REVIEW

Conceptualizing Analyses of Ecological Momentary Assessment Data

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ABSTRACT

Ecological momentary assessment (EMA) methods, which involve collection of real-time data in subjects' real-world environments, are particularly well suited to studying tobacco use. Analyzing EMA datasets can be challenging, as the datasets include a large and varied number of observations per subject and are relatively unstructured. This paper suggests that time is typically a key organizing principle in EMA data and that conceptualizing the data as a timeline of events, behaviors, and experiences can help define analytic approaches. EMA datasets lend themselves to answering a diverse array of research questions, and the research question must drive how data are arranged for analysis and the kinds of statistical models that are applied. This is illustrated with brief examples of diverse analyses applied to answer different questions from an EMA study of tobacco use and relapse.

INTRODUCTION

This paper discusses the use of ecological momentary assessment (EMA; Shiffman, Stone, & Hufford, 2008; Stone & Shiffman, 1994)—collection of real-time data in subjects' real-world environments—to study tobacco use. It begins by briefly introducing basic concepts of EMA and explaining why these methods are particularly well suited for the study of tobacco use. The paper is not intended to be a comprehensive exposition on EMA methods, nor a review of EMA studies of tobacco. This paper's purpose is to fill a gap in the EMA literature by illustrating by example some of the ways EMA data can be structured and analyzed to answer theoretically and clinically relevant questions about tobacco use. Reviews of EMA methods, including practical and technological considerations, are available (Hufford, 2007; Shiffman et al., 2008; Stone, Shiffman, Atienza, & Nebeling, 2007), and their application to tobacco and substance abuse has also been reviewed (Shiffman, 2009; Shiffman, in press), as have the relevant statistical methods (Li, Root, & Shiffman, 2006; Raudenbush & Bryk, 2002; Schwartz & Stone, 2007; Singer & Willett, 2003; Snijders & Bosker, 2011; Zeger, Liang, & Albert, 1988). Yet, analysis of EMA data continues to be a daunting task for many investigators, seemingly deterring adoption of EMA methods, and questions about how to conceptualize and structure analyses of EMA data continue to arise for investigators and reviewers, who sometimes wonder how such voluminous, complex, and unstructured data can be analyzed meaningfully.

While it focuses on data analysis, the paper is not intended as a step-by-step guide to EMA analysis, nor as a statistical text. Indeed, this paper argues that no such guide is possible because the approach to analysis needs to be dictated by the research question, not by fixed rules. Rather, this paper presents examples of EMA analyses of tobacco use, as a way of demonstrating the flexibility of EMA data, and the diversity of approaches to analyzing it to address a diverse set of research questions. This paper argues that the framing of a clear research question, and the organization of the EMA data to address that question, and not just the selection of a statistical model, is the EMA investigator's primary challenge. Finally, although this article focuses exclusively on analyses of tobacco use, the concepts articulated here are broadly applicable to a broad range of behaviors and research questions that EMA data can address.

WHAT IS EMA?

EMA methods are defined by repeated collection of real-time data in subjects' real-world environments. An example of EMA data collection on tobacco use would be the use of diaries to capture data on the circumstances in which smokers light up. EMA's focus on subjects' natural environment derives from an interest in ecological validity, in studying how tobacco use (or any other endpoint of interest) varies under the range of realistic circumstances that subjects encounter in their daily lives. EMA's focus on momentary assessment—collecting data about what is going on right at the moment or over the very recent past—derives from two sources. First is the concern that retrospective recall is subject to serious biases (Bradburn, Rips, & Shevell, 1987; Hufford & Shiffman, 2002; Shiffman, Hufford,

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et al., 1997) that can impair valid scientific inference; asking subjects about what is happening here-and-now has advantages over asking what happened there-and-then. Second is the interest in understanding how events, behaviors, and experiences play out over time and context, which requires data with degree of temporal resolution appropriate to the dynamics of the behavior of interest. The actual degree of temporal resolution needed should be determined by theory or data about the timeframe for relevant processes (Collins, 2006); some processes (e.g., impulsive responses to emotional change) might be very rapid, while others (e.g., exhaustion of motivation to quit) might progress more slowly. An important consideration is that phenomena that might initially be thought to be relatively stable often turn out to be quite volatile, when measured with greater temporal resolution (e.g., changes in self-efficacy [SE] documented in Gwaltney, Shiffman, & Sayette, 2005). Temporal resolution is limited by the density of data collection, so these issues need to be considered when first designing an EMA study.

EMA typically involves numerous assessments over time, yielding what has sometimes been called intensive longitudinal data (Collins, 2006; Walls & Schafer, 2006). The need for many assessments follows from several considerations. Assessments focus on particular moments, but the individual moments themselves are seldom of interest to the investigator. Instead, the investigator may conceptualize them collectively as samples of the subject's experience and require a number of assessments to characterize the overall experience. The arraying of assessments over time also allows investigators to trace the trajectory of experience over time and context, demanding many assessments. Indeed, consideration of the role of time can help structure analyses of EMA data, as will be illustrated later in this paper.

EMA Designs

A useful way to conceptualize collection of EMA data is to consider how assessments are scheduled. Assessments may be linked to events, such as occasions when the subject is about to smoke a cigarette. Such "event-contingent" assessments (Shiffman, 2007; Wheeler & Reis, 1991) are typically triggered by the subject reporting that they are about to smoke or have smoked; thus, these assessments are sometimes referred to as subject-initiated. But they need not actually be initiated by the subject. Researchers are developing systems that can automatically detect smoking (Ali et al., 2012), and an event might be defined by some other objective measure, such as entering a particular location, detected by Global Positioning System (Kirchner, Cantrell, et al., 2013). Smoking event data inform the investigator about how many smoking events occurred and when they occurred, allowing temporal patterns to be analyzed. If the assessments also collect data about the person's situation at the time of smoking, they can document such circumstances, for example, characterizing smokers' locations or moods when they smoke.

Another approach to scheduling EMA data is to schedule assessments for certain times, most often at random; randomly time sampling subjects' state provides a representative and unbiased estimate of subjects' typical state. Other variations include scheduling assessments at random, but within blocks of time of day, assuring that all blocks of time are sampled, or scheduling assessments at regular intervals, ensuring equal spacing. To prompt the subject for assessment at scheduled times, EMA studies typically use a device that can "beep" at the appropriate time (e.g., mobile phones, palmtop computers, pagers), and these sorts of assessments are sometimes referred to as "signal-contingent" assessments (Shiffman, 2007; Wheeler & Reis, 1991).

A final way to schedule assessments is to tie them to particular milestone times, rather than administer them throughout the day. Examples include having subjects complete a diary "every evening," while leaving the exact timing to the subject's discretion, or having subjects complete diary "when first waking up." Such assessments should not typically be treated as representing the subject's overall experience but are meant to collect somewhat retrospective data on experience over larger intervals (e.g., how stressful the day was) or to capture particular experiences that are time bound (e.g., sleep quality).

It can be useful to combine these different modes of assessment scheduling. A very common EMA design combines event-contingent assessments of smoking episodes with signal-contingent assessments of nonsmoking moments. For investigators interested in characterizing smoking events, the nonsmoking data add value in at least two ways. First, without a contrast to nonsmoking moments, the data collected about smoking events are hard to interpret and can be misleading (Paty, Kassel, & Shiffman, 1992). For example, someone who reports being anxious when smoking may not be prompted to smoke by anxiety—the individual may just be anxious all the time. The nonsmoking assessments function like the controls in a case–control design, enabling valid inference by contrasting cases and controls. Second, randomly sampled data can also be used to characterize the subject's general experience and the trajectory of experience over time. A previous paper discussed these assessment types and design considerations in more detail (Shiffman, 2007).

EMA IN TOBACCO RESEARCH

EMA methods are particularly well suited to studying tobacco use. Tobacco use itself is a discrete event that lends itself to event-based assessment. Moreover, many theoretical accounts of tobacco use reference proximal influences that drive tobacco use. For example, theory suggests that smoking may be triggered by symptoms attending a drop in nicotine levels (Benowitz, 2008; Stolerman & Jarvis, 1995), by stimuli previously associated with smoking (Marlatt & Gordon, 1985; Niaura et al., 1988), or by a need to mitigate acute negative affect (Kassel, Stroud, & Paronis, 2003). Similarly, during cessation, theory suggests that lapses (limited episodes of use) may be triggered by craving (West & Schneider, 1987), by negative affect (Sinha, 2001), or by conditioned cues (Marlatt & Gordon, 1985; Niaura et al., 1988). EMA is ideally suited to assessing such microprocesses, examining proximal influences on such episodes. Accordingly, it is not surprising that EMA methods are being widely applied to studies of tobacco use, particularly smoking. EMA methods have been used to study antecedents and consequences of smoking in adolescents (Mermelstein, Hedeker, & Wesintein, 2010) and adults (Carter et al., 2010; Warthen & Tiffany, 2009), in smokers with posttraumatic stress disorder and other disorders (Beckham et al., 2008; Epstein, Marrone, Heishman, Schmittner, & Preston, 2010; Piper, Cook, Schlam, Jorenby, & Baker, 2011), during

ad libitum smoking (Shapiro, Jamner, Davydov, & James, 2002) and smoking cessation (Bolt, Piper, Theobald, & Baker, 2012; Cooney et al., 2007; Minami, McCarthy, Jorenby, & Baker, 2011), and in relation to a range of variables ranging from alcohol use (Holt, Litt, & Cooney, 2012; Piasecki, Wood, Shiffman, Sher, & Heath, 2012; Witkiewitz et al., 2012) to worried thoughts about smoking (Magnan, Köblitz, McCaul, & Dillard, 2013), and exposure to media messages (Shadel, Martino, Setodji, & Scharf, 2012) or proximity to tobacco sales outlets (Kirchner, Cantrell, et al., 2013). EMA methods have also been fruitfully applied to study the effects of treatment, both to define treatment outcome (Shiffman et al., 2000; Shiffman et al., 2006) and to examine the processes that mediate treatment effects (Ferguson, Shiffman, & Gwaltney, 2006; McCarthy et al., 2008; Piper et al., 2008).

STRUCTURING ANALYSES OF EMA DATA

Conceptualizing EMA Analysis

One of the aspects of EMA that investigators new to the methods find most intimidating is data analysis. Not only do EMA data include multiple observations per person, but the number of observations, and their timing, varies between subjects. Such data are not amenable to analysis by simple methods requiring independent observations. However, a variety of methods for handling such data are now available and accessible in several popular statistical packages, the most common of these being hierarchical or multilevel regression models (Rabe-Hesketh & Skrondal, 2008; Raudenbush, Bryk, Cheong, & Congdon, 2010; Singer, 1998; Snijders & Bosker, 2011; see Schwartz & Stone, 2007).

Nevertheless, many investigators continue to find analysis of EMA data daunting. Given the availability of accessible statistical methods and software, this is not so much a statistical challenge as a conceptual one of formulating appropriate analyses for EMA data. EMA data are often relatively unstructured, consisting of a detailed temporal record of subject experiences, from which investigators aim to extract meaningful relationships. In these datasets, subjects' behaviors and experiences often determine which observations or portions of the data are of interest, for example, when stress peaks or when a smoking lapse occurs. This makes selection and framing of the data for analysis more challenging, but crucial, as illustrated below.

Two Illustrative EMA Studies of Smoking and Relapse

Illustrating the relatively unstructured nature of EMA data are studies conducted by our research group to understand antecedents of ad libitum smoking and the processes that lead to relapse in smoking cessation. The two studies used illustratively below were studies of smoking and relapse process in which smokers were observed while smoking and then followed through a quit attempt (Chandra, Shiffman, Scharf, Dang, & Shadel, 2007; Ferguson et al., 2006; Shiffman et al., 2002; Shiffman, Hickcox, et al., 1996; Shiffman, Paty, Gnys, Kassel, & Hickcox, 1996; Shiffman et al., 2006). The studies combined event-contingent and signal-contingent assessments throughout the day, as well as daily assessments at waking and in the evening. Subjects used palmtop computers to monitor smoking episodes by making event entries for 2 weeks before a target quit date. Each cigarette "event" is recorded. A random subsample of these smoking events is selected for a more extensive assessment of the surrounding circumstances. This more complete assessment was thought to be too burdensome to implement for every cigarette smoked. During this time, subjects were also prompted at random (nonsmoking) times to complete parallel signal-contingent assessments. After the target quit date, subjects monitored lapses (limited episodes of smoking) and episodes of temptation to smoke for 4–6 weeks, while continuing to receive randomly scheduled signal-contingent assessment prompts. Subjects were considered to have quit when the EMA data indicated they had gone without smoking for 24 hr and were considered relapsed when they smoked ≥5 cigarettes on 3 consecutive days. One study (Shiffman, Paty, et al., 1996) enrolled 304 smokers who were all provided with cognitive behavioral treatment; a second enrolled 412 smokers and subsequently randomized 324 to high-dose patch or placebo (Shiffman et al., 2006).

The first study illustrates the challenges faced by EMA investigators in determining how to analyze their data. The final database contained 191,841 records. Of these, 74,270 were momentary assessments (45,959 signal-contingent assessments, and 28,311 event assessments: 22,016 smoking occasions, 1,729 lapses, and 4,566 temptations); each assessment comprised 45–73 individual variables. An additional 22,825 records were associated with two types of daily assessments (morning and evening). The remaining 94,746 records represent recorded events without any self-report assessment (71,895 smoking events not selected for assessments and 22,851 records of bedtime and waking), for which only the timing is known. Figure 1 shows graphically the records for five subjects and illustrates the relatively unstructured nature of the data. As there were 304 subjects in the study, the volume and variety of data seen in Figure 1 must be multiplied 60-fold. Such EMA datasets are rich, but also large, complex, and potentially overwhelming.

The richness of EMA data is an asset: A single dataset can lend itself to answering many different questions. But the richness comes at a price. The data structure does not inherently dictate the nature of the analysis, and many different analyses are possible—the particular research question dictates the analysis, what part of the data are of interest, and how the data needs to be structured for analysis. Before one can ask which statistical procedure might be appropriate, the investigator has to frame the research question and appropriately structure the data. This involves selecting the appropriate part of the data (as will be seen, many questions are best addressed by a subset of observations), and structuring it in a way that can answer the question, and that fits an appropriate statistical model. The task of analyzing EMA data requires that investigators and analysts think very explicitly and very hard about what question they are asking of the data and how the data might be selected, structured, and analyzed to answer that question.

The examples that follow, drawn from the studies described above, are intended to illustrate a range of analytic approaches to EMA data on smoking, organized according to how they incorporate time. Each example briefly states the research question, explains how data were selected and structured (including the unit of aggregation or analysis), how the data were analyzed, and what the results showed. As Figure 1 illustrates, time is often the key organizing principle for EMA data;

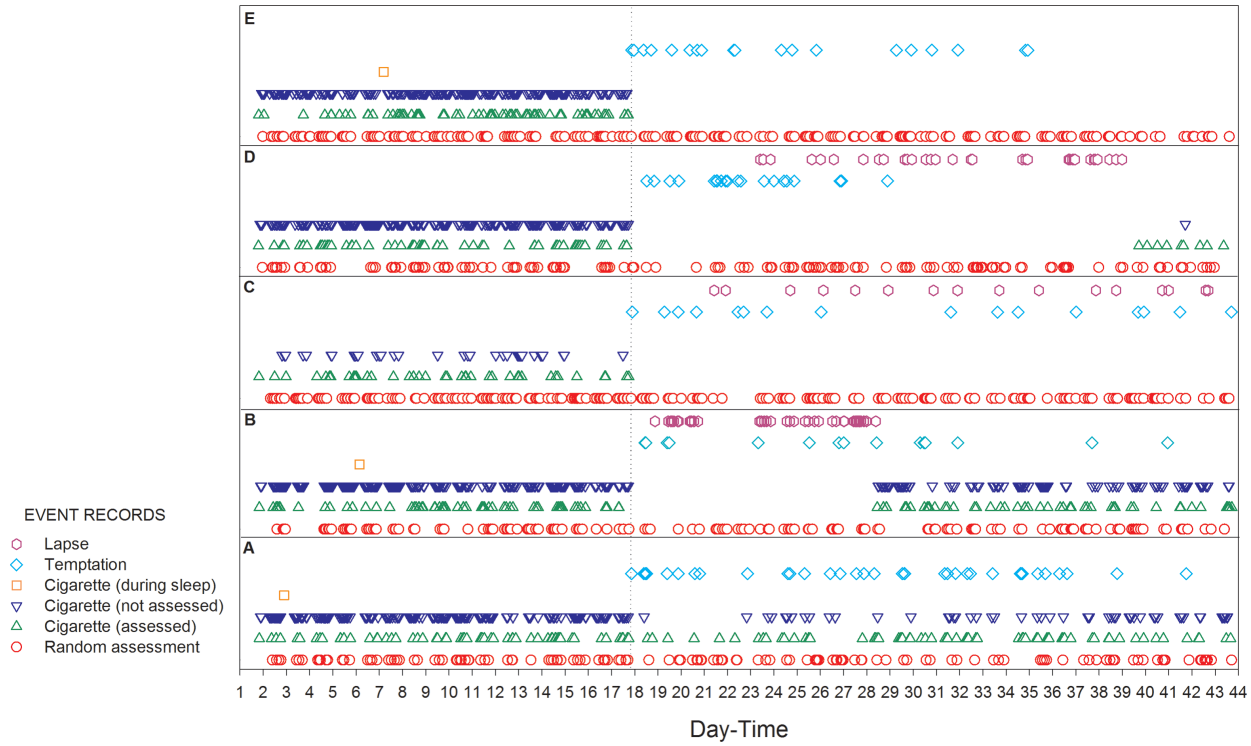

Figure 1. The figure shows the data stream for five subjects in the study, indicated as horizontal blocks A–E. Each point represents an observation of a particular type (see legend). The x-axis is continuous time, marked by days in the study. The end of Day 17, indicated by the vertical dotted line, was designated as the Target Quit, the time after which subjects were expected to abstain. The different markers indicate the different kinds of records, as identified in the legend. Thus, the graph shows the timeline of events for each subject. The bottom-most subject (A) did not quit, as indicated by the presence of cigarette records in the dates following the quit date. Subject B quit, as indicated by the absence of cigarette records after the quit date, but then frequently lapsed, as indicated by many lapse records, and eventually relapsed, as indicated by the return of smoking records around Day 28. Subject C quit, and lapsed, but did not relapse while in the study. Subject D did not lapse until Day 23 but had frequent temptations in the preceding days. Subject E quit and did not report any lapses, though some temptations were reported, at progressively sparser frequency. Daily milestones of waking up and going to bed and daily waking and evening assessments are not shown.

EMA data are anchored in time and create a timeline of subject experiences and events over time, allowing investigators to explore behavioral process over time.

Illustrative Analyses of EMA Data

This section presents 11 different analyses of the EMA data from the sample studies, each illustrating a different selection and organization of the data and a different approach to statistical modeling, in order to answer a different kind of research question. The examples are distinguished by how they conceptualize the role of time and represent it in the analysis. The illustrative examples are summarized in Table 1.

Collapsing Time: Between-Subjects Analyses

Time need not always figure explicitly in EMA analyses. Some research questions may be about differences between individuals, with no reference to change over time. An example comes from assessment of nicotine dependence. The Drive subscale of the Nicotine Dependence Syndrome Scale (Shiffman, Waters, & Hickcox, 2004) purports to assess the tendency to experience craving when smokers abstains from smoking, a core construct in dependence. The research question was whether smokers scoring higher on Drive experience more intense craving when they quit. Since this was very much a subject-level question, data were collapsed over time, averaging craving ratings for each subject from all signal-contingent assessments they completed in the first 2 days after quitting in order to derive a single craving score. Using simple Pearson correlation across subjects, Drive correlated with postquit craving significantly, but modestly, at $r = .20$ (Shiffman et al., 2004).

As this was a between-subjects analysis, it seems not to incorporate any effect of time. Yet, the analysis is actually quite time dependent, in that the period over which craving was assessed was defined by time: the 2 days after the subject had first abstained for 24 hr (note that time here is not anchored in the calendar but is anchored in a subject-specific event observed via EMA). The time sampling via signal-contingent assessments was also crucial in assuring representative sampling of craving during those 2 days, and the aggregation of multiple assessments increases the reliability of the craving measure. Thus, the time anchoring of EMA assessments played a role even in this "timeless" analysis.

Collapsing Time Into Events: Contrasting Events

The prior example showed how time-bound observations could usefully be collapsed to contrast subjects. Observations may also be collapsed over time when contrasting events or contexts

Table 1. Summary of Illustrative Designs and Analyses

Illustrative design and analysis	Treatment of time	Example content/research question
Between-subjects differences	Time is not represented in the analysis, though observations may be selected by time	Whether more dependent smokers experience more intense craving
Contrasting events (case–control)	Contrasts observations collected at different "times"—that is, in different situations—but without respect to their temporal ordering	Whether the probability of drinking differs between when the person is smoking versus not smoking
Event rates: events/unit time	Uses time to calculate a rate of events (e.g., smoking) per unit of time	Whether smoking rate increases when smokers are feeling restless
Sequence of events	Uses time to establish a temporal ordering of events	Whether negative affect is higher at the time of a lapse than during a prior, randomly selected, occasion
Clock and calendar time	Time is represented conventionally, as a time of day or day of week	Whether smoking rate varies by time of day
Time defined by event	Time is defined by a contrast of before versus after an event	Whether self-efficacy drops after a lapse, compared to its level before the lapse
Time following an anchoring event	Data are analyzed for trends over time, running forward from a key event	How craving intensity changes after a smoker establishes abstinence
Time preceding an anchoring event	Data are analyzed for trends over time, preceding and leading up to a key event	Whether negative affect is on the rise in the time leading up to a lapse
Time-to-event analyses: time as risk	The analysis focuses on the time elapsed until a certain event occurs (if it occurs at all), with shorter times indicating a greater risk per unit time	Whether smokers who are more demoralized after a lapse progress more quickly to a second lapse
Events recurring over time	Analyzes time-to-events, as above, but allows for multiple cycles of event recurrence	How the time between one lapse to the next changes across a sequence of lapses
Change in effects over time	Analyzes whether the relationship between two variables changes over time	How the relationship between self-efficacy and craving changes over time

within persons. This example focuses on the role played by alcohol consumption in triggering smoking (Shiffman et al., 2002). The research question was whether smoking was more likely to occur when the individual had been drinking. To address this, the analysis used a case–control design (actually, case-crossover), contrasting the proportion of occasions that each subject was drinking when they were smoking (cases, from event assessments) versus when not smoking (controls, from signal-contingent assessments). The analysis used Generalized Estimating Equations (GEEs; Zeger et al., 1988), a regression-based method that accounts for nesting of observations within subjects, to contrast the probability of drinking prior to smoking versus nonsmoking episodes. Smoking was associated drinking: Subjects reported drinking on 11% of the occasions when they were smoking versus 6% of nonsmoking occasions (*OR* = 2.10, 95% *CI*: 1.80–2.45). This analysis focuses on differences between events rather than between subjects: It contrasts, across persons, the likelihood of drinking over multiple smoking and nonsmoking occasions. Time is not explicitly referenced in the analysis, yet the entire analysis is based on contrasting data collected at two different "times"—when smoking and when not smoking.

Cigarette Consumption per Unit Time

An alternative approach to analyzing the relationship between situational variables and smoking more explicitly incorporates time. Point process analyses (Rathbun, Shiffman, & Gwaltney, 2007) do not focus on single smoking events, but rather on the smoking "intensity" or rate—that is, cigarettes per unit time—as a function of covariates. The analysis also takes into account the sampling scheme for EMA data. One question addressed using point process analysis of the data on ad libitum smoking, prior to quitting, concerned the relationship between smoking rate and restlessness. Some evidence suggests that restlessness may be a particularly good and specific indicator of nicotine withdrawal (Shiffman, Paty, et al., 1996), in contrast to broader measures of negative affect, which are heavily affected by other influences. Accordingly, it was expected that smoking rate would show specific increases as restlessness increased.

A point process analysis using individual observations of event-contingent smoking and signal-contingent nonsmoking data (i.e., with no aggregation) confirmed the hypothesis: Smoking rate increased by 16% for every 1-point increase in the 4-point restlessness rating (Shiffman & Rathbun, 2011). In contrast, a more global measure of negative affect was unrelated to the smoking rate. Considering time as part of a calculation of smoking *rate* allows for more powerful analyses of influences on smoking.

Sequences of Events Over Time

Most of the prior analyses do not take into account the particular sequence in which recorded events or assessments took place. But sometimes the sequencing can be very important and can inform our understanding of process. In this example,

the research question was whether initial lapses to smoking occurred in the context of emotional distress. The very first lapse is important because it breaks the momentum of abstinence and often leads to relapse (Kenford et al., 1994). In the study, subjects who lapsed recorded their emotional state at the start of the episode, and their ratings indicated emotional distress (Shiffman, Paty, et al., 1996). However, such event data are interpretable only by contrast to data from a control observation, which this EMA design provides through the randomly sampled, signal-contingent (nonlapse) assessments. Unlike in the prior example, the selection of control observations must be sensitive to temporal sequence because the subject's emotional state *after* the lapse could be influenced by the lapse itself, confounding any analysis based on postlapse records.

For this analysis, then, affect preceding the first lapse was compared to the affect in a single signal-contingent assessment that *preceded* the lapse (see Shiffman, Paty, et al., 1996 for information on how the assessment was selected). Since each subject contributed only one observation of each type, the analysis used a simple dependent *t* test. Comparison of affect ratings confirmed that lapse episodes were associated with elevated distress, compared to the preceding random assessment (*T*-score [$M = 50$, $SD = 10$] of 57.8 vs. 50.0, $p < .0001$). Besides avoiding confounding, the fact that the less-distressing random assessment came first also allowed an important further inference. Because withdrawal intensity decreases over time for most subjects (though see Piasecki et al., 2000; Piasecki, Jorenby, Smith, Fiore, & Baker, 2003), the increase in distress seen in the later (lapse) observation could not readily be attributed to nicotine withdrawal. Thus, the example illustrates the importance of establishing temporal ordering of events and experiences. It also illustrates an exception to the earlier statement that EMA researchers are seldom interested in any one moment or event. The first lapse is considered to be an important unique milestone that dramatically changes the smoker's trajectory towards abstinence or relapse. Thus, EMA researchers may not only be interested in events and experiences over time but also in experience at particular unique moments in time.

Clock and Calendar Time

One way for an analysis to take account of time is to examine how behavior and experience vary over time, as defined conventionally by the clock or calendar. This analysis aimed at documenting how smoking rate varied by time of day and assessing whether different temporal patterns were associated with differences in dependence and in relapse risk. More dependent smokers are thought to smoke more in the morning because most of the nicotine they absorbed the previous day will have been excreted overnight. To explore circadian patterns of smoking, Chandra et al. (2007) tallied how many cigarettes each subject smoked in each of eight time blocks (roughly 2 hr each), representing the waking day, and then aggregated across days. Thus, each subject's data were reduced to 8 data points, representing their average smoking rate during eight time blocks. Importantly, for this analysis, absolute clock time could not be used because subjects wake up and go to bed at different times (varying on different days), and it is the distribution of cigarettes within the waking day that is considered most relevant. Accordingly, Chandra et al. (2007) normalized time to span each subject's waking day and divided it into eight time blocks of equal length. These temporal profiles were then submitted to cluster analysis to identify common circadian patterns. Figure 2 shows the rate of cigarette consumption (relative to each person's daily average), by time blocks, for the different clusters. Most of the groups in this heavy-smoking sample smoked more in the morning; "Flatline" smokers were the exception. As hypothesized, Flatliners were lighter and less dependent smokers. Moreover, using subject-level survival analysis, the analysis showed that the cluster groups differed in time to lapse (with or without a nicotine patch), confirming that circadian patterns of consumption are relevant to cessation outcome. This analysis focused on between-subject differences, but those differences were defined by how subjects' behavior varied by time of day. This analysis was also notable in that the EMA data consisted solely of event records, without any subjective self-report data.

Time as Defined by an Event

For some hypotheses, the passage of time itself is not of interest, but rather the occurrence of key events, which define time simply as before the event or after. Marlatt and Gordon's (1985) theory of relapse emphasizes smokers' psychological reactions to lapses as the determining factor in subjects' subsequent trajectory and outcome. They hypothesized that a lapse causes smokers' SE to decline, putting them on a course towards further smoking, whereas successfully avoiding smoking when tempted would cause SE to increase, putting them on a trajectory towards continued abstinence. To address this hypothesis, the analysis (Shiffman, Hickcox, et al., 1997) identified each smoker's first lapse episode, assessment of which included a rating of their SE after the lapse. Each smoker's

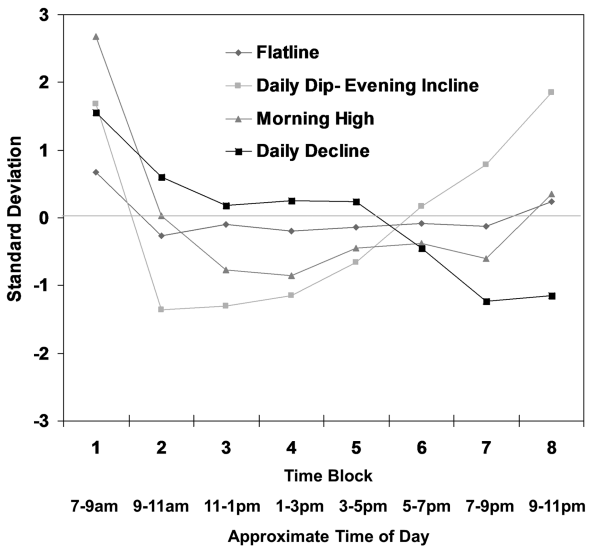

Figure 2. The figure shows the relative frequency of smoking in each of eight 2-hr blocks defined by time of day, with approximate times reported below the axis. Actual times and span of each block differed by subject and day, according to when they woke up and went to bed. Smoking frequency is indicated on a standard scale, relative to each subject's average. The lines represent patterns seen in different clusters defined by their circadian patterns of smoking. Figure from Chandra et al. (2007), reprinted with APA permission.

prelapse SE was estimated by looking back at ratings made at a single randomly scheduled, signal-based assessment—the one that most closely preceded the lapse (averaging about 8 hr prior). A single temptation episode was selected for analysis from a prior day close to the lapse (temporal precedence being deemed important) and was similarly paired with a single preceding random assessment. This set up traditional, balanced repeated-measures analyses contrasting pre- versus postepisode SE levels, in lapses and temptations (this study also included GEE analyses of multiple temptations). These analyses make explicit use of time, defining time by anchoring it to lapse and temptation events to create pre- versus postevent measures. The data showed that SE did indeed decline after a lapse but, sadly, did not increase after smokers successfully resisted temptation (Shiffman, Hickcox, et al., 1997).

Time Following an Anchoring Event

The idea of defining time by anchoring it in an event of interest can be extended beyond a simple pre- and postevent analysis. Some events are seen as leading to a change in experience over time. One research question concerns the trajectory of craving intensity over time after a person quits smoking. Some theory suggests craving should progressively increase as abstinence grows longer. To construct such a timeline, time is anchored by the achievement of abstinence; the time axis cannot be anchored by the calendar or study schedule, since individuals quit at different times (Shiffman et al., 2006). For the analysis, craving ratings from random, signal-contingent time sampling assessments were aggregated by day to form a series of days beginning with each subject's initial abstinence and ending when they reported lapsing to smoking (Shiffman, Engberg, et al., 1997). Since the research question concerned the course of craving over days and weeks, not its pattern within a day, it was appropriate to aggregate data to the day level, making the trajectory more interpretable and smoothing out circadian variations. Anchoring the timeline on the quit day and censoring on the lapse day allowed the trend to be interpreted as referring to the course of craving during abstinence. Using GEE methods, the analysis showed that "background" craving (i.e., "steady-state" craving in the absence of provocatuve cues; Shiffman, 1989) did not rise over time but actually declined rather steeply to low levels as abstinence progressed.

Time Preceding an Anchoring Event

The prior example used EMA data to follow experience forward from an index event such as quitting smoking. It is sometimes even more useful to look backwards from an index event, such as the first lapse after quitting. As already noted, such lapses represent key turning points in a quit effort. Thus, an important research question concerns experiences, such as emotional distress, that lead up to a lapse, and may cause it. As one is interested in events preceding a lapse, and the timing of lapses is unpredictable, one has to look backwards in the EMA data stream to retrieve data on experience preceding the lapse.

Two analyses were performed, on different data at different levels of aggregation, to address the trajectory of affect leading up to the lapse (Shiffman & Waters, 2004). The first analysis used GEE to examine temporal trends in affect (assessed by signal-contingent assessments) in the 4 days preceding the first lapse (it was limited to 4 days because many lapsers did not have abstinence data going further back). Figure 3 shows that there was no significant increase in negative affect over the preceding days. Analyses of stress measures collected just once each evening yielded similar results. This shows that day-level variation in affect does not influence lapse risk.

A second analysis was more fine grained and more proximal: It examined data on the day of the lapse itself and did not aggregate the data, but instead looked at the individual, unaggregated assessments on the lapse day, arrayed by time (4 min to 18 hr), running back from the time of the lapse. GEE methods were used to examine temporal trends over that interval. As shown in Figure 3, on the lapse day itself, emotional distress increased in the hours leading up to the lapse episode. Although retrieved in retrospect, these data were collected prospectively and thus overcome concern that the subjects' post facto response to the lapse would bias their recall of their mood. Running time backwards yielded a prospective timeline that could shed light on the precursors of later events. The analyses also illustrate the important effects of time scale: Emotional distress in the *days* before a lapse did not matter, but emotional distress in the *hours* before a lapse did. This highlights the importance of thinking carefully about different units of analysis and different timeframes to assess the effects of interest and shows the potential for EMA to provide data fine grained enough to examine the effects of acute changes in experience over a period of hours. However, even data collection as intensive as that in this study has limited temporal resolution. In this study, 20% of subjects had no assessments preceding the lapse on the lapse day, and those who did have assessments averaged only four assessments in the 9 hr (average) preceding the lapse episode, limiting the detail in which the timecourse of affect could be described.

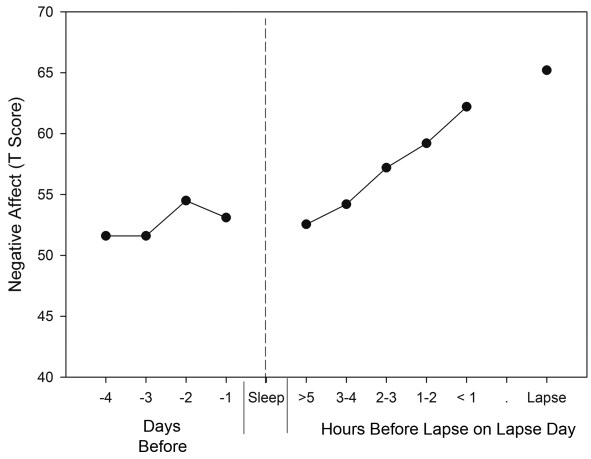

Figure 3. The figure shows the negative affect reported by subjects who lapsed, by time prior to the first lapse; the final point represents the negative affect reported to have been experienced just before the lapse. The data are limited to subjects who attributed their lapse to negative affect or stress. The left panel shows data aggregated to daily averages, for the 4 days preceding the first lapse. The right panel is based on reports on the day of the lapse itself, but preceding the lapse. The points represent a smoothed moving average of affect reported at individual assessment occasions. Based on Shiffman and Waters (2004), reprinted with APA permission.

Time-to-Event Analyses: Time as Risk

In the examples above, the analysis documents subject-reported experience collected over time to display the trajectory of experiences over that interval. Time can figure into EMA-based analyses in another way: as an opportunity to observe the occurrence and timing of events of interest. Important research questions revolve around the process of progression from one lapse—particularly the very first—to the next. Although it is known that a lapse almost always progresses to relapse (Kenford et al., 1994), it is not known what influences drive that progression. Marlatt and Gordon (1985) hypothesized that smoker demoralization in response to a lapse can lead to further lapses. This research question was evaluated using smokers' reports of whether they felt like giving up after experiencing their first lapse.

One way to assess how this affected progression to a subsequent lapse is to use survival analysis or time-to-event methods (Hosmer, Lemeshow, & May, 2008), which analyze the risk of an event, such as a lapse. Events occurring sooner indicate greater risk (per unit time), and the analysis takes into account that some events are unobserved or censored (e.g., a lapse could occur after the study ended). A survival (or time-to-event) analysis (Cox proportional hazards) related subjects' readiness to give up after a lapse to the length of time they maintained abstinence before lapsing again (or not). The analysis showed that subjects who felt like giving up did indeed progress to the next lapse more quickly (Shiffman, Hickcox, et al., 1996). Note that this analysis does not use any data collected during the interval from the first lapse to the second: It just uses the record of the second lapse (if any) to define the time-to-relapse. Thus, in such analyses, time is a crucial focus, but just as a basis for understanding the risk of an event such as a recurring lapse. In such analyses, the ability of EMA to provide precise timing for the relapse was crucial, as was the ability to get data on subjects' immediate response to the lapse.

Events Recurring Over Time

The preceding analysis analyzed a single instance of progression from one lapse (the first) to another. But smokers may experience multiple lapses during their progression to relapse. One question is whether the process of re-lapsing accelerates over this series of lapse episodes and whether treatment with nicotine replacement could help mitigate this acceleration (Kirchner, Shiffman, & Wileyto, 2012). The dataset in this analysis consisted of the first 25 lapse episodes reported by each individual (the data grew too sparse beyond that point), arrayed in sequence. The analysis was based on recurrent event survival methods (Hosmer et al., 2008), which allow for multiple successive events, and examined whether the re-lapsing process was accelerating; that is, whether the time between lapses grew progressively shorter. Figure 4 shows that it did. Importantly, the analysis and the graph also show that the process was moderated by nicotine replacement treatment, in a complex way. Being on active patch initially slowed progression to the next lapse quite dramatically (from 36 hr on placebo to 90 hr on patch), but this protective effect declined over successive lapses, disappearing after about eight lapse episodes. Thus, the effect of patch on relapse time fades over successive lapse episodes. This implies that pharmacotherapy can mitigate the progression from lapse to relapse and suggests that, both on patch and off, there is a limited window during which other interventions might be able to slow or reverse the slide towards relapse.

This complex analysis includes time in multiple ways. The x-axis in Figure 4 does not represent time, per se, but successive lapse episodes; in effect, it represents time as a sequence of events, without regard to their spacing in time. The y-axis represents, for each successive episode, the median time-to-relapse; each point in the graph is itself an estimate derived from the recurrent event survival analysis. Note, too, that no EMA self-report data are used in this analysis—just the EMA data on the timing of events and the subject-level treatment assignment are used. Yet, the analysis is almost entirely about time, while also addressing treatment effects.

Change in Effects Over Time

The preceding analysis illustrates an important principle: The effect of one variable on another can vary over time. Models known as time-varying effects models (TVEMs; Li et al., 2006) are designed to capture such effect moderation in very flexible ways. The analysis does not force temporal trends to fit a particular parametric function but allows for very flexible nonparametric fitting. Marlatt and Gordon (1985) hypothesized that low SE would promote craving. However, both SE and craving vary substantially over the course of a quit effort, leading Shiyko, Lanza, Tan, Li, and Shiffman (2012) to examine whether the relationship between SE and craving might vary over time, perhaps in different ways for successful versus unsuccessful quitters.

Using event-level data, a TVEM analysis indeed showed differences. As shown in Figure 5, among successful quitters, higher SE was associated with lower urges throughout the interval. The relationship was more dynamic among relapsers: SE and urges were unrelated in the first 2 days of quitting, but the association grew stronger over time, reaching the degree of association seen among successful quitters about a week later,

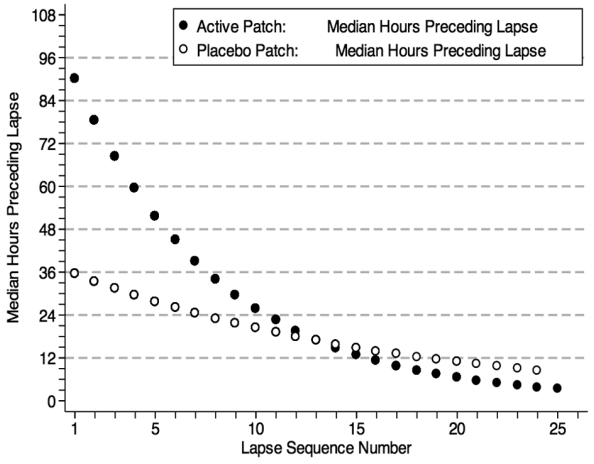

Figure 4. The figure shows the lag between successive smoking lapses, as subjects progressed from one lapse to the next. The x-axis represents successive lapses from 1 to 25. The y-axis represents the median time between lapses, for successive lapses. Data are shown separately for subjects randomized to treatment with active nicotine patch or placebo. Figure from Kirchner, Shiffman et al. (2012), reprinted with APA permission.

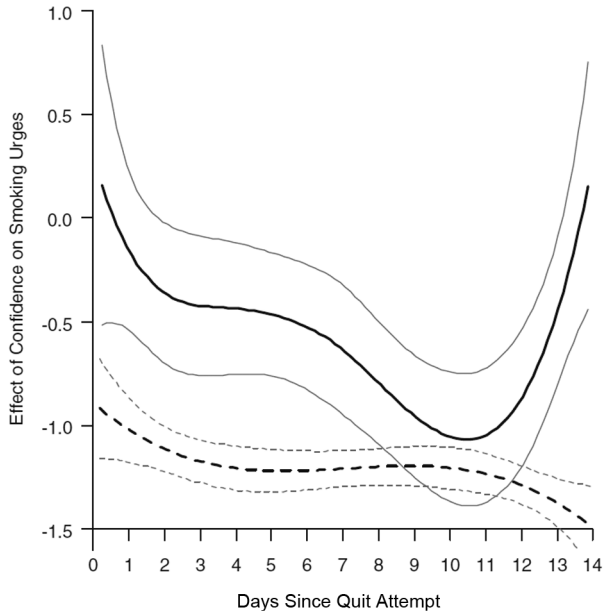

Figure 5. A graphical summary of slope functions of the time-varying effects of self-efficacy (SE) on smoking urges for relapsers (solid line, $N = 40$) and successful quitters (dashed line, $N = 207$) over the course of 2 weeks postquit. Each curve shows the estimated slope for smoking urges versus SE (confidence); negative values indicated that higher SE is associated with lower urges. The grey lines (solid and dashed) surrounding each line represent the 95% CI for each curve. Figure from Shiyko et al. (2012), reprinted with permission of Springer Science and Business Media.

only to diminish again towards the end of the interval. This illustrates how time may act as a moderator of the relationship between two other variables. Examples applying TVEM analyses to EMA data are included in this special issue.

ADDITIONAL CONSIDERATIONS

The examples discussed here do not exhaust the potential approaches to analyzing EMA data or to representing time in EMA data. One important issue for investigators to consider is when time should be considered and analyzed as a continuous variable, versus being considered categorical or analyzed piecewise. Piecewise analyses may be particularly useful for analyzing the effects of quitting because quitting represents an abrupt transition in process—in effect, an interruption of the timeline. See McCarthy, Piasecki, Fiore, and Baker (2006) for an example of handling of the quit-day transition in this way. Similar approaches might be fruitfully used to model how the process changes when a treatment is introduced or changed. Since EMA data typically produce a continuous timeline, the decision on how to operationalize time in the analysis can be individualized to the needs of the particular research question.

While the examples given here largely focus on naturalistic processes outside of treatment, it is important to recognize the potential contribution of EMA data and analyses to our understanding of treatment effects. EMA data can be used not only to capture outcomes in a more refined or precise way (e.g., precisely estimating the time to first lapse) but can make unique contributions to understanding mediation and moderation of treatment effects. For example, several EMA studies (Ferguson et al., 2006; McCarthy et al., 2008; Piper et al., 2008) have examined whether the ability of approved smoking cessation medications to reduce craving can account for their effect on abstinence. The studies consistently find that craving-reduction effects do mediate efficacy. Analyses of EMA data have also identified mediators of behavioral treatment (McCarthy et al., 2010). Moderation effects could also be examined using EMA. For example, one might speculate that the effects of medication may vary by state, for example, with craving-reducing effects only seen when craving is elevated. EMA can contribute to understanding treatment effects.

EMA analysis is an active field of development. As illustrated in this special issue, new approaches are being creatively applied to answer a variety of questions using EMA data (see also Walls & Schafer, 2006). As with current analytic techniques, the research question, and not the availability of statistical models or software, must drive the approach to analysis. Theoretical considerations should also lead investigators to examine other time-based effects, such as cumulative effects (e.g., does the accumulation of stress, rather than its current level, promote relapse?) and reciprocal effects (e.g., does lapsing increase craving, which in turn leads to more lapsing, which…). Such questions and models will require yet different data structures and analytic model suitable to the investigator's research questions.

CONCLUSION

The examples given here illustrate how EMA data, which lack some of the structure of other designs, can be arranged and analyzed in different ways to answer a variety of research questions. EMA data provide a detailed timeline of subject behavior and experience, thus allowing a variety of time-based analyses. This flexibility allows investigators to answer a broad range of questions, even those not anticipated when the study was designed. Yet, this very flexibility challenges investigators to carefully and clearly frame research questions, so that they can be operationalized by appropriate selection and arrangement of the data and addressed by appropriate statistical analysis. In EMA data, as in other kinds of data, the approach to analysis must be driven by the research question. The challenges are typically more conceptual than operational, and the challenges of statistical analysis of EMA data should not be an impediment to creative application of EMA to studying tobacco and nicotine use.

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DECLARATION OF INTERESTS

The author consults to and has an interest in eRT, which provides electronic diary services for clinical research. The author also consults to GlaxoSmithKline Consumer Healthcare exclusively

on matters related to smoking cessation. GlaxoSmithKline Consumer Healthcare provided the nicotine patches used in the patch study reported in this paper.

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