

# Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards

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**PURPOSE** To provide standards for medically integrated dispensing of oral anticancer drugs and supportive care medications.

**METHODS** An Expert Panel was formed, and a systematic review of the literature on patient-centered best practices for the delivery of oral anticancer and supportive care drugs was performed to April 2019 using PubMed and Google Scholar. Available patient-centered standards, including one previously developed by the National Community Oncology Dispensing Association (NCODA), were considered for endorsement. Public comments were solicited and considered in preparation of the final manuscript.

**RESULTS** A high-quality systematic review that was current to May 2016 was adopted into the evidence base. Five additional primary studies of multifaceted interventions met the inclusion criteria. These studies generally included a multicomponent intervention, often led by an oncology pharmacist, and also included patient education and regular follow-up and monitoring. These interventions resulted in significant improvements to patient quality and safety and demonstrated improvements in adherence and other patient outcomes.

**CONCLUSION** The findings of the systematic review were consistent with the NCODA patient-centered standards for patient relationships and education, adherence, safety, collection of data, documentation, and other areas. NCODA standards were adopted and used as basis for these American Society of Clinical Oncology/NCODA standards. Additional information is available at [www.asco.org/mid-standards](http://www.asco.org/mid-standards).

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## INTRODUCTION

For the most part, antineoplastic drugs are delivered intravenously; however, the prescription of oral anticancer drugs is becoming more common, and many of the new antineoplastic agents currently in development are oral options.<sup>1</sup> Oral administration can be more convenient for patients because hospitalization is not required; however, it also presents unique challenges, with patients and caregivers being responsible for correct adherence to prescriptions that are self-administered in the home, as well as financial and other challenges.<sup>2</sup>

Typically, prescriptions for oral medications are submitted to centralized pharmacies and delivered to patients through mail order.<sup>3</sup> While this model may offer an economy of scale, many practices have cited delays in receipt of mail order prescriptions due to processing and transit times.<sup>4</sup> In addition, filling

prescriptions through pharmacies that are located remotely from the clinical practice may result in fragmentation of care provision, inadequate follow-up and monitoring of patients, and insufficient exploration of the possibilities for financial assistance for patients.<sup>5</sup> More recently, to address these limitations, an increasing number of oral anticancer drug prescriptions are being filled under an alternative model called medically integrated dispensing (MID), wherein patients' prescriptions are processed and dispensed through a pharmacy located within the oncology clinic, rather than via mail order. Proponents of MID cite the advantage of convenience for patients, because medications can be dispensed at the time of the clinic appointment. Cost savings to the system may also be realized; mail order pharmacies usually deliver prescriptions prior to the start of the next chemotherapy cycle and may not have the capacity to respond to changes in prescriptions in a timely way. By contrast,

### ASSOCIATED CONTENT

#### Appendix

#### Data Supplement

Author affiliations and support information (if applicable) appear at the end of this article.

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## THE BOTTOM LINE

### Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards

#### Research Question

What patient-centered interventions improve the quality and safety of medically integrated dispensing (MID) of oral or other oncology drugs?

#### Target Population

Outpatients who have been prescribed oral anticancer drugs or supportive care medications in the setting of MID

#### Target Audience

Medical oncologists, pharmacists, nurses, and other members of the MID team

#### Methods

An Expert Panel was convened to develop standards based on a systematic review of the medical literature, and consideration of existing standards.

#### Patient-Centered Standards

##### 1.1 Patient Relationships

- 1.1.1 Communications related to the dispensing process, whether directly with the patient or on the patient's behalf, should be documented in the patient record.
- 1.1.2 Direct access for patients to the MID team is required. Patients should have access to direct phone lines, and after-hours phone numbers should be available. All calls left on voicemail must be returned by the next business day.

##### 1.2. Education

- 1.2.1 Prior to initiation of an oral anticancer drug, a formalized patient education session should occur with an experienced clinical educator such as a nurse, physician, pharmacist, nurse practitioner, or physician's assistant. The discussion should include drug name (generic and brand), drug dose, schedule, potential adverse effects and how to properly manage them, fertility (where applicable), treatment goal, duration of therapy, and financial and affordability considerations.
- 1.2.2 An informed consent form (or assent if applicable) that includes the intent of patient therapy should be reviewed by the patient (and caregiver, if applicable) with a patient educator. After signing the informed consent form, the patient will receive a copy, and the original document will be included in the patient record. The patient should sign the form after all questions are answered, with the patient retaining a copy.
- 1.2.3 Patient education will include review of the clinical treatment-related parameters for which the patient and/or caregiver should contact the oncology team. Emergency and secondary (nonemergent) points of contact for the patient should be established and documented in the patient record.
- 1.2.4 At the time of any new therapy initiation, written patient education should be provided. This information should be provided in the language of preference, wherever possible, and the provider should ensure that the patient understands the information contained in the written materials.
- 1.2.5 Prescribing information required by law must be given to patients.

##### 1.3 Adherence and Persistence

The following tools and policies should be part of the MID services to maximize adherence:

- 1.3.1 Calendars or other scheduling communications are helpful. If a patient calendar is provided, the calendar should include refill dates and medication schedules, clearly outlining specific dates to take medication. Include documentation of calendar information in the patient record.
- 1.3.2 A systematic comprehensive follow-up process that is documented in the patient record within 7 days of dispensing the oral oncolytic is required. Communication to patients is an essential element of patient education to assess adherence and toxicities. Communications should be tailored to presentation, specific medications, and patient comorbidities. Subsequent calls to the patient should be based on individual patient requirements and assessment of patient risk factors (education comprehension, (continued on following page)

## THE BOTTOM LINE (CONTINUED)

- performance status, tolerance to previous therapies, and so on). The prescriber must be notified directly when issues related to compliance are identified by the MID team.
- 1.3.3 Pill caddies may be appropriate and helpful for patient adherence.
  - 1.3.4 Continually evaluate electronic and manual tools that may be helpful in advancing patient adherence.
  - 1.3.5 Establish a plan for assessment of patient adherence and toxicity at each clinical encounter. Variances should be documented within the patient record.
  - 1.3.6 Adherence assessment and documentation should include (1) confirmation patient received the prescription, (2) start date for the medication, and (3) verifying that the patient understands how to take the medication, including taking with or without food, taking whole or crushing, safe handling, and so on.
  - 1.3.7 Monitoring of drug toxicity, laboratory tests, and any prescription, over-the-counter, or herbal medication changes. Contact provider in a timely manner to address potential problems/issues.
  - 1.3.8 Discussion of any financial issues that may be affecting adherence by the patient, and assessment of the need for increased assistance.

### **1.4 Safety**

The pharmacist or provider must check the following prior to dispensing:

- 1.4.1 Patient identity should be verified using two patient identifiers (eg, name, date of birth, address) at the time of entering the prescription and at the time of dispensing the prescription.
- 1.4.2 Appropriate diagnosis, allergies, correct drug, dose, and directions. The most recent provider note should be reviewed to validate treatment plan.
- 1.4.3 Prescriptions for an oral oncolytic, either retained internally for processing or referred to an external pharmacy, will be reviewed by the MID personnel for potential drug interactions and/or potential toxicity risks.
- 1.4.4 If a patient does not pick up a prescription or accept delivery for an oncolytic, the pharmacist will notify the prescriber and verify therapy status.
- 1.4.5 Patient profile is reviewed for duplicate therapies.
- 1.4.6 The prescription should only be filled after patient education and consent forms have been completed.
- 1.4.7 Drug interactions must be actively reviewed at each patient encounter. This includes a review of the patient record as well as a conversation with the patient about recent medication changes, including over-the-counter medications, alternative medicines, and/or herbal therapies.
- 1.4.8 Do not refill medication unless verified with the prescriber and/or prescriber's agent and the patient/caregiver.
- 1.4.9 The MID team will verify that a toxicity evaluation and management—visit with a provider has been scheduled for approximately 2 weeks after initiation of new oncolytic therapy.
- 1.4.10 Labeling of prescriptions should follow legal labeling requirements.

### **1.5 Refilling of Prescriptions**

- 1.5.1 Prior to refilling an oral anticancer drug, the MID team will review patient records for clinically relevant information (abnormal laboratories, prescription changes, latest progress note, and cycle of therapy, if appropriate).
- 1.5.2 Interventions involving a patient's refill of medication should be documented in the patient record (eg, coordination with intravenous chemotherapy, and new medications prescribed). The MID team may need to clarify this intervention with the patient and be prepared to respond to any questions the patient may ask.

### **1.6 Documentation**

- 1.6.1 Every clinical encounter with a patient will be documented in the patient record. In most cases this would be an electronic medical record, and the Expert Panel for these standards endorses the use  
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of electronic documentation. All questions posed by the patient regarding his or her therapy will be documented in the patient's record.

### 1.7 Benefits Investigation

- 1.7.1 All aspects of benefit investigation and patient assistance will be coordinated by the MID team, including prescription coverage and copay determination, copay assistance, and foundation and pharmaceutical industry patient assistance programs. All patients will receive evaluation for financial support.
- 1.7.2 Results of the benefit investigation information should be documented in the patient's record.

### 1.8 Medication Disposal

- 1.8.1 The MID will have a standard operating procedure in place to ensure the proper disposal of patients' unused medications and expired drugs.
- 1.8.2 Patient education will include directions to ensure the proper disposal of unwanted or expired medications.
- 1.8.3 Brochures addressing proper disposal may be helpful in providing locations and addresses of local sites that accept unwanted medications.

### 1.9 Patient Satisfaction

- 1.9.1 Practices are encouraged to solicit feedback from patients using surveys such as the National Community Oncology Dispensing Association patient satisfaction survey, to identify and address continuous improvement opportunities at MID practices.

**Note:** In addition, foundational elements recommended for the successful implementation of an MID organization and to support ongoing operations, as well as recommended health and prescriber-level data elements to be collected, are included in the Appendix (online only).

in the MID model, the in-practice pharmacy can be immediately responsive to prescription holds or changes in dose, thereby avoiding unnecessary dispensing waste.<sup>6</sup> Other advantages of MID include immediate verification of insurance coverage, support and assistance with investigation of options for financial assistance, ability to ensure that subsequent fills of the prescription beyond the first fill are completed and received on time by the patient, integration of patient information (eg, laboratories, other medications) with prescription information, and pharmacist in-person verification of adherence with the patient. In addition, MID clinics generally provide more personalized individual follow-up with patients, resulting in higher adherence rates.<sup>3</sup>

As oral anticancer drugs have become more common, and MID has emerged as a delivery model, a need has been identified for quality standards for patient monitoring, education, and follow-up.<sup>7</sup> This is important within the ambulatory care setting because studies have shown that there is a risk of patients discontinuing medication without consulting their physician,<sup>8</sup> or otherwise not adhering to the prescription due to toxicity or for other reasons. Studies have shown that reduced adherence can decrease treatment efficacy and compromise the goals of treatment.<sup>9</sup> Adoption of standards can help MID practices obtain optimal adherence and persistence rates, minimize the risk of toxicity with therapy, and positively affect patient health

outcomes. In addition, there is an underlying need for clinics that are engaging in or planning to initiate MID to demonstrate that they are providing a high level of patient-centered care, to achieve recognition and reimbursement from health insurance payers.

In recognition of this need, the American Society of Clinical Oncology (ASCO) has partnered with the National Community Oncology Dispensing Association (NCODA) to create joint evidence-based standards for MID. NCODA is an organization that was established in 2014 by a group of community-based oncology pharmacists with the goal of facilitating and promoting the MID model to improve patient care and convenience. These joint ASCO/NCODA standards build on that work through a systematic review of the quality improvement interventions that have been studied for ambulatory patients receiving oral anticancer and supportive care drugs, and provide an environmental scan of existing standards, tools, and resources. A multidisciplinary Expert Panel (Appendix Table A1, online only) further refined the standards. After a 2-week open comment period, public feedback was reviewed and integrated. These standards fill a gap, because we are currently not aware of existing evidence-based standards for the MID setting, and will provide a blueprint for safety and quality of care for outpatients who are prescribed oral oncology drugs in MID practices.

## METHODS

### Standards Development Process

This standard addresses the following key question: What patient-centered interventions improve the quality and safety of MID of oral or other oncology drugs?

This standard was developed by a multidisciplinary Expert Panel that included individuals with expertise in medical oncology, pharmacy, nursing, and health care administration, including a patient representative and an ASCO staff member with health research methodology expertise. Members of the Expert Panel were nominated by the ASCO Quality Oncology Practice Initiative (QOPI) Certification Program Steering Group and the ASCO Clinical Practice Committee, or by NCODA leadership. Prior to issuing invitations to the entire Expert Panel, the nominations were reviewed by the panel co-chairs to ensure geographic

diversity and sufficient expertise in relevant areas. Members of the Expert Panel were permitted to be using MID in their current practice. This was not considered to be a conflict of interest because the standard does not recommend for or against using MID, or promoting MID as a delivery model, nor recommend for or against the prescription of oral chemotherapy or supportive care drugs generally or specifically. The Expert Panel met via teleconference and/or Webinar and corresponded through e-mail. Based on consideration of the evidence, the authors were asked to contribute to the development of the standard, provide critical review, and finalize the standard. The standard statements were sent for an open comment period of 2 weeks, allowing the public to review and comment on the draft document after submitting a confidentiality agreement. These comments were taken into consideration while finalizing the standard statements. The document

**TABLE 1.** Tools and Resources for Oral Anticancer Drug Dispensing

Name of Organization/Study	Tool or Resource
National Community Oncology Dispensing Association ( <a href="http://ncoda.org">ncoda.org</a> )	Oral chemotherapy education:
	Cost avoidance and waste tracker
	Patient satisfaction survey
	Positive quality interventions
Chemocare.com	Web resource for drug and side-effect information, wellness information, and other resources ( <a href="http://chemocare.com/">http://chemocare.com/</a> )
Oncolink Rx	Information about anticancer and supportive care medications that can be used as handouts for patients ( <a href="https://www.oncolink.org/cancer-treatment/oncolink-rx">https://www.oncolink.org/cancer-treatment/oncolink-rx</a> )
Hematology Oncology Pharmacy Association Oral Chemotherapy Resources ( <a href="http://hoparx.org">hoparx.org</a> )	Tools and resources for:
	Best practices
	Therapy initiation
	Financial resources
	Education
	Monitoring
	Symptoms
Cancer Care Ontario	Adherence
	Drug safety and administration:
	Recommended criteria of a preprinted order: oral chemotherapy take-home prescriptions
	Clinical verification of cancer drug prescriptions checklist: cancer centers and specialty pharmacies. This checklist was developed as a tool to assist with the clinical verification of take-home cancer drug prescriptions at cancer centers and pharmacies where patient information is easily accessible.
Michigan Oncology Quality Consortium	Oral oncolytics resource guide:
	Therapy initiation resources
	Oral oncolytic checklist
	Medication reconciliation process summary
	Oral oncolytic initiation template
	Initial dose mailer
	Calendar
	Education and monitoring resources
Oncology Nursing Society	Checklist for a new start oral chemotherapy

was reviewed by the Quality of Care Council and ultimately approved by the ASCO Board of Directors. All funding for the administration of the project was provided by ASCO.

A preliminary environmental scan resulted in the identification of several existing standards by ASCO,<sup>10,11</sup> NCODA,<sup>12</sup> and other organizations,<sup>13-16</sup> or published in peer-reviewed journals.<sup>17,18</sup> Of these documents, only the NCODA standard was specifically developed for the setting of MID in the context of the United States health care system; therefore, this document was retained for potential endorsement, pending the results of the systematic review.

A preliminary scan for existing systematic reviews located a relevant systematic review that included studies of the quality and safety of oral dispensing interventions and was current to May 2016. This systematic review scored highly on the Assessment of Multiple Systematic Reviews tool<sup>19</sup> and was included in the evidence base. To avoid duplicate included studies, the inclusion criteria for the systematic review were subsequently designed to look for primary studies published after May 2016. This systematic review included searches of PubMed; search terms were (antineoplastic agents/administration & dosage\* and administration, oral [MeSH Terms]) or (adherence [title/abstract] administration, oral [MeSH Terms]) or (oral [Title/Abstract] and oncolytic) and Google Scholar (May 2016 to April 2019). Studies were considered eligible for inclusion if they included a patient population that was prescribed oral anticancer drugs or other cancer therapy–related drugs as outpatients and had an intervention and comparison group. Prospective or retrospective studies were eligible for inclusion. Eligible study outcomes were effects on patients, such as adherence and toxicity (rather than effects on the health system or processes).

Articles were excluded from the systematic review if they were (1) meeting abstracts; (2) editorials, commentaries, letters, news articles, case reports, narrative reviews; (3) studies published in a non-English language; or (4) studies that compared MID with other models of care delivery.

In the course of the evidence review, a concurrent informal environmental scan was conducted for tools and resources that could be helpful in the implementation of the standards. Those tools and resources were identified through the formal systematic review, as well as through searches of Web sites of relevant organizations that are involved with the dispensing of oral anticancer drugs, such as NCODA, the Hematology Oncology Pharmacy Association, the Oncology Nursing Society, Cancer Care Ontario, and others, or any tools or resources mentioned in background materials or studies included in the evidence base. These could include checklists, algorithms, templates for patient education materials, or other resources. The Expert Panel considered these tools and chose to recommend some as potentially helpful for practices to implement (Table 1).

The ASCO Expert Panel and standards staff will work with co-chairs to keep abreast of any substantive updates to this standard, and updates will be performed as needed. This is the most recent information as of the publication date.

## Standards and Conflicts of Interest

The Expert Panel was assembled in accordance with ASCO's Conflict of Interest Policy Implementation for Clinical Practice Guidelines ("Policy," found at <http://www.asco.org/rwc>). All members of the Expert Panel completed ASCO's disclosure form, which requires disclosure of financial and other interests, including relationships with commercial entities that are reasonably likely to experience direct regulatory or commercial impact as a result of promulgation of the standards. Categories for disclosure include employment; leadership; stock or other ownership; honoraria, consulting or advisory role; speakers' bureau; research funding; patents, royalties, other intellectual property; expert testimony; travel, accommodations, expenses; and other relationships. In accordance with the Policy, the majority of the members of the Expert Panel did not disclose any relationships constituting a conflict under the Policy.

## RESULTS

### Systematic Reviews

As outlined previously, an initial environmental scan located a high-quality systematic review that included studies of interventions that were designed to improve the quality and safety of care for patients receiving oral anticancer drugs.<sup>1</sup> The search strategy for this review was current to May 24, 2016. The results of that review are summarized subsequently within this section. Eligible studies were those that included patients who were receiving ambulatory care with traditional cytotoxic or targeted oral anticancer agents and where a prospective or retrospective comparison group was specified. Sixteen studies (3,612 patients) met the inclusion criteria,<sup>20-35</sup> including seven randomized controlled trials<sup>20-23,25,27,29</sup> and nine observational studies.<sup>24,26,28,30-35</sup> Interventions were categorized according to the following domains: prescribing (n = 1), preparation/dispensing (n = 2), education (n = 11), administration (n = 5), monitoring (n = 14), and storage/disposal (n = 1), which were delivered for the most part by nurses and/or pharmacists, and consisted of algorithms for assessing toxic effects, tools to track adherence and provide reminders, and increased interactions beyond the clinic visit. Adherence and persistence were the most common primary outcomes found in the included studies. Other outcomes included safety/toxicity and the frequency of taking chemotherapy above the recommended dose. Zerillo et al<sup>1</sup> used the Revised Standards for Quality Improvement Reporting Excellence–SQUIRE2–reporting framework as a quality assessment tool and found that most items (eg, context, methods, results, funding source) were included for most studies.<sup>36</sup> Many of the interventions had multiple

components, and most studies were published recently and had fewer than 100 patients. Seven studies reported statistically significant results,<sup>21,23,24,26,29,33,34</sup> including:

- A multi-institution study of patients with chronic myelogenous leukemia found that an initial education session and follow-up as needed related to adverse effects, drug interactions, and adherence significantly increased the medication possession ratio.<sup>31</sup>
- Adherence was significantly improved with a program that included contact by pharmacists and nurses on day 10 and 20 of treatment, and monthly thereafter.<sup>33</sup>
- Daily adherence was also significantly improved in a multiple-institution case-control study that provided an initial education session with a pharmacist and ongoing counseling.<sup>24</sup>

Other interventions that resulted in improvements in adherence included ongoing adverse events and adherence counseling,<sup>26</sup> prefilled pillboxes,<sup>30</sup> and personalized feedback on adherence data;<sup>32</sup> however, significance tests were not performed for these comparisons. There was no improvement in adherence found with monitoring using text messages.<sup>20-22,28</sup>

In terms of safety and toxicity, the following significant results were found in single-institution studies:

- A reduction in toxic effects, improvement in quality of life, and reduced inpatient hospitalization with “patient education and phone calls by nurses using toxicity algorithms within the first week of treatment and ongoing thereafter”<sup>29</sup>
- A cohort study reported lower toxicity scores with a nurse-led telephone intervention.<sup>34</sup>
- In a case-control study, pharmacist education regarding adverse events and ongoing adherence counseling resulted in increased detection of drug-related errors, and adherence (medication possession ratio > 90%).<sup>26</sup>

Other interventions that demonstrated improvements in single institution studies included “initial education and phone call assessment with drug diaries, to e-health reminders and assessments with as-needed triage to a clinician”; however, significant tests were not performed for these comparisons.<sup>1</sup>

A study that addressed cost savings did not report out-of-pocket costs for patients.<sup>33</sup> Zerillo et al<sup>1</sup> provided limited conclusions based on their review, including a recommendation that initial education and telephone monitoring within the first few weeks of treatment would be beneficial. They consider technological interventions to be an active area of investigation.<sup>1</sup>

## Results of the Systematic Review for Primary Studies

**Study characteristics.** Five primary studies met the systematic review inclusion criteria (Data Supplement Fig 1, online only), including four observational studies<sup>8,9,37,38</sup> and

one randomized controlled trial<sup>39</sup> (Data Supplement Tables 1 to 6, online only). Most studies were conducted in the United States,<sup>8,9,38,39</sup> and one study was conducted in Spain.<sup>37</sup> Most observational studies included a pre-intervention/postintervention comparison, either at a single institution or delivered across multiple sites. Most studies included patients with any tumor site, and one study included patients with castrate-resistant prostate cancer.<sup>9</sup> The patient population was prescribed a wide variety of oral anticancer medications. Interventions included (1) pharmacotherapy follow-up/monitoring programs,<sup>9,37</sup> (2) an automated telephone intervention,<sup>39</sup> (3) a workflow modification,<sup>8</sup> (4) an integrated oral anticancer drugs program, compared with usual care, or a less intense intervention model.<sup>38</sup> Most of the interventions had multiple components that were not evaluated separately. Outcomes varied across studies and included adverse events, drug interactions, food interactions, rate of drug discontinuation without notifying a physician, rate of start date of chemotherapy within 1 week of prescription, adherence to prescription, mean number of interventions per patient, and relative dose intensity (ratio of dose consumed by patient to dose prescribed by oncologist). Study sample sizes ranged from 31<sup>9</sup> to 272.<sup>39</sup>

**Study outcomes.** Adherence to laboratory parameter monitoring, which is used for early identification and management of adverse effects, was significantly improved (OR, 4.95; 95% CI, 1.03 to 29.44) after intervention with a pharmacist-led oral anticancer drugs monitoring program, compared with prior to the start of the program in a study of patients with metastatic castrate-resistant prostate cancer. This study also found a significantly higher mean number of interventions per patient with the monitoring intervention ( $P = .002$ ).<sup>9</sup>

In a study of reminder calls and weekly symptom management calls using an interactive voice response system, compared with weekly standard care and symptom assessment calls only by interactive voice response, there was no difference in the ratio of dose consumed by the patient to dose prescribed by the oncologist (ie, relative dose intensity) at any time period up to 12 weeks after treatment. There was a significant difference in the adjusted mean number of symptoms above a severity threshold at the end treatment with this intervention, but this significant difference did not persist during the follow-up time period (12 weeks after treatment).<sup>39</sup>

Significant differences were found before and after a multicomponent workflow modification that included “symptom assessment...adherence questionnaire, improved patient monitoring and management of symptoms.”; significant improvements were noted in patients starting drug treatment within 1 week after prescription (relative risk, 1.74; 95% CI, 1.11 to 2.71), and no patients discontinued drugs without notifying a physician after the workflow modifications were in place.<sup>8</sup>

There were also several outcomes that showed change in a positive direction but did not achieve statistical significance (eg, a nonsignificant reduction in “interruption of chemotherapy without informing a physician” after the launch of an integrated oral chemotherapy program).<sup>38</sup>

In summary, interventions that showed a statistically significant effect include:

- A pharmacist-led oral chemotherapy monitoring program improved adherence to laboratory monitoring and increased the mean number of interventions per patient in a single institution study of patients with metastatic castrate-resistant prostate cancer.<sup>9</sup>
- An automated telephone intervention with daily adherence reminder calls was found to improve the mean number of symptoms above a severity threshold immediately after intervention, but this effect did not persist at follow-up.<sup>39</sup>
- A multicomponent workflow intervention resulted in higher rates of patients starting therapy within 1 week of prescription and resulted in no patients discontinuing therapy without notifying their physician.<sup>8</sup>

Overall, the systematic review found several studies of multifaceted interventions, many of them including an oncology pharmacist component, that were effective with respect to improving adherence and other patient outcomes. Because these interventions included multiple components that were implemented simultaneously, it is difficult to draw conclusions about which aspects of the interventions were most effective; however, it is likely that the multi-intervention strategies studied here, including patient education about drug interactions, potential toxicity, and other topics, as well as regular follow-up and monitoring, can contribute to improving the quality and safe administration of oral anticancer drugs in the outpatient setting.

In addition, tools and resources were found during systematic review and environmental scan (Table 1), which may be useful for MID practices.

## PATIENT-CENTERED QUALITY STANDARDS

Based on consensus-based standards statements previously developed by NCODA and supported by the evidence for a multicomponent approach to MID, these ASCO/NCODA standards provide statements that are intended to optimize the quality and safety of dispensing of oral anticancer drugs and other cancer therapy-related drugs in the MID setting. In addition, to assist practices that may be considering the adoption of an MID model, consensus-based best practices for the foundational elements that would be recommended before commencing the delivery of MID are included in the Appendix. Health information technology data elements are also included in the Appendix.

MID practices must adhere to the following standards to ensure that dispensing processes are centered on patient safety and education while maximizing treatment outcomes.

## Domain 1. Patient-Centered Quality Standards

### 1.1 Patient relationships

- 1.1.1. Communications related to the dispensing process, whether directly with the patient or on the patient's behalf, should be documented in the patient record.
- 1.1.2 Direct access for patients to the MID team is required. Patients should have access to direct phone lines, and after-hours phone numbers should be available. All calls left on voicemail must be returned by the next business day.

### 1.2. Education

- 1.2.1 Prior to initiation of an oral anticancer drug, a formalized patient education session should occur with an experienced clinical educator such as a nurse, physician, pharmacist, nurse practitioner, or physician's assistant. The discussion should include drug name (generic and brand), drug dose, schedule, potential adverse effects and how to properly manage them, fertility (where applicable), treatment goal, duration of therapy, and financial and affordability considerations.
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### 1.3 Adherence and persistence

The following tools and policies should be part of the MID services to maximize adherence:

- 1.3.1 Calendars or other scheduling communications are helpful. If a patient calendar is provided, the

- calendar should include refill dates and medication schedules, clearly outlining specific dates to take medication. Include documentation of calendar information in the patient record.
- 1.3.2 A systematic comprehensive follow-up process that is documented in the patient record within 7 days of dispensing the oral oncolytic is required. Communication to patients is an essential element of patient education to assess adherence and toxicities. Communications should be tailored to presentation, specific medications, and patient comorbidities. Subsequent calls to the patient should be based on individual patient requirements and assessment of patient risk factors (education, comprehension, performance status, tolerance to previous therapies, and so on). The prescriber must be notified directly when issues related to compliance are identified by the MID team.
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  - 1.3.7 Monitoring of drug toxicity, laboratory tests, and any prescription, over-the-counter, or herbal medication changes. Contact provider in a timely manner to address potential problems/issues.
  - 1.3.8 Discussion of any financial issues that may be affecting adherence by the patient and assessment of the need for increased assistance.

#### 1.4 Safety

The pharmacist or provider must check the following prior to dispensing:

- 1.4.1 Patient identity should be verified using two patient identifiers (eg, name, date of birth, and address) at the time of entering the prescription and at the time of dispensing the prescription.
- 1.4.2 The most recent provider note should be reviewed to validate treatment plan (appropriate diagnosis, allergies, correct drug, dose and directions).
- 1.4.3 Prescriptions for an oral oncolytic, either retained internally for processing or referred to an external pharmacy, will be reviewed by the MID personnel for potential drug interactions and/or potential toxicity risks.
- 1.4.4 If a patient does not pick up a prescription or accept delivery for an oncolytic, the pharmacist will notify the prescriber and verify therapy status.
- 1.4.5 Patient profile is reviewed for duplicate therapies.
- 1.4.6 The prescription should only be filled after patient education and consent forms have been completed.
- 1.4.7 Drug interactions must be actively reviewed at each patient encounter. This includes a review of the patient record as well as a conversation with the patient about recent medication changes, including over-the-counter medications, alternative medicines, and/or herbal therapies.
- 1.4.8 Do not refill medication unless verified with the prescriber and/or prescriber's agent and the patient/caregiver.
- 1.4.9 The MID team will verify that a toxicity evaluation and management—visit with a provider has been scheduled for approximately 2 weeks after initiation of new oncolytic therapy.
- 1.4.10 Labeling of prescriptions should follow legal labeling requirements.

#### 1.5 Refilling of Prescriptions

- 1.5.1 Prior to refilling an oral anticancer drug, the MID team will review patient records for clinically relevant information (abnormal laboratories, prescription changes, latest progress note, and cycle of therapy, if appropriate).
- 1.5.2 Interventions involving a patient's refill of medication should be documented in the patient record (eg, coordination with intravenous chemotherapy, new medications prescribed). The MID team may need to clarify this intervention with the patient and be prepared to respond to any questions the patient may ask.

#### 1.6 Documentation

- 1.6.1 Every clinical encounter with a patient will be documented in the patient record. In most cases, this would be an electronic medical record, and the Expert Panel for these standards endorses the use of electronic documentation. All questions posed by the patient regarding his or her therapy will be documented in the patient's record.

#### 1.7 Benefits investigation

- 1.7.1 All aspects of benefit investigation and patient assistance will be coordinated by the MID team, including prescription coverage and copay determination, copay assistance, and foundation and pharmaceutical industry patient assistance programs. All patients will receive evaluation for financial support.
- 1.7.2 Benefit verification information should be documented in the patient's record.

## 1.8 Medication disposal

- 1.8.1 The MID will have a standard operating procedure in place to ensure the proper disposal of patients' unused medications and expired drugs.
- 1.8.2 Patient education will include directions to ensure the proper disposal of unwanted or expired medications.
- 1.8.3 Brochures addressing proper disposal may be helpful in providing locations and addresses of local sites that accept unwanted medications.

## 1.9 Patient satisfaction

- 1.9.1 Practices are encouraged to solicit feedback from patients using surveys such as the NCODA patient satisfaction survey, to identify and address continuous improvement opportunities at MID practices.

## DISCUSSION

These ASCO/NCODA standards for MID have been developed by a multidisciplinary panel and include an evidence review of interventions to improve outcomes for patients who are being prescribed oral anticancer drugs and supportive care medications in an outpatient setting. Within the standards document, we have provided an updated systematic review of interventions, a table of suggested tools and resources, and a list of best practice foundational elements. These standards are supportive of ASCO's Quality Oncology Practice Initiative (QOPI) and QOPI Certification Program.

While there is a significant body of literature that demonstrates the benefits of multifaceted interventions, the Expert Panel recognizes the limitations of the evidence base and calls for more prospective controlled research studies to fill gaps in knowledge, such as which specific components of interventions are most effective and which are most applicable to various target populations.

In conclusion, we hope that these standards will advance the quality of care within the emerging delivery model of MID. These standards will be reviewed for currency on an annual basis and revised as new evidence becomes available.

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## PATIENT AND CLINICIAN COMMUNICATION

For recommendations and strategies to optimize patient-clinician communication, see Patient-Clinician Communication: American Society of Clinical Oncology Consensus Guideline.<sup>40</sup>

## OPEN COMMENT

The draft standards were released to the public for open comment from June 19, 2019, through July 3, 2019. Two responses were received. Response categories of "Agree as written," "Agree with suggested modifications," and "Disagree. See comments" were captured for every proposed recommendation. Both respondents either agreed or agreed with modifications to most recommendations. Modifications were made accordingly throughout the standards, where considered by the Expert Panel to be feasible and within scope. For some recommendations, additional clarification was sought regarding requirements for documentation in the patient record, and the Expert Panel responded by clarifying that the group supports the use of an electronic medical record.

## ADDITIONAL RESOURCES

More information, including slide sets, and clinical tools and resources, is available at [www.asco.org/mid-standards](http://www.asco.org/mid-standards). Patient information is available at [www.cancer.net](http://www.cancer.net) and [www.ncoda.org/pqji](http://www.ncoda.org/pqji) and [www.oralchemoedsheets.com](http://www.oralchemoedsheets.com).

## RELATED ASCO STANDARDS

- 2016 Updated ASCO/Oncology Nursing Society Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology<sup>10</sup> (<http://ascopubs.org/doi/10.1200/JOP.2016.017905>)
- Safe Handling of Hazardous Drugs: ASCO Standards<sup>11</sup> (<http://ascopubs.org/doi/10.1200/JCO.18.01616>)

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## EDITOR'S NOTE

This American Society of Clinical Oncology/National Community Oncology Dispensing Association standard provides recommendations, with comprehensive review and analyses of the relevant literature for each recommendation. Additional information, including slide sets, clinical

tools and resources, and links to patient information at [www.cancer.net](http://www.cancer.net), is available at [www.asco.org/mid-standards](http://www.asco.org/mid-standards).

## EQUAL CONTRIBUTION

M.S.D. and M.R. were Expert Panel co-chairs.

## REPRINT REQUESTS

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## AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST AND DATA AVAILABILITY STATEMENT

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**AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST AND DATA AVAILABILITY STATEMENT**

**Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards**

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Open Payments is a public database containing information reported by companies about payments made to US-licensed physicians ([Open Payments](#)).

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## APPENDIX

## 1. Foundational Elements of the Medically Integrated Dispensing Program

The Expert Panel recommends consideration of the following elements for the implementation of a successful Medically Integrated Dispensing (MID) program:

### 1.1 Mission statement

- 1.1.1 A mission statement should include three elements: our cause (the who, what, and where), our actions (what we do), and our impact (changes for the better)

### 1.2 The MID team should have an organizational chart

### 1.3 Business plan:

- 1.3.1 Scope of business
- 1.3.2 State requirements or restrictions: this may be either a licensed pharmacy or a physician dispensing program
- 1.3.3 Proforma analysis: review prescription coverage and payer or pharmacy benefits manager limitations
- 1.3.4 Awareness of any closed distribution limitations. Practices should define these limitations and have a plan to let patients know how this will impact patients (eg, order ahead of time)
- 1.3.5 Defined regional payer relationships
- 1.3.6 MID practices should document scope of medicines that they are able to provide, including medicines for oral anticancer drugs and supportive care (refer to state law formulary)
- 1.3.7 Documentation of the planned staffing model with a rationale for the model, including either an Oncology Pharmacist (preferred), Certified Pharmacy Technician, Dispensing Nurse Navigator, Oncology Certified Nurse
- 1.3.8 Assessment and documentation of space requirements/renovations needed

### 1.4 Implementation timeline

- 1.4.1 In addition to the physical space design and time for construction, regulatory State Board of Pharmacy and payer contracts must be completed well in advance of the first prescription being processed.
- 1.4.2 A timeline for opening MID services must be developed.

### 1.5 Operational elements

- 1.5.1 Workflow and process flow diagrams, for practice (single/multisite) and dispensing area
- 1.5.2 Ensure that the Central business office is aware of accounting considerations that are specific to the prescription of oral anticancer drugs in the MID setting, including:
- 1.5.3 Integration of billing services and billing reconciliation
- 1.5.4 Contracting and payer implementation
- 1.5.5 Prior authorization process
- 1.5.6 Group purchasing organization affiliation
- 1.5.7 Liability insurance
- 1.5.8 Claims accounting (editing, adjudication, and reconciliation)
- 1.5.9 Audit preparation and readiness
- 1.5.10 Establishment of a relationship with a credit card processing company
- 1.5.11 Standard operating procedure (SOP) for waste minimization tracking and documentation (cost avoidance and waste tracker)

- 1.5.12 Designation of an individual within the MID practice who will be responsible for financial counseling and patient advocacy

### 1.6 Dispensing space requirements

- 1.6.1 Patient counseling area
- 1.6.2 The need for the following infrastructure items should be considered: storage areas/shelving, workstations, counting trays, records, bags, prescription bins, sink, refrigerator, software and hardware, and adequate work space for employees

### 1.7 Communication plan

- 1.7.1 • To the physicians, staff, and patients
- To practice leadership
  - To practice business office/contracting department
  - Marketing materials (eg, brochure and practice flyer, announcement on Website)
  - Kickoff meeting(s) to increase staff awareness and explain process flow

### 1.8 SOPs

Continuous Quality Improvement and Corrective Action/Preventative Action assessment and standards will be applied with the implementation of SOPs for:

- 1.8.1 Daily dispensing operations/workflow
- 1.8.2 Staff training
- 1.8.3 Audit readiness guidance
- 1.8.4 Home delivery to patients
- 1.8.5 Returning medications to stock
- 1.8.6 Staff duties
- 1.8.7 Delivery to satellite locations
- 1.8.8 Expired drugs
- 1.8.9 Recalled drugs
- 1.8.10 Contingency plans for loss of power, weather-related emergency data backup, telephone support, holiday delivery schedule from Group Purchasing Organization
- 1.8.11 Compliance with Health Insurance Portability and Accountability Act requirements regarding personal health information
- 1.8.12 Central business office
- 1.8.13 Medication delivery to patients if home delivery is part of the MID services. The SOP should outline a process for shipping, tracking, and confirmation of medication deliveries independent of patient confirmation.

### 1.9 Process flow map

- 1.9.1 Establish practice decision tree/flow map for dispensing a prescription, from script generation by provider to delivery of medication to patient.

### 1.10 Electronic medical records and pharmacy dispensing system infrastructure

- 1.10.1 The practice electronic medical record (EMR), pharmacy dispensing system, and practice management system should be integrated
- 1.10.2 Care plans within the EMR or pharmacy dispensing system
- 1.10.3 Dual Screens for EMR and Rx Program
- 1.10.4 Printer/Copier/Fax/Scanner

### 1.11 Processes and guidance for handling of medication

- 1.11.1 Employee (USP 800 standard, ASCO standards for Safe Handling)
- 1.11.2 Receiving drug order: safe handling guidelines USP, the National Institute for Occupational Safety and Health, Occupational Safety and Health Administration
- 1.11.3 Sharps disposal for patients
- 1.11.4 Medication handling for patients
- 1.11.5 Guidance for unused medication disposal

## 2. Health Information Technology Data Elements

### 2.1 Prescriber-level data elements to be collected include:

- 2.1.1 Name of prescriber
- 2.1.2 Name of drug, dose, dose schedule, and quantity dispensed
- 2.1.3. Speed to therapy data elements, including date prescription received, date prescription filled, and date prescription dispensed to patient. Include supporting documentation for circumstances that may impact the speed to therapy for the patient.
- 2.1.4. Diagnosis and diagnosis code (International Classification of Diseases [10th revision])
- 2.1.5. Line of therapy; if not first line, ensure medications prescribed in earlier lines of therapy are captured in the patient's record.
- 2.1.6 Patient's Insurance company and pharmacy benefits manager

### 2.2. Discontinuation of treatment

- 2.2.1 First month discontinuation rate; related data elements to be collected include:
  - Name of drug and reason for discontinuation
  - Laboratory data or clinical information relevant to discontinuation
  - Record hospitalization or ER visits, if due to oral oncology drug therapy
- 2.2.2 Reasons for prescription discontinuation, including:
  - Name of drug and reason for discontinuation
  - If due to adverse drug reaction (ADR), describe the ADR and provide any interventions recommended or performed to allow patient to keep receiving therapy (see 2.3 ADR Tracking).
  - Number of months and days patient was receiving treatment
  - Hospitalization or ER visits due to oral oncology drug therapy

### 2.3 ADR tracking

- 2.3.1 Data elements related to actively identifying and managing ADRs include:
  - Name of drug
  - Outcome (yes/no):
    - Treatment held
    - Dose reduction
    - Life threatening
    - ER or hospitalization
    - Disability or permanent damage
    - Death
  - Date of ADR
  - Description of ADR
  - Grade of ADR according to Common Terminology Criteria for Adverse Events scale
  - Is the ADR new or previously reported?
  - If previously reported:
    - Review previous intervention for effectiveness
    - Revise intervention as needed
  - If new:
    - If not expected, submit Med Watch Form FDA 3500A
    - Interventions recommended

### 2.4 Data elements to be collected related to patient financial support

- 2.4.1 Individual patient financial support:
  - Name of drug
  - Source of financial support obtained (free drug, co-pay card, foundation)
  - Amount of support obtained and spent
    - Practices shall have a system in place that will allow for the reporting and tracking of current balances of support.
  - Length of time to obtain financial support
    - From first contact to when support confirmed
- 2.4.2 Percentage of patients who received financial support

**TABLE A1.** Medically Integrated Dispensing Standards Expert Panel Membership

<b>Name (and Designation)</b>	<b>Affiliation/Institution</b>	<b>Role/Area of Expertise</b>
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