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BMJ

Pulmonary embolism

Hospitals should develop their own strategies for diagnosis and management

The management of suspected pulmonary embolism is a subject in which consensus has been difficult to achieve due to the lack of firm evidence.[1] Against this background, the British Thoracic Society has suggested a "practical approach to suspected acute pulmonary embolism."[2] After a comprehensive review of current literature, the report makes several recommendations, graded for evidence, and finishes with a series of charts designed for a junior doctor's handbook covering diagnosis and management. While some of the recommendations lack top grade evidence and inevitably will be controversial, the authors achieve what they set out to do and provide a practical approach to a difficult subject using new knowledge "little of which," as the report bluntly states, "has filtered through to clinical practice." Certain items in this comprehensive report are worth emphasising.

Pulmonary embolism is both underdiagnosed and overdiagnosed. Ten per cent of all hospital deaths are due to acute pulmonary embolism, most of which are diagnosed only at necroscopy. It is easily missed in patients with cardiorespiratory disease (in whom even small emboli can be fatal), elderly patients, and those presenting with isolated dyspnoea. On the other hand, only a third of patients with clinically suspected pulmonary embolism have positive pulmonary angiograms. Clinical signs and symptoms are highly non-specific, but in the absence of key features—namely, dyspnoea with tachypnoea and/or pleuritic chest pain—the diagnosis is highly unlikely (less than 3% of cases). Of patients with a proved pulmonary embolus, 80%-90% have a major predisposing risk factor. The report has put together a simple scheme for assessing the clinical likelihood of an embolus based on assessment of the clinical features and the presence or absence of a major risk factor. The authors point out that oral contraception is not a major risk factor. The scheme still needs to be validated, but it should help direct immediate treatment and guide subsequent investigations, while an assessment of clinical likelihood assists interpretation of the isotope lung scan.

Basic investigations, like signs and symptoms, are non-specific, but an electrocardiogram and chest *x* ray should be performed if only to exclude other diagnoses. Arterial blood gases are deemed mandatory, although the evidence for performing this unpleasant test is not convincing[3] and is unlikely to alter immediate management.

For a stable patient, the next diagnostic investigation is the isotope lung scan. The report, on good evidence, states that the ventilation phase rarely adds to the accuracy of the scan, which should be good news to clinicians without access to ventilation scanning. If the ventilation phase is to be used the report suggests that krypton-81m or a technetium-99m DTPA aerosol be used as they give clearer multiview images compared with the unidimensional view of the more commonly used xenon-133, perhaps resulting in fewer intermediate scan reports. Seventy per cent of lung scans are reported as being intermediate or representing a 16%-66% risk of pulmonary embolism depending on the clinical likelihood. The next recommended investigation is a Doppler ultrasound scan of the leg veins, and a consensus of opinion is developing to support this position. If the ultrasound scan is negative various management options are suggested, including pulmonary angiography. This is a difficult area for evidence based guidelines, and has recently been reviewed.[4]

For a patient presenting with collapse or hypotension, the first investigation recommended is echocardiography, which can show well defined abnormalities in patients with large central pulmonary embolism. Alternatively, it may show another cause for the clinical presentation. If it is inconclusive, pulmonary angiography or spiral computed tomography should be considered, although the report concedes that the precise investigations used in this situation will depend on local availability and expertise. Spiral computed tomography is highly sensitive for proximal emboli down to the segmental arteries, and smaller emboli are unlikely to present as collapse. As the technology becomes more widely available, spiral computed tomography will probably be the preferred test in this situation, but, as the report makes clear, in the absence of anything else a perfusion scan alone can be very helpful. Thrombolysis is the proposed treatment of choice for large central emboli presenting as collapse or hypotension. The simplest regimen recommended, though untested in this clinical situation, is an infusion of alteplase 100 mg over 2 hours.

Perhaps one of the most important recommendations made in the report is that hospitals should develop their own strategies for the diagnosis and management of pulmonary embolism particularly in unstable patients, when time is at a premium. This will require discussion and cooperation between clinicians and radiologists. The report makes a plea for more widespread access to pulmonary arteriography, but this is unlikely to occur as there is a real prospect that Doppler ultrasound and spiral computed tomography,

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alone or in combination, will make angiography unnecessary in most cases.[5] The report introduces the idea that pulmonary embolism in low risk patients may be a relatively benign condition that does not require extensive investigation. Studies of cost effective non-invasive strategies for diagnosis will have to take this into account. Appropriate endpoints for studies would be the outcome for patients if treatment is withheld on the basis of negative tests rather than relating these tests to the results of angiography.

This excellent document should be read by all clinicians in emergency medicine together with their radiological colleagues, and the section for junior doctors' handbooks would be an ideal topic for your next clinical meeting. Hopefully, this report will improve patient care, as well as stimulate further research.

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Vitamin B-6: food or medicine?

The rules—and the politics—are different

The recent spat between the House of Commons Agriculture Select Committee and the government's Food Advisory Committee about vitamin B-6 was inevitable.[1] The problem started in June 1997 when the Food Advisory Committee, on the advice of the Department of Health's Committee on Toxicity of Chemicals in Food, Consumer Products, and the Environment, recommended that vitamin B-6 should be seen either as a food supplement, in which case the daily dose would be limited to 10 mg, or as a medicine, when it could be available in higher doses. The draft regulations, issued in April 1998 with a 26 June deadline for comments, stipulated that over the counter sales of vitamin B-6 from pharmacies should be limited to daily doses of 11-49 mg; for doses of 50 mg and over the vitamin would have to be prescribed. This position was fiercely contested by the Agriculture Select Committee in its report, conveniently published on 23 June. This argued that limiting the daily "food" dose to 10 mg/day was scientifically unsound and infringed individuals' rights to decide what they ate.[2]

Whether or not the Food Advisory Committee has got it right—and it probably has—some guidelines were certainly needed. The daily dietary requirement of pyridoxine, which plays an essential part in amino acid metabolism, is around 1.4 mg for men and 1.2 mg for women, and in those who are B-6 deficient the *British National Formulary* recommends up to 150 mg daily. Good evidence also exists that vitamin B-6 can prevent (daily dose 10 mg) or reverse (150 mg/day) isoniazid induced neuropathy and treat idiopathic sideroblastic anaemia (up to 400 mg/day). Here then are the bona fide food and medicinal requirements for vitamin B-6.

A survey for the Food Advisory Committee in 1997 showed that of the 400 vitamin B-6 products available as dietary supplements in the United Kingdom, around 50 contained daily doses of over 50 mg and four contained doses of 250 mg.[3] What these higher doses were being used for is not clear, but vitamin B-6 is often taken to reverse symptoms of the premenstrual syndrome, the menopause, and depression: for none of these is the evidence of benefit persuasive. Here then is the nub: at the doses at which vitamin B-6 is being used as a medicine—for conditions such as premenstrual tension—there is, according to the *British National Formulary*, "little sound evidence to support the claims."

How then can a substance be used in such high doses as a foodstuff? Legally it is somewhat arbitrary whether a substance is a medicine or a foodstuff, and the decision often depends on how the manufacturer presents the product. Guidelines have been published,[4] but even so a judgment by the licensing authority may be challenged in the courts. Briefly, a product should be classified as a medicine if it is manufactured or supplied wholly or mainly for treating or preventing disease. Support for its being a medicine would come if its sale was accompanied by curative or remedial claims. A manufacturer who uses such claims would know that the product should be classed as a medicine. A second manufacturer, who argues that the product is purely a food supplement, might be permitted to market accordingly. The new recommendations make it clear that for vitamin B-6 the government has decided that at doses over 10 mg/day vitamin B-6 is a medicine.

Once a product moves from being a food to a medicine the benefit:risk analysis to which it is subject alters. While there is little in British food regulation relating to formal benefit:risk assessment, for medicines the science of assessment is mature. The licensing authority aims to balance the potential benefit from the product with both its unwanted effects and the inherent dangers of the underlying condition itself. Accordingly, the risk of serious unwanted effects from a drug used to treat an otherwise fatal cancer might be more acceptable than a trivial side effect from a drug used for a minor symptom. Into the equation must also go the numbers of patients likely to be damaged. The potent anti-inflammatory drug phenylbutazone was withdrawn from general use in arthritis because it caused deaths from bone marrow suppression at a rate of around 5.8 times per million scripts; no such limitation was applied to indomethacin, for which the

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equivalent figure was 1.4 per million scripts.[5] These are fine judgments, which can result in denial of a medicine to many thousands to avoid a serious unwanted effect in one.

But is there a risk in taking vitamin B-6? This is probably the most contentious part of the current debate. The Committee on Toxicity argued that there was.[2] It is recognised that vitamin B-6 can cause peripheral neuropathy in high daily doses. It seemed most persuaded by a study from 1987 showing that over half of a group of 172 women taking vitamin B-6 for around three years in doses averaging 117 mg/day developed symptoms such as parasthesia, hyperaesthesia, weakness, or numbness which reversed when the vitamin was stopped. The results were not consistent with other studies and the trial design was weak, but it seems inescapable that with such large numbers some women will indeed have developed neuropathy at these low doses. Once this step was taken the next follows easily: for conditions where there is no clear benefit from the vitamin any exposure of a woman to risk, even a small one should only be permitted after discussion with a prescriber.

The debate between the rights and wrongs of central (government) and peripheral (individual) decision making is important and is bound to surface again when the new National Institute for Clinical Excellence starts advising prescribers on best treatment. Clearly decisions should be made as closely as possible to individual consumers, but when major technical assessments are involved and when the results apply to communities rather than individuals the place for decisions lies more centrally. The Commons Agriculture Committee argues that if the product is adequately labelled, individuals should be left to decide for themselves. However, I find the Committee on Toxicity's centralist and restrictive position on vitamin B-6 more appealing.

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Improving the management of soft tissue sarcoma

Diagnosis and treatment should be given in specialist centres

Musculoskeletal sarcomas comprise 1% of all malignancies and have traditionally been associated with a poor prognosis. However, the past two decades have shown a dramatic improvement in prognosis for osteosarcoma and Ewing's sarcoma when treated by teams of pathologists, radiologists, oncologists, and surgeons who can provide the necessary combination of chemotherapy, surgery, and radiotherapy. A similar evolution has also occurred in some places in the treatment of soft tissue sarcoma. However, whereas no one questions that patients with bone sarcomas should be treated at specialist tumour centres, many patients with soft tissue sarcoma (which is at least twice as common) are treated outside such centres, often with a poor outcome.

Last December Clasby et al reported recent treatment outcomes for soft tissue sarcoma in the South East Thames region of England.[1] The first surgical procedure was a marginal excision (shelling out) in two thirds of cases. Less than half of these patients were given radiotherapy or had a re-excision with wider margins. This means that almost half of the patients had inadequate treatment. Consequently, the local recurrence rate was high and, with longer follow up, recurrence will probably occur in at least a third of the patients. This poor treatment is not unique: most reports from specialist centres all over the world include a substantial proportion of patients first referred after local recurrence because of earlier inappropriate treatment.[2–4] How many patients who are not referred at all is not known. In a Swedish study the local recurrence rate was three times higher in patients treated outside a tumour centre.[5] Local recurrence may be detrimental to the patient and is expensive. In a recent Scandinavian investigation the median cost of operation for local recurrence was £7000 (US$11 000) and a fifth of the patients needed an amputation (C Trovik, personal communication).

Soft tissue sarcomas are commoner with increasing age but do occur in younger people. Two thirds of the tumours are situated in the extremities and often present as a lump incidentally noticed by a patient in good general health with no pain or loss of function despite a tumour that may be large: the median size of deep seated extremity sarcomas is 9 cm.[6] This presentation makes soft tissue sarcomas easy to misdiagnose as benign tumours, such as lipomas, or muscle ruptures. Optimal treatment requires preoperative staging, including magnetic resonance imaging of the tumour, chest radiographs, and biopsy (incisional or needle). For a correct diagnosis of the over 50 histological types of soft tissue sarcoma conventional light microscopy often has to be supplemented by immunohistochemistry, electron microscopy, DNA cytometry, and cytogenetics or molecular genetics.

Limb sparing procedures—often with the help of plastic surgery—can be performed in nine tenths of patients and are often combined with radiotherapy. This treatment requires referral before surgery: anatomical staging is impossible after shelling out, and the risk of local recurrence is high even after re-excision with a wider margin.[7] Also open biopsy

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before referral is dangerous: outside a specialist centre wrong diagnoses are common because of inexperienced surgeons (who do not sample representative tissue) or pathologists (who do not seek second opinions).[8] Patients managed in specialist centres are regularly followed for early detection of recurrence, either local (in 10-15% of patients) or distant (in more than a third, the commonest being pulmonary metastases). Chemotherapy and metastatectomy are increasingly used. With this treatment programme, morbidity and mortality from soft tissue sarcoma have decreased substantially.

How can we ensure that more patients get the benefit of optimal treatment? Twenty five years ago we faced the same problem as Clasby et al and started a sarcoma centre in the southern region of Sweden. We soon realised that the mere existence of a centre was not sufficient: during the first five years of our tumour service data from the Swedish national cancer registry showed that only a third of patients with soft tissue sarcoma were referred before surgery and a third were not referred at all. Most of the patients referred before surgery had been seen by orthopaedic surgeons, whereas general surgeons usually shelled out all lumps for diagnosis—Clasby et al found the same. We lacked clearcut guidelines on which tumours to select for referral from among the overwhelming numbers of benign lesions that were 200 times more common.

Based on epidemiological data we formulated the following simple guidelines: refer to our centre before surgery all patients with soft tissue lesions that are *(a)* larger than 5 cm or *(b)* deep seated (muscular) or *(c)* otherwise suspected of malignancy. We repeatedly lectured at local hospitals explaining the advantage of following these guidelines. We gave the same information to all medical students during their course in pathology and again during general surgery and orthopaedics. Doctors who referred patients with sarcoma before surgery were sent personal letters outlining the specific advantages for their patients. The outcome was remarkable: over the past 10 years over four fifths of all patients in our region with a deep seated soft tissue sarcoma of the extremity or trunk wall have been referred before surgery.[9] This experience exemplifies one strategy for achieving the necessary centralisation of soft tissue sarcoma.

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Bournewood: an indefensible gap in mental health law

Capacity is set to become a major clinicolegal issue

In December 1997 the Court of Appeal ruled that it was unlawful to admit an autistic adult to a psychiatric hospital on an informal basis when the patient lacked the capacity to take part in that admission, even if he did not object. In so doing the court determined that any patient who was incapable of consenting to informal admission could only lawfully be admitted under the statutory procedures of the Mental Health Act 1983, thereby enjoying the protections afforded by the act. The judgment has now been overturned by the House of Lords,[1] seemingly assuaging the concern of professionals and the Department of Health that having to detain all such patients would have major resource implications (through increasing the average number of detained patients from 13 000 to 35 000[1]). The House of Lords' judgment turned on a legal technicality, as well as discussing at length whether the patient was "detained" and, if he was, whether such detention could be justified in terms of the common law doctrine of "necessity." Yet, an ethical and legal gap remains, since, as Lord Steyn argued, "there can be no justification for not giving to compliant incapacitated patients the same quality and degree of protection as is given to patients admitted under the Act of 1983."

Despite the House of Lords upholding what had been the status quo, professional practice is unlikely to remain unchanged. The legal and ethical issues raised by both Bournewood and *Who Decides?*[2] (which considered the scope for reform of the law for managing the affairs of those unable to make decisions for themselves[3]) have probably raised professional consciousness of the "incapacity" criterion for clinicolegal decision making beyond complete redress. Professional practice is likely to shift, however subtly, in favour of more sectioning, whether as a consequence of greater legal defensiveness or of increased awareness by practitioners of some of the advantages of detention.

As Lord Steyn observed, the case also exposes "an indefensible gap in our mental health law" for a large

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class of vulnerable incapacitated patients. It is therefore incumbent on both lawyers and clinicians to propose safeguards for patients who are "de facto detained"—that is, patients who are not detained in law but who, because of their mental or physical disabilities, cannot leave. These include not only patients with learning disabilities and dementia but also many severely mentally ill psychotic patients who are admitted informally under the necessity principle applied in Bournewood.

However, deciding on the means of safeguarding should not be precipitous. We have little knowledge about how effective the current safeguards are for detained incapacitated patients. Such patients are, for example, eligible to apply for tribunal review—indeed, hearings take place automatically when patients do not exercise this right or even when they resist it. Yet we know little of the protective effect of this enforced safeguard, though we do know that tribunals can sometimes cause distress.[4] Rather, we should start with a number of objectives and consider carefully how these might best be satisfied. Bynoe and Holland argue, for example, that these objectives should include identifying more clearly cases where intervention is justified, introducing some system of independent objective review, and encouraging minimum standards of fairness in the process of decision making.[5]

What safeguards might at least be considered for non-detained patients who lack capacity? Although its likely protective effect involves substantial speculation, extending the remit of the Mental Health Act Commission to all informal patients is an obvious candidate. This would probably be the least costly option but it would be inefficient, through also covering many patients who retain their capacity. So, should such a provision cover only those deemed clinically to lack capacity, or those flagged up as vulnerable by close relatives. Alternatively, should there be some formal review mechanism (tribunal or otherwise) relating to incapacitated patients?

A different approach would be for a court to appoint someone as a "guardian" on a clinical finding of incompetence or to expand the possible responsibilities of a Guardian ad Litem (a legally qualified representative appointed to protect the interests of the patient). Alternatively, aspects of the Law Commission's proposals in relation to treatment of incapacitated patients' physical disorders might embrace all treatment of all incapacitated patients, this approach perhaps even being extended to replace the principles underpinning the Mental Health Act 1983. An advantage of this would be that it could directly address the increasingly obvious chasm between common law and statute. This chasm is well illustrated by a case where a patient was determined in common law to retain her capacity to refuse nasogastric feeding and where it would not have been in her best interests to be treated even if she had lost her capacity, yet she could be treated against her will under section 63 of the 1983 act.[6]

Of crucial importance to doctors, however, is that what is chosen should be not only ethical and rational but also easily understood and operated. Avoiding having to continue to deal in different ways legally with the treatment of mental and physical disorders would represent a first step. That would almost certainly require legislation. Any solution, however, is bound to increase the responsibility on clinicians to assess capacity. Fortunately, clinicolegal advice, both British[7 8] and North American,[9] is already available.

What is not in place in Britain is widespread clinicolegal experience in assessing capacity or research into its assessment. Both will soon become imperative in relation to assessing patients who require either psychiatric or physical medical interventions. Capacity is set to become a major clinicolegal issue in this country.

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Quality to the fore in health policy—at last

But the NHS mustn't encourage quality improvement with punitive approaches

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In its own words, the consultation document on quality in the English NHS sets out a formidable agenda for change. Nevertheless, it constitutes a major advance, putting quality improvement at the heart of the service.[1] The proposals describe a national approach that encompasses the National Institute of Clinical Excellence (NICE); the Commission for Health Improvement (CHIMP); national frameworks in key disease areas; the previously described performance management framework, with indicators relevant to NHS priorities; and a national patient survey. Locally, implementation and monitoring will be delivered through clinical governance, supported by national and local systems for lifelong learning, and reviewed systems of professional self regulation. Do all these elements add up to a coherent approach?

The national institute will appraise evidence and develop and disseminate guidance and audit methods. It will coordinate or take over current activities such as guideline development and effectiveness bulletins. This

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is desperately needed because the plethora of guidelines—of variable quality and developed by multiple bodies—has created confusion in the service.[2] But how will it deliver this huge agenda, apparently without additional resources? The original role of the Agency for Health Care Policy and Research in the United States was similar, but even with huge resources it could not address the 30-50 annual appraisals proposed here and has had its role considerably curtailed. A further consultation document on appraisal is promised, but the danger exists that the national intitute's influence will be diluted by the requirement to engage closely with sponsoring companies for new drugs and technologies and to consult widely on its conclusions. What will be the status of its conclusions? Will its advice be clear and acted on? Will it be able to meet the differing needs of the Department of Health, of clinicians, and of commissioners? How would it deal with Viagra (sildenafil)?

The Commission for Health Improvement will undertake a rolling programme of provider and service reviews. The experience with not dissimilar visits to schools by the Office for Standards in Education (Ofsted) is anecdotally one of frenzied and distracting preparatory activity and of a process that may fail to identify issues worthy of improvement. The former Health Advisory Service (not mentioned here) had a similar role and was criticised for inconsistently applying implicit standards and the absence of mechanisms for follow up action. Public reports and follow up action plans may meet some of the concerns about previous NHS review mechanisms, but the Ofsted experience suggests that not all concerns will be met. Furthermore, the role of the commission as a troubleshooter, and threats to send it in to sort out problems, may mean that it creates conflict and defensive reactions. I also worry about the publication of indicators for named hospitals and specialty by specialty. Even if they are over time to be risk adjusted, major concerns about the use and abuse of publicly available indicators exist.[3-6] These concerns may be ignored in the drive to increase public accountability boosted by the recent Bristol case.[7] Measurement for improvement is not measurement for judgment.[8]

Thus, there may be a problem with reconciling the laudable commitment to continuous quality improvement with elements of the bad apple approach.[9] While we need mechanisms to prevent serious problems, the external inspectorial nature of the commission and the publication of performance indicators may be counter to the underlying aims of the strategy, and may distract from the otherwise positive approach.

The national patient survey is not convincing. What information is it seeking and why? Effort might be better placed in engaging the public in discussions on priority setting rather than eliciting their views on mixed sex wards. Will the survey ask about satisfaction, or health status and social circumstances, both of which are mentioned? Major methodological issues exist in assessing patient satisfaction.[10] If the first survey is to take place later this year, what opportunity will there be for rigorous development?

The phrase "lifelong learning" is new to this document and—alongside multidisciplinary learning and team working—is welcome. Education underpins quality, but much needs to be done to support lifelong learning for health professionals. While reform of the specialist registrar grade has produced educational improvements for doctors in training, present systems of continuous professional development, based around time and points accumulated, are oversimplistic and take little account of individual needs. Nor is there a system of appraisal of career grade doctors to support the proposed personal development plans. And what of other clinical professionals? At present nurses scrape around for small sums of money to attend local courses while their medical colleagues attend lavish international conferences; the balance will have to change.

If we get it right, clinical governance will be the critical element for change.[11] The history of quality improvement activity in the NHS has been one of fragmentation and marginalisation.[12] Clinical governance offers a way of bringing together the many disparate components. Making quality of care a board level function is crucial: indeed, it seems absurd that financial issues have dominated boardroom discussion while quality of care has not. Nevertheless, work needs to be done to engage doctors and other clinicians and assuage their fears about the concept.

Most encouraging overall is the consistency and coherence of the approach of *A First Class Service*, with a sense of coordination across policy areas. For example, the proposals will mesh with the forthcoming strategies on human resources and information technology. Too often NHS staff have had to change their values when moving from one policy area to another and have been judged against measures (such as the efficiency index) that reflect their achievements as accurately as fairground distorting mirrors. Previously services have been forced by NHS policy to concentrate on finance and activity. This should now change. Despite some concerns, the NHS now has an organisation-wide approach to implementing effective systems of quality improvement within its grasp: we must not allow the opportunity to slip through our fingers.

I thank Paula Whitty and John Spencer for their advice.

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