AAP Policy Summary

Use of Chloral Hydrate For Sedation in Children

Editor's note: The full text of this policy statement will appear in an upcoming issue of Pediatrics. *Individual copies of the statement also are available from the AAP Publications Office, 141 Northwest Point Blvd., PO Box 927, Elk Grove Village, IL 60009-0927; (800) 433-9016.*

Summary

Publicity about the possible carcinogenicity of chloral hydrate along with the suggestion that alternative sedatives should be used in children has generated concern among physicians, dentists, and their patients. Replacement of chloral hydrate with other sedatives would represent a major change in practice since it is one of the drugs most widely employed to sedate young children undergoing dental and medical procedures, and imaging studies. This statement is to assist the practitioner in making an informed decision regarding the use of chloral hydrate by summarizing: (1) information pertaining to the potential for carcinogenesis associated with use of chloral hydrate; (2) the risk/benefit considerations of available sedatives; and (3) risks associated with prolonged sedation with chloral hydrate.

Some of the concern regarding potential carcinogenicity of chloral hydrate is based on the assumption that chloral hydrate is a reactive metabolite of trichloroethylene, an industrial solvent, and is responsible for the carcinogenicity of trichloroethylene.

There are no studies pertaining to chloral hydrate-associated carcinogenicity in humans. The evidence that chloral hydrate is carcinogenic comes from two studies in male mice. Chloral hydrate damages chromosomes in selected mammalian test systems under certain experimental conditions.

Chloral hydrate is not the only sedative that is a carcinogen in experimental animals. Some of the benzodiazepine and barbiturate sedatives also have been shown to be carcinogenic in animal studies. In addition, the barbiturates have been associated with a possible increased incidence in malignant tumors in humans.

The acute toxicity of chloral hydrate when used in recommended single doses for sedation is low. The lethal to therapeutic dose ratio is much lower than with the barbiturates. However, acute overdoses may cause cardiorespiratory depression. It is common practice in many hospitals to administer chloral hydrate in repetitive doses to maintain prolonged sedation in infants and children during mechanical ventilation. However, there is reason to be concerned about this practice.

Currently, sufficient data are not available in infants and children to establish any of the available sedatives as superior with respect to either efficacy or safety.

Conclusions and Recommendations

1. Chloral hydrate is an effective sedative with a low incidence of acute toxicity when administered orally in recommended dosage for short-term sedation. There is a great deal of experience with chloral hydrate and most practitioners are familiar with its use.

2. Repetitive dosing of chloral hydrate is of concern because of accumulation of the metabolites, trichloroethanol and trichloroacetic acid, which may produce excessive central nervous system depression, predispose newborn infants to conjugated and non-conjugated hyperbilirubinemia, decrease albumin binding of bilirubin, and contribute to metabolic acidosis.

3. Although available information regarding theoretical long-term risk of carcinogenicity is of concern, it does not provide a basis for sufficient concern to warrant selection of an alternative sedative rather than chloral hydrate.

4. Sufficient data are not available for children to establish any of the available sedatives as superior with respect to either efficacy or safety. A sudden switch by physicians and dentists from a sedative with which they are familiar to one with which they have less experience and for which there are not sufficient safety and pharmacologic studies in children may pose a greater immediate risk to children than a theoretical risk of carcinogenesis from short term sedation with chloral hydrate.

5. Additional well-designed studies in infants and children need to be conducted to provide the information necessary for the safest and most efficacious use of sedatives in pediatric patients.

The recommendations in this publication do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate. This policy statement is not for release to the media until May 20.

AAP Policy Statement

Prohibition of Pre-existing Condition Restrictions in Health Insurance Policies

Background

The use of medical underwriting by health insurers denies children access to the health care system. Pre-existing condition exclusions clauses, waiting periods, medical testing for insurability, and rated premiums are accelerating in use.

A new and disturbing trend occurring in the health insurance market is the use of these medical underwriting techniques to deny coverage for children with common childhood illnesses.

To aggressively counter the inappropriate use of medical underwriting techniques by health insurers, the AAP's Committee on Child Health Financing developed this statement to: (1) support legislation and AAP advocacy efforts in this area; (2) inform parents of the use of pre-existing conditions exclusion clauses; and (3) educate pediatricians on how their practice is affected by medical underwriting detrimental to children.

The Statement

Employers and insurers are placing increasing restrictions on health insurance coverage of children and adults with pre-existing conditions. These typically come in the form of waiting periods, pre-existing condition exclusions or reimbursement caps, and risk-adjusted premium rates. In addition, outright exclusion of health insurance coverage is a technique used by some, primarily small companies, to reduce their risk of incurring costly medical claims.

These insurance practices obstruct access to care for those most in need. Affected children and their families are placed at risk for inadequate medical care and financial stress. Recent estimates indicate that over one-half million families fear switching jobs because they may lose coverage for someone in the family with a pre-existing condition.

A growing number of childhood diseases are being listed as pre-existing conditions by insurance companies. Some are severe problems such as spina bifida, hemophilia or cystic fibrosis. Others are relatively common childhood diseases such as asthma, otitis media, urinary tract infections, and heart murmurs.

Data on the number of children who are presently affected by such exclusionary policies are unavailable, but, in 1989, 14% of children under the age of 18 or 490,000 youths with chronic disabling conditions were uninsured. The increasing number of restrictions has increased the number of children and adolescents who are denied coverage.

The American Academy of Pediatrics is concerned about the growing failure of employers to insure children in a timely manner because of pre-existing conditions. We support reforms in employer-based insurance to ensure the availability of insurance for all children. Such reform should be based on the principle of community rating, open enrollment, and prohibition of pre-existing condition limits. The American Academy of Pediatrics recommends that all health insurance policies fulfill the following requirements:

(1) No waiting periods for enrollment.

(2) No limitation of coverage or reimbursement because of either severe chronic or common recurring childhood illnesses.

(3) Premium rate increases should be based only on community rating, rather than an experience.

(4) Guaranteed renewability.

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