Feedback from Group 3: Innovative Performance –Based Outcomes Agreements

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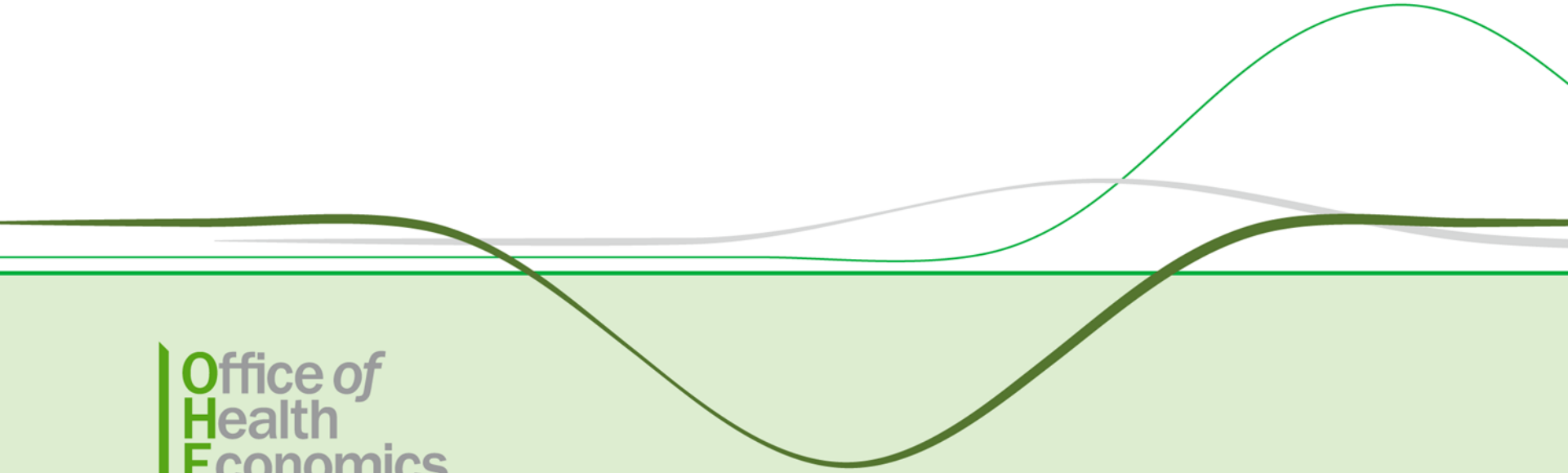
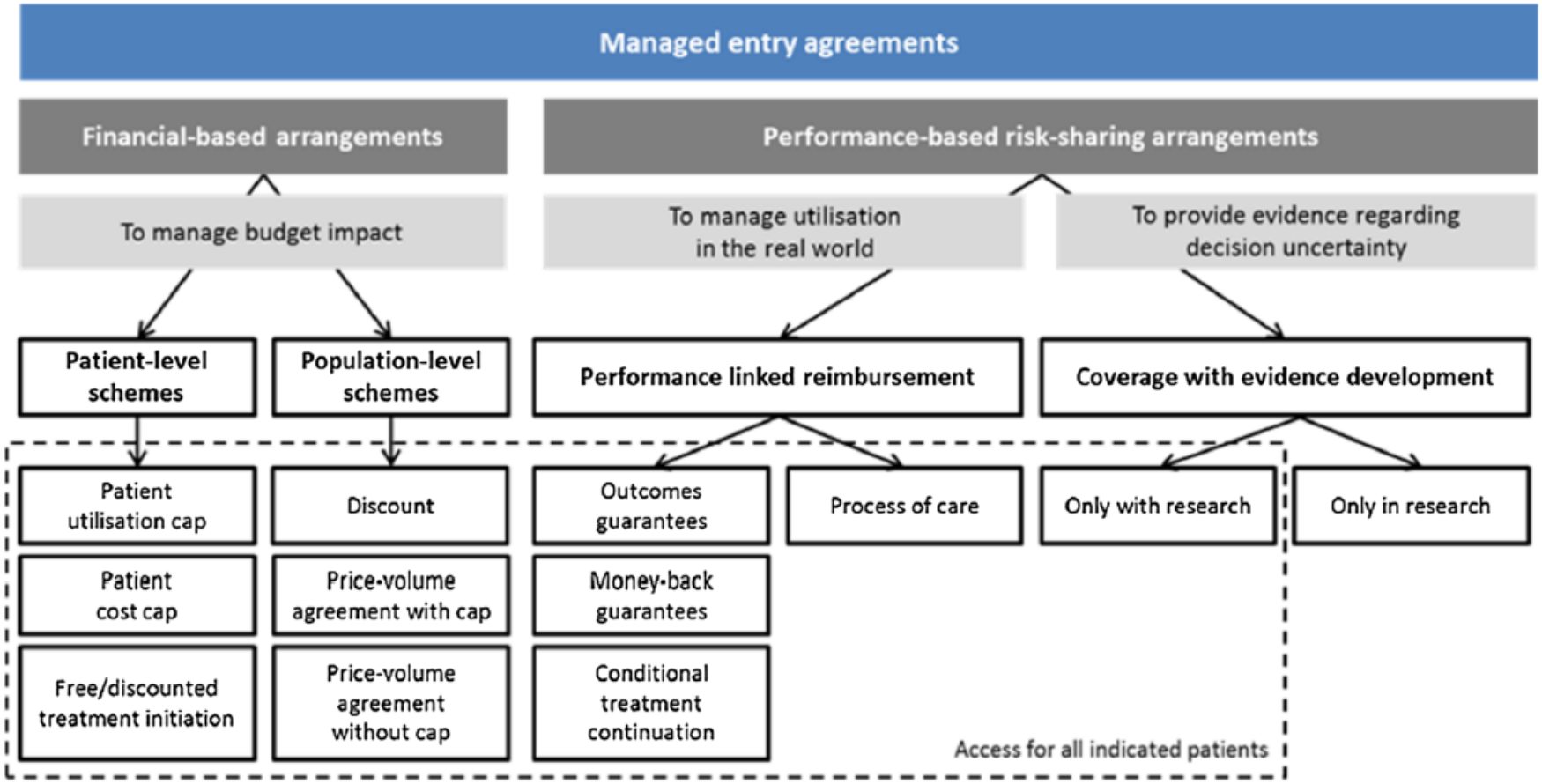


Office of Health Economics
Research

Managed Entry Agreement terminology



MEAs are typically classified into finance based agreement and outcome based agreement

Source: Garrison (2013)

Implementation Challenges

Data

- Data collection and validation processes
- Viability of implementation – firewalls, data capture, consistency of data
- Data protection
- Resource and investment to collect and share data
- Evolving/ growing with experience

Implementation

- Operational issues – clinical setting suitability
- Roles of stakeholders – clinicians and patient groups
- Engagement of stakeholders to develop and implement
- Agreed processes to validate changes to MAA
- Patient responsibilities

Break out 1: challenges and solutions

- Choosing relevant outcomes
  - Openness to tackling uncertainty
  - Early and broad discussions
  - Interview clinical trial patients
- Need to balance desire to know it works with burden on patients
  - Support for patients through process, e.g. nurse manager

Break out 2: challenges and solutions

- Timing – who to include when?
  - A "year minus one" so you are validating the base case in advance
- Burden on patients
  - Using different ways of collecting outcomes data (e.g. digital) to filling in an outcomes data form after a two hour journey to a hospital
- Taking ownership – who has responsibility, holding the data, quality assurance?
  - an academic group? Providing they are willing to share. ERNs? EUnetHTA?

Break out 3: challenges and solutions

- Inter-operability across sites and countries, pharmacovigilance,
  - Case for guidelines across countries on registries as part of procurement - technical standards
- Shortage of patients – not CVD with 000s of patients:
  - need to use data modelling synthesis; "Virtual physiological patient"
- Data protection – more complex with few patients:
  - Adapt consent forms so patient is clear about ability to anonymise when they consent
  - Penalties for breach of patient confidentiality

Final thoughts ..

- "We need adaptability and subjectivity when studying and assessing rare diseases"