India hit by contaminated blood scandal

A complaint that the Red Cross blood bank in Bombay supplied several hospitals with blood that was contaminated with HIV threatens to snowball into India's biggest blood scandal since the government made screening for HIV mandatory six years ago. A former Red Cross doctor has told government investigators that he has evidence that several hundred bottles of blood whose contamination status is unknown remain unaccounted for in the blood bank's records.

The controversy arose last month when blood bank officers complained to the government that Red Cross staff had supplied fifteen 300 ml bottles of blood known to be contaminated with HIV to city hospitals between February 1992 and July 1994. "It is about time authorities took note of the irregularities at the blood bank," said Dr Avinash Shejale, former medical director of the blood bank, who alerted authorities.

Dr Shejale wrote to the chairman of the Blood Transfusion Service of the Indian Red Cross Society in Bombay earlier this year, saying: "The techniques of blood collection, storage, inventory control, and processing were far from satisfactory."

The equipment for enzyme linked immunosorbent assay at the blood bank was not functional for at least 18 months. Internal investigations showed that the number of bottles received, tested, and supplied to hospitals did not tally with the final balance. "Blood bags marked for destruction because of contamination with HIV, hepatitis B virus, or both viruses are missing," said Dr Shejale, alleging that blood was being pilfered by staff for sale.

Dr Shejale, who was sacked by the local Red Cross management a day after the domestic press broke the news, said that he was transferred from a government hospital to the Red Cross blood bank in October 1994 and so could not be held responsible for events from 1992 until July 1994.

The Food and Drug Administration in Bombay is now investigating the affair to identify procedural and administrative lapses that led to the supply of the contaminated blood to hospitals. The agency has withdrawn the Red Cross blood bank's licence but has allowed it to continue providing transfusions to children with thalassaemia registered with the bank.

Hospitals in Bombay have reported that as many as 60 children with thalassaemia who regularly receive blood transfusions

Many Indian hospitals do not countercheck the blood they receive

have become infected with HIV. It is not yet known how many of these transfusions came from the Red Cross blood bank.

The Indian government made it mandatory in 1989 for all blood to be screened for HIV before use for transfusions. Private blood banks without testing facilities are expected to send samples to zonal screening centres. The Red Cross blood bank in Bombay, one of 16 zonal centres around the country, supplied nearly 30% of the blood required for transfusions in the city.

Dr Ishwar Gilada, secretary general of the Indian Health Organisation, a non-government medical agency, said: "Most hospitals do not countercheck blood-received from zonal testing centres. It is possible several hundred patients who received the contaminated bottles have become infected."

Dr Gilada said that the Indian Health Organisation was about to file public interest litigation seeking to "reinstate Shejale, make blood screening procedures more transparent, and press health authorities to bring the real culprits to book." The organisation also plans to appeal to patients who might have received blood from the Red Cross blood bank during the 30 month period to get themselves tested for HIV infection and hepatitis B—MEENAL MUDUR, freelance journalist, New Delhi

Report urges safety standards for dental anaesthesia

National safety standards to protect patients in Britain having dental treatment under general anaesthesia are urgently required, according to a report published last week. The quality of training, facilities, staff, and equipment varies from clinic to clinic and between hospitals in the NHS, says the report from the Clinical Standards Advisory Group.

The report warns that being unconscious during dental treatment carries special risks because the dentist and anaesthetist are both working around the mouth and airway, increasing the likelihood of breathing problems.

Functioning and up to date equipment as well as properly trained staff must be available to deal with problems, including dangerous reactions to anaesthetic drugs, when they occur. The report calls for national standards to be established to ensure that safety is the top priority wherever and whenever patients need a general anaesthetic.

"The biggest problem is the wide variety of anaesthetic practice," said Professor

Headlines

Polio outbreak hits Chechnya:

The war torn region of Chechnya is now fighting to control an outbreak of polio. There have been 70 cases at the main hospital in the capital, Grozny, since July. Health care has suffered as a result of the secessionist war, and many places lack facilities such as running water.

Former NHS workers to sue health authority:

During the first NHS buyout over 100 computer and support staff at the West Midlands Regional Health Authority transferred into the private sector, to QA Business Services, in 1989; they lost their jobs and pensions when the company subsequently collapsed. With the help of the union Unison they intend to sue for £3m.

US to cut disability benefits:

The General Accounting Office claimed to a House of Representatives subcommittee that thousands of Americans continue to collect disability benefits after they have recovered and that savings of \$1.7bn (£1200m) could be made by stopping them. The office claimed that the social security services had a bad record for reviewing the health of recipients and returning them to work.

Antiabortionists win Senate vote:

The US Senate voted to ban the coverage of abortions in federal employee health plans except in cases of rape or incest or when the mother's life was in danger. The bill was carried by a majority of six and will affect nine million Americans.

Battle continues against female genital mutilation:

The World Health Organisation estimates that between 85 million and 115 million girls and women have undergone female genital mutilation and suffer from its adverse health effects. An estimated two million young girls are victims of the practice each year, and the WHO is campaigning for its elimination.

Epidemic of salmonellosis hits south Florida:

As many as 1800 people in Palm Beach were affected by a single outbreak of salmonella infection. They had all eaten at the same restaurant—one of the oldest in the area. Health inspectors believe that the sources of the infection were uncooked chicken and improperly stored food.

Leo Strunin, professor of anaesthesia at the Royal London Hospital. "A lot of community dental anaesthesia is carried out by practitioners outside the mainstream of anaesthesia. It's very difficult for them to keep up to date with developments, and at the moment there's no way of keeping track of them and their work. One option would be for dentists to take responsibility for the standard of anaesthetists they take on and insist that they are accredited or at least have some recognised training in anaesthesia."

National surveys carried out for the report show that more than a third of dental general anaesthetics are given by doctors other than anaesthetists. A quarter of dental clinics surveyed had no electrocardiograph, the simplest form of heart monitoring, and nearly a fifth had no way of measuring patients' blood pressure during treatment.

The report criticises dentists for offering general anaesthesia when local pain killing injections would be safer and just as good.

According to the Faculty of Dental Surgery, general anaesthesia should be reserved for patients with learning disabilities, patients in whom attempts at local pain relief have failed, patients who are allergic to local anaesthetic, and nervous adults or children who are having multiple extractions.

Other recommendations in the report include better education for dentists and for patients, urging them to avoid unnecessary general anaesthesia; the development of standard consent forms; the promotion of specialist centres to provide dental anaesthesia.

The Department of Health has welcomed the report and endorsed the call for national safety standards, which it says is in line with government policies. But it says that any additional funds to improve standards will have to be found locally.—

ALISON TONKS, *BMJ*

Dental General Anaesthesia is available from HMSO bookshops, price £7.95.

Dentists should avoid unnecessary general anaesthesia

New York doctor guilty of murder in abortion death

A jury of five women and seven men took only two hours to convict Dr David Benjamin of murdering Guadalupe Negron on 9 July 1993. Mrs Negron, a 33 year old Honduran immigrant to the US and a mother of four, was about 20 weeks pregnant and allegedly paid \$800 (£530) for an abortion. Dr Benjamin, whose licence had been revoked in 1993 because of charges of gross incompetence and negligence in abortions performed on five women in 1990, was continuing to practise pending the outcome of his appeal.

In court the prosecution alleged that Dr Benjamin lacerated Mrs Negron's cervix and perforated her uterus while removing the fetus. About two hours after the procedure Mrs Negron was wheeled out of the examination room on a stretcher, bleeding profusely and complaining of pain. Dr Benjamin gave instructions that she should be cleaned up and then began another abortion.

Mrs Negron was placed in a recovery area, where she continued to bleed. No trained staff were available to observe her condition, and no equipment was provided to monitor her vital signs. She was noticed to be unwell and an ambulance was called.

On arriving at the centre a paramedic team from New York City's emergency medical service found Mrs Negron pulseless and not breathing. A tube had been inserted into her oesophagus rather than her trachea in an attempt to resuscitate her. As Mrs Negron was being placed on a stretcher the paramedics noticed a large pool of blood under her body. She was pronounced dead on arrival at the hospital.

The jury, in finding Dr Benjamin guilty of murder, rejected the lesser charges of manslaughter and criminally negligent homicide. They found him guilty "of having performed [an abortion] in a reckless and grossly negligent manner, and with depraved indifference to the life of his patient." Dr Benjamin, who faces from 25 years to life in prison, will be sentenced on 12 September.

According to Queens district attorney Richard A Brown, this is the first case in New York of a doctor charged with murder in connection with the death of a patient during a medical procedure. There has been only one other case nationwide of a doctor being convicted of murder in connection with the death of a patient. In 1989, in Los Angeles, Dr Milos Klvana was convicted of the deaths of eight infants and a fetus for his actions in trying to deliver babies at home.

Michele Allen, a spokesperson for the National Right to Life Committee, an anti-abortion group, said, "Unfortunately, we see this type of thing happening all over the US. Just because abortion is legal doesn't mean it's safe.—FRED B CHARATAN, freelance journalist, Boca Raton

WHO asks world court's opinion on nuclear weapons

The International Court of Justice in the Hague will have to rule on the legitimacy in international law of nuclear weapons after a request from the World Health Organisation. The world court, as it is also known, is the judicial wing of the United Nations and, as such, the highest international court in the world, although it is not recognised by all countries.

The case, beginning on 30 October, will answer WHO's question: "In view of the health and environmental effects, would the use of nuclear weapons by a state in war or other armed conflict be a breach of its obligations under international law including the WHO constitution?"

So far 44 states, including Britain, have submitted evidence. About two thirds of these states will argue that atomic warfare is illegal. A spokesman for the Foreign Office said that Britain would argue that nuclear weapons have had a beneficial effect in deterring war for the past 50 years. He said, "Our contention is that there's no question to be answered. The court has its place, but we really think its involvement in this issue is superfluous. We, and the other responsible powers, recently had a ringing endorsement from 178 countries in the form of the renewed non-proliferation treaty, which extended indefinitely the right of the nuclear powers to keep their weapons."

George Farebrother, British secretary of the World Court Project, which lobbied the UN and the WHO to raise the issue, disputes Britain's claims about the illegitimacy of the court and the purpose of the non-proliferation treaty. "There is nothing in the treaty which says that anyone has a right to keep nuclear weapons. It recognises the situation but does not condone it. The whole purpose of the treaty, as it expressly states, is to work towards the elimination of these weapons. For Britain to argue otherwise by pulling out one clause and relying on that against the spirit of the thing is bad faith. If Britain believes the world court has no jurisdiction in this, why did the government make submissions to the court?"

Britain has already made clear that it will ignore any ruling by the court that questions its right to hold nuclear weapons. Nevertheless, such an outcome would add to international pressure for a ban on such weapons similar to the Chemical Weapons Convention. It would also undermine the legitimacy of the current unwritten qualification for membership of the Permanent Security Council—namely, the possession of nuclear weapons.

Asked whether Britain would attempt to deny the UN court's legality or simply accept that it was violating international law to carry on anyway, the spokesman for the Foreign Office said: "We'll cross that bridge when we come to it."—OWEN DYER, freelance journalist, London

Britain maintains that nuclear weapons have deterred war

REX FEATURES

Study criticises protocols for labour

A high proportion of the protocols provided by hospitals for women in normal labour are unsatisfactory, according to a new report from the Clinical Standards Advisory Group. The report cites regular vaginal examination during labour as an example of a routine procedure performed "without providing evidence of benefit."

The advisory group took a representative sample of UK maternity units (98 hospital and 29 GP units) and examined the protocols used in the units. It also performed a prospective study of 3160 women delivering babies in the hospital units. Among the 64 protocols the group reviewed it found 48 that were sufficiently detailed for analysis of the management of normal labour and to provide a set of common principles.

All the protocols emphasised that labour should be managed with care and respect for the woman's wishes.

But the report says: "Some procedures are apparently recommended almost routinely. The assumption that they are necessary, in the interests of the child and woman, may be questioned. For example regular vaginal examinations (at least every 2 or 4 hours), rupture of the membranes at a cervical dilatation of 3-4 cm and the management of the second stage of labour."

In addition, says the report, there were considerable variations about when specific procedures should be performed, and the indications for performing an episiotomy were not given in any of the protocols that were analysed in detail.

Many of the protocols, says the report, seemed to be aimed at new members of the junior medical staff "rather than providing multidisciplinary guidance on good practice for the unit as a whole."

Criteria for inclusion in the prospective study were strict. Mothers selected had to

be NHS patients having their first baby, delivering in hospital with an uneventful antenatal period, after 36 completed weeks of pregnancy with the fetal head presenting. There were several other criteria for exclusion. As a result, the type of deliveries studied represented only 16% of all deliveries in England and Wales.

A total of 3149 live births occurred in the prospective, hospital based study and no infant deaths were recorded, although 12 babies were diagnosed as having a congenital anomaly. Most mothers (71%) were delivered by a midwife, with nearly one third delivering in a dorsal and one third in a sitting position.

Comparison of the expected number of vaginal examinations indicated by the protocols with the number actually performed during labour showed that 71% of women had more vaginal examinations than expected. Wide disparities were also found between recommendations in protocols on fetal monitoring and actual practice. All protocols recommended the use of partograms throughout labour, whereas 87% of women had their labour monitored in this way.

The Clinical Standards Advisory Group recommends a central register of maternity services of all kinds in the United Kingdom and suggests a further study, on women having their second babies. It also recommends that guidelines for normal labour should be developed by the Royal Colleges of Midwives and of Obstetricians and Gynaecologists in conjunction with the Royal College of General Practitioners and should be evaluated.

It identifies two urgent areas for research: "the optimal time to perform an artificial rupture of membranes once labour is established" and a study in response to the finding that "the episiotomy rate in women from the Indian subcontinent and the Orient seemed high."—CLAUDIA COURT, BMJ

Women in Normal Labour is available from HMSO bookshops, price £7.95.

Action against contraceptive implant threatened

Lawyers in Britain are threatening litigation over subcutaneous implants of the contraceptive levonorgestrel (Norplant), already the subject of group legal actions in several states in the US. They allege that insertion of the implant, which goes under the skin of the upper arm, by untrained doctors has led to painful and difficult removals and has left women with scarred arms. They also claim that insufficient warnings have been given about possible side effects, such as mood swings and continuous vaginal bleeding.

The Medical Defence Union said that it had been notified about a handful of potential claims against general practitioners. A solicitor in Nottingham, Paul Balen, is investigating two dozen cases with a view to a group action against Hoechst Roussel, which markets the implant in Britain. The progestogen only implant, which lasts five years, has been used by 40 000 British women since its introduction in 1993. In the US it has been on the market since 1991.

The implant has highlighted a gap in Britain's drugs licensing laws. Hoechst says that it wants implants to be inserted only by the 8000 doctors who have been trained in the technique, but once a product is licensed the company marketing it has no power to restrict its use to trained doctors. Only one in five general practice surgeries has a doctor trained in inserting the implants, though most of the larger practices do, according to Hoechst.

Last month the company wrote to gynaecologists advising them not to attempt to extract the implant unless they had been trained in the removal technique. Caroline Foster, one of the women considering legal action, has undergone two operations to remove the implant, both of which were only partly successful. The first left her with two of the six flexible rods containing the hormone still in her arm. After the second operation, carried out under general anaesthesia last week, she was told that the final rod would have to remain because it was embedded in muscle. Ms Foster, aged 25, said that she bled for up to 30 days at a time after the contraceptive was implanted and never went longer than eight days without bleeding. She had since found out that her general practitioner, who inserted the implant, was not trained to do so.

Tony Eaton, a spokesman for Hoechst, said: "You only get a problem removal if there's been a problem insertion. We believe Norplant should only be put in by trained doctors, but once a product licence is approved for general release to GPs and family planning doctors it's not within the pharmaceutical company's power to restrict it."

Another of Paul Balen's clients developed severe acne on her face. Her hair started falling out, she lost 13 kg, her breasts shrank, and she developed facial

hair. She suffered tearful outbursts of depression and mood swings, which are not mentioned as side effects on the product leaflet for patients. When she tried to have the implant extracted she found that it had attached itself to the muscle in her arm and part of the muscle had to be removed.—CLARE DYER, legal correspondent, *BMJ*

Clinton aims to ban under age smoking

The Clinton administration has taken a definitive stand against teenage smoking in the US, with the president proposing a set of regulations to end the sale of cigarettes to anyone aged under 18. President Clinton's decision follows weeks of discussions between Congress, the administration, and tobacco companies and comes on the heels of the Food and Drug Administration's finding that nicotine is an addictive substance.

Stating that the number of under age smokers was increasing considerably—one third more eighth graders (13 year olds) and one quarter more 10th graders (15 year olds) smoke than four years ago—and that one in five high school seniors (17 year olds) is a daily smoker, President Clinton authorised the Food and Drug Administration to "initiate a broad series of steps all designed to stop sales and marketing of cigarettes and smokeless tobacco to children."

Mr Clinton called on those who produce and market cigarettes to "take responsibility for your actions, sell your products only to adults, draw the line on children, show by your deeds as well as your words that you recognise that it is wrong as well as illegal to hook one million children a year on tobacco."

The new proposals include a ban on all cigarette vending machines and self service displays; allowing sales of cigarettes and smokeless tobacco only to customers who can prove that they are over 18; a ban on sales of individual cigarettes and packs of

fewer than 20 cigarettes; and a ban on brand name advertising at sporting events and on products not related to tobacco use, such as T shirts and hats.

The proposals also include a requirement that tobacco companies pay for an annual \$150m (£100m) advertising campaign aimed at stopping young people from smoking; a ban on outdoor tobacco advertising within 300 m of schools and playgrounds; a restriction on advertising in publications that reach a significant number of children and teenagers to black and white text only, with no pictures; and transferring the onus for under age sales to manufacturers, distributors, and retailers.

Reaction from tobacco companies was swift. Five tobacco companies, including Brown and Williamson Tobacco Corporation, whose parent company is the London based BAT Industries, filed suit immediately to block the Food and Drug Administration in the federal district court in Greensboro, North Carolina, home state to many tobacco plants. Also included in the suit was an advertising agency, Coyne-Beahm.

The plaintiffs claim that the Food and Drug Administration is impeding their ability to compete in the marketplace and infringing their rights by restricting advertising. The suit challenges the administration's authority to overstep its bounds of regulating medicine, medical products, and pharmaceutical companies by exercising jurisdiction over tobacco.

It is now up to Congress to determine whether the proposals will go forward, be amended, or be blocked completely. Many government watchers predict that Mr Clinton may have compromised his chances of reelection as both Democrats and Republicans who hail from the southern tobacco states have denounced his proposals.

However, Virginia's Republican representative, Thomas J Bliley Jr, the chairman of the House Commerce Committee, which has jurisdiction over the Food and Drug Administration, said that it was up to the courts and not Congress to decide how far the administration could go.—TERRI L RUTTER, freelance journalist, Boston

"Wrong as well as illegal"

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