

## The 2018 Revision to the Process of Care Model for Evaluation of Erectile Dysfunction

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### ABSTRACT

**Background:** Erectile dysfunction (ED) is a common condition that may affect men of all ages; in 1999, a Process of Care Model was developed to provide clinicians with recommendations regarding the evaluation and management of ED.

**Aim:** To reflect the evolution of the study of ED since 1999, this update to the process of care model presents health care providers with a tool kit to facilitate patient interactions, comprehensive evaluation, and counseling for ED.

**Methods:** A cross-disciplinary panel of international experts met to propose updates to the 1999 process of care model from a global perspective. The updated model was designed to be evidence-based, data-driven, and accessible to a wide range of health care providers.

**Outcomes:** This article summarizes the resulting discussion of the expert meeting and focuses on ED evaluation. The management of ED is discussed in an article by Mulhall et al (J Sex Med 2018;15:XXX-XXX).

**Results:** A comprehensive approach to the evaluation of ED is warranted because ED may involve both psychological and organic components. The updated process of care model for evaluation was divided into core and optional components and now focuses on the combination of first-line pharmacotherapy and counseling in consideration of patient sexual dynamics.

**Clinical Implications:** Patient evaluation for ED should encompass a variety of aspects, including medical history, sexual history, physical examination, psychological evaluation, laboratory testing, and possibly adjunctive testing.

**Strengths & Limitations:** This update draws on author expertise and experience to provide multi-faceted guidance for the evaluation of ED in a modern context. Although a limited number of contributors provided input on the update, these experts represent diverse fields that encounter patients with ED. Additionally, no meta-analyses were performed to further support the ED evaluation guidelines presented.

**Conclusion:** Comprehensive evaluation of ED affords health care providers an opportunity to address medical, psychological/psycho-social, and sexual issues associated with ED, with the ultimate goal being effective management and possibly resolution of ED. While some or all techniques described in the updated model may be needed for each patient, evaluation should in all cases be thorough. **Mulhall JP, Giraldi A, Hackett G, et al. The 2018 Revision to the Process of Care Model for Evaluation of Erectile Dysfunction. J Sex Med 2018;XX:XXX-XXX.**

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## INTRODUCTION

By definition, erectile dysfunction (ED) is the “consistent or recurrent inability to attain and/or maintain penile erection sufficient for sexual satisfaction.”<sup>1</sup> This condition is projected to affect more than 320 million men worldwide by 2025.<sup>2</sup> The prevalence of ED increases with age and, in a variety of studies employing different ED definitions and methodologies, generally were <10% among men aged <40 years, <15% for men aged between 40 and 49 years, approximately 20–30% for men aged 50–69 years, 20–40% for men aged 60–69 years, and 50–100% for men aged  $\geq$ 70 years.<sup>3</sup>

Improvements in ED can be achieved by lifestyle changes, such as weight control, smoking cessation, a healthy diet, and exercise, which play a complementary role in ED management.<sup>4</sup> The management of specific comorbidities may also help improve ED. Treatment of obesity and hyperlipidemia have been associated with improved erectile function, whereas the impact of treating diabetes and depression is less clear.<sup>5,6</sup> Phosphodiesterase type 5 (PDE5) inhibitors (PDE5Is) are considered first-line treatment for most men with ED unless contraindicated.<sup>7,8</sup> These drugs act by slowing the degradation by PDE5 of cyclic guanosine monophosphate, an important regulator of intracellular calcium that plays a key role in the smooth muscle relaxation and subsequent blood accumulation in the corpora cavernosa required for an erection.<sup>8</sup>

In 1999, following the approval of sildenafil to orally treat ED, a group of psychiatrists, urologists, and 1 family medicine physician collaborated to write “The Process of Care Model for Evaluation and Treatment of Erectile Dysfunction.”<sup>9</sup> However, the 1999 model was developed during an era in which ED was considered to be within the purview of clinical specialists rather than a broad range of health care professionals. Currently, ED is evaluated and managed by a diverse group of clinicians, including primary care physicians, nurse practitioners, andrologists, urologists, oncologists, pharmacists, and others. Moreover, the 1999 model emphasized altering reversible causes of ED rather than risk factors and comorbidities and did not discuss sexual dynamics as a critical part of patient evaluation. Nor did the 1999 model focus on guidance for patient examination to reduce barriers to diagnosis. To address these changes in the field, a cross-disciplinary group of international experts that included urologists, endocrinologists, psychiatrists, and other specialists (2017 Process of Care in Erectile Dysfunction Expert Panel)\* met to propose updates to the 1999 process of care model from a global perspective. Guidance from the British Society for Sexual Medicine<sup>10</sup> and the European Association of Urology<sup>11</sup> was taken into consideration during the update.

\*2017 Process of Care in ED Expert Panel members: Urologists (John P. Mulhall, USA; Landon Trost, USA; Wayne J. G. Hellstrom, USA); Endocrinologist (Emmanuele A. Jannini, Italy); Sexologist and Urologist (Geoff Hackett, UK); Psychiatrist (Annamaria Giraldo, Denmark); Sexologist (Eusebio Rubio-Aurioles, Mexico).

The current article summarizes the resulting discussion and focuses on ED evaluation. The management of ED is discussed in a separate article by Mulhall et al<sup>12</sup>.

The updated model was designed to be evidence-based, data-driven, and accessible to all types of sexual health professionals. In addition, the model was divided into core and optional components and now focuses on the combination of first-line pharmacotherapy and counseling in consideration of patient sexual dynamics. The goal of this review is to present health care providers with a tool kit to facilitate patient interactions, comprehensive evaluation, and counseling for ED.

## OVERVIEW OF PATIENT EVALUATION

The evaluation of patients for ED involves a variety of techniques that have evolved with greater understanding of the condition. All techniques may not be needed for each patient, but evaluation should be thorough in each case. In the past, organic ED (ie, due to vascular, neurologic, anatomic, or endocrinologic factors) and nonorganic ED (ie, due exclusively or predominantly to psychological or interpersonal factors) were distinguished from one another.<sup>13</sup> Nonorganic ED (also called idiopathic or psychological ED) was frequently assumed to be the cause of ED in men aged <40 years.<sup>14</sup> Young men with acute-onset ED may have been referred to sexual counseling for psychological ED, without further medical diagnostic evaluations being conducted.<sup>14</sup> Conversely, older men with a slow onset of ED may have been automatically categorized as having organic ED and prescribed a PDE5I. If success was suboptimal, these older patients may have failed to seek additional care when counseling may have been useful.<sup>15</sup> Both of these examples may actually constitute mixed ED, with both psychological and organic components.<sup>16,17</sup> As the study of ED has evolved, it is now more appropriate to view ED as a symptom or marker of another disease (eg, metabolic, neurologic, or a combination) vs a primary condition, suggesting that a variety of evaluations may be necessary to secure an accurate diagnosis.

The initial evaluation of a patient presenting for ED differs from that for a patient presenting with reports of risk factors associated with ED (described below). The patient who seeks help for ED has already bypassed the sometimes significant barrier of being too embarrassed to discuss their condition. Clinician-patient communication can begin with a discussion of the patient’s goals and expectations in seeking treatment, taking into consideration the goals of the couple if applicable. Clinicians can then emphasize the importance of evaluating and addressing any underlying conditions rather than simply treating the symptom of ED. During the initial and subsequent visits, the clinician should explain the effect of comorbidities and biological (eg, age) and psychosocial (eg, sexual history, relationship, anxiety) factors on sexual health, offer support, and offer the option to include the sexual partner in discussions of ED treatment.

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