Safety Standards Workgroup: Meeting Two

August 6, 2014

MARYLAND
DEPARTMENT OF HEALTH
& MENTAL HYGIENE

Meeting Overview

- Summary of Meeting One
- NIOSH Presentation
- Provider's and ASCO Perspective on Barriers to Implementing Safety Standards in an Outpatient Oncology/Rheumatology Setting
- What Other States are Doing
- QOPI Overview
- Next Steps

SUMMARY OF MEETING ONE

Mona Gahunia

MARYLAND
DEPARTMENT OF HEALTH
& MENTAL HYGIENE

Summary: Meeting One

- Reviewed why safety standards are important
- ASCO's own initiative to certify oncology practices based on quality standards
- Reviewed several documents as the basis of uniform standards:
  1) 2013 ASCO-ONS Standards for Safe Chemotherapy Administration
  2) CDC Basic Infection Control Plan for Outpatient Oncology Settings
  3) NIOSH Alert
  4) ASHP Guidelines for Handling of Hazardous Drugs
- Group consensus that uniform minimum standards in the areas of accurate dosing/administration, infection control, and handling of hazardous drugs are needed
- Initial thoughts and discussion about the challenges in a community-based outpatient setting
- Need to get more specific information standards for rheumatology infusion centers

NIOSH/CDC PRESENTATION

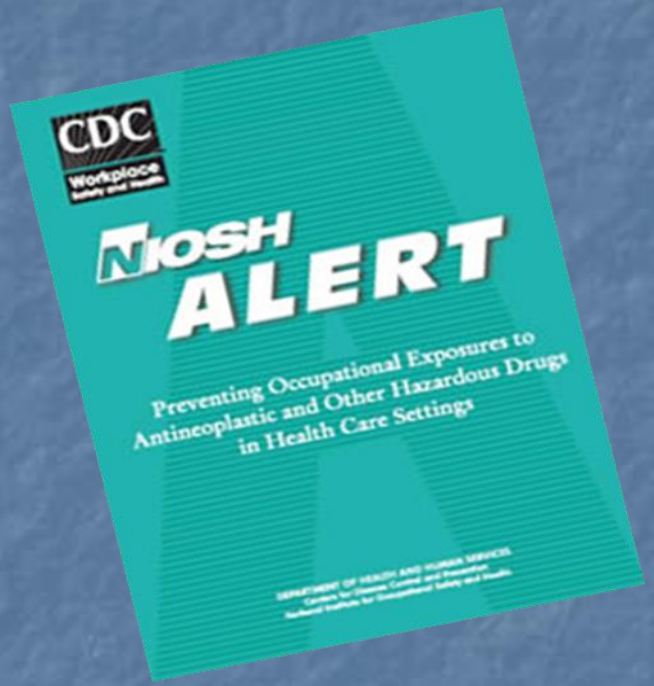
Thomas Conner and Ken Mead

NIOSH Activities on Occupational Exposure to Hazardous Drugs

Item	Year Published
NIOSH Alert on Antineoplastic and Other Hazardous Drugs in Health Care Settings	2004 (2015 update underway)
NIOSH List of Hazardous Drugs	2004, 2010, 2012, 2014 (2016 underway)
Personal Protective Equipment for Health Care Workers Who Work with Hazardous Drugs	2009
Safe Handling of Hazardous Drugs for Veterinary Healthcare Workers	2010
Medical Surveillance for Healthcare Workers Exposed to Hazardous Drugs	2013

2004 NIOSH Hazardous Drug Alert

- NIOSH published Alert in 2004
- Product of NIOSH Hazardous Drug Working Group (~50 partners/stakeholders)
- Utilized established lists of hazardous drugs from 4 institutions
- Added 5th list generated by PhRMA
- Plan was to update list "annually"



NIOSH Criteria for Hazardous Drugs

- Any drug identified by at least one of the following six characteristics:
  - Carcinogenicity
  - Teratogenicity or developmental toxicity
  - Reproductive toxicity in humans
  - Organ toxicity at low doses in humans (<10 mg/day) or animals (<1mg/kg/day)
  - Genotoxicity
  - New drugs that mimic existing hazardous drugs in structure or toxicity

(NIOSH, 2004)

NIOSH Hazardous Drugs

- NIOSH conducts a *Hazard Identification*
- We do not do a *Risk Assessment*
- The risk depends on:
  - how the drug is used
  - in what setting
  - how often it is used
- Each institution should determine risks for the drugs they use

Hazardous Drug Update Process

- Review all new FDA drug approvals (~2-years)
- Review all FDA (MedWatch) warnings
- Initial triage (remove obvious non-hazardous drugs)
- NIOSH review/recommendations
- Panel meeting/review
- NIOSH review
- Federal Register Notice (60-day comment period)

Hazardous Drug Update Process

- NIOSH review/reply to Docket comments
- Panel review
- Submission to NIOSH Office of Director
- Review with NIOSH OD
- Prepare final document
- Final submission to NIOSH OD
- FDA notification
- Publish in Federal Register and on NIOSH webpage

NIOSH Updates to List of Hazardous Drugs

- New NIOSH format for hazardous drug list
- 2014 list will have three categories
  - ***Antineoplastic Drugs* (AHFS 10:00)**
  - ***Non-antineoplastic Hazardous Drugs***
  - ***Drugs with Reproductive Effects***

NIOSH Medical Surveillance

- No Specific Biomarkers
- Annual Medical History
- Annual Reproductive History (when appropriate)
- Laboratory Tests:
  - Following an exposure
  - When a health issue arises

BARRIERS

Edward Lee


Tinsley North

OTHER STATES' ACTIVITIES

Celeste Lombardi

Washington Law on Occupational Safety for Handling Hazardous Drugs

- SB5594 was signed April 2011 and requires the Washington Department of Labor and Industries to develop rules that are consistent with recommendations from NIOSH.
- Washington was the first state to require health care employers to take precautions to prevent exposure of the health effects associated with hazardous drugs.
- The Hazardous Drug Advisory Committee was formed to advise the Department of Labor and Industries on new NIOSH updates and unanticipated issues related to the safe handling of hazardous drugs.
- The committee has until January, 2015 to develop a written control plan. By July 2015, employee training needs to begin. By January 2016, appropriate ventilation systems need to be installed.

Retrieved from www.safetyandhealthmagazine.com/law-protects-Washington-state-health-care-workers-from-hazardous-drugs, http://www.wsmos.org/assets/Britell_Handouts.pdf

Hazardous Drug Legislation – Enforcement Authority

Washington State – RCW 49.17

- Director, Dept. of Labor & Industries (or agent)
- Authority to:
  - Conduct inspections (may not give advance notice)
  - Issue citations (or notices for de minimis violations)
  - Issue restraining orders for dangerous conditions
  - Impose civil penalties not to exceed $70,000 per violation
  - Refer for criminal penalties for certain offenses (e.g., violation causes death of employee; failure to comply with restraining order; giving advance notice of inspection)

California Legislation on Occupational Health and Safety Standards: Hazardous Drugs

- California Assembly Committee on Labor and Employment passed a bill in April 2013 (AB1202) requiring the Occupational Health and Safety Standards Board to adopt a standard relating to the safe handling of antineoplastic and other hazardous drugs (as defined by NIOSH) in health care facilities, regardless of setting.

- The Standards Board is the standards setting agency within California's OSHA Program. They will consider input from hospitals, practicing physicians whose specialties are impacted including oncologists, organizations who represent health care personnel and other stakeholders.

- The standard shall be consistent with the NIOSH 2004 alert entitled "Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings" and 2010 update.

- The bill was sponsored by Becton Dickinson and Company (BD Medical) arguing that the NIOSH guidelines for safe handling of hazardous drugs has been voluntary and reported to be sporadic.

Retrieved from www.leginfo.ca.gov, AB1201 Assembly Bill-Bill Analysis

Hazardous Drug Legislation – Enforcement Authority

California – Labor Code, Sec. 144.8

- Chief, Division of Occupational Safety & Health (or agent)
- Authority to:
  - Conduct inspections (may not give advance notice)
  - Issue special orders to correct unsafe conditions
  - Issue citations (or notices for de minimis violations)
  - Impose civil penalties (up to $7,000 - $70,000 per violation)
  - Refer for criminal penalties for certain offenses (e.g., serious or repeated violations of standards/orders; violation causes death or serious impairment of employee)

Maine Legislation for Safe Handling of Hazardous Drugs

- Emergency legislation was introduced in December 2013, directing the Commissioner of Health and Human Services to adopt rules establishing an occupational safety and health standard for the safe handling of antineoplastic drugs in health care facilities regardless of the setting. It did not pass as emergency legislation but was re-introduced into the 2014 legislative session.

- The standard must be consistent with the recommendations of the Department of HHS, the CDC, NIOSH 2004 alert and 2010 update.

- Key stakeholders whose input shall be considered in the new requirements include hospitals, practicing physicians from impacted specialties including oncologists, organizations representing health care personnel including nurses and pharmacists, and other stakeholders. They shall also determine a reasonable time for implementation of the new requirements.

Retrieved from www.mparx.com LD-1599-HHS-to-create-standard-for-the-handling-of-antineoplastic-drugs-in-health-care-facilities.pdf

North Carolina Law for Safe Handling of Hazardous Drugs

- House bill 644 was passed in April, 2013. It requires the Commissioner of the Department of Labor to create and develop a separate division known as the Occupational Safety and Health Division, which will adopt rules following the NIOSH recommendations for the safe handling of hazardous drugs.
- A director will administer this division, under the direction of the Commissioner. The Commissioner shall enforce the rules and investigate complaints in accordance with the law.

Retrieved from http://www.ncleg.net/Applications/BillLookUp/LoadBillDocument.aspx

Closed System Transfer Devices

NIOSH recommends that in addition to the use of personal protective equipment (gown, gloves, mask, cap, biological safety cabinet), health care workers should use an effective closed system transfer device.

The CSTD minimizes the exposure to hazardous drugs and their harmful effects. A CSTD is defined by NIOSH as a system that "mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system". Several companies have FDA approved devices, including BD PhaSeal, Chemolock needle-free system, Equashield, and Braun closed systems.

Impact of Using a Closed System Transfer Device on Reducing Occupations Exposure to Hazardous Drugs

- A study from a Japanese hospital in April 2013 reported on the efficacy of using BD's PhaSeal in reducing environmental and occupational exposure to cyclophosphamide(CP). Environmental and staff sampling was performed using sampling wipes and obtaining 24 hour urine samples pre- and post-institution of BD's PhaSeal system. After 7 months of initiating the use of the closed system, minimal levels of CP was detected on 1 of 6 sampling wipes. Minimal levels of CP were detected in the urine samples of staff. (retrieved fromhttp://www.ncbi.nlm.nih.gov/pmc/articles/PMC3698436/ http://dx.doi.org/10.1186%2F2193-1801-2-273)

- An article published in the Journal of Oncology Pharmacy Practice (Feb 2010) reported on an Australian hospital's pre and post-implementation study of PhaSeal. CP was the surrogate marker for all cytotoxic drugs. After 12 months, surface contamination was reduced by 75%. (retrieved from doi:10.1177/1078155209352543)

OTHER STATES' ACTIVITIES

Karen Michaels

What are other states doing?

- Kentucky – no separate regulations for outpatient oncology; just follow USP 795/797
- Nevada – no separate regulations; follow USP 797
- Indiana – USP 797; medical licensing board has control over physician offices but no compliance officers in the field

What are other states doing?

- Michigan – new regulations passed 2 Jul 2014 related to sterile compounding
  - Essentially summary of USP 797
  - No specific statues related to hazardous compounding
- Utah - no separate regulations for outpatient oncology; just follow USP 795/797
- Ohio - no separate regulations for outpatient oncology; just follow USP 795/797

What about ASHP?

- Infection control/Dosing
  - Joint Commission and CMS standards
    - Likely most commonly used standards due to reimbursement issues
  - ASHP's Best Practices
    - Not enforceable; often used as reference by regulatory bodies
- Disposal of hazardous materials
  - NIOSH
  - USP 797
    - Technically enforceable…but is it being enforced??
  - USP 800
    - Not yet enforceable

QOPI

Paul Celano

Quality Oncology Performance Initiative

Paul Celano, MD

President, Maryland DC Society of Clinical Oncology

'To measure is to KNOW'

'If you cannot measure it, you cannot improve it'

QOPI® The Quality Oncology Practice Initiative

Quality Cancer Care: Pursuing Excellence

Quality assessment and improvement program for US-based outpatient hematology-oncology practices – to create a culture of self-examination and improvement

Pursuing Excellence

QOPI® The Quality Oncology Practice Initiative

Quality Cancer Care: Pursuing Excellence

Rapid Cycle Quality Improvement

One look is never enough…

- Standardized process and tool for ongoing assessment and improvement in practice
- Key to successful participation is to identify the QOPI Champion within your practices
- QOPI is only part of the rapid cycle quality improvement process. QOPI can help inform your improvement efforts by identifying areas upon which to focus for improvement strategies

ASCO® American Society of Clinical Oncology

Evolution of QOPI®

QOPI offered to full ASCO membership (2006)

QOPI Pilot Phase (2002-2005)

Measure and content expansion (2006-2010)

QOPI Certification Program Launched (2010)

Expansion and design changes (2013-2014)

eQOPI
iQOPI

ASCO CANCER•LINQ

Joseph Simone, MD

"Unless one engages practicing physicians in the basic structure, quality will never become part of the fabric of practice…

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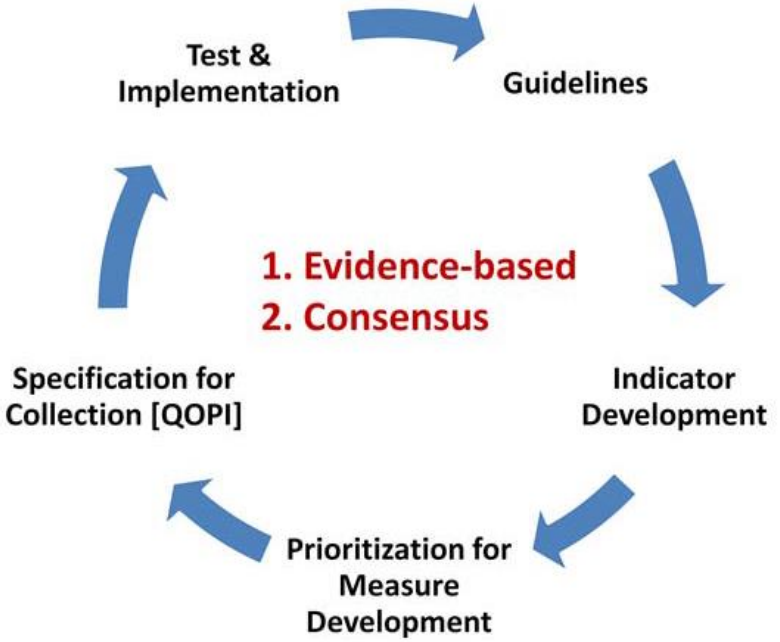
QOPI® The Quality Oncology Practice Initiative

Quality Cancer Care: Pursuing Excellence

Comprehensive library of reliable and tested measures…

Measures are selected and adapted by practicing oncologists



More than 160 measures in use and maintained

Ongoing efforts include:

- Radiation Oncology
- Prostate Cancer
- Palliative Care
- Patient Reported Outcomes and outcome measures

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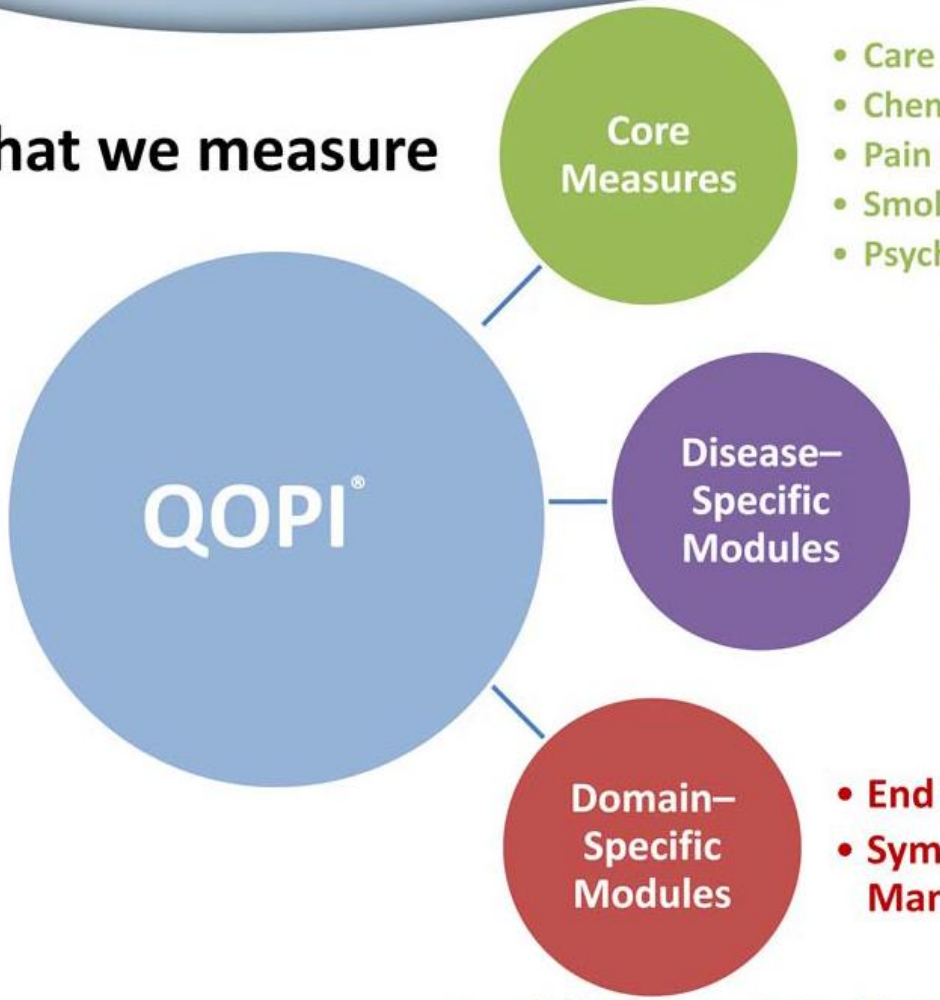
What we measure



- Care Documentation
- Chemo Administration
- Pain Management
- Smoking Cessation
- Psychological Support

- Breast Cancer
- Colorectal Cancer
- Non-Hodgkin's Lymphoma
- Non-small cell Lung Cancer
- Ovarian, Fallopian Tube, Primary Peritoneal (gynonc)

- End of Life Care
- Symptom/Toxicity Management

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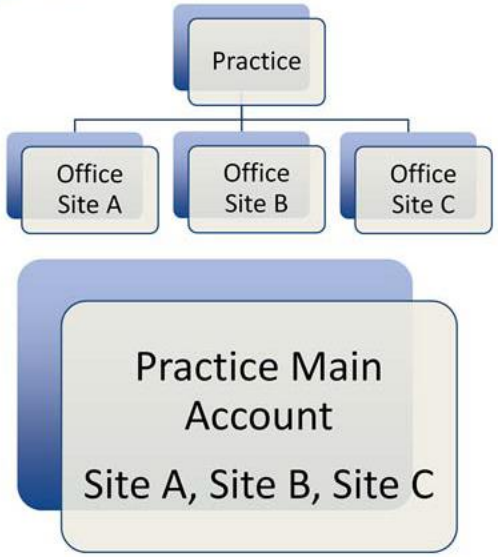
Flexibility in how you report data…



Reports by office location and practice roll-up

Reports by practice roll-up only

- Practices with more than one office location can submit information by office location or using one main account
- How you sample your charts impacts eligibility to apply for QOPI® Certification
- Physician-level reporting is also included

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QOPI® The Quality Oncology Practice Initiative

Quality Cancer Care: Pursuing Excellence

Methodology - Overview

Who?

- Corresponding physician and QOPI account administrator
- Nurses, NP, PA, MDs, fellows, admin with clinical oversight

How?

- Manual abstraction into web-based system
- QOPI provides chart selection methodology, abstraction guide, and training

Time?

- 1 day first time for training (documentation, calls, webinars)
- 1 day to 1 week to identify charts
- 45 min – 1 hour per chart in the beginning

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Web-based system…

Key sections on the HOME PAGE of the web-based application:

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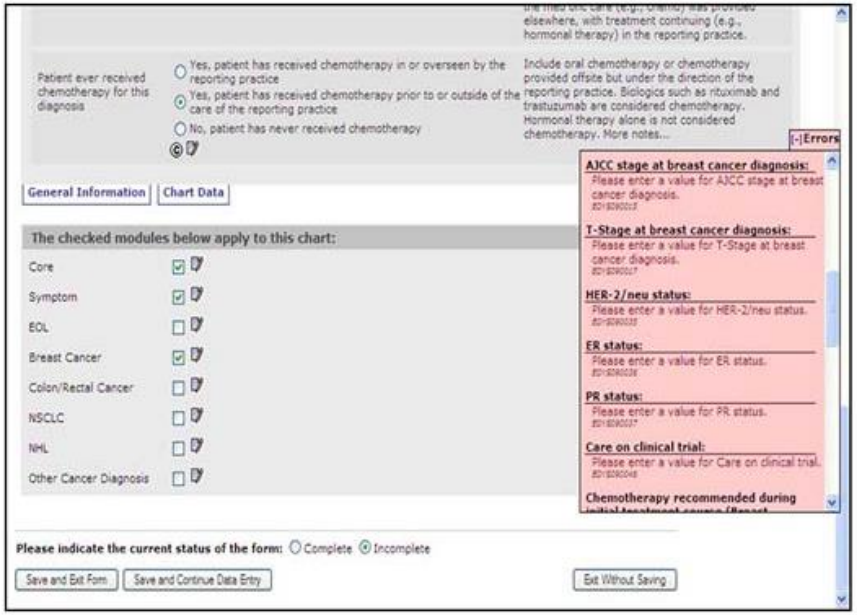
Enter a New Chart:



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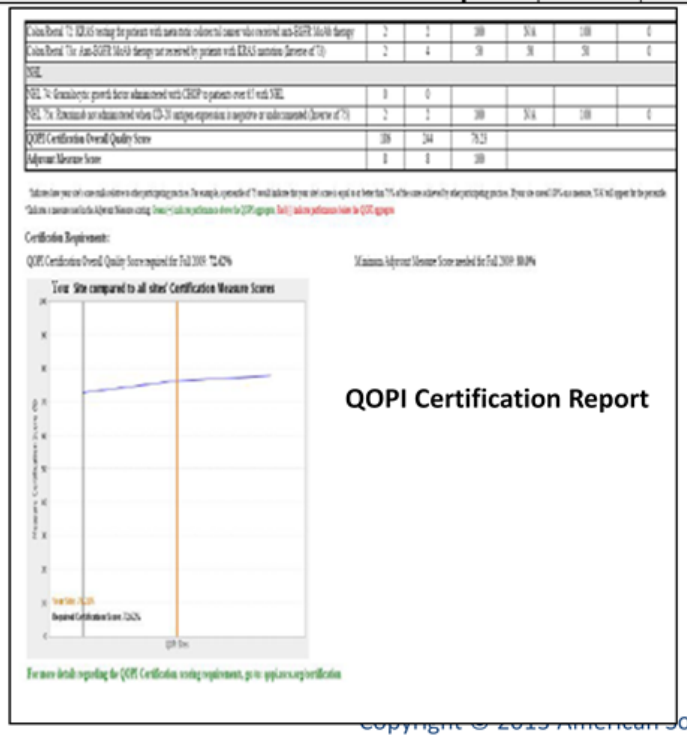
Feedback and Monitoring

Ability to add relevant comparison groups

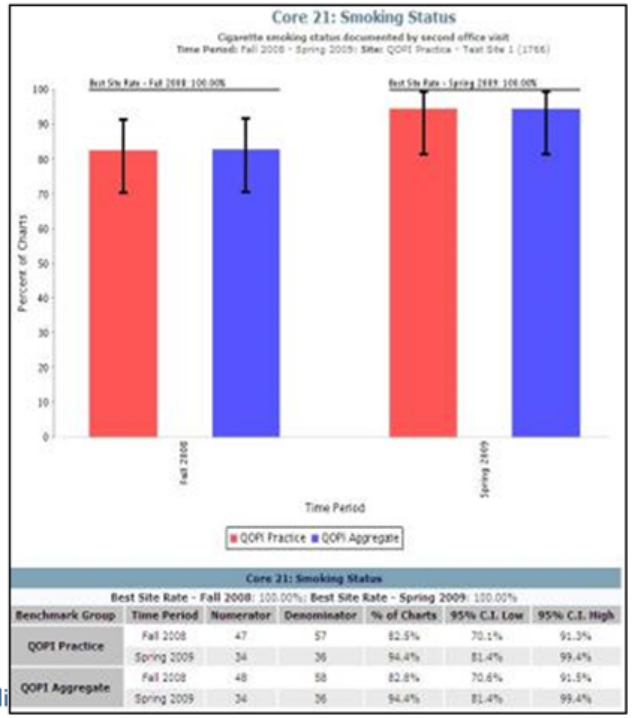
Print | Export to Excel | Export to CSV | Close Window

QOPI® Measures Summary Report

#	Measure (%)	Oncology			Employee Aggregate					QOPI Aggregate Data				
		Fall 2012			Fall 2012					Fall 2012				
		Num	Denom	Rate	Mean	Min	Max	N Charts	N Sites	Mean	Min	Max	N Charts	N Sites
Core														
1	Pathology report confirming malignancy	24	25	96.00%	98.76%	90.00%	100.00%	7716	105	98.42%	86.36%	100.00%	25609	397
2	Staging documented within one month of first office visit	11	11	100.00%	84.39%	43.48%	100.00%	7603	105	83.58%	35.00%	100.00%	25215	397
3	Pain assessed by second office visit	24	25	96.00%	93.91%	35.00%	100.00%	7716	105	91.05%	10.20%	100.00%	25609	397
4a	Pain intensity quantified by second office visit (Includes documentation of no pain)	22	24	91.67%	92.64%	43.24%	100.00%	7212	104	90.00%	36.36%	100.00%	23280	392
5	Plan of care for moderate/severe pain documented	0	0		82.08%	7.69%	100.00%	1233	98	75.50%	7.69%	100.00%	3583	339



QOPI Certification Report

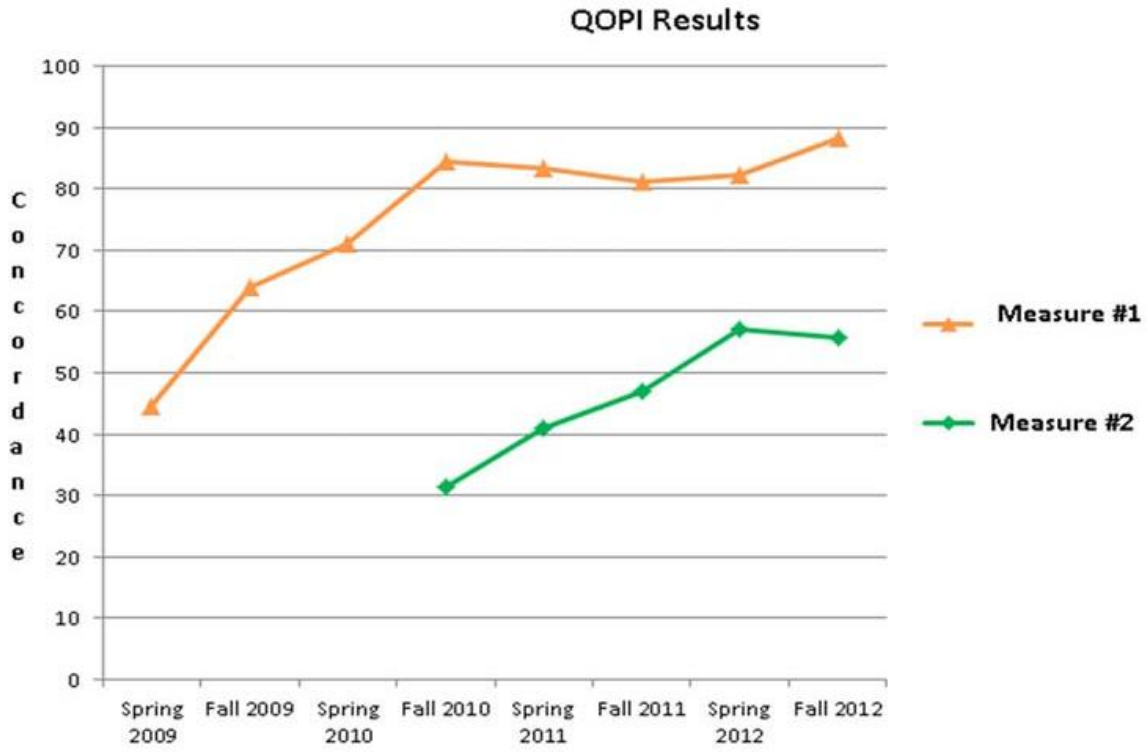


Core 21: Smoking Status

Best Site Rate - Fall 2008: 100.00%; Best Site Rate - Spring 2009: 100.00%

Benchmark Group	Time Period	Numerator	Denominator	% of Charts	95% C.I. Low	95% C.I. High
QOPI Practice	Fall 2008	47	57	82.5%	70.1%	91.3%
	Spring 2009	34	36	94.4%	81.4%	99.4%
QOPI Aggregate	Fall 2008	48	58	82.8%	70.6%	91.5%
	Spring 2009	34	36	94.4%	81.4%	99.4%

Guidance Uptake and Demonstrated Improvement



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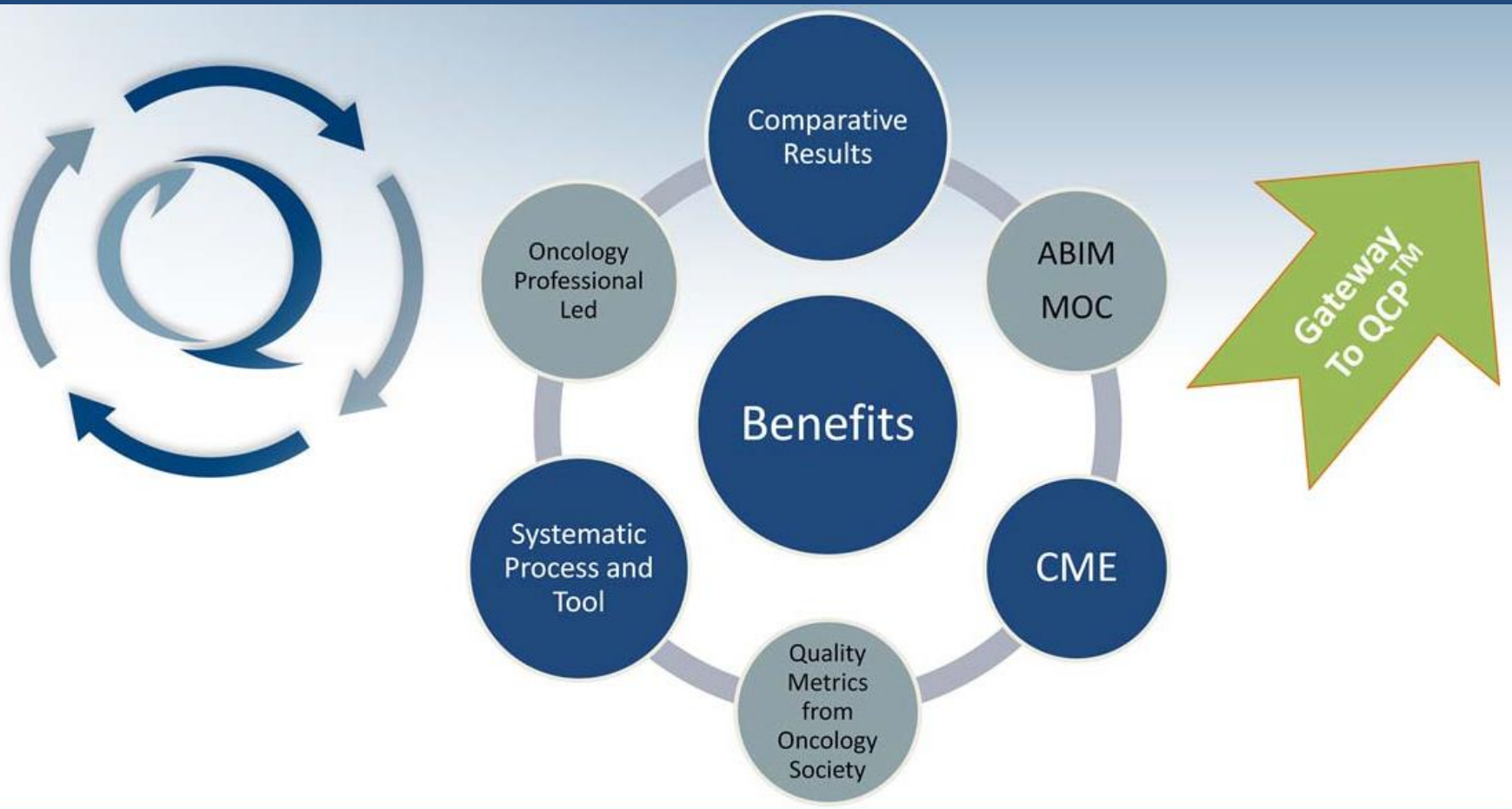
American Society of Clinical Oncology

Resources for Potential Gaps in Care

- Fertility preservation
- Treatment summary to patient
- Infertility risks discussed
- Treatment summary process complete
- Smoking cessation counseling
- Enrolled in hospice more than 7 days
- Hep B virus test prior to rituximab (NHL)
- Adjuvant chemotherapy recommended Stage IA NSCLC (Lower Score - Better)

ASCO
American Society of Clinical Oncology



Continuous Quality Assessment and Improvement

QOPI® The Quality Oncology Practice Initiative

Quality Cancer Care: Pursuing Excellence

ASCO® American Society of Clinical Oncology

Program Goal: Practice Improvement

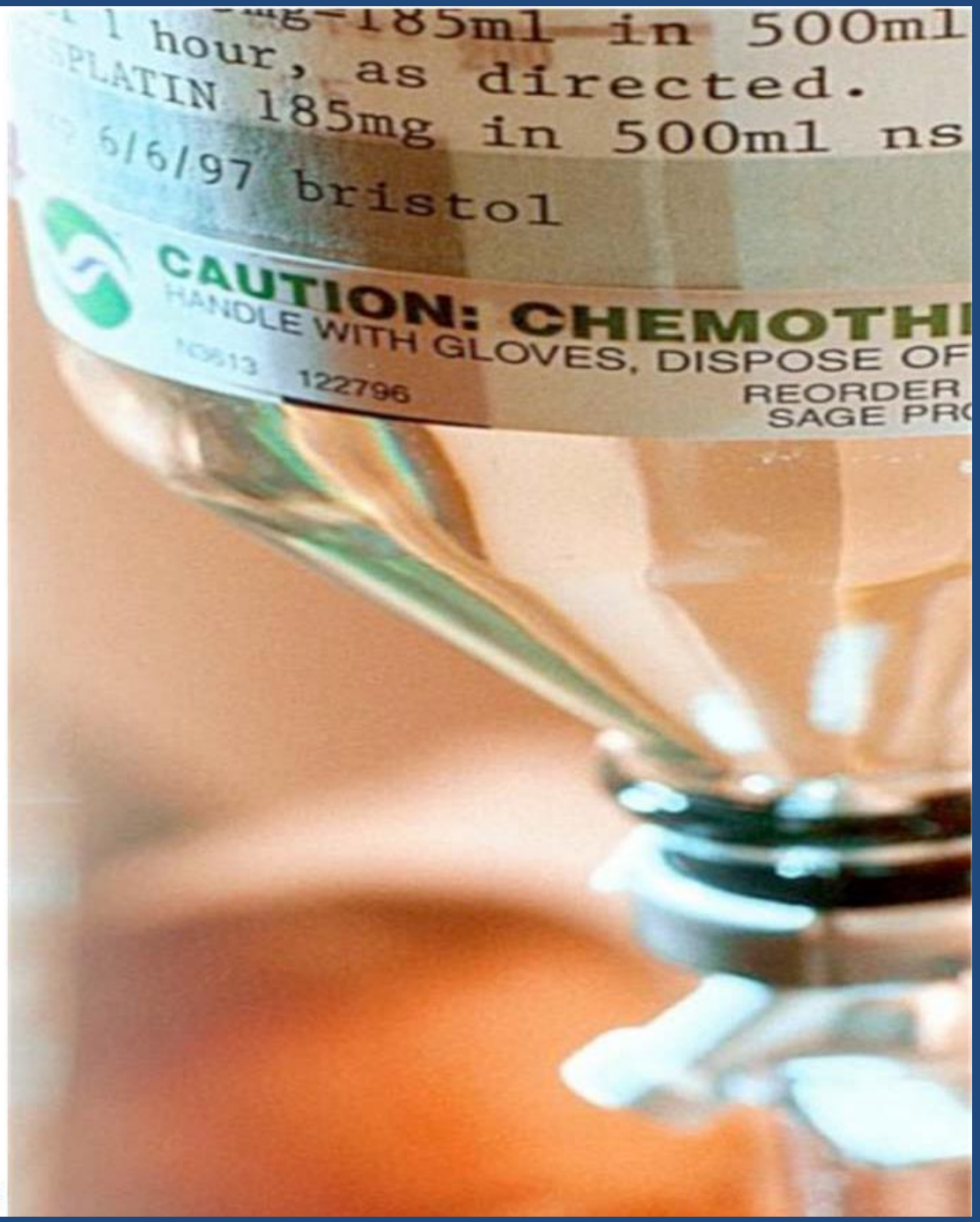
- Promote the highest quality cancer care as defined by the clinician experts
- Provide a trusted solution to satisfy external demand for quality activities.

QCP
QOPI Certification Program
Quality Cancer Care: Recognizing Excellence

★ Administration of anticancer agents is complex and fraught with the potential for patient harm

★ Clinicians seek to provide safe, high quality patient care

★ ASCO's Quality Oncology Practice Initiative Certification Program provides a Pathway and Designation of achieving safe and high quality cancer care.



QCP
QOPI Certification Program

Standards

There is growing appreciation that as the complexity of our interactions increase, standardization of care improves outcomes and increases safety.

The *QOPI Certification* designation can be used by certified practices to demonstrate a commitment to quality

BENEFITS OF QOPI CERTIFICATION INCLUDE:

- **Practice Improvement** – Benchmark performance, implement improved systems, and provides structural standards to aid practice management.
- **A Demonstration of Quality** – Benchmark against national standards and demonstrate improved standards and processes to safeguard both practice and patients.
- **Improved Efficiency, Effectiveness** – Translate policies and procedures into practice and streamline interdepartmental communications to keep better records and avoid costly errors.
- **Public Trust, Competitive Edge** – Achieve recognition from health plans and incorporate QOPI Certification status in practice marketing materials to patients, caregivers, and your medical community.

QCP

QOPI Certification Program

Quality Cancer Care: Recognizing Excellence

20 Certification Standards

Practices applying for QOPI Certification must meet the 20 Certification Standards, based on the ASCO/ONS Standards for Chemotherapy Administration

PRACTICE AREAS	
	Staffing
	Treatment Planning & Chart Documentation
	Informed Consent
	Chemotherapy Orders
	Drug Preparation
	Chemotherapy Administration
	Patient Monitoring and Assessment
	Preparedness for emergency situations
	Oral Chemotherapy
	Patient Education

QCP

QOPI® Certification Program

Quality Cancer Care: Recognizing Excellence

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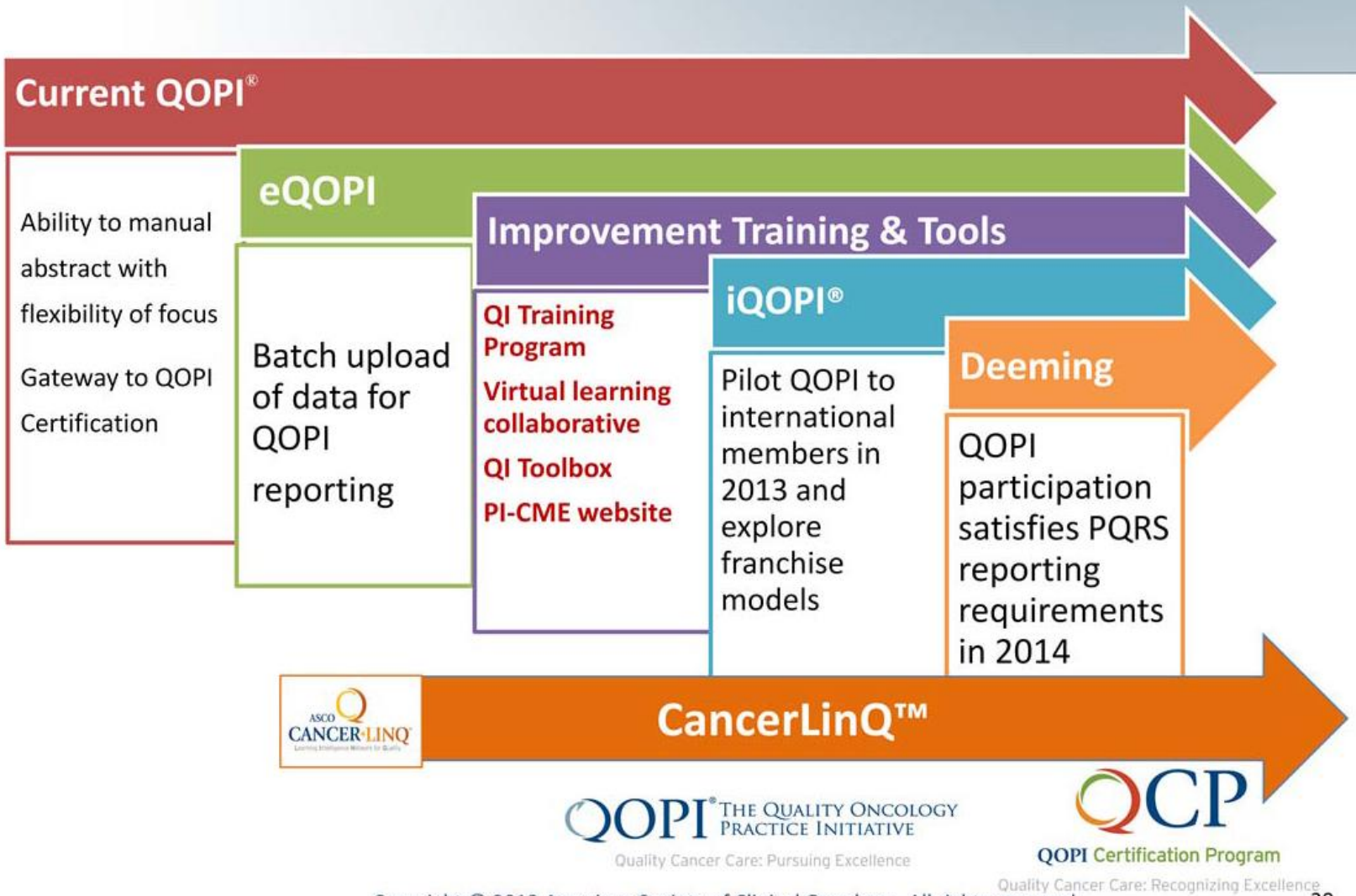
Program Eligibility

QCP
QOPI Certification Program
Quality Cancer Care: Recognizing Excellence

- Certification is awarded on the practice level. To be eligible to apply, a practice must:
  - participate in a QOPI collection round and abstract charts for the 5 modules required for Certification (symptom/toxicity management, EOL, Breast, CRC and NSCLC) (Specialty clinics abstract only for modules that apply.),
  - follow the QOPI sampling methodology and meet your target number of charts per module, and
  - meet the scoring requirements.
- Multi-site practices must participate in QOPI and apply with all practice sites. For the purposes of Certification the defining feature of a "practice" is use of the same policies and procedures. Practice must demonstrate they are functionally integrated.

Where we are heading….



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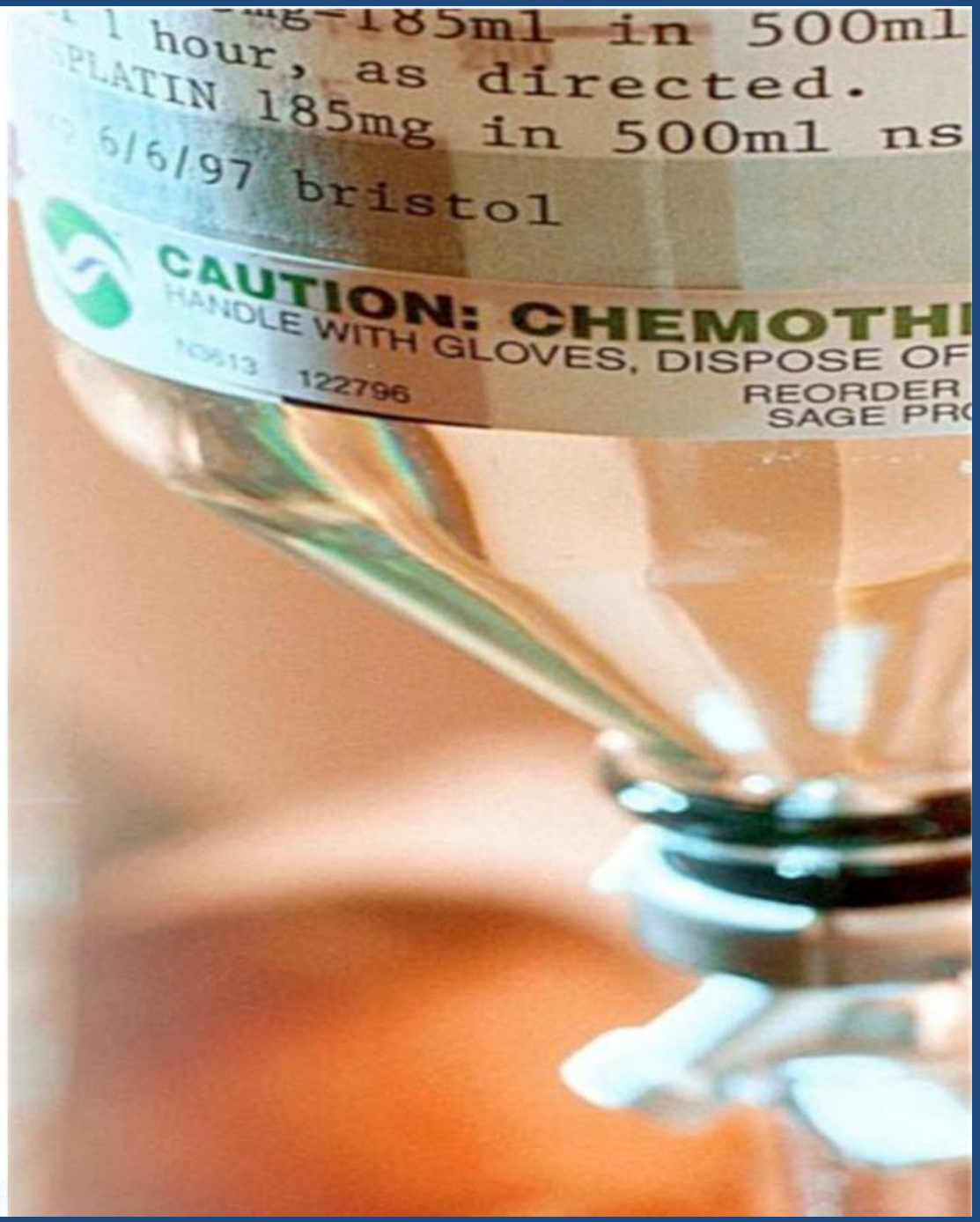

Original Contribution

2013 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards Including Standards for the Safe Administration and Management of Oral Chemotherapy

By Michael N. Neuss, MD, Martha Polovich, PhD, RN, AOCN, Kristen McNiff, MPH, Peg Esper, MSN, RN, ANP-BC, AOCN, Terry R. Gilmore, RN, Kristine B. LeFebvre, MSN, RN, AOCN, Lisa Schulmeister, MN, APRN-BC, OCN, FAAN, and Joseph O. Jacobson, MD, MSc

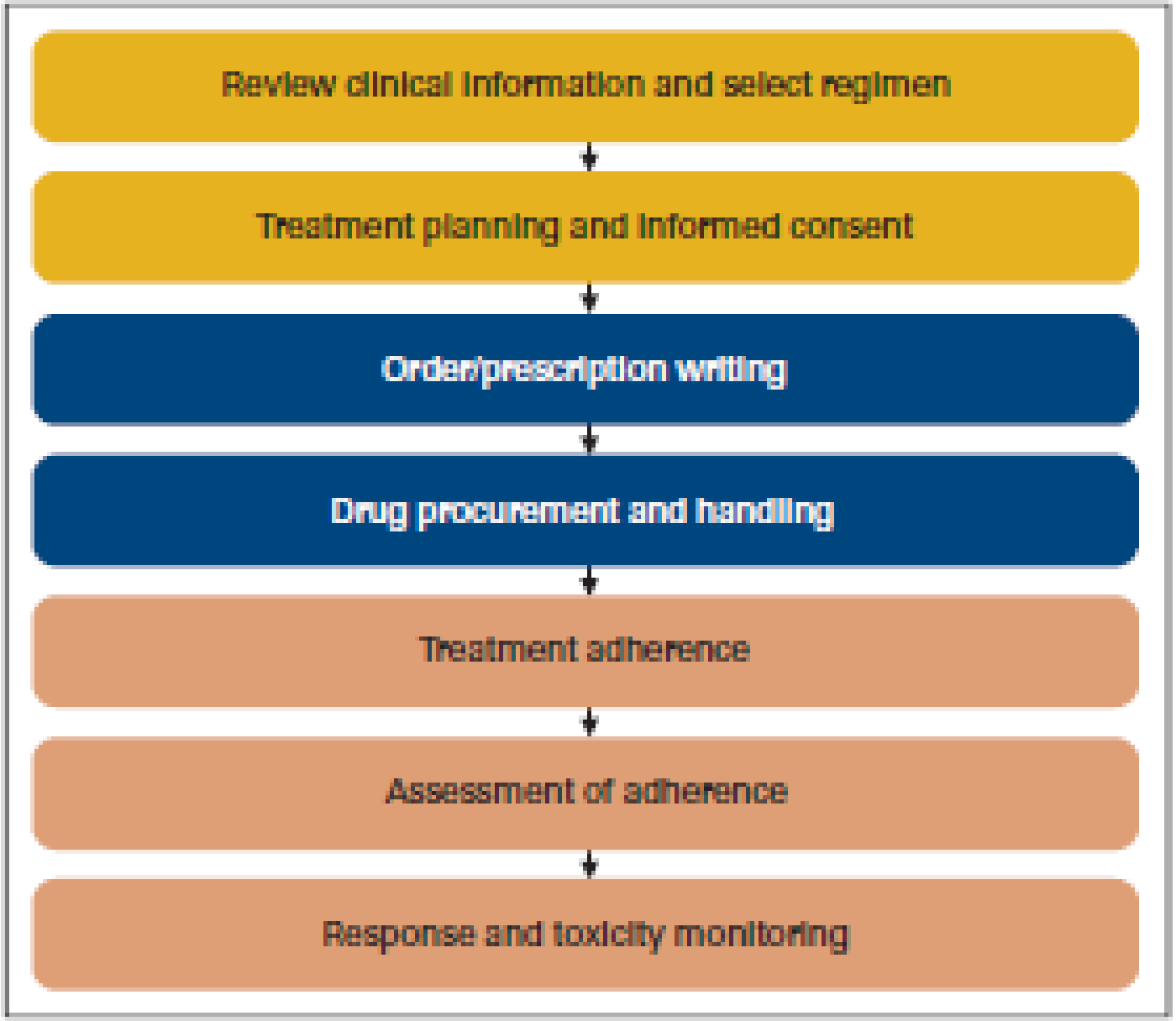

Figure 1. Oral chemotherapy administration flow.

Table 1. ASCO/ONS Chemotherapy Administration Safety Standards: Definitions

Term	Definition
Adherence	The degree or extent of conformity to the provider's recommendations about day-to-day treatment with respect to timing, dosing, and frequency (synonymous with compliance).
Chemotherapy	All antineoplastic agents used to treat cancer, given through oral and parenteral routes or other routes as specified in the standard. Types include targeted agents, alkylating agents, antimetabolites, plant alkaloids and terpenoids, topoisomerase inhibitors, antitumor antibiotics, monoclonal antibodies, and biologics and related agents. Hormonal therapies are not included in the definition of chemotherapy for the standards.
Chemotherapy regimen	One or more chemotherapeutic agents used alone or in combination in a well-defined protocol, generally administered cyclically.
Chemotherapy setting (site)	All chemotherapy treatment settings (inpatient and outpatient).
Clinical encounter	Clinical encounters include each inpatient day, practitioner visits, and chemotherapy administration visits, but not laboratory or administrative visits.
Compliance	The degree or extent of conformity to the provider's recommendations about day-to-day treatment with respect to timing, dosing, and frequency (synonymous with adherence).
Persistence	The ability of a person to continue to take medication over the prescribed and chronic course of an illness, including getting and taking refills on initial prescriptions, often reflecting education.
Practitioner	Licensed independent practitioner, including physicians, advanced practice nurses (nurse practitioner or clinical nurse specialist), and/or physician assistants, as determined by state law.

Table 2. Summary of Changes and Additions to the 2011 ASCO/ONS Chemotherapy Administration Safety Standards

2011 Standard	Changes	Public Comment (% "yes" responses rounded down)	2013 Standards
1D	Added "and safe handling of hazardous chemotherapy agents"	96%—No changes made.	1D
1F	Added "in the health care setting"	93%—No changes made.	1F
New	Proposed fertility discussion/pregnancy screening	91%—Split into two standards; pregnancy screening added to 2C and fertility education added to 18D.	2C and 18D
New	Proposed assessment of barriers before initiation of oral chemotherapy	86%—Proposed standard revised on the basis of comments.	2I
New	Proposed standard addressing drug storage	96%—Minimal edits made on the basis of comments.	8
8	Proposed documentation of changes made to oral chemotherapy regimens	96%—No changes made.	9
New	Proposed items to include in a prescription for oral chemotherapy	92%—Proposed standards revised on the basis of comments.	12
New	Proposed communication for discontinuation of oral chemotherapy	91%—Minimal edits made based on comments.	14
13	Additions of labeling requirements specific to oral chemotherapy	95%—No changes made.	16
New	Proposed standard to document patient engagement	80%—Comments raised concerns about the ability to measure engagement. Dropped as a standard; concept incorporated into existing standard.	18
15	Proposed additions to patient education materials.	98%—Revised to reflect specific needs of oral chemotherapy.	20
18	Proposed verification of IV pump rate if applicable.	88%—Edited language to improve clarity and the ability to assess.	21B
New	Proposed assessment of adherence to oral chemotherapy	87%—Considerations raised in public comment were discussed at the workshop. Changed from policy to process in place.	25
New	Proposed medication reconciliation and drug-drug interaction analysis at each clinical encounter.	90%—Minor edits from workshop discussion and comments. Revised existing standard.	27
25	Proposed addition of "monitoring visits" to existing standards.	91%—Proposed change not made, as the standard incorporates all types of visits.	25
27	Proposed changes to enhance communication	87%—Edited current standard for clarity in response to public comment.	31
New	Proposed standard to monitor adherence and toxicity in oral chemotherapy	93%—No changes made.	35

Abbreviation: IV, intravenous.

Table 4. American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards

Chemotherapy Administration Safety Standards
Staffing-related standards
1. The practice/institution has policies, procedures, and/or guidelines for verification of training and continuing education for clinical staff.
A. Orders for parenteral and oral chemotherapy are written and signed by licensed independent practitioners who are determined to be qualified by the practice/institution according to the practice's/institution's policies, procedures, and/or guidelines.
B. Chemotherapy drugs (oral or parenteral) are prepared by a pharmacist, pharmacy technician, or nurse determined to be qualified according to the practice's policies, procedures, and/or guidelines.
C. Only qualified physicians, physician assistants, advanced practice nurses, or registered nurses administer chemotherapy.
D. The practice/institution has a comprehensive educational program for new staff administering chemotherapy, including a competency assessment, or the practice/institution uses an established educational program regarding chemotherapy administration that ends in competency assessment. Education and competency assessment regarding chemotherapy administration includes all routes of administration used in the practice/institution site (eg, parenteral, oral, intrathecal, intraperitoneal, intravesicular), and safe handling of hazardous chemotherapy agents.
An example of an established educational program is the ONS Chemotherapy and Biotherapy Course.
E. The practice/institution has a standard mechanism for monitoring chemotherapy administration competency at specified intervals.
Annual competency reassessment is recommended.
F. There must be at least one clinical staff member who maintains current certification in basic life support on site during chemotherapy administration in the health care setting.
Certification should be from a nationally accredited course. Clinical staff includes staff involved in patient care; RNs, MDs, NPs, etc.

Table 4. American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards

Chemotherapy Administration Safety Standards

Chemotherapy planning: Chart documentation standards

2. Before the first administration of a new chemotherapy regimen, chart documentation available to the practice/institution includes:

   A. Pathologic confirmation or verification of initial diagnosis. If original pathology report is unobtainable, note of explanation is in chart or a reference to primary source pathology.

      This standard does not imply the need to rebiopsy if not clinically necessary.

   B. Initial cancer stage or current cancer status. Cancer stage is defined at diagnosis. Cancer status includes a current description of the patient's disease since diagnosis/staging, if relevant (eg, recurrence, metastases).

   C. Complete medical history and physical examination that includes, at minimum, height, weight, pregnancy screening (when applicable), and assessment of organ-specific function as appropriate for the planned regimen.

      Example of assessment of organ-specific function as appropriate for the planned regimen: patient plan for cisplatin requires pretreatment assessment of kidney function.

   D. Presence or absence of allergies and history of other hypersensitivity reactions.

   E. Documentation of patient's comprehension regarding chemotherapy regimens (and associated medications), including information regarding disease.

   F. Assessment regarding psychosocial concerns and need for support, with action taken when indicated.

      Documentation of psychosocial concerns may include copy of distress, depression, or anxiety screening form in the chart; patient self-report of distress, depression, or anxiety; or chart documentation regarding patient coping, adjustment, depression, distress, anxiety, emotional status, family support and care giving, coping style, cultural background, and socioeconomic status.

   G. The chemotherapy treatment plan, including, at minimum, chemotherapy drugs, doses, anticipated duration, and goals of therapy.

   H. For oral chemotherapy, the frequency of office visits and monitoring that is appropriate for the individual and the antineoplastic agent and is defined in the treatment plan.

   I. Before initiation of an oral chemotherapy regimen, assessment of the patient's ability to obtain the drug and administer it according to the treatment plan is documented, along with a plan to address any identified issues.

      Assessment includes socioeconomic, psychosocial, financial, administrative and regulatory factors that may influence initiation and/or adherence to prescribed regimen.

General chemotherapy practice standards

3. The practice/institution:

   A. Defines standard chemotherapy regimens by diagnosis with references readily available, and/or

   B. Identifies source(s) for chemotherapy regimens, including local or centralized institutional review board–approved clinical research protocols or guidelines.

4. For orders that vary from standard chemotherapy regimens, practitioners provide a supporting reference. Reasons for dose modification or exception orders are documented.

   Exception orders may include notation that standard treatment is contraindicated as a result of pre-existing comorbidity, organ dysfunction, or prior therapy.

5. The practice/institution maintains written statements that determine the appropriate time interval for regimen-specific laboratory tests that are:

   A. Evidence based when national guidelines exist (eg, American Society of Clinical Oncology or National Comprehensive Cancer Network guidelines), or

   B. Determined by practitioners at the site.

   Documentation of regimen-specific laboratory tests may be part of standardized regimen orders.

6. The practice/institution maintains a policy for how informed consent is obtained and documented for chemotherapy.

   The practice/institution may provide options for consent (eg, use of chart documentation of patient consent or a signed patient consent form) that allow for variation among practitioners in the practice/institution.

7. If the practice/institution administers chemotherapy that is prepared (mixed) off site, the practice/institution maintains a policy for quality control of that chemotherapy.

8. If practice/institution manages its own pharmacy, the practice/institution has a policy regarding the storage of chemotherapy (including separation of look-a-like products, sound-a-like products, and agents available in multiple strengths). Chemotherapy is stored in a designated area according to regulatory guidelines.

Chemotherapy order/prescription standards

9. The practice/institution does not allow verbal orders except to hold or stop chemotherapy administration. New orders or changes to orders, including changes to oral chemotherapy regimens (eg, dose adjustments communicated directly to patients), are documented in the medical record.

   Fax and e-mail orders are considered written orders.

10. The practice/institution maintains and uses standardized, regimen-level, preprinted or electronic forms for parental chemotherapy prescription writing.

    Standardized forms may be incorporated into e-prescribing software or electronic health records.

11. Order forms inclusively list all chemotherapy agents in the regimen and their individual dosing parameters. All medications within the order set are listed using full generic names and follow Joint Commission standards regarding abbreviations.

    Brand names should be included in orders only where there are multiple products or when including the brand name otherwise assists in identifying a unique drug formulation.

    Complete orders must include:

    A. Patient's full name and a second patient identifier (eg, medical record number, DOB)

    B. Date

    C. Diagnosis

    D. Regimen name and cycle number

    E. Protocol name and number (if applicable)

    F. Appropriate criteria to treat (eg, based on relevant laboratory results and toxicities)

    G. Allergies

    H. Reference to the methodology of the dose calculation or standard practice equations (eg, calculation of creatinine clearance)

    I. Height, weight, and any other variables used to calculate the dose

    J. Dosage

    Doses do not include trailing zeros; use a leading zero for doses < 1 mg.

    K. Route and rate (if applicable) of administration

    L. Length of infusion (if applicable)

    M. Supportive care treatments appropriate for the regimen (including premedications, hydration, growth factors, and hypersensitivity medications)

    N. Sequence of drug administration (if applicable)

    Practices/institutions are not expected to be in full compliance with this standard if they currently have electronic ordering systems that prevent compliance. Appropriate changes should be implemented as soon as possible to ensure that electronic ordering systems integrate all of these elements. If the information cannot be captured in the electronic system, it should be documented within the patient record.

12. Complete prescriptions for oral chemotherapy include:

    A. Patient's full name and a second patient identifier (eg, medical record number, DOB)

    B. Drug name

    C. Date

    D. Reference to methodology of dose calculation, height, weight and other variables (as applicable)

    E. Dosage

    F. Quantity to be dispensed

    G. Doses may be rounded to the nearest tablet size or specify alternating doses each day to obtain the correct overall dosage

    Doses do not include trailing zeros; use a leading zero for doses < 1 mg

    H. Route and frequency of administration

    I. Duration of therapy number of days of treatment (if the medication is not to be taken continuously)

    J. Number of refills (including none)

Practices/institutions are not expected to be in full compliance with this standard if they currently have electronic ordering systems or electronic prescribing systems that prevent compliance. Appropriate changes should be implemented as soon as possible to ensure that electronic ordering or prescribing systems integrate all of these elements. If the information cannot be captured in the electronic system, it should be documented within the patient record.

13. Orders for parenteral/oral chemotherapy should be written with a time limitation to ensure appropriate evaluation at predetermined intervals.

14. The practice/institution maintains procedures for communicating discontinuation of oral chemotherapy, including patient education regarding time to stop treatment, and patient education regarding disposal of remaining medication.

In certain circumstances, it may be appropriate to alert the dispensing pharmacy when the oral chemotherapy is discontinued.

Drug preparation

15. A second person (a practitioner or other personnel approved by the practice/institution to prepare or administer chemotherapy) independently verifies each order for chemotherapy before preparation, including confirming:

    A. Two patient identifiers

    B. Drug names

    C. Drug dose

    D. Drug volume

    E. Route of administration

    F. Rate of administration

    G. The calculation for dosing (including the variables used in this calculation)

    H. Treatment cycle and day of cycle

16. Chemotherapy drugs are labeled immediately upon preparation, including, at minimum:

A. Patient's full name and a second patient identifier (eg, medical record number, DOB)

B. Full generic drug name

C. Drug administration route

D. Total dose to be given

E. Total volume required to administer this dosage

F. Date of administration

G. Date and time of preparation

H. Date and time of expiration when not for immediate use

Immediate use must be defined by institutional policy, state, and federal regulations (eg, use within 2 h)

I. Special handling instructions as appropriate

J. Administration instructions (oral agents)

K. Number of refills (oral agents)

L. Prescriber name (oral agents)

Practices/institutions are not expected to be in full compliance with this standard if they currently have electronic systems that are unable to meet these labeling requirements. Appropriate changes should be implemented as soon as possible to ensure that electronic labels integrate all of these elements.

17. Practices/institutions that administer intrathecal medication maintain policies specifying that intrathecal medication will:

A. Not be prepared during preparation of any other agents

B. Be stored, once prepared, in an isolated container or location with a uniquely identifiable intrathecal medication label

C. Be delivered to the patient only with other medication intended for administration into the CNS

Patient consent and education

18. Before initiation of a chemotherapy regimen, each patient is given written documentation, including, at minimum:

A. Information regarding his or her diagnosis

B. Goals of therapy

C. Planned duration of chemotherapy, drugs, and schedule

D. Information on possible short- and long-term adverse effects, including infertility risks

E. Regimen- or drug-specific risks or symptoms that require notification and emergency contact information, including:

- How to contact the practice or organization
- Symptoms that should trigger a call
- Who should be called in specific circumstances (oncologist or other provider)

F. Plan for monitoring and follow-up, including appointments with practitioners or laboratory testing

Patient education materials should be appropriate for the patient's reading level/literacy and patient-caregiver understanding. Documentation should include patient feedback reflecting understanding and engagement.

19. Informed consent for chemotherapy must be documented prior to initiation of a chemotherapy regimen.

The consent process should follow appropriate professional and legal guidelines. For more information and sample forms, see http://www.asco.org/consent.

20. All patients who are prescribed oral chemotherapy are provided written or electronic patient education materials about the oral chemotherapy before or at the time of prescription.

Chemotherapy Administration Safety Standards

A. Patient education includes:

- The storage, handling, preparation, administration, and disposal of oral chemotherapy
- Concurrent cancer treatment and supportive care medications/measures (when applicable)
- Possible drug/drug and drug/food interactions
- The plan for missed doses

B. The education plan includes family, caregivers, or others based on the patient's ability to assume responsibility for managing therapy.

Patient education materials should be appropriate for the patient's reading level/literacy and patient-caregiver understanding. Documentation should include patient feedback reflecting understanding and engagement.

Chemotherapy administration

21. Before chemotherapy administration:

A. A practitioner who is administering the chemotherapy confirms with the patient his/her planned treatment prior to each cycle

B. At least two practitioners or personnel approved by the practice/institution to prepare or administer chemotherapy, verify the accuracy of:

- Drug name
- Drug dose
- Drug volume
- Rate of administration
- Expiration dates/times, if applicable; expiration date/time is not required if for immediate use

(Immediate use must be defined by intuitional policy, state, federal regulations, eg, use within 2 h)

- Appearance and physical integrity of the drugs
- Rate set on infusion pump, when utilized

C. A practitioner who is administering the chemotherapy documents that the verification in B was done

D. At least two individuals, in the presence of patient, verify the patient identification using at least two identifiers (eg, medical record number, DOB)

22. Extravasation management procedures are defined and align with current literature and guidelines; antidote order sets and antidotes are accessible.

23. A licensed independent practitioner is on site and immediately available during all chemotherapy administration in licensed infusion centers and acute care settings.

A licensed practitioner must be on site for the initiation of first doses of parenteral chemotherapy and should remain available throughout the administration unless the patient is transitioned to a home care or nonacute facility. Patients/caregivers are educated in procedures for unplanned events and circumstances when subsequent doses are administered in either a home care or nonacute facility.

Monitoring and assessment

24. The practice/institution maintains protocols for response to life-threatening emergencies, including escalation of patient support beyond basic life support.

It is recommended that emergency protocols be reviewed annually.

25. The practice/institution maintains a written policy and/or procedure to complete an initial assessment of patients' adherence to oral chemotherapy. The policy must include a plan for clinical staff to address any issues identified within a time frame appropriate to the patient and regimen.

Examples of assessment for adherence to an oral chemotherapy treatment plan include:

- *Confirmation that the patient filled the prescription as written*
- *Inquiry regarding concerns about treatment costs*
- *Verification that the patient understands how to take the prescribed oral chemotherapy (eg, frequency, with/without food, whole or crushed, etc)*
- *Verification that the patient understands what to do in case of missed doses*
- *Assessment for potential toxicity*

26. On each clinical visit or day of treatment during chemotherapy administration, staff:

A. Assess and document clinical status and/or performance status

B. Document vital signs and weight

C. Verify allergies, previous reactions, and treatment-related toxicities

D. Assess and document psychosocial concerns and need for support, taking action when indicated

This standard applies to all clinical encounters (including each inpatient day, practitioner visits, and chemotherapy administration visits, but not laboratory or administrative visits).

27. At each clinical encounter, staff review and document the patient's current medications, including over-the-counter medications and complementary and alternative therapies. Any change in the patient's medications prompts a review for drug-drug interactions.

This standard applies to all clinical encounters (including each inpatient day, practitioner visits, and chemotherapy administration visits, but not laboratory or administrative visits).

28. The practice/institution maintains referral resources for psychosocial and other supportive care services.

29. The practice/institution has a procedure for documentation and follow-up for patients who miss or cancel scheduled visits and/or chemotherapy treatments.

Chemotherapy Administration Safety Standards

30. The practice/institution evaluates and documents treatment-related toxicities using standard definitions or criteria selected by that practice/institution.

Examples include NCI Common Toxicity Criteria and WHO Toxicity Criteria.

31. The practice/institution has policies and procedures that identify:

A. A process to provide 24/7 triage to a practitioner (eg, on-call practitioner, emergency department) for care of toxicities

B. Consistent documentation and communication of toxicities, modifications in dose or schedule, or discontinuation of treatment, within the practice/institution

32. The practice/institution has a system in place to promote a safe handoff between all sites of care, including evaluating and communicating appropriateness of, and schedule for, chemotherapy administration in another setting.

33. Toxicity assessment documentation is available for planning subsequent treatment cycles.

34. The practice/institution has a process to track cumulative doses of chemotherapy agents associated with a risk of cumulative toxicity.

35. The practice/institution maintains a plan for ongoing and regimen-specific assessment of each patient's oral chemotherapy adherence and toxicity. The policy includes, at minimum, patient assessment for adherence and toxicity at each clinical encounter at the practice/institution, as well as a plan for clinical staff to address any issues identified.

36. The practice/institution uses standard, disease-specific processes to monitor treatment response (e.g., use of evaluations, laboratory results, or scans/imaging) that are based on published literature/guidelines or are determined by the practice/institution.

37. The practice/institution encourages the reporting of errors and near misses and has a formal process for evaluating the data. Error and near-miss reports are reviewed and evaluated at least semiannually.

NOTE: The current version of these consensus standards reflects modifications that are intended to extend the standards to address the safe use of oral chemotherapeutic agents. The American Society of Clinical Oncology/Oncology Nursing Society (ASCO/ONS) standards are intended to reflect current thinking on best practices and, as such, are intended to be a "living" document; future modifications are expected.

Although the ASCO/ONS standards were not developed to address this issue, ASCO and ONS endorse the safe handling of chemotherapy agents. Published guidelines define the expectations for organizations and health care workers related to the use of safe handling precautions (American Society of Health System Pharmacists: Am J Health Syst Pharm 63:1172-1193, 2006; National Institute for Occupational Safety and Health: DHHS publication No. 2004-165, 2004; Occupational Safety and Health Administration: OSHA technical manual, 1995; Polovich M et al: Pittsburgh, PA, Oncology Nursing Society, 2009; US Pharmacopeial Convention, Rockville, MD, 2008). Education, training, and competency validation for chemotherapy administration must necessarily include this aspect of practice. Organizations should focus on a culture of safety, because of the relationship between patient and health care worker safety (Friese CR et al: BMJ Qual Saf, 2011; Polovich M, Clark PC: Oncology Nursing Forum, 2012).

The standards are not deemed comprehensive and do not account for individual patient variation. It is the responsibility of each administering agent to determine the best methods for chemotherapy administration for each patient. The standards are not medical advice or legal advice. To the extent that the standards conflict with applicable federal, state, or local legal requirements, practitioners should comply with those requirements. The administering agent is solely responsible for, and assumes all risks of, administering chemotherapy drugs notwithstanding any adherence to the standards herein. ASCO and ONS disclaim any and all liability with respect to the standards and the execution of the standards by any party.

Abbreviations: DOB, date of birth; NCI, National Cancer Institute; NP, nurse practitioner; RN, registered nurse.

ASCO/ONS standards were not developed to address this issue, ASCO and ONS endorse the safe handling of chemotherapy agents.

Published guidelines define the expectations for organizations and health care workers related to the use of safe handling precautions

American Society of Health System Pharmacists:
National Institute for Occupational Safety and Health:
US Pharmacopeia Convention

Education, training, and competency validation for chemotherapy administration must necessarily include this aspect of practice.

Organizations should focus on a culture of safety, because of the relationship between patient and health care worker safety.

Next Steps

- Review ASCO-ONS, CDC, and NIOSH standards
- Next Meeting:
  - Achieve consensus on infection control and potency standard recommendations
  - Send to DHMH what you think the standard should be for infection control and potency by **Friday, August 29th**