Buvidal Implementation in Secure Environments:

A Service Evaluation of the Spectrum Community Health Pilot Sites[1]

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Spectrum Community Health CIC

Weekly/Monthly Buvidal®
BUPRENORPHINE
PROLONGED-RELEASE SOLUTION FOR INJECTION

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Executive Summary

With approximately one third of people in prison in England and Wales in custody for a drug-related crime[2], and around half of drug treatment patients seeking support for opioid dependence, there's a need for effective opioid dependence treatment (ODT) in prisons.[3] **For patients seeking treatment for opioid dependence in secure settings, only 17% successfully completed their treatment programmes between 2020 and 2021.**[3]

- ODT is a critical component of treatment for patients diagnosed with opioid dependence, and methadone and oral buprenorphine are both effective forms.[4] However, both have drawbacks in prison, including the diversion of drugs to third parties, and associated bullying/intimidation, plus the stigma ODT patients experience while queuing for their daily medication[1]
- Significant progress has been made in the development of innovative forms of ODT in recent years, with the approval of Buvidal, developed by Camurus.[1] This innovative prolonged-release buprenorphine injection was approved for use in the UK in 2018[5]
- In January 2021, Spectrum Community Health CIC and Camurus Ltd embarked on a joint project to implement Buvidal in secure environments in England and Wales[1]

The overarching aim was to develop step-by-step operational guidance to facilitate the implementation of a clinically effective care pathway into three prison estates – HMP Holme House, HMP Lancaster Farms, and HMP Kirkham.[1]

Spectrum Community Health CIC undertook service evaluation of Buvidal implementation in three prisons, to establish[1]:

- Reasons people accepted or rejected Buvidal
- Typical journey on to Buvidal
- Main advantages and disadvantages of using Buvidal in these settings
- Main facilitators and barriers of Buvidal implementation in prison
- How healthcare teams ensured continuity of care of people on Buvidal
- What can be done to support further rollout of Buvidal in prison estates

The evaluation used a mixed-methods design, including qualitative interviews with staff members and quantitative data collection from clinical records.[1]

Eleven interviews were conducted with members of staff in key groups between February and September 2022. These were transcribed verbatim and analysed using thematic analysis. Quantitative data for the first 80 Buvidal patients was extracted by clinical care teams in the prisons from SystmOne records.[1]

Introduction

Opioid dependence treatment (ODT) is the main treatment for people diagnosed with opioid dependence, both in the community and prison. Methadone and buprenorphine are both effective forms of ODT, particularly within the optimal dose range.[4]

Both methadone and oral buprenorphine are recommended by NICE, the National Institute for Health and Care Excellence.[6]
There is strong evidence to support the use of these two forms of ODT: [4, 7, 8]

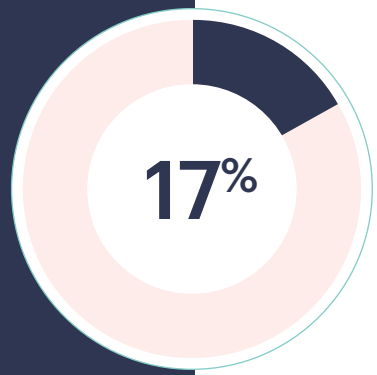
- Effective at suppressing illicit opioid use
- Lowering risk of mortality
- Reduced engagement in criminal activity

Despite these benefits, the provision of methadone and buprenorphine in prison has several reported drawbacks.[1]

In prison settings, people are primarily given daily oral doses of methadone, taken under the supervision of both health and operational staff. There's little provision for buprenorphine to manage opioid dependence in prisons as, historically, misuse has been extremely prevalent.[1]

- Diversion of methadone to third parties
- Bullying and intimidation
- Stigma around daily queuing for medication
- Interference with prisoners' other purposeful activity
- Burdensome administration creates staff pressures

Despite high numbers engaging in ODT, **only 17%** of those seeking treatment for opioid dependence in secure settings between 2020 and 2021 successfully completed treatment.[3]



Bringing scientific progress to secure estates

Significant progress has been made in the last decade in the development of ODT options. One such innovation is Buvidal, a prolonged-release buprenorphine injection.*[1]

Each dose is administered weekly or monthly via subcutaneous injection by a healthcare professional. A sustained concentration of buprenorphine is then released at a controlled rate.[1]

Alongside ODT treatment efficacy,[1] relieving some of the daily methadone administration burden is a clear benefit of Buvidal. Added to which is the potential to reduce drug diversion and abuse in the prison setting.[1]

*Buvidal is a prolonged-release formulation of buprenorphine indicated for the treatment of opioid dependence within a framework of medical, social and psychosocial treatment. Administered weekly or monthly, it is intended for use in adults and adolescents aged 16 years and over. Buvidal is manufactured by Camurus, a pharmaceutical company innovating in opioid dependence and other chronic conditions.

In January 2021, Spectrum Community Health CIC and Camurus Ltd embarked on a joint project to implement Buvidal in secure environments in England and Wales.[1]

The overarching aim was to develop step-by-step operational guidance to facilitate the implementation of a clinically effective care pathway.[1]

Offering support and guidance to prison and healthcare teams on the prescribing and monitoring of Buvidal.[1]

Three prison sites were chosen where Spectrum Community Health CIC were already the primary healthcare provider.[1]

HMP Holme House:

Category C adult males only, operational capacity of 1179

HMP Lancaster Farms:

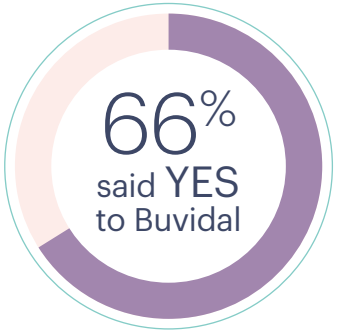
Category C adult males only, operational capacity of 560

HMP Kirkham:

Category D adult males only, operational capacity of 657

Initiation results of the first 80 recipients

When offered Buvidal, two thirds accepted stating a preference for monthly medications.



The third who declined Buvidal had worries about titrating down to methadone 30mg and about how Buvidal might make them feel.[1]

Twenty of the first 80 people given Buvidal tapered their daily methadone dose down to the required 30mg.[1]

Across 80 people, the median time on weekly injections was 4 weeks. Two patients continued to receive weekly doses for over 12 months.[1]

For people that progressed to monthly Buvidal injections, 59% started on 128mg.[1]

20% were able to reduce their monthly dose as they progressed through their treatment journey.[1]

- Almost 50% of the first 80 people prescribed Buvidal had been released from their original prison by April 2023[1]
- 40% were still receiving Buvidal in the prison they were initiated in[1]
- 3% (4 people) transferred back to their original ODT[1]
- One person successfully completed treatment and was drug-free after planned Buvidal discontinuation[1]

Key factors that enabled successful implementation of Buvidal[1]:

1. Collaborations and partnerships between prison staff and representatives from Health and Justice partners, HMPPS, and Camurus.
2. A collaborative approach to treatment was supported by thorough training.
3. Experiences of Buvidal shared by word of mouth to other potential recipients.

Advantages of Buvidal in secure environments

In-depth conversations with staff across three prisons revealed specific benefits of Buvidal, particularly in contrast to traditional daily-dosed ODT.

"Methadone or nothing is not a choice. Buvidal lets them choose."

Buvidal provides choice[1]

Prior to the introduction of Buvidal, most people were only offered methadone as a maintenance option.

- Sublingual buprenorphine, widely available in the community, has not been prescribed due to risk of diversion
- People are now able to choose methadone or buprenorphine

This has been welcomed by staff as it brings prison ODT more in line with clinical guidelines, which promote choice to suit individual needs.

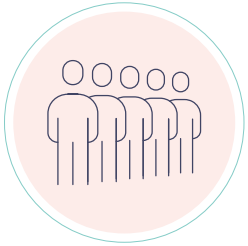
"You notice a change in appearance – pallor changes, sleep gets better, energy is up."

Mental and physical wellbeing[1]

Staff spoke about how increased 'clarity of mind' with Buvidal was positive for many patients.

- People appear less sedated than on methadone and were more focussed on engaging with meaningful activities – typically recovery orientated goals, or dealing with past trauma
- Staff explained that Buvidal is a partial opioid agonist, so drowsiness-type side effects are less likely than with a full opioid agonist like methadone

Both health staff and custodial staff noticed improvements in general wellbeing, including weight management, better eating and taking care of their appearance.



"In a CAT D open unit, prisoners can get on with their life when they're not restrained by 8am methadone queues."

Benefit to the medicines queue[1]

Weekly or monthly administration means people spend less time queuing and streamlines prison operations.

- People can engage in purposeful activity, such as work or education
- Some of the more desirable jobs in prisons require an 8.30am start which isn't possible for people queuing for medication each morning

Not queuing daily also helps reduce stigma.

"There's no potential to regurgitate."

Buvidal can reduce risk of diversion[1]

Staff believe one of Buvidal's greatest advantages is a reduced risk of diversion.

- Sublingual buprenorphine was particularly amenable to diversion, so was not permitted in prisons
- Inability to divert Buvidal helps reduce illicit drug use and the bullying or intimidation associated with it

Reduced risk of diversion can have widespread benefits to the people receiving the medication and to the prison environment.

Advantages of Buvidal beyond the prison gate

Participants described how they felt the advantages for people under their care extended beyond the prison gate, with numerous benefits specific to a community setting. All advantages stemmed from the removal of the daily need to attend community pharmacies to receive ODT.[1]

Benefits through the prison gate

Newly released people can engage with 'normal' activities

- Sustained employment is more practical without the need to schedule a community pharmacy visit each day[1]
- With less daily social exposure to drug-using peers at the pharmacy, triggered relapses may be prevented[1]

Pharmacies providing ODT have high numbers of drug users attending. The prolonged-release formulation of Buvidal can help limit exposure to this type of environment.[1]

"People prescribed methadone in the community can be targeted by drug dealers trying to encourage illicit use."

The continuity of care pathway for people on Buvidal is perceived to be similar to other forms of ODT – with greater flexibility for community appointments.[1] Due to restrictions, it was not possible to track anyone following release from their original prison. This means the evaluation was unable to ascertain the number of people who continued their Buvidal treatment following release into the community or transfer to another secure estate.[1]

Considerations for Buvidal in prison:

1. Some disadvantages were highlighted by prison staff[1]

- Reduced contact between both prison staff and peers
- People welcome the assurance of a daily check-in with a health professional
- Staff like to regularly monitor people in their care
- People value time outside their cell

2. Greater mental clarity (Buvidal vs methadone) can create issues[1]

- Some people prefer the state of feeling sluggish
- Some may not be ready to deal with emerging thoughts or feelings
- Staff were trained to put specific measures in place, both awareness pre-initiation and a range of medical interventions, including appropriate psychosocial support

3. Some physical discomfort is expected[1]

- Most people experienced physical discomfort transferring from methadone to Buvidal due to having having to reduce their methadone dose to 30mg, and then go a day without
- Staff utilised different methods to help people experiencing discomfort, including symptomatic relief for withdrawal symptoms, top-up doses and increasing one-to-one psychosocial support

4. Potential cost[1]

- Staff responsible for managing budgets noted the higher cost of Buvidal compared to methadone
- Higher costs didn't prevent patient initiation at the time the interviews were conducted, though a small number of staff felt cost plus decreasing budgets could prevent future Buvidal initiations
- Staff recognised potential of cost savings longer-term and the prospect of a healthier prison population that would be less of a system burden

Staff perspective on implementation

Staff across all three sites considered what had contributed to the successful implementation of Buvidal in their respective environments.[1]

Collaborative and partnership working

Implementation group meetings were called out for being particularly helpful.[1] These were attended by multiple stakeholders, managers and health specialists:

- Regional/area managers – Spectrum and Humankind[1]
- Site clinical nursing and prescribing staff[1]
- Site non-clinical and psychosocial teams[1]
- Pharmacy staff[1]
- Representatives from NHS England Health and Justice Commissioning[1]
- Representatives from HMPPS and Camurus[1]

Implementation meetings acted as much as a space to share learning experiences as they did a forum for sharing information.[1]

"Different specialities coming together was really beneficial and a good learning curve."

Staff from HMP Kirkham and HMP Lancaster Farms specifically referred to how beneficial the experience and lessons learnt by HMP Holme House had been – their staff had gone live with Buvidal initiation a year prior.[1]

Support from Camurus, developer of Buvidal

- Shared implementation experiences from secure estates in Scotland, Germany and Australia[1]
- Understanding issues and previous experience of overcoming barriers was invaluable[1]
- In-depth training provided to relevant staff was crucial to effective implementation across all three sites[1]

Staff recognised that using Buvidal as an ODT could have significant advantages for them and their team.[1]

- Reducing the burden of daily administration can lead to time savings as nursing and operational staff supervise daily consumption of medications, including methadone[1]

Some staff did explain that as the number of patients on Buvidal was relatively low, noticeable efficiencies had yet to materialise.[1]

- The view was that once larger numbers had switched to Buvidal, greater time savings were possible[1]

Recovery outcomes and future aspirations

Buvidal is a recent option in prisons, so staff were asked about recovery outcomes. Their responses suggest Buvidal can contribute to a positive future.[1]

Achieving stability is a positive outcome[1]

- Buvidal may encourage people to remain in drug treatment and help reduce illicit opioid use
- People may be at reduced risk of harm when released into the community
- An increased ability to focus on other areas of life may improve relationships with family and friends, improve employment prospects and encourage volunteering opportunities

Future aspirations for Buvidal within secure estates:

In HMP Holme House and HMP Lancaster Farms, where a large number of people receive ODT, staff were keen for larger numbers to be offered Buvidal. Many staff spoke about their desire and intention to scale up the peer support and wraparound psychosocial support.[1]

The staff felt that Buvidal treatment should be expanded across the wider prison estate, with a view to promoting equality and continuity of care. Choice in the community should be reflected in the prison service.[1]

Overall, staff agreed the rollout of Buvidal across the whole prison estate should be an imminent priority. They hoped that future expansion could build on the learnings from this service evaluation to facilitate smooth implementation, without overwhelming the service.[1]

Ensuring Buvidal success in secure estates

This evaluation demonstrates that Buvidal has an important role to play in people's recovery and can be implemented within prison sites.[1] The prolonged-release properties and weekly, or monthly, administration have potentially important advantages over other widely used ODT.[1]

Key recommendations for Buvidal users

- Buvidal brings ODT choice into the secure environment that can continue as people move into the community or between prisons[1]
- People considering Buvidal should be given clear information on treatment expectations and potential withdrawal when transferring from methadone, including the potential for precipitated withdrawal if the transfer from methadone is not managed with care[1]
- Care needs to be given to the language used when discussing Buvidal – given the relative recent introduction, some patients were worried they were being given an untested treatment[1]
- People choosing Buvidal should be encouraged to engage in purposeful activity, receive individualised psychosocial support and be referred for mental health assessment where the need is identified[1]
- Buvidal-specific peer-support groups should be made available in prisons[1]

Key recommendations for prison implementation

- Work closely with local commissioning teams to secure funding – for commissioners, this may mean increasing the budget for ODT in prison healthcare services[1]
- Involve and collaborate with all key stakeholders throughout implementation[1]
- Buvidal training should be provided for all healthcare staff, not just those responsible for substance misuse services – consider face-to-face training as well as online[1]
- Staff capacity must be able to facilitate initiating, monitoring and patient support[1]
- Prison healthcare services must collaborate with community drug treatment partners to ensure community services are prepared for Buvidal continuity[1]

Acknowledgements

We would like to thank everyone who has contributed to this joint project through sharing their expertise, advice, experience, and professional opinion. This includes members of the Buvidal Project Implementation Group who comprised representatives from various organisations, including Spectrum Community Health CIC, Camurus Ltd, HM Prisons and Probation Service, and NHS England.

We are particularly grateful to clinical and operational staff working across the three prison evaluation sites who, during challenging times, implemented changes to their clinical substance misuse services and provided invaluable feedback to the project.

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Prescribing Information for Buvidal® (buprenorphine prolonged-release solution for injection)

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Active ingredient: Buprenorphine. Prolonged-release solution for injection in pre-filled syringes. Weekly injection (8 mg, 16 mg, 24 mg, 32 mg) or monthly injection (64 mg, 96 mg, 128 mg, 160 mg).
Indication: Treatment of opioid dependence within a framework of medical, social and psychological treatment. Treatment is intended for use in adults and adolescents aged 16 years or over.
Dosage: To avoid precipitated withdrawal, initiate when objective and clear signs of mild to moderate withdrawal are evident, considering the duration of action of the opioid, time since last dose and degree of opioid dependence. Do not start until ≥6 hours after last heroin or short-acting opioid. Reduce methadone to ≤30 mg/day and start Buvidal® ≥24 hours after the last methadone dose. Buvidal® may trigger withdrawal symptoms in methadone-dependent patients. *Initiation in patients not already receiving buprenorphine:* Patients not previously exposed to buprenorphine, administer 4 mg sublingual buprenorphine and observe for an hour to confirm tolerability. Recommended starting dose of Buvidal® is 16 mg, with one or two additional 8 mg doses at least 1 day apart (target dose of 24 mg or 32 mg during the first week). The dose for the second week is the total dose administered during the first week. May transfer to monthly Buvidal® after four weeks and once stabilised. *Switching from sublingual buprenorphine:* Switch directly to weekly or monthly Buvidal®, starting on the day after the last sublingual buprenorphine dose. See SmPC for dose recommendations. *Maintenance:* Weekly or monthly as needed. One supplemental Buvidal® 8 mg dose may be administered between regular weekly or monthly doses (except 160mg). The maximum dose is 32 mg weekly, with an additional 8 mg dose, or 160mg monthly. Weekly doses may be administered up to 2 days before or after the weekly time point, and monthly doses may be administered up to 1 week before or after the monthly time point. If a dose is missed, administer the next dose as soon as practical. *Termination:* Consider prolonged-release characteristics and any withdrawal symptoms. If switching to sublingual buprenorphine, do so one week after the last weekly dose or one month after the last monthly dose of Buvidal®. *Elderly:* No dosing recommendations over 65 years. Consider renal and hepatic function.
Administration: Administration of Buvidal® is restricted to healthcare professionals only. For subcutaneous administration only. Inject slowly and completely into sufficient subcutaneous tissue of the buttock, thigh, abdomen, or upper arm area. Do not re-inject the same injection site for at least 8 weeks (each area can have multiple injection sites).
Contraindications: Hypersensitivity to buprenorphine or excipients. Severe respiratory insufficiency. Severe hepatic impairment. Acute alcoholism or *delirium tremens*.
Special warnings and precautions for use: Must not be administered intravenously, intramuscularly or intradermally. Monitor for any attempts to remove the depot. Some precautions associated with buprenorphine class. *Prolonged-release properties* of the product should be considered during treatment. Patients with concomitant medicines and/or co-morbidities should be monitored for signs and symptoms of toxicity, overdose or withdrawal. *Respiratory depression:* Deaths reported with buprenorphine. Care in respiratory insufficiency. *CNS depression:* Buprenorphine may cause drowsiness. Dependence: Chronic administration of buprenorphine can produce opioid dependence. *Serotonin syndrome:* Concomitant serotonergic agents (e.g. monoamine oxidase inhibitors, selective serotonin re-uptake inhibitors, serotonin and noradrenaline re-uptake inhibitors or tricyclic antidepressants) may result in serotonin syndrome, a potentially life-threatening condition – if clinically warranted, observe carefully, particularly during initiation and dose increases and consider reducing or discontinuing therapy if serotonin syndrome is suspected. *Hepatitis, hepatic events and hepatic impairment:* Recording of baseline liver function tests and viral hepatitis status recommended. Hepatic injury reported with buprenorphine. Caution with buprenorphine in moderate hepatic impairment – monitor for signs and symptoms of opioid withdrawal, toxicity and overdose. Monitor hepatic function regularly. *Drug withdrawal syndrome (GB):* Before starting any opioids, discuss withdrawal strategy with the patient. Dose tapering over weeks or months may be required. Risk of neonatal withdrawal syndrome following use in pregnancy. *Precipitation of opioid withdrawal syndrome:* Buprenorphine products have precipitated withdrawal symptoms in opioid-dependent patients when administered before the agonist effects from recent opioid use or misuse have subsided. *Renal impairment:* Caution in severe renal impairment. *QT-prolongation:* Caution with other medicines that prolong the QT interval and in patients with a history of long QT syndrome or other risk factors for QT prolongation. *Acute pain management:* A combination of opioids with high mu-opioid receptor affinity, non-opioid analgesics and regional anaesthesia might be necessary. Monitor and titrate, considering potential risk of overdose and/or death. *Sleep-related breathing disorders:* Opioids can cause sleep-related breathing disorders. *Opioid class effects:* See SmPC for details. *Interactions:* See SmPC for buprenorphine interactions. *Pregnancy and lactation:* Caution – see SmPC for details. *Driving and operating machines:* Minor to moderate influence, including drowsiness, dizziness or impaired thinking – likely to be pronounced by alcohol or CNS depressants. See SmPC for details of what individual patients should be told by the prescriber.
Undesirable effects: *Very common:* insomnia, headache, nausea, hyperhidrosis, drug withdrawal syndrome, pain. *Common:* infection, influenza, pharyngitis, rhinitis, lymphadenopathy, hypersensitivity, decreased appetite, anxiety, agitation, depression, hostility, nervousness, abnormal thinking, paranoia, medical dependence, somnolence, dizziness, migraine, paraesthesia, syncope, tremor, hypertonia, speech disorders, lacrimal disorder, mydriasis, miosis, palpitations, vasodilation, hypotension, cough, dyspnoea, yawning, asthma, bronchitis, constipation, vomiting, abdominal pain, flatulence, dyspepsia, dry mouth, diarrhoea, gastrointestinal disorder, rash, pruritus, urticaria, arthralgia, back pain, myalgia, muscle spasms, neck pain, bone pain, dysmenorrhea, injection site reactions (pain, pruritus, erythema, swelling, reaction, induration, mass), peripheral oedema, asthenia, malaise, pyrexia, chills, neonatal withdrawal syndrome, chest pain, abnormal liver function tests. *Other:* urinary retention, injection site reactions (abscess, ulceration and necrosis). See SmPC for further details.
Overdose: Apply general supportive measures, closely monitoring and treating respiratory and cardiac status. Consider long duration of action of buprenorphine and prolonged release from the depot.
Package quantities and UK net price: 1 pre-filled syringe per pack. Weekly injection (8 mg (0.16 ml), 16 mg (0.32 ml), 24 mg (0.48 ml), 32 mg (0.64 ml)): £55.93. Monthly injection (64 mg (0.18 ml), 96 mg (0.27 ml), 128 mg (0.36 ml), 160 mg (0.45 ml)): £239.70.
Marketing authorisation numbers: *GB:* PLGB 42800/0001, PLGB 42800/0003-9. *ROI and NI:* EU/1/18/1336/001-7, EU/1/18/1336/009.
Legal category: POM. **Marketing authorisation holder:** Camurus AB, Ideon Science Park, SE-223 70 Lund, Sweden. Email: camurus.uk@camurus.com Additional information available on request. **Date of revision:** May 2024 FPI-0008

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