22-ID-06

Committee: Infectious Disease

Title: Revision of Public Health Reporting and Timeframes for National Notification for Animal Rabies

☑ Check this box if this position statement is an update to an existing standardized surveillance case definition and include the most recent position statement number here: 09-ID-12.1

Synopsis: This position statement updates the animal rabies case definition through the addition of new laboratory criteria and updating reporting variables and timeframes for significant animal rabies events, as required for international reporting. Animal rabies should continue to be nationally notifiable.

I. Statement of the Problem

Animal rabies has been nationally notifiable since 1944. The last revision to the case definition was implemented in 2010. Since that time, new laboratory diagnostic tests have been developed to detect rabies virus in animal specimens. In addition, CDC is obligated to notify international entities, including the World Organisation for Animal Health (WOAH) and the World Health Organization (WHO), of significant animal rabies events in real time. This position statement updates the case definition to reflect the new laboratory diagnostic options and adds new reporting variables and timeframes needed to comply with international notifications required by WOAH and WHO. Clarification of the minimum data elements to be included in the notification to CDC are included in Appendix 1 to increase completeness of notification by jurisdictions.

II. Background and Justification

Rabies virus infection results in an acute, progressive, and fatal encephalitis in humans and mammals. Although all mammals are susceptible to rabies virus infection, there are multiple species-specific variants of the virus, which have adapted to certain species that serve as viral reservoirs. These species-specific variants are transmitted primarily between members of the same species and, with the exception of bats, occur in geographically distinct regions. The primary reservoir species in the United States (U.S.) are bats (throughout the 49 continental states), raccoons (endemic on the Eastern seaboard), striped skunks (North Central, South Central, Southwest States and California), gray foxes and arctic foxes (Southwest States and Alaska), and mongooses (Puerto Rico).

Reported rabies cases among domestic animals declined in the U.S. with the introduction of animal control and vaccination programs in the 1940s and 1950s, which led to the elimination of the canine variant rabies in the U.S. in 2007. Wild animals have accounted for over 90% of animal rabies cases since 1991.

The collection and reporting of animal rabies data is crucially important for multiple reasons. Public health testing and surveillance testing are used to monitor the epizootiology of animal rabies and provide critical information about human and animal exposure risk. Testing, combined with risk assessment, informs recommendations for life-saving human rabies post-exposure prophylaxis (PEP), booster vaccination in eligible animal species, and euthanasia recommendations for unvaccinated animals. The information from routine data collection, reporting, and notification of animal cases is especially critical for informing appropriate public health and animal management actions when the exposing animal cannot be tested. More than four million Americans are bitten by an animal each year, and the vast majority are able to avoid the expense of PEP as a result of the routine reporting and notification of rabies data that informs PEP and animal management risk assessments. In addition, monitoring animal data over time can be used to inform, direct, and evaluate interventions such as oral rabies vaccination programs, pet rabies vaccination clinics, and educational campaigns.

In addition to laboratory diagnostic tests used to detect rabies virus in animal specimens, molecular and antigenic testing methods can be used to further characterize the virus variant type and its geographic origin. This additional testing and notification of viral characterization results are used to identify major events or shifts in enzootic activity.
III. Statement of the desired action(s) to be taken

CSTE recommends the following actions:

1. Implement a standardized surveillance case definition for animal rabies
   A. Utilize standard sources (e.g., reporting*) for case ascertainment for animal rabies. Surveillance for animal rabies should use the recommended sources of data to the extent of coverage presented in Section V.
   B. Utilize standardized criteria for case ascertainment for animal rabies presented in Section VI and Table VI in Technical Supplement.
   C. Utilize standardized criteria for case classification for animal rabies presented in Section VII and Table VII in Technical Supplement.

2. Utilize standardized criteria for case ascertainment and classification (based on Sections VI and VII and Technical Supplement) for animal rabies and update animal rabies on the Nationally Notifiable Condition List
   - Immediately notifiable, extremely urgent (within 4 hours)
   - Immediately notifiable, urgent (within 24 hours)
   - Immediate (urgent) notification of animal rabies to CDC under the following circumstance in order to comply with international reporting requirements:
     - The detection of a case of rabies or non-rabies lyssavirus occurring in an animal imported from outside the continental U.S. within the previous 365 days, unless variant testing identifies a variant known to circulate in the U.S.
     - The detection of a rabies virus variant or non-rabies lyssavirus in a new geographic area as determined by the state or jurisdiction.
     - The identification of sustained transmission of any rabies virus variant or non-rabies lyssavirus among animals of a previously unrecognized reservoir species for that virus or virus variant.
   - See Appendix 2 for additional information to assist with identification of cases meeting criteria for immediate notification to CDC.
   - Routinely notifiable
     - Routine (standard) notification of positive and negative animal rabies test results to CDC for all other situations that do not meet the above criteria for immediate notification. Routine notification should occur no less frequently than monthly.
     - Negative results from certain laboratory tests (direct fluorescent antibody, direct rapid immunohistochemical (dRIT), immunohistochemistry (IHC) on formalin-fixed tissues and pan-lyssavirus real-time RT-PCR) should also be included in the notification.
   - No longer notifiable

3. CSTE recommends that all States and Territories enact laws (statute or rule/regulation as appropriate) to make this disease or condition reportable in their jurisdiction. Jurisdictions (e.g., States and Territories) conducting surveillance (according to these methods) should submit case notifications** to CDC.

4. Expectations for Message Mapping Guide (MMG) development for a newly notifiable condition: the National Notifiable Diseases Surveillance System (NNDSS) is transitioning to HL7-based messages for case notifications; the specifications for these messages are presented in MMGs. When CSTE recommends a new condition be made nationally notifiable, CDC must obtain Office of Management and Budget...
Paperwork Reduction Act (OMB PRA) approval prior to accepting case notifications for the new condition. Under anticipated timelines, notification using the Generic V2 MMG would support transmission of the basic demographic and epidemiologic information common to all cases and could begin with the new MMWR year following the CSTE annual conference. Input from CDC programs and CSTE would prioritize development of a disease-specific MMG for the new condition among other conditions waiting for MMGs.

5. CDC should publish data on animal rabies as appropriate (see Section IX). CSTE recommends the following case statuses be included in the CDC Print Criteria:

☒ Confirmed
☐ Probable
☐ Suspect
☐ Unknown

6. CSTE recommends that all jurisdictions (e.g., States, Localities, or Territories) with legal authority to conduct public health surveillance follow the recommended methods outlined in this standardized surveillance position statement.

7. CDC should develop a standardized case report form to assist jurisdictions with collecting all appropriate information for specific scenarios.

8. CDC should submit aggregate national counts of reports of cases of animal rabies to WHO annually and WOAH-required notifications as needed per international reporting regulations.

*Reporting: process of a healthcare provider or other entity submitting a report (case information) of a condition under public health surveillance to local, state, or territorial public health.
**Notification: process of a local or state public health authority submitting a report (case information) of a condition on the Nationally Notifiable Conditions List to CDC.

IV. Goals of Surveillance

The goals of surveillance are (1) to collect standardized animal rabies data to monitor the temporal, geographic, and demographic occurrence of cases in a timely manner to facilitate prevention and control and (2) to comply with international notification requirements.

V. Methods for Surveillance: Surveillance for animal rabies should use the recommended sources of data and the extent of coverage listed in Table V.

The majority of animal rabies cases are identified through testing at public health, and federal and state agriculture laboratories. Cases are identified as part of passive public health surveillance or through enhanced surveillance activities. They may occasionally be identified through comprehensive diagnostic testing of animals initially not suspected of being rabid. Surveillance for animal rabies should use the sources of data and the extent of coverage listed in Table V.

<table>
<thead>
<tr>
<th>Source of data for case ascertainment</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Population-wide</td>
</tr>
<tr>
<td>Clinician reporting</td>
<td>X</td>
</tr>
<tr>
<td>Laboratory reporting</td>
<td>X</td>
</tr>
<tr>
<td>Reporting by other entities (e.g., hospitals, veterinarians, pharmacies, poison centers), specify: veterinarians, biologists, United States Department of Agriculture and other federal and jurisdictional wildlife agencies</td>
<td>X</td>
</tr>
<tr>
<td>Death certificates</td>
<td>X</td>
</tr>
<tr>
<td>Data Source</td>
<td>Note</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Hospital discharge or outpatient</td>
<td></td>
</tr>
<tr>
<td>records</td>
<td></td>
</tr>
<tr>
<td>Data from electronic medical records</td>
<td></td>
</tr>
<tr>
<td>Telephone survey</td>
<td></td>
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<tr>
<td>School-based survey</td>
<td></td>
</tr>
<tr>
<td>Other, specify: N/A</td>
<td></td>
</tr>
</tbody>
</table>

**VI. Criteria for case ascertainment**

**A. Narrative: A description of suggested criteria for case ascertainment of a specific condition.**

**A1. Clinical Criteria for Reporting**

N/A

**A2. Laboratory Criteria for Reporting**

Report all results, positive, negative or unsatisfactory/inconclusive
- Any rabies virus direct fluorescent antibody test; OR
- Any rabies virus direct rapid immunohistochemical test (dRIT); OR
- Any rabies virus test by immunohistochemistry (IHC) on formalin-fixed tissue; OR
- Any pan-lyssavirus probe-based real time reverse transcription-polymerase chain reaction (RT-PCR) test.

Report positive results only
- Detection of lyssavirus nucleic acid by genomic sequencing; OR
- Isolation of rabies virus (in cell culture or in a laboratory animal).

*While central nervous system (CNS) tissue is most commonly tested and is the preferred tissue type for ruling out a rabies virus or non-rabies lyssavirus infection, identification of rabies virus or a non-rabies lyssavirus in any tissue or body fluid provides evidence of infection.*

**A3. Epidemiologic Linkage Criteria for Reporting**

N/A

**B. Disease-specific data elements to be included in the initial report**

For Rabies Positive Animals Meeting Criteria for Immediate International Notification AND For Animals Tested for Rabies and Meeting Criteria for Routine Notification

Species (to the Genus species level)

Location of Animal
- County and State AND
  - At least one of the following location data types:
    1. Latitude/Longitude; OR
    2. Street Address, and City; OR
    3. Zip Code

Type of laboratory test

Date of test

Test result

Rabies virus variant (if known for positive animals)

See Appendix 1 for full list of data elements required to be sent with notification to CDC. The additional data elements included in the appendix are generally collected through case investigation following the initial report to the jurisdiction.
VII. Case Definition for Case Classification

A. Narrative: Description of criteria to determine how a case should be classified.

A1. Clinical Criteria
N/A

A2. Laboratory Criteria*

Confirmatory laboratory evidence:
- A positive rabies virus direct fluorescent antibody test; OR
- A positive rabies virus direct rapid immunohistochemical test (dRIT); OR
- A positive rabies virus test by immunohistochemistry (IHC) on formalin-fixed tissue; OR
- A positive pan-lyssavirus probe-based real time reverse transcription-polymerase chain reaction RT-PCR test; OR
- Detection of lyssavirus nucleic acid by genomic sequencing; OR
- Isolation of rabies virus (in cell culture or in a laboratory animal).

Presumptive laboratory evidence:
N/A

Supportive laboratory evidence:
N/A

*While central nervous system (CNS) tissue is most commonly tested and is the preferred tissue type for ruling out a rabies virus or non-rabies lyssavirus infection, identification of rabies virus or a non-rabies lyssavirus in any tissue or body fluid is evidence of infection.

Note: The categorical labels used here to stratify laboratory evidence are intended to support the standardization of case classifications for public health surveillance. The categorical labels should not be used to interpret the utility or validity of any laboratory test methodology.

A3. Epidemiologic Linkage
N/A

A4. Case Classifications

Confirmed: Meets confirmatory laboratory evidence.

Probable: N/A

Suspect: N/A

B. Criteria to distinguish a new case of this disease or condition from reports or notifications which should not be enumerated as a new case for surveillance
N/A

VIII. Period of Surveillance
Surveillance for animal rabies should be on-going.
IX. Data sharing/release and print criteria

CSTE recommends the following case statuses* be included in the ‘case’ count released outside of the public health agency:

- ☒ Confirmed
- ☐ Probable
- ☐ Suspect
- ☐ Unknown

* Which case statuses are included in the case counts constitute the “print criteria.”

Jurisdictions (e.g., States and Territories) conducting surveillance under this case definition can voluntarily submit de-identified case information to CDC, if requested and in a mutually agreed upon format.

Production of national data summaries and national data re-release for non-NNCs:

- Prior to release of national data summaries CDC should follow the CDC/ATSDR Policy on Releasing & Sharing Data, issued on April 16, 2003 and referenced in 11-SI-01 and custodians of such data should consult the CDC-CSTE Intergovernmental Data Release Guidelines Working Group report (www.cste2.org/webpdfs/drgwgreport.pdf) which contains data release guidelines and procedures for CDC programs re-releasing state, local, or territorial-provided data.
- CDC programs have a responsibility, in collaboration with states, localities, and territories, to ensure that CDC program-specific data re-release procedures meet the needs of those responsible for protecting data in the states and territories.

X. Revision History

<table>
<thead>
<tr>
<th>Previous PS ID</th>
<th>Section of Document</th>
<th>Revision Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>09-ID-12</td>
<td>VI. Criteria for case ascertainment</td>
<td>Added reverse transcriptase PCR (RT-PCR), direct rapid immunohistochemical test (dRIT) and Immunohistochemistry (IHC) on formalin-fixed tissue as confirmatory tests</td>
</tr>
<tr>
<td>09-ID-12</td>
<td>VII. Case definition for case classification</td>
<td>Added reverse transcriptase PCR (RT-PCR), direct rapid immunohistochemical test (dRIT) and Immunohistochemistry (IHC) on formalin-fixed tissue as confirmatory tests</td>
</tr>
<tr>
<td>09-ID-12</td>
<td>III. Statement of the desired actions to be taken</td>
<td>Added criteria for certain cases to be immediately notifiable and added recommended time frame for routine reporting</td>
</tr>
<tr>
<td>1997</td>
<td>New position statement format</td>
<td>Added tables for electronic disease reporting</td>
</tr>
<tr>
<td>1997</td>
<td>Created standardized case definition</td>
<td>Specified lab evidence as positive direct fluorescent antibody tests or isolation of rabies virus</td>
</tr>
<tr>
<td>1944</td>
<td>N/A</td>
<td>Added animal rabies to the NNC list</td>
</tr>
</tbody>
</table>

XI. References

1. Position Statement 09-ID-12, Title: Public Health Reporting and National Notification for Animal Rabies


### XII. Coordination

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Table VI. Table of criteria to determine whether a case should be reported to public health authorities.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Animal Rabies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Criteria for Reporting</td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Laboratory Criteria for Reporting*</td>
<td></td>
</tr>
<tr>
<td>Any rabies virus direct fluorescent antibody test - all results</td>
<td>S</td>
</tr>
<tr>
<td>Any rabies virus direct rapid immunohistochemical test (dRIT) – all results</td>
<td>S</td>
</tr>
<tr>
<td>Any rabies virus test by immunohistochemistry (IHC) on formalin-fixed tissue – all results</td>
<td>S</td>
</tr>
<tr>
<td>Any pan-lyssavirus probe-based real time reverse transcription-polymerase chain reaction (RT-PCR) test – all results</td>
<td>S</td>
</tr>
<tr>
<td>Detection of lyssavirus nucleic acid by genomic sequencing – positive results only</td>
<td>S</td>
</tr>
<tr>
<td>Isolation of rabies virus (in cell culture or in a laboratory animal) – positive results only</td>
<td>S</td>
</tr>
<tr>
<td>Epidemiological Linkage Criteria for Reporting</td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

Notes:
S = This criterion alone is SUFFICIENT to report a case.
*While central nervous system (CNS) tissue is most commonly tested and is the preferred tissue type for ruling out a rabies virus or non-rabies lyssavirus infection, identification of rabies virus or a non-rabies lyssavirus in any tissue or body fluid provides evidence of infection.

Table VII. Classification Table: Criteria for defining a case of animal rabies

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Confirmed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Evidence</td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Laboratory Evidence*</td>
<td></td>
</tr>
<tr>
<td>Positive rabies virus direct fluorescent antibody test</td>
<td>S</td>
</tr>
<tr>
<td>Positive rabies virus direct rapid immunohistochemical test (dRIT) – all results</td>
<td>S</td>
</tr>
<tr>
<td>Positive rabies virus test by immunohistochemistry (IHC) on formalin-fixed tissue – all results</td>
<td>S</td>
</tr>
<tr>
<td>Positive pan-lyssavirus probe-based real time reverse transcription-polymerase chain reaction (RT-PCR) test</td>
<td>S</td>
</tr>
<tr>
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<td>S</td>
</tr>
<tr>
<td>Isolation of rabies virus (in cell culture or in a laboratory animal)</td>
<td>S</td>
</tr>
<tr>
<td>Epidemiologic Linkage Evidence</td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

Criteria to distinguish a new case:
N/A

Notes:
S = This criterion alone is SUFFICIENT to classify a case.
*While central nervous system (CNS) tissue is most commonly tested and is the preferred tissue type for ruling out a rabies virus or non-rabies lyssavirus infection, identification of rabies virus or a non-rabies lyssavirus in any tissue or body fluid provides evidence of infection.
Appendix 1. Data elements to be reported to CDC

This is the minimum dataset of elements to be sent with notification to CDC. CDC may request additional data elements specific to the scenario being investigated.

To be reported for all animal specimens being tested for rabies by direct fluorescent antibody, direct rapid immunohistochemical (dRIT), immunohistochemistry on formalin-fixed tissues and pan-lyssavirus real-time RT-PCR, regardless of result:
 Origin State
 Reporting State
 Animal ID
 Species (to the Genus species level)
 Date Collected
 Location of Animal*
   County and State AND
   At least one of the following address data types:
     1. Latitude/Longitude; OR
     2. Street Address and City; OR
     3. Zip Code
 Rabies Symptoms (Y/N)
 Laboratory Test Type
 Laboratory Test Result
 Laboratory Test Date

To be reported for all animal specimens testing positive rabies, regardless of test methodology:
 Rabies virus variant
 GenBank ID
 Human Exposures (#)
 Animal Owned (Y/N)
 Vaccination Status
 Last Vaccination Date
 International Travel/Importation Within 1 Year (Y/N)

*Location of animal should be determined using the following hierarchy (listed in order of preference). Report the highest preferred location available:
  1. Location where animal developed first symptoms; OR
  2. Location where animal was found; OR
  3. Location where the (human or animal) exposure occurred; OR
  4. Location where the animal was submitted.
Appendix 2. Examples and further information about types of events meeting criteria for immediate notification to CDC

**CDC to WOAH NOTIFICATION CRITERIA**

1) First occurrence of a listed disease in a country, a zone, or a compartment;
2) recurrence of an eradicated listed disease in a country, a zone, or a compartment following the final report that declared the event ended;
3) first occurrence of a new strain of a pathogenic agent of a listed disease in a country, a zone, or a compartment.
4) recurrence of an eradicated strain of a pathogenic agent of a listed disease in a country, a zone, or a compartment following the final report that declared the event ended;
5) a sudden and unexpected change in the distribution or increase in incidence or virulence of, or morbidity or mortality caused by, the pathogenic agent of a listed disease present within a country, a zone, or a compartment;
6) occurrence of a listed disease in an unusual host species.

**SAMPLES OF EPIDEMIOLOGICAL IMPORTANCE (SEI)**

**Terrestrial SEI Category**

1) Introduction of novel rabies virus variants (including importation events)
   a. All dogs, domestic animals, or livestock in Florida and southern border state (Arizona, California, New Mexico, and Texas)
   b. Any mammal with a history of international travel in the preceding 12 months
2) Translocation of rabies virus variants not previously documented within geographic areas
   a. Any coyote, cougar, bobcat, wolf, deer, or bison
   b. Raccoons located west of the USDA’s Oral Rabies Vaccination (ORV) zone front
   c. Terrestrial mammals located in a USDA-enhanced rabies surveillance zone
   d. Domestic and livestock mammals with a history of travel across rabies virus variant territory boundaries (see map) in the preceding 6 months
3) Host-shift events
   a. Foxes and mammals in areas designated as “terrestrial rabies free”
4) Unusual rabies-related incidents
   a. Rodents, cluster events in livestock, animals that are rarely found to be rabid in the area from which they were reported

**Bat-Associated SEI Category**

1) Introduction of a rabies virus variant among nonindigenous rabid bat species
   a. Rabid bats in southern border states (Arizona, California, New Mexico, and Texas), or Florida, Puerto Rico, and the U.S. Virgin Islands
2) Early detection of a host-shift event
   a. Rabies-positive bat species that are not commonly found to be infected with rabies virus in the area from which they were reported