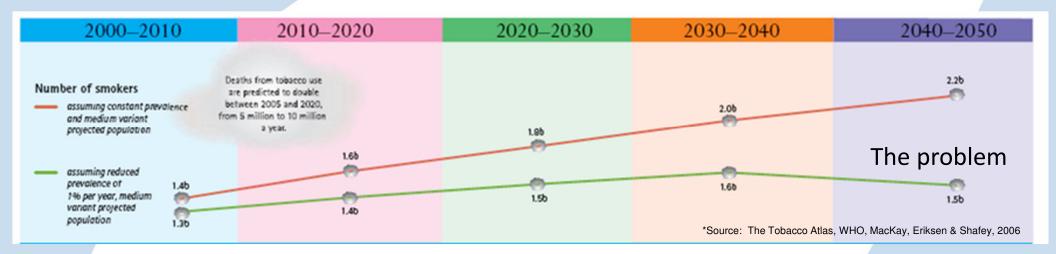
# E-Cigarettes: What's the Real Medical Innovation Breakthrough?

Dr Sudhanshu Patwardhan, MBBS, MS, MBA Senior International Engagement Manager, Nicoventures

ESoF, Copenhagen, 25th June 2014



#### One of the greatest public health opportunities of all time?



#### The solution?

- Nicotine without tobacco smoke
- New nicotine products, regulated for safety and quality



#### Can e-cigarettes help reduce EU smoking prevalence?



Source: Eurobarometer 2012. http://ec.europa.eu/health/tobacco/docs/eurobaro\_attitudes\_towards\_tobacco\_2012\_en.pdf accessed on 20/06/2014



# E-cigarettes are increasingly effective and popular as a tobacco cigarette substitute

- An online survey in 10 European languages of more than 19,000 users from around the world reported
  - Electronic cigarettes may be an effective substitute for smoking even in highly dependent subjects who are heavy smokers.
  - Significant benefits among users in physiologic functions and in some disease conditions.
- A randomised controlled trial in New Zealand showed comparable cessation outcomes for e-cigarettes and nicotine patches<sup>2</sup>
- A recent UK study reported that among smokers trying to stop without any
  professional support, those who use e-cigs are more likely to report abstinence
  than those who use licensed product bought OTC or used no aid to cessation.
- 1. Characteristics, Perceived Side Effects and Benefits of Electronic Cigarette Use: A Worldwide Survey of More than 19,000 Consumers. Farsalinos et al, April 2014
- 2. Electronic cigarettes for smoking cessation: a randomised controlled trial. Bullen et al The Lancet Sept 2013.
- 3. Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. Robert West et al. Addiction, May 2014



#### E-cigarette puzzle - the key pieces

- What are e-cigarettes and how do they work?
- Some advances:
  - Speed of nicotine delivery
  - Mimicking smoking experience
- Remaining challenges:
  - Providing accurate information to smokers
  - Getting product quality and safety regulations right
  - Monitoring the market place for misuse and unintended consequences



### No tobacco. No Burning. A "cleaner" nicotine alternative for smokers to switch to?

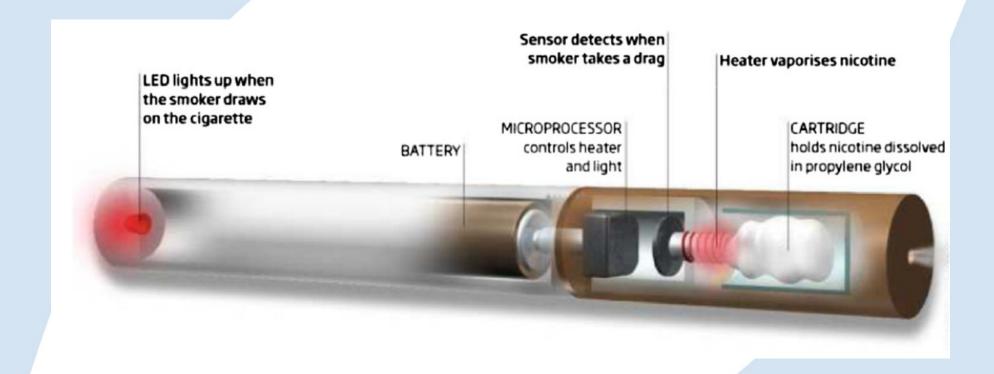
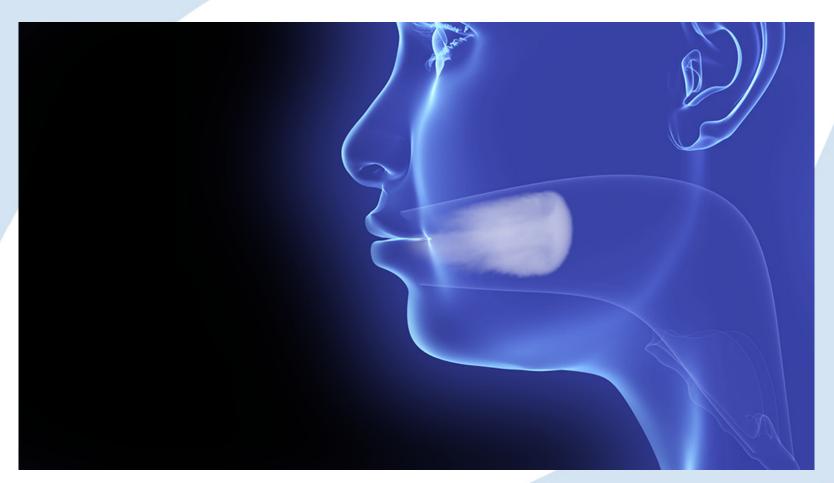


Diagram source: A fresh look at tobacco harm reduction: the case for the electronic cigarette. Polosa et al. Harm Reduction Journal 2013



#### Nicotine in the vapour gives the throat sensation



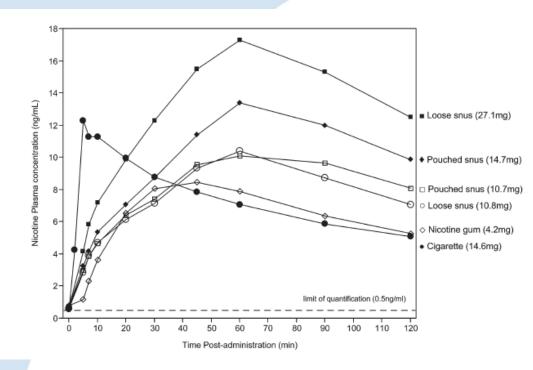


#### Nicotine in aerosol can potentially go beyond the throat

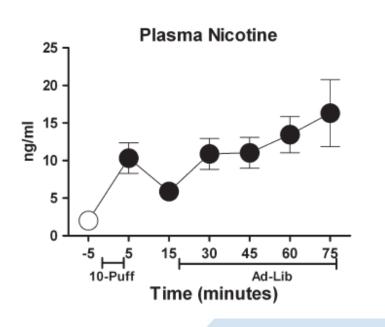




#### Products deliver nicotine at different speeds and levels



Determination of Nicotine Absorption from Multiple Tobacco Products and Nicotine Gum. Digard et al, Nicotine and Tobacco Research, Advanced access published May 2012



Electronic Cigarettes: Effective Nicotine Delivery After Acute Administration, Vansickel et al, Nicotine and Tobacco Research, January 2013



### Maximising e-cigarettes' public health potential



Potential to reduce smoking related diseases....safety concerns should be considered relative to significant health risks from tobacco...

### Electronic Cigarettes



Electronic cigarettes produce a vapour typically containing nicotine, which users inhale. There is debate about their potential role in tobacco

- Electronic cigarettes produce a vapour typically containing nicotine that users
- An estimated 1 3m people in the UK use e-
- ■These products have the potential to reduce smoking-related disease and death, but concerns remain about their safety and quality, their marketing, the involvement tobacco industry, impact on smoke-free legislation, and whether the products will renormalise tobacco smoking.
  - Regulatory options include a compl

..flaws in e-cigarette labelling and design...poor shelf life of cartridges...health implications of inhaling some of the flavourings and other impurities are uncertain...



Generating a lot of media debate



#### Our approach to e-cigarettes' product regulation

- Underpinned by product quality and safety standards
- Include:
  - Use of pharmaceutical grade nicotine and diluents in e-liquid
  - Toxicology based risk assessment approach for e-liquid ingredients and aerosol chemistry
  - Working towards robust quality assurance systems
  - Compliance with existing directives for electrical testing, battery testing, child resistance, and accurate labelling



#### Summary

- It is the smoke from burning cigarettes, not the nicotine, that causes cancer, heart disease and lung disease.
- E-cigarettes mimic smoking and have the potential to deliver nicotine effectively without the
  accompanying smoke toxicants, thus offering a safer alternative to conventional cigarettes.
- The use of pharmaceutical grade nicotine in the e-liquid, a toxicological assessment of ingredients and vapour contents, and good manufacturing practice, are fundamental to meeting smokers' and regulators' expectations of quality and safety from e-cigarettes.
- Although there is little evidence currently regarding normalisation of smoking due to ecigarette use and e-cigarettes acting as a gateway into smoking, we need to ensure responsible marketing of the products to smokers and continue to monitor how these products are used in the society.

