The Time and Quality Advantages of Electronic VAS Scale vs. Paper VAS Scale Utilization in Studies

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ABSTRACT

Capturing data in an accurate and timely fashion is important in clinical research trials. Visual analog scale (VAS) assessment is often used to evaluate participants' subjective responses to Potential Reduced Exposure Products (PREPs). Advances in technology are enabling researchers to move from traditional, paper-based data collection to an e-tablet based methodology. We performed two clinical trials each involving three different tobacco products with 24 subjects. In each study, subjects used either paper forms or an e-tablet to investigate the abuse liability potential of given products with two questionnaires: VAS Tobacco/Nicotine Withdrawal Scale and the VAS Direct Effects Questions. Both studies had similar protocol design, inclusion/exclusion criteria, and patient demographics. Data was collected on the following: 1) time to complete the surveys and perform quality assurance checks 2) number of queries answered by staff.

With paper assessments, there was an average of nine (9) queries per subject involving measurement of the VAS line or documenting time/date for a total of 216 queries. The e-tablet based surveys had four (4) queries in total among all 24 subjects, a 54 x improvement. The mean times to complete the paper VAS/ per subject were 40.1 seconds for the Tobacco/Nicotine Withdrawal Scale and 38.8 seconds for the Product Effects Questionnaire. The e-tablet questionnaires were completed in 38.2 seconds and 36.9 seconds respectively. Mean query time by staff on the paper surveys was 3 minutes and 18 seconds. The e-tablet did not require any query time from the site perspective. While both methods captured the subject responses in nearly the same amount of time, the e-tablet based collection method reduced queries from entry error significantly and the total query time by staff by 30 minutes per subject, or 12 hours for 24 subjects. This represents a significant improvement in quality and an appreciable reduction in time spent managing the scale data.

INTRODUCTION

Potential reduced exposure products (PREPs) developed by the tobacco industry may reduce toxicant exposure, and it is hypothesized that this can reduce health risks. An important and common assessment measure employed across different types of studies examining PREPs is the participant's subjective responses to the PREP with various surveys. These surveys encompass the self-reported expressions of the participant's experience using the product and include product evaluation scales, sensory evaluation scales, drug-liking and drug effect ratings, as well as withdrawal scales. Visual Analog Scales (VAS) are often used to measure these areas by evaluating both the positive (e.g., liking the product, satisfaction from the product) and adverse reinforcing effects (e.g., reducing negative affect, withdrawal symptoms, and craving). Again, measuring the positive or negative impact of a product can be challenging, but VAS use allows the research to collect data that traverses a comprehensive continuum of responses that will vary in intensity or frequency. Very commonly, a VAS is a horizontal line of fixed length (100 mm), as illustrated in the accompanying picture. The ends of the horizontal line are defined as the extreme limits of the parameter to be measured (urges to smoke, urges to dip, irritability, etc.) and. scales can be uni polar or bi-polar in nature. Traditionally, these are captured with pen and a paper source, but there are ways to obtain this same data using an electronic tablet as well. Using a secure cloud platform, CANTAB Connect Research (Cambridge Cognition, LTD, Cambridge UK) provides software on an electronic tablet that captures VAS data with a touchscreen interface. The responses are then tabulated across subjects and treatment areas.

METHODS

Two clinical trials each involving three different tobacco products were executed over the course of one week. Both studies were designed to investigate the abuse liability potential of given products and employed two questionnaires: VAS Tobacco/Nicotine Withdrawal Scale (Hughes and Hatsukami (1986) and the VAS Product Effects Questions (Hanson et al. (2009). On one study, paper forms were used capture this data, and on the other, an electronic tablet (iPad) with software containing the questionnaires was employed (Cambridge Cognition, LTD, Cambridge UK). Both studies had similar protocol design, inclusion/exclusion criteria, and patient demographics. Training for subjects on completion of a paper source VAS was done as a group by demonstrating the proper way to inscribe a vertical line on the actual VAS line as well as review where to place the date/time.

The e-tablet training involved a trial of completing the VAS questionnaires on the actual e-tablet and was similar in duration to the paper VAS training. In the study involving paper source, the subjects were given a pen and clipboard containing the VAS questionnaire(s) for that specific timepoint. The paper source was organized by staff before study start to accommodate for the various time points for that session. VAS collection in the study using the e-source, subjects were given the e-tablet at designated time points. The software contained VAS questionnaires in the precise order and time sequence for that particular session. Data was collected as to the utility of paper source versus e-tablet software source in the following areas: 1) Time to complete the surveys and have staff perform quality checks 2). The number of queries answered by staff once the sessions were completed

FIGURE 1:

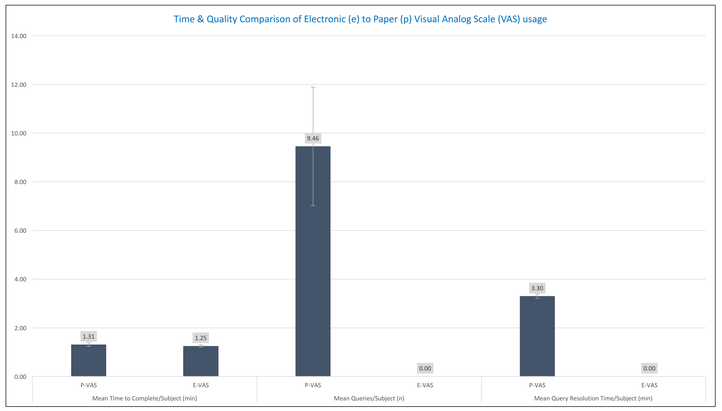
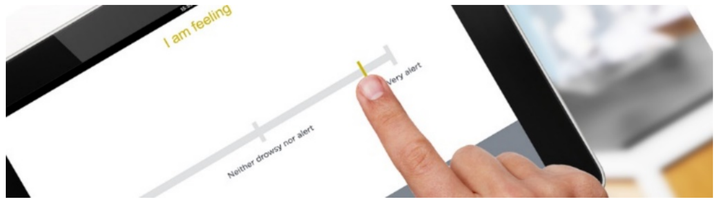


FIGURE 2:



RESULTS

There were 24 subjects enrolled in both studies. There were 216 queries to staff in the study involving paper VAS scales. More specifically, the paper assessments had a mean number of queries of 3.4 on the measurement of the VAS line per subject and a mean number of 5.6 time/date queries/ per subject respectively. The e-tablet surveys had four queries in total involving three subjects which involved duplication of a survey. The mean time to complete the paper VAS per subject was 40.1 seconds for Nicotine Withdrawal Scale and 38.8 seconds for the Product Effects Scale. The e-tablet questionnaires were completed in 38.2 and 36.9 seconds respectively. Quality assurance checking by staff on paper surveys was 1 minute 48 seconds per Nicotine Withdrawal Scale and 1 minute 29 seconds per Direct Effects of Tobacco Scale, for a total review time of 3 minutes and 18 seconds. The e-tablet did not require any query time from the site perspective.

CONCLUSIONS

Obtaining accurate clinical trial data in a timely fashion is absolutely vital to ensure top quality data for trustworthy conclusions; obtaining it faster in a less resource-intense manner is imperative from a business perspective. While both methods captured the subject responses in nearly the same amount of time, the e-tablet based collection method reduced queries from entry error significantly and the total query time by 30 minutes per subject, or 12 hours for 24 subjects. Even in this relatively small study, the time comes at the cost of professional clinical researcher's hourly rate and rapidly increases with the size of the study or the addition of more VAS scales. As some study designs can include multiple scales this time costs become prohibitive if performed manually. The emergence of electronic applications are increasingly common in clinical research trials and offer a means to collect data accurately and in a time efficient manner.

SOURCES

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Hanson, K, O'Connor R, Hatsukami D (2009). Measures for Assessing Subjective of Potential Reduced-Exposure Products, Cancer Epidemiology Biomarkers and Prevention, 18(12): 3209-3224

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