Tufts Global Alcohol Guidance Labeling Project: Topics for Global Guidance Labels

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Introduction

Harmful alcohol use is a global problem, contributing to 3.3 million deaths each year (1). Alcohol misuse is the leading risk factor for premature death and disability among people between the ages of 15 and 49, and the fifth leading risk factor among all age groups (2). Excessive alcohol use can have both immediate and long-term effects on health. In addition to having health consequences, harmful alcohol use is associated with significant social and economic losses for both individuals and society (3, 4). Patterns of alcohol use and the associated harms vary across populations.

In this document, we provide a prioritized list of globally and regionally relevant topics for development in to alcohol guidance labels. The topics are prioritized based on ranking criteria developed by the Tufts Global Alcohol Guidance Labeling Investigative Team.

The topics presented here represent a key step in achieving the evidence-based labeling strategy that resulted from the Global Alcohol Guidance Labeling Consensus Conference. The experts called for a set of 3-11 labels addressing diseases and harms associated with alcohol. It was further specified that message content should be identified using a set of ranking criteria.

Overview of Labeling Strategy

Increasing alcohol health literacy is one of the four Global Smart Drinking Goals. Our working definition of alcohol health literacy is "The degree to which people are able to access, understand, evaluate, and apply information about alcohol to prevent personal and community harms from alcohol." The industry role in alcohol health literacy is to make information about alcohol accessible and understandable so that empowered consumers can safely use products. Based on the working definition of alcohol, health literacy label messages should be designed to provide and reinforce information necessary to achieve smart drinking goals. This includes basic information about alcohol guidelines, potential outcomes related to consumption, and strategies to avoid harms.

The labeling strategy proposed at our consensus conference called for a series of labels to be developed for rotation; first a label communicating lower risk drinking guidelines, as well as 3-11 labels communicating diseases and harms. It was stressed that the labels should include both information to raise awareness, as well as actionable advice. The informational and advice labels need to address both the outcomes and actions that are of greatest concern from a population health perspective and also those most relevant to consumers. Because drinking patterns and alcohol-related outcomes vary across populations, not all outcomes and actionable advice will be relevant or applicable in all markets. Therefore, in this document we outline the process we used to prioritize topics so that each market would be able to select labels with information or messages likely to be effective for their consumers. Though we believe that all topics on our list merit consideration for development into a label, we needed a logical approach to make decisions about where to begin label development.

Topic Selection Process

Our goal is to develop between 3 and 11 labels that can be used globally to advance alcohol health literacy. To construct a ranked topic list we examined all diseases and health outcomes associated with alcohol consumption, more proximal harms that result from consumption and the actionable advice associated with the harm. This process led to two lists, one of health outcomes and another we called harms and actionable advice. We applied separate ranking procedures to each list and then merged the two lists. The raked topic list presented here represents a convergence of the top alcohol-related health outcomes and topics addressing alcohol harms and advice on avoiding them.

Ranked Topic List

- 1. Lower Respiratory Infections
- 2. Alternate, substitute non-alcoholic drinks on drinking occasions: Stay hydrated, space drinks with water; For every alcoholic drink have a non-alcoholic drink
- 3. Road Injuries; Driving: Plan for a safe ride home; don't drink and drive; Stopping others from driving while drunk: Friends don't let friends drive drunk; Ask a sober friend to drive
- 4. Taking food with alcohol: Eat before and while drinking; Include food
- 5. Accidents; Injuries/ Accidents (non-driving): Falls; Fires; Machinery; Work accidents
- 6. Tracking consumption on drinking occasion: Don't drink more than you intend to; Count your drinks; Pace of drinking: Drink slowly; opt out of rounds; Decline offers of excess alcohol: Skip a round; It's ok to say no
- 7. HIV
- 8. Planning to limit consumption on drinking occasions: Make a plan to drink less; Tell others you plan to drink less; set your limit; Frequency of drinking: Plan non-drinking days
- 9. Violence; Excessive alcohol can lead to violence; aggressive behavior
- 10. Financial problems: Drink within your means; set an alcohol budget
- 11. FASD
- 12. TB
- 13. Not serving minors: Stop underage drinking; not for minors
- 14 Suicide
- 15. Weight Gain: Alcohol can lead to weight gain; Alcohol calories
- 16. Liver Cancer
- 17. Colorectal Cancer
- 18. Alcohol Use Disorders; Alcohol is a drug: Alcohol is addictive
- 19. Impairs judgement: Affects self-control; The more you drink the less you think;
- 20. Breast Cancer
- 21. Family relations & parenting: Excessive drinking can ruin families; Excessive drinking can ruin relationships with others
- 22. Esophageal Cancer
- 23. Sex-related: Excessive drinking can lead to unsafe sex; erectile disfunction
- 24. Cancer of the Pancreas
- 25. Rates of metabolizing, length of time alcohol effects persist: Excessive drinking can have extended effects
- 26. Throat Cancer
- 27. Atrial Fibrillation
- 28. Lip and Oral Cancer
- 29. Poisoning

We expect that as the label development process progresses, the execution of the labels may not strictly adhere to this list. New insights may be gained from the development process that will provide greater

insight into the feasibility and relevance of the topics for the populations in which initial labels are developed. In addition, local markets will need to select from the labels those which are most appropriate for their consumers. The selection process should be based on the most prevalent alcohol-related health outcomes, local drinking patterns (e.g. rates of binge drinking, prevalence of drinking among women, how "drinks" are served, incidence of drink driving), and current health promotion efforts by local public health authorities.

Alcohol-Related Health Outcomes

We developed a list of health outcomes related to alcohol around which scientific consensus has been reached. Our primary source for determining scientific consensus was the work presented in the Global Status Reports on Alcohol published by the World Health Organization between 1999 and 2014. These reports are available at http://www.who.int/substance_abuse/activities/gsrah/en/. We also provide an overview of the inclusion of health outcomes by year and the main studies cited in Appendix A. We added HIV to the list based on recent discussions in the literature (6, 7). These topics were then assessed in terms of their appropriateness for a label.

Selection Criteria

The consensus conference participants noted that the primary function of the label would be to remind people of a something they have learned from somewhere else. While health promotion campaigns as a whole can be designed to communicate complex information and nuance, labels can by nature include only minimal amounts of information. Nuances may be lost or difficult to communicate. Therefore, the first step in selecting health topics for this label was to assess whether the topic could be clearly communicated on a label with minimal potential for misinterpretation. A health-related outcome may not be appropriate for label development in the following cases.

- The outcome is essentially a larger group of more specific outcomes with different etiologies for which alcohol only plays a role for some, but not all (e.g. cardiovascular disease, cancer). If the more general outcome is named on the label, a warning of the link to alcohol would not be accurate. In this case, consumer trust in the label could be lost if is the information communicated is viewed as inaccurate or false in some way.
- 2. The disease is linked only to frequent or sustained binge drinking and there is no appreciable risk of the outcome at lower levels of drinking. In this case, the outcome would only apply to a sub-set of drinkers. Including such an outcome on the label could diminish consumer trust in the label (e.g. cirrhosis of the liver).
- 3. There is not a clear causal pathway linking alcohol to the outcome. In some cases, there may be an underlying cause/condition that leads both to alcohol use and to the outcome (e.g. Depression). In other cases, alcohol may exacerbate an underlying condition, but is not a risk factor for its development (e.g. Pancreatitis, epilepsy). However, if alcohol increases the susceptibility to a condition a label may be considered (e.g. TB, HIV). In this case, the wording could not indicate that alcohol was a cause, but rather that it increases risk.

4.

Table 1: Application of exclusion criteria to alcohol-related health outcomes

Outcome	Included	If excluded: Rationale
Alcohol Use Disorders	Х	
Accidents- drowning	Х	
Accidents- falls	Х	
Accidents- motor vehicle	Х	
Cancer		Category is too broad, cancers must be specified
Cancer- oral	Х	
Cancer- throat	Х	
Cancer- esophageal	X	
Cancer- liver	X	
Cancer- breast	X	
Cancer- colorectal	Х	
Harms to others- violence	Χ	
Harms to self- poisoning	Х	
Harms to self- suicide	X	
Heart Disease		Category is too broad. The science is not settled yet for
		some forms of heart disease.
Liver Cirrhosis		Linked only to sustained heavy drinking
Pancreatitis		??? Alcohol appears to exacerbate pancreatitis, but not
		cause the disease.
Depression		Causal pathway is not clear.
Epilepsy		Alcohol appears to cause seizures in those with
		undiagnosed epilepsy, but does not appear to be a risk
		factor for the condition itself.
Fetal Alcohol Spectrum	Х	
Disorders		
Lower Respiratory	Х	Alcohol reduces immune function and can interfere with
Infection		adherence to treatment. While there is not a clear link
		to the outcome, labels emphasizing that alcohol
		increases susceptibility may be appropriate.
Tuberculosis	Х	Alcohol reduces immune function and can interfere with
		adherence to treatment. While there is not a clear link
		to the outcome, labels emphasizing that alcohol
		increases susceptibility may be appropriate.
Conduction Disorders	Х	
HIV	Х	Alcohol reduces immune function and can interfere with
		adherence to treatment. While there is not a clear link
		to the outcome, labels emphasizing that alcohol
		increases susceptibility may be appropriate.

Ranking

The goal of the outcomes label is to inform consumers of potential outcomes associated with alcohol consumption. We ranked the health outcomes in terms of their contribution to the global burden of disease to determine those that would be most critical to communicate to consumers, and based on the prevalence of the outcome, might also be of special concern. Data from the Institute for Health Metrics and Evaluation (IHME) **GBD Compare Data Visualization tool (**Available

from http://vizhub.healthdata.org/gbd-compare) were used. This data set provides information about the contribution of various health outcomes to the overall loss of healthy life years in units of DALYs. DALYs for a disease or health condition are calculated as the sum of the Years of Life Lost (YLL) due to premature mortality in the population and the Years Lost due to Disability (YLD) for people living with the health condition or its consequences.

Some of the alcohol-related health outcomes included in the WHO reports did not align perfectly with the Global Burden of Disease (GBD) data set. For example, there is no data on Fetal Alcohol Syndrome as it is not a cause of morbidity and mortality. Therefore, we substituted preterm birth as the outcome of concern. In the case of accidents, they were not broken out in the Global Burden of Disease dataset at the same level of detail as in the WHO report. The global burden of disease ranking of alcohol associated health outcomes is shown in Table 2.

Table 2. Global Burden of Disease: Alcohol-Associated Health Outcomes

	% of total DALYs
Lower Respiratory Infection	3.85
Road Injuries	2.99
Accidents*	2.92
Preterm birth	2.6
HIV	2.41
Tuberculosis	1.83
Suicide**	1.47
Violence	0.99
Liver - Cancer	0.89
Colorectal - Cancer	0.72
Alcohol Use Disorders	0.68
Breast - Cancer	0.63
Esophageal - Cancer	0.39
Pancreas - Cancer	0.34
Throat cancer*** -Cancer	0.25
Atrial fibrillation & flutter	0.25
Lip and oral cavity - Cancer	0.19
Poisoning	0.13

Data are from 2016 for all ages, male and female

Source: https://vizhub.healthdata.org/gbd-compare/

^{*}Consists of falls, drowns, fire, and other unintentional

^{**}Listed in this dataset as "self-harm"

^{****}Consists of larynx and pharynx cancer

The global burden of disease does not accurately represent regional variations in disease. The labels must be designed for use in specific regions, and the goal of the project is to have a set of labels from which to choose the most locally relevant. Therefore, we examined the top five outcomes for 23 regions. The detailed rankings for each region are available in APPENDIX B. To prioritize topics to include on the labels, we determined topics that ranked first in these 23 regions. We then looked at topics that would have to be added to included all topics ranked #1 and #2 in these regions. We repeated this process until all topics ranking among the top 5 burdens of disease for these 23 regions were included. These data are presented in Table 3. Within these lists the topics are ordered according to their overall global prevalence.

Table 3. Top Ranked Health Outcomes Across Global Regions

All #1 ranked	Add to include all	Add to include all #3 &	Add to include all #5	Not in top 5 outcomes
outcomes	#2 outcomes	#4 outcomes	outcomes	in any region
LRI	Preterm Birth	Alcohol Use Disorders	Breast Cancer	Cancer of the Pancreas
Road Injuries	ТВ		Esophageal Cancer	Throat Cancer
Accidents	Suicide			Atrial Fibrillation
HIV	Liver Cancer			Lip and Oral Cancer
Violence	Colorectal Cancer			Poisoning

Based on this analysis we propose that health topics be ranked in the following order:

- 1. Lower Respiratory Infections
- 2. Road Injuries
- 3. Accidents
- 4. HIV
- 5. Violence
- 6. FASD
- 7. TB
- 8. Suicide
- 9. Liver Cancer
- 10. Colorectal Cancer
- 11. Alcohol Use Disorders
- 12. Breast Cancer
- 13. Esophageal Cancer
- 14. Cancer of the Pancreas
- 15. Throat Cancer
- 16. Atrial Fibrillation
- 17. Lip and Oral Cancer
- 18. Poisoning

Alcohol Harms and Actionable Advice

The labeling strategy seeks to balance informing consumers of potential outcomes from alcohol consumption with providing information about harms and actionable advice on avoiding those harms. Health outcomes, such as road injuries, accidents, violence, and FASD are already frequently communicated in the form of actionable advice, either with respect to behaviors to avoid (e.g. "it is best not to drink while pregnant") or with respect to behaviors to adopt (e.g. "plan for a safe ride"). To develop a list of topics for harms and actionable advice, we reviewed the scientific literature, grey literature, and websites of industry and non-profit organizations to categorize the types of messages already being communicated. We found that messages addressing alcohol consumption and shorter-term outcomes can be broadly grouped into the following categories: harms that can result from intoxication, strategies to avoid intoxication or reduce consumption on an occasion or overall, increasing awareness of shorter-term effects of alcohol, and social messages about protecting others. They are described with examples in Table 4.

Table 4: Public health and industry message categories: Harms and Advice

Message category	Specific topics/messages included in existing campaigns
Harms that can result from intoxication	
Driving	Plan for a safe ride home; don't drink and drive
Injuries/ Accidents	Falls; Fires; Machinery; Work accidents
(non-driving)	
Violence	Excessive alcohol can lead to violence; aggressive
	behavior
Sex-related	Excessive drinking can lead to unsafe sex; erectile
	disfunction
Impairs judgement	Affects self-control; The more you drink the less you
	think;
Family relations & parenting	Excessive drinking can ruin families; Excessive
	drinking can ruin relationships with others
Strategies to avoid intoxication/reduce	
amount consumed overall or on occasion	
Pace of drinking	Drink slowly; opt out of rounds
Frequency of drinking	Plan non-drinking days
Taking food with alcohol	Eat before and while drinking; Include food
Planning to limit consumption on	Make a plan to drink less; Tell others you plan to
drinking occasions	drink less; set your limit
Tracking consumption on drinking	Don't drink more than you intend to; Count your
occasion	drinks
Alternate, substitute non-alcoholic	Stay hydrated, space drinks with water; For every
drinks on drinking occasions	alcoholic drink have a non-alcoholic drink
Decline offers of excess alcohol	Skip a round; It's ok to say no
Increasing awareness of shorter-term	
effects of alcohol	
Rates of metabolizing, length of time	Excessive drinking can have extended effects
alcohol effects persist	
Alcohol is a drug	Alcohol is addictive
Financial problems	Drink within your means; set an alcohol budget
Weight Gain	Alcohol can lead to weight gain; Alcohol calories
Social Messages about protecting others	
Stopping others from driving while	Friends don't let friends drive drunk; Ask a sober
drunk	friend to drive
Not serving minors	Stop underage drinking; not for minors

Ranking

It is important to note that harms and actionable advice will be applicable only in so far as they resonate with the local drinking contexts and patterns. Contexts and patterns are culturally determined and vary substantially among populations, thus limiting our ability to identify which potential messages would be most likely to be effective at a global or regional level. Therefore, we did not take an empirical approach as we did with the health outcomes to ranking potential actionable advice messages. Instead the topics have been arranged to emphasize those that lend themselves to actionable advice that could be conveyed positively and simply on a label. Our rationale is that many of the health outcomes identified

as relevant could only be developed into informative messages and our strategy is to balance information with actionable advice. In addition, in the discussions during the consensus conference, there was agreement that positive actions, expressed as "DO" would be more appealing than prohibitions beginning with "DON'T."

The ranking is as follows:

- 1. Alternate, substitute non-alcoholic drinks on drinking occasions: Stay hydrated, space drinks with water; For every alcoholic drink have a non-alcoholic drink
- 2. Taking food with alcohol: Eat before and while drinking; Include food
- 3. Tracking consumption on drinking occasion: Don't drink more than you intend to; Count your drinks; Pace of drinking: Drink slowly; opt out of rounds; Decline offers of excess alcohol: Skip a round; It's ok to say no
- 4. Planning to limit consumption on drinking occasions: Make a plan to drink less; Tell others you plan to drink less; set your limit; Frequency of drinking: Plan non-drinking days
- 5. Financial problems: Drink within your means; set an alcohol budget
- 6. Driving: Plan for a safe ride home; don't drink and drive; Stopping others from driving while drunk: Friends don't let friends drive drunk; Ask a sober friend to drive
- 7. Not serving minors: Stop underage drinking; not for minors
- 8. Weight Gain: Alcohol can lead to weight gain; Alcohol calories
- 9. Injuries/ Accidents (non-driving): Falls; Fires; Machinery; Work accidents
- 10. Violence: Excessive alcohol can lead to violence; aggressive behavior
- 11. Impairs judgement: Affects self-control; The more you drink the less you think;
- 12. Family relations & parenting: Excessive drinking can ruin families; Excessive drinking can ruin relationships with others
- 13. Sex-related: Excessive drinking can lead to unsafe sex; erectile disfunction
- 14. Rates of metabolizing, length of time alcohol effects persist: Excessive drinking can have extended effects
- 15. Alcohol is a drug: Alcohol is addictive

Mandatory and voluntary label topics and messages

The health outcomes and harms included in the topic lists overlaps with information and advice already included on labels required in some jurisdictions. Using data available from the International Alliance for Responsible Drinking (IARD), we compiled a listing of the messages on required and voluntary labels (5) And have summarized them here. Details of the label messages in countries that require them can be found in APPENDIX C

General health warnings such as

- Excessive consumption is harmful to your health
- Alcohol abuse is dangerous to your health
- Seriously damages health

More specific health warnings, such as

- Harmful to unborn baby
- Carcinogen
- Addictive

 Severe diseases of the human nervous system and internal organs

Advice, including

- Do not operate machinery
- Do not drive
- Not for children
- Don't walk on the road
- Pregnant or nursing women should not drink
- Drink in moderation
- Do not drink in excess
- Alcohol is not your friend
- Drink responsibly
- Destroys your family

Specific outcomes, including

- Liver cirrhosis
- Personal injuries
- Violence and crime
- Impaired judgment
- Congenital anomaly
- Stroke
- Memory loss
- Dementia

- Cancer
- Liver cancer
- Gastric adenocarcinoma
- Sexual impotency
- Loss of consciousness
- Death

- Diseases of the kidneys
- Diseases of digestive organs
- Birth defects

References Cited

- 1. World Health Organization, Management of Substance Abuse Unit, Global status report on alcohol and health, 2014.
- 2. Lim, S.S., et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet, 2012. 380(9859): p. 2224-60.
- 3. Booth, B.M. and W. Feng. The impact of drinking and drinking consequences on short-term employment outcomes in at-risk drinkers in six southern states. J Behav Health Serv Res, 2002. 29(2): p. 157-66.
- 4. Leonard, K.E. and J.C. Rothbard. Alcohol and the marriage effect. J Stud Alcohol Suppl, 1999. 13: p. 139-46.
- 5. International Alliance for Responsible Drinking. Health Warning Labeling Requirements. [Cited 24 September 2018]. Available from: http://www.iard.org/resources/health-warning-labeling-requirements/.
- 6. Rehm, J., et al., Does alcohol use have a causal effect on HIV incidence and disease progression? A review of the literature and a modeling strategy for quantifying the effect. Population health metrics, 2017. 15(1): p. 4.
- 7. Williams, E.C., et al., Alcohol use and human immunodeficiency virus (HIV) infection: current knowledge, implications, and future directions. Alcoholism: Clinical and Experimental Research, 2016. 40(10): p. 2056-2072.

APPENDIX A: Harms linked to Alcohol: Overview of WHO Global Status Reports on Alcohol and Health, 1999-2014

	Global Status	Global Status	Global Status	Global Status
	Report on	Report on	Report on	Report on
	Alcohol 1999	Alcohol 2004	Alcohol and	Alcohol and
			Health 2011	Health 2014
Accidents- drowning	✓	✓	✓	✓
Accidents- falls	✓	✓	✓	✓
Accidents- motor vehicle	✓	✓	✓	✓
Cancer- oral	✓	✓	✓	✓
Cancer- throat	✓	✓	✓	✓
Cancer- esophageal	✓	✓	✓	✓
Cancer- liver	✓	✓	✓	✓
Cancer- breast	✓	✓	✓	✓
Harms to Others- homicide	✓	✓	✓	✓
Harms to Others- violence	✓	✓	✓	✓
Harms to Self- poisoning	✓	✓	✓	✓
Harms to Self- suicide	✓	✓	✓	✓
Heart Disease	✓	✓	✓	✓
Liver Cirrhosis	✓	✓	✓	✓
Pancreatitis	✓	✓	✓	✓
Depression	Х	✓	✓	✓
Epilepsy	X	✓	✓	✓
FASD	Х	✓	✓	✓
Cancer- colorectal	Х	Х	✓	✓
Lower Respiratory Infection	Х	Х	✓	✓
Tuberculosis	Х	Х	✓	✓
Conduction Disorders	X	X	X	✓

Source:

http://www.who.int/substance_abuse/activities/gsrah/en/

Evidence cited in the reports:

Accidents

Drowning and Falls

- Both included in WHO's 1999 Report, which shares alcohol-attributable fractions based on three different studies:
 - English DR, et al. (1995) The quantification of drug caused morbidity and mortality in Australia, 1995 edition. Commonwealth Department of Human Services and Health, Canberra. Produced by the Australian Government Publishing Service.
 - Schultz J, et al. (1991) Quantifying the disease impact of alcohol with ARDI software.
 Public health reports 106, 443 450.
 - Single E, et al. (1998) The economic costs of alcohol, tobacco and illicit drugs in Canada in 1992. Addiction 93, 983-998.

Motor Vehicle

- Included in WHO's 1999 Report: "Alcohol-related motor vehicle crashes are among the most serious acute consequences of alcohol use"
 - Cites [Zador T (1989) Alcohol-related risk of fatal driver injuries in relation to driver age and sex. Washington DC, Insurance Institute for Highway Safety.]
- WHO's 2004 Report separates out motor vehicle traffic accidents, motor vehicle nontraffic accidents, bicycle accident injuries, other road vehicle accident injuries, water transport accident injuries, and air-space transport accidental injuries.
- WHO's 2011 and 2014 Reports include "road traffic accidents" and motor vehicle accidents, but do *not* specify boat/water transport or bicycle accident injuries

Cancer

Oral, Throat, Esophagus, Liver

- WHO's 1999 Report mentions association between alcohol and cancers of the oral cavity, pharynx, larynx, esophagus, liver, and breast
 - Cites [IARC (1988) [International Agency for Research on Cancer] IARC monographs on the evaluation of carcinogenic risks to humans. Vol. 44. Alcohol drinking. Lyon, IARC, 1988.]
 - Cites [Smith-Warner SA, et al. (1998) Alcohol and breast cancer in women A pooled analysis of cohort studies. *JAMA – Journal of the American medical association*, 279(7):535-540.]

Colorectum

- WHO's 2011 Report adds cancer of the colorectum; 2004 report describes evidence of causal relationship between alcohol and colon and rectum cancer as "weak and inconclusive"
 - 2011 Report cites [Baan R et al. on behalf of the WHO International Agency for Research on Cancer Monograph Working Group (2007). Carcinogenicity of alcoholic beverages. *Lancet Oncology*, 8:292–293.]

Pancreas

• WHO's 2014 Report adds that alcohol is "likely to cause pancreatic cancer," but it does not appear that scientific consensus has been achieved

Harms to Others

Homicide

- Included in WHO's 1999 Report
 - o Cites [Collins J, Schlenger W (1988) Acute and chronic effects of alcohol use on violence. Journal of studies on alcohol 49:516-521.]
- Mentioned in subsequent WHO reports but with minimal focus (causal relationship names but not discussed)

Violence

- Included in WHO's 1999 Report—mentions interpersonal violence including aggravated assault, spouse and child abuse, sexual assault and rape
 - O Cites [Edwards G, et al. (1994) Alcohol policy and the public good. Oxford medical publication. Oxford university press.]; [Collins J, Schlenger W (1988) Acute and chronic effects of alcohol use on violence. Journal of studies on alcohol 49:516-521.]; and [CSAP (1997) [Center for Substance Abuse Prevention] Descriptions of substance abuse problems, available Problem Indicator, Problem Indicator Data and Cost Estimation. Rockville, MD. Substance Abuse and Mental Health Services Administration.]
- WHO's 2004 Report notes that "Alcohol is strongly associated with violent crime, although this
 association varies considerably across settings" and discusses that the mechanism for the causal
 relationship between alcohol and violence is not solely pharmacological, but "psychopharmacological"
 - This report includes a section on "Alcohol and domestic violence," referred to as "spouse abuse" in the 1999 Report
- WHO's 2011 report distinguishes between alcohol as a "causal factor" for various diseases, and a "precursor" to injury and violence

Harms to Self

Poisoning

- Included in WHO's 1999 Report
 - Cites [Anderson P (1995) Alcohol and risk of physical harm. In: Holder HD, Edwards G, eds. Alcohol: evidence and issues. Oxford, England: Oxford University Press, 82-113.]

Suicide

• Included in WHO's 1999 Report

 Cites studies as early as 1988: [Norström T (1988) Alcohol and suicide in Scandinavia. British journal of addiction, 83:553-559.]

Heart disease

- WHO's 1999 Report focuses on protective effects for coronary heart disease, but also mentions that alcohol is associated with higher death rates from haemorrhagic stroke
 - O Cites [Donahue RP, et al. (1986) Alcohol and hemorrhagic stroke: the Honolulu Heart Program. *JAMA Journal of the American medical association*; 2311-4.]
- Stroke, ischaemic heart disease, other cardiac diseases, and hypertensive disease are listed as "measured adverse outcomes of exposure [to alcohol]" in WHO's 2002 World Health Report, and in subsequent WHO alcohol reports

Liver Cirrhosis

- Included in WHO's 1999 Report
- First linked to alcohol by Baillie in 1793—[Duffin JM (September 1987). "Why does cirrhosis belong to Laennec?". CMAJ. 137 (5): 393–6.]
- Longest researched and best-established alcohol-related health harm

Pancreatitis

- Acute and chronic pancreatitis are both included as alcohol-related conditions in the WHO's 1999 Report
 - Cites [Singh M, Simsek H (1990) Ethanol and the pancreas: current status.
 Gastronenterology. 98:1051- 1062.] –consensus is clear but little knowledge on pathogenesis

Depression

- WHO's 2004 Report states that sufficient evidence exists to establish a causal link between alcohol consumption and depression, but notes that this relationship is "controversial."
 Causality was determined by noting the large proportion of people for whom alcohol use precedes depression, plus the proportion who experience remission from depression during abstinence.
 - A key cited study includes: [Merikangas KR et al. Comorbidity of substance use disorders with mood and anxiety disorders: Results of the International Consortium in Psychiatric Epidemiology. Addictive Behaviors: An International Journal, 1998, 23(6):893-907.]
- WHO's 2011 Report specifies that the connection is between alcohol and "unipolar depressive disorder" (rather than other forms of depression)

Epilepsy

- First mentioned in WHO's 2004 Report
 - O Cites studies as early as 1995: [Martín R et al. Etiological and prognostic factors in the late onset epilepsy. Revista de Neurologia, 1995, 23(120):285-289.]

FASD

- First mentioned in WHO's 2004 Report
 - Cites studies as early as 1995, e.g. [Shu XO et al. Maternal smoking, alcohol drinking, caffeine consumption, and fetal growth: results from a prospective study. Epidemiology, 1995, 6(2):115-120.
 - Cites key publications from 1998, e.g. [Alvear J, Andreani S, Cortes F. Fetal alcohol syndrome and fetal alcohol effects: importance of early diagnosis and nutritional treatment. Revista Medica de Chile, 1998, 126(4):407-412.]
- WHO's 1999 Report makes no mention of effects of prenatal alcohol exposure

Lower Respiratory Infection

- First mentioned in WHO's 2011 Report—"new evidence points to a causal link between alcohol
 and infectious disease. Namely, alcohol consumption weakens the immune system, thus
 enabling infections by pathogens, which cause pneumonia and tuberculosis"—no citations
 provided
- Cited in WHO's 2014 Report: [Samokhvalov AV, Irving HM, Rehm J (2010a). Alcohol consumption as a risk factor for pneumonia: systematic review and meta-analysis. Epidemiology and Infection. 138(12):1789–95.

Tuberculosis

- First mentioned in WHO's 2011 Report
 - o Cites [Lönnroth K et al. (2008). Alcohol use as a risk factor for tuberculosis a systematic review. *BMC Public Health*, 8:289.]
 - o Case-control studies as early as 1960s revealed association between TB and alcohol

Conduction disorder

- First mentioned in WHO's 2014 Report, combined in list of other cardiovascular diseases
 - Cites [Samokhvalov AV, Irving HM, Rehm J (2010c). Alcohol as a risk factor for atrial fibrillation: a systematic review and meta-analysis. European Journal of Cardiovascular Prevention and Rehabilitation. 17(6):706–712.]

APPENDIX B: Burden of Diseases Ranked by Region

Version Date: 7/12/18

Source: https://vizhub.healthdata.org/gbd-compare/

Data is 2016 for all ages, both male/female, represented as % of total DALYs

Rank	Southern Latin America	Latin America & Caribbean	Central Latin America	Andean Latin America	Tropical Latin America	North Africa & Middle East	Sub- Saharan Africa	Southern Sub- Saharan Africa
1	LRI*	Violence	Violence	LRI	Violence	Road Injuries	HIV	HIV
2	Road Injuries	Road Injuries	Road Injuries	Road injuries	Road Injuries	Preterm birth	LRI	LRI
3	Accidents#	LRI	LRI	Preterm birth	Accidents#	LRI	Preterm birth	ТВ
4	Suicide	Accidents#	Accidents#	Accidents	LRI	Accidents#	ТВ	Road injuries
5	Preterm birth	Preterm birth	Preterm birth	Violence	Preterm birth	Suicide*	Accidents	Violence

^{*}LRI=lower respiratory infection

#Consists of falls, drowns, fire, and other unintentional

Rank	Western Sub- Saharan Africa	Eastern Sub- Saharan Africa	Central Sub- Saharan Africa	High- income North America	United States	Australasia	High- income Asia Pacific
1	LRI	HIV	LRI	Accidents#	Accidents#	Accidents#	Accidents#
2	HIV	LRI	ТВ	Road Injuries	Road Injuries	Suicide	Suicide
3	Preterm birth	ТВ	HIV	Suicide	Suicide	Road Injuries	LRI
4	Accidents	Preterm birth	Preterm birth	Colorectal Cancer	Colorectal Cancer	Colorectal Cancer	Colorectal Cancer
5	ТВ	Accidents	Accidents	LRI	LRI	Breast Cancer	Liver Cancer

Ran	Western	Eastern	Central	Central	East Asia	Southeast	Oceania	South Asia
k	Europe	Europe	Europe	Asia		Asia		
1	Accidents #	Accidents #	Accidents #	LRI	Road Injuries	LRI	LRI	LRI
2	Colorectal Cancer	Suicide	Colorectal Cancer	Accidents #	Liver Cancer	Road Injuries	Preterm birth	Preterm birth
3	Suicide	Alcohol Use Disorders	Road Injuries	Road Injuries	Accidents#	Tuberculosi s	Road Injuries	Accidents#
4	Road Injuries	Road Injuries	Suicide	Preterm birth	Suicide	Accidents#	Accidents #	Tuberculosi s
5	Breast Cancer	LRI	LRI	Suicide*	Esophagea I Cancer	Preterm birth	Suicide*	Road Injuries

APPENDIX C: Governmental labeling requirements (IARD)

Region	Country	Overview	Specific Health Outcomes	General warnings
Africa	Kenya	Labels of all beverages of ABV 0.5% or higher must include at least two of these health warning messages, on no less than 30% of the total surface area of the package, in English or Kiswahili, and on a rotating basis:	"Excessive alcohol consumption can cause liver cirrhosis";	"Excessive alcohol consumption is harmful to your health"; "Excessive alcohol consumption impairs your judgment"; "Do not drive or operate machinery"; "Not for sale to persons under the age of 18 years".
	Mauritius	All alcoholic beverages shall bear a label both in English and French indicating that an excessive consumption of alcoholic drinks causes serious health, social and domestic problems.		, , , , , , , , , , , , , , , , , , , ,
	Mozambique	Labels of all alcoholic beverages must contain the following phrase in upper case, easily readable letters:		"Sale to and consumption by persons under 18 years of age is prohibited."
	Togo	Packaging of alcoholic beverages must bear the warning "seriously damages health" and the ABV of the beverage.		"seriously damages health"
	South Africa	1) Container labels for alcohol beverages must contain at least one of the [seven] health messages. (2) A health message referred to in subregulation shall – (i) be visible, legible, and indelible and the legibility thereof shall not be affected by any other matter, printed or otherwise; (ii) be on a space specifically devoted for it, which must be at least one eight of the total size of the container label; and (iii) be in black on a white background.	"Alcohol is addictive" "Alcohol increases your risk to personal injuries" "Alcohol is a major cause of violence and crime" "Drinking during pregnancy can be harmful to your unborn baby"	"Alcohol abuse is dangerous to your health" "Don't drink and walk on the road, you may be killed" "Alcohol reduces driving ability, don't drink and drive"

	Zimbabwe	Labels of all alcoholic beverages of 0.2% ABV or higher must bear two warnings:		"Alcohol may be hazardous to health if consumed to excess, the operation of machinery or driving after the consumption of alcohol is not advisable." "Not for sale to persons under the age of 18 years."
Asia Pacific North	China	Labels of beverages of ABV above 0.5% are required to include		"Excessive drinking is harmful to health" or "Pregnant women and children shall not drink"
	Japan	Displayed in an easy-to-read location on the container, using uniform Japanese font, at least 6 pts in size:	-"Drinking alcohol during pregnancy or nursing may adversely affect the development of your fetus or child"	"Be careful not to drink in excess" "Drink in moderation" Self-Regulatory Code of Advertisement Practices and Container Labeling for Alcoholic Beverages (2016)
	Korea, Republic of	Labels of beverages of 1% ABV or higher must include one of three warnings:	Drinking during pregnancy increases the risk for congenital anomaly. Alcohol is [a] carcinogen, so excessive drinking causes liver cancer, gastric adenocarcinoma and so on. Drinking during pregnancy, underage drinking, and excessive drinking cause congenital anomaly, brain development disruptions and cancer, respectively. Drinking during pregnancy increase[s] the risk for congenital anomaly, Excessive drinking cause[s] stroke, memory loss and dementia.	
Asia Pacific South	Malaysia	Labels of beverages of ABV 2% or higher must include, in a non-serif font of not less than 12 point size, the words		'MEMINUM ARAK BOLEH MEMBAHAYAKAN KESIHATAN' ('Alcohol can harm health')

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	India	effective April 1, 2019: Labels of all beverages of greater than 0.5%ABV shall include the following warning in not less than 3mm size: The warning must be in English or in the official state or regional language. Labels of wines must include a non-vegetarian logo if processing aids of animal origin were used.		"Consumption of alcohol is injurious to health. Be safe – don't drink and drive".
	Indonesia	Labels of alcoholic beverages must state "Alcoholic beverage" and bear the warning "Those under age 21 and pregnant women should not drink" in Indonesian.		"Those under age 21 and pregnant women should not drink"
	Uzbekistan	Labels of all alcoholic beverages of greater than 1.5% ABV must include the following warning, occupying not less than 40% of the label area: The content of the warning shall be reviewed every five years.	"The excessive consumption of alcoholic beverages leads to severe diseases of the human nervous system and internal organs."	
	Thailand	Warning pictures and messages for disadvantages or dangers of alcoholic beverages shall be made in pictures with 4 colors, provided that each form shall be used for 1,000 containers: (a) if the containers are square shape, the warning pictures shall have the size of not less than 50% (b) if the containers are in cylindrical shape, the warning pictures shall have the size of not less than 40% of the total space of the containers.	"Liquor drinking may cause cirrhosis and sexual impotency" "Liquor drinking may cause less consciousness and death" "Liquor drinking is dangerous to health and causes less consciousness" "Drunk driving may cause disability or death"	"Liquor drinking is harmful to you and destroys your family"
	Australia	Alcohol producers may apply the "Get the facts" logo and additional issue-specific message		"It is Safest Not to Drink While Pregnant" or the "pregnant lady" pictogram developed by <u>DrinkWise</u> <u>Australia</u>
Europe	France	Labels of beverages of ABV above 1.2% must include	"Consumption of alcoholic beverages during pregnancy,	

	either the text "Consumption of alcoholic beverages during pregnancy, even in small	even in small amounts, can have serious consequences for the child's health." or a	
	amounts, can have serious consequences for the child's health." or a pictogram to that effect.	pictogram to that effect.	
	The health warning must appear in the same visual field as the obligatory alcohol content indication.		
Germany	Labels of sweetened alcoholic beverages (alcopops) of ABV between 1.2% and 10% must display the following warning in the same typeface, size, and color as the brand or trade name or, where there is neither, as the product designation:		"Sale is prohibited to persons under 18 under § 9 of the Youth Protection Act"
Lithuania	Labels of distilled beverages of 1.2%ABV or higher and fermented beverages of 0.5% or higher are required to include a pictogram warning of the potential effects of drinking alcohol during pregnancy.	include a pictogram warning of the potential effects of drinking alcohol during pregnancy	
Russian Federation	Labels of wine and spirits, including vodka, must contain the message	"Alcohol is not for children and teenagers up to age 18, pregnant and nursing women, or for persons with diseases of the central nervous system, kidneys, liver, and other digestive organs."	
Slovenia	Labels of foodstuff containing alcohol (not alcohol beverages) must include a warning that they are not suitable for children, printed in capital letters that are clearly visible, readable and are a distinctly different color from the background.		warning that they are not suitable for children
Turkey	Labels of all alcoholic beverages must include the text		"Alcohol is not your friend." and three pictograms: against drinking by minors aged below 18, against drinking by pregnant women, and against driving

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	United Kingdom	The Department of Health Guidance: Communicating the UK Chief Medical Officers' low risk drinking guidelines 2017 recommends the following messages:	-	under the influence of alcohol. -The UK Chief Medical Officers recommend adults do not regularly drink more than 14 units per week. -Drinkaware.co.uk -It is safest not to drink alcohol when pregnant, or
Latin America COPEC	Colombia	The labels of beverages of ABV 2.5% or higher must exhibit on their labeling the warnings 1. "Excessive use of alcohol is harmful to health". This warning must take up, at a minimum, a tenth of the label's area, be placed on the front, and be located at the bottom in easily readable font contrasting with the background		"Excessive use of alcohol is harmful to health". "It is prohibited to sell intoxicating beverages to minors."
	Ecuador	Warnings must be legible, using distinguishable colors: Beverages of above 5% ABV: "Warning: The excessive consumption of alcohol limits your capacity to operate machinery and can cause harm to your health and family. Ministry of Health of Ecuador. Sale prohibited to minors below 18 years old." The warning must occupy at least 10% of the total surface area. Beverages of 5% ABV and below: "Warning: The excessive consumption of alcohol can cause harm to your health. Ministry of Health of Ecuador." The		"Warning: The excessive consumption of alcohol limits your capacity to operate machinery and can cause harm to your health and family. Ministry of Health of Ecuador. Sale prohibited to minors below 18 years old."

		warning must occupy at least 6% of the total surface area.	
	Peru	Labels of all fermented and distilled beverages must contain, on an area no smaller than 10% of the packaging, in easily readable capital letters, the phrase	"Excessive drinking of alcoholic beverages is harmful."
Latin America North	Brazil	Beverages with 13% ABV and above:	"Avoid Excessive Alcohol Consumption."
	Dominican Republic	The packaging of beer and alcoholic beverages for national consumption should include the following warning: written in easily readable font and in contrasting color.	"Alcohol consumption harms health."
	Guatemala	Labels of all alcoholic beverages must include	"The excess consumption of this product is harmful to the consumer's health"
Latin America South	Argentina	Labels of all alcoholic beverages must include	"Drink in moderation" "Not to be sold to anyone under 18 years of age"
	Bolivia	Labels of all alcoholic beverages must include the warnings:	"Excessive consumption of alcohol is harmful to health" "Sale prohibited to minors
	Chile	Compañia Cervecerias Unidas S.A. (CCU) places warnings on its products:	below 18" "CCU asks you to drink responsibly" "Product for those 18 and older"
Middle Americas	Costa Rica	Labels of all beverages of ABV higher than 0.5% must include a cautionary panel with the message "excessive consumption of alcoholic beverages is harmful to health" or similar.	"excessive consumption of alcoholic beverages is harmful to health"
	El Salvador	Warnings must be legible, using distinguishable colors and occupy 10% of the total surface area.	"Warning: The excessive consumption of alcohol limits your capacity to operate machinery and can cause harm to your health and family" "The sale of this product is

	Honduras	Labels of all alcoholic beverages must include Labels of all beverages of ABV higher than 0.5% must include a cautionary panel with the message "excessive consumption of alcoholic beverages is harmful to	prohibited for those younger than 18 years old" "Warning: Abuse of the beverage harms your health. IHADFA" "excessive consumption of alcoholic beverages is harmful to health"
North	Mexico	health" or similar. Labels of alcoholic beverages of 2.0% to 55%ABV must include "The abuse of the consumption of this product is harmful to health." The warning must be in uppercase and in a contrasting color. The required size of lettering varies by beverage ABV. Labels of alcoholic beverages of higher than 6.0%ABV: Of three pictogram warnings (against consumption by minors aged under 18 and by pregnant women and against driving under the influence of alcohol), either all three must be included simultaneously, or a single one may be included in which case the pictogram chosen must be changed on a rotating principle every four months. Labels of alcoholic beverages with ABV 2.0-6.0% must display a modified pictogram warning against consumption by minors aged under 18. Labels may voluntarily include the statement "For more information visit the page: www.conadic.salud.gob.mx, where there is information on the harmful use of alcohol".	"The abuse of the consumption of this product is harmful to health." "For more information visit the page: www.conadic.salud.gob.mx, where there is information on the harmful use of alcohol". "This product contains % of alcohol. Not recommended for children."

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	United States	Labels of alcoholic beverages of ABV below 2.0% must include "This product contains % of alcohol. Not recommended for children." The health warning statement must appear on the brand label or separate front label, or on a back or side label, separate and apart from all other information. It must be readily legible under ordinary conditions, and must appear on a contrasting background. Labels bearing the warning must be firmly affixed to the container. Minimum type size is specified for containers of various sizes.	"GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems"	
Middle East	Israel	Labels of beverages of up to 15.5% ABV must include "Warning: Contains alcohol - it is recommended to refrain from excessive consumption". Labels of beverages of 15.5% ABV and higher must include "Warning: Excessive consumption of alcohol is life threatening and is detrimental to health!"		"Warning: Contains alcohol - it is recommended to refrain from excessive consumption". "Warning: Excessive consumption of alcohol is life threatening and is detrimental to health!"