Received: 14 September 2021 | Accepted: 17 January 2022

DOI: 10.1111/add.15832

SHORT REPORT

ADDICTION SSA

Infrequent detection of unintentional fentanyl use via urinalysis among people who regularly inject opioids in Sydney and Melbourne, Australia

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Funding information
Open access publishing facilitated by Monash University, as part of the Wiley - Monash University agreement via the Council of Australian University Librarians.

Abstract

Background and aim: The current phase of the North American 'opioid crisis' is characterised by illicit fentanyl use; however, the presence of illicit fentanyl in Australia is unknown. This study aimed to monitor unintentional fentanyl consumption in Australia.

Design: Rapid urine drug screens (UDS) paired with surveys conducted within supervised injecting facilities (SIFs) and confirmatory laboratory testing.

Setting: Sydney and Melbourne, Australia.

Participants: Clients who used heroin within the past 2 days (n = 911 tests, 2017–2021). Participants were demographically similar to the overall client base (median age 43, 72% male).

Measurements: UDS were conducted using BTNX Rapid Response fentanyl urine strip tests with cross-reactivity to numerous fentanyl analogues. Positive urine samples were analysed using liquid chromatography coupled with tandem mass spectrometry. Surveys covered past 3 day drug use and lifetime report of fentanyl in heroin.

Findings: Two percent of participants reported intentional use of fentanyl, mostly through fentanyl patches. Of the 911 rapid UDS conducted, 17 (1.9%) yielded positive results. Eight of these (all from Melbourne) were not explained by survey-reported fentanyl use in the past 3 days. Of these 8 unexplained positives, confirmatory laboratory analysis was conducted on 6, with 4 deemed to be false positives, and 2 confirmed for

the presence of fentanyl. This represents the first confirmation of unintended use of fentanyl type substances in this population.

Conclusion: There is limited evidence of unintentional fentanyl use among people in Sydney and Melbourne, Australia who regularly inject heroin, suggesting that, currently, there is very little illicit fentanyl in Australian drug markets accessed by supervised injecting facilities attendees. This study demonstrates the feasibility of quick onsite testing to cost-effectively screen large samples for fentanyl; however, the high false positive rate emphasises the need for confirmation of positive tests through advanced analytical techniques.

KEYWORDS
Fentanyl, heroin, immunoassay, opioid, sentinel surveillance, Supervised Injecting Centers

INTRODUCTION

Each wave of the North American 'opioid crisis' is characterised by different opioid types—pharmaceutical opioids, heroin, then synthetic opioids such as illicitly produced fentanyl [1]. Because synthetic opioids are more potent, faster acting and often sold in unknown concentrations, they have driven a dramatic increase in fatalities [2,3].

Synthetic opioids are often sold as 'heroin' [4], with up to 97% of heroin supplies in two Mid-Atlantic syringe programs testing positive for high-potency illicit synthetic opioids. Urine screening has been used in health settings to monitor the unintended consumption of fentanyl [5–10]. In United States samples of young people who use drugs and syringe services program clients, up to half of clients reported changing their behaviour as a result of a fentanyl positive test result (e.g. taking less, keeping naloxone handy and sharing information about fentanyl) [11,12].

Fentanyl test strips (FTS) are relatively easy to conduct, cost-effective, rapid onsite testing method. Validation studies have found that the FTS have high sensitivity and specificity compared to other portable testing methods, although less able to detect very low (≤5%) fentanyl concentrations [13,14]. A range of compounds such as ascorbic acid [15], diphenhydramine, methamphetamine and 3,4-methylenedioxymethamphetamine (MDMA) [16] can contribute to the estimated 3.7% FTS false positive rate [15].

Because Australia's opioid harms have broadly reflected the first two waves of the North American trends, health experts have remained vigilant for synthetic opioid harms in recent years [17]. There have been occasional public health notices about cases involving 'fentanyl-laced heroin' [18], including a cluster of nine deaths in Melbourne in 2015 [19]. In 2017, it was reported that the Australian Border Force regularly intercepts shipments of illicit opioids [20], including carfentanil [21]. In response to this, in 2017 we established a urinalysis surveillance study to monitor for presence of fentanyl [22].

This study aimed to monitor unintentional fentanyl consumption in Australia through rapid drug screening tests administered in the country's two supervised injecting facilities (SIFs). A secondary aim was to explore the use of a rapid urine drug screens (UDS) in sentinel surveillance.

METHODS

Study design

A rapid UDS accompanied by client survey, with positive urine samples sent for confirmatory analyses in a laboratory was the study design.

Setting

Australia has two SIFs that operate out of its two largest cities—the Medically Supervised Injecting Centre in Sydney and the Medically Supervised Injecting Room in Melbourne. Data collection was completed over 10 waves from 2017 to 2021, with each wave lasting 1 to 3 weeks (Table 1).

Participants

Recruitment occurred through posters and staff invitation at the SIFs. Participants were 18+ years old, able to provide verbal consent, had used heroin in the past 48 hours and able to provide a urine sample. No identifying information was marked on the survey or samples. Clients could only participate once per data collection wave, but could contribute to each wave.

Data sources

A brief self-report survey covered demographics, recent drug use (survey day, and the 2 days prior reflecting the approximate 48-hour detection period for fentanyl with UDS), and lifetime encounters of fentanyl in heroin [22].

TABLE 1 Data collection waves and participant characteristics

		City					
		Melbourne		*Sydney*		*Total*	
		Count	*%*	*Count*	*%*	*Count*	*%*
Data collection							
Wave[a]	Oct 2017	a		66	18.6	66	7.2
	Mar 2018	a		50	14.1	50	5.5
	Sep 2018	82	14.7	65	18.3	147	16.1
	Feb 2019	92	16.5	53	14.9	145	15.9
	Jun 2019	75	13.5	54	15.2	129	14.2
	Jan 2020	87	15.6	14	3.9	101	11.1
	Jun 2020	65	11.7	10	2.8	75	8.2
	Sep 2020	53	9.5	19	5.4	72	7.9
	Dec 2020	52	9.4	24	6.8	76	8.3
	Jun 2021	50	9.0	a		50	5.5
	Total	556	100	355	100	911	100
Participant demographics							
Gender	Male	404	73.3	245	69.6	649	71.9
	Female	141	25.6	105	29.8	246	27.2
	Transgender	3	0.5	2	0.6	5	0.6
	Other	3	0.5	0	0.0	3	0.3
	Total	551	100	352	100	903	100
Age	Average	41		46		43	
	Median (IQR, R)[b]	41 (36–47, 21–72)		45 (40–52, 18–67)		43 (37–49, 18–72)	
	Total	551		349		900	
Participants' past 3-day heroin use							
Heroin shots	Median (IQR, R)	6 (3–10, 1–78)		5 (3–8, 1–60)		5 (3–9, 1–78)	
	Total	543		347		840	
Sources of heroin	Local	506	92.5	268	76.8	774	86.4
	Elsewhere	133	24.3	121	34.7	254	28.3
	Total[c]	547	100	349	100	896	100
No. of heroin sources	Median (IQR, R)	2 (1–3, 1–12)		1 (1–2, 1–20)		2 (1–2, 1–20)	
	Total	545		344		839	

[a]The Melbourne supervised injecting facility (SIF) opened in June 2018 so it could not contribute to the two earliest data waves in October 2017 and March 2018 [24]. The Sydney SIF was operating under restricted conditions because of COVID-19-related lockdowns in June 2021 so could not contribute data to this wave. The Melbourne COVID-19-related lockdowns during the study period were as follows: lockdown 1 (April-May 2020), lockdown 2 (July-September 2020), lockdown 3 (5 days in February 2021) lockdown 4 (June 2021) lockdown 5 (12 days in July 2021).
[b]IQR = interquartile range, R = range. Medians presented for number of heroin shots and sources because of positive skew of data.
[c]Participants could source heroin from both local and non-local sources so percentages do not sum to 100%.

After survey completion, clients provided a urine sample that was tested by a SIF staff member with the BTNX Rapid Response Single Drug Test Strip (Fentanyl) [23]. Samples were tested for fentanyl/norfentanyl (cut-off concentration 20 ng/mL, with reported cross-reactivities to 3-methylfentanyl, acetylfentanyl, butyrylfentanyl, carfentanil, furanylfentanyl, ocfentanil, p-fluorofentanyl, remifentanil, sufentanil and valeryl fentanyl). After 5 minutes, results were provided to the clients with relevant harm reduction advice.

Following ethical clearance, from February 2019 samples positive for fentanyl were sent to the Victorian Institute of Forensic Medicine for confirmatory testing. Two liquid chromatography–tandem mass spectrometry systems were used to screen for 477 unique drugs including 37 fentanyl analogues, where the lower limit of quantification in urine was 1 ng/mL (see Supporting information Box S1, Supporting information Table S1 and Table S2 for further detail on methods and drugs tested for). A selection of samples that were not

rapid UDS positive, or were showing faint lines, were also sent to the laboratory for testing as controls.

Analyses

This study used exploratory analysis using descriptive statistics such as percentages and interquartile ranges.

Ethics

This study received ethical approval through the University of New South Wales (HC17283) and Monash University (22250).

RESULTS

A total of 911 UDS paired with surveys were completed. Participants were 72% male, and were on average 43 years old (Table 1). These demographics appeared broadly similar to the overall client base at both sites (Melbourne, 75% male, 41 years [24]; Sydney, 74% male, 34% ages 35–44 years and 36% ages 45–54 years). Over the past 3 days, participants reported a median of five injections of heroin, mostly acquired in locations near the SIF, and through a median of two sources (Table 1). Two percent of the total sample (1.4% in Melbourne and 3.4% in Sydney) reported intentional fentanyl use in the past 3 days (Figure 1).

UDS

Of 911 rapid tests, 17 were deemed positive, of which eight were not explained by self-reported fentanyl use in the past 3 days (Table 2). These eight positives were all from Melbourne, and subsequent confirmatory analysis was conducted on six of these samples. Four (two in February 2019, one in January 2020, one in September 2020) appeared to be possible false positives, and two (June 2019) were confirmed to contain fentanyl, representing our first laboratory confirmation of unintended use of FTS. The two positive samples were from the same source, a couple who verbally reported to SIF staff they purchased their supply from someone who had indicated they had purchased their supply from overseas. The four false positives all detected a variety of non-heroin-related substances—for example, diphenhydramine and/or methamphetamine was present in three of the four samples. Eleven rapid UDS negative samples (including two with faint lines) sent to the laboratory as controls returned negative results.

Beliefs

Almost half the participants believed they had never had fentanyl in their heroin (41% Melbourne, 50% Sydney), almost a third believed there had ever been fentanyl in their heroin (36% in Melbourne, 22% in Sydney), and a quarter were not sure (23% Melbourne, 28% Sydney; n = 820). Of the two Melbourne participants that returned laboratory positives for fentanyl, but did not report intentionally ingesting fentanyl, both reported they did not notice anything unusual or different about their heroin. One participant reported they did not believe they had ever had fentanyl before, and the other reported they believed they had, but in Sydney.

DISCUSSION

We conducted more than 900 rapid tests and found limited evidence of fentanyl in Australia's two largest cities. This study demonstrates

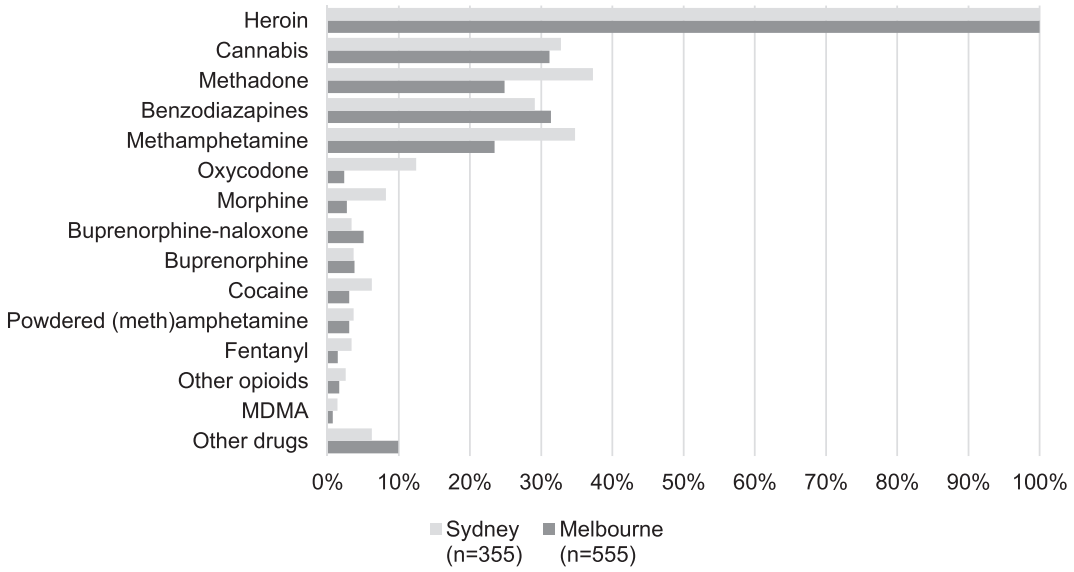

FIGURE 1 Self-reported drugs used in the 3 days before UDS, by city

TABLE 2 Fentanyl test result by city and wave

	Melbourne (n = 556)					*Sydney (n = 355)*				
	Rapid UDS at SIF			*Laboratory*		*Rapid UDS at SIF*			*Laboratory*	
	Negative	*Positive*	*Positive not explained*[a]	*Sent to lab*	*Lab positive*	*Negative*	*Positive*	*Positive not explained*[a]	*Sent to lab*	*Lab positive*
Oct 2017	N/A[b]	N/A	N/A	N/A	N/A	64	2	0	N/A	N/A
Mar 2018	N/A	N/A	N/A	N/A	N/A	49	1	0	N/A	N/A
Sep 2018	81	1	1	N/A	N/A	63	2	0	N/A	N/A
Feb 2019	90	2	2	2	0	50	3	0	N/A	N/A
Jun 2019	72	3	3	2	2	54	0	0	N/A	N/A
Jan 2020	86	1	1	1	0	13	1	0	N/A	N/A
Jun 2020	65	0	0	N/A	N/A	10	0	0	N/A	N/A
Sep 2020	52	1	1	1	0	19	0	0	N/A	N/A
Dec 2020	52	0	0	8	0	24	0	0	3	0
Jun 2021	50	0	0	5	0	N/A	N/A	N/A	N/A	N/A
Total	548	8	8	19	2	346	9	0	3	0

[a]Positive urine drug screen (UDS) not explained by self-reported fentanyl use over the past 3 days ('today', 'yesterday' or 'day before'). Ethics approval was granted to send positive instant tests for confirmatory laboratory analyses in February 2019, so the first positive not explained by intentional use from September 2018 was not sent to Victorian Institute of Forensic Medicine. The second positive not explained and not sent to the laboratory was from June 2019, was not retained for further testing in error.

[b]The Melbourne supervised injecting facility (SIF) opened in June 2018 so could not contribute to the two earliest data waves in October 2017 and March 2018. The Sydney SIF was operating under restricted conditions because of COVID-19-related lockdowns in June 2021 so could not contribute data to this wave. The Melbourne covid-19-related lockdowns during the study period were as follows: lockdown 1 (April-May 2020), lockdown 2 (July-September 2020), lockdown 3 (5 days in February 2021) lockdown 4 (June 2021) lockdown 5 (12 days in July 2021).

In December 2020, 8 dipstick negative samples (including 2 with faint lines) from Melbourne and 3 from Sydney were sent as controls to the laboratory. In June 2021, 5 dipstick negative samples from Melbourne were sent as controls to the lab.

the feasibility of simple, low-resource and quick onsite testing to monitor fentanyl trends.

Increasingly, FTS are being used off-label to test drug solutions before injection, rather than urine [16]. One advantage of testing urine, in the context of a low prevalence of fentanyl in the heroin market, is that one test covers all heroin use occasions over the past 2 to 3 days, providing a broader surveillance coverage than testing individual drug samples.

False positive results have been identified as an issue with both drug checking and urine testing with FTS [15,16]. Of our six positive dipstick results that were not explained by self-reported use and were able to be sent to the laboratory, only two were confirmed as positive. This high false positive rate emphasizes the need to better understand issues, such as how other drugs and contaminants can generate false positives, and how to interpret faint lines on the test.

Of our four false positives from Melbourne, three contained diphenhydramine and/or methamphetamine, drugs that can generate false positives on FTS, and are commonly used by our participants [16]. A quarter of this study's Melbourne participants self-reported using methamphetamine in the past 3 days, and 16% of injection episodes at the Melbourne SIF are for the specific combination of heroin and diphenhydramine [24]. Similarly, in another study with 720 actively injecting participants from Melbourne, a third reported co-injecting substances, most commonly heroin-diphenhydramine and heroin-methamphetamine [25]. Ascorbic acid is commonly used in brown heroin preparations and can also generate false positives on direct drug checks with FTS [15], but is not routinely screened for in laboratory analyses. Brown heroin is rare in Australia [26], but some appearances were noted during the course of this study coinciding with drug market changes during the COVID-19 pandemic. There are potentially further cross reactivities with new psychoactive substances not yet available as reference materials in forensic drug analyses.

One recent study suggested faint lines on strips should be interpreted as the presence rather than absence of fentanyl [27], however, our study's fainter second line samples were considered true negatives through laboratory testing. A common experience initially was that staff misread strips as positives when then were negative, with a second faint line. Both user error and interpretation of faint lines remain important areas for further work.

Although many participants believed they had experienced fentanyl in their heroin, the two participants who provided the only fentanyl-positive laboratory results that were not explained by self-reported use or possible false positives, had not suspected this to be the case. This is in contrast with a recent North Carolina study where participants' perceptions aligned well with FTS results [28], although this difference may be explained by participants in the United States having much greater exposure to and experience with fentanyl compared with those in Australia.

There are a number of strengths of this work. First, the 4-year data collection period from the only two SIFs in the country

represents the largest fentanyl monitoring study in Australia and provides important experience on the feasibility of using this surveillance method. Second, the use of confirmatory testing provides additional information that raises questions about the false positive rate with these strips. Third, our time period covers 2020 to 2021 when the drug market was interrupted by the pandemic [29–32], with one possible change being the emergence of fentanyl in Australia. Fourth, the combining of urine testing with surveys meant that we were able to differentiate between intentionally consumed fentanyl and likely fentanyl-contaminated heroin, which provides an important advantage over wastewater analysis for this purpose [33].

There are also limitations to consider. We used convenience sampling and had small sample sizes in some waves, particularly during COVID-19-related lockdowns that coincided with reduced SIF attendance rates. Our monitoring occurs during specific intervals, as opposed to continuously, so we cannot rule out fentanyl positive heroin in between our testing periods. We also do not have coverage of samples outside Melbourne and Sydney, noting that there have been small clusters of fentanyl found in a variety of drugs outside the SIFs' geographic regions [18,34].

Although the role of routine use of FTS is unclear within current low-fentanyl contexts such as Asia and the Pacific region [35], findings from this research can inform the development of a rapid response should signals of increased fentanyl prevalence in the heroin market emerge. In Australia, we have a window of opportunity to implement more advanced surveillance systems and co-design appropriate responses with consumers to mitigate against the scale of opioid crisis like that seen in North America [18,35].

Surveillance for changes in the market need to be unobtrusive, timely, easy to implement, considering ways to reduce false positives (e.g. training on the interpretation of FTS, detection of cross-reactive compounds) and any positives need to be laboratory confirmed to avoid communicating false information and generating undue alarm. Assuming a continuing low prevalence of fentanyl in Australia [33] and that surveillance resources could go toward other harm reduction activities, at the time of publication, we are completing a series of co-design workshops with varying experts (site staff, toxicologists, consumers etc.) to determine how to best address these issues in the longer term. In conclusion, our study, which sampled from SIF attendees in Melbourne and Sydney, did not frequently detect fentanyl. Testing urine with FTS is a low-cost way to monitor for fentanyl and provide an early signal if additional harm reduction measures are required.

ACKNOWLEDGEMENTS

This project is supported by funding from the National Centre for Clinical Research on Emerging Drugs (NCCRED; NCR3SF16), funded by the Australian Government Department of Health. S.N. is the recipient of an NHMRC Career Development Fellowship (1163961). Open access publishing facilitated by Monash University, as part of the Wiley - Monash University agreement via the Council of Australian University Librarians.

DECLARATION OF INTERESTS

In the past 5 years, S.N. has been an investigator on untied education grants from Indivior, unrelated to the current work. S.N. has provided training to health care professionals on identifying and treating codeine dependence, for which her institution has received honoraria from Indivior. T.L. and S.N. have been investigators on untied education grants from Seqirus, unrelated to the current work.

AUTHOR CONTRIBUTIONS

Tina Lam: Data curation; formal analysis; investigation; project administration. **Monica Barratt:** Conceptualization; formal analysis; investigation; methodology. **Mark Bartlett:** Investigation; project administration; resources. **Julie Latimer:** Investigation; project administration; resources. **Marianne Jauncey:** Conceptualization; investigation; methodology. **Sarah Hiley:** Data curation; investigation; project administration; resources. **Nico Clark:** Conceptualization; resources. **Dimitri Gerostamoulos:** Conceptualization; formal analysis; investigation; methodology; supervision; validation. **Linda Glowacki:** Formal analysis; investigation; methodology; validation. **Claude Roux:** Investigation. **Marie Morelato:** Investigation. **Suzanne Nielsen:** Conceptualization; formal analysis; funding acquisition; investigation; methodology; supervision.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

How to cite this article: Lam T, Barratt MJ, Bartlett M, Latimer J, Jauncey M, Hiley S, et al. Infrequent detection of unintentional fentanyl use via urinalysis among people who regularly inject opioids in Sydney and Melbourne, Australia. Addiction. 2022;117:2331–7. https://doi.org/10.1111/add.15832