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Navigators Are Key in Encouraging Oral Therapy Adherence

Welcome to our first newsletter in the *Conquering the Multiple Myeloma Continuum* series, which focuses on adherence to oral medications in patients with multiple myeloma (MM). In the first newsletter, you learned about some of the major causes of nonadherence that patients and their providers face; this second newsletter provides some strategies and solutions!

For those of you who know me, you know that I have several philosophies. One of them is that "You cannot manage what you do not measure." Therefore, you will read about methods for assessing adherence, because, otherwise, you will not know how severe the problem is or the specific causes that prevent patients with MM from taking their medications as prescribed (see **below**). Barriers to adherence, interventional strategies for improving medication adherence, and adherence tools and resources are also discussed in detail. There is a great Health Belief Model that allows for better understanding of patients' motivations, beliefs, and barriers so navigators can facilitate appropriate adherence interventions. This model consists of 5 concepts, including perceived susceptibility, perceived severity, perceived benefits, perceived barriers, and cues to action.

You will also read information on how to incorporate compliance to oral therapy into the daily routine of patients with myeloma (see page **46**). Cindy Chmielewski, a patient advocate and mentor, discusses challenges associated with oral oncolytics in patients with myeloma, how to overcome these barriers, and how to best support your patients.

In another commentary, we provide information and words of wisdom by Deborah Christensen, RN, BSN, HNB-BC, an oncology nurse navigator (see page **46**). She explains how stressed patients are when they are dealing with a diagnosis like MM, which can result in the patient's inability to listen and process information. Just because patients nod their heads up and down does not mean they retain anything. Oncology nurse navigators, however, have a proven track record of being some of the most trusted people in the eyes of their patients. Patients will confide in navigators the difficulties they are experiencing with taking their medications as prescribed. This, in turn, allows the opportunity for a successful intervention.

We know this type of information will enable you to better support your patients and treat them more effectively. We must make sure patients' responsibilities to take their medications as prescribed can happen consistently, confidently, and easily. ■

FEATURE ARTICLE

A New Era of Oral Therapies for Multiple Myeloma

Implementing routines and strategies to promote adherence

Sabby Muneer, PhD

Recent advancements in the treatment of multiple myeloma (MM) have led to significant improvements in patient outcomes, including unprecedented survival rates.[1] Such progress has allowed a paradigm shift toward a chronic care model, with attention increasingly focused on improving patients' quality of life. This MM treatment evolution has ushered in a new era of oral anticancer agents. Several of these therapies are currently approved by the US Food and Drug Administration, including thalidomide, lenalidomide, pomalidomide, and panobinostat, as well as others that are in clinical development.[2] There are numerous benefits to these oral oncolytic therapies. They are easier and faster to administer, less invasive, and more flexible and convenient than injections and infusions, resulting in minimal disruption of patients' activities of daily living, and improvements in their quality of life.

The advent of oral anticancer agents has had a major impact on the practical management of MM; they are challenging traditional attitudes toward myeloma care, redefining the roles and responsibilities of providers and patients, and demanding a new model of oncology services for patient education, monitoring, and support. Importantly, the incorporation of oral oncolytic therapies has caused a shift in medication responsibility. Although healthcare providers are traditionally responsible for the administration of intravenous medications, this burden has now shifted to patients, creating new challenges for healthcare professionals to maintain medication adherence.[3]

This monograph reviews these emerging concepts that were developed to address the unique issues presented by the increasing use of oral therapies, with a focus on their relevance to oncology nurses and nurse navigators, considering their essential role in the oncology team, and their presence on the frontline of MM care.

Barriers to Adherence

Adherence is defined as the extent to which a patient's behavior coincides with instructions from a healthcare provider.[4] Nonadherence is associated with suboptimal drug efficacy, resulting in poor clinical outcomes and increased healthcare costs.[5] Medication nonadherence is identified as the largest driver of avoidable US healthcare costs, accounting for >$200 billion annually.[6] Unfortunately, available reports indicate that nonadherence to oral oncolytic therapy is rampant, ranging from <20% to 100%, contrary to healthcare providers' assumptions that it is a nonissue compared with the gravity of the disease.[7] Because of the clinical and economic implications of nonadherence to oral oncolytic therapies, it is imperative that healthcare providers acknowledge and address the unique issues of adherence.

Adherence behavior has been proposed as a continuum from fully adherent to totally nonadherent, and can be classified into 6 behavior types, including adherer, partial adherer, overuser, erratic user, partial dropout, and dropout.[8,9] The reasons dictating adherent behavior may differ for each patient's situation. Many barriers to medication adherence have been identified that may be broadly grouped as treatment-, patient-, physician-, and environment-related variables.[3-5] Patient-related factors may include poor understanding of the disease and associated risks, a perception of being cured or having asymptomatic disease, a lack of belief in treatment benefits, reluctance to change behaviors, age and sex, cognitive impairment (eg, forgetfulness), comorbid conditions, and polypharmacy.

Treatment-related factors, such as medication side effects and drug–drug interactions, can result in medication nonadherence when the patient is unprepared or

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Table 1 Methods to Assess Adherence to Oral Therapies

Method	Potential limitations
Direct methods	
Directly observed therapy	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 or urine	Variations in metabolism and "white coat adherence" can give a false impression of adherence; expensive
Indirect methods	
Patient questionnaires/ patient self-reports	Susceptible to error with increases in time between visits; results are easily distorted by the patient
Pill counts	Data easily altered by the patient (eg, pill dumping)
Rate of prescription refills	A prescription refill is not equivalent to ingestion of medication; may require access to pharmacy system
Assessment of the patient's clinical response	Factors other than medication adherence can affect clinical response
Electronic medication monitors	Expensive; requires return visits and downloading data from medication vials
Measurement of physiologic markers	Marker may be absent for other reasons (eg, increased metabolism, poor absorption, lack of response)
Patient diaries	Easily altered by the patient

Source: Adapted from Oncology Nursing Society. Tools for oral adherence toolkit. www.ons.org/sites/default/files/oral%20adherence%20toolkit.pdf. Updated December 24, 2009. Accessed October 15, 2015.

unable to manage his or her symptoms. In addition, the complexity of the regimen, such as a complicated dosing schedule, may negatively impact the patient's ability to follow a regimen; typically, longer treatment duration is associated with noncompliance. Physician-related barriers include poor patient–provider communication, lack of positive reinforcement from the healthcare provider, insufficient educational measures on the medication regimen or importance of adherence, and infrequent follow-up. Socioeconomic factors, such as lack of health insurance, medication cost, limited access to healthcare facilities and/or pharmacies, social lifestyle, lack of family or social support network, and inadequate supervision, are also strong determinants of medication nonadherence.

Because of these varied logistic, perceptual, physiologic, and social impediments to treatment, it is critical that healthcare providers identify individual barriers to, and facilitators of, oral oncolytic therapy, and work with patients to isolate strategies that would enable them to take their medications as prescribed. In the practice context, the onus of identifying and addressing specific patient adherence barriers falls largely on oncology nurses and nurse navigators, owing to their skills of helping patients with side effect management, procurement, routine handling of medications, and follow-up care. Indeed, nursing interventions have been shown to positively impact medication adherence, as well as symptom management.[10,11]

Medication Adherence Assessment

In providing patient-centered oncology care, it is important to perform routine assessments of medication adherence to oral therapies. There is no gold standard medication adherence measurement, but several strategies are available that may be broadly grouped as direct and indirect methods, as outlined in **Table 1**; each has its own advantages and limitations, and may not assess all aspects of prescription adherence.[12] Direct methods include directly observed therapy, measurement of the level of a drug or its metabolite in blood or urine, and measurement of a biologic marker in the blood. Direct approaches are one of the most accurate methods of measuring adherence, but they are expensive and may require additional physician visits that could compromise patient convenience.

Indirect methods include patient questionnaires, patient self-reports, pill counts, rates of prescription refills, assessment of the patient's clinical response, electronic medication monitors, measurement of physiologic markers, and patient diaries.[7,12] However, these methods are subjective and susceptible to alteration by patients, inaccurate data entries, recall bias, or errors because of increased intervals between patient visits. Patient questionnaires and self-reports are simple, inexpensive, and widely used in clinical settings, although they may be easily distorted by patients. Pill counts may also be easily manipulated, and do not provide information about adherence to the dosing schedule. Using pill containers with a microelectronic monitoring system allows for tracking of the opening of the pill container, but this cannot be correlated with pill ingestion, and is cost-prohibitive. Evidence of a clinical response can confirm patient adherence to oral medication, but be affected by other factors. Assessing prescription filling and insurance records is considered to provide the most accurate estimate of actual medication use over a period of time; however, it does not necessarily translate to pill consumption, or provide information about whether the patient is taking the medication as prescribed.

Table 2 Strategies to Improve Medication Adherence

- Implement a collaborative approach to decision-making, because patient involvement in decision-making is essential in improving medication adherence
- Simplify medication regimen and customize to patient characteristics
- Education regarding their disease, treatment, and potential side effects must be established at initial visit
- Emphasize the importance of adherence, including adherence to treatment and persistence
- Educate patients to be proactive about management of side effects
- Instruct patients to contact their healthcare provider when severe side effects occur
- Routine adherence monitoring
- Establish patient–healthcare provider relationship
- Schedule frequent follow-ups (face to face, phone calls, e-mails, text messages) to discuss difficulties
- Provide tools to facilitate dose management and monitoring at home (written instructions, pillbox, calendar, cell phone/text message reminders, diary, financial and social support groups)
- Provide short-term prescriptions or money-saving refill options
- Collaborate with patient to incorporate the medication regimen into his or her daily regimen

Source: Adapted from Cheung WY. Difficult to swallow: issues affecting optimal adherence to oral anticancer agents. *Am Soc Clin Oncol Educ Book*. 2013:265-270.

Interventional Strategies to Improve Medication Adherence

It is well-accepted that improving patient adherence requires a multifaceted approach, and cannot rely on one method. Typically, models of adherence interventions are based on the key elements of patient education, behavioral interventions, and affective support, which may include symptom management, simplifying medication regimens, improving patient–provider communication, and applying reminder cues, as outlined in **Table 2**.[3] In fact, a Cochrane review recently found that successful adherence interventions for long-term care involved education, reminders, self-monitoring, reinforcement, counseling, family and caregiver therapy, psychological therapy, crisis intervention, manual telephone follow-up, and supportive care.[13,14] Importantly, because of the lifestyle differences among patients, identifying individual barriers and tailoring adherence interventions to their individual needs is critical.[15]

Foremost, patient education regarding the disease, treatment plan, risks and benefits of treatment, side effects, drug–drug or drug–food interactions, and importance of adherence is essential to ensure that oral oncolytic therapies are being taken correctly.[3,16] Education may alleviate patients' fears and concerns regarding the side effects of the prescribed drugs, and must include early recognition signs, how to proactively prevent side effects with supportive agents, and how and when to contact their healthcare provider.[3,16] In addition, all concomitant medications must be reviewed with the patient to avoid potential drugs that may cause additional adverse events.[3] During counseling, the unique characteristics of an oral drug treatment plan must be emphasized, including the patient's role in managing his or her drug administration, the patient's responsibility to report these effects to the oncology care team, the importance of adherence, and that patients are entering into a partnership with their healthcare provider.[17] Ongoing education must be implemented as part of routine care for patients receiving oral oncolytic therapies; working from a check-off list may be helpful, and may ensure consistency and completeness of information.[17]

Instructions and information pamphlets that are provided during counseling in the clinic setting alone may not be sufficient for many patients. In addition, patients may need clear, simple, written instructions for reference at home regarding correct medication dosing and timing, as well as the adverse consequences of missing or rationing doses.[3] A comprehensive treatment plan that includes the goal of therapy, timing and dosing of therapy, special considerations, monitoring and follow-up procedures, and symptom management must also be provided.[17]

The frequency of monitoring and follow-up strategies, such as office visits, Internet-based patient portals, and phone-based check-ups that are appropriate for the patient and the oncolytic agent prescribed must be determined and defined in the treatment plan.[18] It is recommended that an office visit is scheduled once per cycle for an assessment; most importantly, follow-up visits, calls, e-mails, or text message reminders must be used as opportunities to reiterate the importance of adherence.[19] During these follow-up visits, medication adherence must be assessed, and any identified barriers must be addressed.

The Health Belief Model allows for better understanding of patients' motivations, beliefs, and barriers to facilitate appropriate adherence interventions.[20] This model consists of 5 concepts, including perceived susceptibility, perceived severity, perceived benefits, perceived barriers, and cues to action. Other concepts, such as self-efficacy and facilitation, may also be incorporated to define a workable model in everyday practice, as shown in the **Figure**.[20]

Perceived susceptibility is defined as patients' beliefs about their risk of disease progression, symptom worsening, and survival with and without medication, whereas perceived severity is patients' beliefs on the extent of their disease severity; together, they account for the perceived threat of myeloma.[20] This understanding is essential for patients to make a change in their adherence behavior. Oncology nurses and nurse navigators need to work with patients to educate them about the disease threat based on patients' baseline levels of understanding. On a related note, perceived benefits refer to patients' understanding of the short- and long-term efficacies of their prescribed oral oncolytics for myeloma control; perceived barriers are patient-specific barriers to medication adherence.[20] Oncology nurses and nurse navigators need to identify and address individual barriers, and convey that the benefits of medication adherence outweigh the barriers.

Facilitation is defined as the process of providing the tools and resources necessary to enable patients to adhere to their medications. Oncology nurses and nurse navigators need to address any modifiable factors that have been identified. Before the initiation of an oral regimen, the best practice is to conduct an assessment of the patient's ability to obtain the drug and administer it according to the treatment plan, along with a plan to address any identified issues. The assessment should include socioeconomic, psychosocial, financial, administrative, and regulatory factors that may influence initiation and/or adherence to the prescribed regimen.[18] In this context, oncology nurses and nurse navigators may also need to assist patients with medical access and acquisition, and work with insurers and oncology pharmacists to complete the authorization processes, understand the refill policy and medication delivery time frame, and determine a start date.[17] They may also need to connect patients with prescription drug assistance programs to enable patients to afford their medications. Thus, the role of oncology nurses and nurse navigators is to reduce barriers to adherence, and provide patients with the skills and resources necessary to adhere to medications after the intervention ends. To facilitate adherence behavior, the navigator will need to employ cues to action that are individually tailored to the patient's specific needs. The cues may be in the form of e-mails, text messages, or phone calls depending on the patient's preference.

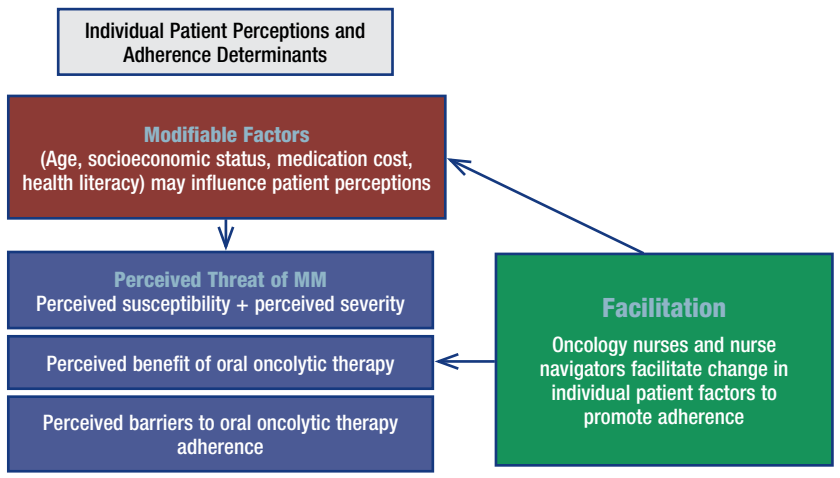
Self-efficacy can be defined as a patient's belief in his or her ability to engage in the behaviors necessary to adhere to oral medication.[7] To improve self-efficacy, oncology nurses and nurse navigators must be trained in motivational interviewing techniques to engage the patient in discovering and developing new beliefs, expectations, and strategies for overcoming barriers to adherence.[19] Motivational interviewing emphasizes more patient engagement, and several other techniques—such as reflective listening and the use of open-ended questions—are more effective methods to assess adherence, identify barriers, and establish adherent behavior, as well as a nurse–patient collaborative partnership. In contrast to traditional healthcare provider-driven counseling that dictates certain behavioral changes and does not focus on patient engagement, motivational interviewing respects patients' self-determination, acknowledges autonomy, and recognizes that the patient decides whether or not to change his or her own behaviors. In this context, the concept of change theory may also be applied to modify adherence behaviors, and focuses on the decision-making abilities of the individual rather than the social and biological influences on his or her behavior.

Adherence Tools and Resources

Patients should be encouraged to use adherence aids and reminder cues to improve adherence outcomes.[3] There are several reminder triggers that can be used to improve patients' adherence to their oral therapies, such as pillboxes, pill diaries, and treatment calendars.[15] Reminders set up on the phone or with text messages based on the dosing schedule are popular methods that may be employed. Calendars, checklists, and postcards or e-mails may be used as refill reminders so that patients have an adequate supply of medications.

The Oncology Nursing Society has developed an oral adherence toolkit that includes tools, resources, and information for interventional strategies that nurses may employ to promote medication adherence.[12] These include information on adverse effects and drug–drug interactions associated with common oral drugs, adherence assessment methods, sample treatment calendars and schedules that map a weekly oral treatment, pharmacy and reimbursement/financial resources to direct patients to financial assistance, motivational interviewing, and counseling, as well as concept of change theory.[12] The medication calendar typically maps out a weekly oral treatment plan, and includes the number of pills per dose, the number of doses per day, and times to take the medication. Patients can then record the times their medication was taken.[12] The Multinational Association of Supportive Care in Cancer Oral Agent Teaching Tool is a framework that helps clinicians identify barriers and facilitators to adherence; ensures that adherence assessment, symptom management, and adherence strategies are addressed; provides suggestions for patient education; and provides examples of its usefulness in clinical settings.[21]

Figure Role of Oncology Nurses and Patient Navigators in Promoting Adherence



Source: Original art based on information in Janz NK, Becker MH. The health belief model: a decade later. *Health Educ Q*. 1984;11:1-47.

Conclusion

The advent of oral oncolytic therapy predicts a future of effective, convenient regimens for patients with MM; however, this will necessitate changes in current management practices. To optimally implement best practices, all stakeholders in the delivery of care to patients with MM—including physicians, oncology nurses, nurse navigators, patients, and caregivers—must be engaged in the process and collaborate effectively to ensure adherence to oral oncolytic therapy. ■

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Incorporating Oral Therapy Compliance into the Routine of Patients with Myeloma

Cindy Chmielewski, *Patient Advocate and Mentor*

Oral oncolytics represent 25% to 35% of the drugs in the oncology pipeline.[1] They are patient friendly, allow patients to manage their treatment, and overall, have a less disruptive effect on patients' everyday lives. In addition, fewer clinic visits are needed, and scheduled visits are shorter because there is no need to wait for an intravenous infusion to be completed. Many patients with myeloma can also continue working through their treatment, and traveling is more convenient. Oral oncolytics offer the ease of self-administration to patients. There is no prodding for stubborn veins, and no need for a port. Therefore, oral therapies empower patients, and often lead to improved quality of life.

However, there are also challenges associated with oral oncolytics use in patients with myeloma. With patients being responsible for the administration of their own therapy, the issues of adherence and side effect management need to be addressed. There is a 37% rate of nonadherence to oral cancer agents[2]; overadherence, or taking more medication than prescribed, can lead to increased toxicities, whereas patients who forget or choose to take less than the prescribed dose can be at higher risk for disease progression.

Efforts need to be made to overcome these challenges. Clinical trials assessing adherence rates routinely show that a good patient–healthcare provider relationship increases adherence.[3] Because patients taking oral oncolytics need to visit the clinic less often, greater effort is needed to cultivate the patient–healthcare provider relationship. Patients with myeloma should have an oncology nurse or nurse navigator specifically assigned to them. The oncology nurse or nurse navigator should intentionally engage with patients and caregivers, especially at the onset of their treatment journey.

Oncology nurses or nurse navigators should have a thorough understanding of the oral therapy that their patient is taking. This "nursing buddy" should initiate contact with the patient and caregiver frequently in the beginning weeks of treatment. A once-monthly check-in at the end of a treatment cycle is not enough when the patient is starting a new protocol. Contact can be made through phone calls, e-mails, text messages, video calls (eg, Skype, FaceTime), patient portals, or drop-in visits—whichever is best for the patient and caregiver. During these planned interventions, the oncology nurse or nurse navigator should educate his or her patient, assess financial needs, share side effect management tips, evaluate psychological state, and discuss family life. Patients should be given an easy-to-read, written summary of everything that was discussed during these conversations. Through meaningful contact, a trusting patient–healthcare provider relationship will develop.

The oncology nurse or nurse navigator should also direct the patient and caregiver to the appropriate online and in-person support communities and mentoring organizations. Ongoing support, especially from someone who is following the same oral protocol, can be extremely helpful.

In addition to developing a trusting relationship, there are other ways to incorporate compliance to oral therapy into the daily routine of patients with myeloma. Education is critical. Patients need to be educated about their disease and the available treatment options to make informed decisions. If patients are a part of this decision-making process, they will feel a sense of ownership, and will be more likely to comply. Patients need to understand the goal of treatment, the duration of treatment, and what may happen if they stop or adjust their dose without discussing this decision with their physician. Patients should also understand how their response to treatment is being monitored. When patients are educated on side effect management and reporting, they may be less likely to discontinue therapy because of preventable complications.

Electronic reminders via text messages, smartphone applications, or e-mails may be helpful, especially if the medication is not taken daily. Pillboxes can be used when appropriate as a self-check system. Having a friend or family member help support medication adherence at home may also be beneficial; 2 sets of eyes are better than 1! Treatment calendars that outline complicated dosing schedules should be employed. These calendars can be paper, electronic, or application-based on smartphones.

The ease of getting the prescription filled also needs to be evaluated. Can the medication be picked up at the clinic or local pharmacy, or is a specialty pharmacy needed? Who is responsible for ordering the medication? How long will it take the prescription to be filled? If the medication is delivered to the patient's home, will a signature be needed? Is there a 24-hour pharmacist available to answer questions? Patients cannot take their medication if they do not physically have it in their possession.

Finally, access issues need to be addressed. Patients often stop or spread out the doses of their medication because costs can be astronomical. The oncology nurse or nurse navigator should discuss the various financial assistance programs that are available, and should help patients apply for assistance. All stakeholders, including healthcare providers, patients, caregivers, pharmaceutical companies, and payers, must work together to ensure adherence to oral oncolytic therapy. ■

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How to Communicate with Patients with Myeloma to Achieve the Best Outcomes

Deborah Christensen, RN, BSN, HNB-BC, *Oncology Nurse Navigator, Dixie Regional Medical Center, St. George, UT*

Treating cancer with oral medications that are taken at home sounds like a great idea, and it is, once adherence barriers are addressed. Likewise, years ago it was unthinkable that surviving cancer would have a downside, but because late and long-term effects of cancer treatments were not adequately addressed, survivorship quality was suboptimal. The good news is that if survivorship issues can be resolved, so can the problems associated with oral therapy adherence.

The featured article, "A New Era of Oral Therapies for Multiple Myeloma," covers many of the barriers associated with shifting cancer medication management from the provider to the patient. This commentary will discuss the techniques for providing patient-centered education, developing a trusting relationship with patients and caregivers, and establishing processes that focus on oral therapy adherence.

Healthcare providers have likely heard a patient or caregiver say, "No one told me about...." Chances are the issue at hand was addressed, but not at a time or in a way that promoted comprehension. Research has shown that people under stress do not process information the same way, or as effectively as when they are not stressed. The uncertainty and stress associated with a new cancer diagnosis often continues until treatment begins, placing patients at risk for not fully understanding information. It is important to validate this fact and genuinely listen to the patient's story. Meeting patients where they are in the moment is invaluable.

Assessing a patient's learning preference and health literacy can assist nurses in customizing information. Pictures, videos, and infographics are useful when describing the disease process and how a medication works. The teach-back technique assesses comprehension by asking patients to voice their understanding of the information and instructions. Notably, nurses who preface this technique with, "I want to be sure I have explained this in an understandable way," put the responsibility for comprehension on the nurse, not the patient.

Would methods for monitoring adherence be necessary if patients had a person on the healthcare team whom they could confide in and trust? The general population lists nurses as one of the most trusted healthcare professionals. Nurses begin to develop trusting relationships when they acknowledge likely barriers, such as forgetting to take the medications, fitting dosing into a normal routine, and financial concerns. Follow-up phone calls have also been shown to improve patients' self-determination for managing the challenges associated with managing their cancer medications at home.

When barriers to adherence are addressed—initially and in the long term—properly taking oral therapies will become a way of life. Importantly, healthcare providers must not assume that once medication adherence is achieved that it will continue. Over time, a lack of disease symptoms or ongoing medication side effects can lead to a decrease in adherence.

Trusting relationships must be nourished. Developing a timeline for continued follow-up at 3 months, 6 months, yearly, when medication changes, or at the first sign of a problem can promote medication adherence and patient satisfaction with the treatment plan and his or her healthcare team. ■

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