

Alcohol Guidelines Review – Report from the Guidelines development group to the UK Chief Medical Officers

(published January 2016 with the consultation on the language and understanding of the UK Chief Medical Officers low-risk alcohol guidelines)



Executive Summary

Health evidence expert group and behavioural expert group, 2013-14

1. In late 2012 the UK Chief Medical Officers commissioned two expert groups to consider whether previous alcohol guidelines should be updated. Both expert groups worked through 2013 and reported to the UK CMOs in February 2014.

2. The **Health evidence expert group** examined the evidence¹ from 44 systematic reviews and meta-analyses published since the 1995 *Sensible drinking* report², and consulted experts recently involved in the updating of the Australian and Canadian alcohol guidelines.

3. The group concluded³ that there is significant new, good quality evidence available on the effects of alcohol consumption on health, which was not available at the time of the 1995 review. This applies for both men and women. In particular, stronger evidence has emerged that the risk of a range of cancers, especially breast cancer, increases directly in line with consumption of any amount of alcohol.

4. Meta-analyses have identified that for some conditions, notably ischaemic heart disease (IHD), drinking alcohol at low levels may have a protective effect (compared to not drinking), particularly for all-cause mortality. However, the group noted that:

- any potential protective effect seems mainly relevant to older age groups;
- unresolved confounding and health selection (for instance, the health of people who can afford to drink more in older age may be better than those who do not) may explain a substantial part of the protection observed;
- mortality from IHD is continuing to decrease substantially; and
- the peak of any protective effect is achieved at very low levels of consumption (around one unit a day).

5. The group therefore concluded that the evidence supporting protective effects today is now weaker than it was at the time of the 1995 report and that there are substantial uncertainties around direct attribution to alcohol of the level of protection still observed. Taking this into account alongside all the known acute and chronic risks to health from drinking even at low levels, supports the conclusion of the group that there is no justification for recommending drinking on health grounds, nor for starting drinking for health reasons.

6. For alcohol consumption in pregnancy, more recent systematic review evidence concludes that the risks of low birth weight, preterm birth, and being small for gestational age all may increase above consumption of 1-2 units/day. Overall consideration of the evidence published since the NICE review in 2008 supports precautionary guidance that it is safest to avoid drinking in pregnancy.

¹ CMO Alcohol Guidelines Review – A summary of the evidence of the health and social impacts of alcohol consumption; CMO Alcohol Guidelines Review – Mapping systematic review level evidence; both reviews were written by the Centre for Public Health, Liverpool John Moores University

² Department of Health (1995) Sensible drinking: Report of an inter-departmental working group

³ CMO's Review of Alcohol Guidelines: Conclusions of the Health Evidence Expert Group

7. For alcohol consumption by young people under 18, the group found very little new evidence had been published since guidance was published by the English CMO in 2009 and subsequently by the other countries' CMOs.

8. The **Behavioural expert group** found little evidence⁴ regarding the impact of any guidelines in changing health behaviours. It concluded⁵ that there are, however, some general principles both from evidence reviews in the field of public health and from other fields (social marketing, goal setting, behavioural psychology etc.) that could be used to maximise understanding and acceptance, if the UK does introduce new guidelines based on new evidence. Based on these, the group recommended that:

- the justification for any guidelines should be clearly spelt out and they should be:
 - simple,
 - specific,
 - measurable,
 - timebound; and
 - realistic

9. Neither of the expert groups felt there was adequate justification for having separate guidelines for different age or social groups.

Guidelines development group, 2014-2015

10. In early 2014, the CMOs asked members from the two previous groups to combine, to advise on the most appropriate methodological approach to developing guidelines (in particular comparing the Australian and Canadian approaches used to develop their recent guidelines), and to advise on appropriate guidelines.

11. Terms of reference for the Guidelines development group are at <u>Annex A</u>.

12. The group considered carefully its approach and the evidence for advice to the public on the health risks from drinking. It based its advice on the following principles:

- People have a right to accurate information and clear advice about alcohol and its health risks, and
- There is a responsibility on Government to ensure this information is provided for citizens in an open way, so that they can make informed choices.

13. As the Guidelines development group, we feel that throughout the dissemination of the guidelines it is critical this is seen as a process to inform individuals so that they can take informed decisions about their own drinking.

14. Australia used an absolute risk approach whereby the guidelines were set at a point above which individuals would experience a 1% lifetime risk of dying due to alcohol.⁶ Canada used a relative risk approach which set the guidelines at a point at which alcohol harms and benefits were balanced, in terms of the numbers of deaths caused and prevented.

15. The Guidelines development group requested Public Health England to put out a public call for tenders to:

⁴ CMO Alcohol Guidelines Review – A summary of the evidence on understanding and response to public health guidelines, Centre for Public Health, Liverpool John Moores University

⁵ CMO Alcohol Guidelines Review: Report from the Behavioural Expert Group

⁶ Currently the average lifetime risk of dying from an alcohol-related cause in the UK is about 4%

- 4 Alcohol Guidelines Review Report from the Guidelines Development Group to the UK Chief Medical Officers (published January 2016 with the consultation on the language and understanding of the UK Chief Medical Officers low-risk alcohol guidelines)
- i. provide quantified risk estimates for the mortality and morbidity (the latter defined as person-specific hospital admissions) associated with different levels and patterns of alcohol consumption for drinkers in the UK; and
- ii. report on the guideline thresholds that would be derived from applying approaches similar to those used in Canada and Australia to UK mortality and morbidity risk estimates.

16. Sheffield University was awarded the tender for this work, and used the Sheffield Alcohol Policy Model as the basis for its report.⁷

17. The Guidelines development group also consulted additional experts (see list of contributors at <u>Annex B</u>); and were briefed about recent findings from focus group research, which explored public understanding of the current guidelines. Research with the public commissioned by Public Health England explored their response to the draft guidelines below.

18. The Guidelines development group recommends that women who are pregnant or planning a pregnancy should be advised that **the safest approach is not to drink alcohol at all**. There is no scientific basis for setting a limit below which alcohol consumption will not harm the fetus. There is evidence that the second part of the current English guidelines (*If they (pregnant women) do choose to drink, to minimise the risk to the baby, they should not drink more than one to two units of alcohol once or twice a week and should not get drunk*) can be seen as either having equal weight with or being inconsistent with the first part (*Pregnant women or women trying to conceive should avoid drinking alcohol*), and there is no clear scientific evidence to support a quantified limit for drinking in pregnancy such as that in the second part of the current advice.

19. This guidance is precautionary. It will be important to inform women that the risk of harm to the baby is likely to be low if they have drunk only small amounts of alcohol before being aware of a pregnancy. Nevertheless, we cannot rule out the risks altogether.

20. Harmonising the pregnancy guidelines across the UK, and making them consistent with those of other jurisdictions, would be helpful in delivering a clear and scientifically credible message.

21. The Guidelines development group recommends a new weekly guideline for regular drinking, and, in addition, new guidance in the form of narrative advice on reducing the short-term risks from single occasion drinking. The guideline for weekly consumption is designed to reduce both the risk of deaths from regular drinking and the chronic, long term health harms that alcohol causes. This recommendation for a low risk level is the same for men and women. The new advice concerning single occasion drinking is designed to enable individuals to reduce their risks of acute, short-term harms from drinking.

22. There is evidence that there is currently some confusion about weekly and daily guidelines. Health Survey for England data (2011) suggest that most people who drink do so infrequently, with the majority of the population drinking on no more than 2 days per week. The current guidelines of 'regularly no more than 3 to 4 units per day for men and 2 to 3 for women' can be seen as inappropriate (and therefore largely ignored) by those who only drink, for example on Fridays and Saturdays or on special occasions. The formulation of 3 to 4 and 2 to 3 can also be seen as confusing and potentially suggesting an optimum range rather than a limit for regular drinking.

23. The Sheffield model, which included a number of sensitivity analyses and estimates based on numbers of days drinking a week, shows that roughly similar conclusions can

⁷ Mortality and morbidity risks from alcohol consumption in the UK: Analyses using the Sheffield Alcohol Policy Model (v.2.7) to inform the UK Chief Medical Officers' review of the UK lower risk drinking guidelines

be reached from using the Canadian relative risk approach and an absolute risk approach adapted from that used in Australia.

24. As well as taking account of the point at which the risk of death from alcohol outweighs any potential health benefits, the group's report also took account of research showing levels of drinking where alcohol would be expected to cause an overall⁸ 1% lifetime risk of death in setting the proposed guideline on regular drinking. The guideline is at a level around or a little below this 1% risk.

25. Hence, the Guidelines development group recommend that for men and women who drink regularly or frequently i.e. most weeks, the guideline should be that 'you are safest not to drink regularly more than 14 units of alcohol per week'.

26. The group's view is that, the weekly guideline on regular drinking also requires an additional recommendation, concerning the need to avoid harmful regular heavy drinking episodes, as there is clear evidence that such a pattern of drinking increases risk to health. Hence, we also recommend that it is best, if you do drink as much as 14 units per week, to spread this evenly over 3 days or more. If you have one or two heavy drinking sessions, you increase your risks of death from long term illnesses and from accidents and injuries.

27. In the group's judgement, there are strong arguments on scientific grounds related to the extensive health harms caused by alcohol (discussed more fully in the report) why a guideline for a low risk level of drinking in the UK should be recommended not to be higher than 14 units weekly for both women and men. The advice takes account of a likely previous overestimation and substantial uncertainties in the current estimate of protective effects directly attributable to drinking, as well as the greater evidence available on risks of heart disease, liver disease and certain cancers. The specific selection of 14 units is based on:

- careful consideration of the results of the scientific modelling,
- the detailed analysis of risks to the UK population from drinking,
- consideration of what is likely to be acceptable to be considered low risk, and
- the need to have a clear, understandable and specific message.

28. The recommendation not to exceed 14 units is both pragmatic and evidence-based.

29. The Guidelines development group recommends that the CMOs should give advice on short term health risks of alcohol related to any single drinking occasion:

- there are short term health risks, such as accidents and injuries, (and death caused by accidents or injuries) for anyone drinking to levels that cause intoxication.
- these risks can arise for people drinking within the weekly guidelines for regular drinking, if they drink too much or too quickly on a single occasion – and for people who drink at higher levels, whether regularly or infrequently.
- the advice should cover the nature of the risks relating to accident and injury and actions people can take to reduce the risks of injury and accident, in addition to limiting their drinking.

⁸ Unlike the absolute risk method used in Australia, the method used in the Sheffield model does take account of deaths prevented, e.g. from ischaemic heart disease. So the 1% lifetime risk of death is a 'net' risk for the population taking account of both deaths incurred and prevented.

30. The group does not recommend providing an additional guideline level for low risk drinking on any one occasion – in recognition of the individual variation of short term risks and the ability to reduce risks by other means.

31. The modelling shows that although the risks of alcohol consumption vary between men and women, between different types of consumption and harm, and between different age groups, there is good evidence to justify recommending a single low risk threshold for men and women. But there is insufficient consistent evidence relating to age to be able to recommend different low risk guidelines for different age groups.

32. In providing further information and narrative about the risks of alcohol, the CMOs could usefully provide a general explanation about how the risks might differ between individuals; for example because of effects of age, body size, familiarity with alcohol, the risks of breast cancer for women, or the risks of falls among older people.

33. The Guidelines development group has built on the work of the previous two expert groups. The group agreed that the weight of evidence to date suggests that:

- The benefits for heart health of drinking alcohol are less, and apply to a smaller group of the population, than previously thought. The Sheffield report commissioned for the expert group included a UK analysis which has found that the net protective effect⁹ from mortality that may be attributable to drinking regularly at low levels appears now to be significant only for women aged 55+ (with men aged over 55+ showing such a net protective effect only of negligible size).
- The fact that the adverse effects of drinking alcohol on the risk of a range of cancers has now been strongly established, has the important consequence of the need to communicate that drinking any amount of alcohol regularly, does increase the risks of such serious harms (even though the risks of cancer attributable to alcohol are normally low if drinking is within the proposed guideline levels). However there is now evidence of an increased risk of certain cancers even at low levels of consumption.
- Both the above points taken together mean that we **recommend** to the CMOs that there is a need to be clear as a core message in future communications that the new guidelines are for 'low risk' drinking not 'safe' drinking. And that the vast majority of the population can reduce health risks further if they reduce drinking below the guideline levels, or do not drink at all.

34. The approach taken by the Guidelines development group has been to propose guidelines and advice to inform the public about the known health risks of different levels and patterns of drinking, particularly for people who want to know how to keep long term health risks from regular drinking of alcohol low. The regular drinking guideline provides advice which most of the population can use to keep their long term health risks low.

35. Many people, for personal or cultural reasons, drink no alcohol at all, most drink very moderately and only once or twice a week or less; and many drink for positive social and other benefits they perceive from drinking, including some who drink above low risk guideline levels. People vary in how they metabolise or react to alcohol, so people can be affected differently by drinking similar amounts.

36. Individuals will make their own judgements as to risks they are willing to accept from alcohol, whether to drink alcohol, and how much and how often to drink. To help people make informed judgements, we have provided a narrative with as much information as possible about the basis of the guidelines and the advice.

⁹ Taking account of mortality from all causes. For other groups, risk reductions for death from cardiovascular conditions are either largely or wholly outweighed by risk increases for other conditions.

37. The Guidelines development group **recommend** that as well as publishing the two specific new guidelines on pregnancy and regular drinking and the narrative advice on reducing the short-term risks from single drinking occasions, the CMOs publish a more extensive narrative about the basis for the new guidelines, and communicate clearly that:

- the risk of a number of cancers increases from any level of regular drinking;
- there is good evidence that cardio-protective effects have previously been overestimated and there are substantial uncertainties around the level of protection still observed; and
- the net cardio-protective effects from mortality attributable to drinking regularly at low levels are likely to be limited in the UK to women over the age of 55.

38. There is some limited evidence at present of the effects of having days free from alcohol consumption routinely for all drinkers. However, within a pattern of regular consumption, we **recommend** that adopting alcohol free days may be a useful way for drinkers to moderate their consumption.

39. Evidence is clear that there are other situations where it is advisable not to drink alcohol at all, or to exercise special caution, such as before and during driving, before, during, or directly after physical sport, before using machinery, before working where functioning in work would be adversely affected by alcohol, or when taking medication for which alcohol is contraindicated.

40. We **recommend** that the Government should run supportive social marketing campaigns for the public, developed in collaboration with the public. There should be a well funded Big Launch campaign. Campaigns should include education about both short and long term risks and alcohol units.

41. We **recommend** that the Department of Health works with health professionals and experts to review its guidance on higher risk drinking levels, in light of the new evidence underlying this report.

42. We **recommend** that health warnings and consistent messaging appear on all alcohol advertising, products, and sponsorship.

43. We **recommend** that systematic research be commissioned into the understanding, acceptability and uses of the new guidelines by the public, health professions and alcohol industry, including the impact of the supportive social marketing campaigns we recommend.

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Final Report

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Alcohol Guidelines Review – Report from the Guidelines development group to the UK Chief Medical Officers

Final Report

Introduction

Rationale underpinning the report - the overall approach to the draft guidelines

1. Previous reports from the Health evidence expert group and the Behavioural expert group set out the evidence behind their recommendation to develop new alcohol guidelines.

2. The Guidelines development group considered carefully its approach in reviewing the current guidelines and the evidence for advice to the public on the health risks from drinking. In proposing up-to-date guidance for the UK public, it based its advice on the following principles:

- People have a right to accurate information and clear advice about alcohol and its health risks
- There is a responsibility on Government to ensure this information is provided for citizens in an open way, so they can make informed choices

Evidence on public understanding and response to guidelines

3. While there is little systematic evidence about the effectiveness of guidelines in changing health behaviours, there are some general lessons both from evidence reviews and from other fields (social marketing, goal setting, behavioural psychology etc.) which should be taken into account in introducing new guidelines based on new health evidence:

• the justification for any guidelines should be clearly spelt out

and they should be:

- simple,
- specific,
- measurable,
- timebound; and
- realistic

4. It is crucial to present important public health information in a usable and comprehensible way that reflects the evidence base on health risk and the evidence base on effective communication of health messages

Regular drinking advice [this applies for people who drink regularly or frequently i.e. most weeks]

New weekly guideline

The Chief Medical Officers' guideline for both men and women is that:

- You are safest not to drink regularly more than 14 units per week, to keep health risks from drinking alcohol to a low level
- If you do drink as much as 14 units per week, it is best to spread this evenly over 3 days or more. If you have one or two heavy drinking sessions, you increase your risks of death from long term illnesses and from accidents and injuries.
- The risk of developing a range of illnesses (including, for example, cancers of the mouth, throat and breast) increases with any amount you drink on a regular basis
- If you wish to cut down the amount you're drinking, a good way to help achieve this is to have several drink-free days each week.

Evidence underpinning the advice

5. There is up-to-date epidemiological evidence on risks of health harm and mortality that were analysed for the UK in a report commissioned by Public Health England from the Sheffield Alcohol Research Group, University of Sheffield.

6. Some key findings are shown below based on both levels and frequency of drinking.¹⁰ Tables 1 and 13 are taken from the Sheffield report.

¹⁰ The Sheffield report describes the Canadian and Australian methods: (1) In Canada, the guideline was based around epidemiological evidence suggesting that low levels of alcohol consumption are associated with reduced annual risk of mortality when compared with not drinking (i.e. there is some evidence that low levels of alcohol consumption provide a 'protective effect'). The Canadian guidelines for average daily consumption were thus set at the level at which risks of drinking were equivalent to those of abstaining from alcohol. In other words, the threshold level was chosen such that, at the population level, the estimated harmful effects and the estimated protective effects were counterbalanced equally against each other and net mortality risk was the same as if everyone abstained from alcohol. (2) In Australia, an alternative approach was used which focused on the absolute mortality risk due to drinking compared to the mortality risks from other causes. Thus the Australian guideline was set such that if the population all drank at that level, 1% of annual deaths would be attributable to alcohol. Selection of this 1% level was informed by guidance and regulations relating to other environmental and health risks and also by risks which appear to be acceptable to the public for other activities (e.g. the risk associated with driving a car regularly).

| | | Units p | er week | Units per day | |
|---|------------------------------|---------|---------|---------------|---------|
| Threshold | Drinking days per week | Males | Females | Males | Females |
| | 1 | 3.4 | 10.0 | 3.4 | 10.0 |
| | 2 | 5.8 | 12.0 | 2.9 | 6.0 |
| | 3 | 7.4 | 12.8 | 2.5 | 4.3 |
| Canadian: RR=1.0 RR- Relative Risk | 4 | 8.2 | 13.2 | 2.1 | 3.3 |
| nn- nelative nisk | 5 | 8.9 | 13.4 | 1.8 | 2.7 |
| | 6 | 9.4 | 13.6 | 1.6 | 2.3 |
| | 7 | 9.8 | 13.6 | 1.4 | 1.9 |
| | 1 | 6.0 | 12.0 | 6.0 | 12.0 |
| Australian: Proportion deaths attributable alcohol=1% | 2 | 9.4 | 14.0 | 4.7 | 7.0 |
| | 3 | 11.3 | 14.8 | 3.8 | 4.9 |
| | 4 | 12.3 | 15.2 | 3.1 | 3.8 |
| | 5 | 13.1 | 15.4 | 2.6 | 3.1 |
| | 6 | 13.7 | 15.6 | 2.3 | 2.6 |
| | 7 | 14.1 | 15.7 | 2.0 | 2.2 |

Table 1: Implied lower risk drinking guidelines under different approaches by number of drinking days and based on mortality data

7. The strengths and limitations of the data on risk were considered carefully and a range of sensitivity analyses were considered by the group, in order to underpin a robust, but transparent, establishment of a low risk level for regular drinking.

| | | Units per week | | | | | | | | | |
|------------|----------|----------------|-----------|------------|------|---------|------|-----------|------------|------|-------|
| | | | | Males | | Females | | | | | |
| | Drinking | | SA1: | | SA3: | SA4: | | SA1: | | SA3: | SA4: |
| | days per | Base | Threshold | SA2: No | 10 | CVD | Base | Threshold | SA2: No | 10 | CVD |
| Threshold | week | case | effect | protective | yrs | risks | case | effect | protective | yrs | risks |
| | 1 | 3.4 | 6.4 | - | 3.5 | 3.6 | 10.0 | 9.7 | - | 10.3 | 6.8 |
| Canadian | 2 | 5.8 | 12.4 | - | 6.1 | 6.0 | 12.0 | 13.1 | - | 12.1 | 8.5 |
| RR=1.0 | 3 | 7.4 | 15.8 | - | 7.6 | 7.4 | 12.8 | 14.6 | - | 12.6 | 9.2 |
| RR = | 4 | 8.2 | 17.7 | - | 8.6 | 8.2 | 13.2 | 15.1 | - | 13.0 | 9.6 |
| Relative | 5 | 8.9 | 18.7 | - | 9.3 | 8.7 | 13.4 | 15.4 | - | 13.2 | 9.8 |
| Risk | 6 | 9.4 | 19.3 | - | 9.8 | 9.2 | 13.6 | 15.6 | - | 13.4 | 10.0 |
| | 7 | 9.8 | 19.2 | - | 10.2 | 9.5 | 13.6 | 15.8 | - | 13.5 | 10.1 |
| | 1 | 6.0 | 8.2 | 1.5 | 6.4 | 6.0 | 12.0 | 11.2 | 2.3 | 12.4 | 9.2 |
| | 2 | 9.4 | 14.9 | 2.1 | 10.0 | 9.3 | 14.0 | 14.6 | 2.8 | 14.4 | 11.1 |
| Australian | 3 | 11.3 | 18.5 | 2.4 | 11.8 | 10.9 | 14.8 | 16.2 | 3.1 | 15.1 | 11.9 |
| Proportion | 4 | 12.3 | 20.1 | 2.6 | 13.0 | 11.9 | 15.2 | 16.9 | 3.2 | 15.5 | 12.3 |
| =1% | 5 | 13.1 | 21.5 | 2.7 | 13.8 | 12.6 | 15.4 | 17.2 | 3.3 | 15.8 | 12.6 |
| | 6 | 13.7 | 22.1 | 2.8 | 14.6 | 13.2 | 15.6 | 17.5 | 3.3 | 15.9 | 12.8 |
| | 7 | 14.1 | 22.2 | 2.9 | 15.1 | 13.5 | 15.7 | 17.6 | 3.4 | 16.0 | 12.9 |

Table 13: Implied guideline for mean weekly consumption under different sensitivity analyses

Table 13, Sensitivity analyses included, based on different assumptions, are:

- SA1: The impact of assuming a threshold effect in the function relating peak daily consumption to risk for acute alcohol-related conditions such as injuries or accidents. The modelled threshold assumed risk equivalent to abstainers up to 3 units for females and 4 units for males.
- SA2: The impact of assuming no protective effects for cardiovascular conditions.

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 - SA3: The impact of modelling a longer time period; namely 10 years. This allows shifts in the demographic structure of the population to occur following reduced premature mortality
 - SA4: The impact of accounting for recent trends in mortality rates from cardiovascular conditions, using the most recent available figures from 2013

8. The group also considered what evidence had changed or had been added from that which underpinned the current advice that was issued in 1995.

9. There were a number of areas that required some specific further consideration, that are discussed below, including the basis of a low risk threshold for regular drinking, the current evidence for a 'beneficial effect of drinking', the evidence favouring a format of weekly or daily low risk advice, and the utility of drink-free days.

What evidence has changed on regular drinking guidelines?

- 10. The science has changed since the current guidelines came out in 1995:¹¹
 - There is much more evidence on the link between alcohol and cancer alcohol is now recognised as a cause of certain cancers by the International Agency for Research on Cancer.¹² There is an increased risk at low levels of consumption for breast, oesophageal, oral cavity, pharynx and at higher levels for e.g. liver and colorectal cancers.
 - A consequence of this is that drinking any amount of alcohol regularly can cause harm; the risks of cancer for most people are present even at a low level of consumption, but are lower if drinking is within the proposed weekly guideline levels.
 - Evidence for a net protective effect of alcohol from risk of death (which has been linked to possible reduced risks of heart disease late in life) is considered less strong than it was. A reduced risk still exists, but, in the UK, it now appears to matter overall in a significant way only for women aged 55 or older.¹³ The 1995 report for the current guidelines found this protective effect applied at that time to men over 40 and postmenopausal women. This change in understanding is consistent with changes in the profile of heart disease in the UK and a changing population.
 - Evidence produced concerning understanding of the core 'daily' guideline introduced in 1995, has suggested a degree of misunderstanding by some members of the public about whether the daily limit was intended to apply as a limit for any single day or single occasion of drinking (which it was not).¹⁴

¹⁴ Qualitative evidence from previous Department of Health campaigns

¹¹ CMO Alcohol Guidelines Review – A summary of the evidence of the health and social impacts of alcohol consumption; CMO Alcohol Guidelines Review – Mapping systematic review level evidence; both reviews were written by the Centre for Public Health, Liverpool John Moores University

¹² IARC Evaluations, 1988 Vol 44 (oral cavity, pharynx, larynx, oesophagus and liver); 2007 Vol 96 (colo-rectum and female breast); 2009 Vol 100 (oesophagus, head and neck)

¹³ Taking account of mortality from all causes. For other groups, risk reductions for death from cardiovascular conditions are either largely or wholly outweighed by risk increases for other conditions.

• Recent evidence confirms that most people do not drink every day or even most days, and do not always find the current guideline, focussed on regular daily drinking, useful.^{15,16}

Weekly or daily guidelines?

11. We have chosen to present the analysis of the evidence in weekly terms. This is consistent with the evidence base on risk and in a simple, comprehensible form. This is in line with the principles for effective communication of health messages (to be accurate but as simple as possible).

12. There is evidence that a daily guideline may tend to be misunderstood as a maximum amount to drink on any occasion. There is evidence that only a minority of the UK population drink on more than two days each week and evidence that many find a daily guideline less useful as a result.

13. Using a weekly format also offers an inherently easier benchmark for those whose drinking amounts per day, and days per week, vary.

14. The group believes that a weekly guideline on regular drinking requires an additional recommendation, concerning the need to avoid harmful regular heavy drinking episodes, as there is clear evidence that such a pattern of drinking increases risk to health. The additional guideline we recommend is: If you do drink as much as 14 units per week, it is best to spread this evenly over 3 days or more. If you have one or two heavy drinking sessions, you increase your risks of death from long term illnesses and from accidents and injuries.

The basis for determining a low risk threshold for regular drinking

15. The analysis of the evidence on levels of alcohol consumption for a number of different health harms reviewed by the group, including the evidence on cancer risks, make it apparent that there is no level of regular drinking that is completely without risks to health in the long term.

16. We have used the extensive national and international data on health risks and risks to mortality due to different levels and patterns of drinking. A key benchmark in this report is the estimate of the contribution of alcohol to risk of death. It is the point at which any apparent protective effect of drinking on mortality rate is balanced by an increased risk of death. Although there are more uncertainties concerning the level of this protective effect related to the amount consumed, the presence of the effect in the data is a consistent finding, particularly in regard to heart disease mortality, and we have taken this as a key consideration for those who wish to have a low risk of harm from drinking.

17. This is consistent with the methodology used to develop recent Canadian alcohol guidelines. Canada used a relative risk approach which set the guidelines at a point at which alcohol harms and benefits were balanced, in terms of the numbers of deaths caused and prevented.

18. The Sheffield report, which included a number of sensitivity analyses and estimates based on numbers of days drinking a week, shows that roughly similar conclusions can be reached drawing upon the Canadian relative risk approach and an absolute risk approach adapted from that used in Australia.

¹⁵ Interpretation and use of drinking guidelines and approaches by adult men and women, Presentation to the Guidelines Development Group, September 2014, University of Sheffield and Institute of Social Marketing, Stirling University

¹⁶ Lovatt M, et al. (2015) Lay epidemiology and the interpretation of low risk drinking guidelines by adults in the United Kingdom. *Addiction* 110

19. As well as looking at the point at which the risk of death from alcohol outweighs any potential health benefit, the proposed UK guideline on regular drinking is also broadly consistent with, and takes account of, the research showing levels of drinking where alcohol would be expected to cause an overall 1% lifetime risk of death¹⁷ for those drinking at these levels. The proposed guideline is around or a little below this level.

20. The Guidelines development group **recommend** that for those who drink regularly or frequently i.e. most weeks, **the guideline should be not to exceed 14 units of alcohol a week**. This conclusion draws on that range of analyses considered by the group described above, and the group also took account of the following considerations:

- the need to take account of a likely overestimation of protective effects in much of the research.
- mortality from ischaemic heart disease (IHD) has been falling in the UK population for many years, which means there is now less risk of death from this disease for which low alcohol consumption might give protection; this may also lead to overestimation of protective effects at the population level.
- the evidence for alcohol having an adverse effect on a wide range of diseases that may not cause death, which is not taken into account directly in the modelling in the Sheffield report.
- neither of the Canadian or Australian methods takes account of the fact that more of the deaths prevented are deaths that occur late in life (mainly heart disease), whilst many of the deaths caused by alcohol tend to occur at younger ages, for example liver disease and accidental deaths, which means that overall many more years of life are lost due to alcohol than are saved – even for those drinking within the guideline level.
- The guideline level was determined after taking account of evidence of the risks from a range of drinking patterns including incorporating the risk to those drinking 7 days per week. Most UK adults report in surveys that they drink on 2 days a week, or less often;¹⁸ those drinking 5 days or more a week are a small proportion of the population. Risks are higher if a given amount of alcohol is drunk on fewer days.
- 21. Hence, the specific selection of 14 units is based on:
 - careful consideration of the results of the scientific modelling,
 - the detailed analysis of risks to the UK population from drinking,
 - consideration of what is likely to be acceptable as a low risk level of drinking, and
 - the need to have a clear, understandable and specific message.
- 22. The recommendation of 14 units is both pragmatic and evidence-based.

Is there a level of 'safe' drinking? Are there acceptable risks from alcohol?

23. The 1995 guidelines have sometimes been presented as advising 'safe' drinking levels. While they did not suggest this, the method was different in detail from either method used

¹⁷ Unlike the absolute risk method used in Australia, the method used in the Sheffield model does take account of deaths prevented, e.g. from ischaemic heart disease. So the 1% lifetime risk of death is a 'net' risk for the population taking account of both deaths incurred and prevented.

¹⁸ Health Survey for England, 2011, Chapter 7, Drinking Diary: This is the case in England whether or not teetotallers are included in the calculation. Adult Drinking Habits in Great Britain, 2013, ONS, 2015: Those who say they drank alcohol on 5 or more days each week fell from 17% in 2005 to 11% in 2013.

for the recent Canadian¹⁹ and Australian²⁰ guidelines. It was closer to the Canadian method in looking at relative risks, but did not explicitly seek to balance harms and benefits. The 1995 report said:

'Most researchers have based their assessment of where the recommended upper level of alcohol consumption should be placed at the point where they judge the evidence indicates a steady increase of relative risk rising significantly from a lowest allcause mortality point on the J-shaped curve.'

24. The 1995 Inter-Departmental Working Group followed a similar method.

25. A Canadian method, seeking the point where harms and benefits balance in the population as a whole, necessarily means that there is a significant body of harm, including deaths, from regular drinking within the guideline. It should be understood that at a population level the net harms and the benefits vary by age. Broadly, the net harms in terms of mortality occur under age 65 and the benefits in terms of extended life happen mostly over age 75.

26. The Australian method used an approach involving an assessment of absolute lifetime risk of dying from an alcohol-related condition to help them benchmark an acceptable low risk level against certain other kinds of acceptable risk-taking choices made in society (such as the risk to drivers of dying in a car accident). This is the level of drinking where alcohol would be expected to cause an overall 1% lifetime risk of death for those drinking at these levels.

27. Although we did not consider this Australian approach focussing solely on absolute risks to be adequate for our own analysis, the group did commission a report of guideline thresholds derived from the Australian approach and based on UK mortality risk estimates, using this as part of a balanced approach to determining an acceptable level of low risk, and leading to our final recommendation 'to drink at no more than 14 units per week would represent a low risk level'. We drew upon the analyses based on both the Australian approach and the Canadian approach, alongside other analyses to test the robustness of the risk curves being used, and considered all these elements in the context of our expert knowledge of the uncertainties in the research.

28. The proposed guideline gives particular consideration to the balance of risks and benefits, but it is also set at a level around and a little below that which would be suggested by an analysis of absolute 1% lifetime risk of death.

29. Therefore, the proposed new guideline would <u>not</u> eliminate all health risks from drinking alcohol if all the UK population were all to drink 14 units of alcohol every week.

30. Drinking alcohol even at low levels contributes to a wide range of health harms, to a range of diseases and to hospital admissions. Hence, there is no level of drinking that can be recommended as completely safe long term, and advice to the public should be clear that many of these risks can be reduced by drinking at levels below the 14 unit weekly guideline limit, or by not drinking at all.

31. Different individuals will have different views as to what constitutes an acceptable risk of harm from their drinking.

32. We recognise that many people obtain benefits from drinking alcohol, including social pleasure. The guideline on regular drinking would be consistent with a little under a 1% lifetime risk of death from alcohol for people who follow this consistently. This implies that people need to understand that any drinking of alcohol carries some risks, like some other regular or

¹⁹ The basis for Canada's new low risk drinking guidelines: A relative risk approach to estimating hazardous levels and patterns of use, by Tim Stockwell et al. Drug and Alcohol Review (March 2012), 31, 126-134

²⁰ Australian Guidelines to reduce health risks from drinking alcohol, National Health and Medical Research Council, 2009

routine activities.²¹ These are risks that people can reduce further, by choosing to drink less, or not to drink at all, if they wish.

33. This is in contrast to some other areas of safety, such as safety of drinking water, where the aim of regulation is generally to reduce health risks, such as risks of cancer, to the lowest level practicable (while avoiding disproportionate costs), as drinking water is not something people can choose to avoid.

34. Some will consider that any increased risk of death from their drinking (alongside the increased risk of illness from various alcohol-related health conditions) is worth avoiding, i.e. they would take a more cautious view than implied by these guidelines.

Individual variation

35. These guidelines on regular drinking provide a guide for people in the UK as a whole, who wish to keep risks to their health from drinking at a low level. They are based on typical or average drinkers.

36. Other factors may increase the risks of harm for individuals associated with alcohol, such as:

- risk factors for certain diseases
- low body weight
- current health problems, or
- previous problems with alcohol

37. People will need to take account of these alongside the low risk weekly guidelines.

38. Similarly, for women over 55, any protective effect from death from heart disease for low levels of drinking is likely to be offset if there are other risk factors, e.g. being overweight.

39. Younger adult drinkers and younger males, in particular, have higher acute risks from drinking.

40. Middle aged or older drinkers may have accumulated risks from long term drinking, may have more relevant health conditions and in old age may be more liable to falls.

41. Differences between men and women in the immediate risks of drinking are more relevant to younger than older adults.

42. The weekly guideline is advice for the general population, which individuals need to consider in the light of their own individual characteristics – as well as their own attitudes to risk.

43. It can also be seen as a benchmark to enable people to monitor their own drinking levels.

44. Figures 12 and 13 from the Sheffield report show how risks of death vary by age and frequency of drinking.

²¹ A close comparison is the lifetime risk of death from vehicle accidents, which was one in 240 in the UK in 2004, Department for Transport: Road Casualties Great Britain 2006 – Annual Report



Figure 12: Male relative risk of alcohol-related mortality by mean weekly consumption, number of drinking days and age

Figure 13: Female relative risk of alcohol-related mortality by mean weekly consumption, number of drinking days and age



Men and women

45. It has also been possible to use available evidence to make better estimates of risks of immediate harm (accidents and injuries and deaths from these) due to drinking alcohol. These risks mainly happen with heavy drinking in a single session or in one or two days.

46. These risks are greater for men than for women, in part because of men's underlying risk taking behaviours; their risks of injury and accident are, on average, much greater than for women, even before taking account of the effects of alcohol. This means that men are more affected by increased risks of immediate harm from drinking alcohol.

47. The proposed weekly guideline is the same for men and women. Women's long-term health can be affected more by alcohol, but on average men are at much greater risk from the more immediate harms such as accidents and injuries.

48. Risks of immediate harms in women are much less than for men at the same level of consumption, but their risks of long term illness and death generally increase to a greater degree than men's as drinking increases. This is consistent with the medical understanding of general differences in biological vulnerability to exposure to alcohol over time.

Reduced risks from low levels of alcohol consumption

(i) Heart disease

49. The evidence²² about any protective effect of drinking small amounts (1 unit or less a day) of alcohol in reducing risks of death, mainly from ischaemic vascular disease such as heart disease, has been taken account of in framing the regular drinking guideline and was part of the research used to inform that.

50. The expert group concluded that people who do not drink any alcohol at all should not be recommended to start drinking in the interests of their health because such advice cannot be justified for a number of reasons:

- (a) the evidence for a direct, protective, effect of alcohol on mortality is a subject of continuing scientific discussion;
- (b) methodological limitations in the evidence base mean there is uncertainty on the extent of the effect;
- (c) ischaemic vascular disease including heart disease, which is the key condition in the evidence of reduced risk, mainly affects older adults and particularly deaths in older age. Deaths from this type of disease have been falling in the UK population for some years, which means there is less risk for which low alcohol consumption might give protection;
- (d) lifestyle changes, such as stopping smoking, increasing levels of physical activity, and eating a healthy diet, can help protect against heart disease, so any potential protective effects from alcohol could be achieved in other ways, which avoid the other health risks which come with any drinking of alcohol.

51. After accounting for these limitations in the evidence used within the Sheffield model, the best specific evidence available on protective effects suggests that the maximum net reductions in deaths are present in those regularly drinking only 1 unit or less a day.

52. Previous analyses suggested the protective effect was only likely to be relevant to men from age 40 onwards and for post-menopausal women. The Sheffield report commissioned for the expert group included a UK analysis, which has found that the net protective effect that may be attributable to drinking regularly at low levels appears now to be significant only for women aged 55+ (with men aged over 55+ showing such a protective effect only of negligible size). The Sheffield report estimates that for females aged 55 and over, the greatest risk reductions occur in those drinking approximately five units per week (mean weekly consumption).

53. The impact of any such apparent protective effect would be expected to vary, for example, with differences in the risk of heart disease in the population over time, and so this recent finding is not necessarily inconsistent with previous evidence.

²² CMO Alcohol Guidelines Review – A summary of the evidence of the health and social impacts of alcohol consumption; CMO Alcohol Guidelines Review – Mapping systematic review level evidence; both reviews were written by the Centre for Public Health, Liverpool John Moores University

54. There is no good basis to suggest women should start drinking in the interests of their health. But we would not advise any women aged 55+ who might currently be drinking up to a unit every day to try and obtain a reduced risk of death from heart disease, that they should reduce the number of days on which they drink.

(ii) Other conditions

55. In addition to the evidence for a protective effect on risk of ischaemic heart disease mortality, particularly from low levels of alcohol consumption, there is also evidence of a reduced risk for ischaemic stroke mortality (and morbidity); and for mortality related to type II diabetes mellitus. These effects have been taken account of in in the analyses that underpin the low risk weekly guideline for regular drinking.

Harmful effects of alcohol and consideration of risks at different levels of consumption

56. The evidence on the 'long term health risks' from regularly drinking alcohol has continued to develop over the last 2 decades, particularly confirming the importance of alcohol in the development of cancers including breast cancer; and in identifying its contribution to the risk of diseases even at low levels of use. Although there is clearly a level of drinking that can be described as low risk, it is now much more evident there is no completely safe level. This link with their alcohol use may not be obvious to the person affected. For example, even an individual who may have a potential greater life expectancy of a number of months in old age (for example, as a result of drinking around 1 unit daily), may have required extensive treatment for an alcohol-related cancer (with some risk of death) that they could otherwise have avoided. It is important to quantify any such risks to assist the public in making choices.

57. We commissioned from Sheffield University, through Public Health England, a scientifically robust report that incorporated analysis on levels of risk for a wide range of conditions related to drinking. They used a combination of published meta-analyses of risk relationships, analysis of the proportion of cases of alcohol related conditions attributable to alcohol and UK mortality and morbidity rates for 43 relevant alcohol-related conditions to provide the most up-to-date UK-specific analysis of these risks. Whilst this analysis clearly confirms the range and scale of harms attributable to alcohol at different levels of consumption in the UK, it is not possible to provide a completely comprehensive picture of all the risks. Hence, the extent of harm will actually be greater than quantified in the report.

58. The Sheffield report confirms there are a number of conditions that can be wholly attributed to the single occasion or regular use of alcohol such as accidental poisoning by alcohol, mental and behavioural disorders due to use of alcohol, alcoholic liver disease and alcohol-induced chronic pancreatitis. It describes an even greater number of health conditions (such as high blood pressure, cardiac arrhythmias and a number of cancers) to whose development it is clear that regular drinking contributes but for which conditions it is not possible to prove the role of alcohol in any individual case. Hence, despite the enormous extent of these health harms caused by alcohol, it is not widely recognised by the public that drinking has this scale and range of health harms. It will, therefore, be important to use the data from the Sheffield report (and other sources as appropriate) to make clear the nature and scale of these harms from different levels of drinking, in order to assist the public in making informed choices about low risk drinking (understanding alcohol's role in the development of a wide range of acute and chronic illnesses and its contribution to mortality from a number of alcohol-related diseases and traumatic conditions). The data and analysis in the report can also be used to communicate information to the public on how much the risks of developing various conditions in the future is increased when someone drinks above the low risk level.

59. Conditions that show increasing risk of harm, morbidity and mortality, from even low levels of consumption of alcohol, include cancers of the lip, oral cavity, pharynx, oesophagus and breast; and at higher levels, increasing risk of cancers such as liver and colorectal cancer. Alcohol also contributes to the risk of: epilepsy and status epilepticus, hypertensive diseases, cardiac arrhythmias and of haemorrhagic and other non-ischaemic stroke, lower respiratory infections and pneumonias, to cirrhosis of the liver and to acute and chronic pancreatitis.

60. The data on risk and consumption provide evidence of a reduced risk of mortality from ischaemic heart disease, ischaemic stroke and diabetes at low levels of consumption. However, drinking at higher levels is associated with an increased risk of harm from these conditions.

61. It is important to understand that epidemiological evidence usually provides estimates of average levels of alcohol-related harms across the population. In reality, the actual risk for any individual will vary with factors such as age and gender and with a number of individual characteristics such as low body weight, the presence of co-existing health problems, and their genetic makeup. In addition, different individuals are likely to accept a different level of risk. Despite these factors, providing clear information on how risk generally increases with levels of consumption is clearly essential for making fully-informed choices.

62. Figure 2 of the Sheffield report shows risk curves for the conditions where risk of harm increases with any increase in drinking (with the curves approximating a straight line type or exponential type from even low levels). Other curves show conditions with evidence of reduced risk at low levels of consumption (with the characteristic j-shaped or u-shaped curves typical of this).

63. A number of the risk curves show differing risks of harm by alcohol consumption, broken down by gender, and reiterate the already well-established greater susceptibility of women to chronic consequences of alcohol use (with a greater risk of harm than men at the same level of drinking) particularly above the low risk guideline level. Despite evidence of a greater biological susceptibility to alcohol in women, acute harms in women are much less than men at the same level of consumption, which is attributed to a greater propensity for men, on average, to expose themselves to risks when under the acute effects of alcohol than do women.

64. A key health risk quantified in the University of Sheffield report is the impact of alcohol on the risk of death (overall and on the risk from particular diseases/conditions). Whilst the epidemiological data used to estimate mortality risk focuses on the numbers of deaths (for which risk from alcohol is associated either positively or negatively depending on amounts consumed), this gives only a partial view, because it does not take account of whether a death, caused or saved, occurs in a young person or an older person. This is important in understanding the total scale of harm from alcohol. Much of the loss of life that is avoided due to low levels of drinking relates to deaths from ischaemic heart disease that typically occur at older ages; whilst many of the deaths actually incurred in association with drinking regularly, tend to be deaths. This means that understanding the actual harm from drinking, including the balance of years of life lost due to alcohol (at younger ages) and the ones saved (at older ages) is not adequately described by taking account only of the effect of drinking on numbers of deaths.

65. Tables 10 and 11 in the Sheffield report present absolute risk of alcohol-related mortality for those drinking at 7, 14, 21, 28, 35, 42 and 49 units per week. They are repeated below. The data as presented are able to highlight whether drinking at such levels (and patterns) leads to (i) a reduced risk of mortality; or (ii) an increased risk. These are shown as negative and positive values respectively. Additionally, the tables are shaded to show whether

in the case of an increased risk, the overall lifetime risk is at least 1 in 10; at least 1 in a 100 (but below 1 in 10); or less than 1 in a 100. In the table, 0.01 means a one in 100 risk.

| Mean | Drinking days per week | | | | | | | |
|-----------------------------|------------------------|---------|---------|---------|---------|--------|--------|--|
| consumption (units/week) | 7 | 6 | 5 | 4 | 3 | 2 | 1 | |
| 7 | -0.0052 | -0.0047 | -0.0039 | -0.0027 | -0.0012 | 0.0027 | 0.0142 | |
| 14 | 0.0095 | 0.0106 | 0.0121 | 0.0144 | 0.0178 | 0.0252 | 0.0465 | |
| 21 | 0.0285 | 0.0300 | 0.0322 | 0.0355 | 0.0409 | 0.0514 | 0.0814 | |
| 28 | 0.0511 | 0.0531 | 0.0558 | 0.0599 | 0.0670 | 0.0802 | 0.1178 | |
| 35 | 0.0773 | 0.0796 | 0.0829 | 0.0877 | 0.0960 | 0.1114 | 0.1550 | |
| 42 | 0.1070 | 0.1097 | 0.1133 | 0.1187 | 0.1277 | 0.1449 | 0.1928 | |
| 49 | 0.1403 | 0.1431 | 0.1471 | 0.1529 | 0.1621 | 0.1806 | 0.2312 | |

Table 10: Absolute lifetime risk of male alcohol-attributable mortality by consumption frequency and quantity

Table 11: Absolute lifetime risk of female alcohol-attributable mortality by consumption frequency and quantity

| Mean | Drinking days per week | | | | | | | |
|-----------------------------|------------------------|---------|---------|---------|---------|---------|---------|--|
| consumption (units/week) | 7 | 6 | 5 | 4 | 3 | 2 | 1 | |
| 7 | -0.0231 | -0.0228 | -0.0224 | -0.0218 | -0.0208 | -0.0188 | -0.0130 | |
| 14 | 0.0018 | 0.0023 | 0.0031 | 0.0043 | 0.0061 | 0.0099 | 0.0205 | |
| 21 | 0.0367 | 0.0374 | 0.0384 | 0.0400 | 0.0425 | 0.0476 | 0.0625 | |
| 28 | 0.0776 | 0.0785 | 0.0797 | 0.0816 | 0.0846 | 0.0907 | 0.1089 | |
| 35 | 0.1230 | 0.1240 | 0.1254 | 0.1275 | 0.1309 | 0.1377 | 0.1582 | |
| 42 | 0.1720 | 0.1731 | 0.1746 | 0.1768 | 0.1806 | 0.1880 | 0.2096 | |
| 49 | 0.2239 | 0.2251 | 0.2267 | 0.2290 | 0.2330 | 0.2408 | 0.2626 | |

Black text, green background – overall protective effect Red text, light orange background – overall lifetime risk less than 1 in 100 Black text, orange background – overall lifetime risk at least 1 in 100, but below 1 in 10 White text, red background – overall lifetime risk at least 1 in 10

66. It is also possible, drawing on the data underlying the curves in Figure 2 from the Sheffield report, to present to the public the 'relative risks' of mortality/morbidity from the various alcohol-related conditions analysed. For some individuals this way of presenting risk in relative terms will be an easier way of comprehending the data. For example, presenting the relative risk of mortality or morbidity for a condition for those drinking at 14/28/35/50 units per week (for conditions such as breast cancer, mouth cancer, cirrhosis or hypertension) can be quite a clear way to show the increasing risk with consumption. Presenting the data on risk this way could be used to emphasise both low relative risk at 14 units a week or below, and higher relative risks at higher thresholds. Such examples of relative risks (relative to non-drinkers) underlying the curves in Figure 2 of the Sheffield report are shown below.

For female breast cancer, relative risks of both illness and death from the disease increase:

- by 16% if drinking regularly at 2 units (16 grams) per day (equivalent to the proposed guideline level)
- by 40% if drinking regularly at 5 units (40 grams) per day (more than double the proposed guideline level)

For cirrhosis of the liver, for men, relative risks of death from the disease increase:

- by 57% if drinking regularly at 2 units (16 grams) per day (equivalent to the proposed guideline level
- by 207% if drinking regularly at 5 units (40 grams) per day (more than double the proposed guideline level)

For ischaemic stroke, for men, relative risks of death from the disease:

- decrease by 11% if drinking regularly at 2 units (16 grams) per day (equivalent to the proposed guideline level
- increase by 3% if drinking regularly at 5 units (40 grams) per day (more than double the proposed guideline level)

For cardiac arryhthmias, for men, relative risks of illness and death from the disease increase:

- by 13% if drinking regularly at 2 units (16 grams) per day (equivalent to the proposed guideline level
- increase by 34% if drinking regularly at 5 units (40 grams) per day (more than double the proposed guideline level)

67. Drawing upon these analyses, and recent clinical benchmarks of risk, it is reasonable to present a threshold of higher risk drinking, particularly to assist in communicating the increasing risks of alcohol, and its extensive harms, and particularly for individuals seeking medical advice related to their drinking. These can be useful for incorporating in supporting materials and for use in future campaigns.

68. Typically, women regularly drinking over 35 units per week and men regularly drinking over 50 units per week have been considered at greater risk of harm.²³ Although overall risks for men and women at low risk levels of consumption are similar, the increased susceptibility of women to health harms from regular drinking over time, when compared to men, becomes clearer at higher levels, reflected in diverging thresholds of risk. The group **recommends** that the Department of Health works with health professionals and experts to review its guidance on higher risk drinking levels in light of the risk curves set out in the Sheffield report and other evidence considered by the group.

Drink-free days

69. The expert group noted there are several studies that have found evidence that among heavy drinkers having alcohol-free days lowers the risk of alcoholic cirrhosis mortality in both men and women. Whilst the group concluded that it may be useful to advise heavy drinkers on the value of drink-free days, it did not find evidence sufficient to justify recommending this routinely to all drinkers. However, the group did **recommend** for those who have made a decision to cut down the amount they are drinking, that a good way to help achieve this is to have several drink-free days each week. The group made clear that this is intended to mean

that any reduction in alcohol consumption on days that are drink-free should not simply be compensated for by higher consumption on other days.

Single occasions of drinking

Advice on short term effects of alcohol

The Chief Medical Officers advise men and women who wish to keep their short term health risks from a single drinking occasion to a low level that they can reduce these risks by:

- limiting the total amount of alcohol you drink on any occasion;
- drinking more slowly, drinking with food, and alternating with water;
- avoiding risky places and activities, making sure you have people you know around, and ensuring you can get home safely.

The sorts of things that are more likely to happen if you don't judge the risks from how you drink correctly can include: accidents resulting in injury (causing death in some cases), misjudging risky situations, and losing self-control.

These risks can arise for people drinking within the weekly guidelines for regular drinking, if they drink too much or too quickly on a single occasion; and for people who drink at higher levels, whether regularly or infrequently.

Some groups of people are likely to be affected more by alcohol and should be more careful of their level of drinking on any one occasion:

- young adults
- older people
- those with low body weight
- those with other health problems
- those on medicines or other drugs

As well as the risk of accident and injury, drinking alcohol regularly is linked to long term risks such as heart disease, cancer, liver disease, and epilepsy.

Why give advice about drinking on any one occasion?

70. It is now quite clear from research on injuries and the associated levels of alcohol consumption, that risk increases with the amount of alcohol consumed; and that this risk accelerates as the amount consumed increases. It is particularly from around 5-7 units per drinking occasion on average that risks of injury and accident accelerate.

71. Deaths resulting from this type of drinking, linked to drunkenness, are also an important risk, particularly in young men; but some injuries can also be devastating for those affected. Harm to bystanders or third parties can also be linked to excessive drinking. It is clearly not simply a matter of individual choice where risks are imposed on other people.

72. It is also, however, clear from the research literature that there is considerable variation in the risks of harms between individuals from the amount consumed (most obviously as between men and women), that a lack of experience of drinking heavily can negatively affect the risk, and that there are a series of actions that can be taken to reduce the risks of harm (whether drinking above or below the guideline level of drinking).

73. For all these reasons taken together, the group concludes that it is possible to provide evidence-based advice on lowering risk of injury and accident – and note that such risks,

which do not result in death, are not fully accounted for in the proposed weekly guideline for regular drinking.

74. Whilst the group does not recommend providing an additional specific unit-based low risk guideline level for drinking on any one occasion (in recognition of the individual variation of short term risks and the ability of individuals to reduce such risks by other means), the group did identify a substantial increase in risks with amount consumed. It is clear that there is a many-times increased risk of injury seen when drinking around 5-7 units (within the preceding 3-6 hours). The risk increases at a faster rate the more alcohol is consumed above this level. It will be important, therefore, when providing more detailed information and advice to the public on the risks from single episode drinking, to include this information on these substantial increases in risk faced, particularly by young men, both of serious injury and fatalities (including from fatal motor vehicle accidents) also need to be communicated appropriately.

Are there acceptable risks from single drinking occasions?

75. There is little established consensus in the research literature on what constitutes acceptable risk for different levels of injury.

76. What the acceptable risk is for any individual involves decisions across a range of such factors; and as for regular drinking involves weighing up the risks, mainly of injury, against the perceived benefits of drinking in a single occasion at higher levels. Clearly, those who are drinking with a view to getting drunk are exposed to more serious risks, but they may still benefit in planning to reduce risks through other modifiable risk factors such as arranging safe transport home.

The basis of the advice

77. The Alcohol Guidelines Review health evidence expert group found that the increased risks from single episodes of heavy drinking are well established:²⁴

- There is consistent evidence that the risk of ischaemic heart disease increases significantly with heavy drinking sessions, compared to regular moderate drinking.
- Injury risk is associated in a non-linear fashion with acute alcohol consumption.
- Any cardio-protective effects of moderate alcohol consumption [are] cancelled out by irregular heavy drinking occasions (>7.5 units per occasion at least monthly) mixed with an average frequency of low to moderate consumption.²⁵

78. The Sheffield report does not detail the risks and harms directly but states: "The Group may also wish to factor into [their] considerations alternative literature-based evidence which speaks more directly to the risks of single occasion consumption. Examples of this literature can be seen in the reports of the Canadian and Australian Guideline Development Groups *and a more recent report by the EU Joint Action on Health RARHA project.*"²⁶

79. The EU Reducing Alcohol-related Harm (RARHA) report states "To summarize the results:

- ²⁵ Roerecke M, Rehm J (2010) Irregular heavy drinking occasions and risk of ischemic heart disease: a systematic review and meta-analysis. *Am J Epidemiol.* 2010 Mar 15;171(6):633-44.
- ²⁶ Rehm, J., Gmel, G., Probst, C., & Shield, K.D. (2015). Lifetime-risk of alcohol-attributable mortality based on different levels of alcohol consumption in seven European countries. Implications for low-risk drinking guidelines. Toronto, On, Canada: Centre for Addiction and Mental Health.

²⁴ CMO Alcohol Guidelines Review – A summary of the evidence of the health and social impacts of alcohol consumption; CMO Alcohol Guidelines Review – Mapping systematic review level evidence; both reviews were written by the Centre for Public Health, Liverpool John Moores University

- The relationship between alcohol use before injury and *the risk of injury* is exponential, with considerably elevated risk at higher levels.
- However, even at lower levels of consumption, there is significantly elevated risk, and no indication for a protective effect.
- These results are in line with biological research on the effects of low dose consumption on psychomotor skills and other behavioural effects of the central nervous system. The general result of a causal impact of prior alcohol use on injuries has also been corroborated by other reviews and meta-analyses.

80. The Australian guidelines expert group also considered evidence on harm and found evidence suggesting that:

- "as more alcohol is consumed on a single occasion, skills and inhibitions decrease while risky behaviour increases, leading to a greater risk of injury during or immediately after that occasion"
- "while women reach a given blood alcohol concentration with a lower amount of alcohol, on average, men take more risks and experience more harmful effects"
- "drinking 5 UK units²⁷ on a single occasion more than doubles the relative risk of an injury in the six hours afterwards, and this relative risk rises even more rapidly when more than 5 UK units are consumed on a single occasion" (although they noted: "results from breath-tests in the WHO study (WHO 2004)²⁸ suggest that under-reporting by injury patients of how much they had consumed may have produced the apparent threshold of around 5 UK units").
- From emergency department presentations:
 - The studies used "calculated the relative risk of injury after drinking specific numbers of drinks, compared with not drinking, and show an increase in risk of injury by between about two and 10 times, depending on the amount of alcohol consumed.";
 - "A new meta-analysis found that the relative risk of injuries other than in motor vehicles is doubled after 5 UK units, compared with not drinking (Taylor et al 2010²⁹).
 - The studies also showed that the risk of injury increased more for people whose level of consumption varied significantly from time to time, and was particularly high for those who 'occasionally' drank much more than their usual amount.
- From cognitive performance studies
 - There is evidence indicating that drinking decreases cognitive performance, even at low levels of consumption. The acute effects of alcohol increase with the amount consumed, along with the risk of adverse outcomes.
 - as the blood alcohol level increases, cognitive function and psychomotor performance decrease rapidly (Easdon et al 2005³⁰);

²⁷ Converted from Australian standard drinks

²⁸ World Health Organization (2004) *Global Status Report on Alcohol 2004* World Health Organization, Geneva.

²⁹ Taylor et al (2005) The more you drink the harder you fall: a systematic review and meta-analysis of how acute alcohol consumption and injury or collision risk increase together. *Drug Alcohol Depend* 2010 Jul 1; 110(1-2): 108–116.

³⁰ Easdon C, Izenberg A, Armilio M et al (2005) Alcohol consumption impairs stimulus- and error-related processing during a go/no–go task. *Brain Res Cogn Brain Res* 25: 873–83.

- 26 Alcohol Guidelines Review Report from the Guidelines Development Group to the UK Chief Medical Officers (published January 2016 with the consultation on the language and understanding of the UK Chief Medical Officers low-risk alcohol guidelines)
 - consumption of less than [2.5 UK units] "potentially" results in effects that increase risk of injury_Tagawa et al 2000³¹; Howland et al 2001³²; Marinkovic et al 2001³³; Marinkovic et al 2004³⁴; Moulton et al 2005³⁵; Breitmeier et al 2007³⁶);
 - From review of the tables of risk in the Appendices of the Australian guidelines report:
 - The Australian threshold chosen for an unacceptable alcohol-related mortality risk set at 1% for combined injury and alcohol-related disease
 - is not reached at all for those drinking 'twice a month' or 'less' (even if drinking as much as 10 UK units per occasion);
 - is only reached by 'regular once-weekly drinkers' when drinking around 6 UK units per occasion;
 - A 1% risk threshold for 'injury death alone' is reached for 'regular once-weekly drinkers' at around 7.5 UK units per occasion in men and 8.75 UK units per occasion for women.
- 81. The <u>Canadian guideline expert group</u> found:
 - For motor vehicle and for non-motor vehicle injury, starting <u>drinking at just 1.75 UK units</u> <u>over a three-hour period</u>, the estimated <u>risk of injury is large and accelerates</u> with each additional drink.

In summary

82. There is therefore good evidence of risks from occasional, single episodes of drinking and that such risk increases with amounts consumed, particularly above around 5-7 units.

83. This is additional advice on lowering risk of injury and accident – such risks, which do not result in death, are not fully accounted for in the proposed weekly guideline for regular drinking.

84. Risks can be affected by the characteristics of individuals, the contexts of drinking, and actions individuals can take taken to modify the acute risks.

85. The expert group also took account of good evidence that, for any heavier drinking session, personal skills and inhibitions are reduced. This can also negatively affect the health and well-being of others.

86. This is advice for the general population, which individuals need to consider in the light of their own individual characteristics, other actions they can take to reduce risks – as well as their own attitudes to risk.

- ³³ Marinkovic K, Halgren E, Maltzman I (2001) Arousal-related P3a to novel auditory stimuli is abolished by a moderately low alcohol dose. *Alcohol Alcohol* 36: 529–39.
- ³⁴ Marinkovic K, Halgren E, Maltzman I (2004) Effects of alcohol on verbal processing: an event–related potential study. *Alcohol Clin Exp Res* 28: 415–23.
- ³⁵ Moulton P, Petrosb T, Apostalb K et al (2005) Alcohol-induced impairment and enhancement of memory: A test of the interference theory. *Physiol Behav* 85: 240–245.
- ³⁶ Breitmeier D, Seeland-Schulze I, Hecker H et al (2007) The influence of blood alcohol concentrations of around 0.03% on neuropsychological functions a double blind placebo-controlled investigation. *Addiction Biol* 12: 183–89.

³¹ Tagawa M, Kano M, Okamura N et al (2000) Relationships between effects of alcohol on psychomotor performances and blood alcohol concentrations. *Japanese J Pharmacol* 83: 253–60.

³² Howland J, Rohsenow DJ, Cote J et al (2001) Effects of low-dose alcohol exposure on simulated merchant ship piloting by maritime cadets. *Accid Anal Prev* 33: 257–65.

87. There is clear evidence that regular heavy drinking increases risk to health, including risks of death. These risks include both long term risk – including risks of death and illness – and immediate risks such as accidents and injuries.

88. Individual variations are even more important to take into account for this advice than for the regular drinking guideline.

Drinking and pregnancy

Guideline on Pregnancy and drinking

The Chief Medical Officers' guideline is that:

- If you are pregnant or planning a pregnancy, the safest approach is not to drink alcohol at all, to keep risks to your baby to a minimum.
- Drinking in pregnancy can lead to long-term harm to the baby, with the more you drink the greater the risk.

Most women either do not drink alcohol (19%) or stop drinking during pregnancy (40%).³⁷

The risk of harm to the baby is likely to be low if a woman has drunk only small amounts of alcohol before she knew she was pregnant or during pregnancy.

Women who find out they are pregnant after already having drunk during early pregnancy, should avoid further drinking, but should be aware that it is unlikely in most cases that their baby has been affected. If you are worried about how much you have been drinking when pregnant, talk to your doctor or midwife.

Rationale

89. Despite some new studies concerning the effects of alcohol in pregnancy since 2007, when the last substantial review of evidence took place that underpinned advice to the public, definitive evidence particularly on the effects of low level consumption, remains elusive.³⁸

90. There is some evidence that the second part of the current English CMO guidance may have been read as implying a recommendation to drink alcohol at low levels during pregnancy, which was not the intention³⁹. Whilst all current sources of guidance referred to in the UK apply some form of precautionary approach, because of some uncertainties in the evidence base about exact levels of risk at low levels of drinking which have led to differences in wording from different parts of the UK and between different bodies, this has created some concerns about clarity and credibility.

91. The expert group was asked by the UK CMOs to consider the differing approaches within the UK and to advise on how far a possible approach harmonised across the UK would be justified based on evidence of health risks and any evidence of behavioural impacts.

³⁷ UK figures from Infant Feeding Survey, 2010. A recent study (*Prevalence and predictors of alcohol use during pregnancy: findings from international multicentre cohort studies; BMJ Open, 11 August 2015*) shows that, 84% of mothers in the UK drank any alcohol in the first trimester of pregnancy. In the second trimester, 39% of mothers drank any alcohol. In the second trimester, 37% of mothers drank no more than 1 to 2 units weekly, 2% drank more than that, with median consumption at 0.8 units weekly. That compares with the first trimester - 28% of mothers drank no more than 1 to 2 units weekly, 56% drank more than that, with median consumption at 4 units weekly.

³⁸ CMO Alcohol Guidelines Review – A summary of the evidence of the health and social impacts of alcohol consumption; CMO Alcohol Guidelines Review – Mapping systematic review level evidence; both reviews were written by the Centre for Public Health, Liverpool John Moores University

³⁹ Alcohol Guidelines Exploratory Research with recent mothers, Summary findings, by Sheffield University and Institute of Social Marketing, Stirling University presented to the Guidelines development group on 9 September 2014

92. In providing their proposed advice on alcohol and pregnancy, the group has taken account of a number of relevant elements: the epidemiological evidence base on risks, the evidence of the known harmful actions of alcohol on the developing fetus, the importance of clarity and simplicity in providing meaningful health messages to the public; and the importance of continuing a precautionary approach on low risk drinking where the evidence is not robust enough to be completely conclusive.

Factors taken into account by the expert group

93. There are good arguments for a 'precautionary approach' when dealing with risks that may have lifelong effects for a baby.⁴⁰

94. In thinking about the need for a precautionary approach, the group took account of a number of other points including:

- The need to avoid harm there is a risk for women who discover they are pregnant and worry unduly about any alcohol they have previously drunk, if advice is more certain than the science warrants.
- The need to be open about limitations in the evidence.

95. Alcohol, like a number of drugs, is a teratogen,⁴¹ which means something that can disturb the development of a fetus. Teratogens may cause a birth defect, or may halt the pregnancy.

96. Alcohol can have a wide range of differing impacts. These include a range of lifelong conditions, known under the umbrella term of Fetal Alcohol Spectrum Disorders (FASD). The level and nature of the conditions included under this term can be related to the amount drunk and the developmental stage of the fetus at the time.

97. Drinking heavily during pregnancy can cause a baby to develop fetal alcohol syndrome (FAS). FAS is a serious condition, in which children have:

- restricted growth
- facial abnormalities
- learning and behavioural disorders, which may be severe and lifelong

98. Drinking lesser amounts than this either regularly during pregnancy or in episodes of heavier drinking (binge drinking), is associated with a group of conditions within FASD that are effectively lesser forms of problems seen with FAS. These conditions include physical, mental and behavioural features including learning disabilities which can have lifelong implications. The risk of such problems is likely to be greater the more you drink.

⁴⁰ A paper discussed by the Guidelines development group on 8 April 2015, 'Harmonising the guidance across the UK – is it possible and, if so, what should the new guidance be?' cited some recent evidence and discussed the arguments for a precautionary approach

⁴¹ Review of the Fetal Effects of Prenatal alcohol exposure, Rpeort to the Department of Health, May 2006 by Ron Gray and Jane Henderson, National Perinatal Epidemiology Unit, University of Oxford is a comprehensive discussion of the evidence of prenatal harm up to that date

Evidence on low levels of consumption

99. Studying the effects of low levels of alcohol on the fetus is difficult, not least because women will not know they are pregnant at the earliest stages. Relevant good quality studies are few.⁴² Hence, despite little evidence of harm from low levels of drinking, it is not possible to say that such drinking carries no risks of harm to the fetus at all. It is plausible scientifically that alcohol, even at such low levels, could cause some harm.

100. For any woman who has drunk at low levels during the early stages of pregnancy, the risk of harm to their own baby is likely to be small, so this does not need to be a cause of undue worry.

- 101. Some studies do indicate a moderate level of alcohol may be linked to harms to the fetus:
 - increased likelihood of child behaviour problems following moderate prenatal exposure to alcohol (4-5 units per occasion and no more than 9 units per week)⁴³
 - risks of low birth weight, preterm birth and being small for gestational age were higher if the mother's drinking was more than 1-2 units per day, and rose further with higher levels of drinking⁴⁴
 - drinking more than 1.5 units per day is associated with an increased risk of miscarriage in the first 3 months of pregnancy.⁴⁵

102. Given that these quite low levels of drinking may be linked to certain harms, women who wished to continue drinking would need to be particularly careful to stay below those levels, as it can be easy to under-estimate actual unit consumption. The safer option is not to drink alcohol at all during pregnancy.

Effects throughout gestation

103. Early pregnancy is a period of intense fetal development and structural change, reflected, for example, in the greater risk of birth defects, miscarriage and developmental abnormalities, associated with drinking heavily in the first 3 months of pregnancy. Learning and behavioural disorders that manifest during childhood can be linked particularly to damage caused by alcohol to the baby's brain and central nervous system during this stage of development.

104. Drinking also affects how the brain and body grows and develops throughout the pregnancy and so continued drinking in later pregnancy can contribute to problems with general growth and development and with cognitive and behavioural development.

105. This guidance does not include advice on the effects of alcohol on fertility.

What should women do if they find they are pregnant, having recently drunk alcohol?

106. Women who find they are pregnant have the opportunity to make positive choices on their health and lifestyle that will make the rest of the pregnancy as healthy as possible.

⁴⁴ CMO Alcohol Guidelines Review – A summary of the evidence of the health and social impacts of alcohol consumption reports a recent meta-analysis looking at these effects

⁴² Guidelines for pregnancy: What's an acceptable risk, and how is the evidence (finally) shaping up?, by C.M. O'Leary and C. Bower, Drug and Alcohol Review, Vol 31, No 2, March 2012 includes a discussion of the studies on low consumption

⁴³ O'Leary CM, Bower C, Zubrick SR, Geelhoed E, Kurinczuk JJ, Nassar N. A new method of prenatal alcohol classification accounting for dose, pattern and timing of exposure: improving our ability to examine fetal effects from low to moderate alcohol exposure. J Epidemiol Community Health 2010: 64: 956-62

⁴⁵ A study cited in the 2008 updated NICE guidance on an antenatal care (NICE clinical guideline 62: www.nice.org.uk/ guidance/CG062)

107. For any individual woman who has drunk at low levels during the early stages of pregnancy, the risk of harm to their own baby is likely to be small, and so this does not need to be a cause of undue worry.

108. Any woman concerned about the effects of their drinking in pregnancy should seek advice from their doctor or midwife.

Other general considerations on the proposed guidelines and related advice

Situations where it is advisable not to drink alcohol at all

109. Evidence is clear that there are other situations where it is advisable not to drink alcohol at all, or to exercise special caution for safety reasons, in situations where cognitive ability and physical coordination should not be impaired. Examples of these are:

- before and during driving or cycling,
- before swimming
- generally, before, during, or directly after active physical sport,
- before using machinery, electrical equipment, ladders, etc
- before working, or in the workplace where functioning in work would be adversely affected by alcohol, or
- when taking medication, where alcohol is contraindicated

How clinicians might use new guidelines in public health advice

110. The new guidelines need to be a valuable resource to all types of clinicians, whether they are responsible for the health of populations or individuals. With alcohol impacting over 200 health conditions, clinicians would include (but not be limited to): Directors of Public Health; clinicians in alcohol related specialties; specialists in other areas of health and health care; and generalists including critically those in primary care (including those in pharmacy and other community services). We have outlined below some the uses for the guidelines across these groups but also emphasised the environmental conditions that would be necessary for clinicians to use the guidelines effectively. We feel that throughout the dissemination of the guidelines it is critical this is seen as a process to inform individuals so that they can take informed decisions about their own drinking. It is about empowering the individual and not about the "nanny state". In this context it is key that in the dissemination of the guidelines it is made clear they apply to the reduction of long-term conditions and disability, acute harms and premature death.

Cancer and Alcohol

111. Links between cancer and alcohol consumption are generally poorly understood by the public but, when recognised, appear to have a greater impact than links with other health conditions. Providing information on how alcohol consumption increases risks of cancers, such as breast cancer, would be an important part of the information clinicians use to promote interest in the new guidance. We would suggest that key messages linking consumption to increased cancer risk should be available to all types of clinicians. These messages can be expressed as warnings but may also be expressed in a positive fashion (for example "reducing your alcohol consumption by just xx will reduce your risk of a certain type of cancer by half").

Addressing public misunderstanding about benefits of drinking

112. It is critical that all clinicians are equipped to address public misunderstandings about benefits from alcohol consumption. Clinicians need clear information about how any potential benefits are limited to specific sections of the older population and that for the majority of drinkers there is no evidence of such benefits. Information available for clinicians also needs to clarify that even in those groups where some benefits might results from low-level consumption, maximum gains are typically available when drinking at levels much lower than the new guidelines. Information available for clinicians should also make it clear that a single heavy drinking session (e.g. a bottle of wine in one session) just once a month will wipe out any potential cardiovascular benefits older moderate drinkers may accrue.

Information on Injury and Harms to Others

113. The new drinking guidelines include estimates of harms through injury as well as through acute and chronic disease. For some groups (particularly younger individuals who binge) injuries are a major health risk of alcohol consumption. It is important that this information is understood by clinicians so that risks of injury from alcohol consumption are readily available to the public. Emphasising the harm to bystanders or third parties from drinkers is particularly important in harnessing the guidelines. Harms to others are crucial in countering claims that drinking is a matter for individual choice and that to argue otherwise smacks of a 'nanny state'. In relaying new guidelines it must be clear that individuals drinking may not only hurt themselves but hurt others too and that the costs of tackling health harms caused by drinking (e.g. treatment and crime) fall on everyone. Consequently, the state has a legitimate role in informing the public about the harms caused by alcohol and how to avoid them.

The guidelines are conservative in the estimation of harm

114. It is important that clinicians and the wider public understand that in developing the guidelines the 'health community' have not over-estimated or been overly cautious when assessing risks relating to alcohol consumption. In addressing this clinicians should be aware that many harms to others (the health impacts on one person from another's drinking) are not included in the calculation of the guidelines. Furthermore, guidelines are based on risks of mortality, whereas risks of ill health and disability are evident at much lower levels of alcohol consumption. Overall therefore, the guidelines are likely to be conservative in their estimations of harms.

There is no health case to start drinking if you do not drink or not to quit if you wish to give up

115. Information accompanying the guidelines needs to be clear there is no health case to start drinking alcohol if you do not already drink. Further, there is no health-based reason to continue drinking if you wish to abstain. Even older low-level drinkers (who do not have occasional heavy sessions) can reduce risks of conditions such as cancer through not drinking and can retain any cardiovascular benefits through modest changes in exercise and diet – if they wish.

Clarity that clinicians are themselves adopting the guidance

116. Much in the way that clinicians were early adopters of smoking cessation messages it is important that they show leadership by personally adopting as well as advocating new drinking guidelines. Working with the support of the British Medical Association and the Royal

Colleges in the release of the guidance would be an important part of this. Equally, local NHS employers, such as in hospital Trusts and general practices, should make clear their commitment to drinking within new guidelines.

Who develops the materials for clinicians and others?

117. All materials and messages developed to inform clinicians and for clinicians to use with the general public should be developed without any influence from the alcohol industry or its affiliates. The materials and messages should be developed by public health professionals and will need refreshing regularly to catch and maintain public interest. The absence of industry influence is critical in avoiding commercial interests in the messages and also in ensuring that the materials and messages are viewed by clinicians as being underpinned by evidence and integrity.

A Big Launch Campaign followed by continued promotion

118. If they are to be heard and well understood against a background of regular and extensive promotion of alcohol by industry, the guidelines will need a well-funded launch campaign linked to the messages and materials available to clinicians. Such alcohol campaigns can have good penetration into public awareness over the short-term, but without sustained campaigning their impact dwindles rapidly. The campaign should make use of established media and new social media as well as approaches that harness endorsements by key individuals influential with the target audiences. The campaign should be long-term (at least three years in the first instance), should include the ability to renew and refresh messages, make use of partners' websites from a wide range of the organisations and include evaluation elements.

Equity of Health Information with Alcohol Promotion

119. While public funding is essential to support the initial campaign to launch and promote the new guidelines, it is unlikely that this will be sustainable in the long term. Health warnings, developed alongside the guidelines, should appear on all alcohol adverts at a stipulated size and proportion of the advert size. The evidence behind this approach has been well established with tobacco. Such health warnings building on the guidelines should feature on billboards, newspaper and magazine, television, web-based outlets and all other promotional media. Equally, consistent messages (developed and monitored independently from industry) should appear on all alcohol products again at stipulated sizes, colours and positions to ensure that health messages and guidelines are prominent. Sponsorship linked with alcohol should also carry the same stipulated health warnings.

Pregnancy and Underage Drinking

120. The principles of independence from industry influence (outlined above) should also be applied to the specific guidelines for pregnancy and those under 18 years of age.

Midwifery and Maternity Services in a leadership role

121. For pregnancy guidelines, there is a clear leadership role for individual health professionals such as midwives who need organisationally and individually to show commitment to the guidelines.

How might guidelines support changes at the community and population level, e.g. through social marketing campaigns?

Marketing Insights

122. Marketing is first and foremost a philosophy which places the customer at the heart of the business process. A premium is therefore put on researching public desires, motivations and behaviour, recognising that these will have both rational and emotional dimensions. In addition, marketers pay attention to the macro environment because they know that systemic drivers also have a big impact on customer behaviour.

123. The new drinking guidelines, for example, may influence alcohol industry consumer and stakeholder marketing campaigns.

124. In addition the last two decades have seen marketers put an increasing emphasis on building long term customer relationships (for example through branding, loyalty schemes and store cards) and on partnership working and co-creation.

125. Social marketing can genuinely cater for people's real needs, work in partnership with them to raise awareness and help generate support for a range of policies and interventions that enable the co-creation of better health. The new drinking guidelines can be an important building block in this approach.

Helping people decide

126. The aim of the new guidelines should be to enable UK citizens to exercise their right to make informed choices about issues that affect their own health.

127. The important new evidence – and hence the need to revise the guidelines – is that we now know that any amount of regular drinking can cause harm. In particular it carries an increased risk of cancer. The good news is that at moderate levels of consumption these risks are low – akin to some other regular or routine behaviours like driving or travelling in a car. The revised guidelines will enable people to make decisions about their alcohol consumption which keep these risks at what they feel is an acceptable level.

Wider campaigns

128. The guidelines have been informed by research with members of the public. We wanted to make sure that their voice was heard along with that of medical science. Guidelines are one important source of objective information which people use to make decisions about their drinking. The research also shows that there is an appetite for clear information on the science about alcohol and its health risks.

129. To help this process we **recommend** that the Government run supportive social marketing campaigns. As with the guidelines themselves these should be developed in collaboration with the public.

The possible use of new technology to help people understand risks and keep track of their own drinking

130. There appears to be very little or no evidence for effects of digital alcohol interventions on moderate or low risk drinkers. Most research concerns digital interventions for those 'increasing risk' or 'higher risk' drinkers, who wish to reduce their drinking. There is also very little research on maintaining low risk levels of drinking.

131. Professor Eileen Kaner, a member of the guidelines development group, has written a short briefing paper on *'Effectiveness of, and engagement with, digital alcohol interventions to reduce heavy drinking'*. This is <u>Annex C</u> to this report.

Should we continue to use the current UK unit of alcohol?

132. 'Units' or 'standard drinks' are widely used internationally as a common measure of the alcohol in any drink. The definition of a unit varies from country to country. Unit content is determined by the alcoholic strength and the size of any drink. In the UK, a unit contains 8 grams or 10 millilitres of pure alcohol.

133. The group has been made aware of evidence from work by Stirling and Sheffield Universities on public understanding that:

- awareness of units is high
- ability to measure and count intake is poor: a self-pouring exercise showed that consumers regularly underestimate the unit content of self-poured drinks and so underestimate their intake from in home drinking
- when measuring their intake, consumers tend to think in terms of containers rather than units or volume (ml) e.g. they count the number of pints / glasses / cans / bottles / fractions of a bottle (wine or spirits)
- 134. We also understand from previous surveys by the ONS⁴⁶ that:
 - most people have heard of units
 - about two thirds of the population can roughly state the units in standard strength beer and spirits; less than one third can state this for wine, when asked
 - only 13% of people say they monitor their unit intake

135. Since 1998, voluntary agreements with UK industry have included unit content on the labels of most alcoholic drinks. 49% of people surveyed in 2009 said they have seen this content on labels, when asked.⁴⁷

136. When 'units' first began to be used widely in the UK in the 1980s, it was a little easier to relate this to common alcoholic drinks. This has become more difficult over time, as:

- alcoholic strength of most wine has increased
- there is a wider variety of strength in other products, e.g. more high strength beers and ciders than 30 years ago, and, to some degree, more low strength beers
- there is a wider variety of mixed drinks, e.g. spirits mixed with non-alcoholic drinks, which make it harder to estimate alcohol content
- the trend towards more drinking of alcohol at home is an important factor; it was only in the year 2000 that for the first time more than half of alcohol was drunk at home in the UK;⁴⁸ currently, about two thirds of alcohol is drunk at home

137. There appears to be no simple solution and no easy way to make drinks more standard in strength and size. If there is a better alternative to the UK unit, we have yet to hear of it. We are aware of discussions as part of the EU Joint Action on Alcohol and Health, which may consider a possible standard EU-wide unit. If this is to aid public understanding, rather than causing more difficulties, it is vital that this work takes account of differing consumer practices and understandings across Member States.

⁴⁸ British Beer & Pub Association Statistical Handbook, 2014

⁴⁶ Drinking: adults' behaviour and knowledge in 2009: Office for National Statistics and NHS Information Centre for Health and Social Care, Opinions Survey Report No. 42

⁴⁷ Drinking: adults' behaviour and knowledge in 2009: Office for National Statistics and NHS Information Centre for Health and Social Care, Opinions Survey Report No. 42, Table 5.7

138. We **recommend** that the Government makes renewed and sustained efforts to educate the public about unit content of common alcoholic drinks. Former Government campaigns such as 'Know Your Limits' included some good practice examples.

Annex A

Review of Alcohol Guidelines

Guidelines Development Group Terms of Reference

Taking account of the summary conclusions and reports from the Health Evidence Expert Group and the Behavioural Expert Group and the decisions made by the UK CMOs Oversight Group, the Guidelines Development Group should inter alia:

• Provide initial advice to the UK CMOs Oversight Group on an appropriate methodology for developing lower risk alcohol guidelines for adults.

Based on the UK CMOs Oversight Group's decision for a methodology, the Guidelines Development Group should:

- Advise what lower risk guidelines should be and how they should be framed for adult alcohol consumers in the UK.
- Advise on guideline limits for consumption and a narrative as a basis for public health messages, taking account of both the Health Evidence Expert Group's reports on the science on health risks from alcohol and the Behavioural Expert Group's report setting out principles for such guidelines.
- Examine any evidence on the most effective communication methods for guidelines how to express risks and advice ('do vs. 'don't,' immediate vs long term risk, etc).
- Consider how clinicians might use new guidelines in public health advice.
- Consider how new guidelines might be mediated by industry.
- Consider how guidelines might support changes at the community and population level, e.g. via social marketing campaigns.
- Consider the possible use of new technology to help people understand risks and keep track of their own drinking.
- Consider how guidelines might be best framed to support behaviour change in line with the principles recommended by the Behavioural Expert Group.

Based on the request by the UK CMOs Oversight Group for further advice on guidelines on alcohol and pregnancy, the Guidelines Development Group should examine the differing approaches within the UK; taking account of the Health Evidence Expert Group's conclusions, the Group is asked to advise on how far a possible approach harmonised across the UK would be justified based on evidence of health risks and any evidence of behavioural impacts.

Secretariat and support

The Department of Health's Alcohol Policy Team provides a secretariat to the Guidelines Development Group and administrative support to the two co-chairs.

The Department will provide or commission additional evidence on matters such as public understanding, where required, subject to resources being available.

Public Health England provides support to the Guidelines Development Group by carrying out work to review the scientific evidence and to model how this should be reflected in different approaches to possible new guidelines, where this is commissioned by the Group.

The Department of Health and Public Health England will work together to support the Guidelines Development Group.

Annex B

Members of the Guidelines Development Group and additional experts consulted

Guidelines Development Group

Joint chairs

Sally Macintyre, Professor Emeritus, University of Glasgow

Mark Petticrew, Professor of Public Health Evaluation, London School of Hygiene & Tropical Medicine

Members

Mark Bellis, Director of policy, research and international development, Public Health Wales

Chris Day, Pro-Vice-Chancellor, Faculty of Medical Sciences and Professor of Liver Medicine at Newcastle University

Ian Gilmore, Chair of the Alcohol Health Alliance

Gerard Hastings, University of Stirling, Director of the Institute for Social Marketing

John Holmes, University of Sheffield, School of Health and Related Research (no longer a member after September 2014)

Eileen Kaner, Professor of Public Health and Primary Care Research, Newcastle University

Mike Kelly, Director of the Centre for Public Health, NICE (retired from NICE and no longer a member of the group from the end of December 2014)

Una Canning, NICE (after December 2014)

David Leon, Professor of Epidemiology, London School of Hygiene & Tropical Medicine

Theresa Marteau, Director of the Behaviour and Health Research Unit, University of Cambridge

Vivienne Parry, freelance science journalist and broadcaster

Additional experts consulted

Colin Angus, University of Sheffield, School of Health and Related Research

Linda Bauld, Professor of Health Policy, Institute of Social Marketing, Stirling University

Ron Gray, Director of the National Perinatal Epidemiology Unit

John Holmes, University of Sheffield, School of Health and Related Research (after ceasing to be a member of the group)

Melanie Lovatt, University of Sheffield, School of Health and Related Research

Petra Meier, University of Sheffield, School of Health and Related Research

David Spiegelhalter, Winton Professor of the Public Understanding of Science at Cambridge University

Annex C

Effectiveness of, and engagement with, digital alcohol interventions to reduce heavy drinking – a short briefing paper by Professor Eileen Kaner, Chair of Public Health & Primary Care Research, Newcastle University

Background

1. There appears to be very little or no evidence for effects of digital alcohol interventions on moderate or low risk drinkers. Most research concerns digital interventions for those 'increasing risk' or 'higher risk' drinkers, who wish to reduce their drinking. There is also very little research on maintaining low risk levels of drinking.

2. A proven strategy for reducing heavy drinking across populations is to offer brief intervention delivered by GPs, nurses or other generalist practitioners. A Cochrane review of 22 high quality trials found that brief interventions in primary care were effective (compared to controls) at reducing heavy drinking; with an average reduction of 38 grams or 4-5 UK standard drink units per week (Kaner et al. 2007). Indeed there are now over 56 brief intervention trials which have consistently produced positive outcomes (O'Donnell 2013) when delivered by a range of practitioners (Sullivan et al 2011) and they are cost-effective alcohol risk reduction strategies (Purshouse et al. 2013).

3. Brief alcohol intervention typically consists of a screening process, to identify individuals who are experiencing alcohol-related risk or harm, followed by structured advice or motivational counselling of 5-60 minutes to provide: personalised feedback on alcohol use and harms; identification of high risk situations for drinking and coping strategies; suggestions of ways to maintain motivation for positive behaviour change; and the development of personal plans to help reduce drinking levels, patterns or problems. Whilst there are clear benefits of face-to-face brief alcohol interventions, actual delivery rates in health systems are low as practitioners have limited time and other priorities (O'Donnell et al 2013). In addition, some groups of excessive drinkers are reluctant to seek help or simply too busy to attend health services.

4. Recent technological innovation allows people the opportunity of seeking health information directly via computers, mobile devices or smartphones (Khadjesari 2011). Moreover, digital interventions may appeal to some groups who tend not to present to health services, such as young people (Kaner & Bewick 2011) or those busy at work (Khadjesari et al. 2015). A research overview in 2012 (Kaner 2012) identified 35 digital alcohol intervention trials in a rapidly growing field covering a wide ranging contexts (Carey 2009; Khadjesari 2011; Rooke 2010) and sometimes multiple health behaviours (Webb et al. 2010). Digital interventions tended to produce positive, small effects, especially when compared to weak control groups (e.g. no input or assessment only) although they rarely out-competed active comparators (e.g. face-to-face input). No adverse effects of digital interventions have been reported.

5. Four more systematic reviews of digital alcohol interventions were published in the last three years (Bhochhibhoya et al. 2015; Dedert et al. 2015; Donoghue et al. 2014; Riper et al. 2014). The most recent review included 28 unique trials focused on adults and college students who were excessive drinkers or who had alcohol problems (Dedert et al 2015). This meta-analysis reported small reductions in alcohol consumption of around one drink per week at six months but not at 12 months; there was also no statistically significant effect on drinking

within recommended guidelines in adults or on binge drinking or social consequences of alcohol use in students. This review included just one mobile phone (App-based) intervention.

6. An additional Cochrane review, funded by the NIHR School of Public Health Research, is due to complete in September 2015 (Kaner et al. 2015). This includes 55 outcome focused trials with more App-based work (Kaner et al. 2015) plus a linked systematic review focused on user engagement (Beyer et al. 2015). In the engagement review, 8 qualitative studies explored views about digital alcohol intervention in: students (Fraeyman et al 2012; Nygaard and Paschall 2012); rural and urban community groups (Kay-Lambkin et al 2011; Gorman et al 2013); US veterans (Lapham et al 2012), pregnant women in prenatal clinics (Witbrodt et al 2007); disadvantaged Scottish men accessing mobile phone input (Irvine et al 2012); and general practice patients (Goodyear-Smith et al 2013). Overall digital interventions were perceived as useful initial step within a larger therapeutic process. Despite the heterogeneity of the groups, all studies reported positive engagement with digital interventions:

I found the results of the test interesting because I had a score of 7. A score of 8 would have put me in the second risk category. That made me think for a second: "maybe I should be aware..." Because I expected a lower score. (Fraeyman et al 2012)

"It's good! It kind of scares you straight for a little bit. You don't normally see this, you just think, Oh a couple of drinks, but you know, really, health-wise it's a lot of calories. It hurts your health and your baby, it's sad. But our generation or people that live around here, and who probably didn't know they were pregnant, are out drinking." (Gorman et al. 2013)

I liked this page, because I was like "Oh my god" (laughs). Cause I just didn't realize. . . putting it on the most that you drank in one night, I was like, "Wow, remind me not to do that very often." I'll think about that a lot more. (Lapham et al 2012)

7. Privacy and anonymity were key facilitators of user engagement.

"I just had a thought, you are from a small town ... there is a privacy thing, everyone knows everyone, if you are in the waiting room, somewhere, you really don't want someone to see you in a waiting room somewhere... it is the privacy thing of the internet, you know at least getting some of the idea, getting started..." (Kay-Lambkin et al 2011)

"I think if it was private and the information was solely provided to the individual. . .you might have a better impact on that individual. . .for them to be more open and truthful about themselves." (Lapham et al 2012)

"I think it's good [that it's Web-based] because some people would maybe be embarrassed to enter some information to a stranger, and about their family history, some people get weirded out." (Gorman et al. 2013)

8. Receiving personalized feedback about alcohol-related behaviour was also felt to be important.

I remember the blood alcohol content meter thing, you type in numbers and it tells you like what your blood alcohol content would be. (Nygaard and Paschall 2012)

"I was appalled at how much calories I had consumed. . .it was just like 'Oh, geez."" (Veteran G) (Lapham et al 2012)

Conclusion

9. Digital alcohol intervention tend to produce small, positive effects in recipients although these may not persist over a longer time period. No adverse impacts of these interventions have been reported. Whilst digital intervention rarely out-perform interventions delivered by practitioners, they are relatively inexpensive (once developed) to deliver at scale. Early user engagement findings have highlighted that digital interventions are seen as useful and broadly acceptable to a range of users. These interventions may be most appealing if they ensure anonymity, provided personalized feedback about alcohol-related risk, practical strategies to reduce drinking behaviour and signpost additional resources.

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