# THE TIMES THURSDAY JULY 14 1988

## Off the beach



New York residents have been barred from their favourite beaches following contamination by

carelessly disposed hospital waste. They may have been less annoyed if they had read a recent report in the New England Journal of Medicine which showed that 5 per cent of patients attending an innercity accident and emergency department were HIV positive. The main risk to any New Yorker who strayed on to the beach would be by pricking themselves with contaminated needles or other instruments, or by standing with cut feet on blood-contaminated dressings. Swimming would pose no threat.

Although America is some years ahead of Britain in the Aids epidemic we should not be too complacent. A little publicized report from St Bartholomew's Hospital, London, involved anonymous testing of 1,200 women attending its ante-natal clinic. (The women did not know their blood was going to be tested, but their serum was carefully processed so that no particular result could be related to any one patient.) It produced nine positive results: of the 800 white or Asian women, three were HIV positive. Three of the 144 black women who gave their country of origin as being in Africa were HIV positive (one of them with HIV2, a related virus); two of the 167 black women born in the UK or Europe and one of the 89 from the Caribbean were HIV pos-itive. A further testing of 1,000 women's serum, not divided by country of origin, gave confirmatory results.

Health care workers can be at risk from HIV positive patients, particularly when undiagnosed. In America there are now 11 known cases of health care workers being infected at work.

DAILY MIRROR, Thursday, July 14, 1988

# BRITS FIND 'AIDS CURE'

THREE British scientists have made a major breakthrough in the search for an AIDS cure.

A team at the research centre at Porton, Wilts, has discovered a substance that kills the HIV virus. It could be ready for trials on patients in 18 months.

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#### Latent period

AIDS Monitor reports on the growing awareness that antibodies against the human immunodeficiency virus can take months and even years to develop (26 May, p. 40, 23 June, p. 37). A leading AIDS expert is quoted saying: "We're just beginning to realise that there is a true latency with antibody negativity." Another scientist says that such a long period between infection and seroconversion was not anticipated.

And yet it was! This development was anticipated by Michael G. Koch in his 1985 book AIDS—var framtid? (Swedish Carnegie Institute, Stockholm), and in the German translation AIDS—vom Molekul zur Pandemie (Spektrum der Wissenschaft, Heidelberg, 1987). The English translation of his book will appear under the title AIDS—from molecule to pandemic this year.

Koch's reasoning linked sporadic serological evidence with early indications of the role of the macrophage-cell lineage in harbouring and hiding the human immunodeficiency virus. New Scientist's readers know this scientist from his excellent article on the anatomy of HIV (26

scientist from his excellent article on the anatomy of HIV (26 March 1987, p 46).

At the 3rd International Conference on AIDS in Washington, A. Ranki et al presented a thorough study which should have left little doubt that long seroconversion latency periods are quite common. This work was published in The Lancet under the title "Long latency precedes overt seroconversion in sexually transmitted HIV infection" (12 September 1987, p 580-93).

Our multinational group in mathematical modelling began looking at the epidemiological consequences of a long latent period with presumably very low infectiousness as early as July 1987. It seems that the effects of even quite short latent periods are very marked. Our work suggests that a latent period induces an amplified delay in HIV spread of the order of magnitude of 10 times the length of the latent period itself.

We believe that long latency periods may play an important part in the long delay of the AIDS epidemic among heterosexuals. There is growing awareness that AIDS occurred in the sixties and perhaps even earlier in Europe and US ("Early AIDS in Norway", 16 June, p 30). We presented our results at the 4th International Conference on AIDS, in Stockholm last month. Jose J. Gonzalez AIDS-Spread Simulations and Projections.

Projections Agder College of Engineering Grimstad Norway

# Health officers 'altered' data on AIDS test

GOVERNMENT laboratory in Britain A Stands accused of altering scientific data relating to the accuracy of a newly developed blood test for antibodies to the AIDS virus. In consequence, the new test, instead of performing better than rival test kits in the same batch, appeared

to perform badly. This affects the chances of the test kit becoming a commercial success, according to the inventor of the test, Abraham Karpas.

Chris Smith, a Labour MP, wants the government to explain why the data have seemingly been altered. "This has important implications, especially since the test for antibodies to the AIDS virus carries such consequences for life insurance and such like," he told New Scientist.

Last year, the Virus Reference Laboratory in North London, part of the Public Health Service

Laboratory Service of the Department of Health and Social Security (DHSS), evaluated five test kits from different manufacturers. The evaluation is part of the government's attempt to ensure that there is a scientifically objective account of how many false positive and false negative results each test vields.

Scientists from the Virus Reference Laboratory carried out the evaluations on selected blood samples that in the past have proved difficult to assess for antibodies to the AIDS virus. The idea is that if the tests perform well on these notoriously difficult samples, they should work with improved precision on typical blood donations to the transfusion service.

After performing the evaluation on one of the test kits, which was designed by Karpas, an AIDS researcher from the University of Cambridge, the Virus Reference Laboratory sent an "interim report" to the DHSS. This interim report was written by Philip Mortimer, the director of the **Steve Connor** 

laboratory, and a researcher, Gary Bayliss. Mortimer also sent a copy of this interim report to Karpas for his information. Later, when Karpas received a draft copy of the



Abraham Karpas is aggrieved by "false negatives"

final report (which presented the results of the same evaluation in tables), he noticed discrepancies in the data from the two

reports.

The result, he says, is that his test, which performed well according to the interim report, appeared to perform badly in the light of data presented in the final report.

In the interim report, Mortimer and Bayliss say that in a group of 20 "potentially false positive" blood sera, the Karpas test gave one "equivocal" result. The test had correctly found the rest of the group negative. However, in a table of results presented in the draft final report, the Virus Reference Laboratory added a false positive result. As an equivocal result is treated in the evaluation as a false positive, or false negative, this means that the final report treated the Karpas test as if it had two false positives instead of one, so lowering the test's specificity.

Further anomalies exist. For instance,

the interim report says that the Karpas test found that one out of 15 weakly positive blood samples (which are truly positive but difficult to detect) was negative—a false negative in other words. However, the table in the final draft report includes an equiv-

ocal result as well as this false negative. Therefore, instead of there being one false negative, there are now two—which lowers the sensitivity of the test.

The interim report says that the Karpas test relies on subjective assessments by the people carrying out the evaluation. A second person ("reader examining the slides identified seven false positives and two false negatives, according to the interim report. However, a second table giving the assess-ment of "reader B" in the final draft report indicates that there was also an equivocal result in this group of samples—meaning that there were eight false posi-

Furthermore, the Virus Reference Laboratory has added another false negative in this table, bringing the total to three. Again, this has resulted in lowering the specificity and the sensitivity of the Karpas test.

Sensitivity is defined as the chance of correctly giving a positive result, whereas specificity is the chance of correctly giving a negative result. Karpas claims that the data in the interim report show that his test was 96.4 per cent sensitive and 99 per cent specific, which would make the test the best of the batch of five kits. But the final report quotes a sensitivity of 93 per cent and a specificity of 96 per cent, which makes the test appear much worse.

When Karpas objected to the data in the final draft report, the DHSS decided to withdraw its evaluation of his test from the official evaluation rather than publish the data as they appeared in the interim report. Karpas claims that this puts his test at a commercial disadvantage because laboratories are unlikely to buy a test kit that the DHSS has not evaluated.

When Smith asked the minister of health, Tony Newton, to explain the discrepancy in the two sets of data, replied, in a parliamentary answer: "The interim report was a summary which did not evaluate the findings in detail. The draft final report rested on the same data obtained at evaluation, but gave a fuller interpretation of it."

Karpas says that he does not dispute the right of the Virus Reference Laboratory to interpret the data in whichever way it chooses but, he says, the laboratory should not alter data from one report to another when there has been no further evaluation.

Mortimer refuses to discuss the details of the interim and final draft reports. "I'm not in the business of tampering with data. I've been over this with Karpas and if he wants to pursue this in the courts he can," he said. The two reports, he added, were never published so the data in question are not in the public domain.

A spokeswoman for the DHSS said that she could make no further comment other than to repeat Newton's statement.

### Actuaries eye up AIDS victims

A LL APPLICANTS for life insurance should be tested for antibodies to the AIDS virus, according to a group of re-searchers working for the British insurance industry. The latest report from the Insti-tute of Actuaries AIDS Working Party, says that AIDS poses considerable difficulties for insurance companies. One problem is that death certificates frequently fail to cite AIDS as the cause of death among people who have in fact died of it.

Another difficulty is trying to estimate at what stage of the disease a person will make a claim on policies called permanent health insurance, when the contract specifies that the insurance company will pay the salary of someone unable to work through illness. The industry wants to know whether to pay claims when the policy-holders know that they are positive for the human immunodeficiency virus (HIV), or when they have the first symptoms of infection, or when they become sufferers of AIDS itself.

The working party takes two extreme

scenarios: when only people with AIDS make claims, or when all people who are positive for HIV, including asymptomatic carriers, make claims. In the latter situation, the rate of insurance claims among 35-year-old men could equal and even exceed the number of claims made by people in their 60s.

The report says: "Ideally, from the point of view of protecting the portfolio, and in the interests of policyholders generally, all applicants should be tested for HIV antibodies...However, an alternative approach in the case of permanent health insurance business would be to introduce exclusion or cancellation clauses for AIDS or for HIV infection."

The working party recommends that if insurance companies pay claims to people who are infected with HIV, they must only do so for those with AIDS. Otherwise "the cost of additional sickness benefits would, at younger ages, equal or even exceed the cost of benefits payable during all other