

# High-Dose Interleukin-2

## Evaluation of a standardized order set for biotherapy in an intensive care unit

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**BACKGROUND:** Life-threatening toxicity may result from administration of high-dose (HD) interleukin-2 (IL-2). Patients receiving HD IL-2 treatment often experience severe adverse side effects, which result in the interruption of treatment.

**OBJECTIVES:** A standardized order set (SOS) was developed for patients with melanoma or renal cell carcinoma receiving HD IL-2. The aims of the study were to determine compliance of clinicians to the SOS, report the completed doses and major side effects of HD IL-2, and document the satisfaction level of clinicians.

**METHODS:** A retrospective chart review of 40 health records of patients with melanoma or renal cell carcinoma who were treated with HD IL-2 was conducted to determine compliance to the SOS. Staff satisfaction with the SOS was surveyed.

**FINDINGS:** The SOS was successfully implemented with a provider compliance rate of 90%. Cardiovascular side effects were the most common. Clinicians found the SOS very satisfactory or superior in guiding care and treatment of side effects.

### KEYWORDS

high-dose interleukin-2; metastatic melanoma; renal cell carcinoma; toxicity

### DIGITAL OBJECT IDENTIFIER

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**HIGH-DOSE (HD) INTERLEUKIN-2 (IL-2) RESULTS IN** objective clinical regression of metastatic cancer in 15%–17% of patients with melanoma and renal cell carcinoma (Fisher, Rosenberg, & Fyfe, 2000). Durable complete regression of all metastases is seen in 6%–8% of patients (Atkins, Kunkel, Sznol, & Rosenberg, 2000; Fisher et al., 2000; Rosenberg, Yang, White, & Steinberg, 1998). Based on these findings, the U.S. Food and Drug Administration approved the use of HD IL-2 for the treatment of patients with metastatic melanoma and renal cell carcinoma. However, HD IL-2 induces severe and sometimes life-threatening side effects, including vascular leak syndrome (Gallagher et al., 2007), cardiac arrhythmias (Margolin et al., 1989; Singla & Denmeade, 2008), fever, and end organ damage (Schwartzentruber, 2000).

Despite the use of HD IL-2 biotherapy for more than 20 years, its administration and management of potential side effects remain unstandardized in many hospital settings. Acquavella et al. (2008) conducted a retrospective chart review of 41 consecutive patients with metastatic melanoma (n = 33) or renal cell carcinoma (n = 8) who were treated with a modified HD IL-2 regimen and admitted to monitored hospital beds. They found that about 10% of patients required vasopressors for severe hypotension, and 24% were transferred electively or emergently to the intensive care unit (ICU) because of decline in status. Quan et al. (2005) studied 15 patients aged 70 years or older who were treated with HD IL-2 in an oncology inpatient unit or intermediate unit. Twenty percent required the use of dopamine infusion for blood pressure support. A study by Allard et al. (2015) suggested that patients receiving HD IL-2 were increasingly being treated in teaching hospitals and concluded that centralization of care is needed.

The HD IL-2 program was initiated at University of California, San Francisco (UCSF) Medical Center for patients with metastatic renal cancer and melanoma because of the complexity of care and severity of adverse events. The collaborative team developed a standardized order set (SOS) based on the best evidence so that patients receiving HD IL-2 could be closely monitored for any life-threatening complications to be detected and treated expeditiously.

Following the implementation of the SOS, a quality-improvement project was implemented with four aims: (a) determine compliance to the SOS,