Inclusion Criteria
- Previously healthy children

Exclusion Criteria
- Neonates (0-28 days of life)
- Renal patients
- Sickle Cell Disease patients

Background
Intravenous fluids are used frequently in hospitalized children. Many previously healthy children are administered this intervention to maintain hydration status when enteral nutrition cannot be utilized. Health care providers report a large amount of variation in IV fluid selection that is not based on patient specific variables. This evidence summary serves as a guide to determine the most appropriate initial IV fluid selection in previously healthy children requiring IV fluids. Specific recommendations are not made based on patient diagnosis in this clinical standard.

Critically Analyze the Evidence
The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. The table below defines how the quality of evidence is rated and how a strong versus a weak recommendation is established.

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Type of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>STRONG</td>
<td>Desirable effects clearly outweigh undesirable effects or vice versa</td>
</tr>
<tr>
<td>WEAK</td>
<td>Desirable effects closely balanced with undesirable effects</td>
</tr>
<tr>
<td>Quality</td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies</td>
</tr>
<tr>
<td>Moderate</td>
<td>Evidence from RCTs with important limitations (e.g., inconsistent results, methodological flaws, indirect evidence, or imprecise results) or unusually strong evidence from unbiased observational studies</td>
</tr>
<tr>
<td>Low</td>
<td>Evidence for at least 1 critical outcome from observational studies, from RCTs with serious flaws or indirect evidence</td>
</tr>
<tr>
<td>Very Low</td>
<td>Evidence for at least 1 critical outcome from unsystematic clinical observations or very indirect evidence</td>
</tr>
</tbody>
</table>

PICO Question 1: In previously healthy infants and children, does hypotonic intravenous fluids compared to isotonic intravenous fluids increase the risk of electrolyte imbalance?

Recommendation(s):
Strong recommendation with moderate quality evidence that in previously healthy pediatric patients requiring continuous intravenous (IV) fluids whom serum electrolyte results are unavailable, isotonic fluids should be administered. IV fluids with different sodium concentrations may be appropriate for patients requiring intensive care monitoring, with sickle cell, neonatal (day of life 28 or less), renal diseases and/or other diagnoses that inhibit electrolyte regulation. (1-11)

Strong recommendation with moderate quality evidence that in previously healthy pediatric patients IV fluids containing <0.45% sodium should not be used routinely for initial continuous fluids.

Remarks: If anticipated IV fluid administration is for greater than 24 hours, consider checking serum electrolyte levels.

A review of the evidence on this topic revealed four meta-analyses and four randomized controlled trials. Three external guidelines/practice points outlined recommendations for care for the use of IV fluids in this population. In most studies, the use of isotonic IV fluids was found to be protective against the risk of hyponatremia. There was no difference reported in the studies in the rate of hypernatremia when patients were allocated to hypotonic versus isotonic IV fluids. McNab 2015 reported that two patients in the isotonic IV fluids group developed episodes of overhydration as compared to no patients in the hypotonic group. No other
adverse events were reported in the reviewed evidence. The body of literature on this topic is limited due to inconsistency of the intervention (different concentrations of sodium in the hypotonic IV fluid groups). *(1-4)*

The Canadian Paediatric Society recommended that for children with a low risk of antidiuretic hormone secretion and a normal sodium level, isotonic is preferred over hypotonic IV fluids. *(9)* This recommendation is similar to that of the National Institute for Health and Care Excellence (NICE) guideline on IV Fluids in Children. The organization recommends to initially administer isotonic crystalloids for IV fluids in children and young people. The organization further recommends to obtain serum electrolytes in this population and base subsequent IV fluid prescriptions on laboratory results. *(10)*

**Critical Points of Evidence**

**Evidence Supports**

- In previously healthy pediatric patients requiring continuous intravenous (IV) fluids whose serum electrolyte results are unavailable, isotonic fluids should be administered. IV fluids with different sodium concentrations may be appropriate for patients requiring intensive care monitoring, with sickle cell, neonatal (day of life 28 or less), renal diseases and/or other diagnoses that inhibit electrolyte regulation. – Strong recommendation, moderate quality evidence
- In previously healthy pediatric patients, IV fluids containing <0.45% sodium should not be used routinely for initial continuous fluids. – Strong recommendation, moderate quality evidence

**Remarks:** If anticipated IV fluid administration is for greater than 24 hours, consider checking serum electrolyte levels.

*NOTE: The references cited represent the entire body of evidence reviewed to make each recommendation.

## References

**Clinical Standards Preparation**

This clinical standard was prepared by the Evidence-Based Outcomes Center (EBOC) team in collaboration with content experts at Texas Children’s Hospital. Development of this clinical standard supports the TCH Quality and Patient Safety Program initiative to promote clinical standards and outcomes that build a culture of quality and safety within the organization.

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No relevant financial or intellectual conflicts to report.

**Development Process**

This clinical standard was developed using the process outlined in the EBOC Manual. The literature appraisal documents the following steps:

1. **Review Preparation**
   - PICO questions established  
   - Evidence search confirmed with content experts

2. **Review of Existing External Guidelines**
   - Risk of Acute Hyponatremia in Hospitalized Children and Youth Receiving Maintenance Intravenous Fluids, Canadian Paediatric Society; Inpatient Pathway for Continuous Administration of IV Fluids, Children’s Hospital of Philadelphia; IV Fluids in Children: Intravenous Fluid Therapy in Children and Young People in Hospital, National Institute for Health and Care Excellence

3. **Literature Review of Relevant Evidence**
   - Searched: PubMed, Cochrane

4. **Critically Analyze the Evidence**
   - 4 meta-analyses and 4 randomized controlled trials

5. **Summarize the Evidence**
   - Materials used in the development of the clinical standard, literature appraisal, and any order sets are maintained in a Sodium Content in Maintenance IV Fluids evidence-based review manual within EBOC.

**Evaluating the Quality of the Evidence**

Published clinical guidelines were evaluated for this review using the **AGREE II** criteria. The summary of these guidelines are included in the literature appraisal. **AGREE II** criteria evaluate the following aspects of the quality and applicability of guidelines:

**GUIDELINE SCOPE AND PURPOSE**

- **Quality**
  - Desirable effects clearly outweigh undesirable effects
  - Desirable effects closely balanced with undesirable effects
  - Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies
  - Evidence from RCTs with important limitations (e.g., inconsistent results, methodological flaws, indirect evidence, or imprecise results) or unusually strong evidence from unbiased observational studies
  - Evidence for at least 1 critical outcome from observational studies, RCTs with serious flaws or indirect evidence
  - Evidence for at least 1 critical outcome from unystematic clinical observations or very indirect evidence

**STAKEHOLDER INVOLVEMENT**

- Necessary involvement

**CLARITY AND PRESENTATION**

- Clear and comprehensive

**APPLICATION**

- Applicable to a wide range of providers

**CREDITABILITY**

- Evidence-based recommendations

**COMMUNICATION**

- Accessible and understandable

**EDITORIAL INDEPENDENCE**

- Freedom from undue influence

**Recommendations**

Practice recommendations were directed by the existing evidence and consensus amongst the content experts. Patient and family preferences were included when possible. The Content Expert Team and EBOC team remain aware of the controversies related to sodium content in maintenance IV fluids for children. When evidence is lacking, options in care are provided in the clinical standard and the accompanying order sets (if applicable).

**Approval Process**

Clinical standards are reviewed and approved by hospital committees as deemed appropriate for its intended use. Clinical standards are reviewed as necessary within EBOC at Texas Children’s Hospital. Content Expert Teams are involved with every review and update.

**Disclaimer**

Practice recommendations are based upon the evidence available at the time the clinical standard was developed. Clinical standards (guidelines, summaries, or pathways) do not set out the standard of care and are not intended to be used to dictate a course of care. Each physician/practitioner must use his or her independent judgment in the management of any specific patient and is responsible, in consultation with the patient and/or the patient’s family, to make the ultimate judgment regarding care.