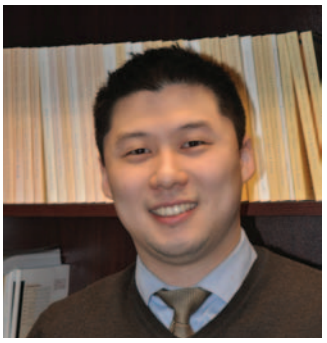
Editorial

Journal of the National Comprehensive Cancer Network



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The ideas and viewpoints expressed in this commentary are those of the author and do not necessarily represent any policy, position, or program of the NCCN.

A Quick REMS Update and a Clinical Focus

We are pleased to present the second *JNCCN–The Journal of the National Comprehensive Cancer Network,* Special Edition: NCCN Oncology Pharmacy & Policy, dedicated to issues related to pharmacy and drug policy in the United States. In the first special edition, we presented the NCCN Oncology Risk Evaluation and Mitigation Strategies (REMS) White Paper, which contained recommendations by the NCCN REMS Work Group and the ruminations from the NCCN REMS Oncology Policy Summit held on May 7, 2010. In the time since the White Paper was published, some significant updates have occurred with REMS.

First, the NCCN REMS White Paper discussed the limitations of medication guides as a risk mitigation tool (e.g., patient health literacy issues). The FDA has recognized these limitations, and has decided to address patient medication information on a larger scale. They convened a 2-day meeting on September 27–28, 2010, to obtain input regarding a new framework for developing and distributing a single patient medication information document. Through this material, the FDA seeks to consolidate the different types of information given to patients, including medication guides.

On October 6–7, 2010, the American Pharmacist's Association convened a stakeholder meeting with the overall goal of taking concrete steps toward designing a REMS system that is effective in mitigating medication risks, is efficient to providers, and maintains patient access to medications. Issues related to effective REMS tools, standardization of REMS, and business models for adequate financial compensation were discussed. The stakeholders at this meeting represented primarily pharmacists, but included stakeholders from other provider groups (including NCCN), patients, and the health technology industry. Representatives from the FDA were present as observers. The outcome of the meeting will be a white paper containing consensus statements regarding the issues.

Interestingly, one opportunity to address some of the issues with REMS could be through the reauthorization of the Prescription Drug User Fee Act (PDUFA). The Food and Drug Administration Amendments Act (FDAAA) of 2007 contained a reauthorization of the PDUFA until 2012, and as the date draws closer to reauthorize the next program for 2013 through 2017, the FDAAA requires the FDA to hold public meetings with stakeholders and industry to gather recommendations. Since July 2010, the FDA has held these meetings at least once per month, and REMS has been among the topics discussed.

Notably, the FDA proposed better ways to standardize and integrate complex REMS into the health care system.[1] During the September 29th meeting with stakeholder groups, the FDA stated that REMS involving restricted distribution systems (of which there are currently more than 30) could be standardized so that providers are better able to incorporate requirements, such as mandatory provider education, patient monitoring, or enrolling patients into a registry, into the current health care system. A major challenge identified by the NCCN REMS Work Group was a lack of such standardization, and the FDA recommended that stakeholders be gathered to work on this issue. Based on this acknowledgement, it appears the FDA has heard the concerns voiced by the provider community.

Although the last special edition focused primarily on policy issues such as REMS, this edition is more clinically focused, presenting 2 case studies (one which offers continuing education credit) that incorporate timely therapeutic advances in prostate cancer and chronic myelogenous leukemia (CML).

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We chose to focus on prostate cancer because 2 new therapeutic options were introduced in 2010 for metastatic disease (sipuleucel-T and cabazitaxel). Dr. Goetz provides a brief review of the evidence and presents the clinical scenarios in which treatment with these newly approved agents may be appropriate. Additionally, because sipuleucel-T is a novel type of therapy (autologous cellular immunotherapy), a stepwise process is presented that pharmacists must follow to procure and dispense the therapy. Important monitoring and toxicity concerns are also discussed.

Some groundbreaking advances also occurred in CML. Recently, 2 studies published in *The New England Journal of Medicine* challenge the notion of imatinib for first-line therapy for CML.[2,3] These 2 studies found a superior effect in terms of complete cytogenetic remission, time to remission, and rate of progression to accelerated phase or blast crisis when treating patients with nilotinib or dasatinib as first-line therapy versus imatinib. Dr. Harnicar presents a case for which this new evidence must be considered, along with other clinical considerations pertinent to pharmacists, such as drug–drug interactions and safety concerns.

Additionally, this issue contains an institutional case study outlining how an NCCN Member Institution incorporated chemotherapy pathways into its computerized prescriber ordering process. Anecdotally, the use of computerized prescriber order entry (CPOE) for chemotherapy seems to be lower than for other types of medications. For institutions in the process of implementing CPOE, chemotherapy orders may be the last area to "go live" because of the potential for disastrous consequences if an error occurs. In this report, Hoffman et al. at St. Jude Children's Research Hospital provides guidance and insight into their process of developing CPOE for chemotherapy, with an emphasis on safety throughout. This report is descriptive in nature, and is intended to share the authors' experiences in integrating all chemotherapy orders into the CPOE system. For example, several key lessons for successful implementation are provided. Notably, it took approximately 15 years to fully integrate chemotherapy orders into CPOE. It should be noted that a discussion of the data leading the authors to conclude that the process is safe is beyond the scope of their article.

We hope you find the information in this second special edition useful in your practice. Future issues of *JNCCN Special Edition: NCCN Oncology Pharmacy & Policy* will continue to focus on clinical, practice management, and policy issues relevant to pharmacists and other providers.

References

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