



Department
of Health

Post-consultation Addendum to the Guidelines Development Group Report

August 2016

Introduction

The Chief Medical Officers (CMOs) were quite clear in the scope they set for their consultation, that they were seeking views on the clarity, expression, and usability of the guidelines by members of the public. They were not consulting on the evidence reviewed by the expert group, or on the modelling commissioned on their behalf. The rationale behind this decision was that it is critical that the new guidelines make sense for the public and that the explanations need to be as clear and comprehensible as possible. It was also based on the decision that it was right to take the very thorough reviews of the scientific and behavioural evidence, already completed by the various expert groups between 2013 and 2015, as the basis for the new guideline recommendations.

This position was supported subsequently by the fact that no issues were raised during the consultation regarding the evidence underpinning their recommendations to the CMOs which caused the Guidelines Development Group (GDG) to change their advice. It was apparent, however, that some respondents felt the rationale for the recommendations had not been explained sufficiently clearly in certain important areas.

The GDG has, therefore decided to provide a narrative to respond to queries and criticisms received since the guidelines were published. These are set out on the following pages.

The process of developing the guidelines

1. The work of the Guidelines Development Group (GDG), and the Health Evidence and Behavioural Expert Groups

The review of the alcohol guidelines was announced in the Government's Alcohol Strategy published in March 2012. The strategy stated that the review would also take account of the available science on how we can best communicate the risks from alcohol, improving the public's understanding of both personal risks and societal harms.

The review began in 2013 when two Expert Groups (the Health Evidence, and Behavioural, Expert Groups) were established to support the CMOs of England, Northern Ireland, Scotland, and Wales in a review of the alcohol guidelines. The task of these two groups was to review the evidence, and to present a summary to the CMOs with recommendations on the development of new alcohol guidelines. The Health Evidence Expert Group was asked to review the evidence on health impacts from alcohol, paying particular attention to whether there was any significant new evidence since the 1995 review. The Behavioural Expert Group was asked to examine the evidence of how the public respond to official public health guidance and to consider the implications for the current alcohol guidelines.

These groups were made of up international experts in the fields of epidemiology, public health, liver disease, behavioural science, science communications and evidence-based alcohol policy. The process is described in more detail below. The full reports from both these groups are available on the Department of Health website.¹ These reports formed the basis for the work of the subsequent Guidelines Development Group which met during 2015-2016 before making its final recommendations to the CMOs.

The GDG included members from the two previous expert groups, and it included similar areas of expertise as those outlined above.

¹ See *Conclusions of the Health Evidence Expert Group* and the *Report from the Behavioural Expert Group* in Folder 1.18 – Summary conclusions and reports – health evidence and behavioural expert groups

2. The strength of evidence

In developing their recommendations, the GDG drew on the comprehensive review of multiple evidence sources and new analyses to reach their overall conclusions. The evidence gathering process involved four strands:

First, the existing evidence from systematic reviews was carefully examined. This included commissioning a thorough new review of the evidence from Liverpool John Moores University. This new review aimed to be comprehensive and included all high-quality systematic reviews and meta-analyses published since the 1995 *Sensible Drinking report* that synthesise evidence from studies of the health and social impacts of alcohol consumption. Thus it examined the evidence on a wide range of impacts, including heart disease, cancers, stroke, liver disease, and many other conditions. It also rigorously examined the evidence on injuries and violence, as well as the effects of alcohol consumption in pregnancy. The review was completed in 2013 and is available on the Department of Health website.²

Second, as well as examining the existing evidence, in 2014 the GDG then asked Public Health England to initiate a competitive tendering process for bids to:

- model the risk of harm to the adult UK population (separately for men and women) from different levels of (i) regular and (ii) single occasion alcohol consumption;
- consider the most appropriate methodologies to use for this purpose, including those used to inform the development of the recent Canadian and Australian lower risk guidelines; and
- consider any advantages or disadvantages in a UK context of relative risk or absolute risk analyses/methodologies, and the implications of these approaches for UK low risk guidelines.

The contract was awarded to the University of Sheffield's Alcohol Research Group. This modelling was itself based on previous meta-analyses (see sections 3-4 below).

Third, the expert group consulted with national and international experts, who advised them on interpretation and use of the evidence and informed the group about any new research which they were aware of. It also consulted the Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (CoC), which was then reviewing the evidence on the consumption of alcoholic beverages and risk of cancer.³

Finally, new research on the public understanding and acceptance of the draft guidelines was also commissioned from Public Health England. This showed that the public supported the new guidelines, and did not find them to be 'nannying'. The research also helped improve the wording and presentation of the messages in the new guidelines.

The Sheffield model

3. Did the University of Sheffield's modelling take account of evidence that moderate drinking may be good for people's health?

Yes, the University of Sheffield's modelling does take account of the most recent high quality evidence on both the risks and the benefits to health from alcohol consumption. Much of

² See *Conclusions of the Health Evidence Expert Group* and the *Report from the Behavioural Expert Group* in Folder 1.18 – Summary conclusions and reports – health evidence and behavioural expert groups

³ <https://www.gov.uk/government/publications/consumption-of-alcoholic-beverages-and-risk-of-cancer>

this evidence comes from meta-analyses which are seen as the gold-standard of scientific evidence as they summarise findings from all of the currently available studies on a topic.

The most recent high quality meta-analyses for five illnesses showed evidence of beneficial health effects from moderate drinking and this evidence was included in the model. The illnesses were: ischaemic heart disease (also known as coronary heart disease), ischaemic stroke, haemorrhagic stroke, hypertensive diseases (also known as high blood pressure) and Type II diabetes.

There is a scientific debate about whether the protective effects of moderate drinking are overestimated. To explore the implications of this for their results, the University of Sheffield team undertook a 'sensitivity analysis' where protective effects for the above illnesses were excluded. The results of this and other sensitivity analyses helped the GDG understand how precisely the risks of drinking can be estimated.

Further information on how the GDG addressed potential protective effects of moderate drinking is provided in the response to Question 5 below.

4. The University of Sheffield's modelling did not use evidence from studies of all-cause mortality. Why?

The University of Sheffield's modelling focuses on the relationship between alcohol consumption and risk of death from 43 health conditions (e.g. alcoholic liver cirrhosis, motor vehicle accidents and breast cancer).

Some consultation responses asked why these health conditions were examined separately rather than within an all-cause mortality approach which simply looks at the overall risk of death irrespective of health condition. An example of an all-cause mortality approach is the 2006 meta-analysis by Di Castelnuovo et al⁴ which was referred to in some consultation responses.

Both the condition-specific approach and the all-cause approach are well-established scientific methods. However, the University of Sheffield used the former for the following reasons:

- **Better understanding of the risks of different drinking patterns:** All-cause mortality studies cannot separate risks for chronic conditions associated with alcohol consumption over several years (e.g. alcoholic liver cirrhosis, breast cancer) from risks for acute conditions associated with short-term intoxication (e.g. alcohol poisoning, injuries). Separating chronic and acute risks allowed the expert group to understand how the effects of drinking varied if people consumed 14 units on one day a week compared to two units on every day of the week. It also better reflects how drinking patterns differ by age and gender in the UK.
- **Better understanding of the risks faced by different age groups:** The alcohol-related risks faced by those aged under 30 are very different to those aged over 50. More of the risk for the under-30s is from acute health conditions (e.g. falls, injuries, alcohol poisoning) while the risk for over-50s is more strongly connected to chronic health conditions (e.g. cancers, heart disease, liver disease). Modelling each health condition separately allowed the GDG to better understand how the risks of drinking differ with age.

⁴ Di Castelnuovo A, Costanzo, S, Bagnardi V, Donati, MB, Iacoviello, L, de Gaetano, G. Alcohol dosing and total mortality in men and women: an updated meta-analysis of 34 prospective studies. Arch Intern Med. 2006 Dec 11-25; 166(22) : 2437-45 (<http://www.ncbi.nlm.nih.gov/pubmed/17159008>)

- **Evidence that is tailored to the UK:** The percentage of total deaths resulting from each health condition differs between countries for a wide range of reasons. For example, if people in the UK are less likely to smoke and have better diets than people in other countries, then they are less likely to die of heart disease, all else being equal. This means that when the overall risk of death from alcohol consumption is calculated for UK drinkers, heart disease will be less important in the calculations than it would be in other countries. Similar arguments can be made for other health conditions which are caused by several different factors including alcohol (e.g. cancers, diabetes and injuries). Examining each health condition separately more accurately reflects the conditions people die from in this country and, like accounting for drinking patterns, allows the model to provide evidence that is tailored to the UK.
- **All-cause mortality studies can have problems:** All-cause mortality studies do not distinguish between deaths caused by alcohol and deaths not caused by alcohol. This can lead to the risks of drinking being under-estimated or over-estimated. For example, smoking causes lung cancer while alcohol consumption does not; however, many smokers are also heavy drinkers. If an all-cause mortality study does not properly control for this co-occurrence, it will overestimate the risks of alcohol consumption as some deaths from lung cancer will be assumed to result from alcohol use. As drinking is correlated with a wide range of health-promoting and health-harming factors, it is very difficult to solve this problem satisfactorily. However, looking at each health condition separately does improve the situation as it allows the exclusion of any deaths that could not possibly be caused by alcohol.

The above arguments do not mean that all-cause mortality studies are inherently flawed or that the Di Castelnuovo meta-analysis is suspect. They simply mean that, in this instance, the condition-specific approach used by the University of Sheffield was more appropriate.

The conclusions drawn in the report and the basis for the recommendations

5. The evidence that moderate drinking may be good for people's health appears to be downplayed. Why?

In producing their report and recommendations, the GDG took account of evidence that moderate drinking may reduce risks of death, particularly from ischaemic vascular diseases (e.g. heart disease). However, the group also took account of a large body of evidence demonstrating that these potential benefits of moderate drinking are likely to be overestimated due to the limitations found in most studies of the long-term health consequences of alcohol consumption.

These limitations include:

- classifying former heavy drinkers as abstainers (because studies typically only ask about current drinking levels);
- restricting who is eligible for inclusion in such studies;
- problems with how alcohol consumption is measured; and
- comparing the risks of alcohol consumption against the risks of abstaining when non-drinkers often have very different characteristics to drinkers (including abstainers having poorer health for reasons unrelated to alcohol and also being of lower socio-economic status).

The GDG considered this evidence alongside modelling by the University of Sheffield which included protective effects for five health conditions but weighed that evidence against the alcohol-related risks of mortality from other health conditions. After doing so, the GDG reached two conclusions:

- i. Any benefit to cardiovascular health for moderate drinkers in the UK is largely cancelled out by their increased risk to health from other diseases, and
- ii. Any remaining benefits to health from moderate drinking are small and uncertain.

Some consultation responses asked whether this was a change from the previous guidance on lower risk drinking, issued in 1995. The report on the 1995 guidelines said that the protective effects against ischaemic vascular disease, as understood at that time, did not apply to men under 40 or women pre-menopause. This is partly because there is virtually no heart disease below these ages against which moderate drinking might protect.

As noted above, the consensus of expert opinion has changed in more recent decades as evidence has emerged that the protective effects of moderate drinking, even in older age groups, are likely to be substantially over-estimated due to methodological difficulties in the underlying studies. The GDG took account of this evidence and reflected it in their recommendations.

6. 'Low risk' vs 'no safe limit'

Some consultation responses questioned the emphasis placed on the association between low levels of alcohol consumption and increased risk of cancer, when communicating the guidelines, particularly in the context of the downplaying of any benefits to cardiovascular health for moderate drinkers.

As discussed above, the GDG concluded that although low levels of alcohol consumption may be protective against poor health, the evidence for this is not robust. It also concluded that, since the 1995 review, strong evidence has emerged which shows that alcohol consumption increases drinkers' risk of developing cancers of the mouth, throat, liver, breast and lower digestive system. This is supported by the CoC's recent report on consumption of alcoholic beverages and risk of cancer.⁵

This increased risk is small at low levels of alcohol consumption but increases as the amount of alcohol consumed goes up. The aim of the new low risk drinking guidelines is to provide information to allow people to make their own judgement about risk so that they can keep their risk at a low level – because these are *low risk* guidelines, not *no risk* guidelines. Highlighting new evidence on the risks associated with cancer and the degree and robustness of any protective effects for overall mortality or cardiovascular disease is part of that process.

7. Why the guideline is now the same for men and women

The evidence has changed and we have a better analysis now than we did in 1995 of the risks of alcohol to health, both short and long term, for men and women. A key difference is that we now have a good analysis of short term risks to health which quantifies the extent to which men, when compared to women, are at greater risk from the short-term harms of drinking. We did not have this analysis in 1995.

The new analyses show that men are actually at slightly greater risk, compared to women, from longer-term harms at around the guideline levels and below. This position is reversed

⁵ <https://www.gov.uk/government/publications/consumption-of-alcoholic-beverages-and-risk-of-cancer>

at higher levels of consumption, from around 21-28 units per week, such that women are at greater risk from long term harms than men. Taking these considerations into account, there is no longer evidence to support a gender difference, and overall, the total health risks for levels of consumption close to the guideline are sufficiently similar that the expert group saw a simple unified guideline for men and women as justified.

8. The UK guidelines in comparison to other countries' advice

Comparisons between countries can be misleading because there are large variations in how different countries define 'low risk' drinking, and even how they define a standard drink.⁶ Comparing alcohol guidelines between countries is therefore problematic.

Guidelines for women tend to be closer to the new UK guidelines. In Europe, guidelines for women in Estonia, Italy, Malta, the Netherlands, Slovenia, Sweden and Switzerland are close to or below the new UK guidelines. Guidelines for men are all higher, with only those for Estonia, the Netherlands, and Slovenia, arguably, close to the new UK ones.

This can, however, be explained in part by the fact that no other European country has carried out a full scientific review of their alcohol guidelines at least in the last ten years. In addition, the basis for guidelines in other countries is not well documented and it may be that other countries have designed their guidelines with reference to different understandings of risk or to achieve different aims when compared to the UK guidelines.

It is important to note that the risk estimates used in the Sheffield model (which informed the new guidelines) are linked to UK-specific consumption and harm data.

9. The risk of cancer

The full extent of the link between alcohol and cancer was not previously understood when the guidelines came out in 1995.

The International Agency for Research on Cancer (IARC) has evaluated alcohol as carcinogenic to humans over recent years through a number of reviews:

- 1988 – oral cavity, pharynx, larynx, oesophagus and liver
- 2007 – all the above confirmed and colo-rectum and female breast
- 2009 – all the above confirmed and pancreas (limited evidence)

The mechanism by which alcohol causes cancer is not fully established, although acetaldehyde – a by-product in the human body from alcohol – is strongly implicated as a possible causative agent, though not necessarily the only one.

The alcohol guidelines review and the CoC have both conducted full systematic reviews of the evidence, including evidence since the IARC's last review in 2009. This includes consideration of the levels of alcohol consumption which cause different types of cancer, including some of the most common cancers. There is an increased risk:

- at low levels of consumption, effectively from any level of regular drinking, for female breast, oesophageal, oral cavity and pharynx cancer, and
- at higher levels for liver and colorectal cancers.

⁶ Kalinowski A and Humphreys K (2016); *Governmental Standard Drink Definitions and Low-Risk Alcohol Consumption Guidelines in 37 Countries*; *Addiction* 111: doi:10.1111/add.13341

The CoC also found a ‘probable’ risk at higher levels for pancreatic cancer. This was not taken into account by the alcohol guidelines review in setting a low risk guideline and is not directly relevant here.

Although a protective effect of alcohol consumption for a small number of less common cancers has been claimed (e.g. kidney cancer), the CoC’s recent report concluded that no biological mechanism has been identified to support the view that alcohol consumption can protect against these cancers. Instead, the CoC agreed with the conclusions of the IARC which state that there is no causal relationship between alcohol consumption and either increased or decreased risk for these cancers.

In summary, the full, systematic review undertaken in developing the guidelines has shown that the risks, for some cancers, start from any level of regular drinking and rise with the amount being drunk. The new guidelines have been set at a level to keep the risk of mortality from cancers or other diseases low. These risks were corroborated by the CoC’s independent report on alcohol and cancer, also published on 8 January 2016.

10. Applying advice on low risk drinking to individual circumstances

The available evidence does not allow robust useful advice to be given on levels of low risk drinking for more specific subgroups of the population, such as those at particular ages or at particular body weights. However, given the use of epidemiological data on risk inevitably leads to an averaging of risks, it is quite reasonable for individuals who wish to maintain a low risk from drinking alcohol to consider whether they may be at a greater risk from their drinking than the average, for a variety of reasons.

Personal common-sense considerations that might affect whether people choose to drink less than the recommended low risk advice, either for regular drinking or for single occasions, can include whether:

- they may already have a health problem that could be affected by alcohol;
- they are on medication that could be made less effective by drinking;
- they have a low body weight;
- they have previously experienced harm from similar alcohol use; and
- they have mobility or other physical problems which could be made worse by alcohol use.

The GDG did not identify a clear association between regularly drinking at low levels and the risk of developing specific mental disorders. However, it is widely accepted that mental health problems can be adversely affected or exacerbated by alcohol use, and that those with mental health problems can also be at increased risk of alcohol use disorders such as dependence. Hence, for people experiencing mental health problems understanding these possible negative effects of alcohol can be important when making choices about their own drinking.

11. Higher risk guidance

The Guidelines Development Group made a recommendation to the UK CMOs that ‘*The Department of Health work with health professionals and experts to review its guidance on higher risk drinking levels, in light of the new evidence underlying this report*’. The Department of Health and Public Health England have agreed to undertake this work at a UK level through

a consensus process in partnership with the Devolved Administrations. The outputs of the process will be published once the evidence has been considered.

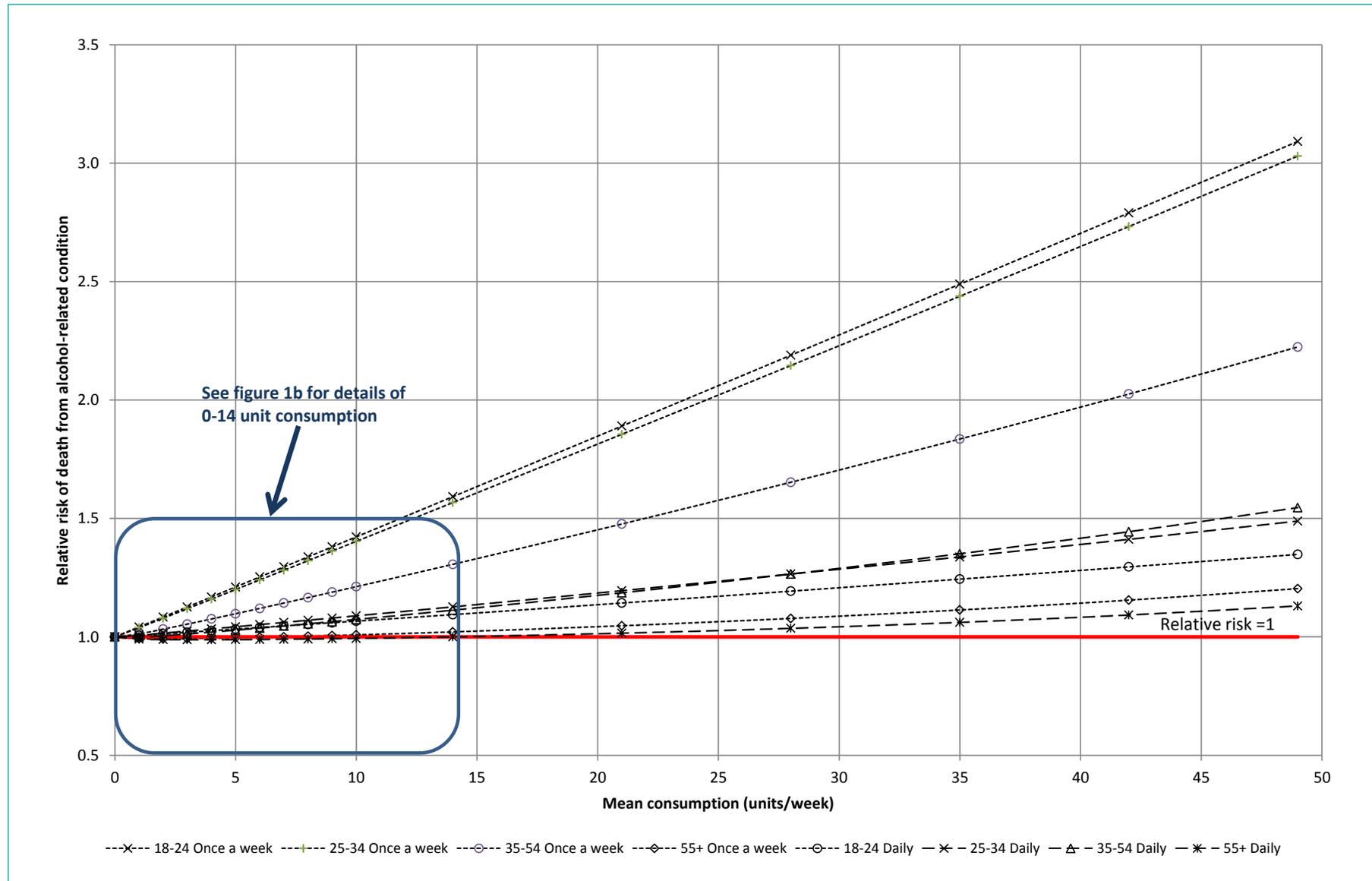
Presentation of the information in the Guidelines Development Group report

12. Clarity of the mortality graphs

There was feedback from a few respondents that the graphs setting out the relative risks of alcohol-related mortality by mean weekly consumption, number of drinking days and age for men and women (page 17 of the GDG report) were not as clear as they could be. The concern was that the quality of the graphs did not enable readers to see how they supported the conclusions of the group, with the different age group lines crossing and obscuring each other.

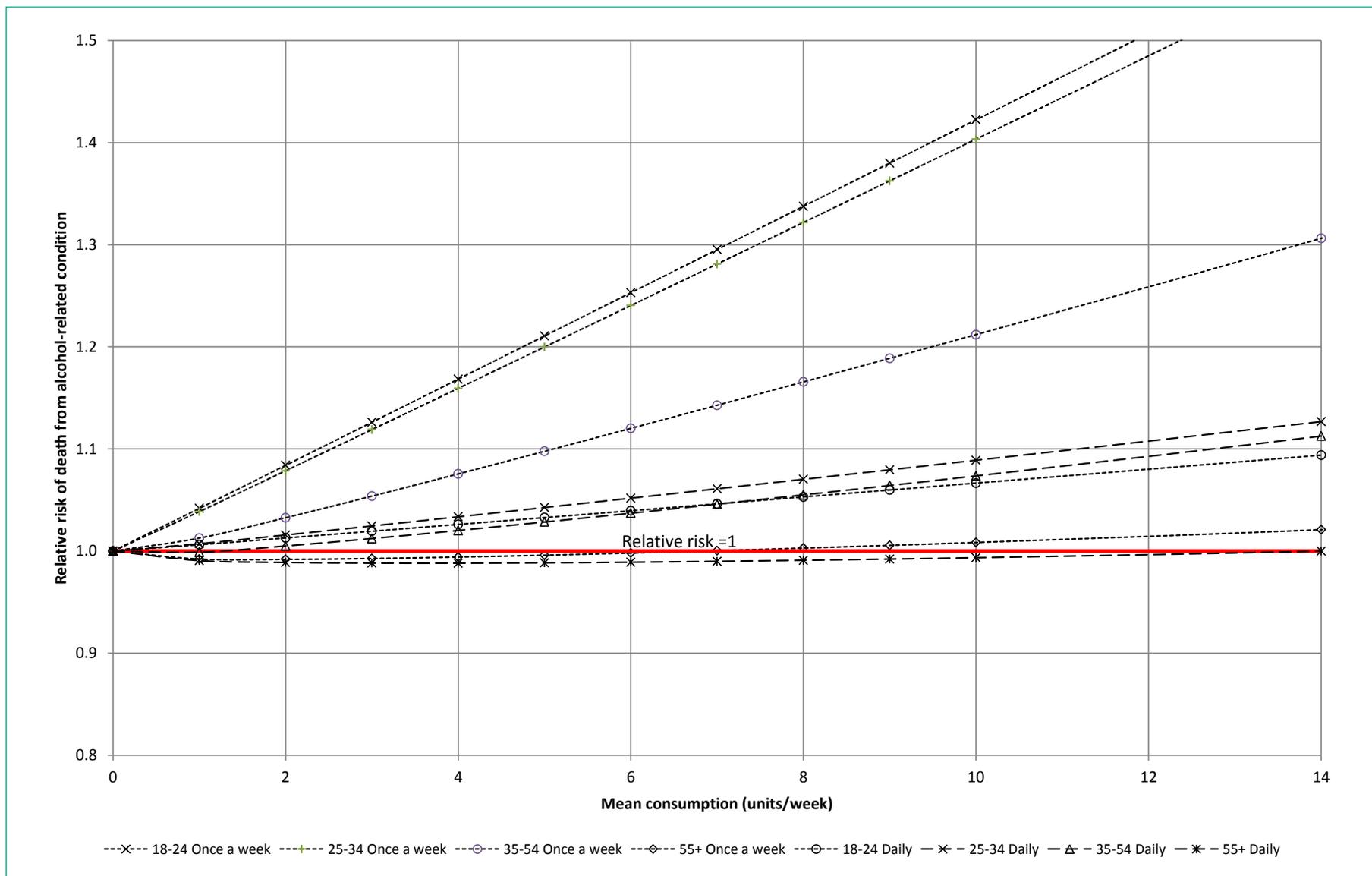
To address this, the graphs have been redesigned and an additional expanded version of zero to 14 units providing more detail in the most critical range.

Figure 1a: Male relative risk of alcohol-related mortality by mean weekly consumption, number of drinking days and age in UK



Source: Sheffield Alcohol Research Group at SchARR, The University of Sheffield

Figure 1b: Male relative risk of alcohol-related mortality when drinking 0-14 units by number of drinking days and age in UK



Source: Sheffield Alcohol Research Group at SchARR, The University of Sheffield

Figure 2a : Female relative risk of alcohol-related mortality by mean weekly consumption, number of drinking days and age in UK

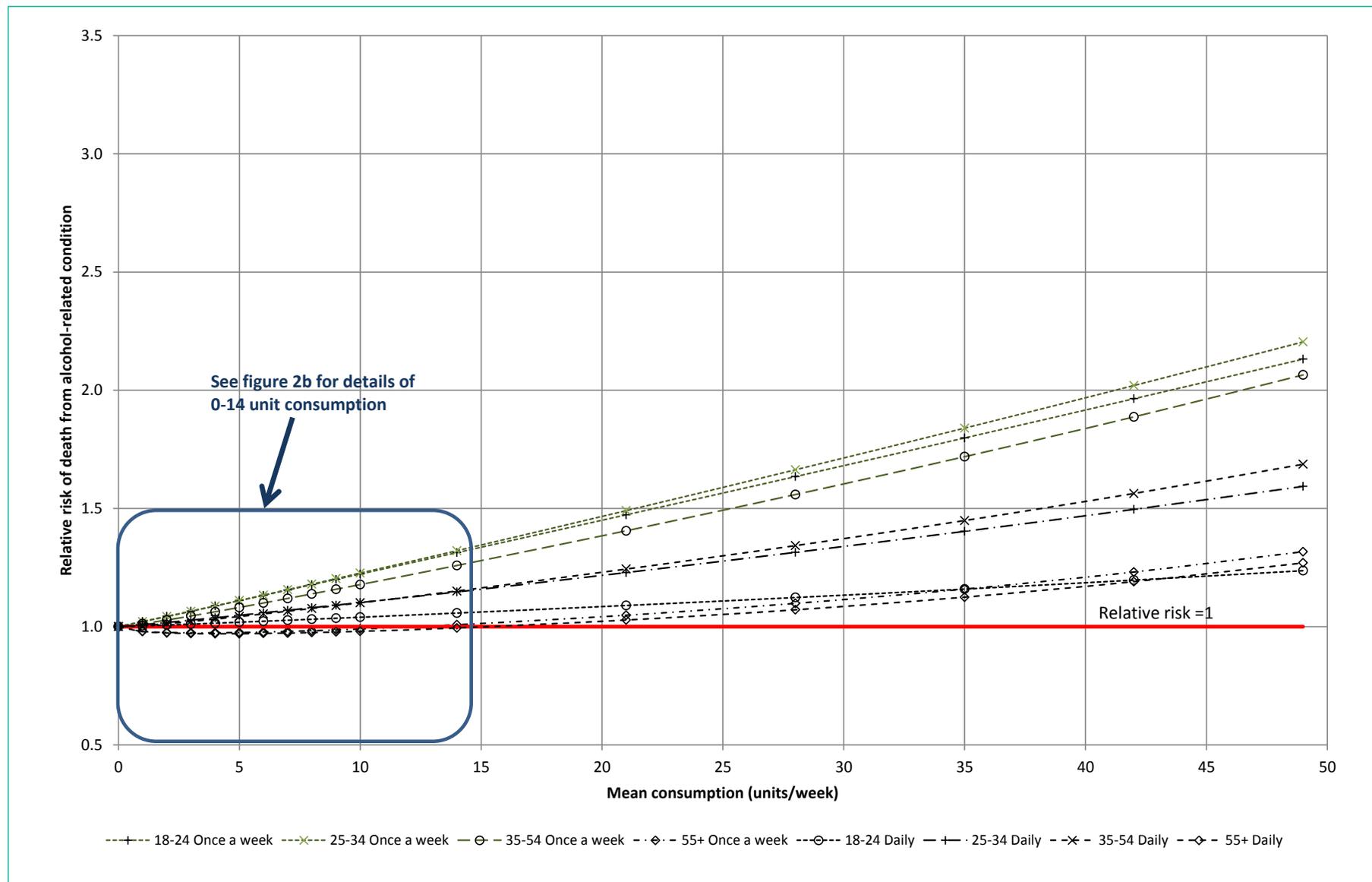
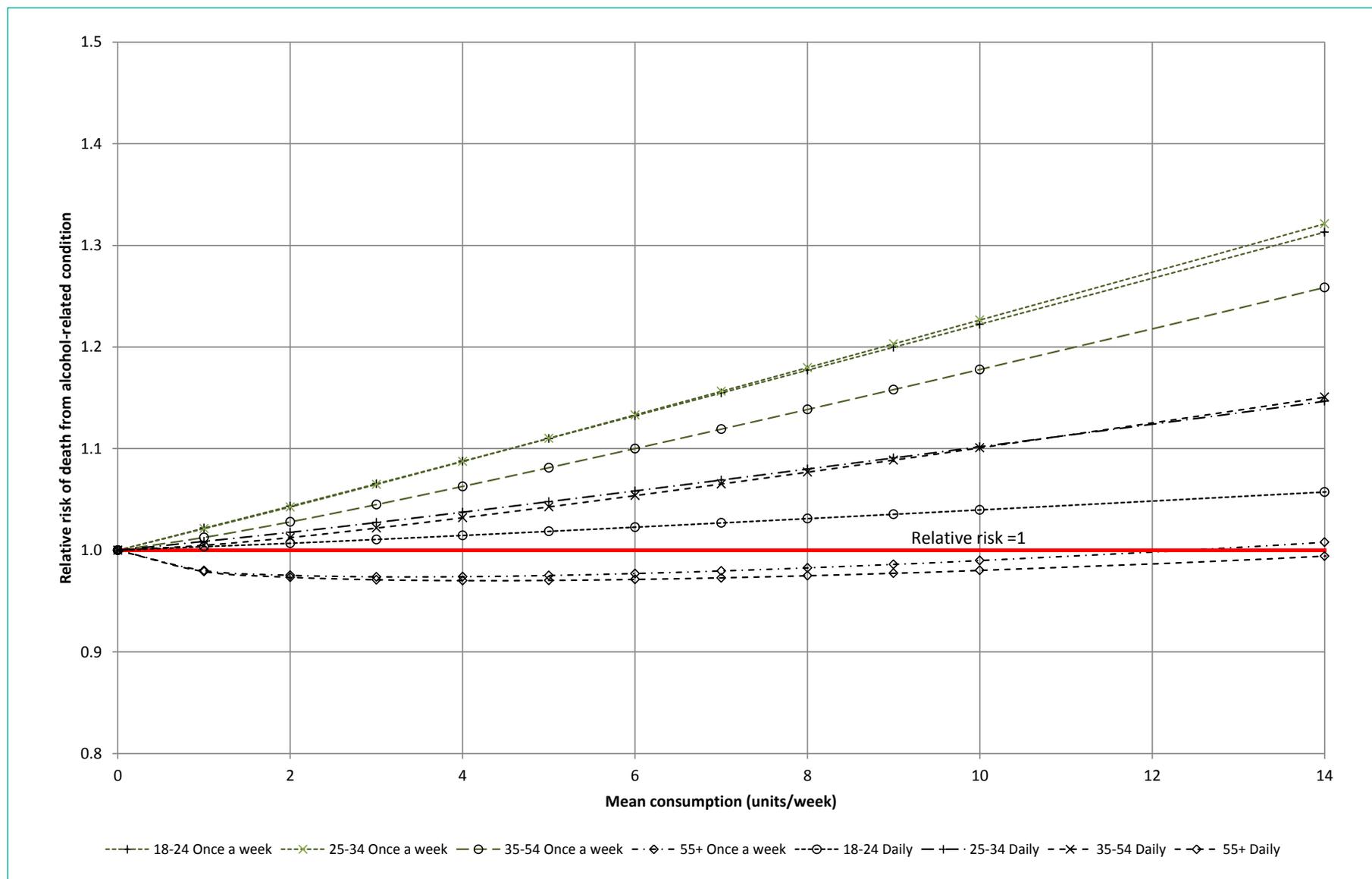


Figure 2b: Female relative risk of alcohol-related mortality when drinking 0-14 units by number of drinking days and age in UK



Source: Sheffield Alcohol Research Group at SchARR, The University of Sheffield



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