

## Background: Constructing a Case Definition

A case definition is needed to establish whether a patient is linked to the outbreak under investigation or not. The case definition is a set of criteria for determining this. As such, it is an epidemiological tool for counting cases – and not used to guide clinical practice. A case definition need to be simple and practical and should include the following components:

- A restriction by “time”, to define a period of time during which cases of illness are considered to be associated with the outbreak.
- A restriction by “place” – for example, limiting the group to patrons of a particular restaurant, attendees of a conference or meeting, or residents of a particular town
- A restriction by “person” which may include:
  - personal characteristics – such as defined population groups, for example certain age groups or gender
  - A restriction by clinical and laboratory criteria that define whether a person has the illness under investigation; the clinical features should be significant or hallmark signs of the illness.

### ***Sensitivity versus specificity in a case definition***

Case definitions for investigation of international FWD outbreaks pose specific challenges. Ideally, a case definition will include all cases (high sensitivity) but exclude any person who does not have the illness (high specificity). A sensitive case definition will detect many cases but may also count as cases individuals who do not have the disease. A more specific case definition is more likely to include only persons who truly have the disease under investigation but also more likely to miss some cases. There are no rules about how sensitive or specific a case definition should be. In the early stage of an outbreak investigation the aim is to detect as many cases as possible; this requires a sensitive case definition (e.g. a person with three or more loose stools in a 24-hour period).

### ***Creating multiple case definitions***

Because a single case definition that suits all needs is rare, it is quite common for case definitions to change during an investigation or for different case definitions to be used for different purposes. Many investigators use the following (or similar) case definitions in parallel:

- Confirmed cases – have a positive laboratory result (isolation of the causative agent or positive serological test). This case definition has high specificity.
- Probable cases – have the typical clinical features of the illness but without laboratory confirmation.
- Possible cases – have fewer or atypical clinical features. This case definition has high sensitivity.

In some investigations, different case definitions may be used for descriptive epidemiology versus analytical epidemiology.

Some descriptive epidemiology data is already available when a possible international FWD outbreak is declared. Review of this data should enable a provisional definition of an outbreak case to be formulated, in terms of

- TIME: the beginning of the outbreak period,
- PLACE: the countries affected.
- PERSON: the characteristics of the pathogen,

Additional information collected in the outbreak information template [Task 2, Annex 2], such as recent travel history or specific population characteristics (i.e. age group, gender, risk population) may allow the study population and the case definition to be refined.

### ***Subtyping used for case definitions***

The use of subtyping methods to differentiate strains or subtypes of pathogens enables more precise and efficient outbreak detection and source tracking through the food chain. Particularly for illnesses caused by pathogens that occur frequently outside outbreaks, subtyping allows for only those cases that are associated with the outbreak to be included.

If the subtype or phage of a given foodborne pathogen has been identified, including this specific information in the case definition can assist in capturing only those cases that are linked to the outbreak under investigation. While including microbiological features in the case definition will allow for more a specific case definition, it adds the extra requirement to test all possible cases for confirmation.