[insert LPC name/logo]

Supervision of opiate substitution therapy and shared care – the future of commissioning

Background

According to Public Health England (PHE), drug misuse and dependency can lead to a range of harms for the user including:

- Poor physical and mental health and ultimately death;
- Unemployment;
- Homelessness;
- Family breakdown; and
- Criminal activity.

But drug misuse also impacts on all those around the user and the wider society. Investment in treatment services has been highlighted as not only helping to save lives, but investment also substantially reduces the economic and social costs of drug-related harm. Research has shown that every £1 invested in drug treatment results in a £2.50 benefit to society.[1]

As part of the approach to support patients undergoing opiate substitution therapy (OST), community pharmacies provide supervised consumption of methadone and buprenorphine as part of a locally commissioned service through either the Local Authority or via a subcontracted provider of shared care services. Supervision is designed to support service users on their road to recovery by providing a structured approach to receiving OST along with reducing the risk of diversion or harm caused by others consuming the medication, especially children. Supervision at least in the first three months of OST, seeks to reduce this risk.[2] Following the introduction of supervised consumption in England and Scotland, methadone related deaths reduced fourfold.[3]

A key benefit of the service that community pharmacies have historically provided is the community pharmacist, as a clinician, is often the one healthcare professional that service users encounter most frequently (depending on their treatment). Although the service is often referred to as a 'supervision' service, when contracts are reviewed, the pharmacy provides far more than just the observation of a service user consuming their OST medication. Service specifications also include requirements such as:

- Wellbeing checks with the patient to see how they are coping;
- Monitoring the service user's response to treatment and looking for any signs of 'on top' use of illicit substances;
- Notifying the prescriber or key worker of any missed doses, for example, missing three consecutive days;
- Looking out for signs that the service user is intoxicated and refusing supply in these cases; and
- Identification of any child or vulnerable adult safeguarding concerns.

A number of these are part of the National Institute for Health and Care Excellence (NICE) guidance on managing, monitoring, referral and follow up of patients on OST (NICE CKS Opioid dependence: Scenario: Management).[4] They are also listed in the Orange Guidelines.[5] However, where these requirements do occur in contracts, there is often no formally agreed process to facilitate rapid and secure communication between the pharmacist and the treatment team. Most existing reporting mechanisms simply capture when doses of medication are supervised and, in some cases, this data is not actually seen by a client's individual key worker. Instead, the data is mainly used to support payment processes.

The importance of these elements of additional care has become even greater during the COVID-19 pandemic, as most treatment teams, based on guidance from the Department of Health and Social

Care (DHSC) and PHE, have moved to remote monitoring and are unable to have that face-to-face interaction with all their clients. The key exceptions to this within the guidance are where a person is seen as a vulnerable service user, those undergoing healthcare interventions, people newly starting treatment and community alcohol detoxification services.[6] This means there is a key opportunity for the service to be reconsidered and expanded beyond a simple supervised consumption service, to also provide support and information to treatment teams on the overall welfare of the service user.

Problem statements

Impact on supervision volume

At the start of the COVID-19 pandemic, OST clients were identified as being potentially more at risk from COVID-19-related illness or complications, particularly if they were also categorised as clinically vulnerable.[6] OST clients were also more likely to be affected by pandemic restrictions which could impact on their ability to both be supervised and to regularly access the pharmacy. It was also recognised that community pharmacies and the medicines supply chain were under pressure due to increased demand for prescriptions and increased rates of staff sickness because of the COVID-19 pandemic.

Therefore, to protect services users and maintain continuity of supply, it was necessary for treatment providers to review their service users and move them to less frequent collection regimes. Service users were screened by key workers and risk stratified to determine the level of risk posed by moving them to twice weekly, weekly or fortnightly unsupervised collections of their OST. These risk assessments were then shared with prescribers who ultimately made decisions to move clients to twice weekly, weekly or fortnightly unsupervised collections. Prescriptions were then issued with these new directions. This resulted in a significant number of service users no longer being supervised. This reduction in supervision fees has meant a decline in the payment mechanic for community pharmacies that has traditionally supported the overall welfare check of patients and provided some elements of feedback to treatment teams. The perceived quality and lack of information shared to demonstrate the value and impact of these additional welfare checks and treatment team feedback was no longer therefore seen as valid by some commissioners and consequently, service payments have either stopped or have begun to be reduced to match current patient access levels. However, the expectation of treatment teams on pharmacies to maintain levels of feedback about clients in some cases has stayed in place and has resulted in further pressure of unremunerated work.

Treatment teams are also realising that they have been too rigid in the maintenance of patients on supervised regimes. The pandemic has allowed these teams to see that more of their patients can be trusted and therefore the frequency of collection need not be daily and in a number of cases, that supervision is not necessary.

It is, however, important to note, that several Local Authorities and subcontracted providers have honoured the payments to pharmacies in recognition of the additional support they provide to service users and in line with Cabinet Office guidance.[7]

Impact on dispensing fees

Further compounding the financial impact on community pharmacies, the reduced frequency of collection of medication and increased take home doses has also meant a reduction in the number of fees associated with dispensing of OST.

When examining the income associated with the dispensing of methadone, for each patient interaction the pharmacy would be remunerated £2.56 with an additional 55p where an additional dose was provided to take home. Each prescription also attracts a fee of £2.50 for the dispensing of

methadone. The table below summaries the impact in the changes in pick-up frequency as a result of changes to assist patients during the pandemic per fortnightly prescription.

Activity per fortnightly prescription	Daily dispensing (based on opening 6 days / week)	Three times per week collection	Twice weekly collection	Weekly collection
Daily doses	14	14	14	14
Pick-ups / interactions	12	6	4	2
Packaged Dose fees per prescription	2	8	10	12
Total interaction fees	£30.74	£15.37	£10.25	£5.12
Total Packaged Dose fees	£1.10	£4.40	£5.50	£6.60
Methadone Fee per prescription	£2.50	£2.50	£2.50	£2.50
Total dispensing fee per patient	£34.35*	£22.27*	£18.25*	£14.22*
Bank Holiday closure impacts – 8 holidays per year (8 less picks and 8 more packaged dose fees)	-£16.10	Nil	Nil	Nil
Total dispensing fee per patient per year (assuming 26 prescriptions per year)	£877.00*	£579.02	£474.50*	£369.72*

*Excludes any container fees.

Where a patient previously collected daily, a change to three times a week reduces annual dispensing fees for the pharmacy by £297.98. A change to twice weekly from daily collections reduces the annual dispensing fees for the pharmacy by £402.50 per patient and a change to weekly collections from daily collections reduces the annual pharmacy dispensing fee return by £507.28 per patient. While dispensing fees are part of the contract sum and so unearned income remains as part of the contract sum to be shared across the sector, overall, the pharmacy will still experience a fall in income value.

Impact of branded prescribing and rebate schemes

In some parts of the country, branded prescribing is a problem for contractors resulting in a reduction in dispensing margin associated with dispensing OSTs. When products are prescribed generically, pharmacies seek to obtain the best available price for the product, driving down the prices being charged by wholesalers and manufacturers and in turn the Drug Tariff reimbursement prices and costs for the NHS. Prescribing branded generics or off-patent branded medicines profoundly affects the competition that drives down prices in the generics market and acts to drive up costs to the NHS. It can also lead to unequal geographical distribution of the funding under the NHS contractual framework.

Some pharmaceutical companies will offer a retrospective rebate to treatment teams, usually based on volume usage (from ePACT or sales data, for example). The confidential rebate price effectively reduces the price charged to the treatment team for that drug. This distorts the fair distribution or availability of margin to contractors which is important to overall community pharmacy funding. Any local savings on prescribing budgets which result in lost margin for pharmacy contractors do not save money for the NHS overall - since the lost pharmacy margin needs to be made up elsewhere. It is the same argument as the one against Clinical Commissioning Group led switches to branded generics. If the lost margin is greater than the saving in local drug spends, then it is a net loss for the NHS.

Within OST prescribing as an example of this, some treatment teams have moved to prescribing of Physeptone instead of generic methadone. In this example if a rebate has been negotiated by a treatment team, this would ensure that Physeptone remains below generic methadone prices. Any margin made by pharmacy contractors on purchases of generic methadone may therefore be eroded which in the long run would end up costing the NHS more. While this lost margin would be re-distributed to other molecules, there is still a loss in margin to the pharmacy.

Reduced numbers of patients being supervised results in reduced services income. Reduced pick-up frequency results in a decrease in dispensing fee income. The prescribing of specific brands linked to prescribing rebates affect pharmacy margin. The combination of all three of these changes has dramatically reduced pharmacy income associated with the service and has meant that a number of pharmacy contractors are now either exiting provision of these services or considering an exit from the provision of supervised OST service contracts. In a situation where workload to dispense the medication remains the same, but the remuneration associated with the provision of the service has reduced, contractors are understandably reviewing their future engagement with the service.

Proposal to service commissioner

Stage 1

[Insert LPC name] would like to consult with [insert commissioning organisation name] as the service commissioner regarding the existing service provisions in the contract to ensure that appropriate remuneration is made for all requirements beyond supervision of OST. These suggested additional elements of care are in line with both NICE[4] and the Orange Book[5] guidance and are of value to both treatment teams and clients.

The Orange Book[5] lists the following aims that treatment teams should look to achieve to support OST clients who are being supervised as part of a community pharmacy service:

- Ensuring the patient receives the prescribed dose;
- Reducing diversion of prescribed doses;
- Providing an opportunity for the pharmacist to make a regular assessment of patient compliance with treatment and of their general health and wellbeing;
- Providing an opportunity for the pharmacist to build a therapeutic relationship with the patient that is beneficial to promote heath and harm reduction;
- Reducing the risks of drug related overdose and deaths; and
- Minimising the risk of accidental consumption by children.

While some of these aims are achieved via the provision of medication outside a supervision service as a result of dispensing, there are several elements that fall outside the requirements of the dispensing function of the pharmacy. These additional elements of care should not be expected to be provided by contractors where there is no remuneration, particularly outside the umbrella of a supervised medicines service contract.

[[Insert LPC name] would like to discuss possible changes to the existing contract with an aim for it to provide a remunerated package of care to support the wellbeing of clients with OST. As part of this discussion we would like [insert commissioning organisation name]as the service commissioner to consider the following elements:

- Two-way communication between the pharmacist and members of the drug treatment team responsible for a patient's care.[4] It is recommended than an IT platform is introduced to allow

rapid and direct communication between the care providers. Systems should be quick and easy to use, while providing a secure and auditable method of communication;

- Using the face-to-face contact and frequency that the pharmacist will have with OST clients, pharmacists can look for signs of withdrawal that would suggest that the dose of medication is not sufficient;[6]
- Pharmacists can provide indications of when a client's physical appearance or mental health seems to be deteriorating;[4]
- Pharmacists can report signs of intoxication and incidences of when doses are refused due to intoxication;[6]
- Pharmacists can report when clients are missing doses, not just when they are off-script after missing three days of medication;[4]
- Pharmacists can reinforce when clients are due an appointment;[4]
- With patient consent, pharmacists who additionally provide needle and syringe programmes can flag if an OST client is collecting needles and syringes;
- Pharmacists can flag if there are any safeguarding concerns linked to childcare;
- Pharmacists can flag if there are any safeguarding concerns linked to exploitation or intimidation of the OST client; and
- Pharmacists can share concerns associated with any OTC repeat purchasing or refusals to sell an opioid containing medication.

A remunerated service that provides the above would appropriately fund the use of a pharmacist's time to support OST clients, provide the current missing key worker face-to-face visual assurance that the OST client appears to be well and provides a rapid method of communication between the pharmacy and the treatment team to support any additional measures that need to be considered to aid the client. Drug treatment teams would have a more robust way to communicate client appointment reminders, prescription holds pending review instructions and provide more effective tools to support more robust auditing and review. These could all better support patient care and provide better opportunities for treatment teams to respond to client welfare.

Working together we feel it should be possible to achieve a remuneration package to provide the elements of welfare for all OST clients on prescriptions with a pharmacy, and a separate additional fee to cover any requirements of supervision of medication.

Stage 2

There are additional service opportunities that could also assist both treatment teams and clients to maintain and improve patient care. [Insert LPC name] would be happy to discuss these opportunities as packages of additional care to further develop the contract.

These additional services could include:

- **Needle and Syringe programmes (NSP)** - The NICE guidance[9] on needle and syringe programmes recommends that commissioners use pharmacies, especially those with longer opening hours, to provide this service to help ensure geographical and demographic coverage. The guidance also recognises the potential for using pharmacies to provide young people with this service especially as they can also encourage young people to make contact with specialist services.

  The same issues that have impacted on the number of patients being supervised on OST have also impacted the number of people able to access NSPs. In a published study that looked at enhanced data monitoring during the pandemic, the number of NSP clients decreased by 36%, visits by 36%, and needles distributed by 29% (Whitfield, M, et al; 2020).[10] A review of

supervision contracts should equally prompt a review of NSP contracts with a focus to ensure there is better pharmacy provision and coverage. Reviews of NSPs should seek to ensure provision is focused on ensuring pharmacy staff are aware of, encourage and can refer people to, other healthcare services including drug treatment services. NSP services from pharmacies should also ensure that pharmacy staff can offer wider health promotion advice, relevant to individuals.[10]

- **Brief alcohol interventions** - Every year alcohol related harm costs the UK in excess of £21 billion (£3.5 billion in NHS costs in England, £11 billion for alcohol related crime in England and Wales and £7.3 billion of lost productivity because of alcohol in the UK).[11]

  Screening and extended brief interventions are recommended in people aged 16 or 17 years. Screening and structured brief advice are recommended as the first step in people aged 18 years and older. For those who do not respond to structured brief advice, an extended brief intervention is recommended.[12] The NICE Quality Standard recommends that commissioners ensure they commission services that opportunistically carry out screening and brief interventions for hazardous (increasing risk) and harmful (high-risk) drinking as an integral part of practice and develop commissioning frameworks that review this practice to ensure effectiveness.[13]

  While alcohol intervention and brief advice (IBA) services largely sit in general practice, the accessibility of community pharmacy to support provision of these interventions is largely underutilised and under researched. While the Orange Book recommends drug users who are also using alcohol should be offered alcohol treatments,[5] there is an opportunity for commissioners to deliver an alcohol IBA service through opportunistic interventions targeting any patients that attend the pharmacy as well as service users engaged with drug treatment services, e.g. clients collecting OSTs and those using NSP.

- **Naloxone supply** - Across Europe, illicit opioid users are 10 times more likely to die than their peers of the same age group and gender, and 6,100 deaths were attributed directly to opioid overdose in 2012.[5] With the increase in OST clients receiving take-home medication due to the pandemic, provision of naloxone to prevent accidental overdoses could be considered to further safeguard OST clients. With the agreement of the individual at risk, it could also be supplied to family members, friends and peers.[1]
  Due to the change in legislation in October 2015, pharmacists can lawfully supply naloxone for parenteral administration in the course of provisions of lawful drug treatment services and only where required for the purpose of saving life in an emergency, making it easier for drug treatment agencies to distribute naloxone to 'at risk' opiate users.[5]

- **Injectable depot buprenorphine administration** - Buprenorphine prolonged-release injection may be an option where there is a risk of diversion of opioid substitution medicines or concerns about the safety of medicines stored at home. It may also be an option for people who have difficulties adhering to daily supervised opioid substitution medication, such as for people who are working or in education. However, the higher drug acquisition cost of buprenorphine prolonged-release injection compared with other treatments for opioid dependence will need to be taken into account.[13] Pharmacists could be commissioned to administer the injection to OST clients and could provide support, particularly in more rural areas.
  Pharmacy pilots 'game changing' buprenorphine injection | Chemist+Druggist (chemistanddruggist.co.uk)

  https://www.kaleidoscopeproject.org.uk/news/what-is-buvidal-and-is-it-right-for-you/

- **General drug screening** - can be a useful tool in diagnosis and assessment and in monitoring compliance and outcomes of treatment. The use of general drug screening also fits well with a focus on the wellbeing of the client, providing an opportunity to reflect back to the individual, real evidence of good or continuing poor progress and to share information about the risks and about the concerns of use on top of prescribing.[5]

  While general drug screening has typically been provided by treatment teams at their treatment sites, newer methods of screening and the reduced frequency of face-to-face contact with clients at treatment centres as a result of the pandemic could mean that community pharmacy could offer further support. The face-to-face care provided in pharmacies as well as their ease of accessibility to the clients could be further harnessed to provide routine general drug screening.

  Making use of fingerprint drug testing through community pharmacies could provide a quick, simple and hygienic method of providing both more local testing for patients, but also supporting treatment teams with on-going monitoring of patients and their wellbeing.

Further additional service examples include:

- **Hepatitis B vaccination** - All at-risk drug users should be offered vaccination against hepatitis B (and against hepatitis A and tetanus, when indicated);[5] and

- **Sexual health services**.

These services would need to be developed and negotiations held locally regarding the service fee associated with provision of the additional service.

Summary

Community pharmacy has for a long time provided an entire support package for OST clients that has been 'badged' as a supervised consumption service. The reduced numbers of patients being supervised, the reduced patient collection frequency resulting in reduced dispensing income and rebate practices that continue to have an impact on pharmacy margin, are all having an impact on funding. An impact that means pharmacies can no longer sustain unremunerated care or service provision. It is imperative that a funded wellbeing package is considered to support clients as part of the provision of supervised OST. This will further support and maintain appropriate levels of care and service. These elements of care are in line with NICE and drug misuse and dependence guidance. They will further strengthen provision of care by treatment teams.

Not all community pharmacies provide OST services; however, for the pharmacies that do, the combined impact of reduced numbers of patients being supervised, reduced pick-up frequency resulting in a decrease in dispensing fee income and the impacts on dispensing margins is making the provision of these services less viable. As contractors exit service provision due to the reduced income and potential losses incurred in provision, there will be a knock-on effect to patient care and accessibility of the service. To prevent an impact on OST clients, the pharmacies willing to provide the service need to be better supported.

Additional services can also be considered in pharmacies; however, these are builds on the existing funded care model, not a substitution for the wider contractual requirements of a 'supervision' contract.

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