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**The effect of reducing the threshold for carbon monoxide validation of smoking abstinence - evidence
from the English Stop Smoking Services**

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Abstract

Introduction: The most commonly used threshold of expired-air carbon monoxide (CO) concentration to validate self-reported smoking abstinence is <10 parts per million (ppm). It has been proposed to reduce this threshold. This study examined what effect a reduction would have on short-term success rates in clinical practice.

Methods: A total of 315,718 quit attempts supported by English NHS Stop Smoking Services were included in the analysis. The proportion of 4-week quits as determined by the Russell standard (<10ppm) that also met lower thresholds was calculated for each unit change from <9ppm to <2ppm. Additionally, associations of established predictors with outcome were assessed in logistic regressions for selected thresholds.

Results: At <10ppm, 35% of quit attempts were regarded as successful. Differences for a single unit reduction increased with each reduction; small reductions had very little impact (e.g. <8ppm: 34.7% success), but at <3ppm, only 26.3% would still be regarded as successful. With the threshold reduced to <3ppm established predictors of cessation showed a weaker association with outcome than with the threshold at <10ppm suggesting an increase in error of outcome measurement.

Conclusions: Reducing the threshold for expired-air CO concentration to validate abstinence would have a minimal effect on success rates unless the threshold were reduced substantially which would likely increase error of measurement.

Keywords: smoking cessation, outcome criteria, carbon monoxide, success rates

1. Introduction

Measurement of biochemical markers of smoking (e.g. cotinine, carbon monoxide) can provide more accurate information on smoking status than self-report (Jarvis, Tunstall-Pedoe, Feyerabend, Vesey, & Saloojee, 1987; SRNT Subcommittee on Biochemical Verification, 2002) and is recommended as standard in clinical trials and routine clinical practice (Department of Health, 2011; SRNT Subcommittee on Biochemical Verification, 2002; West, Hajek, Stead, & Stapleton, 2005). Biochemical markers are widely used in research and clinical practice (e.g. Department of Health, 2011; Fidler, et al., 2011; Stapleton & Sutherland, 2011).

Although the nicotine metabolite cotinine is an optimal biomarker for discriminating smokers from non-smokers (Jarvis, et al., 1987) expired-air carbon-monoxide (CO) also has good sensitivity (percent of non-smokers classified correctly) and specificity (percent of smokers classified correctly) (SRNT Subcommittee on Biochemical Verification, 2002). As it is cheaper and easier to use, provides immediate results and, unlike cotinine, can be used with people who are obtaining nicotine from nicotine replacement therapy, it is recommended for use in routine clinical practice (Department of Health, 2011; West, et al., 2005).

The most commonly used CO threshold for validating smokers' self-reported abstinence is 10 parts per million (ppm), as for example defined by the Russell Standard (Clinical) (Department of Health, 2011; West, et al., 2005).

It has been argued that the threshold should be reduced to increase specificity, and a number of lower thresholds have been proposed, ranging from 6.5ppm (Deveci, Deveci, Acik, & Ozan, 2004) through 5 ppm (Low, Ong, & Tan, 2004; Maclaren, et al., 2010; Middleton & Morice, 2000; Secker-Walker, Vacek, Flynn, & Mead, 1997) to 2-3ppm (Cropsey, Eldridge, Weaver, Villalobos, & Stitzer, 2006; Javors, Hatch, & Lamb, 2005). However, little information is available on the effect of different thresholds in practice.

The UK has the most extensive coverage of smoking cessation support clinics of any country and information is recorded on the clients attending the services, the support they receive and success rates as defined according to the Russell Standard (Department of Health, 2011). The available information provides a unique opportunity to assess the effect lower thresholds would have on success rates reported in clinical

practice. Because no other objective measure of abstinence such as cotinine is being recorded in the services, it is not possible to calculate sensitivity and specificity, thus the aim of this study was to assess the impact of reducing the threshold for expired-air CO below 10ppm on success rates in clinical practice.

2. Material and methods

2.1. Design

Data were obtained from QuitManager (North 51, Nottingham, UK), an online database system for recording information on client and intervention characteristics in accordance with the Department of Health's standard monitoring requirements (Department of Health, 2011). In 2011, there were about 150 stop smoking services across England, of which 58 Services used QuitManager and 47 agreed to share anonymised data for the current audit.

2.2. Participants

As defined by the Department of Health, a treatment episode is completed with a follow-up four weeks after the quit date. Out of all 315,718 completed treatment episodes between April 2009 and June 2011, we identified 111,046 completed treatment episodes in which the client reported abstinence and expired-air CO was assessed.

2.3. Measures

The main outcome measure was CO-validated 4-week quit rates as defined by the Department of Health in England (2011), i.e. the client reports abstinence from smoking between weeks 2 and 4 and records an expired-air CO concentration below a pre-defined threshold, currently 10ppm. CO concentration in expired air was measured using CO monitors, which are required to be calibrated and checked regularly across the Services. For those not reporting abstinence, CO concentration were only recorded for a very small minority (4.9%), so they were not included in any analysis.

Information on some known predictors of quit success (Bauld, Bell, McCullough, Richardson, & Greaves, 2010; Brose, et al., 2011) were recorded; this included participants' age, gender, exemption from

prescription charges (exemption, pays for prescription, unknown), and medication used during the quit attempt (none, single form of nicotine replacement therapy or combination of two or more forms of nicotine replacement therapy, bupropion, varenicline).

2.4. Analysis

The proportions of those who, at 4-week follow-up, reported not having smoked for at least two weeks and had an expired-air CO concentration of less than 10ppm who would also have met stricter criteria were calculated for each unit decrease from <9ppm to <2ppm.

Additionally, the association of known predictors of successful quit attempts and quit rates was calculated using logistic regression for selected thresholds (<10ppm and <3ppm). A reduction in association was interpreted as an indication of decreased accuracy.

3. Results

Out of all 315,718 completed treatment episodes, 110,558 (35.0%) reported abstinence and had a CO value of less than 10ppm. The size of the difference for a single unit reduction increased with each reduction; initial single unit reductions made a very small difference, while the two lowest thresholds reduced the proportion of quit attempts defined as successful by about a quarter and by about a half, respectively (Table 1).

Logistic regressions showed weaker associations for all established predictors when the outcome was defined using the threshold of less than 3ppm (Table 2). This was indicated by smaller odds ratios and confidence intervals that did not include the odds ratio obtained from the model using the 10ppm threshold for all predictors with the exception of the 'unknown' group for prescription charge exemption. A smaller Nagelkerke's R^2 (0.04 versus 0.06) also indicated reduced fit for the model using the 3ppm threshold.

4. Discussion

We found evidence that a reduction of the threshold for expired-air CO concentration to validate abstinence would reduce success rates in clinical practice only marginally unless very low thresholds were introduced. An extreme reduction also weakened the association of quit success with previously established predictors, suggesting that more error would be introduced and accuracy reduced if such a threshold were used. Low thresholds may however be useful in specific situations in which the aim is to maximize identification of those exposed to tobacco smoke or other sources of CO.

The main strength of this study is that it was based on a large sample of smokers who sought help to stop smoking. The clients and intervention of the included services have been shown to be representative for those across England (Brose, et al., 2011). The main limitation of the study is the lack of information on CO measurements in those not reporting abstinence and the lack of other biochemical measures of smoking status, which made it not possible to calculate sensitivity and specificity for the various thresholds. However, the present data clearly show the impact (or lack thereof) that any changes would have on clinical practice.

4.1. Conclusion

A reduction of CO thresholds used to determine abstinence from smoking would have a very small effect on the success rates of attempts to stop smoking in clinical practice, unless thresholds were reduced drastically, which likely would decrease accuracy.

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Table 1: Validated short-term success rates using different expired-air CO thresholds.

Expired-air CO threshold	CO-validated short term success	Classified as non-smoker, N (%)
Less than:	rates, % of total N=315,718	
10ppm (Current standard)	35.0	110,558 (100)
9ppm	34.9	110,128 (99.6)
8ppm	34.7	109,508 (99.1)
7ppm	34.4	108,537 (98.2)
6ppm	33.6	106,211 (96.1)
5ppm	32.6	102,976 (93.1)
4ppm	30.7	96,839 (87.6)
3ppm	26.3	83,186 (75.2)
2ppm	18.9	59,737 (54.0)

Table 2: Logistic regression models predicting short-term abstinence using <10ppm and <3ppm expired-air CO thresholds, N=315,331.

	Odds ratio (95% Confidence Interval), p-value	
	Validated by CO <10ppm	Validated by CO <3ppm
Age (per 10 year increase)	1.20 (1.19 to 1.20), <0.001	1.16 (1.16 to 1.17), <0.001
Gender (referent: Female)	1.04 (1.03 to 1.06) <0.001	0.93 (0.92 to 0.95), <0.001
Medication (referent: None)		
Single NRT	1.42 (1.38 to 1.46), <0.001	1.39 (1.34 to 1.43); <0.001
Bupropion	1.80 (1.67 to 1.95), <0.001	1.64 (1.51 to 1.79); <0.001
Combination NRT	2.25 (2.19 to 2.32), <0.001	1.84 (1.78 to 1.90); <0.001
Varenicline	2.72 (2.64 to 2.80), <0.001	2.22 (2.15 to 2.29); <0.001
Prescription charges (Referent: exempt)		
Pays	1.30 (1.27 to 1.32), <0.001	1.25 (1.23 to 1.28), <0.001
Unknown	0.86 (0.84 to 0.88), <0.001	0.89 (0.87 to 0.92), <0.001

*Missing data: N=344