

Commitment of the Taiwanese Continence Society in the Development of Clinical Practice Guidelines for Male Lower Urinary Tract Symptoms/Benign Prostatic Hyperplasia

Yat-Ching Tong, M.D.

Department of Urology, College of Medicine, National Cheng Kung University, Tainan, Taiwan

INTRODUCTION

Benign prostatic hyperplasia (BPH) is associated with lower urinary tract symptoms (LUTS). The prevalence of LUTS suggestive of BPH (LUTS/BPH) is increasing in Taiwan because the number of older males in the population is increasing. Consequently, the economic burden associated with LUTS/BPH is increasing as well. On the other hand, the rapid developments in equipment and technique have increased a urologist's choices in diagnosis and treatment. Increased demand and increased options, with limited health resources means that health care delivery must be effective, economical and evidence-based.

Clinical guidelines are aimed to rationalize the diagnosis, treatment and follow-up of a particular disease. Guidelines developed under the sponsorship of the World Health Organization (WHO) were among the first to provide definitions and recommendations for the diagnostic evaluation and treatment of LUTS/BPH [1]. These WHO recommendations were based on a thorough review of the available literature and the opinion of experts on focused committees. In follow-up, other LUTS/BPH guidelines have been put forth by different organizations, including the American Urological Association (AUA) [2], Australian National Health and Medical Research Council (NHMRC) [3], British Association of Urological Surgeons (BAUS) [4], Canadian Urological Association [5], European Association of Urology (EAU) [6] and the 5th International Consultation on BPH [7]. Guidelines can be applicable on an international scale or may be country specific. Practicing urologists might be confused by different recommendations from these guidelines. Moreover, it has been shown that many guidelines on the management of male LUTS have failed to change the clinical behavior of general practitioners and are poorly accepted by the urologic community [8]. Obviously, if a set of guidelines is to stand the test of time, it must be updated regularly, because new evidence continues to emerge. Moreover, guidelines are only useful in a country if it takes into consideration the local healthcare environment and system. In Taiwan, the Bureau of National Health Insurance is pushing forward implementation of the Diagnosis Related Group (DRG) reimbursement system which would have a profound effect on clinical practice. So, Professor Hann-Chorng Kuo, the incumbent president of the Taiwanese Continence Society (TCS), has proposed a three-year project to establish clinical practice guidelines for five entities of lower urinary

tract dysfunction (LUTD): LUTS/BPH, overactive bladder (OAB), stress urinary incontinence/pelvic floor prolapse (SUI/POP), interstitial cystitis (IC) and geriatric incontinence (GI). We hope these guidelines will provide a useful roadmap for healthcare practitioners and providers when dealing with patients with LUTD.

WHY DO WE NEED OUR OWN GUIDELINES IN TAIWAN?

1. Although a number of foreign national and international clinical guidelines for LUTS/BPH already exist, there are differences in both the diagnostic and therapeutic recommendations made by these guidelines.
2. The context and instruments (such as questionnaires for evaluation of symptoms and quality of life) used in these foreign guidelines need linguistic and cultural adaptations. Currently we do not have properly validated documents in Mandarin Chinese or Taiwanese.
3. Environmental and ethnic differences exist in the practice of medicine. In addition, the healthcare and health insurance systems differ in different countries. Only country-specific guidelines can incorporate the special features of our own clinical environment in Taiwan.

ESSENTIAL ELEMENTS IN FORMULATING GUIDELINES: EVIDENCE-BASED MEDICINE AND EXPERTS

High-quality healthcare implies a practice that is consistent with the best available evidence. Evidence-based medicine (EBM) is the conscientious, explicit and judicious use of the current best evidence in making decisions about the care of individual patients [9]. Originally, clinical evidence was sought by meta-analysis of published, randomized, controlled trials and was a research method in its own right. Gradually, meta-analysis has evolved into a systemic review which includes not only published data from randomized controlled trials but also data from unpublished sources such as correspondence with principal investigators, conference proceedings and abstracts. Obtaining and critically appraising the evidence in the context of an individual's circumstances, is beyond the time, skills, and resources of most clinicians. To overcome these limitations, clinical practice guidelines have been developed with the aim of providing an evidence-based framework on which clinicians base their practice. Thus clinical practice guidelines are systemically developed statements designed to assist practitioner and patient decisions about appropriate health care for specific clinical conditions and/or circumstances. The purpose of practice guidelines is to reduce unwanted variations by setting agreed

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Address correspondence to: Dr. Yat-Ching Tong, Department of Urology, National Cheng Kung University Hospital, 138, Sheng-Li Road, Tainan, Taiwan
E-mail: yctong@mail.ncku.edu.tw

standards based on the best available evidence. As the contemporary diagnosis and therapy for LUTS/BPH has become more complicated and controversial, clinical guidelines based on EBM are needed to help doctors decide what tests to perform and what treatments to use. A clinical guideline can only be as good as the evidence upon which its recommendations are made. However, the selection, utilization and organization of evidence are in the hands of experts. One of the greatest challenges in developing clinical practice guidelines is the availability of evidence. Clinical recommendations based on randomized controlled trials are relatively straightforward. However when no convincing evidence exists, recommendations have to be based on expert opinion and consensus. The choice of guideline experts should emphasize not only depth, but also width. For LUTS/BPH, multidisciplinary representatives from the realms of urology, neurourology, urooncology, family medicine and geriatric nursing should be involved. According to the National Health Service (NHS) of the United Kingdom, the criteria for a good clinical guideline should include [10]:

- Validity
- Reproducibility
- Representativity/Multidisciplinarity
- Clinical applicability
- Cost-efficacy
- Flexibility
- Clearness
- Reviewability
- Amenability to clinical audit

The development of guidelines is a robust, time-consuming task involving different types of expertise. Thus the TCS should seek and welcome cooperation from government agencies, the medical/pharmaceutical industry, institutions and other organizations. With the collaboration of these sectors, high quality yet affordable healthcare services can be provided to the people of Taiwan.

THE TCS GUIDELINE ACTION PLAN

The essential steps in the development of a guideline include [11]:

- Setting the objectives
- Defining the issues and controversies
- Systemic search, extraction, rating and analysis of the evidence
- Cost analysis
- Drafting recommendations
- Guideline piloting
- Monitoring feedback and draft revision
- Guideline dissemination and implementation

Five *ad hoc* sub-committees (LUTS/BPH, OAB, SUI/POP, IC and GI) have been set up under the TCS Guideline Committee. Dr. Chih-Shou Chen is in charge of the LUTS/BPH committee. Nationally and internationally acclaimed scholars, physicians, scientists and medical personnel will be invited to participate in discussions of clinical evidence, current controversies and recent developments in LUTS/BPH. Conferences will be held in different parts of Taiwan to include opinions from all regions of the country. Under this plan, the first draft of diagnostic guidelines should be completed the first year and treatment guidelines the second year. By the end of the second year, a preliminary report on LUTD guidelines will be published for health professionals. During the third year, pilot clinical testing will be performed. Feedback concerning the preliminary recommendations will be gathered and evaluated, after which the guidelines will be

amended and updated with any new evidence. The final report of the recommendations will be released at the end of the third year.

Finally, it is obvious that development is not the only goal in setting guidelines. Guidelines are to be disseminated, utilized and validated. Developing and publishing a guideline does not automatically result in practice changes [12]. Prospective studies are necessary to help shape and maintain the most cost-effective, user-friendly and patient-focused clinical pathway for LUTS/BPH. Consequently, follow-up reviews of new evidence and updates of recommendations should be important parts of this long-term project of the TCS Guideline Committee for many years to come.

CONCLUSION

Taiwan is a rapidly aging society, so the clinical and economic burden in the treatment of patients with LUTS/BPH will be enormous. A roadmap for cost-efficient healthcare delivery to these patients has become a necessity. The TCS aims to develop guidelines that are effective, economical and evidence-based. However, we believe that implementation and utilization of the recommendations is not just an organizational responsibility of the TCS alone, but rather the individual responsibility of every person involved in the healthcare system.

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