

into a state akin to the seasonal anoestrus of animals and, as melatonin can suppress the growth of human breast cancer cell lines *in vitro*, protect them from breast cancer at the same time.⁵ Presumably the pill must be taken in the evening because of the profound hypnotic effects of such a massive dose of melatonin. The induction of sleepiness alone could make it a very effective contraceptive.

Further work is under way to isolate and characterise melatonin's receptor in the hope of designing synthetic agonists and antagonists. A simple derivative of tryptophan and serotonin, melatonin is cheap enough to make, but unfortunately it will still cost millions of dollars to complete the acute and chronic toxicity tests required by drug regulatory authorities. The evidence that taking melatonin benefits jet lagged travellers, shift workers, blind people, and elderly

people with sleep disturbances becomes stronger by the day.^{1,2,5} Let's hope that we will soon see it on the market.

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Outcomes in intensive care

Are related to case mix, but we still need much better measures

This issue of the *BMJ* includes two papers that examine aspects of intensive care in the United Kingdom and Ireland.^{1,2} They represent the first large collaborative study of intensive care activities and outcome to have been conducted in these two countries, and the results have implications for medical audit in general as well as for intensive care. What are these implications, and what do the studies tell us about intensive care practice?

That differences in case mix should influence outcome of medical care is not surprising. Case mix refers to factors that characterise the patient population in terms of diagnosis, age and sex, severity of illness, and available treatment. The influence of case mix on medical outcomes is well recognised,^{3,4} but it is not easy to measure. In an era of managed health care in which budgets and contracts govern medical activities, intensive care units (and other disciplines) will find it reassuring to be able to measure the impact of case mix on outcome rather than having substantial variations attributed to differences in quality of care.

The interrelations between different components of case mix need to be explored in detail. For example, increasing age may inherently include other risk factors such as pre-existing chronic disease. The reported impact of age on outcome varies among countries,^{5,7} suggesting that it is biological age, not chronological age, that is important. International and intranational comparisons may have to wait for the development of better measures of physiological reserve and population health. Multivariate analysis will help to clarify some of these issues, but statistical manipulation of biological variables is less complex than measuring them in the first place, and Rowan and her colleagues are right to draw attention to the need to standardise terminology on case mix. Severity of illness is a good place to start.

The American APACHE II system had a considerable impact on intensive care because it described the important but nebulous concept of severity in terms of homeostatic disturbance by attaching numerical values to physiological variables and chronic health status.³ In conjunction with weighted coefficients for specific diagnoses these values could then be used to calculate the risk of death for groups of patients. By comparing predicted with actual outcomes (the standardised mortality ratio), comparisons could be made between different treatments, and indeed between different intensive care units,⁸ by controlling for the main components

of case mix. Can this tool be used to assess intensive care performance in the United Kingdom?

Rowan *et al* have shown that, when a large cohort of patients is examined in this way as a group, the APACHE II system fits the United Kingdom and Irish data almost as well as the American data from which it was derived. Indeed, for 22 of the 26 contributing intensive care units, if we assume that mortality ratios are normally distributed, the APACHE II system seemed to be able to account for all the observed differences in mortality. This is impressive.

Nevertheless, significant differences appear between predicted and actual outcomes when certain subgroups—for example, those defined by age or diagnostic category—are tested. The authors discuss possible causes for these discrepancies, but the importance of this finding is that the same unmeasured factors may also be responsible for the differences in mortality ratios in the remaining four intensive care units, three of which “performed” significantly better, and one worse, than the majority. Are these differences real or is the measuring device poorly calibrated?

Indeed, could the score be manipulated to give an unfair advantage? If in future such data were to be collected for resource allocation and contracting it might be possible to select values for physiological variables that would result in attractively low standardised mortality ratios: in a competitive health care system commercial advantage may not necessarily respect scientific truth. Physiologically based systems are also susceptible to treatment, and while this feature can be used to improve predictive ability,⁹ it may also be a source of significant error in comparisons of performance if patients receive substantial physiological support before admission,¹⁰ a phenomenon known as lead time bias.

The revised APACHE II system adjusts for this effect as well as incorporating new variables and diagnostic coefficients, but the improvement in predictive power is modest and the coefficients and equation for calculating risk are not in the public domain.¹¹ Automated systems facilitate collection of certain physiological variables but will not replace manual verification of all data. Binary methods (requiring yes/no responses) like the mortality prediction model¹² may well be useful adjuncts to physiologically based systems because they are independent of treatment and can be used to stratify patients before admission to intensive care and could therefore provide a form of cross referencing. Once again, however,

certain elements significantly related to outcome in the United States (malignancy and previous admission to intensive care) do not seem to be important factors in the United Kingdom and Irish cohort. Finally, interobserver variations remains a significant potential source of error, which may have profound effects on calculated probabilities of survival.¹³

Where does this leave audit of intensive care? The Intensive Care Society's APACHE II studies and others tell us that scoring systems predict the risk of a particular outcome: they do not predict the outcome for a particular patient, and they cannot be used as a substitute for clinical judgment. For example, a predicted risk of death of 50% identifies a critically ill population, but it also tells us that for any patient within that mortality band the outcome could not be more uncertain. Similarly, scoring systems may show comparative performance between groups of intensive care units, but they cannot be used to make judgments about single units in isolation.

The United Kingdom Intensive Care Society has recently established a national centre for audit and research, one of whose functions should be to develop reliable measures of case mix which would take into account temporal changes or regional differences in resources, population health, or treatments. This important initiative provides a unique opportunity to establish a national database for intensive care, as well as links with other European countries. Most intensivists will want to contribute to it provided that support for collection of data, confidentiality, and ownership of data can be assured and that assessment of performance is conducted in the spirit of constructive scientific inquiry.

A useful starting point for the centre would be to investigate the high mortality after discharge from intensive care described in the Intensive Care Society's APACHE II study, a

surplus mortality for individual units of 6-16%—or a total of 860 people. Why are these patients dying on the wards? Did pressure on beds precipitate premature discharge from intensive care? Were no high dependency facilities available? Was admission to intensive care inappropriate? Whatever the reason, it represents an important additional waste of lives and resources.

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The end of the GMC?

The government, not the GMC, is looking at underperforming doctors

Not with a bang but with a whimper the General Medical Council is slipping into history. Early this week the Department of Health announced that it had set up a group to "update current guidance and procedures relating to the poor performance of doctors." The sparse press release does not mention that the GMC has spent the past four years looking at exactly that subject. Nor does it mention that in the summer the government said it would not be able to find parliamentary time to enact the GMC's proposals. The government is sidelining the GMC and with it the self regulation the profession has enjoyed since 1858. What's more, it seems to be trying to do so with little public and professional debate.

History has overtaken the GMC, and already we can look back and see the flow of events that has led to its emasculation. The council's central task is to keep a register of doctors and guarantee to the public that everybody on that list is competent and professional. After its inception the council fought for decades to gain control over undergraduate education, but it never gained control over postgraduate education.

Undergraduate education is a mess, and postgraduate education has been "sorted out" by the government through the Calman report. The same Kenneth Calman, the chief medical officer, is to chair the new committee on underperforming doctors.

At the beginning of its 145 year period of influence the GMC paid little attention to registered practitioners who were rogues, but eventually it created disciplinary machinery to

remove them from the register. For many years it was criticised for being more concerned about adulterous doctors than incompetent ones, and those complaints are still heard. In the 1970s the council created a mechanism to deal with sick doctors, and it then began belatedly to debate what to do about incompetent or underperforming doctors.

During this prolonged debate—because the elephantine council works by achieving consensus across the profession—the power of doctors has declined and that of managers increased. The managers have been vocal about underperforming doctors, and a series of high profile disasters, together with tabloid treatment of doctors infected with HIV continuing to practise, have created public concern about the professionalism of doctors. Eventually the politicians have acted. The Labour party has already announced its intention to get rid of the GMC.

Some doctors—particularly some of the bright young things on Dr Calman's committee—may shed no tears over the passing of an atherosclerotic and increasingly anachronistic body, but when a profession loses self regulation it may cease to be a profession. The government may insist that self regulation is not ditched, but it's hard to accept that line. At the very least we need a full debate over self regulation, and at best we need medical leadership that can regain the initiative—for the interest of all.

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