1. Introduction

Decision-makers within the National Institute for Health and Clinical Excellence (NICE) use 'economic evaluation' to decide whether a new healthcare product represents value to the NHS, by comparing it to current practice in terms of:

**Cost-effectiveness plane: New device compared with current practice**

- Impact on healthcare resources ($\Delta$Cost); and
- Impact on patient health ($\Delta$Health).

The **Headroom Method** incorporates this demand-side reimbursement process (decision to buy) into supply-side investment decisions (decision to develop). It is to be used as early as possible, ideally at 'concept' stage of a new device (pre-development).

**Headroom**

Determines the maximum reimbursable price of the new device

Can the manufacturer afford to develop the product for this price?

- **Develop**
- **Abandon**

**WTP**: What the NHS is Willing To Pay for extra health benefit, normally measured in QALY's [Quality Adjusted Life Year]

2. The Problem

The device sector is highly innovative but not all innovations represent value for money

99% of manufacturers are small and medium enterprises, with low resources and little time

Industry needs a simple decision-making tool to determine the viability of a new device idea as early as possible

"...there isn't an unlimited pot. Cost-effectiveness decisions are here to stay" for Michael Rawlins, NICE chairman

3. The ‘Solution’

**Primary Research Question**: Is the Headroom Method a useful tool for device developers?

**Case studies**
- Two prospective: COPD home monitor; Leg ulcer protector
- Twenty retrospective: 20 devices from the NHSC* database

**Realist Evaluation**

**Interviews**
- To obtain the perspective of seven distinct stakeholders

*NHSC: National Horizon Scanning Centre: http://www.nhsc-healthhorizons.org.uk/

4. Methods

5. Results

- For the first time, the possible implications of basing development decisions on a headroom analysis has been explored.
- **Headroom is most easily elicited where the change proposition is straightforward**
- Development decision implied by headroom analysis related / partially related to actual market success / failure in 85% of cases.
- BUT when combined with the 'extra considerations' identified (see below) the method quite accurately predicts the market prospects of new devices, even at a very early stage.

6. Conclusion

- The headroom method is a quick (=9 hours) and useful way to consider the investment opportunity at a very early stage
- The clinical and market context of the innovation is important, and should always be considered alongside the ‘headroom’

**Does it work?**

**Case Study example**: Silver-coated endotracheal tube for the prevention of ventilator-associated pneumonia (VAP).

**Time perspective taken**: 2005

1. Identify key benefits
- Could reduce the likelihood of VAP in mechanically ventilated patients by 50%

2. What does this mean for patient care?
- Half of all VAP episodes are avoided, thus reducing length of hospital stay and improving quality of life

3. What is this worth to the NHS? **Headroom**

**Follow-up**

The product is now sold for around £110: Headroom would have indicated plenty of room for development. The device is available globally.

**Cost**
- £1,556 (hospital costs)
- £55 (price of current tubes)

**QALY**
- 0.00025

**Headroom**: £1,556+£55+(0.00025*£20,000)

= £1,616