The changing face of medical regulation: the view from the GMC

Finlay Scott reflected on the changing face of medical regulation at a joint meeting of the *British Journal of Hospital Medicine* and the Indian Medical Association (Lancashire) members on 28 September 2009, in Blackburn. This was his last public speaking engagement before retiring as Chief Executive of the General Medical Council (GMC).

Recently the Medical Act 1983 was modified to include: 'the main objective of the General Medical Council in exercising their functions is to protect, promote and maintain the health and safety of the public'.

Mr Scott felt that essentially, over the years, the General Medical Council has performed four functions, to promote high standards of medical education, to foster good medical practice through definition of standards, to keep an up-to-date register of qualified doctors and to deal fairly and firmly with doctors whose fitness to practise has been called into question.

In Mr Scott's view, the General Medical Council's strapline 'protecting patients, guiding doctors' is sometimes not clearly understood by the general public who often feel that protecting patients relates to the way in which the General Medical Council deals with doctors, rather than protecting patients by ensuring good standards.

In terms of regulation, the General Medical Council has worked towards a system of risk-based regulation and using risk assessment as an essential means of directing regulatory resources to where they can have the maximum impact on outcomes.

Medical regulation has moved to a four-layer model of personal regulation, team-based regulation, workplace regulation and national regulation, with international cooperation and dimensions. However, Mr Scott is convinced that local systems must be properly exploited before more is loaded onto regulators. If properly developed and well-resourced, local systems and clinical governors could provide the most effective means of identifying poor performance at an early stage and of helping, supporting and guiding doctors who may need assistance.

In terms of appraisal within the Good Medical Practice framework it is important to embed good medical practice standards in an enhanced system of appraisal which has four domains – of knowledge, skills and performance, safety and quality, communication partnership and teamwork, and maintaining trust. Mr Scott felt that it was very important to have a starting point where the role of regulator and revalidation is viewed as a success and that we risk highlighting too much poor practice of unacceptable behaviour rather than the fact that the overwhelming majority of doctors will meet, and exceed, the standards required.

Reflecting on the state of the nation, Mr Scott spoke about personal regulation being well embedded but that team-based and workplace regulation had considerable room for improvement and that national regulation was improving rapidly in the UK.

Questions and discussions centred around the General Medical Council's Fitness to Practise procedures, the role in undergraduate and postgraduate education and issues around credentials and revalidation for doctors not in structured training or career grades.

Professor Iqbal Singh and Professor Rob Campbell, who jointly chaired the meeting, paid tribute to the distinguished contributions of Finlay Scott both to the General Medical Council and to the development of medical regulation, and on behalf of the Journal and Indian Medical Association, wished Mr Scott a very happy and successful retirement.

Iqbal Singh, Rob Campbell

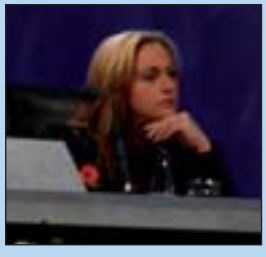
Reducing the length of stay for patients with complex wounds

St Helens and Knowsley Teaching Hospitals NHS Trust reduced the average length of hospital stay by 21.3% in a year by developing a discharge pathway with local primary care trusts for patients with complex wounds treated with vacuum-assisted closure (VAC) therapy.

Lord Darzi's *Transforming Services for Acute Care Closer to Home* report highlighted community-based wound care as having some of the highest potential for improving care and achieving the best quality services in the NHS. The report highlighted that evidence-based therapies, such as VAC therapy, could be used as part of an integrated approach to community services to provide joined-up local care initiatives.

Presenting findings of such an initiative at the Wounds UK conference in Harrogate, Lead Tissue Viability Nurse at the Trust, Debbie Gleeson, said: 'Patients requiring VAC therapy were being hospitalized unnecessarily. The discharge pathway developed resulted in a 20% saving from earlier discharge and reduced VAC hire expenditure.'

Debbie Gleeson, Lead Tissue Viability Nurse, St Helens and Knowsley Teaching Hospitals NHS Trust



During 2006–7 costs for VAC treatment alone reduced by £15 724 and there was a potential 44.8% rise in the number of patients treated with VAC therapy in the 750-bed trust as a result of collaborative working at no extra cost to the trust.

The trust predicts £37 724 savings will be made from VAC treatment costs alone as a direct result of earlier discharges from patients treated by the tissue viability service in 2009–10. Ms Gleeson added: 'This joined up approach has resulted in a reduction in spend on therapy, more patients treated faster and improved quality of life for discharged patients in line with the themes of the QIPP [quality, innovation, productivity and prevention] programme.'

David Melbourne, Deputy Chief Executive of Heart of Birmingham Teaching Primary Care Trust, said: 'This is a concrete example of how we can use innovations to increase NHS productivity. The win for the Trust is that wounds are healed quicker giving us savings in district nurse time.'

Rhonda Siddall

Poor diet linked with depressive symptoms

People who eat a diet laden with processed and high-fat foods may put themselves at greater risk of depression, according to new research. Eating a 'whole food' diet with plenty of fresh vegetables, fruit and fish could help prevent the onset of depressive symptoms in middle age.

The study (Akbaraly et al, 2009) is the first to examine the association between overall diet and depression. Previous studies have focused on the effect of individual nutrients.

Researchers from University College London studied 3486 participants from the Whitehall II Study, who had an average age of 55 years and worked in civil service departments in London. Each participant completed a questionnaire about his/her eating habits, and a self-report assessment for depression.

The researchers found that people with the highest intake of whole food were less likely to report symptoms of depression, whereas high consumption of processed food was associated with increased odds of depression.

The associations between diet and onset of depressive symptoms remained after controlling for other indicators of a healthy lifestyle, such as not smoking, taking physical activity and a healthy body mass.

The authors said: 'Our results suggest that consuming fruits, vegetables and fish may afford protection against the onset of depressive symptoms, whereas a diet rich in processed meat, chocolates, sweetened desserts, fried food, refined cereals and high-fat dairy products would increase people's vulnerability.'

Suggested explanations for these findings include the protective effects of either high levels of antioxidants in fruits and vegetables or the high levels of long-chain polyunsaturated fatty acids in fish. It is possible that a whole food diet protects against depression because of the combined effect of consuming nutrients from lots of different types of food.

The researchers called for further research to explain these findings.

Akbaraly TN, Brunner EJ, Ferrie JE, Marmot MG, Kivimaki M, Singh-Manoux A (2009) Dietary pattern and depressive symptoms in middle age. *Br J Psych* **195**: 408–13

Prandial insulin best as needed in type 2 diabetes

Type 2 diabetes patients requiring insulin do best if they start with a basal insulin and prandial insulin is added as needed, according to the results of a long-awaited study presented at the International Diabetes Federation World Diabetes Congress in Montreal, Canada. The 4-T study (Holman et al, 2009) also showed that good blood glucose control with a low rate of major hypoglycaemia is possible for type 2 diabetes patients even with intensive insulin treatment.

Lead author Professor Rury Holman from the Diabetes Trials Unit at Oxford University presented the results of the 3-year study in which 708 patients with suboptimal glycosylated haemoglobin (HbA_{1c}) levels on metformin and sulphonylurea therapy were assigned to receive biphasic insulin aspart twice daily, insulin aspart three times daily or insulin detemir. A second insulin was added if hyperglycaemia became unacceptable during the first year or if HbA_{1c} was more than 6.5%.

Professor Holman explained: 'Large-scale direct comparisons of complex insulin regimens have not been performed and there has been no evidence-based consensus about which insulin formulation should be used to initiate or which complex insulin regimen might be most appropriate.'

The 4-T results suggest that patients with type 2 diabetes who require insulin on top of oral therapy do better if they start on a basal insulin with prandial insulin added as needed. Median HbA_{1c} levels were similar for patients receiving biphasic (7.1%), prandial (6.8%) and basal (6.9%) insulin-based regimens (P=0.28).

Fewer patients had a level of 6.5% or less in the biphasic group (31.9%) than in the prandial (44.7%, P=0.006) or the basal group (43.2%, P=0.03), with 67.7%, 73.6% and 81.6% respectively taking a second type of insulin (P=0.002).

Median rates of hypoglycaemia per patient per year were lowest in the basal group (1.7), higher in the biphasic group (3.0), and highest in the prandial group (5.7) (P<0.001 for the overall comparison). The mean weight gain was higher in the prandial group than in either the biphasic group or the basal group.

Professor Holman said: 'These findings provide clear evidence to support starting insulin therapy in people with type 2 diabetes with a once-a-day basal insulin with the subsequent addition of a mealtime insulin if glycaemic targets are not met.'

Rhonda Siddall

Holman RR, Farmer AJ, Davies MJ et al, for the 4-T Study Group (2009) Three-year efficacy of complex insulin regimens in type 2 diabetes. *N Engl J Med* **361**: 1736–47

Chronic pain: disease or symptom?

A review of brain imaging studies on patients with chronic pain, published in the ***Journal of Pain***, showed that after several years of suffering chronic pain there are functional, chemical and structural changes to the brain. This raises the question of whether chronic pain should be treated as a disease in its own right rather than as a symptom.

Reducing hip fracture risk in elderly women

The first study to demonstrate the effectiveness of an oral bisphosphonate in reducing the risk of hip fractures in elderly women up to the age of 100 years shows that risedronate is efficacious in older postmenopausal women with established osteoporosis, reducing the risk of hip fracture by 46% compared with placebo (***P***=0.019).

Improved seizure control with once-daily antiepileptic

Eslicarbazepine acetate (Zebinix), a once-daily antiepileptic, offers improved seizure control. It has been developed from carbamazepine, the 'gold standard' treatment, but with molecular changes to avoid formation of metabolites associated with side effects.

AMERICAN SOCIETY OF NEPHROLOGY – RENAL WEEK 2009
SAN DIEGO, CALIFORNIA, OCTOBER 27–NOVEMBER 1

Delaying renal replacement therapy in chronic kidney disease

Guidelines for the management of patients with advanced chronic kidney disease may have to be revised if data from a small UK study demonstrating the beneficial effects of discontinuing renin–angiotensin–aldosterone system inhibition can be confirmed.

Dr Aimun Ahmed and colleagues from the Sheffield Kidney Institute, Northern General Hospital, Sheffield examined the impact of stopping angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers in patients with chronic kidney disease stages 4–5 who were about to embark upon renal replacement therapy.

Dr Ahmed said that the rationale for this current study was that these patients have already progressed to end-stage renal disease, would soon require renal replacement therapy, and that discontinuing a potentially nephrotoxic agent at this stage might do some good, and could do no harm from the standpoint of disease progression.

He highlighted findings on 52 patients on angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers (21 women, 31 men, mean age 73.3 years) who were referred to the low clearance clinic at the Sheffield Kidney Institute in 2005–6 in anticipation of starting renal replacement therapy.

At 12 months after stopping angiotensin-convertingenzyme inhibitors or angiotensin-receptor blockers, the majority of chronic kidney disease patients had no significant onset or exacerbation of chronic kidney disease-related signs or symptoms.

Dr Ahmed concluded: 'Discontinuation of angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers has undoubtedly delayed the onset of renal replacement therapy in the majority of those studied. Indeed, a few patients improved to the extent that they were discharged from the renal services back to their GP after discontinuing angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers.

He continued: 'This observation may justify a rethink of our approach to renin–angiotensin–aldosterone system inhibition in patients with advanced chronic kidney disease who are approaching renal replacement therapy, or in those who we may be considering for conservative management.'

Stephen Pinn

This report is published online at www.doctors.net.uk/conferencehighlights

Inappropriate prescribing in older chronic kidney disease patients

More than half of elderly kidney disease patients admitted to UK hospitals may have been prescribed inappropriate drugs – often with 'catastrophic' consequences. According to a new study, antibiotics top the list of potentially harmful prescribing, followed closely by antihypertensive drugs.

The new data presented during Renal Week indicate that the prevalence of potential inappropriate medication prescribing in geriatric chronic kidney disease patients is unacceptably high.

Dr Anoop Amarnath from Hull Royal Infirmary, Kingston-upon-Hull, East Yorkshire reported that potential inappropriate medication prescribing is a global problem, leading to significant mortality and morbidity in the elderly. Until now, however, the prevalence of potential inappropriate medications in acutely ill geriatric chronic kidney disease patients had not been widely studied.

He outlined details of a retrospective analysis involving 100 such patients (>70 years, chronic kidney disease stages 4–5) admitted to this university teaching hospital over a 6-month period.

His study looked specifically at prescribing practices in elderly kidney disease patients – both in terms of the appropriateness or otherwise of the drugs prescribed and the doses involved.

The potential inappropriate medication prevalence in this cohort was 56% (56 patients having one or more potential inappropriate medications prescribed). Of the 622 prescriptions written for these patients, 81 (13%) were considered to be inappropriate, as defined by the latest British National Formulary guidance and the modified Beer's prescribing criteria.

Antibiotics accounted for 17 of the 81 potential inappropriate medications (21%), with vancomycin, penicillins and sulphonamides most commonly implicated. Antihypertensive drugs represented 15 of the 81 potential inappropriate medications (18.5%) – mainly angiotensin-converting enzyme inhibitors and angiotensin-receptor blockers.

Hypoglycaemic agents accounted for 12 of the potential inappropriate medications (14.8%), while there were nine analgesic potential inappropriate medications (11.1%).

'There are many unwanted consequences of inappropriate prescribing – ranging from unnecessarily and wasteful high-dose prescriptions to catastrophic illnesses and fatalities,' said Dr Amarnath.

There is no excuse for bad prescribing practice, he insisted. 'We have simple, but highly scientific, tools to identify more accurately what is appropriate and what is not, and these tools need to be used more frequently so that potentially harmful prescribing practices can be curtailed.'

Dr Amarnath emphasized: 'Only then will we ensure that high-risk patients – especially elderly patients with chronic kidney disease – are not being prescribed unsuitable drugs at the wrong doses.'

Stephen Pinn

This report is published online at www.doctors.net.uk/conferencehighlights

EUROPEAN ASSOCIATION FOR THE STUDY OF DIABETES
VIENNA, AUSTRIA, 27 SEPTEMBER–1 OCTOBER

Metformin reduces cancer risk in type 2 diabetes

Metformin was found to reduce the risk of pancreatic and colon cancers in patients with type 2 diabetes in an epidemiological study.

Professor Edwin Gale from the University of Bristol said: 'Our observational study suggests that metformin could play a significant role in pancreatic cancer.'

The retrospective cohort study was based on 300 British general practice records. Patients were excluded if they had had previous cancer. There were 60 cancer events per 1000 patient-years in the group exposed to the highest amount of insulin alone, compared with 34 cancer events per 1000 patient-years in the insulin plus metformin group. After adjustment for age, sex, and smoking status, the same ratio was true for insulin plus metformin *vs* insulin alone (5.73 *vs* 3.20).

Dr Craig Currie, a medical epidemiologist from Cardiff University in Wales, who co-authored the study, said: 'In the insulin-only group, there was a distinct dose–response relationship, with a six-fold increase in all forms of cancer in the highest group, compared with metformin monotherapy.'

The data were presented at a session on diabetes and cancer. Chairing the session, Professor Ulf Smith from Sahlgrenska University Hospital in Göteborg, Sweden acknowledged that further research is needed to determine whether the relationship with cancer rates is the result of high insulin doses or the insulin resistance that is associated with type 2 diabetes.

Professor David Russell-Jones from the University of Surrey gave an overview of a new meta-analysis of safety data about insulin detemir in the session. In studies lasting about 24 weeks, the risk for cancers of all types among 3983 patients with either type 1 or type 2 diabetes on detemir was 0.36 per 1000 person-years of exposure, compared with 0.92 for 2661 similar patients using NPH insulin. 'This data suggests that detemir has a lower incidence of malignancy *vs* conventional insulin,' commented Professor Russell-Jones.

Rhonda Siddall

Improved blood glucose control with liraglutide

Data from the extension phase of the Liraglutide Effect and Action in Diabetes (LEAD-6) phase III study suggest that patients switched from exenatide to liraglutide experienced improved blood glucose control and less nausea.

Professor Stephen Gough, professor of medicine at the University of Birmingham, said: 'These new data confirm that liraglutide might be a useful treatment option for type 2 diabetes especially when weight loss and hypoglycaemia are major considerations.'

In the 14-week extension study patients switched to liraglutide from exenatide had a statistically significant 0.32% (P<0.0001) improvement in glycosylated haemoglobin and a 0.9 mmol/litre improvement in fasting plasma glucose (P<0.0001), as well as significant improvements in beta-cell function.

The original 26-week LEAD-6 study showed that treatment with liraglutide, in addition to background therapy with metformin and/or glimepride, produced significantly greater changes in glycosylated haemoglobin than additional therapy with exenatide in 464 type 2 diabetes patients.

Professor Stephen Gough, Professor of Medicine and Consultant Physician/Diabetologist, University of Birmingham

In the 2-week extension 389 completers either switched from exenatide 10 µg twice daily to liraglutide 1.8 mg once daily following a 2-week lead-in of 0.6 mg once daily for 1 week and 1.2 mg once daily for 1 week, or continued on liraglutide 1.8 mg once daily.

Statistically significant additional reductions were seen in body weight and systolic blood pressure for the exenatide-to-liraglutide group (P<0.001), as well as for the liraglutide-to-liraglutide group (P<0.05).

Rhonda Siddall

Comorbidity important in severe mental illness

A joint statement calling for greater awareness of the excess cardiovascular mortality associated with severe mental illness was issued by the European Society of Cardiology, the European Association for the Study of Diabetes and the European Psychiatric Association.

'People with schizophrenia and bipolar disorder die prematurely, on average 10–20 years earlier than the general population,' said Professor Richard Holt from the University of Southampton. 'It's becoming more and more apparent that not only do these people have mental disease, but they are at considerably higher risk of cardiovascular disease and of developing diabetes,' he added.

Professor Holt explained that much of this excess risk among the mentally ill can be attributed to lifestyle factors. The joint statement documents the relationship between diabetes, cardiovascular disease and mental illness, and provides guidance about the screening that people should receive.

'There needs to be an increasing awareness that cardiovascular disease is more common among people with mental illness and also that it occurs at a much younger age', Professor Holt said.

Rhonda Siddall