



Better Health Through Prevention



Fourth Annual Report of the
Chief Medical Officer



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Acknowledgements

As in other years, I wish to acknowledge the contribution of the staff in the CMO's Office to the preparation of the Annual Report and to the carrying out of their work this year. During a particularly challenging period, the members of the office carried out their duties with an enormous sense of professional and personal integrity, dedication to public service and commitment to the health and well-being of the Irish people. It is a great pleasure for me to work with them.

Dr John Devlin,
Deputy Chief Medical Officer

Dr Rosemary Boothman,
Deputy Chief Medical Officer

Dr Eibhlín Connolly,
Deputy Chief Medical Officer

Dr Tony Holohan,
Deputy Chief Medical Officer

Dr Emer Shelley,
National Heart Health Advisor

Ms Pauline Brady,
Administration

Ms Frances Norris,
Administration

Dr Jim Kiely
Chief Medical Officer

Introduction

Previous reports from the Chief Medical Officer have dealt with particular themes, i.e. inequalities, child health and population health. This year, the report consists essentially of commentary on a number of issues which are not directly connected to each other except that in recent times they have been the subject of wide debate in the public domain, are in the main related to lifestyle and behaviour and, above all, have a serious significance for public health.

Consumption of alcohol has increased dramatically in Ireland over the past decade and will have inevitable short and long-term implications. How to deal with this issue in purely public health terms is constrained by the fact that issues of commercial interest such as tourism development, competition, deregulation, manufacturing and advertising, coupled with law and order issues, are part of the mix that goes into public policy decisions in this area. This section of the report refocuses on the public health aspects of alcohol use and abuse.

One of the major priorities for the Department of Health and Children in relation to the cancer, cardiovascular and other strategies is that of prevention and early identification and treatment of remediable conditions. In this regard, the report comments on two approaches to strengthening this approach, i.e. reducing tobacco consumption and improving the understanding and utilisation of screening.

As Chief Medical Officer, one of my main objectives is to tackle the public health scourge of tobacco and its devastating consequences. The CMO's Office supports this initiative by providing evidence, analysis and advice to the Minister and the Department on the public health aspects of tobacco consumption – thus informing policy decisions – and by continuing to advocate for public health in this area. The most recent initiative taken by the Minister for Health and Children, that of protecting the health and welfare of workers and customers in the workplace by banning smoking in working environments, is a balanced, proportionate and effective response to deal with the substantial health risks identified in respect of environmental tobacco smoke.

The initiation and maintenance of successful screening programmes such as breast screening and screening for metabolic diseases inevitably draws attention to other forms of screening and often results in calls for their introduction. This section of our report again draws the clear distinction between population-based screening programmes with all the implications these have in terms of ethics, organisation, resources, quality assurance and service delivery, and individual opportunistic case finding which is often confused with population-based screening. In reiterating these fundamentals of screening, I would like to call upon all those, especially health professionals, who debate these issues in public, particularly in the popular media, to be aware of the relevant factors before engaging in public discourse on this matter.

Prevention is the cornerstone of any rational health policy and, in this regard, the prevention of neural tube defects in babies is of significant importance in Ireland. There is a higher than average incidence of this condition in this country and an information and education campaign has been in place in recent years to improve knowledge of and utilisation of folic acid supplements by women in the child-bearing years with the aim of preventing this condition. The report provides information and commentary on a further initiative to improve uptake of folic acid, that of flour fortification which has been introduced and has proven to be successful in other jurisdictions.

The issue of accidents, and their importance in terms of mortality and morbidity in health service utilisation, is a perennial subject for commentary and we make no apology for commenting again on this cause of eminently preventable mortality and injury.

Finally, the report turns again to the subject of vaccination and reiterates the necessity of maintaining high levels of uptake of vaccines in the fight against preventable illness and death in children. Research and development of vaccines to increase their effectiveness, safety, ease of administration and general acceptability continues and our role is to bring all relevant developments in these areas to bear on the formulation and

implementation of national vaccination policy. Parallel with these developments, resistance to vaccines such as MMR continues, supported, unfortunately, on occasions by members of the caring professions. Genuine concerns of parents in this area have to be understood and we need to develop more effective communication with the general public, parents and health-care professionals so that we can deal better with these concerns. It also requires constant vigilance and action by those with policy and service delivery responsibilities to advocate on behalf of the health and welfare of our children in this vital area of health protection and to expose the use of badly conducted research as a basis for opposition to the rational use of this safe and effective intervention.

Chapter 1

Alcohol and public health

Trends in alcohol consumption per adult over the last forty years show a gradual increase up to the mid-1990s.

However, since then there has been a dramatic increase in consumption to the point where in 2000, the total alcohol consumption per adult was 14.2 litres of pure alcohol.

Alcohol and public health

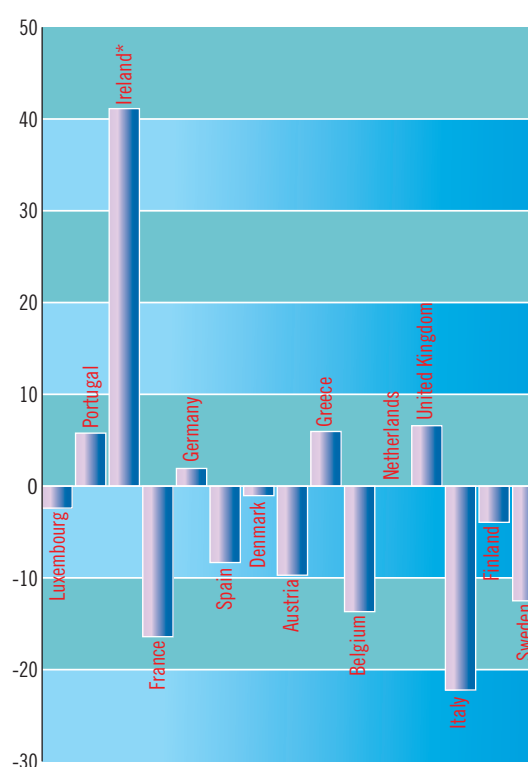


In 2002, the Minister for Health and Children established the Strategic Task Force on Alcohol and asked it to report on any measures that might be required to protect public health in the light of the worrying increase in the volume of alcohol being consumed in Ireland and changes in the pattern of consumption. The Chief Medical Officer chaired the Task Force and this commentary draws significantly on the analysis and recommendations made in its report.

Alcohol consumption in Ireland

In the last decade, Ireland has seen changes that have been unprecedented in terms of their nature, their magnitude and the speed with which they have occurred. Economic prosperity and income per capita, with a consequent increase in disposable, discretionary income, have increased to European Union averages. Against this backdrop, between 1989 and 1999, Ireland had the highest increases in alcohol consumption among EU countries. In that time, alcohol consumption per capita in Ireland increased by 41 per cent, while ten of the European Union Member States showed a decrease and three other countries showed a modest increase (Figure 1). Ireland's consumption continued to increase in 2000 and ranked second after Luxembourg with a rate of 11 litres of pure alcohol per head of population.

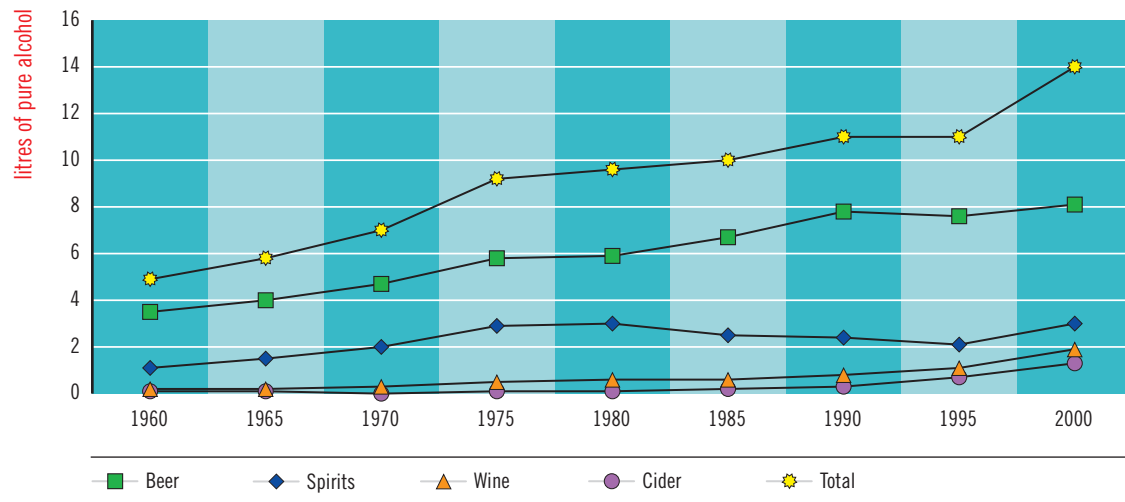
Figure 1: Percentage change in per capita alcohol in EU countries, 1989-1999



Source: Ireland – Revenue Commissioners and CSO; others – World Drinks Trends

FIGURE 2

Consumption of beer, spirit, wine and cider per adult (15 year and over), in litres of pure alcohol, Ireland 1960-2000



Source: Revenue Commissioners and CSO Annual Reports

Measuring alcohol consumption per capita, in those aged 15 years and over, is a more accurate reflection of consumption at the population level, given that children under 15 years are primarily non-drinkers and represent 21 per cent of the population. Trends in alcohol consumption per adult over the last forty years show a gradual increase up to the mid-1990s. However, since then there has been a dramatic increase in consumption (Figure 2) to the point where in 2000, the total alcohol consumption per adult was 14.2 litres of pure alcohol. While beer continues to be the most popular drink consumed, the sales of wine and cider have seen substantial growth. Since 1996, when there was a 10 per cent increase in spirit sales, growth has also continued in the sales of that product.

Drinking patterns

As previously mentioned, drinking patterns have been influenced by such factors as changing lifestyles and expectations and higher disposable income and are characterised by:

- Younger drinking
- Binge drinking and
- Higher volumes consumed.

Underage drinking

Research has shown that over half of Ireland's young people begin experimenting with alcohol before the age of 12. In the under-15 year age group more boys than girls are current drinkers and about one in five of the 12-14 year age group boys are so described.

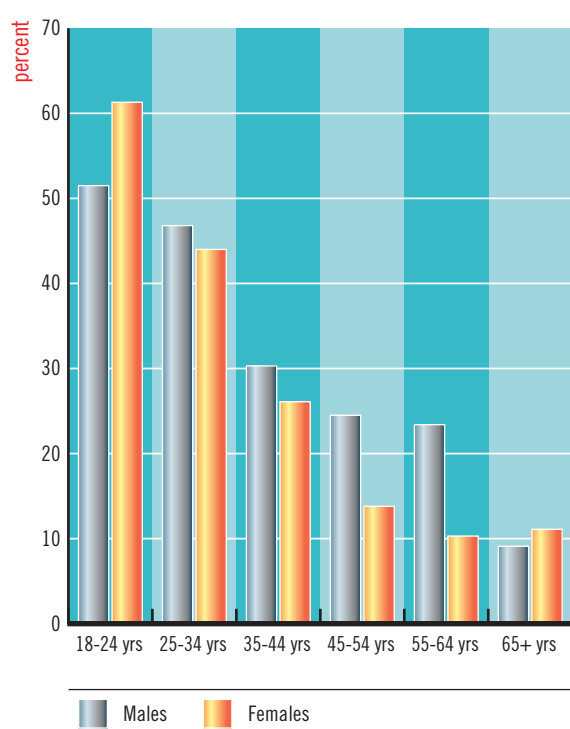
In addition to the large quantities of alcohol being consumed, it is of particular concern that one-third of the 15-16 year age group reported binge drinking (five or more drinks in a row) three or more times in the previous month; one-quarter reported having been drunk three or more times in the previous month.

Adult drinking

The first national lifestyle survey (SLÁN), commissioned by the Department of Health, reported in 1999 on the drinking habits of those aged 18 years and over. Important age differences emerged which showed that over half in the younger age group (18-24 years) were more likely to engage in binge drinking when they drank, but drank less frequently (fewer times per week) than older age groups. More females than males in the 18-24 year age group were likely to engage in high-risk drinking, both in terms of binge drinking and drinking over the recommended weekly upper limits (Figure 3).

FIGURE 3

High-risk drinking per session for those aged 18 years and over



High-risk drinking: 70 grams or higher of pure alcohol for males; 50 grams or higher of pure alcohol for females

Source: SLÁN Survey, 1999

Alcohol-related harm

The adverse effects of alcohol extend beyond physical health issues to mental, social and financial problems including:

- Once-off problems such as a fall, an accident, a fight or an episode of unprotected sex
- Recurring problems such as poor work performance, financial hardship and relationship difficulties
- Chronic illness such as cancer and liver damage
- Sustained dependence on alcohol.

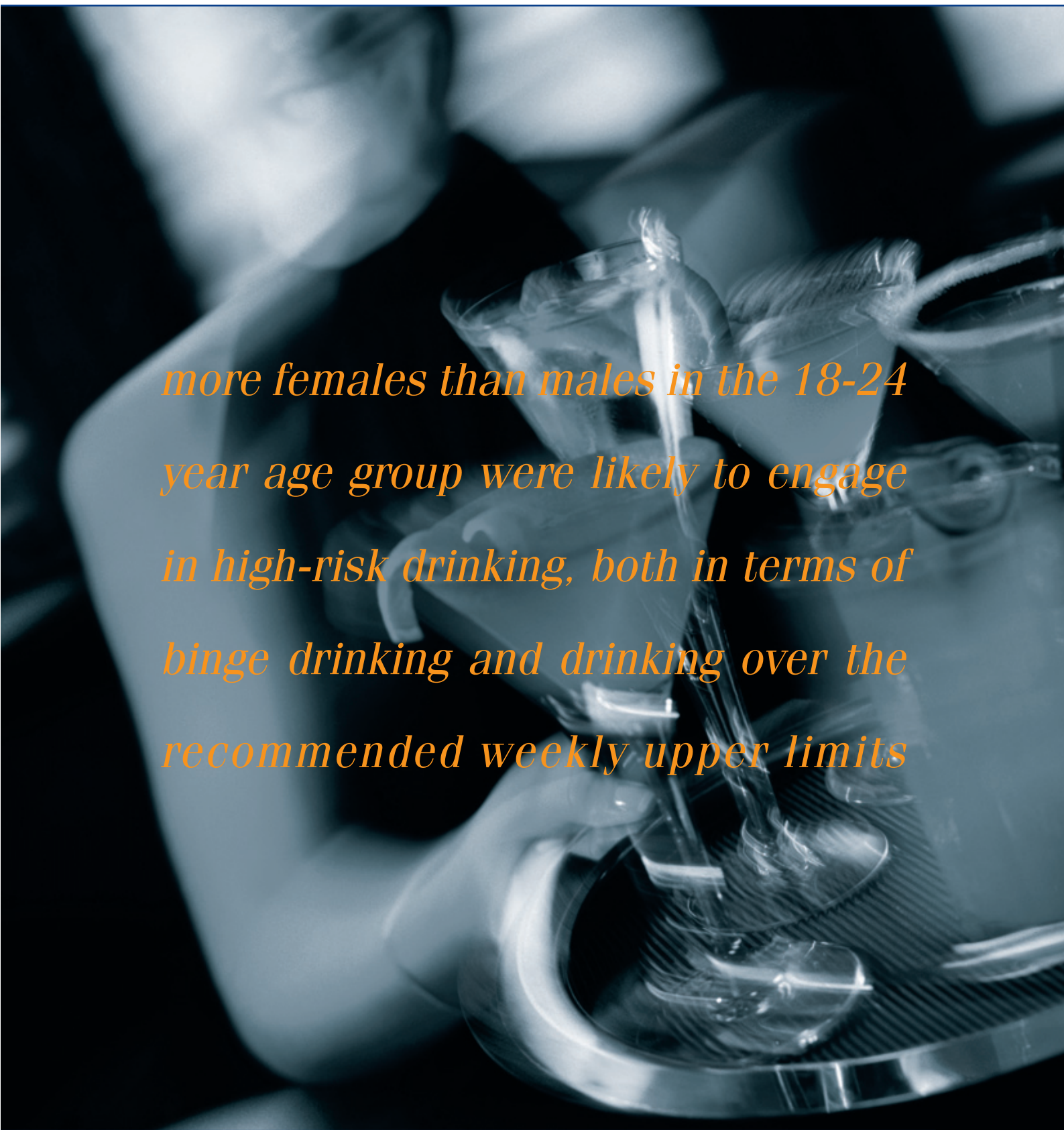
In assessing the harm that ensues from the abuse of alcohol, a number of standard indicators were used by the Task Force:

- Unintentional injuries
- Personal relationships
- Interpersonal violence/public safety
- Drink driving
- Alcohol-related mortality
- Mental health problems.

Unintentional injuries

Many falls, drownings and burns resulting in injury and death have been linked to alcohol consumption.

A pilot study of alcohol-related attendance in a major Accident and Emergency Department showed that alcohol was a factor for one in four (25 per cent) of those in attendance at the hospital and 13 per cent were clinically intoxicated. The vast majority of patients whose condition was alcohol related were in attendance between 6pm and 8am.



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Personal relationships

The social and personal consequences of alcohol-related harm not only affect the individual drinker but can also damage wider family, friends and work relationships. Children of problem drinking parents are particularly vulnerable to a range of problems and marriage counselling services have reported that alcohol abuse is the primary presenting problem in up to 25 per cent of cases.

Young people also experience social and personal problems as a result of their own use and abuse of alcohol by way of poor school performance, accidents, relationship problems and delinquency problems.

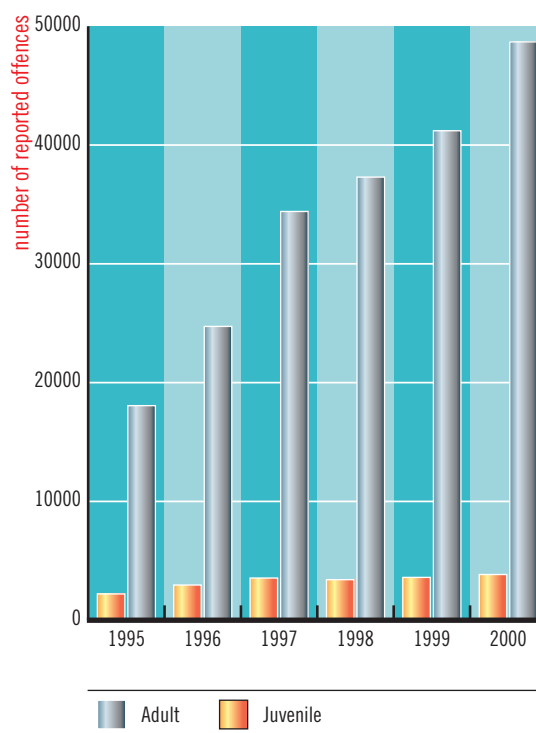
A major Irish research project on crisis pregnancy identified alcohol as one of the factors that contributed to the incidents of unwanted pregnancies. A study among school-going Irish teenagers reported that 35 per cent of the sexually active respondents said alcohol was an influencing factor for their engaging in sex and has also been identified as one of the main risk indicators in relation to teenage pregnancy and an increased risk of sexually transmitted infections.

Interpersonal violence/public safety

Excessive drinking increases the risk of drunkenness, fights, assaults and violence and the Garda Commissioner has highlighted the link between alcohol and the rise in violence. He noted that in 2000 there were 62,000 incidents of public order offences of which 38,000 people were charged and the remaining 24,000 were cautioned. Many of such public order cases are alcohol related. Serious assaults also increased during 2000, many of which were alcohol related, giving the total number of offences relating to street violence where proceedings were taken at 48,682 (Figure 4). These alcohol-related offences were committed by adults. Alcohol-related offences for juveniles also increased over the same period.

FIGURE 4

Alcohol-related offences for adults and juveniles



Source: An Garda Síochána, Annual Reports

Drink driving

It is estimated that alcohol is associated with at least 30 per cent of all Irish road accidents and 40 per cent of all fatal accidents. Drink driving offences dropped in 1995 to approximately 5,000 offences the year after the introduction of the lower BAC level of 80 mg/100ml. However, since then a steady increase has been reported. In 2000 the Gardaí made approximately 10,500 detections for drunk driving. The vast majority (93 per cent) of detections were over the BAC legal limit and 62 per cent of those were over twice the limit. Overall, while there has been a decrease in the number of people killed and

injured from road accidents since 1997, the number of people killed during the time period most associated with drink driving (9pm-4am), which represents about one-third of all those killed, has not substantially decreased.

psychosis, alcohol dependency syndrome and alcohol abuse) also showed an increase over the last decade.

Alcohol-related mortality

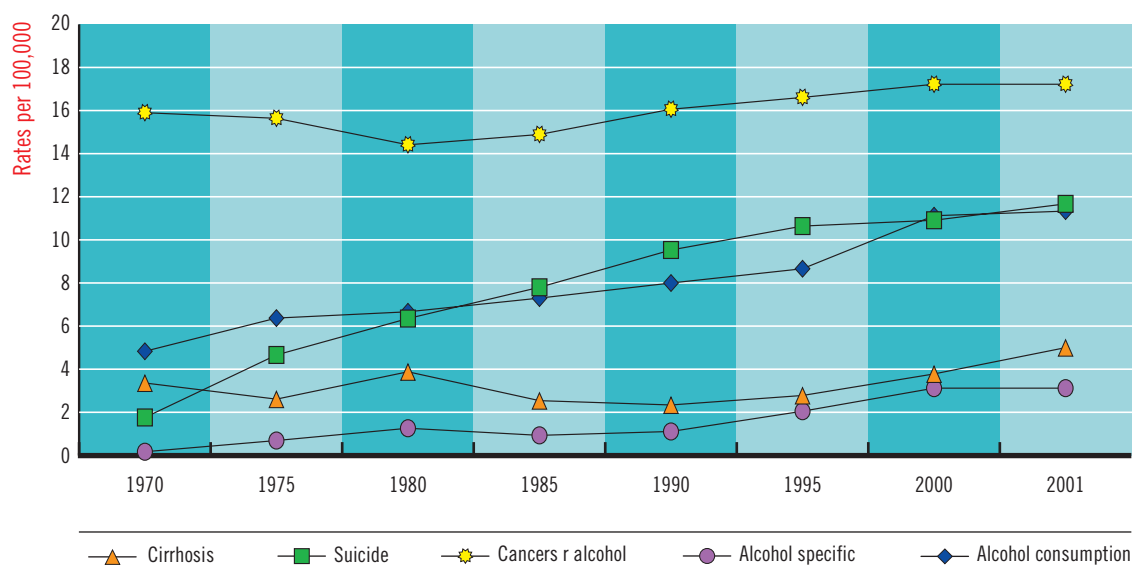
In addition to being a contributory factor to many deaths involving accidental falls, suicide, homicide and accidents, there is also convincing evidence to show that regular alcohol consumption increases the risk of liver cirrhosis, cancers of the mouth, pharynx, larynx, oesophagus and liver. During the last decade increases have occurred in some of the alcohol-related mortality rates such as accidental falls, suicide and cirrhosis in Ireland (Figure 5). Cancer mortality related to alcohol showed some increased in the mid-1990s. Other conditions specifically related to alcohol (alcohol poisoning, alcohol

Mental health

Alcohol abuse is a significant risk factor in suicide and compounds some of the other suicide risk factors. There has been a sharp increase in male suicides especially in the 15-29 year age group and overall it is the commonest cause of death in men aged 15-35 years in Ireland. Alcoholic disorders continue to be a main cause of admissions to psychiatric hospitals and accounted for 26 per cent of male admissions and 11 per cent of female admissions to psychiatric hospitals in 1999. Research in an Irish general hospital reported that 30 per cent of all male patients and 8 per cent of female patients were identified as having underlying alcohol abuse or dependency problems. However, the admitting

FIGURE 5

Alcohol-related mortality & alcohol consumption (per capita), 1970-2001



Alcohol specific = alcohol poisoning, alcohol dependency, alcohol psychosis, alcohol abuse, toxic effect of alcohol

Source: Vital Statistics, CSO

medical team did not detect many of these cases. The study highlights the under-recording of alcohol-related problems in the hospital setting.

The Strategic Task Force on Alcohol has made a number of significant recommendations **aimed at reducing the overall consumption of alcohol in Ireland**. The rationale for this is two-fold:

- a** The EU has identified alcohol as a key determinant in the burden of disease in member states and in the Union generally and the World Health Organisation (WHO) has recognised that reducing alcohol-related harm is one of the most important public health actions a country can undertake to improve quality of life.
- b** Research studies undertaken in Europe in the last number of years have clearly demonstrated the link between per capita consumption and alcohol-related harm. . The amount of harm experienced varies depending on the predominant drinking patterns in a culture, especially if drinking to intoxication and regular binge drinking are part of the pattern.

Given this evidence and the situation described in Ireland, it is urgent that public health be protected by measures to reduce the overall level of alcohol consumption in this country. These measures must form an integrated framework within which public policy measures can work together to reduce the rising incidence of alcohol-related harm.

Framework

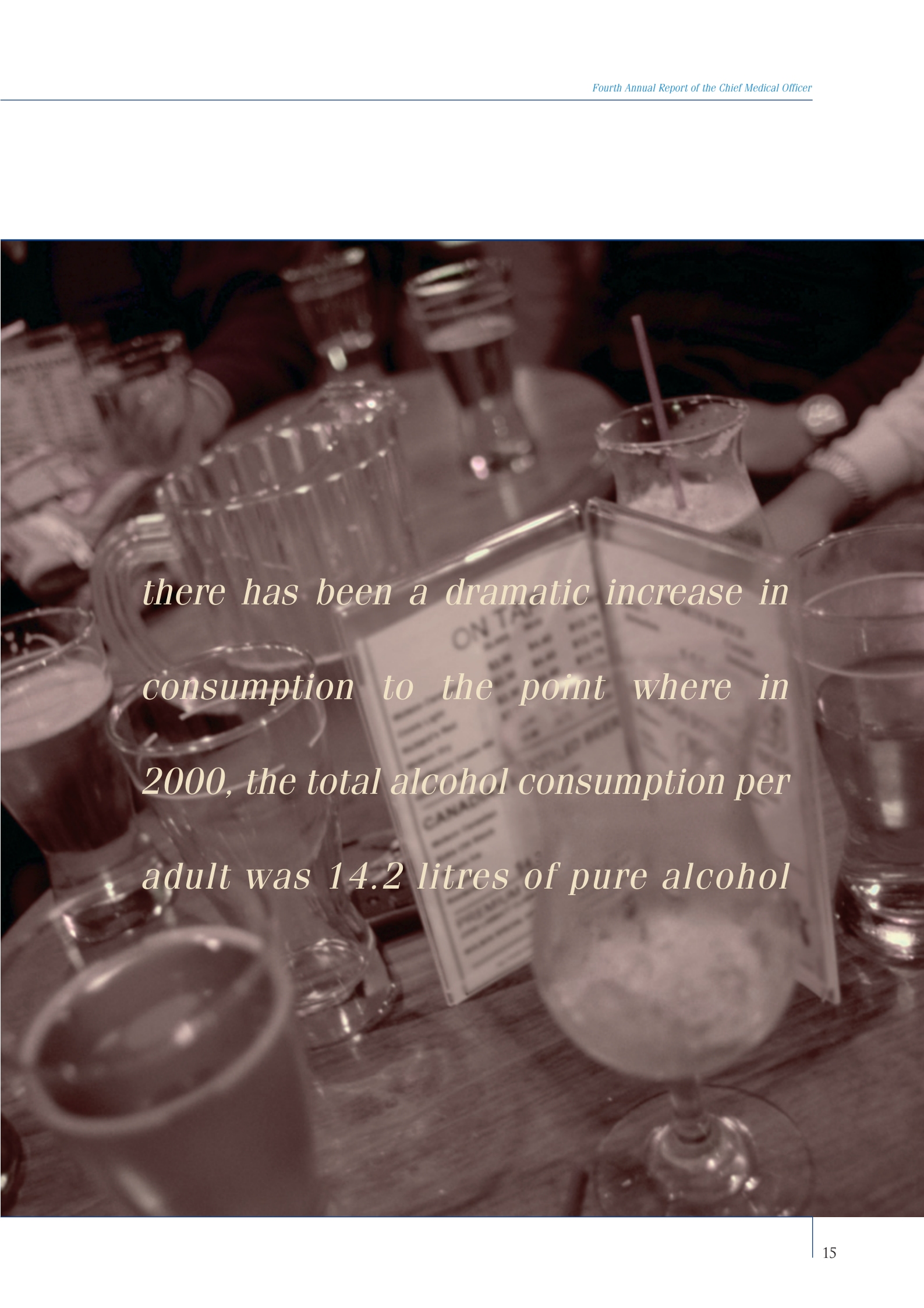
Ireland, through its membership of WHO, has both contributed to the formulation of, and endorsed, the European Charter on Alcohol, the European Alcohol Action Plan and the Declaration on Young People and Alcohol. These documents have provided ethical principles and goals for advancing alcohol policy and a template for the development of strategies for alcohol action. Ireland has also adopted the EU Council Recommendation on the drinking of alcohol by young people, in particular children and adolescents.

The recommendations of the Strategic Task Force on Alcohol were framed using the ten strategy areas for alcohol action outlined in the European Charter on Alcohol. These strategies are based on sound scientific evidence and this year's CMO's report endorses them as an effective approach to the reduction of alcohol consumption:

- Regulate availability
- Discourage drink driving
- Ensure effective treatment services
- Protect public, private and working environments
- Implement control on alcohol promotions
- Foster responsibility in the alcohol beverage industry
- Provide information and education
- Enhance society's capacity to respond to alcohol harm
- Support non-governmental organisations
- Formulate a broad-based alcohol policy and monitor progress.

The most immediate objectives are:

- To reduce total alcohol consumption at a population level to the EU average
- To reduce harmful consumption of alcohol at an individual level, especially binge drinking and regular heavy drinking
- To provide greater protection for children and adolescents from the pressures to drink
- To prevent and reduce the risk of alcohol-related harm on the roads
- To prevent and reduce the risk of alcohol-related harm in the drinking environment.

A photograph of a bar scene with various glasses of alcohol and a menu. The image is overlaid with text. The background shows a wooden bar counter with several glasses, including a large pitcher, a glass of beer, and a glass of water. A menu is visible in the center, with the words "ON TAP" and "CANADIAN" visible. The text is in a serif font and is italicized.

*there has been a dramatic increase in
consumption to the point where in
2000, the total alcohol consumption per
adult was 14.2 litres of pure alcohol*

Measures to achieve these objectives

As an initial step towards achieving the specific objectives outlined, the following set of targeted measures needs to be implemented without delay. The main thrust of these measures is to protect public health and public safety, as well as creating an environment that helps people make healthy choices.

- Regulate availability
- Reduce drink driving
- Limit harm in drinking environments
- Protect children and reduce pressure on adolescents to drink
- Provide information, education and services
- Research and monitor data.

The breadth and complexity of these measures clearly points to the necessity for a cross-departmental, multi-agency approach. The regulation of availability by strictly enforcing licensing laws regarding closing time, underage serving, and off-licence sales will reduce overall consumption; and the implementation of the road traffic laws will help prevent accident, mortality, morbidity and disability. The responsible serving of alcohol to customers will reduce the incidence of intoxication and subsequent possible violence and harm in the environment of licensed premises, an objective which can also be achieved by effective and sensitive policing.

This commentary locates alcohol policy firmly within the area of public health policy. Assigning this central role of public health, while recognising other values such as free trade, allows public policy to be directed towards proactive, preventive interventions rather than placing the focus on management of alcohol dependence and treatment of related conditions such as cirrhosis and injuries. This debate is not yet over and more needs to be done.

Chapter 2

Smoking in Ireland

The incidence of asthma is higher among children whose parents smoke and research has shown that parental smoking increases the risk of sudden infant death.

Cigarette smokers have more acute and chronic illness, more restricted activity and disability days and more absenteeism from work than those who do not smoke.

Smoking in Ireland



As Chief Medical Officer, tackling the public health scourge of tobacco consumption remains one of my top priorities. Tobacco consumption is the single most important preventable cause of illness and death. Over 7,000 people die from smoking-related disease in Ireland every year. These deaths are preventable.

Smokers lose an average of 10-15 years from their life expectancy. Smoking is a major causative factor in 95 per cent of lung cancer deaths. Smoking is also a risk factor for vascular disease, which can lead to stroke, gangrene and limb amputation. Smoking during pregnancy can impact on foetal growth and is associated with adverse pregnancy outcomes, including an increased incidence of low birth weight. Higher infant mortality occurs in mothers who smoke, compared with those who do not.

The incidence of asthma is higher among children whose parents smoke and research has shown that parental smoking increases the risk of sudden infant death. Cigarette smokers have more acute and chronic illness, more restricted activity and disability days and more absenteeism from work than those who do not smoke.

Smoking-related diseases place an enormous burden on the health system. It is estimated that it may cost the exchequer €1 billion per year to provide health services for smokers.

In the mid-1970s approximately 45 per cent of all adults smoked. That fell to about 28 per cent in the early 1990s but the figure rose again in the later 1990s. The year 1998 saw the publication of the first SLÁN survey which provided the most comprehensive information on lifestyle factors, including smoking.

The SLÁN survey was repeated in 2002 and it found that there has been a fall in reported cigarette smoking rates in virtually every demographic category since the first survey in 1998. Overall, 27 per cent of the adult population reported being regular or occasional cigarette smokers, compared with 31 per cent in 1998. Rates have fallen among both men (28 per cent) and women (26 per cent).

Marked age gradients continue to exist among both men and women, with highest smoking rates among younger people. There continues also to be an inverse relationship with level of education. Among school-going children, 19 per cent overall report they are current smokers, down from 21 per cent in 1998, and rates have dropped most particularly in the key 12-14 year age group, suggesting the possibility of delayed initiation, a key part of any successful health promotion strategy. While rates among boys in social class 5-6 appear to have risen, rates have dropped in all social class categories among girls.

These findings in 2002 suggest a real decline in smoking rates, given the consistency of the trends. In addition there are positive trends in exposure to passive smoke. Rates of exposure at home, in the workplace, on public transport, in pubs or clubs and other places are all down among adult men and women, though exposure rates at work (29 per cent men and 16.6 per cent women), are much lower than in pubs and clubs (47.3 per cent men and 31.6 per cent women) suggesting the importance of legislation in regulating exposure.

The SLÁN surveys indicate that progress has been made over the last number of years in reducing the burden of smoking. However, while there may be some grounds for cautious optimism, there is no room for complacency. Tackling smoking requires sustained actions on all fronts. These include fiscal, legislative, environmental, health promotion and other measures. The ban on smoking in the workplace is an essential part of this.

Ban on smoking in the workplace

The tobacco industry has consistently sought to play down the possible health effects of passive smoking. This is in spite of the fact that there is an international scientific consensus concerning the significant dangers associated with environmental tobacco smoke (ETS). The World Health Organisation's International Agency for Research on Cancer has classified ETS as a carcinogen.

Some of the effects reported in studies that have examined the health effects of ETS include the following:

- An increased risk of lung cancer (up to 20-30 per cent)
- An increased risk of heart disease (up to 25-30 per cent)
- An increased risk of stroke (up to 82 per cent)
- A reduction in birth weight of infants born to mothers exposed to ETS
- An increased frequency of chronic respiratory symptoms such as cough, phlegm production, shortness of breath and chest colds.

The awareness that ETS is harmful to health places an onus on government to safeguard public health by providing legislation to protect the general public from passive smoking. Current legislation prohibits smoking in certain categories of workplace but there are many exceptions such as pubs, nightclubs and bookmakers. Workers in these and other leisure industries are exposed to high levels of ETS due to smoking by their customers.

In recognition of the very significant risks associated with ETS exposure, the Health and Safety Authority and the Office of Tobacco Control commissioned an independent scientific working group to 'identify and report on the degree of consensus that exists among leading international scientific authorities on the question of the hazard and risk posed by environmental tobacco smoke to human health in the workplace'.

This report provides an expert and independent assessment of the evidence concerning ETS and its effects, together with recommendations as to how the dangers from ETS can best be avoided. In so doing it provides a clear conclusion that exposure to ETS is a major public health risk that must be addressed.

Control mechanisms for ETS

The EU Commission has called on member states to 'provide adequate protection from exposure to passive smoking at workplaces, in enclosed public places and in public transport and to strengthen smoking prevention programmes'.

Ventilation and legislation are two approaches to reduce exposure to ETS. However, research suggests that current ventilation technology, at best, has the potential for a 90 per cent reduction in ETS levels. While this might seem impressive, it would still leave exposure levels 1,500 to 2,500 times the acceptable risk level for hazardous air pollutants.

Removal of the particulate smoke matter from the air may make it seem clean but it cannot effectively reduce the carcinogenic risk from exposure to ETS.

In September of 2003, the Joint Research Centre of the European Commission published a study which establishes that changes in ventilation rates during smoking do not have a significant influence on the air concentration of tobacco components. This means that, in spite of their promotion by the hospitality and tobacco industries, ventilation systems cannot provide adequate protection of health for the public or for staff from exposure to passive smoking in the workplace. In other countries the tobacco industry has led the hospitality industry into a position of advocacy in relation to ventilation systems. This advocacy is not supported by evidence.

Experience in Finland and the United States has clearly shown the advantages of using a legislative approach as opposed to voluntary codes on workplace smoking. Voluntary codes have been the approach up to now in Ireland and in a number of other countries. They have not been effective in reducing workplace exposure to ETS, particularly in the hospitality industry.

In light of the evidence concerning ventilation and legislation, a total ban on smoking in the workplace provides the most effective basis for addressing this issue. The core rationale is the protection of the health of employees and the public from exposure to toxic environmental tobacco smoke. This has to be the overriding consideration. A total prohibition on smoking in the workplace is a proportionate and balanced measure to deal with the substantial risks that arise from environmental tobacco smoke. The Minister for Health and Children has signed the regulations to give effect to such a ban beginning in January 2004, an act of great symbolic and public health importance.

Other measures to tackle tobacco consumption

Despite increases in the tax on tobacco, the price barrier has fallen significantly in real terms in recent years. Fiscal policy for tobacco should focus

primarily on raising prices of tobacco products to at least the rate of income growth with the objective of reducing 'affordability'.

It is essential that fiscal policy reflects the sensitivity of smoking prevalence to real increases in the price of tobacco. The maintenance of tobacco in the consumer price index provides a barrier to substantial increases in the price of cigarettes and other tobacco products. The amendment of the consumer price index to remove the effect of tobacco costs should be a matter of government priority to enable substantial increases in the price of tobacco to be levied. This has been shown to be effective in leading to significant reductions in the prevalence of smoking particularly among young people.

There will be a need for health services to provide balanced supports in the form of health education, brief interventional counselling, nicotine replacement therapy and other supports which ensure that those who are in genuine financial difficulty and who are addicted to tobacco products are helped as much as possible to quit.

Other general measures which now deserve further consideration include advertising restrictions that limit the effects of product placements and advertising from other non-direct sources. Direct advertising of tobacco products in newspapers and magazines has been restricted for a number of years. However, advertising is still widespread in imported publications, particularly from the UK. Direct advertising is totally banned on radio and television but the industry still engages in high-profile sponsorships to circumvent this.

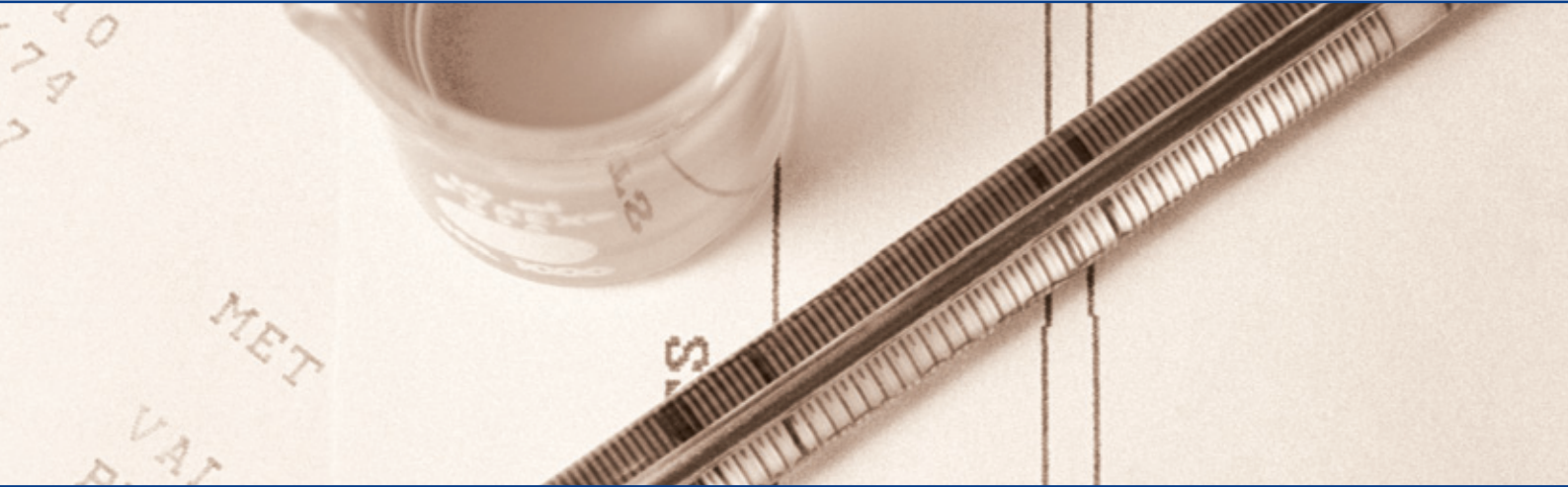
Chapter 3

Screening for cancer

Criteria that should be satisfied before the introduction of population-based screening programmes were first published by the World Health Organisation in 1968.

These criteria have, in general, stood the test of time. However, they require modification in the light of experience of the last 30 years.

Screening for cancer



Screening is a means of detecting disease before it has developed to the point where it results in symptoms. It can allow detection of cancers at an early stage of invasiveness or even before they become invasive. Screening aims to improve survival from cancer, limit morbidity from cancer, and improve the quality of life of those who have developed cancer.

Screening is different from most other forms of health care and there is often confusion about its purpose. Screening does not diagnose illness. Its purpose is that of risk reduction. It is not a guarantee of diagnosis and cure. Those who are screened and have a positive screening test result require confirmatory diagnostic testing before definitive diagnoses can be established and appropriate treatment planned.

Screening may be population based or may focus on high-risk groups. Population screening is aimed at an entire cohort in the population selected on the basis of general demographics, e.g. all women aged 50-64. High-risk screening is usually based on more individual characteristics, e.g. family history.

Screening may be undertaken pro-actively or opportunistically. In pro-active screening members of a target population will attend for testing in a systematic programme which will cover the whole of that population over a defined period of time, e.g.

BreastCheck. Conversely, opportunistic screening is the offer of a test for an unsuspected disorder at a time when a person visits a health professional for another reason, e.g. blood pressure screening.

Population-based screening for cancer

There is evidence pertaining to some specific cancers (e.g. breast) which shows that population-based screening can improve population health in terms of survival, morbidity and quality of life. However, for a number of other cancers the evidence is less clear-cut and these are therefore the subject of debate, dispute and confusion. In spite of this, the predominantly healthy populations at whom population-based screening is aimed generally perceive screening to be uncontroversial, with obvious benefits.

In addition to the beneficial effects of screening, there may also be negative side-effects on the screened population. The ethical responsibility attached to screening is significantly higher than in ordinary clinical practice.

It is necessary, therefore, to ensure that the introduction of organised national population-based screening programmes for cancer will only be

considered where clear evidence exists of benefit to the health of the whole population to be screened, outweighing harm and at reasonable cost. This principle has international acceptance.

Criteria that should be satisfied before the introduction of population-based screening programmes were first published by the World Health Organisation in 1968. These criteria have, in general, stood the test of time. However, they require modification in the light of experience of the last 30 years. In the development of the original criteria, insufficient emphasis was placed on the harmful effects of screening, the quality of the evidence on the effectiveness of screening was not

specified and opportunity costs of implementing a screening programme were not considered.

Consequently, more comprehensive updated criteria have been developed, by the UK National Screening Committee, using rigorous standards of evidence to prove effectiveness. These criteria were considered by the National Cancer Forum which regards them as a robust framework for guiding decisions concerning national population-based screening programmes. The criteria are set out below and are the subject of a more detailed paper produced by the National Cancer Forum which is available from www.nationalcancerforum.ie.

Criteria to guide decision concerning the introduction of population-based screening

The condition

- 1 The condition should be an important health problem
- 2 The epidemiology and natural history of the condition, including development from latent to declared disease, should be adequately understood and there should be a detectable risk factor, disease marker, latent period or early symptomatic stage
- 3 All the cost-effective primary prevention interventions should have been implemented as far as practicable

The test

- 1 There should be a simple, safe, precise and validated screening test
- 2 The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed
- 3 The test should be acceptable to the population
- 4 There should be an agreed policy on the further diagnostic investigation of individuals with a positive test and on the choices available to those individuals

The treatment

- 1 There should be an effective treatment or intervention for patients identified through early detection, with evidence of early treatment leading to better outcomes than late treatment
- 2 There should be agreed evidence-based policies covering which individuals should be offered treatment and the appropriate treatment to be offered
- 3 Clinical management of the condition and patient outcomes should be optimised by all health care providers prior to participation in the programme

The screening programme

- 1 There should be evidence from high-quality, randomised, controlled trials that the screening programme is effective in reducing mortality or morbidity
- 2 There should be evidence that the complete screening programme (test, diagnostic procedures, treatment/intervention) is clinically, socially and ethically acceptable to health professionals and the public
- 3 The benefit from the screening test should outweigh the physical and psychological harm (caused by the test, diagnostic procedures and treatment)
- 4 The opportunity cost of the screening programme (including testing, diagnosis and treatment) should be economically balanced in relation to expenditure on medical care as a whole
- 5 There should be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards
- 6 Adequate staffing and facilities for testing, diagnosis, treatment and programme management should be available prior to the commencement of the screening programme
- 7 All other options for managing the condition should have been considered, e.g. improving treatment, providing other services

Opportunistic screening for cancer

There is a considerable level of cervical smear testing, Prostate Specific Antigen testing and non-BreastCheck mammograms being carried out by health professionals. While many of these tests may well be carried out as diagnostic procedures, significant numbers are carried out in the belief that they constitute screening and bring with them the benefits associated with organised screening programmes. However, without appropriate quality assurance mechanisms, clear referral and follow-up procedures, call and recall processes among many other organisational attributes, this form of testing does not carry the benefits of organised population-based screening and may actually be more injurious to health. Such testing should only be carried out when patients and health professionals both know and understand its significant limitations. I intend to ask the National Cancer Forum to address this issue in the context of the work it is carrying out at present in the development of a new National Cancer Strategy.

Chapter 4

Road traffic accidents

Nearly half of all child deaths are caused by motor vehicle crashes. All children are at risk as car passengers; as toddlers the risk of pedestrian accidents increases and as they get older, they become vulnerable as cyclists and later as motor cyclists.

Finally, young people, particularly young men, are at highest risk of death and injury from car accidents.

Road traffic accidents



Previous annual reports have dealt with the issue of accidents and non-intentional injuries, with particular reference to this phenomenon in children. While there has been a relative improvement in some aspects of accident prevention in recent years, nevertheless they continue to be a major cause of death and illness in Ireland. Cardiovascular disease and cancer are by far the most important causes of morbidity and mortality in the population as a whole. However, when it comes to the age group under 25 years, the picture is very different. Accidents and unintentional injuries are the commonest cause of death and illness in this group. The issue of most particular relevance is that there continues to be wide scope for preventing them and, in this regard, we draw attention to the issue of road traffic accidents in this year's report.

Recent statistics from the National Roads Authority (NRA) indicate that 411 persons were killed on Irish roads in 2001, a reduction overall of 4 or 1 per cent on the previous year's figures. The number of

fatalities among car users fell by 30 to 230 compared to the year 2000 and of these, 32 or 15 per cent were in the 18-24 year age group. However, the numbers of fatalities among other road users, i.e. pedestrians and motorcyclists, increased.

To put this figure in context, there were over 500 deaths from road accidents in 1973, approximately 450 in 1983 and 425 in 1993. An interesting feature of the pattern of fatalities on the road over the past decade is that, while the numbers that have been killed have reduced slowly, the significant increase in car ownership has resulted in a very significant reduction in persons killed per million registered vehicles. This may be a result of the protective measures taken such as better vehicle design, child restraints, speeding restrictions, better medical care, and greater survival following accidents. Despite the reductions noted, however, the number of potential years lost in such accidents continues to be considerable.

FIGURE 6

All motor vehicle accidents: total number of deaths by sex, 1980-2001

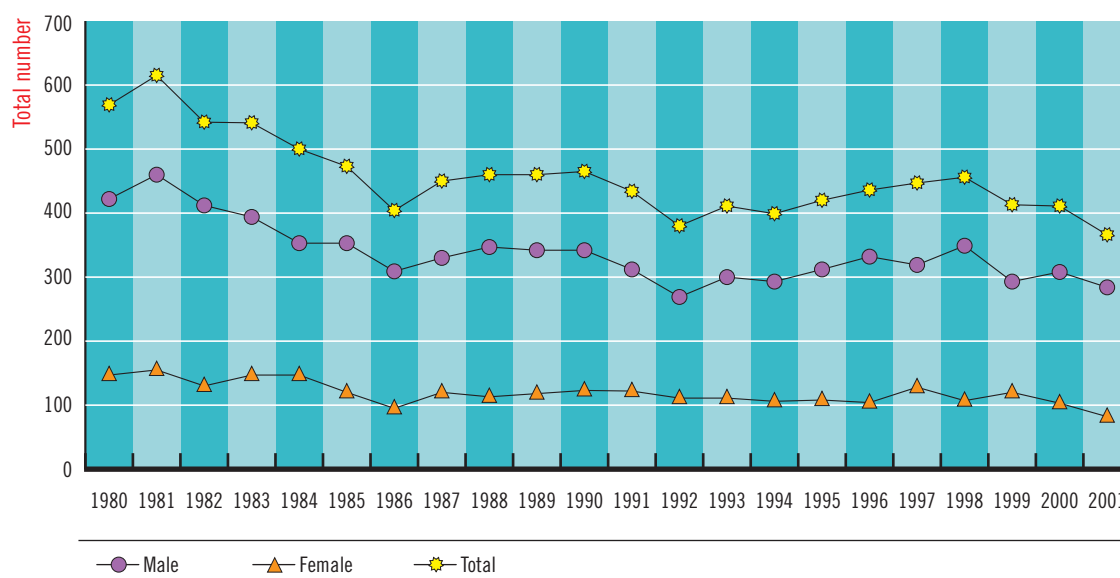
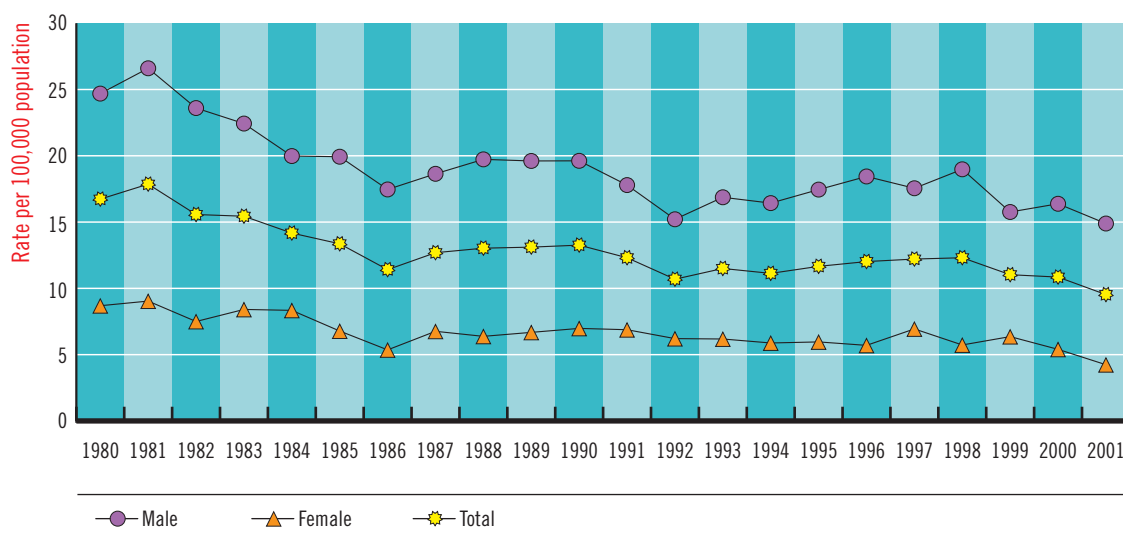


FIGURE 7

All motor vehicle accidents: mortality rate per 100,000 population by sex, 1980-2001



Injuries from road traffic accidents continue to require significant responses from our acute hospital services. Males between 18 and 24 years, who are injured in RTAs, occupy 8 per cent of all bed days

occupied by this cohort for all causes. Average length of stay in hospital is also greater in these patients than in other hospital patients.

FIGURE 8

Number of potential years of life lost due to motor vehicle accident deaths by gender, 1980-2001

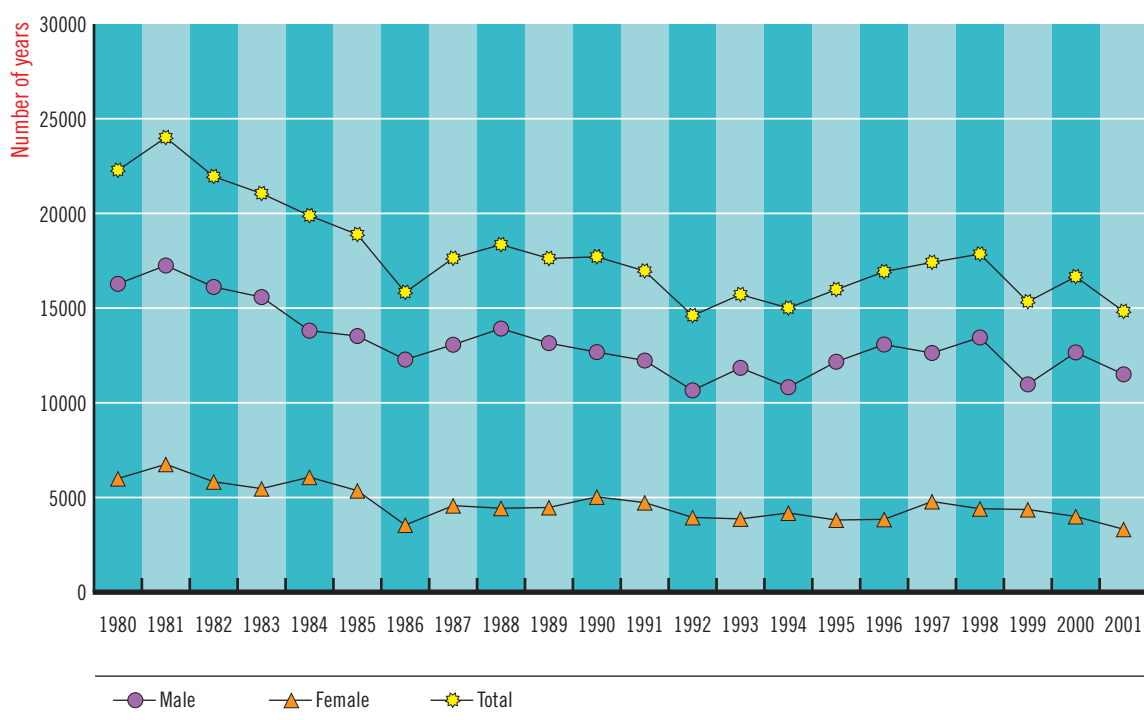


FIGURE 9

Percentage distribution of deaths among males due to motor vehicle accidents, 1980-2000

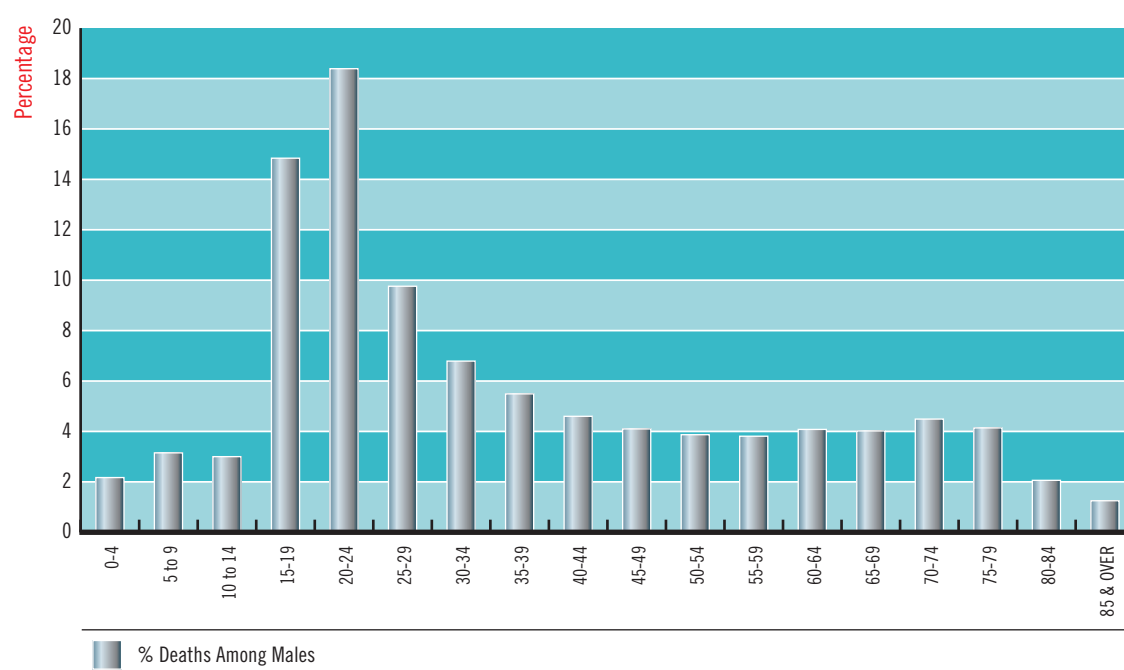


FIGURE 10

Motor vehicle accidents: Bed days as a percentage of total bed days by age and sex, 2001

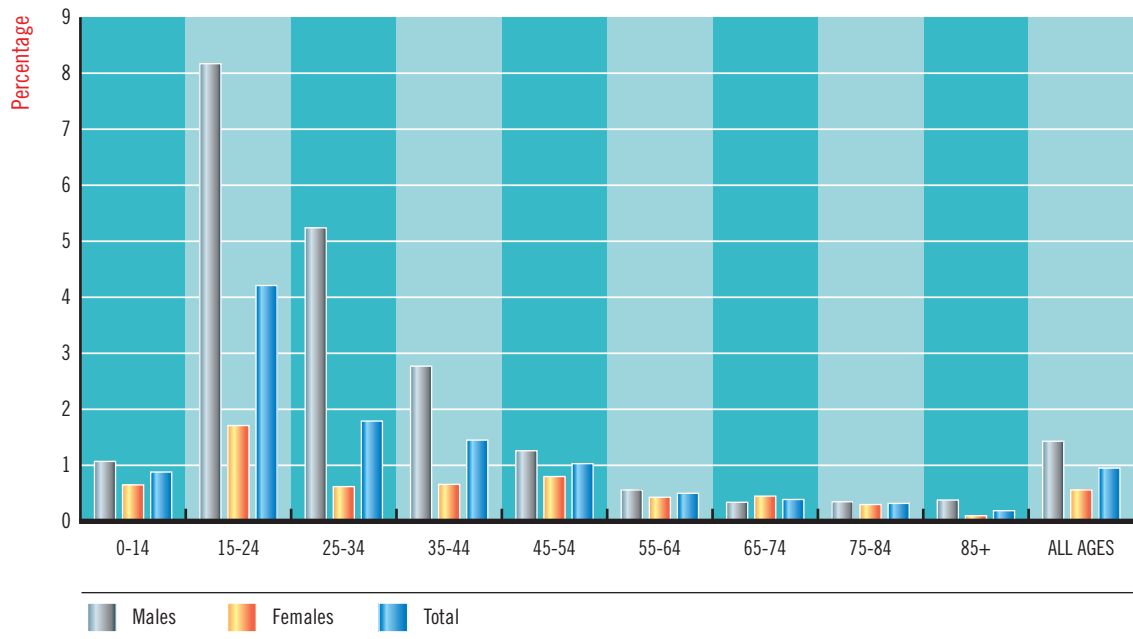
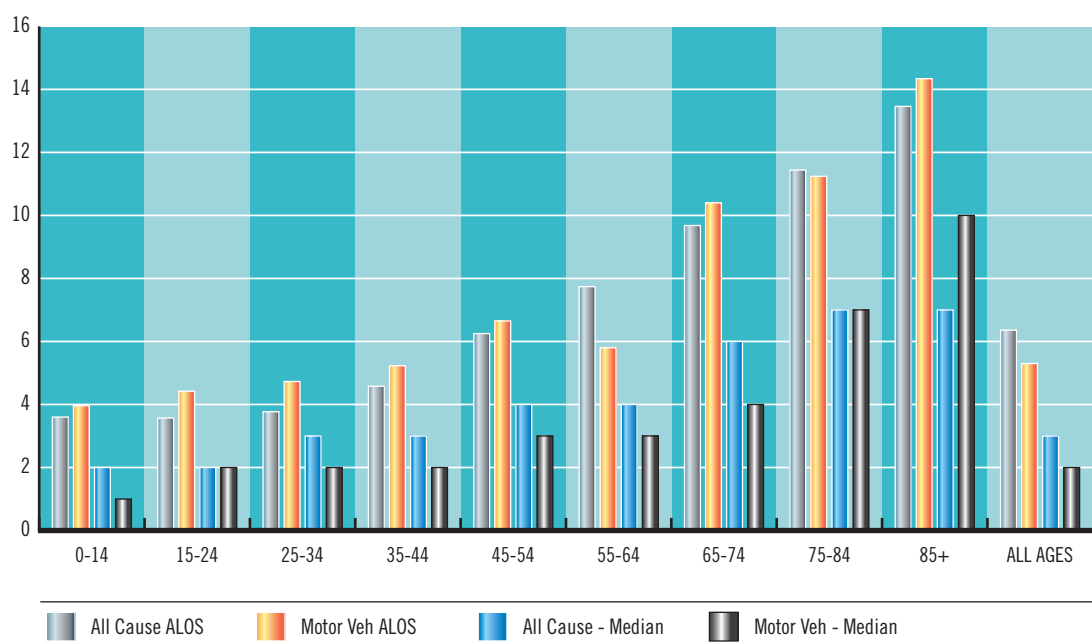
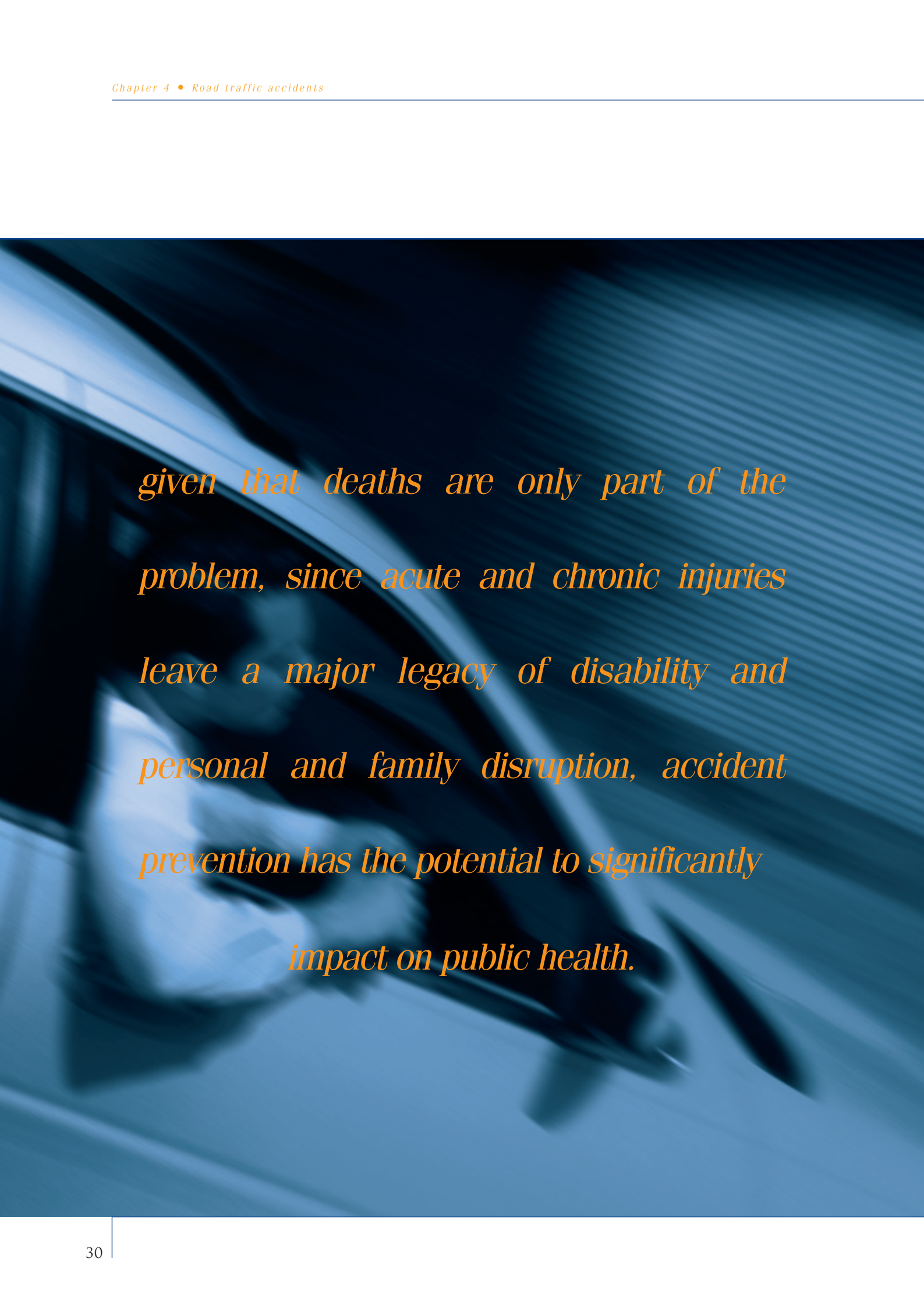


FIGURE 11

Average and median length of stay for all causes of motor vehicle accidents, 2001





given that deaths are only part of the problem, since acute and chronic injuries leave a major legacy of disability and personal and family disruption, accident prevention has the potential to significantly impact on public health.

In addition to the mortality and burden of acute injuries arising from road traffic accidents, chronic injuries and permanent disability continue to be a significant outcome for many as a result of these accidents. In recent years, the sequelae in terms of chronic brain injury has been of particular concern and research and experience have identified a whole new range of intellectual, social, employment, psychological and family problems occurring in this group of injured people, requiring service and support responses with which our system is only beginning to deal.

Factors associated with road traffic accidents

Data from the National Roads Authority identifies a number of factors associated with a significant proportion of road accidents.

These include the fact that:

- In 2000, the number of fatal accidents between the hours of 9.00pm and 3am, the hours most closely associated with drinking and driving, were 102 and resulted in 111 fatalities. This constitutes 28 per cent of fatal accidents and 27 per cent of fatalities recorded, the largest single category
- As previously mentioned, alcohol is associated with 30 per cent of all Irish road accidents and 40 per cent of all fatal accidents
- Saturdays and Sundays are the worst two days for fatalities, accounting for almost 40 per cent of the total recorded
- The contributory factors identified by the Gardai in fatal and injury accidents change little over the years. Driver error is by far the commonest contributory factor, at 82 per cent, followed by pedestrian error at 11 per cent, road factors at 4 per cent, environmental factors at 2 per cent and vehicle factors less than 1 per cent
- Single vehicle accidents have been reported in 31 per cent of fatal accidents, a phenomenon associated with two causal factors, namely excessive speed and/or alcohol.

Any measures formulated with a view to reducing the number of both road traffic accidents and fatalities, have to take particular account of the phenomenon of young men driving cars in the late night/early morning periods of the weekend, taking avoidable risks and making wrong judgements under the influence of alcohol, leading to accidents, injuries and death.

International comparisons

On the basis of road deaths of 11 per 100,000 population, Ireland ranked joint seventh out of 15 Member States of the European Union.

Discussion and recommendations

As previously mentioned, in terms of accidents and non-intentional injuries, road traffic accidents are our biggest problem. Nearly half of all child deaths are caused by motor vehicle crashes. All children are at risk as car passengers; as toddlers the risk of pedestrian accidents increases and as they get older, they become vulnerable as cyclists and later as motor cyclists. Finally, young people, particularly young men, are at highest risk of death and injury from car accidents.

The annual number of road accidents and deaths arising from them is not acceptable, given that so many of them are eminently preventable. Also, given that deaths are only part of the problem, since acute and chronic injuries leave a major legacy of disability and personal and family disruption, accident prevention has the potential to significantly impact on public health.

It is important that interventions that have been proven to work are implemented, particularly in those groups most at risk of unintentional injury. Such approaches cross all boundaries between all government departments and should become a central duty for collaborative action between relevant central government departments, local authorities, and the health system.

In the short term, however, it is essential to continue

to implement and rigorously enforce a number of measures directed at reducing death and injury on our roads.

These are as follows:

- Continue to implement the penalty points system. It is significant that, in the initial period of this initiative, both the number of deaths and the rate of admission to spinal injuries units were reduced
- Introduce random breath testing and rigorous penalties for conviction
- Reduce permissible level of blood alcohol
- Review the Road Safety Strategy to take account of developments in a number of areas since 1997.

Quality and Fairness: A Health System for You highlighted the cross-sectoral nature of the determinants of health. Given the range of variables which contribute to road traffic accidents, the importance of this approach in combating the problem is self-evident. The structures being set up under the Health Strategy will facilitate such an approach but any collaborative initiative will depend on the clear identification of the issues to be addressed. This in turn points to the necessity for developing an Injury Prevention Strategy and the outline and central elements of such a strategy will be developed in the course of 2004.

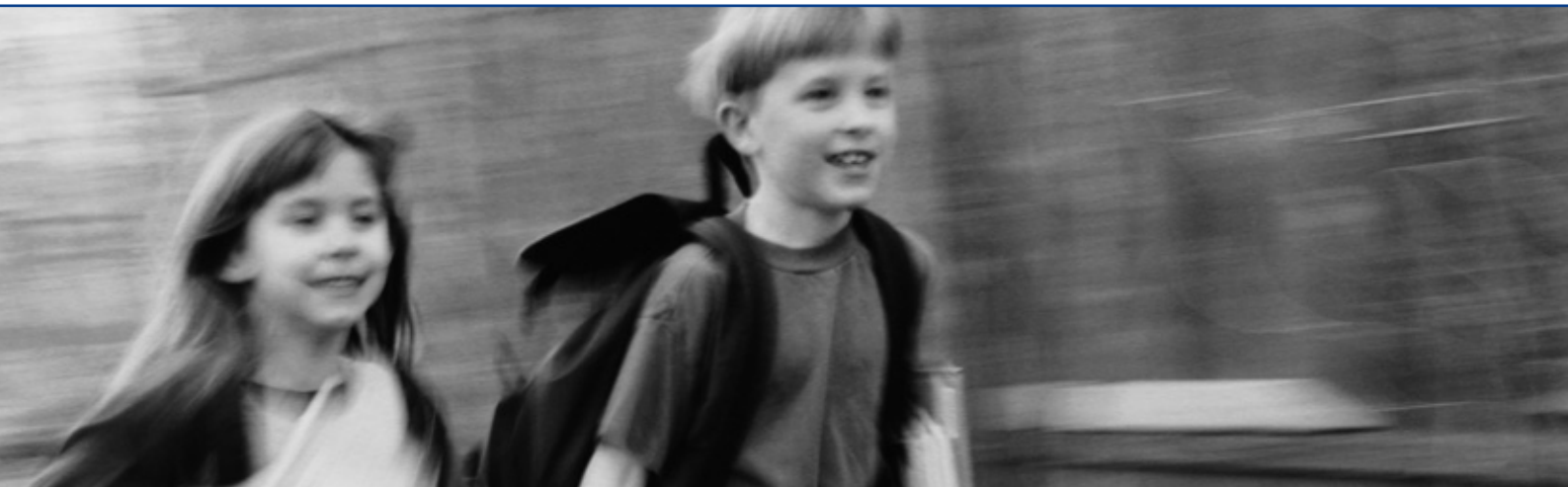
Chapter 5

Vaccination in Ireland

Several factors have contributed to the decline in communicable disease in the developed world over past decades, particularly improved economic and social conditions, the provision of safe drinking water, improved nutrition and better hygiene.

However, the importance of immunisation programmes in the reduction of vaccine-preventable disease cannot be overstated.

Vaccination in Ireland



Vaccination is one of the safest and most effective of all health-care interventions, which has contributed enormously to improved health status, particularly in children. Previous reports from the Chief Medical Officer have dealt in some detail with this important topic, and have described how the immunisation programme is constantly monitored and reviewed to ensure optimum vaccine safety and effectiveness. Recent years have seen important improvements and expansions such as the adoption of acellular pertussis vaccine into the programme, the use of polyvalent vaccines and the commencement of new vaccination programmes against diseases such as meningococcal C. However, as highlighted in earlier reports, vaccine uptake in Ireland has been suboptimal for several years. In this year's report, I am returning again to this major public health issue because of my serious concern at the ongoing low uptake of vaccination and the consequences this has for public health.

Impact of immunisation

It is difficult for us nowadays to appreciate the dramatic changes that have taken place in the incidence of communicable diseases over the past half-century and the impact this has had on our experience of life. When the Department of Health was established in 1947, high mortality from

infectious diseases was an everyday reality, with children being particularly affected. Life expectancy for Irish children and adults was considerably shorter as a result of such vaccine preventable diseases as whooping cough, diphtheria, tuberculosis, measles and polio as well as other communicable diseases including typhoid fever, scarlet fever, gastro-enteritis and pneumonia. As well as relatively high death rates, many more individuals suffered serious morbidity, some with subsequent lifelong disability from these diseases.

Several factors have contributed to the decline in communicable disease in the developed world over past decades, particularly improved economic and social conditions, the provision of safe drinking water, improved nutrition and better hygiene. However, the importance of immunisation programmes in the reduction of vaccine-preventable disease cannot be overstated. The worldwide elimination of smallpox through vaccination is one of the greatest achievements of modern medicine. Polio has already been eliminated in the European region, and global eradication of this disease is becoming an increasing possibility.

Since the introduction of a number of vaccination programmes throughout the latter half of the last century, the incidence of vaccine-preventable diseases, together with their associated complications, has greatly declined in Ireland.

Diseases such as smallpox, polio and diphtheria have been eliminated. The dramatic reduction in recent years in life-threatening meningitis caused by *Haemophilus B* influenza and Meningococcal C infection is a major public health success. Other vaccine-preventable diseases of childhood, such as pertussis, measles and mumps, although still regrettably common, have declined considerably from the very high levels seen prior to the introduction of vaccination.

The importance of vaccine uptake

The success of vaccination programmes depends critically upon achieving a high level of vaccine uptake among the target population. If there are sufficient numbers of unvaccinated individuals, outbreaks of vaccine-preventable diseases continue to occur, albeit at a lower level than if there was no vaccination. An important objective in vaccination is that of achieving high vaccination uptake or herd immunity in the general population. This prevents the spread of disease and protects the most vulnerable such as very young infants or those with long-term diseases, who may not be vaccinated, from infection.

Unfortunately, in Ireland, vaccine uptake over several years has consistently fallen below the level required for us to realise the full benefit of vaccination programmes. This problem was compounded in the past by patchy, inadequate and untimely availability of vaccine uptake information, so that monitoring of uptake and the implementation of remedial 'catch-up' measures in areas with particularly poor uptake have been difficult. Although the timeliness and availability of information has improved considerably in recent years, there are several ways in which it could be further enhanced.

The report of the National Review of the Immunisation/Vaccination Programme, undertaken by the health boards and published in 2002, made recommendations under a number of headings to improve the quality, effectiveness and efficiency of the programme, including programme organisation, communications, and information system developments. Implementation of these recommendations is a priority of the Department of

Health and Children and the health boards. Significant progress has been made and work in this area is continuing under the auspices of the Health Boards Executive. However, the achievement of target uptake rates for all vaccines in the programme, particularly the measles, mumps and rubella (MMR) vaccine, is an ongoing challenge.

An unfortunate consequence of the success of vaccination programmes is that as vaccine-preventable diseases become increasingly uncommon, public and professional perception of their seriousness declines. The occurrence of vaccine-preventable diseases in childhood is then considered to be a 'normal' part of development and the serious morbidity and mortality which can occur in a small minority of children, particularly those who are most vulnerable, is not appreciated. In contrast to developing countries where vaccine-preventable diseases continue to constitute a major public health burden – for example, over 1 million children worldwide die from measles each year – in countries such as Ireland, parents, families and health professionals are often unfamiliar with these diseases and their complications. As a result of this complacency, concerns about possible side-effects of vaccines can outweigh the perceived benefits of vaccination in the public mind and vaccination uptake levels may suffer.

Vaccine safety concerns and MMR

Experience in Ireland and elsewhere has shown that vaccine uptake rates are greatly influenced by the reporting of 'scares' about vaccine safety in the public media. This has been especially evident in recent years in the case of the MMR vaccine. Although uptake of all vaccines in the primary immunisation programme has been below target in the past several years, the performance in respect of MMR has been particularly poor. A report was published in the *Lancet* in 1998, postulating a possible link between MMR vaccine and autism. This report was widely criticised and its findings have been consistently refuted by other studies and emphatically rejected by all recognised national and international medical vaccination authorities in the intervening years. As recently as October 2003 one

A close-up photograph of a young child with curly hair, smiling broadly and showing their teeth. The child is wearing a dark vest with white polka dots over a light-colored shirt with a small pattern. Their hands are clasped together in front of them. The background is a solid, muted brown color.

In 2000, when more than 1,500 cases of measles were reported in Ireland, the United States reported only 86 cases during the same period despite having a population 77 times larger

FIGURE 12

MMR % uptake rates, Ireland and Northern Ireland, 2000-2003



Source: National Disease Surveillance Centre, Communicable Disease Surveillance Centre, Northern Ireland

of the authors of the original report, writing again to the Lancet, has stated that *no other vaccine has been studied in such depth and the evidence for its overall safety is overwhelmingly consistent and comprehensive ... there is now unequivocal evidence that MMR is not a risk factor for autism*. Despite the overwhelming weight of evidence on one side of the argument, there has been ongoing presentation of this in some parts of the media as a situation of scientific uncertainty and genuine debate between experts.

This led in past years to considerable public anxiety and a drop in MMR uptake. The target uptake for MMR vaccination to prevent the spread of measles is 95 per cent. During the period when coverage of this scare in the media was most intense, MMR uptake rates fell to well below 80 per cent nationally and to less than 70 per cent in some areas, with inevitable consequences.

In January 2000, a measles epidemic arose in North Dublin and spread to other areas. This epidemic resulted in more than 1,500 cases, several hundred hospitalisations including admissions to intensive care, and three measles-related deaths. It is perhaps not appreciated by the public generally how unusual Ireland is in this respect. In fact, Ireland is a 'world leader' among developed countries for its high

incidence of measles infections, which is completely unacceptable. In 2000, when more than 1,500 cases of measles were reported in Ireland, the United States reported only 86 cases during the same period despite having a population 77 times larger.

Of course, reduced MMR coverage also increases the risk of mumps and rubella infections, with a particular concern that increased rubella infections in the population could affect child-bearing women and cause a recurrence of disabling congenital rubella infections, which are fortunately now very rare.

Reports from the National Disease Surveillance Centre (NDSC) indicate that MMR uptake at age 24 months has shown a slight upward trend throughout 2002 and into the first quarter of 2003 and it is to be hoped that this will be sustained (see Figure 12). However, the national average MMR uptake for this age group in the first quarter of 2003 at just 77 per cent remains considerably short of the target of 95 per cent and, as Figure 12 demonstrates, average uptake for the MMR vaccine in this state compares unfavourably with the uptake levels achieved in Northern Ireland over the past three years. Given our poor uptake rates, it is unfortunately not surprising that well over 500 clinical cases of measles have been notified in 2003 to date.

Lessons from the MMR experience

The World Health Organisation has set a target for the elimination of measles in Europe by 2007. Based on our current situation, considerable additional efforts will be necessary in order to achieve this in Ireland. These will include the institution of enhanced measles surveillance, vigorous outbreak response measures and follow up of reported cases. However, unless MMR uptake is dramatically increased, elimination will be virtually impossible to achieve.

The challenge for the health system is to find new ways of ensuring maximal vaccine uptake. This will require action at several levels: health professionals have to be educated and motivated to recognise the essential advocacy role they have in informing parents and promoting uptake, and sustained improvements in information systems, infrastructure and work practices are needed to facilitate monitoring and targeting of resources to where they are most required. Perhaps most importantly, it has to be accepted that the health system in recent years has not adequately communicated the important health benefits of vaccination and it has failed to respond effectively to the dissemination of incorrect and misleading information from other sources.

Health commentators in the media have a professional responsibility to provide the public with balanced, well-informed commentary about important health issues and to recognise the great potential for harm of ill-researched, sensationalist reporting. Notwithstanding this, however, the health system also has a duty to respond more effectively to the publication of spurious media 'scares' which impact negatively on important public health programmes. New ways of achieving communication with parents, the media and the general public have to be sought.

Chapter 6

Folic acid and the fortification of foods

Approximately half of pregnancies are unplanned which means that public education can have only a limited effect. While there is general awareness of the benefits of folic acid supplementation among women,

the majority of women are not taking folic acid supplementation at the time of conception.

Folic acid and the fortification of foods



Folate describes a group of vitamins including folic acid which is used as a nutritional supplement either alone or as part of a multivitamin preparation. It has been recognised for some time that folic acid, taken before conception and during early pregnancy, is associated with a significant reduction in the incidence of neural tube defects (NTDs) in infancy. Many countries, including Ireland, recommend that women likely to become pregnant should take folic acid supplementation prior to conception and during the first three months of pregnancy. While this policy has contributed to a reduction in the incidence of NTDs in recent years, there are significant numbers of women in the target group who do not receive folic acid supplementation, despite public information campaigns.

This has prompted debate on the need for additional strategies to ensure more comprehensive prevention of NTDs.

Since 1998, public health policy in the US and Canada has led to the fortification of cereal with folic acid. This resulted in a 19 per cent reduction in NTD birth prevalence in the two years following its implementation. Such a policy was not followed in other countries. In the UK, despite a detailed report by the Committee on Medical Aspects of Food and Nutrition Policy (COMA), which recommended universal folic acid fortification of flour, the Food Standards Agency declined by majority decision to

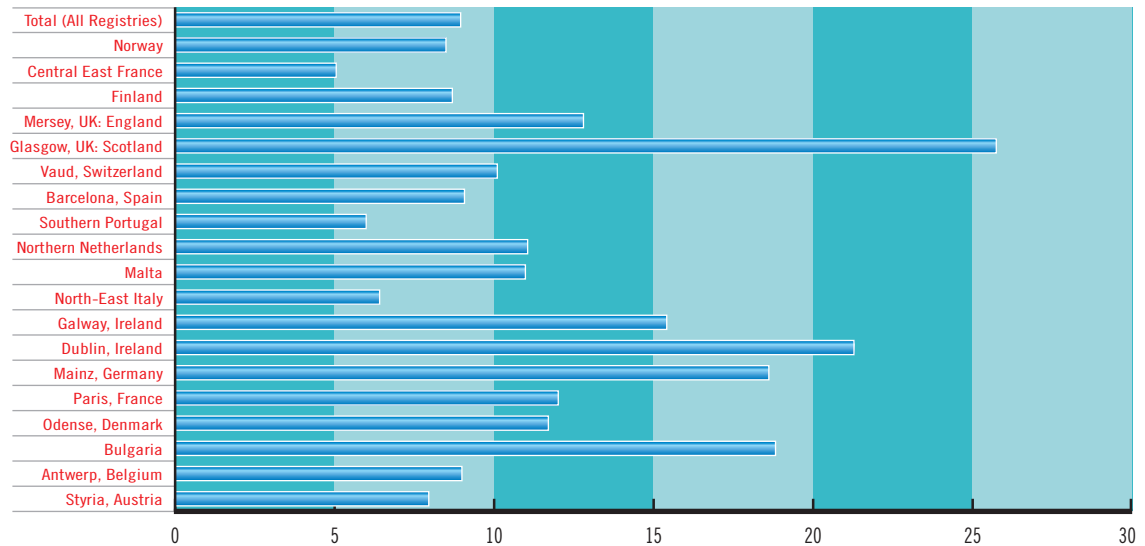
recommend mandatory fortification of flour for the UK population.

The decision was made on the basis that the risks were considered sufficient to warrant further review of emerging international evidence. This has generated considerable debate in Ireland and other countries on the risks and benefits of fortification of staple foods with folic acid. In 2003, the Food Safety Authority of Ireland (FSAI) published a report which recommended the universal fortification of flour with folic acid at 200µg per 100g in food products. This included a detailed risk/benefit analysis of mandatory fortification of flour where the effects of flour fortification with folic acid on intakes of different groups in the population was estimated. Based on this analysis and other international studies, the key issues to be addressed are:

- The need to fortify wheat flour with folic acid
- If fortification is considered desirable, whether this is on a voluntary or mandatory basis and what are the next steps
- What should be put in place to minimise the risks.

This chapter will address these key issues and make recommendations for further action.

FIGURE 13
Neural tube defects



Source: EUROCAT Registries, 1980-2000

NTD in Ireland

Neural tube defects are congenital malformations of the central nervous system. The resulting spectrum of disability ranges from anencephaly to minor forms of spina bifida. Most of the children affected have either moderate or severe handicap. Compared to other European countries, Ireland has a high incidence of NTD (Figure 13). It is encouraging, however, that the incidence of NTD in Ireland has reduced in recent years.

Folic acid and NTD

The relationship between folate intake and the risk of NTD has been established for many years. Early observational studies pointed to the link between maternal folate blood levels and the risk of NTD. This was followed by intervention studies and, in 1991, the Medical Research Council (MRC) vitamin trial in the UK demonstrated a significant reduction in the recurrence of NTD by supplementing daily diet with 4mg of folic acid in women at high risk. Later research indicated that the first occurrence of

NTD could also be prevented by daily supplements containing 800µg of folic acid. Further studies including Irish research indicated that women taking daily supplements of 400µg sufficiently increased blood levels of folate that were associated with a low incidence of NTD.

Overall, approximately two-thirds of NTD-affected pregnancies are associated with folic acid and can be prevented. The cause of the remaining third of NTDs are not clear but probably include genetic and other environmental factors. The implications for public health policy are that, even with folic acid fortification, NTDs would still occur; however, these would be at significantly lower levels.

In the early 1990s, Ireland was among the first European countries that issued guidelines on folic acid supplementation for women planning a pregnancy. All women likely to become pregnant were recommended to take an extra 400µg of folic acid prior to conception and during the first 12 weeks of pregnancy. In Ireland, as in many other countries, the experience with public information campaigns has been varied. Approximately half of pregnancies are unplanned which means that public

education can have only a limited effect. While there is general awareness of the benefits of folic acid supplementation among women, the majority of women are not taking folic acid supplementation at the time of conception. By the time a woman realises she is pregnant, it is usually too late to prevent an NTD by taking supplements. This raises the question of what is the most effective way of reducing the incidence of NTD, in particular the fortification of the food supply with folic acid so that even women with unplanned pregnancies can have a greater chance of preventing NTD.

Other potential benefits

It is known for some time that individuals with raised blood levels of homocysteine are at greater risk of cardiovascular disease including stroke and heart attacks. Research has also indicated an association between low intake of folate and raised plasma homocysteine in the general population and that increasing folate intake can reduce plasma homocysteine. Cardiovascular disease is a leading cause of morbidity and mortality in Ireland which gives rise to the potential for reducing this risk by increasing dietary folate. The difficulty, however, is that this research requires confirmation by intervention studies and randomised trials. Folate status has also been associated with neuropsychiatric disorders such as dementia and Alzheimer's disease and the development of certain cancers. Again, however, further research is required to confirm that increasing the level of folate will sufficiently reduce the development of these conditions.

Safety and folic acid

Folic acid is generally considered safe for medicinal use even up to doses of 10-20mg per day. At higher levels, it may interfere with certain anti-inflammatory drugs and medication for epilepsy.

The main concern, however, is its relationship with vitamin B12. B12 deficiency causes anaemia similar to that caused by folate deficiency and, in the longer term, causes damage to the nerves and spinal cord,

leading to significant disability. The anaemia appears first, allowing for early detection of vitamin B12 deficiency before nerve damage occurs. This is important because if folic acid supplementation is raised in excess of 1mg per day, it can delay or prevent anaemia caused by vitamin B12 deficiency. This masks the diagnosis of B12 deficiency but does not prevent the nerve damage which may become irreversible once it is progressed beyond a certain stage. The condition generally affects older people because of their inability to absorb vitamin B12 and other groups such as vegans who do not eat foods of animal origin.

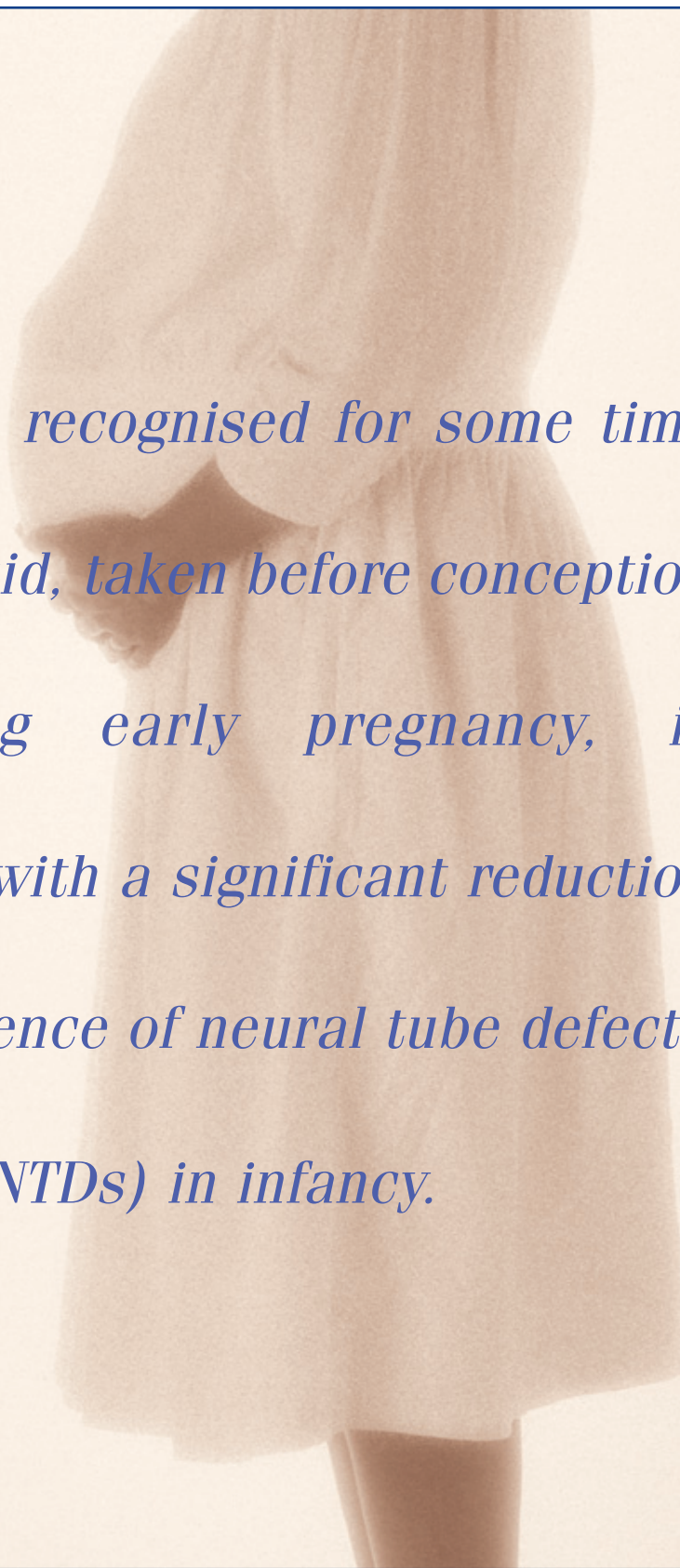
The frequency of vitamin B12 deficiency in the population is estimated to be of the order of 3-4 per cent in 65-74 year olds and 5 per cent among those aged 75 years or older. These figures are estimates because B12 deficiency often goes undiagnosed in older people.

The level at which excessive folic acid intake is judged unlikely to present adverse health threats is called the tolerable upper intake level (UL). In adults, the UL is set at 1mg per day. This value is derived from a lowest observed adverse effect level (LOAEL) of 5mg per day for masking the anaemia and possible longer term neurological effects. The UK uses a 5-fold safety factor to take account of variation within the population. This margin of safety is considered sufficient by the Food Safety Authority in Ireland, the EU and the US.

Risk benefit analysis

The Food Safety Authority of Ireland (FSAI) recently completed a risk benefit analysis of fortification of flour in Ireland. As with similar approaches in the UK and elsewhere, the analysis relied on certain assumptions because specific information was not available.

Dietary intake data from the North/South of Ireland food consumption survey indicated that average daily intake of folate in women of reproductive years was 270µg, which is below that recommended to reduce NTD. An extra 400µg of folic acid would increase total folate intake to over 600µg and reduce the incidence of NTDs substantially. The analysis

A woman in a white dress is holding a baby, with the text overlaid on the image.

It has been recognised for some time that folic acid, taken before conception and during early pregnancy, is associated with a significant reduction in the incidence of neural tube defects (NTDs) in infancy.

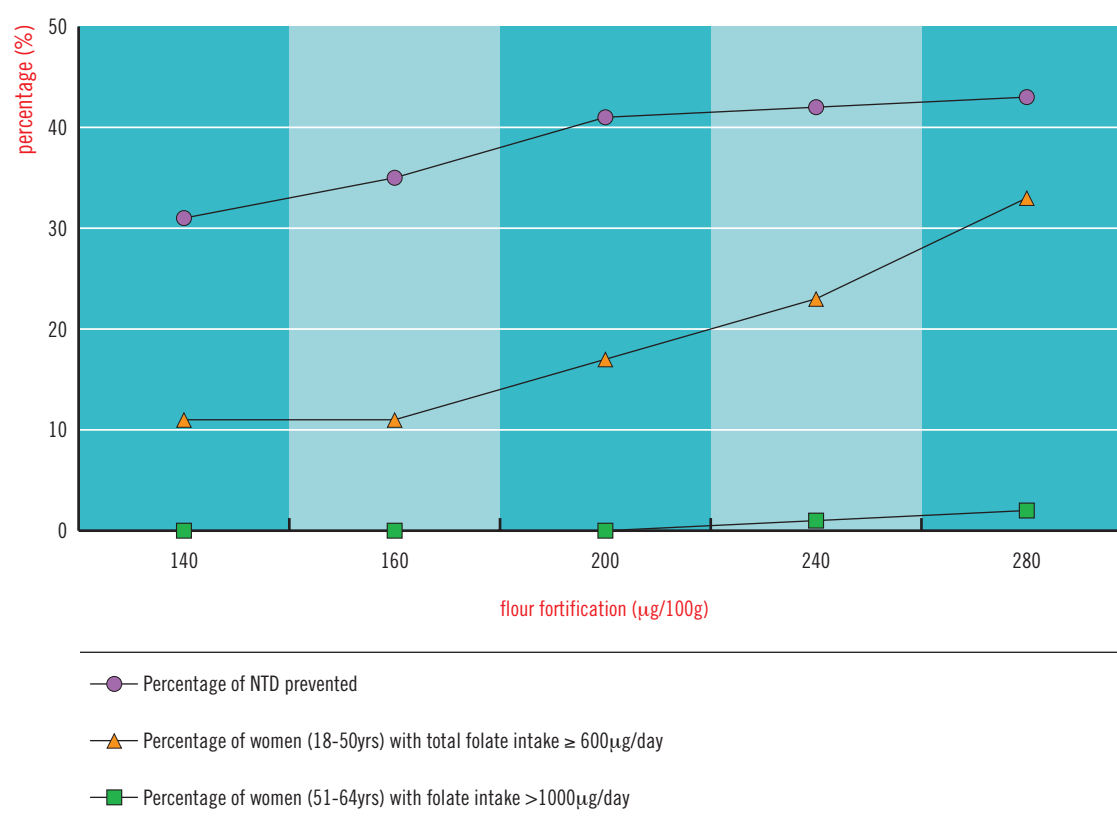
examined 5 levels of fortification of wheat flour as consumed in finished products, namely 140, 160, 200, 240 and 280µg per 100g. At each fortification level, an estimation was made of the proportion of NTD births each year which would be prevented, as well as the percentage of people over 50 years who would be exposed to a folic acid intake greater than the UL. The analysis made certain assumptions including the following:

- That all wheat flour is fortified
- That there was no change in the folic acid intake from other dietary sources on food consumption patterns in adults older than 65 years
- On the true prevalence of vitamin B12 deficiency

- On the flour content of certain food products
- The robustness of the model detailing relationships between folate intake, red cell folate in women and the relationship with NTD.

Figure 14 illustrates the effects over a range of fortification levels. Average daily intake of folic acid in women aged 18-50 years increases by 146-291µg per day. This in turn increases average total folate intake to between 414-559µg per day. The proportion of women achieving a total folate intake of greater than 600µg per day would increase from 4 per cent to 33 per cent. The estimated proportion of NTD births that could be prevented by fortification ranged from 31-44 per cent. On the risks side of the equation, the probability of exceeding the UL for

FIGURE 14
FSAI risk-benefit analysis of flour fortification



Source: FSAI

folic acid in older adults was very low, only reaching 0.8 per cent at 240µg and 1.6 per cent at 280µg per 100g flour. At fortification levels where excess folic acid intake occurred, this was much closer to the UL of 1mg per day than the LOAEL of 5mg per day.

The risk of an adverse event relates to:

- The prevalence of undiagnosed vitamin B12 deficiency
- The consumption of excessive folic acid.

The analysis assumes that B12 deficiency is in the order of 5 per cent among those aged 75 years and older. In this age group, the model estimates that the proportion of adults who would exceed the UL and also have undiagnosed vitamin B12 deficiency would be 0, 0, 0.02, 0.04 and 0.08 at the increasing fortification levels. The respective figures for adults aged 65-74 years (where the prevalence of undiagnosed B12 deficiency is assumed to be 4 per cent) are 0, 0, 0.016, 0.032 and 0.064 per cent respectively.

Implications of FSAI analysis

The FSAI report indicates that current average folate intake in women of reproductive years is substantially below that recommended to minimise the risk of NTD. The proportion of women aged 18-50 years achieving a dietary intake of total folate of >0.6mg per day would increase from the current 4 per cent to between 11-33 per cent, depending on the fortification level. In turn, this would prevent between 31-44 per cent of NTD-affected births, depending on the fortification level. As can be seen in Figure 14, the benefits increase with increasing fortification level up to 200µg per 100g flour, resulting in a 41 per cent reduction in risk of NTD. There is little further increase in benefit at fortification levels above this. On the negative side, the risk of adverse events is generally low and only apparent at fortification levels of 200µg per 100g flour or greater. On the basis of this risk benefit model, the FSAI has recommended the universal fortification of flour with folic acid at 200µg per 100g in food products as consumed.

The FSAI methodology is similar to the approach followed in the UK. The analysis quantifies the benefits and also the risks relating to fortification of flour at different levels. Not all of the potential benefits have been quantified. For example, the impact of lowering homocysteine in the adult population and, in addition, the actual risk of adverse events in older adults is likely to be significantly lower than the model suggests because the predicted excess of folic acid intake is much closer to the UL than the LOAEL, the latter considered to be the level at which risk becomes apparent.

Implications of fortification of foods with folic acid

Many foods are already fortified by the addition of nutrients including calcium, iron, thiamin, and niacin. Most breakfast cereals and some breads are fortified on a voluntary basis with folic acid by the food industry. Flour has been recommended as the appropriate food to fortify with folic acid on account of its widespread consumption by the target population. There are, however, a number of issues that require consideration prior to the introduction of folic acid fortification of flour. These include the technical aspects of adding folic acid to flour and the putting in place of a system to measure the effectiveness and safety of the fortified flour products. There are likely to be legal issues relating to a mandatory flour fortification policy. Approximately 40 per cent of wheat flour used in Ireland is imported and the introduction of a mandatory policy could be perceived as a 'barrier to trade'. The views of the European Commission would be relevant here as is current EU legislation with regard to labelling implications.

Conclusion

The FSAI study provides a comprehensive risk benefit analysis of fortification of flour in Ireland. This approach has been used to similar effect in other jurisdictions. In an analysis of this nature, certain assumptions are made because not all of the

information is available. These assumptions, however, appear reasonable and the scientific model used in the analysis is considered to be appropriate.

The analysis recommended fortification of flour with folic acid at a level of 200µg per 100g in food products as consumed. The FSAI analysis is considered to be robust and the level (200µg per 100g) of folic acid fortification of flour is optimal as it would significantly reduce NTDs while maintaining risks at a very low level (fortification at this level would mask the anaemia caused by vitamin B12 deficiency in approximately 0.02 per cent of adults under 65 years of age).

While the incidence of NTD in Ireland has reduced in recent years, it nevertheless remains high compared to other developed countries. It is noteworthy that there is not international consensus on the need for fortification. Some countries, namely the USA and Canada, have implemented this policy while others, for example the UK and Norway, have not. This may be explained by the differing levels of benefit and risk that apply in these jurisdictions.

The analysis indicates that there would be considerable benefits in implementing this policy, e.g. reducing the incidence of NTD by 41 per cent. At the same time, however, every effort should be made to minimise the potential risks. In particular, a system for the early detection and treatment of vitamin B12 deficiency in the elderly population should be implemented. It is also noteworthy that the FSAI model only considered the benefits of NTD reduction and that there may be other benefits such as reducing the incidence of cardiovascular disease; however, further research is needed to confirm this.

Implementing a policy of fortification of flour would require intersectoral action and the FSAI report highlighted a number of issues, e.g. trade, legal, technical, etc, that require further consideration. The case for fortification of flour is now considered sufficiently robust to recommend moving to the next stage, namely a consultative process to deal with the technical and other aspects of implementing this policy.

Summary



Various definitions of health which have emanated from such sources as the World Health Organisation and other institutions in recent years have stressed the notion that health is a human and social resource to be protected and developed so as to enable people to attain their maximum physical and mental capacity. The question that society must pose and answer is how best to use its political, social, intellectual and economic resources so as to make the greatest impact on health. In the main, however, the public debate on health issues revolves around that of acute services or, in fact, how the use of such services can be systematically managed to get the best value for the resources available.

It is interesting to note that on the one recent occasion in which major public debate has focused on an issue of health protection rather than health service provision, i.e. the proposal to protect workers from the ravages of environmental tobacco smoke (ETS), much of the debate has revolved around how best to oppose the measure and to subvert its well-documented positive health effects, all in the interests of commercial and other advantage.

Successive reports from this office have sought to focus the debate on issues of health rather than health services and have drawn attention particularly to inequalities in health, the state of our

children's health and the role of the population health concept in promoting the first national goal of the health strategy, that of better health for everybody.

The matters discussed of this year's report are very much in line with this perspective. Smoking prevention, folic acid supplementation, reducing alcohol consumption, reducing road accidents and improving vaccination uptake are classical public health interventions which are based on sound evidence, are of proven effectiveness in reducing the burden of ill health and death in our community and, therefore, can contribute significantly to improving population health.

