Developing a Case Definition for Health Effects from UOGD
A Discussion

Leslie Walleigh, MD, MPH

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What is a Case Definition?

A case definition is a set of uniform criteria used to define a disease or condition for public health surveillance.
- CDC 2015
Public health surveillance is the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice. - WHO
Public Health Surveillance

Public health surveillance is the ongoing systematic collection, analysis, and interpretation of data, closely integrated with the timely dissemination of these data to those responsible for preventing and controlling disease and injury (Thacker and Berkelman 1988).
What is a Case Definition?

A case definition should not be used by healthcare providers to determine how to meet an individual patient’s health needs – CDC
What is a Case Definition?

Types of Case definitions
- Infectious diseases
- Chemical poisonings
Case Definition for Chemical Poisoning

Case definition for chemical poisonings:
Clinical description
Laboratory criteria for diagnosis
Case classification
Case Definition for Chemical Poisoning

Clinical description:
Physical signs or experienced symptoms compatible with the recognized effects of the exposure of concern. Typically addresses only acute health symptoms.
Case Definition for Chemical Poisoning

Laboratory criteria:
Presence of the chemical in a biologic specimen

or

Presence of the chemical in an environmental specimen
Case Definition for Chemical Poisoning

Case classification:
- Confirmed
- Probable
- Suspect

The case classification is based on the degree of certainty that the case is actually a poisoning.
Example of Case Definition

Council of State and Territorial Epidemiologists (CSTE)
Case Definition for Carbon Monoxide (CO) Poisoning (abbreviated)
Case Definition CO Poisoning

Confirmed Case:
(C1) A carboxyhemoglobin level, as measured by a blood sample, of > 5% in non-smokers -OR-
(C2) A carboxyhemoglobin level, as measured by a blood sample of > 10% in smokers or for whom smoking status is unknown. -OR-
(C3) In the absence of laboratory confirmation of an elevated COHb level, signs or symptoms consistent with acute carbon monoxide poisoning AND a positive environmental exposure consistent with CO poisoning.
Case Definition CO Poisoning

Probable Case:
(P1) A carboxyhemogoblin level, as measured by a blood sample, that is $9\% \leq \text{COHb} \leq 10\%$ in smokers or for those whom smoking status is unknown. -OR-
(P2) A carboxyhemoglobin level, as measured by a pulse co-oximeter of $> 10\%$. -OR-
(P3) Loss of consciousness or death without alternative explanation AND exposure to a source of CO.
Case Definition CO Poisoning

Suspect Case:
(S1) A carboxyhemoglobin (COHb) level, as measured by a pulse co-oximeter, of equal to or greater than 9% and less than or equal to 10%.
(S2) In the absence of laboratory confirmation of an elevated COHb, a report of a patient with non-specific symptoms (headache, dizziness, and/or fatigue/weakness) AND environmental monitoring consistent with an exposure to CO. -OR-
Case Definition CO Poisoning

Suspect case: (continued)
(S3) A report of a patient with an environmental exposure consistent with CO poisoning. -OR-
(S4) In the absence of laboratory confirmation of an elevated COHb, a report of a patient with non-specific symptoms (headache, dizziness, and/or fatigue/weakness) AND exposure to a source of CO. 10% in smokers or for whom smoking status is unknown.
Clinical Description

What are the acute symptoms anticipated from recognized exposure sources?

- Air
- Water
- Other

What are the acute symptoms that have been reported?
Acute Symptoms from Recognized Exposures

Air

“Potential health effects due to inhalation of low-level environmental air contaminants generated by UOGD related activities”
<table>
<thead>
<tr>
<th>Chemical</th>
<th>Short term Exposures, Acute Health Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbon monoxide (CO)</td>
<td>Decreased exercise tolerance, decreased vigilance, increased risk for cardiac ischemia in individuals with heart disease</td>
</tr>
<tr>
<td>Nitrogen oxides (NOx)</td>
<td>Respiratory symptoms, worsening asthma</td>
</tr>
<tr>
<td>Particulate Matter 2.5 (PM2.5)</td>
<td>Asthma attacks, acute bronchitis, heart attacks in individuals with cardiac disease</td>
</tr>
<tr>
<td>Volatile Organic Chemicals (VOC’s)</td>
<td>Varies with individual chemical. See following examples: Benzene, Ethyl Benzene, Toluene, Xylene</td>
</tr>
<tr>
<td>Benzene</td>
<td>Headache, dizziness</td>
</tr>
<tr>
<td>Ethyl benzene</td>
<td>Eye and throat irritation</td>
</tr>
<tr>
<td>Toluene</td>
<td>Headaches, sleepiness, confusion</td>
</tr>
<tr>
<td>Xylenes</td>
<td>Eye, nose, throat, and skin irritation</td>
</tr>
<tr>
<td>Methylene Chloride</td>
<td>Decreased attentiveness and decreased hand-eye coordination</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>Nose and eye irritation, impaired short term memory, asthma attacks</td>
</tr>
<tr>
<td>Diesel Exhaust (contains VOC’s and PM2.5)</td>
<td>Eye, nose, throat and lung irritation. Headaches, dizziness, nausea</td>
</tr>
<tr>
<td>Hydrogen sulfide</td>
<td>Eye, nose, and throat irritation. Asthma attacks.</td>
</tr>
<tr>
<td>Polycyclic Aromatic Hydrocarbons</td>
<td>Eye and skin irritation, asthma attacks, acute cardiac events, adverse effects on developing fetus.</td>
</tr>
<tr>
<td>Ozone</td>
<td>Chest pain, coughing, throat irritation, congestion. Increased symptoms in bronchitis, emphysema, and asthma.</td>
</tr>
</tbody>
</table>
Acute Symptoms from Recognized Exposures

Water
Both EPA and PADEP have acknowledged sporadic water contamination
Limitations on Water Testing

Need pre and post drilling results
Need to test for expanded panel of chemicals
Unable to test for undisclosed potential contaminants
No tests available for some potential contaminants
Contaminants may not have applicable health standards
Standard collection procedures may be inadequate
Reported Acute Symptoms

Community surveys
   Earthworks 2012
Randomized studies
   Rabinowitz, et al 2014
EHP results
   2012-2015
# Gas Patch Roulette
## Earthworks 2012

<table>
<thead>
<tr>
<th>Symptom category</th>
<th>Percent of individuals reporting conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sinus/respiratory</td>
<td>88%</td>
</tr>
<tr>
<td>Behavioral/mood/energy</td>
<td>80%</td>
</tr>
<tr>
<td>Neurological</td>
<td>74%</td>
</tr>
<tr>
<td>Muscles/joints</td>
<td>70%</td>
</tr>
<tr>
<td>Digestive/stomach</td>
<td>64%</td>
</tr>
<tr>
<td>Ear/nose/mouth</td>
<td>66%</td>
</tr>
<tr>
<td>Skin reactions</td>
<td>64%</td>
</tr>
<tr>
<td>Vision/eyes</td>
<td>63%</td>
</tr>
</tbody>
</table>
Rabinowitz et al, 2014

“Proximity to Natural Gas Wells and Reported Health Status: Results of a Household Survey in Washington County, Pennsylvania”

Individuals living within 1 km of gas wells reported more skin conditions and upper respiratory symptoms than those living further away.
Environmental Health Project

61 adult residents of Southwest PA living within 1 km of facilities extracting, transporting, processing or storing unconventional natural gas or resulting waste products who had been evaluated by the EHP nurse practitioner.

Excluded individuals with primary occupational exposure to UOGD activities
Environmental Health Project
Intake Form

Exposure History
Review of Systems (Symptoms)
Medical History
Psychological Assessment
Environmental Health Project
Intake Form

Exposure history
Household
  Water Source
  Heating source
  Other
Occupational
Environmental
  Details regarding nearby UOGD activities
  Questions regarding other potential nearby sources
Environmental Health Project
Intake Form

Review of Systems (Symptoms)
Details regarding an extensive list of potential recent health symptoms, including dates of onset, worsening, or resolution.
Environmental Health Project
Intake Form

Medical History
Current diagnosed medical conditions
Historically diagnosed medical conditions
Medications
Smoking status
Environmental Health Project
Intake Form

Psychological Assessment
Current symptoms in Review of Systems
Questions on psychological/emotional status
EHP Analysis of Symptoms

Case inclusion criteria

61 adults from SWPA evaluated by EHP nurse practitioner for varying reasons. GIS confirmed proximity < 1km to at least one UOGD site at time of intake. Excluded individuals with primary occupational exposures.
EHP Analysis of Symptoms

Symptoms were divided into 12 system categories. Symptoms were included as potentially related to UOGD exposures if:

Onset or worsening occurred after onset of potential UOGD exposure

Symptoms were not as likely to be a result of an underlying medical condition or a different exposure source
<table>
<thead>
<tr>
<th>SYMPTOM CATEGORY</th>
<th>N</th>
<th>%</th>
<th>SYMPTOM</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
</table>
| UPPER RESPIRATORY SYMPTOMS           | 39  | 64%| Nose or throat irritation    | 25  | 41%
|                                       |     |    | Sinus pain or infections    | 17  | 28%
|                                       |     |    | Nose bleeds                  | 8   | 13%
| CONSTITUTIONAL SYMPTOMS              | 33  | 54%| Sleep disruption             | 26  | 43%
|                                       |     |    | Fatigue                      | 13  | 21%
|                                       |     |    | Weak or Drowsy               | 9   | 15%
| NEUROLOGICAL SYMPTOMS               | 32  | 52%| Head ache                    | 25  | 41%
|                                       |     |    | Dizziness                    | 11  | 18%
|                                       |     |    | Numbness                     | 9   | 15%
|                                       |     |    | Memory loss                  | 8   | 13%
|                                       |     |    | Dizziness                    | 11  | 18%
| PSYCHOLOGICAL SYMPTOMS             | 32  | 52%| Worry                        | 6   | 10%
|                                       |     |    | Stress or anxiety            | 23  | 38%
|                                       |     |    | Irritable or moody           | 12  | 20%
### Symptoms Temporally Related to UOGD Activity (N=61)

<table>
<thead>
<tr>
<th>Symptom Category</th>
<th>N</th>
<th>%</th>
<th>Symptom</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lower Respiratory Symptoms</strong></td>
<td>30</td>
<td>49%</td>
<td>Cough</td>
<td>21</td>
<td>34%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>SOB</td>
<td>19</td>
<td>31%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wheezing</td>
<td>14</td>
<td>23%</td>
</tr>
<tr>
<td><strong>Gastro-Intestinal Symptoms</strong></td>
<td>27</td>
<td>44%</td>
<td>Nausea</td>
<td>13</td>
<td>21%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Abdominal pain</td>
<td>12</td>
<td>20%</td>
</tr>
<tr>
<td><strong>Eye Symptoms</strong></td>
<td>23</td>
<td>38%</td>
<td>Itchy eyes</td>
<td>11</td>
<td>18%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Painful or dry</td>
<td>10</td>
<td>16%</td>
</tr>
<tr>
<td><strong>Dermatological Symptoms</strong></td>
<td>19</td>
<td>31%</td>
<td>Rash</td>
<td>10</td>
<td>16%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Itching</td>
<td>7</td>
<td>11%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lesions or blisters</td>
<td>6</td>
<td>10%</td>
</tr>
</tbody>
</table>
What about Water?

<table>
<thead>
<tr>
<th>Water Source</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any</td>
<td>61</td>
</tr>
<tr>
<td>Unknown</td>
<td>5</td>
</tr>
<tr>
<td>Public</td>
<td>16</td>
</tr>
<tr>
<td>Well</td>
<td>40</td>
</tr>
<tr>
<td>Well with changes or contamination</td>
<td>24</td>
</tr>
</tbody>
</table>
SYMPTOMS BY WATER SOURCE

- CONSTITUTIONAL SYMPTOMS
- RESPIRATORY SYMPTOMS
- EYE SYMPTOMS

Any Water Source
Public Water
Well
Wells W/ Changes
SYMPTOMS BY WATER SOURCE

- Any Water Source
- Public Water
- Well
- Wells W/ Changes

Symptoms by Category:
- Nose and Throat Symptoms
- Gastro-Intestinal Symptoms
- Dermatological Symptoms
- Neurological Symptoms
SYMPTOMS BY WATER SOURCE

- ANY WATER SOURCE
- PUBLIC WATER
- WELL
- WELLS W/ CHANGES

Psychological Symptoms
What Symptoms Should be Included in a Case Definition?

Include symptoms consistent with recognized exposure sources:
- Air
- Water
- Noise?
What Symptoms Should be Included in a Case Definition?

Many symptoms are consistent with exposure to recognized air emissions. Water exposure is probably an independent contributor to symptoms. Psychological symptoms most likely not caused by chemical exposures. Noise and/or psychological factors may contribute to sleep disruption. Upper and lower respiratory can be combined.
NUMBER OF INDIVIDUALS REPORTING DIFFERENT NUMBERS OF SYMPTOMS

<table>
<thead>
<tr>
<th>NUMBER OF SYMPTOM CATEGORIES REPORTED</th>
<th>NUMBER OF INDIVIDUALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 CATEGORIES</td>
<td>4</td>
</tr>
<tr>
<td>1 CATEGORIES</td>
<td>8</td>
</tr>
<tr>
<td>2 CATEGORIES</td>
<td>6</td>
</tr>
<tr>
<td>3 CATEGORIES</td>
<td>5</td>
</tr>
<tr>
<td>4 CATEGORIES</td>
<td>3</td>
</tr>
<tr>
<td>5 CATEGORIES</td>
<td>2</td>
</tr>
<tr>
<td>6 CATEGORIES</td>
<td>1</td>
</tr>
</tbody>
</table>
Laboratory Criteria

Presence of the chemical in a biologic specimen

OR

Presence of the chemical in an environmental specimen
Presence of the Chemical in a Biologic Specimen

Chemical or metabolite present in blood or urine
- Chemical unique to UOGD processes
- Metabolite unique to chemical
- Half-life sufficiently long to avoid false negatives
Presence of the Chemical in an Environmental Specimen

Positive environmental sampling
  Air testing
  Water sample
Proximity to source
  1 km (approximately ½ mile)
Rabinowitz et al, 2014
McKenzie et al, 2012
UOGD CASE DESCRIPTION

Environmental exposure
PLUS
Clinical symptoms
CONFIRMED CASE

Environmental Exposure:
A documented air and/or water exposure* to an emission or contaminant originating from a UOGD site

*Instrument or laboratory measured air contaminant. Laboratory confirmed water contaminant
CONFIRMED CASE

Clinical symptoms
The development of symptoms or worsening of pre-existing symptoms from two or more of the following systems:
1. Respiratory (cough, SOB, throat soreness or irritation, sinus problems, or nosebleeds)
2. Dermal (rash or pruritus)
3. Neurological (headache or dizziness)
4. Gastrointestinal (nausea or abdominal pain)
5. Constitutional (sleep disruption or fatigue)
6. Eye Symptoms (pruritic, painful or dry)
PROBABLE CASE

Environmental Exposure:
A presence for a period of at least 20 hours/week during a minimum of at least one month within one kilometer of one or more facilities extracting, transporting, processing or storing shale gas or waste.
Clinical symptoms
The development of symptoms or worsening of pre-existing symptoms from two or more of the following systems:
1. Respiratory (cough, SOB, throat soreness or irritation, sinus problems, or nosebleeds)
2. Dermal (rash or pruritus)
3. Neurological (headache or dizziness)
4. Gastrointestinal (nausea or abdominal pain)
5. Constitutional (sleep disruption or fatigue)
6. Eye Symptoms (pruritic, painful or dry)
SUSPECT CASE

Environmental Exposure:
A presence for a period of at least 20 hours/week during a minimum of at least one month within one to two kilometers of one or more facilities extracting, transporting, processing or storing shale gas or waste.
SUSPECT CASE

Clinical symptoms
The development of symptoms or worsening of pre-existing symptoms from two or more of the following systems:

1. Respiratory (cough, SOB, throat soreness or irritation, sinus problems, or nosebleeds)
2. Dermal (rash or pruritus)
3. Neurological (headache or dizziness)
4. Gastrointestinal (nausea or abdominal pain)
5. Constitutional (sleep disruption or fatigue)
6. Eye Symptoms (pruritic, painful or dry)