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Classifying alcohol control policies with respect to expected changes in consumption and alcohol-attributable harm: the example of Lithuania

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Abstract: Given the high levels of overall volume of alcohol use, detrimental drinking patterns, and high levels of alcohol-attributable mortality and burden of disease, Lithuania implemented a series of alcohol control policies within a relatively short period of time (2008 to 2019). Based on their expected impact on alcohol consumption and alcohol-attributable harm, as well as their target population, the respective policies were classified using a set of objective criteria and expert opinion. The classification criteria included: positive vs. negative outcomes, mainly immediate versus delayed outcomes, and general population versus specific group outcomes. The judgement of the alcohol policy experts converged on the objective criteria, and, as a result, two tiers of intervention were identified: Tier 1 – general population interventions with an anticipated immediate impact; Tier 2 – other interventions aimed at the general population. In addition, interventions for specific populations were identified. This adaptable methodological approach to alcohol control policy classification is intended to provide guidance and support the evaluation of alcohol policies elsewhere, lay the foundation for the critical assessment of the respective policies to improve health and increase life expectancy, and to reduce crime and violence.

Keywords: alcohol control policy; best buys, classification; evaluation; taxation; availability; marketing; Lithuania

1. Introduction

Lithuania is one of the Baltic countries, located in the northeast of the European Union. It regained independence in 1990 after being part of the Soviet Union for approximately 50 years. Thus, its drinking culture was somewhat impacted during that time, but since Lithuania has a long cultural history of its own, different influences converged [1]. We start the discussion about alcohol policy after independence, when a back and forth between economic and public health interests took place, and led to relatively marked trend changes in alcohol consumption for the country (see Appendix Table 1). Since 1993, the year with the lowest level of alcohol consumption, alcohol consumption in Lithuania has more than doubled, starting at 6.2 litres of pure alcohol *per capita* and reaching its peak in 2011/12 at more than 15 litres *per capita* (see Appendix Table 1; [2,3]). Similarly, the proportion of current drinkers in the adult population has also increased considerably, from 55% in 1993 to 80% in 2016 [2]. Accordingly, the alcohol-attributable mortality in Lithuania was among the highest in 2016 globally, with an estimated 9,894 deaths, or 24.2% of all deaths [4], despite a decline after having introduced some alcohol control policy measures beginning in 2008 which were associated with reductions in the level of alcohol consumption (see Table 2 below).

However, it is difficult to assess the effects of these policy changes in light of the simultaneous global financial crisis of 2008/2009 [5], and sudden changes in Lithuanian non-alcohol taxation policies (e.g., an introduction of a formal requirement to pay health insurance taxes) which led to a sharp increase in the number of declared emigrations in 2010 [6]. Both events resulted in a steep increase in the number of declared emigrations in 2010 and thus a reduction in the official population size of this small country.

Between January 1, 2016 and January 1, 2018, Lithuania once again began implementing a number of far-reaching alcohol control policy interventions, including all three of the World Health Organization's (WHO) "best buys" for alcohol (an increase in prices for alcoholic beverages due to taxation, a reduction of availability of alcoholic beverages and a ban on advertisement of alochol [7,8]). According to the WHO, a "best buy" is defined as an intervention for which there is compelling evidence that it is not only highly cost-effective, but also feasible, low in cost, and appropriate to implement within the constraints of the local health-care system [9]. Before continuing further, we would like to refer to the overview authored by Miščikienė and colleagues [10], which not only lists the individual alcohol control policy interventions, but also gives more context to the historical processes of policy-making in Lithuania over the past 30 years. The current publication will restrict itself to the time period of the past 20 years, a time period which covers all major interventions for alcohol.

Evaluating the impact of alcohol control policy implementation in Lithuania has the advantage of allowing for generalizations to be made for other high-income countries, as it is a high-income country with a stable democracy, is part of the European Union, and is integrated in the North Atlantic Treaty Organization. It is also a country with a population of less than 3 million with strong surveillance systems in place that monitor alcohol consumption and the burden of disease at a great level of detail, allowing for comprehensive analyses. Thus, Lithuania offers a unique opportunity to evaluate the impact of the three "best buys" at the same time on a wide range of outcomes (e.g., total adult alcohol *per capita* consumption, alcohol-attributable hospitalizations, mortality, and violence). Over the course of 12 years, Lithuanian policy-makers have voted in favour of over a dozen alcohol policies, affecting very different aspects

of alcohol use. Prior to evaluating these policies, each must be critically reviewed with regard to their expected effects and possible confounding of their effects with other policies or economic trends. In the following, we undertake this assessment and classify the interventions into two main Tiers, ordered by the degree of impact expected, via a sensitivity analysis of this ordering using a different methodology. In addition to these two Tiers impacting of the whole population, there are also alcohol policies which target specific groups in the population. These will not be discussed in detail here.

The present contribution aims to present a hierarchical classification of the respective policies according to their expected effects. Although research in this area is increasing and various alcohol policy scoring tools have been developed (e.g., [11-14]), to our knowledge this paper represents the first attempt to develop and apply a formalized approach to alcohol policy classification prior to assessing the impact of the respective policies on a variety of outcomes in greater detail.

2. Materials and Methods

2.1 General design of alcohol control policy evaluations

Since the effect of policy changes cannot be tested through traditional randomized controlled trial designs, well-selected, -designed and -analyzed natural experiments are the method of choice for examining the impact of policy changes on outcomes [15-17]. The classic methodology for evaluation is interrupted time-series analysis, where the observed trend is compared to the expected trend, the latter based on data collected prior to the intervention [18]. Obviously, as these are not randomized experiments, but essentially before-and-after comparisons, the more relevant control variables that are included, the better [19]. Thus, statistically controlling for important confounders such as inflation, unemployment, or gross domestic product will help rule out alternative explanations. However, there are limitations due to sample size and statistical power. Most of these potential confounders will be economic variables, as short- and medium-term changes in level of alcohol consumption have been shown to depend to a large degree on economic factors [2,20-22].

For any interrupted time-series analyses, the nature of the effect needs to be specified a priori (e.g., abrupt effects, which are usually expected to start immediately after implementation and are expected to last in their impact except for financial penalties due to inflation; or lagged effects, where only part of the full effect is expected immediately after the intervention is enacted, and the full effect may only be realized after sometime has passed, possibly several years [23]). Given this methodology, there need to be sufficient data points in the period prior to the first big alcohol policy intervention to be analysed (for Lithuania: January 2008), and sufficient data points after the last intervention for it to be modelled. For interrupted time-series analyses, a minimum of 50-100 time points in total would normally be required, with at least 24 before and 24 after the intervention ([18]; see also [24]). We can therefore only use time-series methodology for monthly data (yearly data would not provide a sufficient number of time points). If we start our time series on January 1, 2000 and if we do not evaluate the policies' effects in 2001 (since not enough time points have accrued by then), or evaluate any of the policies which would likely have resulted in greater availability and harm, we would have 72 months of data available before the enactment in 2008 of the first alcohol-policy intervention designed to reduce drinking and harm-this would fulfill the sample size requirements. However, any intervention after January 1, 2018 may run into power issues given the current availability of data (i.e., we would have to wait for more data to become available). These are considerations that are relevant to potential interrupted time-series evaluations of alcohol control policies in general..

2.2 Dimensions of alcohol control policies relevant for evaluating impact

In order to establish hypotheses about alcohol control policies, we applied objective classifications and expert judgement. For the objective classifications, the following dichotomies were deemed to be relevant (based on [25,26]):

- Positive vs. negative outcomes: Policies which are known to increase harm, most often by increasing level of consumption, vs. policies which are known to decrease harm. For instance, considering policies which were implemented in Lithuania, restrictions on availability, e.g., by reducing opening hours, can be expected to decrease use and harm [27,28]). On the other hand, widening availability, for example by liberalizing alcohol sales and production or allowing sales of alcohol in petrol stations, are postulated to increase use and harm ([29]; see Table 2 for the result of this classification).
- Mainly immediate vs. delayed outcomes: Policies, where much of the impact on use or harm is immediate (e.g., availability, price increases via taxation) vs. policies where the impact is more medium- or long-term (ban on advertisements, education).
- General population vs. specific group outcomes: Policies also differ with respect to their population reach: an increase in alcohol excise taxation applies equally to everyone in a country, even though only drinkers and their families will likely be most strongly affected. On the other hand, a change in the minimum drinking age mainly applies to alcohol useby people in this age group, and to the resulting attributable harm to them. Similarly, a law mandating an ignition interlock device for drivers convicted for driving under the influence of alcohol would apply only to drivers. For the latter policy, we would mainly expect consequences to the number of traffic injuries, whereas successfully implemented alcohol policies of general reach should impact many social and health outcomes, including traffic injuries [30].

2.3 Main selection criteria

2.3.1. Tier 1: general population interventions with an anticipated immediate impact

We based our selection of the most impactful interventions on prior empirical evaluations by the WHO [7,8,31] and independent study groups (e.g., [26]). Furthermore, we selected interventions where the impact of the effects on alcohol use was predicted to begin immediately (such as pricing and availability policies), allowing for an estimation of effects via interrupted time-series methodology [13]. Thus, a ban on marketing alone would be excluded from Tier 1 interventions, as main effects would be expected only to be measurable after a longer lag time and distributed over years, based on changes in social norms related to alcohol use [26].

For pricing interventions, we decided to operationalize pricing interventions as a rise in the excise taxation of alcohol, which would be associated with a decrease in affordability in the 12 months following enactment, so that it would be included only when the price of alcohol increased at a higher rate than average disposable income (see also [32]). This definition was operationalized according to the definitions of Statistics Lithuania [33], which publishes a yearly index for the price of alcoholic beverages, and an index for average disposable income per month, per household member. The Affordability Index was then constructed as follows:

Proportional changes in Affordability Index, from year t to year t+1: ((Income t+1/alcohol pricet+1) – (Income t/alcohol price t)) / (Income t/alcohol price t)

Thus, if disposable income increased more than the price (relative to the previous year), the Affordability Index would be positive (higher affordability), and if the opposite were true, the Affordability Index would be negative.

Table 1: Income, alcohol prices, and changes in the Affordability Index over the period of alcohol policy interventions in Lithuania

Year	Average disposable income per month index, per household member 2010 = 100	Alcohol Price Index (API) 2010 = 100	Affordability Index (defined as Disposable income/API) 2010 = 100	Proportional changes in Affordability Index (compared to previous year)
2007	92.4	80.4	115	14.4%
2008	103.9	90.6	115	-0.1%
2009	116.8	98.9	118	3.0%
2010	100.0	100.0	100	-15.3%
2011	88.1	98.9	89	-10.9%
2012	97.1	101.3	96	7.6%
2013	106.4	102.5	104	8.3%
2014	112.3	104.1	108	3.9%
2015	123.7	105.0	118	9.1%
2016	133.0	107.3	124	5.3%
2017	138.6	119.9	116	-6.7%
2018	149.1	122.4	122	5.3%
2019	160.3	124.9	128	5.4%

For Tier 1 interventions which involved taxation and thus price, we only included interventions which were associated with a reduction in affordability (i.e., negative changes in the Affordability Index in Table 1). For availability, we included interventions aimed at reducing alcohol use for large parts of the general population, for instance by restricting hours of sale for alcoholic beverages, and which had shown similar effect sizes in prior research (e.g., [28]). Thus, not all availability restrictions and taxation increases qualified for inclusion in Tier 1. As well, any intervention which targeted only specific groups was excluded from Tier 1.

2.3.2. Tier 2: other interventions aimed at the general population

For Tier 2, as well as to all interventions in Tier 1, we included taxation or price increases up to a change in affordability of 5%, which was the median for the affordability change index.. We also classified general availability restrictions for Tier 2 interventions, which were expected to produce smaller effects, such as increased restrictions which were limited to only certain days (see also [28]).

2.3.3. Alcohol control interventions not aimed at the general population

A number of alcohol control interventions were designed to target specific groups or situations and not the general population. These interventions will be used to test specific hypotheses (e.g., regarding drink-driving interventions impacting on traffic crashes, traffic injuries and traffic fatalities; [34]).

2.4 Sensitivity analysis:

For the sensitivity analysis, interventions were independently established by a panel of alcohol policy experts using a modified nominal group technique [35]. All alcohol control policy measures during the time period 2000-2019 (see Table 2) were rated. Five alcohol control policy experts were selected who were neither familiar with the specific data for Lithuania on the level of alcohol consumption, the mortality and other disease burden data, nor with the data on

affordability in Lithuania to provide the ratings: Sally Casswell, Carina Ferreira-Borges, Shannon Lange, Maria Neufeld, and Robin Room. The ratings were conducted in May of 2020.

Using this procedure, the experts could not be biased by knowledge of the actual Lithuanian history of associations between policies and mortality. The rating scale applied for each policy ranged from 0 to 10, and ratings were based on the perceived immediate impact of alcohol use on health, based on the following instructions: "Please rank the alcohol policy measures in their predicted immediate impact on alcohol consumption and health (think about all-cause mortality as the main health outcome) from 0 to 10 (0=no impact to 10=highest impact)."

Interrater reliability, as measured by the Intraclass Correlation Coefficient, was 0.54, with a 95% CI between 0.35 and 0.72, and a median of 0.71, with an interquartile range of 0.18 for the Spearman rank correlations between raters, indicating fair to good agreement [36].

Dates were then selected as being important for modelling purposes if at least one policy implemented during at a given time point had an average rating of 5 or more (see highlighted rows in Table 2).

3. Results

3.1 Tier 1 alcohol control interventions: highest impact on general population expected

Based on these strict criteria, only three policy enactments qualified between 2000 and 2019 for inclusion: January 1, 2008, March 1, 2017, and January 1, 2018 (further details provided in Table 2 below; see also [10,34]).

On January 1, 2008, the Lithuanian Parliament declared the 'Year of Sobriety' and increased excise tax by 20% for ethyl alcohol, wine, and intermediate products, and by 10% for beer. Furthermore, and not strictly related to Tier 1 interventions but enacted in parallel, drink-driving legislation was toughened by introducing higher penalties, car confiscation, or driver imprisonment for repeat offenders, and a reduction in the blood alcohol concentration (BAC) threshold for young drivers. Lastly, alcohol advertising was restricted during the daytime on TV and radio, with an indication that there would be a full advertising ban in a few years [10,37]. While we cannot rule out that additional measures have confounded the effects of tax increases, this is relatively unlikely, as drink-driving legislation and regulation on advertisement follow other more specific and less immediate pathways to reduce alcohol harm. A global economic crisis hit Lithuania only at the end of 2008, and therefore did not confound the implemented measures (according to economic datan based on GDP after 10/2008; based on [38]).

On March 1, 2017, the highest ever increase in Lithuanian excise tax came into effect during a stable period of gradual economic growth: excise tax for beer and wine increased by 111-112%, by 91-94% for intermediate products, and by 23% for ethyl alcohol. The only other measure implemented in this year (2017), on January 1, was the criminalization of drink-driving for heavily drunk persons. However, the initial version of the amendment had a flaw [10], in addition to it targeting only a specific and narrow population group; thus it is quite unlikely that it had a strong initial effect on the general population in that year.

On January 1, 2018, several strong restrictions targeting availability and marketing came into effect. The minimum legal purchase age was increased from 18 to 20 years old, off-premise sales hours were reduced by two hours (10 a.m. to 8 p.m.), and even further reduced on Sundays (10 a.m. to 3 p.m.). A full alcohol advertising ban (including TV, radio and internet) came into effect, with only small exceptions [10]. As with the 2008 alcohol policy measures, a confounding of availability and marketing measures cannot entirely be ruled out, but appears unlikely to be present in the short-term.

Box 1: Tier 1 interventions

January 1, 2008	(i) drink-driving (increased penalties)
Criterion met:	(ii) marketing/advertising (banned on TV/radio during daytime)
affordability	(iii) taxation/price (increase in excise tax by 10-20%)
March 1, 2017	taxation/price (increase in excise tax: 111-112% for wines and beer; 23% for ethyl
Criterion met:	alcohol)
affordability	
January 1, 2018	(i) availability (increase in legal minimum age & increase enforcement; reduced
Criterion met:	off-premise sales hours)
availability	(ii) marketing/advertisement ban (full ban on TV, radio, and internet advertise-
	ments with very few exceptions)

3.2 Tier 2 interventions: sizable impact on alcohol use and attributable harm in the general population

Based on the definitions provided above, all Tier 1 interventions automatically qualify as Tier 2 intervention. In addition, based on the criteria above, two further policy enactment dates qualify: January 1, 2009 and April 1, 2014.

Box 2: Tier 2 interventions (two additional interventions in addition to Tier 1 are highlighted in blue)

January 1, 2008	 (i) drink-driving (increase in penalties) (ii) marketing/advertising (ban on TV/radio during daytime) (iii) taxation/price (increase in excise tax of 10-20%)
January 1, 2009 New; criteria: affordability and availability	 (i) taxation/price (increase in excise tax of 10-15%, removal of tax exemptions for small beer breweries, relative price of alcohol increases due to global economic crisis) (ii) availability (off-premise sales restricted at night, a ban on having opened alcohol beverages in cars)
April 1, 2014 New; criterion: affordability	taxation/price (increase in excise tax by of 10-47%; 1% for ethyl alcohol)
March 1, 2017	taxation/price (increase in excise tax: 111-112% for wines and beer; 23% for ethyl alcohol)
January 1, 2018	 (i) availability (increase of legal minimum age & increase in enforcement; reduced off-premise sales hours) (ii) marketing/advertisement (full ban on TV, radio, and internet advertisements with few exceptions)

Depending on the research question and statistical methodology selected [18], Tier 1 and Tier 2 interventions will be summed to obtain a cumulative score for alcohol control policies, as follows:

Change from 0 to +1 for January 1, 2008; from 1 to 1.5 on January 2009; from 1.5 to 2 on April 1, 2014 from 2 to 3 on March 1, 2017; from 3 to 4 on January 2018.

3.3 Sensitivity analyses: interventions based on expert judgments

The alcohol control policy interventions selected by the experts are highlighted in Table 2 in light blue. The experts selected all of the Tier 1 and Tier 2 interventions plus two others (from March 1, 2015 and January 1, 2016). In other

words, the expert judgments highly corresponded with the Tier 1 and Tier 2 interventions selected by objective criteria. In some ways, the expert judgements could be seen as simply applying a lower threshold, albeit one without underlying objective data.

#	Date of policy implementation	Type of policy	Policy score	Expected Impact
1	June 1, 2001	taxation/price (increase in excise tax of 6% for ethyl alcohol, change of a taxing format)	0	0
2	November 28, 2001	availability (liberalization of sales and production, sales of alcohol in petrol stations allowed)	0	Negative*
3	June 28, 2002	 (i) availability (state production monopoly abolished; municipalities allowed to decide on alcohol sales) (ii) marketing/advertising (liberalization of advertising, fines for violations reduced) 	0	Negative*
4	July 1, 2002	taxation/price (exemption of excise tax for small breweries)	0	Negative*
5	May 1, 2003	Drink-driving (criminal liability restored in certain cases when individuals are harmed, or property is damaged significantly)	0	0
6	July 16, 2003	marketing/advertising (liberalization of advertising by expanding the range of display places)	0	Negative*
7	January 1, 2004	taxation/price (decrease of excise tax of a sub- category of fermented beverages when equalizing the tax with other similar categories)	0	Negative*
8	May 1, 2004	taxation/price (four alcohol beverage categories formed, licencing changes when joining the EU)	0	0
9	January 1, 2008	 (i) drink-driving (increased penalties) (ii) marketing/advertising (banned on TV/radio during daytime) (iii) taxation/price (increase excise tax by 10-20%) 	Tier 1: Affordability& decrease among others	1
10	January 1, 2009	 (i) taxation/price (increase excise tax by 10-15%, removal of tax exemptions for small beer breweries, relative price of alcohol increases due to global economic crisis) (ii) availability (off-premise sales restricted at night, a ban on having opened alcohol beverages in cars) 	Tier 2: Affordability& < 5%	0.5
11	April 1, 2014	taxation/price (increase excise tax by 10-47%; 1% for ethyl alcohol)	Tier 2: Affordability& <5%	0.5
12	January 1, 2015	drink-driving (0% BAC for select drivers)	0	Specific measure
13	March 1, 2015	taxation/price (increase in excise tax of 10-16%; 2% for ethyl alcohol)	0	0
14	January 1, 2016	availability (sales banned at petrol stations)	0	Specific measure
15	March 1, 2016	taxation/price (increase excise tax by 8%; 2.5% for ethyl alcohol)	0	0
16	January 1, 2017	drink-driving (>0.15% BAC = criminal offense); see #20	0	Specific measure
17	March 1, 2017	taxation/price (increase in excise tax of 111-112% for wines and beer; 23% for ethyl alcohol)	Tier 1: Affordability& descrease	1
18	January 1, 2018	 (i) availability (increase legal minimum age & increased enforcement; reduced off-premise sales hours) (ii) marketing/advertisement (full ban of TV, radio, and internet advertisements with few exceptions) 	Tier 1: availability	1

Table 2. Major alcohol control policies implemented between 2001 and 2019 in Lithuania (for further details, see [10]	0,34])
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19	March 1, 2019	taxation/price (10.5% increase for ethyl alcohol)	0	Not to be considered for time series analysis (power)
20	April 1, 2019	From January 1, 2017, drink-driving with a BAC level higher than 1.5 permilles was criminalized. However, the original law was flawed, since refusal to be tested by the police did not result in criminal offence. This was later amended and came into effect on 1 April 2019.	0	Specific measure; Not to be considered for time series analysis (power)
21	November 1, 2019	'child champagne' ban (prohibited to manufacture and to sell food, toys, and other goods for children and adolescents whose designs mimic alcoholic beverages and/or their packaging).	0	Not to be considered for time series analysis (power)

Affordability& here was defined as yearly changes in the ratio between Real Household Disposable Income and Alcohol Price Index. Higher affordability indicated that alcoholic beverages became more affordable. Negative* here means that the alcohol policy was predicted to lead to an increase in alcohol per capita consumption. Blue-highlighted interventions have been rated by alcohol policy experts as being effective.

3.4 Interventions for specific populations

There are also interventions for specific populations such as those targeting a particular age group (e.g., minimum legal drinking age increase from 18 to 20 years) or for traffic participants (e.g., drunk-driving laws). While such measures, under certain circumstances, may impact the overall drinking level of the population [39], these interventions will mainly be modelled for the specific groups or outcomes intended. For example, the effects of increasing the legal drinking age should be seen among the 18-20-year old age group (i.e., those affected by the policy change), and the drunk-driving laws should mainly affect traffic participation and associated outcomes, such as traffic crashes, injuries, or fatalities [30].

4. Discussion

With the considerations spelled out above, we were able to identify the alcohol control policies where we would expect the highest overall impact. The subjective classifications of the various policiess by the panel of alcohol policy experts converged with the classification of policies using objective criteria alone. Before we discuss these results further, we would like to point out their limitations.

First, not a lot of research exists on the comparative effectiveness of different implementation of the best buys. For instance, increase of excise taxation or setting a minimum unit price in many categorization systems are seen as best buy, even if the taxation increase does not even cover inflation and/or increases in disposible income, or the minumum price is so low, that it would not affect consumer behaviour. While pricing policies clearly are potentially effective and cost-effective, their overall effectiveness will depend on the overall economic situation and on the affordability of the alcoholic beverages affected. In addition, definitions of affordability vary [40,41], as do underlying data sources. We used a simple definition based on disposable income and the average price of alcoholic beverages. There are other definitions which would take into account the Consumer Price Index as well, as this would reflect the price of alternative goods which could be obtained [41]. Future research will have to decide which affordability index is best correlated with actual behaviour, and thus with consumption and alcohol attributable harm. For interventions on availability, there is much less coherent theory and research available which quantitatively compares the impact of different forms

of availability (for general considerations: [26,42]). As a result, the classification of interventions into Tier 1 and Tier 2 categories based on availability is on less solid ground. Finally, while the impact of marketing and advertising on consumption is well established [43], the impact of policies to control these is much less clear (e.g., [26,44,45]). As a consequence, even the classification of the impact of marketing and advertisement bans, such as the one in Lithuana, is difficult. Finally, the interrater reliability ratings of the experts were relatively low. This indicates the need for more research on the evaluation of concrete alcohol control policy measures all around the world.

While many attempts have been made to classify and evaluate the potential impact of alcohol control policies (e.g., [25,26]), fewer attempts have been made to quantify in detail the potential impact based on objective criteria for a particular country to lay the groundwork for formal evaluations. Furthermore, current alcohol policy impact scales are usually based on expert ratings, with only a few studies available to date which test if changes in policy scores were in fact related to changes in consumption or attributable harm. We clearly need more impact studies, and more rigorous ones, with single and combined interventions to make better recommendations on which policies to implement. And these studies should have more important public health endpoints. For instance, only one of the 50 studies in the meta-analyses on taxation and health outcomes by Wagenaar and colleagues [46] examined all-cause mortality, and none examined life expectancy. However, these are the indicators politicians are interested in, as the example of of a recent case study on alcohol policy from Russia amply demonstrated, when it was taken up by many media outlets, discussed at the UN, and in several Parliaments [47].

5. Conclusions

The described classification procedure resulted in the identification of three alcohol policy categories, based not only on experts' opinions but also on objective criteria transparently described and based on available evidence. The resulting classification system allows us to clearly distinguish between expected effects of alcohol control policies and potential confounding factors, such as other policies not related to alcohol regulation or economic trends.

Monitoring and evaluating progress in alcohol policy implementation and identifying policies with the highest impact on a population's health and economic prosperity are key components when implementing health strategies and interventions. The detailed methodological approach to alcohol policy classification within a country as described here can inform monitoring and evaluation approaches for other countries, and can be adapted to different situations based on available data.

Importantly, the present contribution lays the foundation for us to critically assess the potential for the respective alcohol control policies to improve health and increase life expectancy, as well as to reduce crime and violence. The formal evaluation which follows will provide important knowledge about the value of the chosen approach, especially in comparison with various expert scales which to date have not shown high association with actual levels of drinking or alcohol-attributable harms.

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CF-B is a staff member of the WHO, MN is a WHO consultant. The authors alone are responsible for the views expressed in this publication and they do not necessarily represent the decisions or the stated policy of the WHO. The authors declare to have no conflict of interest.

Appendix

Year	Total alcohol <i>per capita</i> consumption* [2]	Recorded alcohol <i>per capita</i> consumption [3]
1990	11.9	
1991	9.9	
1992	8.3	
1993	6.2	
1994	7.3	
1995	9.0	7.9
1996	10.4	7.9
1997	10.4	8.7
1998	10.4	8.0
1999	11.8	8.6
2000	13.9	9.7
2001	15.4	10.5
2002	15.5	11.1
2003	15.8	11.3
2004	15.9	12.2
2005	16.0	12.5
2006	16.0	13.2
2007	15.9	13.9
2008	15.3	13.9

Table A1: Alcohol per capita consumption in Lithuania 1991-2019

2009	15.0	13.1
2010	15.1	13.5
2011	16.1	14.7
2012	16.5	14.7
2013	16.4	14.5
2014	16.1	14.2
2015	15.5	14.0
2016	15.1	13.2
2017	14.7	12.3
2018	14.7	11.2
2019	14.5	11.1

* Total alcohol per capita consumption comprises recorded, unrecorded, and tourist consumption (for definitions see [48,49]

References

 thinkbeforedrink.eu. Lithuania Country Report: Lithuanian drinks: history and nowadays. Available online: http://www.thinkbeforedrink.eu/documentation/TBD Lithuania countryreport.pdf (accessed on 08/01/2021).

- Manthey, J.; Shield, K.D.; Rylett, M.; Hasan, O.S.M.; Probst, C.; Rehm, J. Global alcohol exposure between 1990 and 2017 and forecasts until 2030: a modelling study. *The Lancet* 2019, *393*, 2493-2502, doi:10.1016/s0140-6736(18)32744-2.
- Government of Lithuania. Modern Lithuania 1991-present: Database of indicators. Available online: <u>https://osp.stat.gov.lt/statistiniu-rodikliu-analize#/</u> (accessed on 21/12/2020).
- 4. Shield, K.; Manthey, J.; Rylett, M.; Probst, C.; Wettlaufer, A.; Parry, C.D.H.; Rehm, J. National, regional, and global burdens of disease from 2000 to 2016 attributable to alcohol use: a comparative risk assessment study. *Lancet Public Health* **2020**, *5*, e51-e61, doi:10.1016/s2468-2667(19)30231-2.
- 5. Karanikolos, M.; Mladovsky, P.; Cylus, J.; Thomson, S.; Basu, S.; Stuckler, D.; Mackenbach, J.P.; McKee, M. Financial crisis, austerity, and health in Europe. *Lancet* **2013**, *381*, 1323-1331, doi:10.1016/S0140-6736(13)60102-6.
- Statistics Lithuania. International Migration of the Lithuanian Population 2010. Available online: <u>https://ec.europa.eu/migrant-integration/index.cfm?action=media.download&uuid=FBDBDA30-910C-8A8A-</u> <u>0110ED6B0380EDAA</u> (accessed on 05/09/2019).
- 7. Chisholm, D.; Moro, D.; Bertram, M.; Pretorius, C.; Gmel, G.; Shield, K.; Rehm, J. Are the "Best Buys" for Alcohol Control Still Valid? An Update on the Comparative Cost-Effectiveness of Alcohol Control Strategies at the Global Level. J Stud Alcohol Drugs 2018, 79, 514-522.
- 8. World Health Organization. 'Best buys' and other recommended interventions for the prevention and control of noncommunicable diseases: Updated (2017) appendix 3 of the global action plan for the prevention and control of noncommunicable diseases 2013-2020. WHO: Geneva, 2017.
- 9. World Economic Forum & World Health Organization. *From burden to 'best buys': Reducing the economic impact of noncommunicable diseases in low- and middle-income countries.*; World Economic Forum: Davos, Switzerland, 2011.
- Miščikienė, L.; Midttun, N.G.; Galkus, L.; Belian, G.; Petkevičienė, J.; Vaitkevičiūtė, J.; Štelemėkas, M. Review of the Lithuanian Alcohol Control Legislation in 1990-2020. *International Journal of Environmental Research and Public Health* 2020, 17, 3454, doi:10.3390/ijerph17103454.
- Allamani, A.; Voller, F.; Decarli, A.; Casotto, V.; Pantzer, K.; Anderson, P.; Gual, A.; Matrai, S.; Elekes, Z.; Eisenbach-Stangl,
 I., et al. Contextual determinants of alcohol consumption changes and preventive alcohol policies: a 12-country European study in progress. *Substance Use & Misuse* 2011, 46, 1288-1303, doi:doi: 10.3109/10826084.2011.572942.

- 12. Pan American Health Organization (PAHO). Alcohol Policy Scoring. Assessing the level of implementation of the WHO Global strategy to reduce the harmful use of alcohol in the Region of the Americas. Available online: https://www.paho.org/en/documents/alcohol-policy-scoring-assessing-level-implementation-who-global-strategy-reduce-harmful (accessed on 08/01/2021).
- World Health Organization Regional Office for Europe. Policy in action: A tool for measuring alcohol policy implementation. Available online: <u>https://www.euro.who.int/ data/assets/pdf_file/0006/339837/WHO_Policy-in-Action_indh_VII-2.pdf?ua=1</u> (accessed on 25/08/2020).
- Naimi, T.S.; Blanchette, J.; Nelson, T.F.; Nguyen, T.; Oussayef, N.; Heeren, T.C.; Gruenewald, P.; Mosher, J.; Xuan, Z. A new scale of the US alcohol policy environment and its relationship to binge drinking. *American journal of preventive medicine* 2014, 46, 10-16.
- 15. Shadish, W.R.; Cook, T.D.; Campbell, D.T. *Experimental and Quasi-Experimental Designs for Generalized Causal Inference*; Houghton Mifflin Company: New York, U.S., 2002.
- Craig, P.; Katikireddi, S.V.; Leyland, A.; Popham, F. Natural Experiments: An Overview of Methods, Approaches, and Contributions to Public Health Intervention Research. *Annu Rev Public Health* 2017, 38, 39-56, doi:10.1146/annurevpublhealth-031816-044327.
- Dunning, T. Natural Experiments in the Social Sciences : A Design-Based Approach; Cambridge University Press: Cambridge, 2012.
- 18. Beard, E.; Marsden, J.; Brown, J.; Tombor, I.; Stapleton, J.; Michie, S.; West, R. Understanding and using time series analyses in addiction research. *Addiction* **2019**, *114*, 1866-1884, doi:10.1111/add.14643.
- 19. Rehm, J.; Strack, F. Kontrolltechniken. In *Methodologische Grundlagen der Psychologie*, Hermann, T., Tack, W., Eds. Hogrefe: Gottingen, 1994; pp. 508-555.
- 20. World Health Organization. Global status report on alcohol and health 2018. World Health Organization: Geneva, Switzerland, 2018.
- 21. De Goeij, M.C.; Suhrcke, M.; Toffolutti, V.; van de Mheen, D.; Schoenmakers, T.M.; Kunst, A.E. How economic crises affect alcohol consumption and alcohol-related health problems: a realist systematic review. *Social Science & Medicine* **2015**, *131*, 131-146.
- 22. Rehm, J.; Babor, T.F.; Casswell, S.; Room, R. Heterogeneity in trends of alcohol use around the world: Do policies make a difference? *Drug and Alcohol Review* **2021**.
- 23. Holmes, J.; Meier, P.S.; Booth, A.; Guo, Y.; Brennan, A. The temporal relationship between per capita alcohol consumption and harm: a systematic review of time lag specifications in aggregate time series analyses. *Drug Alcohol Depend* 2012, 123, 7-14, doi:10.1016/j.drugalcdep.2011.12.005.
- 24. Zhang, F.; Wagner, A.K.; Ross-Degnan, D. Simulation-based power calculation for designing interrupted time series analyses of health policy interventions. *J Clin Epidemiol* **2011**, *64*, 1252-1261, doi:10.1016/j.jclinepi.2011.02.007.
- 25. Anderson, P.; Braddick, F.; Conrod, P.; Gual, A.; Hellman, M.; Matrai, S.; Miller, D.; Nutt, D.; Rehm, J.; Reynolds, J., et al. *The new governance of addictive substances and behaviours*; Oxford University Press: Oxford, U.K., 2017.
- Babor, T.F.; Caetano, R.; Casswell, S.; Edwards, G.; Giesbrecht, N.; Graham, K.; Grube, J.; Gruenewald, P.; Hill, L.; Holder,
 H., et al. *Alcohol: No ordinary commodity. Research and public policy. 2nd edition*; Oxford University Press: Oxford, 2010.
- Norström, T.; Skog, O.J. Saturday opening of alcohol retail shops in Sweden: an impact analysis. *Journal of Studies on Alcohol* 2003, 64, 393-401.
- Cook, W.K.; Bond, J.; Greenfield, T.K. Are alcohol policies associated with alcohol consumption in Low and Middle income countries? *Addiction* 2014, 109, 1081-1090.

- 29. Room, R.; Jernigan, D.; Carlini, B.H.; Gmel, G.; Gureje, O.; Mäkelä, K.; Marshall, M.; Medina Mora, M.E.; Monteiro, M.; Natera, G., et al. *El alcohol y los países en desarrollo. Una perspectiva de salud pública*; Organización Panamericana de la Salud & Fondo de Cultura Económica: Mexico, 2013.
- 30. Rehm, J.; Manthey, J.; Lange, S.; Badaras, R.; Zurlyte, I.; Passmore, J.; Breda, J.; Ferreira-Borges, C.; Stelemekas, M. Alcohol control policy and changes in alcohol-related traffic harm. *Addiction* **2020**, *115*, 655-665, doi:10.1111/add.14796.
- 31. Chisholm, D.; Rehm, J.; Van Ommeren, M.; Monteiro, M. Reducing the global burden of hazardous alcohol use: a comparative cost-effectiveness analysis. *J Stud Alcohol* **2004**, *65*, 782-793, doi:10.15288/jsa.2004.65.782.
- 32. Kan, M.Y.; Lau, M. Comparing alcohol affordability in 65 cities worldwide. *Drug and alcohol review* 2013, 32, 19-26.
- 33. Statistics Lithuania. Home page. Available online: <u>https://www.stat.gov.lt/en</u> (accessed on 01/12/2020).
- 34. Rehm, J.; Štelemėkas, M.; Badaras, R. Research protocol to evaluate the effects of alcohol policy changes in Lithuania. *Alcohol and Alcoholism* **2019**, *54*, 112–118, doi:10.1093/alcalc/agy068.
- Rehm, J.; Gadenne, V. Intuitive predictions and professional forecasts. Cognitive processes and social consequences; Pergamon Press: Oxford, 1990.
- 36. Cicchetti, D.V. Guidelines, criteria, and rules of thumb for evaluating normed and standardized assessment instruments in psychology. *Psychological Assessment* **1994**, *6*, 284-290, doi:10.1037/1040-3590.6.4.284.
- 37. Paukste, E.; Liutkute, V.; Stelemekas, M.; Gostautaite Midttun, N.; Veryga, A. Overturn of the proposed alcohol advertising ban in Lithuania. *Addiction* **2014**, *109*, 711-719, doi:<u>http://dx.doi.org/10.1111/add.12495</u>.
- 38. Lithuanian Department of Statistics. GDP per capita, at current prices. Available online: <u>https://osp.stat.gov.lt/statistiniu-rodikliu-analize#/</u> (accessed on 29/12/2020).
- Jiang, H.; Livingston, M.; Room, R. Alcohol Consumption and Fatal Injuries in Australia Before and After Major Traffic Safety Initiatives: A Time Series Analysis. *Alcoholism: Clinical and Experimental Research* 2015, 39, 175-183, doi:<u>https://doi.org/10.1111/acer.12609</u>.
- Blecher, E.; Liber, A.; Van Walbeek, C.; Rossouw, L. An international analysis of the price and affordability of beer. *PLoS One* 2018, *13*, e0208831-e0208831, doi:10.1371/journal.pone.0208831.
- 41. Seabrook, R. A new measure of alcohol affordability for the UK. Alcohol Alcohol 2010, 45, 581-585, doi:10.1093/alcalc/agq072.
- 42. Popova, S.; Giesbrecht, N.; Bekmuradov, D.; Patra, J. Hours and Days of Sale and Density of Alcohol Outlets: Impacts on Alcohol Consumption and Damage: A Systematic Review. *Alcohol and Alcoholism* **2009**, *44*, 500-516, doi:10.1093/alcalc/agp054.
- 43. Sargent, J.D.; Babor, T.F. The Relationship Between Exposure to Alcohol Marketing and Underage Drinking Is Causal. *J Stud Alcohol Drugs Suppl* **2020**, *Sup 19*, 113-124, doi:10.15288/jsads.2020.s19.113.
- 44. Siegfried, N.; Pienaar, D.C.; Ataguba, J.E.; Volmink, J.; Kredo, T.; Jere, M.; Parry, C.D. Restricting or banning alcohol advertising to reduce alcohol consumption in adults and adolescents. *Cochrane Database Syst Rev* 2014, 2014, Cd010704, doi:10.1002/14651858.CD010704.pub2.
- 45. Saffer, H. Evaluating Econometric Studies of Alcohol Advertising. J Stud Alcohol Drugs Suppl 2020, Sup 19, 106-112, doi:10.15288/jsads.2020.s19.106.
- 46. Wagenaar, A.C.; Tobler, A.L.; Komro, K.A. Effects of alcohol tax and price policies on morbidity and mortality: a systematic review. *American journal of public health* **2010**, *100*, 2270-2278.
- 47. World Health Organization Regional Office for Europe. Alcohol Policy Impact Case Study. The effects of alcohol control measures on mortality and life expectancy in the Russian Federation. WHO Regional Office for Europe: Copenhagen, Denmark, 2019.
- 48. Poznyak, V.; Fleischmann, A.; Rekve, D.; Rylett, M.; Rehm, J.; Gmel, G. The World Health Organization's Global Monitoring System on Alcohol and Health. *Alcohol research: current reviews* **2013**, *35*, 244-249.

49. Rehm, J.; Kailasapillai, S.; Larsen, E.; Rehm, M.X.; Samokhvalov, A.V.; Shield, K.D.; Roerecke, M.; Lachenmeier, D.W. A systematic review of the epidemiology of unrecorded alcohol consumption and the chemical composition of unrecorded alcohol. *Addiction* **2014**, *109*, 880-893, doi:10.1111/add.12498.