MEDIZINISCHE UNIVERSITÄT WIEN

INSTITUT FÜR SOZIALMEDIZIN
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Response to enabling good health for all. A reflection process for a new EU health strategy

Introduction

With the following statement I want to take the opportunity to contribute to the discussion process initiated by the European Commission. The experiences gained at the Institute of Social Medicine, Medical University of Vienna, date back to 1973, when the first smoking cessation clinic in Austria was established, the first report on "Smoking and Health in Austria", was published in 1974, in fact 10 years after the famous Terry Report in the US.

We have been working in all fields of tobacco control for the last decades and the most recent development was the establishment of a specific institute devoted to the diagnosis and treatment of tobacco addiction in 1998 (www.nicotineinstitute.com).

We serve on the EU Regulatory Committee on Tobacco and the EU Tobacco Expert Working Group as representatives for Austria, and as WHO counterpart for tobacco control; former assignements where with the UICC special project on smoking cessation and the WHO expert group on tobacco.

The director general public health, Dr.Hubert Hrabcik, authorized me to quote his letter to the commission with regard to the Austrian position on the possible less harmful (than cigarettes) product used in Sweden for nicotine consumption; this letter is attached to the statement.

EU and the future of nicotine consumption

Tobacco control has to be performed in a comprehensive way, applying different strategies from primary prevention to smoking cessation. Political and medical measures have to be used, and the EU is playing a major role in that context.

One additional issue for the future would be a need to provide nicotine in the most harmless way to people who do not want or cannot yet stop smoking.

One has to acknowledge, nicotine is a very widely used psychoactive drug, and itself not very harmful to human health as far as the risk for cardiovascular diseases or cancer is concerned. Because of its capability to regulate mood, nicotine carries a remarkable

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addiction potential. Therefore it is so difficult for many smokers to achieve cessation. In order to overcome that problem, better cessation services have to be implemented, and alternative nicotine delivery systems should be provided for those, who cannot stop consuming nicotine. The real problem (cardiovascular diseases and cancer) starts when people are burning tobacco in order to set nicotine free.

Harm reduction is a political principle applied in many parts of society, nutrition and traffic being examples for that. Harm reduction is also very much associated with consumers rights, another very important political issue within the EU.

Here the EU is confronted with the need for more regulatory measures applied to nicotine delivery systems, being it the "classical" ones (like cigarettes), or the new ones, the alternative delivery systems.

The recent preliminary statement issued by the European Court of Justice on smokeless tobacco acknowledges already the existence of alternative nicotine delivery systems based on tobacco, but asks for more political and scientific action in order to give a sound reason for existing limitations. We are referring to the case of the smokeless tobacco product, called Snus, which is valuable in Sweden but banned in rest of the EU.

When being invited to deliver a plenary lecture at the 9th Central European Lung Cancer Conference 2004 we again came across the striking differences in lung cancer epidemiology in the EU. Lung cancer is a man made epidemic, and approximately 90% of all cases can be linked to tobacco consumption, especially to smoking.

Two European countries present a good illustration of geographical differences in smoking habits on the one hand, and remarkable gender specific differences in lung cancer incidence (Austria and Sweden).

The age and gender distribution of the Swedish and Austrian population are very similar, but Sweden has the lowest male smoking prevalence in Europe, and a low female prevalence. While Austria has a high male smoking prevalence and approximately the same female smoking prevalence as observed in Sweden.

But one has to take into account, that Swedish males use the smokeless tobacco product (Snus) quite extensively (23%). In order to get an accurate information about the nicotine consumption in Sweden, one has to add that kind of nicotine intake to the observed smoking prevalence in that country (among males 16%).

That means: 39% of Swedish men consume nicotine on a regular basis.

The situation in the female population, both in Sweden and Austria, is very similar, as females in Sweden do not use (yet) Snus in a remarkable percentage.

When one compares lung cancer mortality rates, among males in Austria and Sweden, a striking difference is becoming visible: Swedish males have a much lower lung cancer rate than the Austrian counterparts, while lung cancer mortality rates among females are pretty similar in the both countries.

The only explanation for that phenomenon are the differences in the way people perform their nicotine intake in the two countries.

Therefore, from a public health point of view, it is necessary, to come up with a scientifically based European statement on the future of nicotine consumption and its regulation. Banning just one product cannot be the only strategy. Especially when this product is so much less harmful than the nicotine delivery systems were based on burning tobacco.

The basic question is: Do we go for a nicotine free Europe, or do we want to get rid mainly of they way of providing nicotine which kills the customers. One might add, there are already nicotine replacement products on the market, which belong to the category of pharmaceuticals. There is a tendency to market these products more and more like any other consumer good by offering to the customers, not only in the pharmacies, but also by general sales.

The future will tell us, what direction the European citizens want to go, when it comes to nicotine consumption. From a public health point of view, the days of burning tobacco in order to provide nicotine should be counted and time has come for the various types of alternative nicotine delivery systems. A nicotine free society seems not be feasible in the next decades, if ever.

From our point of view it is the obligation of the EU to set up rules and guidelines to control production and distribution of all nicotine containing products and at some stage going for a ban of all products who set nicotine free when being burned.

9th Central European Lung Cancer Conference
Gdansk (Poland), September 23-25, 2004
Primary prevention in the European Union
M.Kunze

Introduction

Lung cancer control is a major public health task, and it is necessary to draw an action plan which highlights the need of primary prevention as therapeutical strategies are not very successful.

Primary prevention of lung cancer is based on strategies to reduce the exposure of carcinogens deriving from tobacco products, especially cigarettes. Smoking is performed mainly to consume nicotine.

Nicotine

Nicotine is probably the world´s second most-used drug after caffeine. It has generally met very little resistance when introduced into our societies and was not regarded as a drug until recently. In psychoactive and dependence-producing drug use, people normally see behavioural changes in individuals, both when they take the drug and when try to abstain from it. Nicotine´s psychotoxic effects – stimulating and tranquillising – are so mild that they are difficult to observe.

Unlike most other drugs, it does not impair performance in judgement, cognition or motor behaviour. On the contrary, nicotine may slightly improve some performances and help people to cope with daily stress; it is possible that use of nicotine will diminish but unlikely that nicotine use can be totally abandoned.

Our societies are fighting against illegal drugs with more profound psychotoxicity. It is therefore important that societies adopt regulatory systems for safer administration of forms of nicotine, alternative nicotine delivery systems and restrict tobacco smoking.

Smoking control

The ultimate purpose of tobacco control campaigning and organisations should be clearly stated: it is to reduce the burden of disease and death, mostly from cancer, cardio-vascular disease and lung disease, arising from tobacco use. The aim is not in

itself to campaign against tobacco. Because of the dominance of the cigarette market, in most situations those two strategies coincide. However, there may be some situations where they conflict – where this is the case, we give priority to reducing disease. Such a case arises where two conditions are met:

- Where the use of a tobacco product is substantially less hazardous than cigarettes;
- Where that tobacco product may substitute for cigarette use or facilitate increased smoking cessation at individual and population level.

This is the situation with oral tobacco products, such as 'snus', a form of oral tobacco widely used in Sweden and to a lesser extent in some other North European countries. New products are also emerging on the US market, which may also be targeted in this way. For this reason, there is a strategic question about how the tobacco control community should respond to such products. This is brought into a sharper focus in the European Union because of legal challenges to EU regulation in this area, and a commitment to review policy by the end of 2004.

A comprehensive approach to smoking control includes among other strategies:

- Health education and health promotion
- Political measures like advertising bans and restrictions in public smoking
- Taxation and price increase
- Product modification and regulatory measures with regard to tobacco products
- Focus on alternative nicotine delivery systems
- Smoking cessation services

Restrictions on the sale of tobacco products (grocery stores, tobacco vendors, gas stations) and advertising of cigarettes should be firmer than they are at present. A stringent law for the protection of youth and efficient steps for primary prevention must assist these procedures. Both the substances added to tobacco products and the harmful substances (e.g. nitrosamine and tar) in cigarettes should be controlled.

The traditional approaches to prevent the onset and maintenance of smoking are manifold.

The most promising are at present:

- The long term oriented health promotion efforts supplemented by price policy of tobacco products
- The focus on high dependent/high risk smokers will show the best outcome of all strategies

Especially with regard to the time-lag between action and effect on lung cancer epidemiology.

Alternative Nicotine Delivery System

According to international experience, nicotine products are adequate means for smoking therapy in terms of secondary and tertiary prophylactic procedures. With a combination of medical advice and nicotine replacement therapy lasting several weeks or months (mostly a combination of different products: patch, gum, nasal spray, microtab, lozenge and inhaler), up to 45% of smokers who want to quit smoking, can be free of cigarettes for 6 months.

Because many smokers enjoy smoking, and refrain from totally quitting despite health conditions such as cardiovascular diseases, lung disease, diabetes mellitus, a harm reduction strategy must be taken into consideration. Harm reduction means that the smoker reduces their daily consumption to a minimum of less than 10 cigarettes a day combined with a controlled application of nicotine replacement products. The treatment should also be possible for a longer period of time (months or longer) if cessation cannot be achieved.

If a smoker who already carries a risk insists on undiminished tobacco consumption and is not willing to use nicotine replacement products for harm reduction, they should be offered e.g. snus, a smoke-free tobacco from Sweden. The harmful characteristics of this tobacco are demonstrably lower than those of a cigarette, because the nitrosamine content in snus tobacco can be controlled.

Hard Core Smokers

The largest group of “hard core” smokers who experience the highest lung cancer risk can easily be identified by measuring the dependence score (Fagerström test) and the actual exposure to toxic substance (CO measurement in the expired air).

For smokers that are addicted to nicotine and cannot or will not stop, it is important that they can take advantage of much less hazardous forms of nicotine and tobacco – the alternative being to “quit or die”… and many die. While nicotine replacement therapies (NRT) have a evidence based role in harm reduction, tobacco-based harm-reduction options may reach more smokers and in a different, market-based, way.

Austria and Sweden: A Comparison

Two European countries present a good illustration of geographical fluctuations in smoking habits. The age and gender distribution of the Swedish and Austrian population are very similar. Sweden has the lowest male smoking prevalence in Europe (16% daily) and low female (22%) prevalence. Austria has a high male smoking prevalence (32%) and a female smoking prevalence of 26%. But 23% of Swedish men use snus.

This is a smokeless oral tobacco. which releases less of the carcinogens that develop mainly through the burning process of cigarettes. Swedish women use of snus is only marginal. Due to European Union legislation snus is not available in the European Union outside Sweden.

The availability of snus is currently the subject of political debate within the European Union. Lung cancer mortality rates attributed to smoking are lower in Swedish men than in Austrian men. Indeed all cancer mortality as well as vascular mortality attributed to smoking is lower in Swedish men than in Austrian men. The rate of lung cancer mortality is similar between Swedish and Austrian women. The incidence of lung cancer in Austria is slowly decreasing in men (from 87.2 in 1983 to 69.8 per 100.000 in 1996). and the incidence in women is going up (from 15 per 100.000 in 1983 to 19.3 per 100.000 in 1996). This trend has been observed in many industrialised countries.

The mean age at death of Austrian female patients has remained fairly stable over the last 20 years but Austrian men with lung cancer die one year earlier in their life than 20 years ago. This is a unique epidemiological pattern. and so far only described for Austria.

Clearly intervention strategies of lung cancer control in Austria are meeting with little success and need to be re-evaluated. Lung cancer control through "chemoprevention" as an alternative nicotine delivery system is one of the approaches under discussion. The clinical evidence of a beneficial effect of chemoprevention in lung cancer is still limited.

Other chemopreventive trials have failed or produced unexpected and disappointing results.

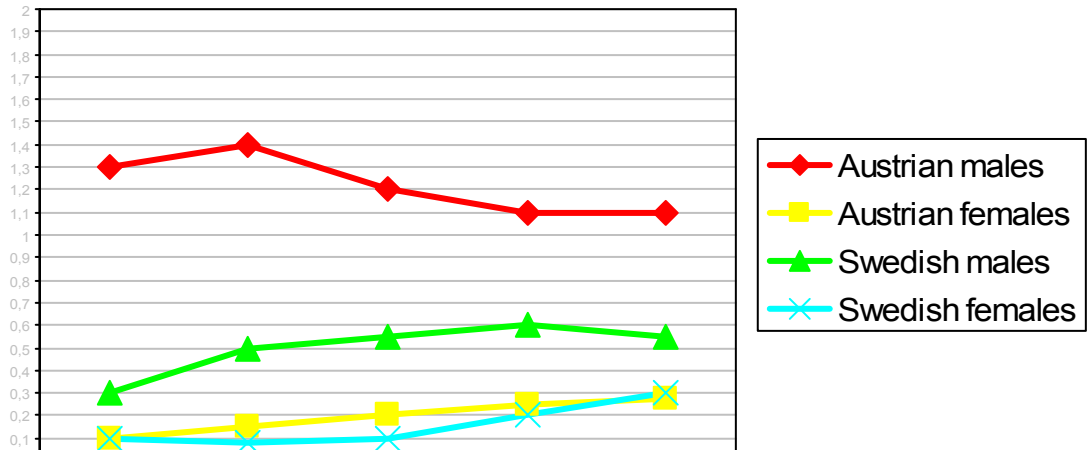

Figure: Annual death rate from lung cancer per 1000 Swedish and Austrian men and women at age 35-39 years.

Vaccination

A vaccination in general is a very complex public health tool but extremely successful in many ways.
Medical history is full of positive experiences with vaccinations; but experiences also tell us: vaccinations may also create new and unexpected issues and problem areas.

The idea of binding the nicotine molecule to a protein and making it unable to act on the specific receptor is fascinating and offers an unique opportunity of primary prevention. But what might the side effects be and how should the vaccination be promoted: then the bulk of available information of classic vaccination programmes come in.

A „therapeutic“ vaccine would be another issue nevertheless being very attractive and for sure a public health message with tremendous impact.

The possible problems and issues are many and complex just to mention one: smokers might try to compensate the vaccine induced reduction of nicotine availability and experience more CO exposure.

An easier task might be the use in relapse prevention, and for helping to perform controlled smoking.

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Betreff: Smokeless Tobacco – Swedish Snus

Sehr geehrter Herr Kommissar!

Unter dem Begriff „smokeless tobacco" wird zur Zeit auf wissenschaftlicher Ebene ein Produkt diskutiert, das in Schweden bei Männern eine lange Tradition hat und unter der Bezeichnung „snus" von der Tabakindustrie (Swedish Match) in Schweden vertrieben wird. Snus wird in kleinen Portionsbeuteln, die, ähnlich einem kleinen Teebeutel, mit Tabak gefüllt sind und zwischen Lippe und Kiefer gelegt werden, wobei auf diese Weise das Nikotin herausgelöst und dem Gehirn zugeführt wird.

Derzeit ist die Inverkehrbringung von Tabak, der für einen anderen oralen Gebrauch als zum Rauchen oder Kauen bestimmt ist, EU-weit verboten. Lediglich Schweden ist aufgrund der langen Tradition von snus von dem Verbot ausgenommen. Die Tabakindustrie (Swedish Match) versucht seit einiger Zeit, gegen dieses Verbot mit verschiedenen Argumenten mobil zu machen und hat auch begonnen, auf rechtlicher bzw. gerichtlicher Ebene dagegen anzukämpfen.

Inzwischen gibt es allerdings auch in der Wissenschaft bereits einige prominente Stimmen, unter ihnen der Vorstand des Instituts für Sozialmedizin der Universität Wien, Univ.Prof.Dr. Michael Kunze, die aufgrund der epidemiologischen Datenlage zwar snus keineswegs als „gesundes" Produkt einschätzen, aber doch den Konsum von snus gegenüber dem Rauchen als weniger riskante Form des Tabak- bzw. Nikotinkonsums einschätzen.

„Snus" wird in Schweden beinahe ausschließlich von Männern verwendet, während Frauen smokeless tobacco kaum konsumieren. Nach den epidemiologischen Forschungsergebnissen von Prof. Karl Fagerstrom (Schweden), Prof. Kunze und anderen Wissenschaftern scheinen schwedische Männer ein wesentlich geringeres Lungenkrebsrisiko zu haben als österreichische Männer oder Männer in vergleichbaren Ländern, während schwedische und österreichische Frauen das gleiche Lungenkrebsrisiko haben. Als Erklärung bietet sich nach Meinung der Wissenschafter die Tatsache an, dass schwedische Männer die Nikotinzufuhr vor allem auch durch das Produkt „snus" in Form oralen Tabaks

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durchführen, während schwedische Frauen diese Produkte noch nicht oder nur in geringem Ausmaß nützen. Schweden weist offenbar auch eine geringere Sterblichkeit durch Herz-Kreislauf-Erkrankungen und auch Mundhöhlenkarzinomen auf, sodass die Wissenschafter davon ausgehen, dass die Zufuhr von Nikotin durch das in Schweden verbreitete „snus" ein wesentlich geringeres Krankheitsrisiko bedingt als der bei uns übliche Zigarettenkonsum.

Es erscheint fraglich, sehr geehrter Herr Kommissar, ob unter Zugrundelegung dieser Datenlage und des heutigen Wissenstandes ein Verbot von „snus" noch angemessen ist, während die risikoreicheren Zigaretten in der EU frei verkauft werden dürfen.

Insbesondere aber könnte diese Form der Nikotinversorgung im Einsatz bei schwerst tabakabhängigen RaucherInnen, bei denen alle anderen Entwöhnungsversuche nichts erreichen konnten, hilfreich sein.

Jedenfalls aber ist zu befürchten, dass bei einer gerichtlichen Aufhebung des Verbots infolge Anfechtung durch die Tabakindustrie, wie sie die Firma Swedish Match derzeit betreibt, ohne rechtzeitige Vorsorge durch Schaffung von Sicherheits- bzw. Qualitätsstandards smokeless tobacco aus anderen Ländern, insbesondere aus Asien/Indien, auf den europäischen Markt gelangen, die tatsächlich ein Gesundheitsrisiko größeren Ausmaßes bergen.

Ich darf Ihnen, sehr geehrter Herr Kommissar, aus diesem Grund ein mir von Herrn Prof. Kunze übermitteltes Schreiben samt Beilagen zur Kenntnis bringen und Sie ersuchen zu prüfen, ob angesichts der daraus ersichtlichen wissenschaftlichen Argumentation die Aufrechterhaltung des Verbots in seiner derzeitigen Form tatsächlich noch zweckmäßig ist, oder ob nicht eine streng reglementierte Freigabe von smokeless tobacco, sofern er zumindest ebenso strenge Auflagen erfüllt wie swedish snus (gothiatek), als zielführender anzusehen wäre. Darüber hinaus biete ich zur allfälligen Unterstützung in der Entscheidungsfindung in gegenständlicher Angelegenheit die Durchführung eines Pilotprojektes Österreichs unter wissenschaftlicher Aufsicht an.

In diesem Sinne empfehle ich mich

mit freundlichen Grüßen

Beilagen: 3