Deprescribing of Benzodiazepines in the Elderly Using A 3Es Model: A Patient Centered Approach

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1. Abstract
Benzodiazepines use in the elderly are associated with morbidity including increased falls, fractures, and mortality. The common reason for re-prescribing benzodiazepine by physicians is dependency. Our project proposal aims to enhance medication safety in the elderly. It requires a multidisciplinary approach and patient-centred care focusing on benzodiazepine deprescribing using the 3Es model of Educating, Empowering, and Engaging. The education starts with patients, providers, and the community about benzodiazepine adverse effects on the elderly and provides alternative approaches for symptoms management. Empowering patients in the decision to deprescribe will prove to be successful when the patient finds value. Engaging stakeholders in the process will facilitate adeptness and attainability in the target community. Using information technology to deliver the protocol will ensure reminders, track changes and suggest alternatives. The project goal is a 50% reduction in benzodiazepine prescription by six months. Limitations, challenges, and modifications anticipated are discussed.

2. Background
We chose this topic for its importance and effect on safety in the elderly. Benzodiazepines increase mortality by 1.2-3.7X/ year compared to non-exposed [1]. The undesirable effect of benzodiazepine use include dependency that causes rebound anxiety, insomnia, dementia, cognitive decline, falls and fractures [2, 3]. A meta-analysis of 22 studies found benzodiazepines as one of the top three drug classes significantly associated with falls in the elderly OR, 1.57 (95% CrI, 1.43-1.72) [3].

Patient literacy was included in patient assessment. Its importance comes as a major determinant for quality of care [4]. About 80%
of patients above 60 have low literacy, and it's a major barrier to communication with the healthcare provider [5]. Low-literate patients in the USA described serious and widespread communication difficulties with their health providers [6]. The assessment tool is called the test of functional health literacy assessment and it is proposed to be utilized by pharmacists or their assistants [7]. Patient apprehension was identified as a major barrier in 1/3 of patients tested with low functional health literacy [8].

3. Rationale for Deprescribing
The three rationales for deprescribing of benzodiazepines are inappropriate prescribing, re-prescribing and the risk of morbidity and mortality. Retrospective database reports from the Netherlands and Norway revealed a prevalence of 20-25% inappropriate benzodiazepine prescription in the elderly [9, 10] and according to the 2002 Beers criteria, inappropriate prescription is about 26% [10]. About 50% of physicians renew benzodiazepine prescription due to patient dependency [11].

4. Subject Community and Its Health System
It is important to define the health system and the community to establish stakeholders and assess infrastructure. The stakeholders in our proposal are the patient, the caregiver, the prescriber, the pharmacist, and the community (Figure 1). Our community would include those who would be involved in the care of the elderly including care facilities for seniors.

5. Intervention Model
Our study population will be more than or equal to 65 years on benzodiazepines medication for at least a month. We will exclude centers with no computerized system, walk-in clinics that cannot arrange follow-up and emergency rooms. We decided to do a before and after study design to collect retrospective and prospective data for ethical reasons (Figure 2).

The intervention will be focusing on stakeholders using the 3Es model for Education, Empowerment and Engagement (Figure 3). The patient and their caregivers will receive one-on-one education from the provider using clinical motivation behavioural techniques to empower and engage in deprescribing. The prescriber will access the deprescribing algorithm and computerized system to alert for deprescribing and offer an alternative. The community will have an outreach program that focuses on education and a deprescribing campaign. The project group will provide feedback to the stakeholders at the end (Figure 2).

Figure 1: Stakeholders
6. Implementation
The implementation will be in six phases (Figure 4), starting with the screening phase based on inclusion and exclusion criteria, then the enrollment phase by either phone or visit. The assessment phase will involve functional assessment, review of all patient's medication, indications for benzodiazepine, and literacy assessment.

The empowerment and education phase will be for both patients and caregivers using motivational, behavioural intervention and the community thought outreach education program. For the evaluation phase, patients will be booked visits as per the deprescribing algorithm and at six months. The final phase will be two-way feedback for and from stakeholders. A computerized system will be used to alert for deprescribing, suggest alternatives and track changes.

7. Protocol
The algorithm (Figure 5) can be found using this link: Benzodiazepine & Drug (BZRA) Deprescribing Algorithm.

The protocol, an evidence-based practice guideline created by the deprescribing group that we will use in our project.
Figure 4: Implementation.

**Implementation**

1. **Screening**
   - Identify study population based on inclusion criteria for each center.

2. **Enrollment**
   - By phone and by visit.

3. **Assessment**
   - Including functional assessment, review of all patient's medication, indication for benzodiazepine.
   - Assessment of patient medical literacy level.

4. **Empowerment and Education**
   - Patient and/or caregiver:
     - Motivational behavior intervention.
     - For Community:
     - Outreach education program.

5. **Evaluation**
   - Each booked visit as per deprescribing algorithm schedule.
   - At 6 months.

6. **Feedback**
   - Stakeholders.

- Alert system to consider deprescribing for patients on benzodiazepine.
- Suggest alternative.
- Computerized algorithm to follow the changes.

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**Benzodiazepine & 2-Drug (BZRA) Deprescribing Algorithm**

**Why is patient taking a BZRA?**

- Insomnia or other sleep disorders
- Underlying complaints managed
- For those ≥ 45 years of age: take BZRA regardless of duration (avoid as first-line therapy in older people)
- For those ≥ 65 years of age: take BZRA 4 weeks

**Engage patients**

- Discuss potential risks, benefits, withdrawal plans, symptoms and follow-up

**Taper and then stop BZRA**

- Taper slowly in collaboration with patient, for example - 15% every two weeks, and if possible, to 5% reductions in half and/or (planned drug-free days)
- For those ≥ 65 years of age
- For those 50-64 years of age
- Offer behavioral sleep strategies; consider CBT if available (see reverse)

**Continue BZRA**

- Minimize use of drugs that worsen insomnia
- Other medication-related conditions
- Consider consulting a sleep specialist

**Monitor every 1-2 weeks for duration of tapering**

- Expected benefits:
  - May improve alertness, cognition, daytime sedation and reduce falls
  - Insomnia, anxiety, irritability, sweating, gastrointestinal symptoms (usually mild and last for days to a few weeks)

- Use non-drug approaches to manage insomnia
  - Use behavioral approaches
  - Insomnia
  - CBT (see reverse)

If symptoms emerge:

- Reduce current BZRA dose for 1-2 weeks, then continue to taper at slow pace

Alternate drugs:

- Other medications have been used to manage insomnia: Assessment of their safety and effectiveness is beyond the scope of this algorithm, see BZRA deprescribing guidelines for details.

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http://acmcasereports.com
8. Evaluation and Assessment

We will look at the number of patients off medication and dose reduction percentage at six months as our primary outcomes for evaluation. The goal is to reach at least a 50% reduction. Secondary outcomes that will be measured are the number of falls and severity (those requiring a hospital visit and admission surgical intervention or movement from initial place of residence to a higher level of care facility), the number of alternative medications prescribed, episodes of aggressive behaviour, mental status, and aspiration pneumonia.

The data assessment we are measuring is both qualitative and quantitative data. The qualitative data include age (range and mode), history of falls on benzodiazepines, cognitive assessment, sex, fall severity, aspiration pneumonia, functional status, comorbidities, patient satisfaction, patient literacy, medications history, and stakeholder’s feedback.

The quantitative data include some metrics focusing on primary and secondary outcomes, as shown in (Table 1).

<table>
<thead>
<tr>
<th>Quantitative data</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients on benzo at enrollment</td>
<td>100%</td>
</tr>
<tr>
<td>No. of patients off benzo at 6 months</td>
<td>≥ 50%</td>
</tr>
<tr>
<td>No. of falls</td>
<td>reduced</td>
</tr>
<tr>
<td>No. of patients requiring alternative prescription for sleep/anxiety</td>
<td>Few</td>
</tr>
<tr>
<td>Episodes of aggressive behaviour</td>
<td>Reduced</td>
</tr>
<tr>
<td>Symptoms recurrence</td>
<td>Reduced</td>
</tr>
<tr>
<td>Time for intervention</td>
<td>30-60 min</td>
</tr>
</tbody>
</table>


9. Scale and Feasibility

For scalability and feasibility, we looked at 5 elements:

1. Given the importance and rationale of deprescribing benzodiazepine in the elderly, we anticipate the effect on improving safety and quality measures. This will make the 3Es project reachable to more communities and be adopted for its importance.

2. Education is key to perform the intervention for both provider and patient and to set up an outreach program for awareness of the benzodiazepine effect on the elderly.

3. Resources need to include training and infrastructure to incorporate algorithm and alert systems and personnel and support personnel for the outreach program.
4. The implementation cost will save patients and the healthcare system money due to reducing unwanted side effects.
5. The system, once it's programmed, will be easily implemented, and data and feedback can be collected.

10. Discussion
The proposal is unique in using 3Es for Educate, Empower and Engage. Patient care is a central approach. The problem we are addressing is important and relates to medication safety in the elderly. Challenges include implementation during the COVID pandemic, language barrier and literacy.

The limitations include the study design, given the lack of a direct comparator group and potentially finding low literacy that might interfere with implementing the intervention. Also, lack of incentive and time-consuming intervention might need additional support staff to administer. The study period is short, and to make cultural and system changes will require buying from health and provisional authorities and time.

As an alternative approach, we might consider cluster randomization. However, due to the importance of deprescribing benzodiazepine in the elderly, we wanted to offer equal chances to people enrolled in the study since side effects are well established and the problem of dependency and re-prescribing. The other modification we might consider is implementing an educational curriculum for deprescribing to a residency program for awareness and behaviour change.

11. Acknowledgment
We want to acknowledge the deprescribing.org group and the authors of Benzodiazepine & Z-Drug (BZRA) Deprescribing Algorithm for the algorithm and using their material. We also want to acknowledge Dr. Alhussaini for articulating and presenting our work.

References