

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 507

Introduced by: Infectious Diseases Society of America

Subject: Resolution on Next Generation Infectious Diseases Diagnostics

Referred to: Reference Committee E

Whereas: The Centers for Disease Control and Prevention (CDC) estimates that 2 million patients become ill and 23,000 deaths occur annually from infections caused by antibiotic resistant bacteria;

Whereas: The turnaround times of traditional infectious diseases (ID) diagnostic tests are too slow to impact the early treatment decisions of physicians;

Whereas: Without an early, accurate diagnosis, physicians often must treat seriously ill patients empirically with multiple broad spectrum antimicrobial drugs while awaiting ID diagnostic results;

Whereas: Empiric treatment subjects the patient to serious adverse events (including potentially deadly *Clostridium difficile* infection) and, by exerting selective pressure, drives the development of antimicrobial resistance;

Whereas: Rapid ID diagnostic tests are critical to guide antimicrobial stewardship;

Whereas: As antimicrobial resistance increases, physicians have fewer and fewer effective options of antimicrobial drugs to treat patients;

Whereas: The failure to rapidly identify the microbial etiology of the patient's illness as well as its antimicrobial susceptibilities contributes to longer hospital stays, increased healthcare costs, and poorer patient outcomes;

Whereas: Emerging rapid ID diagnostic technologies yield faster time to results, enabling physicians to initiate definitive antimicrobial treatment quickly, reducing the need and duration of empiric treatment, lowering healthcare costs associated with delayed diagnosis, and improving patient outcomes;

Whereas: Emerging rapid ID diagnostics face challenges reaching laboratories, including inadequate reimbursement for the cost of testing, regulatory hurdles and declining federal support for research and development, limiting their impact on patient care;

Whereas: Emerging rapid ID diagnostics are not fully and appropriately integrated into patient care and used optimally to convey their full potential benefits to patients;

Be it resolved that: Our AMA supports strong federal efforts to stimulate early research and development of emerging rapid ID diagnostic technologies through increased funding for appropriate agencies to cover clinical testing expenses; (New AMA Policy)

Be it resolved that: Our AMA supports the reduction of regulatory barriers to allow for safe and effective emerging rapid diagnostic tests, particularly those that address unmet medical needs, to more rapidly reach laboratories for use in patient care; (New AMA Policy)

Be it resolved that: Our AMA supports improving the clinical integration of new diagnostic technologies into patient care through outcomes research that demonstrates the impact of diagnostics on patient care and outcomes, educational programs and clinical practice guidelines for health care providers on the appropriate use of diagnostics, and integration of diagnostic tests results into electronic medical records; (New AMA Policy)

Be it resolved that: That our AMA support efforts to overcome reimbursement barriers to ensure coverage of the cost of emerging diagnostics (New AMA Policy)

Relevant References

1. Caliendo AM, Gilbert DN, Ginocchio CC, et al. "Better Tests, Better Care: Improved Diagnostics for Infectious Diseases." *Clin Infect Dis*. 2013; 57 (suppl 3): S139-S170
2. U.S. Centers for Disease Control and Prevention. National Vital Statistics Reports; October 2012. Available at: http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_06.pdf

Relevant AMA Policy

1. D-20.993 Promotion of Rapid HIV Test
Our AMA will work with any and all local and state medical societies, and other interested US and international organizations, to increase access to and utilization of Food and Drug Administration-approved rapid HIV testing in accordance with the quality assurance guidelines for rapid HIV testing developed by the Centers for Disease Control and Prevention. Additionally, pre- and post-test counseling should be performed in accordance with guidelines established by the CDC. (Res. 511, A-05; Modified: CCB/CLRPD Rep. 2, A-14)
2. D-165.999 The Impact of Rapidly Developing Biotechnology on the Delivery of Medical Care
(1) Our AMA Council on Medical Service will continue to study and report on the impact of technological developments on the practice of medicine, the patient-physician relationship, and the physician workforce. (2) Our AMA will accelerate efforts to implement its policy on individually owned and selected health expense coverage (Policy H-165.920), and other policies that promote individual fiscal responsibility for consumption of medical care. (CMS Rep. 14, I-98; Reaffirmed: CMS Rep. 4, A-08)
3. D-460.976 Genomic and Molecular-based Personalized Health Care
Our AMA will: (1) continue to recognize the need for possible adaptation of the US health care system to prospectively prevent the development of disease by ethically using genomics, proteomics, metabolomics, imaging and other advanced diagnostics, along with standardized informatics tools to develop individual risk assessments and personal health plans; (2) support

studies aimed at determining the viability of prospective care models and measures that will assist in creating a stronger focus on prospective care in the US health care system; (3) support research and discussion regarding the multidimensional ethical issues related to prospective care models, such as genetic testing; (4) maintain a visible presence in genetics and molecular medicine, including web-based resources and the development of educational materials, to assist in educating physicians about relevant clinical practice issues related to genomics as they develop; and (5) promote the appropriate use of pharmacogenomics in drug development and clinical trials. (CSAPH Rep. 4, A-06; Reaffirmed: CSAPH Rep. 4, A-10)

4. H-440.938 Multiple-Drug Resistant Tuberculosis - A Multifaceted Problem

- a. (1) Testing for tuberculous infection should be performed routinely on all HIV-infected patients, according to current recommendations from the U.S. Public Health Service.
- b. (2) Testing for HIV infection should be routinely performed on all persons with active tuberculosis.
- c. (3) Reporting of HIV infection and tuberculosis should be linked to enhance appropriate medical management and epidemiologic surveillance.
- d. (4) Aggressive contact tracing should be pursued for cases of active tuberculosis, especially if HIV-infected contacts or multiple-drug resistant tuberculosis strains have been involved.
- e. (5) HIV-infected health care workers and their physicians must be aware of the high risk of clinical TB for persons whose immune systems are compromised, due to HIV or other causes. They should be carefully apprised of their risk, and the risks and benefits of their caring for persons with active TB or suspected TB should be carefully considered.
- f. (6) HIV-infected and other immunocompromised patients should be sufficiently separated from tuberculosis patients and the air they breathe so that transmission of infection is unlikely.
- g. (7) All health care workers should have a tuberculin skin test upon employment, with the frequency of retesting determined by the prevalence of the disease in the community. Individuals with a positive skin test should be evaluated and managed according to current public health service recommendations.
- h. (8) Health care facilities that treat patients with tuberculosis should rigorously adhere to published public health service guidelines for preventing the nosocomial transmission of tuberculosis.
- i. (9) Adequate and safe facilities must be available for the care of patients with tuberculosis; in some areas this may necessitate the establishment of sanitariums or other regional centers of excellence in tuberculosis treatment.
- j. (10) Clinical tuberculosis laboratories should develop the capability of reliably performing or having reliably performed for them rapid identification and drug susceptibility tests for tuberculosis.
- k. (11) Routinely, drug susceptibility tests should be performed on isolates from patients with active tuberculosis as soon as possible.
- l. (12) A program of directly observed therapy for tuberculosis should be implemented when patient compliance is a problem.

- m. (13) The AMA should enlist the aid of the Pharmaceutical Research and Manufacturers of America (PhRMA) in encouraging manufacturers to develop new drugs and vaccines for tuberculosis.
- n. (14) The federal government should increase funding significantly for tuberculosis control and research to curtail the further spread of tuberculosis and encourage development of new and effective diagnostics, drug therapies, and vaccines.
- o. (15) The special attention of physicians, public health authorities, and funding sources should be directed toward high risk and high incidence populations such as the homeless, immigrants, minorities, health care workers in high risk environments, prisoners, children, adolescents, and pregnant women.
- p. (16) The AMA will develop educational materials for physicians that will include but not be limited to the subtleties of testing for TB in HIV-infected individuals; potential risk to HIV-infected individuals exposed to infectious diseases, including TB; and other issues identified in this report.
- q. (17) The AMA encourages physicians to remain informed about advances in the treatment of tuberculosis, including the availability of combination forms of drugs, that may reduce the emergence of drug-resistant strains. (BOT Rep. OO, A-92; Sub. Res. 505, I-94; Reaffirmed and Modified: CSA Rep. 6, A-04; Reaffirmed: CSAPH Rep. 1, A-14)