Drug donations must be strictly regulated

Georgia has tight guidelines

EDITOR,—The economic and social structure of Georgia has deteriorated since independence in April 1991. The government continues to struggle with the change to a market economy and is under pressure because of falling living standards.¹ The official health care system is deteriorating and becoming increasingly dependent on humanitarian aid, including pharmaceutical donations. Despite the existence of clear guidelines, such as those of the Christian Medical Commission² and World Health Organisation,³ large quantities of expired or inappropriate drugs are found among the donations from various donors, including humanitarian organisations, pharmaceutical industries, and governments.

In 1994 one humanitarian aid organisation received, without prior notice, 20 tonnes of silver sulphadiazine ointment, which had expired one year before. The quantity was so large that it took months to incinerate. During a recent visit to one of the government's warehouses Médecins Sans Frontières recorded 12 tonnes of unnecessary or expired drugs. About 9 tonnes had expired before arrival or was due to expire within three months of arrival.

In July last year the donation of a big shipment of short acting insulin that arrived three days before the expiry date prompted the Ministry of Health to formulate an agreement concerning donations of pharmaceutical supplies. By signing this agreement organisations working in Georgia commit themselves to a version of the WHO's guidelines on donations of drugs, which have been adapted to the Georgian requirements. These ensure that medicines that are brought into the Republic of Georgia are on Georgia's essential drug list; are from a reliable producer (the WHO's certificate must be enclosed); arrive in Georgia at least one year before their expiry date; are labelled with their generic (international non-proprietary, or INN) names; are labelled in the Georgian or Russian language; have not already been issued and returned to a pharmacy; are in unimpaired packages (no loose tablets or blisters); and are given with guarantees of continuity.

Donors should know that the donation of inappropriate or expired drugs causes more harm than good. It is encouraging that some governments, as in Georgia, develop policies on donations

of pharmaceutical supplies. These initiatives should be supported.

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- 2 Christian Medical Commission. *Guidelines for donors and recipients of pharmaceutical donations*. Geneva: World Council of Churches, 1990.
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Assortment of drugs causes more problems than it solves

EDITOR,—It is estimated that between 5% and 40% of the drugs that are sold in pharmacies in western Europe are not used.¹ Although the legal framework in the European Union prohibits the collection and export of drugs that have been issued to patients and returned to pharmacies, practice shows that there are many loopholes in the legislation and control.

Several non-government organisations have carried out public campaigns to promote the collection of unused drugs for humanitarian purposes, with slogans such as "giving an unused drug will save the life of a child in the Third World." Thousands of people are involved in drug donations through non-government organisations. Unselected drugs continue to be sent to Africa, Asia, and eastern Europe. Long experience with these donations has shown that the distribution of unused drugs that have been collected is inappropriate.

Inappropriate drug donations have led to many problems. In 1994 the World Health Organisation's office in Zagreb issued a press statement urging potential donors to "think before you send."² A large part of the donations was unusable or even dangerous. Last November a Dutch team from Médecins Sans Frontières stationed in Djibouti was confronted with an epidemic of cholera after flooding in the region. The team received a donation from a French non-government organisation which contained more than 100 kinds of unsorted and partly expired drugs collected in France. The mixture contained antidiarrhoeal drugs such as loperamide and kaolin. Twelve co-trimoxazole tablets were the only drugs in the box that could be considered to be of potential use in the epidemic. No oral rehydration solution or intravenous fluids were included.

Last year a Dutch non-government organisation proposed to study the possibility of collecting and distributing unused drugs for humanitarian purposes. After questions in parliament the Dutch minister of health and the minister for development cooperation clearly stated that the collection of unused drugs is not acceptable according to the WHO's guidelines, to which the Dutch government subscribes. Whether the Dutch position will be a trigger for stricter enforcement remains to be seen.

The public also needs to receive this message. In the past, several Dutch humanitarian non-government organisations have collected unused drugs. Although their policies changed long ago, they still get regular requests from the public to

accept or give unused drugs that have been collected.

The situation in Europe is far from perfect, and it would be worth while if other governments followed the Dutch policy. Professional organisations should take a similar position. Humanitarian non-government organisations should adopt a written drug policy based on the provision and rational use of essential drugs obtained from a reliable source.

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- 1 Pour une Information Médicale Ethique et le Développement. *Les médicaments non utilisés en Europe: recueil, destruction et réutilisation à des fins humanitaires*. Paris: PIMED, 1994.
- 2 World Health Organisation. *Think before you send*. Zagreb: WHO Regional Office for Europe, 1994. (Press release.)

Hospital acquired infections could still be prevented

EDITOR,—P J Sanderson correctly states that many local hospital acquired infections arise because of interventions such as urinary catheterisation or tracheal intubation and infers that infection rates reflect the number of patients subjected to these procedures. Sanderson concludes that these infections are inevitable and not so amenable to conventional infection control. We have a wider view of the role of infection control in reducing hospital acquired infection.

Firstly, infection control is not simply a matter of preventing cross infection. Promoting good practice, such as encouraging the removal of urinary catheters, falls within the remit of the infection control team. This has an impact on the "irreducible minimum" rate of hospital acquired infection. As an example, Haley *et al* showed that rates of pneumonia and urinary tract infection fell in hospitals with good infection control programmes but rose in those with ineffective programmes.²

Secondly, while it is true that infections may arise from the patient's bacterial flora, the organisms responsible are often more resistant or virulent ones acquired by the patient through cross infection in the hospital. Recent outbreaks of respiratory infection due to *Staphylococcus aureus* resistant to methicillin have highlighted this problem.³ Infection control measures such as antibiotic policies, handwashing, and isolation can prevent the emergence and spread of these organisms.

Thirdly, though the concept of an irreducible minimum level of infection is readily understood, it is hard to define or quantify.

To assume that observed rates of hospital acquired infection are close to this minimum risks complacency and lowering of standards. In a recent policy document, the Department of Health estimated that "currently 30% of hospital acquired infection could be prevented."⁴ Clearly, the irreducible minimum is some way off for most hospitals.

Advice to authors

We prefer short letters that relate to a recently published article and we are unlikely to publish letters longer than 400 words and containing over five references. Letters may be shortened. Your letters should be typed with double spacing and include a word count. All authors need to sign the letter and provide one current appointment and address. We encourage you to declare any conflict of interest. Please enclose a stamped addressed envelope if you require an acknowledgment.

In short, the rates of catheterisation and intubation influence the infection rate in a hospital but are not its only determinant. The rate of puerperal sepsis is related to the birth rate, but that did not stop Semelweis from trying to eradicate puerperal sepsis. It is nihilistic and inaccurate to suggest that current rates represent an irreducible minimum. Infection control teams should prevent hospital acquired infection through education and promotion of good practices. If some categories of infection are seen as inevitable it will be hard to motivate staff to follow guidelines, standards will fall, and the infection rate will rise. We suggest that most hospital acquired infection is preventable and that infection control teams should continue to try to prevent it.

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- 1 Sanderson PJ. Preventing hospital acquired urinary and respiratory infection. *BMJ* 1995;310:1452-3. (3 June.)
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Increasing the number of organ transplants

EDITOR,—Colin Francome and colleagues advocate the system of organ donation known as presumed consent or opting out.¹ I recognise that some people do not believe that the NHS's organ donor register will be effective, but most of those working in organ transplantation and the public generally have welcomed it. This is borne out by the encouraging response so far: in just eight months over one million people have applied to join the register.

I note the results of the questionnaire that Francome and colleagues sent to nephrologists. A more recent survey conducted by *Which?* magazine, which is disinterested over the issue, showed that over half of the general public was actively against opting out.

Francome and colleagues assert that the medical profession is in favour of opting out. This assertion seems to be based solely on the results of the questionnaires returned by the nephrologists. The wording of that questionnaire seems to ask if they would favour a system that allowed people to opt out of organ donation. It does not include the important point that under such a scheme anyone's organs can be taken if he or she has not opted out. Every indication suggests that the medical profession is divided. Indeed, the British Transplantation Society, which is made up mainly of transplant surgeons, has indicated that it is opposed.

Although not required to do so by law, doctors always consult relatives before retrieving organs. Even if the law was changed to permit organ retrieval unless the person concerned had opted against it, doctors would be extremely unlikely to change their practice of consulting relatives. We cannot force doctors to take organs against the wishes of relatives. In some cases in the rest of Europe doctors have taken organs against the wishes of relatives, causing severe distress to the relatives and bad publicity, which does the cause of organ donation no good.

Francome and colleagues recommend the system of "weakened presumed consent," which is supposedly followed in Belgium. Officials in the Department of Health recently visited Belgium to look at its system and found that the Belgian public is not well informed about it, donation has risen greatly only in places where donors' families are not well counselled, and the system has inadequate safeguards. I am far from convinced that this change would further the cause of organ donation.

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Oral versus intravenous antibiotics

Exclusion of sickest patients invalidates study

EDITOR,—Robert Chan and colleagues conclude that oral antibiotics are as efficacious as intravenous antibiotics in treating lower respiratory tract infections acquired in the community.¹ Because of the design of their study, which excluded patients who were severely ill, any other conclusion would be surprising. Patients with lower respiratory tract infection and community acquired pneumonia are already treated at home with oral antibiotics by general practitioners, with a mortality of 0-3%.^{2,3} Furthermore, the British Thoracic Society's guidelines for community acquired pneumonia recommend oral antibiotics in moderate illness.⁴ It is therefore arguable whether there was ever any clinical need for intravenous antibiotics in Chan and colleagues' study. It follows that comparison between the three groups is clinically invalid. Many of their patients probably did not even require admission to hospital in view of the absence of radiological changes (58%) and severe illness.

I agree, however, that the route of administration of antibiotics is often inappropriate in hospital. Last year I audited the hospital management of community acquired pneumonia and found that the initial antibiotic or its route of administration was inappropriate in 27% of cases. The main reason for this was poor assessment of the severity of illness on admission. As a result of this audit a management protocol has been formulated and distributed to all junior staff.

The optimal management of lower respiratory tract infection, including community acquired pneumonia, is well established.^{4,5} What is needed is audit showing that best and cost effective practice (including appropriate admission to hospital and the prescription of appropriate antibiotics) is being carried out. Educating doctors on the accurate assessment and management of this condition is essential for this aim to be achieved.

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- 1 Chan R, Hemeryck L, O'Regan M, Clancy L, Feely J. Oral versus intravenous antibiotics for community acquired lower respiratory tract infection in a general hospital: open, randomised controlled trial. *BMJ* 1995;310:1360-2. (27 May.)
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Authors' reply

EDITOR,—We agree that intuitively one would expect the oral route to be appropriate for antibiotic treatment of most lower respiratory tract infections acquired in the community. However, pharmaceutical advertising and, more importantly, practice in many hospitals lead to an inappropriately large number of patients receiving antimicrobial drugs intravenously (communications from doctors since our paper was published and Tsang's own observations confirm this view). What was lacking was a clinically valid study comparing the different routes of administration that would also provide evidence to support many of the current guidelines, which for some recommendations rely on consensus opinion rather than published data.

We agree that, when there is optimal support for both patients and their medical attendants, many patients could be cared for in the community. However, many patients with concomitant medical conditions or who are debilitated and elderly (the mean age in our study was 64) and live on their own are admitted to hospital because their general practitioners are unable to provide regular domiciliary visits. Coincidentally our hospital was participating in a study of the appropriateness of care, which confirmed that facilities were used to an internationally acceptable level of need for admission. The 6% mortality in our study suggests that the infections were severe enough to justify active medical and nursing care. Normal chest radiographic findings in a patient with a fever, a raised white cell count, and clinical signs does not exclude infection and many not be a valid reason to refuse admission to hospital. Furthermore, we did not influence the decision to admit to hospital.

Tsang misses the "positive" findings of our study—namely, that the oral route is more convenient for patient and staff and leads to earlier discharge from hospital. We agree that education to get this message across is appropriate.

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Provision of services for cleft lip and palate

EDITOR,—We wish to add a footnote to our paper on the provision of services for cleft lip and palate, published last year.¹ In it we drew attention to fragmented services with low volume operators and a lack of leadership from the specialty groups involved. Subsequent correspondence highlighted the threat of a war between competing surgical disciplines.²

Happily, this situation has now been corrected with the drawing up of national guidelines by a multidisciplinary steering group, which included consumer representatives, under the aegis of the Royal College of Surgeons (available from the college's Surgical Epidemiology and Audit Unit on request). These guidelines emphasise the necessity of strictly coordinated care by a regionalised hospital and community based team in which the principal providers—surgeon, orthodontist, and speech therapist—treat no fewer than 30 new patients annually. There are several reasons for