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Self-administered dosing of opioid agonist treatment: a qualitative study during the COVID-19 pandemic

Suggested running head: self-administered opioid agonist treatment

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ABSTRACT

OBJECTIVES: During the COVID-19 pandemic, addiction treatment services received official guidance asking them to limit face-to-face contact with patients and to prescribe opioid agonist treatment (OAT) medication flexibly. With the aim for most patients to receive take-home supplies for self-administration rather than attendance for observed daily dosing.

DESIGN: This was a theory-driven, clinically applied qualitative study, with data for thematic analysis collected by semi-structured, audio-recorded, telephone interview.

PARTICIPANTS: Twenty-seven adults (aged ≥18 years) enrolled in sublingual (tablet) buprenorphine and oral (liquid) methadone OAT.

SETTING: Community addictions centre in the London Borough of Lambeth operated by South London and Maudsley NHS Trust.

RESULTS: Four major themes were identified: (1) dissatisfaction and perceived stigma with OAT medication dispensing arrangements before the pandemic; (2) Positive adaptations in response to COVID-19 by pharmacy and centre staff; (3) self-administration of medication reflects a sense of trust and autonomy in the patient and improves effectiveness; (4) positive experience of receiving medication supplies for self-administration. Participants recommended that, according to preference and evidence of adherence, OAT should be a personalised to offer increasing medication supplies for self-administration from as early as seven days after commencement of maintenance prescribing.

CONCLUSIONS: In an applied qualitative study of patients enrolled in OAT during the COVID-19 pandemic, participants endorsed their opportunity to take medication themselves at home and virtual addiction support. Most patients described a preference for self-administration with increased dispensing supplies, from as early as one week into maintenance treatment, if they could demonstrate adherence to their prescription .

STRENGTHS AND LIMITATIONS

- Empathic patient-centred study of experience of opioid agonist intervention and clinical services
- Theory-driven, thematic approach to data analysis.

- This was an opportunistic study commenced with haste and limited patient involvement in the design of the study.
- Data was gathered during COVID-19 pandemic and thus the study's findings need to be considered with caution when generalised to contexts outside of the pandemic.

INTRODUCTION

Opioid use disorder (OUD) [1] is a chronic and debilitating disorder associated with a substantial global burden of disease [2]. England has a longstanding epidemic (largely from heroin), with 141,000 people starting treatment in specialist treatment centres operated by the National Health Service (NHS) and the non-governmental sector during April 2019–March 2020 [3].

Standard care treatment for OUD is either oral (liquid) methadone (MET) or sublingual (tablet) buprenorphine (BUP; or the combination of BUP and naloxone [4:1 ratio]) maintenance therapy with case management and general counselling. Time spent in opioid agonist treatment (OAT) is associated with reduced non-medical opioid use and longer periods of abstinence [4,5] and an attenuated risk of fatal opioid overdose [6,7]. However, overall retention in treatment is not optimal and many patients do not achieve desired outcomes [8]. In England, the largest representative study of patients enrolled in OAT for 12-26 weeks (n=12,745), found 64% used heroin on 10 of the past 28 days at medical review [9].

In the United Kingdom (UK), OAT standard care involves screening with progressive dose induction-stabilisation to achieve a stable maintenance dose. From admission, the patient attends a community retail pharmacy for observed daily dosing [10]. After several weeks, the prescription for adherent patients is progressively adjusted to enable increasing take-home supplies (up to 14-days) for self-administration. Self-administered dosing is favoured by patients and is supported by prescribers [11]. Some patients consider daily observed dosing to be stigmatising and this can motivate the decision to leave treatment [12].

During maintenance, if the pharmacist reports that the patient has not attended as required, further prescribing is curtailed, and if three days are missed, treatment is re-started to reduce their risk of fatal overdose. This requires reassessment with the addiction service of their OUD. If no reassessment is completed, the patient is out of treatment and their OAT prescription stops until re-engagement into the service occurs. This practice has been supported because of evidence that some patients struggle to adhere to OAT regimen [13], and due to public safety concerns that take-home medication may be given or sold to other people, risking opioid poisoning [14].

In March 2020, in response to the UK government's public health and social distancing measures to control the spread of COVID-19 infection, many retail pharmacies were operating reduced opening hours or were closed. On 15 April 2020, the Department of Health and Social Care issued guidance asking addiction treatment services to reduce patient contact where it was judged safe to do so. Services were to offer care remotely to reduce the risk of infection among patients, staff, and the public; and to prescribe OAT medication flexibly with the aim for most patients to receive take-home supplies for self-administration and be closely monitored [15]. In response to the progression of the pandemic, this guidance was withdrawn on 19 July 2021.

This was an unprecedented and time-bound change to the delivery of OAT and afforded a unique opportunity to investigate how patients viewed these measures and responded to them. A focused qualitative service-evaluation was the optimal study design, to ensure patients' views on their treatment experience could be gathered. This design was pragmatic with data collected remotely via telephone or video call. Philosophically, we took an interpretivist stance for the study contending that while there is an objective reality, individuals experience and interpret their experiences in different ways, but this can be understood through empathic interaction.

Our aim to investigate how patients: (1) experienced their service from the treatment centre and their OAT prescription; and (2) believed OAT could be improved.

METHODS

Design, setting and participants

This was a theory-driven, clinically applied qualitative study in response to the implementation of COVID-19 public health measures (in April 2020) impacting on OAT service delivery.

Study data was collected by semi-structured interview and was analysed using deductive and inductive methodologies. Deductively, we expected that study participants' perceptions and behaviours relating to medication adherence – specifically in relation to the instruction to take medication at home as directed – would coalesce around themes deduced from the Necessity-Concerns Framework (NCF). This theory predicts that a medication for a chronic disease will be taken when the patient's beliefs (implicit and explicit) about the necessity of medication exceed any perceived barriers or concerns they have, such as treatment emergent adverse effects [16]. Inductively, we considered that there might be views that did not align with the NCF, so our findings might contribute to advancing knowledge of medication adherence in this population.

The setting was a community addictions centre in the London Borough of Lambeth operated by South London and Maudsley NHS Trust. The study protocol was reviewed and approved by the Chair of the Trust's Addictions Clinical Academic Group (SEP/EF/4/2020). Eligible participants

were adults (18 years and over) enrolled in ongoing OAT at the point where observed dosing was suspended (existing OAT episode) and those who commenced treatment after implementation of the pandemic restrictions (new OAT episode). Participation was voluntary with written consent.

Data collection and procedure

A semi-structured interview schedule was developed with the following topics: perceptions OAT treatment and changes in contact with the service; experience of attending the pharmacy for dispensing of medication for self-administration; and discussion about ways OAT treatment could be improved. Staff at the centre were informed about the study and approached patients already enrolled on OAT or were on a new treatment OAT episode, about their interest in taking part. The research team confirmed eligibility for those identified via the electronic patient record. In accordance with the local information governance policy – personal-demographic information (gender, age, ethnicity) and a brief description of the participant's dispensing regimen was recorded and stored on a password-protected file accessible only to the research team.

All one-off interviewers were conducted between 27 April and 30 June 2020 by authors G.S. (Clinical Psychologist) and S.T. (Assistant Psychologist) via telephone and – subject to additional consent – were audio recorded by QuickTime (version 7.7.9). Notes were taken during all interviews.

Patient and participant involvement

There was no patient or participant involvement due to the opportunistic nature of this project.

Data management and analysis

Data were analysed by G.S. and S.T. following principles of thematic analysis [17] following a sequential and iterative process of categorisation [18], with the following steps:

(1) *Familiarisation* — each audio file was listened to several times, then transcribed verbatim, along with studying of notes to generate a preliminary code list with brief labelling of each topic and flagging of topics that recurred;

(2) *Indexing* – the data was imported into Nvivo (version 12) and each interviewer 'open coded' a sample of six transcriptions to develop a preliminary coding framework. The NCF was applied to the data using numerical code each with a brief description to produce a working then final coding framework; and

(3) *Interpreting major and minor themes* – through consensus discussion and referencing the NCF topics were synthesised into major and sub-themes to indicate consensus among participants and

any contrary views and behaviours, and thematic saturation reached. Uncoded data (containing residual information) was free-coded, inductively.

Results were organised and presented by major and minor themes, with anonymised verbatim quotations to illustrate. Participant quotations were labelled with participant (P) number, gender (M/F) and OAT group (existing/new OAT episode).

RESULTS

Participants

Thirty-five patients expressed interest, however 8 were not contactable. Therefore, 27 patients consented to participate. Two participants declined audio recording but were content for the interviewer's notes to be used for the analysis. The characteristics of the sample are shown in **Table 1**. Most (81.5%) were existing OAT episodes at the time of the guidelines on dispensing, and almost all were subject to new procedure of take-home supplies for self-administration. At the time of interview, no participant reported being advised to socially isolate.

The 27 transcripts yielded 25 unique codes relating to study aims. These codes were organised into the four overarching themes: (1) Negative views of OAT dispensing policy before the April 2020 changes; (2) Positive adaptations in response to COVID-19 by pharmacy and centre staff; (3) Self-administered dosing reflects trust in the patient and is beneficial; (4) OAT should be more personalised according to adherence. Quotations (italics) illustrate these themes below.

Theme 1: Negative views of OAT dispensing policy before the April 2020 changes

Twenty-two participants (81.5%) reported concerns about the way OAT medication had been dispensed before April 2020. There were complaints about the daily attendance requirement; the view that some pharmacies had restricted opening times (which did not suit those in employment); complaints about lengthy wait times to receive dosing; and a sense of embarrassment and perceived stigma by some members of the pharmacy team and customers.

The abrupt cessation of pharmacy supervised dosing was regarded as a good response to maintain provision of treatment during the COVID-19 pandemic. There were also positive comments about the pharmacy service – including staying open despite disruption caused by COVID-19.

Three participants reflected on their experience of attending their local community retail pharmacy before the change to self-administered dosing:

The good thing is I don't have to keep going to the chemist which is a pain, a real pain… normally dealing with my chemist, is unreliable…like they keep changing the pharmacist so you have to go through all the rigmarole of it being controlled and that, proving who you are and where you live and stuff. **(P10/M/existing OAT episode)**

I mean it was a hassle having to go every day and also it's a little bit, embarrassing. **(P6/M/existing OAT episode)**

I can't afford to come every day and I fell off so many times just because there's always something to do or I have work so I took the opportunity to come back. I have a weekly pick up. Actually if I'm honest I had a weekly pick up at that time as well. But it was straight before the weekend and then I didn't go Saturday and Sunday they were closed, and Monday I was too late already. **(P8/F/new OAT episode)**

Theme 2: Positive adaptations in response to COVID-19 by pharmacy and centre staff

There was appreciation that services, including pharmacies had stayed open during the pandemic restrictions, and a consensus that the staff were professional, compassionate, and responsive to individuals' needs.

…I'm getting support that way and I'm getting the medication which is vital and I'm really grateful to yourselves and the chemist for operating and staying open and taking measures to allow me to, and other addicts to get their medication because I was really stressed about that, when things were starting to get worse with coronavirus and I was hoping, I was afraid, that it would affect my supply of methadone so the fact that it's still coming through and I get it every day is a huge relief and I'm super grateful for allowing that to happen. **(P6/M/existing OAT episode)**

…So I pay for my prescriptions because I work and where I was running out of money I couldn't pay for my prescriptions. I had a chat with the guy at the chemist and he let me owe him it and pay him this week. Thursday, I get paid. I said to him "I get paid Thursday, I can bring it in Friday, but it was a bank holiday. He said to me, no that's ok. Bring it in the next time you come in. **(P7/M/existing OAT episode)**

The centre continuing treatment under remote care arrangements was appreciated by patients, there were minimal concerns expressed about the shift from face-to-face to telephone or video contact with staff. Two judged that:

No, face-to-face and the phone is the same. I don't have nothing to hide. It's a treatment I'm doing – and you can talk everything over the phone. You can talk on the phone, or face to face [it] *is the same.* **(P28/M/existing OAT episode)**

I don't mind it, it's pretty much the same. I'm always there, like whenever they've got an appointment I'm always there. But over the phone I do find it quite better…so I don't have to go out my way to go there. If I have something to do, maybe my mum wants me to do something that day, I've always had to go around the appointments. **(P35/M/existing OAT episode)**

Another reported:

Well...the travelling and stuff, not having to go out all the time [is a benefit]. *Some days where I can't get the bus* [due to anxiety]… *yeh its ok, I don't mind. You can't see me here welling up, so I prefer that.* **(P015/F/existing OAT episode)**

Another was satisfied on the way the service had adapted to the abrupt cessation of patient visits:

...Sometimes I suffer from abscesses due to injecting. So, I spoke to my doctor two days ago about one on my leg and I couldn't get a face-to-face appointment, so we did a video call, and I had to show her the leg…it is ok because she saw it. **(P11/M/existing OAT episode)**

However, some raised concerns that the lack of physical access to the centre served to accentuate social isolation and this was especially so among those with limited access to needed technology.

Yeh it's ok, I don't mind...I don't mind, I like calling now. But it's good to go out and get out...Yeh, I like going out and being out. I don't like being stuck in my room. I hate it, stuck in a room and feel a bit mad. **(P015/F/existing OAT episode)**

It's alright still but having it over the phone it not the same as when you are speaking to somebody. When you are in front of somebody you can tell them, you can tell their body language and whatever and what not...Yes, I would still like to have face to face. There is a lot more I can get from face-to-face interactions going to [service name]*.* **(P21/M/existing OAT episode)**

Theme 3: Self-administered dosing reflects trust in the patient and is beneficial

There were mixed reflections on changes to service delivery, some were worried that OAT provision would be stopped; others welcomed the promise of infrequent pharmacy attendance. One service-user reported that staying at home more, partly due to having a reduced collection regime meant there was less temptation to use illicit substances. The reduction in pharmacy attendance inadvertently addressed accessibility barriers for a number of those interviewed, with

one patient not needing to miss paid work to attend the pharmacy for medication collection and another that it enabled them to take medication at a time that suited night work.

Yeah, it's been a lot easier, what with my health being the way it is, it's a struggle getting to the chemist every day...I think it shows trust [to the service-users from the service]*...saves me having to walk to the chemist in agony every time, and now I only have to go once a week.* **(P27/M/existing OAT episode)**

Actually [the pandemic restrictions] *have been really helpful because sometimes before when I was trying to go* [to the pharmacy] *every day…I would sometimes use illicitly whereas now I stay at home. I haven't got that temptation.* **(P18/M/existing OAT episode)**

Just being able to have the weekly pickup you know. It was a godsend not having to worry about not being able to get to the chemist and missing an appointment and things… **(P31/M/existing OAT episode)**

I mean it doesn't bother me, either way but I do want, I am taking it at my own time which I am happy. Because my normal work before the virus I was doing night shifts cleaning. So sleeping all day and I would have to normally wake up to go and going and get my supervision at the pharmacy. Which was a bit messed up in my sleeping pattern. So this way if I could stay off supervision, I would be able to have it late at night, and wouldn't have to wake up and go pharmacy. **(P11/M/existing OAT episode)**

I was working last year and it did help me a lot not to use, so I'm starting to think again about getting back into work, that will be helpful. Some jobs you have to be there at 9, and the pharmacy opens at 9 and if you have to be at work at 9, you won't be able to do it...It just that, sometimes it feels like a very long process you know. **(P33/M/existing OAT episode)**

Views about medication adherence suggested that individual motivations would determine response to take-home supplies. One participant observed:

First day I was supervised because I was higher-ing the dose, but they just give you the pill. You don't take it there. So in this kind of case, it doesn't really matter from this perspective because the person that will want to sell it will just sell it every day, or once a week. It will not make any change for you guys, or for the market of drugs. **(P8/F/new OAT episode)**

A minority of participants – all having been assessed at risk of overdose or medication diversion – had been retained on daily observed maintenance dosing. They all expressed frustration about this.

I just think that one thing that gets to me is that people who are on the supervised, they look at it as, kind of, they feel like it's a punishment if you know what I mean. When some of them are quite stable and yet they, ok they might be doing other things and that, but after 10 or 12 years of it, it's like..., of course there's a minority who are completely, uncontrollable, but just because of those people, everybody suffers. **(P10/M/existing OAT episode)**

Theme 4: OAT should be more personalised according to adherence

Participants reflections on the future of the service as one based on a more personalised approach to balance supervised and self-administered dosing. One participant with previous experience of OAT, but newly admitted for a new episode, offered the following considered perspective:

I would say that from the beginning for people that are first time coming, definitely face-to-face. Later on, depends on the people, if you're working, if you have a full-time job and you have other obligations…I'm putting the service-users into two groups. One group would [visit the service] *just to have safety, and they're normally doing whatever they were doing before. And [then there are] service-users that take* [their] *medication. So, the second group, definitely it's better to do the phone, I would say, because you're already integrating back into society. You have work, you have friends, you have sport, you have other stuff that you are doing. Meanwhile the first group, I don't know. Half of them don't even have a phone, half the time the phone doesn't work, half the time they're running to score. It's not hard to learn who's taking something and who's not...I think it's going way too much by the template. Yeah, definitely think it should be more individual especially for the second group when they see that you are completely clean and that you are really taking only* [OAT medication]. **(P8/F/new OAT episode)**

Another participant reflected:

It's almost like before there's a punishment aspect to it that you've got yourself into this trouble and you know, and it's all the running around and being treated like a child...I just hope this is something that can go forward with the treatment and the present set up. Because it would be funny if in, I don't know, 3 months, 6 months-time if there's been no problems and you go backwards, it would seem like a strange move...Yeah, it means I could go and visit family in another country and take my script with me and, yeah, it would make me more free, which is good. Not tied down to going to the chemist every day. **(P18/M/current OAT episode)**

DISCUSSION

Against a background of several aspects of dissatisfaction with pre-pandemic OAT dispensing (daily pharmacy attendance, pharmacy opening times and waiting times for service, and perceive stigma), participants reported several positive aspects of the abrupt changes in response to the pandemic. Including an appreciation that pharmacies stayed open, the teams were perceived as caring to individual needs, and a ready adaptation to remote contact with the treatment centre. Longer dispensing intervals and self-administered dosing was regarded as conveying trust in the patient, and also gave freedom for work and engagement in other activities. There were few reports that medication was not taken as directed, and in-line with the NCF there was a consensus that OAT medication was valued and provided important benefits.

Our study suggests that the NCF is applicable to OAT medication adherence phenomena. Most patients described continued adherence to the OAT medication, despite considerable changes to their medication delivery or entered into treatment to access OAT medication. Typically, patients described their OAT as vital and reactive anxiety regarding accessing their medication when the COVID-19 pandemic occurred. Together, these reports reflect a sense of necessity for OAT medication and that this outweighs concerns about taking medication and stress associated with contracting COVID-19 virus when accessing treatment.

This study also offers novel insight into the many practical and environmental barriers to being treatment adherent for OUD. These barriers included the cost of attending, attendance to the service risked drug relapse due to environmental cues and detrimental implications on employment. These findings directly speak to Horne and colleagues' call for further investigation into whether practical barriers to care have a greater impact on some population's seeking medications [19]. These results indicate that while medication adherence is particularly nuanced within this clinical population many are impacted by practical barriers. Additionally, COVID-19 triggered changes to medication collection and in turn mitigated these barriers and ought to be maintained in a post covid service delivery. Overall highlighting the need for a personalised approach and questioning the effectiveness of previous rigid treatment protocols for OUD.

The guidelines in which clinicians within addiction services follow, have largely been in response to public health concerns. As a consequence, the application of blanket policy's individuals need to meet in accessing treatment has been the tradition. The results from this study, utilising a person-centred model (NCF) to addiction treatment, calls into question the value of the standard daily dose dispensing and supervised consumption protocol. Here, patients reported benefit from longer dosing pick up and virtual support, by allowing them to feel trusted, engage in out of treatment activities, including employment.

It was notable that patients did not report concerns about OAT side effects or their implications on adherence. A common concern reported within other illnesses that determine medication

adherence. It could be hypothesised that for many individuals within the study perceived OAT as a welcome relief for the aversive symptoms of opiate withdrawal and necessity significantly outweighs concerns [20]. Alternatively, such results could be a consequence of the study design- patients were enrolled or imminently about to be enrolled in OAT, thus medication seeking. Additionally, these responses could be explained by the semi-structured nature of the interview schedule, which did not explicitly enquire about side-effects of medication given the focus was on changes to medication collection in the context of COVID-19.

We recognise that this was a relatively small-scale study and there are several limitations. Firstly, it was beyond the scope of this study to investigate the applicability of the NCF on general OAT adherence within the OUD population outside of a pandemic context. Therefore, additional research ought to investigate the NCF applicability to OAT adherence beyond the pandemic context. Additionally, this was a purposive and self-selecting sample, with potential for response bias. The views of our participants reflect a relatively small sample of patients enrolled in OAT in one London borough and they are not representative of views of patients elsewhere, or to treatment systems overseas. Nevertheless, we contend that our sample was broadly representative of our clinical population including a range of patients with prior experience, those embarking on a new treatment episode and also those identified as high risk with continued daily observed dispensing. As an applied qualitative study, fieldwork was done at pace, and further studies are needed to investigate current views of treatment among this clinical population.

Our findings on the benefits of reduced prescription collection, are consistent with published qualitative research conducted at the same time as this study. In indicating that patients living in rural communities also quickly adapted to changing treatment policy [21]. A further benefit to longer-interval prescribing of OAT facilitates the individual to engage in alternative activities, including employment. Study findings also align with a study of prescribing services in two north London boroughs [22], and a global systematic review of 25 studies published in 2020 (mostly in the USA) on the adaptation of OAT and allied services to pandemic restrictions [23]. In this review, the most common innovation was the offer of telephone or online services, and the longer interval prescribing of medication. For the former, there were examples of innovative solutions to help patients with no access to mobile phones (e.g. distribution of free mobile phones to patients by one treatment provider [24], a service building sanitized phone booths outside their centre for private video calls with staff and to receive counselling [25]. For the latter, comparable arrangements with longer interval dispensing was reported in the US [27], Canada [28], Spain [29], and Italy [30]. We do not know if these were short-term arrangements, but there has been discussion of the implications for more flexible arrangements for patients.

Our findings also contribute to an ongoing discussion internationally about the opportunities for more flexible treatment. We propose an individual approach in which patients are supported to evaluate their capacity for medication adherence at an appropriately early point. Current UK clinical guidelines already promote individualised care – but perhaps there is a case to evaluate a faster process of dose increase to achieve a stable/optimal dose for the patient so that the adherent can receive their first 7-day take-home supply as early as is safe to do so. Supervised dispensing of OAT medications exists to ensure compliance with the prescription and to reduce the risk of medication diversion. There is emerging evidence of an increase of methadone related deaths during the first COVID lookdown both in-treatment and amongst people not in treatment [31]. Balancing these risks with patient-centred care remains a central element of delivering specialist treatment for opiate use disorders.

Overall, this qualitative study collected the subjective experiences, perspectives and concerns of patients, who were representative of those seen in community drug treatment settings. In doing so, this study ceased a unique opportunity in our centre to gather patient insights to inform OAT delivery.

Data availability statement

No data are available. Interview transcripts will be deleted after publication of the report.

Ethics statements

Patient consent for publication not required.

Ethics approval

The study protocol was reviewed and approved by the Chair of the Trust's Addictions Clinical Academic Group (SEP/EF/4/2020).

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Competing interests

In the past three years, J.M. declares research grants to King's College London (KCL) from the National Institute for Health Research (NIHR) for a multi-centre trial of acamprosate for alcohol use disorder; the NIHR Biomedical Research Centre for Mental Health at South London and Maudsley

NHS Mental Health Foundation Trust (SLaM) for a pilot trial of cognitive therapy for cocaine use disorder and related studies, and an unrestricted grant from Indivior to KCL from Indivior for a multi-centre trial of extended-release injectable buprenorphine for opioid use disorder. He is a clinical academic consultant for the US National Institute on Drug Abuse, Centre for Clinical Trials Network.

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The other authors have no interests to declare.

Trial registration

The study was not registered.

The original protocol for the study

Attached.

A data sharing statement:

The audio record for this study is not subject to data sharing.

Supplementary and raw data

Not applicable.

Contribution statement

The design was conceived by JM, LM and MK. GS and ST conducted the interviews, transcribed and analysed the data under supervision from JM. GS and JM drafted the initial manuscript, with contributions from LM, ST, WA, AH, KM and MK for subsequent revisions. GS took the final decision to submit the manuscript for publication.

Patient and public involvement

There was no patient or participant involvement due to the opportunistic nature of this project.

Provenance and peer review

Not commissioned, externally peer reviewed.

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Table 1: Participant characteristics (n=27)

Characteristic	**n**
Age, years	47.3 (8.7)
Sex	
Male	22 (81.5)
Female	5 (18.5)
Ethnicity	
White British	14 (51.9)
Black British	4 (14.8)
Other	9 (33.3)
OAT	
Methadone	17 (63.0)
Buprenorphine	10 (37.0)
OAT episode and regimen	
Existing episode – change to self-administered dosing	20 (74.1)
Existing episode – already self-administered dosing	2 (7.1)
New episode – self-administered dosing from induction	5 (18.5)

Note: numbers in parentheses are standard deviation or percentage.

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Lambeth Addictions

Opiate Substitution Treatment – Service Evaluation

PROTOCOL

APRIL 2020

Service evaluation lead investigators:

Mike Kelleher	
Luke Mitcheson	
John Marsden	

NHS South London and Maudsley NHS Foundation Trust

PURPOSE

Against the background of the 2020 COVID-19 pandemic and the changes to prescribing and community pharmacy dispensing practice an instituted at Lambeth Addictions in response to recommendations by DHSC and PHE (https://www.gov.uk/government/publications/covid-19-guidance-for-commissioners-and-providers-of-services-for-people-who-use-drugs-or-alcohol/covid-19-guidance-for-commissioners-and-providers-of-services-for-people-who-use-drugs-or-alcohol), a service evaluation (via brief telephone interview) is needed to estimate the impact on our patients enrolled in and presented for maintenance medication for opioid use disorder (OUD; i.e. oral methadone mixture and tablet buprenorphine; 'treatment' herein).

This evaluation has been evaluated by the Health Research Authority on 16 April 2020 and is not judged to be research in the NHS (**see Appendix I: HRA classification**).

TARGET OF THE EVALUATION

This evaluation targets the opioid service pathway at Lambeth Addictions and the shift to an unsupervised, 14-day prescribing regimen for patients of the service.

We will target four groups of patients and seek their consent to contribute to the evaluation:

1. Those who have been previously enrolled in methadone and buprenorphine treatment but have been out of treatment for 6 months or more;
2. Those who have been in treatment in the past 6 months and have been re-started 3 or more times;
3. Those who have been continuously enrolled in treatment for the past 3 months or more were dispensed under supervision by the community pharmacist on daily/near daily basis;
4. Those who have been maintained on their existing prescription (i.e. not had supervision and dispensing interval relaxed).

The aim will be to collate views of a sample of these patient groups to estimate the impact of changes to their treatment under the government's COVID-19 social distancing and self-isolation public policy to inform opportunities to improve service delivery.

DESIGN AND METHODS

This service evaluation is a qualitative interview study among patients attended treatment-as-usual at Lambeth Addictions. Data will be gathered during a single semi-structured (topic-guided) <15-minute telephone interview by a member of the psychology team. With consent, the interview will be audio recorded and the data will be analysed thematically by the investigators.

Members of the clinical team at Lambeth Addictions will approach all eligible patients and ask if they would be interested in taking part in the service evaluation.

Those expressing an interest will be contacted by telephone and asked for their verbal consent to take part (**see Appendix II: verbal consent procedure**).

Those giving consent will be asked additionally if they would give their consent for the interview to be audio recorded. Audio recording will be optional.

A master list of patients will be kept by Dr Mitcheson and he will assign each patient a unique service evaluation ID number for recording on the topic guide.

Findings from the evaluation will be presented to CAG Management.

MATERIALS AND STORAGE

Notes from each interview will be recorded on a topic guide which state the name of the interviewer, the date/time of the interview, and the participant ID number (**see Appendix III: topic guide**). The patient's name will not be recorded on the topic guide.

All topic guides will be kept securely by the interviewer at their home address until the national social distancing policy restrictions have been lifted. Completed topic guides will be kept in a locked filing cabinet at Lambeth Addictions.

Audio recordings will be recorded via QuickTime with file names saved using the participant's service evaluation ID number and date of interview. Files will be transferred to a secure folder in Microsoft Teams created for the evaluation (convener: Dr Mitcheson).

PROCEDURE AND SAMPLE

We anticipant that an interview sample of ~40 patients (10 in each target group) will be sufficient for the evaluation, but we may extend this sample if required.

QUESTIONS TO BE INCLUDED IN THE SERVICE EVALUATION

The following 'experience' topics are included:

- COVID-19 and ways affected
- Access to medical care for respiratory conditions
- Other physical and mental health needs
- Starting treatment at Lambeth Addictions
- Collecting medication from the pharmacy
- Perceived impact of new prescribing arrangements
- Receipt of naloxone and use
- Feedback on Lambeth Addictions and the serviced can be improved
- Perception of how COVID-19 has changed the local community
- Perception of changes to local drug distribution market
- How the social distancing/isolation policy had impacted on relationships and finances

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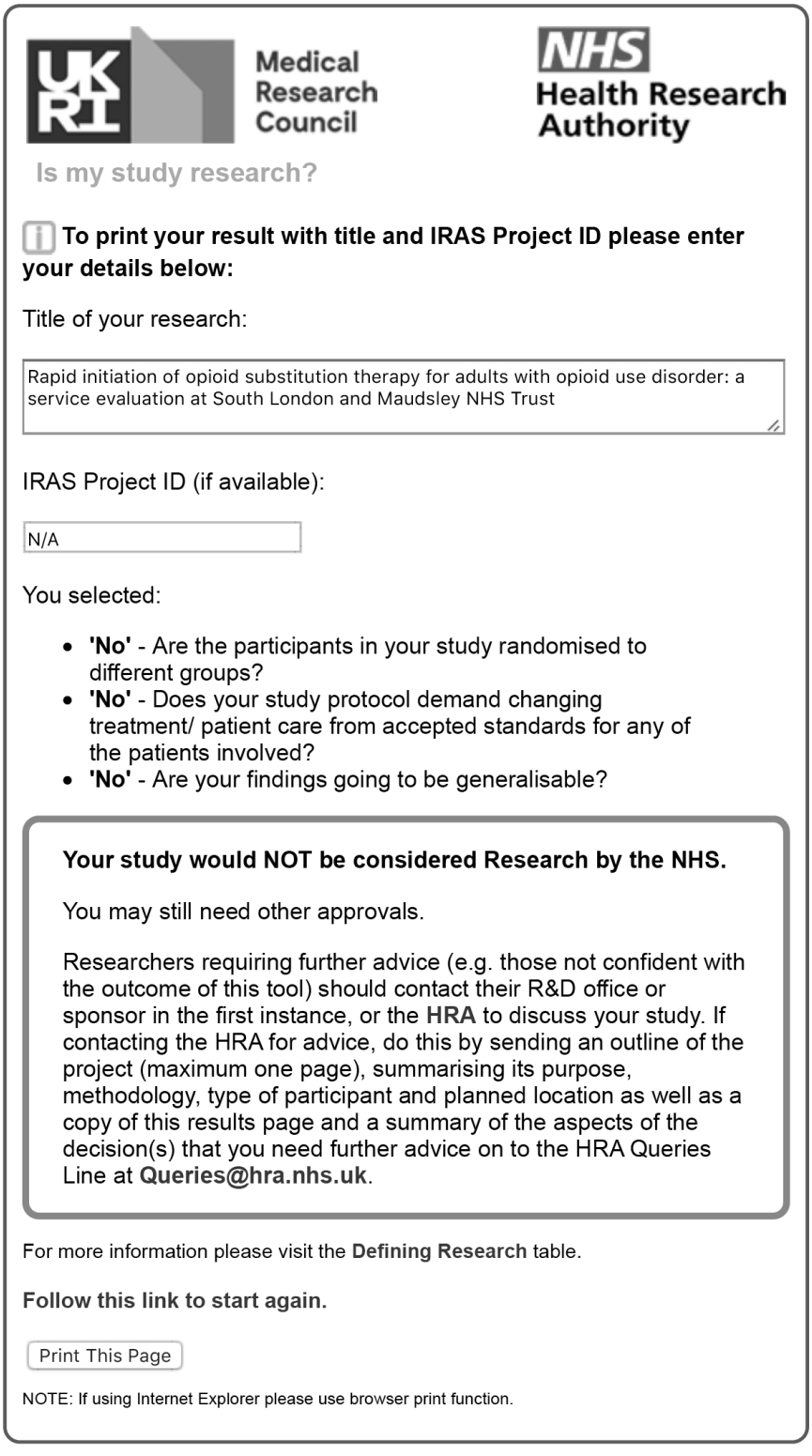
APPENDIX I: HRA CLASSIFICATION



Medical Research Council

NHS Health Research Authority

Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

Rapid initiation of opioid substitution therapy for adults with opioid use disorder: a service evaluation at South London and Maudsley NHS Trust

IRAS Project ID (if available):

N/A

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the **HRA** to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at **Queries@hra.nhs.uk**.

For more information please visit the **Defining Research** table.

Follow this link to start again.

Print This Page

NOTE: If using Internet Explorer please use browser print function.

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APPENDIX II: HRA CLASSIFICATION

VERBAL CONSENT SCRIPT

Hi, my name is [state your name]. I work at Lorraine Hewitt House. I am calling because I understand you are happy to help us evaluate our service and talk to me for a few minutes?

Talking to me today is completely voluntary, of course. Would you be interested?

YES [ ] No [ ]

If yes, continue below.

If no, but the participant is interested in participating, determine time to call back

If no, thank them for their time.

Would it be OK if I record our conversation so I can listen to it and not have to take notes? It will also help us group people's views into themes.

CONSENT FOR AUDIO RECORDING

YES [ ] No [ ]

If No, continue but without recording

Person Obtaining Consent

I have read this form to the participant and they have provided me with oral consent to participate in the following interview.

Name of Participant (CAPS):

Given name: _____

Family name: _____

DATE: _____

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APPENDIX III: TOPIC GUIDE

Lambeth Addictions

Opiate Substitution Treatment – Service Evaluation

Participant ID number for evaluation: _____

NAME OF INTERVIEWER (TEAM MEMBER):

_____

DATE OF INTERVIEW:

TIPS

- Be a listener rather than a talker
- Be empathetic and interested in the conversation
- Go through the information sheet & consent procedures

Before the interview starts:

- Check recording equipment
- Record Participant ID number (no personal identifiable information- name etc), time, date & format of interview (telephone), plus any other notable circumstances
- Introduce self and study to the interviewee
- Go through the information sheet & consent procedures

Ending the interview:

- Check whether the interviewee has anything else they want to add
- Thank the interviewee and turn off the recorder
- Avoid cutting the call short in case the participant wants to talk further
- Once the interview is completely over note any private observations, thoughts & feelings

The below interview topic guide is to be used a reference

INTERVIEW TOPIC GUIDE

Read out:

Thank you for taking the time to talk to me. This chat shouldn't take longer than about 10-15 mins but there is no time limit so feel free to take your time and take as long as you want to speak to me. We are hoping to learn about how people view our prescribing service and how the coronavirus may be affecting treatment.

MAKE SURE YOU ARE RECORDING...

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1. HEALTH

First of all, how are you?	**NOTES – key points**
Prompts: • Have you been sick? • Experienced coronavirus symptoms/tested positive • Have you been affected by the COVID-19 virus/coronavirus? • If you have been unwell, have you needed and been able to access medical care? • How are you feeling mentally? *escalate as per Safeguarding Guidelines if suicidal thoughts.* • Any other concerns that relate specifically to COVID-19/coronavirus? Signpost to UK government advice	

2. ACCESS TO OPIATE SUBSTITUTION TREATMENT (OST)

How has COVID19/ Coronavirus affected your treatment?	**NOTES –**
Prompts: • What opiate medication are you receiving? • When did you start? • Is this your first treatment episode with this service? (Y/N) • When were you last in treatment before now? (over a year ago or not) • Have you had any restarts in the past 3 months (not collecting your medication and having to come her to start again)? How many approx.? • Does the pharmacist supervise you (observe you taking your meds?) • how often are you collecting your prescription from the pharmacy? • How many days supply do you pick up? • Has this supervision / collection regimen changed? How…? • How is this new arrangement affecting you? (good things / not so good things) • Do you inject drugs? • If you inject – have you been able to source clean equipment? How? • Do you have naloxone? • Have you been offered naloxone in the past month?	

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3. VIEWS OF OUR SERVICE

How has Coronavirus/COVID-19 affected our service for you?	**NOTES –**
Prompts: • Could you give us some feedback on our service? • What things did you like? • What things could be better?	

4. LOCAL COMMUNITY

How has Coronavirus/COVID-19 affected the community?	**NOTES –**
Prompts: • How has the Coronavirus affecting the local community? • What's happened to the availability of drugs? • What's happened to price and quality?	

5. OTHER HEALTHCARE NEEDS

Do you have other healthcare needs at the moment?	**NOTES –**

Prompts:
• Other medical conditions, physical or mental health
• Are you getting any health support in person or by phone?
  ○ If so, is that acceptable to you?
  ○ Do you think it is likely to be effective or ineffective?
• Any health concerns or needs that are not being met?
• Any other concerns about health conditions mentioned that relate specifically to COVID-19/coronavirus? Signpost to UK government advice – which advice? lets put link- reference	

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6. Finances

Are you able to take care of your basic needs such as food and shelter?	**NOTES –**
Prompts: • Are you working? – (lost job etc) Yes: What sort of work is this, how many hours a week, what sector? No: Are you receiving benefits? • Use of charitable organisations e.g. foodbanks, housing • Are you able to access your money?	

7. RELATIONSHIPS

How have other people you know been affected?	**NOTES –**
Prompts: • Medical – other cases/deaths within social network • Domestic– *if mention of domestic abuse- escalate as per Safeguarding Guidelines.* • Social- how has Coronavirus affected other people's treatment and recovery? ○ access to treatment services? ○ Do you think it is likely to be effective or ineffective? • Finances- loss of job partners/friends, support- benefits • Use of charitable organisations e.g. foodbanks, housing	

8. Other

Thank you for taking the time to speak to me is there anything else you would like to talk about?	**NOTES –**

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the inter view or focus group?	
Duration	21	What was the duration of the inter views or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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BMJ Open

Patients' perceptions of self-administered dosing to opioid agonist treatment and other changes during the Covid-19 pandemic: a qualitative study.

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Patients' perceptions of self-administered dosing to opioid agonist treatment and other changes during the Covid-19 pandemic: a qualitative study

Suggested running head: self-administered opioid agonist treatment

Gemma Scott 1 §*; Sophie Turner 1*; Natalie Lowry 1,2; Annette Hodge 1; Waniya Ashraf 1; Katie McClean 1; Michael Kelleher 1; Luke Mitcheson 1 **; John Marsden 1,2 **

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Abstract: 283 words

Main text: 6,341

Main body: 1 table

Total pages in manuscript: 21

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KEYWORDS: opioid use disorder; opioid agonist/partial agonist treatment; COVID-19

ABSTRACT

OBJECTIVES: During the COVID-19 pandemic, addiction treatment services received official guidance asking them to limit face-to-face contact with patients and to prescribe opioid agonist treatment (OAT) medication flexibly. With the aim for most patients to receive take-home supplies for self-administration rather than attendance for observed daily dosing.

DESIGN: This was a theory-driven, clinically applied qualitative study, with data for thematic analysis collected by semi-structured, audio-recorded, telephone interviews.

PARTICIPANTS: Twenty-seven adults (aged ≥18 years) enrolled in sublingual (tablet) buprenorphine and oral (liquid) methadone OAT.

SETTING: Community addictions centre in the London Borough of Lambeth operated by South London and Maudsley NHS Trust.

RESULTS: Three major themes were identified: (1) dissatisfaction and perceived stigma with OAT medication dispensing arrangements before the pandemic; (2) Positive adaptations in response to COVID-19 by services. (3) Participants recommended that, according to preference and evidence of adherence, OAT should be personalised to offer increasing medication supplies for self-administration from as early as seven days after commencement of maintenance prescribing.

CONCLUSIONS: In an applied qualitative study of patients enrolled in OAT during the COVID-19 pandemic, participants endorsed their opportunity to take medication themselves at home and with virtual addiction support. Most patients described a preference for self-administration with increased dispensing supplies, from as early as seven days into maintenance treatment, if they could demonstrate adherence to their prescription.

STRENGTHS AND LIMITATIONS

- Empathic patient-centred study of experience of opioid agonist intervention and clinical services
- Theory-driven, thematic approach to data analysis.
- This was an opportunistic study commenced with haste and limited patient involvement in the design of the study.
- Data was gathered during COVID-19 pandemic and thus the study's findings need to be considered with caution when generalised to contexts outside of the pandemic.

INTRODUCTION

Opioid use disorder (OUD) [1] is a chronic and debilitating disorder associated with a substantial global burden of disease [2]. England has a longstanding epidemic of OUD that largely involves heroin. During April 2019–March 2020, 141,000 people starting OUD treatment in specialist treatment centres operated by the National Health Service (NHS) and the non-governmental sector [3].

Standard care treatment for OUD is either oral (liquid) methadone (MET) or sublingual (tablet) buprenorphine (BUP; or the combination of BUP and naloxone [4:1 ratio]) maintenance therapy with case management and general counselling. Time spent in opioid agonist treatment (OAT) is associated with reduced non-medical opioid use and longer periods of abstinence [4,5] and an attenuated risk of fatal opioid overdose [6,7]. Other benefits can include a substantial reduction in the risk of opioid poisoning (overdose), reduced criminal involvement, and improvements in social and occupational functioning [8]. However, adherence and retention in treatment is sub-optimal, and many patients do not achieve their desired outcomes [9]. In England, the largest representative study of patients enrolled in OAT for 12-26 weeks (n=12,745), reported that 64% used heroin on 10 of the past 28 days at medical review [10].

NHS treatment services for OUD are required to adhere to UK national clinical guidelines pertaining to OAT procedures. From admission, the patient attends a community retail pharmacy for observed daily dosing [11]. After several weeks, the prescription for adherent patients is progressively adjusted to enable increasing take-home supplies (up to 14-days) for self-administration. Patients are considered adherent when there is evidence that they are collecting their OAT as directed; urine drug screening indicates medication use and abstinence from illicit opioids. Self-administered dosing is favoured by patients and is supported by prescribers, due to minimising inconveniences of frequent visits and promoting patient agency in their treatment [12]. Some patients consider daily observed dosing to be stigmatising, and this can motivate their decision to discontinue treatment [13].

If the pharmacist reports that the patient has not attended for three consecutive days, the prescription is ceased and the patient must be re-start treatment to reduce their risk of fatal overdose. This practice has been supported because of evidence that some patients struggle to adhere to OAT regimen, risking their safety through illicit use ‘on top’ [14], and due to public safety concerns that take-home medication may be given or sold to other people, risking opioid poisoning [15]. OAT diversion has long been a concern for public safety. Previous research has report a tenge of motives for diversion, including selling medication to fund illicit drug use; an effort to help

others with OUD who have failed to collect their prescription, or those who believe they are not receiving an adequate dose [16].

In March 2020, in response to the UK government's public health and social distancing measures to control the spread of Covid-19 infection, many retail pharmacies were operating at reduced opening hours or were closed. On 15 April 2020, the Department of Health and Social Care issued guidance asking addiction treatment services to reduce patient contact where it was judged safe to do so. Services were to offer care remotely to reduce the risk of infection among patients, staff, and the public; and to prescribe OAT medication flexibly with the aim for most patients to receive take-home supplies for self-administration and be closely monitored [17]. This guidance was withdrawn by the UK government on 19 July 2021.

This was an unprecedented and time-bound change to the delivery of OAT and afforded a unique opportunity for a focused qualitative service-evaluation. This design was pragmatic with data collected remotely via telephone or video call. Philosophically, we took an interpretivist stance for the study contending that while there is an objective reality, individuals experience and interpret their experiences in different ways, but this can be understood through empathic interaction.

Our aim was to investigate how patients with OUD: (1) experienced their addiction treatment from the treatment centre, in particular changes to their OAT prescription regimes and delivery in response to Covid-19 related service adaptations; and (2) how they believed OAT treatment delivery could be improved in the future.

METHODS

Design, setting and participants

This was a theory-driven, clinically applied qualitative study in response to the implementation of Covid-19 public health measures (in April 2020) impacting on OAT service delivery.

Study data was collected by semi-structured interview and was analysed deductively and inductively. We expected that study participants' perceptions and behaviours relating to medication adherence – specifically in relation to the instruction to take medication at home as directed – would coalesce around themes deduced from the Necessity-Concerns Framework (NCF). This theory predicts that utilisation of medication prescribed for a chronic disease is influenced by belief systems held by the patient and prescriber. The NCF proposes that a medication will be taken when the patient's beliefs (implicit and explicit) about the necessity of medication exceed or outweigh any perceived or experienced barriers or concerns they have, such as treatment emergent adverse effects [18]. Therefore, medication adherence is greater when the individual's

beliefs are congruent with the necessity of the medication and such beliefs exceed their concerns. NCF has found support across many disorder and disease domains, including; depression [19], haemophilia [20] and kidney disease [21]. In turn it provides a convincing model for researchers and clinicians to understand patient medication adherence. Inductively, we considered that there might be views that did not align with the NCF, so our findings might contribute to advancing knowledge of medication adherence in this population.

The setting was a community addictions centre operated by South London and Maudsley NHS Trust, situated within the socially and ethnically diverse London Borough of Lambeth. This centre offers treatment via a multi-disciplinary team with psychiatry, nursing, psychology and social work specialties, where patients are assigned a member of the team (key-worker) for case-management. This service provides care for approximately 400 patients with opiate use disorder. The service was selected as the clinicians leading this study were based within the service and the primary aim was to provide a service evaluation of their patient's wellbeing and service's care during the pandemic.

The study protocol was reviewed and approved by the Chair of the Trust's Addictions Clinical Academic Group (SEP/EF/4/2020). Eligible participants were adults (18 years and over) enrolled in ongoing OAT at the point where observed dosing was suspended (existing OAT episode) and those who commenced treatment after implementation of the pandemic restrictions (new OAT episode). Participation was voluntary with written consent.

Data collection and procedure

A semi-structured interview schedule was developed which included the following topics: perceptions of OAT treatment during the Covid-19 related service changes, including changes in contact with the service; experience of attending the pharmacy for dispensing of medication for self-administration; and discussion about ways OAT treatment could be improved. Staff at the centre were informed about the study and approached patients already enrolled on OAT (accessing OUD treatment from the service prior to 23 March 2020) or were on a new treatment OAT episode (those entering into treatment after 23 March 2020), about their interest in taking part. The research aims were discussed with the patients by staff and interested patients were referred to the research team, whom confirmed eligibility for those identified via the electronic patient record. Eligible patients, following verbal consent were interviewed by G.S. and S.T. via telephone and – subject to additional consent – were audio recorded by QuickTime (version 7.7.9). Notes were taken during all interviews.

In accordance with the local information governance policy – personal-demographic information (gender, age, ethnicity) and a brief description of the participant's dispensing regimen was recorded and stored on a password-protected file accessible only to the research team.
No compensation was provided to the participants due to limited resources within the NHS service.

Patient and participant involvement

There was no patient or participant involvement in the study design because it was planned and implemented opportunistically.

Data management and analysis

Data were analysed by G.S. and S.T. following principles of thematic analysis [22] following a sequential and iterative process of categorisation [23], with the following steps:

(1) *Familiarisation* — each audio file was listened to several times, then transcribed verbatim, along with studying of notes to generate a preliminary code list with brief labelling of each topic and flagging of topics that recurred;

(2) *Indexing* – the data was imported into Nvivo (version 12) and each interviewer 'open coded' a sample of six transcriptions to develop a preliminary coding framework. The NCF was applied to the data using numerical code each with a brief description to produce a working then final coding framework; and

(3) *Interpreting major and minor themes* – through consensus discussion and referencing the NCF topics were synthesised into major and minor themes to indicate consensus among participants and any contrary views and behaviours, and thematic saturation reached. Uncoded data (containing residual information) was free-coded, inductively.

Results were organised and presented by major and minor themes, with anonymised verbatim quotations to illustrate. Participant quotations were labelled with participant (P) number, gender (M/F) and OAT group (existing/new OAT episode).

RESULTS

Participants

Thirty-five patients expressed interest, but we could not contact 8. Therefore, 27 patients consented to participate. Two participants declined audio recording but were content for the interviewer's notes to be used for the analysis. The characteristics of the sample are shown in **Table 1**. Most (81.5%) were existing OAT episodes at the time of the guidelines on dispensing,

and almost all were subject to new procedure of take-home supplies for self-administration. At the time of interview, no participant reported being advised to socially isolate.

The 27 transcripts yielded 25 unique codes relating to study aims. These codes were organised into the three overarching themes: (1) Negative views of OAT dispensing policy before the April 2020 changes; (2) Positive adaptations in response to COVID-19 by services; (3) (3) OAT should be more personalised according to adherence. Quotations (italics) illustrate these themes below.

Theme 1: Negative views of OAT dispensing policy before the April 2020 changes

Twenty-two participants (81.5%) reported concerns about the way OAT medication had been dispensed before April 2020. There were complaints about the daily attendance requirement including the cost involved; the view that some pharmacies had restricted opening times (which did not suit those in employment); complaints about lengthy wait times to receive dosing; it conflicting with other activities; and a sense of embarrassment and perceived stigma by some members of the pharmacy team and customers. Three participants reflected on their experience of attending their local community retail pharmacy before the change to self-administered dosing:

The good thing is I don't have to keep going to the chemist which is a pain, a real pain… normally dealing with my chemist, is unreliable…like they keep changing the pharmacist so you have to go through all the rigmarole of it being controlled and that, proving who you are and where you live and stuff. **(P10/M/existing OAT episode)**

I mean it was a hassle having to go every day and also it's a little bit, embarrassing. **(P6/M/existing OAT episode)**

I can't afford to come every day and I fell off so many times just because there's always something to do or I have work so I took the opportunity to come back. I have a weekly pick up. Actually if I'm honest I had a weekly pick up at that time as well. But it was straight before the weekend and then I didn't go Saturday and Sunday they were closed, and Monday I was too late already. **(P8/F/new OAT episode)**

Theme 2: Positive adaptations in response to COVID-19 by services. Within this major theme, a minor theme emerged that highlighted the positive experience participants received in their treatment from pharmacy and treatment centre staff during the pandemic. This included the abrupt cessation of pharmacy supervised dosing, this was regarded as a good response to maintain provision of treatment during the COVID-19 pandemic. There were also positive comments about the running of the pharmacy and treatment service – including staying open despite disruption caused by COVID-19 and remaining professional, compassionate, and responsive to individuals' needs.

…I'm getting support that way and I'm getting the medication which is vital and I'm really grateful to yourselves and the chemist for operating and staying open and taking measures to allow me to, and other addicts to get their medication because I was really stressed about that, when things were starting to get worse with coronavirus and I was hoping, I was afraid, that it would affect my supply of methadone so the fact that it's still coming through and I get it every day is a huge relief and I'm super grateful for [the service] *allowing that to happen.* **(P6/M/existing OAT episode)**

…So I pay for my prescriptions because I work and where I was running out of money I couldn't pay for my prescriptions. I had a chat with the guy at the chemist and he let me owe him it and pay him this week…He said to me, "no that's ok. Bring it in the next time you come in". **(P7/M/existing OAT episode)**

The centre continuing treatment under remote care arrangements was appreciated by patients, there were minimal concerns expressed about the shift from face-to-face to telephone or video contact with staff. Two judged that:

I don't mind it [remote]*, it's pretty much the same. I'm always there, like whenever they've got an appointment I'm always there. But over the phone I do find it quite better…so I don't have to go out my way to go there. If I have something to do, maybe my mum wants me to do something that day, I've always had to go around the appointments.* **(P35/M/existing OAT episode)**

Well...the travelling and stuff, not having to go out all the time [is a benefit]. *Some days where I can't get the bus* [due to anxiety]… *yeh its ok, I don't mind. You can't see me here welling up, so I prefer that.* **(P15/F/existing OAT episode)**

Another was satisfied on the way the service had adapted to the abrupt cessation of patient visits:

...Sometimes I suffer from abscesses due to injecting. So, I spoke to my doctor two days ago about one on my leg and I couldn't get a face-to-face appointment, so we did a video call, and I had to show her the leg…it is ok because she saw it. **(P11/M/existing OAT episode)**

However, a minority raised concerns that the lack of physical access to the centre served to accentuate social isolation and this was especially so among those with limited access to needed technology.

Yeh it's ok, I don't mind...I don't mind, I like calling now. But it's good to go out and get out...Yeh, I like going out and being out. I don't like being stuck in my room. I hate it, stuck in a room and feel a bit mad. **(P15/F/existing OAT episode)**

…Half of them don't even have a phone, half the time the phone doesn't work, half the time they're running to score. It would be really hard to still have phone contact if it was obligational.
(P07/M/existing OAT episode)

It's maybe a little bit difficult [due to technology]*, face to face communication you can, it may be a little bit easier with just seeing the person. (P08, F, New OAT episode)*
Another minor theme that emerged within this theme was specifically related to self-administration OAT dispensing.

Self-administration dosing changes to patients' OAT prescriptions in response to COVID-19 and associated social distancing guidance were strategic and risk assessed, via clinical interview and UDS's. It was common for those whom were deemed safe, to be moved to the next less frequent collection regime, for example weekly to fortnightly. As well as, those supervised to be changed to unsupervised following a period of monitoring and evidence of adherence to their prescription. Most described the change to self-administered dosing reflected trust in the patient and is beneficial. They welcomed the promise of infrequent pharmacy attendance due to the increase in self-administration dosing practices. Reasons for this varied, but the reduction in pharmacy attendance inadvertently addressed accessibility barriers for a number of those interviewed, including those with physical health issues, others did not need to miss paid work to attend the pharmacy for medication collection and it enabled another to take medication at a time that suited night work.

Another described the reduced collection regime helped reduce their illicit drug use, due to staying at home more and having less temptation. For others it reduced the number of appointments and in turn reduced the risk of missing an appointment and subsequent implication on their prescription regime.

Yeah, it's been a lot easier, what with my health being the way it is, it's a struggle getting to the chemist every day...I think it shows trust [to the service-users from the service]*...saves me having to walk to the chemist in agony every time, and now I only have to go once a week.*
(P27/M/existing OAT episode)

I was working last year and it did help me a lot not to use, so I'm starting to think again about getting back into work, that will be helpful. Some jobs you have to be there at 9, and the pharmacy

opens at 9 and if you have to be at work at 9, you won't be able to do it...It just that, sometimes it feels like a very long process you know. **(P33/M/existing OAT episode)**

I mean it doesn't bother me, either way but I do want, I am taking it at my own time which I am happy. Because my normal work before the virus I was doing night shifts cleaning. So sleeping all day and I would have to normally wake up to go and going and get my supervision at the pharmacy. Which was a bit messed up in my sleeping pattern. So this way if I could stay off supervision, I would be able to have it late at night, and wouldn't have to wake up and go pharmacy. **(P11/M/existing OAT episode)**

Actually [the pandemic restrictions] *have been really helpful because sometimes before when I was trying to go* [to the pharmacy] *every day…I would sometimes use illicitly whereas now I stay at home. I haven't got that temptation.* **(P18/M/existing OAT episode)**

Just being able to have the weekly pickup you know. It was a godsend not having to worry about not being able to get to the chemist and missing an appointment and things… **(P31/M/existing OAT episode)**

A minority of participants – all having been assessed at risk of overdose or medication diversion – had been retained on daily observed maintenance dosing. They all expressed frustration about this.

I just think that one thing that gets to me is that people who are on the supervised, they look at it as, kind of, they feel like it's a punishment if you know what I mean. When some of them are quite stable and yet they, ok they might be doing other things and that, but after 10 or 12 years of it, it's like..., of course there's a minority who are completely, uncontrollable, but just because of those people, everybody suffers. **(P10/M/existing OAT episode)**

Views about medication adherence suggested that individual motivations would determine response to take-home supplies. One participant observed:

First day I was supervised because I was higher-ing the dose, but they just give you the pill. You don't take it there. So in this kind of case, it doesn't really matter from this perspective because the person that will want to sell it will just sell it every day, or once a week. It will not make any change for you guys, or for the market of drugs. **(P8/F/new OAT episode)**

Theme 3: OAT should be more personalised according to adherence

Participants reflections on the future of the service as one based on a more personalised approach to balance supervised and self-administered dosing. One participant with previous experience of OAT, but newly admitted for a new episode, offered the following considered perspective:

I would say that from the beginning for people that are first time coming, definitely face-to-face. Later on, depends on the people, if you're working, if you have a full-time job and you have other obligations…I'm putting the service-users into two groups. One group would [visit the service] *just to have safety, and they're normally doing whatever they were doing before. And [then there are] service-users that take* [their] *medication. So, the second group, definitely it's better to do the phone, I would say, because you're already integrating back into society. You have work, you have friends, you have sport, you have other stuff that you are doing. Meanwhile the first group, I don't know. Half of them don't even have a phone, half the time the phone doesn't work, half the time they're running to score. It's not hard to learn who's taking something and who's not...I think it's going way too much by the template. Yeah, definitely think it should be more individual especially for the second group when they see that you are completely clean and that you are really taking only* [OAT medication]. **(P8/F/new OAT episode)**

Another participant reflected:

It's almost like before there's a punishment aspect to it that you've got yourself into this trouble and you know, and it's all the running around and being treated like a child...I just hope this is something that can go forward with the treatment and the present set up. Because it would be funny if in, I don't know, 3 months, 6 months-time if there's been no problems and you go backwards, it would seem like a strange move...Yeah, it means I could go and visit family in another country and take my script with me and, yeah, it would make me more free, which is good. Not tied down to going to the chemist every day. **(P18/M/current OAT episode)**

DISCUSSION

Against a background of several aspects of dissatisfaction with pre-pandemic OAT dispensing (daily pharmacy attendance, pharmacy opening times and waiting times for service, and perceive stigma), participants reported several positive aspects of the abrupt changes in response to the pandemic. Including an appreciation that pharmacies stayed open, the teams were perceived as caring to individual needs, and a ready adaptation to remote contact with the treatment centre. Longer dispensing intervals and self-administered dosing was regarded as conveying trust in the patient, and also gave freedom for work and engagement in other activities. Participants recommended an continuation of self-administered dosing and patient-centred prescribing. There were few reports that medication was not taken as directed, and in-line with the NCF there was a consensus that OAT medication was valued and provided important benefits.

Our study suggests that the NCF is applicable to OAT medication adherence phenomena. Most patients described continued adherence to the OAT medication, despite considerable changes to their medication delivery or entered into treatment to access OAT medication. Typically, patients described their OAT as vital and reactive anxiety regarding accessing their medication when the COVID-19 pandemic occurred. Together, these reports reflect a sense of necessity for OAT medication and that this outweighs concerns about taking medication and stress associated with contracting COVID-19 virus when accessing treatment.

This study also offers novel insight into the many practical and environmental barriers to being treatment adherent for OUD. These barriers included the cost of attending, attendance to the service risked drug relapse due to environmental cues and detrimental implications on employment. These findings directly speak to Horne and colleagues' call for further investigation into whether practical barriers to care have a greater impact on some population's seeking medications [24]. These results indicate that while medication adherence is particularly nuanced within this clinical population many are impacted by practical barriers. Additionally, COVID-19 triggered changes to medication collection and in turn mitigated these barriers and ought to be maintained in a post COVID-19 service delivery. Overall highlighting the need for a personalised approach and questioning the effectiveness of previous rigid treatment protocols for OUD.

The guidelines in which clinicians within addiction services follow, have largely been in response to public health concerns. As a consequence, the application of blanket policy's individuals need to meet in accessing treatment has been the tradition. The results from this study, utilising a person-centred model (NCF) to addiction treatment, further questions the value of the standard daily dose dispensing and supervised consumption protocol. Personalised models of treatment for OUD, as opposed to blanket guidance have long been recommended within the addiction literature [25, 26]. These new qualitative findings born from unprecedented international events and reactive OAT treatment guidance are consistent with this, emphasising flexible approaches that demonstrated trust and allow individuals to adhere to their treatment plans (longer dosing pick up, virtual support) and engage in out of treatment activities, including employment.

It was notable that patients did not report concerns about OAT side effects or their implications on adherence. A common concern reported within other illnesses that determine medication adherence. It could be hypothesised that for many individuals within the study perceived OAT as a welcome relief for the aversive symptoms of opiate withdrawal and necessity significantly outweighs concerns [27]. Alternatively, such results could be a consequence of the study design- patients were enrolled or imminently about to be enrolled in OAT, thus medication seeking. Additionally, these responses could be explained by the semi-structured nature of the interview

schedule, which did not explicitly enquire about side-effects of medication given the focus was on changes to medication collection in the context of the pandemic.

We recognise that this was a relatively small-scale study and there are several limitations. Firstly, it was beyond the scope of this study to investigate the applicability of the NCF on general OAT adherence within the OUD population outside of a pandemic context. Therefore, additional research ought to investigate the NCF applicability to OAT adherence beyond the pandemic context. Additionally, this was a purposive and self-selecting sample, with potential for response bias. Our participants do reflect a relatively small sample of patients enrolled in OAT in one London borough and therefore may not generalise to other addiction clinics including treatment systems overseas. Nevertheless, the study was done at a specialist NHS addictions treatment service providing OAT that is delivered following a clinical protocol among all NHS providers in the UK. Therefore, we contend that our sample was broadly representative of this clinical population including a range of patients with prior experience, those embarking on a new treatment episode and also those identified as high risk with continued daily observed dispensing.

As an applied qualitative study, fieldwork was done at pace, and further studies are needed to investigate current views of treatment among this clinical population and corroborate this study's findings, including from samples across the globe and within different treatment centres. Additionally, future studies would do well with further resources and time, to access more patients within the new to OAT treatment subgroup, given they were a minority group within our sample. As well as, support a co-production model of study design with patients in this clinical population.

Our findings on the benefits of reduced prescription collection, are consistent with published qualitative research conducted at the same time as this study. In indicating that patients living in rural communities also quickly adapted to changing treatment policy [28]. A further benefit to longer-interval prescribing of OAT facilitates the individual to engage in alternative activities, including employment. Study findings also align with a study of prescribing services in two north London boroughs [29], and a global systematic review of 25 studies published in 2020 (mostly in the USA) on the adaptation of OAT and allied services to pandemic restrictions [30]. In this review, the most common innovation was the offer of telephone or online services, and the longer interval prescribing of medication. For the former, there were examples of innovative solutions to help patients with no access to mobile phones (e.g. distribution of free mobile phones to patients by one treatment provider [31]), a service building sanitized phone booths outside their centre for private video calls with staff and to receive counselling [32,33]. For the latter, comparable arrangements with longer interval dispensing was reported in the US [34], Canada [35], Spain [36], and Italy [37]. We do not know if these were short-term arrangements, but there has been discussion of the implications for more flexible arrangements for patients.

Our findings contribute to the international discussion about the opportunities for more flexible treatment. We propose an individual approach in which patients are supported to evaluate their capacity for medication adherence at an appropriately early point. Current UK clinical guidelines already promote individualised care – but perhaps there is a case to evaluate a faster process of dose increase to achieve a stable and effective dose for the patient so that the adherent can receive their first 7-day take-home supply as early as is safe to do so. Supervised dispensing of OAT medications exists to ensure compliance with the prescription and to reduce the risk of medication diversion. There is emerging evidence of an increase of methadone related deaths during the first Covid-19 'lockdown' both in-treatment and amongst people not in treatment [38]. Balancing these risks with patient-centred care remains a central element of delivering specialist treatment for opiate use disorders.

Overall, this qualitative study collected the subjective experiences, perspectives and concerns of patients, who were representative of those seen in community drug treatment settings. In doing so, this study ceased a unique opportunity in our centre to gather patient insights to inform OAT delivery. The NCF was generally applicable to this clinical population and three major themes emerged from the interviews; dissatisfaction with pre-pandemic OAT medication dispensing and changes in guidance and service delivery initiated by the pandemic were mostly perceived as positive and effective. This included positive attitudes and behaviour of pharmacy and centre staff, increased self-administration of medication demonstrated trust and promoted autonomy in the patient and their experience of receiving medication supplies for self-administration during the pandemic were positive. Generally, participants recommended that such changes remain beyond the pandemic, including individualised OAT dispensing plans be based on patient preference and evidence of adherence, along with the option of remote addiction support. Together these findings highlight the perceived importance and necessity of OAT for patients, including through a public health crisis and for most, accessing their treatment was improved by pandemic associated changes. These findings are consistent with the wider literature, pandemic associated NHS service changes were generally well received, offering new opportunities to patients, and that of addiction treatment more widely; patient-centred, personalised and flexible treatments are preferred by patients receiving OAT.

Data availability statement

No data are available. Interview transcripts will be deleted after publication of the report.

Ethics statements

Patient consent for publication not required.

Ethics approval

The study protocol was reviewed and approved by the Chair of the Trust's Addictions Clinical Academic Group (SEP/EF/4/2020).

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Competing interests

In the past three years, J.M. declares research grants to King's College London (KCL) from the National Institute for Health Research (NIHR) for a multi-centre trial of acamprosate for alcohol use disorder; the NIHR Biomedical Research Centre for Mental Health at South London and Maudsley NHS Mental Health Foundation Trust (SLaM) for a pilot trial of cognitive therapy for cocaine use disorder and related studies, and an unrestricted grant from Indivior to KCL from Indivior for a multi-centre trial of extended-release injectable buprenorphine for opioid use disorder. He is a clinical academic consultant for the US National Institute on Drug Abuse, Centre for Clinical Trials Network. M.K. declares an unrestricted grant from Indivior regarding long-acting buprenorphine treatment. He is the principal investigator on a trial of naloxone funded by Mundipharma and on an NIHR grant into telephone interventions in opioid substation therapy. L.M. declares funding from a research grant to Leeds University from NIHR for a realist evaluation of services for people with co-occurring mental health and substance use problems and an unrestricted grant from Indivior to KCL and SLaM from Indivior for a multi-centre trial of extended-release injectable buprenorphine for opioid use disorder. The other authors have no interests to declare.

Trial registration

The study was not registered.

The original protocol for the study

Attached.

A data sharing statement:

The audio record for this study is not subject to data sharing.

Supplementary and raw data

Not applicable.

Contribution statement

The design was conceived by JM, LM and MK. GS and ST conducted the interviews, transcribed and analysed the data under supervision from JM. GS and JM drafted the initial manuscript, with contributions from LM, ST, WA, AH, KM, NL and MK for subsequent revisions. GS took the final decision to submit the manuscript for publication.

Patient and public involvement

There was no patient or participant involvement due to the opportunistic nature of this project.

Provenance and peer review

Not commissioned, externally peer reviewed.

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Table 1: Participant characteristics (n=27)

Characteristic	n
Age, years	47.3 (8.7)
Sex	
Male	22 (81.5)
Female	5 (18.5)
Ethnicity	
White British	14 (51.9)
Black British	4 (14.8)
Other	9 (33.3)
OAT	
Methadone	17 (63.0)
Buprenorphine	10 (37.0)
OAT episode and regimen	
Existing episode – change to self-administered dosing	20 (74.1)
Existing episode – already self-administered dosing	2 (7.1)
New episode – self-administered dosing from induction	5 (18.5)

Note: numbers in parentheses are standard deviation or percentage.

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COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the inter view or focus group?	
Duration	21	What was the duration of the inter views or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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