World Health Organization

Web Annex 3. Protocol for surveillance of the fraction of cirrhosis and hepatocellular carcinoma attributable to viral hepatitis in clinical centres of excellence

In: Consolidated strategic information guidelines for viral hepatitis planning and tracking progress towards elimination

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PROTOCOL FOR SURVEILLANCE OF THE FRACTION OF CIRRHOSIS AND HEPATOCELLULAR CARCINOMA ATTRIBUTABLE TO VIRAL HEPATITIS IN CLINICAL CENTRES OF EXCELLENCE

CONTENTS

BACKGROUND

The importance of mortality data

WHO proposes an approach to viral hepatitis surveillance that examines: (i) acute hepatitis, reflecting the incidence of new infections; (ii) prevalence of chronic hepatitis B virus [HBV] and hepatitis C virus [HCV] infections; and (iii) mortality from sequelae, including cirrhosis and hepatocellular carcinoma *(1)*. Reduction in mortality due to HBV and HCV infection is one of the two criteria that the Global Health Sector Strategy (GHSS) uses to define the elimination of hepatitis as a public health threat by 2030 *(2)*. Hence, countries require methods to measure mortality from HBV and HCV infection.

Technical approaches to estimating HBV- and HCV-associated mortality

In the early 2000s, WHO estimates of mortality from viral hepatitis considered only deaths from acute infections, as they were reported directly with their own International Classification of Disease (ICD)-10 codes. This approach missed out on the majority of mortality that was secondary to cirrhosis and hepatocellular carcinoma, which were reported with their own ICD codes. Since the ICD codes for cirrhosis and hepatocellular carcinoma did not make a reference to hepatitis, the link to hepatitis was broken. Since 2010, various iterations of the Global Burden of Disease project (GBD) have developed estimates of the worldwide mortality secondary to chronic HBV and HCV infections, which accounted for deaths from the sequelae of chronic hepatitis according to their individual viral causes *(3)*. This key step was made possible by estimating the proportion of cirrhosis and hepatocellular carcinoma attributable to HBV and HCV infections at national, regional and global levels on the basis of published studies *(4)*. The GBD and WHO estimates now use this approach to estimate mortality.

Need for national mortality estimates

The “mortality envelope” from cirrhosis and hepatocellular carcinoma is attributed to HBV and HCV on the basis of evidence from published studies that reported the proportion of patients with these sequelae who had HBV and HCV infection (which is referred to as “the attributable fraction”). At the national level, however, most countries lack a systematic process to generate national estimates of mortality from viral hepatitis. Thus, countries need to institutionalize methods that have been used in an ad-hoc manner in the past for published studies and turn these into a routine surveillance system. To generate national estimates of hepatitis-related mortality, it is necessary (i) to estimate mortality from chronic liver disease (including cirrhosis and hepatocellular carcinoma), and (ii) to estimate the fraction of these conditions that are attributable to various hepatitis viruses. For the first step, national mortality data are usually available. Alternatively, in countries where the quality of data from vital registration systems is not optimal, estimates regarding mortality from cirrhosis and hepatocellular carcinoma are available from WHO or the GBD. However, for the second step, most countries lack a system to estimate which proportion of the sequelae is attributable to the various hepatitis viruses and which due to other causes (e.g. alcohol, metabolic syndrome), and consolidate data from various sources in order to estimate mortality.

Estimating attributable fraction in centres providing care for cirrhosis and/or hepatocellular carcinoma

The aim of this protocol is to describe simple methods to be used in sentinel centres (e.g. hepatology or gastroenterology units) to estimate the proportion of patients with cirrhosis and hepatocellular carcinoma who have HBV and HCV infection. In countries where hepatitis D virus (HDV) infection is of public health importance, the prevalence of HBV/HDV coinfection in HBV-infected patients with cirrhosis and hepatocellular carcinoma should also be estimated. This proportion of patients with HBV, HCV or HBV/HDV

infection and cirrhosis or hepatocellular carcinoma may be used to estimate the fractions of these sequelae attributable to HBV and HCV infection, which may be used to estimate national hepatitis mortality rate. Given the impact of recent advances in antiviral treatments for hepatitis B *(5)* and hepatitis C *(6)* on the prognosis of chronic liver disease, we need to estimate this proportion for:

- all patients with cirrhosis or hepatocellular carcinoma;
- patients with late-stage liver disease[a] meeting the European Association for the Study of Liver disease [EASL] criteria) *(7)*;
- patients dying from or who received transplants for cirrhosis or hepatocellular carcinoma.

While the main objective of the selection of patients at sentinel sites is to generate data on the attributable fraction that could be used along with national mortality data, the absolute numbers of cirrhosis and hepatocellular carcinoma cases reported in these centres may also be followed up over time to examine trends.

OBJECTIVES

- To recruit a suitable sample of patients with cirrhosis and hepatocellular carcinoma;
- To assess the HBV and HCV status of these patients through a review of medical records (where/when patients are routinely tested);
- To estimate the proportion of patients with cirrhosis and hepatocellular carcinoma who have HBV, HCV or HDV infection (potentially stratified as per the stage of cirrhosis);
- To estimate the proportion of patients dying from cirrhosis and hepatocellular carcinoma or undergoing liver transplantation who have HBV, HCV or HDV infection;
- To provide input for national estimates of mortality due to the sequelae of viral hepatitis.

ACTIVITIES

Population under surveillance

- Patients with cirrhosis or hepatocellular carcinoma hospitalized or seen as outpatients in referral hepatology or gastroenterology centres.

Investigators

- Participating centres will identify clinicians who will function as investigators for the purpose of the surveillance activities.

Case definitions

- ICD-10 codes may be used to identify patients in health-care facilities.

Cirrhosis

- **Probable case:** case of cirrhosis defined by ultrasound evidence or non-invasive tests
- **Confirmed case:** case of cirrhosis defined by pathological evidence (liver biopsy)

[a] Late-stage liver disease due to chronic viral hepatitis is clinically defined by the presence of decompensated cirrhosis (jaundice, hepatic encephalopathy, clinically detectable ascites, variceal bleeding) and/or hepatocellular carcinoma.

Hepatocellular carcinoma

- Case defined as per the guidelines of the European Association for the Study of the Liver *(8)*, using imaging criteria (two techniques if under 1 cm or one if more than 1 cm) or pathological evidence.

Classification of cases

- Cases included in a given year will be classified as per (a) new diagnosis, (b) already diagnosed patient or (c) death/liver transplantation. For retrospective assessments, the feasibility of distinguishing new diagnoses and already diagnosed patients will need to be explored.
- The availability of information on cirrhosis stage in the data collection form will allow stratification according to severity.

Design

Two design options may be considered.

- **Prospective data collection:** this surveillance project would ideally be conducted prospectively.
- **Retrospective data collection:** in the initial phase, some centres could consider retrospective assessment, for example, examine patients seen in the past year and generate preliminary estimates of the fractions.

Sampling procedure

Reference centres

- Convenience selection of a number of reference centres, so as to reflect geographical and sociological diversity at the national level. Secondary and/or tertiary centres could be considered.
- Liver transplantation centres should also be included and considered separately.

Inclusion of individuals

- In participating centres, investigators will include individuals who meet the case definition when patients are newly admitted/seen as outpatients or inpatients. By default, recruitment will take place consecutively until the sample size has been reached.

Sample size considerations

Estimating the frequency of chronic infection (about 10%) with 5% absolute precision among patients would require 139 patients with cirrhosis and 139 patients with hepatocellular carcinoma over one year for a 95% confidence interval (no design effect). As a first approximation, 250 cases of patients with cirrhosis and hepatocellular carcinoma will be required from each centre. This sample size is indicative. If the proposed number of participants is reached sooner than expected, participating centres could consider continuing for a year to identify possible variations in recruitment throughout the year and to add precision. If the proposed number of participants is not reached after a year, participating centres could analyse the data bearing in mind the possible limitation from lack of statistical power.

Data collection

- For each case of the conditions under surveillance, investigators will extract information from the patients' records using a case report form (Table 1).

- Data extracted will include age, sex, alcohol intake, metabolic syndrome components (weight [current, and before disease onset], diabetes), as well as HBV, HDV and HCV infection. Other rare risk factors for cirrhosis and hepatocellular carcinoma will be aggregated as "other causes".
- As this information would be collected as part of the assessment of a patient with cirrhosis or hepatocellular carcinoma in normal clinical practice, no additional data will be collected for the purpose of the surveillance activity.
- The investigators will not be involved directly in patient care within the department from where data will be collected.

Analysis plan

Estimation of the attributable fraction

Data management

- Patients will be de-duplicated so that they are counted only once each year in each category. This will be done by maintaining a list of patients already included for each category in a given year (but without using identifiers or codes on the data collection forms). However, if a patient is newly diagnosed in January and dies in June, the patient will be counted twice – in new patients as well as in deaths.
- The database will stay at the centre and will not be shared; only aggregated results or re-analysis will be shared.

Attributable fraction

For the attributable fraction, the analysis will proceed as follows:

- A crude analysis, from a surveillance perspective, will calculate the proportion of patients testing positive for HBV and HCV to estimate the attributable fraction (replicating the approach used by Perz et al., Table 2) (*4*). This is possible as a first approximation because of the strength of the association between HBV/HCV infection and cirrhosis/hepatocellular carcinoma.[a]
- An advanced analysis will adjust this estimate for the relative risks (RRs) of cirrhosis and hepatocellular carcinoma among those with the infection, taking into account the interaction between HBV and HCV, and between viruses and other causes of fibrosis (e.g. alcohol, metabolic syndrome).

Other analyses

- Time trends in the fraction of cirrhosis and hepatocellular carcinoma attributable to HBV and HCV (new cases versus deaths) could provide an indication of the impact of new treatments for HBV and HCV infection.

Estimation of mortality

Application of the attributable fraction to the national mortality estimates from cirrhosis and hepatocellular carcinoma will allow estimation of the national mortality from HBV, HDV and HCV infection.

[a] If the relative risk (RR) is large, the attributable fraction among those exposed (RR–1/RR) is close to 100% and the attributable fraction in the population (Pe x [RR–1/RR]) is close to the proportion of the population exposed (Pe).

DATA OWNERSHIP

Attributable fraction

Data generated through the use of this surveillance protocol on the fraction of cirrhosis and hepatocellular carcinoma attributable to HBV, HDV and HCV infection will be managed and owned by the sentinel centres that have generated them. Within the boundaries of their national obligations, rules and regulations, these centres would have freedom in how they make the information publicly available, preferably through peer-reviewed publications available in open-source format. However, WHO encourages direct, real-time data-sharing with national public health authorities in a spirit of public health collaboration.

Application of the attributable fraction data to the national mortality figures

The use of information on the attributable fraction in combination with the national mortality estimates from cirrhosis and hepatocellular carcinoma would require collaboration between the sentinel centres and public health officials in charge of national mortality estimates. This collaboration could be described in a reference document (e.g. memorandum of understanding). National mortality estimates from HBV, HDV and HCV infection will become official only if prepared with the full collaboration of national public health officials. In most countries this would involve a formal clearance process.

PROTECTION OF HUMAN SUBJECTS

This project is about setting up a new surveillance system *(9)*. Surveillance for sequelae is one of the three pillars of a national surveillance system for hepatitis, as recommended by WHO *(1)*. It does not constitute what is defined as research by an ethics committee, as it would not generate generalizable results (results from one country would not apply to another). However, investigators would take care to protect human subjects, as explained below.

Maximizing benefit

Patients will not benefit specifically from this project, since they should have been undergoing these tests as part of their routine medical care for cirrhosis or hepatocellular carcinoma. If a patient included in the protocol does not have some of the information required in the medical record, which should have been considered a part of the normal practice for assessment, the clinician could consider collecting the information if there is a benefit to the patient.

Minimizing harm

In order to ensure confidentiality, only identifier codes (ID codes) will be used on the data collection form. A list of enrolled patients will be maintained to keep track of ID code and of expressed desire to opt out (

Appendix 1). The local investigators will keep the list of identifier codes in a secure manner (e.g. under lock and key or on a high-security computer). This list would be filed in a restricted location on a password-protected computer. No additional blood collection will be required for the purpose of this surveillance. If a patient included in the protocol does not have some of the information required in the medical record because the clinician considers this unnecessary, the information will be marked as missing.

Informed consent

The diagnostic procedure for which the data will be collected is part of routine medical care for patients with cirrhosis or hepatocellular carcinoma. No additional information will be collected and no additional blood

test will be conducted for the purpose of this surveillance. On admission, patients will be informed that the centre is participating in the surveillance activity through an information sheet, which will explain that the information will be collected as part of routine clinical care and be used for surveillance without any identifying information (Appendix 2). No additional data will be gathered for public health monitoring beyond that required for routine medical care of patients with cirrhosis or hepatocellular carcinoma. This form will also explain how a patient may opt out. If a patient would like to opt out, his/her information record will be deleted from the list of patients.

The information sheet fulfils the following conditions:

- Patients need to be aware of its existence.
- Sufficient information needs to be provided.
- Patients need to be informed that they can withdraw their data.
- A genuine possibility of objecting has to be offered.

Ethics clearance

The project consists of setting up a new surveillance activity using data collected as part of routine care. Depending on the national regulations, ethics committee clearance may be required. Hence, the protocol will be submitted to WHO and other relevant ethics committees to determine what applies (exception, expedited approval or full review).

The protocol has been approved by an independent scientific review team composed of scientific experts external to WHO and with no connection to the project.

EXPECTED OUTPUTS

- A suitable sample of patients with cirrhosis and hepatocellular carcinoma
- Estimates of the proportion of patients with cirrhosis and hepatocellular carcinoma who are infected with HBV or HCV (or both).

EXPECTED OUTCOMES

- Improved national mortality estimates (after applying the attributable fraction data to the mortality envelope);
- Capacity built for surveillance of HBV and HCV infection among patients with cirrhosis and hepatocellular carcinoma;
- Lessons learned for extension of the project;
- Creation of a community of practice/partnership with clinicians and laboratory specialists, which could be used to support testing, treatment and in-vitro diagnosis during biomarker surveys.

ELEMENTS OF COSTING TO CONSIDER

The following costing elements need to be considered. However, in some settings (e.g. the European Union), hepatology centres may not require additional financial resources for all of these:

- Initial training workshop

- Support to investigator(s) for data collection
- Biomarker testing kits (anti-HCV and hepatitis B surface antigen [HBsAg] kits for 250 patients; sequential testing may reduce costs). These are part of the normal evaluation of patients with cirrhosis or hepatocellular carcinoma.
- Support to the investigator(s) for data analysis/presentation
- Final dissemination and evaluation workshop.

FUTURE PERSPECTIVES

- Extension of the pilot projects will generate quality information in a sustainable way.
- Centres of clinical excellence will be resource partners, which will make it possible to engage in testing and treatment activities, including quality aspects of in-vitro diagnostics.

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Table 1: Template case report form for recording possible exposures in cases with cirrhosis and hepatocellular carcinoma under surveillance, Country X, 201x

General characteristics				
Centre:				
Date of reporting (dd/mm/yyyy):	__ __ / __ __ / __ __ __ __	ID code:		
Date of birth (dd/mm/yyyy):	__ __ / __ __ / __ __ __ __	Gender:	☐ Male ☐ Female ☐ Transgender	
Sequelae				
Diagnosis of cirrhosis				
Type of case	☐ **New diagnosis**	☐ **End-stage disease**	☐ **Transplantation**	☐ **Death**
Compensated cirrhosis		☐ Yes	☐ No	☐ ?
Clinical diagnosis of cirrhosis		☐ Yes	☐ No	☐ ?
Imaging diagnosis of cirrhosis		☐ Yes	☐ No	☐ Not done
Pathological diagnosis (biopsy)		☐ Yes	☐ No	☐ Not done
Aspartate aminotransferase (AST) [a]		_____	Upper limit of normal:	☐ Not done
Alanine aminotransferase (ALT) [c]		_____	Upper limit of normal:	☐ Not done
Platelet/mm^3		_____		
FibroTest		_____		☐ Not done
FibroScan		_____		☐ Not done
Staging of cirrhosis (Child–Pugh)		☐ A (5–6 points)	☐ B (7–9 points)	☐ C (10–15 points)
Encephalopathy	☐ None (1 point)	☐ Grade 1–2 (2 points)	☐ Grade 3–4 (3 points)	
Ascites	☐ Absent (1 point)	☐ Controlled (2 points)	☐ Refractory (3 points)	
Bilirubin (Child–Pugh point classes)	_____	☐ µmol/L (<34; 34–50 >50)	☐ mg/dL (<2; 2–3;>3)	
Albumin (Child–Pugh point classes)	_____	☐ g/dL (>3.5; 2.8–3.5; <2.8)		
Prothrombin time (Child–Pugh point classes)		_____	seconds (<4; 4–6;>6)	INR:
Diagnosis of hepatocellular carcinoma				
Type of case	☐ **New diagnosis**		☐ **Transplantation**	☐ **Death**
Clinical diagnosis of hepatocellular carcinoma		☐ Yes	☐ No	☐ ?
Imaging diagnosis of hepatocellular carcinoma		☐ Yes	☐ No	☐ Not done
Pathological diagnosis of hepatocellular carcinoma		☐ Yes	☐ No	☐ Not done
Possible exposures				
Infections with hepatitis viruses				
HBV	HBsAg	☐ Positive	☐ Negative	☐ Not done
	HBV DNA	☐ Positive	☐ Negative	☐ Not done
HDV	HDV RNA	☐ Positive	☐ Negative	☐ Not done
HCV	Anti-HCV	☐ Positive	☐ Negative	☐ Not done
	HCV RNA	☐ Positive	☐ Negative	☐ Not done
	HCV core antigen	☐ Positive	☐ Negative	☐ Not done
	HCV genotype	Results:		☐ Not done
Other exposures				
Alcohol use AUDIT C test		Score (1–12):	_____	☐ Not done
Diabetes		☐ Yes	☐ No	☐ Not done
Weight (kg): current and before disease onset[b]		_____ (Current)	_____ (Before)	
Height (cm):[d]		_____		
Alpha-one antitrypsin deficiency		☐ Yes	☐ No	☐ Not done
Wilson disease		☐ Yes	☐ No	☐ Not done
Autoimmune hepatitis		☐ Yes	☐ No	☐ Not done
Primary biliary cirrhosis		☐ Yes	☐ No	☐ Not done
Haemochromatosis		☐ Yes	☐ No	☐ Not done

AUDIT: Alcohol Use Disorders Identification Test; HBV: hepatitis B virus; HBsAg: hepatitis B surface antigen; HCV: hepatitis C virus; HDV: hepatitis D virus; RNA: ribonucleic acid

[a] For calculation of non-invasive fibrosis scores
[b] For calculation of body mass index

Table 2: Dummy table shell for the analysis of surveillance of the prevalence of HBV, HCV and HDV infection in patients with cirrhosis and hepatocellular carcinoma

		Cirrhosis (*N*=XXX)									Hepatocellular carcinoma (*N*=XXX)					
		Chronic HCV infection (HCV RNA +)			Chronic HBV infection (HBsAg +)			Chronic HDV infection			Chronic HCV infection (HCV RNA +)		Chronic HBV infection (HBsAg +)		Chronic HDV infection	
		Compensated	Advanced	Deaths	Compensated	Advanced	Deaths	Compensated	Advanced	Deaths	New	Deaths	New	Deaths	New	Deaths
Age (years)	0–14	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)
	15–29	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)
	30–59	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)
	60+	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)
Sex	Male	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)
	Female	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)
Total		XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)

HBV: hepatitis B virus; HBsAg: hepatitis B surface antigen; HCV: hepatitis C virus; HDV: hepatitis D virus; RNA: ribonucleic acid

Table 3: Dummy table shell for the analysis of surveillance for the prevalence of HBV, HCV and HDV infection in patients with liver transplantation

		Chronic HCV infection (HCV RNA +)		Chronic HBV infection[a] (HBsAg +)		Chronic HBV infection with HDV coinfection	
		Cases	Deaths	Cases	Deaths	Cases	Deaths
Age (years)	0–14	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)
	15–29	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)
	30–59	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)
	60+	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)
Sex	Male	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)
	Female	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)
Total		XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)	XX/XX (XX%)

HBV: hepatitis B virus; HBsAg: hepatitis B surface antigen; HCV: hepatitis C virus; HDV: hepatitis D virus; RNA: ribonucleic acid

[a] Column to be added for HDV if needed

APPENDIX 1: PATIENT LOG FORM

Centre:						
Date of reporting (dd/mm/yyyy):	ID code:	Name:	Date of birth (dd/mm/yyyy):	Gender (M/F/T):	Opt out expressed (Y/N):	Date of record deletion due to expressed desire to opt out (dd/mm/yyyy):
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APPENDIX 2: INFORMATION SHEET FOR PATIENTS ON SURVEILLANCE FOR THE CAUSES OF CIRRHOSIS AND HEPATOCELLULAR CARCINOMA

Title: Surveillance for viral hepatitis infection in patients with cirrhosis and hepatocellular carcinoma

Person in charge of the surveillance activity in the centre: [Insert name, title and contact information]

Survey sponsor: [Insert name of the institution]

Description of the surveillance project

The clinical centre where you are getting care is taking part in a project on liver diseases in [name of country]. The objective of this surveillance is to assess how common hepatitis is in patients who have chronic liver disease. On the basis of these results, the Ministry of Health could improve planning to respond to hepatitis.

As part of this surveillance project, investigators may review your medical records, including some of your blood test results to collect information on the possible causes of your chronic liver disease. This information will be written on a form that will not have any information about your identity. This surveillance activity will not take any of your time or expose you to any risk as it is just about having someone look at your medical records.

We will not conduct additional tests for this project. All tests for which we could use the results are already in your medical records. Hence, your doctor should have discussed them with you already. What we are most interested in is the results of your tests for hepatitis B, hepatitis C and hepatitis D. No payment or compensation will be provided for your participation, as it does not involve any of your time.

You have the right to refuse to allow us to use your data. After your refusal, the data will be destroyed and will not be used for the project.

Note that if you do not allow the use of your data, it will not affect your care at the centre.

Contact information

Feel free to contact [Tittle/Name/institution] if you have questions or concerns about this surveillance project.

Feel free to contact [Tittle/Name/institution] if you have questions or concerns about the ethical aspects of the surveillance project.