Package: iDOVE (via r-universe)

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Type Package

Title Durability of Vaccine Efficacy Against SARS-CoV-2 Infection

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Description Implements a nonparametric maximum likelihood method for assessing potentially time-varying vaccine efficacy (VE) against SARS-CoV-2 infection under staggered enrollment and time-varying community transmission, allowing crossover of placebo volunteers to the vaccine arm. Lin, D. Y., Gu, Y., Zeng, D., Janes, H. E., and Gilbert, P. B. (2021) <doi:10.1093/cid/ciab630>.

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VignetteBuilder utils, knitr

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LinkingTo Rcpp, RcppArmadillo

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`idove` *Durability of Vaccine Efficacy Against Asymptomatic SARS-CoV-2 Infection*

Description

Assesses potentially time-varying vaccine efficacy (VE) against SARS-CoV-2 infection under staggered enrollment and time-varying community transmission, allowing crossover of placebo volunteers to the vaccine arm. The infection time data are interval-censored, and the log hazard ratio is assumed to be a piece-wise linear function of time.

Usage

```
idove(
  formula,
  data,
  constantVE = FALSE,
  plots = TRUE,
  changePts = NULL,
  timePts = NULL,
  tol = 1e-04,
  maxit = 2000
)
```

Arguments

`formula`	A formula object, with all of the time variables on the left hand side of a '~' operator and the covariates on the right. The time variables must be specified through the intCens() function. See ?intCens and Details for further information.
`data`	A data.frame object. The data.frame in which to interpret the variable names in formula. Must contain the entry time, the left interval time, the right interval time, the vaccination time, and any covariates. See Details.
`constantVE`	A logical object. If FALSE (default), VE is assumed to be potentially waning after the last change point; otherwise it is assumed to be constant after the last change point.
`plots`	A logical object. If TRUE (default), plots of the estimated VE in reducing attack rate, the estimated VE in reducing the hazard rate, and their 95% confidence intervals will be automatically generated. If FALSE, plots will not be generated.

changePts	An integer vector object or NULL. The potential change points (in days) of the piece-wise log-linear hazard ratio. See Details for further information. If NULL, the Akaike information criterion (AIC) will be used to select one change point from {28, 35, 42, 49, 56} (weeks 4, 5, 6, 7, 8).
timePts	An integer vector object or NULL. The endpoints (in days) of the time periods for which the VE in reducing the attack rate are to be estimated. The estimated VE in reducing the hazard rate at these endpoints are also returned. If NULL, a default sequence $t_1, 2t_1, 3t_1, \ldots$ will be used, where t_1 is the first change point. The sequence ends at the maximum of the left and and right ends of the time intervals from all participants. This input is ignored when constantVE = TRUE.
tol	A numeric scalar object. The convergence threshold for the EM algorithm. The default value is 0.0001.
maxit	A positive integer object. The maximum number of iterations for the EM algorithm. The default value is 2000.

Details

The information required for an analysis is

Entry Time: The time when the participant enters the trial in whole units days.

Left Interval Time: The last examination time when the test is negative in whole units days.

Right Interval Time: The first examination time when the test is positive in whole units days. If the participant does not test positive during the trial, use NA or Inf.

Vaccination Time: The time when vaccination takes place in whole units days. If the participant is not vaccinated during the trial, use NA or Inf.

Covariates: Baseline covariates (e.g., priority group, age, ethnicity).

The covariates can include categorical variables, for which all other categories are compared to the first category. A model without covariates is also allowed.

Note that all of the time variables are measured from the start of the clinical trial and are specified in whole units of days. Though they need not be provided as integer, all non-NA and finite values must be able to be cast as integers without loss of information. For each individual, the entry_time and left_time should satisfy entry_time $\leq$ left_time. For each individual that tests positive, entry_time $\leq$ left_time $\leq$ right_time. For each individual that is vaccinated, entry_time $\leq$ vaccination_time.

The general structure of the formula input is

```
intCens(entry_time, left_time, right_time, vaccination_time) ~ covariates
```

The left-hand side contains all of the time information. It must be specified through function 'intCens()'. Specifically,

```
intCens(entry_time, left_time, right_time, vaccination_time)
```

If entry_time > left_time, or left_time > right_time, the case will be removed from the analysis and a message will be generated.

The special case of right-censored data is implemented by dove2() in the DOVE package available through CRAN.

Value

An S3 object of class iDOVE containing a list with elements

`call`	The unevaluated call.
`changePts`	The changePts of the analysis.
`covariates`	A matrix containing the estimated (log) hazard ratio of each covariate, together with the estimated standard error, the 95% confidence intervals, and the two-sided p-value for testing no covariates effect. NA if only an intercept is given as the right hand side in input formula.
`vaccine`	A list containing one or three elements, depending on the value of constantVE. If constantVE = TRUE, the only element is named 'VE' and is a vector containing the estimate of constant VE, its standard error estimate, and the 95% confidence interval. If constantVE = FALSE, three matrices are returned. The first matrix named 'VE_a' contains the estimates of the VE in reducing the attack rate at all time points given in timePts, together with the 95% confidence intervals. The second matrix named 'VE_h' contains the estimates of the VE in reducing the hazard rate at timePts. The third matrix named 'VE_period' contains the estimates of VE in reducing the attack rate over successive time periods according to timePts, together with the 95% confidence intervals.

References

Lin, D-Y, Gu, Y., Zeng, D., Janes, H. E., and Gilbert, P. B. (2021). Evaluating Vaccine Efficacy Against SARS-CoV-2 Infection. Clinical Infectious Diseases, ciab630, https://doi.org/10.1093/cid/ciab630

Examples

```
data(idoveData)

set.seed(1234)
smp <- sample(1L:nrow(x = idoveData), size = 250L)

# NOTE: This sample size is chosen for example only -- larger data sets
# should be used.
# See the vignette for a full analysis of the idoveData dataset

# Fit the model with default settings
idove(formula = intCens(entry.time, left.time, right.time, vaccine.time) ~ 1,
      data = idoveData[smp,])

# Specify Week 4 as the change point
# Assume a potentially waning VE after 4 weeks
# Estimate VE_a over 0-4, 4-16, 16-28, 28-40 weeks
idove(formula = intCens(entry.time, left.time, right.time, vaccine.time) ~ 1,
      data = idoveData[smp,],
      changePts = 4*7,
      timePts = c(4, 16, 28, 40)*7)

# Specify multiple change points at Weeks 4 and 8
# Assume a constant VE after 8 weeks
```

```
idove(formula = intCens(entry.time, left.time, right.time, vaccine.time) ~ 1,
      data = idoveData[smp,],
      changePts = c(4, 8)*7,
      constantVE = TRUE)
```

`idoveData` *Toy Dataset For Illustration*

Description

This data set is provided for the purposes of illustrating the use of the software. It was simulated under a blinded, priority-tier dependent crossover design.

Usage

```
data(idoveData)
```

Format

idoveData is a data.frame containing 40,000 participants. The data.frame contains 6 columns,

entry.time The entry time in days.

left.time The left end of the time interval in days.

right.time The right end of the time interval in days.

vaccine.time The time of vaccination in days.

priority A composite baseline risk score taking values 1-5.

sex A binary indicator of sex (male/female).

`intCens` *Specify Time Variables*

Description

This function is used in the model statement of idove() to specify the entry time, left interval time, right interval time, and vaccination time.

Usage

```
intCens(entry_time, left_time, right_time, vaccination_time)
```

Arguments

entry_time	The variable for the time when the participant enters the trial. Entry times must be integer (or be able to be cast as integer without loss of information), non-negative, and complete.
left_time	The variable for the last examination time when the test is negative. Left interval times must be integer (or be able to be cast as integer without loss of information), non-negative, and complete.
right_time	The variable for the first examination time when the test is positive. Right interval times must be integer (or be able to be cast as integer without loss of information), non-negative, and NA or Inf should be used if the participant never tested positive during the trial.
vaccination_time	The variable for the time when vaccination takes place. Vaccination times must be integer (or be able to be cast as integer without loss of information), non-negative, and NA or Inf should be used if the participant was not vaccinated during the trial.

Details

Times must obey the following relationships: (i) For all participants, entry_time <= left_time; (ii) For all participants that tested positive during the trial, entry_time <= left_time <= right_time; and (iii) For all participants that received vaccination, entry_time <= vaccination_time. If a case is found to violate one or more of these relationships, its entry_time is set to NA.

Value

This function is intended to be used only in the model statement of idove(). The result, a matrix, is used internally.

---

plot *Plot Estimated Vaccine Efficacy*

Description

Generates plots of the estimated vaccine efficacy in reducing attack rate, the estimated vaccine efficacy in reducing the hazard rate, and their 95% confidence intervals.

Usage

```
## S3 method for class 'iDOVE'
plot(x, ...)
```

Arguments

x	An iDOVE object. The value object returned by idove().
...	ignored

Value

No return value, called to produce graphical elements.

Examples

```
data(idoveData)

set.seed(1234)
smp <- sample(1L:nrow(x = idoveData), size = 250L)

# NOTE: This sample size is chosen for example only -- larger data sets
# should be used.
# See the vignette for a full analysis of the idoveData dataset

# Fit the model with default settings
result <- idove(formula = intCens(entry.time, left.time, right.time, vaccine.time) ~ 1,
                data = idoveData[smp,])

plot(x = result)
```

---

print *Print the Primary Results of an idove() Analysis*

Description

Print the primary results of an idove() analysis.

Usage

```
## S3 method for class 'iDOVE'
print(x, ...)
```

Arguments

x	An iDOVE object. The value object returned by a call to idove()
...	ignored

Value

No return value, called to display key results.

Examples

```
data(idoveData)

set.seed(1234)
smp <- sample(1L:nrow(x = idoveData), size = 250L)

# NOTE: This sample size is chosen for example only -- larger data sets
# should be used.
# See the vignette for a full analysis of the idoveData dataset

# Fit the model with default settings
result <- idove(formula = intCens(entry.time, left.time, right.time, vaccine.time) ~ 1,
                data = idoveData[smp,])

print(x = result)
```

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