# Third Meeting of the HB 21-1317 Scientific Review Council

April 26, 2022







## Opening Remarks, Introductions and Welcome, Updates on Conflict of Interest

Christopher E. Urbina, MD, MPH Chair, HB 21-1317 Scientific Review Council







### Cannabis Research & Policy Project Team Members

Member	Sub-Team	
Lisa Bero, PhD	Systematic Review	
Ashley Brooks-Russell, PhD, MPH	Subject Area Expertise	
Meghan Buran, MPH	Administration	
Kelsey Phinney, BA	Administration	
Rosa Lawrence, BA	Systematic Review	
Louis Leslie, BA	Systematic Review	
Tianjing Li, MD, PhD, MHS	Systematic Review	
Christi Piper, MLIS	Systematic Review	
Thanitsara Rittiphairoj, MD, MPH	Systematic Review	
Jean-Pierre Oberste, BA	Systematic Review	
Jonathan Samet, MD, MS	Administration	
Greg Tung, PhD, MPH	Administration, Subject Area Expertise	
Sam Wang, MD	Subject Area Expertise	3

### Scientific Review Council Members

Member	Role on Council	Affiliation(s)	
Chris Urbina, MD, MPH (Chair)	Preventive medicine specialist (or preventive medicine public health professional)	Pueblo Department of Public Health and Environment; Former Director of CDPHE	
Gregory Kinney, PhD, MPH	Epidemiologist	Colorado School of Public Health	
David Brumbaugh, MD, MSc	Physician familiar with the administration of medical marijuana pursuant to current state laws with experience recommending medical marijuana to those aged zero to seventeen	Children's Hospital Colorado; University of Colorado School of Medicine	
Kennon Heard, MD	Medical Toxicologist	University of Colorado School of Medicine	
Archana Shrestha, MD	Neurologist	University of Colorado School of Medicine	
Erica Wymore, MD, MPH	Pediatrician	University of Colorado, School of Medicine	
Paula Riggs, MD	Psychiatrist	University of Colorado, School of Medicine	
Susan Calcaterra, MD, MPH	Internal medicine physician (or other specialist in adult medicine)	University of Colorado School of Medicine	
Joseph Schacht, PhD	Licensed Substance Abuse Disorder Specialist	University of Colorado School of Medicine	
Kent Hutchison, PhD	Neuropsychopharmacologist	University of Colorado School of Medicine	
Lesley Brooks, MD	Medical professional (or public health professional) who specializes in racial and health disparities and systemic inequalities in health care and medicine	North Colorado Health Alliance; SummitStone Health Partners 4	

## Review of Agenda

Christopher E. Urbina, MD, MPH Chair, HB 21-1317 Scientific Review Council





Start time	Topic	Presenter(s)
11:15 am	Review of Meeting Minutes and Response to SRC Recommendations	Chris Urbina & Jon Samet
11:25 am	Progress Update	Jon Samet, Lisa Bero, & Tianjing Li
11:40 am	Challenges to Classification of Exposures and Outcomes	Tianjing Li
12:05 pm	Introduction to Evidence Map and Planned Approach	Rosa Lawrence & Lisa Bero
12:30 pm	Educational Campaign Update	Greg Tung & Jon Samet
12:35pm	General Remarks & Discussion	Chris Urbina
12:55 pm	Next Meeting Timing and Closing Remarks	Jon Samet & Chris Urbina

# Review of Meeting Minutes and Response to SRC Recommendations

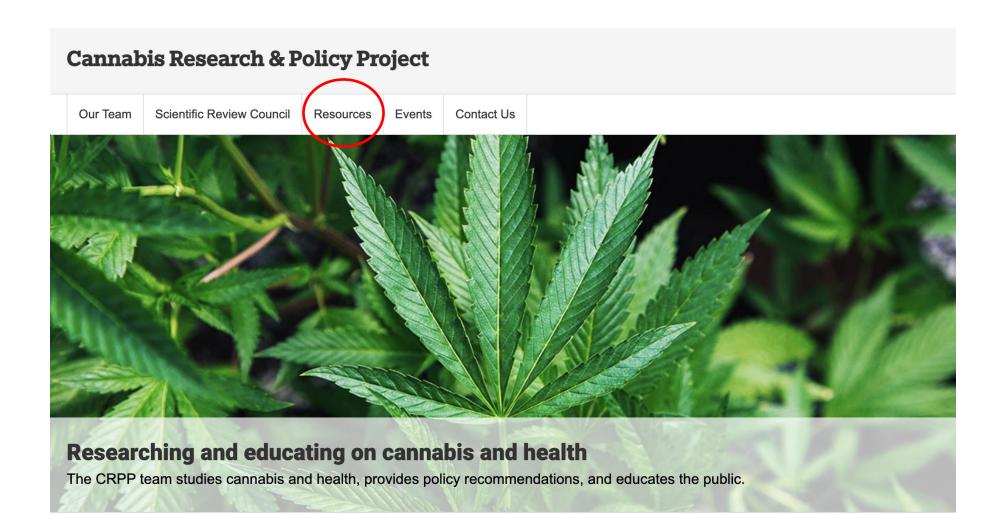
Christopher E. Urbina, MD, MPH Chair, HB 21-1317 Scientific Review Council

Jonathan M. Samet, MD, MS Dean, Colorado School of Public Health









#### Who we are

The Cannabis Research & Policy Project team is a group of researchers from the Colorado School of Public Health and the University of Colorado Anschutz Medical Campus.

## **Progress Update**

Jonathan M. Samet, MD, MS Dean, Colorado School of Public Health

> Lisa Bero, PhD Professor, School of Medicine

Tianjing Li, MD, MHS, PhD Associate Professor, School of Medicine, Colorado School of Public Health







## Charge to the Colorado School of Public Health







## Tasks for the Colorado School of Public Health in HB 21-1317

- Conduct a systematic review of high-potency THC marijuana
- Establish a Scientific Review Council
- Produce a public education campaign

## High-Potency THC Marijuana and Marijuana Concentrate Research

- Conduct a systematic review of high-potency THC marijuana:
  - Systematically curate and synthesize the evidence regarding possible physical and mental health effects
  - Identify needed research
    - Report on gaps identified by 1/31/2022 and what needed to address the gaps, including funding and timeline for new studies
- Provide initial report by 7/1/2022
- Potentially conduct additional research
- The research must be conducted independently without any predetermined outcomes or undue influence from any party

## Systematic Scoping Review







## What type of systematic review? Per House Bill 21-1317

- "...all available scientific evidence-based research regarding the possible physical and mental health effects of high-potency THC marijuana and marijuana concentrates regardless of the location of the research."
- "The research must systematically curate and synthesize existing research, identify evidence gaps, and identify new research that is needed to better understand the health implications of high-potency THC marijuana products and the specific THC potency levels and amounts at which various health concerns arise."

### Research Questions for the Review

- Identify and describe studies that explore the relationship of high-potency cannabis products with <u>beneficial and adverse</u> <u>health outcomes</u>
- Identify and describe studies that report adverse effects of exposure to high-potency products (with no comparison group)

## Why a systematic scoping review?

- 1) to identify the types of evidence available in a given field
- 2) to clarify key concepts
- 3) to examine how research is conducted on a certain topic
- 4) to identify key factors or characteristics related to a concept
- 5) as preparation for further systematic reviews
- 6) to identify and analyze knowledge gaps



#### **Overview of literature**

## Scoping Review Findings



**Future systematic reviews** 



Research gaps

## Progress to Date







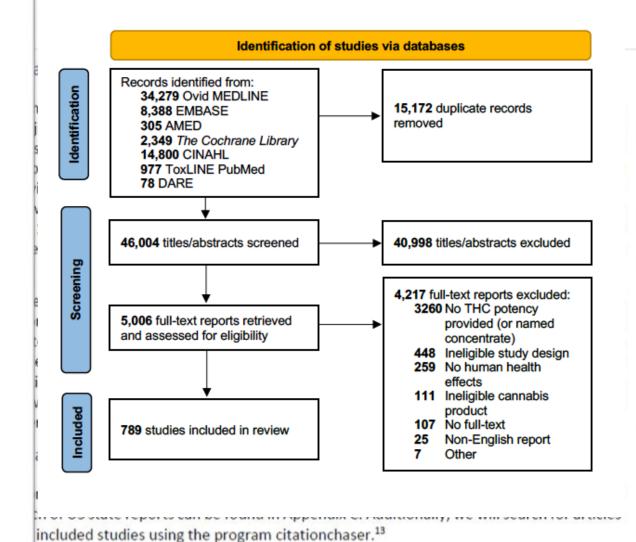
## Over the initial 9 months since project funding was received, the following has been accomplished:

- Assembled the Cannabis Research and Policy Research Team.
- Recruited the Scientific Review Council according to the requirements of HB 21-1317 and has met three times: 11/17/2021, 1/24/2022, and 4/24/2022.
- Screened all staff and Council members for potential conflicts of interest.
- Developed and published the protocol for the review (<a href="https://osf.io/wv7e9">https://osf.io/wv7e9</a>).
- Completed literature search.
- Presented the progress to the CO House Public and Behavioral Health and Human Services Committee on 2/18/2022.
- Screened all titles/abstracts, and subsequently full-text reports for inclusion.
- Developed and pilot tested data extraction forms and procedures.

### Review Timeline

#### Data extraction elements

Data category	Data coding
Bibliographic	Type of publication
information	Journal article
	If journal article, systematic review, original research, other
	Report
	Other?
	Authors (list each)
	Year of Publication
	Journal
	Author Affiliations (for each author)
	COI statement (verbatim for each author)
	Funding Statement (verbatim) (select all that apply)
	Cannabis industry
	Pharmaceutical industry
	Government
	NGO / non-profit
	Other, specify
	Country where published
Study objectives	Study objective (verbatim)
	Overall study objective
	Efficacy
	Harm / safety
Study design	Systematic review
	Review of case reports
	Observational / epidemiological
	Randomized controlled trial
	Other, specify



# Challenges to Classification of Exposures and Outcomes

Tianjing Li, MD, MHS, PhD Associate Professor, School of Medicine, Colorado School of Public Health





### **Exposures**

#### **Specific type of product and route** (Kaczor 2021)

The type of edible was identified and documented in 91% of cases. Chocolates (38%) and gummies (34%) were the most common (Supplementary Table 2), but other types included brownies, juice and other liquids, toaster pastries, and cookies. A specific edible product name was identified and documented in 22% of cases, with product names like TKO Edibles, Stoney Patch, Willy Wonka, Chilly Wonka, and Patriot Care Dispensary (Supplementary Table 3).

#### Specific route but no type (Mauzay 2021)

#### Inclusion/Exclusion Criteria

Given that different routes of administration can produce differential effects across varying periods of time, analyses were restricted to sessions involving inhaled cannabis (e.g., smoking, vaping), which is the most common route of administration (Sexton et al., 2016). Further, only sessions in which symptoms were re-rated within 4 hours of cannabis use were included, since the effects of inhaled cannabis dissipate after 3-4 hours (Grotenhermen, 2003; Menkes et al., 1991). Finally, given concerns about the validity and reliability of user generated data, only sessions for which THC and CBD concentrations were obtained directly from producers were analyzed.

#### **Broad type/potency** (Venkatesan 2020)

#### Cannabis concentrate

Potency of cannabis concentrate

Low (around 20% THC)

Medium (40%)

High (60%)

Very high (80%)

Do not know

Unknown/missing

#### Potency of smoked cannabis

Low (<5% THC)

Medium (10% THC)

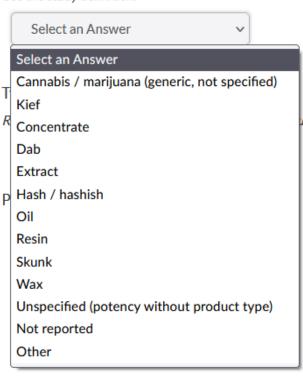
High (15% THC)

Very high (20% THC)

Do not know

Type of cannabis product studied

Use the study definition.



## Potency

#### Potency ranges in % (Venkatesan 2020)

Cannabis concentrate

Potency of cannabis concentrate

Low (around 20% THC)

Medium (40%)

High (60%)

Very high (80%)

Do not know

Unknown/missing

#### Categorical but no thresholds (Di Forti 2014)

Type used independent of frequency of use Hash-like (low potency) Skunk-like (high potency)

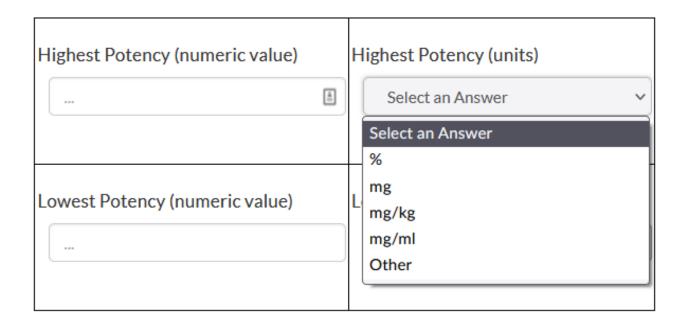
Mg and mg/kg (Kaczor 2021)

THC consumed (mg), median (IQR)

THC dose (mg/kg), median (IQR)

#### THC potency range

List the highest and lowest potency THC reported (numeric and units).



Normalize the potency? Need help!

## Frequency

#### **General frequency** (Venkatesan 2020)

Frequency of smoking highly potent cannabis concentrate

Never

Almost never

Sometimes

Most of the time

Almost always

Always

Do not know

Unknown/missing

#### Daily or non-daily (Di Forti 2014)

Frequency of use independent of type used Less than daily Daily

#### Different frequencies for different products (Bid

Table 1
Comparison of survey respondents who frequently use concentrates (FC) to those who never use concentrates (I rarely use concentrates (FF).

		FC	NC	<b>p</b> -
N		67	64	_
Demographics	Gender (% male)	59.7%	42.2%	0.0
	Age	37.5 (15.8)	47.1 (17.5)	<
	Age at onset of regular cannabis use	21.6 (12.5)	25.2 (16.4)	0.1
	Race/ethnicity			0.7
	White non-Hispanic	78.8%	79.7%	
	White Hispanic	11.5%	7.8%	
	Asian	1.5%	1.6%	
	African American	1.5%	6.3%	
	Native American	3.0%	4.7%	
	Native Hawaiian/Pacific Islander	1.5%	0%	
	Employment status	_	_	0.5
	Full-time employed/student	58.2%	48.4%	
	Part-time employed/student	11.9%	12.5%	
	Unemployed/retired/homemaker	29.9%	39.1%	
Cannabis use	Days vaping/smoking flower per week	6.0 (2.1)	4.2 (3.1)	<
	Percent daily users	79.1%	47.6%	0.0
	Per-day vaping/smoking use sessions (among daily users)	4.6 (1.5)	3.9 (1.7)	
	Days of concentrate use per week	6.7 (0.8)	_	-
	Percent daily users	79.1%	0%	-
	Per-day concentrate use sessions (among daily users)	4.1 (1.7)	_	
	Days of edible use per week	1.4 (2.1)	1.5 (2.3)	0.7

Frequency of intake (verbatim)	
Record VERBATIM with abbreviations spelled out in fu	ıll.
Erequency of intake (select all that apply)	

Frequency	of	intal	ke (	sel	ect	all	that	app	ly)

- Weekly (once weekly vs > 1 time weekly)
- Monthly (once vs > 1 time monthly)

Daily (once vs >1 daily)

- Heavy
- Occasional
- Frequent
- Not reported
- Other

### **Outcomes**

#### **One outcome domain** (Di Forti 2014)

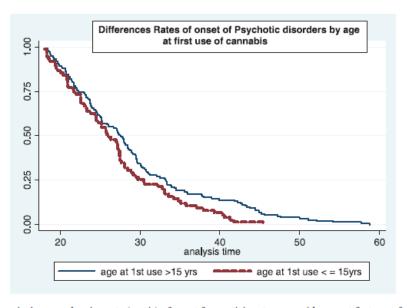
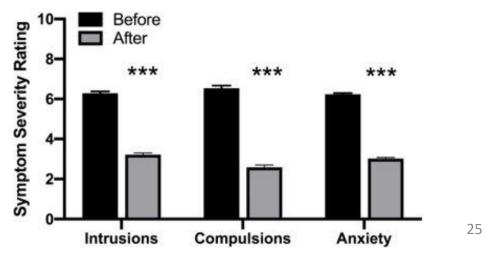


Fig. 2. Kaplan–Meier survival curves showing rate (y axis) of onset for participants grouped by age at first use of cannabis. Subjects who started using cannabis at age 15 years or younger experience their onset of psychosis (x axis in years) earlier compared with those who started using cannabis older than 15 years of age.

#### Multiple outcome domains (Kaczor 2021)

Signs/symptoms, n (%)	Lethargy/somnolence	19 (59%)
	Ataxia/dizziness	16 (50%)
	Confusion	11 (34%)
	Vomiting	9 (28%)
	Seizure	1 (3%)
Vital sign abnormalities, n (%)	Tachycardia	29 (91%)
	Hypotension	24 (75%)
	Hypertension	12 (38%)
	Bradypnea	11 (34%)
	Bradycardia	2 (6%)
	Hypoxia	2 (6%)
	Hypercarbia	2 (6%)

#### Multiple symptoms in one outcome domain (Mauzay 2021)



### Outcomes (cont'd)

Other domain

#### Multiple outcome domains (Venkatesan 2020)

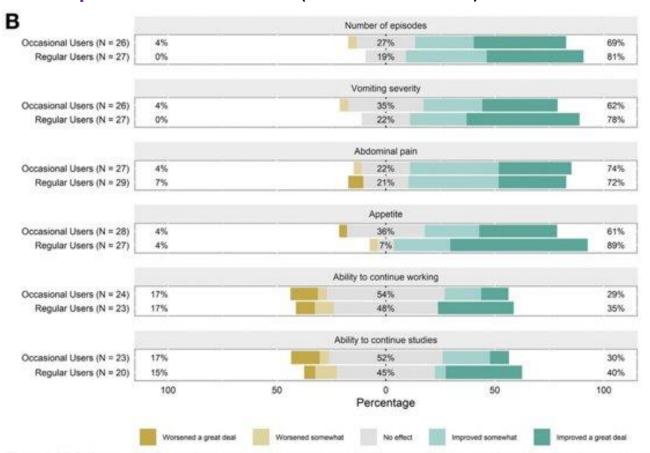


Figure 2. (A) Self-reported effects of cannabis use on symptoms, health care utilization, and functioning in all cannabis users. (B) Denotes effects of cannabis use in occasional and regular users.

Outcomes
Enter all reported outcomes based on domains listed in the review protocol. Contact the review team if you are unsure.
Outcome domains (select all that apply)
Cancer
Cardiometabolic
Gastrointestinal
☐ Immunity
☐ Injury and death
Mental health
☐ Neurological
Ocular
Pain
Pre-, peri-, and neonatal
Pregnancy related outcomes (mother)
Psychosocial
Respiratory
Sexual health and reproductive health
Sleep
Substance use /substance dependence

### **Exposures-Outcomes Association**

#### Quantitative data and analyses

Instructions: This applies to ANY of the listed exposures and outcomes above. Look in the Results section for relevant information.

### Types of users related to outcome but no pote (Venkatesan 2020)

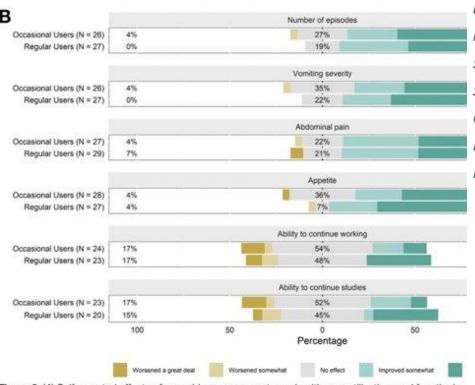


Figure 2. (A) Self-reported effects of cannabis use on symptoms, health care utilization, and functioning (B) Denotes effects of cannabis use in occasional and regular users.

Reported data (select all that apply)

Effect estimate (e.g., difference in means, odds ratios, risk ratios)

Measure of precision (e.g., confidence interval, standard error)

Significance tests (e.g., p-value)

Sample size (e.g., number of people)

Correlation coefficient (e.g., Pearson correlation coefficient)

Regression coefficient

Raw data (e.g., counts sufficient to populate a 2x2 table, proportions)

- ☐ Effect estimate
- Measure of precision
- Significance tests
- Sample size
- Correlation coefficient
- Raw data
- Regression coefficient
- Unclear

In searching for a 'perfect' study...

## An Exploratory Human Laboratory Experiment Evaluating Vaporized Cannabis in the Treatment of Neuropathic Pain from Spinal Cord Injury and Disease

Barth Wilsey, MD<sup>a,b</sup> [Associate Physician], Thomas D. Marcotte, PhD<sup>c</sup> [Associate Professor], Reena Deutsch, PhD<sup>c</sup> [Statistician], Holly Zhao, MD, PhD<sup>a,b</sup> [Associate Professor], Hannah Prasad<sup>a,b</sup> [Research Associate], and Amy Phan<sup>a,b</sup> [Research Associate]

Barth Wilsey: blwilsey@ucdavis.edu; Thomas D. Marcotte: tmarcotte@ucsd.edu; Reena Deutsch: redeutsch@ucsd.edu; Holly Zhao: holly.zhao@ucdmc.ucdavis.edu; Hannah Prasad: hannahprasad89@gmail.com; Amy Phan: atphano7@gmail.com

<sup>a</sup>VA Northern California Health Care System Sacramento VA Medical Center, 10535 Hospital Way, Mather, CA 95655 USA, 916-843-7000 | 800-382-8387

<sup>b</sup>Department of Physical Medicine and Rehabilitation, University of California, Davis Medical Center, Lawrence J. Ellison Ambulatory Care Center, 4860 Y Street, Sacramento, CA 95817 USA

<sup>c</sup>Department of Psychiatry, University of California, San Diego, 220 Dickinson Street, Suite B, MC8231, San Diego, CA 92103-8231 USA

#### **Abstract**

Using eight hour human laboratory experiments, we evaluated the analgesic efficacy of vaporized cannabis in patients with neuropathic pain related to injury or disease of the spinal cord, the majority of whom were experiencing pain despite traditional treatment. After obtaining baseline data, 42 participants underwent a standardized procedure for inhaling 4 puffs of vaporized cannabis containing either placebo, 2.9%, or 6.7% delta-9-tetrahydrocannabinol on three separate occasions. A second dosing occurred 3 hours later; participants chose to inhale 4 to 8 puffs. This flexible dosing was utilized to attempt to reduce the placebo effect. Using an 11-point numerical pain intensity rating scale as the primary outcome, a mixed effects linear regression model demonstrated a significant analgesic response for vaporized cannabis. When subjective and psychoactive side effects (e.g., good drug effect, feeling high, etc.) were added as covariates to the model, the reduction in pain intensity remained significant above and beyond any effect of these

## More Results from Screening

## Full text screening form

Highest THC po	tency studied (number)		
Highest THC po	tency studied (units) wer	Numeric Potency	
		owing? (check all that apply)	
Compared di	ferent dose (dose-respons	e), frequency, duration, route, or type of exp	Dose Response
☐ Interventiona	I study that evaluated the	therapeutic use of cannabis for a medical co	ndition Therapeutic
Study of high	potency THC products (e.	g. concentrates, vaping, edible)	High Potency

Figure 1. Reported 'exposures' for included studies (n = 789)

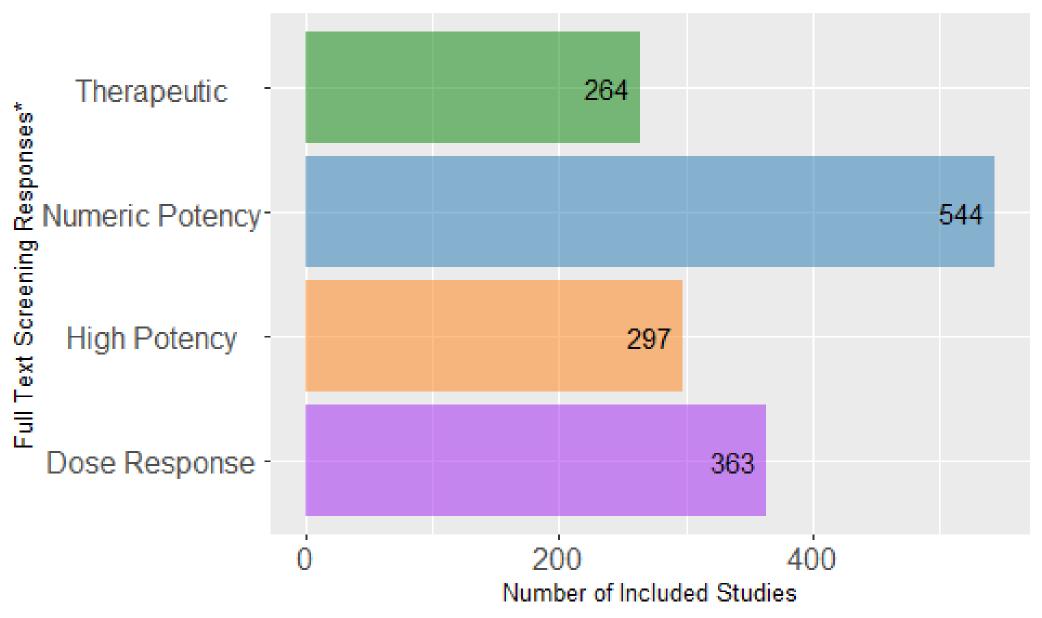


Figure 2. Type of potency reported (n = 789)

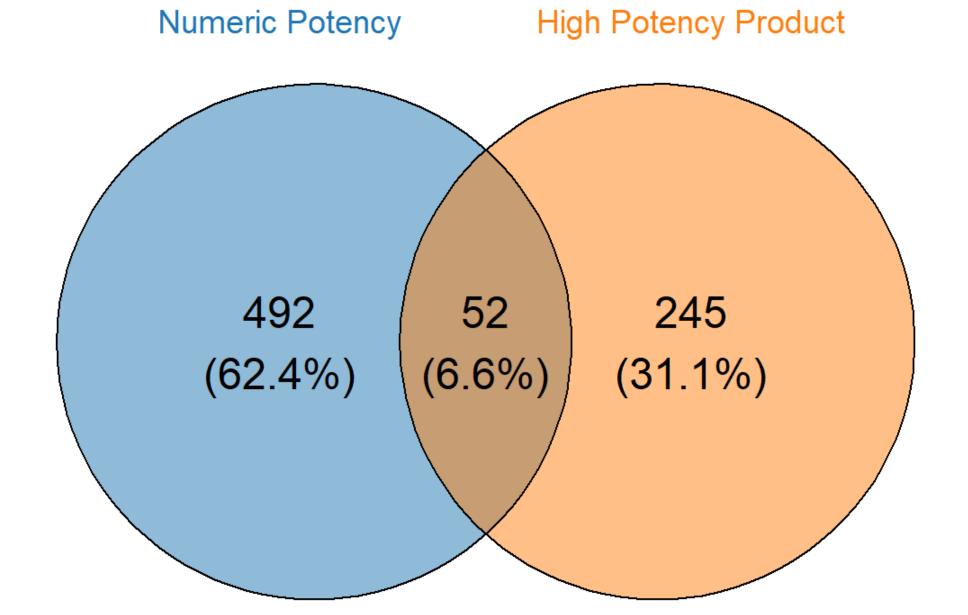


Figure 3. Overlap of all exposures examined for included studies (n = 789)

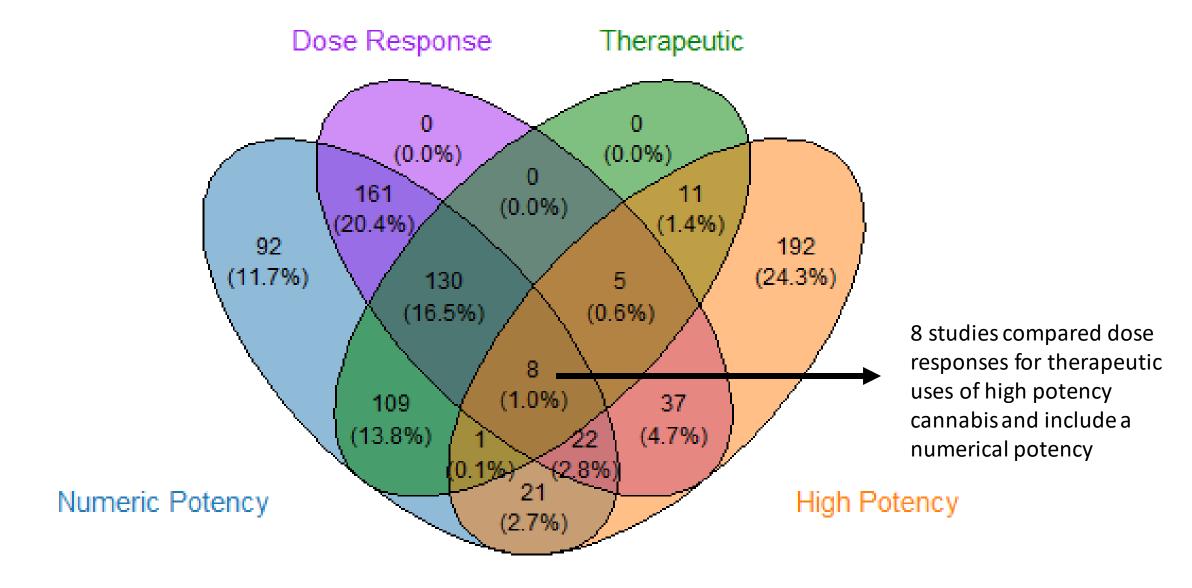


Figure 4. Frequency of **numeric potencies** by unit (n = 470)

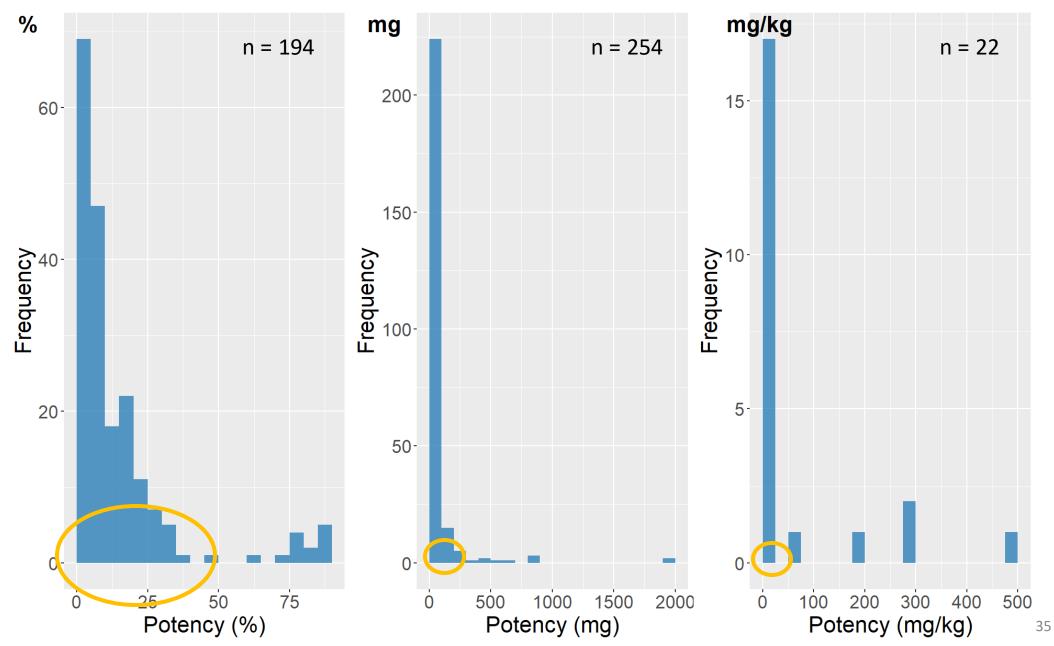
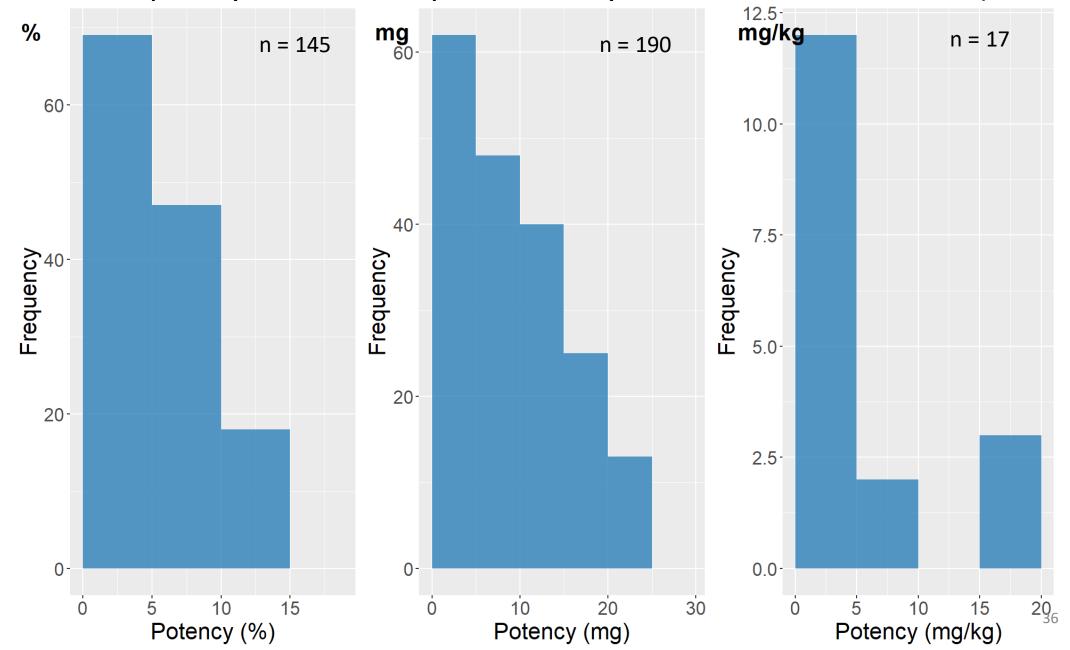


Figure 5. Frequency of numeric potencies by unit, outliers removed (n = 352)



## Interim Results from Data Extraction

### Study Characteristics

- Author affiliations
- Conflict of interest of any author
- Funding of the study
- Study design
- Overall study objectives
- Restrictions on eligibility criteria
- Analyzed indicators of health equity
- Included subgroup analysis or stratification

- Analyzed structural racism or inequities
- Focused exclusively on historically excluded populations
- Country
- Sex
- Race
- Ethnicity
- Age
- Exposure history

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udy design		
Systematic review		
Case report/series		
Observational/epidemiological		
Randomized controlled trial		
Other		
Unclear		
Not reported		
verall study objectives	38	

# Introduction to Evidence Maps and Planned Approach

Lisa Bero, PhD Professor, School of Medicine

Rosa Lawrence, BA Professional Research Assistant, Center for Bioethics and Humanities, University of Colorado School of Medicine





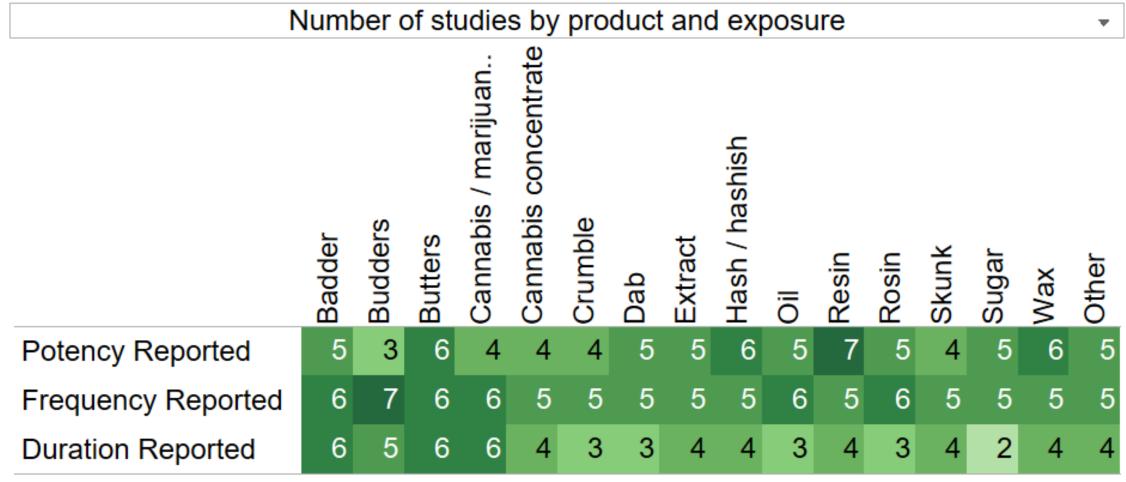


colorado school of public health

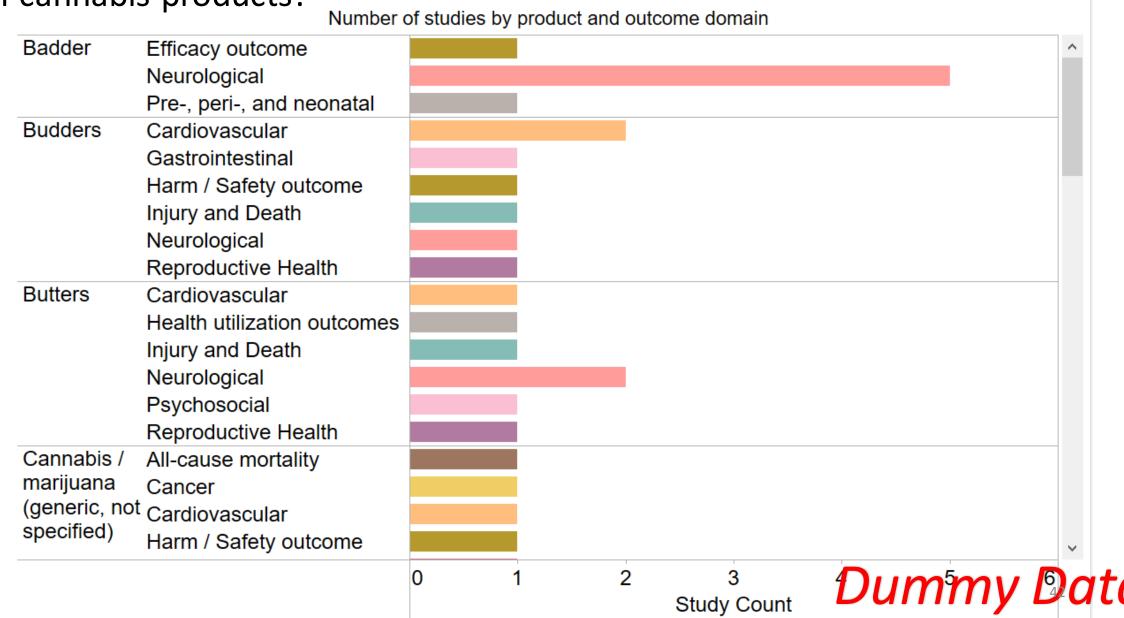
# Projected Results – Evidence Maps

**NOTE:** Dummy data used

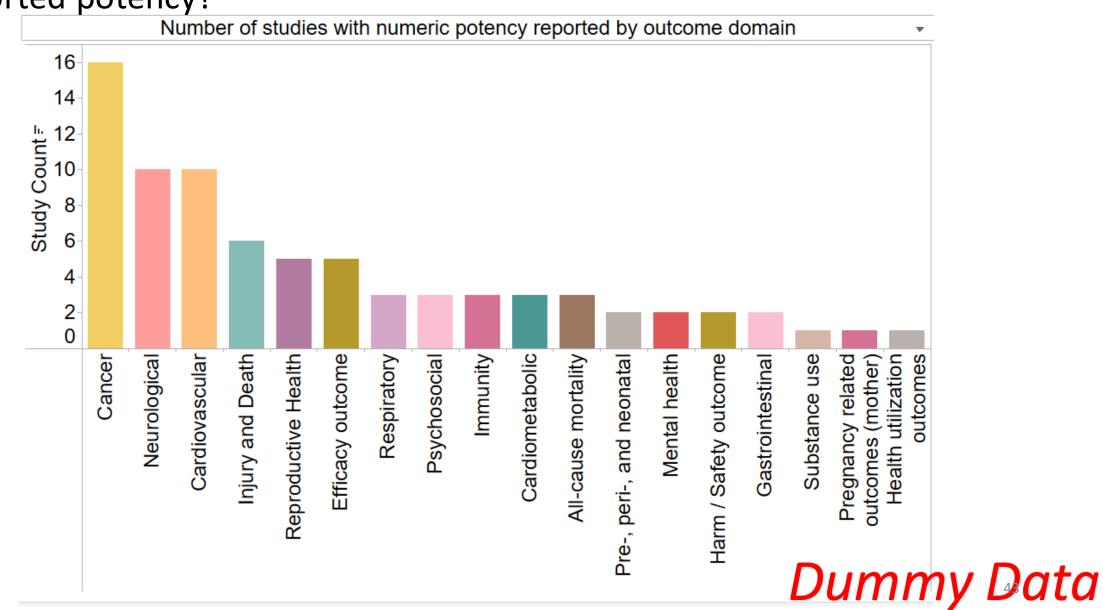
1. Of the different types of cannabis products studied, how many have reported potency, frequency, and/or duration?



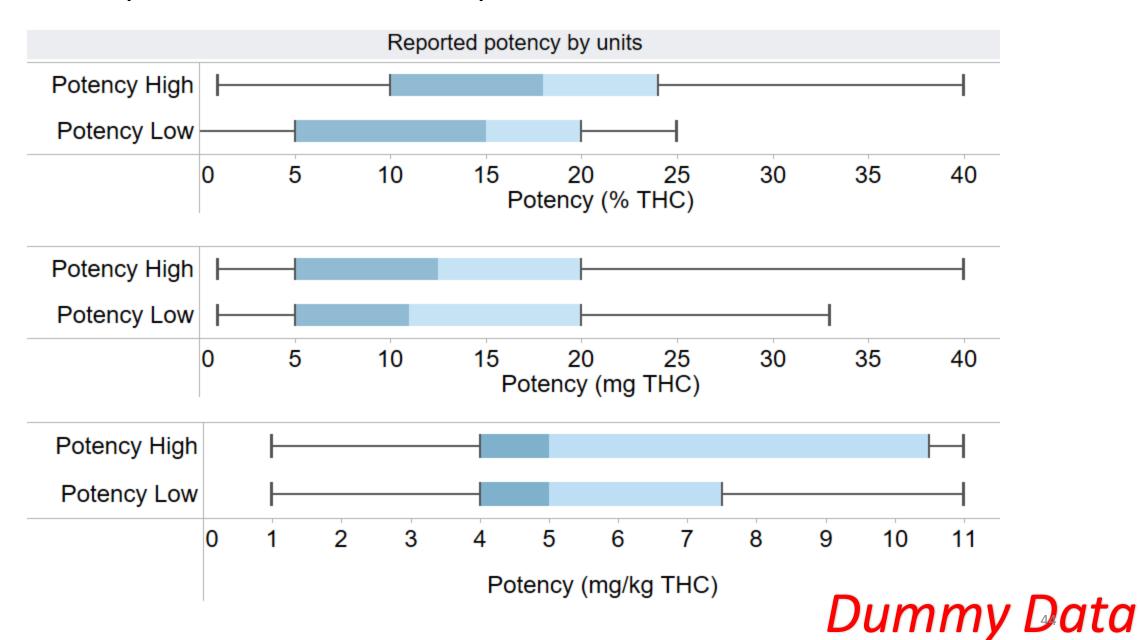
2.A. What types of outcomes have been studied for the different types of cannabis products?



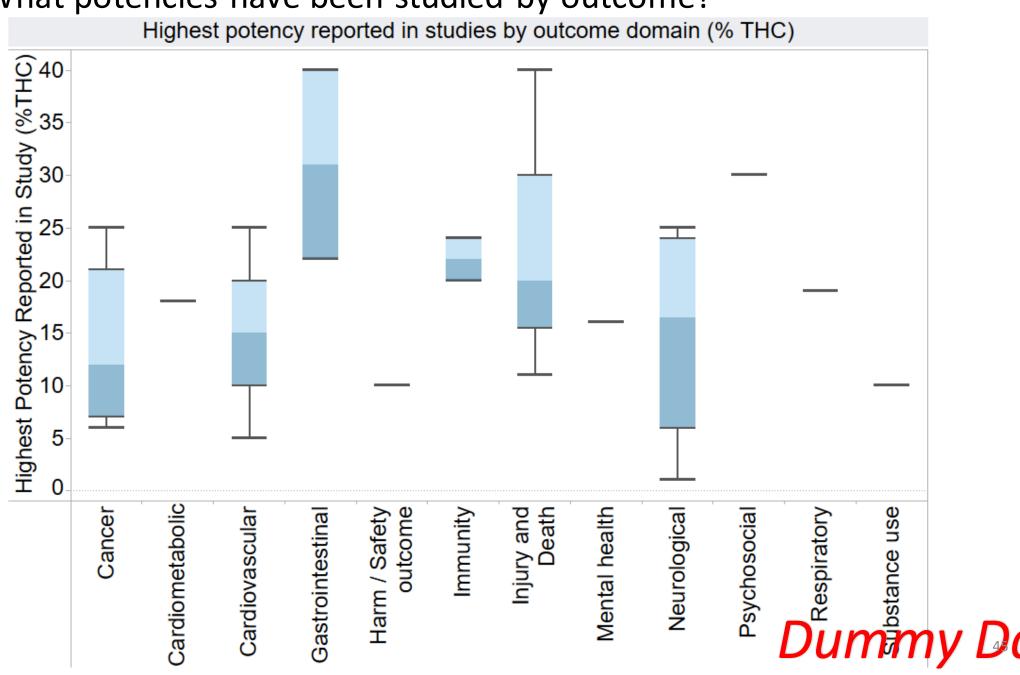
2.B. What types of outcomes have been examined for studies that reported potency?



### 3. What potencies have been reported in the literature?



### 4. What potencies have been studied by outcome?



## Tableau dashboard of study results Study Population Filters:

Age				Ethnicity	Race				
(Multiple	value	s)	•	(Multiple values)	-	(Multiple values)		•	
n									
1		0					D	1228	

Heat map showing the number of studies for outcome domains and study design

Outcome Domain and Study Design for Selected Study Population Design Randomized controlled Other Outcome Domain All-cause mortality, occupational injury, motor veh... Cancer Cardiometabolic Cardiovascular Efficacy outcome Gastrointestinal Harm / Safety outcome Health utilization outcomes (e.g., hospital admissi. **Immunity** Injury and Death Mental health Neurological Ocular Pre-, peri-, and neonatal

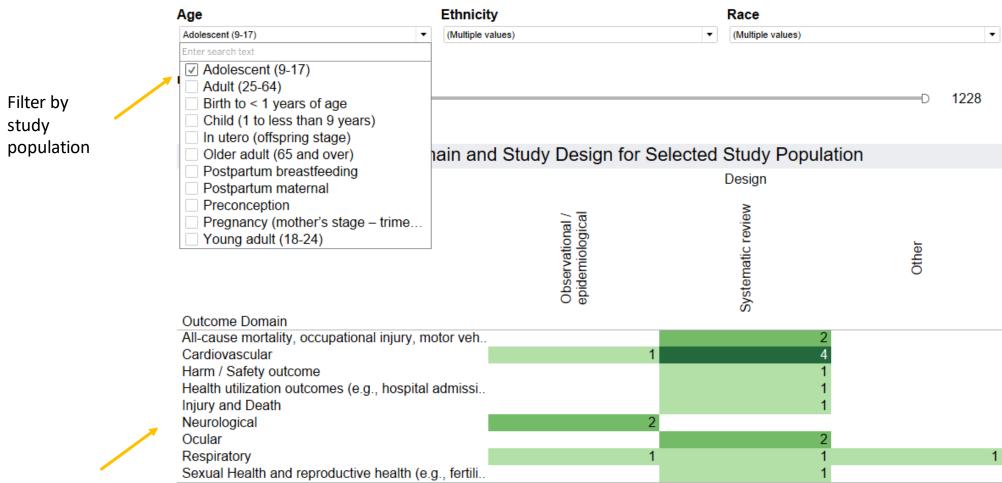
List of included studies

Studies included in selected categories

**Exposure Frequency Exposure Duration** Ref ID Design Outcome.. Product Exposure Route Case rep.. Pre-, peri.. Badder Weekly (once weekly v.. Acute (If so, defined as) https// Inhaled: vaped 18 Observat.. Neurolog.. Badder Inhaled: smoked Heavy Chronic (If so, defined as) https. 34 Case rep.. Sleep Badder Inhaled: vaped Daily (once vs >1 da.. New user (no previous use) https Dummy Dat 50 Systema.. Pregnan.. Badder Inhaled: vaped Monthly (once vs > ... No use in previous year 66 https. Systema.. Cardiova.. Badder Inhaled: vaped Occasional Not described

Link to articles

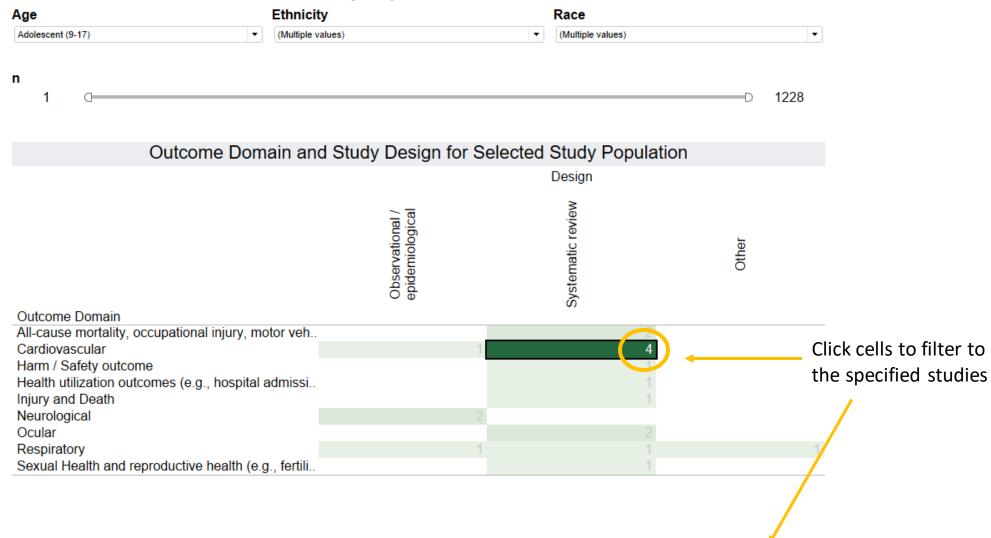
#### **Study Population Filters:**



Filter selections update the tables

Studies included in selected categories									
Ref ID	Design	Outcome	Product 2	Exposure Route	Exposure Frequency	Exposure Duration			
18	Observat	Neurolog	Badder	Inhaled: smoked	Heavy	Chronic (If so, defined as)	https://w		
83	Systema	Sexual H	Budders	Inhaled: smoked	Daily (once vs >1 da	Acute (If so, defined as)	h ps://w	mv	Data
68	Systema	Cardiova	Butters	Ingested: solid by m	Not described	Not described	₩ttμ≅/w	IIIIY	Bata
33	Systema	Ocular	Cannabis /	Inhaled: smoked	Not described	Acute (If so, defined as)	https://w		

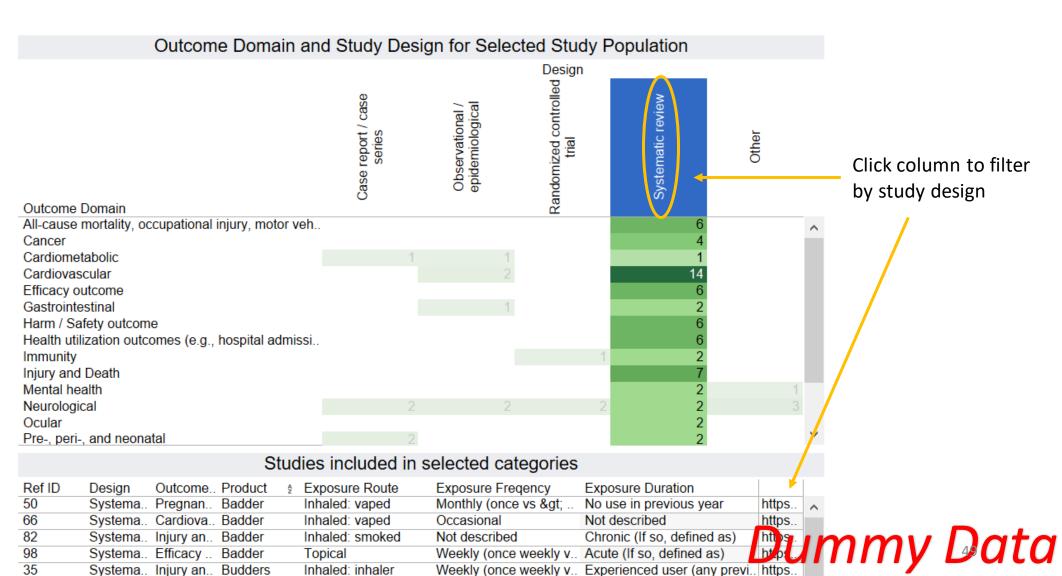
#### Study Population Filters:



Ref ID	Design	Outcome	Product 2	Exposure Route	Exposure Frequency	Exposure Duration			
68	Systema	Cardiova	Butters	Ingested: solid by m	Not described	Not described	https://w		
73	Systema	Cardiova	Hash / hash.	. Inhaled: smoked	Occasional	Not described	hitos://w		
43	Systema	Cardiova	Resin	Inhaled: inhaler	Monthly (once vs >	No use in previous year	htt þi /or i.	mmv	Data
63	Systema	Cardiova	Wax	Inhaled: inhaler	Weekly (once weekly v	Not described	nttps://w	, , , , , , , , , , , , , , , , , , ,	Bata
								_	

#### Study Population Filters:





## **Next Steps**

- Complete data extraction (anticipated by August 2022)
- Assess the scope of the evidence and qualitatively synthesize the evidence identified
- Provide initial review findings to the Science Review Council
- Provide initial recommendations: targeted reviews and modeling, research recommendations, initial policy recommendations
- Plan for the educational campaign