

Results schema of the SelfControlledCaseSeries package

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1 Introduction

This document describes the data model of the output of the SelfControlledCaseSeries (SCCS) package, generated by the `exportToCsv()` function. This vignette assumes you are already familiar with the SelfControlledCaseSeries package, and have read all other vignettes.

1.1 Exposures, covariates of interest, and controls

As described in the ‘Single studies using the SelfControlledCaseSeries package’ vignette, **eras** are cohorts or drug eras extracted from the database. **Covariates** can either be splines, for example representing age or season, or era covariates, derived from eras. When defining covariates using the `createEraCovariateSettings()` function we can either use verbatim era IDs (e.g. cohort IDs), or we can reference a variable (typically called ‘exposureId’). When defining **exposures** using the `exposure()` function, we can define different era IDs to be used for this variable, thereby using the same analysis settings for different exposures and outcomes. For each exposure we can set the `trueEffectSize` if known. Any exposure with known true effect size is considered a

`control`, and will be used for empirical calibration. Some of our covariates can be marked as **covariates of interest** by setting `exposureOfInterest = TRUE` when calling `createEraCovariateSettings()`. This is especially relevant for the results model, since these covariates will be reported in the `sccs_result` table.

1.2 Exposures-outcome-sets, analysis IDs and models

Using the `createExposuresOutcome()` function we can define an outcome with one or more exposures, since an SCCS model can have multiple exposures (e.g. we could have separate exposures for the first and second dose of a vaccine). With the `createSccsAnalysis()` function we can create a set of settings for analysis describing which data to extract from the database, how to transform that data including which covariates to construct, and how to fit the SCCS model. Each analysis setting has a unique analysis ID. Each combination of an exposures-outcome-set and an analysis setting will correspond to one SCCS model. A model can have multiple covariates, and each covariates can be based on multiple eras.

1.3 Fields with minimum values

Some fields contain patient counts or fractions that can easily be converted to patient counts. To prevent identifiability, these fields are subject to a minimum value. When the value falls below this minimum, it is replaced with the negative value of the minimum. For example, if the minimum subject count is 5, and the actual count is 2, the value stored in the data model will be -5, which could be represented as '<5' to the user. Note that the value 0 is permissible, as it identifies no persons. These fields are identified below as having `Min. count = 'Yes'`.

2 Tables

In this section you will find the list of tables and their fields.

2.1 Table `sccs_age_spanning`

| Field | Type | Key | Min. count | Description |
|--|---------|-----|------------|--|
| <code>analysis_id</code> | int | Yes | No | A foreign key referencing the <code>sccs_analysis</code> table. |
| <code>exposures_outcome_set_id</code> | int | Yes | No | A foreign key referencing the <code>sccs_exposures_outcome_set</code> table. |
| <code>database_id</code> | varchar | Yes | No | Foreign key referencing the database. |
| <code>age_month</code> | int | Yes | No | Age in months since birth. |
| <code>cover_before_after_subjects</code> | int | No | Yes | Number of subjects whose observation period covers this month. |

2.2 Table `sccs_analysis`

| Field | Type | Key | Min. count | Description |
|--------------------------|---------|-----|------------|--|
| <code>analysis_id</code> | int | Yes | No | A unique identifier for an analysis. |
| <code>description</code> | varchar | No | No | A description for an analysis, e.g. 'Correcting for age and season'. |
| <code>definition</code> | varchar | No | No | A JSON object specifying the analysis. |

2.3 Table `sccs_attrition`

| Field | Type | Key | Min. count | Description |
|------------------------------|---------|-----|------------|---|
| <code>sequence_number</code> | int | Yes | No | The place in the sequence of steps defining the final analysis. |
| <code>description</code> | varchar | No | No | A description of the last restriction, e.g. 'Removing persons'. |
| <code>analysis_id</code> | int | Yes | No | A foreign key referencing the <code>sccs_analysis</code> table. |

| Field | Type | Key | Min. count | Description |
|-----------------------------|---------|-----|------------|---|
| exposures_outcome_set_id | int | Yes | No | A foreign key referencing the sccs_exposures_outcome_set table. |
| covariate_id | int | Yes | No | A foreign key referencing the sccs_covariate table. The identifier for a covariate. |
| database_id | varchar | Yes | No | Foreign key referencing the database. |
| outcome_subjects | int | No | Yes | The number of subjects with at least one outcome. |
| outcome_events | int | No | Yes | The number of outcome events. |
| outcome_observation_periods | int | No | Yes | The number of observation periods containing at least one outcome event. |
| observed_days | bigint | No | Yes | The number of days subjects were observed. |

2.4 Table sccs_calendar_time_spanning

| Field | Type | Key | Min. count | Description |
|-----------------------------|---------|-----|------------|---|
| analysis_id | int | Yes | No | A foreign key referencing the sccs_analysis table. |
| exposures_outcome_set_id | int | Yes | No | A foreign key referencing the sccs_exposures_outcome_set table. |
| database_id | varchar | Yes | No | Foreign key referencing the database. |
| calendar_year | int | Yes | No | Calendar year (e.g. 2022) |
| calendar_month | int | Yes | No | Calendar month (e.g. 1 is January). |
| cover_before_after_subjects | int | No | Yes | Number of subjects whose observation period covers this month. |

2.5 Table sccs_censor_model

| Field | Type | Key | Min. count | Description |
|--------------------------|---------|-----|------------|--|
| analysis_id | int | Yes | No | A foreign key referencing the sccs_analysis table. |
| exposures_outcome_set_id | int | Yes | No | A foreign key referencing the sccs_exposures_outcome_set table. |
| database_id | varchar | Yes | No | Foreign key referencing the database. |
| parameter_id | int | Yes | No | The parameter number in the censor model (starting at 1). |
| parameter_value | float | No | No | The fitted parameter value. |
| model_type | varchar | No | No | The type of censor model. Can be ‘Weibull-Age’, ‘Weibull-Intensity’, ‘Weibull-Time’. |

2.6 Table sccs_covariate

| Field | Type | Key | Min. count | Description |
|--------------------------|---------|-----|------------|---|
| analysis_id | int | Yes | No | A foreign key referencing the sccs_analysis table. |
| exposures_outcome_set_id | int | Yes | No | A foreign key referencing the sccs_exposures_outcome_set table. |
| covariate_id | int | Yes | No | A unique identifier for a covariate. |
| covariate_name | varchar | No | No | A description for the covariate. |
| era_id | int | No | No | A foreign key referencing the sccs_era table. |
| covariate_analysis_id | int | No | No | A foreign key referencing the sccs_covariate_analysis table. |
| database_id | varchar | Yes | No | Foreign key referencing the database. |

2.7 Table sccs_covariate_analysis

| Field | Type | Key | Min. count | Description |
|-------------------------|---------|-----|------------|---|
| analysis_id | int | Yes | No | A foreign key referencing the sccs_analysis table. |
| covariate_analysis_id | int | Yes | No | A unique identifier for a covariate analysis. |
| covariate_analysis_name | varchar | No | No | A name for a covariate analysis, e.g. ‘Pre-exposure’. |

| Field | Type | Key | Min. count | Description |
|---------------------------|------|-----|------------|--|
| variable_of_interest | int | No | No | Is the variable of interest (1 = yes, 0 = no). |
| pre_exposure | int | No | No | Does the variable represent a pre-exposure period (1 = yes, 0 = no). |
| end_of_observation_period | int | No | No | Does the variable represent the end of the observation period (1 = yes, 0 = no). |

2.8 Table sccs_covariate_result

| Field | Type | Key | Min. count | Description |
|--------------------------|---------|-----|------------|--|
| analysis_id | int | Yes | No | A foreign key referencing the sccs_analysis table. |
| exposures_outcome_set_id | int | Yes | No | A foreign key referencing the sccs_exposures_outcome_set table. |
| database_id | varchar | Yes | No | Foreign key referencing the database. |
| covariate_id | int | Yes | No | The identifier for the covariate. |
| rr | float | No | No | The estimated relative risk (i.e. the incidence rate ratio). |
| ci_95_lb | float | No | No | The lower bound of the 95% confidence interval of the relative risk. |
| ci_95_ub | float | No | No | The upper bound of the 95% confidence interval of the relative risk. |

2.9 Table sccs_diagnostics_summary

| Field | Type | Key | Min. count | Description |
|--------------------------------|-------------|-----|------------|---|
| analysis_id | int | Yes | No | A foreign key referencing the sccs_analysis table. |
| exposures_outcome_set_id | int | Yes | No | A foreign key referencing the sccs_exposures_outcome_set table. |
| covariate_id | int | Yes | No | The identifier for the covariate of interest. |
| database_id | varchar | Yes | No | Foreign key referencing the database. |
| time_stability_p | float | No | No | The p for whether the mean monthly ratio between observed and expected rates is significantly different from 1. |
| time_stability_diagnostic | varchar(20) | No | No | Pass / fail / not evaluated classification of the time stability diagnostic. |
| event_exposure_lb | float | No | No | Lower bound of the 95% CI for the pre-exposure event rate. |
| event_exposure_ub | float | No | No | Upper bound of the 95% CI for the pre-exposure event rate. |
| event_exposure_diagnostic | varchar(20) | No | No | Pass / fail / not evaluated classification of the event-exposure diagnostic. |
| event_observation_lb | float | No | No | Lower bound of the 95% CI for the end of observation event rate. |
| event_observation_ub | float | No | No | Upper bound of the 95% CI for the end of observation event rate. |
| event_observation_diagnostic | varchar(20) | No | No | Pass / fail / not evaluated classification of the event-observation diagnostic. |
| rare_outcome_prevalence | float | No | No | The proportion of people in the underlying population with the rare outcome. |
| rare_outcome_diagnostic | varchar(20) | No | No | Pass / fail / not evaluated classification of the rare outcome diagnostic. |
| ease | float | No | No | The expected absolute systematic error. |
| ease_diagnostic | varchar(20) | No | No | Pass / warning / fail / not evaluated classification of the ease diagnostic. |
| mdrr | float | No | No | The minimum detectable relative risk. |
| mdrr_diagnostic | varchar(20) | No | No | Pass / warning / fail / not evaluated classification of the mdrr diagnostic. |
| unblind | int | No | No | Is unblinding the result recommended? (1 = yes, 0 = no). |
| unblind_for_evidence_synthesis | int | No | No | Is unblinding the result for inclusion in evidence synthesis recommended? (1 = yes, 0 = no). |
| time_trend_p | float | No | No | The p for whether the mean monthly ratio between observed and expected rates is significantly different from 1. |
| pre_exposure_p | float | No | No | One-sided p-value for whether the rate before exposure is significantly different from 1. |
| time_trend_diagnostic | varchar(20) | No | No | Pass / warning / fail / not evaluated classification of the time trend diagnostic. |
| pre_exposure_diagnostic | varchar(20) | No | No | Pass / warning / fail / not evaluated classification of the pre-exposure diagnostic. |

2.10 Table sccs_era

| Field | Type | Key | Min. count | Description |
|--------------------------|------|-----|------------|---|
| exposures_outcome_set_id | int | Yes | No | A foreign key referencing the sccs_exposures_outcome_set table. |

| Field | Type | Key | Min. count | Description |
|-------------|---------|-----|------------|---|
| analysis_id | int | Yes | No | A unique identifier for an analysis. |
| era_type | varchar | Yes | No | The type of era (e.g. 'rx' for drugs). |
| era_id | int | Yes | No | A unique identifier, corresponding to the ID in the source table. |
| era_name | varchar | No | No | A name for the era. Is NULL for eras derived from cohorts. |
| database_id | varchar | Yes | No | Foreign key referencing the database. |

2.11 Table sccs_event_dep_observation

| Field | Type | Key | Min. count | Description |
|--------------------------|---------|-----|------------|---|
| analysis_id | int | Yes | No | A foreign key referencing the sccs_analysis table. |
| exposures_outcome_set_id | int | Yes | No | A foreign key referencing the sccs_exposures_outcome_set table. |
| database_id | varchar | Yes | No | Foreign key referencing the database. |
| months_to_end | int | Yes | No | Number of months until observation end. |
| censored | int | Yes | No | Whether the observation is censored (meaning, not equal to the end of the study). |
| outcomes | int | No | Yes | Number of outcomes observed during the month. |

2.12 Table sccs_exposure

| Field | Type | Key | Min. count | Description |
|--------------------------|-------|-----|------------|---|
| exposures_outcome_set_id | int | Yes | No | A foreign key referencing the sccs_exposures_outcome_set table. |
| era_id | int | Yes | No | A foreign key referencing the sccs_era table. |
| true_effect_size | float | No | No | If known, the true effect size. For negative controls this equals zero. |

2.13 Table sccs_exposures_outcome_set

| Field | Type | Key | Min. count | Description |
|--------------------------|------|-----|------------|--|
| exposures_outcome_set_id | int | Yes | No | A unique identifier for a set of exposures and an outcome. |
| outcome_id | int | No | No | A cohort ID. |
| nesting_cohort_id | int | No | No | A cohort ID. |

2.14 Table sccs_likelihood_profile

| Field | Type | Key | Min. count | Description |
|--------------------------|---------|-----|------------|---|
| log_rr | float | Yes | No | The log of the relative risk where the likelihood is sampled. |
| log_likelihood | float | No | No | The normalized log likelihood. |
| gradient | float | No | No | The gradient of the log likelihood. |
| covariate_id | int | Yes | No | The identifier for the covariate of interest. |
| exposures_outcome_set_id | int | Yes | No | A foreign key referencing the sccs_exposures_outcome_set table. |
| analysis_id | int | Yes | No | A foreign key referencing the sccs_analysis table. |
| database_id | varchar | Yes | No | Foreign key referencing the database. |

2.15 Table sccs_result

| Field | Type | Key | Min. count | Description |
|-----------------------------|---------|-----|------------|---|
| analysis_id | int | Yes | No | A foreign key referencing the sccs_analysis table. |
| exposures_outcome_set_id | int | Yes | No | A foreign key referencing the sccs_exposures_outcome_set table. |
| covariate_id | int | Yes | No | A foreign key referencing the sccs_covariate table. The identifier for the covariate. |
| rr | float | No | No | The estimated relative risk (i.e. the incidence rate ratio). |
| ci_95_lb | float | No | No | The lower bound of the 95% confidence interval of the relative risk. |
| ci_95_ub | float | No | No | The upper bound of the 95% confidence interval of the relative risk. |
| p | float | No | No | The two-sided p-value considering the null hypothesis of no effect. |
| one_sided_p | float | No | No | The one-sided p-value considering the null hypothesis of no effect. |
| outcome_subjects | int | No | Yes | The number of subjects with at least one outcome. |
| outcome_events | int | No | Yes | The number of outcome events. |
| outcome_observation_periods | int | No | Yes | The number of observation periods containing at least one outcome. |
| covariate_subjects | int | No | Yes | The number of subjects having the covariate. |
| covariate_days | int | No | Yes | The total covariate time in days. |
| covariate_eras | int | No | Yes | The number of continuous eras of the covariate. |
| covariate_outcomes | int | No | Yes | The number of outcomes observed during the covariate time. |
| observed_days | bigint | No | Yes | The number of days subjects were observed. |
| log_rr | float | No | No | The log of the relative risk. |
| se_log_rr | float | No | No | The standard error of the log of the relative risk. |
| llr | float | No | No | The log of the likelihood ratio (of the MLE vs the null hypothesis). |
| calibrated_rr | float | No | No | The calibrated relative risk. |
| calibrated_ci_95_lb | float | No | No | The lower bound of the calibrated 95% confidence interval of the relative risk. |
| calibrated_ci_95_ub | float | No | No | The upper bound of the calibrated 95% confidence interval of the relative risk. |
| calibrated_p | float | No | No | The calibrated two-sided p-value. |
| calibrated_one_sided_p | float | No | No | The calibrated one-sided p-value considering the null hypothesis of no effect. |
| calibrated_log_rr | float | No | No | The log of the calibrated relative risk. |
| calibrated_se_log_rr | float | No | No | The standard error of the log of the calibrated relative risk. |
| database_id | varchar | Yes | No | Foreign key referencing the database. |

2.16 Table sccs_spline

| Field | Type | Key | Min. count | Description |
|--------------------------|---------|-----|------------|--|
| analysis_id | int | Yes | No | A foreign key referencing the sccs_analysis table. |
| exposures_outcome_set_id | int | Yes | No | A foreign key referencing the sccs_exposures_outcome_set table. |
| database_id | varchar | Yes | No | Foreign key referencing the database. |
| spline_type | varchar | Yes | No | Either 'age', 'season', or 'calendar time'. |
| knot_month | float | Yes | No | Location of the knot. For age, the month since birth. For season, the month of the year. |
| rr | float | No | No | The estimated relative risk (i.e. the incidence rate ratio). |

2.17 Table sccs_time_to_event

| Field | Type | Key | Min. count | Description |
|--------------------------|---------|-----|------------|--|
| analysis_id | int | Yes | No | A foreign key referencing the sccs_analysis table. |
| exposures_outcome_set_id | int | Yes | No | A foreign key referencing the sccs_exposures_outcome_set table. |
| database_id | varchar | Yes | No | Foreign key referencing the database. |
| era_id | int | Yes | No | A foreign key referencing the sccs_era table. The identifier for the era. |
| week | int | Yes | No | The number of the week relative to exposure. Week 0 starts on the day of exposure. |
| observed_subjects | int | No | Yes | The number of people observed during the week. |
| outcomes | int | No | Yes | The number of outcomes observed during the week. |

2.18 Table `sccs_time_trend`

| Field | Type | Key | Min. count | Description |
|---------------------------------------|---------|-----|------------|---|
| <code>analysis_id</code> | int | Yes | No | A foreign key referencing the <code>sccs_analysis</code> table. |
| <code>exposures_outcome_set_id</code> | int | Yes | No | A foreign key referencing the <code>sccs_exposures_outcome_set</code> table. |
| <code>database_id</code> | varchar | Yes | No | Foreign key referencing the database. |
| <code>calendar_year</code> | int | Yes | No | The calendar year (e.g. 2022). |
| <code>calendar_month</code> | int | Yes | No | The calendar month (e.g. 1 for January). |
| <code>observed_subjects</code> | int | No | Yes | Number of people observed during the month. |
| <code>ratio</code> | float | No | No | Observed over expected ratio, where the expected count assumes no trend. |
| <code>adjusted_ratio</code> | float | No | No | Observed over expected ratio, where the expected count is adjusted for age, season, or calendar time. |
| <code>outcome_rate</code> | float | No | Yes | Number of outcomes divided by the number of subjects. |
| <code>adjusted_rate</code> | float | No | Yes | The outcome rate, adjusted for age, season, or calendar time. |
| <code>stable</code> | int | No | No | Does the adjusted rate not deviate significantly from the mean? |
| <code>p</code> | float | No | No | The two-sided p-value against the null hypothesis that the rate is stable. |