This is a Sample version of the Alzheimer's Disease - Activities of Daily Living Inventory AD-ADL

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- Overview
- Clinical Study Analysis
- Administration guide.
- Scoring Instructions
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Alzheimer's Disease - Activities of Daily Living Inventory AD-ADL

Below is a sample from the study about:

**ADL Clinical Trials with Alzheimer's Disease**

**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 cores of AD patients cross-sectionally; and showed a decline in performance from baseline 10 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 forgeriatric 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 other 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). Man y IADL show a floor effect in AD, i.e., patients lose I ADL very early in the course of dementia, whereas basic ADL show a ceiling effect, with normal performance until late in the course or 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.
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 pre-testing 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 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."

This is the end of the AD-ADL sample clinical trial review. Please purchase for complete clinical study analysis.

AD-Activities of Daily Living (ADL) Inventory

Administration Guide –

A. General Remarks

There are widely varying ways to carry out ADL, especially Instrumental ADL. This leads to difficulty when trying to obtain ADL ratings from an informant in a standardized way for a clinical trial. The AD-ADL Inventory approaches the problem by offering detailed descriptions 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. The informant must not estimate what the patient might be able to do had an opportunity arisen, but on what the patient actually did. The informant should not try to interpret the patient’s thought processes or intentions. To help the informant to remain focused on observed actions and behavior during the past 4 weeks, it may be useful to ask him/her for examples of what the patient did regarding the ADL in question.

B. Administering the AD-ADL Inventory

The AD-ADL Inventory was developed and tested as an interview administered by a rater in person or by telephone. It should not be filled out by the informant.

C. Format of Questions

- For each basic ADL (questions 1-5,6A), there is a forced choice of best response.
- All other ADL consist of a main question followed by subquestions (descriptors).
• Subquestions are arranged in hierarchical fashion, starting with the highest (most independent) level of ADL performance and ending with the lowest.
• For each ADL, the initial response to the main questions is "yes", "no" or "don't know". If an informant gives 4 or more "don't know" responses, it is worth trying to identify an alternative informant.
• After a "no" or "don't know" response, the subquestions are disregarded unless specific instructions indicate otherwise. "No" or "don't know" act as fast forward cues to proceed to the next ADL.
• After a "yes" response, there are 2 possible paths:

1. From several descriptors, the informant chooses the one that best matches the patient's performance (e.g., question 6A). The informant should be offered as many descriptors as necessary to describe the patient's ADL ability, starting from the highest level and proceeding downwards or
2. The informant makes a "yes" or "no" choice for each subquestion. There is a reminder in these cases to ask every question after an initial "yes" (e.g., question 8).

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.

This is the end of the sample version of administration instructions for the AD-ADL. Please go to page 1 to purchase complete version.
AD - Activities of Daily Living Inventory

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Information obtained through:  
☐ Informant visit  
☐ Telephone call

Instructions: For each question, use the subject's name where (s) appears. Before beginning, read the questionnaire guidelines to the informant.

1. Regarding eating:  
Which best describes (s) usual performance during the past 4 weeks?

3 ☐ ate without physical help, and used a knife
2 ☐ used a fork or spoon, but not a knife, to eat
1 ☐ used fingers to eat
0 ☐ (s) usually or always was fed by someone else

2. Regarding walking (or getting around in a wheelchair), in the past 4 weeks, which best describes his/her optimal performance:

3 ☐ mobile outside of home without physical help
2 ☐ mobile across a room without physical help
1 ☐ transferred from bed to chair without help
0 ☐ required physical help to walk or transfer

3. Regarding bowel and bladder function at the toilet, which best describes his/her usual performance in the past 4 weeks:

3 ☐ did everything necessary without supervision or help
2 ☐ needed supervision, but no physical help
1 ☐ needed physical help, and was usually continent
0 ☐ needed physical help, and was usually incontinent

Galasko, D., Bennett, D., Sano, M., Ernesto, E., Thomas, R., Grundman, M., and Ferris, S.  
Alzheimer Disease and Associated Disorders 1997; 11:S33-S39.

This is the end of the sample AD-ADL questionnaire version. Please go to page one to purchase complete (8 page) AD-ADL questionnaire.