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Harm reduction programs for addiction treatment

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ABSTRACT

The limited effectiveness of anti-addiction pharmacotherapy encourages the introduction of the so-called harm reduction programs. They enable to significantly reduce the health-related, social and economic damage sustained by addicts and their families. The simplest form of harm reduction is substitution therapy. You can use the same psychoactive substance (e.g. nicotine in patches) or administer a different one (e.g. methadone vs. morphine). Harm reduction programs are often criticized for allegedly extending the addiction period. However, the experience of many countries shows that they are effectively contributing to addiction recovery. Considering the fact that smoking is the main modifiable cause of diseases and, at the same time, that there are no sufficiently effective methods of treating the addiction, the use of harm reduction programs – based on the so-called novel tobacco products – seems to be the most appropriate choice. Precedent registrations of consecutive Modified Risk Tobacco Products in the US have created conditions that enable a pragmatic replacement of tobacco products in which smoking occurs with smokeless products, that are less harmful for tobacco users.

Key words: harm reduction programs, novel tobacco products, modified risk tobacco products, heat-not-burn products

HIGHLIGHTS
Harm reduction programs decrease health-related, social and economic losses caused by psychoactive substances intake.

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WHAT ARE HARM REDUCTION PROGRAMS?

Harm reduction programs consist in a substitutional administration of psychoactive substances with a view to reducing even greater health and social risks. By accepting the fact of "controlled addition", we bring our patients closer to the final withdrawal of all psychoactive products.

To illustrate the extent of risk reduction in such programs, one might indicate that the level of carcinogens included in novel tobacco products is 10 to 25-fold lower as compared with regular smoking [1].

Harm reduction programs have been part of standard psychiatric interventions' repertoire for decades. In the meantime, the notion has evolved from a simple concept of replacing a drug that a patient is addicted to with another psychoactive substance to much more complex psychopharmacological and social treatments [2].

PHARMACOLOGICAL MECHANISMS IN HARM REDUCTION PROGRAMS

From the pharmacological point of view, there are four types of programs:

1. The most traditional program consists in administering lower amounts of the same substance that caused dependence (e.g. nicotine patches, sprays or gums).
2. As an alternative, a substance similar to the one that caused dependence may be administered (e.g. methadone or buprenorphine vs. natural opiates, cytisine vs. nicotine).
3. To put in more general terms, one may also define harm reduction programs as the administration of substances that alleviate withdrawal symptoms (and in particular emotional disorders) which occur in the course of psychoactive substance use (e.g. naltrexone vs. alcohol, antidepressants vs. addictions).
4. Products administered as part of harm reduction programs may additionally be free from some of the ingredients that increase the risk of dependence [3]. For instance, tobacco smoke contains ingredients that are highly addictive (harman, norharman and acetic aldehyde, acting as monoaminooxidase inhibitors), whereas smokeless products are devoid of them, which is why their addictive potential is lower.

BEHAVIORAL MECHANISMS IN HARM REDUCTION PROGRAMS

The insufficient efficacy of nicotine-based substitution therapies (nicotine gums, patches, sprays or inhalers) demonstrates how important the behavioral aspects of addiction are [4]. Substitution therapies only serve to satisfy the biochemical need for nicotine intake, while cigarette smoking is also a social ritual, part of a lifestyle and an element of different cultural codes.

That is why novel tobacco products, which embrace the behavioral pattern, may be of great help in reducing smoking as a whole. Once several heated tobacco devices have been introduced on the Japanese market, the number of cigarette smokers dropped by 27% within 2 years in the country, which is a record-breaking finding [5]. Importantly, the most recent Japanese studies indicated that those products have not gained interest amongst non-smokers, and thus they have not generally contributed to the initiation of nicotine habit [6]. It is also confirmed by a Polish study published in 2020 by the National Institute of Public Health-National Institute of Hygiene in Poland [7].

A similar phenomenon has been observed in the UK, with as many as 3 million smokers switching over to novel tobacco products, and one of the highest drops in the number of cigarette smokers across the European Union over the recent years [8]. Benefits stemming from harm reduction programs have been duly noted by the Public Health England executive agency (a public institution responsible for scientific counseling within the entire British healthcare system), which stated in its report that smokeless nicotine products constitute an alternative for cigarette smokers that is 95% less noxious than tobacco smoking (on condition that one gives up smoking completely) [9].

A great majority of nicotine users in Iceland have already converted to smokeless products, and there has been a 12% drop in the number of smokers over the course of 2 years in the country [8].

THE PRAGMATIC ASPECT OF HARM REDUCTION PROGRAMS

Harm reduction programs have not been designed in order to moralize or create promises to be fulfilled in a distant future. What harm reduction programs have in common are the following aspects (based on [10], with amendments):

- focus on practical goals
- reduction of clearly defined harmful effects
- a non-judgmental approach to addicted people
- identification of program benefits that outweigh the losses
- supporting the patients' most important life goals.

As may immediately be seen, the approach is pragmatic to the core. It resembles projects such as "Home First" for the homeless. The premise that all harm reduction programs are based on is the belief that one may not simply "rise" from a profoundly destructive state. In such situations the proverbial "fishing rod" is not enough, and it is the fish that is needed.

Harm reduction programs are supported by international bodies such as the Harm Reduction International, an organization affiliated with the United Nations, as well as the UN agencies themselves. For instance, a harm reduction program is an inherent element of The

Joint United Nations Program for HIV/AIDS (UNAIDS). One of their main principles is the conviction that health-related problems (including addictions) should not be penalized or judged upon. One should not place an additional burden on the victims of addiction, blaming them for not coping with their problems on their own, in a situation, where there are no effective drugs available, and states make profit out of distributing substances that cause dependence. One might just as well hand out fines to diabetic patients for putting sugar in their tea, or send patients with hypertension to prison for using excessive salt in their meals, followed by a consistent decline of help and public stigmatization.

It should be self-evident for psychiatrists and psychotherapists that patients need to be helped and not judged, and that medical assistance should never be subjected to judgment or based on any conditions.

THE IDEOLOGICAL ASPECT OF HELP

Controversies linked with harm reduction programs result primarily from a fundamental cognitive dissonance. For a significant part of society, addictions appear to be a result of an unspecified weakness or personality, a deficit that may allegedly be "filled" with the help of mentoring activities or information campaigns. Viewed from that perspective, dependence should be overcome with the strong will of a mature person. Exercising one's strong will might involve different behavioral techniques and the like. Thus, it is an understanding that hardly leaves any room for compromise such as harm reduction programs.

For others, addiction is not just "weakness," but also a "moral issue", which takes the debate into a yet another realm, involving ethical dimension, and the fight between the good and evil. That paradigm leaves even less room for compromise. Paradoxically, it is a standpoint that helps one account for the failure of withdrawal policies, blaming their ineffectiveness on a message that is not vivid enough, the need for more time, etc. Aversive therapies used to be developed in that vein, involving methods such as apomorphine-induced vomiting (associated with the ingestion of a given psychoactive substance), as were electroshocks.

Cigarette packs have been covered with deterrent images for many years now, but long-term effects of that approach are limited [4]. It would be better to have descriptions of effective addiction recovery placed on them.

Proponents of such ideas seem to ignore issues that they are uncomfortable with, i.e. the very genesis of dependence, which does not stem from someone's mistakes or weaknesses, but rather from falling into a specific trap of one's internal emotional mechanisms, and also from the inability to "remove" the addiction, and finally, from the lack of sufficiently effective cures.

An additional difficulty in the implementation of harm reduction programs consists in the fact that (as is always the case, when an issue is ideologized) certain people identify themselves strongly with the mission of fighting addictions. It is characteristic of their approach that they fail to consider all the damage sustained by victims of addictions, which could be spared to them with the help of harm reduction programs. At the same time, the society would not have to struggle with so much pathology.

CRITICISM OF HARM REDUCTION PROGRAMS

Apart from the moral or ideological critique, there are also more technical reservations voiced with respect to harm reduction programs, including the following:

- harm reduction programs are ones whose efficacy has allegedly not yet been verified from the clinical and research perspective
- harm reduction programs are believed to discourage people from a complete withdrawal of substance use
- harm reduction programs are sometimes interpreted as a an ambiguous message sent to young people, and a potential incentive to a liberal use of psychoactive substances
- harm reduction programs are accused of being a transitional phase ("Trojan horse") leading up to using even more harmful substances.

Unfortunately, such criticism takes place without the involvement of patients themselves. Listing multiple objections vis-á-vis those programs results in a situation, where specific patients, whose names and surnames are well known, are being deprived of help and exposed to irreversible damage. It reminds one of the idle discussions preceding the establishment of MONAR (a Polish NGO focused on helping drug addicts, established in 1978), and in the following years, before the introduction of methadone substitution therapy. MONAR took it upon themselves to deal with the "unwanted" tasks, neglected by the official healthcare system, successfully limiting the epidemic of opiate addiction.

Somatic complications of alcohol or nicotine addiction (cigarette smoking) are practically speaking only a matter of time exposure. Thus, a continuous multiplication of reservations with respect to harm reduction programs, in light of a real possibility of counteracting the negative effects of such prolonged exposure (especially in the case of cigarette smoking), is both medically and ethically inappropriate.

Moreover, the above mentioned criticism is not based on any systematic studies, but rather boils down to enumerating doubts, and putting off in time solutions that would be beneficial for patients. Nevertheless, as was the case of the landmark FDA registration of the first heat-not-burn tobacco product with the risk of toxic sub-

stance inhalation reduced by 90–95%, it is difficult to uphold the hypothesis of "uncertain" knowledge for too long [4].

Anyhow, such criticism is largely disconnected with the actual goals of harm reduction programs, which are focused on the addicted persons. Preventing young people from initiating psychoactive substance use is a separate issue altogether, and should be implemented with different methods.

WHAT ARE THE GOALS OF HARM REDUCTION PROGRAMS?

Such therapies are not aimed at a direct "cure," but instead concentrate on pragmatic goals and, thanks to their stabilizing effects, facilitate eventual cessation of psychoactive substance use.

Harm reduction programs are associated with measurable benefits, such as improved/stabilized psychological condition, improved social/family functioning, continuation of schooling, maintenance of employment/studies, reduction in aggression/violence levels, decriminalization, prevention of prostitution, improvement of somatic states, reduction in the risk of infectious diseases and severe somatic complications (including cancers), and a reduced number of deaths. They are applied in persons addicted to psychoactive substances, both legal and illicit.

A decision that symbolized the above mentioned approach was the opening of kiosks with novel tobacco products in the first two UK hospitals in 2019 [4].

A REVIEW OF HARM REDUCTION PROGRAMS

Barbiturates

The first historical example of a systematic harm reduction program was gradual barbiturate withdrawal. Those drugs may not be withdrawn abruptly, as the potential consequences are severe, including seizures, impaired consciousness, and first and foremost withdrawal syndrome, involving emotional discomfort that is hard to bare. Hence, the drug intake was reduced very slowly, e.g. for a year, but the initial dose could even be increased at the outset to reduce the intensity of withdrawal symptoms.

Benzodiazepines

We act in a similar way, when withdrawing benzodiazepines. The process may also take months. It is standard procedure that short-acting formulas (producing the most euphoric effects) are replaced with long-acting ones. The purpose of that replacement is reduction in mood swings, and flattening out of the specific cycle of euphoria and withdrawal. Supplementation with other sleeping pills is possible in the case of addiction to hypnotic benzodiazepines, but it entails a risk of cross addiction.

Methadone and buprenorphine

Methadone is a symbolic drug in Poland indeed, constituting a milestone in the development of harm reduction programs, and considered by many to be the most important example of such programs, and a testimony to their efficacy. Its introduction in 1999 to patients addicted to opiates was delayed (due to social resistance) by several decades as compared with highly developed countries. Establishment of a treatment facilities network was extremely tempestuous due to the protests of local communities.

However, the story of methadone goes to prove that it is possible to resolve such conflicts. It was of key importance to move beyond the purely ideological dispute. Health and social benefits stemming from methadone substitution therapy simply testified to the effectiveness of the approach. Methadone is a "smart" drug, which does not result in a narcotic euphoria, and significantly reduces the risk of overdose related to intravenous opiate use.

Buprenorphine is applied in a similar way. Patients no longer need to resort to delinquency in order to get hold of the drugs. The risk of opportunistic infections (HIV, *hepatitis*) is also done away with. They may continue their studies or go back to work. In the wake of the great success of those first harm reduction programs, the following regimens were introduced in a manner that was largely "unnoticeable," including the harm reduction programs based on opioid receptor antagonists such as naltrexone and nalmephene in alcohol dependence. Methadone-based harm reduction programs are presently carried out and reimbursed by the National Health Fund.

Alcohol

Alcohol is a good example of how difficult or even impossible it may be to use the same substance in smaller doses. Practically speaking, any dose of alcohol is harmful. Reducing alcohol dose is based on a popular therapeutic myth, only prolonging the state of intoxication. It is in fact a form of continuous and further addiction to alcohol, leading up to long-term complications. A true reduction in the amount of alcohol consumed translates into fewer biological losses and fewer social conflicts, and that is the approach followed by the proponents of synthetic opioid receptor antagonists, naltrexone and nalmephene, which may even be used after alcohol consumption. They reduce the amount of alcohol consumed and stabilize one's psychosocial condition.

Nicotine

Taking into account that fact that cigarette smoking is the most significant modifiable cause of diseases, any action that is conducive to a reduction in the harmful effects of smoking should be sup-

ported [4]. The landmark FDA registration of the first *heat-not-burn* system has opened up different possibilities of using such heated tobacco products in harm reduction programs [11].

Interestingly enough, practically all currently registered drugs applied in the treatment of nicotine dependence, including the *off-label* regimens, are administered in a way that emulates the approach of harm reduction programs:

- nicotine supplementation – in the form of nasal sprays, patches, nicotine gums or inhalers
- nicotine substitution with cytisine or its synthetic analogue varenicline
- counteracting primary and secondary mood disorders in the course of dependence – antidepressants: bupropion SR, nortriptyline, SSRIs.

Unfortunately, the efficacy of those agents ranges from 19–25% as regards smoking withdrawal for 6 months, while the effectiveness of placebo amounts to 14% [4].

In such a situation, international efforts, and especially those of the American and UK agencies, are focused on using smokeless tobacco products (well-tested heated tobacco devices, e-cigarettes or oral snus) in harm reduction programs. In the US, the category of modified risk tobacco products (MRTP) was introduced already in 2009 to denote products that may be labeled as less harmful than traditional cigarettes. It is not a coincidence then that the biggest drop in the smoking rate amongst the EU member states was observed in the UK over the recent years (2000/2016 → 27%/16%), when at the same time the country opened up more than others to novel tobacco products [4]. The UK also serves as a good example of an effective debate in the field, and of efficient implementation of pragmatic solutions, given that a few years before a complete ban on the use of novel tobacco products had been considered due to the general "uncertainty of knowledge" [8].

No country in the world has been successful at eliminating cigarette smoking. Even in Bhutan, where cigarette trade and smoking in public places was prohibited in 2004, individual import of cigarettes and smoking at home is still permitted. Canada and Sweden have announced that they will be "free from smoking" by 2025, which in fact only means that less than 5% of the population will still be smoking. Thus, even a most restrictive approach is based on the premise that smoking may not be completely eliminated in the entire society. An absolute ban on smoking is only announced in Turkmenistan as of 2025. Presently, a pragmatic goal consists rather in replacing cigarette smoking with smokeless products, which is part of an ever more common consensus [4].

The World Health Organization (WHO), known for the most conservative approach to nicotine addiction, has also been paying ever more attention to new technologies of nicotine delivery. In 2020, the WHO Regional Office for Europe published a document, in which it recommended that state governments introduce national assessment systems for novel tobacco products prior to marketing authorization [12]. WHO has observed that some of those products may result in a significant reduction in the exposure to noxious substances, but in order to prevent authorization of untested products, marketing authorization should be preceded by a thorough documentation of the lower exposure as compared to cigarette smoke. At the same time, WHO has recommended that adequate warnings should be maintained on novel tobacco product packs, and that measures that are aimed at preventing under-age persons and adult non-smokers from reaching for those novel devices should be implemented.

As regards electronic nicotine delivery systems (e-cigarettes), it has been noted that in some smokers, those devices may be helpful in giving up tobacco smoking [13]. WHO recommends that specific actions should be undertaken by governments in order to standardize such devices and to reduce the amount of carcinogens, mutagens and substances that are toxic for the reproductive tract contained in the heated liquids. The organization has also noted that with the knowledge we have now, it would not be justified to introduce a ban on a specific liquid flavor or scent. To reduce the population health risks, all vape liquids should undergo chemical composition analysis. Both of the quoted WHO briefs [12, 13] present a valuable incentive to single out novel tobacco products as safer with respect to traditional products (cigarettes). Perhaps the two documents herald more active WHO recommended programs in the future.

SUMMARY

Ideas of a healthy lifestyle, free from the impact of psychoactive substances, are by all means correct and worth promoting. However, validity of those ideas does not guarantee their implementation, and may sometimes actually be counterproductive. In the history of psychoanalysis, the story of doctor Moritz Schreber's family is well known. He was a pioneer of a healthy lifestyle, and an advocate of physical exercise, but at the same time an extremely dogmatic and authoritarian person, which undoubtedly led to his two sons' mental disorders and tragic fate [14].

An inherent part of personality is one's emotional system. Mental processes such as motivation, striving to be rewarded, being consistent in action, etc., are all sensitive to the impact of psychoactive substances, and also to the risk of addition. As a result, one cannot "cure" or "prohibit" addictions, because a person's emotional system is *per se* their inherent and irremovable part. Understandably then, both registered drugs and off-label therapies may only be partially effective. Hence, the significance of harm reduction programs has been on the rise.

The situation of public ambivalence is also problematic. On the one hand, people mostly purchase psychoactive substances from legal sources, and on the other hand they do not receive appropriate assistance when needed, or the assistance offered is quite dogmatic ("stop drinking," "quit smoking"). Ideological tirades against harm reduction programs only give the impression of being a psychological rationalization of the status quo. Only "weak" or "immature" people are believed to give in to addictions. Still, Schreber's idea on how to develop one's physical prowess and spiritual fortitude never brought the intended results.

Health and social benefits resulting from harm reduction programs are evident and confirmed by the collected data [1, 11]. Their criticism stems largely from the approach that focuses on fighting addictions rather than helping patients. Patients with dependencies are perceived as "inferior" and ones who "should blame themselves" for their situation, and should "get a grip." In fact, for many years now the criticism has remained unchanged, irrespective of the specific arguments expressed: we should be careful, we should wait, we need to collect more data, etc. Such criticism fails to take into consideration the urgent needs of the patients and their families.

Presently, the greatest benefits are to be drawn from harm reduction programs offered to cigarette smokers, as smoking is the main modifiable cause of diseases. Patients with nicotine dependence should be informed that their toxicological risk may be reduced by 90–95% in the case of cessation of smoking and replacement of cigarettes with novel tobacco products. Clearly, a reliable information campaign is missing now. Cigarette packs should also include information on effective and evidence-based methods of treating nicotine dependence, and on how to participate in harm reduction programs instead of the aversive graphic warnings placed on them now.

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