EVALUATION OF HEPATITIS A SURVEILLANCE DATA AND OUTBREAK DETECTION IN YUNNAN PROVINCE, CHINA, FROM 2004 THROUGH 2009

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Abstract. Hepatitis A outbreaks may be averted if detected early. The current study objectives were to evaluate the quality and timeliness of hepatitis A surveillance data from Yunnan Province, China, and to evaluate the sensitivity of the system for reporting outbreaks. The study period was from January 1, 2004 through December 31, 2009. Records from the National Infectious Diseases Surveillance System (NIDSS) were compared with those from local hospitals. The timeliness of case detecting, reporting and updating was also analyzed. The numbers of cases in a specific location during a moving time interval were computed to identify past outbreaks which were then validated against reported cases. The NIDSS received 38,095 reports during the study period; of which 6% were duplicates, and 26% had serological confirmation. The sensitivity and positive predictive value of cases were 96% and 98%, respectively. Time from onset to diagnosis remained constant over the 6-year period. Delays in reporting became shorter, and quality control of data improved over the period, but the timeliness of identifying duplicate records did not. Based on data from NIDSS, 9 outbreaks should have been reported, but only 3 were reported. The 3 reported outbreaks were shorter in duration than the 6 unreported ones, but the numbers of cases involved were not significantly different. Surveillance data needs improvement in updating timeliness. The system for outbreak detection and reporting needs to be improved.

Keywords: hepatitis A, surveillance evaluation, sensitivity, positive predictive value, timeliness, outbreak detection

INTRODUCTION

Hepatitis A is a widespread acute illness caused by infection with the hepatitis A virus (HAV), a nonenveloped ribonucleic acid (RNA) picornavirus that infects only primates. The disease varies in clinical severity from a mild illness that lasts 1-2 weeks, to a severely disabling disease that lasts several months. Clinical manifestations of hepatitis A include fever, malaise, anorexia, nausea, and abdominal discomfort, followed within a few days by jaundice. Prolonged, relapsing hepatitis for up to one year occurs

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in 15% of cases; no chronic infection is known to occur. The disease is spread primarily through ingestion of food or water that has been contaminated with the fecal matter of someone who is infected or through close, personal contact (WHO, 2000; Cuthbert, 2001; Klevens *et al*, 2008; CDC, 2010).

Even with improvement in sanitation and the use of vaccination (since 1995) have lowered the incidence of hepatitis A in the last 20 years it still causes a high disease burden and is considered a public health problem in both developed and developing countries. Over the first decade of the 21st century, outbreaks of hepatitis A occurred in many countries worldwide, including the United States of America (Wheeler *et al*, 2005), England (Edelstein *et al*, 2010), Australia (Lee *et al*, 2004; Rowe *et al*, 2009), and Spain (Syed *et al*, 2003; Arce *et al*, 2004; Tortajada *et al*, 2009).

In China, hepatitis A is a serious public health problem. In 1988, 47 deaths (case-fatality rate of 0.015%) were reported in a large epidemic in Shanghai, China, which involved more than 300,000 adolescents and young adults (Cooksley, 2000). Serum IgG positive prevalence among the general population has been reported to be as high as 81% in China (Xiao *et al*, 2007). From 1990 to 1999, more than 200,000 cases (incidence rate $>17/10^5$ population) have been reported annually. From 2000 to 2007, the reported incidence rate declined from 10.8 to $5.9/10^5$ population. The China Centers for Diseases Control and Prevention (CDC) categorizes all provinces of mainland China into three strata: high ($>8/10^5$ population/year), intermediate ($4\text{-}8/10^5$ population/year), or low incidence ($<4/10^5$ population/year). Yunnan, where this study was conducted, is one of the 10 high-incidence provinces (Cui *et al*, 2009).

Mass post-exposure vaccination to contain the spread of HAV in established outbreaks has been proven to be efficacious in curbing emerging epidemics (Delpech *et al*, 2000; Arce *et al*, 2004, 2007; Shen *et al*, 2008; Diaz *et al*, 2010; Edelstein *et al*, 2010). The World Health Organization (WHO), the Advisory Committee on Immunization Practices (ACIP) of the USA (Fiore *et al*, 2006), and the Ministry of Health of China (Wang, 2006) have recommended mass hepatitis A vaccination to interrupt outbreaks at an early stage.

In China, hepatitis A has been included in the Notifiable Infectious Disease Surveillance System (NIDSS) since 1990. In 2004, an online, real-time reporting system was established (Wang *et al*, 2008). At 93% of hospitals and 66% of township health centers (in 2006), 18 terms of specific information (including age, sex, address, occupation, onset date, diagnosis date) about suspected or confirmed cases are collected with a standard structured card and entered into the NIDSS within 24 hours of diagnosis (Ma *et al*, 2006). County-level CDCs then check the information, delete duplicates, and confirm the report through the NIDSS within another 24 hours. Duplicate records are identified by comparing name, age, onset date, and diagnosis. If the NIDSS is unavailable, health centers or hospitals will fax the paper card to county-level CDCs to perform the entering process. Upper-level CDCs can view the database and results of the format-structured analysis online and retrieve the database for further analysis. If five or more cases occur in one village within one week, the county government will announce an outbreak. Immediate responses include active case finding, case administration and treatment, mass vaccination, improving sanitation, and endorsement of health education. The event information is reported through another online real-time outbreak report system that is linked to NIDSS.

The objectives of this study were to evaluate the validity, quality, and timeliness of hepatitis A surveillance data, and to evaluate the system's sensitivity in reporting outbreaks in Yunnan Province based on the analysis of NIDSS data. These are necessary components to trigger reliable outbreak announcements and subsequent control and prevention measures.

MATERIALS AND METHODS

Study setting

Yunnan is a province in southwestern China with a population of almost 45 million. It has 16 prefectures containing 129 counties.

This study was divided into three parts. The first part involved the use of a field investigation to compare the validity and quality of data from the online surveillance system with that of the medical records. The second part was based on analysis of the online surveillance system data to evaluate the timeliness. In the third part, the outbreaks reported through the outbreak surveillance system were compared with the outbreaks detected through the NIDSS.

Validity and quality of surveillance data

An evaluation of the validity of a surveillance system generally includes two measurements: sensitivity and positive predictive value (PVP) (German *et al*, 2001; Buehler *et al*, 2004). Sensitivity refers to the probability that an actual case has been correctly reported. PVP refers to the probability that a person reported as a case actually is a case. Data quality refers to the proportion of consistent data values in the surveillance system compared to the "true" values from relevant medical records (German *et al*, 2001; Buehler *et al*, 2004; Porta, 2008). Since hepatitis A is a seasonal disease in China (Cui *et al*, 2009), we studied the cases that occurred in June and December during each year from 2004 to 2009, to represent high and low incidence months.

Six counties were randomly selected as study sites. In each selected county, the county hospital and two randomly chosen township health centers that had previously reported hepatitis A were used. Information from medical records (inpatient records and outpatient log books) was treated as the gold standard for evaluating surveillance information.

According to Chinese national diagnostic criteria, hepatitis A is classified into probable or confirmed (Ministry of Health of China, 2008). A probable case is defined as any acute illness with discrete onset of symptoms compatible with hepatitis A (*eg*, fever, weakness, and digestive tract symptoms, such as anorexia, nausea, jaundice, bilirubin in the urine), elevated serum aminotransferase levels, with evidence that links this probable case with a confirmed case or outbreak. A confirmed case was defined as any probable case testing positive for anti-HAV IgM (in the absence of recent vaccination) or a 4-fold rise in specific IgG antibody. Acute hepatitis without laboratory confirmation but associated with an outbreak was defined as unclassified viral hepatitis. All probable, confirmed, and unclassified cases must be reported through the NIDSS.

In our study, cases of hepatitis A (confirmed and probable) in the data base were evaluated regardless of whether they were laboratory confirmed, or diagnosed as probable, unclassified, or not a real

Table 1
Sumbols for number of cases classified by type of report and diagnosis, Yunnan Province, China, 2004-2009.

	Confirmed hepatitis A	Probable hepatitis A	Unclassified hepatitis[a]	Non-hepatitis A (other type of hepatitis)	Total
Reported as confirmed hepatitis A	a	b	c	d	P
Reported as probable hepatitis A	e	f	g	h	Q
Reported as hepatitis unclassified [a]	i	j	-	-	-
Did not report as hepatitis A	k	l	-	-	-
Total	M	N	-	-	-

[a] The third column denotes negative result for reported case checking. The total number was not used for calculations.
To evaluate the surveillance system, sensitivity is the ability of the surveillance system to identify true cases, and PVP is the proportion of cases reported by a surveillance system that are true cases. Thus, we used the following formulas:

Total sensitivity = (a+b+e+f)/(M+N)x100%
Sensitivity for confirmed cases = a/Mx100%
Total PVP = (a+b+e+f)/(P+Q)x100%
PVP for confirmed cases = a/Px100%

case. Data from these cases were evaluated for sensitivity and PVP (Table 1). We also checked the onset date, diagnosis date, and report date from the NIDSS data base compared to information from the medical record.

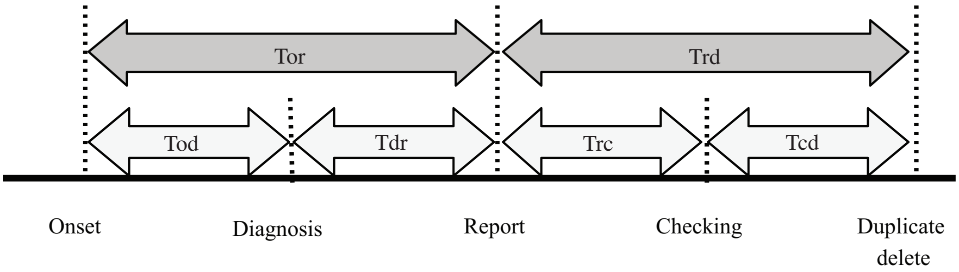
Timeliness of hepatitis A surveillance

Specific case information for 2004 - 2009 was retrieved from the NIDSS computer system. Nine variables for specific cases, including index number, gender, age, address, onset date, diagnosis date, report date, checking date, and deletion date of duplicate cases were obtained for use in evaluation of timeliness. There were five time points during the process of case reporting: onset, diagnosis, report, check, and duplicate case deletion. Six intervals were introduced as illustrated in Fig 1 where the time intervals are assigned abbreviations that were defined and used for the results.

An estimated 30-day incubation period for hepatitis A was used for this study as a surrogate measure for the period of communicability (Cuthbert, 2001; Klevens *et al*, 2008). This period is critical for considering when to implement effective prevention and control measures (Jajosky and Groseclose, 2004). To assess whether data from the NIDSS support the timely identification of an outbreak, the percentage of NIDSS cases reported during one incubation period was calculated.

Outbreak report and detection

Reported outbreaks were obtained from the Yunnan CDC, which received its reports from the county CDC office. For analyzing of the NIDSS data set, a probable outbreak was defined as an occurrence of hepatitis A in one township during any continuous 30-day period in 2009 greater than the baseline calculated as the mean plus two times the standard deviation of



Tor, time interval from onset to report; Tdr, time interval from diagnosis to report; Tod, time interval from onset to diagnosis; Trc, time interval from report to information checking; Tcd, time interval from information checking to duplication deletion; Trd, time interval from report to duplication deletion.

Fig 1–Time points and intervals during case reporting procedures, Yunnan Province, China, 2004-2009.

the number of cases that occurred in the same area and the same time period in each of the years 2004 - 2008 (Yang *et al*, 2004). Probable outbreaks were then scrutinized by a panel of experts, which included epidemiologists and medical specialists (Buehler *et al*, 2004). Finally, six attributes were given to each identified outbreak: specified place of outbreak, date outbreak started, date outbreak peaked, date outbreak stopped, number of cases involved in the outbreak, and occupation of most victims.

RESULTS

Incidence and diagnosis of hepatitis A

From January 1, 2004 to December 31, 2009, a total of 38,095 cases were reported to the NIDSS in Yunnan Province (Table 2). The numbers of reported cases rose from 2004 to 2007 and declined during subsequent years. The proportion of duplicate records ranged from 6% to 9%, mainly due to the fact that some patients were seen at more than one hospital. The proportion of laboratory-confirmed cases varied from 16% to 33%. These levels are much lower than the national average of 52%.

Sensitivity and positive predictive value for case detection, and validity of reporting value

Table 3 displays cross-classification between data from the report (row) and from the NIDSS (column) at the 6 selected county hospitals and 12 selected township health centers. The inconsistency between the two sources was minor. NIDSS had a sensitivity of 96% and a positive predictive value of 98%.

Of 136 confirmed and probable cases, 130 (96%) had consistant information about onset date and diagnosis date with medical record and 118 (87%) had consistant date of report.

Timeliness of surveillance

Table 4 summarizes variation in the six types of time intervals defined in Fig 1. The time interval from onset to diagnosis (Tod) remained quite constant over the 6-year period, whereas the time interval from diagnosis to report (Tdr), time interval from onset to report (Tor), and time interval from report to checking (Trc) continued to improve, and the time interval from checking to duplicate deletion (Tcd) and time interval from report

Table 2
Diagnosed and reported cases of hepatitis A, Yunnan Province, China, 2004-2009.

Year	No. of cases reported	Percent with duplicate records	Percent confirmed by laboratory
2004	5,780	6.5	26.3
2005	6,228	6.7	32.9
2006	7,565	6.7	30.0
2007	8,104	7.4	24.4
2008	5,969	8.6	20.5
2009	4,448	8.0	15.9
Total	37,095	6.1	25.6

Table 3
Number of cases reported or diagnosed as hepatitis A in six counties of Yunnan Province, China, during June and December, 2004-2009.

	Confirmed hepatitis A	Probable hepatitis A	Unclassified hepatitis	Non-hepatitis A (other type of hepatitis)	Total
Reported as confirmed hepatitis A	38	2	0	1	41
Reported as probable hepatitis A	5	88	2	0	95
Reported as hepatitis unclassified	0	0	-	-	-
Did not report as hepatitis A	0	6	-	-	-
Total	43	96	-	-	-

Sensitivity = (38+5+2+88)/ (38+5+2+88+6) = 95.7%
Positive predictive value = (38+5+2+88)/ (38+5+2+88+1+2) = 97.8%

to duplicate deletion (Trd) did not show any specific trend.

Outbreak report and detection

Table 5 lists the hepatitis A outbreaks in Yunnan Province in 2009. Nine outbreaks were identified from NIDSS historical data; however, only three of these were actually reported. The numbers of reported probable or confirmed cases in the three reported outbreaks were 31, 41 and 12. Thirty more cases were detected in the NIDSS for the second outbreak, making this the largest outbreak (71 cases) in this series.

The three reported outbreaks were announced 3-10 days after the number of cases peaked. In response, the local government performed control measures, such as case management, mass vaccination, and health education. The outbreaks stopped within two incubation periods.

All three reported outbreaks were confirmed in, and confined to, schools, whereas four of the six unreported outbreaks also involved persons in the community. However, the proportion of

Table 4
Timeliness of hepatitis A surveillance, Yunnan Province, China, 2004-2009.

Type of time interval	Year						Total
	2004	2005	2006	2007	2008	2009	
No. of cases reported[a]	5,780	6,228	7,565	8,104	5,969	4,448	37,095
Percent confirmed by laboratory	26.3	32.9	30.0	24.4	20.5	15.9	25.6%
Tod (from onset to diagnosis)							
Median (days)	6	6	6	6	6	5	6
IQR(days)[b]	3-9	3-9	3-9	3-9	3-9	2-9	3-9
Tdr (from diagnosis to report)							
Median (days)	2	1	1	1	0	0	1
IQR (days)	1-7	0-2	0-1	0-1	0-1	0-1	0-1
% within 1 day[c]	42.7	66.3	76.8	86.7	95.8	99.9	77.7
Tor (from onset to report)							
Median (days)	10	8	7	7	6	6	7
IQR(days)	6-18	4-12	4-11	4-11	3-9	3-9	4-11
% within 1 incubation period[d]	89.0	93.4	95.8	96.7	96.7	97.6	94.9
Trc (from report to checking)							
Median (days)	0	0	0	0	0	0	0
IQR(days)	0-1	0-1	0-1	0-0	0-0	0-0	0-1
% within 1 day[c]	88.0	86.5	89.7	95.1	98.9	100	92.7
No. of duplicate cases reported	377	417	504	603	515	356	2,272
Tcd (from checking to delete)							
Median (days)	2	4	4	5	2	1.5	3
IQR (days)	0-27	1-16	1-20	1-19	0-10	0-7	0-14
Trd (from report to delete)							
Median (days)	3	5	5	5	3	2	4
IQR(days)	0-28	1-16	1-20	1-19	1-10	1-7	1-15

[a] Including duplicate cases; [b] IQR, interquartile range; [c] Nation stated time limit; [d] 30 days (According to Control of Communicable Diseases Manual, 19th ed).

reported and unreported outbreaks was not significantly different (Fisher's exact test, p=0.167). The unreported outbreaks appeared to last longer (rank-sum test, p=0.038) but were not significantly different from reported outbreaks in terms of number of cases (rank-sum test, p=0.89) and time from onset to reporting (rank-sum test, p=0.824) of involved cases.

DISCUSSION

Early detection of hepatitis A outbreaks may assist in the control of further spread of the disease because they can be stopped by effective vaccination programs (Arce *et al*, 2007; Xiao *et al*, 2007; Shen *et al*, 2008; Cui *et al*, 2009). For further studies of the performance of prospective outbreak detection, it is necessary to evaluate data from surveillance both for individual cases and outbreaks (German *et al*, 2001; Buehler *et al*, 2004).

In our study, duplicate reports of hepatitis A cases were not uncommon.

Table 5
List of outbreaks of hepatitis A reported and detected from Yunnan Province, China, 2009.

ID [a]	Extent of outbreak [a]	Date outbreak starts	Date outbreak peaks	Date outbreak ends	Date outbreak announced	Duration of outbreak (days)	Number of cases involved	Median (IQR) of cases [b]
Reported outbreak								5 (4, 8) [c]
No.1	S	Mar 23	Mar 28	Apr 5	Apr 1	18	31	5 (3,7.8)
No.2	S	Apr 16	May 1	Jun 18	May 8	63	71	5 (4,7.5)
No.3	S	Oct 12	Oct 20	Nov 2	Oct 30	27	12	7 (5,8)
Unreported outbreak								6 (4, 8) [c]
No.4	S+C	Apr 17	Apr 30	Jul 17	-	91	58	5 (1.2,7)
No.5	S+C	Apr 19	Jun 2	Jul 28	-	100	40	5 (4,7)
No.6	S	Apr 20	Jul 1	Jul 10	-	81	18	7.5 (5.2,11)
No.7	S+C	May 1	May 27	Jul 13	-	74	40	7 (4.8,12)
No.8	S+C	May 5	Jul 27	Sep 5	-	123	43	4 (3,6)
No.9	S	Jun 4	Jun 16	Aug 5	-	63	26	6 (5,8)

[a] S, school; C, community
[b] Time interval in days from date of onset to date of report calculated from timeliness of outbreak-associated cases
[c] Not statistically significant using the rank-sum test, p=0.824

Laboratory confirmation was obtained in fewer than one-third of reported cases. Sensitivity and positive predictive value for case notification were both >95%. The timeliness of notification improved over time, but the timeliness for deleting duplicate records did not. Nine outbreaks were detected from analysis of NIDSS data, but only three of them were reported to the system. All nine outbreaks involved schools. Unreported outbreaks lasted longer, but did not involve more cases than reported outbreaks. Although not all the outbreaks involving the community were reported, the number of outbreaks was too small to test whether a report not in the system was associated with involvement of the community.

Undeleted duplicate records included in a recent data set may increase the probability of an outbreak being falsely detected. Duplicate records are difficult to avoid because patients are free to seek medical service anywhere they wish, and each time they visit a hospital a report must be made to the surveillance system. However, the complicated process of deleting duplicate reports involves a significant amount of work and subjective judgment (Hu *et al*, 2008; Huang *et al*, 2010). Surveillance systems in some countries assign a unique number for each person to avoid duplicate reports (German *et al*, 2001). We suggest a unique identification number, such as a health insurance number should be used to distinguish patients with the same name, date of birth, and other attributes.

Serologic diagnosis can be clinically useful because different types of hepatitis have different prognoses and complication patterns. From a descriptive epidemiological point of view, hepatitis A and E are water- and food-borne, whereas types B and C are transmitted by blood and other body fluids (Cuthbert, 2001; Sharapov and Hu, 2010). Vaccines are currently available for types A and B but not for types C, D, and E (CDC, 2010). However, during routine surveillance, hepatitis is difficult to divide into specific types of virus based only on clinical presentation (Sharapov and Hu, 2010). Lack of diagnostic facilities and limited patient finances were the main reasons for a low proportion of laboratory confirmed diagnoses for other diseases in China (Xu *et al*, 2010). For hepatitis A, if serologic confirmation is required, the patient must pay 10 Yuan (USD 1.5) more for their medical examination (Yunnan Provincial Health Bureau, 2005). Health financial reform is needed if these data are to be obtained.

Sensitivity and PVP are the most important validity measurements for a surveillance system and for outbreak detection. False-positive reports can lead to unnecessary interventions and subsequent false outbreak reports (German *et al*, 2001). Specificity and negative predictive value cannot be defined because the number of true negatives has not yet been clearly defined. Compared with hepatitis A surveillance in other countries or regions, such as in Taiwan (32%) and Italy (79.4%), mainland China's surveillance system has a higher sensitivity (Lopalco *et al*, 2002; Hsieh *et al*, 2009).

With the Chinese reporting system, Tdr, but not Tod, improved over the six years of the study. This difference was probably due to the fact the Tod was based partly on the patient's promptness in seeking health care and partly on the ability of the health system to diagnose the case in a timely manner (Jajosky and Groseclose, 2004; Yoo *et al*, 2009). The Tod for hepatitis A has not improved, whereas the Tdr improved continuously. This discrepancy indicates improvement in the surveillance data was more on the health service side than on the community side. The challenge is how to shorten Tcd and Trd, which reflect the health service side (Huang *et al*, 2010).

Our study shows reported outbreaks were of shorter duration but do not involve fewer cases than unreported outbreaks. A shorter outbreak is easier to confirm and is more likely to be reported. The absence of a report leads to less intense intervention and may allow the outbreak to last longer. All the reported outbreaks were followed by mass vaccination for hepatitis A in schools and communities. It is difficult to judge whether the vaccine or other measures stopped the outbreaks. The cost-benefit of the mass vaccination also needs further study.

Our study found students are a high-risk group for hepatitis A since all the outbreaks we evaluated were closely related to schools. An earlier country-wide study reported the same pattern. About a half (49%) of outbreaks occurred in schools during 2004 - 2007 (Cui *et al*, 2009). This may be explained by the high population density, close contact, and other risk-generating behaviors found among the school pupils (WHO, 2000; Cuthbert, 2001; Roberts and Palmer, 2006; Pelletier *et al*, 2010). School health education has been found useful for reducing the occurrence of hepatitis in several outbreak investigations (Leoni *et al*, 1998; Marks *et al*, 2001). Further studies to predict outbreaks among school pupils are needed.

Our study was based on NIDSS data, which is more complete than surveillances in the past which only reported cases monthly (Wang *et al*, 2008). The data demonstrate the size of the outbreak and the way to report them. One study limitation was assuming the logbook was the gold standard. However, with such a low percentage of laboratory-confirmed cases of hepatitis A and a lack of laboratory confirmation in the medical records, there may be unreported cases.

In conclusion, using the medical logbook as a gold standard, the sensitivity and specificity of hepatitis A cases in NIDSS were high. However, duplicate records were not uncommon, and the percent of cases with laboratory confirmation was less than 30%. Two-thirds of the outbreaks were not reported. This needs further improvement.

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