Wikiprint Book

Title: HICDEP

Subject:

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HICDEP 1.30

This article describes the HICDEP version 1.30 which was released on the 28th of March 2008. It is the latest released version. For a more detailed version history, please refer to the ChangeLog.

General data format

The table pages referenced in the overview describe the specific tables' structure in detail and present a list of suggested codes, both standard and human readable.

All codes apart from trivial no, yes or unknown codes are presented as lookup tables, the usage of these are described in the the article Considerations for using the format to create a database.

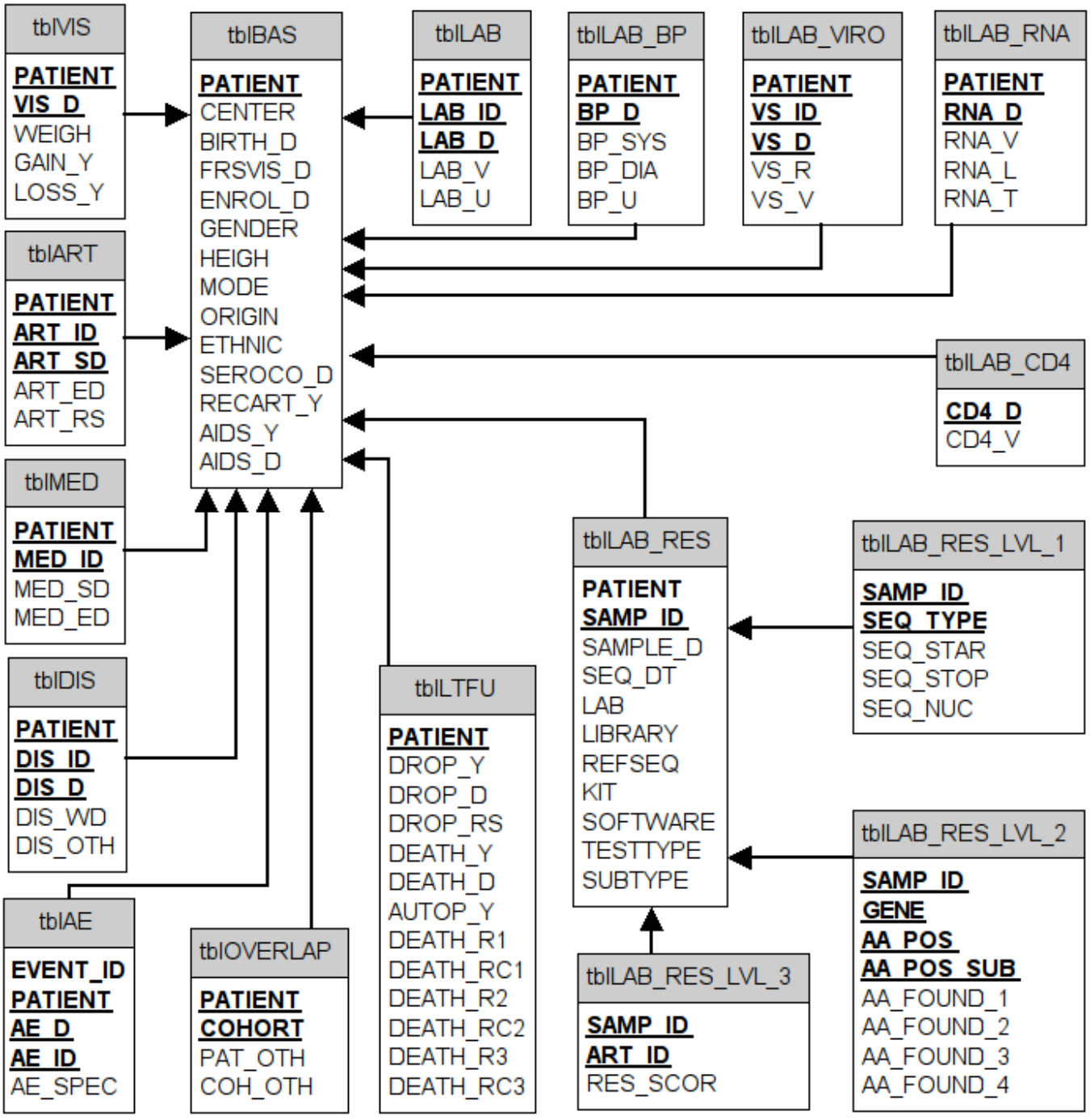
Along with the basic structure described in each ?Core fields? section, additional fields containing additional or more specific data are described in the ?Additional fields? sections. These fields were taken from several cohort collaborations but with the required changes that were needed for the specific data structures. This is presented to the reader to show that the core structure is not a fixed proposal but rather a basic structure, which can be altered by adding fields.

Issues regarding duplicates are discussed in Considerations For Data Management.

Overview of data tables

Table	Content
tblAE	holds type and date of **adverse events** including serious non-AIDS conditions
tblART	holds type of **antiretroviral drug**, start and stop dates and reason for stopping
tblBAS	holds **basic** information such as demographics, basic clinical information, date of AIDS diagnosis, death and drop-out information
tblDIS	holds type and date of CDC-C **diseases**.
tblLAB	holds type, date, value and unit of **laboratory tests**.
tblLAB_BP	holds date, diastolic and systolic values and unit of **blood pressure** measurements.
tblLAB_CD4	holds date and value of **CD4 measurements**.
tblLAB_RNA	holds date, value, detection limit and type of **viral assay**.
tblLAB_RES	holds **background information** on the resistance test, **laboratory**, library, kit, software and type of test
tblLAB_RES_LVL_1	holds nucleoside sequence for the PRO and RT sequences
tblLAB_RES_LVL_2	holds mutations and positions of these.
tblLAB_RES_LVL_3	holds resistance result in relation to antiretroviral drug.
tblLAB_VIRO	holds test results for **viro-/serological tests** (hepatitis etc.)
tblLTFU	holds data in **death and drop-out**
tblMED	holds type, start and stop dates for other HIV related **medicines**.
tblOVERLAP	holds information on the patient's **participation in other cohorts**
tblVIS	holds **visit related information**, weight, wasting.

Diagram



Structure of data

From flat files towards a normalized structure

The data collected in HIV collaborations is presented on the following pages in a set of data files/tables. Typically data would be put into one data file that would hold one line/record per patient where each field is represented as a separate column in that dataset. Often a dataset could contain more than 3000 columns of data.

The implication of going from thousands of fields to fewer fields means that data is in fact transposed from the flat format into the normalised format.

Example of a flat file structure:

PATIENT	ALAT_D	ALAT_V	ALAT_U	ASAT_D	ASAT_V	ASAT_U
999999	01-01-2000	15	U/l	01-01-2000	12	U/l

The normalised structure would then be like this:

PATIENT	TYPE_ID	LAB_DATE	LAB_VAL	LAB_UNIT
999999	1	01-01-2000	15	U/l
999999	2	01-01-2000	12	U/l

The type of measurement is identified through the TYPE_ID field. Here 1 codes for ALAT and 2 codes for ASAT:

Code	Description
1	ALAT - Alanin-Aminotransferase
2	ASAT - Aspartat aminotransferase

Technical considerations

To enable a normalised structure that minimises the number of columns dramatically, the one file solution must be broken into several minor tables. These breakdowns are driven by the different data characteristics.

Each table has a basic structure that includes the patient identifier, a code that represents e.g. drug, adverse event or laboratory test performed. Along with this combination values like date, result, unit etc are present for each record.

A record for a laboratory measurement would include:

- Patient identifier
- Measurement type identifier
- Measured value
- Unit of value
- Date of determination

A record for usage of an antiretroviral drug would include:

- Patient identifier
- Drug identifier
- Start date for usage
- End date for usage
- Reason for discontinuation

These issues imply that a set of distinct tables must be generated based on the ?nature? of the data. Since laboratory, medication and event data both cannot and should not be mixed at least 3 tables must be designed. Additionally there are other types of information that need their own domains: background information on the patient (height, birth date etc.), visit related data (weight, blood pressure, wasting etc.), and resistance testing (the latter requires more consideration due to the diversity of data present).

In this protocol further separation of data into different tables are presented. These separations are not only based on the rules for the relational model and normalisation, but they are ?culturally? related.

For example: antiretroviral treatment medication is kept in one table and other medication in another table; CD4 cell measurements and HIV-RNA measurements are put into separate tables, that are also different from the general laboratory table. These separations are done simply because data in these tables are of distinct importance in analysis and often are gathered more frequently and with more attention than other variables.

Coding Conventions

Date codes

Although it is best to have precise dates in the format of `YEAR-MONTH-DAY` ISO standard, it might be that some cohorts are limited to representing date data at the level of the month only, or information kept on the patient in the charts only defines dates to the month and in some cases only to the year. To solve this a set of date codes are presented here.

Day unknown

In this case the date should be coded as the 15th of the month ? so that `1999-12-??` becomes `1999-12-15`. This enables the date to be no more than 15 days away from the actual date.

Month and day unknown

Best approach to this is to apply something similar, as with unknown dates, this would then mean that `1999-??-??` becomes `1999-07-01`.

Year unknown

If the year is unknown but the presence of the date value is needed as in case of opportunistic infections or adverse events (see later in this document) a fictive date should be used that couldn?t be mistaken with an actual date. An unknown year should be coded as `1911-11-11`.

Specification of precision

An alternative to the above is to apply an additional field to each date field for which it is known that there might be issues regarding the precision of the dates. The field is then used to specify at which degree of the day, month or year the date is precise:

Code	Precision of date
<	Before this date
D	Exact to the date
M	Exact to the month
Y	Exact to the year
>	After this date
U	Unknown

ICD-10 codes

The coding system is the official standard for coding of diseases, however there is a wide set of ?homebrew? codes used within the HIV field in data coding in general, often it?s a 3 or 4 letter codes that is an abbreviation for the AIDS defining disease. ICD-10 doesn?t have single codes that represent all single CDC-C events and as a consequence of this a list of 3 to 4 letter codes is the recommended way of coding for all CDC stage C events

ICD-10 codes are however the recommended for codes AE?s since it would become impossible for this protocol to maintain a complete list of all possible AE?s. ICD-10 is also recommended for causes of death.

ATC codes

ATC is a hierarchical structure for coding medication. The structure and hierarchy are best explained with an example of how a drug code is defined. Here it is on Indinavir:

J
: ANTIINFECTIVES FOR SYSTEMIC USE (1st level, anatomical main group)

J05
: ANTIVIRALS FOR SYSTEMIC USE (2nd level, therapeutic subgroup)

J05A
: DIRECT ACTING ANTIVIRALS (3rd level, pharmacological subgroup)

J05AE
: Protease inhibitors (4th level, chemical subgroup)

J05AE02
: Indinavir (5th level, chemical substance)

This hierarchy has some benefits as will be explained later, but one of its limitations is that it?s impossible to ?read? the code compared to the widely used 3 letter mnemonic codes for antiretroviral drugs.

Example:

Drug	Code	ATC code
Indinavir	IDV	J05AE02

The difference is that the IDV code is easily readable, where the ATC code is not; going from a flat file structure to a normalised structure the human readable aspect becomes increasingly important. In the flat file format the column names and the possibility of labels makes data more or less readable; in the normalised format only the coding can help. Because of this the 3 letter codes are being presented in this document. However it must be stressed that usage of the ATC coding should be used to diminish the risk of several homebrew and non-compatible coding schemes.

Currently however, the ATC scheme does not provide sufficient detail on the specific drugs, there is e.g. no official way to code Saquinavir as hard or soft gel. Thus a slight alteration to the set of codes will be presented in the sections of the ART and MED tables. The alterations are designed to extend the existing structure of ATC.

One of the benefits is that the structure of ATC allows easier statistics on e.g. drug classes

- J05AE Protease inhibitors
  - J05AE01 Saquinavir
  - J05AE02 Indinavir
  - J05AE03 Ritonavir
  - J05AE04 Nelfinavir
  - J05AE05 Amprenavir
  - J05AE06 Lopinavir
- J05AF Nucleoside and nucleotide reverse transcriptase inhibitors
  - J05AF01 Zidovudine
  - J05AF02 Didanosine
  - J05AF03 Zalcitabine
  - J05AF04 Stavudine
  - J05AF05 Lamivudine
  - J05AF06 Abacavir
  - J05AF07 Tenofovir disoproxil
  - J05AF30 Combinations1
- J05AG Non-nucleoside reverse transcriptase inhibitors
  - J05AG01 Nevirapine
  - J05AG02 Delavirdine
  - J05AG03 Efavirenz

Although the codes might be harder to read they provide grouping mechanisms in the way they are coded. Interested readers should go to the ATC Website to learn about the structure of ATC. A fully updated database of ATC codes and DDD (Defined Daily Dosage) is available for querying.

Other codes

It is often necessary to code for values like ?Yes?, ?No? and ?Unknown?, this document suggests that the following codes should be used:

Code	Description
0	No
1	Yes
9	Unknown

Unknown should be used to identify the difference between a value that has not yet been collected (Empty) and a value that cannot be collected (Unknown). Empty values should be required where Unknown values make little sense to keep querying for a value.

Example ? weight:

Depending on the unit in which weight is measured, a different value for Unknown should be applied. In the case of kg the ?Unknown? code should be 999 and not just 9 or 99, the last two could be actual values.

Blank values, for SAS users also known as `"."` and for database programmers known as `NULL`, should be used wherever specified in this protocol. However, sometimes it might be more correct just to omit the record if no value has been recorded, test has not been performed etc.

tblAE - Adverse Events

holds type and date of adverse events including serious non-AIDS conditions

Core fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

- *EVENT_ID*: foreign key to event tables
- ***PATIENT***: identifies patient
- ***AE_D***: date of event
- ***AE_ID***: identifies type of event
- *AE_SPEC*: further specification
- *SRCDOC_Y*: whether the source documentation is available
- *SRCDOC_D*: date for source documentation verification
- *VERIFY_Y*: Has the monitor verified the source documentation?
- *VERIFY_D*: date for monitor verification
- *APPROV_Y*: final verification/approval
- *APPROV_D*: final verification date
- *APPROV_S*: signature for final verification

TODO

where to put the following text?

Please see the HICDEP website for examples of detailed AE tables for the events listed in 3.16.2 below. Data format is available in the HICDEP DAD event forms document.

Additional fields

- *AE_Y*: has the patient had an event?
- *AE_NAME*: full name of the event
- *AE_DESCRIP*: full description of the event
- *AE_R_Y*: relation to treatment

AE_D field

containing table

tblAE

explanation of variable

Date of event

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

AE_DESCRIP field

The actual text description of the event, especially in clinical trials where the physician's full diagnose might be required.

containing table

tblAE

explanation of variable

full description of the event

format of data

character

exists since HICDEP version

1.30

AE_ID field

containing table

tblAE

explanation of variable

Code to identify event

format of data

character. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Download this table as CSV file

Code (AE_ID)	Adverse Event
AMI	Acute myocardial infarction
CLD	Chronic liver disease
COR	(Possible) Coronary Death
DIA	Diabetes mellitus
ESRD	End stage renal disease
FAT	Fatal case with insufficient data
ICP	Invasive Cardiovascular Procedures
NADM	Non-AIDS defining malignancies
STR	Stroke (infarction or haemorrhagia)

Case definitions

HICDEP Code	ICD-10 codes	Adverse Event	Definition
AMI	I21.9	Acute myocardial infarction	Definitive myocardial infarction (MI) i) definitive electrocardiogram (ECG), ii) symptoms together with probable ECG and abnormal enzymes, iii) typical symptoms, abnormal enzymes and ischaemic/non-codable/not available ECG, or iv) fatal cases with naked-eye appearance of fresh MI and/or recent coronary occlusion found at necropsy. Please see the MONICA manual for further criteria.

STR	I64.9	Stroke, not specified as haemorrhage or infarction	Rapidly developed clinical signs of focal or global disturbance of cerebral function lasting more than 24 hours (unless interrupted by surgery or death), with no apparent cause other than a cardiovascular origin. Secondary stroke caused by trauma should be excluded. The differentiation between infarction and haemorrhage should be based on results of cerebral scanning or necropsy. In case of uncertainty (results not interpretable, or test not performed), please indicate so on the event form. Please see the MONICA manual and the DAD MOOP (Manual of Operations) for further criteria.
DIA	E14 (also E10 ? insulin dependent and E11 non-insulin-dependent)	Unspecified diabetes mellitus	The diagnostic criteria is: fasting blood glucose > 7 mmol/l Please see the ADA (the American Diabetes Association) criteria for classification.
ICP - BYP	n/a	Coronary artery by-pass grafting	Procedure
ICP - END	n/a	Carotic endarterectomy	Procedure
ICP - ANG	n/a	Coronary angioplasty/stenting	Procedure
LAC		Lactate acidosis	Elevated S-lactate > 2.5 mM (>22.3 mg/dL) AND plasma pH < 7.35 (alternatively: Bicarbonate/HCO_3<= 20 mM (<= 20 meq/L)) AND otherwise unexplained recent onset of at least one of the following: Abdominal distension, anorexia, abdominal pain, nausea, vomiting, diarrhea, increased liver function enzymes, jaundice, dyspnea, fever, neuropathy, generalized weakness, ascending neuromuscular weakness, myalgias, paresthesias, weight loss or hepatomegaly.
PAN		Pancreatitis	Typical clinical history (i.e. severe abdominal pain), plus one or more of the following: elevated serum amylase > 1.5x ULN, elevated serum lipase, radiological findings.
ESRD	N18.0 (N18.8/9, N25.9, N26, N0.5, N04, N08)	End stage renal disease	A. Hemodialysis or peritoneal dialysis expected to last at least three months, documented in a clinical note B. A kidney transplant, documented in a clinical note Confirmed: A or B Probable: Not applicable

AVN		Avascular necrosis in the femural head	Diagnosed by the combination of clinical symptoms (pain, walking difficulties) and imaging findings (MRI, bone scintigraphy)
FRA	Several depending on location	Bone fracture	Diagnosed by X-ray
HEP		Severe hepatic encephalopathy (stage III or IV)	Stage III: marked confusion, incoherent speech, asterixis, sleeping but arousable - Stage IV: coma
CLD		Chronic liver disease ?severe clinical manifestations	A. 1. Clinical symptoms of end-stage liver failure in patients with chronic liver disease, based on the diagnosis documented in a clinical note of either (i) bleeding from gastric or esophageal varices (ii) hepatic encephalopathy stage III or IV (iii) hepatorenal syndrome A. 2 liver transplantation documented in a clinical note B. Pathology report or fibro-scan report documenting severe liver fibrosis or cirrhosis (Metavir F3 or F4 or fibroscan liver stiffness >= 8 kPa) Confirmed: A1 and B; or A2 Probable: A1

NADM		Non AIDS defining cancers	A.Diagnosis of cancer (other than: AIDS defining (non-Hodgkin?s lymphoma, Kaposi's sarcoma), or invasive cervical cancer); and basal and squamous cell skin cancers) in a pathology report that established the diagnosis B. Diagnosis of cancer (other than: AIDS defining (non-Hodgkin?s lymphoma, Kaposi's sarcoma, or invasive cervical cancer); and basal and squamous cell skin cancers) in a hospital discharge summary or consultation note from the hospitalization or clinic visit during which the diagnosis was established C. In the absence of A or B: Strong suspicion of cancer supported by (i) evidence from radiological or other imaging technique, (ii) or biochemical assay D. In the absence of A, B or C: Strong suspicion of cancer by visual inspection (e.g. skin metastasis, suspected malignant melanoma, tissue growth resembling cancer visualized during endoscopy/anoscopy) not explained by other known conditions. Confirmed: A or B Probable: C Possible: D * The date of diagnosis is the month, day and year the tumor was first diagnosed by a recognized medical practitioner, whether clinically or microscopically confirmed.

AE_NAME field

The full name as it might have been entered into the database or presented on a case report form.

containing table

tblAE

explanation of variable

full name of the event

format of data

character

exists since HICDEP version

1.30

AE_R_Y field

containing table

tblAE

explanation of variable

relation to treatment

format of data

numeric:

- 0 = not related
- 1 = definitive
- 2 = remote/unlikely
- 3 = possible
- 4 = probable

exists since HICDEP version

1.30

AE_SPEC field

containing table

tblAE

explanation of variable

Code to further specify the event identified by AE_ID.

format of data

character. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Download this table as CSV file

Code (AE_ID)	Code (AE_SPEC)	Description
AMI	DAMI	Definitive Myocardial infarction
AMI	PAMI	Possible Myocardial infarction
ICP	ANG	Invasive Cardiovascular Procedures: Coronary angioplasty/stenting
ICP	BYP	Invasive Cardiovascular Procedures: Coronary artery by-pass grafting
ICP	END	Invasive Cardiovascular Procedures: Carotic endarterectomy
NADM	ALL	Leukemia: Acute lymphoid
NADM	AML	Leukemia: Acute myeloid
NADM	ANUS	Anus cancer
NADM	BLAD	Bladder cancer
NADM	BRCA	Breast cancer
NADM	CERV	Cervical dysplasia/carcinoma in situ
NADM	CLL	Leukemia: Chronic lymphoid
NADM	CML	Leukemia: Chronic myeloid
NADM	COLO	Colon cancer
NADM	COTC	Connective tissue cancer
NADM	HDL	Hodgkin lymphoma
NADM	KIDN	Kidney cancer
NADM	LEUK	Leukemia: unspecified
NADM	LIPC	Lip cancer
NADM	LIVR	Liver cancer
NADM	LUNG	Lung cancer
NADM	MALM	Malignant melanoma
NADM	MEAC	Metastasis: of adenocarcinoma
NADM	MEOC	Metastasis: of other cancertype
NADM	MESC	Metastasis: of squamuos cell carcinoma
NADM	META	Metastasis: unspecified
NADM	MULM	Multiple myeloma

NADM	PENC	Penile cancer
NADM	PROS	Prostate cancer
NADM	RECT	Rectum cancer
NADM	STOM	Stomach cancer
NADM	TESE	Testicular seminoma
NADM	UTER	Uterus cancer
STR	SHAE	Stroke: Haemorrhagia
STR	SINF	Stroke: Infarction
STR	SUNK	Stroke: Unknown

AE_Y field

This field should be more or less obsolete if the date codes are applied, otherwise it could be used to state that an event had occurred but the date (if left blank) was not known or, if coded 9 (Unknown), that the centre was not aware if an event has occurred or not.

containing table

tblAE

explanation of variable

Whether or not the patient had an event.

format of data

numeric: 1 = Yes, 0 = No, 9 = Unknown

exists since HICDEP version

1.30

APPROV_D field

containing table

tblAE

explanation of variable

Final verification date

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

APPROV_S field

containing table

tblAE

explanation of variable

Final verification by - signature/name

format of data

character.

exists since HICDEP version

1.30

APPROV_Y field

containing table

tblAE

explanation of variable

Final verification/approval

format of data

numeric: `1` = Yes, `0` = No

exists since HICDEP version

1.30

EVENT_ID field

containing table

tblAE

explanation of variable

Unique Event Identifier (foreign key to the different event tables)

format of data

numeric

exists since HICDEP version

1.30

PATIENT field

containing table

tblAE

explanation of variable

Code to identify patient (Cohort Patient ID)

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

SRCDOC_D field

containing table

tblAE

explanation of variable

The date for source documentation verification

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

SRCDOC_Y field

containing table

tblAE

explanation of variable

Whether or not the source documentation is available

format of data

numeric: `1` = Yes, `0` = No

exists since HICDEP version

1.30

VERIFY_D field

containing table

tblAE

explanation of variable

The date for monitor verification

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

VERIFY_Y field

containing table

tblAE

explanation of variable

Whether or not the monitor has verified the source documentation

format of data

numeric: `1` = Yes, `0` = No

exists since HICDEP version

1.30

tblART - Antiretroviral treatment

holds type of antiretroviral drug, start and stop dates and reason for stopping

Core fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

- ***PATIENT***: identifies patient
- ***ART_ID***: represents the antiretroviral treatment
- ***ART_SD***: date of initiation of treatment
- *ART_ED*: date of stopping treatment
- *ART_RS*: reason for stopping treatment

Additional fields

Depending on the aim of the study it might be needed to gather both the dosage and the frequency of the dosage taken. However many cohorts do not collect this date and thus these fields are optional.

- *ART_DO*: Dosage (mg or mL)
- *ART_FR*: Frequency

ART_DO field

containing table

tblART

explanation of variable

Dosage (mg or mL)

format of data

numeric

exists since HICDEP version

1.30

ART_ED field

containing table

tblART

explanation of variable

Date of stopping treatment

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

ART_FR field

containing table

tblART

explanation of variable

Frequency

format of data

numeric. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Code	Frequency
1	1 daily dose/qd
2	2 daily doses/bid
3	3 daily doses/tid
4...	code gives number of daily doses

ART_ID field

containing table

tblART

explanation of variable

Code representing the antiretroviral treatment

format of data

character. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

A set of extended ATC codes are being presented here in order to code both more specific on subtypes of the drugs, e.g. saquinavir hard and soft gel, but also to enable coding of drugs that are at their trial stage and have not yet been assigned an ATC code. To do this the drug will be assigned the code elements as far down the levels as possible. Given two examples to illustrate this:

Saquinavir - Hard Gel

J05AE01-SQH

Saquinavir - Soft Gel

J05AE01-SQS

Saquinavir - not specified

J05AE01

This will ensure the fidelity needed to distinguish between hard and soft gel and not specified, but also for analysis easily include all records which coding starts with J05AE01, regardless if the drug is hard or soft gel.

See the ATC Index for the individual codes.

Download this table as CSV file

Code (Extended ATC Codes)	Anti-Retroviral Drugs
J05A	ART unspecified
J05A-BEV	Beviramat
J05A-PBT	Participant in Blinded Trial
J05AE	PI unspecified
J05AE-MOZ	Mozenavir (DMP-450)
J05AE01	Saquinavir (gel, not specified)
J05AE01-SQH	Saquinavir hard gel (INVIRASE)
J05AE01-SQS	Saquinavir soft gel (FORTOVASE)
J05AE02	Indinavir (CRIXIVAN)
J05AE03	Ritonavir (NORVIR)
J05AE03-H	Ritonavir high dose (NORVIR)
J05AE03-L	Ritonavir low dose (NORVIR)
J05AE04	Nelfinavir (VIRACEPT)
J05AE05	Amprenavir (AGENERASE)
J05AE06	Lopinavir/Ritonavir (Kaletra)
J05AE07	Fos-amprenavir (Telzir, Lexiva)
J05AE08	Atazanavir (Reyataz)
J05AE09	Tipranavir (Aptivus)

J05AE10	Darunavir (TMC-114, Prezista)
J05AF	NRTI unspecified
J05AF-ALO	Alovudine
J05AF-AMD	Amdoxovir (DADP)
J05AF-FOZ	Fozivudine tidoxi
J05AF-LDN	Lodenosine (trialdrug)
J05AF-RVT	Reverset
J05AF01	Zidovudine (AZT, RETROVIR)
J05AF02	Didanosine (ddI) (VIDEX)
J05AF03	Zalcitabine (ddC) (HIVID)
J05AF04	Stavudine (d4T) (ZERIT)
J05AF05	Lamivudine (3TC, EPIVIR)
J05AF06	Abacavir (1592U89) (ZIAGEN)
J05AF07	Tenofovir (VilREAD)
J05AF08	Adefovir (PREVEON)
J05AF09	Emtricitabine
J05AF10	Entecavir
J05AF11	Telbivudine
J05AG	NNRTI unspecified
J05AG-CPV	Capravirine
J05AG-DPC083	DPC 083
J05AG-DPC961	DPC 961
J05AG-EMV	Emivirine (MKC442)
J05AG-ETV	Etravirine (TMC 125)
J05AG-LOV	Loviride
J05AG-RPV	Rilpivirine (TMC-278)
J05AG01	Nevirapine (VIRAMUN)
J05AG02	Delavirdine (U-90152) (RESCRIPTOR)
J05AG03	Efavirenz (DMP-266) (STOCRIN, SUSTIVA)
J05AR01	Combivir (Zidovudine/Lamivudine)
J05AR02	Kivexa (Lamivudine/Abacavir)
J05AR03	Truvada (Tenofovir/Emtricabine)
J05AR04	Trizivir (Zidovudine/Lamivudine/Abacavir)
J05AR05	Douvir-N (Zidovudine/Lamivudine/Nevirapine)
J05AR06	Atripla (Emtricitabine/Tenofovir/Efavirenz)
J05AX-EVG	Elvitegravir (Gilead)
J05AX-VIC	Vicriviroc (Schering)
J05AX07	Enfurvirtide (Fuzeon, T-20)
J05AX08	Raltegravir (Merck)
J05AX09	Maraviroc (Pfizer)

L01XX05	Hydroxyurea/Hydroxycarbamid (Litalir)

ART_RS field

containing table

tblART

explanation of variable

Reason for stopping treatment

format of data

character. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Download this table as CSV file

Code	Reason for Stopping Treatment
1	Treatment failure (i.e. virological, immunological, and/or clinical failure
1.1	Virological failure
1.2	Partial virological failure
1.3	Immunological failure - CD4 drop
1.4	Clinical progression
2	Abnormal fat redistribution
3	Concern of cardiovascular disease
3.1	Dyslipidaemia
3.2	Cardiovascular disease
4	Hypersensitivity reaction
5	Toxicity, predominantly from abdomen/G-I tract
5.1	Toxicity - GI tract
5.2	Toxicity - Liver
5.3	Toxicity - Pancreas
6	Toxicity, predominantly from nervous system
7	Toxicity, predominantly from kidneys
8	Toxicity, predominantly from endocrine system
8.1	Diabetes
9	Haematological toxicity (anemia etc.)
10	Hyperlactataemie/lactic acidosis
88	Death
90	Side effects - any of the above but unspecified
90.1	Comorbidity
91	Toxicity, not mentioned above
92	Availability of more effective treatment (not specifically failure or side effect related)
92.1	Simplified treatment available
92.2	Treatment too complex
92.3	Drug interaction

93	Structured Treatment Interruption (STI)
93.1	Structured Treatment Interruption (STI) - at high CD4
94	Patient's wish/decision, not specified above
94.1	Non-compliance
95	Physician's decision, not specified above
96	Pregnancy
97	Study treatment
98	Other causes, not specified above
99	Unknown

Although most reasons mentioned above could be coded in ICD-10 codes, it is still certain that many reasons will never be defined in terms of ICD-10 (STI, physicians and patients decision), so to avoid a mixture of two different coding systems it is advised to go with the above list and build upon that for now.

ART_SD field

containing table

tblART

explanation of variable

Date of Initiation of treatment

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

PATIENT field

containing table

tblART

explanation of variable

Code to identify patient (Cohort Patient ID)

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

tblBAS - Basic clinical, background and demographic information

holds basic information such as demographics, basic clinical information, date of AIDS diagnosis, death and drop-out information

Core fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

- ***PATIENT***: Code to identify patient (Cohort Patient ID)
- *CENTER*: Code for Clinic/Centre/Hospital where patient is seen.
- *BIRTH_D*: Birth date.
- *FRSVIS_D*: First seen at clinic
- *ENROL_D*: Date of enrolment into the cohort
- *GENDER*: Gender/sex
- *HEIGH*: Height of patient at visit/most current
- *MODE*: Mode of infection
- *ORIGIN*: Nationality or region of origin of patient
- *ETHNIC*: Ethnicity of patient
- *SEROCO_D*: Date of seroconversion
- *RECART_Y*: Has the patient received antiretroviral treatment?
- *AIDS_Y*: Has patient been given an AIDS diagnosis?
- *AIDS_D*: IF YES, date of AIDS diagnosis

Additional fields

TODO

> why is DEATH_OT in tblBAS and not tblLTFU?

For mode of infection, origin and death a set of other fields are often used to capture what cannot be coded. These fields are represented here as optional fields as it is the intention that the suggested codes applied to the MODE, ORIGIN, DEATH_R1-3 and ICD10_1-3 should be able to cover all possible values.

- *MODE_OTH*: Mode of infection OTHER
- *ORI_OTH*: Origin of patient OTHER
- *DEATH_OT*: Reason for death ? other - description

AIDS_D field

containing table

tblBAS

explanation of variable

IF AIDS_Y = 1, date of AIDS diagnosis

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

AIDS_Y field

containing table

tblBAS

explanation of variable

Has patient been given an AIDS diagnosis?

format of data

numeric: `1` = Yes, `0` = No, `9` = Unknown

exists since HICDEP version

1.30

BIRTH_D field

depending on local laws it might be needed to code this as the year only, it is however strongly suggested to use a date value rather than an age or year in numeric form if possible.

containing table

tblBAS

explanation of variable

Birth date. Leave BLANK if not able to give this information

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

CENTER field

containing table

tblBAS

explanation of variable

Code for Clinic/Centre/Hospital where patient is seen.

format of data

character

exists since HICDEP version

1.30

DEATH_OT field

containing table

tblBAS

explanation of variable

Reason for death ? other - description

format of data

character

exists since HICDEP version

1.30

ENROL_D field

containing table

tblBAS

explanation of variable

Date of enrolment into the cohort

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

ETHNIC field

containing table

tblBAS

explanation of variable

Ethnicity of patient

format of data

numeric. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Download this table as CSV file

Code	Ethnicity of patient
10	White
20	Black
21	Black African
22	Black Caribbean
30	Hispanic
40	Asian
50	Americas
60	Indigenous
1020	1+2
1040	1+4
2030	2+3
3040	3+4
98	Prohibited
99	Unknown

FRSVIS_D field

containing table

tblBAS

explanation of variable

First seen at clinic

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

GENDER field

containing table

tblBAS

explanation of variable

Gender/sex

format of data

numeric:

- 1 = Male
- 2 = Female
- 9 = Unknown

exists since HICDEP version

1.30

HEIGH field

containing table

tblBAS

explanation of variable

Height of patient at visit/most current

format of data

numeric (metric): 999 = Unknown

exists since HICDEP version

1.30

Please note that this field would be more appropriate to include in the tblVISIT table if data is collected for children.

MODE field

containing table

tblBAS

explanation of variable

Mode of infection

format of data

numeric. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Download this table as CSV file

Code	Mode of infection
1	homo/bisexual
2	injecting drug user
3	(1+2)
4	haemophiliac
5	transfusion, non-haemophilia related
6	heterosexual contact
7	(6+2)
8	Perinatal
90	other, (specify)
99	unknown

MODE_OTH field

containing table

tblBAS

explanation of variable

Mode of infection OTHER

format of data

character

exists since HICDEP version

1.30

ORI_OTH field

containing table

tblBAS

explanation of variable

Origin of patient OTHER

format of data

character

exists since HICDEP version

1.30

ORIGIN field

containing table

tblBAS

explanation of variable

Nationality or region of origin of patient

format of data

character (1-3 letter/numeric codes). see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Download this table as CSV file

Code	Region of origin
10	Africa
11	Northern Africa
12	Sub-Saharan Africa
20	Asia
30	Oceania (not Australia)
40	Australia & New Zealand
50	Americas
51	North America
52	Central & South America
60	Middle East
70	Europe
71	Western Europe
72	Eastern Europe
99	Unknown

In case of a need for a more detailed level of origin (nationality) codes should be the ISO 2-letter or 3-letter codes.

PATIENT field

containing table

tblBAS

explanation of variable

Code to identify patient (Cohort Patient ID)

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

RECART_Y field

containing table

tblBAS

explanation of variable

Has the patient received antiretroviral treatment?

format of data

numeric: `1` = Yes, `0` = No, `9` = Unknown

exists since HICDEP version

1.30

SEROCO_D field

containing table

tblBAS

explanation of variable

Date of seroconversion

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

tblDIS - Opportunistic infections

holds type and date of CDC-C diseases.

Core fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

- ***PATIENT***: Code to identify patient (Cohort Patient ID)
- ***DIS_ID***: Code to identify event
- ***DIS_D***: Date of event
- *DIS_WD*: Means of diagnosis
- *DIS_OTH*[1]: Other location, only to be filled out if code alone is not sufficient

[1] DIS_OTH might be part of the record's unique identification

Additional fields

Please see tblAE - Adverse Events for specification on optional fields.

DIS_D field

containing table

tblDIS

explanation of variable

Date of event

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

DIS_ID field

containing table

tblDIS

explanation of variable

Code to identify event

format of data

character. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Download this table as CSV file

Code	Severe Opportunistic Infection/Malignancies
DEM	AIDS dementia complex
BCNE	Bacterial pneumonia, recurrent (>2 episodes within 1 year)
CANO	Candidiasis, oesophageal, bronchi, trachea, or lungs
COCC	Coccidioidomycosis, disseminated or extrapulmonary
CRCO	Cryptococcosis, extrapulm.
CRSP	Cryptosporidiosis (duration > 1 month)
CMVR	Cytomegalovirus (CMV) chorioretinitis
CMVO	CMV ? other location
HERP	Herpes simplex virus ulcers (duration > 1 month) or pneumonitis/esophagitis
HIST	Histoplasmosis, extrapulm.
WAST	HIV Wasting Syndrome
ISDI	Isosporiasis diarrhoea (duration > 1 month)
LEIS	Leishmaniasis, visceral
MCDI	Microsporidosis diarrhoes (dur. > 1 month)
MC	Mycobact. avium complex (MAC) or Kanasii, extrapulm.
MCP	Mycobact. tuberculosis pulm.
MCX	Mycobact. tuberculosis extrapulm
MCPO	Mycobact. pulm., other
MCXO	Mycobact. extrapulm., other
PCP	Pneumocystis carinii pneumonia (PCP)
LEU	Progressive multifocal leucoencephalopathy
SAM	Salmonella bacteriaemia (non-tyhpoid) (recurrent)
TOX	Toxoplasmosis, brain
FBLS	Focal Brain lesion
KS	Kaposi Sarcoma
HG	Hodgkins Lymphoma
NHG	Non-Hodgkin Lymphoma -not specified
NHGB	Non-Hodgkin Lymphoma ? Burkitt (Classical or Atypical)

NHGI	Non-Hodgkin Lymphoma ? Diffuse large B-cell lymphoma (Immunoblastic or Centroblastic)
NHGU	Non-Hodgkin Lymphoma - Unknown/other histology
NHGP	Non-Hodgkin Lymphoma - Primary Brain Lymphoma
CRVC	Cervical Cancer

TODO

in the above table, starting from KS, they are titled "Malignancies" in the .doc. How to handle that? Is it in error?

Case definitions

Download this table as CSV file

Code	Severe Opportunistic Infection/Malignancies	Definitive/Autopsy or presumptive?	Definition
DEM	AIDS dementia complex	D	Disabling cognitive and/or motor dysfunction, or milestone loss in a child, and no other causes by CSF exam and brain imaging or by autopsy
DEM	AIDS dementia complex	P	Same as above but no CSF and brain imaging performed
BCNE	Bacterial pneumonia, recurrent (>2 episodes within 1 year)	D	New X-ray evidence not present earlier and culture of pathogen that typically causes pneumonia (other than P .carinii or M. tuberculosis
BCNE	Bacterial pneumonia, recurrent (>2 episodes within 1 year)	P	Acute radiological findings (new X-ray evidence not present earlier) and acute clinical findings
CANO	Candidiasis, oesophageal, bronchi, trachea, or lungs	D/A	Gross inspection by endoscopy/autopsy or by microscopy (histology)
CANO	Candidiasis, oesophageal, bronchi, trachea, or lungs	P	Recent onset retrosternal pain on swallowing and confirmed oral or pharyngeal candidiasis
CRCO	Cryptococcosis, extrapulm.	D/A	Microscopy, culture of, or antigen detection in affected tissue
CRSP	Cryptosporidiosis (duration > 1 month)	D/A	Microscopy. Duration of diarrhoea for more then 1 month
CMVR	Cytomegalovirus (CMV) chorioretinitis	P	Loss of vision and characteristic appearance on serial ophtalmoscopy, progressing over serial months
CMVO	CMV ? other location	D/A	Microscopy (histology or cytology)
HERP	Herpes simplex virus ulcers (duration > 1 month) or pneumonitis/esophagitis	D	Microscopy, culture of, or antigen detection in affected tissue
HIST	Histoplasmosis, extrapulm.	D/A	Microscopy, culture of, or antigen detection in affected tissue
WAST	HIV Wasting Syndrome	D	Weight loss (over 10% of baseline) with no other cause, and 30 days or more of either diarrhoea or weakness with fever

ISDI	Isosporiasis diarrhoea (duration > 1 month)	D/A	Microscopy (histology or cytology). Duration of diarrhoea for more than 1 month
LEIS	Leishmaniasis, visceral	D/A	Histology or culture of Leishmania amastigotes in bone marrow or detection of amastigotes in tissue/fluid from affected organ in a patient with symptoms and signs consistent with disseminated Leishmaniasis
MCDI	Microsporidosis diarrhoes (dur. > 1 month)	D/A	Stool microscopy or rectal biopsy in patient with persistent diarrhoea
MC	Mycobact. avium complex (MAC) or Kanasii, extrapulm.	D	Culture
MCP	Mycobact. tuberculosis pulm.	D	Culture
MCX	Mycobact. tuberculosis extrapulm	D	Culture
MCPO	Mycobact. pulm., other	D	Culture (indicate type)
MCPO	Mycobact. pulm., other	P	Acid fast bacteria (species not identified by culture) in sputum
MCXO	Mycobact. extrapulm., other	D	Culture (indicate type)
MCXO	Mycobact. extrapulm., other	P	Acid fast bacteria (species not identified by culture) on microscopy of normally sterile body fluid/tissue
PCP	Pneumocystis carinii pneumonia (PCP)	D	Microscopy (histology or cytology)
PCP	Pneumocystis carinii pneumonia (PCP)	P	Recent onset of dyspnoea on exertion or dry cough, and diffuse bilateral infiltrates on chest X-ray and pO2 <70 mmHg and no evidence of bacterial pneumonia
LEU	Progressive multifocal leucoencephalopathy	D/A	Microscopy (histology or cytology)
LEU	Progressive multifocal leucoencephalopathy	P	Progressive deterioration in neurological function and CT/MR scan evidence
SAM	Salmonella bacteriaemia (non-tyhpoid) (recurrent)	D	Culture
TOX	Toxoplasmosis, brain	D	Microscopy (histology/cytology)
TOX	Toxoplasmosis, brain	P	Recent onset focal neurological abnormalities or reduced level of consciousness, and mass effect lesion on scan, and specific therapy response
FBLS	Focal Brain lesion	?	TODO:: To be updated ASAP
KS	Kaposi Sarcoma	D/A	Histology
KS	Kaposi Sarcoma	P	Characteristic erythematous/violaceous plaque-like lesion on skin or mucous membranes
HG	Hodgkins Lymphoma	?	TODO:: To be updated ASAP

NHG	Non-Hodgkin Lymphoma -not specified	?	TODO:: To be updated ASAP
NHGB	Non-Hodgkin Lymphoma ? Burkitt (Classical or Atypical)	D	Histology
NHGI	Non-Hodgkin Lymphoma ? Diffuse large B-cell lymphoma (Immunoblastic or Centroblastic)	D	Histology
NHGU	Non-Hodgkin Lymphoma - Unknown/other histology	?	TODO:: To be updated ASAP
NHGP	Non-Hodgkin Lymphoma - Primary Brain Lymphoma	D	TODO:: To be updated ASAP
NHGP	Non-Hodgkin Lymphoma - Primary Brain Lymphoma	P	Recent onset of focal neurological symptoms and signs or reduced level of consciousness, CT/MR scan evidence of a lesion or lesions having mass effect, no response to toxo therapy, no evidence of lymphoma outside the brain
CRVC	Cervical Cancer	D/A	Histology

DIS_OTH field

containing table

tblDIS

explanation of variable

Other location, only to be filled out if code alone is not sufficient

format of data

character

exists since HICDEP version

1.30

DIS_WD field

containing table

tblDIS

explanation of variable

Means of diagnosis

format of data

numeric. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Download this table as CSV file

Code	Means of diagnosis
1	Definitive diagnosis
2	Presumptive diagnosis
3	Diagnosis from autopsy
4	Diagnosis from registry

PATIENT field

containing table

tblDIS

explanation of variable

Code to identify patient (Cohort Patient ID)

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

tblLAB - Laboratory values

holds type, date, value and unit of laboratory tests.

Core fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

- ***PATIENT***: Code to identify patient (Cohort Patient ID)
- ***LAB_ID***: Code representing the measurement
- ***LAB_D***: Date of measurement/sample
- *LAB_V*: Value of measurement
- *LAB_U*: Unit of measurement

Additional fields

Other detailed information regarding the patient and the measurement would be relevant, like the proposed fasting information shown below.

- *LAB_FA*: Was the blood sample taken while fasting?
- *LAB_ST*: Specimen type

Depending on the set of measurements collected and the mandatory fields applicable to these individual measurements, it might be useful to separate the LAB table into several sub tables. This is already shown for the CD4 and RNA measurements: the level of detail needed for CD4 is less than for the LAB variables in general (no unit since it?s always the same), while for RNA the data required is more detailed (assay and detection limit).

LAB_D field

containing table

tblLAB

explanation of variable

Date of measurement/sample

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

LAB_FA field

containing table

tblLAB

explanation of variable

Was the blood sample taken while fasting?

format of data

numeric: `1` = Yes, `0` = No, `9` = Unknown

exists since HICDEP version

1.30

LAB_ID field

containing table

tblLAB

explanation of variable

Code representing the measurement

format of data

character. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Download this table as CSV file

Code	Measurement
ALB	Albumine
ALP	Alk.P.tase
ALT	Alanin-Aminotransferase
AMY	Amylase
APT	Alk. Phosphatate
AST	Aspartat aminotransferase
BIL	Total Bilirubin
CD3	CD3
CD3P	% CD3 of leukocytes
CD8	CD8
CD8P	% CD8 of leukocytes
CHOL	Total Cholesterol
CL-	Cl-
CRE	Creatinine
GLUC	Glucose
GLYCE	Glycemia
HAEM	Haemoglobin
HDL	Serum HDL
HEMA	Hematocrit
INR	Quick/INR
LACT	Lactate
LEUK	Leukocytes
LYM	Lymphocytes
LYMP	% Lymphocytes of leukocytes
MCV	MCV
NA+	Na+
NEU	Neutrophils
PHA	PH arterial
PHV	PH venous

PLT	Platelet count
PP	PP factor (II, VII, X)
THR	Thrombocytes
TRIG	Serum Triglyceride
URA	Uric acid
WBC	WBC count

LAB_ST field

containing table

tblLAB

explanation of variable

Specimen type

format of data

character:

- `WB` = Whole Blood
- `P` = Plasma
- `S` = Serum

exists since HICDEP version

1.30

LAB_U field

containing table

tblLAB

explanation of variable

Unit of measurement

format of data

character. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Download this table as CSV file

in case of measurement of	Unit Code	Unit String
Alanin-Aminotransferase	5	IU/L (u/L)
Alanin-Aminotransferase	11	µkat/L
Albumine	2	gm/L
Alk. Phosphatate	5	IU/L (u/L)
Amylase	5	IU/L (u/L)
Amylase	11	µkat/L
Creatinine	6	µmol/L
Glucose	1	mmol/L
Haemoglobin	1	mmol/L
Haemoglobin	2	gm/L
Haemoglobin	3	gm/dL
Lactate	1	mmol/L
Lactate	4	mg/dL
Lymphocyte count	8	1E+9/L
Lymphocyte count	9	1E+6/L
Lymphocyte count	10	cells/µL
Platelet count	8	1E+9/L
Platelet count	9	1E+6/L
Platelet count	10	cells/µL
Quick/INR	7	INR
Serum HDL	1	mmol/L
Serum HDL	2	gm/L
Serum HDL	3	gm/dL
Serum HDL	4	mg/dL
Serum HDL	5	IU/L (u/L)
Serum Triglyceride	1	mmol/L
Serum Triglyceride	2	gm/L
Serum Triglyceride	4	mg/dL
Total Bilirubin	6	µmol/L

Total Cholesterol	1	mmol/L
Total Cholesterol	2	gm/L
Total Cholesterol	3	gm/dL
Total Cholesterol	4	mg/dL
WBC count	8	1E+9/L
WBC count	9	1E+6/L
WBC count	10	cells/µL

It is recommended to use the string codes from the above table since this makes the data human readable.

LAB_V field

containing table

tblLAB_V

explanation of variable

Value of measurement

format of data

numeric: `-1` = undetectable or detection limit as negative value

exists since HICDEP version

1.30

PATIENT field

containing table

tblLAB

explanation of variable

Code to identify patient (Cohort Patient ID)

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

tblLAB_BP - Laboratory values - Blood pressure

holds date, diastolic and systolic values and unit of blood pressure measurements.

Core fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

- ***PATIENT***: Code to identify patient (Cohort Patient ID)
- ***BP_D***: Date of Measurement/Sample
- *BP_SYS*: Systolic Blood Pressure
- *BP_DIA*: Diastolic Blood Pressure
- *BP_U*: Unit of measurement

BP_D field

containing table

tblLAB_BP

explanation of variable

Date of Measurement/Sample

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

BP_DIA field

containing table

tblLAB_BP

explanation of variable

Diastolic blood pressure

format of data

numeric

exists since HICDEP version

1.30

BP_SYS field

containing table

tblLAB_BP

explanation of variable

Systolic Blood Pressure

format of data

numeric

exists since HICDEP version

1.30

BP_U field

containing table

tblLAB_BP

explanation of variable

Unit of measurement

format of data

numeric. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Download this table as CSV file

Code	Unit for blood pressure
1	mmHg
2	cmHg
3	Kpa

PATIENT field

containing table

tblLAB_BP

explanation of variable

Code to identify patient (Cohort Patient ID)

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

tblLAB_CD4 - Laboratory values

holds date and value of CD4 measurements.

Note: If needed, a CD8 table (tblLAB_CD8) could be formed from the same structure.

Core fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

- ***PATIENT***: Code to identify patient (Cohort Patient ID)
- ***CD4_D***: Date of measurement
- *CD4_V*: Value of CD4 measurement

Additional fields

CD4_V is assumed to contain absolute CD4 cell counts per mL as standard. In case CD4 % should be collected as well, please append the following field to the table:

- *CD4_U*: Unit of measurement

CD4_D field

containing table

tblLAB_CD4

explanation of variable

Date of measurement

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

CD4_U field

containing table

tblLAB_CD4

explanation of variable

unit of measurement

format of data

numeric with codes (or full string):

- 1 = cells/µl
- 2 = %

exists since HICDEP version

1.30

CD4_V field

containing table

tblLAB_CD4

explanation of variable

Value of CD4 measurement

format of data

numeric (per microliter): `-1` = undetectable or detection limit as negative value

exists since HICDEP version

1.30

PATIENT field

containing table

tblLAB_CD4

explanation of variable

Code to identify patient (Cohort Patient ID)

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

tblLAB_RES - Resistance testing

holds background information on the resistance test, laboratory, library, kit, software and type of test

TODO

it is somewhat unclear to me which paragraph from the .doc is mapped to which specific article -> double-check.

Note: This table is tightly linked to tblLAB_RES_LVL_1, tblLAB_RES_LVL_2 and tblLAB_RES_LVL_3.

Resistance should be reported at lowest level of interpretation possible ? so if the nucleotide sequence is available this should be reported rather than the list of mutations or resistance scores. However, the resistance test results should be captured if they have been part of the physician?s treatment decisions for the patient.

These four tables are designed to capture several possible formats the clinics and cohorts might have recorded resistance test data in. Once this data is gathered it should like all other tables be quality assessed. For the full nucleotide sequences a short guide on ?Sequence Quality Control? can be found here:

TODO

fix the following link

http://hiv-web.lanl.gov/content/hiv-db/CONTAM/contam_main.html

Core fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

- ***PATIENT***: Code to identify patient (Cohort Patient ID)
- ***SAMP_ID***: The assigned sample ID
- *SAMPLE_D*: Date of the actual sample taken (NOT the test date)
- *SEQ_DT*: Date and time when the sequencing was performed
- *LAB*: Name of laboratory where the test was performed
- *LIBRARY*: Library/algorithm used to identify resistance mutations
- *REFSEQ*: Name/identifier of reference HIV strain used to find mutations
- *KIT*: Vendor and version/name of the kit used for the test
- *SOFTWARE*: Software and version used to determine resistance
- *TESTTYPE*: Type of test
- *SUBTYPE*: Subtype of HIV-RNA

Additional fields

As shown with the core fields, the *SAMP_ID* is the link between the 3 levels of data and the test background information table. The sample identifier, however, must be unique for the format to work. This might not always be the case. If needed *SAMPLE_D* could be used as an additional part of the key, or just *SAMPLE_D* along with the *PATIENT* key[1].

Some prior assessment of the assigned sample identifiers has to be done in order to avoid duplicates.

In a running database the duplicate issues are easily resolved by adding a unique auto-generated key as the identifier between 3 levels of data and the test background information table *SAMP_ID*.

Along with the *SAMP_ID* it might be necessary to store the ID assigned to the sample at both the testing laboratory but also the centres laboratory in order to track the sample. Each of these could also be used as the *SAMP_ID* value.

[1]: However this raises the issue about several aliquots from the same day will look like duplicates in the tables.

- *SAMP_LAB*: The assigned sample ID at the lab where the resistance test is preformed.
- *SAMP_INT*: The assigned sample ID from the centre.

KIT field

containing table

tblLAB_RES

explanation of variable

Vendor and version/name of the kit used for the test

format of data

character

exists since HICDEP version

1.30

LAB field

containing table

tblLAB_RES

explanation of variable

Name of laboratory where the test was performed

format of data

character

exists since HICDEP version

1.30

LIBRARY field

containing table

tblLAB_RES

explanation of variable

Library/algorithm used to identify resistance mutations

format of data

character

exists since HICDEP version

1.30

PATIENT field

containing table

tblLAB_RES

explanation of variable

Code to identify patient (Cohort Patient ID)

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

REFSEQ field

containing table

tblLAB_RES

explanation of variable

Name/identifier of reference HIV strain used to find mutations

format of data

character

exists since HICDEP version

1.30

SAMP_ID field

containing table

tblLAB_RES

explanation of variable

The assigned sample ID

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

SAMP_INT field

containing table

tblLAB_RES and the tables for the three levels.

explanation of variable

The assigned sample ID from the centre.

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

SAMP_LAB field

containing table

tblLAB_RES and tables for the tree levels.

explanation of variable

The assigned sample ID at the lab where the resistance test is preformed.

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

SAMPLE_D field

containing table

tblLAB_RES

explanation of variable

Date of the actual sample taken (NOT the test date)

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

SEQ_DT field

containing table

tblLAB_RES

explanation of variable

Date and time when the sequencing was performed

format of data

`yyyy-mm-dd hh:mm`

exists since HICDEP version

1.30

SOFTWARE field

containing table

tblLAB_RES

explanation of variable

Software and version used to determine resistance

format of data

character

exists since HICDEP version

1.30

SUBTYPE field

containing table

tblLAB_RES

explanation of variable

Subtype of HIV-RNA

format of data

character

exists since HICDEP version

1.30

TESTTYPE field

containing table

tblLAB_RES

explanation of variable

Type of test

format of data

numeric

exists since HICDEP version

1.30

Coding Table

Code	Test type
1	Genotype
2	Phenotype
9	Other

tblLAB_RES_LVL_1 - Nucleotide sequences (PRO, RT, GP41, GP120)

holds nucleoside sequence for the PRO and RT sequences. No entry is made if the test was a phenotype test.

Note: This table is tightly linked to tblLAB_RES.

Core fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

- ***SAMP_ID***: The assigned sample ID
- ***SEQTYPE***: Type of nucleotide sequence if available
- *SEQ_START*: Start position for the sequence
- *SEQ_STOP*: Stop position for the sequence
- *SEQ_NUC*: Nucleotide sequence if available

Additional fields

In cases where the amino acid sequence is collected rather than the nucleotide sequence, the field *SEQ_NUC* might be replaced with *SEQ_AA*, which is the nucleotide sequence, expressed in an amino acid sequence:

- *SEQ_AA*: Amino acid sequence if available (empty if test was phenotype)

However using the amino acid sequence does not give the same detail of data as the nucleoside sequence: wobbles in the nucleoside sequence can either complicate the reading and alignment of the amino acid sequence or the wobbles can be lost and silent mutations are lost.

SAMP_ID field

containing table

tblLAB_RES_LVL_1

explanation of variable

The assigned sample ID

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

SEQ_AA field

containing table

tblLAB_RES_LVL_1

explanation of variable

Amino acid sequence if available (empty if test was phenotype)

format of data

character

exists since HICDEP version

1.30

SEQ_NUC field

containing table

tblLAB_RES_LVL_1

explanation of variable

Nucleotide sequence if available

format of data

character

exists since HICDEP version

1.30

SEQ_STAR field

containing table

tblLAB_RES_LVL_1

explanation of variable

Start position for the sequence

format of data

numeric

exists since HICDEP version

1.30

SEQ_STOP field

containing table

tblLAB_RES_LVL_1

explanation of variable

Stop position for the sequence

format of data

numeric

exists since HICDEP version

1.30

SEQTYPE field

containing table

tblLAB_RES_LVL_1

explanation of variable

Type of nucleotide sequence if available

format of data

character:

- PRO = PRO sequence
- RT = RT sequence
- GP41 = GP41 sequence
- GP120 = GP120 sequence

exists since HICDEP version

1.30

tblLAB_RES_LVL_2 - Mutations

holds mutations and positions of PRO and RT sequences.

Note: This table is tightly linked to tblLAB_RES.

Core fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

- ***SAMP_ID***: The assigned sample ID
- ***GENE***: Type of sequence/gene (PRO, RT, GP41, GP120)
- ***AA_POS***: Position of the mutation in the sequence
- ***AA_POS_SUB***: Subposition used to code insertions
- *AA_FOUND_1*: Mutation (Amino acid) found in the sequence
- *AA_FOUND_2*: Mutation (Amino acid) found in the sequence (if more than 1)
- *AA_FOUND_3*: Mutation (Amino acid) found in the sequence (if more than 2)
- *AA_FOUND_4*: Mutation (Amino acid) found in the sequence (if more than 3)

AA_FOUND_# could be extended if mixtures with more than 4 amino acids are found.

AA_FOUND_1 field

containing table

tblLAB_RES_LVL_2

explanation of variable

Mutation (Amino acid) found in the sequence

format of data

character. empty = Amino acid has been deleted.

exists since HICDEP version

1.30

AA_POS field

containing table

tblLAB_RES_LVL_2

explanation of variable

Position of the mutation in the sequence

format of data

numeric

exists since HICDEP version

1.30

AA_POS_SUB field

containing table

tblLAB_RES_LVL_2

explanation of variable

Subposition used to code insertions

format of data

character:

- a = first
- b = second
- etc.

exists since HICDEP version

1.30

GENE field

containing table

tblLAB_RES_LVL_2

explanation of variable

Type of sequence/gene (PRO, RT, GP41, GP120)

format of data

character:

- `PRO` = PRO sequence
- `RT` = RT sequence
- `GP41` = GP41 sequence
- `GP120` = GP120 sequence

exists since HICDEP version

1.30

SAMP_ID field

containing table

tblLAB_RES_LVL_2

explanation of variable

The assigned sample ID

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

tblLAB_RES_LVL_3 - Resistance test result

holds resistance result in relation to antiretroviral drug.

Note: This table is tightly linked to tblLAB_RES.

Core fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

- ***SAMP_ID***: The assigned sample ID
- ***ART_ID***: Drug code of antiretroviral
- *RES_SCOR*: Score of resistance or recommendation given from the test.

Additional fields

For phenotype test results it will be necessary to extend the table with a field to store the cut-off value:

- *RES_CUT*: Cut-off value for phenotype test result

However using the amino acid sequence does not give the same detail of data as the nucleoside sequence: wobbles in the nucleoside sequence can either complicate the reading and alignment of the amino acid sequence or the wobbles can be lost and silent mutations are lost.

ART_ID field

containing table

tblLAB_RES_LVL_3

explanation of variable

Drug code of antiretroviral

format of data

character. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Please refer to the coding table for tblART/ART_ID.

RES_CUT field

containing table

tblLAB_RES_LVL_3

explanation of variable

Cut-off value for phenotype test result

format of data

character

exists since HICDEP version

1.30

RES_SCOR field

These scorings and recommendation will have to be unified towards a common scoring system in order to use these for analysis. This step is however a final step that should be carried out after the collection and merging of data.

containing table

tblLAB_RES_LVL_3

explanation of variable

Score of resistance or recommendation given from the test.

format of data

character

exists since HICDEP version

1.30

SAMP_ID field

containing table

tblLAB_RES_LVL_3

explanation of variable

The assigned sample ID

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

tblLAB_RNA - Laboratory values

holds date, value, detection limit and type of viral assay.

Core fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

- ***PATIENT***: Code to identify patient (Cohort Patient ID)
- ***RNA_D***: Date of Measurement/Sample
- *RNA_V*: HIV-RNA measurement value
- *RNA_L*: Lower Limit of HIV-RNA Assay
- *RNA_T*: IF AVAILABLE, What type of VIRAL ASSAY was used for this measurement?

Additional fields

- *RNA_UL*: IF AVAILABLE, Upper Limit of assay

PATIENT field

containing table

tblLAB_RNA

explanation of variable

Code to identify patient (Cohort Patient ID)

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

RNA_D field

containing table

tblRNA_D

explanation of variable

Date of Measurement/Sample

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

RNA_L field

containing table

tblLAB_RNA

explanation of variable

Lower Limit of HIV-RNA Assay

format of data

numeric

exists since HICDEP version

1.30

RNA_T field

containing table

tblLAB_RNA

explanation of variable

IF AVAILABLE, What type of VIRAL ASSAY was used for this measurement?

format of data

numeric. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Download this table as CSV file

Code	Viral assay used
5	Roche TaqMan
10	Roche 1.0
15	Roche 1.5 ultra-sensitive
19	Any Roche (unspecified)
20	NASBA
21	NASBA ultra-sensitive
29	Any NASBA (unspecified)
31	Chiron b-DNA 1.0
32	Chiron b-DNA 2.0
33	Chiron b-DNA 3.0
39	Any Chiron (unspecified)
40	Abbott ultra-sensitive
41	Abbott LCx
50	Monitor 1.0
51	Monitor 1.0 ultra-sensitive
55	Monitor 1.5
56	Monitor 1.5 ultra-sensitive
65	Cobas 1.5
66	Cobas 1.5 ultra-sensitive
90	Other
99	Unknown

RNA_UL field

containing table

tblLAB_RNA

explanation of variable

IF AVAILABLE, Upper Limit of assay

format of data

numeric

exists since HICDEP version

1.30

RNA_V field

containing table

tblLAB_RNA

explanation of variable

HIV-RNA measurement value

format of data

numeric: `-1` = undetectable or detection limit as negative value

exists since HICDEP version

1.30

tblLAB_VIRO - Laboratory values - viro-/serology

holds test results for viro-/serological tests (hepatitis etc.)

Core fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

- ***PATIENT***: Code to identify patient (Cohort Patient ID)
- ***VS_ID***: Viral test
- ***VS_D***: Measurement date
- *VS_R*: Measurement result
- *VS_V*: Measurement value (HCV-RNA & HBV-DNA only) (copies/ml)
- *VS_U*: Measurement unit

Additional fields

- *VS_LL*: IF AVAILABLE, Lower limit of assay
- *VS_UL*: IF AVAILABLE, Upper limit of assay
- *VS_T*: IF AVAILABLE, type of ASSAY used for this measurement

PATIENT field

containing table

tblLAB_VIRO

explanation of variable

Code to identify patient (Cohort Patient ID)

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

VS_D field

containing table

tblLAB_VIRO

explanation of variable

Measurement date

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

VS_ID field

containing table

tblLAB_VIRO

explanation of variable

Viral test

format of data

character. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Download this table as CSV file

Code	Viral Test
BVA	Bacterial vaginosis unspecified method
BVAC	Bacterial vaginosis - clinical
BVAG	Bacterial vaginosis - gram stain
CHLA	Chalmydia
CMVA	CMV anitbodies
GONO	Gonorrhoe
HBV	Marker for hepatitis B infection (=HBVAC) - test unknown
HBVAC	HBV antibody (core)
HBVAE	HBV antibody (envelope)
HBVAS	HBV antibody (surface)
HBVD	HBV-dna
HBVGE	HBV antigen (envelope)
HBVGS	HBV antigen (surface)
HCV	Marker for hepatitis C infection - test unknown
HCVA	HCV antibody
HCVG	HCV antigen
HCVR	HCV-rna
HIV-1	HIV-1 test
HIV-2	HIV-2 test
HIVAE	HIV antibodies ELISA
HIVAWB	HIV antibodies Western blot
MYCO	Mycoplasma
P24AG	P24 Ag
RUB	Rubella
STR	Streptococcus, group B
TOXA	Toxo antibodies
UREP	Ureaplasma

VS_LL field

containing table

tblLAB_VIRO

explanation of variable

IF AVAILABLE, Lower Limit of assay

format of data

numeric

exists since HICDEP version

1.30

VS_R field

containing table

tblLAB_VIRO

explanation of variable

Measurement result

format of data

numeric: `1` = Positive, `0` = Negative, `9` = Unknown/borderline

exists since HICDEP version

1.30

VS_T field

containing table

tblLAB_VIRO

explanation of variable

IF AVAILABLE, the type of ASSAY used for this measurement

format of data

character. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Download this table as CSV file

Code	Viral test used
1	Roche qualitative (Amplicor) [HCV and HBV]
2	Roche quantitative test for HBV (Cobas Amplicor HBV monitor)
3	Bayer Bdna quantitative [HCV]
4	Bayer Bdna quantitative [HBV]
5	Roche Taqman
6	Other

VS_U field

containing table

tblLAB_VIRO

explanation of variable

Measurement unit

format of data

character. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Download this table as CSV file

Code	Test measurement unit
1	copies/mL
2	IU/mL
3	Geq (millions of genome equivalent)

VS_UL field

containing table

tblLAB_VIRO

explanation of variable

IF AVAILABLE, Upper Limit of assay

format of data

numeric

exists since HICDEP version

1.30

VS_V field

containing table

tblLAB_VIRO

explanation of variable

Measurement value (HCV-RNA & HBV-DNA only) (copies/ml)

format of data

numeric

exists since HICDEP version

1.30

tblLTFU - Death and drop-out

holds data in death and drop-out

Core fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

- ***PATIENT***: Code to identify patient (Cohort Patient ID)
- *DROP_Y*: Has the patient DROPPED OUT?
- *DROP_D*: IF YES, Date of Last Visit
- *DROP_RS*: IF YES, Reason for DROP
- *DEATH_Y*: Has the patient died?
- *DEATH_D*: Date of Death
- *AUTOP_Y*: Was an autopsy Performed?
- *DEATH_R1*: Cause of death
- *DEATH_RC1*: Coding of causal relation of the code given in DEATH_R1 to the death
- *DEATH_R2*: Cause of death
- *DEATH_RC2*: Coding of causal relation of the code given in DEATH_R2 to the death
- *DEATH_R3*: Cause of death
- *DEATH_RC3*: Coding of causal relation of the code given in DEATH_R3 to the death

List of *DEATH_R#* and *DEATH_RC#* should be continued for as many reasons that are recorded.

The *DEATH_RC#* fields should enable cohorts to transfer data in accordance with the Coding of Death project (CoDe). You are welcome to contact the CoDe group for electronic sample forms for detailed collection of data used for the CoDe review process.

CoDe defines 1 immediate, 2 contributing and 1 underlying cause of death.

Additional fields

- *ICD10_1*: Cause of death as ICD-10 if available
- *ICD10_2*: Cause of death as ICD-10 if available
- *ICD10_3*: Cause of death as ICD-10 if available

List of *ICD10_#* inplace of or together with *DEATH_R#* and together *DEATH_RC#* and should be continued for as many reasons that are recorded.

CoDe defines 1 immediate, 2 contributing and 1 underlying cause of death.

- *L_ALIVE*: Last date known to be alive

AUTOP_Y field

containing table

tblLTFU

explanation of variable

Was an autopsy Performed?

format of data

numeric: `1` = Yes, `0` = No, `9` = Unknown

exists since HICDEP version

1.30

DEATH_D field

containing table

tblLTFU

explanation of variable

Date of Death

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

DEATH_R1 field

containing table

tblLTFU

explanation of variable

Cause of death

format of data

character. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Download this table as CSV file

Code	Cause of Death
1	Myocardial Infarction
2	Stroke
3	Other cardiovascular diseases
4	Symptoms caused by mitochondrial toxicity
4.1	Lactic acidosis
5	Complications due to diabetes mellitus
6	Pancreatitis
7	Complications due to hepatitis
7.1	Hepatitis related
7.2	Liver failure not related to hepatitis or mitochondrial toxicity
8	HIV-related
8.1	AIDS defining event
8.2	Invasive bacterial infection
9	Renal failure
10	Bleeding (haemophilia)
20	Non AIDS defining cancer
90	Other
91	Suicide
92	Drug Overdose
93	Accident
99	Unknown, Fatal case with no information

DEATH_RC1 field

containing table

tblLTFU

explanation of variable

Coding of causal relation of the code given in DEATH_R1 to the death

format of data

character with codes:

- `I` = Immediate cause
- `U` = Underlying cause/condition
- `C` = Contributing cause
- `N` = Not available

exists since HICDEP version

1.30

DEATH_Y field

containing table

tblLTFU

explanation of variable

Has the patient died?

format of data

numeric: `1` = Yes, `0` = No

exists since HICDEP version

1.30

DROP_D field

containing table

tblLTFU

explanation of variable

IF DROP_Y = 1, Date of Last Visit

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

DROP_RS field

containing table

tblLTFU

explanation of variable

IF DROP_Y = 1, Reason for DROP

format of data

numeric. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

Download this table as CSV file

Code	Reason for Drop Out
1	Patient lost to follow-up / not known to be dead
2	Patient has not had visit within required amount of time
3	Patient moved away
4	Patient moved and is followed by another centre
5	Patients decision
6	Consent withdrawn
7	Incarceration/jail
8	Institutionalisation (drug treatment, psychological ?etc.)
9	Other

Note: If consent is withdrawn, all patient data except for the patient id and reason for drop out *may* have to be deleted.

DROP_Y field

containing table

tblLTFU

explanation of variable

Has the patient DROPPED OUT?

format of data

numeric: `1` = Yes, `0` = No

exists since HICDEP version

1.30

ICD10_1 field

containing table

tblLTFU

explanation of variable

Cause of death as ICD-10 if available

format of data

character

exists since HICDEP version

1.30

L_ALIVE field

containing table

tblLTFU

explanation of variable

Last date known to be alive

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

PATIENT field

containing table

tblLTFU

explanation of variable

Code to identify patient (Cohort Patient ID)

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

tblMED - Other medication

holds type, start and stop dates for other HIV related medicines.

Core fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

- ***PATIENT***: Code to identify patient (Cohort Patient ID)
- ***MED_ID***: Code representing the treatment
- ***MED_SD***: Date of Initiation of Treatment
- *MED_ED*: Date of stopping treatment

Additional fields

Please see tblART - Antiretroviral treatment.

MED_ED field

containing table

tblMED

explanation of variable

Date of stopping treatment

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

MED_ID field

containing table

tblMED

explanation of variable

Code representing the treatment

format of data

character. see coding table for valid codings.

exists since HICDEP version

1.30

Coding Table

See also the notes on the extended ATC-Codes and the ATC Index.

Download this table as CSV file

Codes (Extended ATC-Codes)	Other HIV-related drugs
A10A	Insulin or derivatives hereof
A10B	Oral antidiabetic agents
A14A	Anabolic steroids/appetite stimulants
B01AC	Anti-platelets
C-HYP	Other anti-hypertensive agents [C02, C03, C04, C07, C08]
C09	ACE inhibitors
C10	Lipid lowering agents
HICDEP_code	HICDEP_description
J01AA08	Minocycline (MINOCIN)
J01EA01	Trimethoprim (MONOTRIM, NOPIL)
J01EC02	Sulfadiazine
J01EE	Cotrimoxazole - Comb. of sulfonamides and trimethoprim (BACTRIM, EUSAPRIM, NOPIL)
J01EE01	Sulfamethoxazole and trimethoprim (Bactrim)
J01EE03	Sulfametrole and trimethoprim - Cosoltrime (MADERAN)
J01FA09	Clarithromycine (KLACID)
J01FA10	Azithomycine (ZITHROMAX)
J01FF01	Clindamycine (DALACIN)
J01GB06	Amikacine (AMIKINE)
J01MA02	Ciprofloxacine (CIPROXINE, CILOXAN)
J01MA12	Levofloxacin (TAVANIC)
J01MA14	Moxifloxacin
J01RA02	Cosoltrime (MADERAN)
J02AA01	Amphotericin B (FUNGIZON)
J02AB	Imidazoles (DAKTARIN, NIZORAL, PEVARYL ?)
J02AB02	Ketoconazole
J02AC01	Fluconazole (DIFLUCAN)
J02AC02	Itraconazole (SPORANOX)

J02AC03	Voriconazole
J02AC04	Posaconazole
J02AX01	Flucytosine
J04AB02	Rifampin (RIMATICIN)
J04AB04	Rifabutin (MYCOBUTIN)
J04AC01	Isoniazide (RIMIFON)
J04AK01	Pyrazinamide (PYRAZINAMID)
J04AK02	Ethambutol (EMB, MYAMBUTOL)
J04AM02	RIFATER
J04BA01	Clofazimine (LAMPREN)
J04BA02	Dapsone
J05AB01	Aciclovir (ZIVORAX)
J05AB04	Ribavirin
J05AB06	Ganciclovir (CYMEVENE)
J05AB09	Famciclovir
J05AB11	Valaciclovir (VALTEX)
J05AB12	Cidofovir (VISTIDE)
J05AB15	Valganciclovir
J05AD01	Foscarnet (FOSCAVIR)
L01AA01	Cyclophosphamide (ENDOXAN)
L01AD02	CCNU (LOMUSTINE)
L01AX04	Dacabazine (DTIC - Dome)
L01BA01	Methotrexate
L01CA01	Vinblastin (VELBE)
L01CA02	Oncovin (VINCRISTINE)
L01CB01	Etoposide (VEPESIDE, EXITOP 100)
L01DB01	Doxorubicine, Adriamycine (DOXIL, CAELYX, ADRIBLASTIN)
L01DC01	Bleomycine
L01XB01	Procarbazine (NATULAN)
L03AA02	G-CSF/Filgastrim (NEUPOGEN)
L03AB	Interferons
L03AB-AL2	Peginterferon alfa-2a/alfa-2b (PEGINTRON, PEGASYS)
L03AB10	Peginterferon alfa-2b (PEGINTRON)
L03AB11	Peginterferon alfa-2a (PEGASYS)
L03AC-IL2	Interleukin 2 (PROLEUKIN)
P01AX06	Atovaquone (WELLVONE, MEPRONE)
P01BA03	Primaquine
P01BD01	Pyrimethamine (DARAPRIM)
P01BD51	Pyrimethamine/Sulfadoxine (FANSIDAR)
P01CX01	Pentamidine aerosol (PENTACARNET)

V03AF03	Folinate of calcium (LEUCOVORINE)

MED_SD field

containing table

tblMED

explanation of variable

Date of Initiation of Treatment

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

PATIENT field

containing table

tblMED

explanation of variable

Code to identify patient (Cohort Patient ID)

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

tblOVERLAP - Cross-cohort identification

holds information on the patient's participation in other cohorts

Core fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

- ***PATIENT***: Code to identify patient (Cohort Patient ID)
- ***COHORT***: Code/name of the cohort
- *PAT_OTH*: Unique patient identifier in other cohorts
- *COH_OTH*: Name of the cohort

Patients of an ?original?-cohort who also participate in a ?super?-cohort should be analysed within the ?original?-cohort only. To suppress these patients from the datasets of the ?super?-cohorts the identifier used in the ?super?-cohort is needed. It is suggested that ?original?-cohorts report id?s from the ?super?-cohorts, since the ?super?-cohorts might not even know the other ID?s. Often this information is only available at centre level.

A record should be present for each cohort that the patient is participating in (apart from it?s own ?original?-cohort).

COH_OTH field

containing table

tblOVERLAP

explanation of variable

Name of the cohort

format of data

character

exists since HICDEP version

1.30

COHORT field

containing table

tblOVERLAP

explanation of variable

Code/name of the cohort

format of data

character

exists since HICDEP version

1.30

PAT_OTH field

containing table

tblOVERLAP

explanation of variable

Unique patient identifier in other cohorts

format of data

character

exists since HICDEP version

1.30

PATIENT field

containing table

tblOVERLAP

explanation of variable

Code to identify patient (Cohort Patient ID)

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

tblVIS - Basic follow-up/visit related data

holds visit related information, weight, wasting.

Core fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

- ***PATIENT***: Code to identify patient (Cohort Patient ID)
- ***VIS_D***: Date of patient visit
- *WEIGH*: Weight of patient at visit
- *GAIN_Y*: Is the patient gaining fat in the abdomen, neck, breast or other defined locations?
- *LOSS_Y*: Is the patient experiencing loss of fat from extremities, buttocks or face?

Depending on the collaboration this data might be collected in intervals of a year, e.g. from July last to July this year. In that case all visit dates or a fixed number of visit dates for that period should be gathered, if the patient did not have a visit in the defined period, a record with the PATIENT id and empty fields for VIS_D etc. should be included.

GAIN_Y field

containing table

tblVIS

explanation of variable

Is the patient gaining fat in the abdomen, neck, breast or other defined locations?

format of data

numeric: `1` = Yes, `0` = No, `9` = Unknown

exists since HICDEP version

1.30

LOSS_Y field

containing table

tblVIS

explanation of variable

Is the patient experiencing loss of fat from extremities, buttocks or face?

format of data

numeric: `1` = Yes, `0` = No, `9` = Unknown

exists since HICDEP version

1.30

PATIENT field

containing table

tblVIS

explanation of variable

Code to identify patient (Cohort Patient ID)

format of data

character (or numeric if possible)

exists since HICDEP version

1.30

VIS_D field

containing table

tblVIS

explanation of variable

Date of patient visit

format of data

`yyyy-mm-dd`

exists since HICDEP version

1.30

WEIGH field

containing table

tblVIS

explanation of variable

Weight of patient at visit

format of data

numeric (metric: kg): 999 = Unknown

exists since HICDEP version

1.30