Electronic Cigarettes and UNDERWRITING

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E-cigarette use has become a hot topic in our profession as we grapple with how to underwrite users.

Are there any major health issues linked to e-cigarette (e-cig) use? Will e-cigarette users test positive for cotinine? How should we underwrite e-cigarette use?

This paper will look at what is currently known regarding the epidemiology, toxicology and implications of e-cigarette use.

It will also report on a June 2014 survey of chief life underwriters and offer thoughts on how to deal with e-cigarette use that this time.

BACKGROUND

What are e-cigarettes?

They are battery-operated devices that contain cartridges typically (but not always) filled with nicotine. [Riker]

They may also contain various flavorings, either alone or with nicotine. [Bullen-1]

There are now anecdotal reports of using e-cigarettes to smoke hashish oil, which has a far higher tetrahydrocannabinol (THC) level than that typically found in marijuana cigarettes. [Coombes]

When were e-cigs introduced?

They first appeared in China in 2004, and in Europe and North America in 2006 and 2007, respectively. [Noel]

What other terms are used in conjunction with e-cigs?

The device may be referred to as an electronic nicotine delivery system.

The aerosol generated by puffing on the e-cigarette is usually – but inaccurately – referred to as a "vapor." [Callahan-Lyon, Cheng].

As a result, the term "vaping" refers to the process of puffing on the device, and persons using e-cigs may be dubbed "vapers."

What are the two chemicals found in virtually all e-cigs?

Propylene/polyethylene glycol and glycerine/glycerol.

Propylene glycol is the most abundant chemical. It is also found in smoke used in theatrical and musical productions, as well as in cosmetics, asthma inhalers, toothpaste and foodstuffs. [Flouris-1, Pellegrino, Uchiyama]

Is propylene glycol an irritant?

Yes.

While it has been judged to be harmless based on acute exposure from smoke-making devices used in the entertainment industry, it can induce transient adverse effects mainly affecting the eye and respiratory tract. [Bertholon, Callahan-Lyon, Werley]

The author of a new toxicology review paper concluded that there are *"currently no grounds to be concerned about the immediate or chronic effects of exposure."* [Burstyn]

How many e-cigarette products are on the market?

There were over 300 brands in 2012; this has surely increased in the interim. [Riker]

Do e-cigs vary widely?

Yes, in a variety of ways, including the extent of puffing effort needed to activate aerosol delivery, nicotine content, potentially significant toxic contents, etc. [Benowitz, Goniewicz-1]

EPIDEMIOLOGY

How widely are e-cigarettes used?

According to a CDC document dated 2/28/13, 21% of adults who smoked regular cigarettes had also used e-cigs in 2011, which was a 10% increase over 2010. Roughly 10% of all adults had at least tried an e-cigarette.

Who uses e-cigarettes?

In two 2012 surveys encompassing 6,507 community respondents, 80% of e-cig users were current smokers, 15% were ex-smokers, and just 5% had not previously used conventional cigarettes. [Pearson]

A more recent Canadian survey of 1,188 subjects, ages 16-30, also found that 5% of e-cig indulgers were lifetime nonsmokers.
Current smokers were twice as likely as ex-smokers to use them. [Czoll]

In a new UK survey, 20% of current smokers also used e-cigs. [Brown-1]

Giovenco reported that the odds of being an established e-cig user were 3-fold higher if one was an ex- vs. current smoker.

Two additional UK investigations noted that < 1% of e-cigarette devotees were never-smokers, and most of this group who tried them did not continue using e-cigs. [Dockrell, Kmietewicz]

Given these findings we know that:

- Most e-cigarette users are current or former cigarette smokers.
- Lifetime nonsmokers account for no more than 5% of e-cigarette users.

Are there any "risk factors" associated with a higher probability of using e-cigarettes?

In addition to being a current or ex-smoker, a few other factors have been pinpointed thus far: [Brown-1, Dutra, Goniewicz-2, Tan]

- Under age 30 (and disproportionately age 18 or younger)
- Higher relative level of education
- Higher relative socioeconomic standing
- At least one attempt to quit smoking regular cigarettes in the past year
- The perception that e-cigs are either harmless or far less harmful than regular cigarettes

These revelations suggest that e-cigarette use may be disproportionally highest among younger adults who are part of the population subset most likely to purchase individual insurance products, based on income and education.

Given the perception that e-cigs are largely or wholly harmless, this could also translate to a high incidence of nondisclosure.

Are there any additional factors that motivate current or ex-smokers to use e-cigs instead?

Yes. [Callahan-Lyon, Czoll, Dawkins-1]

- The desire to smoke where conventional smoking is forbidden
- The desire to quit quickly
- The desire to cut down, but not quit entirely
- The lower cost of e-cigs compared to heavily taxed conventional cigarettes
- The favorable effect of e-cigs on memory performance without the restraints on tobacco smoking in certain environments (studying in libraries, smoke-free dorms, etc.)

How effective is e-cigarette use as a means to quit or cut down?

"We know already that e-cigarettes function like any other form of nicotine replacement therapy but seem to be more attractive to smokers. They are now the most commonly used cessation aid in England. ***About one in six English smokers use electronic cigarettes concurrently with smoking."*** [emphasis added]

Paul Aveyard and Nicola Lindson-Hawley

Oxford University
British Medical Journal
348(May 24, 2014):18

We found six studies that looked at the impact of e-cigs in this context.

- In a survey of 5,863 smokers who made at least one attempt to quit in the prior 12 months, e-cigarette users were substantially more likely to report abstinence (odds ratio 2.2) than those using the patch or other nicotine delivery alternatives. [Brown-2]
- Polosa followed a cohort of smokers using e-cigarettes and found that > 50% reported a substantial reduction in cigarette use (mean 24/day to 4/day) over 24 months. In addition, 40% were wholly abstinent at the end of the follow-up interval.
- In another investigation, 46% of dual users had quit cigarettes over one year, and 86% using e-cigs were still doing so 24 months later, whether or not they still used regular cigarettes [Etter-3]
- A fourth study showed that e-cigs were significantly more effective than the transdermal patch. [Bullen-2]
- An Italian study revealed that among smokers not intending to quit, use of e-cigs greatly reduced cigarette consumption and *"…elicited enduring tobacco abstinence."* [Caponnetto]
- A Web-based survey was the only report to contradict these findings, with e-cigarette use not predictive of either quitting or reducing consumption over 12 months. [Grana]

On balance, the weight of evidence tells us that e-cigarettes are a better nicotine delivery system than the patch and other alternatives in terms of both cutting down and quitting.

What aspects associated with e-cigarettes are thought to account for their advantages in this context?

Barbeau elicited feedback from users of e-cigs and the patch, reporting that feedback favored e-cigarettes in all five domains of comparative impact.

Riker showed that the main advantage of e-cigs was the rapid delivery of nicotine into the body via inhaling.

Siegel found that e-cigarettes had fewer withdrawal symptoms than other nicotine replacement options.

ADVERSE EFFECTS

What are the short-term adverse effects from e-cigarette use?

The main ones are transient peripheral airway resistance, throat and eye irritation, nausea/vomiting and insomnia, all to a lesser extent than in conventional smoking. [MMWR 63(2014):292, Hua, Vardavas]

A study just published in Circulation reviewed the literature and found no significant differences in adverse event rates when comparing e-cigs to the patch. [Franck]

Cantrell showed that adverse effects attributed to e-cigs are *"unlikely to result in serious toxicity."*

In terms of other short-term effects, all of the following findings are quite favorable when contrasting conventional vs. e-cigarettes:

- The change in blood pressure immediately following e-cig use is just 3.5%, which is far less than the change caused by tobacco cigarettes. [Hua]
- There is no significant increase in heart rate. [Vansickel]
- No acute cardiac effects were found with echocardiography. [Farsalinos-1]
- Unlike conventional cigarettes, e-cigs do not increase inflammatory markers. [Tzatzarakis]
- E-cigarettes exert no adverse effects on CBC components. [Flouris-2]

E-cigs do generate some degree of indoor air pollution, but no significant risks are anticipated in this regard. [McAuley, Ruprecht, Schober].

Nevertheless, bet on indoor use being banned in most settings!

All of these findings are consistent with the assumption that e-cigarettes are safer than tobacco cigarettes.

TOXICOLOGY

This section looks at the concerns regarding various carcinogenic and otherwise harmful chemicals.

We know these substances are found abundantly in tobacco and account for most of its longer-term adverse impact on mortality and morbidity.

Are these substances also significantly prevalent in e-cigarettes?

> *"By the standards of occupational hygiene, current data do not indicate that exposures to vapors from contaminants in electronic cigarettes warrant a concern."*
>
> Igor Burstyn
> Drexel University School of Public Health
> BMC Public Health
> 14(2014);18

What are the key chemicals found in e-cigarettes, other than propylene glycol and glycerine (already discussed above)?

Riker listed all of these chemicals based on their detection in at least one study:

- Tobacco-specific nitrosamines – major carcinogens
- Anabasine – an alkaloid found in the tree tobacco plant
- Myosmine and beta-nicotyrine – other alkaloids
- Ethyl alcohol and its metabolite acetaldehyde
- Acetone, cresol and other volatile organic compounds
- Formaldehyde – a known carcinogen

Various researchers have looked closely at the prevalence and implications of these chemicals.

- Uchiyama found that concentrations of formaldehyde, acetaldehyde, etc., varied from none present to significant quantities, based on testing 13 e-cigarette brands. Four brands did not have any of these substances present.
- Another study showed that the levels of the most important substances cited by Riker were present at concentrations ranging from nine to fifty times lower than found in conventional cigarettes, which, in the authors' view, makes an argument for their safe use in quitting smoking. [Goniewicz-3]

- Similar findings were reported in another study. [Etter-1]
- Cahn revealed that the levels of tobacco-specific nitrosamines were minimal and similar to levels found in nicotine patches.
- In a comprehensive review of the literature by university-based public health investigators, there was no credible evidence of significant exposure to nitrosamines, polycyclic aromatic hydrocarbons (including formaldehyde) or heavy metals. [Burstyn]

While all evidence is thus far reassuring, some experts maintain that we have only limited toxicology data to date, which is *"…insufficient to allow a thorough toxicological evaluation."* [Farsalinos-2, Laugesen, Orr]

There is also huge variation between e-cigarette products, and thorough analysis of these risks will only be possible once e-cigarettes are standardized via government regulation. [Riker]

Based on the evidence at hand, the risks of exposure to these various carcinogens and other toxic chemicals with e-cigarettes appear to be at least far lower, and may in fact be negligible.
Studies to date suggest that e-cigarettes pose no greater risk in this regard than other widely used nicotine delivery systems.

NICOTINE/COTININE LEVELS IN E-CIGARETTES

The principal issue here is whether regular use of e-cigarettes will lead to a positive cotinine test based on industry cut-offs in urine and oral fluid.

Do nicotine levels vary widely by e-cig brand?

Yes.

They vary anywhere from hardly at all (1% difference) to as much as 2-fold different between brands. [Callahan-Lyon, Goniewicz-4, Riker, Trehy]

Are cotinine levels from e-cigarettes likely to be similar to those found in conventional cigarettes, assuming daily use?

The studies done on this far vary considerably:

- In one study involving 14 regular e-cigarette users who were abstinent from conventional cigarettes and stopped e-cigarette use 12 hours prior to testing, plasma nicotine levels were 17 times higher after a single use.

[Dawkins-2]

- Van Staden tested 13 cigarette smokers, averaging 20/day, who used e-cigarettes instead for 2 weeks. Cotinine levels were significantly lower after e-cigarette use than after tobacco cigarette consumption.
- In a study of 71 e-cigarette users who had no tobacco or other nicotine replacement therapy for 5 days, mean oral fluid cotinine was 353 ng/mL. The authors concluded that e-cig users took in as much nicotine as tobacco cigarette smokers. [Etter-2]
- Schroeder reported that current e-cig users had systemic cotinine concentrations similar to smokers of traditional cigarettes if they were current or former tobacco cigarette users.
- Yet another investigation concluded that mean serum cotinine levels in e-cigarette users were no different from those in tobacco cigarette smokers. [Flouris-3]
- Lechner found that e-cigarette users tend to decrease the strength of nicotine in their products despite increased frequency of use.

Based on the foregoing findings, we must assume that daily e-cigarette users seeking to quit or cut down their use of tobacco cigarettes are likely to have levels of urinary and oral fluid cotinine sufficient to cause a positive insurance screening test.

Are we likely to learn more about all aspects of e-cigarette use in the near future?

Yes.

The number of new papers is increasing.

Large studies conducted on a prospective basis are now underway. For example, Manzoll is now engaged in a 60-month assessment of 1,500 subjects, looking at tobacco cigarette cessation rates, e-cig adherence, self-reported adverse events and other endpoints.

E-CIGARETTES & THE U.S. FOOD AND DRUG ADMINISTRATION (FDA)

What are the FDA's issues with e-cigarettes?

They have stated concerns regarding: [Kuschner]

- How will they be marketed?
- Will manufacturers promote nicotine addiction, delay or derail attempts to quit traditional cigarettes, and/or encourage tobacco use among children and adolescents?
- Could flavored e-cigarettes promoted as "green" or "healthy" serve as a new "starter product" for nonusers of nicotine and tobacco?
- Will tobacco cigarette smokers who use e-cigarettes become dual users?
- Are there public health benefits – chiefly increasing the success rate in quitting tobacco cigarettes – that justify a favorable posture with regard to their use?

These concerns are different from our two main issues:

- Will e-cigarette users test positive for cotinine?
- What are the mortality and morbidity issues, if any, related to e-cigarette use?

Will the FDA regulate e-cigarettes?

They have just now announced their intention to do so. Under their plan, all brands would have to be submitted to the FDA for approval before marketing them.

E-CIGARETTES & UNDERWRITING

Is there any way for insurers to distinguish e-cigarette use from tobacco smoking?

Potentially…

Thiocyanate is a byproduct of tobacco smoking that is not elevated by nicotine use.

In studies done years ago, thiocyanate was shown to correctly distinguish between smokeless tobacco and tobacco smoking in over 80% of cases. [Sears, personal communication]

However, there are false-positive thiocyanate tests caused by various foodstuffs.
Industry labs are equipped to do thiocyanate blood testing.

Before they offer this to insurers, it would be ideal if they conducted studies to determine the efficacy of thiocyanate testing in this context.

The cost of thiocyanate reflexing is uncertain at this time, and we do not know whether cost/benefit studies will justify its use in underwriting.

Where do we stand at this writing in terms of how chief underwriters perceive the implications of e-cigarette use, and what underwriting practices are currently being used in this regard?

Please see APPENDIX A, the report of a survey conducted in June 2014.

It is also interesting to consider this comment made in an article titled "E-Cigs Cloud Life Underwriting" that appeared in the May 2014 issue of *Best's Review*:

"Due to constraints of the current testing process, e-cigarette users are, for now, classified as tobacco users. At this time, there are a few notable carrier exceptions that currently classify e-cigarette users as nonsmokers."

Josh Jackson, CAS, ALMI, ACS
Zenith Marketing Group, Freehold, NJ

One would assume that in his role as a competition analyst, Mr. Jackson's observations regarding insurers' practices are likely accurate, at least for major brokerage market carriers.

Questions to be resolved:

- Should e-cigarette users who are former tobacco smokers or, rarely, lifetime nonsmokers, be underwritten on the same basis as tobacco smokers?
- Does it matter whether cotinine is positive vs. negative?
- Should we ask specifically about e-cigarette use on applications and/or teleinterviews?
- How should we underwrite alleged e-cigarette use in simplified underwriting, where most carriers do not do cotinine testing?

SUMMARY OBSERVATIONS

Based on all of the studies reported to date, we offer the following observations for your consideration:

1. Nearly all e-cigarette users are current or former tobacco cigarette smokers.
2. Only a tiny percentage of users have never smoked tobacco, making this stipulation by applicants quite improbable.
3. Most e-cigarette users indulge in these devices either to quit smoking or cut down their tobacco cigarette use, making e-cigarettes largely another alternative nicotine delivery system.
4. Some individuals, especially at younger ages, will likely use e-cigarettes solely to consume flavored vapor without nicotine.
5. E-cigarettes can be used to smoke hashish oil and potentially other drugs of abuse.
6. Because nicotine has putative ameliorating effects on symptoms of Tourette syndrome, ulcerative colitis, Parkinson disease and (potentially) other disorders, we will encounter occasional applicants alleging they use e-cigarettes for these reasons.
7. At this time, e-cigarette use does not appear to confer insurability-significant exposures to toxic substances, including carcinogens and other byproducts of tobacco smoking.
8. Daily e-cigarette use probably leads to nicotine levels which are sufficient to cause positive urine and oral fluid cotinine tests.
9. All things considered, at this time we believe the best approach to underwriting e-cigarette use is to do it on the same basis of use of other non-tobacco nicotine delivery systems.

We expect many more studies to be published on this subject, and we will track them, reporting on those with significant underwriting implications in **Hot Notes**.

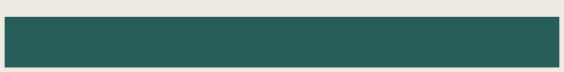
APPENDIX A: REPORT OF A JUNE 2014 SURVEY OF E-CIGARETTE PRACTICES AND PERCEPTIONS

We surveyed direct company chief underwriters that are members of our two life underwriting study groups.

This survey was completed by 25 of them.

These are the results of this survey:

1. Do you ask specifically about e-cigarette use on your fully underwritten life application?		
Yes		8.0%
No – but we plan to do so		32.0%
No – and we have no plans to do so		**60.0%**

2. What is your current fully-underwritten practice when an applicant admits to using ecigarettes and denies current use of tobacco or nicotine products?		
Accept at nonuser rates if the cotinine test is negative		12.0%
Accept at nonuser rates regardless of the cotinine test result		4.0%
Rate as tobacco user regardless of cotinine test result		**80.0%**
Other		4.0%

3. What is your current simplified life underwriting practice when the applicant says he uses e-cigarettes and does not use tobacco or other nicotine products?		
We do not offer simplified life coverage		32.0%
Accept as nonuser of tobacco		8.0%
Rate as user on same basis as cigarettes		**60.0%**

4. Does your primary reinsurer have a stated practice for underwriting e-cigarette use on automatic business?		
No		**60.0%**
Yes – and we agree with it		28.0%
Yes – but we disagree with it		12.0%

5. Please indicate if you agree or disagree with the following statements based on your knowledge of e-cigarette use.		
	Agree	Disagree
The use of e-cigarettes is increasing substantially	**88.0%**	12.0%
All e-cigarette devices contain nicotine	28.0%	**72.0%**
The vast majority of e-cigarette users are also tobacco cigarette smokers	**76.0%**	24.0%
Current tobacco cigarette smokers mainly use e-cigarettes to cut down or quit smoking	**68.0%**	32.0%
The chemicals in e-cigarettes that produce the vapor mist have major adverse implications for users	44.0%	**56.0%**
E-cigarettes have a much lower overall risk of significant bodily damage than tobacco cigarettes	**64.0%**	36.0%
Cotinine tests at current industry testing cutoffs are likely to be positive on most daily e-cigarette users	**52.0%**	48.0%
The determination of insurability for e-cigarette users who do not use tobacco or other nicotine products should be based on their cotinine level, with those having a negative cotinine test given non-tobacco rates	32.0%	**68.0%**

It is clear from this survey that there are widely differing viewpoints regarding how to underwrite e-cigarette use.

It is equally clear that the timing of this literature review paper could not have been better, considering the differences in perceptions among chief underwriters on the questions addressed here.

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