

Official Title: Value-based Formulary-Essentials: Testing and Expanding on Value in Prescription

Drug Benefit Design

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Aim 1 Statistical Analysis Plan

Aim 1: Assess impact of VBF-e on the use of medications.

Study Design: Difference in Differences

Study Period: Jan 1st, 2015 – December 31st, 2019

Unit of Analysis: per member month

Analytic Sample: Premera Blue Cross beneficiaries less than 65 years of age

Censoring Events:

Month at which an individual:

- disenrolled for more than 1 month during study period
- turned 65 years of age

Administrative censoring at:

- end of study period (December 31st, 2019)

Administrative left truncation at:

- 24 months prior to index date

Exclusion criteria:

Exclude individuals with:

- missing gender information
- missing zip code level demographics at all member months

Inclusion criteria:

Individuals:

- aged 0-64
- Continuously enrolled in an employer-sponsored health plan for at least 12 months (with one-month allowable gap) prior to the index date
 - For individuals in the exposed group, the index date is defined as the start date of value-based formulary implementation at the employer group level
 - For individuals in the control group, the index date is defined as the index date of the matched exposed individual

Employer groups:

- that transition to the value-based formulary if they transitioned **all** enrollees in that employer group (no individual selection)

Outcomes:

Primary outcome(s): change in area under the curve one year after index date for all outcomes

Secondary outcome(s): change in area under the curve 2 and 3 years after index date for all outcomes

Actual outcome list:

Days supply of medications.

Exposure: VBF-E4 and non-VBF-E4

Covariates:

Adjustment variables:

Covariates	Time of Measurement	Notes	Specification
Gender	Month before E4 transition = index time		Indicator
Age	Index time	Centered	Continuous
Relationship to contract holder	Index time		Categorical <ul style="list-style-type: none">Contract Holder,Dependent,Spouse/Domestic Partner)
ACS	Index time (or closest to this)	For individuals with missing ACS variables at index time, set to closest observed value.	Quintile
Percent 25 years old or older with a bachelor's degree			Quintile
Median household income			Quintile
Population size			Quintile
Percent White			Quintile
Funding Type	Index time		Categorical (self, full)
Elixhauser	12 months prior to transition time		Categorical variable <ul style="list-style-type: none">01>=2
Time from index date	At all observations	0 = index time, 1 = E4 transition month	Continuous (-23 to 36)
Post	At all observations	Indicator for post period	indicator

Seasonality	At all observations	Adjust for calendar year and separately adjust for calendar month	Categorical (1 through 12 for elig_mth) and (2015 through 2019 for elig_yr)
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Effect Modifiers: None.

Exploratory Data Analysis:

- Plot outcomes across time across all index times
- 12-month enrollment for patient member months
- Histogram of age
- Univariate statistics, bivariate
- Conduct a Table 1
- Loss to follow-up

Statistical Analyses:

We will use a DID approach^{1,2} to study the impact of the E4 transition and generalized linear models to model the impact of the E4 transition via changes in outcomes. Time will be anchored at the month prior to the transition (e.g., index time is set to the month prior to the transition) for the E4 group. Each of the E4 transition members will be matched to two controls via propensity score methods. Non-E4 transition members will be assigned to an index date corresponding to their E4 transition match. We will not adjust for the matching in our models³.

To match controls to E4 members, we will model the propensity score based on covariates we believe may be related to exposure: Gender, ACS Population Size, ACS Household Income in past 12 months, ACS Percent 25 years and older with a Bachelor's degree, ACS Percent White, and Year of birth. Then, we will obtain the log odds (logit) of the fitted values (e.g., estimates) of the propensity score for everyone (both E4 and possible controls) and order the log odds of the treatment (E4) group from largest to smallest (in decreasing order). For each E4 member, we will find the two nearest neighbor controls, e.g., the controls with the closest propensity score to that of the E4 individual with 12 months of continuous prior enrollment at the E4 individual's index date. After completing matching, we will check for covariate balance across groups based on the standardized mean differences and Kolmogorov–Smirnov statistic.

To address the zero-inflated and right skewed nature of the outcomes, we will use a two part-model. In the first stage of the two-part model, we will estimate the probability of the response being greater than zero and in the second stage we will model the non-zero portion. We will choose the most appropriate mean-variance relationship by performing goodness-of-fit tests (Pearson's correlation, Pregibon link, modified Park, and modified Hosmer-Lemeshow tests)^{4,5} on the outcomes. We will assume independence in the mean modeling to estimate the area under the curve change at 1 (primary), 2 and 3 years after index, and use the cluster bootstrap to obtain standard errors that account for repeated measurements within an individual (clustering on the individual level). We will adjust for individual-level (age, gender, and Elixhauser comorbidity score) and census ZIP-code level characteristics (educational attainment, median household income, race/ethnicity and urban residence) in all models.

Model:

Denote spending for member i at time t as y_{it} , with $i \in \{1, \dots, N\}$, $t \in \{-23, \dots, 0, \dots, 36\}$, and N the number of members. Let M be the number of covariates included in the model and $x_{m,it}$ denote the m^{th} covariate for member i at month t .

Then the two-stage model is:

$$\begin{aligned} p_{it} &\sim \text{Bernoulli}(\theta_{it}), \\ \text{logit}(\theta_{it}) &= \alpha_0 + \sum_{m=1}^M \alpha_m x_{m,it}, \\ (y_{it} \mid y_{it} > 0) &\sim \text{Poisson}(\mu_{it}), \quad \text{and} \\ \mu_{it} &= E(y_{it} \mid y_{it} > 0, X_i), \end{aligned}$$

where X_i is the matrix for all observed covariates for member i . We model the mean, μ_{it} , as

$$\log(\mu_{it}) = \beta_0 + \sum_{m=1}^M \beta_m x_{m,it}.$$

We suppose,

$$\begin{aligned} \sum_{m=1}^M \alpha_m x_{m,it} &= \alpha_1 E4_i + \alpha_2 post_{it} + \alpha_3 month_{it} + \alpha_4 E4_i * post_{it} + \alpha_5 E4_i * month_{it} + \\ &\alpha_6 post_{it} * month_{it} + \alpha_7 E4_i * post_{it} * month_{it} + \alpha_8 Age_i + \\ &\alpha_9 Gender_i + \alpha_{10} Elixhauser_i + \alpha_{11} Relationship_i + \\ &\alpha_{12} FundingType_i + \alpha_{13} ACSPopulation_i + \alpha_{14} ACSIncome_i + \\ &\alpha_{15} ACSPercentWhite_i + \alpha_{16} ACSEducation_i, \end{aligned}$$

and

$$\begin{aligned} \sum_{m=1}^M \beta_m x_{m,it} &= \beta_1 E4_i + \beta_2 post_{it} + \beta_3 month_{it} + \beta_4 E4_i * post_{it} + \beta_5 E4_i * month_{it} + \\ &\beta_6 post_{it} * month_{it} + \beta_7 E4_i * post_{it} * month_{it} + \beta_8 Age_i + \\ &\beta_9 Gender_i + \beta_{10} Elixhauser_i + \beta_{11} Relationship_i + \\ &\beta_{12} FundingType_i + \beta_{13} ACSPopulation_i + \beta_{14} ACSIncome_i + \\ &\beta_{15} ACSPercentWhite_i + \beta_{16} ACSEducation_i, \end{aligned}$$

for member i where:

- $E4_i$ = indicator of whether the i^{th} member is enrolled in VBF-E4
- $post_{it}$ = indicator of whether the i^{th} member is in the post index period, $t \geq 1$
- $month_{it}$ = time in months from the i^{th} members index date
- Age_i = centered age for the i^{th} member at index
- $Gender_i = i^{\text{th}}$ members gender at index
- $Elixhauser_i$ = Elixhauser comorbidity score for member i at index
- $Relationship_i = i^{\text{th}}$ members relationship to contract holder at index
- $FundingType_i = i^{\text{th}}$ members funding type at index
- $ACSPopulation_i$ = ACS population at the zip code level for member i at index

- $ACSIIncome_i$ = ACS median household income in the prior 12 months at zip code level for member i at index
- $ACSPercentWhite_i$ = ACS percent of white people at the zip code level for member i at index
- $ACSEducation_i$ = ACS percent of people 25 years or older with a Bachelor's degree in the prior 12 months at the zip code level for member i at index

Missing Data:

Complete-case analyses.

Aim 2 Statistical Analysis Plan

Aim 2: Assess impact of VBF-e on patient out-of-pocket spending and health plan spending for prescription drugs and non-drug medical care.

Study Design: Difference in Differences

Study Period: Jan 1st, 2015 – December 31st, 2019

Unit of Analysis: per member month

Analytic Sample: Premera Blue Cross beneficiaries less than 65 years of age

Censoring Events:

Month at which an individual:

- disenrolled for more than 1 month during study period
- turned 65 years of age

Administrative censoring at:

- end of study period (December 31st, 2019)

Administrative left truncation at:

- 24 months prior to index date

Exclusion criteria:

Exclude individuals with:

- missing gender information
- missing zip code level demographics at all member months

Inclusion criteria:

Individuals:

- aged 0-64
- Continuously enrolled in an employer-sponsored health plan for at least 12 months (with one-month allowable gap) prior to the index date
 - For individuals in the exposed group, the index date is defined as the start date of value-based formulary implementation at the employer group level
 - For individuals in the control group, the index date is defined as the index date of the matched exposed individual

Employer groups:

- that transition to the value-based formulary if they transitioned **all** enrollees in that employer group (no individual selection)

Outcomes:

Primary outcome(s): change in area under the curve one year after index date for all outcomes

Secondary outcome(s): change in area under the curve 2 and 3 years after index date for all outcomes

Actual outcome list:

Total spending for prescription drugs

Patient out-of-pocket spending for prescription drugs

Health plan spending for prescription drugs

Total healthcare spending

Total health plan and patient spending for vision

Exposure: VBF-E4 and non-VBF-E4

Covariates:

Adjustment variables:

Covariates	Time of Measurement	Notes	Specification
Gender	Month before E4 transition = index time		Indicator
Age	Index time	Centered	Continuous
Relationship to contract holder	Index time		Categorical <ul style="list-style-type: none">Contract Holder,Dependent,Spouse/Domestic Partner)
ACS	Index time (or closest to this)	For individuals with missing ACS variables at index time, set to closest observed value.	Quintile
Percent 25 years old or older with a bachelor's degree			Quintile
Median household income			Quintile
Population size			Quintile
Percent White			Quintile
Funding Type	Index time		Categorical (self, full)
Elixhauser	12 months prior to transition time		Categorical variable <ul style="list-style-type: none">01

			• ≥ 2
Time from index date	At all observations	0 = index time, 1 = E4 transition month	Continuous (-23 to 36)
Post	At all observations	Indicator for post period	indicator
Seasonality	At all observations	Adjust for calendar year and separately adjust for calendar month	Categorical (1 through 12 for elig_mth) and (2015 through 2019 for elig_yr)

Effect Modifiers: None.

Exploratory Data Analysis:

- Plot outcomes across time across all index times
- 12-month enrollment for patient member months
- Histogram of age
- Univariate statistics, bivariate
- Conduct a Table 1
- Loss to follow-up

Statistical Analyses:

We will use a DID approach^{1,2} to study the impact of the E4 transition and generalized linear models to model the impact of the E4 transition via changes in outcomes. Time will be anchored at the month prior to the transition (e.g., index time is set to the month prior to the transition) for the E4 group. Each of the E4 transition members will be matched to two controls via propensity score methods. Non-E4 transition members will be assigned to an index date corresponding to their E4 transition match. We will not adjust for the matching in our models³.

To match controls to E4 members, we will model the propensity score based on covariates we believe may be related to exposure: Gender, ACS Population Size, ACS Household Income in past 12 months, ACS Percent 25 years and older with a Bachelor's degree, ACS Percent White, and Year of birth. Then, we will obtain the log odds (logit) of the fitted values (e.g., estimates) of the propensity score for everyone (both E4 and possible controls) and order the log odds of the treatment (E4) group from largest to smallest (in decreasing order). For each E4 member, we will find the two nearest neighbor controls, e.g., the controls with the closest propensity score to that of the E4 individual with 12 months of continuous prior enrollment at the E4 individual's index date. After completing matching, we will check for covariate balance across groups based on the standardized mean differences and Kolmogorov–Smirnov statistic.

To address the zero-inflated and right skewed nature of the cost outcomes, we will use a two part-model. In the first stage of the two-part model, we will estimate the probability of the response being greater than zero and in the second stage we will model the non-zero portion. We will choose the most appropriate mean-variance relationship by performing goodness-of-fit tests (Pearson's correlation, Pregibon link, modified Park, and modified Hosmer-Lemeshow tests)^{4,5} on the primary cost outcome. We will assume independence in the mean modeling to estimate the area under the curve change at 1 (primary), 2 and 3 years after index, and use the cluster bootstrap to obtain standard errors that account for repeated measurements within an individual (clustering on the individual level). We will adjust for

individual-level (age, gender, and Elixhauser comorbidity score) and census ZIP-code level characteristics (educational attainment, median household income, race/ethnicity and urban residence) in all models.

Model:

Denote spending for member i at time t as y_{it} , with $i \in \{1, \dots, N\}$, $t \in \{-23, \dots, 0, \dots, 36\}$, and N the number of members. Let M be the number of covariates included in the model and $x_{m,it}$ denote the m^{th} covariate for member i at month t .

Then the two-stage model is:

$$p_{it} \sim \text{Bernoulli}(\theta_{it}),$$

$$\text{logit}(\theta_{it}) = \alpha_0 + \sum_{m=1}^M \alpha_m x_{m,i},$$

$$(y_{it} \mid y_{it} > 0) \sim \text{Gamma}(a, b_{it}),$$

with a as the shape parameter and b as the rate parameter of the Gamma distribution, and

$$\mu_{it} = E(y_{it} \mid y_{it} > 0, X_i) = \frac{a}{b_{it}},$$

where X_i is the matrix for all observed covariates for member i . We model the mean, μ_{it} , as

$$\log(\mu_{it}) = \beta_0 + \sum_{m=1}^M \beta_m x_{m,it}.$$

We suppose,

$$\begin{aligned} \sum_{m=1}^M \alpha_m x_{m,it} = & \alpha_1 E4_i + \alpha_2 post_{it} + \alpha_3 month_{it} + \alpha_4 E4_i * post_{it} + \alpha_5 E4_i * month_{it} + \\ & \alpha_6 post_{it} * month_{it} + \alpha_7 E4_i * post_{it} * month_{it} + \alpha_8 Age_i + \\ & \alpha_9 Gender_i + \alpha_{10} Elixhauser_i + \alpha_{11} Relationship_i + \\ & \alpha_{12} FundingType_i + \alpha_{13} ACSPopulation_i + \alpha_{14} ACSIncome_i + \\ & \alpha_{15} ACSPercentWhite_i + \alpha_{16} ACSEducation_i, \end{aligned}$$

and

$$\begin{aligned} \sum_{m=1}^M \beta_m x_{m,it} = & \beta_1 E4_i + \beta_2 post_{it} + \beta_3 month_{it} + \beta_4 E4_i * post_{it} + \beta_5 E4_i * month_{it} + \\ & \beta_6 post_{it} * month_{it} + \beta_7 E4_i * post_{it} * month_{it} + \beta_8 Age_i + \\ & \beta_9 Gender_i + \beta_{10} Elixhauser_i + \beta_{11} Relationship_i + \\ & \beta_{12} FundingType_i + \beta_{13} ACSPopulation_i + \beta_{14} ACSIncome_i + \\ & \beta_{15} ACSPercentWhite_i + \beta_{16} ACSEducation_i, \end{aligned}$$

for member i where:

- $E4_i$ = indicator of whether the i^{th} member is enrolled in VBF-E4
- $post_{it}$ = indicator of whether the i^{th} member is in the post index period, $t \geq 1$

- $month_{it}$ = time in months from the i^{th} members index date
- Age_i = centered age for the i^{th} member at index
- $Gender_i = i^{th}$ members gender at index
- $Elixhauser_i$ = Elixhauser comorbidity score for member i at index
- $Relationship_i = i^{th}$ members relationship to contract holder at index
- $FundingType_i = i^{th}$ members funding type at index
- $ACSPopulation_i$ = ACS population at the zip code level for member i at index
- $ACSIIncome_i$ = ACS median household income in the prior 12 months at zip code level for member i at index
- $ACSPercentWhite_i$ = ACS percent of white people at the zip code level for member i at index
- $ACSEducation_i$ = ACS percent of people 25 years or older with a Bachelor's degree in the prior 12 months at the zip code level for member i at index

Missing Data:

Complete-case analyses.

Aim 3 Statistical Analysis Plan

Aim 3: Assess impact of VBF-e on the number of emergency department visits, number of outpatient visits, and number of days in hospital.

Study Design: Difference in Differences

Study Period: Jan 1st, 2015 – December 31st, 2019

Unit of Analysis: per member month

Analytic Sample: Premera Blue Cross beneficiaries less than 65 years of age

Censoring Events:

Month at which an individual:

- disenrolled for more than 1 month during study period
- turned 65 years of age

Administrative censoring at:

- end of study period (December 31st, 2019)

Administrative left truncation at:

- 24 months prior to index date

Exclusion criteria:

Exclude individuals with:

- missing gender information
- missing zip code level demographics at all member months

Inclusion criteria:

Individuals:

- aged 0-64
- Continuously enrolled in an employer-sponsored health plan for at least 12 months (with one-month allowable gap) prior to the index date
 - For individuals in the exposed group, the index date is defined as the start date of value-based formulary implementation at the employer group level
 - For individuals in the control group, the index date is defined as the index date of the matched exposed individual

Employer groups:

- that transition to the value-based formulary if they transitioned **all** enrollees in that employer group (no individual selection)

Outcomes:

Primary outcome(s): change in area under the curve one year after index date for all outcomes

Secondary outcome(s): change in area under the curve 2 and 3 years after index date for all outcomes

Actual outcome list:

Number of emergency department visits

Number of days in hospital

Number of outpatient visits

Exposure: VBF-E4 and non-VBF-E4

Covariates:

Adjustment variables:

Covariates	Time of Measurement	Notes	Specification
Gender	Month before E4 transition = index time		Indicator
Age	Index time	Will be centered.	Continuous
Relationship to contract holder	Index time		Categorical <ul style="list-style-type: none">Contract Holder,Dependent,Spouse/Domestic Partner)
ACS	Index time (or closest to this)	For individuals with missing ACS variables at index time, set to closest observed value.	Quintile
Percent 25 years old or older with a bachelor's degree			Quintile
Median household income			Quintile
Population size			Quintile
Percent White			Quintile
Funding Type	Index time		Categorical (self, full)
Elixhauser	12 months prior to transition time		Categorical variable <ul style="list-style-type: none">01>=2
Time from index date	At all observations	0 = index time, 1 = E4 transition month	Continuous (-23 to 36)

Post	At all observations	Indicator for post period	indicator
Seasonality	At all observations	Adjust for calendar year and separately adjust for calendar month	Categorical (1 through 12 for elig_mth) and (2015 through 2019 for elig_yr)

Effect Modifiers: None.

Exploratory Data Analysis:

- Plot outcomes across time across all index times
- 12-month enrollment for patient member months
- Histogram of age
- Univariate statistics, bivariate
- Conduct a Table 1
- Loss to follow-up

Statistical Analyses:

We will use a DID approach^{1,2} to study the impact of the E4 transition and generalized linear models to model the impact of the E4 transition via changes in outcomes. Time will be anchored at the month prior to the transition (e.g., index time is set to the month prior to the transition) for the E4 group. Each of the E4 transition members will be matched to two controls via propensity score methods. Non-E4 transition members will be assigned to an index date corresponding to their E4 transition match. We will not adjust for the matching in our models³.

To match controls to E4 members, we will model the propensity score based on covariates we believe may be related to exposure: Gender, ACS Population Size, ACS Household Income in past 12 months, ACS Percent 25 years and older with a Bachelor's degree, ACS Percent White, and Year of birth. Then, we will obtain the log odds (logit) of the fitted values (e.g., estimates) of the propensity score for everyone (both E4 and possible controls) and order the log odds of the treatment (E4) group from largest to smallest (in decreasing order). For each E4 member, we will find the two nearest neighbor controls, e.g., the controls with the closest propensity score to that of the E4 individual with 12 months of continuous prior enrollment at the E4 individual's index date. After completing matching, we will check for covariate balance across groups based on the standardized mean differences and Kolmogorov–Smirnov statistic.

To address the zero-inflated and right skewed nature of the outcomes, we will use a two part-model. In the first stage of the two-part model, we will estimate the probability of the response being greater than zero and in the second stage we will model the non-zero portion. We will choose the most appropriate mean-variance relationship by performing goodness-of-fit tests (Pearson's correlation, Pregibon link, modified Park, and modified Hosmer-Lemeshow tests)^{4,5} on the outcomes. We will assume independence in the mean modeling to estimate the area under the curve change at 1 (primary), 2 and 3 years after index, and use the cluster bootstrap to obtain standard errors that account for repeated measurements within an individual (clustering on the individual level). We will adjust for individual-level (age, gender, and Elixhauser comorbidity score) and census ZIP-code level characteristics (educational attainment, median household income, race/ethnicity and urban residence) in all models.

Model:

Denote spending for member i at time t as y_{it} , with $i \in \{1, \dots, N\}$, $t \in \{-23, \dots, 0, \dots, 36\}$, and N the number of members. Let M be the number of covariates included in the model and $x_{m,it}$ denote the m^{th} covariate for member i at month t .

Then the two-stage model is:

$$p_{it} \sim \text{Bernoulli}(\theta_{it}),$$

$$\text{logit}(\theta_{it}) = \alpha_0 + \sum_{m=1}^M \alpha_m x_{m,it},$$

$$(y_{it} \mid y_{it} > 0) \sim \text{Poisson}(\mu_{it}), \quad \text{and}$$

$$\mu_{it} = E(y_{it} \mid y_{it} > 0, X_i),$$

where X_i is the matrix for all observed covariates for member i . We model the mean, μ_{it} , as

$$\log(\mu_{it}) = \beta_0 + \sum_{m=1}^M \beta_m x_{m,it}.$$

We suppose,

$$\sum_{m=1}^M \alpha_m x_{m,it} = \alpha_1 E4_i + \alpha_2 post_{it} + \alpha_3 month_{it} + \alpha_4 E4_i * post_{it} + \alpha_5 E4_i * month_{it} +$$

$$\alpha_6 post_{it} * month_{it} + \alpha_7 E4_i * post_{it} * month_{it} + \alpha_8 Age_i +$$

$$\alpha_9 Gender_i + \alpha_{10} Elixhauser_i + \alpha_{11} Relationship_i +$$

$$\alpha_{12} FundingType_i + \alpha_{13} ACSPopulation_i + \alpha_{14} ACSIncome_i +$$

$$\alpha_{15} ACSPercentWhite_i + \alpha_{16} ACSEducation_i,$$

and

$$\sum_{m=1}^M \beta_m x_{m,it} = \beta_1 E4_i + \beta_2 post_{it} + \beta_3 month_{it} + \beta_4 E4_i * post_{it} + \beta_5 E4_i * month_{it} +$$

$$\beta_6 post_{it} * month_{it} + \beta_7 E4_i * post_{it} * month_{it} + \beta_8 Age_i +$$

$$\beta_9 Gender_i + \beta_{10} Elixhauser_i + \beta_{11} Relationship_i +$$

$$\beta_{12} FundingType_i + \beta_{13} ACSPopulation_i + \beta_{14} ACSIncome_i +$$

$$\beta_{15} ACSPercentWhite_i + \beta_{16} ACSEducation_i,$$

for member i where:

- $E4_i$ = indicator of whether the i^{th} member is enrolled in VBF-E4
- $post_{it}$ = indicator of whether the i^{th} member is in the post index period, $t \geq 1$
- $month_{it}$ = time in months from the i^{th} members index date
- Age_i = centered age for the i^{th} member at index
- $Gender_i$ = i^{th} members gender at index
- $Elixhauser_i$ = Elixhauser comorbidity score for member i at index
- $Relationship_i$ = i^{th} members relationship to contract holder at index
- $FundingType_i$ = i^{th} members funding type at index

- $ACSPopulation_i$ = ACS population at the zip code level for member i at index
- $ACSIncome_i$ = ACS median household income in the prior 12 months at zip code level for member i at index
- $ACSPercentWhite_i$ = ACS percent of white people at the zip code level for member i at index
- $ACSEducation_i$ = ACS percent of people 25 years or older with a Bachelor's degree in the prior 12 months at the zip code level for member i at index

Missing Data:

Complete-case analyses.

References

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