Medical Direction and Practices Board
White Paper

Dexamethasone Administration: Using the injectable formulation orally in children

Background

A common challenge when working with the pediatric population is the administration of medication. If commercial products are unavailable, alternative measures are often undertaken, such as crushing and dissolving portions of a tablet, or extemporaneous compounding of oral products. In some cases, an extemporaneous liquid cannot be prepared easily from tablets or capsules and off-label oral use of an intravenous (IV) or intramuscular (IM) preparation is considered. An example of this is administering the *injectable* formulation of dexamethasone *orally* for the treatment of pediatric asthma and croup. This practice is followed in emergency departments around the country.

Safe Use of IV/IM Medications for Oral Use

Several important factors should be considered when assessing whether an IV/IM formulation can be safely administered orally:

- Will the solution be absorbed and bioavailable by the enteral route?
- Is the pH or osmolality safe for children?
- Does the injectable contain preservatives? Preservatives such as benzyl alcohol or propylene glycol, often contained in *multidose* vials, may have *significant adverse effects* in neonates, infants, and children, such as metabolic acidosis, renal failure, seizures, and central nervous system depression.
- Will the volume providing the required dose be tolerated by the child based on age and medical status?
- Will the formulation be palatable?

Applying Principles to Dexamethasone

The question of whether an IV/IM preparation can be given to children orally commonly arises with respect to dexamethasone. The supporting evidence in the literature is limited but can be combined with the general principles discussed above.

Although dexamethasone oral liquid formulations are available in the United States, some of these contain 30% alcohol or have a lower concentration than is clinically impractical. In some situations, toddlers and small children can require doses over 30 mL. Consequently, these

commercially available products may increase the risk for adverse effects from excipients and may also lead to nonadherence in a pediatric population.

The rationale for using dexamethasone injection solution over tablets is that the drug is already dissolved, eliminating the need for crushing/grinding tablets and dissolving the powder. This method also prevents potential physical instability and microbial contamination.

This injectable formulation was evaluated in a large pediatric randomized controlled trial. The efficacy and safety of dexamethasone for the treatment of bronchiolitis and its palatability in children were confirmed. Given previous studies and clinical experience, the IV preparation can be used to make an oral formulation.

Some clinicians have formulated dexamethasone suspensions by adding the dexamethasone phosphate injection to distilled water and cherry-flavored syrup. The flavor of the IV preparation may also be masked by following oral administration with juice or a popsicle.

Please note that at this time, the only IV medication on the MEMS formulary that has been approved to be given orally is single-dose/one-time use dexamethasone.