Evaluation of National Tsutsugamushi Disease Surveillance—Japan, 2000

Epidemiological Report

INTRODUCTION

Tsutsugamushi disease (scrub typhus or mite-borne typhus fever) is caused by *Orientia tsutsugamushi*, which is transmitted by the bite of infected mites. This disease has an incubation period of 6-21 days (1). Although person-to-person transmission has not been documented, infection by contaminated blood products is possible; such transmission can be minimized by predonation screening and treatment of blood products (2). In endemic areas, “typhus islands” exist, some of which cover an area of only a few square meters, where rickettsiae, tick vectors, and suitable rodent hosts exist simultaneously (1).

During the 1950s, almost 100 cases of Tsutsugamushi disease were reported annually from several prefectures in the northern part of Japan during the summer, and during the 1960s and 1970s, almost 10 cases were reported annually. Since the 1980s, Tsutsugamushi disease has re-emerged in Japan. This re-emergence is attributed mostly to newly discovered strains of *O. tsutsugamushi* (3). Most cases in humans occur in rural areas, and the endemic regions have expanded to all prefectures except Hokkaido and Okinawa. In southern Japan, most cases have been reported during late fall to winter, whereas in northern Japan (Tohoku and Hokuriku Districts), most cases have been reported in spring, fall, and winter (3).

Tsutsugamushi disease has an incubation period of up to 3 weeks and is often characterized by an escar, or a primary “punched out” skin ulcer, corresponding to the site of attachment of an infected mite, followed by an acute febrile illness with headache, profuse sweating, and lymphadenopathy. Late in the first week of fever, a dull red maculopapular rash usually appears. Disseminated intravascular coagulation (DIC) can occur if diagnosis or treatment are delayed. The case-fatality rate (CFR) in untreated patients is 1%-60%, depending on the strain of rickettsia and previous exposure to the pathogen, and is consistently higher among older patients (1). Tsutsugamushi disease can be treated effectively with tetracyclines or doxycycline (4,5).

Diagnosis can be confirmed through serologic testing, isolation of the infectious agent by inoculating the patient’s blood into mice, or detection of genetic material of the organisms (i.e., by the polymerase chain reaction [PCR] method) in blood (1). Commercial laboratories routinely test for relatively few strains of *O. tsutsugamushi*. Although prefectural laboratories may be able to test for additional strains, new strains likely will continue to be discovered (6). In addition, serologic tests may not detect all cases of a known strain (7).

Despite its widespread endemicity, the focal transmission of the disease allows for highly targeted prevention in high-risk areas. Transmission can be minimized through health education of residents in or travelers to high-risk areas, recommending that they wear repellant- or insecticide-
impregnated clothes, limiting access to endemic areas, or taking other appropriate prophylactic measures (8). Physicians must be made aware of this disease to facilitate timely diagnosis and appropriate treatment of cases, especially in endemic areas and during high transmission season.

Tsutsugamushi disease surveillance has been conducted in Japan since 1950, and the surveillance system was revised in April 1999 (9). The purpose of this study was to analyze the data from the newly implemented system and to evaluate the system itself.

MATERIALS AND METHODS

Surveillance system: Surveillance for Tsutsugamushi disease is integrated in category IV (i.e., reporting only, no restriction of patient activity) of the national surveillance system under the Infectious Diseases Control Law. One reporting form is used for all 33 notifiable diseases in this category to collect the following information: age; sex; clinical symptoms; laboratory findings; dates of illness onset, first medical consultation, diagnosis, and death; country of residence during the “last few years”; suspected mode, date and country of transmission; outdoor activities and chance of contact with vector; and household contacts to the case-patient with the same symptoms.

Physicians are required to report cases within 7 days of diagnosis and to submit the reporting form to the local health centers, which will transmit the data to the Infectious Disease Surveillance Center (IDSC) of the National Institute of Infectious Diseases (NIID) through the secure online system WISH Net (Wide-area Information-exchange System of the Health, Labour and Welfare Administration Network) via the prefectural infectious disease surveillance centers (PIDSCs). The numbers of cases are posted weekly for each prefecture by date of diagnosis on the IDSC Web site (http://idsc.nih.go.jp/index.html). Although no adjustments for delayed or deleted reports are made in the weekly published data, delayed reports are included in and deleted cases are excluded from the final yearly summary data.

Case definition: A case-patient is defined as a person living in Japan and having at least one of the following symptoms or signs: general fatigue, loss of appetite, headache, chills, fever, lymph node swelling, and rash or punched-out skin ulcer at the site of attachment of an infected mite, in addition to laboratory confirmation of O. tsutsugamushi organism by one of the following tests: isolation or identification of the organisms in blood, PCR, or serologic testing (i.e., detection of serum IgM level or fourfold rise in antibody titer) (10).

Data source and analysis: We analyzed the surveillance data confirmed by each prefecture (i.e., cases diagnosed during the 52-week period of January 3 through December 31, 2000) (11) to calculate national and prefectural-specific incidence rates and CFR. We used the chi-square test to compare expected with observed proportions. We also assessed the completeness of reporting and the quality of data and evaluated the system according to the CDC guidelines for evaluating surveillance systems (12) (see Appendix for description of system attributes).

RESULTS

Description of surveillance data: In 2000, 756 cases were reported from 37 of 47 prefectures (11). The overall annual incidence rate was 6.0/1,000,000, ranging from 0.7 to 75.6/1,000,000 in the 37 prefectures that reported cases (Table 1). Only two fatal cases were reported (CFR: 0.3%). The median age of case-patients was 64 years (range: 2-94 years), and 414 (54.8%) were male. In the Kanto District, 90 (66.2%) of the 136 case-patients were male compared with 324 (52.3%) of 620 in the other districts (P = 0.003).

For 116 (15.3%) of the cases, laboratory confirmation was missing. In addition to mandatory reporting items, information about the strain of O. tsutsugamushi was provided for 247 (38.6%) of the 640 laboratory-confirmed cases.

In northern Japan, most cases were diagnosed in the months of May through July and in the months of October through December, whereas in southern Japan, cases were diagnosed almost year-round with a peak during October through

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<th>Prefecture</th>
<th>Number of cases</th>
<th>Total population (million)</th>
<th>Incidence (million/year)</th>
<th>Rank by incidence</th>
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Evaluation of Tsutsugamushi disease surveillance:

<Objectives>

Although no specific objectives for Tsutsugamushi disease surveillance are provided in the Infectious Diseases Control Law, the overall objectives for the notifiable disease surveillance system are as follows: “Promoting effective and accurate infectious disease control measures by reinforcing and expanding the conventional surveillance system, restructuring the computer-network system to obtain, analyze, and quickly publish the information on a nationwide scale, and conducting active surveillance (9).”

<Usefulness>

The system is useful for describing the basic epidemiology of Tsutsugamushi disease (e.g., providing case counts by demographic characteristics, geographic area, and time), and thus can help monitor disease patterns and trends. However, it does not collect sufficient information to assess possible risk factors (e.g., activity performed at the suspected place of transmission), and because no follow-up information on prognosis is collected, this system cannot be used to adequately estimate related morbidity or mortality.

<Simplicity>

The surveillance system for Tsutsugamushi disease is not simple, because it requires laboratory confirmation and several data reporting and transmission steps. The collection of laboratory information may delay reporting, because laboratory confirmation is needed and commercial or prefectural laboratories must report the results back to the physician. Physicians also need to ask patients for supplementary information (e.g., area of residence during the last few years and whether the patient knows persons with the same symptoms) to complete the reporting form. After confirmation of diagnosis, the physician submits the case-report form to the local health center, where the data are entered into an electronic database, which then is electronically transmitted to the PIDSC. In some prefectures, the case-report form is transferred to the PIDSC, where it is entered into the database before being transmitted to the IDSC.

Japan has only one surveillance system for all notifiable diseases and only one reporting form for all category-IV diseases, which facilitates reporting for Tsutsugamushi disease. The analyzed surveillance data are reported weekly through the IDSC Web site.

<Predictive Value Positive>

The predictive value positive (PVP) has not yet been fully assessed. However, because our surveillance data include both suspected and confirmed cases, we can calculate a crude estimate. If all 116 (15.3%) cases without laboratory confirmation were classified as non-cases and all laboratory-confirmed were true cases, the PVP would be 84.7% ([756-116] / 756).

<Completeness>

Age, sex, and dates of first consultation and diagnosis were reported for all cases. However, the date of illness onset was missing for 30 (4.0%) and the date of suspected transmission was missing for 310 (41.0%) of the reported cases. In addition,
two entries for date of illness and 13 entries for suspected
date of infection were invalid (e.g., the date of consultation
preceded the date of illness onset). Whether these dates were
entered incorrectly by the reporting physician or transcribed
incorrectly into the database could not be assessed.

**<Timeliness>**
Cases were reported a median of 3 days (range: 0-108 days)
after diagnosis, and 590 (78.0%) of the cases were reported
to the local health center within 7 days as required by law, but
only 405 cases (53.6% of the total cases and 68.6% of the 590)
were included in the weekly surveillance summaries of the
Infectious Diseases Weekly Report (IDWR) on the IDSC Web
site (13) (Fig. 2). The reasons for the delayed transmission of
these 185 reported cases are not known; possible explana-
tions are that the forms did not reach the local health centers
in time or the data were not promptly entered.

**<Representativeness>**
The weekly summaries may not be representative of the
real epidemiology of the disease, because nearly half of the
cases are reported late and not included in the weekly data. In
addition, surveillance data are presented by date of diagnosis,
and because delay exists between the onset of symptoms and
diagnosis, a graph of the latter is shifted several weeks to the
right of a graph of the dates of the former (Fig. 3).

**<Flexibility, Sensitivity, and Acceptability>**
The flexibility, sensitivity, and acceptability of the system
have not yet been determined.

**DISCUSSION**
The 756 cases of Tsutsugamushi disease reported in 2000
represent a 43.8% increase over the average number of cases
reported during the 5-year period of 1994-1998, but are lower
than the peak of 957 cases reported in 1984 (14). Assessing
how much of the recent increase reflects a true increase in
disease incidence, improved diagnostic facilities, and/or
improved reporting under the 1999 Infectious Diseases Control
Law is difficult. Possible reasons for an increased incidence
may be associated with increases in infected mite popula-
tions or dissemination of infected mites, which would lead to
increased opportunities for exposure of humans to infected
vectors (15). In addition, a change in drug-use policy may
have increased the likelihood of infected persons being
diagnosed during and after the 1970s. In the 1970s, chloram-
phenicol and oral tetracyclines, which are effective against
*O. tsutsugamushi*, were replaced by penicillins and cepha-
lorosporins as first line drugs for febrile illnesses of unknown
origin. Thus, formerly undiagnosed cases of Tsutsugamushi
disease, which would successfully have been treated by
chloramphenicol or oral tetracyclines before the 1970s, would
not have responded to untargeted antimicrobial therapy after
this period (15,16), increasing the likelihood of a specific
diagnosis. During the past 50 years, an important change in
the natural history and transmission of Tsutsugamushi disease
likely occurred in Japan that may have contributed to some
of this apparent increase in the number of clinical cases.
Changes in the seasonal occurrence and geographic expansion
of the disease may be attributable, in part, to the emergence
of new strains of Tsutsugamushi disease infecting other
species of mites (3).

From 1969 to 1990, the number of prefectures in Japan
classified as endemic areas increased substantially. The
number of endemic areas expanded from 2 of 46 prefectures
(i.e., Niigata and Akita Prefectures [14]) in 1969 to 38 of 48
prefectures in 1990. Since 1969, no cases have been reported
from the southern part of Okinawa Prefecture and the northern
part of Hokkaido (except one imported case in 1993 [3]).
During the 1950s-1970s, almost all cases were reported during
the summer; however, for the last 20 years, the transmission
season has changed for the Tohoku and Hokuriku Districts in
northern Japan, with most cases now being diagnosed in
spring, fall, and winter (3). In the newly endemic areas in the
southern parts of Japan (including the Kanto District), most
cases are diagnosed during late fall to winter (3).

Surveillance data are presented on IDSC Web site accord-
ting to the date of diagnosis. However, the need for laboratory
confirmation leads to a further delay in diagnosis after symptom onset. Displaying the data by date of illness onset would more accurately reflect the seasonality of the disease, because this date is closer to the time of transmission and may enable more targeted interventions.

As surveillance for Tsutsugamushi disease continues to improve after implementation of the 1999 Infectious Diseases Control Law, estimates of disease occurrence will become increasingly reliable, as will estimates of temporal trends and geographic patterns of the disease. These improved data may provide insights into the changing seasonal patterns and expanding endemic areas. However, several improvements should be considered to strengthen the present surveillance system. For example, the current case definition for surveillance is not applied uniformly; e.g., 15% of suspected cases without laboratory confirmation in 2000 were reported by physicians and accepted at all levels of the system (of note, the reporting of suspected cases to the local health center is useful for timely detection of potential outbreaks). The inclusion of both non-laboratory-confirmed and laboratory-confirmed cases may lead to an underestimate of the true number of cases. However, because reporting in most surveillance systems is incomplete, the total number of reported cases might still be an underestimate of the true number of cases of Tsutsugamushi disease. Thus, changes in temporal trends may be difficult to interpret if they are caused by changes in the proportion of confirmed and unconfirmed cases. Finally, establishing specific objectives for Tsutsugamushi disease surveillance may improve reporting by better motivating physicians to report cases and to submit complete report forms.

In some instances, laboratory confirmation for cases may be difficult or impossible to obtain, because commercial laboratories test only for the most common strains, and not all strains may have been detected (6). The information about specific strains may be useful to assess the public health impact of Tsutsugamushi disease, because the clinical severity of a case may be associated with the strain type (17). Collection of information about antibody titers would also be useful to distinguish initial from recurrent infections. However, the section regarding laboratory information on the reporting form is not designed to collect this or other additional information.

Present laboratory tests can only identify a limited number of Tsutsugamushi disease strains, leading to an underestimate of the true number of cases. However, laboratory confirmation for all cases may not be needed, especially in endemic areas. By using the current case definition, the number of cases of Tsutsugamushi disease in Japan is likely being underestimated.

Within the current system, reporting additional information about cases after the initial reporting is not feasible, making accurate assessment of the disease impact (e.g., CFR) impossible. More detailed information about the place of transmission, activity performed there, or the case-patient’s profession would be helpful to better identify possible outbreaks and initiate their investigation. This information would also be helpful to assess possible risk factors for transmission. Research from Oita Prefecture showed that *O. tsutsugamushi* was present even in areas without reported transmission to humans (15). The reason why transmission to humans occurs in some areas but not in others is unknown. If information could be collected on the suspected place of transmission, we might be able to better assess risk factors for transmission. Finally, the report form does not allow for entering “unknown” values for variables, which means that blanks could currently reflect either incomplete reporting or unknown data.

The 1999 Infectious Diseases Control Law currently does not specify who is responsible for data quality. Clarification about this issue may help improve the validity and reliability of case information. Currently, both physicians and local health-center staff should attempt to adhere to the currently published case definition. Also, for preparation of weekly and other surveillance analyses, confirmed and unconfirmed cases should be presented separately.

Effective and timely feedback of surveillance data is important to motivate persons who report and to enable those responsible for taking appropriate public health actions based on the findings. Although the dissemination of the data through the Internet allows for quick and widespread distribution of findings, determining to what extent the data are used by physicians and public health officials will be important.

**CONCLUSIONS**

The current system for Tsutsugamushi disease surveillance is useful for describing epidemiologic patterns by time, prefecture, and demographic characteristics, and therefore should be continued. This system may be useful for planning prevention activities and allocating public health resources, for generating hypotheses about risk factors, and for detecting some outbreaks of Tsutsugamushi disease. However, collection of additional information would likely make the system more valuable for outbreak detection and related public health functions. Such information might help better determine in which areas of Japan Tsutsugamushi disease is endemic. It may also help to explain why the number of Tsutsugamushi disease cases has increased during the last 20 years (e.g., through emergence of new strains of Tsutsugamushi disease) and may help better determine who is at greatest risk for infection or for fatal disease. Although the reporting of surveillance information from health centers to IDSC and the Ministry of Health, Labour and Welfare through the PIDSCs is timely, the completeness and quality of data could be improved.

**RECOMMENDATIONS**

Our evaluation findings suggest recommendations to strengthen the usefulness and quality of the Tsutsugamushi disease surveillance system in the following two areas: improving case reporting and enhancing the usefulness of reported data for making public health decisions.

Improving nationwide detection and reporting of cases requires the support of health-care providers, who are responsible for such reporting. Increasing the education of treating physicians about their legal responsibility to report cases within 7 days of diagnosis according to the 1999 Infectious Diseases Control Law will be important, as will dissemination of the case definition and instructions for its appropriate use to reporting physicians as well as local health center, city, prefectural and national infectious disease surveillance center staff. At the same time, dissemination of the reporting obligations will provide an opportunity to discuss the responsibility for and assurances of confidentiality of patient data during its transfer throughout the reporting cycle.

Perhaps as important will be the development of specific Tsutsugamushi disease surveillance-system objectives by the Ministry of Health, Labour and Welfare to increase under-
standing of the importance of collecting surveillance data, and thus to increase the acceptability of such data collection to physicians. If treating physicians and other surveillance-system participants are aware of the importance of the data and are convinced that it will be used for detecting and investigating outbreaks, assessing high-risk populations, and prevention activities, they likely will be encouraged to report cases to the system. Another important aspect of improving the usefulness of the system to public health partners is the continuous improvement of the quality and contents of the data collected on the disease reporting form. Currently, no specific person or group is responsible for ensuring the accuracy and completeness of data reported to the system, either at the local or national level. Therefore, clarifying rules to ensure data quality and determining who is responsible for maintaining this quality are crucial. Within the reporting form and electronic reporting system, several quality-control features could be easily implemented. For example, the current reporting form does not allow us to distinguish whether variables that are left “blank” signify that the data value is unknown to the physicians or that they simply did not report the value. Because these two situations lead to different actions for data analyses and for the need to further follow-up with the reporting physician for clarifying information, the term “unknown” should be included as a possible answer on the data form. Finally, adding an electronic module to the database that would automatically check the consistency of variables during data entry (e.g., that the date of diagnosis follows the date of exposure) would be useful.

Another way to improve data quality is to consider improving the currently used case definition, e.g., by including both clinically suspected cases (with an epidemiologic link to a confirmed case or an endemic location) and laboratory confirmed cases. Analysis then could be done for both groups separately and combined. In addition to improving the quality of the data, improving and expanding the reporting items on the current form would also improve the usefulness of surveillance-system information. For example, a better understanding of disease transmission would be gained by including variables to assess the suspected place of transmission as well as the activity involved in transmission (e.g., professional or recreational activity). Collecting information about the strain of *O. tsutsugamushi* and antibody titer in patients would also help to better characterize the epidemiology of the disease.

To minimize reporting burden for the physician, variables of questionable reliability or usefulness (e.g., area of residence during the last few years) could be deleted. Adding revised data relating to the death of a case-patient would allow for better understanding of the relative morbidity and mortality of the disease (including the calculation of CFR), but may also require additional follow-up time and resources. However, the needs of the other diseases under surveillance in category IV should also be taken into account.

One of the most important ways of improving the value of surveillance data is to ensure that such data are regularly used as information for public health action. Therefore, it would be of great value to assess and strengthen how these data are regularly disseminated to and used by constituencies at every level for planning, prevention, and other public health activities. Thus, regular analysis and dissemination of data by region and other key characteristics by NIID, as well as developing innovative analyses (e.g., by date of illness and date of diagnosis) and sharing results with partners at the local level may be among the best ways to strengthen the Tsutsugamushi disease surveillance system.

**APPENDIX**

Description of system attributes.

- **Usefulness** is assessed by describing the actions that have been taken as a result of the data from the surveillance system.
- **Simplicity** is assessed by looking both at the structure and ease of operation of the surveillance system.
- **Predictive Value Positive** (PVP) is the proportion of persons identified as having cases who actually do have the condition under surveillance.
- **Completeness** is assessed by examining the percentage of reporting forms for which information was provided for a specified variable.
- **Timeliness** is determined by the speed (or delay) between steps in a surveillance system.
- **Representativeness** is assessed by how accurately the data reflect the actual occurrence of a health event over time and the distribution in the population by place and person.
- **Flexibility** is judged retrospectively by observing how well a system responded to a new demand (e.g., to collect additional information about a disease).
- **Sensitivity** is assessed by the proportion of cases of a disease detected by the surveillance system and the ability to detect epidemics.
- **Acceptability** is assessed by the willingness of individuals and organizations to participate in the surveillance system.

**REFERENCES**

11. Ministry of Health, Labour and Welfare and National Institute of Infectious Diseases (2001): Infectious Disease Surveillance Data in Japan 1999/4-2000/12. (This summary was made as CD-ROM file and distributed to the public health authorities. This CD is not for on sale.)