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Development of consumer information leaflets for deprescribing in older hospital inpatients: a mixed-methods study

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ABSTRACT

Objective To develop information leaflets for older inpatients and/or their carers to support deprescribing of antipsychotics, benzodiazepines/Z-drugs and proton pump inhibitors (PPIs).

Design An iterative mixed-methods approach involving face-to-face user testing and semi-structured interviews was performed over three rounds with consumers and hospital health professionals.

Setting Sydney, New South Wales, Australia.

Participants Thirty-seven consumers (or their carers) aged 65 years or older admitted to hospital in the previous 5 years and taking at least one regular medicine (not the medicine tested) completed user testing. Health professionals included a convenience sample of seven pharmacists and five doctors.

Methods The antipsychotic leaflet was tested in round 1 (consumers, n=10) and revised and retested in round 2 (consumers, n=9; health professionals, n=5). Findings from rounds 1 and 2 informed the design of the benzodiazepine/Z-drug and PPI leaflets tested in round 3 (benzodiazepine/Z-drug consumers, n=9; health professionals, n=7; PPI consumers, n=9). Findings from round 3 informed the final design of all leaflets. Consumer user testing involved 12–13 questions to evaluate consumers' ability to locate and understand information in the leaflet. Usability by health professionals was assessed using the System Usability Scale (SUS).

Results At least 80% of consumers correctly found and understood the deprescribing information in the leaflets (9 of 12 information points in round 1 (antipsychotic); 10 of 12 in round 2; 12 of 13 (benzodiazepine/Z-drug) and 11 of 12 (PPI) in round 3). Consumers perceived the leaflets to be informative, well-designed and useful aids for ongoing medication management. The SUS scores obtained from health professionals were 91.0±3.8 for the antipsychotic leaflet and 86.4±6.6 for the benzodiazepine/Z-drug leaflet, indicating excellent usability.

Conclusions Understandable and easy-to-use consumer information leaflets were developed and tested by consumers and health professionals. The feasibility and utility of these leaflets to support deprescribing at transitions of care should be explored in clinical practice.

Strengths and limitations of this study

► This study was strongly informed by consumers, including in the initial identification and prioritisation of the need for written consumer information on medicines deprescribed in hospital and the components of information content for its development.

► Consumer information leaflets were tested across multiple rounds with consumers (or their carers) aged over 65 years and multidisciplinary hospital health professionals.

► Further testing of consumer information leaflets in older hospital inpatients who have been deprescribed the medicine of interest is needed to inform further revisions, if required.

► This study did not explore the feasibility and effectiveness of consumer information leaflets to support deprescribing and reduce inappropriate medication use in older people.

INTRODUCTION

Polypharmacy and inappropriate medication use are highly prevalent in older people and may lead to adverse health outcomes including adverse drug events, falls, hospitalisations and mortality.[1–3] Deprescribing, or the supervised withdrawal of inappropriate medications,[4] may reduce inappropriate polypharmacy and its associated harm in older hospital inpatients.[5] The process of deprescribing is often challenging and presents with several prescriber-related barriers (eg, prescribers' fear of negative consequences, poor insight into the appropriateness of their prescribing and low self-efficacy)[6] and patient-related barriers (eg, fear of cessation, attachment to medications, and perceived lack of time and support from prescribers to deprescribe).[7 8] Resources to assist clinicians to deprescribe have resulted in the development of a number of drug class-specific deprescribing guidelines targeting

benzodiazepines and Z-drugs, antipsychotics and proton pump inhibitors (PPIs).[9][10]

Qualitative research into patient preferences for deprescribing has highlighted the importance of shared decision-making in enabling deprescribing,[8][11] although time constraints can be a barrier to this process.[12] How health professionals communicate with patients will depend on whether they are resistant to deprescribing, disinterested in their medicines overall or feel ambivalent towards deprescribing.[8]

Increasing attention on the importance of involving consumers and their carers in decision-making, and acknowledgement of their willingness to have their medicines deprescribed,[13] has resulted in the development of consumer resources to support deprescribing.[14][15] This includes deprescribing plans for PPIs developed by the Australian not-for-profit organisation responsible for supporting quality use of medicines, NPS MedicineWise,[15] and the Eliminating Medications Through Patient Ownership of End Results (EMPOWER) brochures developed by the Canadian Deprescribing Network.[14] EMPOWER brochures for sedatives and hypnotics, PPIs, sulfonylureas, antipsychotics, antihistamines and non-steroidal anti-inflammatory drugs have been designed to empower older people to drive reductions in inappropriate prescribing.[14] These brochures are intended as self-directed education tools to encourage patients to initiate discussions about deprescribing with their physician. A systematic review of patient education material targeting deprescribing found fewer than half presented benefits and harms of deprescribing and most were suitable only for patients with above-average reading levels.[16] Health literacy refers to the degree to which people are able to access, understand, appraise and apply health information in order to make decisions about their health.[17] Low health literacy is associated with poorer interpretation of medication labels, increased risk of hospitalisation and mortality.[18] Development of material suitable for older people who may have lower levels of health literacy and understanding of medicine information is crucial to enable shared deprescribing decision-making and improved health outcomes.[19]

Existing consumer resources to support deprescribing do not specifically target hospital inpatients and do not provide a personalised weaning plan. Although communication of changes made to medicines during hospital admission and particularly at transitions of care is critical to maintaining continuity of care, it is often inadequate.[20] A cohort study of patients discharged from tertiary hospital in the USA identified only 22% of patients and/or family members were involved in decisions made to their medicines during their hospital admission, despite 35% with plans to discontinue their regular medicines.[21]

Development of consumer information leaflets for older hospital inpatients to support deprescribing of the most common potentially inappropriate medications may assist in improving shared decision-making, self-management, and communication of medication changes initiated in hospital at transitions of care to patients, their families and their regular prescribers. Patient and public involvement in the coproduction of patient material is actively promoted and increasingly a necessity in health research.[22] Despite this, involvement of consumers is variable, is often limited to written patient information within medicine packaging[23] and is often not undertaken across all stages of research.[24] Furthermore, consumer or patient involvement is very rarely conducted at the onset of written material development. Involvement of consumers in the development of information leaflets is essential to ensure material is relevant, readable and understandable to the population of interest. Highly prevalent potentially inappropriate medications among older hospital inpatients include antipsychotics (up to 40% with dementia),[25][26] benzodiazepines (up to 30%)[27–29] and PPIs (up to 40%).[27–29] The aim of this study was to develop consumer information leaflets for older hospital inpatients and their carers on the deprescribing of antipsychotics, benzodiazepines or Z-drugs and PPIs to support the deprescribing process during hospital admission and following hospital discharge.

METHODS
Study design
Three consumer information leaflets were developed and user tested with consumers and hospital health professionals via an iterative mixed-methods approach over three rounds.

Participants
Advertisements to recruit consumers and their carers were widely distributed across local health and media networks and research institutes in Sydney, Australia between May and August 2018. Face-to-face recruitment was also performed by researchers at local senior community and church events and in hospital waiting areas. Approximately 10 participants for each round of consumer user testing were sought, in line with existing user testing procedures to develop patient medication information.[23] Consumers and their carers were reimbursed for their actual costs of travel and/or parking.

Consumers (and/or their carers) were eligible for inclusion in the study if they were aged 65 years and over, were admitted to hospital within the previous 5 years and took one or more regular medications. A carer was defined as a person who provides unpaid care and support to a family member or friend to manage their medications and/or medical condition.[30] Consumers and their carers were excluded from participating in user testing of a leaflet if they self-reported prior or current use of the medicine of interest (antipsychotic, benzodiazepine/Z-drug or PPI). This is consistent with the recommendations for the development of consumer medicine information (CMI).[23]

Purposive and snowball sampling techniques were used to recruit hospital health professionals from general medicine and geriatric services, who may be more likely

to practise deprescribing than those working in other services. This included recruitment through presentations at local hospital clinical meetings across two local health districts in Sydney, Australia. All hospital doctors and pharmacists were eligible to participate in user testing irrespective of level of experience. Recruitment continued until saturation of themes was reached and no further changes to the leaflets were identified.

Initial design of leaflets

All three consumer information leaflets are targeted towards hospital inpatients aged 65 years and over (and/or their families/carers), for whom hospital clinicians have considered deprescribing of an antipsychotic, benzodiazepine/Z-drug and/or PPI. These leaflets were designed to be provided to patients and/or their families during their hospital admission and/or at discharge to aid in their understanding of medicine changes made during their hospital admission, and support shared decision-making of deprescribing decisions between patients, their families and health professionals. In addition, a personalised weaning plan, to be completed by a hospital clinician on hospital discharge, was included to support ongoing weaning of a medicine and communication with the patient's general practitioner. Although the leaflets were designed to be broad and encompass different indications of inappropriate use, the antipsychotic leaflet primarily targeted patients prescribed antipsychotics for behavioural and psychological symptoms of dementia.

The initial design and content of the two-page antipsychotic consumer information leaflet by the research team were based on available published literature, consumer resources and guidelines for the development of consumer information and the use of antipsychotics in older people.[14 15 31–33] The research team had multidisciplinary clinical and research expertise in geriatric pharmacotherapy and research expertise in the development of patient-centred resources and shared decision-making. Development of the leaflets considered design features to accommodate age-related changes in vision (eg, increased font size), memory and cognition (eg, avoidance of medical jargon, use of short messages).[34] Page 1 of the leaflet included general information on the use and deprescribing of the medicine (indication, common side effects, rationale for deprescribing, plan, withdrawal symptoms and monitoring, and non-drug options), as well as individualised information regarding the decision made during hospital admission or discharge about the use of the medicine (reduced dose, stopped or referral to general practitioner to review). Page 2 (reverse) contained a personalised initial 2-week weaning plan to be completed by the hospital pharmacist or doctor to assist patients and carers to follow their care plan. Separation of information from the personalised weaning plan over two pages was chosen to accommodate design principles for older people (eg, increased text size, white space),[34] and provide display and storage options for the weaning plan for consumers (eg, display on the fridge at home). The Flesch-Kincaid Grade Level was calculated to assess the readability of the leaflets.[35] Information in the leaflets was written below the recommended high school level (US eighth grade or lower).[36]

Study procedure and analysis

Three rounds of face-to-face consumer and health professional user testing and semi-structured interviews were performed by one of two research pharmacists experienced in qualitative research between May and August 2018 (SC and NJ). The antipsychotic leaflet was tested in rounds 1 and 2 (revised leaflet) and the benzodiazepine/Z-drug and PPI leaflets in round 3 (figure 1).

Consumer data collection

Self-reported characteristics were recorded for consumers, including age, gender, level of education and health literacy. Health literacy was measured using a self-reported validated scale that comprised three questions.[37 38]

Consumer participants were provided with background information on the user testing process and were provided with one of three consumer leaflets to read prior to questioning. During the consumer interviews, the research pharmacist administered 12–13 user testing questions (UTQs) to evaluate the consumer's ability to locate and understand information, followed by semi-structured interview questions to obtain broader feedback on design and content. UTQs were developed via consensus within the research team and related to key elements within the leaflet, including rationale and plan for deprescribing, withdrawal symptoms, monitoring and non-drug options (online supplementary file 1 table S1). Responses to UTQs were timed and recorded as 'found' if consumers were able to identify the correct location in the leaflet, 'found with difficulty' if located after two or more minutes and/or required two or more non-leading prompts (significant rewording of the question), and as 'understood' if their response aligned with the predetermined answers (online supplementary file 1 table S2). This user testing was based on the process previously performed in the design and user testing of CMI[31] and medication labels.[39]

At the completion of the user testing, a semi-structured interview was performed with each participant to obtain broader feedback on the design and content of the leaflets (see interview guide in online supplementary file 2). Interviews were audio-recorded and transcribed externally by a professional transcription service.

Consumer user testing analysis

Response times for time to first location and understanding of information were described at the conclusion of each round. Questions found to create confusion with consumers in the first round of user testing were reworded for clarity for subsequent rounds. Following each round, responses to UTQs were compared with predetermined answers to identify information that was difficult to identify
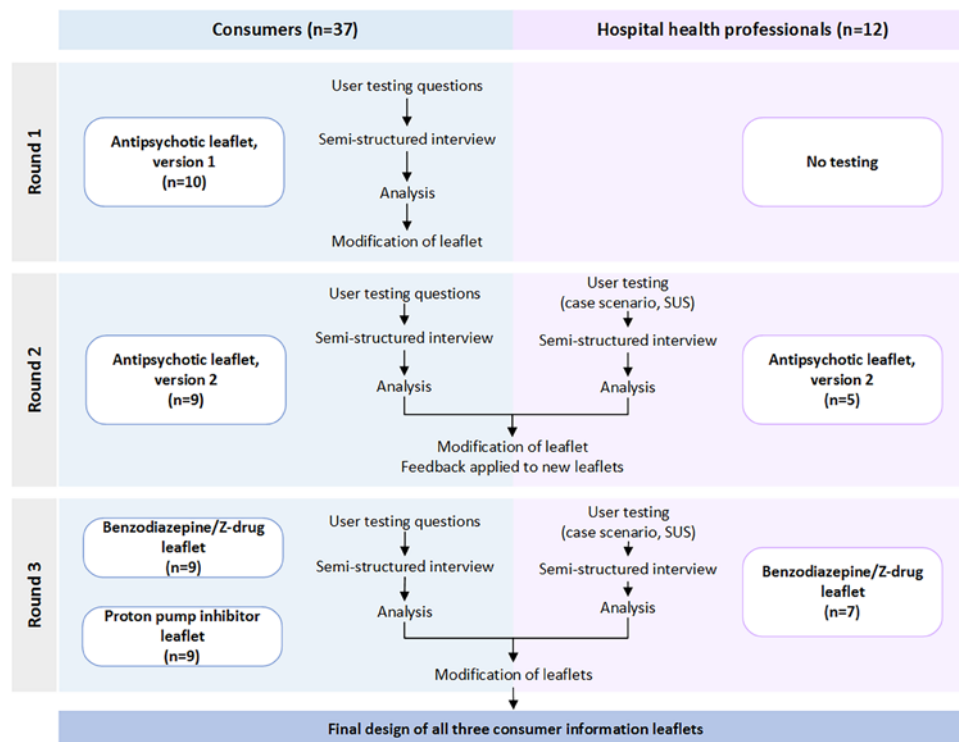
Figure 1 Redesign process with consumers and health professionals. SUS, System Usability Scale.

and/or understand, and required design and/or content changes prior to the next round. Coding of responses to UTQs was performed by one researcher and reviewed by members of the research team where responses did not clearly align with predetermined answers.

Responses to the three health literacy questions were coded using the 5-point Likert scale, where 1=always requiring assistance, difficulty learning all the time and no confidence completing medical forms, and 5=requiring no assistance, no difficulty learning and extremely confident completing medical forms. A score of 1–4 was categorised as having limited health literacy and score of 5 as adequate health literacy.[40 41]

Hospital health professional data collection

Profession, specialty and years of experience for each hospital health professional were recorded.

A research pharmacist provided participants with an example case scenario of an older hospital inpatient with a weaning plan for their antipsychotic or benzodiazepine/Z-drug. Participants were requested to complete the necessary patient and medicine details, including a 2-week weaning plan on the relevant draft leaflet. Time to complete both pages of the leaflet was recorded. This was then followed by completion of a self-administered System Usability Scale (SUS) to assess their perceived usability of the leaflet. The SUS consists of 10 questions answered on a 5-point Likert scale to assess perceived usability of a product or tool.[42] Although originally used for electronic-based tools, the SUS has since been used to assess the usability of paper-based tools.[43 44]

Questions were adapted from 'this system' to 'this leaflet' for relevance.

Feedback on the design, content and usability of the leaflets was obtained via one-on-one semi-structured interviews (see interview guide in online supplementary file 2). All interviews were audio-recorded and transcribed by a professional transcription service.

Hospital health professional user testing analysis

The mean scores for individually completed SUS questionnaires and time taken to complete both pages of the leaflet were summarised. SUS scores range between 0 and 100, with scores above 70 considered to indicate good usability.[45]

Semi-structured interview analysis

Thematic analysis of consumer and health professional semi-structured interview transcripts to identify themes and subthemes was performed in NVivo V.11. Initial themes were identified using an inductive approach and subthemes further explored. These themes related to the content, design (layout, text, length) and usability of the information leaflets. Coding of themes and construction of matrices to summarise data were performed by one researcher and reviewed by members of the multidisciplinary research team for consensus.

Redesign of leaflets

The design of the leaflets was refined by the research team following feedback obtained from consumers and health professionals after each round. Collective changes were made to all leaflets following round 3 of user testing to

ensure consistency in design and content across all leaflets. Final leaflets were produced by an external professional graphics design company.

Reporting of the results are in line with the Standards for Reporting Qualitative Research checklist.[46]

Patient and public involvement

Patient and public involvement in the coproduction of the consumer information leaflets occurred across several stages in this study. This included consumer representation in the initial identification and prioritisation of the need for written consumer information on medicines deprescribed in hospital, components of information content for its development and dissemination of the study. Patients and the public were not involved in data analysis or interpretation. Patient and public involvement in this study has been summarised in the Guidance for Reporting Involvement of Patients and the Public (GRIPP2) short form[47] (see online supplementary file 3 table S1).

The research question and the development and testing of consumer information were informed by the priorities, experiences and preferences of consumer representatives on the steering committee for reducing inappropriate polypharmacy in older inpatients. Consumer representatives on the steering committee ensured consumer needs were considered throughout the study. Development of the consumer information leaflets was an iterative process, informed at each stage by consumer responses to UTQs and semi-structured interviews. Participants were recruited via consumer groups and networks.

The design of the study was based on the research team's multidisciplinary expertise in medicines information development and clinical studies with older people, as well as expertise and previous research on the development of usable CMI. Participants were not asked to assess the burden of the intervention and time required to participate in the research. The structure of interviews was based on consumer feedback in previous studies evaluating medicines information, and each participant selected their preferred time and location for the interview.

The final leaflets will be reviewed by consumer representatives on the steering committee. A lay report describing the results of the study will be disseminated through the consumer networks involved.

RESULTS

Consumers

Consumer characteristics are summarised in table 1. Thirty-seven consumers, of whom eight were carers (who participated without the presence of the person they cared for), participated across three rounds of user testing. The majority of consumers were aged between 70 and 89 years, were female, born in Australia and spoke English as their main language at home. Approximately a quarter of consumers had perceived limited health literacy in one

or more domains, reporting difficulty reading hospital or medicine information (n=14, 24%), difficulty learning about their medical or medicine information due to difficulty reading hospital or medicine information (n=9, 27%), and lack of confidence completing medical forms (n=10, 38%).

At least 80% of consumers located and understood the majority of information presented in the leaflet in each round (table 2). This included 9 of 12 information points found (including with difficulty) and understood in round 1, 10 of 12 in round 2, and 12 of 13 (benzodiazepine/Z–drug leaflet) and 11 of 12 (PPI leaflet) in round 3. Of the consumers who located information, no more than two consumers required longer than 2 min or two or more prompts from the interviewer across all rounds. This included across two points of information tested in round 1, two in round 2, seven in benzodiazepine/Z-drug and two in PPI user testing in round 3.

Questions that were found to be difficult for consumers to understand and required rewording are presented in online supplementary file 1 table S1. This primarily occurred following round 1 user testing and included questions related to the decision made about the medicine in hospital, reason for stopping, increasing side effects with age and what to do if they experience withdrawal symptoms. Following rewording of these UTQs, in addition to revision of wording and formatting of the presentation of this information (use of tick boxes, tables) in the leaflet in round 2, approximately 80% of consumers were able to locate and understand these four points of information, increasing to 90%–100% in round 3.

All consumers correctly located and understood 10 of 13 information points in round 3 of testing the benzodiazepine/Z-drug leaflet and 10 of 12 information points in round 3 of testing the PPI leaflet. The only information points which were not found and understood in fewer than 90% of consumers in round 3 were the time over which benzodiazepines/Z-drugs are weaned (found and understood by 67%) and side effects experienced while taking the PPI (found and understood by 78%). The wording of the duration over which benzodiazepines/Z–drugs were weaned and order of appearance of side effects was subsequently changed following further questioning about these items during the semi-structured interviews.

Although the majority of consumers identified and understood what action to take if they experienced withdrawal symptoms, confusion remained over the difference between side effects, withdrawal symptoms and symptoms of the underlying condition returning. Greater emphasis using capitalisation of the words 'while taking' and 'coming off' in the headings and repositioning of this information in the leaflet were used to help distinguish between the timing of side effects and withdrawal symptoms. Although bolding and underlining of these words were suggested by consumers, capitalisation was chosen as this allowed for greater emphasis in the headings which were already bolded and presented in reverse type. These changes assisted in the identification of when

Table 1 Summary of consumer characteristics (n=37)

| Characteristics | Antipsychotic | | Benzodiazepine/Z-drug | Proton pump inhibitor |
	Round 1 (n=10)	Round 2 (n=9)	Round 3 (n=9)	Round 3 (n=9)
Participant				
Consumer	8	9	6	6
Carer	2	0	3	3
Age (years)				
50–59	1	0	2	2
60–69	1	2	2	3
70–79	4	4	3	2
80–89	4	3	2	1
90–99	0	0	0	1
Gender				
Male	5	4	1	3
Female	5	5	8	6
Country of birth				
Australia	6	8	7	8
Overseas	4	1	2	1
Main language spoken at home				
English	10	9	9	8
Other	0	0	0	1
Other languages spoken at home				
None	8	9	8	7
Other	2	0	1	2
Highest level of education				
University degree or higher	5	2	3	3
Diploma	1	4	1	3
Certificate	1	1	1	0
Completed year 12	1	1	1	3
Completed year 10	1	1	3	0
Primary school	1	0	0	0
Confidence completing medical forms				
Extremely	9	6	3	0
Quite	1	1	5	5
Somewhat	0	2	0	4
A little	0	0	1	0
Not at all	0	0	0	0
Requires assistance to read hospital/medicine information				
None of the time	9	7	6	6
A little of the time	0	1	3	2
Some of the time	1	1	0	1
Most of the time	0	0	0	0
All of the time	0	0	0	0
Difficulty learning about medical condition/ medicines due to difficultly reading hospital/ medicine information				

Continued

	Antipsychotic		Benzodiazepine/Z-drug	Proton pump inhibitor
Characteristics	Round 1 (n=10)	Round 2 (n=9)	Round 3 (n=9)	Round 3 (n=9)
None of the time	8	7	5	7
A little of the time	1	0	4	2
Some of the time	0	2	0	0
Most of the time	1	0	0	0
All of the time	0	0	0	0

Table 1 Continued

symptoms would likely occur; however, explanation of the underlying difference between withdrawal symptoms, side effects and the symptoms of the underlying condition returning remained challenging across rounds:

> Well, you go back to the feeling, that you had before you started taking the medication. And that's what I never want to do. (Benzodiazepine R3, P9)

> Withdrawal symptoms…to me means certain side effects once the medicines have been ceased. (Antipsychotics R2, P3)

A summary of consumer perceptions is presented in table 3. The user testing process was found to be challenging for consumers who revealed feeling overwhelmed due to unfamiliarity with the medicine tested and no opportunity to read the leaflet at home multiple times prior to the user testing process. Overall, the majority of consumers found the leaflets to be informative and well designed, and perceived the leaflets to be useful aids to assist with their understanding and ongoing plan for their medicines following discharge from hospital:

> It's altogether positive. It's letting you understand the treatment that's been given to you - the why - there's a little bit of how it works, there's the possible side effects. Then in this case, how do you stop it? So, there's understanding and control, and I think it empowers the patient if they're willing. But if it's not empowering the patient, at least it's empowering the carer. (Benzodiazepine R3, P8)

Hospital health professionals

Twelve hospital health professionals, comprising seven pharmacists and five doctors, participated in user testing (table 4). The majority of participants were female and had practised for between 1 and 10 years.

Participants took an average of 3:44 min (range: 2:07–6:20 min) (pharmacists: 4:22 min, doctors: 2:55 min) to complete both pages of the consumer leaflet. A summary of SUS scores for each question is presented in figure 2. The average±SD SUS score for use of the antipsychotic leaflet was 91.0±3.8 and 86.4±6.6 for the benzodiazepine/Z-drug leaflet, indicating excellent usability.[45]

A summary of health professional perceptions is presented in table 5. Overall, health professionals found the leaflets easy to understand, clear and useful for patients and themselves as education aids. All participants agreed or strongly agreed that the leaflets were easy to use, components within the leaflet were well integrated, and that they would feel very confident to use the leaflet in practice and use it frequently. Participants found the leaflets would be particularly beneficial for carers who often manage medicines:

> I think it's good to give something to the patient or carer because just telling them we're stopping it is not enough. And also what I find is that sometimes when pharmacists see the patient on the ward - they are usually the patients who are not going to be caring for their medicines. So if you can have something in writing that can be passed on to the carer, it would help a lot. (Antipsychotics R2, P2-Pharmacist)

> I just wonder if someone with cognitive impairment and dementia is going to benefit from reading that – probably not. But most of the patients we see probably wouldn't read it. So it could be given to the carer as well in this scenario. (Benzodiazepines R3, P6-Junior Medical Officer)

As was the case in consumer interviews, suggested improvements to the leaflets included use of colour and reduced content; however, there was uncertainty as to which or whether any content could be removed:

> There are a lot of words but I can't think of anything that you would remove to make it less cluttered. It's not that cluttered to begin with. (Antipsychotics R2, P7-Junior Medical Officer)

Health professionals differed in perceptions on who is likely to complete the leaflet in clinical practice (ie, pharmacist or junior doctor) and perceived that time and resources (eg, adequate staffing to perform additional tasks) to be potential barriers to providing counselling and completing the leaflet:

> Ideally, I'd like to use it as a counselling aid, but I think practically, I'd be strapped for time and would end up just handing it to them with the discharge summary paperwork. (Antipsychotics R2, P7-Junior Medical Officer)

> I believe pharmacists would probably be better in

Table 2 Summary of quantitative findings from consumer user testing

Leaflet information tested by UTQs	Round 1 Antipsychotic (n=10)			Round 2 Antipsychotic (n=9)			Round 3 Benzodiazepine/Z-drug (n=9)			Round 3 Proton pump inhibitor (n=9)		
	F(d*)	U	% F&U	F(d*)	U	% F&U	F(d*)	U	% F&U	F(d*)	U	% F&U
Name of medicine being stopped	8	8	80	8	8	89	9 (1)	9	100	9 (1)	9	100
Decision made (in hospital) about the use of the medicine	5	5	50	7	7	78	8 (1)	8	89	9	9	100
Usual duration of medicine	N/A	N/A	N/A	N/A	N/A	N/A	9 (2)	9	100	9	9	100
Side effects/harms while taking the medicine	9	8	80	8	8	89	9 (1)	9	100	9	7	78
Overall reason for stopping the medicine	7 (1)	6	60	9 (1)	8	89	9 (1)	8	89	8	8	89
Increased side effects with age	8 (1)	8	80	9	9	100	9	9	100	9	9	100
How to stop the medicine	8	8	80	9	9	100	9	6	67	9	9	100
Stopping the medicine too quickly causes withdrawal symptoms	10	8	80	9 (2)	7	78	9 (1)	9	100	N/A	N/A	N/A
Example of a withdrawal symptom	10	10	100	9	9	100	9	9	100	N/A	N/A	N/A
Action to take for 'serious' withdrawal symptoms	7	6	60	9	9	100	9	9	100	9	9	100
Action to take for 'other' withdrawal symptoms	9	9	90	9	9	100	9 (1)	9	100	9 (1)	9	100
Non-drug options	10	10	100	9	9	100	N/A	N/A	N/A	9	9	100
Acting on a non-drug option—suitable time to eat	N/A	N/A	N/A	N/A	N/A	N/A	9	9	100	9	9	100
Action if continue to feel worse while coming off the medicine and do not want to continue weaning	9	9	90	8	8	89	9	9	100	9	9	100

See online supplementary file 1 table S1 for UTQs asked in each round of user testing.
d*, number of participants who found the answer with difficulty (≥2 min and/or ≥2 prompts); F, found;N/A, information on the leaflet which was not tested by UTQ; U, understood;UTQ, user testing question.

completing it, especially because they check the discharge summary and sometimes they put in the dates and change the format and things. So if they can do this, I think they will be, yeah, a bit more meticulous and better. (Benzodiazepines R3, P11-Registrar)

Redesign of leaflets

Changes made to the content and design of leaflets following each round of feedback from consumer and health professionals are summarised in online supplementary file 1 table S3. The majority of changes were made in the first round of consumer testing and included increases in font size, spacing, reduction in content, and clarity in wording and presentation of information. Final designs of all three leaflets were produced as editable PDFs to enable completion by a hospital doctor or pharmacist electronically if preferred (online supplementary file 4). Readability of each leaflet, as assessed by the Flesch-Kincaid Grade Level, increased in subsequent rounds and remained below the recommended eighth-grade level

Table 3 Summary of consumer perceptions of the consumer information leaflets from semi-structured interviews

Themes	Summarised perceptions		Illustrative quotes
	Positive	**Negative***	
Content ▲ Quantity of information. ▲ Type of information. ▲ Personal plan.	▲ Sufficient quantity of information. ▲ Informative. ▲ Personal plan is clear, easy to use and supports medication management.	▲ A lot of information. ▲ Repetition of certain points.	"Might be a lot of words there for an older person – maybe cutting it down a little bit to make it clearer possibly…I want to see something more simplified." (Antipsychotic R1, P4) "I don't think there's too much that you could take out because… people don't always have an understanding of why they're taking things, so that's important…I don't think there's anything I could see to leave out." (Benzodiazepine R3, P6) "If a patient was given a leaflet like this, they wouldn't have to go to Dr. Google and potentially get all sorts of complicated information, not necessarily pick up the right site and get unhelpful information, but also, it outlines what the drug is, what it's used for, why. It's a really good overview of what's going on." (Benzodiazepine R3, P8) "I just want – what happens, what are the symptoms, what are the contraindications, what are this, what are that, quickly, very easily, you know I mean, like straight because we don't expect to know too much….By the time you read about it, it's too confusing." (Benzodiazepine R3, P4) "If they're on this medication, I think they would have been told about how they work and what they're used for. I think they'd already know that…Well, I don't know because sometimes people forget and then get mixed up and so on. So, maybe it's quite straightforwardly put." (Antipsychotic R1, P10) "I think for people over 65 and upwards, that [personal plan] will be a good idea that they're having in black and white more or less. They can read and they can do what they have to do… It's so easy to read and so easy to manage. I don't think anybody would say it's no good." (Antipsychotic R1, P1) "I think that's [personal plan] essential, absolutely essential and tick it off each day because – particularly, if they've got dementia." (Antipsychotic R2, P8)

Table 3 Continued

Summarised perceptions

Themes	Positive	Negative*	Illustrative quotes
Layout ▲ Bullets. ▲ Columns. ▲ Headings. ▲ Navigation. ▲ Order and organisation. ▲ Spacing. ▲ Tables.	▲ Use of bullet points to simplify reading. ▲ Columns made text less overwhelming. ▲ Headings are succinct, easy to read and direct you to appropriate information. ▲ Easy to navigate. ▲ Tables are clear and separate.	▲ A lot of information presented. ▲ Preference to present symptoms from most to least severe, then plan of action. ▲ Increase white space.	"I like bullet points because they can be more succinct with what you're going to say. People don't read things… it's easy to see a dot point…simplifies it." (Antipsychotic R2, P6) "If you had it all across, it's just - that can be overwhelming." (Antipsychotic R2, P6) "The headings are good too. They are really punchy in the eye." (Antipsychotic R1, P1) "I like the way that [the headings] says 'how do antipsychotics work?', 'what are they used for?' - the format, so it's that question and answer format, that's quite good." (Antipsychotic R1, P8) "I think it's easy [to navigate], it's well done, I mean it. If I sat down quietly and read it I'm sure I could cope." (Benzodiazepine R3, P9) "It wasn't very clear from the start…it should go with how important it is from the worst side effects to the least dangerous side effects and when to call the GP, when to go the emergency department or call 000, and then there should be something to reassure the patients that most of these side effects can be controlled so no need to panic." (Antipsychotic R1, P6) "The other thing that makes things easier to read – and it's not bad actually - is that the use of white space…probably spread out a bit more." (Antipsychotic R1, P2) "The advantage of the table is that you've got the headings, you've got it broken into parts, and it's very clearly in boxes what to do if, and because you've got multiple symptoms, it's sensible to have them in a table, with the action beside it." (Benzodiazepine R3, P8) "Yes, I think that's [withdrawal symptoms table] good because it keeps it clear, the serious ones, the not so serious ones, what to do for each type. It doesn't get lost in with the rest of the leaflet." (Antipsychotic R2, P4)
Text ▲ Bolding. ▲ Colour. ▲ Font style. ▲ Font size.	▲ Bolding emphasises significant points. ▲ Font style is simple and easy to read.	▲ Additional bolding of timing (ie, number of weeks over which medicines are reduced). ▲ Prefer colour (eg, in headings, boxes). ▲ Increase font size but keep length to a page.	"The first thing your eye goes to is the black and then to the bolds and then you start reading - because they're the important ones. It's quite good." (Antipsychotic R1, P6) "The boxes could be in colour. Black is a bit severe but I wouldn't put shading on any of the other boxes because that can sometimes make it very difficult to read." (Antipsychotic R2, P8) "Keep it simple. Don't do fancy fonts." (Antipsychotic R1, P5) "Absolute minimum, 12. Better 14 - for people with vision impairment…which means you're not going to fit in on a page." (Antipsychotic R1, P2) "I think that's quite big enough so the writing just fits nicely on the page." (Benzodiazepine R3, P9)

Continued

Table 3 Continued

Themes	Summarised perceptions		Illustrative quotes
	Positive	**Negative***	
Length	▲ No more than one page (double-sided).	▲ Nil.	"I like one page really. Sometimes I lose the second page and all that, so if you keep it on a page, that's good." (Antipsychotic R2, P2) "Because anything more than that, as a carer – we're so busy." (Benzodiazepine, R3, P4)
Language	▲ Plain language. ▲ Easy to understand.	▲ Some terminologies need to be better differentiated (eg, withdrawal symptoms and side effects). ▲ Complex terminology (eg, neuroleptic malignant syndrome).	"Except for the fact that I didn't differentiate between side effects and withdrawal symptoms because they're interrelated…The only thing that's not clear is this to stop the medication altogether or just to reduce it?" (Antipsychotic R1, P6) "Understand the biggest words there, psychosis and hallucinations, I know what they are. I didn't know what neuroleptic malignant syndrome was." (Antipsychotic R1, P7) "There's no big words, no words you haven't heard of which is good because half the time you read things and you think; what are they talking about." (PPI R3, P1)
Emotions	▲ Overall positive: improves understanding and confidence. ▲ Empowering for patients and/or carers.	▲ Potentially overwhelming.	"Like a million dollars. It's just bringing it home – what affects me – some of these things, most of them actually from time to time." (Antipsychotic R1, P3) "If you're leaving hospital and not feeling terribly confident, this would certainly give you a lot of confidence, thinking I can follow on the leaflet on what it wants to do." (Antipsychotic R2, P4) "It's altogether positive. It's letting you understand the treatment that's been given to you – the why – there's a little bit of how it works, there's the possible side effects. Then in this case, how do you stop it? So, there's understanding and control, and I think it empowers the patient if they're willing. But if it's not empowering the patient, at least it's empowering the carer." (Benzodiazepine R3, P8) "I think it's information that people need to have. They often don't have it. So, I think it's probably a very good idea." (PPI R3, P6)

Table 4 Summary of health professional characteristics

Characteristics	Health professionals (n=12)
Gender	
Male	4
Female	8
Age (years)	
18–29	4
30–39	6
40–49	1
50–59	1
Profession	
Pharmacist	7
Junior doctor	4
Registrar	1
Length of time as practitioner (years)	
<1	1
1–5	4
6–10	4
>10	3
Area of specialty	
General	7
Geriatrics	3
Other	2
Time in specialty (years)	
<1	3
1–5	4
6–10	4
>10	1

(antipsychotic: from 9.1 to 6.9; benzodiazepine/Z-drug: from 6.4 to 6.1; PPI: from 6.1 to 6.0).

DISCUSSION

This is the first study to report consumer and health professional user testing of consumer information leaflets for deprescribing in people over the age of 65 years. Patient and public involvement across several stages of this study ensured consumer needs were considered in the development of consumer-friendly leaflets. Over 80% of consumers correctly found and understood the majority of information in the leaflets and perceived the leaflets to be informative, well designed and a valuable resource to assist with deprescribing following hospital discharge. The leaflets were perceived to have excellent usability by hospital health professionals and perceived as likely to be completed by pharmacists and/or junior doctors depending on time and resources available.

Previous Australian studies of development and user testing of CMI and medicine labels have been performed in consumers younger than 70 years.[48 49] In line with Farage *et al*,[34] challenges in designing and user testing of medication information in an older cohort were due to age-related decline in memory and cognition, including difficulty learning and retaining new information, interpreting written and verbal information, and reduced processing speed. Although self-reported health literacy was high among consumer participants, several challenges were found during the user testing process. Consumers reported feeling overwhelmed during questioning and that they would benefit from the opportunity to read the leaflet multiple times at home prior to user testing, which could occur in practice but is not part of standard user testing methodology. Particularly challenging terminology and design included the 'decision made to stop the medicine', which was not found and understood by 50% of consumers in round 1, despite being among the first piece of information presented in the leaflet. In addition to a change in wording for subsequent rounds, design modifications including the use of check boxes (ie, reduced, stopped, refer to general practitioner) and increased spacing were necessary to improve consumers' understanding of this component of the leaflet. This highlights the complexity in designing medicine information in this population and the need for consideration of design elements (eg, larger font size, spacing, bolding) in addition to content. Difficulty understanding the underlying differences between withdrawal symptoms and side effects was also evident across rounds, suggesting the need for additional verbal counselling from a health professional in clinical practice and/or use of visual aids.[50]

Hospital health professionals were positive overall about the design, content and perceived benefit of the leaflets in practice. Suggested design and content changes largely aligned with consumer perceptions and suggestions. Existing consumer information leaflets or brochures targeting deprescribing of potentially inappropriate medications comprise generalised weaning plans.[14 15] A unique feature of the leaflets designed in this study is the personalised weaning plan for the initial 2 weeks following hospital discharge, to be completed for each patient by a health professional. The inclusion of this personal plan was perceived positively by both health professionals and consumers, and particularly beneficial for medications with longer and more complex weaning plans, such as those seen with benzodiazepines and antipsychotics.[10]

Existing consumer resources for deprescribing of inappropriate medications, including the EMPOWER brochures[14] and NPS PPI leaflet,[15] provide general guidance for weaning medicines and alternative management, with the intention for older people to seek a health professional to discuss a plan to discontinue their medicines. Use of the EMPOWER brochures has been explored in the community and hospital setting to reduce
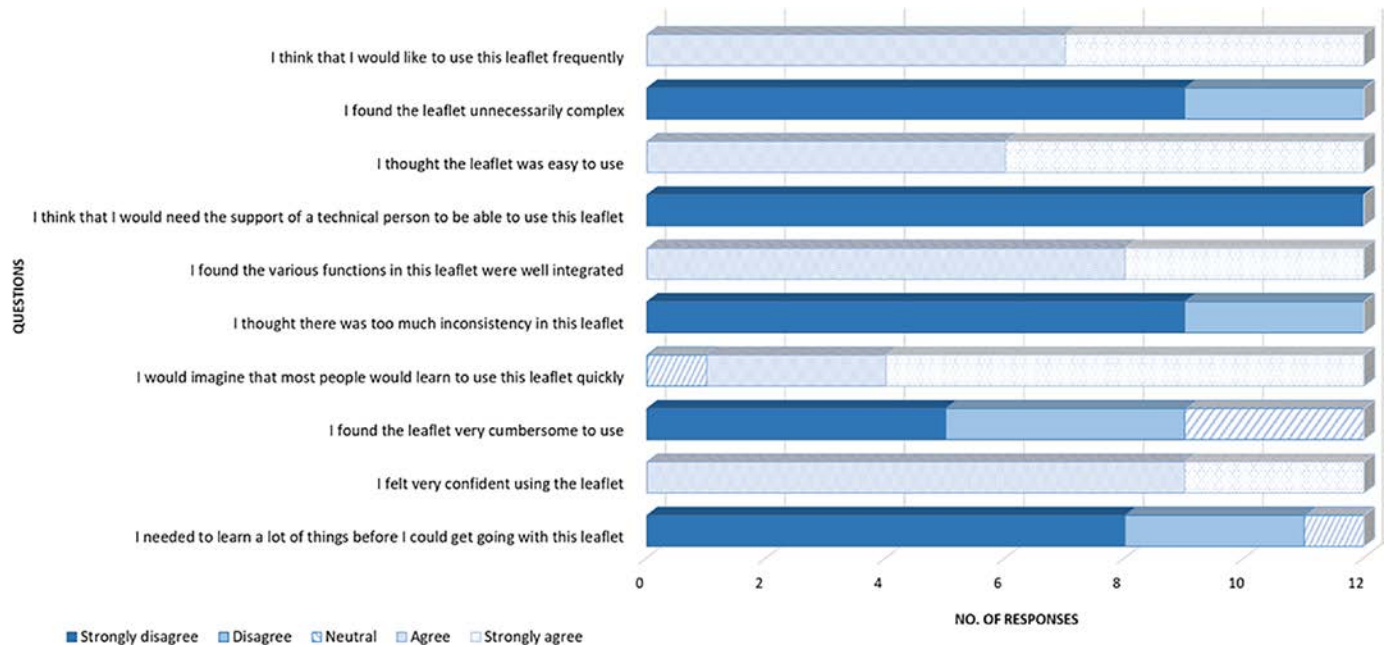
Figure 2 System Usability Scale responses from health professionals for antipsychotic and benzodiazepine consumer information leaflets.

inappropriate use of benzodiazepines and Z-drugs in older adults aged 65 years and over.[51 52] In contrast, the consumer leaflets developed in this study were designed to be provided to older hospital inpatients at the time a decision has been made by a clinician to start the deprescribing process.

Involvement of consumers in primary care research is variable and most frequently involves representation in steering committees and dissemination of research findings.[24] Although participation of consumers in user testing of information leaflets appears to be increasing,[53 54] these are primarily focused on CMIs and are currently only mandatory in Europe.[23] Coproduction of information leaflets across all stages of the research process is uncommon and has not yet been performed for leaflets specific to deprescribing. In Australia, previous research into alternative formats of CMI has described the involvement of consumers across multiple stages of research.[31] This included consumer and health professional participation in an initial needs analysis to investigate perceptions of CMI and to inform the development of alternative CMI formats. Evaluation of these leaflets was undertaken via a user testing process.[31] The method from this report was used to inform the design of this study and to increase involvement of consumers in the development of consumer information leaflets.

This study had a number of strengths and limitations. A significant strength of this study is the high level of consumer engagement from initial development of the research question to testing of the consumer information leaflets to ensure their readability and understandability. The leaflets were tested across multiple rounds with input from consumers and multidisciplinary hospital health professionals. This included contribution from carers who are likely to provide medical care and/or support medication management for older people, particularly for those living with dementia. Although the same leaflet was not tested across all three rounds with 10 participants, which is typical in user testing,[23] the design and content were largely consistent across all leaflets, with the exception of medicine-specific information including indication, side effects and withdrawal symptoms. This method also provided the opportunity to test the content of three different medication leaflets. Efforts were made to ensure wording was consistent between the three leaflets where possible. Design and content changes reflected feedback from participants and overall recommendations for the design of material for older people.[34] Patient and public involvement did not occur at data analysis and interpretation stages. Inclusion of consumer representatives at these stages could provide further patient perspectives and identify themes missed or misinterpreted by researchers.

The leaflets were not tested with consumers who had previously taken the medicine, thereby reducing potential bias from existing medicine knowledge.[23] Previous profession of consumers was not recorded and therefore consumers with prior healthcare backgrounds may have been included. Participants may not be representative of all older patients in whom deprescribing decisions are made in hospital. For example, approximately three-quarters of consumers in this study had perceived adequate health literacy in one or more domains, compared with findings from the 2018 Australian Health Literacy Survey which identified 39% of people over 65 years found it always easy to understand health information well enough to know what to do.[19] The leaflets were not retested following incorporation of all findings after round 3. Further testing in the population of

Table 5 Summary of hospital health professional perceptions of the consumer information leaflets from semi-structured interviews

Themes	Summarised perceptions		Illustrative quotes
	Positive	**Negative**	
Content ▲ Quantity of information. ▲ Type of information. ▲ Target population. ▲ Personal plan.	▲ Sufficient quantity of information. ▲ Inclusion of relevant information for patients. ▲ Targeted to older people. ▲ Personal plan was clear and easy to use.	▲ Personal plan was time-consuming to complete.	"It's definitely more concise than the CMIs [consumer medicine information leaflets] that we would [currently] hand out." (Antipsychotics R2, P5—Pharmacist) "There are a lot of words but I can't think of anything that you would remove to make it less cluttered. It's not that cluttered to begin with." (Antipsychotics R2, P7—JMO) "My favourite part about it was probably when you do give withdrawal symptoms then you had something of what the patient should do about it, which I think is something that's often missed in a lot of the information that is provided to patients." (Antipsychotics R2, P1—Pharmacist) "Personally, I'm not very good at the lifestyle part of the counselling of medication, so having this here [non-drug options] was good for me as a prompt to say 'okay, let's talk about non-drug options'." (Antipsychotics R2, P1—Pharmacist) "This section 'how do I stop my medicine' is good because the expectation for the patient or family is that it won't be in two weeks' time; it may be longer. So they psychologically prepare for that, not just abruptly stop." (Antipsychotics R2, P10—Pharmacist) "Seems to be geared primarily towards older people, which is obviously a good target for it. Younger people on antipsychotics – probably shouldn't be weaning them as much." (Antipsychotics R2, P7—JMO) "I just wonder if someone with cognitive impairment and dementia is going to benefit from reading that – probably not. But most of the patients we see probably wouldn't read it. So it could be given to the carer as well in this scenario." (Benzodiazepines R3, P6—JMO) "Completing every single day [of the personal plan] was quite arduous. And as a pharmacist, yes, I can do that, but - a doctor will not do that. They will probably put 7.5 mg and then put an arrow." (Antipsychotics R2, P1—Pharmacist)
Language	▲ Simple language, easy to understand.	▲ Some terminologies could be confronting for patients (eg, indications for antipsychotic).	"I like the information on this is quite simply worded, quite easy to understand." (Antipsychotics R2, P7—JMO) "If I read that an antipsychotic was used to treat severe aggression, agitation, hallucinations, and people with dementia, and I had early onset dementia, I'd be like 'what do you mean? I'm not aggressive, agitated. I don't hallucinate.' I might find that a little bit intense." (Antipsychotics R2, P1—Pharmacist) "I really like this part 'as you age, you can get increased side effects'. So the whole idea is 'I'm okay now but maybe it's not okay in two years' time because I'm getting older.' I think that's a very nice way of putting it." (Benzodiazepines R3, P9—Pharmacist)

Continued

Table 5 Continued

Summarised perceptions

Themes	Positive	Negative	Illustrative quotes
Layout ▲ Bullet points. ▲ Columns. ▲ Headings. ▲ Navigation. ▲ Order and organisation. ▲ Spacing. ▲ Tables/boxes.	▲ Easy to read with bullet points and columns. ▲ Clear headings. ▲ Easy to navigate and identify relevant information. ▲ Tables highlight key information.	▲ Increase white space.	"Dot points make it very easy to read. Makes it much, much easier" (Antipsychotics R2, P7—JMO) "The columns are good. I think it's much easier to read as well." (Antipsychotics R2, P5—Pharmacist) "You've got the heading and things quite clear with the black background and white font, so that's quite nice as well." (Benzodiazepines R3, P11—Registrar) "I like how you start with the fact of what's going to happen with the medication… so it kind of personalises the leaflet to the patient, which I think is really good." (Antipsychotics R2, P1—Pharmacist) "It's quite close together…I'm just think as an elderly person, whether they just want a little bit more space between…just to make it easy to read." (Antipsychotics R2, P1—Pharmacist) "It's good that the symptoms are highlighted [in a table]. So they can clearly identify that….that's the main concern from medical staff, so they can quickly escalate onwards." (Benzodiazepines R3, P12—JMO)
Length	▲ No more than one page (double-sided).	▲ Nil.	"It's good, you don't want two pages." (Benzodiazepines R3, P6—JMO)
Text ▲ Bolding. ▲ Colour. ▲ Font style, size.	▲ Bolding emphasises important points. ▲ Clear font style. ▲ Adequate font size.	▲ Add colour.	"I like how the things that are more important are actually bolded as well, so they stand out for the patient. So maybe it will be easier to remember." (Antipsychotics R2, P5—Pharmacist) "It looks very bland…it doesn't encourage me to read it….You can have a coloured version and a black and white version." (Benzodiazepines R3, P8—Pharmacist) "I think black and white is fine." (Benzodiazepines R3, P9—Pharmacist) "To me, it's fine [font style, size]." (Antipsychotics R2, P10—Pharmacist)

Continued

Table 5 Continued

Themes	Summarised perceptions		Illustrative quotes
	Positive	**Negative**	
In practice ▲ Perceived usefulness. ▲ Perceived integration into workflow.	▲ Act as a counselling aid—information prompts discussion during counselling. ▲ Provision of written information for carers who may not be present during discharge counselling. ▲ Who will complete the leaflet (doctor vs pharmacist) is dependent on resources and relationship between health professionals. ▲ Pharmacists may be better suited to complete the leaflet on discharge (greater attention to detail, compare details with discharge summary).	▲ Doctors are time-poor. ▲ Leaflets may be handed out to patients/carers without counselling.	"I think it's good to give something to the patient or carer because just telling them we're stopping it is not enough. And also what I find is that sometimes when pharmacists see the patient on the ward - they are usually the patients who are not going to be caring for their medicines. So if you can have something in writing that can be passed on to the carer, it would help a lot." (Antipsychotics R2, P2 — Pharmacist) "I like leaflets because it means that I don't have to stand there for a while thinking about everything and the risk of missing stuff. Leaflets makes it much, much easier. (Antipsychotics R2, P7—JMO) "Ideally, I'd like to use it as a counselling aid, but I think practically, I'd be strapped for time and would end up just handing it to them with the discharge summary paperwork" (Antipsychotics R2, P7—JMO) "What would happen is the doctors, hopefully it will be a multidisciplinary team meeting or even just the doctor and the pharmacist, the pharmacist has highlighted 'we want to stop this', the doctor and the pharmacist talk saying 'this would be the plan', and we go to the patient, talk to them, and tell them why we should stop." (Antipsychotics R2, P2—Pharmacist) "I think it probably will be the doctors, only because they are the prescribers…it does depend on the resources and….that relationship between pharmacy and the prescribers out on the ward….Maybe it's completed and left for the doctors just to make sure that it's right or something, but it probably does depend on the relationship that the pharmacy and the doctors have." (Benzodiazepines R3, P8—Pharmacists) "I think we're very time-limited. So, if family aren't there and then, I'm sure we can give them a phone call, but that doesn't always happen. I mean, if we wean things anyway, usually we just have a plan in the discharge and either supply them with some medications with, 'See your GP for ongoing supply'." (Benzodiazepines R3, P6—JMO) "I think if someone else was to complete it, it would increase my uptake." (Benzodiazepines R3, P12—JMO) "I believe pharmacists would probably be better in completing it, especially because they check the discharge summary and sometimes they put in the dates and change the format and things. So if they can do this, I think they will be, yeah, a bit more meticulous and better." (Benzodiazepines R3, P11—Registrar)

JMO, junior medical officer; p, participant number; R2, round 2 testing of antipsychotic leaflet; R3, round 3 testing of benzodiazepine leaflet.

interest (older hospital inpatients who have the medicine of interest deprescribed) is needed to inform additional revisions of the leaflets, if required. Previous studies have performed user testing in older people up to the age of 70 years,[48 49] whereas consumers in this study were primarily aged over 70. Difficulties encountered undertaking the user testing process in this study suggest that further consideration of a person's degree of independence and ability to self-manage their medications may be necessary. The use of colour was frequently suggested by consumers and health professionals; however, the leaflets were designed in black and white as there is likely to be limited availability of colour printing in hospitals. Researchers considering the development of consumer information leaflets for additional medicines should ensure user testing with consumers is performed to develop specific design and content features understandable by the population of interest. The feasibility and effectiveness of the consumer leaflets to support deprescribing and reduce inappropriate medication use in older hospital inpatients were not explored in this study and should be considered in future studies.

CONCLUSION

Three consumer information leaflets to support deprescribing for older inpatients have been developed and tested by consumers and health professionals. Patient and public involvement in this study ensured the needs of consumers were considered across different stages in the research process. Future studies should also consider consumer involvement in the analysis and interpretation of user testing results and interview transcripts to provide additional patient perspectives. Further testing in clinical practice may inform additional modifications. The feasibility and effectiveness of the leaflets to support deprescribing at transitions of care should be explored in clinical practice.

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