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Editorial

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Gynecologic Cancer Research at a Crossroads

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Gynecologic cancer research is currently at a crossroads. Recent changes in the NCI's approach to clinical cancer research have resulted in a complex makeover of the federal clinical research community. This was prompted by perceived inefficiencies in the existing model, as well as the realities of stagnant (or declining) funding for the foreseeable future.

Perhaps more than any other discipline, gynecologic cancer research has been dramatically affected by these changes. The Gynecologic Oncology Group (GOG) was founded in 1971, an outgrowth of President Nixon's "War on Cancer" and the growing recognition in that era of gynecologic oncology as a separate and distinct subspecialty. In the 43 years since, the GOG has been responsible for virtually every step forward in the treatment of gynecologic cancers. The following represent just a handful of the GOG's findings: the efficacy of combination chemotherapy with paclitaxel and cis- or carboplatin for ovarian cancer, along chemotherapy with paclitaxel and cis- or carboplatin for ovarian cancer, with intraperitoneal administration of those drugs; the modern concept of surgical staging for endometrial cancer, which was adopted by the International Federation of Gynecology and Obstetrics (FIGO) in 1988, and revised in 2010; the use of chemotherapy in combination with radiation to improve the survival of women with locally advanced cervical cancers; the feasibility of minimally invasive surgery for gynecologic cancers; and most recently, identifying agents such as bevacizumab, which can be targeted at the molecular level of gyn cancers.

However, as of March, 2014, the GOG will no longer exist. The NCI has consolidated the nine existing cooperative group organizations in its' clinical research portfolio into five new groups. The GOG has been combined with the Radiation Therapy Oncology Group (RTOG) and the National Surgical Adjuvant Breast/Bowel Program (NSABP) to form the NRG, which will have responsibility for all the studies formerly handled by those three so-called "Legacy" groups. NRG leadership will be a rotating co-Chairmanship made up of the chairs of the three legacy groups. The former GOG office in Philadelphia and statistical office in Buffalo will take over management of the NRG as a whole.

This reorganization was based on the Institute of Medicine's (IOM) 2010 analysis of NCI clinical research. This report was highly critical of the inefficiency of the process by which the cooperative groups carry out their trials. Historically, relatively few U.S. oncologists have even participated in clinical research, mostly from academic institutions. Community oncologists, who see the great majority of American cancer patients, have generally been reluctant to participate in federal clinical research due to the bureaucratic burden and low reimbursement. As a result, more than half of the trials initiated by the NCI's cooperative groups do not meet their accrual goals and are closed, generating no data. Further, the attendant bureaucracy ensures that each new Phase III trial startup costs well over a million dollars, which becomes a total loss when a trial closes early. The IOM made a number of recommendations for improving and streamlining that process, including the consolidation of the groups.

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The GOG was, however, an exception to this poor showing. The GOG has a much higher rate of participation by gyn oncologists, such that nearly 90% of American women with a gyn cancer are seen by physician/investigators involved with the GOG. As a result, the GOG completes a much higher percentage of its' trials, compared to the other groups. GOG leadership argued for the right to "stand alone" in the reorganization based on its' very specific target population and its' success, much like the Children's Oncology Group (COG) was allowed to do. Unfortunately, that argument was not accepted.

So, we enter a new era of gynecologic cancer research, in which limited resources must be shared with other disciplines. The reasons for the GOGs' historic success (widespread participation, adequate number of trials for the population) will receive less support. Committee membership in the NRG will be scrutinized and limited. Seats must be reserved on each committee for members from the other legacy groups. The Cancer Prevention and Control Committee for example, must accommodate former NSABP and RTOG members, replacing gynecologists and gynecologic oncologists for a limited number of seats. It has also become clear that the threshold for approving a new trial will be much higher than in the past, resulting in fewer total trials. Fewer questions will be asked or answered. These changes will require that investigators become more efficient in the design of new trials. They must generate precise questions that are simultaneously intended to have broad impact. And, all new questions must truly be answerable in the clinical trial format-there must be high likelihood that accrual will be completed.

Those are tall orders. As a result there is much uncertainty among investigators about the future. No one can predict whether gynecologic cancer research will proceed with the level of success it has become known for. Grumbling and discouragement are the order of the day among many former GOG (now NRG) researchers.

In view of these events, it's more important than ever for gynecologic cancer patients, their families and friends to get involved. The federal government works for you, but it must hear your collective voices, and historically gynecologic cancer patients have been among the quietest of cancer interest groups. Now is the time to change that. Approach local and national advocacy groups, including the Foundation for Women's Cancer (http://www.foundationforwomenscancer.org), the Gynecologic Cancer Awareness Project (http://www.thegcap.org), No Evidence of Disease (http://www.nedtheband.com) and/or many others and volunteer. Never hesitate to personally contact your representative (http://www.house.gov/representatives/find/) -nothing is more effective than direct communication from a constituent. Don't allow your government to decrease its' commitment to prevent and treat gynecologic cancer at this critical time. Make sure your representatives know that you demand no less than the continuation of our past success. Our wives, mothers and daughters deserve no less.