The future of smoke-free legislation

Will cars and homes follow bans on smoking in public spaces?

SIEGFRIED KUTTIG/ALAMY

RESEARCH, pp 545, 549, 553

Simon Chapman professor of public health, University of Sydney, NSW 2006, Australia
sc@med.usyd.edu.au

Competing interests: None declared.

Provenance and peer review: Commissioned; not externally peer reviewed.

BMJ 2007;335:521-2
doi:10.1136/bmj.39315.616169.BE

A tide of epidemiological,[1] clinical,[2] and toxicological[3] research has gradually transformed the meaning of the quiet, convivial cigarette into a health hazard for others, and smokers into stigmatised, regulated exiles from public spaces.[4] Bans on smoking in enclosed public places have moved into global overdrive in the past decade. Three studies in this week's *BMJ* provide evidence of the clinical and social effects of legislation to prohibit smoking in almost all enclosed public places and work places—including bars, restaurants, and cafes—in Scotland implemented in March 2006.[5-7]

The hospitality and tobacco industries forecast the end of civilisation after banishing smoking from bars.[8] The bar economy and tourism would collapse. The vibrant tradition of pub life would be sacrificed on the altar of risk aversion. Drinks left on the bar while smokers stepped outside would be spiked by rapists,[9] and street fights would increase. Smoking would be displaced to homes where angry men would ruin their families' health, beat their wives, and even cause more house fires.[10] At least these were the arguments the tobacco industry used publicly. Privately, they admitted as long as 13 years ago that "These arguments simply had no credibility with the public, which isn't surprising when you consider that our dire predictions in the past rarely came true."[11]

Smoke-free bars remain full from Dublin to New York, Auckland, Vancouver, Oslo, Sydney, Rome, and Glasgow. The study in this issue by Haw and colleagues shows that the Scottish smoke-free legislation has been followed by remarkable falls in cotinine concentrations in smokers and non-smokers living in both smoking and non-smoking households.[6] The study also found no evidence of displacement of smoking from public places into homes, confirming earlier findings from Ireland.[12] The study by Akhtar and colleagues also in this issue found that cotinine reductions in primary school children were significant only in households where no parent or only the father smoked,[5] suggesting that mothers' smoking in houses and cars continues to be an important source of exposure in children.

Cars are an intriguing and symbolically important interface between public and private worlds. While the interior of cars is considered by many to be a "private" space, the law has long regarded cars as effectively public spaces. Their occupants are subjected to legal requirements regarding seat belts, car standards, driving conduct, and mobile phone use designed to protect public safety (harm to others) and the safety of the occupants (via the benevolent paternalism inherent in seat belt legislation).

Several US jurisdictions and South Australia have legislated bans on smoking in cars when children are on board. These laws have taken a legislative first step into outlawing what has until now been assumed to be a private self regulated behaviour (parents' freedom to expose their children to high concentrations of tobacco smoke in settings assumed to be private). The ability of parents to exercise this "freedom" in public settings such as on public transport and in enclosed shopping precincts is now denied in many nations, including Scotland, through reference to the health and amenity of others. This creates a paradox—why should parents be prevented from placing their children's and others' health at risk in public vehicles but be allowed to do so in private vehicles? Legislation on smoking in cars—which is focused on a setting where those harmed are most likely to be family members—moves the boundaries of health protection legislation in an important new direction.

As public smoking bans proliferate, homes are now the most important source of exposure to secondhand smoke, and unconsenting minors are often exposed. No nation has ventured to legislate against domestic smoking, although increasingly public awareness campaigns are successfully urging many people to make their homes smoke free.[13] Homes are assumed to be the "castles" of their occupants, where a wide range of private freedoms of expression are sanctified that are prohibited in public. It would seem inconceivable in any but the most authoritarian states for smoking to be banned in homes.

However, there are many ways that households can be encouraged and supported to implement smoke-free rules. The qualitative study in the trio of papers reported in this week's issue[7] offers many insights into themes that have resonated with people who have already taken this step. Public awareness campaigns are important, but health workers such as general practitioners, hospital consultants (for example, those in paediatric asthma clinics), health visitors, midwives, and specialists in cessation have vital roles. They should offer advice and support to individuals, particularly parents, grandparents, and other carers. Ex-smokers often cite their children as important influences on their decision to quit. Children should therefore also be supported in their efforts to request their parents to at least smoke outdoors.

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Achieving health equity for all

The Commission on Social Determinants of Health sets out its vision and goals

FEATURE, p 538

Alan Maryon-Davis president, Faculty of Public Health, London NW1 4LBl
president@fph.org

Competing interests: AM-D is a member of a Department of Health technical group considering the CSDH statement.
Provenance and peer review: Commissioned; not externally peer reviewed.

BMJ 2007;335:522-3
doi:10.1136/bmj.39328.478044.80

This week the Commission on Social Determinants of Health (CSDH), established in 2005 by the then director general of the World Health Organization (WHO), the late Lee Jong-Wook—has released an interim statement.[1] It sets out a new vision to achieve what it calls worldwide "health equity"—fairness of opportunity to achieve and maintain good health. The intention is to kickstart a global movement to tackle, at all levels and in all sectors, the social, environmental, economic, and political factors that underpin inequities in health—the so called "causes of the causes" of ill health.

Nearly 30 years ago, WHO brought the community of nations together to issue a call for "health for all by the year 2000." The Declaration of Alma Ata[2] focused on accessible and affordable primary health care worldwide, and on tackling the social and economic causes of ill health. It affirmed that health is a fundamental human right. And it called on governments, international organisations, and the world community to create the opportunity for everyone to attain a level of health that would enable them to lead socially and economically productive lives. Alma Ata was a seminal moment in the history of global public health.

Thirty years on, the world is a very different place. Increased urbanisation, larger trading blocks, increased globalisation, massive aid programmes, deforestation, climate change, international terrorism, cheap air travel, the internet, the collapse of the Soviet Union, the rise of rapidly emerging "tiger" economies, sweatshop working conditions, and low pay have all contributed to major shifts in the world order, and to fundamental changes in the health of the world's peoples.

The commission's interim statement has four main elements. Firstly, it outlines the philosophy and principles behind the new movement—strengthening health equity by seeking to rebalance the socially determined conditions in which people grow, live, work, and age. Secondly, it provides overviews of some of the problems that need to be dealt with, such as differences in life expectancy, health, and wellbeing between different countries and regions, and between people of different sexes, ethnic groups, classes, occupations, and other forms of social stratification. Thirdly, it looks at the main ways in which these gaps can be minimised—the big levers for change. And lastly, it outlines how the commission is amassing the evidence and engaging governments, international organisations, civil societies, and other global big players in driving the messages home.

To pull together the evidence, the commission has established nine "knowledge networks." It has collected, collated, analysed, and synthesised a vast body of information on a wide range of themes—globalisation, health systems, urban settings, employment and working conditions, early child development, social exclusion, women and equity between the sexes, measurement and evidence, and priority public health conditions. The quest is to identify the most important causal relations, the key areas for action, and the most effective interventions to tackle socially determined inequities worldwide.

Poverty is usually the ultimate cause of inequity. But the commission looks beyond poverty, at the many factors that enmesh people in a poverty trap—from drought and war to sex bias, religious castes, language barriers, unemployment, corruption, lack of investment, and sheer bad government. How can the world community help to ameliorate some of these influences?

The commission admits it has no magic wand. But what it does have—and what has previously been lacking—is a thorough understanding of the links between the various social determinants and the types of ill health they can lead to, and a much better evidence base of how they can be tackled. The statement looks in depth at three case studies. Firstly, a union of female street vendors in India which has set up a wholesale service, crèche facilities, a cooperative bank, and an insurance

scheme. Secondly, a state run welfare scheme for poor families in Brazil, with cash grants to mothers, linked to child immunisation and better education. Lastly, a two pronged programme to increase employment and promote cardiovascular health in an economically depressed part of northern Sweden. All three schemes are making a big difference and are sustainable.

The other weapon in the commission's armoury is the mechanism it has set up to engage with the world's movers and shakers. Part of this comes from the high level influence of its 19 prestigious members—from ex-heads of state to world renowned academics, and from senior ministers to leaders of international organisations—and part from the expanding family of "partner countries" who signed up to the process and who are cascading the principles and practice through their own internal networks.

Given that the biggest gains are likely to be made outside the healthcare system, what part can health professionals play in all this? The answer is potentially a very large part. Health networks are among the most firmly established and extensive in the world. As the recent Crisp Report has urged,[3] we have powerful means for sharing our knowledge, skills, and expertise with communities and nations who could most benefit from them.

Next year, 30 years after Alma Ata, the Commission will launch its final report with detailed recommendations. But this interim statement initiates the tasks of building a wider and more solid consensus, adding direct experience to the knowledge base, and developing and testing the levers for change. The vision is clear, stark, and unambiguous—health equity is a fundamental human right, a matter of social justice. No self respecting nation should tolerate the persistence of such colossal unfairness and disadvantage. The Commission on Social Determinants of Health seeks not only to open our eyes to this injustice, but to galvanise us all, wherever we are, into doing something about it.

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Problems with performance related pay in primary care

Payments should be based more on treatment and prevention and less on risk factor measurement

ANALYSIS, p 542

David S Wald consultant cardiologist and senior lecturer, Wolfson Institute of Preventive Medicine, Barts and the London School of Medicine and Dentistry, London EC1M 6BQ
d.s.wald@qmul.ac.uk

Competing interests: None declared.
Provenance and peer review: Commissioned; not externally peer reviewed.

BMJ 2007;335:523-4
doi: 10.1136/bmj.39329.384329.BE

General practice in the United Kingdom has the largest healthcare pay for performance programme in the world—the quality and outcomes framework (QOF).[1] By earning the maximum number of performance indicator "points," an average sized practice can earn about £125 000 (€185 000; $252 000) in addition to its usual sources of income. In this week's *BMJ*, Guthrie and colleagues discuss the effectiveness of the system in relation to the management of cardiovascular disease. They show how general practices can earn many points and extra payments without this necessarily indicating a reduction in the risk of cardiovascular disease.[2]

For example, a practice could receive nine points (each worth about £125) for generating a list of patients with hypertension. The completeness and accuracy of this list might be subject to external audit by the Primary Care Organisation. An extra 30 points would be earned if 90% or more of such patients have a record of risk factors (blood pressure and smoking history) in their notes, and 56 more points would be earned if 70% or more of such patients have a record of blood pressure lowered to below specified target values (150/90 mm Hg). Overall, 15% of payments, worth an estimated £200m across the approximate 11 000 general practices in the UK,[3] arise from measuring cardiovascular risk factors (such as blood pressure and serum cholesterol) and recording whether they are below specified values.

Whether or not doctors should receive financial incentives for providing medical care is debateable.[4 5] Should police officers be paid extra for catching criminals and should firemen be paid incentives for putting out fires? A balance is needed between encouraging doctors to exercise independent professional judgment and paying them for carrying out specific tasks. The balance has moved too far towards payment per task done, and this is de-professionalising medical practice. The treatment and prevention of cardiovascular disease is becoming a series of isolated tasks predicated on financial rather than clinical value. Linking each task to the receipt of money means that money rather than medical judgment drives practice.

In addition, the need to count cases and fill in forms requires extra resources and increases bureaucracy. Baroness Deech, head of the Office of the Independent Adjudicator, said in relation to the bureaucracy of postgraduate education, "We live in an age of over-regulation. I do think universities are over-regulated."[6] The same criticism can be applied to the National Health Service.

A further problem with the QOF relating to cardiovascular disease is that many of the measurements documented are not worth documenting. If doctors are to be paid for performance it should be for treating and preventing disease. In vaccination, payments increase with numbers of children vaccinated, as all children are susceptible to infections. The same principle applies

to cardiovascular disease—everyone is susceptible. Identifying people on the basis of a high risk factor cut-off value is inappropriate because relatively few events occur in people with high risk factor levels. Most events occur in the majority of people whose risk factor values are closer to the average.

Blood pressure and serum cholesterol measurements are commonly used in screening because these important causes of coronary heart disease and stroke are thought to be useful for predicting who will and will not develop such an event. However, with certain exceptions (such as familial hypercholesterolaemia[7]), this is not the case. Aetiologically important risk factors are rarely useful as screening tests.[8] It is often assumed that combining information on several cardiovascular risk factors will overcome the problem that individually they are poor predictors, but such an approach is only a little more precise than simply basing a person's risk estimate on age alone, and is not worth the extra cost and complexity.[9] Most heart attacks and strokes (more than 90%) occur in people over the age of 55, which is why 55 has been proposed as a reasonable age above which to prescribe drugs to reduce cardiovascular risk.

The QOF, now in its third year, has been useful in drawing attention to the importance of the treatment and prevention of cardiovascular disease, but not how best to do so. The QOF expert panel, assembled by the BMA and the NHS Employers is currently reviewing the QOF programme. This provides an opportunity to improve and simplify the system.

Guthrie and colleagues argue for increased incorporation of treatment information into outcome indicators.[2] This makes sense, because it is the treatment of risk factors that reduces risk, not their measurement. Performance indicators should not be based on the measurement of risk factor levels, but on the proportion of people with existing vascular disease or diabetes, or those above a given age who receive effective preventive treatment, in addition to encouraging sensible dietary and lifestyle measures (such as smoking cessation).

The resources currently used to fund the management of risk factors and the QOF payments that follow them could be redirected into paying for the drugs used. The financial element would then be directly linked to treatment and prevention rather than the process. Much unnecessary medical activity and cost could be avoided—£200m from the existing cardiovascular disease specific QOF payments alone. Further savings would arise from better use of time in general practice, avoidance of risk factor measurement, and reduced administrative costs. Incentive payments would be better used sparingly to encourage selected effective interventions that need specialist examinations, such as screening for diabetic retinopathy in people with diabetes.[1]

Such a revised QOF system would be simpler and would release valuable general practitioner time and resources. Greater importance would be attached to medical judgment, rather than to robotic tasks. The QOF expert panel is expected to deliver its recommended changes this autumn. Hopefully, it will have time to reflect on these matters and advocate a much simpler strategy for treating and preventing cardiovascular disease—one that is linked to more focused incentive payments, while protecting the independent professional status of doctors in the UK.

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Dealing with scientific misconduct

Europe needs policies for good scientific practice and for investigating misconduct allegations

Xavier Bosch consultant internist, Department of Internal Medicine, Hospital Clínic, 08036-Barcelona, Spain **xavbosch@clinic.ub.es**

Competing interests: XB is responsible for the elaboration of Research Integrity Guidelines for the IDIBAPS Research Institute and the Hospital Clínic of Barcelona.

Provenance and peer review: Not commissioned; externally peer reviewed.

BMJ 2007;335:524-5
doi:10.1136/bmj.39325.624618.BE

International awareness of scientific misconduct is low.[1] Codes of good practice and procedures for handling allegations of misconduct involving research throughout Europe are either underdeveloped or non-existent.

To help resolve this problem, the first world conference on research integrity will take place in Lisbon on 16-19 September 2007 (http://tinyurl.com/2b54xo). It was organised by the US Office of Research Integrity and the European Science Foundation—an association of 78 scientific research organisations in 36 European countries. The event is an opportunity to discuss the harmonisation of policies on scientific misconduct at European and international level.

Unlike in the United States, where the Office of Research Integrity oversees allegations of scientific misconduct involving research supported by US Public Health Service funds, oversight of research in Europe is fragmented and varies widely between countries. With the exception of Scandinavia and—to a lesser degree, Germany, France, and the United Kingdom—little or no regulation exists to govern scientific misconduct. Regrettably, the European Commission (EC) has drawn up no regulations about potential

problems arising from its multibillion framework of research programmes in Europe.

Europe has a long history of allegations of scientific misconduct, but recent cases have highlighted the limitations of current oversight systems.[1-3] At first glance, it may seem that misconduct is more frequent in Northern Europe than in Southern Europe,[4 5] but this may reflect the lack of reporting and monitoring in the south. In Spain, for example, most research institutions have no codes of scientific integrity or policies to handle misconduct.[6] It has been suggested that most European countries hide individual cases of fraud as a result of the lack of specific rules,[7] but we do not know whether research misconduct is more common in countries that do not have monitoring standards than in those that do.

What steps should be taken? At a national level, countries without formal systems for investigating allegations (mainly in Southern and Eastern Europe) can learn from models in other countries. As an initial step, a local ombudsperson could be appointed to act as an impartial third party. This person could be approached by people seeking advice about scientific misconduct and might even be empowered to conduct (if necessary) preliminary inquiries. If the ombudsperson thinks that further investigation is needed, the matter should be referred to the institution where the study was carried out. The findings of the national monitoring body should be published annually. Decisions about whether to disclose the names of scientists proved to have been dishonest should take into account the prevailing culture and sensibilities. However, there is clearly a need to retract research that is found to be fraudulent. Implementation could be enforced by research funding agencies (and private foundations) providing funding only to institutions that adhere to scientific integrity guidelines.[8]

In most European countries legislation does not cover cases of scientific misconduct. In the absence of appropriate legislation, internal regulations may offer solutions through conciliation or arbitration; for example, as happens in the Deutsche Forschungsgemeinschaft.[9]

Modern research often has many authors, and problems can arise when authors from different countries are treated inconsistently. This could be prevented by establishing Europe wide policies on scientific dishonesty, with uniform procedures for violations.[10 11] However, on the basis of current political, legal, cultural, and ethical differences between European nations, it is not feasible to set up a legally binding, unified, pan-European oversight framework. In addition, unlike other matters, the Treaty of the European Union specifies that ethics are within the competence of the member states and, therefore, no such directive can be imposed or prevail over national legislation.

A more realistic and timely pan-European scenario would be where most countries (or most research institutions) have regulations in place, which are complemented by additional Europe wide efforts, mainly focused on agencies that fund research. Thus, pan-European research funding bodies, notably the EC and the European Research Council, could set up regulatory mechanisms and compel institutions to formulate rules about research integrity and procedures for handling allegations of misconduct.

Jurisdiction (such as funding by the EC) is an essential requirement that must be met to make the system work by recognising a research agency's right to enforce compliance. The EC and the European Science Foundation are well suited to appoint independent scientific experts to investigate misconduct in projects financed by the framework research programmes and the European Research Council, especially as the combined budget of the 2007-13 seventh framework research programme and the European Research Council is €48bn (£32.5bn; $65.5bn). In addition, once these steps are taken, a European network of committees handling misconduct and fraud in research, as proposed by the Finnish National Advisory Board on Research Ethics,[12] could be of great use.

International cooperation might tackle the problem of scientists moving to countries where employers are unaware that they have committed misconduct. Moreover, albeit heterogeneous, European academic societies and associations could define principles of good scientific practice for their area of expertise and make them binding on their members.

Independently, the EC could ask its advisory European Group on Ethics in Science and New Technologies to draw up a set of recommendations within a pan-European framework. Although not legally binding, the standards described by this group could be adopted by those countries that lack regulatory mechanisms. Alternatively, they might consider implementing some of the national oversight scenarios proposed above.

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Direct to consumer advertising of drugs in Europe

Evidence on its benefits and harms is available but is being ignored

Nicola Magrini clinical pharmacologist, CeVEAS, NHS Centre for the Evaluation of the Effectiveness of Health Care, Modena Local Health Authority, 41100 Modena, Italy
n.magrini@ausl.mo.it
Maria Font pharmacist, International Society of Drug Bulletins, Pharmaceutical Department, Verona Local Health Authority, 37122 Verona, Italy

Competing interests: None declared.
Provenance and peer review: Commissioned; not externally peer reviewed.

BMJ 2007;335:526
doi: 10.1136/bmj.39310.506308.AD

The promotion of prescription drugs to the public ("direct to consumer advertising") is currently used only in the United States and New Zealand. A systematic review of the clinical and economic consequences confirmed that this form of advertising influences patient demand and doctors' prescribing behaviour, but evidence of health benefits or improvements in underuse was lacking.[1] A more recent report from the Institute of Medicine confirmed that direct to consumer advertising increases the early use of new drugs and asked for a two year moratorium of such advertising for newly approved drugs.[2] Requests were made to revise the legislation towards limiting or even banning such advertising both in the US and in New Zealand[3 4] after rofecoxib (a heavily advertised drug) was withdrawn from the market because it increased heart attacks.[5] A proposal to modify the current ban on direct to consumer advertising will be considered by the European parliament in the next few months in the context of a wider series of reforms "to improve the regulatory, non-regulatory and research and technological development framework for pharmaceuticals" (summarised in a document now open for public consultation until 12 October).[6]

At the request of the European parliament, the Enterprise and Industry Directorate General of the European Commission released a report for consultation at the end of April 2007 on "current practice with regard to provision of information to patients on medicinal products." The report focuses on information publicly available on the internet from regulatory bodies or official sources in member states,[7] which consists mostly of information on package leaflets, databases of approved drugs and regulatory reports, and other sources of information from regulatory bodies on approved drugs.

The conclusion of the report is clear though problematic: "Member States may not be in a position to fully address patients' needs in terms of the substance of information and the access via different means. In turn, the pharmaceutical industry possesses the key information on their medicines but this information can currently not be made available to patients and healthcare professionals through Europe."[7] In other words, after an unsystematic review of information for patients available in Europe through regulatory bodies or Ministry of Health websites, the report states that the available information is not sufficient for patients' needs, and it suggests that the information possessed by the producers could plug this gap. Curiously, the document never mentions direct to consumer advertising but calls for a partnership in the production of information, supporting the idea that producers are a reliable source of information for patients and consumers.

Although the aims of the report are laudable, the methods it uses are scientifically weak: the report does not describe how literature was reviewed or the data collected; many statements are unsupported; and several comprehensive documents recently published on this subject are not mentioned.[1-4 8-10] Also, the identity of the authors is unclear.

Despite what is stated in the report, several examples of good information sources for patients are now available in Europe.[11] The difficulty for the public is finding them and distinguishing between promotional material and unbiased evidence based information. Information should be reliable (evidence based, arising from a systematic evaluation, and unbiased), comparative (with respect to all treatment options), and adapted to users (evaluating the potential problems of generalising to other populations, with consideration of patients' values and preferences).[11] These three principles also apply to prescribers in evaluating the risk-benefit profile of an intervention and in defining the strength of a recommendation when producing a guideline.[12]

The idea of a public-private partnership stems from the recent second progress report of the European Commission's High Level Pharmaceutical Forum that proposes "to organise a platform to bring together relevant stakeholders to explore ways to exchange good practices and on ways to overcome barriers to accessing information."[13] Although it does not support direct to consumer advertising, this standpoint suggests that reliable information could come jointly from producers and regulatory bodies. However, such a partnership would confuse their separate roles and responsibilities.

So where do we go from here? We think that a partnership between drug companies and drug regulatory authorities in the area of information, and even more so in the field of drug evaluation,[14-16] would be confusing. Therefore, we propose two areas of real partnership with the drug industry that would reinforce public trust in the system.

The first would entail a real commitment to waive confidentiality and give full access to data on the effectiveness and safety of drugs. Giving full access to all clinical trial protocols (not just those that are registered for publication purposes) and to the periodic safety update reports available to regulatory agencies would enhance transparency.

A second more institutional partnership is based on the fact that patients' needs and not industry patents should be the focus of regulatory bodies. For this reason, the European Medicines Evaluation Agency should move from the commission's Enterprise and Industry Directorate General to its Health and Consumer Protection Directorate General to avoid the current conflict between supporting the competitiveness of the drug industry and the interests of patients.

The most sensible way to protect public health would be to identify sources of unbiased and systematically reviewed information and maintain the current European legislation on drug promotion, while reinforcing the role of the European Medicines Evaluation Agency.