APPENDIX A – KEY INFORMANT INTERVIEW PARTICIPANTS

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APPENDIX B – SELECT RESOURCES USED BY QUITLINES

REFERENCES (Contributed by National Jewish Health)

Grana R, Benowitz N and Glantz SA. E-Cigarettes: A Scientific Review. *Circulation.* 2014;129:1972-1986 Online at http://circ.ahajournals.org/content/129/19/1972.

Polosa R, Caponnetto P, Morjaria JB, Papale G, Campagna D, Russo C. Effect of an electronic nicotine delivery device (e-cigarette) on smoking reduction and cessation: a prospective 6-month pilot study. *BMC Public Health*. 2011;11:786.

Goniewicz ML, Kuma T, Gawron M, Knysak J, Kosmider L. Nicotine levels in electronic cigarettes. 2013;15(1):158-166.

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Caponnetto P, Russo C, Bruno CM, Alamo A, AmaradioMD, Polosa R. Electronic cigarette: a possible substitute for cigarette dependence. *Monaldi Arch Chest Dis*. 2013;79(1):12-19.

Adkison SE, O'Connor RJ, Bansal-Travers M, et al. Electronic nicotine delivery systems: international tobacco control four-country survey. *Am J Prev Med*. 2013;44(3):207-215.

SCRIPT (Contributed by JSI Research and Training Institute, Inc.)

Other Tobacco Use

***Q 1 – In the past 30 days, have you used an electronic cigarette, also known as e-cigarette or vapor cigarette, such as NJOY, V2, or Blu?)**

o Yes

o No

o Don't know

o Refused

***Q 2– In the past 30 days, how many days did you use an e-cigarette?**

o 1- 30 days

o Don't know

o Refused

Q 3 What is the main reason you started using the e-cigarette?

_____

Q 4– Do you plan to quit using the e-cigarette in the next 30 days?

o Yes

o No

o Don't know

o Refused

If client answers "yes" to Q1, read the following statement after Q4:

Before we move on, I'd like to share some information with you about the e-cigarette:

- The e-cigarette is not approved by the Food and Drug Administration to help people quit smoking
- The amount of nicotine in each e-cigarette is unknown.
- The ingredients in the e-cigarette are also unknown and can be very different depending on the brand
- Because the e-cigarette is a newer product, there is not much research done about it

***Q5 – Do you want the Helpline to help you with quitting your e-cigarettes?**

o Yes

o No

o Don't Know

o Refused

POLICY/PROTOCOL (contributed by Alere Wellbeing)

Alere Position Statement on E-Cigarettes

Alere is a leading provider of tobacco cessation services to employers, government organizations and health plans via our state quitlines and Quit For Life® Program, backed by the American Cancer Society. Our programs are evidence-based and consistent with clinical guidelines. At this time, there is insufficient evidence to support the use of e-cigarettes as a cessation aid, and given the uncertainty about their safety we advise participants that we do not know if they are safe to use long-term and offer assistance to quit e-cigarettes if they are using them.

- **We strongly encourage e-cigarette users to enroll in our services for help with quitting**. We offer assistance to both traditional cigarette smokers and e-cigarette users, and those who want to quit any other tobacco product. Our Quit Coach® curriculum includes training our Quit Coach staff to be non-judgmental, educating participants on the products and how to quit using evidence-based methods.
- **Participants who report using e-cigarettes are provided assistance by Quit Coach staff to stop use of these products.** Quit Coach staff explain to e-cigarette users that it is unknown if e-cigarettes are safe to use long-term or effective as a cessation aid. Alere has adapted best practices for treating the use of combustible cigarettes for e-cigarette cessation. The treatment approach has both behavioral and pharmacological evidenced-based components that help e-cigarette users transition to therapeutic use of FDA-approved NRT.
- **We have not changed the way we report our quit rate outcomes.** We believe it is premature to consider e-cigarette only users who have quit other tobacco products to be "unsuccessful" in their quit attempt. Currently, there are no industry standards for reporting quit status among e-cigarette users. **Our primary quit outcome considers those who have quit all traditional tobacco products (combustible tobacco and smokeless tobacco) as quit; e-cigarette only users are considered quit in this calculation.** We collect data on use of e-cigarettes at follow-up and make this data available to clients who prefer to view e-cigarette only users as continued tobacco users.

Alere Recommendations on E-Cigarette Use

Alere does not endorse e-cigarette use as a safe alternative to traditional tobacco products at this time. We remain cautiously optimistic that electronic cigarettes may play a role in harm reduction and/or smoking cessation treatment in the future. We recommend that:

- **E-cigarette use not be encouraged as a way to quit smoking until there is good empirical evidence that they are effective and safe as a quitting tool.** Most of the information we have today about e-cigarette use as a cessation aid is anecdotal. What we do know is current evidence-based cessation treatment approaches backed by solid research are highly cost-effective[1]. Whether e-cigarettes are a tool that can be added to existing treatments is yet to be determined. Well-designed randomized trials will give us this information. While one e-cigarette ingredient, propylene glycol, is considered by the FDA to be "generally recognized as safe," the health effects of long-term inhalation are unknown.
- **E-cigarettes not be encouraged as a harm-reduction approach to smoking, but smokers inclined to switch should *not be discouraged* from doing so.** We simply do not know enough about the long-term health effects of e-cigarettes to *encourage* such a switch. Smoking (traditional tobacco) is still the leading cause of preventable death in the U.S.[1], but we really did not understand the true health implications of daily cigarette smoking for many years after they were commercially marketed to the general public at the beginning of the 20th century[1] [1]. Some experts suggest that the risk of e-cigarette use is far less than the use of traditional combustible tobacco and only slightly higher than Nicotine Replacement Therapy (NRT) products that are recognized as being very safe.[1]
- **E-cigarette use not be allowed in any locations where use of traditional tobacco products (cigarettes, cigars, pipes, and smokeless products) is not permitted.** While e-cigarettes do not technically produce "smoke," they do produce a vapor or aerosol that contains exhaled nicotine, flavoring compounds and other chemicals. Until long-term exposure to these ingredients is proven to be safe, non-smokers should not have to be exposed to second-hand vapor. Another reason for banning e-cigarettes in smoke-free locations is that it is very difficult to determine from a distance whether a person is smoking a traditional tobacco cigarette or an e-cigarette. This requires those in charge of enforcement to approach individuals for a close inspection, which can result in awkward situations and needless ambiguity.

Additional Information

FDA Proposed Regulations

The Food and Drug Administration (FDA) announced April 24, 2014 that it deems e-cigarettes to be within their jurisdiction to regulate, along with cigars, hookah tobacco (flavored tobacco smoked via a water pipe), and some dissolvable tobacco products not already being regulated. As of the day of the announcement, members of the public have 75

days to comment publicly on the proposed rule, after which time the FDA will finalize what regulatory action they will take. The last day to comment is August 9, 2014.

Electronic cigarettes, also referred to as e-cigs, are a disruptive technology that has challenged long-standing beliefs in tobacco control and tobacco dependence treatment about how to view nicotine delivery. There is still much to be learned about e-cigarettes and their use, and the Centers for Disease Control (CDC) and U.S. Public Health Service (USPHS) have not issued any best practices for treating e-cigarette use. Use of e-cigarettes continues to grow. Approximately 21% of adult smokers in the U.S. who smoked traditional cigarettes in 2011 had also tried e-cigarettes, as had 6.2% of all adults in the U.S. in the same year. [1]

What We Know About E-Cigarette Use Today

E-cigarettes come in a variety of shapes and sizes, but they all share several key components: a mouth piece, battery, heating element, and a solution that usually contains nicotine. When puffed on they emit a vapor that the user inhales into their mouth or lungs and then exhales, just like smoking. While this vapor looks like smoke, it is not. It is usually made up of water vapor, nicotine, propylene glycol, and may contain some flavorings. Users refer to their use of e-cigarettes as "vaping", not smoking.

E-cigarettes are not a "single" product. There are currently over 250 different brands with over 25 different nicotine strengths and 80 distinct flavorings. Moreover, the terminology for the category we think of as e-cigarettes continues to expand (e.g., e-hookahs, vapor sticks/pens, personal vaporizers). Some e-cigarette products are labeled as no nicotine.

New e-cigarette design has resulted in a range of products that may be superior in their functioning than first generation e-cigarettes. "Second generation" e-cigarettes are defined as those with higher powered batteries and a tank atomizer design that appears to be capable of delivering higher doses of nicotine and allowing the user to more fully manipulate the devices.[1] While e-cigarettes are shown to deliver less nicotine than traditional cigarettes, experienced e-cigarette users appear able to achieve systemic nicotine levels similar to those delivered by traditional cigarettes.[1] E-cigarette technology will undoubtedly continue to improve, resulting in more effective delivery of nicotine to the user.

Future directions. Alere will continue to closely monitor e-cigarette product updates, regulatory action by the FDA, prevalence patterns and scientific research. We are engaged in ongoing projects assessing e-cigarette use patterns. We will continue to communicate our findings to our clients. If we have not addressed a concern you have about electronic cigarettes in this document, please feel free to let your Client Services Manager know, and we will respond as quickly as possible.

APPENDIX C – SELECT PUBLICATIONS FROM NATIONAL SOCIETIES, ASSOCIATIONS AND EXPERTS

Borderud SP, Li Y, Burkhalter JE, Sheffer CE, Ostroff S. Electronic cigarette use among patients with cancer: Characteristics of electronic cigarette users and their smoking cessation outcomes. Cancer 2014.

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Kandra KL, Ranney LM, Lee JGL, Goldstein AO. Physicians' attitudes and use of e-cigarettes as cessation devices, North Carolina, 2013. PLOS ONE2014;9(7):e103462.

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