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Public Health

journal homepage: [www.elsevier.com/puhe](http://www.elsevier.com/puhe)

## Original Research

# Assessment of timeliness, representativeness and quality of data reported to Italy's national integrated surveillance system for acute viral hepatitis (SEIEVA)

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## ARTICLE INFO

## Article history:

Received 15 July 2014

Received in revised form

30 January 2015

Accepted 6 February 2015

Available online xxx

## Keywords:

Acute viral hepatitis

Surveillance

Evaluation

Representativeness

Quality

Timeliness

Hepatitis A

Hepatitis B

Hepatitis C

## ABSTRACT

**Objectives:** Periodic assessment of surveillance systems is recommended to verify whether they are appropriately monitoring the public health problem under surveillance. The aim of this study was to evaluate timeliness, data quality and representativeness of data reported to the Italian Integrated Epidemiological System for Acute Viral Hepatitis (SEIEVA).  
**Study design:** Cross-sectional analysis of surveillance data.

**Methods:** Quantitative indicators were used to evaluate representativeness of reported cases, data quality, and timeliness between surveillance steps, for reports of acute viral hepatitis cases with date of onset of symptoms from 2009 to 2012 (N = 4516).

**Results:** Representativeness was 75%. Over 95% of records reported information on age, sex, city of residence, risk factors for hepatitis A and vaccination status. Information on risk factors for hepatitis B and C were reported less consistently (83%), as was information on early outcome (60%). Wide delays were found between surveillance steps.

**Conclusions:** The system collects high quality data on acute viral hepatitis cases in Italy. Timeliness was found to be the main limit and needs to be improved by optimizing web-based reporting procedures, increasing communication with participating centres, improving feedback and increasing dissemination of surveillance results. The study highlights the importance of reporting timeliness to detect outbreaks of acute viral hepatitis.

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<http://dx.doi.org/10.1016/j.puhe.2015.02.015>

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## Introduction

Viral hepatitis is a major public health problem worldwide because of its burden of illness and death and its potential for outbreaks and epidemic spread. It is most frequently caused by infection with one of five different viruses: hepatitis A virus (HAV), hepatitis B virus (HBV), hepatitis C virus (HCV), the HBV-associated delta agent or hepatitis D virus (HDV) and hepatitis E virus (HEV). HAV and HEV are transmitted almost exclusively by the faecal-oral route and generally cause self-limiting infections, while HBV, HCV and HDV are transmitted via the parenteral route (exposure to blood and body fluids) and have the potential to cause chronic liver disease (chronic hepatitis, cirrhosis, hepatocellular carcinoma).<sup>1,2</sup> The various types of viral hepatitis cannot be differentiated clinically, but can be distinguished by specific serologic testing.

Thanks to improvements in socio-economic status and hygienic conditions, increased use of disposable materials in medical settings, improved safety of blood supplies, and introduction of a compulsory vaccination programme for HBV, in the past two decades there has been a progressive decrease in the incidence of acute viral hepatitis in most economically developed countries. However, the global burden of disease due to viral hepatitis continues to be high.<sup>3</sup> Globally, every year there are an estimated 1.4 million new HAV infections and three million acute cases of HEV. Hepatitis B and C disease burden includes not only acute disease but also chronic infections. It is estimated that about two billion people have been infected with HBV worldwide; of these, 240 million are chronically infected. About 150 million people are chronically infected with HCV. Approximately one million people die each year (~2.7% of all deaths) from causes related to viral hepatitis, most commonly liver disease, including liver cancer.<sup>3</sup> Hepatitis A and B can be prevented through safe and effective vaccines while no vaccines are currently available to protect against the other hepatitis types.

In Italy, rates of HBV and HCV infections have declined respectively from four cases/100,000 population in 1992 to 0.9/100,000 in 2012 and from 2/100,000 in 1992 to 0.3/100,000 in 2012.<sup>4</sup> The introduction, in 1991, of a compulsory vaccination programme has contributed to the drop in incidence of HBV infection.<sup>5,6</sup> Despite a decreased incidence, 2000–2500 acute hepatitis infections, about 50% of which attributable to HAV, 35% to HBV, and 10% to HCV, are notified each year. Occasional HAV outbreaks continue to occur.

In Italy, viral hepatitis is included in the national notifiable infectious diseases surveillance system.<sup>7</sup> In this mandatory system, implemented in 1975, physicians are required to report any clinically suspected case of acute viral hepatitis to the local health unit (LHU) within 48 h of diagnosis. They are also required to specify the hepatitis type diagnosed (HAV, HBV or nonA-nonB infections), based on serological tests performed (including detection of specific antigens or antibody responses to HAV or HBV). LHUs report individual cases to the Ministry of Health. Collection of information for each case is restricted to age, sex, profession, place of residence, date of onset of symptoms, hospitalization and vaccination status.

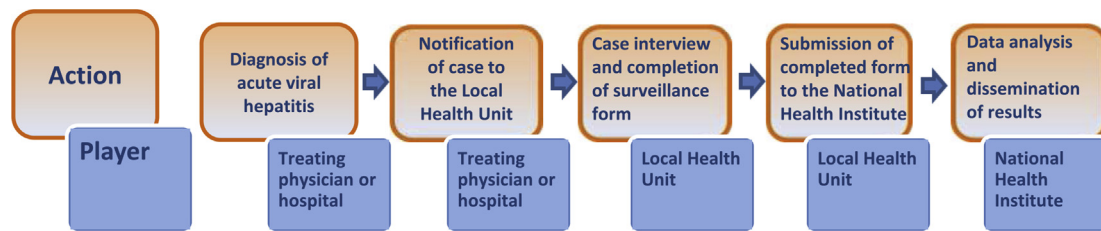
In addition to the mandatory notification system, a voluntary surveillance system was implemented in 1984 to improve epidemiological investigation of cases and collection of risk factor information. This system, named 'SEIEVA', an acronym for 'Integrated Epidemiological System for Acute Viral Hepatitis', consists of a network of LHUs located throughout Italy and is coordinated by the National Centre for Epidemiology, Surveillance and Health Promotion of the National Institute of Health (Istituto Superiore di Sanità – ISS).<sup>8</sup> In participating LHUs, cases of acute viral hepatitis reported by physicians through the mandatory reporting system are interviewed by a staff health care worker (either face-to-face or by telephone), by using a structured questionnaire to collect information on sociodemographic characteristics, parenteral risk factors in the six months prior to disease onset, faecal-oral risk factors in the previous six weeks, and disease outcome (occurrence of encephalopathy, fulminant disease, need for liver transplant and death). The questionnaire form used is identical regardless of hepatitis type. However, since risk factors and time period for potential exposures vary by type of hepatitis, risk factor information for the different hepatitis types is collected in different sections.

Completed questionnaires are sent to the coordinating centre at the ISS through a dedicated website (85% of participating LHUs) or, alternatively, by post or fax. Surveillance steps are shown in Fig. 1. The case definition used is based on clinical and serological criteria, as described in the Methods section.

Incidence rates and percentage of cases reporting specific risk factors are calculated and published yearly in a dedicated web-site. Surveillance data is also disseminated through publication of articles in the international literature.<sup>5,6,9,10</sup>

Besides monitoring burden of disease and trends in incidence of each hepatitis type, SEIEVA's main objectives are to detect outbreaks, identify at-risk groups, generate hypotheses on sources of infection and modes of transmission, identify research needs and disseminate information to health professionals.

The availability of risk factor information has allowed SEIEVA to highlight the role of specific risk factors in viral hepatitis transmission. Examples include the risk of acquiring parenteral hepatitis after a surgical procedure or after exposure to certain beauty salon treatments.<sup>9,10</sup> Also, since its introduction, SEIEVA has shown to be a flexible system; for example, it introduced collection of laboratory testing results for antiHCV in a timely manner, soon after testing became available in clinical practice, thus allowing for the differentiation between HCV and nonA-nonB hepatitis cases. However, a recent large outbreak of hepatitis A cases involving various Italian regions was not promptly detected by the surveillance system.<sup>11</sup> Several international alerts were released in April 2013 because of an observed increase in the number of HAV cases reported in several European countries,<sup>12–14</sup> following which local SEIEVA contacts were asked to promptly report any new HAV cases to the system. This allowed for rapid collection of data regarding cases, including risk factor information. Despite initial delays, the system therefore proved to be a very useful tool for assessing the outbreak at the national level, including sources of infection.<sup>11</sup>



**Fig. 1 – Surveillance steps in the Italian national integrated surveillance system for acute viral hepatitis (SEIEVA).**

Periodic evaluation of surveillance systems should be performed to verify whether they are operating efficiently and appropriately monitoring the public health problem under surveillance.<sup>15–23</sup> In particular, those attributes that are of the highest priority for a given system and its objectives should be addressed. The aforementioned hepatitis A outbreak prompted the coordinating centre to evaluate the performance of SEIEVA, particularly with regards to the attributes of timeliness, data quality and representativeness of data.

## Methods

A descriptive analysis was conducted of all cases of acute viral hepatitis reported to SEIEVA with onset of symptoms between 1 January 2009 and 31 December 2012. In this system, the case definition used is the same as that used in the clinical setting: a case is defined as a person with an acute illness compatible with hepatitis and a significant (greater than ten-fold) increase of serum alanine transferase (ALT). Hepatitis types are distinguished by using the following serological criteria: acute hepatitis A – positive assay for HAV-specific IgM antibodies, regardless of other viral markers; acute hepatitis B – positive assay for IgM anti-HBc and negative assay for IgM anti-HAV, regardless of other viral markers; acute hepatitis C – negative assay for IgM anti-HAV and IgM anti-HBc and positive assay for anti-HCV or HCV-RNA. Cases reporting negative assays for IgM anti-HAV, IgM anti-HBc, and anti-HCV/HCV-RNA are classified as NonA-NonC.

Appropriate indicators were selected to assess representativeness, data quality and timeliness of data. The numerators and denominators used for each indicator are listed in Table 1. Representativeness was assessed by calculating the percentage of LHUs which participate in the system (number of participating LHUs over the total number of LHUs). Data quality, in terms of completeness of surveillance data, was assessed by nine indicators measuring the percentage of reported cases in whom a specific diagnosis was possible or the percentage of reports with information on selected items (see Table 1). Timeliness was assessed by three indicators measuring the speed between steps in the surveillance system. More specifically, the median number of days between the onset of symptoms and the date of interview, between the date of interview and the reporting date, and between the date of serological testing and the reporting date were measured.

Indicators were calculated for the four-year period from 2009 to 2012 and also for each individual year in the study

period, at the national level and for each of three geographical areas (North, Centre, South/Islands). As specified in Table 1, indicators regarding specific hepatitis types were calculated by using as the denominator the number of reported cases of the hepatitis type considered.

## Statistical analysis

Differences by year and geographical areas, between performance indicators expressed as proportions, were tested by the Chi-square test or by the Fisher test when necessary. Linear trends over time on proportions were tested by the Armitage–Cochran test. Differences between indicators expressed as continuous variables (timeliness) were tested by the non-parametric Kruskal–Wallis test and by Cuzick’s rank-sum test for trend. All statistical analyses were performed using STATA Statistical software version 11.2.

## Results

During the four-year study period, 4516 viral hepatitis cases with a median age of 38 years (range 1–96 years) were reported to SEIEVA. The number of reported cases, by year, geographical area and hepatitis type are shown in Table 2. These represent the denominators used to calculate performance indicators. The prevalent area of notification was central Italy. Almost half of the reported cases (46.6%) were caused by HAV, 36.8% by HBV and 9.3% by HCV.

Table 3 shows results of the performance assessment. Overall, representativeness was 74.7% and did not vary significantly during the study period. Sixty-seven per cent of reports had data on all relevant serological markers and in 96.2% of cases a specific diagnosis of hepatitis type was possible, based on the available markers. Age and sex data were each reported consistently across the study period in over 99.8% of cases, and 95.5% of reports had information on the city of residence; the latter percentage significantly improved during the study period. The percentage of reports with complete information on sex, age and city of residence (all three variables) grew significantly during the study period, from 92.3% in 2009 to 97.9% in 2012.

Data on major risk factors for HAV were available for 97.2% of cases, while risk factors for HBV and HCV were available respectively in only 83.2% and 82.5% of cases. The percentage of cases with information on HAV and HBV risk factors showed a decreasing trend during the study period.

**Table 1 – Indicators used to evaluate the SEIEVA surveillance system for acute viral hepatitis and methods used to calculate each indicator, Italy 2009–2012.**

| Attribute          | Numerator   | Denominator                             | Unit                         |
|--------------------|---|---|------------------------------|
| Representativeness | Number (N.) of participating Local Health Units   | Total n. of Local Health Units in Italy | %                            |
| Data quality       | N. of records reporting serological markers <sup>a</sup>                                      | Total n. of reported cases              | %                            |
|                    | N. of cases in whom a specific diagnosis was possible   | Total n. of reported cases              | %                            |
|                    | N. of records reporting age   | Total n. of reported cases              | %                            |
|                    | N. of records reporting sex   | Total n. of reported cases              | %                            |
|                    | N. of records reporting city of residence   | Total n. of reported cases              | %                            |
|                    | N. of records reporting age, sex and city of residence  | Total n. of reported cases              | %                            |
|                    | N. of records of hepatitis A cases reporting risk factors <sup>b</sup> for infection          | N. of reported cases of hepatitis A     | %                            |
|                    | N. of records of hepatitis B cases reporting risk factors <sup>b</sup> for infection          | N. of reported cases of hepatitis B     | %                            |
|                    | N. of records of hepatitis C cases reporting risk factors <sup>b</sup> for infection          | N. of reported cases of hepatitis C     | %                            |
|                    | N. of records of hepatitis A cases with information on vaccination status                     | N. of reported cases of hepatitis A     | %                            |
|                    | N. of records of hepatitis B cases with information on vaccination status                     | N. of reported cases of hepatitis B     | %                            |
|                    | N. of records reporting outcome of infection  | Total n. of reported cases              | %                            |
| Timeliness         | N. of days between date of onset of symptoms and date of interview                            | N.A.                                    | median n. days (min; max)    |
|                    | N. of days between date of interview and date of reporting to the coordinating centre         | N.A.                                    | median n. of days (min; max) |
|                    | N. of days between date of serologic testing and date of reporting to the coordinating centre | N.A.                                    | median n. of days (min; max) |

N.A.: not applicable.

<sup>a</sup> IgM anti-HBc, HCV, IgM anti-HAV.

<sup>b</sup> Risk factors were distinguished according to the type of acute hepatitis. For HAV infections, the following risk factors were considered: eating raw or undercooked shellfish and travelling to countries where hepatitis A is common, in the previous six weeks. For HBC and HCV infections, the following risk factors were taken into consideration: surgical intervention or endoscopy, admission to hospital, intravenous drug use, tattooing and body piercing, haemodialysis, HBsAg or anti-HCV positive sexual partner, unprotected sex with occasional partners, in the previous six months; Results were reported separately for hepatitis A and B.

**Table 2 – Number of cases reported to the SEIEVA surveillance system for acute viral hepatitis, by year, geographical area and hepatitis type, Italy 2009–2012.**

| Number of cases          | Hepatitis type |      |     |           | Total |
|--------------------------|----------------|------|-----|-----------|-------|
|                          | A              | B    | C   | NonA-NonC |       |
|                          | 2106           | 1663 | 419 | 328       | 4516  |
| <b>Year</b>              |                |      |     |           |       |
| 2009                     | 990            | 478  | 106 | 93        | 1667  |
| 2010                     | 468            | 406  | 99  | 77        | 1050  |
| 2011                     | 313            | 421  | 110 | 86        | 930   |
| 2012                     | 335            | 358  | 104 | 72        | 869   |
| <b>Geographical area</b> |                |      |     |           |       |
| North                    | 1001           | 687  | 165 | 152       | 2005  |
| Centre                   | 883            | 890  | 206 | 143       | 2122  |
| South                    | 222            | 85   | 47  | 33        | 387   |

Data on vaccination status of patients was available for a high percentage of reported cases (97.1% for HAV vaccine and 95.1% for HBV vaccine); on the contrary, only 60.4% of cases reported information on early outcome. No significant differences were observed by year for these three indicators.

Information on date of onset of symptoms and date of interview was available for all cases. The median duration between the two dates was 16 days (range 0–355 days). The median duration between the interview and reporting to the central level was 79 days (range 0–1397 days) while that between serologic testing and reporting to the central level was 91 days (range 0–1276 days) (Table 3). All timeliness indicators show a significantly improving trend over the study period, in particular the median time from interview to reporting decreased by 45%.

Table 4 shows indicators stratified by geographical area. Statistically significant differences in representativeness were

observed between geographical areas and higher values were reported in central Italy, compared with other areas. Specifically, 94.4% of LHUs located in central Italy participate in SEIEVA while only 44.3% of southern LHUs participate. Information on age, sex, city of residence and risk factors for HAV was reported for over 90% of cases in all geographical areas. A significantly higher percentage of cases in central Italy, with respect to both northern and southern Italy, reported complete information on risk factors for HAV, HBV and HCV, HAV vaccination status, outcome of infection, serological markers, and diagnosis of a specific hepatitis type.

Statistically significant differences in timeliness were observed between geographical areas, with northern regions reporting in a more timely manner with respect to central and southern regions.

## Discussion

This study evaluated representativeness, data quality and timeliness of the SEIEVA surveillance system for acute viral hepatitis. Overall, level of participation in the system is high, especially considering that participation is voluntary, and indicates that collected data is sufficiently representative of the occurrence and distribution of acute viral hepatitis cases in the national population. However, significant differences were found between geographical areas and the number of participating LHUs in southern Italy needs to be increased.

The quality of data collected by SEIEVA is also high, and has improved over the four years examined. This is especially true for the completeness of data on age, sex, geographical location and risk factor information, and the possibility of diagnosing hepatitis type.

**Table 3 – Representativeness of data, data quality (percentage of reported cases with information on selected items or in whom a specific diagnosis was possible) and timeliness of the SEIEVA surveillance system for acute viral hepatitis, by year, Italy, 2009–2012.**

| Indicator                        | Year                  |              |              |            |            | P-value for trend |
|----------------------------------|-----------------------|--------------|--------------|------------|------------|-------------------|
|                                  | 2009–2012             | 2009         | 2010         | 2011       | 2012       |                   |
| <b>Representativeness (%)</b>    |                       |              |              |            |            |                   |
| Participating Local Health Units | 74.7 (aver.)          | 74.6         | 74.6         | 74.6       | 75.1       | ns                |
| <b>Data quality (%)</b>          |                       |              |              |            |            |                   |
| Serological markers              | 67.0                  | 68.3         | 65.6         | 65.4       | 68.1       | ns                |
| Diagnosis possible               | 96.2                  | 96.8         | 96.3         | 95.2       | 95.9       | ns                |
| Age                              | 99.8                  | 99.8         | 99.9         | 100        | 99.5       | ns                |
| Sex                              | 99.9                  | 99.9         | 100          | 99.9       | 99.8       | ns                |
| City of residence                | 95.5                  | 92.5         | 97.1         | 96.1       | 98.5       | <0.001            |
| Age, Sex, city of residence      | 95.2                  | 92.3         | 97.0         | 96.0       | 97.9       | <0.001            |
| Risk factors for HAV             | 97.2                  | 97.7         | 97.9         | 96.8       | 95.2       | 0.024             |
| Risk factors for HBV             | 83.2                  | 86.0         | 85.0         | 81.9       | 79.0       | 0.004             |
| Risk factors for HCV             | 82.5                  | 85.9         | 82.8         | 81.8       | 79.6       | ns                |
| Vaccination status HAV           | 97.1                  | 97.5         | 96.6         | 97.1       | 96.4       | ns                |
| Vaccination status HBV           | 95.1                  | 95.8         | 95.8         | 95.7       | 92.7       | ns                |
| Outcome of infection             | 60.4                  | 59.0         | 61.6         | 58.4       | 63.6       | ns                |
| <b>Timeliness (n. days)</b>      | <b>Median (range)</b> |              |              |            |            |                   |
| Onset of symptoms – interview    | 16 (0–355)            | 15 (0–355)   | 15.5 (0–350) | 18 (0–335) | 16 (0–340) | 0.009             |
| Interview – reporting            | 79 (0–1397)           | 118 (0–1397) | 65 (0–974)   | 66 (0–690) | 59 (0–501) | <0.001            |
| Serologic test – reporting       | 91 (0–1276)           | 131 (0–1276) | 76 (0–798)   | 79 (0–498) | 72 (0–480) | <0.001            |

ns = not statistically significant.

**Table 4 – Representativeness of data, data quality (percentage of reported cases with information on selected items or in whom a specific diagnosis was possible) and timeliness between surveillance steps, by geographical area. SEIEVA surveillance system for acute viral hepatitis, Italy 2009–2012.**

| Indicator                        | Geographical area     |            |               | P-value         |
|----------------------------------|-----------------------|------------|---------------|-----------------|
|                                  | North                 | Centre     | South/Islands |                 |
| <b>Representativeness (%)</b>    |                       |            |               |                 |
| Participating Local Health Units | 88.6                  | 91.4       | 44.3          | <0.001          |
| <b>Data quality (%)</b>          |                       |            |               |                 |
| Serological markers              | 61.5                  | 73.8       | 58.4          | <0.001          |
| Diagnosis possible               | 95.2                  | 97.6       | 93.3          | <0.001          |
| Age                              | 99.9                  | 99.8       | 99.5          | ns <sup>a</sup> |
| Sex                              | 99.9                  | 99.9       | 100           | ns <sup>a</sup> |
| City of residence                | 93.6                  | 97.1       | 96.4          | <0.001          |
| Age, sex, city of residence      | 93.5                  | 96.8       | 95.9          | <0.001          |
| Risk factors for HAV             | 96.9                  | 98.1       | 95.0          | 0.037           |
| Risk factors for HBV             | 81.5                  | 86.1       | 67.1          | <0.001          |
| Risk factors for HCV             | 81.8                  | 87.4       | 63.8          | 0.001           |
| Vaccination status HAV           | 96.4                  | 98.3       | 95.0          | 0.009           |
| Vaccination status HBV           | 94.0                  | 96.1       | 94.1          | ns <sup>a</sup> |
| Outcome of infection             | 43.7                  | 79.2       | 43.2          | <0.001          |
| <b>Timeliness (days)</b>         | <b>Median (range)</b> |            |               |                 |
| Diagnosis – interview            | 15 (0–350)            | 16 (0–340) | 16 (0–355)    | 0.013           |
| Interview – reporting            | 59 (0–874)            | 91 (0–893) | 217 (0–1397)  | <0.001          |
| Serologic test – reporting       | 74 (0–883)            | 98 (0–772) | 211 (7–1276)  | <0.001          |

<sup>a</sup> Fisher's Exact Test.

The percentage of cases with risk factor information was slightly lower for HBV and HCV cases with respect to HAV but this is to be expected since HBV and HCV risk factors involve sensitive data. The completeness of risk factor information showed a slightly decreasing trend over the examined period, indicating the need for informing LHUs of the importance of fully completing questionnaires.

Complete information on all serological markers was available for only 67% of cases but a specific diagnosis of hepatitis type was possible in 96%. This indicates that physicians, justifiably, do not always order the complete set of hepatitis markers but often request only those markers that will confirm their clinical suspicion. In this context, the percentage of reported cases in which a specific diagnosis of hepatitis type was possible is a more appropriate indicator for evaluating the quality of surveillance data, with respect to the availability of information on all serological markers.

Despite high data quality, the main limit encountered by SEIEVA was suboptimal timeliness between the different surveillance steps. Although wide delays were found between symptom and interview dates, the main problem seems to lie in the timeliness of reporting to the coordinating centre. Various authors have suggested that delays can be minimized by optimizing reporting procedures and by using fast communication methods such as electronic reporting.<sup>24–26</sup> Timeliness of reporting to SEIEVA has indeed improved with the introduction of web-based reporting in 2007 but there continue to be significant delays and the goal is to increase to 100% the percentage of LHUs reporting via web. Better communication with participating LHUs to increase awareness about the importance of timeliness, as well as improved feedback on surveillance data, may also contribute to reducing reporting delays.<sup>27,28</sup>

Dissemination of surveillance results also needs to be enhanced to improve system utility. This may be done by

preparing monthly or trimonthly reports with key surveillance data, rather than a yearly report.

Many published studies have evaluated infectious diseases surveillance systems,<sup>24,27,29–32</sup> but only a few focus on systems for the surveillance of viral hepatitis.<sup>33–35</sup> Overall, evaluations of acute viral hepatitis surveillance systems have shown levels of data quality comparable with SEIEVA but lower rates of laboratory confirmation of cases.<sup>33,34</sup> Evaluation of timeliness is not performed in a standardized manner so is not always comparable. The development of standardized measures of timeliness is needed.<sup>24</sup>

Lack of regular funding may have affected performance of SEIEVA. A study comparing the quality of data reported to the Centers for Disease Control and Prevention (CDC) from sites that received funding for acute viral hepatitis surveillance and sites that had electronic infrastructure to collect data but did not receive funding, showed that data was more complete and reported in a more timely manner in the funded sites with respect to the non-funded sites.<sup>33</sup> Data were compared for completeness of demographic and risk behavior/exposure information, adherence to case definition and timeliness of reporting.

### Study limits

This study is subject to one main limitation: sensitivity, or the proportion of cases of disease in the population that are detected by the surveillance system, could not be assessed because of the lack of an independent and more complete means of ascertainment (gold standard) to identify acute viral hepatitis cases in Italy. Measuring sensitivity will require an 'ad hoc' study.

In conclusion, this study highlights the importance of reporting timeliness to detect outbreaks of acute viral hepatitis. The SEIEVA surveillance system collects high quality data on acute viral hepatitis cases in Italy. However,

timeliness needs to be urgently improved by optimizing web-based reporting procedures, increasing communication and feedback with participating centres and increasing dissemination of surveillance results. Surveillance systems should be periodically evaluated and standardized measures of timeliness are needed.

## Author statements

### Acknowledgements

The authors thank the Members of the SEIEVA collaborating group:

L. Ferrigno, S. Crateri, G. Iantosca (Istituto Superiore di Sanità, Roma); L. Sudano, M. Ruffier (Regione Valle d'Aosta); J. Simeoni, M. Fischer, S. Gamper (Prov. Aut. Bolzano); V. Carraro, C. Grandi (ASL Prov. Aut. Trento, Trento); C. Zotti, S. Scoffone, S. Malaspina, A. Castella, A. Gallone, M.T. Galati, G. Valenza, V. Silano, G. Ara, M.G. Tacca, S. Iodice, A.M. Costantino, F. Giovanetti, A.M. Marchisio, F. Susani (Regione Piemonte); M. Binotto, Pincirolì G., Pesci L., Senegaglia P., S. Crippa, G. Altomonte, M.T. Rizzi, L. Boldori, P. De Grada, A. Gattinoni, M. Nieri, F. Sambo, S. Lodola, I. Aquino, C. Nespoli, A. Donadini, R. Brugnoli, A. Belloni, L. Pasquale, G. Piedacci, N. Castelli, E. Zecca (Regione Lombardia); F. Russo, F. Zanella, R. Mel, M. Soppelsa, M. Mazetto, A. Todescato, R. Zolin, N. Bacciolo, D. Rizzato, A. Pupo, L. Nicolardi, M. Flora, F. Boin, C. De Sisti, G. D'Ettore, V. Caracciolo, M.G. Penon, M. Bellè, L. Caffara, G. Zivelonghi, S. Soffritti, M. Foroni (Regione Veneto); F. Zorzut, G. Rocco, G. Brianti, T. Gallo, M. Zuliano, A. Breda, O. Feltrin (Regione Friuli Venezia Giulia); M. Mela (ASL Imperia), M.P. Briata, M. Giuliano, V. Turello, A. Opisso, G. Zoppi, P. Torracca, M.A. Ricci, A. Capellini (Regione Liguria); A.C. Finarelli, B.M. Borrini, C. Gualanduzzi, A. Capra, A.R. Sacchi, B.M. Borrini, G. Mattei, L. Gardenghi, A.R. Gianninoni, R. Sancini, E. Dalle Donne, R. Rangoni, M. Cova, L. Bevilacqua, E. Fiumana, B. Bondi, A. Pecci (Regione Emilia Romagna); L. Pecori, E. Balloccini, F. Mazzotta, G. Ghiselli, P. Marchini, A. Di Vito, W. Wanderlingh, E. Raso, F. Mazzoli, C. Berti, N. Galletti, E. Grandi, M.S. Ferrentino, M.G. Marinari, A. Lombardi, A. Barbieri, A. Bagnoli, M. Bandini, I. Lezzi, F. Verdelli, A. Beltrano, R. Bindi, C.M. Sansone, G. Boncompagni, F. Zucchini, S. Baretta, O. Baroncini, C. Staderini, P. Filidei, L. Chiapparini, F. Barghini, M. Cadoni (Regione Toscana); A. Tosti, G. Guaimo, A. Buscosi, A. Pasquale, C. Ciani, F. Santocchia, M.L. Proietti (Regione Umbria); G. Tagliavento, D. Fiacchini, N. Damiani, A.R. Pelliccioni, G. Peccerillo, A. Vaccaro, M.R. Spadoni, R. Rossini, F. Pasqualini, A. Priori, N. Burattini, S. Cimica, V. Vitale, F. Laici, F. Migliozi, G. Moretti, G. Ciarrocchi, S. Impulliti, C. Angelini (Regione Marche); A. Ercole, P. Russo, C. Cerocchi, P. Grillo, M. Loffredo, A. Pendenza, M.R. Nappi, P. Bueti, L. Santucci, F. Mangiagli, D. Varrenti, S. Aquilani, P. Dionette, D. Corpolongo, G. Di Luzio (Regione Lazio); F. D'Eugenio (Abruzzo); M.A. Ferrara, A. Citarella, E. Fossi, A. Parlato, R. Alfieri, M. Scotto (Regione Campania); M. Chironna, R. Prato, R. Matera, S. Menolascina, R. Colamaria, N. Azzollini, A. Madaro, G. Scalzo, A. Ancona, P. Pedote, G. Moffa, I. Pagano, R. Angelillis, M. Ferraro, V. Aprile, G.L. Turco, S. Minerba, G. Caputi (Regione Puglia); F.S. Negrone, M. Maldini, T. Russo (Regione Basilicata);

F. Aloia, S. Giuffrida (Regione Calabria); R. Mangione, R. Con-sacra, M. Cuccia, S. Rinnone (Regione Sicilia); F. Delogu, D. Fracasso, A. Saba, A. Puggioni, O. Frongia, M.V. Marras, M.G. Crasta, G. Mereu, G.C. Steri (Regione Sardegna).

### Ethical approval

Not required, analysis of routine surveillance data.

### Funding

None.

### Competing interests

None declared.

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