Brief Communication

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The bioethical challenge of innovation: the off-label application of procedures and interventions in psychiatry: official document of the Commission on Procedures and Interventions in Psychiatry, ABP

O desafio bioético da inovação: a aplicação off label de procedimentos e intervenções em psiquiatria: documento oficial da Comissão de Procedimentos e Intervenção em Psiquiatria, ABP

El desafío bioético de la innovación: la aplicación off label de procedimientos e intervenciones en psiquiatría: documento oficial de la Comisión de Procedimientos e Intervención en Psiquiatría, ABP

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The interventions and procedures in psychiatry have become an area of great interest not only for the scientific community but also for healthcare professionals and the general population. It is worth noting that there is no formal recognition of the medical specialty known as "Interventional Psychiatry" in specialty manuals or medical specialization councils in Brazil. Although the term has been used in academic articles and fellowship programs in various institutions, it does not appear as an officially recognized specialty by regulatory bodies or medical councils responsible for defining specialization titles. This formal absence implies that the use of the term still constitutes a functional description or emerging field rather than a regulated specialty with legally recognized standardized training requirements [1 – 2].

Among the interventions currently used in psychiatry, Electroconvulsive Therapy (ECT), Transcranial Magnetic Stimulation (TMS), and ketamine administration stand out. Their formal indications have consistent support in scientific literature and, in the Brazilian context, are also regulated by official agencies such as the National Health Surveillance Agency (ANVISA) [3] and the Federal Council of Medicine (CFM) [4 – 5].

However, given the complexity of many chronic and treatment-resistant psychiatric conditions, which often fail to respond adequately to conventional therapies, there is increasing demand for innovative

therapeutic alternatives. In this scenario, well-established techniques such as ECT, TMS, and ketamine begin to be explored for indications beyond those formally approved. This expansion of applicability, although motivated by clinical need to offer options to patients with mental disorders, raises important questions regarding safety, efficacy, and, above all, the bioethical implications of such practices.

In the field of psychiatry, clinical practice frequently imposes the need for complex therapeutic deliberations, especially due to the insufficiency of treatments approved specifically for certain conditions, age groups, or vulnerable populations. In such circumstances, the adoption of off-label prescribing is observed with relative frequency, defined as the use of medications or interventions in contexts different from those previously authorized by regulatory agencies,whether regarding clinical indications, dosage, or age group [6].

Although off-label prescribing is legal and, in many cases, supported by scientific evidence, its use may raise concerns about therapeutic effectiveness and clinical safety, generating zones of uncertainty that challenge medical decision-making. In this context, ethical and legal dilemmas of great relevance arise, as the professional must balance risks and benefits in situations where clear guidelines or established consensus are lacking. It is precisely at this point that the fundamental bioethical principles, autonomy, beneficence, non-maleficence, and justice, become indispensable: autonomy ensures the patient's right to clear information and free consent; beneficence and non-maleficence impose the obligation to maximize benefits and reduce potential harms; and justice ensures equity in access to treatments and the distribution of health resources. Thus, bioethical reflection not only legitimizes but also guides responsible clinical practice in the face of uncertainties inherent in off-label prescribing [7].

It should be emphasized that access to safe, effective, and high-quality healthcare is a fundamental human right, enshrined in international declarations and reiterated by World Health Organization guidelines. In this sense, the clinical decision to adopt off-label approaches cannot be restricted solely to assessing the available scientific evidence or applying bioethical principles; it must also incorporate the commitment to safeguarding human rights. Such commitment implies recognizing the intrinsic dignity of the person, protecting their safety, and promoting their well-being, ensuring that medical practice remains aligned not only with

the best evidence but also with the universal values that sustain ethics in healthcare [8 – 9].

In the Brazilian context, although there is no explicit regulatory prohibition of off-label prescribing, its use is conditioned upon strict observance of the principle of informed consent, which must be obtained robustly and properly documented. National legislation allows the prescription of medications outside approved indications, provided that the physician ensures the patient receives clear, comprehensive, and understandable information about potential benefits, risks, and uncertainties related to the proposed treatment [6]. Failure to meet this requirement not only compromises patient autonomy but may also result in civil liability for the professional, especially in cases where adverse events occur or therapeutic effectiveness is lacking. In this context, informed consent is not merely a legal formality, but an ethical core element that ensures transparency, shared responsibility, and respect for the patient's dignity throughout the decision-making process [10].

The bioethical analysis of off-label treatments in psychiatry, particularly regarding procedures and interventions, reveals the ongoing tension between the pursuit of relief from psychological mental disorders and the need to ensure safety, transparency, and justice. These interventions, although supported by evidence in certain clinical contexts, have their application expanded beyond formal indications, motivated by the resistance of many conditions to conventional treatments. It is in this space of uncertainty that ethical dilemmas become most evident, requiring the professional to adopt a prudent stance grounded not only in beneficence and non-maleficence but also in attentiveness to autonomy and the patient's right to be fully informed.

The use of off-label interventions in psychiatry therefore presents a complex ethical dimension that extends beyond isolated clinical decision-making. To avoid unnecessary risks or violations of the right to dignified and safe care, it is essential that the practice be grounded in updated scientific evidence, clarity in informed consent, and institutional policies that establish parameters of action. The absence of these elements may compromise not only patient integrity but also the credibility of psychiatric practice. In this sense, regulatory agencies, educational institutions, and healthcare professionals hold the responsibility to develop guidelines, promote continuous education, and ensure that innovation in psychiatry progresses in alignment with fundamental bioethical values.

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References

1. Conselho Federal de Medicina. Resolução CFM nº 2.221, de 2018. Atualiza a relação de especialidades e áreas de atuação médicas aprovadas pela Comissão Mista de Especialidades (CME)[Internet]. Brasília: CFM; 2018[cited 2025 Sep 23]. Available at: https://sistemas.cfm.org.br/normas/visualizar/resolucoes/BR/2018/2221

2. Associação Brasileira de Psiquiatria. Provas de Título e áreas de atuação [Internet]. Rio de Janeiro: ABP; 2025 [citet 2025 Oct 6]. Available at: https://www.abp.org.br/provadetitulo

3. Agência Nacional de Vigilância Sanitária. Resolução-RE nº 4.413 de 29 de outubro de 2020 [Internet]. 2020 [cited 2025 Sep 23]. Available at: https://anvisalegis.datalegis.net/action/UrlPublicasAction.php?acao=abrirAtoPublico&num_ato=00004413&sgl_tipo=RES&sgl_orgao=RE/GGMED/ANVISA/MS&vlr_ano=2020&seq_ato=000&cod_modulo=134&cod_menu=1696

4. Conselho Federal de Medicina. Utilização da Estimulação Magnética Transcraniana (EMT) [Internet]. Brasília: CFM; 1986 [cited 2025 Sep 23]. Available at: https://portal.cfm.org.br/images/stories/pdf/1986transcraniana.pdf

5. Conselho Federal de Medicina. Resolução CFM nº 1.640, de 2002. Dispõe sobre a utilização da Eletroconvulsoterapia (ECT) [Internet]. Brasília: CFM; 2002 [cited 2025 Sep 23]. Available at: https://sistemas.cfm.org.br/normas/arquivos/resolucoes/BR/2002/1640_2002.pdf

6. Conselho Federal de Medicina. Parecer CFM nº 02/2016: Prescrição de medicamentos off label e Resolução CFM nº 1.982/2012 [Internet]. Brasília: CFM; 2016 [cited 2025 Sep 23]. Available at: https://cfm.org.br

7. Beauchamp TL, Childress JF. Principles of biomedical ethics. 8th ed. New York: Oxford University Press; 2019.

8. Organização Mundial da Saúde. Direitos humanos e saúde mental [Internet]. Genebra: OMS; 2021 [cited 2025 Mayo 18]. Available at: https://www.who.int/publications/i/item/9789240025707

9. United Nations. Universal declaration of human rights [Internet]. Paris: United Nations; 1948 [cited 2025 Mayo 18]. Available at: https://www.un.org/en/about-us/universal-declaration-of-human-rights

10. Rabelo MSF Jr, Goulart LK. Prescrição de medicamentos "off label": uma análise da (ir)responsabilidade civil médica sob o prisma do consentimento informado. Rev Ibero-Am Humanid Cienc Educ. 2023;9(1):1417–33. https://periodicorease.pro.br/rease/article/view/8348