

## ERECTILE FUNCTION

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

John P. Mulhall, MD,<sup>1</sup> Annamaria Giraldi, MD, PhD,<sup>2</sup> Geoff Hackett, MD,<sup>3</sup> Wayne J. G. Hellstrom, MD,<sup>4</sup> Emmanuele A. Jannini, MD,<sup>5</sup> Eusebio Rubio-Aurioles, MD, PhD,<sup>6</sup> Landon Trost, MD,<sup>7</sup> and Tarek A. Hassan, MD, MSc<sup>8</sup>

## ABSTRACT

**Introduction:** Erectile dysfunction (ED) is a common condition the treatment of which over the years has expanded from specialty care settings to various other clinical settings. A Process of Care Model was developed in 1999 to provide primary care physicians with guidance in the diagnosis and management of ED.

**Aim:** This update to the Process of Care Model aims to reflect current ED management practices, because the study of ED has changed since 1999.

**Methods:** Updates to the Process of Care Model were developed during a meeting of international experts from diverse disciplines. The updated model is data-driven, evidence-based, and relevant to a wide range of healthcare providers.

**Main Outcome Measures:** This article summarizes the results of the expert meeting and focuses on ED management. The evaluation of ED is discussed in a separate article.

**Results:** The updated model presents modification of risk factors and correction of comorbidities frequently associated with ED as critical parts of patient management. Patients should be encouraged to make positive lifestyle changes such as improving diet and increasing physical exercise. Lifestyle changes may be accompanied by the first-line medical therapies of sexual counseling and therapy, which takes into consideration patient sexual dynamics and pharmacotherapy with phosphodiesterase 5 inhibitors (PDE5Is).

**Clinical Implications:** The updated model provides guidance regarding risk factors associated with ED, their modification, sexual counseling, and PDE5I selection, dosing, and patient education.

**Strengths and Limitations:** This update leverages the extensive clinical expertise and experience of the authors to provide updated, comprehensive guidance for ED management. The model reflects the views and experiences of a limited number of contributors; however, these authors draw upon a diverse array of clinical specialties and are regarded as experts in their fields. Additionally, no meta-analyses were performed to further support the ED evaluation guidelines presented.

**Conclusion:** Effective management of ED may be achieved through a combination of patient risk factor modification and first-line therapy, taking into consideration any patient comorbidities known to be associated with ED. Treatment goals should be individualized to restore sexual satisfaction to the patient and/or couple and improve quality of life based on the patient's expressed needs and desires. **Mulhall JP, Giraldi A, Hackett G, et al. The 2018 Revision to the Process of Care Model for Management of Erectile Dysfunction. J Sex Med 2018;XX:XXX–XXX.**

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<sup>1</sup>Memorial Sloan Kettering Cancer Center, New York, NY, USA;

<sup>2</sup>Sexological Clinic, Psychiatric Center Copenhagen, Department of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark;

<sup>3</sup>Aston University Birmingham, Birmingham, UK;

<sup>4</sup>Tulane University Medical Center, New Orleans, LA, USA;

<sup>5</sup>Endocrinology and Medical Sexology (ENDOSEX), Department of Systems Medicine, University of Rome Tor Vergata, Rome, Italy;

<sup>6</sup>Asociación Mexicana para la Salud Sexual, A.C. (AMSSAC), La Joya, Mexico City, Mexico;

<sup>7</sup>Mayo Clinic, Rochester, MN, USA;

<sup>8</sup>Pfizer Inc, New York, NY, USA

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## INTRODUCTION

Erectile dysfunction (ED) is defined as the “consistent or recurrent inability to attain and/or maintain penile erection sufficient for sexual satisfaction.”<sup>1</sup> It is an age-dependent symptom, estimated to occur in 16% to 22% of men.<sup>2</sup> Reported prevalence stratified by age varies with study design, ED definition, and methodologies used but usually ranges from 1% to 10% for men < 40 years old, 2% to 15% for men aged 40 to 49 years, 22% to 31% for men aged 50 to 69 years, 20% to 40% for those aged 60 to 69, and 50% to 100% for men older than 70 years.<sup>2</sup> Some studies have found a higher reported prevalence in certain countries of Asia compared with those in Europe or South America.<sup>2</sup> The rate of ED is also higher for men with diabetes, heart disease, hypertension, and lower education.<sup>3</sup>

With the development of phosphodiesterase 5 inhibitors (PDE5Is) for the treatment of ED nearly 20 years ago, management of ED moved from an exclusive specialty urology care setting to include primary care physicians. This shift led to the development of a Process of Care Model in 1999—just 1 year after sildenafil citrate (Viagra, Pfizer Inc, New York, NY) was approved by the U.S. Food and Drug Administration (FDA) as the first PDE5I for treatment of ED—to help guide primary care physicians in the diagnosis and management of ED.<sup>4</sup> The model was instrumental in providing a stepwise approach for the treatment of men with ED, guiding physicians on best practices. Several advances in ED evaluation and management have occurred in the nearly 2 decades since that initial model was developed.

Previously, ED was considered a disease itself, whereas ED is now generally acknowledged to be a manifesting sign of 1 or more of several contributing factors such as anatomic, vascular, endocrine, metabolic, neurologic, or iatrogenic symptoms,<sup>5</sup> including depression, anxiety,<sup>5,6</sup> and relationship issues,<sup>7</sup> cardiovascular disease,<sup>8</sup> diabetes,<sup>9</sup> illegal drug abuse,<sup>10</sup> heavy alcohol consumption,<sup>11</sup> hormone abnormalities,<sup>12</sup> and lower urinary tract symptoms.<sup>13</sup> Indeed, ED is a viable predictor of occult cardiovascular disease and is associated with a similar or greater risk of cardiovascular events than dyslipidemia, family history of myocardial infarction, or current or past history of smoking.<sup>8</sup> In the past, the etiology of ED was thought to be classified easily into organic (vascular) and nonorganic (psychogenic) causes, but we now know that most ED is a combination of organic and non-organic contributing factors. This “mixed etiology” reflects the interplay among physiological factors such as erection hardness and psychological factors such as confidence and anxiety, which underscore the potential complexity of managing ED.<sup>14</sup> Thus evaluation and management of ED is now overseen by a broader range of healthcare professionals, including primary care physicians, urologists, nurse practitioners, andrologists, endocrinologists, psychiatrists, psychologists, cardiologists, oncologists, pharmacists, and sexual medicine practitioners, among others. In addition, the approach to conducting patient examinations to minimize barriers to diagnosis has evolved, as well as the

understanding of the need for treatment goals to be individualized for the patient and/or couple.

These substantial changes within the ED field merit an update to the Process of Care Model to reflect contemporary ED management practices, with input gathered from an international multidisciplinary group of experts (2017 Process of Care in ED Expert Panel\* that included psychiatrists, urologists, endocrinologists, and sexologists), as well as guidance from the European Association of Urology<sup>15</sup> and British Society for Sexual Medicine.<sup>16</sup> This portion of the updated model focuses on patient management. A separate update will include information regarding which examinations to conduct and how to conduct them. Whereas the original model highlighted modifying reversible causes of ED, the updated model discusses modification of risk factors and correction of comorbidities. Moreover, the first model divided treatments into first-, second-, and third-line therapies; the updated model focuses on first-line pharmacotherapy along with sexual counseling and consideration of patient sexual dynamics.

## PATIENT MANAGEMENT

The goal of patient management is to bring the patient or couple back to sexual satisfaction and improve quality of life based on the patients' expressed desires and needs. Counseling based on those needs is an essential component of patient management and requires establishing good communication to foster positive patient–clinician interactions that ensure patient concerns are addressed and clinician advice is implemented. This section presents a tool kit to aid healthcare providers in addressing patient goals. Goals will vary for individuals based on age, sexual habits, relationship status, sexual orientation, culture/religion, and health status/comorbidities. ED significantly affects quality of life on both the emotional and sexual life scales of the Psychological Impact of Erectile Dysfunction measure.<sup>17</sup> Important collateral benefits of managing ED to improve quality of life are the health benefits achieved by modifying risk factors shared with cardiovascular disease, diabetes, and depression.

### Risk Factors and Modifications

There are several risk factors associated with ED (Table 1), suggesting that sexual health may be a reflection of overall health.<sup>21,22</sup> As such, managing these risk factors is an important component of ED treatment. Lifestyle changes such as quitting smoking, losing weight, increasing physical activity, and changing diet may contribute to improved erectile function.<sup>23</sup> For

\*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 Giraldi, Denmark); Sexologist (Eusebio Rubio-Aurioles, Mexico).

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