Belgian recommendations on perioperative maintenance fluid management of surgical pediatric population


Abstract: The European recommendations on perioperative maintenance fluids in children have recently been adapted from hypotonic to isotonic electrolyte solutions with lower glucose concentrations. In Belgium, however, the commercially approved solutions do not match with these recommendations and there is neither consensus nor mandate about the composition and volume of perioperative maintenance fluids in children undergoing surgery despite the continuing controversy in literature. This paper highlights the significant challenges and shortcomings while prescribing fluid therapy for pediatric surgical patients in Belgium. It is sensible to the authors to address these issues with national guidance through an organization such as The Belgian Association for Paediatric Anaesthesiology, and to propose Belgian recommendations on perioperative fluid management in surgical children, with the intention of improving the quality of care in this population.

Key words: Belgian recommendations; perioperative fluid therapy; children undergoing surgery; isotonic fluids; maintenance fluid.

Abbreviations: ADH: antidiuretic hormone; BAPA: Belgian Association for Paediatric Anaesthesia; ESPA: European Society for Paediatric Anaesthesiology; iv: intravenous.

INTRODUCTION

The administration of intravenous (iv) maintenance fluids in children was originally described in 1957 by HOLLIDAY and SEGAR, who suggested the use of hypotonic fluids with the addition of 5% glucose (1). These recommendations were actually planned to match free water requirements and energy expenditure in healthy children, but they may not necessarily be appropriate to apply to all children in the perioperative setting, where energy expenditure, glucose, electrolyte and intravascular volume requirements deviate significantly from those of the original population described (2). However, Holliday and Segar’s practice was adopted for many years without questioning its adequacy and safety in the surgical pediatric population.

In recent years, there have been reports of postoperative deaths or significant neurological damage due to hospital-acquired hyponatremia in previously healthy children receiving hypotonic maintenance solutions during and after elective surgery (3, 4). These, together with the results of the systematic reviews validating the growing concerns in this regard, have raised questions about potentially hazardous complications in our current practice (5). As a consequence, guidelines of several different associations of pediatric anesthesiologists have adapted the recommendations for perioperative fluid management in children from hypotonic...
to isotonic electrolyte solutions with lower glucose concentrations (1-2.5% instead of 5%) to avoid electrolyte and glucose imbalance (6, 7). Traditionally, intraoperative fluid management has been the anesthetists’ responsibility. Thereafter, once the child is admitted to a pediatric or surgical ward, the care is handed over to either surgeons or pediatricians. During the perioperative period, calculating the appropriate volume of iv. fluid needed is challenging, particularly in small children, where determination of the intravascular volume status needs to be estimated. In addition, the recently published guidelines may increase the difficulty in decision-making regarding the fluid composition, as the recommended solutions are neither currently commercially supported nor indeed available on the Belgian market. Therefore, the clinicians may tend to use suboptimal fluids or to compose their own fluid mixture, which could potentially lead to iatrogenic complications or medical errors.

The purpose of this paper is to outline the rationale of perioperative fluid management in children and to address the currently available options for crystalloid fluid management in Belgium, and thus to propose clinical recommendations through our national organization, The Belgian Association for Paediatric Anaesthesia (BAPA).

Maintenance fluid requirements

In 1957, Holliday and Segar (1) first reported the relationship between physiologic fluid losses and caloric expenditure. They demonstrated that caloric consumption mirrors water requirements: in normal circumstances, in children 1 mL of water is required to metabolize 1 kcal of energy expended, accounting for both insensible water losses through the skin and respiratory tract, and urinary water losses. Based on the computed caloric needs of the average hospitalized patient, they suggested the daily fluid requirement as the “100-50-20 rule”.

Subsequently, this weight-based formula has been further developed into the well-known “4-2-1 rule” for hourly maintenance fluid requirement in children (Table 1). Moreover, considering the electrolyte composition of human milk and cow’s milk, Holliday and Segar recommended daily needs of 2 mEq/100 kcal of both potassium and chloride and 3 mEq/100 kcal of sodium (1). These maintenance fluid and electrolyte requirements are theoretically met by the hypotonic maintenance solutions more commonly used in hospitalized children in Belgium today, where 1/4th of daily fluid volume is calculated as 5% glucose added to 0.9% NaCl and 3/4th as 5% glucose added to water or much better known as 5% glucose with 0.2% NaCl.

### Perioperative fluid requirements

Perioperative fluid therapy is aimed at providing basal metabolic requirements, compensating for pre- and peroperative fasting deficit and replacing ongoing losses incurred during the surgical procedure thus at maintaining a correct fluid and electrolyte homeostasis, an adequate tissue perfusion and, therefore, normal cardiovascular stability (8).

**Preoperative fasting** is a prerequisite for elective surgery in order to reduce the link between feeding and pulmonary aspiration of gastric contents. The preoperative fasting time has been dramatically reduced over the last 20 years. In 2011, the European Society of Anaesthesiology published the revised recommendations with intake of clear fluids being allowed up to 2 hours before induction of anesthesia (9). When these guidelines are followed, fasting fluid deficit is expected to be minimal. However, we know that children undergoing day-case surgery often still experience a prolonged fasting time of more than 12 hours and also that healthy children are not dehydrated after a normal 10 to 12 hours night of sleep. In fact, there are presently no data to determine the exact amount of

<table>
<thead>
<tr>
<th>Body weight (kg)</th>
<th>Maintenance fluid requirement</th>
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<tbody>
<tr>
<td></td>
<td>mL/day</td>
</tr>
<tr>
<td>0-10</td>
<td>100 mL/kg/day</td>
</tr>
<tr>
<td>10-20</td>
<td>1000 mL + 50 mL/kg/day</td>
</tr>
<tr>
<td>for each kg more than 10 kg</td>
<td>for each kg more than 10 kg</td>
</tr>
<tr>
<td>20 and more</td>
<td>1500 mL + 20 mL/kg/day</td>
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<td>for each kg more than 20 kg</td>
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fluid deficit that occurs in normal fasting children, but strong evidence suggests that healthy adult patients maintain a normal intravascular volume status despite a prolonged fasting (10). In general, it is accepted to calculate the fasting deficit by multiplying the hourly maintenance fluid requirement by the number of hours of restriction and to replace 50% of it in the first hour, followed by 25% in the second and third hours respectively (11). The amount of fluid given should be reduced if children are fasting for a short period of time or if the child is already receiving iv. fluid prior to surgery. In clinical situations such as vomiting, diarrhea, and fever where some degree of dehydration is likely to occur, classical clinical signs, the degree of weight loss and monitoring of urinary output are mandatory for evaluating and treating any fluid deficit (8).

In addition, there is considerable debate regarding the existence of “third space losses” which would refer to the sequestration of intravascular fluid to a non-functional extracellular space that is beyond osmotic equilibrium with the vascular space. However, a recent review of predominantly adult literature concluded that a classic “third space” does not exist (12). Several studies in adults have also revealed that the functional fluid space is unchanged or expanded rather than contracted after surgery whereas substantial amounts of fluid have been accumulated in the interstitial space secondary to volume overload with crystalloid infusions (12). In pediatrics, it has been proposed that, depending on the nature of the surgical procedure, from 1 mL/kg/h to as much as 15 mL/kg/h of additional fluids might be necessary to compensate for these continuing losses (8, 13).

Moreover, as stated by Taylor and Durward (14), approaching water requirements through energy expenditure and thus via weight, overestimates the volume of water required for maintenance. Most energy expenditure (80%) occurs in the major metabolic organs (heart, liver, kidney and brain), which account for only 7% of total body mass, so relating increased weight to increased energy expenditure will always produce an overestimation. During the perioperative period, the stress response to surgery causes maximal vasopressin release and thus much less overall insensible water losses. In addition, anesthetized children or those in early postoperative period are less active than their healthy counterparts from whom the recommendations were first derived (1).

Overall, there is little evidence regarding this topic in pediatric patients. It is possible that in major pediatric surgery, in line with the several studies in adults (15, 16), outcomes may be improved by conservative and individualized fluid management in the perioperative period. However, this is a totally challenging area in daily pediatric practice as non-invasive tools to guide and determine optimum intravascular volume status in children are currently lacking (17).

Perioperative fluid management

1. The risk of hyponatremia

As described above, the current practice of prescribing maintenance iv. fluids is based on historical data (1). However, whether these principles provide optimal fluid and electrolyte balance in all surgical children is yet to be validated in well conducted clinical trials using patient-important outcomes. Nevertheless, clinicians may often extrapolate the “4-2-1 rule” and the accompanying hypotonic solutions to clinical situations where adherence may not be justifiably applicable and could, in fact, be potentially harmful (5, 13, 18).

Despite apparent heterogeneity in study design, participants, and quality among studies examined in the meta-analysis, adverse clinical outcomes nevertheless appear to be remarkably consistent across the majority of studies in the surgical population (3-5, 18). The perioperative period is characterized by various factors affecting the physiology of a previously healthy child and even more so during an acute illness. Recently, both the composition and the volume of maintenance fluids have been criticized in this setting. While the calculation of the volume of the maintenance requirements often seems to be exaggerated in a perioperative child (2), the current level of evidence suggests that the administration of hypotonic solutions significantly increases the risks of hyponatremia and hyperglycemia which have occasionally resulted in permanent neurological damage or even death (3-5, 8, 18-20).

Although its true incidence is not known, perioperative hyponatremia has been reported in as high as 31% of surgical children (21). It has been demonstrated that perioperative hyponatremia occurs as a result of an impaired ability to excrete hypotonic urine due to an increased antidiuretic hormone (ADH) secretion, in combination with a positive balance of electrolyte- free water administration (4, 22). An increased ADH release results from both osmotic and a variety of non-osmotic stimuli such as pain, stress, nausea, hypovolemia, narcotics, and non-steroidal anti-inflammatory
drugs (13). The majority of these factors are commonly encountered in the perioperative period and they are able to override the osmotic control of ADH secretion. This situation prevents a surgical patient from eliminating electrolyte-free water even in the presence of extracellular water excess. Moreover, recent surveys demonstrate that children are generally administered iso-osmolar glucose-saline solutions, which, as the glucose is metabolized in vivo, become effectively hypotonic and a source of electrolyte free water thus promoting hyponatremia (13).

Considering that sodium is the main extracellular cation and the principal determinant of extracellular volume, hyponatremia leads to an osmotic movement of free water across cell membranes from the extracellular to the intracellular compartments. This expansion of intracellular fluid volume is of major importance in the brain. Hence it responds by an adaptive mechanism whereby, in the early phase of hyponatremia, sodium is transported from the intracellular to the extracellular compartments using the 3Na-2K-ATPase system. This enzyme activity is however, impaired in small and prepubescent children (23).

The brain of a child has only limited ability to expand as it grows rapidly, achieving adult size by the age of 6 yrs, whereas the skull continues to grow until the age of 16 yrs (13, 18, 20). Cerebrospinal fluid buffers brain expansion, but its volume around the brain is relatively smaller in children than adults. And finally, the cerebral intracellular concentration of sodium is about 27% higher in children than adults (20). Other factors that may contribute to a poor outcome in children with hyponatremia are both the lack of timely treatment resulting from a low index of clinical suspicion and the lack of routinely performed electrolyte monitoring (13, 20). In addition, the early symptoms of hyponatremia include a decreased level of consciousness, disorientation, lethargy, headache, nausea and vomiting which are often seen in the postoperative period. However, in children, seizures, a respiratory arrest or sudden death from brain stem herniation have also been reported as the primary events that have triggered identification of hyponatremia (5, 13, 18). Given all these features, children, regardless of gender, are particularly at risk for acute hyponatremia and its effects while receiving hypotonic fluids.

It is argued that there would be at least 2 potential problems if maintenance fluids were to be given solely as normal saline (NaCl 0.9%) at the current recommended volumes. The first is the process of desalination; the raised ADH concentration associated with the perioperative period prevents the kidneys from excreting dilute urine, while the expansion of the extracellular compartment by the near isotonic fluid administered results in hypertonic urine being passed (24). This phenomenon, described in the adult population, may be the etiology of the slight hyponatremia exhibited in some children receiving isotonic fluids (24, 25). Secondly, there is a concern that the large volume of normal saline administered could be responsible for hyperchloremic metabolic acidosis, although the potential for significant morbidity associated with this issue, has not yet been determined (26). The issue that isotonic maintenance fluids may cause hypernatremia is not supported in the studies reviewed (5, 13, 25).

2. The risk of hyperglycemia

Due to their higher metabolic rate and lower glycogen stores compared to adults, the lack of oral intake during preoperative fasting, children were generally thought to be at greater risk of preoperative hypoglycemia. Much of the published work regarding fluids in children has therefore been mainly concerned with the need for glucose during surgery (27, 28). However, more recent studies, estimated the incidence of preoperative hypoglycemia at < 1% up to max 2.5% which has been usually associated with long fast durations, far beyond the current recommended fasting guidelines (27).

Both hypo- and hyperglycemia have been recognized as detrimental to the brain. Hypoglycemia, depending on its severity, induces a stress response and alters cerebral blood flow and metabolism. This may result in permanent neurodevelopmental impairment mainly in small infants even if hypoglycemia is mild and particularly if it occurs in association with mild hypoxia or ischemia (29). In addition, the lack of glucose supply enhances lipolysis leading to the production of ketone bodies and free fatty acids which is not necessarily accompanied by hypoglycemia (30). At any rate, should hypoglycemia occur, it might go unrecognized and thus untreated in an anesthetized child.

Conversely, hyperglycemia causes osmotic diuresis and subsequently dehydration and electrolyte abnormalities (27). Furthermore, there is evidence that, in the presence of an ischemic or hypoxic event, the impaired metabolism of excess glucose causes an accumulation of lactate, and a decrease in intracellular pH, which severely

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compromises cellular function. This appears to result in global or focal cerebral ischemia and cell death, and it worsens neurologic outcomes, morbidity and mortality in the pediatric population (27, 31).

Hence, the choice of glucose concentration in the perioperative setting of surgical children should be a compromise between avoiding hypoglycemia, lipolysis and hyperglycemia. Several clinical trials comparing the perioperative use of infusion solutions containing no glucose, 1%, 2.5%, 4% or 5% glucose showed that the administration of 1% glucose prevents hypoglycemia, ketogenesis and lipid mobilization and is associated with blood glucose concentrations in the normal range with no life-threatening event in the case of accidental hyperhydration (32). Whereas, intra-operative administration of ≥ 2.5% glucose solutions often resulted in both hyperglycemia due to stress-induced insulin resistance and dilutional hyponatremia (27, 28, 30).

Although no consensus has been reached, administration of a maintenance infusion with an increased glucose concentration and close monitoring of blood glucose levels should be considered mandatory in children in whom hypoglycemia is a potential threat, i.e., children suffering hepatic dysfunction or disorders of metabolism, those requiring preoperative glucose infusion, parenteral nutrition or on ß-blockade treatment, and during long operations (8, 13).

3. How to prevent perioperative hyponatremia and hyperglycemia ?

Perioperative fluids are used both as ‘maintenance’ fluid to replace insensible and urinary losses as long as oral intake is suspended and as ‘replacement’ fluid to expand the extracellular volume, to counter the effect of anesthetic agents in maintaining arterial blood pressure or to replace ongoing losses associated with surgery (2). Most of these fluids, deficits and losses serve mainly in balancing the extracellular compartment as discussed previously and should logically be replaced by a solution approximating the composition of the extracellular fluid lost. Nevertheless, it appears that the current practice of anesthetists with respect to the perioperative fluid prescription most likely relies on the commercial availability of the solutions, their training in pediatric anesthesia, the local departmental policy for fluid prescription and the awareness of the care providers regarding the potential hazard of iatrogenic hyponatremia and hyperglycemia associated with the use of hypotonic solutions rather than the child’s needs both in the intraoperative and postoperative period (33). Furthermore there is the temptation to use one sort of fluid for intraoperative maintenance, surgical loss replacement and as volume therapy for anesthetic drug induced hypotension (33).

As stated by the European Society for Paediatric Anaesthesiology (ESPA) and demonstrated recently by various studies, an appropriate intraoperative fluid strategy should include the use of an isotonic solution with a nearly physiologic electrolyte composition in order to avoid hyponatremia, and a metabolic anion (preferably acetate) as bicarbonate precursor to avoid acid-base imbalances (i.e. hyperchloremic acidosis) and it should also have an osmolarity and acidity close to those of the plasma, despite the presence of low glucose concentration, to avoid hypoglycemia, lipolysis and hyperglycemia (7, 32).

Table 2 summarizes the currently marketed iv. fluid solutions in common use in pediatric practice in Belgium. It demonstrates clearly that such an isotonic solution with low glucose concentration i.e. 1% is, as of now, not approved in Belgium.

It should also be noted that iv. fluids for general use which are classified as isotonic include Plasmylate® (Baxter, Lessines, Belgium), Hartmann® (Baxter, Lessines, Belgium), 0.9% NaCl, and 0.9% NaCl + 5% glucose. Fluids classified as hypotonic include 0.45% NaCl + 5% glucose, 5% glucose and 10% glucose (Table 2). The currently available hypotonic fluids indeed meet the predicted maintenance requirements of water. Adding 5% glucose to these fluids makes the solution iso-osmolar in vitro. When administered, however, glucose enters very rapidly into the intracellular compartment to be metabolized and, thus in vivo these solutions subsequently become clearly hypotonic (13). Lactate is a metabolic anion, that in vivo, metabolizes in the liver while releasing equimolar amounts of bicarbonate. Theoretically, the administration of a large volume of a lactate containing solution may produce dilutional acidosis. Conversely, acetate metabolizes significantly faster, more independently of hepatic function, with a lower increase in oxygen consumption, hence it ensures a more stable acid-base status. In addition it does not interfere with the diagnostic use of lactate as a marker of low tissue perfusion. In a previous study, acetate was used for correction of acidosis even in neonates and pre-term babies (34). For all these reasons, it may be considered as an appropriate alternative to lactate in the majority of surgical children, regardless of age (32). Normal saline
(NaCl 0.9%) has been widely accepted as a “physiologic” solution. Nevertheless, a significant body of proof has demonstrated that administration of a large volume of normal saline may lead to acid-base imbalances, hyperchloremic metabolic acidosis, and the phenomenon of desalination (24-26).

Recently in Germany, an isotonic balanced electrolyte solution with 1% glucose has been licensed. The electrolyte composition of this solution without added glucose is very close to that of plasma. Several studies have also proved its large margin of safety, stable electrolytes and glucose concentration, and acid-base status (32) even in the event of accidental hyperhydration. Although there is currently no Belgian marketing authorization for such a solution, its composition also corresponds closely to that of Plasmalyte® and Hartmann® without added glucose, which are both commercially licensed in Belgium.

Belgian recommendations on perioperative fluid therapy in surgical children

Considering the rationales for perioperative fluid management in children, Belgian recommendations on behalf of the advisory board of BAPA are proposed. These recommendations applicable to all pediatric surgical patients aged 1 month to 16 years old [apart from a few exceptions] receiving iv. fluid therapy, are summarized in Figure 1.
As the actual needs vary significantly between the different patient groups in different perioperative settings, the rationale for fluid administration should be carefully adapted during the intraoperative and postoperative periods in children undergoing either minor or major surgery.

In an attempt to appropriately match the recommended composition of the intraoperative fluid by ESPA (7) with the commercially approved fluids in Belgium (Table 2), it would be more rational to use an isotonic electrolyte solution (Plasmalyte®, Hartmann®) with 1% glucose added (10 ml glucose 50% in 500 ml isotonic solution) as the intraoperative maintenance fluid for surgical children.

The majority of children undergoing uncomplicated day-case surgery or minor surgery are expected to resume eating and drinking soon after the operation. Administration of intraoperative fluids in these cases has been shown to be associat-ed both with a reduced incidence of postoperative nausea and vomiting particularly in those children receiving opioids (35), and with a significantly reduced postoperative increase in ADH concentration. The latter presumed to be a result of correction of hypovolemia. Therefore, for these children, a full volume maintenance fluid would be appropriate during the short intraoperative and immediate postoperative period.

For children expected to remain nil-by-mouth for at least 24 hours after surgery or undergoing major surgery, a full volume maintenance fluid should be administered during the intraoperative period. In the postoperative period, maintenance fluids are required to replace insensible losses, urinary losses and to provide a source of energy. However, urine output may vary according to the clinical situations and the effects of ADH, and caloric expenditure is also reduced in hospitalized

### Table 2
Composition of plasma and commonly used intravenous maintenance fluids in Belgium

<table>
<thead>
<tr>
<th>Fluid solutions</th>
<th>Glucose (g/L)</th>
<th>Electrolytes (mEq/L)</th>
<th>Osmolarity (mOsm/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Cations</td>
<td>Anions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Na</td>
<td>K</td>
</tr>
<tr>
<td>Plasma</td>
<td>142</td>
<td>4.5</td>
<td>5</td>
</tr>
<tr>
<td>Glucose 5%</td>
<td>50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucose 10%</td>
<td>100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucose 5%-NaCl 0.45%</td>
<td>50</td>
<td>77</td>
<td></td>
</tr>
<tr>
<td>Glucion 5%</td>
<td>50</td>
<td>54</td>
<td>26</td>
</tr>
<tr>
<td>Glucion 10%</td>
<td>100</td>
<td>54</td>
<td>26</td>
</tr>
<tr>
<td>Hypotonax</td>
<td>50</td>
<td>25</td>
<td>20</td>
</tr>
<tr>
<td>NaCl 0.9%</td>
<td>154</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NaCl 0.9%-glucose 5%</td>
<td>50</td>
<td>154</td>
<td></td>
</tr>
<tr>
<td>Plasmalyte</td>
<td>140</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Plasmalyte 148%-glucose 5%</td>
<td>50</td>
<td>140</td>
<td>5</td>
</tr>
<tr>
<td>Hartmann</td>
<td>131</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Hartmann-glucose 5%</td>
<td>50</td>
<td>131</td>
<td>5</td>
</tr>
<tr>
<td>Isotonax</td>
<td>140</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Isotonax-glucose 5%</td>
<td>50</td>
<td>143</td>
<td>10</td>
</tr>
<tr>
<td>Balanced salt solution-glucose 1%*</td>
<td>10</td>
<td>140</td>
<td>4</td>
</tr>
</tbody>
</table>

* Isotonic balanced electrolyte solution with 1% glucose currently available in Germany (32).
** ND : Not documented (32).
‡ Osmolarity calculated without glucose.
children. Therefore, during the first postoperative day, decreased volumes of the maintenance fluid consisting of an isotonic solution at two-thirds or 70% of the calculated maintenance rate is recommended, provided the child is normovolemic (8, 13, 36). This solution would preferably be enriched with glucose 5% (50 ml glucose 50% in 500 ml fluid) in order to provide an adequate caloric supply as recommended (4 to 8 mg glucose/kg/min). In addition, the osmolarity of such a solution makes it possible to be administered on a peripheral venous access. Recognizing that fluids used to replace ongoing losses should reflect the electrolyte composition of fluid lost, NaCl 0.9% has been considered as appropriate in most cases. Isotonic fluids including colloids are to be used as a bolus in the event of hypovolemia (33).

Implications of Belgian perioperative fluid recommendations in children

For the Belgian care providers in charge of surgical children, the application of these recommendations would mean:

- Prescribing fluid volume and composition appropriately.
- Considering iv. fluids as medications.
- Using isotonic solutions instead of hypotonic solutions during the intraoperative and postoperative period.
- Restricting the administration of hypotonic solutions to very specialized clinical areas based on careful monitoring of plasma electrolytes.
- Replacing ongoing losses with fluids reflecting the electrolyte composition of fluid lost. NaCl 0.9% is appropriate in most cases.
- Administering isotonic fluids (saline 0.9%, Plasmalyte®, Hartmann® or colloids) as a bolus in the event of hypovolemia.
- Monitoring plasma electrolytes and glucose concentrations regularly i.e. once daily or more if clinically indicated (documented plasma [Na] < 135 mmol/L) (18).

It is hoped that the BAPA guidelines will have several positive outcomes in improving the care and the safety of children, in alerting clinicians to the importance of individualizing fluid administration, and in providing consistency of management regardless of where or by whom they are treated. This would also lead eventually to the availability of isotonic solutions containing glucose 1% in Belgium to facilitate the application of these recommendations. Finally, the authors acknowledge that these recommendations would serve as a framework that should be adapted to clinical situations.

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