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ORIGINAL ARTICLE



## Development of a visual, patient-reported tool for assessing the multi-dimensional burden of endometriosis

Sawsan As-Sanie<sup>a</sup> , Marc R. Laufer<sup>b,c,d</sup>, Stacey A. Missmer<sup>b,e,f,g</sup>, Ally Murji<sup>h</sup>, Katy Vincent<sup>i</sup>, Samantha Eichner<sup>j</sup>, Sarah Cross<sup>j</sup>, Ahmed M. Soliman<sup>j</sup> and Frank Tu<sup>k</sup>

<sup>a</sup>Department of Obstetrics and Gynecology, University of Michigan, Ann Arbor, MI, USA; <sup>b</sup>Boston Center for Endometriosis, Boston Children's and Brigham and Women's Hospitals, Boston, MA, USA; <sup>c</sup>Division of Gynecology, Boston Children's Hospital and Harvard Medical School, Boston, MA, USA; <sup>d</sup>Department of Obstetrics, Gynecology, and Reproductive Biology, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA; <sup>e</sup>Department of Epidemiology, Harvard T.H. Chan School of Public Health, Boston, MA, USA; <sup>f</sup>Division of Adolescent and Young Adult Medicine, Boston Children's Hospital and Harvard Medical School, Boston, MA, USA; <sup>g</sup>Department of Obstetrics, Gynecology, and Reproductive Biology, Michigan State University, Grand Rapids, MI, USA; <sup>h</sup>Department of Obstetrics and Gynecology, Mount Sinai Hospital, University of Toronto, Toronto, Ontario, Canada; <sup>i</sup>Nuffield Department of Women's and Reproductive Health, University of Oxford, Oxford, UK; <sup>j</sup>AbbVie Inc., North Chicago, IL, USA; <sup>k</sup>Department of Obstetrics and Gynecology, NorthShore University Health System & Pritzker School of Medicine University of Chicago, Evanston, IL, USA

### ABSTRACT

**Objective:** Inadequate communication about endometriosis symptom burden between women and healthcare providers is a barrier for optimal treatment. This study describes the development of the EndoWheel, a patient-reported assessment tool that visualizes the multi-dimensional burden of endometriosis to facilitate patient-provider communication.

**Methods:** Assessment questions for the tool were developed using an iterative Delphi consensus process. A consensus phase included additional practitioners and specialists to broaden perspectives and select revised statements. Semi-structured qualitative interviews were conducted with 13 women with endometriosis to assess the scoring and content of the measures.

**Results:** Symptoms included in the tool were pelvic pain, vaginal bleeding, bowel/bladder symptoms, energy levels, fertility, impact on activities, emotional and sexual well-being, and self-perceived global health. Additional life impact areas included relationships, social and occupational activity, and self-perception. The 13 interviewees completed the tool in approximately 5–6 min (range 4.0–7.5 min). Most participants (92%) perceived that the tool would enable better patient-provider communication, including addressing symptoms and areas of impact not normally discussed during office visits.

**Conclusion:** Similar to visual circular tools used in burden assessment of other chronic diseases, the tool may facilitate improved patient dialogue with providers around endometriosis treatment goals and options.

### ARTICLE HISTORY

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### KEYWORDS



Endometriosis; infertility; laparoscopy; pelvic pain; surgery

## Introduction

Endometriosis is a gynecologic disorder that affects 6–10% of women of reproductive age and has a substantial and multifaceted burden<sup>1–4</sup>. The condition is often characterized by chronic pelvic pain and/or infertility and can negatively impact quality of life, intimate relationships, education and work, and emotional well-being<sup>5–12</sup>. As seen in other chronic pain conditions, women experiencing chronic pain due to endometriosis may be at risk for depression, anxiety, and chronic fatigue<sup>12,13</sup>. Women with endometriosis are impacted financially, with healthcare costs ranging from more than \$1000–\$12,000 per patient per year<sup>14,15</sup>. These women report missed work/school due to poorly controlled symptoms, resulting in short- and long-term disability claims, and, based

on preliminary studies assessing the occupational impact of endometriosis, the severity of symptoms correlates with productivity losses<sup>16–19</sup>. Endometriosis can affect sexual quality of life; negative impacts on desire, satisfaction, and frequency of intercourse are associated with the severity of endometriosis-related dyspareunia<sup>20,21</sup>. Concerns about infertility also negatively influence psychosocial well-being in women with endometriosis, with reports that 50% of couples experience conception problems<sup>22</sup>.

Women report inadequate communication with healthcare providers regarding the multi-dimensional impact of endometriosis on quality of life and treatment decisions, including difficulty describing pain (85%) and not feeling believed (89%)<sup>23</sup>. The gap in patient-physician dialogue, dismissal of pain as a normal aspect of menstruation, and misattribution

**CONTACT** Sawsan As-Sanie  [sassanie@med.umich.edu](mailto:sassanie@med.umich.edu)  Department of Obstetrics and Gynecology, University of Michigan Health System, L4100 Women's Hospital, 1500 East Medical Center Drive, Ann Arbor, 48109, MI, USA

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of pain to a purely psychological cause are commonly reported by women with endometriosis<sup>22,23</sup>.

Visual assessment tools have been developed and used to simplify assessment of disease burden in other chronic health conditions. The PSODisk and IBD Disk have been developed to facilitate evaluation of psoriasis and inflammatory bowel disease, respectively, and provide patients with a graphic representation of the multi-dimensional impact these conditions have on their lives<sup>24,25</sup>.

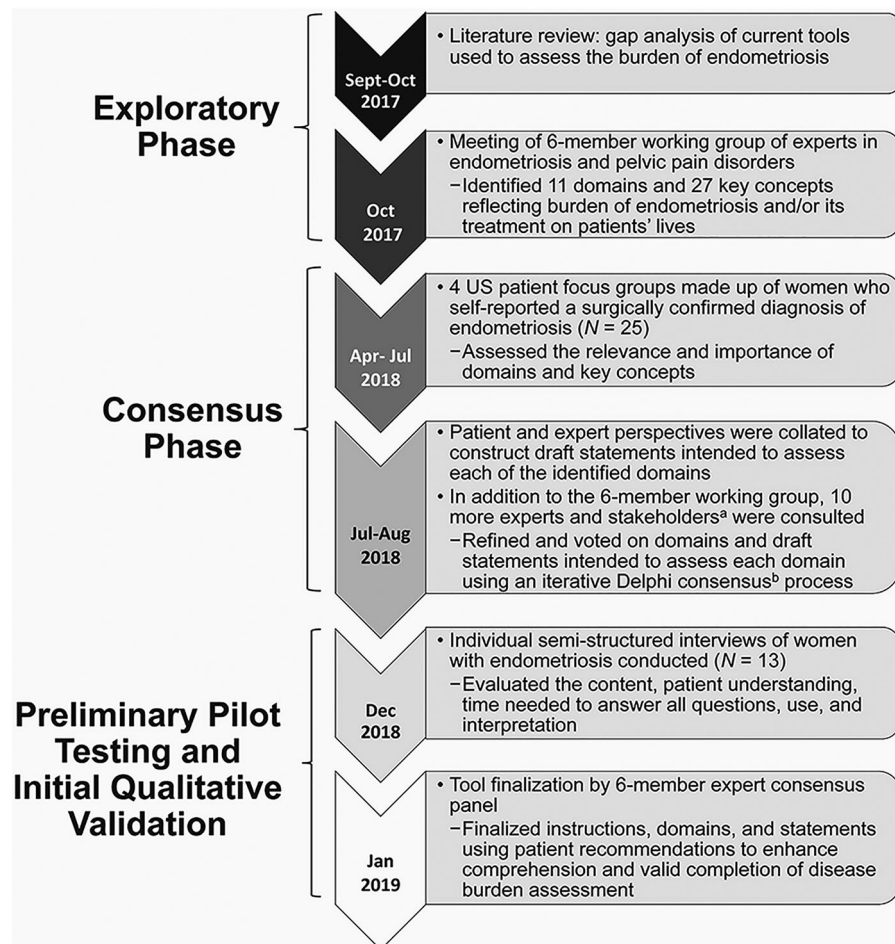
Although there are existing patient-reported outcome tools that assess the multi-dimensional burden of endometriosis, they are intended for endometriosis-focused research and are neither quick to complete nor easy to score. This unmet need for a short, clinically useful assessment motivated the development of the EndoWheel (AbbVie Inc., North Chicago, IL, USA), a patient-reported tool that provides immediate visual representation of the broad impact of endometriosis disease burden, expanding beyond just pain or infertility. In this article, we describe the use of an iterative Delphi consensus process utilized to develop the tool.

## Methods

Development of the EndoWheel tool was conducted in several stages: an exploratory phase, consensus phase, and

preliminary assessment and finalization phase (Figure 1). Qualitative design and evaluation of the tool started with an informal literature search on PubMed. Between September and October 2017, a gap analysis of current tools used to assess the disease burden in patients with endometriosis was conducted by the Lighthouse Medical Communications Group (New York, NY, USA). These tools included "EPHect Endometriosis Patient Questionnaire Standard," "Endometriosis Health Profile," "NIH PROMIS questionnaires," "Medical Outcomes Study Short Form 36," "Forquet tool," "EuroQOL," and "patient-administered digital applications." A six-member expert consensus panel of women's health specialists, which included gynecologists and scientists with expertise in pelvic pain, endometriosis, and reproductive medicine, reviewed the domains and key concepts that described disease impact used in the other assessment tools. These key concepts and domains were then narrowed down, ranked, and voted on using a modified, iterative Delphi process.

Voting on preliminary domains and items by the expert panel working group was conducted in three rounds using a ranking scale of 1 (strongly disagree) to 9 (strongly agree), with consensus defined as  $\geq 80\%$  of respondents indicating high agreement scores in the range of 7–9. The expert panel was joined by 10 additional participants for the consensus



**Figure 1.** Flow chart of the exploratory phase, consensus process, and patient focus group analysis. Timeline of the methods for development of the EndoWheel tool. <sup>a</sup>Individuals consulted included a pain specialist, a fertility specialist, general practitioners, community physicians, patient advocates, and patients. <sup>b</sup>The Delphi process was used, with voting on a 9-point scale. Consensus was defined as both  $\geq 80\%$  of respondents indicating high agreement scores in the range of 7–9 and  $\leq 20\%$  indicating low agreement scores in the range of 1–3.

phase. These participants included general practitioners, community physicians, an additional pain specialist, an additional fertility specialist, patient advocates, and patients, who widened the group's perspective, and, using an iterative Delphi consensus process, further refined domains and drafted individual burden items for the tool after each round of voting.

To assess the patient perspective on the relevance and importance of the selected domains and determine what burden the domains have on women's lives, semi-structured qualitative interviews were performed with four patient focus groups of women with endometriosis. A total of 25 women participated in the focus groups, six in the first group and seven in the second group in Dallas, Texas, and six each in both groups in Boston, Massachusetts. Eligibility criteria for participation in the focus group included women aged 18–49 years who self-reported a surgical diagnosis of endometriosis via laparoscopy, laparotomy, or other procedure; were premenopausal or perimenopausal; and could read and understand English.

Patients were not eligible to participate in the focus group if they were currently pregnant; had a history of hysterectomy or oophorectomy; or had cessation of periods for a year due to reasons other than pregnancy, breastfeeding, contraceptive use, or medical treatments for endometriosis. The objective of the focus groups was to obtain feedback on the relevance, importance, and potential burden of the items identified by the clinical expert panel for inclusion on the tool.

After the consensus phase and incorporation of the focus groups' feedback, the updated tool was assessed in an additional round of individual semi-structured interviews of 13 women with endometriosis to evaluate the content of the tool, define its use, determine patient understanding, and establish the time needed to answer all questions. Interviewees were recruited at two sites, one in Dallas, Texas, and one in Raleigh, North Carolina, for an hour-long interview in December 2018. Women eligible to participate in the interviews were chosen from the same source, and according to the same criteria listed above, as those who participated in the focus groups. Guided interviews began with an introduction to the tool. Participants were then asked to complete the assessment tool without assistance from interviewers. Interviewers recorded participants' initial reactions, any questions that caused confusion, and length of time taken to complete the tool. No formal hypothesis was tested in this qualitative study and descriptive statistical analysis was performed.

Following a review and exemption by the RTI Health Solutions (Research Triangle, NC, USA) international institutional review board, medical recruiters from Fieldwork (Dallas, TX, USA and Boston, MA, USA) recruited and screened potential focus group participants. Specifically, recruiters identified possible participants using the Fieldwork database of individuals who had previously reported a surgically confirmed diagnosis of endometriosis or those who had expressed interest in participating in qualitative research.

## Results

Results from the gap analysis revealed the unmet need for a patient-reported, visual assessment tool that covered the full breadth of impact of endometriosis symptoms on women's lives that could be completed within the limited time afforded during average office visits. After the multiple aforementioned stages of tool development, the working group reached final consensus to include 10 symptom domains that are reported by women with endometriosis: pelvic pain, vaginal bleeding, bowel and bladder symptoms, energy and fatigue, sexual well-being, fertility, social and recreational activities, work/school/other daily tasks, self-image and perception, and emotional well-being. It is important to note, the tool is not intended to be diagnostic for endometriosis, since many of the symptoms can be caused by other conditions that co-occur in women with endometriosis.

Characteristics of the twenty-five women who participated in one of the four semi-structured focus groups are presented in Table 1. Using feedback from these focus groups, the wording and appearance of the 12 statements representing the 10 domains of impact of endometriosis symptoms were refined by the experts based and the final tool is displayed in Figure 2. The directions instruct women to document their level of agreement on a numeric rating scale from zero (do not agree at all) to 10 (completely agree) with statements pertaining to their symptoms in the past 3 months regarding pelvic pain (period pain, non-menstrual pelvic pain, sexual pain), vaginal bleeding (bothersome, heavy, or unexpected), bowel/bladder symptoms (painful urination or defecation, bloat/gas, diarrhea/constipation), energy and fatigue (daytime exhaustion, restless or disturbed sleep), sexual well-being (satisfaction with sex life or intimate relationships), fertility (concern about ability to have children), relationships, effect on activities (work, school, daily tasks), self-perception (self-image, appearance, ability to achieve personal expectations), and emotional well-being (mood, mental health). Answers are marked within a wedge of the tool. Longer distance from the center of the wheel indicates a greater burden of that endometriosis-associated domain. Adjacent answers can be connected with lines,

**Table 1.** Baseline demographics and characteristics of consensus-phase focus group participants.

Characteristic	Total participants (N = 25)
Age (years)	35.4 (18–49)
Age at surgical diagnosis (years)	28.6 (15–46)
Age at first period (years)	12.0 (9–16)
Race/ethnicity	
White	11 (44.0)
African American	9 (36.0)
Hispanic	4 (16.0)
Native American	1 (4.0)
Education	
High school diploma/GED	2 (8.0)
Some college	7 (28.0)
Associate degree	3 (12.0)
College degree	11 (44.0)
Professional/advanced degree	2 (8.0)

Data are presented as mean (range) or *n* (%), unless otherwise stated. Abbreviation. GED, general equivalency development.



**Statements and Agreement Scale**

For each statement below, indicate your level of agreement by circling the score directly on the colored EndoWheel on the following page.

I do not agree at all      I completely agree

0   1   2   3   4   5   6   7   8   9   10

<b>Pelvic pain over the past 3 months</b> <small>Note: Pain may include cramping, shooting, stabbing, and/or dull aching pain in the back or lower belly/abdomen, and/or pain that shoots down the legs.</small>	<b>Period pain:</b> I have been bothered by pain or discomfort in the lower part of my belly/abdomen a day or two before and/or during my period. <b>Nonmenstrual pelvic pain:</b> I have been bothered by pain or discomfort in the lower part of my belly/abdomen that is <b>unrelated to my periods</b> . <b>Sexual pain:</b> I have been bothered by <b>pain during sexual activity, or within 24 hours after sexual activity</b> , particularly pain in the belly/abdomen or deep pressure in the vagina.
<b>Vaginal bleeding over the past 3 months</b>	I have been bothered by heavy or unexpected vaginal bleeding.
<b>Bowel and bladder symptoms over the past 3 months</b>	I have been bothered by one or more of the following: • Pain when I pass urine (pee) or stools (poop) • Feeling bloated or gassy • Diarrhea (unusually frequent, loose/liquid poop) • Difficulty passing stools (constipation)
<b>Energy and fatigue over the past 3 months</b>	I have felt fatigued or exhausted during the day and/or have experienced restless or disturbed sleep.
<b>Sexual wellbeing over the past 3 months</b>	My symptoms have affected how satisfied I am with my sex life and/or intimate relationships.
<b>Fertility over the past 3 months</b>	I have been concerned that I may not be able to have children/more children because of my physical symptoms.
<b>Social activities and relationships over the past 3 months</b>	My symptoms have affected my personal relationships and/or my ability to participate in activities that I enjoy.
<b>Work, school, and other daily activities over the past 3 months</b>	My symptoms have affected my work or school and/or my ability to do other daily activities, such as driving, running errands, shopping, and household chores.
<b>Self image and self-perception over the past 3 months</b>	My symptoms have affected the way I feel about myself, the way I look, and my ability to achieve the personal expectations I have for myself.
<b>Emotional wellbeing over the past 3 months</b>	My symptoms have affected my mood and mental health.



**Figure 2.** Questionnaire and image of the assessment EndoWheel tool. The tool and the 12 impacts of endometriosis are assessed. Patients are instructed to circle numeric rating scale scores based on their responses to each statement.

creating a polygon shape, where a larger surface area indicates an overall greater burden of disease (Figure 3).

Preliminary pilot testing of the proposed tool and its functionality was conducted with 13 individual interviewees (mean age [range] 36.5 years [26–47 years]) in a diverse patient population (Table 2). The average self-reported age at surgical diagnosis of endometriosis was 27.7 years (range 16–40 years), with the women experiencing endometriosis-related symptoms anywhere from less than 1 year to 20 years prior to diagnosis. Three participants (23.1%) reported that their only symptom at the time of diagnosis was presentation for fertility testing or treatment. At the time of the interview, three women reported current use of oral contraceptives, two had an intrauterine device, two reported use of other hormone therapy, and one reported use of Lupron Depot (AbbVie Inc., North Chicago, IL, USA) for treatment of endometriosis symptoms; eight women reported no current hormonal treatment. Women treated with hormones reported receiving their current endometriosis treatment regimens for a range of 2–7 years. At screening, all patients reported current symptoms of endometriosis including backache, headache, joint pain, and other pain before and during periods.

Most patients (92%) reported pelvic/abdominal or lower back pain before or during periods that limited activities or required medication. Patients also reported pain with sexual intercourse (62%), pain with bowel movements before and/or during periods (54%), and pain with urination before and/or during periods (23%).

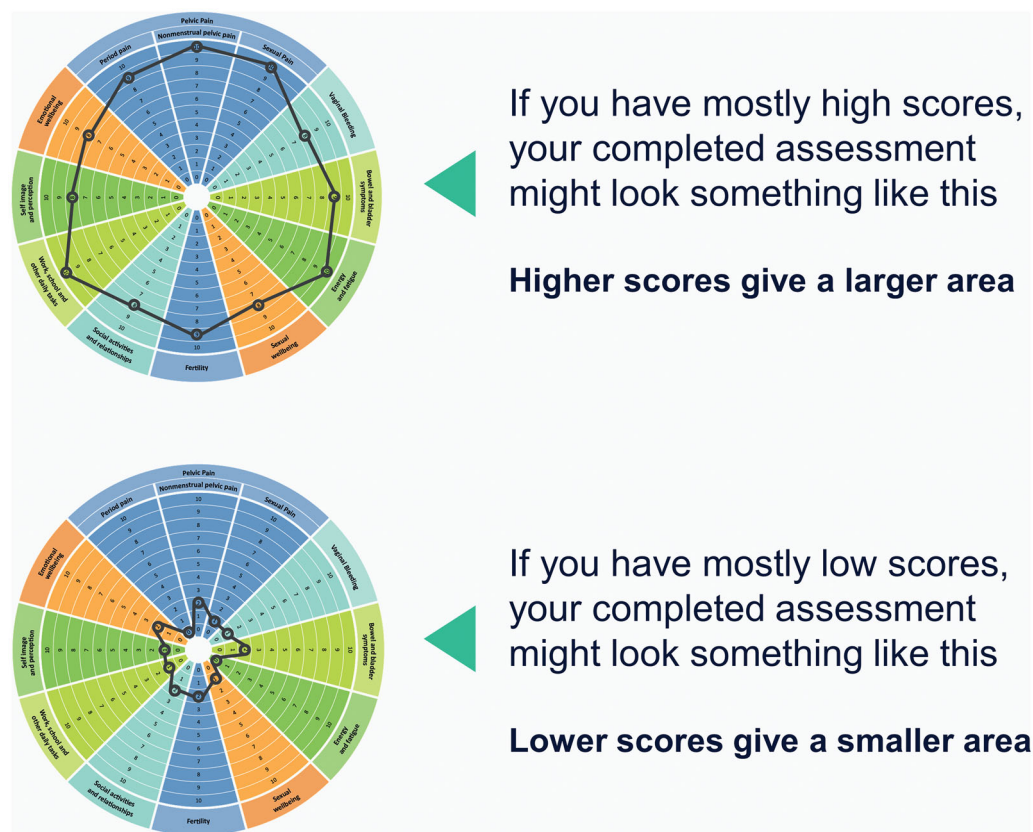
The mean time for participants to complete their assessment with the tool was 5–6 min (range 4.0–7.5 min). Twelve of 13 participants (92%) perceived that using the tool was acceptable and would enable them to better communicate

with their healthcare providers, including addressing symptoms and areas of impact that they did not normally consider raising or have the opportunity to discuss during office visits.

**Discussion**

Following a Delphi process that incorporated expert-provider insight, patient input, and patient usability refinement, the EndoWheel tool was developed to assess the presence and severity of 10 pertinent health domains of endometriosis. This novel tool has been developed in response to the unmet need for a comprehensive, patient-administered assessment of the multi-dimensional burden of endometriosis. The tool provides patients and providers with an intuitive, graphic, real-time representation of the burden of symptoms and the impact of disease on social and emotional health and ability to function. The assessment wheel captures the impact of endometriosis across health domains patients have identified as being most impactful: pelvic pain, vaginal bleeding, bowel/bladder symptoms, energy levels, and impact on activities, emotional and sexual well-being, and fertility. Vaginal bleeding was included as a health domain because it is commonly reported by women with endometriosis<sup>26</sup> but may be due to other etiologies. Further, vaginal bleeding is a common side-effect of all hormonal medications used to treat endometriosis. We felt it was important to assess this symptom, as it is reported to be bothersome by women with endometriosis.

The tool was acceptable to focus groups of women with endometriosis, and the average completion time was 5–6 min. Nearly all participants perceived that using the tool



**Figure 3.** Examples of possible completed EndoWheel assessments. The size of the area formed from connecting the scores in each domain allows for visualization of the disease burden.

**Table 2.** Baseline demographics and characteristics of preliminary pilot testing and initial qualitative analysis of individual interviewees.

Characteristic	Total participants (N = 13)
Age (years)	36.5 (26–47)
Age at surgical diagnosis (years)	27.7 (16–40)
Age at first period (years)	12.2 (9–15)
Race/ethnicity <sup>a</sup>	
White	8 (61.5)
African American	3 (23.1)
Hispanic	2 (15.4)
Native American	1 (7.7)
Education, n (%)	
Some college	2 (15.4)
Associate degree	3 (23.1)
College degree	5 (38.5)
Professional/advanced degree	3 (23.1)

Data are presented as mean (range) or n (%), unless otherwise stated.

<sup>a</sup>One participant reported more than one race/ethnicity.

would enable them to communicate better with their health-care providers, including addressing symptoms and areas of impact that patients did not normally consider sharing or have the opportunity to discuss during office visits.

Women are often reluctant to discuss their full burden of endometriosis-related symptoms because of normalization or stigmatization of pelvic pain, limited time available during appointments to discuss all patient issues, and the multifactorial burden of symptoms<sup>16</sup>.

Medical, surgical, and complementary treatments for endometriosis have been shown to impact health-related quality of life in women<sup>10</sup>; for example, improvements in sexual function and reduction of sexual distress have been reported in patients with endometriosis who received 6 to

24 months of dienogest treatment<sup>27</sup>. The tool has the advantage of keeping providers and patients focused on achieving broader wellness goals rather than focusing solely on improvement in menstrual pain or fertility status. Despite its broad coverage, the tool can be completed within the wait time of a normal office visit.

Although the tool can be used in routine clinical care to assess endometriosis-associated symptoms, there is also a potential role for its use in longitudinal studies, clinical trials, quality-improvement programs, or multi-site ambulatory-based pragmatic research projects. Development of various delivery platforms of the tool is ongoing, and electronic application versions are being finalized.

The tool has several limitations in that it is not yet validated in large clinical samples and has not been correlated with previously validated instruments that assess similar domains. Furthermore, the tool was designed to assess the burden of disease in English-speaking adult women from Western countries with self-reported surgical diagnosis of endometriosis and has not been evaluated in other demographic groups at risk for endometriosis. Additionally, studies are also needed to compare changes in disease burden over time and define what constitutes a meaningful change or response to an endometriosis treatment or intervention. The tool is not intended to diagnose endometriosis, and symptoms measured by the tool may not be solely attributed to endometriosis but may reflect comorbidities.

The tool offers advantages over other available assessments because of the intuitive, visual nature of the tool, the

short time to complete it, and the focus on multi-faceted impact of symptoms. Although the number of women with endometriosis who contributed to the focus groups and interviews was small, they provide real-world views of symptoms that have the most impact on patients with endometriosis.

It is hypothesized that, when the tool is used longitudinally, the area of the shape created by connecting patients' scores on the wheel will vary according to the severity of symptoms and current life goals (e.g. fertility goals) and evolve over the disease course and in response to treatment because the spectrum and impact of endometriosis symptoms are not static over time. This longitudinal approach has the potential to provide valuable insight into a patient's disease journey, including symptom management and overall well-being, while facilitating improved patient-provider communication.

The tool has the potential to impact patient care by facilitating communication between patients and healthcare providers through a convenient presentation of a woman's multi-dimensional burden of endometriosis. The advantage of self-administration of the tool lies in the generation of explicit agenda items to express and prioritize their concerns and maximize limited time during office visits. The tool may also increase awareness and diminish stigma among women with endometriosis by expanding awareness of the disease's multi-dimensional impact and by facilitating increased patient-provider communication of symptom burden that may not normally be discussed during routine office visits. Future validation studies are needed with a large, diverse study population of women with endometriosis and also among diverse practitioners to provide more insight into the application of this tool in the general population of women with endometriosis. Specifically, further quantitative validation studies are required to evaluate the psychometric properties of the tool, and larger clinical studies are necessary to assess its ability to facilitate patient-physician discussions about symptoms and effects on quality of life and the impact that this tool-facilitated interaction has on treatment selection and patient-centered outcomes.

## Conclusions

The EndoWheel assessment tool, which is similar to visual circular tools used to assess the burden of other chronic diseases, may facilitate improved patient dialogue with providers around endometriosis treatment goals and options.

## Transparency

### Declaration of funding

This study was supported by AbbVie Inc.

### Declaration of financial/other relationships

SA-S has received research support from the National Institutes of Health; honorarium for consultancy for AbbVie, Bayer, Eximis, and Myovant; and author royalties from UpToDate. MRL has received funding

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## Author contributions

Conception and design: SA-S, MRL, SAM, AM, KV, SE, SC, AMS, and FT; data acquisition: SA-S, MRL, SAM, KV, SE, SC, and FT; data interpretation: SA-S, MRL, SAM, KV, SE, SC, AM, AMS, and FT; overall responsibility for the accuracy of the data: SA-S; review and critique of the manuscript: all authors; approval of the final manuscript draft submitted for publication: all authors. All authors agree to be accountable for all aspects of the work, ensuring the accuracy and integrity of the publication.

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## Data availability statement

AbbVie is committed to responsible data sharing regarding the studies we sponsor. This includes access to anonymized, individual, and trial-level data (analysis data sets), as well as other information (e.g. protocols and Clinical Study Reports), if the trials are not part of an ongoing or planned regulatory submission. This includes requests for clinical trial data for unlicensed products and indications.

This data set can be requested by any qualified researchers who engage in rigorous, independent scientific research and will be provided following review and approval of a research proposal and Statistical Analysis Plan (SAP) and execution of a Data Sharing Agreement (DSA). Data requests can be submitted at any time and the data will be accessible for 12 months, with possible extensions considered. For more information on the process, or to submit a request, visit the following link: <https://www.AbbVie.com/our-science/clinical-trials/clinical-trials-data-and-information-sharing/data-and-information-sharing-with-qualified-researchers.html>.

## ORCID

Sawsan As-Sanie  <http://orcid.org/0000-0002-7166-1979>

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