

CENTERS FOR DISEASE CONTROL AND PREVENTION

**DES National Education Campaign
Formative Research Proposal**

DRAFT/NOT FINAL

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BACKGROUND

The Centers for Disease Control and Prevention (CDC) is developing the Diethylstilbestrol (DES) National Education Campaign, a national effort to construct sustainable communication processes and programs that promote information-seeking action and that enhance DES-specific encounters between the general public and the medical professionals and organizations which serve their health care needs. This program will build on the results of the coordinated consumer/primary care provider interventions developed by five regional pilot educational efforts conducted by the National Cancer Institute (NCI) between 1993 and 1997, as well as two meetings with the DES NEC Working Group.

Although communication research regarding DES issues already exists, the Working Group has recommended that additional research be conducted before moving into the creative stage of the campaign for several reasons. Baseline surveys were conducted at the five NCI pilot study sites, yet these sites were areas where DES was heavily prescribed, thus the data may not reveal the full range of knowledge, attitudes, beliefs, and behaviors. Moreover, the full results from the studies are not yet available, and the partial data is not comparable. In addition, several years have elapsed since the data from the NCI pilot sites was collected. Most important, the Working Group has recommended segmenting the public and primary care provider audiences, and research is needed to go beyond defining the broad characteristics of the audiences and develop a deep, personal understanding of each subgroup's perceptions, issues, and motivations.

Thus, important questions remain unanswered and invite further exploration. This research will work toward the broader campaign objectives for each target audience.

The desired outcomes among the general public include:

- ! Heightened awareness of the conditions under which DES exposure might have occurred and its possible consequences;
- ! Increased motivation and ability among the general public, both men and women, to query their own and/or family members' DES exposure status;
- ! Enhanced ability to apprise the primary health care physician of possible DES exposure and to expect DES-specific screening and/or treatment from appropriate specialists.

The desired outcomes among the health care community include:

- ! An increase in current and accurate knowledge about DES, its health effects, screening and treatment guidelines
- ! The development of a bias to action with respect to identifying, screening, treating, and referring patients to a range of current DES information and appropriate treatment resources.

The findings from the formative research will be used (a) to supplement existing information about the target audiences, and (b) to guide development of audience-specific communication objectives, strategies, and tactics, including recommendations for materials.

RESEARCH DESIGN

Audience Segmentation

The Working Group has recommended that the campaign's two audiences, the public and health care community, be segmented in the following manner. We will work with CDC to refine the characteristics of each segment and develop appropriate screening criteria.

1. Public

Mothers and their daughters and sons who could have been exposed to DES face different issues, thus the Working Group has recommended that research be conducted with these audiences separately.

1. DES Daughters and Sons

The segment of the public of primary concern consists of the daughters and sons of mothers who could have taken DES while pregnant during 1948-67, which is when the largest dosages of DES were prescribed. The Working Group has recommended segmenting DES children according to their awareness of their DES-exposure status and experience with symptoms consistent with DES exposure in utero.

1. Exposed: These people know that they were exposed to DES in utero and may or may not be experiencing health problems consistent with DES exposure in utero. Although people in this segment are already knowledgeable about DES to a certain extent, they may have misinformation and misperceptions.
2. Symptomatic: People in this segment are unaware of whether they were exposed to DES in utero, but they are experiencing health problems consistent with DES exposure in utero and they are in the appropriate age group. These people need to be informed about DES so that, if they decided to do so, they will be able to investigate their DES exposure status and seek screenings for other DES-related health problems that they have not already experienced.

DES-related health problems include fertility problems, pre-term labor, miscarriages, and genital structure abnormalities. We will turn to CDC for guidance in identifying the specific health conditions that people must have to be eligible for participation.

3. At-Risk: These people are unaware of whether they were exposed to DES, and they are not experiencing health problems consistent with DES exposure in utero; however, they are in the appropriate age group. They need to be aware of their potential exposure to DES and have the information needed to investigate their exposure status and make informed choices about screening for DES-related health problems.

With this particular segment, it will be important to identify those most open to receiving information and to understand the most effective means for disseminating information to them. Thus we will use Porter Novelli's Healthstyles Health Information Seeking segmentation scheme to develop screening criteria for identifying and recruiting those who classify as Independent Seekers, Doc-Dependent Actives, and Moderates. Compared to the others, these segments are more active in seeking health information, are more confident in their ability to understand the health information received, and are more strongly oriented toward health prevention. They differ in that Doc Dependent Actives rely much more heavily on doctors for health information than Independent Seekers and Moderates do. For this research, we will recruit roughly equal numbers from each Healthstyles segment.

All of the above subgroups will be segmented by gender (male and female). Sons were not targeted by the NCI pilot study, thus little is known about their knowledge, attitudes, beliefs, and behaviors regarding DES. In addition, research participants representing each subgroup must meet the following criteria:

- ! Mix of urban, suburban, and rural communities
- ! Mix of races/ethnicities

- ! Mix of education levels
- ! Plus or minus \$20,000 of the aggregate median household income for the geographic area in which the groups will be held (based on 1999 Census Bureau data)

2. DES Mothers

The next segment of the public of concern is mothers who were born 1928-47. DES mothers need to know about their potential exposure to DES and their potential increased risk for breast cancer, and they also can act as communication channels for their children. The Working Group has recommended segmenting DES women according to their awareness of their DES-exposure status and experience with symptoms consistent with DES exposure, which with few exceptions will be parallel to the manner in which the DES daughters and sons will be segmented.

1. Exposed
2. Symptomatic (Compared to DES daughters and sons, DES mothers who are symptomatic experience a different set of health problems. In particular, research to date has shown that DES mothers are at higher risk of experiencing breast cancer.)
3. **At-Risk**

Participants representing each segment must meet the following criteria:

- ! Mix of urban, suburban, and rural communities
- ! Mix of races/ethnicities

II. Primary Care Providers

The Working Group has recommended that the upcoming formative research focus on primary care physicians as well as other types of health care providers in primary care fields. Primary care providers are being targeted because the DES National Education Campaign will focus on reaching providers through patient demand, and those in the primary care fields are likely to see more of the patients being targeted. In essence, the following groups are viewed as being on the **Afrontline@** of patient care, and they are therefore in need of education so that they will know how to respond to patient inquiries.

1. Primary Care Physicians: The primary care providers of primary focus are physicians. People in this segment are likely to act as gatekeepers and refer patients to the more specialized providers.
- B. Nurse Practitioners and Physician Assistants:** This segment is of secondary focus. The Working Group has concluded that, although the NCI pilot baseline studies included non-physician health providers, the data cannot be used to form conclusions because the sample sizes were small. Nurse practitioners and physician assistants are likely to conduct the patient intake procedures and thus be in the best position for asking about DES exposure. Furthermore, physicians often rely on them to counsel and educate patients, and patients tend to gravitate more often toward nurse practitioners and physician assistants because they are perceived as having more time than doctors do. Research with these groups should be conducted separately because they come from different training backgrounds and may operate from different perspectives in terms of patient care.

The Working Group has recommended that each health care segment be further divided by type of practice:

- ! OB/GYN
- ! Other primary care field (i.e., general practice, family practice, general internal medicine)

In addition, research participants in each subgroup must meet the following criteria:

- ! Participants must be state licensed to practice (although they will NOT necessarily have to be board certified)
- ! Participants must have spent the majority of their time in their current area of practice for the past 3 years consecutively
- ! Participants must have a patient population comprised of a significant proportion of the public targeted by the DES Education Campaign
- ! Participants must see approximately equal numbers of males and females
- ! Mix of ages and genders
- ! Mix of types of practice such as network, private, HMO, group, etc.

III. Office Staff

The Working Group has recommended that this research include staff members who work in offices where physicians, nurse practitioners, and physician assistants may focus on DES issues. They are the gatekeepers to the primary care providers and are likely to serve as important local information sources. Moreover, they can give a sense of how primary care providers filter the vast amount of health information they receive.

In addition, research participants must meet the following criteria:

- ! Mix of ages and genders
- ! Mix of types of practice such as network, private, HMO, group, etc.

Recruitment Methods

All of the research participants will be recruited in advance of the discussion. We will work with CDC to finalize the characteristics of each subgroup and subsequently develop screeners that will ensure we recruit the appropriate people to interview. A variety of methods will be necessary to complete recruitment in a timely and cost-effective manner.

- ! **DES mothers and DES daughters and sons who are exposed or symptomatic:** DES issues are a unique health challenge, and it is unlikely that traditional recruitment methods will be time- or cost-effective. We will therefore recruit these participants through physicians and advocacy organizations that are working with people experiencing DES-related problems and that are networked with the Working Group.

We will try to recruit people who are not extremely knowledgeable about or involved with DES issues (e.g., people who are not highly active members of advocacy organizations). Still, by employing the recommended strategy, we are more likely to find people who have a higher degree of knowledge about DES (e.g., through educational materials disseminated). Finding more knowledgeable people may be advantageous in that they may be better able to articulate their experiences and concerns, which is important because individuals who are completely uninformed about DES are unlikely to be able to contribute to any discussion.

- ! **DES mothers and DES daughter and sons who are at-risk:** There are few restrictions that will make it difficult to recruit these participants, thus we recommend recruiting these people through focus group facilities that have demonstrated the ability to recruit in a time- and cost-effective manner.
- ! **Health Care Professionals:** We will recruit these participants through partnerships with organizations that have volunteered their databases and that have networked with the Working Group. Such organizations could include the American Medical Association, Nurse Practitioners in Women's Health, and American Academy of Physicians Assistants.

Research Methodologies

The sensitive nature of DES-related issues and likely recruitment difficulties dictate that a variety of formative research methodologies be employed with the different audience segments. The following tables illustrate the different research methodologies we recommend for each target audience.

As an important note, we will look toward the Working Group to determine whether it is possible to recruit enough people in the exposed and symptomatic segments to hold a focus group in-person at one location. If not, then we will conduct the groups over the telephone. We will also look toward the Working Group for guidance as to where the in-person groups should take place. We are aware that the Working Group has already recommended that the research take place in at least four geographic locations to account for differences due to DES population shifts, DES usage, medical practice patterns, and communication channels.

Public

	Exposed	Symptomatic	At-risk
Daughters Born 1948-67	2 telephone/ in-person focus groups	1 telephone/in- person focus group AND 10 telephone interviews	2 in-person focus groups
Sons Born 1948-67	20 telephone interviews	20 telephone interviews	2 in-person focus groups
Mothers Born 1928-1947	2 telephone/in- person focus groups	1 telephone/in- person focus group AND 10 telephone interviews	2 in-person focus groups

Primary Care Providers

	OB/GYN	Other Primary Care
Primary Care Physicians	2 telephone focus groups	2 telephone focus groups
Nurse Practitioners	2 telephone focus groups	2 telephone focus groups
Physician Assistants	2 telephone focus groups	2 telephone focus groups

Office Staff

20 telephone interviews

Following is our reasoning behind the methodologies recommended for each audience segment:

- ! **In-person focus groups:** In-person focus groups are recommended for audience segments that are easier to recruit and that are concentrated in one geographic location (e.g., at-risk). They allow for project members to observe the groups and thus listen to participants comments as well as observe their body language, both of which are important for gauging reactions to topics or issues. In addition, this type of direct exchange makes it easier for discussion leaders to facilitate the focus group process. We recommend limiting the length of each focus group to 1.5-2 hours and the number of participants to 9.
- ! **Telephone focus groups:** Telephone focus groups are recommended for audience segments that are more difficult to recruit and that are not necessarily concentrated in one geographic location (e.g., exposed, symptomatic, primary care providers). They also enable recruitment from geographically dispersed locations. Current technology makes it possible to observe telephone focus groups and identify who is speaking. We recommend limiting the length of each focus group to 1.5 hours (because participants have greater freedom to leave a group when they grow physically tired or bored of the conversation) and the number of participants to 6 (because it is easier for the moderator to facilitate a discussion of fewer people over the phone).
- ! **Telephone one-on-one interviews:** Unlike their female counterparts, DES sons/ exposed or symptomatic could be more hesitant to discuss DES and related health problems, both of which are highly sensitive topics (as noted by the founder of DES Sons Network, who estimates that most callers to the organization’s information line are mothers or spouses of sons rather than DES sons themselves). Telephone focus groups can afford a certain degree of privacy and allay fears of evaluation from other group members. Yet if the topics are highly sensitive and require an even safer environment, then telephone one-on-one interviews can be better because they can afford a greater degree of privacy and avoid any negative group dynamics. Telephone interviews also allow for researchers to talk to participants across the

US. Because of the sensitivity of the discussion topics and the lack of group dynamics for maintaining the attention of participants, we recommend limiting each interview to 45 minutes-1 hour.

Focus groups and interviews with the public will be conducted by a person of the same gender and of an appropriate age. Focus groups and interviews with primary care providers will be conducted by a person trained in conducting groups with these audiences.

All participants will receive a cash incentive. In addition, participants in the in-person focus groups will receive a light meal.

DISCUSSION TOPICS

Following are the proposed topics to be explored for each audience segment in this round of formative research. They are based on the research already conducted to date (e.g., NCI pilot study surveys). We will work with CDC to refine these topics and develop guides that include them.

Exposed Mothers, Daughters, and Sons

We already know from previous research that being exposed to DES stimulates intense emotional responses including anger, a sense of betrayal, guilt, and helplessness. From the loss of fertility to radical hysterectomies, to the potential for increased cancer risks and even third generation involvement, DES has wrought intense pain and distress on families across the country. Such feelings are entirely different from those evinced by high blood pressure, smokers=cough, or even a lump in the breast. In addition, we know that, compared to the other segments, the exposed are generally more knowledgeable about DES health risks. Yet along with this greater knowledge comes the greater potential for misinformation. Additional research is needed to explore how to correct misperceptions, as well as how to create a sense of trust that has been lost. Following are topics to be explored in the upcoming research:

- ! How DES-exposure was discovered
- ! Emotional reaction to knowledge of DES exposure and the issue of DES
- ! Reactions of healthcare providers to DES status
- ! Behaviors related to DES (doctor use, preventive habits, discussions with doctors, discussions with mothers)
- ! Symptoms, if any; response to symptoms
- ! Reaction to message preliminary concepts
- ! Sources of health information

Symptomatic Mothers, Daughters, and Sons

Compared to the exposed and at-risk public, the least is known about the symptomatic. Thus it will be necessary to explore their knowledge, attitudes, beliefs, and behaviors regarding DES. In particular, it will be important to gain a sense of how people might react as they become aware of DES and realize how their current health problems may be connected to DES. Topics to explore include:

- ! How current health problems have affected their lives
- ! Emotional reaction to how their conditions have affected them
- ! Awareness, knowledge and perceptions of DES
- ! Level of concern
- ! Behaviors related to awareness of DES status (discussions with mothers or doctors, search of medical files, etc.)

- ! Barriers to exploring DES status
- ! Reactions to preliminary message concepts
- ! Health information sources

At-Risk Mothers, Daughters, and Sons

Previous research has shown that the general public, despite being at-risk for DES-related health problems due to age, is unlikely to know about DES because it affects a relatively small proportion of the American population, it happened a relatively long time ago, and the odds of suffering health problems due to DES exposure are relatively small. Members of the public therefore view DES as a unique health problem, unlike heart disease, cancer, and other better known illnesses. The upcoming research will need to explore ways to raise awareness without raising undue concern. Topics to explore might include:

- ! Awareness, knowledge and perceptions of DES
- ! Level of concern
- ! Behaviors related to awareness of DES status (discussions with mothers or doctors, search of medical files, etc.)
- ! Barriers to exploring DES status
- ! Reactions to preliminary message concepts
- ! Health information sources

Physicians, Nurse Practitioners, Physician Assistants (OB/GYNs and other primary care providers)

The Working Group has concluded that data from the five NCI pilot study sites, which often was in disagreement, cannot be used to draw definite conclusions in terms of primary health providers=knowledge, attitudes, beliefs, and behaviors regarding DES, thus these areas need to be further explored. It will also be important to determine how practice setting affects behaviors. For example, in one study regarding folic acid, health care providers said there are more opportunities to counsel and educate the public in private and public health clinics than in managed care settings. Research will also need to explore how to overcome barriers to provider outreach. Interviews conducted by the National Cancer Institute for a cervical cancer awareness program revealed that physicians often lack the time to educate patients due to heavy patient loads as well as other time pressures. The folic acid study indicated that non-physician providers often experience time pressures as well, due to the added responsibilities of administrative tasks. The following topics could be included in the upcoming research:

- ! Awareness of DES and related conditions
- ! Perceived professional (rather than personal) relevance
- ! Perceived importance of DES
- ! Interactions with patients regarding DES
- ! Barriers to routine detection of DES exposure
- ! Sources of new health information
- ! Credibility of information sources
- ! Reactions to preliminary message concepts

Office Staff

Research to date has shown that the most effective strategies for disseminating information to physicians are patient-mediated efforts, academic detailing, and reminders. Research also has shown that physicians view opinion leaders as credible sources of information. Yet little is known about how office staff play a role in information dissemination.

Furthermore, research with this audience could reveal how office staff are trained to filter health information. Following are topics that can be explore in the upcoming research:

- ! Perceptions of how the roles of the various types of health care professionals in the office differ
- ! Management and organization of the office (e.g., who makes final decisions on the content of intake forms, who counsels patients)
- ! Sources of new health information
- ! Credibility of information sources
- ! Methods of filtering health information received from different sources (i.e., who receives it, to whom is it forwarded)
- ! Appropriate incentives

REPORTING PROCEDURES

All focus groups and interviews will be observed by at least one note taker, and CDC and Working Group members will also be able to observe. The note taker will use the notes to develop topline reports. The moderators will review the topline reports summarizing the groups they conducted. Thirteen toplines presenting the preliminary findings will be written:

- ! DES children/exposed, 1 for males and 1 for females
- ! DES children/symptomatic, 1 for males and 1 for females
- ! DES children/at-risk, 1 for males and 1 for females
- ! DES mothers, 1 for exposed, 1 for symptomatic, 1 for at-risk
- ! Physicians, 1
- ! Nurse practitioners, 1
- ! Physician Assistants, 1
- ! Office Staff, 1

All of the groups will be audiotaped and transcribed. The toplines and transcripts will be used to develop a final report, which will synthesize the findings from the groups and highlight differences by DES-status, gender, age, and health care practice.

TIMELINE

The following proposed timeline outlines all of the activities required to complete this project. It begins with project approval and ends with the finalization of the full report.

<u>Activity</u>	<u>Week(s)</u>
Project approval from CDC	May 15
Screeners development	May 15-19
Recruitment	May 22-July 14
Guide development	May 22-June 9
Focus groups conducted	June 12-July 14
Topline development	June 19-August 4
Transcription	June 19-August 4
Full report development	August 7-September 1