Society for Women's Health Research

February 1, 2018

Submitted electronically to: publiccomments@icer-review.org

Steven D. Pearson, MD, MSc, President
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

Re: Society for Women's Health Research Input on Endometriosis

Dear Dr. Pearson:

The Society for Women's Health Research (SWHR®) appreciates the opportunity to provide input to the Institute for Clinical and Economic Review (ICER) on a range of chronic, debilitating conditions disproportionately or exclusively affecting women. SWHR, a nonprofit organization based in Washington, DC, is widely recognized as a thought leader in promoting research on biological differences in disease and eliminating imbalances in care for women through science, advocacy, and education.

Endometriosis presents one such example of a complex, heterogeneous estrogen-driven disorder associated with pelvic pain and infertility. Endometriosis occurs in about 6-10% of reproductive age women, and is most often diagnosed when they are in their 30s and 40s.[1]

An estimated two-thirds of women with endometriosis are symptomatic, while the remaining third may have no symptoms. Endometriosis symptoms can include painful menstrual cramps, pain in the lower back and pelvis, pain during or after sex, intestinal pain, painful bowel movements and urination during menstrual periods, bleeding or spotting between menstrual periods, and digestive problems. Infertility and reduced fecundity is

[1] American Congress of Obstetrics and Gynecology. *Obstet Gynecol*. 2010;116(1):223-226.

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also common,[2] with one study finding that among the 71% of women with endometriosis who attempted to conceive, 90% experienced difficulties.[3]

On average, women with endometriosis make seven healthcare professional visits before seeing specialists, with an average diagnostic delay of 6.7 years, and nearly three-quarters of the women experiencing a misdiagnosis[4]. Among the reasons for delays in the diagnosis of endometriosis include: attitudes toward menstruation and the "normalization" of pain by women, their mothers, and healthcare providers; nondiscriminatory exams (both digital examination and transvaginal ultrasound); intermittent use of contraception causing hormonal suppression; and misdiagnosis.[5] As a result, patients suffering from endometriosis may experience stigma, including feelings of discomfort about themselves or negative reactions from others, which can prevent patients from getting appropriate care, treatment, and compassion.

As a stigmatized disease that solely impacts women in their prime working and childbearing years, the burden of endometriosis has significant negative effects. Endometriosis often causes issues in performing daily tasks such as household chores; and can negatively impact sexual relations, productivity in the workplace, appetite, exercise, and sleep.[6] Total productivity loss in employed women with endometriosis averages 6.3 hours per week, with the majority of lost productivity due to presenteeism.[7]

Due to stigma and lack of information about the disease, many healthcare providers do not adequately or appropriately treat endometriosis. In the most extreme example, some women with endometriosis have hysterectomies at a young age, many of which are medically unnecessary. The burden of endometriosis is further complicated by comorbid conditions including depression, anxiety, autoimmune and endocrine disorders, and migraine,[8,9,10] which impacts diagnosis, treatment, and cost of a disease that has not seen innovation in decades.

New diagnostic and therapeutic options have the potential to improve health quality significantly for patients, and thus reduce the social and economic burdens associated with this complex, estrogen-driven disease. We appreciate ICER's intent to employ a patient-centered (in this case, female-centered) approach when assessing the value and effectiveness of new treatment options. We urge ICER to use progressive modeling techniques that capture the indirect costs of the stigma and societal burden of this

[2] The Practice Committee of the American Society for Reproductive Medicine. *Fertil Steril*. 2012;98(3):591-598.
[3] Fourquet et al. *Fertil Steril*. 2010;93(7):2424-28. doi: 10.1016/j.fertnstert.2009.09.017.
[4] Nnoahahm et al. *Fertil Steril*. 2011 Aug;96(2):366-373.e8. doi: 10.1016/j.fertnstert.2011.05.090.
[5] Hudelist et al. *Hum Reprod*. 2012 Dec;27(12):3412-6. doi: 10.1093/humrep/des316.
[6] Fourquet et al. *Fertil Steril*. 2010;93(7):2424-28. doi: 10.1016/j.fertnstert.2009.09.017.
[7] Soliman et al. *J Manag Care Spec Pharm.* 2017;23(7):745-754.
[8] Laganà et al. *Int J Womens Health*. 2017;9:323–330.
[9] Sinaii et al. *Hum Reprod*. 2002 Oct;17(10):2715-24.
[10] Tietjen et al. *Headache*. 2007 Jul-Aug;47(7):1069-78.

debilitating estrogen-driven condition and the cost benefit of gains in functioning associated with treating endometriosis to improve a woman's management of co-morbid conditions, such as those identified above.

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SWHR appreciates the opportunity to provide the above input and we look forward to serving as a resource to ICER on a range of chronic conditions affecting women.

If you have questions or if we can provide further information to inform ICER's analysis, please contact Sarah Wells Kocsis, Vice President of Public Policy, at 202.496.5003 or swellskocsis@swhr.org.

Sincerely,

Amy M. Miller, PhD
President and Chief Executive Officer
Society for Women's Health Research