Management of Symptomatic Vulvovaginal Atrophy in the Postmenopausal Woman
Request for Proposals

Pfizer Independent Grants for Learning & Change and North American Menopause Society
August 16, 2013

I. Background

The mission of Pfizer Independent Grants for Learning & Change (IGL&C) is to accelerate the adoption of evidence-based innovations that align the mutual interests of patients, healthcare professionals, and Pfizer, through support of independent professional education activities. The term "independent" means the initiatives funded by Pfizer are the full responsibility of the recipient organization. Pfizer has no influence over any aspect of the initiatives, and only asks for reports about the results and impact of the initiatives which it may share publicly.

The intent of this document is to encourage organizations with a focus in healthcare professional education and/or quality improvement to submit letters of intent (LOIs) in response to a Request for Proposal (RFP) that is related to education in a specific disease state, therapeutic area, or broader area of recognized educational need. The RFP model is a two stage process: Stage 1 is the submission of the LOI. If, after review, your LOI is accepted, you will be invited to submit your full program proposal. Stage 2 is the submission of the Full Grant Proposal.

When a RFP is issued, it is posted on the Pfizer IGL&C website (www.pfizer.com/independentgrants) and is sent via e-mail to all registered organizations and users in our grants system. Some RFPs may also be posted on the websites of other relevant organizations as deemed appropriate.

II. Sponsor and Partner

The sponsor and funder of this request for proposal (RFP) is Pfizer Independent Grants for Learning and Change (IGL&C). The mission of the IGL&C is to accelerate the adoption of evidence-based innovations that align the mutual interests of healthcare professionals, patients, and Pfizer through support of independent professional education activities. IGL&C has partnered for this RFP with The North American Menopause Society (NAMS). The mission of NAMS is to promote the health and quality of life (QOL) of all women during midlife and beyond through an understanding of menopause and healthy aging. The IGL&C and NAMS are collaborating to offer a new grant opportunity. The sponsors share a common goal of improving QOL for postmenopausal women.

III. Purpose

The goal of this RFP is the design and implementation of a scalable, sustainable program for healthcare providers (HCPs) and patients designed to improve the management of vaginal health in postmenopausal midlife and aging women experiencing symptomatic vulvovaginal atrophy (VVA).

The Pfizer IGL&C and NAMS collaboration will support efforts aimed at improving vaginal health (and the often associated dyspareunia) in postmenopausal women experiencing symptomatic VVA by closing gaps in clinical practice. This RFP seeks applications that explore evidence-based approaches to raising awareness of the clinical problem, to discussing the condition with the patient, and to managing the condition when appropriate.

IV. Specific Area of Interest for this RFP

Symptoms associated with VVA affect 20% to 45% of midlife and older women,[1,2] but only a small number of women seek help or are offered help by their HCPs. Vasomotor symptoms (hot flashes, night sweats) that accompany loss of ovarian estrogen production can improve over time even without estrogen treatment, but symptoms associated with VVA can be progressive and less likely to resolve without estrogen treatment.

The term VVA refers specifically to the changes in the vagina and vulvar surfaces that on examination become thin, pale, and dry. The vagina can shorten and narrow, especially in the absence of sexual intercourse. The vaginal lining becomes thinner, less elastic, and smoother as rugal folds decrease. Vaginal blood flow diminishes, and although the sebaceous glands remain prominent, their secretions diminish, and lubrication during sexual stimulation is decreased and delayed.[3]

But the discomfort women with VVA experience involves far more than just vaginal dryness. A number of surveys of postmenopausal women have shown that VVA negatively affects a woman's QOL and sexual health. According to the VIVA (Vaginal Health: Insights, Views & Attitudes) online survey,[8] when postmenopausal women in the United States (n=500) were asked how vaginal discomfort affected their lives

- 80% considered it to negatively affect their lives
- 75% reported negative consequences on sex life
- 68% reported that it makes them feel less sexual
- 36% reported that it makes them feel old
- 33% reported negative consequences on marriage/relationship
- 26% reported a negative effect on self-esteem
- 25% reported it lowers QOL

Vulvar and vaginal atrophic changes increase the likelihood of trauma, infection, and pain. Left untreated, severe VVA can result in a vaginal surface that is friable, with petechiae, ulcerations, and tears, accompanied in some cases by stenosis. Bleeding may occur from minimal trauma, such as speculum insertion. On questioning, patients may acknowledge bleeding with intercourse or wiping.

Symptoms of VVA can be severe enough to interfere with a woman's ability to have pain-free sexual activity.[9-12] Decreased genital arousal and vulvar pain disorders may occur as a consequence of VVA. Atrophy and phimosis of the prepuce of the clitoris may result in dyspareunia that leads to sexual abstinence.[13]

Women should be informed that VVA may worsen over time without proactive management. Women often do not report symptoms of VVA and related sexual concerns, so HCPs should address this issue for all perimenopausal and postmenopausal women as part of a routine review of systems.

Data are lacking about the value of proactively educating women about potential vaginal changes that can occur in a low-estrogen state. Because the changes occur gradually and without symptoms in the sexually abstinent cohort, these women can be very distressed that they are unable to have intercourse once they want to resume sexual intimacy at a later time.

Average life expectancy for an American woman is 85 years. If the average age of menopause is 51 years, many women will live about a third of their lives after menopause and, left unmanaged, may experience the ill effects of VVA for a long time. Primary care providers in their role of providing routine care to women have an opportunity to offer appropriate identification and management of VVA symptoms

V. Practice gaps and barriers to closing them

A gap in management of vaginal health is considered to be the difference between what is currently happening and what should be happening to meet the highest standard of care. Gaps may be related to

- The knowledge base and/or communication skills of HCPs
- Constraints in the healthcare system, such as patient time allotted and levels of reimbursement
- Discomfort discussing this topic on the part of the patient and/or the HCP
- Other factors related to the external environment or patient population, such as the geographic region, social culture, socioeconomic level, or other individual patient medical conditions

Knowledge gaps and barriers exist for both clinicians and postmenopausal women with regard to the topic of vaginal health after menopause and have been documented as noted:

1. Many clinicians and women are not aware of the silent changes in the vagina that occur during menopause, and HCPs may not know how to diagnosis and manage VVA.

The REVEAL survey showed that although most postmenopausal women had heard of the "traditional" symptoms related to menopause (mood swings, hot flushes, night sweats), less than half of respondents had heard of women experiencing VVA symptoms as a normal part of menopause.[17] In a NAMS 2010 survey of its members, staying current with relevant scientific and clinical developments and the lack of patient education or the misinformation found in the media were cited as challenges.

Researchers found through a survey of 510 ob/gyn residents that fewer than 1 in 5 had received formal training in menopause medicine.[19] Most residents reported limited knowledge in the areas of the pathophysiology of menopause symptoms (67%), hormone therapy (68%), and nonhormone therapy (79%), among other areas. Fourth-year residents, ready to enter into clinical practice soon, reported gaps in knowledge in these same areas (46%, 54%, and 69%, respectively).

A recent survey of 3,520 US, Canadian, and European postmenopausal women showed that approximately 45% of these women reported experiencing vaginal symptoms.[8] However, just 4% of women attributed their symptoms to VVA, and 63% did not recognize VVA as a chronic condition.

2. Women are uncomfortable initiating discussions with clinicians about VVA and its effect on their sexuality.

The REVEAL survey found that although most women recognize the importance of their sexual health, about half said that they do not talk about it with their HCPs.[17] Reasons include a reluctance to acknowledge that they are experiencing VVA symptoms, believing nothing can be done medically to help, being embarrassed to talk about it, or simply learning to live with VVA as a normal part of getting older.

3. Clinicians are uncomfortable initiating discussions about the vaginal changes of menopause and their effect on their patients' sexuality.

Suffering in silence could be cultural, with women understandably reluctant to talk about sexual matters, especially with male clinicians; however, some HCPs are also reluctant to ask postmenopausal women about VVA symptoms.[20] Physicians are often uncomfortable with and poorly educated about obtaining a comprehensive sexual history from women experiencing sexual dysfunction[21]; however, all HCPs should be able to discuss the symptoms associated with VVA.

4. Time for clinician-patient interaction is limited.

The NAMS 2010 member survey showed that sufficient time for patient consultation/education was cited as professional challenge. The Association of Reproductive Health Professionals stated in a 2010 report that managing time allotment and billing issues related to female sexual dysfunction should be incorporated into a provider's practice-related skills.[22]

VI. Letters of Intent/Proposals

This RFP model employs a 2-stage process: Stage 1 is the submission of the LOI. If your LOI is selected, you will be invited to submit a full program proposal. Stage 2 is the submission of the Full Grant Proposal.

The focus should be on improving the management of symptomatic VVA in primary care settings and gynecology clinics.

The goals of the proposed program should

- Improve physician and patient knowledge of VVA
- Increase assessment and management of VVA in the clinical setting
- Demonstrate improvement of QOL

Successful proposals will include a detailed plan to generate quantitative evidence that the educational intervention has had an effect on physician behavior that is likely to be long-lasting and that this change in behavior is associated with changes in clinical outcomes. Competitive proposals will include the use of a control group.

Programs must describe how the intervention, when implemented, will directly affect patient care and provide evidence of scalability (eg, integration with an electronic medical record system) and sustainability (eg, plan for dissemination/applicability beyond the proposed institution).

Successful applicants will be able to describe the specific clinical practice gaps that exist for their own providers, healthcare system, or patient community and describe what they will do to close these gaps or problems. Site-specific obstacles to success should be identified and coupled with strategies to overcome the obstacles.

Examples of potential approaches include

- Identification and implementation of strategies to raise VVA awareness among HCPs

- Implementation of strategies to raise awareness among women of VVA's link to menopause
- Incorporation of multiple ways to communicate with patients through EHRs and other technologies
- Combining educational and clinical approaches to achieve the specific goal
- Adaptation of a specific intervention to different geographic populations, clinician specialties, and practice settings
- Collaborations that bring special expertise to the project, such as research clinics, information technology, and clinical communications
- Plan for maintenance and expansion of strategies and program elements demonstrated to be effective in raising awareness and increasing appropriate assessment and management of VVA
- Development of innovative approaches to measure outcomes
- Setting up an evaluation for a population-based intervention monitoring
- Use of a control group or comparison group
- Development of a self-sustaining program

Pfizer and NAMS are particularly vested in supporting programs that develop and implement interventions that are followed by rigorous assessment of the efficacy of the program, examining outcomes that may include short- and long-term improvements in physician effectiveness and patient care.

Proposed interventions should aim to effect meaningful change in clinical outcomes, such as an increase in provider and patient knowledge of VVA and an increase in appropriate management of VVA. Applicants should estimate the amount of change in these clinical outcomes that they are expecting to see as a result of their proposed intervention.

Interventions may also include a practice intervention, such as incorporation of treatment guidelines into the EHR and provision of decision support at the point of care (usually through the EHR). Other components might include having women fill out a vaginal health questionnaire on a tablet in the waiting room before their visit. The proposal should describe how such interventions that use EHR and other technologies could be easily scaled to multiple institutions and/or health systems.

VII. Potential outcomes and metrics

- Diagnosis rates for VVA in age-appropriate women
- Use of validated screening tools for menopause symptoms and QOL such as the MenQOL, Menopause Rating Scale, Women's Health Questionnaire, Utian Quality of Life scale, and the Greene Climacteric Scale
- Documentation of appropriate assessment and management of VVA such as
  - Women's understanding of VVA, vaginal health, and related treatment options
  - Clinician understanding of VVA, vaginal health, and related treatment options
  - Patient satisfaction scores related to the management of VVA symptoms
  - Chart or EHR documentation of patient counseling related to VVA
  - Use of validated tools to measure program effect on VVA
  - Use of VMI and vaginal pH as objective clinical measures of improvement
- Women's satisfaction with management of their vaginal health
- HCP understanding of the effect of symptomatic VVA on a postmenopausal woman's QOL

Examples of online patient education activities

Title	Activity	Sponsor
Sexual Health and Menopause Online	Online patient education modules www.menopause.org/for-women/sexual-health-menopause-online	NAMS
Symptomatic Vulvovaginal Atrophy at Menopause: Identification and Intervention	Webcast for CME www.mycme.com/symptomatic-vulvovaginal-atrophy-at-menopause-identification-and-intervention/activity/1333/	NAMS; produced by Haymarket Medical Education
Vaginal Atrophy	Online patient information www.mayoclinic.com/health/vaginal-atrophy/DS00770	Mayo Clinic
Vaginal Atrophy (Atrophic Vaginitis)	Patient education center http://patienteducationcenter.org/articles/vaginal-atrophy-atrophic-vaginitis/	Harvard Medical School
Vaginal Atrophy	Patient education www.bannerhealth.com/_Banner+Medical+Group/Office+Locations/_Banner+Health+Clinic+-+Obstetrics+and+Gynecology+-+Loveland+-+North+Boise/For+Our+Patients/Patient+Education/_Vaginal+Atrophy.htm	Banner Health Clinic

VIII. RFP key information

Total awards	Up to $2M is available to fund grants for this RFP. Grant requests should not exceed $500K. Individual projects can be funded for up to a maximum of 24-months' duration.
Specific area of interest	Symptomatic VVA
Target settings	The focus of the program should be generating meaningful change in primary care providers (such as family medicine, internists, obstetricians/gynecologists, nurse practitioners, and physician assistants), patients, and healthcare systems.
Geographic scope	United States only
Recommended format	Research protocol, with IRB approval if necessary
Eligible applicants	Healthcare institutions, health systems, professional associations, academic institutions, and other not-for-profit entities.
Selection criteria	Applicant organizations will be evaluated on the basis of

	• Knowledge of and experience with the area • Capability of carrying out the work • Collaboration if appropriate • Potential effect and expected outcomes of the project • Dissemination strategies
Key dates/deadlines	**August 16, 2013**—RFP released **September 13, 2013**—Letters of Intent due **Week of October 07, 2013**—Applicants notified via email; invited to submit full proposal **November 6, 2013**—Full proposals due date **Week of December 16, 2013**—Notification of decisions **December 21, 2013**—Funded project starts

IX. How to Submit:

Please go to the website at www.pfizer.com/independentgrants and click on the button "Go to the Grant System".

If this is your first time visiting this site in 2013 you will be prompted to take the *Eligibility Quiz* to determine the type of support you are seeking. Please ensure you identify yourself as a first-time user.

Select the following Area of Interest: **Symptomatic VVA**

X. Requirements for submission:
Complete all required sections of the online application and upload the completed LOI template. (*see Appendix)*

XI. Letter of intent

The LOI is a brief concept document that describes the proposed project at a high level. The Proposal Review Committee will select letters of intent that are best aligned with the purpose of the RFP. All applicants will be notified with either an acceptance or a declination. Successful applicants will be asked to submit a full grant proposal for funding consideration.

Appendix: Letter of Intent Submission Guidance

Submission requirements

1. The letter of intent should be no more than three (3) pages, single spaced, using Calibri 12-point font and 1-inch margins. It should contain the following information about the proposed project:
    a. Project title
    b. Organization(s) involved
    c. Principal investigator
    d. High-level project description, including
        i. Primary goal(s)

   ii. Description of how the proposal builds on existing work, projects, or programs
   iii. Anticipated challenges and solutions
   iv. Expected outcome and how the impact of the project will be evaluated
e. Deliverables and dissemination strategies

2. A letter of intent longer than three pages will be **RETURNED UNREVIEWED**
3. Submit the letter of intent online via the Pfizer IGL&C website
   a. Please go to the website at www.pfizer.com/independentgrants and click on the button "Go to the Grant System."
   b. If this is your first time visiting this site in 2013 you will will be prompted to take the *Eligibility Quiz* to determine the type of support you are seeking. Please ensure you identify yourself as a first-time user.
   c. Submit your letter of intent in the Symptomatic VVA clinical area.
4. Complete all required sections of the online application and upload the completed letter of intent template

Full proposals

A limited number of applicants will be invited to submit for consideration a full proposal of no more than 10 pages, accompanied by a line-item budget. The full proposal format will be shared with the invitation to submit.

Questions

If you have questions regarding this RFP, please direct them in writing to the Education Director for this clinical area, Robert Kristofco at robert.kristofoco@pfizer.com with the subject line, "**Management of Symptomatic Vulvovaginal Atrophy in the Postmenopausal Woman** ." .

Terms and conditions

1. Complete **TERMS AND CONDITIONS** for Certified and/or Independent Professional Healthcare Educational Activities are available on submission of a grant application on the Medical Education Group website at www.pfizer.com/independentgrants.
2. This RFP does not commit Pfizer to award a grant or to pay any costs incurred in the preparation of a response to this request.
3. Pfizer reserves the right to accept or reject any or all applications received as a result of this request or to cancel in part or in its entirety this RFP, if it is in the best interest of Pfizer to do so.
4. Pfizer reserves the right to announce the details of successful grant application(s) by whatever means ensures transparency, such as on the Pfizer website, in presentations, and/or in other public media.
5. For compliance reasons and in fairness to all applicants, all communications about this RFP must come exclusively from the Medical Education Group. Failure to comply will automatically disqualify applicants.
6. All output (eg, products, research, data, software, tools, processes, papers, and other documents) from funded projects will reside in the public domain.

Transparency

Consistent with our commitment to openness and transparency, Pfizer publicly reports its medical educational grants and support for medical and patient organizations in the United States. A list of all letters of intent selected to move forward may be publicly disclosed, and whatever emanates from this RFP is in the public domain. In addition, all approved full proposals, as well as all resulting materials (eg, status updates, outcomes reports, etc) may be posted on the website. Grantees will be required to submit periodic quarterly reports and/or updates.

Issued RFPs are posted on the Pfizer IGL&C website at www.pfizer.com/independentgrants and are emailed to all registered organizations and users in our grants system.

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