



### OBJECTIVES

- Define malnutrition and describe its current management in infants
- Review evidence on infants managed with energy and nutrient-dense formulas
- List clinical applications of energy and nutrient-dense formulas

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### What is Malnutrition?



**"An imbalance between nutrient requirement and intake, resulting in cumulative deficits of energy, protein or micronutrients that may negatively affect growth, development and other relevant outcomes."**

*Academy of Nutrition & Dietetics  
American Society of Parenteral & Enteral Nutrition*

Mehta, et al. J Parenter Enteral Nutr. 2013;37(4):460-481

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### Malnutrition: Etiology




Supply concerns  
Improper mixing  
Reflux  
Feeding difficulties  
Neglect/abuse  
Acute illness

Increased Energy Needs



Chronic lung disease  
Congenital heart defects  
Renal failure  
Hyperthyroidism  
Chronic infection

Inadequate Absorption



GI conditions  
Cystic fibrosis  
Milk protein allergy  
Inborn errors of metabolism

Carvalho-Salemi, et al. J Acad Nutr Diet. 2018;118(1):40-51

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### Malnutrition: Risk Factors

Medical

- Low birth weight
- Reflux
- Congenital anomalies
- Acute and chronic illness

Psychosocial

- Poor feeding techniques
- Post-partum depression (PPD)
- Poverty
- Abuse

Homan, American Family Physician. 2016;94(4):295-300

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### Malnutrition: Diagnostic Criteria

Primary Indicators when a **Single Data Point** is Available

	Wt-for-lt z-score	BMI-for-age z-score	Lt/ht-for-age z-score	MUAC z-score
Mild Malnutrition	-1 to -1.9	-1 to -1.9	No data	≥ -1 to -1.9
Moderate Malnutrition	-2 to -2.9	-2 to -2.9	No data	≥ -2 to -2.9
Severe Malnutrition	-3 or greater	-3 or greater	-3	≥ -3 or greater

Primary Indicators when **Two or More Data Points** are Available

	Wt gain velocity (<2y)	Wt loss (2-20y)	Deceleration in wt-for-lt/ht z-score	Inadequate nutrient intake
Mild Malnutrition	<75% expected	5% usual BW	Decline of 1	51-75% estimated
Moderate Malnutrition	<50% expected	7.5% usual BW	Decline of 2	26-50% estimated
Severe Malnutrition	<25% expected	10% usual BW	Decline of 3	≤25% estimated

Groth, et al. Reference data on gains in weight and height during the first two years of life. Pediatrics. 1991;119(3):553-562. World Health Organization data for patients >2 years old. Reproduced from Becker, et al. Nutr Clin Pract. 2005; 20(3):147-161. © 2015, American Society of Parenteral and Enteral Nutrition.

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### Malnutrition: Prevalence in US

45%

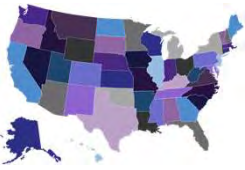
Of children with chronic disease having nutrition risk

10%

Of infants in primary care settings

4%

Of hospitalized infants



Daymont, et al. Acad Pediatr. 2020;20:405-412. Cavaitho Salemi, et al. J Acad Nutr Diet. 2018;118:40-51

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**Poll Question**  
RESPOND IN THE RIGHT-HAND PANEL IN THE LIVE EVENT – CLICK ‘SUBMIT’ WHEN DONE

Estimate the percentage of infants you see with malnutrition

A. Less than 4%

B. About 4%

C. More than 4%

D. Does not apply to my practice

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**Malnutrition: WHO recommendations**

Target intake:  
105-126kcal/kg/d

Weight gain:  
5-10g/kg/d

World Health Organization, Food and Agriculture Organization of the United Nations. Protein and amino acid requirements in human nutrition. 2007  
WHO = World Health Organization

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**Malnutrition: Nutrition Management in the US**

1 Feed more volume, more often

2 Concentrate formula

3 Use a higher-calorie formula at standard concentration

4 Start with a “base” and then supplement or fortify



Simental. J Pediatr Gastroenterol Nutr. 2020;71:5413

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**Malnutrition: Nutrition Management Abroad**

**Energy and nutrient dense formula**

- 30kcal/oz term infant formula
- High protein/nutrient content
- 360mOsm/kg
- Ready to feed/sterile
- Nutritionally complete
- Used in Europe for 20+ years
- Supported by clinical evidence



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**Poll Question**

RESPOND IN THE RIGHT-HAND PANEL IN THE LIVE EVENT – CLICK ‘SUBMIT’ WHEN DONE

Which practice do you use most often for feeding infants with growth failure?

- A. Increase volume and frequency of feeds
- B. Concentrate powdered formula
- C. Use a higher-calorie formula at standard concentration
- D. Start with a “base” and then supplement or fortify

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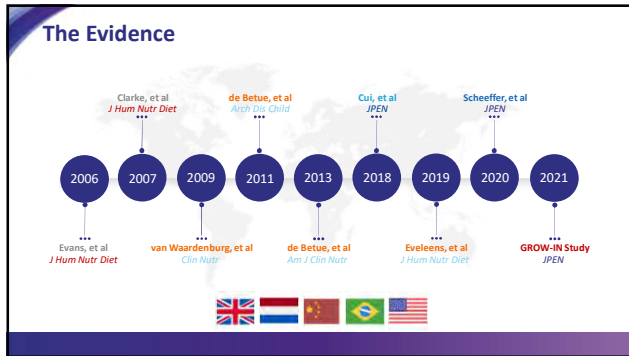
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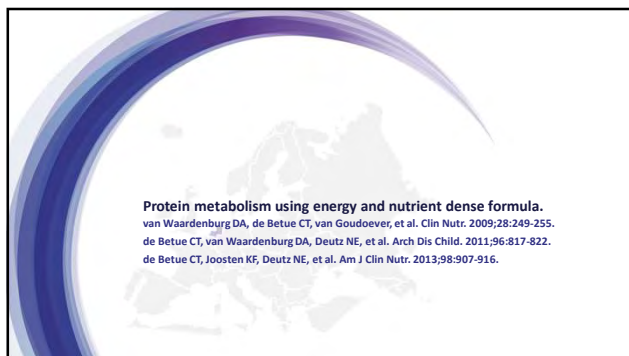
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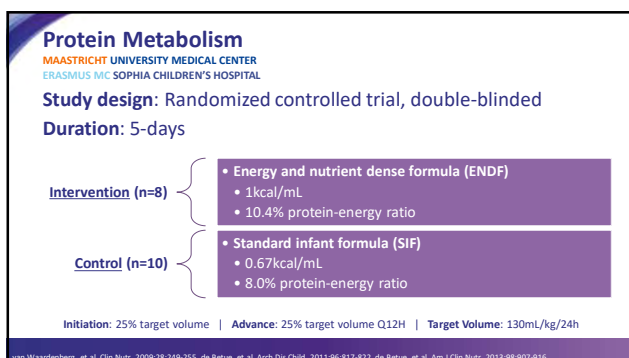
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**Protein Metabolism**  
MAASTRICHT UNIVERSITY MEDICAL CENTER  
ERASMUS MC SOPHIA CHILDREN'S HOSPITAL

**Study Population: n=18**

- *Route of nutrition:* enteral
- *Age:* 4 weeks to 12 months
- *Gestation:* term or preterm, **but** >40 weeks postmenstrual age
- *Diagnosis:* respiratory syncytical virus



van Waardenberg, et al. Clin Nutr. 2009;28:249-255; de Betue, et al. Arch Dis Child. 2011;96:817-822; de Betue, et al. Am J Clin Nutr. 2013;98:907-916.

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**Protein Metabolism**  
MAASTRICHT UNIVERSITY MEDICAL CENTER  
ERASMUS MC SOPHIA CHILDREN'S HOSPITAL

**Nitrogen balance**

**Plasma amino acid**

**Stable isotope**

- Whole body protein
- Splanchnic phenylalanine extraction
- Arginine and citrulline tracer

van Waardenberg, et al. Clin Nutr. 2009;28:249-255; de Betue, et al. Arch Dis Child. 2011;96:817-822; de Betue, et al. Am J Clin Nutr. 2013;98:907-916.

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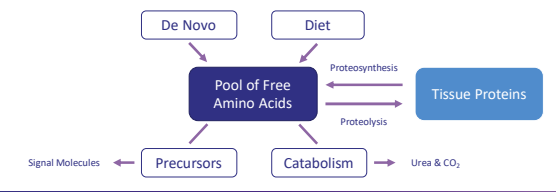
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**Protein Metabolism**  
MAASTRICHT UNIVERSITY MEDICAL CENTER  
ERASMUS MC SOPHIA CHILDREN'S HOSPITAL

**Plasma amino acid**



Furst, e-SPEN. 2009;2(4):e62-e65; Hoffer, JPEN. 2016;40(4):460-474; Avenous, et al. (2016). The molecular nutrition of amino acids and protein (pp.289-303). Academic Press.

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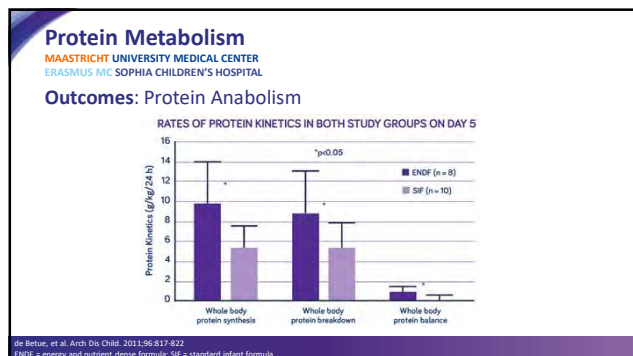
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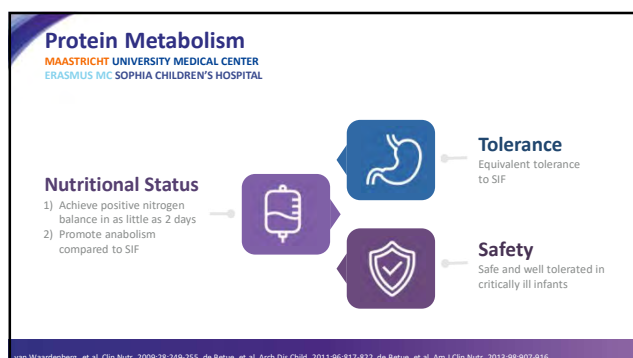
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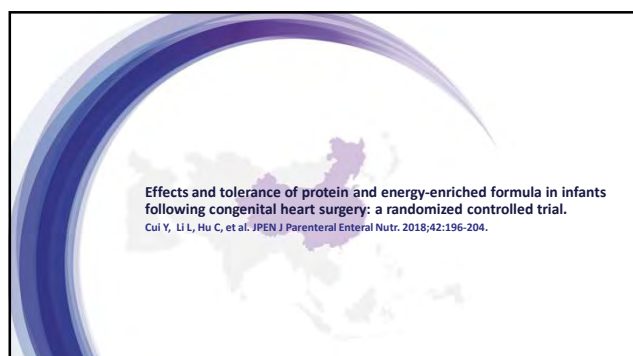
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**Cui, et al. 2018.**  
GUANGZHOU WOMEN AND CHILDREN'S MEDICAL CENTER

**Study design:** Randomized controlled trial, double-blinded  
**Duration:** 5-days

<b>Intervention (n=26)</b>	<ul style="list-style-type: none"> <li>• Energy and nutrient dense formula (ENDF)</li> <li>• 1kcal/mL</li> <li>• 10.4% protein-energy ratio</li> </ul>
<b>Control (n=24)</b>	<ul style="list-style-type: none"> <li>• Standard infant formula (SIF)</li> <li>• 0.67kcal/mL</li> <li>• 8.0% protein-energy ratio</li> </ul>

Initiation: 12-24h post-op at 1mL/kg/h | Advance: 1mL/kg/h Q6H as tolerated | Target Volume: 130mL/kg/24h

Cui, et al. JPEN J Parenter Enteral Nutr. 2018;42:196-204

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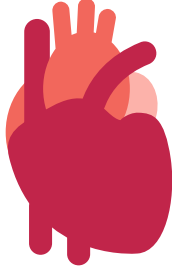
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**Cui, et al. 2018.**  
GUANGZHOU WOMEN AND CHILDREN'S MEDICAL CENTER

**Study Population: n=50**

- Route of nutrition: enteral
- Age: 4 weeks to 12 months
- Diagnosis: CHD
- Surgical Status: post-operative biventricular repair



Cui, et al. JPEN J Parenter Enteral Nutr. 2018;42:196-204  
CHD = congenital heart defects

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**Cui, et al. 2018.**  
GUANGZHOU WOMEN AND CHILDREN'S MEDICAL CENTER

**Outcomes: Nutrient Intake**

Days	ENDF vs. SIF			Adequate kcal & Protein*
	Higher kcal	Higher Protein	Higher CHO & Fat	
1	✓	✓✓	✓✓	
2	✓	✓		ENDF
3	✓	✓	✓	ENDF
4	✓	✓	✓	ENDF
5	✓	✓	✓	ENDF

\*87kcal/kg/d, 2.67g protein/kg/d; ✓✓p<0.01; ✓p<0.05

Cui, et al. JPEN J Parenter Enteral Nutr. 2018;42:196-204  
ENDF = energy and nutrient dense formula, SIF = standard infant formula, CHO = carbohydrates

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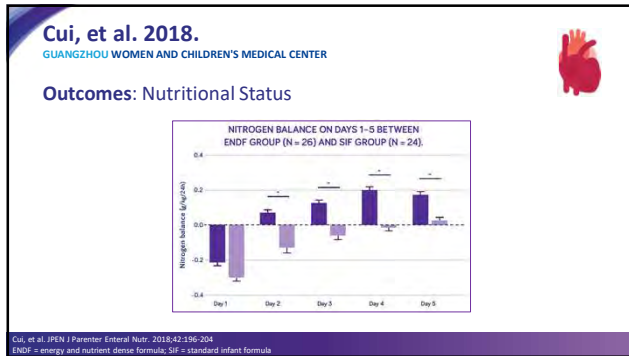
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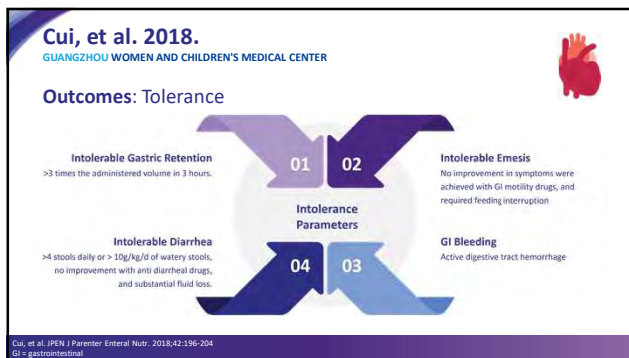
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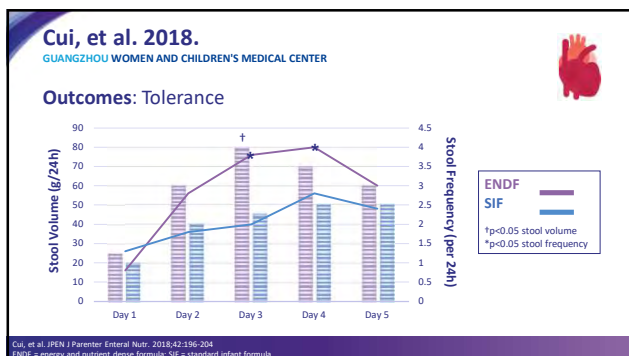
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**Cui, et al. 2018.**  
GUANGZHOU WOMEN AND CHILDREN'S MEDICAL CENTER

The diagram illustrates a flow from Nutritional Status to Tolerance and Safety. Nutritional Status is represented by a purple box with a syringe icon. Tolerance is represented by a blue box with a stomach icon. Safety is represented by a purple box with a shield icon. Arrows indicate the flow from Nutritional Status to Tolerance and then to Safety.

**Nutritional Status**

- 1) Achieve positive nitrogen balance in as little as 2 days
- 2) Promote anabolism compared to SIF

**Tolerance**

- 1) Equivalent tolerance to SIF
- 2) Well-tolerated in critically ill infants, including infant's post-op for CHD repair

**Safety**

Safe in infants with growth failure due to CHD & other causes of growth failure

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**Should high-energy infant formula be given at full strength from its first day of usage.**  
Evans S, Twaissi H, Daly A, et al. J Hum Nutr Diet. 2006;19:191-197.

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**Evans, et al. 2006.**  
BIRMINGHAM CHILDREN'S HOSPITAL

**Study design:** randomized controlled trial, non-blinded  
**Duration:** 2-weeks

Group	Intervention
Intervention (n=18)	<ul style="list-style-type: none"><li>• Energy and nutrient dense formula (ENDF)</li><li>• Full strength (30 kcal/oz) at day 1</li></ul>
Control (n=12)	<ul style="list-style-type: none"><li>• Energy and nutrient dense formula (ENDF)</li><li>• Titration schedule:<ul style="list-style-type: none"><li>• Day 1: 80% (24 kcal/oz)</li><li>• Day 2: 90% (27 kcal/oz)</li><li>• Day 3: 100% (30 kcal/oz)</li></ul></li></ul>

Evans, et al. J Hum Nutr Diet. 2006;19:191-197

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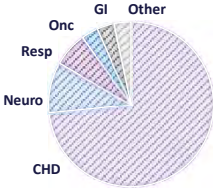
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**Evans, et al. 2006.**  
BIRMINGHAM CHILDREN'S HOSPITAL

**Study Population: n=30**

- *Route of nutrition:* PO or enteral
- *Previous feed:* 93% - standard infant formula (20kcal/oz)
- *Age:* < 12 months
- *Diagnosis:* failure to thrive



Evans, et al. J Hum Nutr Diet. 2006;19:191-197  
PO = per os, GI = gastrointestinal, Onc = oncology, Resp = respiratory, Neuro = neurological, CHD = congenital heart defects

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**Evans, et al. 2006.**  
BIRMINGHAM CHILDREN'S HOSPITAL

**Outcomes: Tolerance**

	Day 1 + 2		Day 3 + 4	
	Full Strength	Stepwise	Full Strength	Stepwise
Stools per day:	6.5 (0-11)	2.0 (1-6)	3.5 (0-13)	2.0 (1-8)
	p=0.02		p=0.06	
Vomits per day:	0.5 (0-9)	0.0 (0-5)	0.0 (0-4)	1.0 (0-7)
	p=0.17		p=0.20	

Evans, et al. J Hum Nutr Diet. 2006;19:191-197

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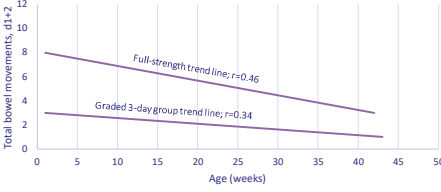
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**Evans, et al. 2006.**  
BIRMINGHAM CHILDREN'S HOSPITAL

**Outcomes: Tolerance**

**Days 1+2 bowel movements by age**



Evans, et al. J Hum Nutr Diet. 2006;19:191-197

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**Evans, et al. 2006.**  
BIRMINGHAM CHILDREN'S HOSPITAL

**Tolerance**

- 1) Full strength from day 1
- 2) Gradual introduction in infants <12 weeks old



**Safety**

Safe in infants with growth failure due to CHD & other causes of growth failure



Evans, et al. J Hum Nutr Diet. 2006;19:191-197  
CHD = congenital heart defects

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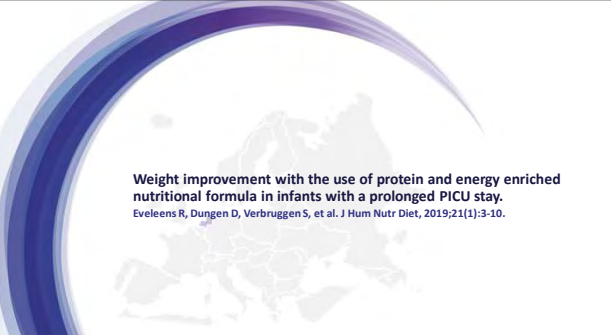
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**Weight improvement with the use of protein and energy enriched nutritional formula in infants with a prolonged PICU stay.**  
Eveleens R, Dungen D, Verbruggen S, et al. J Hum Nutr Diet, 2019;21(1):3-10.

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**Eveleens, et al. 2019.**  
ERASMUS MC SOPHIA CHILDREN'S HOSPITAL

**Study design:** Retrospective Cohort Study  
**Duration:** 2+ weeks



**1**  
Breast Milk

If not available:

**2**  
Energy and Nutrient Dense Formula

Once goal weight achieved:

**3**  
Standard Infant Formula

Eveleens, et al. J Hum Nutr Diet. 2019;32:3-10

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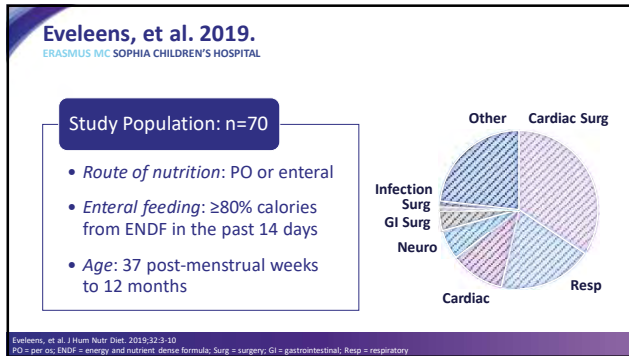
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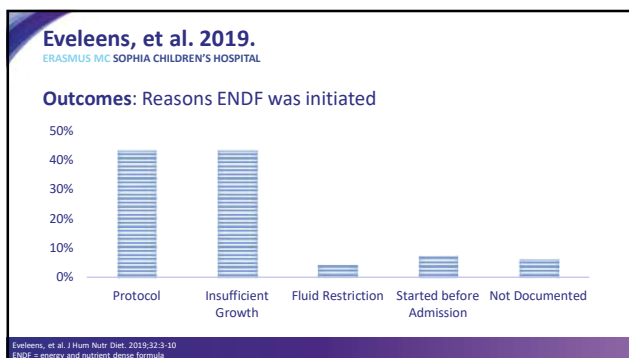
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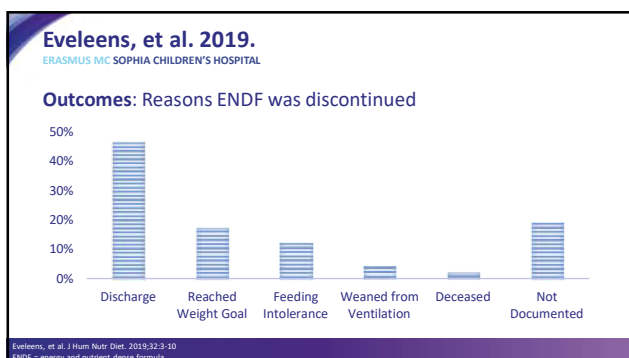
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**Eveleens, et al. 2019.**  
ERASMUS MC SOPHIA CHILDREN'S HOSPITAL

**Outcomes: Nutritional Intake**

**Route of Nutrition:**

- Post-pyloric: 45 (64%)
- Feeding strategy
  - Continuous: 27 (39%)
  - Bolus: 10 (14%)
  - Both: 33 (47%)

**Nutrient Intake:**

- Energy: 104.6±19.4 kcal/kg/d
- Protein: 2.72±0.50g/kg/d

Eveleens, et al. J Hum Nutr Diet. 2019;32:3-10

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**Eveleens, et al. 2019.**  
ERASMUS MC SOPHIA CHILDREN'S HOSPITAL

**Outcomes: Growth**

Eveleens, et al. J Hum Nutr Diet. 2019;32:3-10  
ENDF = energy and nutrient dense formula

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**Eveleens, et al. 2019.**  
ERASMUS MC SOPHIA CHILDREN'S HOSPITAL

**Outcomes: Tolerance**

Eveleens, et al. J Hum Nutr Diet. 2019;32:3-10  
GI = gastrointestinal

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## Case Study

### - Baby Girl Christina -

Amy Gelfand, MPH, RDN, LD  
Medical Science Liaison

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**Case Study – Baby Girl Christina**  
ROYAL ALEXANDRA CHILDREN'S HOSPITAL

**Clinical Features**

- Admitted at 4 weeks with viral illness
- Observation: tachypneic
- ECG: confirmed ventricular septal defect (VSD)

**Feeding History**

- Feeding difficulties: breastfeeding → standard infant formula
- 4 weeks: sporadic, but on average intake was 110mL/kg/d (75kcal/kg/d)
- 7 weeks: unsuccessful achieving target volume (120mL/kg/d), therefore
  - Introduced ENDF
  - NG-tube placed

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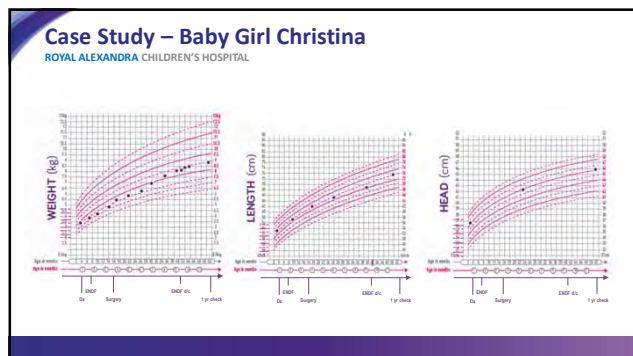
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**Case Study – Baby Girl Christina**  
ROYAL ALEXANDRA CHILDREN'S HOSPITAL

- 1 ENDF was well-tolerated
- 2 Weight gain pattern improved while on ENDF
- 3 Growth patterns successfully maintained after ENDF was discontinued

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Randomized comparison of a nutrient-dense formula with an energy-supplemented formula for infants with faltering growth.  
Clarke SE, Evans S, Macdonald A, et al. J Hum Nutr Diet. 2007;20:329-339.

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**Clarke, et al. 2007.**  
BIRMINGHAM CHILDREN'S HOSPITAL

**Study design:** randomized controlled trial, open-label  
**Duration:** 6-weeks

<b>Intervention (n=26)</b>	<ul style="list-style-type: none"> <li>• Energy and nutrient dense formula (ENDF)</li> <li>• 1kcal/mL</li> <li>• 2.6g protein/100kcal [10.4% PE]</li> </ul>
<b>Control (n=23)</b>	<ul style="list-style-type: none"> <li>• Energy supplemented formula (ESF)</li> <li>• 1kcal/mL</li> <li>• 1.4g protein/100kcal [5.5% PE]</li> </ul>

Initiation: step-wise over 4 days | Target kcal intake: 150-200kcal/kg/d

Clarke, et al. J Hum Nutr Diet. 2007;20:329-339

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**Clarke, et al. 2007.**  
BIRMINGHAM CHILDREN'S HOSPITAL

**Study Population: n=49**

- Route of nutrition: PO or enteral
- Age: < 12 months
- Diagnosis: failure to thrive

Clarke, et al. J Hum Nutr Diet. 2007;20:329-339  
PO = per os; CHD = congenital heart defect; GI = gastrointestinal; CF = cystic fibrosis

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**Clarke, et al. 2007.**  
BIRMINGHAM CHILDREN'S HOSPITAL

**Outcomes: Nutrient Intake**

	Daily Volume
ENDF	140mL/d
ESF	143mL/d

Clarke, et al. J Hum Nutr Diet. 2007;20:329-339  
ENDF = energy and nutrient dense formula; ESF = energy supplemented formula

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**Clarke, et al. 2007.**  
BIRMINGHAM CHILDREN'S HOSPITAL

**Outcomes: Growth**

	Within ENDF group (n=26)	Within ESF group (n=23)	Between groups
Weight-for-age z-score	0.29 p=0.007	0.49 p=0.006	p=0.26
Length-for-age z-score	-0.18 p=0.42	-0.28 p=0.01	p=0.30

Clarke, et al. J Hum Nutr Diet. 2007;20:329-339  
ENDF = energy and nutrient dense formula, ESF = energy supplemented formula

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**Clarke, et al. 2007.**  
BIRMINGHAM CHILDREN'S HOSPITAL

**Outcomes: Nutritional Status**

- *ENDF*: BUN stayed within normal limits for all in group
- *ESF*: 50% decrease in BUN concentration

Clarke, et al. J Hum Nutr Diet. 2007;20:329-339  
ENDF = energy and nutrient dense formula, ESF = energy supplemented formula, BUN = blood urea nitrogen

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**Clarke, et al. 2007.**  
BIRMINGHAM CHILDREN'S HOSPITAL

**Outcomes: Tolerance**

	ENDF (n=26)	ESF (n=23)	P-value
Stools per day	2.5 (0.7-4.5)	2.5 (1.0-4.8)	NS
Emesis per day	0.33 (0-1.8)	0.30 (0-5)	NS

Clarke, et al. J Hum Nutr Diet. 2007;20:329-339  
ENDF = energy and nutrient dense formula, ESF = energy supplemented formula

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**Poll Question**  
RESPOND IN THE RIGHT-HAND PANEL IN THE LIVE EVENT – CLICK 'SUBMIT' WHEN DONE

What is your typical approach to advance to high-energy feedings? (*high energy* = >20 kcal/fl oz)

A. No transition – straight to goal

B. 1 to 2 days to transition

C. 2 to 3 days to transition

D. 3+ days to transition

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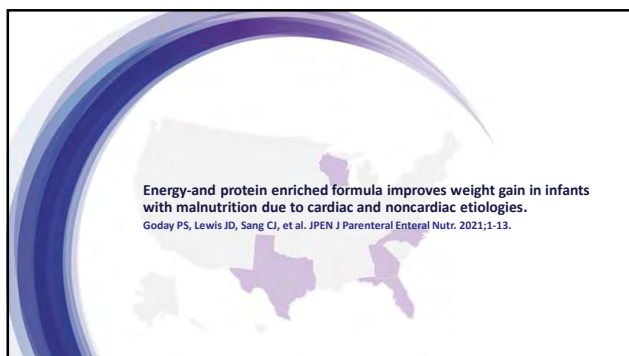
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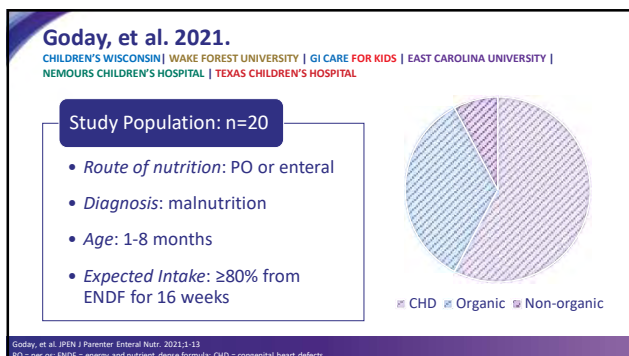
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**Goday, et al. 2021.**  
CHILDREN'S WISCONSIN | WAKE FOREST UNIVERSITY | GI CARE FOR KIDS | EAST CAROLINA UNIVERSITY |  
NEMOURS CHILDREN'S HOSPITAL | TEXAS CHILDREN'S HOSPITAL

**Outcomes: Nutrient Intake**

	kcal/kg/d
Total energy intake	123±32
ENDF intake	116±32

94%

Goday, et al. JPEN J Parenter Enteral Nutr. 2021;1-13

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CHILDREN'S WISCONSIN | WAKE FOREST UNIVERSITY | GI CARE FOR KIDS | EAST CAROLINA UNIVERSITY |  
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**Outcomes: Growth**

Weight-for-Age	Length-for-Age	Weight-for-Length	Head Circumference
+0.86 ± 0.74 mean WAZ from baseline (p=0.0001)	+0.25 ± 0.61 mean LAZ from baseline (p=0.003)	+0.77 ± 0.81 mean WLZ from baseline (p=0.0001)	+0.54 ± 0.68 mean HCZ from baseline (p=0.001)

Goday, et al. JPEN J Parenter Enteral Nutr. 2021;1-13  
WAZ = weight-for-age z-score; LAZ = length-for-age z-score; WLZ = weight-for-length z-score; HCZ = head circumference z-score

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**Goday, et al. 2021.**  
CHILDREN'S WISCONSIN | WAKE FOREST UNIVERSITY | GI CARE FOR KIDS | EAST CAROLINA UNIVERSITY |  
NEMOURS CHILDREN'S HOSPITAL | TEXAS CHILDREN'S HOSPITAL

**Outcomes: Growth**

Percentage of infants who achieved weight gain velocity > WHO median:

87% → ≥1 time point  
63% → Overall study period  
13% → "Early Success"

Goday, et al. JPEN J Parenter Enteral Nutr. 2021;1-13  
WHO = World Health Organization

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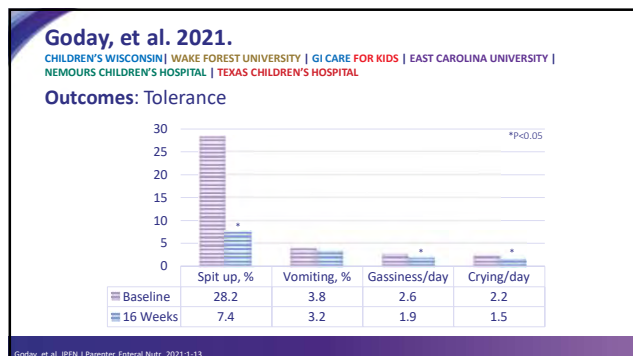
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**Poll Question**  
RESPOND IN THE RIGHT-HAND PANEL IN THE LIVE EVENT – CLICK 'SUBMIT' WHEN DONE

Which finding from the US-based GROW-IN clinical trial is most relevant to your practice?

A. WELL TOLERATED in infants with poor growth

B. SUPPORTS GROWTH: ENDF supported improvement in 4 anthropometric z-scores

C. SUPPORTS NUTRIENT INTAKE: helped meet target energy intakes

D. SAFE: Safe in infants with growth failure due to CHD & other causes

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Summary of Evidence						
	Well-tolerated	Higher nutrient intake	Helps meet goals sooner	Support weight gain	Supports anabolism	Studied in CHD
van Waardenburg 2009 de Betue 2011 de Betue 2013	●	●	●		●	
Cui 2018	●	●	●		●	●
Evans 2006	●					
Eveleens 2019	●			●		●
Scheeffter 2020	●			●		●
Clarke 2007	●	●		●		●
Goday 2022	●	●		●		●

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Application based on the Evidence				
	Initiation	Advancement	Target	
			Volume	Calories
van Waardenburg 2009 de Betue 2011 de Betue 2013	25% target	25% target q12h	130mL/kg/24h	-
Cui 2018	1mL/kg/h	1mL/kg/h q6h	130mL/kg/24h	-
	Full strength	-	-	-
Evans 2006	24kcal/oz	Day 2: 27kcal/oz Day 3: 30kcal/oz	-	-
Eveleens 2019	-	-	-	Twice REE
Scheeffter 2020	-	-	-	120-150kcal/kg/d
Clarke 2007	Stepwise over 4 days		-	150-200kcal/kg/d
Goday 2022	Set by site PI, and based on individual needs (age, medical condition)			

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Guidelines to Successfully Introduce ENDF	
Infants <12 weeks of age:	
<ul style="list-style-type: none"> <li>Administer full strength formula &amp; alternate with current feed, OR</li> <li>Dilute to 24kcal/oz and titrate to full strength over 3 days to avoid frequent stools</li> </ul>	
Infants >12 weeks to 18 months	
<ul style="list-style-type: none"> <li>Full strength and full transition from day 1</li> <li>Alternate breast milk/feeding and ENDF feeding</li> </ul>	

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## Summary

### Clinical research has shown that:

- 1 ENDF provides optimal energy, protein, and micronutrients to support lean tissue gain for catch-up growth and support increased protein needs during critical illness.
- 2 ENDF has equivalent tolerability to standard (20kcal/oz), and energy supplemented (30kcal/oz) infant formula.
- 3 ENDF promotes catch-up growth in disease and non-disease related growth failure.

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## Type your questions in the Q&A panel

Make sure you select 'All Panelists'



### 1. Please provide feedback through the survey - 3 ways to access:

Aim your smartphone camera at this → QR code

OR  
access the survey at:  
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