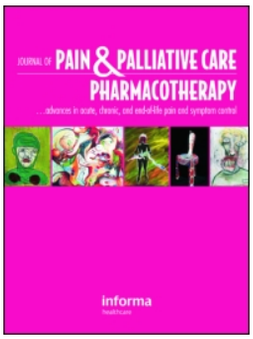

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ABSTRACT

The UK Medical Cannabis Registry is the largest real world data platform for medical cannabis outcomes in the UK, providing insight into clinical outcomes and monitoring safety of this novel therapy. This study aims to assess the functionality and accessibility of the online data collection platform and patient priorities for future research. Descriptive statistics were used to analyze quantitative data. For open-ended questions an inductive thematic analysis was performed. 600 responses were recorded. 554 (92.3%) patients had used the platform. 272 (90.4%) patients believed it was easy to input medications. 52 (8.67%) patients recorded an adverse event with 38 (73.1%) finding it easy to record. 535 (96.6%) patients had completed health questionnaires with 490 (91.6%) patients finding this easy to do. 553 (92.2%) patients agreed that contributing to the registry would impact the medical care of future patients. 'Assessing the impact of medical cannabis on quality of life generally' was the top research priority for 357 (59.3%) patients. This study demonstrates that most enrolled patients found the platform easy to use and believed they were positively impacting future medical cannabis patient care. Future patient research priorities included assessment of quality of life and condition-specific outcomes.

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Cannabis; medical cannabis; cannabinoids; research priorities

Introduction

In recent years there has been a growing recognition in the importance of patients contributing to the design and implementation of future research, known as Patient and Public Involvement (PPI) (1). A study conducted in 2009 estimated that at least 85% of all clinical research fails to generate sufficient impact, partly due to a prioritization of research questions or studies deemed irrelevant to clinicians and patients (2). PPI seeks to address this issue, allowing clinical research to be tailored toward patient priorities and feedback, reducing 'research waste' and financial costs (3). The engagement of patients and public is thought to have three important roles in biomedical research. Firstly, as a component of ethical research conduct, PPI is integral in reducing the power disparity between researchers and participants, giving patients the right to influence the research performed on themselves or peers (4–6). Moreover, through engaging with patients' lived experience, PPI can improve the efficacy of performed research by ensuring that the outcomes are desirable for patients and clinically relevant. In addition, PPI can also help ensure research is performed in a patient-friendly approach improving recruitment and retention (5, 7). Finally, the involvement of patients improves transparency and accountability for conducted research (5, 8).

With respect to developing evidence on medical cannabis there are global barriers to conducting traditional randomized controlled trials, including complex pharmacology, difficulty identifying an appropriate placebo, and cost (9). In addition, there have been legal restrictions on the ability to research the therapeutic value of cannabis leading to a paucity of evidence (10). Whilst countries such as the United Kingdom (UK), Australia, Canada, and Israel are now progressing with clinical research on medical cannabis, in countries such as the United States cannabis is classified as a Schedule I substance

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and is under tightly controlled regulations, creating legal and logistical barriers to cannabinoid research (10). Consequently, the utilization of real-world evidence from observational data has served a necessary purpose in advancing the known clinical effects of medical cannabis. The UK Medical Cannabis Registry was set up in December 2019 to collect anonymized data from patients prescribed cannabis-based medicinal products (CBMPs) (11). The Registry uses an online platform, allowing clinicians and patients to input essential data including demographics, prescribed CBMPs, concurrent medications, efficacy metrics, adverse events, and patient-reported outcome measures (PROMs). It is an important pharmacovigilance system to support clinical prescribing, considering CBMPs are unlicensed medications in the UK (12). To date there have been several publications from the UK Medical Cannabis Registry which have assessed outcomes in patients prescribed CBMPs, including bespoke analysis of those with anxiety, chronic pain and those requiring palliative care (13–17).

Despite data from the UK Medical Cannabis Registry providing novel insights into the outcomes of UK-based patients prescribed CBMPs to aid present clinical practice, it is still unknown as to whether the methods of data collection are acceptable to participants and whether the chosen study priorities align with those of patients. This study therefore aims to assess the acceptability and ease of utilizing the patient-facing data collection platform for the UK Medical Cannabis Registry. In addition, it aims to identify participant perspectives on the importance of research using the Registry and future priorities for focused assessment.

Methods

A cross-sectional, online survey study was conducted between 18th August to 3rd November 2021 utilizing patients enrolled in the UK Medical Cannabis Registry. All conditions as previously stated by the International Committee of Medical Journal Editors have been met. On advice from the Health Research Authority in the UK, this study was designated as patient and public involvement rather than research and therefore did not require formal ethics approval.

The survey was distributed electronically on 18th August 2021 to participants enrolled in the UK Medical Cannabis Registry. Participants were excluded if they had been enrolled for fewer than 30 days. The Registry is a bespoke real-world evidence platform for collecting patient reported outcome measures, efficacy measures and adverse events in patient prescribed cannabis-based medicinal products in the UK (11). Data is collected utilizing a remote electronic portal, supplemented by clinician documentation.

The survey was designed via a consensus approach between coauthors (S.E. & M.H.S) to assess functionality of electronic data collection for patients and priorities for future research utilizing the Registry. The questionnaire consisted of 17 questions, containing nine 'Yes' or 'No' questions (Figure 1), three questions with a five-point Likert scale (Figure 2), one question asking patients to rank a list of priorities for future research (Figure 3) and four open-ended questions relating to patient experiences inputting medications, adverse events, and research priorities (Tables 1–4).

Responses to closed questions were analyzed utilizing descriptive statistics. For open-ended questions an inductive thematic analysis was performed. Individual responses were coded according to a consensus approach by two independent researchers (J.T. and S.E.). Any discrepancies were planned to be resolved by a third senior author (M.H.S.). The codes were then reviewed and attributed to a consensus of themes and subthemes for narrative analysis. All analyses were conducted using Microsoft Excel (Microsoft, Redmond, WA).

Results

The questionnaire was distributed to 1672 of the 1910 participants enrolled in the UK Medical Cannabis Registry who met the inclusion criteria. A total of 600 (35.89%) participants completed the questionnaire. Of these, 554 (92.3%) reported that they had utilized the remote electronic portal to capture adverse events, clinical efficacy measures, or patient reported outcome measures (Figure 1). From those who had used the

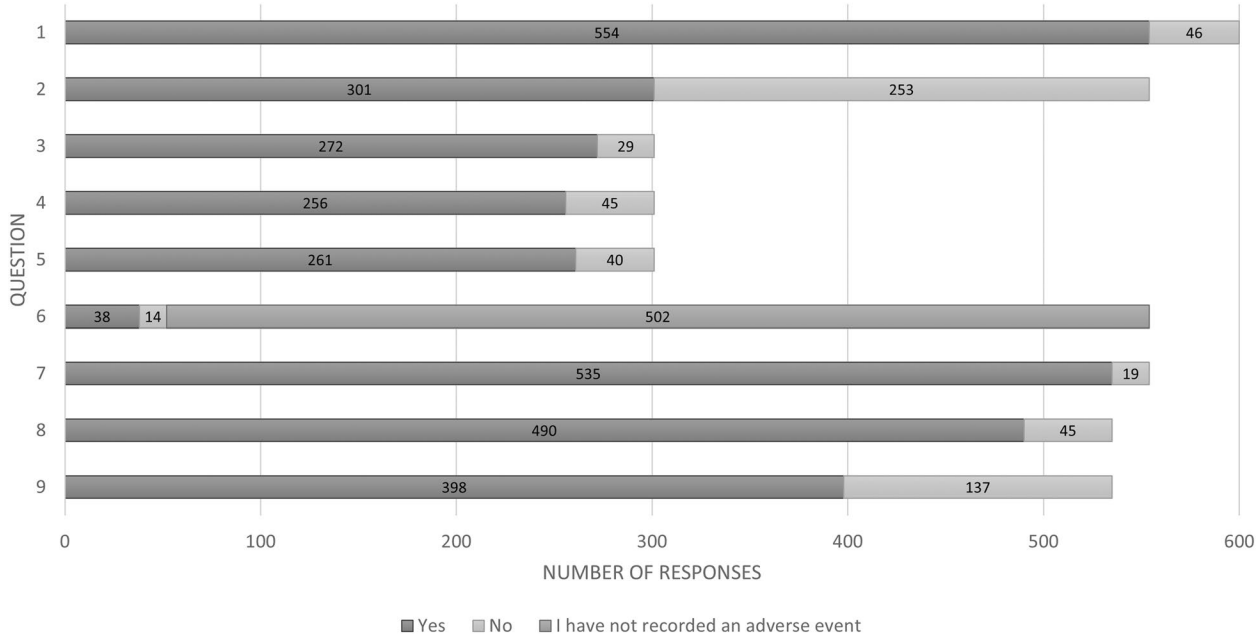


Figure 1. Patient responses for survey questions 1–9.
Patients were sent a survey to provide feedback on the Registry's electronic data collection process.
The first nine questions were as follows:
1. Have you used your online platform?
2. Have you used the function to record your current and previous medications?
3. Did you find it easy to input drug names?
4. Did you find it easy to input drug doses?
5. Did you find it easy to input route of administration?
6. If you have recorded an adverse event, did you find this easy to do?
7. Have you completed any health questionnaires?
8. Did you find it easy to complete your health questionnaires?
9. Do you find it helpful to see the responses to your health questionnaires on the online platform?

Note: Numbers within bars display the number of responses for each option.

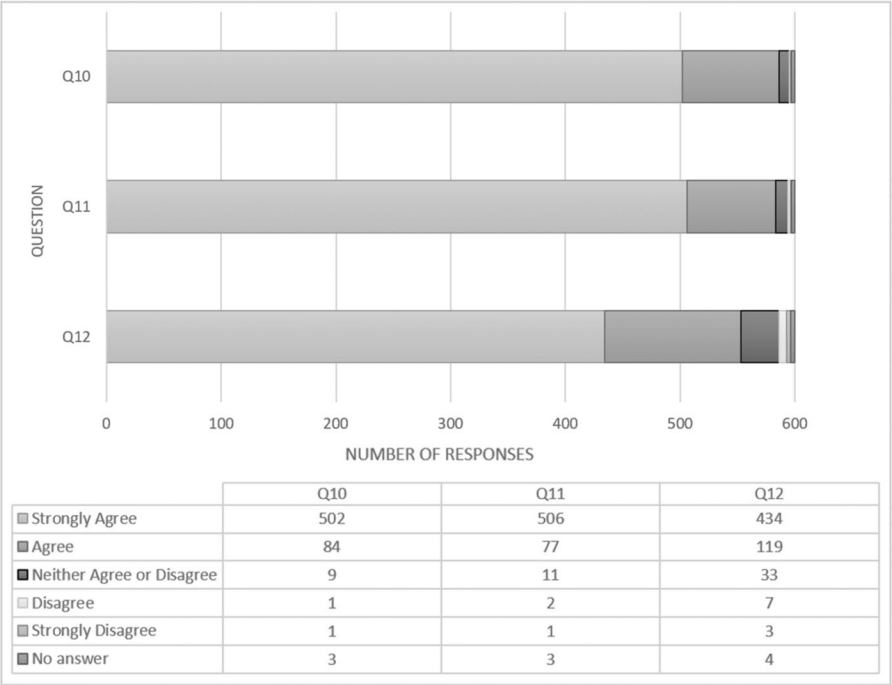
electronic portal to record their medications (n = 301; 54.3%), 90.4% (n = 272) and 85.0% (n = 256) of patients found it easy to input medication names and dosages respectfully. Most patients (n = 261; 86.7%) also found it easy to input the route of administration. Few patients (n = 52; 8.67%) recorded an adverse event, of which 73.1% (n = 38) found it easy to do so. The majority of patients (n = 535; 96.6%) had completed health questionnaires with 91.6% (n = 490) finding this easy to do so.

Table 1 outlines responses to an open question regarding feedback for recording medications. Over two-thirds of patients (n = 118; 64.1%) reported that it was easy to record medications through the platform. The most common constructive feedback included 12.0% (n = 22) of patients expressing difficulty when adding medication names and 9.24% (n = 17) of patients struggling to add 'as required' medication.

Table 2 outlines reasons why patients found it easy to record adverse events. Reasons under the 'Straightforward' theme included describing it as 'Easy to use', 'Easy to navigate' and 'Nice and simple'. Reasons given under the 'Constructive feedback' theme include 'Straightforward but lots of questions' and 'The questionnaire format was helpful but a box where I could write a particular incident like an incident report would be helpful'. In contrast, Table 3 outlines themes for why patients did not find it easy to record adverse events, with 41.7% (n = 5) of patients struggling to find the correct link to access the online data collection portal and one-third of patients (n = 4; 33.3%) preferring to input their own side effects.

Involvement in research

Questions 10–12 in the survey asked patients to rank the importance of contributing to medical



	Q10	Q11	Q12
Strongly Agree	502	506	434
Agree	84	77	119
Neither Agree or Disagree	9	11	33
Disagree	1	2	7
Strongly Disagree	1	1	3
No answer	3	3	4

Figure 2. Patient responses for survey questions 10–12.
Patients were sent a survey to provide their perspectives on the importance of the Registry and medical cannabis research.
Questions 10–12 were as follows:
10. 'It is important to me to contribute to research on medical cannabis so that we can better understand its effects in patients like me'.
11. 'It is important to me to contribute to research on medical cannabis to help improve access to medical cannabis'.
12. 'I believe that through contributing to the UK Medical Cannabis Registry I will impact the medical care of future patients'.

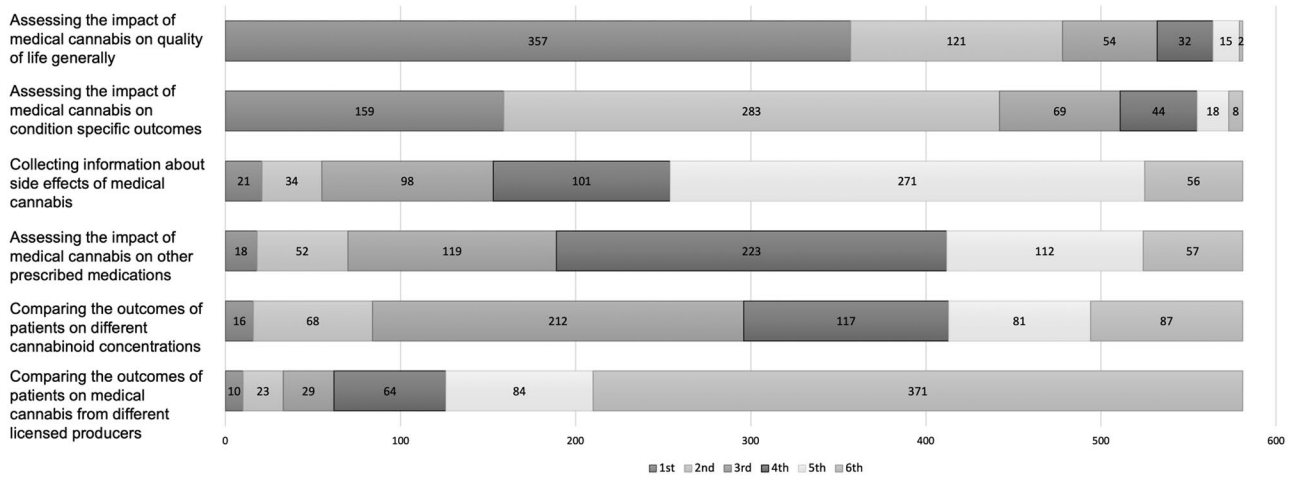


Figure 3. Patient perspectives on future medical cannabis research priorities.
Patients were given a list of six priorities and asked to rank them in order of importance, with the 1st choice being the top priority and the 6th choice being the last. 19 out of the 600 patients did not answer this question.

cannabis research and the Registry (Figure 2). Most patients (n = 556; 92.6%) strongly agreed or agreed that it was important to contribute to medical cannabis research such that its effects can be greater understood. The majority of patients (n = 583; 97.2%) also strongly agreed or agreed it was important to contribute to medical cannabis research to improve patient access. Finally, patients (n = 553; 92.2%) strongly agreed or agreed that contributing to the UK Medical Cannabis Registry would impact the medical care of future patients.

Table 1. Categorized responses for the question 'Please share any comments about recording medication including anything you did or didn't like about the feature?'.

Comment theme	Number of responses (%)
Easy to use	118 (64.1%)
Difficulty adding medication name	22 (12.0%)
Difficulty recording 'as required' medication	17 (9.2%)
Difficulty adding dosages	11 (6.0%)
Difficulty remembering medication	8 (4.4%)
Long and/or repetitive to insert medications	3 (1.6%)
Required help navigating technology	3 (1.6%)
Not esthetically pleasing	2 (1.1%)

Table 2. Categorized responses for the question 'Please share why you found it easy to record an adverse event'.

Comment theme	Number of responses (%)
Straightforward	30 (83.3%)
Constructive feedback	3 (8.3%)
Non-specific positive feedback	2 (5.6%)
Received help	1 (2.8%)

Table 3. Categorized responses for the question 'Please share why you did not find it easy to record an adverse event'.

Comment theme	Number of responses (%)
Difficulty accessing link	5 (41.7%)
List own side effects	4 (33.3%)
Required help	1 (8.3%)
Non-specific negative feedback	1 (8.3%)
Unrelated	1 (8.3%)

Medical cannabis research priorities

Figure 3 describes in full the ranking priorities of six pre-specified research priorities. 'Assessing the impact of medical cannabis on quality of life generally' was the top priority for 59.3% (n = 357) of patients and second choice for 20.2% (n = 121). Table 4 details the responses to an additional open-ended question regarding additional research priorities, with answers coded and categorized according to an inductive thematic analysis. The most popular theme was research into more conditions (n = 39, 34.2%), including depression, anxiety, dementia, cancer, and Tourette's Syndrome.

Table 4. Categorized responses for the question 'Please share any final thoughts on research priorities you would like us to consider'. CBMPs = Cannabis-based medicinal products (N = 114).

Comment theme	Number of responses (%)
Research into more conditions	39 (34.2%)
Research more strains/products	27 (23.7%)
Research effects with other medication	11 (9.7%)
More prescription information	7 (6.1%)
Research different strains	6 (5.3%)
Research into route of administration	5 (4.4%)
Side effects/Long term use	5 (4.4%)
Patient experience	2 (1.8%)
Effects of homegrown cannabis	2 (1.8%)
Research into benefits of data collection	2 (1.8%)
Research into the entourage effect	2 (1.8%)
If CBMPs help after surgery	1 (0.9%)
Patient opinion on general cannabis industry	1 (0.9%)
Impact on random drug testing	1 (0.9%)
Social implications of cannabis use	1 (0.9%)
Impact of support groups	1 (0.9%)
Individual differences to cannabis tolerance	1 (0.9%)

Discussion

This study sought to assess patient acceptability of data collection through the UK Medical Cannabis Registry, as well as identify participant opinions on future priorities and the importance of the Registry for conducting research. Results showed that most patients found the data collection platform easy to use when inputting relevant information and believed they were contributing to medical cannabis research by doing so. Regarding priorities, patients largely agreed that the most relevant research priorities should be regarding the impact of medical cannabis on quality of life and condition specific outcomes.

This study demonstrates that most patients who have used the features of the remote electronic data collection platform have found it easy to record patient reported outcome measures, medications, and adverse events. The theoretical benefits of utilizing a remote data collection system are to reduce barriers to participation through making it more convenient to enroll and continue reporting outcomes (18, 19). This subsequently helps improve diversity and generalizability of results to a general population (18, 19). Common themes, identified in previous studies for non-completion of digitally reported outcomes included ill-health preventing completion, challenges with engagement, emotional distress during completion, poor user experience, technical difficulties, and concerns with privacy and data security (20). Both quantitative and thematic analysis in the present study highlighted that each surveyed aspect of the Registry was considered by most participants to be easy to use. However, adaptations which improve user experience in writing drug names, inserting as required

medications, and completing adverse events, may reduce further barriers to completing outcomes digitally. With respect to recording medications and adverse events, incorporating predictive text to help with challenging medication names or specific adverse events may improve ease of reporting either item. To combat difficulty accessing the link for self-reporting adverse events, clinicians can now directly report these into the Registry if reported verbally during a consultation.

To date, there is a paucity of research into patient and public priorities for medical cannabis research. A survey administered to attendees at the 2019 American Medical Marijuana Physicians Association meeting found that respondents desired future research to investigate the effect of medical cannabis on numerous conditions, with chronic pain, cancer and anxiety as the top priorities (21). The top safety concerns pertained to dosing, smoking and drug interactions (21). However, in this study, the sample size was limited to 46 respondents, largely consisting of physicians and only 10 patients. Despite this, the results agree with the findings presented in this study in that more research is needed into various conditions to fully ascertain the treatment potential for medical cannabis. This is echoed by the recent task force statement from the International Association for the Study of Pain which highlighted a paucity of high-quality, transparent, reproducible research (22). Furthermore, a paper published in 2019 collated priority research considerations from an international group of cannabis experts, finding the top priorities as: determining the effect of route of administration, optimizing cannabinoid concentrations and individual dosing, investigating long term effects of cannabis use, and lastly, any drug interactions with medical cannabis (23). These findings highlight an academic and physician-centric approach to clinical research. Whilst these are undoubtably important research priorities, they represent a divergence from participants surveyed in the present study, who prioritize identifying effects on quality of life and individual conditions, compared to adverse effects. However, it must be considered that these are intrinsically linked outcomes. In particular, participants emphasized the importance of research in depression, anxiety, dementia and cancer, compared to other conditions. This highlights the importance of PPI in a developing field with many directions for research. This ensures that research is tailored toward patient and public priorities to improve the quality and clinical relevance of medical cannabis research.

There are notable limitations to this study. Firstly, the survey was electronically distributed to patients. It is possible that technologically informed patients would be more likely to complete the survey; the same can be said for utilizing the online platform. Accordingly, survey responses may not be representative of all patients present in the Registry. It is also plausible that patients with positive experiences with engaging with the UK Medical Cannabis Registry were more likely to complete the survey, increasing a bias toward positive opinions. Secondly, the survey was limited to patients enrolled in the UK Medical Cannabis Registry, therefore assessment of priorities was limited to patients being treated with CBMPs and therefore may not be truly representative of other patients with chronic illness who are not receiving treatment with CBMPs or other members of the public. To address this, it would be beneficial to perform a separate survey non-inclusive to the UK Medical Cannabis Registry for a true population study.

In summary, the results presented in this study show that the UK Medical Cannabis Registry is deemed important to medical cannabis research by the patients that partake in the Registry, and that the data collection platform is acceptable for participants. In particular, the majority of patients found it easy to complete medication information, patient reported outcome measures and adverse events. Furthermore, this study reveals the priorities of patients for future medical cannabis research. Specifically, patients placed the greatest priority on research into effects on quality of life and condition-specific outcomes. This will help inform future analyses of the UK Medical Cannabis Registry which must incorporate validated assessments of health-related quality of life and condition-specific patient reported outcome measures to ensure they are tailored toward patient priorities, with the aim to increase

patient recruitment, retention, and satisfaction. Additionally, these patient priorities can guide future medical cannabis research, ensuring that research is more relevant and better designed with the concerns of medical cannabis patients in mind.

Author disclosure statement

J.T. is a medical student at Imperial College London.

S.E. is a junior doctor and undertakes paid consultancy work at Sapphire Medical Clinics. He is an honorary clinical research fellow at Imperial College London.

M.H.S. is a consultant hepatopancreatobiliary surgeon, a director at Sapphire Medical Clinics and a consultant at Imperial College NHS Trust, London. He is a senior clinical lecturer at Imperial College London. He is the Chief Medical Officer at Curaleaf International.

Declaration of interest

SE & MHS are the founding clinicians of Sapphire Medical Clinics, which is the first clinic registered with the CQC to evaluate patients for medical cannabis in England. Full declarations and conflicts of interest are provided at the end of the manuscript.

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