Rapid review of the Emergency Department-Initiated Buprenorphine for Opioid Use Disorder.

Short Title: Review of ED Initiated Buprenorphine

Key words: Opioid Use Disorder, Emergency, Buprenorphine

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This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: [10.1111/1742-6723.13654](https://doi.org/10.1111/1742-6723.13654)

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Disclosures:

PD has received investigator-initiated funding from Gilead Sciences and an untied education grant from Indivior. PD is supported by an Australian NHMRC Senior Research Fellowship. PH declares investigator-initiated research funding from Gilead Sciences (2014-2019) and Abbvie Pharmaceuticals (2015-2017) for research not connected to this manuscript. The remaining authors have no conflicts of interest to declare. MLJ has received a payment from Indivior for providing professional education.

Funding: No funding was received to undertake this research.

Authorship declaration:

JH, MLJ, PD, AS, HS, KC conceived and designed the study. JH, HS performed the review. JH, HS, AS, RZ, KC, PD, PH, MLJ contributed to the manuscript preparation.

We would like to acknowledge Helen Wilding, Senior Research Librarian Carl de Gruchy Library, St Vincent's Hospital Melbourne for assistance in conducting the search.

Data sharing is not applicable to this article as no new data were created or analyzed in this study. No ethics approval was required to perform this review.

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ABSTRACT

Opioid related harms have been increasing in Australia over the last five years. People with opioid use disorder are over-represented in emergency department (ED) presentations. Opioid agonist treatment is the most effective community-based treatment. Buprenorphine is considered the safest of these treatments to use in the ED setting. This rapid review investigated the effectiveness of initiating Buprenorphine in the Emergency Department setting. Medline, Embase, Emcare, PSYCinfo, CINAHL and Cochrane Central Register of Controlled Trials databases were searched. Randomised and non-randomised studies published in peer reviewed journals that involved the initiation of buprenorphine in the ED setting were considered eligible. The search revealed 350 articles of which 11 were included in the review; three articles representing two randomised controlled trials and eight observational studies. Data were extracted from included papers and risk of bias assessed on the randomised controlled trials. Two randomised controlled trials showed that buprenorphine initiated in the ED does improve treatment engagement up to two months after an ED visit. Eight observational studies, one with a comparator group reported positive results for this intervention. There is strong evidence that clinicians should consider commencing buprenorphine in the ED for patients with opioid use disorder when combined with a direct and supported referral or “*warm handover*” to

community care. Further implementation studies and investigation of long-acting injectable buprenorphine treatment are required.

Key words: Opioid Use Disorder, Emergency, Buprenorphine

Introduction

Opioid use disorder (OUD), describes the chronic condition arising from opioid dependence and its associated harms (1). It carries a high individual, societal and economic burden (2). In Australia, between 2014 and 2019 there was a 40% increase in heroin-related harms and a significant increase in heroin-related emergency department (ED) attendances (3). It is critical for Australia to address the increasing incidence of opioid related deaths to prevent mirroring the “Opioid Epidemic” of North America (4, 5). Maintenance pharmacotherapy with opioid agonist treatment (OAT) has been shown to reduce withdrawal symptoms, cravings, non-medical opioid use, HIV infection rates and mortality (6, 7). In addition, OAT promotes patient satisfaction, psychological stability, social functioning and treatment engagement (2, 6, 7). One OAT that is considered appropriate for initiation in ED is buprenorphine/naloxone typically given sublingually (as Suboxone®) (8).

Some people with OUD have complex health needs, often feel marginalised from primary care and may have limited resources meaning that they often seek health care from the ED (9). Despite the high rates of overdose deaths post-ED discharge, this population is not routinely

granted access to treatment with buprenorphine, which is potentially life-saving and can alleviate the symptoms of withdrawal (10). The ED may offer an opportunity to engage people with OUD in treatment, link them in with longer term services, and promote strategies to reduce drug-related harms such as post-discharge overdose (11).

Buprenorphine is a partial opioid agonist which slowly dissociates from the μ -opioid receptor. It demonstrates a ceiling effect with regards to respiratory depression and euphoria, accounting for its increased safety in overdose (7, 12). Its long half-life provides the option of alternate-day dosing and patients report greater clarity of mind compared to other types of OAT such as methadone (2, 12). Induction is also safer than with methadone, and the maintenance dose can be reached within 2-3 days (2). Given its partial agonist action and strong affinity for the μ -opioid receptor, buprenorphine can precipitate withdrawal if given too soon after a full opioid agonist, such as heroin (2, 12). To prevent this, during induction the first dose should be delayed until the patient is experiencing moderate withdrawal symptoms (2). Buprenorphine is often combined with naloxone and delivered orally or sublingually in a combined film (as Suboxone®) (12). Naloxone, when delivered by this route, is not absorbed adequately to antagonize the buprenorphine but may do so if the buprenorphine/naloxone combination is injected; a potential deterrent (12). Compared to methadone, buprenorphine is safer in overdose, has fewer drug interactions, less dose variability between patients, is easier to titrate and is more difficult to divert (13). For these reasons, buprenorphine is typically considered the best choice of agent for initiation in the ED where close follow up in the days after discharge is often difficult.

The bulk of community-based OAT prescribing in Australia is carried out by a small number of specifically licenced private general practitioners (GPs) (10, 14, 15). Currently, these few prescribers cannot meet the needs of an increasing number of patients, and the current model for OAT is inadequate for those without a regular GP or a fixed address (3, 16). In 2019, long-acting injectable buprenorphine (LAIB) became available in Australia and may alleviate some of the difficulties of long-term treatment (17, 18). Injections given weekly or monthly, could reduce the demand on GPs and pharmacies and could improve quality of life by negating the need to attend a pharmacy frequently for supervised dosing of buprenorphine (17).

Opioid withdrawal has historically been neglected in EDs (19). The recommended treatments simple analgesia, antiemetics, anti-diarrhoeal agents, benzodiazepines, antipsychotics and alpha-2 adrenergic agonists clonidine that target individual symptoms are often insufficient and may have unwanted side-effects (19). Untreated opioid withdrawal has been shown to result in high risk illicit opioid use and increased mortality after discharge (20). When people in acute withdrawal are not offered effective treatment, they often choose to leave against medical advice, even in circumstances where medical treatment is essential (21).

Buprenorphine can rapidly relieve these symptoms in the ED. In this review we examine the effectiveness of ED-initiated buprenorphine for reducing withdrawal symptoms, increasing addiction treatment engagement and reducing harms in the months after index visit.

Methods

A literature search was conducted using Ovid Medline(1946-present), Embase(1974-present), Emcare(1995-present), PSYCinfo(1809-present), CINAHL and Cochrane Central Register of Controlled Trials databases.

Medical subject heading search terms, text and keywords associated with emergency department-initiated buprenorphine were used (Appendix 1). Bibliographies of included articles were also inspected for additional references. There were no limits imposed. Randomised and non-randomised studies published in peer reviewed journals that involved the initiation of buprenorphine in the ED setting were considered eligible.

Results

The search yielded eleven studies that investigated buprenorphine initiation in the ED for OUD (Figure 1.). The RCT conducted by D’Onofrio *et al.* in 2015 was identified as the landmark study (8). In 2017, the same authors published a subsequent paper on the longer-term outcomes of this RCT (11). These constitute level I evidence (22). The other RCT identified was conducted by Srivastava *et al* (23). These studies are detailed in Table 1.

RCTs

In the study conducted by D’Onofrio *et al.* the patients included were seeking treatment for OUD, or post-opioid overdose or identified on screening as having OUD. Opioid dependence

was confirmed with DSM4 criteria and an opioid-positive urine screen. Participants were randomly assigned to: a) referral to community-based treatment (Referral), b) brief intervention and facilitated referral to community-based treatment (BI) or c) brief intervention and ED-initiated buprenorphine and referral to primary care for 10 weeks of ongoing buprenorphine (Buprenorphine). The primary outcome was enrolment in addiction treatment at 30 days. Secondary outcomes were self-reported 7 days of illicit opioid use, urine toxicology for illicit opioids, HIV risk behaviour and use of addiction treatment services.

A maximum of 8mg of buprenorphine was initiated in the treatment arm if participants displayed withdrawal symptoms (49, 43%), otherwise they underwent unsupervised home induction (65, 57%). The participants were given take-home doses to bridge them until an appointment in primary care within 72 hours. They were then prescribed buprenorphine from a primary care service for 10 weeks.

The participants had similar characteristics to individuals in Australia who inject drugs and present to EDs (9) (Table 1). However, Australians rarely present to the ED purely for assistance with withdrawal (9).

Non-English speakers and those with insufficient contact information were excluded. In Australia, OUD has greatly affected the homeless population, many of whom may not have a mobile phone (24). This vulnerable population has traditionally not engaged in addiction

treatment services and would likely benefit from EDIB (24). In addition, this study did not include patients who were admitted to hospital.

Those allocated to the Buprenorphine group significantly increased engagement in treatment at 30 days compared to BI or Referral groups . It also significantly reduced self-reported 7-day illicit opioid use for both time and intervention effects and decreased use of inpatient addiction services. However, there was no difference across all three groups in the rate of positive urine samples or self-reported HIV risk-taking behaviour at 30 days.

Using treatment engagement at 30 days as the primary outcome has been criticised for being misleading and vague (25). Critics have argued that improvement in the primary outcome without improvement in secondary outcomes such as urine results and HIV risk behaviour may in fact be a marker of buprenorphine diversion (25). However, there is a reliable body of evidence showing that treatment engagement can be used as a surrogate measure for reduced mortality and decreased criminal activity (26, 27). The study has also been criticised for purporting to show that EDIB reduces illicit opioid use, yet the rate of positive urine tests was similar across the groups (28). Urine toxicology results, however, should be interpreted cautiously. A positive urine results only shows illicit opioid use in the last 72 hours, does not indicate the frequency or intensity of use and is not an ideal marker for OUD which is better measured by self-report (29). Complete abstinence from illicit opioids is not a useful primary goal of treatment and in patients not on OAT has been be associated with an increased risk of fatal overdose due to reduced tolerance (2, 30).

Subsequent analysis of longer-term outcomes, however, revealed the benefits of EDIB did not persist beyond 2 months, after which participant's care was transferred to a community provider or they opted to discontinue treatment (11). Buprenorphine is most effective at reducing mortality and hospitalisation when maintained for at least 12 months compared to discontinuation within five months (31). This disparity between the 2 and 6 and 12-month results show the importance of not only initiating buprenorphine but facilitating its maintenance by direct and supportive communication to community care (32). This has been termed a "warm handover".

Despite the authors making attempts to reduce bias by blinding care providers to participant's answers and verbally ensuring confidentiality, it remains unclear whether the self-reports were confounded by a social desirability bias.

In the RCT by D'Onofrio *et al.*, patients were provided with take home doses to initiate themselves. This is unlikely to be immediately feasible in many EDs. A barrier to implementation in both the US and Australia is likely to be emergency physicians' lack of confidence in prescribing an unfamiliar drug (33). Dedicated training of physicians would be required before this intervention could be applied to EDs universally.

Risk of Bias

These studies by D'Onofrio *et al.* were assessed for bias according to the Cochrane Risk of Bias (RoB) criteria (Figure 2). With regards to selection bias, random sequence generation and allocation concealment was used, D'Onofrio *et al.*'s study demonstrates a low risk of bias. As an open label study, neither the participants nor the clinicians were blinded to the intervention, so performance bias is possible. This can be mitigated by the authors having used objective outcome measures. Data on all outcomes were collected by researchers not involved in the patient's care, mitigating any effects of detection bias.

D'Onofrio's 2015 study was low risk for attrition bias. For the primary outcomes the statistical method accounted for all available data and included those with missing data. However, in the subsequent paper, few urine drug samples were obtained, accounting for a noteworthy amount of missing data with only the 2- and 6-month data reported. However, the utility of urine toxicology as an outcome measure, has been discussed (28). The analysis of longer-term outcomes completed in 2017 was conducted on 88% of the original sample. The population did not differ on variables such as gender, insurance and types of drugs used, subsequently this reduced bias. Both 2015 and 2017 papers are low risk for reporting bias because the outcomes prospectively identified are the same as those that were reported in the final paper.

In summary, this assessment demonstrates that D'Onofrio *et al.*'s RCT and its follow-up analysis are pieces of high-quality, level II evidence that show that buprenorphine initiated in

the ED is a more effective treatment than brief intervention and referral for up to 2 months post discharge. Furthermore, the treatment group had reduced use of inpatient addiction services, so it is possible that EDIB may be a cost-effective treatment. For 27% of participants, this was their first experience with treatment, hence EDIB may engage patients in treatment who might otherwise be unable to access OAT.

Srivastava *et al.* conducted an RCT in a single centre in Canada. This study compared the efficacy of buprenorphine to clonidine for the treatment of opioid withdrawal(23). The outcome measures were: a) the participant's attendance at a rapid access addiction clinic in the five days after their ED visit and b) their OAT status one month after randomisation (Table 1). The authors found that those who received buprenorphine in the ED were more likely to be engaged in OAT at one month.

The most striking limitation of this study is its small sample size (n=26) with consequent risk of type 1 error. In addition, unlike the previous study, Srivastava *et al.* did not track or screen all eligible ED patients. Instead, the study relied on ED physicians to enrol patients. Consequently, there is a high risk of confounding and selection bias. Moreover, there was a considerable amount of missing data resulting in attrition bias. Despite its limitations, this study provided some evidence that buprenorphine is a better choice of drug than clonidine in the ED.

Non-Randomised Observational Studies

Our search revealed eight non-randomised observational studies, mostly performed in the last two years (see Table 2). These have demonstrated that when buprenorphine is initiated in the ED with a *warm handover* (direct communication) to outpatient care, there is substantial engagement in formal addiction treatment in the following months (34-40). In some cases, this was achieved by utilising peer workers, social workers and rapid access bridge clinics; a model that is likely to overcome the extra workload perceived by physicians and prevent loss to follow up during this high-risk period (33, 34, 39, 40).

In all studies, the majority of participants presented to their first follow up appointment, and at 30 days more than two thirds of participants were retained(35-39). In one study, 37% of participants were still in active treatment at 6 months(37). Notable strengths of some include their large sample sizes and multicentre implementation (34, 40) . However, for all studies, their largely retrospective design and lack of comparison groups leaves them vulnerable to bias and so can only offer level IV evidence.

Additionally, Hu *et al.* found that patients maintained on buprenorphine had significantly fewer ED visits at 3 and 6-months compared to those who did not attend their first follow up or who stopped and re-started treatment (37).This mirrors the earlier findings of Berg *et al.* that buprenorphine, when given to relieve withdrawal symptoms in the ED, decreased 30-day ED attendance, compared to symptomatic treatment(41). This is level III evidence highlighting a health benefit of EDIB for the individual and a resource benefit for the health

service. In the small Dunkley *et al.* cohort (n=19), 47% of participants were identified as homeless, exhibiting the feasibility of this model in a vulnerable population (35).

In many of these studies, a large proportion of participants attended the ED specifically seeking treatment for OUD. This indicates that they are at the preparation stage of behaviour change and may be more likely to engage in treatment. It is possible that this treatment may not be transferable to EDs outside of North America where fewer people present to ED for treatment of OUD. In Australia and New Zealand, there are not large numbers of presentations to EDs that are seen in North American studies where only a very small proportion of people with OUD seek treatment and access to opioid agonist treatment is severely limited. These studies demonstrate the feasibility of ED initiated buprenorphine in the North American context. There is a gap in the literature for Australian-based evidence.

Discussion

The current review illustrates similar findings to those of Chen *et al.* in which the evidence from one well conducted trial supported the practise of EDIB(42). This model by D'Onofrio's has been replicated and successfully implemented in EDs in a diverse range of hospitals throughout North America (43). In 2019, the American College of Medical Toxicology (ACMT) published a position statement supporting EDIB that was endorsed by the American College of Emergency Physicians (ACEP) (44).

Additional Considerations

Implementation of Emergency Department-Initiated Buprenorphine

The reviewed literature has identified factors that limit the implementation and success of EDIB including extra physician workload (33). This is reflected in the lack of treatment focus for OUD in the acute care setting. In addition, when patients are engaged in long-term treatment, they are less likely to present to ED with other drug-related presentations such as overdose, cellulitis or endocarditis (37, 45). Australian EDs are constrained by significant time pressures, so EDIB protocols need to be efficient and make best use of available resources. In many tertiary hospitals in Australia there are addiction medicine consultant liaison services that have the potential to facilitate “warm handovers” and educate and support emergency physicians. Although there may be concern from clinicians that EDIB might increase ED presentations, this has not been reported in America(45). In Australia there is not a large population seeking treatment through EDs. EDIB may increase presentations to already overcrowded Australian EDs. Alternatively, novel community-based approaches such as rapid-access clinics could also alleviate the demand for OAT. It is possible that employing a combination of community and ED strategies could be further studied and employed in Australia. EDs are well placed to provide treatment in a time-responsive manner and are “open all hours”. Buprenorphine is a simple to use and relatively safe intervention to rapidly treat people with OUD.

A number of Level II evidence implementation studies are currently underway. D'Onofrio *et al.* are set to complete an implementation study by 2021, and a multicentre trial has been commenced by Melnick *et al.* (46, 47). Moreover, Kawasaki *et al.* have had successful preliminary results from their *Hub and Spoke* model of EDIB (48). Resources to promote uptake include peer workers, social workers, ED-based pharmacists and user-centred clinical decision support programs (47, 49). From a review of the available literature, it is clear that the benefits of initiating buprenorphine within ED outweigh any risks that have been identified.

Long-Acting Injectable Buprenorphine (LAIB)

Future research could examine whether pathways from sublingual to LAIB in the ED are more effective for long-term treatment. A multi-site community study with a small Australian arm (10%) demonstrated the benefit of LAIB over SL buprenorphine with higher retention rates and lower levels of illicit opioid use(50), While a further study showed that LAIB had high satisfaction (88%) and a 7% increase in employment rates(17).

Conclusion

These findings comprise Level I evidence supporting a recommendation for uptake of EDIB. EDIB has the potential to improve the management of people with OUD attending Australian EDs, provided linkages to community care are facilitated by a warm handover.

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Table 1. Randomised Control Trials of Emergency Department-Initiated Buprenorphine

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Appendix

Appendix 1: Search Strategy

▼ Search History (11)					View Saved	
#	▲	Searches	Results	Type	Actions	Annotations
1		exp buprenorphine plus naloxone/ or exp buprenorphine/	18475	Advanced	Display Results More ▾	Contract
2		(buprenorphine or suboxone or bupivac) t,ab.	9667	Advanced	Display Results More ▾	
3		1 or 2	19057	Advanced	Display Results More ▾	
4		exp emergency ward/	141496	Advanced	Display Results More ▾	
5		(emergency department* or trauma cent* or "accident and emergency" or emergency service) t,ab.	160152	Advanced	Display Results More ▾	
6		4 or 5	209701	Advanced	Display Results More ▾	
7		3 and 6	443	Advanced	Display Results More ▾	
8		exp opiate addiction/	19362	Advanced	Display Results More ▾	
9		("opioid use disorder" or opioid dependence or opioid withdrawal or heroin) t,ab.	22217	Advanced	Display Results More ▾	
10		8 or 9	37897	Advanced	Display Results More ▾	
11		7 and 10	262	Advanced	Display Results More ▾	
Save Remove Combine with: AND OR						
Save All Edit Create RSS View Saved						

Basic Search | Find Citation | Search Tools | Search Fields | **Advanced Search** | Multi-Field Search

1 Resource selected | Hide | Change
Embase 1974 to 2020 April 10

▼ Search History (11)					View Saved	
#	▲	Searches	Results	Type	Actions	Annotations
1		exp buprenorphine plus naloxone/ or exp buprenorphine/	6485	Advanced	Display Results More ▾	Contract
2		(buprenorphine or suboxone or bupivac) t,ab.	3047	Advanced	Display Results More ▾	
3		1 or 2	6574	Advanced	Display Results More ▾	
4		exp emergency ward/	66439	Advanced	Display Results More ▾	
5		(emergency department* or trauma cent* or "accident and emergency" or emergency service) t,ab.	64133	Advanced	Display Results More ▾	
6		4 or 5	87771	Advanced	Display Results More ▾	
7		3 and 6	203	Advanced	Display Results More ▾	
8		exp opiate addiction/	8147	Advanced	Display Results More ▾	
9		("opioid use disorder" or "substance use disorder" or opioid dependence or opioid withdrawal or heroin or addiction) t,ab.	28917	Advanced	Display Results More ▾	
10		8 or 9	33666	Advanced	Display Results More ▾	
11		7 and 10	120	Advanced	Display Results More ▾	
Save Remove Combine with: AND OR						
Save All Edit Create RSS View Saved						

Basic Search | Find Citation | Search Tools | Search Fields | **Advanced Search** | Multi-Field Search

1 Resource selected | Hide | Change
Ovid Emcare 1995 to 2020 week 15

▼ Search History (7)					View Saved	
#	▲	Searches	Results	Type	Actions	Annotations
1		exp Buprenorphine/	5208	Advanced	Display Results More ▾	Contract
2		(buprenorphine or suboxone or subutex or bupivac) t,ab.	6745	Advanced	Display Results More ▾	
3		1 or 2	7527	Advanced	Display Results More ▾	
4		exp Emergency Service, Hospital/	76552	Advanced	Display Results More ▾	
5		(emergency department* or trauma cent* or "accident and emergency" or emergency service) t,ab.	107370	Advanced	Display Results More ▾	
6		4 or 5	138851	Advanced	Display Results More ▾	
7		3 and 6	127	Advanced	Display Results More ▾	
Save Remove Combine with: AND OR						
Save All Edit Create RSS View Saved						

Basic Search | Find Citation | Search Tools | Search Fields | **Advanced Search** | Multi-Field Search

1 Resource selected | Hide | Change
Ovid MEDLINE(R) ALL 1946 to April 10, 2020

▼ Search History (7) View Saved

#	Searches	Results	Type	Actions	Annotations
1	exp buprenorphine/ or exp maintenance therapy/ or exp medication-assisted treatment/ or exp narcotic agonists/	7227	Advanced	Display Results More	
2	(buprenorphine or suboxone or buvidal).ti,ab.	2735	Advanced	Display Results More	
3	1 or 2	8059	Advanced	Display Results More	
4	exp emergency medicine/ or exp emergency services/	10585	Advanced	Display Results More	
5	(emergency department* or trauma cent* or "accident and emergency" or emergency service).ti,ab.	9993	Advanced	Display Results More	
6	4 or 5	16507	Advanced	Display Results More	
7	3 and 6	43	Advanced	Display Results More	

Combine with:

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 [Search Tools](#) |
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 [Advanced Search](#) |
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1 Resource selected | [Hide](#) | [Change](#)
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Searching: **CINAHL** | [Choose Databases](#)

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Search History/Alerts

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 [Retrieve Searches](#) |
 [Retrieve Alerts](#) |
 [Save Searches / Alerts](#)

☐ Select / deselect all

Search ID#	Search Terms	Search Options	Actions
☐ S3	S1 AND S2	Search modes - Boolean/Phrase	View Results (35) View Details Edit
☐ S2	(MH "Emergency Service+")	Search modes - Boolean/Phrase	View Results (61,950) View Details Edit
☐ S1	(MM "Buprenorphine")	Search modes - Boolean/Phrase	View Results (2,181) View Details Edit

Fedup Cochrane 13_04

Last saved on: 13/04/2020 09:54:14

✓ Search saved.

<input type="button" value="-"/>	<input type="button" value="+"/>	#1	MeSH descriptor: [Buprenorphine] explode all trees	MeSH ▼	<input type="button" value="1122"/>
<input type="button" value="-"/>	<input type="button" value="+"/>	#2	buprenorphine:ti or suboxone:ti or buvidal:ti	Limits	<input type="button" value="1713"/>
<input type="button" value="-"/>	<input type="button" value="+"/>	#3	#1 or #2	Limits	<input type="button" value="1967"/>
<input type="button" value="-"/>	<input type="button" value="+"/>	#4	MeSH descriptor: [Emergency Service, Hospital] explode all trees	MeSH ▼	<input type="button" value="2269"/>
<input type="button" value="-"/>	<input type="button" value="+"/>	#5	emergency department*:ti or trauma cent*:ti or "accident and emergency":ti or emergency service:ti	Limits	<input type="button" value="3667"/>
<input type="button" value="-"/>	<input type="button" value="+"/>	#6	#4 or #5	Limits	<input type="button" value="4931"/>
<input type="button" value="-"/>	<input type="button" value="+"/>	#7	#3 and #6	Limits	<input type="button" value="15"/>

☐ Highlight orphan lines

Figure 1. Flow diagram of record review selection

Figure 2.Cochrane Risk of Bias Tool for RCTs

	Risk of bias domains					
	D1	D2	D3	D4	D5	Overall
D'Onofrio 2015						
D'Onofrio 2017						
Srivastava 2019						

Study

Domains:
D1: Bias arising from the randomization process
D2: Bias due to deviations from intended intervention.
D3: Bias due to missing outcome data.
D4: Bias in measurement of the outcome.
D5: Bias in selection of the reported result.

Judgement
 High
 Some concerns
 Low

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Author/s:

Salter, H;Hutton, J;Cantwell, K;Dietze, P;Higgs, P;Straub, A;Zordan, R;Lloyd-Jones, M

Title:

Review article: Rapid review of the emergencydepartment-initiatedbuprenorphine for opioid use disorder

Date:

2020-10-21

Citation:

Salter, H., Hutton, J., Cantwell, K., Dietze, P., Higgs, P., Straub, A., Zordan, R. & Lloyd-Jones, M. (2020). Review article: Rapid review of the emergencydepartment-initiatedbuprenorphine for opioid use disorder. EMERGENCY MEDICINE AUSTRALASIA, 32 (6), pp.924-934. <https://doi.org/10.1111/1742-6723.13654>.

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