The Royal College of Physicians of Edinburgh

The College welcomes this consultation paper enthusiastically. The ethical basis for public health has been a neglected area in matters of public policy in a complex democracy. This paper sets out crisply a framework, 5 case studies and ethical issues.

College Members and Fellows have been involved in each of these issues in several different capacities. It is just that set of perspectives that creates the challenge of responding to a specific case study in a particular way.

Each of the consultation questions is worthy of an essay. No doubt, the Council has already made its own critique of essays in each areas, so the College's comments will cover these matters briefly. It would be happy both to debate these issues in further detail, as the Council wishes and, indeed, to host the Council's view to a consultation and debate of these matters.

In Scotland, we have had the opportunity to approach a number of these public debates ahead of other parts of the UK. For instance, the Court of Session in Edinburgh hosted the first civil action against a tobacco company in a European Court; Scotland was the first UK country to introduce a ban on smoking in public places and an Alcohol Action Plan, the first to propose to FSA the addition of folic acid as a supplement to food, the most recent to debate and set aside plans for fluoridation of water through Parliamentary legislation. It is about to introduce revising legislation for the prevention and control of infectious diseases, having worked through policy-level consultation on the principles (and benefited greatly from the Nuffield Trust's longstanding commitment in this area). Finally, as the paper points out, Scotland has an even greater challenge to face on obesity than England, and has already engaged, through the Royal Colleges on that issue and on matters of alcohol misuse. Our democratic system is therefore new, legislative processes closer to the people, and the articulation of these ethical matters surfaces in public discourse. The public health and medical community therefore have a high level of engagement and participation in legislative proposals in Scotland, realising on the way through the powers that lie in other legislatures - chiefly, Westminster and the EU.

There are 2 overall issues that are touched on implicitly in the Council paper, and we wish to highlight here:

The new era of "Right v Right" - as the debate on MMR and fluoridation have illustrated, scientific debate can argue vigorously, using the same or very similar bodies of evidence, and come to different conclusions. In many cases, as set out in the paper, over-interpretation of the importance of data may be at issue. Other cases lay greater or lesser emphasis on the upsides and downsides of factors - for instance, the potential damage done to older people as a result of fluoridation. The balance of maximising benefit, which the consultation paper chooses to occlude

from direct discussion, from the minimisation of harm, brings us to the realisation that not everyone can be right, and there are winners and losers. No public health measure, if effective in any way, fails to affect the rights of autonomy of other groups. Indeed, the very definition of a public health incident seems to encompass threats to the interests of others. "Right v Right" is a flawed concept in seeking the truth and a policy direction.

Second, this paper emerges at a time when policy on parenting is rising quickly up the public agenda. For that reason alone, this paper is most welcome. Parenting is an area where policy makers have feared to tread, for very good reason. But only recently have policy makers come to terms with the reality that not every parent is a beneficent influence on their child, or children more generally. Even the best parents do not remain flawless throughout that career. For instance, if one takes the consumption of alcohol, the majority of parents drink, at some times, unhealthy levels of alcohol and, one must assume, in the majority of cases, they remain in charge of their children. The assumption of parental infallibility amongst these ethical arguments is a timely reminder that this mirage is cracking, and such opinions bear on future policies relating to the autonomy of parents to decide for their children.

To the list of questions:

1. The Definition of Public Health

We prefer the Acheson definition to the Institute of Medicine definition. The Institute of Medicine definition is couched in free market terms, or the "minimal state" as the paper describes at section 5. "Healthy people" is a term which is both absolute, relative and liable to extremes. It has humanitarian and economic drive and is too loose a phrase to interpret comfortably. In a socially just society which places solidarity more centrally, people are both individuals and parts of a population; they do not so much "collectively do" as embark on "organised efforts" as in the Acheson definition. Reference also to equity would be helpful.

2. Factors That Influence Public Health

We agree with the 5 factors as set out. The importance of all these factors depends on the context and the audience. We must also recognise the inter-dependence between the influences. Occupational factors are distinct and sufficiently important to list separately. The social dimension also has many sub-sets, ranging from personal to political.

3. Prevention of Infectious Diseases Through Vaccination

There is a very useful review of the topic of compulsory vaccination in a recent Lancet article (reference below). It raises 4 key points:

- First, compulsory vaccination may be effective in preventing disease outbreaks, reaching and sustaining high immunisation coverage rates, and expediting the introduction of new vaccines.

- Second, to be effective, compulsory programmes must have a reliable supply of safe and effective vaccines and most people must be willing to be vaccinated.

- Third, allowance of exemptions to compulsory vaccination may limit public backlash.

- Finally, compulsory vaccination may increase the burden on Governments to ensure the safety of vaccines [from Salmon et al, Lancet 2006; 367, 436-442].

Compulsory vaccination, or vaccination with coercive conditions, is a culturally sensitive issue. In the UK, choice is more informed and more free than, for instance, the US, where vaccination is a condition of school entry; and African and other developing countries where "vaccination days" is reliant on tribal leadership and peer support, with very high levels of success in terms of vaccination coverage. In a complex democracy and post-modern society such as the UK where, also, science, politics and figures of authority are under question, we are past the stage where herd immunity is achievable through compulsory treatment intervention, even for the most compelling of reasons.

The role of parents on behalf of their children - this may be the most contentious area with respect to the MMR debate, but immunisation has always been at the forefront of public health debate and public scepticism has meant scientific intransigence often, with explosive results. The riots of 1830 were violent compared to the vigorous debate of 2000.

The prevailing UK position is that the benefits of compulsory vaccination are outweighed by the associated ethical problems and it is difficult to depart from this. We need to educate and persuade people. The recent MMR debate in the UK suggests that the UK population would not accept compulsory vaccination. The herd immunity argument is not yet sufficiently over-riding to justify this policy. The case of fluoridation is more problematic.

In society, there is an increasing concern/negative view of vaccinations and lack of information has been shown to be associated with negative attitudes about immunizations and toward health care providers (see e.g. Gust DA et al, Parent Attitudes Toward Immunizations and Healthcare Providers the Role of Information, Am J Prev Med. 2005; 29:105-12).

Parental decisions on the part of children, of course, depend on the age of the child. In Scots Law, there is a sliding scale depending on the competence of the child, say, at the age of booster vaccination in the teen years. In the present policy climate where competent parents unquestionably hold sway, there is no prospect of taking the decision-making away from the child or the vaccinator. There may be future scenarios such as Smallpox where the scale of threat to life, need for haste and for implicit consent to override incomplete response rate, to contemplate an assumption of the wishes of parents. That is not the same as overriding their wishes. We do

not foresee such an eventuality. Therefore, the decision is poised depending on the seriousness of the infectious threat to the child and, secondarily, to the population, the balance of scale and immediacy of the potential threat.

Then there is vaccination as part of standard treatment - for instance, Tetanus booster following injury. It is an arguable point whether a parent would need to consent separately for repair of the injury and subsequent prevention of Tetanus through toxoid injection. In an extreme case, of course, the parent has a right to refuse. It is ultimately the role of the medical or other health professional to provide full and balanced advice on which a person can make a competent decision. Moreover, it is good practice that the decision-taker should feel fully involved in making these decisions from the earliest practicable state.

4. Control of Communicable Disease

In a final analysis, there are few measures that should be considered out of the question. In some scenarios, selective non-treatment may be an unpalatable option, as long as such treatment does not abandon a victim to inadequate care. There are possibilities where the threat may require such drastic measures that individual determination and personal choice are minimised in order for control measures for the greater good to prevail. Betraying the trust inherent in that decision will, of course, subvert credibility for future occasions. So rapid, decisive and drastic action must be proportionate, transparently decided, and taken at the right level of public decision-making.

The issue of forced quarantine is topical at present with concerns about MDR tuberculosis. This has to be retained as a policy which would only be implemented under circumstances of grave public danger. A key issue is that the "legal authority and procedures for implementing interventions should be understood in advance and should respect cultural differences and human rights" (see e.g. Bell DM, Emerg Infect Dis. 2006;12: 88-94). This would apply to mandatory testing also.

Triggers to intervene in outbreaks of disease are always difficult judgements. Even in limited clinical practice, there can be conscientious debate about whether the incidence of disease is above that normally expected and, therefore, when an outbreak is beginning to occur. A person or organisation contemplating intervention must assess the competence and insight or incumbent arrangements, along with full knowledge of local and empirical data relating to the threat. They should assess the integrity of the public health system; the willingness of other parties to allow collaboration, assistance or assumption of responsibility for the conduct of an outbreak. The international community, through the WHO, has had recent and valuable experience in the control of SARS with respect to intervention at country and world level. Successful control of SARS coming out of China has done no harm to the credibility of the WHO in future intervention. However, any such interventions must weigh the interests of the host country, its dignity and accountability, against the interests of the wider international community, no matter how poor or poorly served.

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Many of the issues related to for example flu pandemics are relevant (see e.g. WHO checklist for influenza pandemic preparedness planning at (http://www.who.int/csr/resources/publications/influenza/FluCheck6web.pdf).

On trade and travel, the International Health Regulations have just been implemented and it is early to propose additional measures. Clearly, they are a substantial advance on the previous set, and reflect new circumstances. Again, country-level integrity of public health systems is key to adequate and early effective surveillance. The earlier comments about reputation of the WHO are also relevant here.

On Tuberculosis and HIV/AIDS, these are very different epidemic pathogens. Tuberculosis is airborne and carriers pose a threat to other susceptible people, even with non-physical contact in an enclosed environment. By contrast, HIV/AIDS can only be passed on through intimate physical contact between persons and/or body to body fluid. Testing for both organisers is already compulsory as a protection against the movement of people between some countries around the world for the purposes of international travel and residency. Mandatory testing may be acceptable if a TB outbreak poses substantial threat to international health but, we judge, not acceptable under any humanitarian circumstances for HIV/AIDS. However, there may be economic considerations underpinning the effective threat to the viability of local health care systems that make decisions outwith the scope of an organisation of physicians.

5. Obesity

Future rises in the level of obesity in countries, are matters more susceptible to economic argument. The consumption of food, and the consequences of obesity, are high budget issues, where politics, economics and health belong together. Downstream health care costs for the future epidemic will be substantial. However, it is essential for a policy to be inclusive, empathic, taking care not to demonise nor to medicalise a health state. The key issues must be of consensus and cross-sectoral action ranging from physical design through all activities including catering. An element of our response to obesity has to be cultural, health-informed but not imposed, and has to be consensual.

With prevention of obesity, both similar and different factors arise. There has to be a balance between health and commercial interests, private and governmental endeavour, the balance of self-regulation and state-backed position of regulation; the advance of social acceptability towards prevention, as much led by the market as by opinion formers and other players; and, underpinning this effort, a robust and science-based endeavour to identify and counter obeseogenic interests.

NHS services dependent on whether a person is obese or not - where there is evidence, public servants have a responsibility to consider and apply that evidence. Recent debate on fertility treatment adds to the examples set out in the document. There are arguments that centre around the capacity to benefit in a market which will always be constrained by resources, therefore, cost-effectiveness of interventions, wider value for money considerations, and priority setting. But,

behind this all, physicians must deal with the consequences of allocation of resources one way and the other, including the psychological consequences for those who are not covered by a public health care system.

6. Smoking

There are many lessons to learn from the smoking debate. Variables include national and local culture, notions of individual choice, strength of evidence, commercial power and influence, the assumed lack of popularity of public health measures, the balance of harm to ones self as opposed to others (and the extent to which that evidence is concealed by the tobacco industry). Coming to the aid of pro-health interests has been the framework of principles encompassed in the European Convention of Human Rights which helpfully, argues the balance of rights over emphasis on individual over public interests which has formed the backdrop to much public health political debate until recently.

There are lessons to learn from other countries, but they should not be confined to the intervention. Lessons should include study of local political motives, culture, philosophy of approach, then the framework of legislation before understanding these variables in our own context and then seeking to apply them.

The responsibilities of tobacco companies - Members and Fellows of this College have witnessed and studied and, indeed, taken part in, the civil action taken against Imperial Tobacco Group which completed in 2004 with the judgement of Lord Nimmo-Smith at the Court of Session in Edinburgh. The judge, while stressing that his dismissing of the action against Imperial Tobacco Group was based on the evidence set before him, confined Imperial's responsibility to no more than the provision of a product within the Trade Descriptions Act - in other words, that the cigarette did what it said it would do. The judge assigned responsibility to Governments and NGOs in highlighting the hazards to health, as soon as they were clear in scientific evidence. He judged that Imperial had no responsibility in this area and other players, respectively, bore all the responsibility. We believe this judgement to be untenable in the long-run. Producers make implicit claims of health benefit for their product =- even cigarettes in the short-term (sociability, sophistication, sexual success, an adjunct to leisure and a treatment for addiction), while they take no responsibility to imply the downsides. We do not believe the Government to be solely responsible, nor are health professionals or NGOs such as ASH Scotland, for pointing out the hazards. That would place pro-health interests in an impossible position.

Equally toxic, is the influence of commercial interest in taking half-measures dressed up as enthusiastic compliance to inform consumers - effectively, a smoke-screen of their own choosing, which we will come on to consider in the context of alcohol and food industries. The tobacco industry avers that they pay tax and therefore expect the Government to use them to do their duty. If there is compelling evidence, as in the case of tobacco taxation recently, there are incentives to promote healthy products. That could work both ways, although there are hazards in defining what

may be a healthy product, for instance, the oil industry may advise the benefits of petrol in carers getting to meet and benefit their users, whilst still reeking damage to the environment through the carbon legacy. In conclusion, then, companies have responsibilities to the consumers that go past the safety of the product, go past the restraints on health claims to place accurate and full information before the consumer.

Smokers' entitlement in the public health care system - the argument is that smokers pay higher taxation and insurance premiums for their habit. They argue that common smoking-related diseases are associated with swiftly fatal outcomes and may be cheaper than some long-term conditions. There is a counter-balancing and strong humanitarian argument on the value of life. Unless there are effective Government-led public health actions to regulate lifestyle choices, health care systems are faced with the consequences in a publicly funded health system which is constrained in its resources. Public solidarity implicit in our national health system assumes some degree of restriction of choice and inter-relatedness of responsibilities. Everyone is capable of making the wrong choices and it would be invidious to make a judgement on whether a smoker is any more wrong than an excessive eater, or someone else habituated to health damaging lifestyles. To do so, would begin a slippery slope that ends with such court actions as in France where brain damaged children have sued for wrongful life for being harmed by inter-uterine damage sustained by their mother or through an omission of her health attendance.

The choice to smokers - public attitudes towards smoking turned when, first, there was a sense of social nuisance (James XI's Counterblaste to Tobacco), then stepped-up further when scientific evidence showed harm to the smoker, then further when evidence emerged of harm to non-smokers who breathed the same environment. Once tobacco became legal and socially active, especially amongst the more privileged classes, then it was presumably impossible to ban its sale. There may be a point, even in a complex democracy, where further restrictions on sale are possible, through licensing and restricting availability in this way. However, such measures are dependent on changes in public support. An unprecedented change has already taken place with regard to smoking in public places and it is not possible to judge the distance this common support may travel. However, there are limits. Public policy, for instance, relating to banning beef on the bone marked a turning point to the degree to which the public would accept Government-directed public health action, effectively removing individual choice.

Governments generally wish to pursue popular policies and are reluctant to provide leadership which they believe does not command public support. In recent times, increasing public understanding of the risks has led to such support. The availability of clear evidence of harm coupled to communication of that message to the public is essential. Governments need to be encouraged to be bold and lead rather than follow on issues such as banning of advertising or banning of smoking in public places or greatly increasing taxation on cigarettes. Advocacy and lobbying of Governments by the public health community does not happen effectively in the UK. This function deserves more prominence and increased funding. It is an important role of health related charities/NGOs.

In conclusion, then, laws are already enforced for many matters in this and other areas - particularly alcohol misuse. Fuller enforcement of the law is possible - for instance underage sale in both tobacco and alcohol - but further measures may be necessary. Public support is necessary, whatever, in a democracy - specifically supportive parents and enforcers in the sale of cigarettes and alcohol. There is further to go in use of existing laws and regulations.

7. Alcohol

First, the general public have yet to realise that average consumption and, certainly, common patterns of consumption amongst the majority are health-damaging, for the consumer and also the society in which they consume. However, alcohol arguments are much more complex in that there is evidence for and against health effects of consumption, and cultural identification with alcohol products in all developed Western countries and democracies. There is an evident contemporary lack of public support for measures to reduce availability and increase unit cost of alcoholic beverages - the 2 key evidence-based measures that exist in the alcohol policy debate. Until that changes, there will be limited success in turning the tide of alcohol consumption. There is also institutional tolerance, starting with the public sector and including health professional groups, that promote and support the persistence of alcohol-damaging behaviour. Until these influences on public thinking change, there is limited capacity for important change in public policy relating to alcohol.

The roles and responsibilities of agents with respect to consumption of alcohol - these questions invite very detailed reply. Some existing roles and responsibilities are already set out in law. Voluntary codes of good practice and largely ineffective in our current experience and we are on the point, as a country in Scotland, of starting to deal with such failings. There is an emerging acceptance that the consequences of public health resources coping with the consequences carry alarming implications for the police, social work, health care and the courts. Producers have a responsibility to their shareholders, to market their products and promote the image of the product and the company, and they do so with great success. Retailers have responsibility to their shareholders to compete successfully on price and availability, and they do so with great success. Both of these main influences act against the health interest, unless Government intervention compels them to present a less contentious and more balanced view of the consequences of drinking to excess.

8. Supplementation of Food and Water

This issue presses against the leading edge of modern notions of autonomy. It also brings contemporary examples of the way in which the public and politicians regard science and its independence from the physical process. Food additives that are currently allowable data back to more paternalistic times. Then, there was acceptance of authority and professional expertise. Countries and states that have been successful recently in fluoridation of water attain these qualities, and conduct less libertarian politics and culture. However, adding additives in water is a matter

that affects, emotionally and in terms of autonomy, a basic commodity where there is lack of choice. Fluoridation of water, or additives in bread, is an "all or nothing" matter, different on a qualitative basis with other matters.

Dealing with population benefits of fluoridation specifically, these debates came at a time when science began to be questioned, and the assumed beneficence of scientific advice to Governments became questionable. The debate with respect to children and decisions taken on their behalf has swung very strongly towards protection bar-none. We are in new policy territory in vetting and barring of people who deal with children. The pendulum has swung even more to the role of the state in limiting the activity to the individual. In that context, decisions on adding further - for instance, folate - to flour or other foodstuffs, will be easier to achieve.

9. Ethical Issues

Consent and trust are 2 fundamental principles, on which other principles are founded. The notions of consent and of trust have changed and become more complex recently. No longer is there unqualified primacy and authority of Government and its advisers. Therefore, the remaining 4 principles are dependent on context, issues, the balance of risk and benefit, the balance of risk of inactivity or its consequential hazard. We note also the lack of beneficence as a principle, being the opposite to the harm principle.

A hierarchy of importance - as before, these are context specific. Each of the 5 case studies merits separate and detailed consideration. The Council will be well aware of the balance to be struck in each case. The very implication of this consultation paper recognises that there is no one enduring true, or prime value.

Principles in any of these areas - on vaccination, the interests of the child are of prime importance, and their decision is of prime importance where that is competent. However, we envisage no alternative to the key role of parents other than to note that the debate of MMR is between good and poor interpretation of science, whereas there is an absence of debate on the risk of benefit or harm in polio immunisation for the individual UK child in the context of the world picture.

As to other subjects for discussion, the Council has chosen 5 of the most vivid and illustrative examples. A broader and more diffuse issue might be the debate on measures to eradicate child poverty, nationally and internationally; measures to counter the increase in inequalities in health; measures to minimise harm and maximise freedom of people with mental illness, particularly in the forensic field; a real-time analysis of emerging parenting policy; the emerging health debate on the effects of global warming and suitable, proportionate measures to counter this tendency; and pro-active research design on ethical issues raised in a flu pandemic.

For those of us engaged in public health research we have seen the damaging consequences of a society policy that gives primacy to individual autonomy. Whilst it is highly likely that there would be widespread public support for the use of data for public health purposes (e.g. use of cancer registry data) nevertheless, the use of these data has been restricted/made more difficult to access. This is on the basis on

theoretical risks to individuals with very little evidence of actual harm. The harm of this policy is difficult to quantify but is real. In contrast, the increased emphasis on informed consent is appropriate in my view. The relative importance of these issues is mostly relative to the circumstance in question and no simple answer can be given here.

In conclusion, the College welcomes this consultation paper as the start of an exciting new period of debate on the ethics of public health and public policy relating to health. It looks forward to engaging with the Council on future occasions and supports the initiative.

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