

“Addictiveness” - Measures and Methods

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SSPT ST22

Regulatory Demands

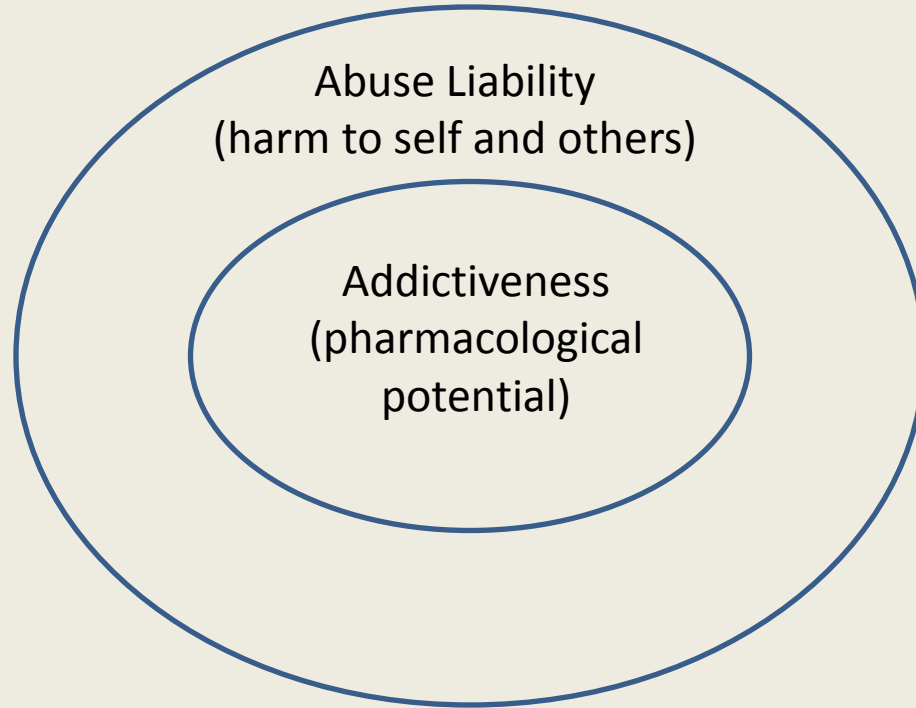
- *“Member States and the Commission require comprehensive information...to assess the attractiveness, addictiveness and toxicity of tobacco products...”*

(EU TPD 2014)

- *“The (PMTA) discussion should include information such as:... (8) Assessment of abuse liability (i.e., the addictiveness and abuse and misuse potential of the new product...)”*

(FDA 2016)

Abuse Liability & Addictiveness



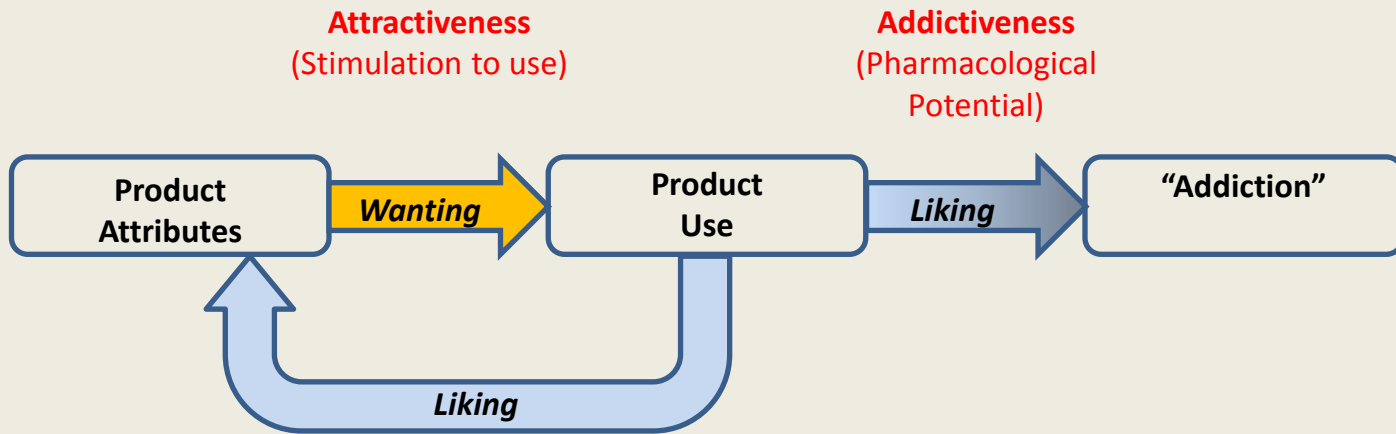
Attractiveness (SCENIHR 2010)

- *“Attractiveness is defined as the stimulation to use a product”*
- *“The attractiveness of tobacco products may be increased by a number of additives but is also influenced by external factors such as marketing, price etc.”*



Addictiveness (SCENIHR 2010)

- *“Addictiveness refers to the pharmacological potential of a substance to cause addiction”*

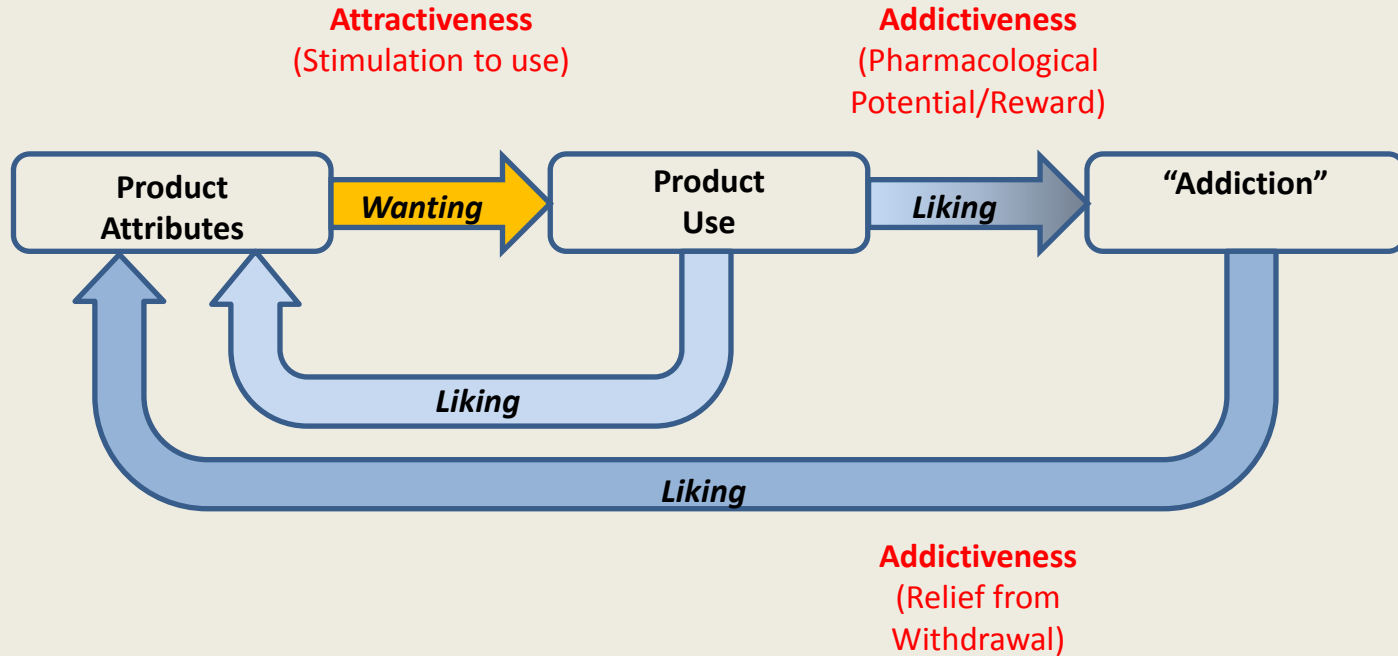


Addictiveness (EU TPD 2014)

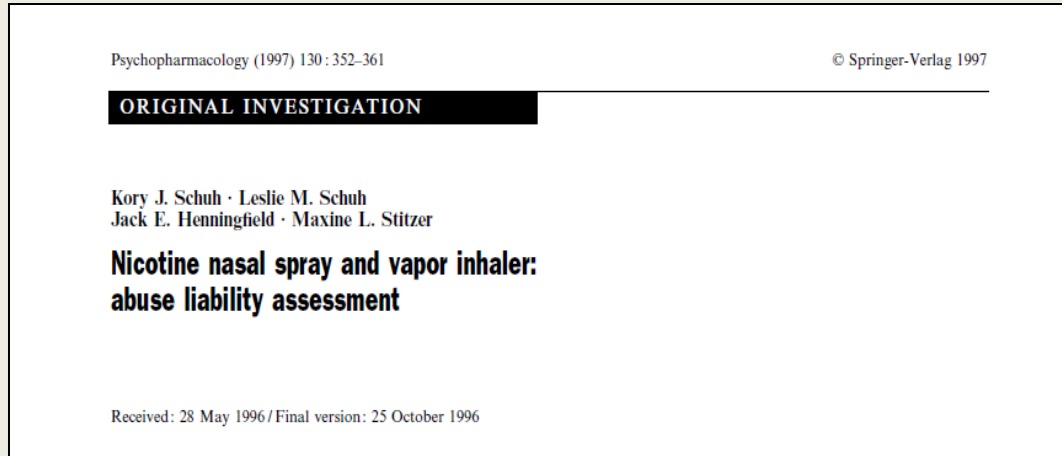
- *“Addictiveness means the pharmacological potential of a substance to cause addiction, a state which affects an individual’s ability to control his or her behaviour, typically by instilling a reward or a relief from withdrawal symptoms, or both”*

(emphasis added)

The “Standard” Model



Abuse Liability NNS / Vapor Inhaler



“While smokers clearly liked cigarette puffs, there was much less evidence of liking produced by either nasal spray or vapor inhaler; only modest elevations on a measure of good drug effects were observed.”

Abuse Liability Nicotine Lozenge

Psychopharmacology (2003) 167:20–27
DOI 10.1007/s00213-002-1361-2

ORIGINAL INVESTIGATION

Elisabeth J. Houtsmuller · Jack E. Henningfield ·
Maxine L. Stitzer

Subjective effects of the nicotine lozenge: assessment of abuse liability

Received: 24 April 2002 / Accepted: 15 November 2002 / Published online: 4 March 2003
© Springer-Verlag 2003

“The nicotine lozenge did not increase ratings of traditional abuse liability predictors (good effect, like effect, MBG scale of the ARCI)...”

Visual Analogue Scale I

(example for discussion only)

Compared to *<control>* how much did you like using *<product>*?

-----0-----

much less

slightly less

the same

slightly more

much more

Visual Analogue Scale II

(example for discussion only)

Did you experience any good effects after using *<product>*?



not at all

extremely

ARCI - MBG

ARCI Addiction Research Center Inventory

Protocol: _____

Investigator: _____

Volunteer ID: _____

Date: _____

Research Data Assistant: _____

Study day: _____

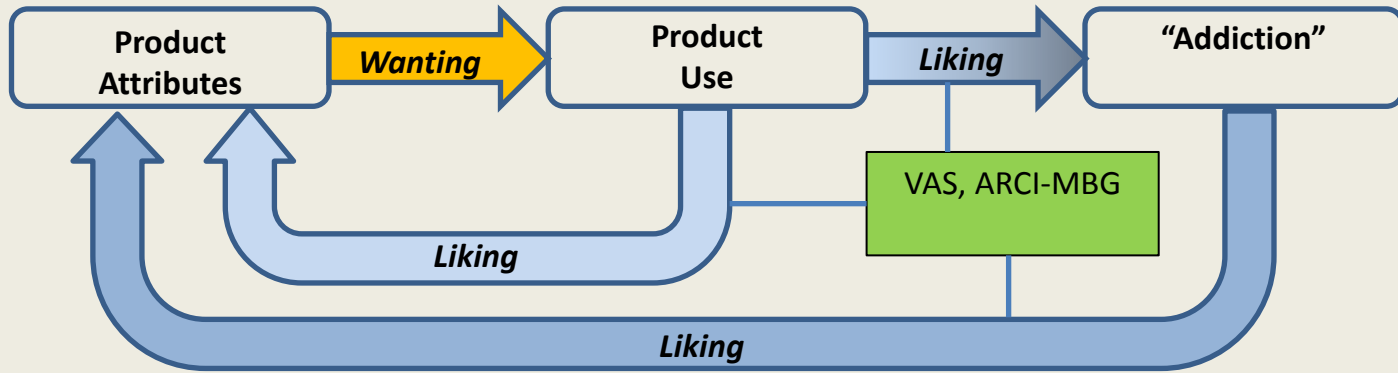
Time: _____

Timepoint: _____

Mark T (for TRUE) next to each item that does describe how you feel RIGHT NOW,
and F (for FALSE) for each item that does not describe how you feel RIGHT NOW.

- | | | | |
|--|-----|--|-----|
| 1. My speech is slurred. | T F | 19. I would be happy all the time if I felt as I feel now. | T F |
| 2. I am not as active as usual. | T F | 20. I feel so good that I know other people can tell it. | T F |
| 3. I have a feeling of dragging along rather than coasting. | T F | 21. I feel as if something pleasant had just happened to me. | T F |
| 4. I feel sluggish. | T F | 22. I would be happy all the time if I felt as I do now. | T F |
| 5. My head feels heavy. | T F | 23. I feel more clear headed than dreamy. | T F |
| 6. I feel like avoiding people although I usually do not feel this way. | T F | 24. I feel as if I would be more popular with people today. | T F |
| 7. I feel dizzy. | T F | 25. I feel a very pleasant emptiness. | T F |
| 8. It seems harder than usual to move around. | T F | 26. My thoughts come more easily than usual. | T F |
| 9. I am moody. | T F | 27. I feel less discouraged than usual. | T F |
| 10. People might say that I am a little dull today. | T F | 28. I am in the mood to talk about the feeling I have. | T F |
| 11. I feel drowsy. | T F | 29. I feel more excited than dreamy. | T F |
| 12. I am full of energy. | T F | 30. Answering these questions was very easy today. | T F |
| 13. Today I say things in the easiest possible way. | T F | 31. My memory seems sharper to me than usual. | T F |
| 14. Things around me seem more pleasing than usual. | T F | 32. I feel as if I could write for hours. | T F |
| 15. I have a pleasant feeling in my stomach. | T F | 33. I feel very patient. | T F |
| 16. I fear I will lose the contentment that I have now. | T F | 34. Some parts of my body are tingling. | T F |
| 17. I feel in complete harmony with the world and those about me. | T F | 35. I have a weird feeling. | T F |
| 18. I can completely appreciate what others are saying when I am in this mood. | T F | 36. My movements seem faster than usual. | T F |

Continue on reverse side



Recently Used Metrics

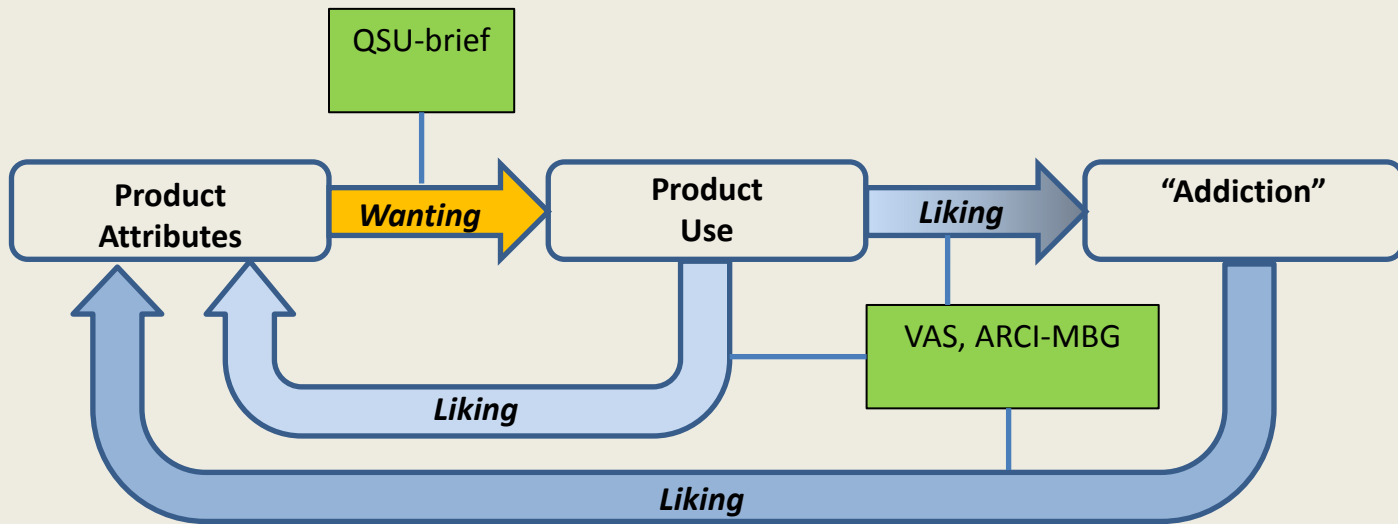
- QSU-brief (Brief Questionnaire of Smoking Urges)

QSU-brief

Questionnaire on smoking urges (QSU) (1=strongly disagree to 7=strongly agree)

1. I have a desire for a cigarette right now
2. Nothing would be better than smoking a cigarette right now
3. If it were possible I would probably smoke now
4. I could control things better right now if I could smoke
5. All I want right now is a cigarette
6. I have an urge for a cigarette
7. A cigarette would taste good now
8. I would do almost anything for a cigarette now
9. Smoking would make me less depressed
10. I am going to smoke as soon as possible

(Cox *et al* 2001)



Recently Used Metrics

- QSU-brief (Brief Questionnaire of Smoking Urges)
- MNWS-R (Minnesota Withdrawal Scale – Revised)

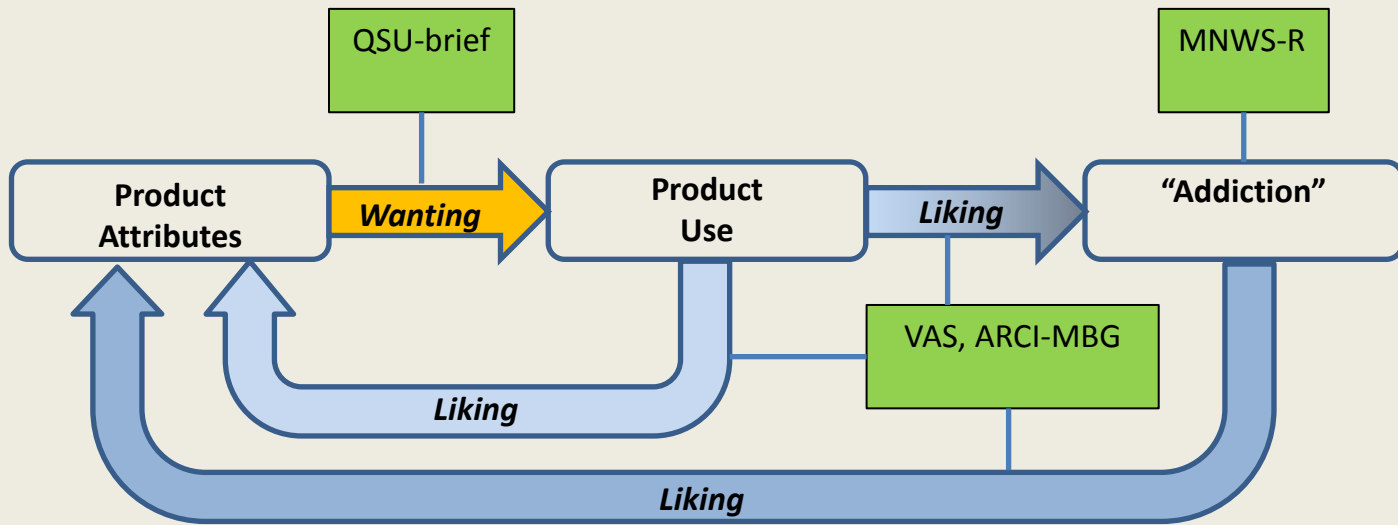
MINWS-R

Please rate yourself for the period for the last _____

0 = none, 1 = slight, 2 = mild, 3 = moderate, 4 = severe

1. Angry, irritable, frustrated	0	1	2	3	4
2. Anxious, nervous	0	1	2	3	4
3. Depressed mood, sad	0	1	2	3	4
4. Desire or craving to smoke	0	1	2	3	4
5. Difficulty concentrating	0	1	2	3	4
6. Increased appetite, hungry, weight gain	0	1	2	3	4
7. Insomnia, sleep problems, awakening at night	0	1	2	3	4
8. Restless	0	1	2	3	4
9. Impatient	0	1	2	3	4
10. Constipation	0	1	2	3	4
11. Dizziness	0	1	2	3	4
12. Coughing	0	1	2	3	4
13. Dreaming or nightmares	0	1	2	3	4
14. Nausea	0	1	2	3	4
15. Sore throat	0	1	2	3	4

(Hughes and Hatsukami 1986)



Recently Used Metrics

- QSU-brief (Brief Questionnaire of Smoking Urges)
- MNWS-R (Minnesota Withdrawal Scale – Revised)
- mCEQ (Modified Cigarette Evaluation Questionnaire)

mCEQ

Table 1

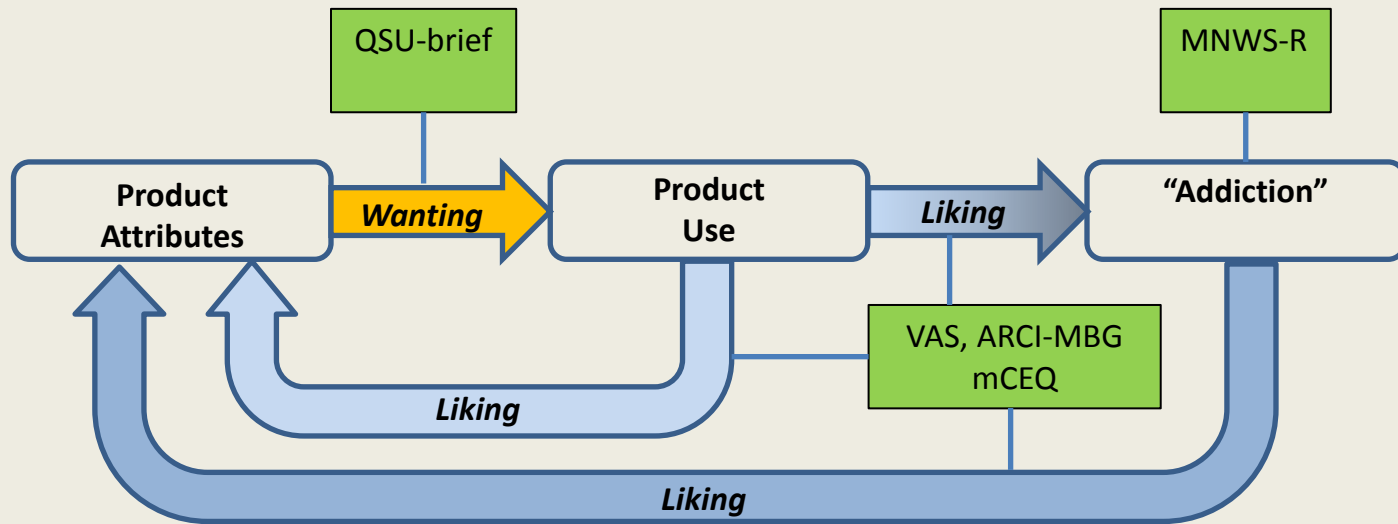
Modified Cigarette Evaluation Questionnaire (mCEQ)*

If you have smoked since you last completed this questionnaire, please mark the number that best represents how smoking made you feel (1—not at all, 2—very little, 3—a little, 4—moderately, 5—a lot, 6—quite a lot, 7—extremely).

1.	Was smoking satisfying?
2.	Did cigarettes taste good?
3.	Did you enjoy the sensations in your throat and chest?
4.	Did smoking calm you down?
5.	Did smoking make you feel more awake?
6.	Did smoking make you feel less irritable?
7.	Did smoking help you concentrate?
8.	Did smoking reduce your hunger for food?
9.	Did smoking make you dizzy?
10.	Did smoking make you nauseous?
11.	Did smoking immediately relieve your craving for a cigarette?
12.	Did you enjoy smoking?

* Items 1, 2, and 12 were presumed or taken to measure “Smoking Satisfaction”; Items 4 through 8 were taken to measure “Psychological Reward”; Items 9 and 10 were taken to measure “Aversion”; Item 3 was taken to measure “Enjoyment of Respiratory Tract Sensations”; and Item 11 was taken to measure “Craving Reduction”.

(Cappelleri *et al* 2007)



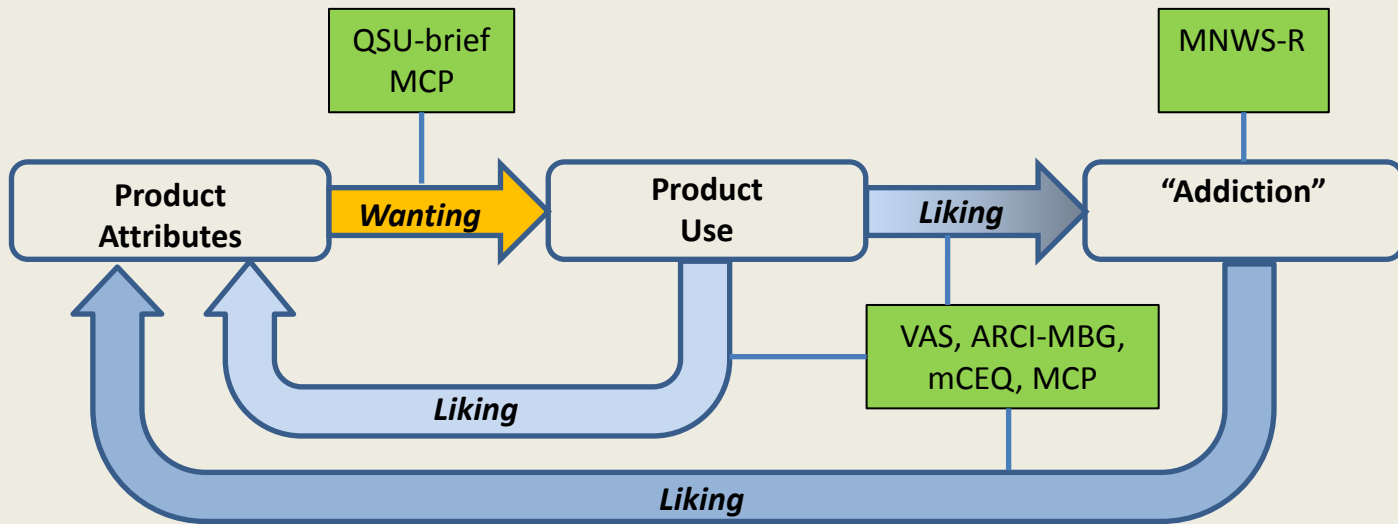
Recently Used Metrics

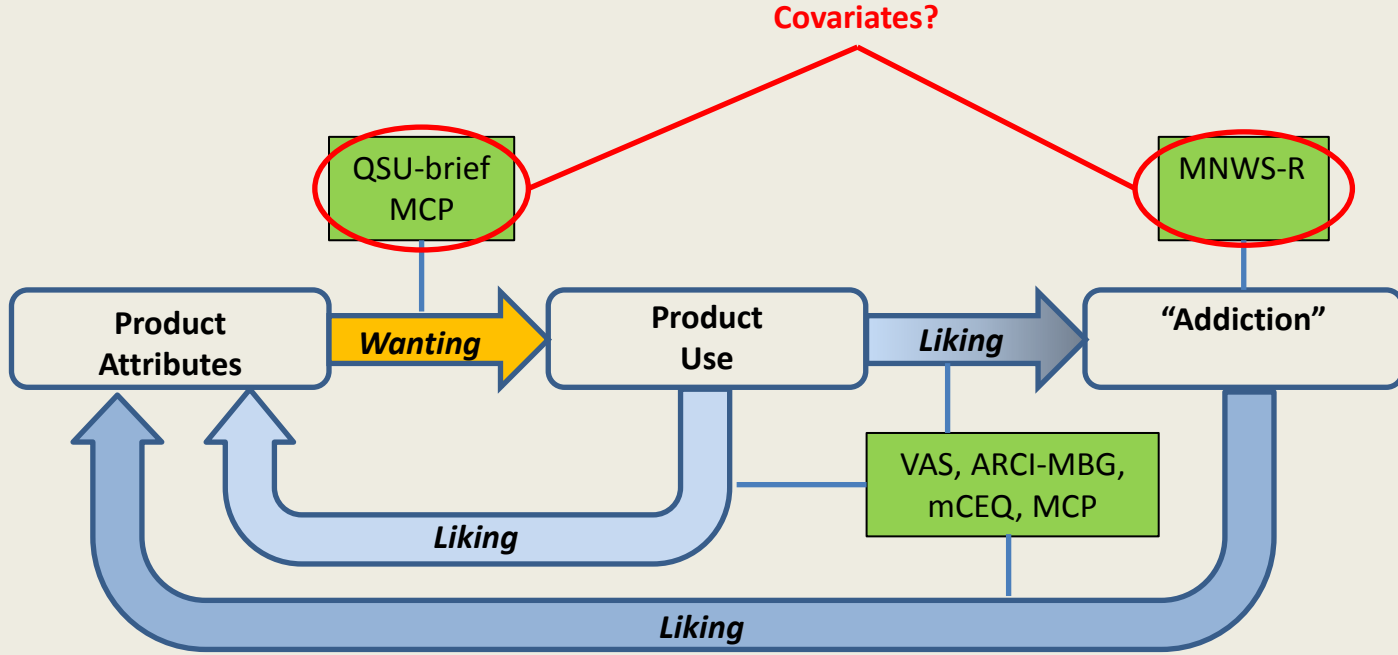
- QSU-brief (Brief Questionnaire of Smoking Urges)
- MNWS-R (Minnesota Withdrawal Scale – Revised)
- mCEQ (Modified Cigarette Evaluation Questionnaire)
- **MCP (Multiple Choice Procedure)**

MCP

10 Puffs	\$ 0.01
10 puffs	\$ 0.02
10 puffs	\$ 0.04
10 puffs	\$ 0.08
10 puffs	\$ 0.16
10 puffs	\$ 0.32
10 puffs	\$ 0.64
10 puffs	\$ 1.28
10 puffs	\$ 2.56
10 puffs	\$ 5.12

(Vansickel *et al* 2012)





Conclusions

- As defined and demonstrated by various scientific bodies, “Addictiveness” (a component of Abuse Liability) can be assessed for tobacco and nicotine containing products by measures of liking (e.g. VAS, ARCI-MBG, mCEQ, MCP after consumption)
- Some measures which have been used (e.g. QSU-brief, MCP before consumption) appear more closely related to wanting; others still (e.g. MNWS-R) to Smoker Status. These may be useful covariates in analyses of “Addictiveness”.

Thank You

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