## Changing the Paradigm of Primary Care: Behavioral Interventions, Subsidies and Taxes to "Change Lifestyle"

Cambiar el paradigma de la atención primaria: Intervenciones conductuales, subsidios e impuestos para "cambiar el modo de vida"

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# MATTI UUSITUPA

## BACKGROUND

Many of us -primary care physicians, clinicians and cardiologists- believe that we are doing the right primary prevention when we treat with drugs asymptomatic patients meeting the current criteria for high blood pressure, hyperglycemia or high cholesterol, and we believe that we are doing it efficiently because they take the drugs we prescribe.

In fact, we believe it because we see only a selfselected population, those who become our patients, follow us and adhere to treatment. The other patients we attended occasionally and prescribed medications but did not come back -of course we do not remember them- are the majority, and probably did not accept or follow our recommendations. As Prior & Volpp (1) point out, "Prescribing a medication is simple for a provider, but taking a medication does not appear to be simple for many patients. Outside of clinical trials, adherence to medications is often low."

As we discussed in previous letters, should pills be the only answer to unhealthy lifestyles, which cause the current epidemic of non-communicable diseases? (2)

As Fiona Godlee, BMJ chief editor, writes (3) "More than half of adults aged over 45 will be labelled as hypertensive if new US guidelines are adopted, concludes a study in The BMJ this week (doi: 10.1136 / bmj.k2357), This equates to 70 million people in the US and 267 million people in China being eligible for antihypertensive drugs, a marked increase on already high rates of drug treatment for high blood pressure. Furthermore, the study calculates that 7.5 million people in the U.S. and 55 million in China would be advised to start drug treatment, while 14 million in the U.S. and 30 million in China would be advised to receive more intensive treatment. The evidence from trials indicates some benefit from drugs in terms of reduced risk of stroke and heart disease, but is mass medication really what we want?"

And she concludes that "This is an appalling prospect. All health systems are under pressure, and it's right that we stop doing things that don't work, as Ann Robinson finds (doi: 10.1136 / bmj.k3028). But pills can't be the answer to diseases caused by unhealthy living. As well as unsustainable cost for often marginal benefit, they always cause harm. Rather than medicating almost the entire adult population, let's invest our precious resources in societal and lifestyle change, public health, and prevention."

But instead of using drugs, primary prevention changing habitual behaviors for a healthier lifestyle was already tested 16 years ago by Knowler et al. in a study that was the starting point of a new era. It was demonstrated that the lifestyle modification program known as Diabetes Prevention Program (DPP) reduced the incidence of diabetes by 58% compared to habitual behavior, but also surprisingly with respect to metformin –the commonly used drug. (4)

Recently, the DiRECT clinical trial (5) demonstrated that intensive weight management, with weight loss of 15 kg, results in an incredible 85% remission to a non-diabetic state and off antidiabetic drugs in noninsulin diabetic patients.

As Matti Uusitupa points out in the editorial, (6) type 2 diabetes remission is not an 'impossible mission'. Uusitupa writes: "These results are impressive and strongly support the view that type 2 diabetes is closely associated with excessive body fat mass." But the social component should not be left aside, and he concludes: "However, disease prevention should be maintained as the primary goal that requires both individual-level and population-based strategies, including taxation of unhealthy food items to tackle the epidemic of obesity and type 2 diabetes."

We health care professionals must encourage a change in the paradigm of primary prevention, impossible to achieve in a short medical visit, promoting peer groups or individuals in the same situation, with a structured program led by a healthy lifestyle promoter AND, at the same time, being leaders in the promotion of taxes and subsidies to prevent monopolistic food, beverage and tobacco corporations from subjecting the consumption of the population to the needs of their profits.

Recently, "A review (7) has found that taxes on alcohol, tobacco and soft drinks offer a particularly effective strategy for reducing chronic diseases among the poorest people in society who are disproportionately affected by unhealthy products." (8)

And it ends: "Taxing unhealthy products can produce greater health profits, and evidence shows that they can be implemented fairly, without disproportionately harming the poorest in society."

In the next lines we will develop the evidences we have to change the current paradigm of primary prevention, which was ineffective to stop the increase of non-communicable diseases.

## BEHAVIORAL CHANGES TO A HEALTHY LIFESTYLE PREVENTION AND REMISSION OF DIABETES

#### **Diabetes Prevention Program Study**

Some diabetes risk factors are potentially reversible, such as high fasting plasma glucose or after an oral glucose load, overweight, and a sedentary lifestyle.

The hypothesis was that modifying these factors with a lifestyle-intervention program (a 7 percent weight loss and at least 150 minutes of physical activity per week) or the administration of metformin would prevent or delay the development of diabetes.

A total of 3234 nondiabetic persons with elevated fasting and post-load plasma glucose concentrations were randomly assigned to 3 groups: a) placebo, b) metformin (850 mg twice daily), or c) a lifestyle-modification program. The mean age of the participants was 51 years and the mean body-mass index (BMI) was 34.0 kg/m2.

The average follow-up was 2.8 years. The incidence of diabetes was gradually decreasing: 11.0, 7.8, and 4.8 cases per 100 person-years in the placebo, metformin, and lifestyle groups, respectively. The lifestyle intervention reduced the incidence by 58 percent (CI 95%, 48 to 66%) and metformin by 31 percent (CI 95%, 17 to 43%), as compared with placebo; the lifestyle intervention was significantly more effective than metformin. To prevent one case of diabetes during a period of three years, 6.9 persons would have to participate in the lifestyle-intervention program, and 13.9 would have to receive metformin.

The authors conclude that lifestyle changes and treatment with metformin both reduced the incidence of diabetes in persons at high risk, and that lifestyle intervention was more effective than metformin.

#### The Diabetes Remission Clinical Trial (DiRECT)

We all know that type 2 diabetes is a chronic disorder that requires lifelong treatment; the question would be whether intensive weight management within routine primary care would achieve complete remission of type 2 diabetes.

For that purpose, Michael Lean et al. report the results at one year from the cluster-randomized trial Di-RECT that studies the effect of weight management in primary care in patients with type 2 diabetes of up to 6 years' duration. A total of 49 primary care practices were randomly assigned with 298 individuals aged 20–65 years who had been diagnosed with type 2 diabetes, had a BMI of 27-45 kg / m<sup>2</sup> and were not receiving insulin, to a) weight management program group administered by trained dietitians or nurses (n = 149), or b) best-practice care control group by guidelines (n = 149). The weight management program started with a low-calorie formula (825-853 kcal / day) for 3-5 months, followed by structured food reintroduction for 2–8 weeks, and support for weight loss maintenance.

Antidiabetic and antihypertensive drugs were discontinued in the intervention group at baseline. The co-primary outcomes were weight loss of 15 kg or more and diabetes remission, defined as glycated hemoglobin (HbA1c) < 6.5% at 12 months. Weight loss of 15 kg or more was recorded in 36 (24%) participants in the intervention group and no participants in the control group (p<0.0001). Diabetes remission (with no antidiabetic drug) was achieved in 46% participants in the control group (OR 19.7, 95% CI 7.8–49.8; p < 0.0001). Remission was closely associated with the amount of weight loss, starting 34% with 0-5 kg and 57% with 10-15 kg, and reaching 86% with15 kg or more.

These findings show that, at 12 months, almost half of participants under intensive weight loss approach (average 10 kg) achieved remission to a nondiabetic state and off antidiabetic drugs, and 86% achieved that goal with 15 kg loss. Therefore, remission of type 2 diabetes should be a practical target for primary care.

## FINANCIAL INCENTIVES FOR SMOKING CESSATION

Financial incentives are another example of effective behavioral intervention for smoking cessation during pregnancy, which has not been into routine practice despite the many studies that prove it. A Cochrane review determined that financial incentives are the most effective intervention in this population and may lead to a rate of smoking cessation 4 times higher than that achieved with other interventions. Smoking during pregnancy is the main cause of morbidity and mortality for mother and child, mainly in poor socioeconomic sectors. However, such incentives have not been implemented in routine care of pregnant women. In a recent pragmatic clinical trial between routine practice and four smoking-cessation interventions for tobacco cessation, 6,006 smokers employed by 54 companies were randomly assigned. (9) While the incentive of USD 600 deposited and redeemable only in quit smoking, only 2.9% reached stop inhaling against 2.0% of USD 600 as a reward, 1% of free use of e-cigarettes, 0.5% of free use of nicotine replacement and 0.1% without intervention. However, progressive increase in consumer taxes on cigarettes is by far the most effective method, as those personal methods are far from being almost halved when the price is threetimes increased by progressive consumer taxes.

## LIFESTYLE CHANGES INDUCED BY TAXES AND SUBSIDIES

It is argued that only 3 personal behaviors, heavily influenced by the social environment, such as tobacco, alcohol and overweight or obesity, contribute to approximately 14 million premature deaths. Today, tobacco is estimated to kill more than 7 million people, and harmful use of alcohol more than 3 million people each year. Worse yet, the global number of young people aged 5–19 years who are overweight and/or obese has increased from 11 million in 1976 to the fabulous number of 124 million in 2016, being the major contributors in consumption of carbohydrates and sugarsweetened beverages. Therefore, the increase in Body Mass Index claims the sad merit of killing 4 million lives each year. It is also known that it disproportionately affects people with low socioeconomic status and low-income countries.

The Sugar, Tobacco, and Alcohol Taxes (STAX) group of the London School of Hygiene & Tropical Medicine states that: (10) "More than a decade after the adoption of the WHO Framework Convention on Tobacco Control, there is compelling evidence that raising tobacco prices substantially through taxation is the single most effective way to reduce tobacco use and save lives. Similarly, alcohol taxation is a cost-effective way to reduce alcohol consumption and harm. With growing evidence, sugar taxes are another fiscal tool to promote health and nutrition."

In a society that encourages consumption for the development of the current economic structure, variations in the prices of products produce a discrepancy with demand, that is, family shopping has what economists call "elasticity" to price demand. It means that if the purchase of a food or beverage has an elasticity -1.0, it means that if the price increases by 20% the purchase will decrease by 20%; with half of the elasticity (-0.5), the same increase of 20% would reduce demand by 10%, half the previous one.

One way for the State to raise prices and reduce demand is to impose consumption taxes (value added tax) to discourage the consumption of products that are harmful to health, such as those we are considering here. However, governments rarely use this resource, probably due to the lobby of the 3 largest corporations (tobacco, alcohol, and food) monopoly, which even state the false and unfounded argument of the potentially regressive impact on the low-income populations. (11)

Despite industry efforts, taxation is gaining more attention from policy makers as a win-win-win policy measure for public health, domestic resource mobilization, and equity. "Taxes on sugar, tobacco, and alcohol have been, or are now being, introduced in diverse contexts, including Botswana, Chile, Ecuador, India, Mexico, Nigeria, Peru, Saudi Arabia, South Africa, the United Arab Emirates, and the UK. Tobacco and alcohol taxes are recognized by WHO as "Best Buys" to prevent and control NCDs..." (10)

In order to estimate patterns of expenditure on potentially unhealthy products by socioeconomic status, Sassi et al used data from household expenditure surveys, with a primary focus on low-income and middleincome countries.

The data were selected on the basis of the availability of good quality data since 2000; these countries were four in Latin America (Chile, Guatemala, Panama, Nicaragua), three in central-eastern Europe (Albania, Poland, Turkey), one in central Asia (Tajikistan); one in sub-Saharan Africa (Tanzania), two in west Africa (Niger, Nigeria), and two in south and east Asia (India, Timor-Leste). These countries cover a wide range of national income levels, from high income (Chile and Poland) to low income (Niger, Tanzania), but exclude OECD countries with the highest income.

Summarizing, they argue that "Price policies affect the consumption and expenditure of a larger number of high-income households than low-income households, and any resulting price increases tend to be financed disproportionately by high-income households. As a share of all household consumption, however, price increases are often a larger financial burden for low-income households than for high-income households, most consistently in the case of tobacco... Large health benefits often accrue to individual lowincome consumers because of their strong response to price changes. The potentially larger financial burden on low-income households created by taxation could be mitigated by a pro-poor use of the generated tax revenues." (7)

Over the past decades, sugar-sweetened beverages contributed to the increase of calories and BMI. In U.S., "In particular, between 1980 and 2011 it was 2.2 times more expensive to buy fresh fruits and vegetables compared to carbonated beverages. But at the same time, the global price elasticity of demand for sugar-sweetened beverages was estimated to be -1.21. This estimation is based on 12 studies on elasticity of sugar-sweetened beverages; it implies that the index increasing beverage taxes by 20% would reduce global consumption by 24%." (12)

#### Tobacco

There is no clear or consistent pattern of prevalence of tobacco use by socioeconomic status in the selected countries in the household survey.

But the clearest gradient in expenditure between the top and bottom quintile of the wealthiest households, which have an absolute expenditure more than six times greater than poor-income households, can be observed in countries such as India, Timor-Leste, and Guatemala.

"The demand for tobacco products in low-income and middle-income countries (LMICs) is at least as responsive, and often more responsive, to price as it is in high-income countries, with some study findings suggesting the demand in LMICs could be twice as responsive as in high-income countries.

Evidence suggests that young and low-income consumers within countries have the strongest response to price changes, although evidence of a socioeconomic gradient in price elasticity is less consistent in LMICs." (7)

#### Alcohol

Price policies affect more high-income households than low-income households. Because, as Sassi et al point out:

"Socioeconomic patterns are clear for alcohol use.

High socioeconomic status is associated with a high prevalence of alcohol use in most countries in our analyses." And "The gradient in average expenditure on alcohol is substantially steeper than the gradient in consumption prevalence, with the wealthiest households spending larger amounts than households at the bottom of the socioeconomic scale..." (7)

#### Soft Drinks and Snacks

The patterns for soft drink consumption are similar to those for alcohol; use and expenditures on these beverages are highest in the wealthiest households, though somewhat less steep. Patterns are less clear for snacks, but expenditure gradients are consistent with those seen for soft drinks.

"Within countries, price elasticities for different food and beverage products are higher in lowest-income groups [...] It is 1.14–1.21 higher... Results are similar for sugar-sweetened beverages." (7)

## CONCLUSIONS

Chronic non-communicable diseases, increasingly prevalent in today's world, are caused by lifestyle changes involving unhealthy behaviors –such as tobacco smoking, harmful alcohol intake, processed foods or soft drinks– influenced by the surrounding community and global society.

Treating patients individually in an office setting, out of their community context, in few-minute interviews with other medical problems, and seeing them months later, has not solved or even stabilized the problem.

It seems necessary to try changes in the paradigm of primary health care. A promising change may be the creation of peer groups (patients in the same situation) meeting with someone who facilitates the periodic functioning of the group –initially health professionals and then community health workers trained to do so– allowing the learning of the whole, to know that others have our same problem, to feel supported and to have someone to turn to.

In frankly poor and scattered settings such as those in rural India, face-to-face peer support groups for chronic diseases were experimented with, and they were called communitization of health care.

In their essay, Yogesh Jain and Priyank Jain (13) published that after a decade of effort, the outcomes were discouraging; at best, adherence to treatment was 20% - 40%, and they decided to provide them with educational interventions; the first personal sessions became group sessions in a short time, guided by trained community health workers. They observed something interesting: patients began to offer solutions and support to others. The group turned from an informal meeting into a much desired forum where information was shared and a real community was built. Within a year, multiple support groups were formed; sessions began with members sharing ups and downs since the last meeting and questions about illness and treatment. The role of the health care worker was to share new knowledge, correct the mistakes and provide the medications to stable patients, following the established algorithms. In the sessions, physical activities such as games and exercises were intertwined, and they designated a leader and secretary within the group to organize the meetings and the agenda. Since then, people who were not considered for decision making, began to have power of decision and act collectively.

The result was that, in the 49 groups, the recording of drug refilling showed a continued attendance of over 90%, from 20% to 44% before the groups began. (13)

The authors state that "Group meetings were intended to be non-threatening, and to encourage mutual learning between members and health workers. An intangible result of this is a feeling of belonging and greater self-esteem. We believe that social connection that emerges from suffering adversity together is the key to focusing recovery-and being able to support others in their recovery." (13)

At the other end of society, in the U.S. Medicare, diabetes risk reduction can be achieved in a digital health system with peers and human coaching interacting; at 12 months, participants lost 7.5% of initial body weight, glycated hemoglobin and total cholesterol decreased significantly. (14)

In turn, it is important for society to demonstrate what healthy behaviors are through State decisions including taxing harmful behaviors (tobacco, alcohol, ultra-processed foods, and soft drinks) and rewarding healthy behaviors (fruits and vegetables) with subsidies. In this way, the social context of rejecting harmful behaviors and promoting healthy behaviors is created, as was partly achieved in recent decades with tobacco.

Rachel Nugent, from the non-profit research organization RTI International in Seattle, USA, and director of the Lancet Taskforce, said that "Non-communicable diseases are a major cause and consequence of poverty around the world. Meeting this challenge requires great investments to improve the health care system worldwide, but there are immediate and effective tools at our disposal. Taxing unhealthy products can produce greater health profits, and evidence shows that they can be implemented fairly, without disproportionately harming the poorest in society." (8)

For those who are still concerned about regressive taxes: "First, concern about unfair taxes needs to be put in the context of unfair disease burdens. In most countries, the burden of preventable NCDs associated with tobacco, alcohol, and obesity is itself regressive. Compared with richer households, people with lower incomes get sick more often and die earlier from consuming tobacco, alcohol, and non-essential energy dense foods. These factors contribute to the general pattern of increased premature NCD mortality among lower socioeconomic groups, as Louis Niessen and colleagues report in their paper. For example, one study showed that if cigarette taxes were raised by 50% in Thailand, the lowest socioeconomic class would pay only 6% of an increase in tobacco tax revenues but benefit from 58% of averted premature deaths." (15)

The time has come for health care professionals to stop using consultations -useful for diagnosing diseases- for managing primary prevention, and rather try to change the paradigm by using new creative ways to change unhealthy behaviors, letting the community participate with its peers in changing the behaviors it produces, and encouraging direct State involvement with taxes and subsidies, with proven direct and indirect effects that publicly demonstrate what society's healthy behaviors are.

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#### REFERENCES

1. Pryor K, Volpp K. Deployment of preventive Interventions—Time for a Paradigm Shift. N Engl J Med 2018;378:1761-3. http://doi.org/ cstz

**2.** Doval HC. Es necesario cambiar el modo de vida para hacer desaparecer las enfermedades cardiovasculares. Rev Argent Cardiol 2017;85:299-3.

3. Godlee F. Pills are not the answer to unhealthy lifestyles. BMJ 2018;362:k3046. http://doi.org/cstm

**4.** Knowler WG, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 2002;346:393-403. http://doi.org/cdzztf

**5.** Lean ME, Leslie WS, Barnes AC, Brosnahan N, Thom G, McCombie L, et al. Primary care-lead weight management for remission of type 2 diabetes (DiRECT): an open-label cluster-randomised trial.

Lancet 2018;391:541-51. http://doi.org/chn5

6. Uusitupa M. Remission of type 2 diabetes. Mission not impossible. Lancet 2018;391:515-6. http://doi.org/chn7

7. Sassi F, Belloni A, Mirelman AJ, Suhrcke M, Thomas A. Equity impacts of price policies to promote healthy behaviours Lancet 2018 April 4, 2018 http://doi.org/gdk4jw

**8.** Mayor S. Taxes on alcohol, tobacco, and soft drinks are fair and produce health gains, review finds. BMJ 2018;361:k1524. 10.1136/ bmj. k1524 (published 5 April 2018)

 Halpern SD, Harhay MO, Saulsgiver K, Brophy C, Troxel AB, Volpp KG. A pragmatic trial of e-cigarettes, incentives, and drugs for smoking cessation. N Engl J Med 2018. 10.1056/NEJMsa17155757.
Sugar, Tobacco, and Alcohol Taxes (STAX) Group (London School of Hygiene & Tropical Medicine, London) WC1H 9SH, UK robert.marten@lshtm.ac.uk. Sugar, tobacco, and alcohol taxes to achieve the SDGs. Lancet 2018;391: Published Online May 29, 2018 http://doi.org/cstv

**11.** Niessen LW, Mohan D, Akuoku JK, et al. Tackling socioeconomic inequalities

and non-communicable diseases in low-income and middle-income

countries under the Sustainable Development agenda. Lancet 2018; published online April 4. http://doi.org/gdk9ws

**12.** Powell LM, Chriqui JF, Tamkeen K, Wada R, Chaloupka FJ. Assessing the Potential Effectiveness of Food and Beverage Taxes and Subsidies for Improving Public Health: A Systematic Review of Prices, Demand and Body Weight Outcomes. Obes Rev 2013;14:110-28. http://doi.org/f4j269

**13.** Jain Y, Jain P. Communitisation of healthcare: peer support for chronic disease care in rural India BMJ 2018;360:k85 (Published 10 January 2018) http://doi.org/cstx

**14.** Castro Sweet CM, Chiguluri V, Gumpina R, Abbott PM, Madero EN, Payne M, et al. Outcomes of a digital health program with human coaching for diabetes risk reduction in a Medicare population. J Aging Health 2018;30:692-710. http://doi.org/cstw

15. Summers LH. Taxes for health: evidence clears the air. Lancet 2018 April 4, 2018 http://doi.org/cstn