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Harm Reduction Approach to Increasing Self-Reported Safe Medication Storage Among Pregnant and Parenting People Receiving Opioid Use Disorder Treatment --Manuscript Draft--

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Abstract:	<p>Objectives: The expansion of access to buprenorphine-naloxone (BUP-NAL) for the treatment of opioid use disorder (OUD) is critical to combat the overdose crisis. Evidence is lacking to guide providers on how to best promote BUP-NAL medication safety for their patients. This study assessed: 1) the current medication storage practices among a sample of pregnant and parenting people receiving BUP-NAL for OUD; 2) the feasibility and acceptability of providing a lockbox for safe medication storage.</p> <p>Methods: Pregnant and/or parenting patients receiving sublingual BUP-NAL in an outpatient OUD clinic were recruited between June and November 2021. Participants completed a baseline survey, received a lockbox, and a follow-up survey three to eight weeks later. The primary outcome of current self-reported safe medication storage practice was defined by storing BUP-NAL in a locked/latched place 'almost always' or 'always' on the baseline survey. Outcomes were analyzed using simple proportions.</p> <p>Results: 63 participants completed the baseline survey, and 50 completed the follow-up survey. Baseline survey results indicated that only a quarter of patients (26.6%) were practicing safe BUP-NAL medication storage practices. At follow up, 93.6% of patients were using the lockbox provided by the study, 93.4% reported being satisfied with the lockbox, and most participants (89.3%) reported safe BUP-NAL medication storage practices.</p> <p>Conclusion: Many pregnant and parenting patients with OUD receiving BUP-NAL do not store their medications safely. The provision of a lockbox as part of OUD treatment is a feasible, acceptable, and potentially effective harm reduction intervention.</p>

1 **Harm Reduction Approach to Increasing Self-Reported Safe Medication**
2 **Storage Among Pregnant and Parenting People Receiving Opioid Use**
3 **Disorder Treatment**

4
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26

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34 of opioid use disorder (OUD) is critical to combat the overdose crisis. Evidence is lacking to
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38 a lockbox for safe medication storage.

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41 survey, received a lockbox, and a follow-up survey three to eight weeks later. The primary
42 outcome of current self-reported safe medication storage practice was defined by storing BUP-
43 NAL in a locked/latched place ‘almost always’ or ‘always’ on the baseline survey. Outcomes
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45 **Results:** 63 participants completed the baseline survey, and 50 completed the follow-up survey.
46 Baseline survey results indicated that only a quarter of patients (26.6%) were practicing safe
47 BUP-NAL medication storage practices. At follow up, 93.6% of patients were using the lockbox
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49 (89.3%) reported safe BUP-NAL medication storage practices.

50 **Conclusion:** Many pregnant and parenting patients with OUD receiving BUP-NAL do not store
51 their medications safely. The provision of a lockbox as part of OUD treatment is a feasible,
52 acceptable, and potentially effective harm reduction intervention.

53

54 **Introduction**

55 Overdose is a leading cause of death, including during pregnancy and postpartum.^{1,2} Medications
56 for opioid use disorder (MOUD) reduce overdose risk, facilitate recovery, and are safe and cost-
57 effective.^{3,4} Buprenorphine-Naloxone (BUP-NAL) is increasingly utilized for the treatment of
58 opioid use disorder (OUD) during pregnancy. Its office-based administration^{5,6} allows for
59 flexibility (e.g., transportation, childcare) and can reduce the stigma associated with seeking
60 addiction treatment which is amplified during pregnancy and parenting.⁷

61

62 Despite its advantages, having BUP-NAL at home poses risks. First, patients risk losing or
63 having it stolen, leading to interruptions in MOUD continuity and increasing overdose risk.
64 Second, having MOUD at home puts others at risk for unintentional ingestions. Drug poisonings
65 are a major cause of morbidity and mortality among children and adolescents,^{8,9} especially
66 children under 5 years old with a maternal history of substance use disorder.¹⁰ Safe medication
67 storage is an important preventative practice that could reduce these risks of lost, stolen, or
68 unintentional ingestion of medications. Previous studies have investigated medication storage
69 practices in patients receiving methadone^{11,12} and in individuals prescribed opioids for pain.^{13,14}
70 However, to our knowledge, the prevalence of safe medication practices and the subsequent
71 impact of providing a lockbox to improve safe medication storage in pregnant and parenting
72 individuals patients receiving MOUD has not been investigated.

73

74 One approach to promote safe medication storage is providing a locked or latched place, such as
75 a lockbox. This approach was utilized for caregivers in a pediatric emergency department,
76 resulting in a 86% increase in safe medication storage.¹⁴ No study has reported on the need for

77 nor the feasibility of interventions to increase safe medication storage among patients receiving
78 MOUD. The primary aim of our study was to assess the prevalence of safe medication storage
79 practices among a sample of pregnant and parenting people receiving BUP-NAL in an outpatient
80 OUD treatment clinic. Our secondary aim was to assess the feasibility and acceptability of
81 providing a lockbox for safe medication storage.

82

83 **METHODS**

84 **Study sample**

85 A convenience sample of pregnant and parenting people from an outpatient addiction clinic
86 completed two surveys between June and November 2021. Participants were English-speaking
87 and at least 18 years old, diagnosed with OUD, identified as cisgender woman or transgender
88 man, currently taking sublingual BUP-NAL and had at least one child < 18 years of age living in
89 the home. Exclusion criteria included: living in or moving to a group home, depending on
90 others for medication adherence, or having a significant cognitive or psychiatric impairment.
91 Participants were recruited from a research registry and when presenting for a clinic
92 appointment.

93

94 **Study procedures**

95 After informed consent, participants completed a baseline survey, received a lockbox, then
96 completed a follow-up survey three to eight weeks later (Supplemental Digital Content 1).
97 Surveys took 10 minutes, and participants were compensated. The sample size of 50 follow-up
98 survey completers for this exploratory study was pre-determined based on prior literature

99 assessing medication safety practices in other clinical samples.¹⁵ This study was approved by the
100 Virginia Commonwealth University IRB (HM20022004).

101

102 **Outcome measures**

103 The primary outcome of current self-reported safe medication storage practices was defined by
104 storing BUP-NAL in a locked/latched place ‘almost always’ or ‘always’ as self-reported on the
105 baseline survey.¹⁵ The secondary outcomes, assessed on the follow-up survey, were (1)
106 feasibility of providing a lockbox for medication storage as defined by answering ‘yes’ to using
107 the lockbox provided by the study and (2) acceptability as defined by being ‘very satisfied’ or
108 ‘somewhat satisfied’ with the lockbox. Two groups (safe medication storage and non-safe
109 medication storage) were created based on the primary outcome.

110

111 **Analysis**

112 Descriptive analyses were performed using JMP® 16, SAS Institute Inc., Cary, NC, USA.
113 Comparisons between the two groups were assessed using chi-squared and Student t-tests.

114

115 **RESULTS**

116 63 participants completed the baseline survey, and 50 completed the follow-up survey. Table 1
117 describes participant demographics. Participants were on average 31.07 (± 4.81) years old; 38.1%
118 identified as Black race, and 23.4% were currently pregnant. Most participants (78.1%) cared for
119 1 to 3 children in their home in the past three months. Over half (56.3%) had experienced
120 intimate partner violence, and 12.5% had experienced homelessness in the past three months.

121 Common locations (Supplemental Digital Content 2) for storing medications prior to receipt of
122 lock box among participants not reporting safe storage included: unlocked purse (23.1%),
123 bathroom cabinet (19.2%), keeping them on their dresser (13.5%) and in an unlocked drawer
124 (7.7%). Almost three quarters (73.4%) were not practicing safe medication storage (Figure 1);
125 most (84.6%) reported the primary reason for not doing so as not having a place that
126 latches/locks. Overall, more than 50% reported being ‘somewhat dissatisfied’ or ‘dissatisfied’
127 with their current medication storage methods, and almost half (44.4%) reported worrying about
128 a child getting access to their medication. The majority (64%) reported that, if given a free
129 lockbox, they would store their medications in it.

130

131 After provision of the lockbox (Supplemental Digital Content 3), follow-up survey results
132 (median follow-up 34 days) indicated high feasibility and acceptability of the lockbox (Figure 1).
133 Almost all (93.6%) participants used the lockbox, and 93.4% reported being ‘very satisfied’ or
134 ‘somewhat satisfied’ with it. The proportion practicing safe medication storage was much higher
135 at follow-up than at baseline (89.3% vs. 26.6%) (Figure 1). Most participants (79.5%) reported
136 using the lockbox to store their medication “always,” and 91.5% reported that having a lockbox
137 from this study improved their ability to store their medication in a locked/latched place all the
138 time.

139

140 **DISCUSSION**

141

142 In a sample of pregnant and parenting people receiving BUP-NAL in an outpatient OUD clinic,
143 few patients reported practicing safe medication storage, largely due to not having a locked or
144 latched location. In this pilot study, participants were provided a lockbox, and follow-up results

145 indicated high feasibility and acceptability of this preventative practice. Results indicate that safe
146 medication storage is a priority for pregnant and parenting patients in OUD treatment, and
147 provision of a lockbox with MOUD could meet this need.

148 Prior research from chronic pain clinics has elucidated how patients commonly do not store their
149 opioid medications safely.¹⁵ Webb et al. found that only 4% of caregivers presenting to an urban
150 pediatric emergency department reported safe medication storage practices, with almost 40%
151 stating that their main barrier to doing so was not having a locked or latched place.¹⁴ Our study
152 findings indicate how these low utilization rates of safe medication storage practices extend into
153 an OUD treatment clinical population.

154

155 Our study findings also demonstrated high feasibility and acceptability of providing a lockbox
156 for patients receiving BUP-NAL, similar to prior work not specific to an OUD population.^{14,15}
157 At follow-up, most of our pregnant and parenting participants reported storing their medications
158 safely, compared to only a quarter before being provided the lockbox. These preliminary
159 findings demonstrate the need for additional research in OUD treatment settings to guide
160 incorporation of evidence-based harm reduction interventions, such as those focused on safe
161 storage of prescribed medications and non-prescribed substances.¹⁶⁻¹⁸

162

163 Our findings should be interpreted in the context of study limitations. We relied on self-report for
164 our outcomes, leading to social desirability bias. Generalizability is limited, given our single site.
165 Lastly, the sample size represents a subset of our clinic; findings should be interpreted as
166 preliminary.

167

168 **CONCLUSIONS**

169 Nationwide, efforts to increase utilization of BUP-NAL are underway to combat the overdose
170 crisis. In our sample of pregnant and parenting people with OUD, the majority were not
171 practicing safe medication storage. We found the provision of a free lockbox to be a feasible and
172 acceptable preventative practice to promote safe medication storage in this unique patient
173 population. In line with a harm reductionist approach, further investigation of person-centered
174 interventions to optimize medication safety in MOUD samples is warranted.

175

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230
231

232 **Table 1:** Demographic, psychosocial, and clinical characteristics for study sample of pregnant
 233 and parenting people receiving buprenorphine for OUD, by baseline medication safety practices

	Total N (%) (N=63)	Safe Medication Storage N (%) (N=17)	Non-Safe Medication storage N (%) (N=46)	p - value
Age (Mean ±SD)	31.07 (4.81)	30.76 (6.18)	31.20 (4.28)	0.77
Race				0.15
Black	24 (38.09)	9 (52.94)	15 (32.61)	
White	39 (61.90)	8 (47.05)	31 (67.39)	
Ethnicity				0.55
Hispanic/Latinx	2 (3.17)	0 (0.00)	2 (4.35)	
Non-Hispanic/ Latinx	61 (96.83)	17 (100.00)	44 (95.65)	
Single marital status	24 (37.50)	9 (52.94)	15 (31.91)	0.15
Education				0.46
High school education	52 (82.54)	13 (76.47)	39 (84.78)	
More than high school education	11 (17.46)	4 (23.53)	7 (15.22)	
Current Living Situation				0.30
Alone	2 (3.17)	1 (5.88)	1 (2.17)	
With sexual partner and children	51 (80.95)	15 (88.24)	36 (78.26)	
With parents/family/friends	10 (15.87)	1 (5.88)	9 (19.57)	
Length of time on BUP-NAL				0.76
≤1 year	29 (46.03)	7 (41.18)	22 (47.83)	
>1 year	34 (53.97)	10 (58.82)	24 (52.17)	
Mental health comorbidity	60 (93.75)	17 (100)	43 (91.49)	0.56
*Homeless in the past 3 months	6 (9.38)	1 (5.88)	5 (10.64)	1.0
**Intimate partner violence in the past 3 months	36 (56.3)	8 (47.06)	28 (59.57)	0.3

234 * Homelessness was defined by self-reporting ‘yes’ to living on the street, in a shelter, in a single
 235 room occupancy hotel or in a car in the past three months.

236 **Scoring greater than 10 on the Hurt, Insult, Threaten and Scream: (HITS) Tool for Intimate
 237 Partner Violence Screening.

238

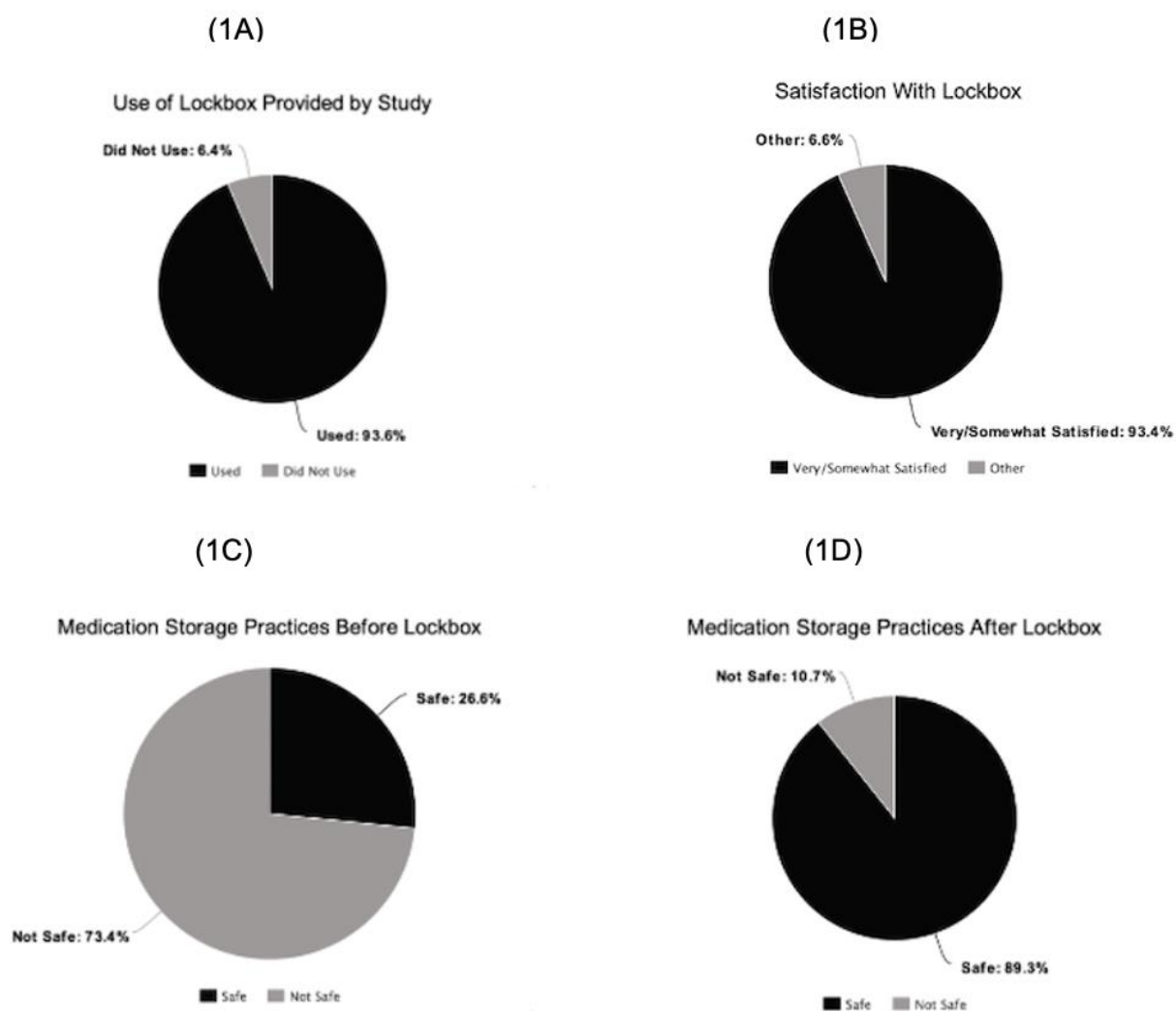
239 **Figure 1:** Feasibility and acceptability of providing a lockbox for medication storage to pregnant
 240 and parenting patients with OUD receiving BUP-NAL (n=50)

241 1A: Feasibility of lockbox provision

242 1B: Acceptability of lockbox provision

243 1C: Safe medication storage practices by participants before reception of lockbox

244 1D: Unsafe medication storage practices by participants after reception of lockbox



245