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Guidelines for managing HIV infection

The goal is maximal suppression of HIV replication for as long as possible

The medical management of HIV infection and AIDS has finally been rewarded with some success, witnessed by falls in AIDS associated deaths in industrialised countries, fewer opportunistic infections, and fewer admissions for HIV infection.[1 2] What constitutes optimal practice, however, remains a topic of debate. Two widely publicised sets of guidelines on antiretroviral treatment have appeared over the past year, one from the International AIDS Society in the United States,[3] and the other from the British HIV Association.[4] While their emphasis was different, the recommendations were broadly similar.

The guidelines agreed on the need for regular monitoring of HIV-1 plasma RNA ("viral load") and for using antiretroviral treatment in people with low CD4 lymphocyte counts or symptomatic disease. The British guidelines were less prescriptive and placed less emphasis on introducing treatment for people with CD4 cell counts $>300\times10^6$/l and high viral load.[4] Both guidelines endorsed combinations of nucleoside analogues such as zidovudine and didanosine (AZT/ddI), zidovudine and zalcitabine (AZT/ddC), or zidovudine and lamivudine (AZT/3TC) as first line treatments and discussed indications and options for switching treatments.[3 4]

Practice in many quarters, however, has moved beyond these guidelines.[5 6] Many doctors now use triple therapy including a protease inhibitor as first line treatment for all HIV infected patients, and some start treatment earlier. Logic and current concepts of pathogenesis supporting such an approach are that virus replication is intense from initial infection,[7 8] viral load is the most important prognostic marker of risk of progression,[9 10] drug resistant strains emerge in the face of incomplete suppression of replication,[11] treatment with two nucleoside analogues does not provide long term suppression in most cases,[12-15] and favourable clinical outcome is most likely if virus replication is maximally suppressed before the immune system is irreversibly damaged.

Several arguments have been advanced in favour of delaying treatment or using only two nucleoside analogues initially. These are that clinical evidence for a more aggressive approach is lacking, long term side effects of these drugs are unknown, early use of the most potent combinations limits later therapeutic options, asymptomatic patients may be turned into pill-taking invalids, long term adherence to treatment by asymptomatic people is unlikely, and, inevitably, the greater cost of triple therapy.

This debate has now been joined by heavy hitters from the United States in the guise of two panels that have just published draft reports for public comment.[16 17] A panel convened by the National Institutes of Health has defined the scientific principles that should guide treatment and its monitoring in clinical practice. The second panel, sponsored by the Department of Health and Human Services and the Henry J Kaiser Family Foundation, developed recommendations based on these principles for the clinical use of antiretroviral treatment. Together, the documents clearly state that triple therapy (generally consisting of two nucleoside analogues and a protease inhibitor) should be the standard treatment for any person with HIV infection, including as initial therapy. Treatment is recommended essentially for all people with CD4 cell counts $<500\times10^6$/l, as well as for asymptomatic people with counts $>500\times10^6$/l and active viral replication ($>10\,000$ viral copies/ml). It is stated, however, that many experts would advise treatment for HIV infected people with CD4 cell counts $>500\times10^6$/l and any detectable level of virus.

The guidelines emphasise that the goal of treatment should be maximal suppression of HIV replication for as long as possible. For people undergoing treatment for primary HIV infection, the recommendation is for indefinite treatment with triple therapy. After a 30 day period for public comment, the documents will be published in their final form in the *Morbidity and Mortality Weekly Report*, and they will be updated when necessary.

The debate raises many issues. HIV infection illustrates the limits of the paradigm of practice based exclusively on controlled trials using clinical endpoints. Some guidelines usefully grade the quality of evidence on which recommendations are based and acknowledge that some depend on biological plausibility rather than clinical results.[4 18] Even if evidence of more favourable clinical outcome with triple therapy compared with two nucleoside analogues is only just emerging,[19] analogy with diseases such as tuberculosis or lymphoma, plus subjective assessments ("What would you take if...?"), will persuade many that triple therapy should now be the standard of care for HIV infection. It is likely that international prescribing practices will ultimately vary more over when to start treatment than what to start with. Nevertheless, practice based on data using surrogate markers (viral load and CD4 cell counts) requires careful follow up to ensure that clinical response and survival continue to correlate with changes in markers.[20] The initial promise

but ultimate failure of zidovudine monotherapy must not be forgotten.

We must ensure that care for HIV infected patients across the United Kingdom meets international standards. Anecdotal reports suggest antiretroviral therapy and monitoring of viral load are not equally available in all NHS trusts and that some patients use the open access policies of distant sexually transmitted disease clinics to obtain treatments not available locally. More extensive assessment is required of performance of viral load tests for non-B subtypes of HIV-1, which predominate in heterosexual subjects in Europe.[21 22] Inevitably, spending on antiretroviral drugs and monitoring of viral load will increase as treatments are started earlier, triple therapy becomes more widely used, and reduced mortality from AIDS results in its increased prevalence.[23]

The promise of modern antiretroviral therapy is threatened by the emergence of drug resistance, the strongest risk factors for which are non-adherence to treatment and the use of suboptimal regimens. Surveillance for transmission of drug resistant strains and research into improving adherence of patients and their doctors to treatment should be priorities. Finally, although current discussions have concerned only industrialised countries, antiretroviral drugs are also in circulation in developing countries, where most of the world's HIV infected people live. Their use in settings with few resources will therefore increase. If thought is not given to the rational use of antiretroviral drugs everywhere their long term utility may be jeopardised by the spread of resistant viral strains.

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Bringing epilepsy out of the shadows

Wide treatment gap needs to be reduced

The history of epilepsy can be summarised as 4000 years of ignorance, superstition, and stigma followed by 100 years of knowledge, superstition, and stigma. Knowing that seizures result from sudden, excessive, abnormal electrical discharges of a set of neurones in the brain has done little to dispel misunderstanding about epilepsy in most of the world. More than three quarters of sufferers remain untreated despite the availability in phenobarbitone of a cheap antiepileptic drug. Epilepsy remains a hidden disease associated with discrimination in the work place, school, and home.

Epilepsy—a state of recurrent and usually unprovoked seizures—is a truly universal disorder. People of both sexes, all ages, and every race, country, and socioeconomic group are susceptible to it. Its annual incidence is about 50 per 100 000 in the developed world, twice that in the developing world, and in some parts up to 190 per 100 000.[1] About 40 million people worldwide have epilepsy; 100 million will have it some time in their life; and many more suffer its consequences as relatives, friends, employers, and teachers. Epilepsy accounts for 1% of the world's burden of disease, the same as for breast cancer in women or lung cancer in men.[2] Yet, with appropriate treatment, three quarters of people with epilepsy can be seizure free.[3]

As 85% of the world's people live in developing countries most people with epilepsy live in developing countries: the industrialised economies bear less than 7% of the burden as estimated by disability adjusted life years.[4] About 80-98% of patients in the developing

countries are untreated.[5 6] The reasons for this treatment gap have not been well studied, but they include failure to understand that epilepsy is treatable, limited neurological and medical services, early discontinuation of treatment by patients, recourse to traditional healers, and the cost of treatment. Not all antiepileptic drugs are expensive, however: in India one year's supply of phenobarbitone costs less than £4, and the drug is distributed free in government hospitals. Thus, the cost of drugs is not the main reason for the treatment gap.

Discrimination against people with epilepsy and ignorance about the disorder is worldwide. Patients often suffer more from the attitudes of others than from seizures. A survey in Germany in 1996 showed that about 20% of people interviewed thought that epilepsy was a mental disorder; a similar number objected to their children marrying a person with epilepsy.[7] Seventeen states in the United States prohibited people with epilepsy from marrying till 1956, and denying them access to public places like theatres and restaurants was legal until the 1970s. Discrimination in developing countries is more blatant and widespread. In India, where most marriages are arranged, a girl with epilepsy has little chance of getting married, and a recent survey from Turkey showed that 70% of people thought that epilepsy resulted from supernatural causes.[6]

Negative attitudes to epilepsy are also reflected in charitable donations. In Britain, for example, the Charities Aid Foundation in 1996 showed that £215m was raised for cancer, nearly £9m for leprosy (of which Britain has no new cases), and only £2m for epilepsy —despite there being 400 000 people with the disorder.

The need for a global effort against this universal disorder is compelling. The first such initiative, "Out of the shadows," was launched last month by the International League Against Epilepsy, the International Bureau for Epilepsy, and the World Health Organisation. According to president of the league and initiator of the campaign, Professor Ted Reynolds, its mission is to improve the acceptance, treatment, and prevention of epilepsy worldwide.

Part of the campaign is an awareness programme to emphasise that epilepsy is a treatable brain disorder, but there are also practical programmes to help governments identify and meet the needs of people with epilepsy cost effectively. The campaign will seek to implement research findings and identify regional and national centres of excellence. Funds will be raised from national governments, the World Bank, and pharmaceutical and related industries. Indicators of progress will include the number of governments that participate and a reduction in the treatment gap.

People with epilepsy have experienced misunderstanding and neglect for at least 4000 years. This campaign, which will run for four years, will hopefully bring epilepsy out of the shadows for the next millennium.

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Five years down the road from Rio

The earth has not moved much

Five years ago in Rio de Janeiro the earth summit agreed on Agenda 21, a 40 chapter plan of action for achieving sustainable development. Progress has been poor, heads of state and environmental ministers heard at a special session of the general assembly of the United Nations last week,[1] but it was not all bad news. Some promising developments have occurred in international policies and agreements. And we now know more about those aspects of global change with important implications for human health: global warming, the loss of biodiversity, and persistent organic pollutants.[2-5]

Global warming will probably bring extremes of weather, new infectious illnesses, threats to food production, flooding, forced migration, and a rise in sea level. Destruction of habitats and extinction of species result in the loss of materials for medical research and ecological services (such as water cleansing, pollination, and soil production) necessary for good health. Organic pollutants, particularly chlorinated hydrocarbons, may contribute to the rising incidence of reproductive disorders.

Since 1992, limited progress has been made in the development of binding international agreements regarding climate change, biodiversity, and persistent organic pollutants. The parties will go to Kyoto in December to agree on quantitative targets for emissions of greenhouse gases, with the United Kingdom seeking 20% reductions of 1997 levels by the year 2010. Despite strong pressure from France and Germany, the United States will not commit to quantitative goals.

Last year the United Nations Environment Programme issued the global biodiversity assessment, which provides baseline estimates of species numbers and extinction rates as well as critically reviewed methodology. Although work on the biodiversity convention is stalled, progress has been made in the

convention on international trade in endangered species (CITES) and, to a limited degree, in policies on water, forests, and fisheries.

Products containing chlorinated hydrocarbons, which are used in many industries, have long been recognised as dangerous to human health. These fat soluble, toxic chemicals are not easily degraded, persist for many years in the environment, concentrate up the food chain, and accumulate in animal and human tissues. Two developments have drawn renewed attention to the health risks of these persistent organic pollutants: the identification of medical waste as an important source of toxic pollution and the discovery of an extremely important new toxicological mechanism, endocrine disruption.

Rachel Carson described but did not name this mechanism in her book *Silent Spring*, which alerted the world to the reproductive and developmental effects of pesticides on wildlife. Endocrine disrupters are chemicals that, often at extremely small doses, imitate or block hormones. They include many persistent organic pollutants, pesticides, and industrial emissions, and they have a wide range of toxic effects. The incidence of breast, prostate, and testicular cancers and male reproductive disorders, including undescended testes, have increased in recent decades. Occupational exposures to some pesticides have caused reduced sperm counts and infertility in men. It is speculated that persistent organic pollutants may be associated with the global fall in human sperm counts.[5] The children of women who have eaten food contaminated with polychlorinated biphenyls have impaired intelligence and nervous system function.[4]

As long as healthcare professionals remain relatively unaware of the health threats posed by these endocrine disrupting agents—particularly those originating in healthcare facilities—society is unlikely to take the actions necessary to prevent this form of pollution. Efforts to promote good waste management practices in hospitals and healthcare facilities, specifically reducing the use of incineration, are critical.

In the past five years, the effects of environmental change on healthy people have attracted increasing attention. Environmental issues such as the quality of water, air, and food have become more prominent in public health programming worldwide. The United States has seen a series of conferences and publications by leading scientific organisations, including *Climate Change and Human Health*—a joint publication by the United Nations Environment Programme, World Meteorological Organisation, and World Health Organisation, which outlines the health consequences of climate change and the relevant science developed over the past five years[2] —and *Biodiversity and Human Health*—released by the Smithsonian Institution and the National Institute for Environmental Health Science.[3] The WHO, which has responsibility for the health issues listed in Agenda 21, issued a major new report on health and the environment at last week's meeting.[6]

The scene in the United States is particularly discouraging. The sober, at times apocalyptic, messages of scientists at last week's meetings were poorly covered by the press. President Bill Clinton's assertion that "the science is clear and compelling. We humans are changing the global climate" went virtually unreported. While acknowledging the "real and imminent" threat of global warming to produce drought, floods, and the spread of infectious disease, President Clinton refused to commit the United States to reduce emissions of greenhouse gases or to set quantitative goals for emissions of carbon dioxide. He needs to follow the example of leaders in Britain, Germany, and France and offer environmentally sound energy policies. Mr Clinton is delaying hard choices by claiming that he must first educate the American people and Congress that global environmental change is real and dangerous. Medical, public health, and environmental communities must hold him to his word.

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Making the diagnosis of asthma

Common tests measure different aspects of the disease

Asthma is becoming more common in all parts of the world, and establishing the diagnosis is as important to clinical practitioners as it is to epidemiologists. For both the "gold standard" is still a clinical diagnosis based on a characteristic pattern of symptoms: episodes of cough, of dyspnoea, and of chest tightness or wheeze. The epidemiologist, however, wants further objective diagnostic tests to distinguish affected from unaffected people and then to compare populations and monitor trends. Most recent prevalence studies have relied on measurements of bronchial hyperresponsiveness to histamine or methacholine or to an exercise challenge as well as on tests of lung function. Toelle et al have proposed that for epidemiological purposes current asthma should be defined as appropriate symptoms in the previous 12 months together with evidence of increased airway responsiveness.[1]

The need for a clinician to use more specialised diagnostic testing is less clearly defined, but it may be

summarised as the need to establish the diagnosis and assess the severity. International guidelines broadly agree on the management of established asthma, but they differ in their emphasis on confirmatory diagnostic testing. The British guidelines do not mention even the simplest of investigations,[2] but those published by the US National Heart Lung and Blood Institute provide a detailed algorithm.[3] Perhaps the lack of emphasis on diagnostic testing in the British guidelines is based on the difficulties clinicians meet in gaining access to tests as well as in their interpretation. Nevertheless, improving diagnostic accuracy is important in patients with equivocal symptoms—for example, cough-variant asthma—especially given that a commitment to long term treatment usually means inhaled corticosteroids.

Tests correlate poorly

Some recent research from Siersted *et al* on behalf of the Odense Schoolchild Study group evaluated the strengths and weaknesses of four commonly used diagnostic tests for asthma among a group of 495 schoolchildren. These were: simple spirometry (the ratio of forced expiratory volume in one second to forced vital capacity), serial peak flow measurements over 14 days with a calculation of variability, exercise testing, and a methacholine challenge.[4] The traditional "reversibility" test was not included.

In this selected population (which included 203 children with a history suggesting asthma) 27% had current symptoms of asthma and 10% had been diagnosed as having asthma. Children with symptoms of asthma and a positive result for at least one test were classed as having asthma for the purposes of the study. This showed that the sensitivity of the tests was variable but generally low, ranging from 18% for the ratio of forced expiratory volume in one second to forced vital capacity to 59% for the methacholine challenge. The predictive value of a positive test ranged from 45% for serial peak flow monitoring to 72% for a methacholine challenge.

By contrast, the specificity of individual tests was invariably high with the negative predictive value for all four tests similar at around 75%. Furthermore, there were only weak correlations between the tests, confirming the established view that each measures a different pathophysiological facet of the asthma syndrome.[5] The results showed that, of the tests used, methacholine responsiveness detected more children with symptomatic asthma as well as those diagnosed as having asthma than any other test.

For clinicians, however, the most relevant observations were those on the 52 children who were "probably asthmatic." Half had only one positive test result, and three quarters of these were identified using the methacholine challenge. Nearly 90% in the "probable" category had the diagnosis confirmed when the results of peak flow monitoring and methacholine challenge were used together.

Clearly there will be fewer positive results in patients who are "possibly" rather than "probably" asthmatic, but the results nevertheless encourage the use of these two diagnostic tests in children in whom the diagnosis of asthma needs to be confirmed. These results show how various methods complement one another, and they also reinforce the message that asthma cannot be defined by a single physiological measurement. Finally, they provide justification for the diagnostic pathway outlined in the American guidelines.[3]

Well performed serial peak flow measurements over days (or preferably weeks) are more sensitive than either spirometry or the response to a bronchodilator[5] in establishing the presence of abnormal airway function. Spirometric measurements remain, however, an important way of assessing the severity of established disease (which may be falsely underestimated using peak flow measurements alone[6]) and they provide other valuable clinical information. For example, although the forced expiratory volume in one second after a bronchodilator is a relatively insensitive test in making a diagnosis of asthma, it may be helpful in distinguishing the degree of airflow obstruction due to oedema, mucous plugging, and perhaps airway remodelling rather than to reactive bronchospasm. Because of its greater reproducibility, the accurate assessment of individual trends over time is also best achieved by spirometry.

Bronchial provocation testing in the laboratory ought to be available and used in cases of diagnostic difficulty, and it is probably more practical than exercise testing. It is more sensitive than the exercise test even when exercise related symptoms may predominate,[7] but the correlation between the two is low.[8] An exercise test seems to be clinically useful when asthma has to be distinguished from some other form of lung disease as the cause for symptoms associated with effort.[9]

In practical terms, therefore, the diagnosis of asthma ought to rely on a careful history followed by spirometry in all cases. When doubts linger, peak flow monitoring or methacholine challenge or both should be undertaken[1]: one positive result is enough. Only occasionally will other investigations be necessary. Once asthma has been diagnosed, serial peak flow measurements are important in further assessing severity and response to treatment.

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Career guidance for doctors

Draw clear boundaries between appraisal and counselling—and develop both

British doctors may not be deserting the profession,[1] but there is no doubt of the disillusionment that currently afflicts them.[2] If morale is the difference between current perceptions and future expectations, it is reasonable to suppose that better information, advice, and counselling about career and employment would help doctors to narrow that gap. Yet career advice for doctors can be hard to come by. At medical school students often do not have access to university career services[3] and, even when they do, do not always use them.[4] After graduation, sources of advice are much less clear. The *BMJ*'s Career Focus section, one year old this week, provides a forum for gathering and channelling this information. It attempts to address the paradox that, although doctors are the most expensive workforce within the NHS, little information has been available for them to make informed decisions about their careers.

The diversity of sources of information on doctors' careers is part of the problem: much of the relevant information exists in the grey literature of the royal colleges and departments of health, regional postgraduate deans, and the BMA's central information bank, but it is less accessible where it is needed—in the libraries of district general hospitals, training practices, and medical schools. Career Focus provides access to that information, for those who need advice and those who advise, and is available in full text on the internet (www.bmj.com/careerfocus/cf-arch.htm).

Even with the best information, a nagging doubt exists that many doctors embark on career paths that they are not suited for—in part because of an undergraduate culture that sees any departure from the path to a consultant post in one of the general hospital specialties as an irrevocable fall from the career ladder. Part of Career Focus's mission has been to remind medical students and doctors of the wide range of specialties, which can provide a niche for the diverse range of talents and personalities within medicine.

We have encouraged authors to provide an honest appraisal of the advantages and disadvantages of a career in a given specialty, particularly for the guidance of the many doctors who are responsible for advising colleagues on career possibilities. The adviser's role demands a wide knowledge of the social fabric of medicine: if someone is not cut out for a career in a particular area a trainer or adviser should be able to make constructive suggestions as to where he or she might prosper. In medicine career counselling has become a synonym for informing those who have failed in a specialty, rather than something that is part of a doctor's normal career development and part of all trainers' obligations to their trainees.

There are two types of career related guidance that all doctors should have access to. Firstly, there is appraisal designed to allow a trainer and trainee to exchange information and views about how the trainee is performing in a post. High quality appraisal is objective and relevant, takes place in protected time, and is conducted regularly enough within a post to enable feedback and for the trainee to show demonstrable improvement. In medicine, however, even this basic technique is rare: fewer than 5% of senior house officers in a recent study had formal appraisal procedures, mainly because of a lack of training among their consultants into how to appraise.[5]

Appraisal in post must not be mistaken for career counselling (the second form of guidance): this seeks to integrate the personal development and lives of doctors with the work they are doing now, with their own priorities, and with their aspirations. It is here that doctors may learn, if they do not know it already, that a career is a part of life but not all of it. Career counselling with the characteristics of a helping relationship is hard to come by.[6] Several independent organisations offer it,[7 8] though such informal discussions are the very stuff of conversation in every mess, common room, and coffee break.

This informal approach has strengths, but when it is muddled up with, and substituted for, formal appraisal two sorts of problems arise. Firstly, tensions inevitably exist between the needs of organisations and individuals.[9] The second problem is more subtle. Informal relationships, traditionally characterised in medicine by patronage, work best when the people involved share social and cultural values. Now that British doctors are no longer overwhelmingly male and white, the results of patronage are too often discriminatory.[10] Such a system serves neither the people discriminated against nor the employer.

The first need, therefore, is for proper appraisal systems within medicine. Recent initiatives to pay hospital consultants who train, in the same way as general practitioner trainers are paid, could help,[2] but there is a long way to go. Providing better individual career counselling will be harder, though mentoring in general practice represents progress for doctors who wish to combine their personal and career development.[11] In the meantime the onus is on the individual to recognise his or her own needs and act to achieve them. As the Zen aphorism has it: when the pupil is ready, the master arrives.

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The full list of Career Focus articles is available on the internet at www.bmj.com/careerfocus/cf-arch.htm.

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