

Guidance for substantiating the evidence for beneficial effects of probiotics: Results from the ILSI Probiotic Task Force

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Expert group

Academia

- Ger Rijkers
- Stig Bengtmark
- Paul Enck
- Dirk Haller
- Marko Kalliomaki
- Sylvie Rabot
- Joseph Rafter
- Hania Szajewska
- Bernhard Watzl
- Jerry Wells

Industry

- Jean-Michel Antoine
- Udo Herz
- Satoshi Kudo
- Irene Lenoir-Wijnkoop
- Annick Mercenier
- Eveliina Myllyluoma
- Danielle Wolvers

Available probiotic documentation

The screenshot shows a Microsoft Internet Explorer browser window displaying the PubMed website. The address bar shows the URL <http://www.ncbi.nlm.nih.gov/pubmed/?term=probiotic>. The search bar contains the term "probiotic". The page displays search results for "probiotic", showing 7157 results. The first four results are listed below.

Results: 1 to 20 of 7157

1. [Probiotics and prebiotics: clinical effects in allergic disease.](#)
Tang ML, Lahtinen SJ, Boyle RJ.
Curr Opin Pediatr. 2010 Aug 20. [Epub ahead of print]
PMID: 20733491 [PubMed - as supplied by publisher]
[Related citations](#)

2. [A dairy bacterium displays in vitro probiotic properties for the pharyngeal mucosa by antagonizing group A streptococci and modulating the immune response.](#)
Guglielmetti S, Taverniti V, Minuzzo M, Arioli S, Zanoni I, Stuknyte M, Granucci F, Karp M, Mora D.
Infect Immun. 2010 Aug 23. [Epub ahead of print]
PMID: 20732995 [PubMed - as supplied by publisher]
[Related citations](#)

3. [Impact of lipoteichoic acid modification on the performance of the probiotic Lactobacillus rhamnosus GG in experimental colitis.](#)
Claes IJ, Lebeer S, Shen C, Verhoeven TL, Dilissen E, De Hertogh G, Bullens DM, Ceuppens JL, Van Assche G, Vermeire S, Rutgeerts P, Vanderleyden J, De Keersmaecker SC.
Clin Exp Immunol. 2010 Aug 20. [Epub ahead of print]
PMID: 20731672 [PubMed - as supplied by publisher]
[Related citations](#)

4. [Testing of probiotic and bacteriocin-producing lactic acid bacteria towards Eimeria sp.](#)
Strompfová V, Lauková A, Marcináková M, Vasilková Z.
Pol J Vet Sci. 2010;13(2):389-91.
PMID: 20731198 [PubMed - in process]
[Related citations](#)

5. [Probiotic and Probiotic Fortified Milk in Prevention of Morbidities among Children: Community Based, Randomized, Double Blind, Controlled Trial](#)

Filter your results:
All (7157)
[Review \(1860\)](#)
[Free Full Text \(1432\)](#)
[Manage Filters](#)

Also try:
probiotic bacteria
probiotic lactobacillus
probiotic antibiotic
probiotic yogurt
probiotic prebiotic

Titles with your search terms
Recommendations for probiotic use--2008. [J Clin Gastroenterol. 2008]
The impact of probiotic on gut health. [Curr Drug Metab. 2009]
Use of probiotic Lactobacillus preparation to prevent diarrhoea associated with antibiotics:
[See more...](#)

The browser's taskbar at the bottom shows several open applications: "probiotic - PubMed re...", "Arthur Ouwehand - Inbo...", "Reference Manager 12 - ...", "My Documents", "PDF articles", and "Microsoft PowerPoint - [I...".

EFSA and health claims

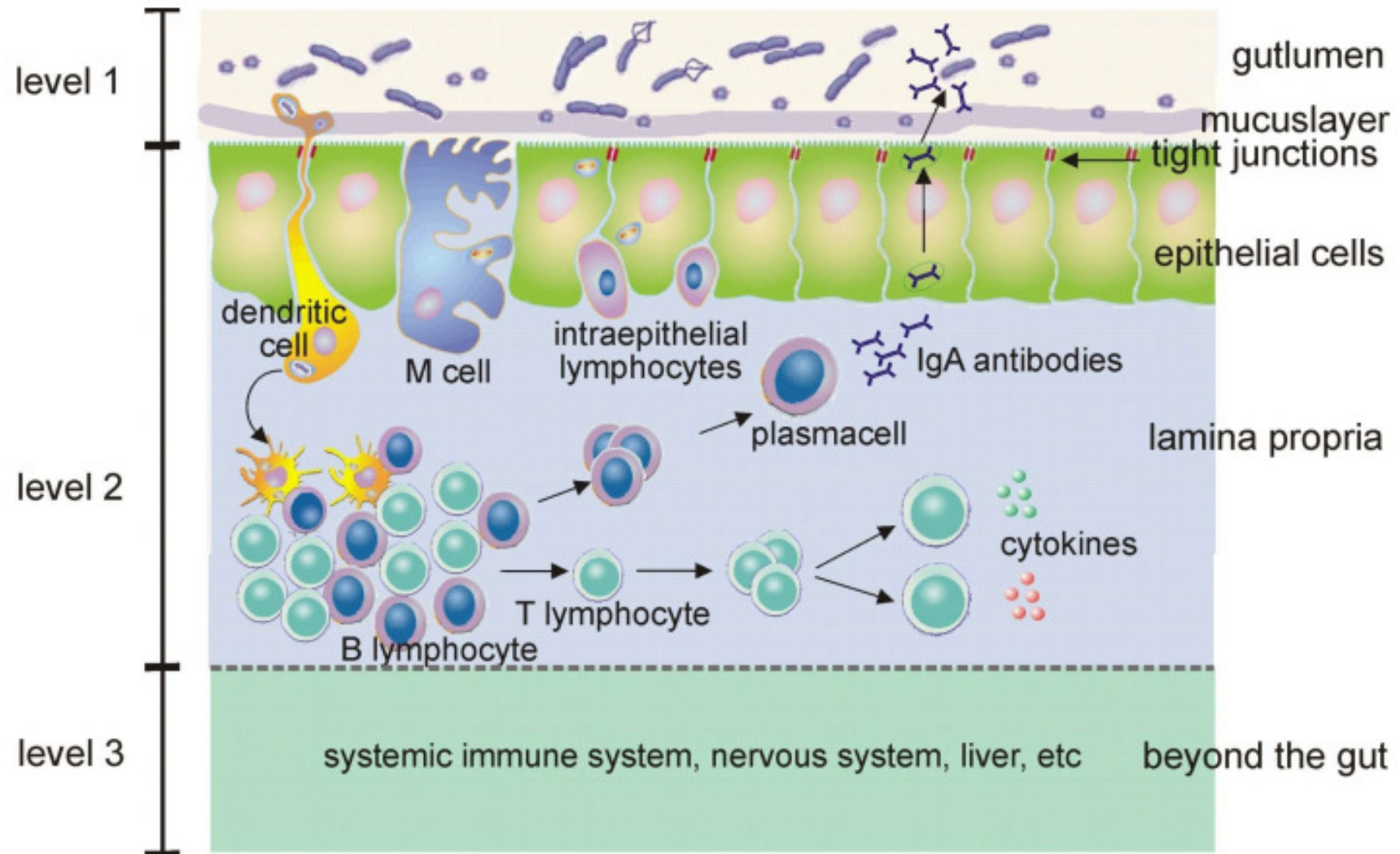
The claimed effect needs to be specific enough to be testable and measurable by generally accepted methods. For example, “gut health” is too general (unclear what measure can be used) but ‘transit time’ is specific (measurable by generally accepted methods).

In the preparation of an application, a rationale/evidence should be provided that the claimed effect is beneficial in the context of the specific claim.

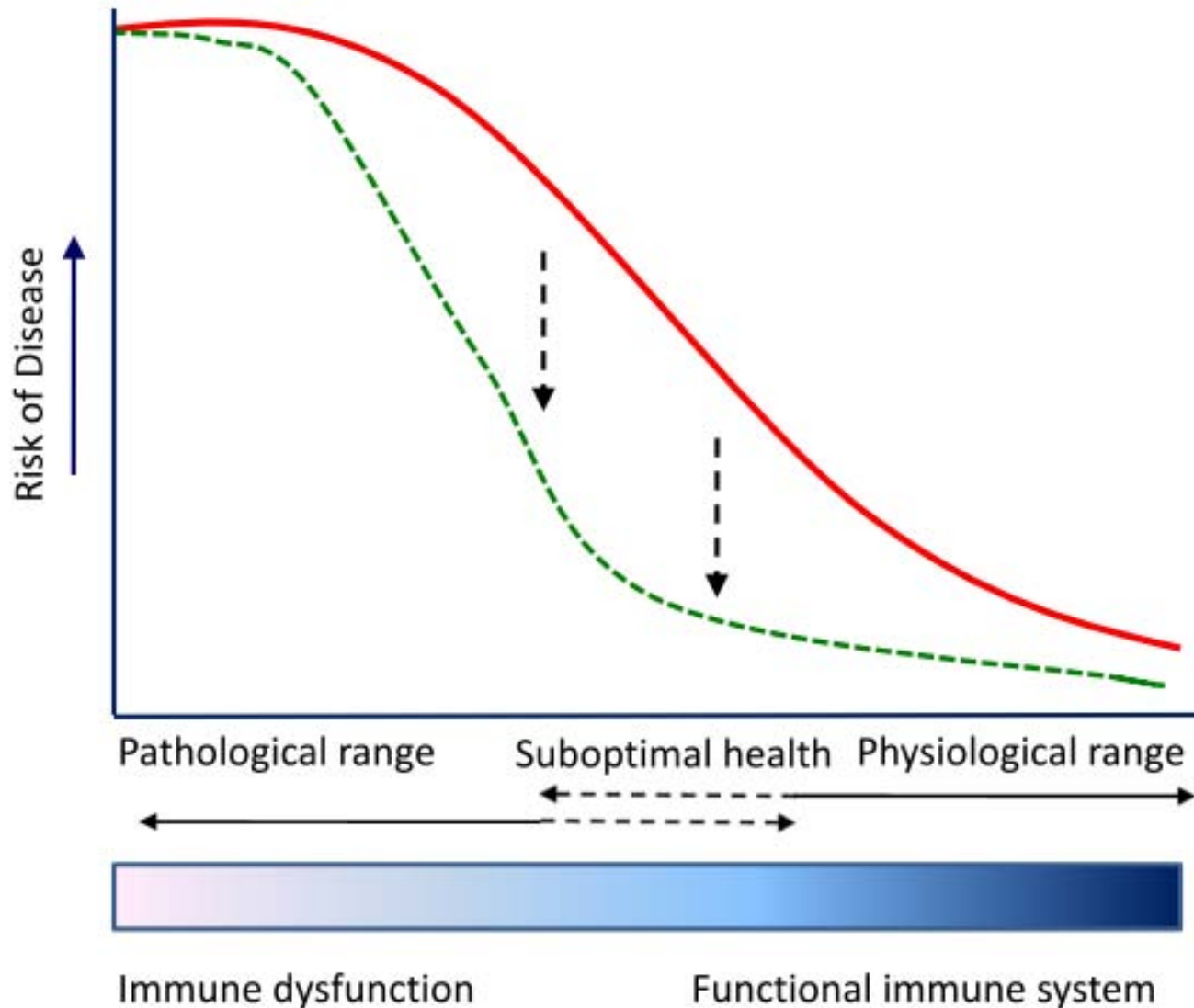
Example

group. Immune parameters such as phagocytosis, natural killer (NK) cell activity and cytokine production were secondary outcomes. The applicant did not provide any evidence that the observed changes in counts of faecal bifidobacteria, NK cell activity, production of inflammatory cytokines and phagocytosis activity constitute beneficial changes in the immune system. The Panel considers this study as having limited relevance for the substantiation of the claimed effect.

Physiological levels at which probiotics (and the microbiota) can act



Health and disease is not a matter of either or. Target and study populations



Expert group focal areas

- Impact of probiotics on digestive system metabolism (Rabot et al. J. Nutr. 140: 677S–689S, 2010)
- Probiotics in chronic inflammatory bowel disease and the functional disorder irritable bowel syndrome (Haller et al. J. Nutr. 140: 690S–697S, 2010)
- Prevention and management of infections (Wolwers et al. J. Nutr. 140: 698S–712S, 2010)
- Prevention and management of allergic disease (Kalliomäki et al. J. Nutr. 140: 713S–721S, 2010)

Guidance for Substantiating the Evidence for Beneficial Effects of Probiotics: Probiotics in Chronic Inflammatory Bowel Disease and the Functional Disorder Irritable Bowel Syndrome¹⁻³

Dirk Haller,⁴ Jean-Michel Antoine,⁵ Stig Bengmark,⁶ Paul Enck,⁷ Ger T. Rijkers,⁸ and Irene Lenoir-Wijnkoop⁹

- Inflammatory Bowel Disease
 - Ulcerative colitis
 - Crohn's Disease
 - Pouchitis

Maintenance of remission
- Irritable Bowel Syndrome

Recommendations (IBS)

- Sufficiently long interventions
- Broad spectrum of patients (report recruiting strategies)
- Clinically meaningful endpoints
- Mechanistic studies

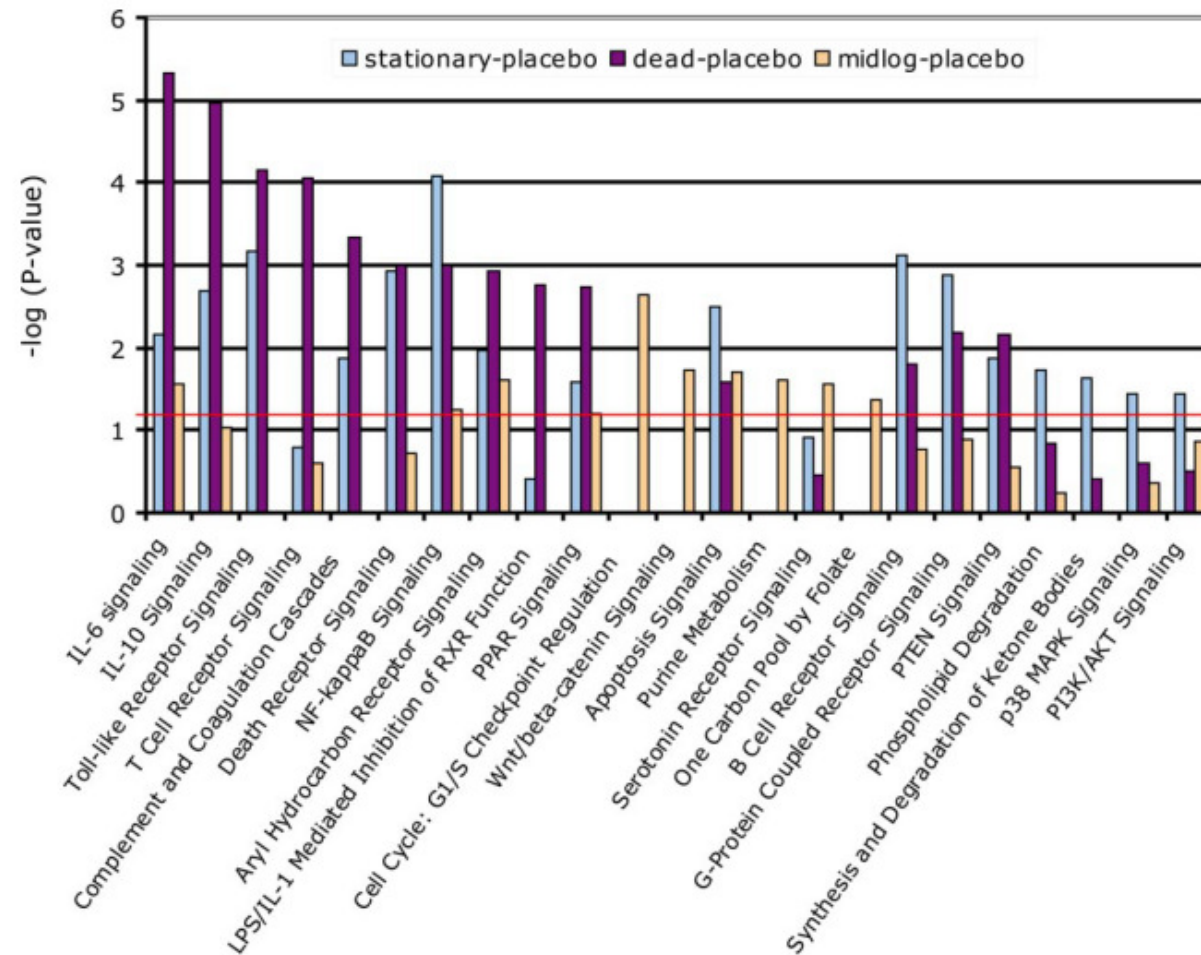
Guidance for Substantiating the Evidence for Beneficial Effects of Probiotics: Impact of Probiotics on Digestive System Metabolism¹⁻³

Sylvie Rabot,⁴ Joseph Rafter,⁵ Ger T. Rijkers,⁶ Bernhard Watzl,⁷ and Jean-Michel Antoine⁸

- Effects on lactose (mal-) digestion
- Effects on lipid metabolism
- Effects on oxalate metabolism
- Effects on microbiota metabolism and composition
- Effects on indigestible dietary components
- Effects on gastrointestinal mucosa and liver metabolism

Recommendations

- Strain selection and matrix
 - physiological state



Recommendations

- Strain selection and matrix
 - physiological state
- Background diet
- Markers and models
 - harmonisation
 - metabolomics

Guidance for Substantiating the Evidence for Beneficial Effects of Probiotics: Prevention and Management of Infections by Probiotics¹⁻³

Danielle Wolvers,⁴ Jean-Michel Antoine,⁵ Eveliina Myllyluoma,⁶ Juergen Schrezenmeir,⁷ Hania Szajewska,⁸ and Ger T. Rijkers⁹

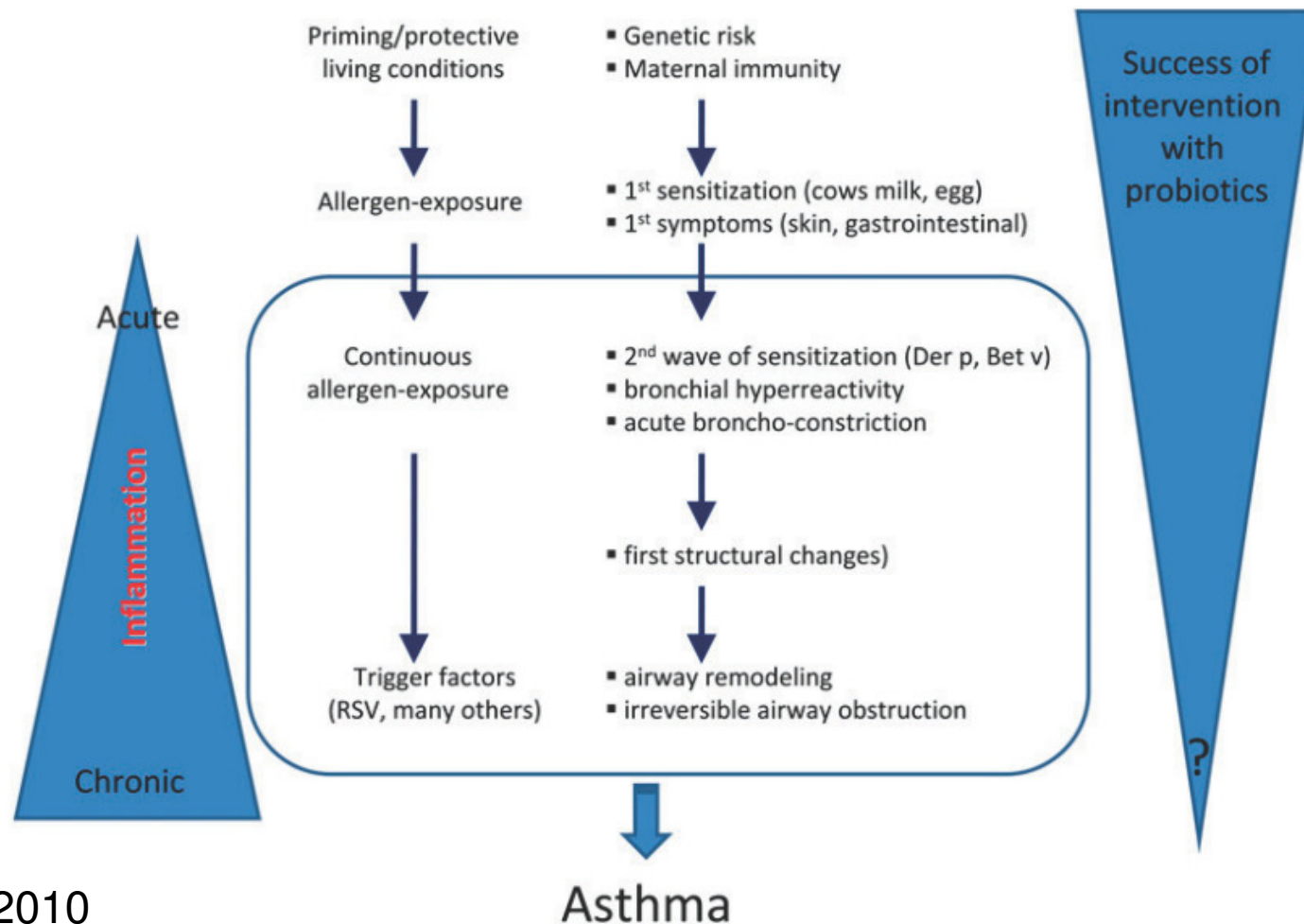
1. Infectious diarrhea in infants and children including acute infectious diarrhea and antibiotic-associated diarrhea (AAD).¹⁰
2. Traveler's diarrhea (TD).
3. Necrotizing enterocolitis (NEC) in infants.
4. *Helicobacter pylori* infection.
5. Respiratory tract infections in adults and children.
6. Ear, nose, and throat (ENT) infections.
7. Infectious complications in surgical and critically ill patients.

Recommendations

- Report both clinical out-comes and immune biomarkers (to elucidate potential mechanisms)
- Identification of pathogens
- Studies with sufficient statistical power
- Reporting of confounding factors (population, medication, etc.)

Guidance for Substantiating the Evidence for Beneficial Effects of Probiotics: Prevention and Management of Allergic Diseases by Probiotics¹⁻³

Marko Kalliomäki,⁴ Jean-Michel Antoine,⁵ Udo Herz,⁶ Ger T. Rijkers,^{7,8} Jerry M. Wells,⁹ and Annick Mercenier¹⁰



Recommendations

- Identification of allergic disease based on uniform criteria
- Identify subpopulations
- Genotyping of patients (to identify better responding groups)
- Validated and uniform symptom scores
- Recording of antiallergic and other medication and other confounding factors

Over all recommendations

- Ensure sufficient statistical power and length of study
- Identify and report the study population (selection procedure)
- Report confounding factors (medication, diet, etc.)
- Report clinical outcomes and biomarkers (to identify mechanisms)
- Harmonise symptom scoring (to be able to compare between studies)