What Must Change If Future Evidence Pricing And Access Challenges Are To Be Successfully Overcome?

HTA192

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Introduction and objective

- To identify future evidence pricing and access challenges, and solutions for overcoming these, highlighting the systemic, stakeholder, and organisational changes required.

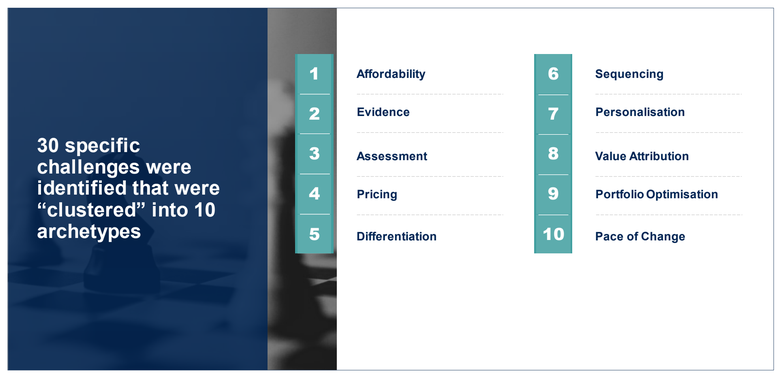
Methodology

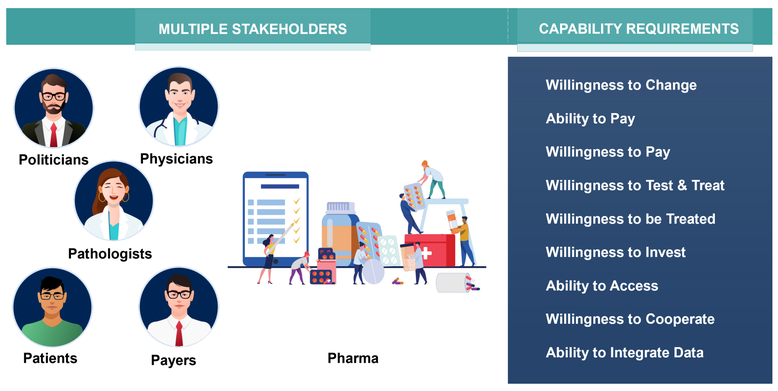
- Using the ISPOR top 10 HEOR trends 2022/3 as catalyst, a 2-cycle delphi approach based on broad expert opinion (n=41) was used to determine the key evidence pricing and access challenges over the period 2023-30.
- Scope covered complete lifecycle pathway, evolution of digital health and genomic insight, and consideration of value attribution. Cluster analysis was used to structure the output.

  For each cluster, solutions to overcoming the challenges were identified.

Results

- The majority of the 30 specific challenges were applicable to most therapy areas.
- The 30 challenges involved multiple stakeholders and capability requirements.





- The research indicated that the challenges can rarely be solved in isolation, in a single company or departmental silo, or based on single data sources.

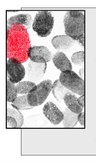
  Collaboration and access to multiple 'integratable' data sources will be critical success factors.
- The largest cluster (7/30) comprised personalisation challenges (digital and molecular diagnostics / biomarkers linked to therapeutic).

  These challenges must be addressed if the promises of improved economic, clinical and humanistic outcomes are to be delivered[1 & 2].

Three key challenges need to be addressed for digital health to be successful

The first challenge: speed of evolution

Technology is evolving faster than the regulatory, behavioural, healthcare funding, and health technology assessment (HTA) systems that are required for successful implementation.



The second challenge: evidence

There are various challenges to evidence development in this environment, including:

- *Relevance, robustness, and rigor*
- *Difficulty and cost of evidence development*
- *Timeliness of evidence delivery*
- *Continued validity of evidence in a rapidly evolving environment*
- *Measurement and attribution of co-dependent value between developers of the different disease management components.*

The third challenge: value

Value will be attributed and assessed in different ways:

- Value contribution of 3 different elements: monitoring, intervention & prediction (the MIP paradigm).
- Value segmentation based on 3 outcome types: economic, clinical & humanistic
- Value perception based on 3 stakeholder groups: patient, payer & physician
- Value attribution, informing value-based reimbursement allocation

Eight barriers to molecular diagnostics and five to therapy use will need to be removed for biomarker driven healthcare to be successful

Barriers to molecular diagnostic use may include:

- Funding
- Access to and availability of testing
- Testing methods and process: difficulty of obtaining sample, complexity, and turnaround time
- Test performance: will the test be (or be perceived to be) insufficiently accurate or ambiguous?
- Population selected for testing: will the population tested be as broad as the drug's indication?
- Physician's adoption of the test proposition
- Patient demand for testing, and willingness to be tested
- Conversion rate: will physicians prescribe other drugs despite a "positive" test result?

Barriers to therapy use may include:

- Affordability, access and availability: of drugs, diagnostic testing, reimbursement, and of data/evidence
- Timing: delays in updating treatment guidelines, delays in Health Technology Assessments and implementation, and time lag in adopting technology
- Preference: influenced by context, personal experience, and outcomes of earlier treatment(s)
- Policy & priorities
- Power: Physician vs. payer, HTA vs. medical society, and treatment guideline perspectives differing from patients' perspectives.

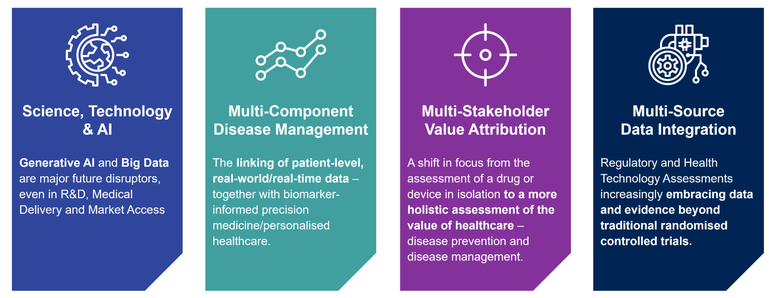
Conclusions

- To overcome challenges, **changes** will be required in 5 areas[4]:

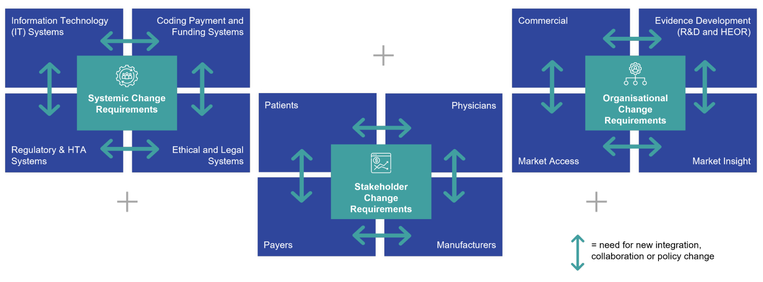
1. Systemic changes (Information Technology (IT) Systems, Regulatory and Health Technology Assessment Systems, Coding Payment and Funding Systems, Ethical and Legal Systems}
2. Stakeholder changes (Physicians, Patients, Payers, Manufacturers)
3. Organisational changes (Commercial, Evidence Development (R&D and HEOR), Market Access, Market / Business insight)
4. Strategic collaboration between manufacturers and data providers to access data
5. Integration of data from multiple sources (Prescription data, Electronic medical records (EMRs), Health resource utilisation (HRU), Claims data, Real-time / wearable data, Social media data)

Solutions

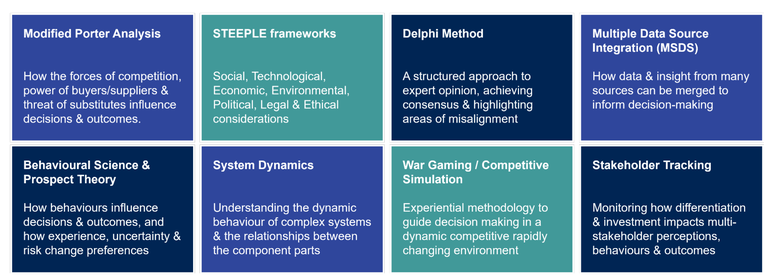
Evidence, pricing and access will need to be re-engineered to address four factors



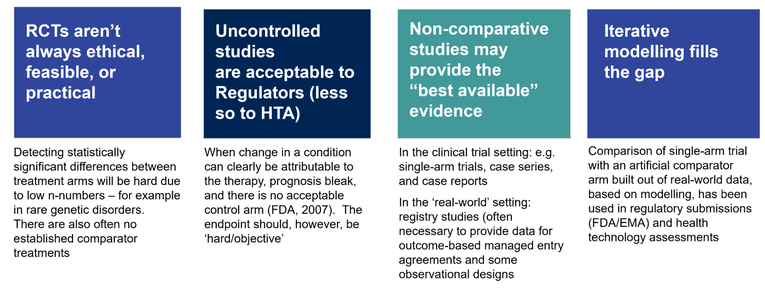
Fundamental changes will be required to overcome the evidence availability, accessibility, and acceptability challenge



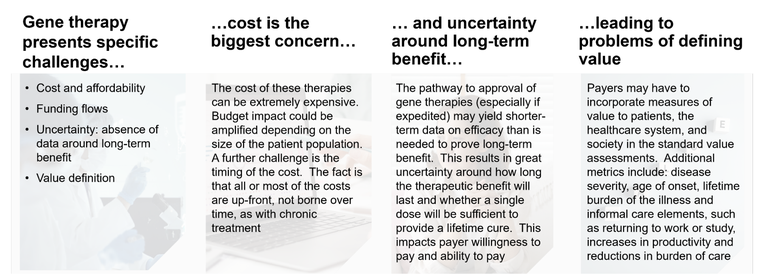
New methodologies will need to be applied to help decision-makers understand drivers of change



Non-comparative data, plus modelling solutions, will increasingly be required



Financial engineering will be needed to address the challenges of gene, and other therapies, with high price density



New payer-types will emerge, and funding flows will need to change to relieve financial pressures

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