2018

Measurement Methods of Dual Tobacco Use Behaviors: Cigarettes and Smokeless Tobacco

Colleen N Warren

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Measurement Methods of Dual Tobacco Use Behaviors: Cigarettes and Smokeless Tobacco

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Thesis submitted
to the Eberly College of Arts and Sciences
at West Virginia University

in partial fulfillment of the requirements for the degree of

Master of Science in
Psychology

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Morgantown, West Virginia
2018

Keywords: smokeless tobacco, dual use, smoking, cigarettes, tobacco, measurement

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ABSTRACT

Measurement Methods of Dual Tobacco Use Behaviors: Cigarettes and Smokeless Tobacco

Colleen N. Warren, M.A.

Cigarette use in the United States is decreasing while use of other tobacco products is increasing. As other tobacco products such as smokeless tobacco (SLT) have become more popular, concurrent use of tobacco products is becoming a phenomenon in need of further study. In order to study such behavior, researchers must have valid and reliable measurement methods. The current study contributed to this necessity by providing an evaluation of the validity and reliability of non-manipulated measurements of daily behaviors of West Virginian dual cigarette-SLT users including retrospective self-reports, prospective self-monitoring, and biochemical sampling.

The results included data from 52 adult dual cigarette-SLT users in West Virginia. This observational study employed a longitudinal design over 14 consecutive days with laboratory visits on Days 1, 3, 9, and 15. Outcome measures included global self-reports of cigarette and SLT use at screening, prospective reports of cigarette and SLT use via electronic diary, collected butts from cigarettes smoked, and salivary cotinine samples. Global retrospective reports of CPD and SLT use per day were reliable, but not valid since they are over-estimated, while days SLT was used per week could be valid, but is not reliable when reported retrospectively. Cigarette butts collected and prospectively logged CPD are valid and moderately reliable, as long as participants are held to firm compliance standards. Prospectively logged days of SLT use per week is valid, but dips per day is not, and neither are reliable measures. Salivary cotinine is likely valid, but logged dips per day affects its correlation with total product use prospectively. These findings need to be further studied to determine true validity when there are significant differences between measures.

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Abbreviations:

CI (confidence interval)

CO (carbon monoxide)

CPD (cigarettes per day)

DPD (dips per day)

DPW (days per week)

ED (electronic diary)

EMA (ecological momentary assessment)

ICC (intraclass correlation)

IVR (interactive voice response)

LC-MS/MS (liquid chromatography-tandem mass spectrometry)

Mini-IPIP (Mini-International Personality Item Pool)

NCHS (National Center for Health Statistics)

NSDUH (National Survey on Drug Use and Health)

PD (paper-and-pencil diary)

SLT (smokeless tobacco)

TLFB (time-line follow-back)

USDA (United States Department of Agriculture)

Measurement Methods of Dual Tobacco Use Behaviors: Cigarettes and Smokeless Tobacco

Current Landscape of Tobacco Use in America

Overall, cigarette use in the United States is declining. Specifically, smoking among adults aged 18 and older has decreased from 20.9% in 2005 to 15.1% in 2015 (CDC, 2016a). Simultaneously, rates of use of other tobacco products have either remained unchanged or increased for this same age group. For instance, use of smokeless tobacco (SLT) has increased in men from ~4% in 2000 to ~6.7% in 2014 (CBHSQ, 2015). As of 2014, ~3.4% of American adults are SLT users (CBHSQ, 2015). Rates of SLT use in West Virginia are notably higher than this national average, with ~8.5% (9 out of 100 adults) using this form of tobacco (CDC, 2016b).

Moreover, many tobacco users regularly use multiple products concurrently, a phenomenon known as dual (two tobacco products) or polytobacco use (more than two tobacco products). Increases in the concurrent use of multiple products have been observed over the past two decades. For instance, data from 2002 to 2011 of the National Survey on Drug Use and Health showed a significant increase in dual use of cigarettes and SLT during that time (Fix, et al., 2014).

Dual cigarette-SLT use within the state of West Virginia has also been on the rise, with significant increases observed from 2011 (6.4%) to 2013 (8.4%) (Nguyen, Marshall, Hu, & Neff, 2015). It is important to note that there are differing definitions of dual use, ranging from using both products daily, to one product daily but the other product nondaily (Klesges, et al., 2011). The current study will employ use of the latter definition, specifically individuals who use cigarettes daily but SLT on a nondaily basis. Cigarettes remain the most widely used tobacco products (NCCDPHP, 2014), and smokers are more likely to use other tobacco products than

nonsmokers (McMillen, Maduka, & Winickoff, 2012). In WV, 12% of smokers use SLT, and 30.5% of SLT users also smoke (WVPRC, 2014).

Dangers to dual users of cigarettes and SLT are great. Both products can expose users to carcinogens like tobacco-specific nitrosamines (USDHHS, 2014). Smoking causes cancer, cardiovascular disease, stroke, diabetes, lung disease, chronic obstructive pulmonary disease (COPD), emphysema, chronic bronchitis, and male erectile dysfunction (CDC, 2017a).

Similarly, SLT use can cause cancers of the mouth, esophagus, and pancreas, along with gum disease and tooth decay (CDC, 2017b). When used in combination however, the risks of these conditions greatly increase. For instance, dual users of cigarettes and SLT have been found to be at an increased risk for acute myocardial infarction when compared with cigarette-only smokers (Teo et al., 2006) and may be exposed to greater levels of nicotine. Risks to these diseases are reduced when tobacco users quit; however, cessation is difficult because of exposure to the dependence-producing drug nicotine. Moreover, dual users experience higher nicotine dependence and prevalence of withdrawal symptoms during quit attempts when compared to smokers (Post, Gilljam, Rosendahl, Bremberg, & Galanti, 2010), so they may be less likely to attempt (Tomar, Alpert, & Connelly, 2010) and achieve tobacco cessation (Wetter et al., 2002).

Given these increased health risks associated with dual cigarette-SLT use, it is important to understand the associated behaviors. However, the current understanding of dual use derives primarily from surveys. That is, no work exists that follows dual users throughout their typical day. Since these surveys suggest that the dual use phenomenon is increasing, and since dual users are less likely to quit using tobacco than users of cigarettes-only or SLT-only (Wetter et al., 2002), it is necessary to understand these relatively new patterns of tobacco use. These survey data demonstrate the relatively high rates of dual use and that dual use of cigarettes and SLT is

on the rise. In order to determine how to best address dual use of these products, it is necessary to characterize the natural patterns. In particular, measurement of the patterns of dual users over a period of time are needed. Thus, the current study was designed to meet such a goal.

Methods of Measuring Tobacco Use

Given that additional information is needed about dual users, it is vital to have valid and reliable measurement methods. Tobacco use is typically measured using the following methods: retrospective self-reports, prospective self-monitoring, and biological fluid sampling. Each of these measurement methods, including their strengths and weaknesses, is described briefly below.

Retrospective self-reports. Retrospective self-reports ask that respondents report on their tobacco product use by thinking back over a specific period of time and recalling their behaviors. A common assessment of cigarette smoking is a global question of tobacco use, for which a participant gives a single answer that essentially estimates their use over a period of days/weeks/months. Such questions include the following: “How many cigarettes do you smoke on each day of a typical week?” (Bailey, et al., 2012), “How many cigarettes per day, on average, do you smoke?” (Blank et al., 2016), “Have you smoked at least 100 cigarettes in your life?” (Gilpin & Pierce, 2003), and “On how many of the past 30 days did you use cigarettes?” (Gilpin & Pierce, 2003). Similar questions have also been used to assess SLT use such as, “On how many of the past 30 days did you use smokeless tobacco?” (Gilpin & Pierce, 2003). Yet, SLT use is more challenging to measure by self-reported items than cigarettes because of the nature of the product. Cigarettes, for example, have standardized packaging such that all packs include 20 cigarettes, and each cigarette is of roughly the same size and weight. In contrast, SLT products come in different forms (i.e., loose leaf, pouched) and thus the amount of SLT in a

“dip” or “chew” is not uniform among users. For loose leaf SLT, users can pinch as much as they prefer at a time, while for pouched SLT the amount is pre-determined. These product packaging differences have led some researchers to develop questions based on the number of “dips” or “chews” used over a specified period of time (regarding how many tins/cans are used per week; Ferketich, Wee, Shultz, & Wewers, 2007; Mushtaq, Beebe, & Vesely, 2012, or “On average, how many dips/chews do you take each day?”; Boyle, Jensen, Hatsukami, & Severson, 1995), the duration of use of each individual “dip” or “chew” (“On average, how many minutes do you keep a fresh dip or chew in your mouth?”; Boyle et al., 1995) and the duration of use of an entire container of SLT (“How many days does a tin/can last you?”; Boyle et al., 1995).

Another method of retrospective reporting used is the timeline followback (TLFB) approach in which an interviewer asks a participant to think retrospectively about their tobacco use, but guides them by giving anchors such as dates, holidays, work schedule, or personal events to help them remember each day more accurately (Gariti, Alterman, Ehrman, & Pettinati, 1998; Duhig, Cavallo, McKee, George, & Krishnan-Sarin, 2005). This method is adapted from a method created by Sobell, Sobell, Leo, and Cancilla (1988) originally used for alcohol measurement. A participant gives an answer for each individual day over a period of days/weeks/months, similar to filling in a calendar of tobacco use. Thus, they provide many answers which are then averaged to produce a single tobacco use estimate (Gariti et al., 1998). This method has been used to assess cigarette use over the past 30 days (Duhig, et al., 2005). It has been found that individuals are fairly consistent when reporting their cigarettes smoked per day (CPD), whether assessed via a global question or TLFB (Blank et al., 2016; Gariti et al., 1998; Fals-Stewart, O’Farrell, Freitas, McFarlin, & Rutigliano, 2000). For instance, high test-retest reliability (Pearson $r = 0.86$) has been observed when participants are asked to provide

their average number of CPD via a global question administered via telephone and then again in-person (Blank et al., 2016).

Interactive voice response (IVR) reports have also been used for retrospective self-reporting, in which a participant places a phone call at given times to report on their behaviors. For example, participants have been asked to call in to a toll free number each morning for seven days in a row to answer questions about their smoking behavior by typing numerical responses on their phone keypad, and this reporting method was compared with TLFB (Toll, Cooney, McKee, & O'Malley, 2005). Over the seven days, 84% of requested IVR reports were made, compared to 96.3% of TLFB reports, and only 49.9% of the sample provided complete IVR data compared to 93.2% providing complete TLFB data. It was found that there were declines in IVR compliance over the seven days (Toll et al., 2005). Both IVR and TLFB were described as having poor sensitivity, (i.e. correctly identifying individuals who have smoked as smokers) but good specificity (i.e. correctly identifying those who have not smoked as nonsmokers). Both methods were significantly correlated when reports for each of the seven days and the total sum of smoked cigarettes reported for the seven days were analyzed (i.e. Day 1: $r(109) = 0.84$, Total: $r(44) = 0.99$; Toll et al., 2005). IVR, however, is subject to memory biases in two ways: participants must reflect and report on their behaviors over the time elapsed since the last call, and participants must remember to call in at the instructed times.

In any of these abovementioned retrospective reporting measures, participants may over- or under-estimate their CPD, possibly because of rounding to the closest multiple of five per day (Clark, Gautam, Hlaing, & Gerson, 1996). This rounding, also called digit bias or heaping, is a form of self-report bias where individuals tend to round an estimate to a multiple of five, and is frequently observed in studies of cigarette smokers (Shiffman, 2009; Klesges, Debon, & Ray,

1995; Lewis-Esquerre et al., 2005). This rounding may occur because of cigarettes being sold as 20 per pack. Specifically, when asked about CPD, smokers will often answer with “about a half pack,” “around a pack,” “a pack and a half,” or “two packs a day.” Instead of giving a possibly more accurate 18 or 22, CPD will just be reported as a pack, or 20. Surveys with self-reported averages continue to be used frequently, especially for screenings for studies with tobacco users (Clark et al., 1996; Blank & Eissenberg, 2010; Perkins, Jao, & Karelitz, 2012; Blank et al., 2016). For studies in which a more observational approach is needed, or data during a certain time period is necessary, a retrospective report cannot be used, so a prospective self-monitoring method may be employed.

Prospective self-monitoring. Prospective self-monitoring requires participants to monitor their behaviors as they occur during a specified period of time, such as throughout a typical day. This measure of tobacco product use often includes the use of logs or journals, in paper-and-pencil (Hatsukami et al., 2011; Hurt et al., 1994; Perkins et al., 2012; Collins, Kashdan, & Gollnisch, 2003; Stone, Shiffman, Schwartz, Broderick, & Hufford, 2003) or electronic formats (Collins, et al., 2003; Shiffman, 2009; Gwaltney, Bartolomei, Colby, & Kahler, 2008; Stone, et al., 2003). Both forms of logs allow for ecological momentary assessments (EMA), or the assessment of a behavior in real time and in the tobacco users’ natural environment (see Ferguson & Shiffman, 2011 for review). For instance, cigarette smokers have been asked to carry a paper-and-pencil log called a “tally card” that fits inside of their cigarette pack so that they easily record their behavior each time they choose to smoke. Over three consecutive days, daily CPD tallies were found to be correlated ($ICC = 0.78$; Perkins et al., 2012). In other work, smokers may be asked to record their cigarette use via an electronic device such as a mobile phone which houses specialized software for behavior measurement

(Chandra, Scharf, & Shiffman, 2011; Shiffman et al., 1997) or a hand held computer (Gwaltney, et al., 2008). For example, participants have been trained to use electronic diaries (ED) to monitor smoking over two weeks. The ED would additionally randomly prompt participants a few times per day (Shiffman et al. 1997). While these methods can be helpful by not requiring a participant to recall behaviors retrospectively, therefore preventing digit bias, it cannot always be verified that entries are recorded in real time. For instance, a paper-and-pencil diary can be filled in after a behavior is performed (e.g., multiple cigarettes smoked earlier but logged at a time later in the day). Some diaries can have time- and date-stamp capabilities when entries are made, but there is still no verification that the entry occurred when the behavior occurred, or that the responses are truthful. For example, in a 21-day study, some participants were given an ED and some were given a paper and pencil diary (PD), both of which had time-stamp capabilities (Stone et al., 2003). They were asked to complete entries at three specific times throughout the day and report the time that they completed them. The PD was a binder that recorded the time/date only when the binder was opened and closed, not specifically when an entry was made. Therefore, it could not accurately provide when an entry was made, but when an entry was not made. Participants in the PD group were not told that the binder could record the time and date, so that compliance could be analyzed. Participants in both groups were told that recording anywhere within 15 minutes before or after the requested times were acceptable. In this paradigm, *reported* compliance was when a PD was completed and the time the participant reported was within the acceptable time frame. *Actual* compliance was when the PD was completed and the time stamp verified that the participant-recorded time was possible. *Faked* compliance was when there was a discrepancy between reported and actual compliance. It was found that reported compliance was 90.5%, but actual compliance was only 10.9%, resulting in faked compliance being 79.5%. In the

ED group, actual compliance was 93.6%. Faked compliance was not possible in this group since the device only allowed for reports to be completed during the acceptable time frame. Actual compliance was significantly higher for the ED group than the PD group, and actual compliance declined significantly from week 1 to week 3 in the PD group, while the ED group's actual compliance did not significantly change over time (Stone et al., 2003).

Another method that has been used to prospectively measure tobacco use is the recording of used and/or unused products. For smoking, participants have been asked to return their butts from those cigarettes smoked so that they can be counted (Blank & Eissenberg, 2010; Clark et al., 1996; Etter & Perneger, 2001). In one study, the butts were not only counted, but also measured with a ruler to estimate how much of the cigarette was actually smoked by the participant (Clark et al., 1996). In another study, participants were given a daily supply of cigarettes, and were required to return both the used (i.e. cigarette butts) and unused (i.e. cigarettes not smoked) cigarettes for comparison (Blank & Eissenberg, 2010). A similar approach has been used in studies of SLT use. For example, participants have been provided up front with tobacco pouches or tobacco lozenges and instructed to record the amount of product they used throughout each day in a diary. They returned any unused products to the laboratory for comparison to their diary logs (Hatsukami et al., 2011). While this method may not be subject to digit bias, it has several limitations. Participants could share products with others and/or fail to store products used. To measure this potential discrepancy, researchers can use a cutoff for the number of products "missing" relative to the number given (Blank & Eissenberg, 2010). In one study, participants were removed if their total used plus unused products was different from the amount of product provided to them for study use (Blank et al., 2016).

Biological sampling. The use of tobacco can also be measured via examination of biological specimens that contain carbon monoxide (CO) (Blank & Eissenberg, 2010; Joseph et al., 2005; Hurt et al., 1994; Gray, Breland, Weaver, & Eissenberg, 2008), nicotine (Hurt et al., 1994; Gray et al., 2008), or cotinine (Chandra et al., 2011; Hurt et al., 1994; Blank & Eissenberg, 2010; Breland, Acosta, & Eissenberg, 2003; Clark et al., 1996; Boyle, et al., 1995; Gray et al., 2008).

CO is found in expired air, measured with a device into which a participant breathes. This measure provides a nonintrusive, quick, and simple method to assess the use of a combustible product like cigarettes. Thus, expired air CO is unable to detect use of non-combustible tobacco products like SLT. Because CO has a short half-life, it has been found that 12 ppm is a reliable indicator of someone having smoked within the past eight hours (Sandberg, Skold, Grunewald, Eklund, & Wheelock, 2011). This short half-life makes CO a good indicator of cigarettes smoked recently, but a poor indicator of smoking behavior over the course of days.

Nicotine and cotinine, a metabolite of nicotine, can be detected in saliva (Binnie et al., 2004; Shiffman, 2009; Lewis-Esquerre et al., 2005; Mushtaq et al., 2012; Ferketich et al., 2007; Boyle et al., 1995), urine (Blank & Eissenberg, 2010; Joseph et al., 2005), blood serum (Bright, Civalier, & Krahn, 2010; Clark et al., 1996), and plasma (Jarvis, Primatesta, Erens, Feyerabend, & Bryant, 2003). Fortunately, these measures can be used to detect use of either cigarettes and/or SLT, given that both of these products contain nicotine. However, if a participant uses multiple nicotine products, there is not a way to parse out specific usage of each. Although nicotine is only reflected in blood for a matter of hours, cotinine is reflected for a few days, making it the more robust method to assess daily use (Benowitz, 1996). This provides a better method for measuring habitual use, rather than acute use, of nicotine-containing products as the levels

reflected will not be from nicotine used that same day. These methods cannot be influenced by participant memory or compliance, but they are expensive to analyze.

Summary. All the above mentioned methods of measurement have their own strengths and weaknesses, and thus it is important to compare them in terms of their reliability and validity. While there has not been a comprehensive comparison of all methods, some studies have begun comparing some methods to determine the best ways in which to monitor tobacco use.

Measurement Method Comparisons

Measurement methods for cigarette use are more prevalent, and have been more widely studied than those for SLT use. The below sections serve to describe studies that have compared directly multiple measurement methods of interest for use of either product.

Comparison of smoking measurement methods. Global self-reports of cigarettes smoked per day have been compared to numerous other smoking measures in previous work. For example, global self-reports have been found to be associated significantly with prospective reports in the form of tally card-type daily logs (Perkins et al., 2012), retrospective daily reports using the TLFB method (Gariti et al., 1998), and cigarette butts returned (Blank et al., 2016; Clark et al., 1996). In each of these cases, average CPD as measured by a global self-report question has been correlated positively with average CPD as measured by the aforementioned measure. Significant correlations have also been found between global self-reported CPD and biochemical measures of expired air CO (Joseph, et al., 2005), urinary cotinine (Joseph et al., 2005; Binnie et al., 2004), salivary cotinine (Binnie et al., 2004; Etter & Perneger, 2001), and serum cotinine levels (Vartiainen, Seppala, Lillsunde, & Puska, 2002; Bright et al., 2010). Still, in a study that compared self-reported CPD with biological samples, linear associations were not

found for CO or cotinine (Joseph et al., 2005). Similarly, another study that compared global self-reported CPD, returned cigarette butts, and cotinine levels over five days, found that while global self-reported CPD did not significantly differ from mean butt counts, global self-reported CPD was not significantly associated with baseline cotinine levels or change in cotinine levels over the course of the study (Blank et al., 2016). Therefore, correlations between global self-reported CPD and biochemical measures are not as reliable since over- and under-estimations of biological levels have been observed when global self-reporting is used (Joseph et al., 2005). Global self-reports have also been analyzed with respect to test-retest reliability. Specifically, it has been found that when mean global self-reported CPD are requested at telephone recruitment interviews and again at in-person screening, these global reports are significantly positively correlated ($r = 0.86$; Blank et al., 2016). These studies suggest that global self-reports are a valid method to predict CPD, especially for the purposes of characterizing average daily behaviors like for use of screening participants, but may not be a valid method to predict tobacco-specific toxin levels.

Prospective monitoring methods have also been compared to other smoking measures. For example, in a study where participants were asked to log each time they smoked over three weeks using an ED, CO readings were found to be positively associated with number of cigarettes entered in the past 24 hours ($r = 0.43$; Gwaltney et al., 2008). Each time the participants visited the study site, their CO was taken and their ED was reviewed for any entries over the past 24 hours. On 100% of days where CO was greater than 5 ppm, a cigarette had been reported using the ED. On days where no cigarettes had been reported as smoked in the past 24 hours, CO readings were consistently under 5 ppm (Gwaltney et al., 2008). In another study, participants used an ED to log smoking behavior for a period of two weeks and these reports

were compared with TLFB, CO, and cotinine levels (Shiffman, 2009). It was found that mean CPD reported using the ED were significantly correlated with TLFB reports ($\beta = 0.77$), and that within-subject daily reports were less, but still significantly, associated between ED and TLFB ($\beta = 0.29$). Mean ED reports were significantly associated with salivary cotinine levels ($\beta = 0.41$), and on days where CO was taken at the study site, the number of cigarettes reported on the ED over the previous two hours was significantly correlated ($\beta = 0.23$; Shiffman, 2009). In paper-pencil prospective measures, the mean CPD of daily smoking reported on tally cards over three consecutive days was highly related to retrospective global reports of CPD at screening ($\beta = 0.78$), and the daily CPD tallies were found to be correlated across days ($ICC = 0.78$; Perkins et al., 2012).

Tobacco products returned per day, specifically returned cigarette butts, have been previously compared to other smoking measures. For example, cigarette butts returned have been shown to be significantly correlated with mean self-reported CPD in some studies (Clark et al., 1996; Blank et al., 2016), but not all (Etter & Perneger, 2001). In a recent comparison study where consolidated data from three studies over five days were analyzed, there was a significant linear association between daily butt counts and cotinine levels found ($\beta = 39.89$), and butt counts were not significantly different from self-reported CPD (Blank et al., 2016). In terms of consistency across days, cigarette butts returned were collapsed and compared across the four days that they were collected ($ICC = 0.66$, Chronbach's $\alpha = 0.89$), and difference scores revealed that cigarettes varied by $\pm 20\%$ of the global self-reported CPD (Blank, et al., 2016).

Cotinine has been measured in smokers and nonsmokers via unstimulated and stimulated saliva for comparison with self-reported smoking or self-reported tobacco smoke exposure. It was found that cotinine levels significantly differed between smokers and nonsmokers in the

biological samples, and there was a significant dose-response relationship between self-reported CPD and cotinine in the saliva samples (Binnie et al., 2004). Cotinine levels have also been shown to have a significant linear association with daily butt counts ($\beta = 39.89$; Blank et al., 2016) and global self-reports of CPD (Binnie et al., 2004; Etter & Perneger, 2001), ED reports ($\beta = 0.41$; Shiffman, 2009), and TLFB reports ($\beta = 0.38$; Shiffman, 2009).

There is a lack of knowledge about test-retest reliability and changes over time in salivary cotinine levels. There also needs to be better documentation of correlations between days and changes over time in ED reporting. Importantly, cigarette-only users have been well-observed as participants. With dual use rising, it is important to understand if the measurement methods used for smokers will produce similar results in the dual use population. It is also necessary to investigate if these methods can similarly be used to measure SLT use.

Comparison of SLT use measurement methods. In one study, a single saliva sample was collected from each participant, and correlations were run between the cotinine concentrations and self-reported items via a questionnaire that included questions about SLT use. It was concluded that global self-reports of years of SLT use were significantly, positively related to salivary cotinine levels (no coefficient reported), while no correlation was found between self-reported cans used per week and salivary cotinine ($\rho = 0.10$; Ferketich, et al., 2007). Another study requested that participants mail in a saliva sample for cotinine analysis and a completed questionnaire regarding SLT use. When simple linear regressions were used to explore associations with single items, it was found that cotinine concentrations were significantly associated with retrospectively self-reported years of SLT use ($\beta = 0.378$), everyday SLT use ($\beta = 9.31$), number of chews/dips per day ($\beta = 0.896$), and number of cans used per week ($\beta = 1.223$; Mushtaq et al., 2012). Although another study's focus was on comparing SLT

users' tobacco dependence with cotinine levels, a noteworthy descriptive finding was reported. Salivary cotinine levels (although it is not reported if one sample was provided by each participant or if a mean over time was taken for each participant) were significantly correlated with retrospectively self-reported dips/chews per day ($r = 0.21$) and number of tins used per week ($r = 0.20$; Boyle et al., 1995).

Other comparisons among the SLT measures of interest are lacking. SLT measurements commonly used are blood (Agaku & King, 2014; Ebbert et al., 2004; Rostron, Chang, van Bommel, Xia, & Blount, 2015) or urine (Blank & Eissenberg, 2010) for biological sampling purposes, and researchers have compared measures of use to nicotine dependence (Mushtaq et al., 2012; Ferketich et al., 2007; Boyle et al., 1995). SLT measurement comparisons have not been conducted at all with daily diary recording. This lack of information in the current literature emphasizes the field's need for the proposed study.

While many researchers have made great strides in measurement comparisons, more comprehensive comparisons of these methods are needed.

Statement of Problem

While cigarette use is declining in America, the use of SLT and its concurrent use with cigarettes are increasing. Because of the many negative health-related outcomes, this is a behavior that needs further study. There are various measurement methods used to investigate smoking and SLT use behaviors, but their reliability and validity are not yet known. Therefore, in order to allow for further studies, such as those that could more directly benefit health effects, treatment options, and cessation protocols, better understanding of the patterns of dual use and an assessment of the associated measurement methods' reliability and validity are vital to the advancement of the field. None of the aforementioned studies can take place if there is no way to

measure the behaviors being addressed. For example, if we do not have a good way to measure, and therefore do not know how much someone is smoking, how do we know if they actually reduce cigarette intake? Also, if we are trying to titrate, how do we know where to start? The current study can be referenced by researchers who are trying to learn more about the different measurement options so that they can choose the most suitable method of measurement for their purposes. The current longitudinal study of West Virginian dual cigarette-SLT users meets the need to understand more about the reliability and validity of measurement methods by utilizing several measures that include retrospective self-reports, prospective self-monitoring, and biochemical sampling. Specific outcome measures utilized include global, retrospective self-reports of CPD and SLT use, prospective daily diary logs of tobacco use behaviors using an ED, returned cigarette butts, and salivary cotinine samples. The data derived from a 14-day study (the longest period of time yet used for observation of dual users) that required laboratory visits on Days 1, 3, 9, and 15. This observational study not only is the first of its kind to provide information about daily dual tobacco use behaviors, but also provides novel data regarding the reliability and validity of the included measures.

Current Study

The current study evaluated the reliability and validity of five measures of cigarette use and four measures of SLT use. It is especially novel because of its comprehensive use of self-reported average tobacco use (retrospective self-reports), electronic daily diaries (prospective self-monitoring), returned product counts (prospective self-monitoring), and salivary cotinine (biological measure). Additionally, this study was longitudinal over 14 days, while the most similar study to date (regarding its combination and comparison of measurement methods) combined data from participants of three different studies for only five days to make some of

these comparisons (Blank, et al., 2016). Finally, it observed behaviors of dual users, rather than users of only cigarettes or SLT. Since dual use is on the rise, it is important to better understand these users' daily behaviors and if they respond differently to measurement methods than users of only cigarettes or SLT.

Specific Aim #1: Assess reliability and validity of five measures of cigarette use:

1. Global, retrospectively self-reported average CPD at telephone screening
2. Global, retrospectively self-reported average CPD at in-person screening
3. Daily diary log of cigarettes smoked per day over two weeks
4. Cigarette butts returned per day over two weeks
5. Salivary cotinine levels

Hypothesis 1: Average number of cigarettes per day will be correlated positively between global self-reports from telephone and in-person screening interviews (Blank, et al., 2016; Clark et al., 1996).

Hypothesis 2: Number of cigarettes smoked per day will be correlated positively for self-reports via electronic diary across days (Blank, et al., 2016; Perkins et al., 2012).

Hypothesis 3: Average number of cigarettes smoked per day will not differ significantly between global self-reports at the in-person screening and electronic diary logs, collapsed across days of the observation period (Shiffman, 2009; Blank, et al., 2016).

Hypothesis 4: Number of cigarette butts returned will be correlated positively across days during the observation period (Blank, et al., 2016, Clark et al., 1996).

Hypothesis 5: Average cigarettes smoked per day will not differ significantly between global self-reports at the in-person screening and returned cigarette butts, collapsed across days of the observation period (Blank, et al., 2016; Clark et al., 1996).

Hypothesis 6: Number of cigarettes smoked per day will correlate positively between electronic diary logs and returned cigarette butts on each day of the observation period.

Specific Aim #2: Assess reliability and validity of four measures of SLT use:

1. Global, retrospectively self-reported average SLT use at telephone screening
2. Global, retrospectively self-reported average SLT use at in-person screening
3. Daily diary log of SLT used per day over two weeks
4. Salivary cotinine levels

Hypothesis 7: Average number of SLT uses per day will correlate positively between global self-reports from telephone and in-person screening interviews (Blank, et al., 2016; Clark et al., 1996).

Hypothesis 8: SLT uses per day will be correlated positively for self-reports via electronic diary across days (Blank, et al., 2016; Perkins et al., 2012).

Hypothesis 9: Average number of SLT uses per day and average number of days SLT was used per week will not differ significantly between global self-reports at the in-person screening and electronic diary logs, collapsed across days of the observation period (Shiffman, 2009; Blank, et al., 2016).

Hypothesis 10: The average total number of tobacco products (cigarettes plus SLT uses) logged via electronic diary will correlate positively with average salivary cotinine levels collapsed across days of the observation period.

Method

Participants

Participants

Seventy two participants gave informed consent and completed the in-person screening questionnaire. Sixteen participants were determined to be ineligible to participate at the in-person screening for reasons that included excessive alcohol use, e-cigarette use, illicit drug use, alternative tobacco product use, insufficient CO readings, insufficient SLT uses per day or week, reduction in tobacco use behaviors over the past month, and psychiatric disorder diagnosis. At the session on Day 3, four participants either quit the study or were discontinued for failure to record product use. Thus, all procedures and analyses described in this study include the 52 participants who completed at least one week of data collection.

Sample characteristics. Participants were 52 dual users of SLT and cigarettes recruited from three counties in the state of West Virginia. Recruitment locations included Monongalia County (n=37), Raleigh County (n=14), and McDowell County (n=1). Demographic characteristics of completed participants are reported in Table 1 and their tobacco use characteristics are reported in Table 2. According to the Mini-IPIP, the sample showed no overall trends indicating extremes in regards to the Big Five personality traits (agreeableness, conscientiousness, openness, extraversion, neuroticism). Means were around 3 for all traits, on a scale of 1 to 5 (Table 1).

Inclusion criteria. Participants were required to be between 18 and 60 years old, report smoking at least five cigarettes per day for at least one year, and report use of SLT at least twice per day for at least four days per week for at least the past six months. At the in-person screening visit, participants had to provide an exhaled CO level of at least 7 ppm and yield a urinary cotinine level of at least 3, or 100 ng/mL (Accutest NicAlert, Encino, CA). These cutoffs were used to verify that the participants were regular users of both cigarettes and smokeless tobacco. These inclusion criteria are outlined in Appendix A.

Exclusion criteria. Participants were excluded from the study if they reported diagnosed schizophrenia or bipolar disorder or were pregnant or breastfeeding at the time of the study, as exposure to nicotine/tobacco can be harmful to a fetus or infant (Bardy, et al., 1993; Schulte-Hobein, Schwartz-Bickenbach, Abt, Plum, & Nau, 1992). They were also excluded if they reported use of marijuana more than five days in the past month, other illicit drugs in the past three months, or consumption of alcohol more than 15 days out of the past month. They were excluded if they reported use of other tobacco products besides SLT and cigarettes (e.g., waterpipe/hookah, electronic cigarettes, cigars, etc.) on a weekly basis, as this would affect biological measurements and confound the tobacco use behaviors that were being studied. Use of cessation medications (e.g., nicotine replacement products, Chantix[®], etc.) or attempts to reduce nicotine/tobacco use at the time of the study were also cause for exclusion. These exclusion criteria are outlined in Appendix B.

Recruitment and Screening

Recruitment. To recruit participants, IRB-approved advertisements were posted to websites (e.g., Craigslist, Facebook community and employment groups) and local classifieds (e.g., Ol' Mountain Trader, Southern WV). Flyers were posted around the West Virginia University campus and at locations in the counties where recruitment efforts were focused (e.g., Monongalia County, Raleigh County, McDowell County). Potential participants also heard about the study by word-of-mouth.

Screening. Individuals who responded to advertisements were provided with a description of the study purpose and requirements via telephone (see Appendix C). Those who were interested in participating then completed an initial telephone-based questionnaire (see Appendix D) that inquired about their general health status and history of substance use. If this

screening revealed that the individual may be eligible to participate, they were scheduled to visit the laboratory for a more detailed in-person screening. Specifically, individuals completed the IRB-approved consent process (see Appendix E), answered additional health- and substance-related questions (see Appendix F) including the Fagerstrom Test for Cigarette Dependence (Appendix G; Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991) Severson Smokeless Tobacco Dependence Scale-Short Form (Appendix H; Ebbert, Severson, Danaher, Schroeder, & Glover, 2012), and Mini-International Personality Item Pool (Appendix I; Donnellan, Baird, & Lucas, 2006). Although the Mini-IPIP was administered as part of the screening questionnaire, it was simply used to determine if any personality trends existed in our sample. This 20-item measure assessed the Big Five personality traits: agreeableness, conscientiousness, openness, extraversion, neuroticism. Participants were asked to respond to statements indicating how well that statement described them on a scale of 1 (Very Inaccurate) to 5 (Very Accurate). Also as part of the screening requirements, participants provided a urine sample for cotinine analysis and provided an expired breath sample to measure CO (PiCO+ Smokerlyzer, CoVita, Haddenfield, NJ). If all of these measures determined that the participant was eligible, the participant began the study on that same day.

Study Design

The current study used a prospective, longitudinal design to observe participants over 14 consecutive days. During this two week period, they used an electronic diary to log their use of cigarettes and SLT throughout each day. They also collected the butts from all cigarettes smoked, as well as collected a sample of their saliva each night for later measurement of cotinine. These materials were returned to the laboratory on Days 3, 9, and 15. All of these

measurements were compared within and across days, and to retrospective reports of cigarette and SLT use at the in-person screening visit.

Study Procedures

Day 1. An eligible participant was first trained on how to use the electronic diary. This training involved how to a) log cigarettes smoked and SLT used, b) respond to “random prompts,” c) suspend the device when unavailable, d) respond to wake and bedtime reports, and e) record their collection of a saliva sample. They were also provided with an instruction packet to reference as they engaged with their electronic diary over the duration of the study. Each of the electronic diary features is explained in detail below:

Logging products. The participant was instructed to either select “Cigarette” or “Chew” on the screen of the electronic device each time they used that particular tobacco product. After a cigarette was entered, the screen would often then show the statement, “A cigarette has been logged,” which completed the action. When a chew was logged, the participant would also be asked to answer questions about the type and amount of SLT product used before, “A chew has been logged” was shown and the action was completed. Sometimes, however, an interview would commence, where the participant answered questions about feelings, craving, environment, and behaviors (measures not reported here) at the time that the choice was made to smoke or use SLT. The number of these interviews per day depended on the reported frequency of use at screening.

Responding to “random prompts.” The participant was made aware that the electronic diary would prompt them to respond to random interviews throughout the day. Specifically, the ED would vibrate or “beep” to alert the participant that an interview was ready to be completed. These questions pertained to feelings and symptoms of tobacco use (measures not reported here)

at that point in time. There were four to five random prompts throughout the day to ensure that participants were engaging with the device regularly. These procedures modeled previously published procedures (Carter et al., 2010; Ferguson & Shiffman, 2011; Gwaltney et al., 2008; Shiffman et al., 2002).

Suspending the device. Participants were instructed to suspend the electronic diary if they were unable to answer prompts (e.g., while driving, in a meeting, in the shower, taking a nap) and to unsuspend when they were able to respond again. To do this, the participant selected the “Suspend” option on the screen and selected an amount of time for up to two hours. This setting prevented the electronic diary from prompting them to complete a questionnaire when they were unavailable, so that their compliance rate was not affected. In this study, participants were required to have at least 80% compliance to remain in the study.

Responding to wake and bedtime reports. The participant was instructed to answer the wake and bedtime reports that appeared each morning and evening, respectively. These reports asked general questions about feelings (measures not reported here) throughout the day.

Recording saliva sample collection. When the bedtime report was available, a reminder to collect the saliva sample also appeared on the screen. The participant simply selected the option, and selected “Yes” when asked if the sample was collected.

Participants were then trained on the use of the saliva kits and were given an instruction page for reference when they collected their sample each night. They were also trained on the collection and storage of the butts from those cigarettes smoked. Participants thus left the laboratory with an electronic diary, two days’ worth of saliva kits, three days’ worth of cigarette butt collection cups, and written instructions. At the end of this training session, participants

were scheduled for the next in-person visit on Day 3 of the study. They were reminded to bring their electronic diary and collected cigarette butts, and saliva swabs to the next visit.

Day 3. On Day 3, participants' electronic diary, cigarette butts, and saliva samples were collected. Saliva samples were counted and then stored at -80 degrees for later analysis of cotinine (Thermo Fisher Scientific). Cigarette butts were also counted and then logged for each study day. Next, data from the electronic diary were downloaded for compliance checks. For instance, returned butt counts were compared to the number of cigarettes logged on the electronic diary to examine reliability of reporting. Compliance with responding to random prompts was also evaluated. In this study, participants were required to have at least 80% compliance to remain in the study. Participants whose compliance was suboptimal were either given a warning or discontinued. Cutoffs for determining compliance were based on a combination of all requirements. For instance, if a participant was not collecting cigarette butts, had low random prompt compliance, or was not logging cigarettes, they could be dismissed. If they were collecting butts and logging cigarettes, but random prompt compliance was only 70%, they may be given a warning that if their compliance does not increase at Day 9, they will be dismissed. Participants who were able to remain in the study were then provided with seven additional cigarette butt cups, six additional saliva kits and the electronic diary. They were compensated \$50 and were reminded to return all materials to the laboratory at their next visit, which was scheduled for Day 9 of the observation period.

Day 9. On Day 9, all procedures were identical to those on Day 3. For those participants whose compliance was suboptimal on Day 3, an evaluation of their improvement with following the study requirements was conducted. Participants who continued the study were given six additional cigarette butt cups, six additional saliva kits, and their electronic diary. They were

compensated \$100 and their appointment for Day 15 was scheduled. They were again reminded to bring all materials to the next appointment.

Day 15. On Day 15, the final laboratory visit, all materials were collected and checked for compliance. Participants were also asked to complete a questionnaire about their motivations for and beliefs about SLT use (Appendix J). Compliant participants were paid their final compensation of \$150, totaling \$300 for the entire study.

Outcome Measures

Cigarettes per day.

Self-reports. At both the telephone screening and the in-person screening, participants reported their average number of cigarettes smoked per day. Both interviews used the same question to report this behavior, “*On average, how many cigarettes do you smoke per day?*” Participants responded to this questionnaire verbally via telephone and in writing via the in-person screening.

Diary logs. On the electronic diary, participants were instructed to log every cigarette smoked throughout the day. This measure therefore provided the number of cigarettes logged each day for the 14 consecutive days of the study.

Returned cigarette butts. On Days 3, 9, and 15, butts from those cigarettes smoked and stored in pre-labeled containers for each day of the week were returned to the laboratory. The butt counts for each study day of the 14-day period were used as a measure of daily smoking behavior.

SLT uses per day.

Self-reports. At both the telephone screening and the in-person screening, participants reported their pattern of SLT use. The questions used at both screenings are as follows: “*On*

average, how many days per week do you use that [SLT] product?” and “On the days that you use that product, about how many dips/chews/pouches do you use?” Together, these questions provided a measure of daily and weekly SLT use.

Diary logs. On the electronic diary, participants were instructed to log each SLT use throughout the day. This measure gave us the number of times SLT use was logged each day for the 14 consecutive days of the study.

SLT Motivations/Beliefs Survey. To learn more about our sample, a survey regarding motivations and beliefs about SLT use was administered at the end of the study (Appendix J). Seven items adapted from a previous study (McClave-Regan & Berkowitz, 2011) inquired about motivations for SLT initiation and current use, beliefs regarding the harmfulness of SLT compared to cigarettes, and beliefs regarding the potential helpfulness of SLT for smoking cessation. Specifically, participants were first asked why they initiated use of SLT, and then why they currently use SLT with response choices of: To improve health, To assist with quitting smoking, To use in places where I can't smoke, and Other. For these first two questions, participants could select all answer choices that applied. Participants were then asked to indicate how they thought the harmfulness of snuff/dip/chew compared with cigarettes, and how they thought the harmfulness of Snus compared with cigarettes. For both of these questions, participants could select: More, Less, Same, or I don't know. They were then asked if they thought snuff/dip/chew helped smokers quit cigarettes, and if they thought Snus helped smokers quit cigarettes, with the response choices of: Help, Do not help, or I don't know. Finally, they were asked if it was true or false that they use SLT in places where they cannot smoke. For each of these questions, participants could select only one answer choice.

Salivary cotinine. Participants were instructed to collect their saliva samples around the same time each night. They were instructed to abstain from eating, drinking, and brushing their teeth for an hour before taking the sample. When taking the sample using the kit provided (SalivaBio, State College, PA), they were required to rinse their mouth with water, wait 10 minutes, place the saliva swab under their tongue for two minutes, place it in the tube labeled with their participant number and the correct day, and store it in their home freezer. All samples were expected to be returned to the laboratory at their visits on Days 3, 9, and 15.

These procedures obtained a saliva sample of greater than 1 mL for extraction and liquid chromatography-tandem mass spectrometry (LC-MS/MS) analysis. Samples were thawed to room temperature, and 0.05 mL of saliva was combined with deuterated internal standard, base, and 90:10 methyl-t-butyl ether:tetrahydrofuran. The samples were evaporated and reconstituted for injection into the LC-MS/MS where the cotinine was monitored using multiple reaction monitoring (MRM) and chromatography was completed (Cappendik, et al., 2010). All analyses were handled by the Bioanalytical Laboratory at Virginia Commonwealth University (Richmond, VA).

Data Analyses

For comparative analyses of measurement methods, IBM SPSS Statistics version 24 was used and alpha values were set at $p < 0.05$, unless a Bonferroni correction was used, as is specified when appropriate. The data was inspected for outliers, which were defined as being outside of three standard deviations from the mean (Brownlee, 2018). Since all data that could be considered statistical outliers were still realistic data and did not appear to be errors, all analyses were first run with them. For example, a statistical outlier for Day 8 could technically be 31 CPD, but 31 was not statistically an outlier for all the other days of logged CPD, and was within

the range of cigarette butts returned in the study, so it was likely still real data. No data of 70 CPD, for example, were found, which may be considered unrealistic because of a typo or noncompliance. However, when analyses were surprising or odd, outliers were assessed to see if they explained the results, and no outlier-based explanations appeared.

For all analyses, only the data of participants who were in the study for at least seven days were included (n=52). Throughout the results, it may be noticed that some analyses have a lower sample size than this 52. Missing data were excluded from all analyses. For example, some individuals had data for Week 1 but not Week 2 (six participants were removed for noncompliance at the Day 9 compliance check). Some participants failed to return butts or log tobacco use on certain days, so the paired samples t-tests have different sample sizes across the 14 days. For example, in such a case where a participant may have failed to turn in butts on a specific day, they would not have been excluded for all analyses, but would have been excluded for that day's t-test comparing logged CPD to returned butts.

The following analyses were used to test the hypotheses.

Cigarette Smoking

Test-Retest Reliability of Global, Retrospective Self-Reports. A bivariate Pearson correlation was used to compare average CPD as measured by global self-reports at telephone versus in-person screening interviews.

Consistency of Cigarette Use across Days. Two-way random effects, absolute agreement, single rater/measurement Intraclass Correlations (ICCs) (Koo & Li, 2016) were run with 95% Confidence Intervals (CIs) across days 1 through 14, 1 through 7, and 8 through 14 to evaluate smoking consistency across days for the daily diary and cigarette butt measures (Blank et al., 2016).

Validity of Global, Retrospective Self-Reports versus Prospectively Logged

Cigarettes versus Returned Butts. Paired samples *t*-tests were used to compare global, self-reported average CPD at in-person screening with average cigarettes recorded in daily diaries, collapsed across study days. Similarly, global, self-reported average CPD at in-person screening was compared with average cigarette butts returned, collapsed across study days, by using a paired samples *t*-test. A bivariate Pearson correlation was used to compare average diary reports of smoking with average cigarette butts returned, collapsed across study days. Finally, 14 paired samples *t*-tests were used to compare logged CPD in the daily diary with returned cigarette butts for each of the 14 study days. These 14 paired samples *t*-tests were run with Bonferroni corrections with alpha values set at $p < 0.00357$. Because some researchers claim that Bonferroni corrections may be too conservative (Columb & Sagadai, 2006; Newman, 2009; Schwager, 1984), these analyses were also run without Bonferroni corrections.

SLT Use

Test-Retest Reliability of Global, Retrospective Self-Reports. A bivariate Pearson correlation was used to compare global, self-reported average SLT uses per day at telephone screening with global, self-reports at the in-person screening.

Consistency of SLT Use across Days. To evaluate consistency of SLT use recorded in daily diaries, two-way random effects, absolute agreement, single rater/measurement Intraclass Correlations (ICCs) (Koo & Li, 2016) were run with 95% Confidence Intervals (CIs) across days 1 through 14, 1 through 7, and 8 through 14.

Validity of Global, Retrospective Self-Reports versus Prospectively Logged SLT Use. Paired samples *t*-tests were used to compare global, self-reported average SLT uses per day and per week at in-person screening with average SLT uses logged in daily diaries, collapsed

across study days. Note that the screening questionnaire included separate questions for estimating the number of SLT use episodes per day and per week. Therefore, an average of how many days per week a participant logged using SLT was constructed for each participant. Another mean of the number of logged SLT uses per day (only using the days that SLT was used) was constructed for each participant. Each of these constructed means was used for analyses to compare with the global reports.

Dual Use

Validity of Global, Retrospective Self-reports versus Salivary Cotinine Levels. A bivariate Pearson correlation was used to evaluate the average total number of tobacco products reported (sum of cigarettes and SLT) in daily diaries with average salivary cotinine levels, collapsed across study days. Specifically, a mean was constructed for each participant from all the daily sums of tobacco products recorded. Another mean was constructed for each participant from all daily salivary cotinine levels. Therefore, a single correlation between those two constructed means was performed from data collapsed across the observation period.

Results

Descriptive statistics were calculated for participant demographics (Table 1) and tobacco use characteristics (Table 2). Briefly here, participants were primarily single, White, non-Hispanic males around 30 years old who had completed a high school education (Table 1). Participants reported having smoked, on average, 20 CPD for about 11 years, and having used SLT about five times per day, six days per week, for around nine years. The most common types of SLT used were snuff and dip. Participants' average scores on the dependence scales were 5.98 (SD = 2.61) on the FTCD and 8.69 (SD = 3.91) on the Severson scale (Table 2), indicating moderate levels of dependence for both cigarettes and SLT.

Cigarette Smoking

Test-Retest Reliability of Global, Retrospective Self-Reports. Global, self-reported CPD at telephone screening was significantly correlated with ($r(46)=0.833, p<0.001$), and not significantly different from ($t(46)=-1.568, p=0.124$) global, self-reported CPD at in-person screening. See Table 4 for means and standard deviations. Given these findings, the in-person screening reports were used for subsequent analyses that involved a global, self-report measure of smoking behavior.

Consistency of Cigarette Use across Days. Mean logged CPD via electronic diary was significantly greater for Week 1 ($M=11.89, SD=5.99$) than Week 2 ($M=9.64, SD=5.61$), $t(44)=3.514, p<0.001$. No significant differences were found between mean returned cigarette butts in Week 1 ($M=11.28, SD=5.12$) and Week 2 ($M=10.51, SD=5.20$), $t(45)=1.762, p=0.085$.

ICC's (95% CI's) across study days 1-14 were 0.565 [0.451, 0.690] (Cronbach's alpha = 0.954) for logged cigarettes and 0.591 [0.487, 0.703] (Cronbach's alpha = 0.957) for returned cigarette butts. A similar pattern of results was observed when ICC's were run separately for Days 1-7 and 8-14. For logged cigarettes, the ICC's (95% CI's) were 0.588 [0.474, 0.704] (Cronbach's alpha = 0.916) and 0.647 [0.530, 0.762] (Cronbach's alpha = 0.928) for these periods, respectively. For returned cigarette butts, the ICC's (95% CI's) were 0.537 [0.423, 0.657] (Cronbach's alpha = 0.899) and 0.677 [0.569, 0.780] (Cronbach's alpha = 0.943).

Difference scores showed that logged cigarettes differed across days by at least 20% of the global, self-reported CPD for 50 (98%) of 51 participants. Similarly, difference scores showed that returned cigarette butts differed across days by at least 20% of the global, self-reported CPD for 51 (98%) of 52 participants.

Validity of Global, Retrospective Self-Reports versus Prospectively Logged

Cigarettes versus Returned Butts. Table 5 displays paired samples *t*-test results for comparisons between measurement methods. As shown in this table, mean global, self-reported CPD was significantly different from mean logged CPD, collapsed across study days ($p<0.001$). A similar pattern was observed when mean global, self-reported CPD was compared to mean returned cigarette butts, collapsed across study days ($p<0.001$). For both comparisons, mean global, self-reported CPD at in-person screening was significantly greater than prospective measures (see Table 4 for means and SDs).

When diary logs were compared with returned cigarette butts (Table 5), it was found that mean logged CPD, collapsed across study days ($M=10.43$, $SD=5.14$) had a strong positive correlation with and was not significantly different than mean daily returned cigarette butts, collapsed across study days ($M=10.87$, $SD=4.70$).

After the means were compared, fourteen paired samples *t*-tests (with Bonferroni corrections, with alpha values set at $p<0.00357$) were run between each day of returned cigarette butts and logged CPD (Table 5). It was found that logged CPD were positively correlated (also with Bonferroni corrections applied) with and did not significantly differ from returned cigarette butts on all days except for Days 2, 9, and 11. These analyses were also run without Bonferroni corrections, and no new significant differences appeared. The days that significantly differed were inspected for any explanations that could be made regarding these findings. On Day 2, there were no outliers identified that could explain this finding. On Day 9, participants returned to the lab for a compliance check, so some participants were ultimately discontinued on this day. Specifically, there were six participants with missing data for returned products, who were then discontinued because of noncompliance. There was still data recorded for that day on the ED,

however this would have only been for the day up until the lab visit, and would not have included the part of the day after the visit, but there were not returned products. This likely caused the significant difference for this day. On Day 11, there were no outlier identified that could explain the significant findings.

Difference scores between cigarette butts and global, self-reports showed that all participants over- or under- returned butts by 20% or more on at least one study day during the two-week period. Additionally, 26 (50%) participants consistently returned fewer cigarette butts than the number of cigarettes reported via global self-reports. Only one participant consistently returned more cigarette butts than was shown via global self-reports.

A similar pattern of results was observed when difference scores were calculated between logged cigarettes and global self-reports. Specifically, all participants over- or under-reported cigarettes by 20% or more, at least once. It was found that 34 (65%) of the participants consistently logged fewer cigarettes than they had self-reported at screening. No participants consistently logged more cigarettes than their global, self-reported CPD.

Comparisons between global self-reports and prospective measures (diary logs and returned butts) were also made using calculations of heaping and the Whipple's index. For global, self-reported CPD, substantial heaping was observed. As shown in Figure 1, the most commonly reported average number of CPD using this measurement method was 20 (n=13), followed by 30 (n=12), and then 15 (n=6). Whipple's index further shows that these reports were rounded to 0 or 5 over four times greater than expected (Table 3). In contrast, this pattern was not observed when prospective measurement methods were used. As examples, Figures 2 and 3 depict the frequency of returned cigarette butts and logged cigarettes, respectively, for Day 5 of the study. Day 5 was selected since it included all participants' data that were included in the

analyses, since participants used in the analyses provided at least one week of data. Day 5 was representative of most of the days of the study since Days 2, 9, and, 11 were the days that provided different findings. For cigarette butts, the most common numbers returned were 6 ($n=6$), 16 ($n=5$), 7 ($n=5$), and 4 ($n=5$). Similarly, for diary logs, the most common numbers logged were 7 ($n=8$), 4 ($n=5$), 6 ($n=4$), and 9 ($n=4$). Consequently, Whipple's index shows that logs and returned butts fit the expected distribution of values.

SLT Use

Test-Retest Reliability of Global, Retrospective Self-Reports. Global self-reported dips per day (on days that SLT is used) for telephone and in-person screening measures was significantly correlated ($r(36)=0.380$, $p=0.021$), and not significantly different ($t(36)=-0.090$, $p=0.929$). For global self-reported days of SLT use per week, these same measurement methods were significantly correlated ($r(46)=0.422$, $p=0.003$), but also significantly different ($t(46)=-3.213$, $p=0.002$). Table 4 displays the respective means and standard deviations. Reports from the in-person screening were used for analyses.

Consistency of SLT Use across Days. Figure 5 depicts an example day of logged SLT use. Again, Day 5 was selected since it included all participants' data that were included in the analyses, and was representative of most of the days of the study. Similar to logged CPD, heaping was not observed when dips per day were prospectively self-reported. The most common numbers logged were 2 ($n=10$), 0 ($n=8$), 3 ($n=6$), and 4 ($n=5$).

It was found that mean logged SLT use was significantly higher for Week 1 ($M=2.23$, $SD=1.51$) than Week 2 ($M=1.60$, $SD=1.27$), $t(34)=2.533$, $p=0.016$.

ICC's (95% CI's) across Days 1 through 14 of logged SLT was 0.416 [0.285, 0.590] (Cronbach's alpha = 0.913). Across days 1 through 7 of logged SLT, the ICC coefficient was

0.581 [0.446, 0.720] (Cronbach's $\alpha = 0.910$), and the ICC coefficient across days 8-14 was 0.539 [0.383, 0.709] (Cronbach's $\alpha = 0.901$).

Difference scores showed that logged dips per day differed across days by at least 20% of the global, self-reported DPD for all participants.

Validity of Global, Retrospective Self-Reports versus Prospectively Logged SLT

Use. It was found that global, self-reported dips per day on days SLT was used at in-person screening (see Table 4 for means and SDs) had no significant correlation with and was significantly greater than mean logged dips per day on days SLT was used ($M=2.40$, $SD=1.15$). See Table 5 for test statistics.

When difference scores between logged SLT and global self-report were analyzed, it was found that 10 (19%) of the participants consistently logged fewer DPD than the global DPD they had self-reported at screening. No participants consistently logged more DPD than their global, self-reported DPD. All participants over- or under- logged DPD by 20% or more, on at least one day of the observation period. Figure 4 depicts the frequency of global, self-reported values of dips per day in a histogram. As illustrated, and in contrast to global, self-reported CPD, heaping was not observed.

Mean logged days of SLT use in Week 1 ($M=5.53$, $SD=1.98$) had a strong positive correlation with ($r(29)=0.711$, $p<0.001$), and was not significantly different ($t(29)=0.235$, $p=0.816$) than mean logged days of SLT use in Week 2 ($M=5.47$, $SD=2.10$).

Global, self-reported days of SLT use per week (see Table 4 for means and SDs) at in-person screening had a moderate positive correlation with, and was not significantly different than mean logged days of SLT use per week ($M=5.53$, $SD=1.87$). See table 5 for test statistics.

SLT Motivations/Beliefs Survey. Table 6 shows frequencies of answer choices from the SLT motivations and beliefs survey. Most participants reported that their motivation for initiation and continued use of SLT was to use tobacco in places where they cannot smoke (a.k.a. indoor smoking restrictions). Most believed that SLT is equally as harmful to their health as cigarettes, regardless of type of SLT. There was almost an even split among participants when they were asked if they thought dip could be helpful when used to assist with smoking cessation. When they were asked if Snus could be used for smoking cessation about half indicated that it would not help, while around a quarter indicated it could help, and a quarter did not know.

Dual Use

Validity of Global, Retrospective Self-reports versus Salivary Cotinine Levels. It was found that mean logged tobacco products used per day ($M=12.88$, $SD=5.85$) had no significant correlation with ($r(33)=0.109$, $p=0.540$) mean salivary cotinine levels ($M=362.37$ ng/mL, $SD=159.45$), collapsed across days.

Discussion

While previous studies have made great contributions to the field of tobacco use, more comprehensive comparisons of measurement methods were needed. This study compared dual tobacco use measures that had not previously been compared to assess their validity and reliability. Retrospective global self-reports, prospective logs, returned products, and biological samples were all evaluated in this study.

Cigarette Smoking

It was found that global, self-reports of CPD were greater than both prospectively logged CPD and returned cigarette butts, which did not support the hypotheses. When difference scores were calculated between prospectively logged cigarettes and global, self-reports, all participants

over- or under-reported cigarettes by 20% or more, at least once. It was found that most of the participants consistently logged fewer cigarettes than the global CPD they had reported at the in-person screening and no participants consistently logged more cigarettes than their global, self-reported CPD. Similarly, difference scores between cigarette butts and global self-reports showed that all participants over- or under-returned butts by 20% or more at least once. It was found that half of the participants consistently returned fewer cigarette butts than the number of cigarettes reported via global, self-reports, and only one participant consistently returned more cigarette butts than was shown via global self-reports.

These findings contradict some previous research regarding returned cigarette butts (Blank et al., 2016; Clark et al., 1996) and support other findings (Etter & Perneger, 2001). Researchers of the study that was supported stated that they had difficulty collecting cigarette butts from participants, with many participants not providing any (Etter & Perneger, 2001). We may have had similar issues in the current study with participants not returning the true amount used, however participants of the current study were discontinued if they failed to return butts at all. This does not, however, mean that we assume the ED was the true amount used, since we have no way of knowing if the butts or logs were more representative of what happened in actuality. These findings could be explained by fatigue due to the longer length of time that the current (our) study ran.

These findings also contradict a study with prospective logs (Perkins et al., 2012), but this could be because the previous study used tally-card type logs instead of electronic logs. With the tally cards, there was a place to log the behavior inside the same box from which a cigarette was pulled, so that the participant had a visible reminder to log the behavior at the same time each smoke began. In the current study, the participant was required to remember to log an entry

on an electronic device that was not directly attached to their box of cigarettes whenever they smoked. Practically speaking, this may mean that it is helpful if researchers find a way to provide some reminder to participants to record their behavior each time they use tobacco.

It was found that mean logged cigarettes were not significantly different from mean cigarette butts returned, supporting the hypothesis. While cigarette butts have been compared to global self-reported CPD in previous work (Clark et al., 1996; Blank et al., 2016; Etter & Perneger, 2001), they have not before been compared with electronic diary records. That logs and butts were not significantly different suggests that participants may have over-estimated their daily smoking when asked to report their behavior via a global measure. On the other hand, participants could smoke a higher number of cigarettes per day than that shown by the diary logs and returned butts, even though the variability in their patterns of use is best reflected by these daily measures.

Diary logs and returned butts were found to be fairly to moderately reliable across the 14-day period. However, difference scores showed that values for both measures differed across days by at least 20% of the global, self-reported CPD for the large majority of participants (>98%). When examined as a function of week, consistency was higher for Week 2 than Week 1. The participants who may have been less reliable would have had data included in the Week 1 statistics, and after being removed, only the more reliable participants contributed to data in the Week 2 statistics. In a previous study with tallied prospective logs, reliability was higher than in our study with electronic logs, but again this could be due to the tally cards being a visible reminder in the cigarette box to log each smoke (Perkins et al., 2012). This pattern might also be explained by differences in the duration of the data collection period (e.g., 3 versus 14 days), and thus the burden placed on participants. Still, tally cards can be filled in retrospectively rather than

when a behavior was actually performed. It has been previously reported that when a timestamp capability, unbeknownst to participants, was included in a paper-and-pencil diary, the diaries were retrospectively filled in all at once rather than throughout the day as behaviors occurred (Stone et al., 2003). Since reliability is moderate, the variability across days be a as important a piece of information to further assess as the actual number logged. This is supported by previous studies that have shown that the number of cigarettes smoked per day has been influenced by factors like time of day (Morgan, Gust, Pickens, Champagne, & Hughes, 1985), work-place restrictions (Chapman, Haddad, & Doungkamol, 1997), and concurrent drug use (Henningfield & Griffiths, 1981; Griffiths, Bigelow, & Liebson, 1976).

SLT Use

It was found that global, retrospective self-reports of days per week where SLT is used were not different from prospective logs, supporting the hypothesis. Contrary to the previous finding, global retrospective self-reports of dips per day were greater than mean prospectively logged dips per day, which did not support the hypothesis. Difference scores revealed that 10 of the participants consistently logged fewer DPD than the global DPD they had retrospectively self-reported at screening, and no participants consistently prospectively logged more DPD than their global, retrospectively self-reported DPD. All participants over- or under- logged DPD by 20% or more, at least once. This could be due to over-estimation when participants gave a global, retrospective self-report, or could be due to lack of compliance when prospectively logging. Because prospective logs for Week 1 were not different from Week 2, it does not seem that fatigue across time is a factor. However, overall fatigue (i.e. not wanting to fully engage with the device) could be. That is, because the mean number of DPD was significantly higher via

self-report than via diary logs, participants may not have recorded every SLT product used each day.

Prospectively logged dips per day were found to be poorly reliable across 14 days, which did not support the hypothesis. Specifically, difference scores showed that logged dips per day differed across days by at least 20% of the global self-reported DPD for all participants. These findings are likely due to the nature of dual use in the study. Participants were daily cigarette smokers who sometimes used SLT. These individuals also stated that they use SLT primarily in places where they cannot smoke. It might be expected, therefore, that situational factors drive their patterns of use. In that case, they may have more variable patterns of use than those who are solely cigarette smokers or daily SLT users.

As described in the introduction, the only previously published SLT measurement method comparisons that can be compared to the current study's findings involve cotinine levels and various self-report measures, which will be described below. This lack of literature comparing these methods further illustrates the importance of the current study's findings.

Biological Sampling

The hypothesis that mean logged tobacco products per day would be positively correlated with mean salivary cotinine levels was not supported, as there was no correlation found. These findings contradict those reported previously where logged cigarettes in an ED were associated positively with salivary cotinine levels (Shiffman, 2009). Further, it had previously been found that salivary cotinine levels were associated with global, self-reported number of chews/dips per day and number of cans/tins used per week (Mushtaq et al., 2012; Boyle et al., 1995). Of course, in this previous work, users of only a single tobacco product (i.e., either cigarettes only or SLT only) were examined. In a study that did not support our findings, smokers with a mean self-

reported CPD of 26 and a mean EMA CPD of 22 had a mean salivary cotinine level of 319 ng/mL (Shiffman, 2009). The current study had a mean salivary cotinine level of 362 ng/mL for dual users with a mean of 20 cigarettes per day and five SLT uses per day. In a study with smokers only, it was found that the mean salivary cotinine level of 236 ng/mL was associated with the global, retrospectively self-reported average of 18 cigarettes per day (Etter & Perneger, 2001). The amount of actual tobacco use, regardless of type of tobacco, is likely the most largely contributing factor.

Strengths, Limitations, and Future Directions

The current study met a necessity in the field since such little information is known about measurement methods for and characteristics of dual use. This is the first study that has compared such a wide selection of retrospective, prospective, and biological measurement methods for dual tobacco use. Global, retrospective self-reporting, prospective logging on an electronic device, prospective product collection, and salivary cotinine samples were all utilized and compared. These have not all been compared previously in a single study to give insight regarding their reliability and validity. Previously, researchers would have to look at several different studies with various variables and factors at play and try to compare the different results. This study provided these comparisons among a single sample, under a single protocol. The current study provided groundbreaking information that further studies can not only build upon, but use as a basis when making decisions regarding which measurement methods should be utilized to best meet their own study aims. These findings can help others study baseline behaviors, and therefore behaviors after treatments to help inform cessation protocols. They can additionally be used when studying dual use behaviors as new products emerge. They can even

be used to study dual use behaviors in long-term longitudinal studies to learn more about health impacts and morbidity.

A significant limitation of this study pertains to generalizability to the greater Appalachian region. The sample size was fairly small and lacked diversity, as it was largely made up of White males. While dual users may be predominantly White males (Tomar et al., 2010; Rostron et al., 2015), so that the sample is representative of the dual user population based on gender and race, it still lacks diversity based on location, and therefore culture. Although the sample was recruited in Appalachia, it was localized to two counties in southern WV, and one county in northern WV. While recruitment efforts were put forth to sample from some other areas, the attempts failed. Had these attempts been more successful to include other locales of WV, or even greater Appalachia, this study might be more generalizable to a greater region. Additionally, while these participants were recruited in WV, their histories were unknown. They could have been currently living or working near the recruitment areas, but have been raised in another geographic region. Future studies could sample from other areas in Appalachia to determine if this sample is representative of this greater region.

While participant motivations for participating in this study may be similar to other studies (i.e. compensation), many participants were recruited from job boards on Craigslist. While compensation is the motivating factor for employed and unemployed participants for scientific studies, twenty-three (44.2%) of the current study's participants were unemployed, suggesting that compensation may have been an even more influential motivator in this study. This recruitment method, therefore, could have also affected generalizability. Additionally, behaviors may have been affected by unemployment for this population, meaning these findings may not be representative of employed dual users.

It is important to note that this population should not be generalized to solely cigarette smokers or SLT users. Among the dual cigarette-SLT users included here, their average FTCD score was higher than that observed among cigarette smokers (Chandra et al., 2011; Breland et al., 2009; Blank & Eissenberg, 2010), and the Severson score was lower than that observed for SLT-only users (Ebbert et al., 2012). Scores on these measures are currently not available in dual users of cigarettes and SLT, and thus comparisons are unable to be made with our sample. Many dual use studies have used other dependence measures, often a single question like using a tobacco product within 30 minutes of waking (Tomar et al., 2010) or how many minutes until first cigarette (Wetter et al., 2002).

Future directions should include learning more about these types of dual users. It is necessary to know if this study provides information regarding behaviors, motivations, and dependence scores that are generalizable to other nondaily SLT, daily smoking dual users. Additionally, more studies of this kind are necessary for replication to provide further information about which measures are most valid and reliable. Other studies should compare the measures used here to other cotinine analyses. For example, plasma, serum, or urine could be used. Observational studies would be helpful as well, to determine what measures are most indicative of actual behaviors.

Conclusion

Global, retrospective self-reports of CPD and SLT use per day did not seem to be valid, but seem to be reliable. However, global, retrospective self-reports of days SLT was used per week could be valid, but were not reliable. Cigarette butts collected and prospectively logged CPD seemed valid and moderately reliable, as long as firm compliance standards are in place. Prospectively logged days of SLT use per week seemed valid, but dips per day did not, and these

were both poorly reliable measures. Salivary cotinine was likely valid since this is not a measure that can be faked or altered, but a correlation was not found due to the small sample size and the analyses not taking into account the time the nicotine needed to metabolize. Many of these findings are new to the field, and need to be further studied to determine true validity when there are significant differences between measures.

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doi:10.1006/pmed.2002.1032

Table 1

Participant Demographics

	Mean	Standard Deviation	Percentage	Frequency
Age (Years)	30.35	8.84		
Education (Years)	12.58	1.47		
Gender				
Males			94.2%	49
Females			5.8%	3
Ethnicity				
Hispanic			1.9%	1
Not Hispanic			98.1%	51
Race				
Caucasian/White			94.2%	49
Black/African American			1.9%	1
Asian/Pacific Islander			1.9%	1
American Indian/ Alaska Native			1.9%	1
Marital Status				
Married			26.9%	14
Divorced			7.7%	4
Separated			1.9%	1
Single			63.5%	33
Employment				
Full-time			36.5%	19
Part-time			9.6%	5
Unemployed			44.2%	23
Student			9.6%	5
Mini-IPIP* (Personality)				
Agreeableness	3.69	0.73		

Extraversion	3.44	0.94
Conscientiousness	3.63	0.85
Neuroticism	2.78	0.75
Openness	3.66	0.64

* The Mini-IPIP for Big 5 personality traits scores range from 1-5 on each trait, 1=low in that trait (i.e. reported that statements reflecting extraversion, for example, were very inaccurate descriptors for them), 5=high in that trait.

Table 2

Participant Tobacco Use Characteristics

	Mean	Standard Deviation	Range	Percentage	Frequency
Cigarette Use					
Cigarettes per Day	19.71	9.02	5-40		
Years Smoking	10.98	7.13	1-29		
Fagerstrom Score*	5.98	2.61	0-10		
Exhaled CO (ppm)	24.27	14.33	7-71		
Smokeless Tobacco Use					
Uses/Day	4.58	2.60	2-14		
Days Used/Week	5.69	1.57	2-7		
Years of SLT Use	9.01	5.74	1-30		
Severson Score**	8.69	3.91	1-18		
Types of SLT					
Snuff				40.4%	21
Dip				34.6%	18
Snus				7.7%	4
Chew				3.8%	2
Combination				13.5%	7
SLT Flavor					
Wintergreen/Mint/Frost				55.8%	29
Straight/Regular/Natural				19.2%	10
Fruit				7.7%	4
Other				5.8%	3
Combination				11.5%	6

* The Fagerstrom Test for Cigarette Dependence scores range from 0 (low) to 10 (high).

** The Severson Smokeless Tobacco Dependence Scale-Short Form scores range from 0 (low) to 19 (high).

Table 3

Whipple's Indices and Heaping

Measure	Mean	Standard Deviation	Median	Mode	Whipple's Index	Heaping
Global CPD						
Telephone	21.04	9.99	20	20	436.2	87.2%
In-person	19.71	9.02	20	20	432.7	86.5%
Returned Butts						
Day 1	9.29	5.74	9	8	115.4	23.1%
Day 2	11.27	6.21	11	8	115.4	23.1%
Day 3	13.98	8.44	13	8	105.8	21.2%
Day 4	10.90	5.74	11	7	48.1	9.6%
Day 5	11.02	5.40	10.5	4	76.9	15.4%
Day 6	10.52	5.81	11	11	125.0	25.0%
Day 7	10.62	5.65	10	10	163.5	32.7%
Day 8	10.48	5.93	10	9	96.2	19.2%
Day 9	12.91	7.40	11	10	141.3	28.3%
Day 10	9.35	5.91	10	-	206.5	41.3%
Day 11	11.22	5.96	11	11	119.6	23.9%
Day 12	9.57	5.15	10	10	195.7	39.1%
Day 13	10.07	5.67	11	13	119.6	23.9%
Day 14	9.84	5.71	9.5	4	130.4	26.1%
Logged CPD						
Day 1	9.78	6.10	9	9	88.2	17.6%
Day 2	13.53	7.07	13	8	68.6	13.7%
Day 3	13.53	8.17	13	6	88.2	17.6%
Day 4	11.84	7.66	9	7	70.0	13.7%
Day 5	10.68	7.21	8	7	90.0	18.0%
Day 6	10.58	7.17	10	11	150.0	30.0%

Day 7	10.39	6.52	9	6	71.4	14.3%
Day 8	9.96	6.23	9	7	81.6	16.3%
Day 9	9.66	6.05	8	4	80.0	16.0%
Day 10	10.00	6.78	9	4	155.6	31.1%
Day 11	9.44	5.93	8	6	55.6	11.1%
Day 12	10.09	7.00	9	6	81.4	16.3%
Day 13	8.81	6.59	7	2	116.3	23.3%
Day 14	8.62	5.83	7	6	83.3	16.7%

Table 4

Means (Standard Deviations) and Sample Sizes of Outcome Measures

	Phone screen	In-person screen	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Cigarettes																
Global Self-Reports	21.04 (9.99)	19.71 (9.02)														
	n=47	n=52														
Electronic diary			9.78 (6.10)	13.53 (7.07)	13.53 (8.17)	11.84 (7.66)	10.68 (7.21)	10.58 (7.17)	10.39 (6.52)	9.96 (6.23)	9.66 (6.05)	10.00 (6.78)	9.44 (5.93)	10.09 (7.00)	8.81 (6.59)	8.62 (5.83)
			n=51	n=51	n=51	n=50	n=50	n=50	n=49	n=49	n=50	n=45	n=45	n=43	n=43	n=42
Returned butts			9.29 (5.74)	11.27 (6.21)	13.98 (8.44)	10.90 (5.74)	11.02 (5.40)	10.52 (5.81)	10.62 (5.65)	10.48 (5.93)	12.91 (7.40)	9.35 (5.91)	11.22 (5.96)	9.57 (5.15)	10.07 (5.67)	9.85 (5.71)
			n=52	n=52	n=52	n=52	n=52	n=52	n=52	n=52	n=46	n=46	n=46	n=46	n=46	n=46
SLT																
Self-reports (DPD)*	4.42 (2.28)	4.58 (2.60)														
	n=39	n=45														
Self-reports (DPW)**	6.31 (1.14)	5.69 (1.57)														
	n=47	n=52														
Electronic diary			1.72 (1.56)	2.78 (2.29)	2.31 (1.92)	2.23 (1.93)	2.17 (1.81)	1.89 (2.07)	2.15 (1.88)	2.65 (2.10)	1.86 (1.56)	1.47 (1.37)	1.94 (1.79)	1.69 (1.23)	1.66 (1.78)	2.07 (1.72)
			n=36	n=36	n=36	n=35	n=35	n=35	n=34	n=34	n=35	n=32	n=31	n=29	n=29	n=28

*DPD = dips per day

**DPW = days per week

Table 5

Paired Samples t-tests and Correlations for Outcome Measures

	Overall	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Cigarette smoking															
Global vs. Diary															
t-tests	9.285+														
correlations	0.565+														
Global vs. Returned Butts															
t-tests	8.560+														
correlations	0.550+														
Diary vs. Returned Butts															
t-tests	1.085	0.56	2.614*	0.608	1.181	0.639	0.137	0.208	1.102	3.174*	0.617	2.532*	0.291	1.851	1.788
correlations	0.833+	0.572+	0.626+	0.607+	0.667+	0.710+	0.699+	0.599+	0.710+	0.583+	0.600+	0.588+	0.581+	0.630+	0.525+
SLT Use															
Global DPD vs. Diary															
t-tests	3.697+														
correlations	0.198														
Global DPW vs. Diary															
t-tests	0.178														
correlations	0.426*														

*p<.05

+p<0.001

Table 6

Participant Motivations and Beliefs Regarding SLT Use

	Percentage	Frequency
Reason for Initiation*		
Improve Health	3.8%	2
Assist Quitting	19.2%	10
Indoor Smoking Restrictions	65.4%	34
Other	19.2%	10
Reason for Current Use*		
Improve Health	1.9%	1
Assist Quitting	13.5%	7
Indoor Smoking Restrictions	71.2%	37
Other	17.3%	9
Dip Harm vs Cigarettes**		
Less Harm	17.3%	9
More Harm	11.5%	6
Same Harm	57.7%	30
Do not know	5.8%	3
Snus Harm vs Cigarettes**		
Less Harm	19.2%	10
More Harm	9.6%	5
Same Harm	42.3%	22
Do not know	21.2%	11
Dip Help Smokers Quit**		
Do Help	38.5%	20
Do not help	42.3%	22
Do not know	11.5%	6
Snus Help Smokers Quit**		
Do Help	25.0%	13
Do not help	44.2%	23
Do not know	23.1%	12

Use when Cannot Smoke**

True	90.4%	47
False	1.9%	1

* As many answer choices as applied could be selected.

** Only one answer choice could be selected.

Figure 1. The figure displays the frequency for global averages of cigarettes smoked per day reported at the in-person screening. Note how heaping occurred around values ending in 0 or 5.

Figure 2. The figure displays the frequencies of returned cigarette butts on Day 5. Note how heaping did not occur.

Figure 3. The figure displays the frequencies of logged cigarettes via electronic diary on Day 5.

Note how heaping did not occur.

Figure 4. The figure displays the frequency for global averages of dips per day reported at the in-person screening. Note how heaping did not occur.

Figure 5. The figure displays the frequencies for logged SLT uses via electronic diary on Day 5.

Note how heaping did not occur.

Appendices

Appendix A

Dual cigarette and smokeless tobacco use**Protocol #: 1405293042****Subject ID:**

	Yes	No
Age between 18 and 60 years	☐	☐
Smoke ≥ 5 cigarettes per day for ≥ 1 year	☐	☐
SLT use:		
at least 2 uses per day	☐	☐
at least 4 days per week	☐	☐
at least 6 months of use	☐	☐
CO reading ≥ 7 ppm: _____	☐	☐
Urinary cotinine > 3 : _____	☐	☐
If any of the above were answered “no”, the individual is not eligible for this study.		

Appendix B

Dual cigarette and smokeless tobacco use

Protocol #: 1405293042

Subject ID:

	Yes	No	
Diagnosis of schizophrenia or bipolar disorder	☐	☐	
Use of marijuana >5 days in past month	☐	☐	
Illicit drug use in past 3 months	☐	☐	
EToH use >15 days in past month	☐	☐	
Weekly use of other tobacco products	☐	☐	
Current use of nicotine/tobacco pharmacotherapy	☐	☐	
Active engagement in cigarette/SLT reduction	☐	☐	
<u>Women Only</u>	N/A		
Positive urine pregnancy test	☐	☐	☐
Current breast-feeding	☐	☐	☐
<p>If any of the above are answered “yes”, the individual is not eligible for the study.</p>			

Appendix C

Dual use of cigarettes and smokeless tobacco

Purpose: The purpose of this research study is to examine the patterns of dual use of cigarettes and smokeless tobacco.

Study: If you agree to join this study, you will be asked to use an electronic device every day for 14 consecutive days. Specifically, we will ask that you record your use of every cigarette and smokeless tobacco product using the device. We will also ask you to tell us what you are doing and how you feel at different times throughout the day. Each assessment will take only 1 minute of your time. Each night before you go to bed, we will also ask you to provide a sample of your saliva using kits that we give you to take home.

On four days of the 14 day period, you will have to visit the designated research site in your area. The days that you will be required to visit us will be the first, 3rd, 9th, and 14th day. On the last day you will be asked to fill out more questionnaires about your beliefs about tobacco products.

Payment: If you complete all phases of the study you can earn a total of \$300. Specifically, you can earn \$50 on Day 3, \$100 on Day 9, and \$150 on Day 14 if you comply with all of our procedures.

Screening Visit: If you think you are interested in participating, you will first need to complete an in-person screening visit. During this visit, we will ask you to provide informed consent to participate, as well as fill out some questionnaires and take a breath test and a urine test to confirm that you are a tobacco user. If you are eligible for the study based on this screening visit, then you will be scheduled for your first study visit.

Appendix D

Telephone Screening Questionnaire**Date:** _____**Interviewer:** _____

Interviewer: “I would like to ask you some questions about yourself and your health status as well as your use of tobacco, alcohol, and other drugs. The purpose of these questions is to determine whether or not you are eligible to participate in the study that I just described to you. All of your responses are confidential. You are not required to answer any question and you may stop this interview at any time. May I begin the questions?”

Document caller's response by circling either:

Yes or No

If Yes: begin form. If No: thank the caller and stop the interview.

How did you hear about us/our study? _____

Personal Information:

1. “What is your first name?” _____

2. “What is a phone number at which you can be contacted?” _____

3. “If we call and you are not available, may we leave a message?” *Yes or No*

4. “What is your date of birth?” _____

General health status:

1. Do you have any psychiatric conditions such as schizophrenia or bipolar disorder?

Yes or No

If Yes: “Please describe the condition”:

For women only:

6. “Are you currently pregnant?”

Yes or No

7. “Are you currently breast-feeding a child?”

Yes or No

Cigarette Use:

1. “Do you currently smoke tobacco cigarettes?”

Yes or No

If No: Skip to the section on smokeless tobacco use

2. “What brand of cigarettes do you smoke?” _____

Regular / Light / Ultra-light Hard / Soft Pack Regular / Menthol Regular / 100s / Other

3. "On average, how many cigarettes do you smoke per day?" _____ (*numb of cigs*)

[Guide to report one number that best represents their average/day; do not provide a range]

4. "For how long have you smoked this number per day?" _____ (*months / years*)

Smokeless Tobacco Use:

1. "Do you currently use any oral or smokeless tobacco product(s)?" *Yes or No*

If No: Skip to the section on other tobacco use

2. "What type of smokeless tobacco product do you use?" (circle all that apply)

Chew Dip Snuff Snus Other: _____

3. "What brand of that product do you use?" _____

4. "What flavor of that product do you use?" _____

5. "On average, how many days per week do you use that product?" _____

6. "On the days that you use that product, about how many dips/chews/pouches do you use?" _____

[Guide to report one number that best represents their average/day; do not provide a range]

7. "For how long have you used that amount of product?" _____ (*months / years*)

Other Tobacco Use:

1. "Have you used any of the following other nicotine/tobacco products in the past week?"

			If 'yes', estimate how many days you have used this product in the past week?
Large cigars	No	Yes	
Cigarillos (e.g., Black & Milds) or small cigars	No	Yes	
Waterpipe (a.k.a. hookah or shisha)	No	Yes	
Electronic cigarettes	No	Yes	
Other: _____	No	Yes	

Smoking Cessation History:

1. “Are you currently using any nicotine replacement products?” *Yes or No*
(e.g., patch, gum, inhaler, nasal spray)
2. “Are you currently using any prescription medications for cessation?” *Yes or No*
(e.g., Chantix, Zyban, etc.)
-

Illicit Drug Use:

- 1. “Have you used any of the following other drugs for recreational purposes in the past month?”*

			If ‘yes’, estimate how many days you have used this product in the past month?
Alcohol	No	Yes	
Marijuana / Spice / K2	No	Yes	
Stimulants (e.g., cocaine, amphetamine, etc.)	No	Yes	
Opiates (e.g., heroin, oxycodone, etc.)	No	Yes	
Other:	No	Yes	

Interviewer: “Thank you for responding to these questions. I need to pass on your responses to the principal investigator who will then determine whether or not you are eligible to participate in a study. If you are eligible, someone will contact you within approximately one week. If you are not eligible for this study, then you will *not* be contacted.”

[If respondent does not have a phone, they can call us back in a few days]

Appendix E

**Only Minimal Risk
Consent Information and HIPAA Form**

Principal Investigator Melissa D. Blank, Ph.D.

Department Psychology

Protocol Number 1405293042

Study Title Dual cigarette and smokeless tobacco use

Co-Investigator(s) Dr. Daniel Elswick, M.D.; Dr. Nicholas Turiano, Ph.D. Nicholas Felicione, Jenny Ozga; Sara Hanks; Summer Kuhn; Catherine Morton-McSwain; Mary McMillion; Colleen Warren

Sponsor (if any) National Institute of Drug Abuse

Contact Persons

In the event you experience any side effects or injury related to this research, you should contact Dr. Melissa Blank at (304) 293---8341. If you have any questions, concerns, or complaints about this research, you can contact Dr. Melissa Blank at this same number.

For information regarding your rights as a research subject, to discuss problems, concerns, or suggestions related to the research, to obtain information or offer input about the research, contact the Office of Research Compliance at (304) 293---7073.

In addition if you would like to discuss problems, concerns, have suggestions related to research, or would like to offer input about the research, contact the Office of Research Integrity and Compliance at 304---293---7073.

Introduction

You have been asked to participate in this research study, which has been explained to you by a trained staff member. This study is being conducted by Dr. Melissa Blank, Department of Psychology; Dr. Nicholas Turiano, Department of Psychology; Nicholas Felicione, Department of Psychology; Jenny Ozga, Department of Psychology; and Dr. Daniel Elswick, Department of Behavioral Medicine & Psychiatry. Funding is provided by the National Institute of Drug Abuse.

Purpose(s) of the Study

The purpose of this study is to evaluate your use of both cigarettes and smokeless tobacco over 14 consecutive days. That is, the study is designed to characterize when you use these products, as well as what you are doing and how you feel when you are using them, every day during this two week period. Additionally, we will examine your exposure to

Approved: 30-Jun-2016 Number: 1405293042

nicotine by testing your saliva through samples that you collect at home each evening. The goal is to understand the patterns of tobacco use among people who use both types of tobacco products. Additionally, we are interested in examining the relationship between personality traits and tobacco use. WVU expects to enroll as many as 150 participants.

Description of Procedures

If you agree to join the study, you will be asked to use an electronic device every day for 14 consecutive days. Specifically, we will ask you to record your use of cigarettes, smokeless tobacco, and any other tobacco products every day during this time period. We will also ask you to tell us what activities you are engaged in (e.g., driving, working, eating, etc.) and how you feel (e.g., your mood and craving for nicotine/tobacco) at different times throughout the day. Each record that you provide will take only about 1 minute of your time. There will also be times when you will be able to set the device to “silent” so that you are not disturbed (e.g., during a meeting, while watching a movie, etc.). Also during this two week period, we will ask you to provide a sample of your saliva each night. You will be able to provide this sample using kits that we give you to take home.

On four days of the two week period, you will be required to visit the research site. The days that you will be required to visit us will be the first, third, ninth, and fourteenth days. Each time you come to the research site you must bring your electronic device and all saliva samples collected. We will also ask you to bring any cigarette butts of the cigarettes that you have smoked and any tins of the smokeless tobacco that you have used. We will provide you with labeled containers for these materials. On the last visit to the research site (i.e, the fourteenth day), we will ask you to fill out some questionnaires about your beliefs about tobacco products.

Discomforts

Tobacco use may involve risks to the unborn child. For this reason, women who are pregnant will not be accepted. If you are a woman who could become pregnant, you will not be allowed to participate in this study until you have had a urine pregnancy test and the test has indicated that you are not pregnant.

If you find any effects or data collection procedures unacceptable, you may stop your participation at any time.

Alternatives

This study provides no therapeutic benefits. You have the alternative not to participate in this study.

Benefits

You will derive no personal benefit from this study. However, your participation will help us in the future as we understand the potential effects of using multiple tobacco products. The knowledge gained from this study may eventually benefit others.

Financial Considerations

You will be paid \$50 on Day 3, \$100 on Day 9, and \$150 on Day 14 of the two week period. The total amount of compensation able to be earned for completing all phases of this study and following the requirements is \$300. If you withdraw your participation before the requirements are met, you will not be paid for those requirements that you did not complete fully. You will be asked to provide your Social Security Number and verification of U.S Citizenship or Permanent Resident Status to receive payment.

Confidentiality

Any information about you that is obtained as a result of your participation in this research will be kept as confidential as legally possible. Your research records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by the study sponsor or federal regulatory authorities (including the FDA if applicable) without your additional consent.

In addition, there are certain instances where the researcher is legally required to give information to the appropriate authorities. These would include mandatory reporting of infectious diseases, mandatory reporting of information about behavior that is imminently dangerous to your child or to others, such as suicide, child abuse, etc.

All data collected from you will be kept locked up and will be destroyed as soon as possible after the research is finished. In any publications that result from this research, neither your name nor any information from which you might be identified will be published without your consent.

HIPAA

We know that information about you and your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others for research purposes.

You can decide to sign or not to sign this authorization section. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make about this research study will not have an effect on your access to medical care.

Persons/Organizations Providing the Information

Study participants

Persons/Organizations Receiving the Information

All research and medical staff affiliated with this study.

The members and staff of the WVU Institutional Review Board (IRB) that oversees this research study.

West Virginia University Office of Research Compliance and Office of Sponsored Programs.

The National Institute of Drug Abuse, which sponsors this research.

The Following Information Will Be Used

We will collect personal information such as basic demographics (e.g., race, ethnicity, gender, date of birth), and previous and current use of licit (e.g., tobacco, alcohol) and illicit (e.g., marijuana, cocaine, opiates) drugs. At the screening visit we will also collect breath and urine samples to verify tobacco use. During the two week study period, we will collect information about your use of tobacco products, your engagement in daily activities, your mood, your craving for nicotine/tobacco, and your exposure to cotinine (a metabolite of nicotine) through saliva samples. On the last day of the two week period, we will collect information about your beliefs about tobacco products.

The Information is Being Disclosed for the Following Reasons

Review of your data for quality assurance purposes
Publication of study results (without identifying you)
Other research purposes such as improving the design of future studies

You May Cancel this Authorization at Any Time by Writing to the Principal Investigator

Melissa Blank, Ph.D. West Virginia University
Department of Psychology PO Box 6040
Morgantown, WV 26506---6040

If you cancel this authorization, any information that was collected already for this study cannot be withdrawn. Once information is disclosed, according to this authorization, the recipient may re---disclose it and then the information may no longer be protected by federal regulations.

You have a right to see and make copies of your personal information records. You will not be able to see or copy your records related to the study until the sponsor has completed all work related to the study. At that time you may ask to see the study doctor's files related to your participation in the study and have the study doctor correct any information about you that is wrong.

This authorization will expire at the end of the study unless you cancel it before that time.

Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time.

Refusal to participate or withdrawal will involve no penalty to you. Refusal to participate or withdrawal will not affect your future care, or your employee or student status at West Virginia University.

In the event new information becomes available that may affect your willingness to participate in this study, this

information will be given to you so that you can make an informed decision about whether or not to continue your participation.

You have been given the opportunity to ask questions about the research, and you have received answers concerning areas you did not understand.

Upon signing this form, you will receive a copy. I willingly consent to participate in this research.

Equipment

This study requires that you use certain equipment, including an electronic diary (similar to a cell phone). WVU owns this equipment, and you will be permitted to borrow the equipment during the course of the 2-week study. You are responsible for the equipment while it is in your possession, and you should promptly notify us if the equipment is damaged, lost, or stolen. You must return this equipment to WVU when the study ends or when you stop participating in the study. If you do not return the equipment within thirty (30) days of the end of the study or the date you stop participating in the study, we will request payment for the cost of replacing the equipment, which in this study is \$100.

Signatures

Signature of Subject

Printed Name

Date

Time

The participant has had the opportunity to have questions addressed. The participant willingly agrees to be in the study.

Signature of Investigator or Co-Investigator

Printed Name

Date

Time

Chestnut Ridge Research Building
Ridge Road
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Appendix F

In-person Screening Questionnaire

Please complete the survey below.

Thank you!

Demographics

Participant ID

What is your age in years?

What is your race?

American Indian/Alaskan Native

Black or African American

Asian/Native Hawaiian or other Pacific Islander

White

Other/Unknown

Are you hispanic or latino?

Yes

No

What is your gender?

Male

Female

What is your marital status?

Single

Married

Separated

Divorced

Widowed

Please enter your education in years. For example, high school =12, college degree=16, etc.

What is your primary employment?

Unemployed

Part-time (0-30 hrs/wk)

Full-time (>30 hrs/wk)

Student

Health Status Form

Do you have any psychiatric conditions? Please describe.

Yes

No

Are you currently pregnant?

Yes

No

Are you currently breast-feeding a child?

Yes

No

Do you currently smoke tobacco cigarettes?

Yes

No

On average, how many cigarettes do you smoke per day?

For how many years have you smoked this number of cigarettes per day?

What brand of cigarettes do you smoke?

Regular, Light, or Ultra-Light?

Menthol or non-menthol?

Hard pack or soft pack?

King size (standard) or 100s?

Have you ever made an attempt to quit or reduce your smoking?

Yes

No

Have you made any attempts to quit or reduce your smoking in the last 30 days?

Yes

No

Are you currently making an attempt to quit or reduce your smoking?

Yes

No

Do you currently use any oral or smokeless tobacco product(s)?

Yes

No

What type of smokeless tobacco product do you use? Choose all that apply.

Chew

Dip

Snuff

Snus

Other

What brand of smokeless tobacco product do you use?

What flavor of that product do you use?

On average, how many days per week do you use that product?

On the days that you use that product, about how many dips/chews/pouches do you use?

For how many years have you used that amount of product?

Are you currently using any nicotine replacement products? (e.g., patch, gum, inhaler, nasal spray) Please describe

Yes

No

Are you currently using any prescription medications for cessation? (e.g., Chantix, Zyban, etc.)

Yes

No

Do you currently use any other tobacco or nicotine products?

Yes

No

What other tobacco products do you use?

Little cigar, cigarillo, or large cigar

Waterpipe (a.k.a hookah)

Electronic Cigarettes

Other

Please select the answer for each product that best describes how often you use them:

Little cigars (e.g., Phillies, Swisher Sweets)

Never

Daily

Weekly

Monthly

Cigarillos (e.g., Black & Mild)

Never

Daily

Weekly

Monthly

Large Cigars (e.g., Garcia y Vega, Macanudo)

Never

Daily

Weekly

Monthly

How many times in the last 30 days have you smoked tobacco in a waterpipe?

For how long have you been smoking a waterpipe this often? (months or years)

Have you used alcohol in the past month?

Yes

No

How many days out of the last 30 have you used alcohol?

Have you ever been treated for alcohol use/dependence?

Yes

No

Have you used any marijuana in the past 30 days?

Yes

No

How many times have you used marijuana in the past 30 days?

Have you used any other illicit drugs in the past 30 days?

Yes

No

Please describe

Appendix G

Fagerstrom Test for Cigarette Dependence (FTCD)

How soon after you wake up do you smoke your first cigarette?

Within 5 minutes

Within 6-30 minutes

Within 30-60 minutes

After 60 minutes

Do you find it difficult to refrain from smoking in places where it's forbidden? (e.g. in church, at the movies, at the library)

Yes

No

Which cigarette would you hate to give up the most?

First one in the morning

All others

How many cigarettes a day do you smoke?

10 or less

11-20

21-30

31 or more

Do you smoke more frequently during the first hours after waking than during the rest of the day?

Yes

No

Do you smoke if you are so ill that you're in the bed for most of the day?

Yes

No

Appendix H

Severson Smokeless Tobacco Dependence Scale – Short Form

How many days does a tin/can last you?

< 1

1

2

3

4

5

6

7

>7

Do you experience strong cravings for a pouch/dip/chew when you go more than 2 hours without one?

Yes

No

How soon after you wake up do you use a pouch/dip/chew?

0 to 30 min

> 30 min

When you go without a pouch/dip/chew do you find yourself getting anxious more quickly?

Never

Seldom

Sometimes

Often

Always

When you go without a pouch/dip/chew do you find yourself getting drowsy more quickly?

Never

Seldom

Sometimes

Often

Always

I use more pouch/dip/chew when I am worried about something.

Not at all

A little

Quite a bit

Very much so

I use more pouch/dip/chew when I am rushed and have lots to do.

Not at all

A little

Quite a bit

Very much so

I get a definite lift and feel more alert when using a pouch/dip/chew

Not at all

A little

Quite a bit

Very much so

Appendix I

Mini-International Personality Item Pool (IPIP)

Please use the rating scale below to describe how accurately each statement describes you.

Very Inaccurate

Moderately Inaccurate

Neither Accurate or Inaccurate

Moderately Accurate

Very Accurate

Describe yourself as you generally are now, not as you wish to be in the future. Describe yourself as you honestly see yourself, in relation to other people you know of the same sex as you are, and roughly your same age.

So that you can describe yourself in an honest manner, your responses will be kept in absolute confidence. Please read each statement carefully, and then fill in the bubble that corresponds to the number on the scale.

Am the life of the party

Sympathize with others' feelings.

Get chores done right away.

Have frequent mood swings.

Have a vivid imagination.

Don't talk a lot.

Am not interested in other people's problems.

Often forget to put things back in their proper place.

Am relaxed most of the time.

Am not interested in abstract ideas.

Talk to a lot of different people at parties.

Feel others' emotions.

Like order.

Get upset easily.

Have difficulty understanding abstract ideas.

Keep in the background.

Am not really interested in others.

Make a mess of things.

Seldom feel blue.

Do not have a good imagination.

Appendix J

SLT Motivations/Beliefs

Please complete the survey below.

Choose the reason(s) that best describe why you initiated use of smokeless tobacco

To improve health

To assist with quitting smoking

To use in places where I can't smoke

Other Please describe: _____

Choose the reason(s) that best describe why you currently use smokeless tobacco:

To improve health

To assist with quitting smoking

To use in places where I can't smoke

Other Please describe: _____

I believe that snuff / dip / chew products are _____ harmful than cigarettes.

Less

More

Same

I don't know

I believe that Snus products are _____ harmful than cigarettes.

More

Less

Same

I don't know

I believe that snuff / dip / chew products _____ smokers quit cigarettes.

Help

Do not help

I don't know

I believe that Snus products _____ smokers quit cigarettes.

Help

Do not help

I don't know

I use smokeless tobacco when I cannot smoke.

True

False

Not sure