

MINI-SENTINEL MODULAR PROGRAMS

MODULAR PROGRAM 9: BACKGROUND RATES AND CHARACTERIZATION OF HEALTH OUTCOMES OF INTEREST AMONG INDIVIDUALS WITH OR WITHOUT CONDITION(S) OF INTEREST

Documentation version: 3.0

**Prepared by the Mini-Sentinel Operations Center
For use with Modular Program 9 version 3.0
December 17, 2013**

Mini-Sentinel is a pilot project sponsored by the [U.S. Food and Drug Administration \(FDA\)](#) to inform and facilitate development of a fully operational active surveillance system, the Sentinel System, for monitoring the safety of FDA-regulated medical products. Mini-Sentinel is one piece of the [Sentinel Initiative](#), a multi-faceted effort by the FDA to develop a national electronic system that will complement existing methods of safety surveillance. Mini-Sentinel Collaborators include Data and Academic Partners that provide access to health care data and ongoing scientific, technical, methodological, and organizational expertise. The Mini-Sentinel Coordinating Center is funded by the FDA through the Department of Health and Human Services (HHS) Contract number HHSF223200910006I.

Table of Contents

I.	OVERVIEW	- 1 -
II.	TERMINOLOGY	- 1 -
III.	PROGRAM SUMMARY	- 2 -
IV.	PROGRAM PARAMETER AND INPUT FILE SPECIFICATIONS	- 2 -
	A. PROGRAM PARAMETER SPECIFICATIONS.....	- 2 -
	B. INPUT FILE SPECIFICATIONS.....	- 6 -
	1. <i>Query File</i>	- 6 -
	2. <i>Incident Query File</i>	- 10 -
	3. <i>Inclusion/Exclusion Conditions File</i>	- 13 -
	4. <i>Output Table Selection File</i>	- 17 -
V.	KEY DEFINITIONS	- 18 -
	A. ENROLLMENT REQUIREMENTS.....	- 18 -
	B. PREVALENCE-BASED COHORT.....	- 19 -
	C. INCIDENCE-BASED COHORT.....	- 19 -
	1. <i>Minimum Incidence (MIN)</i>	- 19 -
	2. <i>Single Incidence (SING)</i>	- 20 -
	3. <i>Multiple Incidence (MULT)</i>	- 20 -
	4. <i>Examples</i>	- 20 -
	D. COHORT INCLUSION OR EXCLUSION BASED ON CONDITIONS OF INTEREST.....	- 22 -
VI.	DENOMINATORS AND BACKGROUND RATES	- 22 -
VII.	PROGRAM STEPS	- 24 -
VIII.	PROGRAM EXECUTION	- 24 -
IX.	OUTPUT TABLES AND ANALYSIS TOOLS	- 25 -
	A. OUTPUT TABLES.....	- 25 -
	B. ANALYSIS TOOLS.....	- 27 -
	1. <i>Attrition Table</i>	- 27 -
X.	EXAMPLE	- 28 -

Modification History

Version	Date	Modification	By
3.0	12/17/2013	<ul style="list-style-type: none"> Updated output tables to include amount supplied metrics Added macro parameter "RunID" 	Mini-Sentinel Operations Center
2.0	8/28/2013	<ul style="list-style-type: none"> Added Macro parameter "COVERAGE" Added Query File parameter "ENRDAYS" Added "SING" washout type option in Query File Updated Attrition Table Tool to break out enrollment episode exclusions by coverage type Added parameter "DESCR" to Query, Incident Query, and Inclusion/Exclusion Conditions files 	Mini-Sentinel Operations Center
1.0	6/21/2013	<ul style="list-style-type: none"> Created a new Modular Program 9 that enhances MP2 to include MP5 functionality Added optional Output Table Selection module to instruct the MP9 to preserve only certain output tables in the final output library. Added standard attrition table available by default for each run of MP9. Revised the way the MP9 matches codes of interest to allow either exact code match and/or wildcard match. 	Mini-Sentinel Operations Center

I. OVERVIEW

Mini-Sentinel modular programs (MPs) allow rapid implementation of standard queries across the Mini-Sentinel Distributed Database (MSDD). MPs are designed to run against the Mini-Sentinel Common Data Model (MSCDM).¹ They are written in SAS and can be customized using various parameter settings that define health outcomes of interest (HOIs), date ranges, age ranges, and other implementation details. This document describes the key program specifications and main assumptions underlying each of the query parameters for Modular Program 9 (MP9) version 3.0. Program specification requirements, formats, and default values of all parameters are defined. A [sample program specification](#) is provided along with [output from a sample scenario](#).

II. TERMINOLOGY

For simplicity, the term “scenario” is used throughout this document to refer to a set of parameters and criteria used to define an execution of the MP. The “requester” refers to an individual (or group of individuals) who initiates the MP request and defines the scenarios. The term “request programmer” refers to an individual who creates request Input Files and distributes the MP to the Data Partners.

The terms “health outcome of interest” and “HOI” are used to represent exposure to a medical product, a procedure or a diagnosis as defined by the MP requester. An HOI can be defined using any mix of National Drug Codes (NDCs), International Classification of Diseases (ICD-9) procedure or diagnosis codes, or Healthcare Common Procedure Coding System (HCPCS) procedure codes. For example, exposure to a drug product dispensed in the outpatient setting can be defined as observation of one or more NDCs in the pharmacy dispensing file, whereas exposure to a vaccine can be defined based on observation of specific procedure codes in the procedure file.

The term “condition” is used to represent a medical code (or a group of codes) that identify a medical condition of interest. In MP9, the cohort can be restricted to members with and/or without condition(s).

The term “claim” is used throughout the document to represent either an outpatient pharmacy dispensing or medical encounter/record with any of the codes for the HOI(s).

The term “member” is used to represent an individual with relevant criteria for enrollment, HOI(s), and condition(s) (as specified by the MP parameters). A member can be further defined as a “user” if evidence of HOI(s) is found. Whenever a user is identified, the service date on the claim of the first observed HOI during the relevant period of interest is labeled the “index date”.

The execution of MP9 allows information for multiple scenarios and HOIs to be generated at the same time. Results from all scenarios are included in the MP output tables and can be differentiated using “query group names” defined by the requester. This document describes the process for only one scenario to be tested.

¹ See http://www.mini-sentinel.org/data_activities/ for more information about the MSCDM.

III. PROGRAM SUMMARY

MP9 is used to characterize the use of HOI(s) observed among members during a period defined by a start and end date (*i.e.*, the query period). MP9 also has an optional inclusion/exclusion feature that allows the user to restrict analyses to members with and/or without “conditions” before or after the index date, defined using any combination of NDCs, diagnosis and/or procedure codes. By default, MP9 generates metrics for both prevalence (*i.e.*, ever exposed during query period) and incidence (*i.e.*, newly exposed during query period) based cohorts of users for each HOI.

One run of MP9 generates a total of thirteen result tables. Ten stratified output tables (five for each of the prevalent and incident cohorts) characterizing HOIs are created: overall for the entire period, by year, by year/month, by age group, and by sex. The metrics reported in all ten tables include the number of users, the number of claims with HOIs, the total number of days and amount supplied (for outpatient pharmacy dispensing²), and the total members and eligible member days used to estimate background rates ([Section IX](#)). In addition, tables for [incidence based cohorts](#) include the number of incident claims. An eleventh table allows the requester to assess the attrition of the cohort of interest after each selection criterion is applied. A twelfth table, the numerator table, contains results for all possible combinations of strata (*e.g.*, by year/age group/sex). Finally, a thirteenth table containing denominator information for all strata is generated. Combining the information from the numerator and denominator tables allows the requester to generate population-based background rates ([Section VI](#)).

MP9 requires the specification of several parameters to define a scenario. These include program parameters that specify a request identifier, execution (run) identifier, query period, age range(s), coverage type requirements, and enrollment criteria. The names of input files (built as SAS datasets) containing several other parameters must also be specified.

The first input file is the [Query File](#) that defines HOIs. The second file is the [Incident Query File](#); it is optional and is used to refine how incident HOIs are defined. The third file is the optional [Inclusion/Exclusion Conditions File](#) that defines what outpatient pharmacy medications, medical procedures and/or diagnoses should be used to restrict the cohort to members with and/or without conditions of interest. The fourth file, the [Output Table Selection File](#), is optional and defines the subset of MP9 output files to generate.

All parameters and input file specifications are described in [Section IV](#).

IV. PROGRAM PARAMETER AND INPUT FILE SPECIFICATIONS

A. PROGRAM PARAMETER SPECIFICATIONS

There are eleven [main program parameters](#) that may be specified. These include a request identifier, a run identifier, start and end dates for the query period, age stratifications, coverage type requirements, an allowed enrollment gap used to create continuous enrollment periods, and four input files (the [Query](#)

² For the purpose of days supply and amount supplied output metrics, diagnosis and procedure codes are assigned a value of 1.

[File](#), [Incident Query File](#), [Inclusion/Exclusion Conditions File](#) and [Output Table Selection File](#)). Table 1 contains detailed specifications for each of these required parameters.

Table 1: Main Program Parameter Specification

Parameter	Field Name	Description
Request Identifier	REQUESTID	<p>Details: a request identifier. The identifier is appended to all output file names.</p> <p>Note 1: must be 5 characters in length. The REQUESTID should start with “mpr” and include two additional digits with the assigned request number.</p> <p>Defined by: Request programmer Input type: Required Format: Alphanumeric Example: REQUESTID=mpr01</p>
Run Identifier	RUNID	<p>Details: a run identifier to denote each execution of the program. The identifier is appended to all output file names.</p> <p>Note 1: must be 3 characters in length. The RUNID should start with “r” and include two additional digits with the assigned execution number.</p> <p>Defined by: Request programmer Input type: Required Format: Alphanumeric Example: RUNID=r01</p>
User-Defined Coverage Type Requirement	COVERAGE	<p>Details: an optional parameter to allow medical and drug coverage type requirements to be user-defined and not CODETYPE dependent.</p> <p>Valid values are:</p> <ul style="list-style-type: none"> • M: only enrollment spells with at least medical coverage should be considered by the MP algorithm • D: only enrollment spells with at least drug coverage should be considered by the MP algorithm • MD: only enrollment spells with both medical and drug coverage should be considered by the MP algorithm (default value) <p>Note 1: the type of coverage required is enforced for both the required Washout Period and the Minimum Enrollment Pre-Index Days features (see WASHPER and ENRDAYS parameters in the Query File section).</p> <p>Note 2: if the COVERAGE value is left blank, or contains invalid values (i.e., values other than “M”, “D”, or “MD”), the MP algorithm will consider only enrollment spells with both medical and drug coverage by default.</p> <p>Defined by: Requester</p>

Parameter	Field Name	Description
		<p>Input type: Optional (default value is MD)</p> <p>Format: SAS character \$2</p> <p>Example: MD</p>
Enrollment Gap	ENROLGAP	<p>Details: sets the number of days that will be bridged between two consecutive enrollment periods to create a “continuously enrolled” period. For example, if ENROLGAP=45 and a member is eligible for medical coverage in periods 1/1/2007-3/27/2007 and 4/1/2007-12/21/2007 (<i>i.e.</i>, a 4-day gap between two consecutive enrollment episodes), the member will be considered continuously enrolled from 1/1/2007 to 12/21/2007. Any gaps in enrollment greater than 45 days will result in a new enrollment period, and all the days in the gap will be considered un-enrolled.</p> <p>Note 1: a gap of 45-days is recommended for most uses.</p> <p>Note 2: multiple continuous enrollment periods per member may be assessed.</p> <p>Defined by: Requester</p> <p>Input type: Required</p> <p>Format: Numeric</p> <p>Example: ENROLGAP=45 (gaps less than or equal to 45 days will be “bridged” to form one “continuously enrolled” sequence)</p>
Query Start Date	QUERYFROM	<p>Details: date for the start of the query identification period. If QUERYFROM=03/01/2008, only claims with a service date on or after this date will be considered.</p> <p>Defined by: Requester</p> <p>Input type: Required</p> <p>Format: mm/dd/yyyy</p> <p>Example: QUERYFROM=03/01/2008</p>
Query End Date	QUERYTO	<p>Details: date for the end of the query identification period. If QUERYTO=03/31/2009, claims after this date will not be considered.</p> <p>Defined by: Requester</p> <p>Input type: Required</p> <p>Format: mm/dd/yyyy</p> <p>Example: QUERYTO=03/31/2009</p>
Query File	QUERYFILE	<p>Details: name of the SAS dataset defining the query HOI(s). It lists the HOI codes of interest and contains various parameters to specify how each code must be queried. The file name, including its extension, must be entered. For specific details on the content of this file, see Section IV.B.</p> <p>Named by: Request programmer</p> <p>Input type: Required</p> <p>Format: .sas7bdat or .cport file format</p> <p>Example: QUERYFILE=query.sas7bdat or query.cport</p>

Parameter	Field Name	Description
Incident Query File	INCQUERYFILE	<p>Details: name of the SAS dataset refining the incident HOI definition(s). It contains additional codes and various parameters to further refine how incident use of each HOI must be defined. The file name, including its extension, must be entered. For specific details on the content of this file and for an example of when this file is used and how it is different from the QUERYFILE, see Section IV.B.</p> <p>Named by: Request programmer Input type: Optional Format: .sas7bdat or .cport file format Example: INCQUERYFILE=incquery.sas7bdat or incquery.cport</p>
Inclusion/Exclusion Conditions File	CONDFILE	<p>Details: name of the SAS dataset defining the inclusion or exclusion of condition(s) of interest. It lists the codes of interest and contains various parameters to specify how each code must be queried. The file name, including its extension, must be entered. For specific details on the content of this file, see Section IV.B.</p> <p>Named by: Request programmer Input type: Optional Format: .sas7bdat or .cport file format Example: CONDFILE=cond.sas7bdat or cond.cport</p>
Output Table Selection File	OUTTABLESFILE	<p>Details: name of the SAS dataset defining the output table(s) to be preserved in the output folder. The file name, including its extension, must be entered. For specific details on the content of this file, see Section IV.B.</p> <p>Named by: Request programmer Input type: Optional Format: .sas7bdat or .cport file format Example: OUTTABLESFILE = output.sas7bdat or output.cport</p>
Age Groups	AGESTRAT	<p>Details: age group categories for reporting. Specifying this parameter will (1) restrict to certain age groups and (2) specify how age groups will be stratified in the result tables. For example, to have results stratified by 20 year increments for members 40-99 years of age, AGESTRAT=40-59 60-79 80-99 would be entered.</p> <p>Note 1: age is determined at the index date.</p> <p>Note 2: various units of time can be used. Valid values are:</p> <ul style="list-style-type: none"> • D: days • W: weeks • Q: quarters • M: months • Y: years (default value) <p>Note 3: lower value is binding. If AGESTRAT=0-5 5-10, then all 5 year olds will</p>

Parameter	Field Name	Description
		<p>be placed in the second age group. If AGESTRAT=0-5 6-10, then all 5 year olds will be placed in the first age group.</p> <p>For example, to have results stratified by 6 month increments for the first two years of life and then by 2 year increments until the age of 6, AGESTRAT = 00M-05M 06M-11M 12M-17M 18M-23M 02Y-03Y 04Y-05Y needs to be entered.</p> <p>Defined by: Requester Input type: Optional (default value is 00-01 02-04 05-09 10-14 15-18 19-21 22-44 45-64 65-74 75+ in years) Format: AA-AA BB-BB ZZ-ZZ Example: AGESTRAT=40-59 60-79 80-99</p>

B. INPUT FILE SPECIFICATIONS

In addition to the [main program parameters](#), several required and optional parameters need to be specified in the [Query File](#), [Incident Query File](#), [Inclusion/Exclusion Conditions File](#), and [Output Table Selection File](#).

1. Query File

The [Query File](#) is required. It contains the comprehensive set of codes used to define the HOI(s). NDCs, ICD procedure and diagnosis codes, or HCPCS codes can be used to define HOIs. HOI(s) can be defined using any mix of allowed code types.

The structure of the [Query File](#) must reflect how codes should be queried to define a unique HOI. The GROUP field is used to group all codes pertaining to a given HOI. For example, a group for “HOI1” could be defined by all NDCs for any oral forms of anti-diabetic medications, a group for “HOI2” by a mix of NDC and HCPCS codes for certain insulin products, and another group for “HOI3” by only those NDCs for a recently approved oral form of anti-diabetic medication. Table 2 below describes specifications for this file.

Table 2: Query File Specification

Parameter	Field Name	Description
Name of Query Group	GROUP	<p>Details: standardized name used to refer to a query GROUP for HOI(s) to be queried.</p> <p>Note 1: multiple HOIs/query groups can be defined within the same query file. In this case all HOIs are queried independently and results are reported separately and labeled using each query GROUP name specified.</p> <p>Named by: Request programmer Input type: Required Format: Alphanumeric; SAS character \$30; no special characters (e.g., commas,</p>

Parameter	Field Name	Description
		periods, hyphens, etc) allowed, and underscores must be used to mark spaces. Example: Insulin
Query Code Type	CODETYPE	<p>Details: type of each code value included in the CODE field (below) of this file.</p> <p>Valid values are all those allowed by the MSCDM:</p> <ul style="list-style-type: none"> • DX09: ICD-9-CM diagnosis • DX10: ICD-10-CM diagnosis • DX11: ICD-11-CM diagnosis • RX11: 11-digit NDC • RX09: 9-digit NDC • PX09: ICD-9-CM procedure • PX10: ICD-10-CM procedure • PX11: ICD-11-CM procedure • PXC4: CPT-4 procedure (<i>i.e.</i>, HCPCS Level I) • PXHC: HCPCS procedure (<i>i.e.</i>, HCPCS Level II) • PXH3: HCPCS Level III procedure • PXC2: CPT Category II procedure • PXC3: CPT Category III procedure <p>Note 1: for CODETYPE=RX09, a nine-digit NDC value must be included in the CODE field (below).</p> <p>Defined by: Request programmer Input type: Required Format: Alphanumeric; SAS character \$4. Example: See valid values</p>
Query Codes of Interest	CODE	<p>Details: NDC, ICD, and HCPCS code values for the HOI(s).</p> <p>Note 1: Codes are matched using exact values (<i>i.e.</i>, 3-digit code lookup requires an exact 3-digit code match). Wildcard match (*) functionality is also available (<i>e.g.</i>, querying “250*0” would be used to find any ICD-9-CM diagnosis codes for diabetes type II, or “250*” to find ICD-9-CM diagnosis codes for all diabetes codes that start with “250”).</p> <p>Note 2: for NDCs, either 9 or 11 digit codes can be entered.</p> <p>Note 3: remove decimal points in the code value.</p> <p>Note 4: CODETYPE must be consistent with the expected format of the CODE value (<i>e.g.</i>, MP9 will not find any valid matches in the data for CODETYPE=RX11 and a 9-digit NDC value).</p> <p>Note 5: duplicate CODETYPE-CODE combinations in a given query GROUP are removed by the MP9 algorithm.</p>

Parameter	Field Name	Description
		<p>Named by: Requester, with support from MSOC as needed</p> <p>Input type: Required</p> <p>Format: Alphanumeric; SAS character \$11.</p> <p>Example: 12345678911</p>
Query Code Description	DESCR	<p>Details: description of the NDC, diagnosis, or procedure code listed in the CODE field. Used primarily by request programmers to include meaningful code definitions in input files.</p> <p>Note 1: this parameter is optional (i.e., the MP algorithm will not fail if this parameter is excluded from the Query File)</p> <p>Defined by: Request Programmer</p> <p>Input type: Optional</p> <p>Format: SAS character \$30.</p> <p>Example: Insulin Lispro</p>
Query Incidence Type	WASHTYP	<p>Details: selects how incidence will be defined. As detailed in Section V, the incidence type can take the following values:</p> <ul style="list-style-type: none"> • MIN: minimum incidence -- identifies and reports metrics only for the <i>first</i> valid incident HOI during the query period, and uses ALL prior observed claims to define incidence. That is, incidence is defined as the first HOI during the query period with no evidence of prior HOI using all available data. • SING: single incidence -- identifies and reports metrics only for the <i>first</i> valid incident HOI during the query period, and uses claims observed during the specified WASHPER days to determine incidence. That is, incidence is defined as the first HOI during the query period with no evidence of prior HOI during WASHPER days. • MULT: multiple incidence -- identifies and reports metrics for <i>all</i> valid incident HOIs during the query period, and uses claims observed during the specified WASHPER days to determine incidence. That is, incidence is defined as any HOI during the query period with no evidence of HOI during the prior WASHPER days. <p>Note 1: WASHTYP parameter is used in conjunction with the Query Washout Period (WASHPER; below) to define a valid incident claim.</p> <p>Note 2: the set of all HOIs reported using the single incidence case is a subset of all HOIs from the multiple incidence case.</p> <p>Note 3: the MP9 algorithm may use days before QUERYFROM to ensure incidence criteria are met.</p> <p>Note 4: MIN setting should be used with caution as interpretation is complex. An HOI that meets the MIN criteria must occur during the query period and cannot be preceded by a disqualifying HOI at <i>any time</i> during enrollment; that</p>

Parameter	Field Name	Description
		<p>is, the look-back period to define incidence is not limited to the washout period. See Section V.C for details.</p> <p>Defined by: Requester, with support from the MSOC as needed Input type: Required Format: Alphanumeric; SAS character \$4; case sensitive (upper case only). Example: See valid values</p>
Query Washout Period	WASHPER	<p>Details: length of washout period in days. The washout period is a period before an incident HOI index date during which a member cannot have any evidence of HOI (s) of interest or any other HOI (s) specified in the Incident Query File.</p> <p>Note 1: length of washout period days must be the same within a given GROUP.</p> <p>Note 2: used in conjunction with any Query Incidence Types.</p> <p>Note 3: the MP algorithm may use days before QUERYFROM to determine if continuous enrollment and incidence criteria are met.</p> <p>Note 4: when WASHTYP=MIN, WASHPER is only used to assess continuous enrollment eligibility.</p> <p>Note 5: in conjunction with the ENROLGAP, COVERAGE, and minimum pre-index enrollment days (ENRDAYS) parameters, the washout period parameter is used to ensure that appropriate enrollment requirements are met. Since at least WASHPER days of enrollment must be found prior to index date this minimum enrollment days requirement can only be binding if ENRDAYS > WASHPER (See Section V.A). If enrollment requirements prior to index date are not met, HOI incidence cannot be determined and thus the claim is excluded from output metrics.</p> <p>Defined by: Requester Input type: Required (0 must be entered if no washout is required) Format: Numeric Example: 183</p>
Minimum Pre-Index Enrollment Days	ENRDAYS	<p>Details: irrespective of what query incidence type (WASHTYP) is specified, optional parameter to further restrict the number of days of continuous enrollment prior to incident HOI index date to reach a certain minimum.</p> <p>Note 1: if not specified by the requester a default value of 0 day is used by the MP algorithm.</p> <p>Note 2: if specified must be the same within a given query GROUP.</p> <p>Note 3: in conjunction with the ENROLGAP, COVERAGE, and WASHPER parameters, the minimum pre-index enrollment days parameter is used to</p>

Parameter	Field Name	Description
		<p>ensure that appropriate enrollment requirements are met. Since at least WASHPER days of enrollment must be found prior to index date this minimum enrollment days requirement can only be binding if ENRDAYS > WASHPER (See Section V.A). If enrollment requirements prior to index date are not met, HOI incidence cannot be determined and thus the HOI is excluded from output metrics.</p> <p>Defined by: Requester Input type: Optional (default value is 0) Format: Numeric Example: 365</p>
Care Setting	CARESETTING	<p>Details: the care settings considered for the diagnosis and procedure codes used to define HOIs. If all care settings are wanted, leave the field blank. The following are valid entries; all entries must be quoted and separated by a space:</p> <ul style="list-style-type: none"> • IP: inpatient hospital stays • IS: non-acute institutional stays • ED: emergency department visits • AV: ambulatory visits • OA: other ambulatory visits <p>Note 1: CARESETTING is allowed to vary between CODEs within the same GROUP. For example, CARESETTING is allowed to equal 'IP' for one diagnosis code and 'IP' 'ED' for another diagnosis code <i>in the same GROUP</i>.</p> <p>Defined by: Requester Input type: Optional Format: Alphanumeric; SAS character \$20. Example: 'IP' 'ED'</p>
Principal Diagnosis Indicator	PRINCIPAL	<p>Details: for a diagnosis CODETYPE (e.g., DX09, DX10, DX11), if PRINCIPAL is set equal to YES, only principal diagnoses in the IP and ED settings will be chosen. However, if PRINCIPAL is set equal to NO, all diagnoses for the specified care settings will be chosen. For codes other than diagnosis codes, PRINCIPAL must be set equal to NO.</p> <p>Defined by: Requester Input type: Required Format: Alphanumeric; SAS character \$3. Example: YES</p>

2. Incident Query File

The [Incident Query File](#) is optional. If defined, the file contains the comprehensive set of codes used to refine the incidence definition of the HOI(s). Just like the [Query File](#), HOI(s) can be defined using any mix of the following allowed code types: NDCs, ICD procedure and diagnosis codes, or HCPCS codes.

The GROUP structure of the [Incident Query File](#) must match that of the [Query File](#). That is, for each GROUP defined in the [Incident Query File](#) a matching GROUP must be found in the [Query File](#).

By default, for a given query GROUP MP9 uses the list of codes included in the [Query File](#) to determine the incident status of identified HOIs (as of the index date). That is, incidence is defined as no HOI in the WASHPER days before the HOI claim date. The [Incident Query File](#) is used to refine incidence based on a set of codes different than those used to define the HOI in the [Query File](#). For example, a requester may be interested in examining the use of Drug A, but wants all incident users of Drug A to be free of Drug A, B and C in the 183 days before the Drug A index date. In this case, the list of codes for Drug A would be included in the [Query File](#), and the list of codes for Drugs B and C would be included in the [Incident Query File](#).

Table 3 describes specifications for the [Incident Query File](#).

Table 3: Incident Query File Specification

Parameter	Field Name	Description
Name of Query Group	GROUP	<p>Details: standardized name used to refer to a query GROUP for HOI(s) to be queried.</p> <p>Request Programmer Note 1: in many cases value must match GROUP values from the Query File. In the case where all codes in the Incident Query File are used to assess incidence for <i>all</i> GROUPs in the Query File, this field may be left blank.</p> <p>Named by: Request programmer Input type: Required Format: Alphanumeric; SAS character \$30; no special characters (<i>e.g.</i>, commas, periods, hyphens, etc) allowed, and underscores must be used to mark spaces. Example: Insulin</p>
Incident Only Code Type	CODETYPE	<p>Details: type of each code value included in the CODE field (below) of this file.</p> <p>Valid values are all those allowed by the MSCDM:</p> <ul style="list-style-type: none"> • DX09: ICD-9-CM diagnosis • DX10: ICD-10-CM diagnosis • DX11: ICD-11-CM diagnosis • RX11: 11-digit NDC • RX09: 9-digit NDC • PX09: ICD-9-CM procedure • PX10: ICD-10-CM procedure • PX11: ICD-11-CM procedure • PXC4: CPT-4 procedure (<i>i.e.</i>, HCPCS Level I) • PXHC: HCPCS procedure (<i>i.e.</i>, HCPCS Level II)

Parameter	Field Name	Description
		<ul style="list-style-type: none"> • PXH3: HCPCS Level III procedure • PXC2: CPT Category II procedure • PXC3: CPT Category III procedure <p>Note 1: for CODETYPE=RX09, a nine-digit NDC value must be included in the CODE field (below).</p> <p>Defined by: Request programmer Input type: Required Format: Alphanumeric; SAS character \$4 Example: See valid values</p>
Incident Only Query Codes	CODE	<p>Details: NDC, ICD, and HCPCS code values to be used to refine the incident definition for the HOI(s). For example, if a requester is examining exposure to DRUG A, but wants incidence of DRUG A to be defined with respect to DRUG A <i>and</i> DRUG B, the Incident Only Query Code fields would include DRUG B codes.</p> <p>Note 1: Codes are matched using exact values (<i>i.e.</i>, 3-digit code lookup requires an exact 3-digit code match). Wildcard match (*) functionality is also available (<i>e.g.</i>, querying “250*0” would be used to find any ICD-9-CM diagnosis codes for diabetes type II, or “250*” to find ICD-9-CM diagnosis codes for all diabetes codes that start with “250”).</p> <p>Note 2: remove decimal points in the code value.</p> <p>Note 3: CODETYPE must be consistent with the expected format of the CODE value (<i>e.g.</i>, MP9 will not find any valid matches in the data for CODETYPE=PXC4 and a 3-digit code value).</p> <p>Note 4: duplicate CODETYPE-CODE combinations in a given query GROUP are removed by the MP9 algorithm.</p> <p>Defined by: Requester, with support from MSOC as needed Input type: Required Format: Alphanumeric; SAS character \$11 Example: 12345678922</p>
Incident Query Code Description	DESCR	<p>Details: description of the NDC, diagnosis, or procedure code listed in the CODE field. Used primarily by request programmers to include meaningful code definitions in input files.</p> <p>Note 1: this parameter is optional (<i>i.e.</i>, the MP algorithm will not fail if this parameter is excluded from the Incident Query File)</p> <p>Defined by: Request Programmer Input type: Optional Format: SAS character \$30.</p>

Parameter	Field Name	Description
		Example: Insulin Lispro
Care Setting	CARESETTING	<p>Details: the care settings considered for the diagnosis and procedure codes used to define <i>incident</i> HOIs. If all care settings are wanted, leave the field blank. The following are valid entries; all entries must be quoted and separated by a space:</p> <ul style="list-style-type: none"> • IP: inpatient hospital stays • IS: non-acute institutional stays • ED: emergency department visits • AV: ambulatory visits • OA: other ambulatory visits <p>Note 1: CARESETTING is allowed to vary between CODEs within the same GROUP. For example, CARESETTING is allowed to equal 'IP' for one diagnosis code and 'IP' 'ED' for another diagnosis code <i>in the same GROUP</i>.</p> <p>Defined by: Requester Input type: Optional Format: Alphanumeric; SAS character \$20. Example: 'IP' 'ED'</p>
Principal Diagnosis Indicator	PRINCIPAL	<p>Details: for a diagnosis CODETYPE (<i>e.g.</i>, DX09, DX10, DX11), if PRINCIPAL is set equal to YES, only principal diagnoses in the IP and ED settings will be chosen. However, if PRINCIPAL is set equal to NO, all diagnoses for the specified care settings will be chosen. For codes other than diagnosis codes, PRINCIPAL must be set equal to NO.</p> <p>Defined by: Requester Input type: Required Format: Alphanumeric; SAS character \$3. Example: YES</p>

3. Inclusion/Exclusion Conditions File

The [Inclusion/Exclusion Conditions File](#) is optional. It is used to 1) include in the cohort only those members having evidence of certain conditions; 2) exclude from the cohort those members having evidence of certain conditions; or 3) combine inclusion and exclusion criteria to define the cohort. If defined, this file contains the comprehensive set of codes used to define the inclusion and exclusion condition(s) of interest.

The MP9 [Inclusion/Exclusion Conditions File](#) allows the following code types: NDCs, ICD diagnosis and procedure codes, and/or HCPCS codes. Condition(s) can be defined using any mix of these allowed code types. A different lookback period can be defined for each condition code specified. Values of the GROUP fields must match between the [Query File](#) and the [Inclusion/Exclusion Conditions File](#). Table 4 describes specifications for the [Inclusion/Exclusion Conditions File](#).

Table 4: Inclusion/Exclusion Conditions File Specification

Parameter	Variable Name	Description
Name of Query Group	GROUP	<p>Details: standardized name used to refer to a query GROUP for HOI(s) to be queried.</p> <p>Note 1: must match GROUP values from the Query File.</p> <p>Named by: Request programmer Input type: Required Format: Alphanumeric; SAS character \$30; no special characters (<i>e.g.</i>, commas, periods, hyphens, etc) allowed, and underscores must be used to mark spaces. Example: Insulin1</p>
Condition Code Type	CODETYPE	<p>Details: type of each code value included in the CODE field (below) of this file.</p> <p>Valid values are all those allowed by the MSCDM:</p> <ul style="list-style-type: none"> • RX11: 11-digit NDC code • RX09: 9-digit NDC code • DX09: ICD-9-CM diagnosis • DX10: ICD-10-CM diagnosis • DX11: ICD-11-CM diagnosis • PX09: ICD-9-CM procedure • PX10: ICD-10-CM procedure • PX11: ICD-11-CM procedure • PXC4: CPT-4 procedure (<i>i.e.</i>, HCPCS Level I) • PXHC: HCPCS procedure (<i>i.e.</i>, HCPCS Level II) • PXH3: HCPCS Level III procedure • PXC2: CPT Category II procedure • PXC3: CPT Category III procedure <p>Note 1: for CODETYPE=RX09, a nine-digit NDC value must be included in the CODE field (below).</p> <p>Defined by: Request programmer Input type: Required Format: Alphanumeric; SAS character \$4 Example: PXHC</p>
Condition Code	CODE	<p>Details: code values to be used to define condition(s) of interest.</p> <p>Note 1: Codes are matched using exact values (<i>i.e.</i>, 3-digit code lookup requires an exact 3-digit code match). Wildcard match (*) functionality is also available (<i>e.g.</i>, querying “250*0” would be used to find any ICD-9-CM diagnosis codes for diabetes type II, or “250*” to find ICD-9-CM diagnosis codes for all diabetes codes</p>

Parameter	Variable Name	Description
		<p>that start with “250”).</p> <p>Note 2: remove decimal points in the code value.</p> <p>Note 3: CODETYPE must be consistent with the expected format of the CODE value (<i>e.g.</i>, MP will not find any valid matches in the data for CODETYPE=PXC4 and a 3-digit CODE value).</p> <p>Note 4: duplicate CODETYPE - CODE combinations are removed by the MP algorithm.</p> <p>Defined by: Requester, with support from MSOC as needed Input type: Required Format: Alphanumeric; SAS character \$11 Example: J3490</p>
Condition Code Description	DESCR	<p>Details: description of the NDC, diagnosis, or procedure code listed in the CODE field. Used primarily by request programmers to include meaningful code definitions in input files.</p> <p>Note 1: this parameter is optional (the MP9 algorithm will not fail if this parameter is excluded from the Inclusion/Exclusion Conditions File)</p> <p>Defined by: Request Programmer Input type: Optional Format: SAS character \$30. Example: AMI</p>
Inclusion/Exclusion Indicator	INCLUSION	<p>Details: indicates whether each condition CODE specified is for an inclusion (=1) or exclusion (=0) criterion.</p> <p>Named by: Requester Input type: Required Format: Numeric Example: 1</p>
Lookback Period Start	CONDFROM	<p>Details: used in combination with CONDTO to define the start of the lookback period for each condition code specified, expressed in terms of “days from Index Date”. For example, if Index Date=01/08/2009 and CONDFROM for a given condition code is set to -7, the MP algorithm will start looking for that condition code on 01/01/2009.</p> <p>Note 1: individual condition codes within a same Query GROUP are allowed to have different lookback periods and therefore have different CONDFROM and CONDTO values.</p> <p>Note 2: the index date is “day zero”. Therefore, if zero is included</p>

Parameter	Variable Name	Description
		<p>in the CONDFROM-CONDTO interval for a given condition code, the index date is included in the lookback period.</p> <p>Note 3: if CONDFROM > 0 then the lookback period will start after the index date.</p> <p>Named by: Requester Input type: Required Format: Numeric Example: -180</p>
Lookback Period End	CONDTO	<p>Details: used in combination with CONDFROM to define the end of the lookback period for each condition code specified, expressed in terms of “days from Index Date”. For example, if Index Date=01/08/2009 and CONDTO for a given condition code is set to -1, the MP algorithm will look for that condition code between the CONDFROM date through 01/07/2009.</p> <p>Note 1: individual condition codes within the same Query GROUP are allowed to have different lookback periods and therefore have different CONDFROM and CONDTO values.</p> <p>Note 2: the index date is “day zero”. Therefore if zero is included in the CONDFROM-CONDTO interval for a given code the index date is included in the lookback period.</p> <p>Named by: Requester Input type: Required Format: Numeric Example: -1</p>
Condition Care Setting	CARESETTING	<p>Details: contains the care settings considered for the individual condition diagnosis or procedure codes. If all care settings are wanted, leave the field blank. The following are valid entries; all entries must be quoted and separated by a space:</p> <ul style="list-style-type: none"> • IP: inpatient hospital stays • IS: non-acute institutional stays • ED: emergency department visits • AV: ambulatory visits • OA: other ambulatory visits. <p>Note 1: CARESETTING is allowed to vary between CODEs within the same GROUP. For example, CARESETTING is allowed to equal ‘IP’ for one diagnosis code and ‘IP’ ‘ED’ for another diagnosis code <i>in the same GROUP</i>.</p> <p>Defined by: Requester</p>

Parameter	Variable Name	Description
		Input type: Optional Format: Alphanumeric; SAS character \$20. Example: 'IP' 'ED'
Principal Diagnosis Indicator	PRINCIPAL	Details: for a diagnosis CODETYPE (<i>e.g.</i> , DX09, DX10, DX11), if PRINCIPAL is set equal to YES, only principal diagnoses in the IP and ED settings will be chosen. However, if PRINCIPAL is set equal to NO, all diagnoses for the specified care settings will be chosen. For codes other than diagnosis codes, PRINCIPAL must be set equal to NO. Defined by: Requester Input type: Required Format: Alphanumeric; SAS character \$3. Example: YES

4. Output Table Selection File

The [Output Table Selection File](#) is optional. It is used to instruct the MP algorithm to preserve only a subset of all output tables generated by one run of the MP. If defined, it contains parameters used to specify which output tables generated by the MP should be kept in the output folder of the MP run.

Unlike other MP input files, the GROUP field is not part of the set of required parameters. One instance of the OUTTABLESFILE input file can be used for multiples runs of the MP no matter what GROUP values are used.

There are several required parameters that must be specified, all by the request programmer. Moreover, the input file must contain one line for each of the output files generated by each run of MP9. Table 5 contains detailed specifications for the [Output Table Selection File](#), and a template is provided in [Section X](#).

Table 5: Output Table Selection File Specification

Parameter	Variable Name	Description
Name of Table in MP Documentation	DOCTABNAME	Details: contains the name of the table as specified in the MP documentation. Note 1: this is not the actual name used inside the program but the name as listed in the documentation. Named by: Request programmer Input type: Optional, for reference only, dropped at the start of the MP execution. Format: Alphanumeric; SAS character \$30. Example: Table1

Parameter	Variable Name	Description
Description of Table in MP Documentation	DOCTABDESCR	<p>Details: contains the description of the table as specified in the table titles of the modular program documentation.</p> <p>Named by: Request programmer</p> <p>Input type: Optional, for reference only, dropped at the start of the MP execution.</p> <p>Format: Alphanumeric; SAS character \$150.</p> <p>Example: Counts of Members, Total Dispensings and Days of Supply</p>
Name of Table Generated by MP	TABNAME	<p>Details: contains the name of the table generated by the modular program.</p> <p>Note 1: must be entered in lower case.</p> <p>Note 2: this is the actual table name used inside the program.</p> <p>Named by: Request programmer</p> <p>Input type: Required</p> <p>Format: Alphanumeric; SAS character \$10.</p> <p>Examples: table1, table11</p>
Table Inclusion Indicator	TABREQUIRED	<p>Details: indicates whether TABNAME must be preserved. Valid values are:</p> <ul style="list-style-type: none"> • Y: preserve table in output • N: remove table from output <p>Named by: Request programmer</p> <p>Input type: Required</p> <p>Format: Alphanumeric; SAS character \$1.</p> <p>Example: Y</p>

V. KEY DEFINITIONS

A. ENROLLMENT REQUIREMENTS

For either prevalent or incident scenarios, all claims used by the MP algorithm to select members of interest and identify HOIs must occur during valid enrollment periods. All requirements used to build valid enrollment periods are fully customizable using a set of requester-defined input parameters.

First, the main COVERAGE parameter allows the requester to select the type of coverage required for each run of the MP based on whether medical, drug, or both medical and drug coverage are required during all enrollment periods. The default option is to require both medical and drug coverage.

Continuous enrollment periods are then constructed by bridging all enrollment records of the correct coverage type. That is, using the main ENROLGAP parameter, two (or more) consecutive enrollment periods separated by (no more) than ENROLGAP days are bridged together to form a longer, continuous

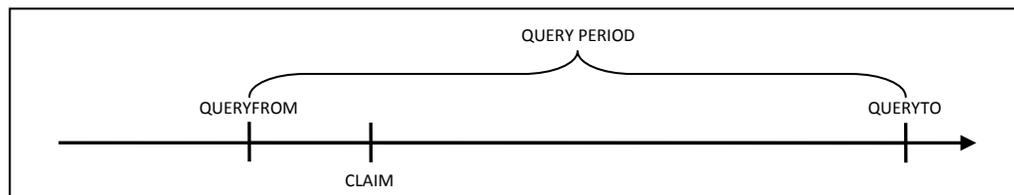
enrollment episode of the relevant coverage type. Such continuous enrollment episodes are then used to confirm whether claims with query codes of interest and other characteristics can be used toward identification of HOIs and other inclusion/exclusion criteria.

Since each HOI can only be considered incident with at least WASHPER days free of any prior HOI of interest (or any other HOIs(s) specified in the [Incident Query File](#)), the MP algorithm by default ensures that at least WASHPER days of continuous enrollment with the relevant coverage type are found before the index date **no matter how many minimum pre-index enrollment days are requested** (as specified by the ENRDAYS parameter of the [Query File](#)). Therefore the minimum pre-index enrollment days requirement can only be binding if it requires more days than those already requested by the required WASHPER parameter (i.e., if ENRDAYS > WASHPER). For example, if the required WASHPER is set to 183 days, a minimum number of pre-index enrollment days of ENRDAYS=183 (or less) does not impact what records are used to select the desired cohort of members.

B. PREVALENCE-BASED COHORT

The [prevalence-based cohort](#) is composed of all members meeting inclusion/exclusion conditions criteria who have at least one claim that qualifies as an HOI during the query period, delimited by the QUERYFROM to QUERYTO dates as illustrated in Figure 1. The claim date for each HOI considered must fall during a continuous enrollment period of relevant coverage type (See [Section V.A](#)).

Figure 1: Prevalence-based Cohort



C. INCIDENCE-BASED COHORT

The [incidence-based cohort](#) is a subset of the [prevalence-based cohort](#) that represents members who meet the incidence definition during the query period. When generating metrics for the [incidence-based cohort](#), the MP9 algorithm allows members to have one of the two following options: (1) [minimum incidence](#), where only one claim can be considered incident (specified using the WASHTYP=MIN option) or (2) [multiple incidence](#), where multiple claims can be considered incident (specified using the WASHTYP=MULT option).

1. Minimum Incidence (MIN)

Under the [minimum incidence](#) option, members can have only one incident HOI claim during the query period and that claim must be the first one observed for that member in all enrollment periods of relevant coverage type considered by the program. Minimum incidence is thus defined as evidence of one HOI claim observed during the query period that satisfies the following conditions:

1. Claim date falls during a continuous enrollment period of relevant coverage type.

2. Member is continuously enrolled at least ENRDAYS (if specified by the Minimum Pre-Index Enrollment Days parameter in the [Query File](#)) and WASHPER days (specified by the Washout Period parameter) before the HOI index date.
3. Member has no evidence of another claim with an HOI code or [Incident Query File](#) code during any enrollment period before the HOI index date. That is, the MP algorithm queries the set of data available before the index claim date (regardless of the specified query period) to ensure that no claim with an HOI code or [Incident Query File](#) code is observed during enrollment periods of relevant type under consideration.

This option should be used with caution as interpretation can be complex (*i.e.*, incidence is a function of the length of the member's available enrollment history).

2. Single Incidence (SING)

Under the single incidence option, members can have only one incident HOI during the query period, and the claim used to define the incident HOI must meet the following incidence conditions:

1. Claim date falls during a continuous enrollment period of relevant coverage type.
2. Member is continuously enrolled at least ENRDAYS (if specified by the Minimum Pre-Index Enrollment Days parameter in the [Query File](#)) and WASHPER days (specified by the Washout Period parameter) before the HOI index date.
3. Member has no evidence of a claim with a HOI code or [Incident Query File](#) code during the WASHPER days prior to the claim date.
4. Claim is the first claim meeting conditions 1 -3 during the query period. Under this condition, a member can only have one incident HOI claim during the query period.

3. Multiple Incidence (MULT)

Under the [multiple incidence](#) option a member can have multiple incident HOI claims as long as each claim meets the following incidence conditions. This definition is commonly used on epidemiologic assessments as it limits the period used to define incidence to a washout period that is equal for all members.

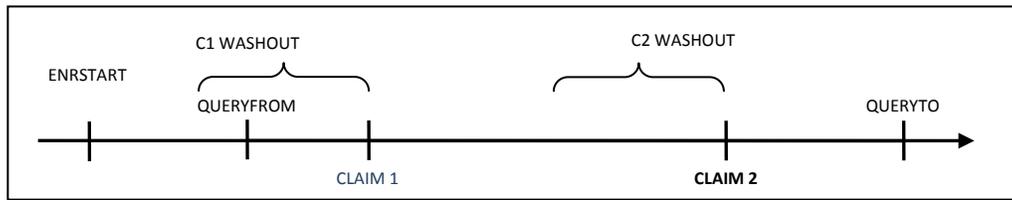
1. Claim date falls during a continuous enrollment period of relevant coverage type.
2. Member is continuously enrolled at least ENRDAYS (if specified by the Minimum Pre-Index Enrollment Days parameter in the [Query File](#)) and WASHPER days (specified by the Washout Period parameter) before the HOI index date.
3. Member has no evidence of a claim with a HOI code or [Incident Query File](#) code during the WASHPER days prior to the claim date.

4. Examples

The following examples illustrate the implications of incidence type options. While the MP9 algorithm can evaluate multiple enrollment periods per member, for simplicity, each scenario depicted here includes members with only one enrollment period. The following examples also assume that the MP9 algorithm has already restricted the cohort to members with and/or without a condition of interest (as specified in the [Inclusion/Exclusion Conditions File](#)) and that no additional codes have been included in the [Incident Query File](#) to refine the incidence definition.

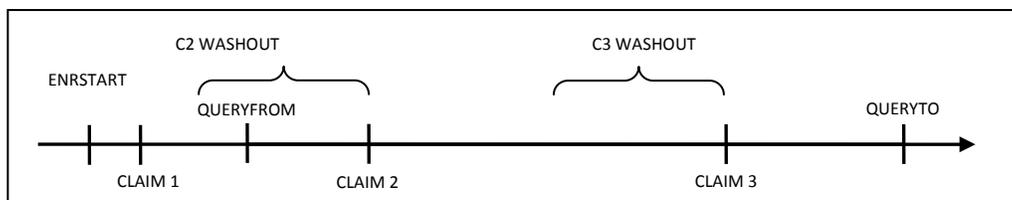
Figure 2 illustrates how the MP9 algorithm identifies a claim using the minimum incidence option.

Figure 2: Incident Claim Identification Using the Minimum Incidence Option



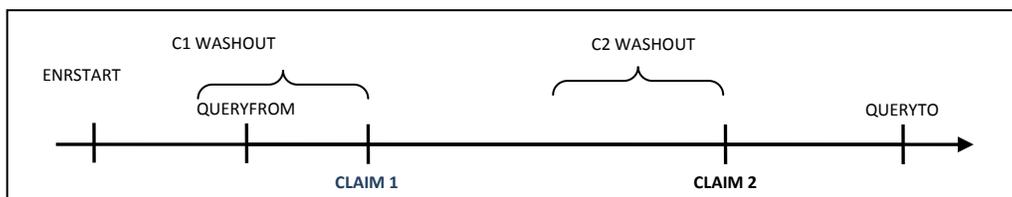
In the scenario depicted in Figure 2, ENRSTART indicates the member’s start of enrollment in drug and/or pharmacy benefits (depending on the user-defined COVERAGE requirements). CLAIM 1 would be selected as the incident claim in this scenario, as the member satisfies enrollment criteria and has no HOI claim before CLAIM 1. CLAIM 2 also satisfies enrollment criteria, but prior CLAIM 1 excludes CLAIM2 from being considered incident using the [minimum incidence](#) option. Figure 3 depicts a scenario where a member does not have an incident claim under the [minimum incidence](#) option.

Figure 3: No Incident Claim Using the Minimum Incidence Option



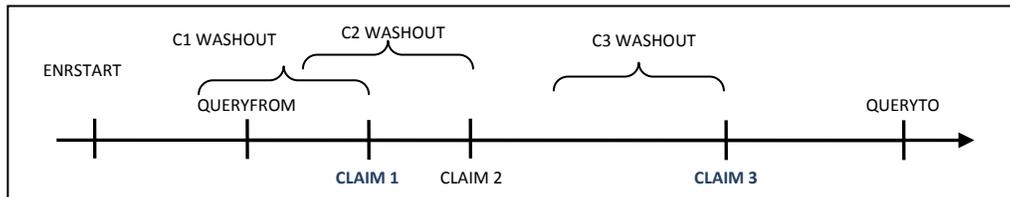
In this scenario CLAIM 1 is not considered incident since it did not occur within the query period. While CLAIMs 2 and 3 satisfy the enrollment period condition, the presence of CLAIM 1 prior to the query period, but during the member’s history excludes these as incident claims under the [minimum incidence](#) option. Figure 4 illustrates how the MP9 algorithm identifies a claim using the [single incidence](#) option.

Figure 4: Incident Claim Identification Using the Single Incidence Option



In the scenario depicted in Figure 4, CLAIM 1 is selected as the incident HOI, as the member satisfies the enrollment condition and has no query claim in the WASHPER days before the CLAIM 1 index date. While CLAIM 2 also satisfies the enrollment and washout conditions, CLAIM 1 excludes CLAIM 2 from being considered incident under the [single incidence](#) option. Figure 5 illustrates how the MP9 algorithm identifies a claim using the [multiple incidence](#) option.

Figure 5: Incident Claim Identification Using the Multiple Incidence Option



In Figure 5, CLAIMS 1 and 3 will be considered incident using the [multiple incidence](#) option since a washout period free of any claim (query or from the incident only list) is observed and both satisfy the enrollment condition. CLAIM 2 is not considered incident since it does not meet the washout criteria (*i.e.*, CLAIM 1 occurs during the CLAIM 2 washout period).

D. COHORT INCLUSION OR EXCLUSION BASED ON CONDITIONS OF INTEREST

The requester can restrict the cohort using inclusion and/or exclusion criteria using the optional [Inclusion/Exclusion Conditions File](#). Members can be included or excluded from the cohort if certain conditions are recorded during a specific lookback period. Conditions can be defined by any combination of valid diagnoses, procedures and/or NDCs.

The condition lookback period is defined by a combination of start and end dates (expressed in terms of days from index date, where day zero refers to the index date). Note that the start and end dates can include and go beyond the index date (Day 0 of the interval). For example, if start = -30 and end = 30 the MP9 algorithm will search for conditions in the period starting 30 days before the index date and ending 30 days after.

The lookback period can also be defined at the code level. For example, the requester could require members to have a code for diabetes in the 183 days before index date OR a code for AMI in the 365 days before index date.

The presence of a claim with one of the desired inclusion condition codes is a sufficient condition to meet the inclusion criterion. However, in the case of exclusions, the absence of any claims with one of the desired exclusion condition codes is a necessary but not sufficient condition to meet the exclusion criterion. To fully satisfy the exclusion criterion the member also needs to be continuously enrolled for medical and/or drug coverage for the complete exclusion lookback period. For example, if a member is free of an exclusion claim in the -180 to -90 days before the index date, but was only enrolled from days -120 to -90, the MP algorithm cannot classify this member “free of the exclusion claims” since there is no way to know whether an exclusion claim would have been recorded during days -180 to -121.

VI. DENOMINATORS AND BACKGROUND RATES

In addition to metrics on use of HOI(s), all output tables include metrics on denominators associated with each result stratum. Denominator metrics include (1) count of members and (2) eligible member days. These metrics are different for the [prevalence-based](#) vs. [incidence-based cohort](#). The members included in any denominator metrics are all the “eligible” members, *i.e.*, members who can potentially

be identified by the MP algorithm as a user (*i.e.*, either prevalent or incident) of the HOI(s) defined in the query group.

Prevalence-Based Cohort: Eligible Members and Member-Days

The denominator member count for the [prevalence-based cohort](#) is composed of all members with at least one enrollment day (of relevant type; see [Section V.A](#)) during the query period. If inclusion/exclusion conditions are specified, the member must also satisfy the condition requirements to be included. Eligible member days for this cohort are simply the sum of all such enrollment days during the query period for the aforementioned members included in the denominator.

Incidence-Based Cohort: Eligible Members and Member-Days

The denominator member count for the [incidence-based cohort](#) is composed of all members enrolled for one period (or more) of continuous enrollment (of relevant type) of at least WASHPER+1 days (*i.e.*, WASHPER days for incidence requirement and one day to allow for HOI to be observed) overlapping but prior to the end of the query period and meeting any specified inclusion/exclusion conditions criteria. These members may be different depending on what Incidence Type is chosen.

For the [minimum incidence](#) type the following will be reported:

1. Members to be reported must be free of query claims or claims from HOI(s) found in the [Incident Query File](#) during all prior enrollment periods of relevant type in the member's history.
2. Eligible member days reported are equal to the number of days of enrollment (of relevant type) falling during the query period that are (1) preceded by a period of at least WASHPER days and b) prior to a query claim date or a claim for an [Incident Query File](#) code.

If, however, the [multiple incidence](#) option is chosen, the following will be reported:

1. Members to be reported must be free of query claims or claims from HOI(s) found in the [Incident Query File](#) during the washout period only.
2. Eligible member days reported are equal to the sum of all days of enrollment (of relevant type) falling during the query period that are preceded by a period of at least WASHPER days free of any query claims or claims from HOI(s) found in the [Incident Query File](#).

Background Rates

Once denominator metrics are available, MP9 allows for the calculation of background rates for each Query GROUP specified. For example, the requester can calculate the proportion and rate of new users of HOIs in Query GROUP Z. The *proportion of new users* would be defined as the number of new users (*i.e.*, the numerator) per X enrolled members (*i.e.*, the denominator), whereas the *rate of new users* would be defined as the number of new users per Y person-time (*e.g.*, person-years, member-days). For MP9, background proportions and rates are calculated for members meeting any specified inclusion/exclusion conditions criteria.

VII. PROGRAM STEPS

The general program steps are:

1. Extract HOI claims from the MSDD outpatient pharmacy, diagnosis, and procedure tables to create HOI dates for each member.
2. Identify members with conditions of interest according to the specifications of the [Inclusion/Exclusion Conditions File](#).
3. For each Query GROUP, assess prevalent and incident status, and extract all claims of interest during query period to calculate utilization by member and Query GROUP.
4. For each Query GROUP, calculate denominator member counts and days enrolled.
5. Calculate age at index date and extract sex for each cohort member using the MSDD demographic file.
6. Create output tables for both prevalent and incident users along with denominators and member days.

VIII. PROGRAM EXECUTION

When implementing modular programs within the MSDD, the Mini-Sentinel Operations Center (MSOC) uses a uniform folder structure across Data Partners to facilitate communications between MSOC and Data Partners and to streamline file management.

Each request distributed by MSOC is assigned a unique Request ID. Upon receipt of the request, Data Partners create a folder named after the Request ID and several subfolders to organize program inputs and outputs. One of the folders contains output to be sent to MSOC and another contains intermediate files that remain with the Data Partner, but could be used to facilitate follow-up queries if necessary. Appropriate retention policies apply.

Table 6 defines the local environment variables that must be initialized by the user to execute the program (i.e., defined by the Data Partner prior to execution of the program). Please note that these values cannot be left blank. Each Data Partner is required to enter user inputs at the beginning of the SAS Program sent with each request. These inputs are unique to each Data Partner.

Table 6: Environment Variable Definitions

Label	Field Name	Description
Data Partner ID	DPID	Two character Partner ID
Site ID of Data Partner	SITEID	Two character Site ID
Enrollment Table Name	ENRTABLE	Name of the Data Partner's MSCDM Enrollment table
Demographics Table Name	DEMTABLE	Name of the Data Partner's MSCDM Demographics table
Dispensing Table Name	DISTABLE	Name of the Data Partner's MSCDM Dispensing table
Procedure Table Name	PROCTABLE	Name of the Data Partner's MSCDM Procedure table
Diagnosis Table Name	DIATABLE	Name of the Data Partner's MSCDM Diagnosis table
Input file folder	INFOLDER	Path where the input files will be saved
Output file folder	MSOC	Path where the shared output tables will be saved
Local data folder	DPLOCAL	Path where the local SAS datasets will be saved
Libname of the MSCDM	INDATA	Path where the local MSDD data is saved

IX. OUTPUT TABLES AND ANALYSIS TOOLS

A. OUTPUT TABLES

Thirteen output tables are created by MP9 are output in .sas7bdat format. Five output tables each are created for the [incident-based cohort](#) and the [prevalence based cohort](#). Additionally, one numerator table, one denominator table, and one attrition table containing full query summary statistics are also output. The numerator and denominator tables contain all data necessary to calculate incident and prevalent rates stratified by month/year, age and gender. Tables can be identified by the following suffixes:

- _ITABLEX
- _PTABLEX
- _DENTABLE0
- _NUMTAB0
- _ATTRITIONTABLE

The “I” and “P” correspond to incident and prevalent tables, respectively, and the “X” corresponds to the table number and takes the values 1 to 5. There is only one denominator table (DENTABLE0) and one numerator table (NUMTAB0). Below are examples of the incident and prevalent output tables, produced using the multiple incidence option.

ITABLE1 - Counts of Members and Claims over the Query Period

Group	Users	Incident Claims	Claims	Days of Supply	Amount Supplied	Eligible Members	Eligible Days
DRUGGROUP1	10,132	10,910	35,053	1,639,188	1,969,234	512,592	257,978,008
PROCGROUP1	51,994	55,525	60,525	60,525	75,203	512,584	257,978,008

First row interpretation of ITABLE1: Within the QUERYFROM to QUERYTO period, 10,132 members (users) had at least one incident claim for any drug within the DRUGGROUP1 category. For these members, 10,910 HOIs (incident claims) and 35,053 individual claims were observed for a total of 1,639,188 days of supply. Finally, 512,592 members could potentially have been included as incident users (eligible members) for a total of 257,978,008 eligible days.

PTABLE1 -Counts of Members and Claims over the Query Period

Group	Users	Incident Claims	Claims	Days of Supply	Amount Supplied	Eligible Members	Eligible Days
DRUGGROUP1	12,152	---	50,042	1,999,192	2,099,991	695,412	322,866,001
PROCGROUP1	59,888	---	60,991	60,991	79,239	695,412	322,866,001

First row interpretation of PTABLE1: Within the QUERYFROM to QUERYTO period, 12,152 members (users) had at least one prevalent claim for any drug in DRUGGROUP1. For these members there were 50,042 individual claims, for a total of 1,999,192 days of supply. Finally, 695,412 members could potentially have been included as prevalent users (eligible members) for a total of 322,866,001 eligible days.

ITABLE2 - Counts of Members and Claims over the Query Period Stratified by Year/Month

Group	Year	Month	Users	Incident Claims	Claims	Days of Supply	Amount Supplied	Eligible Members	Eligible Days
DRUGGROUP1	2007	6	206	206	210	8,451	9,245	154,258	4,617,269
DRUGGROUP1	2007	7	256	256	265	9,907	10,309	237,408	7,343,258
PROCGROUP1	2007	6	931	931	939	939	1,099	151,368	4,512,364
PROCGROUP1	2007	7	1,468	1,468	1,478	1,478	1,890	232,771	7,161,371

First row interpretation of ITABLE2: In June 2007, 206 members (users) had at least one incident claim for any drug in DRUGGROUP1. In the same month for these members, 206 HOIs (incident claims) and 210 individual claims were observed for a total of 8,451 days of supply. Finally, 154,258 members could potentially have been included as incident users in June 2007 (eligible members) for a total of 4,617,269 eligible days. The explanation above can also be applied for prevalent table interpretations. Replace “incident” with “prevalent” in the above explanation and set the value of “Incident Claims” to missing as this is irrelevant for prevalent rates. Note that counts should be higher for prevalent tables relative to incident tables.

ITABLE3 - Counts of Members and Claims over the Query Period Stratified by Age Group

Group	Age Group	Users	Incident Claims	Claims	Days of Supply	Amount Supplied	Eligible Members	Eligible Days
DRUGGROUP1	10 to 19	660	677	1,000	22,511	27,652	91,828	41,772,749
DRUGGROUP1	20 to 39	1,229	1,280	2,688	80,320	91,237	168,623	67,572,698
DRUGGROUP1	40 to 55	2,682	2,877	8,523	335,332	366,298	161,300	78,439,389
DRUGGROUP1	56+	5,586	6,076	22,309	1,178,290	1,389,345	123,135	70,193,172
PROCGROUP1	10 to 19	8,247	8,794	9,450	9,450	11,234	91,512	40,292,790
PROCGROUP1	20 to 39	15,739	16,706	18,328	18,328	20,004	167,595	64,641,268
PROCGROUP1	40 to 55	15,008	15,909	17,259	17,259	19,995	161,522	76,633,096
PROCGROUP1	56+	13,221	14,116	15,374	15,374	17,389	124,179	70,189,592

First row interpretation of ITABLE3: 660 members (users) have at least one incident claim for any drug in DRUGGROUP1 within the QUERYFROM to QUERYTO period while being in the 10 to 19 year age group. For these members, 677 HOIs (incident claims) and 1,000 total claims for a total of 22,511 days of supply were counted. Finally, 91,828 members in the 10 to 19 year age group could potentially have been included as incident users (eligible members) for a total of 41,772,749 days eligible when in the age group. The explanation above can also be applied for prevalent table interpretations. Replace “incident” with “prevalent” in the above explanation and set the value of “Incident Claims” to missing as this is irrelevant for prevalent rates. Note that counts should be higher for prevalent tables relative to incident tables.

ITABLE4 - Counts of Members and Claims over the Query Period Stratified by Sex

Group	Sex	Users	Incident Claims	Claims	Days of Supply	Amount Supplied	Eligible Members	Eligible Days
DRUGGROUP1	F	6,687	7,201	23,135	1,081,864	1,200,111	338,311	170,265,485
DRUGGROUP1	M	3,445	3,709	11,918	557,324	601,888	174,281	87,712,523
PROCGROUP1	F	34,316	36,647	39,947	39,947	48,543	338,305	170,265,485
PROCGROUP1	M	17,678	18,878	20,578	20,578	27,886	174,279	87,712,523

First row interpretation of ITABLE4: In the QUERYFROM to QUERYTO period, 6,687 female members (users) had at least one incident claim for any drug in DRUGGROUP1. For these members, 7,201 HOIs (incident claims) and 23,135 total claims were observed for a total of 1,081,864 days of supply. Finally, 338,311 members could potentially have been included as incident users (eligible members) for a total

of 170,265,485 eligible days. The explanation above can also be applied for prevalent table interpretations. Replace “incident” with “prevalent” in the above explanation and set the value of “Incident Claims” to missing as this is irrelevant for prevalent rates. Note that rates should be higher for prevalent tables relative to incident tables.

ITABLE5 - Counts of Members and Claims over the Query Period Stratified by Year

Group	Claim Year	Users	Incident Claims	Claims	Days of Supply	Amount Supplied	Eligible Members	Eligible Days
DRUGGROUP1	2007	660	677	1,000	22,511	29,008	91,828	29,772,749
DRUGGROUP1	2008	1,229	1,280	2,688	80,320	89,221	168,623	52,572,698
PROCGROUP1	2007	8,247	8,794	9,450	9,450	12,356	91,512	29,292,790
PROCGROUP1	2008	15,739	16,706	18,328	18,328	22,349	167,595	52,641,268

First row interpretation of ITABLE5: In 2007, 660 members (users) had at least one incident claim for any drug in DRUGGROUP1. In the same year for these members, 677 HOIs (incident claims) and 1,000 total claims were observed for a total of 22,511 days of supply. Finally, 91,828 members could potentially have been included as incident users in 2007 (eligible members) for a total of 29,772,749 eligible days. The explanation above can also be applied for prevalent table interpretations. Replace “incident” with “prevalent” in the above explanation and set the value of “Incident Claims” to missing as this is irrelevant for prevalent rates. Note that counts should be higher for prevalent tables relative to incident tables.

B. ANALYSIS TOOLS

1. Attrition Table

A standalone analysis tool that is executed by default for each run of MP9 is the Attrition Table. This tool outputs a table containing the count of remaining and excluded members following application of inclusion and exclusion criteria at various stages of the MP algorithm. It allows the requester to see how the cohort of interest evolves after successively applying these criteria. The attrition table tool will enable the requester to summarize this information in a single output table.

**Table 7: Example of Attrition Table:
Counts of Remaining and Excluded Members for Modular Program 9 Selection Criteria**

Query Group	Criterion Number	Criterion Description	Members Remaining	Members Excluded
DRUGGROUP1	1	Initial Member Count - Members with a non-missing birth date/sex and at least one enrollment episode overlapping the query period	100,000	
DRUGGROUP1	2	Exclusion – members must be excluded if they only have episodes with DrugCov=N and MedCov=Y during the query period	100,000	0
DRUGGROUP1	3	Exclusion – members must be excluded if they only have episodes with DrugCov=Y and MedCov=N during the query period	100,000	0
DRUGGROUP1	4	Exclusion – members must be excluded if they only have episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y during the query period	100,000	0
DRUGGROUP1	5	Exclusion - members must satisfy the age range condition within the query period	80,000	20,000
DRUGGROUP1	6	Exclusion - members must have at least one QUERYGROUP claim within the query period	5,000	75,000
DRUGGROUP1	7	Exclusion - members must have at least one QUERYGROUP claim	4,000	1,000

Query Group	Criterion Number	Criterion Description	Members Remaining	Members Excluded
		satisfying the Query enrollment requirement (i.e., member is continuously enrolled for WASHOUT days)		
DRUGGROUP1	8	Exclusion – members must have at least one QUERYGROUP claim satisfying Query washout criteria (i.e., no query group claim for WASHOUT days)	3,500	500
DRUGGROUP1	9	Exclusion – members must have at least one QUERYGROUP claim satisfying Query incidence criteria (i.e., no incident query group claim for WASHOUT days)	3,500	0
DRUGGROUP1	10	Exclusion - Members must have at least one QUERYGROUP claim satisfying the Exclusion enrollment requirement	3,400	100
DRUGGROUP1	11	Exclusion – members must have at least one QUERYGROUP claim satisfying Exclusion conditions (from CONDFILE)	3,100	300
DRUGGROUP1	12	Exclusion – members must have at least one QUERYGROUP claim satisfying Inclusion conditions (from CONDFILE)	3,000	100

X. EXAMPLE

Tables 8-11 show examples of a [Query File](#), an [Incident Query File](#), an [Inclusion/Exclusion Conditions File](#), and an [Output Selection File](#) (e.g., queryfile.sas7bdat, incqueryfile.sas7bdat, condfilere.sas7bdat, outputselect.sas7bdat):

Table 8: Example of [Query File](#)

Group	Code	CodeType	WashPer	EnrDays	WashTyp	CareSetting	Principal
Group1	1111111100	RX11	180	365	MIN		NO
Group1	111111112	RX09	180	365	MIN		NO
Group2	99999	PXC4	360	365	MULT		NO
Group2	99998	PXC4	360	365	MULT		NO

Table 9: Example of [Incident Query File](#)

Group	Code	CodeType	CareSetting	Principal
Group1	1111111101	RX11		NO
Group2	77777	PXC4		NO

Table 10: Example of [Inclusion/Exclusion Conditions File](#)

Group	Code	CodeType	Inclusion	CondFrom	CondTo	CareSetting	Principal
Group1	WWW	DX09	1	-180	-1		NO
Group2	YYY	DX09	1	-360	-1		NO

Table 11: Example of [Output Table Selection File](#)

DOCTABNAME	DOCTABDESCR	TABNAME	TABREQUIRED
	Global Denominators	dentable0	Y
	Global Numerators	numtab00	Y
	Information About Inclusion/Exclusion Criteria	attritiontable	Y
Itable1	Incident - Counts of Members and Claims over the Query Period	itable1	Y
Itable2	Incident - Counts of Members and Claims over the Query	itable2	Y

DOCTABNAME	DOCTABDESCR	TABNAME	TABREQUIRED
	Period Stratified by Year/Month		
ITable3	Incident - Counts of Members and Claims over the Query Period Stratified by Age Group	itable3	Y
ITable4	Incident - Counts of Members and Claims over the Query Period Stratified by Sex	itable4	Y
ITable5	Incident - Counts of Members and Claims over the Query Period Stratified by Year	itable5	Y
PTable1	Prevalent - Counts of Members and Claims over the Query Period	ptable1	Y
PTable2	Prevalent - Counts of Members and Claims over the Query Period Stratified by Year/Month	ptable2	N
PTable3	Prevalent - Counts of Members and Claims over the Query Period Stratified by Age Group	ptable3	N
PTable4	Prevalent - Counts of Members and Claims over the Query Period Stratified by Sex	ptable4	N
PTable5	Prevalent - Counts of Members and Claims over the Query Period Stratified by Year	ptable5	N

In this example, the requester specifies that, in addition to the codes listed in the [Query File](#), the codes from the [Incident Query File](#) for the Group1 and Group2 Query Groups need to be considered to determine incidence. Additionally, the [Inclusion/Exclusion Conditions File](#) requires that each HOI Group be restricted to members with a code for a condition of interest in the WASHPER days prior to the index claim.

In the example above, the requester additionally instructed the request programmer to use the following SAS macro parameters:

- To be selected members need to have medical and drug coverage
- Any enrollment gap of less than 45 days is considered administrative and must be ignored
- For incident scenarios members need to have at least 365 days of enrollment of correct coverage type prior to HOI index date
- The query period spans the years 2007 to 2010
- The results should be segmented according to 5 year age groups from 10 to 49 years old
- Only certain output tables should be preserved

For this request, the program could be executed using the following SAS macro call:

```
%MODULARPROGRAM9 (
    REQUESTID=mpr01,
    RUNID=r01,
    COVERGE=MD,
    ENROLGAP=45,
    QUERYFROM=01/01/2007,
    QUERYTO=12/31/2010,
    QUERYFILE=queryfile.sas7bdat,
    INCQUERYFILE=incqueryfile.sas7bdat,
    CONDFILE=condfile.sas7bdat,
```

```
OUTTABLESFILE= mp_output_select.sas7bdat,  
AGESTRAT=10-14 15-19 20-24 25-29 30-34 35-39 40-44 45-49);
```