Correspondence

New therapeutic products and difficult decisions

Sirs,

There are people dying from haemophilia every day in parts of the world where factor VIII is unobtainable or there are no resources to purchase it from a national health expenditure of only a few pounds per year. The United Kingdom is fortunate; we have a National Health Service and an annual gross domestic product per capita in excess of US$18,000, which is large enough to resource it. Green and Akehurst's paper1 about recombinant factor VIII (rFVIII) was intended to stimulate debate in an area where many of the variables on which to make rational decisions are unknown.

The presence of prion agent in blood products has yet to be proved or disproved, and it may be several years before the facts are established. On the other hand, we do know that the cost of rFVIII is subject to market forces: the NHS could buy in bulk in the same way that childhood vaccines are purchased, and the possibility of removing VAT is a political decision, not a matter awaiting years of scientific scrutiny.

The health benefits of rFVIII are to be found in two areas. The first is in the mental health of haemophiliacs and their families. The stress consequent on previous blood contamination episodes with hepatitis B, HIV and hepatitis C viruses should not be underestimated. The second area is, of course, the one that will not be clear for 20 years or more, the avoidance of nvCJD. By the time we know about the magnitude of the risk it will be clear that we have either over-reacted or been negligently incompetent. Personally, I would rather be guilty of over-reaction – but that is the nature of debate, is it not?

Reference


Reply

Sirs,

The letter by Dr Schweiger once again raises a number of important issues related to the introduction of new technologies, in this instance recombinant factor VIII. First, the letter puts things in perspective and highlights that in the developed world we are able to provide the safest of therapeutic products for the treatment of haemophilia, products associated with only very small risks.

Second, the letter draws attention to the possible presence of prion agents in blood products, and we agree that this issue is of great importance. However, it is an issue associated with recombinant factor VIII, which at present contains human blood products, as well as plasma-derived factor VIII. We, of course, agree that the risk to the lives of the population should be minimized. However, Dr Schweiger overlooks the important point that a decision to spend resources on more expensive blood products for uncertain gain automatically takes the resources from areas where there is currently known gain. The problem for purchasers is to weigh up those gains and losses, in the context of uncertainty, to purchase the best outcome for the population.

We have enormous sympathy for the experiences of haemophiliacs, some of whom have suffered appallingly in the past, but the fact remains that a decision to provide them with more expensive factor VIII is a decision to devote more resources to a group that already receives a great deal of support at the expense of other, less visible, less organized groups of patients from whom the resources will be taken.

This dilemma is common for all purchasing decisions, and our purpose in writing our paper was to highlight the difficulties purchasers face in dealing with uncertainties, especially where new therapeutic products are introduced and supported with guidelines ill-equipped to address the potential patient benefits.

Amidst all of the unknowns and hypotheticals, the purchasers of health care are charged with making difficult decisions. We recommend that where guidelines are presented for the introduction of new therapeutic products, the needs of purchasers are considered. Such consideration will ease the implementation of new products and deliver any available benefits to the patient with greater speed.

Yours faithfully

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© Faculty of Public Health Medicine 1999
Body mass index: a comparison between self-reported and measured height and weight

Sirs,

Anthony Hill and Julian Roberts report that self-reported heights and weights are unreliable and if used for monitoring health targets should be treated with caution. However, the data presented do not support this conclusion.

First, there is no indication of how the initial sample size was chosen. The authors do not mention a power analysis and no allowances are described for potential drop-out of subjects. Although the sample may have been representative of the district under study, it is unlikely that it is representative of the population of England and Wales. Therefore extrapolation of data to give national inferences is invalid.

Second, the chosen study design was inadequate to accurately compare self-reported and measured height and weight. One particular flaw is the time delay, between questionnaire completion and measurement, of up to four months. Both weight and height can change drastically in such a period of time, especially in growing adolescents. Therefore, it was inadvisable to include people under the age of 21 in the study. However, if the design had allowed for immediate measurement after self-reporting, inclusion of this age group would have been valid. Although the authors acknowledge this problem, it is surprising that they chose this approach, particularly when the design of a previous study, quoted in their paper, seemed more appropriate.

Finally, guidelines exist for statistical methods and presentation of results, and these are accepted by many journals, including the Journal of Public Health Medicine. The authors quote t-values, but these are meaningless without the associated degrees of freedom. It would have been more helpful to adhere to the guidelines and quote actual p-values to two significant figures. The results should be treated with caution, as multiple t-tests were carried out. The authors omitted to mention this in the text. In light of this, perhaps only p-values <0.01 should be considered as significant. However, we accept that these changes would not alter the conclusions of the paper.

In conclusion, we believe that the very low participation rate seriously compromises both internal and external validity. In view of this, no useful conclusions can be drawn, and as such the impact of this study is limited.

References
Minor surgery in general practice

Sirs,

Lesley Finn and Sarah Crook found major failings in infection control in the 11 general practices they audited, and recommend the introduction of agreed minimum standards. Infection control does not form a significant part of the core curriculum for nursing or medical training, so it is hardly surprising if practices do not understand basic principles. We are surprised that any of the practices audited had written infection control policies or guidelines for inoculation injuries. Every practice in West Pennine has these documents, regularly updated, because we have provided them. Written policies are not of themselves sufficient, and practices need to be supported with continuing training. In recent years, training has been provided for practice staff by the Communicable Disease Control Team at West Pennine Health Authority, and we are now developing a network of link nurses to assist in maintaining standards in primary care. This continuing education is reflected in the results of recent audits, which compare very favourably with those from Dorset (Table 1). Most of the failures we found would incur little or no cost to rectify.

We find that most practices are eager to receive infection control training and information in an accessible format. Much of the standard documentation is confusing and obscure to non-experts in the field. Finn and Crook comment on Health Technical Memorandum (HTM) 2010 on maintenance of benchtop sterilizers. A simplified version of this (MDA DB 9605) has now been produced specifically for people using steam sterilizers, and we recommend that our practices follow this guidance.

Finn and Crook comment on practices’ failures to meet minimum requirements under HSG(96)31 but they do not say whether any of the practices audited were undertaking secondary care procedures (as opposed to minor surgery). In our experience, very few practices do so and are therefore not subject to HSG(96)31. Rather than setting minimum standards for a tiny minority as recommended by Finn and Crook, we believe that infection control in primary care can best be addressed by educating everyone. This needs a high level of commitment by the Communicable Diseases Team; we consider this time well spent.

References

3 Department of Health, Medical Devices Agency. The purchase, operation and maintenance of benchtop steam sterilizers (MDA DB 9605). 1996.

Yours faithfully
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Resurgence in gonorrhoea and syphilis in UK might be due to cyclic patterns of variations

Sirs,

I have read with great interest the review by the PHLS Centre, published in your Journal. In view of the recent trends in
attendance rates of out-patients with gonorrhoea and syphilis in the UK, I would like to express my concerns regarding the underlying statistical methods and, therefore, results and hypotheses as presented. The authors have reported only the surveillance methods used but not the statistical ones. None the less, they have observed, for the first time since 1973, peaks in the number of cases for both diseases in 1989. The authors have suggested that the continuing increase in gonorrhoea since 1989 is largely due to the increasing rates in men aged over 25 with the latter being, probably, homosexuals. Although this might be true for gonorrhoea, what about the peak in syphilis? Moreover, the authors have not commented on the temporal dynamics of syphilis at all.

I would like to note that overall temporal patterns of outpatient attendance rates in the UK might be considered similar to those of population-based incidence rates in Slovakia.\(^1\) Incidence data on gonorrhoea and syphilis were analysed as obtained from the paper by Hegyi et al.\(^2\) One similarity with UK data is that the trend of total incidence rates for syphilis in Slovakia has decreased since 1947 (study period till 1994). The difference is that the overall trend of gonorrhoea in Slovakia has increased since 1959 (study period till 1992) but individual values have started to decrease mainly since 1970. However, both trends were best fitted by non-linear equations that suggested a significant role for the variations in the complex dynamics of disease time series in Slovakia.\(^2\) A peak in variations of incidence rate for syphilis in Slovakia has been observed in 1971–1974 (probably, the second similarity to the UK\(^1\)) but not in 1989 (the second difference from the UK\(^1\)). Peaks in incidence rates of gonorrhoea in Slovakia have been observed in 1980–1983 (probably, the third difference) and 1989–1993 (the third similarity). Consequently, the above variations were analysed by a periodogram regression analysis (PRA). It should be noted that PRA was used successfully to reveal cyclic patterns of variations in time series of malignant melanoma of the skin in the UK and elsewhere,\(^3–6\) as well as of meningococcal infection.\(^7\) When applied to the above data from Slovakia, PRA revealed three cycles in variations of incidence rates with periods \(T = 12, 16.75\) and 25.25 years for syphilis, and a cycle with a period \(T = 14.75\) years for gonorrhoea (all at \(p < 0.05\)). It is probable that cycles could be revealed for data in the UK but, without additional analyses, it might appear that both peaks in 1989 were not real, considering the overall dynamics of time series.

I would like to suggest that the specialists from the PHLS Communicable Disease Surveillance Centre in the UK should use more powerful statistical techniques in their studies. When analysing time series data, the authors should not rely on graphical presentation of rates (even on a log scale; see Fig. 1 in Ref. 1) and percentage distributions, but they should also apply linear and non-linear regression models over time as well as sophisticated time-series methods (Box–Jenkins, ARIMA, spectral analysis, fast Fourier transforms, PRA, etc.) to more deeply analyse trends and variations. It should be noted that deterministic patterns of time series such as cyclic variations may not only allow for better forecasting of rates but will also contribute to the understanding of prevalence of risk factors and their role in the epidemiology of sexually transmitted diseases. For instance, apart from the explanation of resurgence of STD in the UK with the increase in homosexual men, another (or additional) consideration might be the temporally correspondent influence of different environmental factors (temperature, humidity, atmospheric pressure, heliogeophysical activity, chemical pollution, etc.\(^4–7\)) on the activity of pathogens, immune response and susceptibility of individuals to infection.

References


Yours faithfully
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Reply

Sirs,

Dr Dimitrov has expressed his concerns on the statistical techniques used for the interpretation of trends in cases of gonorrhoea and syphilis seen at genitourinary medicine (GUM)
clinics in England, presented in the ‘Quarterly Communicable Disease Review October to December 1991’. The paper in question presented a descriptive overview of recent trends in sexually transmitted infections (STIs) in England and Wales between 1981 and 1990 (with brief reference to trends in gonorrhoea since 1973). In 1992, data on diagnoses at GUM clinics in England and Wales were available only at the aggregated national level, and as such were not amenable to rigorous statistical analyses of long-term trends. For data from 1995 onwards, since when computerized data have been available at the individual GUM clinic level, we have used Poisson linear regression analysis to estimate underlying trends in cases of syphilis, gonorrhoea, genital chlamydia, genital herpes and genital warts seen in genitourinary medicine clinics in England. We believe that this is the most appropriate technique for examining annual changes over the short term. The strengths and limitations of these data, and the statistical methods used to interpret them, are discussed in the relevant papers.

References

Yours faithfully
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The two communities in Northern Ireland

Sirs,

In their paper on deprivation and ill health in Northern Ireland, O’Reilly and Stevenson seem to have obfuscated about one potential independent variable – family size.

In their discussion section, they say it is debatable whether the higher percentage of overcrowded houses in the Catholic population represents ‘real disadvantage or a propensity of Catholics to have larger and younger families’.

For anyone with knowledge of Northern Ireland this comment would seem a mite disingenuous. Their next paragraph refers to findings from the USA that although Catholic family size in the 1970s was higher than that of Protestants, by the late 1980s this had reversed. The USA is not Northern Ireland, and why shift the discussion there when there are available data on the situation in Northern Ireland?

I recall a presentation to public health staff by a lecturer from the Department of Geography at the New University of Ulster in the early 1980s. His findings showed that, on average, Catholic family size was twice that of their Protestant counterparts.

It would be a reasonable supposition to make at the genesis of such a study that having a large number of children might have some influence on unemployment, deprivation and ill health. However, in their study the authors seem to have avoided such analysis. The authors note at the beginning that ‘Northern Ireland is a very polarized society’. Might I suggest that it is not likely to become less polarized if there is any perception that what should be objective and scientific studies are biased, and seem to avoid addressing facts that might be unpalatable to one particular ‘side’.

Reference

Yours faithfully
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Reply

Sirs,

In respect of Dr Sloan’s criticism of the authors’ handling of the ‘overcrowded households’ variable we would make the following points:

(1) Townsend popularized the concept of an overcrowded household (defined as more persons than rooms for living) as an indicator of deprivation. It is also one of the four constituent deprivation indicators used by Carstairs in studying the
relationship between deprivation and ill-health in Scotland.\(^2\) However, we believe that any indicator that may have been valid in particular areas within Great Britain, \textit{circa} the 1981 Census, should not be applied uncritically to another area and at a different time.

(2) Northern Ireland, unlike the other parts of the UK, has a very young population. In 1992, 20.2 per cent of the population of England and 20.1 per cent of Scotland’s was aged less than 15 years old; the equivalent figure for Northern Ireland was 25.5 per cent.\(^3\) We would argue in the context of this demography that overcrowding does not necessarily have the same meaning in terms of ‘level of housing circumstances’ or ‘lack of substantial command of resources’, that Townsend initially suggested. In Northern Ireland, where overcrowding, according to this definition, is present it usually means young children sharing bedrooms rather than multiple family households, which may be more characteristic of inner city areas in Great Britain. For many of the former the sharing of a bedroom is not considered a disadvantage or undue hardship.

(3) Dr Sloan suggests that having a large number of children might ‘have some influence on employment and deprivation’. Does he propose that poor families with larger numbers of children should be castigated for being the authors of their own misfortune? We would argue it is more probable that the relationship acts in the direction opposite to the one he suggests.

Finally, it is unfortunate that in the face of Dr Sloan’s accusation of bias that the point has to be made that the authors come from both ‘sides of the community’ in Northern Ireland.

References


Yours faithfully
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Distribution of stable iodine

Sirs,

Having been involved in emergency planning in the event of a mishap at Sizewell nuclear power station (albeit some years ago), I was interested to read Sally Millership’s paper on the distribution of stable iodine tablets.\(^1\)

I was never in any doubt that the police were best placed to carry this out. If there has been a release of radioactive material sufficient to necessitate use of potassium iodate tablets then the area is not safe and evacuation should be imminent, and this would be carried out by the police. Iodate tablets are not, as some members of the public seemed to believe, a talisman against all forms of radiation, but offer protection to one organ from one radioactive isotope. Certainly, when I was involved, we would have considered it less than honest to offer stable iodine without offering evacuation. In the event of even a partial evacuation the last thing the situation demands is a host of NHS staff moving into the area. Iodate tablets have no other medical uses, so health staff are unlikely to be able to offer more authoritative advice than a well-briefed policeman.

The most important contribution to be made by members of the health professions is twofold: dealing with the casualties from the causal industrial accident at the nuclear plant and meeting the health care needs of a local population disrupted and distressed by evacuation.

I believe that the most serious issue raised in Dr Millership’s study is not the variety of responses received from Health Authorities but their apparent inadequacy. For those involved to accept complacently that their own plans are likely to fail is to make disaster a foregone conclusion.

I do, however, recognize the problem. I found barriers to effective planning; these were often subtle and psychological, and I list some of them here:

1. The NHS is a busy and overstretched organization, and it does not like wasting time on planning for events that are very unlikely to arise.
2. The response ‘We never asked the nuclear industry to come to this area. Let those who did sort out the problems!’
3. Nuclear energy is still viewed as sinister by many, partly because radioactivity is an invisible hazard and probably because old cold war fears of the military applications linger on.
4. In this, as in many civil disaster scenarios, the medical role is small. Basic health needs, shelter, water, food and sanitation predominate, and these are provided by other agencies. The NHS is at its best when it is the lead agency and is less than comfortable in what it sees as a secondary role.

To overcome these difficulties is not easy, and I do not presume to have a ready answer, but some progress can be made by encouraging the key players in the NHS to work directly with the other agencies in the planning process. By this means the thoroughness and professionalism of the other agencies tends to spur the health service staff to develop plans which are mutually compatible, will work, and in which the staff will have confidence.
Reference


Yours faithfully

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Reply

Sirs,

I note Dr Bush’s comments with interest. Although I agree that the police may be well placed to distribute stable iodine, in England and Wales they are no longer willing to undertake this task. I understand this partly relates to manpower problems and partly to a view that handing out a pill amounts to taking responsibility for any adverse reactions.

I would strongly disagree that it is dishonest to offer potassium iodate without evacuation. There may be circumstances where predicted radiation levels are such that sheltering is the best option. In any case, pharmacological studies make it clear that the maximum benefit of stable iodine is gained by taking it just before exposure. If evacuation through a contaminated area becomes necessary, ideally iodine should be taken first.

Neither I nor my colleagues accept complacently that plans will fail. This is an area about which we are very worried but which to a large extent is subject to influences outside our control. Nuclear exercises concentrate on the response to a limited number of severely injured casualties, whereas the public health aspects, a much larger problem, are rarely if ever fully exercised. The reasons for this are not solely resource related. There is a perception amongst other agencies that rehearsing tablet distribution or monitoring is acknowledging that nuclear power is dangerous to large numbers of people and that such an admission is undesirable.

If we are to take nuclear emergency planning seriously then all aspects of the response, and not just those which are convenient, should be rehearsed.

Yours faithfully

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