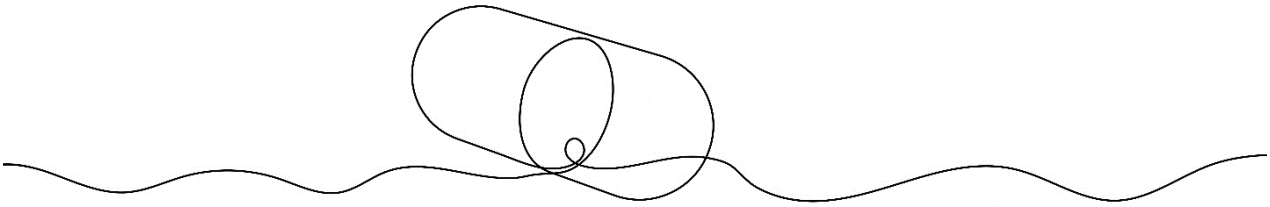
BE-SAFE

Implementing a patient-centred and evidence-based intervention to reduce **BE**nzodiazepine and sedative hypnotic use to improve patient **SAFE**ty and quality of care



Educational material for physicians and patients public deliverable report **D3.2**

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Abbreviations

BZRA	Benzodiazepine receptor agonists
BSH	Benzodiazepines and sedative hypnotics
CBT-I	Cognitive behavioural therapy for insomnia
GP	General practitioner
HCP	Healthcare professional
RCT	Randomised controlled trial
SDM	Shared decision making
WP	Work Package

1. Introduction

The objective of this deliverable report is to describe the educational materials for physicians and patients that will be used in the BE-SAFE trial. These materials aim to train physicians on how to perform an intervention aimed at reducing and discontinuing the use of benzodiazepine receptor agonists (BZRA) in older patients (aged ≥65 years) with sleep problems. BZRA may pose significant adverse effects and associated costs, particularly in older adults. These include an increased risk of falls, fractures, hospitalizations, impaired functioning, cognitive impairment, delirium, and mortality. Addressing the overuse of BZRA in older adults is therefore an urgent priority to enhance patient safety [1].

The BE-SAFE project, short for 'Implementing a patient-centred and evidence-based intervention to reduce Benzodiazepine and sedative-hypnotic use to improve patient safety and quality of care,' is a 5-year research initiative funded by the European Commission through the Horizon Europe Research Programme (Grant agreement 101057123; 09/2022-08/2027) and by the Swiss State Secretariat for Education, Research, and Innovation (SERI) under contract No 22.00116. This collaborative effort involves partners from six countries (Belgium, Greece, Norway, Poland, Spain, and Switzerland) and promotes BZRA deprescription as an essential component of good medical practice. The aim of the BE-SAFE project is to design, implement, and test the effectiveness of an intervention to reduce BZRA use in the population over 65 years of age through a cluster randomized clinical trial (RCT). This deliverable report outlines the components and delivery of the intervention for physicians, providing their rationale and detailing various delivery methods. This information should facilitate the consistent delivery of the core components of the BE-SAFE intervention. The therapeutic protocol for patients is described in public deliverable report D3.1 "Therapeutic protocol for BSH discontinuation BE-SAFE".

2. Work performed

2.1. Rational for developing educational and information materials for physicians and patients

The high prevalence of sleep problems and the frequent use of sedative-hypnotics in older adults represent a major health concern in developed countries [2]. Addressing the overuse of benzodiazepines and sedative-hypnotics (BSH) in older adults is an urgent priority to enhance patient safety[3]. To meet this need, an international consortium of six European partners (Belgium, Greece, Norway, Poland, Spain, and Switzerland) develops an evidence-based intervention within the BE-SAFE project to discontinue the use of BSH for sleep problems in older adults (aged 65 and older). BE-SAFE, which stands for 'Implementing a patient-centred and evidence-based intervention to reduce benzodiazepine and sedative-hypnotic use to improve patient safety and quality of care,' is a 5-year research project funded by the European Commission through the Horizon Europe Research Programme (Grant agreement 101057123; 09/2022-08/2027) and by the Swiss State Secretariat for Education, Research, and Innovation (SERI) (contract No 22.00116).

The developed intervention will be initiated by physicians working in a hospital ward or outpatient clinical setting. The aim of this report is to describe the development of the educational materials developed for physicians and patients within the BE-SAFE project.

Developing educational materials for physicians to deprescribe BSH is rooted in several important rationales:

1) BSH are associated with numerous risks, including dependency, cognitive impairment, falls, and increased mortality, especially among older patients [1]. Educating physicians about these risks helps them support the patient to make informed decisions about BSH deprescription [4].
2) Educational materials help physicians understand and effectively implement the clinical practice guidelines [5].
3) Many patients prescribed BSH could potentially benefit from alternative treatments, such as cognitive-behavioural therapy for insomnia [6]. Educating physicians about these alternatives empowers them to provide comprehensive care while minimizing reliance on BSH.
4) Deprescribing BSH demands focusing on individual patient needs, preferences, and goals. Educational materials can help physicians engage patients in shared decision-making regarding the risks and benefits of BSH use [7].

5) Physicians have a professional responsibility to optimize medication in older adults. Providing educational resources on deprescribing BSH equips physicians with the knowledge and skills [8] to fulfill this responsibility effectively.

The rationale for developing patient educational materials is supported by current data highlighting patient education as the most evidence-based non-pharmacological intervention to support BSH deprescription (systematic review performed within WP2/WP3 of BE-SAFE project - publication in preparation; [9–11]).

2.2. Global overview of the intervention

The intervention consists of different components and will be performed in 3 sequential steps, as illustrated in Figure 1. First, the intervention physician will be invited to take the training modules and encouraged by a senior physician to consider BSH deprescription in all eligible patients and to monitor and assess their performance with a self-monitoring tool. Second, the intervention physician will apply the steps of the deprescribing algorithm with all patients who consented to participate in the trial until a shared decision is made with the patient. Third, the decision made and information on follow-up actions will be communicated in writing to the primary care physician and the patient.

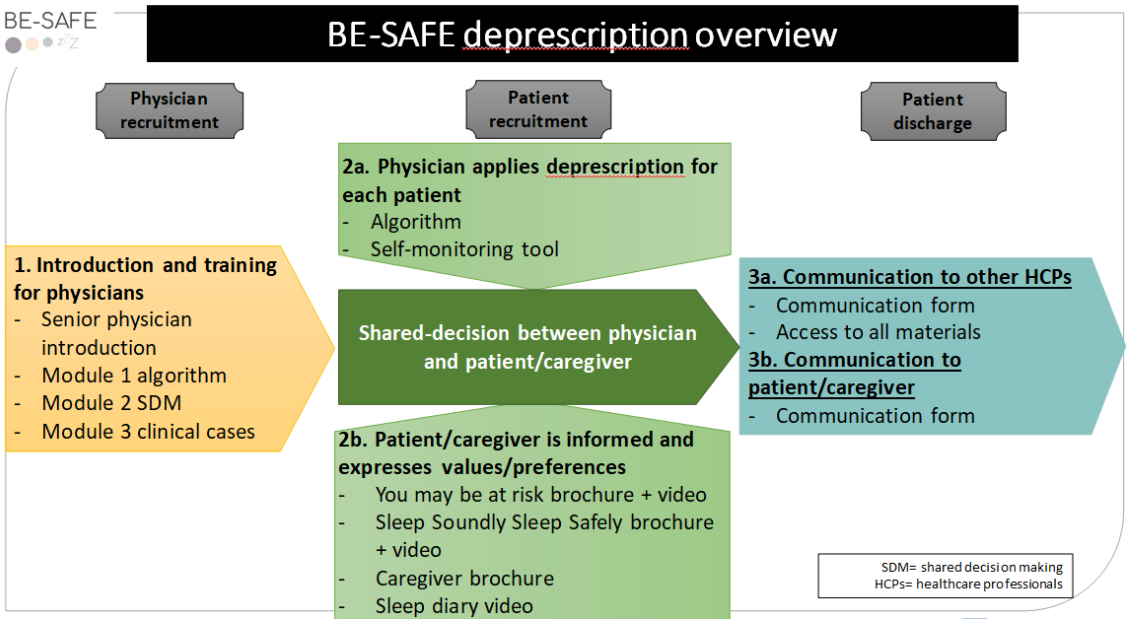

Figure 1: Three sequential steps of BE-SAFE intervention

Several materials have been developed as part of this intervention, for both patients and physicians, and are further described in the sections below. These materials will be used by:

- Intervention physician: hospital physician who participates in the RCT and was randomly allocated to the intervention arm.
- Senior physician: hospital physician supervising the intervention physician (e.g., head of department or direct superior).
- Patient: person who agreed to participate in the RCT.
- Caregiver: another person present and assisting the participant while making any decision in the following steps (e.g., partner, family member).

The material may also be used by other HCPs: any HCP caring for the participant, e.g., general practitioner, other hospital specialist, clinical or community pharmacist, or psychologist.

2.3. Intervention materials for physicians

The BE-SAFE research team developed the materials for physicians, they were then pilot-tested with 24 physicians from the 6 participating countries, and feedback led to adjustments. Each material was later translated from English to the local languages.

In the description below, we first describe the content of each material, then briefly explain its rationale, and finally elaborate on possible modes of delivery. Each country will select the mode that best fits its own context.

2.3.1. Senior physician endorsement

This material is available in **Appendix 6.1**.

- Content: This material supports senior physicians to communicate to an intervention physician that considering BSH deprescription in all adults 65+ taking a BSH for insomnia, irrespective of the presence of adverse events, is an important goal for the department. The senior physician encourages the intervention physician to take the training modules as soon as possible.
- Rationale: Setting goals and involving a credible source aims to tackle the perception that BSH deprescription is not a priority for the ward/department.
- Possible modes of delivery:
    - Face-to-face session: e.g. 15-minute session (with all intervention physicians at the same time, or individually); could be done at a time when they usually have meetings, to have

this integrated into the current context but this can only be done with the intervention physicians
    - Written communication: form provided by paper or e-mail
    - Individual face-to-face discussion

2.3.2. Training modules

This material is available in the BE-SAFE public website, under a specific password-protected section.

- Content: This training module consists of three videos (5-10 min each).
    - Module 1 video: Introduction to BSH deprescription and how to use the deprescription algorithm. It covers the Importance of considering BZRA deprescription for all older adults with chronic use; how to overcome initial inertia; convince that it takes limited time; information about CBTi; persuasion about capability; then elaborates on the deprescribing process by showing how to use the deprescription algorithm.
    - Module 2 video: This video focuses on shared decision-making by covering what it is, why it is important (tackling myths) and how to do it.
    - Module 3: This video consists of clinical cases and shared decision-making practice; the vignettes were developed to reflect different participant typologies, various styles of conversation, and different decisions taken.
- Rationale: Providing instructions on why and how to deprescribe and demonstrating the behaviour aims to improve physicians' skills and beliefs about their capability to engage in deprescribing even with limited time.
- Possible modes of delivery: The online whiteboard video (10 min) will be available with local language subtitles on a hidden page of the BE-SAFE public website, protected by a generic password. Training with these videos can occur in different ways:
    - Onsite session with all intervention physicians
    - Individual session, each physician to take the online modules at a convenient time

2.3.3. Self-monitoring tool

This material is available in **Appendix 6.2.**

- Content: This is a 1-page document to support self-monitoring. After the training, intervention physicians will be asked to practice deprescribing with a few patients and reflect on their performance. They are invited to check if and how they performed each step of the deprescribing algorithm, identify one action for improvement, and reflect on one improvement strategy.

- Rationale: self-monitoring and setting easy-to-perform tasks will contribute to improving skills and beliefs about capabilities.
- Possible delivery modes: The physician performs the process individually, on a paper or electronic version.

2.3.4. Deprescription algorithm

This material is available in **Appendix 6.3**.

- Content: This is a 2-page document providing practical instructions on how to deprescribe. The front page details 5 subsequent steps to follow (i.e., check if deprescription is recommended; engage with the patient- SDM; reach a decision [4 options: start tapering with aiming to stop; start tapering without aiming to stop; postpone decision; BZRA continuation] and if applicable, select a tapering schedule and support measures; plan follow-up; and perform follow-up). The backside presents practical information on various aspects such as: triggers; expected benefits; potential risks ; main barriers and how to address them; (non) pharmacological support measures.
- Rationale: Providing instructions on how to deprescribe by adding a new object to the physicians' environment (i.e., the algorithm) will increase the physician's capacity to deprescribe.
- Possible modes of delivery: This 2-page document is available in an electronic version and can be printed.

2.3.5. Communication to other healthcare professionals (HCPs)

This material is available in **Appendix 6.4.**

- Content: This is a 2-page document. The frontside is to be completed by the hospital physician and aims to provide individualised information on the patient: information on clinical aspects and on patient's values and preferences; summary of decisions and actions taken; follow-up recommendations. The backside provides general information to support HCPs in follow-up actions. It includes: a link and/or QR code on how to access training material, handouts, and participant brochures; summary on non-pharmacological alternatives; follow-up / monitoring instructions suggestions on further steps / follow-up. This form is intended for all HCPs that the participant/caregiver feels involved in their care: general practitioner, other primary care provider, community pharmacist, other specialist... The physician should discuss with the participant to whom it will be sent. This form should be sent within one week after the decision is made.

- Rationale: Deprescription is a multiple step process that takes several weeks or months to complete. Ensuring seamless care is essential, and this includes sharing information with other HCPs.
- Possible modes of delivery: to be defined locally based on what is feasible and most efficient
    - Filling out the form: paper or online
    - Sending the form: online form added to the online health record; electronic letter sent to the GP through a secured health messaging system; paper form given to the GP by post or through the participant.

2.4. Intervention material for patients

The materials for patients were developed by the BE-SAFE research team and optimized to address the specific needs of older adults, including low health literacy, numeracy, or education levels. They were subsequently evaluated by all partners and the Patient Advisory Committee (PAC), and feedback led to adjustments. Each material was later translated from English into the local languages. In the description below, we outline the content and purpose of each material.

2.4.1. Educational brochures

The intervention material for patients consists of **three brochures**:

- The 'You May Be at Risk' brochure was developed based on a brochure validated in the Empower study [9]. It was designed to provide information about the risks associated with BZRA use in older age and the principles of BSH discontinuation.
- The 'Sleep Soundly, Sleep Safely' brochure is intended to help patients understand how to address their sleep problems using CBT-I techniques instead of relying on BSH.
- The Caregiver brochure was developed to engage the caregiver in the process of BSH discontinuation and increasing the social support for the patients.

The development and content of these brochures is described in the public deliverable report D3.1 “Therapeutic protocol for BSH discontinuation BE-SAFE”.

2.4.2. Educational animations

In addition to the brochures, the intervention was enhanced with **three animations**:

- "You May Be at Risk" animation is based on the information provided in the corresponding brochure. It presents and reinforces core information about the risks associated with BSH use

among older people, principles of BSH tapering, safer methods to improve sleep, encourages patients to consult with physicians, and to read the brochure. The duration of the animation is 3 minutes and 25 seconds.

- "Sleep Soundly, Sleep Safely" animation is based on information provided in the corresponding brochure. It introduces the main techniques of Cognitive Behavioural Therapy for Insomnia (CBT-I), beginning with behavioural activation and planning activities during the day, relaxation and sleep time scheduling with sleep restriction and stimulus control techniques. It educates about sleep regulation and offers a small amount of cognitive restructuring related to dysfunctional beliefs about sleep. The duration of the animation is 5 minutes and 27 seconds.
- "Your Sleep Diary" animation was prepared after receiving feedback from the PAC indicating that the description of the sleep diary presented in the 'Sleep Soundly, Sleep Safely' brochure may not be fully sufficient to explain or motivate older people on how to use it. The animation demonstrates to patients how to effectively utilize a sleep diary to implement sleep restriction, which is the most effective Cognitive Behavioural Therapy for Insomnia (CBT-I) technique for enhancing sleep duration and quality. The duration of the animation is 2 minutes and 31 seconds.

2.4.3. Communication form for patients/caregivers

This material is available in **Appendix 6.5**.

- Content: This is a 2-page document for the patient. The front side provides individualised data on the deprescribing conversation and decisions taken, and the tapering plan whenever applicable. The back side provides information on existing resources (with a link and QR code on how to access brochures and videos), possible symptoms during dose reduction, and some blank space for the patient to write some notes. The intervention physician will complete this form and will be given to the patient (or caregiver) at discharge or at the end of the consultation. The physician will encourage the patient to show this form to future HCPs.
- Rationale: Deprescription is a multiple-step process that takes several weeks or months to complete. Ensuring seamless care is essential and this includes sharing information with other HCPs.
- Possible modes of delivery: The form will be provided in paper or may be sent by e-mail or integrated in a secured App.

2.5. Partners involved

Work Package 3 was led by Prof. Adam Wichniak (Institute of Psychiatry and Neurology, Warsaw, Poland)

and Prof. Thomas Berger (University of Bern, Switzerland). Educational material for patients was developed by J. Salbert, M. Walęcka, K. Gustavsson, M. Kaznowski, M. Iwański and A. Wichniak (Institute of Psychiatry and Neurology, Warsaw, Poland) and Prof. Thomas Berger (University of Bern, Switzerland). Educational materials for physicians were developed by FX. Sibille, M. de Saint-Hubert and A. Spinewine from Université catholique de Louvain (Belgium)

BE-SAFE partners from Greece (University of Athens), Norway (Oslo University Hospital), Spain (Fundació Salut i Envelliment), and Switzerland (University Hospital Bern), as well as researchers from Poland (Institute of Psychiatry and Neurology), participated in adapting and improving the materials to healthcare providers' needs. Researchers from Canada (Ottawa Health Research Institute) provided expert guidance on the implementation science in healthcare.

3. Conclusions, next steps

The BE-SAFE deliverable "Educational and information materials for physicians and patient card" describes the educational and informational materials for physicians and patients prepared within the BE-SAFE project. These materials aim to support patients and to train physicians on how to perform an intervention aimed at reducing and discontinuing the use of benzodiazepine receptor agonists (BZRA) in older patients (aged ≥65 years) with sleep problems. The intervention will be delivered by physicians working in hospital wards or outpatient centres on a single occasion and will include two patient brochures and one caregiver brochure. The efficacy of the interventions will be assessed in the BE-SAFE randomized clinical trial (RCT).

4. Acknowledgments

BE-SAFE received funding from the European Union's Horizon Europe research and innovation programme under the grant agreement Nr. 101057123, and from the Swiss State Secretariat for Education, Research and Innovation (SERI) under the contract Nr. 22.00116.
François-Xavier Sibille was supported by a grant "Clinical Master Specialist Applicant for a Ph.D." of the Fonds de la Recherche Scientifique – FNRS (Belgium).

The BE-SAFE consortium partners wish to acknowledge the support from national and international Patients Advisory Council (PAC), whose remarks were a valuable aid in optimizing the educational materials for physicians, especially in understanding the patients' values and preferences to engage in BZRA deprescription.

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6. Annexes

6.1. Senior physician endorsement

INTRODUCTION BY A SENIOR PHYSICIAN

BE-SAFE

Dear,
BE-SAFE is a HORIZON Europe funded project (HORIZON-HLTH-2021-CARE-05-01) aiming to improve patient safety by addressing knowledge and practice gaps related to the reduction of benzodiazepine receptor agonists (BZRAs) in order to provide resources for patients, healthcare professionals (HCPs), healthcare systems and policymakers throughout the diverse European healthcare landscape to reduce BZRA use.

In the first steps of this project, it appeared that BZRA deprescription was not perceived as a priority in most of hospital departments. Therefore, we believe that your support is important.

We would like the physicians working under your supervision and enrolled in the intervention cluster:

- To realize that considering BZRA deprescription in all adults aged 65 years or older is a priority for the department;
- To be encouraged to take the training modules and use the tools provided. They will be provided with
  - training materials:
    - one video introducing BZRA deprescription and how to use the algorithm
    - one video explaining shared-decision making and how it applies to BZRA deprescription
    - one video putting shared-decision making into practice through clinical cases
  - materials to hand over to the patient and the caregiver
    - The Patient Sleep safely sleep soundly brochure and video
    - The Patient You may be at risk brochure and video
    - The Sleep diary video
    - The Caregiver brochure
  - materials to use in front of the patient:
    - An algorithm to guide you in the complete process
    - A tool to communicate the discussion and its results to the patient/caregiver
    - A tool to communicate to other healthcare professionals, especially the general practitioner

We encourage you to have a face-to-face meeting, but you could also use a written communication. In that case, we provide you with a template below.

E-MAIL PROPOSAL

BE-SAFE

As you know benzodiazepine receptor agonists (BZRAs) have an unfavourable harms-benefits balance in older adults. Their benefits are at best modest and short term, as their potential harms are numerous and serious: risk of prolonged sedation, confusion, impaired balance, falls, road traffic accidents.

BZRAs are often used for insomnia. Clinical guidelines recommend avoiding BZRAs in adults aged 65 years or older, especially in chronic use. Therefore, it is recommended to consider deprescribing, the planned and supervised process of dose reduction or stopping of a medication. You receive this e-mail because you are going to collaborate to the BE-SAFE trial (webpage link).

As hospital physicians taking care of older adults, it is our responsibility to engage patients regarding BZRA deprescription. Time is a crucial factor in your practice but it's worth taking some time to discuss this matter with our patients. Training and materials provided will help you to be time-efficient, and bring benefits for both you and your patients.

You will be provided with training materials:

- one video introducing BZRA deprescription and how to use the algorithm
- one video explaining shared-decision making and how it applies to BZRA deprescription
- one video putting shared-decision making into practice through clinical cases

You will be provided with brochures and videos to hand over to the patient and the caregiver:

- The Patient "Sleep safely sleep soundly" brochure and video
- The Patient "You may be at risk" brochure and video
- The Sleep diary video
- The Caregiver brochure

You will also be provided with materials to use in front of the patient:

- An algorithm to guide you in the complete process
- A tool to communicate the discussion and its results to the patient/caregiver
- A tool to communicate to other healthcare professionals, especially the general practitioner.

Best regards,

6.2. Self-monitoring tool

BENZODIAZEPINES AND Z-DRUGS (BZRA) DEPRESCRIPTION SELF-MONITORING

BE-SAFE

It is well described that asking the person to monitor and record their behaviour is an efficient way to promote and improve behaviour. We therefore encourage you to record, for the first patients with whom you will address BZRA deprescription, if you addressed the various steps of the process. Take 30 seconds to reflect and be more efficient for the next patient.

	Patient 1		Patient 2		Patient 3	
Patient characteristics/context						
I explored the clinical triggers	☐ yes!	☐ not entirely	☐ yes!	☐ not entirely	☐ yes!	☐ not entirely
I sought patient/caregiver participation	☐ yes!	☐ not entirely	☐ yes!	☐ not entirely	☐ yes!	☐ not entirely
I helped patient/caregiver explore options (including their benefits/ risks)	☐ yes!	☐ not entirely	☐ yes!	☐ not entirely	☐ yes!	☐ not entirely
I explored the patient's values and preferences	☐ yes!	☐ not entirely	☐ yes!	☐ not entirely	☐ yes!	☐ not entirely
We reached a decision and I documented it in the patient's record	☐ yes!	☐ not entirely	☐ yes!	☐ not entirely	☐ yes!	☐ not entirely
We defined a follow-up plan	☐ yes!	☐ not entirely	☐ yes!	☐ not entirely	☐ yes!	☐ not entirely
I provided written information to the patient and to other healthcare professionals	☐ yes!	☐ not entirely	☐ yes!	☐ not entirely	☐ yes!	☐ not entirely
One strategy I can use to improve my behaviour						
Notes						

This work is part of the BE-SAFE project supported by the European Union's Horizon Europe research and innovation programme under the grant agreement No 101057123, and by the Swiss State Secretariat for Education, Research and Innovation (SERI) (contract No 22.00116). Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or of the SERI. Neither the European Union nor the SERI can be held responsible for them.

6.3. Deprescription algorithm

BENZODIAZEPINES AND Z-DRUGS (BZRA) FOR INSOMNIA IN ADULTS – DEPRESCRIPTION ALGORITHM

BE-SAFE

1. Check for any reason why BZRA should be continued

- Uncontrolled anxiety
- Severe depression
- Alcohol withdrawal
- Epilepsy
- Current psychotic disorder
- Current bipolar disorder
- End-of-life

→ Any of them → Deprescribing NOT recommended

None ↓

2.Engage with the patient - Shared-decision making

- Explore when and why BZRA was initiated; if patient made previous attempt to stop and what failed.
- Identify clinical triggers for BZRA deprescription (see A).
- Inform patients on why to consider deprescribing, expected benefits and risks, and how this can be done (give brochures) (See E).
- Explore values and preferences (see E).

3. Reach a decision and document in patient's record

Or →

Postpone decision or decision not to deprescribe

- If decision postponed: document conditions for resuming discussion (e.g. other physician, other moment,...) and communicate to other healthcare professionals.
- Remember values and preferences are contextual and not fixed.

Either ↓

Initiate deprescription with(out) aiming to stop

- Prescribe the tapering schedule, using the same molecule.
- ↘ by 25% every 2 weeks; ↘ more slowly (e.g. by 10-12,5% instead of 25% and/or every 4 weeks) if patient/caregiver preference; clinical perception of higher dependance; complex psychosocial context.
- Consider alternate day dosing if dosage forms are limited.
- Define non-pharmacological measures to support deprescription and sleep.
- Sleep hygiene; social support; CBT-I (use **Sleep soundly, sleep safely**).
- Using a substitute medication is NOT recommended.
- Remind about potential withdrawal symptoms (see D).

Minimize the risk of adverse events in BZRA users

- Give preference to intermediate acting BZRA with no active metabolite (e.g. lorazepam, oxazepam).
- Minimize other central nervous system-acting drugs (e.g. opioids, antidepressants, antipsychotics).
- Minimize substances interfering with sleep (e.g. caffeine, nicotine, alcohol, amphetamines, pseudoephedrine, steroids, dopamine agonists, b-blockers, fluoxetine).
- Consider refering the patient to psychologist, psychiatrist, sleep specialist

4. Plan follow-up

- Define follow-up with patient/caregiver (frequence, length of consultation).
- Provide written information to the patient and other healthcare professionals (e.g.,general practioner, specialist, pharmacist).

5. Perform follow-up

- Assess BZRA intake: current dosage; reasons for any deviation in tapering plan.
- Assess benefits and withdrawal symptoms related to tapering.
- Remind expected benefits (see C) and potential risks (see D)
- Validate next steps (e.g. continue or pause tapering, add or reinforce non-pharmacological approach,...).

RESOURCES FOR PATIENTS AND CAREGIVERS

- Patient **Sleep soundly, sleep safely** brochure and video
- Patient **You may be at risk** brochure and video
- **Sleep diary** video
- **Caregiver** brochure

RESOURCES FOR HEALTHCARE PROFESSIONALS

- **Training module 1:** introduction to BZRA deprescription and how to use the algorithm
- **Training module 2:** shared-decision making and how it applies to BZRA deprescription
- **Training module 3:** clinical cases

A. Triggers for BZRA deprescription

- **High risk of adverse event:** age>65, polypharmacy, coprescription of opioids, frailty, cognitive disorder, respiratory insufficiency.
- **Current/previous adverse event** (see B).

B. Current evidence and recommendations

- **Risks of BZRA use:** 5 times more memory/ concentration problems; 4 times more daytime sleepiness; 2 times more falls/fractures; 2 times more motor vehicle accident.
- **Benefits of BZRA use:** 34 additional minutes of sleep and 0.6 less awakening per night.
- **Deprescription of BZRA in insomnia disorder guidelines:**
  - » Offer deprescription rather than usual care (MAGIC).
  - » Offer multi-component intervention (MAGIC).

C. Expected benefits

- Preserve/improve daytime functioning
- Natural and restful sleep
- Improve thinking and memory
- Safer driving

- ↓Daytime sedation
- ↓Respiratory exacerbations
- ↓Falls/ fractures
- ↓Drug burden/ drug-drug and drug- disease interactions

D. Potential risks: Withdrawal symptoms

Minor or moderate withdrawal symptoms: rebound insomnia, rebound anxiety, irritability, sweating,gastrointestinal symptoms, tremors

- → Mostly mild and disappear within a few weeks or months
- → Management: reinforce non-pharmacological alternatives; pause tapering if needed

Severe withdrawal symptoms: agitation, delirium, seizure

- → Rare, risk factors: sudden cessation, initial high doses, seizure disorders
- → Management: Return to the previous step and request specialist advice

E. Communication tips to address frequent barriers to BZRA deprescription

- **Remember the 3-talk model:** Team talk → Option talk→ Decision talk.
- **Initial reluctance:** 60% of older adults are willing to consider decreasing the dose if their physician recommends it. So, your role is crucial.
- **Social and material support:** Share that you are there to support; encourage them to identify who else could help; provide written information on why and how to stop (see A-D).
- **Feeling too old, too long use:** Insist that it is never too late to consider stopping and that tapering off remains feasible and relevant (and is even more) in case of older age with the right plan and support; talk about deprescribing in a positive way.
- **Fear for sleeplessness:** Acknowledge that sleeping well is important; explain that it is possible to sleep well without medication; refer to the Sleep Soundly Sleep safely brochure; reassure that tapering will reduce rebound sleep problems and that you can decide together the dates and rates of dose changes.
- **Misperception of harms:** Highlight side effects they may already have or share your concerns about potential future side effects.
- **Substitute medication:** Explain that other ways to sleep well are safer and more effective than pills.
- **Previous attempt:** Look at what may have hindered the previous attempt, encourage them to try again, and ensure reinforced support.
- **Persistent reluctance:** Acknowledge that it is not easy, highlight that it is always possible to revert back to the previous dosage if needed, or that we can wait for a better moment to discuss again the opportunity for tapering.

F. Non-pharmacological alternatives

- All patients: sleep hygiene and social support
- Cognitive Behavioural Therapy for insomnia (CBT-i): some or all ingredients
  - » Sleep scheduling (stimulus control + sleep restriction)
  - » Cognitive restructuring
  - » Relaxation training

G. Pharmacological assistance / substitution

- **NOT recommended** MAGIC
- None of the molecules tested in randomised trials to assist tapering of BZRA showed any substantial benefit in discontinuation of BZRA. Most have no good evidence on efficacy and can cause side effects.
- Review all medications and treat underlying conditions if relevant.

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6.4. Communication to other healthcare professionals (HCPs)

BZRA DEPRESCRIPTION-COMMUNICATION TO HEALTHCARE PROFESSIONALS

BE-SAFE

Your patient (surname; first name) was at (name of hospital or other site) on (date dd/mm/yyyy) He/she agreed to take part in the BE-SAFE study that aims to help older adults better manage sleep problems, with the final goal of increasing patient safety. Your patient is currently taking a (drug name + dosage) for sleep problems.

We think that deprescribing this Benzodiazepine Receptor Agonist (BZRA) is relevant to consider because of:

High risk of adverse effect(s):	Current/ previous adverse effect(s):	Values/preferences of patient/caregiver:
☐ age>65 ☐ polypharmacy ☐ co-prescription of opioid ☐ frailty ☐ cognitive disorder ☐ other:	☐ fall/fracture ☐ daytime sleepiness ☐ cognitive impairment ☐ motor vehicle accident ☐ other:	☐ preserving/improving daytime functioning ☐ restoring natural sleep ☐ taking as few sleeping pills as possible other:

The patient/carer identified the following resources to support him/her:

Healthcare Professional(s): **Relative(s):**

SUMMARY OF ACTIONS TAKEN

☐ We delivered brochures addressing sleep and the 'why' and 'how' to stop sleeping pills.

☐ Other:

Decision made with the patient/caregiver	→	Next steps: We suggest that you:
☐ dose reduction in order to stop. ☐ dose reduction but not aiming to stop. decrease dosage by % every week(s): see the personalized tapering scheme handled to the patient.	→	☐ monitor benefits and withdrawal symptoms. ☐ discuss support measures. ☐ adapt the tapering scheme if needed.
☐ postpone decision to: ☐ better moment: ☐ discussion with: ☐ no change	→	☐ discuss again deprescription in a next appointment.

Hospital physician contact:

[phone number and/or e-mail]:

DEPRESCRIPTION OF BENZODIAZEPINE RECEPTOR AGONISTS (BZRA): PRACTICAL INFORMATION

BE-SAFE

Materials to support physicians - available on the BE-SAFE website:

- A 2-page BZRA deprescription algorithm
- Training modules: 3 short videos
  - » Introduction to BZRA deprescription and how to use the deprescription algorithm
  - » Shared-decision making and how it applies to BZRA deprescription
  - » Clinical cases and shared-decision making practice

Materials to support patients - available on the BE-SAFE website:

- BZRA "You may be at Risk" brochure + video
- Sleep "Sleep Soundly Sleep Safely " brochure + video
- Sleep diary video
- Caregiver brochure

THREE KEY MESSAGES THAT ARE DELIVERED IN THE ALGORITHM AND VIDEOS

BZRA WITHDRAWAL SYMPTOMS AND HOW TO MANAGE THEM

- Common withdrawal symptoms: rebound anxiety, rebound insomnia, irritability, sweating, gastrointestinal symptoms, tremors
  - » Mostly mild and disappear within a few weeks or months
  - » Management: reinforce non-pharmacological alternatives; pause tapering if needed; reassure that there is no difference in insomnia compared with usual care or continuation of BZRA at 12 months
- Severe withdrawal symptoms: agitation, delirium, seizure
  - » Rare, risk factors: sudden cessation, initial high doses, seizure disorder
  - » Management: Return to previous step and request specialist advice

SUPPORT MEASURES

Non-pharmacological measures will help improve sleep and minimize withdrawal symptoms:

- Sleep hygiene: schedule daytime (outdoors) activities, avoid naps, avoid bright or blue lights the last hour before bedtime, and provide a quiet, dark and cool bedroom.
- Minimize substances interfering with sleep (caffeine, nicotine, amphetamines, pseudoephedrine, steroids, dopamine agonists, b-blockers, fluoxetine...)
- Cognitive Behavioural Therapy for insomnia (CBT-I) : simple key messages on CBT-I are explained for patients in the Sleep Soundly Sleep Safely brochure.

Pharmacological substitution is not recommended. You may consider specific pharmacological treatment of underlying conditions (pain, major depression...).

HOW TO TAPER

- Taper using the same molecule.
- ↘ by 25% every 2 weeks; ↘ more slowly (e.g. by 10-12,5% instead of 25% and/or every 4 weeks) if patient/caregiver preference; clinical perception of higher dependence; complex psychosocial context.
- Consider alternate day dosing if dosage forms are limited.

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6.5. Communication form for patients/caregivers

YOUR PLAN TO REDUCE YOUR SLEEPING PILL

BE-SAFE

REMINDER

You are/your relative is currently taking ..... (drug name + dosage) for sleep problems.

We discussed at (name of hospital or other site) ..... on ...../...../.....(date dd/mm/yyyy) that this medication should best be reduced to:

- Preserve/improve your daytime functioning
- Restore your natural sleep
- Take as few sleeping pills as possible
- Avoid possible side effects of your sleeping pill (falls and fractures, memory loss, daytime sleepiness, motor vehicle accidents, respiratory exacerbations)
- Not to be dependent on sleeping pills
- Follow trustworthy medical guidelines and recommendations
- Reduce the cost of your treatment

YOUR PERSONAL PLAN TO REDUCE THE SLEEPING PILL

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Week 1							
Week 2							
Week 3							
Week 4							
Week 5							
Week 6							

BE-SAFE

REMEMBER YOUR RESOURCES:

- "Sleep Soundly Sleep Safely" brochure and video
- "You may be at risk" brochure and video
- Sleep diary video
- Caregiver brochure
- Healthcare professionals: .....
- Relatives / caregiver: .....
- Other: .....

SYMPTOMS YOU MIGHT EXPERIENCE DURING DOSE REDUCTION

Most of these are mild and temporary with gradually reducing the dose. If you are uncomfortable, reach out to a healthcare professional.

Common withdrawal symptoms: recurrence of anxiety, recurrence of sleep problems, irritability, sweating, gastrointestinal symptoms, tremors.

Personal notes

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Access to brochures and video

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