Policy, guideline and clinical practice limitations surrounding nicotine replacement therapy (NRT)

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Context - Current limitations surrounding NRT

There are a number of structural policy, guideline and clinical practice limitations including:

- Narrow Therapeutic Goods Administration (TGA) indications for NRT
- Information currently contained in the Royal Australian College of General Practitioners (RACGP) Supporting smoking cessation: A guide for health professionals guidelines
- Absence of National Health and Medical Research Council (NHMRC) Clinical Practice Guidelines for smoking cessation

Context - Nicotine replacement therapy (NRT)

- **Increases quit rates by around 60% compared to placebo (Stead etal. 2012)**
- **Seven forms of NRT available in Australia**
  - Transdermal- patches
  - Intermittent- gum, lozenge, mini-lozenge, mouthspray, oral strip, inhalator
- **NRT has minimal addictive potential (Zwar etal. 2006, Etter 2007, Perkins 2009).**
- **Variation in metabolism, fast metabolisers need larger doses (Benowitz, 2009)**
- **Evidence to support use of NRT during a lapse; safety (Hughes, 2012) and efficacy (Ferguson etal. 2012)**
- **Smoking and using NRT concurrently is safe (Shiffman 2008, Fagerström etal. 2002)**
- **No serious side effects; usually minor (Scollo etal. 2015)**

Literature

Combination therapy

- Combining the nicotine transdermal patch with an intermittent form of NRT has been shown to increase quit rates by 34-54% compared to patch alone (Stead etal. 2012)

Higher dose

- Adding a second patch produce modest increase in quit rate, 14% (Stead etal. 2012)

Longer durations of NRT

- Schnoll etal. 2010- nicotine patches for 30 weeks (extended) compared to standard 8 weeks
  - Week 24- point prevalence abstinence was two times greater for extended vs. standard
  - Week 52- prolonged abstinence 29.1% vs 21.3% p=0.027

Experts (n=5)

- **Unanimous that TGA listings for NRT with respect to dose, combination and duration of therapy fell short of the current evidence**
- **Unanimous the TGA indications not reflective of their current practice or those of colleagues working in smoking cessation**
- **All wished to see TGA indications expanded**
- **All agreed RACGP somewhat evidence based, largely restricted by TGA and generally support approved use only**
- **Uncertainty regarding the transferability of RACGP guidelines beyond general practice setting**
- **All wished to see clinical guidelines developed that are evidence based**

Health Professionals (n=79)

- **Significant variability in recommendations for NRT and use of RACGP guidelines**
  - 60% recommend NRT in combinations
  - 50% recommend NRT in higher doses, or for longer durations
- **Clear view that dosage and frequency of NRT should reflect individual needs and preferences**
- **87% support TGA indications being extended**
- **80% support extension of RACGP guidelines**
- **85% support development of new clinical guidelines**

Consumers (n=87)

- **Varied perspectives of and experiences with NRT**
- **Use of NRT was heavily influenced by the product labelling and information leaflets which are based on TGA indications**
  - 91% would follow instructions on packaging and leaflet (if purchased NRT unassisted)
  - 78% would still follow instructions, even if recommended by health professional and their advice differed
- **Found the sometimes-contradictory advice confusing and frustrating**
- **Agreed that if there was evidence that current labeling and recommendations were not optimal, then changes should be made to ensure best practice support for people who smoke**

Summary

- **Evidence to support the use of NRT in combination, higher doses and longer duration that is currently indicated by TGA and RACGP guidelines**
  - Literature
  - Expert, health professionals, consumers
- **Existing practice is highly variable**
- **Practice improvement in the area of smoking cessation is likely to prompt more people who smoke to attempt to quit, and also to significantly increase the effectiveness of those attempts.**
- **Continuation of the existing TGA indications and variable clinical guidelines may, in many cases, result in suboptimal use of NRT for smoking cessation thereby reducing successful quitting.**

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