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Recognizing endometriosis as a social disease: the European Union-encouraged Italian Senate approach

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Started at the grassroots level, increased awareness and investment in research has resulted in unprecedented recognition of endometriosis by the European Parliament, taken up by the Italian Senate in a 5-year action plan. This offers welcome assurance to the scientific community. (Fertil Steril® 2007;85:1285–7. ©2007 by American Society for Reproductive Medicine.)

THE CHALLENGE OF ENDOMETRIOSIS

Endometriosis is defined as the presence of endometrial-like tissue outside the uterus, which induces a chronic inflammatory reaction. The condition is predominantly found in women of reproductive age, in all ethnic and social groups (1). It is associated with pelvic pain and infertility, which can impact on the physical, mental, and social well being of a woman and can have a profound effect on her life, including the ability to finish an education, maintain a career, or to bear children (1).

The endometriosis-associated costs to society, including delayed diagnosis and “hit-and-miss” treatments (2–4), are considerable but yet poorly identified, as are the costs to the individual when disease symptoms interfere with day-to-day life at work or at home. Based on a review of cost estimates, the annual costs of endometriosis attained \$22 billion in 2002 in the United States. These costs are considerably higher than those related to Crohn's disease or to migraine (4).

In three steps we aim to describe how community action in Europe has addressed the need for more awareness and recognition of this social and economic effect of endometriosis.

STEP ONE: GETTING THE EUROPEAN PARLIAMENT INVOLVED

In 2004, members of the most active national endometriosis support organizations in Europe approached the European

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Parliament to highlight the challenges associated with endometriosis. This prompted a group of Members of the European Parliament to publish a Written Declaration on Endometriosis (5) in March 2005 calling for:

1. Member States' governments and the European Commission to promote Endometriosis Awareness Week and to support awareness-raising initiatives by national organizations;
2. Major information campaigns targeting the public, health professionals, and legislators;
3. The European Commission to include prevention of endometriosis in future Community Action Programs for Public Health to allow more research into the causes, prevention, and treatment of endometriosis.

STEP TWO: BUILDING A STRATEGIC ALLIANCE

All national endometriosis support groups in Europe, joined together as the European Endometriosis Alliance in October 2004, subsequently got involved in the campaign, and highlighted the challenges associated with endometriosis to their local Members of the European Parliament and urged them to sign The Written Declaration. This effort was supported by endometriosis specialists across Europe, who lent their support by writing to parliamentarians emphasizing the importance of The Written Declaration.

This new strategic alliance between patients and physicians to reach out to politicians with respect to an important women's health issue has been unprecedented in Europe—and it worked. By the deadline of June 9, 2005, 36% of Members of the European Parliament had signed the Written Declaration.

This is the highest number of signatures achieved for a human health issue and the sixth most successful Written Declaration since 1998.

Subsequently this enabled the European Endometriosis Alliance to meet with officials in the European Commission, and in January 2006, the European Union Community Public Health Programme included a specific reference to the need for “information and definition of indicators to improve relevant information for specific aspects of women’s gynaecological and menopausal health (e.g., endometriosis).”

For the first time “women’s health” was on the European Commission’s agenda—and with endometriosis as a specific example.

STEP THREE: MAKING IT HAPPEN—ITALY LEADS THE WAY

The Investigation

Based on the initiative taken by the European Parliament, and encouraged by Italian gynecological societies, the Associazione Italiana Endometriosi Onlus and the European Endometriosis Alliance, a group of Italian senators submitted a motion to the Italian Senate informing their members about the contents of the European Union Written Declaration. Consequently, the Senate’s Standing Committee on Hygiene and Health responded to the invitation of the European Parliament to raise awareness of the problem by organizing a fact finding investigation (6) to:

1. assess the impact of endometriosis in Italy from both a social and an economic standpoint, and, thus, evaluate potential direct and indirect costs;
2. provide information and guidance for the adoption of public policies consistent with the European and worldwide guidelines;
3. identify Socio-economic health indicators for the disease, potentially instrumental in reducing expenses and in directing dedicated economic resources.

The Result

The Senate Committee’s investigation concluded that endometriosis has to be recognized as a disease with an important economic impact on the family and working life of a woman (e.g., lost days at work, lay-offs, having to change jobs, sick leave, time off for having surgery). The Committee also recognized a significant association with health costs related to a diagnostic delay and therapeutic expenses including surgery, drugs, and assisted reproductive technologies (ART). The cost incurred by the Italian National Health System for hospital admissions for endometriosis was estimated at 2,773.80 euros for each patient, totaling some 54 million euros per year.

The 5-Year Plan

Concluding that endometriosis needs to be viewed as a social disease, the Senate Committee has proposed the following policy for implementation during the next 5 years (6):

1. Identification of specific disease indicators such as a dedicated diagnosis-related group (DRG) for reimbursement, appropriately differentiated in accordance with the various types of surgical interventions including the establishment of similar reimbursement tariffs nationwide;
2. Promoting collaboration between the Ministry of Labor and Social Policies, the National Institute for Insurance against Accidents at Work (INAIL), and the Institute of Social Medicine (INPS), and to highlight the burdensome effects on working conditions and on absence from work;
3. Developing a process that will establish national referral centers for the first treatment and centers of excellence for subsequent follow-up, including training of pelvic surgeons;
4. Encouraging research by allocating ad hoc funds and promoting specific actions for the prevention of endometriosis in the context of the Community Action Plans for Public Health;
5. Setting up regional registers and a dedicated national register;
6. Developing solutions for providing pharmacological treatment free of charge for those with long-term (chronic) needs for oral contraceptives (OC), GnRH analogues and other drugs for symptomatic relief;
7. Developing a package of supporting measures for women with particularly severe or recurrent forms of endometriosis that would include: free follow-up diagnostic tests; free medical products to safeguard the health and fertility of these women; and, the assignment of a stage of disability under Act no. 104 of February 5, 1992, for severe cases where the psychological and physical state of health of the patient, who undergoes several surgical interventions, is severely undermined and when there are major relapses and recurrent chronic pelvic pain;
8. Carrying out health education and information campaigns in schools and for the public;
9. Establishing a National Endometriosis Day for women affected by endometriosis.

STEPPING FORWARD

In this article we have documented a process, which is based on community action, where all stake holders have recognized that to truly address a disease as prevalent as endometriosis, a strategic alliance between patients, physicians, scientists, and legislators is essential, if progress for millions of women with endometriosis across the world is to become reality. A disease, which has such a profound effect on society, needs to be recognized and dealt with by society.

The very core of the Italian Senate’s Investigative Committee’s findings summarizes the challenge of endometriosis: there is no cure, treatments are often “hit-and-miss,” those who treat endometriosis are often inadequately reimbursed, and there is too little data available to truly establish the

tremendous personal, financial, and socioeconomic burden that endometriosis leaves in its wake.

In reaction to this we have seen, as a first in the European Union's history, a patient-triggered action, in collaboration with physicians and open-minded politicians, which has resulted in the recognition of endometriosis at a European Union level; and a country—Italy—has responded to the European Union's call for action and moved forward at a national level.

The new strategic alliances, which have been formed as a result of the European Union and Italian initiatives, are an important step forward in addressing all aspects of endometriosis, including a call for action to:

- fund causal and preventive research;
- recognize that a chronic, multifactorial disease such as endometriosis needs to be treated in centers of excellence by a multidisciplinary team, and work toward the establishment of such centers based on peer-reviewed treatment guidelines (7);
- fund national and international awareness campaigns to reduce time to diagnosis, reduce “hit-and-miss” treatments, and ensure timely multidisciplinary expert care;
- establish national and international registries to monitor morbidity and effectiveness of treatment with a subsequent aim to preserve fertility, improve quality of life, and reduce personal and socioeconomic burden.

The achievement in the European Union, and in Italy, is an excellent example of a new era of collaboration between

stake holders, which could have an unprecedented impact on the scientific community. It is now time for the European Union and the countries therein—indeed countries across the world—to heed the call for action set out in the 2005 Written Declaration and provide resources for and regulation of the treatment of endometriosis. It is now time for all nations to follow the Italian example and recognize endometriosis as a disease that needs to be dealt with by society as a whole.

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