

EDUCATIONAL OBJECTIVES

After participating in this activity pharmacists and pharmacy technicians will be able to:

- Recognize and define types and leading causes of treatment/medication refusal
- Describe the ethical and legal principles associated with medication refusal, covert medication, and surreptitious prescribing
- Determine treatment alternatives for patients with dietary, religious, or other restrictions
- Identify and implement key components of a medication refusal protocol



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Patient Safety MEDICATION REFUSAL: UNDERSTANDING WHY “THEY JUST SAY NO”

ABSTRACT: Based on the principle of informed consent, competent patients always have the right to refuse medical treatment. Patients may refuse treatment for a variety of reasons, including dietary restrictions, religious reasons, medical misconceptions, a desire to avoid adverse effects, and mistrust of the medical team. Patient refusals can create serious dilemmas in the healthcare setting. On the one hand, clinicians have an ethical and legal obligation to honor patient autonomy. On the other hand, a patient’s refusal of treatment often leads to adverse medical outcomes, resulting in harm to the patient. Healthcare professionals should search for acceptable treatment alternatives that honor patients’ wishes while meeting their medical needs. Every institution—whether in the community, long-term care, or inpatient setting—should have a protocol to guide and standardize the approach to managing treatment refusals. In complex cases, it may be beneficial to use expert ethics consultations.

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INTRODUCTION

“Drugs don’t work in patients who don’t take them,” remarked former U.S. Surgeon General C. Everett Koop.¹ He spoke those words in 1985, but the problem persists 35 years later. Medication refusal and nonadherence remain prominent issues in many healthcare settings (see **SIDEBAR, page 2**). Patients fail to fill up to 30% of prescriptions, and simply don’t take 50% of chronic disease medications as prescribed. In addition to notably increasing morbidity and mortality rates, this nonadherence results in billions of dollars in U.S. healthcare costs.²

To address this issue, it’s important for pharmacy staff to understand the reasons behind refusal. Many patients have misconceptions about their treatment, or fail to understand its importance. For example, patients taking preventive medications like statins may discontinue the medication since it does not provide externally evident benefits. Others may perceive prescription medications as unnatural, harmful chemicals and opt to self-treat with OTC products instead. Additional reasons for refusal include fear of adverse reactions, religious prohibition, dietary restrictions, desire for self-harm, or altered mental status.

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Patients have the right to autonomy—that is, they have the final say as to whether they accept treatment. However, that doesn't mean that a patient's initial refusal closes the door to all subsequent treatment. Often, tailored patient education can resolve misconceptions and persuade hesitant patients to attempt a treatment. Other patients may be open to alternatives—for example, a vegan may refuse a medication that contains animal products, but accept an animal-free option. It's critical that pharmacists and technicians understand the reasons for refusal; only then can they identify alternative solutions that meet patients' medical needs while staying true to their values.

REASONS FOR REFUSAL

Dietary Restrictions

Patients may refuse medications based on their personal beliefs, religions, or food sensitivities/allergies. Five percent of Americans consider themselves vegetarians, and 3% self-identify as vegans.⁵ Islam, Hinduism, and Sikhism—3 of the largest religions worldwide—do not approve of the use of certain animal-derived products.⁶ However, many widely-used medications contain ingredients that are sourced from animals, including gelatin (from pigs, cattle, or fish), lactose (from cattle), and magnesium stearate (from animal fat or vegetable matter).⁷ Additionally, the majority of drugs use animal testing in preclinical trials; the most commonly prescribed drugs were all tested on multiple animal models.⁸

Patients with irritable bowel syndrome, lactose or gluten intolerance, or a peanut oil allergy—just to name a few—may need to avoid medications that contain even trace amounts of agitating ingredients. Unfortunately, 93% of oral medications contain at least one common potential allergen.⁹

Pharmacists and pharmacy technicians should work with patients to identify medications compatible with dietary restrictions. It's important to recognize that patients may wish to comply with their beliefs to the greatest extent possible,

SIDEBAR: What's in a Name? Non-Adherence vs. Refusal

Medication adherence is the extent to which a patient follows treatment recommendations. Non-adherence occurs, for example, when patients forget to take their medications, take the wrong amount, take them at the wrong time, or discontinue medications. Other names for non-adherence include non-compliance, non-persistence, and non-concordance. Non-adherence may be intentional or unintentional³:

- *Intentional non-adherence* is an active process in which the patient decides not to follow treatment recommendations. This may be caused by factors including skepticism about treatment efficacy, intolerable adverse effects, or medication-associated stigma.³
- *Unintentional non-adherence* is a passive process—unplanned behavior that results in deviation from the recommended treatment regimen. For example, patients may forget to take a dose, misunderstand the directions, or confuse their medications.³

Medication refusal occurs when patients reject the treatment and do not give their consent to receiving it. Refusal may be active or passive⁴:

- *Active refusal* occurs when a patient directly refuses to accept treatment. Such behavior is apparent and easy to observe.⁴
- *Passive refusal* occurs when a patient appears to accept treatment, but secretly takes measures to refuse it. For example, a patient may take the medication when offered, then later spit or vomit it out.⁴

even if they can't do so completely. For instance, it may be medically necessary for vegan patients to use animal-tested medications, but they still have the freedom of choosing between gelatin-containing vs. gelatin-free products, and should be informed accordingly. See **Table 1** and the **Tech Talk** for common ingredients that prompt patients' concerns.

Table 1. Common Ingredients to Watch in Patients with Dietary Restrictions^{7,9,10}

Ingredient	Potential concern/s	% Occurrence in Medications	Common medications containing ingredient
Magnesium stearate	Animal-derived product	72%	Lisinopril (Mylan), metoprolol tartrate (Mylan) gabapentin (AvKARE), aripiprazole (Otsuka)
Lactose	Allergen, animal-derived product, exacerbation of IBS symptoms, lactose intolerance	45%	Prednisone (Activase), anastazole (Teva), benazepril (Teva), warfarin (Exalan), losartan (Sandoz)
Gelatin	Allergen, animal-derived product	17%	Tamsulosi (Teva), celecoxib (Teva), benzonatate (Major), omeprazole (Mylan)
Peanut oil	Allergen	0.10%	Valproic acid (Mylan), progesterone (Teva)

Tech Talk: Your Insider Guide to Spotting Hidden Ingredients

At first glance, it can be hard to tell which medications are safe to use in patients with dietary restrictions. Many healthcare professionals don't check ingredient lists before prescribing or dispensing. Even if they do, they may not recognize animal products and allergens referred to by scientific or alternate names. Here are some tips to make it easier to spot hidden ingredients.

- **Decode the label**—and show the patient how, too. OTC products have FDA-mandated Drug Facts labels that list both active and inactive ingredients. Prescription drug labels aren't FDA-regulated and vary between pharmacies, but FDA-approved information is available online through sources like [Dailymed](https://dailymed.nlm.nih.gov/dailymed/) (<https://dailymed.nlm.nih.gov/dailymed/>).¹¹
- **It's all about the excipients.** Although health records often document patient allergies to active ingredients—like penicillin, aspirin, or ibuprofen—it's actually the inactive ingredients, or excipients, that cause the most problems. Manufacturers add excipients to improve the drug's absorption, stability, taste, appearance, or accessibility, and they make up over 75% of the drug's mass.⁹ Read the drug label carefully to identify which excipients are in the product.
- **Allergens have aliases;** they can go by many alternate names. For example, *magnesium stearate* is a salt of *stearic acid*; it may be referred to as one or the other in an ingredients list. Additionally, for lactose- or gluten-intolerant patients, it's not always clear what products to avoid (besides the obvious lactose and gluten). Depending on their level of sensitivity, lactose-intolerant patients may need to avoid casein, whey, and other milk proteins, too. And gluten may be present in other wheat-based products like mannitol, sorbitol, xylitol, and hydrogenated starch hydrolysates.¹² Be aware of these alternate names when reading the drug label and don't hesitate to research unfamiliar names.
- **Not all formulations are created equal.** Just because one particular product doesn't work doesn't mean that active ingredient isn't an option. Different manufacturers and dosage forms use different excipients. For example, amoxicillin capsules contain gelatin, while amoxicillin tablets do not.¹⁰ And one manufacturer's product may use ingredients that another's doesn't. Do your due diligence to find alternatives, using resources like [Pillbox](https://pillbox.nlm.nih.gov/) (<https://pillbox.nlm.nih.gov/>).
- **Know your sources.** There are plenty of valid sources available for healthcare workers and patients alike to find the right product:
 - [Pillbox](https://pillbox.nlm.nih.gov/) (<https://pillbox.nlm.nih.gov/>): This National Institute of Health's (NIH)-run database allows searching by drug name, ingredient, and appearance and offers information about physical appearance, active and inactive ingredients, manufacturers, and more.
 - [Dailymed](https://dailymed.nlm.nih.gov/dailymed/) (<https://dailymed.nlm.nih.gov/dailymed/>): This NIH-run database allows searching by drug name, class, NDC code, or Set ID. It provides FDA-approved drug label information.
 - [The Green Book](https://animaldrugsatfda.fda.gov/adafda/views/#/search) (<https://animaldrugsatfda.fda.gov/adafda/views/#/search>): This list of FDA-approved animal drug products is updated monthly. Users can search by drug name, active ingredient, or application number.
 - [PETA's animal-derived ingredients list](https://www.peta.org/living/food/animal-ingredients-list/) (<https://www.peta.org/living/food/animal-ingredients-list/>): This list contains common animal-sourced products used in medications, cosmetics, and other products. It may be helpful for vegan, vegetarian, Muslim, Hindu, and Sikh patients.
 - *Medication manufacturers:* Look for information on manufacturer websites or call them.

Religious Refusal

Seventy-five percent of Americans consider religion very important or fairly important in their lives.¹³ Religious beliefs may influence what treatment options a patient chooses and adheres to. Sometimes, a patient's beliefs conflict with medical advice, causing the patient to refuse treatment. For example, Christian Scientists may choose prayer and faith healing over conventional treatment. Many Jehovah's Witnesses accept conventional treatments except blood transfusions. Some religions view health issues as the outcome of immoral, sinful behavior.¹⁴ Or, as previously discussed, patients who practice religions such as Islam, Hinduism, and Sikhism may have dietary restrictions that would be violated by certain products.⁶

In emergency, life-threatening situations, some religions may allow a little leeway and permit otherwise unacceptable treatment options.⁶ However, depending on the patient and religion, this is not always the case. Things get especially complicated when it comes to the care of children, whose medical decisions are largely determined by their parents. In

complicated situations, healthcare professionals can request ethics consultations, legal counsel, and religious advice, where appropriate.

Medical Misconceptions

Often, insufficient or inaccurate knowledge prevents a patient from accepting treatment. In the hectic healthcare setting, providers may not have time to explain treatments fully or correct patient misconceptions. Additionally, in today's digital world, it's easy for false information to propagate rapidly.

A prime example is the anti-vaccination movement. Vaccines are a critical part of preventive healthcare and have significantly decreased the rate of many deadly infectious diseases. Unfortunately, there has been a recent rise in anti-vaccination sentiment, which has spread into mainstream culture. Most opposition comes from the false belief that vaccines cause autism and other severe adverse effects. Correspondingly, immunization rates have dropped, and there have been outbreaks of previously eliminated diseases, such as measles.¹⁵

Patients may also refuse vaccinations due to misconceptions about who can and should be immunized. Society tends to place a higher emphasis on vaccinating children, so many patients may not realize that adults, too, need certain vaccines. For example, though an annual flu shot is recommended for everyone six months and older without contraindications, only 45% of adults are vaccinated, compared to 63% of children.¹⁶ Consequently, the prevalence of vaccine-preventable illnesses is higher among adults than children.¹⁷

Some patients may reject medically recommended treatments in favor of self-treating with OTC products or using complementary/alternative approaches. While these treatment options are useful in certain situations, they lack a strong evidence base. Patients who rely solely on alternative approaches may have worsened health outcomes, especially for severe diseases that warrant immediate, heavy-hitting treatment. For instance, disease-modifying therapies (DMTs) delay the progression of multiple sclerosis (MS) and prevent relapses. However, up to 31% of MS patients refuse DMT recommendations; one of the most common causes for refusal is a preference for a complementary medicine approach.¹⁸

Healthcare professionals should identify and address patient misconceptions regarding treatment and counsel patients accordingly. Even a few minutes of patient education may have a long-lasting positive impact. The case study (on the right) demonstrates this principle.

PAUSE AND PONDER: What medical misconceptions do your patients have? How can you address and resolve their misconceptions?

Mental Status Refusals in Long-Term Care

More than 8.3 million Americans use long-term care—supportive services for patients with a limited capacity for self-care due to elderly age, mental disability, chronic illnesses, or other health-related conditions.²⁰ Due to their comorbidities, these patients often need to receive multiple medications, making treatment refusal and nonadherence an ongoing issue. Some residents refuse medications because they are difficult to swallow or unpleasant-tasting (see **Table 2, next page**).²¹ Others may reject medications due to schedule conflicts—administration times sometimes interfere with their planned activities or rest schedules.¹²

Additionally, many long-term care patients suffer from altered mental status due to psychiatric illnesses or diseases that are more common with aging, such as dementia. In these situations, navigating medication refusal becomes a challenge. Like informed consent, informed refusal requires the patient to be competent, sufficiently informed, and acting voluntarily.²² It can be difficult, however, to determine whether long-term care patients are mentally competent enough to make their own

Case Study: Medical Misconceptions In Ebola¹⁹

“They’ll inject you, and you’ll die.” This was the overwhelmingly mistrustful local attitude to medical teams who responded to the 2013-2016 West African Ebola epidemic. That Ebola outbreak was the largest recorded yet, necessitating the establishment of Ebola Treatment Units (ETUs), where patients were treated symptomatically to manage Ebola complications.

To the healthcare professionals, ETUs were a way to observe, isolate, and treat infected patients. To the locals, ETUs were a place to die. They believed that ETU staff were poisoning them with the treatments, food, and drink offered at the centers. Family and friends bombarded patients with phone calls, warning them that they would die if they consumed anything. Patients actively and passively refused medications, either outright rejecting them or secretly disposing of them. One patient drank frozen juice prior to temperature checks to hide her fever and avoid receiving medication.

Multiple factors contributed to this extreme mistrust. Minority populations were initially hit the hardest by the epidemic, which politicized the disease and sparked fear that it was a targeted genocide attempt. ETUs represented a foreign, government-associated environment, and locals blamed the deaths that occurred there on the administered treatment rather than the disease. “People said that when you arrive there, the doctors give you a shot and even if you don’t have Ebola, they say that you have Ebola just to kill you,” described one patient. Since Ebola is incurable, patients could only be treated symptomatically and did not always recover, prompting even more suspicion.

Fortunately, patients’ perceptions changed as they spent more time in the ETUs. Healthcare workers played a critical role, taking time to educate patients about what the medications were used for and debunking local rumors. Some even ingested the medications themselves to prove their safety to wary patients. More experienced patients encouraged the newly admitted to accept treatment, describing their own positive experiences to persuade the newcomers.

Although this is a somewhat extreme account of medication refusal, the healthcare principles still apply to other areas of practice. Empathetic, individualized patient counseling is an effective tool in any medication refusal setting.

healthcare decisions. And mental status isn’t static; a patient with dementia may become incompetent as the disease course progresses, or a patient with bipolar disorder may end a manic cycle and regain competency.

Brain disorders

There are multiple reasons why patients suffering from brain disorders may be unwilling to receive treatment. Illness-associated stigma is a major barrier to treatment, as it makes patients ashamed to seek out or accept care. Stigmatization has many sources, including patients themselves (self-stigma), healthcare

Table 2. Factors Affecting Older Patients' Acceptance of Oral Solid Dosage Forms²¹

Factor	Potential Issues	Potential Solutions
Dimensions/size	<ul style="list-style-type: none"> • Too big: difficult to swallow, causes anxiety about taking medications • Too small: difficult to handle and locate 	<ul style="list-style-type: none"> • Identify patient preferences and choose formulations accordingly • Advise patients to take medication with water to improve ease of swallowing • Consider alternative dosage forms, such as chewable pills or suspensions • Use smoothly coated medications when available • Suggest taste masking by taking medication with food or drink
Palatability: texture, mouthfeel, coating, taste	<ul style="list-style-type: none"> • Chalky formulations are difficult to swallow, cause anxiety about taking medication • Medications with no, rugged, or sticky coatings get stuck in the mouth and throat • Bitter and unpleasant-tasting medications discourage adherence 	
Appearance	<ul style="list-style-type: none"> • Patients may have difficulty distinguishing between similar-looking medications • Some dosage forms, such as granules, are less acceptable to older patients 	

workers, friends and family, and societal policies.²³

Some patients may believe that they do not require treatment. Consider a severely underweight patient with anorexia who doesn't wish to stop his food-limiting behavior, or an artist with bipolar disorder who wants to maintain the creative euphoria evoked by the disease's manic phases. Other patients may be suspicious or confused about treatment due to their disease—for example, a patient with schizophrenia may become paranoid about medication.²⁴

Patients may object to medications other than psychiatric medications. Long-term care patients often refuse non-psychiatric medications as well, including treatments for cardiovascular, gastrointestinal, and endocrine illnesses. Reasons for refusal include adverse drug reactions, lack of disease symptoms, and delusional fears regarding the medication. This is particularly concerning because patients with brain disorders have an increased risk for medication-preventable comorbidities, such as cardiovascular disease.²²

Dementia

Behavioral and psychological symptoms of dementia (BPSD) occur in 90% of dementia patients; resulting cognitive and functional impairments complicate treatment. Notable BPSD include agitation and irritability,²⁵ which is compounded in patients who feel they have lost their independence. These patients may resent long-term care staff and therefore refuse treatment.¹² Other symptoms (e.g., delusions, hallucinations, and anxiety) may make patients suspicious of and nonreceptive to treatment.²⁵

One particularly concerning BPSD is depression, which is exacerbated by the patient's loss of health, self-esteem, and independence.²⁵ Patients suffering from depression may refuse medication out of self-destructive intent, using medication refusal as a form of self-harm.¹² Long-term care workers must be particularly vigilant for this behavior, especially since dementia patients may have an increased risk for suicidal behavior.²⁶

Regardless of its challenges, proper treatment is critical for long-term care patients. Medication refusal increases morbidity, mortality, and healthcare costs.²² Healthcare workers should strive to identify and address barriers to treatment for these vulnerable populations.

Refusal of Cancer Treatment

Up to 19% of cancer patients partially or completely refuse chemotherapy, and some patients refuse conventional treatment entirely.²⁷ In these situations, it's critical to understand and address the patient's emotional and cognitive status. Often, refusal is a rational, carefully-considered decision. However, some patients may be cognitively compromised, pressured by external factors, or misinformed about the treatment. Each patient's unique situation requires him or her to balance many factors.

Chemotherapy is notorious for its side effects, which include hair loss, nausea and vomiting, fatigue, mood changes, urine and bladder changes, and neuromuscular problems.²⁸ While it may somewhat extend a patient's life span, it significantly decreases quality of life. It's not so surprising, then, that many patients refuse treatment to avoid severe adverse effects, maintain their quality and control of life, and preserve their dignity.²⁷ Interpersonal relationships also affect the choice to refuse. Family and friends have a major influence; they may pressure the patient into making certain decisions, or patients may refuse treatment to avoid burdening their loved ones. The treatment team's relationship with the patient is also a major determinant of care. Patients who are misinformed or resentful from previous medical experiences may reject treatment out of distrust for the system.²⁹

Some patients may not be mentally competent, making treatment refusal complex. A quarter of cancer patients suffer from major depression, which can cause sporadic mood swings, feelings of worthlessness, and suicidal ideation or attempts.³⁰ Most cancer patients also have multiple risk factors for delirium, which affects judgment and behavior.³¹ In situations like these, a



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patient's rational decision-making ability is compromised, and family members may need to make difficult treatment decisions. However, this is something that must be carefully assessed; clinicians should not automatically assume incompetence when a patient refuses treatment against medical advice.

Ultimately, healthcare professionals must respect and honor a competent patient's decision, regardless of whether they personally agree. Many patients who refuse care feel that their providers do not respect their decision and consider it irrational, which discourages patients from communicating their values, emotions, and reasons for refusal.^{27,32} It's especially important to maintain an open, respectful dialogue with cancer patients, who are looking for a trusted professional that will support them throughout their painful journey.²⁷ Additionally, patients may be open to altering their management plan as the disease progresses, new treatment options emerge, or personal factors change.

DEALING WITH MEDICATION REFUSAL

Patient Autonomy and Informed Consent

Medication refusal is associated with many ethical and legal principles, the foremost of which is patient autonomy. Based on this ethical principle, patients have the right to their own thoughts, choices, and actions regarding their medical care.³³ Therefore, competent patients always have the right to refuse treatment. Autonomy is preserved through informed consent—the process by which patients are educated about, and consent to, a treatment's risks, benefits, and alternatives.

Providers are legally and ethically obligated to obtain informed consent,³³ but a patient's refusal to consent can create ethical dilemmas. *Primum non nocere*—that is, “first, do no harm”—is one of healthcare's fundamental tenets. This is also known as the principle of non-maleficence. Another ethical principle, beneficence, describes the act of promoting good and ensuring that actions are beneficial to patients. Autonomy conflicts with beneficence and non-maleficence when a patient's refusal causes harm to the patient.³⁴

One exception to the requirement for informed consent occurs when a patient is incapacitated.³⁵ Such patients are physically or mentally incapable of making fully informed decisions due to conditions such as unconsciousness, delirium, or brain disorders. Instead, a designated healthcare proxy, family members, or provider may make medical decisions. In situations of mental incapacitation, it can be challenging to determine whether a patient is competent. Since capacity can fluctuate, providers should assess mental status every time a healthcare decision must be made.³⁴

Covert Medications, Surreptitious Prescribing

Repeated medication refusal and nonadherence are common in patients with brain disorders, which may cause frustrated healthcare staff and caregivers to employ questionable administration practices. Covert medication is the practice of concealing medications in the patient's food or drink. Surreptitious prescribing occurs when clinicians supply medications to a patient's caregiver, knowing that the patient will likely be medicated without his/her knowledge or consent.³³

Are either of these practices ever warranted? Many healthcare workers think so. Up to 57% of long-term care nurses report practicing covert medication,³⁶ and 96% of clinicians who work with vulnerable patients feel that it's justified on some occasions.³⁷ The general consensus is that this behavior is not ethically justifiable for mentally competent patients, but what about for patients who are incapacitated?

Serious risks and costs can occur when brain disorders go untreated, including increased morbidity, prolonged suffering, and self-destructive behavior. In cases where treatment is necessary, covert medication is a less disruptive and upsetting approach than aggressive methods like restraints and forced injections. Additionally, although covert medication may violate patient autonomy, some medications are actually intended to restore mental capacity, which has the ultimate result of restoring patient autonomy.³³

On the other hand, covert medication may be perceived as an abuse of power and a breach of trust. Patients who discover the truth may feel angry, betrayed, and paranoid regarding future treatment. Patients who remain unaware may attribute medication-derived benefits to other factors, or use their improved condition as proof that they are not ill and do not require treatment. Covert medication also raises safety concerns, as patients may consume other products that interact dangerously with the medication.³³

Ultimately, the decision to practice covert administration must be carefully balanced with other treatment factors. Clinicians should carefully consider a patient's condition, history, and loved ones before making a choice. It's also important to assess the patient's mental status regularly for any changes in capacity.³³

PAUSE AND PONDER: Is covert medication or surreptitious prescribing ever justifiable in mentally competent patients?

Establishing an Institutional Protocol

It can be difficult to make optimal treatment decisions in the chaotic, fast-moving healthcare environment. Things only get more complicated when ethical dilemmas come into play. Establishing an institution-specific protocol helps guide decision-making, resulting in more streamlined, fair, and consistent healthcare delivery. Adhering to standardized guidelines also makes it easier for multiple healthcare workers to coordinate their care for a patient.³⁸

Ideally, a medication refusal protocol should integrate patient-clinician communication and allow for external consultants as necessary. An effective guideline would include the following steps^{4,12,39}:

- *Verify that refusal or nonadherence is occurring.* In the long-term care setting, patients may practice passive refusal, which requires close observation to detect. In the outpatient and community settings, patients may be hesitant to admit nonadherence.
- *Identify the reason for refusal.*^{4,12,39}
 - Assess your patients' lifestyles and beliefs. Are they limited by any dietary or religious restrictions? Do they have medical misconceptions? Does the treatment administration interfere with their schedules?
 - Assess your patients' perceptions of the treatment. Do they understand the purpose of the treatment, and the results of refusing it? Does the medication cause unpleasant side effects? Is it difficult to take the medication? Is the treatment too costly?

- *Consider an ethics consultation for complicated cases.*¹²
 - Many healthcare institutions employ ethics counselors, who help navigate and clarify complex situations without dictating a final decision.^{12,40}
 - Most ethics counselors are trained by the American Society for Bioethics and Humanities in core competencies (situational assessment, moral reasoning, communication facilitation, legal and institutional policy, etc.)^{12,41}
 - Exact protocols vary by institution, but in most cases, consultations are free, and anyone involved in the case (patients, families, legal representatives, doctors, nurses, social workers, etc.) can request help.^{40,42-44}
- *Identify and implement solutions.*^{4,12,39}
 - Consult the provider to discontinue unneeded medications, or change them from scheduled to as-needed administration.
 - Consider alternate dosage forms (smaller pills, chewable dosage forms, liquids) for patients who have difficulty swallowing.
 - Collaborate with the patient to identify alternative options, depending on the patient's objections. For example, find products without gelatin for vegetarian patients.
 - Change the time of administration if it is inconvenient for the patient, interfering with planned activities or sleep. For example, if a patient skips breakfast, give a medication that must be taken with food at dinnertime instead.
 - Adapt to patients' disease state behavior. Some dementia patients may respond favorably to repeated attempts—even after initially refusing, they may accept after a few more queries. Other patients may prefer certain staff members and only accept medications from these workers.
- *Document, document, document!*^{4,12,39}
 - Note incidences of refusal and nonadherence, what interventions and strategies were employed, how the patient responded, and what the current regimen is.
 - Documentation greatly facilitates shared patient care and transition of care.

All healthcare settings in which medication refusal or significant nonadherence are prominent should implement a protocol to address these incidents effectively.

PAUSE AND PONDER: Who is responsible for implementing a medication refusal protocol in your workplace? Where can you document the relevant information?

Table 3. Interviewing RULES

Resist the righting reflex	Avoid directly telling patients what to do, or where they're wrong. Behavioral change is more effective when it's self-articulated and self-motivated.
Understand the patient's motivations	Don't assume that you already know patients' motivations. Allow patients to set the pace and divulge their reasoning, motivations, and barriers.
Listen with empathy	Try to understand the patient's position and avoid judgment. Ask open-ended questions for clarification.
Empower the patient	Encourage the patient to set achievable goals. Collaborate with the patients' healthcare provider to develop techniques to overcome barriers.

Implementing the Protocol, Maintaining Patient Trust

Even after establishing a set of guidelines, things might not be smooth sailing. Before implementing the protocol, healthcare workers need to build trust and cultivate a respectful relationship with patients. The patient-provider relationship strongly influences a patient's acceptance of and adherence to treatment, especially in vulnerable populations.

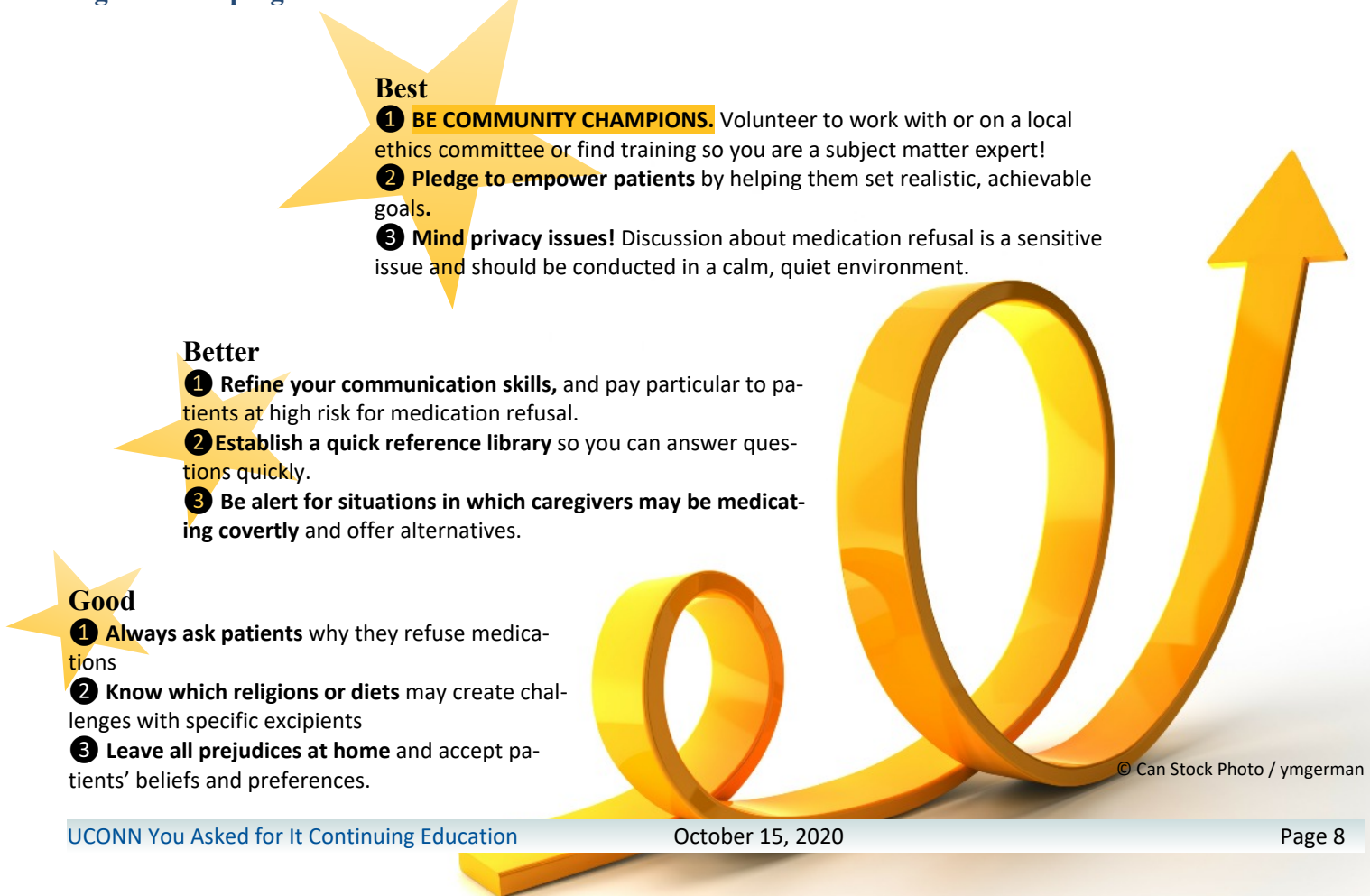
Patients who trust their physicians are more likely to believe that their medication is necessary, resulting in adherence rates that are up to three times higher.^{41, 45} Additionally, an increased level of trust results in safer medication management.⁴⁵ Conversely, when patients feel that a provider does not respect their decisions, they may stop communicating and terminate their relationship with that provider.³²

It may take some time and repeated interactions before patients trust the provider enough to divulge and explain their refusal or nonadherence. Clinicians need to be patient, nonjudgmental, and empathetic, as well as utilizing techniques such as motivational interviewing (see **Table 3** for the interviewing RULEs of thumb). Once they understand the patient's motivations, they can implement and tailor the protocol accordingly.

CONCLUSION

Medication refusal is an ongoing healthcare issue that continually frustrates clinicians and caregivers. Although it may be tempting to override a patient's refusal, healthcare workers are obligated ethically and legally to honor patient autonomy. There are no easy solutions, but institutional protocols can help by streamlining and standardizing the healthcare response. Ideally, implementing a protocol will shed light on patient motivations for refusal, guiding the selection of acceptable alternatives.

Figure 1. Helping Patients Understand the Need to Take Medication as Recommended



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REFERENCES

- Lindenfeld J, Jessup M. 'Drugs don't work in patients who don't take them' (C. Everett Koop, MD, US Surgeon General, 1985). *Eur J Heart Fail*. 2017;19(11):1412-1413. doi:10.1002/ehf.920
- Viswanathan M, Golin C, Jones C, et al. Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States. *Ann Intern Med*. 2012;157(11):785. doi:10.7326/0003-4819-157-11-201212040-00538
- Hugtenburg JG, Timmers L, Elders PJ, Vervloet M, van Dijk L. Definitions, variants, and causes of nonadherence with medication: a challenge for tailored interventions. *Patient Prefer Adherence*. 2013;7:675-682. doi:10.2147/PPA.S29549
- Resident's Refusal To Take Medications*. North Carolina Assisted Living Association; 2013. <https://www.ncala.org/training/med-aid-training/Section%201%20Basic%20Med%20Adm%20Information/Section%201%20Handouts/Handout-1F-Residents-Refusal-to-Take-Meds.pdf>. Accessed June 17, 2020.
- Snapshot: Few Americans Vegetarian or Vegan. Gallup.com. <https://news.gallup.com/poll/238328/snapshot-few-americans-vegetarian-vegan.aspx>. Published 2018. Accessed June 17, 2020.
- Eriksson A, Burcharth J, Rosenberg J. Animal derived products may conflict with religious patients' beliefs. *BMC Med Ethics*. 2013;14:48. doi:10.1186/1472-6939-14-48
- Tatham KC, Patel KP. Suitability of common drugs for patients who avoid animal products. *BMJ*. 2014;348:g401. doi:10.1136/bmj.g401
- Animal Research Behind Top Drugs. National Association for Biomedical Research. <https://www.nabr.org/biomedical-research/laboratory-animals/animal-research-behind-top-drugs/>. Published 2015. Accessed June 17, 2020.
- Reker D, Blum SM, Steiger C, et al. 'Inactive' ingredients in oral medications. *Sci Transl Med*. 2019;11(483):eaau6753. doi:10.1126/scitranslmed.aau6753
- Pillbox. US Library of Medicine. <https://pillbox.nlm.nih.gov/>. Accessed June 17, 2020.
- Llamas M. How to Read Over-the-Counter and Prescription Drug Labels. Drugwatch.com. <https://www.drugwatch.com/health/how-to-read-a-drug-label/>. Published 2020. Accessed June 17, 2020.
- Haskins DR, Wick JY. Medication Refusal: Resident Rights, Administration Dilemma. *Consult Pharm*. 2017;32(12):728-736. doi:10.4140/TCP.n.2017.728
- Religion. Gallup.com. <https://news.gallup.com/poll/1690/religion.aspx>. Published 2019. Accessed June 17, 2020.
- Linnard-Palmer L, Kools S. Parents' refusal of medical treatment based on religious and/or cultural beliefs: the law, ethical principles, and clinical implications. *J Pediatr Nurs*. 2004;19(5):351-356. doi:10.1016/j.pedn.2004.05.014
- Hussain A, Ali S, Ahmed M, Hussain S. The Anti-Vaccination Movement: A Regression in Modern Medicine. *Cureus*. 2018;10(7):2919. doi:10.7759/cureus.2919
- Flu Vaccination Coverage, United States, 2018–19 Influenza Season. Centers for Disease Control and Prevention. <https://www.cdc.gov/flu/fluview/coverage-1819estimates.htm#summary>. Published 2019. Accessed June 17, 2020.
- Williams W, Lu P, O'Halloran A, et al. Surveillance of Vaccination Coverage among Adult Populations — United States, 2015. *MMWR Surveill Summ*. 2017;66(11):1-28. doi:10.15585/mmwr.ss6611a1
- Stratos K, McGarragle K, Thistle J, Vyas MV, Lee L. Non-compliance with disease modifying therapies in patients with Multiple Sclerosis: A qualitative analysis. *Mult Scler Relat Disord*. 2020;41:102016. doi:10.1016/j.msard.2020.102016
- Sams K, Desclaux A, Sow S. 'They'll inject you and you'll die': from medication non-compliance to acceptance in Guinea's Ebola treatment units. *Anthropol Med*. 2020;27(1):1-16. doi:10.1080/13648470.2019.1615749
- Vital and Health Statistics, Series 3, Number 43. National Center for Health Statistics. https://www.cdc.gov/nchs/data/series/sr_03/sr03_43-508.pdf. Published 2019. Accessed June 17, 2020.
- Shariff ZB, Dahmash DT, Kirby DJ, Missaghi S, Rajabi-Siahboomi A, Maidment ID. Does the Formulation of Oral Solid Dosage Forms Affect Acceptance and Adherence in Older Patients? A Mixed Methods Systematic Review. *J Am Med Dir Assoc*. 2020;S1525-8610(20):30146-8. doi:10.1016/j.jamda.2020.01.108
- Umotong E. Management of Older Inpatients Who Refuse Nonpsychiatric Medication Within Birmingham and Solihull Mental Health NHS Foundation Trust. *J Nerv Ment Dis*. 2016;204(12):950-954. doi:10.1097/nmd.0000000000000622
- Knaak S, Mantler E, Szeto A. Mental illness-related stigma in health-care: Barriers to access and care and evidence-based solutions. *Healthc Manage Forum*. 2017;30(2):111-116. doi:10.1177/0840470416679413
- Owiti JA, Bowers L. A narrative review of studies of refusal of psychotropic medication in acute inpatient psychiatric care. *J Psychiatr Ment Health Nurs*. 2011;18(7):637-647. doi:10.1111/j.1365-2850.2011.01713.x
- Cerejeira J, Lagarto L, Mukaetova-Ladinska EB. Behavioral and psychological symptoms of dementia. *Front Neurol*. 2012;3:73. doi:10.3389/fneur.2012.000073
- Diehl-Schmid J, Jox R, Gauthier S, et al. Suicide and assisted dying in dementia: what we know and what we need to know. A narrative literature review. *Int Psychogeriatr*. 2017;29(8):1247-1259. doi:10.1017/S1041610217000679
- Frenkel M. Refusing treatment. *Oncologist*. 2013;18(5):634-636. doi:10.1634/theoncologist.2012-0436
- Chemotherapy Side Effects. American Cancer Society. <https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy/chemotherapy-side-effects.html>. Published 2020. Accessed June 17, 2020.
- Goldberg RJ. Systematic understanding of cancer patients who refuse treatment. *Psychother Psychosom*. 1983;39(3):180-189. doi:10.1159/000287739
- Chemotherapy Side Effects. American Cancer Society. <https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy/chemotherapy-side-effects.html>. Published 2020. Accessed June 17, 2020.
- Delirium (PDQ®)—Patient Version. National Cancer Institute. <https://www.cancer.gov/about-cancer/treatment/side-effects/memory/delirium-pdq>. Published 2019. Accessed June 17, 2020.
- Huijter M, van Leeuwen E. Personal values and cancer treatment refusal. *J Med Ethics*. 2000;26(5):358-362. doi:10.1136/jme.26.5.358
- Latha K. The Noncompliant Patient in Psychiatry: The Case For and Against Covert/Surreptitious Medication. *Mens Sana Monogr*. 2010;8(1):96. doi:10.4103/0973-1229.58822
- Bingham SL. Refusal of treatment and decision-making capacity. *Nurs Ethics*. 2012;19(1):167-172. doi:10.1177/0969733011431925
- Shah P, Thornton I, Turrin D, Hipskind J. Informed Consent. StatPearls. <https://www.ncbi.nlm.nih.gov/books/NBK430827/>. Published 2020. Accessed June 17, 2020.
- Wright D. Medication administration in nursing homes. *Nurs Stand*. 2002;16(42):33-38. doi:10.7748/ns2002.07.16.42.33.c3223
- Treloar A, Beats B, Philpot M. A pill in the sandwich: covert medication in food and drink. *J R Soc Med*. 2000;93(8):408-411. doi:10.1177/014107680009300805

38. Heymann T. Clinical protocols are key to quality health care delivery. *Int J Health Care Qual Assur.* 1994;7(7):14-17. doi:10.1108/09526869410074702
39. *GUIDELINES: Management Of Client Refusal To Take Prescribed Medication.* Continuum of Care at the University of New Mexico Health Sciences Center; 1995. <https://coc.unm.edu/common/resources/guidelines.pdf>. Accessed June 17, 2020.
40. *Not Sure What To Do? Ask For An Ethics Consultation.* VA Health-care https://www.ethics.va.gov/docs/integratedethics/ec_brochure_veterans.pdf. Accessed June 17, 2020.
41. Pellowski JA, Price DM, Allen AM, Eaton LA, Kalichman SC. The differences between medical trust and mistrust and their respective influences on medication beliefs and ART adherence among African-Americans living with HIV. *Psychol Health.* 2017;32(9):1127-1139. doi:10.1080/08870446.2017.1324969
42. Center for Bioethics. Cleveland Clinic. <https://www.clevelandclinic.org/bioethics/policies/consult.html>. Published 2020. Accessed June 17, 2020.
43. Healthcare Ethics: Clinical Ethics Consultation. Cedars-Sinai.org. <https://www.cedars-sinai.org/programs/healthcare-ethics/consultation.html>. Published 2020. Accessed June 17, 2020.
44. Clinical Ethics Consultation. The MacLean Center for Clinical Medical Ethics. https://macleanethics.uchicago.edu/consultation/clinical_ethics_consultation/. Published 2020. Accessed June 17, 2020.
45. Maidment ID, Brown P, Calnan M. An exploratory study of the role of trust in medication management within mental health services. *Int J Clin Pharm.* 2011;33(4):614-620. doi:10.1007/s11096-011-9510-5
46. Hall K, Gibbie T, Lubman DI. Motivational interviewing techniques - facilitating behaviour change in the general practice setting. *Aust Fam Physician.* 2012;41(9):660-667.
47. Gagneur A. Motivational interviewing: A powerful tool to address vaccine hesitancy. *Can Commun Dis Rep.* 2020;46(4):93-97. doi:10.14745/ccdr.v46i04a06