Communication Approaches for Patients and Care Partners When Initiating Amyloid Targeting Therapies

A communication support framework to guide interactions with patients and care partners on expectations for treatment and monitoring after initiation of amyloid targeting therapies.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Disclaimer

This resource was developed by Eli Lilly and Company. This work was inspired by established peer reviewed research and insights from experts in Alzheimer's disease based on their perspectives and opinions as well as from data on file from multiple Lilly advisory boards.

The communication style presented is a suggestion of technique and not to be portrayed as conclusive guidance.

Please note that this is a relatively new clinical topic. The science and the clinical opportunities evolve rapidly, and so does the need to continue evolving the communication – we are providing what is currently acknowledged as best practices. However, this is likely to change as the clinical landscape advances.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Table of Contents

1 Introduction

2 Communicating Treatment Options with Patients in early Alzheimer's Disease

3 Communicating Amyloid Targeting Therapy

4 Educational support

5 Additional considerations

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Section 1

Introduction

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Background

Educational Needs

1

Support on stimulating and ensuring understanding of the information provided.[1]

2

Support on communicating uncertainty.[1]

3

Careful communication and management of expectations.[2]

Considerations

4

Gaining more clinical experience does not inevitably improve communication skills.[3]

5

Training courses significantly improve key communication skills.[3]

1. Hendriksen H et al. Alzheimers Res Ther. 2023;15(1):131. **2.** Belder CRS et al. Lancet Neurol. 2023;22(9):782-3. **3.** Fallowfield L et al. Lancet. 2002;359(9307):650-6.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Background

Impact of Communication Training

To provide healthcare providers with ***tools for clear and helpful communication***

To ***increase confidence in a new, relatively complex clinical topic*** with evolving needs in communication

To help patients and care partners ***understand the treatment options***, and to make informed decisions about their care

To facilitate patient ***access to pharmacological and non-pharmacological treatment***

Lilly

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Purpose

Goal

- To increase healthcare providers' confidence in communicating about ATTs as a treatment option with patients and their care partners.

Objectives

- To present methods for clear communication when introducing ATTs as a treatment option in patients with early symptomatic Alzheimer's disease.
- To provide patient-centered explanations of ATT, mechanism of action, benefits, risks, and administration.
- To obtain best practice recommendations for situational guidance (cognitive impairment, treatment, care partner involvement, managing uncertainty).

Limitations

- This slide deck encompasses techniques for communicating treatment options after Alzheimer's disease diagnosis and does not provide insight on guidance after treatment initiation.

ATT: Amyloid Targeting Treatment

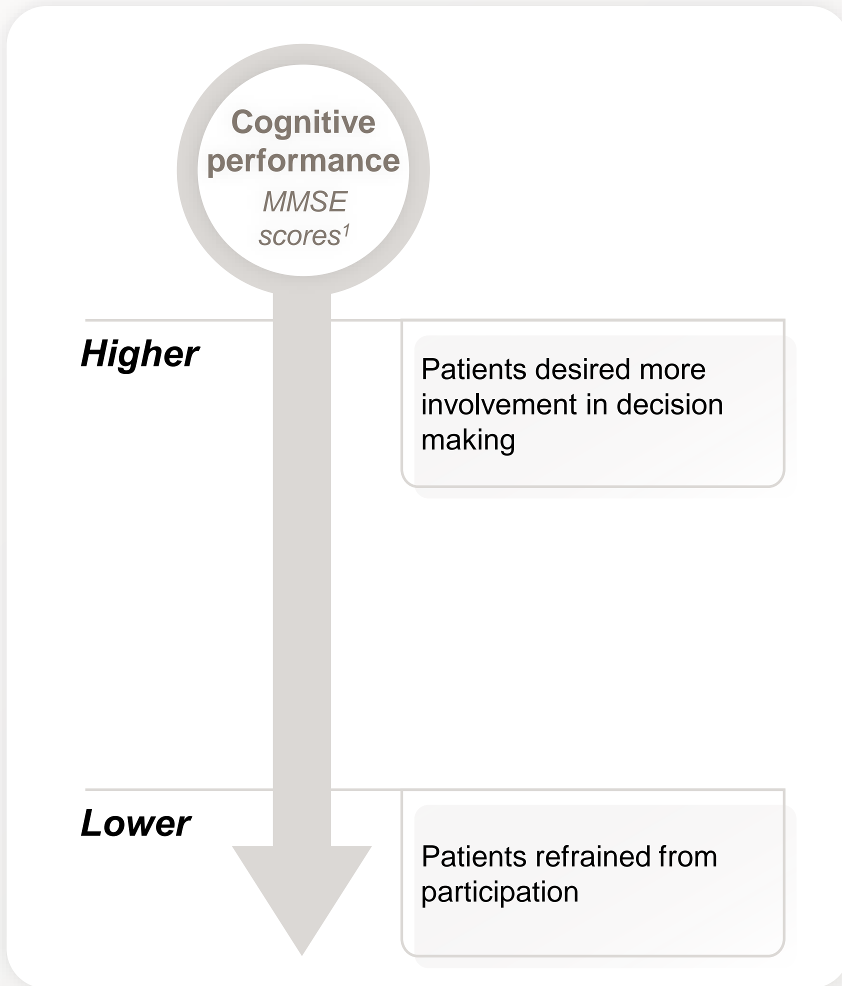
Lilly

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Communicating Treatment Options with Patients in early Alzheimer's Disease

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Conversations With Patients With Cognitive Impairment



DECISION-MAKING PREFERENCES FROM A PATIENT PERSPECTIVE[1]

Patients	*Patients prefer greater input on social decisions*
Physicians	*Patients prefer for clinician guidance on medication decisions*
Care partner	*Patients prefer minimal input from care partners on social or medical decisions*

Patients with early symptomatic AD[2-4]

- are able to comprehend and participate in discussions regarding potential benefits, risks, and care requirements
- have difficulty utilizing feedback to make optimal decisions under risky situations
- have compromised decision-making ability in ambiguous situations

AD: Alzheimer's disease; MMSE: Mini-Mental State Examination

1. Hamann J et al. J Am Geriatr Soc. 2011;59(11):2045-52. **2.** Cummings J et al. J Prev Alzheimers Dis. 2023;10(3):362-77. **3.** Zhang Y et al. J Alzheimers Dis. 2022;87(3):1215-27. **4.** Sun T et al. Front Psychiatry. 2020;18;11:218.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Conversations With Patients Experiencing Cognitive Impairment

Different types of patients require different types of communication

APOE carrier	Just needs info	Keen to participate	Controlling care partner	Apprehensive
Patients who are APOE carriers require specific counseling and discussions.	Neither overly proactive nor avoidant and seek only to understand. *The most common type.*	Proactive, excited about new treatments, often due to family history.	Patients with care partners who wish to have greater direction and influence over treatment.	Unwilling or scared to accept diagnosis.

APOE: Apolipoprotein E
1. Data on file.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Lilly

Conversations With Patients Experiencing Cognitive Impairment

CHALLENGES

Lack of trust in healthcare provider may make patients withhold their health problems.[1]

Misinformation through the internet or social media.[1]

Healthcare providers withhold information (i.e., due to fear of destroying hope) or are overly optimistic regarding prognosis.[2]

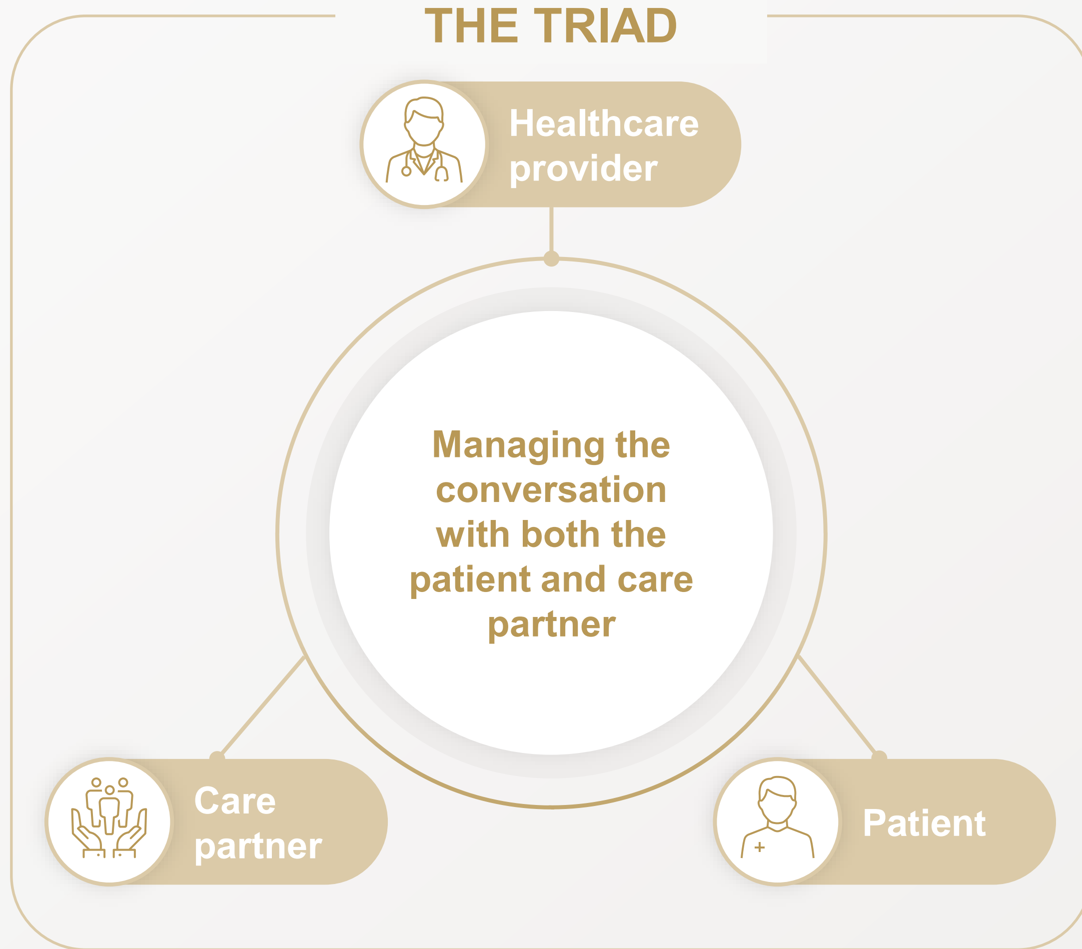
Establishing communication channels for effective AE discussions between the patient and healthcare provider.[1]

AE: Adverse Event

1. Cummings J et al. J Prev Alzheimers Dis. 2023;10(3):362-77. **2.** Berkey FJ et al. Am Fam Physician. 2018;98(2):99-104.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Considerations for Having a Treatment Discussion



The presence of a third person, creating a triad instead of the standard dyad, may **impact the relationship between physician and patient:**

Positively

- Enhancing communication
- Superior comprehension and involvement

Negatively

- Limiting patients' involvement and assertiveness
- Exclusion from the care discussions

This triad may have **distinguishing characteristics** when the patient is **elderly with cognitive impairment**.

1. Karnieli-Miller O et al. Patient Educ Couns. 2012;88(3):381-90.

Lilly

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Considerations for Having a Treatment Discussion

THE TRIAD

CONSIDERATIONS	GENERAL ADVICE
Manage diverse patient and care partner needs effectively.[1,2]	Set clear intentions in terms of **roles and conduct** (who talks, about what, when) while emphasizing the importance of each member of the triad being heard.[1,2]
Encounters may turn into dominant-marginalized dyadic conversations.[1]	**Articulate the goal** of ensuring patient participation in care decisions; despite challenges, exclusion should be avoided.[1,2]
Infantilization of the patient.[1]	**Be concrete** with treatment options and recommendations, and **direct the conversation** to the patient, preferably accompanied by hand-outs.[2]

1. Karnieli-Miller O et al. Patient Educ Couns. 2012;88(3):381-90. **2.** Stubbe DE. Focus (Am Psychiatr Publ). 2017;15(1):65-7.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Considerations for Having a Treatment Discussion

THE TRIAD

CONSIDERATIONS

Confusion about speaking roles signaled through verbal and nonverbal cues.[1]

Initial focus on the patient, then shift to the care partner.[1]

Uncertainty around care partner's role, interruptive vs. essential involvement.[1]

GENERAL ADVICE

Understand, acknowledge, and give **time for the shift of the companion to also becoming the care partner** – this is typically not a 'switch' done in one visit.[1]

Talk separately with care partners to feel comfortable speaking openly about their worries and with the patient for satisfactory conversation and exploration of feelings.[2]

Adopt **cross-culturally sensitive communication practices** and increase access to private and community education.[3,4]

1. Karnieli-Miller O et al. Patient Educ Couns. 2012;88(3):381-90. **2.** Lecouturier J et al. BMC Health Serv Res. 2008;8:95. **3.** Stubbe DE. Focus (Am Psychiatr Publ). 2017;15(1):65-7. **4.** Mahoney DF et al. Gerontologist.2005;45(6):783-92.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Shared Decision-Making

WHAT IS IT?

Shared decision-making is a collaborative process in which the healthcare provider works together with the patient to reach a joint decision about care and may be a method that is currently used in your clinical practice.[1]

BENEFITS

Improve patient satisfaction[2]

Improve treatment adherence[2]

Improve clinical outcomes[2]

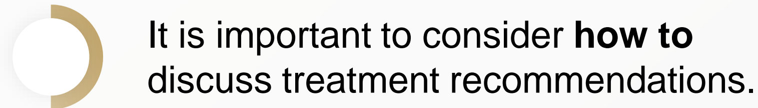
Shared decision making is also preferred by patients with dementia, cognitive impairment or Alzheimer's disease.[3,4]

1. NICE guideline. Available at: https://www.nice.org.uk/guidance/ng197/resources/shared-decision-making-pdf-66142087186885 17 June 2021 [Accessed April 22, 2024]. **2.** Dooley J et al. Br J Psychiatry. 2019;214(4):213-7. **3.** Dooley J et al. Int Psychogeriatr. 2015;27(8):1277-1300. **4.** Mattos MK et al. Dementia (London) 2023;22(4):875-909.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Shared Decision-Making

TREATMENT RECOMMENDATION



It is important to consider **how to** discuss treatment recommendations.

TIP Using assertions to initiate medication discussions *(see below)* may facilitate a more sensitive transition.

Treatment recommendations can be made with different **levels of authority** indicating **different degrees of autonomy** for patients.

Pronouncements	**No choice** – 'I will start you on a medication'
Proposals	**Invited to endorse or collaborate with idea** – 'How about trying a medication?'
Suggestions	**Medication is endorsed but patient is given the choice** – 'Would you like to try a medication?'
Offers	**Willingness to prescribe but no active endorsement of medication** – 'I can prescribe a medication'
Assertions	**State the fact that medication exists without endorsement or explicit recommendation** – 'There is a medication'

1. Dooley J et al. Br J Psychiatry. 2019;214(4):213-7.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Shared Decision-Making

PATIENT RESPONSES

Patients can respond with different **degrees of acceptance, passive or active resistance**. Considering that disagreement is socially complicated, especially in authority situations, disagreement most often takes the form of passive resistance.

Acceptance	**Quick positive acceptance** – 'I'd like to have that'
Passive resistance	**Minimal verbal or non-verbal acknowledgment** – 'mhm' or nodding, or no response
Active resistance	**Questioning the purpose of medication or indicating a desire not to take the medication** – 'I'm not very keen I don't want to take more tablets'

Association between recommendation format and patient response

- **Proposals** led to higher acceptance rates, while **suggestions** led to higher resistance rates.
- **Satisfaction** was **significantly lower** when **pronouncements** were used, compared to other formats.
- There were **no associations** between **level of cognitive impairment and recommendation format**.

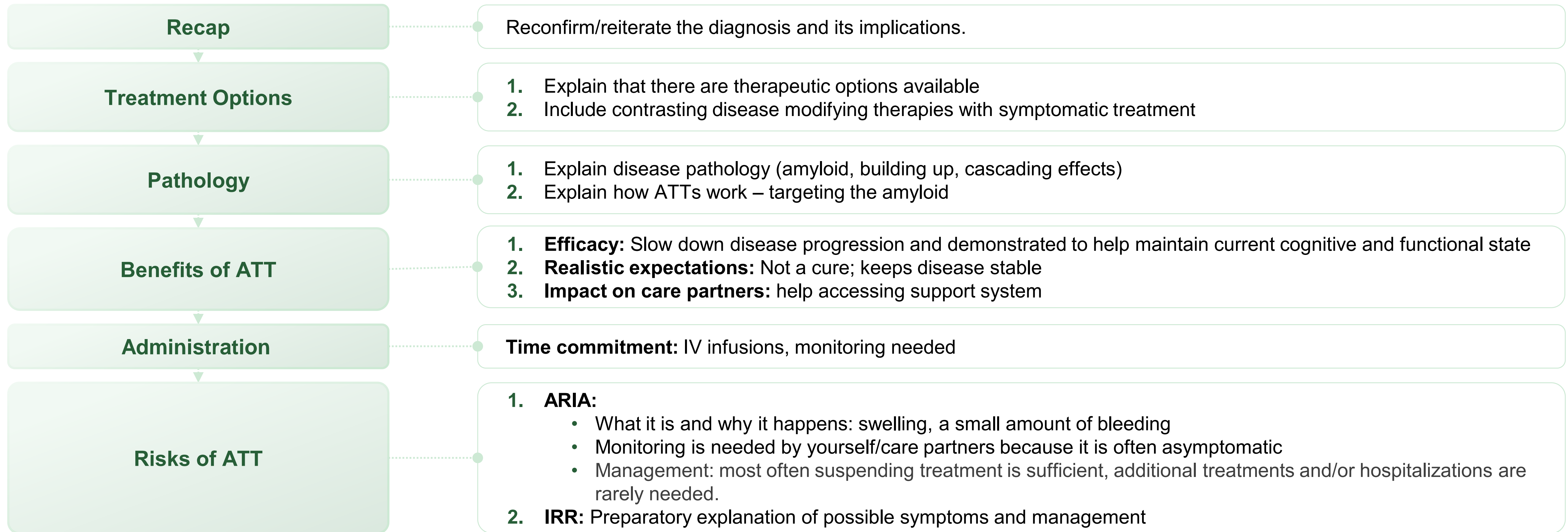
1. Dooley J et al. Br J Psychiatry. 2019;214(4):213-7.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Communicating Amyloid Targeting Therapy

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Overview of the Suggested Communication Flow



ARIA: Amyloid-Related Imaging Abnormalities; ATT: Amyloid Targeting Treatment; IRR: Infusion-Related Reaction; IV: Intravenous; MRI: Magnetic Resonance Imaging

1. Data on file.

Lilly

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Establishing the Basis

WHAT TO TALK ABOUT

Establish the foundational premises[1]

- Quality of life is deserved and valued across the whole age spectrum.
- Patients and families value the preservation of function.
- Memory loss is not a normal part of aging.
- There are treatments available, and patients deserve to know their options.
- Treatment is a time limited opportunity.
- Treatment guidelines should be communicated.

Restate diagnosis/recap[1]

- Defining the scope of the conversation and expectations of today's visit
- Reconfirm/reiterate the diagnosis and its implications.

CONSIDERATIONS

- Emphasize the importance of treating early.[1]
- Use inclusive, first-person language i.e., 'we', 'our'.[1]
- Keep in mind that denial is a common coping mechanism after getting bad news.[2]
    - Look for verbal and non-verbal cues such as delaying appointments, failing to grasp the implications of their illness, or displaying unrealistic optimism.[3]

SAMPLE CONVERSATION

"I thought we might just start by recapping what we discussed last time and then having a think about what our options are, and particularly about treatment options."

"We now have treatments, and those treatments are available and effective when used early. So being timely in making this diagnosis properly is important."

"Memory impairment, memory disorders, and memory loss are not a normal part of aging; this is something that we all have to remember. In the diagnosis of memory disorders, it's very important to make a precise and accurate diagnosis, because for some of our memory disorders, there are now treatments available."

1. Data on file. **2.** Storstein A. Acta Neurol Scand Suppl. 2011;(191):5-11. **3.** Travis AC et al. Am. J. Gastroenterol. 2011;106(6):1028-30.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Treatment Options

WHAT TO TALK ABOUT

- Use an assertion, introducing neutrally that there are new therapeutic options available.[1,2]
- Explain the difference between symptomatic treatment if the patient is already using it.[1,3]
- Mention that there are "´'brain health' lifestyle modifications available as complement.[1]

CONSIDERATIONS

- Assertions relieve the patient from immediate decision-making pressure, easing the transition to treatment discussions.[2]
- Since many patients with early AD are already on symptomatic treatment, they are likely to wonder about the distinction of this new treatment.[1]
- DMT and symptomatic treatments should not be framed as 'either/or' but explained as a combination complementing each other.[1]

SAMPLE CONVERSATION

"Nowadays we have a treatment we can start in order to slow down the progression of the accumulation of amyloid in the brain."

"Now, we do have some new treatments that are available in addition to the medication that you're already on. And I think it's important for us to discuss some of your options."

"The symptomatic medication that you're on right now helps your brain cells communicate with each other a little bit better, but it really doesn't do much as far as the damage that's occurring to your brain.

Some of the new medications that have become available attack the illness itself by minimizing some of the damage that's occurring to the brain."

AD: Alzheimer's Disease; DMT: Disease-Modifying Therapy

1. Data on file. **2.** Dooley J et al. Br J Psychiatry. 2019;214(4):213-7. **3.** Cummings J et al. J Prev Alzheimers Dis. 2023;10(3):362-77.

Lilly

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

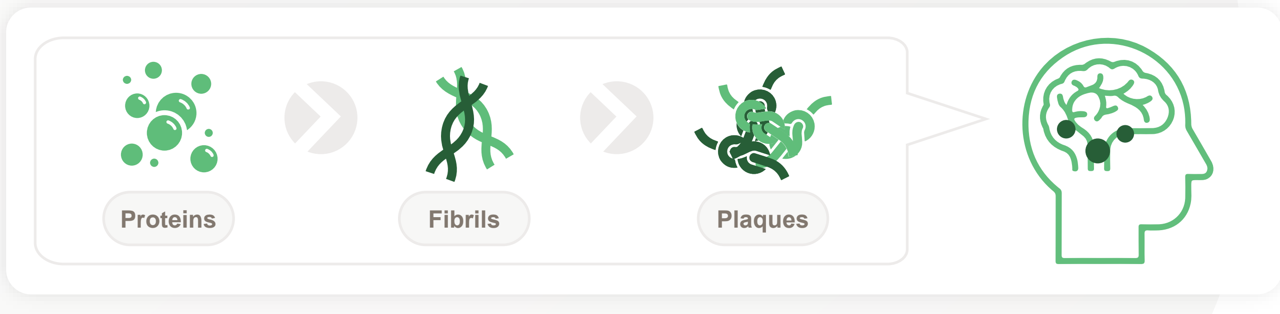
Pathology & Mechanism of Action

WHAT TO TALK ABOUT

- Explain disease pathology – introduce the term amyloid; explain that this protein is building up and has cascading effects.
- Explain how ATTs work – removing/reducing amyloid.

CONSIDERATIONS

- Talk about the treatment in third-person instead of directed, i.e., ‘the brain’ instead of ‘your brain’.
- Use hedging language, i.e., ‘may be able’, ‘perhaps’, ‘a chance’.
- Use of imagery or metaphors for amyloid plaques, i.e., ‘gunk’, ‘blocks’.
- Visual aids (like the image below) can be used to explain the disease pathology, i.e., amyloid build up.



SAMPLE CONVERSATION

“There are soluble proteins that may clump together to form insoluble fibrils and finally accumulate in the brain as plaques i.e., ‘Gunk’. This gunk can in turn damage and destroy brain cells.”

“There are medications that target these amyloid deposits ‘gunk’ and help in removing or reducing their deposition in the brain.”

“We suspect that amyloid is involved in a cascade that leads to brain cell death and damage. By removing that amyloid from the brain, we can perhaps minimize some of that damage and help slow the disease progression.”

ATT: Amyloid Targeting Treatment
1. Data on file.

Lilly

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Benefits & Efficacy

WHAT TO TALK ABOUT

- Emphasize slowing down disease progression and stabilizing the disease state as an efficacy outcome.[1,2]
- Translate efficacy parameters for clinical meaningfulness.[3]
- Discuss the implications of not treating.[3]

CONSIDERATIONS

- Repeat the same message in different ways.[1]
- Use clinically meaningful parameters like QoL to explain benefits/efficacy.[1]
- Explicitly acknowledge and encourage that this is a valuable goal.[1]
- Use health, cognitive, behavioral, and functional status as a measure of treatment success.[4]
- Keep a hopeful tone.[1]
- Use metaphors, i.e., ‘put the brakes on’.[1]

SAMPLE CONVERSATION

“You're still driving; you're still working. I want to keep you that way for as long as possible. We now have a treatment given intravenously that targets the underlying brain changes of Alzheimer’s disease, something called amyloid.”

"So, your memory difficulties are mild, and you do most things perfectly well. And the idea is to keep you doing that for a longer period of time. All right?”

“But the hope is that with these new therapies, we may be able to put the brakes on and slow how quickly you lose memory and thinking function. Basically, we're trying to maintain your quality of life for as long as possible and make sure that you remain who you are and continue to live and enjoy your life as long as possible.”

QoL: Quality of Life

1. Data on file. **2.** Sarkisian C et al. Ann Intern Med. 2024;177(2):246-8. **3.** Cummings J et al. J Prev Alzheimers Dis. 2023;10(3):362-77. **4.** Hampel H et al. Nat Aging. 2022;2(8):692-703.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Realistic Expectations

WHAT TO TALK ABOUT

- Establish realistic expectations: The notion of improvement as the only relevant treatment benefit is unrealistic.[1,2]
- Emphasize slowing down disease progression and stabilizing the disease state as an efficacy outcome.[1,2]
- The goal is to maintain quality of life and 'remain you longer'.[1]
- Emphasize that the treatment is not a cure; it will neither stop the disease nor reverse the damage already caused.[1]

CONSIDERATIONS

- Reiterate that the stabilization of illness can also be utilized as a measure of efficacy.[3]
- Switch to directed language instead of objective language, i.e., 'keep you', 'you lose memory'.[1]
- Emphasize that patients with Alzheimer's disease can achieve years of good quality if the symptoms are stabilized.[3]

SAMPLE CONVERSATION

"In terms of the benefits, I think it's important for us to understand that this medication is not a cure. It's not going to turn back the clock and make everything like it was. But what we're looking for is that this medication can slow things down. And what that means is that you can continue doing the things that you want to do for longer."

"One of the most important objectives we can actually reach is to maintain your activities of daily life as they are today so you can continue doing what you are doing now."

"I cannot say that your challenges will improve, but a real objective could be to slow down the progression of these disturbances. That is a very important goal to achieve, and we can do that."

1. Data on file. **2.** Sarkisian C et al. Ann Intern Med. 2024;177(2):246-8. **3.** Wilkinson D, Deas K. Eur. Neurol. Rev. 2007;1:37-9.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Risks & Safety – ARIA

WHAT TO TALK ABOUT

- Explain what it is and why it happens, include the following pointers:
  - Amyloid removal may sometimes cause damage to blood vessels.[1]
  - Removal of amyloid may cause extravasation of fluid and leakage of blood from damaged blood vessels.[1,2]
  - Leakage of fluid can result in swelling in the brain.[1,2]

CONSIDERATIONS

- Can be explained in different detail levels[1]:
  - Non-technical but detailed, i.e., builds up between brain cells, but also in the walls of blood vessel; when removed, pores open up [1].
  - By targeting and removing proteins in the brain, this can result in damage to blood vessels.
- Use imagery, non-technical words, i.e., 'open up pores', 'leak', 'spots of bleeding'.[1]

SAMPLE CONVERSATION

"Some people on these amyloid clearing medicines will experience something we call ARIA. And this comes about because blood vessels become a little bit leaky, and there can be spots of bleeding or areas of swelling in the brain."

"The medications target amyloid, this abnormally folded protein. As a result of targeting this protein, it may also target some other areas in the brain."

"Amyloid likes to build up between brain cells, where we believe it does most of the damage. But unfortunately, amyloid also builds up inside blood vessel walls in the brain. And as we're dissolving that amyloid in the brain, we can't selectively dissolve it just in between brain cells; we're dissolving it everywhere."

ARIA: Amyloid-Related Imaging Abnormalities

1. Data on file. **2.** Cummings J et al. J Prev Alzheimers Dis. 2023;10(3):362-77.

Lilly

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Risks & Safety – ARIA

WHAT TO TALK ABOUT

- Mention the frequency and severity of occurrences, including deaths, and highlight the importance of seeking help.[1,2]
- Emphasize the need for regular monitoring by patient/care partners and through MRI scans because ARIA is often non-symptomatic.[1,3]
- Management: a decision will be made based on severity to pause treatment, change dosing, or stop treatment.[1,3]

CONSIDERATIONS

- Emphasize and repeat that the risk of experiencing severe symptoms is small.[3]
- Use of inclusive language, indicating responsibility and involvement, i.e., ‘we would monitor you very closely’, ‘we have to perform an MRI’, ‘we pick up on scans’.[3]
- Use more generic language, i.e., ‘brain scans’, ‘imaging’, ‘MRI’.[3]

SAMPLE CONVERSATION

“Luckily, the ARIA phenomenon in most cases is not something that presents with clinical symptoms. So, most people don't even know that they have it. And it is something that we can pick up on imaging, like an MRI of the brain, which means if you were to undergo this treatment, we would monitor you very, very closely with regular MRIs.”

“And although that sounds very dramatic and scary, most of the time, there are no symptoms.”

“It generally clears over a few months, and most of the time, if there are symptoms, these are mild or moderate, rarely serious or severe. But nonetheless, we take this seriously, and we will monitor you to keep you safe.”

ARIA: Amyloid-Related Imaging Abnormalities; MRI: Magnetic Resonance Imaging

1. Cummings J et al. J Prev Alzheimers Dis. 2023;10(3):362-77. **2.** Sarkisian C et al. Ann Intern Med. 2024;177(2):246-8. **3.** Data on file.

Lilly

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Risks & Safety – IRR

WHAT TO TALK ABOUT

- Provide a preparatory explanation (for vigilance) of possible symptoms, i.e., 'that you can get a reaction after an infusion'.[1,2]
- Mention the potential risk.[2]
- Mention that they will be monitored for any allergic response and appropriate steps will be taken for management/therapy.[1,2]

CONSIDERATIONS

- Use a reassuring tone, saying that they will be monitored, and that appropriate treatment will be administered in the event of any serious reaction.[1]

SAMPLE CONVERSATION

"One may be an infusion reaction, so when the medication is infused, you may have a transient feeling of unease, chills, and flushing, which will go away."

"You might be allergic to the medication. And as we know, if you're allergic to anything, you are no longer to have that medication."

IRR: Infusion-Related Reaction

1. Data on file. **2.** Cummings J et al. J Prev Alzheimers Dis. 2023;10(3):362-77.

Lilly

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Administration & Practicalities

WHAT TO TALK ABOUT

- Highlight that a time commitment will be needed for treatment .[1,2]
- Explain that there will be a need for regular IV infusions.[1-3]
- Mention again the need for MRI monitoring for safety management to ensure the patient/caregiver receive a holistic picture of the time required.[1-3]

CONSIDERATIONS

- Use contrasting language, i.e., ‘not as simple as taking a pill’, ‘different to the one you’re taking’.[1]
- Use non-technical explanations of IV infusions, i.e., ‘drip into the arm’.[1]

SAMPLE CONVERSATION

“This new kind of medication is not a simple tablet that you take, it’s slightly more complicated, but the brain is a more complicated organ. The medication is given as a drip in the arm. So, you'd have to come up to the unit regularly and have these infusions.”

“Like we talked about, we’ll also need to monitor things to make sure everything's safe. So, what I want all of my patients and care partners to know is that this type of medication requires a degree of commitment in time and travel.”

IV: Intravenous; MRI: Magnetic Resonance Imaging

1. Data on file. **2.** Sarkisian C et al. Ann Intern Med. 2024;177(2):246-8. **3.** Cummings J et al. J Prev Alzheimers Dis. 2023;10(3):362-77.

Lilly

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Specific Situations – Eligibility & Counseling

WHEN APPLICABLE	CONSIDERATIONS
Eligibility for treatment and expectations.[1]	Patients who want treatment but might not be eligible due to advanced disease or cognitive impairment due to non-Alzheimer's disease pathology.
APOE genotyping recommendation and counseling.[2,3]	Certain genetic makeup (APOE) is associated with an increased risk of ARIA development and can be determined by a blood test. **Example:** "We would need to check your genetic status because we know that there are certain individuals that are more prone to developing ARIA, and those are the individuals that have a certain genetic variant called the *APOE* ε4 allele. So, we can have a simple blood test done to determine if you might be a candidate for this new therapy."
Discussing the failure of treatment.[1]	Not achieving clearance or continuing to progress clinically. Treatment is no longer appropriate, or the burden outweighs the benefit.
Contraindications related to emergent changes in health status.[2,4]	Consider if caution should be exercised when additional medications are administrated.

APOE: Apolipoprotein E; ARIA: Amyloid-Related Imaging Abnormalities

1. Belder CRS et al. Lancet Neurol. 2023;22(9):782-3. **2.** Data on file. **3.** Cummings J et al. J Prev Alzheimers Dis. 2023;10(3):362-77. **4.** Greenberg BD et al. Alzheimers Dement (N Y). 2023;9(4):e12426.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Specific Situations – Socioeconomic Factors

WHEN APPLICABLE	CONSIDERATIONS
Culture-specific communication.[1-3]	➢ Ethnic/racial differences in amyloid positivity, relationship between *APOE* ε4 and dementia. ➢ Small number of patients from underrepresented groups in trial populations.
Other demographic and health related limitations in the trial population include possible risks.[2]	Having multiple chronic conditions, age.
Uncertainties in relation to personal values or situational circumstances.[3]	Such as disliking interaction with the health care system, a lack of social support for monitoring risks, and being located far way from the clinic.
Financial implications.[3]	➢ Physicians have a responsibility to inform patients and care partners that the full costs of treatment may not be covered and about the financial ramifications of decisions to pursue treatment. ➢ Personal financial costs and logistic burdens associated with treatment play a role in treatment decision.

APOE: Apolipoprotein E; ARIA: Amyloid-Related Imaging Abnormalities

1. Cummings J et al. J Prev Alzheimers Dis. 2023;10(3):362-77. **2.** Greenberg BD et al. Alzheimers Dement (N Y). 2023;9(4):e12426. **3.** Sarkisian C et al. Ann Intern Med. 2024;177(2):246-8.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Section 4

Educational Support

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Improving the Conversation for Recall and Understanding

GENERAL APPROACHES

1 TELL
- Present information in small 'digestible' amounts.[1]
- Do not give too much information in one session.[2,3]

2 AIDS
Use aids to support comprehension, i.e., draw diagrams.[1]

3 PAUSE
Take a moment to check for patient understanding.[1]

4 AIDS
Additional resources could aid understanding and recall.[1]
- i.e., printed handouts, selected websites, handwritten instructions, audio recording of the visit.

CONSIDERATIONS

The amount of information presented has an impact on recall.[3]

Data presented at the start and end tends to be remembered more effectively than items in the middle.[3]

Advice tends to be better remembered if specific rather than general i.e., *'you will heal in 5-7 days'*, compared to *'you will heal shortly'*.[3]

1. Epstein RM et al. JAMA. 2004;291(19):2359–66. **2.** Lecouturier J et al. BMC Health Serv Res. 2008;8:95. **3.** Watson PWB, McKinstry B. J R Soc Med. 2009;102(6):235-43.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Improving the Conversation for Recall and Understanding

USING VISUAL AIDS

Structured, interactive information tailored to the individual will increase patient understanding.[1]

Visual aids can influence both attention, comprehension, and recall.[2-4]

- Simple visual aids reinforce information in written or spoken instruction.[2,3]
- Displaying statistical information can increase the likelihood of patients using the information in decision-making.[5,6]

Presentation of data

- **Probabilistic data.** Best represented as event rates rather than words, probabilities, or effect measures (i.e., RRR).[1]
- **Illustrations** (i.e., cartoons or simple charts) appear to aid understanding.[1]

RRR: Relative Risk Reduction

1. Trevena LJ et al. J Eval Clin Pract. 2006;12(1):13–23. **2.** Lee K, Nathan-Roberts D. Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care. 2021;10(1):257-62. **3.** Watson PWB, McKinstry B. J R Soc Med. 2009;102(6):235-43. **4.** Schubbe D et al. Patient Educ Couns. 2020;103(10):1935-60. **5.** Hawley ST et al. Patient Educ Couns. 2008;73(3):448-55. **6.** Fagerlin A et al. Med Decis Making. 2005;25(4):398-405.

Lilly

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Improving the Conversation for Recall and Understanding

USING WRITTEN MATERIALS

Provide written summaries of diagnoses, plans, and relevant resources.[1]

Relevant resources

- Provide education about their disease and direct them to high-quality resources.[1]
- Limit and clarify misleading information that may be available i.e., through internet searches.[1]

Written record / care plan

- Helps patients and care partners remember key elements from the session.[1]
- Recalling healthcare advice is essential to adherence.[2]

CONSIDERATIONS

There are patients with low literacy levels, for whom **pictograms** could be a helpful supplement.[2]

Improve recall by **going through** the materials handed out to the patient.[2]

1. Armstrong MJ et al. Neurol Clin Pract. 2024;14(1):e200223. **2.** Watson PWB, McKinstry B. J R Soc Med. 2009;102(6):235-43.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Communicating About Risks & Uncertainty

Important distinction between subjective and objective risks.[1,2]

Perceived probability[3]: i.e., the likelihood of getting ARIA.

RISK PERCEPTION

Risk is perceived and evaluated within the own context of the individual.[1,2]

Perceived severity[3]: i.e., the extent of harm believed to follow ARIA.

ARIA: Amyloid-Related Imaging Abnormalities

1. Stevenson M et al. Dementia (London) 2018;17(3):359-90. **2.** Infanti J et al. A literature review on effective risk communication for the prevention and control of communicable diseases in Europe. Stockholm: ECDC; 2013. **3.** Weinstein ND, Klein WM. Health Risk Appraisal and Optimistic Bias. International Encyclopedia of the Social & Behavioral Sciences (Second Edition). 2015;698-701.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Communicating About Risks and Uncertainty

CONSIDERATIONS

Prioritize and limit the number of disclosed side effects (one to four)[1]

- ✔ Improves recall
- ✔ Minimizes the nocebo effect
- ✔ Improves adherence

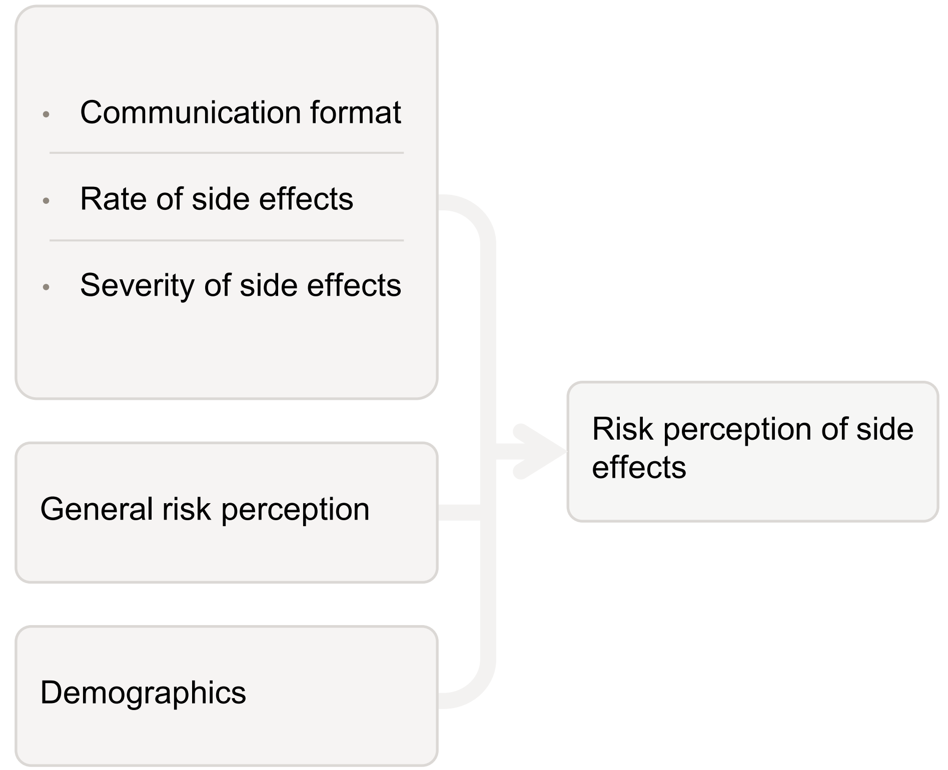
Avoid verbal descriptions of risks only[2,3]

- Descriptive words such as ‘rare’ or ‘common’ can be interpreted very differently between people.[2]
- The likelihood of experiencing low-rate side effects might be overestimated when using only verbal descriptions.[3]

Keep in mind that many patients have low numeracy skills[4]

- ✔ Use absolute risk instead of relative risk to present statistical information. Relative risk tends to make changes in risk appear larger.
- ✔ Use pictographs to communicate risk and benefit information.

ILLUSTRATION[3]



1. Barker JM, Faasse K. Intern Med J. 2023:53(9):1692-6. **2.** Siegel CA. Aliment Pharmacol Ther. 2011;33:23–32. **3.** Sawant R, Sansgiry S. Pharm Pract (Granada). 2018;16(2):1174. **4.** Fagerlin A et al. J Natl Cancer Inst. 2011;103(19):1436-43.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Section 5

Additional Considerations

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

Additional Considerations

Support & Future

- Reminder on advanced directive support and planning for the future.
- Quality of life is inherently reliant on the perception and communication abilities of the patient. Therefore, a record of future care preferences could be highly beneficial in the early disease stage.[1]
- The potential for miscommunication and leaving the patient out of the loop in terms of services and treatment planning is an ever-present danger.[2]

HCP – HCP Communication

- Doctors feeling more competent in discussions with radiologists will lead to better patient care.[3]
- Poor communication in explaining radiological imaging can result in a delay in investigation and potentially adverse clinical outcomes.[3]

ALZ-NET Registry

- ALZ-NET offers medical professionals access to real-world data, resources, and instructions regarding ALZ-NET operations, dementia care, and imaging services for sites and clinicians.

ALZ-NET: Alzheimer's Network; HCP: Healthcare Provider

1. Watt AD et al. J Alzheimers Dis. 2019;68(4):1321-3. **2.** Stubbe DE. Focus (Am Psychiatr Publ). 2017;15(1):65-7. **3.** Chuang YH et al. Postgrad Med J. 2021;97(1147):321-4.

Lilly

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

References (1/3)

- Armstrong MJ, Bedenfield N, Rosselli M et al. Best Practices for Communicating a Diagnosis of Dementia: Results of a Multi-Stakeholder Modified Delphi Consensus Process. Neurol Clin Pract. 2024;14(1):e200223.
- Barker JM, Faasse K. Influence of side effect information on patient willingness to take medication: consequences for informed consent and medication adherence Intern Med J. 2023:53(9):1692-6.
- Belder CRS, Schott JM, Fox NC. Preparing for disease-modifying therapies in Alzheimer's disease. Lancet Neurol. 2023;22(9):782-3.
- Berkey FJ, Wiedemer JP, Vithalani DN. Delivering Bad or Life-Altering News. Am Fam Physician. 2018;98(2):99-104.
- Chuang YH, Jones V, Trail M et al. Enhancing communication between foundation doctors and radiologists: a quality improvement project. Postgrad Med J. 2021;97(1147):321-4.
- Cummings J, Apostolova L, Rabinovici GD et al. Lecanemab: Appropriate Use Recommendations. J Prev Alzheimers Dis. 2023;10(3):362-77.
- Dooley J, Bass N, Livingston G et al. Involving patients with dementia in decisions to initiate treatment: effect on patient acceptance, satisfaction and medication prescription. Br J Psychiatry. 2019;214(4):213-7.
- Dooley J, Bailey C, McCabe R et al. Communication in healthcare interactions in dementia: a systematic review of observational studies. Int Psychogeriatr. 2015;27(8):1277-1300.
- Epstein RM, Alper BS, Quill TE. Communicating evidence for participatory decision making. JAMA. 2004;291(19):2359-66.
- Fagerlin A, Zikmund-Fisher BJ, Ubel PA. Helping patients decide: ten steps to better risk communication. J Natl Cancer Inst. 2011;103(19):1436-43.
- Fagerlin A, Wang C, Ubel PA. Reducing the influence of anecdotal reasoning on people's health care decisions: is a picture worth a thousand statistics? Med Decis Making. 2005;25(4):398-405.
- Fallowfield L, Jenkins V, Farewell V et al. Efficacy of a Cancer Research UK communication skills training model for oncologists: a randomised controlled trial. Lancet. 2002;359(9307):650-6.
- Greenberg BD, Lemere CA, Barnes LL et al. Prescribing anti-amyloid immunotherapies to treat Alzheimer's disease: Fully informing patient decisions. Alzheimers Dement (N Y). 2023;9(4):e12426.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

References (2/3)

- Hamann J, Bronner K, Margull J et al. Patient participation in medical and social decisions in Alzheimer's disease. J Am Geriatr Soc. 2011;59(11):2045-52.
- Hampel H, Au R, Mattke S et al. Designing the next-generation clinical care pathway for Alzheimer's disease. Nat Aging. 2022;2(8):692-703.
- Hawley ST, Zikmund-Fisher B, Ubel P et al. The impact of the format of graphical presentation on health-related knowledge and treatment choices. Patient Educ Couns. 2008;73(3):448-55.
- Hendriksen H, van Gils AM, van Harten AC et al. Communication about diagnosis, prognosis, and prevention in the memory clinic: perspectives of European memory clinic professionals. Alzheimers Res Ther. 2023;15(1):131.
- Infanti J, Sixsmith J, Barry MM et al. A literature review on effective risk communication for the prevention and control of communicable diseases in Europe. Stockholm: ECDC; 2013.
- Karnieli-Miller O, Werner P, Neufeld-Kroszynski G et al. Are you talking to me?! An exploration of the triadic physician-patient-companion communication within memory clinics encounters. Patient Educ Couns. 2012;88(3):381-90.
- Lee K, Nathan-Roberts D. Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care. 2021;10(1):257-62.
- Lecouturier J, Bamford C, Hughes JC et al. Appropriate disclosure of a diagnosis of dementia: identifying the key behaviours of 'best practice'. BMC Health Serv Res. 2008;8:95.
- Mahoney DF, Cloutterbuck J, Neary S et al. African American, Chinese, and Latino family caregivers' impressions of the onset and diagnosis of dementia: cross-cultural similarities and differences. Gerontologist.2005;45(6):783-92.
- Mattos MK, Gibson JS, Wilson D et al. Shared decision-making in persons living with dementia: A scoping review. Dementia (London) 2023;22(4):875-909.
- NICE guideline. Shared decision making. 2021. Available at: https://www.nice.org.uk/guidance/ng197/resources/shared-decision-making-pdf-66142087186885 17 June 2021 [Accessed April 22, 2024].
- Sarkisian C, Romanov A, Mafi JN. Talking With Patients About the New Anti-amyloid Alzheimer Disease Medications. Ann Intern Med. 2024;177(2):246-8.
- Sawant R, Sansgiry S. Communicating risk of medication side-effects: role of communication format on risk perception. Pharm Pract (Granada). 2018;16(2):1174.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.

References (3/3)

- Schubbe D, Scalia P, Yen RW et al. Using pictures to convey health information: A systematic review and meta-analysis of the effects on patient and consumer health behaviors and outcomes. Patient Educ Couns. 2020;103(10):1935-60.
- Siegel CA. Review article: explaining risks of inflammatory bowel disease therapy to patients. Aliment Pharmacol Ther. 2011;33:23–32.
- Stevenson M, McDowell ME, Taylor BJ. Concepts for communication about risk in dementia care: A review of the literature. Dementia (London) 2018;17(3):359-90.
- Storstein A. Communication and neurology – bad news and how to break them. Acta Neurol Scand Suppl. 2011;(191):5-11.
- Stubbe DE. The Health Care Triad: Optimizing Communication in Dementia Care. Focus (Am Psychiatr Publ). 2017;15(1):65-7.
- Sun T, Xie T, Wang J et al. Decision-Making Under Ambiguity or Risk in Individuals With Alzheimer's Disease and Mild Cognitive Impairment. Front Psychiatry. 2020;18;11:218.
- Travis AC, Pawa S, LeBlanc JK et al. Denial: what is it, how do we recognize it, and what should we do about it? Am. J. Gastroenterol. 2011;106(6):1028-30.
- Trevena LJ, Davey HM, Barratt A et al. A systematic review on communicating with patients about evidence. J Eval Clin Pract. 2006;12(1):13–23.
- Watson PWB, McKinstry B. A systematic review of interventions to improve recall of medical advice in healthcare consultations. J R Soc Med. 2009;102(6):235-43.
- Watt AD, Jenkins NL, McColl G et al. "To Treat or not To Treat": Informing the Decision for Disease-Modifying Therapy in Late-Stage Alzheimer's Disease. J Alzheimers Dis. 2019;68(4):1321-3.
- Weinstein ND, Klein WM. Health Risk Appraisal and Optimistic Bias. International Encyclopedia of the Social & Behavioral Sciences (Second Edition). 2015;698-701.
- Wilkinson D, Deas K. Is the Reduced Worsening of Clinical Symptoms a More Realistic Expectation of Treatment Outcome in Patients with Alzheimer's Disease? Eur. Neurol. Rev. 2007;1:37-9.
- Zhang Y, Wang J, Sun T et al. Decision-Making Profiles and Their Associations with Cognitive Performance in Mild Cognitive Impairment. J Alzheimers Dis. 2022;87(3):1215-27.

VV-MED-152980 © 2024 Lilly USA, LLC. All rights reserved.