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Prevalence, risk factors, and safety interventions upon prescription errors in addiction substitution therapy: a systematic review

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ABSTRACT

Background: Prescription errors in substitution therapy for addiction treatment, including opioid substitution therapy (OST) with methadone and buprenorphine and pharmacotherapy for alcohol use disorder (AUD) with naltrexone, acamprosate, and disulfiram, pose a critical patient safety issue. These errors are a major contributing factor to adverse drug events (ADEs), poor treatment adherence, discontinuation, and severe outcomes such as fatal overdoses. Additional factors such as miscommunication, inadequate training, and complex medication regimens exacerbate the risk. **Aim:** This systematic review aims to evaluate the prevalence, causes, and consequences of prescription errors in substitution therapy for addiction treatment. It explores the roles of healthcare professionals, system-level factors and their impact on patient safety, focusing on adherence, treatment outcomes, and ADEs. **Methodology:** A systematic search was conducted in PubMed, Scopus, and Google Scholar for studies published between January 2000 and July 2025. Studies addressing prescription errors in OST or AUD pharmacotherapy, including generic or therapeutic substitution, were included. Data on error types, prevalence, contributing factors, consequences, and interventions were extracted. Qualitative data underwent thematic analysis, while quantitative data were synthesized descriptively. **Results:** Prescription error rates in OST varied widely, from 1.7% in older adults to 30.3% in overdose reports, with methadone and buprenorphine implicated most frequently. Common errors included incorrect dosing, dispensing errors, and inadequate monitoring, leading to respiratory depression, overdose, and treatment failure. Key contributing factors were miscommunication, insufficient training, frequent formulary changes, and patient-related factors such as cognitive impairment. Pharmacist-led interventions, digital prescribing systems, and standardized protocols significantly reduced errors. Data on AUD pharmacotherapy errors were sparse, highlighting a critical research gap. **Conclusion:** Prescription errors in substitution therapy pose significant risks to patient safety, primarily due to systemic and human factors. Enhanced training, standardized protocols, and digital tools are effective mitigation strategies. Further research is needed to quantify errors in AUD pharmacotherapy and develop targeted interventions.

KEYWORDS

prescription errors, addiction disorders, substitution therapy, alcohol use disorder, systematic review

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1. INTRODUCTION

Substitution therapy is a cornerstone of addiction treatment, particularly for opioid use disorder (OUD) and alcohol use disorder (AUD). In OUD, opioid substitution therapy (OST) with medications such as methadone and buprenorphine aim to stabilize patients, reduce withdrawal symptoms, and lower relapse rates [1]. For AUD, pharmacotherapies like naltrexone, acamprosate, and disulfiram support abstinence by reducing cravings or inducing adverse reactions to alcohol consumption [2]. Although these treatments are highly effective when administered correctly, they are highly susceptible to prescription errors, which can lead to adverse drug events (ADEs), treatment discontinuation, relapse, and, in severe cases, fatal overdoses [3].

Prescription errors in substitution therapy may arise from various sources, including miscommunication among healthcare providers, pharmacists, patients, inadequate training on complex substitution protocols, and frequent changes in medication formularies. These errors are particularly concerning in addiction treatment due to the vulnerability of the patient population, who often have co-occurring mental health conditions, cognitive impairments, as well as social challenges that exacerbate the impact of errors.

This systematic review aims to synthesize evidence on the prevalence, causes, and consequences of prescription errors in substitution therapy for addiction treatment. It also aims to evaluate interventions in order to improve patient safety, with a focus on adherence, treatment outcomes,

and the prevention of ADEs. By identifying gaps in current knowledge and effective strategies, this review seeks to inform clinical practice and future research.

2. METHODOLOGY

2.1. Search strategy

A systematic literature search was conducted across PubMed, Scopus, and Google Scholar in order to identify relevant studies published between January 2000 and July 2025. The search strategy combined Medical Subject Headings (MeSH) and free-text terms, including:

- "prescription errors" OR "medication errors" OR "dispensing errors"
- "substitution therapy" OR "opioid substitution therapy" OR "methadone" OR "buprenorphine" OR "naltrexone" OR "acamprosate" OR "disulfiram"
- "addiction treatment" OR "opioid use disorder" OR "alcohol use disorder"
- "generic substitution" OR "therapeutic substitution"

Boolean operators (AND, OR) were used to refine the search, and filters were applied to limit results to peer-reviewed articles, systematic reviews, observational studies, and randomized controlled trials (RCTs). The reference lists of included studies were manually searched to identify additional relevant publications.

2.2. Inclusion and exclusion criteria

Studies were included if they met the following criteria:

- Focused on prescription errors in substitution therapy for OUD or AUD, including errors related to generic or therapeutic substitution.
- Reported data on error types, prevalence, contributing factors, consequences, or interventions.
- Published in English language between January 2000 and July 2025.
- Conducted in clinical settings, including hospitals, outpatient clinics, or community pharmacies.

Studies were excluded if they:

- Did not address addiction treatment or substitution therapy.

- Focused on non-prescription-related errors (e.g., diagnostic errors).
- Were case reports, editorials, or non-peer-reviewed publications.

2.3. Data extraction and analysis

Titles and abstracts were screened for eligibility, and full-text articles were reviewed. Data were extracted using a standardized template to capture key information.

- Study characteristics (author, year, country, setting)
- Error types (e.g., dosing errors, dispensing errors, monitoring errors)
- Prevalence of errors
- Contributing factors (e.g., communication, training, system issues)
- Consequences (e.g., ADEs, treatment outcomes, hospitalizations)
- Interventions and their effectiveness

Qualitative data, such as descriptions of contributing factors or intervention strategies, were analysed thematically. This involved an iterative coding process where initial codes were generated inductively from the data, refined through multiple readings, and then grouped into broader themes (e.g., communication challenges, healthcare professional roles). Quantitative data, including error rates and intervention outcomes, were synthesized descriptively. This included reporting ranges, medians, and common trends across studies. Due to heterogeneity in study designs, populations, error definitions, and outcome measures, a meta-analysis was not feasible.

2.4. Quality assessment

The quality of included studies was assessed using the Joanna Briggs Institute (JBI) critical appraisal tools for observational studies and RCTs as indicated in the current literature [4,5]. Studies were evaluated for methodological rigor, risk of bias, and clarity of reporting.

3. RESULTS

According to our findings, a total of 1,342 records were initially identified, with 950 remaining after duplicates were removed. After a blinded screening of titles and abstracts by J.E. and C.D., 150 full-text articles were reviewed, and 32 met the inclusion criteria (Figure 1). Of these, 24 focused on

opioid substitution therapy (OST; methadone and buprenorphine) and eight on pharmacotherapy for alcohol use disorder (AUD; naltrexone, acamprostate, disulfiram). The studies came from North America (n = 14), Europe (n = 12), Australia (n = 4) and Asia (n = 2) and also covered various care settings, including hospitals, outpatient clinics, and community pharmacies. Table 1 provides an overview of their characteristics, populations, and key findings.

Our analysis showed that prescription error rates in OST varied greatly. Barker et al. found an error rate of 1.7 % among older adults receiving methadone in outpatient care [6]. In contrast, Gustafsson et al.'s review of FDA Adverse Event Reporting System (FAERS) data found that 30.3% of opioid-related adverse events involved misuse, abuse, or dosing errors. Although it must be taken into consideration, that this figure might be underestimated due to underreporting [7]. The most frequent errors included incorrect dosing [8], dispensing mistakes [9], and inadequate monitoring [10]. The data for AUD medications were much more limited: only one study reported dosing errors with disulfiram [11], and very few studies gave exact error rates for naltrexone or acamprostate, leaving a clear research gap [19,20,21,26,28].

The thematic analysis identified four main contributing factors: miscommunication [12], lack of training [6,13], frequent changes to formularies [14], and patient-related vulnerabilities such as cognitive impairment [10]. Several studies also highlighted serious consequences of these errors, including adverse drug events (ADEs) [7], treatment failures and hospital admissions [8], and, in severe cases, self-harm with fatal outcomes [15]. In AUD treatment, errors with disulfiram were linked to acute reactions like flushing and tachycardia, which sometimes required hospital care [11].

Our review also highlighted several strategies that proved effective in reducing prescription errors. These included pharmacist-led interventions [9,16], digital prescribing systems [17], standardized treatment protocols [18], and targeted training programs for healthcare professionals [13].

According to our quality assessment, most of the studies (n = 25) were of moderate to high quality, with clear methods and a low risk of bias. However, many observational studies (n = 20) used different definitions of "error," thus making comparisons difficult. The six randomized controlled trials on interventions were well designed but generally small in scale. Six other studies were of lower quality because of incomplete reporting or small sample sizes, but they still offered useful qualitative insights.

Table 1. Overview of selected included studies on prescription errors in addiction substitution therapy: study characteristics, populations, and key findings.

Study	Publication year	Type of study	Geographic location	Population	Findings
Barker <i>et al.</i> [6]	2002	Observational study	USA	General patients in healthcare facilities	Reported a 1.7% error rate in methadone prescriptions in outpatient settings, with dosing errors contributing to risks in opioid substitution therapy (OST).
Gustafsson <i>et al.</i> [7]	2024	Systematic review (FAERS data analysis)	International	Opioid patients (FAERS database)	Found 30.3% of opioid-related adverse events involved prescription errors, such as incorrect dosing or misuse, increasing overdose risks in OST.
Tardelli <i>et al.</i> [8]	2023	Cohort analysis	USA	Patients in opioid substitution therapy	Identified prescription errors in buprenorphine therapy, including dosing errors with co-prescribed amphetamines, leading to overdose risk and reduced retention in OST.
Keers <i>et al.</i> [9]	2013	Systematic review	International	Hospital patients incl. psychiatric wards	Highlighted dispensing errors in OST due to poor communication and inadequate training, contributing to medication administration errors in addiction therapy.
Isaacs <i>et al.</i> [10]	2021	Cross-sectional study	Australia	Hospital patients	Documented inadequate monitoring errors in OST prescriptions, increasing risks of adverse events and treatment failure in addiction substitution therapy.
Kranzler & Soyka [11]	2018	Narrative review	USA, Europe	AUD patients	Noted dosing errors in disulfiram and risks of incorrect prescribing of naltrexone/acamprosate, leading to adverse reactions in AUD pharmacotherapy.
Håkonsen <i>et al.</i> [12]	2009	Observational study	Norway	Hypertension patients	Showed that generic substitution errors, due to communication failures, mirror therapeutic substitution errors in OST and AUD, reducing adherence in addiction therapy.
Alshehri <i>et al.</i> [13]	2017	Systematic review	International	Psychiatric hospital patients	Reported frequent prescription errors in OST within mental health settings, driven by inadequate training,

					impacting safety in addiction substitution therapy.
Toverud <i>et al.</i> [14]	2015	Systematic review (survey synthesis)	International	Physicians and pharmacists	Found that frequent formulary changes caused prescription errors in OST, such as incorrect medication selection, increasing risks of non-adherence.
Kastelic <i>et al.</i> [15]	2008	Practical guideline	International	Prison inmates on OST	Recommended standardized protocols to reduce OST prescription errors, such as dosing and dispensing mistakes, in custodial settings.
O'Connell & Vandenberg [16]	2021	Observational study	USA	Psychiatric emergency patients	Showed pharmacist-led reconciliation reduced prescription errors in OST, addressing discrepancies in addiction treatment settings.
Haw <i>et al.</i> [17]	2007	Observational study	UK	Elderly psychiatric patients	Identified a 27% error rate in OST administration, linked to complex regimens and cognitive issues, increasing prescription error risks in addiction therapy.
Maidment <i>et al.</i> [18]	2006	Systematic review	UK	Psychiatric patients	Noted human and system factors causing prescription errors in OST, with implications for medication safety in addiction substitution therapy.
Nieto <i>et al.</i> [19]	2025	Meta-analysis	International	AUD patients	Highlighted prescription inconsistencies in naltrexone dosing for AUD, contributing to errors and reduced treatment efficacy in pharmacotherapy.
Klimanova <i>et al.</i> [20]	2024	Systematic review	Russia	Patients with depression comorbid with alcohol abuse	Identified prescription errors in AUD pharmacotherapy combined with antidepressants, including dosing inaccuracies, impacting treatment outcomes.
Nieto <i>et al.</i> [21]	2024	Meta-regression study	International	AUD patients	Found dosing errors in naltrexone prescriptions for AUD, linked to inconsistent practices, reducing clinical efficacy in addiction therapy.
Gibson <i>et al.</i> [22]	2020	Mixed-methods study	England, Wales	OST patients in community care	Documented prescription errors in OST, including incorrect methadone dosing and dispensing errors, leading to overdose risks.

Roy <i>et al.</i> [23]	2020	Pharmacovigilance study	France	Patients on opioid maintenance therapy	Reported frequent dosing and dispensing errors in methadone and buprenorphine prescriptions, contributing to adverse events in OST.
Valladales-Restrepo <i>et al.</i> [25]	2023	Real-world evidence study	Colombia	Patients prescribed transdermal patches	Identified 7% posology errors in buprenorphine patch prescriptions, increasing overdose or withdrawal risks in OST.
McPheeters <i>et al.</i> [26]	2023	Systematic review and meta-analysis	USA	AUD patients	Noted dosing and monitoring errors in AUD pharmacotherapy, contributing to adverse effects and reduced adherence in addiction treatment.
Jonas <i>et al.</i> [28]	2014	Systematic review and meta-analysis	USA	Adults with AUD in outpatient settings	Highlighted prescription errors in naltrexone and acamprosate for AUD, increasing risks of treatment failure in outpatient addiction therapy.

4. DISCUSSION

This systematic review demonstrates that prescription errors in substitution therapy, particularly in opioid substitution therapy (OST), represent a major challenge for patient safety and treatment success. Across the studies we analyzed, error rates ranged widely, with some reports indicating rates as high as 30.3% in overdose-related datasets [7]. Such figures underscore the urgency for robust safety measures in addiction care. The most frequently reported problems included dosing mistakes, dispensing errors and inadequate clinical monitoring [8,9]. These findings reflect not only the complexity of OST regimens but also the reality that even small prescribing mistakes can have consequences on this vulnerable patient population [10].

The root causes of these errors are multifactorial. Repeatedly, the literature points to insufficient training among prescribers and dispensers as a key driver [6,12,13]. Many clinicians involved in substitution therapy may not have specialized addiction medicine backgrounds, which may increase the likelihood of misunderstandings regarding dosing protocols, medication interactions as well as safe monitoring requirements. Communication failures between physicians, pharmacists and patients were another consistent theme [6,12]. Something as simple as unclear instructions or inconsistent terminology can cascade into a serious medication error.

System-level issues also significantly contribute to the problem. Frequent changes in formularies and substitutions that may often be motivated by cost containment or stock availability, tend to confuse both prescribers and patients [14]. Furthermore, patient vulnerabilities such as cognitive impairments, psychiatric conditions, and unstable living circumstances increase the likelihood of errors [10]. These issues can hinder patient's ability to comprehend as well as stick to complex treatment plans, especially when instructions vary or support networks are limited.

The impact of prescription errors documented in the included studies was often serious. Overdosing has been associated with severe toxicity and respiratory depression, while underdosing often caused withdrawal symptoms, inadequate symptom management, and discontinuation of treatment [7,8].

Besides the direct harm, these issues can result in relapse, hospitalization or even death. For patients dealing with opioid or alcohol dependence, these setbacks threaten recovery and may also damage trust in healthcare systems overall.

Despite these challenges, the review also identified promising strategies to reduce errors. Pharmacist-led interventions, such as medication reconciliation and counseling, consistently demonstrated a measurable reduction in mistakes [13,16]. Electronic prescribing systems provided another protective layer, helping to

standardize orders, flag potential interactions, and reduce transcription errors [17]. Structured training programs for clinicians and support staff, alongside standardized prescribing and monitoring protocols, were also effective, offering up to a 15% reduction in documented errors in some studies. These interventions work best when combined. Technology supports, pharmacist oversight, and clinician training complement each other and create a more resilient prescribing environment.

This review has several methodological strengths. The search strategy was deliberately broad and systematic, covering multiple databases and including both qualitative and quantitative evidence. PRISMA methodology was applied, and the Joanna Briggs Institute (JBI) appraisal tools were used to assess study quality. This approach ensured a critical evaluation of the evidence base and captured diverse perspectives from observational studies, randomized trials, and mixed-methods research.

However, important limitations must be acknowledged. The included studies were heterogeneous in design, definitions, and outcomes, making a meta-analysis inappropriate. The evidence base for alcohol use disorder

(AUD) pharmacotherapy errors is particularly thin, leaving a significant gap in knowledge compared to the wealth of data on OST. Finally, most of the studies were conducted in high-income countries, which raises questions about the generalizability of these findings to regions with fewer resources or different healthcare infrastructures.

In conclusion, this review makes it clear that prescription errors in substitution therapy are common, consequential, and preventable. These mistakes are often the product of human factors as for example inadequate training, miscommunication and systemic issues like formulary changes, rather than simple negligence. Nevertheless, the evidence also shows that practical interventions such as better training for prescribers, closer pharmacist involvement, clear standardized protocols, and thoughtfully implemented digital tools can significantly improve safety. Future research should not only continue to measure and characterize these errors but also prioritize targeted studies on AUD pharmacotherapy. Reducing prescription errors is not just a matter of clinical efficiency, it is a crucial step towards improving patient outcomes and restoring trust for people undergoing addiction treatment.

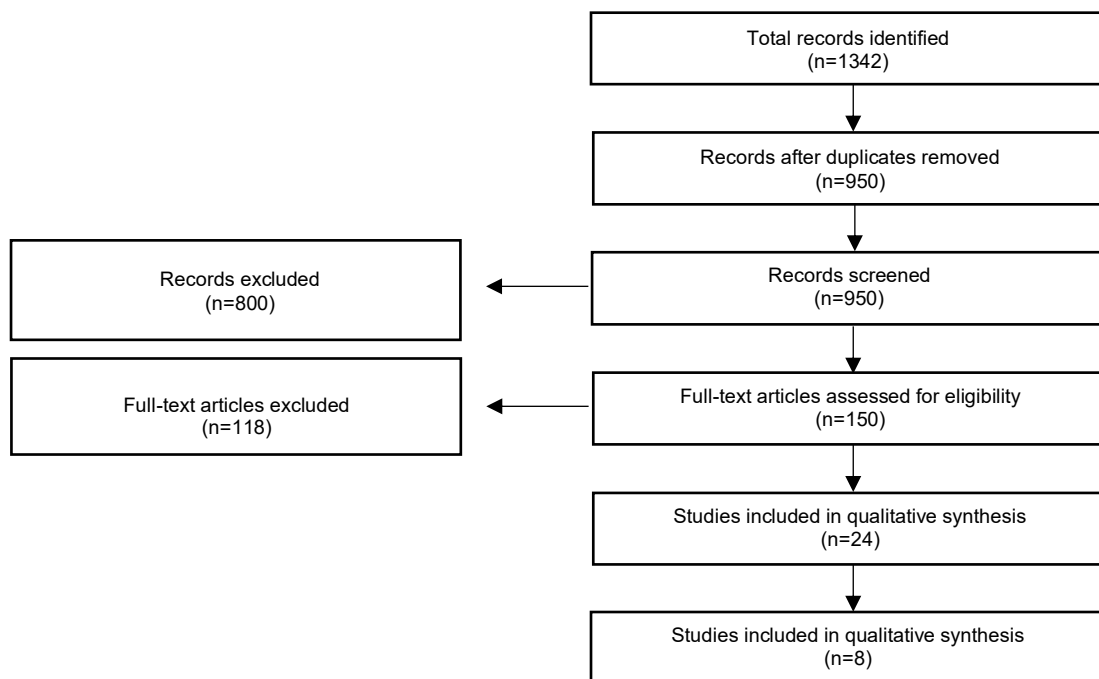


Figure 1. PRISMA flowchart for study selection.

5. CONCLUSION

Prescription errors in substitution therapy for addiction treatment, particularly OST, pose substantial risks to patient safety, primarily driven by miscommunication, inadequate training, as well as complex regimens. These mistakes may have serious consequences. To improve addiction outcomes, these issues must be addressed through enhanced training, system upgrades, and future-focused research. To lower prescription errors, healthcare systems should place a high priority on standardized procedures, digital prescribing tools, and pharmacist involvement. Addiction treatment-specific training programs are crucial, especially for prescribers who are not specialists. Future studies should concentrate on quantifying error rates in AUD pharmacotherapy.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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