

The Microbiome & Probiotics in Clinical Practice

- the way forward -

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The microbiome & probiotics in clinical practice – the way forward

Summary



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- Introduction
- Microbiome concepts
- Defining probiotics
- Guideline-based probiotic prescription
- Key points

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Introduction

Should we prescribe probiotics & which one?

Google search results for "probiotics in south africa".

The search results display a variety of probiotic products and market information:

- Biogen**: In stock Supreme Probiotic 9-Strain.
- Rawbiotics**: You gut this! free delivery on all orders over R50. Rawbiotics Defence | Pro...
- The Good Stuff**: In stock THE REAL THING Pro-p...
- The Olio Store**: Probiotics Capsules - 30...
- Online Vitamins & ...**: Solal Probiotic Ma...
- MedPharm Publications**: gut health up to scratch ...
- Wellvita**: Probiotic 9 Strain- ...
- Organic Choice**: In stock Florish Spore Probiotic (Se...
- www.provenprobiotics.co.za**: ProVen
- NutriTech**: In stock VITATECH PROBIOTIC C...
- RM Research and Markets**: South Africa Probiotics Market ...
- R^e ResearchGate**: The South African probiotic ...
- LinkedIn**: Reuterina South Africa on Li...
- www.rawbiotics.co.za**: Probiotics South Africa | Rawbiotics ...
- The Olio Store**: Probiotics Capsules - 300mg ...
- We Thrive**: GutFora Probiotic Strawberry ...
- reuterina.co.za**: Reuterina: The Probiotics for Life

Introduction

Should we prescribe probiotics & which one?

Google search results for "probiotics in south africa".

Mini Matters · In stock
Probiotic Laundry Liqu...

Facebook
ProbiFlora - Every lovi...

Optimized
Prebiotic + Probiotic - ...

South African Mom Blogs
Blogger Opportunity: Reuterina ...

Silkworm Shop · In stock
Probivet Probiotic Po...

Mama Skincare · In stock
Colic Calm Probiotic 1...

Faithful to Nature · ...
Buy The Real Thin...

Ubuy South Africa · In stock
Just Thrive Probiotic & An...

ResearchGate
vaginal health in So...

happyculture.co.za
South Africa's favourite pr...

Retail Brief Africa
probiotic yogurt drinks ...

Related searches

- probiotic clicks
- dischem probiotics 9 strain
- probiotics benefits

Essentially Natural · In stock
Rawbiotics Defence (Liqu...

Dischem
Best Probiotic Suppl...

Research and Mark...
South African Prob...

Insight Survey
B2B Market Research Company Sout...

Perfectly Healthy
Spore Based Probiotics - Opti...

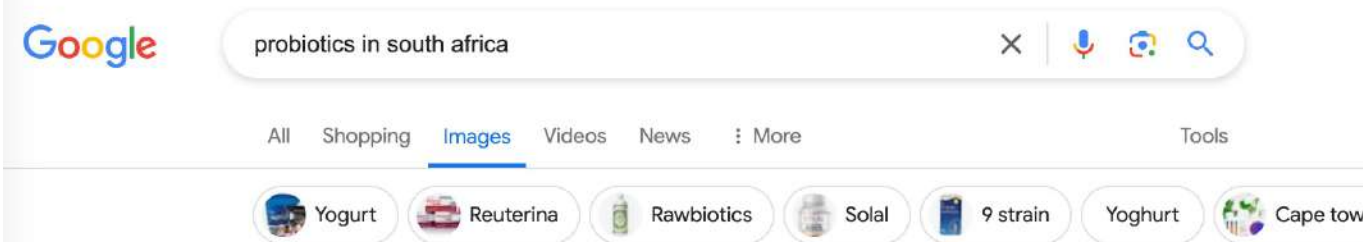
Eco Mom · In stock
CalmCo@ Probiotic ...

Holisteeq · In stock
Rawbiotics Daily Bal...

Instagram
Reuterina (@reuterin...

Introduction

Should we prescribe probiotics & which one?



Sponsored :

 Adcock Ingram... R 389.00 takealot.com ★★★★★ (7)	 ProbiFlora Adult Intensi... R 219.00 takealot.com	 Entiro Daily Probiotics - ... R 295.00 takealot.com	 Rawbiotics Gut 1 Litre R 275.00 takealot.com ★★★★★ (569)	 Probiotec Capsules 30's R 379.00 takealot.com	 Latero-Flora Probiotic R 997.00 progresshea...	 Probiotic Tablets High... R 219.00 takealot.com ★★★★★ (156)
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MedPharm Publications
First DuoCap probiotic launches...



Clicks · In stock
Clicks 9- Strain Probiotic...



SOLAL
Probiotic Maximum P...



Wellvita · In stock
Probiotic 9 Strain- ...



We Thrive · In stock
Rawbiotics Gut Correct ...



We Thrive
Metagenics UltraFlora B...

Clicks · In stock
Entiro Probiotic 10 Caps...

Introduction

Should we prescribe probiotics & which one?



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Forget Probiotics, Beer Is Great For Gut Health |
2oceansvibe News | South African and international...

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Introduction

Probiotic hype

- Media headlines
- On-line stores
- Health shops
- Pharmacies
- Grocery stores
- Pet shops
- Agriculture
- Prescriptions
- Soaring public consumption



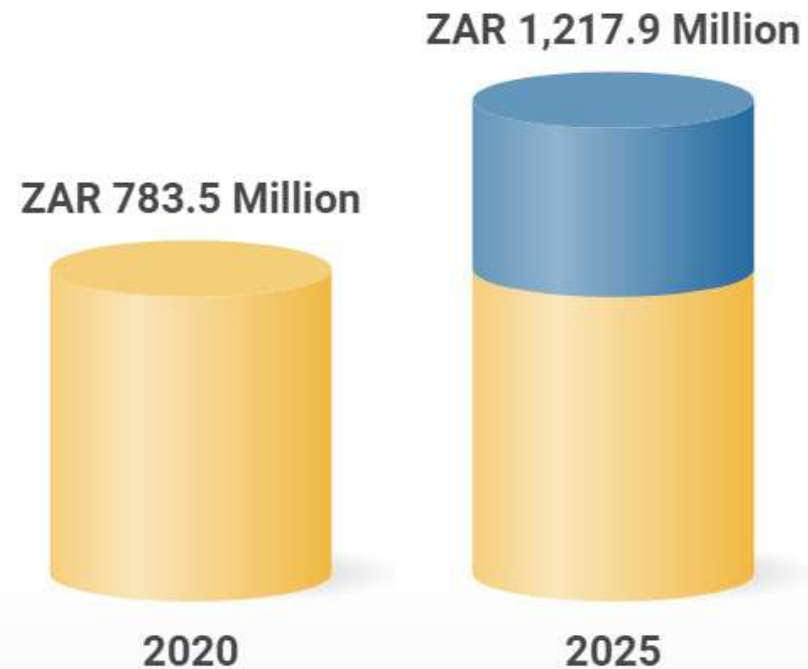


Introduction

South African probiotic market

South African Probiotics Industry

Market forecast to grow at a CAGR of 9.2%

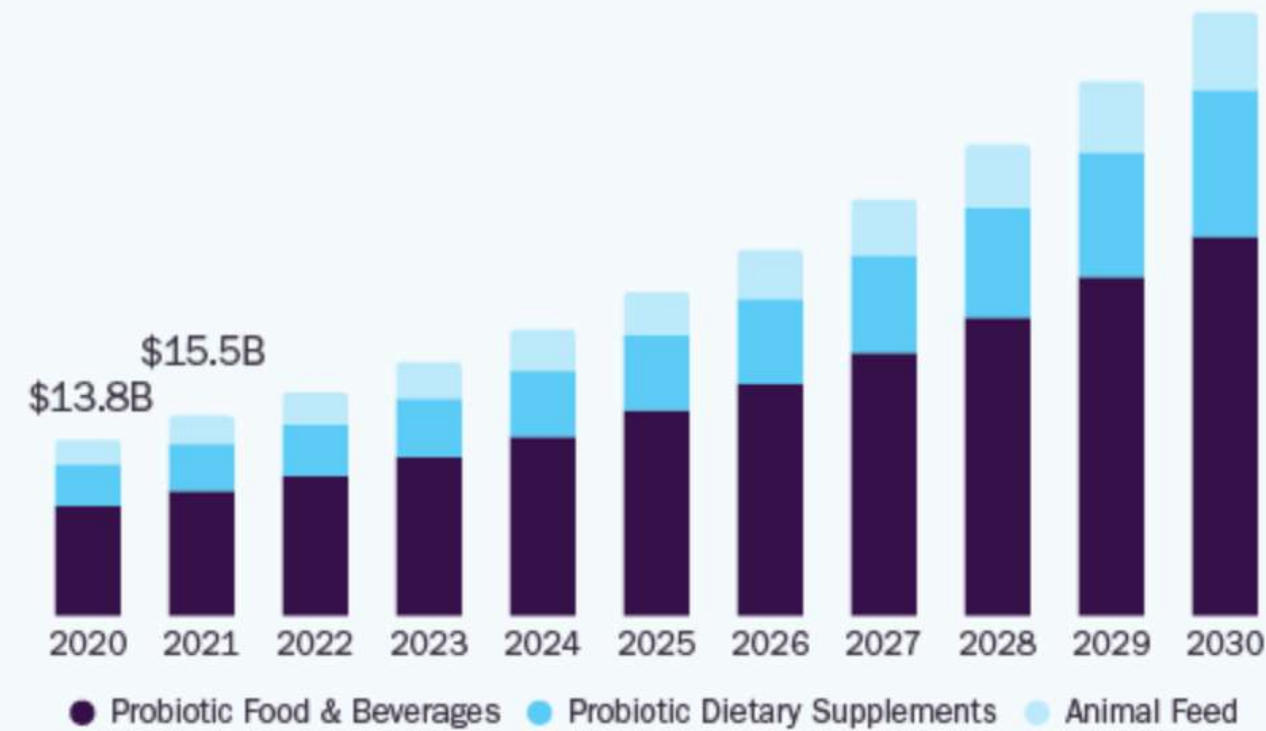


Introduction

The probiotic market

U.S. Probiotics Market

Size, by Product, 2020 - 2030 (USD Billion)



GRAND VIEW RESEARCH

13.2%

U.S. Market CAGR,
2023 - 2030

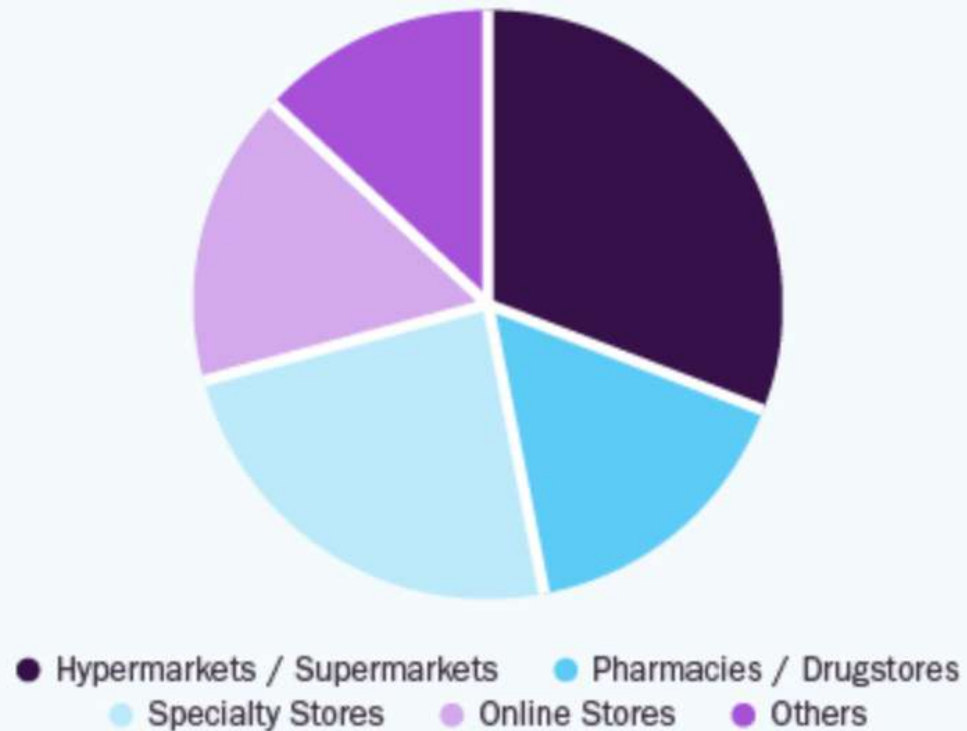
Source:
www.grandviewresearch.com

Introduction

The global probiotic market

Global Probiotics Market

Share, by Distribution Channel, 2022 (%)



GRAND VIEW RESEARCH

\$77.1B

Global Market Size,
2022

Source:
www.grandviewresearch.com

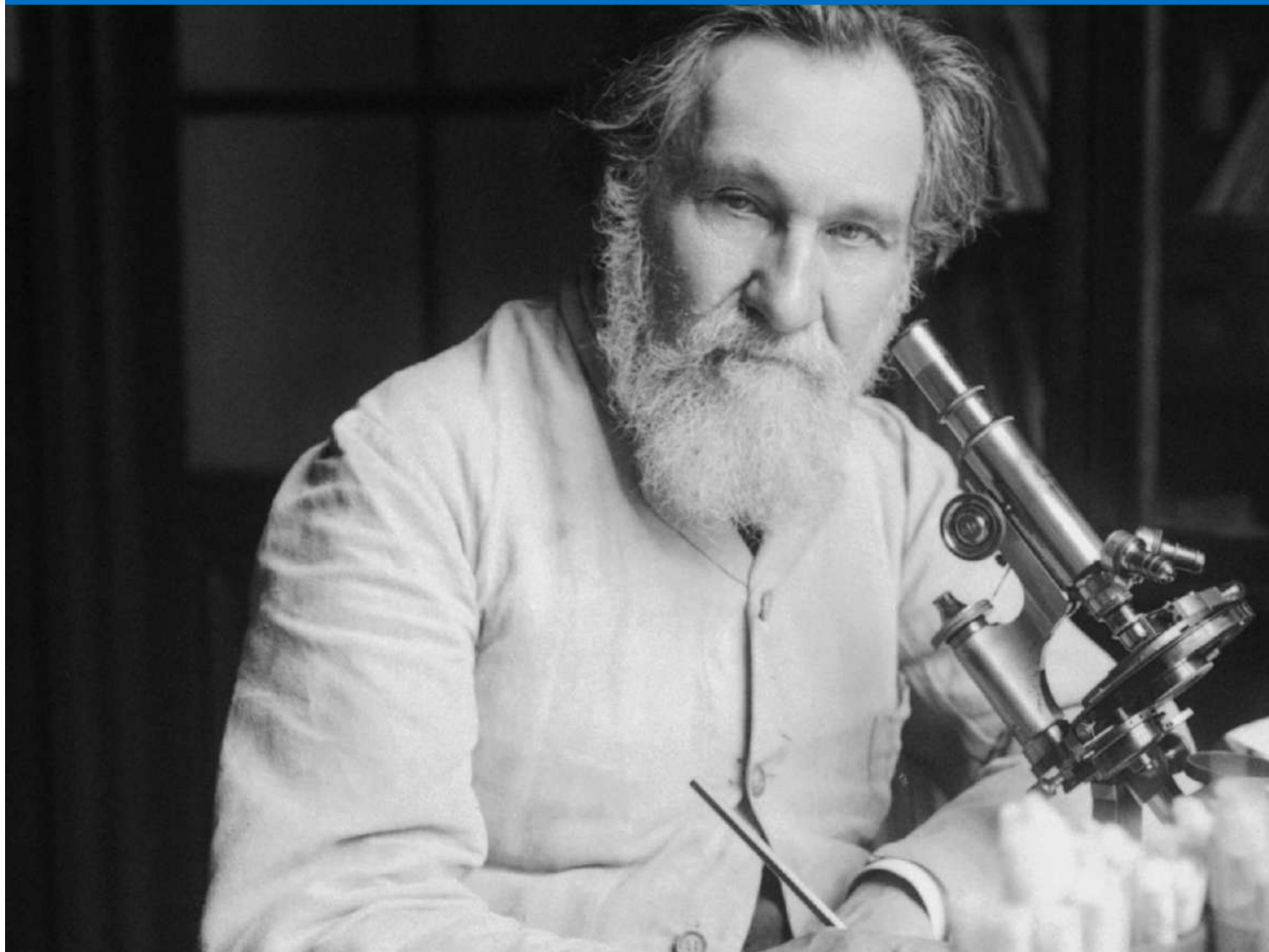
Introduction

Human commensal microbial landscape & longevity



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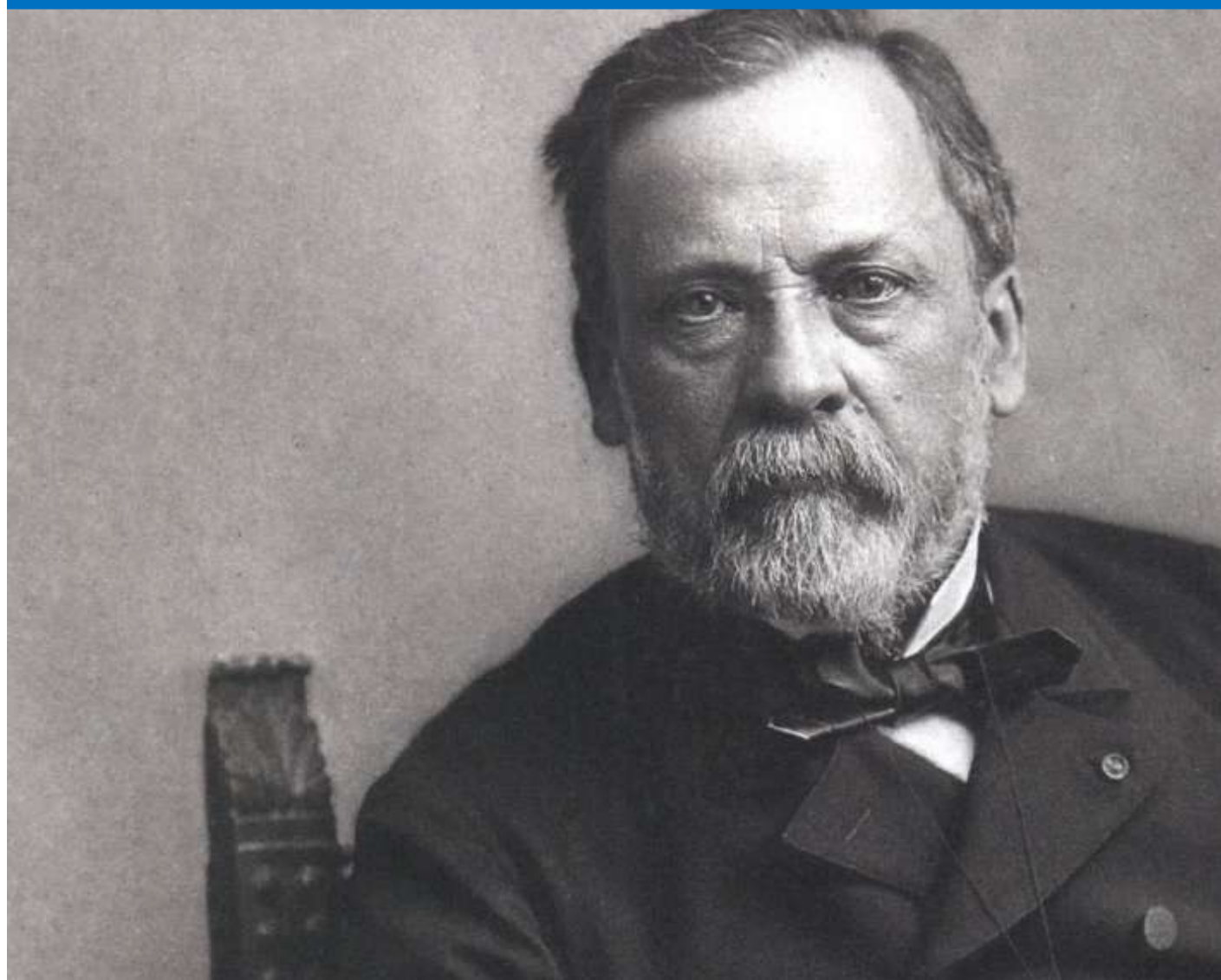
- Ilya Mechnikov (1845-1916):
 - the majority of diseases begin in the digestive tract when 'good' bacteria are no more able to control 'bad' bacteria





Introduction

Our commensal microbial landscape: 'Old friends'



- Pasteur (1885) hypothesis:
 - Microbiome essential for life
- Henry Tissier (1899):
 - 'y'-shaped bacteria
 - Treatment of diarrhoea
- Wostmann (1981) proof:
 - Microbiome critical for health
 - Wostmann BS. Ann Rev Nutr 1981;1:257-279
- First inventory :
 - Human Microbiome Project
 - Nature 2012;486:207–214

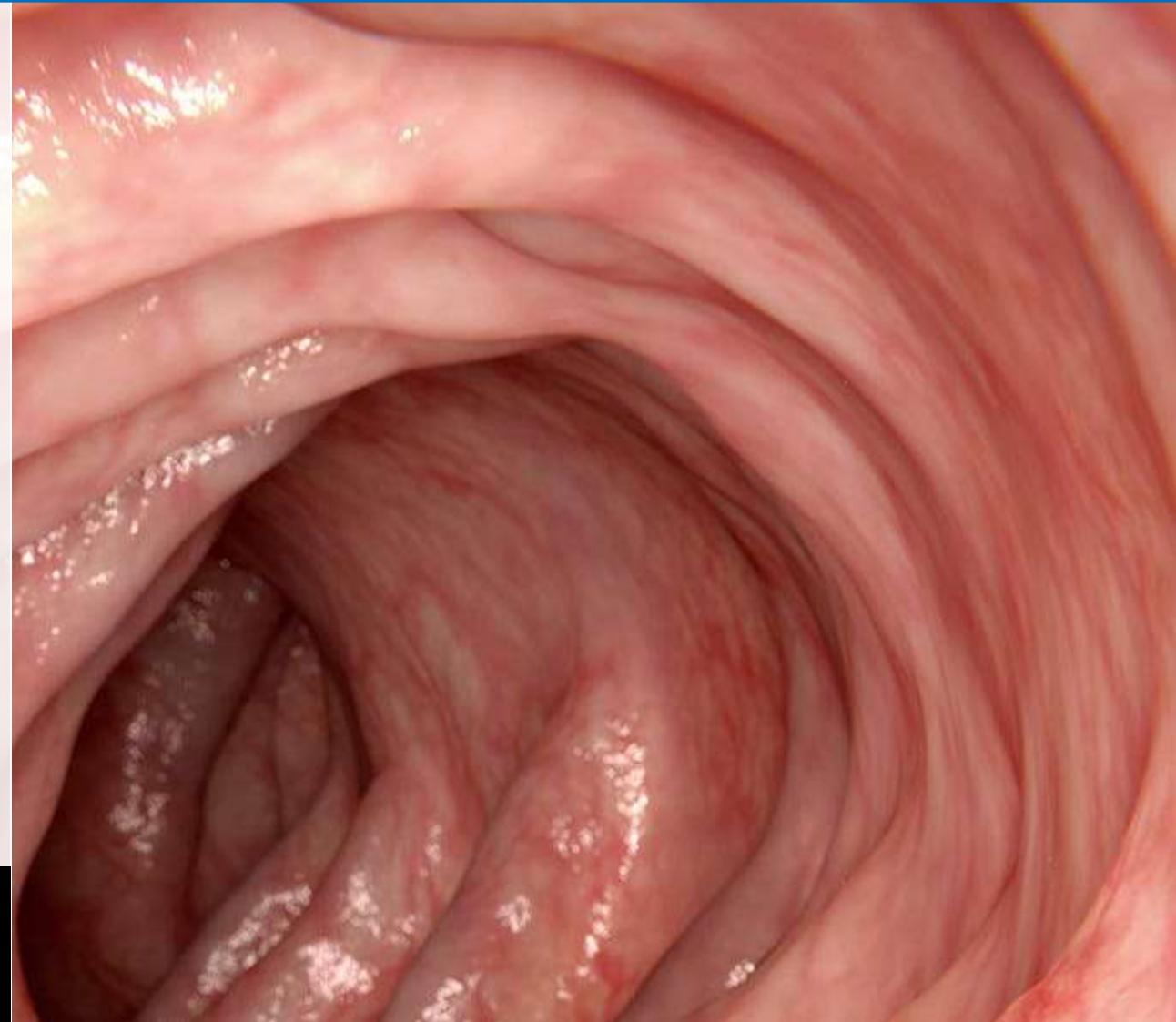


Introduction

Mucosal immunology

- Mucosa → defined compartment of the immune system
- Permeable:
 - Absorb
 - Secrete
 - Vulnerable to infection
- Exposed to many antigens:
 - Some to tolerate
 - Some to defend against
- Compartment that must develop immune memory

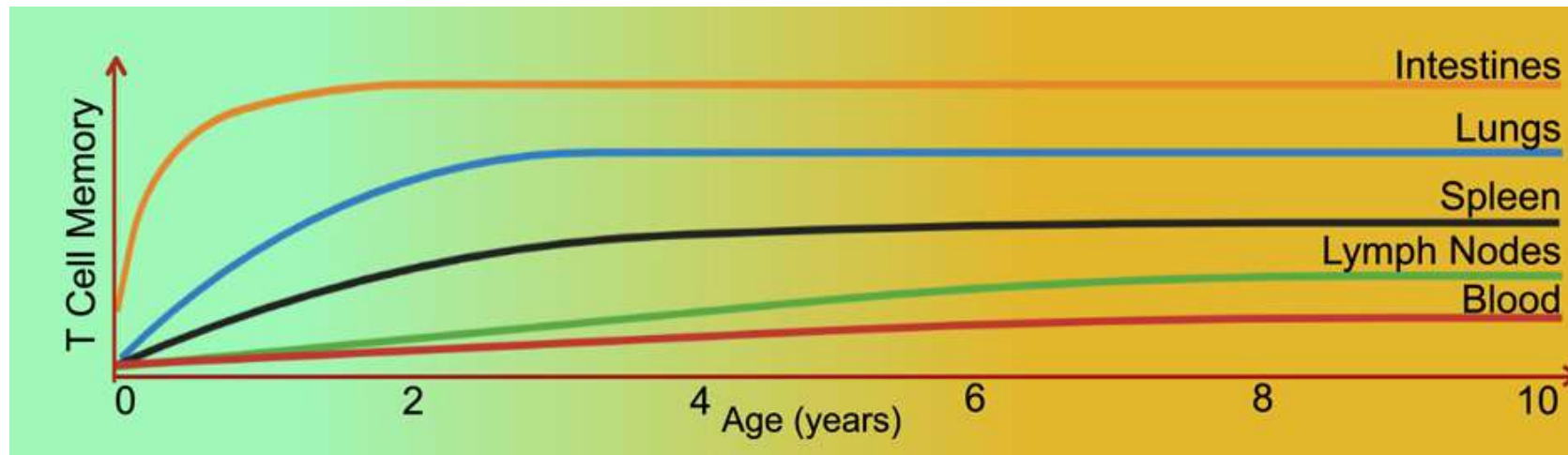
Microbiome forms an integral part of the mucosal immune compartment



Site-specific development and progressive maturation of human tissue-resident memory T cells over infancy and childhood

- Connors TJ, et al. Immunity 2023;56:1-16

- Key milestones in development of T-cell memory:
 - Intestinal & airway mucosal sites earlier & more dominant compared to blood & lymphoid organs



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- **Microbiome concepts**
- Defining probiotics
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Microbiome concepts

What is the microbiome?

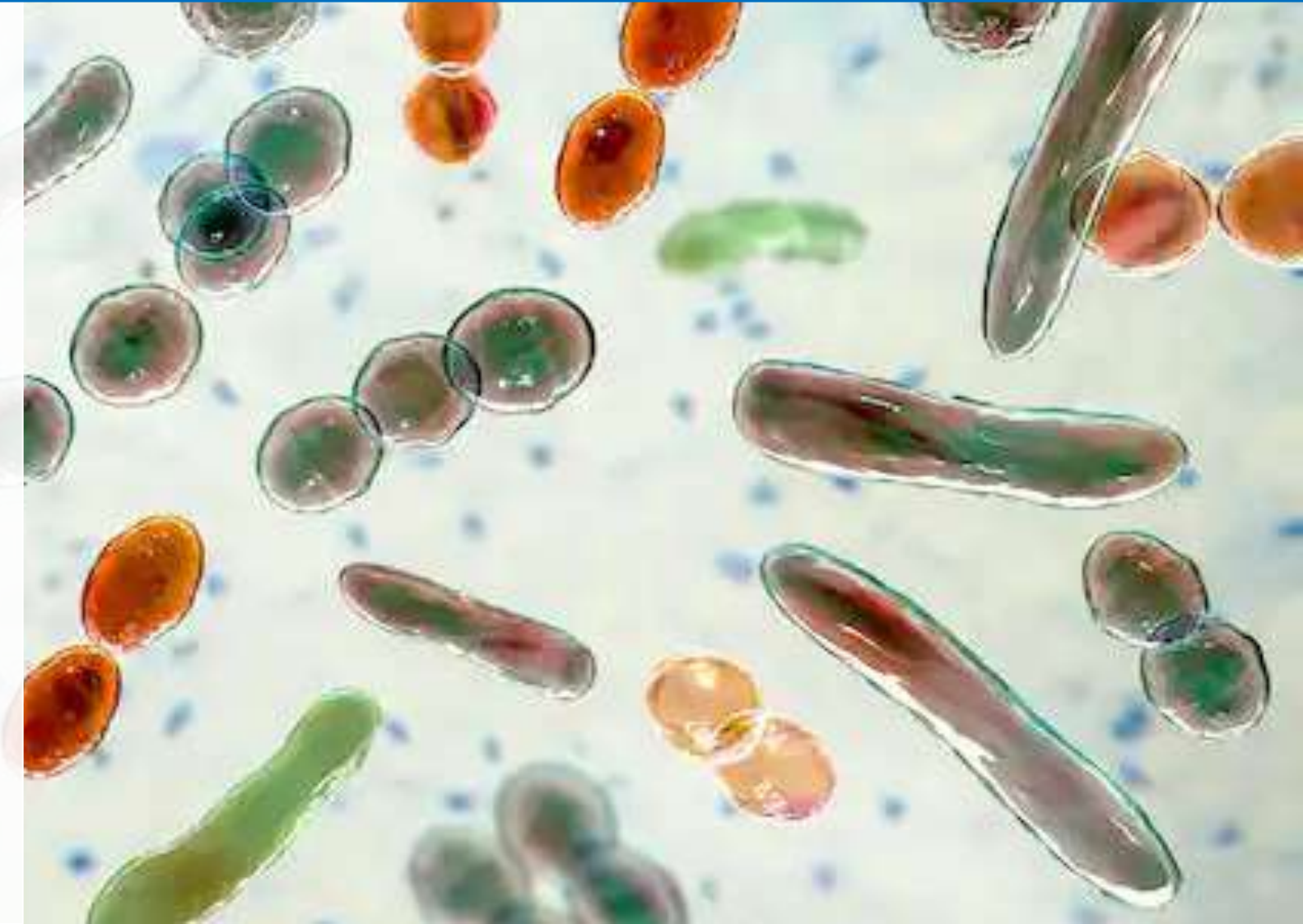


Populations of highly personalised microbes that live on our body in a deep symbiotic relationship with each other & the host

Microbiome concepts

'Anatomy' of the human microbiome

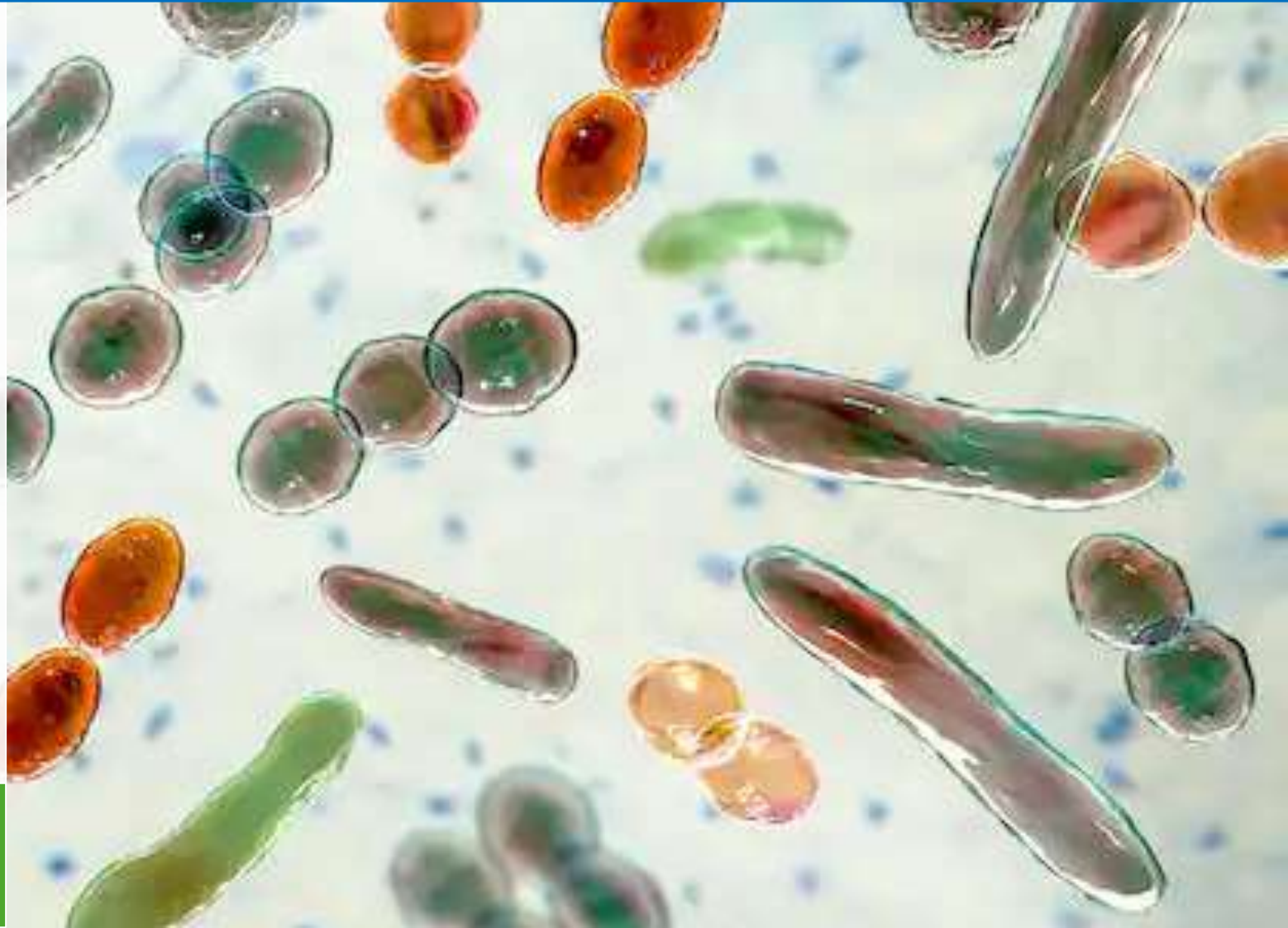
- Multi-species populations consisting of:
 - Bacterial
 - Archaeal
 - Fungal
 - Viral &
 - Bacteriophage genomes
- Operational taxonomic units across body surface:
 - Composition vary according to specific microbial districts



Microbiome concepts

'Anatomy' of the human microbiome

- 10^{10} - 10^{11} Microbial cells per wet-weight gram of faeces
- Weight \approx 500g
- Ratio of microbial : human cells \approx 1:1
- 150x more protein coding genes than the human genome:
 - Human protein coding genes + Microbiome protein coding genes = 'Hologenome'

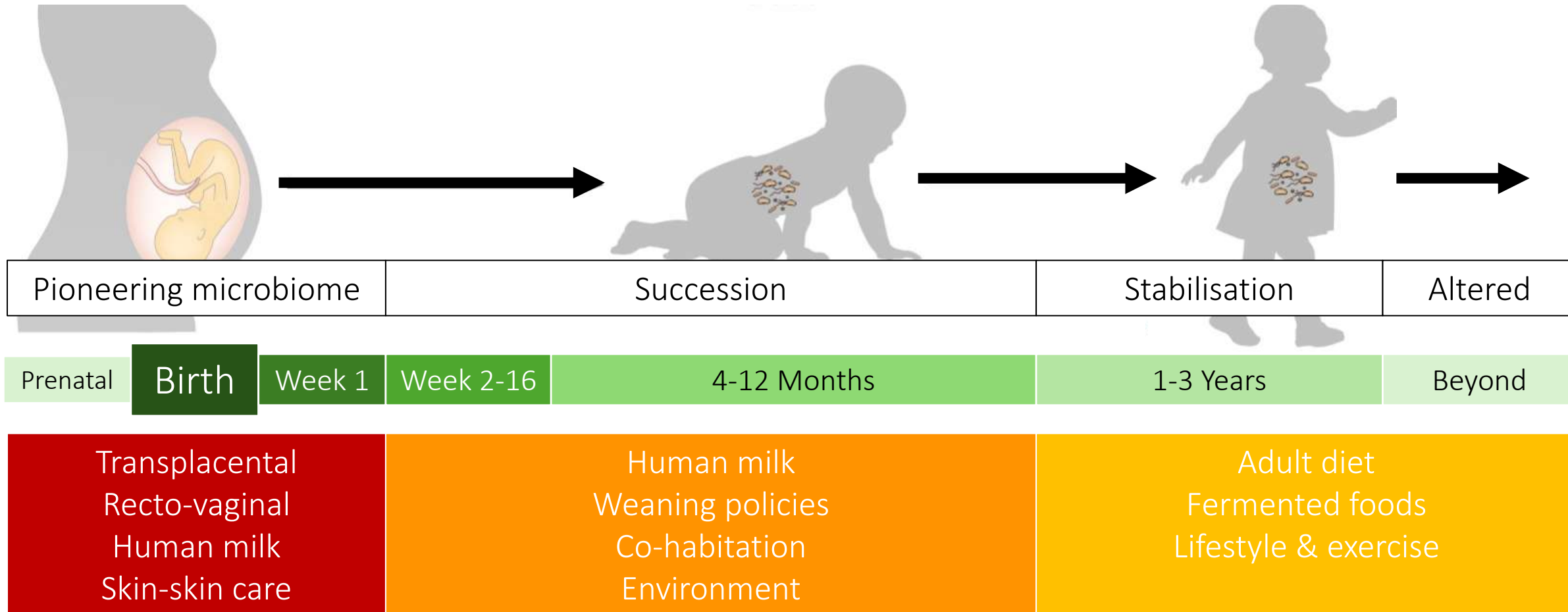


Provides functional features that humans have not evolved



Microbiome concepts

Stages of human microbiome assembly

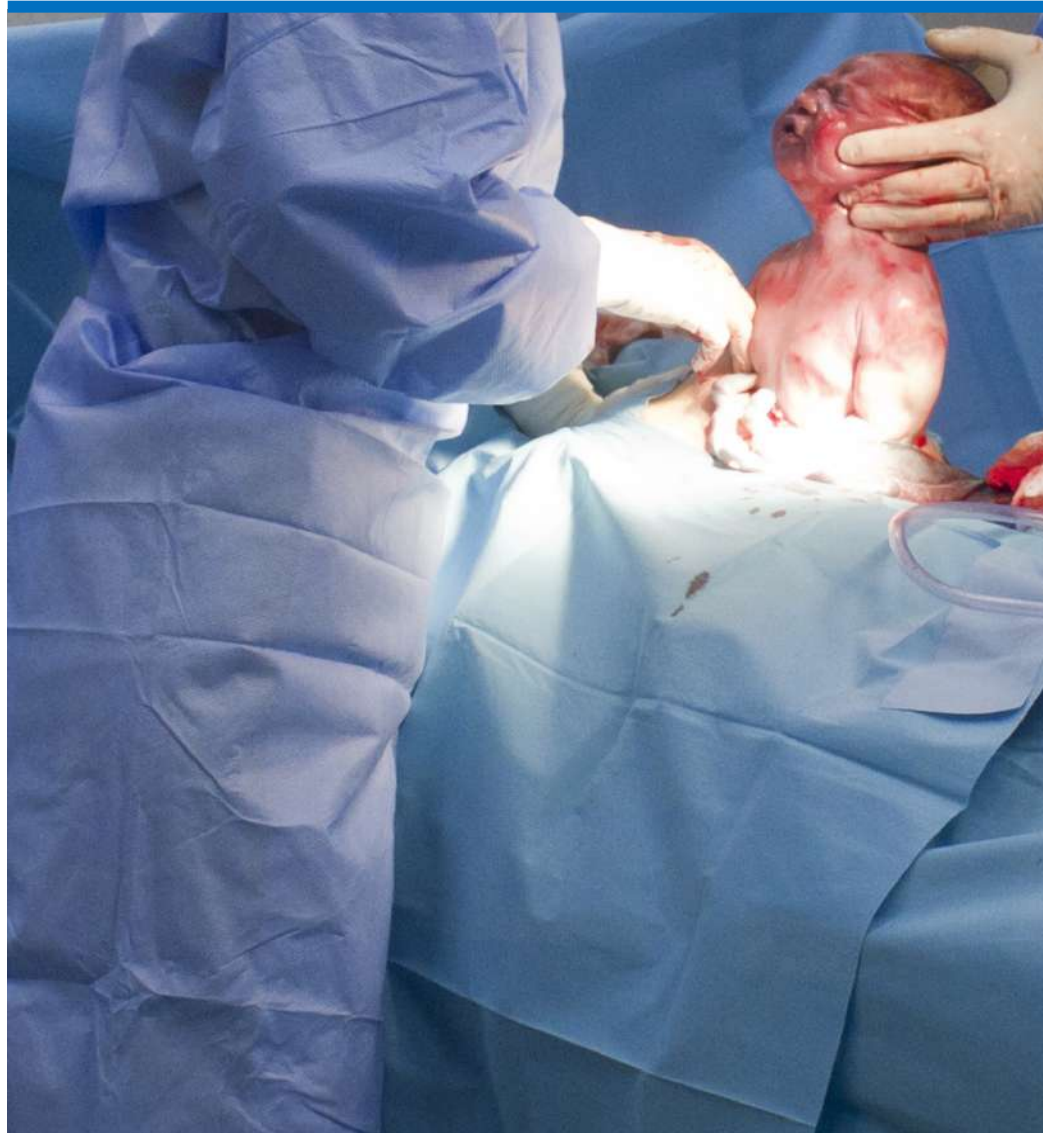


Microbiome concepts

Seeding inoculum



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Delivery mode shapes the acquisition & structure of initial bacterial microbiota

- Dominguez-Bello M, et al. Proc Natl Acad Sci 2010;107;11971-11975

- 16S rRNA NGS comparison between c-section & VB babies on:
 - Maternal vagina, skin & nasopharynx samples 1h before delivery
 - Baby skin & nasopharynx (<5 min after birth) & meconium (<24 hours after birth)
- Method of delivery determines the newborn's communities at all sites:
 - VB: all sites characterise the vaginal microbiota
 - C-section: all sites deprived & characterise maternal skin microbiota

Microbiome concepts

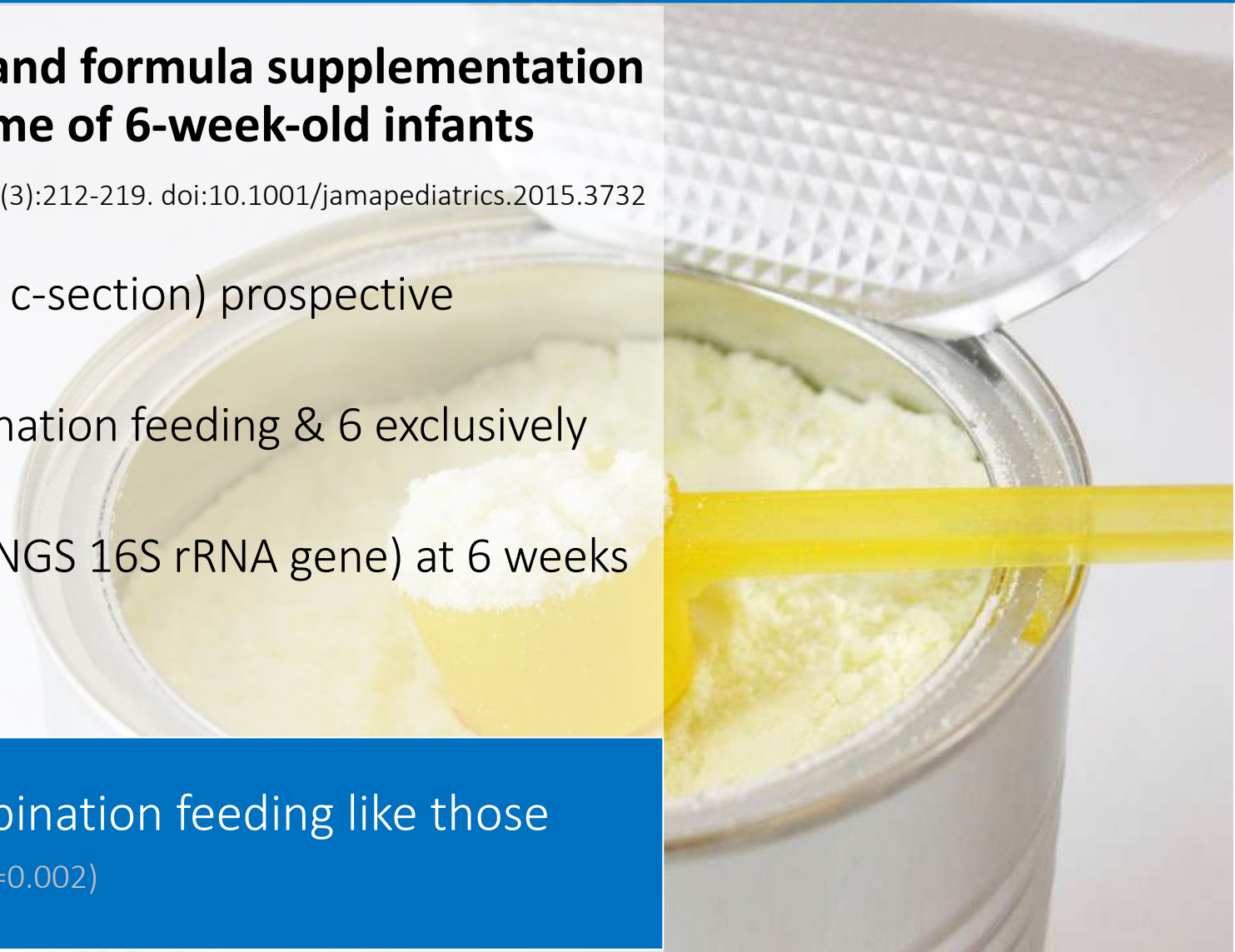
Altered microbiome after mixed feeding

Association of cesarean delivery and formula supplementation with the intestinal microbiome of 6-week-old infants

- Madan JC et al. JAMA Pediatr. 2016;170(3):212-219. doi:10.1001/jamapediatrics.2015.3732

- American birth cohort (70 VB & 32 c-section) prospective observational study
- 70 exclusively breastfed, 26 combination feeding & 6 exclusively formula fed
- Characterised faecal microbiome (NGS 16S rRNA gene) at 6 weeks

- Bacterial communities with combination feeding like those with exclusive formula feeding ($p=0.002$)





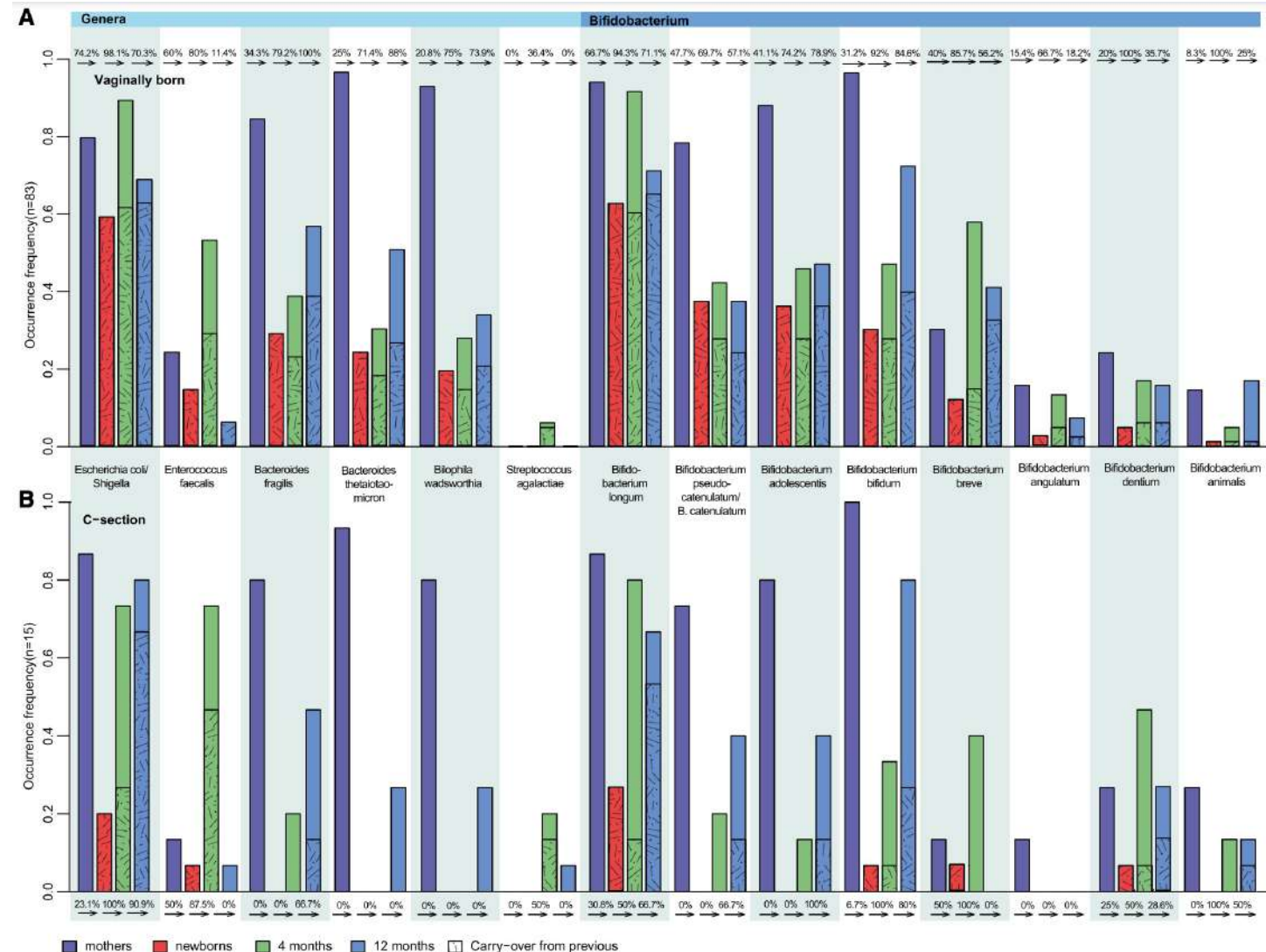
Microbiome concepts

Microbial succession after birth

Dynamics and Stabilization of the Human Gut Microbiome during the First Year of Life

- Bäckhed et al. Cell Host & Microbe 2015;17:690-703

- Metagenomic analysis on faecal samples
- n=98 Swedish mother-infant pairs
- Assessed impact of mode of delivery & feeding on microbiome assembly



Microbiome concepts

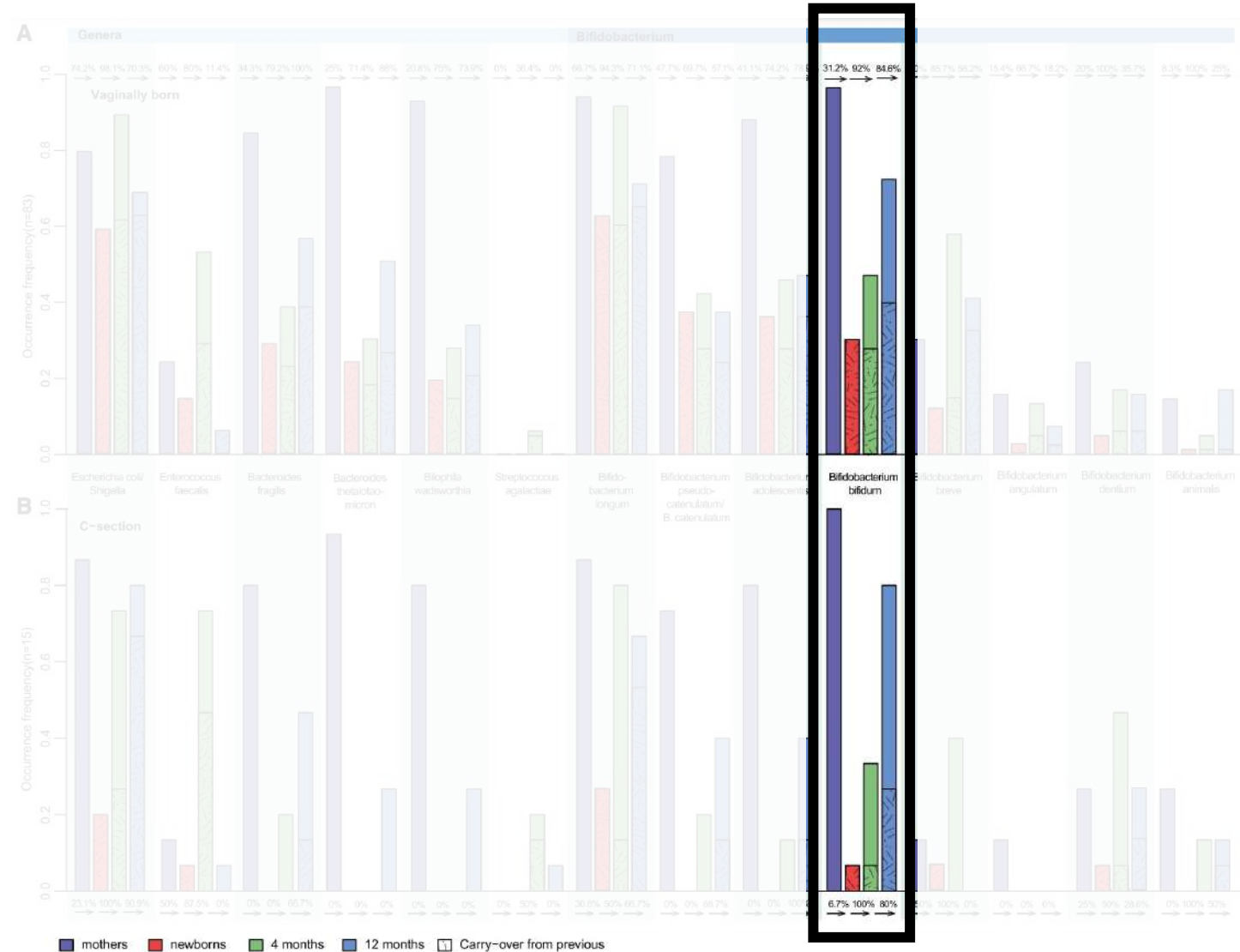
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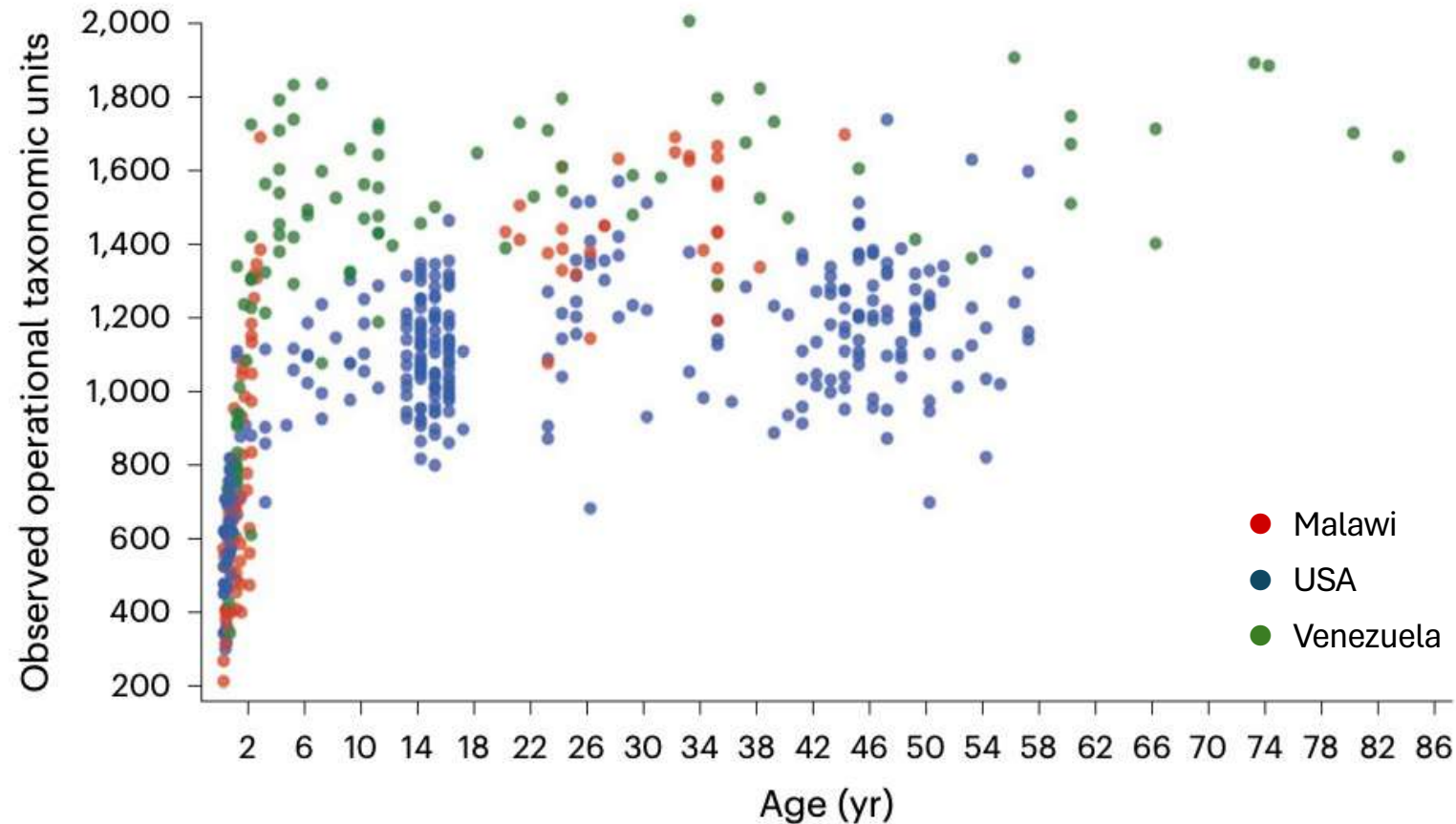
- Metagenomic analysis on faecal samples
- n=98 Swedish mother-infant pairs
- Assessed impact of mode of delivery & feeding on microbiome assembly

Cessation of breastfeeding required for maturation into adult-like microbiota



Microbiome concepts

The resulting microbiome



Human gut microbiome viewed across age and geography

- Yatsunenکو T, et al. Nature 2012;486:222-227

- Significant increase in diversity in first years of life
- Plateau in childhood

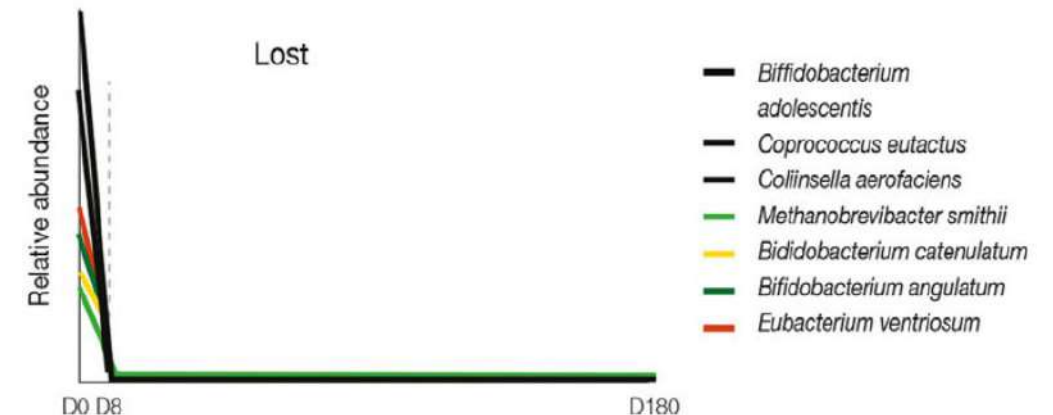
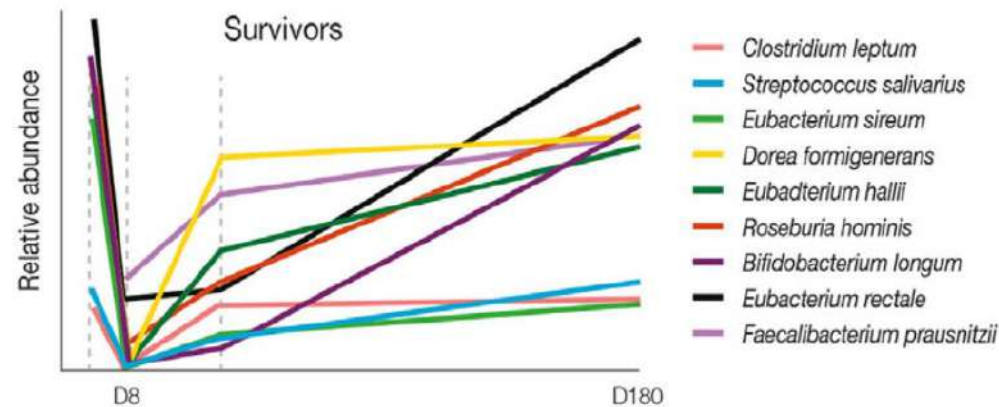
Microbiome concepts

Antibiotic disruption of the microbiome

Antibiotics as Major Disruptors of Gut Microbiota

- Ramirez J et al. Front. Cell. Infect. Microbiol. 2020. doi 10:572912 & Palleja A et al. Nat Microbiol. 2018;3:1255-1265

- After 4 days of antibiotic treatment:
 - Reduced diversity for 1.5 months
 - Several species remain undetectable after 180d



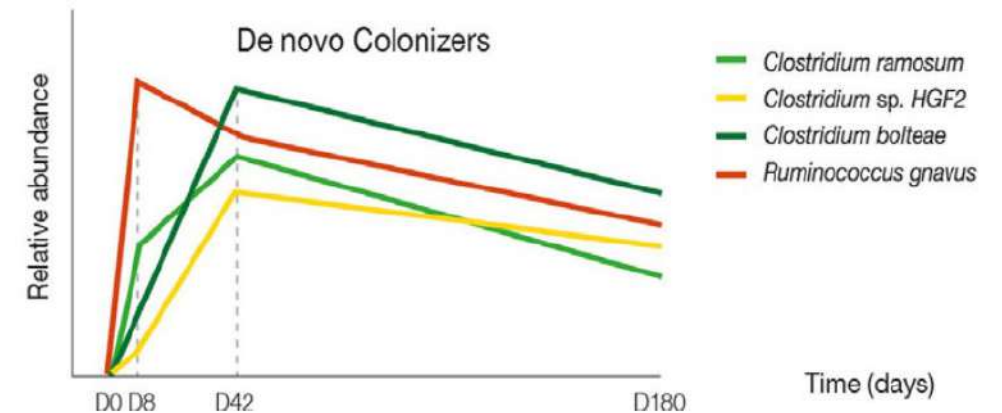
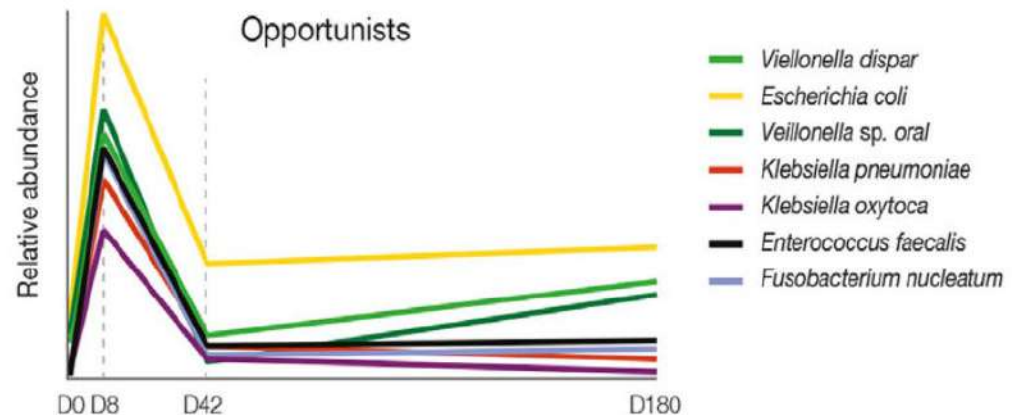
Microbiome concepts

Antibiotic disruption of the microbiome

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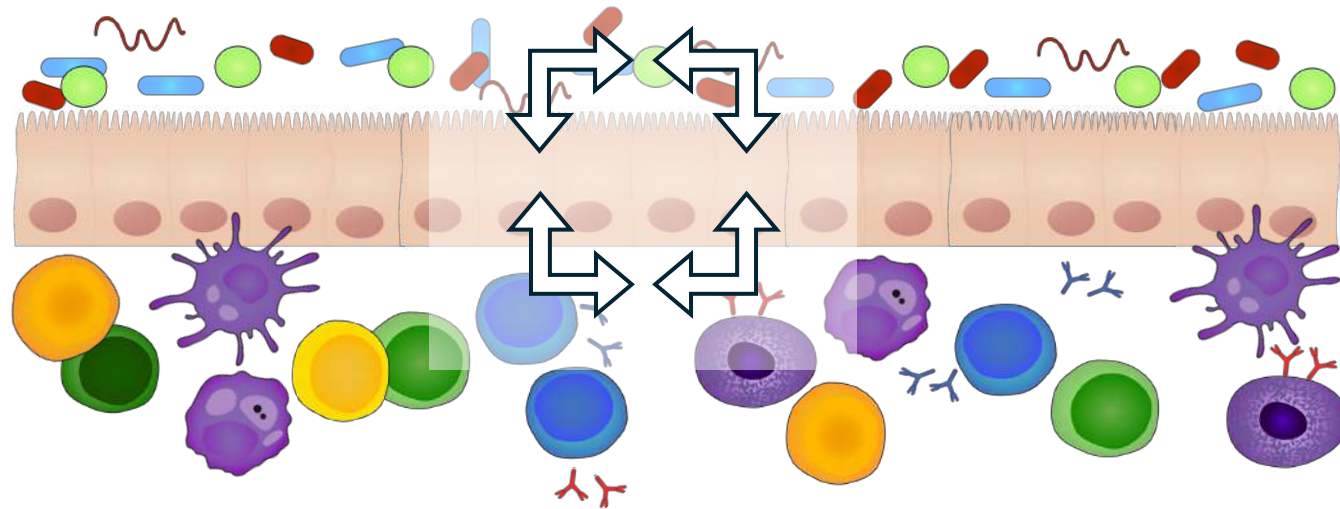
- Ramirez J et al. Front. Cell. Infect. Microbiol. 2020. doi 10:572912 & Palleja A et al. Nat Microbiol. 2018;3:1255-1265

- After 4 days of antibiotic treatment:
 - Reduced diversity \neq reduced total numbers
 - Opportunist emergence of antibiotic resistant strains
 - De novo colonisers



Microbiome concepts

Function of the human microbiome



Microbiome

Epithelial layer

Mucosa-associated immune cells

Microbiome concepts

Function of the human microbiome

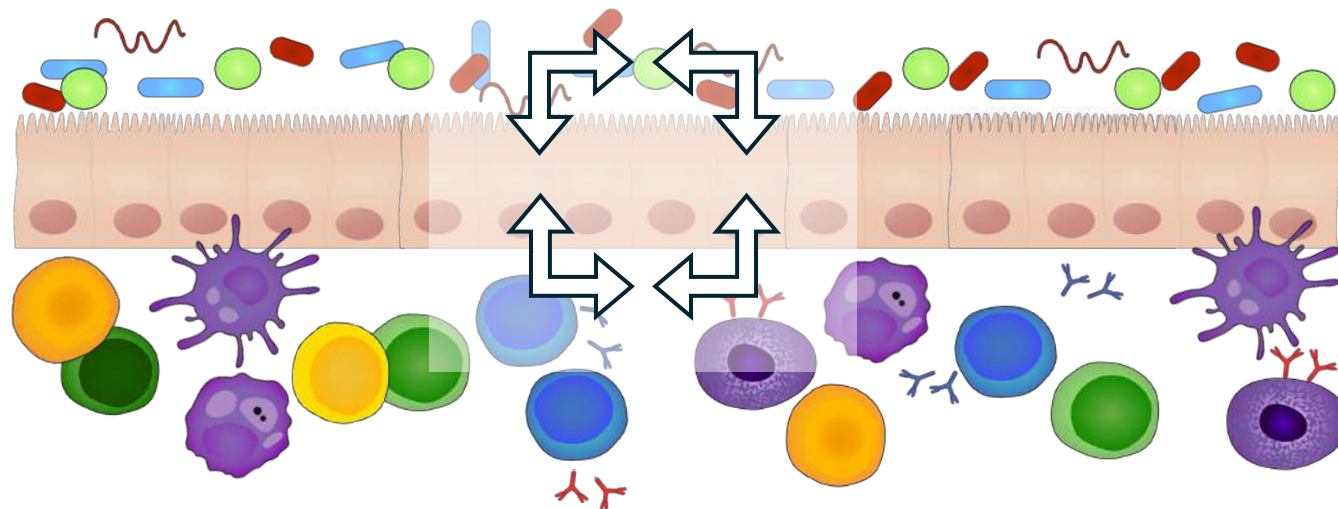
Complex interactions → important functional consequences

Physiologic processes:

- Competition
- Presentation of antigens
- Enzyme & biochemical pathways
- Biosynthesis & metabolism
- Secretion
- Fermentation, nutrient & energy extraction
- Stimulation
- Induction
- Regulation

Local consequences

Systemic & peripheral consequences

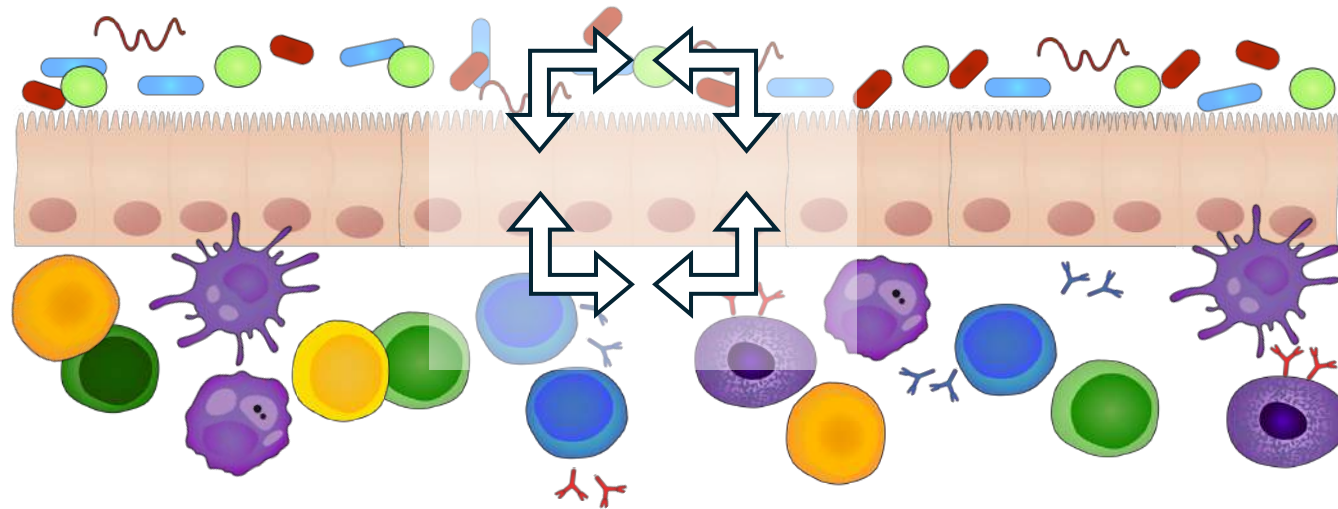


Microbiome concepts

Function of the human microbiome

Local
consequences

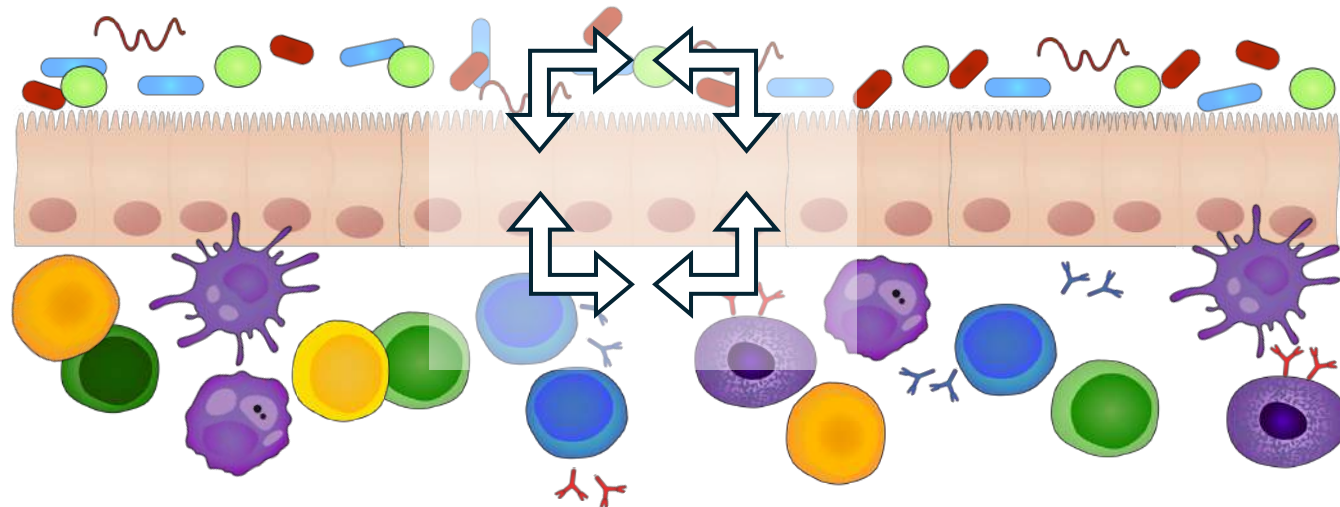
Systemic &
peripheral
consequences



Microbiome concepts

Function of the human microbiome

Local consequences



- Outcompete pathogens
- Stimulate IgA secretion
- Antimicrobial compounds
- Induce antimicrobial proteins
- Synthesis of SCFA
- Vitamin K, B12 synthesis
- Ca, Fe, Mn absorption
- Polyphenol breakdown
- Choline & amino-acid breakdown
- Polyamine production
- Xenobiotic drug metabolism
- Maintain epithelial integrity
- Regulate crypt formation
- Stimulate peristalses
- etc.

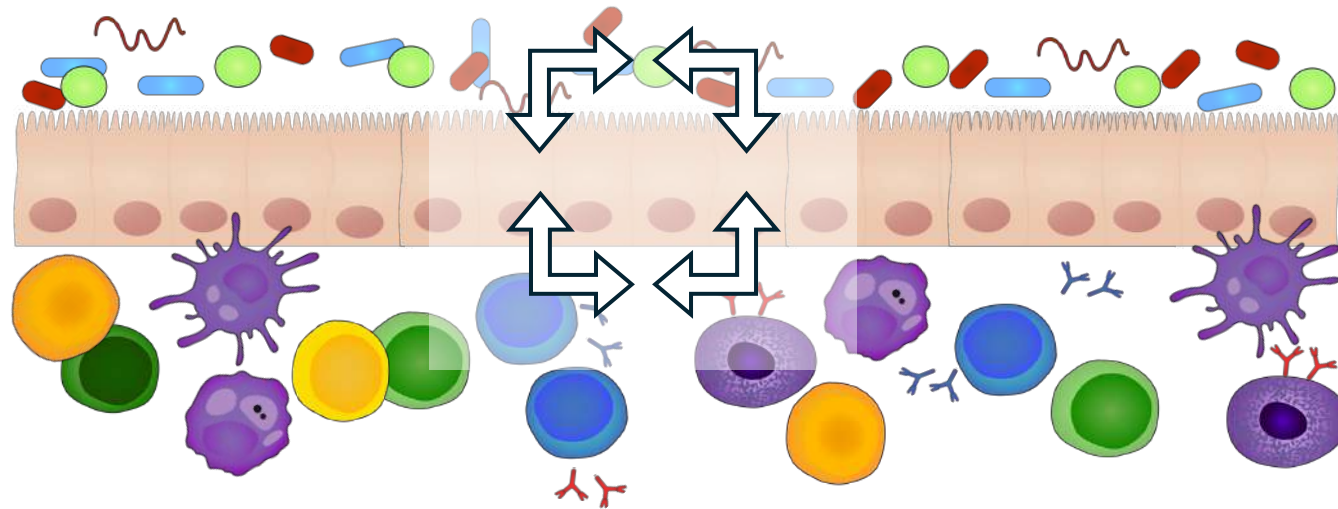


Microbiome concepts

Function of the human microbiome

Local
consequences

Systemic &
peripheral
consequences

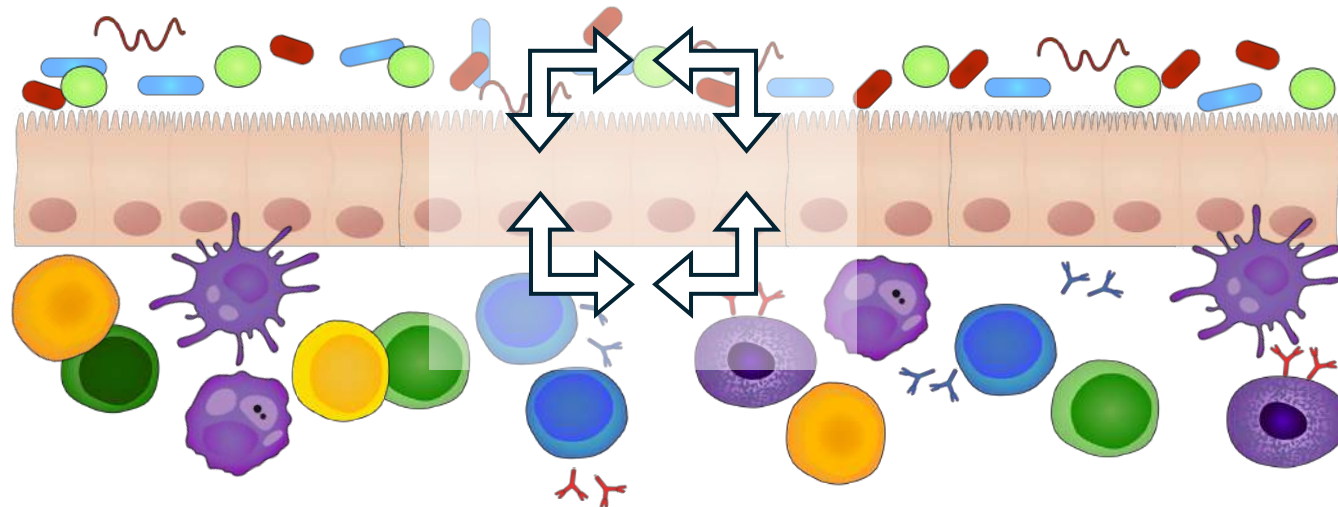


Microbiome concepts

Function of the human microbiome

Systemic & peripheral consequences

- Immune regulation:
 - Innate & adaptive immune development
 - Express tolerance transcription factors & cytokine profiles
- Gut-Brain axis:
 - Neurophysiology & anatomy
 - Mood, anxiety, behaviour
 - Cognition
- Gut-lung axis:
 - Asthma
 - Allergic rhinitis
 - Airway infection
- Metabolic syndrome:
 - Obesity
 - Diabetes mellitus
 - Non-alcoholic liver steatosis
 - Atherosclerosis



The microbiome & probiotics in clinical practice – the way forward

Summary



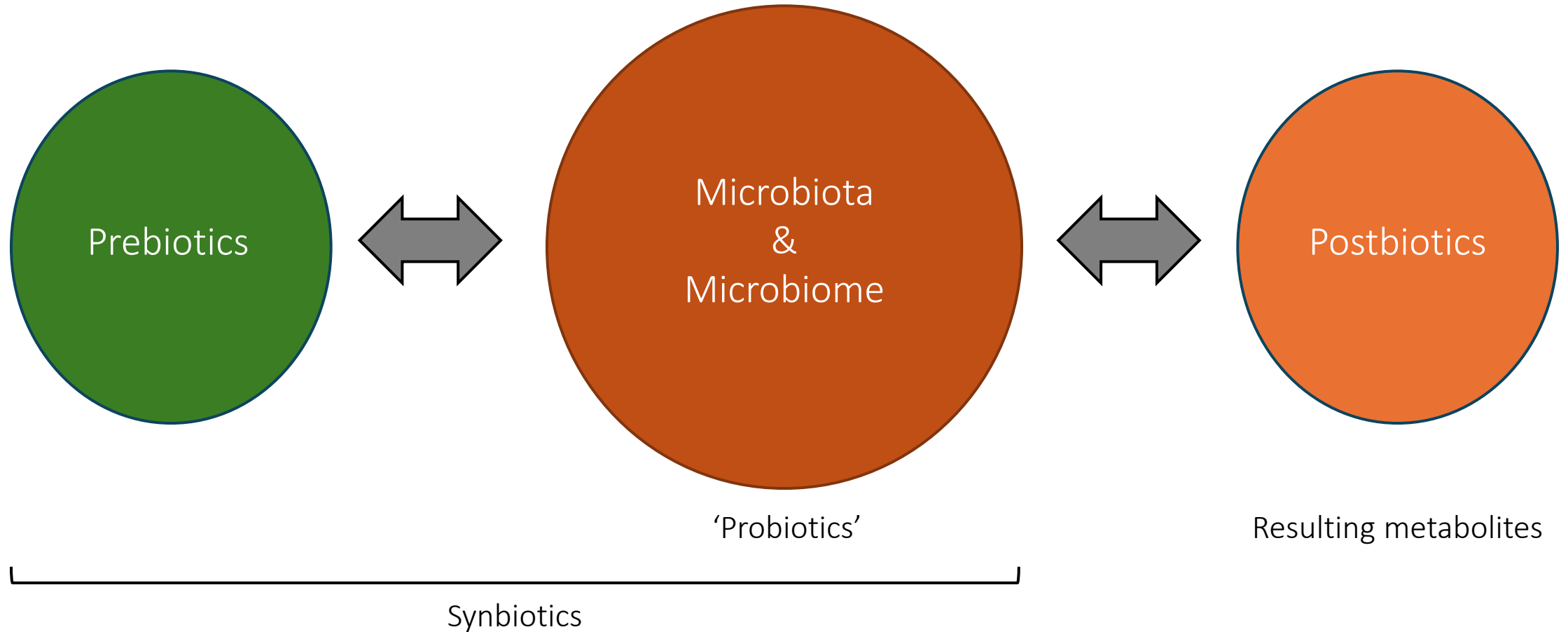
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Defining probiotics

Pre-, Pro-, Syn- & Postbiotics





Defining probiotics

What defines a probiotic?

‘Live microorganisms which, when administered in adequate amounts confer a health benefit on the host.’

- Joint working group of the Food and Agricultural Organization of the United Nations and World Health Organization.
<ftp://ftp.fao.org/es/esn/food/wgreport2.pdf>

- Essence of probiotics: microbial; alive; beneficial to health; dose-dependent

Defining probiotics

‘Contains live probiotics’

‘Probiotic’ reserved for specifically identified live microbial strains shown in controlled human trials to defer **general** or **specific** health benefits to the recipient when administered at an effective dose.

‘Live cultures’



Defining probiotics

Regulatory environment

- Regulatory guidelines are complex & not standardised (globally)
 - Marketed as dietary supplements
- Lacking 3rd party regulation
- Probiotic drug labels must specify:
 - Ingredients & allergens
 - Genus, species (subspecies) & alphanumeric identification of the specific probiotic strain
 - Viable CFUs as total count & counts for each strain guaranteed until expiry date
 - Dose to be consumed daily
 - Specific health claim / indication
 - Storage requirements
 - Expiry date
 - Company contact for info & AE reporting





Defining probiotics

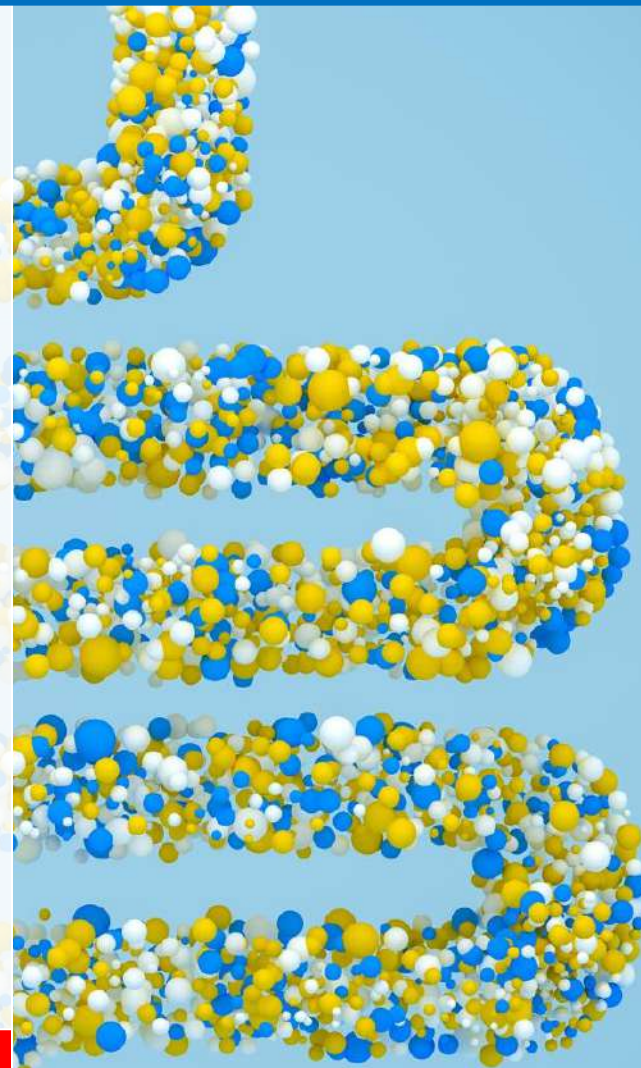
Probiotic drugs in South Africa

An evaluation of nine probiotics available in South Africa

- Elliot E et al. S Afr Med J. 2004;94:121-4

- Evaluation of 9 products available in SA:
 - Poor correlation between advertised & determined content
 - $\frac{3}{9}$ contained the probiotics indicated on label
 - Found potential pathogens in $\frac{2}{9}$

Find a trusted manufacturer first!



Defining probiotics

Probiotic safety



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- Generally considered as safe:
 - Isolated from fermented food or the human gut microbiota
 - Pathogenic potential considered low
- Reporting on safety often lacking
- Administering living microbes can be unsafe in:
 - Immune compromised
 - Underlying serious diseases
 - Infants

The microbiome & probiotics in clinical practice – the way forward

Summary



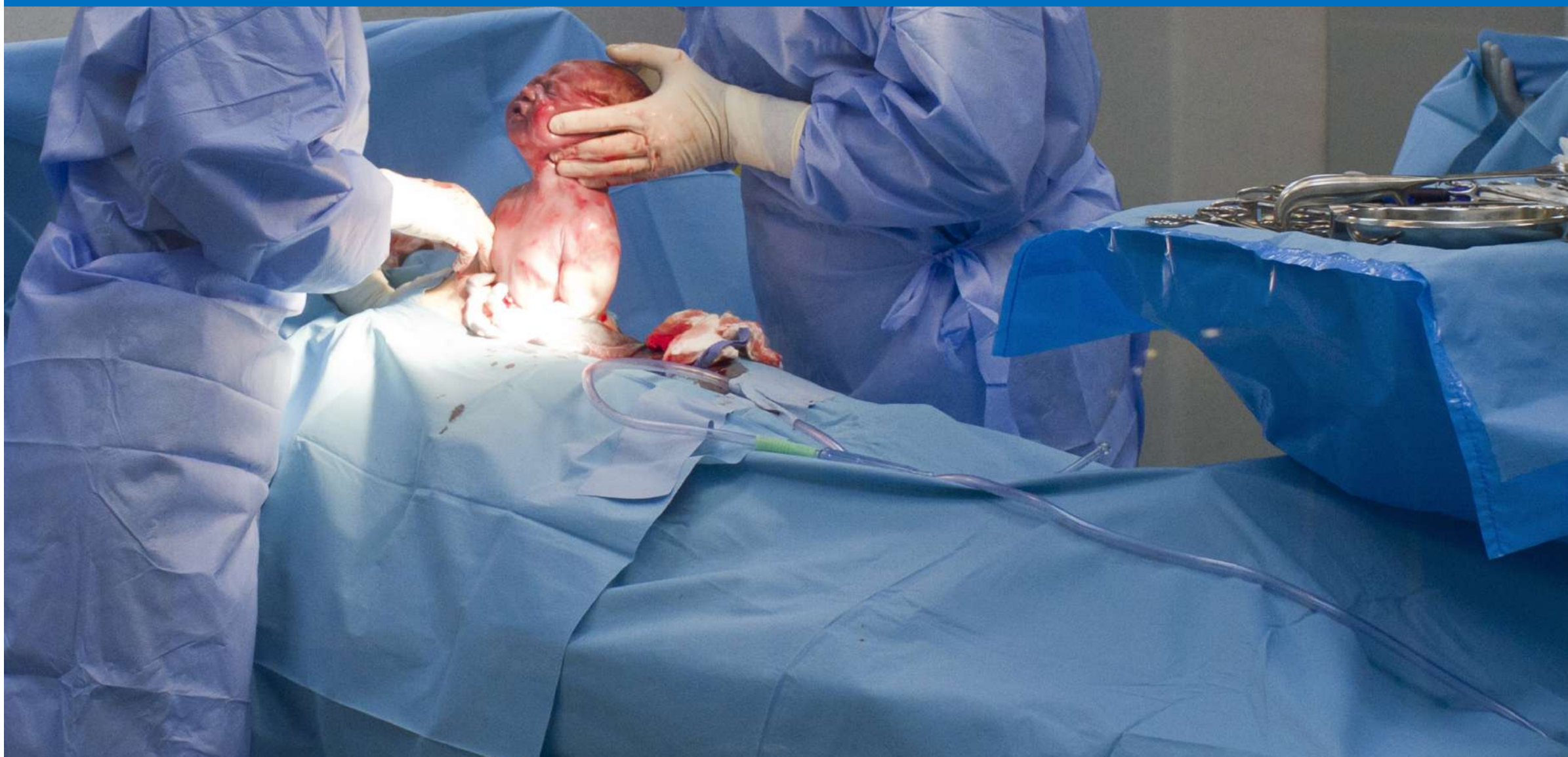
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Guideline-based probiotic prescription To remedy iatrogenic harm to the microbiome



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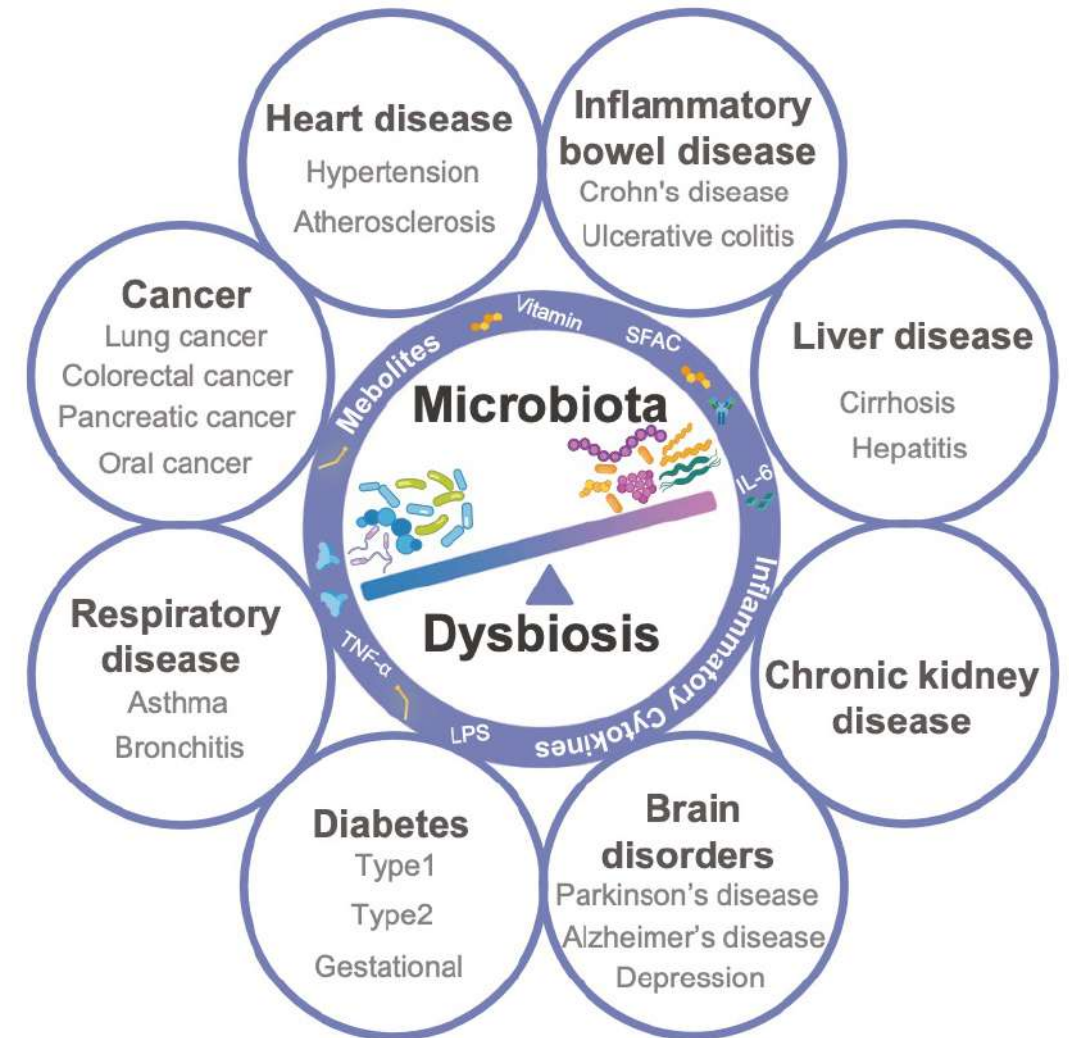
Guideline-based probiotic prescription

Microbiome associated disease

Microbiota in health and diseases

- Hou K, et al. Signal Transduct Target Ther. 2022;7:135. doi:10.1038/s41392-022-00974-4

- Affected by a myriad of variables:
 - Defining specific tipping points remain unclear
- Disease may be associated with:
 - Loss of beneficial functions
 - Introduction of maladaptive functions



Not a matter of one prescription fits it all!

Guideline-based probiotic prescription

Probiotic classes



Property	Yeast probiotic	Bacterial probiotic	Spore probiotic
• Viability in GI environment ¹	Unaffected	Limited	Unaffected
• Hinders pathogen adhesion ¹	More effective due to its larger size	Less effective	Effective
• Use with antibiotics ^{2,3}	Naturally resistant	Limited efficacy	Multi-drug resistant
• Interaction with normal gut microbiota ^{3,4}	None (not normally present in the human gut)	Can cause subtle changes in the balance	None

1. Pois P et al. J Fungi 2020;6:78 2. Kelsside T et al. Therap Adv Gastroenterol. 2012;5:111-125 3. 3. Vandenplas Y. Bacteria. Clin Microbial Infect. 1999;5:299-307; 4. Kho ZY et al. Front Microbiol 2018;9:1835

Guideline-based probiotic prescription

Prescriptions for 'improved health' claims

- 'Improved gut health':
 - Can be ascribed to probiotics in general
 - Non-strain specific claims e.g. Bifidobacterium & Lactobacillus at 1×10^9 CFU per intake
- Not plausible to make such claims for most indications (e.g. improved immune health)



Guideline-based probiotic prescription

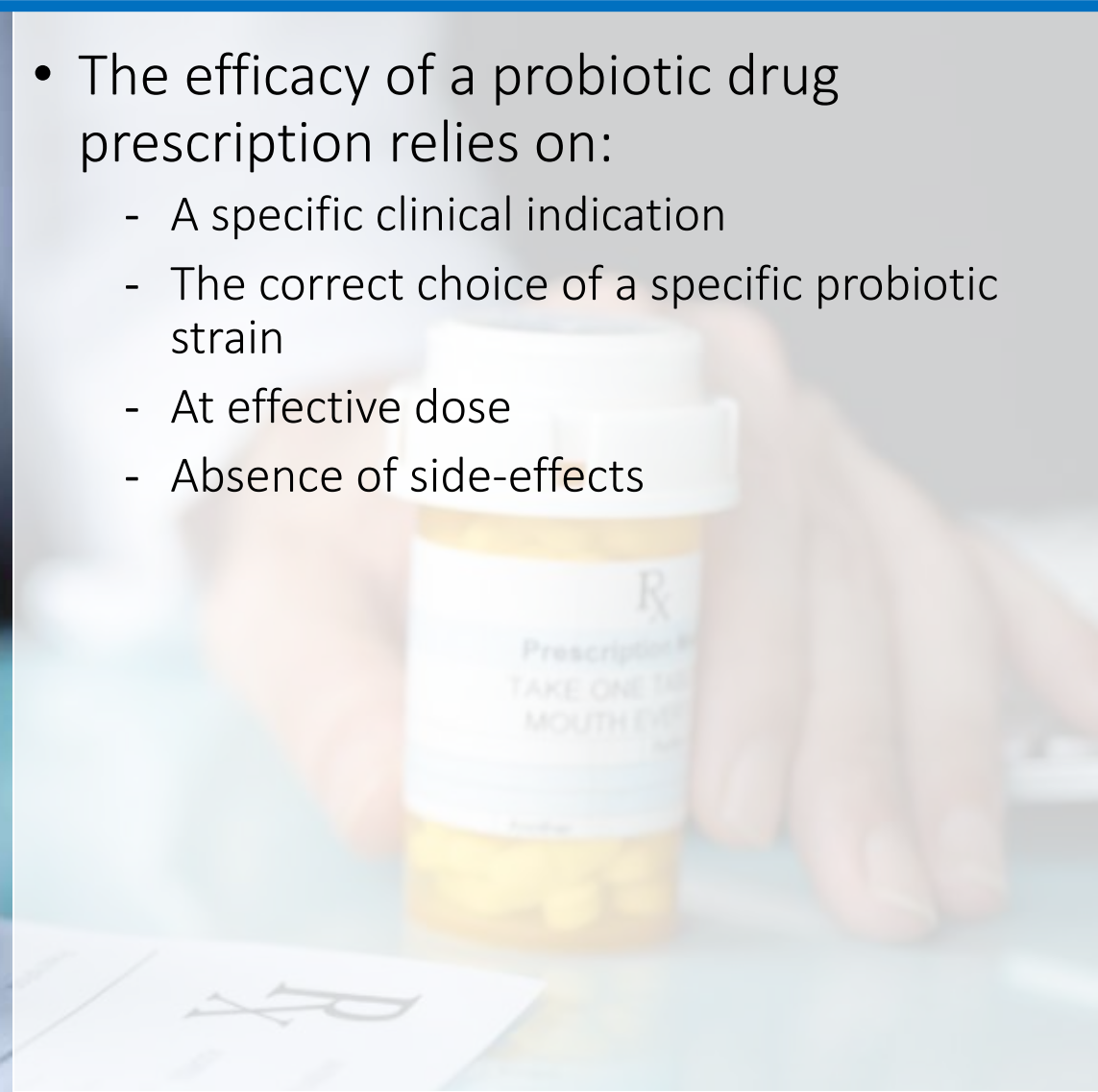
Prescriptions for specific medical indications



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- The efficacy of a probiotic drug prescription relies on:
 - A specific clinical indication
 - The correct choice of a specific probiotic strain
 - At effective dose
 - Absence of side-effects





Guideline-based probiotic prescription

Prescriptions for specific medical indications



- Obstacles to an effective prescription:
 - Unsubstantiated claims
 - Low-quality evidence
 - Heterogeneity of trial designs resulting in inconclusive meta-analyses
 - Die-off during storage
 - Contamination
 - Lacking quality control
 - Under-reporting of side-effects
 - Lacking 3rd party oversight

Lacking 3rd party regulatory oversight raises scepticism & haunts the benefits of probiotic drugs

Guideline-based probiotic prescription

Prescriptions for specific medical indications



Indication	ESPGHAN recommendation (Quality of evidence)	AGA recommendation (Quality of evidence)
Treatment of acute infective diarrhoea	Conditional weak (low)	None (moderate)
Prevention of antibiotic associated diarrhoea	Conditional to strong (moderate)	Conditional for specific probiotics (low)
Treatment of Clostridioides difficile-associated diarrhoea		Only in context of a clinical trial (knowledge gap)
Treatment of Crohn's disease	None	None (knowledge gap)
Treatment of ulcerative colitis	None	None (knowledge gap)
Treatment of pouchitis	None	Conditional for specific 8-strain probiotic drug (very low)
Treatment of irritable bowel syndrome	None	Only in the context of a clinical trial (knowledge gap)
Prevention of necrotising enterocolitis in premature infants <37w	Conditional (low)	Conditional for specific probiotic drugs (moderate /high)
Treatment of infant colic	Conditional weak for breastfed infants (moderate)	
Prevention of infant colic	None	
Eradication of Helicobacter pylori	Conditional weak (very low)	
Reduction of pain intensity in functional abdominal pain disorders	Conditional weak (moderate)	
Treatment of functional constipation	Weak (moderate)	
Management of celiac disease, small intestinal bacterial overgrowth & pancreatitis	No evidence	

 Children only

 Children & adults



Guideline-based probiotic prescription

Probiotic prescription for the prevention of AAD

Probiotics for the prevention of pediatric antibiotic-associated diarrhea

- Goldenberg J, et al. Cochrane Database of Systematic Reviews 2019, Issue 5. Art. No.: CD004827

- Objective:
 - Assess efficacy & safety of probiotics (any specified strain or dose) used for the prevention of AAD in children
- Included:
 - n=33 trials involving 6,352 patients (2w-17y)
 - Reported treatment with *Bacillus* spp., *Bifidobacterium* spp., *Clostridium butyricum*, *Lactobacilli* spp., *Lactococcus* spp., *Leuconostoc cremoris*, *Saccharomyces* spp., or *Streptococcus* spp., alone or combinations
- Main results:
 - AAD in control group → 19% (598/3120)
 - AAD in the probiotic group → 8% (259/3232)
 - 33/33 trials → precise benefit in favour of adding probiotics to prevent AAD (moderate-certainty evidence)



Guideline-based probiotic prescription

Probiotic prescription for the prevention of AAD

Effect of adding probiotics to an antibiotic intervention on the human gut microbial diversity and composition: a systematic review

- Fernández-Alonso M, et al. J Med Microbiol 2022;71. doi: 10.1099/jmm.0.001625

- Aim:
 - To evaluate whether co-prescription of probiotics with antibiotics can revert the changes in alpha diversity & gut microbial composition observed in adult participants receiving antibiotics
- Methods:
 - n=29 studies
- Conclusion:
 - Probiotic co-prescription seems to preserve alpha diversity & ameliorate antibiotic induced gut microbial changes





Guideline-based probiotic prescription

Probiotics for prevention of allergy

World Allergy Organization-McMaster University Guidelines for Allergic Disease Prevention (GLAD-P): Probiotics

- Fiocchi A, et al. World Allergy Organ J 2015;8:4. doi: 10.1186/s40413-015-0055-2

- Systematic review process → evidence-based recommendations on the use of probiotics to prevent allergy in children
- No evidence to support probiotic supplementation for allergy prevention
- A likely net benefit resulting primarily from prevention of eczema
- The WAO guideline panel in favour of using probiotics:
 - In pregnant women at high risk for having an allergic child
 - In woman breastfeeding infants at high risk of developing allergy
 - In infants at high risk of developing allergy
- Conditional recommendations (low quality evidence)



WORLD ALLERGY ORGANIZATION

A World Federation of Allergy, Asthma
& Clinical Immunology Societies



Guideline-based probiotic prescription

Vaginal seeding & FMT after c-section birth



- Vaginal seeding:
 - Pilot study: 18 deliveries
 - Vaginal seeding to mouth, face & body of baby via vaginal gauze swab
 - Partial restoration was possible via vaginal microbial transfer
 - Dominguez-Belo M et al. Nat Med 2016;22:250-253
- Breast milk supplemented FMT:
 - Proof of concept study
 - Maternal to infant FMT can restore c-section associated microbiome harm
 - Korpela K et al. Cell 2020;183:324-334

ACOG Committee opinion: Vaginal seeding should not be performed outside of an institutional review board-approved research protocol

The microbiome & probiotics in clinical practice – the way forward

Summary



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- Introduction
- Microbiome concepts
- Defining probiotics
- Guideline-based probiotic prescription
- Key points

Conclude Dysbiosis



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Dysbiosis associated with
compromised short- &
long-term health
outcomes



Conclude

Microbiome preservation



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Ecologically engineered by our mothers, method of birth, nutrition & early life events



Need strategies to effectively landscape our microbial communities

Conclude Uncertainty



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Rapidly changing field of science



Still shrouded in uncertainty, controversy &
conflicting results



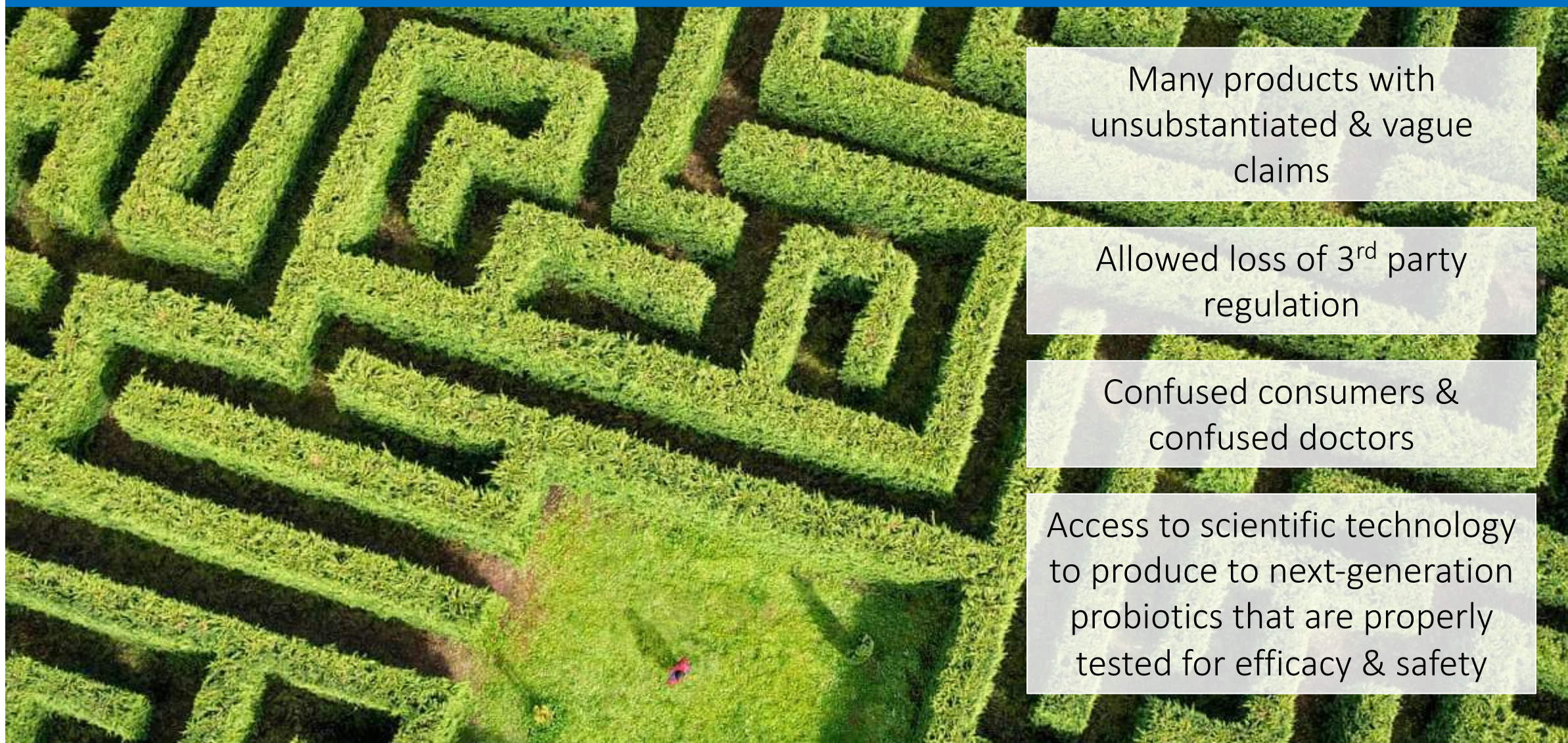
Appreciate the difference between
association & causality





Conclude

Time for next-generation probiotics



Many products with unsubstantiated & vague claims

Allowed loss of 3rd party regulation

Confused consumers & confused doctors

Access to scientific technology to produce to next-generation probiotics that are properly tested for efficacy & safety

Conclude Dawn of a new era



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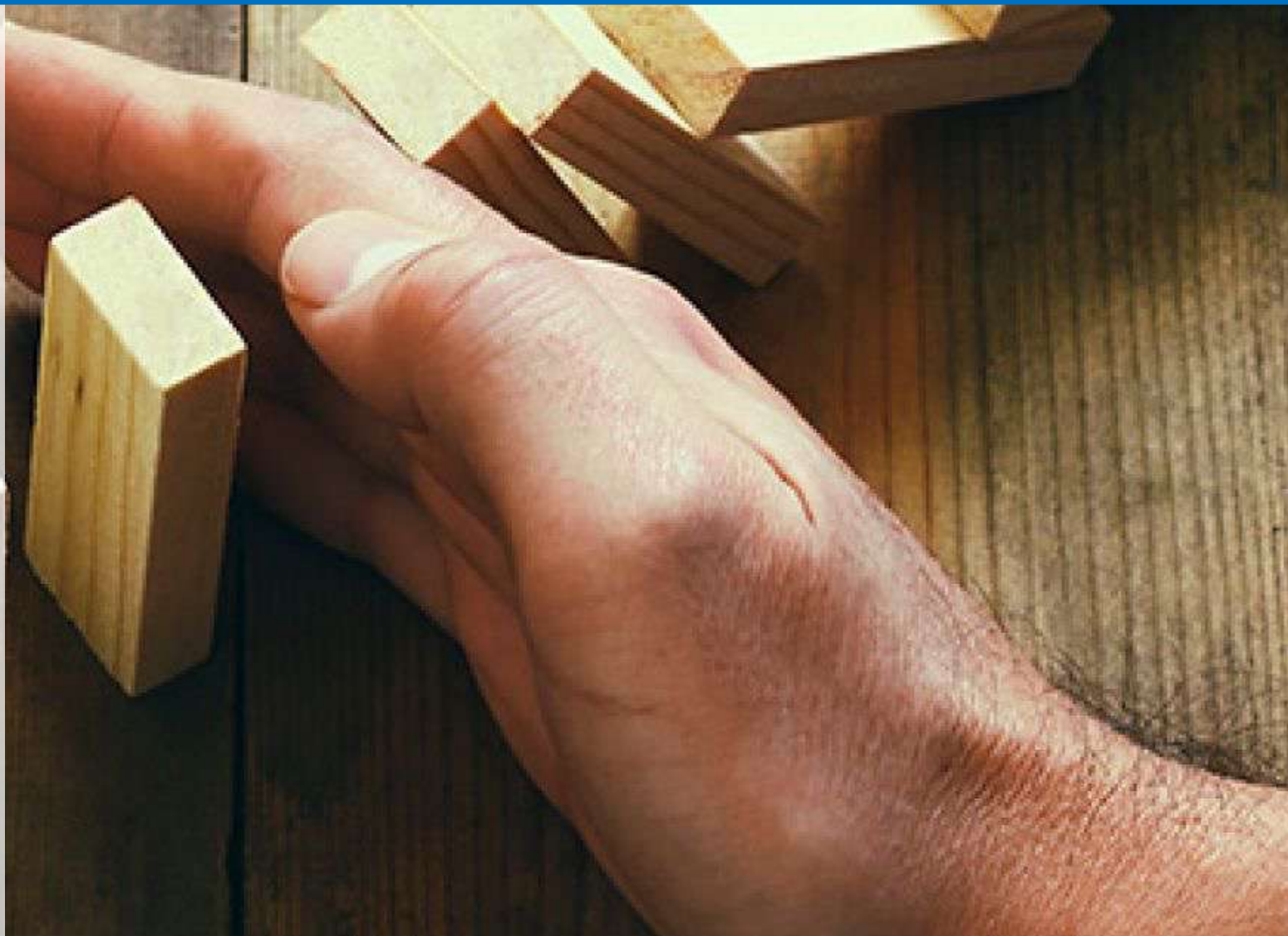


Next-generation probiotics should play an important role in the future of good medicine

Conclude

In the meantime, . . .

- In patients' interest to use probiotic drugs when the evidence is convincing
- 'Become the 3rd party regulator':
 - Choose a reliable supplier
 - Learn about product-specific research, indications & side-effects
 - Prescribe for the intended indication (not in general)
 - Select the correct dose





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The microbiome & probiotics in clinical practice – the way forward

Thank you



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Ampath National Laboratories

ALLSA Executive & PIDDSA Team

UP Department of Paediatrics

UP Department of Immunology

World PI week

Systemic corticosteroids in IEI



World PI Week

Test. Diagnose. Treat.

22-29 April 2024