Form Approved
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Protocol for Case Reporting for Diamond Shruumz Outbreak Investigation

Background

On June 3, 2024, The Arizona Department of Health Services notified CDC of four patients with severe illness (including seizures, central nervous system depression and other symptoms) following consumption of Diamond Shruumz chocolate bars. Subsequently, several additional cases have been identified through reporting to poison centers. On June 7, 2024, FDA issued an adverse event investigation notice, advising people not to eat, sell, or serve Diamond Shruumz Brand Microdosing Chocolate Bars. As of June 11, 2024, 12 cases had been reported, with a case being defined as a human exposure call to a poison center (PC) using a product code for a Diamond Shruumz product (chocolate bars, cones, or gummies) or for chocolate containing mushrooms, with a clinical outcome of moderate, major, or death. On June 12, 2024, a Health Advisory was distributed via the CDC Health Alert Network to alert clinicians about the illnesses. As of June 13, 2024 several state health departments had contacted CDC to inquire about standardized procedures for investigation of cases and for reporting of cases that had not been reported to poison centers. The following procedures are being developed to standardize case investigation and reporting procedures for state, territorial, or tribal health departments.

Objectives

The objectives of this effort are as follows:

- Document the magnitude and extent of the outbreak and determine whether it is ongoing.
- Collect clinical information about cases to support investigation into the causative agent and to provide an understanding of the severity and spectrum of disease.
- Collect more complete exposure data to understand the range of products involved, how they are used or consumed, and potential risk factors for more severe outcomes such as dose consumed, co-ingestions and co-morbid conditions.

Procedures

A standard case investigation form (see Appendix A) will be provided to health departments. The case investigation form has two parts. The first part would most likely be completed based on information from a clinician caring for a patient or from the medical record. The second part would most likely be completed based on information about exposures obtained directly from the patient. However, all of these sources might contribute to both sections of the case investigation form.

- Up to this point, cases have been identified through reporting to poison centers using the following case definition, which is based on data from the National Poison Data System (NPDS):

NPDS case definition: A human exposure call to a poison center using a product code for a Diamond Shruumz product (chocolate bars, cones, or gummies) or for chocolate containing mushrooms, with a clinical outcome of moderate, major, or death, during January 1, 2024 through the present.

- Going forward, if a poison center receives a call regarding a potential case, poison center staff will conduct their usual activities, but are asked to also notify the health department of the jurisdiction (e.g., state, territory, or tribal land) in which the potential case-patient lives. CDC will also notify health departments of potential cases that it becomes aware of through NPDS, using the NPDS case definition listed above.
- If a health department is notified of a case by a poison center, or by a source other than a poison center, health department staff are asked to complete the case investigation form, which will likely require 1) obtaining information from clinicians who cared for the patient or from the patient's medical record, and 2) interviewing the case-patient. Once case investigations are complete (to the extent possible), health department staff will submit the information to CDC by entering the information into REDCap.

Case Definition

Health departments will be asked to complete a case investigation form for all persons who meet the following case definition:

Case definition for health department investigations: Illness with moderate or major clinical effects,* or death, occurring in a person who ate any Diamond Shruumz product (chocolate bars, cones, gummies or other) or another chocolate product marketed as containing mushrooms, during January 1, 2024 through the present.

*Clinical effects are classified using the definitions used by poison centers, which are as follows:

Minor: The patient exhibited some symptoms as a result of the exposure, but they were minimally bothersome to the patient. The symptoms usually resolve rapidly and often involve skin or mucous membrane manifestations. The patient has returned to a pre-exposure state of well-being and has no residual disability or disfigurement.

Moderate: Patient exhibited symptoms which are more pronounced, more prolonged or more of a systemic nature than minor symptoms. Usually, some form of treatment is or would have been indicated. The symptoms are not life-threatening and there is no residual disability/disfigurement.

Major: Patient has exhibited symptoms that were life-threatening or resulted in significant residual disability or disfigurement.

Data Analysis

CDC will maintain a line list of all cases reported by health departments through their case investigations. In addition, case investigation form data received through REDCap will be analyzed by staff in the Health Studies Program in the National Center for Environmental Health to summarize the characteristics of reported cases.

Appendix A: Case Investigation Form

Note: Items that are considered core items are highlighted in yellow. Please complete as much of the case investigation form as possible but prioritize providing complete information for the core items.

Interviewer and medical record abstractor information (please list everyone who contributed to the information on this form and their data sources):

Name of interviewer or abstractor	**Institution (e.g., name of health department, name of poison center) for interviewer or abstractor**	**Data source (select all that apply from the following choices: 1, Interview of patient 2, Interview of proxy for patient 3, Interview of clinician who cared for patient 4, Medical record abstraction)**

Demographics

State or territory of Residence (spelled out): _____

Jurisdiction's Case ID: ____

Poison Center ID (if applicable): ____

FDA consumer complaint ID (if applicable): _____

Age in years: __ (numeric field)

Sex (select all that apply):

__ Female

__ Male

__ Transgender, non-binary, or another gender

__Unknown

Race and/or ethnicity (select all that apply):

__ American Indian or Alaska Native

__ Asian

__ Black or African American

__ Hispanic or Latino

__ Middle Eastern or North African

__ Native Hawaiian or Pacific Islander

__ White

__Unknown

Occupation: _____

How did the health department become aware of this case? (Check all that apply.)

□ Notification of a record in NPDS by CDC

□ Notification from a poison center

□ Notification from FDA of a consumer complaint

□ Other means of notification (please specify)

Part I: Clinical Presentation (Note: This section would most likely be completed based on interviews with clinicians who cared for the patient or review of the medical record, but information from those sources could be supplemented with information from an interview with the patient.)

History of illness associated with consumption of a Diamond Shruumz or another chocolate product marketed as containing mushrooms

Please answer the following questions **regarding the illness with moderate or major clinical effects** (as defined above**), or resulting in death, that occurred after consumption of a Diamond Shruumz product, or another chocolate product marketed as containing mushrooms (referred to as the "index illness")**:

Date and time of consumption of the Diamond Shruumz or similar product before the index illness onset. If the product was consumed over a period of time before illness onset, please record the time when use started; use 24-hour time format: mm/dd/yyyy h:m

Date and time of first onset of symptoms for the index illness: mm/dd/yyyy h:m

Please confirm the length of the time interval between the time when product consumption started and the first symptom onset (in minutes): __ minutes. <will be a calculated field>

If this is not correct, please recheck the dates and times listed above.

Signs and symptoms for the Index Illness

Please indicate which of the following signs and symptoms occurred during the index illness, and for those that occurred, the date and time of onset.

Symptom	**Yes/No/Don't know**	**If yes, Date/Time of onset (please use 24-hour time format)**
Seizure		

If yes, specify whether the following types of seizures occurred: Generalized seizure Focal seizure Other type of seizure (please specify)		
Central nervous system depression If yes, please specify the extent of central nervous system depression: Mental slowness Difficulty staying awake Loss of consciousness		
Hallucinations/delusions		
Confusion		
Agitation		
Clonus		
Myoclonus		
Muscle rigidity		
Tremor		
Hyperthermia		
Erythema/flushing		
Diaphoresis		
Excess secretions		
Mydriasis		
Miosis		
Bradycardia		
Tachycardia		
Cardiac Arrhythmia If yes, please specify the type of cardiac arrhythmia: _____		
Hypotension		
Hypertension		
Nausea		
Vomiting		
Dyspnea		
Respiratory depression		
Hyperventilation/tachypnea		
Cough		
Impaired gag reflex or inability to protect airway		
Rash		
Other signs or symptoms (please specify)		

Was the patient seen in the emergency department? Yes/No/Don't know

If yes, date and time of presentation to the emergency department: _____

If yes, state or territory in which emergency department is located: ____

Was the patient hospitalized? Yes/No/Don't know

If yes, hospitalization date: _____

If yes, state or territory in which hospital is located ____

If yes, discharge date: _____

Was the patient admitted to an intensive care unit? Yes/No/Don't know

Was the patient intubated? Yes/No/Don't know

If yes, how long was the patient intubated (in days)? ___

Did the patient die? Yes/No/Don't know

Laboratory and Clinical Assessments

Please indicate whether the following types of laboratory and clinical tests were done as part of the patient's evaluation for the index illness, and if so, whether the results were abnormal.

Laboratory or clinical test	**Was this test performed? (Yes/No)**	**Was the test result abnormal? (Yes/No/Pending)**	**If the test result was abnormal, please specify the results, including the units (if applicable)**
Aspartate amino transferase (AST)			
Alanine amino transferase (ALT)			
Hemoglobin			
Hematocrit			
White blood cell count			
Creatinine			
Blood urea nitrogen (BUN)			
Glucose			
Lactate			
Creatine phosphokinase			
Arterial blood gas measurements			
Venous blood gas measurements			
Blood alcohol level			
Urine drug screen			
Acetaminophen			
Salicylates			
Other toxicologic testing (please specify the type of test and all compounds detected)			
Electrocardiogram			

Other laboratory or clinical tests (please specify)			

Past Medical History

Please indicate whether the person has a previous medical history of the following conditions:

Illness	**Yes/No/Don't Know**
Neurologic, Psychiatric, and Sleep conditions	
Seizures	
Anxiety	
Depression	
Bipolar disorder	
Schizophrenia	
Schizoaffective disorder	
Hallucinations without a diagnosis of schizophrenia or schizoaffective disorder	
Substance Abuse Disorder	
Insomnia	
Chronic headaches, such as migraine headaches	
Nerve damage/neuropathy	
Other type of chronic pain	
Stroke	
Movement disorder	
Other neurologic, psychiatric or sleep condition (please specify):	
Cardiovascular conditions	
Heart attack	
Irregular heart rhythm	
Syncope	
Other heart disease (please specify):	
Respiratory conditions	
Asthma	
COPD	
Other respiratory disease (please specify):	
Thyroid disease (please specify):	
Diabetes (please specify type):	
Gastrointestinal problems (please specify):	
Liver disease (please specify):	
Kidney disease (please specify):	
Rheumatologic or autoimmune disease (please specify):	
Hematologic disease (please specify):	
Dermatologic disease (please specify):	
Cancer (please specify):	
Other type of disease (please specify)	

Part II: Exposure History (Note: This section would most likely be completed based on an interview directly with the patient, but that information could be supplemented with information from the medical record or clinician interviews)

Product Consumption History

Did the patient eat a product with a Diamond Shruumz label before index illness onset?
Yes/No/Don't know

If yes, please specify whether the patient consumed each of the following types of products before the index illness onset: (indicate yes/no/don't know for each type of product)

Product	Yes/No/Don't know
Chocolate bars (all have 15 pieces in package)	
Dark chocolate	
Birthday cake	
Cookies and Cream	
Cinnamon Bar	
Cookie Butter	
Fruity Cereal	
Gummies: Micro dose (all have 15 pieces per package, weight of pieces not listed)	
Strawberry Kiwi- Micro dose	
Grape Lemonade- Micro dose	
Sour Apple Peach- Micro dose	
Rainbow- Micro dose	
Hawaiian Punch- Micro dose	
Blue Razz Watermelon- Micro dose	
Gummies: Mega dose (all have 5 pieces per package, 1000 mg each)	
Blue Razz Euphoria- Mega dose	
Watermelon Wonderland- Mega dose	
Radical Rainbow- Mega dose	
Lucid Lemon Lime- Mega dose	
Peach Paradise- Mega dose	
Cones (all have 2 pieces per package)	
Double chocolate chip	
Mint chocolate chip	
Sprinkles	
Cookies and cream	
Strawberry cheesecake	
Other	
Other type of Diamond Shruumz product not listed above	
If yes, please specify:_____	

For **each** Diamond Shruumz product consumed, please specify the following:

Date and time of the start of consumption before the index illness onset. If the product was consumed over a period of time before illness onset, please record the time when use started: mm/dd/yyyy h:m

Date and time of last consumption before the index illness onset: mm/dd/yyyy h:m
Please confirm the length of the time interval between the start of consumption and the last consumption before the index illness symptom onset (in minutes): ____ <will be a calculated field>

What was the total amount that the person consumed before the index illness onset (number of pieces) ____

Which of the following describes the pattern of consumption before the index illness onset? (check one)

□ Consumed all at once

□ Consumed in multiple doses (of any size, such as a starting does with additional doses)

If multiple doses, please specify the number of separate doses that the person consumed before the index illness onset: ___

If multiple doses, please describe the way in which the person consumed the product before the index illness onset (e.g., ate X pieces, waited X minutes, then ate X more pieces)

_____

Where did the person obtain the product? (If it was at a store, please provide the name and location of the store):_____

On what date did the person obtain the product? (If it was ordered on-line, please list the date ordered.): mm/dd/yyyy

Is a receipt or other proof of purchase available from the product purchase?
☐ Yes ☐Maybe ☐ No ☐ Don't Know
If yes, would the person be willing to share a picture of the purchase receipt with health officials?
☐Yes ☐Maybe ☐No ☐ Don't know

Was there a lot/batch number on the product package? Yes/No/Don't know

If yes, please specify the lot/batch number on the package:___

Was there a "Best if used by date" on the product package? Yes/No/Don't know

If yes, please specify the "Best if used by" date on the package: mm/dd/yyyy

Is any of the product still in their home or in their possession?
☐ Yes ☐Maybe ☐ No ☐Don't know

If yes, is the product in its original packaging? ☐ Yes ☐ Maybe ☐ No ☐ Don't know

(*Regardless of packaging*) Would the person be willing to have the leftover product collected by health officials for testing if needed? ☐ Yes ☐Maybe ☐ No ☐Don't know

Note to interviewer: If any of the product is still in their home or in their possession and the person indicates a willingness to have leftover product collected by health officials, please ask the person to save the product. The health department should then contact their FDA emergency response coordinator.

Is this the first time the person consumed this product? Yes/No/Don't know

If No:

How long has the person been consuming the product? (in months)

On approximately how many previous occasions has the person consumed the product? ____

Has the person experienced unexpected health effects after consuming the product in the past (before the use associated with the index illness)?

If yes, please specify the following:

Please describe the unexpected health effect that the person previously experienced after consuming the product _____

What was the date of onset of the previous unexpected health effects that the person experienced after consuming the product? Please use the mm/dd/yyyy format and list multiple dates if needed. _____

Did that illness meet the case definition for this outbreak? Yes/No/Don't know

If yes, please list the Jurisdiction's Case ID for that case _____

Did the patient eat a chocolate product of **another brand (other than Diamond Shruumz)** marketed as containing mushrooms before the index illness onset? Yes/No/Don't know

If yes, for **each** product please specify the following: <allowing for two other products>

Please list the other product brand name _____

Please list the name of the other specific product that the patient ate before the index illness onset. _____

Date and time of the start of consumption of the other product before the index illness onset. If the product was consumed over a period of time before illness onset, please record the time when use started; use 24 hour time format: mm/dd/yyyy h:m

Date and time of last consumption before index illness onset (use 24-hour time format): hh:mm

Please confirm the length of the time interval between the start of consumption of the other product and the last consumption before the index illness symptom onset (in minutes):____ <will be a calculated field>

What was the total amount of the product that the person consumed before the index illness onset (number of pieces)? ____

Which of the following describes the pattern of the product consumption before the index illness onset? (check one)

□ Consumed all at once

□ Consumed in multiple doses (of any size, such as a starting does with additional doses)

If multiple doses, please specify the number of separate doses of the product that the person consumed before the index illness onset: ___

If multiple doses, please describe the way in which the person consumed the product before the index illness onset (e.g., ate X pieces, waited X minutes, then ate X more pieces)

_____

Where did the patient obtain the product? (If it was at a store, please provide the name and location of the store):_____

On what date did the patient obtain the product? (If it was ordered on-line, please list the date ordered): mm/dd/yyyy

Is a receipt or other proof of purchase available from the product purchase?
☐ Yes ☐Maybe ☐ No ☐ Don't Know
If yes, would the person be willing to share a picture of the receipt for the product with health officials?
☐Yes ☐Maybe ☐No ☐ Don't know

Was there a lot/batch number on the product package? Yes/No/Don't know

If yes, please specify the lot/batch number on the product package:___

Was there a "Best if used by date" on the product package? Yes/No/Don't know

If yes, please specify the "Best if used by" date on the product package: mm/dd/yyyy

Is any of the product still in their home or in their possession?
☐ Yes ☐Maybe ☐ No ☐Don't know

If yes, is the product in its original packaging? ☐ Yes ☐ Maybe ☐ No ☐ Don't know

(*Regardless of packaging*) Would the person be willing to have the leftover product collected by health officials for testing if needed? ☐ Yes ☐Maybe ☐ No ☐Don't know

Note to interviewer: If any of the product is still in the patient's home or in the patient's possession and the patient indicates a willingness to have leftover product collected by health officials, please ask the patient to save the product. The health department should then contact their FDA emergency response coordinator.

Is this the first time the person consumed the product? Yes/No/Don't know

If No:

How long has the person been consuming the product? (in months) ____

On approximately how many previous occasions has the person consumed the product? ____

Has the person experienced unexpected health effects after consuming the product in the past (before the use associated with the index illness)?

If yes, please specify the following:

Please describe the unexpected health effect that the person previously experienced after consuming the product: _____

What was the date of onset of the previous unexpected health effects that the person experienced after consuming the product? Please use the mm/dd/yyyy date format and list multiple dates if needed.

Did that illness meet the case definition for this outbreak? Yes/No/Don't know

If yes, please list the Jurisdiction's Case ID for that case _____

Did the patient eat the products indicated above (either Diamond Shruumz products or chocolate products of another brand marketed as containing mushrooms) alone or with other people?

□ Alone

□ With other people

□ Don't know

If with other people, please indicate the following:

Number of other people ____

Did any of those people become ill? Yes/No/Don't know

If yes, how many of those people became ill? ___

How many of those people were hospitalized? ____

Did the patient eat the products indicated above (either Diamond Shruumz products or chocolate products of another brand marketed as containing mushrooms) with other foods or beverages? Yes/No/Don't Know

If yes, please list the foods and beverages: _____

Did the patient use any other substances (alcohol, nicotine, marijuana, synthetic cannabinoids, opioids, cocaine, or other substances) at the same time when they ate the products indicated above (either Diamond Shruumz products or chocolate products of another brand marketed as containing mushrooms)? Yes/No/Don't know

If yes, please list the substances: _____

If yes, please list the amount used for each substance: _____

Other than the specific products noted above as having been consumed prior to the index illness onset, has the person previously consumed a food or candy product marketed for having psychoactive effects (of any brand)? Yes/No/Don't know

If yes:

How long has the patient been consuming food or candy products (of any brand) marketed for having psychoactive effects, other than the specific products noted above? (months)____

On approximately how many previous occasions has the person consumed food or candy products (of any brand) marketed for having psychoactive effects, other than the specific products noted above? ___

Has the patient previously experienced unexpected health effects after consuming a food or candy product (of any brand) that is marketed for having psychoactive effects, other than the specific products indicated above? Yes/No/Don't know

If yes, please specify the following:

Brand or brands of product:_____

Specific product type or types: _____

Types of unexpected health effects:_____

Date or dates of onset of unexpected health effects:_____

Did that illness meet the case definition for this outbreak? Yes/No/Don't know

If yes, please list the Jurisdiction's Case ID for that case _____

Medication Use

Please list all prescription medications that the person had been taking during the week before the index illness onset (include any long-acting medications that might still had effects in that time period):

Prescription Medication name	**Dose, amount**	**Dose, units (e.g., mg)**	**Frequency, # times**	**Frequency, units** **Options: (per day, per week, per month, other [please specify])**	**Route** **(options: oral, intravenous, inhalational, dermal, other)**	**Date of last use before index illness onset**

Please list all over-the-counter medications that the person had been taking during the week before the index illness onset:

Over-the counter Medication name	**Dose, amount**	**Dose, units (e.g., mg)**	**Frequency, # times**	**Frequency, units** **Options: (per day, per week, per month, other [please specify])**	**Route** **(options: oral, intravenous, inhalational, dermal, other)**	**Date of last use before index illness onset**

Please list all nutritional supplements or herbal medications that the person had been taking during the week before the index illness onset:

Nutritional supplement or herbal	**Dose, amount**	**Dose, units**	**Frequency, # times**	**Frequency, units**	**Route**	**Date of last use before index**

medication name		**(e.g., mg)**		**Options: (per day, per week, per month, other [please specify])**	**(options: oral, intravenous, inhalational, dermal, other)**	**illness onset**

Substance Use

Please indicate which of the following substances the person used during the month before the index illness onset, the date of last use before the index illness onset (within the prior month), and the amount used during the week before the index illness onset.

Substance	**Did the person use the substance during the month before the index illness onset? (Yes/No/Don't know)**	**Date of last use before index illness onset (within the prior month)**	**Amount used during the week before index illness onset**
Alcohol			# of drinks:
Nicotine (smoking, vaping, chewing tobacco, snuff, snus)			
Marijuana			
Synthetic cannabinoids			
Cocaine			
Amphetamines			
Phencyclidine (PCP)			
Benzodiazepines (e.g., alprazolam, lorazepam, clonazepam)			
Opioids (e.g., fentanyl, heroin, morphine, oxycodone)			
Barbiturates			
Kratom			
Psilocybin-containing mushrooms (magic mushrooms)			

Amanita muscaria mushrooms			
Other hallucinogens			
Other substances (please specify)			

Supplemental Notes

Please provide any additional comments or notes that you would like to include about the case in the following field: _____