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

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ILSI Europe Probiotic Task Force

International Life Sciences Institute

- Branches in US, Europe, South-America, etc
- Task forces — lead and funded by industry
- Expert group — academia + industry
  academia > industry
- Results/findings — monograph
  publication

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ILSI Probiotic Task Force
Expert group

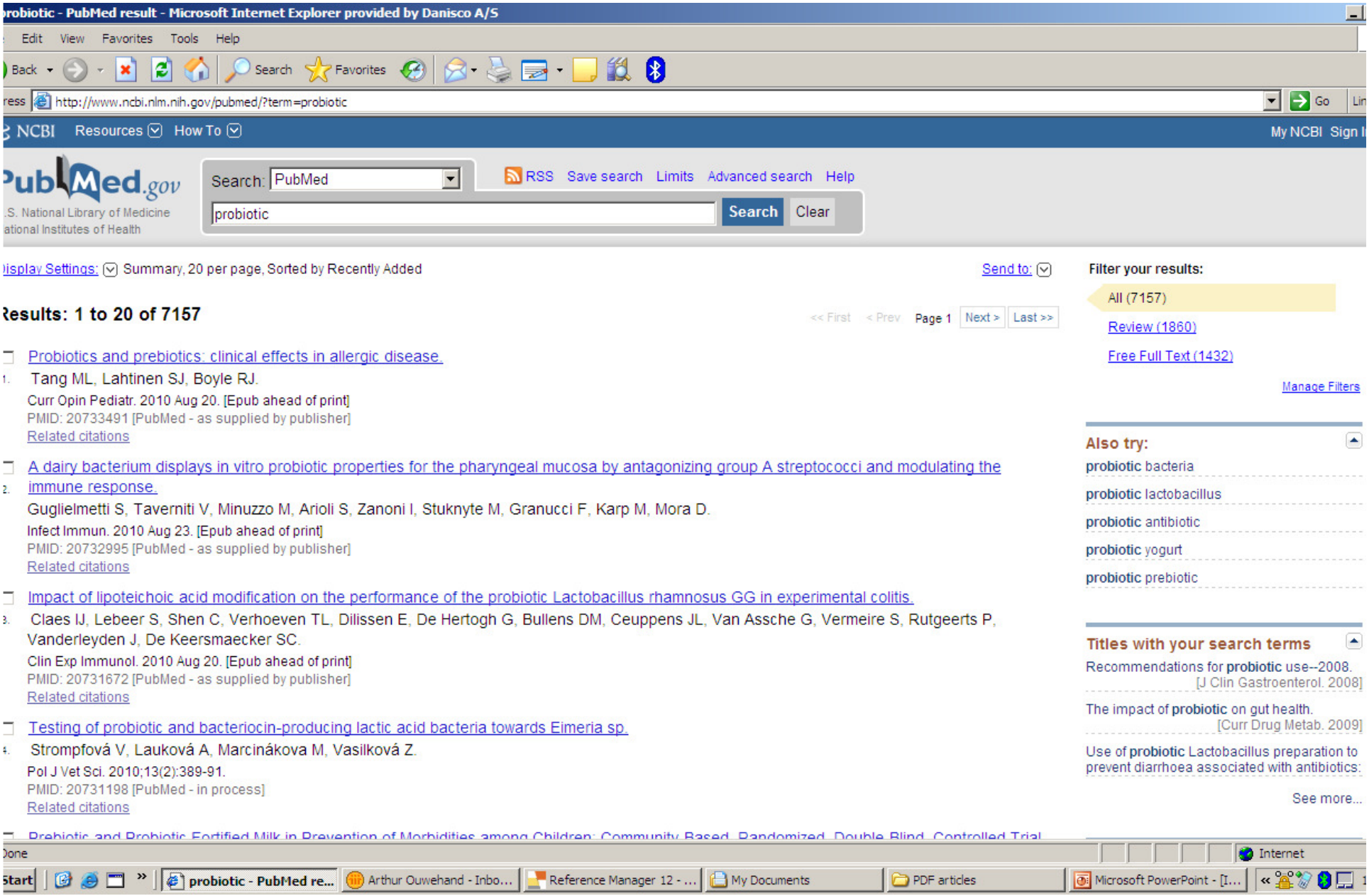
Academia

- Ger Rijkers
- Stig Bengmark
- 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



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).

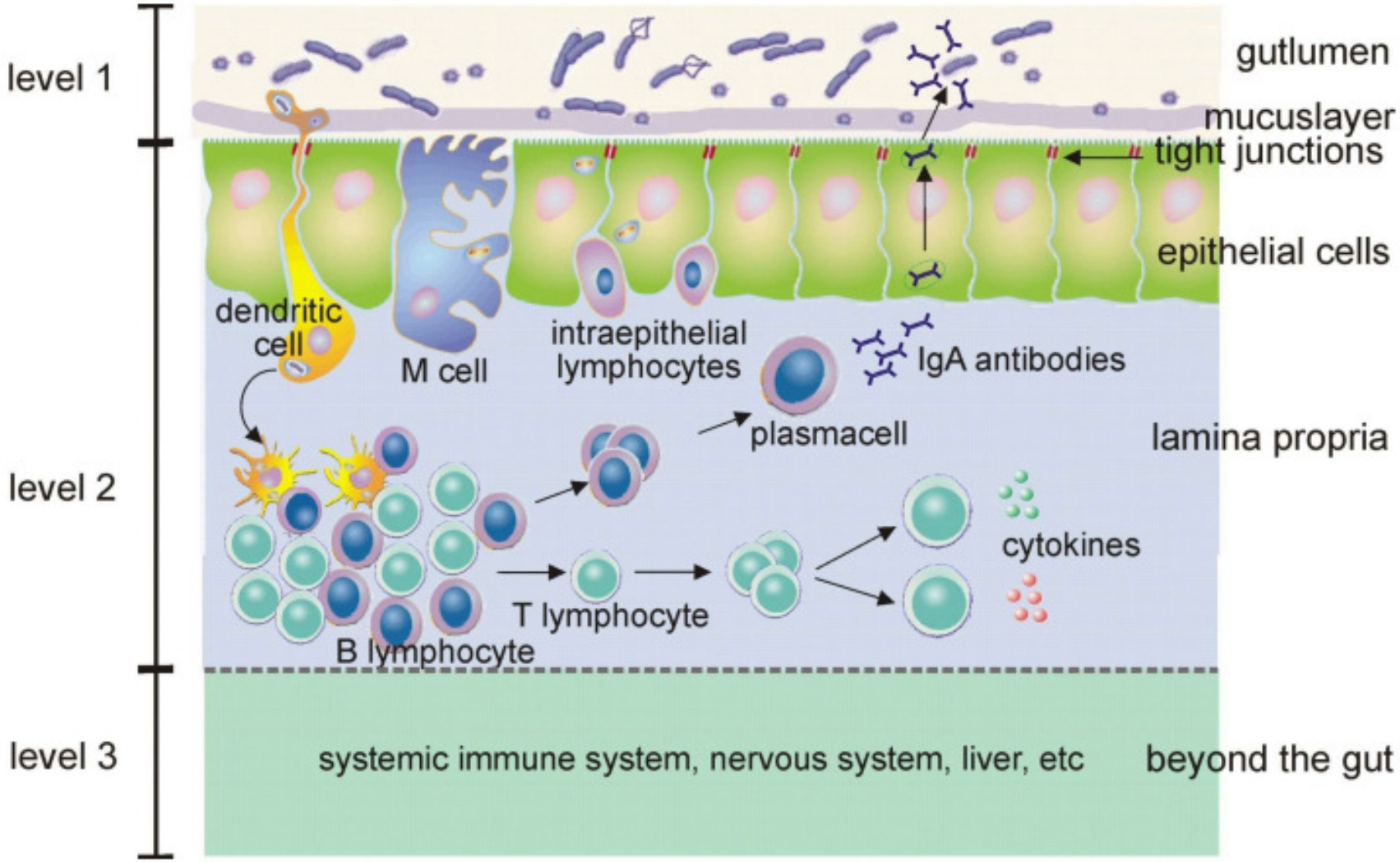
In the preparation of an application, a rationale/evidence should be provided that the claimed effect is beneficial in the context of the specific claim.

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.

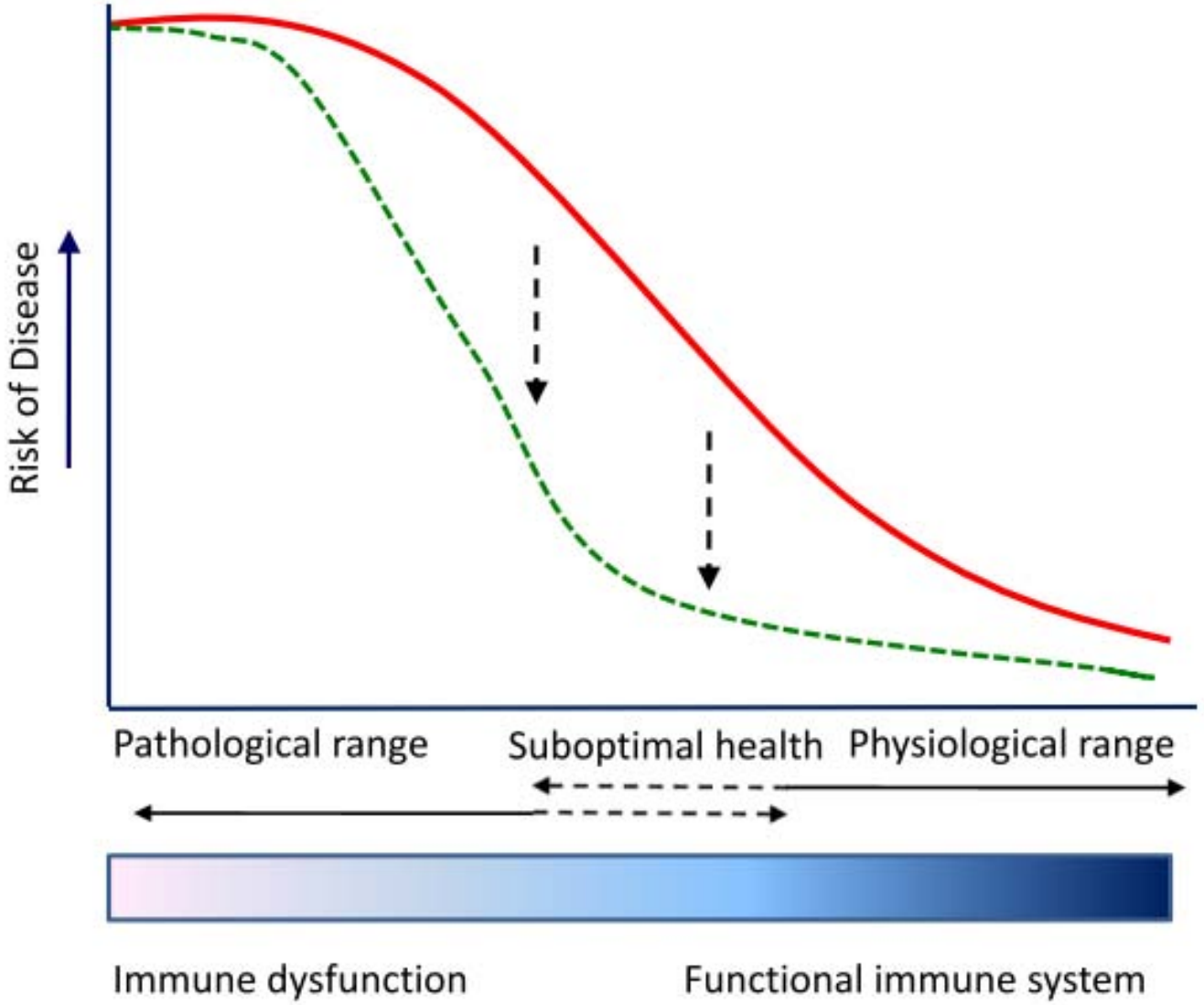
EFSA 2009

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



Rijkers et al. 2010

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



Rijkers et al. 2010

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 (Wolvers 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 Syndrome[1–3]

Dirk Haller,[4] Jean-Michel Antoine,[5] Stig Bengmark,[6] Paul Enck,[7] Ger T. Rijkers,[8] and Irene Lenoir-Wijnkoop[9]

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

  Maintenance of remission
- Irritable Bowel Syndrome

Haller et al. 2010

Recommendations (IBS)

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

Haller et al. 2010

Guidance for Substantiating the Evidence for Beneficial Effects of Probiotics: Impact of Probiotics on Digestive System Metabolism[1–3]

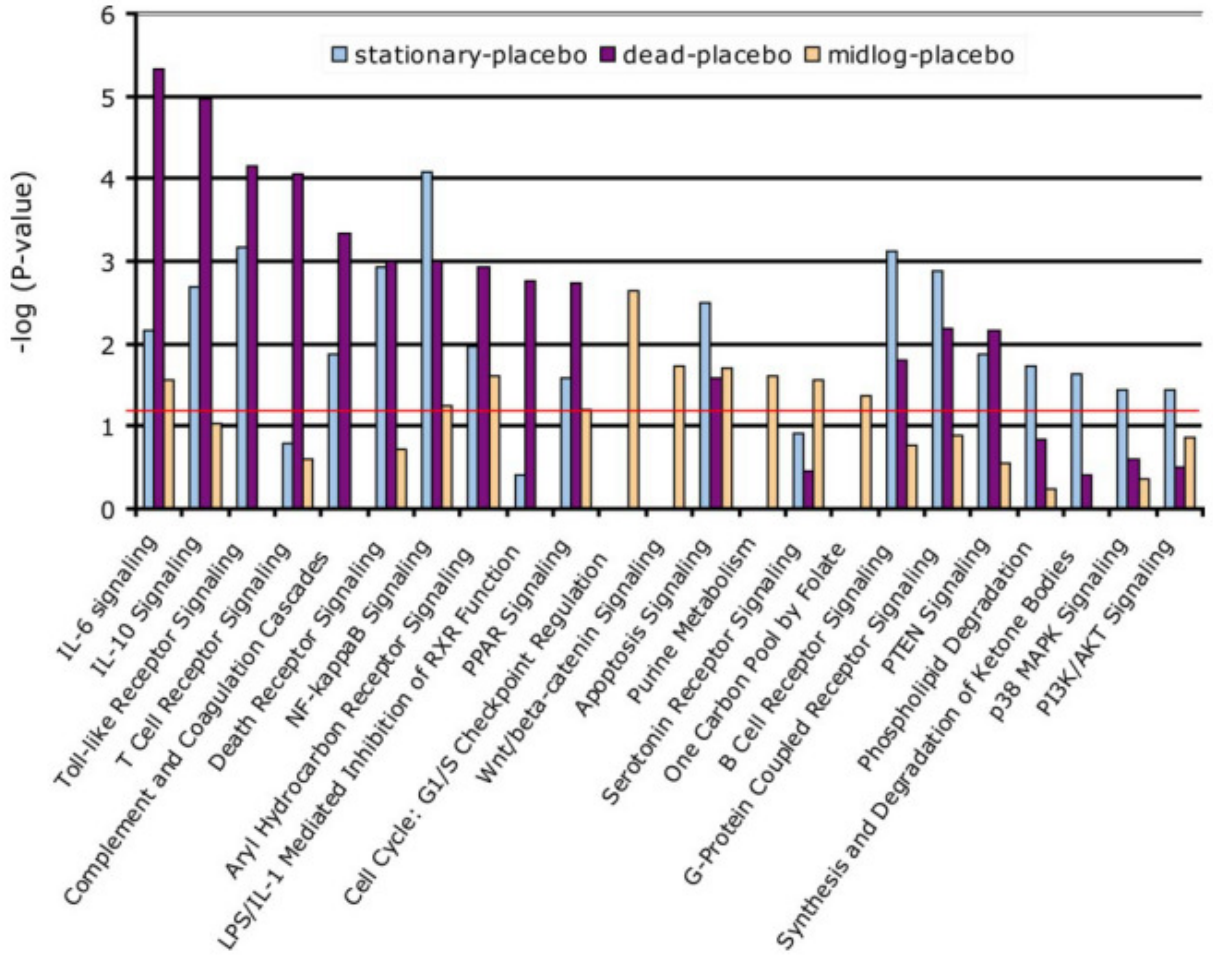
Sylvie Rabot,[4] Joseph Rafter,[5] Ger T. Rijkers,[6] Bernhard Watzl,[7] and Jean-Michel Antoine[8]

- 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

Rabot et al. 2010

Recommendations

- Strain selection and matrix
  - physiological state



van Baarlen et al. 2009

Recommendations

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

Rabot et al. 2010

Guidance for Substantiating the Evidence for Beneficial Effects of Probiotics: Prevention and Management of Infections by Probiotics[1–3]

Danielle Wolvers,[4] Jean-Michel Antoine,[5] Eveliina Myllyluoma,[6] Juergen Schrezenmeir,[7] Hania Szajewska,[8] and Ger T. Rijkers[9]

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.

Wolvers et al. 2010

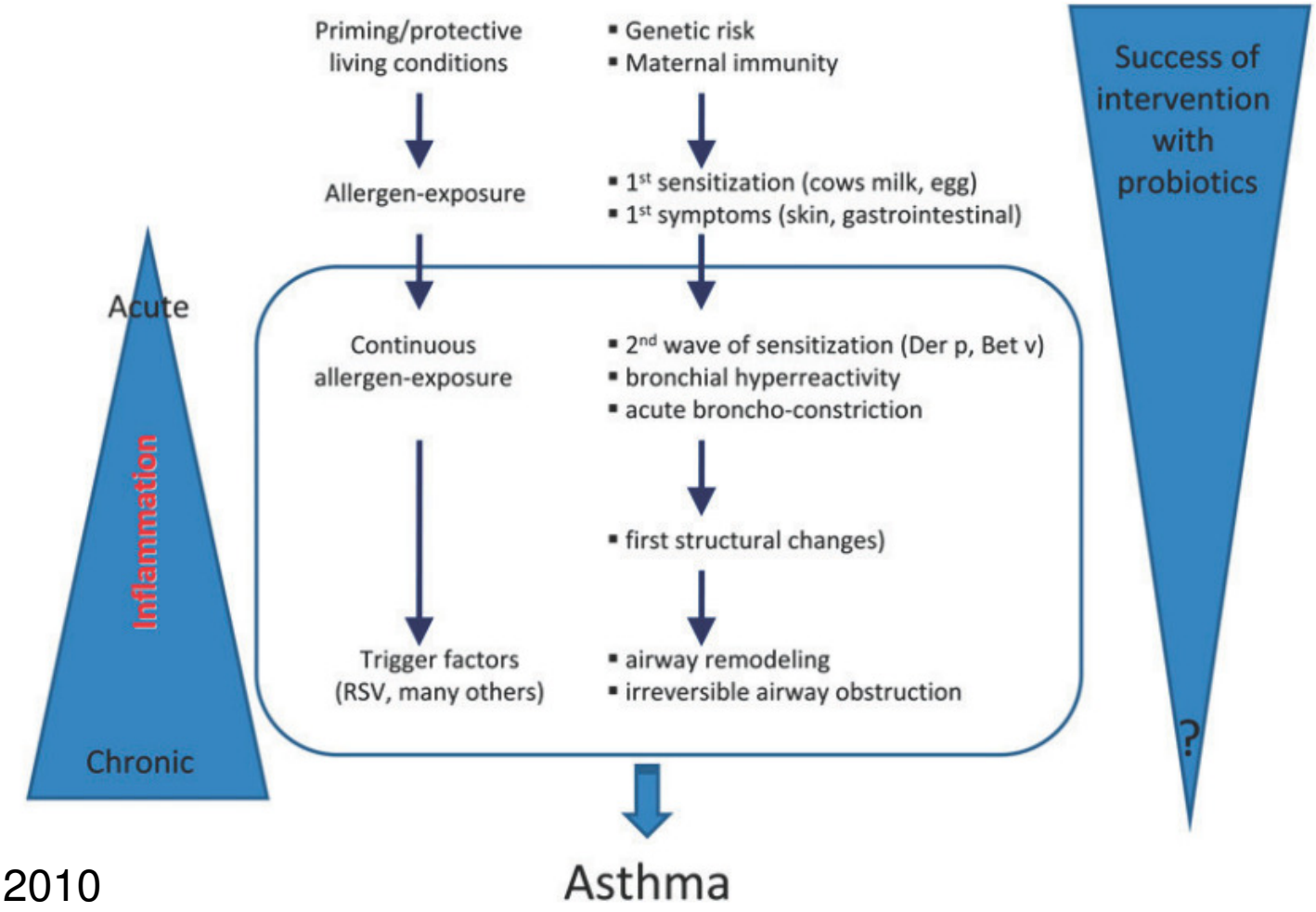
Recommendations

- 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.)

Kalliomäki et al. 2010

Guidance for Substantiating the Evidence for Beneficial Effects of Probiotics: Prevention and Management of Allergic Diseases by Probiotics[1–3]

Marko Kalliomäki,[4] Jean-Michel Antoine,[5] Udo Herz,[6] Ger T. Rijkers,[7,8] Jerry M. Wells,[9] and Annick Mercenier[10]



Wolvers et al. 2010

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

Kalliomäki et al. 2010

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)