Time to Get Serious About Improving the Safety of Oral Chemotherapy

By Monika K. Krzyzanowska, MD, MPH, FRCPC

With their narrow therapeutic index and potential to cause serious toxicity in patients as well as providers who prepare and administer them, intravenous cancer drugs have been the initial focus of guidance documents on safe administration of chemotherapy. Over the last decade, a number of organizations, including the American Society of Clinical Oncology (ASCO) in collaboration with the Oncology Nursing Society (ONS), have published standards and recommendations for the safe administration of chemotherapy. The joint ASCO/ONS effort first published its recommendations in 2009 after an extensive multistakeholder consensus process that took into account decades of research and experience with predominantly intravenous chemotherapeutics and a period of public comment. The focus of the initial document was on chemotherapy administered in the outpatient setting. In 2012, the standards were updated to take into account issues related to delivering chemotherapy in the inpatient setting. The standards have been used by institutions to understand and improve their processes of care for chemotherapy delivery.

Until recently, oral chemotherapy made up a relatively small proportion of drugs administered to treat cancer, but over the last decade, the number of oral anticancer drugs and their use have significantly increased and are predicted to continue to rise. With the increasing use of oral chemotherapy, there has been heightened appreciation of the unique challenges associated with its use, especially in relation to prescribing, dispensing, reimbursement, adherence, and patient and family education, with a clear need for guidance about what is considered safe delivery of oral chemotherapy. In response to this need, in *Journal of Oncology Practice* (JOP), the ASCO/ONS chemotherapy administration safety standards are receiving a timely and much-awaited update that focuses on oral chemotherapy. The update includes revisions to several existing standards to take into account oral chemotherapy-specific considerations as well as addition of nine new standards, a majority of which address issues specific to oral cancer agents, such as the need to monitor adherence.

The updated standards represent a set of expectations and a framework for individual providers as well as practices and institutions in relation to oral chemotherapy. The next challenge lies with implementation of the standards, specifically with how they can be used to guide practice and facilitate improvement. Previous experience with implementation of parenteral chemotherapy safety standards, which is the focus of one of the other articles in *JOP*, has shown that initially many practices may not be fully compliant but can become compliant with some effort. Therefore, the immediate first step is for practices and providers to review their current processes for delivery of oral chemotherapy against the standards to identify areas for improvement. Once that is complete, the challenging work of changing practice begins; this is an area where sharing of learning will be essential. I would strongly encourage practices to share their experiences with both the gap analysis as well as any work undertaken to implement the standards. This can be done through publications or presentations of their work at meetings such as the ASCO Quality Symposium. The electronic version of the standards also has a link for additional comments (www.asco.org/safety) and is a great venue for additional feedback from the oncology community. Of note, only 14 physicians provided comments on this document during the public comment phase.

As with any guidelines, there are areas for future growth. There has been concern among members of the oncology community regarding issues related to prescribing and dispensing of oral chemotherapy, especially inappropriate prescribing by non–oncology-trained providers or drug dispensing by pharmacies with little or no experience with oral chemotherapy agents. Although limiting who prescribes or dispenses oral chemotherapy could solve the problem to some extent, this could also theoretically lead to unintended negative consequences for patients with respect to access to treatment, especially in geographic areas where there may be only a few oncologists supervising other providers in delivery of cancer services. At the moment, apart from theoretical concerns and anecdotes, we have little evidence to help refine this standard, and more concrete evidence would be welcome. Providers can contribute to this debate by facilitating incident reporting related to oral chemotherapy prescribing and dispensing (as per standard 37). In Canada, the National System for Incident Reporting launched in 2010 was recently updated to include easier reporting related to chemotherapy incidents. One of the goals of this voluntary reporting project is to help facilitate incident reporting on all chemotherapy drugs including oral agents at the local and national levels to help inform debates such as this one. In the meantime, I would encourage institutions to develop appropriate credentialing processes for providers who prescribe oral chemotherapy as a way to meet this standard.

Another area where further learning will be needed involves monitoring and facilitating adherence with oral chemotherapy. A number of methods for monitoring adherence to drugs exist, ranging from patient reporting to use of electronic devices embedded in medication caps to monitoring of drug metabolites in blood or urine. To date, there have been a limited number of studies focusing on adherence
issues related to oral oncology drugs, and further research in this area is needed.

Last, but certainly not least, is the role of patients and their families in ensuring safe oral chemotherapy delivery. Compared with intravenous chemotherapy, when it comes to oral cancer drugs, patients have a significantly more active role to play. We, as providers, need to both support them appropriately through effective education as well as actively engage them in the implementation of the standards. Oral chemotherapy is an area where quality improvement projects using experience-based design methods may be especially well suited. Experience-based design is an approach to improving health care and redesigning service delivery by bringing patients and providers together and using their experiences of care to guide quality improvement.8,9

The publication of the updated standards marks the beginning of a new era in the journey toward safer oral chemotherapy. I hope the publication of these standards facilitates an active dialogue between the stakeholders involved, including patients, providers, decision makers, and researchers, to realize the vision defined by the standards and ensure safe oral chemotherapy now.

Author’s Disclosures of Potential Conflicts of Interest
Although all authors completed the disclosure declaration, the following author(s) and/or an author’s immediate family member(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a “U” are those for which no compensation was received; those relationships marked with a “C” were compensated. For a detailed description of the disclosure categories, or for more information about ASCO’s conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

Employment or Leadership Position: Monika K. Krzyzanowska, American Society of Clinical Oncology (U), Cancer Care Ontario (C)
Consultant or Advisory Role: Monika K. Krzyzanowska, Bayer HealthCare Pharmaceuticals (U)
Stock Ownership: None
Research Funding: None

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DOI: 10.1200/JOP.2013.000913

References
8. Bate P, Robert G: Experience-based design: From redesigning the system around the patient to co-designing services with the patient. Qual Saf Health Care 15:307-310, 2006