

Effects of Regulation on Methadone and Buprenorphine Provision in the Wake of Hurricane Sandy

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ABSTRACT *Hurricane Sandy led to the closing of many major New York City public hospitals including their substance abuse clinics and methadone programs, and the displacement or relocation of thousands of opioid-dependent patients from treatment. The disaster provided a natural experiment that revealed the relative strengths and weaknesses of methadone treatment in comparison to physician office-based buprenorphine treatment for opioid dependence, two modalities of opioid maintenance with markedly different regulatory requirements and institutional procedures. To assess these two modalities of treatment under emergency conditions, semi-structured interviews about barriers to and facilitators of continuity of care for methadone and buprenorphine patients were conducted with 50 providers of opioid maintenance treatment. Major findings included that methadone programs presented more regulatory barriers for providers, difficulty with dose verification due to impaired communication, and an over reliance on emergency room dosing leading to unsafe or suboptimal dosing. Buprenorphine treatment presented fewer regulatory barriers, but buprenorphine providers had little to no cross-coverage options compared to methadone providers, who could refer to alternate methadone programs. The findings point to the need for well-defined emergency procedures with flexibility around regulations, the need for a central registry with patient dose information, as well as stronger professional networks and cross-coverage procedures. These interventions would improve day-to-day services for opioid-maintained patients as well as services under emergency conditions.*

KEYWORDS *Hurricane Sandy, Opioid maintenance treatment, Emergency planning, Continuity of care*

INTRODUCTION

Hurricane Sandy was an unprecedented natural disaster for New York City that caused widespread power outages, shutdowns of public transportation, and property damage. Several New York City hospitals experienced evacuations and closures lasting weeks to months including New York University Langone Medical Center, the Manhattan campus of the VA New York Harbor Healthcare System,

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Hospital, Bellevue Hospital Center, and Coney Island Hospital. Storm damage compounded by the medically vulnerability of patients at these clinics created unexpected medical risks, especially for opioid-dependent patients. During prior comparable states of emergency, such as Hurricane Katrina in New Orleans and 9/11 in New York City, relapse rates for opioid-maintained patients increased due to discontinuity of care, and clinician uncertainty regarding emergency procedures and access to health information.^{1,2}

A 2006 data analysis estimates there to be over 92,000 illicit opioid users in New York City,³ and the New York State Office of Alcoholism and Substance Abuse Services (OASAS) estimates that more than 75 % of patients at 112 substance abuse treatment programs in New York City had interruptions in treatment due to program closures during Hurricane Sandy.⁴ Previously, during Hurricane Katrina and 9/11, substance abuse treatment was disrupted for many reasons. Maxwell and colleagues found that during Hurricane Katrina, methadone dispensing was difficult because of the low number of publicly funded clinics available to low-income patients and the lack of a centralized information system documenting dosing treatment histories.⁵ Increases in drug use occurred during Hurricane Katrina for especially vulnerable populations such as low income African Americans.¹ During disasters, opioid treatment programs are especially burdened by ambiguous emergency laws and strict regulations.⁶ In contrast, flexible regulation implementation in clinics has been correlated with resilience during natural disasters.⁷ During 9/11, methadone programs stayed open, but lacked telephone communication and therefore the capacity to verify doses, leading to difficulty making decisions regarding take-home methadone doses and to high stress and anxiety among staff.⁸ While a higher incidence of positive urine toxicology screenings were reported after 9/11,⁹ changes in drug use after 9/11 were varied and affected by income, geography, and access to services.²

In the case of Hurricane Sandy, New York City subways were suspended and highways were closed down due to damage for days to weeks, complicating patients' commute to their clinics. Although this affected both methadone and buprenorphine patients, transportation issues may have disproportionately affected methadone maintenance patients in outpatient programs who were required to come into clinic daily for their dosing, while many buprenorphine treatment patients come less regularly for prescription refills.

Buprenorphine and methadone have different dispensing methods that are dictated by their narcotic classifications and corresponding Federal oversight. Since 1971, US regulations require methadone, a schedule II drug, to be dispensed for maintenance treatment on site in specialty clinics. In contrast, buprenorphine, a schedule III, was US FDA approved for office based treatment by prescription in 2002. Qualified physicians can apply for a Federal waiver to prescribe buprenorphine after completing 8 hours of training in buprenorphine management.¹⁰

Given the recent approval of buprenorphine for treatment of opiate dependence relative to methadone, few direct comparisons of buprenorphine and methadone within health service systems have been made. Hurricane Sandy presented a natural experiment to test the relative advantages and disadvantages of methadone and buprenorphine regulations and dispensing methods in the face of a major disruption of service. To analyze the effects of regulatory differences between methadone and buprenorphine on the continuity of care after Hurricane Sandy, we interviewed providers and administrators in New York City public sector clinics and practices that provide buprenorphine and/or methadone maintenance treatment.

METHODOLOGY

In an attempt to better understand the effects of Hurricane Sandy on substance abuse treatment in New York City, we analyzed semi-structured interviews with providers and administrators that offer pharmacological treatment for opioid dependence using methadone and/or buprenorphine in public clinics and in Medicaid accepting community practices. Face-to-face interviews with providers and administrators were conducted 8 to 20 weeks after the storm. Interviews lasted 30–60 min and addressed topics such as the impact of regulations for both methadone and buprenorphine on service provision after the storm, barriers to continuity of care, communication with regulators and agency leadership as well as patients and other care providers, and navigation of hospital emergency plans.

Public sector buprenorphine prescribers were recruited during site visits to the nine municipal hospitals and three VA medical centers in New York City that offer outpatient methadone and/or buprenorphine treatment. Participants were also recruited from a list of New York City buprenorphine certified prescribers, provided online by the Substance Abuse and Mental Health Services Administration (SAMHSA), cross-referenced with a list of physicians who accept New York State Medicaid. Index participants were asked to identify additional public sector buprenorphine prescribers for inclusion in the study in a modified snowball sampling technique in which new participants were solicited until no new names were offered. Of the 119 public sector buprenorphine and methadone prescribers contacted for participation in the study, 50 completed interviews between January and March of 2013 and 69 could not be reached or declined participation. Trained graduate-level interviewers conducted face to face semi-structured interviews lasting 30–60 min regarding regulation barriers and facilitators pertaining to methadone and/or buprenorphine, as well as on diversion and barriers to treatment.

Interview transcripts were analyzed using iterative thematic coding techniques, including continuous comparison and pragmatic adaptation of grounded theory in order to develop relevant coding categories.^{11–14} Multiple coders were used for all transcripts to check inter-coder reliability. Discrepancies between coders were resolved through team discussion and consensus.

This research was conducted with oral informed consent procedures, data storage techniques designed to safeguard the confidentiality of participants' identities, and participant protection from court subpoena of the study's data as provided by a US Health and Human Services Certificate of Confidentiality. The study was approved by New York University School of Medicine's Institutional Review Board.

RESULTS

Eight administrators, 41 providers, and 1 provider/administrator agreed to the interview regarding their clinical experiences during and after Hurricane Sandy (Table 1).

Methadone Regulations

Methadone providers and administrators faced challenges in navigating regulatory agencies and providing continuity of care. Four themes emerged from our interviews: (1) poor communication with regulatory agencies, (2) clinic relocation

problems, (3) lack of emergency preparedness strategies, and (4) dosage and patient status verification difficulties (see Table 2).

1. Communication with regulatory agencies

Methadone providers and administrators were more likely than buprenorphine providers and administrators to report communication problems with regulatory agencies such as the New York State Office of Alcoholism and Substance Abuse Services (OASAS), the US Drug Enforcement Agency (DEA), and the New York City municipal hospital administration. Problems included lack of contact with these agencies. Administrators and providers wanted greater clarity on the guidelines regarding releasing extra methadone doses before Hurricane Sandy. Overall, providers and administrators reported that if regulatory agencies had communicated with them prior to the hurricane, they would have released additional take-home doses of methadone to last patients through the disaster, therefore easing their continuity of care (see Table 2). Providers and administrators also commented on certain regulatory agencies' inflexibility and their difficulty navigating agency guidelines for methadone. In one instance, because of a technical compliance issue, an agency shut down a methadone clinic in the middle of clinic hours. During a visit to another clinic, an agency demanded the hospital "cease and desist" the clinic's emergency methadone dispensation as the three-day emergency dosing window had lapsed. Providers and administrators attempted to relocate the patients to another methadone program the same day and were dosing methadone until 7 pm that night.

2. Clinic relocation problems

Many complications emerged after providers began to realize that Hurricane Sandy's impact would last much longer than the DEA's three-day maximum emergency distribution of methadone. Some public hospital clinics had to be relocated to other public hospitals which hosted their patients and staff. The largest issue pertaining to clinic relocation was transitioning the large patient population, their records, and obtaining the proper accreditation for residents and fellows to assist with methadone treatment. The large number of patients physically overcrowded hospital facilities and staff were overwhelmed. Attempts to relocate staff from closed facilities were met with accreditation problems for trainees with the Accreditation Council for Graduate Medical Education (ACGME); one of the providers we interviewed stated that he was the only doctor for a week before the addiction fellows and residents were approved to assist by the ACGME. As many as one third of clinic patients fell out of treatment due to clinic relocation and breakdowns in communication.

3. Lack of emergency preparedness strategies

Other methadone providers and administrators described uncertainty regarding emergency preparedness and emergency procedures. In particular, there was no

TABLE 1 Number of administrator and provider participants

	Buprenorphine only	Methadone only	Buprenorphine and methadone	Total
Administrators	3	2	3	8
Providers	30	1	10	41
Administrator and Provider	0	0	1	1

TABLE 2 Methadone provider interview themes

Methadone treatment emergency theme	Supporting quote
Communication with regulatory agencies: Uncertainty about flexibility of state regulation due to lack of contact	<p>“The issue was more on the other end – we made great precautions in advance, as soon as we got [regulatory agency] recommendations, we provided sufficient bottles for our patients ... We were one of the designated [agency] sites to stay open.”</p>
Inflexibility of DEA regulation enforcement	<p>“[Regulatory agency] has the power to contact all sites. [Agency] started communicating weeks later, and they seemed surprised that we had issues!”</p> <p>“Our records need to be consistently updated contact information – inter-staff, inter-hospital; there should be a central contact number for [regulatory agencies].”</p> <p>“It’s certainly an advantage to have more patients treated with buprenorphine than methadone. I don’t see any way around the [agency] regulations – changing the laws obviously but that’s bigger than us. Regulations of prescribing methadone in emergency situations are a legislative issue.”</p>
Clinic Relocation Problems Overcrowding Regulatory licensure red tape Disruption of relationships with providers	<p>“Frankly [the biggest problem] was being displaced to another hospital that had to absorb us... The inevitability of being in a different hospital system. Our methadone patients were lining the hallways, and they only had one window to dispense methadone. The whole thing was tough in the beginning.”</p> <p>“[The host hospital] had their own methadone program. Our program is bigger than theirs, but they had to fix days for methadone for our patients. [Our hospital’s] patients would come Monday and Friday, and we would give [the patients] extra supplies”</p> <p>“[The host hospital] was totally overwhelmed.”</p> <p>“Wait times were 5–6 hours and patients received tablet instead of liquid”</p> <p>“I was the only MD for first week at [the host hospital], I couldn’t get the additions fellow here because the fellows and residents were in total stasis because of ACGME approval pending”</p> <p>“We couldn’t dispatch anyone until we knew that [the host hospital] is an ok training facility.”</p> <p>“Since a lot of the problems came from licensing issues – if there was a policy of what to be done under emergency circumstances or if there were some provision for emergently treating patient that was clear, we would have averted this problem in the future”</p>

TABLE 2 *Continued*

Methadone treatment emergency theme	Supporting quote
	“A lot of the patients were lost, their records are gone. They’re from a different community. We’re away from where we were. We used to be 10mins by car... Our old place was destroyed. We’re sharing space with another clinic right now, patients tend to be more reluctant to come to the new site, we lost contact with at least 1/3 of the patients and haven’t recuperated most of them.”
Lack of emergency preparedness strategies	“Unclear when the emergency ends. At what point is it no longer ‘ok’ to administer in an emergency.”
Emergency adjustment strategies	“The pharmacy was helpful; [they] bent the law a little bit.”
Dosage and patient status verification difficulties	“People getting here was a big problem – some of them said they paid \$50 - \$100 for a taxi. As a team we decided that people living far – we could verify dose we gave them take homes so they didn’t have to come every day. We tried to manage doses.”
Inconvenience to Patients	“It was sort of refreshing that we could rely on trust, but if patients were not being candid, the risk was high.”
Incorrect Dosage Risks	“They just said, according to [regulatory agency], just dose them and trust them.”
	“I spoke to each patient about the risks of taking methadone at a very high dose especially if they were not being candid, and I let them know that the risks included death. We made it clear to them to go to ED [in the event of an overdose].”

clear indication of when the emergency state ended. One respondent reported that due to lack of clarity surrounding emergency procedures, the pharmacy had to bend rules in order to maintain continuity of care. Administrators from hospitals that had to move their methadone program to a new facility after the storm worried that their license did not cover the new facility.

Another concern was that patients crowded emergency department by turning to them for medication. This resulted in suboptimal, and sometimes dangerous dosing of methadone patients by emergency room doctors who either refused to dose methadone patients, or who, upon patient request, gave patients higher doses of methadone than their usual dose, risking fatal overdose. One provider reported that when patients had nowhere else to go for their medication, she would dose them out of her office. During this crisis, wait hours were so long, patients arrived as early as 5:30 am to wait to be dosed.

4. Dosage and patient status verification difficulties

Difficulty verifying dose was another problem faced by methadone providers. Despite there being no regulatory guidelines that demanded dose verifications, methadone providers unsuccessfully attempted to verify doses. Some regulatory agencies recommended that in emergency conditions, providers take patients at their word, but providers felt great discomfort in doing so. Providers attempted to verify

doses by accessing patient databases at other programs to improve upon the “just dose them and trust them” strategy. Patients presented used methadone bottles that did not always have doses or dates printed on them. Providers ultimately had to make judgment calls regarding dosing, and warned patients about the dangers of overdose.

Buprenorphine Regulations

Buprenorphine providers faced fewer regulatory issues than methadone providers. The emergent themes regarding buprenorphine included (1) buprenorphine clinic relocation, (2) lack of emergency preparedness strategies, and (3) dose verification (see Table 3).

1. Buprenorphine clinic relocation

One issue mentioned was the difficulty of relocating to a new buprenorphine clinic. One buprenorphine provider described going through many bureaucratic steps before relocating. However, another buprenorphine provider stated that once buprenorphine treatment was relocated, physician accreditation was quick and they were able to resume care almost immediately.

2. Lack of emergency preparedness strategies

A common report was that public buprenorphine clinics ordinarily relied heavily on medical residents and fellows to provide buprenorphine, but following Hurricane Sandy, clinics that were forced to relocate had difficulty transferring their medical residents with them. Since accreditation of resident and fellow training facilities had to be approved by the ACGME on a national level, the accreditation process was slow and delayed restoration of buprenorphine services.

3. Dose verification

One provider mentioned that a barrier to prescribing buprenorphine to patients was a lack of electronic system with centralized records that would facilitate dosing during an emergency. Another provider noted that a lack of such a record led to dose reductions. The relocation clinic did not dispense film strips, therefore dose verification was also complicated by the switch from buprenorphine film strips to tablets due to different dispensation procedures required for each.

Patients who relied on Medicaid were disproportionately affected since they could only fill out their prescriptions at the municipal hospital, which was shut down, while those who were privately insured could go to outside pharmacies to refill their prescriptions.

DISCUSSION

Methadone providers reported more barriers to continuity of patient care than buprenorphine providers, including lack of clarity around emergency regulations, lack of communication with regulators, as well as lack of centralized electronic systems to confirm dosage. Methadone licenses only provided Methadone programs three days to dispense methadone in emergency facilities, and programs often needed the flexibility to do so for longer periods of time. During Hurricane Sandy, there was no established central registry to verify doses, despite this having been a major concern shortly after the similar crisis of Hurricane Katrina in New Orleans.

TABLE 3 Buprenorphine provider interviews emergent themes

Buprenorphine treatment emergent theme	Quotes
Buprenorphine clinic relocation	"... the amount of red tape when moving to a different hospital [was a major issue]"
Regulatory relocation red tape	"[At the host hospital, providers] were able to get things like emergency accreditation for all the doctors [quickly]"
Patient loss during relocation	" In [the transfer of our patients to a host hospital], about 10 % of our patients were unaccounted for because some were homeless, and some we were unable to get in touch with...We also had issues in the beginning of a mechanism of getting them their buprenorphine a) because having our providers available there b) having space available to see the patients thirdly, having [the host hospital] set up the mechanism to register and see our patients" "In primary care there's no centralized record of who's getting what and where."
Resident licensing issues	"... Foot-dragging and answers from educational higher-ups, this was a country-wide issue that went to the national overseers of residents. Like we couldn't dispatch anyone until we know that [the host hospital] is an 'Ok' training facility."
Dose verification Patient information loss	"Dose verification and identity verification comes up but for instance the drug is being switched over to strips from tabs; however, this pharmacy uses tablets for those people without insurance...I write in by hand that strips are also available, especially for patients with insurance they have to go to outside pharmacists."
Dose verification at relocation clinic	"It's important to keep a list of Suboxone patients. Know who they are, update contacts. Dosing guidelines at [our clinic] were different from our host clinic]. Patients were cut down from 30-day buprenorphine to 28-day buprenorphine – so [their] pharmacy denied [prescriptions]. Patients were under-dosed/under-supplied" "For patients with Medicaid, we called in prescriptions for them but getting patients access to buprenorphine who also rely on [the hospital] pharmacy—we couldn't call in a script, the pharmacy made it difficult—[the hospital] pharmacy was closed, we had no clinic and [the host hospital's] pharmacy would not honor scripts written by [our] doctors unless there was a visit on the same =day at [the host hospital] yet there was no clinic space to actually see patients at [the host hospital]. Other providers saw as many people as they could in [the host hospital]"

Buprenorphine treatment centers generally faced fewer problems providing continuity of care in the wake of Hurricane Sandy than methadone programs. Because

patients could be prescribed up to a month's supply of buprenorphine, they often had sufficient supplies during their dislocation from their clinics. Buprenorphine providers reported a lack of cross-coverage by colleagues. Their reliance on resident physicians in public clinics was hampered by the need for temporary clinics' training credential approval. Buprenorphine providers also reported that their patients often had difficulties filling out their prescriptions in pharmacies whose supplies were affected by the storm. The flexibility of buprenorphine dispensing was an advantage under emergency conditions, but the guest dosing policies of methadone clinics provided a network of cross-coverage that was unavailable for buprenorphine patients.

This study had several limitations, including that only municipal and VA hospitals in four of the five boroughs of New York City were included in this study, which may limit the generalizability of our findings. There were many other areas affected by Sandy, including Staten Island, Long Island, and New Jersey, as well as private methadone and buprenorphine programs in New York City with providers who may have had different experiences than those interviewed. In addition, just under half of the physicians identified as public sector buprenorphine and methadone prescribers agreed to participate in the study, which may have biased the results.

Despite these limitations, our findings suggest a number of interventions that would improve continuity of care for opioid-maintained patients during times of service disruptions. They include equipping methadone treatment for flexible dosing, creating a central registry for buprenorphine dosing, a central database for methadone maintenance programs, strengthening cross-covering networks of buprenorphine providers and allowing for credential exemption for medical trainees during emergency settings.

Enhancing methadone maintenance program flexibility to approach that of buprenorphine treatment, such as facilitating guest dosing in alternate clinics, would not only facilitate care in the event of an emergency, but would also enhance daily care for patients who often experience treatment interruptions due to difficulties traveling to clinics because of comorbidities or lack of resources, for example. Central databases for buprenorphine and methadone treatment would similarly allow for comprehensive knowledge of dosing histories and treatment plans while easing administrative hurdles to continuity of care.

Stronger networks of buprenorphine providers have eased buprenorphine dispense in the past and can help improve the continuity of care for buprenorphine patients who are displaced from their primary clinic.¹⁵ Such networks promise not only to enhanced cross-coverage during routine and emergency service disruptions, but also to address a widespread concern among current and potential buprenorphine prescribers about the lack of professional support and mentoring available to prescribers in managing buprenorphine patients.¹⁶ During Hurricane Sandy, providers depended on the prescribing capabilities of residents and fellows, and credentialing delays for these trainees became increasingly cumbersome for continuity of care of patients at host hospitals. The ACGME's creation of exemptions for trainees working under emergency conditions would benefit underserved areas where teaching hospitals often preside. The implementation of centralized database for opioid maintenance programs, provider cross-coverage networks, and flexible methadone treatment would also prevent delays in treatment due to emergencies and due to routine system disruptions in resource poor settings, therefore decreasing patients' risk of withdrawal and relapse.

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