Title: Evaluation of the acute hepatitis B surveillance system in the country of Georgia, 2015-2020

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Abstract

Background: In 2012, the country of Georgia established an electronic integrated disease surveillance system (EIDSS) for acute hepatitis B virus (HBV) infection. All medical facilities must report laboratory-confirmed acute HBV cases to the regional public health centres (PHCs) within 24 hours, which are subsequently registered in EIDSS.

Objective: To evaluate the acute hepatitis B surveillance system in Georgia in order to identify areas for improvement and develop recommendations that enhance its capacity to inform prevention and response efforts, supporting the elimination of viral hepatitis.

Methods: For the evaluation of acute HBV cases notified in 2015-2020, we used the Centres for Disease Control and Prevention updated guidelines. We assessed data completeness by calculating the percentage of missing values for key variables. We assessed simplicity, acceptability and flexibility by describing surveillance processes and by surveying PHC epidemiologists. We evaluated representativeness by comparing cases registered in EIDSS with cases registered in hospital discharges. We assessed timeliness by calculating the number of days from the date of diagnosis to the date of notification in EIDSS. We calculated the positive predictive value (PPV) as the proportion of cases notified during 2018-2020 having documentation of confirmatory tests in their medical records, meeting the confirmed case definition.

Results: During 2015–2020, 270 cases of acute viral hepatitis B were reported to EIDSS. All notified cases were HBsAg positive. However, only 53% of the 19 key variables were complete. Hepatitis B test results were missing in most reported cases, despite 82% being classified as "confirmed". Simplicity and acceptability of the system were affected by 30% respondents experiencing challenges with the EIDSS reporting form. The system had limited flexibility due to cumbersome procedures to implement any changes. Representativeness was limited, as only 41% of confirmed cases recorded in the hospital discharge database were reported to EIDSS. The average notification delay was 72 hours. Among 106 cases notified in 2018-2020, 67 met the case definition, leading to PPV 63%.

Conclusions: The surveillance system for acute HBV infection was timely but not representative and did not correctly ascertain cases. We recommend reconsidering the statutory notification time of 24 hours, revising notification forms and providing clear guidelines for data entry, and reporting of all test results needed for adequate case classification to enhance data completeness and reliability of case classification.

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Conclusions: The surveillance system for acute HBV infection was timely but not representative and did not correctly ascertain cases. We recommend reconsidering the statutory notification time of 24

hours, revising notification forms and providing clear guidelines for data entry, and reporting of all test results needed for adequate case classification to enhance data completeness and reliability of case classification.

Keywords: Acute hepatitis B, evaluation, surveillance system, Country of Georgia

Introduction

Hepatitis B as a global health challenge

Hepatitis B is a potentially life-threatening liver infection caused by the hepatitis B virus (HBV). It can cause acute and chronic disease and increases the risk of death from cirrhosis and liver cancer (1). Hepatitis B is transmitted by exposure to contaminated blood (injection drug use, unsafe medical injections, unscreened blood and blood products) and body fluids (perinatal, sexual transmission). The incubation period for HBV ranges from 2 to 6 months (2). Laboratory tests including IgM to hepatitis B core antibodies (IgM anti-HBc) and hepatitis B surface antigen (HBsAg) are needed to confirm acute HBV infection and differentiate acute from chronic infections. Acute hepatitis B is more common in adults as children exposed to hepatitis B are mostly asymptomatic and have a high risk of progressing to chronic HBV infection (2). Hepatitis B is preventable by vaccination and the World Health Organization (WHO) recommends three doses of hepatitis B vaccine for all children, healthcare workers, and persons at high risk of HBV infection (3).

The role of viral hepatitis surveillance

Viral hepatitis surveillance is essential to detect outbreaks, monitor disease trends, identify risk factors for recent infections, estimate the burden of viral hepatitis and its sequelae, and assess the impact of vaccination and other preventive services. Surveillance for acute viral hepatitis through reporting and investigation of patients with symptoms of acute hepatitis presenting to healthcare facilities can help detect outbreaks and identify leading risk factors for infection which informs development of prevention and response activities. Prevalence of chronic HBV infection is mainly assessed through nationally representative serological surveys which can monitor disease trends over time (2).

Hepatitis B in Georgia

Georgia implemented both acute hepatitis B surveillance and nationally representative hepatitis B serosurveys (4). In 2015 and 2021, the Georgian National Centre for Disease Control and Public Health (NCDC) and the US Centres for Disease Control and Prevention (CDC) conducted two serosurveys throughout the country to determine the burden of viral hepatitis. Results showed that in 2021, hepatitis B surface antigen (HBsAg) prevalence was 0.03% in children and 2.7% in adults. In comparison prevalence of HBsAg in adults in 2015 was 2.8% indicating the need to scale up prevention, screening and treatment of hepatitis B in adults (4).

Acute hepatitis B notification and reporting system in Georgia

In 2005, Georgia included acute hepatitis B in the list of notifiable diseases, and healthcare providers were mandated to report cases to the national surveillance system (5). Since 2012, reporting of acute hepatitis B cases is done using electronic case reporting forms in the electronic integrated disease surveillance system (EIDSS). EIDSS is directly linked to the Georgian civil registry, meaning that the national unique identification number (ID) and date of birth in the notification section are automatically identified. This guarantees the accuracy of the personal ID number belonging to the notified case. If the case subject does not have a personal ID number (immigrant or refugee), he/she cannot be linked to the Georgian civil registry. In such situations, the epidemiologist is required to register the case in EIDSS by noting the passport number in the annotation. In addition, reporting of acute cases of hepatitis B is done using electronic module of registration of discharged inpatients (IV-066). This is a separate register that collects aggregated number of medical records from all patients discharged from hospitals across the country by the end of each month.

Evaluating the acute hepatitis B surveillance system

WHO recommends assessing viral hepatitis surveillance to identify potential barriers that might

impact data quality and influence use of data for action (2). Surveillance of acute hepatitis B in Georgia has never been evaluated. We conducted an evaluation of the acute hepatitis B surveillance system in Georgia to identify areas for improvement and provide recommendations to ensure surveillance can inform prevention and response efforts and advance the elimination of viral hepatitis.

Methods

Description of acute hepatitis B surveillance system in Georgia

Suspected cases of acute hepatitis B are usually identified in outpatient and inpatient facilities, or private laboratories. The physician and laboratory personnel requesting the diagnostic tests are responsible for providing the patient with feedback regarding their test results. The physician is required to report each suspected or confirmed acute hepatitis B case within 24 hours to the municipal or regional primary healthcare centre (PHC). Subsequently, the PHC epidemiologist completes a case investigation form to collect relevant epidemiological data and enters the collected information in the EIDSS within 72 hours of receiving notification.

The EIDSS case reporting form contains three sections: (i) notification of data, (ii) case investigation, and (iii) laboratory results (Table 1). The notification section includes general demographic information (personal ID number, age, date of birth, sex, current residence, permanent residence, telephone number), symptom history and the primary diagnosis. The case investigation section includes details of patient symptoms, exposures, hospitalization, vaccination history, information about contact and final case classification. The laboratory investigation section includes test results.

Table 1. Description of variables in the electronic integrated disease surveillance system (EIDSS) case reporting form, Georgia, 2022

Section	Sub-Section	Description of contents

Notification	Demographic Information	Personal ID number, age, date of birth, sex, current residence, permanent residence, telephone number (If not residing in Georgia, records the country of residence.)
Notification	General Information	date of completion of the paper form, reporting institution and receiving institution information, as well as investigator, investigator organization, initial date of investigation.
Notification	Clinical Information	Date of symptoms onset, status of the patient at time of notification (alive or dead), initial diagnosis (If known), date of diagnosis and current location of the patient (hospital or house).
Notification	Note	Epidemiologists used this space for any additional comments. Additionally, if the case was not a resident of Georgia, epidemiologists entered the passport ID here.
Case Investigation	Clinical Information	Initial case classification, date of exposure, date of symptoms onset, location of exposure, facility where patient first sought care, date patient first sought care, non-reported diagnosis from facility where patient first sought care, hospitalization, date of hospitalization, and antibiotic/ antiviral therapy administered before specimen collection.
Case Investigation	Samples Collection	Specimen type, date of reception/registration.
Case Investigation	Contact list	Demographic information of the patient’s close contacts
Case Investigation	Case clinical classification	Clinical symptoms selected from a general list composed of all the symptoms characteristic of 74 communicable diseases.
Case Investigation	Epidemiological links and risk	Hepatitis B immunization history, risk factors and source of infection, information on medical manipulations and

	factors	safety practices for potential sources of infection.
Case Investigation	Final case classification and outcome	Final case classification, final diagnosis, link to an outbreak, outcome and additional comments.
Laboratory results	Tests	Results of diagnostic tests, selected from a list.

All epidemiologists working at municipal, regional and central levels have access to the EIDSS. There is a web version of EIDSS accessed from any device connected to the internet. Each epidemiologist has an individual username and password. The web version and analytical module are available in three languages (Georgian, English, Russian). Furthermore, epidemiologists at the NCDC have access to the EIDSS analytical module, allowing further analysis and preparation of annual surveillance reports.

Another source of data on acute hepatitis B cases is the hospital discharge form IV-066 which collects information from 265 hospitals in 11 regions throughout Georgia. Each hospital is required to submit the list of discharge records to the NCDC's statistics department no later than the 10th day of the month following the admission of the patient. The IV-066 form consists of patient demographics, facility information, medical chart number, and confirmed diagnosis.

Case definition for Acute Hepatitis B

During 2015–2020, the following case classifications for acute hepatitis B were used in Georgia:

Suspected case: A person, who has the following signs and symptoms: fever, headache, weakness, thirst, nausea, vomiting, diarrhoea, abdominal pain and one of the following: jaundice or a serum alanine aminotransferase (ALT) level > 100 IU / L. If there is a documented negative HBsAg test (HbsAg, "e" antigen – HbeAg or HBV NAT) within 6 months of receiving a positive test result, the case was considered a suspected acute viral hepatitis B without clinical signs.

Confirmed Case: A suspected case having both IgM anti-HBc and HBsAg positive

Data collection

We restricted the evaluation of acute hepatitis B surveillance system to the period from 1 January 2015 to 31 December 2020, as the case definition for acute hepatitis B was revised in January 2015.

To assess the acute HBV surveillance system, we used the CDC updated guideline "Updated Guidelines for Evaluating Public Health Surveillance Systems" (6). We considered the following system attributes: Flexibility, simplicity, acceptability, data completeness, representativeness, timeliness, positive predictive value (PPV).

We assessed the flexibility of the EIDSS by describing the procedures required to adapt the system to new requirements, including the process for modifying questionnaires.

To assess the simplicity and acceptability of EIDSS, during March–August 2022, we distributed an online questionnaire (Appendix 1) to epidemiologists working across 59 PHCs in 10 regions and two out of nine regional branches of the NCDC. We did not estimate a sample size due to the qualitative nature of the survey and we attempted to include all PHC epidemiologists. We allowed the respondents 2 months to complete the questionnaire. During this period, we called and reminded them once every 2 weeks and sent a reminder e-mail once a month.

We assessed data completeness in EIDSS by calculating the percentage of complete information for selected variables (demographic, laboratory, and case classification).

We evaluated representativeness by comparing the number of hospitalized cases recorded in the IV-066 database and those notified to EIDSS by year and region, and calculated reporting ratios by dividing cases registered in EIDSS by cases registered in IV-066. Even though the IV-066 database has never been evaluated, for this calculation, we assumed that cases registered in the IV-066 database reflect HBV infections correctly diagnosed among hospitalised patients.

To assess timeliness, we calculated delays between diagnosis and notification (target: maximum 24 hours) and between notification and the start of the epidemiological investigation (target: maximum 72 hours).

To assess the positive predictive value (PPV), we reviewed medical histories of suspected and confirmed acute hepatitis B cases registered in EIDSS during 2018-2020. This period was selected because recent patient documentation was available in the hospital archives. We compiled a list of acute hepatitis B cases registered in the EIDSS during 2018-2020 based on location of hospitalization and if this information was missing, based on the region of residence. We distributed the list to hospitals or regional PHCs according to the patient's region of residence and hospital information and asked them to complete the following information based on review of medical records: date of birth, age, place of residence, date of notification, date when the case was registered in EIDSS, date of onset of symptoms, date of the patient’s first visit to the first care facility, name of the medical facility, whether or not there was hospitalization, and if so the date of hospitalization and date of discharge, date of final diagnosis, presence of clinical signs, IgM anti-HBc and HBsAg laboratory tests results, outcome (recovered, died or unknown), and final case classification. Then we calculated PPV as the proportion of cases reported to EIDSS that met criteria of confirmed acute hepatitis B case.

Results

During 2015–2020, 270 suspected or confirmed cases of acute hepatitis B were reported to EIDSS while 657 confirmed cases were reported in the hospital discharge registries (IV-066). A total of 104 regional epidemiologists and PHC employees responded to the survey. Most respondents, (85%) were female, and 79% were epidemiologists.

Flexibility of the surveillance system

To incorporate changes to information collected in EIDSS, NCDC’s epidemiologist need to submit an Excel form with all proposed changes. Their proposed changes need to be approved by the head

of communicable diseases department. After approval, the list of approved changes is sent by mail to the developer of the EIDSS database. Any changes to the form usually take 2-3 months. Following each major change, PHC epidemiologists need to be trained on the new changes.

Simplicity and acceptability of EIDSS

Of 104 survey respondents, 30% (31) found that the EIDSS case reporting form was difficult to complete. Most respondents (62%; 65/104) believed that information on "safe practices" in health facilities was obsolete as municipal public health services do not have the mandate to evaluate infection prevention and control measures in medical facilities. Only 45% (47/104) of respondents reported sufficient knowledge of acute hepatitis B investigation, including which details they needed to obtain from patient medical documentation and during case interviews. Of 33 respondents who were not able to thoroughly investigate the notified cases, 16 (48%) could not access relevant laboratory results. The predefined list of tests included in the EIDSS case investigation form does not include the IgM anti-HBc for acute hepatitis B, required for the confirmed case ascertainment.

Completeness of Data in EIDSS

While demographic information such as sex, age, and place of residence were recorded with completeness rates of 96%, 99%, and 100% respectively, critical variables, such as hepatitis B vaccination date and laboratory test results, were entirely missing. Reasons for missing hepatitis B vaccinations were noted in only 21% of cases. While 82% of cases were classified as "confirmed," this was often based only on HBsAg positivity without results of IgM anti-HBc undermining the accuracy of this classification (Table 2).

Table 2: Completeness of key variables, in the acute hepatitis B case reporting form submitted to the electronic integrated disease surveillance system— Georgia, 2015–2020

Variable	%(n)

	N=270
Sex	96 (260)
Age	99 (267)
Place of residence	100 (270)
Hospitalized	86 (231)
Outpatients	6 (17)
Information about last vaccination date	0 (0)
Reason why hepatitis B vaccination was not given	21 (58)
Laboratory test (HBsAg, IgM anti-HBc, HBeAg)	0 (0)
Final classification “probable”	2 (5)
Final classification "possible/suspicious” "lost from supervision" " rejected"	3 (8)
Final classification “confirmed”	82 (223)

Representativeness of EIDSS

Based on review of hospital discharge forms (IV-066), during 2015-2020, 657 confirmed cases of acute hepatitis B were diagnosed in hospitals of which 270 (41%) were registered in EIDSS. The incidence of cases recorded in hospital discharges (IV-066) varied between 2 and 4 cases per 100,000 inhabitants. In 2015, the incidence was 2 per 100,000, reaching its peak at 4 per 100,000 in 2017. Subsequently, the incidence slightly declined to 3 per 100,000 in 2018 and 2019, and further dropped to 2 per 100,000 in 2020. As for the EIDSS data, incidence remained constant at 1 case per 100,000 each. This comparison suggests that EIDSS reporting did not capture the trend in incidence of suspected acute hepatitis B that was observed in hospital discharge forms.

Timeliness of EIDSS

The average delay between diagnosis and notification to the PHCs was 72 hours, while the national guideline required notification within 24 hours. Almost half (51%; 139/270) of reported acute HBV cases were notified within 24 hours. Furthermore, on average there was a 48-hour time lapse between case notification and the beginning of the epidemiological investigation, which falls within

the national guideline that mandates the investigation to begin within 72 hours of receiving notification.

Positive Predictive Value of EIDSS reports

Medical chart reviews were used to validate 106 patients who were registered as suspected or confirmed cases of acute hepatitis B during 2018-2020. Of these, 39 (36.8%) lacked sufficient information on clinical or laboratory data to determine if the patient was a confirmed case of acute hepatitis B.

Thus, we estimated the PPV at 63%, since only 67 cases met the criteria for a confirmed case. All confirmed acute HBV cases presented with jaundice and dark urine. Their average age was 36 years old, and 44 (66%) were men. Most (79%) resided in Tbilisi (Table 3). All true positive cases were hospitalized. The average ALT level for these 67 true positive cases was 2313 IU/L. HBV DNA testing was performed in 46 out of 67 cases (Table 3).

Table 3: Demographic and clinical characteristics of confirmed (true positive) acute hepatitis B cases in Georgia, 2018-2020

Variable	**n (N-67)**	**%**
Gender		
Men	44	66%
Women	23	34%
Region of residency		
Guria	1	2%
Ajara	13	19%
Tbilisi	53	79%
Symptoms		
Fever	27	40%
Stomach-ache	37	55%
Nausea	53	79%
Lack of appetite	63	94%
Weakness	64	96%
Fatigue	65	97%
Jaundice	67	100%

Dark urine	67	100%
Average age (years)	36 years	
Average ALT level (IU/L)	2313 IU/L	

Discussion

The first comprehensive evaluation of the acute hepatitis B surveillance system in Georgia revealed both its strengths and areas of improvement. Georgia's acute hepatitis B surveillance reporting in EIDSS was timely as 51% of acute hepatitis B cases were reported within 24 hours, as required by national guidelines. However, the system was not sufficiently representative and did not correctly ascertain cases.

While Georgia’s system adapted to the new requirements, implementing changes is complicated and takes time (2-3 months). This delay affected the system's ability to respond promptly to public health needs. Accelerating adaptation timelines would enhance the Georgian system's flexibility.

The simplicity of Georgia’s EIDSS case reporting system was another area of concern. Although the reporting form for acute hepatitis B aimed to collect comprehensive data on transmission modes, risk factors, and contacts, public health specialists lacked access to key required information, which resulted in incomplete forms; this limited the utility of the epidemiological investigation section at the national level. Additionally, local epidemiologists reported technical difficulties collecting and entering key variables like IgM anti-HBc results into the EIDSS. Without access to laboratory data, PHC epidemiologists often submitted incomplete notifications, complicating case classification at the national level which led to a decreased PPV of 63%. This highlighted the importance of reporting all test results to enable accurate case classification and public health action.

Our survey of regional epidemiologists found that only 45% had sufficient knowledge of acute hepatitis B investigation, leading to potential misclassification of cases and reduced validity of

notifications. These findings emphasize the need for further training at the regional and health facility levels to improve understanding of case definitions, investigation methods, and data reporting to EIDSS.

Incomplete data was an issue, with important fields such as vaccination status and the source of infection often left blank. Improving data completeness in Georgia is essential for ensuring the accuracy and reliability of the surveillance system. Underreporting undermined the representativeness of the system. The overall reporting ratio was 41%, with significant variation across regions. Discrepancies between the number of suspected cases reported to EIDSS and those recorded in the hospital discharge database highlighted the need for cross-referencing data from multiple systems to ensure the representativeness and completeness of case reporting.

Study Limitations

The survey of regional epidemiologists may not reflect the experience of all surveillance users. We selected a convenience sample of employees of Public Health Centres and collected mostly qualitative feedback. To address this potential shortcoming, we tried to contact all PHCs and send several reminders to include as many eligible respondents as possible.

In addition, a sub-study validating the classification of acute hepatitis B cases utilized medical histories from reported cases between 2018 and 2020. This period did not cover the full period of our investigation. However, as we obtained complete information on these cases, we believe our results reflect true case classification practices.

Access to diagnostic testing is another aspect of surveillance that can affect the reliability of surveillance notifications. Although we did not investigate access to diagnosis, it is generally recommended to be performed in all regional hospitals.

The completeness of data relies heavily on the accuracy of entries by epidemiologists. If there are inconsistencies or gaps in data entry, the assessment may underestimate or overestimate the actual

completeness.

The assumption that all hospitalizations in IV-066 are correctly classified as acute HBV infections might introduce errors. Misclassifications or omissions in either database (IV-066 or EIDSS) may affect the accuracy of the representativeness analysis, leading to an under- or over-estimation of reporting ratios.

Comparison with similar studies

Similar evaluations were performed in China(7) Armenia (8) Germany (10), and South Korea,(9). Similar to Georgia, China's hepatitis B surveillance system, particularly in Fujian, Hainan, and Gansu provinces, relied on case reporting through the National Notifiable Disease Reporting System (NNDRS) (7). The system depended on clinicians to report hepatitis B cases and classified them as acute or chronic, according to national guidelines as it does in Georgia. Both Georgia and China had electronically integrated surveillance data, allowing public health authorities to gather, monitor, and analyse data efficiently, providing near real-time data access. Both China and Georgia faced challenges with misclassification and data quality in hepatitis B surveillance. While China’s system demonstrated problems with underreporting and inconsistent testing practices, Georgia also had data quality issues, especially with incomplete laboratory confirmations and misclassification of cases based on HBsAg without IgM anti-HBc.

Both Georgia’s and South Korea’s hepatitis B surveillance systems focused on acute cases. South Korea, which transitioned to mandatory reporting in 2011, demonstrated high positive predictive value (94.4%) and good data quality (9). However, it faced challenges with chronic cases being misreported as acute, a misclassification also identified in Georgia. Unlike South Korea, Georgia faced more significant challenges in data completeness and misclassification.

Similar to Georgia, Armenia's surveillance systems, reflected the legacy challenge from the Soviet

public health framework. Armenia's system, modelled on the Soviet-era framework, was extensive and involved reporting at various administrative levels (8). It collected both aggregated and case-based data for numerous infectious diseases. It lacked complex procedures and standardized case definitions. Georgia, on the other hand, struggled with incomplete reporting of key variables and regional underreporting.

Both Germany and Georgia faced challenges with data completeness, though the focus of these issues differed: Germany struggled with recording transmission routes and vaccination status, while Georgia faced gaps in laboratory results and vaccination information. Germany operated a mandatory surveillance system under the Protection Against Infection Act, requiring physicians and laboratories to report acute hepatitis B cases (10). The system was well-established with a clear data flow through local, state, and national public health authorities. Although Germany’s system performed well in terms of timeliness it has experienced a decline in data quality over the 10-year evaluation period, especially in capturing transmission routes and vaccination history.

Conclusions

Acute hepatitis B surveillance in Georgia suffers from unnecessary complex investigation procedures. The complicated case reporting forms are time-consuming and cumbersome to complete. The users are not able to complete the information necessary for classifying cases. In particular, the information on confirmatory testing is not recorded reliably, leading to misclassification of a large proportion of notified cases. In addition, a large proportion of regional epidemiologists are not aware of the notification procedures and case definition criteria. Despite these challenges, the system demonstrated positive results in terms of timeliness; This study provides essential insights into the strengths and weaknesses of the Georgian hepatitis B surveillance system, offering targeted recommendations to enhance data accuracy, improve case classification, and ultimately strengthen public health response capabilities.

Recommendations

We recommend revising the EIDSS case reporting form to simplify data entry and ensure that only essential information for case classification is required, improving data completeness, simplicity of EIDSS, and acceptability. Additionally, to improve representativeness and PPV, we recommend developing clear guidelines on proper case notification and investigation procedures, particularly focusing on the use of confirmatory tests, disseminating for regional epidemiologists and reporting physicians, and providing easy-to-access training in notification procedures.

DECLARATIONS

Ethics approval and consent to participate

The survey of regional epidemiologists who reported on their experience with EIDSS and notification was determined by the US CDC to represent a non-research public health activity and, therefore, did not require CDC's Institutional Review Board (IRB) review. The protocol was approved by the NCDC IRB (registration number for the IRB decision letter: IRB # 2022-027) (11).

Consent for publication

N/A

Availability of data and materials

The data that support the findings of this study were collected from the Electronic Integrated Disease Surveillance System managed by the Georgian National Centre for Disease Control and Public Health (NCDC), medical chart reviews, and questionnaires. Due to Georgian legislation on data confidentiality and restrictions imposed by the Georgian Government, these data are not publicly available. However, data may be available upon reasonable request to the corresponding author, subject to approval from the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia, and the NCDC.

Competing interests

The authors declare that they have no competing interests

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Author Contributions

LK, PS, KG, MT, KZ, and SS contributed to the study conception and design. LK and KG contributed to the study implementation and data collection. LK, KG, PS, and ER, contributed to data analysis and interpretation. LK and PS drafted the manuscript. All authors reviewed and provided critical feedback, and approved the final version of the manuscript.

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List of abbreviations

ALT: Alanine aminotransferase

CDC: US Centres for Disease Control and Prevention

EIDSS: Electronic Integrated Disease Surveillance System

HBeAg: Hepatitis B e Antigen

HBsAg: Hepatitis B surface antigen

HBV NAT: Hepatitis B Virus Nucleic Acid Testing

HBV: Hepatitis B virus

IgM anti-HBc: Immunoglobulin M antibody to hepatitis B core antigen

IRB: Institutional review board

IV-066: Electronic module of registration of discharged inpatients

NCDC: National Centre for Disease Control and Public Health

NNDRS: National Notifiable Disease Reporting System

PHC: Public health centre

PPV: Positive Predictive Value

Total HBV DNA: Total Hepatitis B Virus DNA

WHO: World Health Organisation

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Appendix 1: Survey of user experience with acute hepatitis B notifications.

Questionnaire ID _____

Name of establishment ----------

1. **Sex:**

a) Female

b) Male

2. **Occupation**

a) Epidemiologist

b) Person responsible for immunization

c) Other ----------

3. **Have you been trained in viral hepatitis surveillance?**

a) Yes

b) No (Skip to q6)

c) I don’t know (Skip to q6)

4. When did you receive training in viral hepatitis surveillance?

a) <1 year

b) 1-3 years ago

c) 3-5 years ago

5. Who provided the training?

a) NCDC representative

b) Infectious disease doctor

c) I did an independent online training

d) Other: _____

6. Which of these cases are subjects to urgent notification (it is possible to mark several answers)?

a) Possible/suspected case of acute hepatitis B.

b) Probable case of acute hepatitis B.

c) Confirmed case of acute hepatitis B.

d) Case of any classification of acute hepatitis B.

e) Case of chronic hepatitis B.

f) Acute hepatitis B is not subject to urgent notification

7. Do you receive urgent notifications of acute hepatitis B cases (F. #58/1)?

a) Yes

b) No (go to q15)

c) I don’t know (go to q15)

8. From where do you get the acute hepatitis B notification from (it is possible to mark several answers)?

a) From Clinics

b) From laboratories

c) From patients

d) Reporting an acute hepatitis B case is not mandatory

9. On average how soon after receiving a diagnosis/laboratory test result do you receive notifications of acute hepatitis B?

a) 12 hours

b) 24 hours

c) 72 hours

d) After a month

e) Other _____

10. How often do you receive reports of acute hepatitis B from clinics / laboratories based only on a positive HBsAg test result?

a) Always or most of the time

b) Occasionally

c) Rarely

d) Never

11. How often do you receive reports of acute hepatitis B from clinics / laboratories based only on a positive IgM anti-HBc test result?

a) Always or most of the time

b) Occasionally

c) Rarely

d) Never".

12. In what form do you get a notification of an acute hepatitis B case (it is possible to mark several answers)?

a) E-mail

b) Phone

c) Printed form (form 58/1)

d) In various forms (Specify)_____

13. When you receive report about acute HBV, on average how complete is the information reported in the case of acute hepatitis B (according to the standard case definition)?

a) Complete (The notification includes complete information on the demographic, risk factor, clinical, and laboratory variables included in form 58/1)

b) Sufficient (The notification includes partial information on the demographic, clinical, and laboratory variables included in form 58/1)

c) Insufficient (The notification only demographic variables included in form 58/1)

14. From how many clinics/laboratories did you receive report about acute HBV in the past 12 months (Specify exact number)?

a) _____

b) We didn't receive notifications (Please indicate the reason)

_____

c) I don't know/I don't remember

15. When did the registration of cases of acute hepatitis B in EIDSS start In Georgia?

_____/_____

a) (mm/yy)

b) I don't know/ I don't remember

16. **How do you act in the time between receiving an acute hepatitis B case report before registering it in EIDSS? (it is possible to mark several answers)**

a) I collect case information in accordance with Form 58/1 variables

b) I record the received information in a 60/B journal paper form

c) I check case data in EIDSS to avoid duplication

d) All of the above

17. When you receive urgent notification about acute hepatitis B, on average how soon do you start the epidemiological investigation of the case?

a) Within 24 hours of notification

b) Within 48 hours of notification

c) Within 72 hours of notification

d) I do not think that time is important

18. **How do you conduct an epidemiological investigation for acute hepatitis B (it is possible to mark several answers)?**

a) I conduct a telephone interview with an infected person

b) I contact the institution that sent the message with the purpose of clarifying the information

c) I study the medical history of the case in detail at the clinic

d) I conduct an epidemiological investigation with the patient at home

e) I don't conduct an epidemiological investigation

19. What is most useful for acute hepatitis B epidemiological investigation:

a) Gather information from illness history

a) Gather information by interviewing the patient

b) Finding information in both of the abovementioned ways

c) I do not know

d) Other (specify)_____

20. Do you think that you are doing a thorough epidemiological examination of an acute hepatitis B case (meaning checking information on all variables in the epidemiological questionnaire)?

a) Yes (go to q22)

b) No

c) I don’t know

21. **In your opinion what is the reason why you are not always able to carry out a thorough epidemiological investigation of an acute hepatitis B case (it is possible to mark several answers)?**

a) Access to the medical history is restricted/limited

b) The medical history does not include all the information required by the epidemiological questionnaire

c) There is no complete diagnosis at the city/municipality level and patients are referred to another clinic

d) Due to the delayed notification, it is inconvenient to retrospectively interview the case

e) Other (Please specify)

_____

22. What type of data knowledge is required to be granted "confirmed" status in a possible case of acute hepatitis B?

a) Existence of clinical signs of acute viral infection

b) Alteration of liver enzymes

c) The blood sample is HbsAg positive

d) The blood sample is IgM anti-HBc positive

e) None of the above

f) All of the above

23. Does the acute hepatitis B epidemiological questionnaire in EIDSS allow the case to be assigned a "possible/suspicious" or "probable" or "confirmed" status in the final classification?

a) Only possible/suspicious

b) Only probable

c) Only confirmed

d) According to the provided information, any status can be granted

e) I don’t know

f) Other (specify)

24. From your experience how difficult is it to complete the Acute Hepatitis B Epidemiological Questionnaire in EIDSS?

a) Very Easy (go to q26)

b) Easy (go to q26)

c) Hard

d) Very hard

25. From your experience which field/variable of the epidemiological questionnaire is difficult for you to fill?

a) About the reporting institution

b) About case contacts

c) About clinical symptoms

d) About epidemiological links

e) About risk factors

f) About testing

g) About safe practices

h) All of the above

i) I do not know

26. How do you research information about "safe practices" during an acute hepatitis B case study in EIDSS?

a) I research this in the facility notifying the case

b) I research it during an interview with a patient

c) I am not researching this issue

d) I do not know what is meant by this variable

e) Other (Specify)_____

27. Do you think that the variables on "safe practice" should be removed from the questionnaire of the acute hepatitis B case study in EIDSS?

a) Yes, I think they should be removed

b) No, I think they should stay

c) I do not know

28. Do you have the necessary technical support (individual computer, constant internet, uninterruptible power supply, etc.) to work in EIDS?

a) Yes

b) No

c) Partially (specify)_____

29. Does the Public Health Centre provide any feedback to the reporting institutions after the epidemiological investigation?

a) Yes, Specify_____

b) No

c) I don’t know

30. Who do you consult for issues related to acute hepatitis B surveillance?

a) From a NCDC epidemiologist

b) From a regional/LSS/ZDL epidemiologist

c) From an infectious disease specialist

d) Other (Specify)

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31. **Do you receive feedback from NCDC on acute hepatitis B surveillance?**

a) Yes

b) No

c) I don’t know