#### **GUIDELINES**

## Japanese guideline for clinical research of antimicrobial agents on urogenital infections: the first edition

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Revision of criteria for evaluation of clinical efficacy of antimicrobial agents on UTI (including the title in the revised edition)

In the 1970s, clinicians and researchers specializing in urinary tract infections (UTIs) established and published the first-ever Criteria for Clinical Evaluation of Drug Efficacy on UTI. There had so far been no uniform criteria for the evaluation of drug efficacy, and different criteria for determining drug efficacy had been used in the development of drugs, which had caused problems in determining drug efficacy and had made it impossible to compare efficacy between drugs. To resolve these challenges, the Criteria for Clinical Evaluation of Drug Efficacy on UTI were established on the basis of the results of a large number of studies. The late Dr. Masaaki Ohkoshi, the late Dr. Joji Ishigami, the late Dr. Tsuneo Nishiura, Dr. Toyohei Machida, Dr. Yoshiaki Kumamoto, Dr. Joichi

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Department of Urology, Division of Disease Control, Research Field of Medical Sciences, Graduate School of Medicine, Gifu University, 1-1 Yanagido, Gifu 501-1194, Japan e-mail: super7@gifu-u.ac.jp Kumazawa, Dr. Yukimichi Kawada, Dr. Sadao Kamidono, and other senior physicians made efforts to create the world's first Criteria for Clinical Evaluation of Drug Efficacy on UTI, which had contributed enormously to the development of antimicrobial agents for UTIs. In 1989, an International Symposium entitled "Clinical Evaluation of Drug Efficacy on UTI" was held in Tokyo and offered opportunities to get international recognition of the Criteria for Clinical Evaluation of Drug Efficacy on UTI. Thereafter, the International UTI Symposium was established and came to be held biennially in conjunction with the International Congress on Chemotherapy. The joint symposium has been held ten times to date.

In Japan, the Criteria for Evaluation of Clinical Efficacy of Antimicrobial Agents on UTI were created by the UTI study group. The Criteria, which were those of the revised 3rd edition, involved various urological infections, including prostatitis, epididymitis, and urethritis, in addition to UTIs. Meanwhile, Infectious Diseases Society of America (IDSA)/ Food and Drug Administration (FDA) guidelines and the Criteria for Clinical Evaluation of Drug Efficacy were established in the United States and Europe, respectively, which led to an increased need for international harmonization as well as globalization of the development of antimicrobial agents. To move with the times and to allow compatibility between data accumulated in Japan and data from other countries, the Study Group on Urology, the Committee of Clinical Evaluation Methods, and the Japanese Society of Chemotherapy discussed and created the 4th edition of Criteria for Evaluation of Clinical Efficacy of Antimicrobial Agents on UTI (tentative) and its supplement in 1996.

However, further international harmonization was needed, as international drug development, extrapolation of clinical data from other countries, and bridging studies had been increasing. In bringing about international



harmonization, there were many challenges due to differences between Japan and Western countries in the classification and diagnosis of UTIs and in the criteria for the clinical evaluation of drug efficacy and for clinical response. Moreover, the 4th edition of the Criteria for Evaluation of Clinical Efficacy of Antimicrobial Agents on UTI (tentative) was not user-friendly, such that some clinicians suggested that the clinical evaluation of drug efficacy should be simplified for clinical practice. Based on these suggestions, we decided to review the Criteria for Clinical Evaluation of Drug Efficacy on UTI for revision.

The following committee proceeded with the review of the 4th edition and agreed that a new revised version should be called the 5th edition of the Criteria for Clinical Evaluation of Drug Efficacy on UTI. However, when the committee introduced the outline of the 5th edition at the 19th symposium on UTI and discussed it among the members, the majority agreed that the new edition should be named "Japanese Guideline for Clinical Research of Antimicrobial Agents on Urogenital Infections". In addition to creating this guideline, we would like to express gratitude for the cooperation of the members of the Japanese UTI Research Group, who will be listed later.

#### Introduction

This guideline aims to objectively evaluate the efficacy of antimicrobial agents for the treatment of UTIs.

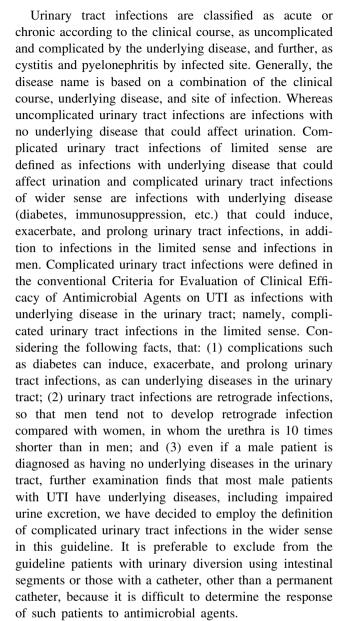
We have made efforts to allow use of the guideline in both general clinical studies and comparative studies and objective comparisons of individual study results. We have established the minimum necessary criteria in the guideline so that there is allowance to change items when considering individual cases or according to the practice of each institution.

#### **General considerations**

#### Target infections

Urological infections are classified as urinary tract infections (cystitis, pyelonephritis) and genital infections (urethritis, prostatitis, epididymitis) according to the site of infection. These infections are non-specific inflammations caused by common bacteria and are not specific inflammations caused by fungi, Mycobacterium species, viruses, etc.

Urinary tract infections include acute uncomplicated cystitis, acute uncomplicated pyelonephritis, and complicated urinary tract infection.



Genital infections include urethritis, acute bacterial prostatitis, and acute epididymitis.

Prostatitis is classified into four categories according to clinical condition by the NIH: category I, acute bacterial prostatitis; category II, chronic bacterial prostatitis; category III, chronic pelvic pain syndrome/chronic pain syndrome associated with prostatitis (A, inflammatory; B, noninflammatory); category IV, asymptomatic prostatitis. We include only category I; namely, acute bacterial prostatitis, in this guideline because the disease is clearly associated with bacteria, antimicrobial agents are used for the treatment of the disease, and it is possible to evaluate the efficacy of antimicrobial drugs over a relatively short period. Likewise, regarding epididymitis, we include only acute epididymitis in the guideline.



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