

Written evidence from Besins Healthcare UK [WRH0052]

Introduction

- Besins Healthcare (Besins) is a pharmaceutical company specialising in the development of hormone medicines for the well-being of men and women throughout their life.
- Besins is a 138-year-old company with its headquarters in Brussels and has been operating in the UK for 10 years in its own right. We have established a strong and reputable name in the production of medicines for the treatment of gynaecological, fertility and obstetric conditions in women. Besins is a leader in the provision of HRT for women and provides androgen/testosterone replacement therapies for men.
- Given our expertise, we have created this document as a submission to the Committee's Call for Evidence surrounding Reproductive Health and the challenges that women face.
- Besins will be commenting on endometriosis in particular, and how women are misdiagnosed, diagnosed, and treated throughout their reproductive life which constitutes a significant barrier to reproductive health, and the wider health and wellbeing, for many women in the UK.

Terms of reference

- The committee has cited it is interested in women's reproductive health and the challenges that women face when they are being diagnosed and treated with various reproductive health, gynaecological, and urogynaecological conditions which include, but are not limited to heavy menstrual bleeding, premenstrual syndrome (PMS), premenstrual dysphoric disorder (PMDD), endometriosis, adenomyosis, fibroids, polycystic ovary syndrome (PCOS), urinary incontinence and vaginal prolapse.
- The inquiry will consider any disparities that exist in the diagnosis and treatment, and the impact of women's experiences on their health and lives.

Introduction to Endometriosis

- Endometriosis is a chronic and often debilitating gynaecological disorder that affects an estimated 10% of reproductive-aged individuals worldwide and approximately 1.5 million women in the UK – roughly 1 in 10.^{1,2,3}
- On average it takes 7.5 - 8 years from onset of symptoms to get a diagnosis.^{3,4,5}
- In this case, we call for improved systems and processes to manage diagnosis and treatment of endometriosis, highlighting the potential benefits for patients, healthcare systems, and society as a whole.

The Committee has already cited in your call for evidence that in the UK Government Women's Health Strategy call for evidence public survey, access to information was found to be a key issue. Only 8% of respondents felt they had access to enough information on gynaecological conditions. Women also said that they often had to speak to

¹ Rogers PA, D'Hooghe TM, Fazleabas A, et al. Priorities for endometriosis research: recommendations from an international consensus workshop. *Reprod Sci* 2009;16(4):335-46.

² ESHRE Endometriosis Guidelines 2022.

³ Endometriosis facts and figures, Endometriosis UK. Available from: <https://www.endometriosis-uk.org/endometriosis-facts-and-figures>.

⁴ NICE 2017 Endometriosis Guidelines

⁵ Endometriosis in the UK: Time for Change - APPG on Endometriosis Inquiry Report 2020

multiple doctors over several months to receive a diagnosis. When it comes to endometriosis diagnosis, 58% of women visit their GP more than 10 times with symptoms before they are diagnosed.⁶

Scope: The Committee invited written evidence on the following questions:

- **What constitutes healthy periods and reproductive health.**
- What are women's **experiences of being diagnosed with, undergoing procedures**, and being treated for gynaecological or urogynaecological conditions.
- What **disparities exist** in the **treatment and diagnosis** of gynaecological or urogynaecological conditions.
- What **barriers exist** in the treatment and diagnosis of gynaecological or urogynaecological conditions.

Besin Healthcare UK's submission to Call for Evidence

Q1. What constitutes healthy periods and reproductive health?

- We would classify healthy periods to be those that involve regular menstrual cycles with manageable and consistent flow, minimal pain, or discomfort (possibly managed with light pain relief), absence of severe emotional disturbances and ultimately a woman's periods should not interfere with her activities of daily living and daily life.
- We believe that the NHS England recognised definition of a period, does not convey the wide breadth of gynaecological conditions that can negatively impact normal periods and this lack of information up front can mask the complexity of the realities for many women.
- We believe that there is a lack of clinical consensus about what is 'normal' which means there isn't a standard awareness of what constitutes a healthy period and believe that many women suffer needlessly until their pain is unbearable before seeking medical attention fearing their pain will be dismissed as "normal". We believe this directly translates to diagnostic barriers in women's gynaecological and reproductive health.
- A healthy reproductive system encompasses the overall well-being of the reproductive system, including regular ovulation, proper hormonal balance, and the ability to conceive and carry a pregnancy to term without significant complications.
- There is an under-recognition of the problems that women with menstrual dysfunction face, with many women not realising their periods are not 'normal'.⁶
- There are many things that can disrupt a healthy reproductive system such as endometriosis which leads to issues with symptoms such as intense pelvic pain, heavy bleeding, and infertility. Pain is one of the hallmark symptoms of endometriosis. Women with endometriosis often experience chronic pelvic pain, painful periods (dysmenorrhea), and pain during intercourse (dyspareunia). This can have a significant impact on quality of life.
- Endometriosis symptoms, such as pelvic pain and heavy menstrual bleeding, are sometimes normalised or attributed to other causes. Raising awareness about these symptoms and encouraging women to seek medical attention when they experience them is important.

Q2. What are women's experiences of being diagnosed with, undergoing procedures, and being treated for gynaecological or urogynaecological conditions.

⁶Agarwal SK, Chapron C, Giudice LC, Laufer MR, Leyland N, Missmer SA, Singh SS, Taylor HS. 2019. 'Clinical diagnosis of endometriosis: a call to action.' Am J Obstet Gynecol;220(4):354.e1-354.

- Early diagnosis of endometriosis is essential due to the numerous benefits it offers to individuals, both in terms of their physical well-being and overall quality of life. Endometriosis is a progressive condition, meaning it tends to worsen over time if left untreated. Tissue growth and inflammation can lead to the formation of adhesions, scar tissue, and cysts, which can cause more severe pain, organ dysfunction, and fertility problems.⁷ Early diagnosis allows for interventions to be implemented before the disease reaches an advanced stage.
- However, women's experiences of being diagnosed with endometriosis can vary widely.
- Many women report facing diagnostic delays, where their symptoms are dismissed or attributed to other causes. The diagnostic journey often involves multiple doctor visits, various tests, and sometimes invasive procedures like laparoscopy for confirmation.
- A recent systematic literature review lead by Dr Davenport at Aston University discovered patients in the studies were not sure if their pain was unusual or severe enough to seek treatment and when patients did seek medical help, some found that their own GP was doubtful, or dismissive of their symptoms.⁸ During the study two GPs admitted that they found it difficult to differentiate problematic pain from ordinary menstrual symptoms and there was a general mention that GPs had a lack of knowledge about endometriosis.

Endometriosis and impact on Quality of Life (QoL)

- Endometriosis as a chronic gynaecological disease has several negative effects on women's life, thereby placing a huge burden on the patients and the health system.⁹
- Endometriosis has a significant impact on physical, mental, and social well-being.¹⁰
- Endometriosis significantly diminishes the quality of life for those affected, causing severe pain, fatigue, and fertility challenges.¹¹ It can lead to missed school or work, strained relationships, and mental health issues. Addressing endometriosis more effectively would reduce the individual suffering and societal burden, leading to healthier and more productive lives.
- The physical symptoms of endometriosis can take a toll on emotional and mental well-being. Chronic pain, fatigue, and uncertainty about the future can lead to anxiety, depression, and reduced overall quality of life.¹² Early diagnosis and treatment can mitigate these psychological burdens, improving mental health outcomes.

Economic burden

⁷ Horne A W, Missmer S A. Pathophysiology, diagnosis, and management of endometriosis *BMJ* 2022; 379:e070750 doi:10.1136/bmj-2022-070750

⁸ Davenport S, Smith D, Green DJ. Barriers to a Timely Diagnosis of Endometriosis: A Qualitative Systematic Review. *Obstet Gynecol.* 2023 Jul 13.

⁹ Márki G, Vásárhelyi D, Rigó A, Kaló Z, Ács N, Bokor A. Challenges of and possible solutions for living with endometriosis: a qualitative study. *BMC Women's Health.* 2022 Jan 26;22(1):20.

¹⁰ Rogers, R., D'hooghe, T. and Fazleabas, A., et al. 2009. 'Priorities for endometriosis research: recommendations from an international consensus workshop', *Reprod Sci*;16(4):335-46.

¹¹ Simoens S, Dunselman G, Dirksen C, et al. The burden of endometriosis: costs and quality of life of women with endometriosis and treated in referral centres [published correction appears in *Hum Reprod.* 2014 Sep;29(9):2073]. *Hum Reprod.* 2012;27(5):1292-1299. doi:10.1093/humrep/des073

¹² Missmer SA, Tu F, Soliman AM, et al. Impact of endometriosis on women's life decisions and goal attainment: a cross-sectional survey of members of an online patient community. *BMJ Open* 2022;12:e052765. doi:10.1136/bmjopen-2021-052765

- While women face lengthy delays to receiving a diagnosis and the subsequent impact on their health and well-being, untreated or inadequately managed endometriosis imposes significant economic burdens on healthcare systems and societies.
- The economic burden of endometriosis in the UK is estimated to be £8.2bn.1 Untreated or inadequately managed endometriosis imposes significant economic burdens on healthcare systems and societies. Increased investment in early diagnosis and effective treatment can lead to reduced healthcare costs associated with emergency room visits, surgeries, and long-term disability, ultimately resulting in substantial savings.

Diagnostic delay

- In 2017 NICE¹³ reported the average time to diagnosis was approximately 7.5 years, however a recent research paper published by Dr Sharon Davenport¹⁴ suggests this time to diagnosis could actually be around 8 years on average. However, there may have been some progress since that time and some patients may not have had such a lengthy time to diagnosis.
- Addressing endometriosis in its early stages can lead to better long-term outcomes and provides an opportunity for healthcare providers to develop personalised treatment plans that address the specific needs and preferences of the individual. By managing the condition effectively from the beginning, individuals can reduce the likelihood of requiring more invasive surgical procedures, extensive medication regimens, or long-term disability.
- The APPG on Endometriosis Inquiry Report 2020 found that prior to getting a diagnosis, and with symptoms, 58% of women visited their GP more than 10 times, 43% visited doctors in hospital over 5 times and 53% visited A&E on at least one occasion.¹⁵
- The Royal College of Obstetricians and Gynaecologists 'Left for too long' report reveals that gynaecology waiting lists across the UK have now reached a combined figure of over 570,000 women across the UK – just over a 60% increase on pre-pandemic levels.¹⁶

Impact on fertility

- Endometriosis can affect the prevalence of infertility among women with endometriosis can be as high as 30–50%.¹⁷
- GPs should receive better education and training in how to recognise endometriosis symptoms and how to treat early to avoid surgery and potential fertility issues in later years. Women also need to know what the likely progression of the disease will be and receive counselling and support to make informed decisions about preserving their fertility.

Importance of early diagnosis and early intervention

- Timely diagnosis of endometriosis is crucial for preventing disease progression and minimising its impact.
- Early endometriosis diagnosis:

¹³ NICE 2017 Endometriosis Guidelines.

¹⁴ Davenport S, Smith D, Green DJ. Barriers to a Timely Diagnosis of Endometriosis: A Qualitative Systematic Review. *Obstet Gynecol.* 2023 Jul 13.

¹⁵ APPG Endometriosis Report.

¹⁶ 'Left for too long' report. Royal College of Obstetricians and Gynaecologists. [More than half a million women face prolonged waits for gynaecology care | RCOG](https://www.rcog.org.uk/news/more-than-half-a-million-women-face-prolonged-waits-for-gynaecology-care/). <https://www.rcog.org.uk/news/more-than-half-a-million-women-face-prolonged-waits-for-gynaecology-care/>

¹⁷ Meuleman C, Vandenabeele B, Fieuws S, Spiessens C, Timmerman D, D'Hooghe T. High prevalence of endometriosis in infertile women with normal ovulation and normospermic partners. *Fertil Steril* 2009;92(1):68-74.

- enables intervention before advanced disease stages which may lead to less invasive treatments and a higher likelihood of preserving fertility.
 - allows better pain management, enhancing quality of life¹⁸;
 - enables discussion and treatment for fertility preservation which improve chances of conception.
 - yields better long-term outcomes both in terms of their physical well-being and overall quality of life.
 - provides access to education, support, and specialised care for the individual.
- Addressing endometriosis in its early stages can lead to better long-term outcomes and provides an opportunity for healthcare providers to develop personalised treatment plans that address the specific needs and preferences of the individual. By managing the condition effectively from the beginning, individuals can reduce the likelihood of requiring more invasive surgical procedures, extensive medication regimens, or long-term disability.

Need for improved education of healthcare professionals (HCPs) and potential use of better diagnostic tools.

- Improved awareness among healthcare professionals, coupled with the development of non-invasive diagnostic tools such as biomarkers and advanced imaging techniques, can facilitate early detection. Early intervention may lead to less invasive treatments and a higher likelihood of preserving fertility.
- The multiple doctor visits and delay in receiving a diagnosis suggest that access to better diagnostic tools is required at the GP level where many women initially present with menstrual pain. GPs should receive better education and training in how to recognise endometriosis symptoms and how to treat early to avoid surgery and potential fertility issues in later years. Women also need to know what the likely progression of the disease will be and receive counselling and support to make informed decisions about preserving their fertility.

Q3. What disparities exist in the treatment and diagnosis of gynaecological or urogynaecological conditions?

Disparity in access to Endometriosis Centres and more complex clinical pathway

- Waiting lists for specialist Endometriosis Centres remain extensive, ranging from 6-12 months to 2 years.
- Also, Endometriosis Centres are not evenly distributed across the country, meaning that many women have no access to specialist care.
- Referrals depend on whether there is a local Endometriosis Centre, whether the woman is informed about services and requests referral to an Endometriosis Centre and current waiting lists.
- Referral pathways vary considerably across the country and the 4 nations reflecting local service provision and initiatives to reduce wait times.
- The clinical pathway is more complex than represented in the NICE guidelines. An increasing number of women with private health insurance are being identified by Well Woman Health Assessments rather than presenting to their GP or at A&E.

¹⁸ Horne A W, Missmer S A. Pathophysiology, diagnosis, and management of endometriosis BMJ 2022; 379 :e070750 doi:10.1136/bmj-2022-070750

Disparities in experience of endometriosis diagnosis

- Women may have multiple GP appointments and visits to A&E prior to a provisional endometriosis diagnosis.
- Ultrasound scans are being performed in primary care, but these are usually negative as the sonographers often lack the experience to find lesions.
- Diagnostic laparoscopies are still performed by general gynaecologists but in Endometriosis Centres a diagnosis is made based on history and examination in combination with ultrasound scans.
- MRI is used to determine the extent of deep endometriosis prior to surgery. Laparoscopies are therefore only performed if there is a real uncertainty about the diagnosis, if the surgeon is expected to remove endometriosis lesions, or if it's a woman's preference.

Disparities in management in both primary and secondary care

- There is a wide variation in primary care management of endometriosis, with some GPs initiating hormonal therapy, while others refer women with suspected endometriosis straight to secondary care.
- As with primary care, there is a wide variation in the management of endometriosis in general gynaecology and Endometriosis Centres.

We believe that reform of endometriosis care is currently long overdue. This could be achieved by elevating endometriosis care transformation as a critical performance indicator of the Women's Health Strategy. Things that need to be addressed are:

- Bringing a timely intervention by the most appropriate health care professional in the optimal setting.
- Providing access to support and services nearer to the patient.
- Healthcare professional training and education.
- Data – standardising recording and removing NHS clinical coding variation.
- Wrapping ongoing clinical, emotional, wellbeing, advice, and guidance support around the patient.
- Reducing health inequalities across socio-economic groups and marginalised communities.²⁰

Disparities across socio-economic status and ethnicities

- Improving access to healthcare for endometriosis, across socio-economic groups and particularly for young women and those from marginalised communities, can help reduce diagnostic delays.
- The relationship between race/ethnicity and endometriosis has been explored for over a century. Historical bias and poorly conducted research have led to the idea that this condition is less likely to be diagnosed in certain racial groups, such as Black women.¹⁹

Q4. What barriers exist in the treatment and diagnosis of gynaecological or urogynaecological conditions.

Lack of prioritisation of endometriosis and women's health within NHS care

- There is a lack of prioritisation of endometriosis care across the NHS and NHS Trusts.

Lack of multidisciplinary care in endometriosis

¹⁹ [Revisiting the impact of race/ethnicity in endometriosis - PMC \(nih.gov\)](#)

- Collaboration among various medical specialties, including gynaecology, pain management, psychology, and nutrition, is essential for managing the multifaceted aspects of endometriosis.
- A holistic approach that considers the physical, emotional, and social dimensions of the disease can improve patients' overall well-being and help them manage the condition more effectively.

Lack of research and innovation in endometriosis

- Investing in research to better understand the underlying causes and mechanisms of endometriosis is critical. This knowledge can drive the development of novel treatment options, including targeted therapies and more effective pain management strategies. Advancements in technology, such as telemedicine and digital health tools, can also enhance patient education, self-management, and support.
- Research and development are ongoing in this field, and artificial intelligence (AI) applications for diagnosing and managing endometriosis continue to evolve. AI can accelerate research by analysing vast amounts of data, aiding in understanding the mechanisms of endometriosis and developing targeted therapies. AI can identify patterns in large datasets, enabling more accurate identification of endometriosis-related factors, such as genetic predisposition or hormonal imbalances. AI models have been shown to display good diagnostic and predictive capacity in detecting endometriosis using simple classification scenarios (i.e., differentiating between cases and controls), showing promising directions for AI in assessing endometriosis in the near future.²⁰ This may potentially aid in non-invasive or less invasive diagnosis and monitoring of the condition.

Lack of medical education of HCPs and general public about endometriosis

- Raising awareness about endometriosis within the general population and among HCPs is crucial for reducing stigma, increasing timely diagnoses, and ensuring appropriate treatment.
- By empowering individuals with accurate information about their condition, we can foster a more informed and proactive patient population as well as address stigma.

Lack of specialised providers and need for multidiscipline care.

- Endometriosis requires specialised care from gynaecologists or healthcare providers with expertise in the condition. Ensuring an adequate number of specialists and promoting training in endometriosis diagnosis and management can enhance patient care. Endometriosis often involves multiple systems and organs. A multidisciplinary approach involving gynaecologists, pain specialists, mental health professionals, and other relevant specialists can provide more comprehensive care.
- Addressing these barriers requires a collaborative effort between healthcare providers, researchers, policymakers, patient advocacy groups, and the broader community. By working together, it's possible to improve the diagnosis and management of endometriosis, ultimately enhancing the quality of life for those affected by the condition.

Concerns regarding invasive diagnosis

- Currently, laparoscopic surgery is the gold standard for diagnosing endometriosis definitively. This invasive procedure can lead to hesitation among both patients and providers. Developing non-invasive or less invasive diagnostic methods, such as advanced imaging techniques, could help address this barrier.

Barrier of stigma and gender bias in delivery of care

²⁰ Sivajohan B *et al.* Clinical use of artificial intelligence in endometriosis. *Npj Digital Medicine* (2022); 5; 109. <https://www.nature.com/articles/s41746-022-00638-1>

- The stigma around women's health issues and gender bias in medicine can affect how seriously endometriosis symptoms are taken. Healthcare providers should be educated about these biases and encouraged to provide compassionate and attentive care.

Barrier of limited research and funding

- More research is needed to understand the underlying causes of endometriosis and develop better diagnostic tools. Increased funding for research on endometriosis can lead to advancements in diagnosis and treatment.

Cultural and language barriers

- Language barriers, cultural beliefs, and taboos around discussing reproductive health can hinder open communication about endometriosis symptoms. Culturally sensitive education and outreach can help overcome these barriers.

Barriers/lack of access to increased access via telemedicine and digital health access

- Leveraging telemedicine and digital health platforms can improve access to healthcare, especially in rural or underserved areas. Patients can consult with specialists remotely, potentially reducing diagnostic delays.

Conclusions

- We believe experiences of endometriosis care in the UK varies considerably and the delivery of healthcare for endometriosis is long overdue for reform.
- There is a lack of prioritisation of endometriosis care across the NHS and NHS Trusts and a lack of Endometriosis Centres also leads to discrepancies in the delivery of care based on geography.
- Improvements in endometriosis care could be achieved by elevating endometriosis care transformation as a critical performance indicator of the Women's Health Strategy in its second year.
- We believe that enhancing the diagnosis and treatment of endometriosis is not only a matter of healthcare improvement but also a matter of social justice and gender equality.
- By advocating for comprehensive care, research, and education, the landscape of endometriosis management can be transformed for the better offering affected women the chance to lead healthier lives, preserving their reproductive health and fertility, allowing them to live more fulfilling and productive lives while alleviating the clinical and economic burden on healthcare systems and society as a whole.

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