TO RESUSCITATE…OR NOT?

The media’s unbalanced and sensationalist reporting of ‘do not resuscitate’ (DNR or NFR) orders has caused confusion and worry, says Dr Neville Goodman. People think DNR means “withdraw treatment and leave to die”. It does not. What is more, the “strict new guidelines” ordered by the Government in September are no more than what any sensible hospital already does. So what is the truth?

The word ‘resuscitate’ has a broad meaning: the institution of rapid (though not necessarily immediate) treatment to correct acute physiological disturbance. In DNR, resuscitate has a specific meaning: the institution of (immediate) cardiac massage and artificial ventilation (CPR: cardiopulmonary resuscitation) in someone whose heart has stopped. Contrary to the impression given by the media, DNR does not mean that all treatment of any sort is stoppe d and the patient left to die.

People need to be aware of the realities of DNR. All acute hospitals have cardiac arrest teams. They get to the patient’s bedside within 2-3 minutes of being called. The chances of successfully restarting the heart are small, and the chances that the patient will leave hospital are even smaller. Looking at the overall figures, for all cardiac arrest calls, fewer than one in twenty patients will leave hospital. CPR works well in patients who suffer an electrical disturbance in an otherwise healthy heart, typically after a heart attack that affects the conducting tissues more than it affects the heart muscle itself. More than 90% of these patients will survive to leave hospital. Even an elderly patient will have a good chance of survival, and an otherwise healthy 85 year old who suffers an uncomplicated heart attack deserves (and will receive) CPR.

The difficulty arises with patients who have other diseases as well. Most of the cardiac arrest calls in hospital are to patients who have been ill for some time, and have been steadily deteriorating. Their hearts stop not because of a sudden electrical disturbance but as the final event. The likely result of ‘successful’ CPR is then days or weeks on the intensive care unit before eventual death.

The main issue in CPR precipitated by the media attention is autonomy: should patients, or their relatives, be involved in decisions about whether CPR would be wanted or appropriate if the circumstances arose? This is a complex issue. My own view is that there are some patients who would welcome these discussions; there are others for whom discussions would be cruel and pointless. Involving relatives may sound the right thing to do, but how do we know they will do what is best for the patient rather than for themselves? I feel strongly that doctors must take professional responsibility for decisions about patient care; indeed, I believe it is part of being a doctor to do so, and a negation of professional duty to place responsibility anywhere else. It is the doctor’s duty to lead the patient, if necessary, to the right decision. Obviously, this sometimes goes wrong, but that is better than doctors hiding behind the shield of patients and relatives making the decisions.

Anyone interested in the widely differing points of view held about CPR should read the editorial written by Ebrahim in the British Medical Journal (1), and the correspondence it provoked in the e-BMJ (2). Towards the end of the many contributions was one from Roger Goss, who is Director of Patient Concern. He wrote, “Do not resuscitate orders at any age, without discussion, are unethical. Eradicating this practice in the NHS requires legislation—full stop.” It is clear from this that he and I have no common ground, and that he does not understand the complexities of CPR.

Neville Goodman, Consultant Anaesthetist Southmead Hospital, Bristol

References

ARE CANCER PATIENTS PROPERLY INFORMED ABOUT NEW DRUGS?

Leading oncologist Dr Michael Henk is concerned that commercial interests may be driving the way in which cancer chemotherapy is promoted. He says, "There is a danger that inappropriate emphasis on trials of cytotoxic drugs may put an undue strain on hospital facilities, thereby delaying investigation and treatment of potentially curable cancer patients". Dr Henk writes here about how he feels patients and the public are at risk of being confused or distressed by misleading publicity.

New drugs for chemotherapy of cancer are attracting publicity, much of it emotional and lacking objective appraisal. We hear a lot about "post-code prescribing", which means that some health authorities are prepared to fund a new drug on the National Health Service while others are not.

The cancer drugs that command most attention have most or all of the following characteristics in common. They are expensive, under patent, have a high incidence of toxic side effects, and no demonstrated effect on long-term disease-free survival. They are judged on response-rates, but when tested in controlled trials show little or no survival benefit.

An example is temozolomide, earlier this year hailed by The Times as a "wonder drug for brain cancer". The Times claimed that temozolomide was developed in Britain but is being denied to British patients while being much more widely available abroad. An authoritative review (1) in The Lancet in April this year by Dr T Batchelor of the Brain Tumor Center at Massachusetts General Hospital concluded that studies to date show that the beneficial effect of this drug is marginal at best—hardly a wonder drug! A cancer drug with none of the above characteristics is the radiosensitiser nimorazole. In a well-conducted large double-blind randomised controlled trial in Denmark, nimorazole improved long-term local control by radiotherapy of head and neck cancers by 16%, and reduced the relative risk of death from the cancer by a factor of 26%. The toxicity of the drug is minor, and the cost per patient approximately £250. This result was highly significant, so that nimorazole is now given routinely to head and neck cancer patients receiving radiotherapy in Denmark. Nevertheless, this drug has received no media attention or interest from the pharmaceutical industry, and is not available elsewhere. It would seem that evidence from clinical trials is not the only factor influencing publicity and enthusiasm for drugs to treat cancer.

It is therefore disappointing to see how the excellent cancer support organisation CancerBACUP is becoming more politically active on the drug front. A front-page article in the summer 2000 edition of CancerBACUP News welcomes the decision of the National Institute of Clinical Excellence (NICE) to reverse an earlier decision and recommend that taxanes be made generally available to treat advanced breast cancer not responding to first line chemotherapy. (Controlled trials have shown that taxanes increase median progression-free survival by between 5 and 16 weeks in this situation). It claims that the change of heart resulted from an appeal by CancerBACUP. The writer goes on to say that the organisation will continue to campaign for new drugs to be made available to all patients who would benefit from them, but lists a number of agents of questionable value including temozolomide. They say they are campaigning for more money to be made available for these drugs without leading to cuts elsewhere in the Health Service. Maybe this is a worthy objective, but is surely unrealistic when a more important factor reducing survival rates in the UK is the long waiting time for curative treatment by surgery or radiotherapy.

The issue of CancerBACUP News to which I refer acknowledges the financial support of 21 pharmaceutical companies, and states, “Several companies have also contributed to the advocacy programme through which we raise important issues with parliamentarian and opinion leaders.” Also in this issue there is an article on complementary therapies for cancer pain. Most of this is unexceptional, but reflexology is mentioned as applying pressure to zones of the feet to treat corresponding parts of the body. Also, patients are advised to buy various homeopathic preparations according to the quality of their pain, none of which have been subjected to clinical trials. It is worrying that cancer patients and their relatives may not be receiving objective information on which treatments are, and are not, of proven accuracy.

Michael Henk
Consultant Clinical Oncologist Royal Marsden Hospital, London

References
News

JOHN DIAMOND TO ADDRESS HEALTHWATCH AGM

On Thursday 24th October HealthWatch will present its annual award to the journalist John Diamond, columnist and author of C: Because Cowards Get Cancer Too (Vermilion, £6.99). This frank and personal account of his life since he was diagnosed with cancer of the tongue, the condition which has robbed him of his power of speech, has been acclaimed both by medical experts and the media.

The HealthWatch annual award is presented annually to those who have made significant steps either in medical research or in improving the public’s understanding of health issues by, as in John Diamond’s case, clarifying complicated and often misunderstood medical matters for the general public.

John Diamond will receive his award during the HealthWatch Annual General Meeting and will (with the help of audio-visual aids) address the meeting on his chosen subject of Close Encounters with Alternative and Conventional Medicine.

All—members and non-members alike—are welcome to the meeting, which will take place at The Medical Society of London, Lettsom House, Chandos Place, London W1. The meeting will be chaired by Nick Ross, president of HealthWatch. There will be a reception at 6.30 pm and the presentation will follow AGM business at 8 pm.

There is no charge for the reception or for the meeting. A buffet supper will be served after the meeting, for which a charge of £25 will be made. Those who wish to stay for the supper must inform us not later than 17th October and pay in advance. Cheques (made out to HealthWatch) to John Garrow, The Dial House, 93 Uxbridge Road, Rickmansworth, Herts WD3 2DQ.

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IAIN CHALMERS RECEIVES KNIGHTHOOD

HealthWatch welcomes the recent announcement that Iain Chalmers of the Cochrane Collaboration, a leading research group for evidence-based medicine, is to be awarded a knighthood. Formal recognition also goes to his colleagues at the Australian Cochrane Centre, Chris Silagy and Bob Douglas, both of whom are to receive The Order of Australia.

"The awards recognise the importance of four principles," say Iain Chalmers and his colleagues. "First, unbiased, up-to-date reviews or relevant research are needed to help maximise beneficial effects and minimise unintended adverse effects of health care.

"Second, these systematic reviews of research must be made accessible to inform the choices of users, providers and funders of health care.

"Third, ways need to be found to involve users of health care more actively in decisions about what research to do, and how to design, interpret and disseminate it.

"Fourth, promotion of these principles requires collaboration among people with a wide variety of backgrounds and experience. These four principles are promoted by all those individuals contributing to the international Cochrane Collaboration.’ The awards are also a tribute to institutional support for work based on the Cochrane principles, notably through the NHS Research and Development Programme and the Health Departments in England, Scotland, Wales and Northern Ireland and the Department of Health and Aged Care in Australia, as well as a number of Australian universities.

Welcoming the news, HealthWatch Committee member Andrew Herxheimer commented, "At last. The first evidence-based knight!"
being studied did not work—that did not get published, even though the results were often significant and of importance to researchers working in the health field.


HOMOEOPATHY MAY be more effective than placebo, claims a team from the Glasgow Homoeopathic Hospital in a controversial study published in the BMJ. Their results have, however, come under considerable fire. The trial involved just 50 allergy sufferers. Nasal air flow reportedly improved by 28% in the homoeopathy group compared with 3% after placebo. An accompanying BMJ editorial emphasises the importance of high quality randomised trials in the evaluation of homoeopathy. They suggest that the new challenge is to do the large trials. (The January 2001 issue of the HealthWatch Newsletter will include a feature on the problems of subjecting homoeopathy to clinical trials.) BMJ 2000; 321: 471-476; and BMJ 2000; 321: 476.

WITCHCRAFT WAS blamed for 11 deaths in central Mexico during a single week in August, according to a report in The Independent. The botched exorcism of a troubled teenager in Tetla, a town in the central state of Tlaxcala, left seven people suffocated, including the exorcist. Days later, four more people were found dead on the floor of a witches’ chamber in Toluca Valley, near Mexico City. Veronica Velazquez, 43, was convinced that a spiteful neighbour had put a curse on her. At a ritual cleansing, at which her brother-in-law was also present, local curadoras the Gutierrez sisters of San Bunaventura tossed herbs onto embers to produce scented smoke. But they apparently miscalculated how air-tight their room was on a thundery night. No one survived.

Meeting report

SUBMISSION TO THE HOUSE OF LORDS

HealthWatch have made a submission to the Science and Technology Committee of the House of Lords, who are preparing a report on Complementary and Alternative Medicine. The subcommittee will make recommendations to the UK Government later this year.

Lord Winston had invited HealthWatch to explain the particular areas of complementary and alternative medicine which we consider give most cause for concern. The submission, made by Committee members Thurstan Brewin and John Garrow, was heard by 11 members of the House of Lords, including Lord Winston, at a public hearing. (A verbatim transcript is available from HMSO or through the Parliamentary Hotline Lo-call 0845 023474).

Extracts from HealthWatch’s submission follow.

Specific components of complementary and alternative medicine (CAM) operate against the public interest, generally by conveying false information to the public. We do not suggest there is necessarily a deliberate intent to deceive: often the originator of the information sincerely believes it to be true. Sometimes the motive is, at least in part, commercial gain.

Treatment

Professor di Bella sincerely believed he had an extraordinarily effective treatment for cancer, based on the administration of four hormones associated with the regulation of cell division, but his results had never been verified by proper controlled trials (see HealthWatch Newsletter, issues 31 and 34). When his theories were tested by controlled trials the treatment was shown to be worthless, but meanwhile many patients had received sub-optimal treatment, many had their expectations unreasonably raised, and substantial resources from the Italian Health Service were used in showing that the treatment was ineffective.

Diagnosis

Extravagant claims are made for the ability of various CAM procedures to diagnose disease that is undetectable by conventional clinical tests. An example is hair analysis, which is promoted by Foresight to diagnose excess or deficiency of trace elements or toxins that may account for problems in childbirth. This test is not reliable, and there is no evidence that the detection, or correction, of these trace element deviations contributes to successful pregnancy (see HealthWatch Newsletter, issues 4 and 9). Similarly there is no evidence of the reliability of applied kinesiology, iridology or reflexology to diagnose disease. It is a serious problem if individuals (especially children) are wrongly told they have nutritional imbalances, and are persuaded to make unnecessary dietary restrictions, or consume unnecessary nutritional supplements.

Healthcare books

There are no effective legal controls on books that give false information on matters such as diet. A recent example is Living Food for health (HealthWatch Newsletter, issue 38). A long list of health benefits is claimed for a diet high in raw fruit, nuts and sprouted seeds, because these provide enzymes from which digestive enzymes are claimed (wrongly) to be derived. We are not suggesting that there should be a law against publishing such books. However there should be a reliable source of impartial information available to the public (probably via the media) concerning the validity of the advice given. This is a need for which HealthWatch tries (inadequately) to provide.

Pseudo-scientific “food supplements”
Untrue claims are made for “food supplements” such as Chitosan, which is claimed to inhibit the absorption of fat from the diet (see HealthWatch Newsletter, issue 26). Such misleading claims are, in the long term, controlled by Trading Standards Officers using the Trade Descriptions Act but this mechanism is slow, and mail-order companies often switch products before effective action can be taken. Obesity is a very serious public health problem in the UK, and misinformation about how body fat can be controlled can only make matters worse.

**Mainstream meets Complementary Medicine**

There is, furthermore, cause for concern about the relationship between mainstream medicine and complementary medicine in general.

In HealthWatch we fully acknowledge both the many mistakes that have been made by mainstream medicine (MM) and also the sincerity of many CAM practitioners and the various ways they may help patients. But we feel it is important to be as honest as possible about whether or not there is valid evidence for different kinds of benefit.

We strongly agree with Professor Ernst, whose oral evidence preceded ours, that training in the use of a particular therapy can never be a substitute for evidence that this therapy is effective.

We have the impression that many of the public imagine that the “evidence” in the phrase Evidence Based Medicine comes from something “scientific” in the world of test tubes or microscopes. They don’t realise that it is based on comparing results—a simple concept that everyone understands and will recognise as a valid and sensible thing to do in CAM as much as in MM—and indeed in many non-medical situations.

The need for randomisation is much harder to explain, but should not be too difficult after all the recent talk about the need to compare “like with like” when comparing the performance of, for example, different schools in league tables.

There are obviously problems with the emotive term “guinea pig”. We have to work harder to convince the public that with properly conducted randomised comparisons this is not an appropriate term.

HealthWatch tries to explain this sort of thing to journalists, who often want the story of how just one patient did far better than expected. Although certain lessons can be learned from a single individual case, we point out, one case is no help when it comes to comparing the outcome after different remedies.

For example, HealthWatch believes that many patients are doubtful whether or not to add some form of CAM immediately after completing MM therapy (for example for early breast cancer) If such patients would agree to be randomised—so that they either do or do not add CAM to the MM—convincing evidence would gradually emerge as to whether or not this added therapy makes any difference to the outcome.

**Priorities**

For both the individual and for the community the objective must be not to spend too much time and money on some particular intervention, if the outcome would have been just as good without it. CAM gives much comfort by consultation, advice, mental and physical relaxation and placebo therapy of various kinds (in the same way that MM has always done when nothing better is available), but it does not make the sort of progress that MM has made. By rational problem solving based as much as possible on the painstaking weighing of evidence as to the real nature and causes of ill health, mental or physical, MM has improved quality of life and prevented many premature deaths.

**Treatments**

**THE CHANGING FACE OF REFRACTIVE SURGERY**

*Laser eye surgery is becoming more popular but reports of side effects and unsatisfactory results appear frequently in the press. What is the state of the art, and what kind of results can the public realistically expect? Eye surgeon Mr Sunil Shah explains.*

The visual disorders (called refractive errors) of shortsightedness, long-sightedness or astigmatism are the most common vision problems worldwide. Refractive eye surgery is a general term for surgical procedures that can improve or correct the eye’s focus.

“Refractive error” describes an inability of images to focus properly on the retina of the eye. This happens when the curve of the cornea is abnormally shaped (too steep or too flat) or the length of the eye is too short or long. When the cornea is of normal shape and curvature, it bends, or refracts, the light on to the retina with precision. However, when the curve of the cornea is abnormally shaped, the cornea bends light imperfectly on to the retina. This affects good vision.

The goal of glasses, contact lenses and now refractive surgery is to correct or improve refractive errors by helping images to focus closer to or on the retina.
Refraction eye surgery is usually performed on the cornea (the clear window of the eye) but may be performed within the eye if the refractive error requires it. It can correct or reduce: myopia (shortsightedness), hyperopia (long sightedness) and astigmatism. There is ongoing research on the surgical treatment of presbyopia (this is when the lens loses some of its elasticity with age, making it difficult to focus on near objects).

**Expectations are important**
The surgeon aims to reduce or eliminate dependence on corrective contact lenses or glasses. Refractive eye surgery is not suitable for patients who expect perfect vision without a refractive aid after surgery—although there is a good chance that this will happen, if it does not, the patient with unrealistic expectations is bound to be unhappy. According to a recent article in the Times, 1% of Americans who have surgery each year are less than happy with the results. One has to question how these patients were counselled prior to surgery—it is one thing to hope for perfect vision and not achieve it yet be satisfied with the change in lifestyle produced by the result; it is quite another to be very disappointed because of a less than perfect refractive result.

An optician I treated recently was intolerant of her glasses and contact lenses. Her corneas were too thin to perform a full correction with LASIK (she was -10D pre-operatively). We achieved close to what we had agreed upon: -1.5D and she was tolerant of her much thinner glasses. She had some side effects: halos at night which were persistent. Her parting comments to me were "Thank you for changing my life". Realistic expectations are the key.

There are a number of surgical options for the treatment of refractive error. The most widely used forms of surgery are radial keratotomy and excimer laser correction of the refractive errors.

**Radial keratotomy**
Serial radial cuts are made in the periphery of the cornea (the clear window of the eye) extending to approximately 90 to 95% of the depth of the cornea. This allows the corneal surface to flatten and, consequently, reduces its converging (bending of light rays) power. 85% of patients can see well enough to drive a car without correction. The main side effects include fluctuating vision, a weakened cornea (to a direct blow) and late change in refractive error. This form of surgery is rapidly being superseded by excimer laser surgery.

**The Excimer Laser**
This rather sophisticated piece of equipment uses laser energy to shave off microns (fractions of a millimetre) of corneal tissue to reshape the cornea, much like the way your optician would grind a piece of glass before fitting it onto your spectacles.

The excimer laser was initially used for etching computer chips for IBM. Unlike other lasers that damage surrounding tissue, the cold light from the excimer laser creates no thermal damage and leaves clean cuts. Computer controlled ultraviolet laser energy pulses lasting only a billionth of a second disrupt the molecules between the corneal cells with accuracy up to 0.25 microns. The first excimer laser procedure was performed in 1988. Since then, the excimer laser has undergone many refinements and well over a million procedures have been performed worldwide.

Excimer laser correction of errors of the refraction can be done in two ways: a) Surface based treatments also called Photorefractive Keratectomy (PRK). In this method, the surface cells of the cornea are first mechanically brushed off and the laser energy is applied to the firm corneal tissue called the stroma. This leaves behind a surface 'scratch' which causes pain for 24 to 48 hours after the procedure. The procedure itself is absolutely painless. The surface defect takes up to 3 or 4 days to heal. After treatments, during the healing and settling down phase, vision may be worse than before the treatment, but rapidly improves over the first few weeks. b) The 'flap and zap' method or LASIK (laser in-situ keratomileusis) involves treatment in the middle of the cornea. By this technique, a thin flap of the corneal tissue which includes the surface cells, is first made with an automated instrument. This flap is hinged and is folded back so that the laser treatment can be applied to the stroma as in PRK. Once the laser application is completed, the flap is replaced and sticks back into position within 3 to 5 minutes. Unlike PRK, LASIK is essentially pain free with very rapid (next day) recovery of vision. LASIK, however, is technically more difficult to perform and has more potential risks—hence the need for an experienced surgeon. Haze hardly occurs with this technique although the possibility of surgical complications is higher.

In the USA, more than 70% of procedures performed are LASIK, whereas in Britain, the majority of procedures are still PRK. This is largely consumer driven because of the "wow" effect of being able to see the next day after LASIK. However, the long-term results of LASIK in randomised trials appear to be no different from PRK. There is a significant difference in price between the two procedures (two fold in some centres) with LASIK requiring considerably more training (many recommend that LASIK should be performed only by Consultant eye surgeons, i.e. those who are Consultants on the NHS, or those who are on the specialist register which is a testimony to their training.

Complications with PRK (haze and regression) increase with magnitude of treatment whereas LASIK has a 3-5% complication rate (flap related complications) regardless of treatment size. The predictability reduces with increasing magnitude of correction and with additional treatment of astigmatism.

**Other forms of refractive surgery**
For low myopia, some surgeons are using intrastromal rings where a ring is placed in the periphery of the cornea to flatten it. For high myopia or hyperopia, corrective lenses have been developed which go inside the eye (phakic intraocular lenses). If there is a degree of cataract in the eye or a very high refractive error with a relatively thin cornea, the refractive error can be treated with removal of the cataractous lens and replacement with an intraocular lens. This is different from the phakic intraocular lenses, as there, the patient’s own lens is not removed.

Recent controversies Night vision problems following laser surgery have been known about for many years. They are under investigation at present. My own feeling is that the newer lasers do not lead to a very significant problem.

One London surgeon has been promoting radial keratotomy as far superior to laser surgery. It is quite possible that in his hands, that is the case. However, world opinion has gone away from radial keratotomy because of the predictability and safety of laser surgery.

Some surgeons have stated in the press that they have had not one post-operative complication. One has to ask what their definition of a post-operative complication is and how critical their audit procedure was.

A London Ophthalmic professor (a professor dealing in laboratory research primarily) has recently gone on record with the press to state his worries about LASIK. He has to be commended on bringing to the public attention the uncertainties about the long-term with LASIK. However, corneal surgeons and professors of ophthalmology with clinical corneal interest worldwide are performing this procedure. It may be a calculated risk, but surgeons, particularly in the litigious USA, are going to take the safe option. In their minds, and mine, LASIK is a relatively safe option.

Stand alone laser clinics can not offer anything other than laser surgery. With more complex/higher refractive error, laser surgery may not be the appropriate mode of treatment.

QUESTIONS AND ANSWERS

How successful is excimer laser treatment?
In the large FDA clinical trials, two-thirds of patients who had PRK could see 6/6 (20/20 vision) or better without corrective lenses. 96% could see well enough to drive a car without correction. LASIK has accuracy very similar to that of PRK, but is suitable for worse prescriptions as well. For short sightedness of less than -3D, the surface based method of the PRK generally gives the same outcome as LASIK. Between -3 and -6D, either technique can be used depending on the surgeon and patients preferences. Above -6 and up to -12D, LASIK is the procedure of choice.

Will the effect of the procedure last forever?
Over time, some slippage of the correction may occur. In some instances, the refractive error of the individual may naturally increase, necessitating the use of glasses or contact lenses or the need for repeating the laser surgery.

Is the surgery guaranteed to rid me of glasses or contact lenses?
No. No one can be give you the guarantee that you will get rid of glasses or contact lenses. The vast majority of patients undergoing refractive surgery do end up not having to wear glasses or contact lenses for distance or wearing them very sparingly, for example only for driving. Refractive surgery to correct to distance vision will not get rid of the need for reading glasses after the age of 40.

Can refractive surgery be done at any age?
The surgery is only done if the refractive error has not changed recently. In younger individuals the error is usually unstable and changes over time. As a general rule it is not recommended for individuals below 21 years of age.

Individuals in the 40s, with low degrees of myopia can read without the use of reading glasses. Individuals without a refractive error in the same age group require reading glasses. If a person with low myopia in the stage undergoes laser correction, the individual will become normal and therefore now require reading glasses. In effect, they will swap the distance glasses for reading glasses. Some individuals may prefer to have one eye treated for distance vision and keep the other without treatment, for reading. This is called mono-vision. If you wear contact lenses, you can try this by wearing your lens in one eye only.

What can go wrong?
Any surgical procedure, no matter how minor, has associated risks. Common complications reported are haze, de-centred treatment or healing, irregular or delayed healing, loss of lines of best corrected vision i.e. after laser treatment the best possible vision even with glasses may not be quite as good as before the treatment. Other possible problems include glare, scarring, infection, and under or over correction, and difficulties with night
vision. Dry eyes post surgery are common.

With LASIK, there are particular complications related to the cutting of the flap and how well it lays back down. This is between 3-5%. However, a very small proportion of the complications affect the sight long term. Other LASIK complications include epithelial ingrowth (growth of surface cells under the flap) and interface keratitis (inflammation beneath the flap).

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The author states that he has no proprietary interest in the development or marketing of any excimer laser or other refractive surgery device and is not a paid consultant to any company.

Further information
http://www.rcophth.ac.uk/departments/excimer.html
http://www.ascrs.org
http://www.ascrs.org
http://www.aao.org
http://www.aao.org/Refractive Surgery/Shah/Opinion

THE FIRST REAL TEST OF THE NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

The first real test of the National Institute for Clinical Excellence (NICE) is underway. Will it pass? Neville Goodman has doubts.

When the political climate is such that internal memos between cabinet ministers are leaked, it was never likely that NICE would prevent leaks of newsworthy clinical decisions, especially if those decisions risked upsetting pressure groups and the pharmaceutical industry.

In April this year, the BBC leaked that NICE would allow the prescription of the taxanes, a group of new anti-cancer drugs. Andrew Dillon, the Chief Executive of NICE, disowned the information, although it turned out to be accurate when NICE eventually issued its guidance (see http://www.nice.org.uk). The BBC, knowing what else NICE was up to, drew parallels with the use of beta-interferon in the treatment of multiple sclerosis.

Multiple sclerosis is the most common purely neurological disease. It affects one in a thousand people, with varying severity, and up until now there has been no effective treatment. Beta-interferon is the first drug to slow the disease’s progress, but it is not uniformly effective and is expensive. The BBC interviewed a sufferer in April, and he made it quite plain that for NICE to disallow beta-interferon would be for him nothing less than a death sentence. I commented (1) that the BBC would no doubt interview him again “when NICE’s verdict on beta-interferon is leaked sometime next year”.

Sure enough, earlier than expected in July this year, the media leaked that beta-interferon would not be available, to the predictable outrage of the pressure groups. There has been no response from NICE on their website but Professor Sir Michael Rawlins, NICE’s chairman, pretty well confirmed to the media (see Guardian (2), 18 July) that this was their decision. After “very careful consideration of the evidence,” he said, “modest clinical benefit appears to be outweighed by their very high cost”.

As a societal decision this is probably right. The cost of beta-interferon is usually given as £10,000 per patient per year. The MS society estimates that 10,000 of the 250,000 sufferers should receive the drug, but it may not be easy to deny treatment to sufferers who do not properly fit the criteria. Some have suggested that the £10,000 would be better spent giving sufferers and their carers better help and support, but such spending is unlikely. We are (sometimes) willing to increase health budgets for new drugs; non-specific welfare is less likely to come from the NHS.

Judging real costs is difficult. Even if £10,000 is an over-estimate, this way of quoting costs of treatment is misleading: beta-interferon is a drug with uncertain benefit; it will have no effect in some of the patients treated, and it has many side-effects. A truer estimate of cost is £300,000 per QALY (quality adjusted life year), although QALYs are not accepted by ever yone as a valid measure of equivalence of medical treatments.

But whatever the correct societal decision, individual MS sufferers will feel aggrieved. It is a frightening, uncertain disease. It may be a cliche, but beta-interferon is seen by the sufferers as a ray of hope. If NICE denies it to them, the tenor of the media response will be the snuffing out of that ray. A great deal of hard-headedness will be needed from NICE and from the government to underline that the responses and feelings of individuals, even when gathered into groups, cannot be allowed to dictate policy. What would be the correct decision if a
certain cure for MS was found that cost £10 million pounds per patient? NICE would have done better to ignore costs altogether, concentrate on the difficult enough issue of evidence of clinical effect, and leave the balancing of cost and effect to the politicians (see HealthWatch Newsletter, issue 36 January 2000). We await NICE’s decision, but so far the only concession to the individual sufferer is that anyone who has received beta-interferon on the NHS will continue to receive it. If that is the final decision, it is not fair, but it is pragmatic. It is easier to find a reason not to throw a lifebelt to someone than to wrest one from their arms. It should be for NICE to decide whether the lifebelts work, and for the government to decide whether we should buy them.

Meanwhile, completely overlooked and uneked, NICE has issued advice on the prescription of certain drugs in the treatment of gastrointestinal ulcers. It may not be fair, but it is clear that even in the world of the new and open NHS, squeaky wheels are still likely to get the most oil.

Neville Goodman
Consultant Anaesthetist Southmeads Hospital Bristol


Book review

THE COMPLETE GUIDE TO INTEGRATED MEDICINE

by Dr David Peters and Anne Woodham
Doring Kindersley, London 2000

Medical treatment resembles a sausage: there is a mass of ill-defined components within the outer envelope. To continue the sausage analogy, we may think of one end containing principally treatments with prescription drugs or surgery, applied to patients diagnosed by hi-tech scanners, isotope tracers, etc. that are the hallmark of modern conventional medicine.

At the other end of the sausage are the procedures belonging to alternative medicine: acupuncture, chiropractic, osteopathy, homoeopathy, etc. which are regarded with varying degrees of scepticism by conventional practitioners. The main bulk of the sausage in the middle is filled with therapies which do not belong exclusively in either camp, such as diet, exercise, control of smoking, alcohol and recreational drug abuse, stress management and counselling. Also there are therapies in transition from alternative to conventional: for example hypericum from the plant St John’s Wort has been shown to be effective in some conditions: if and when it is a licensed drug its use will become conventional rather than alternative.

The central tenet of this beautifully produced book by Peters & Woodham is that patients will benefit if they learn “to adopt a more integrated approach to your own healthcare, drawing on both complementary and conventional methods.” (p 7). They introduce a “three-circle approach to well-being”, the circles indicate the three realms of the mind-body. These are biochemical (cells, hormones, enzymes etc.), structural (muscles, bones, physical environment, etc.) and psycho-social (thoughts, feelings, relationships, etc.). The book lists 40 ailments which are considered particularly to benefit from this integrated approach. For example one of the 40 ailments is acne. The conventional treatments listed are topical creams, antibiotics, ultraviolet light and perhaps psychotherapy. The complementary options are western herbalism, nutritional therapies, aromatherapy, psychotherapy and counselling. For each ailment there is a “case study” in which advice from a complementary practitioner was followed by a good result. In this instance complementary advice included hygiene, “live” yoghurt to restore friendly gut bacteria, dietary advice to reduce fat intake and oral supplements of 15mg zinc daily. A conventional practitioner will wonder why psychotherapy is listed under both conventional and complementary treatments, and why have complementary therapists seized the middle ground of hygiene and diet? Also, how effective is the zinc, the yoghurt, or the aromatherapy?

An excellent feature of the book is that for each “complementary” therapy there is a number (1 to 5) indicating evidence of efficacy. To a sceptic the categories seem rather too lenient: a rating of 1 means “rumoured to be effective”, a rating of 2 “effective in practitioners opinion”, and 3 “Possibly effective, but research inconclusive.” All the complementary therapies listed for acne are rated either 2 or 3. Ratings of 5 (definitely effective by randomised trials) are hard to find in the treatment of any of the 40 chosen ailments. There is a “bibliography” on pages 182-185 of the book , with citations to relevant literature, but again I found these were interpreted unduly generously. For acne there is a paper published in 1990 which compared tea-tree oil versus benzoyl peroxidase: this is said in the text of the book (p 29) to show they were of equal efficacy. The paper reported that when benzoyl peroxidase (conventional) or tea-tree oil (complementary) was dabbed onto the acne lesions the conventional treatment was better for inflamed lesions (p>0.001) but there was no significant difference for un-inflamed lesions. I do not think this can be accurately summarised “antiseptic essential oil of tea-tree (is) as effective as benzoyl peroxidase”. Anyway I was surprised that “aromatherapy” encompassed the application of an oil to the skin as an antiseptic.
Similar problems arise when the bibliography is consulted for evidence of efficacy of complementary treatments for other ailments. For example for food sensitivities the rating of efficacy of nutritional therapies is 4 ("probably effective—positive evidence from randomised and/or controlled trials"). The bibliography lists only two references. One paper, published in 1989, reports the effect of a strict exclusion diet for 3 weeks on 200 patients with irritable bowel syndrome. Of the 189 patients who completed the trial 42% showed symptomatic improvement after 3 weeks. There was no control group. The other cited paper, published in 1972, concerns the effect of enzyme-potentiated desensitisation on anaphylactic sensitivity in guinea-pigs, rats and mice. I would not regard this as evidence of efficacy in human subjects of nutritional therapies for food sensitivity from randomised or controlled trials. One of the rare examples of a rating of 5 is for acupuncture at Pericardium 6 to relieve nausea after cancer chemotherapy. There is a review by Vickers (1996) which supports this rating, although others have reviewed the same set of trials and come to a less favourable conclusion.

So, should the lay person who reads this book be convinced that Integrated Medicine offers the best of both worlds? The answer depends on two crucial factors. First, is the specifically "alternative" component effective? So far, there is little good evidence that it is. The second question concerns the ownership of the middle ground between conventional and alternative medicine: the hygiene, diet, exercise and lifestyle factors. If it is true that conventional doctors today do not have the time or interest to deploy anything but the much-vaunted modern advances in technology, then there is certainly a need for someone (perhaps a complementary practitioner) to re-integrate this treatment with the more holistic approach which I was taught as a medical student 50 years ago.

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