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The blood transfusion service and the National Health Service

In 1974 the Medical Research Council's blood transfusion research committee expressed its concern at the continued inability of the UK transfusion services to meet the blood product needs of patients with haemophilia.[1] This view was reiterated in 1977 by Dr Rosemary Biggs, on behalf of the haemophilia centre directors, and concern was also expressed at the predicted rapid rise in demand, the high cost of commercial products, and their higher risk of transmitting viruses when compared with products derived from voluntary blood donors.[2] In 1974 the average annual amount of factor VIII used per patient in the UK was 12 500 IU, of which almost a third was from commercial sources; in 1985 the corresponding figures for patients in England and Wales were 30 000 IU and two thirds respectively. In Scotland, on the other hand, in 1985, though the annual usage per patient was identical, there were no commercial purchases. The consequences of these figures in terms of infection with the human immunodeficiency virus in this group of patients is self evident.

The sustained failure of the transfusion services in England and Wales, known as the National Blood Transfusion Service, over the past two decades to meet the needs of the National Health Service extends far beyond the provision of factor VIII concentrates. In London and the home counties there are chronic and occasionally serious shortages of blood, which have an appreciable impact on both the NHS and a large uncontrolled private sector. There are many areas of the country in which the supply of platelet concentrates from regional blood transfusion centres is restricted for operational reasons, and there are severe shortages throughout England and Wales of specific immunoglobulin preparations and albuminoid products.

In common with many parts of Europe, the conduct of affairs at the clinical interface of blood transfusion throughout the UK leaves much to be desired.[3] There is widespread evidence of inappropriate supervision of the use of blood and blood products by the hospital blood banks, which is often left to technical staff. As a consequence there is both overprescribing and underprescribing and thus unnecessary exposure of patients to iatrogenic hazards and waste of precious, often irreplaceable, and costly resources.[4]

Many general managers of regional health authorities must view their regional blood transfusion centres with some concern. These centres continue to produce therapeutic products against no nationally agreed specifications, yet are within nine months of new legislation on product liability. They are aware of severe shortages in adjacent regions but have no mechanism to give or receive help. For supplies of blood to the private sector general managers are expected to ensure that priority is given to the NHS yet know that their task and that of others is virtually impossible. Many regional general managers must be increasingly aware that the function of their transfusion centres is central to the viability of the Blood Products Laboratory at Elstree yet there are no mechanisms which permit the regions to have a voice in the management of the Blood Products Laboratory. Some may be aware of and concerned at the infrequency with which the DHSS convenes its Blood Transfusion Service Advisory Committee and the indifferent quality of its business, whereas others will be bemused by the departure of their staff to meetings of the National Blood Transfusion Service directors where important decisions are made that have vital policy implications, which are accepted by some regional health authorities and not others.

What went wrong?

What went wrong with the National Blood Transfusion Service—which in the 1950s and 1960s was regarded as pre-eminent in the world? There is no simple answer to this question but part is that the notion that the service was pre-eminent in the world? There is no simple answer to this organisation: it is a myth, a central government fantasy. The transfusion services in England and Wales are managed by regional health authorities and any past pre-eminence, which has certainly now been largely lost, arose as a result of the efforts of distinguished research workers working in isolation in regional centres or independent institutes. The National Blood Transfusion Service is a fragmented and disorganised shambles. Thus it has been possible, and on many occasions, for severe shortages of blood to arise in one part of the country while less than 10 miles away (in another region) the regional health authority is dismantling part of its blood collection programme because of sustained excesses. Efforts by regional transfusion centre directors to help colleagues in other regions have often been made difficult by finance officers, who understandably have sought to recoup their region's financial expenditure. Somehow the concept of the "gift relationship" of the voluntary donor and the needs of the patient have been lost by a service which in truth is a series of tight compartments with little or no facility to work together. This system of management is wholly inappro-

priate for modern blood transfusion practice; it is both wasteful and dangerous.

Undoubtedly over the past 25 years there has been a remarkable failure of senior civil servants and therefore politicians of all political colours to recognise the unique and strategic importance of the nation's blood donors, their donations, and the associated work of the blood transfusion services. It has not been simply a matter of budgetary restrictions but primarily a lack of interest, vision, and commitment. Perhaps the most striking example of this has been the circumstances surrounding the capital expenditure of over £60m on the building of the new Blood Products Laboratory at Elstree. The need arose because of years of central managerial neglect, made possible by the strict use of crown immunity. Notwithstanding this, the old facility was eventually declared unfit for good manufacturing practice by the Department of Health's medicines division. The response has been a crash building programme which is strategically seriously ill conceived, so that there are no facilities for operational back up in the event of planning or production failure. This error of judgment will play a key part in preventing England and Wales ever achieving and sustaining self sufficiency in plasma derived products and thereby ensure the need to maintain a strong commercial presence in the UK. Moreover, no investment has been made in the provision of pilot plant or research laboratories at the Blood Products Laboratory—a prerequisite to the survival of any modern pharmaceutical manufacturing establishment.

Enough plasma for Elstree?

The massive expenditure at Elstree has not been associated with central action to ensure that regions will provide sufficient plasma. No decisions have been made to ensure that this new facility will operate within the code which pertains to its counterparts in industry—no immunity from prosecution for sustained failure to meet the requirements of the Medicines Inspectorate and a statutory requirement to obtain manufacturing and product licences. In contrast, substantial efforts have been made by the DHSS to ensure that the Blood Products Laboratory will operate in all other respects as a commercial organisation. The most obvious example has been to devise cross charging schemes between the Blood Products Laboratory and regional health authorities and between transfusion centres and districts. These schemes are unlikely to achieve their objective—budgetary control of the use of blood products at the bedside—but they will cost money to operate and raise some serious moral questions which could have a deleterious impact on the voluntary blood donor programme. There is also evidence that the DHSS has developed policies which will ensure that over the next 20 years the Blood Products Laboratory will move its operational centre of gravity away from servicing the NHS's needs to making money in the international market place for plasma products.

Some of our honourable institutions have contributed to the demise of the National Blood Transfusion Service over the past three decades. The insistence by the Royal College of Pathologists that young doctors wishing to be consultants in regional transfusion centres must be subject to professional examinations which are almost identical to those for hospital based haematologists has proved to be a major factor in its decline. The facility of this college to play a key part in England and Wales (but not Scotland) in the appointment of consultants in regional transfusion centres has ensured that its policy will be enforced. This policy, as many regional general managers are now aware, has resulted in serious difficulties in recruiting high calibre doctors into transfusion centres and as a consequence has had an impact on the quality of management and research. Of no less importance was the disbanding of the Medical Research Council's blood transfusion research committee in 1982 at a time when in many other countries efforts were being made to earmark and enhance investment in blood transfusion associated research.

Finally in this catalogue of tribulations, the directors of the UK transfusion services have been increasingly aware, despite the statement by the Under Secretary of State for Health and Social Security in 1980,[3] that the present government is no longer committed to self sufficiency in blood and blood products. At an operational level this view has the support of several distinguished directors of haemophilia centres, who resist the notion that their prescribing practices might become dependent on a state monopoly—the National Blood Transfusion Service.

A foundation for change

In the early 1980s senior UK transfusion centre directors, conscious of the recommendations that were to emerge from the Council of Europe, took a series of steps which have laid the foundation for change. They sought and obtained the support of the Royal College of Physicians (Edinburgh) to establish a group which would report to the council of this college on the development of an examination in transfusion medicine specifically designed for doctors wishing to work as consultants in regional transfusion centres. Of no less importance has been the recent decision by the Royal College of Pathologists to set up a committee to examine the training of haematologists in hospital based blood transfusion practice. In 1983 the transfusion centre directors initiated moves to establish the British Blood Transfusion Society and took particular care to ensure that its membership consisted of both medical and scientific colleagues. This society is now flourishing with an increasing overseas membership.

The transfusion centre directors also persuaded the DHSS to establish a study on the future operational management of the National Blood Transfusion Service. The DHSS management team has now completed its studies and is preparing its report. It is widely believed that its members have been seriously concerned by many of their findings and recognise there is an urgent need for change. The only option that will provide the quality of service the health services in England and Wales need, and the one that will give the blood donors an assurance that their gifts are appropriately used, is the creation of an integrated National Blood Transfusion Service which is removed from direct regional health authority funding and managed by a new and separate health authority which includes the Blood Products Laboratory. This new organisation must operate in the future beyond the reaches of crown immunity and be subject to the disciplines imposed by licensing authorities. It must have identified academic units committed to substantive research programmes, many of which are designed to ensure that we compete effectively with industry in terms of product quality and availability. Above all, the overriding operational priority must be a commitment to provide blood and blood products to the NHS that is based on patient need in a cost effective manner. Current trends which view the voluntary blood donor as a source of marketable commodities need to be challenged and debated.

Many good friends and colleagues in England and Wales may take exception to criticisms of the National Blood Transfusion Service by the national medical director of its wee sister in Scotland. Undoubtedly my critique is partly based on "self" interest: the continued decline of the National Blood Transfusion Service is now having a destabilising effect on the Scottish service. Nevertheless, the overriding reason for this cri de coeur is my belief that unless the vital importance of the blood transfusion services to the well being of the health services in the UK is better understood, and the decline in performance arrested, then within the next decade the consequences will be grave.

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2 Biggs R. Haemophilia treatment in the United Kingdom from 1969 to 1974. *Br J Haematol* 1977;35:487-504.
3 *Study of the current position of training programmes for future specialists in blood transfusion in Council of Europe member states and in Finland.* Report Prepared by a Study Group. Strasbourg: Council of Europe 1985.
4 Jones J. Abuse of fresh frozen plasma. *Br Med J* 1987;295:287.
5 Adjournment debate. *House of Commons Official Report (Hansard)* 1980 Dec 15.

Cholesterolosis: a physical cause of "functional" disorder

Does cholesterolosis of the gall bladder produce symptoms or is it merely a pathological curiosity? This question has been debated ever since the enigmatic condition was first described by Virchow more than 100 years ago[1] and has still not been satisfactorily resolved. While some observers have shown that patients with cholesterolosis may have severe symptoms that are usually relieved by removing the gall bladder,[2-4] others have suggested that the changes in the gall bladder are merely a coincidental finding in patients with unexplained abdominal pain.[5-7]

The pathological features of cholesterolosis are not disputed. It is an acalculous biliary disease of the gall bladder characterised by the accumulation of lipids in the mucosa of the gall bladder wall.[8,9] The characteristic golden yellow lipid deposits in the mucosa have led some observers to call this the "strawberry gall bladder" appearance.[10] The aetiology of cholesterolosis is not fully understood, but several theories have been proposed. One is that the mucous membrane synthesises the surplus lipids[11]; another is that the submucosal macrophages fail to metabolise or excrete cholesterol absorbed from the bile.[12] The human gall bladder can absorb small amounts of cholesterol from bile,[13] and patients with cholesterolosis have a high (supersaturated) biliary cholesterol content.[9,14] Supersaturated bile is present in both cholesterol cholelithiasis and cholesterolosis, and these two conditions often coexist.[14] The mucosal changes therefore might arise simply because of increased cholesterol uptake from bile containing extra cholesterol.

Cholesterolosis is common, and surgical studies show a prevalence varying from 9% to 26%,[2,4,15,16] while a necropsy study reported the prevalence to be about 12%.[17] Surgical studies show that cholesterolosis occurs commonly in women aged 30 to 50,[4,16] although the lipid deposition may occur in patients as young as 13.[18]

As cholesterolosis is common and yet few patients undergo cholecystectomy the disorder clearly does not often cause severe symptoms,[2] but a few patients do have symptoms, which are often severe. In a study of 269 symptomatic patients who underwent cholecystectomy for cholesterolosis Salmenkivi found that 96% had abdominal pain.[2] The pain was often colicky and severe, was situated in the right hypochondrium or epigastrium, and had persisted for more than two years in most patients. Other studies have confirmed that colicky abdominal pain is the main symptom.[15] Salmenkivi also found that nausea and vomiting (61%), dyspepsia (60%), and selective food intolerance (92%) were common, and the foods most often implicated were fatty or fried foods, cabbage, peas, and citrus fruits. Clearly this condition may be mistaken for the irritable bowel syndrome.

Cholesterolosis can be diagnosed only with difficulty because oral cholecystography will at best detect only 30% of cases,[19] and the diagnostic rate for oral and intravenous cholecystography may be as low as 5-10%.[2] Preoperative ultrasonography is of limited use, but intraoperative ultrasonography has a higher diagnostic yield for acalculous biliary disease and may be useful in patients undergoing laparotomy for unrelated conditions. One study in morbidly obese patients undergoing gastric operations showed the technique to be safe and accurate, with a false positive rate of less than 2%.[20] Normal results of ultrasonographic or cholecystographic examination, or both, thus do not exclude cholesterolosis, and other techniques for diagnosing this condition must be used. Symptomatic patients with acalculous biliary diseases seem to have their pain reproduced by an intravenous injection of cholecystokinin.[21-24] After cholecystectomy most of these patients find their symptoms relieved, and histological examination of the gall bladders shows abnormalities in them all. A recent double blind study from Newcastle comparing infusions of saline and cholecystokinin showed that cholecystokinin could reproduce the pain in patients with acalculous biliary disease; cholecystectomy cured them all.[24] The problem with the cholecystokinin test is, however, that cholecystokinin also causes contraction of the gut smooth muscle and may cause intestinal colic.[25] Ways of improving the test have been advocated,[26,27] and laparoscopy may also be helpful in showing adhesions around the gall bladder—because adhesions may be present in half of patients.[24]

Thus cholesterolosis should be considered in patients with symptoms suggestive of biliary disease and with no abnormality on cholecystography and ultrasonography. Laparoscopy or a cholecystokinin provocation test (with or without cholecystography), or both, may make the diagnosis, and cholecystectomy should provide symptomatic relief. This approach is necessary to prevent patients being mistakenly labelled as having "functional disorders" and thereby suffering unnecessary symptoms (often for many years) or, alternatively, being submitted to an unnecessary operation when they have an irritable bowel.

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