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Editorial

New world order(s): Healthcare metrics, international borders, and gravitational waves

Erickson et al. should be commended for thinking outside of the box, and rather than assuming that their National Comprehensive Cancer Network (NCCN) cancer center provides NCCN-adherent care for women with ovarian cancer, the authors turned the camera eye inwards in a study of self-appraisal [1]. Not one to provide spoilers in the Editorial, I leave it to you to read their well-written, concise paper and consider their findings carefully. Although most of their data is derived through a registry, because it involves one institution, the authors were not constrained by the typical shortcomings of database studies and were also able to obtain information regarding upper abdominal procedures, extent of cytoreduction, involvement of a Gynecologic Oncologist, and participation of patients in clinical trials. The manuscript is timely not only for the high profile of the subject matter given its simultaneous presentation with its companion piece by Bristow et al. [2] at the Society of Gynecologic Oncology's (SGO) 2013 Annual Meeting on Women's Cancer in Los Angeles, CA (the latter making the front page of the *New York Times* on March 11, 2013) [3] but also because of the national debate surrounding the Affordable Care Act (ACA) [4,5] and the provision that reimbursement reflect provider performance on quality metrics based on adherence to certain care processes, scores on patient satisfaction surveys, and/or patient outcomes. A new world order.

With 18% of the Gross Domestic Product (GDP) being spent on healthcare, current projections indicate that without true reform, the nation's healthcare spending will continue to outpace economic growth, and by 2021, 20% of the GDP will be comprised of healthcare expenditures [6]. We can no longer afford to exist within our own little microcosm of Gynecologic Oncology and must take an active role in the discussion on the table. To paraphrase what *Time Magazine* lists as one of the 100 greatest novels since the beginning of Time in 1923 [7], we should ask, "Who watches the Watchmen?" [8]. If we don't step up and do this for ourselves, some other agency will. Gynecologic Oncology is unique among all surgical and oncologic subspecialties by virtue of the fact that Gynecologic Oncologists are equally at home performing advanced cytoreductive surgery and prescribing third line chemotherapy. Additionally, many of us conduct translational research and speak the language of the basic scientist. No government organization or physician group has the training or expertise to define our benchmarks, and provided that we do not abuse the privilege, it is best that we police ourselves and develop reliable quality metrics which accurately mirror what is feasible in the real world. This will require self-reflection and a critical assessment of our own performance.

The NCCN is an alliance comprised of 25 of the world's leading cancer centers. For 15 years, the NCCN has developed Clinical Practice

Guidelines in Oncology that document evidence-based, consensus-driven management to ensure that all patients receive preventive and diagnostic treatment, and supportive services that are most likely to lead to optimal outcomes. The above-mentioned study by Bristow et al. analyzed data from the California Cancer Registry and showed that adherence to NCCN guidelines for treatment of ovarian cancer correlated with improved survival and that high volume centers (>20 cases per year) were more likely to be NCCN-adherent [2]. By acknowledging that optimal adherence to NCCN treatment guidelines can only occur in a perfect system, Erickson et al. have stepped back and rather than asking what is ideal (and essentially unrealistic in our current broken system), they ask what is reasonable [1]. Using just two NCCN criteria for the primary management of advanced ovarian cancer, the authors calculate metrics for the percentage of patients who underwent stage-appropriate surgery and recommended chemotherapy during the period under investigation at their NCCN cancer center. In terms of defining metrics for our subspecialty, this is a good start, albeit a small one.

The type of metrics we develop for determining quality of oncologic care are dependent on the questions we are asking. Erickson et al. have asked about cytoreduction and intravenous platinum-based combination chemotherapy [1] but this oversimplifies the problem. The NCCN rates their recommendations according to categories of evidence and consensus, with most recommendations falling into category 2A:

- Category 1: high-level evidence, uniform NCCN consensus
- Category 2A: lower-level evidence, uniform NCCN consensus
- Category 2B: lower-level evidence, some NCCN consensus exists
- Category 3: any level of evidence, major NCCN disagreement.

In developing our quality metrics are we to rely entirely on NCCN guidelines? If so, how do we reconcile in our practice that neoadjuvant chemotherapy is given category 1 status while primary cytoreduction (although recognized by the NCCN writing group as the standard of practice in the United States) cannot be granted category 1 designation because all of the data that supports this approach is retrospective. Even more problematic is the issue of combined intravenous–intraperitoneal chemotherapy. There have now been three phase III randomized trials using this therapeutic modality in advanced ovarian cancer and all three showed a survival advantage, and yet none of them have changed the standard of practice. And yet, the NCCN lists intravenous–intraperitoneal chemotherapy as category 1 and allows intravenous carboplatin plus paclitaxel to enjoy category 1 status for those patients for whom intraperitoneal chemotherapy cannot be used (e.g., poor performance status). Meanwhile, despite showing an overall survival advantage in the

Japanese randomized phase III trial, weekly dose-dense paclitaxel is listed as category 2A while the anti-angiogenesis agent, bevacizumab, has been relegated to category 3 notwithstanding four positive phase III randomized trials in advanced and recurrent disease [9].

Taken further, what will be our position on secondary cytoreduction? And given the plethora of randomized trials in recurrent disease, what will be recognized as the quality metrics for second line therapy for patients with partially platinum sensitive disease who relapse between six and 12 months? If we move to another organ site such as endometrial cancer, how will we devise metrics that define what constitutes a pelvic and/or para-aortic lymphadenectomy or even whether lymphadenectomy is necessary? How do we rate vaginal cuff brachytherapy vs pelvic radiotherapy, recognizing that neither adjuvant modality has been shown to improve survival in this disease. In the cervical cancer world, how do we separate physician bias concerning radical hysterectomy with lymphadenectomy and tailored adjuvant therapy vs primary chemoradiation plus brachytherapy for FIGO IB2 tumors? And finally, following the ASCO 2013 presentation of GOG 240, the cisplatin–paclitaxel–bevacizumab triplet was listed as category 2A nearly eight months in advance of the paper. With the primary manuscript now published [10] it may flip to category 1 but without US Food & Drug Administration approval, only some patients with HMOs or PPOs will be able to receive the drug, while those on Medicare and Medicaid will not. Although London's *Guardian* reported that following publication of the primary GOG 240 manuscript, England's Cancer Drug Fund made bevacizumab available for advanced cervical cancer [11], we do not have such a mechanism in the United States that specifically is charged with making available drugs that are efficacious but not cost-effective. How are we to rate NCCN adherence in this type of situation when a large majority of patients will not be able to receive an intervention even if it were listed as category 1?

Clearly we cannot rely entirely on NCCN guidelines when developing quality metrics in our subspecialty. What Erickson et al. have provided, however, is a training set that can be amended and then externally validated at other NCCN cancer centers in the United States. Taking initiative from the SGO's recent white paper on clinical trial endpoints [12], our Society is well-positioned to weigh in and frame the questions in light of the arguments detailed above. The need for critical introspection in our subspecialty has never been greater.

Our work in women's cancer consumes us. If we were to pause for a moment and gaze beyond the microcosm of Gynecologic Oncology we would realize that not only is the healthcare system in the States in desperate need of repair, but the geopolitical world topography has been dismantled and will require reaffirmation of United Nations' metrics concerning international boundaries and territorial disputes. Vladimir Putin's lightning annexation of Crimea suggests he subscribes to the doctrine through which a frontier can be redrawn based on subjective principles. If such ideology were adopted throughout the world, this would result in global instability, strife, and territorial disputes between India and China, India and Pakistan, and even, conceivably, the Americas. We must recognize that those who believe that the Soviet collapse allowed for unchallenged supremacy for the United States and Western meddling and moralizing, it is still the American system which maintains open sea lanes and skyways, trade agreements, respect for national borders, and observance of international law [13]. As a consequence of Crimea, Russia has been ousted from the Group of 8 industrialized economies by the United States and its closest allies, and should sanctions on Russian oil be imposed, the Russian economy will suffer as its population keeps aging while the birth-rate continues to decline. Russia is unlikely to receive help from China (even if European-bound oil must be diverted there) as it can neither condemn nor praise the annexation of Crimea because of Taiwan on the one hand and Tibet on the other. While the Russian government claims the thousands of troops massing on the northeast border of Ukraine are just exercising, the likelihood of invasion seems imminent. What happens next will either reaffirm international law as dictated by the UN or will radically

change it. We find ourselves living in a world where anything may be used as a pretext for aggression and the need for international metrics has never been more implicit. Another new world order.

For several well-documented reasons, the ACA has become anathema to many who find themselves living in its looming shadow. However, as maligned as it may be, without some imposed system of quality metrics that can be reliably reported and confirmed upon request, we will have substandard institutions and rogue physicians doing whatever they please, disregarding NCCN guidelines and evidence-based medicine. Not only are patients likely to suffer, but cost-containment will not be possible. Furthermore, similar to the analogy concerning UN sanctions, those who are unable to meet quality metrics will not be able to participate in various financial incentives and may even be subjected to penalties. The ability to self-appraise and institute appropriate practice changes that serve to better approximate NCCN definitions of adherent care will be a boon for physicians living in the new world order where quality metrics will likely inform the standards of care and physician reimbursement.

If left unchecked, human nature will permeate all systems and the natural order of all systems is to always strive towards entropy. Superceding the UN example, our framework can be applied to an even grander scale, where the inflationary model of the universe can only be predicted if general relativity as described by Einstein can be reconciled with quantum theory. While general relativity is concerned with things of celestial magnitude [14], quantum mechanics is the study of forces that operate on the scale of atomic nuclei [15]. On March 17, 2014, astronomers from BICEP2 (Background Imaging of Cosmic Extragalactic Polarization) announced the Nobel Prize-worthy discovery of primordial gravitational waves, the existence of which provides the first direct evidence that in the 10^{-34} s following the big bang, the universe expanded exponentially by a factor of 10^{25} [16]. Because these early gravitational waves have been overwritten by many other signals over time, in order to observe this signal from the literal dawn of time, astronomers had to scrape away the outer layers, just as archeologists excavate the highest levels of ancient cities. The gravitational waves are the missing link which allow for the co-existence of general relativity and quantum theory. In this analogy of yet another new world order, the delivery of quality care can only be sustained through adherence to informed metrics (gravitational waves) that serve to reconcile healthcare expenditure (general relativity, big picture) with patient outcome (quantum theory, small picture).

It has been said that every great civilization peaks and then collapses into slow decline. For the United States to be the exception, the out of control spending in healthcare must be reigned in. At this point, no one is in control and the world is rudderless. We may ask if history itself has its own architecture, in which certain motifs are repeated? Do the gravitational waves that inform the pre-inflationary universe and physical world constitute one such motif which is repeated on the geopolitical stage, catching us in its riptide as we struggle to find our place in the new world order of healthcare reform? We should take the lead from Erickson et al. and critically assess our own performance in an effort to position ourselves as Gynecologic Oncologists favorably at the table when the time comes to initially describe or amend what constitutes a realistic set of metrics. As written, NCCN guidelines can only be applied reliably to an idealized world, but what is required are quality of care metrics that conform to the real, everyday practice of medicine.

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