Title: Commercializing equitable, accessible oral microbiome transplantation therapy

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Abstract:

Chronic oral diseases, such as caries and periodontal disease, may be treated by oral microbiome transplant (OMT) technology. OMT therapy involves collecting a donor oral microbiome and transplanting into a recipient to either prevent or treat oral diseases linked to a change (i.e., dysbiosis) in the oral microbiome. Given the great promise of this technology, we must consider the ethical and practical implications of how it is developed to maximise its accessibility and affordability. Here, we examine ways that OMT technology can commercialized in the context of equity and accessibility in both clinical or do-it-yourself settings. We do this while making the assumption that the technology can be developed for humans in ways that are equally effective at the individual and population-levels. We discuss how the technology should be developed, highlighting the need for OMT therapy to be 1) cost-effective, 2) understood by end users and clinicians, 3) easy to access even in rural or remote communities, and 4) providing donors with equitable compensation for their microbiomes. These key elements will only be achieved through partnerships between scientists, clinicians, investors and stakeholders throughout development. Therefore, proper acknowledgement and equitable evaluation of contributions in this team will also be critical to ensuring that this technology can be globally accessed. While OMT is likely to reshape how we prevent or treat oral disease, consciously guiding its development toward equity and accessibility to all people may significantly aid in improving health for those without access to dental care.

Introduction

Two of the most common chronic diseases in many industrialised countries, including the United States, the United Kingdom, and Australia, are oral diseases – dental caries and periodontal disease. Dental caries is characterised by demineralising a tooth's enamel by the acid by-products of microbes within dental biofilms adherent to the tooth surface (Pitts *et al.*, 2017; Selwitz *et al.*, 2007). Despite being preventable, its prevalence has increased, especially in disadvantaged populations. The oral microbiome also collectively contributes to periodontal disease, marked by gingiva inflammation, alveolar bone resorption and, eventually, tooth loss. Worldwide, periodontal disease is the 6th most prevalent disease, increasing by 57.3% from 1990 to 2010 (Tonetti *et al.*, 2017). The primary component of preventive care are brushing at home with fluoride toothpaste, while dental clinic visits, with fluoride application and professional cleaning, can also be integrated, although everyone may not find feasible (Arora *et al.*, 2020; S and M, 2017). Invasive treatments are necessary in severe situations, but they are hampered by a lack of funding and access, disproportionately affecting marginalised populations (Benzian *et al.*, 2021; Watt, 2007). Innovative, approachable, and egalitarian solutions are required to solve these issues. Oral Microbiome Transplantation (OMT) treatment is a promising strategy that uses the beneficial bacteria found in the mouth to treat oral disorders. This strategy may open up new possibilities for managing dental cavities and periodontal disease, while advancing everyone's oral health (Nascimento, 2017; Nath *et al.*, 2021).

Oral Microbiome Transplant (OMT) Therapy

Oral microbiome transplant (OMT) therapy has the potential to revolutionise how dental diseases are understood, treated, and managed. However, OMTs have yet to be deployed or tested in human clinical trials, despite microbiota transplants being utilised elsewhere in the body with success. While oral microbiome transplant therapy has not yet been examined in humans, it has been trialled in many animal models, including dogs and rodents (Beikler et al. 2021; Xiao et al. 2021). While we do not anticipate OMT therapy will be a cure-all for oral diseases, we do predict that it can help overcome polymicrobial oral diseases that are currently recalcitrant to treatment or cannot be prevented using existing means, such as severe dental caries and periodontal disease. As alterations in oral microbiota (*e.g.* a dysbiosis or shift from a comparative, healthy community) are linked to nearly all oral diseases examined to date, additionally including gingivitis, halitosis, oral cancers, mucositis, and xerostomia (Dewhirst *et al.*, 2010; Kilian *et al.*, 2016), effective OMT could further aid in the treatment of a multitude of other oral diseases. Further, periodontal disease is also a associated with several systemic diseases, including diabetes, cardiovascular disease, chronic kidney disease, osteoporosis, and Alzheimer's disease (Tonetti *et al.*, 2017) – suggesting that OMT could also contribute measurable improvements to other non-oral diseases (Mira *et al.*, 2017; Pozhitkov *et al.*, 2015)

While OMT remains to be untested in humans, Nath and colleagues (2021) proposed a novel strategy for advancing OMT technology. First, they recommend optimising donor-recipient matches by carefully choosing donor oral microbiomes based on context related to health and sickness. Second, to cultivate donor microbiomes and ensure safety, variety, and desirable disease-fighting properties, an *in vitro*, 3D printed growing system is employed. These developed donor microbial communities can be embedded in biosafe hydrogels or stored for transplantation. Like at-home whitening kits, hydrogels can be applied directly to patients' teeth or positioned in trays for application. For a transplant to be successful, the recipient's microbiome must be eliminated, most likely via physical plaque removal and therapy with 0.4% chlorhexidine. No testing has been done on people regarding transplant frequency or duration. This approach offers a potential therapy option for oral diseases, calling for more animal model research.

However, there are still some technical issues with OMT technology. Future research should investigate the protective microbial species within the mouth against oral diseases and explore how laboratory-grown microbial communities can establish themselves in recipients. Additionally, choosing hydrogels or dental materials for OMT needs further study. Clinical research should focus on effectively removing recipients' existing microbiota and assessing OMT's preventive and therapeutic potential against oral and systemic diseases. Critically, OMT therapy must be equally effective in all populations, as variation in efficacy will only further propagate health disparities. We also acknowledge that OMT technological development prior to commercialization must employ equitable frameworks, such as the ones proposed by Lala (in this issue) or by Bader, et al. (Bader *et al.*, 2023). While challenges lie ahead, the potential benefits of disease treatment and prevention make this research imperative.

Accessibility and inclusion should be given a priority in the commercialization of OMT technology, particularly for underserved groups who experience inequities in oral health. Collaboration between researchers and business partners is essential to develop a broadly accessible, reasonably priced solution that can be used in remote and rural locations (Nath *et al.*, 2021). Beyond dental offices, portable OMT implementation can provide fair health outcomes for all. OMT transplants must be guided by cultural and evolutionary sensitivity, honouring each person's own oral microbiota and ancestry (Handsley-Davis *et al.*, 2022). Investigating the nexus between OMT technology, public health, business ethics, and entrepreneurship is necessary, as is actively incorporating users and development teams in the technology's future development (Bello *et al.*, 2018).

Equitable, accessible commercialization for OMT Technology end-users

We must take into account accessibility, affordability, education, portability, equity, and cultural sensitivity to ensure the commercialization and development of fair and equitable OMT technology. It will also be likely to use different strategies to meet different demands (i.e., in person vs. population-scale contexts). As a result, we can propose that OMT technology is commercialized for two different consumers: oral health professionals for use in clinics or public consumers for do-it-yourself (DIY), at-home use, similar to whitening kits. Professionals might use supplied donor microorganisms in OMT as part of standard care, or patients could buy kits and self-administer. Employing OMT's utility for both types of clients can increase its reach and influence. This adaptable method might treat less severe conditions at home, such as halitosis, or target particular disorders clinically. Here, we discuss four key considerations of commercializaing equitable OMT technology assuming that the technology can be developed in ways that are effective in humans for all populations – a rather large assumption.

1.) Cost effective considerations and potential solutions

Using OMTs to achieve oral health equity requires addressing financial obstacles throughout decisions to manufacture and develop the technology. Large, reusable *in vitro* flow cells are used in the Nath *et al.* (2021) technology to cultivate donor oral microbiota material cost-effectively. Improvements in 3D printing technology make it possible to produce more robust, inexpensive flow cells, increasing productivity and requiring less work to ensure quality. This is different from FMT techniques, which frequently use single donors for single recipients, although there are certain FMT in vitro growing methods available to lower the need for donors in large-scale applications (Haindl *et al.*, 2021). How OMT is provided to beneficiaries also affects its cost-effectiveness. The expense of recipient microbiota removal varies based on the setting, such as clinical removal with scaling and antimicrobial treatments or at-home options, such as a chlorhexidine mouthwash. The choice of hydrogel for OMT delivery should also be considered, as cost varies among commercially available options. Application methods, such as painting hydrogels on teeth or using trays/mouth guards, must balance cost with short-term and long-term efficacy (Lee *et al.*, 2010). Moreover, those with restricted access to healthcare may need more reasonably priced at-home solutions. DIY OMT kits may decrease clinical visits even if clinical advice is advised for OMT; nonetheless, they may also raise the likelihood of treatment failure or adverse consequences. It is critical to balance safety and cost-effectiveness, and OMT use should follow clinical guidelines.

2.) **Education for technology transparency and competency**

Given that oral microbiome research is a relatively new field, dental professionals have limited training in how these polymicrobial communities interact to cause disease and are still uncovering new mechanisms and models for disease aetiology and treatment (Kilian *et al.*, 2016; Mira *et al.*, 2017). As such, it is unreasonable to accept that the public would also understand the benefits and risks of OMT technology. Transparency and education about the risks and benefits of OMT technology are paramount to ensuring that individuals understand how and when OMT can support their health goals and when OMT may not be effective for them. Public education about the causes, existing treatments, and how OMT fits into broader themes of oral health need to be a critical component of any commercial entity developing OMT therapy. This strategy could be integrated into its marketing campaigns, which are made more accessible through social media and online platforms that provide direct-to-consumer advertising and novel opportunities for engagement through education (Spallek *et al.*, 2015). However, companies must consider their audience and ensure goals are set to reach diverse audiences, including those without tertiary education who may benefit the most from OMT technology, not only those who can afford it. Companies developing OMT technology could also seek to provide education through school systems and opportunities for secondary levels of education to understand more about microbial ecology and its relationship with human health, both in the mouth and elsewhere in the body. Education is also needed in the dental industry to provide the rationale behind OMT technology. Its potential benefits and risks must be fully described and made clear to dental professionals so that they can accurately provide recommendations that currently sit outside of dental professional training and education and communicate this rational to their clients (Sun *et al.*, 2021).

Transparency and education also need to be considered while recruiting donors. It can be complex to describe to a donor how their microorganisms will be grown, maintained, used, and transplanted into hundreds or thousands of individuals. Researchers and companies must be incredibly clear about the utility and advantages of donor material and the potential risks involved. For example, for-profit companies may have vast returns on investment from OMT technology, but this is often not reciprocated to the donors of the microbiome material – but may need to be for equitable donation. Future OMT collection can move beyond the strategy used in FMTs, where donors typically provide material, are only compensated for time spent, and told of the potential benefits their donation may provide for society (Bénard *et al.*, 2022). We must educate donors about the importance of their microbes, their utility, and the potential ownership rights that individuals may have over their own microbes (Handsley-Davis *et al.*, 2023). It is also possible that someone may be identified from their donor material; microbial strain tracking has been used in forensic casework and studies of human movement and mobility (Eisenhofer *et al.*, 2017; Fierer *et al.*, 2010; Moitas *et al.*, 2022). Understanding potential risks when donating dental plaque is critical for equitable, transparent plaque collection. This is especially important when recruiting donors from marginalized or indigenous communities (Bader *et al.*, 2023; Handsley-Davis *et al.*, 2023). As part of the donation process, education for donors on OMT technology, its development, and the potential benefits and risks should be introduced. Donor education ensures that the process is transparent and ensures that people willingly donating their dental plaque to science understand there is the potential for commercialisation and development of this technology.

3.) Portability for Rural or Remote Communities

As discussed earlier, one OMT market may be to provide DIY OMT kits, which could include ordering live microorganisms delivered to their homes. However, many communities lack access to reliable mail service or pharmacies, so alternative methods may need to be considered. While this may be attainable in most areas of industrialised countries, such as the United States, it may be challenging to obtain in rural areas or other countries. Global viability and accessibility are crucial, considering the widespread nature of caries and periodontal disease. One such solution would be to create mobile healthcare facilities that could offer OMT services to reach rural and underserved communities. Unlike traditional mobile clinics that provide one-time treatments with limited-term effects, OMT may have longer-lasting effects. These units could administer OMT with a focus on monitoring short-term side effects. Furthermore, mobile clinics could develop systems that leverage local donors for OMT therapy, as these have been shown to improve access to healthcare in vulnerable populations (reviewed by Yu *et al*. 2017). While privacy would need to be maintained, a culturally specific, localised approach with microbes adapted to local diets, shared genetics, similar environments, and maintained cultural or social practices would likely mean greater success for OMT. The development of practical tools to quickly and concisely cultural donor microbiota while screening for known pathogens (i.e., using PCR-based approaches) and assaying specific desired phenotypes (i.e., buffering capacity for caries prevention) would provide many more opportunities for people to receive OMT, even in rural or remote settings. This also avoids the need for cold chain storage and transport, which is a key burden during the distribution of healthcare to rural and isolated populations. However, creating mobile clinics will require collaboration among researchers, clinicians, and business partners during development, personnel training, and community education. The effectiveness of OMT delivery (i.e., via mail or mobile health clinics) to separate, underserved people would need to assessed within discrete populations; for example, ensuring issues of connectedness, intersectionality, flexibility, inclusivity, and community-centeredness in this approach are also critical to successfully improving minority health care during this process (Gkiouleka et al. 2023). This approach also requires developers and investors to include access to underserved populations and promote a societal benefit mindset. Non-profit organisations, as extensions of corporate entities, can also play a pivotal role in bridging the gap and benefiting communities. This collaborative model breaks the misconception that businesses and societal welfare are mutually exclusive, fostering community-centric dental medicine development (Dacin *et al.*, 2022).

4.) Equitable benefits and compensation for donors and co-contributors

Equitable commercialization of OMT technology requires fair compensation and shared benefits for individuals contributing as donors, lab researchers, and clinicians. Recent discussions explored applying patenting laws to an individual's microbes, acknowledging their unique practices, diets, and experiences that shape microbiome compositions (Handsley-Davis *et al.*, 2023) . This raises ethical concerns about donor rights and entitlements. Importantly, indigenous or remote community microbiomes maintain microbes that are now valuable given the diversity of these communities (Bello *et al.*, 2018), so we must ensure these marginalised populations benefit from the development of technology, have access to it, and receive fair compensation for their microbiome donations (Bader *et al.*, 2023). A key issue with the proposed OMT approach is that someone could donate their microbiome once and never have to do it again, as the microorganisms can be propagated *in vitro* and stored in freezers for long term use. Therefore, we must think about how we design shared benefits in both short- and long-term contexts.

Equal compensation in microbiome research has been only nascently explored in the context of the transplantation (Bénard *et al.*, 2022). We can look to other models of financial compensation during donation that currently exist, such as blood plasma, bone marrow, or human sperm/eggs in the United States, as a model to determine the microbiome donation compensation (Chen *et al.*, 2021); however, many of these models use repetitive donation and compensate people mainly for their time, only after the physical collection of a particular biospecimen (Chen *et al.*, 2021). If OMT donations can be preserved for long-term storage and regrowth *in* vitro, single donations may be a better model; we could compare this to unique single donations such as a kidney, where financial incentives are typically not legally allowed (Allen and Reese, 2013). However, quantifying the worth of a single donation microbiome becomes incredibly difficult, as one-time lump sums for 'organs' or similar are not without their own complications (Allen and Reese, 2013). It could also depend on how many people received microbes from that specific donor or which specific diseases that donated microbiome can prevent or treat (Chen *et al.*, 2021). Perhaps one could divide a proportion of the potential profits gained from OMT originating from that donor, but this would require long-term relationships with donors and does not provide short-term benefits for those willing to donate. The potential for this larger sum of compensation could be seen as coercion for donation, while delayed gratification for donation may not be sufficient for some people. In remote or indigenous communities, valid compensation for donation may also look very different than that of industrialized cultures (Bader *et al.*, 2023; Smith *et al.*, 2018), where donation may be an expectation of a community, on behalf of the community, such that compensation is paid to a group of people. As a result, benefits to indigenous communities may also look very different than those currently employed by research teams and could include community-based compensation funds, infrastructure for a community, greater access to long-term dental health care, or educational endowment funds (Novoselov *et al.*, 2021). Regardless, the benefits need to match the donor and the community where they reside, and a mixture of both short- and long-term benefits are likely to be needed.

Reimagining benefits for donors may also lead to revisioning how a company designed for OMT development may be operated, owned, or maintained. Deeply valuing these partnerships requires addressing existing power dynamics in both academia and private industry during the process and fully recognising the contributions that each person makes to a team. To value these contributions, companies leading OMT development could be framed as worker-owned companies, such as Co-Ops, but these companies also need clear direction and large influxes of investment funds for biomedical research that are unlikely to come from such a model. An alternative model would be a B-Corp, where society or social benefit is weighed equally with profits and within the business's charter (Diez-Busto *et al.*, 2021), although certification can be challenging to obtain in some instances (Diez-Busto *et al.*, 2022), especially for smaller start-up companies with limited resources. Furthermore, patenting of OMT, as with many microbiome-associated technologies (Handsley-Davis *et al.*, 2023), has already begun and will also place the rights of OMT in the hands of some and not in all. Incentivizing the vision for OMT equity could be achieved through shared patent ownership, stock options, or shared benefits in other ways (i.e., donations to community, access to care, educational funds, etc.), as incentives can genuinely motivate individuals to achieve success and improve employee value (Anik *et al.*, 2013), especially in emerging economies (Liu and Liu, 2022). Non-traditional business models, such as B-Corps, are also much more likely to attract diverse team members and further societal objectives outside of the United States (Saiz-Álvarez *et al.*, 2020), further ensuring the OMT technology is developed in ways that can be well integrated into many global communities.

Conclusion

The development of equitable OMT technology will require much planning and foresight to ensure that we all benefit from this new technology. It will require leaders with clear goals throughout the entire process and ensure that societal benefit is weighed equally with return on investment. Businesses that develop technologies with benefits to minoritized and underrepresented populations must have a commitment to the greater good and equitable access of their product. Discussion, planning, and integration of the ideas discussed here can ensure that teams are contributing to reducing health disparities rather than adding to the global burden. Through partnerships of scientists, clinicians, and investors, OMT technology can become a model for other emerging technologies that have the chance to change the way we see the world.

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LSW conceived the idea of the manuscript and drafted the manuscript. LMJ conceived the idea of the manuscript, contributed to drafting, and critically reviewed the manuscript. SN contributed to drafting, and critically reviewed the manuscript. All authors read and approved the final version.

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