Alzheimer's disease pharmacological trials for several years, to answer this question.

From June 2006 to June 2009, nine pharmacological clinical trials were conducted to assess the safety, tolerability, and efficacy of drugs for Alzheimer's disease (AD). The main inclusion criterion was the presence of probable AD. In an outpatient clinic, 1,246 individuals with dementia (mean age 80.4 ± 6.9; mean Mini-Mental State Examination score 18.2 ± 5.7; 70.7% female) were evaluated for inclusion in clinical trials. Seven hundred forty-five (59.8%) had a diagnosis of probable AD, but 29.3% of these (n = 218) were rejected because they did not fully satisfy the other inclusion criteria because of physical comorbidity or drug therapy.

After a telephone contact, 527 of the eligible individuals (68.3%) were eventually rejected for unavailability of the caregiver because of logistical problems (9%) or negative prejudice about clinical trials (41%) or worsening of dementia or other somatic diseases during the previous 6 months (50%).

One hundred nine (8.7%) of 1,246 individuals were randomized to clinical trials (Figure 1). This led to the observation that people with cognitive impairment are excluded not only from studies that consider elderly adults, but often also from trials specifically developed for AD.

Although the high selectivity of these inclusion criteria allows us to better evaluate the efficacy of a drug, it makes the sample less representative of the cognitively impaired population, far from the real world, and does not allow the results to be generalized, as underlined by previous studies.

Taylor et al. have a good point about the necessity of developing a theoretical frame to help researchers understand when, how, and why the exclusion of cognitively impaired individuals from studies regarding the elderly population should be considered appropriate or not. As has been suggested, this could be applied also to studies specifically designed for individuals with AD.

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References

Stamp the Foreheads of People with Alzheimer's Disease

To the Editor: Do I really want my wife and others with Alzheimer’s disease (AD) to walk around with their foreheads stamped? Of course not. But I must confess, there are times when I do wish that such a stamp existed. The imprint would be, “I have Alzheimer’s … Please speak to my caregiver, not to me.”

We need to better sensitize everyone in the medical field to the realities of AD. People with AD cannot be expected to understand or remember what is asked of them, what is said to them, what is done to them, or what they have just been told to do. That is why everyone in the medical profession must always remember to speak directly with the caregivers of their patients with AD.

Receptionists at medical facilities and in doctors’ offices, laboratory technicians, rehabilitation workers, therapists, healthcare aides, nurses, physician assistants, dentists, dental hygienists – and, sadly, on occasion, even some doctors – need always to be aware that they should never discuss important information with individuals with AD when their caregivers are not present. Individuals with AD
Caregivers should be present with individuals with AD when they are being examined or should be present whenever any discussion of that examination takes place. Medical personnel should never ask individuals with AD for important information about current medications or medical problems during examinations when caregivers are not present. Remember that stamp!

Medical personnel must also be sensitized to the futility of communicating with most individuals with AD by telephone. Telephone messages should never be left with an individual with AD. Individuals with AD will often not remember receiving such calls, will not process that information, or will forget to share that information with their caregiver. As a caregiver for a spouse with AD, I’ve had to call back medical offices to indicate that my spouse remembered receiving a telephone message but did not remember what was said. I have also had to call back to say that my spouse relayed a telephone message to me that I knew could not possibly be accurate. Members of my weekly support group for spouses of individuals with AD report similar incidents. Were important information communicated directly to caregivers, these frustrations and misunderstandings could be easily avoided. Remember that stamp!

Ethical standards and legal guidelines direct the medical profession to legitimately protect the privacy rights of their patients, but Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule regulations allow doctors and medical professionals to exercise reasonable judgment in determining what information may be shared with relatives and friends of patients. In my particular situation, for example, my wife cannot be expected to give anyone accurate information about anything anymore – not about her medical history, not about her medications, not about her current symptoms, and not about her six activities of daily living. I must be present to answer such questions and provide such information. Similarly, my wife cannot be expected to remember information she is given, nor can she be expected to share that information accurately with me. If individuals with AD are in the early or moderate stages of AD, they can probably provide specific permission for doctors to share all medical information with their caregivers. But if they are unable to communicate such permission, and doctors and medical personnel feel uncomfortable about sharing all medical information with caregivers, they can simply ask caregivers to provide them with copies of their durable power of attorney to authorize such communication. Remember that stamp!

Let’s stop expecting individuals with AD to provide accurate information about themselves or their medical condition. Always speak directly with their caregivers if you want to obtain such information. And let’s stop communicating important test results or any other relevant medical information solely to individuals with AD. Speak with your patients with AD only when their caregivers are present, or just communicate directly with their caregivers. Remember that stamp!

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My wife, Clare Vann, has AD and has given me permission to note this in my article.

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