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Pediatric Sedation: Practical Approaches to Avoid Mishaps, Adverse Reactions, and Catastrophic Outcomes

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Editorial

Despite conscientious efforts by multiple disciplines over the past three decades to insure pediatric patient safety when sedation techniques are employed in office and clinic settings, mishaps, adverse reactions, and catastrophic outcomes continue to occur. This editorial looks at the historical perspective of the development of sedation guidelines, its evolutionary definition of how sedation level and depth is assessed when seeking to manage varying levels of childhood dental apprehension, resistance and uncooperative behavior. Common denominators plaguing sedation mishaps are addressed with an intent to develop a pragmatic approach to eliminate their occurrence, and suggestions are made for state and university/training program regulatory mechanisms. Fatal outcomes both recently and during the past three years involving poor clinician judgment and failure to comply with existing safety guidelines are cause to warrant a more proactive look at how these events might be prevented.

Historical evolution of the development of sedation guidelines

First published in 1985, guidelines from the American Academy of Pediatric Dentistry [1] and subsequently by the American Dental Association, the American Academy of Pediatrics, the American Society of Anesthesiology, and American Association of Oral and Maxillofacial Surgery were originally designed to define levels of sedation and recommend measures to insure patient and practitioner safety. Through multiple revisions, the next decade described improved definitions of what constituted conscious (versus deep sedation), patient monitoring appropriate for the needs of the patient and level of sedation obtained, proper facility, personnel and resuscitative equipment, maintenance of a comprehensive sedation record, and clarification of post-operative and discharge management criteria. Revisions and updates are presented on a regular basis among the various disciplines, sometimes developed in conjunction with one another. Despite these fundamental axioms, reports of morbidity and mortality continue to this day, most recently one week ago. Retrospective actions of state regulatory agencies, professional societies, and university constraints to eliminate the use and higher dosing of certain well studied agents have begun to appear. While once popular and used abundantly to safely permit treatment in younger children (under age 6), agents such as chloral hydrate have been removed from manufacture because of excessive dosage and misuse. While some actions have been reactive in nature, many go unreported due to litigation which carries the power to restrict disclosure of full events for a given outcome.

Significant concerns have arisen over how practitioners have assessed levels of sedation achieved with various regimens

and their proficiency in recognizing and managing an adverse and developing problem.

Guidelines have since focused on providing better definitions of what constitutes safe and manageable depths of sedation in an office setting. Distinction between the levels of sedation sought and achieved in a specific clinical situation have at present gravitated to being either "Light" (full and continuous consciousness and verbal responsiveness), to "Moderate" sedation (where appearances of full consciousness begin to dissipate, and/or disappear , yet can manifest a return to full consciousness by verbal stimulation or ultralight physical stimulation, or "Deep Sedation," (whereby arousal to manifest consciousness necessitates profound physical stimulation and can be accompanied by loss of protective reflexes) a state of unconsciousness that conspicuously borders or is difficult to differentiate from general anesthesia. With the exception of "Light" sedation, general belief follows that proficiency of the practitioner and dental team must be coincident with the highest levels of medical management, ability to recognize a developing problem, and capacity to safeguard the patient in an appropriately equipped facility. The instance in which a recipient of sedative medication closes his/her eyes, regardless of the intent to induce light, moderate, or deep sedation, all responsibilities to know the level of sedation attained and to insure the patency of the airway, cardiovascular and central nervous system normality are that of the clinician. Strict adherences to existing safety guidelines have zero tolerance for deviation.

The frequency with which departures from compliance with contemporary sedation guidelines for the elective use of sedation in an office or clinic setting are largely unknown or undetectable until an incident with adverse outcome occurs. Man power limitations of state agencies do not readily permit on-site inspection and verification of practitioner and facility proficiency in a timely fashion. Licensure state to state which delineates varying sedation level skills vary; efforts to sophisticate and develop uniform state and national standards have yet to be developed. To date, no efforts have been made to require state or national data base recording of morbidity and mortality. Professional societies from a legal perspective choose to defer participation or endorsement of maintaining such logs, and any efforts to adjudicate guilt or innocence on the basis of proven departures from the standards of care. On occasion, recommendations for transient license censure, need for rehabilitative continuing education, or termination of drug utilization privileges are among the most aggressive sanctions suggested.

Common denominators of sedation mishaps

Several pediatric papers [2-5] have outlined cases and etiology in which adverse consequences have resulted from unsound operator judgment, inadequate knowledge and proficiency in the clinicians' abilities to recognize, intercept, or manage an adverse reaction when patient responses "go south." The most common causes include:

i. Unfamiliarity with proper dosing of single agents or combinations with respect to potential to induce deeper than intended levels of sedation

ii. Administration of drugs possessing respiratory and/or CNS depressant capabilities prior to office arrival without adequate supervising personnel

iii. Failure to adequately assess pre-sedation level risk or physical status and system review implications

iv. Failure to follow guidelines for the safe use of local anesthetic while approaching and exceeding maximum toxic dosing, or the impact on dosing when combined with local anesthetic possessing central nervous system depressant qualities

v. Failure to employ monitoring appropriate to the needs of the patient and the level of sedation achieved, pre-administration, intra-operatively, and post-operatively till full return to pre-sedation levels of arousal are verified and documented

vi. Premature discharge, failure to verify that discharge criteria have been fulfilled and patient supervision can safely be relinquished to non-trained personnel. Inadequate transport positioning to monitor airway issues and potential emesis; failure to recognize delayed recovery from long-lasting medications which carry prolonged active metabolites and potential for recurrent respiratory depression and /or CNS depression; adequate hydration in immediate post-op and recovery periods.

vii. Excessive pressure on chest wall restricting circulatory and respiratory function and patency from use of fixed restraints during treatment and or following discharge/transport.

Practical solutions to prevent sedation mishaps

i. Mandate the objective of securing no deeper than moderate sedation for all in-office pediatric sedation procedures where the oral route of administration is used.

ii. Prohibit the use of agents and dosages which carry known propensity to induce deeper than moderate sedation.

e.g. no use of Chloral hydate in dosages exceeding 30-35 mg/kg, alone or in combination with adjunctive agents such as hydroxyzine and/or meperidine; dosages of midazolam at or in excess of 1.0 mg/kg; long-acting benzodiazepines (diazepam) with long-acting metabolites where dosages exceed 0.5 mg/kg alone or in combination with other agents

iii. Use of agents and dosing which have the capacity to induce deep sedation shall be limited to those qualified (licensed) to administer general anesthesia.

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iv. Attempt to limit selection of agents for which reversal is possible; while most attractive, limitations exist with respect to agent availability with this capacity.

v. Avoid usage of diazepam (with long-acting metabolites) in dosages exceeding 0.5 mg/kg.

vi. Proper use of restraints which carry potential for limiting chest wall expansion and access to monitor respiration and ventilatory capacity;

vii. Rigid satisfaction of discharge criteria which insures that no further need for trained supervision exists; transport requirements are fulfilled, i.e. accompaniment of a second responsible adult other than driver, and use of approved safety seat.

State and regulatory mechanisms to be considered to offset and eliminate risk and mishap

I. Creation of a National Data Bank for occurrences involving morbidity or mortality is recommended. Establishment of a Registry of Practitioners involved in mortalities where sedation has been employed and non-compliance with existing safety guidelines has been documented, is recommended. Precedent for establishment of national data banks has existed for several decades; one example exists for members of a hospital staff who has lost privileges and appointment for episodes of wrongdoing. The intent serves to protect the public from inappropriate practices by identification of doctors found in violation of ethical practices. The loss of a child due to gross negligence, intentional departure from established standards of care, or unethical and harmful practice should at the very least warrant similar documentation.

II. Legislation is needed to prevent suppression of recording litigation outcomes of cases involving morbidity and mortality which includes ages involved, agents, and dosing (such listings would carry only the intent to inform, educate, illustrate and differentiate etiology from idiosyncratic causes) without violation of privacy .

III. A state by state listing of agents and/or dosages banned or discouraged from use should be available for all health care providers.

IV. Uniformity, state by state listing of Licensure Requirements for the Use of

a. Light/Moderate Sedation

b. Deep Sedation/General Anesthesia

Where appropriate, names, photos and identification of involved parties should remain protected so as to avoid litigation in the aftermath of contested outcomes. While protection of the rights of practitioners is strictly enforced, it begs the question of the responsibility of society's guardians to protect the public from practitioners deliberately found to violate existing guidelines to insure patient safety.

Summary

Current safety guidelines for the use of pediatric sedation, while considered state of the art, appear insufficient to prevent unacceptable outcomes from occurring. Energies to insure proficiency in airway and medical management, facility and personnel preparedness to recognize and manage an adverse reaction are needed on a state by state and/or national level. Limitations and shortcomings based on training skills, and judgment to safely utilize agents capable of the induction of varying levels of consciousness, can be identified to help intercept horrific outcomes. A proactive rather than reactive approach seems warranted.

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