In the linked analysis article, Purcell Jackson and Tarpley describe their concern that surgical trainees in the United States might be forced to work within a maximum 80 hour week.1 Meanwhile, the European Working Time Directive (EWTD) demands that all trainee doctors in Europe work an average of only 48 hours a week;2 and the Royal College of Surgeons of England is appealing for all their trainees to be allowed a 65 hour average week.3 Although Purcell Jackson and Tarpley’s concern that a maximum of 80 hours a week is insufficient for surgical trainees to gain the necessary experience, their argument that all surgical trainees need to be available all the time—for example, to observe rare procedures such as elective surgery on conjoined twins—overstates the case. How can we strike the right balance between gaining sufficient experience, ensuring safe working practices, and allowing doctors to have a life outside work?

The American College of Surgeons reflects Purcell Jackson and Tarpley’s position by also rejecting the 80 hour week; this implies that American surgeons believe that working with little rest is necessary for successful surgical training.4 However, evidence shows that patients do not want a familiar but exhausted person operating on them.5 Perhaps the next time a surgeon tries to obtain informed consent before a procedure they should tell the patient how much sleep they have had.

The EWTD was introduced in 1993 without a risk assessment (unlike more recent European directives), and its adverse effects on health care have been serious.6 Nor are we yet experiencing its full effect. The European Union has failed to publish its own 2008 survey of medical trainees’ compliance with a 56 hour week, but we know that many countries are not complying; the Greek government and Irish employers are already in court for non-compliance. Meanwhile Britain’s shortage of doctors is being masked by moonlighting and allegedly fraudulent work returns as some juniors work many more than the requisite 48 hours per week.7 This is neither safe nor sustainable. Member states are realising that they cannot just ignore the regulations, so what is to be done? Revision of the EWTD may take years of negotiations, but solutions are needed now.

Creating greater flexibility around current working would be one possible solution, rather than the blanket 65 hours a week for all trainees being called for by the Royal College of Surgeons. The EWTD has two separate elements: the first is strict entitlement to an 11 hour rest period in every 24 hours, plus 24 or 48 hours off every week or fortnight, respectively; the second is the limitation of an employee’s work to an average 48 hours a week. Almost all the safety benefits for doctors and patients come from the entitlement to rest.8 Although safety is one driver for reducing long hours, the limitation of working hours probably has as much to do with creating employment for European workers in general, which is not appropriate for health care in 2009 when we have too few doctors.

Could we not leave the rules about rest unchanged but exploit the existing flexibility around the number of working hours? This would not be easy—many disciplines require a seamless supply of doctors for 168 hours a week, and people increasingly expect to work fewer hours, to be able to work part time when their families need them, and to have a life outside work. However, medical training is no longer a matter of serving time but of acquiring skills and will inevitably vary in length depending on the discipline and the balance of full and part time work during an individual’s career. So why can’t we develop and implement a flexible system of training and service provision in place of the present “one size fits all”?

The present working time regulations can already be applied flexibly. Every employee in the United Kingdom can choose to opt out of the 48 hour week to work up to 78 hours a week; junior doctors can decide to opt out and to return immediately to a 56 hour week, but they are limited by the New Deal—the junior doctors’ employment contract that by enforcing an absolute 56 hour limit is even more restrictive than the EWTD.9 In addition, they can also be non-resident on call for up to an average 72 hours a week.10 Few surgical trainees in England or their consultants now operate at night. Hence, junior surgeons can be non-resident on call for up to 72 hours a week and can choose to work up to 56 hours a week—essentially what is demanded by the Royal College of Surgeons in England.

The old ways of training, time serving apprenticeships, and inflexible (essentially continuous) work are over. The training and service elements of each post need to be identified and considered separately, as do emergency and elective clinical work. Much effort needs to be invested into researching and improving continuity of care, because none of the workforce now works continuously—not even consultants.

The current system of rigid rotas is not ideal. In future, rotas must take account of part-time working, individual decisions about opting out of the working hours regulations, and the day to day measurement of hours of work when non-resident on call. The Department of Health

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4 American College of Surgeons (2009).
6 Royal College of Surgeons. (2009).
must move from their single minded implementation of the 48 hour week, to the flexibility that can now be provided by sophisticated rostering, thereby helping to improve patient safety, service delivery, and medical training.


Supine positioning after intrauterine insemination

Shows promise in increasing pregnancy rates

In the United Kingdom, intrauterine insemination is the mainstay of fertility treatment carried out before couples embark on in vitro fertilisation. It is recommended by the National Institute for Health and Clinical Excellence (NICE) and by a recent international workshop1 for couples with mild male factor infertility, unexplained infertility, and mild endometriosis.2

Intrauterine insemination is attractive to couples who want minimal drug treatment, low costs, and fertilisation in the fallopian tube, as in natural conception. Many people who have religious or moral objections to in vitro fertilisation find intrauterine insemination acceptable, and the procedure is often provided in small local clinics that cannot support more costly and complex treatments. However, the approach to intrauterine insemination varies, and it is unclear which approach is best.3,4 Success rates vary from 5% to 70%.4 In the linked randomised controlled study, Custers and colleagues compared the effectiveness of 15 minutes of immobilisation, during which women stayed in a supine position, with immediate mobilisation after intrauterine insemination.5

Intrauterine insemination has three steps. Firstly, the woman receives gentle ovarian stimulation with oral clomifene citrate or injectable follicle stimulating hormone or no stimulation at all in the natural cycle approach. Ovarian follicle growth is monitored by ultrasound, and women with too many mature follicles have their treatment cancelled or they undergo in vitro fertilisation, to minimise the risk of multiple pregnancy. Secondly, when the lead follicle diameter reaches a point deemed to signify follicle and oocyte maturity, a single injection of human chorionic gonadotrophin is given to allow ovaulation to be timed. Thirdly, about 36 hours later a prepared sample of the motile fraction of sperm is placed into the uterine cavity using a Cusco’s speculum and a fine flexible transfer catheter. Pregnancy rates per cycle do not approach those of in vitro fertilisation (in the UK 29% for the first cycle of in vitro fertilisation versus 12% for intrauterine insemination in women under 35), but the simplicity and low cost of intrauterine insemination allow for several cycles to be carried out quickly with acceptable cumulative conception rates. This technique has recently joined the list of procedures licensed by Human Fertilisation and Embryology Authority in the UK, and it is one of the most widely used forms of assisted reproductive technology.6

Three randomised trials have assessed various aspects of intrauterine insemination in recent years—the use of gonadotrophin stimulation compared with clomifene citrate,7 single versus double insemination,8 and whether intrauterine insemination is superior to expectant management in unexplained infertility.9 However, little attention has been paid to the mechanics of the procedure, so scientists have had to rely on evidence from case series and other less rigorous forms of evidence to make rational decisions on treatment.

Custers and colleagues found that of the 391 couples who were randomised, the ongoing pregnancy rate per couple was significantly higher in women who were immobilised than in those who were immediately mobilised (27% v 18%; relative risk 1.5, 95% confidence interval 1.1 to 2.2). Live birth rates were 27% and 17%, respectively (1.6, 1.1 to 2.4).

Their findings agree with the intuitive idea that lying with a “feet up” tilt for a few minutes after insemination, either after intercourse or intrauterine insemination, allows the sperm to ascend into the uterine cavity, before standing up brings the negative influences of gravity into play. Such postcoital positioning was advocated in the United States many years ago but did not seem to improve conception rates after sex.

The study can be criticised. Overall pregnancy rates are lower than is seen in many centres that do not use immobilisation, and the use of ovarian stimulation varied considerably between centres, with about a third of women receiving no stimulatory drugs and...
Prediction rules in cervical spine injury

Can reduce unnecessary imaging, without missing fractures or increasing adverse events

“Clinical prediction rules” or “decision rules” are designed to suggest a pathway of probability of a pathological condition and help the clinician choose a diagnostic or therapeutic course of action. The rules reduce the uncertainty inherent in medical practice—for example, in emergency medicine and trauma—by appraising clinical findings to make predictions. Because these rules affect patient care and health costs, they must be carefully evaluated before implementation. For this purpose, guidance and methodological standards exist for users and developers of clinical prediction rules.1,2 In the linked cluster randomised controlled study,3 Steill and colleagues assess the effectiveness of a knowledge translation strategy to implement the validated Canadian c-spine rule in 12 emergency departments in Canada.

Specific algorithms and prediction rules for the initial assessment of patients with cervical spine injury have been proposed in the literature. Since the early 1990s, the National Emergency X-Radiography Utilization Study’s low risk criteria (NEXUS)4 and the Canadian C-Spine (cervical spine) Rule (CCR)5-6 have evolved as two of the most promising decision rules to guide the use of cervical spine radiography in patients with trauma. Both tools have been derived and validated using robust statistical methods, with multiple head to head comparisons.7,8

Steill and colleagues3 study is well designed and carefully conducted in a large number of cases. Applying the findings to practice can be difficult, because several reasons make it hard to evaluate trauma patients who are at risk of cervical spine injury. Firstly, patients vary in their symptoms and the location and degree of pain; secondly, it is relatively hard to elicit objective symptoms. Because this makes it difficult to diagnose the severity of the damage, clinicians are keen to order radiographic

tests to obtain more information. Use of the Canadian C-Spine Rule can shorten the patient’s stay in the emergency department, but it is unlikely that it will lead to a rapid decrease in imaging rates. This is because in the case of accidents doctors often “overcall” the diagnosis on the basis of their own assumptions rather than the history and complete physical examination. In addition, patients tend to exaggerate the severity of accidents. However, despite these factors, Stey1l and colleagues show that the Canadian C-Spine Rule can reduce the number of radiographic tests by half, with no missed fractures or adverse events. The sensitivity (100%) and specificity (42.5%) of this rule mean that it is a reliable and safe way of identifying cervical spine injuries.2

Nevertheless, it is important to be realistic about how successful the rule is in reducing imaging rates in practice. As the authors suggest, lack of communication between clinicians increased the imaging rate, so repeated education is essential to keep the rate low. Thus, it might be better to set a target of carrying out radiography in only 40-50% of cases at the beginning of implementation.

Cervical spine clearance after traumatic injury remains a controversial subject. Regardless of which rule is used, cervical spine radiographs are ordered in more than two thirds of trauma cases, yet important injuries are identified in only 2%.11 So adoption of any validated cervical spine decision rule could substantially reduce wasteful use of medical resources, which is especially important in the current economic climate.

Clinical decision rules are intended to provide doctors with tools to help them choose the most appropriate care. They cannot replace clinical judgment or dictate the care of individual patients, however, and clinicians will have to make choices on the basis of available research and their own expertise. The success of implementation will depend on every member of the team being trained in how to use the rule, including triage nurses in emergency departments and paramedics.

Smoking cessation agents and suicide

The risk is uncertain, so patients should make an informed decision

Success in giving up smoking can be improved through social support, problem solving or skills training, and various drugs. A combination of drugs and other treatments is most effective.1 Drugs include nicotine replacement products, varenicline (Champix), and bupropion (Zyban and generics). Varenicline and bupropion inhibit the craving to smoke through unknown mechanisms. Both drugs influence the dopamine system, which regulates cognition, mood, and behaviour.2 Both varenicline and bupropion have been associated with “changes in behaviour, agitation, depressed mood, suicidal ideation, and attempted and completed suicide” in patients who had no psychiatric history and were not taking psychotropics.3 4 Nicotine replacement products have no such known associations.3 In the linked study, Gunnell and colleagues report the first retrospective cohort study to examine suicidal thoughts and behaviours after exposure to smoking cessation products.5

In the United States, changes to labelling of varenicline have been based on biological plausibility and voluntary spontaneous reports, which represent only a small fraction of all adverse drug reactions.6 Between May 2006 and November 2007, 37 suicides and 127 cases of suicidal ideation were reported in people taking varenicline.7 The Food and Drug Administration (FDA) plans to pay “more specific attention” to psychiatric side effects in clinical trials of smoking cessation agents in the future.2

Gunnell and colleagues assessed 80 660 men and women aged 18-95 who were prescribed a new course of a smoking cessation product between 2006 and 2008. They found no association between varenicline or bupropion and fatal or non-fatal self harm.8 Failure to find such evidence or failure to attain statistical significance is not the same, however, as finding evidence that supports the null hypothesis over competing hypotheses.7 The authors note multiple sources of potential confounding. In addition, FDA analyses of varenicline noted adverse effects within the first two weeks of exposure.9 Patients experiencing severe adverse events may have discontinued the prescription before it was
Current knowledge on products used for smoking cessation

Nicotine replacement products may be useful as a “first line” approach for smoking cessation. Consistent with the varenicline label, patients should strive to quit “cold turkey” on a specified date to minimise exposure. Before prescribing or refilling a prescription for varenicline or bupropion, a psychiatric history and suicide risk assessment using the Beck scale for suicide ideation may be useful. Current morbidity or distress may suggest use of cessation counselling and postponement of drugs other than nicotine replacement products. Varenicline is labelled for use in conjunction with counselling, which may also provide an opportunity to screen for suicidal thoughts or behaviours. Psychiatric morbidity that emerges during treatment should be referred to a mental health provider. Any serious adverse effects should be reported to the Medicines and Healthcare Products Regulatory Agency in the UK or the FDA in the US.

Alcohol use in South Asians in the UK

Is under-recognised, and alcohol related harm is disproportionately high

Ethnic minorities make up almost 8% of the population in the United Kingdom, yet their contribution to the cost of alcohol related harm, estimated at £20bn (£22bn; $32bn) a year,1 is not widely known. This has led to public health policies based on incorrect assumptions.

The evidence base is limited, but if place of birth is used as a proxy for ethnicity, alcohol related mortality in England and Wales is about the national average for Eastern European men and women, Sri Lankan men, and East African men, whereas men and women born in the Middle East, North Africa, West Africa, Bangladesh, Pakistan, China, and the West Indies and women born in India, Sri Lanka, and East Africa have lower mortality. Mortality is particularly high in Irish and Scottish people as well as in Indian men.2

Alcohol consumption in Irish and Scottish people is high,2 so it is not surprising that mortality is also high. In contrast, men born in India reportedly drink less than the general population,1 so mortality and alcohol related harm should be low. However, Indian men have higher rates of alcohol related admission to hospital in England than do British white men.4

Data limitations about the risk of suicide may contribute to reports of doctors disregarding these FDA warnings. In a study of black box warnings on suicide for gabapentin (used for epilepsy, chronic neuropathic pain, herpes zoster, and hot flushes), almost half the US neurologists studied reported that the warning would not affect their practice.5 Most did not routinely assess depression, and neither did they warn patients about the potential risk of suicidal thoughts or behaviours, even when they discussed the risk of other adverse events. Yet, the drug safety literature suggests that patients would prefer therapeutic failure (to keep smoking) rather than risk therapeutic harm (suicidal ideation, self harm, or suicide).6 The potential adverse event is severe, irreversible, immediate, and involves a “dread disease,” whereas other smoking cessation interventions (nicotine replacement, social support, problem solving, or skills counselling) are effective and carry no known risk of such side effects. Finally, patients cannot report suicide related adverse events or make a treatment preference if doctors do not fully inform them about the risks, uncertain though they may be.

This evidence does not support the myth that alcohol related harm is low in all UK South Asians (those from India, Pakistan, Bangladesh, Sri Lanka, and Nepal). This myth is perpetuated in the government report that informed the Alcohol Harm Reduction Strategy for England. It has been criticised for categorising different ethnic groups from South Asia—such as Indian Hindus and Sikhs, Pakistani Muslims, Bangladeshi Muslims, and Sri Lankans—into one group. It also does not account for the large differences in ethnicity between people from different states—for example, Punjab or Gujarat.

The degree and pattern of alcohol use among UK South Asians varies greatly. This can be explained by how the miscellaneous religious taboos around substance use interweave with cultural differences arising from geographical, historical, and socioeconomic factors, which result in contrasting social sanctions. Differences between generations and increased alcohol consumption from acculturation further complicate the picture.

One possible explanation for greater alcohol related morbidity in South Asians relates to the biological factors that increase end organ damage. For example, South Asians who presented with alcohol dependency had much higher rates of acetaldehyde mediated haemoglobin modification than British white people, despite having a shorter history of drinking heavily. The standardised mortality ratio of deaths from alcoholic liver disease in South Asian men is almost four times that of British white men; Sikh men made up 80% of the mortality.

Understanding how the differences in religion, culture, history, and socioeconomic position interact with biology is the key to making sense of the evidence and developing equitable services to tackle the problem. Local community groups should be involved in designing, reviewing, and modifying clinical services. An ethnic staff mix reflecting the local population would improve cultural competence and ensure that the right language skills, world views, religious contexts, gender roles, family structures, and dynamics are generic to services.

To tackle key problems in setting up services for minority groups, the Alcohol Education and Research Council recommended stronger and more flexible operational links with other stakeholders, such as domestic abuse agencies, homelessness services, antenatal clinics, probation services, and prisons. Strategies should include outreach workers developing trusted links with the relevant South Asian communities and actively promoting community services, specialist inpatient services, and residential rehabilitation services.

Collaboration between clinicians and social scientists would help to construct health messages that are consistent with differing health beliefs and world views. Delivering those messages through media that are tailored to the population, such as Asian TV channels, would improve the poor level of awareness. Reluctance to access support beyond primary care and the immediate family should be tackled by primary care practitioners who should promote the view that it is a disease rather than an affliction, that they are happy to discuss it, and that treatment is available.

The UK’s current health strategy for alcohol is failing a substantial proportion of citizens. Some subgroups of South Asians in the UK have a major problem with alcohol and seem to be more susceptible to its effects. Evidence suggests that the problem will worsen with acculturation.

Research will benefit not only the UK, but countries such as the United States, Canada, and Australia, where large numbers of people come from these ethnic groups. Understanding the rise in alcohol related harm in India would be potentially illuminating.

6. Alcohol Concern. 100% proof: research for action on alcohol. Alcohol Concern, 2002.