Statistical Analysis Plan

Advance Choice Documents Implementation (ACDI): Work package 3

Retrospective controlled study of ACD creation and its relationship to health service use and routinely collected outcomes

Study Aims

The overall aim of Work Package 3 (WP3) is to evaluate the effectiveness of Advance Choice Document implementation on routinely collected outcomes in an NHS Mental Health Trust

WP3 primary objective

To evaluate the effect of Advance Choice Document implementation on rates of detention under the Mental Health Act (MHA)

WP3 secondary objectives

To evaluate the effect of Advance Choice Document implementation on:

i. Mental health service use (non-MHA inpatient admissions and associated bed days, Community Mental Health Team (CMHT) events, Home Treatment Team (HTT) events, acute mental health and emergency service use
ii. Rates of restraint, seclusion, and involuntary medication
iii. Safety events (violence, self-harm, consequences of self-neglect and other serious untoward incidents)
iv. Contact with police related to use of mental health services, imprisonment, length of time in prison
v. General health service use (inpatient admissions and associated bed days, A&E attendances, outpatient appointments)
vi. Routinely collected patient outcomes

Study design and sample

We propose to carry out a retrospective controlled study using data from the Clinical Record Interactive Search (CRIS) database at South London and Maudsley NHS Foundation Trust (SLaM). CRIS is a deidentified case register extracted from the SLaM electronic health record[1].

To assess the impact of ACD implementation on outcomes, at least six months of follow-up data is required for each participant. Six months prior to the end of the ACDI study (1st October 2026), the retrospective cohort will be created comprising service users who have had ACDs in place for at least six months (last ACD included made on 1st April 2026) and matched controls without ACDs. Control participants will be current SLaM service users who have been detained under the Mental Health Act (MHA) at least once and last been discharged from an MHA-related admission in the last 24 months. Study follow-up periods will begin when the ACD is recorded on a service user's health record (index date). Each control participant will have the same follow-up period as their matched ACD holder. The first ACD made as part of the ACDI study

was created on 31st January 2025 meaning the maximum follow-up will be 20 months. The study timeline for WP3 is portrayed in Figure 1.

Procedure

We will use data from the Clinical Research Interactive Search (CRIS) database at SLaM NHS Trust to create the retrospective cohort in a two-stage data extraction process:

Stage 1: Control matching

ACD holders will be identified by the presence of an ACD in the patient's correspondence in their electronic health record. ACDs will be identified in correspondence using the following search terms:

Advance Choice Document

Advance decision

Advance Directive

Advance statement

Joint crisis plan

Crisis pack

The SLaM Biomedical Research Centre (BRC) will then provide the ACDI team with an anonymised dataset comprising ACD holders and all current (at the time their counterpart's ACD was created) SLaM service users who had ever been detained under the Mental Health Act (MHA) and had last been discharged from an MHA-related admission in the last 24 months. This dataset will be used for control matching and will contain the following – age (when ACD was created), gender, ethnicity, time since last MHA detention (months) and forensic status.

We will use an appropriate matching technique to identify controls (1:1), matched on age, gender, ethnicity, time since last MHA detention, and forensic status. Only those with complete data on all matching variables will be included in the cohort. Once matched, controls will be assigned the same index date as their corresponding ACD holder. Assigning index dates in this way means that cases and matched controls will have the same follow-up durations. Patients who have not been matched as controls will be removed from the dataset resulting in the matched study cohort. Three follow-up periods will be applied to this dataset: 6, 12, and 18 months. A variable (yes/no) will be created to indicate which cases and controls should be included in each follow-up period.

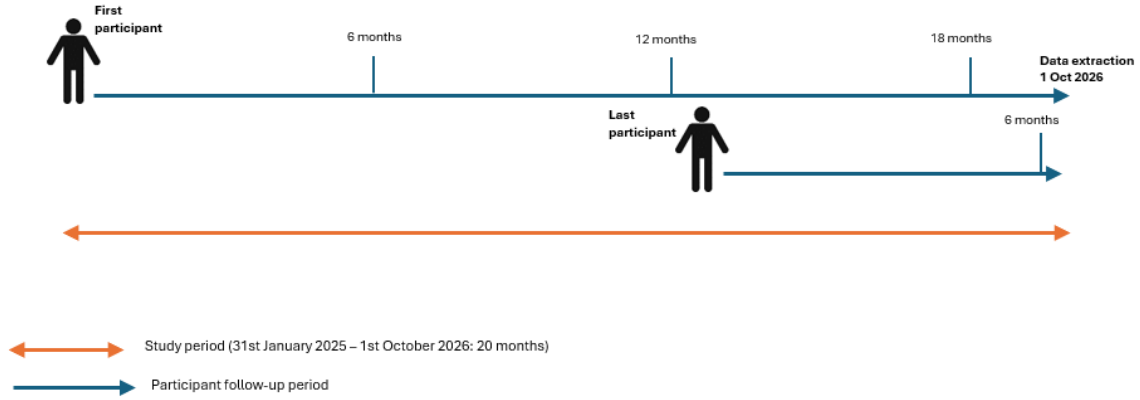

Figure 1. Follow-up periods of the retrospective cohort study at SLaM.

The first participant and matched control enter the study on 31st January 2025 (when the ACD was created) and therefore can be followed up for 6-, 12-, and 18-month periods. The last participant and matched control will enter the study at the latest on 1st April 2026 and will have 6 months of follow-up only.

Stage 2: Extraction of study outcome data

An anonymised dataset containing cases and controls with study IDs and index dates will be returned to the CRIS extraction team at SLaM BRC. Mental health service use data will be extracted both pre- and post-index date for each person in the cohort over 6-, 12-, and18-month periods. Pre-index date data will also be extracted to support the application of the most appropriate study design (e.g. difference-in-differences design).

Study outcomes

Mental health service use outcomes will include number of admissions under the MHA, section type (Section 2, 3, 135 and 136) and associated bed-days, number of non-MHA inpatient admissions and associated bed-days, number of home treatment team (HTT) events and days spent under the care of HTT, number of community mental health team events, psychiatric liaison team events (in emergency departments). The number of events will be requested for all follow-up periods (and the corresponding pre-index date periods).

Rates of restraint, seclusion, involuntary medication, safety events, contact with police, and imprisonment across each follow-up period will also be extracted from CRIS. As these events are not recorded in structured fields, free-text entries will be searched to identify all events containing the words detailed in Table 1.

Table 1. Search terms for identifying restraint, seclusion, involuntary medication and safety events	
Outcome	**Search terms**
Seclusion[2,3]	'Seclusion', 'supervised confinement'
Restraint	'Restrained', 'restraint'
Involuntary medication	TBC
Safety events	TBC
Contact with police related to use of acute mental health services	TBC
Imprisonment, length of time in prison	TBC

Physical health service use will be measured through data linkage with Hospital Episode Statistics (HES). At SLaM, these data can be obtained at a national level for all SLaM service users. We will request HES data for the cohort over the entire study period. This data will be provided in a separate dataset, allowing for calculation of health service use over the studies defined follow-up periods which can then be linked to the main study dataset. Physical health service use outcomes will include: inpatient admissions and associated bed days (this will include Healthcare Resource Group codes, associated primary and secondary diagnostic codes, admission category, and treatment specialty code), Emergency Department (ED) attendances (this will include Healthcare Resource Group codes, diagnosis classifications, investigations codes, treatment codes, arrival mode, and attendance disposal codes), and outpatient appointments (this will include appointment information such as first appointment or follow-up, consultant or nurse, treatment specialty code, priority status).

If possible, we will extract routinely collected outcomes such as the Health of the Nations Outcomes Scale (HoNOS)[4]. HoNOS is a 12-item measure of health and social functioning completed by clinical staff. Each item is scored on a five-point Likert scale, with higher scores indicating poorer functioning.

Note: Make sure to submit data extraction specification well before October 2026 to allow time for discussion and reiteration.

Potential for increasing sample

It may be possible to identify service users who created ACDs before the beginning of the ACDI study. Based on information from the clinical members of the ACDI study team, it is likely that the first ACD was created at SLaM in 2007. These ACDs will be identified using the CRIS Front End Tool which allows researchers to access anonymised versions of the patient electronic health record.

If it is possible to include patients with ACDs created before the ACDI study, we will extend follow-up periods as sample sizes permit (e.g. 2 years, 5 years, 10 years).

Covariates

As the cases and controls will be matched on several relevant sociodemographic and clinical variables we will need to adjust statistically for the following: mental health diagnosis, smoking status, substance use, index of multiple deprivation (IMD), pre-index date health service use. The number of 'active SLaM days', i.e. the number of days a patient is in an active episode of care, over each study follow-up period will be included as a covariate or offset variable where appropriate.

Statistical analysis

Sample characteristics will be described using means and standard deviations (SD), medians and interquartile ranges (IQR), and frequencies.

We will compare all differences in all outcomes between ACD holders and matched controls. As health service use data is rarely normally distributed, are frequently over-dispersed, and frequently contain many zero values, these differences will be assessed using Poisson, negative binomial, and zero-inflated negative binomial regression where necessary. When assessing count data (e.g. number of inpatient events), larger or smaller counts may be observed based on the amount of time spent measuring a particular unit (i.e., the follow-up period). Therefore, the amount of time a participant spent in an episode of care at SLaM during each follow-up period (i.e. active SLaM days) will be included as the offset variable. The regression coefficient for an offset variable is constrained to be 1, thus allowing the model to represent rates rather than counts. Logistic regression models will be used to assess the occurrence (yes/no) of restraint, seclusion, involuntary medication, and safety events over follow-up periods.

To ascertain the impact of ACDs on routinely collected outcomes (i.e. HoNOS scores), we will use linear regressions due to the continuous distribution of these variables.

Economic analysis

The unit costs for healthcare resources will be identified to calculate the total cost for cases and controls from the UK health and social care provider perspective. Standard sources for unit costs including the Personal Social Services Research Unit (PSSRU) for primary care service costs, and the National Cost Collection for the NHS for emergency care and secondary care service costs will be used. Costs will be inflated to 2025/2026 using the most up-to-date NHS Cost Inflation Index – Pay and Prices.

Contingency

Outcome data will be provided in a format which allows several study designs to be applied to the data. We propose to compare the cases and matched controls on outcomes over several follow-up periods. However, if the control matching is deemed unsuccessful (i.e. the control participants look very different to the cases on variables we have not matched on) we will consider implementing a difference in differences design, which involves the comparison of

changes in outcome over time, or a before and after study where the cases act as their own controls.

Sensitivity analyses

If our overall sample comprises any SLaM patient who has an ACD in place, we will also analyse those patients who had ACDs created as part of the ACDI study to assess the impact of these ACDs separately.

References

1 Perera G, Broadbent M, Callard F, *et al.* Cohort profile of the South London and Maudsley NHS Foundation Trust Biomedical Research Centre (SLaM BRC) Case Register: current status and recent enhancement of an Electronic Mental Health Record-derived data resource. *BMJ Open* 2016; **6**: e008721.

2 Cullen AE, Bowers L, Khondoker M, *et al.* Factors associated with use of psychiatric intensive care and seclusion in adult inpatient mental health services. *Epidemiology and Psychiatric Sciences* 2018; **27**: 51–61.

3 Rogers JP, Lewis G, Lobo M, *et al.* Identifying predictors of adverse outcomes after termination of seclusion in psychiatric intensive care units. *BJPsych Open* 2024; **10**: e120.

4 Wing JK, Beevor AS, Curtis RH, Park SGB, Hadden J, Burns A. Health of the Nation Outcome Scales (HoNOS): Research and development. *The British Journal of Psychiatry* 1998; **172**: 11–8.