

SAMMSU-ID: _____ (please insert on all pages)

Questionnaire – Cross sectional study within SAMMSU May 2018 and May 2019

How to enter not precisely known dates:

If the day is unknown, enter "15/MM/YYYY". If day and month are unknown, enter "15/07/YYYY".

1) On the reference date, what was the patient's HCV-antibody- and HCV-RNA-status?
(0 = negative, 1 = positive, 9 = never tested)

	HCV-antibody	HCV-RNA
1.5.2017		
1.5.2018		
1.5.2019		

1a)-1d) The same values might appear more than once (i.e. "first ..." and "last ..." may be on the same date or tests may not have been repeated between the reference dates, respectively).

a) if HCV-antibody-neg.(0), last neg. HCV-antibody-test before the respective date:

1.5.2017: ____/____/____ (DD/MM/YYYY)

1.5.2018: ____/____/____ (DD/MM/YYYY)

1.5.2019: ____/____/____ (DD/MM/YYYY)

b) if HCV-antibody-pos.(1), first pos. HCV-antibody-test: ____/____/____ (DD/MM/YYYY)
if applicable **first pos. HCV-RNA-test after diagnosis: ____/____/____ (DD/MM/YYYY)**
if applicable **first neg. HCV-RNA-test after diagnosis: ____/____/____ (DD/MM/YYYY)**
(To determine the duration of infectiousness, please also give the first neg. HCV-RNA-test after a first pos. HCV-RNA-test, i.e. after spontaneous clearance or under successful treatment.)

c) if HCV-antibody-pos.(1)/HCV-RNA-neg.(0), last neg. HCV-RNA before the respective date:

1.5.2017: ____/____/____ (DD/MM/YYYY)

1.5.2018: ____/____/____ (DD/MM/YYYY)

1.5.2019: ____/____/____ (DD/MM/YYYY)

d) if HCV-antibody-pos.(1)/HCV-RNA-pos.(1), last pos. HCV-RNA before the respective date:

1.5.2017: ____/____/____ (DD/MM/YYYY)

1.5.2018: ____/____/____ (DD/MM/YYYY)

1.5.2019: ____/____/____ (DD/MM/YYYY)

2) On the reference date, was the patient ever treated for hepatitis C?

(0 = no, 1 = yes, 9 = unknown)

	Ever HCV-treatment
1.5.2017	
1.5.2018	
1.5.2019	

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a) On the reference date, main reason for no HCV-treatment despite pos. HCV-RNA:

(1 = reimbursement restrictions, 2 = non-compliance with appointments, 3 = patient not motivated enough, 4 = uncontrolled substance use, 5 = uncontrolled alcohol use, 6 = uncontrolled psychiatric disorder, 7 = uncontrolled somatic disease, 8 = unstable life situation, 9 = other)

	Main reason for no HCV-treatment	if other(9), specify
1.5.2017		
1.5.2018		
1.5.2019		

Comments: _____

b) All HCV-treatments in chronological order: from when until when, with what,

(IFN (interferon): 0 = no, 1 = interferon-alpha, 2 = pegylated interferon;

RBV (ribavirin): 0 = no, 1 = yes, 9 = unknown;

DAA (direct-acting antivirals)/other: 0 = no, 1 = Incivo (telaprevir), 2 = Victrelis (boceprevir), 3 = Sovaldi (sofosbuvir), 4 = Harvoni (ledipasvir/sofosbuvir), 5 = Viekirax/Exviera (ombitasvir/paritaprevir/ritonavir/dasabuvir), 6 = Viekirax (ombitasvir/paritaprevir/ritonavir), 7 = Daklinza/Sovaldi (daclatasvir/sofosbuvir), 8 = Zepatier (grazoprevir/elbasvir), 9 = Epclusa (velpatasvir/sofosbuvir), 10 = Maviret (glecaprevir/pibrentasvir), 11 = Vosevi (sofosbuvir/velpatasvir/voxilaprevir), 12 = other (specify under comments), 99 = unknown)

HCV-genotype (gt),

(Num. (number): 1-7, 9 = unknown; Let. (letter): 1 = a, 2 = b, 3 = c, 4 = d, 5 = multiple subtypes, 9 = subtype not defined)

and outcome

(0 = ongoing treatment, 1 = SVR (sustained virological response), 2 = EOT (end of treatment response; if HCV-treatment is completed, but SVR not yet determined), 3 = relapse, 4 = viral breakthrough, 5 = non-response, 6 = PTS (pre-term stop)), 9 = unknown;

Why PTS: 1 = toxicity/complication related to HCV-treatment, 2 = medical complication not related to hepatitis C treatment, 3 = patient's wish, 4 = loss to follow-up, 5 = death, 6 = other (specify under comments), 9 = unknown):

	Start (DD/MM/YYYY)	End (DD/MM/YYYY)	Medication			HCV-gt		Out- come	Why PTS
			IFN	RBV	DAA/other	Num.	Let.		
1 st									
2 nd									
3 rd									
4 th									
5 th									

Comments: _____

c) What about adherence during HCV-treatments (in chronological order)?

DOT = Directly observed therapy

*(0 = no, 1 = yes, 9 = unknown), # (Adherence: 1 = excellent, 2 = moderate, 3 = bad, 9 = unknown)

	DOT (≥5x/week)*	Weekly dispensing in pill box*	Adherence [#]
1 st			
2 nd			
3 rd			
4 th			
5 th			

Comments: _____

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d) Current liver fibrosis stage (last available result: 1.5.2017 (I), 1.5.2018 (II) and 1.5.2019 (III)); if HCV-treatment, additionally results before (B) and after (A) 1st, 2nd, 3rd, ... treatment (The same examination might appear more than once.)

	Fibroscan					Liver biopsy	
	Date (DD/MM/YYYY)	Median stiffness (kPa)	IQR (kPa)	Valid measurements	Success Rate (%)	Date (DD/MM/YYYY)	Fibrosis-Score (F0-4)
(I)							
(II)							
(III)							
B 1 st							
A 1 st							
B 2 nd							
A 2 nd							
B 3 rd							
A 3 rd							
B 4 th							
A 4 th							
B 5 th							
A 5 th							

3) On the reference date, has the patient ever experienced HCV-reinfection?

* (0 = no, 1 = yes)

(After: 1 = spontaneous clearance, 2 = successful treatment)

§ (1 = unsafe intravenous drug use, 2 = unsafe intranasal drug use, 3 = unsafe anal intercourse, 4 = other (specify under comments), 9 = unknown)

§ (Outcome: 1 = spontaneous clearance, 2 = chronic infection, 9 = unknown)

	Ever HCV-Reinfection*		Diagnosis of HCV-reinfection (DD/MM/YYYY)	After#	Most likely reason for HCV-reinfection§	Outcome§
1.5.2017		1 st				
1.5.2018		2 nd				
1.5.2019		3 rd				

Comments: _____

4) Drug use on the reference date

* (Ever: 0 = no, 1 = yes, 9 = unknown)

(Cont. (continued): 0 = no (last use >12 months ago), 1 = yes (last use ≤12 months ago), 9 = unknown)

	intravenous		intranasal	
	Ever*	Cont.#	Ever*	Cont.#
1.5.2017				
1.5.2018				
1.5.2019				

a) first year of intravenous drug use: _____ (YYYY)

b) first year of intranasal drug use: _____ (YYYY)

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5) Please enter all available HCV-RNA-values into the SAMMSU-database!

Thank you very much!

	Cross sectional study 01.05.2018	Cross sectional study 01.05.2019
Last contact with the patient (DD/MM/YYYY)		
Completed by:		
Date:		

Please note:

For patients recruited after the 01/05/2018, please complete the whole questionnaire, i.e. both cross sectional studies (01/05/2018 and 01/05/2019) in 2019.