Study protocol

Based on the HARPER template

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Research question and objectives

Protocol version

Contributors

Primary investigator contact information:

Contributor names:

Study registration

Site:

Identifier:

Sponsor

Organization:

Contact:

Conflict of interest

Table 1: **?(caption)**

Milestone	Date
<Milestone description>	<Date>
<Milestone description>	<Date>
<Milestone description>	<Date>

Abstract

Amendments and updates

Version date	Version number	Section of protocol	Amendment or update	Reason
<Date of the protocol version change>	<Number or other identifier for the protocol version>	<Brief text description of which sections of the protocol were amended>	<Brief text description of what changes were involved with the protocol amendment>	<Brief text description of the rationale for the protocol amendment>

Milestones

Rationale and background

What is known about the condition:

What is known about the exposure of interest:

Gaps in knowledge:

What is the expected contribution of this study?

The purpose of this protocol is to describe the emulation of trial INSERT TRIAL NAME. The primary trial estimate targeted for emulation is INSERT. Market availability of EXPOSURE began DATE.

Research question and objectives

Research methods

Study design

Research design (e.g. cohort, case-control, etc.):

Rationale for study design choice:

Study design diagram

Setting

Context and rationale for definition of time 0 (and other primary time anchors) for entry to the study population

Context and rationale for study inclusion criteria

Context and rationale for study exclusion criteria

Variables

Context and rationale for exposure(s) of interest

Algorithm to define duration of exposure effect:

Table 2: **?(caption)**

Study element	Specification
Objective:	<Text>
Hypothesis:	<Text>
Population (mention key inclusion-exclusion criteria):	<Text>
Exposure:	<Text>
Comparator:	<Text>
Outcome:	<Text>
Time (when follow up begins and ends):	<Text>
Setting:	<Text>
Main measure of effect:	<Text>

Study element	Specification
Objective:	<Text>
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Exposure:	<Text>
Comparator:	<Text>
Outcome:	<Text>
Time (when follow up begins and ends):	<Text>
Setting:	<Text>
Main measure of effect:	<Text>

Table 3: **?(caption)**

Study population name(s)	Time Anchor Description (e.g. time 0)	Number of entries	Type of entry	Washout window	Care setting	Code type	Diagnosis position	Incident with respect to...	Measurement characteristics/validation	Source of algorithm

Table 4: **?(caption)**

Criterion	Details	Order of application	Assessment window	Care settings	Code Type	Diagnosis position	Applied to study populations:	Measurement characteristics/validation	Source of algorithm

Table 5: **?(caption)**

Criterion	Details	Order of application	Assessment window	Care settings	Code Type	Diagnosis position	Applied to study populations:	Measurement characteristics/validation	Source of algorithm

Table 6: **?(caption)**

Exposure group name(s)	Details	Washout window	Assessment window	Care settings	Code Type	Diagnosis position	Applied to study populations:	Incident with respect to...	Measurement characteristics/validation	Source of algorithm

Table 7: **?(caption)**

Outcome name	Details	Primary outcome?	Type of outcome	Washout window	Care settings	Code Type	Diagnosis position	Applied to study populations:	Measurement characteristics/validation	Source of algorithm

Table 8: **?(caption)**

Time point	Select all that apply	Specify
Follow up start	NA	NA
Follow up end	NA	NA
Date of outcome	NA	NA
Date of death	NA	NA
End of observation in data	NA	NA
Day X following index date	NA	NA
End of study period	NA	NA
End of exposure	NA	NA
Date of add to/switch from exposure	NA	NA
Other date	NA	NA

Table 9: **?(caption)**

Characteristic	Details	Type of variable	Assessment window	Care settings	Code Type	Diagnosis position	Applied to study populations:	Measurement characteristics/validation	Source of algorithm

Table 10: **?(caption)**

Analysis element	Specification
Hypothesis:	<Text>
Exposure contrast:	<Text>
Outcome:	<Text>
Analytical software	<Text>
Model(s):	<Text>
Conofunding adjustment method	Name method and provide relevant details, e.g. bivariate, multivariable, propensity score matching (specify matching algorithm ratio and caliper), propensity score weighting (specify weight formula, trimming, truncation), propensity score stratification (specify strata definition), other
Missing data methods	Name method and provide relevant details, e.g. missing indicators, complete case, last value carried forward, multiple imputation (specify model/variables), other.
Subgroup Analyses	List all subgroups

Analysis element	Specification
Hypothesis:	<Text>
Exposure contrast:	<Text>
Outcome:	<Text>
Analytical software	<Text>
Model(s):	<Text>
Conofunding adjustment method	Name method and provide relevant details, e.g. bivariate, multivariable, propensity score matching (specify matching algorithm ratio and caliper), propensity score weighting (specify weight formula, trimming, truncation), propensity score stratification (specify strata definition), other
Missing data methods	Name method and provide relevant details, e.g. missing indicators, complete case, last value carried forward, multiple imputation (specify model/variables), other.
Subgroup Analyses	List all subgroups

Context and rationale for outcome(s) of interest

Context and rationale for follow up

Context and rationale for covariates (confounding variables and effect modifiers, e.g. risk factors, comorbidities, comedications)

Data analysis

Context and rationale for analysis plan

A. Primary analysis

Table 11: **?(caption)**

Analysis	What is being varied?	Why (expected learning)?	Strengths of the sensitivity analysis compared to primary	Limitations of the sensitivity analysis compared to primary
<Text>	<Text>	<Text>	<Text>	<Text>

Data sources

Context and rationale for data sources

Reason for selection:

Strengths of data source(s):

Limitations of data source(s):

Data source provenance/curation:

Data management

Quality control

Study size and feasibility

Limitation of the methods

Protection of human subjects

Reporting of adverse events

References

Appendices

Change log

Detailed change log based on previous commits.

Table 12: **?(caption)**

Data element	Data 1	Data 2	Data 3
Data Sources:	<Text>	<Text>	<Text>
Study Period:	<Text>	<Text>	<Text>
Eligibile Cohort Entry Period:	<Text>	<Text>	<Text>
Data version (or date of last update):	<Text>	<Text>	<Text>
Data sampling/extraction criteria:	<Text>	<Text>	<Text>
Type(s) of data:	<Text>	<Text>	<Text>
Data linkage	<Text>	<Text>	<Text>
Conversion to CDM:	<Text>	<Text>	<Text>
Software for data management:	<Text>	<Text>	<Text>

```
Sun, 16 Apr 2023 19:20:26 -0400
Changes made by: jweberpals@bwh.harvard.edu
Commit hash:  f0bde2b
Changes made: first HARPER draft; TODO: Tables in pdf

Sun, 16 Apr 2023 19:12:50 -0400
Changes made by: jweberpals@bwh.harvard.edu
Commit hash:  34b0c71
Changes made: initial commit
```