

# Implementing a Systematic Approach to Meeting Patients' Cancer and Fertility Needs: A Review of the Fertile Hope Centers of Excellence Program

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## Abstract

**Purpose:** National guidelines recommend patients with cancer of reproductive age be informed of their risk for infertility resulting from cancer treatment. Despite existing technologies to preserve fertility, many patients report not receiving timely information about fertility risk, and oncology providers report multiple barriers to discussing or referring patients on this topic.

**Methods:** Nine cancer centers have been recognized as Fertile Hope Centers of Excellence, a designation awarded to cancer centers with an institutionalized approach to addressing fertility issues. Individual semistructured interviews were conducted with each of these centers to identify strengths of and challenges to their approaches.

**Results:** All institutions had procedures for the provision of topical professional and patient education and for notification of

patients. Notification methods varied widely, from use of customized consent forms to highly automated electronic alerts for providers. Referral routines and enactment of institutional policies also differed. Key components of successful programs emerged, including the value of internal champions, affiliation with complementary programs, and resource sharing.

**Conclusion:** The programs described provide examples of systems that can be assembled in different types of clinical settings, depending on the availability of resources and infrastructure. As institutions develop programs, metrics to evaluate notification systems, in particular, as well as the supportive program components, should be used so identification of best practices can continue. Widespread adoption of programs that incorporate the baseline elements identified will not only comply with national guidelines but also address patients' reproductive needs and fundamentally affect future quality of life.

## Introduction

Almost 140,000 Americans of reproductive age are diagnosed with cancer annually, and an estimated 30% to 75% of men and 40% to 80% of women in this group face the risk of infertility as a result of their treatment.<sup>1</sup> Although the exact definition of reproductive age varies, we included everyone diagnosed at age < 45 years, including pediatric patients (age 0 to 15 years), because they are also at risk for reproductive damage. Although patients with cancer frequently report anxiety about their ability to have children in the future,<sup>2,3</sup> many do not recall discussing potential infertility with their physicians or other health care providers,<sup>4</sup> and some remain unsure of their reproductive status after completion of treatment.<sup>5</sup> Studies suggest those who receive information regarding their reproductive health have lower levels of psychologic distress than those who did not.<sup>6,7</sup> One study of adolescent boys also indicated that patients and families felt treatment delays were acceptable to allow for sperm banking.<sup>8</sup> In the late 1990s, with survivorship rates increasing and new fertility techniques emerging, the oncology community began to evince greater awareness of its duty to meet patients' fertility needs, especially around sperm banking.<sup>9,10</sup> Broader, collective recognition of the issue, however, came in 2006, when the American Society of Clinical Oncology

(ASCO) published fertility recommendations.<sup>11</sup> These advised oncologists to discuss fertility risks and preservation strategies and make referrals to fertility specialists for interested patients as early as possible. Nonetheless, studies continue to indicate providers are not routinely offering fertility information and referrals to their patients.<sup>12,13</sup> In fact, a 2011 survey found a substantial majority of National Cancer Institute (NCI)–designated Comprehensive Cancer Centers had no formal procedures to address fertility preservation, nor were they following the ASCO fertility guidance.<sup>14</sup>

Before the ASCO recommendations,<sup>11</sup> patient advocates had begun to call for improvement in this arena. One effort was led by Fertile Hope (FH), a nonprofit organization focused on addressing unmet needs associated with cancer-related infertility. In 2005, FH launched the FH Centers of Excellence (FHCOE) program to recognize cancer centers that had institutionalized their approach to fertility, hoping to inspire the replication of similar systems nationwide.

In 2010, LIVESTRONG (a nonprofit organization with the mission of supporting and empowering cancer survivors) acquired several of the programs and assets of FH. FH then undertook a comprehensive review of its FHCOE program to evaluate the program criteria, describe the means of compliance

of its designees, and issue program recommendations to LIVESTRONG.

In this article, we discuss the development of the FHCOE program, our review methodology, our findings, and the implications of these findings for clinical practice. In conclusion, we provide suggestions toward improving the systematic delivery of fertility information by oncology providers to their patients.

## Methods

### FHCOE Program

FH created the FHCOE program in response to the 2004 President's Cancer Panel (PCP) report<sup>15</sup> on survivorship, which highlighted the failure of cancer centers to adequately alert their patients to their potential reproductive risks and available fertility preservation options. The PCP report contained four fertility-related recommendations, including a call for written and verbal information to be provided before treatment. These recommendations—in conjunction with the FH review of the literature, findings from previously conducted focus groups (unpublished data), and discussions between staff and medical advisors of the organization—formed the FHCOE program criteria (Table 1). These were selected to remedy specific, identified barriers to fertility discussions, including insufficient time, providers' lack of knowledge of reproductive techniques and options, concerns about cost and where to refer, and lack of patient resources.<sup>16</sup> Centers could implement their own strategies to satisfy the criteria, allowing for differing approaches across diverse clinical settings.

In 2005, Taussig Cancer Center became the inaugural FHCOE designee, with Stanford Cancer Institute recognized shortly thereafter. Dialogue with these centers was vital to the development of the program. A formal application was created, and FH invited all NCI cancer centers to participate. Applicants were entirely self-selected; any hospital could submit a form and demonstration letter. The form sought practical data, such as the number of age-eligible patients seen per year, the reproductive clinics and sperm banks to which patients were referred, and whether the center had relevant programs such as survivorship or adolescent and young adult clinics. Additionally, the signature of the medical director and the designation of an internal cancer and fertility contact were required. The demonstration letter required the applicant to provide a detailed explanation of how it met each of the FHCOE criteria. Subsequent to the NCI outreach mailing, FH reviewed applications as submitted, with designation usually occurring as the result of an iterative process requiring dialogue, submission of supporting materials, and clarification between FH and the applicant. Over several years, FH interacted with and supplied advice and resources to many hospitals; ultimately, nine institutions satisfactorily completed the process and were recognized as FHCOEs (Table 2).

### Methodology for Review of the FHCOE Program

To compare practice variations across the FHCOEs, a comprehensive qualitative review of each center's application and its

2010 follow-up statement was conducted (J.D.R.). Subsequently, an interview guide was created, and a qualitative, semi-structured, open-ended telephone interview was conducted with the named contact of each center to assess the institutional impetus for designation, satisfaction with the FHCOE criteria, and perspectives on the strengths and weaknesses of the approach of the center (J.D.R.). In addition to specific questions, the interview format allowed for the offer of additional information deemed relevant by the interviewee (Table 3). Handwritten notes were taken during the telephone interviews, and the responses were summarized (J.D.R.). We report the results, along with several emergent themes.

## Results

### Findings

Although all the FHCOE hospitals were well-respected institutions, some of their structural characteristics differed. For example, some were large academic medical centers or NCI-designated Comprehensive Cancer Centers, and others were pediatric or smaller facilities. The number of age-eligible patients treated annually ranged widely, from approximately 400 to 4,000. Seven had institutionally affiliated reproductive departments, but two did not. Because of variations in environment and needs, designees implemented different strategies to meet the criteria. We describe successful approaches as well as some hurdles.

### Professional Education

All of the centers held live presentations, such as grand rounds, departmental in-services, and so on, to provide professional education on fertility. The frequency with which sessions were conducted ranged from an average of one talk per year to monthly events. Other than identifying the talks by title, speaker, and date, no information about specific content, the number of health care providers trained, the provision of continuing education credit, and so on, was provided.

### Patient Education

Our review revealed a consistent primary means of providing patient education: printed brochures. Several institutions also created supplemental Web-based patient materials. Patient brochures were available in educational centers/libraries and in select clinic waiting areas and/or were included in new patient packets.

### Notification Procedures

The most significant difference in notification systems among FHCOEs was that some employed paper systems, whereas others had created automated, electronic systems. Designees employing low-technology notification methods frequently revised their chemotherapy and radiation consent forms to include unambiguous language concerning the risk of infertility. For example, Kimmel Cancer Center added a paragraph about reproductive risks that requires a separate signature from age-eligible patients. Some of these centers assigned responsibility

**Table 1.** FHCOE Criteria

Criterion	Definition	Rationale for Inclusion
Professional education	Provide education on cancer-related infertility and fertility preservation	Lack of content knowledge identified as barrier to discussion  Developments in reproductive medicine exceed scope of oncologists' training and knowledge
Patient education	Printed resources available for patients and survivors	Provides substantive detail for patients to review after notification
Notification procedures	Systems to notify eligible patients of fertility risk and options, verbally and in writing, before initiation of therapy	PCP recommendation <sup>15</sup>  Procedures minimize subjectivity and biases noted in studies
Referrals	Refer patients to appropriate reproductive specialists	Information is actionable  Multidisciplinary approach alleviates burden on oncology team
Policy*	Policy stating commitment of institution to fertility needs of its patients	Reflects and documents institutional commitment  Empowers (and requires) clinical staff to address topic

Abbreviations: FHCOE, Fertile Hope Centers of Excellence; PCP, President's Cancer Panel.

\* Criterion added in 2009.

for patient notification to an individual or team. For instance, at the Children's Hospital of Philadelphia, a fertility team reviews the daily admitting records to identify appropriate patients for individualized fertility discussions.

In contrast, several FHCOEs created automated fertility notification systems by using existing electronic intake infrastructure. Lurie Cancer Center was the first FHCOE to create fertility screens for its Epic electronic medical record system. The initial fertility screen asks whether the patient has been informed about the impact that his or her treatment may have on fertility; if yes, a second screen asks if the patient wants fertility preservation information. If a consultation is desired, a full-time fertility navigator is notified. A similar system at Oregon Health & Science University (OHSU) integrated a best practice alert into the Epic intake process for all patients age < 45 years. It also connects to printable fertility content or referral forms. These systems require the provider to actively contemplate fertility before moving on with the intake process.

Our interviews, however, did yield some challenges attendant to the automated electronic approach. Creating these systems was a time-consuming, often bureaucratic process. Additionally, designees voiced concerns about how best to balance the goal of universal disclosure with respect for physician

autonomy. For example, at Lurie, the original fertility screens were modified to include "not applicable" selections and comment fields because of a strong push for this opt-out from oncology physicians for circumstances in which they felt the topic was inapplicable or inappropriate.

### Referrals

On their applications, designees identified the sperm banks and in vitro fertilization clinics to which they referred their patients. Our interviewees demonstrated fluency about the locations, practices, and procedures of the named facilities, indicating working relationships had been established, and referrals were occurring. Referral processes generally remained patient driven, with contact information provided on request. Designees had taken steps, however, to facilitate the process, ranging from simple measures, such as customizing brochures with dedicated telephone numbers, to more complex procedures, such as using a full-time patient navigator to actively guide patients through the process.

The FHCOEs that were not affiliated with reproductive specialists undertook significant efforts before recommending outside entities to their patients. For example, Moffitt Cancer Center partnered with the University of South Florida In Vitro

**Table 2.** FHCOE Designees

Cancer Center	Institution	Location	Year of Designation
Taussig Cancer Institute	The Cleveland Clinic	Cleveland, OH	2005
Stanford Cancer Institute	Stanford University	Stanford, CA	2005
NYU Cancer Institute	NYU Medical Center	New York, NY	2005
Abramson Cancer Center	University of Pennsylvania	Philadelphia, PA	2006
Robert H. Lurie Comprehensive Cancer Center	Northwestern University	Chicago, IL	2006
Kimmel Cancer Center	Thomas Jefferson University	Philadelphia, PA	2008
The Children's Hospital of Philadelphia		Philadelphia, PA	2009
OHSU Knight Cancer Institute	OHSU	Portland, OR	2009
H. Lee Moffitt Cancer Center	University of South Florida	Tampa, FL	2009

Abbreviations: FHCOE, Fertile Hope Centers of Excellence; NYU, New York University; OHSU, Oregon Health & Science University.

**Table 3.** Interview Guide

Topic
<p>FHCOE program/process</p> <ol style="list-style-type: none"> <li>1. To the best of your knowledge, please explain the impetus/history behind your FHCOE designation.</li> <li>2. What were your institution's desired goals in participating in the FHCOE program?</li> <li>3. Has the designation helped you achieve these goals?</li> <li>4. Has the designation and/or the process of achieving the designation changed the treatment of reproductive risk/option disclosure at your institution? Describe.</li> <li>5. Please identify the overall strengths and weaknesses of the FHCOE program.</li> <li>6. Please identify any changes you would recommend to the FHCOE program/process.</li> <li>7. Are you committed to maintaining your FHCOE status?</li> <li>8. Are you committed to maintaining, expanding, and/or further developing the underlying cancer and fertility disclosure and referral systems that were implemented for FHCOE designation?</li> </ol>
<p>FHCOE criteria</p> <p>Discuss each of the required criteria (reference the submitted data). Explain which are working well/not working, etc. Please identify any changes you would recommend to the FHCOE criteria.</p> <ol style="list-style-type: none"> <li>1. Policy</li> <li>2. Notification procedures</li> <li>3. Professional education</li> <li>4. Patient education</li> <li>5. Referrals</li> <li>6. Research</li> </ol>
<p>Additional</p> <p>Please share any particularly salient patient stories, anecdotes, perceptions, etc.</p> <p>Please share any additional thoughts/concerns/questions.</p>

Abbreviation: FHCOE, Fertile Hope Centers of Excellence.

Fertilization and Reproductive Endocrinology Center to establish practices tailored to the unique needs of patients with cancer, including expedited consultations and appointments, egg freezing, and preimplantation genetic diagnosis screening for hereditary cancers. Similarly, the Children's Hospital of Philadelphia vetted several locations to ensure a suitable environment for their pediatric patients, an anomalous cohort for typical sperm banks. It then chose a facility willing to adapt its accommodations and conduct staff training.

### Policy

As a result of program review in 2008, FH added a policy requirement to directly advance a fundamental goal of the program: the institutionalization of this practice. Because this criterion was added in 2009, only two centers were required to draft and implement policies to achieve designation. In 2010, during follow-up interviews, a few centers expressed skepticism about the value of implementing a policy retroactively; however, all were willing to do so to retain their designation. Notably, the centers that enacted policies pursuant to the requirement voiced strong support for this criterion.

Our interviews also revealed supplementary factors, discussed below, that helped support the development of systematic fertility approaches.

### Role of Internal Champion

FHCOE contacts consistently reported that internal champions played a significant role in the decision of the institution to

seek designation and in shepherding the resources needed for program creation. Typically, these individuals had professional interest in cancer-related fertility antecedent to pursuing FHCOE designation.

### Affiliation With Associated Programs

At the time of their designation, several centers had complementary programs in which cancer-related infertility was relevant. For example, OHSU had an innovative adolescent and young adult oncology program; Abramson and Kimmel Cancer Centers had formal survivorship programs; Taussig, New York University, and particularly Lurie, were affiliated with pioneering researchers and/or clinicians in fertility preservation. Where related programs had initiatives that dovetailed with the FHCOE criteria, designees did not have to build their systems *de novo*.

### Resource Sharing

Throughout the duration of the FHCOE program, FH was able to share a growing supply of resources with applicants. Provision of template policies, intake screens, and practice examples, along with free FH brochures and educational resources, expedited the FHCOE attainment of applicants.

A parallel example of this type of resource sharing used within an institution was the creation by OHSU of a fertility kit. A physical box of materials was distributed to all clinics, as both a visual reminder to discuss fertility and a one-stop shop

for tools ranging from brochures and referral forms to semen collection cups and privacy door hangers.

## Discussion

This description of the FHCOE program, its criteria, and the additional features of the individual systems of the designees offers a starting point for the consideration of elements and strategies that may be helpful in the creation of cancer and fertility programs. To ascertain whether these criteria are effective and/or represent the best practices for such programs, evaluation measures need to be established. In our interviews, all of the designee centers identified the lack of evaluation measures as the most significant weakness of the program.

For example, quantitative measures for the number of professional education talks given, providers trained, patient brochures distributed, referrals made, fertility consultations provided, and so on could be easily established. Similarly, qualitative comparisons could be made of professional and patient materials and even of the impact of policy issuance. Analysis of these data would be a critical first step toward measuring the relative effectiveness of individual program components as well as the overall effectiveness of complete systems.

Although our interviews yielded no clear consensus about the specific measures needed, the emergence of the notification process as central to a successful system was evident. Studies and anecdotal evidence have shown for years that significant numbers of patients have not understood that their fertility might be compromised as a result of their cancer treatments or that options might be available to help mitigate this potential loss.<sup>2,5</sup> Indeed, it is this finding that motivated the development of the FHCOE program. Thus, although we endorse all of the FHCOE criteria, we conclude that they are of secondary value to the notification process. These criteria enhance the likelihood that notice will occur and that it will be substantive and useful. For example, a policy confers authority to these efforts; professional education raises the knowledge base and comfort level of providers with regard to this topic; patient education augments basic comprehension; and referrals make the information actionable. However, until and unless a systematic approach ensures a transfer of information to the patient—actual notification—these additional system components are ineffectual and thereby superfluous.

By focusing on the effectiveness of contrasting notification systems, key aspects of that information can be compared. For example, was notification timely? Was the content satisfactory to the patient? Did it allow the patient to make informed decisions about the preservation of fertility? How is this transfer of information captured and recorded? Did the timing, delivery, or content of this notification affect the patient's immediate or long-term quality of life?

In our interviews, a trend toward use of electronic systems for patient intake, order entry, and clinical documentation was noted. Almost universally, the FHCOE contacts concurred that these systems were important tools in achieving more consistent patient notification. In fact, the institutions that did not use

them at the time of their FHCOE designation were interested in future implementation.

Because of the centrality of the notification requirement, we believe that electronic systems offer key advantages over low-technology methods for a number of reasons. Embedding fertility reminders into electronic intake systems seems to increase the likelihood that patients will have discussions with their providers at as early a stage in treatment planning as possible—a result that is consistent with the PCP recommendations<sup>15</sup> and ASCO guidelines.<sup>11</sup> In practice, of course, early notification is critical for patients interested in accessing fertility preservation services.

In addition, electronic notification systems can be linked to objective patient criteria such as patient age, diagnosis, and treatment plan. Use of impartial triggers could ameliorate subjective barriers to notification and discussion noted in the literature, including provider discomfort with the subject matter, perceived financial status of the patient, biases about patients' sexual orientation or marital status, poor prognosis, and so on.<sup>1,16,17</sup>

Systems that capture fertility disclosures, discussions, and requests for referrals electronically also offer practical means for documenting and evaluating notification practices. Patterns and gaps in disclosure could be more easily identified (compared with similar hard-copy file reviews) and consequently remedied.

We acknowledge this review offers a subjective analysis of a single program designed to positively affect the disclosure of fertility information at a limited number of high-level, self-selected cancer centers. The data relied on were self-reported by the designees, because neither site visits nor third-party verification of practices were feasible. In addition, as discussed, evaluation measures to test the effectiveness of the FHCOE program criteria have yet to be established. Despite these limitations, we believe this review of cancer and fertility systems at highly credible, respected clinical institutions offers important insights into the development of such programs.

In conclusion, over the past several years, progress has been made in increasing the dialogue between oncology health care professionals and their patients about the potential implications of cancer treatment on future fertility and parenthood options. Publications have identified predominant barriers to patient notification; reports and guidelines have elucidated key features of sufficient notification. By creating systems that methodically attack these barriers and integrate these features, cancer centers can begin to meet their patients' fertility needs.

Although articulation of detailed best practices addressing the content and context of this information would be ideal, we believe that nonetheless, the time for the development of these systems has arrived. The ongoing failure to raise this topic with at-risk patients carries ethical and psychosocial implications at least as profound as those surrounding disclosure.

FH, LIVESTRONG, and other organizations have created numerous free patient and provider resources including financial assistance programs, educational brochures, and informational Web sites to support these programs. Simultaneous advances in reproductive medicine, including refinement of oocyte freezing, available institutional review board–approved ovarian tissue freezing, and advanced techniques for obtaining

and using sperm, mean that fertility preservation is now a viable, realistic option for an ever-increasing number of patients. Perhaps most significantly, ASCO has published recommendations<sup>11</sup> on fertility that obligate its members—oncology professionals—to proactively meet this challenge.

The programs described herein provide examples of systems that can be assembled in different types of clinical settings, depending on the available resources and infrastructure. Identification of an internal champion, coordination with aligned programs, and resource sharing are factors that may expedite implementation. As institutions design their own programs, measures to evaluate the critical notification process as well as the supportive system components should be integrated so that the identification of best practices within this context can occur.

We believe that widespread adoption of systematic approaches similar to those described in this article represent the next step in meeting patients' reproductive needs. LIVESTRONG is currently developing a program and resources to aid institutions in this endeavor. Cancer centers that incorporate and evaluate the baseline elements identified here—institutional endorsement (formal policy), professional education, patient information, patient referrals, and, most significantly, actual notice of reproductive risk in a timely, objective, documented fashion—will not only comply with the ASCO fertility recommendations but also fundamentally improve patients' quality of life.

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