SPECIAL REPORT

'A shocking lack of evidence'

The trial in Libya of six medics accused of infecting children with HIV ends next week. With the defendants facing possible execution, Declan Butler asked AIDS experts to assess the case against them.

A scientific report being used in the case against six foreign medical workers facing the death penalty in Libya is nothing but conjecture and supposition, say international experts. The evidence, commissioned from Libyan medics, has bolstered the charge that the six knowingly infected more than 400 children with HIV at the Al-Fateh Hospital in Benghazi in 1998.

The court has denied requests by defence lawyers to hear evidence from international experts. Instead, five Libyan physicians testified in August that they stand by the conclusions of their 2003 report, commissioned by the court in an earlier trial, and on 29 August the prosecution called for the medics to be given the death penalty. The trial is due to end on 31 October (see 'Countdown to a verdict').

With a guilty verdict looking likely, *Nature* obtained an English translation of the Libyan report, which has been key to the prosecution's case, and asked leading international experts to assess it.

"I don't see any evidence in it," says Janine Jagger, an epidemiologist and MacArthur fellow who heads the International Health Care Worker Safety Center at the University of Virginia in Charlottesville. "It wouldn't meet the lowest standards of epidemiological evidence for establishing any causal relationship."

In 2003, the court also ordered a report from Luc Montagnier, who discovered the AIDS virus and is president of the World Foundation for AIDS Research and Prevention, and Vittorio Colizzi, an AIDS researcher at Rome's Tor Vergata University. They concluded that the infections were caused by poor hospital hygiene, and started before the medics arrived in Libya (see "Montagnier and Colizzi's conclusions"). But the court threw out this report, on the grounds that the Libyan panel had reached the opposite conclusion. The panel had dismissed the external report as "hypothetical" and "lacking precision".

'That's tosh'

"The [Libyan] report refutes the Montagnier and Colizzi report on the grounds that there is no written record of the reuse of injecting equipment, and a blank denial that indwelling catheters were ever used," says Robin Weiss, an AIDS virologist at University College London. "It wrongly turns lack of evidence into evidence of absence."

The report argues that HIV and hospital hygiene were not a problem in Libya (the prosecution describes the Al-Fateh Hospital as a "model") and that the outbreak is so large that deliberate, malicious infection of HIV cannot be excluded. "I don't agree with that statement," says Weiss. "And even if I did, it does not amount to sufficient evidence to incriminate the accused medical staff."

The Libyan report also suggests that because the genetic sequence of the Benghazi HIV strain is different from any lodged in public databases, there are grounds for suspecting foul play. "That's tosh," says Weiss. Montagnier agrees, pointing out that the virus was a new natural recombinant of a highly infectious

Countdown to a verdict

The next, and last, session of the trial of five Bulgarian nurses and a Palestinian doctor, on charges that could see them face the death penalty (see main piece), is scheduled for 31 October, with a verdict expected days or weeks later.

The retrial began on 11 May, with a handful of sessions since, but little new evidence. The medics were condemned to death in May 2004, but the Supreme Court quashed their convictions last December, following international protests.

International pressure eased once a retrial was won, but Emmanuel Altit, head of the defence team, is pessimistic about the upcoming verdict, from the same Benghazi Criminal Court. "The decision will more than likely be a very bad one," he predicts.

As the trial draws to a close, many scientific and human-rights bodies have renewed calls for the court to hear independent evidence (see *Nature* **443,** 612–613; 2006). The New York Academy of Sciences and the Federation of the European Academies of Medicine have recently launched campaigns, and this week, *Science* will publish a letter calling for the release of the six, signed by AIDS researcher Robert Gallo and dozens of other scientists.

The six medical workers' retrial has been running since May.

M. TURKIA/AFP/GETTY

"It's exactly what we need, to pressure the Libyan authorities," says Altit. Even if too late for the current trial, such pressure might help influence the Supreme Court, who would hear an appeal if the medics are found guilty.

Altit believes the medics were charged so that officials wouldn't have to admit responsibility for the healthcare system's failings. But the case is embarrassing for the government, he says, so there is hope of a resolution. **D.B.**

S. NENOV/REUTERS

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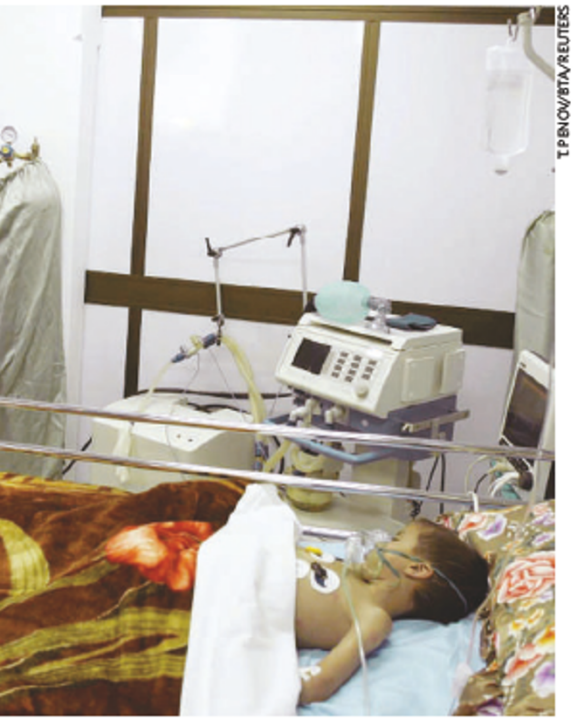
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Bulgarian president Georgi Parvanov (left) visits HIV-positive children in Benghazi, Libya, in 2005.

strain common in Central and West Africa, which has replaced most other strains in the region over the past few years.

In contrast, Weiss describes Montagnier and Colizzi's report as excellent. "Colizzi has done a really superb job in difficult circumstances," he says. After studying both reports, Weiss concludes: "There are no grounds for suspicion of deliberate infection by any staff, and strong evidence of hospital-acquired infection before the arrival, and after the departure, of the Palestinian physician and the Bulgarian nurses."

'Completely inadequate'

Jagger, an expert in occupational exposures to blood-borne pathogens, says she is astonished that the medics were even arrested, given the flimsiness of the prosecution's scientific evidence. In this sort of case, she says the minimum standard should be a thorough field study that tracks all medical procedures carried out during the outbreak, and calculates attack rates, epidemic curves and other standard epidemiology measures for inferring cause. She describes the Libyan data as "completely inadequate".

To firmly establish any cause, a case-control study should also have been done, Jagger adds, comparing risk factors and medical procedures used between the HIV-infected patients and a similar uninfected group to try and explain transmission. "Inexcusably, there has been no attempt by Libyan officials to conduct an epidemiological study that could establish a causal link between the infected patients and individual care givers."

Montagnier and Colizzi's conclusions

- Many of the children were also infected with hepatitis B and C, suggesting unsafe medical practices were common in the hospital.
- Two nurses at the hospital were infected with the same strain of virus as the children, again suggesting poor hygiene.
- The outbreak began by 1997, before the accused medical workers arrived in Libya.
- The virus responsible belongs to the HIV-1 subtype A/G, a recombinant strain common in Central and West Africa that is highly transmissible and virulent — not a genetically modified strain as suggested by the Libyan authorities.
- There is no evidence for deliberate injection of HIV-contaminated material.

Luc Perrin, a clinical virologist at Geneva University Hospital in Switzerland, who has treated many of the infected children, describes the Libyan report as "a lot of generalities that are not always correct". The report also fails to provide any evidence for its assertion that HIV infection has not been seen in children at other Libyan hospitals, he says.

Perrin is an expert on primary HIV infection. He has analysed samples from 148 of the infected children, collected in September 1998, and has obtained further data on 37 of them and 46 of their parents, when they were treated in Switzerland. Perrin says his genetic data support Colizzi's analysis, and that many of the 1998 samples have protein profiles corresponding to infections well over a year old: "I can tell for sure that the HIV infection cases occurred before September 1997 and the first cases most likely before 1996." The accused medics first arrived in Libya in March 1998.

"There are no grounds for suspicion of deliberate infection, and strong evidence of hospital-acquired infection."

The Libyan report is also silent on the prevalence of hepatitis at Al-Fateh Hospital and other Libyan hospitals, notes Perrin — who found that half of the HIV-infected children were also infected with hepatitis B or C. He says these high levels "clearly indicate" that the children were exposed to infection via contaminated blood or other medical material. Moreover, many of the children were infected with several subtypes of hepatitis, suggesting they were exposed to hospital contamination on multiple occasions, possibly when receiving vaccination injections. "If a single source of contaminated blood had caused the HIV outbreak, all the children would be infected by the same hepatitis C subtype," says Perrin. "What we observed can [instead] be explained by the reuse of syringes or poor sterilization procedures."

Perrin believes the most likely scenario is that a child who was infected with HIV in Al-Fateh in 1997 or earlier, returned to the hospital in 1998. "The child now is highly infectious, so poor medical procedures or sterilization procedures will rapidly translate into a number of new HIV infections."

'Sinister legacy'

Perrin was commissioned to write reports for the Libyan government in 2000 and 2001, and for President Muammar Gaddafi in 2004, but says that they received no response. "It is strange that I was asked by the World Health Organization representative of Libya to investigate, and received a grant for that, that I sent the reports accordingly and finally the report is not considered," he says. Testimony he submitted to the court was also rejected, he adds.

The purported 'smoking gun' in the Libyan report is the detection of HIV antibodies in vials allegedly found at one of the nurses' homes during a raid in 1999, but not tested until 2003. Both Montagnier and Colizzi have seen the results of a western blot, a test to detect proteins: they are "indeterminate", says Montagnier. "They say nothing," adds Colizzi. In 2002 Libya promised that they could test the samples independently, but neither has ever been given access.

Even a positive test could detect only antibodies to HIV. It would not show that the vials had contained the virus, points out Massimo Amicosante, a biologist also at Tor Vergata. "This is one of the main weak and controversial points of the Libyan report," he says. Finding the virus would require testing for HIV RNA, which has not been done.

After reviewing the evidence, experts are in no doubt as to the consequences of a guilty verdict. "If the accused are found guilty, it will be a travesty of justice," says Weiss. "Moreover, it would be foolhardy for any expatriate healthcare worker, whether from the Arab world or elsewhere, to work in Libya."

Jagger's conclusions are similar: "There is a shocking lack of evidence in this case," she says. "The Libyan government stands to carry out an act that would not be forgotten by the international healthcare community. Such a horrific humanitarian tragedy would stand for ever as a sinister legacy of the Libyan government." ■