Current pharmacological treatment of Alzheimer's disease (AD) chiefly consists of inhibition of the enzyme acetylcholinesterase (AChE), to result in greater availability of the neurotransmitter acetylcholine (ACh). While the “better memory through ACh” hypothesis has its critics, AChE inhibition (AChEI) has produced statistically significant differences, favouring treatment, across a range of trials. Nevertheless, whether these differences translate into observable treatment effects in patients’ daily lives is often questioned.

Although no standard method of determining clinical importance is accepted, some requirements for antidementia trials have been proposed, and many seem to have been met. A biologically plausible hypothesis exists: there is a reproducible, dose response effect, and the outcome measures converge. Still, a ready summary of clinical meaningfulness has proved elusive despite the requirement that trials undertaken for regulatory approval use a global clinical measure as a primary outcome.

Of note, none of these measures incorporate the preferences of patients and carers in the assessment of benefit, even though this is held to be both an essential part of a clinically meaningful effect and a practical guide to prescribing cholinesterase inhibitors. Moreover, most standard measures assume that successful treatment will reverse the pattern of decline, such that regaining a certain score on a given scale in which points are lost without treatment can be used as the basis for inferences about treatment effects.

Clinical importance is more likely if treatment meets the expectations of patients, carers and physicians. Goal Attainment Scaling (GAS) is a formal method of assaying such expectations. GAS requires that individualised treatment goals be defined at the outset, monitored regularly, and summarised according to a formula, which classifies the degree of goal attainment. To better understand clinical meaningfulness in AD treatment, we elicited goals from patients and their carers and from treating physicians in a multicentre trial of donepezil, compared each group's goal attainment with standard assessments of treatment effects, and explored patterns of goal setting by patients/carers and physicians.

**Objectives:** To understand the treatment goals of Alzheimer’s disease (AD) patients, carers, and physicians; to estimate whether clinically important goals are met during treatment with donepezil; and to compare a measure of goal attainment with standard measures used to evaluate AD treatment.

**Methods:** In a 12 month phase IV trial, 108 patients with mild to moderate AD, their primary carers, and treating physicians set goals assigned to five domains, using Goal Attainment Scaling (GAS) as the primary outcome. Goal attainment was assessed quarterly. GAS scores were correlated with standard outcomes, including the Alzheimer’s Disease Assessment Scale-Cognitive (ADAS-cog), and the Clinician’s Interview-Based Impression of Change-Plus (CIBIC-plus).

**Results:** Physicians set fewer goals (342, mean (SD) per patient=3 (1)) than patients/carers (855, mean=9 (3)), particularly in leisure (20% by physicians compared with 76% by patients/carers), and social interaction (24% versus 49%). Physicians observed statistically significant improvement in global goal attainment for six months, and patients/carers for nine months. Patients/carers described consistent goal attainment, whereas physicians observed variable effects, such as decline in cognition but improved social interaction and behaviour. Physician global GAS scores correlated highly with the CIBIC-plus at weeks 12 (r=−0.82) and 52 (r=−0.80), but not with the ADAS-cog (r=0.12 and r=−0.45, respectively). Patient/carer global GAS scores correlated moderately with the physician’s CIBIC-plus (week 12 r=−0.51; week 52 r=−0.56), and nominally with the ADAS-cog.

**Conclusions:** Patients/carers and physicians differ in their expectations and impressions of treatment effects. Clinically important changes correlated only modestly with psychometric tests. Attainment of treatment goals does not accord with a simplistic model in which successful AD treatment means that all declines uniformly improve.
In this study, we set two groups of goals. The treating physicians and nurses set “clinician goals” during the baseline office visits and recorded them using their own words, based upon patient examinations, clinical observations, and information provided by the patient and carer informants. Field researchers conducted in depth home interviews with patients and carers within one week of the baseline clinic visit. During home visits, patients and their carers discussed their experiences of AD, its effect on their daily lives, and their expectations for treatment. Field researchers assisted patients and carers in the identification of treatment goals. This resulted in the development of separate “patient/carer goals” recorded by the field researcher using the patients’ and carers’ own words. In each case, patients, carers, and physicians could choose to set as many goals or as few (including none) as they wished (that is, it was not a requirement of the study that patients have a goal set in each domain). Individualised goals were categorised into domains at the study centre, where social interaction emerged as a fifth domain.

For example, a typical goal such as memory fell into the domain of cognition. A description of a memory problem might be “Dad asks me the same question over and over—more than five times a day on most days. He has trouble shopping now, even with a list because he has problems remembering whether he has picked up the items and must constantly recheck the cart. He often doesn’t remember the names of the grandchildren when they come over.” Using this as the baseline level of performance (scored as “0” on the GAS follow up guide, table 1), descriptions of better and worse outcomes were then elicited from the patient and/or carer. A worse outcome might be that the patient repeats questions more than 10 times per day and/or that he cannot remember...

Design and instruments
Participants were recruited to participate in a 52 week open label, prospective study of treatment with donepezil hydrochloride. At baseline, after obtaining informed consent, diagnostic verification and standard psychometric testing, patients were given 5 mg donepezil tablets, to be taken once daily, for the first 12 weeks of the study. Follow up assessments were conducted at 12, 24, 36, and 52 weeks. If clinically indicated, the donepezil dose was increased to a daily maximum of 10 mg at (or subsequent to) the 12 week follow up visit. At each time point, physicians could choose to set as many or as few goals as they wished. The clinical team met after each follow up visit to review and score the GAS follow up guide, table 1), descriptions of better and worse outcomes were then elicited from the patient and/or carer. A worse outcome might be that the patient repeats questions more than 10 times per day and/or that he cannot remember...

Table 1: Sample GAS follow up guide

<table>
<thead>
<tr>
<th>Goal areas</th>
<th>cognition (judgment-safety)</th>
<th>cognition (memory)</th>
<th>function (cooking)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Much worse than baseline [-2]</td>
<td>Unable to make any judgement or solve problems; Requires 24 hour supervision</td>
<td>No longer recognises daughter</td>
<td>Unable to assist in any meal preparation</td>
</tr>
<tr>
<td>Somewhat worse than baseline [-1]</td>
<td>Severe impairment in judgement and problem solving; Unable to operate stove, microwave, or oven (even under supervision)</td>
<td>Repetitive in questioning/speech &gt;10 times a day; No longer asks for shopping list and cannot use it, even with prompting</td>
<td>Attempts to assist in meal preparation 1-2 times per week, but is unable to complete task, even with assistance</td>
</tr>
<tr>
<td>Baseline status [0]</td>
<td>Impaired judgement with regard to safety concerns; Leaves pots to cook dry on stove; Puts unsafe items in microwave for excessive length of time; Family feels he would not recall or react well in emergency such as fire*</td>
<td>Repetition in speech, talks non-stop and repeats same thing over and over (&gt;5 times a day); Difficultly shopping, even with list, constantly rechecks cart to see for items on list; Does not remember grandchildren when they come over*</td>
<td>No longer cooks meals by self. Assists with meal preparation daily but can only manage one task and requires direction and supervision, Leaves stove burners on for indefinite periods when he attempts to cook alone*</td>
</tr>
<tr>
<td>Somewhat better than baseline [+1]</td>
<td>Only slight impairment in judgement; Can operate stove, oven, and microwave with supervision</td>
<td>Less repetitious (&lt;5 times a day)†</td>
<td>Completes 2 or 3 of the tasks involved in meal preparation (daily) with assistance and supervision (for example, peeling and cooking vegetables, making a salad, setting the table, etc)</td>
</tr>
<tr>
<td>Much better than baseline [+2]</td>
<td>Solves small everyday problems; Uses good sound judgement in regards to safety issues, such as stove/oven operation and locking doors; Remembers emergency plan for fire‡</td>
<td>Able to use and remember items chosen from the list (does not re-check cart for items)</td>
<td>Completes 2 or 3 of the tasks involved in meal preparation (daily) without supervision or assistance†</td>
</tr>
</tbody>
</table>

*Initial score. †Final score.
to ask for the list and can no longer use it with prompting; a
still worse outcome would be that he would no longer recog-
nise his daughter, who is his major carer. Better outcomes
would be that he asked questions less frequently, that he is
able to use a list, and no longer needs to check the cart. From
this inventory, five states can be demonstrated: the present
state, and states somewhat and much better/worse, respec-
tively.

Patient/carer goals identified at baseline were also weighted
on a visual analogue scale in order of relative importance. This
step is optional; clinician goals were not weighted (all goals
were set with weight=1). Note that goal attainment is scored
by the terms specified at the outset. A global score, summaris-
ing attainment across a set of goals, is calculated as
50+{\[10e(w_i)x_i]/[0.7e(w_i)x_i]+0.3(e(w_i)x_i)^{0.5}]}, where x_i=the indi-
vidual attainment level, and w_i=the weight of that level. As
each of the attainment levels is 0, so is their product, and thus
the baseline score is 50. This is a mathematically equivalent
modification of the conventional method, which sets the
baseline status at “−1,” and has the “0” level represent the
treatment goal. This modification incorporates more levels of
decline, which seemed preferable, given that deterioration is
likely.

In addition to GAS, other standardised measures were used.
Cognition was assessed using the Mini-Mental State Exami-
nation (MMSE) and the Alzheimer’s Disease Assessment
Scale-Cognitive (ADAS-cog). To measure various aspects of
physical function we used the Physical Self-Maintenance
Scale (PSMS), Instrumental Activities of Daily Living
(IADL) and the Functional Activities Questionnaire
(FAQ). Depression in patients was measured using the
Cornell Depression Scale (CDS) and the Centre for Epide-
miiologic Studies Depression Scale (CES-D) was used for
carers. The Clinician’s Interview-Based Impression of Change-
Plus caregiver input (CIBIC-plus) was administered by the
treating physician. The CIBIC-plus is a seven point Likert scale
of change from baseline.

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>Mean (SD) age (y) (range) 76 (8) [51–96]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex = female (%)</td>
<td>71 (71)</td>
</tr>
<tr>
<td>Mean (SD) years of education (range)</td>
<td>11 (3) [4–20]</td>
</tr>
<tr>
<td>CDR Memory Score = mild (%)</td>
<td>75 (75)</td>
</tr>
<tr>
<td>AD type = probable (%)</td>
<td>98 (98)</td>
</tr>
<tr>
<td>Mean (SD) duration of illness (range)</td>
<td>1.4 (1.6) [0–9]</td>
</tr>
<tr>
<td>MMSE (SD) (range)</td>
<td>20 (5) [2–29]</td>
</tr>
<tr>
<td>ADAS-Cog (SD) (range)</td>
<td>25 (10) [8–58]</td>
</tr>
<tr>
<td>PSMS (SD) (range)</td>
<td>9 (3) [6–16]</td>
</tr>
<tr>
<td>IADL (SD) (range)</td>
<td>20 (5) [8–30]</td>
</tr>
<tr>
<td>FAQ (SD) (range)</td>
<td>18 (7) [2–30]</td>
</tr>
<tr>
<td>Carer characteristics</td>
<td>Mean (SD) age (y) (range) 61 (14) [28–91]</td>
</tr>
<tr>
<td>Sex = female (%)</td>
<td>66 (66)</td>
</tr>
<tr>
<td>Mean (SD) years of education (range)</td>
<td>12 (3) [3–21]</td>
</tr>
<tr>
<td>Relationship to patient = spouse (%)</td>
<td>48 (48)</td>
</tr>
<tr>
<td>Resides with patient (%)</td>
<td>66 (66)</td>
</tr>
<tr>
<td>Currently employed (%)</td>
<td>36 (36)</td>
</tr>
<tr>
<td>Mean (SD) Depression Score (CES-D) (range)</td>
<td>9 (8) [0–40]</td>
</tr>
</tbody>
</table>

Table 2 Participant characteristics at baseline (n=100)

![Figure 1](https://www.jnnp.com)
Analyses
The analyses of treatment effects used the intention to treat last observation carried forward (ITT-LOCF) principle. Mean change and 95% confidence intervals from baseline were calculated at each follow up visit for all outcome measures. A one way repeated measures analysis of variance was performed on the change scores as a function of time for the primary outcome measures (patient/carer GAS and clinician GAS) with the Bonferroni adjustment for multiple comparisons. Otherwise the mean change values and their 95% confidence intervals are presented. To assess construct validity, Spearman correlation coefficients were calculated for GAS change scores and compared with the secondary efficacy measures; small to moderate correlations were expected. Statistical tests were interpreted at the 5% significance level.

RESULTS
Enrolment
Of 108 patients enrolled, 88 (81%) successfully completed 52 weeks of treatment with donepezil. Premature discontinuation occurred because of: adverse events (n=10), withdrawal of consent (n=5), insufficient clinical response (n=2), death (n=1), and other (n=2). Of the 108 patients enrolled, eight had no observation after first treatment, leaving 100 for analysis.

Table 3  Spearman correlation coefficients by GAS domain

<table>
<thead>
<tr>
<th></th>
<th>Patient/Carer</th>
<th>Clinician</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Week 12</td>
<td>Week 24</td>
</tr>
<tr>
<td>Global goals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMSE*</td>
<td>0.06</td>
<td>-0.24</td>
</tr>
<tr>
<td>ADAS-cog</td>
<td>-0.14</td>
<td>-0.15</td>
</tr>
<tr>
<td>CIBIC</td>
<td>-0.51</td>
<td>-0.62</td>
</tr>
<tr>
<td>PSMS</td>
<td>-0.26</td>
<td>-0.43</td>
</tr>
<tr>
<td>IADL</td>
<td>-0.26</td>
<td>-0.27</td>
</tr>
<tr>
<td>FAQ</td>
<td>-0.21</td>
<td>-0.22</td>
</tr>
<tr>
<td>CSD</td>
<td>0.13</td>
<td>0.20</td>
</tr>
<tr>
<td>Scientist global goals</td>
<td>0.06</td>
<td>-0.20</td>
</tr>
<tr>
<td>Cognition</td>
<td>0.39</td>
<td>0.56</td>
</tr>
<tr>
<td>MMSE*</td>
<td>-0.22</td>
<td>-0.34</td>
</tr>
<tr>
<td>ADAS-cog</td>
<td>-0.18</td>
<td>-0.26</td>
</tr>
<tr>
<td>FAQ</td>
<td>-0.10</td>
<td>-0.15</td>
</tr>
<tr>
<td>Function</td>
<td>0.46</td>
<td>0.34</td>
</tr>
<tr>
<td>PSMS</td>
<td>-0.11</td>
<td>-0.01</td>
</tr>
<tr>
<td>FAQ</td>
<td>0.12</td>
<td>0.01</td>
</tr>
<tr>
<td>CSD</td>
<td>0.41</td>
<td>0.15</td>
</tr>
</tbody>
</table>

*In the MMSE, like GAS, a higher score indicates better performance. Thus, the expected direction is positive, whereas it is negative for the other measures.

All subjects provided written informed consent. This project was approved by the Research Ethics Committee of the Queen Elizabeth II Health Sciences Centre, Halifax, Nova Scotia, and by comparable committees of the other investigating sites.
Most patients were elderly women with mild AD (table 2). Eighty two patients had treatment increased from 5 mg/day to 10 mg/day for at least one dose. At week 12, 69% of patients were receiving 10 mg/day; 67% at week 24; 66% at week 36; and 65% at week 52. Most carers were women (66%), spouses (48%), and younger (mean age=61 years) than the patient set (table 2).

Goals and their attainment

Patients and carers identified a total of 855 goals at baseline (mean (SD)=9 (3) per patient), while clinicians identified 342 (mean=3 (1)). Patients/carers set function goals most often (86% of patients), followed by cognition (83%), leisure (76%), behaviour (58%), and social interaction (49%). Clinicians set more cognition goals (85%), followed by function (68%), behaviour (57%), social interaction (24%), and leisure (20%).

Statistically significant improvements in the global patient/carer GAS scores (fig 1) were seen to week 36 (mean change=3.19, p=0.03); however, by week 52 there was no significant difference from baseline (mean change=1.62, p=0.74). The global GAS score for clinician identified goals improved significantly from baseline to week 24 (mean change=2.39, p=0.04), but was not significantly different from baseline thereafter (week 52 mean change=0.43, p=1.00).

Comparisons with standard measures

While improvement in global GAS scores was observed as noted, the standard cognitive measures (figs 1 and 2) showed significant improvements only at week 12 (MMSE mean change=0.86 and ADAS-Cog mean change=−1.17). Decline from baseline was observed for both measures thereafter (for example, week 52: mean change=−1.04 and mean change=3.07, respectively). The functional assessments showed patterns of initial maintenance of functional performance, followed by later decline (fig 2), with slight differences by level of function (chiefly IADL decline after weeks 24–36, whereas ADL function was more stable). Neither patient (CSD) or carer (CES-D) measures of depression demonstrated much change (fig 2).

Clinician global GAS scores were highly correlated (table 3) with the CIBIC-plus at weeks 12 and 52 but not with the
ADAS-cog results. Patient/carer global GAS scores were only moderately correlated with the CIBIC-plus. Low correlations were observed between patient/carer GAS and the ADAS-cog. Low correlations were observed between the GAS domains of cognition, function, and behaviour and corresponding secondary efficacy measures at week 12, for both clinicians and patient/carers. Moderate correlations appeared between clinician assessed GAS cognition goals and the MMSE ($r$ = 0.51) and the ADAS-cog ($r$ = 0.43) at week 52. Moderate correlations were also observed between clinician function goals and the PSMS ($r$ = 0.53), patient/carer function goals and the PSMS ($r$ = 0.47), and patient/carer function goals and IADL scores ($r$ = 0.44). All remaining correlation comparisons at week 52 were low.

**Patterns of goal attainment, by domain**

Within goal areas (fig 3), patients and carers generally observed improvement, and each domain tended to agree with the others, and thus with the global GAS score. The largest and greatest treatment effects were observed in behaviour.

The pattern of treatment effects observed by physicians was somewhat more complex. They recorded behaviour and social interaction goals above baseline at each time point (fig 4) but in contrast with the patient/carer goals, goal attainment did not proceed in the same direction for each domain. Clinician identified leisure goals changed little, on average. Similar to the standard cognitive measures, clinician identified cognition and function goals had been met at week 12 but these initial gains were not maintained.

**Adverse events**

Of the 108 patients, 96% (n = 104) experienced at least one adverse event. The most frequently reported were: pain (n = 27), diarrhoea (n = 24), nausea (n = 23), dizziness (n = 20), headache (n = 19), dyspepsia (n = 15), and influenza-like symptoms (n = 15). Ten patients withdrew because of adverse events, which included: anxiety (n = 2), weight loss (n = 2), diarrhoea (n = 1), pacing (n = 1), transient ischaemic attack (n = 1), confusion (n = 1), agitated depression (n = 1), and foot pain (n = 1). Twenty two serious adverse events were reported in 16 patients, one of who died of a myocardial infarction. No serious adverse events occurred more than once and none had a clear relation to the study drug.

**DISCUSSION**

In this 12 month, open label study, treatment with donepezil resulted in clinically detectable effects in patients with mild to moderate AD, which largely met the goals of patients, carers, and clinicians for six months. Thereafter, treatment accorded with expectations to varying degrees. The extent of goal attainment was not reflected in standard measures used to evaluate antideementia drugs.

Patients and carers set more goals than physicians, perhaps a product of the more open-ended nature of the field researcher interviews. Physicians seemed to lump items that patients and carers tended to split. For example, whereas patients and carers might describe goals with respect to repetitive questions, needing lists and having to have help in following routines, physicians typically would group all of these under a single goal of memory. In addition, patients and carers set more goals in the domains of leisure, social interaction, behaviour, and function, and fewer in cognition. This probably reflects competing understandings of the disease. Physicians see patients episodically and they seem to think of pathophysiological processes and manifestations that they can test, or about which they are used to inquiring. These dismiss physicians, however, do suggest the 3 mg or 10 mg of donepezil was −1.17 at 12 weeks and 0.72 at 24 weeks. These estimates are comparable with other published reports of −0.67 points (24
week/end point analysis; 5 mg) and about −1.06 (24 week/end point analysis; 10 mg) and about 0.35 points (24 week/end point analysis 5 mg) and about −1.5 (24 week/end point analysis 10 mg) and about −0.2 (12 week/end point analysis 5 mg) and about −0.5 (12 week/end point analysis 10 mg).

Patients and their carers bring a wide range of expectations in relation to AD and treatment effects. Still, patient and carer involvement in goal setting seems both feasible and valid. For example, there were only a small number of goals (about 1%) where donepezil was unlikely, a priori, to have had a treatment effect. These included goals set for mobility, incontinence, pain, and headaches.

The scoring instructions for GAS were specified so that a problem area was identified and the current level of functioning (that is, the present problem) was described at the “0” level. In 106 patient/carer goals (12%), however, while future problems were anticipated, the present level of function was satisfactory. In such cases, goals identified by patient/carer dyads who felt that maintenance was the best that could be hoped for were scored as “0”. Where no improvement could be anticipated, there is no room to capture improvement. Similarly, in the 97 goals (11%) where patient/carer dyads were unwilling to specify a worse outcome, the baseline was scored as “0” and only unspecifed worsening could be captured. Overall, these effects are likely to be largely offsetting, but they do reveal the tension in trying to incorporate patient and carer preferences in the face of a neurodegenerative illness where deterioration is a likely outcome. This can influence not only the appreciation of the present state, but can sometimes reveal situations in which people, perhaps as an aspect of coping, choose not to specify how things might get worse. The neurodegenerative nature of AD also means that the ITT-LOCF strategy might be less cognitive if patients who dropped out early had observations carried forward that did not reflect subsequent decline. We therefore also conducted an observed cases analysis, which did not change any of the main effects here observed.

Our data also have some strengths. We systematically incorporated the expectations of patients and carers, and their treating physicians into an evaluation of treatment. As noted, despite the broad range of expectations that patients and carers bring to the prospect of treatment for AD, they largely set goals that reflect a realistic understanding of what might be possible. Importantly, maintenance often is explicitly understood as the best outcome of treatment. Nevertheless, many of the individual goals hope for a reversal to a previous state, suggesting that the expectations are complex. Maintenance is often desirable, but when people are confronted with describing what might be better, they are likely to specify “the way things were.” The previous state strongly influences the expectation of likely future outcomes.

These data are relevant to understanding the CIBIC-plus. Like it, GAS relies on clinical judgments about individual patients with caregiver input. Recent attempts to standardise the CIBIC-plus, however, have seen increasing standardisation of the domains of inquiry. By contrast, GAS incorporates patient and carer preferences as the basis for evaluation of treatment effects. For example, the test of recent memory is not as a substitute for, standard measures. Rather, the inquiry might be about what might be better, they are likely to specify “the way things were.” The previous state strongly influences the expectation of likely future outcomes.

For example, the test of recent memory is not as a substitute for, standard measures. Rather, the inquiry might be about what might be better, they are likely to specify “the way things were.” The previous state strongly influences the expectation of likely future outcomes. these standard instruments largely assume that as AD gets better the result is chiefly a reversal of the decline in signs and symptoms that mark the disease as it progresses. This might not be the case—what seems more likely is that patients exhibit new combinations of symptoms and signs, as some that were present at baseline improve, while others worsen and still others stay the same. In consequence, we run the risk that new antidementia drugs could bring about systematic and reproducible benefits, which might be missed because our current scales are not sensitive to the new profiles experienced by patients. Our study suggests that important treatment effects might not be reflected in the standard tests now in use as outcome measures in antidementia drug trials and treatments. Judging by its range of correlations with standard measures, GAS seems to be tapping into different constructs than the usual domains of inquiry now used to evaluate treatment effectiveness. At the same time, the extent of correlation is in the range that suggests convergent construct validity of the measures. Validity is likewise suggested by the higher patient/carer-clinician GAS scores. In consequence, we suggest that GAS can supplement the CIBIC-plus (but not replace it) so as to explicitly incorporate patient preferences into our understanding of whether treatment is beneficial.

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Goal setting and attainment in Alzheimer's disease patients treated with donepezil

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