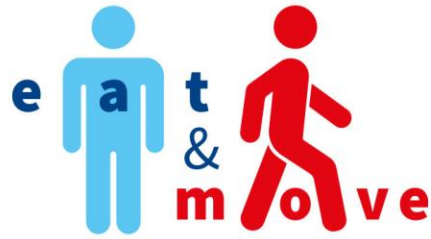
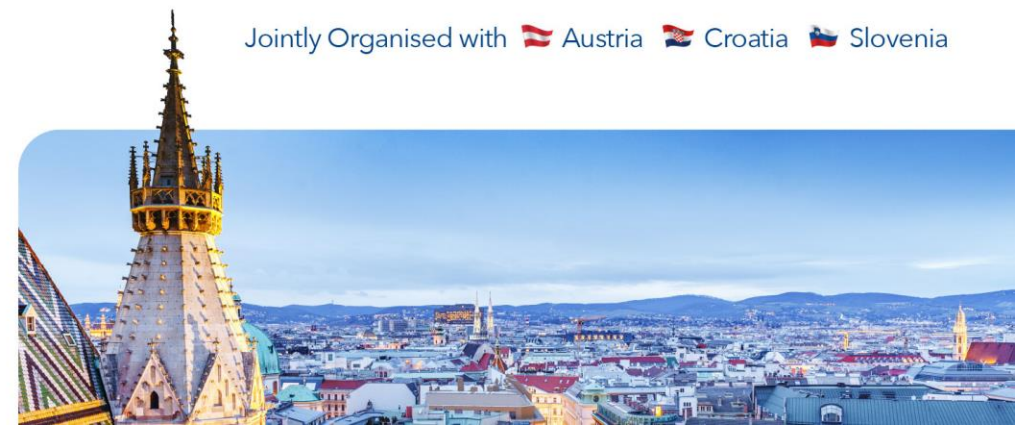




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CONGRESS
ON CLINICAL NUTRITION & METABOLISM
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Parenteral nutrition for the first days of life of newborn infants

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Disclosure for Isabelle Sommer

In compliance with COI policy, ESPEN requires the following disclosures to the session audience:

Shareholder	No relevant conflicts of interest to declare.
Grant / Research Support	No relevant conflicts of interest to declare.
Consultant	No relevant conflicts of interest to declare.
Employee	No relevant conflicts of interest to declare.
Paid Instructor	No relevant conflicts of interest to declare.
Speaker Bureau	No relevant conflicts of interest to declare.
Other	No relevant conflicts of interest to declare.

Presentation includes discussion of the following off-label use of a drug or medical device:

n/a





“The purpose of parenteral nutrition is to correct or prevent nutritional deficiencies when adequate enteral nutrition is precluded by impairment or immaturity of gastrointestinal function.”

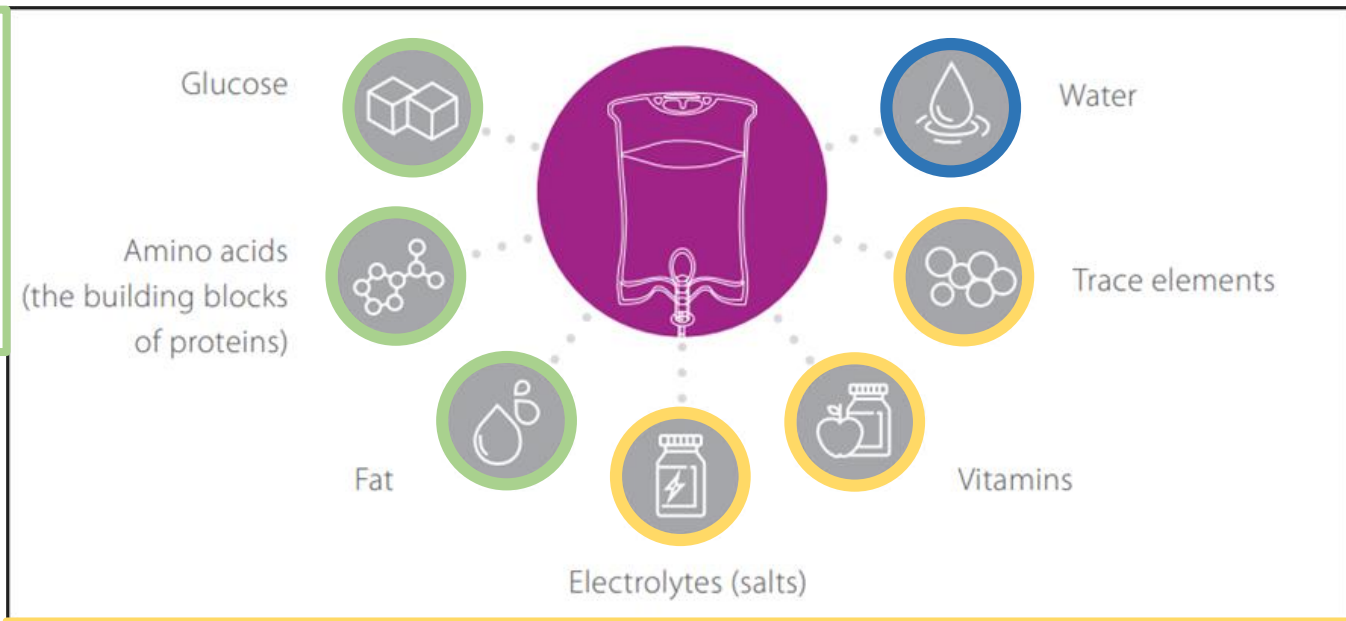
ESPGHAN/ESPEN/ESPR/CSPEN guidelines on pediatric parenteral nutrition: Organisational aspects



Composition of a parenteral nutrition

PN is the artificial, intravenous feeding of patients, bypassing the usual process of oral food intake, the gastrointestinal tube as well as the digestion.

Macronutrients
for energy
(glucose, lipids)
and protein (AA)
supply.



Fluid intake as
carrier for nutrients
and metabolites.

Micronutrients to encounter electrolyte disturbances and to participate at growth, development and metabolism.





Newborn infants

The *World Health Organization* (WHO) defines newborn infants or neonates as babies under 28 days of age.

All newborn infants are at highest risk of dying within these first 28 days of life.



Categorization based on

➤ Gestational age (GA):

- Extremely preterm <28 weeks
- Very preterm 28 to 32 weeks
- Moderate to late preterm 32 to 37 weeks

➤ Body weight at birth :

- Extremely low birth weight ELBW <1'000 g
- Very low birth weight VLBW ≥1'000 g and <1'500 g
- Low birth weight LBW ≥1'500 g and <2'500 g
- Normal birth weight >2'500 g

Appropriate care including adequate feeding is crucial!





Parenteral nutrition in neonatology

Indications:

- Nonfunctional gastro-intestinal tube
- Immature renal function
- Important insensible loss of water
- Reduced electrolytes regulation
- Important metabolic requirements
- Limited fluid intake
- Undeveloped sucking reflex (≥ 32 weeks GA)



Inadequate and retarded postnatal nutrition is related to growth and neurodevelopmental retardation.



An early and aggressive nutritional treatment is indicated and necessary to allow an adequate extrauterine nutrient intake for preterm infants.



Types of parenteral nutrition

Individualized vs. standardized PN

Status of the patient:

- Nutritional requirements
- Clinical status
- Delay until administration

Other decision support:

- Patient safety
- Logistical aspects
- Financial aspects
- Organization



Hospital vs. industrial production

Batch production:

- Modification of the composition
- Production capacity and batch size
- Stability and storage

Marketing authorization:

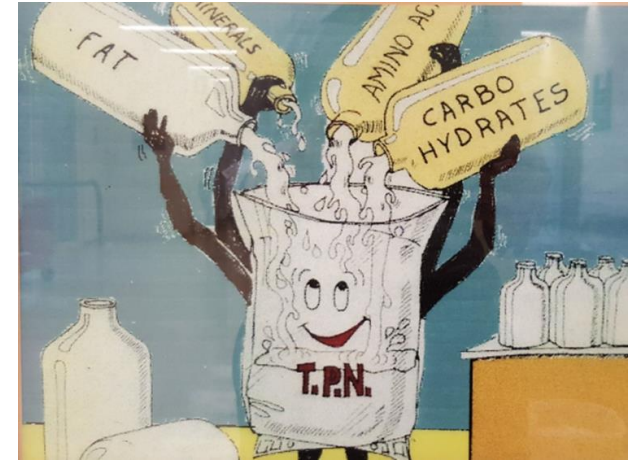
- Product safety
- Clinical research and experience
- Financial benefit
- Organizational advantages



Preparation of parenteral nutrition

→ **PN preparation** is complex and of high risk

- Composed of about 50 ingredients (the majority are AA)
- Varying volumes
- Patients' weight dependent doses
- Glucose as nutrient medium for germs and bacteria



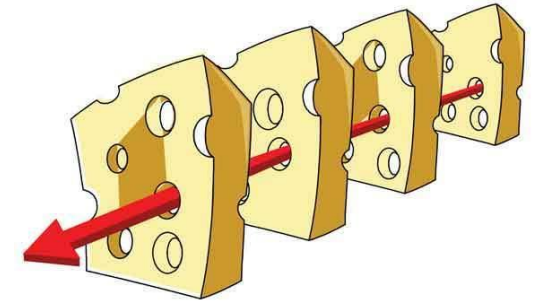
Infant	Adult
Energy 25 - 120 kcal/kg/d	Energy 20 - 30 kcal/kg/d
Progressive administration of lipids	1/3 of energy from lipids
Proteins 1 - 4 g/kg/d	Proteins 1 - 2 g/kg/d



Risks related to parenteral nutrition

→ **Medication errors (ME)** are most frequently related to PN treatment¹

- Ordering (ingredients, calculation, dosage, etc.)
- Transcribing (ingredients, calculation, etc.)
- Compounding (compatibility, precipitation, etc.)
- Dispensing (storage conditions, patient data, etc.)
- Administering (osmolarity, venous access, contamination, etc.)



“Swiss cheese model”

¹Santesteban et al. “Medication errors in neonatal care: A systematic review of types of errors and effectiveness of preventive strategies” <http://dx.doi.org/10.1016/j.jnn.2015.04.002>



Consequences of contaminated parenteral nutrition



Third baby death confirmed from infected parenteral nutrition product

2-Jul-2014

[in](#) [f](#) [t](#)

Infection Control | Microbiology | PH

Regulators suggest contamination wa

Nine Dead In Ala. After IV Treatment

March 30, 2011 · 4:32 PM ET

Public Health England (PHE) and the UK

L'article recherché n'est disponible qu'en archive et ne dispose plus de vidéo

Un autre nourrisson est mort en Allemagne à Mayence, après avoir reçu une perfusion contaminée par des bactéries intestinales. Il est mort cette nuit. C'est le troisième décès de samedi. La clinique universitaire de la ville a précisé que le bébé était un "très petit prématuré", né pendant la 24e semaine de grossesse. Les deux autres qui ont péri étaient âgés de deux à huit mois.

Le directeur de la clinique a souligné ce mardi que la cause de ces 3 décès était encore inconnue.

La veille, le procureur en chef indiquait que l'enquête portait sur un homicide involontaire.

L'état de santé de quatre bébés, qui étaient dans un état critique s'est améliorée d'après la clinique. Au total, la préparation alimentaire contaminée a été administrée à onze enfants vendredi.

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L'Obs > Faits divers

Bébés morts à Chambéry : ce que l'on sait de l'affaire

SUR LE MÊME SUJET

- Bébés morts à Chambéry : Marisol Touraine évoque un 5e décès suspect en décembre 2012
- Chambéry : l'hôpital accusé d'avoir utilisé des poches périmées
- Bébés morts à Chambéry : "On craint qu'il y ait d'autres cas"
- Bébés morts à Chambéry : la justice s'intéresse à un 4e décès suspect
- Chambéry : la bactérie sans nom

Marisol Touraine évoque un cinquième décès suspect en décembre 2012. Que sait-on de ces cas ? Quelle est la bactérie mise en cause ? Qui est responsable ?

UNIKLINIK MAINZ

Unsaubere Schläuche im Visier der Fahnder

Die Obduktion der zwei an der Mainzer Uniklinik gestorbenen Babys hat noch keinen Beweis dafür ergeben, dass sie an der mit Bakterien verunreinigten Nährlösung gestorben sind. Laut Staatsanwaltschaft ist die Verschmutzung aber wahrscheinlich an der Universität und nicht bei einem Hersteller der Bestandteile passiert. Sie stellte Schläuche aus einem Reinraum der Klinik sicher.

23.08.2010 - 12:37 Uhr • 3 Kommentare • Jetzt teilen

HB MAINZ. Verunreinigte Schläuche könnten möglicherweise den Tod zweier Babys an der Universitätsklinik Mainz verursacht haben. Der spezielle Reinraum, in dem die verschmutzten Lösungen für die Säuglinge hergestellt wurden, sei von der Klinik geschlossen worden, sagte der Leitende Oberstaatsanwalt Klaus-Peter Mielke am Montagmorgen in Mainz.

Ein weiteres Baby in der Uniklinik Mainz kämpft noch um sein Leben. Die Schläuche der Apparatur, die die Lösungen für die Säuglinge mischt, stehen im Visier der Fahnder.





Reasons for the development



Situation at our hospital

only 1/3 of nutritional solutions were prepared at the pharmacy under aseptic conditions



Non-conformity to guidelines

ESPGHAN guidelines 2018 recommend standardized parenteral nutrition whenever possible



Lack of commercialized PN

only 1 product that doesn't conform to internal practices



Increased demand

increased work load



Development of the parenteral nutrition solution

- Creation of a working group composed of:

Pharmacists

Neonatologists

Industrials



- Parameters:

- For the first days of life of newborn neonatal patients
- For peripheral and central venous administration → Osmolarity < 900 mOsm/L
- Stability: 18-24 months
- Storage at room temperature

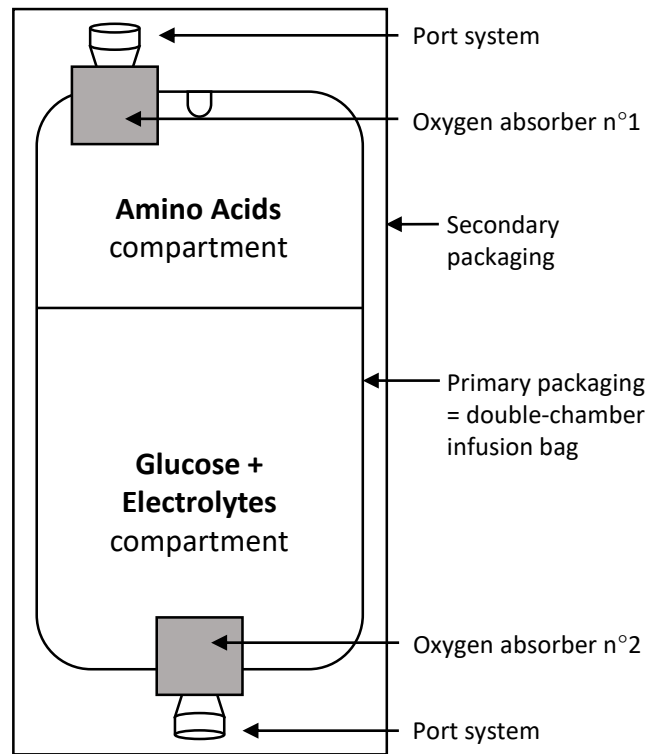
- References:

- ESPGHAN guidelines from 2005 and 2018
- Standardized PN used at another university hospital



Final product and results

- Subcontracted **batch production**
- **High quality** product
- **Ready-to-use** parenteral nutrition
- **Double-chamber** infusion bag
- 250 mL final volume
- Not included: lipids, vitamins, trace elements
- **Final sterilization** by heat steam
- Storage at room temperature for **18 months**



No concentration variation

→ **Improved nutritional treatment**

No manipulation allowed

→ **Increased patient safety**

Standardized solution and procedures

→ **Reduced medication errors**



Discussion

Parenteral nutrition (PN) is a crucial part of the initial nutritional support provided for neonates in critical health situations



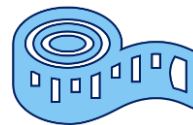
→ Good cerebral and neurologic development, postnatal weight gain and growth

Medication errors are often related to PN including prescription, transcription, preparation and administration errors



→ Growth retardation, developmental disturbances and infections

Patients' varying needs of nutrients and the limited composition flexibility of standardized PN



→ Only few commercialized pediatric PN (PPN) are available for neonatal patients and are not used routinely



Conclusion

Standardized PN as recommended by the nutritional specialists are **high-quality** products with an immediate and **24/7 availability** on wards



- Minimizes the risk of medication errors
- Improves the medical treatment and clinical outcome of the treated inpatients
- Decreases the number of individual infusion bags

Standardization for neonatal patients is difficult but necessary and worth the work!



Thanks for your attention!

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<http://www.chuv.ch/>



<https://doi.org/10.13097/archive-ouverte/unige:159802>

