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Lois Biener University of Massachusetts Boston, lois.biener@umb.edu

Karen Bogen University of Massachusetts Boston, karen.bogen@umb.edu

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PREPs Surveillance

Summary of Cognitive Interviews and Recommendations for PREPs Surveillance Measures

> Lois Biener Karen Bogen

Center for Survey Research University of Massachusetts, Boston

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Introduction

Over the past decade or more, tobacco companies have introduced cigarettes and smokeless tobacco products with lower content of some toxins than their traditional counterpart products. These new tobacco products, referred to as a class as Potential Reduced Exposure Products (PREPs), have typically been introduced into test markets, not nationwide, which means they are not yet widely known or recognized by name or description by most consumers. However, the introduction of these products is of great concern to public health advocates, who do not believe that enough research, particularly long term research, has been done to know whether or not the PREPs, even if proven to have reduced toxins, actually present a reduced health risk. The fear in the public health community is that smokers who might have been motivated to quit may reverse those quit plans if they perceive an alternative safer tobacco option exists with the PREPs. Likewise, there is concern that former smokers could be tempted back to smoking and nonsmokers could be tempted to initiate smoking if they too perceive that PREPs present lower health risks than other cigarettes. Having faced a similar situation with the introduction of "light" cigarettes -- i.e., new product, insufficient research about its health implications -- public health officials are feeling cautious about PREPs and have called for development of a science to evaluate PREPs, as well as ongoing surveillance.

The Center for Survey Research (CSR) at UMass Boston, under contract to the National Cancer Institute, is charged with leading a collaborative effort to develop survey questions for monitoring population responses to PREPs.

Phase One - Review of Existing Measures

The first phase of the development effort was to review and evaluate measures that have been used to date, to recommend refinements or changes, and to propose new items to fill any gaps that may be revealed. With the input and approval of an advisory committee,¹ CSR delivered that report to NCI in August 2006.² The report provided a review and description of existing measures in eight domains:

- Awareness
- Perceptions of risk and/or harmfulness
- Trial
- Interest in trial
- Current use
- PREPs as quit aids
- Smokeless (awareness, risk, trial/current use, quit aids)
- Miscellaneous topics (government safety oversight, tobacco industry image, ad images and terminology, important qualities in switching to a new product, genetically modified tobacco).

¹ Jack Fowler, Gary Giovino, Lynn Kozlowski, Stephen Marcus, Anne McNeill, Rich O'Connor, Mark Parascandola, Linda Pederson, Gordon Willis.

² <u>PREPs Surveillance: Summary of Existing Survey Measures and Recommendations for Ongoing Efforts</u>, by Lois Biener, Karen Bogen, and Catherine F. Garrett, Center for Survey Research, UMass Boston, August 2006.

The second part of the report provided recommendations for development of surveillance items. The report also discussed the need for a separate line of research on communications measures, to see how the population may respond to variations in marketing of PREPs. However, that is seen as a more long-term need, and, instead, the report focused on the more immediate need for population surveillance measures for ongoing tracking in order to detect important trends that could have public health implications. The report presented two strategies for ongoing surveillance -- one approach depended on respondent recall and the other on respondent recognition of PREPs.

Phase Two

With input from our advisory group, we developed a single instrument that combined the recall and recognition approach, to be evaluated by means of two waves of cognitive interviews.

Goals

The goals of the cognitive interviewing were to answer the following questions:

- Do respondents understand the questions as intended?
- Do the questions appear to elicit accurate answers as to questions on
 - o awareness of PREPs
 - o perceptions of their harmfulness relative to conventional products
 - o interest in use?

In addition, we included a number of items that sparked the interest of members of our advisory group:

- How do perceptions of NRT and PREPs compare in terms of harmfulness?
- How are today's cigarettes perceived relative to those smoked 50 years ago?
- Would respondents who have any interest in using smokeless PREPs consider using them instead of smoking, as a stop-gap when smoking isn't permitted or as a stepping stone towards quitting?

Methods

We completed two rounds of cognitive interviews of the test instrument. We interviewed seven people in January 2007 in the Boston, MA area and nine people in Austin, TX in February 2007. Austin was selected because it is a test market for Camel Snus and Skoal Dry, two of the new smokeless products that are lower in nitrosamines than both cigarettes and conventional smokeless tobacco. Copies of the instruments used in the first and second rounds of testing are contained in Appendix A and Appendix B respectively. Appendix C contains a table detailing the differences between the two versions on PREPs surveillance items.

Respondents

We attempted to select respondents who fit the following smoking status/gender/age specifications:

- approximately two-thirds current smokers and one-third former smokers,
- half male and half female, and
- about one-third in each of age groups 18 to 24, 25 to 44, and 45+ (but we limited former smokers to those under 45).

One of the nine Austin respondents was clearly untruthful about her smoking status, making us skeptical of the rest of the data she supplied, so we have excluded her data from our analyses. This left us with 15 respondents, as shown in Table 1.

		AGE		
		18-24	25-44	45+
Current smoker	Male	1	2	2
	Female	2	2	2
Former smoker	Male	2	1	-
	Female	-	1	-

Table 1. Number of cognitive interview respondentsby smoking status, gender, and age

Seven of the 15 had tried smokeless tobacco at some point in their life. One was a current user of smokeless tobacco as well as being a smoker. Two-thirds of the respondents were non-Hispanic white and the remaining were of minority status. Fourteen of the 15 had some education beyond high school.

Process

The Boston-area respondents were recruited by CSR. Some of the respondents came from a pool of participants that CSR has used or screened for other projects; the pool was compiled from responses to newspaper advertisements and craigslist postings over the past few years. All respondents were screened for no participation in CSR's tobacco-related research in the past two years, in order to eliminate people who had gained some familiarity with PREPs as a consequence of contact with CSR's previous research. Other respondents were recruited from flyers posted on UMass campuses in Boston and Dartmouth. The interviews were completed by Lois Biener, Karen Bogen, and a field interviewer who has been trained in cognitive interviewing techniques. The January interviews were completed in private office space at CSR or in respondents' homes.

The Austin respondents were recruited by the Office of Survey Research (OSR) at the University of Texas, Austin. OSR placed an advertisement in a widely-read, local, free weekly newspaper. The interviews were completed by Karen Bogen and Lois Biener in conference rooms at OSR.

Respondents in both cities were paid \$50 for their participation. The interviews, which were conducted using concurrent think-aloud techniques, took approximately 45 minutes to complete, on average. All interviews were audio-taped with participants' permission.

Results and Recommendations on Measures

Measuring Awareness of Combustible PREPs

Questions:

Recall

C1. New types of cigarettes are now being developed that are supposed to be less harmful than ordinary cigarettes. Have you heard of such products?

C1a. (If yes) Can you recall any brand names of these products?

C1b. (If yes) Please tell me the names of any you recall.

Recognition

C2. I'm going to read you some names of some (other) relatively new cigarettes. For each one, please tell me whether or not you have ever heard of it.

Results:

In our cognitive interviews, six of 15 people said Yes to the recall question (C1) about combustible PREPs. Of those, two recalled the name of legitimate PREPs; in probing about these, the two respondents provided appropriate descriptions of the brands that made us believe they were legitimate in their recollection. A third person who said Yes to the recall question could not recall any brand names but described PREPs in a way that makes us believe she really is aware of them (i.e. she reported that they were lower in carcinogens, and that she'd seen a TV documentary about them). The three other people who said Yes to the combustible PREPs recall question went on to name non-PREPs like American Spirit, Winston No Bull, nicotine products, and even Newport Lights.

Therefore, we conclude that a recall question must be followed by a brands question in order to eliminate false awareness. Of the six respondents who said Yes to the combustible PREPs recall question, we believe that only three really are aware and of them, only two could actually name a legitimate combustible PREPs brand. Our recommended strategy -- a YES/NO recall question followed by a name-a-brand question -- would lead to misclassification, as unaware, of one person who may actually be aware. However, without the follow-up brands question, we would have misclassified as aware three people who said Yes to the recall question but who went on to name things that are not PREPs and are, thus, not really aware of PREPs.

Looking more broadly at our 15 respondents, this recommended strategy would conclude that 13% are aware of combustible PREPs (2 of 15 respondents). We believe that number should really be 20% (3 out of 15). Hence this strategy under-estimates true awareness by 33%. That could potentially be alleviated with open-ended follow-up probes as used in the cognitive interviews, but this is probably not feasible in a national data collection. Not asking brand

follow-up, relying exclusively on the yes/no awareness question, would lead one to conclude that 40% (6 of 15) were aware of PREPs, over-estimating true awareness by 100%.

For the recognition questions, the most interesting story is about the false reports. We included distracter brand names -- two out of seven brands listed in the January interviews and three out of eight brands listed in the February interviews were made-up brand names. We did this because past research suggests that respondents may confuse legitimate PREPs brands with names that are shared with other products (e.g. Eclipse gum, Accord cars, Omni hotels). In our interviews, 10 of the 15 people made 12 mentions of recognized brands, but half of those mentions were for our distracter, made-up products -- three said they "recognized" Kool Silver and three "recognized" Westin. As a result of this high level of false recognition, we are doubtful of the reports of actual PREPs because two mentions were for Eclipse and two were for Marlboro Ultrasmooth, both of which could be confused with other products and be "recognized" by virtue of their familiar-sounding names. Probes into what was recalled about the recognized brands (legitimate and bogus) yielded no convincing information that would lead us to believe that the respondent was truly aware of the PREPs.

Considering only the recognition responses (ignoring recall for the moment, even though recognition would be different if it did not follow recall), we would conclude that 4 out of 15 people were aware of combustible PREPs, based on just those who said they recognized a real PREP. Having the distracter names on the lists works as a benchmark as to how much name recognition is about just that, the name, and not about the specific product. We recommend retaining the recognition series, including the distracters, as a way to monitor changes over time in the prominence of particular brands in the future, but we do <u>not</u> recommend using these data to estimate current awareness of combustible PREPs at this time. As awareness increases, and the false reports drop to a small proportion of recognized brands, it will be time to consider how to combine the recall and recognition results as a new measure of awareness.

Measuring Awareness of Smokeless PREPs

Questions:

<u>Recall</u>

January interviews

C7. New types of smokeless tobacco products are now being developed that are put in the mouth, but don't involve chewing or spitting. *Some of these are supposed to be less harmful than ordinary smokeless tobacco*. Have you heard of these products?

C7a. (If yes) Can you recall any brand names of these products?

C7b. (If yes) Please tell me the names of any you recall.

February interviews

C7. New types of smokeless tobacco products are now being developed that are put in the mouth, but don't involve chewing or spitting. *Some come in teabag-like pouches and some come in the form of a lozenge or tablet*. Have you heard of any products like this?

C7a. (If yes) Can you recall any brand names of these products?

C7b. (If yes) Please tell me the names of any you recall.

Recognition

C8. I'm going to read you some names of some (other) relatively new smokeless tobacco products. For each one, please tell me whether or not you have ever heard of it.

Results:

In reviewing awareness of smokeless PREPs, it is important to consider the results from the two sets of interviews separately because the question changed in important ways (italicized above) and also because Austin is a test market for one of the new smokeless PREPs and the results were very different from in Boston, where awareness was minimal.

Only one Boston respondent said Yes to the smokeless PREPs recall question (C7) and, in the follow-up question, that person named Commit, which is an NRT product, not a tobacco product. Essentially, then, no one in Boston recalled a smokeless PREP, that is there was no awareness whatsoever based on recall. With regard to recognition, one person thought he had heard of Skoal Dry and one recognized Camel Snus. There is no way to know whether these recognitions are legitimate or whether they are simply recognition of a familiar brand name. No one claimed to recognize the two distracter products, "Newport Bold" and "Assert".

In February in Austin, however, all eight respondents said "yes" to the recall question. Five of these people named either Camel Snus (4 people) or a Skoal product (2 people). Of the three who could not recall a brand name, one recognized "Stonewall" and described the product accurately. This person also reported knowing about "dip in bag" in response to a probe. The other two did not recognize any of the brand names and probes elicited no awareness of any kind of new smokeless tobacco product. If we accept "yes" followed by a correct brand name recalled as awareness, we would conclude that five of the eight people in Austin (63%) were aware of smokeless PREPs. The actual estimate for Austin should be 75% (6 of 8 respondents), including the individual who clearly knew about Stonewall, so this strategy underestimates awareness in a test market by about 17% (1 of 6).

* <u>RECOMMENDATION for measuring awareness of PREPS</u>

We recommend that awareness of PREPS, both combustible and non-combustible, be measured using the recall question, followed by the request to name a brand, so that non-PREPs can be eliminated. We also recommend including the recognition series, including distracter names, as a way to monitor changes in both real and likely false recognition of PREPs.

Measuring perceptions of harmfulness of PREPs

Questions:

Three-level comparative ratings

C3. Would you say (Combustible Brand) is more harmful, less harmful or as harmful to the smoker as ordinary³ cigarettes?

C9. Would you say (Smokeless Brand) is more harmful, less harmful or as harmful to the user as ordinary smokeless products?

C10. Would you say (Smokeless Brand) is more harmful, less harmful or as harmful to the user as ordinary³ cigarettes?

<u>0 to 10 scale</u>

C14. Think about a scale numbered from 0 to 10, where 0 means there is no health risk at all and 10 means it poses an extremely high health risk. For each product I name, please tell me where you would put it on the 0-10 scale.

Results:

Both of these methods performed well in that responses to probes indicated that people were on track with our definitions of what "harmfulness" referred to and they found the rating task a reasonably easy one to perform. Nevertheless, since very few people were actually aware of combustible PREPs, and the perceived harm questions were asked only of those who were aware, we didn't get many ratings of them. The two respondents who were categorized as aware, rated them as equally harmful as conventional cigarettes. At the ratings item, one of these respondents was consistent with her "equally harmful" answer, giving the PREP and regular, full flavor cigarettes, and light cigarettes all the same ratings (7). The other person was not consistent, giving the PREP cigarette a much higher rating (8) than lights (4), even though she said they were equally harmful.

More respondents (5) were aware of smokeless PREPs, and therefore rated their perceived harmfulness. Three of the five rated them as equally harmful as conventional smokeless; two rated them as less harmful. The reduced harm was attributed to being a controlled dose and having less contact with skin because it was in the pouch, or in a tablet form. Two of the five rated smokeless PREPs as being more harmful than conventional cigarettes, two rated them as less harmful and one as equally harmful. Those who viewed smokeless PREPs as more harmful than cigarettes expressed concern about the consequences of swallowing the juice. Those viewing it as less harmful referred to the absence of smoke in the lungs or lung cancer. In almost every case, the two types of harmfulness ratings were consistent with the 0 to 10 ratings obtained for all products at the end of the interview.

³ Boston respondents were asked to compare to "ordinary light cigarettes"; Austin Rs were asked to compare to "ordinary cigarettes." See Appendix C for an explanation of the change.

The January interviews used either the "ladder" or the "scale" language in describing the 0 to 10 ratings. Respondents seemed to have a slight preference for the "scale" language as it was more common, so the "ladder" language was dropped for the February interviews.

***** <u>RECOMMENDATION for measuring perceived harmfulness of PREPs.</u>

We recommend using either a 3-point scale to get comparative ratings of PREPs against a standard of "ordinary cigarettes" and "ordinary smokeless products" or a 0 to 10 scale with the end-points labeled "no health risk at all" and "an extremely high health risk". In using the 0 to 10 scale it is important to include ratings for the standards against which the researcher desires to assess perceptions of PREPs harmfulness. The choice between the 3-point scale and the 0-to-10 scale would depend on the level of sensitivity that was desired. In addition to the greater sensitivity provided by the 0 to 10 scale, it eliminates ambiguity inherent in the term "ordinary cigarettes" by providing more specific products against which PREPs can be compared.

Measuring interest in trying PREPs

Questions:

C5. If a new cigarette were developed that was scientifically proven to be less harmful than ordinary cigarettes, how likely would you be to try it? Would you say very likely, somewhat likely, not very likely, or not at all likely?

C12. If a new spitless, smokeless tobacco product were developed that was scientifically proven to be less harmful than ordinary cigarettes, how likely would you be to try it? Would you say very likely, somewhat likely, not very likely, or not at all likely?

Results:

These questions performed well. The respondents answered them readily and provided appropriate answers to probes about how they had decided on their answer and what "scientifically proven" meant to them. Eight of the 15 respondents, all of them current smokers, indicated that they would be at least somewhat likely to try a new safer cigarette. Many indicated that they would want to see how it tasted, implying that if it didn't taste good enough, they would not continue with it. On the other hand, only three of the 15 participants, again all of them current smokers, indicated that they would be at least somewhat likely to try the new smokeless product. Most of the others found the notion of smokeless tobacco very distasteful. In our very small sample of 4 former smokers, all were "not at all likely" to try a smokeless product that was safer than cigarettes, but two were "not very likely" to try a "safer" cigarette.

* <u>**RECOMMENDATION**</u> for measuring interest in trying PREPs.</u>

We recommend retaining these questions for measuring interest in trying PREPs, recognizing that as long as awareness and access to these products is low, what we are probably measuring is willingness to experiment with the product. Willingness of former or never users of tobacco to try the products is probably a good indication of their appeal and potential for promoting relapse or initiation.

Other Interesting Results

Perceived harmfulness of conventional tobacco products and NRT

All respondents were asked to rate harmfulness of conventional tobacco products and NRT on the 0 to 10 scale where 0 indicated no health risk and 10 was associated with an extremely high health risk. The average ratings for the 15 respondents are shown in the table.

Product	
Unfiltered regular, full-flavor cigarettes like unfiltered Camels or Lucky Strike	
Filtered regular, full-flavor cigarettes like Marlboro reds or Salem	
Light cigarettes like Marlboro lights or Camel lights	
Ultralight cigarettes like Marlboro ultralights or Carlton	
Chewing or spit tobacco like Copenhagen or Skoal fine cut	7.8
Nicotine Patch	4.9
Nicotine Gum	3.8

It is noteworthy that the average risk associated with conventional smokeless tobacco was higher than that perceived for light cigarettes and nearly as high as filtered regular, full-flavor cigarettes. In fact, the majority of the respondents (10 of the 15) incorrectly rated conventional smokeless tobacco as either equally harmful or more harmful than light cigarettes. Probes indicated that oral cancer, dental problems, and facial disfigurement were prominent in their concerns about smokeless tobacco.

NRT was rated as less risky, on average, than tobacco products. However, the nicotine patch was rated as either equally or more harmful than light cigarettes by 4 respondents and nicotine gum was rated as equally or more harmful than light cigarettes by 3 of the 15.

Perceptions of today's cigarettes

Respondents were asked whether they thought "the cigarettes that most people smoke now are more harmful, less harmful or as harmful as cigarettes smoked fifty years ago." Six thought that today's cigarettes were more harmful due to more chemicals, preservatives and additives. Five thought they were less harmful today because of the filters and the ultralights. Others weren't sure (3) or thought they were equally harmful (1).

How would respondents use a safer smokeless tobacco product?

Since only 3 respondents indicated any willingness at all to use a smokeless PREP, they were the only ones who responded to C13 asking whether they would consider using them instead of

smoking, as a stop-gap when smoking isn't permitted or as a stepping stone towards quitting. All three endorsed use as a stepping stone towards quitting.

Unresolved Issues and Additional Surveillance Needs

Definition of a PREP

In order to monitor awareness of PREPs, we need some agreement about what constitutes a PREP. The most straight-forward definition would be "a tobacco product which is claimed by the manufacturer to entail reduced exposure to toxicants." The problem with this is that many of these products are not currently being advertised as having reduced exposure. To an important extent, the design of the surveillance items being recommended in this report is determined by current PREPs marketing practices. Specifically, because the new snus products are not being advertised as less harmful than cigarettes, the awareness question does not include a statement that they are "supposed to be" or "claim to be" less harmful. Most of the combustible PREPs for which awareness is being assessed were advertised as less harmful during the time that they were being actively marketed, so the awareness question recommended here does include the language about reduced harm. However, current marketing strategies are likely to change. Philip Morris did not make any health claims while test-marketing Marlboro Ultrasmooth, and the Eclipse and Advance web sites, which two years ago featured extensive health claims, are no longer readily accessible. This issue complicates assessment of awareness of PREPs because although the public health community may be aware that the product design suggests an effort to reduce exposure to particular toxins, the general public may be unaware of that effort while still being aware of the new product.

The clearest way to monitor population awareness and perception of PREPs may be to separately assess the following factors: 1) awareness of brands known to the scientific community to be PREPs; 2) exposure to tobacco advertising messages for these brands; 3) exposure to information from other sources claiming tobacco products that may be less harmful than cigarettes; and 4) individual perceptions of relative harm of various products.

Surveillance of the use of other products as harm reduction devices

In addition to the PREPs covered in this report, there are a variety of other products that may be believed to be less harmful than cigarettes, and which may be used by consumers in an effort to reduce their tobacco-related health risks. These include medicinal nicotine, other non-tobacco nicotine products, various tobacco products that claim to be "natural" (i.e. have no additives), etc. A thorough understanding of population perceptions about ways to reduce the risks of smoking (aside from quitting), along with the prevalence of behaviors believed to reduce risk, would be a useful endeavor.

Conclusions

A review of existing research on population awareness of potentially reduced exposure tobacco products (PREPs) as well as results of cognitive interviews suggest that awareness of PREPs is quite low at this time, except in active test-markets. In order to monitor changes in awareness and perceptions of, and receptivity to these products over time, we have proposed using a set of questions as well as coding conventions that appear to result in reasonably accurate estimates of awareness of a particular group of products. The recommended items, which performed will in cognitive interviews, are presented in Appendix D of this report. It must be acknowledged that this report is limited by the need to restrict the number of respondents and by the fact that those included were of relatively high socio-economic status. Prior to any large scale use of these survey items, we recommend that further pre-tests be done using other survey modes (telephone and self-administered), and that an effort be made to include respondents with lower levels of education, and with greater cultural diversity