Challenges in Biological Hazard Identification

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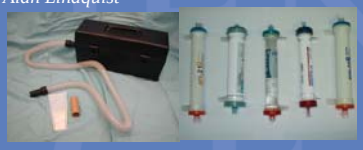

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What is Hazard Identification

- From EPA Glossary
  - –"Determining if a chemical or a microbe can cause adverse health effects in humans and what those effects might be."
  - –http://www.epa.gov/OCEPAterms/

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Hazard Identification OW Thesaurus

1. The process of determining whether exposure to an agent can cause a particular adverse health effect (e.g., cancer, birth defect) and whether the adverse health effect is likely to occur in humans at environmentally relevant doses. (EPA 2004)
2. Determining if a chemical or a microbe can cause adverse health effects in humans and what those effects might be. (EPA 2005b)
3. The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods. (CAC 1999, CAC 2003, FAO/WHO 2003b)
4. The identification of known or potential health effects associated with a particular agent. (FDA 2002)
5. The identification of the type and nature of adverse effects that an agent has as inherent capacity to cause in an organism, system or (sub) population. Hazard identification is the first stage in hazard assessment and the first step in the process of Risk Assessment. (IPCS/OECD 2004)
6. The identification of microbiological biological agents capable of causing adverse health effects and which may be present in water. (KIWA 2004)
7. The determination of whether a particular substance (e.g., chemical, microbiological, or physical element) or particular activity (skiing, climbing a ladder, etc.) is or is not causally linked to particular health, safety, environmental or ecological effects. Hazard identification is a qualitative description based on factors such as kind and quality of data on humans or laboratory animals, the availability of information from other studies (e.g., similarity to other chemicals, viruses or physical hazards) and the weight of the evidence from all of these data sources. (NYS 1998)
8. The process of determining whether exposure to an agent can cause an increase in the incidence of a health condition. (RAIS 2004, SRA 2004)

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- http://www.epa.gov/waterscience/criteria/humanhealth/microbial/thesaurus/T51.html

Components of Hazard ID

- Determining if a microbe can cause adverse health effects
- Determine the nature of those health effects
- May be descriptive, mechanistic or quantitative

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Steps of Hazard ID

- Identify the microorganism as a cause of human illness (Koch's postulates)
- Identify possible routes of transmission
- Identify pathogen characteristics (virulence, life cycle, etc.)
- Identify significant host characteristics
- Use appropriate detection and diagnostic tools for symptoms, infection and the organism
- Understand endemic versus epidemic risks

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Identify the microbe as a cause of human illness

- Presence of individuals exhibiting adverse health effects recognized as arising from the microorganism
- The presence of a known pathogenic microorganism
- Hazard and exposure are inextricably linked
  - –Multiple exposure pathways may be possible
  - –Each exposure pathway may result in a different disease process
- Koch's postulates

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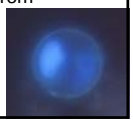
Koch's postulates

- Isolate the organism from every case of the disease
- Propagate the microorganism in pure culture
- Introduce the organism into a healthy host and cause disease
- Re-isolate the identical organism from the innoculated, diseased host

Emergence of a "new" disease

- 1989 and 1990 Kathmandu, Nepal Cyanobacteria-like bodies
- Outbreak in 1990 in physicians in Chicago.
- *Cyclospora* spp. recognized as a cause of human illness, 1993
- Species, *Cyclospora cayetanensis,* proposed by Ortega, Gilman and Sterling 1994
- Recognition of *C. cayetanensis* in outbreaks from produce in 1996 and 1997.
- Other endemic and epidemic areas

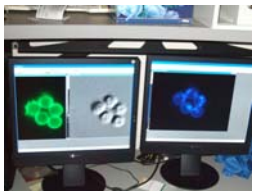


Identification of transmission routes

- *Bacillus anthracis*
  - Inhalation
  - Dermal
  - Gastro-intestinal/oropharyngeal

Second transmission route example

- *Cryptosporidium* spp.
  - Intestinal
  - Extra-intestinal, pulmonary, disseminated, etc.

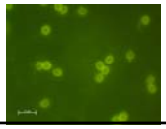


Pathogen characteristics

- *Cryptosporidium* spp. example
  - *Cryptosporidium parvum* and *C. hominis* are both known to cause human illness
    - *C. parvum* has zoonotic potential
    - *C. hominis* has no known naturally occurring non-human hosts
    - At least 4 other species have been found infectious to humans
  - Infectious dose
    - Variability from strain to strain greater than species to species (*C. parvum* vs *C. hominis)*
- There are other intrinsic risk factors for other organisms, including toxins, and virulence factors, biofilms, osmoadaptation, etc.

Host factors

- Another *Cryptosporidium* spp. Example:
- Known to severely impact sensitive sub-populations (immunocompromized individuals)
  - In a mouse model, immune status impacted symptoms, immunocompromized mice had worse symptoms, were more likely to relapse, etc.
  - Chemically immunocompromized mice were less susceptible to infection



Understanding environmental factors, a story in two parts

- In Chiapas state, and near Tapachula in particular, a key malaria vector is *Anopheles albimanus*
  - This species prefers short emergent vegetation like flooded pastures
  - Vector habitat mapping by remote sensing allows good prediction of malaria transmission risk

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Vectors in Belize

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- The primary vector species in these areas appears to be *An. darlingi*, as borne out by the epidemiological investigation of outbreaks and associated habitats
- The floating detritis patches preferred by this species is not amenable to remote sensing techniques

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Diagnostic and detection tools

- Diagnostic tools largely regulated, detection tools largely not
- Data quality criteria for the detection tools
  - Presence absence
  - Quantification
  - Viability
  - Virulence
  - Other data quality parameters

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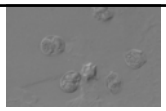

Epidemic versus endemic risk

- *Toxoplasma gondii*:
- Long known for vertical transmission, horizontal transmission through consumption of infected meat, accidental exposure to cat scat
- First cases of waterborne exposure reported in Panama in 1980's
- Large waterborne outbreak in Victoria B.C., Canada, 1995.
- Several waterborne outbreaks including Brazil, India, Guatamala, Turkey
- Survival of oocysts in seawater and shellfish, infection and death of marine mammals along west coast

Summary

- Diseases and our understanding of them are living and evolving
  - Health effects
  - Mechanisms of disease
  - Host/disease agent virulence relationships
  - Potential for causing exposures
  - Natural occurrence or habitat
- Hazard identification is more than detection of genetic elements or living organisms