



## A systematic review of the International Classification of Diseases criteria for the diagnosis of tobacco dependence

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### ABSTRACT

Our objective was to examine the evidence concerning the validity and reliability of the International Classification of Diseases criteria for tobacco dependence (ICD-TD). A literature search was conducted of 16 databases using the search terms addiction, cigarettes, Diagnostic and Statistical Manual of Disease, DSM, dependence, International Classification of Diseases, ICD, nicotine, smoking and tobacco. The search produced 37 relevant articles. We found no data supporting the predictive validity of the criteria, and none supporting the characterization of dependence as having a three-symptom threshold. We found no data concerning the validity or reliability of the official instrument, which inappropriately excludes nondaily smokers from being evaluated for dependence. We found no evidence that the ICD-TD diagnosis had been used for clinical decision making, in a smoking cessation study, or for longitudinal epidemiological surveillance. We contrast the utility of the ICD-TD criteria to an approach of diagnosing tobacco addiction on the basis of a single criterion of a compulsion to use tobacco.

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The International Classification of Diseases (ICD) and the Diagnostic and Statistical Manual of Mental Disorders (DSM) are classification systems proposed to facilitate standardization in nomenclature. In 1977, the World Health Organization (WHO) published criteria for the diagnosis of tobacco dependence in ICD-9 (World Health Organization, 1977). The ICD-9 adapted Edwards' "provisional description" of alcoholism as generic criteria for drug addiction and tobacco dependence (Edwards & Gross, 1976; Woody, Cottler, & Cacciola, 1993). In 1980, DSM-III did likewise, and generic criteria were retained with modifications through DSM-III-R, ICD-10, and DSM-IV (American Psychiatric Association, 1980, 1987, 1994; World Health Organization, 1992). Case studies were not performed to determine if any of these criteria accurately describe tobacco addiction.

The first case-series of tobacco addiction identified the compulsion to use tobacco as the core feature of the disorder (DiFranza, Ursprung, & Carlson, 2010). This compulsion is characterized by wanting, craving or needing to smoke that recurs after each cigarette. During abstinence smokers first experience a wanting for a cigarette. This intensifies into craving, and then needing to smoke to suppress withdrawal symptoms (DiFranza et al., 2010). Smoking provides a time-limited duration of relief (the latency) from the re-emergence of wanting, craving and needing (DiFranza & Ursprung, 2008). There is a

latency to wanting a cigarette, a longer latency to craving, and a still longer latency to needing to smoke (DiFranza et al., 2010). The physiological nature of the latencies is revealed by their periodicity. The latencies limit how long a smoker can comfortably remain abstinent, creating a compulsion to use tobacco.

When the compulsion first appears, a single cigarette can suppress the desire to smoke for weeks (DiFranza et al., 2010). With repeated smoking, the latencies shorten, explaining the typical escalation in smoking frequency (DiFranza et al., 2010; Riggs, Chou, Li, & Pentz, 2007). As the latencies shorten, smokers develop behaviours that are described in the ICD criteria (Table 1). "Impaired capacity to control substance-taking behaviour in terms of onset, termination or level of use..." (World Health Organization, 1992). As the latencies shorten, individuals must smoke more often to relieve their symptoms, and the compulsion makes it difficult to quit. "A physiological withdrawal state..." Smokers feel compelled to smoke to relieve withdrawal symptoms. "Evidence of tolerance to the effects of the substance..." Perkins studied 12 measures of tolerance and concluded that "these results suggest there is no close link between nicotine tolerance and dependence and question the utility of tolerance as one of the criteria for defining dependence" (Perkins et al., 2001). Shortening latencies is the only form of tolerance linked to tobacco addiction (DiFranza & Ursprung, 2008; Fernando, Wellman, & DiFranza, 2006; Perkins, 2002). "Preoccupation with substance use, as manifested by: important alternative pleasures or interests being given up or reduced because of substance use..." Smokers avoid situations that will prevent them from smoking when their latencies demand it. "Persisting with substance use despite clear evidence of harmful

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**Table 1**

The ICD-10 classification of mental and behavioural disorders diagnostic criteria for research.

<i>Dependence syndrome</i>
A. Three or more of the following manifestations should have occurred together for at least one month or if persisting for periods of less than one month then they have occurred together repeatedly within a twelve month period.
(1) A strong desire or sense of compulsion to take the substance.
(2) Impaired capacity to control substance-taking behaviour in terms of onset, termination or level of use, as evidenced by: the substance being often taken in larger amounts or over a longer period than intended, or any unsuccessful effort or persistent desire to cut down or control substance use.
(3) A physiological withdrawal state when substance use is reduced or ceased, as evidenced by the characteristic withdrawal syndrome for the substance, or use of the same (or closely related) substance with the intention of relieving or avoiding withdrawal symptoms.
(4) Evidence of tolerance to the effects of the substance, such that there is a need for markedly increased amounts of the substance to achieve intoxication or desired effect, or that there is a markedly diminished effect with continued use of the same amount of the substance.
(5) Preoccupation with substance use, as manifested by: important alternative pleasures or interests being given up or reduced because of substance use; or a great deal of time being spent in activities necessary to obtain the substance, take the substance, or recover from its effects.
(6) Persisting with substance use despite clear evidence of harmful consequences, as evidenced by continued use when the person was actually aware of, or could be expected to have been aware of the nature and extent of harm.
<i>Withdrawal state</i>
G1. Clear evidence of recent cessation or reduction of substance use after repeated, and usually prolonged and/or high-dose use of that substance.
G2. Symptoms and signs compatible with the known features of a withdrawal state from the particular substance or substances (see below).
G3. Not accounted for by a medical disorder unrelated to substance use, and not better accounted for by another mental or behavioural disorder.
<i>Nicotine withdrawal state</i>
A. The general criteria for withdrawal state are met.
B. Any two of the following symptoms and signs:
(1) Craving for tobacco (or other nicotine-containing products);
(2) Malaise or weakness;
(3) Anxiety;
(4) Dysphoric mood;
(5) Irritability or restlessness;
(6) Insomnia;
(7) Increased appetite;
(8) Increased cough;
(9) Mouth ulceration;
(10) Difficulty concentrating.

consequences..." Smokers may not forgo smoking when sick because craving and needing make them feel worse.

When defined to include withdrawal symptoms, compulsion has 99% sensitivity in identifying which novice smokers will progress to established smoking (DiFranza, Savageau, Fletcher, K., O'Loughlin, et al., 2007; DiFranza, Savageau, Fletcher, Pbert, et al., 2007; DiFranza, Savageau, Rigotti, et al., 2002; Wellman, DiFranza, Savageau, & Dussault, 2004). Compulsion predicted progression to daily smoking with an odds ratio (OR) of 195.8 (DiFranza, Savageau, Fletcher, O'Loughlin, et al., 2007). The average smoker is smoking only two cigarettes per week when he or she first experiences a compulsion to use tobacco (DiFranza, Savageau, Fletcher, O'Loughlin, et al., 2007; DiFranza, Savageau, Fletcher, Pbert, et al., 2007; DiFranza, Savageau, Rigotti, et al., 2002). In a 12-year prospective study, reaching the threshold of smoking two cigarettes per week predicted progression to heavy adult smoking with an OR of 174.0 (DiFranza, Riggs, & Pentz, 2008; Riggs et al., 2007).

Based on these studies and case-histories it has been suggested that compulsion alone is pathognomonic for tobacco addiction, being both necessary and sufficient to make a diagnosis (DiFranza et al., 2010). This contradicts the ICD which contends that addiction is absent until three criteria are present, with compulsion being neither necessary nor sufficient for a diagnosis. We reviewed the literature to examine the evidence supporting the validity, reliability and utility of the ICD criteria.

## 1. Methods

We conducted a systematic review of the literature on ICD-tobacco dependence (ICD-TD) criteria. The search covered January, 1976 through October, 2008. Search terms included every combination of: addiction, cigarettes, dependence, Diagnostic and Statistical Manual, DSM, International Classification of Diseases, ICD, nicotine, smoking and tobacco. Results of the DSM search have been reported separately

(DiFranza, Ursprung, Lauzon, et al., 2010). Databases searched included: Indexmedicus, Medline, the Educational Resources Information Center (ERIC), the Cochrane Library, the American Psychological Association's PsychInfo/PsychLIT Database, Indmed, Koreamed, the World Health Organization Library Information System (WHO-LIS), the World Health Organization's Network of Health Science Libraries across Asia (HELLIS), Latin American and Caribbean Health Sciences (LILACS), the Pan American Health Organization's Head Quarters' Library Catalog (PAHO), Caribbean Health Sciences Literature Database (MEDCARIB), Disaster Documentation Center Collection (DESASTRES), Latin American and Caribbean History of Public Health (HISA), Database of the Regional Program on Bioethics PAHO/WHO (BIOETHICS), and the Association for Health Information and Libraries in Africa (AHILA). An appeal for citations was posted on the Society for Research on Nicotine and Tobacco listserve. Retrieved articles were reviewed for relevant citations. The review was limited to articles available in English.

Using a structured guide, the senior author examined each article for evidence addressing each of the following measure-performance questions. (1) Does evidence confirm that dependence has a three-criterion threshold? (2) Has it been established that a person must have two symptoms to have nicotine withdrawal as provided by ICD? (3) Do the ICD-TD criteria diagnose the same subjects as other measures of dependence? (4) Do instruments that are faithful to the ICD-TD criteria demonstrate a stable factor structure, good internal reliability, good test-retest reliability, and good agreement with each other? (5) Do the ICD-TD criteria have acceptable sensitivity for use in clinical settings (the ability to identify afflicted individuals)? (6) Are the ICD-TD criteria a good predictor of relapse in smoking cessation studies? (7) Have the ICD-TD criteria found a useful role in the clinical setting? (8) Do the ICD-TD criteria have concurrent validity as demonstrated by good correlations with other indices such as nicotine intake, smoking frequency, duration of use, and time to first morning cigarette?

All retrieved articles were reviewed by the senior author. The extant literature did not allow for any statistical summarization such as a meta-analysis, therefore we present a narrative summary.

## 2. Results

A total of 2102 hits were returned on the literature search, resulting in the identification of 70 articles that hit on the ICD search terms. Of these, 66 were available in English and were reviewed for relevance. Thirty-seven English language articles relevant to the ICD-9 or ICD-10 were identified (compared to 169 for the DSM – reported separately).

The ICD-9-TD criteria were mentioned in only one review article and an editorial (Neuman, Bitton, & Glantz, 2005; Pollin & Ravenholt, 1984). We found no data concerning the ICD-9-TD criteria, and could not document that they had ever been used. Hereafter, the term ICD-TD refers only to the ICD-10 criteria. We found 19 articles describing 15 studies in which the ICD-TD criteria were used. The remaining articles mentioned ICD but provided no data that could contribute to our evaluation. Three articles were excluded as they did not use the ICD-TD criteria in relation to tobacco use (Hashimoto et al., 2001; Hughes, Adams, Franzon, Maguire, & Guary, 2005; Hughes, Pillitteri, Callas, Callahan, & Kenny, 2004).

### 2.1. Synopsis of the included studies

Since the relevant studies are few, we provide a brief description of each.

Andrade et al. examined the prevalence of ICD-10 mental disorders in 1464 community residents over age 18 in Sao Paulo, Brazil (Andrade, Walters, Gentil, & Laurenti, 2002). The lifetime population prevalence of ICD-TD was 25%, and past-month prevalence was 9.3%. Data on the prevalence of ICD-TD among smokers were not provided.

Benegal et al. studied substance dependence in India among adult outpatients who chewed the dependence-producing areca nut alone or with tobacco (Benegal, Rajkumar, & Muralidharan, 2008). The prevalence of ICD-10 substance dependence was greater in subjects who used areca in combination with tobacco (80%) than in those who used areca nut alone (41%). Tobacco dependence *per se* was not measured.

In a DSM field trial, Cottler et al. reported that proposed ICD-TD criteria diagnosed more cases than the DSM. It could not be determined if the criteria used in this study were the same as those adopted for ICD-10 (Cottler, 1993).

DiFranza et al. used the ICD-TD criteria in a prospective study of the onset of dependence in a cohort of 217 adolescents who had tried smoking (DiFranza et al., 2007; DiFranza, Savageau, Fletcher, Pbert, et al., 2007). ICD-TD developed in 38%, while 59% experienced a compulsion to smoke as measured by the Hooked on Nicotine Checklist (HONC). Half of those who met ICD-TD criteria had done so by the time they were smoking 1 to 2 cigarettes per day. ICD-TD preceded daily smoking 39% of the time. The prognostic significance of an ICD-TD diagnosis was not reported.

Two reports concerned the same sample of adult Austrian smokers (Hertling et al., 2005; Lesch et al., 2004). Among 430 smokers, 89% were dependent by both ICD-TD and DSM criteria. ICD-TD was diagnosed in nondaily smokers: 8% of the DSM/ICD-TD smokers had a “regular episodic smoking pattern” and 16% had an “irregular episodic pattern.” In analyses that excluded alcoholics, the mean number of ICD-TD criteria endorsed increased with age. Among the non-alcoholic subjects who had an ICD-TD diagnosis, 89% had a strong desire or compulsion, 70% had difficulty controlling use, 70% smoked despite problems, 52% had progressive neglect of alternative pleasures, 51% smoked to cope with withdrawal, and 15% had reduced other activities in order to smoke.

A small American study of 43 adult daily smokers that examined the concordance of ICD with other smoking measures will be detailed below (Hughes, Oliveto, et al., 2004).

Kawakami used the ICD-TD criteria in three studies of Japanese adults (Kawakami, Takai, Takatsuka, & Shimizu, 2000; Kawakami, Takatsuka, Inaba, & Shimizu, 1999; Kawakami, Takatsuka, Shimizu, & Takai, 1998). In a sample of 170 Japanese men who had smoked on average for 29 years, 48% of current smokers had ICD-TD (Kawakami et al., 1998). The concordance rate between ICD-TD and the Fagerström Tolerance Questionnaire was 58% ( $k=0.08$ ). In tests of concurrent validity, ex-smokers were less likely to have a lifetime diagnosis of ICD-TD, but ICD-TD was not related to current or lifetime peak daily cigarette consumption. A separate study evaluated a 10-item screening questionnaire for tobacco/nicotine dependence according to ICD-10, DSM-III-R, and DSM-IV (Kawakami et al., 1999). The authors determined the sensitivity and specificity of their Tobacco Dependence Screener using the ICD-10 as a standard, but provided no data on ICD-TD. In a study of 136 male Japanese current and ex-smokers, ICD-TD was associated with neuroticism (Kawakami et al., 2000).

Makowska used an unspecified combination of DSM and ICD-TD to establish that “nicotine dependence” was the most common mental disorder in a population of 90 Polish outpatients (Makowska, Merez, Moscicka, & Kolasa, 2002).

O’Loughlin et al. compared 5 indicators of nicotine dependence in a survey of 233 Canadian adolescent smokers, ages 12–13 years (O’Loughlin et al., 2002). The prevalence of ICD-TD increased with increasing frequency of smoking. It was 0% among those who had only tried smoking, 1.5% among those who smoked less than once per month, 18% among weekly smokers, and 67% among daily smokers. ICD-TD was not predicted by age of initiation or how much of the cigarette was usually smoked. Subjects who had previously tried and failed to quit endorsed more criteria than those who had quit. This is expected as one of the ICD-TD criteria is repeated failed attempts to quit or cut down. Importantly, the mean number of criteria endorsed by subjects who had failed an attempt to quit smoking (2.3) fell below the threshold of three criteria required for an ICD-TD diagnosis. This indicates that the three-criterion threshold does not correspond to the clinical milestone of when smokers find it difficult to quit.

Three articles from O’Loughlin et al. concerned a prospective study of the onset of ICD-TD in young Canadian adolescents (Gervais, O’Loughlin, Meshefedjian, Bancej, & Tremblay, 2006; Karp, O’Loughlin, Paradis, Hanley, & DiFranza, 2005; O’Loughlin et al., 2003a). The incidence rate of conversion to ICD-TD was 7 per 1000 person-months of smoking. Conversion to ICD-TD generally occurred after smoking 100 cigarettes. An ICD-TD diagnosis generally came long after subjects felt they were addicted (Gervais et al., 2006). ICD-TD was related to smoking frequency in regression analyses (O’Loughlin et al., 2003a). ICD-TD was diagnosed in 0% of those who had only tried smoking, in 3% of those who smoked less often than once per month, in 5% of monthly smokers, in 19% of weekly smokers, and in 66% of daily smokers. These numbers coincide quite closely with those reported above and confirm that ICD-TD develops in nondaily smokers.

To investigate the psychological characteristics of smoking and tobacco dependence, Yoshimura et al. conducted a survey of a community sample of 439 Japanese adult smokers (Yoshimura, 2000). An original questionnaire was modeled on the Composite International Diagnostic Interview but with one important omission: “tolerance was excluded from the CIDI because almost no tolerance results from tobacco” (Yoshimura, 2000). A diagnosis of dependence that was thus based on only five of the six ICD-TD criteria was present in 42% of male and 49% of female smokers. Among smokers, 32% met the ICD-TD criteria for tobacco withdrawal. Absent the tolerance criteria, dependent and nondependent smokers did not differ significantly in their daily cigarette consumption (23 cigarettes versus and 21 respectively,  $p=0.06$ ). ICD-TD was associated with an open personality trait and poorer health.

## 2.2. Indicators of interest for research applications

### 2.2.1. Does evidence confirm a dichotomous structure to dependence with a three-criterion threshold as provided in ICD?

No study evaluated the validity of the ICD-TD three-criterion threshold. We found one study that evaluated the threshold approach in relation to other dependence measures and concluded that “our results indicate that there is no statistical support for a categorical divide between dependent and nondependent smokers, when ND [nicotine dependence] is operationalized as an aggregate of the FTND [the Fagerström Test of Nicotine Dependence], NDSS [Nicotine Dependence Syndrome Scale], and other quantitative measures of tobacco consumption” (Ginestet, Mitchell, & Wellman, 2008). Commentary in the literature was uniformly critical of the threshold approach (Colby, Tiffany, Shiffman, & Niaura, 2000; Ginestet et al., 2008; Johnson, Breslau, & Anthony, 1996).

### 2.2.2. Has it been established that a person must have two symptoms to have nicotine withdrawal?

We found no evidence related to the proposition that two symptoms must be present to have nicotine withdrawal. Etter created a withdrawal questionnaire based on ICD-10 but did not include mouth ulcers, cough, malaise or weakness. The ICD symptoms of insomnia and increased appetite did not predict relapse (Etter & Hughes, 2006). Hughes has concluded that there is no evidence that two of the withdrawal symptoms included in ICD, malaise and weakness, are real withdrawal symptoms (Hughes, 2007).

## 2.3. Convergent validity

### 2.3.1. Do the ICD-TD criteria diagnose the same subjects as other measures of dependence?

Among two samples of adult daily smokers 51% and 82% met ICD-TD criteria, while 63% and 86% respectively met the DSM-IV nicotine dependence criteria (Hughes, Oliveto, et al., 2004). Among 43 daily smokers ICD-TD showed the following correlations: 0.71 with DSM-III, 0.87 with DSM-IV, 0.23 with the Fagerström Tolerance Questionnaire, and 0.32 with the FTND (Hughes, Oliveto, et al., 2004). The ICD-TD criteria did not diagnose the same subjects as the HONC (O'Loughlin, DiFranza, et al., 2002). As different measures are designed to measure different things, low levels of concurrence are not necessarily a problem.

## 2.4. Predictive validity

### 2.4.1. Are the ICD-TD criteria a good predictor of clinical outcomes?

No study evaluated the prognostic significance of the ICD-TD as a predictor of the trajectory of smoking or smoking cessation outcomes.

## 2.5. Concurrent validity

### 2.5.1. Do the ICD-TD criteria have concurrent validity as demonstrated by good correlations with other indices such as nicotine intake, smoking frequency, duration of use, and time to first morning cigarette?

In a study of 43 daily smokers, ICD-TD showed the following correlations:  $-0.06$  with time to first morning cigarette,  $0.22$  with daily cigarette consumption,  $0.57$  with self-rated difficulty quitting, and  $0.58$  with self-rated addiction (Hughes, Oliveto, et al., 2004).

## 2.6. Reliability

### 2.6.1. Do instruments that are faithful to the ICD-TD criteria demonstrate good psychometric properties?

The Composite International Diagnostic Interview (CIDI) is the official WHO instrument. We found no data concerning the internal reliability, factor structure, or test–retest reliability of this instrument.

The CIDI instructs users not to ask nondaily smokers about ICD-TD (Cottler et al., 1991). Since four studies have demonstrated ICD-TD in nondaily smokers, the assumption that only daily smokers have ICD-TD is clearly incorrect (DiFranza, Savageau, Fletcher, O'Loughlin, et al., 2007; Lesch et al., 2004; O'Loughlin, DiFranza, et al., 2002; O'Loughlin et al., 2003a). Using an original questionnaire to assess ICD-TD, O'Loughlin et al. reported an internal reliability (Chronbach's alpha) of  $0.91$  in 233 young adolescents ages 12–13 years, and a one week test–retest reliability of  $100\%$  in 13 of these subjects (O'Loughlin, DiFranza, et al., 2002). Two scales have been developed that claim to represent ICD-TD (Etter, 2005a,b; Etter, Le Houezec, & Perneger, 2003; Kawakami et al., 1999). However, neither accurately represents the ICD-TD criteria and neither uses a three-criterion cutoff, so they do not provide an ICD-TD diagnosis.

## 2.7. Indicators relevant to clinical applications

### 2.7.1. Do the ICD-TD criteria have acceptable sensitivity and specificity for use in clinical settings?

There are no published case-histories of ICD-TD. We could find no evidence that the sensitivity or specificity of the ICD-TD diagnosis has ever been evaluated. An ICD-TD diagnosis generally came long after subjects felt they were addicted, and correlations with self-rated addiction were modest (Gervais et al., 2006; Hughes, Oliveto, et al., 2004). This suggests that the ICD-TD criteria would not be a useful tool with which to identify smokers who may welcome help with cessation.

### 2.7.2. Have the ICD-TD criteria found a useful role in the clinical setting?

We found no evidence that the ICD-TD criteria had ever been used in clinical decision making.

## 3. Discussion

We examined the literature for evidence that the ICD-TD criteria are valid and reliable. The data were quite scant. We found no evidence that the ICD-TD criteria had ever been used in clinical decision making, in a smoking cessation study, or for longitudinal population surveys. We could find no data supporting the assumption that the ICD-TD criteria accurately diagnose tobacco addiction, and no data concerning the predictive validity of the criteria. Therefore, we must conclude that the validity of the ICD-TD diagnostic criteria has not been established, and the assertion that they are “the gold standard for diagnosis of nicotine dependence” (Schmitz, Kruse, & Kugler, 2003) is without scientific foundation.

A strength of this review is the thoroughness of the literature search; yet there may be studies that were not identified by the literature search. A study limitation was the exclusion of articles that were not published in English. It is possible that individuals are using the ICD-TD criteria in clinical settings for purposes other than as a billing code, but have not published their experiences.

Based on case studies, it has been proposed that the ICD-10 criterion of a compulsion to use tobacco is both necessary and sufficient for a diagnosis of addiction (DiFranza, et al., 2010). This contradicts the assumption implicit in the ICD that compulsion is neither necessary nor sufficient for a diagnosis since a diagnosis can be made on the basis of three criteria other than a compulsion. The field of tobacco research is thus presented with two conflicting diagnostic approaches. Based on our review of the ICD-TD literature we can now compare the evidence in support of each approach.

To represent the compulsion to use tobacco as a single criterion, we will rely upon data collected using the HONC. The HONC assesses the compulsion to smoke using a combination of craving, needing, feeling addicted, failed cessation, and withdrawal symptoms. The HONC is appropriate for this comparison, because, of all available multi-item measures of tobacco addiction, it is the only measure that



does not include criteria other than compulsion (Wheeler, Fletcher, Wellman, & DiFranza, 2004).

We found no evidence supporting the predictive validity of the ICD-TD criteria. In a 3-year prospective study of the natural history of tobacco use, a compulsion to use tobacco, as measured by the HONC, was highly predictive of a failed quit attempt ( $OR = 29$ ), continued smoking at 30 month follow-up ( $OR = 44$ ), and daily smoking ( $OR = 58$ ) (DiFranza, Savageau, Rigotti, et al., 2002). In a longitudinal study of college students, the HONC predicted smoking frequency at two-year follow-up (Sledjeski et al., 2007). In a smoking cessation study, each additional HONC symptom increased the likelihood of relapse at the six-month follow-up by 29%, and at one year by 21% (Wellman et al., 2006). In longitudinal studies, the compulsion to use tobacco predicted the clinical course of tobacco use with 99% sensitivity (DiFranza, Savageau, Fletcher, O'Loughlin, et al., 2007; DiFranza, Savageau, Rigotti, et al., 2002; Wellman et al., 2004). Thus, there are no data supporting the predictive validity of the ICD, but several studies support the predictive validity of the compulsion to smoke criterion.

In terms of concurrent validity, the ICD-TD criteria correlate with smoking frequency in young adolescents. In adults they generally show poor correlations with indices of tobacco use such as time to first morning cigarette, cigarettes smoked per day, and peak cigarette consumption, but these observations are based on small numbers (Hughes, Oliveto, et al., 2004). Among adolescents, the HONC demonstrated good correlations with daily consumption ( $r = 0.69$ ) and the number of smoking days in the preceding month ( $r = 0.68$ ) (Wellman, DiFranza, et al., 2006). In a study of 1130 adult smokers, the HONC correlated with the number of smoking days in the preceding month, and correlated at a level of  $r = 0.22$  with the number of cigarettes consumed per day, identical to that for ICD-TD (Hughes, Oliveto, et al., 2004; Wellman et al., 2006). Many studies have shown that individuals who initiate smoking at a younger age develop a stronger addiction (Breslau, & Peterson, 1996; Ershler, Leventhal, Fleming, & Glynn, 1989; Escobedo, Marcus, Holtzman, & Giovino, 1993). The ICD-TD criteria did not correlate with age of smoking initiation (O'Loughlin, DiFranza, et al., 2002), but the HONC did: adults who started to smoke at a younger age had higher HONC scores ( $r = -0.16$ ) (Wellman, Savageau, et al., 2006).

ICD-TD correlated only moderately with self-rated difficulty quitting, and self-rated addiction (Hughes, Oliveto, et al., 2004). The only data addressing concordance between ICD-TD and other measures is based on a single study of 43 American adult daily smokers. The ICD-TD criteria correlate well with DSM criteria, as would be expected since their development was coordinated, and the differences are minor (Edwards, 1986; Edwards & Gross, 1976). ICD-TD correlated poorly ( $r = 0.23$  to  $0.32$ ) with the widely used Fagerström measures. The HONC correlates highly ( $r = 0.83$ ) with the Modified Fagerström Tolerance Questionnaire in adolescents (Wellman, DiFranza, et al., 2006), and correlates better with the FTND in adults ( $r = 0.44$ ) (Wellman, Savageau, et al., 2006) than do the ICD-TD criteria ( $r = 0.32$ ) (Hughes, Oliveto, et al., 2004). These comparisons suggest that the ICD's inclusion of criteria other than compulsion degrades concurrent reliability.

Although the CIDI is the official diagnostic instrument for ICD-TD, no data are available concerning its psychometric properties of factor structure, internal reliability and test-retest reliability. The CIDI's instructions to exclude nondaily smokers from being assessed for tobacco dependence is misguided since four studies document that ICD-TD occurs in this population (DiFranza, Savageau, Fletcher, O'Loughlin, et al., 2007; Lesch et al., 2004; O'Loughlin, DiFranza, et al., 2002; O'Loughlin et al., 2003a). Population estimates of ICD-TD based on the CIDI would understate the true prevalence because of the disqualification of nondaily smokers. The only psychometric data available on any of the ICD-TD measures comes from a single study of 233 Canadian adolescent smokers using an unofficial instrument: internal reliability was excellent (O'Loughlin, DiFranza, et al., 2002). The test-retest of ICD-TD at one week was excellent based on an unofficial instrument

administered to 13 youths. The psychometric properties of ICD-TD measures among adults are completely unknown.

As a measure of the compulsion to smoke, the psychometric properties of the HONC have been thoroughly established for smokers of all ages and levels of tobacco use through numerous studies involving over 33,000 smokers (DiFranza, Savageau, Rigotti, et al., 2002; O'Loughlin, Tarasuk, DiFranza, & Paradis, 2002; Scragg, Wellman, Laugesen, & DiFranza, 2008; Wellman et al., 2005; Wellman, McMillen, & DiFranza, 2008; Wellman, DiFranza, et al., 2006; Wellman, Savageau, et al., 2006; Wheeler et al., 2004). In four samples of adolescent smokers, the internal reliability of the HONC ranged from 0.90 to 0.94 (DiFranza, Savageau, Rigotti, et al., 2002; O'Loughlin, Tarasuk, et al., 2002; Wellman, DiFranza, et al., 2006; Wheeler et al., 2004). Factor analysis indicates a single factor (Wellman, Savageau, et al., 2006). In a two-week test-retest among 74 adolescents, the intraclass correlation was 0.88 (Wheeler et al., 2004). In a study of adolescent smokers ages 14–20, the intraclass correlation over six months was 0.93; over one year it was 0.91 (Wellman, DiFranza, et al., 2006).

A potential clinical application of a measure of tobacco dependence is to identify tobacco users that are in need of assistance with quitting. The ICD-TD criteria appear to lack the sensitivity for this application as most youth had difficulty quitting smoking and felt addicted prior to reaching the three-symptom threshold for an ICD-TD diagnosis (Gervais et al., 2006), and among adults, ICD-TD correlated only modestly with self-rated addiction ( $r = 0.58$ ) (Hughes, Oliveto, et al., 2004). The compulsion to smoke is a much more sensitive clinical tool than the ICD-TD criteria since all smokers who have failed a quit attempt demonstrate a compulsion to smoke. In one adolescent study, an ICD-TD diagnosis was met by 3% of sporadic smokers, 5% of monthly smokers, 19% of weekly smokers, and 66% of daily smokers, while a compulsion to smoke was detected in 78% of sporadic smokers, 94% of monthly smokers, and 100% of weekly and daily smokers (O'Loughlin et al., 2003b). With its 3-criterion threshold, smokers who have a compulsion to smoke as their only symptom “fly under the radar” of the ICD-TD criteria. This makes the ICD-TD criteria an inappropriate tool for early detection and intervention with new onset smokers.

To conclude, the evidence base supporting the validity and reliability of compulsion as a single diagnostic criterion is much stronger than that supporting the any-three-symptom ICD-TD approach. Given that more than 30 years have elapsed since their publication, there is remarkably little published evidence supporting the validity of the ICD-TD criteria. There are no case-histories of ICD-TD, no studies linking the criteria to any important clinical outcome, and no evidence that the ICD-TD diagnosis predicts the clinical course of the illness. We found no evidence that they had been used in clinical decision making, in a smoking cessation study, or for ongoing epidemiologic surveillance. Thus, there is no evidence that the ICD-TD criteria are an accurate characterization of the important features of tobacco addiction, or that they distinguish addicted smokers from non-addicted smokers. (The evidence does not support the validity of the three-symptom threshold for diagnosis under DSM either (DiFranza, Ursprung, Lauzon, et al., 2010)). Case reports reveal that the compulsion to use tobacco is central to the pathophysiology of tobacco addiction. The evidence does not establish the validity of the any-three-symptom diagnostic threshold, and does not demonstrate any advantage of this approach to that of using compulsion as a single criterion, both necessary and sufficient for the diagnosis of addiction.

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#### Contributors

None.

#### Conflict of Interest

The authors have no conflicts of interest to report.

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