### ADCS-MCI Activities of Daily Living Inventory - Page 1 of 11

#### Month 6 Visit

<table>
<thead>
<tr>
<th>Subject Number</th>
<th>Subject Initials</th>
<th>Examiner Initials</th>
<th>Examination Date</th>
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#### INSTRUCTIONS

Complete questions 1-18 and 19-24. Then go back to page 8 of this ADL exam to calculate the total score for questions 1-18 and proceed to page 9 of this ADL exam to complete the “Don’t Know” answers worksheet for questions 1-18.

#### Don’t Know

<table>
<thead>
<tr>
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<th>Yes</th>
<th>No</th>
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#### Information obtained through:

1. Subject visit
2. Telephone call

#### Subscore for Page 1

(Range = 0-10)

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4. In the past 4 weeks, did {S} clean a living-, sitting-, or family room?  
   If yes, which best describes how he/she usually performed:  
   2  without supervision or help  
   1  with supervision  
   0  with physical help

5. In the past 4 weeks, did {S} balance his/her checkbook or a credit card statement?  
   If yes, which best describes how he/she usually performed:  
   2  without supervision or help  
   1  with supervision  
   0  with physical help

6. In the past 4 weeks, did {S} ever write things down?  
   Note: If {S} wrote things only after encouragement or with help, the response should still be ‘yes.’  
   If yes, which best describes the most complicated things that he/she wrote:  
   2  letters or long notes that other people understood  
   1  short notes or messages that other people understood  
   0  his/her signature or name

7. In the past 4 weeks, did {S} clean a load of laundry?  
   If yes, which best describes how he/she usually performed:  
   2  without supervision or help  
   1  with supervision  
   0  with physical help

Subscore for Page 2  
(Range = 0-8)
8. In the past 4 weeks, did {S} keep appointments or meetings with other people, such as relatives, a doctor, the hairdresser, etc.?

   If yes, which best describes his/her awareness of the meeting ahead of time:
   - 3: usually remembered without written or verbal reminders
   - 2: usually referred to notes, a diary, or calendar
   - 1: usually remembered the appointment after verbal reminders on the day
   - 0: usually did not remember, in spite of verbal reminders on the day

9. In the past 4 weeks, did {S} use a telephone?

   If yes, which best describes his/her highest level of performance:
   - 4: made any call necessary e.g., after looking up numbers in white or yellow pages, or by dialing directory assistance
   - 3: made calls only to well-known numbers, without referring to a directory or list
   - 2: made calls only to well-known numbers, by using a directory or list
   - 1: answered the phone and spoke to callers; did not make calls
   - 0: did not answer the phone, but spoke when put on the line

10. In the past 4 weeks, did {S} make him/herself a meal or snack at home?

    If yes, which best describes his/her highest level of food preparation:
    - 3: cooked or microwaved food, with little or no help
    - 2: cooked or microwaved food, with extensive help
    - 1: mixed or combined food items for a meal or snack, without cooking or microwaving (e.g. made a sandwich)
    - 0: obtained food on his/her own, without mixing or cooking it
### ADCS-MCI Activities of Daily Living Inventory - Page 4 of 11

#### Month 6 Visit

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<th>Subject Number</th>
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#### 11. In the past 4 weeks, did {S} get around (or travel) outside of his/her home?
- **If yes,** which best describes his/her **optimal** performance:
  - 3 □ traveled alone, went at least 1 mile away from home
  - 2 □ traveled alone, but remained within 1 mile of home
  - 1 □ traveled only with a chaperone for supervision regardless of the trip
  - 0 □ traveled only with physical help, regardless of the trip

#### 12. In the past 4 weeks, did {S} talk about current events? (This means events or incidents that occurred during the past month.)
- **If yes,** ask questions 12a, 12b, 12c and 12d:
  - 12a) Did {S} talk about regional, national, or international events (including sports)?
    - 1 □ Yes 0 □ No
    - **QSORRES when QSTESTCD=ADL0312A**
  - 12b) Did {S} talk about events **outside home** involving family, friends, or neighbors?
    - 1 □ Yes 0 □ No
    - **QSORRES when QSTESTCD=ADL0312B**
  - 12c) Did {S} talk about events that occurred **at home** that he/she took part in or watched?
    - 1 □ Yes 0 □ No
    - **QSORRES when QSTESTCD=ADL0312C**
  - 12d) Did {S} converse without repeating him/herself, or asking the same questions repeatedly?
    - 1 □ Yes 0 □ No
    - **QSORRES when QSTESTCD=ADL0312D**

### Subscore for Page 4
(Range = 0-7)

- **QSORRES when QSTESTCD=ADL0329**
### ADCS-MCI Activities of Daily Living Inventory - Page 5 of 11

#### Month 6 Visit

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<th>Subject Number</th>
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#### Questionnaire:

**13.** In the past 4 weeks, did {S} read a magazine, newspaper or book for more than 5 minutes at a time?

*If yes, ask questions 13a, 13b and 13c:*

13a) Did {S} usually select or ask for something to read?

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<th>No</th>
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13b) Did {S} usually talk about what he/she read while or shortly after reading (less than 1 hour)?

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13c) Did {S} usually talk about what he/she read 1–24 hours after reading?

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<th>Yes</th>
<th>No</th>
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**14.** In the past 4 weeks, did {S} watch television?

*If yes, ask questions 14a, 14b and 14c:*

14a) Did {S} usually select or ask for different programs or his/her favorite show?

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<th>Yes</th>
<th>No</th>
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14b) Did {S} usually talk about the content of a program while watching it?

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<th>No</th>
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14c) Did {S} talk about the content of a program within a day (24 hours) after watching it?

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<th>Yes</th>
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**Subscore for Page 5**  
(Range = 0-6)
ADCS-MCI Activities of Daily Living Inventory - Page 6 of 11
Month 6 Visit

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15. In the past 4 weeks, did {S} ever go shopping at a store?
   If yes, ask questions 15a and 15b:

   15a) Did {S} usually select correct items without supervision or help?
   1 [ ] Yes 0 [ ] No

   15b) Did {S} usually pay for items on his/her own?
   1 [ ] Yes 0 [ ] No

16. In the past 4 weeks, was {S} ever left on his/her own?
   If yes, ask questions 16a, 16b and 16c:

   16a) Was {S} left away from home, for 15 minutes or longer, during the day?
   1 [ ] Yes 0 [ ] No

   16b) Was {S} left at home, for an hour or longer, during the day?
   1 [ ] Yes 0 [ ] No

   16c) Was {S} left at home, for less than 1 hour, during the day?
   1 [ ] Yes 0 [ ] No

☐ Subscore for Page 6
   (Range = 0-5)

☐ QSORRES when QSTESTCD=ADL0315

☒ QSORRES when QSTESTCD=ADL0316

☒ QSORRES when QSTESTCD=ADL0315A

☒ QSORRES when QSTESTCD=ADL0315B

☒ QSORRES when QSTESTCD=ADL0316A

☒ QSORRES when QSTESTCD=ADL0316B

☒ QSORRES when QSTESTCD=ADL0316C

☒ QSORRES when QSTESTCD=ADL0331
17. In the past 4 weeks, did {S} use a household appliance to do chores? (This does not include a TV.)

If yes, ask question 17a:

17a) For the 1 or 2 most commonly used appliances, which best describes how {S} usually used them:

4. without help, and operated all necessary controls
3. without help, but operated only on/off controls
2. with supervision (e.g., instructions), but no physical help
1. with physical help

Note: plugging in and switching on = 3;
switching on and adjusting volume/power = 4
18. In the past 4 weeks, did (S) perform a pastime, hobby or game?

- Yes
- No
- Don’t Know

If yes, ask about all of the following, check all that apply:

- QSTESTCD=ADL0318A: card or board games (including bridge, chess, checkers)
- QSTESTCD=ADL0318B: bingo
- QSTESTCD=ADL0318C: crosswords
- QSTESTCD=ADL0318D: art
- QSTESTCD=ADL0318E: musical instrument
- QSTESTCD=ADL0318F: knitting
- QSTESTCD=ADL0318G: sewing
- QSTESTCD=ADL0318H: reading
- QSTESTCD=ADL0318I: gardening
- QSTESTCD=ADL0318J: golf
- QSTESTCD=ADL0318K: tennis
- QSTESTCD=ADL0318L: workshop
- QSTESTCD=ADL0318M: fishing
- QSTESTCD=ADL0318N: other

Note: Walking does NOT count as a hobby/pastime for this scale.

If yes, ask questions 18a and 18b:

18a) Did (S) require supervision, or help, to perform any of these hobbies?

- 3: no supervision required
- 2: supervision
- 1: help

18b) List any hobby(ies) that the subject has lost the ability to perform:

Proceed to questions 19-24 on pages 10 and 11 of this ADL exam, then return to this page to total the scores for questions 1-18.

**ADL TOTAL SCORE**

Sum the page subscores for pages 1-8 of the ADL (items 1-18)

**ADL Total Score.**

(Range = 0-53)
ADCS-MCI Activities of Daily Living Inventory - Page 9 of 11
Month 6 Visit

 Were any questions (1-18) answered “Don’t Know”?  

1  ☐  Yes (Complete worksheet below)  
2  ☐  No (Enter 00 for Total “Don’t Know” points)

“Don’t Know” Answers Worksheet

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<th>Points</th>
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<tbody>
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Total Points for “Don’t Know”

Sum the “Don’t Know” points which were entered above. Enter 00 if none.

QSORRES when QSTESTCD=ADL0325
19. In the past 4 weeks, did {S} drive a car?
   If yes, which best describes his/her optimal performance:
   3 {S} drove anywhere, without limitation or help
   2 {S} drove short distances locally, without limitation or help
   1 {S} drove short distances locally, only with a passenger who provided input such as directions or instructions

20. During the past 4 weeks, did {S} take his/her medications regularly?
   If yes, was this:
   4 Independently
   3 Only after frequent verbal reminders to do so
   2 Took medications without help if they were set out or arranged for him/her
   1 Usually or only when someone else gave the medications

21. During the past 4 weeks, did {S} usually carry through complex or time-consuming activities to completion?
   If yes, which best describes extent to which he/she needed reminders:
   3 Rarely or never needed reminders or prompts
   2 Sometimes needed reminders or prompts (several times per week)
   1 Needed regular reminders or prompting (daily)
### ADCS-MCI Activities of Daily Living Inventory - Page 11 of 11
**Month 6 Visit**

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#### Q5: During the past 6 weeks, how long did it **usually** take to complete complex or time-consuming tasks or activities? (check one)
- 3 Rarely or never needed reminders or prompts
- 2 Sometimes needed reminders or prompts (several times per week)
- 1 Needed regular reminders or prompting (daily)

#### Q22: During the past 4 weeks, to what extent did **S** initiate complex daily activities or projects (e.g., hobbies, travel)? (check one)
- 3 Rarely or never needed reminders or prompts
- 2 Sometimes needed reminders or prompts (several times per week)
- 1 Needed regular reminders or prompting (daily)

#### Q23: During the past 4 weeks, how long did it **usually** take **S** to complete complex or time-consuming tasks or activities? (check one)
- 3 Normal speed or duration, compared to **S**’s performance over the past few years
- 2 Slower than would have been the case a year or two ago
- 1 Occasionally failed to complete complex tasks, or made errors

#### Q24: Has an **EXTENUATING CIRCUMSTANCE** (such as a physical health problem, change in residence, change in support network, death of a family member, etc.) contributed to a recent alteration in the subject’s activities of daily living?
- Yes
- No
- Know

If yes, explain: __________________________________________

REMINDER: After completing all of the questions, please go back to pages 8 and 9 of this ADL exam to complete the scoring for questions 1-18.
General Remarks

There are widely varying methods of carrying out activities of daily living (ADL), especially Instrumental ADL. This can lead to difficulty when trying to obtain ADL ratings from an informant in a standardized way for a clinical trial. The ADL Inventory approaches this problem by providing detailed descriptions of key elements of each activity, and by asking the informant to describe observed actions or behaviors.

The informant is asked to focus on the past 4 weeks. In the MCI protocol, subjects will be generally high functioning, and changes may be subtle and intermittent. Information covering the past 2-3 months may be permissible if the ADL in question is only attempted very infrequently.

The informant must not estimate what the subject might be able to do had an opportunity arisen, but should report what the subject actually did. The informant should not try to interpret the subject’s thought processes or intentions. To help the informant to remain focused on observed actions, it may be helpful to ask him/her for examples of what the subject did regarding the ADL in question.

Content of the ADL Inventory for MCI

The ADCS ADL Inventory has been adapted for the MCI protocol, retaining only those questions that distinguished between elderly controls and patients with mild diagnosed AD (CDR 1, MMSE > 20). In addition, several new questions are being tested. The new questions appear at the end of the inventory and are not used in deriving a point score.

Administering the ADL

The Inventory has been developed and tested as an interview given by a rater, either in person or by telephone. It should not be filled out by the informant.

If the most knowledgeable informant is not the person who accompanies the subject to clinic visits during the study, then the information should be collected by telephone from the best informant.

Change of informant: for consistency of information, the same informant should be used throughout the study. If it becomes essential, a change of informant can be made.

Format of ADCS MCI-ADL Questions

Most items start with a main question — “did the subject perform the ADL...?” — for which the first answer is yes, no or don’t know. ‘No’ or ‘don’t know’ responses act as fast forward cues to proceed to the next item.

After an initial ‘yes’ response, there are 3 types of questions:

- forced choice of best response: e.g. #3: getting dressed
- choice of level of ability: independent, with supervision, with physical help (e.g. #1 finding belongings at home)
- a set of sub-questions, each of which has a yes or no response. The instructions direct you to answer each sub-question.

Standardizing ‘independently’, ‘with supervision’ and ‘with help’

Independently = the subject completed the ADL without physical help, and at the most after reminders to do the task, or a brief prompt while carrying out the activity. Time taken to perform the ADL does not matter.

With supervision = the subject required verbal reminders and instructions while carrying out the ADL. This occupied the caregiver/informant’s time.

With physical help = The subject was given some degree of physical help to perform the ADL. The subject still made a useful contribution to the ADL.

For the MCI protocol, the most frequent judgment will be the distinction between independence versus supervision, instructions or guidance.

Usual performance of ADL

Subjects may vary from day to day in their ADL performance. If an informant responds that the subject sometimes performs ADL at one level and sometimes at
another, the interviewer should ask him/her to choose the most consistently applicable description for the prior 4 weeks.

When in doubt about whether there is any degree of loss of independence of a particular ADL, choose ‘independent’ if that is the most consistent way that the subject performs the activity. The rationale is that unequivocal impairment of functional ability is necessary to support the diagnosis of dementia, not inconsistent errors in carrying out ADL — even though these may be warnings that progression to dementia is likely. This is very conservative, and will result in subjects being scored as independent for activities where they are beginning to show decline. However, it will prevent overcalling ADL impairment.

ADL that are not attempted for reasons such as habit, gender, etc.

If specific ADL have not been attempted recently by the subject, they should be scored as ‘no’ regardless of whether they have been abandoned/lost or never habitually performed. This will decrease the subject’s potential ADL total score by the same amount each time the ADL instrument is given, and does not influence progressive decline of ADL ability as measured by serial scores.

ADL where help is provided for physical reasons: e.g. subject has physical impairment such as arthritis.

Here the subject should be scored as requiring supervision or help for the ADL. Again, the ability to perform the specific ADL in question is not likely to change spontaneously on later visits.

Scoring questions for the MCI ADL:

The worksheet on page 9 should be filled out after completing the ADL interview. Follow the instructions on the worksheet to calculate the total points for “Don’t Know” responses.

Comments about specific questions in the Inventory:

1. Find belongings at home: keys, wallet and glasses may be used as prompts for typical belongings.

2. Selecting clothes for the day: implies that subject can find all necessary clothes and make decisions.

3. Dressing: it does constitute supervision if the subject frequently forgets important items of clothing or items essential because of climate conditions e.g. a raincoat, hat or gloves.

4. Clean a room: presumably supervision or help will become necessary as cognition declines. However it is possible that, as a lifelong habit, a cognitively intact subject will clean a room only when helped. In that case, the only type of change over time that can be detected will be complete loss of the ability.

5. Balance checkbook/credit card statement: if the subject gives this task to someone else, they will score no (0) throughout the trial. If he/she always balances the checkbook/statement with help, they do have room to decline; he/she may lose the ability to have meaningful input into this task as their cognition declines.

6. Write things down: MCI subjects can receive full credit for being independent (writing intelligible letters or long notes) even if they show slightly impaired quality of writing. Writing a message that someone else dictates, or preparing an intelligible shopping list or ‘to do’ list would count as writing.

7. Clean a load of laundry: Again note that ‘supervision’ means more than a reminder to get started on the task.

8. Keep appointments or meetings: evaluates memory ability. If the subject sometimes uses memory aids (notes, calendar, etc.), and sometimes not, then choice between the highest and second highest level should depend on the usual pattern of behavior.
9. **Use a telephone:** reminders or prompts are allowable, e.g. the subject can be told to call directory assistance or told where to look up numbers in a commercial or personal directory. If he/she then uses the telephone independently, this should be rated as the highest level.

10. **Prepare a meal or snack:** subtle impairment of cooking ability e.g. errors while cooking complex recipes, will not be captured by this question unless the amount of help changes.

11. **Travel beyond home:** intended to cover the subject's ability to remain oriented, not to get lost and to venture beyond home to any destination. It does not matter whether the subject walks, drives or takes public transport, or is a passenger in a car. The distance of 1 mile is arbitrary and implies travel beyond sight of home. We have decided not to rate getting lost.

12. **Current events:** For most MCI patients, responses are likely to be 'yes' for talking about events regardless of where they occurred. However they may repeat themselves as an early sign of significant memory impairment.

13. **Read a magazine, newspaper or book:** as for the television question, the responses target making choices and recalling details. Subtle decrements in ability may not be captured.

14. **Watch television:** the subquestions assess whether the subject made choices about what to watch or not, and whether they remembered enough about the program to talk about its content afterwards. A subtle change in memory ability will not be captured by these questions.

15. **Shopping:** we have focused on two aspects of shopping: selecting items appropriately, and paying. Transport to the store is covered by a prior question.

16. **Left alone:** this question may not be sensitive enough for most MCI patients, although clear conversion to mild dementia may involve change.

17. **Use a household appliance:** a menu of appliances is provided. An appliance is defined as a device with one or more switches or controls, used to do household chores. It usually has a power supply. For men, power tools would apply, but a hammer or screwdriver would not. Again, supervision goes beyond reminding to begin the task.

18. **Pastime or hobby:** a menu is provided. Hobbies should involve concentration, knowledge and memory, ± manual skills. If a hobby not on the list is selected, please describe what the patient actually does to permit monitoring.

24. **Changes in ADL performance** may occur for reasons other than cognitive decline. This question asks the informant whether other factors could be responsible for ADL worsening, or even improvement. These include a physical problem (e.g. hip fracture); or a change in social circumstances (e.g. moving to a different type of home.) The ‘yes’, ‘no’ or ‘don’t know’ response must be transcribed on the Subject Evaluation Summary.
The next group of questions are new and targeted at MCI subjects. Their data will be entered but should not be tallied into the total ADCS MCI-ADL Score.

Drive a car: loss of driving ability is unlikely for MCI patients before entry to the study. For habitual non-drivers or patients who have stopped driving for physical reasons, there will be no further deterioration over time.

Take medications regularly: this may be a moot point in a drug study, because most subjects are likely to be supervised. We will collect the data to see whether further changes occur over time.

Initiate complex daily activities or projects: Presumably MCI subjects will be involved in some activities that met this standard; hobbies, shopping trips, trips to unfamiliar places or trips with multiple stops are examples. The question probes whether they make the necessary plans and arrangements themselves, or do so only after prodding.

Carry through complex daily activities or projects: having begun a complex activity, does the subject sustain attention and persevere to completion, or is some degree of ongoing encouragement/supervision/help needed?

Time taken to complete complex daily activities or projects: This asks the informant to make a relative judgment on two issues: 1) speed, and 2) accuracy. Again, overall usual performance is assessed, so that occasional infrequent lapses or errors are allowed even at the highest level.
ADCS - ACTIVITIES OF DAILY LIVING (ADL) INVENTORY

NOTES: (1) {P} refers to the participant and should be replaced by the participant’s name or relationship to the study partner each time an ADL question is asked of the study partner.

(2) This ADL inventory must be given in the format of an interview of the study partner, either directly or by telephone. The form should NOT be given to a study partner to complete on his/her own.

READ THE FOLLOWING INSTRUCTIONS TO THE STUDY PARTNER:

I am going to ask you about a number of daily activities that {P} may have performed during the past 4 weeks. Please tell me about {P}’s actual performance, not about what he/she could have done if an opportunity had arisen. For each activity that {P} attempted, I’m going to ask you to choose one out of a number of descriptions that best fits his/her most usual performance.

For some activities, I’ll ask about whether {P} performed independently, or with supervision or help. Let me explain how we are defining these words:

**Independently** means that {P} completed the activity without being helped. We still consider it independent if {P} was reminded or prompted to get started, or received a little prompting while performing the activity.

**With supervision** means that {P} required verbal reminders and instructions while doing the activity.

**With help** means that {P} was given some degree of physical assistance by another person to perform the activity.

INSTRUCTIONS FOR THE RATER:

If the study partner states that {P} had no opportunity to perform the task during the past four weeks (e.g., {P} did not have access to a telephone, therefore could not possibly make phone calls), the response should be recorded as ‘no.’

If either the study partner’s answer or the questionnaire are unclear, please make notes on the case report form detailing the problem.

For questions regarding specific ADL items, please refer to the ADL Response Card.
An Inventory to Assess Activities of Daily Living for Clinical Trials in Alzheimer's Disease

Douglas Galasko, David Bennett, Mary Sano, Chris Ernesto, Ronald Thomas, Michael Grundman, Steven Ferris, and the Alzheimer’s Disease Cooperative Study

Summary: We developed a set of informant-based items describing performance of activities of daily living (ADL) by patients with Alzheimer’s disease (AD) to identify which ADL are useful for assessment of patients in clinical trials. Evaluation of ADL is an important outcome measure in AD clinical trials. For clinical trial measurement, ADL should have broad applicability, good test-retest reliability, scaling to cover a range of performance, and sensitivity to detect change in disease progression. A total of 45 ADL items developed from literature review and clinical experience were administered to informants of 242 AD patients and 64 elderly controls as part of the multicenter Alzheimer’s Disease Cooperative Study Instrument protocol. Half of the subjects were re-evaluated at 1 and 2 months and all at 6 and 12 months. Controls performed virtually all ADL items optimally at baseline and at 12 months. Among subjects with AD, 27 of the 45 ADL were widely applicable, i.e., performed at baseline or premorbidly by >90% of subjects; showed good test-retest reliability between baseline and 1 and 2 months; correlated with MMSE scores of AD patients cross-sectionally; and showed a decline in performance from baseline to 12 months in at least 20% of AD patients. ADL could be identified that capture change in functional ability in patients across the entire range of the MMSE. The remaining 18 ADL included several that may be useful for trials that target specific populations, e.g., women with AD. Because change on specific items depends on baseline MMSE, ADL evaluation should include items relevant to the severity of dementia of patients enrolled in a clinical trial. Key Words: Alzheimer’s disease—Activities of daily living—Clinical trials—Patient assessment.

Functional assessment of patients with Alzheimer’s disease (AD), in terms of performance of activities of daily living (ADL), is a critical element in patient care. For investigational drug studies, changes in ADL performance can be used as a secondary outcome measure to document that cognitive or other effects of an anti-AD drug are clinically relevant. Treatment that enhances cognitive function should lead to improvement in performance of ADL, whereas treatment that slows the progression or delays the onset of AD should be associated with preservation or slower deterioration of ADL performance.

Although scores of ADL scales and cognitive tests are correlated in patients with AD (Pfeffer et al., 1982; Vitaliano et al., 1984), ADL performance also depends on factors such as sustained attention, motivation, and motor performance. It is difficult to predict from overall
cognitive test scores or even from tests of specific cognitive domains which ADL are likely to be impaired or how severe the impairment will be (Loewenstein et al., 1992). The amount of cognitive change needed to produce a change in ADL performance is unknown.

ADL evaluation for clinical trials is an understudied area. Most ADL scales were developed for general geriatric assessment and to help determine the need for services, and focus on basic activities such as walking, feeding, and toileting (Katz et al., 1963; Lawton et al., 1969). A few scales, such as those of Blessed (Blessed et al., 1968), Lawton (Lawton et al., 1969), Pfeffer (Pfeffer et al., 1982), Weintraub (Weintraub, 1986), and the NOSGER (Spiegel et al., 1991) were introduced for geriatric assessment or for clinical evaluation of patients with AD, and include items that assess more complicated activities (instrumental ADL, IADL). Some of these scales contain gender-specific items or items performed at infrequent intervals, such as filling out forms or documents. Others ask whether a subject “can” perform an ADL rather than relying on purely observed activities, which introduces judgment or opinion into the informant’s report. Several scales combine both ADL and behavioral information (Blessed et al., 1968; Spiegel et al., 1991). Many IADL show a floor effect in AD, i.e., patients lose IADL very early in the course of dementia, whereas basic ADL show a ceiling effect, with normal performance until late in the course of AD (Spector et al., 1978). The approach of using loss of ADL or IADL as milestones (Galasko et al., 1995) is similar to that of the Functional Assessment Scale (Reisberg, 1988) and is best suited to clinical studies with long follow-up periods.

Performance ADL (PADL) scales require subjects to perform ADL tasks in a structured setting using props (Loewenstein et al., 1992). Scoring is standardized and can capture elements of performance such as sequencing, initiation, and motivation. However, PADL scales cover a relatively small number of activities, are time-consuming, and do not evaluate performance in the subjects’ own home environments. In view of the limitations of existing instruments for use in clinical trials, the Alzheimer’s Disease Cooperative Study (ADCS) developed a set of informant-based ADL.

**METHODS**

**Development of the Inventory**

A subcommittee of the ADCS, composed of clinicians with expertise in dementia assessment and clinical trials, developed an inventory comprising a wide range of ADL. The initial item pool consisted of activities that normal elderly individuals regularly perform and that were likely to be relevant to patients with AD over a broad range of severity of dementia. The inventory included ADL from existing scales and novel items based on clinical experience, i.e., ADL necessary for personal care, communicating and interacting with other people, maintaining a household, conducting hobbies and interests, and making judgments and decisions.

For each ADL, an informant is first asked whether or not the patient attempted the activity during the past 4 weeks. If a patient did attempt the ADL, the informant is asked to choose the single most accurate definition of the patient’s level of performance from a set of descriptions of alternative methods of carrying out the ADL. For ADL in which different methods of performance do not apply, the informant is asked whether the subject usually carried out the ADL “independently” (the highest level), “with supervision” (needing verbal instructions during ADL performance, an intermediate level of ability), or “with physical help” (a lower level of performance). If a subject needed reminders to get started but then performed an ADL independently and successfully, that is rated as independently. These definitions of levels of independence are explained to informants before the inventory is administered. To verify that nonperformance of ADL was due to loss of ability, for each ADL that was not attempted during the 4-week period, informants were asked whether or not patients performed the activity premorbidly.

The ADL questions were pretested at three sites, modified where necessary to enhance their clarity, and an inventory of 45 ADL was administered to AD patients and controls as part of an ADCS multicenter study.

**Subjects**

The ADCS study of instrument development for AD clinical trials enrolled elderly controls \((n = 64; 24 \text{ men and } 40 \text{ women})\) and subjects with AD \((242 \text{ AD patients; } 94 \text{ men and } 148 \text{ women})\) as described (Ferris et al., this issue). Recruitment of subjects with AD was stratified by Mini-Mental State Examination (MMSE; Folstein et al., 1975) scores at baseline, and all were community-dwelling at the time of enrollment in the study. All subjects were evaluated at baseline and at 6 and 12 months, and half of the subjects were evaluated at 1 and 2 months. The present study made use of data at baseline, 1, 2, and 12 months.

**Procedures**

For each AD patient, an informant who spent at least 2 days per week with the patient was identified and in-
patients were analyzed using the Spearman rank-order correlation for each ADL item and MMSE scores at baseline among AD dementia patients. The overall correlations between ratings of ADL at baseline by ANOVA. If MMSE scores of patients performing an ADL at different descriptors or “levels” of ADL performance did not differ significantly (p < 0.05), we considered collapsing that ADL into fewer descriptors. The overall correlations between ratings of each ADL item and MMSE scores at baseline among AD patients were analyzed using the Spearman rank-order test. To assess whether ADL items showed long-term change, we analyzed the proportion of subjects with AD who declined on each ADL item at 12 months with respect to baseline. Change at 12 months was also broken down for patients in each baseline MMSE stratum.

RESULTS

The demographic features and global test scores for this cohort at baseline through 12 months have been described (Ferris et al., 1997, this issue). Control subjects scored optimally for each ADL item that they performed at baseline, 1 month, 2 months, and 12 months. Because controls’ scores at all evaluation points remained optimal and did not change significantly from those at baseline, the controls’ data are not shown.

We assessed several properties of ADL to divide the inventory into the items that met all requirements specified above (shown in Table 1) and those that failed to meet one or more requirements (shown in Table 2). First, for clinical trials ADL need to be widely applicable or generalizable. Ideally, AD patients who enter a clinical trial should have an opportunity to attempt most ADL that are rated, and the ADL should be regularly performed by healthy elderly individuals. For the first (baseline) visit, we calculated the percentages of elderly controls who performed each ADL, and of AD patients who attempted each ADL or had done so regularly premorbidly. Some ADL were not performed by controls or by AD patients premorbidly for reasons such as gender, habit, or possibly lack of interest or of opportunity. As a cutoff for generalizability, performance rates of 90% or higher among control or AD subjects were required; ADL with rates of nonperformance of 10% or higher were: doing laundry, cleaning a room, setting a table, watering plants, making a bed, regularly taking medications, cleaning up spills, and listening to the radio. There was a marked gender effect: men were significantly over-represented compared to women ($\chi^2, p < 0.01$) as nonperformers of all of the ADL listed above except for taking medications, wiping up spills and listening to a radio.

Another aspect of applicability of ADL is whether patients with a wide range of dementia severity attempt to perform the ADL. Table 1 shows the percentage of subjects in each MMSE severity stratum who attempted each of the listed ADL at baseline, whether independently or not. Only a few ADL were attempted by virtually all patients with AD. These included basic ADL such as walking, eating, and toileting, as well as other ADL such as traveling outside home and watching television. Most ADL showed an intermediate cross-sectional pattern, attempted by progressively fewer patients in each more impaired MMSE stratum. Some ADL, e.g., handling mail, writing, reading, discussing current events, or using a household appliance were performed by controls and mild-to-moderate AD (MMSE $\geq 10$) but were attempted by fewer than 20% of severely demented patients (MMSE <10). These ADL are not suited for the clinical assessment of severely impaired AD patients but are important to evaluate patients with mild AD. Managing a checkbook was an extreme example, attempted by fewer than 10% of AD patients at
baseline, a floor effect that renders it unsuitable for a general-purpose ADL scale.

We next examined short-term (test-retest) reliability, using $\kappa$ statistics to assess the extent to which ratings of performance of each ADL item agreed at baseline and at 1 and 2 months. Over 2 months, the progression of AD should not be great enough to lead to a change in ADL performance. In general, $\kappa$s fell into the 0.4-0.75 range, indicating moderate to very good agreement. Among ADL with the highest $\kappa$s were activities whose ratings were dichotomous (yes or no) and the traditional basic ADL. Several items, i.e., cleaning up spills, being aware of toileting needs, and participating in a group event had low $\kappa$s ($<0.4$, indicating only fair agreement) and were eliminated from contention.

Stepwise scaling of levels of ADL performance and correlation with dementia severity was the next criterion. Tables 1 and 2 include the number of levels specified for each ADL in the inventory; an ADL question with a dichotomous (yes or no) response has two levels, while one that can be performed independently, with supervision, or with physical help has four. To determine whether these levels have hierarchical properties, we first examined the MMSE scores of patients who performed each ADL at each specified level at baseline. As an example, MMSE scores for levels of using a telephone are displayed in Fig. 1. For most ADL, as each level indicated less independent or less complex ADL performance, the MMSE scores showed a pattern of progressive decrease. If two descriptors of an ADL corresponded to a similar range and distribution of MMSE scores, then the descriptors were assumed to represent cognitively equivalent levels of the ADL. This suggested that the pair of descriptors could be merged and performance of that ADL could be adequately described using one level less. This situation arose very infrequently,

### TABLE 1. Metric properties of selected ADL Inventory questions in patients with AD

<table>
<thead>
<tr>
<th>ADL question</th>
<th>Applicability: % of subjects attempting ADL at baseline</th>
<th>Test-retest reliability</th>
<th>Correlation with MMSE</th>
<th>Change at 12 months: % of subjects who declined on ADL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall</td>
<td>By MMSE strata</td>
<td>(k)</td>
<td>Overall</td>
</tr>
<tr>
<td>Handles mail (3)</td>
<td>30</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Discusses current events (4)</td>
<td>44</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Makes a snack or meal (5)</td>
<td>50</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Writes note/letter/name (4)</td>
<td>51</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Uses household appliance (4)</td>
<td>53</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Reads (4)</td>
<td>54</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Hobby/pastime/game (3)</td>
<td>56</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Chooses clothes to wear (3)</td>
<td>56</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Turns off lights (2)</td>
<td>60</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Puts away belongings (4)</td>
<td>61</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Can be left alone (4)</td>
<td>62</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Goes shopping (3)</td>
<td>63</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Keeps appointments (7)</td>
<td>70</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Obtains a beverage (5)</td>
<td>70</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Finds belongings (3)</td>
<td>71</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Clears a table (4)</td>
<td>71</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Disposes of litter (4)</td>
<td>73</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Makes conversation (4)</td>
<td>75</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Grooms (5)</td>
<td>75</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Gets dressed (5)</td>
<td>75</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Bathes (5)</td>
<td>77</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Uses a telephone (4)</td>
<td>80</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Travels outside home (5)</td>
<td>90</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Watches TV (5)</td>
<td>92</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Toileting (4)</td>
<td>92</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Walking (5)</td>
<td>97</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Eating (5)</td>
<td>97</td>
<td>&gt;20</td>
<td>16</td>
<td>10</td>
</tr>
</tbody>
</table>

* ADL are arranged in ascending order according to the overall percentage of patients with AD who attempted the ADL at baseline.

** MMSE strata are as follows: >20, 20-28 points; 16, 16-20; 10, 10-15; 5, 5-9; 0, 0-4. Symbols indicate the percentage of subjects in MMSE strata who attempted each ADL at baseline: ■ >80%; □ 61-80%; ▪ 41-60%; ▫ 21-40%; blank 0-20%. Symbols for the percentage of subjects who declined at 12 months are as follows: ■ >80%; □ 61-80%; ▪ 41-60%; ▫ 21-40%; blank 0-9%.

* ADL descriptors had the format "independently," "with supervision," or "with physical help." All other ADL had specifically worded descriptors of different levels of ADL performance.

*p < 0.01; **p < 0.001.
ADL descriptors had the format "independently," "with supervision," or "with physical help." All other ADL had specifically worded descriptors of different levels of ADL performance.

Sev: impaired performance was noted only in severely demented patients.

Almost exclusively for the descriptors that indicated minimal performance of the ADL (e.g., "with help only") and complete loss of the ADL.

To analyze scaling further, we calculated the Spearman rank-order correlation coefficients between levels of ADL performance and dementia severity, as indexed by MMSE scores. These correlations (R) were generally in the 0.4–0.7 range and were highly statistically significant (Table 1). A few ADL correlated weakly (R < 0.30) or nonsignificantly with baseline MMSE scores, i.e., managing a checkbook, doing laundry, cleaning a room, watering plants, participating in a group event, listening to the radio, awareness of toileting needs, and walking. Very low correlation with MMSE scores was used as a criterion to define these as unsatisfactory ADL items.

To be useful in clinical trials, ADL ratings should show longitudinal change in patients with a broad range of severity of dementia over an interval that is relevant to the study. We examined change of ADL from baseline to 12 months, expecting that the natural history of a group of AD patients would be to decline in ADL ability over this interval. Because each ADL's ratings are categorical, we could not assume that the amount of change between each level or step of an ADL was similar. We therefore analyzed change as any amount of decline or improvement of performance, regardless of whether it represented one step or more for each ADL. At 12 months, for each ADL, a percentage of patients with AD showed decline, no change, or improvement of performance. For an ADL to be retained in Table 1, we required that it show deterioration of ADL performance in at least 20% of patients overall or in 20% or more of

TABLE 2. ADL with properties that did not meet specified criteria for assessment of ADL in clinical trials

<table>
<thead>
<tr>
<th>ADL question (number of levels)</th>
<th>Not attempted by ≥10% of subjects</th>
<th>Reliability (κ)</th>
<th>Weak correlation with MMSE</th>
<th>&lt;20% of subjects declined at 12 months</th>
<th>Otherb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checkbook (4)a</td>
<td>27%</td>
<td>0.62</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Laundry (4)a</td>
<td>15%</td>
<td>0.83</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Cleans a room (4)b</td>
<td>15%</td>
<td>0.65</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Sets a table (4)c</td>
<td>19%</td>
<td>0.59</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Waters plants (4)d</td>
<td>13%</td>
<td>0.69</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Makes a bed (4)e</td>
<td>38%</td>
<td>0.57</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Takes medications regularly</td>
<td>23%</td>
<td>0.38</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Cleans up spills (4)f</td>
<td>10%</td>
<td>0.35</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Listens to radio (4)</td>
<td>5%</td>
<td>0.53</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Chooses food (2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participates in group event</td>
<td>3%</td>
<td>0.43</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Turns faucet on (2)</td>
<td></td>
<td>0.63</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Turns faucet off (2)</td>
<td></td>
<td>0.75</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Turns lights on (2)</td>
<td></td>
<td>0.69</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Uses door key (2)</td>
<td></td>
<td>0.86</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Uses names of friends, relatives</td>
<td></td>
<td>0.55</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Aware of toileting needs (2)</td>
<td></td>
<td>0.14</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Follows 1-step instructions (4)</td>
<td></td>
<td>0.75</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
</tbody>
</table>

a ADL descriptors had the format "independently," "with supervision," or "with physical help." All other ADL had specifically worded descriptors of different levels of ADL performance.

b Sev: impaired performance was noted only in severely demented patients.
patients with mild dementia (MMSE >20), to ensure that change was adequately captured in that subgroup of patients. Among the AD cohort overall, 12 ADL were relatively insensitive to decline at 12 months, as listed in Table 2. Although the rating of walking ability did not meet this criterion, it is included in Table 1 because of its traditional use as a fundamental basic ADL.

We next examined the relationship between baseline MMSE severity stratum and the number of ADL items (from the 27 in Table 1) on which subjects showed decline of performance at 12 months (Fig. 2). Note that subjects with AD in every MMSE stratum showed decline on ADL, but subjects with moderate cognitive impairment at baseline (MMSE 5–20) declined on more ADL than did those with mild or very severe impairment.

**Items Less Suited for ADL Assessment in a Clinical Trial**

Table 2 lists the ADL that failed to meet one or more criteria. The most common problems with ADL in this group were lack of wide applicability (usually due to a gender effect), poor scaling, e.g., low correlation with dementia severity, little change over 12 months, and change restricted to severely demented patients only. Most of these ADL had good reliability, and several of the items in Table 2 would be suitable for use in customized ADL scales for a clinical trial that targets women, or for a study of severely impaired patients.

**DISCUSSION**

Many ADL items were widely applicable, had good test–retest reliability, correlated significantly with the extent of cognitive impairment in AD as measured by the MMSE, and showed decline in performance in a significant percentage of AD subjects at 12 months. These properties indicate that they should prove valuable for rating functional ability in AD clinical trials. The finding that over one-third of the ADL failed to meet one or more of these criteria illustrates the problems inherent in measuring ADL in a spectrum of patients with AD who are typically the subject of clinical trials.

Most of the items showed good test–retest reliability over 1–2 months, which presumably was aided by pretesting the items to improve their clarity, conducting a brief training session, distributing a procedures manual, and specifying the amount of contact an informant had to have with the patient. It is difficult to obtain consistent ratings of intermediate levels of ADL performance, especially when ADL have many potential levels or methods of performance, even when these are specified as carefully as possible. To improve test–retest reliability, it may be necessary to improve the specific descriptors of levels of performance, to collapse levels of performance on some ADL, and to provide additional training to raters.

The validity of informant-derived descriptions of ADL ability is difficult to establish directly. Observation of subjects at home or in the community would be ideal but is not practical. As a substitute, we estimated concurrent validity of ADL reports by comparing ADL ability with cognitive performance and found a substantial cross-sectional correlation between ADL performance and MMSE scores for most items. Longitudinal decline on many ADL items over 1 year among subjects with AD is consistent with decline on cognitive and global measures (Ferris et al., 1997, this issue) and provides a further indication of validity.

The optimal ADL performance by controls in this study needs to be qualified. Among an elderly control population, one would typically expect some degree of ADL impairment as a result of physical disability, impaired special senses, or medical illness. The controls in this study were judged to be cognitively normal, and represent high-functioning individuals living independently in the community. Their results are therefore consistent with expectations for a group of very healthy elderly individuals but do not necessarily extrapolate to the elderly in general, or to the “oldest old.”

The large number of items in the ADL Inventory al-

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**FIG. 2.** Number of ADL items in the Inventory (from the 27 listed in Table 1) on which subjects with AD showed decline in performance at 12 months. The box plot shows the 25th, 50th (median), and 75th percentiles as well as 95% limits for the total number of ADL on which subjects in each MSE stratum declined.