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Research Paper

Evaluating how has care been affected by the Ontario COVID-19 Opioid Agonist Treatment Guidance: Patients' and prescribers' experiences with changes in unsupervised dosing

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ABSTRACT

Background: The COVID-19 pandemic has exacerbated the opioid crisis. Opioid-related deaths have increased and access to treatment services, including opioid agonist treatment (OAT), has been disrupted. The Ontario COVID-19 OAT Treatment Guidance document was developed to facilitate access to OAT and continuity of care during the pandemic, while supporting physical distancing measures. In particular, the Guidance expanded access to unsupervised OAT dosing. It is important to evaluate the changes in unsupervised OAT dosing after the release of the Ontario COVID-19 OAT Guidance based on patients' and prescribers' reports.

Method: Online questionnaires were developed collaboratively with people with lived and living expertise, prescribers, clinical experts, and researchers. Patients ($N = 402$) and prescribers ($N = 100$) reported their experiences with changes in unsupervised dosing during the first six months of the pandemic.

Results: Many patients (57%) reported receiving additional unsupervised OAT doses (i.e., take away doses). Patients who received additional unsupervised doses were not significantly more likely to report adverse health outcomes compared to patients who did not receive additional unsupervised doses. Patients with additional unsupervised doses and prescribers agreed that changes in OAT care were positive (e.g., reported an improved patient-prescriber relationship and more openness between patient and prescriber). Prescribers and some patients reported the need for continued flexibility in unsupervised doses after the pandemic restrictions lift.

Conclusions: Results support the need to re-evaluate historical approaches to OAT care delivery, particularly unsupervised doses. It is crucial to implement policies, regulations, and supports to reduce barriers to OAT care during the pandemic and once the pandemic response restrictions are eased. Flexibility in OAT care delivery, particularly unsupervised dosing, will be key to providing patient-centred care for persons with opioid use disorder.

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The COVID-19 pandemic has exacerbated the impacts of the opioid epidemic. Deaths due to opioid overdose increased by 40% between 2019 and 2020 in the United States (Baumgartner & Radley, 2021). There was a 38% increase in opioid-related deaths in the first 15 weeks of the COVID-19 pandemic (695 deaths; average of 46 deaths weekly) compared to the 15 weeks immediately before the state of emergency declaration in Ontario, Canada on March 17, 2020 (Ontario Drug Policy Research Network, 2020). European countries (e.g., France and Finland) have noted increases in opioid-related deaths, and others (e.g., Bulgaria, Ireland, Cyprus, and Portugal) have reported difficulty in assessing trends in opioid-related deaths due to delays in autopsies and toxicological assessments (European Monitoring Centre for Drugs and Drug Addiction, 2020).

Opioid agonist therapy (OAT) with methadone or buprenorphine is the standard of care for the treatment of opioid use disorder (OUD; Bruneau et al., 2018; Fullerton et al., 2014; Mattick, Breen, Kimber, & Davoli, 2009; Nielsen et al., 2016; Pearce et al., 2020; Thomas et al., 2014). Methadone and buprenorphine were added to the World Health Organization's (WHO) list of essential medicines in 2005 (Herget, 2005). Although OAT is becoming increasingly available worldwide (Larney et al., 2017) and the WHO has developed recommendations for aspects of OAT care (WHO, 2009), there is substantial variation in care delivery (Jin et al., 2020). Despite the availability of OAT in the United States and Canada, many people with OUD do not access care or choose to withdraw from care (Timko, Schultz, Cucciare, Vittorio, & Garrison-Diehn, 2016; Wu, Zhu, & Swartz, 2016). Barriers to OAT care include program requirements such as frequent office visits, rigid schedules for urine drug testing, and the need for daily supervised dosing until strict criteria for unsupervised doses are met (e.g., Frank et al., 2021; Timko et al., 2016). In Canada, many prescribers apply the same treatment regimens used with methadone to patients prescribed buprenorphine, despite their different safety profiles (Marteau, McDonald, & Patel, 2015). Thus, patients prescribed buprenorphine often require more frequent supervised doses and urine drug screens than necessary, which creates barriers to care.

The COVID-19 pandemic has disproportionately affected people who use opioids as it has interfered with their ability to access life-saving OAT, harm reduction, and other supports (Canadian Centre on Substance Use and Addiction, 2020a; 2020b). Despite initial disruptions to care, many OAT providers worldwide quickly adapted to pandemic restrictions by developing novel practices to maintain patient care (European Monitoring Centre for Drugs and Drug Addiction, 2021). Dunlop et al. (2020) offered suggestions for reducing exposure to COVID-19, while maintaining access to care, including the use of long-lasting depot buprenorphine and offering unsupervised doses accompanied by naloxone. In some parts of North America, pharmacists were allowed to adjust OAT doses (Substance Abuse and Mental Health Services Administration, 2020); in Canada, pharmacists were permitted to renew and extend prescriptions for controlled substances, including OAT (Health Canada, 2020). Delivery services for OAT were developed in some countries (e.g., China; Sun et al., 2020) and expanded in others (e.g., Canada), such that more individuals could deliver OAT to patients (e.g., pharmacy technicians, pharmacy employees, and health professionals designated by a patient; Health Canada, 2020). Protocols for remote assessments for OUD and initiations of OAT have been documented in Ireland (Crowley & Delargy, 2020) and Canada (Clarke et al., 2020). Emergency centres with harm reduction supplies and OAT were developed for unstably housed individuals in many countries, including Portugal (European Monitoring Centre for Drugs and Drug Addiction, 2020).

In Ontario, Canada, the Ontario COVID-19 OAT Guidance was developed and disseminated in March 2020, shortly after the declaration of the state of emergency in Ontario. The purpose of the guideline was to facilitate safe access to and continuity of care, while supporting public health recommendations for physical distancing (Lam, Sankey, Wyman, & Zhang, 2020). The guidance document suggested expanding virtual care, reducing the frequency of clinic visits and urine drug testing, and expanding access to unsupervised doses for OAT, by both increasing unsupervised doses beyond the usual limits and allowing limited numbers of unsupervised doses for individuals who would not have met the usual criteria for any unsupervised doses. Clinicians were encouraged to utilize clinical stability as the criteria for unsupervised doses rather than adhere to a traditional contingency management schedule (i.e., monthly adjustments by one unsupervised dose/week after a minimum of two months in treatment and urine drug screen evidence of abstinence from all substance use). Specifically, patients who continued to use substances, including opioids, could receive up to three non-consecutive unsupervised doses of methadone per week as long as they could safely store their doses and were not deemed to be high risk (e.g., experienced recent overdose, injecting opioids, or unstable psychiatric co-morbidity). Patients who had already been receiving unsupervised doses could increase the number rapidly, and negative urine drug screens were required only for patients receiving 5 or 6 unsupervised doses at a time. The maximum number of consecutive unsupervised doses for methadone was increased to 28 for patients with long-standing stability and experience with unsupervised doses. Up to 28 days of unsupervised buprenorphine was permitted regardless of how long patients had been on treatment. The authors of the guidance document acknowledged that the recommendations were intended to supplement and not replace existing guidelines (College of Physicians and Surgeons of Ontario (CPSO), 2011). Treatment providers were encouraged to use their clinical judgement as the basis for any treatment decisions, including returning to pre-pandemic practices if deemed appropriate. This Guidance was widely disseminated across Ontario.

It is important to evaluate the changes to unsupervised doses, to inform post-pandemic clinical guidance. The current study assessed changes in unsupervised OAT dosing after the release of the Ontario COVID-19 OAT Guidance with data derived from surveys of patients and prescribers. We assessed (1) which patients received additional unsupervised doses during the pandemic; (2) the outcomes of unsupervised dosing (e.g., patients' behavioral, health, substance use, and wellbeing outcomes); and (3) patients' and prescribers' experiences with changes in OAT care delivery, including interest in maintaining changes in unsupervised dosing after the pandemic restrictions end.

Materials and methods

All procedures were approved by the institutions' Research Ethics Boards (REB #2020013 and #2020-0084-E).

Participants

Patients prescribed OAT

Patients were recruited from across rural and urban areas in Ontario, including from: (1) clinics that prescribe OAT; (2) pharmacies that dispense OAT; or (3) social media advertisements. 425 individuals responded to advertisements for the online survey. Eligibility criteria included: (1) being 18 or older, (2) living in Ontario, (3) ability to understand English or French, and (4) being prescribed OAT at the time of the survey. The final sample consisted of 402 eligible patients who completed at least one question about their OAT care during the COVID-19 pandemic; the remaining participants were excluded for one or more reasons: did not answer any questions about their OAT care during the pandemic ($n = 14$); not prescribed OAT or not living in Ontario ($n = 9$).

Prescribers

Prescribers were recruited using email advertisements sent to professional networks and social media posts. 134 prescribers responded to advertisements for the online survey. Individuals were eligible if they prescribed OAT in Ontario. The final sample consisted of 100 prescribers who completed at least one question about how they provided OAT care during the pandemic. Participants were excluded if they were not pre-

scribing OAT in Ontario ($n = 4$) or they did not answer any survey questions about their OAT practice during the pandemic ($n = 30$).

Surveys

The contents of the patient and the prescriber survey were developed collaboratively with prescribers, clinical experts, researchers, and people with lived and living expertise. Items from the surveys are available in Supplementary Material. The patient survey included demographic questions, items from validated measures of substance use (i.e., past 30 day substance use from the WHO ASSIST [WHO ASSIST Working Group, 2002]), previously published surveys on virtual care (e.g., Schubert, Backman, Bhatla, & Corace, 2019), and questions developed for the purposes of this study. Patients were asked about changes in the number of unsupervised doses they received,[1] the outcomes of unsupervised doses they received (e.g., patients' behavioral, health, substance use, and wellbeing outcomes), and their experiences with OAT care during the pandemic, including interest in maintaining changes to unsupervised dosing after the pandemic restrictions end.

The prescriber survey included demographic questions and questions developed for the purposes of this study. Prescribers were asked about how their prescribing practices changed, outcomes (health, behavioral, substance use, and well-being) in patients with additional unsupervised doses, and their experiences with providing additional unsupervised dosing during the pandemic, including their interest in maintaining changes to unsupervised dosing after pandemic restrictions are lifted.

Most survey questions were closed-ended; participants were asked to report their experiences (yes or no) or rate their opinions or experiences on a 5-point scale ("strongly disagree" to "strongly agree"). Patients were asked to report the highest number of unsupervised doses they received per week before the pandemic (i.e., before March 17, 2020) and during the pandemic (i.e., after March 17, 2020). Surveys were available in English and French. The majority of respondents (99.7% patients, 96% prescribers) completed the surveys in English. The surveys were hosted by Simple Survey. Participants indicated their consent by clicking "next" to begin the survey after reading a consent form. Patients received a $15 gift card of their choice as compensation for their time. Both the patient and the prescriber surveys were completed between August and mid-September, 2020.

Data preparation and analyses

Patients' responses to a yes/no question ("During the pandemic, were you prescribed more unsupervised doses than before the pandemic?") were used to categorize patients as having additional unsupervised doses or not during the pandemic. To group participants by their level of stability, the number of unsupervised doses pre-pandemic was used to define the following categories: 0-1 unsupervised doses, 2-5 unsupervised doses, or 6+ unsupervised doses. For the Likert-scale responses to opinion questions, we combined "strongly disagree" and "disagree" into one response ("disagree") and "strongly agree" and "agree" into one response ("agree"). "Neither disagree nor agree" remained its own response category in the analyses.

Where there was missing survey data, the participant was excluded from that analysis. Analyses involving unsupervised doses excluded patients prescribed depot buprenorphine (i.e., buprenorphine extended-release injection), as these patients do not receive unsupervised doses. Analyses based on OAT type excluded patients who reported being prescribed multiple types of OAT, as these patients could not be categorized based on OAT type ($n = 41$). The sample size is reported for each survey item in the results or tables.

[1] The survey used the term "carries" for take away or unsupervised doses, as is customary in Canada.

Chi square analyses were used to compare responses to survey items yielding nominal data. We examined the adjusted residual values for significant chi square analyses; we applied the Bonferroni correction to *p*-values when multiple comparisons were made. Mann-Whitney U tests were performed to assess differences in the degree to which patients agreed with statements. A *p*-value of 0.05 was the cut-off for statistical significance, except when the Bonferroni correction was necessary. All analyses were performed using SPSS 27.

Results

Participant characteristics

Patients

Patients' demographic information, substance use, and OAT history are outlined in Table 1. Over half of the patients identified as male (54%). The majority identified as white (78%) and were between 30-44 years old (60%). Most had used tobacco (80%) or alcohol (61%) in the 30 days prior to completing the survey; 42% reported using opioids. Of those who reported using opioids in the past 30 days, most reported using hydromorphone (41%) or oxycodone (37%); 15% reported using fentanyl. Nearly half (46%) reported that their opioid use had increased since the pandemic began, and 55% had used injection opioids in the 90 days prior to completing the survey.

Patients were most frequently prescribed methadone (30%), and the remaining patients were fairly equally divided between buprenorphine (23%), slow-release oral morphine (SROM; 21%), and depot buprenorphine (16%). Of note, 41 patients (10%) reported being prescribed two or more types of OAT. The majority had started their OAT treatment (either for the first time or their most recent treatment course) in the year prior to completing the survey (63%).

Prescribers

Prescribers' demographic information, training, and OAT care experience are outlined in Table 2. Nearly two-thirds identified as male (60%) and as an addiction medicine physician (62%). Some practiced in rural (14%) or remote (18%) settings. Two-thirds had been prescribing OAT for at least six years. The majority (91%) of the prescribers reported that they had read the Guidance. Of those prescribers who read the Guidance, 99% reported it resulted in practice changes in prescribing unsupervised doses for at least some of their patients.

Who received additional unsupervised doses during the pandemic?

Table 3 depicts patients' reports of their unsupervised doses before and during the pandemic. Overall, 22% of patients reported being prescribed 0-1 unsupervised doses prior to the COVID-19 pandemic, 56% reported 2-5 unsupervised doses, and 22% reported 6 or more unsupervised doses. More than half of all patients (57%) reported that they received additional unsupervised doses during the pandemic.

Chi square analyses compared patients' likelihood of receiving additional unsupervised doses based on the OAT medication type they were prescribed. There were no significant differences in patients' likelihood of receiving additional unsupervised doses based on OAT type, χ^2 (2) = 0.62, p = .73. Additional chi square analyses compared patients' likelihood of receiving additional unsupervised doses based on their pre-pandemic maximum number of unsupervised doses. Patients' maximum number of pre-pandemic unsupervised doses affected their likelihood of receiving additional unsupervised doses during the pandemic, χ^2 (2) = 13.60, p = .001. Patients with 2-5 unsupervised doses before the pandemic were most likely to report being prescribed additional unsupervised doses during the pandemic, whereas patients with 6 or more unsupervised doses were least likely to report receiving additional unsupervised doses. Chi square analyses were then conducted for each type of OAT medication, to determine differences based on the number of pre-pandemic unsupervised doses prescribed to patients. For

Table 1
Patients' (n = 402) demographic information, substance use history, and OAT history.

Demographics		***N***	**Percentage**
Age (n = 402)	18-29	117	29%
	30-44	242	60%
	45-59	42	11%
Identify as (n = 402)	Male	217	54%
	Female	179	44%
	Gender fluid, gender queer, non-binary, or intersex	6	2%
Ethnic/Racial Background (n = 402)	White - European or North American	314	78%
	Asian - East or South East	9	2%
	Black - African, Caribbean, or North American	43	11%
	First Nations, Inuit, or Metis	28	7%
	Latin American	6	1%
	Mixed heritage	1	<1%
	Prefer not to respond	1	<1%
Substance use during the pandemic		***N***	**Percentage**
Since COVID-19 (March 2020), has your opioid use: (n = 402)	Increased	185	46%
	Decreased	86	21%
	Not changed	121	30%
	Did not respond	10	3%
Have you ever used any opioids by injection/needles? (n = 402)	Never	122	30%
	Yes, in the past 3 months	220	55%
	Yes, but not in the past 3 months	58	14%
	Did not respond	2	1%
Types of opioids used in the 30 days prior to the survey: (n = 402)	Hydromorphone	165	41%
	Oxycodone	148	37%
	Morphine	119	30%
	Codeine	67	17%
	Fentanyl	58	15%
	Heroin	58	15%
	Not listed	23	6%
Frequency of substance use in 30 days prior:	**Never *n* (%)**	**Once or twice *n* (%)**	**Weekly or more frequently *n* (%)**
Cannabis (n = 400)	265 (66%)	80 (20%)	55 (14%)
Cocaine (n = 399)	302 (76%)	54 (13%)	43 (11%)
Amphetamine type stimulants (n = 399)	319 (80%)	40 (10%)	40 (10%)
Inhalants (n = 399)	335 (84%)	36 (9%)	28 (7%)
Sedatives or sleeping pills (n = 399)	279 (70%)	68 (17%)	52 (13%)
Hallucinogens (n = 400)	338 (85%)	34 (9%)	28 (6%)
Opioids (n = 401)	232 (58%)	67 (17%)	102 (25%)
Alcohol (n = 400)	157 (39%)	61 (15%)	182 (46%)
Tobacco (n = 400)	78 (20%)	52 (13%)	270 (67%)
OAT Care		***N***	**Percentage**
When did you start OAT? (n = 402)	0-2 months ago	18	5%
	2-6 months ago	99	25%
	6-12 months ago	132	33%
	1-2 years ago	95	24%
	2-5 years ago	45	11%
	5+ years ago	13	3%
Which type of OAT are you on? (n = 402)	Methadone	122	30%
	Buprenorphine	91	23%
	Slow release oral morphine	84	21%
	Depot buprenorphine	64	16%
	Multiple OAT types	41	10%

Note: All patients with usable data (i.e., living in Ontario, Canada, prescribed OAT, 18 years or older, and answered at least one question regarding their OAT care during the pandemic) were included.

patients prescribed SROM, those with 2-5 unsupervised doses prior to the pandemic were most likely to report receiving additional unsupervised doses during the pandemic, and those with 6+ unsupervised doses were least likely to report receiving additional unsupervised doses during the pandemic, χ^2 (2) = 12.69, p = .002. The number of pre-pandemic unsupervised doses did not affect the likelihood of patients prescribed methadone or buprenorphine being prescribed additional unsupervised doses, χ^2 (2) = 1.61, p = .45 and χ^2 (2) = 7.29, p = .03, respectively.

Table 4 depicts prescribers' reports of how their prescribing practices regarding unsupervised dosing changed during the pandemic. In general, at least half of the prescribers issued unsupervised doses for patients who previously did not receive them, across all OAT types. The majority of methadone and buprenorphine prescribers increased the number of unsupervised doses above pre-pandemic levels. Less than one-third of prescribers reported decreasing the frequency of unsupervised doses, regardless of OAT type. The majority of prescribers reported

Table 2
Prescribers' (n = 100) demographic information and OAT experience.

		Percentage (%)
Identify as	Male	60%
	Female	39%
	Prefer not to respond	1%
What type of clinic(s) do you work at	OAT clinic	47%
	Hospital-based clinic	32%
	Rapid access addiction medicine clinic	21%
	Community health centre	16%
	Emergency department	12%
	Hospital in-patient setting	12%
Professional identification(s)	Addiction medicine physician	62%
	Family physician	45%
	Emergency medicine physician	18%
	Psychiatrist	7%
	Nurse practitioner	5%
Additional training(s) in addictions medicine	Certificate of added competence in addiction medicine	57%
	Other addiction medicine training	30%
	Addiction medicine fellowship	27%
Years of OAT practice	Less than 1 year	4%
	1 - 5 years	29%
	6 - 10 years	35%
	11 - 15 years	9%
	16 - 20 years	13%
	More than 20 years	10%
Prescribers reporting at least 50% of OAT clients are from	Urban setting	68%
	Rural setting	14%
	Remote setting	18%
	Reserve setting	6%

Note: All prescribers with usable data (i.e., prescribing OAT in Ontario, Canada and answered at least one question regarding their OAT care delivery during the pandemic) were included.

Table 3
Patients' (n = 273) reports of receiving additional unsupervised doses as a function of the number of unsupervised doses they were prescribed prior to the COVID-19 pandemic.

	patients who reported their number of unsupervised doses prior to the pandemic				patients who reported receiving additional unsupervised doses during the pandemic			
# of unsupervised doses before the COVID-19 pandemic	patients prescribed methadone *n*	patients prescribed buprenorphine *n*	patients prescribed SROM *n*	total *n (%)*	patients prescribed methadone *n*	patients prescribed buprenorphine *n*	patients prescribed SROM *n*	total *n (%)*
0-1 unsupervised doses	32	18	9	59 (22%)	20	10	3	33 (12%)
2-5 unsupervised doses	51	52	52	155 (56%)[a]	27	35	39[c]	101 (37%)[a]
6+ unsupervised doses	18	19	22	59 (22%)[b]	8	6	8[c]	22 (8%)[b]
Total	101	89	83	273 (100%)	55	51	50	156 (57%)

Note: Patients with any unsupervised doses during the pandemic are included; patients prescribed depot buprenorphine or reporting multiple types of OAT were excluded. Patients' reports of their number of pre-pandemic unsupervised doses were used to categorize patients. Superscript letters indicate statistically significant group differences ($p < .005$).

Table 4
Prescribers' reports of additional unsupervised doses.

	methadone prescribers *n* (%)	buprenorphine prescribers *n* (%)	SROM prescribers *n* (%)
I decreased the frequency of unsupervised doses for patients	26 (30%)	15 (18%)	5 (12%)
I prescribed unsupervised doses for patients who previously were not prescribed any unsupervised doses	58 (67%)	59 (71%)	21 (50%)
I increased the frequency of unsupervised doses prescribed in patients who had some weekly unsupervised doses	60 (70%)	67 (81%)	15 (36%)
I allowed unsupervised doses for patients where I was unsure about their social or housing stability	18 (21%)	21 (25%)	12 (29%)
I prescribed unsupervised doses only in situations where I felt their social and housing situations were stable	52 (61%)	51 (61%)	13 (31%)
Total # prescribers	86	83	42

Note: SROM = Slow release oral morphine; Prescribers were asked to note each type of OAT that they prescribe and to select each statement that applied to the type(s) of OAT they prescribe.

Table 5
Patients' self-reported behaviors regarding unsupervised doses.

	N	Patients without additional unsupervised doses during the pandemic *n* (%)	Patients with additional unsupervised doses during the pandemic *n* (%)	χ^2	*p* value
Able to take unsupervised doses as prescribed	268	75 (70%)	80 (50%)	10.97	<.001
Lost or misplaced unsupervised doses	269	16 (15%)	38 (24%)	3.11	.08
Unsupervised doses were stolen	268	14 (13%)	30 (19%)	1.57	.21
Requested early refills	269	26 (24%)	50 (31%)	1.55	.21
Shared unsupervised doses with others	268	18 (17%)	104 (65%)	59.16	< .001
Traded unsupervised doses for food or other goods	268	11 (10%)	41 (26%)	9.48	.002
Experienced opioid overdose(s) with or without emergency department visit	268	14 (13%)	25 (16%)	0.37	.54
Visited the emergency department because of substance use	268	10 (9%)	15 (9%)	0.00	.98
Admitted to hospital because of substance use	265	7 (7%)	19 (12%)	2.05	.15

Note: Analyses included patients who reported having at least one unsupervised dose during the pandemic. Analyses excluded patients prescribed depot buprenorphine, but included patients who reported being prescribed multiple forms of OAT. Patients were categorized as having additional unsupervised doses during the pandemic if they answered "yes" to a question asking about having additional unsupervised doses during the pandemic compared to prior to the pandemic. Percentages reflect the proportion of patients within each group (i.e., those with or without additional unsupervised doses) who acknowledged that the events listed in the table occurred.

Table 6
Prescribers' reports of adverse health outcomes in clients who received additional unsupervised doses.

	Methadone prescribers *n* (%)	Buprenorphine prescribers *n* (%)	SROM prescribers *n* (%)
Number individuals prescribing OAT	86	83	42
Non-fatal overdoses (with or without emergency department visit)	21 (24%)	23 (28%)	8 (19%)
Emergency department visits because of substance use	22 (26%)	27 (33%)	6 (14%)
Hospital admissions because of substance use	23 (27%)	18 (22%)	6 (14%)
Deaths due to overdose	10 (12%)	14 (17%)	5 (12%)

Note: SROM = slow release oral morphine; Prescribers were asked to indicate whether they were aware of the incidents listed in the table occurring among their patients with additional unsupervised doses during the pandemic. The values in the table reflect the number (and percentage) of prescribers for each OAT type who reported being aware of the relevant event.

prescribing unsupervised doses only when they felt sure of the patients' social or housing stability.

Outcomes of unsupervised doses

Table 5 depicts patients' self-reported behaviors with reference to use of unsupervised doses (only including those who reported having at least one unsupervised dose during the pandemic, $n = 269$). We can compare patients who received additional unsupervised doses arising from the pandemic-related Guidance change, with patients who did not receive additional unsupervised doses during the pandemic. Half (50%) of the patients who received additional unsupervised doses reported taking the unsupervised doses as prescribed versus 70% of those patients without additional unsupervised doses, $p < .001$. More patients with additional unsupervised doses during the pandemic reported sharing their unsupervised doses with others ($p < .001$) and trading their unsupervised doses for food or other goods ($p = .002$), compared to those who did not receive additional unsupervised doses. However, there were no differences in lost or misplaced unsupervised doses, stolen unsupervised doses, or requests for early refills between these two groups ($ps \geq .08$). Likewise, there were no statistically significant differences in the likelihood of self-reported opioid overdoses, emergency department visits resulting from substance use, or hospital admissions from substance use, between patients who received additional unsupervised doses during the pandemic and those who did not ($ps \geq .15$).

In general, few prescribers reported negative outcomes in large proportions of their patients who received additional unsupervised doses. Less than a quarter of prescribers reported that 50% or more of their patients with additional unsupervised doses reported lost or stolen unsupervised doses (12%; $n = 11$), early refill requests (15%; $n = 14$), sharing their unsupervised doses with others (15%; $n = 14$), increased opioid use (16%; $n = 15$), increased use of other substances (15%; $n = 14$), and decreased stability or wellbeing (19%; $n = 17$).

Table 6 depicts prescribers' reports of significant adverse health outcomes in patients prescribed additional unsupervised doses. Non-fatal overdoses, emergency department visits from substance use, hospital admissions from substance use, or deaths due to overdose were reported by less than one-third of prescribers amongst their patients who received additional unsupervised doses.

How did additional unsupervised doses affect patients' and prescribers' experiences with OAT care?

Of the 171 patients who reported receiving additional unsupervised doses during the pandemic, 53% ($n = 90$) agreed that the additional unsupervised doses helped protect them from COVID-19; nearly half (47%; $n = 81$) reported that they had saved time and a third reported that they had saved money (34%; $n = 58$). A quarter (28%; $n = 47$) reported that their substance use had increased, while fewer reported it decreased (14%; $n = 23$), or had not changed (12%; $n = 21$) as a result of the additional unsupervised doses. A small proportion (17%; $n = 29$) reported feeling more confident.

Table 7 depicts patients' experiences with changes to their OAT care. Mann-Whitney U tests were used to compare experiences between patients with and without additional unsupervised doses during the pandemic. Patients prescribed additional unsupervised doses were significantly more likely to agree that changes to their OAT care helped them to be more open with their prescriber ($z = 2.26$, $p = .02$), that they appreciated their prescriber(s) trying to protect them from COVID-19 ($z = 2.64$, $p = .008$), and that changes to their OAT care made sense to them ($z = 3.93$, $p < .001$). Patients with and without additional unsu-

Table 7
Patients' experiences with changes in OAT care delivery.

	Patients Without Additional Unsupervised Doses				Patients With Additional Unsupervised Doses			
	n	Disagree *n* (%)	Neutral *n* (%)	Agree *n* (%)	*n*	Disagree *n* (%)	Neutral *n* (%)	Agree *n* (%)
Changes to my OAT care have helped me to be more open with my prescriber(s)	138	13 (9%)	36 (26%)	89 (65%)	170	2 (1%)	41 (25%)	135 (74%)
I appreciated my prescriber(s) trying to protect me from COVID-19	138	11 (8%)	19 (14%)	108 (78%)	170	6 (4%)	29 (17%)	135 (79%)
Changes to my OAT care during COVID-19 made sense to me	137	11 (8%)	34 (25%)	92 (67%)	166	4 (2%)	26 (16%)	136 (82%)
I would have liked more information about the changes to my OAT treatment	137	10 (7%)	32 (23%)	92 (67%)	166	4 (2%)	54 (33%)	108 (65%)

Note: Patients rated their agreement on each statement on a 5-point scale (strongly disagree to strongly agree). Responses to strongly disagree and disagree were combined to yield the number and percentage of patients who "disagreed"; the same procedure was done for agree and strongly agree. All patients (including those who reported being prescribed multiple forms of OAT) were included in these values and analyses.

pervised doses were equally likely to want more information about the changes to their OAT care ($z = 0.87$, $p = .38$).

The majority of prescribers (68%; $n = 53$) agreed that providing additional unsupervised doses during the pandemic had improved their relationship with their patients. Even more prescribers (85%; $n = 63$) agreed that their patients appreciated the prescribers' efforts to protect them during the COVID-19 pandemic.

Interest in maintaining changes in unsupervised dosing after the pandemic restrictions end

Overall, 66% (of $n = 309$) of patients wanted to return to the way unsupervised doses were prescribed. We compared responses between patients with additional unsupervised doses during the pandemic and those without. A chi square analysis showed no statistically significant difference between the two groups on interest in returning to pre-pandemic unsupervised doses, χ^2 (1) = 1.08, $p = .30$. Less than half of the prescribers (42% of $n = 76$) agreed that prescribers should return to the previous College of Physicians and Surgeons of Ontario Methadone Maintenance Guidelines for unsupervised dose protocols. The majority of the prescribers surveyed agreed that prescribers should continue to have more flexibility in giving unsupervised doses for both methadone (77%) and buprenorphine (79%).

Discussion

The current study assessed how OAT care delivery, particularly unsupervised dosing, in Ontario has been affected by the COVID-19 OAT Guidance from both the patient and prescriber perspectives. Most of the patients surveyed (57%) received additional unsupervised doses during the pandemic. Despite the increase in unsupervised doses, patients reported no increases in overdoses or emergency department or hospital visits, and were no more likely than patients without additional unsupervised doses to request early refills or report lost or stolen unsupervised doses. On the other hand, patients with additional unsupervised doses were more likely to report sharing or trading their medication compared to those patients without additional unsupervised doses. Half of the patients who received additional unsupervised doses (50%) reported that they were able to take their unsupervised doses as prescribed. Most patients and prescribers agreed that changes in OAT care were positive, by reporting improvements in patient/prescriber relationships. Many prescribers agreed with the need for continued flexibility in OAT prescribing practices, though many patients also expressed interest in returning to pre-pandemic unsupervised dosing. Our results support a recommendation for clinical guideline changes to OAT care delivery, particularly unsupervised dosing, beyond the pandemic to improve access to OAT care.

Additional unsupervised doses

Although patients prescribed additional unsupervised doses were more likely to report sharing or trading their unsupervised doses, it is important to consider the context of these behaviors. It is possible that individuals with unsupervised doses shared their doses for compassionate reasons (i.e., to support others without access to OAT), faced pressure to share or sell their unsupervised doses, or were at increased risk of having their doses lost or stolen due to unstable housing. It is important to work with persons with lived and living expertise to develop innovative solutions to help understand and plan for addressing some of these challenges and support individuals to continue with their OAT care.

Rates of overdose, emergency department visits, and hospitalization were not higher among patients with increased numbers of unsupervised doses, based on patient reports. Given the recognized risk of adverse health outcomes for patients with OUD, and the risks prescribers reported for patients with additional unsupervised doses, all patients on OAT should receive harm reduction counseling and supports. Although risks of adverse outcomes related to OAT are always present, recent evidence from Ukraine and the United States shows that despite changes in OAT prescribing practices (i.e., more unsupervised doses prescribed) during the pandemic, overdoses (Amram et al., 2021) or deaths due to OAT have not increased (Brothers, Viera, & Heimer, 2021; Meteliuk et al., 2021). The results from our study contribute to a growing body of research that suggests relaxing the criteria for unsupervised doses is not associated with significant negative health outcomes and may be a feasible approach to increasing patient engagement in care.

Experiences with changes in unsupervised dosing and OAT care

Patients with additional unsupervised doses were more likely to agree that changes to their OAT care helped them to be more open with their prescriber, that they appreciated their prescriber(s) trying to protect them from COVID-19, and that changes to their OAT care made sense to them. Most patients, regardless of whether they received additional unsupervised doses, agreed that they would have liked more information about their OAT care. Prescribers' reports were consistent with patients' reports; most prescribers agreed that providing additional unsupervised doses had improved their relationship with their patients and that their patients appreciated the prescribers' efforts to protect them during the pandemic.

These results suggest that the relationship or therapeutic alliance between prescriber and patient can be enhanced in OAT care. A strong therapeutic alliance is an important predictor of treatment engagement and retention in the treatment of substance use disorders (Meier, Barrowclough, & Donmall, 2005). Given that treatment retention is asso-

ciated with numerous benefits, including reduced involvement in the criminal justice system (Eastwood, Strang, & Marsden, 2017), reduced substance use (Eastwood et al., 2017; Goldstein & Herrera, 1995), and decreased risks of both all-cause and overdose-related mortality among people with OUD (Degenhardt et al., 2019; Sordo et al., 2017), it is crucial that we address any opportunity to improve treatment retention.

OAT care delivery after the pandemic: The need for flexible and patient-centred care

Many patients reported wanting to return to pre-pandemic care routines related to unsupervised doses. This may reflect a number of elements, including the fact that patients may have been feeling isolated due to a lengthy lock-down period when completing the survey. Although we did not specifically explore the reasons for this preference, it is possible that supervised dosage increases structure and support for some patients. Some patients may not have a place to store their unsupervised doses appropriately, and feel less vulnerable to pressures from peers if they consume their medication in a pharmacy. For others, however, the opportunity for additional unsupervised doses offers flexibility that may improve their ability to keep employment, attend school, and manage their daily lives in multiple ways.

Given that patients' circumstances change over time, prescribers should have ongoing discussions with their patients regarding the format of OAT care that meets their needs and adjust care when appropriate (Lam et al., 2020). Flexibility in OAT care delivery will be key to providing patient-centred care for persons with OUD. The need for flexible and patient-centred treatment options is consistent with previous recommendations for improving treatment outcomes for substance use disorders in general (Marchand et al., 2018; Marchand et al., 2019).

Limitations

There are several limitations to consider with the current study. Our study used a non-random sampling method for data collection. We followed public health recommendations regarding physical distancing and only offered the survey online. Thus, the results may not be representative of the entire population of interest or reflect the experiences of all high priority populations within OAT patients (e.g., those who are unstably housed, those without access to internet or phones). As with many studies related to OAT, our sample was predominantly white. However, we did have similar rates of participation among male and female individuals, which is unusual for research on OUD (Rice et al., 2020). Future research should include more diversity in their sample of participants to ensure a range of perspectives are expressed. Samples in other provinces and jurisdictions should also be studied, as generalization to other jurisdictions may be limited.

The patients and prescribers who responded to the survey may not reflect the patient and prescriber population in other ways. For example, approximately one-third of the patients surveyed reported that they were prescribed methadone, when data shows that methadone accounted for approximately 65% of OAT prescriptions in Ontario in 2020 (Ontario Drug Policy Research Network, 2018). Most of the patients surveyed (63%) in our study reported beginning their OAT treatment (first or current course) within the past year, whereas only 18% of patients prescribed OAT in 2019 in Ontario were considered "new OAT users" (Ontario Drug Policy Research Network, 2018).

OAT patients and prescribers were not directly linked to each other. It is possible that this may account for some of the discrepancies in the results (e.g., differences between patient and prescriber reports of sharing unsupervised doses). Despite the lack of direct linkage, patient and prescriber reports were consistent for many other variables (e.g., serious health outcomes such as overdoses and experiences with changes in OAT care).

Conclusions

The findings of our study demonstrated that following dissemination of the Ontario COVID-19 OAT Guidance, many prescribers implemented more flexible criteria when prescribing unsupervised doses. This was positively received among both patients and prescribers, with no evidence of significant increase in harms. To further improve access to, and quality of OAT in the future, persons with lived or living expertise, policy makers, program managers, and prescribers should continue to actively explore ways to reduce barriers to OAT care beyond the pandemic and tailor OAT care to patient needs as circumstances change. Policy makers may also consider the following suggestions: (1) improve access to lower barrier care; (2) increase availability of other harm reduction services to reduce harms regarding ongoing opioid use, injection drug use, and overdose prevention; and (3) ensure any permanent changes to guidelines are patient-centred and prioritize patient safety and security when prescribing additional unsupervised doses. These actions, including consideration of flexibility with unsupervised doses, may reduce overdose risks while also promoting the ongoing safety and security of individuals prescribed OAT during the pandemic.

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Ethics

The research reported in the submitted manuscript was approved by the Royal Ottawa Health Care Group (ROHCG) and Women's College Hospital's Research Ethics Boards (REB #s: REB #2020013 and 2020-0084-E, respectively).

Declarations of Interest

J. Wyman co-authored the Ontario COVID-19 Opioid Agonist Treatment Guidance.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.drugpo.2021.103573.

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