

Ethical and Regulatory Challenges in Direct-to-Consumer Dental Devices

Ishita Singhal¹

¹Department of Biomedical, Surgical, and Dental Sciences, University of Milan, Milan, Italy.

Corresponding Author

Ishita Singhal

Email ID : Ishita.singhal@unimi.it

Submission: 15.09.2025

Acceptance: 24.10.2025

Publication: 22.12.2025



Abstract: The rapid proliferation of direct-to-consumer (DTC) dental devices—including DIY orthodontic aligners, over-the-counter whitening kits, and home-based tele-orthodontics—has transformed dental healthcare accessibility and delivery. While these innovations promise convenience and affordability, they also raise significant concerns about patient safety, quality control, and regulatory oversight. This review critically examines the ethical and regulatory challenges associated with DTC dental devices. Key impact issues include the lack of professional evaluation prior to device use, which increases the risk of undiagnosed oral conditions, inappropriate treatment selection, and adverse outcomes. Quality control is frequently compromised, with reports of unregulated product formulations, insufficient evidence of efficacy, and potential harm from improper use. Ethical concerns encompass inadequate informed consent, inequality in care quality among vulnerable groups, and diminished professional accountability. Regulatory frameworks remain fragmented, with most regions lacking comprehensive standards or effective monitoring mechanisms for devices delivered outside traditional clinical contexts. The transnational nature of e-commerce further complicates jurisdiction, enforcement, and post-market surveillance. As DTC dental care gains popularity, a multidisciplinary, globally harmonized approach—combining robust pre-market regulation, transparent product labelling, mandatory adverse event reporting, and enforceable marketing guidelines—is urgently needed to safeguard public health and preserve professional standards in dentistry.

Keywords: Consumer Health Information; Dental Appliances; Ethics, Orthodontic Appliances; Removable; Teledentistry; Tooth Bleaching.

Introduction:

The landscape of dental healthcare is being transformed by the rise of direct-to-consumer (DTC) innovations—ranging from do-it-yourself (DIY) clear aligners and over-the-counter whitening kits to entirely virtual, home-based tele-orthodontics. Marketed on the premise of affordability, accessibility, and patient empowerment, these technologies promise a new era of user-driven oral care. However, behind the veneer of convenience lies a complex web of ethical dilemmas and regulatory uncertainty.

Studies and policy statements from leading dental organizations, such as the American Dental Association and the Royal College of Surgeons, highlight serious risks—including irreversible oral damage, missed diagnoses, and patient safety threats—when professional oversight is bypassed⁽¹⁻³⁾. Peer-reviewed literature further underscores that DTC devices commonly lack robust quality controls, clear product labelling, or reliable patient information, amplifying the potential for harm⁽⁴⁻⁶⁾. Regulatory and legal analyses reveal persistent gaps in global oversight, with issues such as misleading marketing, weak cross-border enforcement, and ambiguous practitioner responsibility in teledentistry and home-based care models^(7,8).

As DTC dental products cross borders and blur the lines between commercial enterprise and clinical practice, it is

imperative to scrutinize both their benefits and inherent risks. This manuscript critically appraises the impact and quality control challenges associated with DTC dental devices, calling for a multidisciplinary response that upholds public health and the integrity of dental practice in the digital age.

The Proliferation of DTC Dental Devices:

DTC dental devices gained popularity due to widespread access via online platforms and social media marketing that emphasizes convenience and lower costs compared to traditional dental services. Global events such as the COVID-19 pandemic accelerated telehealth adoption, further fueling remote dental treatment and device sales. Major brands like SmileDirectClub and Byte have become market leaders in at-home orthodontics, while online marketplaces offer a plethora of unregulated whitening products and accessories⁽⁹⁻¹¹⁾.

Impact and Quality Control Issues:

Lack of Professional Evaluation: DIY aligners and whitening kits are often marketed directly to consumers without mandatory professional dental examination, radiography, or assessment of underlying disease. Evidence from regulatory bodies and case reports shows that bypassing dental supervision can result in missed diagnoses of caries, periodontitis, occlusal disturbances, or even oral cancers,

leading to adverse clinical outcomes such as tooth loss, root resorption, and progressive gum disease^(9,12-14).

Unregulated Product Formulation: Many over-the-counter whitening kits and aligner products are inadequately regulated, with inconsistent peroxide concentrations or unlisted additives, creating risks of chemical burns, mucosal irritation, and enamel demineralization. Studies report that some whitening kits exceed legal safety thresholds for active ingredients, and material quality can vary dramatically between brands⁽¹⁵⁻¹⁸⁾.

Insufficient Clinical Evidence: DTC devices rarely present robust evidence of safety or efficacy, as most have not undergone rigorous clinical trial evaluation. Device effectiveness is often inferred from limited case testimonials rather than large-scale, professionally monitored studies, undermining scientific validity and patient trust^(9,19,14).

Risk from Improper Use: Without professional guidance, users of aligners and whitening kits are at greater risk of improper application, overdosing, or failure to recognize complications. Documented consequences include derangement of occlusion, irreversible sensitivity, and oral mucosal lesions^(20,14,18).

Ethical and Social Implications:

Informed Consent and Patient Autonomy: Marketing of DTC devices often minimizes risks and overstates benefits, challenging the ethical principle of informed consent. As such, patients may be unaware of possible side effects, device limitations, or the lack of recourse in case of adverse events^(19,21).

Health Disparities and Equity: DTC devices promise greater accessibility for underserved populations, but may also reinforce inequalities by offering lower-quality unsupervised care to vulnerable groups, who are more likely to forgo professional evaluation due to financial constraints^(19,22,23).

Professional Accountability: The move to DTC care obfuscates accountability pathways, as providers may be corporations or overseas entities not regulated by local dental authorities. This complicates patient recourse for misdiagnosis, malfunctioning devices, or product-related injury^(19,12,13).

Regulatory and Legal Challenges:

Fragmented Oversight: DTC dental products are subject to highly variable regulation. Some countries require only a basic safety review, while others lack pre-market clinical evaluation altogether, leaving significant gaps in device oversight. In practice, many DTC products evade thorough scrutiny, especially when crossing international

borders^(19,12,24,25).

Inadequate Consumer Protections: Current regulatory frameworks struggle to keep up with digital marketing, enforcement of honest advertising, and coordinated product recalls. Many companies operate internationally, exploiting disparities in consumer protection laws between markets^(19,17,25).

Teledentistry and Jurisdictional Ambiguity: Home-based tele-orthodontic models often operate in regulatory grey zones, with questions surrounding practitioner licensing, legal liability, data privacy, and the standard of care expected for remote patient interactions^(19,13).

Recommendations:

1. Mandatory Professional Evaluation: All DTC dental devices, especially aligners and whitening kits, should require a baseline professional dental assessment, either in person or through regulated teledentistry platforms^(9,12,13).

2. Robust Product Labelling: Clear disclosure of active ingredients, safety warnings, and instructions for use must be standardized and enforced across jurisdictions^(16,17,25).

3. Evidence-Based Approval: Regulatory authorities should mandate clinical trials and post-market surveillance for all DTC dental devices prior to approval^(9,13,19).

4. Global Regulatory Cooperation: International collaboration is necessary to harmonize standards, facilitate product recalls, and establish accountability for adverse outcomes across borders^(19,25).

5. Public Education Initiatives: Efforts to educate consumers on the benefits and risks of DTC dental care are essential to support informed and safe health choices^(19,20,23).

Conclusion:

DTC dental devices are reshaping oral healthcare, offering new opportunities but introducing significant risks regarding safety, ethics, and regulatory oversight. Adequate protection of patient health requires bridging regulatory gaps, ensuring rigorous product evaluation, and preserving the accountability integral to dental care. A harmonized, multidisciplinary approach is essential to preserve public trust and professional standards in dentistry as the DTC paradigm continues to expand.

Source of Support: Nil

Conflict of Interest: Nil

Copyright © 2025 Goa Dental College & Hospital Journal of Synergetics in Dental Practice. This is an open access article, it is free for all to read, download, copy, distribute, adapt and permitted to reuse under Creative Commons Attribution Non

Commercial-ShareAlike: CC BY-NC-SABY 4.0 license.

References:

- Nagappan A, Ventakesan V, Sinha S. Ethical issues in direct-to-consumer healthcare: A scoping review. *J Med Ethics*. 2024 Feb 13. <https://pmc.ncbi.nlm.nih.gov/articles/PMC10863864/>
- Australian Dental Association. Policy Statement 2.2.10 - Direct to Consumer and Do-It-Yourself Dentistry. ADA. 2022 Nov 18. <https://ada.org.au/policy-statement-2-2-10-direct-to-consumer-and-do-it-yourself-dentistry>
- American Dental Association. ADA Adopts Further Policy Discouraging Direct-to-Consumer Dental Services. ADA. 2018. <https://www.ada.org/about/press-releases/2018-archives/ada-adopts-further-policy-discouraging-direct-to-consumer-dental-services>
- Faculty of Dental Surgery, Royal College of Surgeons. FDS statement on DIY aligners. RCS England. 2023 Jan 27. <https://www.rcseng.ac.uk/dental-faculties/fds/faculty/news/archive/fds-statement-on-diy-aligners/>
- Supply Chain Game Changer. Tips for Evaluating Quality Standards in Wholesale Teeth Whitening Supplies! 2024 Dec 1. <https://supplychaingamechanger.com/tips-for-evaluating-quality-standards-in-wholesale-teeth-whitening-supplies/>
- Dental Tribune. Dental associations look to regulate teledentistry. 2020 Mar 16. <https://www.dental-tribune.com/news/teledentistry-is-here-to-stay-dental-associations-change-gear-to-regulate/>
- American Association of Orthodontists. AAO Reports Concerns with Mail-Order Orthodontics to FDA. <https://www2.aaoinfo.org/aaoinfo-highlights-concerns-in-response-to-fda-request-for-information-on-at-home-use-medical-technologies/>
- Collins M, Luc D, Karadeniz E, et al. The appeal of 'Do It Yourself' orthodontic aligners: A YouTube analysis. *Australas Orthod J*. 2021;37(2):321-332. <https://researchonline.jcu.edu.au/72596/1/72596.pdf>
- Marouane, M., et al. (2025). User Experience, Satisfaction, and Complications of Direct-to-Consumer Orthodontics. *Medicina* 61(3): 438. <https://pmc.ncbi.nlm.nih.gov/articles/PMC11989835/>
- Rosemont Media. (2025). Social Media Marketing for Dentists and Dental Practices. <https://www.rosemontmedia.com/social-media-marketing/dental/>
- Bahabri, R.H. (2021). The impact of social media on dental practice promotion and patient engagement. *Saudi Dental Journal* 33(2): 71–76. <https://www.sciencedirect.com/science/article/pii/S1658361221000093>
- Carew Dental. (2025). DIY Whitening Strips vs. Professional Teeth Whitening: Pros and Cons. <https://carewdental.com/diy-whitening-strips-vs-professional-teeth-whitening-pros-and-cons/>
- ITV News. (2021). Which teeth whitening kits contain illegal levels of hydrogen peroxide? <https://www.itv.com/news/2021-05-25/unsafe-home-teeth-whitening-kits-found-to-contain-illegal-levels-of-hydrogen-peroxide>
- Nagappan, A., et al. (2024). Ethical issues in direct-to-consumer healthcare: A scoping review. *J Med Ethics*. <https://pmc.ncbi.nlm.nih.gov/articles/PMC10863864/>
- 21st Century Dental. (2023). The Dangers Of Overusing DIY Whitening Kits. <https://www.21stcenturydental.com/blog/the-dangers-of-overusing-diy-whitening-kits/>
- Lesko, L.J., et al. (2023). Ethical Issues Associated With Direct-to-Consumer Genetic Testing. *OMICS: A Journal of Integrative Biology* 27(7): 420-433. <https://pmc.ncbi.nlm.nih.gov/articles/PMC10317585/>
- National Institute of Dental and Craniofacial Research (NIDCR). (2023). Report Reveals Striking Differences in Oral Health Care Across the U.S. <https://www.nidcr.nih.gov/news-events/nidcr-news/2023/report-reveals-striking-differences-oral-health-care-across-us>
- American Dental Association (ADA). (2018). ADA Adopts Further Policy Discouraging Direct-to-Consumer Dental Services. <https://www.ada.org/about/press-releases/2018-archives/ada-adopts-further-policy-discouraging-direct-to-consumer-dental-services>
- Anshasi, R.J., et al. (2025). A study of Jordanian dentists' attitudes towards advertising. *Heliyon* 11(2): e14725. <https://www.sciencedirect.com/science/article/pii/S2405844024171745>
- Bupa Dental. (2022). The risks of at-home clear aligners and DIY orthodontics. <https://www.bupa.co.uk/dental/dental-care/news/understanding-the-risk-of-at-home-clear-aligners>

21. British Dental Association (BDA). (2021). Warning of risks from buying teeth whitening products online. <https://www.bda.org/media-centre/dentists-and-which-warn-of-risks-from-buying-teeth-whitening-products-online/>
22. George, S., et al. (2023). Adverse Events Related to Direct-To-Consumer Sequential Aligners. *Journal of Orthodontic Science* 12: 1. <https://pmc.ncbi.nlm.nih.gov/articles/PMC10378056/>
23. Michael Fernandez DDS. (n.d.). The Risks of DIY Dental Treatments. <https://www.michaelfernandezdds.com/index.php/our-blog/270-the-risks-of-diy-dental-treatments>
24. Tomar, S.L., et al. (2021). Addressing Oral Health Inequities, Access to Care, Knowledge, and Behaviors. *Preventing Chronic Disease* 18: 210065. <https://pmc.ncbi.nlm.nih.gov/articles/PMC8021144/>
25. American Dental Association (ADA). (2020). Direct to Consumer Dental Services—Current Policies. <https://www.ada.org/about/governance/current-policies/direct-to-consumer-dental-services>