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Clinical Use of Blood, Blood Products and HIV–A Legal Review

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ABSTRACT

Human immunodeficiency virus [HIV], the cause of AIDS, was initially confined to homosexual men and needle sharing drug addicts. Later, it was diagnosed in persons who had received medication through intravenous or intramuscular injections and blood transfusions also. The danger of infection with HIV was realized and the regulation for marketing and the use of blood and blood product were introduced internationally to prevent it. This article will discuss effective monitoring of the existing procedure for marketing, supply and therapeutic use of blood and blood products and its legal implications.

Key words: Human immunodeficiency virus, acquired immunodeficiency syndrome, blood, blood products

INTRODUCTION

When a retrovirus, now known as the human immunodeficiency virus [HIV], was discovered in 1984 as the presumed cause of acquired immuno deficiency syndrome [AIDS], tests for evidence of infection were conducted in these patients and in other haemophiliac men with and without symptoms of AIDS. It was found that many of them showed serological evidence of infection with HIV, and also with hepatitis B, C and some other viruses. This had led to further developments and regulations which raise new medical, legal and economic problems in the field of medical services.

In western countries, all bloods used for transfusion and for preparation of concentrates and other products have been treated by heat and chemicals to destroy HIV and other viral contaminants. Tests have been conducted by manufacturers and regulating agencies to ensure the safety of the end products. It is now known that some of the adverse changes reported in haemophiliacs and persons receiving multiple transfusions are due to substances in or derived from the blood or blood products, independently of HIV. Governments of several countries, have agreed to various scales of compensatory payments without admitting liability

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to haemophiliacs who are presumed to have acquired infection with HIV or have developed AIDS as a result of transfusions and the use of blood products.

Regulation is generally well intentioned in democratic countries and designed to protect public and private interests. In the former case it is intended to protect the general public from exploitation by suppliers with some sort of market power or monopoly. In health care, professional qualification is a form of public regulation designed to impose minimum standards for treatment but also a form of private regulation because it enhances the economic rents of the regulated: the health care staff. The public and the private interest can easily conflict, especially where there is a market power, in the form of information asymmetries, as characterised by health care markets, between the producer [physician] and consumer. In the case of AIDS, the reliance of governments on questionable information from medical experts has been shown to be a likely explanation for resource misallocation.

MARKET FOR BLOOD

As medical technology has advanced and new treatments have become available the demand for health care services has increased in all countries. Economic growth has raised living standards and facilitated an increase in supply of health care facilities. The market for transfusable blood is no exception. Blood is a commodity similar to many others but it has come unusual supply characteristics. For example experience of countries in which a price mechanism operates suggests strongly that persons who are happy to make themselves available as blood donors no longer came forward to donate. Blood derived from donors who have every incentive to lie about their previous health record and who are encouraged to sell their very substance on more occasions than is good for them or for their eventual recipients is also less healthy. With these prophetic words Cooper and Culyer (1) reviewed the economic, as distinct from the market, approach to the allocation of the resource blood. Countries allowing blood donors to be paid, such as the United States and many third world countries, have had the worst experience with transfusion and haemophilia associated AIDS cases. Just those people who are most likely to be carrying multiple, concurrent infections are the people who have greatest incentive to donate their blood [for cash]. The "gift" of blood in this case places two people in intimate contact who otherwise would probably avoid one another at all costs. There are many critics of the ethics of paying for blood, especially when it is used by the poor as a form of income support.

In India blood is obtained by voluntary donation. It can be viewed as an act of pure philanthropy. It can also be viewed as a selfish act; part of an individual's utility function whereby the donation gives satisfaction to the donor as a 'feel good factor' or even perhaps moral superiority. It can also be viewed selfishly as a form of insurance because the donor may at some future date be a recipient. In France, the high rate of contamination was made worse by the long-term use of blood from prisoners. It has been established in the courts that there was a delay in the screening of blood in that country, following identification of HIV in

1984. Three health officials, including the former head of a state monopoly blood transfusion centre, have been given four-year custodial sentences for fraud and criminal negligence.

BLOOD PRODUCTS

The risks from transfusions are increased when blood products are used. To prepare these concentrates, large pools of blood from assorted donors are required. The numbers of persons involved may run into many thousands, from more than one pool and sometimes from more than one country. There is no regulatory requirement for manufacturers - as in other industries producing biological products for public use to advise users and recipients. Doubtless this position was facilitates by the asymmetry of information, and hence the trust relationship between patient (consumer) and physician (producer). Other aspects of corporate governance in non-market institutions in the context of AIDS have been analysed by Craven and Stewart (1995). Because of the superiority of concentrates over whole blood in controlling bleeding in haemophilia, they began to be used on a very wide scale, with few if any medical cautions, soon after they became available in the 1970s. The process of concentration did not then exclude viral contaminants, while the sources of supply and manufacture, mainly in the USA, ensured that there would be many drug addicts in the pool.

Since 1985, when the risk of AIDS was recognized and acknowledged by the manufacturers and health authorities, blood and blood products have been treated with heat or chemicals or both to exclude viral contamination. If done properly, the risk of HIV infection is removed. Yet, in 1993, despite all the information about how blood products can be treated to avoid contamination, patients in Germany were infected by products of the firm UB Plasma after quality control standards had not been adhered to. The apportionment of legal responsibility in many of these matters has been decided only in the French courts. Most governments have accepted culpability implicitly by introducing compensation schemes. Meanwhile, clearly there are enormous financial implications for providers and receivers of this aspect of medical care.

THE LEGAL OUTCOMES

Governments in most countries have recognized responsibility for those contracting antibodies to HIV following transfusions of blood and blood products, and most have introduced compensation schemes of varying magnitude and complexity. European countries such as Denmark, Switzerland, Spain, Austria, Belgium and Ireland have provided, in varying degrees, government subsidies for those developing AIDS and HIV seropositivity. Germany is the only European country where the insurance companies have paid full compensation to those developing AIDS from contaminated blood and blood products. Such a regulation is also required in Asian countries including India in addition to the Consumer Protection Act.

In the UK over 1,800 people are believed to have contracted HIV infection as a consequence of receiving transfusions of contaminated blood. Of these 592 are haemophiliacs (586 male), while 1,235 (1,224 male) are sero-positive to HIV (PHLS surveillance Protection, September 1996). The

UK Government announced in November 1989 a compensation scheme for haemophiliacs infected with HIV from contaminated blood or blood products. A further scheme, was announced in February 1992, for those infected with HIV from contaminated blood resulting from National Health Service blood transfusions (Financial Times, 1992). These schemes exclude any admission of liability on the part of the UK government. The then health secretary, William Waldgrave, admitted that whilst the government did not accept the argument for a general scheme of no fault compensation for medical accidents, HIV infection from contaminated blood and blood products is a special case. The option of litigation in the English courts, in the form of an action in negligence against either the blood transfusion service or the appropriate government department, is likely to be too expensive, time consuming and difficult for plaintiffs seeking to show either a breach of the duty of care or causation. Nevertheless, suits have been filed and support from Legal Aid funds has been granted for some test cases in recent months. The possibility of using the Consumer Protection Act 1987, with its concept of strict liability, is an alternative to exgratia compensation payments in India.

NEED FOR REGULATION

Advances in medical and surgical treatments have increased the demand for blood and blood products for necessary and life-saving purposes. This demand has been accompanied by increased supply and use. With many processes, products and services, regulation is deemed necessary. In the UK there has been little governmental action, by way of legislation, in the area of AIDS and HIV infection. To date there have been the Public Health Regulations 1988, made under the Public Health Act 1984 dealing with such issues as medical examination of AIDS patients. The AIDS Act 1987 deals with reporting of AIDS statistics, and the Health and Medicines Act 1988 prohibited the sale of do-it-yourself HIV testing equipment.

The objective of regulation is to protect public and private interests. In practice the efficacy of all regulation is likely to be compromised because of inappropriate choice of regulator, the likelihood of unnecessary or harmful regulation and probable eventual regulator capture. Regulation of blood and blood products was, prior to 1985, insufficient, ineffective and too weak to ensure uncontaminated supplies. The procedures which were technically feasible and available for testing for safety were also compromised. This was certainly the case with transfusable blood, where the required regulation should have come about before the discovery of HIV. Even without formal regulation, the need for self-regulation in the form of screening for other contaminants should have been, and probably was, recognised by medical doctors several years before it occurred. The desire to be politically correct was certainly a contributory factor in explaining why donors were not asked pertinent questions about sexual and social behaviour before 1985. In the case of blood products, it was only the recognition of the risk of hepatitis which eventually led to an exclusion by screening.

It would need to be determined that the causal agent was present in the injected

blood or concentrate given to that case. There are very few instances of this being done or even attempted. Finally, it would need to be established that diagnosis of AIDS had been confirmed. This currently depends upon seropositivity plus a variable array of secondary symptoms and signs. Many articles questioning the specificity of both the ELISA and Western Blot HIV antibody tests, especially in the presence of other infection and immunological disorders, have been published in the Lancet and elsewhere (2-4). In addition to this are the cases where signs of AIDS have developed in recipients of blood and blood products which are HIV antibody-free, but contain other organisms and contaminants which remain after heat treatment. Even if physicians knew that contaminated blood and blood products had been administered to patients, the issue becomes whether physicians believed that the possibility of recipients contracting AIDS involved an unacceptably high risk. Hence it may not be possible to demonstrate acutus reus. At the same time, a civil action in negligence is likely to founder on one of the four grounds. The first would be a failure to establish either a breach of the duty of care owned to the plaintiffs by the defendants, for example, the manufacturers of blood products, or medical personnel. The second would be a failure to establish a causal link between this breach and the resultant damage. The third would be a failure to establish that infectious HIV was transmitted. Finally a civil action would be likely to founder because of a failure to establish that AIDS would result following transmission of infectious HIV.

The circumstances which resulted in a lack of formal regulation are complex and seem to have been a combination of medical uncertainty, incompetence, negligence and capture. Governments throughout Europe have subsequently acknowledged culpability by implementing compensation schemes. Without such schemes two pressure groups would probably have been organized, one representing haemophiliacs infected by blood products, the other representing those infected by contaminated blood transfusions. Another explanation for the implementation of compensation schemes (without admitting liability) is that such schemes do not put the blame on specific individuals or organizations. Whether these outcomes were the intended objective governments' compensation schemes can only be the subject of conjecture. That the issue has been defused is the outcome, regardless of motive.

CONCLUSION

This review article has shown that medical specialists in the find practice ill-equipped to advise speculative and subject to disagreement between themselves. The full political, legal and financial implications of the medical matter relating to AIDS, blood and blood products await fuller disclosures of clinical and other outcomes of current measures of intervention. The aftermath of the accidents described above, it is not unreasonable to expect that the medical profession itself will undertake a more responsible role in monitoring and regulating procedures which they alone can authorise and assess.

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