Standard Operating Procedures

for the 14th merger

Data Management

Data Collection on Adverse Events of Anti-HIV Drugs

The D:A:D study

D:A:D

Participating cohort studies:

EuroSIDA, (20 European countries); Swiss HIV Cohort Study**,** (Switzerland);
ICONA, (Italy); ATHENA Cohort, (The Netherlands); BASS Cohort, (Spain);
CPCRA, (USA); Nice Cohort, (France); Aquitaine Cohort, (France);
HivBIVUS, (Sweden); Brussels St. Pierre Cohort, (Belgium);
Australian HIV Observational Database, (Australia);

Author: Rikke Salbøl Brandt (Data Manager) rsb@cphiv.dk

Copenhagen HIV Programme (CHIP)
University of Copenhagen, Faculty of Health Science
The Panum Institute/Building 21.1
Blegdamsvej 3b
2200 Copenhagen N, Denmark
Phone: +45 35 45 57 57
Fax: +45 35 45 57 58

CHIP COPENHAGEN HIV PROGRAMME

1 Introduction to the D:A:D SOP for the 14th Merger

The D:A:D structure, to the extent possible, conforms to the HICDEP protocol. (See the latest version of HICDEP: HIV Cohorts Data Exchange Protocol at the CHIP website: www.cphiv.dk.) Changes and additions are always part of the on-going process for projects that extend over time, and the D:A:D is no exception.

2 General D:A:D Background

The Data Collection on Adverse events of Anti-HIV Drugs (D:A:D) is a prospective multi-cohort study of HIV-infected persons under active follow up. The primary purpose of the study is to assess the incidence of myocardial infarction among HIV/AIDS patients who are receiving anti-retroviral therapy. This, in turn, will allow us to investigate whether treatment with anti-retroviral drugs is associated with development of cardio-vascular disease, an evaluation of long-term side effects.

The study began in 1999 with eleven cohorts worldwide participating with an initial enrolment of more than 23,000 patients. At the 5th merger, an additional 10,000 patients were included. At the 10th merger an additional 16,500 thousand patients were enrolled. The project is scheduled to continue at least until the completion of the 17th merger in 2016.

The centralized data processing for D:A:D takes place once a year. Each cohort gathers and computerizes its own data; subsequently it is merged in a database in Copenhagen. The core data in the study is information on incident cases of cardiovascular disease, which are reported immediately to the local cohort coordinating office by fax, using event reporting forms (available at www.cphiv.dk).

The data collection also includes information on risk factors for cardiovascular disease, such as previous myocardial infarction or stroke, hereditary tendency, smoking status, diabetes mellitus, dyslipidemia and hypertension. At the 5th merger, data on viral hepatitis testing became part of the collection process and at the 7th glucose measurements were introduced. At the 8th merger we began collecting serum creatinine readings. At the 10th merger we greatly expanded the Adverse Events table to collect new clinical endpoints. At the 12th merger bilirubin measurements have been added to the lab-measurements collected.

3 Timing of the 14th and Subsequent Mergers

The deadline for data submission for this merger is Monday, June 3rd 2013 . During the 6 weeks after the submission of data, until around mid-July, we will send out error and discrepancy information in the form of small databases. We will spend the next 1½ months processing your response to these reports and working closely with you to clean the data. The cleaning of the data should be completed around September 1st.

The data transfer date for the 15th merger is planned for Friday, May 30th 2014.

4 What is New or Different for this Merger?

4.1 Renaming/restructuring the tables to match HICDEP

All tables and fields that match the HIV Cohorts Data Exchange Protocol (HICDEP) are (re-)named according to HICDEP 1.60 (in some cases HICDEP 1.70). More details of the protocol can be found at http://hicdep.org/#. Some tables have been split into two tables - a HICDEP only and a D:A:D specific table. The purpose of this is to ease the burden for the data managers who contribute

to more than one study so that the codes set up to produce the HICDEP compliant table can be reused for all studies, since the D:A:D specific fields are moved to a separate table. The DAD specific tables have the suffix _DAD to distinguish them.

4.2 tblBAS: Renamed/recoded variables

SEROCO_M has been renamed SEROHOW in accordance with HICDEP 1.70 and the coding for this variable has been amended.
MOD_OTH has been renamed MODE_OTH.
The ORIGIN field is recoded to use the United Nations Region codes, which can be found at http://unstats.un.org/unsd/methods/m49/m49regin.htm
The variables for capturing last HIV negative date and First HIV Positive date are removed from this table and will instead be captured via tblLAB_VIRO where all HIV tests are captured with results.
Please note that the field for Birth date (BIRTH_D) should be provided for all patients. For the cohorts where only the Birth year is available, please code the birth date as the unknown date for that year (01/07/XXXX). This will be used instead of providing the age at visit in the tblVIS table.

4.3 tblVIS: Visit related information

The variable Age (at visit) has been removed. Instead the BIRTH_D field in tblBAS needs to be provided. For the cohorts where only the Birth year is available, please code the birth date as the unknown date for that year (01/07/XXXX).
The CAR table fields as well as the non-HICDEP fields from the VIS table have been moved into a separate table called tblVIS_DAD. Please note that in submitting tblVIS_DAD you are not required to submit the values regarding Cardiovascular Treatment if you have not at previous mergers been submitting the CAR table. You are required to submit the D:A:D specific values regarding smoking and family history of AMIs.

4.4 tblLTFU: CoDe Death Coding

The Coding Causes of Death in HIV (CoDe) system is used for causes of death from the 14th merger onwards. Please refer to http://www.cphiv.dk/CoDe/tabid/55/Default.aspx for the CoDe system. The basic CoDe codes are augmented by the more specific D:A:D division of "MI" and "other ischemic heart disease" into two separate codings. Likewise in support of the CoDe coding scheme the field DEATH_RC1 has been added. Please code it "N" for "not available" if you do not collect this information. For version 2 of the 14th merger a field for capturing the Certainty of Diagnosis in relation to the death-code has been added to tblLTFU (this is an optional field).

4.5 tblMED: New drugs for Hepatitis

New drugs for hepatitis have been added to this merger: "boceprevir" (J05AE12) and "telaprevir" (J05AE11) - but as always please refer to http://www.whocc.no/atc_ddd_index/ for any new treatment codes not already covered in this SOP.

4.6 tblMED: Cardiovascular influencing treatments

The Cardiovascular Drugs previously submitted separately to the CAR_N table have been moved to tblMED to support HICDEP.

4.7 tblMED: MED_RS – reason for stopping treatment added

The field MED_RS has been added to tblMED to support HICDEP.

4.8 tblAE: AE_DESCRIP instead of OTH_SPEC

The field OTH_SPEC has been renamed AE_DESCRIP in accordance with the HICDEP fields. This is meant as a description field for describing the event. LOCATION and ICD10 have been

removed. Please provide the ICD10 codes or the location of Cancers in the AE_DESCRIP field where appropriate.

4.9 tblAE: CLD renamed to ESLD, NADM renamed to NADC

The endpoint for liver disease being collected in DAD has been renamed to better reflect the focus of the end point. It is now named End-Stage Liver Disease (ESLD) rather than Chronic Liver Disease (CLD). Other than the name change the end point remains the same.
NADM (Non-AIDS Defining Malignancies) have been renamed to NADC (Non-AIDS Defining Cancers) to reflect that we are talking about cancers.

4.10 tblLAB_VIRO: HIV test results

The HIV test results have been added to the Virology/Serology table. This has happened in the process of making D:A:D HICDEP compliant. The values HIVN_D and HIVP_D for capturing the last HIV negative date and the first HIV positive date were previously found in the BAS table in the D:A:D study, but this information can be found in the results of Virology/Serology measurements.

5 What should be Submitted

For all Cohorts, (I, II, and III), please submit **all** the data you have--**past and present**--for each patient. This also refers to the new clinical endpoints (chronic liver disease, end stage renal disease, and non-AIDS defining malignancies). At the very minimum, **ALL** patients must appear in the BAS (demographic, clinical, and background information) table including those who have died, dropped-out, been lost to follow-up, or not shown up for their 14th merger visit.

6 D:A:D Data-sections

6.1 Demographic, Clinical, and Background Information [tblBAS]

Each patient, whether seen at the 14th merger or not, should appear once in this table.

Please make sure that the enrolment date, ENROL_D, is the date that the patient enrolled in the local cohort. (This has been misinterpreted by some at earlier mergers.) Participation in the D:A:D study begins with the baseline visit date.

Some cohorts are prohibited from reporting certain types of data such as date of birth, origin or race. For ORIGIN, please leave these fields *blank*. For RACE, use the code "98". For BIRTH_D please code the birth date as the unknown date for the birth year (01/07/XXXX).

The structure of this table has changed for this merger – HIVN_D and HIVP_D have been removed and the ENROL variable has been moved into its own table (tblBAS_DAD) since this is not a HICDEP field. See the Appendix for the details.

6.2 Overlap: Cross-Cohort Identification [tblOVERLAP]

Patients who are known to be in other cohorts participating in D:A:D should be entered in this table, once for each cohort. If none of your patients is a member of another cohort participating in D:A:D, please do not submit this table. See the Appendix for details.

6.3 Visit-related Data [tblVIS and tblVIS_DAD]

Please provide visit data for all visits, not just from the last visit. At this merger the Visit table has been divided into two tables – one for core HICDEP variables (tblVIS), and one for the specific D:A:D variables (tblVIS_DAD). See the Appendix for details.

6.4 Treat. for/influencing Cardiovascular Risks (Status) [tblVIS_DAD]

Please submit the data from all visits, not just from the last visit. At this merger this information is added to the tblVIS_DAD table, rather than having its own table, as the information is visit-date related, but not part of the core HICDEP variables. Please note that in submitting tblVIS_DAD you are not required to submit the values regarding Cardiovascular Treatment if you have not at previous mergers been submitting the CAR table. See the Appendix for details.

6.5 Treat. for/influencing Cardiovascular Risks (Drugs) [tblMED]

At this merger the medication for cardiovascular diseases are added to the tblMED table in accordance with the HICDEP protocol. For each drug treatment episode, please provide treatment start date and treatment end date. If the treatment is on-going, please leave the end date field *blank*. The different drug interventions are identified with the ATC code in the MED_ID field. See the Appendix for details.

6.6 Adverse Events [tblAE]

The field AE_DESCRIP has been added instead of the fields LOCATION and ICD10. See the Appendix for details.

6.7 Blood Pressure [tblLAB_BP]

The structure of this table is unchanged for this merger. See the Appendix for details.

6.8 Laboratory Data [tblLAB]

The structure of this table is unchanged for this merger. See the Appendix for details.

6.9 CD4 measurements [tblLAB_CD4]

The structure of this table is unchanged for this merger. See the Appendix for details.

6.10 RNA measurements [tblLAB_RNA]

Measurements under the testing threshold should either be coded as minus the measurement value, or, if no value is available, then as minus 1 (-1). The structure of this table is unchanged for this merger. See the Appendix for details.

6.11 Virology/Serology: Hepatitis [tblLAB_VIRO]

The structure of this table is unchanged for this merger. New values regarding HIV tests have been added. See the Appendix for details.

6.12 Use of Anti-retroviral Treatments(Normalized) [tblART]

The structure of this table is unchanged for this merger. Either the old or the new code may be used to classify anti-retroviral treatments. Each anti-retroviral treatment is identified by its ATC code, which can be up to 12 characters. If the patient has been given ART, enter the proper ATC code in the ART_ID field followed by ART_SD (start date) and ART_ED (stop date). If the patient is currently undergoing treatment, the stop date should be *blank.* See the Appendix for details.

6.13 Other HIV-related Treatments(Normalized) [tblMED]

The structure of this table is unchanged for this merger. The Cardiovascular treatments have been moved to this table and the codes added. Each treatment is identified by an ATC code that can be up to 12 characters. These codes should be entered in the MED_ID field if the patient has been treated with the corresponding drug, followed by the MED_SD (start date) and MED_ED (end date). If the patient is currently undergoing treatment, please leave the end date *blank.* Please notice that a few

of the treatments have the same ATC code and, perhaps what is more important, some of the old codes have been split into two separate ATC codes. See the Appendix for details.

6.14 Severe Opportunistic Infections & Malignancies [tblDIS]

The structure of this table is unchanged for this merger. Each infection/malignancy is identified by a two-to-four letter code, which should be entered in the DIS_ID (disease identity) field if the patient has had the corresponding infection/malignancy. In addition, DIS_D (onset date) and DIS_WD (means of diagnosis) of these infections/malignancies should be reported**.** See the Appendix for details.

6.15 Lost to follow-up and deaths [tblLTFU]

This is a new table added at this merger. It is split off from the BAS table. It will be following the structure and coding of the fields previously submitted in the BAS table.

All of the death and drop-out variables are incorporated in this table. The coding for causes of death conforms to the CoDe (Coding causes of Death in HIV) protocol as referenced by HICDEP.

A patient is considered a drop-out if he/she has left the cohort, withdrawn consent, or if there is no new information on the patient during the preceding twelve months. Patients without a visit date, death date or drop-out date will be considered lost to follow-up.

7 D:A:D Data Format

Please submit your data using the D:A:D formats described in the tables in the Appendix.

7.1 *Blank* Values

A "**.**" represents a missing value in SAS. SAS will automatically convert a *blank* field to the missing value code "**.**". Where a variable is not applicable, or not used, (such as the fasting variable for haemoglobin measurements in the LAB_N table), leave the field *blank.* (This also applies to fields where data collection is legally prohibited, such as BIRTH_D for some cohorts.) If data is missing where a response is required or available, the cohort validation programs should detect this and this information will become part of the database for errors and discrepancies.

7.2 Unknown Values

The category "unknown" indicates that the information needed is unknown or purposely left as missing. The codes 9, 99, and 999 are used to designate this category. Please see the tables in the Appendix for the specific coding.

The date 11/11/1911 is to be used, whenever the use of a drug, a treatment episode, etc., is known to have occurred but the date is unknown. Similarly, for other types of variables, there is most often a "yes/no" question, followed by the "date" question (for example: "Has the patient an AIDS diagnosis?" and then: "If yes, date of AIDS diagnosis"). For these types of questions, if the event is known to have occurred but the date is unknown, code the date as: 11/11/1911. Then the D:A:D validation programs will detect a 'yes AIDS diagnosis'–'unknown date of diagnosis'. If the only information available regarding a date is the year, then it should be entered as July 1, XXXX (01/07/XXXX). If the month and year are given, the date should be entered with the day being the 15th.

8 Data File Transfers to the D:A:D Co-ordinating Centre

Please utilize the HIV Distributed Data Management (HIV DDM) Tool for data submission at this 14th merger.

If unable to use the HIV DDM tool you should submit your data using SAS or ACCESS formats. SAS data sets are preferable—and SAS version 8 or 9 is preferable to version 6. ACCESS 2007, ACCESS 2000 and ACCESS 1997 tables are also acceptable. Please sort each table by its key field(s). (The key fields are marked with an asterisk (*) in the tables.)
In the event of data submission not using the HIV DDM tool, the data will be verified at the coordinating centre using the HIV DDM tool for a uniform QA procedure.

Please submit 14 or 15 raw data sets for this merger. (Submit the tblOVERLAP: Cross-Cohort Identification Table only if you have patients participating in other D:A:D cohorts.). The list of tables to submit is on the first page of the Appendix.

An ftp server (IP-address: 130.226.172.44) has been set-up with a password protected folder for each of the cohorts. Please contact Rikke S. Brandt (rsb@cphiv.dk) for you username and password. Only you and the coordinating centre will have access to your folder. The other cohorts will not be able to look at your submitted data.

9 Error and Discrepancy Reporting

For this merger there may still be additional e-mails with material sent out within six weeks of data submission to the cohort data managers in order for them to check and correct their data and to replace "missing" values. This is in order to ensure we check all data items against all existing QA checks.

Please include the VERIFIED=1 variable for already verified outliers so that you will not spend time re-verifying these.

Please note that the discrepancy reports for this merger will include checks across mergers comparing this year's submission to the latest mergers, especially on the BAS, MED and VIS tables. The reason is that missing values in these tables will affect the risk-profile of the patients and have an impact on a lot of analysis that are performed at the mergers. For example the ability to calculate BMI at baseline is made impossible if the weight value at the visit record closest to the baseline date is missing – this has in previous mergers resulted in the coordinating centre looking at previously submitted data to be able to extract this information. This will hopefully be clarified at this merger with the added checks against 'historic' data.

The cohort data managers should enter the corrected data into their own database and then send the revised tables to the D:A:D data manager. These revised tables will then be re-checked, and then, if there are no further problems, added to the rest of the cohort's data.

Appendix

The following 15 tables describe the formats for the 14th merger data submission.

Shading is used to indicate changes and additions for the 14th merger.

Variables marked with an asterisk (*) are the key variables in each table. Taken in combination, this means that these variables must define a unique table entry.

1.	**tblBAS:**	Demographic, Clinical and Background Information
2.	**tblBAS_DAD:**	Enrolment
3.	**tblOVERLAP:**	Cross-Cohort Identification
4.	**tblVIS:**	Visit-related Data
5.	**tblVIS_DAD:**	Additional Visit-related Data
6.	**tblAE:**	Adverse Events
7.	**tblLAB_BP:**	Blood Pressure
8.	**tblLAB:**	Laboratory Values
9.	**tblLAB_CD4:**	CD4 Measurements
10.	**tblLAB_RNA:**	RNA Measurements
11.	**tblLAB_VIRO:**	Virology/Serology: Hepatitis and HIV-tests
12.	**tblART:**	Use of Anti-Retroviral Treatments
13.	**tblMED:**	Other HIV-Related and Cardiovascular Treatments
14.	**tblDIS:**	Severe Opportunistic Infections & Malignancies
15.	**tblLTFU:**	Lost to Follow-Up and Deaths

1. tblBAS: Demographic, Clinical and Background Information

Explanation of variable	Code to identify patient	Code for clinic/ centre/ hospital where patient is seen.	Gender	Birth date	Patient's height [m]	Region of origin of patient	Region of origin of patient: other	Ethnicity/Race of patient	Date of enrolment in local cohort
Field name	***PATIENT**	**CENTER**	**GENDER**	**BIRTH_D**	**HEIGH**	**ORIGIN**	**ORI_OTH**	**ETHNIC**	**ENROL_D**
Format of data	Character 20	Character 20	1=Male 2=Female 9=Unknown	Date format	999=Unknown	See below for coding	Character 20	Numeric See below for coding	Date format

Explanation of variable	Mode of infection	Mode of infection: other	Date first seen at clinic	Date of seroconversion	Source of the SEROCO_D	Has pt. an AIDS diagnosis	Date of AIDS diagnosis	Has pt. received antiretroviral treatment
Field name	**MODE**	**MODE_OTH**	**FRSVIS_D**	**SEROCO_D**	**SEROHOW**	**AIDS_Y**	**AIDS_D**	**RECART_Y**
Format of data	Numeric See below for coding	Character 20	Date format	Date format	Numeric See below for coding	0=No 1=Yes 9=Unknown	Date format	0=No 1=Yes 9=Unknown

2. tblBAS_DAD: Enrolment

Explanation of variable	Code to identify patient	Cohort group identifier
Field name	***PATIENT**	**ENROL**
Format of data	Character 20	1=I 2=II 3=III

1a. Code (bas_code_origin)	Region	Old codes
002	Africa	10, 2
015	Northern Africa	11, 21
	~~Sub-Saharan Africa~~	12, 22
014	Eastern Africa	12, 22
017	Middle Africa	12, 22
018	Southern Africa	12, 22
011	Western Africa	12, 22
142	Asia	20, 3
145	~~Middle East~~ Western Asia	60, 7
009	Oceania ~~(not Australia)~~	30, 3
053	Australia & New Zealand	40, 5
054	Melanesia	30, 3
057	Micronesia	30, 3
061	Polynesia	30, 3
019	Americas	50, 6
021	North America	51, 61
	~~Central & South America~~	52, 62
013	Central America	52, 62
005	South America	52, 62
150	Europe	70, 8
155	Western Europe	71, 81
151	Eastern Europe	72, 82
999	Unknown	99, 9

Please refer to http://unstats.un.org/unsd/methods/m49/m49regin.htm for any UN region codes not covered above and also to determine which countries belong to each of the regions.

1b. Code (bas_code_ethnic)	Ethnicity/Race
10	White
20	Black
21	Black African
22	Black Caribbean
30	Hispanic
40	Asian
50	Americas
60	Indigenous
1020	White-Black
1040	White-Asian
2030	Black-Hispanic
3040	Hispanic-Asian
102040	White-Black-Asian
97	Other
98	Prohibited
99	Unknown

1c. Code (bas_code_mode)	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

1d. Code (bas_code_serohow)	SEROHOW: Source of SEROCO_D	Old code
1	Midpoint between last neg. and first pos. HIV-1 test	
2	Lab evidence of seroconversion	

3	Seroconversion illness	
4	First pos HIV-1 test	
8	Other	9
9	Unknown	

3. tblOVERLAP: Cross-Cohort Identification

Explanation of Variable	Code to identify your D:A:D patient	Name of the cohort	Name of other D:A:D cohort	Unique patient identifier in other D:A:D cohort
Field name	***PATIENT**	***COHORT**	***COH_OTH**	**PAT_OTH**
Format of data	Character 20	Character 20	Character 20	Character 20

4. tblVIS: Visit-related Data

Explanation of variable	Code to identify patient	Visit date	Patient's weight [kg]	Is pt. experiencing fat loss from extremities, buttocks or face	Is pt. gaining fat in abdomen, neck, breast or other locations
Field name	***PATIENT**	***VIS_D**	**WEIGH**	**LOSS_Y**	**GAIN_Y**
Format of data	Character 20	Date format	999=Un-known	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown

5. tblVIS_DAD: Additional Visit-related Data

Explanation of variable	Patient ID	Visit date	Is the patient currently a smoker	Was the patient ever a smoker	Is pt. experiencing lipodystrophy	First degree relative with AMI before age 50
Field name	***PATIENT**	***VIS_D**	**SMK_Y**	**SMD_Y**	**LIP_Y**	**FAM_Y**
Format of data	Character [20]	Date format	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown

Explanation of variable	Currently taking anti-platelets	Currently taking ACE inhibitors	Currently taking other anti-hypertensive agents	Currently taking lipid lowering agents	Currently taking oral anti-diabetic agents	Currently taking insulin or insulin derivatives	Currently taking anabolic steroids/appetite stimulants
Field name	**PLT_Y**	**ACE_Y**	**HYP_Y**	**LOW_Y**	**ORA_Y**	**INS_Y**	**ANA_Y**
Format of data	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown

Please note that in submitting tblVIS_DAD you are not required to submit the values regarding Cardiovascular Treatment (PLT_Y, ACE_Y, HYP_Y, LOW_Y, ORA_Y, INS_Y, ANA_Y) if you have not at previous mergers been submitting the CAR table.

6. tblAE: Adverse Events

		Do not code!					
Explanation of Variable	Code to identify patient	Unique event identifier	Event type	Further event type specification	Description of the event where the ae_id/ae_spec is not sufficient. For Cancers this could contain either the Location (example: lung) OR ICD10 code	Date of event	
Field name	***PATIENT**	**EVENT_ID**	***AE_ID**	***AE_SPEC**	**AE_DESCRIP**	***AE_D**	
Format of data	Character 20	Numeric	Character 4 See below	Character 4 See below	Character 50	Date format	

NB: Either the LOCATION or the ICD10 code should be provided where available, not both

6a. Coding for Adverse Event types		
AE_ID	**AE_SPEC**	**Adverse Event**
AMI		Acute Myocardial infarction
AMI	DAMI	Definitive Myocardial infarction
AMI	PAMI	Possible Myocardial infarction
STR		Stroke
STR	SHAE	Stroke: Haemorrhagia
STR	SINF	Stroke: Infarction
STR	SUNK	Stroke: Unknown
DIA		Diabetes mellitus
ICP		Invasive Cardiovascular Procedure
ICP	BYP	Coronary artery by-pass grafting
ICP	END	Carotic endarterectomy
ICP	ANG	Coronary angioplasty/stenting
~~CLD~~		~~Chronic Liver Disease~~
ESLD		End stage liver disease
ESRD		End stage renal disease
~~NADM~~ NADC		~~Non-AIDS Defining Malignancies~~ Non-AIDS Defining Cancers
NADC	ALL	Leukaemia: Acute lymphoid
NADC	AML	Leukaemia: Acute myeloid
NADC	ANUS	Anus cancer
NADC	BLAD	Bladder cancer
NADC	BONE	Bone cancer
NADC	BRAC	Brain cancer
NADC	BRCA	Breast cancer
NADC	CLL	Leukaemia: Chronic lymphoid
NADC	CML	Leukaemia: Chronic myeloid
NADC	COLO	Colon cancer
NADC	COTC	Connective tissue cancer
NADC	ESOP	Esophagus cancer
NADC	GALL	Gallbladder cancer
NADC	GYCA	Gynaecologic cancer
NADC	HENE	Head and neck (incl. face) cancers
NADC	HDL	Hodgkin lymphoma
NADC	KIDN	Kidney cancer
NADC	LEUK	Leukaemia: unspecified
NADC	LIPC	Lip cancer
NADC	LIVR	Liver cancer
NADC	LUNG	Lung cancer
NADC	MALM	Malignant melanoma
NADC	MEAC	Metastasis: of adenocarcinoma
NADC	MEOC	Metastasis: of other cancer type
NADC	MESC	Metastasis: of squamuos cell carcinoma
NADC	META	Metastasis: unspecified
NADC	MULM	Multiple myeloma
NADC	PANC	Pancreas cancer

NADC	PENC	Penile cancer
NADC	PROS	Prostate cancer
NADC	RECT	Rectum cancer
NADC	STOM	Stomach cancer
NADC	TESE	Testicular seminoma
NADC	UTER	Uterus cancer
NADC	OTH	Non-Aids Defining Cancer: Other

7. tblLAB_BP: Blood Pressure				
Explanation of Variable	Code to identify patient	Date of Measurement	Systolic blood pressure [mmHg]	Diastolic blood pressure [mmHg]
Field name	***PATIENT**	***BP_D**	**BP_SYS**	**BP_DIA**
Format of data	Character 20	Date format	Numeric	Numeric

8. tblLAB: Laboratory Values							
Explanation of Variable	Code to identify patient	Type of measurement	Specimen type (Glucose only)	Date of measurement	Measurement value	Unit of measurement	Measurement done while fasting
Field name	***PATIENT**	***LAB_ID**	***LAB_ST**	***LAB_D**	**LAB_V**	**LAB_U**	**LAB_FA**
Format of data	Character 20	Character 4 See coding below	Character 2 WB=Whole Blood P=Plasma S=Serum	Date format	Numeric (-1 = undetect. If detectable but under the threshold, then:-<value>)	Character 10 (or numeric) **See coding below**	Numeric 0=No 1=Yes 9=Unknown blank for haemoglobin

8a. Code (lab_code)	Type of measurement
CHOL	Total cholesterol
HDL	Serum HDL
TRIG	Serum triglyceride
HAEM	Haemoglobin
GLUC	Glucose
CRE	Serum Creatinine
BIL	Total Bilirubin
ALB	Albumin
ALT	Alanin-Aminotransferase
AST	Aspartat aminotransferase
PLT	Platelet count

8b. Measurement unit code (lab_code_units)	Definition
1: mmol/L	mmol/L
2: gm/L	gm/L
3: gm/dL	gm/dL
4: mg/dL	mg/dL
5: IU/L	Units/L
6: micromol/L	μ/L
8: 1E+9/L	1E+9/L
11: µkat/L	µkat/L
13: µg/L	µg/L

9. tblLAB_CD4: CD4 Measurements			
Explanation of variable	Code to identify patient	Date of measurement	Measurement [counts/micro litre]
Field name	***PATIENT**	***CD4_D**	**CD4_V**
Format of data	Character 20	Date format	Numeric (-1 = undetectable; if detectable but under the threshold, then: -<value>)

Please note that we do not require the CD4_U variable but you are welcome to provide it – we only collect counts/micro litre and not percent in D:A:D – we will just filter out the percentage values and not use them for D:A:D.

10. tblLAB_RNA: RNA Measurements					
Explanation of variable	Code to identify patient	Date of measurement	HIV-RNA measurement [copies/ml]	Lower limit of HIV-RNA assay [copies/ml]	Type of viral assay used for measurement
Field name	***PATIENT**	***RNA_D**	**RNA_V**	**RNA_L**	**RNA_T**
Format of data	Character 20	Date format	(-1 = undetectable; if detectable but under the threshold, then: -<value>)	999= unknown	Numeric See coding below

10a. Code (lab_rna_code_assay)	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
42	Abbott Real time HIV M200
50	Monitor 1.0
51	Monitor 1.0 ultra-sensitive
55	Monitor 1.5
56	Monitor 1.5 ultra-sensitive
59	Monitor unspecified
65	Cobas 1.5
66	Cobas 1.5 ultra-sensitive
90	Other
99	Unknown

11. tblLAB_VIRO: Virology/Serology: Hepatitis and HIV-tests					
Explanation of Variable	Code to identify patient	Viral test	Measurement date	Measurement result	Measurement value
Field name	***PATIENT**	***VS_ID**	***VS_D**	**VS_R**	**VS_V**
Format of data	Character 20	Character 5 See coding below	Date format	0= negative 1= positive 9= unknown/ borderline	HCVR & HBVD only (-1 = undetectable; if detectable but under the threshold, then: -<value>)

Explanation of variable	Measurement unit	Lower limit of test	Upper limit of test	Type of viral test
Field name	**VS_U**	**VS_LL**	**VS_UL**	**VS_T**
Format of data	See coding below	999= unknown	999= unknown	Numeric See coding below

Please note that we now collect the HIV test results here to be able to determine last HIV-neg date and first HIV-pos date previously collected in tblBAS

11a. Code (vs_id)	Viral test
HCV	Marker for hepatitis C infection - test unknown
HCVA	HCV antibody
HCVG	HCV antigen
HCVR	HCV-rna
HBV	Marker for hepatitis B infection (=HBVAC) - test unknown
HBVAS	HBV antibody (surface)
HBVAE	HBV antibody (envelope)
HBVAC	HBV antibody (core)
HBVGS	HBV antigen (surface)
HBVGE	HBV antigen (envelope)
HBVD	HBV-dna
HIV-1	HIV-1 test
HIV-2	HIV-2 test
HIVAE	HIV antibodies ELISA
HIVAWB	HIV antibodies Western blot

11b. Code (vs_u)	Test measurement unit
1	Copies/ml
2	UI/ml (International units/ml)
3	Geq (millions of genome equivalent)
4	pg/ml (picograms/ml)
9	Other

11c. Code (vs_t)	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
9	Other

12. tblART: Use of Anti-Retroviral Treatments

Explanation of Variable	Code to identify patient	ATC code representing the antiretroviral treatment	Treatment start date	Treatment end date	Reason for stopping treatment
Field name	***PATIENT**	***ART_ID**	***ART_SD**	**ART_ED**	**ART_RS**
Format of data	Character 20	Character 12	Date format	Date format	Numeric See coding below

If a new drug is used that does not appear in the lists in this SOP, then please refer to http://www.whocc.no/atc_ddd_index/ for an updated list.

12a. Extended ATC codes (art_id)	Anti-Retroviral Drugs	Old codes
J05A	ART unspecified	
J05A-PBT	Participant in Blinded Trial	PBT
J05AE	PI unspecified	
J05AE01	Saquinavir (gel, not specified)	SQV
J05AE01-SQH	Saquinavir hard gel (INVIRASE)	SQH
J05AE01-SQS	Saquinavir soft gel (FORTOVASE)	SQS
J05AE02	Indinavir (CRIXIVAN)	IDV
J05AE03	Ritonavir (NORVIR)	RTV
J05AE03-H	Ritonavir high dose (NORVIR)	
J05AE03-L	Ritonavir low dose (NORVIR)	
J05AE04	Nelfinavir (VIRACEPT)	NFV
J05AE05	Amprenavir (141W94) (AGENERASE)	APV
J05AE06	Lopinavir/Ritonavir (ABT-378/r, Kaletra)	ABT
J05AE07	Fosamprenavir (trial drug)	FSP, J05AE-FSP
J05AE08	Atazanavir (ZRIVADA)	BMS, J05AE-ATV
J05AE09	Tipranavir (trial drug)	TPR, J05AE-TPR
J05AE10	Darunavir (TMC114) (PREZISTATM)	J05AE-TMC
J05AE-MOZ	Mozenavir (DMP-450)	
J05AF	NRTI unspecified	
J05AF01	Zidovudine (AZT, RETROVIR)	AZT
J05AF02	Didanosine (ddI) (VIDEX)	DDI
J05AF03	Zalcitabine (ddC) (HIVID)	DDC
J05AF04	Stavudine (d4T) (ZERIT)	D4T
J05AF05	Lamivudine (3TC, EPIVIR)	TTC
J05AF06	Abacavir (1592U89) (ZIAGEN)	ABC
J05AF07	Tenofovir (VIREAD)	TEN
J05AF08	Adefovir (PREVEON)	ADE
J05AF09	Emtricitabine (trial drug)	FTC
J05AF-ALO	Alovudine	
J05AF-AMD	Amdoxovir (DADP)	
J05AF30-COM	Zidovudine/Lamivudine - COMBIVIR (AZT/3TC, RETROVIR/EPIVIR)	COM
J05AF-FOZ	Fozivudine tidoxi	
J05AF30-KIV	Kivexa (3TC + ABC)	J05AF30-KVX
J05AF-LDN	Lodenosine (trialdrug)	
J05AF-RVT	Reverset	
J05AF30-TRU	Truvada	
J05AF30-TZV	Trizivir	TZV

J05AG	NNRTI unspecified	
J05AG01	Nevirapine (VIRAMUN)	NVP
J05AG02	Delavirdine (U-90152) (RESCRIPTOR)	DVL
J05AG03	Efavirenz (DMP-266) (STOCRIN, SUSTIVA)	EFV
J05AG04	Etravirine (TMC125)	J05AG-TMC
J05AG-CPV	Capravirine	
J05AG-DPC083	DPC083 (trial drug)	DPC
J05AG-DPC961	DPC 961	
J05AG-EMV	Emivirine (MKC442)	
J05AG-ETV	Etravirine (TMC 125)	
J05AG-LOV	Loviride	LOV
J05AG-RPV	Rilpivirine (TMC-278)	
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)	
J05AX07	Enfurvirtide (FUZEON, T-20/Ro 29-9800)	T20, ENF
J05AX08	Raltegravir (MK-0518)	
J05AX09	Maraviroc (UK427857)	J05AX-MVC
J05AX-EVG	Elvitegravir (Gilead)	
J05AX-VIC	Vicriviroc	
L01XX05	Hydroxyurea/Hydroxycarbamid (LITALIR)	HYD
P02CB	Atervidine	ATV

12b. Code (art_rs)	Coding for Reason of Stopping Treatment	Old code
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 (anaemia …etc.)	
10	Hyperlactataemie/lactic acidosis	
70	Pregnancy – toxicity concerns	96 (Pregnancy)
75	Pregnancy – prevention of mother to child transmission	96 (Pregnancy)
76	Post-partum prophylaxis	
77	Dose change for height/ weight	
88	Death	
90	Side effects – any of the above but unspecified	
90.1	Co morbidity	
91	Toxicity, not mentioned above	
91	Toxicity, any	
92	Availability of more effective treatment (not specifically failure or side effect related)	
92.1	Simplified treatment available	
92.2	Treatment to 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	

13. tblMED: Other HIV-Related and Cardiovascular Treatments					
Explanation of variable	Code to identify patient	ATC treatment code	Treatment start date	Treatment end date	Reason for stopping treatment
Field name	***PATIENT**	***MED_ID**	***MED_SD**	**MED_ED**	**MED_RS**
Format of data	Character 20	Character 12 See coding below	Date format	Date format	Numeric See coding below

If a new drug is used that does not appear in the lists in this SOP, then please refer to http://www.whocc.no/atc_ddd_index/ for an updated list, this is also the reference for the full ATC codes for drugs. **If you have a more precise ATC code for a drug that only has a partial ATC code in the list below, please provide the more precise code.**

13a. Extended ATC codes (med_id)	Treatments
	Influencing Cardiovascular Risk
B01AC	Anti-platelets (PLT)
C09	ACE inhibitors (ACE)
C-HYP	Other anti-hypertensive agents (HYP) [C02, C03, C04, C07,C08]
C10	Lipid lowering agents (LOW)
A10B	Anti-diabetic agents (ORA)
A10A	Insulin/ insulin derivatives (INS)
A14A	Anabolic steroids/ appetite stimulants (ANA)
	Other HIV-Related Treatments
J01EA01	Trimethoprim
J01EC02	Sulfadiazine
J01EE	Cotrimoxazole (BACTRIM, EUSAPRIM, NOPIL)
J01FA09	Clarithromycine (KLACID
J01FA10	Azithomycine (ZITHROMAX
J01FF01	Clindamycine
J01GB06	Amikacine (AMIKINE)
J01MA02	Ciprofloxacine (CIPROXINE, CILOXAN)
J01MA12	Levofloxacin (TAVANIC)
J01RA02	Cosoltrime (MADERAN)
J02AA01	Amphotericin B (FUNGIZON)
J02AB	Imidazoles (DAKTARIN, NIZORAL, PEVARYL …)
J02AB02	Ketoconazole
J02AC01	Fluconazole (DIFLUCAN)
J02AC02	Itraconazole (SPORANOX)
J02AC03	Voriconazole
J04AB02	Rifampin (RIMATICIN)
J04AB04	Rifabutin (MYCOBUTIN)
J04AC01	Isoniazide (RIMIFON)
J04AK01	Pyrazinamide (PYRAZINAMID)
J04AK02	Ethambutol (EMB, MYAMBUTOL)
J04AM02	RIFATER
J04BA01	Clofazimine (LAMPREN)
J04BA02	Dapsone
J05AB01	Acicloivir (ZIVORAX)
J05AB04	Ribavirin

J05AB06	Ganciclovir (CYMEVENE)
J05AB09	Famciclovir
J05AB11	Valaciclovir (VALTEX)
J05AB12	Cidofovir (VISTIDE)
J05AD01	Foscarnet (FOSCAVIR)
J05AE12	Boceprevir (Victrelis)
J05AE11	Telaprevir (Incivek)
J05AF10	Entecavir
J05AF11	Telbivudine
L01AA01	Cyclophosphamide (ENDOXAN)
L01AD02	CCNU (LOMUSTINE)
L01AX04	Dacabazine (DTIC - Dome)
L01BA01	Methotrexate
L01CA01	Vinblastin (VELBE)
L01CA02	Oncovin (VINCRISTINE)
L01CB01	Etoposide (VEPESIDE, EXITOP 100)
L01DB01	Doxil (CAELYX) Doxorubicine, Adriamycine (ADRIBLASTIN)
L01DC01	Bleomycine
L01XB01	Procarbazine (NATULAN)
L03AA02	2 G-CSF
L03AB	Interferon
L03AC-IL2	Interleukin 2
P01AX06	Atovaquone (WELLVONE, MEPRONE)
P01BD01	Pyrimethamine (DARAPRIM)
P01BD51	Pyrimethamine/Sulfadoxine (FANSIDAR)
P01BD-SUX	Sulfadoxine
P01CX01	Pentamidine aerosol (PENTACARNET)
V03AF03	Folinate of calcium (LEUCOVORINE)

13b. Code (med _rs)	**Coding for Reason of 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 (anaemia …etc.)

10	Hyperlactataemie/lactic acidosis
70	Pregnancy – toxicity concerns
75	Pregnancy – prevention of mother to child transmission
76	Post-partum prophylaxis
77	Dose change for height/ weight
88	Death
90	Side effects – any of the above but unspecified
90.1	Co morbidity
91	Toxicity, not mentioned above
91	Toxicity, any
92	Availability of more effective treatment (not specifically failure or side effect related)
92.1	Simplified treatment available
92.2	Treatment to 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

14. tblDIS: Severe Opportunistic Infections & Malignancies

Explanation of variable	Code to identify patient	Event identification	Event date	Means of diagnosis
Field name	***PATIENT**	***DIS_ID**	***DIS_D**	**DIS_WD**
Format of data	Character 20	Character 4 See coding below	Date format	Numeric See coding below

14a. Code (dis_id)	Severe Opportunistic Infections
DEM	AIDS dementia complex
BCNE	Bacterial pneumonia, recurrent (>2 episodes within 1 year)
CANO	Candidiasis, oesophageal
CRCO	Cryptococcosis, estrapulm.
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 bacteraemia (non-typhoid) (> 2 episodes/recurrent)
TOX	Toxoplasmosis, brain
FBLS	Focal Brain lesion
	Malignancies
KS	Kaposi Sarcoma
NHG	Non-Hodgkin Lymphoma -not specified
NHGB	Non-Hodgkin Lymphoma –Burkitt
NHGI	Non-Hodgkin Lymphoma –Immunoblastic
NHGU	Non-Hodgkin Lymphoma -Unknown/other histology
NHGP	Non-Hodgkin Lymphoma -Primary Brain Lymphoma
CRVC	Cervical Cancer
CRVD	Cervical Dysplasia/ carcinoma in situ

14b. Code (dis_wd)	Means of diagnosis
1	Definitive diagnosis
2	Presumptive diagnosis
3	Diagnosis from autopsy
4	Diagnosis from registry

15. tblLTFU: Lost to Follow-Up and Deaths				
Explanation of variable	Code to identify patient	Has patient dropped out	If dropped out, last contact date	Reason for dropping out
Field name	***PATIENT**	**DROP_Y**	**DROP_D**	**DROP_RS**
Format of data	Character 20	0=No 1=Yes	Date format	Numeric See below for coding

Explanation of variable	Has patient died	Death date	Primary underlying cause of death	Coding of causal relation of the code given in DEATH_R1 to the death	Coding of certainty of diagnosis given in DEATH_R1	Was an autopsy performed
Field name	**DEATH_Y**	**DEATH_D**	**DEATH_R1**	**DEATH_RC1**	**DEATH_RDC1**	**AUTOP_Y**
Format of data	0=No 1=Yes	Date format	Numeric See below for coding	Character See below for coding	Character See below for coding	0=No,1=Yes 9=Unknown

Feel free to provide additional DEATH_Rx, DEATH_RCx and DEATH_RDCx values as suggested in HICDEP. In support of the CoDe coding scheme the fields DEATH_RC1 and DEATH_RDC1 have been added. Please code it "N" for "not available" if you do not collect this information.

15a. Code (DROP_RS)	Reason for dropping out	Old code
1	Patient lost to follow-up / Not known to be dead	1
2	Patient has not had visit within required amount of time	2
2.1	Patient did not respond to several invitations	
3	Patient moved away	3
3.1	Patient moved to another country	
4	Patient moved and is followed by another centre	4
5	Patient's decision	5
6	Consent withdrawn	
7	Incarceration/jail	6
8	Institutionalisation (drug treatment, psychological …etc.)	7
9	Other	8

15b. Code (DEATH_R1)	Primary underlying cause of death (Additional event form may be required for D:A:D events)	Old code
1	AIDS (ongoing active disease)	7
1.1	Infection	7
1.2	Malignancy	7
2	Infection (other than 01.1)	
2.1	Bacterial	
2.11	Bacterial with sepsis	
2.2	Others	
2.21	Others with sepsis	
2.3	Unknown aetiology	
2.31	Unknown with sepsis	
3	Chronic viral hepatitis (progression of/complication to)	6
3.1	HCV	6
3.11	HCV with cirrhosis	6
3.12	HCV with liver failure	6
3.2	HBV	6
3.21	HBF with cirrhosis	6

3.22	HBV with liver failure	6
4	Malignancy (other than 01.2 and 03, 03.1, 03.2)	17
5	Diabetes Mellitus (complication to)	4
6	Pancreatitis	5
7	Lactic acidosis	3
8	MI or other ischemic heart disease	
8.1	AMI	1
8.2	Other ischemic heart disease	2
9	Stroke	1
10	Gastro-intestinal haemorrhage (if chosen, specify underlying cause)	
11	Primary pulmonary hypertension	
12	Lung embolus	
13	Chronic obstructive lung disease	
14	Liver failure (other than 03, 03.1, 03.2)	3
15	Renal failure	
16	Accident or other violent death (not suicide)	
17	Suicide	8
18	Euthanasia	
19	Substance abuse (active)	10
19.1	Chronic Alcohol abuse	10
19.2	Chronic intravenous drug-use	10
19.3	Acute intoxication	10
20	Haematological disease (other causes)	
21	Endocrine disease (other causes)	
22	Psychiatric disease (other causes)	
23	CNS disease (other causes)	
24	Heart or vascular (other causes)	2
25	Respiratory disease (other causes)	
26	Digestive system disease (other causes)	
27	Skin and motor system disease (other causes)	
28	Urogential disease (other causes)	
29	Obstetric complications	
30	Congenital disorders	
31	Symptoms caused by mitochondrial toxicity (other than 06, 07)	3
32	Bleeding (haemophilia)	
33	Sudden infant death	
33.1	Child abuse	
90	Other causes	12
91	Unclassifiable causes	99
92	Unknown	99

15c. Code (DEATH_RC1)	Coding of causal relation to the death
I	Immediate cause
U	Underlying cause/condition
C	Contributing cause
N	Not available

15d. Code (DEATH_RDC1)	Certainty of diagnosis
D	Definite: 95-100% certainty
L	Likely: 80-95% certainty
P	Possible: 50-80% certainty
N	Not available