

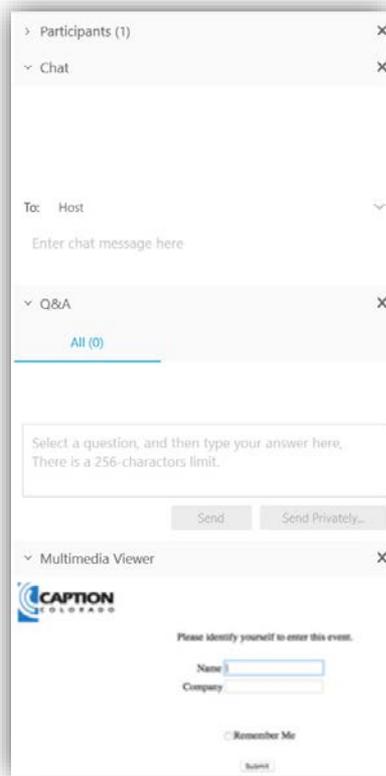
Alcohol and Cancer Control

NOT-CA-20-034

Notice of Special Interest (NOSI) Webinar

*Tanya Agurs-Collins (NCI), David Berrigan (NCI),
Gary Murray (NIAAA), I-Jen Castle (NIAAA)*

Using WebEx and Webinar Logistics



- All lines will be in listen-only mode
- Make sure icons are selected for them to appear as a drop-down option
- Submit questions at any time during the presentation by typing into the Q&A feature on the right-hand side of the WebEx interface.
 - Select Host and a moderator will ask the questions on your behalf
- Closed captioning available by selecting the Media Viewer Panel on the right-hand side of the screen
- This webinar is being recorded and will be posted at a later date

Webinar Presenters and NOSI Contacts



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Webinar Overview

- Overview of NIH Notice of Special Interest (NOSI)
- Background and Purpose of NCI/NIAAA Alcohol and Cancer Control NOSI - [NOT-CA-20-034](#)
- NCI Research Priorities and Research Areas
- NIAAA Research Priorities and Research Areas
- Application and Submission Information
- Q & A

NIH Notice of Special Interest (NOSI)

- Notice posted in the NIH guide that institutes and Centers can use to share and update research priorities.
- NOSIs briefly highlight a specific topic of research or programmatic interest
- NOSIs direct applicants to relevant funding opportunities for grant, supplement or competitive revision submissions
- NOSIs are not generally associated with set aside funds; gradually replacing Program announcements
- Details on NIH NOSIs at [NOT-OD-19-107](#) and [FAQs](#) about grants

Notice of Special Interest: Alcohol and Cancer Control ([NOT-CA-20-034](#))

Release Date: March 18, 2020

First Available Due Date: June 05, 2020

Expiration Date: September 09, 2023

National Cancer Institute (NCI)

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Calls for R01s, R21s, R03s

Purpose: This Notice highlights interest in receiving investigator-initiate dressing the effects of alcohol on human health across the cancer control continuum.

Association Between Alcohol and Cancer Risk

- Alcohol is classified as a Group 1 carcinogen by the International Agency for Research on Cancer (IARC).
- In the US, alcohol use causes 5.6% of cancer cases and 4.0% cancer deaths
- “The overall absolute increase in cancer risk for one bottle of wine per week equals that of five (men) or ten cigarettes per week”

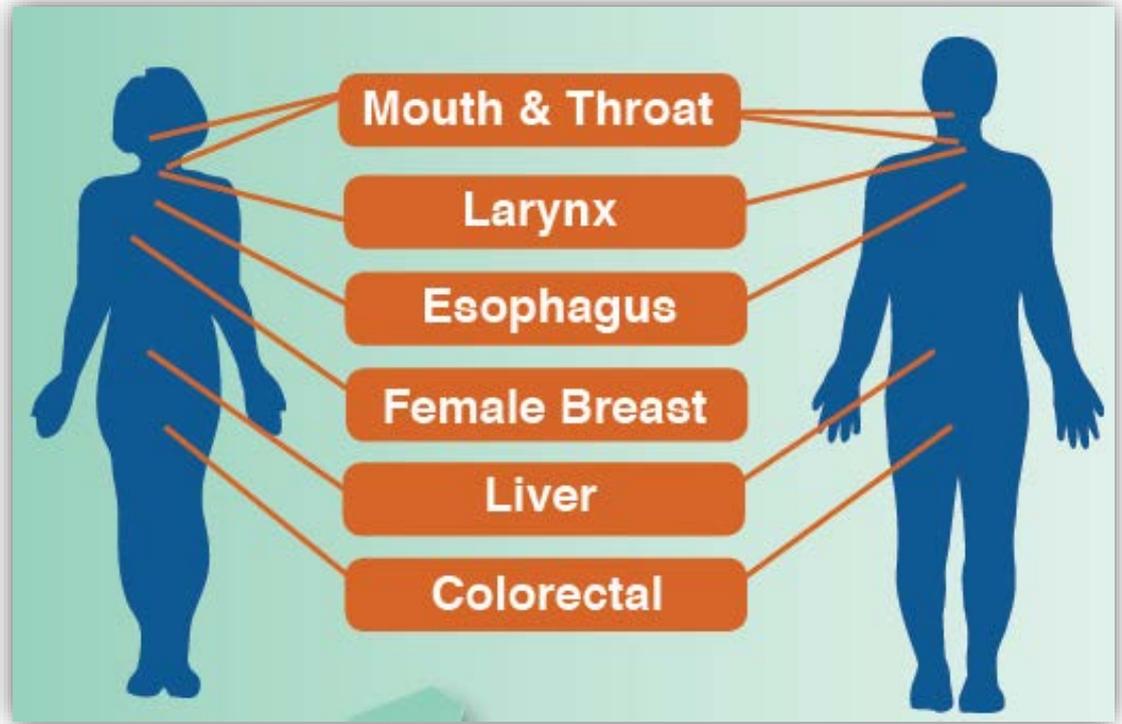
ALCOHOLIC DRINKS AND THE RISK OF CANCER					
WCRF/AICR GRADING		DECREASES RISK		INCREASES RISK	
		Exposure	Cancer site	Exposure	Cancer site
STRONG EVIDENCE	Convincing			Alcoholic drinks ¹	Mouth, pharynx and larynx 2018 Oesophagus (squamous cell carcinoma) 2016 Liver 2015 ² Colorectum 2017 ³ Breast (postmenopause) 2017 ⁴
	Probable	Alcoholic drinks	Kidney 2015 ⁵	Alcoholic drinks	Stomach 2016 ² Breast (premenopause) 2017 ⁴
LIMITED EVIDENCE	Limited – suggestive			Alcoholic drinks	Lung 2017 Pancreas 2012 ² Skin (basal cell carcinoma and malignant melanoma) 2017
STRONG EVIDENCE	Substantial effect on risk unlikely	None identified			

- Alcoholic drinks include beers, wines, spirits, fermented milks, mead and cider. The consumption of alcoholic drinks is graded by the International Agency for Research on Cancer as carcinogenic to humans (Group 1)[3].
- The conclusions for alcoholic drinks and cancers of the liver, stomach and pancreas were based on evidence for alcohol intakes above approximately 45 grams of ethanol per day (about three drinks a day). No conclusions were possible for these cancers based on intakes below 45 grams of ethanol per day.
- The conclusion for alcoholic drinks and colorectal cancer was based on alcohol intakes above approximately 30 grams of ethanol per day (about two drinks a day). No conclusion was possible based on intakes below 30 grams of ethanol per day.
- No threshold level of alcohol intake was identified in the evidence for alcoholic drinks and breast cancer (pre and postmenopause).
- The conclusion for alcoholic drinks and kidney cancer was based on alcohol intakes up to approximately 30 grams of ethanol per day (about two drinks a day). There was insufficient evidence to draw a conclusion for intakes above 30 grams of ethanol per day.

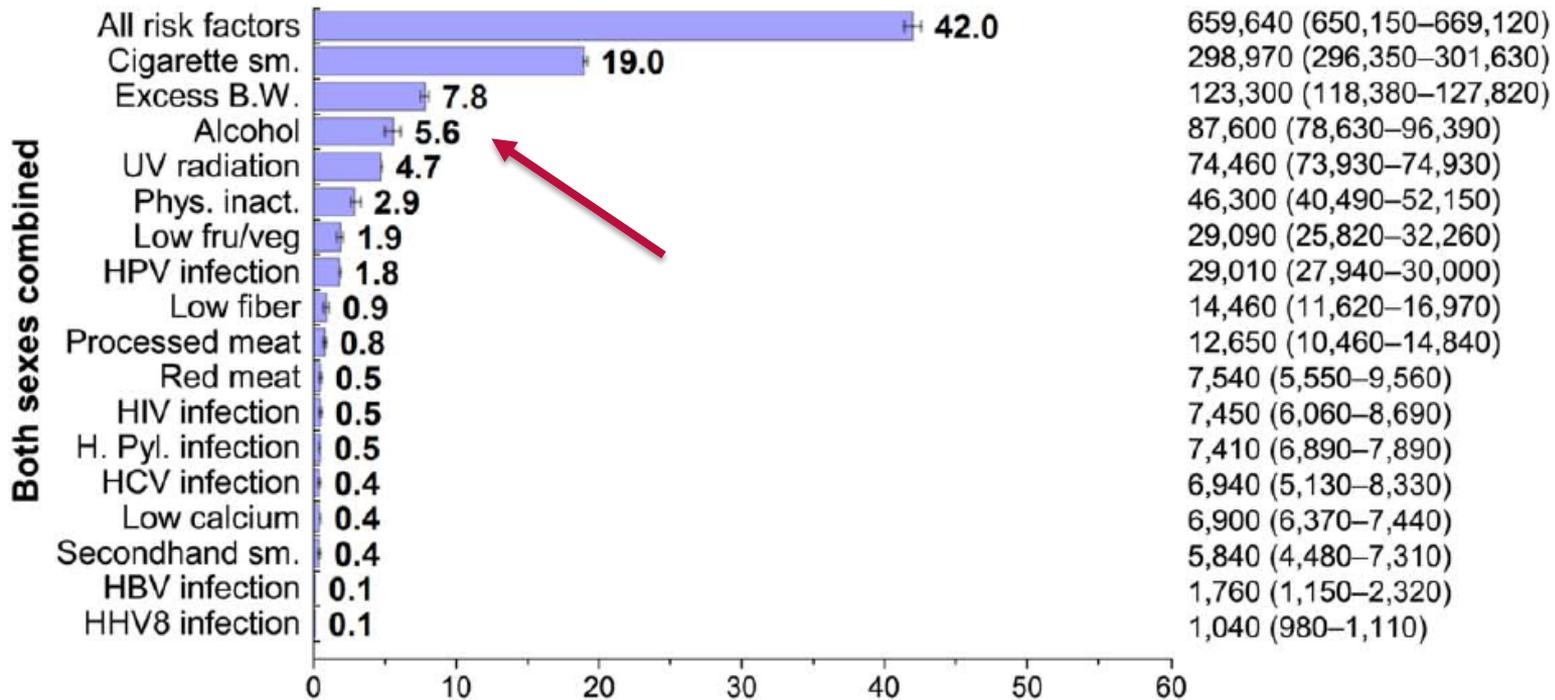
© World Cancer Research Fund International dietandcancerreport.org

Which cancers?

- Mouth
- Throat (pharynx)
- Voice box (larynx)
- Esophagus
- Liver
- Colon and rectum
- Breast
- Alcohol may also increase the risk of cancers of the pancreas and stomach.
- Protective Effects: Kidney, Non-Hodgkins Lymphoma



Alcohol in comparison to other modifiable risk factors



Estimated Proportion and Number of Incident Cancer Cases Attributable to Evaluated Risk Factors in Adults 30+ Years, US, 2014

Renewed focus on Alcohol and Cancer Risk at NCI and Cancer Focused Organizations

Viewpoint

December 13, 2019

Alcohol and Cancer Risk Clinical and Research Implications

William M. P. Klein, PhD¹; Paul B. Jacobsen, PhD²; Kathy J. Helzlsouer, MD, MHS³

[» Author Affiliations](#) | [Article Information](#)

JAMA. 2020;323(1):23-24. doi:10.1001/jama.2019.19133



RECOMMENDED LIMIT

**FOR CANCER PREVENTION, IT'S
BEST NOT TO DRINK ALCOHOL.**

*If you choose to drink, keep amounts to
no more than 1 drink/day for women, or
2 drinks/day for men.*

VOLUME 36 · NUMBER 1 · JANUARY 1, 2018

JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

Alcohol and Cancer: A Statement of the American Society of Clinical Oncology

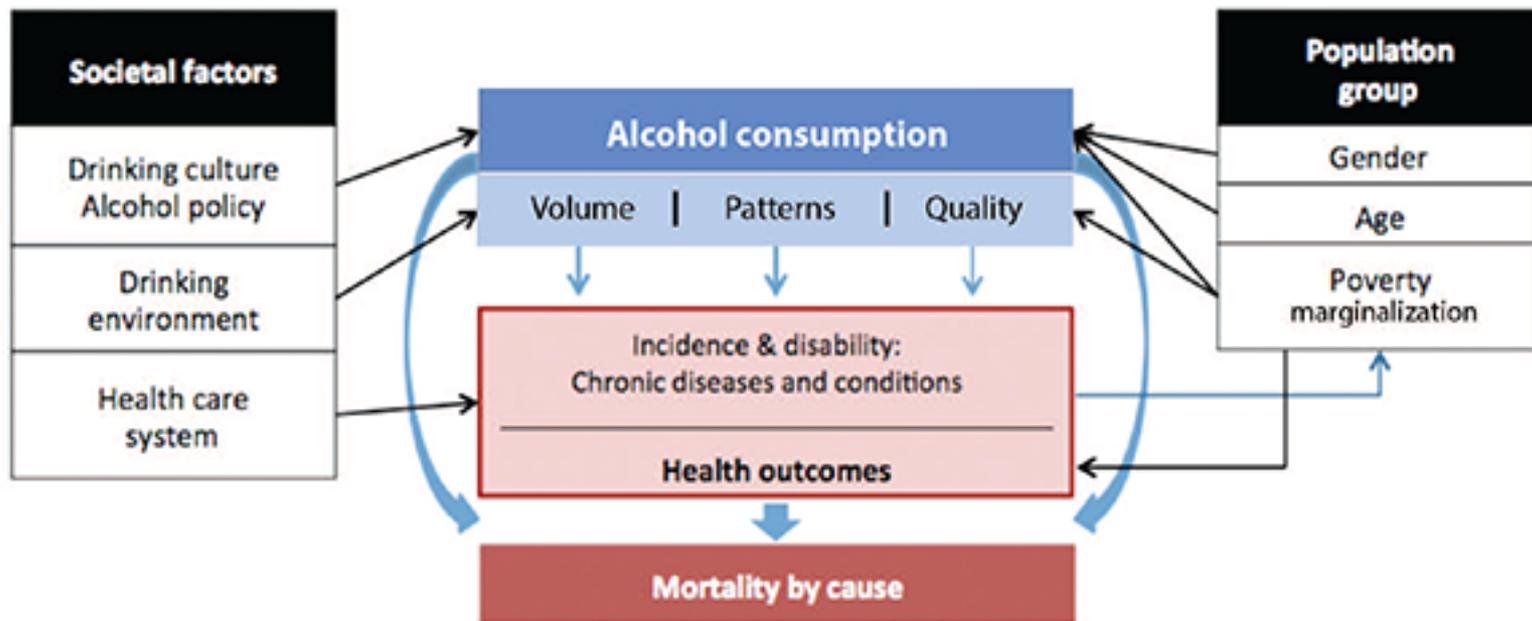
Noelle K. LoConte, Abenaa M. Brewster, Judith S. Kaur, Janette K. Merrill, and Anthony J. Alberg

Relative Ignorance Concerning Alcohol as a Cancer Risk Factor

“In general, although awareness appears to be increasing in many countries, at least half or more of the population does not consider alcohol to be a risk factor for cancer.”



Conceptual model of the effects of alcohol consumption on chronic diseases/cancer and societal and demographic factors



Kevin D. Shield et al. Alcohol Research: Current Reviews. 2013;35(2): 155-173.

Purpose: To enhance research on alcohol and cancer control

- Investigator initiated research across the entire Cancer Control Continuum from mechanistic and epidemiological studies through prevention, diagnosis, treatment and survivorship
- A preponderance of past research has focused on heavy drinkers and alcohol use disorder; this Notice encourages research addressing light and moderate alcohol consumption

NCI's Research Priorities and Research Areas

- **Communication and awareness** of alcohol as a risk factor for cancer
- Interactions between **alcohol use and other health risk behaviors** relevant to cancer
- Alcohol consumption and **outcomes in cancer patients and survivors**
- **Alcohol-related policy and its influence on cancer** and the cancer burden
- Addressing **light and moderate alcohol** consumption,

Topics	Examples of NOSI Research Questions
Communication	<p>Address communicating uncertainty and complexity in relation to alcohol, cancer, and health outcomes</p> <p>Understand and improve patient-provider communication</p>
Effects	<p>Develop and improve measures of alcohol-related behaviors as they relate to cancer</p> <p>Examine effects of light & moderate alcohol consumption and cancer risk</p>
Disparities	<p>Examine disparities in alcohol consumption patterns and the relationship to cancer by race/ethnicity, socioeconomic factors, and sexual and gender minority status.</p>
Prevention	<p>Explore decision-making processes regarding alcohol consumption by patients and caregivers</p> <p>Understanding of mechanisms linking alcohol consumption, cancer treatment effectiveness, and risk of recurrence or second cancers to identify targets for intervention.</p>

CANCER-RELATED RESEARCH INTERESTS OF THE NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)

NIAAA Contacts:

Gary J. Murray, PhD

Division of Metabolism and Health Effects

I-Jen Castle, PhD

Division of Epidemiology and Prevention Research



Mission of NIAAA

To support and conduct research on the impact of alcohol use on human health and well-being.

With respect to cancer NIAAA supports studies directed toward a better understanding of the risks associated with alcohol use and basic studies to identify plausible mechanisms for the development or exacerbation of cancer.

Epidemiology - Risk of Cancer for Heavy Drinkers

Heavy drinking is an important modifier of risk for a variety of cancers.

*Data are from Bagnardi et al., 2001

Upper aerodigestive tract (UADT)

(esophagus, pharynx, larynx, oral cavity)

(RR: 3.5-6.0)

Breast

(RR: 2.7)

Liver

(RR: 1.9)

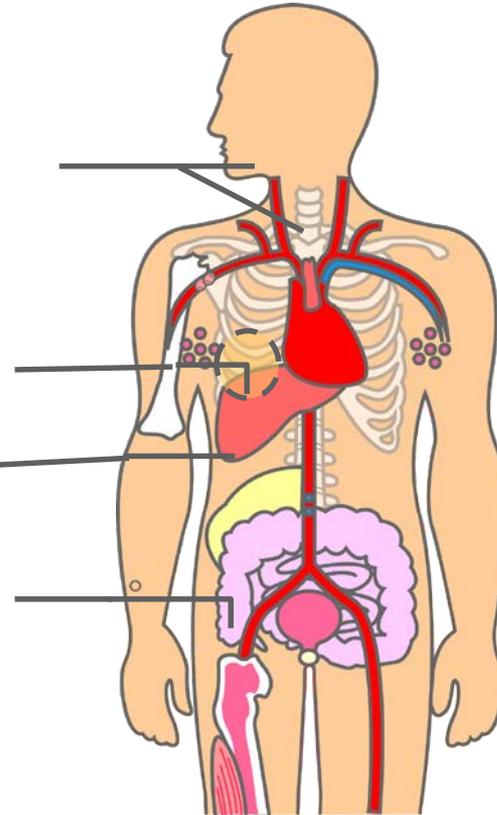
Colorectal cancer

(RR: 1.4)

Other possible sites:

- Lung
- Pancreas

Risk Ratios are calculated at 100g ethanol per day which is equivalent to about 7 standard drinks



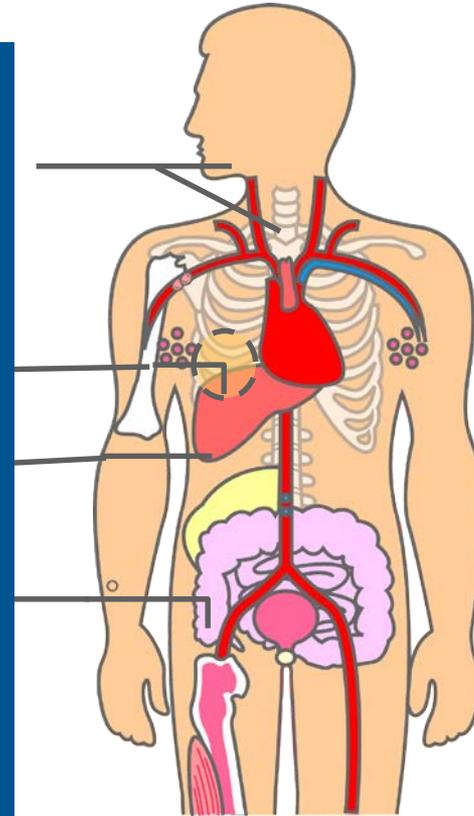
Epidemiology - Risk of Cancer for Heavy Drinkers

Heavy drinking is an important modifier of risk for a variety of cancers.

*Data are from Bagnardi et al., 2001

The strongest association between alcohol use and cancer has been demonstrated for Cancer of the UADT. Epidemiological studies have shown that individuals with one of the naturally occurring mutations in the enzyme ALDH2 that result in accumulation of acetaldehyde have a much higher incidence of this form of cancer (***RR: 3.5-6.0***)

Epidemiology must be paired with basic studies that demonstrate plausible mechanisms at defensible (physiologically relevant) concentrations.



Artwork by Jeanne Kelly © 2004

Program Announcements

NIMHD/NCI/NIAAA

PAR-17-150 and PAR-17-151:

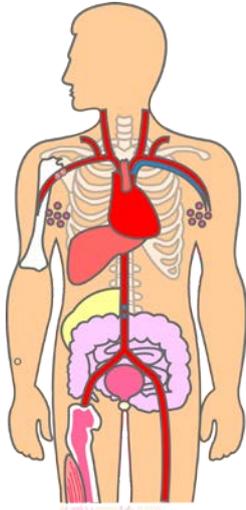
**Mechanisms of Disparities in Chronic Liver Diseases
and Cancer (R01, R21)**

NIAAA

PA-17-219 and PA-17-220

Mechanisms of Alcohol-associated Cancers (R01, R21)

NIAAA Sponsored Research



- ✓ **Basic studies on metabolism** of alcohol, acetaldehyde, retinoic acid and other retinoids --Oxidative Stress, DNA adduct formation, epigenetics, cell damage, the microbiome
- ✓ Alcohol and Breast Cancer - Enhanced aggressiveness of breast cancer
- ✓ **Alcohol and colorectal cancer**
 - Alcohol increased the expression of Monocyte chemoattractant protein-1 (MCP-1) and its receptor CCR2
 - Alcohol-altered CEA processing in liver → liver metastasis
 - ALDH polymorphisms and colorectal cancer
- ✓ **Alcohol and hepatocellular carcinoma**
 - Lipid metabolism, alcoholic fatty liver and links to HCC and other cancers
 - Epigenetics, miRNA signaling, NF- κ B, TGF β pathway, TNF α , IL-17
- ✓ **Alcohol and pancreatic cancer**
- ✓ **Alcohol-induced immunosuppression and cancer**
- ✓ **Alcohol and Non-Hodgkin's lymphoma (reduction in risk)**

CANCER-RELATED RESEARCH SUPPORTED BY NIAAA

www.impactjournals.com/oncotarget/

Oncotarget, Vol. 5, No. 19

Epigenetic signatures of alcohol abuse and hepatitis infection during human hepatocarcinogenesis

Ryan A. Hlady¹, Rochelle L. Tiedemann^{1,2}, William Puszyk³, Ivan Zendejas⁴, Lewis R. Roberts⁵, Jeong-Hyeon Choi², Chen Liu³ and Keith D. Robertson¹

Am J Physiol Gastrointest Liver Physiol 318: G265–G276, 2020.
First published November 25, 2019; doi:10.1152/ajpgi.00218.2019.

Moderate alcohol intake promotes pancreatic ductal adenocarcinoma development in mice expressing oncogenic Kras

◆ Kinji Asahina,¹ Steven Balog,¹ Edward Hwang,¹ Eugene Moon,¹ Emily Wan,¹ Kaitlin Skrypek,¹ Yibu Chen,² Jay Fernandez,¹ Janet Romo,¹ Qihong Yang,¹ Keane Lai,¹ Samuel W. French,³ and Hidekazu Tsukamoto^{1,4}



National Institute
on Alcohol Abuse
and Alcoholism

<http://www.niaaa.nih.gov>



Of interest to NIAAA



<http://imgkid.com/light-bulb-idea.shtml>

Your Groundbreaking
New Hypothesis about
Alcohol & Cancer

- ✓ Understand the **cellular** and **molecular mechanisms** underlying the carcinogenic effects of alcohol especially in minorities and women
- ✓ Clarify the role of alcohol in the development of **breast cancer**
- ✓ Investigate the **synergy** between alcohol and multiple agents especially **viral hepatitis** in exacerbating **liver cancer** and **smoking** in **UADT cancers**
- ✓ Characterize the effects of alcohol on **cancer stem cells**
- ✓ **Among others...**

CANCER-RELATED RESEARCH INTERESTS OF THE NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)

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Highlights of NIAAA Cancer-Related Research Interests

Prevention and Epidemiological Studies



NATIONAL
INSTITUTE
ON ALCOHOL
ABUSE AND
ALCOHOLISM



National Institute
on Alcohol Abuse
and Alcoholism

I-Jen Castle, Ph.D.

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Program Officer

Division of Epidemiology and Prevention Research

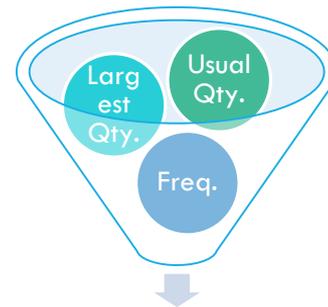
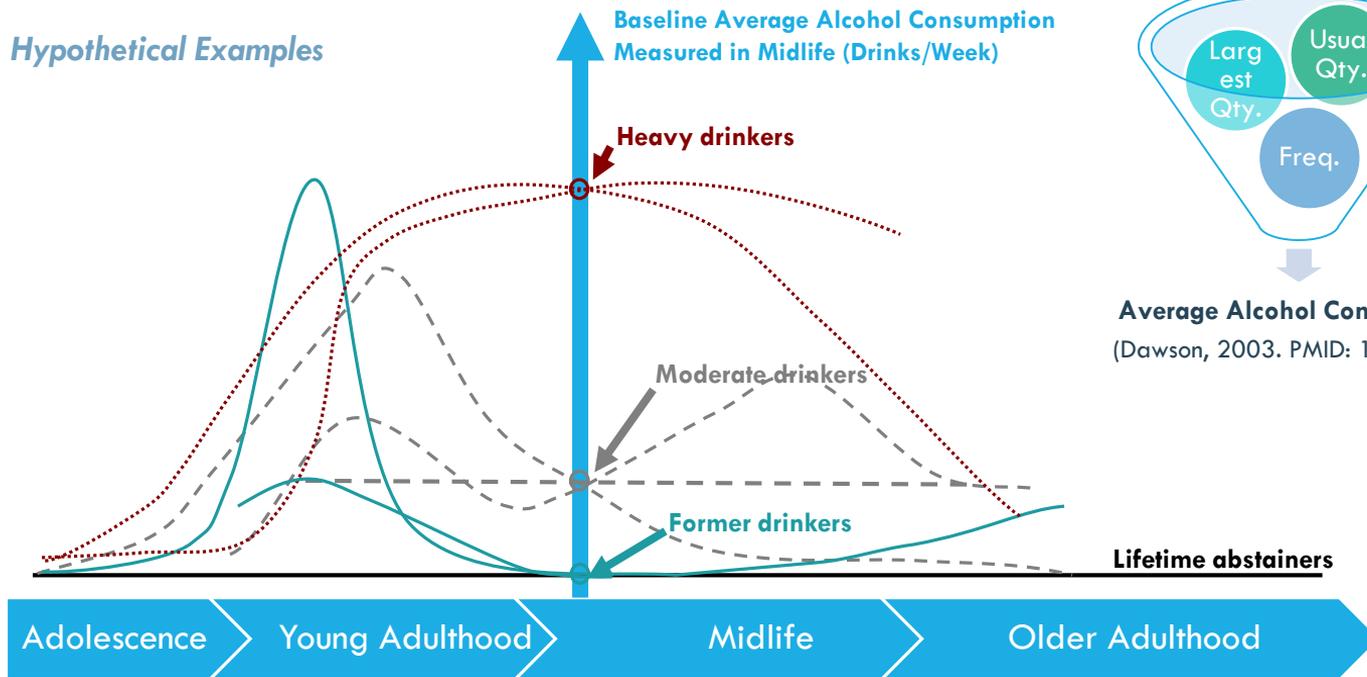
NOT-CA-20-034 Webinar, May 28, 2020

EPIDEMIOLOGICAL STUDIES

- Hypothesis driven and supported by biological mechanisms
- Considering life-course drinking patterns
- Disentangling the interplay of alcohol use and other risk and protective factors (e.g., smoking, drug use, BMI, physical activity, and diet)
- Methodological considerations:
 - e.g., measurement errors, recall bias, healthy drinker effects, survivor bias, effect modification, confounding, and generalizability
 - Analytical approaches, e.g., sensitivity analysis and quantitative bias analysis

LIFE-COURSE DRINKING PATTERNS

Hypothetical Examples



Average Alcohol Consumption
(Dawson, 2003. PMID: 15301397)

Windows of Susceptibility to Cancers ?

EPIDEMIOLOGICAL STUDIES

- Hypothesis-driven and supported by biological mechanisms
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 - Analytical approaches, e.g., sensitivity analysis and quantitative bias analysis

Source: California Breast Cancer Research Program <http://www.cabreastcancer.org/causes/>

Reference: Hiatt et al., 2014 DOI: 10.1158/1055-9965.EPI-14-0403

A Model of Breast Cancer Causation

Visualizing the many factors and relationships influencing breast cancer incidence in women

Interactions

Risk Domain

- Biological
- Behavioral
- Social
- Physical

Strength

Epidemiological

- Strong
- Modest
- Weak

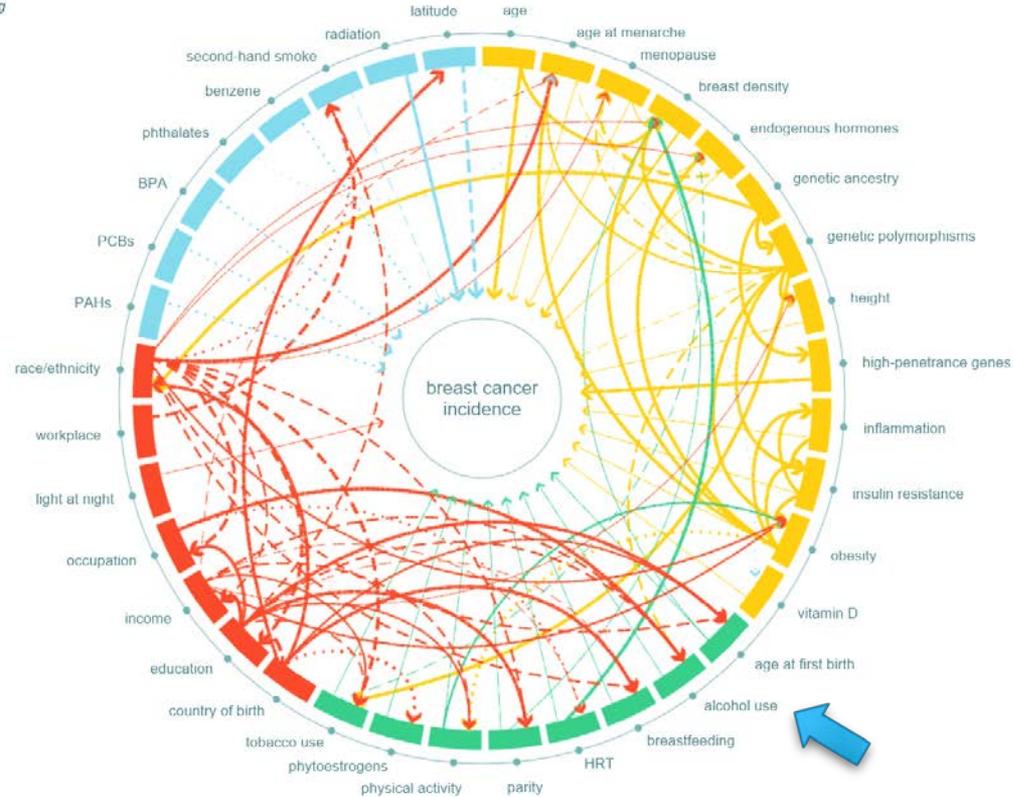
Biological

- Strong
- Modest

Data Quality

- High
- Medium
- Low

RESET



EPIDEMIOLOGICAL STUDIES

- Hypothesis-driven and supported by biological mechanisms
- Considering life-course drinking patterns
- Disentangling the interplay of alcohol use and other risk and protective factors (e.g., smoking, drug use, BMI, physical activity, and diet)
- Methodological considerations:
 - e.g., measurement errors, recall bias, healthy drinker effects, survivor bias, effect modification, confounding, and generalizability
 - Analytical approaches, e.g., sensitivity analysis and quantitative bias analysis

PREVENTION STUDIES

- Evidence-based guidelines
 - Does drinking reduction or cessation reduce risk of recurrence or second cancers, improve cancer prognosis, and improve aging trajectories during cancer survivorship?
- Innovative and integrative interventions which have low barriers to implementation and which can achieve sustained effects
- Alcohol-related policy and its influence on cancer prevention
 - Address effects of warning labels on all alcohol-containing products in relation to alcohol and cancer prevention (JSAD 2020;81(2):222–292)

Resource: Alcohol Policy Information System (APIS) <https://alcoholpolicy.niaaa.nih.gov/>

A project of the National Institute on Alcohol Abuse and Alcoholism

APIS Alcohol Policy Information System

Policy Topics ▾

Policy Changes at a Glance

Resources

About Alcohol Policy

About Cannabis Policy

About APIS



COVID-19 is an emerging, rapidly evolving situation.

Get the latest public health information from CDC: <https://www.coronavirus.gov>

Get the latest research information from NIH: <https://www.nih.gov/coronavirus>

Special Coverage: State-by-State Alcohol-Related COVID-19 Policies (PDF, 1.6 MB)

WELCOME TO THE

Alcohol Policy Information System

The Alcohol Policy Information System (APIS) provides detailed information on a wide variety of [Alcohol-Related Policies](#) in the United States at both State and Federal levels, as well as policy information regarding the [Recreational Use of Cannabis](#). The information and resources available on this site are geared toward alcohol and cannabis policy researchers and others interested in alcohol and cannabis policy issues.

Underage Drinking

APIS provides convenient access to policy topics that pertain to underage drinking, in order to encourage research, evaluation, and outreach efforts in this important area.

- > [Highlight on Underage Drinking](#)
- > [State Profiles of Underage Drinking Laws](#)

Alcohol Policy Topics

Detailed State-by-State information is available for the following alcohol policy topics, or you may [browse all topics](#).

Alcohol Beverages Pricing

- > [Drink Specials](#)
- > [Wholesale Pricing Practices and Restrictions](#)

Alcohol Beverages Taxes

- > [Beer](#)
- > [Distilled Spirits](#)
- > [Wine](#)

Alcohol Control Systems

- > [Retail Distribution Systems for Beer](#)
- > [Retail Distribution Systems for Spirits](#)
- > [Retail Distribution Systems for Wine](#)
- > [Wholesale Distribution Systems for Beer](#)

Pregnancy and Alcohol

- > [Civil Commitment](#)
- > [Legal Significance for Child Abuse/Child Neglect](#)
- > [Limitations on Criminal Prosecution](#)
- > [Priority Treatment](#)
- > [Reporting Requirements](#)
- > [Warning Signs: Drinking During Pregnancy](#)

Retail Sales

- > [Bans on Off-Premises Sunday Sales](#)
- > [Beverage Service Training and Related Practices](#)
- > [Keg Registration](#)

Cannabis Policy Topics

Detailed State-by-State information on the **Recreational Use of Cannabis** is presented in two tables, [Volume 1](#) and [Volume 2](#).

Advertising, Marketing and Mass Media

- **Advertising Restrictions** – see [Columns 10 and 11](#).

Cannabis Product Control

- **Agency with Authority to Regulate** – see [Column 4](#).
- **Legalization of Recreational Use** – see [Volume 1, Column 3](#) and [Volume 2, Column 3](#).
- **Local Authority** – see [Column 13](#).
- **Products Permitted** – see [Column 5](#).

Cultivation and Distribution

- **Cultivation Restrictions** – see [Column 6](#).

KEY POINT

Address research gaps
& move the field forward



Application Process for Alcohol and Cancer Control

[NOT - CA-20-034](#)

- Submit applications for this initiative using one of the 10 funding opportunity announcements (FOAs) or any reissues of these announcements listed in the NOSI
 - Parent RO1s - [PA-19-055](#); [PA-19-056](#)
 - Specific RO1 PAs/PARs - [PAR-19-348](#); [PA-17-220](#) ; [PA-17-135](#)
 - Specific R21 PAs/PARs - [PAR-19-350](#); [PA-17-219](#); [PA-17-132](#); [PA-19-053](#) [PAR-20-052](#)
 - RO3 (NCI) - [PAR-20-052](#)
- Applications referencing this NOSI should be submitted one of the FOAs listed above.

Details on FOAs for Alcohol and Cancer Control NOSI - 1

Activity Code	FOA Title	First Available Due Date
R01	PA-19-055 NIH Research Project Grant (Parent R01 Clinical Trial Allowed)	June 5, 2020
R01	PA-19-056 NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)	June 5, 2020
R01	PAR-19-348 Innovative Approaches to Studying Cancer Communication in the New Media Environment (R01- Clinical Trial Optional)	June 10, 2020
R01	PA-17-220 Mechanisms of Alcohol-associated Cancers (R01)	June 5, 2020
R01	PA-17-135 Public Policy Effects on Alcohol-, Marijuana-, and Other Substance-Related Behaviors and Outcomes (R01)	June 5, 2020

Details on FOAs for Alcohol and Cancer Control NOSI - 2

Activity Code	FOA Title	First Available Due Date
R21	PAR-19-350 Innovative Approaches to Studying Cancer Communication in the New Media Environment (R21- Clinical Trial Optional)	June 10, 2020
R21	PA-17-219 Mechanisms of Alcohol-associated Cancers (R21)	June 16, 2020
R21	PA-17-132 Public Policy Effects on Alcohol-, Marijuana-, and Other Substance-Related Behaviors and Outcomes (R21)	June 16, 2020
R21	PA-19-053 NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)	June 16, 2020
R03	PAR-20-052 NCI Small Grants Program for Cancer Research for Years 2020, 2021, and 2022 (NCI Omnibus R03 Clinical Trial Optional)	June 24, 2020

Application Process **Important Dates**

NOT - CA-20-034

- NOSI expiration date: September 9, 2023
- Earliest submission date: June 5, 2020
- Importantly, application due dates differ for different FOAs with first dates ranging from June 5 – June 24 **Make sure you have the right one!**
- Applicants may submit to any of the reissuances of above announcements through NOSI expiration date.

Application Requirements

- All instructions in the SF424 (R&R) application guide and the FOA used for submission must be followed.
- Applicants must include “NOT-CA-20-034” (without quotation marks) in the Agency Routing Identifier field (box 4B) of the SF424 R&R form.
- Applications without the correct Agency Routing Identifier information will not be considered for the NOSI initiative.
- Applications nonresponsive to terms of this NOSI will not be considered for the NOSI initiative.

Review Criteria

- Standard review criteria as described in eligible R01 FOAs
- Scored review criteria: Significance, Innovation, Investigators, Approach, Environment
- Additional review criteria: Study timeline (for clinical trials), protections for human subjects, inclusion, vertebrate animals, biohazards
- Additional review considerations: Check FOA to see resource sharing plan requirements (e.g., data sharing plan) or other listed requirements

Additional Resources

- NCI Division of Cancer Control and Population Sciences - <https://cancercontrol.cancer.gov/index.html>
- NCI Health Behaviors Research Program - <https://cancercontrol.cancer.gov/brp/hbrb/about.html>
- NIAAA Division of Metabolism and Health Effects - <https://www.niaaa.nih.gov/division-metabolism-health-effects>
- NIAAA Division of – Epidemiology and Prevention Research - <https://www.niaaa.nih.gov/division-epidemiology-prevention-research>
- Sample NCI grants - <https://cancercontrol.cancer.gov/brp/funding/sample-application.html>
- NIH RePORTER - <https://projectreporter.nih.gov/reporter.cfm>

Common Question #1

- **Where can I find more information about *NIH NOSIs*?**
- [NOT-OD-19-107 \(NOSI\)](#) Issued by NIH, June 14, 2019.
- [NIH NOSI FAQs](#) What is a NOSI? How does NIH distinguish applications submitted in direct response to an FOA from applications submitted in response to a NOSI that uses that FOA for submission? Can I include an assignment request when I submit my application to a NOSI?

Common Question #2

- **Can I submit a grant about alcohol and cancer control to an FOA not listed in the NOSI?**
- Yes, but in these cases **do not** list the NOSI in Box 48 of the SF424

Submission Inquiries

Scientific/Research Contacts

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- I-Jen Castle, Ph.D.
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
(for prevention and epidemiological studies)
Telephone: 301-827-4406
Email: i-jen.castle@nih.gov

Peer Review Contact(s)

- Examine your eRA Commons account for review assignment and contact information (information appears 2 weeks after the submission due date).

Financial/Grants Management Contact(s)

- Carol Perry
National Cancer Institute (NCI)
Telephone: 240-276-6282
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- Judy Fox
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
Telephone: 301-443-4704
Email: jfox@mail.nih.gov



Webinar Audience Q & A

*Please type your question
in the Q&A section on
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www.cancer.gov

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