Swiss-Vap Study

Preliminary report, April 2014

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Summary

1. Introduction

The use of electronic cigarette (e-cig) has rapidly increased these last years in many countries and recently raised a public debate. E-cigs include a wide range of devices that deliver vapor. They are composed of a battery, a vaporizer, a liquid container and a mouthpiece. The heating element is activated either by a switch, or when the user draws on the mouthpiece [1].

E-liquids are mainly composed of propylene glycol, vegetal glycerin and distilled water in variable proportions, with or without nicotine, and usually contain aromas.

E-cigs are mainly used by smokers trying to reduce or stop smoking and former smokers [2]. In a 2011 internet survey from a Swiss website including 3587 users, 61% were male, the mean age was 41 years and the median duration of their use of e-cigs was 3 months. They drew a median of 120 puffs/day, used 5 refills/day and 97% used e-liquids containing nicotine [3].

The reasons reported to use e-cigs were the following:

In Switzerland, in a sample of 5081 young men enrolled during mandatory visits at army recruitment centers, 4.9% had tried e-cigs, of which only 12.9% of them were using e-cigs daily. The proportion of subjects who tried was higher among smokers (9.3%), than among former smokers (1.6%) and never smokers (0.4%) [4].

1.1 Components of e-cigs:

Propylene glycol has been used for many years in drugs, cosmetics and as a food additive. It is considered as safe in those conditions, as well as to simulate smoke in night clubs and theatres. Studies on animal exposure to propylene glycol show only dryness of the oral and nasal mucosa and a small reduction of the FEV1/FVC ratio as side effects [5].

Vegetal glycerol is used as an additive in drugs, food, toothpaste or chewing tobacco and is considered safe in those conditions. When heated higher than 275°C (higher than the normal temperature produced by e-cigs), acrolein, a powerful irritant, can be formed [5].

Aromas are either natural or artificial. Many products use aromas that are commonly used as food additives and considered safe for ingestion. But effects when inhaled are unknown, and heating those substances can produce new chemicals.

Nicotine is a potent pharmacological agent. In the brain, its psychological effects may lead to dependence [1]. In large amounts, nicotine is toxic and even deadly. Doses from 2 to 5 mg can already cause toxic symptoms and 10 mg can be deadly for children [6]. Therefore, most e-liquids bottles would contain enough nicotine to kill someone in case of ingestion. However, the lethal dose for adults is being revised, as a dose of 60 mg was thought to be deadly for an adult for over a hundred years, but the actual lethal dose could be 20-fold higher [7].

1.2 Health effects of e-cigs

The immediate effects after short-term use of e-cigs have been described, and include an increase in pulmonary resistance [8].

Side effects reported were mouth and throat irritation, dry cough, dyspnea, headache [9]. Some adverse events can also relate to withdrawal symptoms after smoking cessation.

When non-purified glycerol is used, or when e-liquids are modified by users, an oil inhalation and lipoid pneumonia can occur[10].

There are currently no data about the long-term effects of e-cigs use.

Only few studies have investigated the efficacy of e-cigs to quit or reduce smoking. Smoking reduction and abstinence have been reported by people not intending to quit [9, 11]. Nicotine withdrawal symptoms can be reduced by e-cigs. Participants report a better effort capacity, as well as an improvement of gustatory an olfactory senses with e-cigs instead of tobacco, with a decrease in perceived dependence to e-cigs [12].

Recently, a randomized controlled trial showed that e-cigs were at least as effective as patches to quit smoking at 6 months [13], but statistical power to detect a difference was lowered by overestimation of the effect, and thus not enough participants were enrolled.

1.3 Regulation

In Switzerland, only e-cigs without nicotine can be sold currently. Citizens can buy e-liquids with nicotine abroad or on the internet, with a volume limited to 150ml and for personal use only [14].

In Europe, the UK, in absence of actual regulation, are about to consider e-cigs with nicotine as medicinal products [15]. In Germany, e-cigs are considered as a consumer product (previously considered as a medicinal product, until 2013). In France, e-cigs are not considered as a medicinal product under the following conditions [1]:

- The nicotine quantity in the vial is under 10mg
- The concentration of nicotine in the refill solution under 20mg/ml and
- The product isn't presented as a smoking cessation treatment.

A French expert consensus recommend that e-cigs be considered as drugs when nicotine concentration is above 18mg/ml in e-liquids [5].

A revision of the European directive on tobacco products was adopted by the European parliament on the 26th of February 2014, and by the European council of Ministers on the 14th of March, and will enter into force in May 2014. Sale of e-cigs will be forbidden for minors under 18 years old[16]. Member states who want to consider e-cigs as medicinal products will be allowed to do so, but without forcing the other states to do the same. Quality and security requirements were created:

- Nicotine concentration in e-liquids is limited to 20mg/ml
- Single use cartridge size will be limited to 2 ml
- Volume of refillable containers will be limited to 10 ml

The member states will have 2 years to adopt the new directive.

2. Rationale of the study

Some experts consider e-cig as a possible revolution in the reduction of harm from tobacco [17], that they should therefore be encouraged and not severely regulated, in order to convince as many smokers as possible to switch to e-cigs. Other experts argue that e-cigs could be a trap, that it could be a gateway to nicotine dependence, especially for the young, leading to cigarette smoking. Its use would retard smoking cessation and would renormalize public smoking[18]. However, these hypotheses have not been properly tested to date. We have alternatives smoking cessation products [19]. There is also a fear that e-cigs could be misused, as a way to use marijuana or other illegal drugs.

The regulation will have a big impact on the development of the product, and therefore on the health of the smoking population as well. But without enough scientific evidence to guide health and political authorities, it is difficult to choose how to regulate the e-cigs.

3. Aim of the study

To propose recommendations for health authorities regarding the regulation, sale and use of e-cigs.

4. Materials and Methods

4.1 The Delphi method

We used a process inspired from the Delphi method to synthesize expert opinion [20]. Through different rounds, we submitted an online questionnaire to a panel of Swiss experts, assessing the extent of their agreement on different statements. The questionnaires were modified between different rounds, depending on the results and comments from previous round. The research team has kept the original questionnaires and they are available for consultation.

4.1.1 Selection of the expert panel

The experts invited to the study were:

- Trainer physicians for the program “Vivre sans tabac” (“Frei von Tabak”). This program has 50 physicians from all over Switzerland, trained to teach other physicians how to treat tobacco dependence. To be included in the original program, these physicians had to be [21]:
    - Working with a population of smokers

    - Interested in tobacco control and teaching
    - Recognized by their colleagues
    - Part of a network
- The 8 physicians of the network “Hospital quit support”, a program intended to bring smoking cessation consultations into Swiss hospitals.
- Public health experts, head of the different public health services of Swiss universities.
- Experts known for their implication in clinical or political tobacco prevention, as well as in public health programs, who were recommended by the research team or by the other experts participating in the study.

4.1.2 First round

The first questionnaire assessed 4 categories of issues around e-cigs:

- Regulation
- Sale
- Prescription
- General opinion

Participants had to rate each recommendation on a scale of 1 to 10, where 1 was “strongly disagree” and 10 was “strongly agree”. The recommendations that reached a high level of positive agreement (mean score between 8 and 10), were considered as accepted. The recommendations that reached a high level of negative agreement (mean score between 1 and 3) were considered as rejected.

The questionnaire also involved one open-ended question and the possibility to suggest new recommendations.

At the same time as the questionnaire, participants received some documents about e-cigs. These included 3 national reports (from UK, France and Germany), as well as some representative scientific and political information.

4.1.3 Second round

With the recommendations that didn’t reach a significant level of agreement (mean scores between 3.01 and 7.99), we created a second questionnaire. The recommendations were reformulated following the comments of the experts, either to clarify the recommendation, or to submit subcategories. We used the answers to the open question and the experts’ suggestions and comments to bring new recommendations.

In order to facilitate the interpretation of results, some recommendations were not rated on a scale from 1 to 10, but some propositions had to be put in order from the most appropriate to the least appropriate. The degree of agreement was determined by the proportion of first choice for each proposition. Cut-off limits were set to keep the same intervals used in the other recommendations.

Each expert was provided the anonymized results of the first round with this second questionnaire. The comments and the results of the open questions were not transmitted.

As for the first round, the recommendations that reached a high level of agreement were considered as accepted or rejected.

4.1.4 Third and fourth rounds

The recommendations that didn't reach a significant level of agreement were included into a new questionnaire, like for the first two rounds.

The participants had access to the results of previous rounds to rate the recommendations.

For the last round, we joined 6 position papers to the questionnaire that were published in main medical journals, in order to bring some more arguments to the participants.

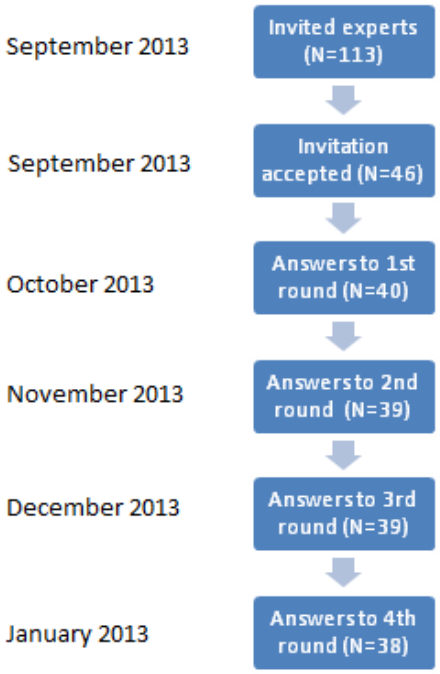

Figure 1: Experts' participation

5. Results

5.1 The expert panel

A total of 113 experts were invited to participate in the study. Of these, 46 accepted to participate in the first round and 40 filled out the first questionnaire. Only the 40 who answered were sent the next questionnaires. The participation rates to the rounds 2, 3 and 4 were respectively 97.5%, 97.5% and 95%.

Of the 40 who participated to the first round, 32 (80%) were invited because of their work in tobacco control, 5 (12%) were member of the Federal Commission for Tobacco Control, and 3 (8%) were proposed by other experts (Tab. 1). 14 (35%) were female (Tab. 2).

55% of the experts work in the French part of Switzerland, 40% the German part and 5% the Italian part (see Tab. 3)

Type of expertise	Invited experts (N=113)	Experts Round 1 (N=40)
Federal Commission for Tobacco Control	17% (N=15)	12% (N=5)
Smoking cessation	68% (N=85)	80% (N=32)
Proposed by other experts	15% (N=13)	8% (N=3)

Tab. 1: Type of expertise

Gender	Invited experts (N=113)	Experts Round 1 (N=40)
Male	68% (N=77)	65% (N=26)
Female	32% (N=36)	35% (N=14)

Tab. 2: Gender

Location of business place	Invited experts (N=113)	Experts Round 1 (N=40)
German-speaking part	57% (N=64)	40% (N=16)
French-speaking part	37% (N=42)	55% (N=22)
Italien speaking part	6% (N=7)	5% (N=2)

Tab. 3: Location of business place

5.2 Consensus reached

The recommendations and statements in this section reached a significant level of agreement and are therefore considered as accepted by the experts.

5.2.1 Regulation

We asked the experts if we should wait until more data were available regarding efficacy as a quitting tool and safety of e-cigs before they could be sold with nicotine in Switzerland. We also asked them, if e-cigs with nicotine were to be sold, what kind of regulation should apply. The experts' panel agreed that e-cigs containing nicotine should be sold in Switzerland without waiting for additional data, but with a specific regulation. The potential of e-cigs to be a much safer alternative to conventional cigarettes was the main argument for making them available as soon as possible. Nevertheless, much consideration was given to the lack of data about long-term effect of e-cigs on health of users. Therefore, they agreed on the need for a regulation that would protect users, by guaranteeing the quality of available products, with an upper limit of authorized nicotine concentration and adequate information on the components of the e-liquids and the addictive potential of e-cigs. In order to be able to control the quality and access to the products, they agreed that e-cigs should be either considered as a medication controlled by Swissmedic, or a new category of products containing nicotine, that would fall under a new, specific regulation.

Regulation
• Nicotine e-cigs should be sold in Switzerland with a specific regulation, but not with a regulation similar to current regulation.
• E-cigs should be considered as either: - A drug (medication), regulated by Swissmedic - A new category of products containing nicotine, with a specific regulation
• E-cigs should not be considered as: - A tobacco product, regulated like other products containing tobacco (such as tobacco cigarettes, tobacco pipes, and tobacco cigars) - A consumer product, without changing the actual regulation
• If e-cigs with nicotine were to be authorized in Switzerland, companies should: - Respect a list of authorized e-liquid components - Be on a list of accepted models with specific requirements - Respect an upper limit of nicotine concentration
• A warning should be stated on the product, especially concerning the addictive potential and the lack of evidence on the long term security of the product.
• The components of e-liquid should be stipulated on the product.

5.2.2 Sale

The benefit of e-cigs for actual tobacco cigarette smokers was largely accepted, but the lack of data on the long-term health effects was considered. It therefore seemed important to the experts to protect minors and actual non-smokers by restricting the sale of e-cigs to adults, as well as by forbidding advertisements in the media, especially all advertisements targeting minors and non-smokers. A consideration was also given to the protection of pregnant women, as we know that nicotine can have negative effects on the fetus[6]. Given the recommendation for regulation, e-cigs should be sold either in pharmacies or in the same places as tobacco products. The experts agreed that a tax on e-cigs should be implemented, high enough to finance independent research on e-cigs, but low enough to keep the product more attractive than conventional cigarettes.

Sale
• Sale restrictions should be proposed for minors.
• If e-cigs were considered as a medication, restrictions should be proposed for minors and pregnant women.
• If nicotine e-cigs were to be authorized in Switzerland, they should not be sold by the tobacco industry or related companies.
• E-cigs should be sold in either: - Pharmacies - The same places as tobacco products
• E-cigs should not be sold: - In specialized shops - Anywhere
• A specific tax should be implemented on e-cigs.
• Advertisement should not be allowed: - In the media - Targeting minors - Targeting non-smokers

5.2.3 Use

The risk for the renormalization of smoking, as well as the currently unknown effects of passive vaping, motivated the experts to recommend that e-cigs should be banned from closed public places.

When asked about who should or shouldn't use e-cigs, it was clear to the experts that health authorities should recommend that non-smokers not start using them. As evidence for the efficacy of e-cigs as a quitting tool is lacking, they also considered that we should not recommend e-cigs as a first-line treatment for quitting conventional cigarettes, but instead should recommend the use of products (nicotine substitutes) and therapies that already have proven efficacy. The role of e-cigs as a second line therapy was not clear to the experts.

Use
• The use of e-cigs should be forbidden in public places.
• Health authorities should advise never smokers not to use e-cigs (e.g. through a public campaign)
• Health authorities should not encourage smokers to shift to e-cigs to help them quit smoking as first line therapy.

5.2.4 General opinion

As e-cigs seem to be a much safer way to deliver nicotine than conventional cigarettes, we asked the expert panel whether nicotine addiction remained a medical and public health issue, or became more of a moral issue. Given the addictive potential and the unknown long-term effects of e-cigs on health, they agreed that nicotine addiction should still be considered as a medical and public health issue.

In light of current data, it seemed legitimate to the experts to consider e-cigs as not dangerous for the health of actual smokers, as there could be a high potential for risk reduction for those who would switch from smoking conventional cigarettes to using e-cigs. More research is needed to assess the risk and benefits of e-cigs.

General Opinion
• If e-cigs become a popular product, nicotine addiction should be seen as a medical and public health issue.
• Research should assess: - Long-term inocuity of the product - Efficacy as a quitting tool - Psychological and social effects - Effect of dual consumption: e-cigs and tobacco products
• Based on currently available data, e-cigs are not dangerous for the health of tobacco smokers

5.3 Consensus not reached

The recommendations and statements that didn't reach a significant level of agreement must therefore be considered as not accepted by the experts. The numbers in parenthesis represent the score they reached in the final round in which they were included.

Recommendations:

As data are lacking, the experts remain divided on the role of e-cigs in healthcare and on whether or not they should be recommended to current tobacco smokers.

The panel was also divided on the recommendation of whether or not to follow or the recent EU legislation. The main benefit of following the European regulation would be to reinforce the effects of

our own legislation, as it could not be bypassed by obtaining different products abroad. The importance of this argument is demonstrated by a mean score that approached the score needed for acceptance, but many experts preferred to wait until the European Directive is ready before deciding whether or not to follow it.

The type of regulation was also not determined, as a strict regulation would limit the potential positive impact that e-cigs could have on public health, but a very light regulation would imply taking some risks on a product for which important data are still missing.

Recommendations
• Health authorities should now encourage smokers to shift to e-cigs: - To help them quit smoking, only as second line therapy (5.57) - As a risk reduction tool (5.63)
• We should wait to have more data about e-cigs before putting in place specific legislation and regulations (4.29)
• The following professionals should now encourage current daily smokers to shift to e-cigs: - Healthcare professionals, on an individual basis (5.92) - Education professionals, on an individual basis (3.97)
• Swiss legislation should follow EU regulation (7.14)
• Given the current situation, with only few data about security, safety and efficacy of e-cigs, what type of regulation would you recommend: - Strict regulation (6.97) - Very light regulation (3.59)

Statements:

The panel agreed that e-cigs are safer than tobacco cigarettes and thus not dangerous for the health of actual smokers, but didn't agree whether e-cigs are dangerous for the health of former and never smokers.

Even if they were close to consensus, they also didn't agree to assert that it was likely that e-cigs would be used on specific purposes, such as a stimulant for sport activities, brain enhancement, mental concentration, weight control or the administration of illegal drugs.

The experts were also close to agree that the likelihood of dual consumption (ie, simultaneous use of tobacco cigarettes and e-cigs, especially where smoking is forbidden) was high, as well as whether dual consumption would decrease the willingness to quit tobacco.

Finally, the experts didn't agree whether or not nicotine addiction should be seen as a moral issue.

Statements
• Based on expert appraisal of the current data, e-cigs are dangerous for the health of: - Former smokers < 6 months (5.16) - Former smokers > 6 months (5.84) - Never smokers (7.03)
• In your opinion, if e-cigs are not regulated, they are likely to be used for the following: - In sports, e.g. hockey (5.34) - For brain enhancement, e.g. for exams, students (7.16) - For weight control (7.13) - For the administration of illegal drugs (7.3) - For one or more of the above unexpected use (7.52)
• Instead of quitting tobacco cigarettes, the likelihood of dual consumption (tobacco cigarettes and e-cigs) by regular tobacco cigarette smokers is high (7.92)
• For regular tobacco cigarette smokers, a dual consumption might decrease the willingness of quitting tobacco smoking (6.26)
• If e-cigs become a popular product, nicotine addiction should be seen as a moral issue (3.94)

6. Discussion

Implications for political authorities:

The main result of this survey is the agreement among the experts that e-cigs with nicotine be authorized in Switzerland, under several conditions.

According to the experts, e-cigs should be either considered as a drug and regulated by Swissmedic, or regulated as a new category of products containing nicotine with the enactment of a specific regulation. The first alternative would need time, as more studies would be required before some e-cigs could be sold as a medical device. But the current project regarding a federal law on tobacco products, which should be publicly discussed in 2014, could be an opportunity to apply the second alternative. A specific regulation could include the other recommendations proposed by the experts, regarding the quality, safety, use and sale of e-cigs.

This law should therefore authorize the sale of e-cigs with nicotine in Switzerland. In order to avoid a renormalization of smoking, and to limit the potential risks due to passive vaping, the use of e-cigs should be forbidden in closed public places. The sale should be restricted to adults, and be accompanied by clear norms for the quality of e-liquids, with the introduction of a restrictive list of authorized components and a fixed limit for nicotine concentration. E-cigs models should be on a list of approved models with specific requirements.

Users should be informed of the content of e-liquids, which should be specified on the bottles of e-liquids. A warning about the risk for addiction and the lack of data regarding the long-term health effects should also be visible on the bottles.

E-cigs should be taxed to finance independent research to get data of long-term use, such as health impact, efficacy as a quitting tool, as well as to obtain a better knowledge of the psychological and social effects of the product, and of the impact of the dual consumption of e-cigs and tobacco products.

Advertisements for the product should be restricted or forbidden in the media, particularly to avoid advertisement targeting minors and non-smokers.

Implications for health authorities and tobacco control experts

Given current knowledge, e-cigs should not be perceived as dangerous for the health of actual smokers as the experts consider them much safer than tobacco cigarettes. Nevertheless, the expert group agreed that health professionals should not propose e-cigs as first line therapy to help smokers to quit, given that data on the efficacy of e-cigs as a quitting tool are lacking and that current therapies are considered safe and efficacious. Whether e-cigs could be proposed as a second line therapy or as a risk reduction tool remains debated.

Health professionals should recommend non-smokers not to use e-cigs as the long-term effects on health are not known.

Limitations of the study

The main limitation is linked to the Delphi method itself, as the results only reflect the opinion of selected experts.

Another limitation is linked to the rapid evolution of the products and the continuous arrival of new data about security and safety. The opinions in this report will certainly change as more data become available.

International regulation comparison with the recommendations of the Swiss-Vap Study

Legislation from	Sold with nicotine	Specific regulation	Status	Use in public places	Advertisements	Warning	Sale to minors
Germany	Yes	No	Consumer product	Depends on the state		Not regulated	
France	Yes	No	Consumer product[1]	Allowed	Forbidden	Not regulated	Forbidden[3]
UK	Yes	No	Consumer product (but government wants to make it a medicinal product)	Not regulated	Allowed	Not regulated	
European Directive[2]	Yes	Yes	Consumer product (but can be considered as medicinal by member states)	Not regulated	Determined by member states	Yes	Forbidden under 18 years old
Switzerland (actual)	No	No	Consumer product	Allowed (specific restrictions apply)	Forbidden	No	Yes
Swiss-Vap	Yes	Yes	Either a drug (medicament) or a new category of products containing nicotine	Forbidden	Forbidden	Yes	Forbidden

1. Unless the product meets requirement for medicinal products
- The nicotine quantity in the vial is under 10mg
- The concentration of nicotine in the refill solution under 20mg/ml and
- The product isn't presented as a cessation treatment.

2. As adopted by parliement on the 26.2.14, and by the Council of Ministers on the 14.3.14

3. Law of the 17th of march 2014

7. Conclusion

The Swiss-vap study allowed a panel of Swiss experts to reach a consensus on several important questions regarding e-cigs, specifically its regulation, sale and use. It also gathered their general opinion on the product. It should be useful for health authorities and healthcare professionals to decide how to handle this topic.

These recommendations together bring 3 principles: the reality principle, as the product is already on the market, the prevention principle, as they provide an alternative to tobacco for actual smokers, and the precautionary principle, as they protect minors and non-smokers as long-term effects are not yet known.

8. Annexes

Annexe A: Experts' list

Participating Experts
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Thilo Burkard, Primary Care Division, University Hospital, Basel
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Daniele Zullino, Division of Substance Abuse, Geneva University Hospitals

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