German blood scandal

EDITOR,—The attention of the media was concentrated recently on the problems faced by patients who had received blood and blood products collected by the German company UB Plasma's According to reports in the lay press, UB Plasma is undergoing criminal investigations with regard to having distributed blood collected from paid donors who had been inappropriately selected and whose blood had been inadequately tested, if at all, for HIV. A similar scandal seems to be brewing in Italy, with suggestions that the Mafia has been involved in the sale of blood.²³

The media interest kept the National Blood Transfusion Service busy on 5 November, when we received calls from numerous radio stations and television channels. In addition, worried patients and donors jammed our switchboard and contacted clinicians in hospitals for reassurance. The scare was heightened because a commercial firm that had obtained plasma for fractionation from UB Plasma was forced to recall two products legitimately imported to Britain-namely, normal immunoglobulin for intramuscular injection and albumin. The recall was totally unrelated to the German scandal: it was due to a failure of good manufacturing practice rather than a fear of transmission of virus. The irony is that Britain did not need to import albumin and normal immunoglobulin because there are plentiful stocks of these products prepared in Britain from plasma collected from unpaid voluntary donors, all tested by the blood transfusion service.

The committee of ministers of the Council of Europe considers that self sufficiency in blood products is one of the basic conditions for minimising the hazard of transmission of infectious diseases by blood transfusion.4 The committee has stated clearly that, until self sufficiency is achieved, health authorities may decide to authorise the importation of blood products. For ethical and security reasons it recommends that blood products are imported from countries where the legislation and practice governing the protection of donors and recipients meet the criteria laid down by the council. Therefore health authorities should, in particular, ascertain the origin of blood and plasma that have been used in the preparation of products. Hence the Council of Europe advocates the use of blood products manufactured from donations from unpaid, altruistic blood donors, whose lower rates of infection with agents transmitted by transfusion compared with rates in paid donors is copiously attested to.56 Unpaid denors have nothing to gain from donating their blood; they are therefore less likely then paid donors to conceal higher risk social or sexual behaviour that would lead to their exclusion as

Modern methods of viral inactivation for plasma products are good but not necessarily perfect, and several cases of transmission of virus by products treated with currently available methods have been reported.⁷⁵ Viral inactivation substantially reduces the viral load, but if the load is high in the original plasma pool the risk of the end product being infectious will also be increased. Obviously, the risk is greatly reduced when only volunteer unpaid donors are used. Isn't it about time that doctors and pharmacists started demanding to know the origin of the plasma used to manufacture the blood products they use rather than trying to make

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minimal cost savings, sometimes under the pretext of clinical freedom?

The cost of collecting blood from volunteer unpaid donors will always be higher than that of collecting blood from paid donors, who are prepared to be at the disposal of the collection agencies, thus maximising output. The ultimate cost of transmission of a viral agent by the transfusion of contaminated products could obviously, however, be much more than the savings accrued by the purchase of commercial products. Surely clinicians will realise that paying a slightly increased cost for added safety could avoid considerable future expense in health care and litigation. If patients receiving these products were adequately informed and knew of safer alternatives would they not demand them?

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Impact of menopausal symptoms

Effect on quality of life exaggerated

EDITOR,—We congratulate Edel Daly and colleagues on their innovative methods of assessing quality of life.¹ Population surveys have shown, however, that about four fifths of women have symptoms at the menopause but only one fifth think that discussing them with their doctor is worth while.² Prospective studies show that the menopausal transition itself has little impact on women's psychological wellbeing. In contrast, women attending a menopause clinic (a select group) report significantly higher levels of psychological distress and more negative beliefs about the menopause than other women.'

The authors asked women to note the impact of menopausal symptoms. Flushes and night sweats are the only specific symptoms that characterise the menopause, but a much broader use of the term seems to be adopted in this article: "severe menopausal symptoms, which covered psychological and social as well as physical symptoms of this condition." It is not surprising that some women rated the impact of menopausal symptoms as severely affecting quality of life if the symptoms were so defined.

The use of hypothetical models may encourage patients to think, "If I answer by minimising possible symptoms will I be denied a prescription for hormone replacement therapy?" High expectations of hormone replacement therapy and increasing anxiety about the menopause lead many women to desire a prescription.

No mention is made of the high response to placebo of all menopausal symptoms, even flushes. Double blind placebo controlled trials show that many women react positively to the idea of hormone replacement therapy rather than to the drug itself. We regret the authors' conclusion that "The use of hormone replacement therapy to relieve symptoms may result in substantial improvement in quality of life." For a few women who experience disabling symptoms such treatment is extremely valuable. For most women, who do not have any symptoms or have mild symptoms, hormone replacement therapy has little effect on their present quality of life but prevents osteoporosis and probably also ischaemic heart disease.

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Study perpetuates false impression

EDITOR,—Edel Daly and colleagues claim that quality of life may be severely compromised in women with menopausal symptoms and may substantially improve with hormone replacement therapy.¹ However, the methods that they used to select the women studied and to make measurements have several limitations.

Their sample may have included some women who had had an oophorectomy, had had an early menopause, were not yet perimenopausal, or were postmenopausal. In addition, women attending menopause clinics differ from women recruited from general practice in that they are likely to have a negative view of the menopause. No sociodemographic data are given in the paper. The researchers did not ask why the non-users were not taking hormone replacement therapy: they may have had contraindications, been people who do not complain, been lacking in knowledge, or have consulted unsympathetic doctors. The sample was therefore extremely heterogeneous.

The ratings of the descriptions of "typical mild and severe symptoms" are derived from clinical