STUDY PROTOCOL

Development of quality indicators for the continued and safe delivery of Opioid Agonist Treatment (OAT), throughout and beyond COVID-19, using a Delphi Consensus technique

[version 1; peer review: awaiting peer review]

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Abstract

Opioid agonist treatment (OAT) is the most effective treatment for opioid dependence, although it relies heavily on regular face-to-face healthcare delivery. Following the emergence of COVID-19, policies were rapidly changed in Ireland to reduce the risk of contracting the virus for both clients and treatment providers. From March 2020, the Health Service Executive (HSE) National Social Inclusion Office introduced a series of national contingency guidelines, to ensure fast and uninterrupted access to OAT while balancing efforts to mitigate COVID-19 risks. The Programme for Government 2020 states they will retain many of the measures introduced during the COVID-19 pandemic to reduce waiting times in accessing treatment services and reduce overdose mortality. It is therefore essential to examine the impacts, benefits and unintended consequences of the special measures introduced during COVID-19 at a national level, thus
informing which measures can and should be sustained throughout and beyond COVID-19 to support effective, safe and patient-centered care promoting the health and wellbeing of all people with opioid dependence. The aim of this project is to identify priorities for quality improvements which will inform clinical decision making throughout and beyond the pandemic. This will be achieved through a Delphi consensus study. Quality indicators will be identified by comparing the national contingency guidelines with the national 2016 Clinical Guidelines. The project steering group will review the proposed indicators, and the agreed quality indicators will be integrated into an on-line Delphi questionnaire. One hundred participants will be invited to form the Delphi consensus panel and will include a wide range of stakeholders, including people accessing OAT services, general practitioners, pharmacists and outreach workers. Evidence generated from this study will inform national policy decisions in relation to improving quality of care in OAT.

Keywords
COVID-19, opioid agonist treatment, quality indicator, Delphi technique, addiction services, drug policy, substance use disorder, harm reduction

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Introduction

Opioid agonist treatment (OAT), using methadone or buprenorphine, is safe and effective in improving mental and physical wellbeing, suppressing illicit opioid use and lowering mortality in people with opioid dependence. In 2021, Santo et al. conducted a systematic review which showed that OAT was associated with a significant reduction in overdose, suicide, alcohol, cancer, and cardiovascular-related mortality as well as all-cause mortality in people with opioid dependence.

The Misuse of Drugs Regulations, introduced in Ireland in 1998, established the Methadone Treatment Protocol, forming the basis of the clinical governance and quality of delivery of drug treatment. Concomitantly, a centralised national treatment register of all patients accessing OAT for opioid dependence, associated with their prescriber and dispensing facility - the central treatment list (CTL) - was created. After an external review of the 1998 Methadone Treatment Protocol in 2010, a set of detailed guidelines was published in 2016, in order to set a standard and enhance quality and safety of OAT care in Ireland. Since 2017, updated regulations grant access to OAT with buprenorphine. In Ireland, the vast majority of people accessing OAT for opioid dependence receive methadone free of charge, either in specialist outpatient addiction services or in primary care.

People accessing OAT may be particularly at risk of becoming infected with COVID-19, as they are more likely to live in socially-deprived areas, and experience poor housing conditions or homelessness. Additionally, a high level of co-existing health conditions may increase the severity of COVID-19 in case of infection. In this context, unforeseen difficulties in accessing OAT – which within the 2016 guidelines depends on frequent in-person healthcare delivery – would be prejudicial to clients. Moreover, possible disruptions to the supply of illicit drugs in the community were expected, which would lead to a rise in demand for substitution treatment.

In order to reduce the spread of COVID-19 while maintaining safety and quality of care, as well as respond to a sudden surge in people newly seeking OAT, several national and local organisations involved with people who use drugs have worked together to implement a rapid, coordinated response. A series of contingency guidelines were introduced by the Health Service Executive in March 2020. In order to support accelerated access to OAT, increased access to buprenorphine and remote consultations took effect. E-prescriptions, home deliveries for clients self-isolating, and, where possible, increased access to take-home doses were also implemented in order to facilitate treatment while protecting clients and healthcare professionals. Finally, harm-reduction measures such as needle exchange, advice for management of alcohol and benzodiazepine dependence, and increased prescribing of naloxone were taken.

A detailed examination of the impacts, benefits and unintended consequences of the policy changes introduced during COVID-19 at a national level, is needed to inform which measures can and should be sustained throughout and beyond COVID-19 to support effective, safe and patient-centred care promoting the health and wellbeing of all people with opioid dependence. For example, while rapid access to OAT is an important marker of quality, as OAT is associated with a marked reduction in mortality, growing evidence suggests that methadone may pose an excess risk of mortality during treatment initiation, if initial doses are too high or co-exist with illicit opioid use. Furthermore, growing evidence suggests that the risk of morality following dropout from OAT, with either methadone or buprenorphine, is high. Therefore, it is important to consider quality indicators in the context of overdose prevention, particularly during periods of transition. Similarly, the benefits of increased take-home doses need to be balanced against the risk of diversion and fatal opioid poisoning. This study aims to identify quality indicators for the continued and safe delivery of OAT throughout and beyond the pandemic using a Delphi consensus methodology. The specific objectives are to (1) identify structural, process and outcome indicators of OAT care introduced under the contingency guidelines which deviate from pre-COVID-19 regulations and clinical guidelines and (2) conduct a Delphi consensus of quality indicators for the safe delivery of OAT in Ireland throughout and beyond COVID-19.

Protocol

Study design

A Delphi Consensus methodology will be used to identify quality indicators for the safe delivery of OAT in Ireland throughout and beyond COVID-19.

Delphi questionnaire preparation

Quality indicators to be included in the Delphi questionnaire will be identified by comparing the national contingency guidelines, which were introduced to mitigate the effects of COVID-19, with the national Clinical Guidelines for OAT, published in 2016. Quality indicators will relate to changes introduced in the contingency guidelines and will include structural (attributes of service provider), process (steps taken in the provision of care) and outcomes (impact of care on health status of clients) where appropriate. Results from HSE National Social Inclusion Office service user experience and national service provider reports will also inform the drafting of quality indicators. A consensus meeting will be held remotely with the Project Steering Group (PSG) to determine the completeness of the list of quality indicators. Two people accessing OAT will be invited to the project steering group consensus meetings.

The agreed quality indicators will be integrated into an online Delphi questionnaire. The questionnaire will be piloted using a convenience sample (n=5) of health care professionals working in OAT, people accessing OAT services from the National Advocacy Service for People who use Drugs in Ireland (UISCE) or Merchants Quay and academics from the Royal College of Surgeons in Ireland (RCSI), to check face validity, understanding and acceptability. Suggested modifications to the questionnaire will be reviewed by members of PSG.
Selection of Delphi panel
One hundred stakeholders from across Ireland will be invited to form the Delphi consensus panel. To ensure the credibility and acceptance of the quality indicators, the panel will reflect the full range of stakeholders who have an interest in the results of this study. As different stakeholders often have very different points of views about quality of care, which will enrich the results of the Delphi procedure, we will create a panel with people accessing OAT services, psychiatrists, general practitioners, community pharmacists, outreach workers, homeless services, voluntary groups, addiction service managers and counsellors. The PSG will propose panellists to invite. We will ensure that both male and female clients accessing OAT services are included in the panel to give both groups a voice.

Online Delphi consensus methodology
Panellists will be invited to participate in the Delphi study via e-mail, with a study invitation letter and information sheet. Individuals will be contacted, via e-mail, one week later to establish their willingness to participate. People accessing OAT services will be recruited through direct approach in collaboration with Merchants Quay Ireland (MQI) and UISCE. If they are interested in taking part, they will receive the web link (Welphi) to the online questionnaire for Round 1 and Round 2 via email. Before commencing the Delphi questionnaire, participants will indicate their consent to take part online.

During the first round, participants will rate their level of agreement with each statement on a 5-point Likert rating scale, ranging from 1 “strongly disagree” to 5 “strongly agree.” Participants will be given the option to select ‘not applicable/unsure’ if they are unable to offer an opinion, along with any additional comments or suggestions for quality indicators. People accessing OAT services will be supported by a peer worker or UISCE/MQI staff to ensure we overcome any literacy/technology barriers. Participants will be allowed four weeks for task completion, with a reminder email to prompt completion of survey after two weeks.

Statistical analysis plan
After each round, the median and Inter Quartile Range (IQR) will be calculated for each quality indicator. Consistent with previous Delphi consensus studies, the consensus level required for an indicator to be retained is defined a priori as a median of 4 or 5 with a lower quartile value of ≥4. If an indicator has an upper quartile value of ≤2, this indicates general disagreement with the indicator between panel members, and the indicator is rejected. If group consensus is not reached, the indicator will be reviewed by the PSG and may be removed or revised based on comments and included in the second round. In the second round, participants are provided with feedback on the quantitative panel results and the respondent’s individual responses at round 1. Using this information, respondents are asked to re-rate the quality indicators at round 2.

Data management and storage
Participants’ details will be pseudonymised using unique individual ID codes. All individuals who consent to participate in the study will be allocated a unique study ID code, which they will use when accessing and completing the online Delphi questionnaire. This will allow personal information to be kept separate from the responses to the Delphi questionnaire. To facilitate the generation of individual feedback reports and to track attrition, the study researchers will review how each individual participant responds to the questionnaires. An electronic log of participants’ name and unique study ID code (i.e. the ‘key’) will be stored on a password-protected Excel spreadsheet. This electronic log will be stored securely on a unique password-protected folder on the RCSI V-Drive that only the lead investigators will have access to. Participants will not be informed of the identities of other individuals taking part in the study and will not be informed of specific answers provided by any other individual member of the panel.

Welphi is hosted with Amazon Web Services (AWS) cloud services (server is based in Frankfurt) and so the database remains encrypted at rest through Amazon Relational Database Service Virtual Private Cloud (RDS VPC) security and an “always encrypted” policy is implemented with AWS key management services. Welphi is GDPR Compliant.

Data extracted from the online tool will be analysed as previously stated and subsequently stored in compliance with the FAIR data principles. On study completion (publication of results), data will be fully anonymised and stored for a minimum of five years in line with RCSI guidelines on good research practice and general audit requirements. After the five-year interval, the folder which contains all study data will be securely deleted.

Ethics
All study procedures have received full ethical approval from the Research Ethics Committee in the Royal College of Surgeons in Ireland (REC 202102010). Informed consent will be obtained from all participants prior to completing the survey.

Dissemination
Study findings will be submitted for publication in a peer-reviewed journal and to relevant national and international conferences. Our study findings will also be disseminated via a research brief or webinar to relevant stakeholders including HSE Social Inclusion Commissioning Team; Department of Health National Oversight Commissioning Team for National Drug and Alcohol Strategy; HSE National Quality Improvement Team; Irish College of General Practitioners; Irish Institute of Pharmacy; College of Psychiatrists of Ireland; and the European Monitoring Centre for Drugs and Drug Addiction. We will also collaborate with UISCE, the national advocacy service for people who use drugs (PWUD), to create a special edition of our research findings in their magazine, which is disseminated nationally to all services PWUD attend. Findings will also be disseminated through the use of social media such as Twitter.

As outlined in the data management plan, after full anonymisation (removal of all identifiers), the level of agreement data (1-5 Likert scale) and associated metadata will be uploaded.
on a repository (e.g. Zenodo) to become findable and citeable without restrictions. Data will be released/shared only upon publication of the study results.

Study status
This study is underway, with the initial drafting of quality indicators complete. The project steering group have met to discuss the initial list of indicators, which are currently under review with the steering group, before we begin pilot testing.

Discussion
The rapid and coordinated response to mitigate the spread of COVID-19, while ensuring continued and safe access to OAT in Ireland, highlights many bright spots of excellent practice across multiple sectors of the Irish health and social care system during a time of crisis. The Programme for Government 2020 has stressed the need to retain many of the contingency measures introduced to ensure shorter waiting times and reduced risk of overdose. However, questions remain: how feasible is it to continue with all the changes which were implemented at this time of crisis; is it appropriate or indeed safe to continue with all changes; are there any unintended consequences? The HSE National Social Inclusion Office, where addiction services are coordinated, along with many other key players, general practitioners, community pharmacists, and other key workers in addiction services now face the challenge of optimising available resources while ensuring continued and safe access to OAT as we learn to live with COVID-19. This project will identify quality indicators for the safe delivery of opioid substitution treatment in Ireland throughout and beyond COVID-19, which will inform evidence-based decision-making.

Data availability
Underlying data
No data are associated with this article.

References