

**THE ECONOMIC CONSEQUENCES OF ALZHEIMER'S DISEASE  
IN THE CONTEXT OF NEW DRUG DEVELOPMENTS**

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**Abstract**

The first national symptomatic treatment for Alzheimer's disease has received a very mixed and perhaps ageist reception from purchasers of health care in the UK. This is largely because detailed information on the long-term effects of this class of drugs is scarce. However, by looking at the published evidence on the economic burden of Alzheimer's disease some observations and assumptions can be made as to the influence of the new drug treatments.

The drug therapies available and those most likely to become licensed are reviewed and the potential economic impact is discussed. Long-term outcome studies would properly address this, but as these drugs have now demonstrated efficacy, particularly in non-cognitive behaviours, it will be ethically more difficult to maintain patients on placebo for long periods. Some assumptions therefore have to be made from long-term open-label studies.

Those drugs currently available, and those in development may offer effective treatment for some of the core symptoms of Alzheimer's disease, slowing the rate of cognitive decline and preserving competence in activities of daily living for longer. If handled correctly, these treatments have the potential to offer cost savings for many patients, and cost-effectiveness improvements look probable.

**Keywords:** Economics; Alzheimer's Disease; Cholinesterase Inhibitors.

## 1. INTRODUCTION

Ironically, it has taken the first symptomatic treatments of Alzheimer's disease to bring broad public attention to the seriousness of this illness. Alzheimer's is a lethal disease, and the fourth most common in the world. European prevalence rates are 3.2% among those aged 70-79, and 10.8% among those aged 80-89 (Rocca et al., 1991), and similar rates have been reported for Japan (Hasegawa et al., 1986). The impact on the sufferer is enormous: depression may be a problem in the early stages, followed by progressive decline in cognition, functioning, self-care ability and behaviour. The financial and psychological impacts on caregivers can be substantial, and as the illness develops, admission to long-term care often becomes inevitable. The costs to health and social services agencies are high.

The ageing of the world population has of course been a major achievement for medical science and for the economic and social policies of the twentieth century, but it also presents challenges. Almost one quarter of the population of the developed world will be aged 65 or over by the year 2025, compared to only one in seven people today (World Bank, 1993). There will be faster increases in the number of people aged over 80. With age-specific prevalence rates for Alzheimer's disease, and for cognitive impairment and disability more generally, apparently consistent over time (Rocca et al., 1991), the numbers of people with the disease will 'outpace the increase in the elderly population as a whole' (Melzer et al., 1997, p.462). In fact, the 'care challenge' will continue to grow, for the combined effects of a number of trends - in demography, labour force participation, geographical mobility and family patterns - are likely to increase the demand for long-term care services.

The provision of formal care services to support elderly people has been growing in most countries for some time, but the greatest proportion of care still comes from *informal* sources. Much of this care comes from elderly spouses. For those living alone, care usually comes from women relatives aged 45-64 (OECD, 1996). The future supply of such caregiver support is threatened by greater inter-generational independence, for more of the 'old-old' will be living alone or as couples with no younger relatives nearby. Already one in four elderly people in Canada and France lives alone, one in three in Italy, the US and UK, over 40% in Germany and Sweden, and over 50% in Denmark (OECD, 1996). The shrinking ratio

of women in middle age to elderly people represents a significant decline in the 'daughter care potential', particularly as the proportion of women in paid employment increases. Averaged over eight European countries, the ratio of women aged 46-69 to the population aged over 70 declined from 2.26 in 1960 to 1.53 in 1990 (Guillemard et al., 1993), and will continue to do so.

The pressure of demand on formal services, particularly long-term care, will clearly increase into the first few decades of the next millennium. But the financial and labour force implications of these higher demands could be difficult to meet, for the ratio of working age to retired populations is falling. Who will provide the care, or pay the taxes to fund it?

'The late 20th century has brought to many the ultimate gift: the luxury of ageing. But like any luxury, ageing is expensive. Governments are fretting about the cost already; but they also know that far worse is to come. Over the next 30 or 40 years, the demographic changes of longer lives and fewer births will force most countries to rethink in fundamental ways their arrangements for paying for and looking after older people' (Beck, 1996).

With the licensing of tacrine (Cognex) in the USA, Australia and some European countries and donepezil hydrochloride (Aricept) in the USA, Canada and the UK and several European countries in 1997, clinicians are now able to offer a symptomatic treatment for mild to moderate Alzheimer's disease and will have to assess its likely impact on the progress of the disease. These new treatment options present a watershed in the management of dementia. Whilst early diagnosis has always been desirable in order to institute appropriate support and management, fear of distress caused by imparting an incurable diagnosis meant specific diagnosis would often be fudged or delayed (Ryan, 1994). Early accurate diagnosis is now also needed to assess suitability for new treatments. Secondary care services may become involved at this stage, whereas they were often only involved in the management of secondary causes of confusion and the behavioural sequelae of established dementia in the past.

More comprehensive assessment and monitoring of efficacy, as well as drug costs, will have resource implications, particularly as health care providers and funders are increasingly

questioning the cost-effectiveness of treatment modes.

Given the expected demographic and social trends of the next 40 years, national governments, health insurance payers and other health and social care funders are aiming to reduce the rate of utilisation of costly long-term care. But they also want to reduce the burden on caregivers. More generally, there are widespread efforts across the world to improve both the targeting of available resources on prioritised needs and the outcomes achieved from those resources (Davies, 1992; Coleman, 1995; OECD, 1996). An important question, therefore, is whether new drug treatments for Alzheimer's disease can help in the achievement of these aims.

## **2. CURRENT TREATMENT AND PATTERNS OF CARE**

The current treatment of Alzheimer's disease is palliative. In the early stages of the disease support is usually provided at home, especially if there is a caregiver living with or near the patient. But as the disease progresses there is usually a need for 24-hour care, which often requires admission to a long-term care facility. It is the high cost of residential and nursing home care, and of hospital in-patient care, which might stimulate the search for treatments, new services and different organisational arrangements which can delay or completely remove the need for admission.

In charting the balance of care in England in 1991, Kavanagh et al. (1995) found that 7% of elderly people with dementia were permanently accommodated in hospital, and another 33% in residential or nursing homes. In Canada, half the elderly people with dementia in 1991 were living in long-term care settings, less than one in eight of whom would probably have been in such settings *without* their dementia (Østbye and Crosse, 1994). Similarly high rates of institutionalisation are reported for some other countries (Fratiglioni et al., 1994; Severson et al., 1994), although not for Spain (Caballero Garcia et al., 1993). A prospective cohort study in the USA found that 73% of people entered into an Alzheimer's disease register had moved into nursing homes within 5 years (Welch et al., 1992).

Cost comparisons usually show hospitals to be more expensive than residential or nursing homes, which in turn are more expensive than home-based care (see below). However,

concerns about the growth of long-term care provision are not prompted solely by its cost, but also by the ‘institutionalising’ nature of some environments, the health and mortality risks associated with admission, and the disruption to personal lives (Davies and Knapp, 1981; Ritchie et al., 1992; Schulz and Brenner, 1977). Policy and practice initiatives have thus been launched to enable elderly people to remain at home whilst maintaining or improving their quality of life. Nevertheless, in a number of countries – for example Ireland, Japan, Canada, France and New Zealand - hospitals continue to provide the bulk of long-term care for elderly people (OECD, 1996).

The search for alternatives to institutional provision has ranged over visiting nursing services, enhanced home care, day centres, respite care, improved housing, and greater financial support for carers. New approaches have been developed or recommended to tackle service fragmentation, such as better central guidance, a single agency for care management, ‘care programmes’ (for people with mental health problems) and universal care plans, a standard assessment tool and linking services (Audit Commission, 1997; Banerjee, 1997). The care of people with Alzheimer’s disease today thus comprises diverse, often complex support networks of formal and informal services, as reflected by a recent study from the UK - see Table 1.

*(Insert Table 1)*

Of course, care arrangements vary from country to country, and also within countries, but universally across the developed world these inputs are considerable. Nevertheless, they are small in comparison to the informal care inputs by relatives and other unpaid carers. In Spain the proportion of Alzheimer’s disease sufferers supported by their family could be as high as 90% (Blanco, 1995), and it is also high in Italy (Cavallo and Fattore, 1994). In England, 50% of people with dementia lived with another adult in the community (Schneider et al., 1993), and four out of 10 of these people lived with another elderly person (Melzer et al., 1994). For every American with Alzheimer’s disease, it has been estimated that there are three caregivers carrying some emotional, physical, social or financial burden (Bass and Noelker, 1996).

### 3. THE COST OF CARE

The distinction can be made between the direct and indirect costs of Alzheimer's disease. Direct costs include hospitalisation, residential care, home care, drugs, laboratory testing and education/training, as well as out-of-pocket expenses incurred by caregivers. Indirect costs are the more intangible resource losses which do not involve direct expenditures, such as those linked to caregiver time and psychological stresses, and premature mortality. In principle, direct costs are more easily measured than indirect costs, although because the former are borne by a mix of organisations and individuals, the boundaries between service-providing organisations (and between funders) can in practice encourage narrow perspectives on even these direct costs (see below).

The direct costs of Alzheimer's disease are high because of its prevalence and severe disabling effects. For example, private nursing home care for an elderly person in England cost £368 per week in England in 1996/97, and a local authority residential home cost £478 (Netten and Dennett, 1997). These figures are not adjusted for the higher costs of accommodating residents with Alzheimer's disease (see section 5), nor do they relate to identical dependency profiles. Overall, in 1992/93 the direct health and social services costs of dementia to the public sector amounted to £850 million in England (calculated from figures in NHSE, 1996). This is equivalent to 3.2% of all attributable public sector health and (adult) social services expenditure (excluding pharmaceuticals and social security payments), which is almost identical to the 3.4% found for the Netherlands (Bonneux, 1996). Only a small proportion of the direct costs is spent on drugs: in Italy, one estimate put the proportion at 4.8%, which was the same as expenditure on incontinence pads, orthopaedic prostheses and other aids (Trabucchi et al., 1995), and this for a country which generally has a high level of expenditure on drugs.

The principal indirect cost of Alzheimer's disease is associated with family and other caregiver support. There is a developing literature on the contribution of informal care to the support of people with Alzheimer's disease and an emerging methodological debate on the costing of this care. A central difficulty in estimating informal care burden is in measuring time spent on caring activities. Once time has been estimated, one way to cost the hours is by

the replacement cost method, valuing each informal care hour at the equivalent hourly wage of a professional. Another approach is to gauge the opportunity cost to the carer in terms of having to give up paid employment or to pass up opportunities for career advancement, together with loss of personal time and stress associated with the hours spent providing hands-on-care or supervision. However, given that many of the spouse and other family carers are retired, this poses a problem for this type of costing (Busschbach et al., 1998). The different techniques in valuing informal care account for some of the variation in findings.

A survey in Lombardy found that an Alzheimer's disease patient requires 18 hours a week of paid non-medical services and 45 hours a week of personal care provided from a primary caregiver (Cavallo and Fattore, 1997), at an annual cost (using the replacement cost method) of 72.9m lire (US \$44700) per patient. In the USA, Rice et al. (1993) estimated the annual informal care costs for non-institutionalised Alzheimer's disease sufferers to be \$34500 (1990 prices), compared to formal care costs of \$12600.

Another USA study of family costs for a sample of Alzheimer's caregivers found that each family spent a lower amount, equivalent to \$18200 annually (Stommel et al., 1994). Four out of five families in Stommel's sample reported out-of-pocket expenditures, averaging \$2088 (14% of the total), but the lion's share (59%) was accounted for by the primary caregiver's time spent providing care (\$11560). The average daily commitment was 3.6 hours. As Stommel points out, the family costs of informal care also include the care time provided by other family members and direct payments for domestic help, visiting nurses and other professionals. The significance of the out-of-pocket payments will depend on a country's health care system, but Rice et al. (1991) found that 60% of all formal care costs in the USA were paid by families. Controversies abound about access to public sector subsidies, the need for a patient to sell their house to pay for long-term care, loss of inheritance and so on.

Informal care has usually been found to cost more than formal care, although the difference varies between countries, contexts and studies, and there are of course continuing disagreements about the appropriate way to value caregiver time. Notwithstanding these caveats, if we express informal costs as a multiple of formal costs, we get estimates of 1.4 in Italy (Cavallo and Fattore, 1997), 1.7 in France (Sou tre et al., 1995), 1.9 (Huang et al., 1988)

and 2.3 (Ernst and Hay, 1994) in the USA, to as much as 3 for all elderly disabled people in the UK (Nuttall et al., 1993).

As well as these measurable costs, caregiver support could also lead to a number of uncosted stresses and burdens, including fatigue, social isolation, poor quality of life and disruption to family relationships (Canadian Study of Health and Aging, 1994; Donaldson et al., 1997; Jones and Peters, 1992; Levin et al., 1989; Ritchie and Ledesert, 1992). Caregiving is also associated with depression and other ill-health (Baumgarten, 1989; Ballard et al., 1996), and consequently greater utilisation of health care services (Ernst and Hay, 1994; Clipp and George, 1990).

The aggregate resource consequences of Alzheimer's disease can be pulled together in *cost (or burden) of illness* studies. Comparisons between such studies are hindered by the different methodologies employed, particularly their estimates of caregiver support. Although some of the more recent studies have been the most comprehensive, most appear to exclude some service or caregiver items. One recent estimate for the USA suggested that the full cost of Alzheimer's disease is \$67.3 billion, 31% of which is direct care cost, 49% unpaid caregiver cost and 20% the value of lost productivity due to illness and premature mortality (Ernst and Hay, 1994; see Max, 1993, for a review of USA studies). Cavallo and Fattore's (1994) estimate for Italy pitched the national cost at 8.9 billion lire (1993 prices). For England, the best available estimate is £1.04 billion (Gray and Fenn, 1993), but this is an under-estimate because of the way that informal care was costed. For *dementia*, some of the figures reported in the international literature are: £5.1 billion for England in 1992/93 (Kavanagh et al., 1995); \$3.9 billion (Cdn) for Canada (Østbye and Crosse, 1994), 30 billion SEK for Sweden (Wimo et al., 1995) and 65 billion DM for Germany (Beske and Kunczik, 1993). These are considerable amounts, but each is probably a conservative estimate of the true societal cost because it is rarely possible to put a monetary value on every direct and indirect cost item.

These cost of illness calculations consistently point to two dominant components: the high and rising cost of long-term care, and the high and uncompensated burdens falling to families and other caregivers. However, because ageing is associated with numerous health problems,

it can be difficult to disentangle the effects of any single condition. Nevertheless, costs generally appear higher for people with Alzheimer's disease than for other elderly people supported in community settings (Ernst and Hay, 1994; Philp et al., 1995; Livingston et al., 1997). For example, the 5.6% of people with dementia in Livingston's representative sample of 700 people aged over 64 in a district of London consumed 15.6% of the community care resources, and this excluded long-term care and caregiver costs. The devastating nature of the illness and the sizeable burden on families also result in higher caregiver costs, and precipitate earlier admission to institutional care. The Association of Directors of Social Services (1994) in the UK noted that:

'the service users who gave [social services] departments the greatest difficulty and cause for concern were ... elderly people suffering from mental infirmity and dementia and especially those presenting challenging behaviour'.

Once admitted to long-term care, the Alzheimer's disease patient usually needs differentially large amounts of staff support, and is correspondingly more costly to accommodate. This is true for a number of countries, and applies to residential care homes (Darton and Knapp, 1984; Darton and Wright, 1992), nursing homes (Fries et al., 1993; Hu et al., 1986; Maas et al., 1988; Trabucchi et al., 1994) and hospitals (Hu et al., 1986; Torian et al., 1992). Welch et al. (1992) found that the median length of nursing home stay for Alzheimer's disease residents in their USA sample (2.75 years) was over 10 times the national median for all diagnoses. Traditional residential and nursing homes can have difficulty coping with the needs of Alzheimer's residents, particularly when there are more than a few in any one facility (Warburton, 1994), which is why various specialist units have been opened (Murphy et al., 1994). The costs of these units can be substantial – over £1000 per week (1996/97 prices) in one UK development of 'domus' provision (Beecham et al., 1994).

These high costs - which are greater for people with the most severe symptoms of Alzheimer's disease - help to explain why governments and health care funding bodies are particularly interested in care arrangements and medical treatments which might reduce the costs of care for people with Alzheimer's disease. Will the new cholinesterase inhibitors help?

#### 4. NEW DRUGS TREATMENTS

It is wise to remember that whilst research into Alzheimer's disease treatments inevitably concentrates on cognitive improvements, it is clear from caregivers that the major problems produced by Alzheimer's disease are non-cognitive. Marginal improvements in memory function may add little to quality of life, whereas reductions in apathy, withdrawal, hallucinations and restlessness can have a major impact. What is clear from studies so far is that these behaviours are often influenced by cholinergic treatments (Raskind et al., 1997). A positive response could greatly improve quality of life for the patient and reduce stress within families and thus must be addressed in the assessment and monitoring of any treatment programme in Alzheimer's disease. We should not become tied to cognitive tests, either in deciding eligibility for treatment or response to it. Individual variation in the disease even in patients on no treatment - as evidenced by quite marked 'placebo' responses in patients on clinical trials - suggests that a change of a few points on a cognitive test alone will be of little help in assessing individual patients in clinical practice, albeit providing evidence of efficacy in large trial populations.

The correlation of lowered acetyl choline levels and ante-mortem disease severity lead researchers to test the effects of cholinergic agents on cognitive core symptoms of Alzheimer's disease. Acetyl choline (ACh) is broken down in the synapse by acetyl cholinesterase (AChE) and the first major strategies for treatment have aimed at inhibiting this enzyme. The amino acridine, tacrine, was the first licensed treatment for Alzheimer's disease. It had been shown to produce significant cognitive improvements based on a four point improvement on the Alzheimer's Disease Assessment Scale (ADAS) cognitive subscale (Rosen and Mohs, 1984), independent clinicians assessments and carers ratings of everyday behaviour (Davies et al., 1992). Whilst this in essence was the first rational prescription for the symptoms of Alzheimer's disease, and as such licensed in many countries, some authorities felt that the improvements did not outweigh the side effects. The side effects of cholinesterase inhibitors are, as one might expect, cholinergic and predominantly gastrointestinal with nausea, vomiting and diarrhoea being the most prominent. Tacrine, however, produced in some patients a rise in liver transaminases, which appeared to be symptomless, totally reversible on withdrawing treatment and 80% of those affected could be

rechallenged without recurrence. Later trials showed greater response on higher doses of the drug, up to 160mgs a day, but as not all patients can tolerate these doses and as only about 40% show response, its suitability is limited (Knapp, Knopman et al., 1994).

Another amino-acridine, Velnacrine, has had similar risk-benefit problems and so far has not been pursued. These drugs are non-specific inhibitors of cholinesterase and have short half lives requiring frequent dosing. Other cholinesterase inhibitors have been rediscovered like the Galantamine (Reminyl) and the organo phosphate Metrifonate, a pro-drug used to treat bilharzia. New drugs have been developed which are more selective for the acetyl rather than butyryl form of cholinesterase e.g. rivastigmine (Exelon) and donepezil. Donepezil has a half life of 70 hours and, like metrifonate, can be given once daily. Donepezil has trial data on more than 1000 patients showing that overall 83% have some improvement in cognition or lack of further deterioration. None of these drugs show the liver transaminitis found with tacrine. There is still little data on long term improvement in activities of daily living, but a recent survival analysis of clinical trial results comparing donepezil with placebo, suggests that deterioration of ADL is delayed for approximately one year in treated patients. This outcome needs to be confirmed in prospective studies but is nevertheless encouraging (Friedhoff and Rogers, 1997). It has been noted that withdrawal of the drug does seem to coincide with a cognitive decrement back to the expected level of deterioration without treatment. This perhaps suggests the drug only has a symptomatic effect with the disease progressing unabated.

Clearly a demonstrable effect on disease progression would be of great interest. There are suggestions that cholinesterase inhibitors influence the APOE pathways necessary for transport of cholesterol and hence synthesis of ACh. There is also some suggestion that raised extracellular ACh levels effect amyloid precursor protein (APP) metabolism with encouragement of the normal alpha synthetase cleavage rather than the abnormal cleavage which may lead to accumulation of amyloid (Lovestone, 1997). This may mean that a disease modifying effect will be seen in long-term use with some of these compounds. The next major source of stimulus to the cholinergic system has been the search for cholinergic agonists which do not rely on the endogenous production of ACh but directly stimulate the post synaptic M<sub>1</sub> agonists e.g. Sabcomeline, Xanomeline and Milameline all in clinical trial at

present, although most of these have proved disappointing so far.

What is very clear in all the trials with cholinergic drugs is the wide variability in response. The seemingly idiosyncratic responses to cholinesterase inhibitors have led to the search for other neurotransmitter deficits which are thought to have direct effects or block the benefits of these drugs. There is ample evidence for deficits in noradrenaline, 5HT, GABA, Glutamate, somatostatin, Neuropeptide Y and corticotrophin releasing factor pathways (Rosser, 1988) and this has led to other therapeutic interventions being investigated.

A significant area of pathology in AD is in the entorhinal cortex, a major source of glutamatergic innervation of the hippocampus, and this has raised interest in glutamate pathways generally. Post synaptic NMDA receptors may prevent calcium influx which occurs as a result of glutamate release in hypoxia. Memantine (Aktinol) a drug which does this is already licensed in Germany and is in trial in the UK. Serotonin exerts an inhibitory influence on ACh release in the cortex, hippocampus and striatum. An antagonis of 5HT<sub>1A</sub> receptors may therefore have a synergistic effect with cholinomimetic agents and one such drug is at present in Propentofylline which appears to prevent microglial and astrocyte activation which occurs in response to  $\beta$  amyloid depositions as well as influencing APOE metabolism. Clearly calcium channel blockers may have a role, but potassium channel blockers like besipirdine and linopirdine have also shown some promising benefits in AD.

Cell membrane lipids and other cell components can be damaged by hydroxyl radicals thought to be released from  $\beta$  amyloid. Anti-oxidants which can neutralise the effect of this free radical production like Vitamin E and Selegiline have also been used. One recent clinical trial (Sano et al., 1997) demonstrated no difference between the groups on a per protocol analysis, but after adjusting for baseline MMSE score showed delay in disease progression in all active treatment groups.

Another drug thought to have anti-oxidant properties, and licensed in Germany, Ginkgo Biloba, has recently shown a significant difference from placebo in a double-blind 52-week study. However, as the placebo group deterioration was only 1.5 points on the ADAS scale, the lack of deterioration in the active treatment group - though possibly showing a long-term

neuroprotective effect - may be a reflection of the mildly effected nature of the group as a whole as there was no difference on Clinical Global Impression (Le Bars et al., 1997). There is also evidence that anti-inflammatory drugs effect amyloid deposition and oestrogens may have an effect on the progress of AD, which would seem to indicate that no one drug will provide a cure.

Alzheimer's disease is a final common pathway for a number of disease processes and a combination of treatments may be required to influence it. None of these treatments is without cost and much of the cost is indirect in the form of increasing public interest in the disease with a need for more accurate early diagnosis. However, the cost of treatments may well be cost-neutral or better if they reduce morbidity and delay the onset of behaviours likely to result in higher degrees of dependency.

## **5. POTENTIAL ECONOMIC BENEFITS OF CHOLINESTERASE INHIBITORS**

The ageing of the world population will bring substantial increases in costs – for pensions, infrastructural services, health and social services, and for family and other caregivers. The economic, social and political challenges of the next few decades will be more manageable if it is possible to reduce either the prevalence of morbidity associated particularly with old age or the costs of its treatment.

Will it be possible to reduce the high costs of Alzheimer's disease? If any new treatment could delay the onset of Alzheimer's disease the prevalence would reduce owing to mortality from other causes, and even a delay of one month in admission to a nursing home could pay for one year's supply of the currently licensed treatment. However, with no new money, can present levels of expenditure and caregive support generate better outcomes? Some of the service innovations which have been reliably evaluated offer encouragement (Gray, 1995; Knapp, Knopman et al., 1994), and changes to the balance of care could reap cost-effectiveness improvements (Kavanagh et al., 1995). Could the advent of donepezil, tacrine and similar compounds in development bring further improvements?

The clinical trials of donepezil and tacrine suggest that decline in cognitive function can be slowed down, as can decline in global functioning, and that patient self-reported quality of life is improved. There is no significant change in life expectancy on these drugs, though one tacrine study showed a trend towards increased survival (Knapp, Knopman et al., 1994; Rogers et al., 1996).

Caregivers' increasing willingness to continue caring may contribute towards the delay in the need for residential care that has been observed (Knopman et al., 1996). One study has reported a significant reduction in caregiver input time in patients on the AChE inhibitor Velnacrine (Clipp and Moore, 1995). However, despite uniform severity across groups, the input time varied enormously and was only significant in the lower dose group. Such measures, whilst apparently objective, are very dependent on the caregiver's sense of well-being and may reflect greater side-effects in the higher-dose group impacting on the carers. In fact, the effects on caregivers will be complex, for if AD patients live for longer in the community (before admission to nursing home or other institutional care) the *aggregate* informal care burden on their families and others may be greater than before.

Caregiver well-being can be non-specifically affected by giving patients a specific treatment which helps to reduce the sense of helplessness and hopelessness. This may not last if there is no change in the patient. If AChE inhibitors influence the non-cognitive symptoms of apathy, restlessness and hallucinations (Raskind et al., 1997), carers may well be more willing to continue looking after someone if they have become more manageable. This may in turn reduce direct costs. Sufferers who are more alert and interested may need less tranquillising medication.

This may also delay admission to long-term care and consequently reduce the personal and social costs of Alzheimer's disease, even though the drugs themselves are more expensive than conventional treatments. The clinical monitoring of the patients on these drugs is more expensive than doing nothing but should allow more targeting of treatments as experience is gained in their use. Decisions about continuing these drugs as patients decline in nursing home care have yet to be widely addressed. If the drug is stopped in a patient who is responding there may be a rapid decline in performance thus increasing the burden of care

and reducing quality of life.

One important consequence is a significant delay in substantial loss of ability in the basic activities of daily living (ADL) (Friedhoff et al., 1997). The links between cognitive function, ADL, IADL and caregiver burden (and privately-borne costs) are well established in the research literature (e.g., Clipp and George, 1990; Levin et al., 1994; Lieberman and Fisher, 1995; Stommel et al., 1994; Weinberger et al., 1993). Melzer et al. (1994) with their large, nationally representative sample of people aged over 69, and Rice et al. (1993) with their smaller, local sample, both found that people with more severe dementia received more intensive informal care than those with milder dementia. In Melzer's sample, 40% of those with moderate/severe cognitive impairment required almost continuous support, compared to 11% of those with mild impairment.

In many health and social care systems across the world the responsiveness of services to needs leaves a lot to be desired (Coleman, 1995; Davies, 1992). Nevertheless, it is *broadly* the case that the more dependent elderly receive greater numbers or intensities of services. Recently, Ernst et al. (1997) have reported findings from a small-sample cross-sectional study which showed that preventing a modest 2-point decline in MMSE score among moderately- to severely-demented elderly people living in domestic accommodation could save \$3,700 (US) each year. However, cognitive impairment is likely to be only one facet of dependency which influences cost, so that a decline in MMSE score may not necessarily pull costs down (Hay et al., 1997).

Whilst Ernst et al. (1997) offer the most directly relevant evidence to date of potential cost savings flowing from delayed cognitive decline, other research findings suggest similar associations. Within the population of Alzheimer's or dementia patients living in the community, severity of illness has been found to be positively linked to the intensity of formal care support or the costs of care delivered by public, private and voluntary (non-profit) organisations. Evidence of this association comes from, for example, Canada (Østbye and Crosse, 1994), France (Souëtre et al., 1995), Italy (Trabucchi et al., 1995), the Netherlands (Boersma et al., 1997), Sweden (Wimo et al., 1994), the UK (Melzer et al., 1994; Banerjee and McDonald, 1996; Souëtre et al., 1998; Kavanagh and Knapp, 1998) and the USA (e.g.

Rice et al., 1993; Osterweil et al., 1995). The gradient linking formal care costs to dependency can be quite marked.

There is another potential consequence of delays in cognitive and ADL decline among community-based Alzheimer's disease patients, which is the patient's continuing ability to identify other health needs and to take greater responsibility for self-medication or other treatment. This could facilitate earlier intervention and more generally assist in the better targeting of services on community and individual needs.

The severity of Alzheimer's disease is linked to the likelihood of moving from community-based to long-term care, although there are of course many other factors which influence the decision to admit, or to be admitted to a residential home, nursing home, or hospital. The UK evidence is reviewed by Warburton (1994; and see Opit and Pahl, 1993), whilst numerous USA studies have reported the link between cognitive function and institutionalisation (e.g., Brodaty et al., 1993; Knopman et al., 1996; Lubeck et al., 1994; Severson et al., 1994), and Boersma et al. (1997) offer interesting comparisons between levels of care in a representative Dutch sample. Often admission is precipitated by a combination of factors, such as a caregiver's eventual inability to cope or the escalating cost of community-based care, some of which may themselves be attributable to the severity of illness. If life expectancy is unchanged by treatment - something which is currently unclear - it is likely that patients taking one of the new generation of cholinesterase inhibitors will spend a smaller proportion of their lives after diagnosis of Alzheimer's disease in a long-term care facility.

One of the consequences could be an overall reduction in the cost of treatment. Long-term care facilities cost more than community-based care (Kavanagh et al., 1995; Knapp, Cambridge et al., 1994; Wimo et al., 1995; OECD, 1996), and these differences appear to persist even after adjusting for patient needs and other characteristics, and after measuring caregiver costs (Davies and Challis, 1986). On the other hand, the drugs themselves are more expensive than conventional treatments, and there are the costs of accurate diagnoses necessary to establish symptoms and appropriateness of treatment.

Although none of the available cost calculations relating specifically to cholinesterase inhibitors is based on a prospective economic evaluation, the emerging evidence is consistent with the argument that would be built up from the previous literature: for many patients cost savings look possible, and cost-effectiveness improvements look probable. One set of estimates based on evidence from the use of tacrine suggested that savings might reach \$2243 to \$4052 per annum (Lubeck et al., 1994), although Knopman (1995) takes a less optimistic view of the same evidence. Henke and Burchmore (1997) tackle some of the reservations voiced by Knopman, and suggest savings of \$9250 from diagnosis to death. Clipp and Moore (1995) outline a trial of another cholinesterase inhibitor, velnacrine maleate, one of whose consequences was a 45% reduction in caregiver time in one treatment group. A recent modelling study by O'Brien et al. (1997) found that, compared to usual care, donepezil is predicted to reduce costs (health care and societal) and improve patient outcomes (more time spent in non-severe stages of Alzheimer's disease) in patients with mild to moderate Alzheimer's disease.

The new cholinesterase inhibitor drugs may or may not reduce aggregate costs, but even if they prove to be *cost-neutral* - bringing neither savings nor additional costs - they would nevertheless be cost-effective compared with current treatment arrangements because they slow down the decline in patient cognition and general functioning, and improve patient quality of life.

## 6. CONCLUSION

International demographic and social trends are putting considerable pressures on health and social services funders. The high costs of long-term care have long been of concern, but it is also recognised that it will not be possible to rely on families and other informal caregivers to take up a greater burden of care. The continuing high rate of divorce may weaken family bonds, and the geographic dispersal of families makes it more difficult to provide or arrange care. Changing female employment patterns are also likely to reduce the supply of caregiver support. However, the most fundamental concern of families remains the same: to ensure that their relatives have access to effective treatments. This, too, is the primary concern of the

general medical practitioner, psychiatrist, social worker or other care professional working with Alzheimer's disease patients. But the growing economic pressures on health and social care systems are also generating demands for treatments which are also *cost-effective* treatments.

The cholinesterase inhibitors may offer an effective treatment for many people with mild or moderate Alzheimer's disease, slowing down cognitive decline, preserving competence in ADL for longer, and improving patient quality of life. Caregiver burden could be reduced, the costs of community care lowered, and admission to long-term care delayed. This is why so much attention is currently being focused on these new drugs.

However, the likely aggregate cost consequences of the new treatments tell only part of the story, for there are many stakeholders in any health or social care system, each with their own constraints and objectives. Clinicians, pharmacy budget holders and funding bodies more generally are concerned with their own budgets, and an increase in the costs which they have to bear without any compensating reduction now or in the future may not be attractive. The problems of inter-agency boundaries and perverse incentives are not new to psychiatry or the care of elderly people (Kavanagh and Knapp, 1995; Audit Commission, 1997), but they still need to be overcome if they are not to represent substantial hurdles in the way of better care. However the single minded attention to the cost of a new treatment leaves us in danger of, like Oscar Wilde's cynic, knowing the price of everything and the value of nothing. We must not forget that some improvements are worth paying for. Cost is not the only consideration in a humane society. Those professionals and agencies with responsibility for the care of Alzheimer's patients need to ensure that boundary problems do not get in the way of better quality of life for patients and their caregivers. The new drugs could dramatically alter the treatment of Alzheimer's disease, and consequently alter the lives of millions of people.

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**Table 1: Percentage of elderly people with dementia receiving selected services in past year.**

<b>Service</b>	<b>Percentage of Patients</b>
GP visit	91
Community nurse	36
Home care worker	24
Chiropodist	16
Social worker	14
Psychiatrist	12
Daycare	12
Hospital Inpatient	16

(Source: Schneider et al, 1993)