

## Evaluation of the surveillance system for hepatitis B and C in Albania during 2013-2014

Elona Kureta<sup>1,2</sup>, Mimoza Basho<sup>2</sup>, Enver Roshi<sup>1,2,3</sup>, Silvia Bino<sup>2,3</sup>,  
Artan Simaku<sup>2</sup>, Genc Burazeri<sup>1,2,3</sup>

<sup>1</sup>Mediterranean Programme for Intervention Epidemiology Training (MEdiPIET);

<sup>2</sup>Institute of Public Health, Tirana, Albania;

<sup>3</sup>Faculty of Medicine, Medical University, Tirana, Albania.

**Corresponding author:** Elona Kureta

Address: Str. Aleksander Moisiu, Nr. 80, Tirana, Albania;

Telephone: +355693600966; E-mail: ekureta@gmail.com

### Abstract

**Aim:** Cases of viral hepatitis in Albania are reported to the Institute of Public Health (IPH) through multiple systems. Reliable epidemiological data is essential to inform policy makers and evaluate strategies to reduce the burden of disease. Our aim was to evaluate the MDBSS for viral hepatitis in Albania during the period 2013-2014.

**Methods:** Qualitative and quantitative attributes of surveillance system were assessed. The updated guidelines of the Center for Disease Control and Prevention regarding the performance of surveillance system were used.

**Results:** The case reporting form has a total of 27 variables (including demographic characteristics, clinical information, exposure to risk factors history and laboratory test results). During the evaluation period, the overall completeness of the forms was 70%. The median time from laboratory diagnosis to reporting was zero days (IQR: 0-1 days). Most of diagnostic tests were performed in private laboratories using rapid tests. Reporting rate by district epidemiologists was higher compared to clinicians or laboratories. The surveillance system is paper-based and it can be tailored as needed. The system is rather simple, stable, flexible, and acceptable and represents the overall population in Albania.

**Conclusion:** National surveillance data for acute viral hepatitis provides the information needed for developing prevention strategies and monitoring their effectiveness. Timeliness is adequate for detecting outbreaks and implementing preventive and control measures. Data quality should be further improved. A web-based reporting system, enhanced laboratory testing and training of staff is required to increase the quality, efficiency, and usefulness of the system.

**Keywords:** Albania, hepatitis B, hepatitis C, surveillance.

## Introduction

Public health surveillance is “*the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health*” (1). Public health surveillance data can be used to assess the burden and time trends of health events being monitored, detect potential outbreaks, guide action on issues of public health interest, support planning and evaluation of prevention activities, assess public policy, improve the use of health resources based on evidence, etc. (2). In order for public health surveillance to accomplish its objectives it needs to be evaluated on regular basis (2). Such effort should include, among other things, the evaluation of system attributes (simplicity, flexibility, data quality, acceptability, sensitivity, predictive positive value, representativeness, timeliness, stability), focusing on aspects most relevant to stated objectives (2).

Hepatitis B and hepatitis C represent inflammations of the liver caused by hepatitis B virus (HBV) and hepatitis C (HCV) (3,4). Both diseases spread through contact with infected blood, infected semen or other infected body fluids (or from infected mother to baby at birth for HBV). HIV, multiple sex partners, homosexual relations and unprotected sex increase the risk of HBV and HCV transmission (3,4). Since the risk of contracting HBV and HCV through blood transfusion is extremely low nowadays, both infections are highly prevalent among injecting drug users or persons undergoing unsafe tattooing or piercing (3,4). HBV and HCV can cause acute or chronic infection; the acute infection could be very mild (mostly undetected) to severe forms requiring hospitalization (3,4). Most persons infected with HBV are able to “clear” the virus but about 85% of those infected with HCV will develop chronic infection (3,4). Chronic HBV and HCV could lead to serious liver and overall health problems, including liver cancer and death (3,4). The best way to prevent HBV is through

vaccination whereas no vaccination exists against HCV (3,4). The prevalence of HBV is reported to be about 0.4% and the prevalence of HCV about 1% in the United States of America (5). In Kosovo, among blood donors the prevalence of HBV and HCV was 4.2% and 0.3%, respectively (6). The prevalence of HBV ranges from 0.1% to 8.0% whereas the prevalence of HCV ranges from 0.1% to 6.0% (7). Pregnant women and blood donors are usually considered as representatives of general population regarding prevalence of HBV and HCV whereas high risk groups comprise injecting drug users, males who have sex with males, migrants, and the like (7,8).

Because both infections are leading causes of hepatic cirrhosis and cancers (7), HBV and HCV surveillance systems established in many countries (7) are important in order to monitor the situation, assess the trends, detect any sudden changes in morbidity rates and suggest further measures to be taken.

The objectives of surveillance of acute HBV and HCV infections include the identification of new cases and risk factors, monitoring of disease trend and transmission patterns and guide preventive and control measures (9). For HBV the main goal of identification of new cases is early treatment and counseling to prevent further spread whereas for HCV efforts will be directed towards prevention since no vaccine is available (9).

Albania is a country still highly endemic for HBV infection (9%) (10) compared with the other countries in the same region like Croatia (2%) (11), Serbia (2.4%), Italy (2.6%), Greece (2%), Romania (5.6%) (12). In Albania there is no surveillance in place for chronic hepatitis.

In Albania regular monitoring of viral hepatitis situation, through surveillance systems generating reliable epidemiological data about HBV and HCV infection, is essential to inform and evaluate strategies to reduce the burden of these diseases based on evidence-based public health decision making. Surveillance data suggest that the incidence

of unspecified viral hepatitis has declined during the years and the incidence of HBV has increased in 2014 compared to 2010. There is no change in the incidence of HCV during 2010-2014. The decline of unspecified hepatitis incidence can be attributed to the introduction of the new vaccine against HBV in 1995 in Albania and improvement of disease surveillance (13,14). On the basis of vaccination coverage data, sero-survey results and epidemiological surveillance data, the national policy of mandatory vaccination of infants against hepatitis B was established from 1994 in Albania as the most useful strategy for long-term control of hepatitis B in a country with a high HBV endemicity (14,15). Vaccination coverage is over 95% at country and district level in Albania whereas the dropout rate is less than 10% at country level, except for some districts. However, the dropout rate in the later has been decreasing through the years (16).

The prevalence of Hepatitis B surface antibodies (anti-HBs) is much higher in vaccinated children than in unvaccinated ones, and Hepatitis B surface antigen (HBsAg) prevalence is much lower among 0-14 years old children compared to older ones (14). Surveillance of HBV and HCV is important as a tool to control and prevent these infections. In this context, the aim of this study was to evaluate the surveillance system for HBV and HCV (evaluation of system capacities corresponding to the objectives of surveillance system, evaluation of system attributes, identification of weak points) in Albania during 2013-2014 in order to provide recommendations for improving quality, efficiency and usefulness of the system.

## Methods

### *Type of study*

This is a cross-sectional study using HBV and HCV surveillance data for the period 2013-2014 in Albania. HBV and HCV surveillance system in our country is based on disease specific surveillance, syndromic surveillance and surveys.

***Disease specific surveillance***, comprising:

- Major Disease-Based Surveillance System (SMBS-14SH): this system entered into force in January 1<sup>st</sup>, 1998 (17). The actual notification system contains 73 nosologic entities of infectious diseases (ICD-9 Code) presented in a standard official form named 14-SH. The infectious diseases are divided in three groups (A,B,C) according to the degree of their public health importance, based on the respective measuring parameters such as the magnitude of the problem (occurrence, frequency), rates of mortality, case-fatality, potential years lost, socio-economic impact, and preventability. The notification of the infectious diseases of the two groups A and B is based on individual level (person characteristics) as well as on specific case definition (suspect or confirmed cases);

- Individual case report form for acute viral hepatitis B and C, established in January 2013 which is included in SMBS: until 2009, in the SMBS were reported only cases with the diagnosis of “Unspecified viral hepatitis” because of the lack of diagnostic test kits of the virus type identification by districts microbiological laboratories. Since 2010, started the reporting for four types of viral hepatitis, unspecified viral hepatitis, A, B and non A non B (includes C and E). In 2013 it was established a new case report form for HBV and HCV, which includes the risk factors for these two diseases as well. The reported cases are based on World Health Organization (WHO) case definitions.

***Syndromic surveillance system – ALERT***, which is a weekly mandatory reporting system of infectious syndrome “*jaundice*”;

***Surveys***, comprising:

- Bio-BSS – biologic behavior surveillance study in high risk groups such as Roma population, injecting drug users (IDU), men who have sex with men (MSM) (2005, 2008, 2011) (18);

- Biological surveillance of infectious agents among individuals receiving multiple transfusions

blood specimens were collected from patients in units of hemodialysis, hematology and onco-hematology in several districts of the country over the period of 2006-2011 (19);

- Sero-prevalence studies in general population and in risk groups (the last one was conducted in Albania in 2008) (20).

In order to evaluate the capacities of the system corresponding to surveillance objectives, all the stakeholders involved were identified.

The attributes of the HBV and HCV surveillance system in Albania were evaluated using the Centers for Disease Control and Prevention guidelines (21), and namely simplicity, flexibility, data quality, acceptability, representativeness, timeliness, stability, positive predictive value (21). In this study it was impossible to calculate the positive predictive value of HBV and HCV surveillance system due to the inability to get data from another source against which to calculate this measure.

The weak points of the surveillance system under study were identified through the analysis of all aspects and/or stakeholders involved directly or indirectly in such a system.

## Results

### *Capacities of the system*

The stakeholders involved in the functioning of HBV and HCV surveillance system in Albania are as follows:

- Epidemiologist in every districts working at the Directory of Public Health;
- General practitioners working in primary health care;
- Microbiologist and laboratory technician;
- Physicians in hospitals, specialist of infectious diseases and gastro-hepatology;
- Public health specialists in the Ministry of Health (MoH);

- Health Insurance Fund;
- Non-profit organizations that work in certain groups of risk such as prisoners, IDU, MSM;
- WHO;
- UNICEF.

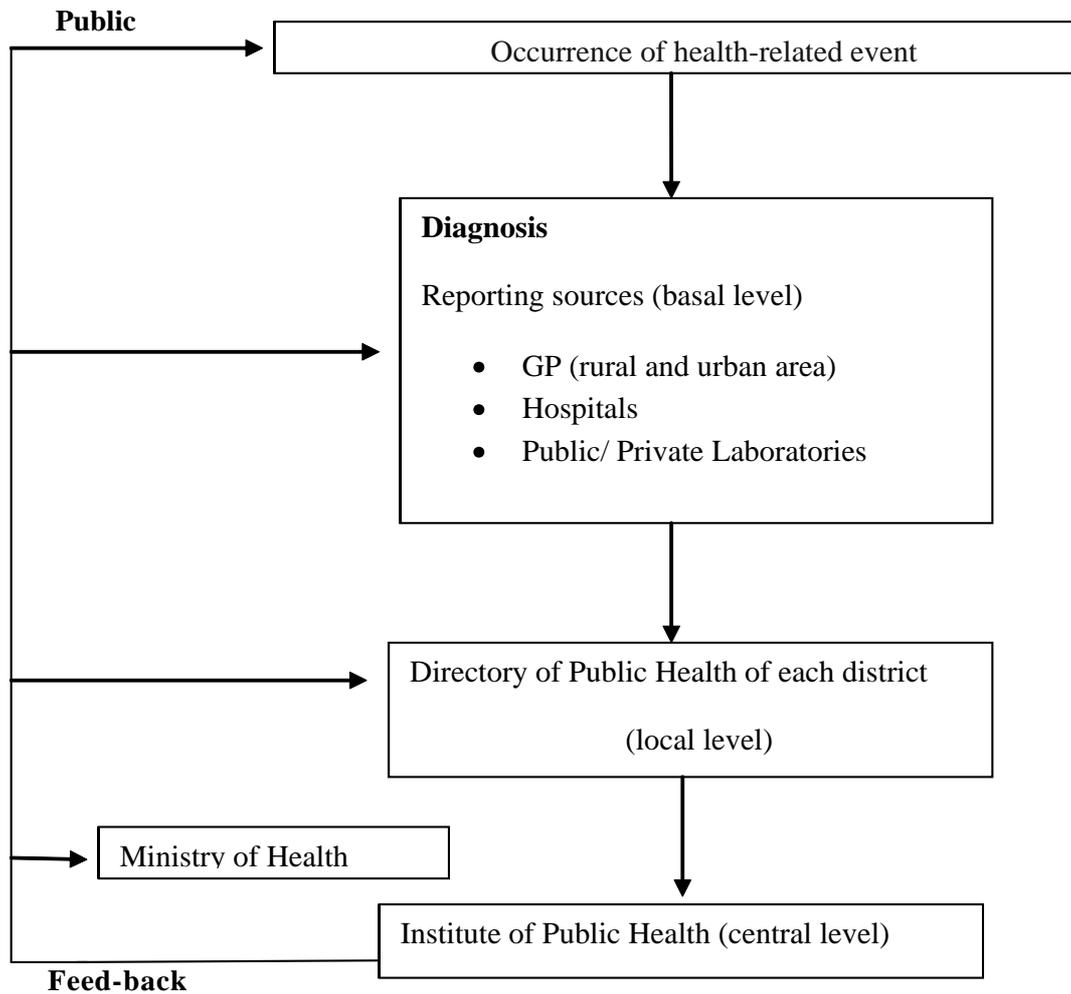
From this perspective the HBV and HCV surveillance system in Albania is capable of meeting system objectives since all the needed stakeholders are in place. It is important that the information is shared among stakeholders in order to improve the capacity of the surveillance system and prioritize.

### *System attributes*

**Simplicity** – *“The simplicity of a public health surveillance system refers to both its structure and ease of operation. Surveillance systems should be as simple as possible while still meeting their objectives”* (2,21). In this case simplicity refers to the amount of data needed (fulfillment of case definition criteria and other information from the individual reporting form) to ensure a health event has occurred (2,21). In Albania case reports are sent from directorates of public health (DPH) to the IPH; the reporting of relevant events is part of the Integrated Surveillance System (SMBS and ALERT); mandatory reporting and collection of data occurs within 24-72 hours from the following sources: GPs, public hospitals, laboratories (public health and private); follow-up to update data on the case if necessary - (lab results).

The data from reporting sources are transferred to IPH and entered into computer, followed by appropriate statistical analysis through EpiInfo program. Feedback information is disseminated to all districts every 3 months. Also, new staff is regularly trained in order to be familiar and competent with surveillance system requirements. Figure 1 visualizes the HBV and HCV surveillance system in Albania.

Figure 1. Flow chart of the HBV and HCV surveillance system



The surveillance system of HBV and HCV in Albania involves some aspects that could make it a complex system, such as:

- Special or follow-up laboratory tests to confirm the case;
- Investigation of the case, including telephone contact or a home visit by public health personnel to collect detailed information;
- Multiple levels of reporting (e.g., with the National Notifiable Diseases Surveillance System, case reports start with the health care provider who makes the diagnosis and reports it to the directory of public health before sending to IPH; and,
- Integration of related systems such as

ALERT in detecting outbreaks, whereby special training is required to collect and/or interpret data.

Flexibility – “A flexible public health surveillance system can adapt to changing information needs or operating conditions with little additional time, personnel, or allocated funds” (2,21). “Flexibility of a surveillance system is evaluated retrospectively observing how the system has responded to a new case report form included in the system” (2,21). In Albania the HBV and HCV surveillance system is paper-based, not electronic one. The case report form was changed and adopted including additional data related to: risk

factors for HBV and HCV; type of laboratory (public/private) that sets the diagnosis; method of testing for HBV and HCV; and, education of each case/patient. This new form is distributed to every Directorate of Public Health in all districts, hospitals, GPs, laboratories and it is currently being used for reporting cases.

Data Quality – “Data quality reflects the

completeness and validity of the data recorded in the public health surveillance system” (2,21), including demographic data, data about the relevant health event as well as information about known risk factors (2,21). Since the focus is on completeness of data recorded then quality of data is assessed by calculating the percentage of “blank” responses to items in reporting form (2,21).

**Table 1. Completeness of reporting for different items in the HBV/HCV reporting form for the years 2013 and 2014 in Albania**

Item Number	Item in the reporting form	% of completeness in 2013	% of completeness in 2014
1	Diagnosis	97.8	98.8
2	Accidental	79.2	82.8
3	Tattoo	79.2	83.4
4	Endoscopy	78.7	83.7
5	Haemodialysis	78.0	83.4
6	Dentist intervention	80.9	82.8
7	Unprotected sex	78.7	83.1
8	Undergoing Surgery	82.6	84.3
9	Blood transfusions	82.0	84.6
10	Injecting drug use	79.8	83.4
11	Laboratory public/private	91.0	98.2
12	Testing method	83.1	94.5
13	Profession	70.2	77.5
14	Epidemiologist	36.5	53.9
15	Date of completion	94.4	88.0
16	Date of notification	57.9	50.2
17	ID of Patient	12.9	2.7
18	Date of birth	93.3	71.4
19	Date of onset	53.9	30.2
20	Date of hospitalisation	24.7	22.2
21	Date of release	15.7	7.0
22	Date of diagnosing	59.6	30.5
23	Physician	27.5	12.6

In Albania the assessment of HBV and HCV surveillance system data shows that there is an improvement in percentages of responses in 2014 compared to the previous year (2013) for almost all the variables included in the case report form, as shown in Table 1. However, for some items (item 15 to 23) the percentage of completeness has decreased in 2014 compared to 2013. These items relate to the date of completion, date of notification, ID of patient, date of birth, date of onset, date of

hospitalization, date of release, date of diagnosis and physician ID, which can be important in order to have a complete picture of the situation. In this regard, the quality of data about risk factors has improved but it has deteriorated for some other important aspects in 2014 compared to 2013. Overall, the completeness of the form during 2013-2014 was 70%.

Some reasons influencing data quality of HBV and HCV surveillance system in Albania include: lack

of diagnostic kits in some laboratories; use of the Rapid test as a method for diagnosing the disease; lack of human and technical capacities in the public labs; high costs of testing in private laboratories; and, lack of electronic surveillance forms.

**Acceptability** – “Acceptability reflects the willingness of persons and organizations to participate in the surveillance system. It refers to the willingness of persons in the sponsoring agency that operates the system and persons outside the sponsoring agency (e.g., persons who are asked to report data) to use the system” (2,21). In Albania quantitative measures of acceptability include:

- The epidemiologist in all districts have totally agreed to use the case report form but we can't say the same about the clinicians or private laboratories;

- The system involves interviews, and sometimes the patient refuses to answer the questions about the risk factors;

- Unanswered questions influence the completeness of the data thus reducing data quality;

- Physicians, laboratories and hospitals are required to report the cases in due time through the surveillance system.

Some factors influencing the acceptability of HBV and HCV surveillance system in Albania include:

- Lack of knowledge by the public of the importance of viral hepatitis B and C;

- Feedback dissemination of aggregate data to all reporting sources and interested parties such as MoH, directorate of public health, NGOs;

- The system's responsiveness to suggestions or comments from the epidemiologist or clinicians;

- Delays in reporting data from the reporting sources to the IPH;

- Absolute confidentiality and privacy of all data regarding the cases, guaranteed by law;

- Case reporting and data collection are mandatory by law.

**Representativeness** – “A public health surveillance system that is representative accurately describes the occurrence of a health-related event over time and its distribution in the population by place and person. Representativeness is assessed by comparing the characteristics of reported events to all such actual events” (2,21). The HBV and HCV surveillance system in Albania includes all the general population, including symptomatic persons and non-symptomatic persons, in all districts, and collects demographic data (age, gender, profession, education); data about date of hospitalization, date of onset of the disease, date of diagnosis; the route of transmission; testing method used for diagnosis; type of laboratory (private or public); and testing method used; reporting source (hospitals, GPs, etc.) (see also Table 1).

All the data reported from different sources are compared and the results are summarized as follows:

- Data are reported from all the districts each month;

- The diseases are diagnosed mostly in private laboratories rather than in public ones;

- The most frequently used testing method is the Rapid test;

- The reporting occurs mostly from physicians than laboratories;

- Dental interventions comprise the most frequent risk factors for transmission of HBV and HCV, followed by unprotected sex and surgery interventions;

- The HBV incidence was higher in 2013 compared to 2014 data;

- The age most affected for both types of viral hepatitis is 25-44 years old;

- More males than females are affected by HBV and HCV (for the two years under study);

- The districts that have reported mostly more consistently are: Berat, Elbasan, Kucova, and Tirana.

**Timeliness** – “Timeliness reflects the speed

*between steps in a public health surveillance system*" (2,21). The steps of the HBV and HCV public health surveillance in Albania comprise as follows:

1. Occurrence of health-related event (suspected case with hepatitis) –GPs, laboratories;
2. Health-related event recognized by reporting source (local level) –DPH;
3. Health-related event reported to responsible public health agency (central level) –IPH;
4. Control and prevention activities;
5. Information/feedback to stakeholders.

Acute Viral hepatitis is part of group B of diseases, notifiable within 1-3 days from data sources to the local level and monthly reported from local to the national level if their occurrence is represented as sporadic cases. In this instance, every case report form is controlled whether completed correctly in each section. Data are compared with the previous month to see any change in the trend of disease and to evaluate if there is any unexpected event that requires intervention.

In case of eventual outbreaks, the reporting timeliness is the same as group A, urgent within 24 hours from data sources to the national level – Institute of Public Health (IPH). In such an instance, a rapid evaluation is done to assess whether there is a true outbreak or just cumulated cases with no epidemiologic link.

In timeliness is important that the date of reporting from the local level and the date of completing the form are the same. The median time from laboratory diagnosis to reporting is zero days IQR (0-1) days.

*Stability – "Stability refers to the reliability (i.e., the ability to collect, manage, and provide data properly without failure) and availability (the ability to be operational when it is needed) of the public health surveillance system"* (2,21). The stability of HBV and HCV surveillance system in Albania is assessed taking into consideration the following aspects:

- The system's computer operates full time;
- The number of unscheduled outages and down times for the system's computer is very low or inestimable;
- If there is any problem with the system, the persons responsible for the repair are ready available and quickly work to fix it;
- The system is paper based, so it takes some time to collect the data; the IPH receives all the case report forms on monthly basis;
- It takes a month for the data to be transferred, entered into EpiInfo program, edited, and backed-up;
- Data are analyzed and reported to interested parties every three months.

#### ***Weak points of the system***

To improve our system of surveillance we need to know the weak points of it. The results of such evaluation are as follows:

- Lack of laboratory capacities for diagnosis of hepatitis B and C;
- Rapid Test is the most used technique by laboratories for the diagnosis of HBV and HCV.
- In the case report form the following aspects are not specified: the incubation period (6 weeks to 6 months); specification of outcome of the disease; reason of testing; status of vaccination;
- Failure to complete all the sections of the reporting form;
- Not all filled-in and reported forms meet the criteria of the case definition;
- Surveillance system is paper based;
- Not all districts do report the cases of HBV and/or HCV.

#### **Discussion**

This study marks the first effort to evaluate the HBC and HCV public health surveillance system in Albania in terms of system capacities, system attributes and weak points. Our results suggest that the HBV/HCV surveillance system has some capacities to meet its objectives but further

investment in infrastructure and training in various aspects is needed. Furthermore, case confirmation efforts, multiple levels of reporting and integration of different systems could lower the simplicity of the system. Efforts have been made to improve the flexibility of the system. Regarding the quality of data, information about risk factors has improved but there is room for improvement especially regarding the items about disease diagnosis, notification, date of onset, date of hospitalization and discharge. The acceptability of HBV/HCV surveillance system can be further improved through increased participation of physicians and/or private laboratories in the system. The representativeness, timeliness and stability of the system are adequate. The major weak points included lack of laboratory capacities for diagnosis of HBV and HCV, the use of rapid testing method to set the diagnosis, failure to complete all items in the case reporting form and lack of reporting from all reporting sites.

Establishing an effective HBV and HCV surveillance system is important in order to monitor actual trends of these diseases and guide prevention and treatment efforts (22). Besides the high burden of both HBV and HCV, the high proportion of infected persons who will develop the chronic form of infection and suffer high risk complications such as liver cirrhosis, cancer and death (23,24), the inverse association of the risk of developing chronic infection with age at infection onset (7) is an additional argument in favor of early detection efforts, detection of high risk groups, through surveillance data, and early prevention efforts based on available evidence. However, monitoring and prevention strategies need to be continuously evaluated (7). Addressing HCV, an increasingly public health concern, could be more challenging than addressing HBV because HCV most often is asymptomatic and there is no vaccination in place (7). As Rantala and van de Laar (7) point out, reporting of asymptomatic cases could be an important aspect for a more accurate estimation of measures of

disease frequency and also for the control and prevention of both HBV and HCV.

The need of an effective surveillance system is even more critical in countries with a high endemicity of HBV infection such as Albania (20,25).

Based on the findings of this study and in order to make the HBV and HCV surveillance system more sustainable and to improve its ability to collect and report data efficiently for acute and chronic hepatitis we recommend as follows:

- Implement the standards related to the case definition;
- Review, standardize and improve the completion of all sections of the individual case reporting form;
- Support the development and implementation of an electronic system for data collection (Electronic Medical Records System);
- Improve and require HBV and HCV reporting from every district;
- Training of medical staff such as family doctors, assistant epidemiologist/epidemiologist regarding case report form changes and modes of reporting, including the Alert System;
- Establish surveillance for chronic hepatitis;
- Implement the national registry for liver cancer;
- Establishment of a financial fund for supporting surveillance activities;
- Provision of microbiological laboratories of the Public Health Departments of districts with necessary equipment and diagnostic kits;
- Training the new staff in laboratories regarding the diagnostic methods of viral hepatitis;
- Meeting the needs of the district microbiological laboratories with microbiologists;
- Introduction and enforcement of mandatory reporting of HBV and HCV cases every month from private hospitals;
- Implement sentinel surveillance in high risk groups such as pregnant women, prisoners, IDUs, and MSMs.

## Conclusion

The HBV and HCV surveillance system in Albania is rather simple, stable, flexible, fairly acceptable and represents the overall population in Albania.

**Conflicts of interest:** None declared.

However it needs to be improved in order to increase its effectiveness in meeting system objectives. To achieve this multiple interventions involving all relevant stakeholders are needed.

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