Development of a Tobacco and Nicotine Products Dependence Instrument

Christelle Chrea[1], Thomas Salzberger[2], Linda Abetz-Webb[3], Esther Afolalu[1], Stefan Cano[4], Jed Rose[5], Rolf Weitkunat[1], Karl Fagerström[6]
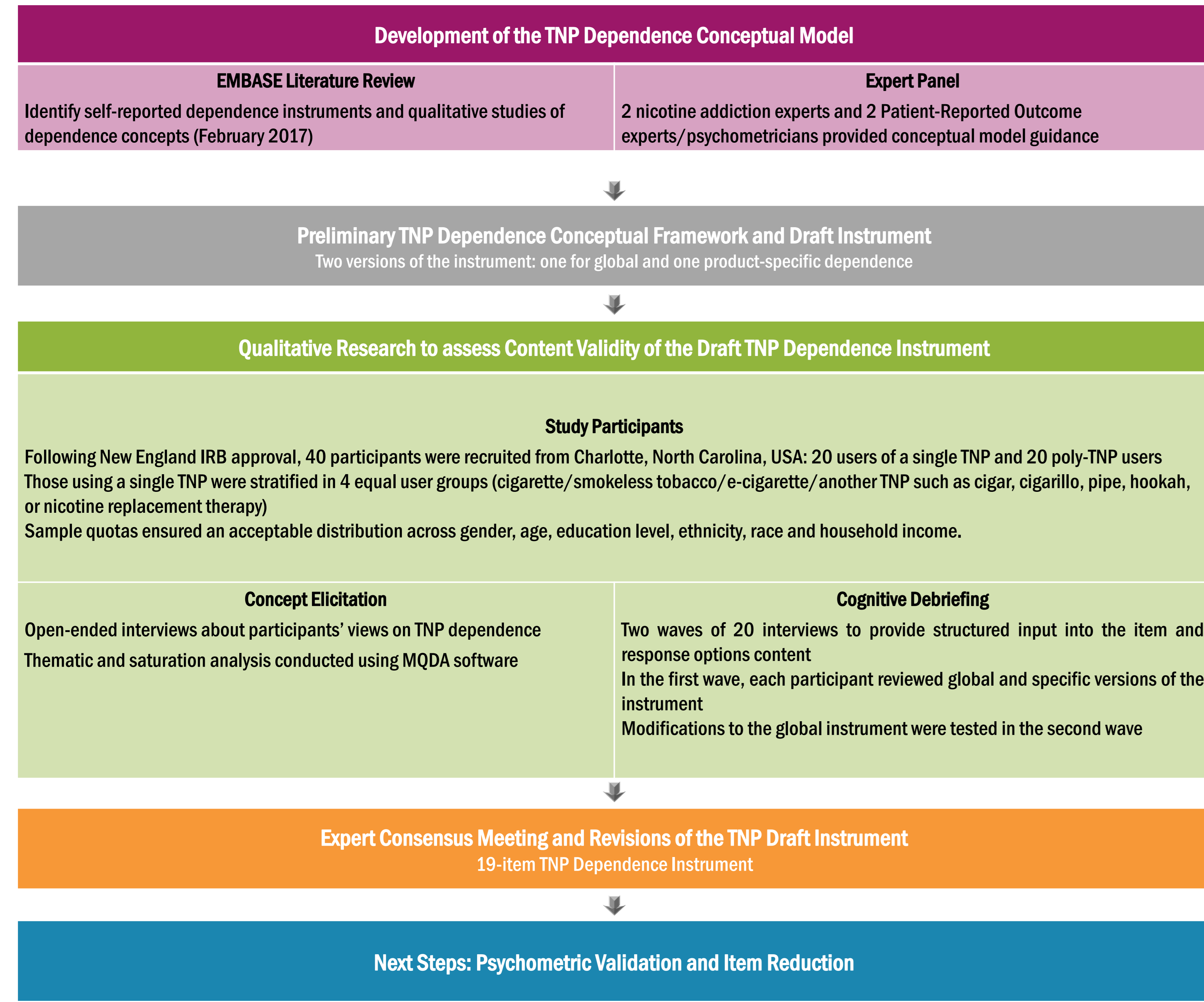
[1] PMI R&D, Philip Morris Products S.A., Quai Jeanrenaud 5, CH-2000 Neuchâtel, Switzerland; [2] University of Economics and Business, Vienna, Austria
[3] Patient-Centered Outcomes Assessments, Ltd, Macclesfield Cheshire, UK; [4] Scale Report, Ltd, Stotfold, UK; [5] Rose Research Center, Raleigh, USA; [6] K. Fagerstrom Consulting AB, Vaxholm, Sweden

Introduction and Objectives

- Dependence on nicotine has historically focused on cigarette smokers, but there has been a diversification of tobacco and nicotine products (TNPs), and concurrent use of these products is increasingly common.
- Currently there is no generally accepted instrument to measure dependence across TNPs.
- The development of a fit for purpose TNP dependence instrument was undertaken. This poster presents the qualitative phase of the instrument development.

Methods

Figure 1: Overview of research methods for the development of a TNP Dependence Instrument.

Development of the TNP Dependence Conceptual Model

EMBASE Literature Review	Expert Panel
Identify self-reported dependence instruments and qualitative studies of dependence concepts (February 2017)	2 nicotine addiction experts and 2 Patient-Reported Outcome experts/psychometricians provided conceptual model guidance

Preliminary TNP Dependence Conceptual Framework and Draft Instrument
Two versions of the instrument: one for global and one product-specific dependence

Qualitative Research to assess Content Validity of the Draft TNP Dependence Instrument

Study Participants
Following New England IRB approval, 40 participants were recruited from Charlotte, North Carolina, USA: 20 users of a single TNP and 20 poly-TNP users
Those using a single TNP were stratified in 4 equal user groups (cigarette/smokeless tobacco/e-cigarette/another TNP such as cigar, cigarillo, pipe, hookah, or nicotine replacement therapy)
Sample quotas ensured an acceptable distribution across gender, age, education level, ethnicity, race and household income.

Concept Elicitation	Cognitive Debriefing
Open-ended interviews about participants' views on TNP dependence Thematic and saturation analysis conducted using MQDA software	Two waves of 20 interviews to provide structured input into the item and response options content In the first wave, each participant reviewed global and specific versions of the instrument Modifications to the global instrument were tested in the second wave

Expert Consensus Meeting and Revisions of the TNP Draft Instrument
19-item TNP Dependence Instrument

Next Steps: Psychometric Validation and Item Reduction

Results

Review of Existing Dependence Instruments

In total, 28 tobacco dependence instruments (25 self-reported and 3 interview-administered) were identified, the majority of which focused solely on cigarette dependence (Table 1). The evidence for content validity and psychometric performance was mixed.
Based on this and discussions with the expert panel, a preliminary conceptual framework was proposed, with *lack of control* as the core concept of dependence (Figure 2).
A pilot version of the instrument was developed to include 9 items that characterized the "severity" of dependence on 3 different response scales (intensity, frequency, duration) adapted to the characteristics of the individual symptoms.

Table 1. Characteristics of existing instruments to measure tobacco and nicotine dependence.

Name of the Instrument	1st Author	Year	Domain	items	Applicability	Item Generation	Item Reduction	Psychometric analyses
Reason for Smoking Scale or Tomkins-Ikard Smoking Scale	Horn	1966	1	23	cigarette	LR	FA	
Modified Horn-Russell Tobacco Scale	Russell	1974	1	9	cigarette	LR,	FA	CV
Minnesota Nicotine Withdrawal Scale	Hughes	1986	na	7	cigarette			TRR
Fagerström Test for Nicotine Dependence	Heatherton	1991	1	6	cigarette			ICR, TRR, CV, PV
Self-administered nicotine dependence scale	Davis	1994	2	32	cigarette	EO	FA	
modified Fagerström Tolerance Questionnaire	Prokhorov	1996	1	7	cigarette		FA	ICR, TRR, CV, KGV
Tobacco Dependence Screener	Kawakami	1999	na	10	cigarette	LR		ICR, CV, KGV
O'Loughlin scale	O'Loughlin	2002	5	56	cigarette	LR		ICR, TRR, CV
Hooked on Nicotine Checklist	DiFranza	2002	1	10	cigarette	LR		ICR, CV
Cigarette Dependence Scale	Etter	2003	1	12/5	cigarette	LR, SI	FA	ICR, TRR
Tobacco Craving Questionnaire	Heishman	2003	4	17/12	cigarette	LR, SI	FA	ICR, CV
Wisconsin Inventory of Smoking Dependence Motives	Pipper	2004	13/11	68/37	cigarette	LR	EO, FA	ICR, CV
Nicotine Dependence Syndrome Scale	Shiffman	2004	5	19	cigarette	LR, SI	EO, SI	ICR, CV
Dimensions of Tobacco Dependence Scale	Johnson	2005	4	54/35	cigarette	LR, SI	FA	ICR, CV
Glover-Nilsson Smoking Behavioral Questionnaire	Glover	2005	1	11	cigarette	EO	EO, FA	ICR, TRR, CV
Kano Test for Social Nicotine Dependence	Yoshii	2006	2	10	cigarette		FA	ICR, KGV, CV
Autonomy Over Smoking Scale	DiFranza	2009	3	12	cigarette	LR, SI, EO	FA	ICR, KGV, CV
Young Adult's Cigarette Dependence	Salameh	2013	4	16	cigarette			
PROMIS - Nicotine Dependence Scale	Shadel	2014	1	32/8	cigarette	LR	SI, EO, FA, IRT	ICR, TRR, CV, KGV
Penn State Electronic Cigarette Dependence Index	Foulds	2015	2	10	e-cigarette	LR, SI		KGV, CV
Fagerström Tolerance Questionnaire for smokeless tobacco	Boyle	1995	1	10	smokeless			ICR, CV
Glover-Nilsson Smokeless Tobacco Behavioral Questionnaire	Ebbert	2012	1	11	smokeless			CV
Severson Smokeless Tobacco Dependency Scale	Severson	2011	1	7+1	smokeless			
Oklahoma Scale for Smokeless Tobacco Dependence	Mushtaq	2014	7	23	smokeless		FA	ICR, CV
Lebanon Waterpipe Dependence Scale	Salameh	2008	4	11	waterpipe	LR	FA	ICR, TRR, KGV, CV
Nicotine Section from the PATH Survey	Hyland	2016	na	48	any TNP	LR	FA	IRT
Alcohol, Smoking, and Substance Involvement Screening Test	WHO	2002	na	7	Global			TRR
Alcohol Use Disorder and Associated Disability Interview Schedule–DSM-IV	Grant	2003	na	22	any TNP			TRR

Abbreviations: CV=concurrent/convergent validity; FA=factor analysis; EO=expert opinion; SI=subject input; LR=literature review; ICR=internal consistency reliability; TRR=test retest reliability; IRT=item response theory; KGV=known group validity;

Figure 2: Preliminary conceptual framework for the TNP Dependence Instrument based on a review of existing instruments and expert opinions.

Dependence on Tobacco and Nicotine Products
Lack of Control

Urgency to use upon waking up	Compulsion to use	Difficulty to cease using	Need to use to function normally	Priority of using over social responsibilities	Automaticity of using	Self-awareness of dependence

Tobacco User Interviews

Participants' demographics were well distributed (Table 2).

Qualitative thematic analysis of the concept elicitation interviews largely confirmed the draft conceptual framework but suggested some changes (Figure 3). Saturation was reached by the end of the 40 interviews.

There were no differences in concepts between poly and single TNP users. However, those who used e-cigarettes and pipes/waterpipes had greater difficulty quantifying their use than those who smoked cigarettes or used chewing tobacco.

Interviews with the first 20 participants led to the removal of 2 problematic items (focused on the 'proportion of available time' for using the product), revisions of some items and response options to enhance comprehension, and the addition of 11 items to specific concepts:

- 'hard to cut down' added to the 'difficulty to cease using'
- 'had to have one', 'hard to control need/urge' added to 'compulsion to use'
- 'use where not supposed to', 'make an excuse to use', 'use product in secret', 'avoid activities', 'sneak off to use', 'stop current activity to use' added to the 'priority of using over social responsibilities'
- 'use more than intended' added to 'automaticity of using'
- 'using is part of who you are' added to 'self-awareness of dependence'

The second wave of interviews confirmed the content validity of the revised global version.
The expert panel reviewed and finalized the conceptual framework and a 19-item draft TNP dependence instrument (Figure 3).

Figure 3: Consolidated conceptual framework on the basis of three sources (experts, consumers and literature).

Table 2. Participants' demographics.

Characteristic	n (%)
Gender	
Male	25 (62.5)
Female	15 (37.5)
Age	
18-34	14 (35)
35-44	12 (30)
45+	14 (35)
Education	
High school education or less	14 (35)
Some college or more	26 (65)
Race/Ethnicity	
Caucasian	18 (45)
African American	12 (30)
Spanish American	8 (20)
Multiracial	2 (5)
Working Status	
Full-time employment	30 (75)
Part-time employment	2 (5)
Student	3 (0.75)
Retired	3 (0.75)
Homemaker	1 (2.5)
Unemployed	1 (2.5)
Income (USD)	
< 20,000	9 (23)
20,000 - <30,000	5 (13)
30,000 - <50,000	10 (25)
50,000 - <70,000	8 (20)
70,000+	8 (20)

Discussion

- This approach was designed to adhere to best research practices to generate evidence from a range of qualitative research steps.
- The findings extend previous conceptualizations of dependence on cigarettes and suggest that a standardized approach to measure dependence, in a directly comparable way, across a wide range of TNPs, is achievable.
- The instrument is currently undergoing quantitative field-testing to identify the items that form final scales and are psychometrically reliable and valid.