'Real-World Data: How To Improve Data Collection and Use in Irish Healthcare'
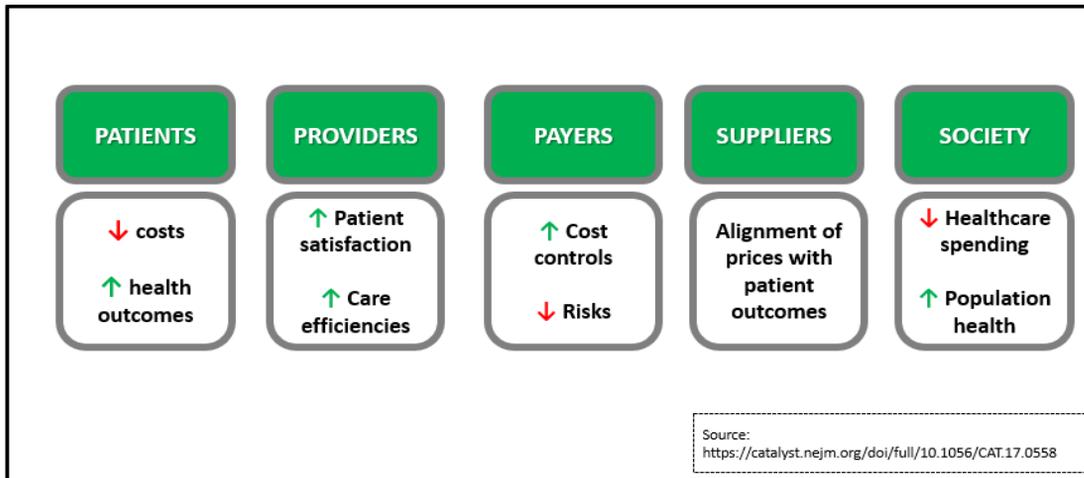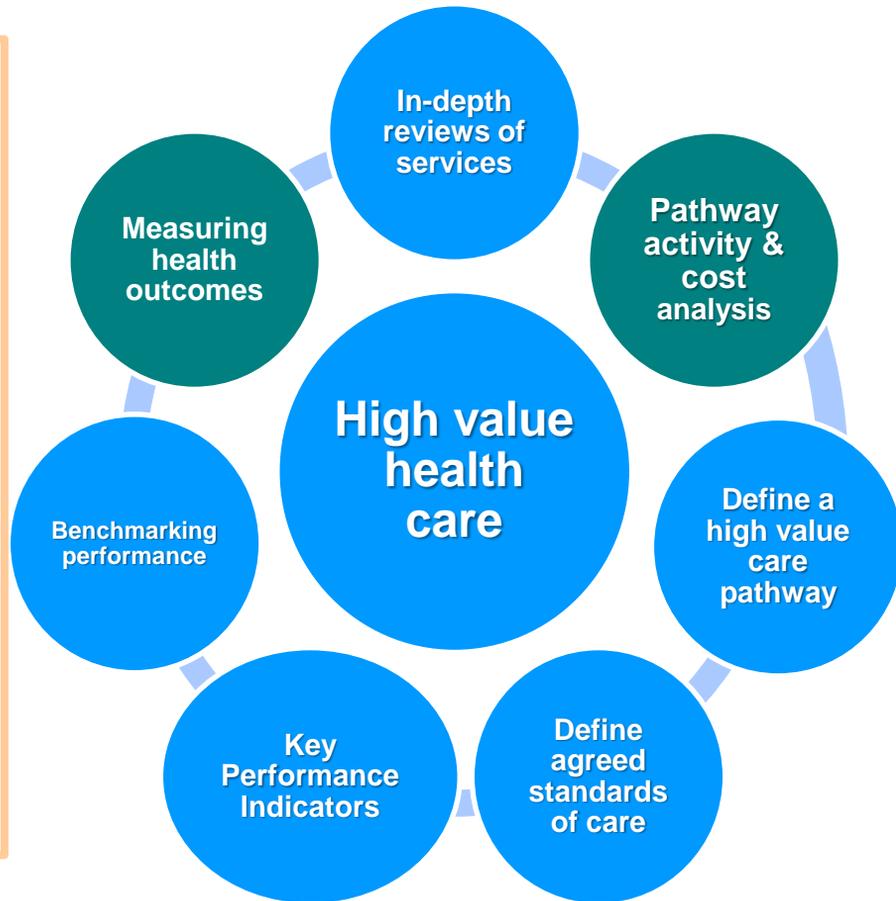
Aisling O'Leary, BSc(Pharm.), Ph.D.

National Centre for Pharmacoeconomics
NCPE Ireland

Value-based healthcare (VBH)

- Patient value = patient-relevant outcomes/costs per patient to achieve these outcomes *(Porter 2006)*
- A healthcare delivery model in which providers, including hospitals & physicians are paid based on a patient health outcomes *(NEJM Catalyst 2017)*
- Equitable, sustainable & transparent use of available resources to achieve better outcomes & experience for every person *(CEBM 2019)*

PATIENTS	PROVIDERS	PAYERS	SUPPLIERS	SOCIETY
↓ costs ↑ health outcomes	↑ Patient satisfaction ↑ Care efficiencies	↑ Cost controls ↓ Risks	Alignment of prices with patient outcomes	↓ Healthcare spending ↑ Population health

Source:
https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0558

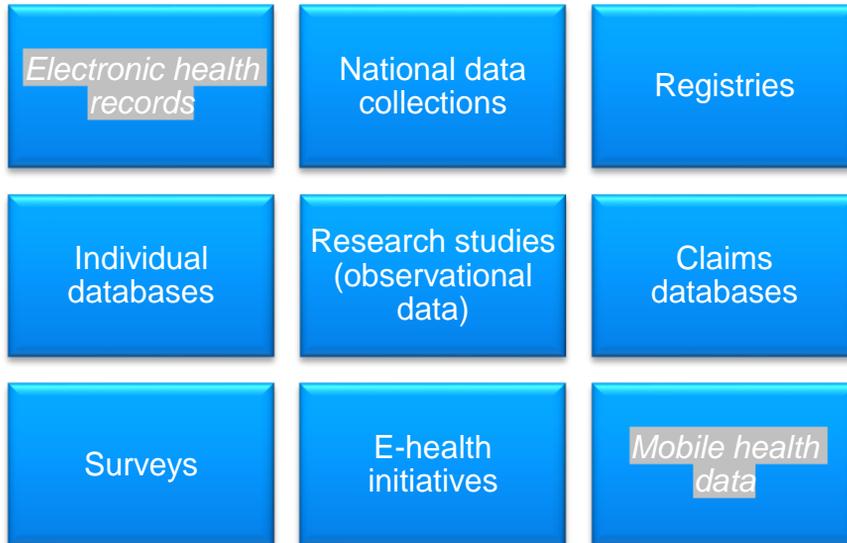# Key enabler of value-based healthcare…information & data

- Porter Domain 6 (2006):
  - Enable a suitable **information technology** platform

- NEJM Catalyst (2017):
  - New healthcare delivery models stress a team-oriented approach to patient care & **sharing of patient data** so that care is co-ordinated & outcomes easily measured

- CEBM Recommendation 5 (2019):
  - Develop the necessary skills in value-based healthcare by training staff in **how to measure** outcomes, patient experience & resource use
  - **Challenge is the need for better data**:
    - The problems of defining, measuring & sharing data about resource use and outcomes and experiences that matter to patients are significant barriers to increasing value

Availability of health information is key

- What do people on the ground actually need to deliver these outcomes?

- Health information that is accurate, timely & relevant

- Requires a **well-designed health information system** to allow access to quality patient information across the **entire spectrum** of the healthcare system

- For both primary and secondary use of health data

Current sources of real world data in Ireland

Electronic health records	National data collections	Registries
Individual databases	Research studies (observational data)	Claims databases
Surveys	E-health initiatives	*Mobile health data*

Traditional uses:

Patient care (primary use)

Pharmacovigilance studies, screening, research outputs, drug utilisation, health status, service planning, status of care etc

Real world data vs real world evidence

Real-world *data (RWD)* are the data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources

Real-world *evidence (RWE)* is the **analysis** of real world data or data relating to patient health status &/or delivery of healthcare routinely collected from a variety of sources

Potential users & uses of real world data

- Users:
  - ☐ Clinicians
  - ☐ Patients
  - ☐ Service providers
  - ☐ Policy makers
  - ☐ Regulatory agencies
  - ☐ HTA agencies
  - ☐ Decision makers/payers
  - ☐ Industry

- Uses
  - ☐ Depends on the user, the user's question(s) & the data available

Use of RWD for health technology assessment (HTA) of new technologies

- Randomised controlled clinical trials (RCTS) remain most robust method of generating efficacy for new technologies

- RWD uses for HTA
  - ☐ Pre assessment setting
  - ☐ Derivation of model inputs
    - Epidemiology, natural history
    - Resource utilisation, drug utilisation, cost estimates
    - Quality of life estimates
    - Transition probabilities
    - Compliance
  - ☐ Post assessment
    - Outcome validation
    - Managed Entry Agreements
    - Managed Entry/Access Protocols

Challenges with the use of RWD/RWE in HTA

- In estimations of comparative treatment effect
  - Multiple biases
  - Confounding
  - Important co-variates missing etc.

- In determination of post-approval outcomes
  - No electronic means to extract relevant information
  - No linkage to allow intelligence to be shared
  - Resource intensive

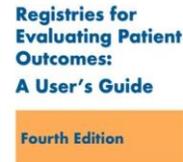| Strengths of RWD	Limitations of RWD
Ability to collect/analyse large numbers of subjects	Important clinical data may be missing
Study of choice for: - Identifying important cohorts - Treatment patterns of care - Prediction rules	Accuracy of data/endpoints - Lack of data validation - Adjudication of end-points
Ability to perform comparative effectiveness studies to generate hypotheses: - Areas with no data - Patient cohorts/disease states in which RCTs not possible or nor undertaken	Comparative effectiveness studies can only be hypothesis generating for: - Confounding by indication - Treatment bias - Immortal time bias
Cost of analysis lower than RCTs	Utilisation of appropriate statistical methods to minimise confounding
Data collection mechanisms can serve multiple purposes - Infrastructure for randomised studies - Quality improvement	
Determining whether outcomes seen in RCTs translates into similar outcomes	
Assessing tolerability & safety	

Supporting quality RWD/RWE

- Several guidelines & frameworks available & more on the horizon with varying focuses

- HIQA's quality data framework

- Registries
  - Glicklich *et al*: Research & evidence quality
  - EUNetHTA ReQuest Tool: Focus on PLEG & HTA
  - Duke Margolis/FDA: Regulatory context
    - Assessment of 'Fit-for-Purpose'
      - Reliability: Data accuracy, completeness, provenance, traceability
      - Relevance: Availability of data elements & sample size

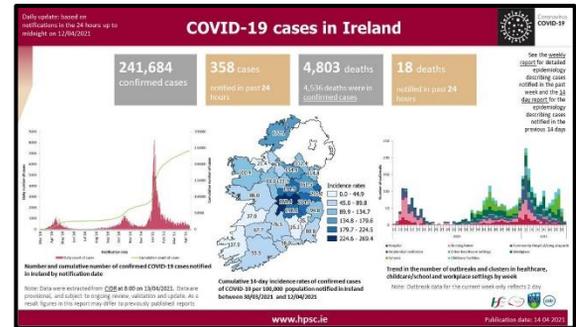- ➤ But challenge is the absence of operational tools

Registries for Evaluating Patient Outcomes: A User's Guide

Fourth Edition

AHRQ
Agency for Healthcare Research and Quality

eunethta

Vision paper on the sustainable availability of the proposed Registry Evaluation and Quality Standards Tool (REQueST)

Determining Real-World Data's Fitness for Use and the Role of Reliability

September 26, 2019

Duke
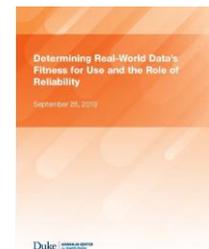
Practically how can we deliver VBH in Ireland?

Primary use: when health data is used to deliver health care to the individual from whom it was collected

Secondary use: is when health data is used outside of health care delivery for that individual.

➤ Translation of data to information
➤ Information to opinions
➤ Opinions to decision making

Health information landscape in Ireland

- *Highly fragmented, 'siloised', insufficient formal co-ordination*
- *Collected by multiple organisations & individuals*
- *In different places*
- *Varying standards of quality*
- *Lack of interoperability (linkage)*
  - *Inability to share/connect*

➢ No unique/individual patient/health identifier in use!

Interoperability: the ability of computer systems or software to exchange and make use of information

Barriers to access and use of healthcare data

Motivational barriers	• No incentive to share • Fear of criticism/blame • Disagreement on data use
Legal barriers	• Consent • Perceived regulatory problems • Data protection e.g. GDPR, Data Protection Impact Assessment (DPIA)
Technical, organisational, workload barriers	• Individual health identifier (IHI) not implemented • Lack of metadata and standards • Insufficient tools and technology
Economic, political and ethical barriers	• Lack of guidelines • Lack of standardised procedures • Lack of resources (legal, IT, data management) • Absence of policies • Who to ask?

What is needed?
...*the unknown knowns?*

- A fundamental culture change and resources commitment around accessing, resourcing and using health data in Ireland

- Use of health data for the public interest should be the overarching tenet of a publicly funded health system

How to address barriers to access and use of healthcare data *(known knowns)*

- **Implement the IHI**
  - ☐ Impossible to link data sets without the individual health identifier
  - ☐ Big concerns in health care community about sharing patient identifiable information but not health data (if pseudo anonymised!)

- **National strategy for data sharing**
  - ☐ Sector wide guidance underpinned by legislation for secondary use

- **Legislation update**
  - ☐ Critical need for specific legislation around collection, use & sharing of data that is GDPR compliant

How to address barriers to access and use of healthcare data *(known knowns)*

- **Involve patients**

- **Roll out the eHealth Strategy**
  - **Dedicated centre within eHealth that supports data sharing**
  - Address concerns about legal and regulatory complexity
  - Address concerns around breach of confidentiality
  - Allocate resources to data sharing
  - Tackle low knowledge and misunderstanding around legality of data sharing
  - Promote benefits of sharing
  - Support technical and organisational groups including completing DPIA, DSAs, internal documentation

Comparison with other jurisdictions

- Strong leadership, governance & management structures in place
- Legislative reform
- Individual health identifier
- Robust information architecture
- Interoperability frameworks *in situ*
- Nationwide registries
- Involvement of patients
- And more…

SLÁINTECARE
IMPLEMENTATION
STRATEGY

Patient is paramount
All care is planned and provided so that the patient is paramount, ensuring appropriate care pathways and seamless transition backed-up by full patient record and information.

Go raibh míle maith agaibh.

Acknowledgements

Staff of NCPE

Staff in treatment sites

National Centre for Pharmacoeconomics

NCPE Ireland