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Ethical Considerations in the Use of Nitrous Oxide in Pediatric Dentistry

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Abstract

Nitrous oxide (N₂O) has become a routine intervention in contemporary American dental practice, especially in the management of children. However, routines translate to confidence which in turn may lead to overconfidence, such that possible risks and misuses are insufficiently acknowledged. This article ethically evaluates the use of nitrous oxide as a practice routine in treating children. Nitrous oxide administration is analyzed in reference to three internationally acknowledged principles of dental ethics: nonmaleficence, beneficence, and patient autonomy. In reference to the principle of nonmaleficence, the potential for adverse effects of N₂O is discussed, particularly when it is administered in conjunction with other sedatives and anesthetics. The importance of abiding by clinical protocols is emphasized. Next, in reference to the principle of beneficence, the authors address the problematic application of N₂O for the benefit of individuals other than the patient (e.g., dentists and parents). Finally, the importance of respecting patient autonomy is discussed, specifically the need to obtain explicit consent for N₂O. The article supports the continued use of nitrous oxide but advises greater attention to how and why it is administered. Four recommendations are offered for an ethically sound usage.

thical analyses in health care tend to focus on complex, critical, and contentious practices. And yet, all medical, and likewise, all dental interventions are subject to the ethical principles that guide the practice of health care, even those routinely administered—or maybe especially those routinely administered. For confidence in safe and established routines can easily turn into overconfidence. A case in point is the administration of nitrous oxide gas (N₂O).

In the final quarter of the last century, the use of nitrous oxide gas attained the status of a routine intervention in American dental practice (Levering & Welie, 2010). The kinds of reports about undesirable side-effects and even deaths that had still appeared with some frequency in the first quarter of the twentieth century, had virtually disappeared with the development of improved drug regimens and methods of administration. However, the current usage of nitrous oxide as a routine may be accompanied by ethical complacency such that potential harms and possible misuses are insufficiently acknowledged. Despite its excellent safety record, N₂O still poses risks and, hence, ethical challenges.



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For example, the ethical principle of nonmaleficence demands that dentists protect their patients against harm. N_2O , though a weak dental sedative, is nevertheless a medication and like all medications possesses the potential for adverse effects, particularly when administered inappropriately or with other medications. This, in turn, underscores the importance of development of and adherence to practice guidelines on sedation. Second, the ethical principle of beneficence demands that dentists develop treatment plans with the patients' best interests in mind. But the current N_2O usage appears to be driven in part by the interest of parties other than the patient, such as dentists and parents who seek expedience. Third, the ethical principle of respect for patient autonomy demands that patients are full partners in their treatment and empowered to ultimately reject unwanted interventions. But research suggests that many dentists do not obtain a written consent for the administration of N₂O and some do not obtain any consent at all.

In this article, we show that even routine interventions demand and merit ethical reflection. We analyze the administration of N_2O in reference to the aforementioned three principles of ethics. The article concludes with four specific recommendations for an ethically sound usage of N_2O .

The Principle of Nonmaleficence

The popularity of N_2O is due in large part to its excellent safety record. When used alone, in the absence of any contraindications, and in carefully calculated and titrated dosages, patients suffer no permanent harm and the most likely side-effect is modest nausea. However, N₂O is a drug and as all drugs, including those with track records of safety, can become harmful, even lethal, when clinicians become a bit too complacent and overlook the adverse drug effects that are still possible.

One of the oldest ethical principles guiding the practice of medicine is the principle of nonmaleficence, requiring that clinicians do not harm their patients. Dating back at least to the oath attributed to Hippocrates, it is one of five principles (the other four are beneficence, autonomy, justice, and veracity) around which the current *Principles of Ethics and Code of Professional Conduct of the American Dental Association* is organized.

Warnings about the possible dangers of N₂O surfaced as early as the mid-1800s when dentists experimented with different delivery methods of the drug in their practices of dentistry. Since N₂O was originally used alone as a general anesthetic, patient deaths occurred with some frequency until oxygen was administered with nitrous oxide and dual delivery systems became standardized at the turn of the century (Lancet Commission on Anaesthetics, 1893: Lymann, 1881). Moreover, their number appears to have been small compared to deaths attributed to chloroform in the same time period (Buxton, 1895). In the 1960s, dentists changed the application

The patient's right of consent is essentially a negative right, a right not to be forced into dental treatment. It is not a positive claim, for a patient cannot demand certain interventions. of N_2O from general anesthesia to analgesia only, changing again in the 1980s to sedation use, which allows for even lower dosages and higher levels of safety, particularly when used alone.

Despite the increasing success and acceptance of nitrous oxide, it remains limited by its weak potency. Some clinicians seek to deepen the sedation by adding additional sedatives, analgesics, and anesthetics. Unfortunately, such "polypharmacy" has occasionally resulted in serious adverse side-effects, including fatalities, thereby tarnishing the safety record of nitrous oxide. An example is the death of a five-year old girl in Chicago in 2006 (State of Illinois, 2007) who received, in addition to N_2O/O_2 (5-0%/ 50%), Lidocaine with epinephrine, Diazepam, Midazolam, atropine, and Talwin. The Illinois Legislature subsequently passed a law tightening the requirements for administering sedatives such as those used by dentists, including N_2O .

In his handbook The Dentist's Legal Advisor, Morris admonishes dentists not to administer N₂O without giving due consideration to the risks associated with it, and to consider whether the benefits gained from the sedation outweigh the possible harms (Morris, 1995). Morris's admonishment underscores the importance of full informed consent, which will be addressed in a later section. But the consent of patients-or in the case of minors, the consent of parentsreleases practitioners neither of their own ethical responsibility nor of their legal liability. The dentist retains the responsibility to justify recommended treatments irrespective of the patient's consent; indeed, only scientifically sound treatments should be presented to the patient for his or her consent. Professional guidelines and protocols can be a major help to dentists by providing

advice on (contra)indications for drugs such as N_2O , effective means of administration, and effective monitoring. They also help, incidentally, to later defend one's recommendations and actions if challenged in court.

Once selected, treatments should be administered with due diligence. Routines tend to produce complacency with inadequate appreciation of the reasons and circumstances for which guidelines and protocols were initially intended. Krippaehne and Montgomery (1992) found that most of the deaths following pharmacosedation and general anesthesia in the dental office were probably due to inadequate monitoring of patients and failure to provide adequate resuscitation when the calamity occurred. Such would be the case of aspirated vomitus for the over-sedated pediatric patient. Diligent adherence to best practice standards can help prevent untoward side-effects.

Assuring Optimal Care: The Evaluation of Guidelines for Nitrous Oxide

The first guideline on pediatric sedation was published in 1985 as a joint venture by the American Academy of Pediatrics and the American Academy of Pediatric Dentistry (AAPD, 1985). The guideline was initiated in response to adverse reactions to the sedative agent Nisentil and the concern for potential litigation based on its misuse by uninformed practitioners (Wilson et al, 1996).

Interestingly, the 1985 guideline mentions "conscious sedation" but does not specifically address N_2O even though this sedative was already widely used by this time. With the exception of very light sedation—leaving the reader wondering what exactly constitutes "very light"—heart and respiratory rates were to be monitored and recorded repeatedly at specific intervals with a precordial stethoscope as the minimum equipment for obtaining this information. Clinical observation was also required, including continuous visual monitoring of nail beds and mucosa, checks of immobilization devices to prevent airway obstruction and any other restrictions of limb perfusion.

The next edition of the guideline for sedation (AAPD, 1993) entailed no change, but in the 1996 edition (AAPD, 1996), N₂O was explicitly mentioned for the first time and classified at the lowest (level 1: mild sedation/anxiolysis) of three newly established levels of conscious sedation. At the same time, the requirements for continuous monitoring of oxygen saturation, heart and respiratory rates were dropped for sedation with N₂O. The 1998 edition once again contained no change regarding N₂O, but in 2004 yet another classification of all pediatric sedation was established in which the level 1 conscious sedation from the 1996 edition was now designated as "minimal sedation." Upon receiving such sedation, patients should continue to respond normally to verbal commands, might have somewhat impaired cognitive function and coordination. but ventilator and cardiovascular function should remain unaffected. Clinical observation was the only monitoring required unless the patient became moderately sedated, in which case additional monitoring guidelines would take effect. It is noteworthy that N₂O was only mentioned specifically once in the new guidelines and only in reference to equipment.

But one year later, a specific guideline was established for N_2O as a distinct form of anxiolytic and analgesic sedation, separate from all other forms of sedation (AAPD, 2005a; 2005b). Patients' responsiveness to commands during N_2O sedation should serve as the primary indicator of the level of consciousness, but the dentist should also continue to observe the patient's color and respiratory rate and rhythm. If any other pharmacologic agent were to be used in addition to N_2O and local anesthetic, monitoring guidelines for the appropriate level of deeper sedation would then have to be followed. The most recent version of the guidelines, which dates from 2009, reiterates the relevant points contained in the 2005 edition with no significant changes (AAPD, 2009)

As this brief summary of successive guidelines makes clear, the primary focus has been and continues to be preventive management of the patient's physiologic status, in accordance with the principle of nonmaleficence. However, what is lacking is a discussion of basic behavior guidance as prerequisite to the need and decision to administer N₂O. Anecdotal reports of practitioners administering N₂O as their first line of behavior management, or even administering N₂O on every patient, child and adult, are not uncommon. Similarly, there is little guidance for the management of that child when N₂O is unsuccessful and is then combined with other sedative agents. For such circumstances the AAPD guidelines merely offer a cautionary note.

Finally, we point out that the British Society of Paediatric Dentistry issued national clinical guidelines in 2002 entitled "Managing anxious children: The use of conscious sedation in paediatric dentistry" (Hosey, 2002) that addressed sedation in a totally different light than those of the American Academy of Pediatric Dentistry (2006). The British guidelines enumerate graded levels of evidence-based practices for varying aspects of sedation (Grade A, consistent high-quality evidence; Grade B, inconsistent or limited evidence; and Grade C, lacking direct evidence). The intent is to encourage improvement in clinical practice and to stimulate research and clinical audits in areas where scientific evidence is inadequate.

The Principle of Beneficence

Ancient oaths, early codes of professional conduct ethics, and modern declarations on dental ethics tend to assign priority to the healthcare interests of the patient. Their interests generally trump those of third parties and even those of the providers themselves. Since those competing interests are often compelling and indeed legitimate, it is not always easy to give priority to the patient's healthcare interests

Sedation with N₂O is a case in point. Parenting occurs within the context of society, is informed by it, and inevitably reflects it as well. Current lifestyles are hurried; the "typical" family unit of the past no longer exists; competition for quality time has become burdensome; and parents are frequently fatigued, feel guilty, and lament the lack of role models for their children. At the same time. some dentists have lamented the failure of many parents to set limits for their children, to discipline them effectively, and to invest time in their children's education and care (Casamassimo et al., 2002; Long, 2004). These changes are paralleled and complemented by an ever greater consumption of drugs that are intended to solve all kinds of medical and nonmedical challenges more readily, requiring less patience, persistence, or tolerance (Ambrose, 2004; Cakic, 2009; Russo, 2007). The issue is not that these drugs are unsafe or lack treatment value. but that the circumstances do not always necessitate, justify, or warrant their use.

There is a general acceptance that societal changes have affected the way dentists manage children in their dental office. Even if dentists themselves do not personally approve of these changes, they nevertheless feel compelled to adopt those behavior management techniques that are better aligned with current Even if dentists themselves do not personally approve of these changes, they nevertheless feel compelled to adopt those behavior management techniques that are better aligned with current parenting styles. Administering N₂O to every child coming into the office, or even presenting that option to all parents as scientifically sound and necessary, is ethically problematic. parenting styles. Parents are quicker to embrace and indeed insist on pharmacologic techniques instead of more traditional interactive methods (Pinkham, 1993; 2001). "Tell-Show-Do" is increasingly replaced by "Do-and-Do-It-Fast." Dentists may fear that if they are unable to meet the demands of their patients' parents, the parents will take their child to a dentist who will not hesitate to use N_2O .

In addition to a perceived advantage for parents, N_2O sedation has some evident benefits for the providing dentists as well. A less anxious and more cooperative child is easier to work on and less likely to create "infectious anxiety" in other children (and parents) in the waiting room or in a nearby clinical area. And in a dental school setting, students gain the additional benefit of prolonged behavior "good-time," which enables them to master their dental skills.

The question now arises whether the administration of N₂O for the sake of parent or provider constitutes a violation of the ethical principle of beneficence, which demands that care providers give priority to the healthcare interests of the child. Since N₂O calms the agitated child, suppresses anxiety, and diminishes unpleasant dental treatment memories, the patient is always a direct beneficiary. Furthermore, the child benefits from the fact that the dentist can work quickly and in a more focused manner, reducing the chance of mechanical error and enhancing the quality of treatment. Fewer dental appointments are not only convenient for the parents but also translate to fewer missed school days for the child. It would therefore appear that N₂O fosters the patient's best interest, even if it also benefits third persons at the same time.

But this line of reasoning fails to consider two important factors. First, as we have already seen, the excellent safety record of N_2O can become compromised when it is managed in a routine manner. Preoccupation with treatment may come at the exclusion of anesthesia oversight; reliance upon untrained auxiliaries for the administration, monitoring, and documentation of the procedure increases the odds of error. These problems are compounded when other medications are added to the N_2O . Common misjudgments include failure to adjust dosages for children (versus adults) and failure to consider the additive effects of all medications used. All of these risks are borne by the child, not the dentist or parent.

The second factor is the rush to administer N₂O without first considering non-pharmacologic means of management, often followed by a continued use of N₂O even though it is no longer needed. There is something amiss when a parent states "My child always has nitrous." Chairside patience on the part of the provider, step-by-step learning and development of coping skills by the child, and improved communication with parents regarding their child's evolving maturity are unquestionably in the best interest of the child and will likely increase the child's own appreciation of dental care into adulthood.

Principle of Respect for Autonomy

It is generally recognized, underscored by codes of dental ethics, and reinforced through law that the rights and responsibilities of healthcare decisions are shared by provider and patient. No longer can a dentist paternalistically determine and initiate the treatment that is "best" for a patient without the latter's input and informed consent. The patient's right of consent is essentially a negative right, a right not to be forced into dental treatment. It is not a positive claim, for a patient cannot demand certain interventions. As the term indicates, "consent" reflects "with-agreement," that is, agreement with an intervention that the dentist, upon a comprehensive diagnostic examination and thoughtful deliberation, considers to be a potentially effective remedy for the patient's complaint or condition.

Although patients may arrive at the dental office with preconceived thoughts regarding their treatment, and these thoughts should be considered in treatment planning, they can never be decisive. It is the dentist who possesses the training, knowledge, and experience enabling him or her to develop a treatment plan. and it is the dentist who ultimately bears the responsibility for the treatment. Conversely, the dentist can never justify his or her actions by merely stating that it was what the patient or parents wanted. By the same token, the dentist cannot justify the treatment plan in terms of "this is what I always do." The treatment plan must be justified in reference to the patient's best interests, assessed by objective, scientific standards. Once such a treatment plan has been developed and explained to the patient, the patient must grant consent. Only then can treatment be initiated.

Pediatric Consent

Respect for autonomy of the pediatric dental patient is no different from that of the adult patient, except that the patient is legally incapable of granting consent. And since consent is a necessary condition for treatment, no treatment (other than emergency treatment) can be given unless a surrogate decision-maker grants consent on behalf of the minor. In most instances, the parent has the legal right and responsibility to make such decisions. Again, the parents' right to grant parental consent does not entail the right to demand treatment. Though the dentist must consult the parents in order to determine exactly what the expected treatment outcomes are, what means are acceptable, and what harmful side-effects might be tolerable, it is the dentist who designs and proposes one or

more alternative treatment plans, which the parents in turn consent to or reject.

In addition to emergency dental care on patients who are incompetent to consent, there is another category of interventions for which informed consent is not a necessary requirement. These are interventions that are part and parcel of more encompassing treatment plans. A dentist may reasonably assume that patients who consent to an amalgam restoration know this restoration will involve various steps, including injection of a local anesthetic, placement of a rubber dam, cavity preparation, etc. While it is a token of chairside professionalism to inform the patient of procedural steps, the dentist is not legally required to obtain explicit consent for each of those steps separately. Consent is implied in the patient's informed and explicit consent to the overall procedure.

Whether consent for a particular intervention must be explicit or may be assumed to be implied is not always easy to determine, in which case the dentist should fall back on an explicit consent. But factors that justify assuming implied consent for an intervention include the conclusions that: (a) the overall treatment plan cannot be realized without this intervention; (b) there are no alternatives for the intervention; and (c) the intervention does not pose significant additional risks or disadvantages for the patient beyond those already entailed by the overall treatment plan.

Bearing in mind these ethical considerations that apply to all of dental care, we can next examine the specific example of nitrous oxide. Since N₂O is a drug, consent by the patient or the patient's legal surrogate is a necessary requirement. This does not mean children or even their parents have the legal right to demand N₂O. Administering N₂O to every child coming into the office, or even presenting that option to all parents as scientifically sound and necessary, is ethically problematic. If a patient's anxiety can probably be managed adequately using means that are less invasive, the dentist ought to recommend such nonchemical behavior management instead. The same is true if the behavior of the patient is such that N₂O is unlikely to be effective or the child suffers from conditions that render N₂O contraindicated. Again, the dentist should recommend other means of managing the child's behavior.

If the dentist concludes that the administration of N₂O can objectively be justified and is therefore indicated, the question arises whether parental consent must be explicit or may be implied. Considering the three cumulative criteria listed above, it appears that in almost all instances in which N₂O is indicated, at least one of these criteria cannot be met. In case of mild apprehension, the alternative of traditional nonpharmacologic behavior management is generally available and should at least be considered. In case of severe anxiety, other sedatives may have to be added to the N_2O , which combination significantly increases the chance of adverse effects. And if the source of the apprehension is actually the parent, it is not the patient who needs to be sedated. We thus conclude that an explicit consent is necessary in all instances in which N₂O will be administered (other than true emergency care when no legally valid source of consent is available).

The most recent guideline from the AAPD (2009) specifically requires consent for all pharmacologic techniques, including N₂O. The guideline requires documentation of the consent but not that the consent itself must be written. A 2004 survey by the AAPD revealed that 42% of the responding dentists obtained written consent for N₂O, 51% of respondents obtained oral consent, and 8% no

consent. In contrast, almost 100% of the respondents obtained written consent for sedation other than with N_2O and a full 100% for general anesthesia (Adair et al., 2004).

Documentation of consent. whether via a form or a detailed note in the record, allows the dentist to keep track of what was covered in previous discussions and can also make it easier to defend against patients who charge that the dentist failed to inform them prior to treatment. But from an ethical perspective, there is no principle difference between an oral and a written consent. If procedures are complex and there is a fear that the patient or parents may not be able to digest all of the information provided orally, a written form can foster understanding such that the subsequent consent is truly informed. A written form can also elicit, facilitate, and streamline discussion between parent and provider. However, the reverse is not true. That is, a signed form does not necessarily constitute an informed consent. This is most evidently the case if the form is in a language the patient does not understand adequately or the language used in the form is far beyond the educational level of the consenter. But problems also arise if a "blanket" form is used, a single form used to obtain consent for a variety of dissimilar interventions. The survey cited above found that 45% of the respondents used such a "blanket" consent form (Adair et al. 2004). Unless "blanket" forms are accompanied by a more specific oral

consent process, one cannot ethically assume them to represent a valid informed consent.

In other words, providing information does not necessarily result in an informed parent. Parents may not know the difference between sedation and anesthesia, let alone the difference between oral sedation, inhalation sedation, "twilight" sedation, and general anesthesia. It is important that providers do not use these terms loosely (thereby adding to parental confusion) and verify in each instance that parents do not assume the proposed administration of, for example, N₂O to be analogous to previously received anesthesia, and vice versa.

In addition to information about the benefits and risks of a specific management technique, parents must also be informed about all alternative modes of accomplishing the same goal. Informed consent discussions must occur in a setting, manner, and language that assure the relevant information is truly communicated, the likelihood of misunderstandings is reduced as much as possible, and parents feel at ease to ask questions and discuss options.

It is important to remember that the validity of a patient's (or parental) consent hinges on the consenter being informed and not coerced. It is the ethical responsibility of the dentist to make sure that the consent is actually an informed consent. With ever more jurisdictions shifting from the "professional community standard" to the "reasonable patient standard," it no longer suffices to go about the informed consent process as every other dentist in town appears to do it. Instead, it is imperative that dentists assure that every patient—or in the case of minors, every parent-is adequately informed and free to consent, even if the intervention proposed has evident benefits and very few side effects.

Conclusions

Nitrous oxide will and should continue to play a significant role in the management of the pediatric dental patient. However, ethical challenges arise when the administration of N_2O becomes so routine that clinicians fail to recognize the small but real possibility of serious risk or when it becomes merely a tool of expedience. To make sure that N_2O serves to truly benefit and protect the child, we propose the following four practical recommendations.

- Nonmaleficence. Sustain diligent awareness when administering N₂O. When used as a routine without the consideration of benefits, risks, and alternatives, the likelihood increases of inappropriate application, erroneous administrations, harmful side-effects, and a false sense of pharmacologic need.
- 2. Beneficence. Focus on the patient's interests. Treatment recommendations should be based on solid evidence and without the bias of provider and parental expedience. The clinical guidelines from the British Society of Paediatric Dentistry are an example of a protocol providing evidence-based directives for sedation, including nitrous oxide.
- 3. **Respect for Autonomy**. Treatment decisions for the pediatric dental patient must include corroborative discussion and education between the provider and parent. Although it is important to pay close attention to the parents' expectations, many parents want the dentist to prevent any and all fear or even discomfort for their child, using either N₂O or other drugs. They do not expect the child to assist or cooperate in his or her own dental care. This may well

be a disservice to the child who is not encouraged and taught to better cope with an unknown situation. Any pharmacologic approach, including N_2O , to behavior management should not be considered until nonpharmacologic behavior management tools have proven to be of little or no promise.

4. **Informed Pediatric Consent**. Consent signifies disclosure, clarifi-

consent signifies disclosure, charmcation, discussion, and deliberation with an ultimate agreement to proceed with a planned treatment. The consent to use N_2O in the course of treatment should be explicit, because N_2O is an intervention distinct from the restorative or surgical treatment, with its own purpose and possible side-effects. In the literature, different views are voiced regarding the need to obtain written (as opposed to oral only) consent. However, we have argued that written consent is imperative in virtually all situations.

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