free prescription for individuals of all ages with a variety of coincident illnesses and drug treatments. Limited release has been suggested with, say, 10 000 treatments being allowed under close scrutiny, but whether this would offer advantages over other varieties of postmarketing surveillance is not clear. Prescription event monitoring has been pioneered in Southampton by Inman and his colleagues.[3] They have shown that large numbers of reports may be collected from cooperating practitioners; thus over 62 000 reports out of some 100 000 sought concerning five anti-inflammatory drugs were collected in a recent investigation. The interpretation of these reports has not always been easy. Thus an association between the use of benoxaprofen and photosensitivity and oncholysis was demonstrable, but there were problems, as with other methods, in deciding if ordinary disease was turning up with greater than expected frequency. Inman and his colleagues have compared event rates with and later without treatment in attempting to deal with this problem, but such sequential comparisons may not produce strictly comparable data. Patients with chronic disease may stop one drug but start another, and they often have coincident but unrelated disease. The problem raised by confounding because of associated disease was illustrated during the surveillance of 10 000 patients taking cimetidine who, by comparison with non-dyspeptic population controls, were about twice as likely to die during the year after prescription of the drug. They were also more likely to attend hospital with other diseases which were clearly coincidental.[4] Considerable difficulty arose in disentangling what was coincidental from what might have been caused by treatment.

Retrospective case-control studies are attractive because they offer the opportunity to compare antecedent drug intake in cases with a set disease and in controls. Such studies, however, demand a pre-existing hypothesis, derived, for instance, from yellow card reports, and they take time. They have also been criticised because they may not necessarily cope with all issues of confounding. Nevertheless, case-control studies did identify the association between venous thromboembolism and oral contraceptive use,[5] and they can generate figures which allow us to estimate the increased risk of takers compared with non-takers. We have lately used the method to suggest that though the risk of peptic ulcer bleeding with anti-inflammatory drugs may not appear large per 1000 prescriptions—and may not even be identifiable in postmarketing surveillance—the risk may nevertheless be substantial when seen in the context of the 20 million prescriptions a year that are currently issued in Britain.[6]

The general issues of adverse reaction surveillance have recently been considered by the Committee on Safety of Medicine's Grahame-Smith working party.[7] This accepted that the yellow card scheme cannot meet all the committee's requirements and recommends that postmarketing surveillance studies should be carried out on most new drugs, particularly when widespread long term use is expected. The working party saw difficulty continuing in detecting rare or long latency reactions and pointed to the possible benefits of record linkage schemes. Problems also arise when new and old drugs are compared, and ad hoc studies seem to be required, particularly as yellow card reports and event monitoring do not seem ideally suited to the purpose.

Determining the risks of drug induced disease does not get easier; indeed, it is getting progressively more costly and taking more time and effort. The public very reasonably wants safer medicines and expects close scrutiny of those on the market. The methods of investigation are, however, only partially effective. If new approaches are to be tried we shall need to examine them critically and to decide whether they are cosmetic or effective.

M J S LANGMAN

Professor of Therapeutics,
University Hospital,
Nottingham NG7 2UH

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The leaking labyrinth

In the inner ear the perilymph and endolymph are separated by extremely delicate membranes. Changes in the pressure of the cerebrospinal fluid are transmitted to the perilymph compartment through the cochlear aqueduct.[1] Pressure changes in the middle ear—such as occur during barotrauma—are also transmitted to the inner ear. If these changes in pressure are excessive the membranes in the inner ear may rupture, and perilymph may then leak into the middle ear through tears at the round or oval window. Tears may also occur inside the labyrinth, mixing perilymph with endolymph and injuring the sensory epithelium.[2]

The pattern of auditory and vestibular symptoms produced by such ruptures is variable. In some series loss of hearing has been the outstanding symptom,[3] while in others vestibular symptoms have predominated.[4] The hearing loss is sensorineural, often of sudden onset, and need not be accompanied by vertigo.[3] The vestibular symptoms may cause ataxia, episodic vertigo, or a sensation of unsteadiness or lightheadedness.[4] Typically the symptoms develop after physical exertion or a change in pressure—such as after diving or flying. Coughing, sneezing, lifting, straining, or parturition may also cause these injuries. Not surprisingly, leaks may result from head injury and penetrating injuries of the ear. In at least one third of cases, however, the onset is apparently spontaneous.[3]

Undue emphasis has been placed on the "fistula test" in the diagnosis of perilymph leaks. The test is performed by inducing positive and negative pressure in the external ear canal by pneumatic otoscopy or by firm digital pressure on the tragal cartilage. The test result is positive if either nystagmus or a sensation of disequilibrium occurs. In one study the test was positive in only six of 17 patients with surgically proved fistulas, and it gave false positive results in five patients out of 10.[5] Indeed, there are no specific auditory or vestibular investigations that will confirm or exclude the presence of a perilymph leak.[2] Diagnosis is heavily dependent on clinical suspicion; it may be made with certainty only when the middle ear is explored surgically.

The approach to treatment of these fistulas must be tempered by the knowledge that many probably heal spontaneously.[2] When a clinical diagnosis is made the patient

should be recommended to have bed rest with the head raised for seven days after the precipitating event. This period allows time for investigation of other causes of acute auditory or vestibular failure. If symptoms persist the next step is a tympanotomy, which allows direct inspection of the oval and round windows. Fistulas of the oval window are the most common, but lesions may occur in both the oval and round windows.[3] If a leak is apparent it should be sealed with either fatty tissue or a patch of perichondrium. Sealing of these leaks controls the vestibular symptoms effectively and often improves tinnitus, but it only rarely improves hearing.[4] Whether or not to explore a particular ear in a patient with the appropriate symptoms and signs but without a history of trauma is a difficult clinical decision. About a quarter of such patients are found to have a perilymph leak.[6]

The importance of perilymph fistulas lies in the fact that they may produce troublesome disequilibrium which may be relieved by a relatively simple surgical procedure. So doctors should be aware of the condition because otherwise many of these cases will remain undiagnosed.

G M O'DONOGHUE
Senior registrar

B H COLMAN
Consultant otolaryngologist

Radcliffe Infirmary,
Oxford OX2 6HE

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AIDS and swimming pools

There is much public anxiety that the virus causing the acquired immune deficiency syndrome (AIDS) may be spread in swimming and hydrotherapy pools. The virus, now called the human immunodeficiency virus (HIV), can be transmitted by sexual intercourse, by transfusion or inoculation of blood and blood products, and by sharing contaminated syringes and needles. There is no evidence, however, that it is spread by social contact; by sharing of washing, eating, and drinking utensils, and other articles commonly used; or by sharing toilet facilities.[1] Nor is the infection transmissible by airborne droplets resulting from coughing or sneezing.

The World Health Organisation and other international agencies are paying great attention to contamination of water and soil by viruses. Though much is known about monitoring and treating bacterial contamination of water, less is known about viral contamination, which is mainly with enteroviruses. Human viruses that may be found in polluted water (often far from the source of contamination) include most enteroviruses, hepatitis A, Norwalk type of gastroenteritis viruses, rotavirus, adenovirus, and parvovirus (adeno associated virus),[2] and the most important sources of viral contamination are human faeces and urine. But swimmers may shed genital and respiratory viruses into water.[3] Less well studied and even unknown viruses (perhaps papovaviruses, certain slow viruses, and possibly human tumour viruses) may also be spread through water.[3]

Swimming in recreational pools, whirlpools, and hydrotherapy pools (especially if the head is immersed) may thus be hazardous if the water is polluted. Specific infections due to *Pseudomonas aeruginosa*,[4] mycobacteria, legionella, and amoebae are described. There is less information on viruses, but water may be swallowed during bathing, and viruses may enter exposed mucous membranes and through breaks in the skin (fresh wounds and abrasions). Pools without free residual chlorine allow viruses to accumulate and survive and may become a source of infection—for example, acute pharyngoconjunctivitis caused by adenoviruses, meningitis due to enteroviruses, and infection with polioviruses. Viral infection might thus be contracted in poorly maintained pools but not, it seems, from properly maintained and disinfected swimming pools.

HIV has been isolated from blood, semen, saliva, tears, and breast milk. It may be present in other body fluids including urine, but there are no reports of its isolation from faeces. Several factors thus make it extremely unlikely that AIDS could be spread by water. Firstly, the most important sources of contamination of water are human faeces and urine. Secondly, dilution greatly reduces the risk of infection —for example, with hepatitis B virus. Thirdly, properly maintained and supervised swimming pools, whirlpools, and hydrotherapy pools pose little risk, but factors such as the bathing load, personal hygiene, type of disinfectant used, amount of residual organic material filtration, pH of the water, and water temperature and circulation are most important (McDougall SM, unpublished observations).

Particular attention should be paid to the disinfectant used. Sodium hypochlorite and chlorinated isocyanurate have been used effectively for many years. Chlorine destroys microbes and removes organic material, and whatever the source of chlorine the active agent is hypochlorous acid. Chlorine remains the disinfectant of choice, the amount of free residual chlorine recommended being 1·5-2·0 mg/l (0·02-0·03 mmol/l), which should be attained constantly and uniformly.

Finally, although the survival of HIV in water has not been investigated, studies on the effect of chemical disinfectants on the virus have shown an inactivation pattern similar to that of other enveloped viruses.[5]

In summary, spread of AIDS by water in properly maintained pools is exceedingly unlikely. But it may be prudent for individuals with open cuts, fresh abrasions, and other open skin lesions not to be treated in hydrotherapy pools and to avoid recreational bathing since it is conceivable that the virus might enter through an open lesion.

ARIE J ZUCKERMAN

Professor of Microbiology,
London School of Hygiene and Tropical Medicine,
London WC1E 7HT

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