

ORIGINAL REPORT

CREATION AND PRELIMINARY VALIDATION OF THE SCREENING FOR SELF-MEDICATION SAFETY POST-STROKE SCALE (S-5)

Franceen Kaizer, BSc, OT¹, Angela Kim, BSc candidate, BSc candidate², My Tram Van² and Nicol Korner-Bitensky, PhD^{2,3}

From the ¹Neurology and Oncology Programs, Jewish Rehabilitation Hospital, Laval, ²School of Physical and Occupational Therapy, Faculty of Medicine, McGill University and ³Centre de recherche interdisciplinaire en réadaptation du Montréal métropolitain (CRIR), Montreal, Canada

Rationale and objective: Patients with stroke should be screened for safety prior to starting a self-medication regime. An extensive literature review revealed no standardized self-medication tool tailored to the multi-faceted needs of the stroke population. The aim of this study was to create and validate a condition-specific tool to be used in screening for self-medication safety in individuals with stroke.

Design: Items were generated using expert consultation and review of the existing tools. The draft tool was pilot-tested on expert stroke clinicians to receive feedback on content, clarity, optimal cueing and domain omissions. The final version was piloted on patients with stroke using a structured interviewer-administered interview.

Results: The tool was progressively refined and validated according to feedback from the 11 expert reviewers. The subsequent version was piloted on patients with stroke. The final version includes 16 questions designed to elicit information on 5 domains: cognition, communication, motor, visual-perception and, judgement/executive function/self-efficacy.

Conclusion: The Screening for Safe Self-medication post-Stroke Scale (S-5) has been created and validated for use by health professionals to screen self-medication safety readiness of patients after stroke. Its use should also help to guide clinicians' recommendations and interventions aimed at enhancing self-medication post-stroke.

Key words: stroke; cerebrovascular accident; self-medication; medication adherence; safety, assessment; screening; instrumentation; medication; elderly.

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Correspondence address: Nicol Korner-Bitensky, School of Physical and Occupational Therapy, McGill University, 3630 Promenades Sir-William-Osler, Montreal, Quebec, H3G 1Y5, Canada. E-mail: nicol.bitensky@mcgill.ca

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INTRODUCTION

Stroke is the primary cause of adult disability in the USA (1). In Canada, approximately 300,000 Canadians are currently living with the consequences of stroke (2). These consequences can include changes in communication, physical functioning, cognition, behaviour, sensation and visual-perception that

all potentially have an impact on the person's ability to self-medicate. Stroke onset is acute in nature and is typically a time when new medications are prescribed and longstanding prescriptions are adjusted. Self-medication has been shown to play a substantial role in self-management of illness and in decreasing utilization of health services (3). It is intuitive that self-medication post-stroke be introduced only once screening for safety has been completed.

A literature review was conducted to identify standardized tools that could be used to screen for safe medication use post-stroke. Nine tools (4–12) were identified and reviewed. Most focus largely on cognitive and behavioural issues of self-medication and, to a lesser extent, on physical requirements. Among the tools found, none were tailored to the multi-faceted needs of the stroke population.

Thus, the purpose of this study was to develop and pilot test a condition-specific tool to be used in screening for self-medication safety in individuals after stroke. The specific objectives included 3 phases: (i) performing a comprehensive review of the literature to identify items and domains from existing instruments that would be appropriate for inclusion in a self-medication tool for those after stroke; (ii) eliciting clinician feedback to determine content validity of the screening tool; and (iii) pilot testing the tool with a purposive sample of individuals after stroke to determine clarity and ease of use. The Institutional Review Board of the Faculty of Medicine, McGill University provided study approval.

MATERIAL AND METHODS

Literature review: Phase 1

In Phase 1 a comprehensive literature review was performed to identify instruments that exist to help determine if a patient is able to self-medicate safely and to determine whether any would be appropriate either in part or as a whole for use with a stroke clientele. The literature review was also used to generate relevant items and domains for the creation of the Screening for Safe Self-medication post-Stroke Scale (S-5). A MEDLINE and PubMed search of publications from 1950 to May 2009, restricted to English language studies with adult subjects, was conducted. The first search was completed using MEDLINE and yielded 290 articles when combining the keywords: self-medication, assessment, geriatric assessment, self-administration, and medication. The second search using PubMed produced 423 articles when combining: assessment, self-administration, medication, and elderly. Articles

that addressed self-management of medication or examined methods for evaluating medication safety were retrieved. Six original articles and 1 review article were found. The 2-step search was supplemented with a third search of references. Overall, 9 tools were identified, as described below.

The *Self-Administration of Medication (SAM)* questionnaire collects demographic data about discharge destination, and on the patient's willingness and competence to self-medicate. It also assesses the patient's knowledge of drugs and experience with self-medication (11). The *Medication Management Ability Assessment (MMAA)* is an assessment for patients with schizophrenia that focuses on a patient's ability to read and interpret instructions, open different types of vials, remove the tablets, and differentiate colors (6). The *Drug Regimen Unassisted Grading Scale (DRUGS)* is performance-based and includes: ability to identify containers, open containers, withdraw the correct number of tablets, and demonstrate when to take the dose at specific times of day (5). The *Hopkins Medication Schedule* is a standardized assessment that involves the ability to read, plan, and sort medications, understand their use, along with the ability to make a schedule and use a pillbox (9). The *Medication Management Instrument for Deficiencies in the Elderly (MedMaIDE)* is a combination of observation and questionnaire format (12). It evaluates the patient's knowledge and whether they know how to take and get their medications. The *Self-Medication Risk Assessment Instrument* (10) is a screening tool that examines areas of difficulty older individuals may have, such as the number of medications, mental state, hearing, vision, social support, motor skills, as well as attitudes towards and knowledge about medications. The *Medication Management Tasks* assesses different dimensions including hand function, vision and medication competence (8). In the *Standardized Medication task (SM task)*, 5 tasks are used: (i) read the prescription label; (ii) interpret the prescription instructions; (iii) open the pill bottle; (iv) cut pills for correct dose administration; and (v) plan the daily dose and timing (4). Finally, the *MedTake Test* (7) evaluates understanding of dosage, indications, schedule, and safety related to co-ingestion of food or water.

Based on the review it was determined that no standardized self-medication safety questionnaire specific to a stroke clientele existed and that none of the tools covered all of the pertinent domains. This justified the need to develop a condition-specific tool that would measure self-medication safety in those with stroke.

In Phase 1 the contents of the 9 instruments described above were scrutinized and items relevant to assessing patients after stroke were considered for inclusion in the new tool. The research team created a rough draft version using domains known to be affected by stroke and known to be important for self-medication. Principles of the Tailored Design Method (13) were used to guide the writing of the questions and the questionnaire formatting and flow.

Assessment of content validity through expert consultation: Phase 2

In Phase 2 the goal was to further develop and assess the content validity of the first draft. This was performed using both the information gleaned from the literature and through consultation with experts in stroke. Towards this end we consulted clinician experts from a variety of disciplines. This phase was completed using a 2-step process of expert consultation. The first series of interviews were performed on 8 clinicians, including 5 occupational therapists, 1 speech language pathologist, 1 neurophysiologist with extensive experience in rehabilitation with a neurological clientele and 1 pharmacist. Once a cleaner version of the tool was generated from the first round of feedback, a second set of interviews was performed with 3 additional clinicians: an occupational therapist, a speech language pathologist and a nurse.

Each expert was either interviewed in person or received the draft version by e-mail and instructed to: (i) review the items; (ii) indicate whether the items were appropriately chosen for screening a patient's safety to self-administer medications; (iii) identify omissions and redundancies; (iv) determine whether the instructions were straightforward and easy to follow or required changes and if so what those

changes should be; and, (v) state whether they would consider this tool to be interesting for use in their clinical practice.

The feedback was collated, each comment was scrutinized, and suggested changes were discussed by the research team who reflected on the relevance and appropriateness of each recommendation based on the global goals of the tool and the literature on self-medication safety. As deemed necessary based on the feedback, new items were generated to add a domain or to add additional items under an existing domain.

Assessment of content validity and feasibility of use in the client group: Phase 3

In Phase 3 the goal was to further assess the content validity and ease of use of the tool by administering the final version to a purposive sample of individuals with stroke. Individuals who were self-medicating at the time of recruitment or who were expected to return home self-medicating, were sought. Purposive sampling was used to insure representation of those with/without diabetes, with/without mild to moderate motor impairment and visual-perception dysfunction.

Potential participants were eligible if they were English speaking and had sufficient comprehension to understand the purpose of the study, as determined by the clinical team. Individuals with and without upper limb paralysis, with and without diabetes, and with and without mild cognitive impairment were sought in order to test the preliminary version of the tool with patients who would be representative of those who would be tested for self-medication readiness. Those with moderate cognitive impairment and aphasia were not considered eligible, as the purpose at this stage was to elicit feedback about the content and ease of use of the tool. Names of potential participants were provided to the lead author (FK), and those who agreed to have the study explained to them were placed in contact with the research assistant who explained the project. The study details and the steps taken to maintain confidentiality were described. For those who provided verbal consent, a convenient time was scheduled for a 25-min in-person audio-taped interview.

On the day of the interview the participant provided written informed consent. The interviewer then administered the items on the draft version and asked the participant first to respond to each item, and then to critique the clarity of each item using a structured series of questions. For example, the patient was asked to state if they understood the item clearly. If not, the interviewer invited the patient to suggest another way to word the item or to suggest cues to make the item clearer. Also, the patient was asked to indicate any tasks or items they felt should be added.

RESULTS

Item generation and creation of the draft version: Phase 1

The literature review identified several domains that are important to self-medication safety. These areas were reviewed in light of the potential sequelae of stroke, including domains related to memory, orientation and physical ability. Other domains that are included in some tools are the patient's ability to comprehend communication, manipulate child restraint containers, and read and interpret labels (4, 11). Items assessing all these aspects were generated. Five studies observed the importance of cognitive ability (5, 8–11): 2 also recognize the importance of executive functions (6, 9). Items responding to each of these domains were generated, including a reading task, opening a pill bottle, assessing comprehension and planning appropriate actions when a prescription is running low. An initial series of items related to 5 domains (cognition, communication, motor function, visual-perception and judgment/executive functions/self-efficacy) was generated by the research team and a first draft of the tool was created.

S-5 tool description

The final version of the tool, the Screening for Self-medication Safety post-Stroke Scale (S-5) includes 16 items that test the aforementioned 5 domains (see Appendix I). The tool is designed to be a performance-based interviewer-administered checklist where the examiner follows specific instructions for each item and checks whether the patient adequately responds or, where appropriate, performs a specific task. Brief criteria are given for possibly ambiguous task responses to exemplify what qualifies as correct performance of the task. The equipment requirements for administration are minimal and are designed to make use of pill bottles, objects, etc. that are readily available in a hospital setting and small in size.

Each item is scored according to a dichotomous yes/no response. Additionally, for each item there is a "Concern" box that can be checked if the clinician has concerns related to that specific item. Finally, a summary "Concerns and Recommendations" section permits the clinician to elucidate specific concerns and recommendations. There is no cumulative score on the scale. Rather, a response of "no" to any one of the items potentially highlights the need for further in-depth assessment or an intervention addressing the problem.

Tool's domain-specific content

Cognition: 1) *Orientation*. The first set of questions asks the patient to indicate the time of the day, month, and place. Screening is stopped if 2 of these 3 questions are not answered correctly. 2) *Memory, immediate recall*. The examiner presents 3 different objects and asks the patient to remember them. Then, the patient is immediately asked to repeat the names of the objects. 3) *Memory, delayed recall*. Later on during testing, the patient is asked to remember the objects that were shown to them during the immediate recall task.

Communication: 1) *Comprehension*. The patient is provided with an open pill bottle containing 8 identical white disc-shaped pills and is asked to distribute the pills to show how they would take 2 pills in the morning and 2 in the evening. The examiner can repeat the instructions once. If the patient properly distributes the pills, it is taken to imply that he or she has adequate comprehension of verbal language. If the patient is unable to understand the task after the second attempt, the examiner should note a concern and proceed to the next item. 2) *Reading*. The patient is provided with specific instructions on a prescription label and is asked to read what is written on the label. The label states "Take one pill 3 times daily".

Motor

The patient is provided with a pill bottle with a childproof cap. The patient is asked to open the bottle and take out one pill. If the patient succeeds in performing this task, the examiner skips the following question that requires the patient to open a non-childproof cap. If the childproof cap proves difficult, the clinician should check the "concern" box and continue to the next question, which consists of opening a pill bottle with a non-childproof cap. If the non-childproof cap also proves difficult, then a recommendation should be made.

A syringe without a needle is provided only to patients who, as part of their usual medication regime, require self-injection of medication. The patient is asked to demonstrate how they would self-administer their medication. The examiner notes whether 1 or 2 hands are used when performing the task. A possible recommendation would include training in the use of 1-handed techniques if post-stroke paralysis of the upper limb reduces bilateral upper limb functioning.

Visual-perception

This section examines different visual and visual-perceptual constructs: shape, color, size, along with visual spatial neglect and figure-ground discrimination. The examiner places 3 pills of different shapes (disc-shaped, oval and capsule) in a triangle and places the pill bottle in the middle. The patient is asked to identify the pills that correspond to the shape indicated by the examiner. The same procedure is then repeated but this time with 3 pills in 3 different colors (blue, orange, and white) and 2 different sizes. It is important to note that the pills should be placed in a layout that permits evaluation of the patient's awareness of both left and right visual fields. A diagram depicting the distribution of the pills is shown in Appendix I.

Judgment/executive functions/self-efficacy

The patient is asked to imagine a situation in which he or she does not have enough pills remaining as indicated on the doctor's prescription. The examiner is permitted to repeat the question once. The patient is asked to find a solution. A correct response would be attempting to fill the prescription either by telephone or in person, or requesting that a family member, care provider or friend fill the prescription. An example of an incorrect response would be to stop taking the medications because the pills have run out. If the patient is unable to understand the task, the examiner should note a concern.

Next, the patient is asked to perform a task that again requires judgment and executive functions. The task consists of opening a liquid medication bottle and pouring a specific quantity of medication (10 ml) into a 30 ml cup with distinct markings. The task is considered to be performed accurately if the patient pours 10 ± 2 ml.

Finally, self-efficacy regarding self-medicating is assessed. The examiner asks the patient if he or she feels confident in his or her ability to self-administer medications.

Expert feedback: Phase 2

When the draft version of the tool was circulated to both groups of expert clinicians, all 11 indicated that a self-medication screening tool was important and would be relevant to their clinical practice. Ten respondents indicated that the order of the presentation of items in the questionnaire was appropriate.

Expert feedback: First draft

One individual suggested broadening the scale's use to include *traumatic brain injury*. After discussion and consideration the research team deemed it important to remain with a stroke-specific focus.

Numerous comments and suggestions were made about the items or domains. With regard to omission of important variables, it was suggested by one respondent that *time since hospital admission* has an important impact on self-medication readiness. However, this information was considered unnecessary to the examiner since it does not determine whether or not the patient is ready to self-medicate. One therapist suggested retrieving the Mini-Mental State Examination (14) scores from the admission assessment given that this screen of cognitive function is broadly used in inpatient stroke assessment. This variable was added in the descriptors. However, it is to be noted that the tool can be administered without this piece of information.

Minor modifications included rephrasing questions and instructions and adjusting terms for clarity and to prevent potentially biased responses. To elucidate, one frequent remark was that the word “*dosette*” used in the first S-5 draft is a term rarely used outside of the province of Quebec, Canada and the term “*pillbox*” would be more easily understood. During further development of the scale, the questionnaire item including these words was eliminated, as it was deemed to take too long for the patient to prepare a dosette/pillbox and the feedback from numerous pharmacists that we consulted regarding the wording used and the likelihood of a patient post-stroke creating their own dosette box indicated that these are usually prepared by the pharmacist. Three experts suggested including a question that would elicit information on whether the patient has social support for physical needs or to provide verbal cues. Because this screening tool was designed to evaluate a person’s ability to self-medicate without assistance, the research team chose not to include this question.

Having the patient state what medications they are currently taking was also suggested. Considering the patient’s new state post-stroke and the possibility of having many changes in medications that have not yet been described to the patient, this information was deemed inappropriate to request early post-stroke.

A question asks the patient to demonstrate how he or she would take medication for one day by following instructions that indicate 2 pills in the morning and 2 in the evening. One suggestion was that this task be framed around a full week. This was not added, primarily in order to keep administration time as short as possible.

Three respondents suggested that it would be appropriate to include a self-assessment of blood sugar in those patients with diabetes. While this suggestion was considered, it was believed to be outside of the scope of a quick screening tool. However, once the screening for self-medication safety shows the patient with diabetes as able to demonstrate correct manipulation of the syringe, a full assessment of readiness to monitor sugars, etc. could be initiated.

The neurophysiologist questioned the necessity of having a section on visual perception. Given that perceptual dysfunctions are prevalent post-stroke and that specific impairments, such as unilateral spatial neglect, may result in an inability to notice medications or label instructions to the left of the person’s midline, it was deemed important to include this domain.

One concern raised was whether clinicians would use the tool in daily practice. It was pointed out by some that there are

major consequences of postponing a patient’s discharge due to inability to manage medications. As one clinician stated, “I need to prove to the team that in fact this patient is clearly unsafe because of point A, B, and C... we will be questioned by the physician, patient and family.”

Expert feedback: Second draft

To assess memory, the patient was asked to remember a specific pill schedule and to repeat it. This was considered difficult by 2 clinicians, and subsequently the research team agreed that this question could be modified by using objects instead of a pill schedule.

In order to accommodate those with receptive aphasia, written and pictorial instructions were included in the comprehension section of the first draft. Two speech language pathologists suggested adding written and pictorial instructions for all items. While the research team took this suggestion into serious consideration and attempts were made to create and administer the tool in pictorial format, these efforts were cumbersome and deemed to be beyond the scope of the current tool and its purpose as a screen.

Two clinicians found that assessing a patient’s ability to express himself or herself is unnecessary, given that verbal expression is not essential for self-medication. After consideration of this comment, all questions evaluating a patient’s expressive skills were omitted.

One expert suggested that the administration of liquid medication be assessed as a motor task. This suggestion was acted upon, but to maintain the integrity of the tool as a quick screen, the task was incorporated as a component of the assessment of execution function.

Patient feedback: Phase 3

Face-to-face interviews were performed on 6 participants with stroke (4 females and 2 males) recruited from an inpatient rehabilitation facility. Five were inpatients and one was an outpatient: ages ranged from 50 to 70 years and most had mild to moderate post-stroke sequelae. All participants completed the questionnaire within a range of 4–6 min. Based on their responses, changes were made for the purpose of clarification in 2 out of the 16 questions. To elucidate, when patients were provided with a pill bottle with 5 different colors and shapes and asked to follow the instructions in question #4, some participants showed confusion and hesitation as to the goal of the task. One of them stated that the task was not conceivable since the pills were different. To reduce the confusion, in the final draft of the tool, the question has been adjusted to provide a pill bottle containing 8 identical white pills. In question #14 where judgment is assessed, certain participants did not immediately understand the hypothetical situation. However, once the interviewer repeated the question, the participants were able to respond. As a result, an additional instruction has been added to instruct the examiner to repeat the question once, if needed.

When the interviewer requested an overall impression of the questionnaire, a majority of the participants indicated that the tool was simple and quick to complete, but some thought that

the questions should be more challenging. This finding was anticipated given that we purposely selected patients who were quite high functioning in terms of cognition and comprehension to complete this first phase of scale validation.

DISCUSSION

To date, there is no published standardized tool that evaluates safe self-medication specific to a stroke population. This research reports on the development and validity testing of the Screening for Safe Self-Medication post-Stroke Scale (S-5). A complete version can be found on the StrokEngine-Assess website (www.strokengine-assess.ca). The S-5, which is administered in a checklist format, has been developed with reference to published literature on important domains affected by stroke, consultation with expert clinicians, and feedback from patients with stroke. Face and content validity were shown to be good and administration time, effort and complexity were acceptable to both clinicians and patients. It is thus anticipated that this tool will serve as a quick 5-min screen for widespread use in screening for self-medication safety of individuals with stroke. The fact that patients found the tool easy, some indicating even too easy, was a finding that was reassuring given that the goal was to create a scale that is easy to understand. Also this finding was anticipated given that we purposely selected patients who were quite high functioning in terms of cognition and comprehension to complete this first phase of validation.

The S-5 has also been developed in a format that cues the clinician to identify concerns and recommendations regarding the patient's ability or potential for self-medication. This cueing provides a structured format for questioning safety, as well as encouraging structured thinking regarding the need for further assessment, education and/or training of the patient. It has been created to be non-discipline specific in respect of the stroke interdisciplinary team present in many hospitals where one or more disciplines might be responsible for conducting self-medication screening.

One limitation of this new tool is that it was created in the English language. Also, the S-5 would benefit from further validity testing, for example, using known groups to test whether the tool discriminates between different groups of individuals with characteristics that should influence self-medication safety; for example, groups with differing levels of cognitive impairment. Also, this tool is not earmarked to be a comprehensive assessment of self-medication. There are aspects of daily medication use, such as drawing insulin, discriminating from a large number of pill bottles and identifying the correct medications to take at the right time of day and under the right circumstance (e.g. with or without food), that were not included. Thus, if the patient succeeds on all items of the S-5 it will still be necessary to assess his or her "real life" medication list, sequencing, ability to self-medicate over a 48- or 72-h period accurately, etc. While many additional aspects of self-medication were considered for inclusion, the integrity and usefulness of this scale as a quick screen will be in

its ease of use. It has been created with a focus on the moving clinician who must keep the key objects in his or her pocket in order to administer this scale quickly by the bedside. A labour-intensive scale is unlikely to be successfully integrated into clinical practice and would not meet the conditions to be categorized as a screening tool. Finally, although created for a stroke clientele the S-5 may serve, in a slightly revised form, to assess other patient groups.

In conclusion, self-medication safety is an important component of community living post-stroke. Even subtle consequences of stroke can impact on safety. By using a structured tool to identify self-medication safety early post-onset, concerns can be identified and appropriate recommendations, referrals, and treatment interventions provided.

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APPENDIX I. Screening for Safe Self-medication post-Stroke Scale (the S-5)

Note: If patient wears glasses, make sure they are worn throughout the test.
 Note: If patient has upper limb paralysis give demonstration using one hand where appropriate.

Materials required

1. Labelled pill bottle with childproof cap
2. Labelled pill bottle without childproof cap
3. Liquid bottle with “push and turn” cover
4. 1 syringe without needle
5. 8 disc-shaped white pills (e.g. shape of a vitamin C)
6. 1 oval-shaped blue pill
7. 1 capsule-shaped orange pill
8. 1 small disc-shaped pill and 1 large disc-shaped pill
9. Three objects including: pen, coin, key
10. Sample of information written on a typical pill bottle label including name of medication, dosage, frequency, time of day to take medication and name of a person

Diagram #1 – indicating placement of pills for questions #11 and #12.

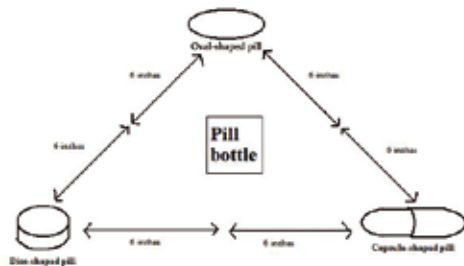


Diagram #2 – indicating placement of pills for question #13.



Evaluator’s name:.....
 Date:.....
 Dysphagia (Y/N):.....
 Mini-Mental State Examination Score (if available):.....
 Imprint Patient Information

<i>Questions 1–3: Patient needs to succeed in 2/3 questions to continue screening</i>	<i>Yes</i>	<i>No</i>	<i>Concern^a</i>
1. Say: What month is it? (Accept \pm 1 month from the correct month)			
2. Say: What time of the day is it? (Should identify morning, afternoon or evening)			
3. Say: Where are we right now? (Should identify name of hospital or ward or site)			
4. Provide an open bottle with 8 identical white disc-shaped pills and say: If you have to take 2 pills in the morning and 2 at night, show me how you would group the pills. (Repeat once if needed)			
5. Provide a pill bottle label and say: Can you read to me what it says on the label?			
6. Present a pen, coin, and key and say: Remember these 3 objects: a pen, a coin and a key. Remove the objects and ask patient to name the objects. Please tell me what they are. (Patient must correctly name all 3 objects.) Then say: I will ask you to remember these objects later.			
7. Provide a pill bottle with childproof cap and say: Open this bottle and take out 1 pill. (If accomplished: skip to #9, If not accomplished: proceed to #8)			
8. Provide a pill bottle without childproof cap and say: Open this bottle and take 1 pill. Self-Injection (Assess if necessary)			
9. Provide a syringe without a needle and ask patient to demonstrate how to inject their medication. Note if patient uses 1 or 2 hands.			
10. Say: Can you name the 3 objects I showed you earlier? (Patient must correctly name 2/3) Randomly place 3 pills (blue, orange, and white) in triangle with pill bottle as in diagram #1.			
11. Say: Point to the disc-shaped pill, then to the oval pill, and finally to the capsule-shaped pill. (Patient must correctly identify all 3)			
12. Say: Point to the blue pill, then to the orange pill and finally to the white pill. (Patient must correctly identify all 3) Place 2 disc-shaped pills (large and small) with pill bottle in the middle as in diagram #2.			
13. Say: Point to the large and then to the small sized pill. (Patient must correctly identify both pills)			
14. Say: Imagine you need to take 3 pills every day for your blood pressure and you only have 1 pill left. Suppose you cannot go to a pharmacy for 4 days, what do you do? (Repeat once if needed)			
15. Provide a liquid medication bottle with “push and turn” cover and say: Open the bottle and pour 10 ml of the liquid into this cup. (Accept \pm 2 ml from 10 ml)			
16. Say: Do you feel confident in taking your medication on your own?			

^aConcerns and recommendations (Note: further testing/referrals needed, recommendations for patient training).