



INFECTIOUS DISEASES INCORPORATED FUIDI PREMISES

Gilles R. G. Monif, M.D.

Infectious Diseases Incorporated

Premises are hypotheses awaiting scientific confirmation

Mycobacterium Avium Subspecies *Paratuberculosis* (Map) is a mycobacterium that is embedded in the food supply of herbivores. In cattle, it infects the gastrointestinal tract and induces transient or chronic enteritis. Using 1990's statistics, Map had an estimated 1.2 billion dollar adverse impact on producers (due to decreased milk and fat production, decreased slaughter weight, reproductive losses, and early replacement of productive animals). Despite the acknowledged economic losses to the dairy industry, producers have been reluctant to address the issue owing to Map's presence in unpasteurized milk and what was then deemed a possible causal relationship between Map and Crohn's disease in humans. USDA initiated a subsidized Map testing on a voluntary basis. To participate in the program, a producer would have had to pay a small portion of the cost plus potentially exposed unfavorable data about his or her herd.

Since 2008, Map has been recognized as a zoonotic pathogen for man. Map or its DNA has been demonstrated primarily in diseased tissue from individuals with inflammatory bowel disease. Similarly, Map has been demonstrated to be in the blood and breast milk of predominantly individuals with Crohn's disease. Governments have been reluctant to respond to the "Map dilemma", given the importance of milk and milk-based products to the national economies.

In 2002, Infectious Diseases Incorporated (IDI) began work on its patented FUIDI Herd Management Schema (FHMS). FHMS is a system that allows infected animals to remain in production yet reduces the amount of Map entering the human food supply through milk and milk-related products.

To create the FHMS, IDI had to free itself from the prevailing opinions/published literature and develop a number of independent sets of premises from its analysis of relevant observations and from its research in order to formulate the hypothesis that became the foundation block for the FHMS.

***Mycobacterium Avium* Subspecies *Paratuberculosis* (Map) and Genomic Variants**

1. Map is present in soil.
2. Map becomes embedded in the food supply of herbivores.
3. Map evolved from *Mycobacterium avium* subspecies *avium* (Ma).
4. Between Ma and Map polymorphic variants exist that can cause chronic enteritis in animals.
5. The older a pathogenic mycobacterium is phylogenically, the less virulence is the species.
6. Map is A cause of chronic enteritis in herbivores and other animals, but not THE sole cause of disease.
7. Pathogenicity varies among Map isolates.
8. Species virulence among pathogenic mycobacterium can be enhanced by current herd management practices that embed and disseminate into the production area environment isolates that have been selected to be effective pathogens for the host species in question.
9. Once introduced into the pasture or production environment, total elimination is at best very difficult.
10. Infected animals are not the ultimate reservoir for Map.
11. Map has the potential to be a zoonotic pathogen for humans.
12. Not all Map isolates are detected by IS900 direct primers.
13. Current commercial MAP ELISA tests do not identify all pathogenic mycobacterium that produce enteric disease in herbivores.



***Mycobacterium Avium* Subspecies *Paratuberculosis* (Map) and Johne's Disease**

1. Map is A cause of Johne's disease.
2. Host susceptibility is inversely related to age (as in humans).
3. Map herbivore infection can occur due to organism acquisition by transplacental transmission, in the newborn period, and in adult life (intra-herd dissemination).
4. The theorized three stage pathogenesis of Map infection cannot with stand scientific challenge.
5. IDI's construction of the natural history of Map infection is foundation for the FUIDI Herd Management Schema.
6. Host containment of Map can be overwhelmed by a combination of factors that alters its immune status.
7. USDA's policy of containing Johne's Disease by testing animal and culling animals with advanced infection reduces the incidence of Johne's disease, but does not reduce the prevalence of herd infection.
8. USDA commercially sanctioned Map ELISA test identify but a limited number of infected animals.
9. Fecal culture is a too insensitive test to anchor epidemiologic studies
10. The "gold standard" for assessing Map infection is PCR analysis of mesenteric and ileocecal lymph nodes.
11. The concept of "pass-through" technically and conceptionally is flawed.
12. Epidemiologic studies predicated upon Map fecal culture and the approved commercial Map ELISA tests are flawed in their foundation premises and are responsible for the current state of confusion concerning Map.
13. The use of confined production areas selects for propagation of the more virulent subgroup of Map.
14. Milk is one of the primary vehicles which expose humans to Map in significant numbers.
15. The virulence of Map isolates in milk are theorized to be greater than Map isolate found in the wild or water not exposed to domesticated herbivores.
16. Because of its replication in clumps, the use of the quantity of Map in a given fecal sample introduces the potential for significant sample and interpretation errors.

***Mycobacterium Avium* Subspecies *Paratuberculosis* (Map) and Crohn's Disease**

1. Directly or indirectly, Map is a zoonotic pathogen for human beings.
2. Map and related mycobacterium cause a spectrum of gastrointestinal conditions that include asymptomatic infections, an increase in bowel movements, irritable bowel syndrome, and inflammatory bowel disease.
3. Article 5.7 of the World Trade Organization's Agreement on Sanitary and Phytosanitary Measures and Principle 15 of the United Nations' Rio Declaration on Food Safety render the debate of direct vs. indirect ethically untenable .
4. Map initiates the production of tumor necrosis factor that is primarily responsible for gastrointestinal tissue damage.
5. Human beings will be perpetually exposed to Map.
6. Selected groups are genetically predisposed to developing inflammatory bowel disease.
7. Specific preventive step are required to protect the most vulnerable human beings (babies and children) without a genetic predisposition.
8. Voluntary monitoring programs without consequences and defined benefits will not work.

Comments and questions will be appreciated.

2012-08-18