I15 Qualitative Analysis on the Ability to Provide Consent of Treatment to Patients With Chronic Neurodegenerative Diseases — Alzheimer's Disease

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After attending this presentation, attendees will recognize characteristics in the use of "off-label" medical treatments in neurocognitive disorders.

This presentation will impact the forensic science community by increasing awareness of the competence of patients with neurocognitive disorders to consent to off-label use of atypical antipsychotic drugs.

In neurocognitive disorders, psychotic symptoms and behavioral dysfunctions are common and atypical antipsychotic drugs are considered, at the moment, preferred treatments; however, in Italy their use in patients (including older adults) with behavioral abnormalities is considered off-label. In Italy, off-label medical treatments are regulated by Law No. 94/98 which authorizes their prescription only after the obtainment of the patient's written informed consent. As is commonly known, informed consent is an essential prerequisite for any treatment. A valid consent may be given, in accordance with the ethical and legal standards of good clinical practice, only after a patient has received adequate information and included their health condition, the risks and benefits of the therapies proposed, possible alternatives have been evaluated, and their intact decision-making capacity ("competence") has been verified. Informed consent is usually in oral or written form, as provided in the recent Italian Code of Medical Ethics (Article 35), in the case of off-label treatments.[1]

The ISTAT (National Institute of Statistics) 2009 data show there is a progressive increase in the number of patients affected by dementia. The most common dementias are among neurocognitive disorders; in this context in recent years, new criteria has been developed for the clinical diagnosis that took into account the findings of research and a better understanding of the neuro-pathological disease.[2] The typical pathological lesions of Alzheimer's disease can be found in cognitively normal subjects, in those who present with Mild Cognitive Impairment (MCI), or in people with full-blown dementia. In these patients, where the risks associated with the recommended treatment are especially high, it is necessary to document the actual will of the person to accept the proposal of the doctor, as in the case of off-label treatments in behavioral disorders. Evidence in the literature suggests that even patients affected by severe chronic degenerative diseases still possess valid levels of competence to make some or all of the decisions about their treatment and thus no state of incompetence should be simply presumed.[3,4] Patients regarded as legally competent to make their own decisions may not be able to completely understand the medical proposals and choices in order to make a truly valid decision and give aware consent. Even the recent Code of Medical Ethics (Article 33) expressly provides information concerning "understandable and comprehensive" therapy. Accordingly, the view is that the failure to give consent must be considered a priori not related to a mental illness, a particular diagnosis, or nosological category; it must be assessed on a case-by-case basis and go beyond the stage of the progression of the deficit and regard the possible impact of the disease on neurocognitive skills that are the basis of decision making. This is to ensure compliance with the rules of law and ethics, but also to provide ethical access to care by all patients in accordance with "freedom of care."

For this reason, formats for adult persons and Parents/Guardian Ad Litem/Custodian/Administrative Support for interdicted or incapacitated beneficiary were designed. In the forms, scientific evidence of efficacy and the safety of proposed off-label treatment reported in the literature are explained. This important work fills a gap in the implementation of bioethical principles in the clinical setting.

References:

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Neurodegenerative Diseases, Off-Label Treatment, Informed Consent