

# Opioid Use in Gynecologic Oncology; Balancing Efficacy, Accessibility and Safety: An SGO Clinical Practice Statement

### October 2016

The problem of opioid misuse has been called an "epidemic" and a "public health crisis"<sup>1</sup>. Though efforts to regulate prescribing practices have focused on non-cancer pain, existing and proposed legislation could significantly impact oncology patients and providers as well. Opioids are first line therapy for all but mild cancer pain<sup>2</sup>. Historically the problem with cancer pain has been under treatment rather than overtreatment<sup>3,4</sup>, and though existence of risk factors for opioid misuse have been documented in patients with cancer, there is currently no direct evidence that prescription of opioids to patients with cancer has contributed to the national issue of opioid misuse<sup>5</sup>. In order promote safety without compromising efficacy of pain control, it is paramount that gynecologic oncologists are aware of current guidelines and proposed legislation and work to address barriers to safe and effective opioid prescribing.

# Legislative Efforts to Address Opioid Misuse

In 2016, the US Food and Drug Administration (FDA) announced an "Opioids Action Plan" to reduce the impact of opioid abuse, the CDC released guidelines on use of opioids for chronic pain ("unrelated to active cancer treatment") and FDA Advisory panels voted to make provider education, which had previously been voluntary, mandatory<sup>5-7</sup>. Bills in Congress related to opioid misuse take a range of approaches from expanding availability of naloxone to expanding disposal sites for unused medications to strengthening Prescription Drug Monitoring Programs (PDMP)<sup>5,8</sup>.

Massachusetts recently passed legislation that could serve as a model for other states<sup>9</sup>. The stipulation limiting new opioid prescription to a seven-day supply does not apply to "pain associated with a cancer diagnosis." However, other elements of the bill would apply to oncology including mandatory continuing education for providers and a requirement that both the physician and the pharmacist check the PDMP for every opioid prescription.

# Safe & Effective Management of Cancer Pain

Patients with cancer may experience pain related to their disease, its treatment or the aftermath of either. Prevalence of pain has been estimated at up to 86% in patients with advanced disease and 35% in cancer survivors<sup>3,10</sup>. Given that pain may wax and wane over the course of illness and persist into survivorship, distinctions sometimes used in opioid-related regulations, such as "active cancer" are potentially unclear.

Multiple guidelines exist for treating cancer pain. ASCO and NCCN guidelines both contain elements of strategies for evaluating and mitigating risk of opioid misuse, including screening for risk factors, monitoring for aberrant behaviors and educating patients about opioid storage and disposal<sup>11,12</sup>. Tools to screen for risk of opioid misuse include the Opioid Risk Tool<sup>13</sup> and the Screener and Opioid Assessment for Patients with Pain Revised (SOAPP-R) tool<sup>14</sup>. Tools to monitor for aberrant behaviors include pill counts, patient-provider agreements (pain contracts),

urine toxicology screens, PDMP review and pain medication diaries. There is not good data for efficacy of these tools, and we agree with ASCO that their use should be individualized, not mandated<sup>5</sup>.

### Opioid Issues Specific to Gynecologic Oncology

Several retrospective studies have concluded that patients with gynecologic malignancies have higher rates of moderate to severe pain and higher rates of opioid use than patients with other solid tumors<sup>15,16</sup>. One study looking at opioid needs of terminally ill patients with gynecologic malignancies found that opioid requirements were highest in patients with pelvic metastases (compared with other sites of disease) and that average opioid use was highest among patient with cervical cancer<sup>17</sup>. Pain control in ovarian cancer also represents a unique challenge in that the disease may take a relapsing and remitting course spread out over the course of years, making distinctions sometimes used in opioid regulations, such as "active cancer" even more imprecise. Furthermore, the ability to take oral opiates may be limited by bowel symptoms, and bowel symptoms may confound the utility of oral opiates in treating ovarian cancer pain.

As the only oncologists that provide both medical and surgical oncology, gynecologic oncologists manage both acute post-operative pain and chronic cancer-related pain. Relatively little data exist about opioid prescribing in the post-op setting and what data there is suggests high rates of patients having unused opioids after surgery<sup>18,19</sup>. We must clinically differentiate acute pain related to surgery from chronic pain related to cancer, and make decisions about opioid appropriateness and duration accordingly.

Insufficient training in opioid prescribing may represent a barrier to optimal use of opioids by gynecologic oncologists. Surveys of Gynecologic Oncology trainees confirm that less than 20% reported being taught how to rotate opioids and only about a third were taught how to assess and treat neuropathic pain<sup>20,21</sup>. Education about pain management and appropriate use of opioids, whether directed by the ACGME for fellowship or by federal or state regulations for practicing Gynecologic Oncologists, must be tailored specifically to our specialty and our patient population.

#### Recommendations to Promote Safe & Effective Opioid Use

Opioid education efforts must target both patients and providers. Any mandated education should be specialty-specific and supported by evidence of efficacy<sup>5</sup>. Providers should educate themselves about state-specific opioid regulations, state PDMP, local opioid take-back resources and locally available resources for specialty pain management, addiction medicine and palliative care. Providers must educate patients about opioid risks and benefits and should consider utilizing existing tools to screen for risk factors for opioid misuse and to follow patients on chronic opioid therapy for any signs of misuse. As it was so aptly put in the ASCO Opioid Policy Statement, "patients are best served with the comprehension that opioid drugs, when appropriately prescribed and used, may provide relief from severe pain, but that like most drugs, there can be serious side effects if the drugs are not used as prescribed"<sup>5</sup>.

In addition to education efforts, promotion of safe and effective opioid use will require additional research and advocacy. Further research could help elucidate the relationship between opioid use in the setting of cancer and patterns of opioid misuse and evaluate efficacy of both legislative and educational efforts to reduce rates of opioid misuse. The Gynecologic Oncology community of patients, caregivers, researchers, advocates and providers must continue to advocate at the state and national level that all regulations be evidence-based and take into account not only the goal of reducing opioid misuse, but also the imperative to maintain accessibility of opioid therapy for those who will benefit from it and to optimize availability and

use of non-opioid methods of pain control. We support the policy recommendations put forth by ASCO including exemption for patients with cancer from prescription limits, avoidance of limiting cancer-related exemptions to those with measurable disease, strengthening patient education regarding safe opioid storage and disposal, creation of a single PDMP, avoidance of use of PDMP data to compare prescription rates among providers and promotion of access to both opioid take-back opportunities and, where needed, addiction treatment<sup>5</sup>.

Effective control of pain is a central tenet of compassionate care of the patient with cancer. Efforts to curtail rising opioid misuse must not compromise the treatment of cancer-related pain. Through education, responsible opioid prescribing and advocacy, we can promote safe, accessible and effective use of opioids for women with Gynecologic Cancer.

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