Introduction and Objectives

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

Methods

- **Development of the TNP Dependence Conceptual Model**
  - **EMBRACE** ( Literature review)
  - **Qualitative research** (concurrent validity concepts)

- **Preliminary TNP Dependence Conceptual Framework and Draft Instrument**
  - **Expert Panel** - 2 nicotine addiction experts and 2 Patient-specific dependence concept guidance

- **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
    - Using a single TNP was stratified in 4 equal user groups (nicotine/saline cigarettes vs. cigarette) vs. other TNP such as e-cigarette, snuff, pipe, hookah, or different replacement behaviors

- **Concept Clarification**
  - Open-ended interviews with participants to capture TNP dependence

- **Cognitive Defining**
  - Two waves of 20 interviews to provide structured input into the items and measure options content

- **Expert Consensus Meeting and Analysis of the TNP Draft Instrument**
  - 130 items/ 10 TNP Development Instrument

Results

Review of Existing Dependence Instruments

- In total, 20 dependence instruments (25 self-report and 3 interview-administered) were identified, the majority of which focused solely on cigarette use.

- Based on the self-discussions with the expert panel, a preliminary conceptual framework was proposed, with use of context as the core concept of dependence.

- A draft version of the instrument was developed to include 9 items that characterized the "severity" of dependence on 2 different response scales (intensity, frequency; domains adapted to the characteristics of the nicotine products).

**Table 2. Characteristics of nicotine dependence among users**:...

**Table 3. Characteristics of dependence on non-TPPs**:...

Discussion

- This approach was designed to achieve test research position to generate evidence from a range of qualification research steps.
- The findings present conceptualization of dependence, and there is agreement that a standardized approach to measure dependence, is a directly comparable way, across a wide range of TNP's is achievable.
- The instrument's currently ongoing quantitative field testing leading to identify the items that have mixed scales and are psychometrically reliable and valid.