dosages. Prolonged effort may be required.
3. Seizure management: benzodiazepines preferred (e.g., intravenous midazolam 0.1–0.2 mg/kg); avoid propofol if cardiovascular instability.
4. Administer 1.5 mL/kg 20% lipid emulsion over ~1 minute to trap unbound amide local anesthetics. Repeat bolus once or twice for persistent cardiovascular collapse.
5. Initiate 20% lipid infusion (0.25 mL/kg per minute) until circulation is restored; double the infusion rate if blood pressure remains low. Continue infusion for at least 10 minutes after attaining circulatory stability. Recommended upper limit of ~10 mL/kg.
6. A fluid bolus of 10–20 mL/kg balanced salt solution and an infusion of phenylephrine (0.1 µg/kg per minute to start) may be needed to correct peripheral vasodilation.

Source: https://www.asra.com/advisory-guidelines/article/3/checklist-for-treatment-of-local-anesthetic-systemic-toxicity.

Personnel

During deep sedation, there must be 1 person whose only responsibility is to constantly observe the patient's vital signs, airway patency, and adequacy of ventilation and to either administer drugs or direct their administration. This individual must, at a minimum, be trained in PALS and capable of assisting with any emergency event. At least 1 individual must be present who is trained in and capable of providing advanced pediatric life support and who is skilled to rescue a child with apnea, laryngospasm, and or airway obstruction. Required skills include the ability to open the airway, suction secretions, provide CPAP, insert supraglottic devices (oral airway, nasal trumpet, LMA), and perform successful bag-valve-mask ventilation, tracheal intubation, and cardiopulmonary resuscitation.

Equipment

In addition to the equipment needed for moderate sedation, an ECG monitor and a defibrillator for use in pediatric patients should be readily available.

Vascular access

Patients receiving deep sedation should have an intravenous line placed at the start of the procedure or have a person skilled in establishing vascular access in pediatric patients immediately available.

Monitoring

A competent individual shall observe the patient continuously. Monitoring shall include all parameters described for moderate sedation. Vital signs, including heart rate, respiratory rate, blood pressure, oxygen saturation, and expired carbon dioxide, must bedocumented at least every 5 minutes in a time-based record. Capnography should be used for almost all deeply sedated children because of the increased risk of airway/ventilation compromise. Capnography may not be feasible if the patient is agitated or uncooperative during the initial phases of sedation or during certain procedures, such as bronchoscopy or repair of facial lacerations, and this circumstance should be documented. For uncooperative children, the capnography monitor may be placed once the child becomes sedated. Note that if supplemental oxygen is administered, the capnograph may underestimate the true expired carbon dioxide value; of more importance than the numeric reading of exhaled carbon dioxide is the assurance of continuous respiratory gas exchange (i.e., continuous waveform). Capnography is particularly useful for patients who are difficult to observe (e.g., during MRI or in a darkened room).[64,67,72,90,96,110,159–162,164–166,167–170,372–375]

The physician/dentist or his or her designee shall document the name, route, site, time of administration, and dosage of all drugs administered. If sedation is being directed by a physician who is not personally administering the medications, then recommended practice is for the nurse administering the medication to confirm the dose verbally before administration. The inspired concentrations of inhalation sedation agents and oxygen and the duration of administration shall be documented.

Postsedation care

The facility and procedures followed for postsedation care shall conform to those described under"moderate sedation." The initial recording of vital signs should be documented at least every 5 minutes. Once the child begins to awaken, the recording intervals may be increased to 10 to 15 minutes. Table 2 summarizes the equipment, personnel, and monitoring requirements for moderate and deep sedation.

Special considerations

Neonates and former preterm infants

Neonates and former preterm infants require specific management, because immaturity of hepatic and renal function may alter the ability to metabolize and excrete sedating medications,[376] resulting in prolonged sedation and the need for extended post-sedation monitoring. Former preterm infants have an increased risk of postanesthesia apnea,[377] but it is unclear whether a similar risk is associated with sedation, because this possibility has not been systematically investigated.[378]

Other concerns regarding the effects of anesthetic drugs and sedating medications on the developing brain are beyond the scope of this document. At this point, the research in this area is preliminary and inconclusive at best, but it would seem prudent to avoid unnecessary exposure to sedation if the procedure is unlikely to change medical/dental management (e.g., a sedated MRI purely for screening purposes in preterm infants).[379–382]

Local anesthetic agents

All local anesthetic agents are cardiac depressants and may cause central nervous system excitation or depression. Particular weight-based attention should be paid to cumulative dosage in all children.[118,120,125,383–386] To ensure that the patient will not receive an excessive dose, the maximum allowable safe dosage (e.g., mg/kg) should be calculated before administration. There may be enhanced sedative effects when the highest recommended doses of local anesthetic drugs are used in combination with other sedatives or opioids (see Tables 3 and 4 for limits and conversion tables of commonly used local anesthetics).[118,125,387–400] In general, when administering local anesthetic drugs, the practitioner should aspirate frequently to minimize the likelihood that the needle is in a blood vessel; lower doses should be used when injecting into vascular tissues.[401] If high doses or injection of amide local anesthetics (bupivacaine and ropivacaine) into vascular tissues is anticipated, then the immediate availability of a 20% lipid emulsion for the treatment of local anesthetic toxicity is recommended (Tables 3 and 5).[402–409] Topical local anesthetics are commonly used and encouraged, but the practitioner should avoid applying excessive doses to mucosal surfaces where systemic uptake and possible toxicity (seizures, methemoglobinemia) could result and to remain within the manufacturer'srecommendations regarding allowable surface area application.[410–415]

Pulse oximetry

Newer pulse oximeters are less susceptible to motion artifacts and may be more useful than older oximeters that do not contain updated software.[416–420] Oximeters that change tone with changes in hemoglobin saturation provide immediate aural warning to everyone within hearing distance. The oximeter probe must be properly positioned; clip-on devices are easy to displace, which may produce artifactual data (under-or overestimation of oxygen saturation).[361,362]

Capnography

Expired carbon dioxide monitoring is valuable to diagnose the simple presence or absence of respirations, airway obstruction, or respiratory depression, particularly in patients sedated in less-accessible locations, such as in MRI machines or darkened rooms.[64,66,67,72,90,96,110,159–162,164–170,372–375,421–427] In patients receiving supplemental oxygen, capnography facilitates the recognition of apnea or airway obstruction several minutes before the situa-tion would be detected just by pulse oximetry. In this situation, desaturation would be delayed due to increased oxygen reserves; capnography would enable earlier intervention.[161] One study in children sedated in the emergency department found that the use of capnography reduced the incidence of hypoventilation and desaturation (7% to 1%).[174] The use of expired carbon dioxide monitoring devices is now required for almost all deeply sedated children (with rare exceptions), particularly in situations in which other means of assessing the adequacy of ventilation are limited. Several manufacturers have produced nasal cannulae that allow simultaneous delivery of oxygen and measurement of expired carbon dioxide values.[421,422,427] Although these devices can have a high degree of false-positive alarms, they are also very accurate for the detection of complete airway obstruction or apnea.[164,168,169] Taping the sampling line under the nares under an oxygen face mask or nasal hood will provide similar information. The exact measured value is less important than the simple answer to the question: Is the child exchanging air with each breath?

Processed EEG (Bispectral Index)

Although not new to the anesthesia community, the processed EEG (bispectral index [**BIS**]) monitor is slowly finding its way into the sedation literature.[428] Several studies have attempted to use BIS monitoring as a means of noninvasively assessing the depth of sedation. This technology was designed to examine EEG signals and, through a variety of algorithms, correlate a number with depth of unconsciousness: that is, the lower the number, the deeper the sedation. Unfortunately, these algorithms are based on adult patients and have not been validated in children of varying ages and varying brain development. Although the readings correspond quite well with the depth of propofol sedation, the numbers may paradoxically go up rather than down with sevoflurane and ketamine because of central excitation despite a state of general anesthesia or deep sedation.[429,430]

Opioids and benzodiazepines have minimal and variable effects on the BIS. Dexmedetomidine has minimal effect with EEG patterns, consistent with stage 2 sleep.[431] Several sedation studies have examined the utility of this device and degree of correlation with standard sedation scales.[347,363,432–435] It appears that there is some correlation with BIS values in moderate sedation, but there is not a reliable ability to distinguish between deep sedation and moderate sedation or deep sedation from general anesthesia.[432] Presently, it would appear that BIS monitoring might provide useful information only when used for sedation with propofol[363]; in general, it is still considered a research tool and not recommended for routine use.

Adjuncts to airway management and resuscitation

The vast majority of sedation complications can be managed with simple maneuvers, such as supplemental oxygen, opening the airway, suctioning, placement of an oral or nasopharyngeal airway, and bag-mask-valve ventilation. Rarely, tracheal intubation is required for more prolonged ventilatory support.

In addition to standard tracheal intubation techniques, a number of supraglottic devices are available for the management of patients with abnormal airway anatomy or airway obstruction. Examples include the LMA, the cuffed oropharyngeal airway, and a variety of kits to perform an emergency cricothyrotomy.[436,437]

The largest clinical experience in pediatrics is with the LMA, which is available in multiple sizes, including those for late preterm and term neonates. The use of the LMA is now an essential addition to advanced airway training courses, and familiarity with insertion techniques can be life-saving.[438–442] The LMA can also serve as a bridge to secure airway management in children with anatomic airway abnormalities.[443, 444] Practitioners are encouraged to gain experience with these techniques as they become incorporated into PALS courses.

Another valuable emergency technique is intraosseous needle placement for vascular access. Intraosseous needles are available in several sizes; insertion can be life-saving when rapid intravenous access is difficult. A relatively new intraosseous device (EZ-IO Vidacare, now part of Teleflex, Research Triangle Park, NC) is similar to a hand-held battery-powered drill. It allows rapid placement with minimal chance of misplacement; it also has a low-profile intravenous adapter.[445–450] Familiarity with the use of these emergency techniques can be gained by keeping current with resuscitation courses, such as PALS and advanced pediatric life support.

Patient simulators

High-fidelity patient simulators are now available that allow physicians, dentists, and other health care providers to practice managing a variety of programmed adverse events, such as apnea, bronchospasm, and laryngospasm.[133,220,450–452], The use of such devices is encouraged to better train medical professionals and teams to respond more effectively to rare events.[128, 131,451,453–455] One study that simulated the quality of cardiopulmonary resuscitation compared standard management of ventricular fibrillation versus rescue with the EZ-IO for the rapid establishment of intravenous access and placement of an LMA for establishing a patent airway in adults; the use of these devices resulted in more rapid establishment of vascular access and securing of the airway.[456]

Monitoring during MRI

The powerful magnetic field and the generation of radiofrequency emissions necessitate the use of special equipment to provide continuous patient monitoring throughout the MRI scanning procedure.[457–459] MRI-compatible pulse oximeters and capnographs capable of continuous function during scanning should be used in any sedated or restrained pediatric patient. Thermal injuries can result if appropriate precautions are not taken; the practitioner is cautioned to avoid coiling of all wires (oximeter, ECG) and to place the oximeter probe as far from the magnetic coil as possible to diminish the possibility of injury. ECG monitoring during MRI has been associated with thermal injury; special MRI-compatible ECG pads are essential to allow safe monitoring.[460–463] If sedation is achieved by using an infusion pump, then either an MRI-compatible pump is required or the pump must be situated outside of the room with long infusion tubing so as to maintain infusion accuracy. All equipment must be MRI compatible, including laryngoscope blades and handles, oxygen tanks, and any ancillary equipment. All individuals, including parents, must be screened for ferromagnetic materials, phones, pagers, pens, credit cards, watches, surgical implants, pacemakers, etc, before entry into the MRI suite.

Nitrous oxide

Inhalation sedation/analgesia equipment that delivers nitrous oxide must have the capacity of delivering 100% and never less than 25% oxygen concentration at a flow rate appropriate to the size of the patient. Equipment that delivers variable ratios of nitrous oxide >50% to oxygen that covers the mouth and nose must be used in conjunction with a calibrated and functional oxygen analyzer. All nitrous oxide-to-oxygen inhalation devices should be calibrated in accordance with appropriate state and local requirements. Consideration should be given to the National Institute of Occupational Safety and Health Standards for the scavenging of waste gases.[464] Newly constructed or reconstructed treatment facilities, especially those with piped-in nitrous oxide and oxygen, must have appropriate state or local inspections to certify proper function of inhalation sedation/analgesia systems before any delivery of patient care.

Nitrous oxide in oxygen, with varying concentrations, has been successfully used for many years to provide analgesia for a variety of painful procedures in children.[14,36, 49,98,465–493] The use of nitrous oxide for minimal sedation is defined as the administration of nitrous oxide of ≤50% with the balance as oxygen, without any other sedative, opioid, or other depressant drug before or concurrent with the nitrous oxide to an otherwise healthy patient in ASA class I or II. The patient is able to maintain verbal communication throughout the procedure. It should be noted that although local anesthetics have sedative properties, for purposes of this guideline they are not considered sedatives in this circumstance. If nitrous oxide in oxygen is combined with other sedating medications, such as chloral hydrate, midazolam, or an opioid, or if nitrous oxide is used in concentrations >50%, the likelihood for moderate or deep sedation increases.[107,197,492,494,495] In this situation, the practitioner is advised to institute the guidelines for moderate or deep sedation, as indicated by the patient's response.[496]

References

1. Milnes AR. Intravenous procedural sedation: an alternative to general anesthesia in the treatment of early childhood caries. J Can Dent Assoc 2003;69:298–302.
2. Law AK, Ng DK, Chan KK. Use of intramuscular ketamine for endoscopy sedation in children. Pediatr Int 2003;45(2):180–5.
3. Flood RG, Krauss B. Procedural sedation and analgesia for children in the emergency department. Emerg Med Clin North Am 2003;21(1):121–39.

4. Jaggar SI, Haxby E. Sedation, anaesthesia and monitoring for bronchoscopy. Paediatr Respir Rev 2002;3(4):321–7.
5. de Blic J, Marchac V, Scheinmann P. Complications of flexible bronchoscopy in children: prospective study of 1,328 procedures. Eur Respir J 2002;20(5):1271–6.
6. Mason KP, Michna E, DiNardo JA, et al. Evolution of a protocol for ketamine-induced sedation as an alternative to general anesthesia for interventional radiologic procedures in pediatric patients. Radiology 2002;225(2): 457–65.
7. Houpt M. Project USAP 2000—use of sedative agents by pediatric dentists: a15-year follow-up survey. Pediatr Dent 2002;24(4):289–94.
8. Vinson DR, Bradbury DR. Etomidate for procedural sedation in emergency medicine. Ann Emerg Med 2002; 39(6):592–8.
9. Everitt IJ, Barnett P. Comparison of two benzodiazepines used for sedation of children undergoing suturing of a laceration in an emergency department. Pediatr Emerg Care 2002;18(2):72–4.
10. Karian VE, Burrows PE, Zurakowski D, Connor L, Poznauskis L, Mason KP. The development of a pediatric radiology sedation program. Pediatr Radiol 2002;32(5):348–53.
11. Kaplan RF, Yang CI. Sedation and analgesia in pediatric patients for procedures outside the operating room. Anesthesiol Clin North America 2002;20(1):181–94, vii.
12. Wheeler DS, Jensen RA, Poss WB. A randomized, blinded comparison of chloral hydrate and midazolam sedation in children undergoing echocardiography. Clin Pediatr (Phila) 2001;40(7):381–7.
13. Hain RD, Campbell C. Invasive procedures carried out in conscious children: contrast between North American and European paediatric oncology centres. Arch Dis Child 2001;85(1):12–5.
14. Kennedy RM, Luhmann JD. Pharmacological management of pain and anxiety during emergency procedures in children. Paediatr Drugs 2001;3(5):337–54.
15. Kanagasundaram SA, Lane LJ, Cavalletto BP, Keneally JP, Cooper MG. Efficacy and safety of nitrous oxide in alleviating pain and anxiety during painful procedures. Arch Dis Child 2001;84(6):492–5.
16. Younge PA, Kendall JM. Sedation for children requiring wound repair: a randomised controlled double blind comparison of oral midazolam and oral ketamine. Emerg Med J 2001;18(1):30–3.
17. Ljungman G, Gordh T, Sörensen S, Kreuger A. Lumbar puncture in pediatric oncology: conscious sedation vs. general anesthesia. Med Pediatr Oncol 2001;36(3):372–9.
18. Poe SS, Nolan MT, Dang D, et al. Ensuring safety of patients receiving sedation for procedures: evaluation of clinical practice guidelines. Jt Comm J Qual Improv 2001; 27(1):28–41.
19. D'Agostino J, Terndrup TE. Chloral hydrate versus midazolam for sedation of children for neuroimaging: a randomized clinical trial. Pediatr Emerg Care 2000;16(1): 1–4.
20. Green SM, Kuppermann N, Rothrock SG, Hummel CB, Ho M. Predictors of adverse events with intramuscular ketamine sedation in children. Ann Emerg Med 2000;35 (1):35–42.
21. Hopkins KL, Davis PC, Sanders CL, Churchill LH. Sedation for pediatric imaging studies. Neuroimaging Clin N Am 1999;9(1):1–10.
22. Bauman LA, Kish I, Baumann RC, Politis GD. Pediatric sedation with analgesia. Am J Emerg Med 1999;17(1): 1–3.
23. Bhatt-Mehta V, Rosen DA. Sedation in children: current concepts. Pharmacotherapy 1998;18(4):790–807.
24. Morton NS, Oomen GJ. Development of a selection and monitoring protocol for safe sedation of children. Paediatr Anaesth 1998;8(1):65–8.
25. Murphy MS. Sedation for invasive procedures in paediatrics. Arch Dis Child 1997;77(4):281–4.
26. Webb MD, Moore PA. Sedation for pediatric dental patients. Dent Clin North Am 2002;46(4):803–14, xi.
27. Malviya S, Voepel-Lewis T, Tait AR, Merkel S. Sedation/ analgesia for diagnostic and therapeutic procedures in children. J Perianesth Nurs 2000;15(6):415–22.
28. Zempsky WT, Schechter NL. Office based pain managemen: the 15-minute consultation. Pediatr Clin North Am 2000;47(3):601–15
29. Kennedy RM, Luhmann JD. The "ouchless emergency department": getting closer: advances in decreasing distress during painful procedures in the emergency department. Pediatr Clin North Am 1999;46(6):1215–47, vii–viii.
30. Rodriguez E, Jordan R. Contemporary trends in pediatric sedation and analgesia. Emerg Med Clin North Am 2002;20(1):199–222.
31. Ruess L, O'Connor SC, Mikita CP, Creamer KM. Sedation for pediatric diagnostic imaging: use of pediatric and nursing resources as an alternative to a radiology department sedation team. Pediatr Radiol 2002;32(7):505–10.
32. Weiss S. Sedation of pediatric patients for nuclear medicine procedures. Semin Nucl Med 1993;23(3):190–8.
33. Wilson S. Pharmacologic behavior management for pediatric dental treatment. Pediatr Clin North Am 2000;47 (5):1159–75.
34. McCarty EC, Mencio GA, Green NE. Anesthesia and analgesia for the ambulatory management of fractures in children. J Am Acad Orthop Surg 1999;7(2):81–91.
35. Egelhoff JC, Ball WS Jr, Koch BL, Parks TD. Safety and efficacy of sedation in children using a structured sedation program. AJR Am J Roentgenol 1997;168(5):1259–62.
36. Heinrich M, Menzel C, Hoffmann F, Berger M, Schweinitz DV. Selfadministered procedural analgesia using nitrous oxide/oxygen (50:50) in the pediatric surgery emergency room: effectiveness and limitations. Eur J Pediatr Surg 2015;25(3):250-6.

37. Hoyle JD Jr, Callahan JM, Badawy M, et al; Traumatic Brain Injury Study Group for the Pediatric Emergency Care Applied Research Network (PECARN). Pharmacological sedation for cranial computed tomography in children after minor blunt head trauma. Pediatr Emerg Care 2014;30(1):1–7.
38. Chiaretti A, Benini F, Pierri F, et al. Safety and efficacy of propofol administered by paediatricians during procedural sedation in children. Acta Paediatr 2014;103(2): 182–7.
39. Pacheco GS, Ferayorni A. Pediatric procedural sedation and analgesia. Emerg Med Clin North Am 2013;31(3): 831–52.
40. Griffiths MA, Kamat PP, McCracken CE, Simon HK. Is procedural sedation with propofol acceptable for complex imaging? A comparison of short vs. prolonged sedations in children. Pediatr Radiol 2013;43(10):1273–8.
41. Doctor K, Roback MG, Teach SJ. An update on pediatric hospitalbased sedation. Curr Opin Pediatr 2013;25(3): 310–6.
42. Alletag MJ, Auerbach MA, Baum CR. Ketamine, propofol, and ketofol use for pediatric sedation. Pediatr Emerg Care 2012;28(12):1391–5; quiz: 1396–8.
43. Jain R, Petrillo-Albarano T, Parks WJ, Linzer JF Sr, Stockwell JA. Efficacy and safety of deep sedation by nonanesthesiologists for cardiac MRI in children. Pediatr Radiol 2013;43(5):605–11.
44. Nelson T, Nelson G. The role of sedation in contemporary pediatric dentistry. Dent Clin North Am 2013;57(1): 145–61.
45. Monroe KK, Beach M, Reindel R, et al. Analysis of procedural sedation provided by pediatricians. Pediatr Int 2013;55(1):17–23.
46. Alexander M. Managing patient stress in pediatric radiology. Radiol Technol 2012;83(6):549–60.
47. Macias CG, Chumpitazi CE. Sedation and anesthesia for CT: emerging issues for providing high-quality care. Pediatr Radiol 2011;41(suppl 2):517–22.
48. Andolfatto G, Willman E. A prospective case series of pediatric procedural sedation and analgesia in the emergency department using single-syringe ketamine-propofol combination (ketofol). Acad Emerg Med 2010;17(2): 194–201.
49. Brown SC, Hart G, Chastain DP, Schneeweiss S, McGrath PA. Reducing distress for children during invasive procedures: randomized clinical trial of effectiveness of the PediSedate. Paediatr Anaesth. 2009;19(8):725–31.
50. Yamamoto LG. Initiating a hospital-wide pediatric sedation service provided by emergency physicians. Clin Pediatr (Phila) 2008;47(1):37–48.
51. Doyle L, Colletti JE. Pediatric procedural sedation and analgesia. Pediatr Clin North Am 2006;53(2):279–92.
52. Todd DW. Pediatric sedation and anesthesia for the oral surgeon. Oral Maxillofac Surg Clin North Am 2013;25 (3):467–78, vi–vii.
53. Committee on Drugs, Section on Anesthesiology, American Academy of Pediatrics. Guidelines for the elective use of conscious sedation, deep sedation, and general anesthesia in pediatric patients. Pediatrics 1985;76(2):317–21.
54. American Academy of Pediatric Dentistry. Guidelines for the elective use of conscious sedation, deep sedation, and general anesthesia in pediatric patients. ASDC J Dent Child 1986;53(1):21–2.
55. Committee on Drugs, American Academy of Pediatrics. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures. Pediatrics 1992;89(6 pt 1): 1110–5.
56. Committee on Drugs, American Academy of Pediatrics. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: addendum. Pediatrics 2002;110(4): 836–8.
57. American Academy of Pediatrics, American Academy of Pediatric Dentistry. Guidelines on the elective use of minimal, moderate, and deep sedation and general anesthesia for pediatric dental patients. 2011. Available at: http://www.aapd.org/media/policies_ guidelines/g_ sedation.pdf. Accessed May 27, 2016.
58. Coté CJ, Wilson S; American Academy of Pediatrics; American Academy of Pediatric Dentistry; Work Group on Sedation. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: an update. Pediatrics 2006; 118(6):2587–602.
59. The Joint Commission. Comprehensive Accreditation Manual for Hospitals (CAMH): the official handbook. Oakbrook Terrace, IL: The Joint Commission; 2014.
60. American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Practice guidelines for sedation and analgesia by non-anesthesiologists. Anesthesiology 2002;96(4):1004–17.
61. Committee of Origin: Ad Hoc on Non-Anesthesiologist Privileging. Statement on granting privileges for deep sedation to non-anesthesiologist sedation practitioners. 2010. Available at: "http://www.asahq.org/~/media/sites/asahq/files/public/resources/standards-guidelines/advisory-on-granting-privileges-for-deep-sedation-to-non-anesthesiologist.pdf". Accessed May 27, 2016.
62. Coté CJ, Karl HW, Notterman DA, Weinberg JA, McCloskey C. Adverse sedation events in pediatrics: analysis of medications used for sedation. Pediatrics 2000;106 (4):633–44.
63. Coté CJ, Notterman DA, Karl HW, Weinberg JA, Mc Closkey C. Adverse sedation events in pediatrics: a critical incident analysis of contributing factors. Pediatrics 2000;105(4 pt 1):805–14.
64. Kim G, Green SM, Denmark TK, Krauss B. Ventilatory response during dissociative sedation in children-a pilot study. Acad Emerg Med 2003;10(2):140–5.

65. Coté CJ. Sedation for the pediatric patient: a review. Pediatr Clin North Am 1994;41(1):31–58.
66. Mason KP, Burrows PE, Dorsey MM, Zurakowski D, Krauss B. Accuracy of capnography with a 30 foot nasal cannula for monitoring respiratory rate and end-tidal CO2 in children. J Clin Monit Comput 2000;16(4): 259–62.
67. McQuillen KK, Steele DW. Capnography during sedation/ analgesia in the pediatric emergency department. Pediatr Emerg Care 2000;16(6):401–4.
68. Malviya S, Voepel-Lewis T, Tait AR. Adverse events and risk factors associated with the sedation of children by non-anesthesiologists. Anesth Analg 1997;85(6):1207–13.
69. Coté CJ, Rolf N, Liu LM, et al. A single-blind study of combined pulse oximetry and capnography in children. Anesthesiology. 1991;74(6):980–7.
70. Guideline SIGN; Scottish Intercollegiate Guidelines Network. SIGN Guideline 58: safe sedation of children undergoing diagnostic and therapeutic procedures. Paediatr Anaesth 2008;18(1):11–2.
71. Peña BM, Krauss B. Adverse events of procedural sedation and analgesia in a pediatric emergency department. Ann Emerg Med 1999;34(4 pt 1):483–91.
72. Smally AJ, Nowicki TA. Sedation in the emergency department. Curr Opin Anaesthesiol 2007;20(4):379–83.
73. Ratnapalan S, Schneeweiss S. Guidelines to practice: the process of planning and implementing a pediatric sedation program. Pediatr Emerg Care 2007;23(4):262–6.
74. Hoffman GM, Nowakowski R, Troshynski TJ, Berens RJ, Weisman SJ. Risk reduction in pediatric procedural sedation by application of an American Academy of Pediatrics/ American Society of Anesthesiologists process model. Pediatrics 2002;109(2):236–43.
75. Krauss B. Management of acute pain and anxiety in children undergoing procedures in the emergency department. Pediatr Emerg Care 2001;17(2):115–122; quiz: 123–5.
76. Slovis TL. Sedation and anesthesia issues in pediatric imaging. Pediatr Radiol 2011;41(suppl 2):514–6.
77. Babl FE, Krieser D, Belousoff J, Theophilos T. Evaluation of a paediatric procedural sedation training and credentialing programme: sustainability of change. Emerg Med J 2010;27(8):57781.
78. Meredith JR, O'Keefe KP, Galwankar S. Pediatric procedural sedation and analgesia. J Emerg Trauma Shock 2008; 1(2):88–96.
79. Priestley S, Babl FE, Krieser D, et al. Evaluation of the impact of a paediatric procedural sedation credentialing programme on quality of care. Emerg Med Australas 2006;18(5–6):498–504.
80. Babl F, Priestley S, Krieser D, et al. Development and implementation of an education and credentialing programme to provide safe paediatric procedural sedation in emergency departments. Emerg Med Australas 2006;18 (5-6):489–97.
81. Cravero JP, Blike GT. Pediatric sedation. Curr Opin Anaesthesiol 2004;17(3):247–51.
82. Shavit I, Keidan I, Augarten A. The practice of pediatric procedural sedation and analgesia in the emergency department. Eur J Emerg Med 2006;13(5):270–5.
83. Langhan ML, Mallory M, Hertzog J, Lowrie L, Cravero J; Pediatric Sedation Research Consortium. Physiologic monitoring practices during pediatric procedural sedation: a report from the Pediatric Sedation Research Consortium. Arch Pediatr Adolesc Med 2012;166(11):990–8.
84. Primosch RE. Lidocaine toxicity in children—prevention and intervention. Todays FDA 1992;4:4C–5C.
85. Dial S, Silver P, Bock K, Sagy M. Pediatric sedation for procedures titrated to a desired degree of immobility results in unpredictable depth of sedation. Pediatr Emerg Care 2001;17(6):414–20.
86. Maxwell LG, Yaster M. The myth of conscious sedation. Arch Pediatr Adolesc Med 1996;150(7):665–7.
87. Coté CJ. "Conscious sedation": time for this oxymoron to go away! J Pediatr 2001;139(1):15–7; discussion: 18–9.
88. Motas D, McDermott NB, VanSickle T, Friesen RH. Depth of consciousness and deep sedation attained in children as administered by nonanaesthesiologists in a children's hospital. Paediatr Anaesth 2004;14(3):256–60.
89. Cudny ME, Wang NE, Bardas SL, Nguyen CN. Adverse events associated with procedural sedation in pediatric patients in the emergency department. Hosp Pharm 2013; 48(2):134–42.
90. Mora Capín A, Míguez Navarro C, López López R, Marañón Pardillo R. Usefulness of capnography for monitoring sedoanalgesia: infl uence of oxygen on the parameters monitored [in Spanish]. An Pediatr (Barc) 2014;80(1): 41–6.
91. Frieling T, Heise J, Kreysel C, Kuhlen R, Schepke M. Sedation-associated complications in endoscopy—prospective multicentre survey of 191142 patients. Z Gastroenterol 2013;51(6):568–72.
92. Khutia SK, Mandal MC, Das S, Basu SR. Intravenous infusion of ketamine propofol can be an alternative to intravenous infusion of fentanylpropofol for deep sedation and analgesia in paediatric patients undergoing emergency short surgical procedures. Indian J Anaesth 2012; 56(2):145–50.
93. Kannikeswaran N, Chen X, Sethuraman U. Utility of endtidal carbon dioxide monitoring in detection of hypoxia during sedation for brain magnetic resonance imaging in children with developmental disabilities. Paediatr Anaesth 2011;21(12):1241–6.
94. McGrane O, Hopkins G, Nielson A, Kang C. Procedural sedation with propofol: a retrospective review of the experiences of an emergency medicine residency program 2005 to 2010. Am J Emerg Med 2012;30(5):706–11.

95. Mallory MD, Baxter AL, Yanosky DJ, Cravero JP; Pediatric Sedation Research Consortium. Emergency physician-administered propofol sedation: a report on 25, 433 sedations from the Pediatric Sedation Research Consortium. Ann Emerg Med 2011;57(5):462–468.e1.
96. Langhan ML, Chen L, Marshall C, Santucci KA. Detection of hypoventilation by capnography and its association with hypoxia in children undergoing sedation with ketamine. Pediatr Emerg Care 2011;27(5):394–397
97. David H, Shipp J. A randomized controlled trial of ketamine/propofol versus propofol alone for emergency department procedural sedation. Ann Emerg Med 2011;57(5): 435–441.
98. Babl FE, Belousoff J, Deasy C, Hopper S, Theophilos T. Paediatric procedural sedation based on nitrous oxide and ketamine: sedation registry data from Australia. Emerg Med J 2010;27(8):607–612.
99. Lee-Jayaram JJ, Green A, Siembieda J, et al. Ketamine/midazolam versus etomidate/fentanyl: procedural sedation for pediatric orthopedic reductions. Pediatr Emerg Care 2010;26(6):408–412.
100. Melendez E, Bachur R. Serious adverse events during procedural sedation with ketamine. Pediatr Emerg Care 2009;25(5):325–328.
101. Misra S, Mahajan PV, Chen X, Kannikeswaran N. Safety of procedural sedation and analgesia in children less than 2 years of age in a pediatric emergency department. Int J Emerg Med 2008;1(3):173–177.
102. Green SM, Roback MG, Krauss B, et al; Emergency Department Ketamine Meta-Analysis Study Group. Predictors of airway and respiratory adverse events with ketamine sedation in the emergency department: an individual-patient data meta-analysis of 8,282 children. Ann Emerg Med 2009;54(2):158–168.e1–e4.
103. Kannikeswaran N, Mahajan PV, Sethuraman U, Groebe A, Chen X. Sedation medication received and adverse events related to sedation for brain MRI in children with and without developmental disabilities. Paediatr Anaesth 2009;19(3):250–6.
104. Ramaswamy P, Babl FE, Deasy C, Sharwood LN. Pediatric procedural sedation with ketamine: time to discharge after intramuscular versus intravenous administration. Acad Emerg Med 2009;16(2):101–7.
105. Vardy JM, Dignon N, Mukherjee N, Sami DM, Balachandran G, Taylor S. Audit of the safety and effectiveness of ketamine for procedural sedation in the emergency department. Emerg Med J 2008;25(9):579–82.
106. Capapé S, Mora E, Mintegui S, García S, Santiago M, Benito J. Prolonged sedation and airway complications after administration of an inadvertent ketamine overdose in emergency department. Eur J Emerg Med 2008;15(2): 92–4.
107. Babl FE, Oakley E, Seaman C, Barnett P, Sharwood LN. High-concentration nitrous oxide for procedural sedation in children: adverse events and depth of sedation. Pediatrics 2008;121(3). Available at: "www.pediatrics.org/cgi/content/full/121/3/e528".
108. Mahar PJ, Rana JA, Kennedy CS, Christopher NC. A randomized clinical trial of oral transmucosal fentanyl citrate versus intravenous morphine sulfate for initial control of pain in children with extremity injuries. Pediatr Emerg Care 2007;23(8):544–8.
109. Sacchetti A, Stander E, Ferguson N, Maniar G, Valko P. Pediatric Procedural Sedation in the Community Emergency Department: results from the ProSCED registry. Pediatr Emerg Care 2007;23(4):218–222.
110. Anderson JL, Junkins E, Pribble C, Guenther E. Capnography and depth of sedation during propofol sedation in children. Ann Emerg Med 2007;49(1):9–13.
111. Luhmann JD, Schootman M, Luhmann SJ, Kennedy RM. A randomized comparison of nitrous oxide plus hematoma block versus ketamine plus midazolam for emergency department forearm fracture reduction in children. Pediatrics 2006;118(4). Available at: "www.pediatrics.org/cgi/content/full/118/4/e1078".
112. Waterman GD Jr, Leder MS, Cohen DM. Adverse events in pediatric ketamine sedations with or without morphine pretreatment. Pediatr Emerg Care 2006;22(6):408–11.
113. Moore PA, Goodson JM. Risk appraisal of narcotic sedation for children. Anesth Prog 1985;32(4):129–39.
114. Nahata MC, Clotz MA, Krogg EA. Adverse effects of meperidine, promethazine, and chlorpromazine for sedation in pediatric patients. Clin Pediatr (Phila) 1985;24(10): 558–60.
115. Brown ET, Corbett SW, Green SM. Iatrogenic cardiopulmonary arrest during pediatric sedation with meperidine, promethazine, and chlorpromazine. Pediatr Emerg Care 2001;17(5):351–3.
116. Benusis KP, Kapaun D, Furnam LJ. Respiratory depression in a child following meperidine, promethazine, and chlorpromazine premedication: report of case. ASDC J Dent Child 1979;46(1):50–3.
117. Garriott JC, Di Maio VJ. Death in the dental chair: three drug fatalities in dental patients. J Toxicol Clin Toxicol 1982;19(9):987–95.
118. Goodson JM, Moore PA. Lifethreatening reactions after pedodontic sedation: an assessment of narcotic, local anesthetic, and antiemetic drug interaction. J Am Dent Assoc 1983;107(2):239–45.
119. Jastak JT, Pallasch T. Death after chloral hydrate sedation: report of case. J Am Dent Assoc 1988;116(3):345–8.
120. Jastak JT, Peskin RM. Major morbidity or mortality from office anesthetic procedures: a closed-claim analysis of 13 cases. Anesth Prog 1991;38(2):39–44.
121. Kaufman E, Jastak JT. Sedation for outpatient dental procedures. Compend Contin Educ Dent 1995;16(5):462–6; quiz: 480.
122. Wilson S. Pharmacological management of the pediatric dental patient. Pediatr Dent 2004;26(2):131–6.

123. Sams DR, Thornton JB, Wright JT. The assessment of two oral sedation drug regimens in pediatric dental patients. ASDC J Dent Child 1992;59(4):306–12
124. Geelhoed GC, Landau LI, Le Souëf PN. Evaluation of SaO2 as a predictor of outcome in 280 children presenting with acute asthma. Ann Emerg Med 1994;23(6): 1236–41.
125. Chicka MC, Dembo JB, Mathu-Muju KR, Nash DA, Bush HM. Adverse events during pediatric dental anesthesia and sedation: a review of closed malpractice insurance claims. Pediatr Dent 2012;34(3):231–238.
126. Lee HH, Milgrom P, Starks H, Burke W. Trends in death associated with pediatric dental sedation and general anesthesia. Paediatr Anaesth 2013;23(8):741–6.
127. Sanborn PA, Michna E, Zurakowski D, et al. Adverse cardiovascular and respiratory events during sedation of pediatric patients for imaging examinations. Radiology 2005;237(1):288–94.
128. Shavit I, Keidan I, Hoffmann Y, et al. Enhancing patient safety during pediatric sedation: the impact of simulation-based training of nonanesthesiologists. Arch Pediatr Adolesc Med 2007;161(8):740–3.
129. Cravero JP, Beach ML, Blike GT, Gallagher SM, Hertzog JH; Pediatric Sedation Research Consortium. The incidence and nature of adverse events during pediatric sedation/anesthesia with propofol for procedures outside the operating room: a report from the Pediatric Sedation Research Consortium. Anesth Analg 2009;108(3):795–804.
130. Blike GT, Christoffersen K, Cravero JP,Andeweg SK, Jensen J. A method for measuring system safety and latent errors associated with pediatric procedural sedation. Anesth Analg 2005;101(1):48–58.
131. Cravero JP, Havidich JE. Pediatric sedation—evolution and revolution. Paediatr Anaesth 2011;21(7):800–9.
132. Havidich JE, Cravero JP. The current status of procedural sedation for pediatric patients in out-ofoperating room locations. Curr Opin Anaesthesiol 2012;25(4):453–60.
133. Hollman GA, Banks DM, Berkenbosch JW, et al. Development, implementation, and initial participant feedback of a pediatric sedation provider course. Teach Learn Med 2013;25(3):249–57.
134. Scherrer PD, Mallory MD, Cravero JP, Lowrie L, Hertzog JH, Berkenbosch JW; Pediatric Sedation Research Consortium. The impact of obesity on pediatric procedural sedation-related outcomes: results from the Pediatric Sedation Research Consortium. Paediatr Anaesth 2015;25 (7):689–97.
135. Emrath ET, Stockwell JA, McCracken CE, Simon HK, Kamat PP. Provision of deep procedural sedation by a pediatric sedation team at a freestanding imaging center. Pediatr Radiol 2014;44(8):1020–5.
136. Kamat PP, McCracken CE, Gillespie SE, et al. Pediatric critical care physician-administered procedural sedation using propofol: a report from the Pediatric Sedation Research Consortium Database. Pediatr Crit Care Med 2015;16(1):11–20.
137. Couloures KG, Beach M, Cravero JP, Monroe KK, Hertzog JH. Impact of provider specialty on pediatric procedural sedation complication rates. Pediatrics 2011;127(5). Available at: "www. pediatrics.org/cgi/content/full/127/5/e1154".
138. Metzner J, Domino KB. Risks of anesthesia or sedation outside the operating room: the role of the anesthesia care provider. Curr Opin Anaesthesiol 2010;23(4):523–531.
139. Patel KN, Simon HK, Stockwell CA, et al. Pediatric procedural sedation by a dedicated nonanesthesiology pediatric sedation service using propofol. Pediatr Emerg Care 2009;25(3):133–8.
140. Koo SH, Lee DG, Shin H. Optimal initial dose of chloral hydrate in management of pediatric facial laceration. Arch Plast Surg 2014;41(1):40–4.
141. Ivaturi V, Kriel R, Brundage R, Loewen G, Mansbach H, Cloyd J. Bioavailability of intranasal vs. rectal diazepam. Epilepsy Res 2013;103(2–3):254–61.
142. Mandt MJ, Roback MG, Bajaj L, Galinkin JL, Gao D, Wathen JE. Etomidate for short pediatric procedures in the emergency department. Pediatr Emerg Care 2012;28 (9):898–904.
143. Tsze DS, Steele DW, Machan JT, Akhlaghi F, Linakis JG. Intranasal ketamine for procedural sedation in pediatric laceration repair: a preliminary report. Pediatr Emerg Care 2012;28(8):767–70.
144. Jasiak KD, Phan H, Christich AC, Edwards CJ, Skrepnek GH, Patanwala AE. Induction dose of propofol for pediatric patients undergoing procedural sedation in the emergency department. Pediatr Emerg Care 2012;28(5):4 40–442.
145. McMorrow SP, Abramo TJ. Dexmedetomidine sedation: uses in pediatric procedural sedation outside the operating room. Pediatr Emerg Care 2012;28(3):292–6.
146. Sahyoun C, Krauss B. Clinical implications of pharmacokinetics and pharmacodynamics of procedural sedation agents in children. Curr Opin Pediatr 2012;24(2): 225–32.
147. Sacchetti A, Jachowski J, Heisler J, Cortese T. Remifentanil use in emergency department patients: initial experience. Emerg Med J 2012;29(11):928–9.
148. Shah A, Mosdossy G, McLeod S, Lehnhardt K, Peddle M, Rieder M. A blinded, randomized controlled trial to evaluate ketamine/propofol versus ketamine alone for procedural sedation in children. Ann Emerg Med 2011;57(5): 425–433.e2.
149. Herd DW, Anderson BJ, Keene NA, Holford NH. Investigating the pharmacodynamics of ketamine in children. Paediatr Anaesth 2008;18(1):36–42.
150. Sharieff GQ, Trocinski DR, Kanegaye JT, Fisher B, Harley JR. Ketamine-propofol combination sedation for fracture reduction in the pediatric emergency department. Pediatr Emerg Care 2007;23(12):881–4.

151. Herd DW, Anderson BJ, Holford NH. Modeling the norketamine metabolite in children and the implications for analgesia. Paediatr Anaesth 2007;17(9):831–40.
152. Herd D, Anderson BJ. Ketamine disposition in children presenting for procedural sedation and analgesia in a children's emergency department. Paediatr Anaesth 2007; 17(7):622–9.
153. Heard CM, Joshi P, Johnson K. Dexmedetomidine for pediatric MRI sedation: a review of a series of cases. Paediatr Anaesth 2007;17(9):888–92.
154. Heard C, Burrows F, Johnson K, Joshi P, Houck J, Lerman J. A comparison of dexmedetomidine-midazolam with propofol for maintenance of anesthesia in children undergoing magnetic resonance imaging. Anesth Analg 2008; 107(6):1832–9.
155. Hertzog JH, Havidich JE. Nonanesthesiologist-provided pediatric procedural sedation: an update. Curr Opin Anaesthesiol 2007;20(4):365–72.
156. Petroz GC, Sikich N, James M, et al. A phase I, two-center study of the pharmacokinetics and pharmacodynamics of dexmedetomidine in children. Anesthesiology 2006; 105(6):1098–110.
157. Potts AL, Anderson BJ, Warman GR, Lerman J, Diaz SM, Vilo S. Dexmedetomidine pharmacokinetics in pediatric intensive care—a pooled analysis. Paediatr Anaesth 2009;19(11):1119–29.
158. Mason KP, Lerman J. Dexmedetomidine in children: current knowledge and future applications [review]. Anesth Analg 2011;113(5):1129–42.
159. Sammartino M, Volpe B, Sbaraglia F, Garra R, D'Addessi A. Capnography and the bispectral index—their role in pediatric sedation: a brief review. Int J Pediatr 2010;2010: 828347.
160. Yarchi D, Cohen A, Umansky T, Sukhotnik I, Shaoul R. Assessment of end-tidal carbon dioxide during pediatric and adult sedation for endoscopic procedures. Gastrointest Endosc 2009;69(4):877–82.
161. Lightdale JR, Goldmann DA, Feldman HA, Newburg AR, DiNardo JA, Fox VL. Microstream capnography improves patient monitoring during moderate sedation: a randomized, controlled trial. Pediatrics 2006;117(6): e1170-8. Available at: "www. pediatrics.org/cgi/content/full/117/6/e1170".
162. Yldzdaş D, Yapcoglu H, Ylmaz HL. The value of capnography during sedation or sedation/analgesia in pediatric minor procedures. Pediatr Emerg Care 2004;20(3):162–5.
163. Connor L, Burrows PE, Zurakowski D, Bucci K, Gagnon DA, Mason KP. Effects of IV pentobarbital with and without fentanyl on end-tidal carbon dioxide levels during deep sedation of pediatric patients undergoing MRI. AJR Am J Roentgenol 2003;181(6):1691–4.
164. Primosch RE, Buzzi IM, Jerrell G. Monitoring pediatric dental patients with nasal mask capnography. Pediatr Dent 2000;22(2):120–4.
165. Tobias JD. End-tidal carbon dioxide monitoring during sedation with a combination of midazolam and ketamine for children undergoing painful, invasive procedures. Pediatr Emerg Care 1999;15(3):173–5.
166. Hart LS, Berns SD, Houck CS, Boenning DA. The value of end-tidal CO2 monitoring when comparing three methods of conscious sedation for children undergoing painful procedures in the emergency department. Pediatr Emerg Care 1997;13(3):189–93.
167. Marx CM, Stein J, Tyler MK, Nieder ML, Shurin SB, Blumer JL. Ketaminemidazolam versus meperidinemidazolam for painful procedures in pediatric oncology patients. J Clin Oncol 1997;15(1):94–102.
168. Croswell RJ, Dilley DC, Lucas WJ, Vann WF Jr. A comparison of conventional versus electronic monitoring of sedated pediatric dental patients. Pediatr Dent 1995;17 (5):332–9.
169. Iwasaki J, Vann WF Jr, Dilley DC, Anderson JA. An investigation of capnography and pulse oximetry as monitors of pediatric patients sedated for dental treatment. Pediatr Dent 1989;11(2):111–7.
170. Anderson JA, Vann WF Jr. Respiratory monitoring during pediatric sedation: pulse oximetry and capnography. Pediatr Dent 1988;10(2):94–101.
171. Rothman DL. Sedation of the pediatric patient. J Calif Dent Assoc 2013;41(8):603–11.
172. Scherrer PD. Safe and sound: pediatric procedural sedation and analgesia. Minn Med 2011;94(3):43–7.
173. Srinivasan M, Turmelle M, Depalma LM, Mao J, Carlson DW. Procedural sedation for diagnostic imaging in children by pediatric hospitalists using propofol: analysis of the nature, frequency, and predictors of adverse events and interventions. J Pediatr 2012;160(5):801–806.e1.
174. Langhan ML, Shabanova V, Li FY, Bernstein SL, Shapiro ED. A randomized controlled trial of capnography during sedation in a pediatric emergency setting. Am J Emerg Med 2015;33(1):25–30.
175. Vetri Buratti C, Angelino F, Sansoni J, Fabriani L, Mauro L, Latina R. Distraction as a technique to control pain in pediatric patients during venipuncture: a narrative review of literature. Prof Inferm 2015;68(1):52–62.
176. Robinson PS, Green J. Ambient versus traditional environment in pediatric emergency department. HERD 2015;8(2):71–80.
177. Singh D, Samadi F, Jaiswal J, Tripathi AM. Stress reduction through audio distraction in anxious pediatric dental patients: an adjunctive clinical study. Int J Clin Pediatr Dent 2014;7(3):149–52.
178. Attar RH, Baghdadi ZD. Comparative efficacy of active and passive distraction during restorative treatment in children using an iPad versus audiovisual eyeglasses: a randomised controlled trial. Eur Arch Paediatr Dent 2015; 16(1):1–8.
179. McCarthy AM, Kleiber C, Hanrahan K, et al. Matching doses of distraction with child risk for distress during a medical procedure: a randomized clinical trial. Nurs Res 2014;63(6):397–407.

180. Guinot Jimeno F, Mercadé Bellido M, Cuadros Fernández C, Lorente Rodríguez AI, Llopis Pérez J, Boj Quesada JR. Effect of audiovisual distraction on children's behaviour, anxiety and pain in the dental setting. Eur J Paediatr Dent 2014;15(3):297–302.
181. Gupta HV, Gupta VV, Kaur A, et al. Comparison between the analgesic effect of two techniques on the level of pain perception during venipuncture in children up to 7 years of age: a quasiexperimental study. J Clin Diagn Res 2014;8(8):PC01–PC04.
182. Newton JT, Shah S, Patel H, Sturmey P. Non-pharmacological approaches to behaviour management in children. Dent Update 2003;30(4):194–9.
183. Peretz B, Bimstein E. The use of imagery suggestions during administration of local anesthetic in pediatric dental patients. ASDC J Dent Child 2000;67(4):263–7, 231.
184. Iserson KV. Hypnosis for pediatric fracture reduction. J Emerg Med 1999;17(1):53–6.
185. Rusy LM, Weisman SJ. Complementary therapies for acute pediatric pain management. Pediatr Clin North Am 2000;47(3):589–99.
186. Langley P. Guided imagery: a review of effectiveness in the care of children. Paediatr Nurs 1999;11(3):18–21.
187. Ott MJ. Imagine the possibilities! Guided imagery with toddlers and pre-schoolers. Pediatr Nurs 1996;22(1): 34–8.
188. Singer AJ, Stark MJ. LET versus EMLA for pretreating lacerations: a randomized trial. Acad Emerg Med 2001;8 (3):223–30.
189. Taddio A, Gurguis MG, Koren G. Lidocaine-prilocaine cream versus tetracaine gel for procedural pain in children. Ann Pharmacother 2002;36(4):687–92.
190. Eichenfield LF, Funk A, Fallon-Friedlander S, Cunningham BB. A clinical study to evaluate the efficacy of ELA-Max (4% liposomal lidocaine) as compared with eutectic mixture of local anesthetics cream for pain reduction of venipuncture in children. Pediatrics 2002; 109(6):1093–9.
191. Shaw AJ, Welbury RR. The use of hypnosis in a sedation clinic for dental extractions in children: report of 20 cases. ASDC J Dent Child 1996;63(6):418–20.
192. Stock A, Hill A, Babl FE. Practical communication guide for paediatric procedures. Emerg Med Australas 2012; 24(6):641–6.
193. Barnea-Goraly N, Weinzimer SA, Ruedy KJ, et al; Diabetes Research in Children Network (DirecNet). High success rates of sedation-free brain MRI scanning in young children using simple subject preparation protocols with and without a commercial mock scanner—the Diabetes Research in Children Network (DirecNet) experience. Pediatr Radiol 2014;44(2):181–6.
194. Ram D, Shapira J, Holan G, Magora F, Cohen S, Davidovich E. Audiovisual video eyeglass distraction during dental treatment in children. Quintessence Int 2010;41 (8):673–9.
195. Lemaire C, Moran GR, Swan H. Impact of audio/visual systems on pediatric sedation in magnetic resonance imaging. J Magn Reson Imaging 2009;30(3):649–55.
196. Nordahl CW, Simon TJ, Zierhut C, Solomon M, Rogers SJ, Amaral DG. Brief report: methods for acquiring structural MRI data in very young children with autism without the use of sedation. J Autism Dev Disord 2008;38 (8):1581–90.
197. Denman WT, Tuason PM, Ahmed MI, Brennen LM, Cepeda MS, Carr DB. The PediSedate device, a novel approach to pediatric sedation that provides distraction and inhaled nitrous oxide: clinical evaluation in a large case series. Paediatr Anaesth 2007;17(2):162–6.
198. Harned RK II, Strain JD. MRI-compatible audio/visual system: impact on pediatric sedation. Pediatr Radiol 2001; 31(4):247–50.
199. Slifer KJ. A video system to help children cooperate with motion control for radiation treatment without sedation. J Pediatr Oncol Nurs 1996;13(2):91–7.
200. Krauss BS, Krauss BA, Green SM. Videos in clinical medicine: procedural sedation and analgesia in children. N Engl J Med 2014;370(15):e23.
201. Wilson S. Management of child patient behavior: quality of care, fear and anxiety, and the child patient. Pediatr Dent 2013;35(2):170–4.
202. Kamath PS. A novel distraction technique for pain management during local anesthesia administration in pediatric patients. J Clin Pediatr Dent 2013;38(1):45–7.
203. Asl Aminabadi N, Erfanparast L, Sohrabi A, Ghertasi Oskouei S, Naghili A. The impact of virtual reality distraction on pain and anxiety during dental treatment in 4-6 year-old children: a randomized controlled clinical trial. J Dent Res Dent Clin Dent Prospect 2012;6(4):117–24.
204. El-Sharkawi HF, El-Housseiny AA, Aly AM. Effectiveness of new distraction technique on pain associated with injection of local anesthesia for children. Pediatr Dent 2012;34(2):e35–e38.
205. Adinolfi B, Gava N. Controlled outcome studies of child clinical hypnosis. Acta Biomed 2013;84(2):94–7.
206. Peretz B, Bercovich R, Blumer S. Using elements of hypnosis prior to or during pediatric dental treatment. Pediatr Dent 2013;35(1):33–6.
207. Huet A, Lucas-Polomeni MM, Robert JC, Sixou JL, Wodey E. Hypnosis and dental anesthesia in children: a prospective controlled study. Int J Clin Exp Hypn 2011;59 (4):424–440.
208. Al-Harasi S, Ashley PF, Moles DR, Parekh S, Walters V. Hypnosis for children undergoing dental treatment. Cochrane Database Syst Rev 2010;8:CD007154.
209. McQueen A, Cress C, Tothy A. Using a tablet computer during pediatric procedures: a case series and review of the "apps". Pediatr Emerg Care 2012;28(7):712–4.
210. Heilbrunn BR, Wittern RE, Lee JB, Pham PK, Hamilton AH, Nager AL. Reducing anxiety in the pediatric emergency department: a comparative trial. J Emerg Med 2014;47(6):623–31.

211. Tyson ME, Bohl DD, Blickman JG. A randomized controlled trial: child life services in pediatric imaging. Pediatr Radiol 2014;44(11):1426–32.
212. Malviya S, Voepel-Lewis T, Tait AR, Merkel S, Tremper K, Naughton N. Depth of sedation in children undergoing computed tomography: validity and reliability of the University of Michigan Sedation Scale (UMSS). Br J Anaesth 2002;88(2):241–5.
213. Gamble C, Gamble J, Seal R, Wright RB, Ali S. Bispectral analysis during procedural sedation in the pediatric emergency department. Pediatr Emerg Care 2012;28(10): 1003–8.
214. Domino KB. Office-based anesthesia: lessons learned from the closed claims project. ASA Newsl 2001;65:9–15.
215. American Heart Association. Pediatric Advance Life Support Provider Manual. Dallas, TX: American Heart Association; 2011.
216. American Academy of Pediatrics, American College of Emergency Physicians. Advanced Pediatric Life Support, 5th ed. Boston, MA: Jones and Bartlett Publishers; 2012.
217. Cheng A, Brown LL, Duff JP, et al; International Network for Simulation-Based Pediatric Innovation, Research, and Education (INSPIRE) CPR Investigators. Improving cardiopulmonary resuscitation with a CPR feedback device and refresher simulations (CPR CARES Study): a randomized clinical trial. JAMA Pediatr 2015;169(2):137–44.
218. Nishisaki A, Nguyen J, Colborn S, et al. Evaluation of multidisciplinary simulation training on clinical performance and team behavior during tracheal intubation procedures in a pediatric intensive care unit. Pediatr Crit Care Med 2011;12(4):406–14.
219. Howard-Quijano KJ, Stiegler MA, Huang YM, Canales C, Steadman RH. Anesthesiology residents' performance of pediatric resuscitation during a simulated hyperkalemic cardiac arrest. Anesthesiology 2010;112(4):993–7.
220. Chen MI, Edler A, Wald S, DuBois J, Huang YM. Scenario and checklist for airway rescue during pediatric sedation. Simul Healthc 2007;2(3):194–8.
221. Wheeler M. Management strategies for the difficult pediatric airway. In: Riazi J, ed. The Difficult Pediatric Airway. 16th ed. Philadelphia, PA: W.B. Saunders Company; 1998:743–61.
222. Sullivan KJ, Kissoon N. Securing the child's airway in the emergency department. Pediatr Emerg Care 2002;18(2): 108–21; quiz: 122–124.
223. Levy RJ, Helfaer MA. Pediatric airway issues. Crit Care Clin 2000;16(3):489–504.
224. Krauss B, Green SM. Procedural sedation and analgesia in children. Lancet 2006;367(9512):766–80.
225. Krauss B, Green SM. Sedation and analgesia for procedures in children. N Engl J Med 2000;342(13):938–45.
226. Ferrari L, ed. Anesthesia and Pain Management for the Pediatrician, 1st ed. Baltimore, MD: John Hopkins University Press; 1999.
227. Malvyia S. Sedation Analgesia for Diagnostic and Therapeutic Procedures, 1st ed. Totowa, NJ: Humana Press; 2001.
228. Yaster M, Krane EJ, Kaplan RF, Coté CJ, Lappe DG. Pediatric Pain Management and Sedation Handbook. 1st ed. St. Louis, MO: Mosby-Year Book, Inc.; 1997.
229. Cravero JP, Blike GT. Review of pediatric sedation. Anesth Analg 2004;99(5):1355–64.
230. Deshpande JK, Tobias JD. The Pediatric Pain Handbook. 1st ed. St. Louis, MO: Mosby; 1996.
231. Mace SE, Barata IA, Cravero JP, et al; American College of Emergency Physicians. Clinical policy: evidence-based approach to pharmacologic agents used in pediatric sedation and analgesia in the emergency department. Ann Emerg Med 2004;44(4):342–77.
232. Alcaino EA. Conscious sedation in paediatric dentistry: current philosophies and techniques. Ann R Australas Coll Dent Surg 2000;15:206–10.
233. Tobias JD, Cravero JP. Procedural Sedation for Infants, Children, and Adolescents. Elk Grove Village, IL: American Academy of Pediatrics; 2015.
234. Committee on Standards and Practice Parameters. Standards for Basic Anesthetic Monitoring. Chicago, IL: American Society of Anesthesiologists; 2011.
235. Mitchell AA, Louik C, Lacouture P, Slone D, Goldman P, Shapiro S. Risks to children from computed tomographic scan premedication. JAMA 1982;247(17):2385–8.
236. Wolfe TR, Braude DA. Intranasal medication delivery for children: a brief review and update. Pediatrics 2010;126 (3):532–7.
237. Bührer M, Maitre PO, Crevoisier C, Stanski DR. Electroencephalographic effects of benzodiazepines. II. Pharmacodynamic modeling of the electroencephalographic effects of midazolam and diazepam. Clin Pharmacol Ther 1990;48(5):555–67.
238. Malviya S, Voepel-Lewis T, Ludomirsky A, Marshall J, Tait AR. Can we improve the assessment of discharge readiness? A comparative study of observational and objective measures of depth of sedation in children. Anesthesiology 2004;100(2):218–24.
239. Coté CJ. Discharge criteria for children sedated by non-anesthesiologists: is "safe" really safe enough? Anesthesiology 2004;100(2):207–9.
240. Pershad J, Palmisano P, Nichols M. Chloral hydrate: the good and the bad. Pediatr Emerg Care 1999;15(6): 432–5.
241. McCormack L, Chen JW, Trapp L, Job A. A comparison of sedation related events for two multiagent oral sedation regimens in pediatric dental patients. Pediatr Dent 2014;36(4):302–8.
242. Kinane TB, Murphy J, Bass JL, Corwin MJ. Comparison of respiratory physiologic features when infants are placed in car safety seats or car beds. Pediatrics 2006;118 (2):522–7.

243. Wyeth Pharmaceuticals. Wyeth Phenergan (Promethazine HCL) Tablets and Suppositories [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals; 2012.
244. Caperell K, Pitetti R. Is higher ASA class associated with an increased incidence of adverse events during procedural sedation in a pediatric emergency department? Pediatr Emerg Care 2009;25(10):661–4.
245. Dar AQ, Shah ZA. Anesthesia and sedation in pediatric gastrointestinal endoscopic procedures: a review. World J Gastrointest Endosc 2010;2(7):257–62.
246. Kiringoda R, Thurm AE, Hirschtritt ME, et al. Risks of propofol sedation/anesthesia for imaging studies in pediatric research: eight years of experience in a clinical research center. Arch Pediatr Adolesc Med 2010;164(6): 554–60.
247. Thakkar K, El-Serag HB, Mattek N, Gilger MA. Complications of pediatric EGD: a 4-year experience in PEDS-CORI. Gastrointest Endosc 2007;65(2):213–21.
248. Jackson DL, Johnson BS. Conscious sedation for dentistry: risk management and patient selection. Dent Clin North Am.2002;46(4):767–80.
249. Malviya S, Voepel-Lewis T, Eldevik OP, Rockwell DT, Wong JH, Tait AR. Sedation and general anaesthesia in children undergoing MRI and CT: adverse events and outcomes. Br J Anaesth 2000;84(6):743–8.
250. O'Neil J, Yonkman J, Talty J, Bull MJ. Transporting children with special health care needs: comparing recommendations and practice. Pediatrics 2009;124(2):596–603.
251. Committee on Bioethics, American Academy of Pediatrics. Informed consent, parental permission, and assent in pediatric practice Pediatrics 1995;95(2):314–7.
252. Committee on Pediatric Emergency Medicine; Committee on Bioethics. Consent for emergency medical services for children and adolescents. Pediatrics 2011;128(2):427–33.
253. Martinez D, Wilson S. Children sedated for dental care: a pilot study of the 24-hour postsedation period. Pediatr Dent 2006;28(3):260–4.
254. Kaila R, Chen X, Kannikeswaran N. Postdischarge adverse events related to sedation for diagnostic imaging in children. Pediatr Emerg Care 2012;28(8):796–801.
255. Treston G, Bell A, Cardwell R, Fincher G, Chand D, Cashion G. What is the nature of the emergence phenomenon when using intravenous or intramuscular ketamine for paediatric procedural sedation? Emerg Med Australas 2009;21(4):315–22.
256. Malviya S, Voepel-Lewis T, Prochaska G, Tait AR. Prolonged recovery and delayed side effects of sedation for diagnostic imaging studies in children. Pediatrics 2000; 105(3):E42.
257. Nordt SP, Rangan C, Hardmaslani M, Clark RF, Wendler C, Valente M. Pediatric chloral hydrate poisonings and death following outpatient procedural sedation. J Med Toxicol 2014;10(2):219–22.
258. Walker RW. Pulmonary aspiration in pediatric anesthetic practice in the UK: a prospective survey of specialist pediatric centers over a one-year period. Paediatr Anaesth 2013;23(8):702–11.
259. Babl FE, Puspitadewi A, Barnett P, Oakley E, Spicer M. Preprocedural fasting state and adverse events in children receiving nitrous oxide for procedural sedation and analgesia. Pediatr Emerg Care 2005;21(11):736–43.
260. Roback MG, Bajaj L, Wathen JE, Bothner J. Preprocedural fasting and adverse events in procedural sedation and analgesia in a pediatric emergency department: are they related? Ann Emerg Med 2004;44(5):454–9.
261. Vespasiano M, Finkelstein M, Kurachek S. Propofol sedation: intensivists' experience with 7304 cases in a children's hospital. Pediatrics 2007;120(6). Available at: "www.pediatrics.org/cgi/content/full/120/6/e1411".
262. Warner MA, Warner ME, Warner DO, Warner LO, Warner EJ. Perioperative pulmonary aspiration in infants and children. Anesthesiology 1999;90(1):66–71.
263. Borland LM, Sereika SM, Woelfel SK, et al. Pulmonary aspiration in pediatric patients during general anesthesia: incidence and outcome. J Clin Anesth 1998;10(2):95–102.
264. Agrawal D, Manzi SF, Gupta R, Krauss B. Preprocedural fasting state and adverse events in children undergoing procedural sedation and analgesia in a pediatric emergency department. Ann Emerg Med 2003;42(5):636–46.
265. Green SM. Fasting is a consideration—not a necessity—for emergency department procedural sedation and analgesia. Ann Emerg Med 2003;42(5):647–50.
266. Green SM, Krauss B. Pulmonary aspiration risk during emergency department procedural sedation—an examination of the role of fasting and sedation depth. Acad Emerg Med 2002;9(1):35–42.
267. Treston G. Prolonged pre-procedure fasting time is unnecessary when using titrated intravenous ketamine for paediatric procedural sedation. Emerg Med Australas 2004;16(2):145–150.
268. Pitetti RD, Singh S, Pierce MC. Safe and efficacious use of procedural sedation and analgesia by nonanesthesiologists in a pediatric emergency department. Arch Pediatr Adolesc Med 2003;157(11):1090–6.
269. Thorpe RJ, Benger J. Pre-procedural fasting in emergency sedation. Emerg Med J 2010;27(4):254–61.
270. Paris PM, Yealy DM. A procedural sedation and analgesia fasting consensus advisory: one small step for emergency medicine, one giant challenge remaining. Ann Emerg Med 2007;49(4):465–7.
271. American Society of Anesthesiologists Committee. Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures: an updated report by the American Society of Anesthesiologists Committee on Standards and Practice Parameters. Anesthesiology 2011;114(3):495–511.
272. Mace SE, Brown LA, Francis L, et al. Clinical policy: Critical issues in the sedation of pediatric patients in the emergency department. Ann Emerg Med 2008;51:378–99.

273. Green SM, Roback MG, Miner JR, Burton JH, Krauss B. Fasting and emergency department procedural sedation and analgesia: a consensus based clinical practice advisory. Ann Emerg Med 2007;49(4):454–61.
274. Duchicela S, Lim A. Pediatric nerve blocks: an evidence-based approach. Pediatr Emerg Med Pract 2013;10(10): 1–19; quiz: 19–20.
275. Beach ML, Cohen DM, Gallagher SM, Cravero JP. Major adverse events and relationship to nil per os status in pediatric sedation/anesthesia outside the operating room: a report of the Pediatric Sedation Research Consortium. Anesthesiology 2016;124(1):80–8.
276. Green SM, Krauss B. Ketamine is a safe, effective, and appropriate technique for emergency department paediatric procedural sedation. Emerg Med J 2004;21(3):271–2.
277. American Academy of Pediatrics Committee on Pediatric Emergency Medicine. The use of physical restraint interventions for children and adolescents in the acute care setting. Pediatrics 1997;99(3):497–8.
278. American Academy of Pediatrics Committee on Child Abuse and Neglect. Behavior management of pediatric dental patients. Pediatrics 1992;90(4):651–2.
279. American Academy of Pediatric Dentistry. Guideline on protective stabilization for pediatric dental patients. Pediatr Dent 2013;35(5):E169–E173.
280. Loo CY, Graham RM, Hughes CV. Behaviour guidance in dental treatment of patients with autism spectrum disorder. Int J Paediatr Dent 2009;19(6):390–8.
281. McWhorter AG, Townsend JA; American Academy of Pediatric Dentistry. Behavior symposium workshop A report—current guidelines/revision. Pediatr Dent 2014; 36(2):152–3.
282. American Society of Anesthesiologists CoSaPP. Practice advisory for preanesthesia evaluation an updated report by the American Society of Anesthesiologists Task Force on Preanesthesia Evaluation. Anesthesiology 2012;116: 1–17.
283. Gorski JC, Huang SM, Pinto A, et al. The effect of echinacea (Echinacea purpurea root) on cytochrome P450 activity in vivo. Clin Pharmacol Ther 2004;75(1):89–100.
284. Hall SD, Wang Z, Huang SM, et al. The interaction between St John's wort and an oral contraceptive. Clin Pharmacol Ther 2003;74(6):525–35.
285. Markowitz JS, Donovan JL, DeVane CL, et al. Effect of St John's wort on drug metabolism by induction of cytochrome P450 3A4 enzyme. JAMA 2003;290(11):1500–4.
286. Spinella M. Herbal medicines and epilepsy: the potential for benefit and adverse effects. Epilepsy Behav 2001;2(6): 524–32.
287. Wang Z, Gorski JC, Hamman MA, Huang SM, Lesko LJ, Hall SD. The effects of St John's wort (Hypericum perforatum) on human cytochrome P450 activity. Clin Pharmacol Ther 2001;70(4):317–26.
288. Xie HG, Kim RB. St John's wortassociated drug interactions: short-term inhibition and long-term induction? Clin Pharmacol Ther 2005;78(1):19–24
289. Chen XW, Sneed KB, Pan SY, et al. Herbdrug interactions and mechanistic and clinical considerations. Curr Drug Metab 2012;13(5):640–651
290. Chen XW, Serag ES, Sneed KB, et al. Clinical herbal interactions with conventional drugs: from molecules to maladies. Curr Med Chem 2011;18(31):4836–50.
291. Shi S, Klotz U. Drug interactions with herbal medicines. Clin Pharmacokinet 2012;51(2):77–104.
292. Saxena A, Tripathi KP, Roy S, Khan F, Sharma A. Pharmacovigilance: effects of herbal components on human drugs interactions involving cytochrome P450. Bioinformation 2008;3(5):198–204.
293. Yang X, Salminen WF. Kava extract, an herbal alternative for anxiety relief, potentiates acetaminophen-induced cyto-toxicity in rat hepatic cells. Phytomedicine 2011;18 (7):592–600
294. Teschke R. Kava hepatotoxicity: pathogenetic aspects and prospective considerations. Liver Int 2010;30(9):1270–9.
295. Izzo AA, Ernst E. Interactions between herbal medicines and prescribed drugs: an updated systematic review. Drugs 2009;69(13):1777-98.
296. Ang-Lee MK, Moss J, Yuan CS. Herbal medicines and perioperative care. JAMA 2001;286(2):208-16.
297. Abebe W. Herbal medication: potential for adverse interactions with analgesic drugs. J Clin Pharm Ther 2002;27 (6):391-401.
298. Mooiman KD, Maas-Bakker RF, Hendrikx JJ, et al. The effect of complementary and alternative medicines on CYP3A4-mediated metabolism of three different substrates: 7-benzyloxy-4-trifluoromethyl-coumarin, midazolam and docetaxel. J Pharm Pharmacol 2014;66(6): 865-74.
299. Carrasco MC, Vallejo JR, Pardo-de-Santayana M, Peral D, Martín MA, Altimiras J. Interactions of Valeriana officinalis L. and Passifl ora incarnata L. in a patient treated with lorazepam. Phytother Res 2009;23(12):1795-6.
300. von Rosensteil NA, Adam D. Macrolide antibacterials: drug interactions of clinical significance. Drug Saf 1995; 13(2):105-22.
301. Hiller A, Olkkola KT, Isohanni P, Saarnivaara L. Unconsciousness associated with midazolam and erythromycin. Br J Anaesth 1990;65(6):826-8.
302. Mattila MJ, Idänpään-Heikkilä JJ, Törnwall M, Vanakoski J. Oral single doses of erythromycin and roxithromycin may increase the effects of midazolam on human performance. Pharmacol Toxicol 1993;73(3):180-5.
303. Olkkola KT, Aranko K, Luurila H, et al. A potentially hazardous interaction between erythromycin and midazolam. Clin Pharmacol Ther 1993;53(3):298-305.
304. Senthilkumaran S, Subramanian PT. Prolonged sedation related to erythromycin and midazolam interaction: a word of caution. Indian Pediatr 2011;48(11):909.

305. Flockhart DA, Oesterheld JR. Cytochrome P450-mediated drug interactions. Child Adolesc Psychiatr Clin N Am 2000;9(1):43-76.
306. Yuan R, Flockhart DA, Balian JD. Pharmacokinetic and pharmacodynamic consequences of metabolism-based drug interactions with alprazolam, midazolam, and triazolam. J Clin Pharmacol 1999;39(11):1109-25.
307. Young B. Review: mixing new cocktails: drug interactions in antiretroviral regimens. AIDS Patient Care STDS 2005;19(5):286-97.
308. Gonçalves LS, Gonçalves BM, de Andrade MA, Alves FR, Junior AS. Drug interactions during periodontal therapy in HIV-infected subjects. Mini Rev Med Chem 2010; 10(8):766-72.
309. Brown KC, Paul S, Kashuba AD. Drug interactions with new and investigational antiretrovirals. Clin Pharmacokinet 2009;48(4):211-41.
310. Pau AK. Clinical management of drug interaction with antiretroviral agents. Curr Opin HIV AIDS. 2008;3(3): 319-24.
311. Moyal WN, Lord C, Walkup JT. Quality of life in children and adolescents with autism spectrum disorders: what is known about the effects of pharmacotherapy? Paediatr Drugs 2014;16(2):123-8.
312. van den Anker JN. Developmental pharmacology. Dev Disabil Res Rev 2010;16(3):233-8.
313. Pichini S, Papaseit E, Joya X, et al. Pharmacokinetics and therapeutic drug monitoring of psychotropic drugs in pediatrics. Ther Drug Monit 2009;31(3):283–318.
314. Tibussek D, Distelmaier F, Schönberger S, Göbel U, Mayatepek E. Antiepileptic treatment in paediatric oncology—an interdisciplinary challenge. Klin Padiatr 2006;218 (6):340-9.
315. Wilkinson GR. Drug metabolism and variability among patients in drug response. N Engl J Med 2005;352(21): 2211-21.
316. Salem F, Rostami-Hodjegan A, Johnson TN. Do children have the same vulnerability to metabolic drug–drug interactions as adults? A critical analysis of the literature. J Clin Pharmacol 2013;53(5):559-66.
317. Funk RS, Brown JT, Abdel-Rahman SM. Pediatric pharmacokinetics: human development and drug disposition. Pediatr Clin North Am 2012;59(5):1001-16.
318. Anderson BJ. My child is unique: the pharmacokinetics are universal. Paediatr Anaesth 2012;22(6):530-8.
319. Elie V, de Beaumais T, Fakhoury M, Jacqz-Aigrain E. Pharmacogenetics and individualized therapy in children: immunosuppressants, antidepressants, anticancer and anti-inflammatory drugs. Pharmacogenomics 2011;12(6): 827-43.
320. Chen ZR, Somogyi AA, Reynolds G, Bochner F. Disposition and metabolism of codeine after single and chronic doses in one poor and seven extensive metabolisers. Br J Clin Pharmacol 1991;31(4):381-90.
321. Gasche Y, Daali Y, Fathi M, et al. Codeine intoxication associated with ultrarapid CYP2D6 metabolism. N Engl J Med 2004;351(27):2827-31.
322. Kirchheiner J, Schmidt H, Tzvetkov M, et al. Pharmacokinetics of codeine and its metabolite morphine in ultrarapid metabolizers due to CYP2D6 duplication. Pharmacogenomics J 2007;7(4):257-65.
323. Voronov P, Przybylo HJ, Jagannathan N. Apnea in a child after oral codeine: a genetic variant—an ultra-rapid metabolizer. Paediatr Anaesth 2007;17(7):684-7.
324. Kelly LE, Rieder M, van den Anker J, et al. More codeine fatalities after tonsillectomy in North American children. Pediatrics 2012;129(5). Available at: "www.pediatrics.org/cgi/content/full/129/5/e1343".
325. Farber JM. Clinical practice guideline: diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics 2002;110(6):1255–7; author reply: 1255-7.
326. Schechter MS; Section on Pediatric Pulmonology, Subcommittee on Obstructive Sleep Apnea Syndrome. Technical report: diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics 2002;109 (4):e69. Available at: "www.pediatrics.org/cgi/content/full/109/4/e69".
327. Marcus CL, Brooks LJ, Draper KA, et al; American Academy of Pediatrics. Diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics 2012; 130(3):576-84.
328. Coté CJ, Posner KL, Domino KB. Death or neurologic injury after tonsillectomy in children with a focus on obstructive sleep apnea: Houston, we have a problem! Anesth Analg 2014;118(6):1276-83.
329. Wheeler M, Coté CJ. Preoperative pregnancy testing in a tertiary care children's hospital: a medicolegal conundrum. J Clin Anesth 1999;11(1):56-63.
330. Neuman G, Koren G. Safety of procedural sedation in pregnancy. J Obstet Gynaecol Can 2013;35(2):168-73.
331. Larcher V. Developing guidance for checking pregnancy status in adolescent girls before surgical, radiological or other procedures. Arch Dis Child 2012;97(10):857-60.
332. August DA, Everett LL. Pediatric ambulatory anesthesia. Anesthesiol Clin 2014;32(2):411-29.
333. Maxwell LG. Age-associated issues in preoperative evaluation, testing, and planning: pediatrics. Anesthesiol Clin North America 2004;22(1):27-43.
334. Davidson AJ. Anesthesia and neurotoxicity to the developing brain: the clinical relevance. Paediatr Anaesth 2011; 21(7):716-21.
335. Reddy SV. Effect of general anesthetics on the developing brain. J Anaesthesiol Clin Pharmacol 2012;28(1):6-10.
336. Nemergut ME, Aganga D, Flick RP. Anesthetic neurotoxicity: what to tell the parents? Paediatr Anaesth 2014; 24(1):120-6.
337. Olsen EA, Brambrink AM. Anesthesia for the young child undergoing ambulatory procedures: current concerns regarding harm to the developing brain. Curr Opin Anaesthesiol 2013;26(6):677-84.

338. Green SM, Coté CJ. Ketamine and neurotoxicity: clinical perspectives and implications for emergency medicine. Ann Emerg Med 2009;54(2):181-90.
339. Brown KA, Laferrière A, Moss IR. Recurrent hypoxemia in young children with obstructive sleep apnea is associated with reduced opioid requirement for analgesia. Anesthesiology 2004;100(4):806-10; discussion: 5A.
340. Moss IR, Brown KA, Laferrière A. Recurrent hypoxia in rats during development increases subsequent respiratory sensitivity to fentanyl. Anesthesiology 2006;105(4): 715-8.
341. Litman RS, Kottra JA, Berkowitz RJ, Ward DS. Upper airway obstruction during midazolam/nitrous oxide sedation in children with enlarged tonsils. Pediatr Dent 1998;20 (5):318-20.
342. Fishbaugh DF, Wilson S, Preisch JW, Weaver JM II. Relationship of tonsil size on an airway blockage maneuver in children during sedation. Pediatr Dent 1997;19(4): 277-81.
343. Heinrich S, Birkholz T, Ihmsen H, Irouschek A, Ackermann A, Schmidt J. Incidence and predictors of difficult laryngoscopy in 11,219 pediatric anesthesia procedures. Paediatr Anaesth 2012;22(8):729-36.
344. Kumar HV, Schroeder JW, Gang Z, Sheldon SH. Mallampati score and pediatric obstructive sleep apnea. J Clin Sleep Med 2014;10(9):985-90.
345. Anderson BJ, Meakin GH. Scaling for size: some implications for paediatric anaesthesia dosing. Paediatr Anaesth 2002;12(3):205-19.
346. Ramsay MA, Savege TM, Simpson BR, Goodwin R. Controlled sedation with alphaxalone-alphadolone. BMJ 1974;2(5920):656-9.
347. Agrawal D, Feldman HA, Krauss B, Waltzman ML. Bispectral index monitoring quantifies depth of sedation during emergency department procedural sedation and analgesia in children. Ann Emerg Med 2004;43(2):247-55.
348. Cravero JP, Blike GT, Surgenor SD, Jensen J. Development and validation of the Dartmouth Operative Conditions Scale. Anesth Analg 2005;100(6):1614-21.
349. Mayers DJ, Hindmarsh KW, Sankaran K, Gorecki DK, Kasian GF. Chloral hydrate disposition following single-dose administration to critically ill neonates and children. Dev Pharmacol Ther 1991;16(2):71-7.
350. Terndrup TE, Dire DJ, Madden CM, Davis H, Cantor RM, Gavula DP. A prospective analysis of intramuscular meperidine, promethazine, and chlorpromazine in pediatric emergency department patients. Ann Emerg Med 1991;20(1):31-5.
351. Macnab AJ, Levine M, Glick N, Susak L, Baker-Brown G. A research tool for measurement of recovery from sedation: the Vancouver Sedative Recovery Scale. J Pediatr Surg 1991;26(11):1263-7.
352. Chernik DA, Gillings D, Laine H, et al. Validity and reliability of the Observer's Assessment of Alertness/Sedation Scale: study with intravenous midazolam. J Clin Psychopharmacol 1990;10(4):244-51.
353. Bagian JP, Lee C, Gosbee J, et al. Developing and deploying a patient safety program in a large health care delivery system: you can't fix what you don't know about. Jt Comm J Qual Improv 2001;27(10):522-32.
354. May T, Aulisio MP. Medical malpractice, mistake prevention, and compensation. Kennedy Inst Ethics J 2001;11 (2):135-46.
355. Kazandjian VA. When you hear hoofs, think horses, not zebras: an evidence-based model of health care accountability. J Eval Clin Pract 2002;8(2):205-13.
356. Connor M, Ponte PR, Conway J. Multidisciplinary approaches to reducing error and risk in a patient care setting. Crit Care Nurs Clin North Am 2002;14(4):359–367, viii.
357. Gosbee J. Human factors engineering and patient safety. Qual Saf Health Care 2002;11(4):352-4.
358. Tuong B, Shnitzer Z, Pehora C, et al. The experience of conducting Mortality and Morbidity reviews in a pediatric interventional radiology service: a retrospective study. J Vasc Interv Radiol 2009;20(1):77-86.
359. Tjia I, Rampersad S, Varughese A, et al. Wake Up Safe and root cause analysis: quality improvement in pediatric anesthesia. Anesth Analg 2014;119(1):122-36.
360. Bhatt M, Kennedy RM, Osmond MH, et al. Consensus Panel on Sedation Research of Pediatric Emergency Research Canada (PERC); Pediatric Emergency Care Applied Research Network (PECARN). Consensus-based recommendations for standardizing terminology and reporting adverse events for emergency department procedural sedation and analgesia in children. Ann Emerg Med 2009; 53(4):426-35.e4.
361. Barker SJ, Hyatt J, Shah NK, Kao YJ. The effect of sensor malpositioning on pulse oximeter accuracy during hypoxemia. Anesthesiology 1993;79(2):248-54.
362. Kelleher JF, Ruff RH. The penumbra effect: vasomotion-dependent pulse oximeter artifact due to probe malposition. Anesthesiology 1989;71(5):787-91.
363. Reeves ST, Havidich JE, Tobin DP. Conscious sedation of children with propofol is anything but conscious. Pediatrics 2004;114(1):e74-6. Available at: "www.pediatrics.org/cgi/content/full/114/1/e74".
364. Maher EN, Hansen SF, Heine M, Meers H, Yaster M, Hunt EA. Knowledge of procedural sedation and analgesia of emergency medicine physicians. Pediatr Emerg Care 2007;23(12):869-76.
365. Fehr JJ, Boulet JR, Waldrop WB, Snider R, Brockel M, Murray DJ. Simulationbased assessment of pediatric anesthesia skills. Anesthesiology 2011;115(6):1308-15.
366. McBride ME, Waldrop WB, Fehr JJ, Boulet JR, Murray DJ. Simulation in pediatrics: the reliability and validity of a multiscenario assessment. Pediatrics 2011;128(2): 335-43.
367. Fehr JJ, Honkanen A, Murray DJ. Simulation in pediatric anesthesiology. Paediatr Anaesth 2012;22(10):988-94.

368. Martinez MJ, Siegelman L. The new era of pretracheal/precordial stethoscopes. Pediatr Dent 1999;21(7):455-7.
369. Biro P. Electrically amplified precordial stethoscope. J Clin Monit 1994;10(6):410-2.
370. Philip JH, Raemer DB. An electronic stethoscope is judged better than conventional stethoscopes for anesthesia monitoring. J Clin Monit 1986;2(3):151-4.
371. Hochberg MG, Mahoney WK. Monitoring of respiration using an amplified pretracheal stethoscope. J Oral Maxillofac Surg 1999;57(7):875-6.
372. Fredette ME, Lightdale JR. Endoscopic sedation in pediatric practice. Gastrointest Endosc Clin N Am 2008;18 (4):739–751, ix.
373. Deitch K, Chudnofsky CR, Dominici P. The utility of supplemental oxygen during emergency department procedural sedation and analgesia with midazolam and fentanyl: a randomized, controlled trial. Ann Emerg Med 2007;49(1):1-8.
374. Burton JH, Harrah JD, Germann CA, Dillon DC. Does end-tidal carbon dioxide monitoring detect respiratory events prior to current sedation monitoring practices? Acad Emerg Med 2006;13(5):500-4.
375. Wilson S, Farrell K, Griffen A, Coury D. Conscious sedation experiences in graduate pediatric dentistry programs. Pediatr Dent 2001;23(4):307-14.
376. Allegaert K, van den Anker JN. Clinical pharmacology in neonates: small size, huge variability. Neonatology 2014; 105(4):344-9.
377. Coté CJ, Zaslavsky A, Downes JJ, et al. Postoperative apnea in former preterm infants after inguinal herniorrhaphy: a combined analysis. Anesthesiology 1995;82(4): 809-22.
378. Havidich JE, Beach M, Dierdorf SF, Onega T, Suresh G, Cravero JP. Preterm versus term children: analysis of sedation/anesthesia adverse events and longitudinal risk. Pediatrics 2016;137(3):1-9.
379. Nasr VG, Davis JM. Anesthetic use in newborn infants: the urgent need for rigorous evaluation. Pediatr Res 2015; 78(1):2-6.
380. Sinner B, Becke K, Engelhard K. General anaesthetics and the developing brain: an overview. Anaesthesia 2014;69 (9):1009-22.
381. Yu CK, Yuen VM, Wong GT, Irwin MG. The effects of anaesthesia on the developing brain: a summary of the clinical evidence. F1000 Res 2013;2:166.
382. Davidson A, Flick RP. Neurodevelopmental implications of the use of sedation and analgesia in neonates. Clin Perinatol 2013;40(3):559-73.
383. Lönnqvist PA. Toxicity of local anesthetic drugs: a pediatric perspective. Paediatr Anaesth 2012;22(1):39-43.
384. Wahl MJ, Brown RS. Dentistry's wonder drugs: local anesthetics and vasoconstrictors. Gen Dent 2010;58(2): 114-23; quiz: 124-5.
385. Bernards CM, Hadzic A, Suresh S, Neal JM. Regional anesthesia in anesthetized or heavily sedated patients. Reg Anesth Pain Med 2008;33(5):449-60.
386. Ecoffey C. Pediatric regional anesthesia—update. Curr Opin Anaesthesiol 2007;20(3):232-5.
387. Aubuchon RW. Sedation liabilities in pedodontics. Pediatr Dent 1982;4:171-80.
388. Fitzmaurice LS, Wasserman GS, Knapp JF, Roberts DK, Waeckerle JF, Fox M. TAC use and absorption of cocaine in a pediatric emergency department. Ann Emerg Med 1990;19(5):515-8.
389. Tipton GA, DeWitt GW, Eisenstein SJ. Topical TAC (tetracaine, adrenaline, cocaine) solution for local anesthesia in children: prescribing inconsistency and acute toxicity. South Med J 1989;82(11):1344-6.
390. Gunter JB. Benefit and risks of local anesthetics in infants and children. Paediatr Drugs 2002;4(10):649-72.
391. Resar LM, Helfaer MA. Recurrent seizures in a neonate after lidocaine administration. J Perinatol 1998;18(3): 193-5.
392. Yagiela JA. Local anesthetics. In: Yagiela JA, Dowd FJ, Johnson BS, Mariotti AJ, Neidle EA, eds. Pharmacology and Therapeutics for Dentistry. 6th ed. St. Louis, MO: Mosby, Elsevier; 2011:246-65.
393. Haas DA. An update on local anesthetics in dentistry. J Can Dent Assoc 2002;68(9):546-51.
394. Malamed SF. Anesthetic considerations in dental specialties. In: Malamed SF, ed. Handbook of Local Anesthesia. 6th ed. St. Louis, MO: Elsevier; 2013:277-91.
395. Malamed SF. The needle. In: Malamed SF, ed. Handbook of Local Anesthetics. 6th ed. St Louis, MO: Elsevier; 2013: 92-100.
396. Malamed SF. Pharmacology of local anesthetics. In: Malamed SF, ed. Handbook of Local Anesthesia. 6th ed. St. Louis, MO: Elsevier; 2013:25-38.
397. Ram D, Amir E. Comparison of articaine 4% and lidocaine 2% in paediatric dental patients. Int J Paediatr Dent 2006;16(4):252-6.
398. Jakobs W, Ladwig B, Cichon P, Ortel R, Kirch W. Serum levels of articaine 2% and 4% in children. Anesth Prog 1995;42(3–4):113-5.
399. Wright GZ, Weinberger SJ, Friedman CS, Plotzke OB. Use of articaine local anesthesia in children under 4 years of age—a retrospective report. Anesth Prog 1989;36(6): 268-71.
400. Malamed SF, Gagnon S, Leblanc D. A comparison between articaine HCl and lidocaine HCl in pediatric dental patients. Pediatr Dent 2000;22(4):307-11.
401. American Academy of Pediatric Dentistry, Council on Clinical Affairs. Guidelines on use of local anesthesia for pediatric dental patients. Chicago, IL: American Academy of Pediatric Dentistry; 2015. Available at: "http://www.aapd.org/media/policies_guidelines/g_localanesthesia.pdf". Accessed May 27, 2016.
402. Ludot H, Tharin JY, Belouadah M, Mazoit JX, Malinovsky JM. Successful resuscitation after ropivacaine and lidocaine-induced ventricular arrhythmia following posterior lumbar plexus block in a child. Anesth Analg 2008; 106(5):1572-4.

403. Eren CS, Tasyurek T, Guneysel O. Intralipid emulsion treatment as an antidote in lipophilic drug intoxications: a case series. Am J Emerg Med 2014;32(9):1103-8.
404. Evans JA, Wallis SC, Dulhunty JM, Pang G. Binding of local anaesthetics to the lipid emulsion Clinoleic™ 20%. Anaesth Intensive Care 2013;41(5):618-22.
405. Presley JD, Chyka PA. Intravenous lipid emulsion to reverse acute drug toxicity in pediatric patients. Ann Pharmacother 2013;47(5):735-43.
406. Li Z, Xia Y, Dong X, et al. Lipid resuscitation of bupivacaine toxicity: long-chain triglyceride emulsion provides benefits over long- and medium-chain triglyceride emulsion. Anesthesiology 2011;115(6):1219-28.
407. Maher AJ, Metcalfe SA, Parr S. Local anaesthetic toxicity. Foot 2008;18(4):192-7.
408. Corman SL, Skledar SJ. Use of lipid emulsion to reverse local anesthetic-induced toxicity. Ann Pharmacother 2007;41(11):1873-7.
409. Litz RJ, Popp M, Stehr SN, Koch T. Successful resuscitation of a patient with ropivacaine-induced asystole after axillary plexus block using lipid infusion. Anaesthesia 2006; 61(8):800-1.
410. Raso SM, Fernandez JB, Beobide EA, Landaluce AF. Methemoglobinemia and CNS toxicity after topical application of EMLA to a 4-year-old girl with molluscum contagiosum. Pediatr Dermatol 2006;23(6):592-3.
411. Larson A, Stidham T, Banerji S, Kaufman J. Seizures and methemoglobinemia in an infant after excessive EMLA application. Pediatr Emerg Care 2013;29(3):377-9.
412. Tran AN, Koo JY. Risk of systemic toxicity with topical lidocaine/prilocaine: a review. J Drugs Dermatol 2014; 13(9):1118-22.
413. Young KD. Topical anaesthetics: what's new? Arch Dis Child Educ Pract Ed 2015;100(2):105-10.
414. Gaufberg SV, Walta MJ, Workman TP. Expanding the use of topical anesthesia in wound management: sequential layered application of topical lidocaine with epinephrine. Am J Emerg Med 2007;25(4):379-84.
415. Eidelman A, Weiss JM, Baldwin CL, Enu IK, McNicol ED, Carr DB. Topical anaesthetics for repair of dermal laceration. Cochrane Database Syst Rev 2011;6:CD005364.
416. Next-generation pulse oximetry. Health Devices 2003; 32(2):49-103.
417. Barker SJ. "Motion-resistant"pulse oximetry: a comparison of new and old models. Anesth Analg 2002;95(4): 967-72.
418. Malviya S, Reynolds PI, Voepel-Lewis T, et al. False alarms and sensitivity of conventional pulse oximetry versus the Masimo SET technology in the pediatric postanesthesia care unit. Anesth Analg 2000;90(6):1336-40.
419. Barker SJ, Shah NK. Effects of motion on the performance of pulse oximeters in volunteers. Anesthesiology 1996;85(4):774-81.
420. Barker SJ, Shah NK. The effects of motion on the performance of pulse oximeters in volunteers (revised publication). Anesthesiology 1997;86(1):101-8.
421. Colman Y, Krauss B. Microstream capnograpy technology: a new approach to an old problem. J Clin Monit Comput 1999;15(6):403-9.
422. Wright SW. Conscious sedation in the emergency department: the value of capnography and pulse oximetry. Ann Emerg Med 1992;21(5):551-5.
423. Roelofse J. Conscious sedation: making our treatment options safe and sound. SADJ 2000;55(5):273-6.
424. Wilson S, Creedon RL, George M, Troutman K. A history of sedation guidelines: where we are headed in the future. Pediatr Dent 1996;18(3):194-9.
425. Miner JR, Heegaard W, Plummer D. End-tidal carbon dioxide monitoring during procedural sedation. Acad Emerg Med 2002;9(4):275-80.
426. Vascello LA, Bowe EA. A case for capnographic monitoring as a standard of care. J Oral Maxillofac Surg 1999; 57(11):1342-7.
427. Coté CJ, Wax DF, Jennings MA, Gorski CL, Kurczak-Klippstein K. Endtidal carbon dioxide monitoring in children with congenital heart disease during sedation for cardiac catheterization by nonanesthesiologists. Paediatr Anaesth 2007;17(7):661-6.
428. Bowdle TA. Depth of anesthesia monitoring. Anesthesiol Clin 2006;24(4):793-822.
429. Rodriguez RA, Hall LE, Duggan S, Splinter WM. The bispectral index does not correlate with clinical signs of inhalational anesthesia during sevoflurane induction and arousal in children. Can J Anaesth 2004;51(5):472-80.
430. Overly FL, Wright RO, Connor FA Jr, Fontaine B, Jay G, Linakis JG. Bispectral analysis during pediatric procedural sedation. Pediatr Emerg Care 2005;21(1):6-11.
431. Mason KP, O'Mahony E, Zurakowski D, Libenson MH. Effects of dexmedetomidine sedation on the EEG in children. Paediatr Anaesth 2009;19(12):1175-83.
432. Malviya S, Voepel-Lewis T, Tait AR, Watcha MF, Sadhasivam S, Friesen RH. Effect of age and sedative agent on the accuracy of bispectral index in detecting depth of sedation in children. Pediatrics 2007;120(3). Available at: "www.pediatrics.org/cgi/content/full/120/3/e461".
433. Sadhasivam S, Ganesh A, Robison A, Kaye R, Watcha MF. Validation of the bispectral index monitor for measuring the depth of sedation in children. Anesth Analg 2006; 102(2):383-8.
434. Messieha ZS, Ananda RC, Hoffman WE, Punwani IC, Koenig HM. Bispectral Index System (BIS) monitoring reduces time to discharge in children requiring intramuscular sedation and general anesthesia for outpatient dental rehabilitation. Pediatr Dent 2004;26(3):256-60.
435. McDermott NB, VanSickle T, Motas D, Friesen RH. Validation of the bispectral index monitor during conscious and deep sedation in children. Anesth Analg 2003;97(1): 39-43.
436. Schmidt AR, Weiss M, Engelhardt T. The paediatric airway: basic principles and current developments. Eur J Anaesthesiol 2014;31(6):293-9.

437. Nagler J, Bachur RG. Advanced airway management. Curr Opin Pediatr 2009;21(3):299-305.
438. Berry AM, Brimacombe JR, Verghese C. The laryngeal mask airway in emergency medicine, neonatal resuscitation, and intensive care medicine. Int Anesthesiol Clin 1998;36(2):91-109.
439. Patterson MD. Resuscitation update for the pediatrician. Pediatr Clin North Am 1999;46(6):1285-303.
440. Diggs LA, Yusuf JE, De Leo G. An update on out-of-hospital airway management practices in the United States. Resuscitation 2014;85(7):885-92.
441. Wang HE, Mann NC, Mears G, Jacobson K, Yealy DM. Out-of-hospital airway management in the United States. Resuscitation 2011;82(4):378-85.
442. Ritter SC, Guyette FX. Prehospital pediatric King LT-D use: a pilot study. Prehosp Emerg Care 2011;15(3):401-4.
443. Selim M, Mowafi H, Al-Ghamdi A, Adu-Gyamfi Y. Intubation via LMA in pediatric patients with difficult airways. Can J Anaesth 1999;46(9):891-3.
444. Munro HM, Butler PJ, Washington EJ. Freeman-Sheldon (whistling face) syndrome: anaesthetic and airway management. Paediatr Anaesth 1997;7(4):345-8.
445. Horton MA, Beamer C. Powered intraosseous insertion provides safe and effective vascular access for pediatric emergency patients. Pediatr Emerg Care 2008;24(6): 347-50.
446. Gazin N, Auger H, Jabre P, et al. Efficacy and safety of the EZ-IO™ intraosseous device: out-of-hospital implementation of a management algorithm for difficult vascular access. Resuscitation 2011;82(1):126-9.
447. Frascone RJ, Jensen J, Wewerka SS, Salzman JG. Use of the pediatric EZ-IO needle by emergency medical services providers. Pediatr Emerg Care 2009;25(5):329-32.
448. Neuhaus D. Intraosseous infusion in elective and emergency pediatric anesthesia: when should we use it? Curr Opin Anaesthesiol 2014;27(3):282-7.
449. Oksan D, Ayfer K. Powered intraosseous device (EZ-IO) for critically ill patients. Indian Pediatr 2013;50(7): 689-91.
450. Santos D, Carron PN, Yersin B, Pasquier M. EZ-IO(®) intraosseous device implementation in a prehospital emergency service: a prospective study and review of the literature. Resuscitation 2013;84(4):440-5.
451. Tan GM. A medical crisis management simulation activity for pediatric dental residents and assistants. J Dent Educ 2011;75(6):782-90.
452. Schinasi DA, Nadel FM, Hales R, Boswinkel JP, Donoghue AJ. Assessing pediatric residents' clinical performance in procedural sedation: a simulation-based needs assessment. Pediatr Emerg Care 2013;29(4):447-52.
453. Rowe R, Cohen RA. An evaluation of a virtual reality airway simulator. Anesth Analg 2002;95(1):62-6.
454. Medina LS, Racadio JM, Schwid HA. Computers in radiology—the sedation, analgesia, and contrast media computerized simulator: a new approach to train and evaluate radiologists' responses to critical incidents. Pediatr Radiol 2000;30(5):299-305.
455. Blike G, Cravero J, Nelson E. Same patients, same critical events—different systems of care, different outcomes: description of a human factors approach aimed at improving the efficacy and safety of sedation/analgesia care. Qual Manag Health Care 2001;10(1):17-36.
456. Reiter DA, Strother CG, Weingart SD. The quality of cardiopulmonary resuscitation using supraglottic airways and intraosseous devices: a simulation trial. Resuscitation 2013;84(1):93-7.
457. Schulte-Uentrop L, Goepfert MS. Anaesthesia or sedation for MRI in children. Curr Opin Anaesthesiol 2010; 23(4):513-7.
458. Schmidt MH, Downie J. Safety first:recognizing and managing the risks to child participants in magnetic resonance imaging research. Account Res 2009;16(3):153-73.
459. Chavhan GB, Babyn PS, Singh M, Vidarsson L, Shroff M. MR imaging at 3.0 T in children: technical differences, safety issues, and initial experience. Radiographics 2009; 29(5):1451-66.
460. Kanal E, Shellock FG, Talagala L. Safety considerations in MR imaging. Radiology 1990;176(3):593-606.
461. Shellock FG, Kanal E. Burns associated with the use of monitoring equipment during MR procedures. J Magn Reson Imaging 1996;6(1):271-2.
462. Shellock FG. Magnetic resonance safety update 2002: implants and devices. J Magn Reson Imaging 2002;16(5): 485-96.
463. Dempsey MF, Condon B, Hadley DM. MRI safety review. Semin Ultrasound CT MR 2002;23(5):392-401.
464. Department of Health and Human Services, Centers for Disease Control and Prevention Criteria for a Recommended Standard: Waste Anesthetic Gases: Occupational Hazards in Hospitals. 2007. Publication 2007-151. Available at: "http://www.cdc.gov/niosh/docs/2007-151/pdfs/2007-151.pdf". Accessed May 27, 2016.
465. O'Sullivan I, Benger J. Nitrous oxide in emergency medicine. Emerg Med J 2003;20(3):214-7.
466. Kennedy RM, Luhmann JD, Luhmann SJ. Emergency department management of pain and anxiety related to orthopedic fracture care: a guide to analgesic techniques and procedural sedation in children. Paediatr Drugs 2004;6(1):11–31.
467. Frampton A, Browne GJ, Lam LT, Cooper MG, Lane LG. Nurse administered relative analgesia using high concentration nitrous oxide to facilitate minor procedures in children in an emergency department. Emerg Med J 2003;20(5):410-3.
468. Everitt I, Younge P, Barnett P. Paediatric sedation in emergency department: what is our practice? Emerg Med (Fremantle) 2002;14(1):62-6.
469. Krauss B. Continuous-flow nitrous oxide: searching for the ideal procedural anxiolytic for toddlers. Ann Emerg Med 2001;37(1):61-2.

470. Otley CC, Nguyen TH. Conscious sedation of pediatric patients with combination oral benzodiazepines and inhaled nitrous oxide. Dermatol Surg 2000;26(11):1041-4.
471. Luhmann JD, Kennedy RM, Jaffe DM, McAllister JD. Continuous-flow delivery of nitrous oxide and oxygen: a safe and cost-effective technique for inhalation analgesia and sedation of pediatric patients. Pediatr Emerg Care 1999;15(6):388-92.
472. Burton JH, Auble TE, Fuchs SM. Effectiveness of 50% nitrous oxide/50% oxygen during laceration repair in children. Acad Emerg Med 1998;5(2):112-7.
473. Gregory PR, Sullivan JA. Nitrous oxide compared with intravenous regional anesthesia in pediatric forearm fracture manipulation. J Pediatr Orthop 1996;16(2):187-91.
474. Hennrikus WL, Shin AY, Klingelberger CE. Self-administered nitrous oxide and a hematoma block for analgesia in the outpatient reduction of fractures in children. J Bone Joint Surg Am 1995;77(3):335-9.
475. Hennrikus WL, Simpson RB, Klingelberger CE, Reis MT. Self-administered nitrous oxide analgesia for pediatric fracture reductions. J Pediatr Orthop 1994;14(4):538-42.
476. Wattenmaker I, Kasser JR, McGravey A. Self-administered nitrous oxide for fracture reduction in children in an emergency room setting. J Orthop Trauma 1990;4(1): 35-8.
477. Gamis AS, Knapp JF, Glenski JA. Nitrous oxide analgesia in a pediatric emergency department. Ann Emerg Med 1989;18(2):177-81.
478. Kalach N, Barbier C, el Kohen R, et al. Tolerance of nitrous oxide-oxygen sedation for painful procedures in emergency pediatrics: report of 600 cases [in French]. Arch Pediatr 2002;9(11):1213-5.
479. Michaud L, Gottrand F, Ganga-Zandzou PS, et al. Nitrous oxide sedation in pediatric patients undergoing gastrointestinal endoscopy. J Pediatr Gastroenterol Nutr 1999; 28(3):310-4.
480. Baskett PJ. Analgesia for the dressing of burns in children: a method using neuroleptanalgesia and Entonox. Postgrad Med J 1972;48(557):138-42.
481. Veerkamp JS, van Amerongen WE, Hoogstraten J, Groen HJ. Dental treatment of fearful children, using nitrous oxide. Part I: treatment times. ASDC J Dent Child 1991; 58(6):453-7.
482. Veerkamp JS, Gruythuysen RJ, van Amerongen WE, Hoogstraten J. Dental treatment of fearful children using nitrous oxide. Part 2: the parent's point of view. ASDC J Dent Child 1992;59(2):115-9.
483. Veerkamp JS, Gruythuysen RJ, van Amerongen WE, Hoogstraten J. Dental treatment of fearful children using nitrous oxide. Part 3: anxiety during sequential visits. ASDC J Dent Child 1993;60(3):175-82.
484. Veerkamp JS, Gruythuysen RJ, Hoogstraten J, van Amerongen WE. Dental treatment of fearful children using nitrous oxide. Part 4: anxiety after two years. ASDC J Dent Child 1993;60(4):372-6.
485. Houpt MI, Limb R, Livingston RL. Clinical effects of nitrous oxide conscious sedation in children. Pediatr Dent 2004;26(1):29-36.
486. Shapira J, Holan G, Guelmann M, Cahan S. Evaluation of the effect of nitrous oxide and hydroxyzine in controlling the behavior of the pediatric dental patient. Pediatr Dent 1992;14(3):167-70.
487. Primosch RE, Buzzi IM, Jerrell G. Effect of nitrous oxide-oxygen inhalation with scavenging on behavioral and physiological parameters during routine pediatric dental treatment. Pediatr Dent 1999;21(7):417-20.
488. McCann W, Wilson S, Larsen P, Stehle B. The effects of nitrous oxide on behavior and physiological parameters during conscious sedation with a moderate dose of chloral hydrate and hydroxyzine. Pediatr Dent 1996;18(1): 35-41.
489. Wilson S, Matusak A, Casamassimo PS, Larsen P. The effects of nitrous oxide on pediatric dental patients sedated with chloral hydrate and hydroxyzine. Pediatr Dent 1998;20(4):253-8.
490. Pedersen RS, Bayat A, Steen NP, Jacobsson ML. Nitrous oxide provides safe and effective analgesia for minor paediatric procedures—a systematic review [abstract]. Dan Med J 2013;60(6):A4627.
491. Lee JH, Kim K, Kim TY, et al. A randomized comparison of nitrous oxide versus intravenous ketamine for laceration repair in children. Pediatr Emerg Care 2012;28(12): 1297-301.
492. Seith RW, Theophilos T, Babl FE. Intranasal fentanyl and highconcentration inhaled nitrous oxide for procedural sedation: a prospective observational pilot study of adverse events and depth of sedation. Acad Emerg Med 2012;19(1):31-6.
493. Klein U, Robinson TJ, Allshouse A. End expired nitrous oxide concentrations compared to flowmeter settings during operative dental treatment in children. Pediatr Dent 2011;33(1):56-62.
494. Litman RS, Kottra JA, Berkowitz RJ, Ward DS. Breathing patterns and levels of consciousness in children during administration of nitrous oxide after oral midazolam pre-medication. J Oral Maxillofac Surg 1997;55(12): 1372-7; discussion: 1378-9.
495. Litman RS, Kottra JA, Verga KA, Berkowitz RJ, Ward DS. Chloral hydrate sedation: the additive sedative and respiratory depressant effects of nitrous oxide. Anesth Analg 1998;86(4):724-8.
496. American Academy of Pediatric Dentistry, Council on Clinical Affairs. Guideline on use of nitrous oxide for pediatric dental patients. Chicago, IL: American Academy of Pediatric Dentistry; 2013. Available at: "http://www.aapd.org/media/policies_guidelines/g_nitrous.pdf". Accessed May 27, 2016.

Supplemental Information

Appendix 1. Recommended Discharge Criteria

1. Cardiovascular function and airway patency are satisfactory and stable.
2. The patient is easily arousable, and protective reflexes are intact.
3. The patient can talk (if age appropriate).
4. The patient can sit up unaided (if age appropriate).
5. For a very young or handicapped child incapable of the usually expected responses, the presedation level of responsiveness or a level as close as possible to the normal level for that child should be achieved.
6. The state of hydration is adequate.

Appendix 2. ASA Physical Status Classification

Class I	A normally healthy patient.
Class II	A patient with mild systemic disease (e.g., controlled reactive airway disease).
Class III	A patient with severe systemic disease (e.g., a child who is actively wheezing).
Class IV	A patient with severe systemic disease that is a constant threat to life (e.g., a child with status asthmaticus).
Class V	A moribund patient who is not expected to survive without the operation (e.g., a patient with severe cardiomyopathy requiring heart transplantation).

Appendix 3. Drugs* That May Be Needed to Rescue a Sedated Patient[44]

Albuterol for inhalation
Ammonia spirits
Atropine
Diphenhydramine
Diazepam
Epinephrine (1:1000, 1:10 000)
Flumazenil
Glucose (25 percent or 50 percent)
Lidocaine (cardiac lidocaine, local infiltration)
Lorazepam
Methylprednisolone
Naloxone
Oxygen
Fosphenytoin
Racemic epinephrine
Rocuronium
Sodium bicarbonate
Succinylcholine

* The choice of emergency drugs may vary according to individual or procedural needs.

Appendix 4. Emergency Equipment† That May Be Needed to Rescue a Sedated Patient‡

Intravenous Equipment

- Assorted IV catheters (e.g., 24-, 22-, 20-, 18-, 16-gauge)
- Tourniquets
- Alcohol wipes
- Adhesive tape
- Assorted syringes (e.g., 1-, 3-, 5-, 10-mL)
- IV tubing
  - Pediatric drip (60 drops/mL)
  - Pediatric burette
  - Adult drip (10 drops/mL)
  - Extension tubing
  - 3-way stopcocks
- IV fluid
  - Lactated Ringer solution
  - Normal saline solution
  - D_5 0.25 normal saline solution
- Pediatric IV boards
- Assorted IV needles (e.g., 25-, 22-, 20-, and 18-gauge)
- Intraosseous bone marrow needle
- Sterile gauze pads

Airway Management Equipment

- Face masks (infant, child, small adult, medium adult, large adult)
- Breathing bag and valve set
- Oropharyngeal airways (infant, child, small adult, medium adult, large adult)
- Nasopharyngeal airways (small, medium, large)
- Laryngeal mask airways (1, 1.5, 2, 2.5, 3, 4, and 5)
- Laryngoscope handles (with extra batteries)
- Laryngoscope blades (with extra light bulbs)
  - Straight (Miller) No. 1, 2, and 3
  - Curved (Macintosh) No. 2 and 3
- Endotracheal tubes (2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, and 6.0 uncuffed and 6.0, 7.0, and 8.0 cuffed)
- Stylettes (appropriate sizes for endotracheal tubes)
- Surgical lubricant
- Suction catheters (appropriate sizes for endotracheal tubes)
- Yankauer-type suction
- Nasogastric tubes
- Nebulizer with medication kits
- Gloves (sterile and nonsterile, latex free)

† The choice of emergency equipment may vary according to individual or procedural needs.

‡ The practitioner is referred to the SOAPME acronym described in the text in preparation for sedating a child for a procedure.

Practice Guidelines for Procedural Moderate Sedation and Analgesia

A Report by the American Society of Anesthesiologists Task Force on Moderate Procedural Sedation and Analgesia, the American Association of Oral and Maxillofacial Surgeons, American College of Cardiology, American College of Emergency Physicians, American College of Radiology, American Dental Association, American Society for Gastrointestinal Endoscopy and American Society of Dentist Anesthesiologists[*]

PRACTICE guidelines are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints, and are not intended to replace local institutional policies. In addition, these practice guidelines are not intended as standards or absolute requirements, and their use cannot guarantee any specific outcome. Practice guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. They provide basic recommendations that are supported by a synthesis and analysis of the current literature, expert and practitioner opinion, open forum commentary, and clinical feasibility data.

[*] Supplemental Digital Content is available for this article. Direct URL citations appear in the printed text and are available in both the HTML and PDF versions of this article. Links to the digital files are provided in the HTML text of this article on the Journal's Web site (www.anesthesiology.org). A complete bibliography used to develop these Guidelines, arranged alphabetically by author, is available as Supplemental Digital Content, http://links.lww.com/ALN/__

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This document replaces the "Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists: an Updated Report by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists," adopted by the ASA in 2001 and published in 2002.[1]

Methodology

Definition of Procedural Moderate Sedation and Analgesia

These Guidelines apply to moderate sedation and analgesia during and after procedures. Sedation and analgesia comprises a continuum of states ranging from minimal sedation (anxiolysis) through general anesthesia, as defined by the American Society of Anesthesiologists and accepted by the Joint Commission *(Table 1)*.[2,3] Level of sedation is entirely independent of the route of administration. Moderate and deep sedation or general anesthesia may be achieved via any route of administration.

These Guidelines specifically apply to the level of sedation corresponding to moderate sedation/analgesia (previously called conscious sedation) which is defined as a drug induced depression of consciousness during which patients respond purposefully† to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway when spontaneous ventilation is adequate.‡ Cardiovascular function is usually maintained. For these Guidelines, analgesia refers to the management of patient pain or discomfort during and after procedures requiring moderate sedation.

Purposes of the Guidelines

The purposes of these Guidelines are to allow clinicians to optimize the benefits of moderate

† Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.
‡ However, as stated in the American Academy of Pediatrics-American Academy of Pediatric Dentistry guidelines on the monitoring and management of pediatric patients during sedation (2016), "in the case of procedures that may themselves cause airway obstruction (e.g., dental or endoscopic), the practitioner must recognize an obstruction and assist the patient in opening the airway."[4]

procedural sedation regardless of site of service; to guide practitioners in appropriate patient selection; to decrease the risk of adverse patient outcomes (*e.g.,* apnea, airway obstruction, respiratory arrest, cardiac arrest, death); encourage sedation education, training and research, and to offer evidence-based data to promote cross-specialty consistency for moderate sedation practice.

Moderate sedation/analgesia provides patient tolerance of unpleasant or prolonged procedures through relief of anxiety, discomfort, and/or pain. If the patient response results in deeper sedation than intended, these sedation practices can be associated with cardiac or respiratory depression that must be rapidly recognized and appropriately managed to avoid the risk of hypoxic brain damage, cardiac arrest, or death. Conversely, inadequate sedation or analgesia can result in undue patient discomfort or patient injury, lack of cooperation, or adverse physiological or psychological responses to stress.

The appropriate choice of agents and techniques for moderate sedation/analgesia is dependent upon the experience, training, and preference of the individual practitioner, requirements or constraints imposed by associated medical issues of the patient or type of procedure, and the risk of producing a deeper level of sedation than anticipated. In some cases, the choice of agents or techniques are limited by federal, state, or municipal regulations or statutes. Because it is not always possible to predict how a specific patient will respond to sedative and analgesic medications, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. For moderate sedation, this implies the ability to manage a compromised airway or hypoventilation, and support cardiovascular function in patients who become hypotensive, hypertensive, bradycardic, or tachycardic.

Focus

These Guidelines focus specifically on the administration of moderate sedation and analgesia for adults and children. The Guidelines exclude patients who are not undergoing a diagnostic or

therapeutic procedure (*e.g.,* postoperative analgesia). Because minimal sedation (anxiolysis) may entail minimal risk, the Guidelines specifically exclude it. Examples of minimal sedation include (1) less than 50% nitrous oxide in oxygen with no other sedative or analgesic medications by any route, or (2) a single, oral sedative or analgesic medication administered in doses appropriate for the unsupervised treatment of anxiety or pain. The Guidelines do not apply to patients receiving deep sedation, general anesthesia or major conduction (*i.e.,* neuraxial) anesthesia, whose care should be provided, medically directed, or supervised by a physician anesthesiologist, the operating practitioner, or another licensed physician with specific training in sedation, anesthesia, and the appropriate rescue techniques. Additional interventions excluded from these Guidelines include but are not limited to: patient-controlled sedation/analgesia, sedatives administered before or during regional and central neuraxis anesthesia, premedication for general anesthesia, interventions without sedatives (*e.g.,* hypnosis, acupuncture), new or rarely administered sedative/analgesics, new or rarely used monitoring or delivery devices, and automated sedative delivery systems.

Application

These Guidelines are intended for use by all providers who perform moderate procedural sedation and analgesia in any inpatient or outpatient setting including but not limited to hospitals, ambulatory procedural centers, hospital-connected or freestanding office practices (*e.g.,* dental, urology or ophthalmology offices), endoscopy suites, plastic surgery suites, radiology suites (magnetic resonance imaging, computed tomography), oral and maxillofacial surgery suites, cardiac catheterization laboratories, oncology clinics, electrophysiology laboratories, interventional radiology laboratories, neurointerventional laboratories, echocardiography laboratories, and evoked auditory testing laboratories. They are intended to serve as a resource for other physicians and patient care personnel who are involved in the care of these patients, including those involved in local policy development.

Task Force Members and Consultants

These Guidelines were developed by an ASA appointed Task Force of 15 members, consisting of physician anesthesiologists in both private and academic practices from various geographic areas of the United States, a cardiologist, dentist anesthesiologist, emergency physician, gastroenterologist, oral/maxillofacial surgeon, radiologist, an ASA staff methodologist, and two consulting methodologists for the ASA Committee on Standards and Practice Parameters.

The Task Force developed these Guidelines by means of a seven-step process. First, criteria for evidence associated with moderate sedation and analgesia techniques were established. Second, original published research studies relevant to the Guidelines were reviewed and analyzed; only articles relevant to the administration of moderate sedation were evaluated. Third, a panel of expert consultants was asked to (1) participate in opinion surveys on the effectiveness and safety of various methods and interventions that might be used during sedation/analgesia and (2) review and comment on a draft of the Guidelines developed by the Task Force. Fourth, survey opinions about the Guideline recommendations were solicited from a random sample of active members of the ASA and participating medical specialty societies. Fifth, the Task Force held open forums at major national meetings to solicit input on its draft recommendations.[§] National organizations representing specialties whose members typically provide moderate sedation were invited to participate in the open forums. Sixth, the consultants were surveyed to assess their opinions on the feasibility of implementing the Guidelines. Seventh, all available information was used to build consensus within the Task Force to finalize the Guidelines.

[§] Council on Dental Education and Licensure: Anesthesia Committee Meeting, April 20, 2017; Combined Annual Meeting of The Southwest Society of Oral and Maxillofacial Surgeons, The Texas Society of Oral & Maxillofacial Surgeons, Midwestern Chapter of Oral and Maxillofacial Surgeons & The Oklahoma Society of Oral and Maxillofacial Surgeons, April 21 2017, Scottsdale, Arizona; Society for Ambulatory Anesthesia 32nd Annual Meeting, May 5, 2017, Scottsdale, Arizona; International Anesthesia Research Society 2017 Annual Meeting and International Science Symposium, Washington, D.C., May 7, 2017; and .....

Availability and Strength of Evidence

Preparation of these updated Guidelines followed a rigorous methodological process. Evidence was obtained from two principal sources: scientific evidence and opinion-based evidence (appendix 2).

Scientific Evidence. Scientific evidence used in the development of these Guidelines is based on cumulative findings from literature published in peer-reviewed journals. Literature citations are obtained from healthcare databases, direct internet searches, Task Force members, liaisons with other organizations, and manual searches of references located in reviewed articles.

Findings from the aggregated literature are reported in the text of these Guidelines by evidence category, level, and direction and in appendix 2. Evidence categories refer specifically to the strength and quality of the *research design* of the studies. Category A evidence represents results obtained from randomized controlled trials (RCTs) and Category B evidence represents observational results obtained from nonrandomized study designs or RCTs without pertinent comparison groups. When available, Category A evidence is given precedence over Category B evidence for any particular outcome. These evidence categories are further divided into evidence levels. Evidence levels refer specifically to the strength and quality of the summarized study *findings* (*i.e.*, statistical findings, type of data, and the number of studies reporting/replicating the findings). In this document, only the highest level of evidence is included in the summary report for each intervention-outcome pair, including a directional designation of benefit, harm, or equivocality.

Category A. RCTs report comparative findings between clinical interventions for specified outcomes. Statistically significant ($P < 0.01$) outcomes are designated as either beneficial (B) or harmful (H) for the patient; statistically nonsignificant findings are designated as equivocal (E).

Level 1: The literature contains a sufficient number of RCTs to conduct meta-analysis,** and meta-analytic findings from these aggregated studies are reported as evidence.

Level 2: The literature contains multiple RCTs, but the number of RCTs is not sufficient to conduct a viable meta-analysis for the purpose of these Guidelines. Findings from these RCTs are reported separately as evidence.

Level 3: The literature contains a single RCT, and findings from this study are reported as evidence.

Category B. Observational studies or RCTs without pertinent comparison groups may permit *inference* of beneficial or harmful relationships among clinical interventions and clinical outcomes. Inferred findings are given a directional designation of beneficial (B), harmful (H) or equivocal (E). For studies that report statistical findings, the threshold for significance is $p < 0.01$.

Level 1: The literature contains observational comparisons (*e.g.,* cohort, case-control research designs) with comparative statistics between clinical interventions for a specified clinical outcome.

Level 2: The literature contains noncomparative observational studies with associative statistics (*e.g.,* relative risk, correlation, sensitivity and specificity).

Level 3: The literature contains noncomparative observational studies with descriptive statistics (*e.g.,* frequencies, percentages).

Level 4: The literature contains case reports.

Insufficient Literature. The *lack* of sufficient scientific evidence in the literature may occur when the evidence is either unavailable (*i.e.,* no pertinent studies found) or inadequate. Inadequate literature cannot be used to assess relationships among clinical interventions and outcomes because a

** All meta-analyses are conducted by the ASA methodology group. Meta-analyses from other sources are reviewed but not included as evidence in this document. A minimum of 5 independent RCTs are required for meta-analysis.

clear interpretation of findings is not obtained due to methodological concerns (*e.g.,* confounding of study design or implementation) or the study does not meet the criteria for content as defined in the "Focus" of the Guidelines.

Opinion-based Evidence. All opinion-based evidence (*e.g.,* survey data, open forum testimony, internet-based comments, letters, and editorials) relevant to each topic was considered in the development of these Guidelines. However, only the findings obtained from formal surveys are reported in the document.

Opinion surveys were developed by the Task Force to address each clinical intervention identified in the document. Identical surveys were distributed to expert consultants and a random sample of members of the participating organizations.

Category A: Expert Opinion. Survey responses from Task Force–appointed expert consultants are reported in summary form in the text, with a complete listing of consultant survey responses reported in appendix 2.

Category B: Membership Opinion. Survey responses from active ASA members are reported in summary form in the text, with a complete listing of ASA member survey responses reported in appendix 2.

Survey responses from expert and membership sources are recorded using a 5-point scale and summarized based on median values.[††]

Strongly Agree:	Median score of 5 (At least 50% of the responses are 5)
Agree:	Median score of 4 (At least 50% of the responses are 4 or 4 and 5)
Equivocal:	Median score of 3 (At least 50% of the responses are 3, or no other response category or combination of similar categories contain at least 50% of the responses)
Disagree:	Median score of 2 (At least 50% of responses are 2 or 1 and 2)
Strongly Disagree:	Median score of 1 (At least 50% of responses are 1)

[††] When an equal number of categorically distinct responses are obtained, the median value is determined by calculating the arithmetic mean of the two middle values. Ties are calculated by a predetermined formula.

Category C: Informal Opinion. Open forum testimony obtained during development of these Guidelines, Internet-based comments, letters, and editorials are all informally evaluated and discussed during the formulation of Guideline recommendations. When warranted, the Task Force may add educational information or cautionary notes based on this information.

Guidelines

Patient Evaluation

Preprocedure *patient evaluation* consists of the following strategies for reducing sedation-related adverse outcomes: (1) reviewing previous medical records for underlying medical problems (*e.g.,* abnormalities of major organ systems, obesity, obstructive sleep apnea, anatomical airway problems, congenital syndromes with associated medical/surgical issues, respiratory disease, allergies, intestinal inflammation); sedation, anesthesia and surgery history; history of or current problems pertaining to cooperation, pain tolerance or sensitivity to anesthesia or sedation; current medications; extremes of age; psychotropic drug use; use of nonpharmaceuticals (*e.g.,* nutraceuticals); and family history, (2) a focused physical examination, and (3) preprocedure laboratory testing (where indicated).

Literature Findings. Although it is well-accepted clinical practice to review medical records, conduct a physical examination, and review laboratory test results, comparative studies are insufficient to evaluate the periprocedural impact of these activities. Observational studies indicate that some adverse outcomes (*e.g.,* unintended deep sedation, hypoxemia‡‡ or hypotension) may occur in patients with pre-existing medical conditions when moderate sedation/analgesia is administered. These conditions include: (1) extremes of age, ASA status III or higher, and respiratory conditions *(Category B2-H evidence)*[5-7] and (2) obstructive sleep apnea, respiratory

‡‡ Unless otherwise noted in this document, hypoxemia is reported in the literature to be oxygen desaturation to ≤ 90%.

distress syndrome, obesity, allergies, psychotropic drug use, history of gastric bypass surgery, pediatric patients who are pre-cooperative or who have behavior or attention disorders, cardiovascular disorders, history of gastric bypass, and history of long-term benzodiazepine use *(Category B3-H evidence).*[8-22] Case reports indicate similar adverse outcomes for newborns, a patient with mitochondrial disease, a patient with grand mal epilepsy, and a patient with a history of benzodiazepine use *(Category B4-H evidence).*[23-26]

Survey Findings. To be determined

Recommendations for Patient Evaluation.

- Review previous medical records and interview the patient or family to identify:
  - Abnormalities of the major organ systems (*e.g.,* cardiac, renal, pulmonary, neurologic, sleep apnea, metabolic, endocrine).
  - Adverse experience with sedation/analgesia as well as regional and general anesthesia.
  - Current medications, potential drug interactions, drug allergies and nutraceuticals.
  - History of tobacco, alcohol or substance use or abuse.
  - Frequent or repeated exposure to sedation/analgesic agents.
- Conduct a focused physical examination of the patient (*e.g.,* vital signs, auscultation of the heart and lungs, evaluation of the airway, [§§] and when appropriate to sedation, other organ systems where major abnormalities have been identified).
- Review available laboratory test results.
- Order additional laboratory tests guided by a patient's medical condition, physical examination, and the likelihood that the results will affect the management of

[§§] See table 2 for additional information related to airway assessment.

moderate sedation/analgesia.

- Evaluate results of these tests before sedation is initiated.

- If possible, perform the preprocedure evaluation well enough in advance (*e.g.,* several days to weeks) to allow for proper patient preparation.***

- Re-evaluate the patient immediately before the procedure.

Preprocedure Patient Preparation

Preprocedure *patient preparation* consists of: (1) consultation with a medical specialist when needed, (2) patient preparation for the procedure (*e.g.,* informing patients of the benefits and risks of sedatives and analgesics, preprocedure instruction, medication usage, counseling), and (3) preprocedure fasting from solids and liquids.

Literature Findings. The literature is insufficient regarding the benefits of consultation with a medical specialist or providing the patient (or legal guardian, in the case of a child or impaired adult) with preprocedure information about sedation and analgesia. A nonrandomized comparative study reported equivocal outcomes (*e.g.,* emesis, apnea, oxygen levels) when preprocedure fasting (*i.e.,* liquids or solids) is compared to no fasting *(Category B1-E evidence).*[27] Another nonrandomized comparison of fasting for less than 2 hours versus fasting for greater than 2 hours reported equivocal findings for emesis, oxygen saturation levels, and arrhythmia for infants *(Category B1-E evidence).*[28] Finally, a third nonrandomized comparison reported equivocal findings for gastric volume and pH when fasting of liquids for 0.5-3 hours is compared with fasting times of greater than 3 hours *(Category B1-E evidence).*[29]

Survey Findings. To be determined

*** This may not be feasible for urgent or emergency procedures, interventional radiology or other radiology settings.

Recommendations for Preprocedure Patient Preparation.

- Consult with a medical specialist (*e.g.,* physician anesthesiologist, cardiologist, endocrinologist, pulmonologist, nephrologist, pediatrician, obstetrician, or otolaryngologist), when appropriate before administration of moderate procedural sedation to patients with significant underlying conditions.
    - If a specialist is needed, select a specialist based on the nature of the underlying condition and the urgency of the situation.
    - For severely compromised or medically unstable patients (*e.g.*, anticipated difficult airway, severe obstructive pulmonary disease, coronary artery disease, or congestive heart failure), or if it is likely that sedation to the point of unresponsiveness will be necessary to obtain adequate conditions, consult with a physician anesthesiologist.
- Before the procedure, inform patients or legal guardians of the benefits, risks and limitations of moderate sedation/analgesia and possible alternatives, and elicit their preferences.[†††]
- Before the day of the procedure, inform patients or legal guardians that they should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying before the procedure.[††† ‡‡‡]
- On the day of the procedure, assess the time and nature of last oral intake.
    - Evaluate the risk of pulmonary aspiration of gastric contents when determining (1) the target level of sedation, and (2) whether the procedure should be delayed.

[†††] This may not be feasible for urgent or emergency procedures.
[‡‡‡] See Table 3 and/or refer to: American Society of Anesthesiologists: Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: Application to healthy patients undergoing elective procedures: An updated report. *ANESTHESIOLOGY* 2017; 126:376-93

241 - In urgent or emergent situations where complete gastric emptying is not possible,
242 do not delay moderate procedural sedation based on fasting time alone.

243 ***Patient Monitoring***

244 Many of the complications associated with moderate sedation and analgesia may be avoided if
245 adverse drug responses are detected and treated in a timely manner (*i.e.*, before the development of
246 cardiovascular decompensation, or cerebral hypoxia). Patients given sedatives or analgesics in
247 unmonitored settings may be at increased risk of these complications. Patient monitoring includes
248 strategies for the following: (1) monitoring patient level of consciousness assessed by the response
249 of patients, including spoken responses to commands or other forms of bidirectional communication
250 during procedures performed with moderate sedation/analgesia;[§§§] (2) monitoring patient ventilation
251 and oxygenation, including ventilatory function, by observation of qualitative clinical signs,
252 capnography and pulse oximetry; (3) hemodynamic monitoring, including blood pressure, heart rate,
253 and electrocardiography; (4) contemporaneous recording of monitored parameters; and (5)
254 availability/presence of an individual responsible for patient monitoring.

255 **Literature Findings.** The literature is insufficient to determine whether monitoring patients'
256 level of consciousness improves patient outcomes or decreases risks. Also, the literature is
257 insufficient to evaluate whether observation of the patient, auscultation, chest excursion, or
258 plethysmography are associated with reduced sedation-related risks.

259 Meta-analysis of RCTs report equivocal findings ($p = 0.015$) for hypoxemic events (*i.e.*, oxygen
260 desaturation to < 90%) when continuous end tidal carbon dioxide monitoring *(i.e.*, capnography) is
261 compared to monitoring without capnography (*e.g.*, practitioners were blinded to capnography
262 results) during procedures with moderate sedation *(Category A1-B evidence).*[30-35] Findings for this

[§§§] Patients whose only response is reflex withdrawal from painful stimuli are deeply sedated, approaching a state of general anesthesia, and should be treated accordingly.

comparison were also equivocal for RCTs reporting severe hypoxemic events (*i.e.,* oxygen desaturation to < 85%),[30,31,33,34] and for oxygen desaturation levels of 92%, 93% and 95% *(Category A2-E evidence).*[32,35-37] Observational studies indicate that pulse oximetry is effective in the detection of oxygen saturation levels in patients administered sedatives and analgesics *(Category B3-B evidence).*[38-64] Observational studies also indicate that electrocardiography monitoring is effective in the detection of arrhythmias, hypotension, premature ventricular contractions, bradycardia, and diaphoresis *(Category B3-B evidence).*[47,50,65]

The literature is insufficient to determine the benefits of contemporaneous recording of patients' level of consciousness, respiratory function or hemodynamics. In addition, the literature is insufficient to evaluate whether the presence of an individual dedicated to patient monitoring will reduce adverse outcomes related to moderate sedation/analgesia.

Survey Findings. To be determined

Recommendations for Patient Monitoring.

Monitoring patient level of consciousness.

- Periodically (*e.g.,* at 5-min intervals) monitor a patient's response to verbal commands during moderate sedation, except in patients who are unable to respond appropriately (*e.g.*, patients where age or development may impair bidirectional communication), or during procedures where movement could be detrimental.
    - During procedures where a verbal response is not possible (*e.g.*, oral surgery, restorative dentistry, upper endoscopy), check the patient's ability to give a "thumbs up" or other indication of consciousness in response to verbal or tactile

(light tap) stimulation; this suggests that the patient will be able to control his airway and take deep breaths if necessary.****

Monitoring patient ventilation and oxygenation.

- Continually monitor ventilatory function by observation of qualitative clinical signs.
- Continually monitor ventilatory function with capnography unless precluded or invalidated by the nature of the patient, procedure, or equipment.
    - For uncooperative patients, institute capnography once moderate sedation has been achieved.
- Monitor all patients by pulse oximetry with appropriate alarms.

Monitoring hemodynamics.

- Determine blood pressure before sedation/analgesia is initiated unless precluded by lack of patient cooperation.
- Once moderate sedation/analgesia is established, continually monitor blood pressure *(e.g.,* at 5-minute intervals) and heart rate during the procedure unless such monitoring interferes with the procedure (*e.g.,* magnetic resonance imaging where stimulation from the blood pressure cuff could arouse an appropriately sedated patient).
- Use electrocardiographic monitoring during moderate sedation in patients with clinically significant cardiovascular disease or those who are undergoing procedures where dysrhythmias are anticipated.

Contemporaneous recording of monitored parameters.

- Record patients' level of consciousness, ventilatory and oxygenation status, and hemodynamic variables at a frequency which depends on the type and amount of

**** A response limited to reflex withdrawal from a painful stimulus is not considered a purposeful response and thus represents a state of general anesthesia.

306 medication administered, the length of the procedure, and the general condition of the
307 patient.
308 - At a minimum, this should occur: (1) before the administration of
309 sedative/analgesic agents[††††]; (2) following administration of sedative/analgesic
310 agents; (3) at regular intervals during the procedure, (4) during initial recovery;
311 and (5) just before discharge.
312 - Set device alarms to alert the care team to critical changes in patient status.

313 ***Availability of an individual responsible for patient monitoring.***

314 • Assure that a designated individual other than the practitioner performing the procedure
315 is present to monitor the patient throughout the procedure.
316 - The individual responsible for monitoring the patient should be trained in the
317 recognition of apnea and airway obstruction and be empowered to seek additional
318 help.
319 - The designated individual may assist with minor, interruptible tasks once the
320 patient's level of sedation/analgesia and vital signs have stabilized, provided that
321 adequate monitoring for the patient's level of sedation is maintained.

322 ***Supplemental Oxygen***

323 **Literature Findings.** Meta-analysis of RCTs indicate that the use of supplemental oxygen
324 versus no supplemental oxygen is associated with a reduced frequency of hypoxemia[‡‡‡‡] during
325 procedures with moderate sedation *(Category A1-B evidence)*.[66-72] The literature is insufficient to
326 examine which methods of supplemental oxygen administration (*e.g.*, nasal cannula, face mask, or
327 specialized devices) are more effective in reducing hypoxemia.

[††††] For rare uncooperative patients (*e.g.*, children with autism spectrum disorder or attention deficit disorder) recording oxygenation status or blood pressure may not be possible until after sedation.
[‡‡‡‡] Reported by authors as oxygen desaturation to ≤ 95% or oxygen desaturation > 5% or 10% below baseline.

Survey Findings. To be determined

Recommendations for supplemental oxygen.

- Use supplemental oxygen during moderate procedural sedation/analgesia unless specifically contraindicated for a particular patient or procedure.

Emergency Support

Emergency support strategies include: (1) the presence of pharmacologic antagonists, (2) the presence of age and weight appropriate emergency airway equipment (*e.g.*, different types of airway devices, supraglottic airway devices), and (3) the presence of an individual capable of establishing a patent airway and providing positive pressure ventilation and resuscitation, (4) the presence of an individual to establish intravenous access, and (5) the availability of rescue support.

Literature Findings. Although it is established clinical practice to provide access to emergency support, the literature is insufficient to assess the benefits or harms of keeping pharmacologic antagonists or emergency airway equipment available during procedures with moderate sedation and analgesia. The literature is insufficient to assess whether the presence of an individual capable of establishing a patent airway, positive pressure ventilation and resuscitation will improve outcomes. In addition, the literature is insufficient to determine the benefits of keeping an individual present to establish intravenous access during procedures with moderate sedation/analgesia. Finally, the literature is insufficient to determine the benefits of rescue support availability during moderate procedural sedation/analgesia.

Survey Findings. To be determined

Recommendations for Emergency Support.[§§§§]

- Assure that pharmacologic antagonists for benzodiazepines and opioids are immediately available in the procedure room.

[§§§§] Refer to Table 4 for examples of emergency support equipment and pharmaceuticals.

- Assure that an individual is present in the room who understands the pharmacology of the sedative/analgesics administered (*e.g.,* opioids and benzodiazepines) and potential interactions with other medications and nutraceuticals the patient may be taking,

- Assure that appropriately-sized equipment for establishing a patent airway is available.
- Assure that at least one individual capable of establishing a patent airway and providing positive pressure ventilation is present in the procedure room.
- Assure that suction, advanced airway equipment, a positive pressure ventilation device, and supplemental oxygen are immediately available in the procedure room and in good working order.
  - Assure that a member of the procedural team is trained in the recognition and treatment of airway complications (*e.g.,* apnea, laryngospasm, airway obstruction), opening the airway, suctioning secretions, and performing bag-valve-mask ventilation.
- Assure that a member of the procedural team has the skills to establish intravenous access.
- Assure that a member of the procedural team has the skills to provide chest compressions.
- Assure that a functional defibrillator or automatic external defibrillator is immediately available in the procedure area.
- Assure that an individual or service (*e.g.,* code blue team, paramedic-staffed ambulance service) with advanced life support skills (*e.g.,* tracheal intubation, defibrillation, resuscitation medications) is immediately available.
- Assure that members of the procedural team are able to recognize the need for additional

support and know how to access emergency services from the procedure room (e.g., telephone, call button).

Sedative/analgesic medications not designed for general anesthesia

For these Guidelines, sedatives not designed for general anesthesia include benzodiazepines (*e.g.,* midazolam, diazepam, flunitrazepam, lorazepam or temazapam) and dexmedetomidine. Analgesics administered with sedatives include opioids such as fentanyl, alfentanil, remifentanil, meperidine, morphine, and nalbuphine. This section of the Guidelines addresses the following topics (1) benzodiazepines and dexmedetomidine, (2) sedative/opioid combinations, (3) intravenous versus non-intravenous sedatives/analgesics not designed for general anesthesia,***** and (4) titration of sedatives/analgesics not designed for general anesthesia.

Literature Findings.

Meta-analysis of RCTs comparing midazolam combined with opioids versus midazolam alone report equivocal findings for pain and discomfort,[73-78] hypoxemia,†††††[74,75,77-80] and patient recall of the procedure.[73-75,77,78,82-84] *(Category A1-E evidence).* When midazolam combined with opioids are compared with opioids alone, RCTs report equivocal findings for patient recall, pain during the procedure, frequency of hypoxemia,††††† hypercarbia and respiratory depression *(Category A2-E evidence).*[76,79,84-86]

One RCT comparing dexmedetomidine with midazolam reports equivocal outcomes for recovery time, oxygen saturation levels, apnea and bradycardia *(Category A3-E evidence).*[87] Another RCT reports a longer recovery time for dexmedetomidine compared with midazolam *(Category A3-H evidence),* with equivocal findings for analgesia scores, oxygen saturation levels, respiratory rate, blood pressure and pulse rate *(Category A3-E evidence).*[88] One RCT reports a lower frequency of

***** All routes of administration were considered, including oral, nasal, intramuscular, rectal, transdermal, sublingual, iontophoresis, and nebulization.

††††† Reported by authors as oxygen desaturation to < 94%, 93% or 90%.

hypoxemia when dexmedetomidine is combined with an opioid analgesic compared with midazolam combined with an opioid analgesic *(Category A3-B evidence).*[89] One RCT reports deeper sedation (*i.e.,* higher sedation scores) and a lower frequency of hypoxemia when dexmedetomidine combined with midazolam and meperidine is compared with midazolam combined with meperidine *(Category A3-B evidence).*[90]

One RCT comparing intravenous midazolam with intramuscular midazolam reports equivocal findings for oxygen saturation levels, respiratory rate and heart rate *(Category A3-E evidence).*[91] One RCT comparing intravenous midazolam with intranasal midazolam reports equivocal findings for sedation efficacy *(Category A3-E evidence)*, but discomfort from the nasal administration was reported for all intranasal patients with no nasal discomfort from the intravenous patients *(Category A3-B evidence).*[92] One RCT comparing intravenous diazepam with rectal diazepam reports lower recall for the intravenous method *(Category A3-B evidence)*; findings were equivocal for sedative effect, anxiety and crying*(Category A3-E evidence).*[93] One RCT comparing intravenous with intranasal dexmedetomidine reported equivocal findings for sedation time, duration of the procedure, and the frequency of rescue doses of midazolam administered. *(Category A3-E evidence).*[94]

One RCT comparing titration (*i.e.,* administration of small, incremental doses of intravenous midazolam combined with meperidine until the desired level of sedation and/or analgesia is achieved) of midazolam combined with an opioid compared with a single, rapid bolus reports higher total physician times, medication dosages, frequencies of hypoxemia, and somnolence scores for titration *(Category A3-H evidence).*[95]

Survey Findings. To be determined

Recommendations for sedative or analgesic medications not designed for general anesthesia.

- Combinations of sedative and analgesic agents may be administered as appropriate for the procedure and the condition of the patient.‡‡‡‡‡
    - Administer each component individually to achieve the desired effect (*e.g.*, additional analgesic medication to relieve pain; additional sedative medication to decrease awareness or anxiety).
- Dexmedetomidine may be administered as an alternative to benzodiazepine sedatives on a case-by-case basis.
- In patients receiving intravenous medications for sedation/analgesia, maintain vascular access throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression.
- In patients who have received sedation/analgesia by non-intravenous routes, or whose intravenous line has become dislodged or blocked, determine the advisability of reestablishing intravenous access on a case-by-case basis.
- Administer intravenous sedative/analgesic drugs in small, incremental doses, or by infusion, titrating to the desired endpoints.
    - Allow sufficient time to elapse between doses so the peak effect of each dose can be assessed before subsequent drug administration.
- When drugs are administered by non-intravenous routes (*e.g.*, oral, rectal, intramuscular, transmucosal), allow sufficient time for absorption and peak effect of the previous dose to

‡‡‡‡‡ The propensity for combinations of sedative and analgesic agents to cause respiratory depression and airway obstruction emphasizes the need to appropriately reduce the dose of each component as well as the need to continually monitor respiratory function. Knowledge of each drug's time of onset, peak response, and duration of action is important. Titration of drug to effect is an important concept; one must know whether the previous dose has taken full effect before administering additional drug.

occur before supplementation is considered.

Sedative/analgesic medications designed for general anesthesia

For these Guidelines, sedatives designed for general anesthesia include propofol, ketamine and etomidate. Sedatives not designed for general anesthesia (*e.g.,* benzodiazepines, nitrous oxide, chloral hydrate, barbiturates, and antihistamines) are included either as comparison groups or in combination with sedatives designed for general anesthesia. Analgesics (*e.g.,* opioids, non-steroidal anti-inflammatory drugs and local anesthetics) are included either in comparison groups or in combination with sedatives designed for general anesthesia. This section of the Guidelines addresses the following topics (1) propofol versus other sedative/analgesics, (2) ketamine versus other sedative/analgesics, (3) etomidate versus other sedative/analgesics, (4) combinations of sedatives designed for general anesthesia versus other sedatives/analgesics, alone or in combination, (5) intravenous versus non-intravenous sedatives/analgesics designed for general anesthesia,***** and (6) titration of intravenous sedatives/analgesics designed for general anesthesia. These Guidelines do not address education, training or certification requirements for practitioners who provide moderate procedural sedation with these drugs.

Literature Findings.

Literature comparing propofol with other sedative/analgesic medications, either alone or in combination, report the following findings: (1) meta-analysis of RCTs report faster recovery times for propofol versus midazolam after procedures with moderate sedation *(Category A1-B evidence)*,[96-100] with equivocal findings for patient recall [96,101-104] and frequency of hypoxemia *(Category A1-E evidence)*.[97,101,103,104] One RCT reports shorter sedation time, a lower frequency of recall and higher recovery scores for propofol versus diazepam (*Category A3-B evidence)*.[105] (2) RCTs comparing propofol versus benzodiazepines combined with opioid analgesics report shorter sedation and recovery times for propofol alone *(Category A2-B evidence)*,[106,107] with equivocal findings for pain,

oxygen saturation levels, and blood pressure *(Category A2-E evidence)*.[106-110] (3) RCTs comparing propofol combined with benzodiazepines versus propofol alone report equivocal findings for recovery and procedure times, pain with injection and restlessness *(Category A2-E evidence)*.[111-113] One RCT comparing propofol combined with midazolam versus propofol alone reports deeper sedation levels and more episodes of deep sedation for the combination group *(Category A3-H evidence)*.[113] RCTs comparing propofol combined with opioid analgesics versus propofol alone report lower pain scores for the combination group *(Category A2-B evidence)*;[114,115] with equivocal findings for sedation levels, oxygen saturation levels, respiratory and heart rate *(Category A2-E evidence)*.[114-117] (4) One RCT comparing propofol combined with remifentanil versus remifentanil alone reports deeper sedation, less recall *(Category A3-B evidence)*, and more respiratory depression *(Category A3-H evidence)* for the combination group.[118] (5) RCTs comparing propofol combined with sedatives/analgesics not designed for general anesthesia *versus* combinations of sedatives/analgesics not designed for general anesthesia report equivocal findings for outcomes including sedation time, patient recall, pain scores, recovery time, oxygen saturation levels, blood pressure and heart rate *(Category A2-E evidence)*.[119-137] (6) RCTs comparing propofol with ketamine report equivocal findings for sedation scores, pain during the procedure, recovery, oxygen saturation levels, respiratory rate, blood pressure, and heart rate *(Category A2-E evidence)*.[138,139] (7) One RCT comparing propofol versus ketamine combined with midazolam reports equivocal findings for recovery agitation, oxygen saturation levels, respiratory rate, blood pressure and heart rate *(Category A3-E evidence)*.[140] (8) One RCT comparing propofol versus ketamine combined with fentanyl reports shorter recovery times and less recall for propofol alone *(Category A3-E evidence)*.[141] (9) RCTs comparing propofol combined with ketamine versus propofol alone report deeper sedation for the combination group *(Category A3-B evidence)*,[142] with more respiratory

depression and a greater frequency of hypoxemia[§§§§§] *(Category A3-H evidence).*[143]

Literature comparing ketamine with other sedative/analgesic medications, either alone or in combination, report the following findings: (1) RCTs comparing ketamine with midazolam report equivocal findings for sedation scores, recovery time, and oxygen saturation levels *(Category A2-E evidence).*[88,144,145] (2) One RCT comparing ketamine versus nitrous oxide reports longer sedation times and higher levels of sedation (*i.e.,* deeper sedation levels) for ketamine (*Category A3-H evidence).*[146] (3) One RCT comparing ketamine with midazolam combined with fentanyl reports a lower depth of sedation for ketamine *(Category A3-B evidence),* with equivocal findings for recall, pain scores and frequency of hypoxemia *(Category A3-E evidence).*[147] (4) RCTs comparing ketamine combined with midazolam versus ketamine alone or midazolam alone report equivocal findings for sedation scores, sedation time, recovery and recovery agitation *(Category A2-E evidence).*[144,148,149] (5) One RCT comparing ketamine combined with midazolam versus midazolam combined with alfentanil reports a lower frequency of hypoxemia *(Category A3-B evidence)* and increased disruptive movements, longer recovery times and longer times to discharge for ketamine combined with midazolam *(Category A3-H evidence).*[150] (6) RCTs comparing ketamine with propofol report equivocal findings for sedation scores, pain during the procedure, oxygen saturation levels, and recovery scores *(Category A2-E evidence).*[138,139] RCTs comparing ketamine with etomidate report less airway assistance required and less myoclonus with ketamine *(Category A2-B evidence).*[151,152] (7) RCTs comparing ketamine combined with propofol versus propofol combined with fentanyl report equivocal findings for recovery times, oxygen saturation levels, respiratory rate and heart rate *(Category A3-H evidence).*[153-155]

Literature comparing etomidate with other sedative/analgesic medications, either alone or in combination, report the following findings: (1) One RCTs comparing etomidate with midazolam

[§§§§§] Reported by author as oxygen desaturation to < 94%

reports shorter sedation times for etomidate *(Category A3-B evidence)*, with equivocal findings for recovery agitation, oxygen saturation levels, and apnea *(Category A3-E evidence)*.[156] (2) One RCT comparing etomidate with pentobarbital reports shorter sedation times for etomidate *(Category A3-B evidence)*, with equivocal findings for recovery agitation and hypotension (*Category A3-B evidence)*.[157] (3) One RCT comparing etomidate combined with fentanyl versus midazolam combined with fentanyl reports deeper sedation (*i.e.*, higher sedation scores) for the combination group *(Category A3-B evidence)*, with equivocal findings for sedation times, recovery times, frequency of oversedation, and oxygen saturation levels *(Category A3-E evidence)*, and a higher frequency of myoclonus *(Category A3-H evidence)*.[158] (4) One RCT comparing etomidate combined with morphine and fentanyl versus midazolam combined with morphine and fentanyl reports shorter sedation times for the etomidate combination *(Category A3-B evidence)*, with equivocal findings for oxygen saturation levels, apnea, hypotension, and recovery agitation *(Category A3-E evidence)*, and a higher frequency of patient recall and myoclonus *(Category A3-H evidence)*.[159] (5) RCTs comparing etomidate with ketamine report more airway assistance required and higher frequencies of myoclonus for etomidate *(Category A2-H evidence)*.[151,152]

One RCT reports shorter sedation onset times, shorter recovery times, and fewer rescue doses administered for intravenous ketamine when compared with intramuscular ketamine *(Category A3-B evidence)*, with equivocal findings for sedation efficacy, respiratory depression, and time to discharge *(Category A3-E evidence)*.[160] One RCT comparing intravenous versus intramuscular ketamine with or without midazolam reports equivocal findings for sedation time, recovery agitation, and duration of the procedure *(Category A3-E evidence)*.[149]

Observational studies reporting titrated administration of sedatives designed for general anesthesia report the frequency of hypoxemia ranging from 1.7%-4.7% of patients,[14,161-164] with oversedation occurring in 0.13%-0.2% of patients.[162,163]

Survey Findings. To be determined

Recommendations for sedative or analgesic medications designed for general anesthesia.

- When moderate procedural sedation with sedative or analgesic medications designed for general anesthesia by any route is intended, provide care consistent with that required for general anesthesia.
    - Assure that practitioners administering these drugs are able to reliably rescue patients from unintended deep sedation or general anesthesia.
- For patients receiving intravenous sedatives designed for general anesthesia, maintain vascular access throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression.
- In patients who have received sedatives designed for general anesthesia by non-intravenous routes, or whose intravenous line has become dislodged or blocked, determine the advisability of reestablishing intravenous access on a case-by-case basis.
- Administer intravenous sedative/analgesic drugs designed for general anesthesia in small, incremental doses, or by infusion, titrating to the desired endpoints.
    - Allow sufficient time to elapse between doses so the peak effect of each dose can be assessed before subsequent drug administration.
- When drugs designed for general anesthesia are administered by non-intravenous routes (*e.g.*, oral, rectal, intramuscular, transmucosal), allow sufficient time for absorption and peak effect of the previous dose to occur before supplementation is considered.

Reversal agents: naloxone and flumazenil

Literature Findings.

One placebo-controlled RCT reports that naloxone effectively reverses the effects of meperidine as measured by increasing alertness scores and respiratory rate *(Category A3-B evidence).*[165]

Reversal of respiratory depression, apnea and oxygen desaturation after naloxone administration in other practice settings is also reported by observational studies *(Category B3-B evidence)*[166,167] and case reports *(Category B4-B evidence)*.[168-171]

Meta-analysis of double-blind placebo-controlled RCTs indicates that flumazenil effectively antagonizes the effects of sedation within 15 minutes for patients who have been administered benzodiazepines *(Category A1-B evidence)*.[172-179] Placebo-controlled RCTs also indicate that flumazenil administration is associated with shorter recovery times for benzodiazepine sedation *(Category A2-B evidence)*.[177,180-182] Meta-analysis of placebo-controlled RCTs indicate that flumazenil effectively antagonizes the effects of benzodiazepines when combined with opioids *(Category A1-B evidence)*.[183-187]

Survey Findings. To be determined

Recommendations for reversal agents.

- Assure that specific antagonists are immediately available in the procedure room whenever opioid analgesics or benzodiazepines are administered for moderate procedural sedation/analgesia, regardless of route of administration.
- If patients become hypoxemic or apneic during sedation/analgesia: (1) encourage or physically stimulate patients to breathe deeply; (2) administer supplemental oxygen; and (3) provide positive pressure ventilation if spontaneous ventilation is inadequate.
- Use reversal agents in cases where airway control, spontaneous ventilation or positive pressure ventilation are inadequate.
    - Administer naloxone to reverse opioid-induced sedation and respiratory depression.******

****** Practitioners are cautioned that acute reversal of opioid-induced analgesia may result in pain, hypertension, tachycardia, or pulmonary edema.

- Administer flumazenil to reverse benzodiazepine-induced sedation and respiratory depression.

- After pharmacologic reversal, observe and monitor patients for a sufficient time to ensure that sedation and cardiorespiratory depression does not recur once the effect of the antagonist dissipates.
- Do not use sedation regimens that include routine reversal of sedative or analgesic agents.

Recovery care

Patients receiving moderate procedural sedation may continue to be at risk for developing complications after their procedure is completed. Decreased stimulation from the proceduralist, delayed drug absorption following non-intravenous administration, and slow drug elimination may contribute to residual sedation and cardiorespiratory depression during the recovery period. When sedation/analgesia is administered to outpatients, medical supervision may not be available once the patient leaves the medical facility. This section of the Guidelines addresses the following recovery care topics: (1) continued observation and monitoring until discharge, and (2) predetermined discharge criteria.

Literature Findings.

Although it is well-accepted clinical practice to continue patient observation until discharge, the literature is insufficient to evaluate the impact of postprocedural observation and monitoring. The literature is also insufficient to evaluate the effects of using predetermined discharge criteria on patient outcomes.

Survey Findings. To be determined

Recommendations for recovery care.

- Following sedation/analgesia, observe and monitor patients in an appropriately staffed and equipped area until they are near their baseline level of consciousness and are no longer at increased risk for cardiorespiratory depression.
- Monitor oxygenation continuously until patients are no longer at risk for hypoxemia.
- Monitor ventilation and circulation at regular intervals until patients are suitable for discharge.
- Design discharge criteria to minimize the risk of central nervous system or cardiorespiratory depression following discharge from observation by trained personnel.[††††††]

Creation and implementation of patient safety processes.

Patient safety processes include quality improvement and preparation for rare events.

Literature findings: Regarding quality improvement, one observational study reported that use of a pre-sedation checklist compared to no checklist use may improve safety documentation in emergency department sedations *(Category B1-B evidence).*[188]

Survey findings:

Recommendations:

- Create and implement a quality improvement process based upon national, regional or institutional reporting protocols, (*e.g.,* adverse events, unsatisfactory sedation).
- Strengthen patient safety culture through collaborative practices (*e.g.,* team training, simulation drills, development and implementation of checklists).
    - Create an emergency response plan (*e.g.,* activating "code blue" team or activating the emergency medical response system--911 or equivalent).

[††††††] Discharge criteria examples are noted in Table 5.

References:

1. American Society of Anesthesiologists: Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists: An Updated Report. *ANESTHESIOLOGY 2002;96:1004-1017*
2. American Society of Anesthesiologists. (October 15, 2014). Continuum of depth of sedation: Definition of general anesthesia and levels of sedation / analgesia. Retrieved December 26, 2016 from http://www.asahq.org/quality-and-practice-management/standards-and-guidelines.
3. Joint Commission on the Accreditation of Healthcare Organizations. The Joint Commission Standards Overview. Retrieved December 26, 2016 from http://ttps://www.tms.va.gov/va_content/ModSed01_v2/lesson01/01_005.htm
4. Coté CJ, Wilson S; American Academy of Pediatrics; American Academy of Pediatric Dentistry: Guidelines for monitoring and management of pediatric patients before, during, and after sedation for diagnostic and therapeutic procedures: update 2016. Pediatrics 2016 Jul;138(1).
5. Muller S, Prolla JC, Maguilnik I, Breyer HP: Predictive factors of oxygen desaturation of patients submitted to endoscopic retrograde cholangiopancreatography under conscious sedation. Arq Gastroenterol 2004; 41:162-6
6. Omata F, Masuda K, Fujita Y, Fukui T: Risk factors of hypoxia during conscious sedation for colonoscopy: A prospective time-to-event analysis. Gastro Endosc 2014; 1:AB224
7. Papachristou GI, Gleeson FC, Papachristou DJ, Petersen BT, Baron TH: Endoscopist administered sedation during ERCP: impact of chronic narcotic/benzodiazepine use and predictive risk of reversal agent utilization. Am J Gastroenterol 2007; 102:738-43
8. Andrade C, Gill J, Kulkarni P, Amodeo D, Goldsmith S, Boyd W, Anderson W, Klein M, Vidyarthi G: Evaluation of the safety of conscious sedation and gastrointestinal endoscopy in the veteran population with sleep apnea. American Journal of Gastroenterology 2013; 108:S480
9. Andrade CM, Patel B, Gill J, Amodeo D, Kulkarni P, Goldsmith S, Bachman B, Geerken R, Klein M, Anderson W, Miladinovic B, Fernandez I, Kumar A, Richter J, Vidyarthi G: Safety of gastrointestinal endoscopy with conscious sedation in patients with and without obstructive sleep apnea. J Clin Gastroenterol 2016; 50:198-201
10. Asserhøj LL, Mosbech H, Krøigaard M, Garvey LH: No evidence for contraindications to the use of propofol in adults allergic to egg, soy or peanut. Br J Anaesth 2016; 116:77–82
11. Bal BS, Crowell MD, Kohli DR, Menendez J, Rashti F, Kumar AS, Olden KW: What factors are associated with the difficult-to-sedate endoscopy patient? Dig Dis Sci 2012; 57:2527-34
12. Cha JM, Jeun JW, Pack KM, Lee JI, Joo KR, Shin HP, Shin WC: Risk of sedation for diagnostic esophagogastroduodenoscopy in obstructive sleep apnea patients. World J Gastroenterol 2013; 19:4745-51
13. Czwornog J, Austin GL: Body mass index, age, and gender affect prep quality, sedation use, and procedure time during screening colonoscopy. Dig Dis Sci 2013; 58:3127-33
14. Heuss LT, Schnieper P, Drewe J, Pfimlin E, Beglinger C: Safety of propofol for conscious sedation during endoscopic procedures in high-risk patients - a prospective, controlled study. Am J Gastroenterol 2003; 98:1751-57
15. Hsu AJ, Carson KA, Yung R, Pham PA: Severe prolonged sedation associated with coadministration of protease inhibitors and intravenous midazolam during bronchoscopy. Pharmacotherapy 2012; 32:538-45
16. Jirapinyo P, Kumar N, Thompson CC: Patients with Roux-en-Y gastric bypass require increased sedation during upper endoscopy. Clin Gastroenterol Hepatol 2015; 13:1432-6

17. Kinder KL, Lehman-Huskamp KL, Gerard JM: Do children with high body mass indices have a higher incidence of emesis when undergoing ketamine sedation? Pediatr Emerg Care 2012; 28:1203-5
18. Kitagawa E, Iida A, Kimura Y, Kumagai M, Nakamura M, Kamekura N, Fujisawa T, Fukushima K: Responses to intravenous sedation by elderly patients at the Hokkaido University Dental Hospital. Anesth Prog 1992; 39:73-8
19. Kotani J, Shimada M: A prospective, multicenter, observational study for the dosage and administration of Dormicum (generic name: Midazolam) for the intravenous sedation in actual dental clinical settings. J Japanese Dental Soc Anesthes 2013; 41:160-170
20. Lubisch N, Roskos R, Berkenbosch JW: Dexmedetomidine for procedural sedation in children with autism and other behavior disorders. Pediatr Neurol 2009; 41:88-94
21. Mehta PP, Albeldawi M, Kochhar GS, Kalra SS, Maurer WG, Tetzlaff J, Lopez R, Sanaka MR, Vargo JJ: Body mass index (BMI) predicts the need for airway intervention and sedation related complications in anesthesiologist-directed propofol sedation for routine EGD and colonoscopy. Gastrointest Endosc 2013; 1:AB177
22. Schmerler BL, Cohen DM, Leder MS, Bonsu BK: Procedural sedation for fracture reduction in children with hyperactivity. Am J Emerg Med 2008; 26:661-4
23. Burtin P, Daoud P, Jacqz Aigrain E, Mussat P, Moriette G: Hypotension with midazolam and fentanyl in the newborn. Lancet 1991; 337:1545-6
24. Mtaweh H, Bayır H, Kochanek PM, Bell MJ: Effect of a single dose of propofol and lack of dextrose administration in a child with mitochondrial disease: a case report. J Child Neurol 2014; 29:NP40-6
25. Robb ND, Hargrave SA: Tolerance to intravenous midazolam as a result of oral benzodiazepine therapy: a potential problem for the provision of conscious sedation in dentistry. Anesth Pain Control Dent 1993; 2:94-7
26. Robb ND: Epileptic fits under intravenous midazolam sedation. Br Dent J 1996; 181:178-9
27. Bell A, Treston G, McNabb C, Monypenny K, Cardwell R: Profiling adverse respiratory events and vomiting when using propofol for emergency department procedural sedation. Emerg Med Australas 2007; 19:405-10
28. Ghaffar S, Haverland C, Ramaciotti C, Scott WA, Lemler MS: Sedation for pediatric echocardiography: evaluation of preprocedure fasting guidelines. J American Society Echocardiography 2002; 15:980-3
29. Ingebo KR, Rayhorn NJ, Hecht RM, Shelton MT, Silber GH, Shub MD: Sedation in children: adequacy of two-hour fasting. J Pediatr 1997; 131:155-158
30. Beitz A, Riphaus A, Meining A, Kronshage T, Geist C, Wagenpfeil S, Weber A, Jung A, Bajbouj M, Pox C, Schneider G, Schmid RM, Wehrmann T, von Delius S: Capnographic monitoring reduces the incidence of arterial oxygen desaturation and hypoxemia during propofol sedation for colonoscopy: a randomized, controlled study (ColoCap Study). Am J Gastroenterol 2012; 107:1205-12
31. Kochhar G, Mehta PP, Kirsh B, Rizk MK, Wang Y, John B, Albeldawi M, Vargo J: Does capnography prevent hypoxemia in ASA 1-2 outpatients undergoing elective EGD targeting moderate sedation? Results from a prospective, randomized, single blinded study. Gastroenterology 2015; 1:S1196
32. Langhan ML, Shabanova V, Li FY, Bernstein SL, Shapiro ED: A randomized controlled trial of capnography during sedation in a pediatric emergency setting. Am J Emerg Med 2015; 33:25-30
33. Mehta PP, Kochhar G, Albeldawi M, Kirsh B, Rizk M, Putka B, John B, Wang Y, Breslaw N, Lopez R, Vargo JJ: Capnographic monitoring in routine EGD and colonoscopy with

moderate sedation: A prospective, randomized, controlled trial. Am J Gastroenterol 2016; 111:395-404
34. Qadeer MA, Vargo JJ, Dumot JA, Lopez R, Trolli PA, Stevens T, Parsi MA, Sanaka MR, Zuccaro G: Capnographic monitoring of respiratory activity improves safety of sedation for endoscopic cholangiopancreatography and ultrasonography. Gastroenterology 2009; 136:1568-76
35. Slagelse C, Vilmann P, Hornslet P, Jørgensen HL, Horsted TI: The role of capnography in endoscopy patients undergoing nurse-administered propofol sedation: a randomized study. Scand J Gastroenterol 2013; 48: 1222-30
36. Deitch K, Miner J, Chudnofsky CR, Dominici P, Latta D: Does end tidal CO2 monitoring during emergency department procedural sedation and analgesia with propofol decrease the incidence of hypoxic events? A randomized, controlled trial. Ann Emerg Med 2010; 55:258-64
37. Lightdale JR, Goldmann DA, Feldman HA, Newburg AR, DiNardo JA, Fox VL: Microstream capnography improves patient monitoring during moderate sedation: a randomized, controlled trial. Pediatrics 2006; 117:e1170-8
38. al-Hadeedi S, Leaper DJ: Falls in hemoglobin saturation during ERCP and upper gastrointestinal endoscopy. World J Surg 1991; 15:88-94
39. Bell GD, Reeve PA, Moshiri M, Coady T, Stapleton PJ: Intravenous midazolam: a study of the degree of oxygen desaturation occurring during upper gastrointestinal endoscopy. Br J Clin Pharm 1987; 23:703-8
40. Bell GD, Morden A, Coady T, Lee J, Logan R: A comparison of diazepam and midazolam as endoscopy premedication assessing changes in ventilation and oxygen saturation. Br J Clin Pharm 1988; 26:595-600
41. Bendig DW: Pulse oximetry and upper intestinal endoscopy in infants and children. J Ped Gast Nutr 1991; 12:39-43
42. Bilotta JJ, Floyd JL, Waye JD: Arterial oxygen desaturation during ambulatory colonoscopy. Gastrointest Endosc 1990; 36:S5-8
43. Cacho G, Pérez-Calle JL, Barbado A, Lledó JL, Ojea R, Fernández-Rodríguez CM: Capnography is superior to pulse oximetry for the detection of respiratory depression during colonoscopy. Rev Esp Enferm Dig 2010; 102:86-9
44. Casteel HB, Fiedorek SC, Kiel EA: Arterial blood oxygen desaturation in infants and children during upper gastrointestinal endoscopy. Gastrointest Endosc 1990; 36:489-93
45. Conlong P, Rees W: The use of hypnosis in gastroscopy: a comparison with intravenous sedation. Postgrad Med J 1999; 75:223-5
46. Froehlich F, Schwizer W, Thorens J, Kohler M, Gonvers JJ, Fried M: Conscious sedation for gastroscopy: patient tolerance and cardiorespiratory parameters. Gastroenterology 1995; 108:697-704
47. Gilger MA, Jeiven SD, Barrish JO, McCarroll LR: Oxygen desaturation and cardiac arrhythmias in children during esophagogastroduodenoscopy using conscious sedation. Gastrointest Endosc 1993; 39:392-5
48. Gombar KK, Dhall JC, Suri RP, Singh B, Gombar S: Effect of diazepam sedation on arterial oxygen saturation during esophagogastroduodenoscopy: a placebo-controlled study. Indian J Gastroent 1996; 15:40-2
49. Gross JB, Long WB: Nasal oxygen alleviates hypoxemia in colonoscopy patients sedated with midazolam and meperidine. Gastrointest Endosc 1990; 36:26-9
50. Hartke R, Gonzalez Rothi R, Abbey N: Midazolam-associated alterations in cardiorespiratory function during colonoscopy. Gastro Endosc 1989; 35:232-8

51. Hinzmann CA, Budden PM, Olson J: Intravenous conscious sedation use in endoscopy: does monitoring of oxygen saturation influence timing of nursing interventions? Gastro Nursing 1992; 15:6-13
52. Iber FL, Sutberry M, Gupta R, Kruss D: Evaluation of complications during and after conscious sedation for endoscopy using pulse oximetry. Gastrointest Endosc 1993; 39:620-5
53. Kassimatis A, Tsoukas A, Ikonomidis I, Joshi J, Nihoyannopoulos P: Routine arterial oxygen saturation monitoring is not necessary during transesophageal echocardiography. Clin Cardiol 1997; 20:547-52
54. Lamireau T, Dubreuil M, Daconceicao M: Oxygen saturation during esophagogastroduodenoscopy in children: general anesthesia versus intravenous sedation. J Pediatr Gastroent Nutr 1998; 27:172-5
55. Matthews RW, Malkawi Z, Griffiths MJ, Scully C: Pulse oximetry during minor oral surgery with and without intravenous sedation. Oral Surg Oral Med Oral Path 1992; 74:537-43
56. Mennuni M, Bianconi L, Antonicoli S, Frongillo D, Molle G, Rossi P, Venturini E, Toscano S: Fast cardiologist-administered midazolam for electrical cardioversion of atrial fibrillation. J Cardiovasc Med (Hagerstown) 2007; 8:176-80
57. Newland CJ, Spiers SPW, Finlay DBL: Technical report: Oxygen saturation monitoring during sedation for chemonucleolysis. Clin Radiol 1991; 44:352-3
58. Putinati S, Ballerin L, Corbetta L, Trevisani L, Potena A: Patient satisfaction with conscious sedation for bronchoscopy. Chest 1999; 115:1437-40
59. Ristikankare M, Julkunen R, Heikkinen M, Mattila M, Laitinen T, Wang SX, Hartikainen J: Sedation, topical pharyngeal anesthesia and cardiorespiratory safety during gastroscopy. J Clin Gastroenterol 2006; 40:899-905
60. Runes J, Strom C: Midazolam intravenous conscious sedation in oral surgery. A retrospective study of 372 cases. Swed Dent J 1996; 20:29-33
61. Visco DM, Tolpin E, Straughn JC, Fagraeus L: Arterial oxygen saturation in sedated patients undergoing gastrointestinal endoscopy and a review of pulse oximetry. Delaware Med J 1989; 61:533-42
62. Wilson S: Conscious sedation and pulse oximetry: false alarms? Ped Dent 1990; 12:228-32
63. Woods SDS, Chung SCS, Leung JWC, Chan ACW, Li AKC: Hypoxia and tachycardia during endoscopic retrograde cholangiopancreatography; detection by pulse oximetry. Gastrointest Endosc 1989; 35:523-9
64. Wright SW: Conscious sedation in the emergency department: The value of capnography and pulse oximetry. Ann Emerg Med 1992; 21:551-5
65. Herman LL, Kurtz RC, McKee KJ, Sun M, Thaler HT, Winawer J: Risk factors associated with vasovagal reactions during colonoscopy. Gastrointest Endosc 1993; 39:388-91
66. Deitch K, Chudnofsky CR, Dominici P: The utility of supplemental oxygen during emergency department procedural sedation and analgesia with midazolam and fentanyl: a randomized, controlled trial. Ann Emerg Med 2007; 49:1-8
67. Deitch K, Chudnofsky CR, Dominici P, Latta D, Salamanca Y: The utility of high-flow oxygen during emergency department procedural sedation and analgesia with propofol: a randomized, controlled trial. Ann Emerg Med 2011; 58:360-4
68. Haines DJ, Bibbey D, Green JRB: Does nasal oxygen reduce the cardiorespiratory problems experienced by elderly patients undergoing endoscopic retrograde cholangiopancreatography? Gut 1992; 33:973-5
69. Reed MW, O'Leary DP, Duncan JL, Majeed AW, Wright B, Reilly CS: Effects of sedation and supplemental oxygen during upper alimentary tract endoscopy. Scand J Gastroent 1993; 28:319-22

70. Reshef R, Shiller M, Kinberg R, Rennert H, Rennert G, Herskovits M, Loberant N: A prospective study evaluating the usefulness of continuous supplemental oxygen in various endoscopic procedures. Isr J Med Sci 1996; 32:736-40
71. Rohlfing GK, Dilley DC, Lucas WJ, Vann WF, Jr: The effect of supplemental oxygen on apnea and oxygen saturation during pediatric conscious sedation. Ped Dent 1998; 20:8-16
72. Rozario L, Sloper D, Sheridan MJ: Supplemental oxygen during moderate sedation and the occurrence of clinically significant desaturation during endoscopic procedures. Gastroenterol Nurs 2008; 31:281-5
73. Barclay J, Hunter K: A comparison of midazolam with and without nalbuphine for intravenous sedation. Oral Surg Oral Med Oral Pathol 1990; 70:137-40
74. Barriga J, Sachdev MS, Royall L, Brown G, Tombazzi CR. Sedation for upper endoscopy: comparison of midazolam versus fentanyl plus midazolam. South Med J 2008; 101:362-6
75. Lee JJ, Lee JH: Middle-ear surgery under sedation: comparison of midazolam alone or midazolam with remifentanil. J Laryngol Otol 2011; 125:561-6
76. Wong DH, Merrick PM: Intravenous sedation prior to peribulbar anaesthesia for cataract surgery in elderly patients. Can J Anaesth 1996; 43:1115-20
77. Yalcin Cok O, Ertan A, Bahadir M: Comparison of midazolam sedation with or without fentanyl in cataract surgery. Acta anaesthesiologica Belgica 2008; 59:27-32
78. Yuksel O, Parlak E, Koklu S, Ertugrul I, Tunc B, Sahin B: Conscious sedation during endoscopic retrograde cholangiopancreatography: Midazolam or midazolam plus meperidine? Eur J Gastroenterol Hepatol 2007; 19:1002-6
79. Froehlich F, Thorens J, Schwizer W, Preisig M, Kohler M, Hays RD, Fried M, Gonvers JJ: Sedation and analgesia for colonoscopy: patient tolerance, pain, and cardiorespiratory parameters. Gastrointest Endosc 1997; 45:1-9
80. Klein EJ, Diekema DS, Paris CA, Quan L, Cohen M, Seidel KD: A randomized, clinical trial of oral midazolam plus placebo versus oral midazolam plus oral transmucosal fentanyl for sedation during laceration repair. Pediatrics 2002; 109:894-7
81. Walton GM, Boyle CA, Thomson PJ: Changes in oxygen saturation using two different sedation techniques. Br J Oral Maxillofac Surg 1991; 29:87-9
82. Cragg AH, Smith TP, Berbaum KS, Nakagawa N: Randomized double-blind trial of midazolam/placebo and midazolam/fentanyl for sedation and analgesia in lower extremity angiography. Am J Roentgenol 1991; 157:173-6
83. Goktay O, Satilmis T, Garip H, Gonul O, Goker K: A comparison of the effects of midazolam/fentanyl and midazolam/tramadol for conscious intravenous sedation during third molar extraction. J Oral Maxillofac Surg 2011; 69:1594-9
84. Milligan K, Howe J, McLoughlin J, Holmes W, Dundee J: Midazolam sedation for outpatient fibreoptic endoscopy: evaluation of alfentanil supplementation. Ann R Coll Surg Engl 1988; 70:304-6
85. DiPalma JA, Herrera JL, Weis FR, Dark-Mezick DL, Brown RS: Alfentanil for conscious sedation during colonoscopy. South Med J 1995; 88:630-4
86. Hart LS, Berns SD, Houck CS, Boenning DA: The value of end-tidal CO2 monitoring when comparing three methods of conscious sedation for children undergoing painful procedures in the emergency department. Pediatr Emerg Care 1997; 13:189-93
87. Demiraran Y, Korkut E, Tamer A, Yorulmaz I, Kocaman B, Sezen G, Akcan Y: The comparison of dexmedetomidine and midazolam used for sedation of patients during upper endoscopy: A prospective, randomized study. Can J Gastroenterol 2007; 21:25-9

88. Surendar MN, Pandey RK, Saksena AK, Kumar R, Chandra G: A comparative evaluation of intranasal dexmedetomidine, midazolam and ketamine for their sedative and analgesic properties: a triple blind randomized study. J Clin Pediatr Dent 2014; 38:255-61
89. Cho JS, Shim JK, Na S, Park I, Kwak YL: Improved sedation with dexmedetomidine-remifentanil compared with midazolam-remifentanil during catheter ablation of atrial fibrillation: a randomized, controlled trial. Europace. 2014; 16:1000-6
90. Lee BS, Ryu J, Lee SH, Lee MG, Jang SE, Hwang JH, Ryu JK, Do SH, Kim YT: Midazolam with meperidine and dexmedetomidine vs. midazolam with meperidine for sedation during ERCP: prospective, randomized, double-blinded trial. Endoscopy 2014; 46:291-8.
91. Ghane MR, Javadzadeh HR, Mahmoudi S, Najafian B, Saburi A: Intramuscular compared to intravenous midazolam for paediatric sedation: A study on cardiopulmonary safety and effectiveness. Afr J Paediatr Surg 2014; 11:219-24
92. Hogberg L, Nordvall M, Tjellstrom B, Stenhammar L: Intranasal versus intravenous administration of midazolam to children undergoing small bowel biopsy. Acta Paediatr 1995; 84:1429-31
93. Lundgren S, Rosenquist J: Comparison of sedation, amnesia, and patient comfort produced by intravenous and rectal diazepam. J Oral Maxillofac Surg 1984; 42:646-50
94. Zhang X, Bai X, Zhang Q, Wang X, Lu L: The safety and efficacy of intranasal dexmedetomidine during electrochemotherapy for facial vascular malformation: a double-blind, randomized clinical trial. J Oral Maxillofac Surg 2013; 71:1835-42
95. Morrow JB, Zuccaro G, Conwell DL, Vargo JJ, Dumot JA, Karafa M, Shay SS: Sedation for colonoscopy using a single bolus is safe, effective, and efficient: a prospective, randomized, double-blind trial. Am J Gastroent 2000; 95:2242-7
96. Carlsson U, Grattidge P: Sedation for upper gastrointestinal endoscopy: a comparative study of propofol and midazolam. Endoscopy 1995; 27:240-3
97. Clark G, Licker M, Younossian AB, Soccal PM, Frey JG, Rochat T, Diaper J, Bridevaux PO, Tschopp JM: Titrated sedation with propofol or midazolam for flexible bronchoscopy: a randomised trial. Eur Respir J 2009; 34:1277-83
98. Hari Keerthy P, Balakrishna R, Srungeri KM, Singhvi N, John J, Islam M: Comparitive evaluation of propofol and midazolam as conscious sedatives in minor oral surgery. J Maxillofac Oral Surg 2015; 14:773-83
99. Riphaus A, Lechowicz I, Frenz MB, Wehrmann T: Propofol sedation for upper gastrointestinal endoscopy in patients with liver cirrhosis as an alternative to midazolam to avoid acute deterioration of minimal encephalopathy: a randomized, controlled study. Scand J Gastroenterol 2009; 44:1244-51
100. Wehrmann T, Kokabpick S, Lembcke B, Caspary WF, Seifert H: Efficacy and safety of intravenous propofol sedation during routine ERCP: a prospective, controlled study. Gastrointest Endosc 1999; 49:677-83
101. Guerra F, Pavoni I, Romandini A, Baldetti L, Matassini MV, Brambatti M, Luzi M, Pupita G, Capucci A: Feasibility of a cardiologist-only approach to sedation for electrical cardioversion of atrial fibrillation: a randomized, open-blinded, prospective study. Int J Cardiol 2014; 176:930-5
102. Patterson KW, Casey PB, Murray JP, O'Boyle CA, Cunningham AJ: Propofol sedation for outpatient upper gastrointestinal endoscopy: comparison with midazolam. Br J Anaesth 1991; 67:108-11
103. Salmon JF, Mets B, James MFM, Murray ADN: Intravenous sedation for ocular surgery under local anaesthesia. Br J Ophthal 1992; 76:598-601

104. Wagner HJ, Nowacki J, Klose KJ: Propofol versus midazolam for sedation during percutaneous transluminal angioplasty. J Vasc Interv Radiol 1996; 7:673-80
105. Nirwan AS, Jain N, Pragasm M, Kamblimath D, Bhargava A, Tiwari S: Randomised comparative study on propofol and diazepam as a sedating agent in day care surgery. J Maxillofac Oral Surg 2014; 13:583-91
106. Ulmer BJ, Hansen JJ, Overley CA, Symms MR, Chadalawada V, Liangpunsakul S, Strahl E, Mendel AM, Rex DK: Propofol versus midazolam/fentanyl for outpatient colonoscopy: administration by nurses supervised by endoscopists. Clin Gastroenterol Hepatol 2003; 425-32
107. Vargo JJ, Zuccaro G Jr, Dumot JA, Shermock KM, Morrow JB, Conwell DL, Trolli PA, Maurer WG: Gastroenterologist-administered propofol versus meperidine and midazolam for advanced upper endoscopy: a prospective, randomized trial. Gastroenterology 2002; 123:8-16
108. Zuo XL, Li Z, Liu XP, Li CQ, Ji R, Wang P, Zhou CJ, Liu H, Li YQ: Propofol vs midazolam plus fentanyl for upper gastrointestinal endomicroscopy: a randomized trial. World J Gastroenterol 2012; 18:1814-21
109. Carmi U, Kramer MR, Zemtzov D, Rosengarten D, Fruchter O: Propofol safety in bronchoscopy: prospective randomized trial using transcutaneous carbon dioxide tension monitoring. Respiration 2011; 82:515-21
110. Stolz D, Kurer G, Meyer A, Chhajed PN, Pflimlin E, Strobel W, Tamm M: Propofol versus combined sedation in flexible bronchoscopy: a randomized non-inferiority trial. Eur Respir J 2009; 34:1024-30
111. Hampl KF, Marsch SC, Erb T, Drewe J, Schneider MC: Intravenous sedation for retrobulbar injection and eye surgery: diazepam and/or propofol? Acta Anaesth Scand 1996; 40:53-8
112. Lee JE, Lee SK, Chung H, Park JC, Shin SK, Lee YC: Comparison of midazolam plus propofol with propofol alone for upper endoscopy: A prospective, single blind, randomized clinical trial. Gastrointest Endosc 2016; 1:AB222
113. Molina-Infante J, Duenas-Sadornil C, Mateos-Rodriguez JM, Perez-Gallardo B, Vinagre-Rodriguez G, Hernandez-Alonso M, Fernandez-Bermejo M, Gonzalez-Huix F: Nonanesthesiologist-administered propofol versus midazolam and propofol, titrated to moderate sedation, for colonoscopy: a randomized controlled trial. Dig Dis Sci 2012; 57:2385-93
114. Holas A, Krafft P, Marcovic M, Quchenberger F: Remifentanil, propofol or both for conscious sedation during eye surgery under regional anaesthesia. Eur J Anaesthesiol 1999; 16:741-748
115. Mahfouz AK, Ghali AM: Combined use of remifentanil and propofol to limit patient movement during retinal detachment surgery under local anesthesia. Saudi J Anaesthesia 2010; 4:147-51
116. Keidan I, Berkenstadt H, Sidi A, Perel A: Propofol/remifentanil versus propofol alone for bone marrow aspiration in paediatric haemato-oncological patients. Paediatr Anaesth 2001; 11:297-301
117. Li S, Yu F, Zhu H, Yang Y, Yang L, Lian J: The median effective concentration (EC50) of propofol with different doses of fentanyl during colonoscopy in elderly patients. BMC Anesthesiol 2016; 16:24
118. Rewari V, Madan R, Kaul HL: Remifentanil and propofol sedation for retrobulbar nerve block. Anaesth Intens Care 2002;30:433-7
119. Akarsu Ayazoğlu T, Polat E, Bolat C, Yasar NF, Duman U, Akbulut S, Yol S: Comparison of propofol-based sedation regimens administered during colonoscopy. Rev Med Chil 2013; 141:477-85

120. Ali AR, El Ghoneimy MN: Dexmedetomidine versus fentanyl as adjuvant to propofol: comparative study in children undergoing extracorporeal shock wave lithotripsy. Eur J Anaesthesiol 2010; 27:1058-64
121. Cimilli Ozturk T, Guneysel O, Akoglu H: Anterior shoulder dislocation reduction managed either with midazolam or propofol in combination with fentanyl. Hong Kong J Emerg Med 2014; 21:346-353
122. Correia LM, Bonilha DQ, Gomes GF, Brito JR, Nakao FS, Lenz L, Rohr MR, Ferrari AP, Libera ED: Sedation during upper GI endoscopy in cirrhotic outpatients: a randomized, controlled trial comparing propofol and fentanyl with midazolam and fentanyl. Gastrointest Endosc 2011; 73:45-51
123. Dunn MJ, Mitchell R, DeSouza CI, Drummond GB, Waite A: Recovery from sedation with remifentanil and propofol, compared with morphine and midazolam, for reduction in anterior shoulder dislocation. Emergency Med J 2011; 28:6-10
124. Eberl S, Polderman JA, Preckel B, Kalkman CJ, Fockens P, Hollmann MW: Is "really conscious" sedation with solely an opioid an alternative to every day used sedation regimes for colonoscopies in a teaching hospital? Midazolam/fentanyl, propofol/alfentanil, or alfentanil only for colonoscopy: a randomized trial. Techn Coloproctol 2014; 18:745-52
125. Holger JS, Satterlee PA, Haugen S: Nursing use between 2 methods of procedural sedation: Midazolam versus propofol. Am J Emerg Med 2005; 23:248-52
126. Kawaai H, Tomita S, Nakaike Y, Ganzberg S, Yamazaki S: Intravenous sedation for implant surgery: midazolam, butorphanol, and dexmedetomidine versus midazolam, butorphanol, and propofol. J Oral Implantol 2014; 40:94-102
127. Khoshoo V, Thoppil D, Landry L, Brown S, Ross G: Propofol versus midazolam plus meperidine for sedation during ambulatory esophagogastroduodenoscopy. J Pediatr Gastroenterol Nutr 2003; 37:146-9
128. Kim N, Yoo YC, Lee SK, Kim H, Ju HM, Min KT: Comparison of the efficacy and safety of sedation between dexmedetomidine-remifentanil and propofol-remifentanil during endoscopic submucosal dissection. World J Gastroenterol 2015; 21:3671-8
129. Kuyrukluyildiz U, Binici O, Onk D, Celik SA, Torun MT, Unver E, Ozcicek A, Alagoi A: Comparison of dexmedetomidine and propofol used for drug-induced sleep endoscopy in patients with obstructive sleep apnea syndrome. Int J Clin Exp Med 2015; 8:5691-8
130. Lee CK, Lee SH, Chung IK, Lee TH, Park S-H, Kim E-O, Lee SH, Kim H-S, Kim S-J: Balanced propofol sedation for therapeutic GI endoscopic procedures: a prospective, randomized study. Gastrointest Endosc 2011; 73:206-14
131. Levitzky BE, Lopez R, Dumot JA, Vargo JJ: Moderate sedation for elective upper endoscopy with balanced propofol versus fentanyl and midazolam alone: a randomized clinical trial. Endoscopy 2012; 44:13-20
132. Manninen PH, Chan AS, Papworth D: Conscious sedation for interventional neuroradiology: a comparison of midazolam and propofol infusion. Can J Anaesth 1997; 44:26-30
133. Netinatsunton N, Attasaranya S, Sottisuporn J, Witeerungrot T, Piratvisuth T, Ovartlarnporn B: Efficacy and safety profiles of sedation with propofol combined with intravenous midazolam and pethidine versus intravenous midazolam and pethidine administered by trained nurses for ambulatory endoscopic retrograde cholangiopancreatography (ERCP). Gastrointest Endosc 2012; 1:AB291
134. Parworth LP, Frost DE, Zuniga JR, Bennett T: Propofol and fentanyl compared with midazolam and fentanyl during third molar surgery. J Oral Maxillofac Surg 1998; 56:447-53
135. Rahman NH, Hashim A: The use of propofol for procedural sedation and analgesia in the emergency department: a comparison with midazolam. Emerg Med J 2011; 28:861-5

136. Sajedi P, Yaraghi A, Niareisy L. A single dose of propofol can produce excellent sedation and comparable amnesia with midazolam in cystoscopic examination. J Research Med Sci 2006; 11:160-163
137. Sienkiewicz E, Albrecht P, Ziolkowski J, Dziechciarz P: Propofol-alfentanil versus midazolam-alfentanil in inducing procedural amnesia of upper gastrointestinal endoscopy in children-blind randomised trial. Eur J Pediatr 2015; 174:1475-80
138. Miner JR, Gray RO, Bahr J, Patel R, McGill JW: Randomized clinical trial of propofol versus ketamine for procedural sedation in the emergency department. Acad Emerg Med 2010; 17:604-11
139. Rai K, Hegde AM, Goel K: Sedation in uncooperative children undergoing dental procedures: a comparative evaluation of midazolam, propofol and ketamine. J Clin Pediatr Dent 2007; 32:1-4
140. Baysal A, Polat TB, Yalcin Y, Celebi A: The use of basic parameters for monitoring the haemodynamic effects of midazolam and ketamine as opposed to propofol during cardiac catheterization. Cardiol Young 2014; 24:351-8
141. Uri O, Behrbalk E, Haim A, Kaufman E, Halpern P: Procedural sedation with propofol for painful orthopaedic manipulation in the emergency department expedites patient management compared with a midazolam/ketamine regimen: a randomized prospective study. J Bone Joint Surg Am 2011; 93:2255-62
142. Phillips W, Anderson A, Rosengreen M, Johnson J, Halpin J: Propofol versus propofol/ketamine for brief painful procedures in the emergency department: clinical and bispectral index scale comparison. J Pain Palliat Care Pharmacother 2010; 24:349-55
143. Mittal N, Goyal A, Gauba K, Kapur A, Jain K: A double blind randomized trial of ketofol versus propofol for endodontic treatment of anxious pediatric patients. J Clin Pediatr Dent 2013; 37:415-20
144. Bahetwar SK, Pandey RK, Saksena AK, Chandra G: A comparative evaluation of intranasal midazolam, ketamine and their combination for sedation of young uncooperative pediatric dental patients: a triple blind randomized crossover trial. J Clin Pediatr Dent 2011; 35:415-20
145. Younge PA, Kendall JM: Sedation for children requiring wound repair: a randomised controlled double blind comparison of oral midazolam and oral ketamine. Emerg Med J 2001; 18:30-3
146. Lee JH, Kim K, Kim TY, Jo YH, Kim SH, Rhee JE, Heo CY, Eun SC: A randomized comparison of nitrous oxide versus intravenous ketamine for laceration repair in children. Pediatr Emerg Care 2012; 28:1297-301
147. Jamal SM, Fathil SM, Nidzwani MM, Ismail AK, Yatim FM: Intravenous ketamine is as effective as midazolam/fentanyl for procedural sedation and analgesia in the emergency department. Med J Malaysia 2011; 66:231-3
148. Barkan S, Breitbart R, Brenner-Zada G, Feldon M, Assa A, Toledano M, Berkovitch S, Shavit I, Kozer E: A double-blind, randomised, placebo-controlled trial of oral midazolam plus oral ketamine for sedation of children during laceration repair. Emerg Med J 2014; 31:649-53
149. Sener S, Eken C, Schultz CH, Serinken M, Ozsarac M: Ketamine with and without midazolam for emergency department sedation in adults: a randomized controlled trial. Ann Emerg Med 2011; 57:109-14
150. Monk TG, Rater JM, White PF: Comparison of alfentanil and ketamine infusions in combination with midazolam for outpatient lithotripsy. Anesthesiology 1991; 74:1023-8
151. Genzlinger MA, Salen P, Grossman M, Stehly C, Stoltzfus J: "Put me out doc": Ketamine versus etomidate for the reduction of orthopedic dislocations. Ann Emerg Med 2012; 60:S52-S53

152. Milazzo A, Villaneuve R, Salen P, Stoltzfus J, Grossman M: A comparison of ketamine versus etomidate for procedural sedation for the reduction of joint dislocations. Annals Emerg Med 2014; 1:S130
153. Akin A, Guler G, Esmaoglu A, Bedirli N, Boyaci A: A comparison of fentanyl-propofol with a ketamine-propofol combination for sedation during endometrial biopsy. J Clin Anesth 2005; 17:187-90
154. Chandar R, Jagadisan B, Vasudevan A: Propofol-ketamine and propofol-fentanyl combinations for nonanesthetist-administered sedation. J Pediatr Gastroenterol Nutr 2015; 60:762-768
155. Takzare A, Soltani AE, Maleki A, Nooralishahi B, Kaheh F, Arab S, Goudarzi M: Comparison of propofol-ketamine vs propofol-fentanyl for pediatric sedation during upper gastroinestinal endoscopy. Arch Anesth Crit Care 2016; 2:216-225
156. Burton JH, Bock AJ, Strout TD, Marcolini EG: Etomidate and midazolam for reduction of anterior shoulder dislocation: a randomized, controlled trial. Ann Emerg Med 2002; 40:496-504
157. Kienstra AJ, Ward MA, Sasan F, Hunter J, Morriss MC, Macias CG: Etomidate versus pentobarbital for sedation of children for head and neck CT imaging. Pediatr Emerg Care 2004; 20:499-506
158. Di Liddo L, D'Angelo A, Nguyen B, Bailey B, Amre D, Stanciu C: Etomidate versus midazolam for procedural sedation in pediatric outpatients: a randomized controlled trial. Ann Emerg Med 2006; 48:433-40
159. Hunt GS, Spencer MT, Hays DP: Etomidate and midazolam for procedural sedation: prospective, randomized trial. Am J Emerg Med 2005; 23:299-303
160. Gharavifard M, Zadeh BBR, Moghadam HZ: A randomized clinical trial of intravenous and intramuscular ketamine for pediatric procedural sedation and analgesia. Emergency 2015; 3:59-63
161. Bell A, Treston G, Cardwell R, Schabort WJ, Chand D: Optimization of propofol dose shortens procedural sedation time, prevents resedation and removes the requirement for post-procedure physiologic monitoring. Emerg Med Australas 2007; 19:411-7
162. Heuss LT, Schnieper P, Drewe J, Pfimlin E, Beglinger C: Conscious sedation with propofol in elderly patients: a prospective evaluation. Aliment Pharmacol Ther 2003; 17:1493-1501
163. Heuss LT, Schnieper P, Drewe J, Pfimlin E, Beglinger C: Risk stratification and safe administration of propofol by registered nurses supervised by the gastroenterologist: a prospective observational study of more than 2000 cases. Gastrointest Endosc 2003; 57:664-71
164. Novak H, Karlsland Akeson P, Akeson J: Sedation with ketamine and low-dose midazolam for short-term procedures requiring pharyngeal manipulation in young children. Paediatr Anaesth 2008; 18:48-54
165. Barsan WG, Seger D, Danzl DF, Ling LJ, Bartlett R, Buncher R, Bryan C: Duration of antagonistic effects of nalmefene and naloxone in opiate-induced sedation for emergency department procedures. Am J Emerg Med 1989; 7:155-61
166. Balsells F, Wyllie R, Kay M, Steffen R: Use of conscious sedation for lower and upper gastrointestinal endoscopic examinations in children, adolescents, and young adults: a twelve-year review. Gastrointest Endosc 1997; 45:375-80
167. Jann M, Fidone G, Gorday M, Rostedt R: Butorphanol as a dental premedication in the mentally retarded. Oral Surg Oral Med Oral Pathol 1987; 63:403-7
168. Ackerman WE, Phero JC, Theodore GT: Ineffective ventilation during conscious sedation due to chest wall rigidity after intravenous midazolam and fentanyl. Anesth Prog 1990; 37:46-8

169. Greenwald B: Narcan use in the endoscopy lab: an important component of patient safety. Gastroenterol Nurs 2004; 27:20-1
170. Miller DL, Wall RT: Fentanyl and diazepam for analgesia and sedation during radiologic special procedures. Radiology 1987; 162:195-8
171. Yaster M, Nichols DG, Deshpande JK, Wetzel RC: Midazolam-fentanyl intravenous sedation in children: Case report of respiratory arrest. Pediatrics 1990; 86:463-6
172. Birch BR, Anson KM, Kalmanovitch DV, Cooper J, Miller RA: Sedation for day-case urology: an assessment of patient recovery profiles after midazolam and flumazenil. Ann R Coll Surg Engl 1991; 73:373-8
173. Birkenfeld S, Federico C, Dermansky-Avni Y, Bruck R, Melzer E, Bar-Meir S: Double-blind controlled trial of flumazenil in patients who underwent upper gastrointestinal endoscopy. Gastrointest Endosc 1989; 35:519-22
174. Clark MS, Lindenmuth JE, Jafek BW, Fryer GE, Jr., Goldberg JR: Reversal of central benzodiazepine effects by intravenous flumazenil. Anesth Prog 1991; 38:12-6
175. Holloway AM, Logan DA: The use of flumazenil to reverse diazepam sedation after endoscopy. Eur J Anaesthesiol Suppl 1988; 2:191-8
176. Pearson RC, McCloy RF, Bardhan KD, Jackson V, Morris P: The use of flumazenil to reverse sedation induced by bolus low dose midazolam or diazepam in upper gastrointestinal endoscopy. Eur J Gastroent Hepatol 1991; 3:829-33
177. Rodrigo MR, Rosenquist JB: The effect of Ro15-1788 (Anexate) on conscious sedation produced with midazolam. Anaesth Intensive Care 1987; 15:185-92
178. Sanders LD, Piggott SE, Isaac PA, Okell RW, Roberts B, Rosen M, Robinson JO: Reversal of benzodiazepine sedation with the antagonist flumazenil. Br J Anaesth 1991; 66:445-53
179. Wille RT, Chaffee BW, Ryan ML, Elta GH, Walter V, Barnett JL: Pharmacoeconomic evaluation of flumazenil for routine outpatient EGD. Gastrointest Endosc 2000; 51:282-7
180. Chang AC, Solinger MA, Yang DT, Chen YK: Impact of flumazenil on recovery after outpatient endoscopy: a placebo-controlled trial. Gastrointest Endosc 1999; 49:573-9
181. Davies CA, Sealey CM, Lawson JI, Grant IS: Reversal of midazolam sedation with flumazenil following conservative dentistry. J Dent 1990; 18:113-8
182. Fennelly ME, Powell H, Galletly DC, Whitwam JG: Midazolam sedation reversed with flumazenil for cardioversion. Br J Anaesth 1992; 68:303-5
183. [No authors listed]: Reversal of central benzodiazepine effects by flumazenil after intravenous conscious sedation with diazepam and opioids: report of a double-blind multicenter study. Clinical Ther 1992; 14:910-23
184. [No authors listed]: Reversal of central benzodiazepine effects by intravenous flumazenil after conscious sedation with midazolam and opioids: a multicenter clinical study. Clinical Ther 1992; 14:878-94
185. Cooper SA, Quinn PD, MacAfee K, McKenna D: Reversing intravenous sedation with flumazenil. Oral Surg Oral Med Oral Path 1991; 72:2-9
186. Peters JM, Tolia V, Simpson P, Aravind MK, Kauffman RE: Flumazenil in children after esophagogastroduodenoscopy. Am J Gastroenterol 1999; 94:1857-61
187. Roberts SP, Hargreaves J, Pollard BJ: The use of midazolam and flumazenil for invasive radiographic procedures. Postgrad Med J 1993; 69:922-6
188. Thurman RJ, Bryce S, Phillips L: Use of a novel electronic pre-sedation checklist improves safety documentation in emergency department sedations. Acad Emerg Med 2013; 20 (Suppl 1):S65

Appendix I: Summary of Recommendations

Patient Evaluation

- Review previous medical records and interview the patient or family to identify:
  - Abnormalities of the major organ systems (*e.g.,* cardiac, renal, pulmonary, neurologic, sleep apnea, metabolic, endocrine).
  - Adverse experience with sedation/analgesia as well as regional and general anesthesia.
  - Current medications, potential drug interactions, drug allergies and nutraceuticals.
  - History of tobacco, alcohol or substance use or abuse.
  - Frequent or repeated exposure to sedation/analgesic agents.
- Conduct a focused physical examination of the patient (*e.g.,* vital signs, auscultation of the heart and lungs, evaluation of the airway, ‡‡‡‡‡‡ and when appropriate to sedation, other organ systems where major abnormalities have been identified).
- Review available laboratory test results.
- Order additional laboratory tests guided by a patient's medical condition, physical examination, and the likelihood that the results will affect the management of moderate sedation/analgesia.
  - Evaluate results of these tests before sedation is initiated.
- If possible, perform the preprocedure evaluation well enough in advance (*e.g.,* several days to weeks) to allow for proper patient preparation.§§§§§§
- Re-evaluate the patient immediately before the procedure.

Preprocedure Patient Preparation

- Consult with a medical specialist (*e.g.,* physician anesthesiologist, cardiologist, endocrinologist, pulmonologist, nephrologist, pediatrician, obstetrician, or otolaryngologist), when appropriate before administration of moderate procedural sedation to patients with significant underlying conditions.
  - If a specialist is needed, select a specialist based on the nature of the underlying condition and the urgency of the situation.
  - For severely compromised or medically unstable patients (*e.g.*, anticipated difficult airway, severe obstructive pulmonary disease, coronary artery disease, or congestive heart failure), or if it is likely that sedation to the point of unresponsiveness will be necessary to obtain adequate conditions, consult with a physician anesthesiologist.
- Before the procedure, inform patients or legal guardians of the benefits, risks and limitations of moderate sedation/analgesia and possible alternatives, and elicit their preferences.*******
- Before the day of the procedure, inform patients or legal guardians that they should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric

‡‡‡‡‡‡ See table 2 for additional information related to airway assessment.
§§§§§§ This may not be feasible for urgent or emergency procedures, interventional radiology or other radiology settings.
******* This may not be feasible for urgent or emergency procedures.

emptying before the procedure.††† †††††††

- On the day of the procedure, assess the time and nature of last oral intake.
    - Evaluate the risk of pulmonary aspiration of gastric contents when determining (1) the target level of sedation, and (2) whether the procedure should be delayed.
    - In urgent or emergent situations where complete gastric emptying is not possible, do not delay moderate procedural sedation based on fasting time alone.

Patient Monitoring

Monitoring patient level of consciousness.

- Periodically (*e.g.,* at 5-min intervals) monitor a patient's response to verbal commands during moderate sedation, except in patients who are unable to respond appropriately (*e.g.*, patients where age or development may impair bidirectional communication), or during procedures where movement could be detrimental.
    - During procedures where a verbal response is not possible (*e.g.*, oral surgery, restorative dentistry, upper endoscopy), check the patient's ability to give a "thumbs up" or other indication of consciousness in response to verbal or tactile (light tap) stimulation; this suggests that the patient will be able to control his airway and take deep breaths if necessary.‡‡‡‡‡‡‡

Monitoring patient ventilation and oxygenation.

- Continually monitor ventilatory function by observation of qualitative clinical signs.
- Continually monitor ventilatory function with capnography unless precluded or invalidated by the nature of the patient, procedure, or equipment.
    - For uncooperative patients, institute capnography once moderate sedation has been achieved.
- Monitor all patients by pulse oximetry with appropriate alarms.

Monitoring hemodynamics.

- Determine blood pressure before sedation/analgesia is initiated unless precluded by lack of patient cooperation.
- Once moderate sedation/analgesia is established, continually monitor blood pressure (*e.g.,* at 5-minute intervals) and heart rate during the procedure unless such monitoring interferes with the procedure (*e.g.,* magnetic resonance imaging where stimulation from the blood pressure cuff could arouse an appropriately sedated patient).
- Use electrocardiographic monitoring during moderate sedation in patients with clinically significant cardiovascular disease or those who are undergoing procedures where dysrhythmias are anticipated.

Contemporaneous recording of monitored parameters.

- Record patients' level of consciousness, ventilatory and oxygenation status, and hemodynamic variables at a frequency which depends on the type and amount of

††††††† See Table 3 and/or refer to: American Society of Anesthesiologists: Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: Application to healthy patients undergoing elective procedures: An updated report. *ANESTHESIOLOGY* 2017; 126:376-93

‡‡‡‡‡‡‡ A response limited to reflex withdrawal from a painful stimulus is not considered a purposeful response and thus represents a state of general anesthesia.

medication administered, the length of the procedure, and the general condition of the patient.

- At a minimum, this should occur: (1) before the administration of sedative/analgesic agents[§§§§§§§]; (2) following administration of sedative/analgesic agents; (3) at regular intervals during the procedure, (4) during initial recovery; and (5) just before discharge.
- Set device alarms to alert the care team to critical changes in patient status.

Availability of an individual responsible for patient monitoring.

- Assure that a designated individual other than the practitioner performing the procedure is present to monitor the patient throughout the procedure.
  - The individual responsible for monitoring the patient should be trained in the recognition of apnea and airway obstruction and be empowered to seek additional help.
  - The designated individual may assist with minor, interruptible tasks once the patient's level of sedation/analgesia and vital signs have stabilized, provided that adequate monitoring for the patient's level of sedation is maintained.

Supplemental Oxygen

- Use supplemental oxygen during moderate procedural sedation/analgesia unless specifically contraindicated for a particular patient or procedure.

Emergency Support

- Assure that pharmacologic antagonists for benzodiazepines and opioids are immediately available in the procedure room.
  - Assure that an individual is present in the room who understands the pharmacology of the sedative/analgesics administered (*e.g.,* opioids and benzodiazepines) and potential interactions with other medications and nutraceuticals the patient may be taking,
- Assure that appropriately-sized equipment for establishing a patent airway is available.
- Assure that at least one individual capable of establishing a patent airway and providing positive pressure ventilation is present in the procedure room.
- Assure that suction, advanced airway equipment, a positive pressure ventilation device, and supplemental oxygen are immediately available in the procedure room and in good working order.
  - Assure that a member of the procedural team is trained in the recognition and treatment of airway complications (*e.g.,* apnea, laryngospasm, airway obstruction), opening the airway, suctioning secretions, and performing bag-valve-mask ventilation.

[§§§§§§§] For rare uncooperative patients (*e.g.,* children with autism spectrum disorder or attention deficit disorder) recording oxygenation status or blood pressure may not be possible until after sedation.

- Assure that a member of the procedural team has the skills to establish intravenous access.
- Assure that a member of the procedural team has the skills to provide chest compressions.
- Assure that a functional defibrillator or automatic external defibrillator is immediately available in the procedure area.
- Assure that an individual or service (*e.g.,* code blue team, paramedic-staffed ambulance service) with advanced life support skills (*e.g.,* tracheal intubation, defibrillation, resuscitation medications) is immediately available.
- Assure that members of the procedural team are able to recognize the need for additional support and know how to access emergency services from the procedure room (e.g., telephone, call button).

Sedative or Analgesic Medications Not Designed for General Anesthesia

- Combinations of sedative and analgesic agents may be administered as appropriate for the procedure and the condition of the patient.********
    - Administer each component individually to achieve the desired effect (*e.g.*, additional analgesic medication to relieve pain; additional sedative medication to decrease awareness or anxiety).
- Dexmedetomidine may be administered as an alternative to benzodiazepine sedatives on a case-by-case basis.
- In patients receiving intravenous medications for sedation/analgesia, maintain vascular access throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression.
- In patients who have received sedation/analgesia by non-intravenous routes, or whose intravenous line has become dislodged or blocked, determine the advisability of reestablishing intravenous access on a case-by-case basis.
- Administer intravenous sedative/analgesic drugs in small, incremental doses, or by infusion, titrating to the desired endpoints.
    - Allow sufficient time to elapse between doses so the peak effect of each dose can be assessed before subsequent drug administration.
- When drugs are administered by non-intravenous routes (*e.g.*, oral, rectal, intramuscular, transmucosal), allow sufficient time for absorption and peak effect of the previous dose to occur before supplementation is considered.

Sedative or Analgesic Medications Designed for General Anesthesia

- When moderate procedural sedation with sedative or analgesic medications designed for general anesthesia by any route is intended, provide care consistent with that required for general anesthesia.
    - Assure that practitioners administering these drugs are able to reliably rescue

******** The propensity for combinations of sedative and analgesic agents to cause respiratory depression and airway obstruction emphasizes the need to appropriately reduce the dose of each component as well as the need to continually monitor respiratory function. Knowledge of each drug's time of onset, peak response, and duration of action is important. Titration of drug to effect is an important concept; one must know whether the previous dose has taken full effect before administering additional drug.

patients from unintended deep sedation or general anesthesia.

- For patients receiving intravenous sedatives designed for general anesthesia, maintain vascular access throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression.
- In patients who have received sedatives designed for general anesthesia by non-intravenous routes, or whose intravenous line has become dislodged or blocked, determine the advisability of reestablishing intravenous access on a case-by-case basis.
- Administer intravenous sedative/analgesic drugs designed for general anesthesia in small, incremental doses, or by infusion, titrating to the desired endpoints.
    - Allow sufficient time to elapse between doses so the peak effect of each dose can be assessed before subsequent drug administration.
- When drugs designed for general anesthesia are administered by non-intravenous routes (*e.g.*, oral, rectal, intramuscular, transmucosal), allow sufficient time for absorption and peak effect of the previous dose to occur before supplementation is considered.

Reversal Agents

- Assure that specific antagonists are immediately available in the procedure room whenever opioid analgesics or benzodiazepines are administered for moderate procedural sedation/analgesia, regardless of route of administration.
- If patients become hypoxemic or apneic during sedation/analgesia: (1) encourage or physically stimulate patients to breathe deeply; (2) administer supplemental oxygen; and (3) provide positive pressure ventilation if spontaneous ventilation is inadequate.
- Use reversal agents in cases where airway control, spontaneous ventilation or positive pressure ventilation are inadequate.
    - Administer naloxone to reverse opioid-induced sedation and respiratory depression.††††††††
    - Administer flumazenil to reverse benzodiazepine-induced sedation and respiratory depression.
- After pharmacologic reversal, observe and monitor patients for a sufficient time to ensure that sedation and cardiorespiratory depression does not recur once the effect of the antagonist dissipates.
- Do not use sedation regimens that include routine reversal of sedative or analgesic agents.

Recovery Care

- Following sedation/analgesia, observe and monitor patients in an appropriately staffed and equipped area until they are near their baseline level of consciousness and are no longer at increased risk for cardiorespiratory depression.
- Monitor oxygenation continuously until patients are no longer at risk for hypoxemia.
- Monitor ventilation and circulation at regular intervals until patients are suitable for discharge.
- Design discharge criteria to minimize the risk of central nervous system or cardiorespiratory depression following discharge from observation by trained personnel.‡‡‡‡‡‡‡‡

†††††††† Practitioners are cautioned that acute reversal of opioid-induced analgesia may result in pain, hypertension, tachycardia, or pulmonary edema.

‡‡‡‡‡‡‡‡ Discharge criteria examples are noted in Table 5.

Creation and Implementation of Patient Safety Processes

- Create and implement a quality improvement process based upon national, regional or institutional reporting protocols, (*e.g.,* adverse events, unsatisfactory sedation).
- Strengthen patient safety culture through collaborative practices (*e.g.,* team training, simulation drills, development and implementation of checklists).
    - Create an emergency response plan (*e.g.,* activating "code blue" team or activating the emergency medical response system--911 or equivalent).

Appendix 2: Methods and Analyses

827 For these Guidelines, a systematic search and review of peer-reviewed published literature was
828 conducted, with scientific findings summarized and reported below and in the document.
829 Assessment of conceptual issues, practicality and feasibility of the Guideline recommendations was
830 also evaluated, with opinion data collected from surveys and other sources. Both the systematic
831 literature review and opinion data are based on *evidence linkages*, or statements regarding potential
832 relationships between interventions and outcomes associated with moderate procedural sedation.
833 The evidence model below guided the search, providing inclusion and exclusion information
834 regarding patients, procedures, practice settings, providers, clinical interventions, and outcomes.

Evidence Model

Patients.

- Inclusion criteria:
  - Any patient having a diagnostic or therapeutic procedure for which moderate sedation is planned
- Exclusion criteria:
  - Patients in whom the level of sedation cannot reliably be established
    - Patients who do not respond purposefully to verbal or tactile stimulation (e.g., stroke victims, neonates)
    - Patients in whom determining the level of sedation interferes with the procedure

Procedures.

- Inclusion criteria:
  - Elective and urgent/emergent procedures
  - Diagnostic and therapeutic procedures
    - Principal procedures (e.g., upper endoscopy, colonoscopy , radiology, ophthalmology, cardiology, dentistry, plastics, orthopedic, urology, podiatry)
    - Diagnostic imaging (radiological scans, endoscopy)
    - Minor surgical procedures in all care areas (e.g., cardioversion)
    - Pediatric procedures (e.g., suture of laceration, setting of simple fracture, lumbar puncture, bone marrow with local, MRI or CT scan, routine dental procedures)
    - Pediatric cardiac catheterization (e.g. cardiac biopsy post transplantation)
    - Obstetric procedures (e.g., labor and delivery)
- Exclusion criteria:
  - Procedures using minimal sedation (*e.g.,* anxiolysis for insertion of peripheral nerve blocks, local or topical anesthesia)
  - Procedures where deep sedation is intended

- Procedures where general anesthesia is intended
- Procedures using major conduction anesthesia (*i.e.,* neuraxial anesthesia)
- Procedures using sedatives in combination with regional anesthesia
- Non-diagnostic or non-therapeutic procedures (*e.g.,* postoperative analgesia, pain management/chronic pain, critical care, palliative care)

Practice Settings.

- Inclusion criteria:
  - Settings where procedural moderate sedation may be administered
    - Hospitals
    - Ambulatory procedural centers
    - Office practices
      - Hospital connected
      - Free-standing
      - Dental office
      - Urology office
      - Ophthalmology office
    - Emergency settings
    - Endoscopy suite
    - Plastic surgery suite
    - Radiology suite (MRI, CT, invasive)
    - Oral and maxillofacial surgery (OMS) suite
    - Cardiac catheterization laboratory
    - Oncology clinics
    - Electrophysiology laboratory
    - Interventional radiology laboratory
    - Neurointerventional laboratory
    - Echocardiology laboratory
    - Evoked auditory testing laboratory
- Exclusion criteria: (None indicated)

Providers.

- Inclusion criteria:
  - All providers who deliver moderate procedural sedation in any practice setting
    - Physician anesthesiologists and anesthetists
    - Cardiologists
    - Dentists
    - Dentist anesthesiologists (DA)
    - Emergency physicians
    - Gastroenterologists
    - Hospitalists
    - Nurse anesthetists
    - Nursing personnel who perform monitoring tasks
    - Oncologists
    - Oral/maxillofacial surgeons
    - Pulmonologists

- Radiologists
- Sedation nurses
- Supervised physicians and dentists in training
- Surgeons

- Exclusion criteria: (None indicated)

Interventions.

- Inclusion criteria:
  - Preprocedure patient evaluation and preparation
    - Medical records review (patient history/condition)
      - Underlying medical problems
        - Abnormalities of major organ systems
        - Obstructive sleep apnea
        - Respiratory distress syndrome
        - Allergies
        - Intestinal inflammation
        - Obesity
      - Sedation history
      - Anesthesia history
      - Surgical history
      - Problems pertaining to cooperation
      - Current medications
      - Extremes of age
      - Psychotropic drug use
      - Nonpharmaceutical (*e.g.,* nutraceutical) use
      - Family history
    - Focused physical examination (*e.g.*, heart, lungs, airway)
    - Consultation with a medical specialist (*e.g.,* physician anesthesiologist, cardiologist, endocrinologist, pulmonologist, nephrologist, obstetrician)
    - Preparation of the patient (*e.g.,* preprocedure instruction, medication usage, counseling, fasting)
  - Patient monitoring
    - Level of consciousness (*e.g.,* responsiveness)
    - Breathing/ventilation
      - Observation (color when the procedure allows)
      - Auscultation, chest excursion
      - Continual end tidal carbon dioxide monitoring (*e.g.,* capnography, capnometry) vs observation or auscultation
      - Plethysmography
        - Plethysmography vs observation or auscultation
        - Plethysmography vs capnography
    - Oxygenation
      - Pulse oximetry
    - Hemodynamic monitoring

- Blood pressure
- Heart rate
- Electrocardiography

- Contemporaneous recording of monitored parameters
- Presence of an individual dedicated to patient monitoring
- Creation and implementation of QI processes

- Supplemental oxygen
  - Supplemental oxygen versus room air or no supplemental oxygen
    - Method of oxygen administration (*e.g.*, nasal cannula, face masks, specialized devices (*e.g.*, high-flow cannula)
- Emergency support
  - Presence of individual(s) capable of establishing a patent airway, positive pressure ventilation and resuscitation (*i.e.*, advanced life-support skills)
  - Presence of emergency and airway equipment
    - Types of airway devices (*e.g.*, nasal cannula, face masks, specialized devices (*e.g.*, high-flow cannula)
    - Supraglottic airway (*e.g.*, laryngeal mask airway)
  - Presence of an individual to establish intravenous access
  - Intravenous access versus no intravenous access
- Sedative or analgesic medications not designed for general anesthesia
  - Sedatives (all routes of administration)
    - Benzodiazepines
    - Dexmedetomidine versus other sedatives or analgesics
  - Sedative/opioid combinations (all routes of administration)
    - Benzodiazepines combined with opioids versus benzodiazepines
    - Benzodiazepines combined with opioids versus opioids
    - Dexmedetomidine combined with other sedatives or analgesics versus dexmedetomidine
    - Dexmedetomidine combined with other sedatives or analgesics versus other sedatives or analgesics (alone or in combination)
  - Intravenous versus non-intravenous sedative/analgesics not designed for general anesthesia (all non-IV routes of administration, including oral, nasal, intramuscular, rectal, transdermal, sublingual, iontophoresis, nebulized)
  - Titration versus single dose, repeat bolus, continuous infusion
- Sedative/analgesic medications designed for general anesthesia
  - Propofol
    - Propofol alone versus non-general anesthesia sedative/analgesics alone
    - Propofol alone versus non-general anesthesia sedative/analgesic combinations
    - Propofol combined with non-general anesthesia sedative/analgesics versus propofol alone
    - Propofol combined with non-general anesthesia sedative/analgesics versus non-general anesthesia sedative/analgesics (alone or in combination)

- Propofol alone versus other general anesthesia sedatives (alone or in combination)
- Propofol combined with sedatives designed for general anesthesia versus other sedatives designed for general anesthesia (alone or in combination)
- Propofol combined with other sedatives designed for general anesthesia versus propofol (alone or in combination)

▪ Ketamine
- Ketamine alone versus non-general anesthesia sedative/analgesics alone
- Ketamine alone versus non-general anesthesia sedative/analgesic combinations
- Ketamine combined with non-general anesthesia sedative/analgesics versus ketamine alone
- Ketamine combined with non-general anesthesia sedative/analgesics versus non-general anesthesia sedative/analgesics (alone or in combination)
- Ketamine alone versus other general anesthesia sedatives (alone or in combination)
- Ketamine combined with sedatives designed for general anesthesia versus other sedatives designed for general anesthesia (alone or in combination)
- Ketamine combined with other sedatives designed for general anesthesia versus ketamine (alone or in combination)

▪ Etomidate
- Etomidate alone versus non-general anesthesia sedative/analgesics alone
- Etomidate alone versus non-general anesthesia sedative/analgesic combinations
- Etomidate combined with non-general anesthesia sedative/analgesics versus etomidate alone
- Etomidate combined with non-general anesthesia sedative/analgesics versus non-general anesthesia sedative/analgesics (alone or in combination)
- Etomidate alone versus other general anesthesia sedatives (alone or in combination)
- Etomidate combined with sedatives designed for general anesthesia versus other sedatives designed for general anesthesia (alone or in combination)
- Etomidate combined with other sedatives designed for general anesthesia versus etomidate (alone or in combination)

▪ Intravenous versus non-intravenous sedatives designed for general anesthesia
▪ Titration of sedatives designed for general anesthesia

o Reversal agents
▪ Naloxone for reversal of opioids with or without benzodiazepines
  o Naloxone versus placebo
  o Intravenous versus non-intravenous naloxone
▪ Flumazenil for reversal or benzodiazepines with or without opioids
  o Flumazenil versus placebo
  o Intravenous versus non-intravenous flumazenil

    - Recovery care
        - Continued observation and monitoring until discharge
        - Predetermined discharge criteria

- Exclusion criteria:
    - Minimal sedation
    - Deep sedation
    - General anesthesia
    - Patient-controlled sedation/analgesia
    - Major conduction anesthetics (*i.e.*, neuraxial anesthesia)
    - Sedatives combined with regional anesthesia
    - Premedication administered before general anesthesia
    - Interventions without sedatives (*e.g.*, hypnosis, acupuncture)
    - New or rarely administered sedative/analgesics (*e.g.*, fospropofol)
    - Automated sedative delivery systems
    - New or rarely used monitoring or delivery devices
    - Bispectral index monitoring

Outcomes.

- Expected benefits:
    - Sedation efficacy
        - Induction time
        - Duration of sedation
        - Successful procedure
        - Patient/family satisfaction
        - Proceduralist satisfaction
    - Improved pain management (*i.e.*, pain during a procedure)
    - Speed of recovery
        - Time to recovery
        - Time to discharge-ready
    - Reduced frequency/severity of sedation-related complications
        - Unintended deep sedation or general anesthesia
        - Conversion to deep sedation or general anesthesia
        - Undersedation
        - Unplanned hospitalization and/or ICU admission
        - Unplanned emergency department visits
        - Unplanned use of rescue agents (naloxone, flumazenil)
        - Re-sedation after discharge criteria met
        - Post procedure neurologic function
        - Need to change planned procedure or technique
        - Respiratory depression
        - Hypoxemia
        - Oxygen desaturation
        - Upper airway obstruction
        - Airway support required
        - Intubation required
        - Airway adjunct required
        - Pulmonary aspiration

- Hypotension
- Arrhythmias
- Cardiac arrest
- Bradycardia
- Hemodynamic support or rescue required
- Assistance request
- Neurologic injury
- Death

Evidence collection.

- Literature inclusion criteria:
  - Randomized controlled trials
  - Prospective nonrandomized comparative studies (*e.g.*, quasi-experimental, cohort)
  - Retrospective comparative studies (*e.g.*, case-control)
  - Observational studies (*e.g.*, correlational or descriptive statistics)
  - Case reports, case series
- Literature exclusion criteria (except to obtain new citations):
  - Editorials
  - Literature reviews
  - Meta-analyses
  - Abstracts greater than 5 years old
  - Unpublished studies
  - Studies in non-peer reviewed journals
  - Newspaper articles
- Survey evidence:
  - Expert consultant survey
  - ASA membership survey
  - Other participating organization surveys
  - Reliability survey
  - Feasibility survey

State of the Literature

For the systematic review, potentially relevant clinical studies were identified *via* electronic and manual searches. Healthcare database searches included PubMed, EMBASE, Web of Science, Google Books, and the Cochrane Central Register of Controlled Trials. The searches covered a 15.5-yr period from January 1, 2002 through ....., 2017. Accepted studies from the previous Guidelines were also re-reviewed, covering the period of August 1, 1976 through December 31, 2002.[1] Only studies containing original findings from peer-reviewed journals were acceptable. Editorials, letters, and other articles without data were excluded.

One thousand four hundred twenty-eight new citations were identified and reviewed, with 286 new studies meeting the above stated criteria. These studies were combined with 210 pre-2002 articles used in the previous Guidelines, resulting in a total of 496 articles found acceptable as evidence for these guidelines. A complete bibliography of articles used to develop these Guidelines, organized by section, is available as Supplemental Digital Content 2, http://links.lww.com/ALN/.....

Results for each pertinent outcome were summarized and, when sufficient numbers of RCTs were found, meta-analyses were conducted. The literature relating to six evidence linkages contained enough studies with well-defined experimental designs and statistical information to conduct formal meta-analyses. These seven evidence linkages are: (1) capnography vs blinded capnography, (2) supplemental oxygen vs no supplemental oxygen, (3) midazolam combined with opioids vs midazolam alone, (4) propofol vs midazolam, (5) flumazenil vs placebo for benzodiazepine reversal, and (6) flumazenil vs placebo for reversal of benzodiazepines combined with opioids *(table 6)*. Odds ratios based on the DerSimonian-Laird (random-effects) method for combining study results are reported for dichotomous outcomes, and raw and standardized mean differences are reported for findings with continuous data. An acceptable significance level was set at $P < 0.01$ (one-tailed). No search for unpublished studies was conducted, and no reliability tests for locating research results were done.

Interobserver agreement among Task Force members and two methodologists was obtained by interrater reliability testing of 36 randomly selected studies. Agreement levels using a kappa (k) statistic for two-rater agreement pairs were as follows: (1) research design, k = 0.57 to 0.92; (2) type of analysis, k = 0.60 to 0.75; (3) evidence linkage assignment, k = 0.76 to 0.85; and (4) literature inclusion for database, k = 0.28-1.00. Three-rater kappa values were: (1) research design, k = 0.70; (2) type of analysis, k = 0.68; (3) linkage assignment, k = 0.79; (4) literature database inclusion, k = 0.43. These values represent moderate to high levels of agreement.

Consensus-Based Evidence

Consensus was obtained from multiple sources, including: (1) survey opinion from consultants§§§§§§§§ who were selected based on their knowledge or expertise in moderate procedural sedation and analgesia, (2) survey opinions from a randomly selected sample of active members of the ASA, and (to be determined), (3) testimony from attendees of two publicly-held open forums at (to be determined) national anesthesia meetings,********* (4) Internet commentary, and (5) Task Force opinion and interpretation. The survey rate of return was ___% (n = __ of __) for consultants. For membership respondents, the survey rate of return for the ASA was __; for … (to be determined). Results of the surveys are reported in Tables 7 and 8, and are summarized in the text of the Guidelines.

Consultants were asked to indicate which, if any, of the evidence linkages would change their clinical practices if the Guidelines were instituted. The rate of return was ___% (n = __ of __). The percent of responding consultants expecting *no change* associated with each linkage were as follows: : preprocedure patient evaluation - __%; preprocedure patient preparation - __%; patient monitoring - __%; contemporaneous recording of monitored parameters - __%; availability of individual dedicated solely to patient monitoring and safety - __%; education and training of sedation/analgesia providers in pharmacology - __%; presence of an individual(s) capable of establishing a patent airway - __%; availability of appropriately sized emergency and airway equipment - __%, use of supplemental oxygen during procedures - __%, use of sedative agents combined with analgesic agents - __%, titration of sedatives/analgesics - __%, intravenous sedation/analgesia with agents designed for general anesthesia - __%, administration of sedative/analgesic agents by the intravenous route - __%, maintaining or establishing intravenous access - __%, availability/use of

§§§§§§§§ Consultants were drawn from the following specialties where moderate procedural sedation/analgesia are commonly administered: Anesthesiology, Cardiology, Dentistry, Emergency Medicine, Gastroenterology, Oral and Maxillofacial Surgery, Pediatrics, Radiology, and Surgery.

********* Meetings to be determined

flumazenil - __%, availability/use of naloxone - __%, observation and monitoring during recovery - __%, special care for patients with underlying medical problems - __%, and special care for uncooperative patients - __%. _____percent of the respondents indicated that the Guidelines would have *no effect* on the amount of time spent on a typical case. __respondents (__ %) indicated that there would be an increase in the amount of time they would spend on a typical case with the implementation of these Guidelines. The amount of increased time anticipated by these respondents ranged from __-__ minutes.

Table 1: Continuum of Depth of Sedation; Definition of General Anesthesia and Levels of Sedation/Analgesia

	Minimal Sedation ("Anxiolysis")	Moderate Sedation / Analgesia ("Conscious Sedation")	Deep Sedation / Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful* response to verbal or tactile stimulation	Purposeful* response following repeated or painful stimulation	Unarousable, even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

Minimal Sedation (Anxiolysis) is a drug induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia ("Conscious Sedation") is a drug induced depression of consciousness during which patients respond purposefully* to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

Deep Sedation/Analgesia is a drug induced depression of consciousness during which patients cannot be easily aroused but respond purposefully* following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia is a drug induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering **Moderate Sedation/Analgesia ("Conscious Sedation")** should be able to rescue patients who enter a state of **Deep Sedation/Analgesia**, while those administering **Deep Sedation/Analgesia** should be able to rescue patients who enter a state of general anesthesia.

*Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

Developed by the American Society of Anesthesiologists: Approved by ASA House of Delegates on October 13, 1999 and last amended on October 15, 2014. Accessed on February 17, 2017: http://www.asahq.org/.../en/2

Table 2: Airway Assessment Procedures for Sedation and Analgesia

Positive pressure ventilation, with or without tracheal intubation, may be necessary if respiratory compromise develops during sedation/analgesia. This may be more difficult in patients with atypical airway anatomy. Also, some airway abnormalities may increase the likelihood of airway obstruction during spontaneous ventilation. Some factors which may be associated with difficulty in airway management are:

History:

- Previous problems with anesthesia or sedation
- Stridor, snoring, or sleep apnea
- Advanced rheumatoid arthritis
- Chromosomal abnormality (e.g. trisomy 21)

Physical Examination:

- Habitus: Significant obesity (especially involving the neck and facial structures)
- Head and Neck: Short neck, limited neck extension, decreased hyoid-mental distance (<3 cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation, dysmorphic facial features (*e.g.*, Pierre-Robin syndrome)
- Mouth: Small opening (< 3 cm in an adult); edentulous; protruding incisors; loose or capped teeth; dental appliances; high, arched palate; macroglossia; tonsillar hypertrophy; non-visible uvula
- Jaw: Micrognathia, retrognathia, trismus, significant malocclusion

Table 3: Summary of American Society of Anesthesiologists Fasting and Pharmacologic Recommendations

Fasting Recommendations[xxxiv]

Ingested Material	Minimum Fasting Period[xxxv]
• Clear liquids[xxxvi]	2 h
• Breast milk	4 h
• Infant formula	6 h
• Non-human milk[xxxvii]	6h
• Light meal[xxxviii]	6h
• Fried foods, fatty foods or meat	Additional fasting time (*e.g.*, 8 or more hours) may be needed

Pharmacologic Recommendations

Medication Type and Common Examples	Recommendation
Gastrointestinal stimulants:	
• Metoclopramide	May be used/no routine use
Gastric acid secretion blockers:	
• Cimetidine	May be used/no routine use
• Famotidine	May be used/no routine use
• Ranitidine	May be used/no routine use
• Omeprazole	May be used/no routine use
• Lansoprazole	May be used/no routine use
Antacids:	
• Sodium citrate	May be used/no routine use
• Sodium bicarbonate	May be used/no routine use
• Magnesium trisilicate	May be used/no routine use
Antiemetics:	
• Ondansetron	May be used/no routine use
Anticholinergics:	
• Atropine	No use
• Scopolamine	No use
• Glycopyrrolate	No use
Combinations of the medications above:	No routine use

[xxxiv] These recommendations apply to healthy patients who are undergoing elective procedures. They are not intended for women in labor. Following the guidelines does not guarantee complete gastric emptying.
[xxxv] The fasting periods noted above apply to all ages.
[xxxvi] Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee.
[xxxvii] Since non-human milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.
[xxxviii] A light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Additional fasting time (*e.g.*, 8 or more hours) may be needed in these cases. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.

Table 4: Emergency Equipment for Sedation and Analgesia

Appropriate emergency equipment should be available whenever sedative or analgesic drugs capable of causing cardiorespiratory depression are administered. The table below should be used as a guide, which should be modified depending upon the individual practice circumstances.

Intravenous Equipment (age and size appropriate).

- Gloves
- Tourniquets
- Alcohol wipes
- Sterile gauze pads
- Intravenous catheters
- Intravenous tubing
- Intravenous fluid
- Assorted needles for drug aspiration, i.m. injection
- Intraosseous access kit
- Appropriately sized syringes
- Tape

Basic Airway Management Equipment (age and size appropriate).

- Source of compressed O_2 (tank with regulator or pipeline supply with flowmeter)
- Source of suction
- Suction catheters
- Yankauer-type suction
- Face masks
- Self-inflating breathing bag-valve set
- Oral and nasal airways
- Lubricant

Advanced Airway Management Equipment (age and size appropriate).

- Supraglottic airway devices
- Laryngoscope handles (tested)
- Laryngoscope blades
- Endotracheal tubes:
- Stylet

Pharmacologic Antagonists.

- Naloxone
- Flumazenil

Emergency Medications.

- Epinephrine
- Ephedrine
- Vasopressin
- Atropine
- Nitroglycerin (tablets or spray)
- Amiodarone
- Lidocaine
- Glucose (IV or oral)
- Diphenhydramine
- Hydrocortisone, methylprednisolone, or dexamethasone
- Benzodiazepines
- Beta blocker
- Adenosine

Table 5: Recovery and Discharge Criteria Following Sedation and Analgesia

Each patient-care facility in which sedation/analgesia is administered should develop recovery and discharge criteria which are suitable for its specific patients and procedures. Some of the basic principles which might be incorporated in these criteria are enumerated below.

General Principles.

- Medical supervision of recovery and discharge following moderate is the responsibility of the operating practitioner or a licensed physician
- The recovery area should be equipped with or have direct access to age and size appropriate monitoring and resuscitation equipment
- Patients receiving moderate sedation should be monitored until appropriate discharge criteria are satisfied. The duration and frequency of monitoring should be individualized depending upon the level of sedation achieved, the overall condition of the patient, and the nature of the intervention for which sedation/analgesia was administered. Oxygenation should be monitored until patients are no longer at risk for respiratory depression.
- Level of consciousness, vital signs, and oxygenation (when indicated) should be recorded at regular intervals
- A nurse or other individual trained to monitor patients and recognize complications should be in attendance until discharge criteria are fulfilled.
- An individual capable of managing complications (*e.g.,* establishing a patent airway, administering a reversal medication when appropriate, and providing positive pressure ventilation) should be immediately available until discharge criteria are fulfilled.

Guidelines for Discharge.

- Patients should be alert and oriented; infants and patients whose mental or physical status was initially abnormal should have returned to their baseline status.
- Patients should be advised to avoid making life-changing decisions and activities that may impact their safety (*e.g.,* operate a vehicle or heavy equipment) until the effects of the sedatives have worn off.
- Cardiovascular function, airway patency, and protective airway reflexes are satisfactory.

- Practitioners and parents must be aware that pediatric patients are at risk for airway obstruction should the head fall forward while the child is secured in a child-safety seat.[xxxix]
- Vital signs should be stable and within acceptable limits.
- Use of scoring systems may assist in documentation of fitness for discharge.
- Sufficient time (up to 2 hours) should have elapsed following the last administration of reversal agents (naloxone, flumazenil) to ensure that patients do not become resedated after reversal effects have worn off.
- Outpatients should be discharged in the presence of a responsible adult who will accompany them home or to a care facility and be able to report any post-procedure complications.
- Outpatients and their escorts should be provided with written instructions regarding post-procedure diet, medications, activities, and a phone number to be called in case of emergency.

[xxxix] Drugs with long durations of action (e.g., chloral hydrate, intramuscular pentobarbital, phenothiazines) will require longer periods of observation even after the child achieves currently used recovery and discharge criteria. This concept is particularly important for infants and toddlers transported in car safety seats who are at risk of resedation after discharge because of residual prolonged drug effects with the potential for airway obstruction.

Table 6. Meta-Analysis Summary[xl]

Evidence Linkages[xli]	N[xlii]	Odds Ratio[xliii]	Confidence Interval[xliv]	Z Value	p	Heterogeneity[xlv]
Patient monitoring.						
Capnography versus blinded capnography						
Hypoxemia (O_2 < 90%) [30-35]	6	0.70	0.47-1.02	-2.44	0.015	0.110
Supplemental oxygen.						
Supplemental oxygen versus placebo						
Hypoxemia (O_2 < 95%) [66-72]	7	0.24	< 0.07-0.81	-3.01	< 0.001	< 0.001
Sedative/analgesics not designed for general anesthesia.						
Midazolam combined with opioids versus midazolam						
Pain/discomfort during procedure [73-78]	6	0.48	0.16-1.42	-1.73	0.083	0.063
Hypoxemia (O_2 < 95%) [75,76,78-81]	6	2.15	0.76-6.08	1.89	0.059	0.139
Recall (no recall during procedure) [73-75,77,78,82-84]	8	1.09	0.58-2.06	0.35	0.726	0.269
Sedative/analgesics designed for general anesthesia.						
Propofol versus midazolam						
Recall [96,100-103]	5	0.40	0.08-2.17	-1.39	0.164	0.003
Hypoxemia (O_2 < 95%) [96,97,99-101]	7	0.92	0.48-1.78	-0.32	0.752	0.640
Sedation recovery (awakening time) [96-100]	5			-4.55	< 0.001	< 0.001
Raw mean difference = -10.01 (-11.63 - -8.39)						
Standardized mean difference = -1.57 (-2.46 - -0.68)						
Reversal agents.						
Flumazenil versus placebo (reversal of benzodiazepines)						
Recovery within 15 min [172-179]	8[xlvi]	14.06	5.59-35.36	7.38	< 0.001	0.065
Flumazenil versus placebo (reversal of benzodiazepines combined with opioids)						
Recovery within 30 min [183-187]	5	7.91	2.83-22.16	5.18	< 0.001	0.042

[xl] Statistics for individual studies and Forest plots are available as supplemental digital content 3, http://links.lww.com/ALN/.
[xli] Evidence linkage with references for included studies.
[xlii] Number of studies included in the meta-analysis.
[xliii] DerSimonian-Laird (random-effects analysis), using Comprehensive Meta-analysis software Version 3.3.070, November 20, 2014.
[xliv] 99% confidence intervals.
[xlv] Statistical significance values for homogeneity/heterogeneity of effect size; a p value of < 0.01 indicates that the studies are significantly heterogeneous.
[xlvi] Double-blind studies only

Table 7. Consultant Survey Responses ‡‡‡‡‡‡‡‡‡‡‡‡

		Percent Responding to Each Item				
1. Patient evaluation:	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
Review medical records	—	—	—	—	—	—
Review hemoglobin/hematocrit test results	—	—	—	—	—	—
Review coagulation profile	—	—	—	—	—	—
2. Preprocedure preparation:						
Inform patient	—	—	—	—	—	—
Patient fasting in accordance with ASA fasting guidelines	—	—	—	—	—	—

(Findings will be added upon receipt of survey responses)

‡‡‡‡‡‡‡‡‡‡‡‡ N = the number of consultants who responded to each item. An asterisk beside a percentage score indicates the median.

Table 8. ASA Membership Survey Responses §§§§§§§§§§§

		Percent Responding to Each Item				
1. Patient evaluation:	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
Review medical records	—	—	—	—	—	—
Review hemoglobin/hematocrit test results	—	—	—	—	—	—
Review coagulation profile	—	—	—	—	—	—
2. Preprocedure preparation:						
Inform patient	—	—	—	—	—	—
Patient fasting in accordance with ASA fasting guidelines	—	—	—	—	—	—

(Findings will be added upon receipt of survey responses)

§§§§§§§§§§§ N = the number of members who responded to each item. An asterisk beside a percentage score indicates the median.