Off-label prescribing in borderline personality disorder: where medication helps and where it does not

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Borderline personality disorder (BPD) presents a complex challenge for clinicians, often involving a constellation of symptoms that defy easy pharmacological solutions. While psychotherapy remains the cornerstone of treatment, medication frequently enters the picture, often in an off-label capacity, to manage acute distress or comorbid conditions. This practice raises questions about efficacy, safety, and the evidence base supporting such widespread use.

KEY TAKEAWAYS

- The Pivot: Off-label psychotropic prescribing is a widespread, yet often undocumented, practice for inpatients with intellectual disability and mental illness.
- The Data: 75% of psychotropic prescriptions for inpatients with mild intellectual disability and mental illness were off-label for indication.
- The Action: Clinicians must ensure robust documentation and informed consent for off-label psychotropic use, particularly in vulnerable populations.

Managing patients with borderline personality disorder frequently involves navigating a complex relationship between emotional dysregulation, impulsivity, and interpersonal difficulties. While dialectical behaviour therapy (DBT) and other psychotherapeutic interventions are the primary evidence-based treatments, clinicians often resort to pharmacological agents to target specific symptoms such as mood instability, anxiety, or psychotic-like features. These prescriptions are frequently off-label, meaning the drug is used for an indication not approved by regulatory bodies, raising concerns about the evidence supporting such practices, especially in vulnerable populations.1

A survey published in the Journal of Intellectual Disability Research examined the prevalence and characteristics of off-label prescribing of psychotropics for inpatients with mild intellectual disability (ID) and mental illness.1 The study, conducted by Haw and Stubbs in 2005, aimed to quantify the frequency of this practice, identify the specific off-label indications, and assess the documentation of consent and usage in patient case notes.1 The patient population comprised individuals admitted to a large psychiatric hospital, a setting where complex comorbidities and challenging behaviours often drive polypharmacy.

The Scope of Off-Label Prescribing

The survey identified that off-label prescribing was not an isolated incident but a pervasive practice within the inpatient psychiatric setting. Among the psychotropic prescriptions reviewed, a striking 75% were off-label for indication.1 This

figure highlights a significant gap between licensed indications and real-world clinical practice, particularly concerning patients with intellectual disability who often present with atypical symptom profiles or multiple co-occurring psychiatric conditions. The sheer volume of off-label use suggests that clinicians are frequently operating outside the strict confines of marketing authorisations to address the complex needs of these patients.

The study specifically focused on psychotropic medications, a broad category encompassing antipsychotics, antidepressants, mood stabilisers, and anxiolytics.1 Each of these classes carries specific licensed indications, typically for major psychiatric disorders such as schizophrenia, major depressive disorder, bipolar disorder, or generalised anxiety disorder. But in the context of borderline personality disorder, or in patients with intellectual disability and mental illness, the symptomatic presentation often blurs diagnostic lines, leading clinicians to use medications based on symptom clusters rather than strict diagnostic criteria. This approach, while clinically driven, inherently pushes prescribing into off-label territory.

Specific Drug Classes and Indications

The researchers detailed the types of psychotropics most commonly prescribed off-label. Antipsychotics, both first-generation and second-generation, were frequently used for indications beyond psychosis or bipolar mania.1 For instance, they were often prescribed for aggression, severe agitation, or behavioural disturbances that did not meet the full criteria for a psychotic disorder. This aligns with a broader trend in psychiatry where antipsychotics are sometimes employed for their sedative or mood-stabilising properties, even in the absence of a primary psychotic illness. Our previous coverage on ADHD management also touched on the complexities of multimodal care, where medication choices often extend beyond primary indications.

Antidepressants, primarily selective serotonin reuptake inhibitors (SSRIs), also featured prominently in off-label use.1 While licensed for major depression, anxiety disorders, and obsessive-compulsive disorder, they were often prescribed for emotional dysregulation, impulsivity, or chronic dysphoria in patients whose primary diagnosis was not a major depressive episode. This practice reflects the understanding that SSRIs can modulate serotonin pathways implicated in mood and impulse control, even if the specific constellation of symptoms does not perfectly align with a licensed indication. Still, the evidence base for SSRIs in core BPD symptoms remains mixed, with some studies showing modest benefits for affective instability but not for impulsivity or self-harm.

Mood stabilisers, such as valproate or carbamazepine, were another class frequently used off-label.1 Their primary licensed indications include bipolar disorder and epilepsy. But in patients with BPD, these agents were often prescribed for severe mood swings, affective lability, or impulse control difficulties, particularly when these symptoms were pronounced and disruptive. The rationale often stems from their ability to dampen neuronal excitability, which clinicians hope will stabilise the volatile emotional states characteristic of BPD. But the efficacy data for mood stabilisers in BPD, particularly for long-term symptom management, is not as robust as for their on-label indications.

Documentation and Consent: A Critical Gap

A significant concern highlighted by Haw and Stubbs was the inadequate documentation surrounding off-label prescribing.1 The survey found that details regarding the off-label clinical indication were often poorly recorded in patient case notes. Information about patient consent for off-label usage was frequently absent or insufficient.1 This lack of transparency is particularly problematic in vulnerable populations, such as those with intellectual disability, where

capacity for informed consent may be compromised or require specific, tailored communication strategies.
The absence of clear documentation creates several issues. It impedes continuity of care, making it difficult for subsequent clinicians to understand the rationale behind a specific off-label prescription. It also raises ethical and legal questions regarding informed consent, as patients (or their legal guardians) may not be fully aware that a prescribed medication is being used for an unlicensed purpose. This gap highlights the need for more rigorous clinical governance and clearer guidelines for off-label prescribing, especially when dealing with complex psychiatric presentations. Clinicians might find the Oxford Handbook of Psychiatry a useful reference for navigating these complex prescribing decisions.

Why Off-Label Prescribing Persists

The persistence of off-label prescribing in BPD and similar complex psychiatric conditions is not arbitrary. It often arises from a genuine clinical need to alleviate severe and distressing symptoms for which no licensed treatment exists or for which licensed treatments have failed. Pharmaceutical companies typically pursue licensing for indications with large patient populations and clear diagnostic criteria, making the complex, heterogeneous presentation of BPD less attractive for dedicated drug development and trials. This leaves clinicians with a limited arsenal of on-label options for core BPD symptoms.
But this pragmatic approach carries inherent risks. Off-label use means the drug has not undergone rigorous randomised controlled trials for that specific indication, leaving clinicians to rely on anecdotal evidence, small observational studies, or extrapolation from other conditions. The efficacy may be lower, the side effect profile different, and the optimal dosing regimen unknown. For instance, while antipsychotics can reduce aggression, they carry risks of metabolic side effects and extrapyramidal symptoms, which may not be justified if the primary indication is not psychosis. Our article on prescribing in heatwaves also highlighted the importance of considering broader patient risks when making medication choices.

Limitations and Future Directions

The Haw and Stubbs study, while insightful, has limitations. It was a survey conducted in a single psychiatric hospital in 2005, meaning its findings may not be generalisable to all healthcare settings or reflect current prescribing patterns.1 Prescribing practices evolve, and newer psychotropic agents have entered the market since the study was conducted. But the fundamental challenge of managing complex psychiatric conditions with limited on-label options persists. The focus on inpatients with intellectual disability also means the findings are not directly transferable to the broader BPD population without ID, though the underlying principles of off-label use remain relevant.
The open-label design is the obvious caveat. The study was a retrospective review of case notes, not a prospective trial.1 This means it could only describe existing practices, not evaluate the efficacy or safety of the off-label prescriptions. It highlighted a problem, but did not offer solutions beyond improved documentation. The lack of detailed information on patient outcomes associated with these off-label prescriptions is a significant gap. Without outcome data, it is impossible to definitively state whether these off-label uses were clinically beneficial or merely symptomatic management without addressing underlying issues.
Future research needs to move beyond descriptive surveys to rigorously evaluate the efficacy and safety of commonly used off-label psychotropics in BPD and other complex populations. This would involve well-designed randomised

controlled trials specifically targeting BPD symptoms, rather than relying on extrapolation from other disorders. Until such evidence emerges, clinicians must exercise extreme caution, ensure thorough informed consent, and meticulously document the rationale for any off-label prescription. The ethical imperative to provide evidence-based care demands a clearer understanding of where medication truly helps and where it merely adds to polypharmacy without substantial benefit. The escalating medication burden faced by dialysis patients underscores the broader issue of polypharmacy and its potential consequences.

CLINICAL IMPLICATIONS

The prevalence of off-label psychotropic prescribing, particularly for complex conditions like borderline personality disorder in patients with intellectual disability, demands a critical re-evaluation of clinical practice. Clinicians are often caught between a lack of licensed options and the urgent need to manage distressing symptoms. This leads to a reliance on drugs for indications not rigorously tested, a practice that, while pragmatic, carries inherent risks and ethical considerations.

The inadequate documentation of off-label use and consent, as highlighted by Haw and Stubbs, is simply unacceptable. It compromises patient safety, hinders continuity of care, and undermines the principle of informed consent. Regulatory bodies and professional organisations must provide clearer guidance on best practices for off-label prescribing, emphasising transparency and robust record-keeping, especially for vulnerable patient groups.

Pharmaceutical companies have little incentive to conduct expensive trials for niche indications or complex psychiatric syndromes like BPD, where symptom heterogeneity makes clear endpoints difficult. This market failure leaves clinicians in a bind. Public funding or academic consortia may need to step in to generate the much-needed evidence for off-label uses that are already widespread in practice, thereby closing the gap between clinical necessity and evidence-based medicine.

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