# Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

If you are using a web page screen reader and are unable to access this document, please contact the Sentinel Operations Center for assistance at info@sentinelsystem.org.

**Request ID:** cber_mpl1r_wp003_nsdp_v01. This is Report 1 of 2.

**Report Description**: This report contains the estimated number of females of child-bearing age, the number of live-births, and the number of live births among women with blood transfusions in the Sentinel Distributed Database (SDD). This report also contains the number of blood transfusions among males and females for all ages.

**Data Source:** Data from January 1, 2008 to November 30, 2015 from 15 health plans contributing to the Sentinel Distributed Database (SDD) were included in this report. See Appendix A for a list of the latest dates of available data for each Data Partner.

**Study Design:** This request was designed to calculate background rates. The rates of qualifying live births in the SDD were calculated overall and were stratified by year.

**Cohort of Interest:** Females of child-bearing age (10-54 years) with live births, overall and among those with blood transfusions. Males and females of all age groups who have blood transfusions were also identified.

**Cohort Eligibility Criteria**: Individuals included in the cohort were required to be continuously enrolled in plans with both medical and drug coverage for at least 293 days before their live birth, during which gaps in coverage of up to 45 days were allowed. Live births were defined using ICD- 9 codes. Please see Appendix B. Blood transfusions were defined using National Drug Codes (NDCs) and procedure codes. Please see Appendix C. The program considered all valid live births between January 1, 2008 and November 30, 2015 for each individual. All valid incident live births that occurred during the study period were included per patient.

**Please see *Appendix D* for the specifications of parameters used in the analyses for this request.**

**Limitations:** Please note, this report includes information from both claims-based and integrated care delivery Sentinel data partners. The algorithm to define blood transfusions may not have identified all transfusions because they may not have resulted in a code in a claim or entered into the electronic health record system. In general, we expect under-ascertainment of inpatient transfusions at claims based sites (which generally have larger numbers of members), and more complete capture of transfusion information at integrated care delivery sites (which generally have fewer members).

**Notes:** Please contact the Sentinel Operations Center Query Fulfillment Team (production@mini-sentinel.org) for questions and to provide comments/suggestions for future enhancements to this document.

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# Glossary of Terms for Analyses Using
## Cohort Identification and Descriptive Analysis (CIDA) Tool*

**Amount Supplied** - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing. This is equivalent to the "RxAmt" value in the SCDM.

**Blackout Period** - number of days at the beginning of a treatment episode that events are to be ignored.  If an event occurs during the blackout period, the episode is excluded.

**Care Setting** - type of medical encounter or facility where the exposure, event, or condition code was recorded.  Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA).  For laboratory results, possible care settings include: Emergency department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). Along with the Principal Diagnosis Indicator, forms the Care Setting/PDX parameter.

**Principal Diagnosis (PDX) -** diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital.  'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

**Cohort Definition (drug/exposure)-** indicates how the cohort will be defined: (1) 01: Cohort includes only the first valid incident treatment episode during the query period; (2) 02: Cohort includes all valid incident treatment episodes during the query period; (3) 03: Cohort includes all valid incident treatment episodes during the query period until an event occurs.

**Days Supplied -** number of days supplied for all dispensings in qualifying treatment episodes.

**Episodes -** treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.

**Years at Risk** - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

**Enrollment Gap -** number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled" sequence.

**Episode Gap -** number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.

**Event Deduplication -** specifies how events are counted by the MP algorithm: (0) 0: Counts all occurrences of an HOI during an exposure episode; (1) 1: de-duplicates occurrences of  the same HOI code and code type on the same day; (2) 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

**Exposure Extension Period -** number of days post treatment period in which the outcomes/events are counted for a treatment episode.

**Exposure Episode Length -** number of days after exposure initiation that is considered "exposed time."

**Lookback Period (pre-existing condition) -** number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).

**Minimum Days Supplied -** specifies a minimum number of days in length of the days supplied for the episode to be considered.

**Minimum Episode Duration -** specifies a minimum number of days in length of the episode for it to be considered.

**Query Period -** period in which the modular program looks for exposures and outcomes of interest.

**Treatment Episode Truncation Indicator -**  indicates whether observation of the incident query code during follow-up requires truncation of valid treatment episodes. A value of Y indicates that the treatment episodes should be truncated at the first occurrence of an incident query code. A value of N indicates that the treatment episodes should not be truncated at the occurrence of the incident query code.

**Users -** number of members with exposure during the query period. Member must have no evidence of exposure(s) of interest (defined by incidence criteria) in the prior washout period. A user may only be counted once in a query period.

**Washout Period (drug/exposure)** - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

**Washout Period (event/outcome)** - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

*all terms may not be used in this report
**incident treatment episodes must be incident to both the exposure and the event

**Table 1: Summary of number of females (0-99 years), females of child-bearing age (10-54 years), number of blood transfusions (both sexes, 0-99 years) among eligible members (both sexes 0-99 years) in the Sentinel Distributed Database (SDD) between January 1, 2008 and November 30, 2015, overall and by year***

| | Eligible Members (M/F; 0-99 years) | Blood Transfusions (M/F; 0-99 years) | Females only (0-99 years) | Females of child-bearing age (10- 54 years) |
|---|---|---|---|---|
| Overall | 94,918,642 | 1,278,611 | 48,157,046 | 33,666,089 |
| 2008 | 39,868,276 | 249,319 | 20,392,302 | 13,543,156 |
| 2009 | 43,077,877 | 301,699 | 22,037,698 | 14,756,254 |
| 2010 | 41,083,609 | 298,462 | 21,056,672 | 13,894,821 |
| 2011 | 39,859,478 | 300,548 | 20,403,335 | 13,298,891 |
| 2012 | 40,792,877 | 304,830 | 20,836,389 | 13,377,153 |
| 2013 | 40,812,142 | 291,567 | 20,809,060 | 13,281,743 |
| 2014 | 41,478,670 | 276,994 | 21,121,775 | 13,268,000 |
| 2015 | 33,297,459 | 161,160 | 16,870,458 | 10,266,266 |

*Individuals included in this table are required to be continuously enrolled in plans with both medical and drug coverage for at least 293 days

Note: The sum of years will not add up to the overall count because individuals can have episodes in multiple years.

**Table 2: Summary of Females of child-bearing age (10-54 years) with and without live births and blood transfusions in the Sentinel Distributed Database (SDD) between January 1, 2008 and November 30, 2015, overall and by year***

|  | Females | Females with Live Births | Females with Blood Transfusions | Females with Live Births AND Blood Transfusions | Females with Blood Transfusions AND NO Live Birth |
|---|---|---|---|---|---|
| All | 33,666,089 | 1,946,032 | 218,562 | 21,048 | 197,514 |
| 2008 | 13,543,156 | 212,865 | 43,380 | 2,402 | 40,978 |
| 2009 | 14,756,254 | 341,344 | 55,180 | 2,971 | 52,209 |
| 2010 | 13,894,821 | 321,276 | 51,740 | 2,791 | 48,949 |
| 2011 | 13,298,891 | 313,615 | 49,979 | 2,990 | 46,989 |
| 2012 | 13,377,153 | 309,685 | 47,579 | 2,943 | 44,636 |
| 2013 | 13,281,743 | 315,419 | 43,174 | 2,798 | 40,376 |
| 2014 | 13,268,000 | 306,161 | 40,545 | 3,013 | 37,532 |
| 2015 | 10,266,266 | 103,264 | 22,897 | 1,390 | 21,507 |

*Individuals included in this table are required to be continuously enrolled in plans with both medical and drug coverage for at least 293 days

Note: The sum of years will not add up to the overall count because individuals can have episodes in multiple years.

**Appendix A: Latest Date of Available Data for Each Data Partner up to Request End Date (11/30/2015)**

| DP ID | End Date |
|-------|----------|
| DP0001 | 12/31/2014 |
| DP0002 | 6/30/2014 |
| DP0003 | 4/30/2015 |
| DP0004 | 3/31/2015 |
| DP0005 | 10/31/2014 |
| DP0006 | 10/31/2015 |
| DP0007 | 2/28/2015 |
| DP0008 | 9/30/2015 |
| DP0009 | 9/30/2015 |
| DP0010 | 7/31/2015 |
| DP0011 | 6/30/2012 |
| DP0012 | 7/31/2014 |
| DP0013 | 11/30/2015 |
| DP0014 | 11/30/2015 |
| DP0015 | 4/30/2015 |

**Appendix B. List of Codes used to define Live Birth in this Request**

| Description | Code | Code Type |
|---|---|---|
| **Live Births** | | |
| SINGLE NEWBORN | V27.0 | ICD-9-CM Diagnosis Code |
| TWINS, BOTH LIVEBORN | V27.2 | ICD-9-CM Diagnosis Code |
| OTHER MULTIPLE BIRTH, ALL LIVEBORN | V27.5 | ICD-9-CM Diagnosis Code |
| SINGLE LIVEBORN | V30 | ICD-9-CM Diagnosis Code |
| SINGLE NEWBORN, BORN IN HOSPITAL | V30.0 | ICD-9-CM Diagnosis Code |
| SINGLE NEWBORN, BORN IN HOSPITAL, DELIVERED WITHOUT MENTIC | V30.00 | ICD-9-CM Diagnosis Code |
| SINGLE NEWBORN, BORN IN HOSPITAL, CESAREAN | V30.01 | ICD-9-CM Diagnosis Code |
| Single liveborn, born before admission to hospital | V30.1 | ICD-9-CM Diagnosis Code |
| Single liveborn, born outside hospital and not hospitalized | V30.2 | ICD-9-CM Diagnosis Code |
| TWIN BIRTH, MATE LIVEBORN | V31 | ICD-9-CM Diagnosis Code |
| TWIN BIRTH MATE LIVEBORN, BORN IN HOSPITAL | V31.0 | ICD-9-CM Diagnosis Code |
| TWIN BIRTH MATE LIVEBORN, BORN IN HOSPITAL DELIEVERED WITHC | V31.00 | ICD-9-CM Diagnosis Code |
| TWIN BIRTH MATE LIVEBORN, BORN IN HOSPITAL DELIVERED BY CESA | V31.01 | ICD-9-CM Diagnosis Code |
| Twin birth, mate liveborn, born before admission to hospital | V31.1 | ICD-9-CM Diagnosis Code |
| Twin birth, mate liveborn, born outside hospital and not hospitalized | V31.2 | ICD-9-CM Diagnosis Code |
| Twin birth unspecified whether mate liveborn or stillborn | V33 | ICD-9-CM Diagnosis Code |
| Twin birth unspecified whether mate liveborn or stillborn born in hosp | V33.0 | ICD-9-CM Diagnosis Code |
| Twin birth, unspecified whether mate liveborn or stillborn, born in ho: | V33.00 | ICD-9-CM Diagnosis Code |
| TWIN, BORN IN HOSPITAL, CESAREAN | V33.01 | ICD-9-CM Diagnosis Code |
| Twin birth, unspecified whether mate liveborn or stillborn, born befor | V33.1 | ICD-9-CM Diagnosis Code |
| Twin birth, unspecified whether mate liveborn or stillborn, before out | V33.2 | ICD-9-CM Diagnosis Code |
| Other multiple birth (three or more) mates all liveborn | V34 | ICD-9-CM Diagnosis Code |
| OTHER MULTIPLE, BORN IN HOSPITAL | V34.0 | ICD-9-CM Diagnosis Code |
| OTHER MULTIPLE, BORN IN HOSPITAL | V34.00 | ICD-9-CM Diagnosis Code |
| OTHER MULTIPLE, BORN IN HOSPITAL, CESAREAN | V34.01 | ICD-9-CM Diagnosis Code |
| Other multiple birth (three or more), mates all liveborn, born before a | V34.1 | ICD-9-CM Diagnosis Code |
| Other multiple birth (three or more), mates all liveborn, born outside | V34.2 | ICD-9-CM Diagnosis Code |
| Other multiple birth (three or more), unspecified whether mates liveb | V37 | ICD-9-CM Diagnosis Code |
| OTHER MULTIPLE, BORN IN HOSPITAL | V37.0 | ICD-9-CM Diagnosis Code |
| OTHER MULTIPLE, BORN IN HOSPITAL | V37.00 | ICD-9-CM Diagnosis Code |

**Appendix B. List of Codes used to define Live Birth in this Request**

| Description | Code | Code Type |
|---|---|---|
| **Live Births** | | |
| OTHER MULTIPLE, BORN IN HOSPITAL, CESAREAN | V37.01 | ICD-9-CM Diagnosis Code |
| Other multiple birth (three or more), unspecified whether mates liveb | V37.1 | ICD-9-CM Diagnosis Code |
| Other multiple birth (three or more), unspecified whether mates liveb | V37.2 | ICD-9-CM Diagnosis Code |
| Liveborn, unspecified whether single, twin or multiple | V39 | ICD-9-CM Diagnosis Code |
| Liveborn, unspecified whether single, twin or multiple, born in hospita | V39.0 | ICD-9-CM Diagnosis Code |
| Liveborn, unspecified whether single, twin or multiple, born in hospita | V39.00 | ICD-9-CM Diagnosis Code |
| Liveborn, unspecified whether single, twin or multiple, born in hospita | V39.01 | ICD-9-CM Diagnosis Code |
| Liveborn, unspecified whether single, twin or multiple, born before ad | V39.1 | ICD-9-CM Diagnosis Code |
| Liveborn, unspecified whether single, twin or multiple, born outside h | V39.2 | ICD-9-CM Diagnosis Code |
| TWINS, ONE LIVEBORN | V27.3 | ICD-9-CM Diagnosis Code |
| OTHER MULTIPLE BIRTH, SOME LIVEBORN | V27.6 | ICD-9-CM Diagnosis Code |
| Twin birth mate stillborn | V32 | ICD-9-CM Diagnosis Code |
| TWIN, BORN IN HOSPITAL, MATE STILLBORN | V32.0 | ICD-9-CM Diagnosis Code |
| Twin birth mate stillborn born in hospital, delivered without mention | V32.00 | ICD-9-CM Diagnosis Code |
| TWIN, BORN IN HOSPITAL, CESAREAN, MATE STILLBORN | V32.01 | ICD-9-CM Diagnosis Code |
| Twin birth, mate stillborn, born before admission to hospital | V32.1 | ICD-9-CM Diagnosis Code |
| Twin birth, mate stillborn, born outside hospital and not hospitalized | V32.2 | ICD-9-CM Diagnosis Code |
| OTHER MULTIPLE, mates stillborn | V35 | ICD-9-CM Diagnosis Code |
| OTHER MULTIPLE, BORN IN HOSPITAL, mates stillborn | V35.0 | ICD-9-CM Diagnosis Code |
| OTHER MULTIPLE, BORN IN HOSPITAL, mates stillborn | V35.00 | ICD-9-CM Diagnosis Code |
| OTHER MULTIPLE, BORN IN HOSPITAL, CESAREAN, mates stillborn | V35.01 | ICD-9-CM Diagnosis Code |
| Other multiple birth (three or more), mates all stillborn, born before a | V35.1 | ICD-9-CM Diagnosis Code |
| Other multiple birth (three or more), mates all stillborn, born outside | V35.2 | ICD-9-CM Diagnosis Code |
| Other multiple birth (three or more), mates liveborn and stillborn | V36 | ICD-9-CM Diagnosis Code |
| OTHER MULTIPLE, BORN IN HOSPITAL, mates liveborn and stillborn | V36.0 | ICD-9-CM Diagnosis Code |
| OTHER MULTIPLE, BORN IN HOSPITAL, mates liveborn and stillborn | V36.00 | ICD-9-CM Diagnosis Code |
| OTHER MULTIPLE, BORN IN HOSPITAL, CESAREAN, mates liveborn and | V36.01 | ICD-9-CM Diagnosis Code |
| Other multiple birth (three or more), mates liveborn and stillborn, boı | V36.1 | ICD-9-CM Diagnosis Code |
| Other multiple birth (three or more), mates liveborn and stillborn, boı | V36.2 | ICD-9-CM Diagnosis Code |

**Appendix B. List of Codes used to define Blood Transfusions in this Request**

| Description | Code | Code Type |
|---|---|---|
| **Blood Transfusions** | | |
| PERIOPER AUTO TRANSFUS BLD/BLD COMP | 9900 | ICD-9-CM Procedure Code |
| EXCHANGE TRANSFUSION | 9901 | ICD-9-CM Procedure Code |
| OTHER TRANSFUSION OF WHOLE BLOOD | 9903 | ICD-9-CM Procedure Code |
| TRANSFUSION OF PACKED CELLS | 9904 | ICD-9-CM Procedure Code |
| TRANSFUSION OF PLATELETS | 9905 | ICD-9-CM Procedure Code |
| TRANSFUSION OF COAGULATION FACTORS | 9906 | ICD-9-CM Procedure Code |
| TRANSFUSION OF OTHER SERUM | 9907 | ICD-9-CM Procedure Code |
| **Red Blood Cells** | | |
| General Codes | P9021 | Healthcare Common Procedure Code |
| General Codes | P9022 | Healthcare Common Procedure Code |
| General Codes | P9039 | Healthcare Common Procedure Code |
| Irradiated | P9038 | Healthcare Common Procedure Code |
| Leukocytes reduced | C1010 | Healthcare Common Procedure Code |
| Leukocytes reduced | C1016 | Healthcare Common Procedure Code |
| Leukocytes reduced | C1020 | Healthcare Common Procedure Code |
| Leukocytes reduced | P9016 | Healthcare Common Procedure Code |
| Leukocytes reduced | P9051 | Healthcare Common Procedure Code |
| Leukocytes reduced | P9054 | Healthcare Common Procedure Code |
| Leukocytes reduced | P9057 | Healthcare Common Procedure Code |
| Leukoreduced and irradiated | C1021 | Healthcare Common Procedure Code |
| Leukoreduced and irradiated | P9040 | Healthcare Common Procedure Code |
| Leukoreduced and irradiated | P9058 | Healthcare Common Procedure Code |
| **Platelets** | | |
| General Codes | 96965 | Current Procedural Terminology |
| General Codes | C9501 | Healthcare Common Procedure Code |
| General Codes | P9019 | Healthcare Common Procedure Code |
| General Codes | P9020 | Healthcare Common Procedure Code |
| General Codes | P9034 | Healthcare Common Procedure Code |
| Irradiated | C9500 | Healthcare Common Procedure Code |

**Appendix B. List of Codes used to define Blood Transfusions in this Request**

| Description | Code | Code Type |
|---|---|---|
| **Blood Transfusions** | | |
| Irradiated | C9502 | Healthcare Common Procedure Code |
| Irradiated | P9032 | Healthcare Common Procedure Code |
| Irradiated | P9036 | Healthcare Common Procedure Code |
| Leukocytes reduced | C1011 | Healthcare Common Procedure Code |
| Leukocytes reduced | C1013 | Healthcare Common Procedure Code |
| Leukocytes reduced | C1014 | Healthcare Common Procedure Code |
| Leukocytes reduced | C1015 | Healthcare Common Procedure Code |
| Leukocytes reduced | C1017 | Healthcare Common Procedure Code |
| Leukocytes reduced | P9031 | Healthcare Common Procedure Code |
| Leukocytes reduced | P9035 | Healthcare Common Procedure Code |
| Leuko reduced and irradiated | C1012 | Healthcare Common Procedure Code |
| Leuko reduced and irradiated | C1019 | Healthcare Common Procedure Code |
| Leuko reduced and irradiated | P9033 | Healthcare Common Procedure Code |
| Leuko reduced and irradiated | P9037 | Healthcare Common Procedure Code |
| Therapeutic Erythrocyta-pheresis | 9973 | ICD-9-CM Procedure Code |
| **Cryoprecipitated Antihemophilic Factor** | | |
| Cryoprecipitated Antihemophilic Factor | P9012 | Healthcare Common Procedure Code |
| **Plasma** | | Healthcare Common Procedure Code |
| General Codes | C1009 | Healthcare Common Procedure Code |
| General Codes | C1022 | Healthcare Common Procedure Code |
| General Codes | C9503 | Healthcare Common Procedure Code |
| General Codes | P9017 | Healthcare Common Procedure Code |
| General Codes | P9020 | Healthcare Common Procedure Code |
| General Codes | P9023 | Healthcare Common Procedure Code |
| General Codes | P9044 | Healthcare Common Procedure Code |
| General Codes | P9059 | Healthcare Common Procedure Code |
| General Codes | P9060 | Healthcare Common Procedure Code |
| PLASMA HUMAN, BLOOD GROUP A | | National Drug Code |
| PLASMA HUMAN, BLOOD GROUP B | | National Drug Code |
| PLASMA HUMAN, BLOOD GROUP AB | | National Drug Code |

**Appendix B. List of Codes used to define Blood Transfusions in this Request**

| Description | Code | Code Type |
|---|---|---|
| **Blood Transfusions** | | |
| PLASMA HUMAN, BLOOD GROUP O | | National Drug Code |
| PLASMA HUMAN, BLOOD GROUP A | | National Drug Code |
| PLASMA HUMAN, BLOOD GROUP B | | National Drug Code |
| PLASMA HUMAN, BLOOD GROUP AB | | National Drug Code |
| PLASMA HUMAN, BLOOD GROUP O | | National Drug Code |
| Plasma | 9907 | ICD-9-CM Procedure Code |
| Therapeutic Plasmapheresis | 9971 | ICD-9-CM Procedure Code |

**Appendix D: Specifications for cber_mpl1r_wp003_nsdp_v01- Blood transfusions- Report 1 (Blood Transfusions among Women With Live Births)**

FDA requested use of the CIDA Tool to examine frequency distributions of females of child-bearing age, frequency of women with live births, and live births among patients with blood transfusions.

|  | |
|---:|:---|
| Enrollment Gap | 45 days |
| Age Groups | 00-09, 10-54, 55+ |
| Query Period | January 1, 2008- November 30, 2015 |
| Coverage Requirement | Medical and Drug Coverage |
| Enrollment Requirement | 293 days |

| Scenario | Incident Diagnosis | Incident w/ respect to: | Washout (days) | Cohort Definition** | Care Setting | Inclusion/Exclusion Crieteia | Include or Exclude | Lookback Start | Lookback End |
|:---:|:---|:---|:---:|:---:|:---:|:---:|:---:|:---:|:---:|
| 1 | Live Birth | Live Birth | 273 | 02 | Any | N/A | N/A | N/A | N/A |
| 2 | Live Birth | Live Birth | 273 | 02 | Any | Blood Transfusion | Include | -293 | 0 |

** Cohort includes all valid incident treatment episodes during the query period