Feedback from Group 3: Innovative Performance -Based Outcomes Agreements

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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”