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Symptomology of Mycotoxin Exposure in Humans

This clinical study examines the physiological effects of human exposure to fungi and their “secondary metabolites” (organic poisons emitted by fungi/mold called “Mycotoxins”) produced in indoor water damaged structures. For decades the United States Federal Government through the Food and Drug Administration (FDA) has regulated and monitored U.S. food resources, supplies and food surpluses for fungal contamination, regarding food stuffs and livestock feeds produced for domestic consumption, and for those food stuffs and feeds designated for export to neighboring countries for the prevention of human / livestock disease and death. While the FDA has set toxicity limits designating what are unacceptable and dangerous levels of these toxins to human health through consumption, they have neglected to screen and set limits for unacceptable levels, or limits of these same toxins that exist in our day to day living environments. These same species of fungi / mold that are screened for by the FDA in U.S. food resources are also the exact same species of fungi documented to exist and thrive in indoor water damaged structures throughout the United States. The mycotoxins produced by these fungi have been documented to produce disabling and deadly organic poisons and are commonly found in water damaged indoor structures inhabited by millions of Americans.¹ These same indoor species of fungi / mold have been documented to produce the exact mycotoxins that have been designated by the FDA as “human pathogens” (disease causing to humans). Once fungi / mold begin to colonize within an indoor environment and have gone unchecked, they can begin to produce mycotoxins. Mycotoxins once released into the indoor environment are consumed, ingested and inhaled by the occupants of those structures producing adverse health effects to humans and animals as documented by the FDA when mycotoxin contaminated foods or feeds are ingested. Mycotoxin exposure from indoor water damaged structures has created an unrecognized and unmet health need throughout the United States and is now estimated to be at epidemic proportion. The objective of this study was to link human exposure to mycotoxins from indoor water damaged structures contaminated by mold / fungal growth, in relationship to the commonality of patient expressed symptoms, neuropathy and disease. The study group consisted of one hundred thirty five (135) subjects made up of seventy five (75) adult females, forty six (46) adult males, five (5) juvenile males and nine (9) juvenile females. Health complaints were surveyed with standardized written questionnaires and a personal one on one interview with each patient individually. A comprehensive battery of tests was used to determine neurocognitive dysfunction. Medical tests were administered for the detection of the presences of mycotoxins in each patient, as well as testing for fungal or yeast colonization. The mycotoxin tests were facilitated by American Medical Laboratories via urine specimens, and the Fungal Cultures were performed by EHAP LABS in collaboration with Mayo Clinic Laboratories via urine specimens. Due to the intercellular nature of mycotoxin poisoning all positive and equivocal mycotoxin results were statistically included.

Introduction

The *Aspergillus* species of fungi is globally the most commonly detected fungus in crops, and also the most prevalent in indoor water damaged structures throughout the United States. The *Aspergillus* species of fungi and its secondary metabolites “Aflatoxin (s)”, have to date been the most widely researched of all fungal species and mycotoxins produced by fungi / mold.

The guidelines and acceptable limits set forth by the United States FDA concerning food stuffs and feeds contaminated by fungus, does not address the “raw count” (number) of fungal spores in, or on the food source, but instead addresses the levels of mycotoxins, or poison present. The unit of measurement

used in the detection process for mycotoxin(s) are calculated in, "Parts- Per- Billion" (ppb). For a better understanding regarding the toxicity (potency) of these organic poisons and to put their toxicity into perspective, we have created the following analogies.

1. One (1) ppb would be the equivalent in the measurement of time, of one (1) second, in a thirty two (32) year period.
2. Or in numeric comparison, one (1) contaminated kernel of corn in ten thousand (10,000) bushel bins of corn. According to the Iowa Corn Grows Association, the average ear of corn has eight hundred (800) kernels.² One hundred (100) bushel bins of corn will yield on average seven million two hundred eighty thousand (7,280,000) kernels of corn. In ten thousand (10,000) bushel bins of corn there would be an estimated seven hundred twenty eight million (728,000,000) kernels of corn, in which no more than twenty (20) ppb of Aflatoxin may be present to be considered not dangerous to human health, this could be as little as one kernel of contaminated corn.³

The United States FDA has done a remarkable job keeping these organic poisons out of the U.S. food and livestock feed supplies. In November of 1997, and February 1998, one hundred seventy (170) people died and estimated tens of thousands of people were infected in Kenya from contaminated corn. In 2004, an Aflatoxin outbreak killed one hundred twenty five (125) more people.⁴

In 2011, the United States Centers for Disease Control (CDC) released documents stating; *"Aflatoxin, a potent fungal toxin, contaminates 25% of crops worldwide. Since 2004, 477 Aflatoxin poisonings associated with eating contaminated maize have been documented in Eastern Kenya, with a case-fatality rate of 40%"*⁵

Mycotoxin poisoning is of such global concern that the United States Centers for Disease Control (CDC) has established a special team which is deployed to sites anywhere in the world where outbreaks of Aflatoxin poisoning has been reported. Their mission is to isolate and quarantine the causes of the outbreak, project the path of outbreak, deliver medical treatment and detoxification to the infected or poisoned inhabitants of those regions.⁶

Aflatoxin is recognized and accepted worldwide as a carcinogen (cancer causing) in human health, by not only the U.S. Federal Government, World Health Organization (WHO), and the governments of hundreds of nations; it has been documented to be the direct cause of liver failure, kidney failure, liver cancer, kidney cancer and death in both humans and livestock. Cornell University published; *"In 1988, the IARC placed Aflatoxin B1 on the list of human carcinogens. This is supported by a number of epidemiological studies done in Asia and Africa that have demonstrated a positive association between dietary Aflatoxin and Liver Cell Cancer (LCC)."* A mycotoxin produced by fungus commonly found in indoor water damaged structures throughout the United States.⁷

While the FDA has solely focused on protecting U.S. food sources from these highly toxic organic poisons, Mayo Clinic has cited a new source of fungal contamination which produces these very same mycotoxins and has virtually gone unaddressed within the United States. Mayo Clinic states that; *"Aspergillus thrives in air conditioning and heating ducts, insulation, and some food and spices. Aspergillus is so common in old buildings, even in older hospitals, that small epidemics have occurred among people with weakened immune systems when nearby buildings have been torn down."*⁸

September 10th 1999, a paper published by Mayo Clinic fell on deaf ears stating; *“An estimated 37 million people in the United States suffer from chronic sinusitis, an inflammation of the membranes of the nose and sinus cavity. Its incidence has been increasing steadily over the last decade. Common symptoms are runny nose, nasal congestion, loss of smell and headaches. Frequently the chronic inflammation leads to polyps, small growths in the nasal passages which hinder breathing”.* *“The researchers studied 210 patients with chronic sinusitis. Using new methods of collecting and testing mucus from the nose, they discovered fungus in 96 percent of the patients' mucus. They identified a total of 40 different kinds of fungi in these patients, with an average of 2.7 kinds per patient.”*⁹ The article concludes that approximately ninety six percent (96%) of all sinusitis is misdiagnosed as bacteriological sinusitis and incorrectly treated with antibacterial drugs, many times leading patients to unnecessary evacuative sinus surgeries, as their treating physicians have totally ignored the possibility of fungal sinusitis.

In 2003, Mayo Clinic released a second article reflecting its 1999 findings stating; *“Chronic Rhino Sinusitis (CRS) is one of the most common chronic diseases in the United States. CRS produces nose and sinus problems characterized by nasal airway obstruction, loss of the sense of smell, postnasal drip, nasal congestion, nasal discharge, and head and face pain lasting three months or longer. It notably decreases the quality of patients’ lives, impairing physical and social functioning, vitality and general health. CRS has a significant impact on health care in the United States. The prevalence of CRS has increased by more than 50 percent in the past 10 years. CRS results in 18.3 million physician visits per year. Overall health-care expenditures attributable to CRS in the United States were estimated to be over \$5.8 billion in 1996. In 2001, 27.9 million prescriptions were issued to treat CRS in the United States. Approximately \$2 billion is spent annually to treat nasal and sinus disorders.”*¹⁰

In the United States the term “Sick Building Syndrome”, has been used in cases of water damaged indoor structures which exhibited fungal / mold growth or contamination, and has given rise to thousands of landlord – tenant disputes, employer- employee disputes, student - school disputes, all involving indoor water damaged structures and claims that the inhabitants of those structures have become ill from fungal / mold exposure from inside of those water damage buildings. The United States Federal Government through the FDA has developed guidelines for what is to be considered “safe” levels of Aflatoxin in various foods for human consumption. The presence of Aflatoxin above those ppb levels are considered hazardous or potentially disease causing in human beings. They are as follows:

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U.S. Food and Drug Administration guidelines for acceptable levels of total aflatoxins in food and feed.

Action level (ppb)	Commodity	Species
0.5 (aflatoxin M1)a	Milk	Humans
20.0	Any food except milk	Humans
20.0	Feed	All species
Exceptions		
100.0	Corn	Breeding cattle, breeding swine and mature poultry
200.0	Corn	Finishing swine (>100 lbs.)
300.0	Corn	Finishing beef cattle
300.0	Cottonseed meal used in feed	All species

While a handful of mold litigation cases claiming illness due to indoor water damaged environments have resulted in multimillion dollar settlements, the majority of these cases have been dismissed, as either frivolous or unsubstantiated. The reason being is that there are few litigation specialists that understand the toxicology of these organic poisons and their chemical impact(s) within the human body, most are unaware that the above referenced FDA guidelines for human consumption of mycotoxins even exists.

The fallacy in modern day Health Department findings, Code Enforcement investigations, and mold litigation cases regarding their failure to link a contaminated environment, or the sick building to the direct cause of disease in human beings is that the investigators, environmentalists, and legal counsels involved in these cases primarily have focused on the raw count of mold spores in any particular environment. In converse, the FDA in its assessment of contamination levels, disease and death caused by fungal exposure, has not focused on mold spores, or raw mold spore counts at all, but only the quantity of mycotoxins that the mold spores have produced and are present in those environments. Few times has an environmentalist measured the levels of mycotoxins in a mold contaminated environment, and then directly correlated those results with a medical professional as to the levels of mycotoxins present in the bodies of those structures inhabitants.

The clinical effects of mold exposure can be divided into three (3) categories.

1. Allergic effects
2. Infectious effects
3. Toxicological effects

Allergic effects

Allergic effects are detected through standard allergy tests, or IgE testing. Patients usually experience recovery after being removed from the contaminated environment with little to no further complaints.

Infectious effects are classified into two (2) major categories.

Fungal infection

- a. Fungal infection sinus
- b. Fungal infection lungs
- c. Fungal infection skin
- d. Fungal infection finger / toe nails
- e. Fungal localized infection internally
- f. Invasive fungal infection

Yeast infection

- a. Yeast infection oral (thrush)
- b. Yeast infection vaginal
- c. Yeast infection skin
- d. Yeast infection bowels
- e. Systemic yeast infection

Contrary to popular medical opinion, both fungal and yeast infections have been documented to have occurred in patients that are "NOT" immuno-compromised, and have healthy immune systems. Mainstream medical opinion states only immuno-incompetent persons having cancer; AIDS or other similar immuno-suppressed conditions are susceptible to fungal infection. This hypothesis is further thwarted by the fact that the fungal species "Cryptococcus gatti", infects the young, the old, the immuno-competent, the immunosuppressed, and has a thirty percent (30%) mortality rate for those infected.¹⁵

Toxicological effects

- a. Aflatoxicosis (aflatoxin poisoning)
- b. Ochratoxicosis (ochratoxin poisoning)
- c. Trichothecene poisoning
- d. Other mycotoxin poisoning * *There are species of fungi known to exist and have been documented to produce mycotoxins, however at this time there are no methods of medical testing available for those mycotoxins detection*
- e. Production of Reactive Oxidative Stress (ROS)
- f. Permanent genetic damage
- g. Damage to, and demyelination of the nervous system

The misdiagnosis of Mycotoxicosis is in a clinical category of its own. Historically, patients with mold exposure have exhibited multiple symptoms which seem unrelated to many attending physicians. These series of seemingly unrelated complex symptoms seem to make no sense to a physician who is not extremely familiar with the toxicological effects of organic compound poisonings. In a best effort to diagnosis and treat these patients, and having little to no experience with these toxic compounds this has led to the consistent misdiagnosis of patients by their attending physicians and many times placing these patients into the following categories of disease or syndromes:

- a. Chronic Sinusitis
- b. Fibromyalgia
- c. Chronic Fatigue Syndrome
- d. Asthma
- e. Lupus
- f. Sarcoidosis
- g. Leaky Gut Syndrome
- h. Chronic inflammation
- i. Extreme Inflammation
- j. Multiple Sclerosis (MS)
- k. Chronic obstructive pulmonary disease (COPD)
- l. Chronic Bronchitis
- m. Crohn's disease
- n. Inflammatory bowel disease (IBD)
- o. Rheumatoid arthritis
- p. Depression
- q. Anxiety
- r. Mental illness

Recently the CDC has released documentation onto its website clearly stating that exposure to the following mycotoxins has been documented as the direct cause of liver failure, kidney failure, kidney cancer, liver cancer, complex multiple symptoms and death in human beings.

- Aflatoxin
- Ochratoxin
- Trichothecene

CDC PAPERS - Detailing Disease and Death from Mycotoxin Exposure

- CDC – Health Studies Program : Chemical exposure – Aflatoxin¹²
- CDC – Statement for the Record Before the Subcommittees on Oversight and Investigations and Housing and Community Opportunity Committee on financial Services United States House of Representatives, “State of the Science on Molds and Human Health” Statement of Stephen C. Redd, MD¹³
- CDC – Case Definition - Chemical Emergencies - Trichothecene Mycotoxins¹⁴

The Environmental Factor

Multiple patients brought their environmental microbiology reports from the indoor water damaged structures where they claimed to have been exposed to mold with them into the medical center. The majority of those reports exhibit only Air-O-Cell, or air quality testing. Though primitive, their environmental testing reports in many cases supported more than a strong weight of evidence that the causal factor of their illnesses was directly derived from their environments and was the direct cause of their infection(s) and / or Mycotoxicosis.

In this study, we will address the consistency of positive and equivocal levels of mycotoxins reported in clinical testing, fungal and yeast colonization reported in clinical testing and their relationship to patient symptomology, commonly or uncommonly expressed by those patients.

Study Parameters

In this study:

1. All patients in this study were self-admitting
2. All patient data was derived from direct patient personal interviews
3. Fungal Culture test yielding positive results for fungal or yeast colonization via urine culture
4. Mycotoxin Testing yielding positive or equivocal results via urine specimen

Mycotoxin testing yields positive results at the following levels, levels less than those are considered equivocal:

- | | | |
|----|----------------|---|
| a) | Aflatoxin: | Positive at equal or greater than 1.0 ppb |
| b) | Ochratoxin: | Positive at equal or greater than 2.0 ppb |
| c) | Trichothecene: | Positive at equal or greater than 0.2 ppb |

Mycotoxin tests yielding positive and equivocal results were both used in this report data and its conclusion(s).

Patent Selection Process

The patients in this study and their data were randomly selected by our custodian of records. The custodian of records was instructed to randomly pull one hundred thirty five (135) patient files of their choosing, and was not given any reason for doing so. Those files were then opened for study. The study group consisted of seventy five (75) adult females, forty six (46) adult males, five (5) juvenile males and nine (9) juvenile females.

Our clinical findings for those patients exposure to indoor water damaged structures, claiming fungal contamination, and their expressed symptomologies are as follows:

Conclusions:

I. Testing Data

Total number of patients surveyed:	135
a. Number of patients showing the presences of Trichothecene:	118
b. Number of patients showing the presences of Ochratoxin:	117
c. Number of patients showing the presences of Aflatoxin:	15
d. Number of patients showing the presences of yeast colonization:	22
e. Number of patients showing the presences of fungal colonization:	21
F. Number of patients showing the presences of yeast & fungal colonization:	7
G. Number of patients showing the presences of co-exposure (exposure to more than one pathogen):	121

II. Testing Data by Percentages

a. Percentage of patients showing co-exposure:	90%
b. Percentage of patients showing the presences of Trichothecene:	87%
c. Percentage of patients showing the presences of Ochratoxin:	86%
d. Percentage of patients showing the presences of Aflatoxin:	11%
e. Percentage of patients showing the presences of yeast colonization:	17%
f. Percentage of patients showing the presences of fungal colonization:	16%
g. Percentage of patients showing the presences of yeast & fungal colonization:	5%

*Percentage margin of error < 1%

II. Common Symptoms

Below are the listed patient symptoms at the time of patient interviews and assessments. The number of the sample group was one hundred thirty five (135) patient files. The number associated with the symptom, represents the total number of patients out of the sample group with that specific symptom.

Total Sample Group Number of Patient Files 135

Total Number of Patients Claiming Fungal / Mold Exposure from Indoor Water Damaged Environment	135
Chronic Fatigue	117
Neurological Dysfunction	108
Headache	107
Short Term Memory Loss	90
Sinus Involvement	87
Pain in Joints and Muscles	78
Eye Irritations	71
Blurred Vision	67
Unspecified Breathing Disorder	59
Skin Rash / Skin Lesions	58
Heart Palpitations	54
Nausea	50
Night Sweats	48
Hair Loss	46
Diarrhea	45
Loss of Appetite	44
Ear Pain	42
Swollen Glands	42
Tightness in Chest	37
Weight Loss	36
Weight Gain	35
Sneezing	32
Nose Bleeds	29
Runny Nose	26
Low Grade Fever on and Off	26
Vertigo / Dizziness	22
Thrush	22
Sleep Apnea	21
Coughing up Blood	19
Loss of Sleep	18
Vomiting	17
Seeing spots	15
Yeast Infection (Vaginal)	13
Tremors	12
Onset High Blood Pressure	12
Chronic Bronchitis	11
Ear Drainage	11
Chest Pain	9
Itching	8
Sore Throat	7
Cough	4
Asthma	3
Muscle Wasting	3
Gum Recession	1

IV. Common Symptoms with the Highest Percentages in Presence

Chronic Fatigue:	87%
Neurological Dysfunction:	80%
Headaches:	79%
Short Term Memory Loss:	67%
Sinus Involvement:	65%
Pain in Joints and Muscles:	58%
Blurred Vision:	50%
Unspecified Breathing Disorder:	44%
Skin Rash / Skin Lesions:	43%

Patient testing positive for co-exposures (exposure to multiple pathogens):	90%
Patients testing for the presence of Trichothecene:	88%
Patients testing for the presence of Ochratoxin:	87%
Patient testing for the presence of Aflatoxin:	12%
Patients testing positive for yeast colonization:	17%
Patients testing positive for fungal colonization:	16%

*Percentage margin of error < 1%

Neurocognitive function testing was administered to one hundred two (102) patients out of the one hundred thirty five (135) parents in the study group. Some patients did not qualify for this type of testing due to medical impairments or did not wish this type of testing preformed. The results are as follows:

Total patients tested:	102
Total patients testing positive for neurocognitive dysfunction:	77
Total patients testing negative for neurocognitive dysfunction:	25
Total patients that did not participate in this test:	33

Percentage of patients testing positive for neurocognitive dysfunction:	76%
Percentage of patients testing negative for neurocognitive dysfunction:	24%

In conclusion, the percentage of patients testing positive or equivocal for the presences of these three types of mycotoxins undeniably share related and comparable symptomology, dysfunction, disease and similar impairments. Of those patients seeking treatment and claiming fungal exposure approximately only sixteen percent (16%) to seventeen percent (17%) had active fungal or yeast colonization present, but all had detectable levels of mycotoxins present. Therefore, the common factor of these patients' symptoms and impairments has been deduced as Mycotoxicosis, derived from indoor water damaged structures which exhibited or tested positive for fungal / mold growth contamination.

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