

## The Millennium Series in Women's Health

# Setting a Local Research Agenda for Women's Health: The National Centers of Excellence in Women's Health

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### ABSTRACT

Although women's health research expanded greatly in the past 10 years, significant gaps in knowledge remain. Prioritization and promotion of research will help assure continuing progress in closing such gaps and improving the health of women. Although a comprehensive agenda for the new millennium has been developed at the national level, the process for establishing a local research agenda is not well defined. The purpose of this study was to describe criteria for and barriers to establishing a local research agenda in women's health. A secondary aim was to describe mechanisms for identifying women's health researchers and for facilitating multidisciplinary research. Directors of Research at National Centers of Excellence in Women's Health (CoEs) ( $n = 18$ ) were surveyed by mail for this information. The results indicate that the local research agenda should emphasize health issues that are prevalent in women, research that is likely to establish treatment, psychosocial/cultural factors, and quality of life issues. The process of setting a research agenda should include input from the communities served as well as from scientists. Critical evaluation of scientific strengths and weaknesses is an essential preliminary step in prioritizing research opportunities in order to implement and evaluate a research agenda in women's health.

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## INTRODUCTION

WITH THE EXPLOSION OF ATTENTION in the past 10–15 years to conditions that afflict women differently from men, efforts have been made to develop a framework that assures continuing progress in the treatment and prevention of diseases or conditions that are unique or more serious for women than for men of comparable age.<sup>1,2</sup> Mandates, such as the National Institutes of Health (NIH) Revitalization Act of 1993,<sup>3</sup> assure that women and minorities are included appropriately in studies that are federally funded. Also mandated, the Women's Health Initiative (WHI) was launched in 1993 as the largest clinical trial among women<sup>4</sup> and is addressing some of the leading causes of death and disability in women as they age. These and other milestones do not necessarily assure that biomedical and behavioral research in women will expand progressively and impact critical areas. One challenge to expanding research is to prioritize scientific opportunities that will close gaps in knowledge and lead to health benefits for women.

Establishing research priorities is critical to advancing knowledge efficiently in specific areas of women's health, with the ultimate aim of reducing the burden of disease and enhancing the lives of women. A research agenda for women's health at the NIH was set in 1991 by the Office of Research on Women's Health (ORWH), based on public hearings and a scientific workshop at Hunt Valley, Maryland.<sup>5</sup> Using a similar format, a series of meetings beginning in 1996 resulted in an updated national agenda for women's health research for the 21st century.<sup>6</sup> Also providing a model for development of a research agenda was the Institute of Medicine's (IOM) report on research priority setting at the NIH.<sup>7</sup> The IOM report focused on public input, burden of disease, and scientific opportunity as criteria for priority setting. In addition to communicating the procedures for priority setting, the IOM suggested that broader input be obtained to strengthen the process.

Although the national agenda has been comprehensively developed and provides an exemplary prioritization of research needs, a process is necessary to locally adopt and implement it. The primary purpose of this study was to describe criteria for and barriers to establishing a local research agenda in women's health. A secondary aim was to document methods to identify

women's health researchers and mechanisms to facilitate multidisciplinary research. Information was obtained from a survey of Directors of Research at the National Centers of Excellence in Women's Health (CoEs), supported by the Office on Women's Health (OWH) of the U.S. Department of Health and Human Services (DHHS). The CoEs, located in leading academic health centers across the United States and Puerto Rico, are developing new models for women's healthcare by integrating comprehensive clinical healthcare, research, medical training, community outreach, and medical school faculty leadership development.

## MATERIALS AND METHODS

A standardized questionnaire was given to all research directors of the originally funded CoEs ( $n = 18$ ) in July 1999. The questionnaire included demographic information about the respondent, including age, degrees, academic rank, extramural funding, major discipline(s), and research interests. It also contained a quantitative section that required rating and ranking a list of criteria to establish a research agenda and ranking the importance of age groups to study. Respondents were asked to list the top three women's health research topics and top three barriers to women's health research as open-ended questions, relying on their expertise in women's health. As a result of collapsing some directors' responses into a broad category, frequencies for these two questions do not total 54. The survey included an open-ended section that requested suggestions for (1) how to determine gaps in research, (2) mechanisms to identify women's health researchers and (3) strategies to facilitate multidisciplinary research in women's health, and (4) procedures to establish a local research agenda. All 18 CoE research directors responded to the survey.

The CoE research directors developed by consensus a list of criteria for setting a women's health research agenda. Then they were asked to rate these criteria on a Likert scale of 1–5, with 5 being of extreme importance and 1 being of little or no importance. Scores are expressed as mean  $\pm$  SD. In addition, CoE research directors were asked to rank the top five criteria in order of importance for setting research priorities. The mean rank and proportion of respondents that ranked the criteria in the top three and top five

were calculated. Information from the qualitative portion of the survey was summarized and categorized where appropriate. No statistical testing was performed because of the limited sample size.

The survey respondents represented 18 different academic institutions across the United States (see Appendix) that, at the time of the survey, were designated as CoEs by the OWH in recognition of their excellence in women's health research, teaching, clinical care, public outreach, and leadership development for female faculty. There were 16 women and 2 men (mean age of  $47 \pm 3.5$  years) who completed the survey. The ethnic composition of the respondents was 83.3% non-Hispanic whites, 11.1% African American, and 5.6% Hispanic. Nearly 80% were at or above the associate professor level. The majority had a Ph.D. ( $n = 12$ ), and 6 had an M.D. degree, with 100% reporting that they receive extramural funding. The research directors represented numerous disciplines, including cardiology, epidemiology, statistics, obstetrics/gynecology, nursing, psychology, geriatrics, physiology, microbiology, and immunology. The research interests of the respondents also were diverse, with women's health cited most frequently.

## RESULTS

### *Criteria to establish a research agenda in women's health*

Ratings for prespecified criteria to set a research agenda are listed in Table 1. The highest-rated criterion was for research focused on health

issues that afflict large numbers of women ( $4.82 \pm 0.83$ ). It was rated as one of the top three criteria by more than half the respondents and was rated in the top five by approximately 70% of the respondents. Research that focuses on information that is likely to establish treatment received the second highest rating ( $4.18 \pm 0.47$ ), followed by studies of psychosocial/cultural factors ( $4.00 \pm 0.47$ ) affecting women's health. Problems that affect quality of life were also rated as important ( $3.88 \pm 0.63$ ), with more than half of the respondents rating this criterion in the top five and 41% rating it in the top three. None of the listed criteria received a score less than 3.0 on the 5-point Likert scale. However, a research question focused on conditions with little or no established treatment was rated lowest on the list ( $3.00 \pm 0.85$ ). Overall, there was good consistency between mean scores based on rating and the ranking of individual items.

CoE research directors were also asked to rank order (from 1 to 5, with 5 as most important) priorities for age groups to be studied. Midlife (40–55 years) was ranked highest (mean rank  $4.31 \pm 4.00$ ), followed by the aging (55–70 years) (mean rank  $4.00 \pm 2.70$ ), adult women (25–40 years) (mean rank  $3.00 \pm 1.90$ ), youth (<25 years) (mean rank  $2.56 \pm 2.20$ ), and the elderly (>70 years) (mean rank  $2.47 \pm 1.40$ ).

### *Top health topic and barriers to setting a research agenda*

Responses to the top three health topics question were grouped into broad categories by content. The most frequently identified topic was cardiovascular disease (CVD) ( $n = 11$ ). This was

TABLE 1. CRITERIA FOR SETTING A WOMEN'S HEALTH RESEARCH AGENDA

<i>Research question focus</i>	<i>Score (5 = top) Mean <math>\pm</math> SD</i>	<i>Rank (5 = top) Mean</i>	<i>% rated in top 5</i>	<i>% rated in top 3</i>
Health issue for large number of women	$4.82 \pm 0.83$	2.35	71	53
Information likely to establish treatment	$4.18 \pm 0.47$	1.53	53	24
Psychosocial/cultural factors	$4.00 \pm 0.47$	0.53	12	12
Problem affecting quality of life	$3.88 \pm 0.63$	1.76	53	41
Previously understudied area	$3.82 \pm 0.46$	0.82	24	18
Biomedical conditions	$3.75 \pm 0.56$	0.53	12	12
Highly lethal condition	$3.71 \pm 0.68$	0.71	24	18
Topic leading to new methodology	$3.71 \pm 0.56$	0.18	12	0
Afflicts only women	$3.59 \pm 0.69$	0.47	24	6
Medical education—women's health	$3.43 \pm 0.72$	0.18	6	6
A fundable question	$3.35 \pm 0.81$	0.76	35	12
Multidisciplinary in nature	$3.35 \pm 0.73$	0.65	24	12
Condition with little or no established treatment	$3.00 \pm 0.85$	0.12	6	0
Other (2 answered)	$1.50 \pm 0.61$			

followed by breast cancer and mental health ( $n = 8$  each), menopause and hormone replacement therapy (HRT) ( $n = 5$ ), and genetic factors ( $n = 4$ ). Access to care and preventive healthcare each had 3 responses, and pregnancy had 2. The remaining health topics included quality of life, environment, diverse populations, aging, smoking cessation, violence, sex-specific treatment, and obesity, with each recorded once as a top priority.

The most common barrier to women's health research was identified as lack of funding ( $n = 11$ ), followed by lack of recognition, acceptance, and sensitivity by researchers ( $n = 10$ ). Lack of appropriate infrastructure and reward system for multidisciplinary/interdisciplinary research ( $n = 7$ ) and lack of academic leaders in women's health ( $n = 6$ ) were also listed as top barriers. Other top barriers included difficulty in recruiting women and the current healthcare system, with 4 and 3 responses, respectively. Other barriers included an insufficient focus in curricula and lack of partnerships with women to determine needs.

#### *How to determine gaps in women's health research*

An initial step in setting a research agenda is to identify gaps in knowledge about the health of women of diverse racial, ethnic, and socioeconomic background. CoE research directors in women's health identified the following procedures to determine gaps in knowledge at the local level:

1. *Evaluate current knowledge and understanding of diseases unique to women.* Are basic and clinical researchers aware of the diseases, disorders, and conditions that affect women and particular research opportunities? Most of the survey participants suggested conducting surveys, workshops, and special conferences to answer this question. Outreach strategies should be developed to communicate the missing information to all interested groups.

2. *Examine diseases with a disparate incidence and mortality rate among women.* This effort requires data collection and analysis in order to recognize the emergence of particular disease trends that affect only women. Potential sources of identifying disease patterns and behaviors among populations include hospital records, the United States Census, insurance company data, and epidemiological studies. These data are available electron-

ically from many agencies, including the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration). In addition, the survey respondents recommended reviewing the scientific literature to identify gaps in knowledge, especially when such information is available for men. Literature review will also help determine disorders of high prevalence in women.

3. *Assess treatment availability for women, especially for conditions requiring interventions that are different from those of men.* Clinical researchers are encouraged to assess if there are differences in the availability and access of treatment or health services or both between women and men in their patient population, as have been observed nationally.

4. *Monitor the enrollment of women in research studies.* To assure adequate representation of women in clinical trials at the local level, survey participants suggested creating a register of ongoing clinical trials to track and monitor women's participation. This local monitoring would assure that the NIH requirements are met as well as that non-NIH trials appropriately involve women.

5. *Identify the ethnicity and socioeconomic status of women who are recruited for or participate in research.* Gaps in women's health research are often a result of the exclusion of low-income and minority women, who also have higher rates and risks of major diseases.<sup>8</sup> Mechanisms to avoid this limitation will be to include women and minorities on the research working groups and to consult with national groups responsible for developing and promoting research agendas for minority women, such as the Society for Analysis of African-American Public Health Issues. Other key mechanisms are involvement of the communities and their representatives in the research process, providing a flexible visit schedule for research participants, and if possible, covering participant transportation and child care.

6. *Review existing research agendas.* The ORWH research agenda, *Report of the National Institutes of Health: Opportunities for Research on Women's Health*, published in 1992,<sup>5</sup> has been supplemented each year to address emerging issues in women's health. A key resource is the multivolume *Agenda for Research on Women's Health for the 21st Century*, developed by the ORWH, which describes national agenda topics in terms of scientific progress, gaps in knowledge, and recom-

mendations.<sup>6</sup> Another source of information is the interest areas published on the NIH website annually from the Office of the Director. Topics of particular interest or strategic plans for research also appear on the web for the individual NIH institutes.

7. *Access funding databases and investigate funding opportunities.* Gaps in women's health research can also be identified by accessing currently available databases of funded research and funding opportunities and correlating the respective data with the diseases, disorders, and conditions specified in the ORWH research agenda or those given special considerations by Congress.

8. *Organize consensus conferences or working groups.* Survey such participants as basic and clinical investigators, women's advocates, institutional and public officials, potential female subjects, study sponsors, and healthcare providers for their perceptions of gaps in women's health research. The information provided by these groups should be used in developing any research agenda.

#### *Mechanisms to identify women's health researchers*

Mechanisms to identify women's health researchers locally and nationally included (1) Internet searches of expertise and funding agency databases and public and private websites by specific topic or keyword, (2) examination of existing databases, such as the NIH Computer Retrieval of Information on Scientific Projects (CRISP) and the Community of Science (COS). Within the COS, a CoE database is available as an affiliated site and provides the opportunity of searching CoE expertise by topic. Additional mechanisms to identify women's health researchers included (3) searching published papers and textbooks, (4) reviewing local and national conference agendas, (5) conducting surveys among local and national professional societies that ask members to identify themselves as women's health researchers, and (6) conducting surveys among department, program, or center chairs or directors or distributing a survey formally or informally to faculty members. It is often possible to build on existing surveys of research interests by simply adding women's health as an option, which will likely improve the response rate over sending a separate survey to

assess research interest in women's health. The response rate may also be optimized by providing an incentive, such as inclusion in a published directory of women's health researchers and notification of funding opportunities.

#### *Mechanisms to facilitate multidisciplinary research in women's health*

Seventy-two percent ( $n = 13$ ) of CoE research directors identified grant funding that required multidisciplinary collaboration as a stimulus for building interdisciplinary research teams. For example, major funding agencies, such as the NIH, might initiate grant programs that fund interdisciplinary research, thereby encouraging broad-based investigations into women's health problems. Expansion of the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) awards would also facilitate multidisciplinary research at the local level. The BIRCWH program seeks to increase the number of researchers working on women's health issues and to mentor junior researchers in an interdisciplinary scientific setting by pairing them with senior investigators. Pilot funding at the local level might also be provided to stimulate innovative research projects and to encourage new investigators. Seven (39%) of the 18 research directors emphasized the importance of forming networks among researchers interested in women's health issues. They suggested the development of colloquia, conferences, discussion forums, e-mail list groups, and research directories to facilitate the establishment of networks. In addition, 4 (22%) of the respondents also suggested that local institutions and private national organizations provide career positions that require multidisciplinary skills and special recognition (e.g., incentives, such as protected time) to encourage the participation of researchers in interdisciplinary teams.

#### *Procedures for setting a local research agenda in women's health*

Key components of establishing a local research agenda in women's health are listed in Table 2. The process should begin with a review of existing agendas at the national level. The following documents suggested by the CoE research directors may be helpful in initiating the process: *Recruitment and Retention of Women in Clinical Trials* from the ORWH,<sup>8</sup> *Report of the National Institutes of Health: Opportunities for Research on*

TABLE 2. STEPS TO ESTABLISH A LOCAL RESEARCH AGENDA FOR WOMEN'S HEALTH

1. Review existing national agendas.
2. Identify gaps in knowledge.
3. Compile research interests and expertise of local scientists.
4. Obtain input from women's health researchers and key leadership.
5. Document demographics and morbidity/mortality trends of targeted communities/populations.
6. Invite public input into process of priority setting.
7. Assess recruitment strategies, feasibility, and significance of proposed research.
8. Develop criteria to prioritize research activities.
9. Establish a communication and implementation plan that facilitates multidisciplinary research activities and network opportunities.
10. Evaluate progress and update agenda on a regular basis.

*Women's Health*,<sup>9</sup> *Action Plan for Women's Health* from the OWH,<sup>10</sup> *Women in Biomedical Careers: Dynamics of Change—Strategies for the 21st Century* from the ORWH,<sup>11</sup> and *Agenda for Research on Women's Health for the 21st Century* from the ORWH.<sup>6</sup>

Important gaps in knowledge can be identified through several mechanisms outlined previously and contained in the CoE program mission. Critical gaps that might be addressed in the context of local expertise should be outlined. The research interests and expertise at the local institution should be cataloged (see section on *Mechanisms to identify women's health researchers*). Input should be obtained from researchers in women's health, particularly veteran researchers, to assist with priority setting. Demographic data for the geographic area should be documented, and partnerships with local departments of health might be useful to achieve this step. Recruitment strategies that include ethnically and socioeconomically diverse groups of women should be outlined. Community involvement should be sought to discuss local health issues for women and to discuss the feasibility of various research priorities. This can be accomplished through working with established community groups, developing community boards to partner with women's health programs, focus groups, conducting surveys at community events, or through direct mail or phone solicitation. Public input, especially from women, is essential to acceptance and successful implementation of a research agenda aimed at improving women's health.

## DISCUSSION

These data confirm that highly prevalent chronic conditions in women should be priority areas of research for all stages of prevention locally as they are nationally. As the population ages, the burden of chronic diseases affecting large numbers of women will continue to rise. Results are consistent with recommendations from the IOM<sup>7</sup> suggesting that the burden of disease should be a criterion in establishing research priorities. Moreover, the findings are consistent with the *Report of the Public Health Task Force on Women's Health Issues*,<sup>6</sup> suggesting that research should emphasize prevalent diseases in women. Researching psychosocial and quality of life issues was rated as important than researching conditions that are highly lethal. Increased survival of women to older ages will require a paradigm shift in study end points, as lengthening life may not be as relevant as improved quality of life for many older women.

Priorities for studying population age groups may reflect the knowledge that biological changes occurring during the midlife due to aging or hormonal changes or both are associated with many adverse health consequences.<sup>12</sup>

The health topics listed as priorities for research in women generally parallel morbidity and mortality data.<sup>13</sup> CVD is the leading cause of death in women and is a significant cause of morbidity, although women tend to have a greater fear of cancer, the second leading cause of death in women.<sup>14</sup> Lung cancer, not singled out by the CoE research directors, claims more lives than breast cancer and presents an important opportunity to reduce disease burden because it is often caused by smoking and is preventable.<sup>15</sup> Mental health disorders are a significant cause of morbidity in women. Major depression is the most common severe mental disorder among women, and it has been estimated that the ratio of depression risk rates is 2:1 for women compared with men.<sup>16</sup> The CoE research directors' top priorities differ from the national agenda<sup>6</sup> in some respects, perhaps with smoking being the most notable. The national agenda also emphasized autoimmune conditions, neurological conditions, and infectious diseases. It is likely that limiting the choice of topics to a total of three restricted the scope of conditions listed in this report. It is unclear why the CoE directors did not emphasize smoking and lung cancer risk, but

they may have considered behavioral changes as implicit in preventive healthcare, which was emphasized in this report.

Our survey results are consistent with those observed by Johnson and Fee.<sup>17</sup> They documented that women's health research needs have been concentrated in three main areas including (1) biological conditions (e.g., menstruation, pregnancy, menopause) and diseases (vaginal, cervical, ovarian, and breast cancer) that affect only women, (2) diseases that affect men and women but are more prevalent in women (osteoporosis, depression, and autoimmune diseases), and (3) diseases and disorders that are expressed differently in men and women (heart disease, substance abuse, AIDS, and violence).

Lack of role models in academia in general, and in women's health in particular, is a modifiable barrier. Fried et al.<sup>18</sup> reported success in career development through long-term interventions at Johns Hopkins University, suggesting that a greater concentration of experienced women investigators might be available with a concerted effort. The problem is not unique to the United States. In a Norwegian study, men leaders in academic medicine outnumbered the women leaders almost 3:1.<sup>19</sup> Women's health issues are global, especially such chronic diseases as CVD, and are leading contributors to death in most developed and developing countries. Training the next generation of scientists in women's health will require development of formal curricula and integration with existing programs. Henrich<sup>9</sup> has made recommendations for training healthcare professionals and states that "implementing these recommendations would go a long way toward ensuring that the nation attains the highest standard of education, training, practice, and research in women's health." In 1992, the ORWH initiated programs to increase opportunities for women in biomedical careers. These programs include reentry programs for women who have interrupted their research careers for family responsibilities; Transitional Career Development Awards in Women's Health Research; Professional Opportunities for Women in Research and Education (POWRE); training projects for high school students, college faculty, and students; and writing courses for young scientists.<sup>6</sup> Development of successful women academic leaders is a central component of the CoEs, and successful programs and strategies have been recognized by the OWH.<sup>20</sup> Other efforts at the national level in-

clude special junior faculty outreach projects, four National Centers of Leadership in Women's Health funded by the OWH,<sup>21</sup> and funding of 11 universities participating in the BIRCWH program, which encourages junior faculty researchers from basic, clinical, behavioral, health services, and public health research areas.

Mechanisms suggested by the CoE research directors to identify women's health researchers locally and nationally included traditional methods, such as electronic or nonelectronic searches of databases and literature and surveys among institutional leaders or faculty themselves. Less traditional mechanisms included seeking out researchers at conferences and surveying expertise among professional societies. The multidisciplinary nature of women's health research<sup>22</sup> makes it difficult to identify individuals with research expertise efficiently using a single source. One previously published strategy to identify and build a multidisciplinary team involved "top down" (e.g., departmental chairs) and "bottom up" (individual faculty members) surveys,<sup>23</sup> but such teams are usually targeted at a single health-related issue. Our recommendations describe several options that may be used in combination to systematically identify researchers from diverse disciplines with experience in issues encompassed by women's health.

The field of women's health is widely recognized by researchers, health providers, educators, and policymakers as being multidisciplinary in nature.<sup>24-27</sup> The complex issues associated with women's health have prompted these professionals to advocate the development of interdisciplinary teams to address patient care, research, and education in women's health. This multidisciplinary approach attempts to integrate perspectives held by diverse disciplines and is generally regarded as superior to older, fragmented methods of addressing women's health.<sup>28</sup>

Proponents of an integrated view of women's health suggest that collaborations include relevant fields in medicine and health, such as internal medicine, family practice, obstetrics/gynecology, pediatrics, nursing, pharmacy, public health, and mental health.<sup>26,28</sup> Cross-discipline training efforts may also lead to interdisciplinary collaboration between internists and obstetricians/gynecologists to advance the competency of physicians and physician-scientists in women's health. Women's health interdisciplinary teams may also include professionals from basic sci-

ence, anthropology, sociology, and psychology.<sup>28</sup> For example, basic scientists join with physician investigators to explore fundamental biological and physiological questions and their relationships to human health. Researchers in the fields of social sciences and behavioral medicine may collaborate with physicians to examine the effects of socioeconomic status, social interactions, cultural factors, and environmental influences on health beliefs and behaviors.

## CONCLUSIONS

Over the past one to two decades, there has been an increased awareness of health issues that uniquely affect women or affect women differently from men. This increased attention coupled with discoveries of gender-based differences ranging from the molecular level to behavioral factors have helped to establish women's health as a focused field of research. The national agenda comprehensively mapped the direction of research across the life-span and by topic.<sup>6</sup> Local implementation requires a multifaceted plan that assumes differences in expertise, interest, and resources among institutions. Such a plan at the local level will help direct energy and resources toward research yielding the greatest health benefits.

In this report, we have described criteria that can be used to establish a local research agenda in women's health, provided specific recommendations for determining gaps in women's research, made recommendations to identify women's health researchers, and suggested ways to facilitate multidisciplinary women's health research. A 10-step process for establishing a local research agenda on women's health was developed from information generated from a survey of 18 CoEs research directors (Table 2). A strength of this study is the systematic approach to collecting information from recognized experts in the field. Limitations include the limited size and the ability to generalize the procedures outside of experienced institutions. Priority setting for research should take into account the strengths and weaknesses of each institution or organization establishing a research agenda. Therefore, these recommendations from the CoEs were designed to provide a general framework, with flexibility for individual organizations to adapt the process to the local environment. There are numerous chal-

lenges to implementation of a research agenda, such as overcoming barriers for women to participate in research and limited financial resources that are beyond the scope of this document. However, a documentation of criteria and procedures to establish a research agenda on women's health is an important first step. A systematic approach to prioritize and strengthen research activities should be a dynamic process, with development of an infrastructure to ensure that new discoveries are translated into improved healthcare for women.

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