RESPONSE TO QUERY – LAURIE SIMMONS, WTKR 13 January 2012

1. Why does the hospital command say there are no federal standards for acceptable levels of mold and determining health risk? The EPA themselves created the ERMI test, which stands for the Environmental Relative Moldiness Index. This determines the relative "mold burden" in the home, and if a home is found with a high burden, then doctors can determine the threat for sickness. Links to EPA website about ERMI test http://www.epa.gov/microbes/moldtech.htm

http://www.epa.gov/microbes/ermifactsht.html

Answer:

The absence of federal standards for acceptable mold levels is a matter of fact and law. According to the Environmental Protection Agency (EPA), standards or Threshold Values for airborne concentrations of mold, or mold spores, have not been set. Currently, there are no EPA regulations or standards for airborne mold contaminants.

According to the EPA, ERMI is a research tool. The EPA also states it is still, "being evaluated in research studies by the U.S. Environmental Protection Agency (EPA)" and "As research continues, the index will be refined". ERMI is a qualitative index and cannot be used as an accurate measure of exposure.

Standards of exposures such as Occupational Safety and Health Administration Permissible Exposure Levels (PELs), American Conference of Governmental Industrial Hygienists Threshold Limit Values® (TLV®) EPA standards are meant to protect the health of the general public and have accurate ways to measure chemicals and particulates accurately and consistently, and have scientific evidence to demonstrate a safe or unsafe level. No such standards exist for mold, organic compounds related to mold, or spores.

It is important to note, the EPA's recommended mold remediation guidance is based on physical inspection for mold and water damage. EPA does not recommend that homes routinely be tested or sampled for mold.

2-A. Are you familiar with new research on humans done by Dr. Ritchie Shoemaker and other doctors associated with Center for Research on Biotoxin Associated Illness? They show that mold does not just cause allergies and respiratory illness, but in 25% of the population causes an actual sickness in people who have a gene deficiency in their DNA.

Answer:

Navy physicians and scientists are aware of Dr. Shoemaker's research. The issue of whether any human disease can be caused by mold is controversial. Many of Dr Shoemaker's claims, conclusions, testing, and treatment methods are in conflict with widely accepted medical and scientific sources of information on the subject of mold exposure and human disease. These sources include the Center for Disease Control; the American Academy of Allergy, Asthma, and Immunology; and, the American College of Occupational and Environmental Medicine. These organizations are widely accepted as providing the most reliable information and medical guidance in the best interest of patient safety. The Navy, as most physicians in the United States, use evidence-based medicine to diagnose and treat their patients.

2-B. Do you require keeping your doctors in the Navy up to date on new research in the field, considering mold has been a problem in many military buildings and ships all over the country?

Answer:

Continuing medical education on current and accepted practices, is a requirement for all Navy doctors.

3. At recent health forums, Navy Public Health officials have handed out information from the CDC and ACOEM. Have you actually looked at the citations of these research papers? Questions have been raised by many in the mold illness field about the legitimacy of their findings, and the fact that these papers are all based on opinions taken from research on rats, not humans.

Answer:

The Centers for Disease Control and Prevention (CDC) and the American College of Occupational and Environmental Medicine (ACOEM) are nationally and internationally recognized organizations independent of the U. S. Navy. The information produced by these organizations represents the work of experts in their fields and is well regarded and accepted in the medical and scientific community. The CDC handout was their current information sheet which we felt would be useful to residents and not a position or research paper.

The NMCPHC reviewed the references in the ACOEM position paper as well as other papers from authoritative sources. The ACOEM position paper titled, "Adverse Human Health Effects Associated with Molds in the Indoor Environment" contains 78 references.

Only eight of those were studies involving animals. The remaining 70 references included epidemiologic and clinical investigations involving humans, reviews and working group reports. The references are robust and of good quality.

The American Academy of Asthma Allergy and Immunology (AAAI) position paper titled , "The Medical Effects of Mold" was also reviewed. This paper contained 44 references. The scientific studies were primarily human studies. No animal studies were found. Additionally, the Institute of Medicine's report titled, "Damp Indoor Spaces and Health" was also reviewed. This report contained a very large number of references, mostly dealing with humans.

The Food & Drug Administration (FDA) has a drug review process that involves animal testing before testing can be performed involving humans. The purpose of this process is to ensure that drugs are safe and effective in humans.

4. Research from the World Health Organization (WHO) has said for years that just being exposed to water damaged buildings, regardless of the levels of mold, will make people sick. Why are Navy doctors telling people that their illnesses in turn cannot be linked to the leaky home they have lived in for months/years?

Answer:

The World Health Organization document titled "WHO Guidelines for Indoor Air Quality: Dampness and Mould" specifically states, "The epidemiological evidence is not sufficient to conclude causal relationships between indoor dampness or mold and any specific human health effect."The WHO considers that there is insufficient evidence of a causal relationship with any of the health outcomes reviewed.

It should be noted the WHO reviewed the scientific literature regarding dampness and/or mold and asthma, and concluded that there was an epidemiologic association between building dampness and/or mold and respiratory health effects. Epidemiologic studies and research investigate health outcomes within populations using probability and statistics. These studies typically report mathematic associations between events or outcomes but a mathematic association in this context does not prove causation. Neither the WHO nor the Institute of Medicine (IOM)found direct causation between dampness and illness – however, both indicate more research is needed. In other words, more weight of evidence is required before causation is established.

To demonstrate the difference between epidemiologic association and causation consider the following scenario. A rooster crows every morning at 5 AM and the sun then rises at 5:15 AM. There is a strong mathematic association between the two events however the rooster crowing does not cause the sun to rise. In summary, association does not mean causation. However, associations are useful to form hypothesis that may be used to support further research to determine causation. **5.** Is the Navy Public Health Center being proactive in launching a comprehensive health survey of all Lincoln Military housing residents knowing there is a problem with mold and water damage in housing, or are they waiting for patients to show up for treatment?

Answer:

NMCPHC does not conduct routine surveillance of non-communicable diseases that are ill-defined or have high variability in the use of diagnosis codes.

The Navy does track persistent asthma as one of its high utilization health indicators at each medical treatment facility and trends can be observed by epidemiologists, but these instances are not associated with housing status. Because the database containing this information has a specific case definition, variability in diagnosis is reduced.

Due to high variability of any exposure data and clinical outcomes, the ability to control exposure and outcome misclassification is limited, requiring a very large study (1000's of people) to accurately assess morbidity as asked in your question. A study for this situation would most likely be inconclusive due to a lack of study precision (number of study participants) and high variability in exposure and diagnosis.

6. Are you concerned about the rising number of families coming forward with sick children, all experiencing high rates of asthma and respiratory illness? Are Navy doctors starting to see a pattern, especially with Lincoln military housing residents?

Answer:

We are always concerned with the health care of all military families. We are not seeing a pattern or trend. Several residents have expressed health concerns and Naval Medical Center Portsmouth staff has been made aware to report clinical concerns to the appropriate specialists and assist patients with referrals, when necessary.

7. Many families say they are having trouble with the Navy and Tricare in getting referrals to see specialists in the field of mold illness. What is being done to make sure these families are taken care of?

Answer:

TRICARE policy is promulgated by the Department of Defense and all services follow that policy. Navy Medicine and the local TRICARE network have numerous specialists to which Primary Care Managers (PCMs) can refer their patients. Patients who are having difficulties navigating the health care system should contact their PCM or the Health Benefits Advisors at the nearest Military Treatment Facility (medical center or clinic).

8. What are your doctors here in Hampton Roads taught about how to deal with patients showing symptoms of mold who are living in Lincoln Housing? What is the protocol for treatment?

Answer:

Regardless of location, all Navy Doctors receive continuing medical education on current and accepted practices as well as peer reviewed research.

9. Does mold "cause" allergies and/or asthma?

Answer:

Mold can be a trigger for genetically pre-disposed individuals with respiratory conditions such as asthma, but is <u>not</u> the cause.

Asthma almost invariably occurs in genetically predisposed individuals, many of whom may demonstrate multiple allergies to a variety of environmental allergens (dust mites, pollen, pet dander, etc.). There are numerous known asthma triggers, such as, viruses, bacteria, pets, and first and second hand tobacco smoke.

Likewise, allergies occur in hypersensitive individuals to environmental exposures, such as, chemicals, viruses, bacteria, plants material, pets, and first and second hand tobacco smoke.

It is very important that individuals with asthma or allergies, or those who exhibit allergy and/or asthma-like symptoms, see their primary care provider or specialist for diagnosis and treatment.

Additional Comment:

EPA's recommended mold remediation guidance is based on physical inspection for mold and water damage. EPA does not recommend that homes routinely be tested or sampled for mold.

Environmental molds are present both indoors and outdoors and are encountered as a normal part of everyday life. On any given day, there are thousands of mold spores per cubic meter of air (indoor or outdoor) that the majority of the U.S. population may be exposed to. This level is highly variable, depending on geographic location, weather, season, and time of day. It is estimated that 10% of the population are allergic to mold but only half of these, or 5%, would be expected to show clinical illness. Additionally, those that are immune compromised individuals (e.g., cancer patients) may also medically react to mold or spores. There is no defined level of active mold growth, spores in air, or dermal exposure that can be determined to elicit allergic or asthmatic symptoms.

There are hundreds of thousands of mold species that exist but we are only commonly exposed to about 200 species depending on where you live. Individual risks from exposure to a particular mold species may vary depending on a number of factors.

Uncertainty is further complicated by a lack of information on specific human responses to well-defined mold contaminant exposures. In combination, these knowledge gaps make it impossible to set simple, meaningful exposure standards for molds and related contaminants.

The Institute of Medicine Report, "Damp Indoor Spaces and Health," states: "...animal studies are important in identifying hazardous substances, defining their target organs or systems and their routes of exposure, and elucidating their toxicokinetics and toxicodynamics, the mechanisms that account for the biologic effects, metabolism, and excretion of toxic substances. Animal studies are also useful for generating hypotheses that can be tested through studies of human health outcomes in controlled exposures, clinical studies, or epidemiologic investigations, and they are useful for risk assessment that informs regulatory and policy decisions." There should not be concern about seeing animal studies in publications concerning conditions effecting humans. This is a part of responsible scientific methodology that in many cases should be performed prior to any studies are conducted in humans.

Additionally, the FDA has a drug review process that involves animal testing before testing can be performed involving humans. The purpose of this process is to ensure that drugs are safe and effective in humans. A description of this process can be found at: <u>http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm</u>.

In brief, animal studies must be conducted before human testing. The FDA will decide whether it is safe to move forward with human testing after it has reviewed the results of animal testing. This is a part of the Investigational New Drug Application (IND) phase.