CROM Symposium 2020

Consumer Reported Outcome Measures in Tobacco and Nicotine Research

December 10, 2020 | 4:00 - 7:00 pm CET

A Virtual Event

Establishing traceability of self-reported dependence measurement through the use of crosswalks

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Key issues



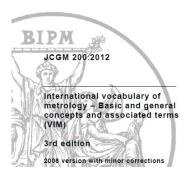
Self-report instruments to measure dependence

- Status quo
- Limitations and challenges
- New scale development: the ABOUTTM—Dependence



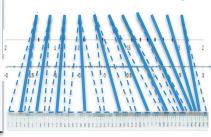
Metrological traceability

- Traceability and uncertainty are fundamental concepts in metrology, the science of measurement
- Traceability: Relating the result of measurement to a reference
- Comparability of measurements based on different instruments



Crosswalk

- Establishing a common metric for measurements based on different instruments
- Ensuring comparability of measurements



Self-reported dependence measurement

Background

- Range of new tobacco and nicotine-containing products (TNPs)
- Less harmful TNPs as a better alternative to smoking if smoking otherwise continued
- All TNPs are a potential source of dependence

Measurement of dependence

- First instruments refer to use of cigarettes (e.g., Fagerström Tolerance Questionnaire FTQ; Fagerström Test for Nicotine Dependence FTND)
- Today, range of instruments tailored to a specific TNP (e.g., cigarettes, e-cigarettes)
- Typically framed as measuring perceived product dependence rather than dependence on nicotine
- Comparative measurement difficult, some approaches refer to a specific comparison of two TNPs

Problems and challenges

- Comparability of perceived dependence associated with the use of different TNPs hampered by incommensurable metrics from different instruments (exclusive users)
- More widespread concurrent use of more than one TNP (poly users)
- No instrument fit for purpose, research gap



Development of the ABOUT-Dependence

Objectives

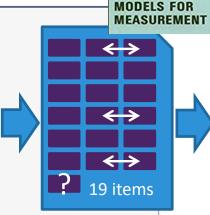
- Measure perceived dependence among exclusive users of various TNPs & users of multiple TNPs (poly users)
- Establish a common metric allowing for comparability

Instrument development in a nutshell



Concept elicitation interviews with users

Conceptual framework
(e.g. compulsion of
use, automaticity, selfawareness of
dependence)



RASCH

• Presented at CORESTA SSPT 2019 Conference Hamburg, Germany, 7th October 2019 (Afolalu et al.)

ABOUT-Dependence

- 12-item instrument capturing three related domains:
 - 1 extent-of-use, 2 signs and symptoms, 3 behavioural impact
- Three domain scores
- One overall score (ABOUT Dependence Index) capturing holistic concept of self-reported dependence
- Common metric of perceived dependence (exclusive users, poly users)



Consolidating perceived dependence measurement

Objectives

- Link past and future research
- Accommodate the continued use of legacy instruments (high product-specificity)
- Allow for comparative measurement

Metrological challenge

- No replicable measurement unit of self-reported dependence based on some reference or principle (yet)
- Measurement instruments need to be linked to one another directly ("horizontally") crosswalks

Psychometric procedure based on the Rasch model for measurement*

• Rasch model establishes common metric for person and item parameters (measurements)

- Rasch model disentangles person and item parameters (measurements) by virtue of parameter separation and invariance (specific objectivity): item parameters become (sample-independent) markers on the latent continuum of perceived dependence
- Linking instruments to the same metric by means of co-calibration (equating)

RASCH MODELS FOR MEASUREMENT



Building crosswalks: FTND↔ABOUT-Dependence €



Objectives

- 1 Converting a raw score on one instrument to the equivalent raw score on another instrument
- 2 Link both instruments to the same linear metric of dependence



The Fagerström Test for Nicotine Dependence

(FTND; Heatherton et al., 1991; in 2011 renamed The Fagerström Test for Cigarette Dependence; Fagerström 2011)

Appendix 1 - Items and scoring for the Fagerström Test for Nicotine Dependence.

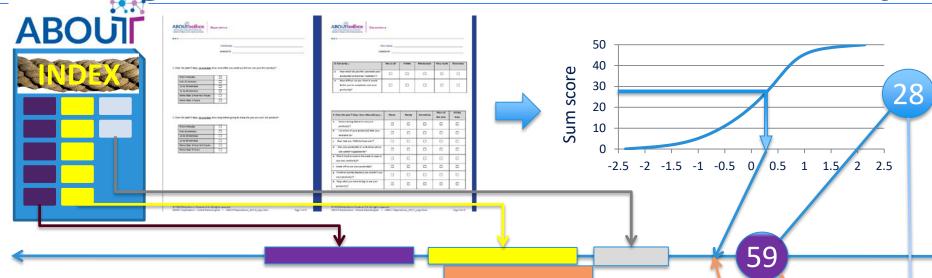
| Question | Answers | Points | |
|---|------------------------------|--------|--|
| 1. How soon after you wake up do you smoke your first cigarette? | Within 5 minutes | 3 | |
| | 6-30 minutes | 2 | |
| | 31-60 minutes | 1 | |
| | After 60 minutes | 0 | |
| 2. Do you find it difficult to refrain from smoking in places where | it Yes | 1 | |
| Sybidden, e.g., in church, at the libra Ring the cinema stc? | re No | 0 | |
| Which cigarette would you most hate to give up? | The first one in the morning | 1 | |
| | Any other | 0 | |
| 4. How many cigarettes/day do you smoke? | 10 or less | 0 | |
| W MEET ON THE W | 11-20 | 1 | |
| | 21-30 | 2 | |
| | 31 or more | 3 | |
| 5. Do you smoke more frequently during the first hours er waking that deep the rest of the day? | ng Yes | 1 | |
| Participant and Company and Participant and Participant and Company and Company | No | 0 | |
| 5. Do you smoke if you are so ill that you are in bed m of the d | ay? Yes | 1 | |
| 20 20 20 | No | 0 | |





Building crosswalks: FTND↔ABOUT-Dependence





Common metric established by the **ABOUT Dependence**

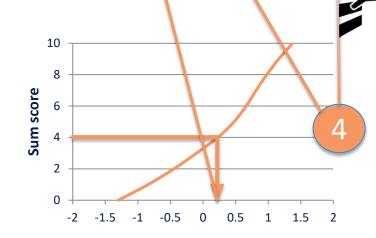


The Fagerström Test for Nicotine Dependence

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| Question | Answers | Points | |
|---|------------------------------|--------|--|
| How soon after you wake up do you smoke your first cigarette? | Within 5 minutes | 3 | |
| | 6-30 minutes | 2 | |
| | 31-60 minutes | 1 | |
| | After 60 minutes | 0 | |
| 2. Do you find it difficult to refrain from smoking in places where it s forbidden, e.g., in church, at the library, in the cinema, etc.? | Yes | 1 | |
| | No | 0 | |
| . Which cigarette would you most hate to give up? | The first one in the morning | 1 | |
| | Any other | 0 | |
| . How many cigarettes/day do you smoke? | 10 or less | 0 | |
| | 11-20 | 1 | |
| | 21-30 | 2 | |
| | 31 or more | 3 | |
| 5. Do you smoke more frequently during the first hours after waking than during the rest of the day? | Yes | 1 | |
| | No | 0 | |
| 5. Do you smoke if you are so ill that you are in bed most of the day? | Yes | 1 | |
| | No | 0 | |

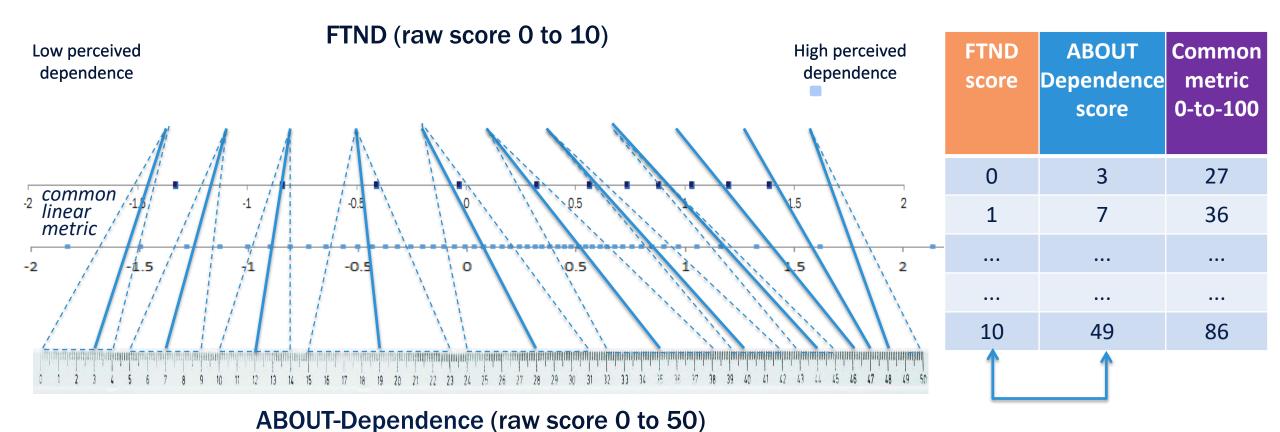
Permission to use this scale for purposes other than research must be obtained from K.O. Fagerström.



Linear transformation to 0-to-100 scale

Crosswalk FTND/FTCD ↔ ABOUT Dependence





Crosswalk

A word on uncertainty



Measurement uncertainty

- Stated range of uncertainty expressed in a comparable metric
- Standard error of measurement informs about calibration uncertainty of person measurements

Introduction to the Guide of Uncertainty in Measurement (GUM)

JCGM 100:2008
JCGM 104:2009

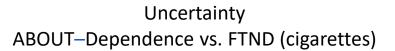
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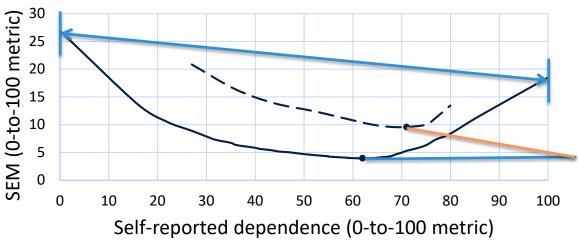
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—— SEM ABOUT−Dependence — — SEM FTND



Broader range of measurement

Smaller uncertainty, more precise measurement

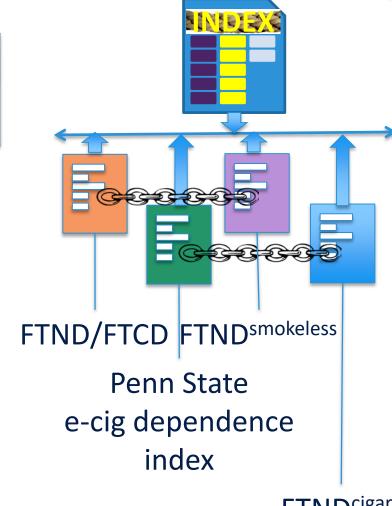
Further crosswalks I

(A)

Objectives

- Linking further instruments to the common metric (crosswalks to ABOUT dependence)
- Comparability of scores from third instruments

| Raw score (sum across items with lowest category scored 0) | | | | Common metric of self-reported dependence (0-to-100)¤ | | | _ | | |
|--|---|-------------------------------------|---------------------------------|---|--------------|-----------------------------|------------------------|--------------|------------|
| FTND (cigarettes)¤ | Penn State Electronic Cig. Dep.Index¤ | FTND-ST (sm okeless tobacco)¤ | FTND-CG (cigars/cigarillos)¤ | ABOUT- Dependence raw scored | | | For smokeless tobacco¤ | | |
| If lowest item response category is scored 1 rather than | | | For Cig.¤ | For e-cig.¤ | smo | For cigars/≁ cigarillos¤ | | | |
| 0, add to t 6□ | he sum scor 10¤ | es listed in t 6¤ | his table:¤ 6¤ | <i>12</i> ¤ | For | For | For | For ciga | |
| [A]¶ | [B]¶ | [C]¶ | [D]¶ | [A]-[D)¶ | [A]¶ | [B]¶ | [C]¶ | [D]¶ | 0 |
| (1)¤ | (2) ¤ | (3) ¤ | (4) ¤ | (5) ¤ | (6) ¤ | (7) ¤ | (8)¤ | (9) ¤ | |
| (0)¤ | (0)¤ | (0)¤ | (0)¤ | 0¤ | 0¤ | 0¤ | 0¤ | Oμ | 20 |
| (0)¤ | (0)¤ | (0)¤ | (0)¤ | 1¤ | 16¤ | 13¤ | 16¤ | 16¤ | 30 |
| (0)¤ | 0 ¤ | 0¤ | (0)¤ | 2¤ | 22¤ | 20 ¤ | 22 ¤ | 23¤ | |
| 0¤ | (0)¤ | (1)¤ | (0)¤ | 3¤ | 27 ¤ | 25¤ | 27¤ | 28¤ | E-40- |
| (0)¤ | 1¤ | 1¤ | (0)¤ | 4¤ | 30¤ | 29 ¤ | 30 ⊭ | 31¤ | |
| (1)¤ | (1)¤ | (1 ≱¤ | (0)¤ | 5¤ | 32¤ | 31¤ | 32¤ | 34¤ | |
| (1)0 | 2 ¤ | -A- | (0)¤ | 6¤ | 35¤ | 34¤ | 35¤ | 36¤ | _ 6 |
| 1¤ | (2)X | (2)X | <u>(0)</u> × | 7 ¤ | 36¤ | 36¤ | 36¤ | 38¤ | |
| (1)0 | (3)¤ | 2¤ | (0)¤ | 8¤ | 38¤ | 38¤ | 38¤ | 40¤ | 70 |
| (1)¤ | 3¤ | (2)× | (0)× | 9¤ | 40¤ | 39 ¤ | 40¤ | 42¤ | E-8- |
| (2)¤ | 4n | (2)¤ | (0)¤ | 10¤ | 41¤ | 41¤ | 41¤ | 43¤ | |
| (2)¤ | (4)¤ | (2)¤ | (0)¤ | 11¤ | 43¤ | 42¤ | 43¤ | 45¤ | 90 |
| (2)¤ | 5¤ | (3)¤ | (0)¤ | 12¤ | 44 ¤ | 44¤ | 44¤ | 46¤ | 101 |

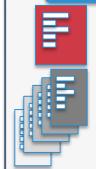


FTNDcigars

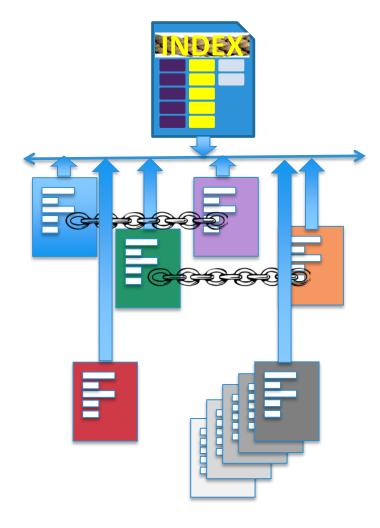
Further crosswalks II



Crosswalks under preparation



- The Wisconsin Index of Smoking Dependence Motives (WISDM)
- Cigarette Dependence Scale, short version (CDS-5), adapted for several TNPs



Summary

A A

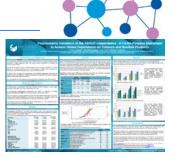
- ✓ The ABOUT-Dependence is a thoroughly developed self-report instrument for perceived dependence associated with the use of TNPs based on a scale development process involving qualitative research that informs the conceptual framework
- ✓ The 12-item ABOUT—Dependence Index is a holistic summary self-report

 measure of perceived dependence involving TNP usage behaviour
 (extent of use), the behavioural impact of TNP use and perceived signs and symptoms
- ✓ The ABOUT—Dependence fills research gaps (lack of valid measurement of perceived dependence in poly users and lack of comparable measurement across different TNPs)
- ✓ Crosswalks allow for linking the ABOUT-Dependence to various legacy instruments that have proved to be useful under certain circumstances, have contributed to research findings, and will continue to be used
- ✓ Thus, crosswalks foster scientific exchange
- ✓ Crosswalks address metrological traceability providing a remedy to a deficiency in social measurement that has compromised progress

Key references

- ✓ Chrea C., Salzberger T., Abetz-Webb L., et al. "Psychometric Validation of the ABOUT-Dependence: A Fit-for-Purpose Instrument to Assess Global Dependence on Tobacco and Nicotine Products. Poster presentation at the Society for Research on Nicotine and Tobacco 25th Annual Meeting, Baltimore, USA (February, 2019). https://www.pmiscience.com/library/publication/psychometric-validation-of-the-about-dependence
- ✓ Chrea C., Salzberger T., Abetz-Webb L., et al. Development of a fit-for-purpose tobacco and nicotine product dependence instrument. Poster presentation at the International Society of Pharmacoeconomics and Outcomes Research 21st Annual European Congress, Barcelona, Spain (November, 2018).
 https://www.pmiscience.com/library/publication/development-of-a-fit-for-purpose-tobacco-and-nicotine-product-dependence-instrument
- Chrea C., Salzberger T., Abetz-Webb L., et al. Development of a tobacco and nicotine products dependence instrument.

 Poster presentation at the Society for Research on Nicotine and Tobacco 24th Annual Meeting, Baltimore, USA (February, 2018).
 - https://www.pmiscience.com/library/publication/development-of-a-tobacco-and-nicotine-products-dependence-instrument
- ✓ Afolalu E., Chrea C., Salzberger T., Abetz-Webb L., Cano S., Weitkunat R., Rose J. (2019). Development and validation of the ABOUT™— Dependence instrument to assess perceived dependence on tobacco and nicotine products. Presented at the CORESTA SSPT 2019 Conference, Hamburg, Germany, 7th October 2019.
- ✓ Salzberger T., Cano S., Abetz-Webb L., Afolalu E., Chrea, C., Weitkunat R., Rose J. (under review). Addressing traceability of self-reported dependence measurement through the use of crosswalks
- ✓ Afolalu E., Chrea C., Abetz-Webb L., Salzberger T., Cano S., Rose J., Fagerström K. (under preparation). Development and initial validation of a fit-for-purpose instrument to assess global dependence on tobacco and nicotine products







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Thank you for your interest and attention.

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