

# Low Risk Alcohol Consumption Thresholds

Update on the risks related to alcohol consumption levels, consumption patterns and type of alcoholic beverages

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Part 1. Update on Low Risk Alcohol Consumption Thresholds





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## Document translation

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# Table of contents

<b>Abbreviations</b>	9
<b>Executive summary</b>	11
<b>Introduction</b>	15
<b>Justification</b>	23
<b>Objectives</b>	27
<b>Methodology</b>	29
<b>Summary of scientific evidence</b>	31
1. Health risk assessments and low risk regular alcohol consumption thresholds	31
2. Health risk assessments and low risk thresholds for binge drinking episodes	34
3. Type of alcoholic beverages and their differential health effects	36
<b>Key messages</b>	39
<b>Future challenges</b>	41
<b>Appendix 1. Definitions of interest</b>	43
<b>Appendix 2. Specific subpopulations or special situations</b>	45
<b>Appendix 3. Health system's approach to alcohol consumption</b>	49
<b>Bibliography</b>	51



# Abbreviations

<b>AAD</b>	Alcohol-Attributable Deaths
<b>DALYs</b>	Disability-Adjusted Live Years
<b>EDADES</b>	<i>Encuesta Domiciliaria sobre Drogas y Alcohol en España</i> (Home Survey on Drugs and Alcohol in Spain)
<b>ESTUDES</b>	<i>Encuesta sobre Uso de Drogas en Enseñanzas Secundarias en España</i> (Survey on Drug Use in Secondary School in Spain)
<b>FAS</b>	Fetal Alcoholic Syndrome
<b>FASDs</b>	Fetal Alcohol Spectrum Disorders
<b>IARC</b>	International Agency for Research on Cancer
<b>NHS</b>	National Health System
<b>SD</b>	Standard Drink
<b>SDO</b>	Sustainable Development Objectives
<b>SES</b>	Socioeconomic Status
<b>SHPP</b>	Strategy for Health Promotion and Prevention in the NHS
<b>WHO</b>	World Health Organization



# Executive summary

Alcohol is the highest consumed psychoactive substance in Spain. In 2017, 91% of the country's population between the ages of 15 and 64 reported having consumed alcoholic beverages sometime in their lives (94% of men and 89% of women) and 63% reported consumption in the previous 30 days (72% of men and 54% of women).<sup>[1]</sup> Regular consumption is double among men (one of every two) than women (one of every four).<sup>[2]</sup> Age at first drink is 14 years of age for both sexes.<sup>[3]</sup>

In Spain, alcohol consumption is the 4<sup>th</sup> health risk factor (i.e., contributor to a reduction of Disability-Adjusted Life Years or DALYs), being 2<sup>nd</sup> among women and 5<sup>th</sup> among men.<sup>[4]</sup> In addition, alcohol consumption resulted in 15,489 annual deaths between 2010 and 2017, 74% of those among men.<sup>[5]</sup>

Alcohol consumption is one of the main disease risk factors and the main one among 15 to 49 year-olds. In 2016, 3.8% of female deaths and 12.2% of male deaths were attributed to alcohol consumption worldwide.<sup>[6]</sup> Not surprisingly, given that alcohol consumption contributes to the development of over 200 health problems and injuries, including cardiovascular, liver, neuropsychiatric, and transmissible diseases, among others.<sup>[7]</sup> Additionally, solid evidence supports an association between alcohol consumption and certain types of cancer, including a positive dose-response relationship with the following ones: oral cavity, pharyngeal, laryngeal, esophageal, colorectal, breast (female), and hepatocarcinoma.<sup>[8-11]</sup> Thus, any level of consumption increases the risk. Further, alcohol is an addictive substance which may lead to dependency.

However, the impact of alcohol consumption goes beyond the health of the individual consuming it, since it can also cause damage to third parties (e.g., traffic accidents, violence, Fetal Alcohol Spectrum Disorders [FASDs]) as well as to the economy and the society overall (e.g., unemployment, violent behavior, productivity loss). In addition, the differential distribution of intake as well as its consequences, affects vulnerable groups the most, deepening socioeconomic, ethnic, age, and gender inequities.<sup>[12-14]</sup> In fact, the consequences of alcohol consumption on health as well as on the environment during infancy, may determine the rest of an individual's life.<sup>[12]</sup>

To reduce the damage produced by alcohol consumption is necessary to use a intersectoral approach, according to international initiatives such as the Global Strategy to reduce the harmful use of alcohol<sup>[15]</sup> and World Health Organization (WHO) SAFER initiative.<sup>[16]</sup> Following suit, the Spanish Ministry of Health launched the Strategy for Health Promotion and Prevention in the National Health System<sup>[17]</sup> which includes approaching alcohol consumption as one of the main risk factors for the development of chronic or non-transmissible diseases. Further, the reduction of alcohol-related harm, especially among the youngest, is one of the National Strategy on Addiction 2017-2024.<sup>[18]</sup>

Within the framework of the united European Action to reduce alcohol-related harm (*Reducing Alcohol Related Harm, RARHA*)<sup>[19]</sup> it was confirmed that, as part of their national guidelines, many countries advised the reduction of consumption using the concept of "low risk" consumption, assuming that, for certain cancers, gastrointestinal diseases, and injuries, there is no safe consumption level.<sup>[20]</sup> The majority of low risk consumption thresholds from countries of similar sociocultural environment as ours are, so far, below Spain's recommendations.<sup>[21]</sup>

Therefore, the Ministry of Health, in collaboration with a panel of experts, performed a review of literature of the available evidence by creating three working groups:

- 1) Estimation of the health risks and low risk thresholds for average alcohol consumption
- 2) Estimation of the health risks and low risk thresholds for binge drinking
- 3) Type of alcoholic beverages and differential effects on health

The objective of this document is to update the thresholds for low risk alcohol consumption, in order to reduce health problems, injuries, harm to others, and social and economic consequences attributable to alcohol consumption.

Based on the results and conclusions of this review of evidence, we elaborated the following key messages targeting healthy general population over 18 years of age.

Alcohol consumption	There is no safe level of alcohol consumption. Not to drink alcohol is the only way of avoiding its damaging effects. Based on current scientific evidence, no health professional or institution should recommend its consumption as a way of improving any aspect of health.
Thresholds for low risk average* alcohol consumption	Set at 20 g/d (2 SDs**) for men and 10 g/d (1 SD) for women, acknowledging that any consumption at all carries risk. Consumption of alcohol above these limits is related to a greater mortality risk when compared to abstaining or drinking below the limits. Also, some international guidelines recommend alcohol-free days during the week. This information should be provided to anyone consuming alcohol.
<i>Binge drinking</i> ***	There is no such thing as low-risk binge drinking. Binge drinking is harmful, with consequences for the drinker's health and their social environment. Thus, it must always be discouraged.
Differential effects by type of drinks	Despite containing substances with potential health benefits, epidemiological evidence fails to show wine and beer consumption having any particularly protective health effect such as the reduction of cardiometabolic risk or any other kind. At this point there is no scientific evidence to support the recommendation of certain alcoholic beverages ascribing them differential health benefits.
At-risk alcohol consumption thresholds	Currently, individuals are considered to present at-risk alcohol consumption if they meet at least one of the following criteria:  – AUDIT Questionnaire: > 7 points for men, > 5 for women. – > 40 g/d (4 SDs/day) for men and > 20-25 g/d (2.0-2.5 SDs/day) for women.  When a person reports consumption intakes above those considered at-risk, the health provider will proceed according to the recommendations found in the Ministry of Health's manual Comprehensive Lifestyle Advice in Primary Care, Linked to Community Resources for Adult Populations. <sup>[21]</sup>

\* Average consumption: usual consumption of an individual over a period of time, it usually refers to daily or weekly consumption.

\*\* Standard Drink (SD) of alcohol: In Spain, an SD equals 10 grams of alcohol which is, approximately, the usual content of a 100ml glass of 13% wine, 1 glass of 300 ml of 4% beer, or 30 ml of 40% liquor.

\*\*\* Binge Drinking: consumption of 60 or more grams of alcohol (6 SDs) for men and 40 or more grams (4 SDs) for women in one single occasion (usually lasting between 4 and 6 hours). During the session, individuals maintain certain degree of intoxication (alcohol level 0.8 g/l or above).<sup>[22]</sup>

Specific sub-populations or special situations	<p>No alcohol consumption:</p> <ul style="list-style-type: none"> <li>- Individuals under 18 years of age</li> <li>- Pregnancy and breastfeeding</li> <li>- Driving a vehicle</li> <li>- Doing any other activities requiring concentration or psychomotor skills</li> <li>- Combined with other substances****</li> </ul> <p>It is recommended to avoid alcohol consumption or, at least, consulting a health professional first if:</p> <ul style="list-style-type: none"> <li>- Taking medicines that interact with alcohol</li> <li>- Presence of mental health issues</li> <li>- Family history of alcohol addiction</li> </ul>
Policy Development	<p>Consuming alcohol is not a decision made in a vacuum, but influenced by social determinants of health. Thus, it is necessary to develop coherent and intersectoral public policies supporting environments where healthy choices are the easiest to make.</p> <p>To reduce inequities it is key to design and evaluate campaigns and interventions, considering the social gradient and other factors such as gender. Further, to ensure that policies benefit all social groups, especially the most underprivileged, any tools must tightly define their target population.</p>

In conclusion, not to drink alcohol is the only way of avoiding alcohol-related risks.<sup>[23,24]</sup> Thus, for non-drinkers the recommendation is not to start drinking. If already a drinker, the recommendation is to reduce consumption to at least below the low-risk thresholds, allowing for some alcohol-free days during the week and staying completely away from binge drinking. In other words, if you drink alcohol, “less is better”.<sup>[25]</sup> It is important to underscore that the risk of alcohol consumption is a continuum and that any intake entails certain risk. Therefore, the message of reducing alcohol consumption below the low risk thresholds, must not send the message that this consumption level is risk-free, which may incentivize non-drinkers to start consuming or those drinking below those thresholds to increase intake to match them.

True freedom of choice and reasoned decision-making require having access to true and complete information regarding benefits, risks, costs, and consequences of alcohol consumption to self and others. Thus, the purpose of this document is to provide an update of scientific evidence of all the risks assumed by an individual when drinking alcohol by establishing the threshold of consumption deemed low risk.

\*\*\*\* Any illicit substances should be avoided but, if consumed, combining it with alcohol or with other drugs must be avoided, as the risk for fatal and non-fatal events substantially increases.



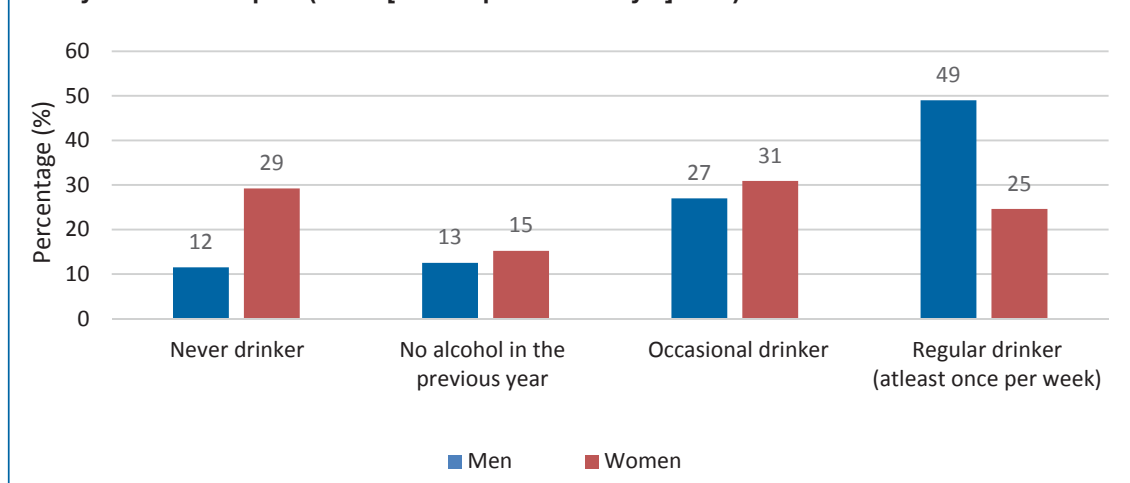


# Introduction

## a) Current situation in Spain

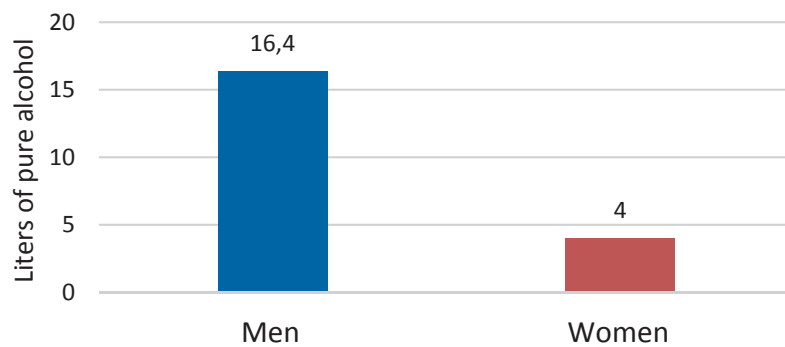
Alcohol is the psychoactive substance with the highest consumption in Spain: In 2017, 91% of the population 15-64 years of age reported having consumed alcoholic beverages at least once in their lifetime (94% of men and 89% of women). Three quarters (81% of men and 69% of women) had drunk alcohol in the previous year and 63% (72% of men and 54% of women) had done so in the previous 30 days.<sup>[1]</sup> Among regular drinkers, twice as many are men (one of every two) as women (one of every four).<sup>[2]</sup>

**Figure 1. Frequency of alcohol consumption in the population aged 15 years and older. National Survey of Health in Spain (ENSE [for its Spanish acronym] 2017)<sup>[2]</sup>**



According to the latest World Health Organization (WHO) report, the 2016 per capita alcohol consumption in Spain was 10 liters of pure alcohol per person per year among those 15 years and older (16.4 liters among men and 4.0 among women). The most prevalent drink was beer (54%) followed by spirits or liquor (28%) and wine (18%). In Europe, the consumption per capita in the same age range was 9.8 liters.<sup>[7]</sup>

**Figure 2. Annual Alcohol per capita (15+) consumption (in liters of pure alcohol) WHO, 2016<sup>[7]</sup>**



Age at first drink is 14 years (for both genders), 76% of youngsters between 14 and 18 years of age reported consuming alcohol in the previous year (74% for men and 78% for women). Further, the vast majority of youth surveyed (95%) believe it is easy or very easy to get access to alcohol,<sup>[3]</sup> even though consumption is banned for those younger than 18 years of age. **These numbers denote that alcohol consumption in Spain is accepted as the norm, even among the youngest and, in addition, the perception of risk associated with its use is the lowest of all other psychoactive substances.**<sup>[1]</sup> Alcohol consumption has historically been considered an intrinsic part of the Spanish culture and strongly associated with Spanish traditions and festivities strengthening the idea that “the normal thing” is to drink and, thus, “it cannot be that bad”. However, one should not forget that behaviors, including those related to health, are learned, spread, and modified by the environment surrounding the individual (e.g., leisure, advertisement, access). Thus, acting upon these mechanisms which shape this learning process is key to preventing alcohol consumption.

**The aforementioned low risk perception is especially stunning regarding binge drinking.** Whereas 9 out of 10 people (89% of men, 93% of women) think that daily consumption of 5-6 drinks may cause many health issues, the sporadic consumption of 5-6 drinks per occasion during the weekend is perceived as a health risk only by half of the population (44% of men and 54% of women).<sup>[1]</sup> Therefore, in addition to warning people about the risks associated to regular alcohol consumption patterns, it is important to inform about the risks associated with binge drinking, defined as the intake of large amounts of alcohol in a short span of time,<sup>[26]</sup> especially over the weekend and among young people. It is especially worrying among minors (32% of 14-18 year-olds have practiced binge drinking during the previous month when defined as drinking 5 or more glasses of alcoholic beverages in about 2 hours).<sup>[3]</sup>

**In Spain, it is estimated that alcohol consumption is the fourth risk factor related to disability-adjusted life years (DALYs), 2<sup>nd</sup> for women and 5<sup>th</sup> for men.**<sup>[27]</sup> Statistics show that in the period 2010-2017 there were 15,489 alcohol-attributed deaths (AAD) in the population aged 15 years or older, 74% of those were men. About 56% of those deaths were premature (i.e., before reaching 75 years of age). Population risk for AAD, measured by annual raw rates (2010-2017), was 39.2 per 100,000 inhabitants and greater among men (59.3 per 100,000) than among women (20.0 per 100,000). Not surprisingly, risk increases substantially with age for both sexes.<sup>[5]</sup>

## B) Consequences of alcohol consumption

**Alcohol consumption is one of the main disease risk factors, contributing to the development of over 200 health problems and injuries, as well as to premature death.**<sup>[7,28]</sup> It is the main risk factor worldwide for the population aged 15 to 49, with 4% of deaths among women and 12% among men considered AAD in 2016.<sup>[6]</sup>

Scientific evidence confirms that alcohol consumption increases the risk of cancer, liver diseases (alcoholic hepatitis, hepatic steatosis or fatty liver, fibrosis, and cirrhosis), psychiatric disorders (depression and suicide), cardiovascular and transmittable diseases (tuberculosis, HVI/AIDS) among others.<sup>[7]</sup> Finally, alcohol is an addictive substance which may cause dependency.

**The relationship between alcohol consumption and cardiovascular risk is complex. Binge drinking increases the risk for heart attacks**<sup>[29]</sup> and consuming 30 g/d of alcohol increases the risk for cardiovascular diseases such as arterial hypertension, atrial fibrillation, alcoholic cardiomyopathy or cardiac failure. Smith and colleagues reported that for doses over 10 g/d for women, or 20 g/d for men, the risk for myocardial infarction (heart attack) decreased by 24% but the risk for cancer increased by 51%.<sup>[30]</sup> Wood and colleagues observed that individuals consuming over 28.5 g/d of alcohol increased their risk for ischemic stroke by 14%, angina by 6%, cardiac failure by 9%, arterial hypertension by 24%, and arrhythmia by 15%. In contrast, they observed a 6% reduction in myocardial infarction.<sup>[31]</sup> The potential protective effect regarding stroke has only been observed with very low alcohol doses and always below 20g/d.<sup>[32]</sup> **Based on the aforementioned results showing a light reduction in mortality by ischemic cardiopathy, the potential cardiovascular benefit derived from alcohol consumption clearly fails to compensate for the increased mortality due to other causes.**

**Additionally, over the previous years, evidence showing an association between alcohol consumption and certain types of cancer has grown. Alcoholic beverages, as well as ethanol and acetaldehyde associated to the metabolism of alcoholic beverages, have been classified as carcinogenic for humans (Group 1) by the International Agency for Research on Cancer (IARC),<sup>[33]</sup> with a clear dose-dependent risk for developing cancers of the oral cavity, pharynx, larynx, esophagus, colon and rectum, female breast, and liver and biliary duct<sup>[8-11,34]</sup> where there is no consumption threshold under which the excess risk disappears.<sup>[11,35]</sup>**

**Table 1. Evidence of the causal association between alcohol consumption and type of cancer (IARC)\***

Degree of Association	International Agency for Research on Cancer (IARC)
<b>Sufficient evidence in humans</b>	Oral cavity, pharynx, larynx, esophagus, colon and rectum, female breast, and liver and biliary duct
<b>Limited evidence in humans</b>	Pancreas

\*Adaptation of the International Agency for Research on Cancer: List of Classifications by cancer sites with sufficient or limited evidence in humans, Volumes 1 to 125a<sup>[36]</sup>

In women, the immediate effects of alcohol take place faster and last longer than in men after drinking similar amounts, this is due, among other factors, to the difference in body composition, metabolism, and alcohol absorption, reaching higher blood concentrations

in women than in men.<sup>[37]</sup> These differences also influence long term health problems in women with a higher probability for liver diseases (with a time period comparatively short and daily consumption level lower than men's),<sup>[38]</sup> greater sensitivity to neuronal<sup>[39]</sup> and cardiac muscle toxicity,<sup>[40]</sup> among others. Also, women present specific risks<sup>[41]</sup> such as breast cancer, infertility, and problems related to alcohol consumption during pregnancy and breastfeeding.<sup>[37,41,42]</sup>

**In addition to the risks to the alcohol consumer's health, there are also damages to third-parties.** These damages may be unintentional injuries such as traffic accidents (in 2018, 27% of the deaths caused by traffic accidents in Spain involved a driver with a blood alcohol level 0.30g/l<sup>[43]</sup> or higher), injuries due to interpersonal (social, domestic, sexual) violence, or harm to a fetus. The latter may include prenatal complications as well as a wide range of disorders such as Fetal Alcohol Spectrum Disorders (FASDs) caused by alcohol intake during pregnancy.<sup>[44,45]</sup>

**Alcohol consumption, especially binge drinking, has additional negative consequences to society** (accidents, physical fights, attacks, vandalism) **and the economy** (property damages, family budget maxed out, work absenteeism, job productivity reduction, increase health care load).<sup>[46-48]</sup> The 2014 assessments for Spain of these alcohol-related social costs amount to 1% of the Gross Domestic Product (GDP) (i.e., over 10,000 million euros).<sup>[49]</sup>

## C) Alcohol Consumption and Inequity

**Also, the combination of factors such as the socioeconomic status (SES), educational level, gender, race/ethnicity,<sup>[50]</sup> or place of residence, among other social determinants of health, amplify the disparities found in the harm associated to alcohol consumption,<sup>[12]</sup> and may moderate them, becoming either strengths or vulnerabilities.**

The relationship between alcohol intake and SES is a complex one.<sup>[14]</sup> Although, at a global level, greater consumption is associated to higher income, at equal intake levels, damages are greater among lower SES individuals. Probably because the social context shapes other environmental exposures and vulnerabilities.<sup>[7,12]</sup> It is also necessary to take into account other factors. For instance, people in disadvantaged social strata may be more likely to participate in other risk factors (smoking, inadequate diet, or sedentarism), may enjoy lower social support from social networks, may underestimate consumption levels, or present differences in consumption patterns.<sup>[13]</sup>

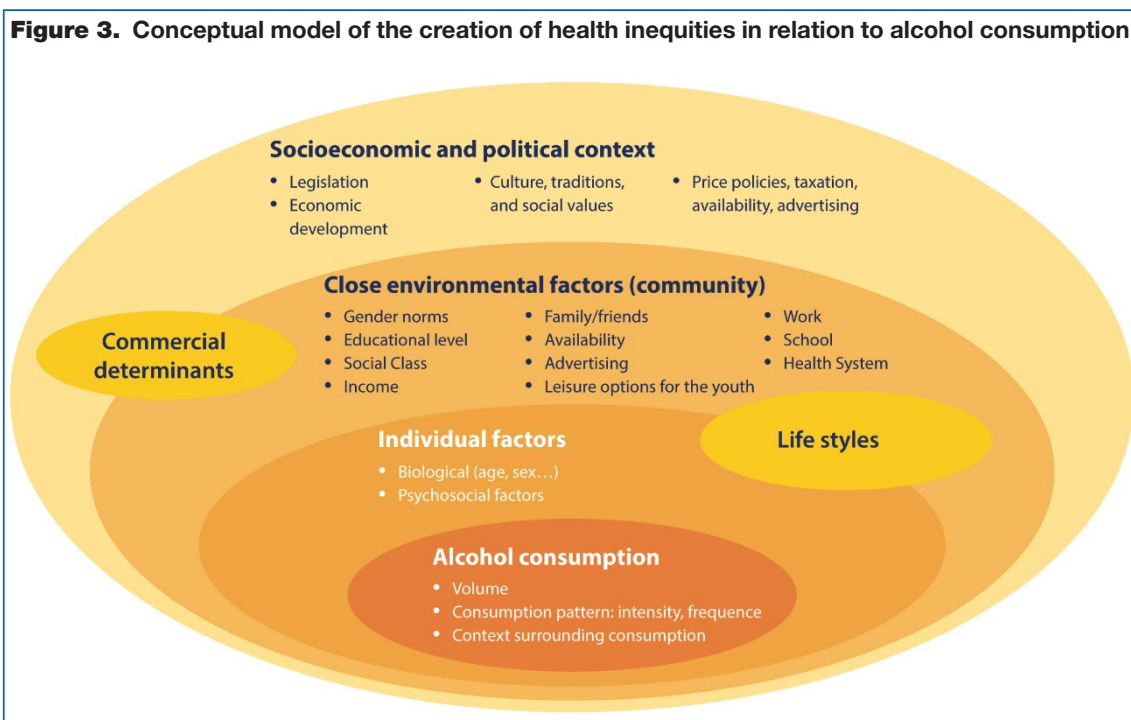
Binge drinking may be a more damaging factor,<sup>[12]</sup> in itself, than the total alcohol consumption. In Spain, the daily consumption is greater for men and women in lower educational and SES groups; however, binge drinking increases as educational level does and for both genders. This is especially remarkable among women, even more than among men.<sup>[13]</sup>

Previous research points to gender roles influencing alcohol consumption, the influence being heavier among men (associated to the traditional masculine role of dominance, risk behaviors, and so on) than among women (linked to the traditional feminine role of family caretaker and home-centered life).<sup>[51]</sup> In Spain adult men consume more alcohol, perceive lower risk related to binge drinking, and are at higher risk for death.<sup>[5]</sup> However, in recent years, the prevalence of alcohol consumption is slightly higher among 14-18 year-old

women. Unfortunately, female alcohol consumption has serious negative consequences as it is one of the risk factors for violence against women.<sup>[52]</sup> At the same time, women victims of domestic or sexual violence are almost twice as likely to endure alcohol consumption-related problems.<sup>[18]</sup>

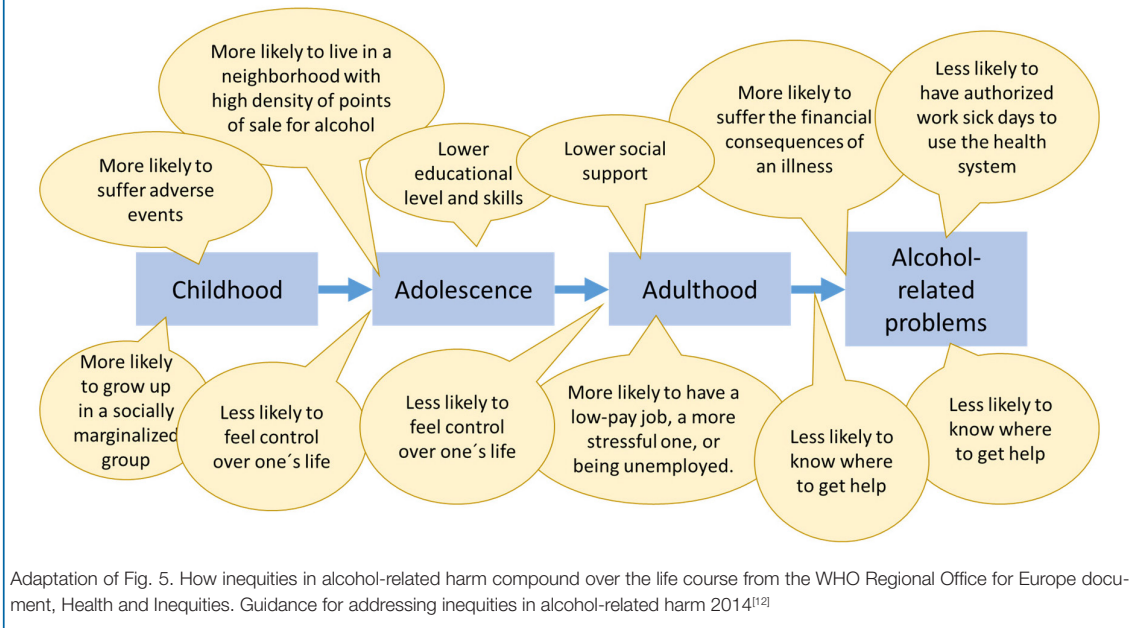
Regarding the influence of the environment (social, urban, and cultural) and its contribution to alcohol consumption, certain factors have been identified as facilitators of alcohol intake, such as greater density of points of sale,<sup>[53,54]</sup> bars and restaurants with easy access to alcohol, product promotion, advertising, low price,<sup>[55]</sup> long store hours, as well as the norms of socialization. These factors, among others, may contribute to the normalization and social acceptance of alcohol consumption.<sup>[55]</sup>

This evidence confirms the importance of designing and evaluating campaigns and interventions taking the social gradient into account as well as accurately defining who the target audience is. All this while ensuring campaigns reach all social groups, especially the more disadvantaged ones, so as to avoid deepening inequalities.<sup>[12]</sup>



Also, it is key to take a life-course perspective when approaching alcohol consumption, taking into account its influence on all developmental levels: during pregnancy, childhood, adolescence, and so on, moderating lifestyles, including alcohol consumption, with an impact that may shape a lifetime, even affecting future generations.<sup>[12]</sup>

**Figure 4. How inequities in alcohol-related harm compound over the life course in Spain**



There is also another key concern when it comes to alcohol consumption, the commercial determinants of health, defined as strategies used by the private sector to promote products and choices that are harmful to our health.<sup>[56]</sup> These determinants play a fundamental role in the social context and individual lifestyles; thus, affecting health at the population-level.<sup>[57]</sup> A clear example is the sponsorship of sports events.<sup>[58]</sup>

## D) Alcohol consumption prevention

**It is important to underscore that alcohol-related damages, to individuals as well as to third parties and society as a whole, may be prevented avoiding alcohol consumption, or may be at least ameliorated by reducing overall intake and binge drinking.**

Many people are under the impression that certain alcoholic beverages obtained through fermentation, versus those obtained through distillation, lower their risk for certain pathologies, especially cardiovascular ones, due to the polyphenol concentration in those beverages. However, this is highly misleading as any potential cardiovascular benefit would be far from compensating the harm caused by the combination of damages associated to its consumption.

During the COVID-19 pandemic, there have also been attempts at granting alcohol with false protecting properties against the virus. This underscores the importance of health organizations disseminating clear and factual messages about the risks of alcohol consumption.<sup>[59]</sup>

Additionally, different communication media, industry, and some international organizations use terms such as “moderate consumption,” “cautious drinking,” “social drinking,” or “responsible drinking” which are ambiguous or, confusing terms which fail to quantify alcohol intake in an objective manner. These terms, by avoiding specifying amounts, allow



for the subjective extrapolation of what is responsible or moderate for each individual, causing confusion. Therefore, by defining alcohol consumption patterns in a quantitative manner we will avoid using those terms.

**All of the above evidence clearly calls for the need to provide reliable and high quality evidence-based information on the risks of alcohol consumption to both people in general and to health professionals. This information, in combination with the right public policies, will help towards the goal of making healthy life styles the easiest ones to adopt.**

However, we cannot ignore that, in order to reduce the impact of alcohol consumption, on population health as well as its social and economic consequences, the various stakeholders must work together. These include alcohol drinkers, their families, civil society, involved professionals, public administrations, the industry, and last, but not least, those serving and selling alcohol.<sup>[7]</sup> An intersectoral approach is needed to launch international recommendations based on renowned evidence such as the initiative SAFER<sup>[16]</sup> or the WHO's Global Strategy to reduce the harmful use of alcohol,<sup>[15]</sup> according to the principle of Health in All the Policies as described in the Helsinki's Declaration (The 8<sup>th</sup> Global Conference on Health Promotion, World Health Organization).<sup>[60]</sup>

Currently, a global commitment to reach the United Nation's Sustainable Development Goals (SDGs) is underway. Regarding alcohol consumption, the SDG 3.5. refers to strengthening the prevention and treatment of substance abuse and addiction, including the improper use of narcotic substances and alcohol abuse. However, alcohol consumption may complicate achieving SDG 10, the reduction of inequalities, by emphasizing disparities among and within countries.<sup>[7]</sup>

In Spain, the Ministry of Health launched the Strategy for Health Promotion and Prevention (SHPP) in the National Health System (NHS),<sup>[17]</sup> approved by the NHS Inter-territorial Council in 2013. Said strategy includes the approach to alcohol use as one of the main risk factors for key non-transmissible chronic diseases. We also have the 2017-2024 National Strategy Against Addictions,<sup>[18]</sup> led by the Governmental Delegation for the National Plan on Drugs.

Finally, we should mention the current situation. The Covid-19 pandemic has quickly changed how we live, how we think, and how we perceive reality and risk, especially when it comes to lifestyles and socializing. Further, it will bring an important economic and social crisis in the short-, and probably, mid- and long-term. We still do not have final data on alcohol consumption and its consequences during this extraordinary situation, but based on previous crises (e.g., SARS-CoV-1, 2003), we may expect an increase in consumption.<sup>[61,62]</sup> Relevant factors seen in 2003 were decreases in emotional well-being<sup>[63]</sup> and increases in stress levels caused by the situation (illness, deaths, economic instability) which may be associated to the increase in alcohol consumption and vice versa. In addition, we may see changes in access to alcohol (increase in online purchases<sup>[63,64]</sup>) as well as in the manner it is consumed (higher intake at home, in front of the children, and so on). To learn of these consequences and be able to act, it is necessary to monitor consumption, separating the main determinants of inequality (age, sex, SES, etc.<sup>[63]</sup>). Likewise, we should focus on informing and involving health and socio-health professionals regarding the approach to alcohol consumption and its consequences. Also, we should keep, support, and develop alcohol consumption preventive policies, as well as any policies that may reduce the social impact of Covid-19, through the coordination and intersectoral action among all stakeholders, sectors, and public administrations.





# Justification

For the last few years, national guidelines from certain countries<sup>[65-67]</sup> have been using the concept of “low risk” consumption, because for certain gastrointestinal conditions, cancer, and lesions, there is no safe consumption level.<sup>[68]</sup> These guidelines inform about consumption patterns and levels carrying the lowest health risks (low risk), emphasizing that the lower the consumption the lower the health risk and that still, for certain individuals, the safest option is not drinking at all. Some guidelines also recommend weekly alcohol-free days. These guidelines are an important public health tool in the mission to reduce the harm associated to alcohol consumption in both the short- and long-term.<sup>[19]</sup>

The report generated within the framework of the Reducing Alcohol Related Harm (RARHA),<sup>[19]</sup> an action plan coordinated by several European countries including Spain, pronounced that most of Spain’s neighbouring countries should reduce alcohol consumption below the amounts recommended by Spain at that moment<sup>[22]</sup> (Table 2). This report put into question the alcohol consumption threshold established as “low risk” in several European guidelines, recommending their update based on a review of the current evidence.

**Table 2. Examples of national recommendations for alcohol consumption considered “low risk” (or guidelines for consumption when there are no “low risk” recommendations published) and most recent Standard Drink (SD) for each country<sup>[69]</sup>**

Country	Low Risk Consumption		Alcohol content per SD in g
	Men	Women	
Spain	Up to 40 g/d	Up to 20 g/d	10 g
Poland	Up to 40 g/d Maximum 5 days/week	Up to 20 g/d Maximum 5 days/week	10 g
Estonia	Up to 40 g/d At least 3 alcohol-free days	Up to 20 g/d At least 3 alcohol-free days	10 g
Malta	18-21 y.o.: no more than 2 SDs (16-20 g) per event, maximum 2 times/week >21 y.o.: Up to 21 SDs (168-210g/week), throughout 5-6 days	18-21 y.o.: no more than 2 SDs (16-20 g) per event, maximum 2 times/week >21 y.o.: Up to 14 SDs (112-140g/week), throughout 5-6 dias	8-10 g
Belgium	Up to 21 drinks/week	Up to 14 drinks/week	-
Greece	Up to 3-4 SDs (24-32 g/d)	Up to 2-3 SDs (16-24 g/d)	8 g
Switzerland	2-3 SDs (20-36 g/d) 2 alcohol-free days/week	1-2 SDs (10-24 g/d) 2 alcohol-free days/week	10-12 g
Hungary	Up to 30 g/d	Up to 15 g/d	10-14 g
Czech Republic	Up to 24 g/d Maximum 5 days/week	Up to 16 g/d Maximum 5 days/week	16-18 g
Denmark	Up to 14 SDs/week (168 g/week) 2 alcohol-free days/week	Up to 7 SDs/week (84 g/week) 2 alcohol-free days/week	12 g
Germany	Up to 24 g/d	Up to 12 g/d	10-12 g
Ireland	Up to 17 SDs (170 g/week) At least 2 alcohol-free days/week	Up to 11 SDs (110 g/week) At least 2 alcohol-free days/week	10 g
Italy	Up to 2 SDs (24g/d)	Up to 1 SD (12 g/d)	12 g
Austria	Up to 24 g/d 2 alcohol-free days/week	Up to 16 g/d 2 alcohol-free days/week	20 g

**Table 2. Examples of national recommendations for alcohol consumption considered “low risk” (or guidelines for consumption when there are no “low risk” recommendations published) and most recent Standard Drink (SD) for each country<sup>[69]</sup> (Continuation)**

Country	Low Risk Consumption		Alcohol content per SD in g
	Men	Women	
Portugal	Up to 24 g/d	Up to 16 g/d	10 g
Rumania	Moderate drinking: Up to 2 SDs (24g/d)	Moderate drinking: Up to 1 SD (12 g/d)	12 g
Sweden	Only high risk consumption is defined as more than 14 SDs (168 g/week) or more than 5 SDs (60 g) per event	Only high risk consumption is defined as more than 9 SDs (108 g/week) or more than 4 SDs (48 g) per event	12 g
France	Up to 10 SDs (100 g/week), never more than 2 SDs (20 g/d) and at least 1 alcohol-free day/week		10 g
Croatia	Up to 2 SDs (20 g/d)	Up to 1 SD (10 g/d)	10 g
Cyprus	2 SDs (20 g/d)	1 SD (10 g/d)	-
Luxembourg	2 glasses of beer (250 ml) or wine (100 ml/d) 2-3 alcohol-free days/week	1 glass of beer (250 ml) or wine (100 ml/d) 2-3 alcohol-free days/week	12 g
Slovenia	Up to 200 ml of wine or 1 bottle (500 ml) of beer or 2 shots of liquor per day (not exceeding 14 SDs (140 g/week) and never more than 5 SDs (50 g) per event. At least 1-2 alcohol-free days/week	Up to 100 ml of wine or 1/2 bottle (250 ml) of beer or 1 shot of liquor per day (not exceeding 7 SDs (70 g/week) and never more than 3 SDs (30 g) per event. At least 1-2 alcohol-free days/week	10 g
Finland	On average no more than 2 SDs (24g/d)	On average no more than 1 SD (12 g/d)	12 g
Norway	Up to 20 g/d Should not exceed the 5% of the energy intake	Up to 10 g/d Should not exceed the 5% of the energy intake	12 g, 15 g
Bulgaria	Up to 15-16 g/d	Up to 8 g/d	-
United Kingdom	Up to 14 SDs (112 g/week) throughout 3 or more days and with some alcohol-free days		8 g
Holland	No alcohol consumption or at least no more than 1 SD (10 g/d)		10 g
Lithuania	Limit alcohol consumption		10 g

Note: Table created based on: Table 3b. Examples of national low-risk drinking recommendations (or drinking guidelines if no low-risk recommendation is in place) and standard units from Alcoholic beverages, Health Promotion and Disease Prevention Knowledge Gateway, European Commission<sup>[69]</sup> (based on RARHA 2016 and national dietary recommendations or guidelines).

SD: Standard Drink; g: grams; d: day; y.o.: year-olds

In our country, the threshold for at-risk consumption was established in 2007, within the framework of the 1<sup>st</sup> Spanish Conference in Prevention and Health Promotion in Clinical Practice, organized by the then named Ministry of Health and Consumption. The proceedings are available in the document titled “**Prevention of the issues caused by alcohol,**” by which the at-risk alcohol consumption levels were established at greater than 40g/d for men and 20g/d for women.<sup>[22]</sup>

In 2015 another document, **Comprehensive advice regarding life styles in primary care, linked to community resources for the adult population,**<sup>[21]</sup> was developed within the framework of the Strategy for Health Promotion and Prevention in the National Health System. This document defines the thresholds for low risk as a consumption up to 40g/d (4 SDs/day) for men and 20-25 g/d (2-2.5 SDs/d) for women. Recent evidence regarding alcohol consumption risks call for updating these thresholds.

Health organisms have the responsibility and duty to inform and raise awareness of alcohol-related damages. At the same time, alcohol users have the right of being informed of the risks involved in alcohol consumption, so that they may reduce or avoid them as established in the article 4 (Right to Information) of the Spanish Legislative Decree 33/2011 on October 4<sup>th</sup>, Public Health General Section<sup>[70]</sup> and article 17 (Information, preparation, and education of consumers and users) of the Spanish Royal Legislative Decree 1/2007 on November 16<sup>th</sup>, by which the consolidated text of the General Law for the Defense of Consumers and Users and other complementary laws are passed.<sup>[71]</sup>

To exercise real freedom of choice and make informed decisions, one must have access to true and complete information about what is consumed, its benefits, risks, costs, and consequences to self and others. With alcohol consumption in mind, **the aim of this document is to facilitate an update on international recommendations and the scientific evidence on risks assumed when alcohol is consumed, establishing an intake threshold which could be considered low risk.** Given that consuming alcohol is not only an individual decision but also a socially-influenced one, it is necessary to develop coherent and intersectoral public policies. Further, these policies must be aligned with international initiatives to promote the kind of contexts where healthy decisions are the easiest to make.

This document offers information directed at healthy men and women, 18 and older. However, as we will see in Appendix 2, some specific population subgroups or especial situations may carry a much greater alcohol-related damage risk. In these situations, either abstinence or seeking advice from the appropriate health professional (in certain instances) is recommended. In any case, identifying specific individualized risks is better left to health professionals.



# Objectives

The **overall objective** of this document is to update the thresholds of alcohol consumption considered low risk, with the goal of reducing health problems, injuries, damages to third-parties, and socio-economic negative consequences derived from alcohol.

The **specific objectives** are:

1. Update the thresholds of low risk alcohol consumption in Spain, evaluating alcohol's impact on population mortality.
2. Provide updates on alcohol-related damage to health professionals, according to levels and patterns of consumption.
3. Provide evidence-based data on the differential potential health effects of alcohol by type of drinks.

Based on the information gathered, we will produce additional specific materials for:

1. Informing and raising awareness among the general population about alcohol-consumption risks, according to levels and patterns of consumption, so that individuals may make informed decisions.
2. Delivering evidence-based information as a tool for public health stakeholders and policy decision-makers. These data should support policy development and the creation of appropriate environments and conditions leading to the reduction of alcohol-related damages at the population level by facilitating the adoption of healthy practices.



# Methodology

After the review of scientific evidence and international guidelines, a working group was charged with the update of the available evidence on alcohol-related health effects. The group included experts on alcohol consumption from the following fields: clinical practice, public health, research, epidemiology, biostatistics, and health policy. Most had already participated in the 2008 document **Prevention of alcohol-related issues**.<sup>[22]</sup>

The review of scientific evidence was performed by three task groups:

- 1) Assessment of the health risks and low risk thresholds for average alcohol consumption
- 2) Assessment of the health risks and low risk thresholds for binge drinking
- 3) Type of alcoholic beverages and their differential effects on health

Systematic reviews with or without meta-analysis (“an umbrella review”) and/or cohort studies were performed. The methodology applied by each task group can be found in the documents mentioned in Part 2.

Based on this evidence and international guidelines, the first part of the document presents the key information to be disseminated to the population and to health professionals upon agreement by the working group and external reviewers.

The second part of the document consists of the detailed results of the three task groups’ reviews.

The document also includes a section with the definitions of interest (Appendix 1). Appendix 2 is directed to specific population groups or special situations. It includes current information based on data from countries which recently reviewed available evidence and guidelines on low risk alcohol consumption thresholds (Australia,<sup>[65]</sup> Canada,<sup>[72]</sup> and United Kingdom<sup>[67]</sup>). Appendix 3 presents relevant information for approaching alcohol consumption in the health system.





# Summary of scientific evidence

Any alcohol consumption bears some risk and that risk is avoided only if alcohol is not consumed. The amount of risk assumed when consuming alcohol is part of a continuum which depends on multiple factors such as the volume consumed, consumption pattern, or the circumstances surrounding consumption.

Regarding average daily consumption, the risk may be assessed based on the frequency and the amount consumed. This may consist of a continuum of intermediate situations, ranging between no consumption or very occasional consumption of amounts below the low risk thresholds up to daily intake of alcohol amounts above the at-risk thresholds.

Binge drinking episodes are always considered at-risk consumption and, thus, should always be discouraged.

It is worth underscoring that both average consumption and binge drinking are not mutually exclusive and that the same person may present them both.

## 1. Health risk assessments and low risk regular alcohol consumption thresholds

In order to establish low risk alcohol consumption thresholds by evaluating its impact on population level mortality, two literature reviews focused on the relationship between regular alcohol consumption and general mortality were carried out.

First, the authors performed a review of systematic reviews with or without meta-analysis, with no time limit,<sup>[73-81]</sup> of articles on regular alcohol consumption and all-cause mortality. This review made it clear that data on the alcohol-mortality association are biased to a great extent. This is due to major biases present in some of the primary studies included in the review when it comes to alcohol's protective cardiovascular health effect, as summarized in Table 3.

**Table 3. Summary of observed biases in publications reporting a protective effect of alcohol on cardiovascular health**

- 1) Classification bias (combining ex drinkers with non-drinkers)
- 2) Bias due to the omission of binge drinking
- 3) Bias due to the omission of confounding variables (SES level, physical activity, and/or diet)
- 4) Selection and generalization bias (mistaking mortality due to illness with all-cause mortality)
- 5) Publication bias (overrepresentation of studies on cardiovascular risk)
- 6) Bias due to incentivized publication (conflicts of interest with industry)

In light of the biases found in our review of systematic reviews, and learning that the greater the quality of the study and ability to bias-reduction, the smaller the protective effect of alcohol reported,<sup>[76]</sup> we went ahead with a second review. This review included only cohort studies published between 2014 and May 2019 and which main objective was to examine the regular alcohol intake-overall mortality relationship (Table 4). In 2014 many

of the biases mentioned in Table 3 are, in general, emphasized. In addition, studies showing conflict of interest with the pharmaceutical or alcohol industry or performed on Asian populations<sup>[82]</sup> are excluded.

Based on this review of cohort studies, the threshold of alcohol intake beyond which mortality increased ranged between 20 and 60 g/d for men and 12 and 20 g/d for women (Table 4).

First Author/yr	Sample Size	Number of	Valor (p<0,05) al que aumenta mortalidad	Umbral bajo riesgo/Valor de mínimo riesgo de mortalidad
Wood, 2018 <sup>[31]</sup>	599,912	19	17-21 g/d	14.2 g/d
Ferrari, 2014 <sup>[83]</sup>	380,453	10 UE (including Spain)	30 g/d	5-15 g/d
Smyth, 2015 <sup>[90]</sup>	114,000	12 across 4 continents	M: 30 g/d W: 20 g/d High Consumption	-
Knott, 2014 <sup>[84]</sup>	53,000	United Kingdom	Not associated to higher mortality	M: 22 g/d W: 11 g/d
Perreault, 2017 <sup>[85]</sup>	36,370	United Kingdom	M: 24 g/d W: 16g/d	M: 16 g/d W: 8 g/d Minimum risk value
Goulden, 2016 <sup>[86]</sup>	24,000	EEUU	35 g/d (never drinkers are the reference group)	14.2 g/d
Bobak, 2016 <sup>[87]</sup>	34,304	4 (Eastern Europe)	60 g/d and 20 g/d, in men and women	M: 10 g/d W: 5 g/d
Luksiene, 2017 <sup>[88]</sup>	6,729	Lithuania	M: 20 g/d. vs. moderate consumption	20 g/d
Licaj, 2016 <sup>[89]</sup>	48,249	Sweden	15 g/d (null association) p>0.05	15 g/d (null association) All p>0.05
Midlöv, 2016 <sup>[90]</sup>	10,766	Sweden	12 g/d	12 g/d
<b>Medians:</b>			<b>Global: 23-25 g/d W: 20 / M: 24</b>	<b>Global: 14.2 g/d W: 10.5 / M: 19</b>

g: grams; d: day; M: men; W: Women

We should mention that one of the review's limitations to assess the relationship between alcohol consumption levels and all-cause mortality, we find that in cohort studies overall mortality will depend of the cohort's distribution of causes of death, which may not be representative of the general population and may exclude groups more vulnerable to alcohol consumption such as the homeless or institutionalized individuals. Therefore, certain causes of death may be under or overrepresented.<sup>[91,92]</sup>

It is worth noting that, although no Spanish studies met the inclusion requirements for the review, some reviews included data from the population of Spain. As an aside, in the near future, it would be important to have mortality analyses by the different specific causes of death of the population of Spain. However, that aim was beyond this document's objective.

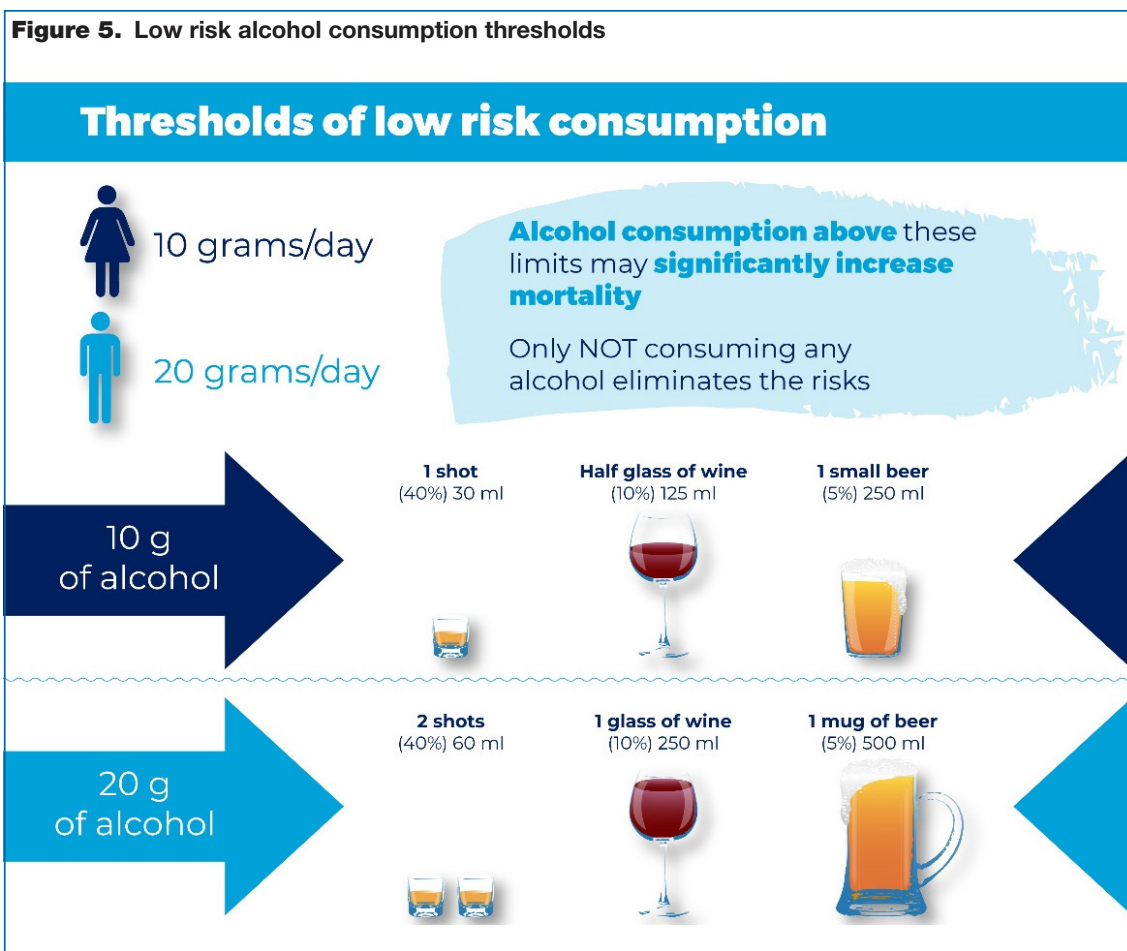
**Based on the review of cohort studies and bias minimization, the thresholds of low risk alcohol consumption should be set to 20 g/d for men and 10g/d for women,<sup>1</sup> assuming there is no such thing as zero risk. We adopted the most conservative figures for average**

<sup>1</sup> It is important to emphasize that the message of reducing alcohol consumption below the low-risk thresholds, must not send the message that this consumption level is risk-free, which may incentivize non-drinkers to start consuming or those drinking below those thresholds to increase intake to match them.

**alcohol consumption above which a significant increase in overall mortality is already observed.** These values match the most conservative figures gathered from the review of systematic reviews, if we were to consider it despite the substantial biases.

The most conservative figures are chosen based on the principle of precaution.<sup>2</sup> And on the fact that the analyses did not take into account alcohol consumption risks such as consequences to third parties, or SES-related outcomes.<sup>[68]</sup>

These data support thresholds established in other European countries such as Portugal (24 and 16 g/d for men and women, respectively); Germany or Italy (24 and 12 g/d, respectively), France (20 g/d for both sexes) or Norway (20 and 10 g/d, respectively) (Table 2).



<sup>2</sup> The principle of precaution is established in the law 33/2011 of October 4<sup>th</sup>, General Public Health<sup>[70]</sup>

## 2. Health risk assessments and low risk thresholds for binge drinking episodes

### 2.1. Definition of binge drinking

There is no single definition for binge drinking due to the vast heterogeneity among different countries when it comes to defining the SD. And also due to individual and contextual factors affecting physiopathological and social effects of binge drinking. Establishing such definition would require taking into account the amount of alcohol consumed, the definition of drinking episode or occasion and the period of time set as reference, establishing sex specific thresholds, and adjusting the estimates by regular consumption and other confounding variables (other lifestyles, sociodemographic variables, etc.).

For these reasons, there are substantial differences in the definition across countries. WHO<sup>[26]</sup> defines binge drinking as a consumption pattern of large amounts of alcohol, over 60g of alcohol on one session,<sup>[7]</sup> within a period of time reserved particularly for this activity.

Nevertheless, it is key to differentiate thresholds by sex due to differences in both body mass and ethanol metabolism.<sup>[93]</sup> National surveys in Spain use different definitions,<sup>[1-3]</sup> and the definition used in clinical practice is the one established in the First Spanish Conference for Prevention and Health Promotion in Clinical Practice.<sup>[22]</sup> Binge drinking was then defined as the consumption of 60 grams of alcohol (6 SDs) or more for men, and 40 grams (4 SDs) or more for women, during one drinking session (usually 4-6 hours), during which a certain level of intoxication is maintained (blood alcohol level not dropping below 0.8 g/l).

Indeed, it is important to identify this pattern because a large portion of the people practicing it presents an average consumption pattern deemed low risk. Nonetheless, the negative consequences of binge drinking for them are the same, or even worse in some cases, to those associated with at-risk average alcohol consumption.

To carry out the identification of binge drinkers and identify the associated health effects, it is not possible to recommend just one threshold. The chosen threshold will dictate the ability to establish causal associations and assess the different health effects. If the cut point is too low the most serious and less common effects could be underestimated. In contrast, a very high cut point (more specific) while allowing to better identify some consequences, would leave out individuals who practice a lighter binge drinking and their corresponding consequences. That is, the chosen definition must take into consideration the main objective of the estimate or combine different definitions or thresholds, thus allowing a more precise and comprehensive identification of the health effects.

**Thus, given the lack of one definition of binge drinking, for practical purposes we will use the definition settled in the document Prevention of alcohol related problems,<sup>[22]</sup> i.e., the consumption of 60 grams of alcohol (6 SDs) or more for men and 40 grams (4 SDs) or more for women, during one drinking session (usually 4-6 hours), during which a certain level of intoxication is maintained (alcohol level not dropping below 0.8 g/l).**

**For research and surveillance purposes, we will keep the definition used or specifically defined in each study or survey according to their objectives.**

## 2.2. Impact of binge drinking

Both acute and chronic harmful effects associated with binge drinking are important. These effects impact the drinker proportionally to the amount consumed during each binge episode, as well as negatively impacting third parties. The most relevant findings from the studies reviewed here point to a clear association between binge drinking and the risks listed below in Table 5.

<b>Table 5. Results of the state of the field on the impact of binge drinking</b>	
Cardiovascular problems	Increased risk of negative impact on cardiovascular system, <sup>[29,94,95]</sup> cardiovascular death, <sup>[96]</sup> ischemic heart disease, <sup>[97]</sup> myocardial infarctions (especially in those 65 and older), <sup>[29]</sup> stroke, <sup>[95]</sup> stroke-related mortality, <sup>[95]</sup> and conduction disorders. <sup>[95]</sup>
Brain development and neuropsychiatric effects	Brain development and maturation disorders which may cause structural damage, learning disability and memory deficiency. <sup>[98]</sup> Later on, it may surface as low academic achievement, greater predisposition to alcohol consumption-related disorders, high-risk behaviors and alcohol and other substance abuse. <sup>[99-101]</sup> Also associated to deficits in attention, memory, and executive tasks. <sup>[98]</sup> Finally, there is no safe consumption level during pregnancy <sup>[102]</sup> and it seems associated to neurodevelopmental damage. <sup>[103]</sup>
Alcohol poisoning	Acute alcohol poisoning carries severe risks even life-threatening (if blood alcohol >3 g/l). <sup>[104,105]</sup>
Unintentional accidents and injuries	Increased risk due to impaired coordination, cognitive processing or delayed reaction time; especially among youth. <sup>[106,107]</sup> Driving under the effects of binge drinking increases the risk of car accidents and other non-intentional injuries exponentially and proportionally to blood alcohol levels. <sup>[108]</sup>
Violence and intentional injuries	Increased risk of violent attacks to others (domestic violence, fist fights, sexual abuse, or homicides) or self-inflicted, especially among youth. <sup>[108-110]</sup>
High risk sexual behaviors	Each 0.1 g/l of blood alcohol increases the risk by 5%. <sup>[108,111,112]</sup>
Negative social effects	Both direct (noise, vandalism) and indirect effects (costs associated to health care or legal assistance, productivity loss, among others) translate into a substantial economic burden for society as a whole. <sup>[113]</sup>
Other negative health effects	Toxic and inflammatory damage to liver and pancreas, to lung and musculoskeletal tissue, <sup>[113-115]</sup> immune system, <sup>[104]</sup> and probable increased risk for type II diabetes. <sup>[104,116]</sup>

It is well known that the risks associated to binge drinking are substantial even if practiced only sporadically.<sup>[117]</sup>

**Thus, a low-risk threshold for binge drinking cannot be established and should always be discouraged. Both frequency of episodes as well as the amount of alcohol consumed during each binge drinking episode should be decreased.**



### 3. Type of alcoholic beverages and their differential health effects

There is a widely spread belief that certain alcoholic beverages, those requiring a fermentation process such as wine (particularly red wine) and beer, have a supposedly beneficial health effect in contrast with liquor which is obtained through distillation. Fermented drinks are ascribed the power to reduce the risk for certain pathologies, mainly cardiovascular ones, due to their polyphenol concentrations.

Additionally, both are key goods in terms of production and consumption at the European level in general, and in the Mediterranean countries, in particular.

Another belief is that the positive health effects reside in their consumption being associated to the Mediterranean diet, a model of balanced food consumption and recommended by most dietary guidelines.<sup>[118-121]</sup> However, two studies evaluating the association between consumption of wine and other fermented drinks (2 glasses in men and 1 in women) during meals found a weak association between this consumption pattern and a Mediterranean dietary pattern.<sup>[122,123]</sup>

In opposition to the potentially beneficial effects, it has been argued that the consumption of high alcohol content beverages, may cause greater adverse effects associated with injuries, than consuming equivalent amounts of ethanol from low alcohol content drinks, although evidence is inconclusive.<sup>[124]</sup>

However, some scientific societies<sup>[93,125]</sup> take an explicitly tolerant stance on their literature in regards to the consumption of fermented beverages. Nevertheless, **neither the General Directorate of Public Health of the Spanish Ministry of Health<sup>[17]</sup> nor the Spanish Agency of Diet and Nutrition Safety (AESAN for its Spanish abbreviation) of the Ministry of Consumption recommend the consumption of any alcoholic drink.**<sup>[126]</sup>

**The review of the evidence on the differential impact of type of drinks on overall mortality showed that, among alcohol drinkers, risk increased with consumption for all alcoholic beverages, with no significant statistical differences among types of drinks.**<sup>[31]</sup>



**Table 6. Results of the review of the evidence on the differential impact of type of drinks on overall mortality**

Cardiometabolic Diseases	Two reviews evaluated the effect of types of drinks on cardiovascular diseases and failed to yield consistent results. First, a meta-analysis <sup>[127]</sup> focused on wine and beer consumption and their effect on cardiovascular mortality/morbidity, reported a lower risk among people who had ever consumed wine or beer (spirits were not examined) when compared to non-drinkers. The second review examined three types of drinks <sup>[31]</sup> among alcohol drinkers, reported a non-differentiated effect since, although beer and spirits seem to have a greater negative impact on health than wine, the observed differences failed to reach statistical significance. Regarding type II diabetes mellitus, a review <sup>[128]</sup> observed a lower risk associated with wine consumption when compared to non-drinkers. No differences were found for beer or spirits.
Cancer	Reviews included here concluded that any alcohol consumption was associated with negative effects in the case of those cancers consistently causally related to alcohol such as oropharyngeal, colorectal, and female breast but failed to detect any differential effect by type of drink. <sup>[129-132]</sup> When it comes to stomach, pancreatic, lung, or prostate cancers, the evidence linking overall alcohol consumption and negative impact remains insufficient. In another review, <sup>[133]</sup> the only inverse effect (lower risk among drinkers than non-drinkers) was observed for very small amounts of wine consumption and lung cancer, and none for beer or spirits even at small doses. Beer and spirits increased risk starting at the consumption of just one SD. Further, in a recently published combined study, <sup>[134]</sup> authors observed a lower lung cancer risk among those consuming very small amounts of wine and spirits, but not beer, than among non-drinkers. These associations held among never-smokers. Thus, the association between type of alcoholic beverages and lung cancer remains inconclusive. There are some types of cancer not associated to alcohol consumption such as kidney and bladder cancers. Still, there are others for which an inverse relationship has been observed, such as cancers of the hematopoietic and lymphatic systems, although consistent causal evidence remains lacking. In fact, in these types of cancer is where alcohol was associated to a lower incidence both globally for all types of alcohol and stratifying for each type of alcohol drink. However, there were very little difference by type of beverage, or when there were differences, results were inconsistent. <sup>[135-138]</sup>
Neurodegenerative Diseases	In terms of type of alcoholic beverages and neurodegenerative diseases, a review reported lower risk with wine consumption (under 14 SDs per week) and a risk increase with beer consumption (at the highest consumption level). However, risk by drink type could not be discerned due to lack of enough studies available. <sup>[139]</sup> Other review failed to observe any associations with any type of drink. <sup>[32]</sup>

Research on differential effects by type of drink report many limitations inherent to the studies. Limitations include different methods of estimating the independent contribution of the type of drink (measure of pure alcohol ingested in each type of drink, type of drink preferences), insufficient control of potential confounders such as demographic variables (sex, age, educational level, and SES), lifestyles (smoking, physical activity), and characteristics of the alcohol consumption pattern. Regarding these, it is worth mentioning that studies do not usually control for the total amount of alcohol consumed, if it is regular or occasional consumption, if alcohol intake takes place during meals or in between meals, and, more importantly, whether binge drinking is practiced. And binge drinking varies greatly by type of drink. In addition, similar to what happens when examining health effects of average alcohol consumption, many studies present classification bias (i.e., the incorrect classification of ex-drinkers) which greatly complicates the comparison and interpretation of results.

Ethanol and phenolic compounds or polyphenols are the potentially beneficial components in alcoholic beverages. However, when speaking of benefits, it is necessary to take into account the proven negative health effects of alcohol consumption (increased mortality related to certain cancer types, most cardiovascular diseases, and overall mortality) and that the concentration of polyphenols in alcoholic beverages is small. Thus, out of the total average intake of polyphenols

in the Spanish diet, only 8-9% comes from wine and 2% comes from beer,<sup>[140]</sup> and these amounts can be easily obtained through a healthy consumption of oranges, apples, or bread.

**To conclude, epidemiological evidence does not support the claim that wine or beer consumption provide any distinctive protective effect regarding cardiometabolic risk or any other type, despite containing substances potentially beneficial to our health. Thus, the recommendation of certain type of alcohol consumption based on distinctive health benefits is not supported by the scientific evidence currently available.**



# Key messages

It is important to emphasize that for certain gastrointestinal diseases, cancer, and injuries there is no safe level of alcohol consumption<sup>[20]</sup> and risks are avoided only with no consumption.<sup>[23,24]</sup> Therefore, the recommendation for non-drinkers is to remain so.

For drinkers, the recommendation is to at least reduce intake below the established low risk thresholds, to include some alcohol-free days during the week, and to stay clear of binge drinking. In sum, “if drinking, the least the better”.<sup>[25]</sup>

Alcohol consumption	There is no safe level of alcohol consumption. Not to drink alcohol is the only way of avoiding its damaging effects. Based on current scientific evidence, no health professional or institution should recommend its consumption as a way of improving any aspect of health.
Thresholds for low risk average <sup>3</sup> alcohol consumption	Set at 20 g/d (2 SDs <sup>4</sup> ) for men and 10 g/d (1 SD) for women, acknowledging that any consumption at all carries risk. Consumption of alcohol above these limits is related to a greater mortality risk when compared to abstaining or drinking below the limits. Also, some international guidelines recommend alcohol-free days during the week. This information should be provided to anyone consuming alcohol.
<i>Binge drinking</i> <sup>5</sup>	There is no such thing as low-risk binge drinking. Binge drinking is harmful, with consequences for the drinker’s health and their social environment. Thus, it must always be discouraged.
Differential effects by type of drinks	Despite containing substances with potential health benefits, epidemiological evidence fails to show wine and beer consumption having any particularly protective health effect such as the reduction of cardiometabolic risk or any other kind. At this point there is no scientific evidence to support the recommendation of certain alcoholic beverages ascribing them differential health benefits.
At-risk alcohol consumption thresholds	Currently, individuals are considered to present at-risk alcohol consumption if they meet at least one of the following criteria: – AUDIT Questionnaire: > 7 points for men, > 5 for women. – > 40 g/d (4 SDs/day) for men and > 20-25 g/d (2.0-2.5 SDs/day) for women. When a person reports consumption intakes above those considered at-risk, the health provider will proceed according to the recommendations found in the Ministry of Health’s manual Comprehensive Lifestyle Advice in Primary Care, Linked to Community Resources for Adult Populations. <sup>[21]</sup>
Specific sub-populations or special situations	No alcohol consumption: – Individuals under 18 years of age – Pregnancy and breastfeeding – Driving a vehicle – Doing any other activities requiring concentration or psychomotor skills – Combined with other substances <sup>6</sup> It is recommended to avoid alcohol consumption or, at least, consulting a health professional first if: – Taking medicines that interact with alcohol – Presence of mental health issues – Family history of alcohol addiction

<sup>3</sup> Average consumption: usual consumption of an individual over a period of time, it usually refers to daily or weekly consumption.

<sup>4</sup> Standard Drink (SD) of alcohol: In Spain, an SD equals 10 grams of alcohol which is, approximately, the usual content of a 100ml glass of 13% wine, 1 glass of 300 ml of 4% beer, or 30 ml of 40% liquor.

<sup>5</sup> Binge Drinking: consumption of 60 or more grams of alcohol (6 SDs) for men and 40 or more grams (4 SDs) for women in one single occasion (usually lasting between 4 and 6 hours). During the session, individuals maintain certain degree of intoxication (alcohol level 0.8 g/l or above).<sup>[22]</sup>

Policy Development

Consuming alcohol is not a decision made in a vacuum, but influenced by social determinants of health. Thus, it is necessary to develop coherent and intersectoral public policies supporting environments where healthy choices are the easiest to make. To reduce inequities, it is key to design and evaluate campaigns and interventions, considering the social gradient and other factors such as gender. Further, to ensure that policies benefit all social groups, especially the most underprivileged, any tools must tightly define their target population.

<sup>6</sup> Any illicit substances should be avoided but, if consumed, combining it with alcohol or with other drugs must be avoided, as the risk for fatal and non-fatal events substantially increases.

# Future challenges

1) Bring alcohol consumption prevention and management to the forefront of Public Health Agenda in all levels of the administration, encouraging coordination and intersectoral collaboration, taking into account social and commercial determinants of health, and supporting the involvement of political decision makers. Only then, it will be possible to start actions with the most cost-effectiveness evidence<sup>7</sup> and make them into law whenever necessary.

2) Develop interventions, strategies, and policies for the prevention of alcohol consumption, incorporating a gender and equity perspective in both the design and evaluation, and reaching consensus across all levels of the administration, sectors, and civil society.

3) Update the strategies of prevention and intervention on alcohol consumption at the health care level, evaluating the new low risk thresholds according to the new evidence, and connecting the intervention to the community resources.

4) Develop sources of support for the existing research and the development of independent Spanish alcohol studies. This research should examine risk levels, update the definition of binge drinking, evaluate the effectiveness and impact of the interventions, strategies, and public policies. This effort should incorporate the equity perspective while differentiating at least SES factors, age, and sex; or supporting studies of specific subpopulations, such as vulnerable groups or older adults.

<sup>7</sup> The 5 areas considered “best investments” by the WHO SAFER<sup>[16]</sup> initiative are:

1. Ban or restrict publicity, sponsorship, and promotion of alcohol.
2. Increase alcohol prices through excise duties and price policies
3. Strengthen restrictions on alcohol availability
4. Promote and enforce laws against drunk driving
5. Facilitate screening followed by brief intervention and treatment.



# Appendix 1. Definitions of interest

**Low risk alcohol consumption:** Average alcohol consumption level from which excess mortality rates increase significantly. This does not mean that there is no excess mortality below that level since the only way of avoiding alcohol-related risks is not to drink alcohol.

Considering the physiological differences and the different ability to metabolize alcohol between men and women, the low risk threshold is set to 20 g/d (2 SDs) for men and 10 g/d (1 SDs) for women, acknowledging that there is no zero risk below those thresholds, unless not drinking any alcohol at all.

**At-Risk Alcohol Consumption:** We currently consider someone to exhibit at-risk consumption if they meet the following criteria:<sup>[21]</sup>

- > 40 g/d (4 SDs/day) for men and > 20-25 g/d (2.0-2.5 SDs/day) for women.
- AUDIT Questionnaire: > 7 points for men and > 5 for women.
- > 28 SDs/week for men and > 17 SDs/week for women.
- ≥ 6 SDs per occasion for men and ≥ 4 SDs per occasion for women.

Based on current recommendations, the protocol to follow with individuals reporting at-risk consumption levels are available in the manual Comprehensive Advice Regarding Lifestyles in Primary Care, linked to community resources for adult population.<sup>[21]</sup>

**Average consumption:** Usual consumption by an individual over a period of time, it usually refers to daily or weekly intake.

**Binge Drinking:** As established in the First Spanish Conference for Prevention and Health Promotion in Clinical Practice,<sup>[22]</sup> binge drinking is defined as the consumption of 60 grams of alcohol (6 SDs) or more for men and 40 grams (4 SDs) or more for women, during one drinking session (usually 4-6 hours), during which a certain level of intoxication is maintained (blood alcohol level does not drop below 0.8 g/l). Since there is still no consensus on one unique threshold, research and surveillance work may use other definitions with various thresholds with different sensitivity and specificity to facilitate assessing the impact of different health issues.

**Standard Drink (SD):** In Spain, this alcohol measurement is equivalent to 10 grams of alcohol, i.e., approximately the average amount of pure alcohol of a glass with 100 ml 13% wine, 1 glass of 300 ml of 4% beer, or 30 ml of 40% liquor. Alcohol content in grams for each type of drink is estimated using the following formula:

$$\frac{\text{Amount of beverage (ml)} \times \text{percent alcohol (\%)} \times 0.8}{100}$$



## Appendix 2.

# Specific subpopulations or special situations

For certain subpopulations or in some special situations, the risk of alcohol-related harm is greater than otherwise, and drinking is discouraged or, in certain cases, getting the advice of a health provider is strongly recommended.

## Pregnancy and breastfeeding

### Pregnancy

Pregnant women, or those planning on getting pregnant, should not consume alcohol. Alcohol is a teratogenic agent<sup>[141]</sup> which may cause permanent damage to the fetus since it quickly crosses the placenta exposing the fetus to the same or higher alcohol concentrations as the mother.<sup>[65]</sup>

Alcohol-related potential damages to fetal development are varied and are referred to as fetal alcohol spectrum disorders (FASDs).<sup>8</sup>

These conditions are difficult to diagnose and may range from mild to severe and last a lifetime. Their impact may be at the physical, behavioral, or cognitive level. The fetal alcohol syndrome (FAS) is its most severe form<sup>[7,142]</sup> and it is characterized by physical and mental developmental delay, and head, brain, and joint abnormalities.<sup>[143,144]</sup>

Scientific evidence is clear in regards to the severe effect on brain and behavioral development of prenatal alcohol exposure, with serious consequences through the life course of the person affected, their family, and society.<sup>[45]</sup> There is no knowledge of any amount of alcohol exposure considered safe for a fetus;<sup>[45,65,102]</sup> thus, health professionals must discourage alcohol consumption at any time during pregnancy. Alcohol may negatively affect the fetus even before the woman knows she is pregnant.

In addition, some studies show that men's alcohol consumption during the preconception period may also have a negative effect on the child's health.<sup>[145,146]</sup> Also worth mentioning is that a partner's alcohol consumption may influence the expectant mother's alcohol intake.<sup>[146]</sup>

### Breastfeeding

Scientific evidence has not identified a risk-free level of alcohol consumption during breastfeeding. Thus, the safest option for the baby is for breastfeeding mothers to abstain. Any alcohol consumed is transferred to maternal milk, where it reaches the same concentration as in blood<sup>[147,148]</sup> between 30 minutes and one hour. Maternal milk is alcohol-free

<sup>8</sup> Different terms are used to describe FADs: a) Fetal alcohol syndrome (FAS), b) Alcohol-related neurodevelopment disorder, c) Alcohol-related birth defects and d) Neurobehavioral disorder associated with prenatal alcohol exposure.

when blood alcohol levels are back to zero, so extracting maternal milk does not speed up the process or reduce the alcohol level of the remaining milk<sup>[148]</sup>.

Alcohol intake during the breastfeeding period is associated with lower breastfeeding efficiency, cessation of milk production (in cases of high intake whichever the consumption pattern), deficit in the child psychomotor development and childhood wake-sleep pattern disturbances,<sup>[148]</sup> reduction in production and flow of maternal milk, and immune system disfunction.<sup>[149]</sup>

Regarding both pregnancy and breastfeeding, we must emphasize that all alcoholic beverages are equally harmful, including wine and beer. Alcohol-free beer is also discouraged. According to the corresponding legislation,<sup>[150]</sup> “no alcohol” beer contains an alcohol level below 1% of volume (usually between 0.6 and 0.9%).<sup>9</sup> And beer sold as “0.0%,” although not contemplated in the legislation and understood to contain no alcohol, may have up to 0.04% of alcohol<sup>[151]</sup> as alcohol extraction processes are not perfect.

## Driving

Alcohol consumption is possibly the most important risk factor for traffic accidents and related injuries.<sup>[152]</sup> Alcohol impairs driving proportionally to the blood alcohol level, substantially increasing the risk of having a traffic accident and suffering related injuries.<sup>[153]</sup> Further, it exacerbates any injuries caused by the accident, increasing the likelihood of lethal injuries or permanent damage, disability, and secondary effects.<sup>[152,154]</sup> Driving with an blood alcohol level of 0.5 g/l doubles the likelihood of having a traffic accident compared to driving completely sober and that likelihood keeps increasing at higher alcohol concentrations in blood.<sup>[152]</sup>

In Spain, the alcohol level allowed by the Spanish Traffic Code<sup>[155]</sup> is 0.25 mg/l in breath tests or 0.5 g/l in blood for most drivers and cyclists. Professional and novice drivers should comply with a stricter alcohol level rule, 0.15 mg/l in breath tests and 0.3 g/l in blood.

However, any alcohol level, no matter how small, may impair driving skills, increasing the risk of accident.<sup>[156]</sup> Individual variability in response to alcohol makes it impossible to define a minimum number of drinks which would keep everyone’s blood level legal. Some European countries require a zero blood alcohol level among drivers.

For all the above reasons, the safest decision is to avoid drinking alcohol before driving any type of vehicle. If alcohol is to be consumed, alternative modes of transportation should be planned before the onset of drinking when feasible (e.g., designate a safe driver, public transportation).

### Minors (under 18 years of age)

Individuals under the age of 18 should not consume any alcohol.

Adolescents starting to drink alcohol at 14 (average age of alcohol consumption onset in Spain<sup>[3]</sup>) are four times more likely to develop alcohol dependency and to report alcohol-related problems.<sup>[157]</sup> There is a clear association between adolescent heavy consumption

<sup>9</sup> According to the Art. 9 of the Royal Decree 1334/1999, July 31<sup>st</sup>, passing the General Regulation of labeling, presentation, and advertisement of food products: “Beverages with volume alcohol levels above 1.2 per 100 must include the alcohol percentage by volume”. Thus, in beverages with volume alcohol levels at or below 1.2 per 100, such information is not required to be displayed in labels.



of alcohol on weekends and poor academic performance and greater difficulty in graduating from high school. Verbal and non-verbal memory, concentration, and spatial skills tests results for drinkers are worse than among their non-drinking counterparts. Alcohol consumption bears long-term cognitive consequences (behavioral, emotional, social, and academic problems<sup>[7]</sup>) and contributes, together with other factors, to academic failure.<sup>[158]</sup>

The role of alcohol consumption in the incidence of accidental and unintentional injuries is also well established. The link resides in how alcohol alters coordination, cognitive processing, and reaction time. These disturbances are particularly important during younger ages, especially when they derive from binge drinking, which increases the risk fourfold compared to non binge-drinkers.<sup>[106,107]</sup> Binge drinking is also associated to an increase in the risk of intentional injuries caused by violent attacks to other people (including fist fights, domestic violence, sexual abuse, and homicides) or self-inflicted (injuries and suicide), especially among the young.<sup>[108-110]</sup>

In addition, alcohol consumption, mainly among the youth, is directly associated with unsafe sexual practices. Alcohol promotes uninhibited behavior, increased impulsivity, loss of self-control, and reduced ability in risk evaluation and decision making.<sup>[159,160]</sup> In this vulnerable state, risk factors grow, making them more likely to have unsafe or unprotected sex which may lead to an unwanted pregnancy or a sexually transmitted disease.<sup>[111]</sup>

## Individuals with mental health issues

Alcohol consumption plays a complex role in the development and progression of mental health diseases.<sup>[65]</sup> Alcohol is a psychoactive substance, with toxic properties and dependence-forming which consumption may lead to diseases and provoke violence and injuries.<sup>[161]</sup> Individuals with mental issues are more likely to practice at-risk alcohol consumption.<sup>[162]</sup> Further, the coexistence of alcohol dependence or at-risk alcohol consumption with mental health issues affect the course, severity, and outcomes of both conditions as well as of treatments' results.<sup>[161,163]</sup> Dependency or at-risk alcohol consumption are related to anxiety disorders, depression, among other conditions, and are risk factors for self-harm and suicide.<sup>[161]</sup>

People with mental health problems are discouraged from drinking alcohol, or, in any case, to at least consult their health professional.

## Family history of alcohol dependency

Individuals with a family history of alcoholic dependency or other alcohol-related problems, are at a greater risk of developing problem drinking patterns compared to the general population.<sup>[164-166]</sup> Therefore, children of parents with alcohol dependency are at a greater risk of developing alcohol dependency themselves than other children.<sup>[167]</sup> In addition, there could be genetic factors playing an important role in how individuals respond to alcohol, including risk of dependency and liver damage.<sup>[65,168]</sup> Individuals with family history of alcohol dependence should avoid alcohol, or at least, consult their health professional.

## Consumption of alcohol together with other substances

Consumption of alcohol together with other substances (both legal and illegal) may have severe consequences, even lethal, to the user's health and safety in both the short- and long-term.<sup>[72]</sup>

Many studies provide evidence that any level of alcohol intake, when combined with other drugs, is an important predictor of overdoses with fatal and non-fatal outcomes.<sup>[169]</sup> These bad outcomes are particularly likely when alcohol is combined with other substances that suppress the central nervous system (opiates such as heroine or benzodiazepines) thus increasing the risk of fatal overdose due to respiratory system failure,<sup>[170]</sup> or with central nervous system stimulants, such as cocaine or amphetamines, which increase the risk of dehydration, cardiac arrhythmia, and convulsions.<sup>[171]</sup>

Thus, any consumption of illegal substances should be strongly discouraged, but, if consumed, they must not be combined with alcohol or with any other illicit substance, as the risk of fatal or non-fatal outcomes is substantially increased.

## Medicines that interact with alcohol

Alcohol consumption, acute or chronic,<sup>[152]</sup> may produce pharmacological interactions which potentially severe consequences.<sup>[172]</sup> Potential interactions between medicines and alcohol may fall under one of these two large groups: 1) alcohol modifies the medicine's effect; or 2) the medicine modifies the metabolism or toxic effect of alcohol.

Therefore, any individual taking any medicines or about to do so, should consult a health professional before consuming any type of alcoholic beverage. This is especially important for people taking multiple medicines, i.e., polymedicated individuals.

## Other activities requiring concentration or psychomotor skills

Alcohol consumption affects different abilities and it usually does so in direct proportion to the blood alcohol level.<sup>[152]</sup> Thus, it is important to take into account that when carrying out activities requiring common sense, attention, concentration and psychomotor skills, no alcohol should be consumed since the acute effects of alcohol intake may affect the drinker and people around. Some of the circumstances and activities during which alcohol should not be consumed include:

- Operating machinery: boats, motor vehicles, tools, or equipment of any type.
- Doing sports: water activities, underwater diving, flying, among others.
- Supervision of individuals practicing any of the activities above.
- Supervision of minors.
- Before or during work.
- People using any type of weapons.

**Figure 7. Specific population groups or special situations during which alcohol should be avoided**



# Appendix 3.

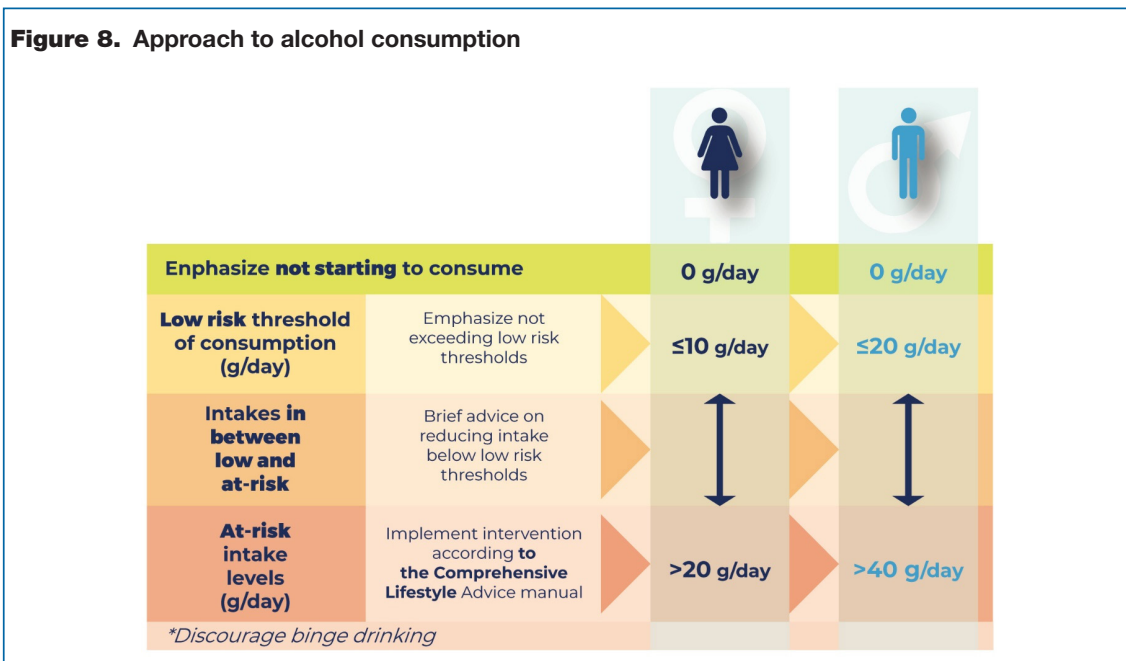
## Health system's approach to alcohol consumption

Health professionals must ask individuals about alcohol consumption, then offer advice on consumption levels and related risks with the goal of reducing or keeping consumption under low risk thresholds. When presented with at-risk consumption levels, these professionals, must also proceed with specific interventions according to the Ministry of Health's manual Comprehensive Lifestyle Advice in Primary Care, Linked to Community Resources for Adult Populations.<sup>[21]</sup> Based on current scientific evidence, **no health professional or institution should recommend alcohol consumption for health promotion.**

On one hand, we should not forget that when it comes to alcohol consumption not only individual factors but also factors associated to close social environment and macro-economic and political context have been identified. Thus, we recommend taking social determinants of health into account, adapt interventions to the appropriate context, and link individuals to community resources and health stakeholders offered in the community.

On the other hand, alcohol consumption, though it may follow a set pattern, it is not necessarily something fixed in someone's life; thus, it must **be enquired upon and discussed periodically** by health professionals. This is particularly important among primary care professionals due to their continuity of care with a patient.

We must underscore that by updating low risk thresholds, there remains an intermediate consumption range between the low risk and the at-risk consumption thresholds. Patients falling into this intermediate level of consumption should be informed of the associated risks and be encouraged to reduce their intake to at least below the low risk thresholds. Nevertheless, at a future date we need to update the intervention strategies regarding alcohol consumption for the healthcare system, a topic beyond the scope of the current document.





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The objective of this document is to update the thresholds of alcohol consumption considered low risk, with the goal of reducing health problems, injuries, damages to third-parties, and socio-economic negative consequences derived from alcohol. Also it provide updates on alcohol-related damage to health professionals, according to levels and patterns of consumption. And provide evidence-based data on the differential potential health effects of alcohol by type of drinks.

