Department of Paediatrics, Saint Mary's Hospital, Manchester M13 0JH
J M Puliyel, *registrar in paediatrics*
A Hughes, *hospital manager*
M L Chiswick, *professor of paediatrics*
M Z Mughal, *consultant paediatrician*

The median age at vaccination was 10 days (range 1-403 days). Infants were seen at the clinic a median of 65 (7 to 139) days after vaccination. A total of 61 infants (11.0%) had adverse local reactions. Forty eight infants (8.6%) had axillary lymphadopathy; one had an axillary lymph node >20 mm in diameter. Six infants had papules >10 mm diameter, and another six had ulcers >10 mm diameter. In one infant an abscess at the injection site was aspirated by needle.

One infant who received this BCG at 6 weeks of age presented at 4 months with severe combined immune deficiency (Omenn syndrome). She was treated with anti-tuberculosis drugs until her death from pulmonary haemorrhage after a bone marrow transplant. A lung biopsy three days before her death did not show histological changes of disseminated BCG.

Comment

The definition of an adverse local reaction to BCG varies greatly. O'Brien *et al* consider axillary lymph nodes >20 mm or vaccination ulcer prolonged for more than six weeks to be mild complications, axillary abscess or fistula to be moderately severe complications, and disseminated BCG infection to be severe complications.[2] By these criteria only one child in our study had a mild reaction.

In older children, a normal BCG ulcer should not exceed >10 mm in diameter and should heal within four weeks.[3] Six of our infants (1.1%) had ulcers >10 mm diameter, but this may be an underestimate as the infants were examined at different times after their vaccination. The size of the BCG ulcer depends on the technique of vaccination as much as the dose. In one report 158 of 403 children vaccinated by a doctor developed adverse local reactions; this was attributed to faulty technique.[3] The low adverse local reaction rate in our cohort may, despite the high dose of BCG used, reflect the experience and good intradermal vaccination technique of the two doctors who administered the vaccine.

Surprisingly, the patient with Omenn syndrome did not show evidence of disseminated BCG infection. This syndrome in its early stage is characterised by polyclonal proliferation of T lymphocytes, and we speculate that these T lymphocytes may have been capable of activating macrophages, thus preventing dissemination of BCG in this patient.

While human error was responsible for this "accident," it is important to note that the ampoules, packaging, and labelling of the Evans intradermal and percutaneous BCG preparations are deceptively similar. Distinctive labelling and packaging of the intradermal and the percutaneous BCG preparations would have helped to draw attention to their different potency.

We thank Ms A Fisher, Dr F N Bamford, Dr R Pumphery, Dr G Morgan, Professor RHD Boyd, and staff of the Central Manchester Healthcare and the Mancunian Trusts.

Conflict of interest: None.

Source of funding: None.

1 Milstein JB, Gibson JJ. Quality control of BCG vaccine by WHO: a review of factors that may influence vaccine effectiveness and safety. *Bull WHO* 1990;**68**:93-108.
2 O'Brien KL, Andrae JR, Marie AL, Desormeaux J, Joseph DJ, McBrien M, *et al*. Bacillus Calmette-Guerin complications in children born to HIV-1-infected women with a review of literature. *Pediatrics* 1995;**95**:414-7.
3 Farries JS. An increase in abnormal reactions to BCG: implications for prevention and treatment. *Community Medicine* 1980;2:312-7.

(Accepted 24 May 1996))

Family members' attitudes toward telling the patient with Alzheimer's disease their diagnosis

Conor P Maguire, Michael Kirby, Robert Coen, Davis Coakley, Brian A Lawlor, Desmond O'Neill

Advances in the accuracy of the diagnosis of Alzheimer's disease as well as progress in the genetics, aetiopathology, and therapeutics of the condition have stimulated a debate on whether patients should be informed of their diagnosis. We report the results of a survey of family members on their attitudes to the disclosure of the diagnosis.

Mercer's Institute for Research on Ageing, Saint James's Hospital, Dublin 8, Republic of Ireland
Conor P Maguire, *research registrar in geriatric medicine*
Michael Kirby, *research registrar in psychiatry*
Robert Coen, *psychologist*
Davis Coakley, *professor*
Brian A Lawlor, *consultant psychogeriatrician*
Desmond O'Neill, *consultant geriatrician*

Correspondence to:
Dr Maguire.

BMJ 1996;**313**:529–30

Patients, methods, and results

A total of 100 consecutive family members accompanying patients with diagnosed Alzheimer's disease to a memory clinic were asked three questions by the assessing physicians (CPM, MK): should the patient with Alzheimer's disease be told their diagnosis; would they themselves want to be told their diagnosis should they develop Alzheimer's disease; and would they make use of a predictive test for Alzheimer's disease should it become available? They were also asked to state the reasons for their decisions.

Only 17 family members said that the patient should be told the diagnosis; 83 said that they should not. The main reason given was that the diagnosis would upset or depress the patient (table 1). In contrast, 71 family members wanted to be told their diagnosis should they develop Alzheimer's disease; most stated that it would be their right to be told their diagnosis. Seventy five family members would use a predictive test for Alzheimer's Disease; 42 of these said it would give them the opportunity to make provisions for their future and thereby reduce the burden on their families.

Comment

The majority of relatives of patients with Alzheimer's Disease would not want the patient told the diagnosis, but would themselves wish to know if they developed the condition. This inconsistency may reflect a generational difference in the perception of the disease, apaternalistic desire by family members to protect patients from the harsh reality of their condition, or a reluctance of relatives to deal with the patient's knowledge and possible grief.

Most of those who opposed disclosure of the diagnosis to the patient felt that it could precipitate symptoms of anxiety and depression. However, Bahro *et al* have shown that when the diagnosis is given, both patients and family members often use denial as a defence mechanism to deal with it.[2] Many patients are aware of their progressive cognitive deficits, regardless of whether or not a diagnosis of Alzheimer's disease has been given. Insight may be an important determinant of reaction to disclosure, with lack of insight providing a degree of psychological protection. Retention of insight varies from patient to patient and seems unrelated to degree of cognitive deterioration.[3] In insightful patients, the risk of depressive reactions or even suicide must be seriously considered after disclosure of any major illness. This seems no different in Alzheimer's disease. Two cases of suicide in patients told their diagnosis have recently been described.[4] In our study, 10 family mem-

Table 1—*Family members' views (n = 100) on telling the diagnosis of Alzheimer's disease*

	Yes		No
Should the patient be told?			
Patient is aware that he/she is ill	7	Diagnosis would depress/agitate patient	51
Patient's right to know	5	Patient has a dread of developing Alzheimer's disease	12
Patient would cope better	4	Would not understand diagnosis	8
Informed consent for drug trials	1	No benefit in knowing	5
		Would not want to be told of any illness	4
		Stigma of the diagnosis	2
		Patient might commit suicide	1
Should you be told?			
My right to know	36	Diagnosis would depress/agitate me	13
Make provisions for my future	26	Would not want to be told of any illness	10
Commit suicide	6	No benefit in knowing	3
Explore treatment options	3	Commit suicide	2
		Stigma of the diagnosis	1
Would you make use of a predictive test?			
Make provisions for my future	42	No benefit in knowing	15
Explore treatment options	18	Diagnosis would depress/agitate me	5
My right to know	8	Would not want to be told of any illness	3
To help research into the disease	5	Not now, but at an older age	2
Commit suicide	2		

bers said that they would consider committing suicide if they were diagnosed as having Alzheimer's disease.

In 1961, 90% of doctors expressed a preference for not telling cancer patients their diagnosis. By 1977 a complete reversal of opinion had occurred, with 97% of doctors favouring disclosure of the diagnosis.[5] The reasons for not telling cancer patients their diagnosis in 1961 were similar to those now given for not telling patients with Alzheimer's disease their diagnosis. The change in policy among doctors coincided with advances in the management and treatment of cancer. Similar advances are being made with Alzheimer's disease today, so clinicians must decide whether to respect the wishes of family members not to tell patients their diagnosis, or to respect individual autonomy, inform patients, and involve them in the management of their condition.

A recent review which advocated disclosure of diagnosis emphasised that clinicians must evaluate each situation individually.[1] Family members as well as patients respond in various ways to the psychological threats presented by the diagnosis of Alzheimer's disease, and the issue of disclosure needs to be dealt with on a patient by patient basis.

Funding: Health Research Board of Ireland and Mercer's Institute for Research on Ageing.
Conflict of interest: None.

1 Drickamer MA, Lachs MS. Should patients with Alzheimer's disease be told their diagnosis? *N Engl J Med* 1992;**326**:947-51.
2 Bahro M, Silber E, Sunderland T. How do patients with Alzheimer's disease cope with their illness? A clinical experience report. *J Am Geriatr Soc* 1995;**43**:41-6.
3 Michon A, Deweer B, Pillon B, Agid Y, Dubois B. Relation of anosognosia to frontal lobe dysfunction in Alzheimer's disease. *J Neurol Neurosur Psychiatry* 1994;**57**:805-9.
4 Rohde K, Peskind ER, Raskind MA. Suicide in two patients with Alzheimer's disease. *J Am Geriatr Soc* 1995;**43**:187-9.
5 Novack DH, Plumer R, Smith RL, Ochitill H, Morrow GR, Bennett JM. Changes in physicians' attitudes toward telling the cancer patient. *JAMA* 1979;**241**:897-900.

(Accepted 24 May 1995)

Can adverse drug reactions be detected earlier? A comparison of reports by patients and professionals

Toine C G Egberts, Maartje Smulders, Fred H P de Koning, Ronald H B Meyboom, Hubert G M Leufkens

The occurrence of previously unknown adverse reactions after the marketing of a new drug is inevitable given the limitations of preregistration clinical trials. Nevertheless, their impact on public health should be minimised by ensuring that reactions are detected as early as possible. The reporting of suspected adverse drug reactions by health care professionals to monitoring agencies[1] and to medical journals[2] has been important in alerting doctors to drug safety problems, but Mitchell *et al* suggested that the time lag to the first reports of adverse reactions might be shortened if patients themselves reported adverse events.[3] For a newly introduced antidepressant we compared the time to reporting of adverse drug reactions by patients and by health care professionals.

Correspondence to:
Dr Egberts.

BMJ 1996;**313**:530–1

Methods and results

A telephone medicines information service was started in 1990 by the Dutch Ministry of Health and the Royal Dutch Association for the Advancement of Pharmacy to promote the correct use of drugs and identify problems related to drug use. Anonymously and free of charge, patients can consult a pharmacist. The pharmacist summarises each call on a standard form. All reports produced by the service in 1992-4 were searched for those indicating an adverse reaction associated with the antidepressant paroxetine. This drug was introduced just before the study (September 1991) and has been prescribed in considerable volume. The time lag between marketing of paroxetine and the date of the phone calls was calculated and compared with the time lag between marketing of paroxetine and the date of suspected reactions reported by health professionals to the Netherlands Pharmacovigilance Foundation. This is a typical spontaneous adverse drug reaction reporting system, which in 1994 covered a population of about two million people in seven regions of the Netherlands. We analysed separately the time lag in both systems for those drug reactions that were not mentioned in the patient information leaflet at the time of the study.

Out of 23 625 calls to the telephone service 120 suggested an adverse reaction to paroxetine. Of the 7665 suspected adverse reactions reported to the Nether-