inhibitors work on a particular mutation is difficult to prove. A deleterious mutation not represented in the registration trial will not make it on the approval list, resulting in a narrow roster of approved mutations eligible for treatment with the PARP inhibitor.

“The companion diagnostic is a major issue,” said Mark E. Robson, M.D., medical oncologist and clinic director of the Clinical Genetics Service at Memorial Sloan–Kettering Cancer Center in New York. “The FDA history is such that they may want the mutations to be specific, to show that for specific mutations this drug works and is safe. But that is hard to do in this setting. There is no other example of this, but there will be in the future.”

The question is whether showing that a specific mutation in a targeted DNA-repair gene renders the tumor deficient in repair is necessary before a patient can enroll in a PARP inhibitor clinical trial.

“You can’t do a separate trial for each genotype—one trial with patients with one gene mutation and then another trial with another gene mutation,” said Allen. “You have to start pooling genotypes and inferring what you find in an aggregated population of patients can be reasonably assumed to be true for any patient within the pool.”

Approaches to define a molecular subset of patients for trials based with a companion diagnostic will continue to evolve as other PARP inhibitors and targeted agents move into registration trials.

“In a way, [the issue] is symptomatic of the challenges we face in precision medicine moving forward,” said Robson.

Looking Good During Cancer Treatments

By Kristine Crane

C elebrity makeup artist Tim Quinn has done the makeup of former Secretary of State Madeline Albright, Second Lady of the U.S. Jill Biden, and the late actress Farah Fawcett. Fawcett was also a personal friend, and Quinn helped her maintain her “chronically beautiful” looks, he said, after she was diagnosed with anal cancer.

Quinn has also done the makeup of hundreds of cancer patients through the Look Good . . . Feel Better program, a nationwide nonprofit that helps cancer patients maintain their appearances while undergoing treatment.

“What I get from working with cancer patients is probably equal to what I get from working with celebrities,” said Quinn, who relates to the patients because he had testicular cancer. When his hair fell out, he wore skull caps. And when his skin became discolored, he did self-tanning in the hospital bathroom where he was undergoing chemo. “That made me feel like me,” he said.

For many cancer patients, changes in appearance can be devastating. Apart from losing their hair, they may lose eyebrows and eyelashes; their skin might get dry; they may gain or lose a noticeable amount of weight. The Look Good . . . Feel Better program steps in to help patients cope with these changes. The American Cancer Society administers the program, and the National Cosmetology Association recruits volunteer professional aestheticians to give workshops across the country. They teach patients, most of whom are women, how to pencil in their brows, create the illusion of eyelashes, and wear scarves and wigs.

“It gives a woman the chance to recreate a sense of normalcy,” said program director Louanne Roark. “The appearance concern is one thing they can put aside and focus on other things.”

Finding Support

The workshops also help patients connect with each other. “Women come into the workshop, a little reticent, and they sit down at a table ready to engage with 6–10 other women. Within 15 minutes, they start to engage. By the end of that workshop 2 hours later, they’ve developed a new support community,” said Roark.

For many patients, this will be their only support group, said Mary Jane Massie, M.D., a psychiatrist at Memorial Sloan–Kettering Cancer Center in New York. Massie has referred all her cancer patients to the program since it began 25 years ago, with participants reportedly experiencing improved self-confidence.
A Harris Interactive survey of 1,226 women found that 70% of program participants felt more in control of their appearances after doing the program, compared with just 60% of those who didn’t do the program. Seventy-six percent of participants were more confident in how they looked, compared with 59% among nonparticipant patients.

Those are good results, Massie continued, given that people’s confidence tends to drop with a cancer diagnosis: The same survey showed the 77% of women felt confident in their appearances before treatment, compared with only 55% afterward.

“This is a disease that takes so many things away,” said Massie. “It’s nice to be able to give something back.”

Re-creating Normalcy
The program gave Nancy Lumb of Chevy Chase, Md., a sense of normalcy. “It’s pretty easy to put on a wig, but if you don’t have eyebrows, you’re not fooling anyone,” she said. “Learning how to re-create a natural eyebrow especially when you are going out . . . is being able to just be normal for a night.”

Lumb saw ads for the program in the room where she received her first chemotherapy treatment, shortly after her diagnosis. “I was 40, and the idea of looking different was terrifying,” she said. “I didn’t cry when they told me I had cancer, or when I told my husband and mother. But I cried when I lost my hair.”

Lumb said that keeping up her appearances has helped her heal faster. “There’s a lot of stuff happening around you, and being able to hold onto yourself allows for faster and better healing,” she said.

Lumb also wanted to keep her illness private, and the program helped her do that. “I work in a building with 1,500 people. I didn’t want to explain to 1,500 people what I was going through,” she explained. “Nobody knew when I transitioned to my wig, and no one knew I had fake eyebrows.”

Global Reach
The Look Good . . . Feel Better program started in 1989, with workshops at Georgetown University’s Lombardi Cancer Center and Howard University Cancer Center—both in Washington, D.C.—and at Memorial Sloan-Kettering. Since then, 16,000 workshops have taken place, with formal programs now in 2,800 medical centers across the U.S. It also conducts online workshops for women in remote areas, and the program has affiliates in 24 countries and has helped an estimated 1.2 million women, said Rouark.

Although most participants are women, workshops are also available specifically for men and teenagers. The program also targets patients at any stage of their disease.

“One of my patients was dying. She had an upcoming event for one of her kids, and she talked about how she wanted to look great,” said Massie.

For Quinn, making people look great and feel better about themselves—is so fulfilling, he said. “I really believe that something a little bit magical takes place in the workshops.”

For more information on the Look Good . . . Feel Better program, and to find out about workshops in your area, visit http://lookgoodfeelbetter.org/.

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DCIS Test Helps Filter At-Risk Patients

By Judy Peres

It’s one of the dilemmas of modern medicine: Early diagnosis through screening has the potential to save lives; but screening also detects disease that might never have become clinically significant, leading to potentially harmful treatment to patients who won’t benefit. DCIS, or ductal carcinoma in situ, has been the poster child of this dilemma for three decades.

DCIS is not life-threatening, and not all cases will progress to invasive cancer. But since there is no reliable way to determine which ones will, virtually all DCIS lesions are excised by either lumpectomy or mastectomy. Most DCIS patients are also offered radiation and tamoxifen.

But now, a new test identifies patients at low risk for recurrence, allowing some patients to skip radiation. And a few researchers are taking the next step, attempting to identify a group of DCIS patients who can avoid surgery as well.

“We’ve been waiting for something objective to change how we treat DCIS patients,” said Michael Alvarado, M.D., associate professor of surgery at the University of California-San Francisco. “I think [the test] will be incorporated pretty quickly.”

Investigators from the Eastern Cooperative Oncology Group, North Central Cancer Treatment Group and Genomic Health Inc. have prospectively validated a multi-gene assay that can distinguish DCIS cases at higher risk of recurrence from those at lower risk. The validation study of the “DCIS Score” has not yet been published but was presented at last December’s San Antonio Breast Cancer Symposium.