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Evaluation of hepatitis C surveillance in Poland in 1998

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SUMMARY

The aim was to evaluate hepatitis C surveillance in Poland during 1998. Hepatitis C reports were obtained from epidemiology offices. Public health staff were interviewed to collect information on surveillance operations. To estimate the proportion of acute cases among the total reported, a study was conducted in the Warsaw district to validate case reports. A total of 1661 (97·2%) hepatitis C cases were studied. Hepatitis C surveillance was timely and acceptable to the user, but did not provide a number of information elements required to differentiate acute from chronic cases of infection. Of the 268 case reports available in the Warsaw district, only 15 (5·6%) met the acute hepatitis C case definition. It is concluded that hepatitis C surveillance in Poland cannot provide useful incidence estimates and information regarding risk factors for acute infection. A strict case definition and a modified case form with specific questions for HCV transmission routes should be applied.

INTRODUCTION

Hepatitis C is increasingly recognized as an emerging public health issue in Poland (1998 population: 39 million). In 1988, the annual number of hepatitis C virus (HCV) infections was estimated to be 5000 (incidence 13·2/100000) for the country. This estimate, however, shows low reliability because it was based on test results of samples taken from 109 selected, HBsAg negative hospital patients with symptoms of hepatitis [1]. The prevalence of HCV infections in Poland was estimated to be 1·4% [2]. The estimate was based on prevalence data taken from published studies and/or data submitted to the WHO. To better direct prevention activities, it is important to estimate incidence rates and to identify risk factors for acute infection.

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Infectious disease surveillance was established in Poland by a 1963 law [3]. Surveillance is passive; requiring physicians, nurses, and other persons to report suspected cases to the local epidemiology office [4]. Following the addition of hepatitis C to the statutory surveillance system in Poland in 1997, 1709 cases of hepatitis C were reported in 1998 [5]. However, this surveillance system has not been evaluated and the quality of these data may have suffered from limitations, including limited sensitivity [6–11]. The purpose of this study was to evaluate the attributes of the hepatitis C surveillance system in Poland.

MATERIALS AND METHODS

Description of the system

We compared the theoretical and actual hepatitis C surveillance systems on the basis of (1) descriptions obtained from the original legal documents and (2)

interviews with public health and hospital staff. This information was organized into a flow chart. In addition, to examine the quality of the surveillance information, we reviewed records of hepatitis C cases reported in 1998 to the local epidemiology offices.

Evaluation of hepatitis C surveillance

Using the US Centers for Disease Control and Prevention guidelines [12] we evaluated the surveillance system's attributes, including simplicity, flexibility, acceptability, timeliness, and positive predictive value. Absence of data and logistic constraints did not allow an evaluation of sensitivity, representativeness, and costs [13]. The simplicity of the system's theoretical and actual organizational framework, case report forms, and data collection procedures was evaluated and described using a chart on the structure and the flow of information. To characterize the ability of the system to adapt to changing needs (flexibility), including the addition of new data-collection elements, we examined how users had adapted the old case report forms, designed before the discovery of HCV, to collect information on hepatitis C cases. To characterize the willingness of individuals to participate in the surveillance system (acceptability), we studied the completeness of the reporting form through calculation of the proportion of missing values. The capacity of the system to provide information early enough for decision-making (timeliness) was assessed by examining the time between date of diagnosis and report.

The positive predictive value of acute hepatitis C

To estimate the positive predictive value (PPV), the proportion of persons reported with hepatitis C who actually presented with acute hepatitis C, a study was conducted in the Warsaw district (1998 population: 2·4 million). Information obtained from case reports was supplemented using medical chart reviews. For this purpose, acute hepatitis C was defined as acute non-A, non-B hepatitis positive for antibodies to HCV (anti-HCV) or HCV PCR positive. Although the detection of anti-HCV has become a convenient tool to indicate past or present infection, its presence does not distinguish between acute, chronic, or resolved infection. There is currently no serological marker of acute HCV infection. Thus, this definition required the presence of three criteria: (1) the detection of anti-HCV by a serological assay or of HCV-RNA by PCR, (2) clinical or biological signs of acute hepatitis (i.e. jaundice or serum aspartate or alanine aminotransferases levels greater than 2·5 times the upper limit of normal), and (3) the absence of serological markers suggesting acute hepatitis A or acute hepatitis B, including IgM antibodies to hepatitis A virus (IgM anti-HAV), IgM antibodies to hepatitis B virus (IgM anti-HBc), and hepatitis B virus surface antigen (HBsAg).

Reported cases were divided into two groups on the basis of information on clinical and biological signs of acute hepatitis and the reported reason for hepatitis C serological testing.

The first group consisted of cases possibly related to acute hepatitis C infections for which a medical chart review was needed. This group included cases with clinical or biological signs of acute hepatitis (i.e. presence of jaundice, serum aminotransferase level 2·5 times greater than the upper limit of normal), cases for which no information was available on the case report to determine whether the patient presented with acute hepatitis, and cases for which the reason for hepatitis C serological testing was not available in the case report.

The second group consisted of cases for which sufficient information was available from the case report to indicate that the patient presented with chronic HCV infection. This group included cases without clinical or biological signs of acute hepatitis (i.e. absence of jaundice and serum aminotransferase level lower than 2·5 times the upper limit of normal) and cases for which the reason for hepatitis C serological testing typically indicated chronic HCV infections, including testing for routine screening purposes (e.g. prior to surgery, blood donation, on the patient's request, or during an annual occupational health visit), hospital admission for treatment of chronic sequelae of hepatitis or for liver biopsy, and cases with a diagnosis of hepatitis C infection made more than 6 months prior to the reported date.

RESULTS

Description of the system

Patients presenting with suspected infectious diseases were usually referred to infectious disease hospitals or to infectious diseases wards of acute care

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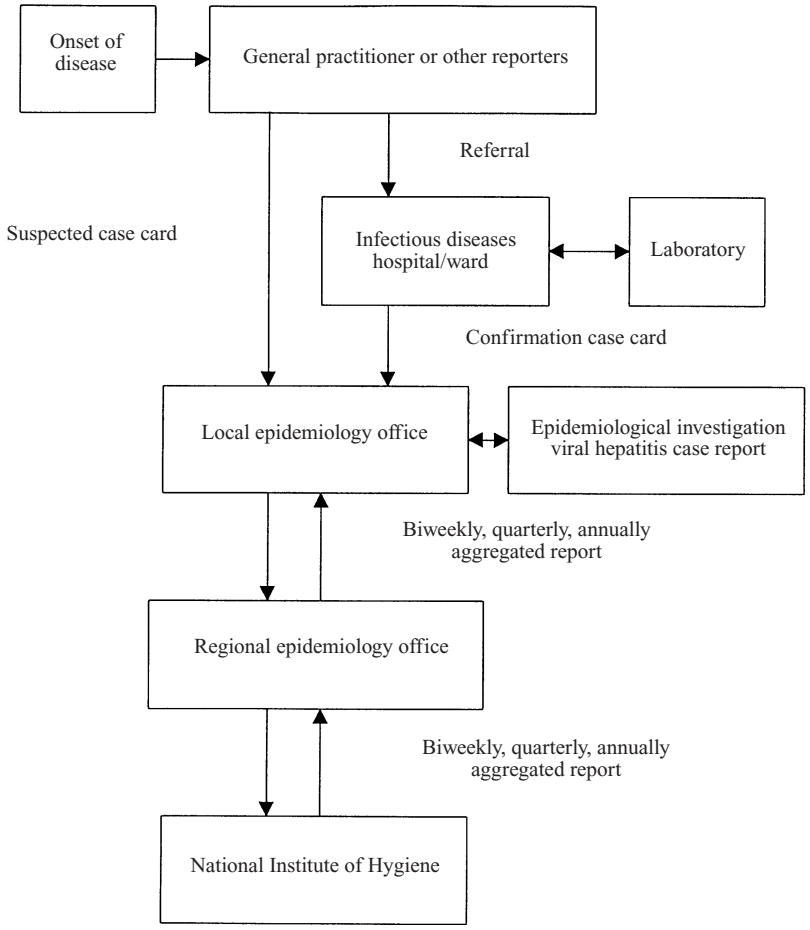

Fig. 1. The theoretical surveillance system of infectious diseases, Poland, 1998.

Table 1. *Characteristics of reported hepatitis C cases, Poland, 1998*

	All reported cases in Poland (n = 1661)				
	Males		Females		
Age group (years)	No.	%	No.	%	Total no.
< 5					
5–9	9	1·0	10	1·4	19
10–19	21	2·2	20	2·8	41
20–29	78	8·2	30	4·2	108
30–39	161	20·0	72	10·1	262
40–49	201	21·2	156	21·9	357
50–59	121	12·7	134	18·9	255
⩾ 60	167	17·6	204	28·7	371
Unknown	2	0·2	1	0·1	3
Total	950	57·2	711	42·8	1661

hospitals. On admission, healthcare workers completed a suspected case card and mailed it to the local epidemiology office. After diagnosis of hepatitis C, healthcare workers completed a case confirmation card and sent it to the local epidemiology office, and the public health worker interviewed the patient and filled out a case report (Fig. 1).

Of the 1709 cases of hepatitis C notified in Poland in 1998, 1661 (97·2%) case reports were available for review. The proportion of males was 57·2% and the

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median age was 44 years (range 0·7–100·8, Table 1). Among 1070 reports for which occupational information was available, 134 (12·5%) were from patients who were healthcare workers. Of 1661 reports that could be used for this analysis, 131 (7·9%; incidence 0·34/100000) included specific documentation that the patient presented with acute hepatitis C.

Evaluation of the system

Simplicity

Epidemiology office workers reported that filling out a case report usually took about 30 min, that they maintained a computer-based database of reports, but that they did not routinely analyse data. The data collection instrument used for viral hepatitis cases was created to distinguish only between type B and not-B as determined by the presence or absence of HBsAg in the blood of the patient. The case report form has 60 variables grouped in 4 pages and 5 sections. Information collected includes demographic data, clinical data, potential risk factors in the 6 months prior to illness, place of residence, and secondary prevention measures. Examination of the case report form showed that while many items were irrelevant for determination of acute hepatitis C infection (e.g. questions concerning the patient's residence – number of household members, number of rooms and beds, water supply system, sewage system, toilet), a number of critical ones were not requested. There were no questions about laboratory and serological test results (serum aminotransferase and bilirubin levels, anti-HBc IgM, and anti-HAV IgM) and other known risk factors, including administration of illegal drugs by injection, having dialysis or kidney transplant, sexual relations with someone of the same sex, and percutaneous exposures (ear piercing, tattooing, acupuncture, needle stick, shots, etc.).

Flexibility

Review of the case report form indicated that in addition to information recorded on standardized items, results of tests for the presence of anti-HCV or HCV-RNA by PCR also often were provided, despite the absence of specific spaces for recording that information. Other information occasionally provided on the report, but not specifically requested, included circumstances of serological testing, aminotransferase levels, vaccination and blood donation records, dates of surgical procedures, and history of injection drug use.

Acceptability

Acceptability was evaluated through examination of the completeness of reports. Sixty questions were analysed. The median proportion of missing values was 11·9% (quartiles 2·8%, 19·9%; range 0–96·6%). HBsAg, anti-HBc IgM, anti-HAV IgM, and anti-HCV test results were reported in 938 (56·5%), 90 (5·4%), 90 (5·4%) cases, and 1465 (88·2%) cases, respectively.

Timeliness

A total of 802 reports presented with available, non-aberrant diagnoses and reporting dates that could be analysed to evaluate timeliness. The median time between diagnosis and reporting was 7 days (range 0–575 days).

Positive predictive value

Of the 270 hepatitis C cases reported in 1998 in the Warsaw district, 268 (99·3%) were available for review. The two that could not be reviewed were inaccessible because of ongoing legal procedures. Of the 268 reports, 140 (52·2%) were assumed to represent cases of chronic HCV infection on the basis of information on the case report form, including miscellaneous reasons to test an asymptomatic person ($n = 82$), admission for treatment or liver biopsy ($n = 20$), and diagnosis in the past ($n = 38$).

One hundred and twenty-eight cases considered to potentially represent cases of acute hepatitis C were validated with medical chart reviews. Criteria prompting a medical chart review included clinical or biological signs unknown or suggesting acute hepatitis (e.g. presence of jaundice, serum aminotransferase level greater than 2·5 times the upper limit of normal) ($n = 40$), and unknown reason for serological testing ($n = 88$).

Out of 128 case reports selected for medical chart review, 92 (71·9%) could be linked with a medical chart that could be studied. Of these, 57 (62·0%) did not contain sufficient information to allow determination of whether or not the patient presented with acute hepatitis C. Information that was missing to determine acute or chronic status included anti-HCV or PCR test results ($n = 5$), HAV IgM test results

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Table 2. *Characteristic of acute hepatitis C cases, Warsaw District, 1998*

Characteristics	Cases identified as acute hepatitis C (no. = 15)	
	No.	%
Age group (years)		
< 5	0	0·0
5–9	0	0·0
10–19	0	0·0
20–29	4	26·7
30–39	0	0·0
40–49	5	33·3
50–59	2	13·3
⩾ 60	4	26·7
Unknown	0	0·0
Gender		
Male	7	46·7
Female	8	53·3
Occupation		
Health care		
Physician	1	6·7
Nurse	0	0·0
Lab technician	0	0·0
Other	0	0·0
Other	8	53·3
Missing	6	40·0
Injections or percutaneous exposure	6	40·0
in outpatient' clinic	1	6·7
in hospital	6	40·0
in nursing home	0	0·0
Transfusion of blood or blood products	0	0·0
Surgery	3	20·0
Dental work	5	33·3
Injection drug use	2	13·3
Unknown	5	33·3

($n = 31$), HBV serological test results ($n = 2$), HBV and HAV serological test results ($n = 5$), and biological signs of acute hepatitis ($n = 14$).

Thus, of the 268 overall cases that could be analysed, 15 (5·6%; incidence 0·63/100000) met the case definition for acute hepatitis C, 156 (58·2%) were chronic HCV infections, 2 (0·8%) were HCV infections in patients presenting with acute HAV infection, 2 (0·8%) were HCV infections in patients presenting with acute HBV infection, and 93 (34·6%) lacked sufficient information to determine acuity.

Among the 15 cases identified with acute hepatitis C, 7 (46·7%) were men and the median age was 46·5 years (range 20·3–67·0 years). Of the nine cases for whom information was available, one (11·1%) was a healthcare worker (Table 2). Potential exposures reported in the 6 months preceding illness included receiving injections in a hospital ($n = 6$, 40·0%), undergoing a dental procedure ($n = 5$, 33·3%), undergoing a surgical procedure ($n = 3$, 20·0%), and reporting injecting drug use ($n = 2$, 13·3%). None of the cases reported transfusions of blood or blood products, although no potential exposure was reported for five (33·3%) cases (Table 2).

DISCUSSION

Hepatitis C surveillance is a part of the Polish national infectious disease surveillance system. The second year of implementation provided a good opportunity for early identification of strengths and areas that could be improved or needed alteration. Our evaluation indicated that hepatitis C reporting was overwhelmed with chronic HCV infection reporting that

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could not be differentiated from acute HCV infections on the basis of the information available, since critical information was not collected. Thus, the system could not provide useful incidence estimates and could not provide information regarding risk factors for acute infection. When we were able to differentiate acute from chronic infection cases in Warsaw, the analysis of reported exposures suggested that healthcare-related exposure may represent a major source of new HCV infections. This route is consistent with previous Polish reports [14–16] and is compatible with information reported from other Eastern European countries [17].

Our evaluation indicated that hepatitis C surveillance in Poland has several strengths. Analysis of the data collected and information gained from interviews with epidemiology office staff indicated that the data instrument was acceptable to the users. It had been used in a flexible fashion as new information regarding HCV infection was added by staff even though the form had not been adapted for hepatitis C surveillance. Case reports were filled out appropriately and transmitted efficiently. In addition, a median interval of 7 days between diagnosis and reporting indicated satisfactory timeliness.

Despite these strengths, hepatitis C surveillance suffered from a number of weaknesses that limited the usefulness of the information routinely collected. First, the instrument used for collecting data, although long and containing many data items, was not designed to collect information to distinguish between acute and chronic hepatitis C infection. Our validation study conducted in the Warsaw district indicated that most cases of hepatitis C captured by the system were cases of chronic infection and that only about 5·6% may represented acute HCV infections. Critical information that was missing from the data collection instrument included serological test results (anti-HAV IgM, anti-HBc IgM, HBsAg) and clinical as well as biological signs of acute hepatitis. Availability of this information would have allowed differentiating cases of acute hepatitis C from cases of acute hepatitis A, acute hepatitis B, and various co-infections. A second weakness of the system was the limited reliability of information regarding potential risk factors. No systematic information was collected regarding important risk factors for HCV infection, including undergoing chronic hemodialysis, having received a kidney transplant, injection drug use, and other percutaneous exposures.

Our evaluation of hepatitis C surveillance in Poland suffered from a number of limitations. Because of logistic constraints, we did not evaluate the sensitivity, representativeness, and cost of hepatitis C surveillance. Although (1) a law currently requires that all patients with acute hepatitis be hospitalized in Poland and (2) hospitalized patients are usually reported it cannot be assumed that the sensitivity of the system is high. That problem needs further evaluation. The calculated time interval between diagnosis and reporting may have been inaccurate. Examination of dates provided on the reports indicated that dates were often inconsistent. Only about half of them were sequential and could be analysed. Another limitation is that reported risk factors for acquisition of acute hepatitis C could not be compared with a control group. Thus, the 15 acute hepatitis cases for which we reported potential sources of infections cannot be conclusively attributed to these sources of infection. Finally, a number of medical charts were not reviewed. However, among those that were not reviewed, the probability of capturing cases of acute hepatitis C cases was likely to be very low. First, liver biopsy is not a common way of identifying a recent HCV infection [18]. Second, several studies have shown that asymptomatic blood donors positive for anti-HCV most often have chronic HCV infection or have recovered [19, 20]. Third, asymptomatic or only mildly symptomatic patients identified through systematic screening prior to surgical procedures, during annual occupational health visits, or on their request usually are in the chronic stage of disease [18].

Two recommendations were proposed to increase the usefulness of hepatitis C surveillance in Poland as a result of this study. First, the accuracy of acute hepatitis C reporting could be improved through improving the quality of data collected. A revised data collection instrument along with training of physicians and public health employees would achieve that goal. A revised case report form should facilitate proper classification of cases and epidemiological analysis. Boxes should be added for the type and the severity of viral hepatitis, as well as additional space for aminotransferases, results of serological tests (e.g. PCR, anti-HCV, anti-HBc IgM, anti-HAV IgM), and other known risk factors. Second, it is necessary to conduct ongoing analysis of data to identify acute cases and risk factors.

Besides recommendations to improve hepatitis C surveillance, results of this study suggested that healthcare exposure might account for a high proportion of new cases of HCV infection in Poland. This

finding should be confirmed in analytical studies (e.g. case control studies). However, in the meantime, a review of the implementation of universal precautions should be conducted in Poland to identify potential breaks in infection control practices and prevent nosocomial acquisition of bloodborne pathogens.

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