



Date: June 17, 2019

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Subject: Recommendation for Interstate Shellfish Sanitation Conference (ISSC) *Vibrio vulnificus* Illness Review (VvIR) Committee procedure change

To: Ken Moore, ISSC Executive Director

### Background

Currently, the ISSC VvIR committee uses information from COVIS to identify cases of *V. vulnificus* that meet criteria for a National Shellfish Sanitation Program (NSSP) Vv case. The current criteria include:

- Isolation of *V. vulnificus* from a clinical specimen, and
- Consumption of shellfish in the 7 days before illness began, specifically raw or undercooked, and
- The product was commercially harvested, and
- The case involved septicemia from consumption

As there is no “septicemia” variable on the COVIS case report form, determining septicemia requires committee members to interpret the available data for an individual case, making clinical judgments to infer whether an illness included septicemia. The clinical data collected on a COVIS case report form are brief. COVIS collects data for the purpose of public health surveillance, not clinical diagnosis. Furthermore, each state and interviewer collects and records data slightly differently. They may conduct patient or patient proxy interviews, review medical records, or interview a health care provider. Interviewers often do not have clinical training, and vary in their level of public health training.

Given the limitations of the surveillance data, it is important for scientific and procedural integrity that a case definition is unambiguous, with no need for clinical interpretation. The case definition should be clear enough that anyone can determine from the available data whether an illness fits the definition.

Septicemia is an outdated term that is no longer commonly used in medicine or public health. An alternative would be to classify cases by severity of disease. However, using only “severe” cases to reflect the magnitude of

risk from food is problematic, because the clinical severity of a case may depend on several factors other than the risk of the food itself, such as the patient's age, underlying health conditions, access to healthcare, bacterial load ingested, and appropriateness of medical treatment. The clinical severity of individual cases does not necessarily reflect the risk to the public of *V. vulnificus*.

### **Recommendation**

The most consistent approach to counting *V. vulnificus* cases for the purposes of monitoring risk would be to count all confirmed cases. Shifting to this broader case definition would require submission of a proposal to ISSC for consideration at the Biennial meeting.

In the interim, CDC recommends defining a case of severe *V. vulnificus* as illness in a person who had *V. vulnificus* infection confirmed by bacterial culture, and either of the following:

1. *V. vulnificus* was isolated from blood or a site that generally indicates spread of infection through the bloodstream, such as central nervous system sites, fluids from which bacteria cannot normally be cultured (excludes urine), and intra-abdominal sites (does not include stool). The table below lists sources that meet these criteria. This specimen source classification standard is used by the Enteric Diseases Epidemiology Branch across surveillance systems for multiple enteric conditions to define sources that likely reflect invasive infection.
2. Any of the following were indicated on the COVIS case report form:
  - a. Fever
  - b. Septic shock
  - c. Death
  - d. Any of the following sequelae: necrosis; or invasive procedure, such as surgery, amputation, skin graft, wound debridement, fasciotomy, or incision and drainage

**CDC recommends immediate adoption of the suggested interim criteria.** This will allow the VvIR committee to resume its case review work. Classification of cases according to these criteria should be reproducible regardless of who is doing the classification.

CDC plans to draft a proposal for conference consideration at the 2019 Biennial Meeting.

**Table: Specimen sources that likely reflect invasive disease**

Blood: Includes plasma and blood components
Vascular: Includes heart, heart valves, aorta, blood vessels
Lymphatic: Includes lymph, lymph nodes, thymus
Spleen: Includes spleen, splenic abscesses
Bone: Includes bone, bone marrow
Placenta and products of conception: Includes fetus, cord blood

Nervous system

Cerebrospinal fluid (CSF)

Other nervous tissue; includes brain abscess

Pleural fluid

Peritoneal fluid

Joint: includes synovial/joint fluid

Hepatobiliary: Gallbladder, bile, liver (includes abscesses)

Pancreas: Includes pancreas, pancreatic cysts, and abscesses

Reproductive: Ovary, fallopian tube, uterus (includes cysts and abscesses in these sites), pelvic abscesses, amniotic fluid

Kidney: Includes renal and perinephric abscess