Soundings

Evaluation and management guidelines

Last year the Health Care Financing Administration issued new rules indicating how doctors must document the services for which they are billing Medicare. The guidelines define four levels of service: problem focused; expanded problem focused; detailed; and comprehensive. For each level there are detailed instructions on how to document the chief complaint, present illness, review of systems, and past, family, or social history. Each history of the present illness is defined as a chronological description which may include one or more of the following elements: location, quality, severity, timing, context, modifying factors, and associated symptoms and signs. The lowest level requires three elements, but for the higher levels at least four are needed.

The review of systems, "patients' positive and negative responses to questions," and the physical examination likewise increase from one system for the lowest level to at least 10 for the most comprehensive level. Details are also given on how many questions doctors must ask when taking the family and social history, depending on the level of service rendered.

To illustrate the reaction to these rules I could do no better than quote from an article in the *Wall Street Journal* by a Dr Robinson, who practises internal medicine in Washington DC:

"To justify a 25 minute visit with a Medicare patient, a physician will have to generate a written record including—just try to follow this—the chief complaint, an extended history of the present illness (four or more elements, or the status of at least three chronic or inactive conditions), a review of systems (an inventory of two to nine bodily systems); pertinent past medical, family and social history: plus either a detailed examination (including at least six organ systems or body areas with at least two elements each or at least 12 elements in two or more organ systems or body areas), as well as two out of three of either multiple diagnoses or management options, a moderate amount or complexity of data to be reviewed, along with the risk of complications or morbidity or mortality."

Dr Robinson goes on to explain that failure to document accurately could subject the "miscreant" physician to fines of up to $10 000 an incident; that a disproportionate amount of time would be consumed by pedantic record keeping; and that since a doctor can do only so much in 15 to 30 minutes all this unnecessary documentation takes away from the real business of making a diagnosis, formulating a treatment plan, writing prescriptions, explaining the problem to the patients, and possibly even comforting and consoling them.

The guidelines, originally set up jointly with experts from the American Medical Association, unleashed a storm of protest by doctors from coast to coast. Several generalist and specialist medical associations declared they were unworkable, too complex (48 pages), and fatally flawed. In the face of continuing protests their implementation was delayed several times and then indefinitely. It was also suggested, to quote Dr Robinson again, that if such guidelines are "good medicine for doctors, perhaps every government official and employee should be subject to similar work-substantiation requirements."

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Personal view

The discovery of cortisone: a personal memory

Fifty years ago this week, Philip Hench showed that "compound E" (cortisone) was capable of reversing the inflammation of rheumatoid arthritis. This discovery resulted from 19 years of imaginative and deductive observation together, perhaps, with that element of serendipity which seems to characterise many fundamental discoveries.

It all started in 1929 when Hench noted a clinical remission in one of his patients who suffered an intercurrent episode of jaundice. Convinced that this was no coincidence he decided to devote himself to the discovery of the nature of "antirheumatic substance X" in remissions associated with jaundice, and later, with pregnancy. His clinical researches involved giving many metabolites related to liver disease and subsequently, female hormones related to pregnancy. They were uniformly unsuccessful.

Because remissions associated with jaundice occurred as frequently in women as in men, Hench concluded that factor X, if a hormone, must be present in both sexes. This led him to consider the adrenal cortex. He also noted that the gross fatigue seen in patients with rheumatoid arthritis bore some resemblance to the anergy which characterises Addison's disease.

By happy chance, his colleague and friend at the Mayo Clinic, Edward Kendall, had, in 1929, switched his research studies to the separation and characterisation of the many unidentified hormones of the adrenal cortex. This work was laborious and the yields extremely small. Nevertheless, Hench persuaded Kendall to allow him to use any extracts he could spare for therapeutic trials. Compounds labelled "A/D" proved ineffective, but compound "E," first administered on 21 September 1948, produced dramatic results.

Thus we learnt of long term bedridden disabled people attempting to dance. One

Philip Hench (right) and Edward Kendall (second from right) in the Mayo Clinic laboratories

patient insisted on taking several baths on the same day to compensate for the years during which such a luxury had been denied her.

Hench tried hard to restrict premature publicity outside the confines of the Mayo clinic until the full implications and complications of his discovery had been studied. However, a medical correspondent from the *New York Times* gained entry to a private meeting of Mayo Clinic alumni and published sensational stories and pictures in the lay press. This forced Hench's hand and he eventually announced his discovery to the Seventh International Congress of Rheumatology in May 1949.

Hench was a renowned Anglophile, and following the congress he invited several of his close British friends to visit the Mayo Clinic so that they could observe the therapeutic potency of cortisone for themselves. They were impressed, and on returning to Britain organised a motley team of clinicians and biochemists who decided to investigate the clinical significance of cortisone in rheumatoid arthritis. I was fortunate to be appointed as their research registrar. On Hench's introduction, they had obtained a promise from Merck Sharpe & Dohme that they would receive the first batch of cortisone which became available for export. There followed a tantalising delay of more than a year, during which time the production of cortisone in commercial quantities defeated biochemist and pharmaceutical companies alike. During this period all that we could do was to perfect our methods of clinical evaluation, while confirming that steroid analogues which did not contain the 17-hydroxy and 11-keto radicals were ineffective. It was precisely these radicals which proved so difficult to synthesise. In those days the only known starting point of semisynthesis was from the bile of sheep and cattle. This seemed likely to limit supplies permanently.

In the United States a black market developed which had serious medical and social repercussions. Patients who had experienced great relief of their symptoms were not prepared to relapse when supplies ran out. They became totally dependent on the drug. Overdosage led to devastating side effects, and the ever escalating cost of maintaining their supplies resulted all too often in financial destitution. Such patients had no alternative but to seek relief by registering as guinea pigs to research groups such as the one at the Bellevue Hospital in New York which I joined in 1952.

Eventually, in 1954, under the joint aegis of the Nuffield Foundation and the Medical Research Council, a British trial was organised in six centres in which the benefits of cortisone were studied in 61 patients with rheumatoid arthritis in a crossover trial against aspirin. The published results startlingly concluded that there was no significant difference between the two groups (*BMJ* 1954;i:1223-7).

Philip Hench was deeply offended by these conclusions especially as they were signed by many colleagues whom he had numbered among his greatest friends. Indeed he was heard to refer to some of the signatories as traitors and he refused any further association with them.

I felt that the crossover nature of the trial and some of the methods of evaluation gave rise to an unrealistic conclusion and I imprudently wrote a letter (*BMJ* 1954;i:1376). My letter drew an angry reply from Sir Austin Bradford-Hill, the distinguished medical statistician who had designed the trial protocol (*BMJ* 1954;i:1437). I met him many years later and he graciously agreed that some of my comments were justified in the light of subsequent events.

A few weeks later, there was a totally unexpected repercussion in the form of a letter to me from Philip Hench, asking me whether I thought that the atmosphere in Britain was propitious for him to accept an invitation to come and address a BMA meeting. He was not prepared to come if there was any risk of being heckled.

From this improbable beginning, a close friendship developed between this great man and my family. In fact he was in our house the day before the birth of my daughter and, at his insistence, she bears the female version of his first name. It was only with some difficulty that we resisted the idea that she should be christened Cortisona.

Philip Hench had a charismatic and generous personality. He was a man of diverse and enthusiastic interests outside medicine. His sensitivity on the subject of his seminal contribution to medicine was unfortunate, and it undoubtedly marred the pleasure he should have derived from his fame and from the Nobel prize for medicine in 1950. It was especially unfortunate in view of his original intention to present his discovery as an investigative tool rather than as a therapeutic breakthrough.

The clinical usefulness of cortisone in rheumatology remains controversial 50 years after the event, but without doubt its discovery transformed the specialty from its Cinderella status of the BC (before cortisone) era. Its significance in general medicine remains beyond dispute.

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Medicine and the media

The rise and fall of Viagra

See p 759, 760, 765

Viagra has probably received more media hype than any other drug. Abi Berger examines how this massive publicity will affect general practitioners, who may eventually have to prescribe the impotence treatment

It must surely be every drug company's dream: to have a product so sexy that the need for marketing and public relations has been obviated by a tidal wave of media hype. Since March 1998, when the little blue pills became available in the United States, we have had news stories, regular updates, features, television and radio programmes, and even serious broadsheet editorials on the myths and legends of what has been dubbed the "Pfizer riser."

Sadly for Pfizer, however, this very hype may be their undoing. The predicted demand for Viagra (sildenafil), and the consequences this demand is expected to have for the national drug budget, has caused the British government to ban its prescription on the NHS, at least for the time being (p 765).

However, it is better to have realised that this drug has critical implications and delay it now (albeit somewhat late in the day considering how long the man in the street has known about Viagra), than blushingly use the retrospectoscope when all hope of control—legal or otherwise—has long gone.

The debate about who should eventually be able to prescribe sildenafil continues to rage. Most general practitioners I know are rather hoping it will become a drug to be prescribed by specialists only. There are two reasons for this. Firstly, it is notoriously difficult to make a diagnosis of true erectile dysfunction—despite Pfizer's chairman and managing director protesting to the *Times* on 7 September that "the diagnosis is straightforward … and best carried out by GPs"—in the knowledge that there may well be a widespread attempt to misuse the drug. Secondly, the cost of the drug may well break the bank, particularly if prescribing it becomes an indiscriminate exercise. As primary care groups become a reality, with fixed prescribing budgets being shared by large groups of general practitioners, this fear has to be taken seriously.

On the other hand, urologists have voted almost unanimously that the prescribing of sildenafil need not be confined to specialists. They argue that their outpatient clinics will become overburdened with impotent men who will now come out of the closet knowing that an acceptable oral solution to their problems now exists. And no doubt hospital drug budgets will also come under fire. The urologists have a point. But if erectile dysfunction becomes less of a taboo subject simply because there is now a more viable treatment than vacuum therapy or penile injections, and a needs assessment reveals the true prevalence of the condition, there will be plenty of pressure to review the budget set aside for it.

Touted as the latest "wonder drug," sildenafil's discovery and introduction follow the pattern of Prozac (fluoxetine). Sildenafil was first discovered by accident—in this case, to be a useful addition to the dispensing repertoire for men who have erectile dysfunction as a result of diabetes and some vascular disorders. Then word got around that it might also enhance sexual performance for those with no obvious impairment. Speculation became "fact," and very quickly the drug arrived in Britain via the internet and was brought in by the caseload for anyone willing to pay for it. By 30 August, reporters from the *Sunday Times* were being offered it as a recreational drug on the British club scene. Coke and "poke" apparently make "a great combination."

Arguably, this drug has been adopted by the media circus simply because sex sells newspapers. But two recent television programmes, all vying for viewers in the days just before sildenafil was awarded its European licence, opened up the debate and were (in some cases) very informative.

WELLCOME TRUST

Maria Marshall's sculpture 'Pod' was created during her first pregnancy and is part of a new exhibition, *Before birth*. The exhibition, which aims to portray the hidden life of the unborn child, can be seen at the Wellcome Trust's Two10 Gallery, 210 Euston Road, London NW1 2BE until 22 January.

On 9 September, Channel 4 gave its primetime slot to *The Rise and Rise of Viagra*. This was a long, somewhat gratuitous review of some of the people who have taken sildenafil on both sides of the Atlantic. I found this programme cliché ridden, very superficial, and, sadly, by the time I heard the comment "no one recognised it was going to be so large," rather boring.

In contrast, *Sexual Chemistry* (a *Horizon* special) shown on BBC2 the following day was far superior. This was a much more in-depth analysis of the drug and explained how it actually works. Knowing what sildenafil does, the presenter explained, has encouraged a whole new exploration of sexuality from a scientific point of view. The action of the drug works by blocking the "off switch" which controls local soft tissue relaxation in the penis and subsequent vasodilatation. This in turn is mediated by nitric oxide. The drug alone does not cause an erection: sexual stimulation is still required to achieve the desired result.

A similar process may well be going on in women, and research is being conducted into the effects of sildenafil on postmenopausal women who seem to have lost their sexual response, particularly after pelvic surgery. The whole of female pelvic anatomy may be redefined once the female response to sildenafil is documented. The computer graphics were superb, the script was well crafted, and the programme had me hooked. I began to lose my cynicism about the drug.

The media are now entering stage two, with the broadsheets beginning to enter into serious and open discussions about rationing and budgets. No wonder Pfizer is getting worried. On 11 September both the *Daily Telegraph* and the *Times* published intelligent and accurate discussions about the difficulties this drug brings to those with responsibility for the NHS purse strings. Estimates of the annual cost waver between £1.25bn (from the BMA's conference in July) to no more than £50m (from Pfizer itself). The true figure will probably fall somewhere between the two. And ultimately, of course, the cost will reflect the rationing of sex.

Clearly, sildenafil is perceived as reaching parts that other drugs cannot reach. Like fluoxetine, it holds a promise that our lives will be transformed by taking it. And, like fluoxetine, there will doubtless be a backlash against it. Eventually, when the honeymoon is over, I hope that sildenafil will find a sensible niche so that the "deserving impotent" will benefit from it on the NHS.

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