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CARE
COMMON ACTION AGAINST HIV/TB/HCV
ACROSS THE REGIONS OF EUROPE

Standard Operating Procedure for data transfer in CARE

Valid for data transfer for work package 6 in CARE

Version 1.0

FACULTY OF HEALTH AND
MEDICAL SCIENCES
UNIVERSITY OF COPENHAGEN

Contents

Introduction

The CARE Standard Operating Procedure (SOP) provides a guideline for electronic data submission of retrospective data for the meta-analysis in the CARE Work Package 6. The SOP aims to standardize data and improve data quality. The SOP covers the procedure of data submission as well as data schema.

The CARE structure, to the extent possible, conforms to the HICDEP standard (HIV Cohorts Data Exchange protocol). The 1.100 release version of HICDEP is available at the HICDEP website: http://hicdep.org/Wiki/v/8/pt/2. Changes and additions are always part of the on-going process for projects that extend over time and CARE is no exception.

Thank you very much for your contribution to this collaborative project!

Data submission

Data preparation

To facilitate your submission of data, please extract your data into the Microsoft Access template provided.

The Tables section describes the table names, data types and how to code numeric and character values, which generally follow the latest HICDEP format.

Appendix 1 contains a checklist of tables. For your convenience this may be used to keep an overview of tables you provide. Please go through a simple checklist (Appendix 2) before your submission.

Data upload

Electronic data must be uploaded via the RESPOND electronic submission tool (REST) – go to www.chip.dk. On the CHIP website in the lower right corner, you can log in after which you will have access to REST through the **Tools & Standards** tab in the top of the webpage. Please refer to the REST user guide provided along with this SOP.
Please make sure you have a login for the tool. Otherwise, please contact the coordinating centre.
REST will perform a number of quality checks of the data and a submission is only considered successful once the data passes the quality check. If your data does not pass the quality check, please make the adjustments as indicated by REST and re-upload.

Note that it is your responsibility to ensure that the data are in accordance with your regional laws on data protection and that you have adjusted the data for submission accordingly.

Deadline

The deadline for data submission is **1st December 2019**.

1. Tables

Please follow the instruction here for table names, field names, field types as well as how to code for values. Please provide all relevant available data.

How to code unknown values:

- For unknown and missing values other than date, please see specification in the corresponding tables.
- If only the day is unknown (yyyy-mm-??), please enter the 15th with the known month and year (yyyy-mm-15). I.e. unknown day in September 2015: 2015-09-15.
- If both day and month are unknown (yyyy-??-??), please enter the 1st July with the known year (yyyy-07-01). I.e. unknown day and month in 2015: 2015-07-01.
- If a date is completely unknown (????-??-??), please enter 1911-11-11.

How to code non-applicable values:
For non-applicable values please leave the field empty. i.e. if a patient does not have weight recorded at the visit, please enter the visit date, but leave the weight field empty

All tables should be submitted with **all fields** shown in the SOP. If no data is available, the table should be left empty.

Bold letter field names indicate required values if a record is provided.

1.1. tblBAS - Basic clinical, background and demographic information

Holds **basic** information such as demographics, basic clinical information and date of AIDS diagnosis

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient
BIRTH_D	Date (yyyy-mm-dd)	Birth date
FRSVIS_D	Date (yyyy-mm-dd)	First seen at clinic
GENDER	Numeric: 1 = Male 2 = Female 3 = Transgender 8 = 0ther 9 = Unknown	Gender/sex
HEIGH	Numeric (metric in cm): 999=Unknown	Height of patient at visit/most current
MODE	Numeric. See coding table for valid coding.	Mode of HCV infection
ORIGIN	Characters (numeric codes). See coding table for valid coding. Please use code 001 for unknown values	Country or region of birth
ETHNIC	Numeric. See coding table for valid coding.	Ethnicity of patient
HCV_POS_D	Date (yyyy-mm-dd)	Date of first positive anti-HCV test
HIV_POS_D	Date (yyyy-mm-dd)	Date of first positive HIV test
AIDS_Y	Numeric: 0 = No 1 = Yes 9 = Unknown	Has the patient ever been given an AIDS diagnosis? (i.e. WHO stage 3 or 4 or CDC category C diagnosis)
AIDS_D	Date (yyyy-mm-dd)	Date of diagnosis, if yes to AIDS_Y
RECART_Y	Numeric: 0 = No 1 = Yes 9 = Unknown	Has the patient ever been given antiretroviral therapy? Includes all ART except ART given as prophylaxis.
RECART_D	Date (yyyy-mm-dd)	Date of initiation of antiretroviral therapy

1.2. tblCEP - Clinical Events and Procedures

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

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient)
CEP_ID	Character. See CEP_ID Coding table below for valid coding	Identify type of events
CEP_D	Date (yyyy-mm-dd)	Date of onset of the event
CEP_SPEC	Character. See CEP_SPEC Coding table below for valid coding.	Further specify the event identified by CEP_ID. Only applicable for CEP_ID: LIVB
CEP_V	Numeric. See CEP_V Coding table below for interpretation.	Depending on CEP_ID and CEP_SPEC: value of the given event. Only applicable for CEP_ID: FIBS

CEP_ID Coding table

Code (CEP_ID)	Description (Event)
ASCI	Ascites
DIA	Diabetes
FIBS	Fibroscan stiffness (please add elasticity value in CEP_V)
ARFI	Acoustic Radiation Force Impulse (please add value in CEP_V)
HEP	Hepatic encephalopathy
HESY	Hepatorenal syndrome
LIVB	Liver biopsy (add value to CEP_V)
LIV	Liver decompensation (unspecified)
LIVT	Liver transplantation
LIVR	Liver cancer (hepatocellular carcinoma)
OESO	Oesophageal variceal bleeding

CEP_SPEC Coding table

Code (CEP_ID)	Code (CEP_SPEC)	Description
LIVB	F0	No fibrosis
LIVB	F1	portal fibrosis without septa

LIVB	F2	portal fibrosis with few septa
LIVB	F3	numerous septa without cirrhosis
LIVB	F4	Cirrhosis
FIBS	F0	No fibrosis
FIBS	F1	portal fibrosis without septa
FIBS	F2	portal fibrosis with few septa
FIBS	F3	numerous septa without cirrhosis
FIBS	F4	Cirrhosis

Fibroscan values should always be reported in kPa if available

CEP_V Coding table

CEP_ID	CEP_SPEC	Interpretation of CEP_V
FIBS		kPa
ARFI		m/s

1.3. tblLAB - Laboratory values

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

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient
LAB_ID	Character. See LAB_ID coding table below for valid coding.	Code representing the measurement.
LAB_D	Date (yyyy-mm-dd)	Date of measurement/sample
LAB_U	Numeric. See coding table for valid coding.	Unit of measurement
LAB_V	Numeric	Value of measurement
LAB_ST	Character: WB = Whole blood P = Plasma S = Serum	Specimen type

LAB_ID Coding table

LAB_ID	Description
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
ALB	Albumin
BIL	Bilirubin
CRE	Creatinine
HAEM	Haemoglobin
INR	International normalized ratio
THR	Thrombocytes (Platelets)

1.4. tblLAB_CD4 - Laboratory values

Holds date and value of CD4 measurements.

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient
CD4_D	Date (yyyy-mm-dd)	Date of measurement
CD4_V	Numeric (per microliter):	Value of CD4 measurement
CD4_U	Numeric: 1 = cells/µl	Unit of measurement

1.5. tblLAB_RNA - HIV-RNA measurements

Holds date, value and detection limit of HIV-RNA

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient
RNA_D	Date (yyyy-mm-dd)	Date of measurement/sample
RNA_V	Numeric -1 = undetectable	HIV-RNA measurement value with unit **copies/ml**
RNA_L	Numeric	Lower limit of detection of HIV-RNA assay

1.6. tblLAB_VIRO - Hepatitis B and hepatitis C

Holds test results for viro-/serological tests of HBV and HCV. For every entry, a value must be entered in either VS_R OR VS_V

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient
VS_ID	Character: See VS_ID coding table below.	Type of viral test
VS_D	Date (yyyy-mm-dd)	Date of measurement
VS_R	Numeric: 0= negative 1= positive 9= unknown/borderline	Measurement result
VS_TT	Numeric. 1 = Quantitative 2 = Qualitative	Type of test (only relevant for HCV-RNA)
VS_V	Numeric -1 = undetectable/below level of detection or detection limit as negative value	Measurement value (HCV-RNA only); quantitative test
VS_U	Numeric: 1=copies/mL 2=IU/mL 3=Geq (millions of genome equivalents)	Measurement unit
VS_LL	Numeric	Lower limit of detection

VS_ID coding table

VS_ID	Description
HBVGS	Hepatitis B surface antigen (HBsAg)
HCVA	HCV antibody (anti-HCV IgG)
HCVR	HCV-RNA

1.7. tblVIS - Basic follow-up/visit related data

Holds information about visit and weight.

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient
VIS_D	Date (yyyy-mm-dd)	Date of visit
WEIGH	Numeric (metric: kg): 999=Unknown	Weight of patient at visit

1.8. tblLTFU – data on death

Holds data on death

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient
DEATH_Y	Numeric: 0 = No 1 = Yes	Has the patient died?
DEATH_D	Date (yyyy-mm-dd)	Date of death
DEATH_R1	Character. See coding table for valid coding.	Underlying cause of death

1.9. **tblVIS_SUBS - Data on substance use**

Holds information on substance abuse

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient
SUBS_D	Date (yyyy-mm-dd)	Date of assessment
SUBS_ID	Character: ALCO = Alcohol IDU = Intravenous Drugs NDU = Non-injecting Drugs SMK = Smoking SMKD = Ever smoked	Type of substance Definition of alcohol abuse. For men: An intake of >25 alcohol containing units a week. For women: An intake of > 20 alcohol containing units a week.
SUBS_Y	Numeric: 0=No 1=Yes 9=Unknown	Patient's substance use at assessment date

1.10. tblMED_HCV - HCV treatment

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient
MED_ID	Character. Please see coding table below for valid coding. If not on the list, please use WHO ATC coding	Code representing the treatment against hepatitis C.
MED_SD	Date (yyyy-mm-dd)	Date of initiation of treatment
MED_ED	Date (yyyy-mm-dd)	Date of stopping treatment. Only if treatment is stopped then you must provide MED_ED
MED_DISC_Y	Numeric: 0 = No 1 = Yes 9 = Unknown	Was treatment interrupted before schedule?
MED_RS	Character. See coding table for valid coding.	If yes, reason for discontinuation

MED_ID coding table

MED_ID	Description
J05AP01	ribavirin
J05AP02	Telaprevir
J05AP03	Boceprevir
J05AP04	faldaprevir
J05AP05	Simeprevir
J05AP06	Asunaprevir
J05AP07	Daclatasvir
J05AP08	Sofosbuvir
J05AP09	Dasabuvir
J05AP51	Sofosbuvir/ledipasvir (Harvoni)
J05AP52	Dasabuvir, ombitasvir, paritaprevir and ritonavir
J05AP53	Ombitasvir/paritaprevir and ritonavir
J05AP54	Grazoprevir/elbasvir (Zepatier)
J05AP55	Sofosbuvir/Velpatasvir (Epclusa)
J05AP56	Sofosbuvir/velpatasvir/voxilaprevir (Vosevi)
J05AP57	Glecaprevir/pibrentasvir (Maviret)
L03AB10	Peginterferon alfa-2b (Pegintron)
L03AB11	Peginterferon alfa-2a (Pegasys)
L03AB-AL2	Peginterferon alfa-2a/alfa-2b (unspecified)
HCV_PBT	Participant in blinded trial
HCVES_OTH	Other drug

1.11. tblLAB_HCV_RES: HCV-genotype and subtype

Holds information on HCV genotype and subtype.

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient
SAMPLE_D	Date (yyyy-mm-dd)	Date of the actual sample taken (NOT the test date)
GENOTYPE	Numeric: 1 2 3 4 5 6	HCV-genotype Please supply a row for each combination of Genotype and Subtype, e.g.: 9999999 2015-01-01 1 a 9999999 2015-01-01 1 b (the genotype and subtype should be submitted in separate columns)
VIROTYPE	2 = HCV	Type of Virus
SUBTYPE	Character: a b c d e f g h i j	HCV-subtype If unknown leave blank

Appendix 1. Table checklist

Table	Mark with x if the table is provided, otherwise leave it empty
tblBAS	
tblCEP	
tblLAB	
tblLAB_CD4	
tblLAB_HCV_RES	
tblLAB_RNA	
tblLAB_VIRO	
tblLTFU	
tblMED_HCV	
tblVIS	
tblVIS_SUBS	

Appendix 2. Checkpoint before data submission

Please check the following before submitting data:

1. Check if the patient ID in the field PATIENT is correct:

To be added

2. Submitted variables correspond to those listed in the coding tables

Please note that submission might fail if the data schema, data types and/or variables don't follow the definitions in this document.

Please contact care.rigshospitalet@regionh.dk you have any questions regarding this SOP.