

# Use of long-acting injectable buprenorphine for opioid substitution therapy

**ROUND 2: RESPONSES** 

## Statement 1

Treatment with depot buprenorphine potentially confers the opportunity to change the way in which opioid substitution services are structured and delivered. The less frequent dosing with depot buprenorphine formulations reduces the regularity of contact between service user and care provider and, while this may offer advantages for some individuals, it may require careful scheduling of clinical reviews and flexible approaches to care planning, for example in the setting where the depot can be delivered.

Of 22 respondents:

- 12 strongly agreed with this statement;
- 6 agreed;
- 1 neither agreed nor disagreed;
- 2 disagreed;
- 1 strongly disagreed.

Eighteen out of 22 (81.8%) respondents agreed or strongly agreed with this statement, so consensus has technically been reached.

Table 1: responses to a	consensus statement 1
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Respondent	Response and comments
1	STRONGLY AGREE I agree services will require to change their approach-more flexibility. May require dedicated team approach- clinical and non-clinical support staff
2	AGREE it affords people the time and removal of constraints in order to progress their recovery and involve themselves in meaningful activity
3	AGREE The use of the phrase "reduced the regularity of contact between service use and care provider" is accurate but I don't think that it reads particularly well and could be quite alarming for some people. I wonder about a phrase like "The less frequent dosing with depot buprenorphine formulation will alter the frequency of contact between the service user and care provider and"
4	AGREE I feel the statement is much better after removal of the word 'challenges'. Happy with it overall but It still feels bit confusing, especially the second sentence. It sounds not balanced. I think dividing the second sentence into two or three sentences would be better to convey the message in a simpler way. For example, The less frequent dosing with depot buprenorphine formulations *may





	reduce the regularity of contact between service user and care provider. This may offer advantages for some individuals as it gives them the opportunity to have time to attend recovery activities and other priorities. For others who need more support, careful scheduling of clinical reviews for example in the setting where the depot can be delivered and flexible approaches to care planning should be considered.
5	STRONGLY AGREE Agree that changed wording improves clarity of meaning.
6	AGREE I feel that LAB obviously confers an opportunity to change the way in which OST services are structured and delivered. The less frequent contact with services may be beneficial to some patients, whereas other patients may require some contact with services in the context of psychosocial therapy. This could be seen as a positive development and a move away from patients needing to attend a community pharmacy on a daily basis.
7	STRONGLY AGREE I am in agreement with this statement
8	STRONGLY AGREE Completely agree with this statement, while less contact with services is good for some patients, others may need more support and find more comfort in seeing clinicians more than once a month. Going from being seen every day in some way to being seen once a month may affect patients psychologically so it's important to discuss this and for clinicians to be flexible.
9	DISAGREE Administration of medication is different from seeing a patient for other psychosocial treatments. Pharmacy dispensing is not "care providers" in the same sense that an addictions team is.
10	STRONGLY AGREE In terms of prescribing yes, less contact, but this does mean that more time cannot be spent in building up that person re: psychological health, heart and lung health, social issues etc.
11	DISAGREE The requirement to have regular contact with the care provider is driven by clinical need not the formulation of the treatment.
12	STRONGLY AGREE I agree the need to review of clients has to be tailored to the individual depending on their level of stability. The depot also promotes a greater level of independence to the client than other OST therapies which require a greater level of supervision.
13	STRONGLY AGREE Fine as written
14	STRONGLY AGREE Patient contact and continuity of care is very important
15	STRONGLY DISAGREE It absolutely does not automatically reduce patient contact. That is and always will be determined clinically
16	AGREE I think this is balanced statement





17	STRONGLY AGREE It requires careful but flexible planning and arrangements from services and patients
18	NEITHER AGREE NOR DISAGREE This is not clear whether support for the individual would be increased/decreased. if it was to be increased I would see this change as positive.
19	STRONGLY AGREE From experience working with patients who have transferred to depot buprenorphine, it is important to ensure that a structured care plan is in place to ensure they are receiving the correct frequency of support to ensure they are not struggling with the reduced frequency of contact with healthcare professionals
20	AGREE I think this statement is balanced, recognising that for some patients less frequent contact with no pharmacy attendance can be positive. Equally for others the loss of pharmacy contact may in fact mean that the team needs to in fact have more frequent contacts and focus on other ways of monitoring and ensuring safety.
21	STRONGLY AGREE I agree with the content and with services taking a flexible approach to the needs of the person accessing the service,
22	STRONGLY AGREE Agree with revisions made and content of statement as stands currently



NHS organisations and contracted services must ensure staff are trained and competent to deliver care. This includes the administration of medicines such as subcutaneous injections. There are no established formal prescribing or administration training standards for depot buprenorphine. Additional training is required to deliver depot buprenorphine which is currently available only in dosed prefilled safety syringe formulations. Standard operating procedures should be developed with staff.

Substance misuse service providers are advised to ensure sufficient staff (including locums) are trained for service resilience. If the administration is delivered by a third party (eg community pharmacy or residential rehab service), service providers are advised to have evidence of training to ensure competence and that training is up to date.

Of 22 respondents:

- 13 strongly agreed with this statement;
- 6 agreed;
- 2 neither agreed nor disagreed;
- 1 disagreed;
- 0 strongly disagreed.

Nineteen out of 22 (86.4%) respondents agreed or strongly agreed with this statement, so consensus has technically been reached.

Respondents' comments are detailed in table 2:

Table 2: Responses to consensus statement 2

Respondent	Response and comments
1	STRONGLY AGREE totally agree with the above
2	STRONGLY AGREE It is important that we have trained staff to ensure that we cause no harm and to engender trust among the patient group.
3	STRONGLY AGREE I think that this reads better now than the original.
4	STRONGLY AGREE No changes needed
5	NEITHER AGREE NOR DISAGREE I would suggest one further small edit to include word prescribing in "This includes the prescribing and administration of medicines" otherwise agree with changed wording.
6	STRONGLY AGREE I feel that a specific training protocol should be developed for LAB, to facilitate the development of Buvidal administration services in third parties, such as community pharmacies.
7	AGREE Agree with first paragraph. Second paragraph -all of the points are relevant regardless of which service delivers. Could this paragraph be simplified to "All services providing depot buprenorphine must ensure that



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they have sufficient, competent staff and that training records are up to date" 8 AGREE I agree with this statement, training is essential to ensure patient safety and continuity. STRONGLY AGREE Nursing staff administering the injection should be 9 trained. This can be provided by the pharma reps or local inductions should include this training. STRONGLY AGREE Governance in this issue can be achieved through 10 Learn Pro and TURAS 11 AGREE I agree that all service providers should be able to provide evidence that they are competent to administer the depot injection and can demonstrate that competence is maintained. 12 STRONGLY AGREE It is important staff are trained to recognise adverse effects, trained in administration and up to date CPR training in case of an emergency and be competent in managing such an occurrence. STRONGLY AGREE Fine as written 13 14 STRONGLY AGREE Training is important to have robust clinical governance 15 AGREE Surely shouldn't be too onerous, but fine. Vast majority of our colleagues can deliver injections already. 16 AGREE I think this is a comprehensive statement that ensures competency 17 STRONGLY AGREE Service needs to be robust and therefore staff need trained to administer and there needs to be sufficient numbers. 18 STRONGLY AGREE This should be standard with any administration of a medicine. 19 STRONGLY AGREE All healthcare professionals should be provided with the sufficient training to ensure their competence in administering a new medication. Healthcare professionals should take responsibility to ensure their own competence and have access to prove this NEITHER AGREE NOR DISAGREE I think this statement recognises that 20 there is a training need, without dictating to local areas how to implement it. But also doesn't give guidance as to what training is acceptable. At present the manufacturer does offer reasonable training, this was in the previous statement but has been removed. I wonder if the statement now leaves it as suggesting training is needed, but gives no reference on how to access it. I wonder if a reference to being able to seek training from the manufacturer as appropriate or a suggestion of using nationally developed training were it to become available may be sensible. I fear that otherwise there may in some areas be delay in the use of LAB as they won't have training that is seen as meeting the standard. 21 AGREE Agree that anybody administering this should have some training and be fully competent in this.



22	DISAGREE My understanding is that appropriate terminology would be
	Substance use service providers, not substance misuse



Service users should be assessed as having capacity to provide informed consent to their usual dose, and to understand warnings regarding risks of sedation and overdose from polysubstance use. If there are concerns that the service user is very intoxicated and unable to understand or follow instructions, the administration of the dose may be deferred and rescheduled.

Of 22 respondents:

- 15 strongly agreed with this statement;
- 3 agreed;
- 2 neither agreed nor disagreed;
- 2 disagreed;
- 0 strongly disagreed.

Eighteen out of 22 (81.8%) respondents agreed or strongly agreed with this statement, so consensus has been reached.

Respondents' comments are detailed in table 3

Respondent	Response and comments
1	STRONGLY AGREE Agree with above. May require to be documented and counter signed by another clinician
2	STRONGLY AGREE It is imperative that the service user is able to make informed decisions.
3	STRONGLY AGREE N/A
4	STRONGLY AGREE Very clear, no changes needed
5	STRONGLY AGREE Agree with this wording, no changes to suggest
6	AGREE Service user should be in a position to provide consent for administration of Buvidal.
7	DISAGREE There is still ambiguity in the last sentence - if the service user is very intoxicatedthe dose may be deferred and rescheduled. If the service user is intoxicated, unable to understand or follow instruction then they cannot provide informed consent. The dose must be deferred. Also consent required for any doses that are not the usual ones too! Suggest "Service users should be assessed as having capacity to provide informed consent to their dose, and to understand warnings regarding risks of sedation and overdose from polysubstance use. If there are concerns that the service user is intoxicated and unable to understand the information provided to make an informed decision then the dose must be deferred and rescheduled."
8	STRONGLY AGREE Completely agree with this statement, well written and very important for patients be able to give consent.

Table 3: Responses to consensus statement 3



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9	AGREE Would be cautious in the administration of medication to anyone who appeared under the influence but next appointment must be made asap to try to offset withdrawals and further illicit use.
10	STRONGLY AGREE Always
11	STRONGLY AGREE Informed consent to treatment is required and patients must have the capacity to provide this. This statement support safe patient centred care.
12	STRONGLY AGREE Safety should be a priority and by managing this situation in this way it encourages the service user to become aware of their own personal safety and take responsibility of it.
13	STRONGLY AGREE Important advice for clinician administering the depot injection. It does however need to work with Statement 4
14	STRONGLY AGREE Capacity is important to allow informed consent. Deferring the usual dose has to be a reasonable option
15	STRONGLY AGREE As in all OAT situations.
16	DISAGREE Rewording:- Service users should be assessed as to whether they have capacity to provide informed consent to their usual dose. If there are concerns that the service user is very intoxicated and unable to understand or follow instructions, the administration of the dose should be deferred and rescheduled.
17	STRONGLY AGREE This is the same as a dose within community pharmacy which should be withheld if the patient appears intoxicated
18	NEITHER AGREE NOR DISAGREE There needs to be a clear assessment protocol! Otherwise if this is left to individual staff to assess the results will vary, based on staff's experience, tolerance to risk, this would make it too subjective! There needs to be a clear defined pathway for assessment of risk if the dose is deferred or rescheduled.
19	STRONGLY AGREE A patient presenting as intoxicated should not be administered medication that may cause any harm or, indeed, if they are not deemed to have capacity at the given administration time. 'Do no harm'
20	NEITHER AGREE NOR DISAGREE Whilst I agree with this statement. I think it can be expanded on to reflect this situation including to highlight risks of not giving treatment. Patients who have been started on LAB have clearly had the treatment explained and consented to it at the start of treatment. Even if intoxicated their decision to choose to present again for the next injection is significant. Capacity judgements take into account clear previous expressed wishes alongside current, in this case even if intoxicated the patient has both previously consented and is by attending expressing continued consent. This alongside the judgement that must then be taken in the room on capacity is significant. There is risk in not giving treatment, patients may not attend again and may come out of treatment. It is frustrating for patients to feel they have come as asked and then be turned away. In a rural area where travel is already a barrier to retention in treatment this becomes even more significant. There are many other examples of capacity assessment and needed treatment given to



	intoxicated individuals, the most obvious being an intoxicated patient in A&E with a laceration. You wouldn't send them away with an open wound and tell them to come back and have it stitched at a later date if they were clearly consenting when the treatment is in their best interests.
21	AGREE I agree with this
22	STRONGLY AGREE Clear and appropriate



Service users who present intoxicated at the time of dose administration should be assessed to identify any safety concerns regarding dosing. Peak plasma and clinical effects occur approximately 12–24 hours after weekly depot buprenorphine injections and 6–10 hours after monthly depot buprenorphine injection, and hence there is usually little clinical indication to withhold a depot injection due to a service user presenting intoxicated, in contrast to intoxicated presentations for sublingual buprenorphine or methadone dosing, where peak medication effects are likely to occur whilst the service user is still intoxicated.

Of 22 respondents

- 2 strongly agreed;
- 7 agreed;
- 7 neither agreed nor disagreed;
- 5 disagreed;
- 1 strongly disagreed.

Nine out of 22 (40.9%) respondents agreed or strongly agreed with this statement, so consensus has NOT been reached.

Respondent	Response and comments
1	AGREE I did not know that! Therefore really important all staff have appropriate training, so also aware. And as I suggested above if withheld requires documentation and counter signatory (for example if someone inexperienced administering)
2	AGREE assessing safety concerns is crucial. From my understanding there is less chance of harm of further sedation given that there is a significant window between the time of presentation and clinical effects.
3	AGREE I think this reads appropriately.
4	STRONGLY AGREE Very clear informative statement
5	NEITHER AGREE NOR DISAGREE Agree with changed wording. Should also include that any decision not to administer should acknowledge the risks of interrupting OST and weigh against any risk of administering.
6	AGREE I feel this is a sensible statement.
7	DISAGREE There may not be a clinical indication to withhold, however there is an ethical one. The service user must have capacity to provide voluntary, informed consent every time. This needs to be clear within this statement. This information is helpful when the patient is intoxicated but still assessed as having capacity to understand, remember and use the information to communicate an informed decision. The assessment of the





staff member will vary depending on prior knowledge of the patient and the clinical relationship.           8         DISAGREE As a clinician I would not be happy to administer Buvidal to a patient that is intoxicated and not clearly able to give consent. I would ask the patient come back the next day.           9         NEITHER AGREE NOR DISAGREE Unsure of this - would still be unsure as the nurse giving this to an intoxicated patients           10         AGREE This should be made transparent by the employing organisation and clearly supported, each episode of care is to be taken on its own merits and this is where peer review, sharing with senior colleague or expert peers should be encouraged to build confidence and body of evidence.           11         STRONGLY DISAGREE This statement does not consider intoxication from illicit substances which may not be opiate or opioid and which could present a danger. e.g. benzodiazepines           12         NEITHER AGREE NOR DISAGREE Unsure about how the management of my organisation and critical incident review panel would view the theoretical example of someone overdosing having presented intoxicated and then receiving treatment. This would need to be discussed and agreed at a local level before I would feel confident about administration.           13         DISAGREE This clashes with Statement 3 as written. There needs to be something about the intoxicated patient still being able to give consent. Perhaps: " should be assessed to determine capacity and identify any safety concerns regarding dosing" "injection due to a service user presenting intoxicated (as long as they have capacity to provide informed consent), in contrast to intoxicated presentations"           14         AGREE NOR DISAGREE I		
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21 NEITHER AGREE NOR DISAGREE this is outside my clinical experience	20	and helps guide clinical decision making, highlighting the low risk nature of
	21	NEITHER AGREE NOR DISAGREE this is outside my clinical experience



22	NEITHER AGREE NOR DISAGREE Out with my area of expertise,
	therefore not able to comment



In community settings, it is recommended to have "did not attend" and "unsuitable for administration" procedures in place for situations where service users do not attend their scheduled appointments or the dose is not administered due to clinical reason (e.g. the service user is too intoxicated to provide consent). The procedures should contain the following:

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- communication system (i.e. who to inform key worker, clinician)
- documentation of actions to be taken to contact and recall the service user if applicable. It should detail who is responsible for carrying out these actions.

Key workers should prepare an individualised "Did Not Attend" plan for each person prescribed depot buprenorphine. This will inform staff unfamiliar with the service user of the actions to be taken when they do not attend appointments.

Of 22 respondents

- 14 strongly agreed;
- 6 agreed;
- 0 neither agreed nor disagreed;
- 2 disagreed;
- 0 strongly disagreed.

Twenty out of 22 (90.9%) respondents agreed or strongly agreed with this statement, so consensus has technically been reached.

Table 5: Responses to	o consensus	statement 5
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Respondent	Response and comments
1	STRONGLY AGREE great idea individualised plan
2	STRONGLY AGREE good communications across teams and an engagement plan are important to ensure patient safety and compliance.
3	STRONGLY AGREE The individual "Did Not Attend" plans will be very useful
4	STRONGLY AGREE Excellent statement - very helpful in making management plans.
5	STRONGLY AGREE no changes to suggest, agree with revised wording
6	AGREE I feel that a DNA procedure, and subsequent communication between services, is essential in terms of Buvidal treatment.
7	AGREE Would it be better to simply have a "did not receive dose" procedure which would cover both events. Actions likely similar for both.
8	STRONGLY AGREE Completely agree with this statement. It is essential to have good and clear communication so all staff members know what to do in this case.
9	STRONGLY AGREE Systems must be in place to take account for these situations, communication is key.



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STRONGLY AGREE MAT Standard 5 is all about retention of the service 10 user with ability to reconnect with no barriers. 11 AGREE This would seem a reasonable approach to provide safe person centred care. 12 STRONGLY AGREE It is important to have a care plan outlining how to manage such a situation to promote confidence in the service and within the staff group to prevent any confusion and keep prescribing safe. AGREE Fine as written 13 14 AGREE Important to have this in place to robust clinical governance STRONGLY AGREE No different to other OAT delivery 15 16 STRONGLY AGREE Very important to have a robust procedure and communication protocol in this situation 17 STRONGLY AGREE Clear documentation of attempts to contact and response should be made 18 DISAGREE This should always be completed by the medical staff! keyworkers are often social care staff and not really involved in the administration of a medication, so why would we expect them to fill out an individualized plan? 19 AGREE Ensures patient centre approach 20 DISAGREE I do agree with pretty much all of the statement. Though I still am unsure of the value of an "individualised" DNA plan is for every patient. It is another use of staff time to create a care plan document for each individual. Are these likely to vary significantly from the service standard plans for these situations? Our experience is not. Our service has an individualised plan only in those cases where it would be seen to add value, rather than a blanket requirement for another care plan document to be completed for all. 21 STRONGLY AGREE have this in place that no one would not receive follow up contact and clearly defines who is responsible for this 22 STRONGLY AGREE Clear and agree with content



A service user's care may be transferred (temporarily or permanently) to another provider (acute/ community/ mental health/ health and justice) and vice versa. There should be clear documentation and communication between professionals at both settings to minimise disruption to the service user's treatment and ensure continuity of care.

Of 22 respondents:

- 19 strongly agreed;
- 3 agreed;
- 0 neither agreed nor disagreed;
- 0 disagreed;
- 0 strongly disagreed.

Twenty two out of 22 (100%) respondents agreed or strongly agreed with this statement, so consensus has technically been reached.

Respondent	Response and comments
1	STRONGLY AGREE Yes, very similar to what I suggested
2	STRONGLY AGREE Good communications are crucial for successful engagement.
3	STRONGLY AGREE Reads well.
4	STRONGLY AGREE No changes needed
5	STRONGLY AGREE Agree with wording
6	AGREE Appropriate communication between services should be paramount when a patient is transferred between providers. A specific document could facilitate this communication.
7	STRONGLY AGREE This is really important - agree
8	STRONGLY AGREE I strongly agree with this statement, as said previously, good and clear communication is of the utmost importance to ensure a smooth transfer and ensure continuity of care.
9	STRONGLY AGREE No additional suggestions
10	STRONGLY AGREE Especially true in Justice settings.
11	SRONGLY AGREE Yes, this will support safe continuity of care across the interfaces experienced by service users.
12	STRONGLY AGREE This would ensure prescribing remains safe and the client is not prescribed additional medication which may cause an adverse reaction. It will also provide the responsible professionals with information regarding and physical health concerns and allergies. This would prevent treatment errors.
13	AGREE Fine as written



	-
14	STRONGLY AGREE To help reduce risks of mistakes being made it is important to have a clear treatment plan
15	STRONGLY AGREE As with all clinical handovers
16	STRONGLY AGREE This is important for good practice and to prevent errors
17	STRONGLY AGREE Clear documentation (and regular documentation and updates) are required to ensure services work seamlessly
18	AGREE This would need to clearly state the level of information required as standard practice! Otherwise you will have staff who choose to input a minimum amount of information.
19	STRONGLY AGREE Clear communication is key during these transfers to ensure that all parties are involved and aware of the service user's care and treatment plan. This ensures patients are not detrimentally affected
20	STRONGLY AGREE No objections to the changes. Remain in agreement.
21	STRONGLY AGREE Strongly agree so as the person can access this service no matter their setting or personal circumstances
22	STRONGLY AGREE Clear and agree with content



Doses should generally be reduced under the following conditions:

- the service user reports buprenorphine dose-related adverse events (e.g. sedation or lethargy, persistent headaches, nausea) or has elevated liver function tests
- the service user wishes to be supported to work towards withdrawal of opioid substitution therapy
- the service user is reporting the dose is 'too high' and/or is seeking a dose reduction and there are no significant concerns regarding deterioration in clinical condition (e.g. substance use, physical or mental health symptoms) that may arise with a dose reduction.

Of 22 respondents:

- 13 strongly agreed;
- 7 agreed;
- 1 neither agreed nor disagreed;
- 1 disagreed;
- 0 strongly disagreed.

Twenty out of 22 (90.9%) respondents agreed or strongly agreed with this statement, so consensus has been reached on the statement section highlighted above.

Table 7: Responses	to consensus	statement 7
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Respondent	Response and comments
1	STRONGLY AGREE Yes, really like as puts the patient/service user first
2	STRONGLY AGREE It is important that we listen to the concerns of the patient and act accordingly.
3	STRONGLY AGREE N/A
4	STRONGLY AGREE No changes needed
5	STRONGLY AGREE Agree with wording, no changes suggested
6	STRONGLY AGREE Happy with these reasons for reducing the dose.
7	AGREE Agree with above statements
8	STRONGLY AGREE I agree with all of these statements, well written and more holistic than last statement.
9	STRONGLY AGREE add urine retention to adverse events
10	AGREE Choice is apparent in this relationship, but a prescriber will always set out the benefits if there are any in this situation for how to do this in partnership
11	DISAGREE Dose reduction is not always required to move towards withdrawal of OST due to formulation's pharmacokinetics.



12	AGREE Service users' physical health and wishes should be considered in dose reductions.
13	AGREE No concerns
14	STRONGLY AGREE Clear instructions for reduction helps with decision making
15	STRONGLY AGREE Recovery belongs to the individual, so their wishes should be respected as far as is practicable.
16	AGREE These reasons are reasonable
17	STRONGLY AGREE Sensible options for dose reductions
18	AGREE This should always be a patient's choice- Unless there is a clear associated risk.
19	STRONGLY AGREE Patients should be involved on an ongoing basis in these decisions and their input and opinions should always be considered.
20	STRONGLY AGREE I have no objection to the changes made and remain in agreement.
21	STRONGLY AGREE Agree with all these reasons for reducing dose
22	NEITHER AGREE NOR DISAGREE Out with my expertise



#### Statement 7a (additional bullet point)

Should the following bullet be added to the statement? (please vote your level of agreement):

#### Doses should generally be reduced under the following conditions:

• the service user is regularly delaying their return appointment longer than the scheduled interval as the medication is still holding them sufficiently.

Of 22 respondents:

- 3 strongly agreed;
- 7 agreed;
- 3 neither agreed nor disagreed;
- 6 disagreed;
- 3 strongly disagreed.

Ten out of 22 (45.4%) respondents agreed or strongly agreed with this statement, so although Statement 7 did achieve consensus, consensus has been NOT been reached with regards to the additional bullet point.

Respondent	Response and comments
1	DISAGREE Guess it depends on length of delay. Put in considerations "may wish to" Would recommend discussing with in key work session
2	NEITHER AGREE NOR DISAGREE This is a discussion for both the patient and the clinician
3	STRONGLY DISAGREE This may not be to do with the dose being too high. There may be other reasons so whilst there may be a reason to reduce the dose it isn't a confirmed so would not feel comfortable with this statement in.
4	DISAGREE I feel this can be covered in the third bullet point in the original statement - whether the dose is too high and need to be adjusted. Including this may worry the service users as they may feel they will be penalised due to being late.
5	STRONGLY DISAGREE May be number of reasons why delaying. Explore all reasons and increase psychosocial supports to ensure patient centred care plan. Change schedule of appointment rather than dose of medication.
6	AGREE I feel this is an appropriate reason to consider reducing the dose, but only with agreement of the patient so as not to destabilise their treatment.
7	AGREE Agree - good addition to the statement
8	NEITHER AGREE NOR DISAGREE Not sure about this one.



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9	DISAGREE Buvidal is its own detox so patients by rights shouldn't ever feel that they are not holding. Dose should be administered every 28 days as per manufactures instruction.
10	AGREE Worthy of discussion in case there are other reasons
11	DISAGREE I do not believe that this, in isolation, is a reason for dose reduction.
12	AGREE This should be in negotiation with the client.
13	AGREE Makes sense
14	STRONGLY AGREE Helpful addition
15	STRONGLY DISAGREE Recovery belongs to the individual. Reduction can be discussed, but medication only works as long as it is being taken.
16	DISAGREE I am not sure that the phrase 'holding them' is a widely understood term - certainly outside addiction services
17	STRONGLY AGREE If there are regular periods where the patient is delaying return but not experiencing withdrawals or concerns dose can be safely reduced
18	DISAGREE There are a number of reasons why a SU might delay their return appointment, if we add this to the statement it may then be assumed that the delay is due to the medication still holding them which might not be the case!
19	STRONGLY AGREE The dosing regime should be reviewed on an ongoing basis and adjusted accordingly to reflect the requirement of the patient. These decisions should be made in conjunction with the patient
20	AGREE In these circumstances having a conversation with the patient and exploring dose reduction would be reasonable.
21	AGREE Agree with this
22	NEITHER AGREE NOR DISAGREE Out of my expertise



Doses should generally be increased under the following conditions:

- the current dose is not meeting the needs of the service user (eg they are experiencing withdrawal symptoms or cravings)
- the service user reports their dose is too low and they would like a dose increase, there are no significant clinical safety concerns AND the services user is not experiencing adverse events related to buprenorphine (eg sedation or lethargy, persistent headaches, constipation, nausea) or elevated liver function tests.

Of 22 respondents:

- 12 strongly agreed;
- 7 agreed;
- 1 neither agreed nor disagreed;
- 3 disagreed;
- 0 strongly disagreed.

Nineteen out of 22 (86.3%) respondents agreed or strongly agreed with this statement, so consensus has technically been reached.

Respondent	Response and comments
1	STRONGLY AGREE Agree
2	STRONGLY AGREE under the MAT standards it is important that we listen to the patient and empower them to make decision in conjunction with the clinician
3	STRONGLY AGREE This seems clinically appropriate.
4	STRONGLY AGREE No changes needed
5	STRONGLY AGREE Agree with changes
6	AGREE These statements appear as appropriate reasons for increasing the Buvidal dose.
7	STRONGLY AGREE Patient centred - agree
8	STRONGLY AGREE I agree with this statement, no other comments.
9	DISAGREE There should be clinical evidence for an increase such as withdrawals or positive drug tests. Second bullet point I disagree with.
10	AGREE It is safer to do so
11	AGREE Agree, the patient is a partner in agreeing the necessary dose to control their symptoms.
12	STRONGLY AGREE They are not within an elderly population with impaired hepatic function or have respiratory impairments. They do not



have any physical impairments which would indicate an increase may exacerbate serious health complaints. AGREE Fine as written 13 14 AGREE Clear instructions for increases important 15 STRONGLY AGREE Makes sense 16 DISAGREE I feel these bullet points are saying similar things and they would be better combined in to one statement. Why else would the service user report their dose is too low? 17 STRONGLY AGREE Good rational for dose increases AGREE Patient centred care! 18 19 STRONGLY AGREE This should be reviewed and discussed on an ongoing basis between patient and health care professional, reasons and rationale explored and if the above criteria was met then this would be an appropriate decision 20 STRONGLY AGREE Agree with changes. As suggested lack of adverse events is not in and of itself a reason to increase dose. 21 AGREE I agree with these reasons for increasing dose 22 NEITHER AGREE NOR DISAGREE Outwith my expertise

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In general, doses should be maintained if the service user:

- is comfortable and not experiencing opioid withdrawals or cravings; and
- is achieving their own treatment goals and wishes; and
- is not experiencing clinically significant dose-related adverse events related to buprenorphine (e.g. sedation or lethargy, persistent headaches, nausea); and
- is satisfied with their current dose, and requesting the dose be maintained.

Of 22 respondents:

- 12 strongly agreed;
- 8 agreed;
- 1 neither agreed nor disagreed;
- 1 disagreed;
- 0 strongly disagreed.

Twenty out of 22 (90.9%) respondents agreed or strongly agreed with this statement, so consensus has technically been reached.

Table 10: Responses to	consensus statement 9
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Respondent	Response and comments
1	STRONGLY AGREE Agree
2	STRONGLY AGREE under the MAT standards it is important that we listen to the patient and empower them to make decision in conjunction with the clinician
3	STRONGLY AGREE This seems clinically appropriate.
4	STRONGLY AGREE No changes needed
5	STRONGLY AGREE Agree with changes
6	AGREE As long as the patient is maintained and stable on treatment, there is no requirement to change dose. I do feel that agreed review dates set at the outset of treatment would be helpful though.
7	STRONGLY AGREE Patient centred approach - agree with this statement
8	STRONGLY AGREE Completely agree with this statement, very patient centred.
9	AGREE but conversations must be ongoing between the service user and their worker abut long term plans and how they plan to eventually come off the drug
10	AGREE If the goal is health and not abstinence, yes, this person will be able to be in recovery and live a different life, hopefully one where they can flourish
11	AGREE This will support patient centred care with the patient as a partner in decisions relevant to their needs and care.



12	STRONGLY AGREE They have not developed health complaints which would indicate they require a dose reduction. If the service user has reached a level of stability on a dose then there would be no requirement to change the dose unless clinically indicated.
13	AGREE Fine as written
14	STRONGLY AGREE Clear instructions for maintenance
15	STRONGLY AGREE Makes sense
16	DISAGREE Should there be some mention of frequency of review of dose and clinician opinion being important as well as service user?
17	STRONG AGREE Sensible dosing advise and rationale for prescribing
18	AGREE Same as Q18
19	AGREE If all 4 points are met then agreed
20	STRONGLY AGREE All points seem reasonable and sensibly worded.
21	AGREE am satisfied that these are all good reasons for maintaining dose.
22	NEITHER AGREE NOR DISAGREE Out with my expertise



## Statement 9a (suggested additional bullet point)

#### In general, doses should be maintained if the service user:

• has reached maximum dose.

Of 22 respondents:

- 3 strongly agreed;
- 6 agreed;
- 4 neither agreed nor disagreed;
- 6 disagreed;
- 3 strongly disagreed.

Nine out of 22 (40.9%) respondents agreed or strongly agreed with this statement, so although Statement 9 did achieve consensus, consensus has technically NOT been reached with regards to the addition of this bullet point.

Table 11: Responses to conse	ensus statement 9a
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Respondent	Response and comments
1	STRONGLY AGREE Agree as there is a max dose
2	DISAGREE I would not include this bullet point. It is a discussion for the patient and the clinician.
3	STRONGLY DISAGREE I think on the whole that this is a given and shouldn't need to be included.
4	STRONGLY DISAGREE I don't think this adds any value. If we have reached maximum dose, we will maintain the dose anyway if no other concerns.
5	DISAGREE I don't think this is required. Don't expect this in guidance for other medications or oral buprenorphine.
6	DISAGREE If the patient has reached maximum dose, there should be an aim to reduce this at some point. This would have to be on agreement with the patient and not negatively affect their relationship with services.
7	NEITHER AGREE NOR DISAGREE Would require further information - if they have reached maximum dose and are still experiencing withdrawals then suitability of depot buprenorphine should be reviewed.
8	DISAGREE No it should not be added as just because a patient has reached a max dose, it does not mean they are stable, it could mean that this is not the medication for them and may need to try something more suitable to their needs.
9	NEITHER AGREE NOR DISAGREE Unsure what this means? Is the maximum dose where they are stable? Then yes. If unstable on this dose, then no, alternative treatment should be sought.



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AGREE Not my area of expertise, but communication and contact with 10 clinician will help monitor this and any changes 11 AGREE If the patient is not controlled at the max dose of depot buprenorphine then they need a different treatment, either back to methadone or a sublingual form of buprenorphine. 12 STRONGLY AGREE It may put the service user's health at risk to prescribe outside of recommended perimeter. 13 AGREE Fine 14 STRONGLY AGREE A ceiling dose is important 15 AGREE However, clinical decision making might mean that a higher dose is required. Using >1 syringe would need to be explained & justified. NEITHER AGREE NOR DISAGREE I am not clear about this and the pros 16 and cons 17 AGREE This may change as new formulations are available e.g. the arrival of the 160mg is due shortly 18 DISAGREE If a SU has reached max dose why would you need this additional bullet point? When max dose is reached maintenance is the only option available- unless the SU expresses a wish to reduce their dose. DISAGREE I don't believe this requires to be added to the statement 19 20 STRONGLY DISAGREE I don't think this is needed, patients would be maintained on the dose they are comfortable and stable on within the wording of existing points. Most importantly I worry this could be misinterpreted as implying that someone should always be titrated to the top dose before it is maintained. 21 AGREE Agree with this 22 NEITHER AGREE NOR DISAGREE Outwith my expertise



#### Statement 9b (additional suggested bullet point)

Should the following bullet be added to the statement? (Please vote your level of agreement):

#### In general, doses should be maintained if the service user:

• has not required any additional top up doses since administration of their last depot.

Of 22 respondents:

- 5 strongly agreed;
- 9 agreed;
- 1 neither agreed nor disagreed;
- 5 disagreed;
- 2 strongly disagreed.

Fourteen out of 22 (63.6%) respondents agreed or strongly agreed with this statement, so although consensus was achieved on Statement 9, consensus has NOT been reached on the addition of this second bullet point.

Respondent	Response and comments
1	DISAGREE put in considerations
2	STRONGLY AGREE yes - this is the logical way forward
3	AGREE I think that this would be an appropriate inclusion.
4	STRONGLY AGREE I think this would be a good addition
5	STRONGLY DISAGREE Unnecessary. Would depend if also was not requesting an increase. Or may not have had top up dose for reason such as not wanting to travel back to clinic but may feel needs increase.
6	AGREE This seems appropriate.
7	AGREE Agree - however new 160 mg monthly dose is maximum monthly dose and additional top-up doses are not licensed at this strength.
8	DISAGREE I don't think this is relevant.
9	AGREE Yes, this would indicate stability
10	AGREE As before
11	AGREE I think this is a useful additional criterion in determining suitability of the current dosing schedule.
12	STRONGLY AGREE This would indicate they have reached a level of stability.
13	AGREE Fine
14	AGREE Looking at patient history is important



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15 STRONGLY AGREE Should mean that they are being treated adequately & appropriately. 16 DISAGREE I think the importance of assessment and review of service user should be emphasised 17 STRONGLY AGREE This is sensible and accurate as the current dose is maintaining the patient 18 **DISAGREE** Same as question above! 19 DISAGREE I don't believe this requires to be added to the statement 20 STRONGLY DISAGREE I think this could be a bit misleading. Sometimes difficult personal circumstances or other stressors may lead someone who is stable to request a top up dose. We have done this even where we have felt it's not needed to control any withdrawal, but to reassure someone who is going through a hard time and worried they may crave. I would not see this as a reason to increase their regular dose unless it was becoming a repeated pattern. If any statement like this were to be included I'd suggest wording like - has not repeatedly required additional top up doses since the administration of their last depot. 21 AGREE Agree with this 22 NEITHER AGREE NOR DISAGREE Out with my expertise



General principles of chronic pain management should be followed and include patient education and engagement in the treatment process, physical interventions (e.g. exercise or physiotherapy), psychosocial interventions (e.g. Cognitive Behavioural Therapy) and the appropriate use of opioid and non-opioid medications (e.g. paracetamol, NSAIDS, gabapentinoids, antidepressants).

Of 22 respondents:

- 5 strongly agreed;
- 11 agreed;
- 0 neither agreed nor disagreed;
- 4 disagreed;
- 2 strongly disagreed.

Sixteen out of 22 (72.7%) respondents agreed or strongly agreed with this statement, so consensus has been reached.

Respondents' comments are detailed in table 13

Respondent	Response and comments
1	AGREE Agree with above, however also need to consider acute pain needs, and none of the above does
2	AGREE good pain management is important in supporting patient compliance with the proscribed regime
3	AGREE This is a very person-centred statement and think that this is in line with clinical treatment for these conditions.
4	AGREE Agree in general but would like to avoid opioid painkillers
5	STRONGLY DISAGREE Opioid medications requires to be removed.
6	DISAGREE I do not feel that patients prescribed Buvidal should be prescribed opioids for pain, unless in exceptional circumstances. It is also likely that patients would require a higher dose of opioids to elicit an effect, due to the partial agonist activity of Buvidal.
7	AGREE Prefer this order of the statement - non-pharmacological interventions first.
8	AGREE I agree with this statement and have no suggestions.
9	AGREE No suggestions
10	STRONGLY AGREE If there is evidence to contrary then this may become a more complex issue, but other treatments for pain adjuvant to prescribed medication are key in these cases, although may present a psychological stressor at times for the patient.
11	DISAGREE add a statement that the blockade effect of buprenorphine will require careful consideration of use of opiate or opioid analgesics at appropriate doses.

Table 13: Responses to consensus statement 10



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12	AGREE In the case of opioid medications being prescribed the service user should be closely monitored and all risks clearly explained. Other options should be explored in the first instance.
13	AGREE Fine - i note the concern about opioid prescriptions. See point below
14	STRONGLY AGREE Self management techniques should be followed.
15	DISAGREE I think that gabapentinoids should NOT be routinely suggested to our patients. They are absolute currency just now. There are other, much less addictive, alternatives that should be suggested instead.
16	DISAGREE I do not think opioids should be used for chronic pain management in this group of patients. There is not a pharmacological rationale. The difference between acute pain management in service users and chronic pain management should be emphasised/clarified
17	STRONGLY AGREE This is good pain management policy and advice for all on OAT.
18	AGREE This would be separate to the management of opioid dependency and should be managed in such a way.
19	STRONGLY AGREE Supports a holistic care approach
20	STRONGLY DISAGREE I fear inclusion of gabapentinoids may be seen as endorsement of their use. In addictions population these drugs are often abused and easily diverted. They are recognised as contributors in high numbers of Scottish drug death cases. I would remove gabapentinoids. Would support rest of the statement.
21	AGREE Agree that all the above principles and strategies should be followed
22	STRONGLY AGREE Clear and agree with content



#### 10a In response to statement 10, group members were also asked:

Should 'opioids' be removed from the statement? (yes or no)

Of 22 respondents:

- 11 agreed and said that 'opioids' SHOULD be removed from the statement
- 11 disagreed and said 'opioids' SHOULD NOT be removed from the statement.

Eleven out of 22 (50%) respondents agreed or strongly agreed with this statement, so consensus has NOT been reached with regards to the removal of the term 'opioid'.

Respondents' comments are detailed in table 14

Table 14: Responses to consensus statement 10a

Respondent	Response and comments
1	NO No
2	YES given the contraindications I agree with opioids should be removed from the statement
3	NO There may be reasons that opioids would be used that may result in a need to change treatment and therefore should still be included.
4	YES As far as I understand, opioid painkillers may cause precipitated withdrawal with buprenorphine (unsure whether it is less concern with depot). Chronic use of opioids have other adverse effect including hyperalgesia, and potential of relapse
5	YES should just read "and the appropriate use of non-opioid medications (e.g.". The guidance should not recommend the general principle of opioid medication when there is receptor blockade.
6	YES Patients prescribed Buvidal would require a higher dose of opioids to elicit a painkilling effect. These higher doses would require regular monitoring to spot signs of a potential overdose (which is made more likely by the requirement for higher dose of opioids).
7	YES Suggest that the final part of the paragraph reads"and the appropriate use of medications (e.g. paracetamol, NSAIDS, gabapentionids, antidepressants)"
8	NO Opioids should not be removed as they can still be used in severe pain management when a patient is on Buprenorphine.
9	NO Opioids should remain in - it must be mentioned despite not being able to be prescribed when on buprenorphine
10	NO Transparency, include positive and negative in terms of inclusion and exclusion.
11	NO as long as the statement is appropriate use of opioids then opioids should stay.
12	YES If they are included the risks should be highlighted. It would make it difficult to establish service user's concordance with treatment if they are



	prescribed as a positive test could be attributed to treatment making misuse difficult to detect. Higher doses are often needed thus increasing the risk of respiratory depression. The increased level of supervision would impact on already stretched resources.
13	NO I am unsure about the effectiveness of opioid analgesia in patients on long acting buprenorphine. I do not know whether they should be removed. However there is no 'don't know' option.
14	YES We should be trying to find treatment options that don't contain opioids as evidence suggests that opioids are not useful in long term chronic pain
15	YES Little point in using opioids routinely as they will be "blocked".
16	YES As above. This is a complex topic, requiring individual case by case management. More than one opioid should not be prescribed for chronic pain. Opioids have little or no place in recent national guidelines on chronic pain management.
17	NO Both OAT (OST) and analgesia need to be administered at times and in certain situations
18	NO I don't see any benefit to removing it.
19	NO Not required to be removed
20	YES I don't think it is necessary for opioids to be in the statement. There are reputable guidelines for management of chronic pain that explore the role of opioids and often lack of efficacy. Removing opioids I think would highlight in this guidance the suggestion of using all other approaches first. Opioids likely to be less effective in patients on buprenorphine due to the blockade effect. They remain more appropriate in acute pain, but this statement refers to chronic.
21	YES feel it docent have to put the focus on opioids.
22	NO Please ignore. Out with my area of expertise but had to enter an answer



## 10b In response to statement 10, group members were also asked:

Depot buprenorphine is used for OST, and not pain management. (yes or no)

Of 22 respondents:

- 16 agreed with the inclusion of the additional statement
- 6 disagreed with the inclusion of the additional statement.

Sixteen out of 22 (72.7%) respondents agreed with the inclusion of the additional statement.

Respondents' comments are detailed in table 15

Table 15: Responses to consensus statement 10b

Respondent	Response and comments
1	YES Makes it clear that buprenorphine can be used as pain management
2	YES That is the intent and purpose
3	YES If it was being used for pain management then this would be an unlicensed indication so I think that it is important to highlight this. It might be worth considering adding that if used for pain then this wold be unlicensed.
4	YES I think it makes the indication very clear.
5	YES I think it's helpful to make this point clearly.
6	YES I feel this an important point to raise. Prescribers of Buvidal should not be put under pressure to increase the dose to control pain in patients who are experiencing chronic pain, where their cravings are suppressed by Buvidal.
7	NO Manufacturer of Buvidal (Camurus) have submitted for EMA approval to use Buvidal in Chronic pain - decision pending. Therefore this statement may become out of date. https://mb.cision.com/Main/13456/3462832/1503159.pdf
8	YES I agree this should be added, no other comments.
9	YES as per the BNF
10	YES I would accept that I am not an expert in this matter and only approach DB from an addictions framework
11	YES This is not a licensed indication for this drug.
12	NO It can support pain management within the OST population but should not be used as a primary treatment.
13	YES Valuable reminder of the indication for long-acting buprenorphine
14	YES Opioids not useful in chronic pain
15	YES Then there is no misunderstanding.
16	NO This is a complex difficult clinical situation and depot buprenorphine may have an analgesic effect and it would is difficult to envisage when it would be clinically appropriate/safe to withdraw someone with a history of



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	addiction from depot buprenorphine and replace it with other opioids for chronic pain.
17	YES this provides clarity of rationale for those not experienced in Substance misuse
18	YES My understanding is that it is licensed for OST and not pain management.
19	NO Not sure this can be added unless this is 100% accurate
20	NO It is difficult and sometimes higher OST doses can be safer in chronic pain than patients seeking to also be on additional opioids or other medications. But shouldn't be first line, I would rephrase, Depot buprenorphine is used for OST, and increases in the dose of depot buprenorphine should not be used as a first line intervention in the management of chorionic pain.
21	YES agree with this
22	NO Please ignore. Outwith my area of expertise but had to enter an answer



Depot buprenorphine should not be used in conjunction with other opioid analgesics (eg morphine, fentanyl, codeine) in chronic pain management given its 'blockade' effect.

Of 22 respondents:

- 4 strongly agreed;
- 5 agreed;
- 8 neither agreed nor disagreed;
- 5 disagreed;
- 0 strongly disagreed.

Nine out of 22 (40.9%) respondents agreed or strongly agreed with this statement, so consensus has NOT been reached.

Respondent	Response and comments
1	DISAGREE change wording to may wish to consider instead of should not be used/may not be as effective if used in
2	NEITHER AGREE NOR DISAGREE as a non-medic I do not feel qualified to make a judgement.
3	AGREE Appropriate statement.
4	STRONGLY AGREE No changed needed
5	STRONGLY AGREE Agree with wording
6	AGREE Higher doses would be required for these opioids to achieve a painkilling effect. This increases the likelihood of overdose. These medications should only be prescribed for these patients in exceptional circumstances, where patients can be continually monitored and signs of overdose reversed in a safe environment (ie in hospital).
7	NEITHER AGREE NOR DISAGREE High mu-receptor affinity opioids may be used to overcome the blockade. However, this is used for acute pain and likely in a hospital setting. Suggest adding "in chronic pain management given high doses required to overcome its "blockade" effect and risk of overdose" or remove "given its blockade effect"
8	DISAGREE It can be used in conjunction with other opioid analgesics but it means a higher amount of the other drug would need to be given to flood the receptors.
9	AGREE Can't find any literature to support the use of opiates in addition to buprenorphine for this reason although I have seen this happen in practice.
10	NEITHER AGREE NOR DISAGREE Unless there are other reasons which aid the individual



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11	DISAGREE can be used if necessary with the appropriate cautions. The SPC make specific reference to the use of fentanyl as an opioid with high mu receptor affinity, for patients using Buvidal
12	STRONGLY AGREE The need for increased doses increases the risk of respiratory depression.
13	AGREE use of opioids in chronic pain management is contentious
14	NEITHER AGREE NOR DISAGREE Probably not a huge issue, however trying to steer away from opioids for chronic pain so probably better to remove opioid analgesic rather than substitute
15	DISAGREE I agree they shouldn't be suggested or used routinely due to blockade. However, it is not an exact science & they might be needed & necessary for a few individuals.
16	STRONGLY AGREE This is not appropriate clinical practice
17	DISAGREE Buprenorphine has a role here but there needs to be careful monitoring of the situation
18	AGREE What would be the purpose of using it with other opioids? they would be have the desired effects for a SU
19	NEITHER AGREE NOR DISAGREE Individual patients' needs/requirements should be taken into consideration
20	NEITHER AGREE NOR DISAGREE This statement fits with best practice, but is very black and white. There are always edge cases. I would suggest - Depot buprenorphine should generally not be used in conjunction with other opioid analgesics (e.g. morphine, fentanyl, codeine) in chronic pain management given its 'blockade' effect. Opioid analgesics may be of limited efficacy in chronic pain. If this were to be considered it should be done with input from prescribers with clear experience and expertise in this area.
21	NEITHER AGREE NOR DISAGREE out with my clinical experience
22	NEITHER AGREE NOR DISAGREE Outwith my area of expertise