

Regional Workshop on IPM Strategies to Reduce Tick-borne Diseases in the Southern United States (maybe we can just call it TICKSOUTH)

Workgroup: Laboratory Diagnosis, Disease Surveillance, and Case Reporting

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DRAFT SUMMARY OF DISCUSSION

Priority Concerns

- Need for active surveillance pilot sites so that defined clinical materials may be obtained for use in support of several initiatives, including proficiency testing, assay development and evaluation, and strengthen validation of existing assays.
- Development of new laboratory tools to enhance diagnostic capability using material obtained via new surveillance programs.
- Need for timely modifications to case definitions to reflect the aggregate etiology of our spotted fever group numbers and to clarify or establish strict criteria for case categorization.
- Need for identification of funding sources for both public health and commercial efforts to achieve these goals.

A. Laboratory Diagnostics: Remedial Actions

- Partner with local, state, and commercial laboratories to facilitate active surveillance efforts, focused research studies, and acquisition of better clinical specimens. Initiate incentive programs on a local/regional level to engage primary care physicians to participate in active surveillance to acquire the clinical specimens.
- Expand availability of defined control clinical specimen materials to improve diagnostic testing strategies to benefit the patient and to improve diagnostic testing strategies that benefit disease surveillance efforts. Collaboratively collect a complete set of specimens (paired sera, acute blood, acute skin biopsy if appropriate) from clinically defined patients.
- Improve availability of defined clinical specimens for use in assay development (both in-house and commercially).

- Improve availability of larger sample volumes of clinical specimens for use in proficiency testing.
- Initiate interchange of currently available specimens among laboratories to better achieve small-scale reciprocal proficiency testing and ensure consistent results (both quantitative and qualitative determinations) among laboratories.
- Establish standardization of analyte specific reagents used in-house, produced for limited distribution to state public health laboratories, or used commercially.
- Establish standardized criteria for serologic assays, including procedural parameters, analytical thresholds, and class-specificity of serologic assays.
- Expand the implementation of molecular testing procedures at the state public health and commercial laboratories so that testing availability is not a limiting factor in either clinical diagnosis or disease surveillance
- Establish standardized criteria for molecular assays, including procedural parameters, analytical thresholds, and specificity of amplification.
- Encourage further research into new serologic and molecular assays for rickettsial diseases to improve sensitivity and specificity for early clinical diagnosis.
- Encourage further research into the use of Western immunoblot assays to better define the immunologic response to rickettsial (*sensu lato*) pathogens.
- Encourage further research into new serologic assays and testing strategies for Lyme disease, particularly any assays for differentiating *Borrelia burgdorferi* infections from other *Borrelia* infections or STARI.
- Strengthen the commitment to making standardized analyte specific reagents, calibrated controls, and assay kits available to public health laboratories by establishing mechanisms for acquisition or production of bulk materials by both commercial and public health entities.
- Collaborate with commercial laboratories to better standardize both interpretive and guidance language incorporated into diagnostic reports. Facilitate the transfer of this information to the original submitter so that proper interpretation of any test result and guidance for laboratory follow-up and surveillance requirements are conveyed.
- Develop innovative methods to educate healthcare providers on testing strategies, test availability, and test interpretation so that patient care may benefit.
- Further educate physicians, laboratorians, epidemiologists, and other public health workers to ensure that appropriate specimens are collected at the appropriate time

in the illness, and tested with the proper assay to provide the most successful and efficient results.

- Improve submission of appropriate specimens so that certain problematic issues might better be resolved (e.g., the spotted fever concern).

B. Disease Surveillance and Case Reporting: Remedial Actions

- Collaborate with the Council for State and Territorial Epidemiologists (CSTE), CDC, and State Public Health Laboratories to propose changes in the current Rocky Mountain spotted fever (RMSF) case definition to reflect the fact that multiple spotted fever group rickettsial species are aggregated into this longstanding named category.
- Collaborate with the Council for State and Territorial Epidemiologists (CSTE), CDC, and State Public Health Laboratories to propose further modifications to the case definitions for Ehrlichiosis, Anaplasmosis, Q Fever, and RMSF to establish standard laboratory parameters and strict surveillance (epidemiological) thresholds for assays available for laboratory confirmation of suspect cases of tick-borne illness.
- Educate physicians, laboratorians, epidemiologists, and other public health workers on the concept that a threshold (“cut-off value”) for an assay has different meanings and uses for laboratory (analytical), clinical (medical), or surveillance (epidemiological) purposes.
- Educate physicians, laboratorians, epidemiologists, and other public health workers on the quality and limitations of existing data distributed through surveillance systems, informative publications, and other means.
- Encourage better transfer of clinical and epidemiological information on each specimen submitted for diagnostic testing so that useful interpretation of any laboratory results may be made.
- Develop incentives to increase participation of primary care physicians in providing a reasoned diagnostic workup that would ultimately be reflected in better case reporting.
- Establish one or more demonstration sites for targeted active surveillance within endemic areas to collect defined control clinical specimen materials to improve diagnostic testing strategies to benefit the patient and to improve diagnostic testing strategies that benefit disease surveillance efforts.
- Consider the concept of sentinel sites in endemic areas so that tick-borne diseases may be monitored in a more intensive manner. Evaluate whether a sentinel site

approach would improve disease surveillance of tick-borne diseases which have an inherently focal pattern of occurrence.

- Establish a more efficient infrastructure to facilitate the reporting of tick-borne disease cases electronically. Incorporate pertinent clinical, epidemiological, and laboratory information into any centralized system to improve disease surveillance.
- Incorporate new technology and assays into disease surveillance systems as they become established, validated, and transferred into public health and commercial laboratories.
- Seek administrative and budgetary support for targeted active surveillance projects to better define epidemiology of tick-borne diseases, specimen collection timing and types, and optimize testing methods and procedures.