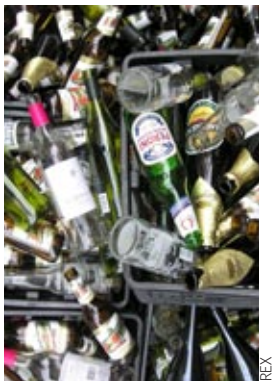
Tackling alcohol misuse in the UK

Higher alcohol taxes and restricting availability are essential



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Thomas F Babor professor and chairman, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT 06030-6325, USA
babor@nso.uchc.edu

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Nations, like people, can develop a pathological pattern of alcohol misuse. Ever since the Blair government consolidated its alcohol control policy around a "partnership" with the alcohol drinks industry,[1] the United Kingdom has been anything but united about how to deal with the nation's alcohol problems.[2 3] While some people have seen collaboration with industry as a way of "disabling the public interest,"[2] the ostensible rationale was to involve alcohol producers and retailers in new initiatives—such as voluntary limits on advertising, safer packaging, and codes of good conduct—to make town centres safer at night. In response to mounting evidence that this approach is not working,[3] this week the BMA voices its opinion on how the problem should be tackled through the release of a report on alcohol misuse.[4] According to the report the long wave of increasing alcohol consumption—which has moved the UK into eighth position in the hard drinking nations of Europe—did not occur by chance. It was facilitated by the progressive dismantling of previously effective alcohol control policies through deregulation and trade liberalisation, exemplified by 24 hour a day opening.

Although the connection between deregulation, consumption, and alcohol related problems is admittedly complex, the BMA report makes a good case for a combination of new regulatory measures, controls on consumption, and approaches to minimise harm. The evidence base for effective alcohol policy reviewed in the report is impressive. Universal strategies like increased alcohol taxes can drive down per capita consumption, especially in younger drinkers, and targeted approaches such as early intervention and specialised treatment are effective ways to deal with hazardous and harmful drinkers.[5] The BMA's recommendations are organised into six areas: controlling access to alcohol, promoting responsible industry practices, introducing measures to reduce drink driving, promoting health education and healthy living, encouraging early intervention and treatment, and supporting international cooperation on alcohol control (see box).

According to the report, the cost of implementing and sustaining these policies would be offset by the revenues gained from increased alcohol taxes. Conspicuously absent from the recommendations are measures to expand school based alcohol education,[6] which is politically popular and easy to implement but ineffective. Instead, the emphasis should shift to public awareness campaigns that specify safe drinking limits (no more than 21 units each week for men, 14 for women) and heighten the perception that drink driving laws will be enforced. Finally, the report suggests that alcohol policy needs to have a global vision, one that moves towards the adoption of an international policy framework modelled after the World Health Organization's framework convention on tobacco control (www.fctc.org).

Although expert committee reports have been seen before in the UK,[1 7 8] a policy to control alcohol has never been proposed with as much authority, vision, and hard evidence to back up its recommendations. The BMA report shows that effective alcohol policies are available, tested, and ready to be implemented. What is refreshing in the report is the absence of exaggerated claims and platitudes, which make it more likely that its recommendations could return the UK to its former status as a temperate nation.

Main alcohol control policies recommended in BMA report

Control access to alcohol
- Reduce easy access to alcohol through controls on hours of sale and outlet density
- Increase alcohol taxes in a way that outpaces inflation and is proportionate to the amount of alcohol in the product

Promote responsible industry practices
- Strict enforcement of licensing laws (for example, use test purchases to monitor sales to underage drinkers)
- Prohibit irresponsible promotional activities, such as marketing of flavoured alcoholic drinks ("alcopops") to young people

Implement measures to reduce drink driving
- Reduce the legal blood alcohol limit from 80 mg/100 ml to 50 mg/100 ml
  Permit use of random roadside alcohol testing without prior suspicion of intoxication

Education and health promotion
- Include in all product labels and alcohol advertisements the standard UK guidelines for alcohol consumption

Early intervention and treatment
- Conduct routine alcohol screening and brief intervention in medical settings to reduce hazardous drinking
- Fund a national initiative to expand specialised treatment for excessive drinkers

International cooperation on alcohol control
- Support alcohol control initiatives through the European Union and World Health Organization

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Medication errors caused by junior doctors

Association with depression and burn-out remains uncertain

RESEARCH, p 488

James McLay senior lecturer in medicine and therapeutics
j.mclay@abdn.ac.uk
Sarah Ross lecturer in medicine and therapeutics, Department of Medicine and Therapeutics, University of Aberdeen, Foresterhill, Aberdeen AB25 2ZD

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The effects of medical errors on patient morbidity and mortality have been highlighted in the United Kingdom and the United States.[1 2] Preventable medication errors account for 10-20% of adverse events in patients admitted to hospital.[1] In the UK, up to 1.5% of hospital prescriptions may contain a medication error, and a quarter of these could result in potentially serious effects.[3] The situation is similar in Australia and the US—medication errors occur in about 1-2% of patients admitted to hospital, resulting in around 7000 deaths a year in the US alone.[2 4] Although junior doctors are responsible for most medication errors in hospital,[5] investigations to date have mainly focused on the role of system failures, rather than factors in prescribers, such as burn-out or depression. The mental health of junior doctors has been studied widely, but no data are available on the possible association between depression and burn-out in prescribers and medication errors. In their accompanying cohort study, Fahrenkopf and colleagues report levels of depression and burn-out and associated medication errors in junior doctors working in two paediatric hospitals.[6] The use of a paediatric setting is particularly relevant because prescribing in children is complicated by the use of off label drugs and non-standard doses and formulations. Consequently, the risk of error is high—5-27% for each medication order for children admitted to hospital.[7] Fahrenkopf and colleagues surveyed 123 junior doctors in two paediatric centres in the US to determine levels of depression and burn-out, and they related the findings to medication errors recorded over a six week period. They found that 20% of junior doctors surveyed met set screening criteria for depression and 74% met the criteria for burnout; these results agree with previous UK and US studies.[8 9] Only depression, however, was associated with a significant (sixfold) increase in medication errors. As sleep deprivation, stress, and burn-out have all been linked to poor performance, the failure to show an association between burn-out and medication error rate is surprising.[10 11] In addition, the reported error rate was remarkably low—0.7% per order—half the reported rate for adults and about a 10th of the rate for children.[7] However, this may just reflect differences in the definitions, methodologies, and denominators used, which make direct comparisons across studies difficult.[12] Although the report by Fahrenkopf and colleagues is interesting and the suggestion that unrecognised depression may be associated with increased medication errors has face validity, the conclusions that can be drawn from this study are limited. The study relies on a small short term survey with a relatively low response rate of 50% and a low number of medication errors. It is therefore highly susceptible to selection bias, as shown by the low medication error rate of 0.7% reported for study participants compared with the overall rate of 1.2% reported for all junior doctors in the participating hospitals. Furthermore, the study cannot determine the direction of any association between depression and medication errors, which is clearly important when designing potential interventions to reduce error rates.

DWAYNE BROWN/BROWNSTOCK/ALAMY

Preventing medication errors and improving patient safety are important goals, which require a better understanding of the complex personal and systems factors involved in generating errors. However, prevention will only be achieved if future studies use standardised methodologies for data collection as well as standardised definitions of medication and prescription errors and a consistent denominator, such as the number of errors for each item prescribed.

Although the suggestion that medication errors may be linked to depression and burn-out seems reasonable, the results reported by Fahrenkopf and colleagues are far from conclusive. Large, prospective, and appropriately designed studies are needed to clarify the roles of individual factors involved in error generation.

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Doubts about DOTS

It's too soon to say that direct observation of short courses of tuberculosis treatment is failing

RESEARCH, p 484

G R Davies specialist registrar
gerrydavies@doctors.org.uk
S B Squire consultant, Tropical and Infectious Diseases Unit, Royal Liverpool University Hospital, Liverpool L7 8XP

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In 1993, the World Health Organization declared the tuberculosis epidemic a global emergency and responded with a new strategy to strengthen tuberculosis programmes dubbed "DOTS" (directly observed therapy short course).[1] Two of the five components of DOTS aimed to promote the use of short course chemotherapy regimens based on rifampicin and to enhance adherence to treatment through directly observed therapy. One of the strategy's key targets was raising the rate of treatment success at six months to at least 85%. Fifteen years later, WHO has made much of international progress towards this goal and of epidemiological projections suggesting that the tuberculosis crisis precipitated by coinfection with HIV may have peaked.[2] In their accompanying paper, however, after reviewing evidence directly related to the treatment strategy approved by WHO, Cox and colleagues question whether DOTS is a suitable approach in all treatment settings.[3] Debates about the directly observed component of the policy draw heavily on the experience of programmes worldwide which successfully co-opted locally appropriate health sector and community resources and achieved strikingly good outcomes for people with tuberculosis. These programmes were an innovative response to the mismatch between patients' needs and the structure of health sector provision in areas where tuberculosis was prevalent, and the application of local knowledge formed the foundation of their success.[4] In contrast, the DOTS strategy has tended to promote a model centred on standardised provision in healthcare facilities.[5] So it is perhaps not surprising that where direct observation strategies have been compared with self administration within individual programmes their effect has been inconsistent or absent, particularly when they are based in health facilities.[6] Cox and colleagues' concerns are even more basic. In the limited number of studies included in their systematic review they found worrying heterogeneity in relapse rates after treatment—the most important measure of treatment efficacy in clinical trials—even after they excluded pioneering studies using twice weekly regimens, which are not approved under DOTS.[7] Results such as these raise concerns about the robustness of short course chemotherapy even under trial conditions. If neither the direct observation nor the short course components of the strategy is as evidence based as we thought, where does this leave the scientific credibility of DOTS?

The lack of evidence for standardised DOTS based interventions is certainly a concern. Much of the explanation for this, however, lies firstly in the strength and breadth of the broader series of clinical trials that led to modern short course regimens

P VIROV/WHO

and secondly in the difficulties of conducting trials designed to unpick the components of complex interventions at community level. The narrow focus of the review obscures these other relevant issues and experience. Even within the review as framed, higher relapse rates tended to occur in trials where the intervention was rated "poor" in quality, while most trial results fell within the non-inferiority limit that would now normally be adopted for trials of new treatment regimens. This argues that the quality of local implementation of DOTS is as important as the global strategy itself. It is premature to conclude that short course regimens, whether daily or intermittent, do not adequately prevent relapse and, all other things being equal, any approach that maximises the adherence to a given regimen would not be expected to be less effective than one that does not.

The most interesting point raised by Cox and colleagues is that all other things may not be equal. Despite the remarkable robustness of short course regimens overall, we are only just beginning to understand or rediscover in detail the factors that most influence treatment outcomes. The interaction between baseline bacillary load, pattern of radiological disease, HIV status, intermittency and duration of administration, and adherence to treatment is clearly complicated.[7 8] This is reflected in the results of recent clinical trials and recognised in current guidelines for treatment.[9 10] Closer scrutiny of "real life" adherence in programmes reporting high rates of treatment success suggests important discrepancies, even when treatment is directly observed.[11] In addition, the relapse end point can be contaminated by a high proportion of reinfections in environments where the rate of transmission of tuberculosis is high.[12] A better understanding of the associations between the bacteriological biomarkers used to monitor treatment

and the pharmacodynamic processes underlying them and more extensive molecular epidemiological studies would help to elucidate the heterogeneity described by Cox and colleagues. Much can also be inferred from enhanced epidemiological surveillance and modelling in different countries, but only more extensive follow-up studies conducted under varied programme conditions can satisfactorily resolve whether variations in relapse rates pose a serious threat to the remarkable public health gains already achieved under the banner of DOTS.

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Safety of very tight blood glucose control in type 2 diabetes

Aim for glycated haemoglobin lower than 6.5%, but without using highly intensive treatment

Philip Home professor of diabetes medicine, School of Clinical Medical Sciences, Newcastle University, Newcastle NE2 4HH
philip.home@ncl.ac.uk

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On 8 February 2008, the glucose lowering arm of a large ongoing randomised controlled trial (ACCORD) of people with type 2 diabetes at high risk of cardiovascular events was stopped 18 months early because of concerns about safety. Intensively lowering blood glucose to a target below current recommendations (glycated haemoglobin (HbA_{1c}) <6.0%) increased the risk of death compared with a less intensive standard treatment strategy (HbA_{1c} 7.0-7.9%). This amounted to an excess of deaths of 3/1000 participant years on a background control rate of 10/1000 participant years.[1]

So what do these findings mean for clinical practice? Several evidence based or consensus guidelines in recent years have recommended target values of HbA_{1c} <6.5% or <7.0%.[2,3] Targets of this kind, however, are rarely tested in clinical trials, which usually compare strategies of different intensity rather than treatment to different targets. Accordingly, the evidence used in target setting is usually secondary—it comes from findings embedded within the results of such treatment trials. This evidence is often supplemented by data from observational studies and within study analyses.

For type 2 diabetes, the core data used in target setting come from the United Kingdom prospective diabetes study. This study achieved HbA_{1c} values around 6.5% for the first five years in both the main glucose control study and the metformin study, with benefits for vascular outcomes of more intensive treatment in the longer term.[4,5] In addition, a within study analysis showed that vascular event rates were lower at HbA_{1c} values as low as 5.5%. In clinical practice, an HbA_{1c} of around 6.5% can be achieved in many people for a variable number of years. Once insulin has to be started, however, studies that treat to target have struggled to achieve average values much below 7.0%.[6,7] This last finding raised the question of whether very strict blood glucose control, using the full range of modern mealtime and basal insulins and multiple oral agents if necessary—aimed at a target HbA_{1c} value within the normal range (<6.0%)—would achieve better vascular outcomes than a higher target HbA_{1c}, such as that used in people with type 1 diabetes (<7.5%). The glucose control arm of the ACCORD study was such a study.[8] It recruited people with high cardiovascular risk in order to improve the power of the study through a higher background event rate.

At first sight, the death rate in the control arm of the ACCORD study (10/1000 participant years) is astonishingly low—below the background population rate for people of the same age in the UK.[1] Study recruitment, however, tends to exclude all people who are likely to die of other disease within the next five years. It may not be safe therefore to dismiss the effect solely on the basis of an inappropriately low death rate in the control group.

No indication has been given as to the cause of the difference in deaths, but two possibilities have been considered. It was announced that the difference was not caused by hypoglycaemia (which, if anything, might be expected to result in an excess of sudden death as a result of cardiac dysrhythmia) or the use of a particular drug, including rosiglitazone.[1] Indeed, with an excess of 54 deaths on a background of 203 deaths it may not be possible to ascertain any useful

pointers. This leaves us with the intervention itself as the possible culprit—the highly intensive treatment (often multiple insulin injection regimens combined with multiple oral agents) aimed at reaching the target of HbA_{1c} <6.0%.

In some ways, the possibility that very intensive treatment caused the increase in deaths in ACCORD is supported by the press release on the ADVANCE study, a study of similar size but of less intensity, which did not have an increased death rate in its more intensive group.[9] Despite achieving comparable blood glucose control as ACCORD, only a small proportion (around 30%) of people in the ADVANCE intensive arm were using insulin when the blood pressure arm of the study was reported last year.[10] Because the study is complete (but the database has not been locked for final analysis), the lack of excess deaths in the intensive group (average HbA_{1c} around 6.5%) means that the rate is either similar to that in the control group or better.

The results from 13 years of follow-up of the multifactorial intervention Steno 2 study were also reported in February.[11] Glucose control in the intensive intervention arm was not so good as in ACCORD and ADVANCE, although by the end of the study, target attainment was not much worse than for systolic blood pressure. Nevertheless, the absolute reductions in mortality, cardiovascular events, and microvascular progression are extraordinary—between 15% and 30%.

What should we conclude pending full publication of the ACCORD and ADVANCE studies? It seems that moderately intensive management to targets of HbA_{1c} <6.5% or lower—if easily attained—need not be abandoned. Meanwhile it would be wise to avoid highly intensive management that combines multiple insulin injection regimens with multiple oral agents.

The problem of increased deaths may in some way be linked to higher doses of injected insulin in combination with stimulation of endogenous insulin secretion (by sulfonylureas) or use of insulin sensitisers (metformin and thiazolidinediones), or both. If insensitivity to insulin is actually a protective mechanism, rather than the pathological outcome of overeating as it is perceived today, then perhaps trying aggressively to overcome it may have adverse cellular effects that we have not yet begun to understand.

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Structured education for people with type 2 diabetes

A step towards a more patient centred approach to delivery of care

RESEARCH, p 491

Sean F Dinneen senior lecturer in medicine, Department of Medicine, Clinical Science Institute, National University of Ireland Galway, Galway, Ireland
sean.dinneen@nuigalway.ie

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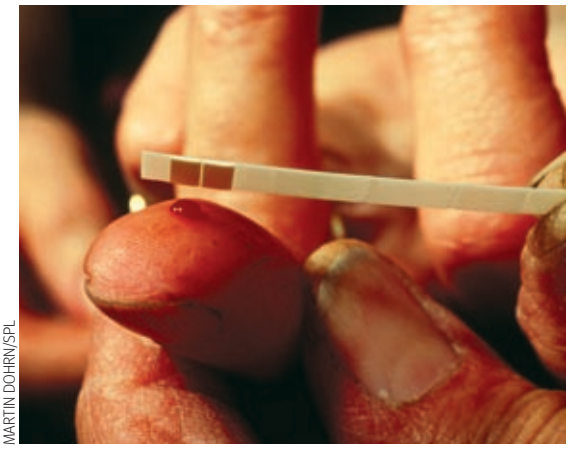
Effective self management is the cornerstone of good care for people with diabetes. High quality structured education that prepares people for a lifetime with the condition is a key enabler of self management. The term structured education programme was defined by a patient education working group in 2005 (box).[1] A good example of such a programme for patients with type 1 diabetes is the DAFNE (dose adjustment for normal eating) programme,[2] which has been endorsed by National Institute for Health and Clinical Excellence (NICE) guidance.[3] High quality trials of structured education for people with type 2 diabetes in the United Kingdom have been lacking, but two new programmes have recently been reported. The first, X-PERT, showed that structured education improved biomedical and psychosocial outcomes for patients with established type 2 diabetes compared with one to one care from a dietitian.[4] The second, the DESMOND (diabetes education for ongoing and newly diagnosed) randomised controlled trial, which accompanies this editorial, studied people with newly diagnosed type 2 diabetes.[5] The DESMOND collaborative is an alliance of clinicians,

Key criteria of a structured education programme

A clear underlying philosophy on which the programme is based
A structured written curriculum
Trained educators familiar with the programme and its delivery
A quality assurance system applied to the structure, process, content, and delivery of the programme
A process of audit of programme outcomes including biomedical, psychosocial, and patient experience


MARTIN DOHRN/SPL

educators, academics, and people with diabetes. The education programme has been carefully constructed and evaluated using the Medical Research Council's framework for complex interventions.[6] It has a sound theoretical basis and involves six hours of group education delivered by trained educators. The trial was undertaken in practices across the UK, so its findings are generalisable. The results show that the DESMOND intervention improved weight loss, rates of smoking cessation, beliefs about illness, and self reported depression. However main outcomes of glycated haemoglobin (HbA_{1c}) and quality of life did not differ significantly between groups. Why did the programme not have a greater effect?

A dramatic improvement in metabolic control is often seen in the period after diagnosis of diabetes, so that any effect of a structured education programme on glycaemic control may have been masked. Also, control practices were given extra funding so that an equivalent amount of time could be spent with participants in these practices as in intervention practices. Although methodologically sound, this may have contributed to the lack of difference in HbA_{1c}.

The DESMOND intervention encourages participants to set personal goals in managing their diabetes. Because HbA_{1c} was improving anyway, DESMOND participants may have chosen goals other than glycaemic control, such as weight loss and smoking cessation. Quality of life may not have improved because this outcome can take a long time to change,[7] or because of the psychometric properties of the instrument used. The personal benefit that participants derive from a patient centred approach like DESMOND may be better captured by qualitative research.

So how do these results translate to clinical practice? General practitioners in the UK have recently been offered financial incentives to meet certain targets associated with good diabetes care. These targets were not only met but often exceeded.[8] The national service framework for diabetes emphasises self management as an important part of diabetes care.[9] Standard 3 states that patients "will receive a service which encourages partnership in decision-making, supports them in managing their diabetes and helps them to adopt and maintain a healthy lifestyle."

The recent emphasis on structured education within the National Health Service and the availability of programmes like DAFNE, DESMOND, and X-PERT should enable this standard to be achieved. However, one of the barriers to success is demonstrated by the DESMOND trial. For self management to be most effective, all patients who could potentially benefit need to be referred for training. The trial showed a major difference in baseline HbA_{1c} between people in intervention practices and control practices. The authors suggest that, in intervention practices, patients with the highest HbA_{1c} concentrations were more likely to be referred for DESMOND training. If this is a reflection of what happens in clinical practice, then a large proportion of patients with lower HbA_{1c} concentrations who could still benefit would be excluded.

As well as offering education to as many patients as possible, another challenge is to maintain the patient centred emphasis beyond the initial delivery of the education programme. This requires input from all healthcare professionals and not just those delivering education. The importance of "diabetes self-management support" has recently been acknowledged by the American Diabetes Association.[10] A good example of how to provide this ongoing support comes from the Turin group,[7] which is evaluating the implementation of supported group care in centres across Italy.[11] Healthcare professionals need to appreciate that structured education represents one element of a patient centred approach to diabetes care and not just another box to tick at the time of annual review.

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