


Patient-Reported Outcomes, Experiences and Satisfaction with Weekly and Monthly Injectable Prolonged-Release Buprenorphine

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Introduction: Prolonged-release buprenorphine (PRB), administered by weekly or monthly injection, for opioid dependence (OD) treatment offers the potential to address some limitations of oral therapy including stigma, difficulty in achieving consistent appropriate dosing, risk of diversion of medications, risk of overdose, and continuing use of other drugs. Patient-reported outcomes (PRO) and experiences are important in the evaluation of OD therapy success. This work aimed to document PRO during PRB therapy to guide future treatment decision-making.

Methods: Qualitative interviews were completed with people on PRB OD treatment. Twenty individuals from four treatment services in England and Wales were asked to participate. A structured interview was developed guided by a person with OD lived experience. Interviews were transcribed, coded and analyzed using iterative categorization.

Results: Fifteen of 20 individuals approached agreed to participate, and 14 completed interviews. The average age of participants was 42 (range 33–54) years, 13 males and 1 woman, the history of problematic opioid use was 14 years (3–25 years), time in treatment was 7 years (1–20 years), and duration on treatment with PRB was 4 months (range 1–8 months). Participants reported treatment experiences leading to coding of 277 unique comments: therapy effectiveness (77% indicated a benefit of, or satisfaction with, PRB therapy, 7% neutral/general, 16% indicated concern or questions about PRB therapy), convenience (81% benefit, 7% neutral/general, 12% concern), and overall satisfaction (81% benefit, 3% neutral/general, 16% concern). Reported benefits include cravings reduction of 10 (71%), self-care improvement of 10 (71%), relationships improvement of 9 (64%), resources management of 6 (43%), positive outlook on life of 12 (86%). Participants reported a range of positive personal experiences; challenges reported included temporary injection discomfort at treatment initiation.

Discussion: In this small, focused population, there was generally a positive level of treatment satisfaction with PRB. These experiences provide insights to explain potential treatment benefit to others and are useful in guiding therapy choices for others in the future.

Keywords: opioid dependence, prolonged-release buprenorphine, patient reported outcomes

Introduction

Pharmacotherapy with methadone or buprenorphine, in combination with psychosocial interventions, is an effective and well-evidenced treatment for opioid dependence (OD).^{1–3} However, limitations to such therapy include difficulty in achieving desired, consistent appropriate regular dosing and therapeutic drug plasma levels, potential for diversion of medications, exposure to others including children in the domestic setting

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and associated risk of overdose.^{4,5} Therapy is often delivered with daily supervised dosing according to guidelines⁶ with benefits of decreased diversion and overdose but the process may be seen as a burden^{7,8} associated with stigma⁹ and social control.¹⁰ People with experience of treatment for OD generally reported positive opinions about the injectable prolonged-release treatment option.^{11,12}

Prolonged-release buprenorphine (PRB) is indicated for the treatment of OD and is administered by weekly or monthly injection.^{13,14} Evidence from randomized clinical studies shows superior efficacy of PRB compared to sub-lingual buprenorphine/naloxone and comparable safety profile, with the exception of injection site reactions.^{15,16} Patient-reported outcomes (PRO) are an important element in the evaluation of treatment success for OD.^{8,17} There is little documentation of the patient experience during treatment with PRB since its successful introduction in Europe. Qualitative methods may be used to support service evaluation of the acceptability of new therapy choices. This work aimed to document experiences of people electing treatment with PRB and to help guide relevant treatment decision-making in the future.

Method

Patient experience was captured in structured, qualitative interviews with patients with a history of OD, electing for treatment with PRB in services in England and Wales. The interviews followed the same protocol at each site with minor variation according to local treatment service organization. Teams at each treatment center were briefed and issued with a site guide before approaching individuals with a current treatment history of PRB.

A structured interview guide was developed following validated examples¹⁸ and published case studies describing PRB treatment outcomes.¹⁹ The guide provided a detailed description of the interview to ensure consistency during discussions. The initial section of the guide focused on satisfaction with PRB treatment, the second section of the guide focused on recovery status. The process was guided for suitability by a person with lived experience of OD. According to common standards,²⁰ Ethical Approval was not required for this service evaluation style work when assessed by the NHS Research Ethics Committee tool.

Patients attending treatment centers were invited to participate by their healthcare team. Written information about the interview was provided to all considering participation. Informed consent including publication of

anonymized responses was obtained from all participants. Participants were offered a small value food voucher for participation. Interviews were completed by telephone, to minimize disruption, led by a person with lived experience of OD.

Evidence from the interviews was anonymized, transcribed, coded and analyzed using iterative categorization. Interview results were transcribed verbatim to the record. A single person familiar with the therapy area coded the results descriptively. Coding was reviewed by another similarly expert person; discrepancies were resolved by consensus. The coding framework comprised deductive codes derived from the discussion guide with inductive codes arising from the data. The coded data were exported to spreadsheets and analyzed inductively using iterative categorization.

Initially, the coded data (satisfaction, recovery themes) were reviewed row by row to inform experience and reported outcomes during treatment with PRB. Thematic data were arranged in sub-themes. Satisfaction theme with sub-themes of overall treatment satisfaction, opinion on treatment effectiveness, opinion on treatment convenience; recovery theme, with sub-themes of drinking and drug use, self-care, relationships, material resources and outlook on life determined inductively.²¹ Data were also coded based on participant-reported sentiment. This thematic organization was used to present the results, using anonymized verbatim quotes and tabulation of the frequency of common responses. Any differences arising before treatment start and after the current period of treatment with PRB were considered and documented in the analytical process.²² The work was supported by funding from the pharmaceutical company producing PRB (Buvidal, Camurus AB).

Results

Four treatment centers in England & Wales planned to offer patients the opportunity to participate in the interviews. Twenty people were invited to participate; fifteen people agreed and finally fourteen completed the interview. The reason cited for not participating was most commonly (4 people) related to time and a wish to focus on recovery journey. Participants were 13 males and 1 female. The average age of participants was 42 (range 33–54) years, the history of problematic opioid use was 14 years (3–25 years), time in treatment was 7 years (1–20 years), duration on treatment with PRB was 4 months

(range 1–8 months), cumulative treatment experience of 49 months.

All participants completed the interview attempting to answer all questions; interview duration was 33 minutes on average. Two hundred and seventy-seven comments related to patient experience were identified in coding. These were grouped into treatment satisfaction theme (204, 74% of comments) and recovery theme (73, 26%). Findings are presented below and illustrated using anonymized verbatim quotations.

Treatment Satisfaction Themes

Overall Satisfaction with Treatment

On review of 61 comments allocated to this sub-theme, 81% indicated a benefit or were positive towards PRB therapy, 3% were neutral or general observations, 16% were concerns or questions about therapy.

All participants reported experiencing positive changes in their life, including “feeling much better now” and “I am very satisfied, I feel like I have a normal life back”. Some claimed the treatment to be “life changing” and expressed a positive attitude “I started looking after myself, it is a good step for me”.

With the exception of one participant, thirteen (93%) reported willingness to continue treatment due to convenience, effectiveness and positive outcomes experience: “I think it is an easier way of receiving treatment, I want to see long term how I feel” and “I will continue for a year. Every three months I see changes, this is why I keep going back [to treatment services]”. Additionally, six (43%) participants mentioned recommending PRB treatment to friends to improve OD management. Comments include “I always tell my mates – if you are ready to sort yourself out then you should hop on” and “I’m over the moon about it – I wish my friends could get it too”.

Two participants expressed concern about coming off the treatment “people get comfortable on the medication and stay on it for years . . . not thinking of when they have to stop it, then they will have to deal with the withdrawal” and “I don’t consider it a long-term option as I will need to detox eventually but given that it is gradual and I am on the lowest dose, I don’t expect it [detoxification] to be too bad.”

Four (29%) participants expressed their view on how “some people” may be more likely to benefit from the medication, often referring to those with a more “stable” approach to treatment and willingness to adhere. “One

thing I have to say, I don’t think it is the best option for everyone, this might be my idea but I think you need to be stable (stable house, income) for it to be effective for you”, “I think it’s easier than other options, I am not sure all could do it - some people are more chaotic”, and “I feel free from OD– I think it is hard for those who live chaotic lives. You have to be in the mindset of wanting to get clean”.

Treatment Effectiveness

All participants considered the treatment effective; 84 comments were inductively allocated to this sub-theme. Seventy-seven percent (77%) indicated a benefit of, or were positive towards PRB therapy, 7% were neutral, 16% indicated concerns or questions about therapy.

Effectiveness was reported in terms of the ease of remaining engaged with treatment “I don’t think about taking medications anymore, which is the main improvement to my life”, “It is great for me, it is consistent throughout the whole month so I don’t think about it”. Further, three (21%) participants commented on the benefit of not having to administer treatment on a daily basis “the main limitation was being mentally dependent to a medication – with the injectable you don’t feel on treatment, it allows you to focus on your day” and “I don’t feel like I wake up and need to take a tablet to get on with my day. It lets you lead a normal life”.

The majority (71%) reported a reduction in cravings, increased clarity of mind and freedom from thinking about opioids and, or having to take medication which is perceived to reinforce or mimic addiction behaviors – “I don’t feel like I crave anymore, it really frees you from having to take something daily – which is good because even the medication can become your fix”. Additionally, five (36%) highlighted how being aware of the lack of possibility to use other opioids eases cravings “It’s in your system always, you stop thinking about it because you know you can’t get high”.

All participants reported that treatment with PRB provided a sense of treatment stability. Additionally, three (21%) participants highlighted how the injectable option provides a sense of constant release of buprenorphine and therefore eases concerns of withdrawal “you know you are not dependable on the medication to get by on a daily basis - I feel safe” and “I have the freedom of leading a life without having to think about withdrawals”.

Most participants (71%) reported perceiving effectiveness within the first week of initiating treatment,

six (43%) participants reported effectiveness after the first injection “physically it worked immediately, even the first day I could already feel stable”. Three participants (21%) reported having to mentally adjust to the change “It took longer to adjust mentally – but given that I didn’t crave heroin, it slowly sunk in”, one reported perceiving full efficacy with the second monthly PRB injection.

Four (29%) participants reported some unwanted effects while on PRB such as grinding teeth during sleep, disturbance to their ability to sleep, constipation, or dehydration. Overall, patients reported that coping with such effects is preferred to not being on this type of treatment “I grind teeth at night – when you first take the injection, the first couple nights it’s hard to sleep. Nothing in comparison to heroin”, “. . . I get constipated from taking it and maybe a bit sleepy”, “It does keep me up at night on Friday when I go get it but [I feel] much better. I feel hungry again, I eat and exercise”, and “The only downsides, as of all opioids, it’s constipation and dehydration such as dry eyes . . . but then you learn how to cope with those after the first month”. However, another four participants (29%) reported improvement in sleeping since the beginning of treatment. In the management of cravings, one patient reported being on a “very low dose” and therefore being able to use additional opioids, no other participant reported such possibility.

When asked about effectiveness since the beginning of treatment, three (21%) participants reported not feeling well in the first few days although stabilizing or feeling an improvement after adapting to the new treatment. “I feel more stable, I didn’t feel too good on the first day but it might have been psychological. The transition was easy. I had some issues sleeping the first night” and “The swap was hard because you feel like you are not taking anything – and you are just waiting for withdrawals to kick in – but you get used to it eventually” or “The first week was not pleasant – I thought I would need to switch to something else. From the second week onwards I felt much better, I feel stable now.”

Treatment Convenience

For treatment convenience, all participants reported ease of planning and attending clinic appointments for treatment administration, 59 comments under this sub-theme, 81% indicated a benefit of, or were positive towards PRB therapy, 7% neutral, 12% raised concerns or questions.

It is reported in the comments of participants that PRB offers an easier treatment routine with a lower risk of missing appointments and removes responsibilities of forgetting to take medications daily, including when travelling. One participant reported how the injection may reduce people from seeking alternative sources of opioids when travelling to manage OD - “People sometimes want to go away for the weekend and they need more [medication] than what they can get. This is when you start to buy more, from illegal suppliers”. Two participants on the weekly plan reported wanting to switch to the monthly PRB to experience further convenience. It is also reported that monthly appointments cause less disruption to personal routines, including work and family “you just need to take off a day of work per month, or half a day, to attend the appointment”. A participant also identified improved job security and less stigma as they would not have to “justify” absence from work to attend medication pick-up. Another reported medication delivery to be more accommodating to their lifestyle, with fewer restrictions and commitments. One participant explained how treatment is effective as it is suitable to his family life “It is life-changing, especially for someone who has a wife and kids – it really improves the way you manage”.

Phone-notification systems to alert service users of their upcoming appointments for PRB administration were positively perceived by participants, “the clinic sends you reminders, you just need to show up to the appointment” and “I have it in my phone, it rings the day before”. One participant reported the benefit of reduced attendance with services and exposure to other users who previously negatively influenced adherence, they reported - “It’s easy to attend, plus you only see the people [other service users] once a month. It was my problem before, how I would go back to using when I met others”.

For administration, a subcutaneous injection is preferred by eleven (79%) participants to options such as oral buprenorphine: “It is an injection so there is no need to take anything orally – which feels like you are medicating yourself” or administration is “very convenient, takes minutes”. One participant highlighted how it is a safer option within house settings “With pills – you need to plan and think to bring them – plus you can’t have a morphine pill around, it puts the kids in danger”. Another participant reported how the injection may facilitate treatment for those who are homeless: “When I was homeless – the pharmacy was only open half a day in the

morning – it's hard for someone who is sleeping in the streets to be up at that time. You stay up all night and when you fall asleep, you will not wake up after 2 hours to go get your script. So, I would miss a lot of appointments and when I did, they would take the methadone away from me.”

Half (7) of the participants reported a perceived benefit from attending appointments “I speak with a key worker twice a month, but that is more to ensure that I am ok” and, or being able to seek other types of interventions, e.g. psychological support “It allows me to go to psychological therapy sessions – this really has helped me, I think the combination of the two is what works for me”.

A patient reported wanting to perform the injection themselves to further minimize travel “It would be better if I could just do the injection myself, there is no difference in my motivation, if I do it myself or if I go to the clinic – but it would save me the trip.” It is noted that the product is not approved for self-administration.

Three participants (21%) reported minor discomfort from the injection such as a sense of burn or light bruising, which do not seem to impact their treatment preference “I don't mind its injection, the needle burns – but after 30 seconds it's fine. It really doesn't bother me . . .” or “Once a week, they change the location of the injection – it could be your shoulder, or your buttocks or your stomach – the latest one gave me a bruise”.

Recovery Theme

All participants reported progress towards recovery following PRB therapy. For 12 of 14 (86%), this was across more than 1 identified sub-theme. Two (14%) reported only improvement in one sub-theme – outlook on life. Reported outcomes for recovery theme are summarized by sub-theme.

Drinking and Drug Use

Majority of participants (57%) reported improvement in drug and alcohol use behavior, including “use-on-top”. “I used to always use on top – now I feel clean”, “You can't get high even if you wanted, which is a very good thing”. The lack of ability to use other additional illicit opioids during treatment is reported as a positive aspect by participants, 10 (71%) reported not experiencing cravings while on treatment.

Self-Care

Self-care improvement was reported by ten (71%) participants since beginning treatment with PRB. Many reported increased motivation to look after their health by engaging in physical activity or being able to gain weight in a healthy manner and improved sleep. “I started cycling and I've taken up yoga”, “I started going to the gym again – I used to go when I was in prison – I lost interest when I was on the tablets, I feel motivated again”. Others reported improvement in mental health “Mental health is the most important for me, I started to see a therapist”.

Relationships

Participants reported facing limitations when on previous treatment options due to factors including low mobility, low self-worth or concern about withdrawals, which negatively impacted sustaining relationships. Improvement is reported by nine (64%) participants in relationship status with family, friends and others. Examples of positive changes include working on family/friends engagements “I have a sense of control over treatment which I previously lacked – this allows me to focus on other things such as working/family”, decrease of concern of withdrawals “My marriage has improved, and I have the freedom of leading a life without having to think about withdrawals” and ability to travel “I now can go visit my mum, she can see I have improved”.

Material Resources

Participants commented on their material resources habits in relation to stable housing, regular income, and managing money. Improvement is reported by six (43%), with those noting an improvement in the ability to work or sustain other activities such as studying “It helped with my work massively, I had a few jobs, but treatment always got in the way because of the pick-up. This is really the biggest change”. For one of the participants, starting PRB made it possible to return to work: “I stopped working when I was on buprenorphine [sublingual] – I couldn't do it. I now work again – I work in a recycling business”.

Outlook on Life

Participants were asked about their outlook on life compared to before use of PRB, thinking about their quality of life, feeling positive, and having realistic hopes and goals. An improvement is reported by twelve (86%) who

expressed a sense of motivation and general improvement in wellbeing with a positive forward-looking attitude “I want to change to the monthly option and get on with my life”, “It is the first time I feel normal in a very long time – I don’t even know who I was before but it is a new start”. One participant reported ceasing sex work, “working the streets”, following PRB initiation.

Discussion

Treatment for OD with pharmacotherapy is effective but current oral and sublingual options have important limitations including those related to the process and organization of care delivery. Many with OD face considerable continuing health disadvantage and low social equity; access to innovative healthcare options for this population is often limited or delayed.²³

Treatment with weekly or monthly injections of PRB represents an increase in the options for people seeking treatment for OD. The experience of those treated with PRB is an important part of the formative evaluation of its introduction. There is an increasing cumulative set of data describing the treatment experience for people electing PRB treatment for opioid dependence.²⁴ Providing lay knowledge, alongside the standard biomedical evidence of treatment acceptability, is important and requested by people managing OD.²⁵

Participants reported positive recovery outcomes including improved drinking and drug use, self-care, relationships, material resources and outlook on life. This might be considered consistent with expected outcomes for high quality or optimal therapy with buprenorphine (at the correct dose, for the correct duration). In this small, focused population, there was a positive level of treatment satisfaction with PRB, overall and specifically with respect to treatment effectiveness and convenience. Patients welcomed the flexibility and choice of weekly or monthly administration and reported improved ease in adhering to treatment regimens. However, some challenges to therapy were reported, focused on temporary injected site discomfort and sensations felt during the initial treatment period. Questions about long-term outcomes or recovery, and pathway forward following the end of pharmacotherapy were raised. Ensuring readiness for management of the full recovery journey beyond initial therapy is important. While the overall experience was positive it will be important to ensure that for all starting PRB, there is sufficient support to navigate such challenges, often experienced early in the PRB treatment experience.

Outcomes reported by the participants indicate the potential to bridge to a healthier lifestyle, including working and maintaining relationships. These outcomes are likely linked also to the removal of treatment system-based limitations of oral methadone or sublingual buprenorphine, such as the requirement for attendance for medication collection or supervised consumption. Concerns about change in structure, routine and access to psychological support are not evident in these reported experiences.

Limitations

The analyses presented are from a set of fourteen qualitative interviews conducted in four treatment centers in England & Wales. The work is limited as any qualitative evaluation with small size and consequent limited generalizability. The work provides foundations for future in depth qualitative interviewing. There are likely subgroups within the population receiving PRB, for example, in preference for weekly or monthly injections. This work cannot reveal those variations. Further evaluation may determine insights related to sex, age, race, education, recovery status. Additionally, discussions focused on only two PRB treatment experience themes, recovery and satisfaction with treatment. As not all invited chose to participate, there may be an inherent limitation in the interviewed population.

Conclusion

Understanding the reported outcomes of people electing for treatment with PRB is an important part of the evaluation of OD treatment delivery. This is particularly relevant as some with OD face significant social inequity and may find it hard to access innovative options in healthcare. This set of insights provides a useful basis of support for people considering PRB as a treatment option, and to assist clinicians in their approach to discussing potential PRB therapy to help guide most appropriate choices.

Disclosure

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