IP7: CHANGING PARADIGM IN THE EVALUATION OF THE VALUE OF MEDICAL DEVICES: WHAT MUST STAKEHOLDERS EXPECT IN THE NEW DECADE?

Department director Øyvind Melien
Assessment interventions, Norwegian Institute of Public Health (NIPH)

BREAKOUT SESSION 2
Monday, November 12, 2018
15:45 - 16:45

Changing landscape - changing paradigms
Expectations - Driving forces - Trends

Unmet needs
Innovations
High speed clinical research
Increase transparency
High speed evaluation/HTA
Early market access
Strengthen patient involvement
Personalized medicine
Cost-effectiveness
High quality of care

How to find the balance points for future?

Example from Norway: Present model HTA processes

Proposal / Horizon scanning

Input
Proposal
Horizon scanning
Commissioning Forum

Health Technology Assessment (HTA)

Input
Full HTA
Commissioning Forum
STA

Prioritizing setting decisions

Sent to the regional health authorities for decision
Decision forum
May be introduced
Not to be introduced
Other (Ranking, disinvestment, etc.)

Implementation
Coordination with National Guidelines

Initiation / Local proposal
Negotiation
Mini HTA
Local decision

NYE METODER
The needs for patients and healthcare

Given limited resources and budgets an increased focus on fundamental and unmet needs is likely to be expected to guide areas and technologies for evaluation.

- Further development/refinement of instruments for selection of topics
  - Prioritization criteria (e.g. severity of disease) corresponding to criteria for healthcare in general

- The future impact of personalized medicine may expand the understanding of unmet needs both at individual and system level.

Need to strengthen the life cycle perspective

Need to build a framework supporting a life cycle perspective for medical technologies

- Significant interest for the launch phase
- In the future a need to extend and strengthen focus on prelaunch and postlaunch phases
  e.g. - what are the unmet needs?
  - what are the outcomes, values in clinical practice?
Future perspectives

Need to improve and extend data collection

Need to improve and extend the data platform for evaluation to correspond to the life cycle of medical technologies allowing for assessments and reassessments of value including:

- Clinical research data
- Health data
- Patient experiences

Novel instrument for collecting data from health care: electronic patient curve systems (Intensive care unit, Norway)

With permission: Harald Noddeland, OUS
Need to build frameworks for more efficient data-sharing throughout the lifecycle of technologies

Clinical research → Evaluation of Evidence → Guidelines → Monitoring & Re-evaluation

International: CRIGH, ECRIN, Nordic Trial Alliance, NORCRIN

Europe: EUnetHTA, INAHTA, Nordic collaboration

Nordic countries: Nordic Guidelines

Norway: «Nye metoder», National Guidelines

Research Data → Health Data → Patient experiences

Data sharing - Reuse of data - Quality assurance
EOSC - GOFAIR - CORBEL - eXtreme Data Cloud (XDC) – OpenAIRE - My Health my data

Future perspectives

Need for broader involvement and dialogue throughout the life cycle

Strengthen dialogue between industry, regulatory authorities, HTA bodies, payers, patient representatives and other stakeholders from an early stage

Clarify needs for data both for regulatory and HTA processes

Early dialogue → Late dialogue

Development of technology → Prelaunch → Launch → Postlaunch

Life cycle perspective
International Initiatives on the Assessment of the Value of Medical Technologies

- **Objective:**
  - Identify the current role of HTA; and other tools/approaches/methods used to assess the value of medical technologies globally and locally; and develop reflections for a future role that HTA could have in assessing medical technologies throughout their lifecycle to inform decisions and healthcare policies.

- **Recommendation:**
  - There is a need to explore more closely how to utilize and adapt HTA as a supportive tool in the life cycle of medical technologies to benefit patients, health systems and society, and consider the value of other tools and initiatives on novel value frameworks to inform decisions and reach policy objectives.