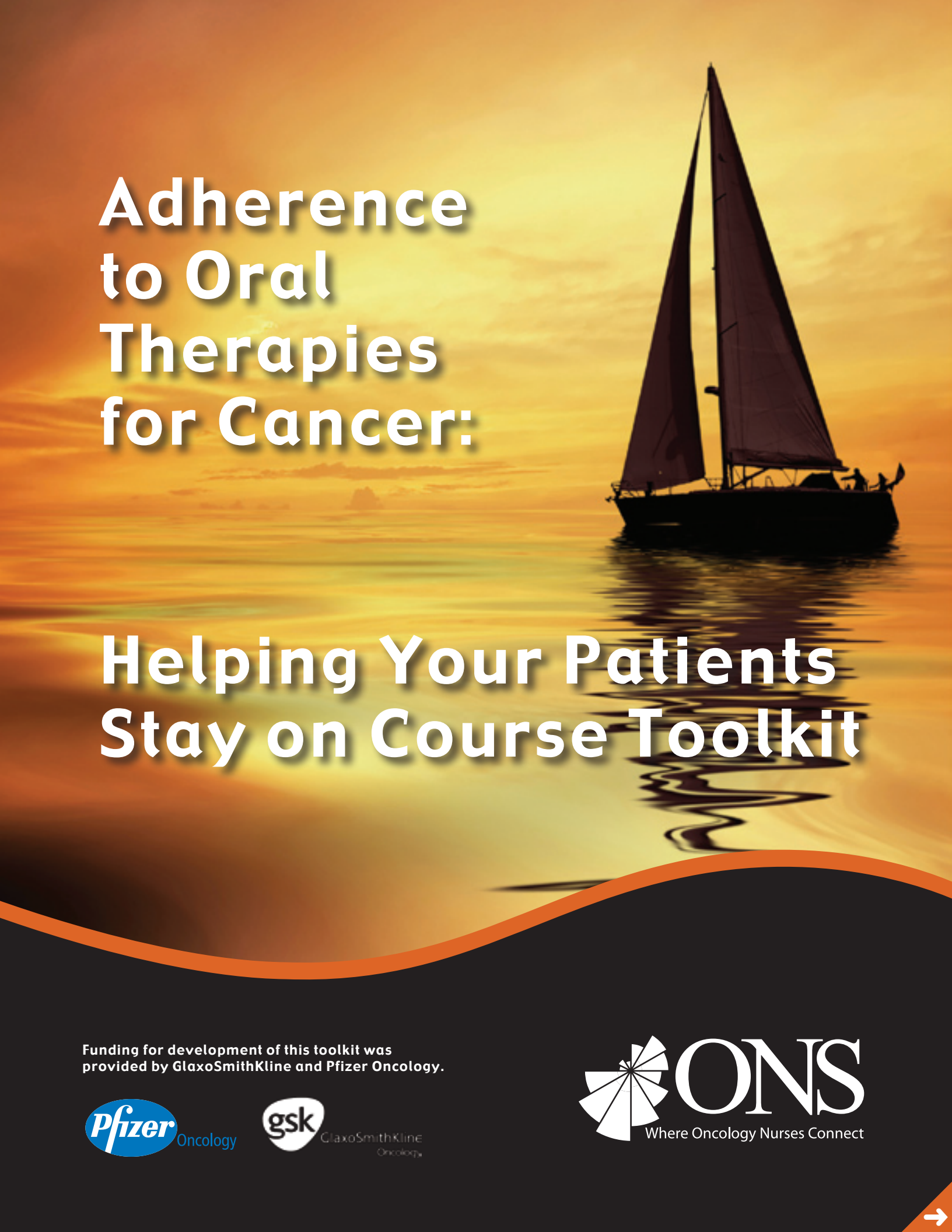

Adherence to Oral Therapies for Cancer:

Helping Your Patients Stay on Course Toolkit

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Adherence to Oral Therapies for Cancer: Helping Your Patients Stay on Course Toolkit

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Section 1

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Section 1 Introduction

Oral formulations of chemotherapy and hormonal therapies have been used for decades and include many familiar agents, such as cyclophosphamide, melphalan, and tamoxifen. Cancer treatment has experienced a rapid increase in oral oncolytics, including cytotoxic agents, small-molecule inhibitors, and agents targeted at receptors that regulate cellular differentiation, growth, and survival. The expansion of oral oncolytics is projected to continue, as an estimated 25% of anticancer agents in the research pipeline are designated for oral administration (Michaud & Choi, 2008). The increase in oral oncolytics affects the infrastructure of chemotherapy administration as the site of care moves from intermittent IV infusions in an infusion center to continuous oral dosing taken in the patient's home. With the increase in oral cancer therapies, concerns about adherence also have increased. This paradigm shift affects how oncology nurses will manage patients under their care and requires nursing resources above and beyond traditional on-site chemotherapy teaching and monitoring.

1.1. Defining Adherence and Recognizing Its Prevalence

The World Health Organization (WHO, 2003) defines adherence as the extent to which a person's behavior in taking medication or executing lifestyle changes agrees with recommendations from a healthcare provider. A patient is considered to be nonadherent if he or she misses doses, takes additional doses to those prescribed, or takes doses either in the wrong quantity or at the wrong time (Ruddy, Mayer & Partridge, 2009). Considering all medications given for all reasons, WHO projects that only about 50% of patients typically take their medicines as prescribed. Adherence issues aren't unique to oncology—primary care healthcare providers (HCPs) have acknowledged the high prevalence of nonadherence to treatment regimens for chronic diseases such as diabetes, heart failure, and HIV antiretroviral therapy. Oncology HCPs generally assume that patients with cancer will adhere to treatment recommendations because of the seriousness of a cancer diagnosis; however, reports in the literature have demonstrated adherence levels as low as 20% (Lebovits et al., 1990; Partridge, Avorn, Wang, & Winer, 2002; Thompson, Dewar, Fahey, & McCowan, 2007).

Adherence to prescribed cancer therapy is more than taking the medicine on time—nonadherence can result in drug resistance and suboptimal response to therapy, disease progression, and death. Poor adherence to tamoxifen, for example, has been significantly associated with increased risk of death from breast cancer (Thompson et al., 2007).

1.2. Using This Toolkit

Oncology nurses recently have begun to identify and address the challenges of supporting an increasing number of patients being treated with oral cancer agents. Osterberg and Blaschke (2005) stated that the ability for an HCP to recognize nonadherence is poor and that results are mixed for standard interventions to improve adherence. This toolkit provides strategies and resources nurses can use to facilitate adherence among patients with cancer:

- ➜ Safety concerns: drug-drug and food-drug interactions, adverse effects
- ➜ Pharmacy and reimbursement/financial resources
- ➜ Monitoring of adherence
- ➜ Motivational interviewing and counseling
- ➜ Change theory and helping patients to change nonadherence into adherence.

Throughout this toolkit you will find links to multiple tools that will provide additional information and resources that can help facilitate care of patients receiving oral therapies. These tools may be printed and copied for your use.

Section 2

Role of Oral Therapies in Oncology

The use of orally administered cancer therapy is likely to increase dramatically in the coming years. Agents such as tamoxifen, procarbazine, and oral cyclophosphamide have long been part of the management of many malignancies. More recently developed oral chemotherapy formulations include fluorouracil derivatives such as capecitabine, and many other novel agents, administered orally, have been approved in the past decade. Oral agents also have a dominant role in the evolving field of chemoprevention of malignancies, where oral administration may improve efficacy in some settings by facilitating chronic exposure to the drug. **Tool 1** includes a listing of oral therapies available at the end of 2009..

Because oral counterparts of IV agents may have different side effect profiles, they may be better tolerated in some circumstances (Carney, 1991). Furthermore, as oncologists pay more attention to patient preferences and quality-of-life issues in clinical care, treatment options that enhance flexibility for patients are likely to be used more often. There is little question that oral regimens are more convenient for patients, and initial research (Liu, Franssen, Fitch, & Warner, 1997) has revealed that patients prefer oral to IV chemotherapy, so long as efficacy is not compromised.

Section 3

Unique Considerations With Oral Therapies

Adherence to an oral cancer therapy regimen can be a challenging commitment for patients and their caregivers. Highly motivated patients who take an active role in their care are well suited to manage home oral administration of chemotherapy, but this does not mean that, with good teaching and support, less motivated patients would be unsuccessful. The challenges for oncology nurses include identifying motivated patients, increasing motivation in others, and addressing barriers that stand in the way of optimal adherence. Challenges for patients include complexity of the medication regimen and scheduling issues, interactions with other drugs and foods, adverse effects, and access to medications.

3.1. Complexity of Oral Therapies in Oncology

The more complex the regimen, the higher the risk of error and nonadherence. This is true for all oral medication regimens, not just those treating cancer. Medication regimens that require multiple daily doses or complicated administration instructions specific to timing, dietary restrictions, or other factors often result in lower adherence (Haynes, McDonald, & Garg, 2002; Partridge et al., 2002).

3.2. Drug-Drug and Food-Drug Interactions

Oral chemotherapy, targeted agents, and chemoprevention agents have drug-drug and drug-food interactions that may or may not mirror their IV counterparts (if any exist.) While some classes of agents, such as the tyrosine kinase inhibitors, share similarities in regard to drug-drug interactions, there is enough variation that the practitioner should not rely on the class of drug to determine these interactions. It is prudent to address each agent individually, relying on published information and experts in the field to determine the type and extent of the interactions and the recommendations for how to deal with them.

Oral cancer therapies can interact with other medicines or food. Some are taken with food or immediately after eating; others must be taken on an empty stomach (up to one hour before or two hours after eating). A regimen may include more than one drug, with each drug having different eating guidelines. An example is the capecitabine-lapatinib combination for metastatic breast cancer. Capecitabine is taken within 30 minutes after eating; lapatinib is taken on an empty stomach. **Tool 1** includes a list of oral therapies, including drug-drug interactions and instructions on timing with meals.

3.3. Adverse Effects

This Toolkit is not designed to provide comprehensive information on the particular adverse effects for each drug. A better resource for that information is the prescribing information for each drug, available from the pharmacy, online at the drug manufacturer's Web site, or via established drug information databases such as MicroMedex®, Lexi-Comp®, or Epocrates®. Patients' anticipation of side effects often is enough to negatively affect their decisions about treatment and can negatively affect adherence as well. Comprehensive patient education at the beginning of therapy will help patients plan for side effects and give them information on what side effects they can safely manage at home or when they need to contact the nurse or doctor for help. Prompt management of side effects as they occur will reassure patients that side effects are manageable and will be addressed by nurses and physicians. **Tool 2** lists common side effects of oral cancer therapies, listed by drug classification. Full side effect profiles for the drugs listed here, as well as additional drugs not listed, can be found in each drug's prescribing information.

3.4. Cost, Insurance, and Access to Medications

A challenge for patients that has a significant impact on adherence is the cost of oral therapies, which can run to more than $10,000 per month. Depending on many variables, insurance plans may or may not cover the drug, and even if they do, sometimes the copay is untenable. The ability to obtain the medication (access) may be a deterrent to adherence, as some pharmacies will choose not to stock the agents because of the cost, and some agents are limited to certain pharmacies by regulatory agencies.

Many drug companies offer patient assistance programs to help with the cost and/or copays, yet these programs can be difficult and confusing to maneuver and monitor. Nurses, pharmacists, or social workers can be invaluable in assisting patients through these issues. **Tool 3** includes information about reimbursement and general resources for patients who may have difficulty paying for their oral therapies for cancer.

Section 3

Unique Considerations With Oral Therapies

What the nurse can do to help the patient navigate a retail pharmacy:

1) Encourage the patient to always utilize one pharmacy. This will help ensure that a current medication profile is maintained and that drug-drug interactions are monitored.

2) Discuss with the patient the importance of disclosing all therapy to all HCPs. Studies show that while up to two-thirds of patients getting treatment for cancer take complementary or alternative medications, only about 10% of those people share that information with the doctor, nurse, or pharmacist (Werneke et al., 2004).

3) Be an advocate for the patient. Ask whether he or she is having any issues accessing the medication from the pharmacy. If so, call and speak with the pharmacist about the importance of the therapy, and determine what barriers exist for successful treatment of the patient.

A listing of the different types of pharmacies that may be available to patients with cancer along with the benefits and concerns for each type is found in **Tool 4**.

Section 4

Challenges to Adherence

Even when patients are motivated to succeed, a number of barriers or challenges—many beyond the control of the patient or HCP—may negatively affect adherence (see **Tool 5**).

4.1. Assessing Patient Adherence

There is a lack of validated tools to assess patient adherence with medications, especially in oncology. One relatively simple tool that has been validated for patient adherence to medications for chronic conditions (Hahn et al., 2008) and can be self-administered by patients is the ASK®-20 survey (available at www.takingmeds.com/index.html).

ASK-20 is a valid and reliable self-administered survey for patients that can identify 20 specific barriers to medication adherence across a spectrum of chronic diseases. It has not been validated in the setting of oral cancer therapies. Use of this survey can help identify barriers and assist nurses with addressing barriers and provide direction for nurses when interviewing patients about their baseline and ongoing adherence. A shorter version, the ASK-12 survey, has been validated in patients with asthma, diabetes, and congestive heart failure but, again, has not been validated in patients with cancer (Matza et al., 2009).

4.2. Monitoring Adherence

Physicians and advanced practice nurses prescribe oral agents for patients with cancer, but the decision about who will monitor and follow the patient for adherence to therapy often remains unclear. Patients should be seen at least once per cycle for a physical assessment and laboratory tests. At that time, HCPs can address questions about adherence with the patient. Between clinic visits, HCPs can use the telephone and e-mail (if the practice permits electronic communication) to check in on patients.

Oral therapy requires a multidisciplinary team for optimal safety and adherence: The physician, nurse, and pharmacist jointly can provide oversight for patients on home-based oral therapies. Nurses have always been key players in teaching patients about IV chemotherapy; however, many nurse clinicians feel less involved in oral chemotherapy teaching. Nurses are patient advocates and should participate in adherence monitoring as part of the multidisciplinary team during the continuum of therapy to increase adherence, promote safety, and evaluate side effects (Winkeljohn, 2007).

Suggest a structured plan of care for these patients during the next patient care meeting. This should include the following:

- Assess and monitor adherence at each visit.
  - Ask about missed doses.
  - Assess for problems.
  - Work toward resolution of problem or problems.
- Use telephone contact to monitor adherence of patients who visit the clinic less regularly, such as those receiving adjuvant long-term hormonal therapy or maintenance dosing.
- Manage side effects early.

Section 4 Challenges to Adherence

4.3. Methods for Monitoring Adherence

Few randomized controlled trials have been conducted to identify a single adherence monitoring method that is superior to others. Most of the methods currently available (see **Tool 6**) are unreliable; for example, patient self-reports tend to overestimate adherence. Further research is still required to optimize adherence in this patient population. A meta-analysis of 61 studies of interventions to improve medication adherence demonstrated a relatively low increase in adherence of 4%–11% (Peterson, Takiya, & Finley, 2003). The investigators also concluded that no single strategy appeared to work best.

There are a number of direct and indirect techniques to monitor individual patient adherence to oral therapy, including pill counts, refill monitoring, patient self-report, and serum drug level assays. The techniques vary from free and noninvasive to invasive tests that involve an economic cost to the patient or healthcare system. The listing of monitoring techniques in **Tool 6** can help HCPs and patients decide which method, if needed, would be most appropriate and provide the most accurate information.

4.4. Treatment Calendars

A relatively easy method to monitor and potentially improve patient adherence is to provide the patient with a personalized treatment calendar listing the dates and times medications are due to be taken. The patient can check off each dose and bring the calendar to appointments for review by the nurse. **Tool 7** contains sample calendars for patients who are on combination chemotherapy-biotherapy for metastatic breast cancer.

Section 5

Strategies for Improving Adherence

Oncology nurses are in an ideal position to help patients identify their barriers to adherence and develop plans to deal with these barriers and improve adherence. Even when external barriers, such as access to medication, have been handled, patients may still face internal barriers such as lack of belief in the treatment or low motivation to stay on course through protracted or complicated medication regimens. Using appropriate interview techniques and helping patients recognize the need to change behavior are tools that oncology nurses can use to improve adherence.

5.1. Patient Interview Techniques

Basic nursing education provides instruction in the principles of patient communication. Listening, being open to discussion about sensitive topics, and using open-ended questions are some of the communication techniques used in everyday nursing practice. The attitude of the nurse toward the patient can affect how open and helpful patient communication will be. Traditional nurse counseling is often directive and focuses on the nurse's assessment and resolution of the problem.

Open-ended questions can't be answered with a "yes" or "no." Rather, they invite patients to share their stories, thus resulting in less-biased data from patients. Open-ended questions allow patients to give spontaneous and unguided responses, which help build trust. Often, the responses to open-ended questions enable nurses to gain information they otherwise might not have considered. Open-ended questions usually begin with the phrase, "Tell me about . . . (how your exercise plan is going)?" or "To what extent . . . (have you been able to take your medication as we had discussed)?" versus closed-ended questions, which usually begin with "Did you . . . (take your medications as prescribed)?" Closed-ended questions focus on the practitioner's agenda and thus place the patient in a passive and less-engaged role.

5.2. Motivational Interviewing

Motivational interviewing (MI) focuses on the patient's perception of the problem and encourages the patient, not the nurse, to find the solution. MI is a method of counseling that is directive and client-centered. It encourages nurses to explore a patient's understanding and concerns and determine his or her readiness for change (Calhoun & Admire, 2005; Levensky, Forcehimes, O'Donohue, & Beitz, 2007; Possidente, Bucci, & McClain, 2005).

MI was developed to counsel patients with addictive behaviors and has not been validated in oncology patient care, including adherence to oral therapies. However, the underlying principles of change and patient-centered approach to minimize resistance to change lend themselves to counseling patients with cancer who are unable to maintain optimal adherence to therapy.

5.3. Core Components of Motivational Interviewing

Empathy and reflective listening are core components of MI. Talking with patients in a supportive, reflective manner will show that the nurse understands the patient's concerns and feelings without judging the patient's actions or goals. Some questions that are concordant with the principles of MI and encourage nonadherent patients to think about the processes that are interfering with adherence include the following:

- "How can I help you?"
- "What do you need to know about _____?"
- "What does this choice mean for treatment of your disease?"

When counseling patients, nurses may feel resistance to their questions. Resistance comes in many forms and is viewed as a problem of communication between the patient and practitioner. Patients may argue with or ignore the nurses, or agree with everything they suggest. It is important to defuse resistance rather than fight it. When encountering resistance, the nurse should consider the following:

- Am I counseling at a level appropriate to the patient's readiness to change?
- Am I pushing the patient to do more than he or she is ready for?
- Am I dismissing the patient's feelings and concerns?
- Am I undermining the patient's sense of personal autonomy?
- Am I acting as expert and telling the patient what to do?

Section 5 Strategies for Improving Adherence

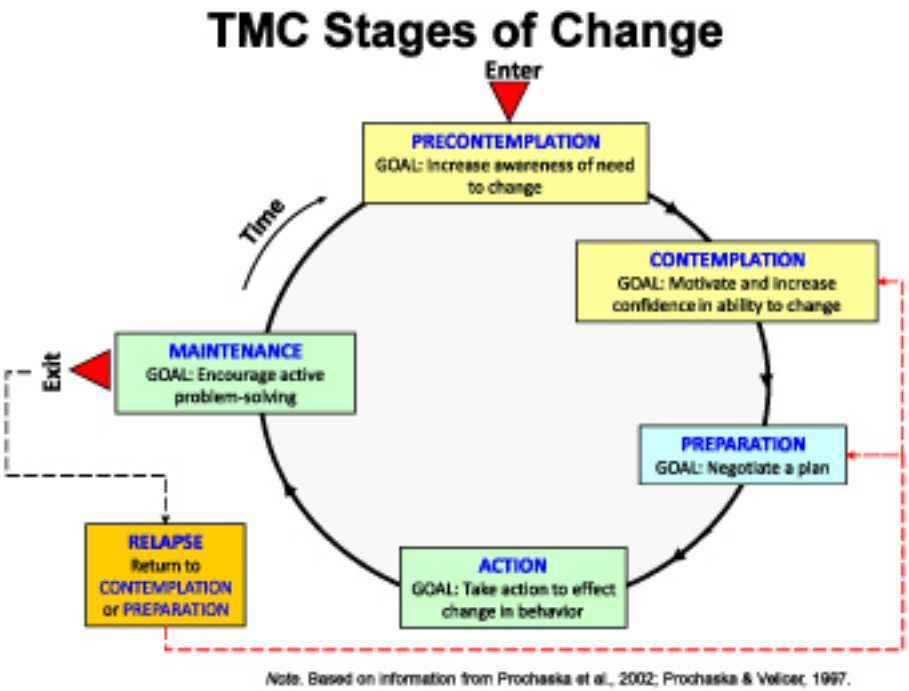
MI can be utilized during procedures such as putting in an IV line or during routine patient education. Nurses do not need to exercise all of the MI techniques but rather should choose those that best fit their own style and their patients' needs. **Tools 8 and 9** contain tables and figures that explain the difference between traditional nurse counseling and MI and also suggest sample dialogue that can help nurses shift to an MI approach.

5.4. Helping Patients Change Behavior to Improve Adherence

Motivation is a fundamental process of change. Once patients are motivated to change behavior that affects adherence, the nurse is able to help them implement behavioral change. Some patients have sufficient internal motivation to recognize personal traits and situations that cause them to stray off course with medication adherence, for example, a busy work or family schedule, travel, forgetfulness, or lack of belief in the need for therapy.

Although motivation needs to come from within the patient—external motivation from the nurse or HCP is not very effective— it is possible to help patients recognize their own ambivalence about the need for change and to change behavior. One model that has been widely used in psychosocial interventions is the Transtheoretical Model of Change (TMC), which involves recognizing the stages of change (see **Figure 1**) and a person's readiness to change behavior (see **Tool 10**) (Prochaska, Redding, & Evers, 2002; Prochaska & Velicer, 1997). Tools for evaluating and assessing the stages of change and readiness to learn are available in **Tools 11 and 12**.

Figure 1. Transtheoretical Model of Change: Stages of Change



Note. Based on information from Prochaska et al., 2002; Prochaska & Velicer, 1997.

5.5. Conclusion

A patient's inability to adhere to oral therapies for cancer can negatively affect clinical benefit and can result in treatment resistance, disease progression, and death. Oral cancer therapies are most effective when patient adherence is optimized. An understanding of patient motivation to adhere to therapy, or to change nonadherent behaviors into behaviors that support adherence, can help patients achieve success in maintaining dosing as prescribed. Interview techniques and change models validated in other disciplines may be applicable to patients with cancer. Nurses, in collaboration with other healthcare professionals, play an important role in monitoring adherence. Identifying potential barriers and implementing intervention strategies will enhance adherence and thus improve clinical outcomes.

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Tool 1

Oral Therapy Agent Information

Drug Name Generic/Brand	Manufacturer City/State	FDA-Approved Oncology Indications	Drug-Drug Interactions	Administration With or Without Food
Bexarotene (Targretin®)	Eisai Inc. Woodcliff Lake, NJ	• Cutaneous T-cell lymphoma	• CYP3A4 inhibitors	With food
Capecitabine (Xeloda®)	Roche Laboratories Nutley, NJ	• Metastatic breast cancer • Metastatic colorectal cancer • Adjuvant colon cancer (stage III)	• Coumarin-derivative anticoagulants	With food
Dasatinib (Sprycel®)	Bristol-Myers Squibb Co. Princeton, NJ	• Chronic myeloid leukemia • Philadelphia chromosome-positive acute lymphocytic leukemia	• CYP3A4 inducers/inhibitors • Antacids • H_2 antagonists • Proton pump inhibitors	With or without food
Erlotinib (Tarceva®)	OSI Pharmaceuticals Inc. Melville, NY Genentech, Inc. South San Francisco, CA	• Non-small cell lung cancer • Pancreatic cancer	• CYP3A4 inducers/inhibitors • H_2 antagonists • Affected by cigarette smoking	Without food
Everolimus (Afinitor®)	Novartis Pharmaceuticals East Hanover, NJ	• Renal cell carcinoma	• CYP3A4 inducers/inhibitors • Grapefruit juice • St. John's wort	With or without food
Gefitinib (Iressa®)	AstraZeneca Pharmaceuticals Wilmington, DE	• Non-small cell lung cancer (restricted access per FDA – see product label)	• CYP3A4 inducers/inhibitors • Coumarin-derivative anticoagulants • H_2 antagonists	With or without food
Lapatinib (Tykerb®)	GlaxoSmithKline Research Triangle Park, NC	• HER2+ advanced or metastatic breast cancer	• CYP3A4 inducers/inhibitors	Without food
Lenalidomide (Revlimid®)	Celgene Corporation Summit, NJ	• Multiple myeloma • Myelodysplastic syndrome	• Digoxin	With or without food
Nilotinib (Tasigna®)	Novartis Pharmaceuticals Corp. East Hanover, NJ	• Chronic myeloid leukemia (Philadelphia chromosome-positive, chronic or accelerated phase)	• CYP3A4 inducers/inhibitors • Grapefruit juice • St. John's wort	Without food
Pazopanib (Votrient®)	GlaxoSmithKline Research Triangle Park, NC	• Advanced Renal Cell Carcinoma	• CYP3A4 inducers/inhibitors • Grapefruit juice • St. John's wort	Without food
Procarbazine (Matulane®)	Sigma-Tau Pharmaceuticals Gaithersburg, MD	• Hodgkin disease (lymphoma)	• Ethyl alcohol • Sympathomimetic drugs • Tricyclic antidepressants	With or without food. Must be on a modified-dose tyramine diet
Sorafenib (Nexavar®)	Bayer Pharmaceuticals West Haven, CT Onyx Pharmaceuticals, Emeryville, CA	• Unresectable hepatocellular carcinoma • Advanced renal cell carcinoma	• Irinotecan • Docetaxel • Doxorubicin • Fluorouracil • CYP3A4 inducers	Without food
Sunitinib (Sutent®)	Pfizer Oncology New York, NY	• Advanced renal cell carcinoma • Gastrointestinal stromal tumor	• CYP3A4 inducers/inhibitors	With or without food
Temozolomide (Temodar®)	Schering Corporation, Kenilworth, NJ	• Glioblastoma • Anaplastic astrocytoma	• No clinically relevant drug interactions	Empty stomach
Thalidomide (Thalomid®)	Celgene Corporation Summit, NJ	• Multiple myeloma	• CYP3A4 inducers/inhibitors • Check prescribing information for listing of drugs that may reduce effectiveness of oral contraceptives.	Administered at bedtime, ≥ 1 hour after evening meal
Vorinostat (Zolinza®)	Merck & Co. Inc. Whitehouse Station, NJ	• Cutaneous T-cell lymphoma	• Coumarin-derivative anticoagulants	With food

**** NOTE: Instructions for taking medication without food generally implies one (1) hour before or two (2) hours after food.**

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Roche Pharmaceuticals. (2006). Xeloda®(capecitabine) [Prescribing information]. Nutley, NJ: Author.
Bristol-Myers Squibb. (2008). Sprycel®(dasatinib) [Prescribing information]. Princeton, NJ: Author.
OSI Pharmaceuticals Inc./Genentech Bio Oncology. (2008). Tarceva®(erlotinib) [Prescribing Information]. Melville, NY/South San Francisco, CA: Authors.
AstraZeneca. (2005). Iressa®(gefitinib) [Prescribing information]. Wilmington, DE: Author.
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Celgene Corporation. (2007). Revlimid®(lenalidomide) [Prescribing information]. Summit, NJ: Author.
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Last updated 11/1/2009

Tool 2

Common Side Effects of Oral Cancer Therapies by Classification

Classification	Common Side Effects
Tyrosine kinase inhibitors	• Rash • Hand-skin reaction • Diarrhea • Nausea/vomiting/dyspepsia • Edema - periorbital & peripheral • Elevated liver function tests • Muscle cramps • Cardiotoxicity • Fatigue • Cytopenias
Angiogenesis inhibitors	• Birth defects • Dizziness • Drowsiness • Rash • Thrombotic disorders • Neuropathy • Cytopenias • Cardiotoxicity
Fluoropyrimidines	• Hand-foot syndrome (HFS) • Dry skin • Nausea/vomiting/dyspepsia • Diarrhea
Selective estrogen receptor modulators (SERMS)	• Hot flashes • Vaginal dryness
Aromatase inhibitors	• Arthralgia • Bone loss • Vaginal dryness

Last updated 12/24/2009

Tool 3

Reimbursement Resources
Table 1: Agent Specific Resources

Drug Name Generic/Brand	Reimbursement/Assistance Information	Web Site	Patient Education Resource Web Site
Bexarotene (Targretin®)	Eisai Oncology Reimbursement Specialists 1-866-613-4724	www.eisai.com/section.asp?ID=191	http://targretin.com/capsules
Capecitabine (Xeloda®)	Oncoline® Patient Assistance Program 1-800-443-6676, option 3	www.xeloda.com/resource-center/xeloda-insurance-coverage.aspx	www.xeloda.com
Dasatinib (Sprycel®)	Destination Access® 1-800-861-0048	www.destinationaccess.com	www.sprycel.com
Erlotinib (Tarceva®)	Tarceva Access Solutions® 1-888-249-4918	www.TarcevaAccessSolutions.com	www.tarceva.com
Everolimus (Afinitor®)	http://www.afinitor.com/assets/pdf/afinitor-afinitrac-information.pdf	www.afinitor.com	Same as previous
Gefitinib (Iressa®)	IRESSA® Access Program	www.iressa-us.com	Same as previous
Lapatinib (Tykerb®)	TykerbCARES® 1-866-489-5372		www.tykerb.com
Lenalidomide (Revlimid®)	RevAssist® 1-888-423-5436	www.celgenepsc.com 1-800-931-8691	www.revlimid.com
Nilotinib (Tasigna®)	Novartis Customer Service 1-866-411-TASIGNA (1-866-411-8274)	www.us.tasigna.com	n/a
Pazopanib (Votrient®)	CARES by GSK Program 1-888-663-4752	www.votrient.com	www.votrient.com
Procarbazine (Matulane®)	Customer Service 1-800-490-3262 Matulane® Patient Assistance Program administered by NORD (National Organization for Rare Disorders) 1-203-744-0100	www.matulane.com	Same as previous
Sorafenib (Nexavar®)	REACH® program 1-877-322-4448 NexConnect 1-866-639-2827		www.nexavar-us.com
Sunitinib (Sutent®)	FirstResource® 1-877-744-5675		www.sutent.com
Temozolomide (Temodar®)	Schering's Commitment to Care® program. 1-800-521-7157	www.temodar.com	
Thalidomide (Thalomid®)	S.T.E.P.S.® program 1-888-423-5436 Patient Support Coordinator 1-800-931-8691	www.celgenepsc.com	www.celgene.com
Vorinostat (Zolinza®)	ACT® program 1-866-363-6379		www.zolinza.com

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Tool 3

Reimbursement Resources
Table 2: Reimbursement and Patient Assistance Resources

Cancer*Care* Co-Payment Assistance Foundation	www.cancercarecopay.org
Cancer Supportive Care Programs National and International Listing of Pharmaceutical Programs	www.cancersupportivecare.com/drug_assistance.html
Chronic Disease Fund	www.cdfund.org 1-877-968-7233
HealthWell Foundation	www.healthwellfoundation.org 1-800-675-8416
The Leukemia and Lymphoma Society Co-Pay Assistance Program	www.lls.org/copay 1-877-557-2672
National Cancer Institute, Support and Resources	www.cancer.gov/cancertopics/support 1-800-422-6327
NeedyMeds	www.needymeds.com
Partnership for Prescription Assistance	www.pparx.org 1-888-477-2669
Patient Access Network Foundation	www.panfoundation.org/
Patient Advocate Foundation	www.patientadvocate.org
Patient Advocate Foundation Co-Pay Relief	www.copays.org 1-866-512-3861

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Tool 4

Pharmacy Descriptions, Benefits and Concerns

Dispensing Site	Benefits	Concerns
Community retail pharmacy	• Is usually located near patient's residence • May be better positioned to monitor for drug-drug interactions if all prescriptions are filled at this pharmacy chain	• Community pharmacist may not have adequate experience to provide counseling for specialized medications • May not stock less frequently used medications, thus resulting in delay in starting cycle • Billing concerns – may not bill correctly when medication is covered under Medicare Part B • Limited resources for patients without insurance or with high copays
Specialty pharmacy	• Has highly experienced and knowledgeable oncology pharmacy staff • Provides additional patient education by phone or mail • Delivers medication to patient at no additional cost • Able to custom pack multi-strength doses to avoid multiple copayments • Works closely with insurance plans & Medicare • Access to patient assistance programs	• May not be local – patient may have concerns about working with pharmacy by phone.
Mail-order pharmacy	• Usually decreased patient co-pay when medication is ordered in 90-day amounts • May have nurse case managers on staff to assist patients on medications for "catastrophic diseases"	• Unlikely that patient will speak directly with an oncology pharmacist • Nurse case manager may not be an oncology nurse • Most require minimum 90-day supply
Practice dispensing pharmacy	• Is convenient – inside oncology office • Has physician or nurse available for questions • Has all personnel available so that double-check of prescription can be performed for safety • Has patient medical record readily available for questions	• Varying levels of physician supervision may be required, depending on regulations • Drug safety rules mandated by HFAP, Joint Commission, OSHA, and public health rules require additional documentation and record-keeping
Hospital pharmacy	• May give patient access to an oncology pharmacist • Allows close communication with practice physician or nurse • Generally follows double-check of prescription if given patient data • May be connected to practice through electronic ordering system	• Travel burden: Hospital pharmacy may not be located on same campus as office • May not have access to patient assistance program information • May limit to 30-day supply, creating travel burden for patients who may be able to extend office visits to 2-3 cycles
Pharmaceutical dispensing program	• Ensures safety in high-risk cancer medications • Access to patient assistance programs • Has highly experienced & knowledgeable oncology staff • Can provide additional patient education by phone or mail	• Requires telephone or online contact with prescriber (MD or APN) • Requires faxed prescription • Delay in receipt of medication by patient • Additional paperwork and phone work by office staff • May not have access to full medication profile, with less ability to screen for drug-drug interactions.

APN: advanced practice nurse; HFAP: Healthcare Facilities Accreditation Program [American Osteopathic Association]; OSHA: Occupational Safety and Health Administration
NOTE: Based on information from Institute of Medicine Committee on Identifying & Preventing Medication Errors, Aspden, Wolcott, Bootman, & Cronenwett, 2007; Schulmeister, 2006; Weingart et al., 2008)

Last updated 12/24/20090

Tool 5

Barriers to Adherence With Oral Therapies

Dimension	Barriers
Socioeconomic	• Low language literacy • Lack of family or social support network • Unstable living conditions; homelessness • Busy work or social lifestyle • Limited access to healthcare facilities and/or pharmacy • Lack of health insurance • Medication cost
Healthcare system	• Poor provider-patient relationship • Poor provider communication skills • Lack of positive reinforcement from the healthcare provider • Lack of knowledge on adherence and of effective interventions for improving it • Patient information materials written at too high of a literacy level • Lack of continuity of care
Disease	• Asymptomatic disease • Severity of symptoms
Treatment-related	• Complex medication regimen • Lack of immediate benefit of therapy • Actual or perceived unpleasant side effects • Treatment interferes with lifestyle or requires significant behavioral changes
Patient-related	• Physical factors • Psychological/behavioral/developmental factors • Knowledge about disease • Expectations or attitudes toward treatment • Perceived benefit of treatment • Confidence in ability to follow treatment regimen • Motivation • Fear of possible adverse effects • Psychosocial stress, anxiety, anger • Alcohol or substance abuse

NOTE: Based on information from American Society on Aging & American Society of Consultant Pharmacists Foundation, 2006; Atkins & Fallowfield, 2006; Haynes et al 2002; Lebovits et al, 1990; Madden et al., 2008; Michaud & Choi, 2008; Osterberg & Blaschke, 2005; Weingart et al., 2008; World Health Organization, 2003.

Tool 6

Techniques for Monitoring Adherence to Oral Therapies

Test	Advantages	Disadvantages
Direct methods		
Directly observed therapy	Most accurate	Patients can hide pills in their mouths and then discard them; impractical for routine use
Measurement of the level of medicine or metabolite in blood	Objective	Variations in metabolism and "white coat adherence" can give a false impression of adherence; expensive
Measurement of biologic marker in blood	Objective; in clinical trials, can also be used to measure placebo	Requires expensive quantitative assays and collection of bodily fluids
Indirect methods		
Patient questionnaires Patient self-report	Simple; inexpensive; the most useful method in the clinical setting	Susceptible to error with increases in time between visits; results are easily distorted by the patient
Pill counts	Objective, quantifiable, and easy to perform	Data easily altered by the patient (e.g., pill dumping)
Rates of prescription refills	Objective; easy to obtain data	A prescription refill is not equivalent to ingestion of medication; may require access to pharmacy system
Assessment of the patient's clinical response	Simple; generally easy to perform	Factors other than medication adherence can affect clinical response
Electronic medication monitors	Precise; results are easily quantified; tracks patterns of taking medication	Expensive; requires return visits and downloading data from medication vials
Measurement of physiologic markers	Often easy to perform	Marker may be absent for other reasons (e.g., increased metabolism, poor absorption, lack of response)
Patient diaries	Helps to correct poor recall	Easily altered by the patient

NOTE: Based on information from Osterberg & Blaschke, 2005; Peterson et al., 2003.

Last updated 11/1/2009

Tool 7

Sample Treatment Calendars

Patient on Combination Oral Therapy: Capecitabine (Xeloda®) + Lapatinib (Tykerb®)

Sample Calendar 1

SUNDAY Date _____	MONDAY Date _____	TUESDAY Date _____	WEDNESDAY Date _____	THURSDAY Date _____	FRIDAY Date _____	SATURDAY Date _____
		Xeloda AM Xeloda PM Tykerb BEDTIME	Xeloda AM Xeloda PM Tykerb BEDTIME	Xeloda AM Xeloda PM Tykerb BEDTIME	Xeloda AM Xeloda PM Tykerb BEDTIME	Xeloda AM Xeloda PM Tykerb BEDTIME
Xeloda AM Xeloda PM Tykerb BEDTIME	Xeloda AM Xeloda PM Tykerb BEDTIME	Xeloda AM Xeloda PM Tykerb BEDTIME	Xeloda AM Xeloda PM Tykerb BEDTIME	Xeloda AM Xeloda PM Tykerb BEDTIME	Xeloda AM Xeloda PM Tykerb BEDTIME	Xeloda AM Xeloda PM Tykerb BEDTIME
Xeloda AM Xeloda PM Tykerb BEDTIME	Xeloda AM Xeloda PM Tykerb BEDTIME	NO XELODA Tykerb BEDTIME	NO XELODA Tykerb BEDTIME	NO XELODA Tykerb BEDTIME	NO XELODA Tykerb BEDTIME	NO XELODA Tykerb BEDTIME
NO XELODA Tykerb BEDTIME	NO XELODA Tykerb BEDTIME	Xeloda AM Xeloda PM Tykerb BEDTIME	Xeloda AM Xeloda PM Tykerb BEDTIME	Xeloda AM Xeloda PM Tykerb BEDTIME	Xeloda AM Xeloda PM Tykerb BEDTIME	Xeloda AM Xeloda PM Tykerb BEDTIME

NOTES:
Take Xeloda within 30 minutes after a meal, approximately 10-12 hours apart (breakfast and dinner).
Take Tykerb on an empty stomach (30 minute before or one hour after eating).

Last updated 11/1/2009

Xeloda® is a registered trademark of Roche Laboratories, Nutley, NJ.
Tykerb® is a registered trademark of GlaxoSmithKline, Philadelphia, PA.

Sample Calendar 2

	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
WEEK 1 Take Xeloda AM Take Xeloda PM Take Tykerb	 X X X	 X X X	 X X X	 X X X	 X X X	 X X X	 X X X
WEEK 2 Take Xeloda AM Take Xeloda PM Take Tykerb	 X X X	 X X X	 X X X	 X X X	 X X X	 X X X	 X X X
WEEK 3 **NO XELODA** Take Tykerb	 X	 X	 X	 X	 X	 X	 X
WEEK 4 Take Xeloda AM Take Xeloda PM Take Tykerb	 X X X	 X X X	 X X X	 X X X	 X X X	 X X X	 X X X
WEEK 5 Take Xeloda AM Take Xeloda PM Take Tykerb	 X X X	 X X X	 X X X	 X X X	 X X X	 X X X	 X X X
WEEK 6 **NO XELODA** Take Tykerb	 X	 X	 X	 X	 X	 X	 X

NOTES: Take Xeloda within 30 minutes after a meal, approximately 10-12 hours apart (breakfast and dinner).

Take Tykerb on an empty stomach (30 minute before or one hour after eating).

Xeloda® is a registered trademark of Roche Laboratories, Nutley, NJ.

Tykerb® is a registered trademark of GlaxoSmithKline, Philadelphia, PA.

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Tool 8

Traditional Counseling Versus Motivational Interviewing

Traditional Counseling	Motivational Interviewing
• Healthcare provider (HCP) is the healthcare expert. • Assumes patient lacks knowledge. • Tells patient what to do. • Hopes patient follows instructions	• HCP develops partnership with patient. • Exchanges information to facilitate an informed decision • Patient has the right to decide own care.
• HCP provides definitive information. • Directives are presumed to be non-negotiable.	• HCP provides information to patient for the purpose of developing discrepancy between present behavior and goal.
• HCP dictates healthcare behavior.	• HCP and patient negotiate behavior and reach agreement.
• Goal is to motivate the patient.	• Goal is to access motivation and elicit patient's commitment to change behavior.
• HCP persuades patient to change behavior.	• HCP understands and accepts patient's action.
• HCP expects respect from patient.	• HCP must earn respect from patient.

NOTE: Based on information from Levensky et al., 2007; Miller & Rollnick, 2002; Possidente et al., 2005.

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Tool 9

Motivational Interviewing Techniques & Sample Dialogue

Technique	Comments	Sample Dialogue
Ask open-ended questions.	• Avoid questions that ask "yes" or "no."	Nurse: Please tell me about the problems you've had in taking your hormonal therapy every day since your last visit.
Use reflective listening.	• Paraphrase clients' comments. • Phrase reflections as statements, not as questions.	*Patient: It's quite a challenge to try to deal with diarrhea while we're traveling on vacation, but I know it's a side effect of the medicine.* Nurse: So, even though the diarrhea interferes with your vacation, you expect it to happen, so you're not caught off guard. *Patient: I can't stop taking this medicine. What would my family think?* Nurse: It sounds like there would be a lot of pressure from your family if you decided to stop.
Elicit self-motivated statements.	• Encourage patients to verbalize how they are changing. • Point out any changes you have observed and ask them how they did this.	Nurse: It sounds like you have made real progress in taking your medicine every day. How do you feel about that?
Affirm.	• Support, encourage, and recognize the patients' difficulties.	Nurse: It sounds like you are still struggling with remembering to take your medicine on an empty stomach, but you have made some changes. How do you think you might be able to do this every day instead of a few days a week?
Summarize.	• Summarize the comments made. • Transition to the next topic or conclude the session.	Nurse: You said you feel strongly that the medicine is helping keep your cancer from coming back. You want to find ways to remember to take it every day. What things do you think you could do to help you remember your medicine every day?

NOTE: Based on information from Levensky et al., 2007; Miller & Rollnick, 2002; Possidente et al., 2005; Zimmerman et al., 2000.

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Tool 10

Transtheoretical Model of Change: Stages of Change

Stage	Construct of Stage	Motivational Interviewing	Healthcare Provider Tasks
Precontemplation	• Does not intend to take action in the foreseeable future • May be in this stage because person is uninformed or underinformed about the consequences of behavior	• Increase perception of risks and problems with current behavior.	• Raise doubts about current behavior.
Contemplation	• Intends to change • Aware of risks and benefits of changing • Risk/benefit balance can produce profound ambivalence.	• Begin to formulate early plan. • Still ambivalent	• Listen to patient concerns. • Support benefits, address concerns about risks.
Preparation	• Intends to take action in the immediate future • Has taken some significant action already • Has a plan of action	• Increase self-efficacy for change.	• Raise reasons for change and risks of not changing.
Action	• Has made specific changes • Action is observable. • Relapse is common.	• Implement the plan. • Problem-solve.	• Help client use skills for problem-solving. • Support self-efficacy.
Maintenance	• Is working to prevent relapse • Is increasingly more confident in ability to continue the change	• Resolve associated problems as they occur.	• Help patient identify and use strategies to prevent relapse.
Regression	• Individuals revert to an earlier stage of change. • Relapse is one form of regression. • Can regress from any stage to any earlier stage • The majority regress from maintenance to contemplation or preparation.	• Recycle through prior stages.	• Support patient's efforts to return to appropriate behavior. • Support positive attitude.

NOTE: Based on information from Prochaska et al., 2002; Prochaska & Velicer, 1997.

Tool 11

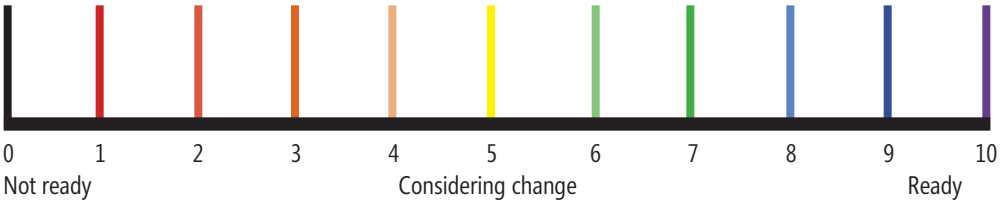
The READS Principles of Health Behavior Change

	Principle	Actions
R	Roll with resistance.	• Be flexible. • Get clarification. • New perspectives are invited, not imposed. • Do not give person a reason to resist more. • Resistance is a signal to respond differently. • Repeat your understanding. • The person is a primary resource in finding answers and solutions.
E	Express empathy.	• An objective identification of another person's emotions (not experience). • Repeat throughout the change process. • Identify and understand resistance and reasons for unhealthy behaviors without judgment. • Create a climate for change through trust. • Empathy positions you as being on the person's side.
A	Avoid arguing.	• Arguing adds to the person's resistance. • Arguing forces people to defend the behavior you are trying to change. • Confront or ask for clarification, but do not argue. • Feelings are not arguable.
D	Develop discrepancy.	• Change is motivated by a perceived discrepancy between present behavior and important personal goals or values. • Discrepancy = Dissonance. • Discuss good things and bad things about change • Go over pros and cons • Throw the system out of kilter. • Restate the discrepancies heard.
S	Support self-efficacy.	• Self-belief in the ability to change is an important motivator. • Notice positive language and behaviors. • Let the person know you have noticed. • The person, not the counselor, is responsible for choosing and carrying out change. • Praise the behavior, not the person. • Develop patient's autonomy to take responsibility for his or her own health. • Continue to support self-efficacy throughout the process.

NOTE: Based on information from Miller & Rollnick, 2002.

Tool 12 Readiness to Change Scale

Readiness to Change Scale



Instructions for Use

1. Ask patient to rate how ready he or she is for change by drawing an arrow to or circling a number in the appropriate area on the scale.
2. A score > 5 indicates patient is ready to work toward changing behavior.
3. Discuss the patient's ranking on the scale with the following questions:
    a How important is this change to you?
    b How confident are you that you can make this change?
    c Why did you choose a _____, not a 10?
    d What would have to happen to make it a ____ [choose number 1-2 up from patient choice]?

NOTE: Based on information from Prochaska et al., 2002; Zimmerman et al., 2000.

Resource List

Professional Resources

American Society on Aging & American Society of Consultant Pharmacists Foundation. (2006). *Adult meducation®: Improving medication adherence in older adults.* Retrieved from **http://www.adultmeducation.com/downloads/Adult_Meducation.pdf**

GlaxoSmithKline. (n.d.). *Healthcare providers' overview—About ASK®*. Retrieved from **http://www.takingmeds.com/hcp/hcp-overview.html**. Includes patient education information and discussion of the ASK-20® (Adherence Starts with Knowledge) adherence survey.

Jacobson, J.O., Polovich, M., McNiff, K.K., LeFebvre, K.B., Cummings, C., Galioto, M., ... McCorkle, M.R. (2009). American Society of Clinical Oncology/ Oncology Nursing Society chemotherapy administration safety standards. *Oncology Nursing Forum, 36*, 651–658. doi:**10.1188/09.ONF.651-658**

Roche Laboratories. (n.d.). *For healthcare professionals: A better-educated patient.* Retrieved from **http://www.oralchemoadvisor.com/hcp/default.aspx**

Patient-Directed Information

American Cancer Society. (2008). *Oral chemotherapy: What you need to know.* Retrieved from **http://www.cancer.org/docroot/ETO/content/ETO_1_2x_Oral_Chemotherapy.asp**

Dana-Farber Cancer Institute. (n.d.). *Oral chemotherapy fact sheet.* Retrieved from **https://www.dana-farber.org/can/patient-instruction/html/oral-chemotherapy-fact-sheet.html**

GlaxoSmithKline. (2008). *ASK®: Adherence starts with knowledge*. Retrieved from **http://www.takingmeds.com/index.html**. Contains information on adherence, including a self-assessment survey (ASK-20®) that identifies barriers to oral medication adherence.

Roche Laboratories. (n.d.). *Oral chemotherapy guide*. Retrieved from **http://www.oralchemoadvisor.com/oral-chemotherapy-guide.aspx**

Helpful Websites

American Cancer Society	www.cancer.org
American Society of Health-System Pharmacists	www.ashp.org
Association of Cancer Online Resources	www.acor.org
Association of Community Cancer Centers	www.accc-cancer.org
Cancer.Net, American Society of Clinical Oncology Patient Information	www.cancer.net
ChemoCare	www.chemocare.com
Epocrates	www.epocrates.com
Leukemia and Lymphoma Society	www.lls.org
Lexi-Comp, Inc.	www.lexi.com
Micromedex	www.micromedex.com
MyMedSchedule.com	https://secure.medactionplan.com/mymedschedule/index.htm
National Cancer Institute	www.cancer.gov
National Coalition for Cancer Survivorship	www.canceradvocacy.org
National Comprehensive Cancer Network	www.nccn.org
Patient Compliance	www.patientcompliance.net
Stand Up to Cancer	www.standuptocancer.org
UpToDate® information resource	www.uptodate.com
U.S. Food and Drug Administration	www.fda.gov

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