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Narrative review

Microbiome research in practice: priorities for clinical translation and impact

Anastasia A. Theodosiou [1,*], Debby Bogaert [2], David W. Cleary [3], Paul-Enguerrand Fady [4], Conor Feehily [1], Jack A. Gilbert [5], Beth Greenhough [6], Luca Guardabassi [7], Lindsay J. Hall [8], Toni Harman [9], Ed J. Kuijper [10], Sarah Lebeer [11], Jamie Lorimer [6], Tim D. Spector [12], Chrissie E. Jones [13]

[1] School of Infection and Immunity, University of Glasgow, Glasgow, UK
[2] Centre for Inflammation Research, University of Edinburgh MRC Centre for Inflammation Research, Edinburgh, UK
[3] Institute of Microbiology and Infection, University of Birmingham, Birmingham, UK
[4] Centre for Long-Term Resilience, Biosecurity Policy, England, UK
[5] Microbiome and Metagenomics Center, University of California San Diego, La Jolla, CA, USA
[6] School of Geography and the Environment, University of Oxford, Oxford, UK
[7] Department of Veterinary and Animal Sciences, University of Copenhagen, Copehnagen, Denmark
[8] Department of Microbes, Infection and Microbiomes, University of Birmingham, Birmingham, UK
[9] Alto Films, Microbirth, UK
[10] LUMC, Medical Microbiology, Leiden, The Netherlands
[11] Bioscience Engineering, University of Antwerp, Antwerp, Belgium
[12] Department of Twin Research and Genetic Epidemiology, King's College London, London, UK
[13] Clinical and Experimental Sciences, University of Southampton, Southampton, UK

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ABSTRACT

Background: Rapid advances in microbiome science have sparked clinical and commercial enthusiasm for interventions, yet translation into practice risks outpacing both mechanistic understanding and the infrastructure required for safe adoption.

Objectives: To outline a coordinated research, clinical, social, and policy agenda for advancing safe, effective, and equitable microbiome-based interventions.

Sources: We convened an interdisciplinary Royal Society-funded expert workshop (Leeds, UK, October 2024) with international leaders in microbiome science, clinical trials, regulation, and social science. Thematic analysis of workshop discussions and written contributions identified priority domains for translation.

Content: Three intersecting priorities emerged: scientific credibility, practical viability, and stakeholder engagement. Scientific credibility demands investment in multiomic and strain-level characterization of host-microbiome interactions on a large scale, benchmarking of clinical and microbiological endpoints, and harmonization of trial conduct and reporting. Clinical adoption requires fit-for-purpose regulation, diversified investment to address funding bottlenecks, and coordinated capacity building. Meaningful stakeholder engagement with clinicians, patients, policymakers, and the public is essential to foster confidence, develop clinically relevant research questions, and ensure equitable implementation of any new technology.

Implications: To realize the clinical impact of microbiome interventions, sustained collaboration across disciplines is essential. This review offers a translational roadmap and actionable priorities to accelerate safe, effective, and equitable microbiome-based interventions—ensuring the field fulfils its clinical potential and delivers real-world impact. **Anastasia A. Theodosiou, Clin Microbiol Infect 2026;▪:1**

* Corresponding author: Anastasia A. Theodosiou, School of Infection and Immunity, University of Glasgow, Sir Graeme Davies Building, 120 University Place, Glasgow G12 8TA, UK.
E-mail address: anastasia.theodosiou@glasgow.ac.uk (A.A. Theodosiou).

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Introduction

The microbiome is increasingly recognized as a modifiable determinant of health, and recent years have seen a welcome shift in focus from observed associations to mechanistically informed clinical interventions [1]. Faecal microbiota transplantation (FMT) is now embedded in clinical guidelines for recurrent *Clostridioides difficile* infection (CDI) [2], and the first licensed medicinal products derived from healthy stool donors have reached the market [3]. Several live biotherapeutic products (LBPs) have now completed phase 2 trials for conditions including CDI, inflammatory bowel disease, rheumatoid arthritis, type 2 diabetes, and graft-versus-host disease [4,5]. Trials are also underway testing the clinical utility of prebiotics (microbe-specific nutrients), postbiotics (microbial metabolites), synbiotics (mixtures of live microbes and their nutrients) [6,7], and dietary interventions [8]. Although most research focuses on the gut microbiome, there is also growing interest in modulating the respiratory, urogenital, and skin microbiomes to improve health [9,10].

Beyond therapy, microbiome characterization also holds promise for disease prediction and diagnosis, with independently validated machine learning models demonstrating predictive accuracy for colorectal cancer, inflammatory bowel disease, and cardiovascular disease [11]. Moreover, microbiome interventions are being explored across broader One Health contexts, including tackling antimicrobial resistance in livestock, suppressing root diseases in plants, and addressing ecological and agricultural challenges [12]. In veterinary medicine, clinical guidelines recommend FMT as an adjunctive microbial-directed therapeutic for canine parvovirus enteritis, canine acute diarrhoea, and chronic enteropathy in both dogs and cats [13].

Despite this progress, barriers to meaningful clinical application persist. International regulation of microbiome-based therapies remains fragmented [14], and consensus is lacking across core scientific concepts including definitions of microbiome health [15], choice of biomarkers [16], methodological standards [17], and assessment of safety [18]. Meanwhile, public and commercial interest continues [19], with enthusiasm often surpassing available evidence and infrastructure. For example, the proliferation of direct-to-consumer microbiome testing has prompted concerns around interpretability, reproducibility, and clinical oversight [20,21].

To move from promise to practice, microbiome-based interventions must be grounded in robust, hypothesis-driven science, evaluated through reproducible clinical trials, and implemented via effective and equitable systems. At the same time, they must be acceptable to end users, including patients, clinicians, and policymakers. Clinical translation therefore demands a coherent interdisciplinary agenda to bring about scientific innovation, coordinated regulation, sustainable funding, and meaningful longitudinal stakeholder engagement.

To define actionable priorities, we convened a Royal Society-funded expert workshop in October 2024, including international leaders in microbiome science, clinical trials, regulation, and social science. Although informed by speaker presentations and facilitated discussions, this article is not a proceedings report; rather, it synthesizes thematic analysis of audio-recorded discussions, presentations, and anonymized written contributions from speakers and delegates (Appendix A). The resulting manuscript provides a roadmap for translational readiness, and our recommendations span three intersecting priority domains: scientific credibility, practical viability, and stakeholder engagement (Box 1). This is a call to action for funders, regulators, researchers, and clinicians to align around a unified agenda aimed at unlocking the translational potential of the microbiome.

Priority 1: scientific credibility

Mechanistic insights and causality

Understanding how exactly the microbiome influences health and disease remains a central challenge demanding greater functional and phenotypic characterization of both individual microbes and microbial communities. Metagenomic and multiomic analyses, incorporating metatranscriptomics, metaproteomics, metabolomics, and metaculturomics, are increasingly applied for the discovery of mechanisms [22]. Looking ahead, we encourage approaches that apply quantitative analysis [23], differentiate live from dead organisms [24], consider 3D spatial biogeography [25], and include underexplored components such as fungi [26], viruses [27], phages [28], archaea [29], protozoa and helminths [30]. Although desirable and feasible, these approaches pose considerable technical, financial, and analytical challenges. Approach-specific considerations also underscore enduring disciplinary silos that fragment expertise, and highlight the pressing need for cross-specialty collaboration and education.

Translating any mechanistic discoveries into clinically meaningful insights requires careful consideration of confounding factors and rigorous validation. Diet, age, ethnicity, and comorbidities are important confounders that need to be considered, particularly where post-hoc microbiome analyses are performed opportunistically on existing datasets [31]. Furthermore, the broader human exposome—the cumulative set of environmental exposures across the life course—interacts dynamically with host and the microbiome, and should be considered when controlling for confounders and independently validating mechanistic work. On the other hand, although mechanistic insight is critical for biological understanding, it should not be a precondition for clinical application, provided an intervention's safety and efficacy can be reproducibly demonstrated.

Biomarkers and clinical endpoints

Defining robust microbial and clinical metrics is fundamental to translating microbiome science into clinical practice. Yet the field lacks consensus on which measures are meaningful, reproducible, and predictive of health outcomes. Commonly used indicators—such as alpha/beta diversity, relative abundance of taxa, or presence/absence of specific microbes—are convenient but poorly standardized across studies, and are rarely validated for diagnostic use. Different pipelines and algorithms generate divergent results, and the current flexibility often comes at the cost of collapsing biological complexity, resulting in poor specificity, sensitivity, and reproducibility across labs and studies [32].

To move beyond taxonomic profiling and blunt relative abundance metrics, microbiome research is increasingly shifting towards phenotypic and functional biomarkers that provide both mechanistic insight and clinical utility [4]. These include microbial gene transcriptional heterogeneity, strain-level genetic signatures, and metabolite production profiles. For example, microbe-derived short-chain fatty acids, which are integral to host immunity and metabolism, can be predicted using community-scale metabolic modelling approaches [33]. Advances in multiomic profiling allow simultaneous interrogation of microbial activity and host responses, improving the resolution of host-microbe interaction signatures [34]. In parallel, computational methods such as quantitative metagenomics and spike-in standards are helping to derive absolute abundances from compositional data, addressing long-standing analytical limitations and enabling more reliable

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Box 1
Expert recommendations to accelerate microbiome translational readiness

Priority 1: Scientific Credibility

Mechanistic Insights and Causality

- Prioritize causal understanding through multiomic analyses, spatial and longitudinal dynamics, live-dead differentiation, and inclusion of nonbacterial taxa (fungi, viruses, archaea, phages, helminths, and protozoa).
- Challenge entrenched disciplinary silos via deliberate cross-specialty collaboration.
- Do not allow mechanistic uncertainty to delay translation when safety and efficacy are well demonstrated.

Biomarkers and Clinical Endpoints

- Complement alpha diversity and single-taxon metrics with phenotypic and functional biomarkers (e.g. gene expression and metabolite profiles).
- Develop context-specific definitions of microbiome health using large, diverse cohorts and harmonized, comprehensive metadata curation.
- Adopt pluralistic outcomes that integrate microbial, clinical, behavioural, and societal endpoints.

Methodological Harmonization

- Promote transparent reporting (e.g. STORMS checklist and STAR protocols) and justification of methods over rigid standardization.
- Invest in harmonized training and open-access protocols to facilitate comparison and validation.
- Encourage preregistration, method comparison, and publication of negative results.

Clinical Trial Design

- Base trials on hypothesis-driven, niche-specific, and biologically plausible designs, rather than convenience or conventional wisdom.
- Improve representation across biological niches and underserved demographics.
- Embrace pragmatic designs for small-sample or hard-to-power trials, such as cross-over studies or meaningful meta-analysis.

Priority 2: Practical Viability

Regulation, Safety, and Quality Control

- Develop fit-for-purpose regulation to ensure safety without stifling innovation, aligning evidentiary standards with the ability to make health claims.
- Close gaps and inconsistencies between jurisdictions to promote equitable access across diverse patient groups and geographies (including low- and middle-income countries).
- Invest in manufacturing and quality control infrastructure, including Good Manufacturing Practice production facilities and harmonized viability and purity standards.

Funding*, Commercialization, and Intellectual Property*

- Reduce over-reliance on industry by increasing public and philanthropic investment in trial funding and infrastructure.
- Support national and international microbiome research clusters to share capacity-building and lower costs.
- Clarify intellectual property frameworks to allow innovation to flourish alongside open science.

Priority 3: Stakeholder Engagement

Embedding Social Science and Public Engagement

- Fund engagement work with public and social scientists, shaping research from design to dissemination.
- Actively address representational bias and avoid reductive, racially coded framings.
- Anchor communication in safety and evidence, avoiding moralization and hype.

Uptake into Policy and Clinical Practice

- Engage policymakers via concise, actionable briefs targeted at relevant committees and inquiries.
- Integrate microbiome science into medical education and professional training.
- Incorporate microbiome considerations into clinical practice and prescribing guidance.

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identification of biomarkers and threshold effects [23]. These advances are already facilitating reporting of common health ranked microbes, rather than change in diversity, in relation to health outcomes [35]. When validated in large, diverse, longitudinal cohorts with high-quality metadata, these tools have the potential to underpin predictive models of disease risk, enable therapeutic stratification, and assess intervention efficacy—thereby advancing the translational readiness of the field.

Rather than chasing universal biomarkers or a single definition of 'microbiome health', the field should shift towards stratified, context-specific profiles. These should account for age, sex, geography, and comorbidities [15]. Achieving sufficient granularity requires large discovery and validation cohorts, comprehensive metadata, better biobanking, and harmonized international consortia. Examples such as the Million Microbiomes from Humans Project reflect the desirability of this approach at scale.

It is also important to consider how microbiome endpoints function alongside clinical endpoints. For microbiome-based interventions intended to act upstream of symptomatic disease, early-phase trials may require endpoints that capture short-term, subclinical, or mechanistic changes in host-microbiome function. These are not proposed as substitutes for traditional outcomes (e.g. disease incidence, symptom burden, hospitalization, treatment response), which ultimately determine patient benefit and regulatory approval, but as translationally relevant intermediates that can de-risk and guide development of new treatment strategies. The nature of such endpoints will necessarily vary with disease and intervention. In gastroenterology, they may include strain engraftment (including abundance and duration of carriage), short-chain fatty acid production, mucosal immunophenotyping, and gut permeability markers, such as lipopolysaccharide binding protein [36]; in metabolic disease, improvements in insulin sensitivity or inflammatory tone; in allergy and immunology, desensitization profiles or cytokine responses; and in oncology, modulation of treatment toxicity or immunotherapy responsiveness. Conversely, clinical endpoints may capture benefit not evident microbiologically, such as reduction in antibiotic exposure, bacteraemia and length of stay after FMT in patients colonized with multidrug-resistant organisms, despite only modest decolonization rates [37].

From a translational perspective, the goal is therefore pluralistic and phased: mechanistic and subclinical endpoints can inform early efficacy and dose-finding, and help identify which interventions merit progression to larger trials powered for clinical outcomes, with the latter remaining essential for regulatory approval and clinical adoption.

Methodological harmonization

Heterogeneity in study methods remains one of the largest barriers to progress, with variability spanning every stage of the research pipeline: study design, sample handling, nucleic acid extraction, sequencing protocols, choice of controls (including synthetic microbial community standards), use of model organisms, bioinformatic pipelines, and data visualization. This impedes meta-analyses and reproducibility, and makes it difficult for scientists, clinicians, and regulators to reach consensus. Heartening progress has already been made towards greater methodological harmonization, including the International Human Microbiome Standards group, the Microbiome Quality Control project, the development of DNA and whole cell reference reagents for evaluating DNA extraction protocols, and the emergence of international knowledge-sharing networks such as EurFMT [17,38].

Yet, total harmonization is neither feasible nor desirable. Project-specific considerations—such as niche biomass, composition, or expected longitudinal dynamics—may necessitate different methods, and prescriptive guidelines risk stifling innovation in a rapidly evolving field. We advocate for a shift in norms: embracing diverse approaches alongside transparent reporting and justification of methods. Tools such as the STORMS (Strengthening The Organization and Reporting of Microbiome Studies) reporting checklist [39] and detailed STAR (Structured Transparent Accessible Reproducible) protocols [40] are an important step forward. Furthermore, we urge harmonized training through shared curricula, open-access protocols, and building a collective understanding of methodological trade-offs. Trial design and statistical analysis plans should be preregistered on platforms such as ClinicalTrials.gov, and negative results should be published. Machine learning may offer a partial solution by integrating heterogeneous datasets, although this cannot compensate for opaque upstream methods.

Clinical trial design

Although the above issues apply broadly across microbiome research, clinical trials introduce distinct challenges. Intervention type—whether LBPs, probiotics, prebiotics, postbiotics, synbiotics, phages, diet, or FMT (Table 1) [3,7,41–48]—has major implications for trial design. Within each modality, key decisions include strain selection, delivery route, pharmacokinetics/pharmacodynamics, suitable placebo, target disease, and target population demographics and comorbidities. These decisions are often shaped by path dependency and legacy practices—for example, use of commercially available probiotic strains with limited mechanistic rationale; repurposing of trial protocols in studies targeting unrelated diseases; and selection of target niche based on ease of sampling and analysis. This tendency is reinforced by risk-averse regulation, which favours established protocols with known safety records over novel approaches that may be more scientifically appropriate but lack precedent. We advocate for a more rigorous approach that prioritizes hypothesis-driven design grounded in clinical need, plausible mechanisms, niche-specific biology, and host-microbe interactions, balanced against feasibility in real-world settings.

Given the high dimensionality inherent to microbiome research, absence of standardized endpoints, and novelty of proposed treatments, meaningful power calculations can be challenging or even impossible. Ideally, clinical trials should include large samples with long-term follow-up. Nevertheless, smaller trials can yield meaningful results, particularly if comparable methods are employed to facilitate meta-analysis, or pragmatic trial designs including cross-over studies. Platform trial designs may also improve efficiency, enabling sequential or parallel testing of multiple microbiome-targeted interventions within specific patient groups, while leveraging shared controls and infrastructure [49]. Additional challenges are encountered when testing microbiome interventions such as bacteriophage therapy, where highly personalized matching of phages to infecting organisms limits the applicability of traditional trial designs.

Potential microbiome interventions may target conditions managed outside clinical microbiology, including gastroenterology, rheumatology, haematology, neurology, oncology, and paediatrics. Early involvement of specialty clinicians in trial design is therefore essential to ensure feasibility, appropriate participant selection, and clinically meaningful endpoints. Initiatives may originate from microbiome researchers, industry, or specialty clinicians themselves, but durable translation requires shared leadership across disciplines.

Ultimately, building scientific credibility means going beyond association: investing in mechanisms, robust biomarkers,

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Table 1
Microbiome-based interventions: classes, definitions, and regulation

Class	Definition	Regulation	References
Probiotic	Live microorganisms which, when administered in adequate amounts, confer a health benefit on the host	• Generally treated as foods/food supplements (if ingested) or consumer/cosmetic products (if applied topically), not as medicinal products, unless a specific health or disease modifying claim is made. • EU (EFSA): Must demonstrate Qualitative Presumption of Safety to be included in food. • USA (FDA): Requires premarket approval as a food additive, or be qualified as Generally Recognized As Safe. • Japan (MHLW): Classed as Foods for Specified Health Uses (require approval by the Consumer Affairs Agency) or Foods with Function Claims (no approval required).	[7,41]
Prebiotic	A substrate that is selectively utilized by host microorganisms conferring a health benefit		
Postbiotic	A preparation of inanimate microorganisms and/or their components that confers a health benefit on the host		
Synbiotic	A mixture comprising live microorganisms and substrate(s) selectively utilized by host microorganisms that confers a health benefit on the host		
Microbiome transplant	The transfer of biologic material containing a minimally manipulated community of microorganisms from a human donor to a human recipient (including autologous use), with the intent to beneficially affect the microbiome of the recipient	• Regulatory classification varies broadly internationally, including investigational biological agent (USA), human tissue (Belgium, Italy), medicinal product (UK), or medical procedure (Scandinavia). • EU: From 2027, human-derived microbiome products will be classed as Substances of Human Origin, alongside human tissues. • USA: Requires IND application for all uses except CDI refractory to standard therapies.	[42–45]
Live biotherapeutic product	• USA (FDA): A biological product that: (1) contains live organisms, such as bacteria; (2) is applicable to the prevention, treatment, or cure of a disease or condition of human beings; and (3) is not a vaccine • EU (PhEur): A medicinal product containing live microorganisms (bacterial or yeasts) for human use	• Generally regulated as medicinal products, including testing, production standards, licensing and postmarketing surveillance. • EU (EMA): LBPs regulated by CHMP, with microbiological purity standards. • USA: Regulated as biologics under Biologics License Application.	[46–48]
Microbiome-derived therapies	• Derived from a donor's microbiome, but processed and standardized into a defined product (including spore preparations). • Not strictly considered LBPs (which are single strains or consortia characterized to strain-level, rather than donor-derived communities).	• Generally treated as medicinal biological products. • Only licensed products to date are VOWST and Rebyota.	[3]

CDI, *Clostridioides difficile* infection; CHMP, Committee for Medicinal Products for Human Use; EFSA, European Food Safety Authority; EMA, European Medicines Agency; EU: European Union; FDA, Food and Drug Administration; IND, Investigational new drug; LBP, live biotherapeutic product; MHLW, Ministry of Health, Labour and Welfare of Japan; PhEur, European Pharmacopoeia.

transparent methods, and hypothesis-driven trials (see Box 1 for detailed recommendations).

Priority 2: practical viability

Regulation, safety, and quality control

Microbiome-based interventions face fragmented regulation that is not fit-for-purpose. Depending on jurisdiction, indication, and manufacturing process, the same product may be classified as a food supplement, medicinal product, human tissue, or biological agent (Table 1). This is particularly problematic for modalities that do not fit clearly into current regulation, such as microbial consortia, bacteriophages, donor breastmilk, and inactivated preparations (such as postbiotics) [14]. Regulatory and manufacturing infrastructure remains underdeveloped in many low- and middle-income countries, raising further concerns around equity and safety.

Regulatory designation acts as a double-edged sword. Probiotics regulated as food or supplements face fewer entry barriers, disincentivizing generation of robust efficacy data, and simultaneously preventing meaningful health claims even when data are robust. Conversely, LBPs and microbiota transplants are subject to stricter regulation and manufacturing standards, improving rigour but also raising practical and significant financial barriers to progress. Lessons from FMT highlight the stakes [42]: despite clear efficacy in recurrent CDI, regulatory ambiguity and stringent donor screening have restricted clinical application. Stringent regulatory barriers also hinder the adoption of microbiome interventions in livestock. Under European Union Feed Regulation (EC) No 767/2009, FMT and other faecal derivatives are prohibited in food-producing animals, reflecting concerns over pathogen transmission [50]. Yet given pressures to reduce antimicrobial use, a supportive framework is needed to enable safe innovation in this space.

Although it may not be possible, or even desirable, to achieve a unified international framework governing all classes of microbiome-based interventions, existing gaps and inconsistencies require plugging urgently. Bespoke regulation should prioritize rigorous demonstration of safety and efficacy, and should be flexible enough to foster innovation, specific enough to give industry, consumers and regulators confidence in new therapies, and agile enough to respond to novel developments such as the new era of postbiotics. Encouragingly, appetite for international harmonization around safety and oversight is emerging, including new European Union regulation that will explicitly classify human microbiome materials as Substances of Human Origin within a unified

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regulatory framework [43], and an international consensus statement cautioning against clinical use of microbiome tests that lack robust validation [20].

Quality control is a further bottleneck, particularly for live consortia (e.g. inherent batch-to-batch variability) and organisms requiring anaerobic cultivation, cold-chain storage, spore preparation, or strain-specific potency assays [51]. Facilities able to achieve Good Manufacturing Practice (GMP) production remain scarce, and industry standards for viability, purity, and dose remain heterogeneous. For interventions such as bacteriophage therapy, different countries have adopted divergent approaches, ranging from full GMP to GMP-like or even magistral preparations produced in pharmacies, with resulting implications for access, scalability, and regulatory oversight [52]. We advocate for shared international capacity-building, to safeguard quality alongside equitable access.

Funding, commercialization, and intellectual property

Translational readiness requires a viable funding and marketing model. Despite over $3 billion investment in microbiome-related companies as of 2019 [53], field enthusiasm has cooled. Indeed, several early leaders, such as 4D Pharma, Evelo Biosciences, and Finch Therapeutics, have either ceased operations or discontinued phase 3 trials [5]. Only two faecally derived human microbiota products have reached market, with prohibitively high per-dose prices (especially compared with alternatives such as FMT), reflecting steep development attrition and costs. The current intellectual property landscape further compounds these issues, and it is unclear whether patents on naturally occurring organisms or their products can be defended if infringed [54].

Nonetheless, creative approaches are emerging. The consumer-supported research infrastructure developed by ZOE, for example, demonstrates how large-scale data collection (current database comprising over 300 000 subjects across USA and UK) and personalized insights can sustain high-cost research even when the end product is a lifestyle intervention rather than a licensable drug [55]. To accelerate translation, increase equitable access to products, and reduce reliance on industry, we argue for strategic public investment—including regional and international microbiome research clusters and pooled manufacturing capacity—as well as greater recognition by charitable and governmental funding bodies of the importance of interventional microbiome research. Publicly funded production models already exist, including FMT produced and delivered within UK National Health Service facilities, demonstrating the feasibility of regulated, noncommercial approaches. Such public or hybrid models may be particularly relevant in low- and middle-income settings, where commercial incentives are weaker but public health need is high. In this context, lessons may be drawn from related sectors, including the long-standing role of institutes such as Butantan in Brazil in producing vaccines, antitoxins, and immunoglobulins at scale and low cost [56].

In summary, translation will only succeed if regulation, manufacturing capacity, and funding models evolve together (see Box 1 for detailed recommendations).

Priority 3: stakeholder engagement

Embedding social science and public engagement

Scientific and practical advances are necessary but insufficient to achieve meaningful clinical translation. We advocate strongly for patient and public involvement and engagement from the outset and throughout, rather than as a subordinate downstream add-on to siloed research agendas [57]. In this way, engagement should shape not just how results are communicated to end-users, but which research questions, methods, and implementation strategies are prioritized, and who benefits from the translation of microbiome research into clinical practice. Large, methodologically robust citizen-science studies demonstrate the feasibility and value of involving public contributors in research design, execution, and dissemination—such as the Isala project analysing the vaginal microbiomes of over 3000 Belgian women [58]. This study employed a cocreative approach, including citizen involvement in defining study aims and target audience, tailored outreach, cultivation of trust, leveraging social media, use of personalized feedback, and self-sampling.

To ensure that such work is not an afterthought, funding for engagement and biosocial activities should be considered as part of translational planning. The Human Genome Project provides a powerful precedent, demonstrating how international interdisciplinary commitment fostered the growth of ethical, legal, and social implications research as a global field of study hand-in-hand with scientific progress [59]. This aligns with broader recognition of the importance of patient and public involvement and engagement research, as highlighted by the recent UK Patient Involvement Strategy [60].

Engagement must also challenge entrenched biases in microbiome science—particularly the disproportionate focus on white, Western, industrialized populations. This is not only essential for improving scientific robustness and generalizability, but also for advancing research equity. We must avoid unhelpfully broad categorizations (e.g. 'non-White', 'non-Western') and language that invokes racial or colonial undertones (e.g. microbiome 'rewilding' that presents populations from which microbes will be sourced as 'primitive' or 'closer to nature') [61]. Ensuring equitable access to microbiome-based interventions must also be a core translational priority. Without deliberate planning, these interventions could reinforce existing structural determinants of health because socioeconomic inequalities can shape both health outcomes and unequal access to novel therapies.

Public-facing communication must be anchored in safety and evidence, avoiding opaque technicality, reductive oversimplification, and alienating moralization (e.g. shaming parents over caesarean delivery, formula feeding, or antibiotic use). Clinical microbiome translation will need to work with lay understandings of microbes and the microbiome, and must also consider evolving public discourse [62]. Where germ theory traditionally framed microbes as dangerous and in conflict with human health, rising awareness of 'antibiotic blowback' (e.g. antimicrobial resistance) has led to more ecologically informed conceptions of microbes, including the notion of 'using life to manage life' [63]. We must also remain alert to the risks of 'naturalness bias', previously associated with vaccine hesitancy [64], which may fuel public interest in unregulated and potentially harmful microbiome 'biohacking' practices such as do-it-yourself FMT or extreme diets [65].

Uptake into policy and clinical practice

In addition to safe and effective products, appropriate regulation and infrastructure, and societal engagement, meaningful clinical microbiome translation requires buy-in from both the medical and policy communities. Scientific literacy amongst policymakers is often limited, compounded by high rates of staff turnover and competing priorities [66]. Meaningful influence requires the microbiome research community to pursue the right channels in the right ways: targeting Parliamentary standing committees, inquiries, or individuals with relevant expertise, and

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presenting succinct briefs with actionable recommendations rather than long, overly technical reports.

Despite growing evidence of the microbiome's role in health, clinician knowledge gaps remain a recognized barrier to implementation [67]. To counter this, we advocate for formal integration of microbiome science into medical school curricula and postgraduate training [68]. Furthermore, pharmaceutically induced microbiome disruption ('microbiotoxicity') is not included in regulatory toxicology, and is therefore often missing from drug testing, licensing, and prescribing guidance [69]. The UK House of Lords Consumer Products (Control of Biocides) Bill, which explicitly cites microbiotoxicity as a threat to human health, signals early appetite for microbiome-mindful legislative progress [70].

In short, true translational readiness demands trust and inclusion: public voices, equitable access, and clinical and policy buy-in (see Box 1 for detailed recommendations).

Conclusions

The microbiome has moved from discovery to intervention, but translation into meaningful clinical and societal impact remains constrained by scientific uncertainty, fragmented regulation, and uneven stakeholder engagement. Our Royal Society workshop highlighted that progress requires action across three intersecting domains. First, scientific credibility must be strengthened through deeper mechanistic insight, robust biomarkers, and transparent, harmonized methods that allow comparison across studies without stifling innovation. Second, practical viability demands regulatory clarity, investment in manufacturing and trial infrastructure, and sustainable funding models that can withstand commercial volatility. Third, stakeholder engagement—from patients and clinicians to policymakers and the wider public—is essential to ensure that microbiome interventions are safe, equitable, and relevant to societal needs.

By aligning scientific innovation with regulatory preparedness and inclusive engagement, the field can move beyond isolated proof-of-concept trials towards reproducible, affordable, and globally accessible microbiome interventions. The agenda we outline provides a translational roadmap to ensure that microbiome research fulfils its clinical promise, to deliver tangible health benefits for people, animals, and societies worldwide.

CRediT authorship contribution statement

-Conceptualization: AAT, CEJ
-Methodology, Funding acquisition: AAT, CEJ, DB, DWC.
-Project administration, Formal analysis, Data curation, Writing Original Draft: AAT.
-Investigation, Writing Review and Editing: all authors.
-Supervision: CEJ.

Transparency declaration

Declaration of competing interests

The Royal Society covered travel, accommodation, and dining costs for invited speakers and chairs (all named authors on this paper) to attend the meeting, but no honoraria were paid. D.B. has received speaker fees from OM Pharma and funding from GSK for an unrelated research project and is Treasurer and Board Member of the International Society for Pneumonia and Pneumococcal Disease. B.G. has received support from the ESRC Festival of Social Science, University of Oxford John Fell Fund, and Economic and Social Research Council (ES/N006968/1). J.G. has received consulting and travel fees from Bened Life and Almond Board of California for scientific advisory board activities, has stocks in BiomeSense Inc and Holobiome Inc, and is President of Applied Microbiology International. J.L. has received payments to the University of Oxford from the Canadian Institute for Advance Research to support research costs. S.L. is a voluntary academic board member of the International Scientific Association on Probiotics and Prebiotics and a scientific advisor for Freya Biosciences and has received research funding from different companies (but none are involved in this manuscript). T.D.S. is a cofounder, shareholder, and part-time employee of ZOE Ltd, a gut nutrition company with a commercial test kit. All other authors declare that they have no conflicts of interest.

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Appendix A. Supplementary data

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