



Safe Use of
Medical Foods
in *Infants*

November 2020

The Immune System in Infancy

**Infant Formulas and Medical Foods –
Formats and Sterility**

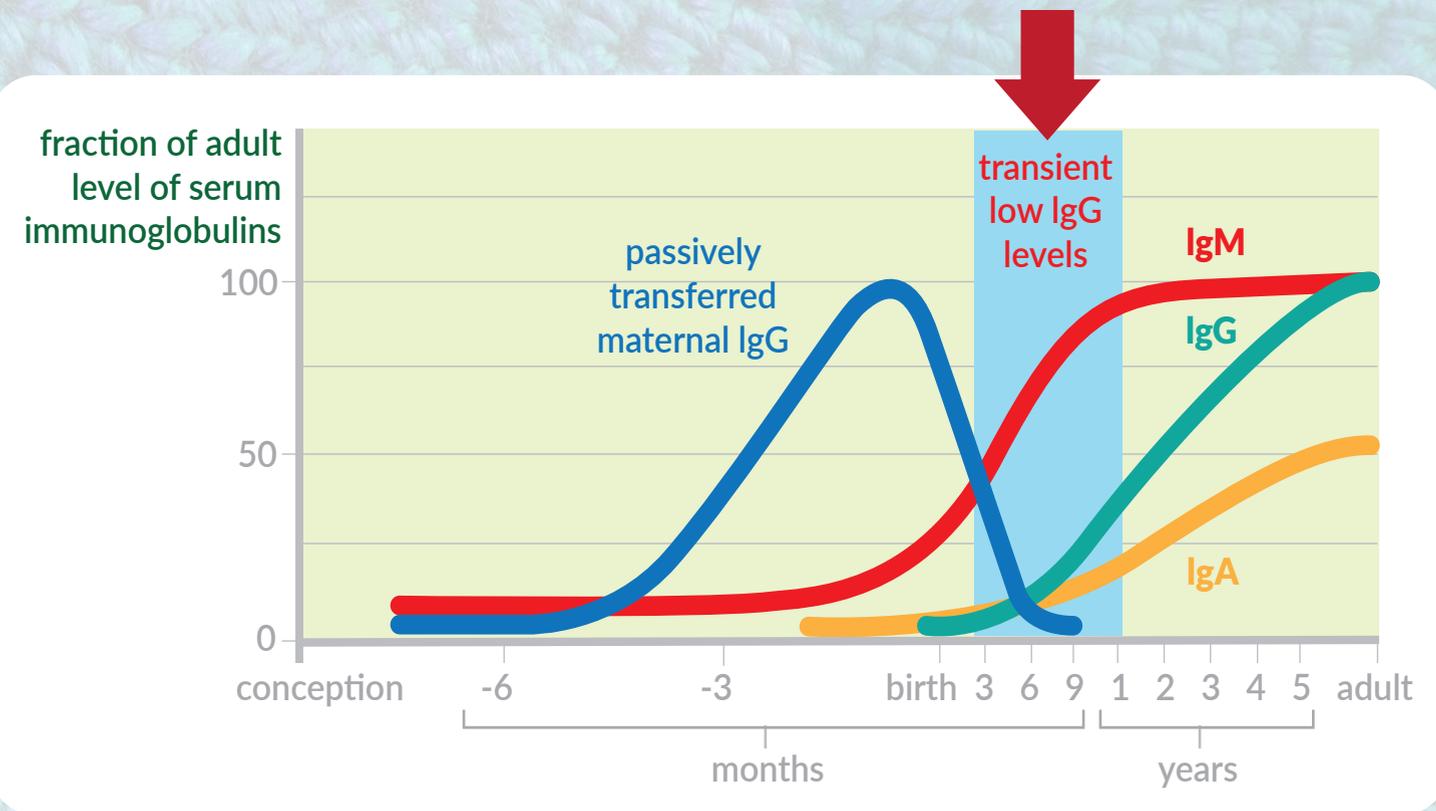
**Recommendations for Storage, Handling
and Preparation of Powdered Formulas**

The Immune System in Infancy

The innate immune system is muted at birth — this makes the newborn relatively susceptible to bacterial and viral infections.

The Innate Immune System

- Is the early first line of defense against invading pathogens
- Infants begin to produce low levels of their own antibodies between 3-6 months, but these are immature until about 1 year of age
- Function of all components of innate immunity is weak in newborns compared with later life



Adapted from 11-11 of Immunology 6/e (Garland Science 2005)

The Immune System in Infancy

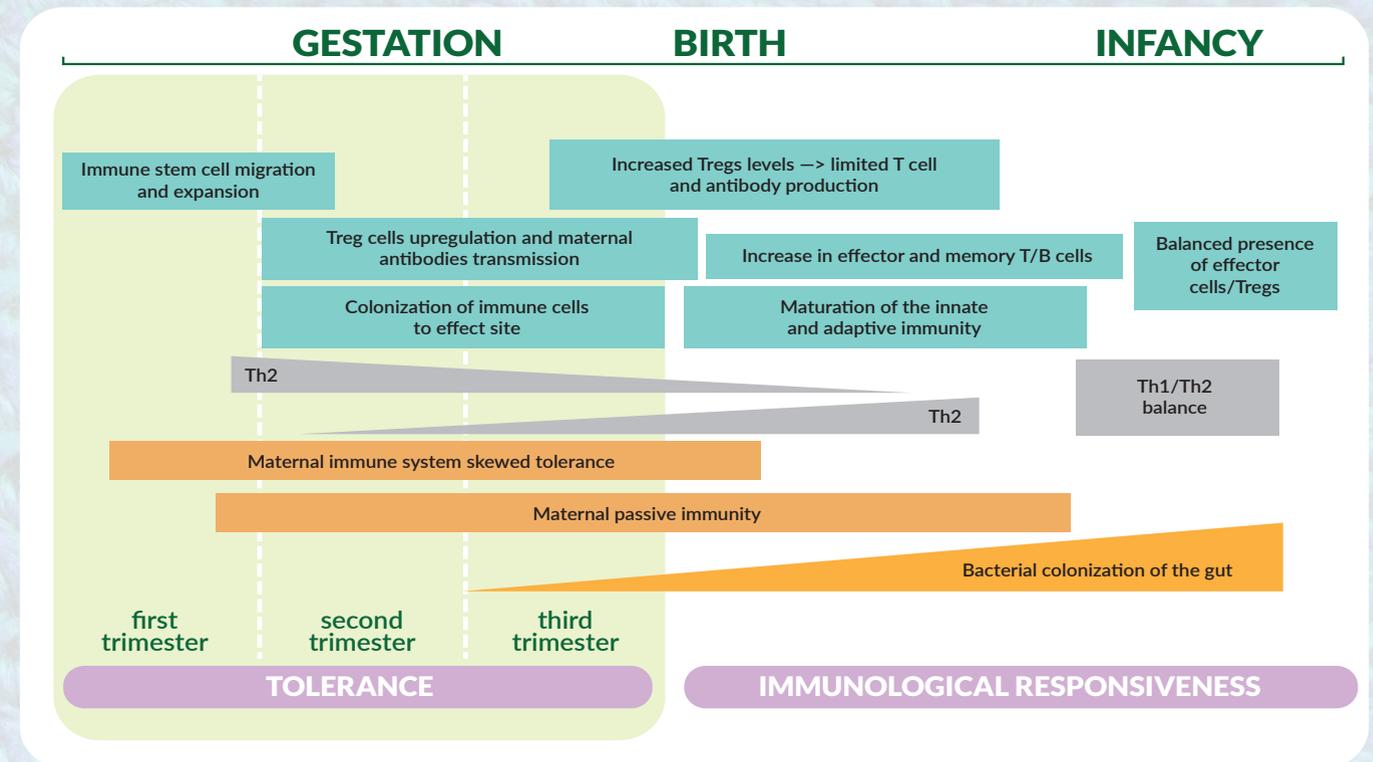
The Adaptive Immune System

- ◆ The immune system gradually matures during infancy
- ◆ Critical early protection against many infectious diseases previously experienced by the mother is given by the passive IgG antibody transferred from the mother
- ◆ Once that fades away, young children become more vulnerable to infections, though by then better armed with the maturing innate and adaptive immune systems
- ◆ The young child, even as the innate and adaptive immune systems start to mature, may be at risk from many pathogenic viruses, bacteria, fungi and parasites

Key Takeaway:

Humans have evolved mechanisms of innate immunity and immunological memory and over the lifetime of an individual, these immune mechanisms change – first to adapt to the change from fetus to infant, and then to mature and expand during growth.

In infants and children with different pathologic conditions, the use of medical foods/FSMPs may be required. Because the immune system in infants is under development, it is important to review the product indications.



Major events occurring in immune system and gut development. Adapted from: Dzidic M, et al. *Med Sci* 2018,6,56

Infant Formulas and Medical Foods – Formats and Sterility

LIQUID, READY-TO-FEED (RTF) FORMULAS

CONCENTRATES WHICH REQUIRE DILUTION

- ◆ Processed and packaged to remain sterile while in their hermetically closed containers
- ◆ Contamination with microorganisms, including pathogens, can occur after opening and during handling

Key Takeaway:

Premature infants and fragile infants during the first days represent the most sensitive patients and, for this reason, the usage of sterile ready-to feed formula is recommended.

POWDERED FORMULAS WHICH REQUIRE APPROPRIATE PREPARATION

- ◆ Manufactured under **stringent hygiene measures** to fulfill safety requirements for the intended (patient) population
- ◆ Safe when stored, prepared and handled properly, according to instructions
- ◆ **However, not considered sterile** and might contain normally low levels of potentially harmless microorganisms and occasionally a very low level of a potentially harmful microorganism
- ◆ Important to handle, store, prepare and feed according to strict hygiene conditions to avoid microbial growth

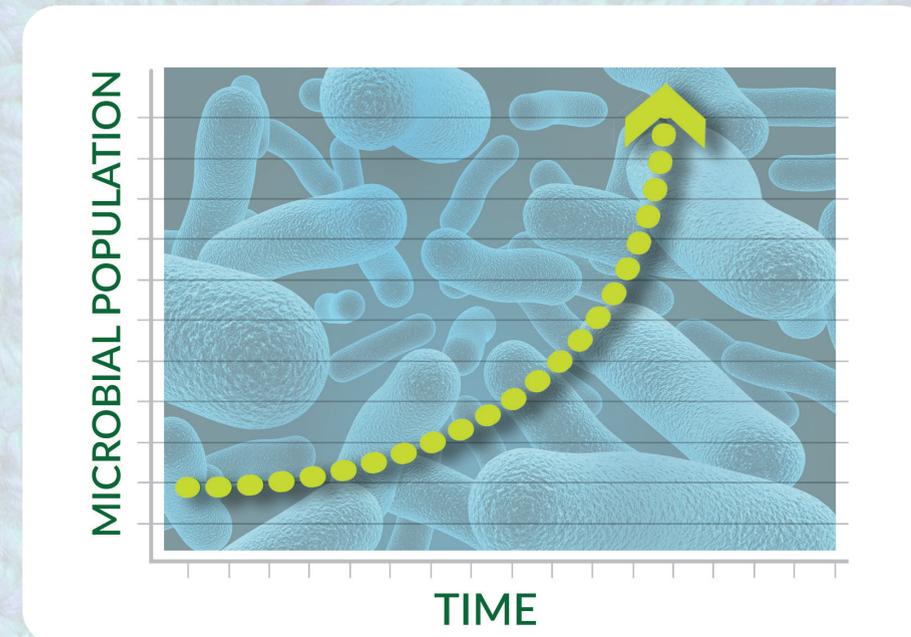
Key Takeaway:

Even products fulfilling the most stringent regulatory standards may occasionally contain microorganisms in very low numbers, which require it to be handled in accordance with the manufacturer's instructions.

Recommendations for Storage, Handling and Preparation of Powdered Formulas

Goal is to **prevent increases** in initial levels of any microorganisms present in formulas

- ◆ Microorganisms in powdered formulas will not grow while in storage due to absence of water
 - Addition of water to formulas creates a favorable condition for microorganisms to grow within **a short period of time**
- ◆ Refrigeration prevents growth only for a certain period of time and does not kill the microorganisms
- ◆ Microorganisms can grow exponentially in certain conditions (e.g., exposure to water, temperatures of 25-40°C)



Recommendations:

- ◆ Formulas should be fed **immediately** post preparation before growth occurs
- ◆ Limit refrigeration of formulas to 24 hours maximum
- ◆ Formulas removed from refrigeration should be warmed to desired temps and fed **immediately**
- ◆ Store properly – see product labels
- ◆ Confirm proper hygiene practices when handling and preparing formulas

Key Points

- ◆ Powders manufactured for infants are produced under stricter standards because of the developing nature of the immune systems of infants. Products intended for older children (e.g., ages 1+) should always be used only as indicated and never with infants.
- ◆ Powdered infant formulas are not sterile and should not be fed to premature infants or infants who may have immune problems unless directed and supervised by the infant's doctor.
- ◆ Liquid ready-to-feed formulas are processed and packaged to remain sterile while in their hermetically closed containers.
- ◆ It is critical to implement clear procedures for the safe receipt, storage, preparation and handling of infant formula products and ingredients to maintain product integrity and reduce safety risk of infants consuming them.