Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

HIQA's role in assessment of cancer interventions

Future of Cancer in Ireland webinar series: Assessing the value of new cancer treatments and innovations

18 May 2023

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Health Information and Quality Authority

Presentation overview

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- About HIQA
- Health Technology Assessment at HIQA
  - Cancer intervention technologies
- Recent assessment work relating to cancer
  - Modifications to cancer screening programmes
  - Gene expression profiling of early stage breast cancer tumours
  - Establishment of generic justification function (for medical exposures to ionising radiation)
- Observations in assessing value of cancer interventions

About HIQA

About HIQA

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- HIQA was established under the Health Act 2007 as an independent statutory authority, reporting directly to the Minister for Health.
- Functions:
  - ✓ Setting standards for health and social care services
  - ✓ Regulating health and social care services
  - ✓ Monitoring services
  - ✓ Health information
  - ✓ National Care Experience Programme
  - ✓ **Health technology assessment**

Safer services and better care for all

Health Act 2007

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The remit of the Authority includes:

- "To evaluate the **clinical and cost-effectiveness** of health technologies including drugs and provide advice arising out of the evaluation to the Minister and the Executive"
- "To review and make **recommendations** as the Authority thinks fit in respect of the services, to ensure the **best outcomes for the resources available**…"

Provide **advice** to the Minister for Health and the HSE

HTA at HIQA

What are health technologies?

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Any intervention used to promote health, diagnose or treat disease, or used in rehabilitation or long-term care:

- Pharmaceuticals (drugs)
- Medical Devices
- Diagnostics
- Medical and surgical procedures
- Public health activities
- Organisational and support systems within which health is promoted and maintained

Repatriation of paediatric stem cell transplant services	Chickenpox vaccine	Newborn screening ('heel prick' test)	Home ventilation services for spinal cord injury	Public health governance structures

What is Health Technology Assessment (HTA)?

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“Health technology assessment (**HTA**) is a **multidisciplinary process** that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a **systematic, transparent, unbiased, robust manner**. Its aim is to **inform** the formulation of **safe, effective, health policies** that are **patient focused** and seek to **achieve best value**.” (EUnetHTA)

Purpose of HTA:

to inform safe and effective health policies that are patient-focussed and achieve best value.

Aspects that may be covered in a HTA

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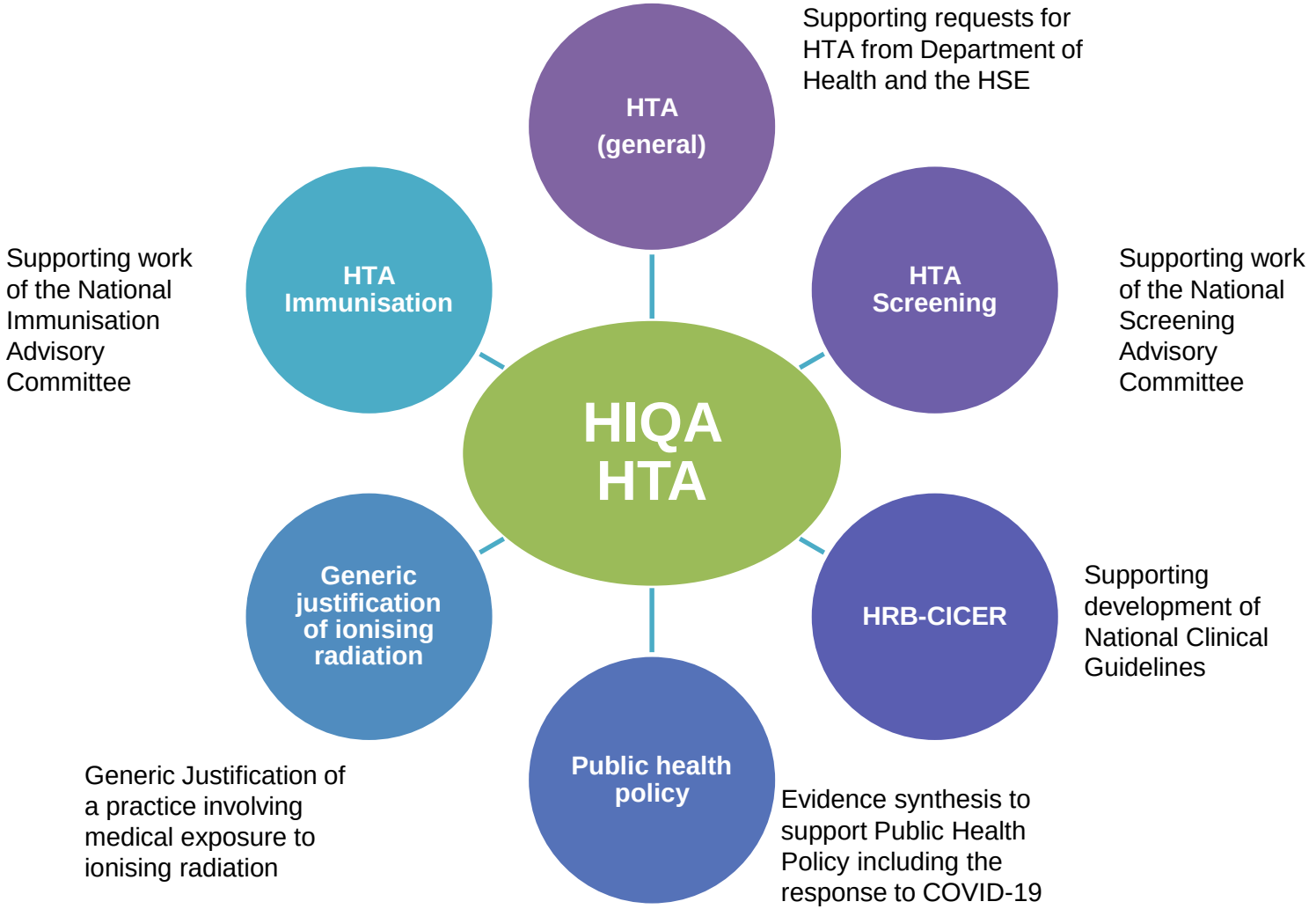
- Health problem and current use of the technology
- Description and technical characteristics of technology
- Safety
- Clinical effectiveness
- Costs and economic evaluation
- Ethical analysis
- Organisational aspects
- Patient and social aspects
- Legal aspects

Our workstreams



Technologies in the cancer continuum

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Primary prevention

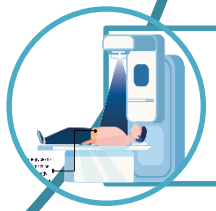
- e.g. HPV vaccination

Secondary prevention

- e.g. CervicalCheck screening

Diagnosis

- e.g. CT scan – staging of cancer



Treatment

- e.g. Radiotherapy

Past cancer-related assessments

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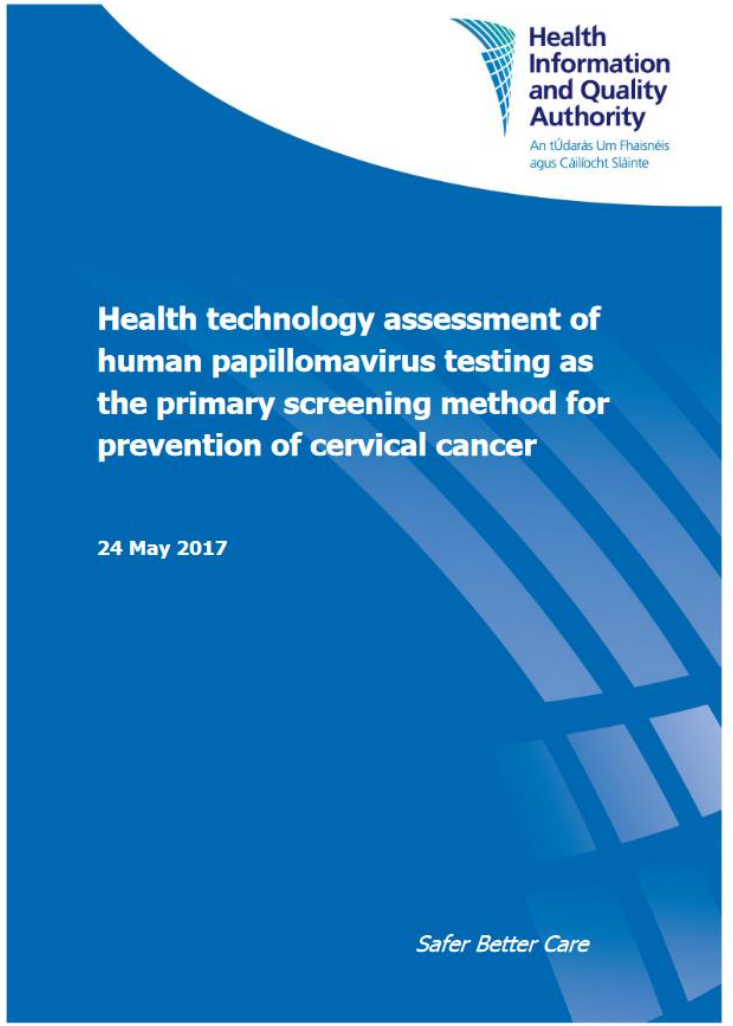
- HTA of HPV Vaccination in Girls – Aug 2008
- HTA of Colorectal Cancer Screening – June 2009
- HTA of Resource Use in Cancer Screening Services – Jan 2010
- HTA of Robot-assisted Surgery (e.g. prostatectomy) – Sept 2011
- HTA of High Risk Breast Cancer Surveillance – April 2013
- HTA of HPV testing for Cervical Cancer Screening – May 2017
- HTA of extending the HPV vaccination to boys – Dec 2018



HPV testing for CervicalCheck

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- Request from the National Screening Service. Final HTA published May 2017.
- Clinical effectiveness evaluation – 2 systematic reviews:
  - Comparison of HPV testing with cytology testing
  - Triage options for HPV-based primary screening
- Economic evaluation of different screening strategies (vaccinated and not vaccinated)
  - Cost effectiveness
  - Budget impact
- Organisational, social, ethical implications

HPV testing for CervicalCheck - Findings

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- *"…For a cohort of women not vaccinated against HPV 16 and HPV 18, primary HPV screening followed by liquid-based cytology (LBC) triage (that is LBC testing if the HPV test is positive) at five-yearly intervals from age 25 to 60 is* ***cost-effective with an incremental cost-effectiveness ratio (ICER) of €29,788 per quality-adjusted life year (QALY).*** *This strategy has similar clinical effectiveness and is cost saving relative to current practice…."*

- *".....extending access to screening from age 60 to 65 years for women who did not have access to organised cervical screening from the age of 25 years, but who were first offered screening from age 50 (that is, women who were 50 years of age when CervicalCheck began in 2008).* ***While extending the screening age is more effective, it is not cost-effective at a willingness-to-pay threshold of €20,000 to €45,000 per QALY****. Given their* ***historic underscreening****, it may be considered appropriate to extend screening to age 65 years for these women for ethical reasons. However, to ensure the benefits of this additional screening round are maximised****, a targeted campaign to encourage uptake*** *in those over 60 would be necessary given the lower uptake of screening in older women….."*

Modifications to cancer screening programmes

Project summary

- Request: April 2022, from National Screening Advisory Committee, based on submissions in the 2021 NSAC Annual Call for proposals.
  - BreastCheck:
    - Age extension to include those aged 45 to 49 years
    - Age extension to include those aged 70 to 74 years
    - Assessment of breast density in younger cohorts
  - BowelScreen:
    - Age extension to include those aged 50 to 54 years

Approach taken

- High level information on the relevant topics across the domains of
  - Epidemiology
  - Current guidelines
  - Potential clinical impact
  - Potential economic impact
  - Feasibility of implementation.
- Scoping methodology:
  - Preference given to secondary research such as assessments and systematic reviews, supplemented with primary research where required.
    - Subset of available information.

Findings and data challenges

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- Scoping report presented for each programme + high-level summary document comparing:
  - BreastCheck
    - Most evidence referred to those aged 40 to 49, as opposed to the specific age range of 45 to 49 requested by NSAC
  - BowelScreen
    - Most evidence referred to those aged 50 to 59, as opposed to the specific age range of 50 to 54 requested by NSAC
    - Only studies relating to FIT considered relevant to potential clinical impact
- Full HTAs required
  - Time…: economic evaluation, resource implications, public consultation.

Next steps

- Project managerment of work packages:
  - cancer vs non-cancer HTA workstreams (newborn screening, infants, adult non-cancer…)

- Determination of capacity to leverage existing work
  - Existing systematic reviews
    - Clinical effectiveness
    - Cost effectiveness
  - Approach to economic evaluation and resource modelling

Gene expression profiling in early stage breast cancer

Project summary

- Request: HSE National Cancer Control Programme

- Aim: to provide advice to the HSE on alternatives to Oncotype DX® that may be used to inform decision-making in relation to the management of early-stage invasive breast cancer.

- Product: *Rapid HTA*

Background to topic

- 2011 - HSE reimbursed the Oncotype DX® GEP test to guide adjuvant chemotherapy decisions in patients with HR+, HER2-, lymph node negative (LN-) early-stage breast cancer:
  - Followed a recommendation by the HSE National Cancer Control Programme (NCCP) Technology Review Committee
- 2019 - reimbursement of Oncotype DX® was extended to patients with LN+ (1-3 nodes) breast cancer
- 2022 – 3 other commercial tests available but not reimbursed in Ireland
  - EndoPredict®
  - MammaPrint®
  - ProSigna®

Approach taken

- Description of technology
  - Test indications
  - Technical considerations (turnaround time, lab location, tissue sampling)
  - List price of test
  - International practice
- Epidemiology
  - Extent of eligible population
  - Burden of disease
- Clinical effectiveness
  - 3 major outcome sets: prognostic ability, predictive ability, impact on decision-making

Clinical effectiveness findings

- Three tests indicated for predictive use. Predictive ability assessed in RCTs for two tests:
  - No head-to-head comparative evidence.
  - Lack of direct evidence that use of tests leads to improved health outcomes
  - MammaPrint® found not to offer predictive value beyond that of an existing algorithm
  - Oncotype DX®: lack of comparator to indicate additional benefit of use of score.
- HIQA advice: Among LN- patients:
  - *…although there are limited data to differentiate between the tests, the available evidence supports the continued use of Oncotype DX®.*
- HIQA advice: Among LN+ patients:
  - *…the evidence most strongly supports the continued use of Oncotype DX® in postmenopausal women, based on available five-year follow-up data.*

Challenges in assessing value…

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- Early adoption of Oncotype DX in Ireland, lack of clarity in ‘baseline’ approach to chemotherapy decision-making:
  - Difficult to assess changes to chemotherapy usage
- Lack of appropriate RCT data to identify the added value of the use of these tests to clinical outcomes
- Lack of adequate long-term follow-up data
- No head-to-head evidence between tests
- Discordance between tests in assigning patients to risk categories

Advice for improvement…

- In order to optimise the management and use of GEP tests in Ireland, consideration should be given to:

  - collecting data on GEP test use, linked to treatment and patient characteristics and outcomes, as part of a national database. These data could help clarify the clinical impact of these tests in Ireland.

  - developing guidance to outline the patient subgroups in which they should be used, the appropriate tumour sampling methods and preparation techniques, and interpretation of test results.

Generic justification of medical exposures to ionising radiation

Medical exposures to ionising radiation

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- Radiation:
  - Can be used to detect cancer and treat cancer
  - ..but can also cause cancer
- Linear no-threshold model:
  - Every increment of radiation dose, no matter how small, constitutes an increased cancer risk for humans.
- Examples of medical exposures:
  - Dental X-ray
  - CT scan
  - Mammography
  - Radiotherapy

HIQA's role

EU Directive → 2013/59/EURATOM

National Legislation → SI 256 2018

Main Scope → Patients, Carers, Comforters, Research Volunteers

Competent Authority → Health Information & Quality Authority

HIQA Directorates → Health Information and Quality Authority

- Healthcare Regulation
- Health Technology Assessment

Justification

- HIQA is the designated competent authority for medical exposures to ionising radiation
  - New practices involving patients‘ exposure to ionising radiation must be ‘justified’ by HIQA

- Justification:
  - Considers both the benefits to an individual person and to society, and the harms to the exposed individual
  - Considers the effectiveness, advantages and risks associated with the available alternative practices which expose the individual to less or no ionising radiation
  - Generic justification: ‘level 2 justification’ → population-level

Current work in this area

- Function commenced 2 Feb 2023

- Work currently in progress (cancer-related):
  - F18 piflufolastat injection
    - Positron emission tomography (PET) agent that targets prostate-specific membrane antigen (PSMA)
    - imaging of metastatic prostate cancer

- Approach outlined in published methods document

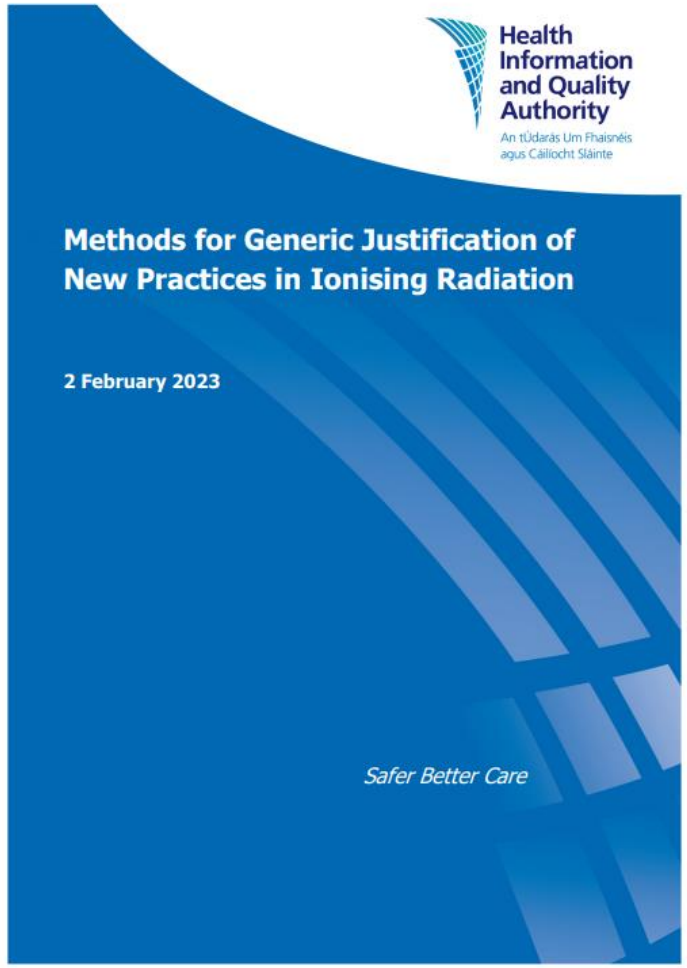
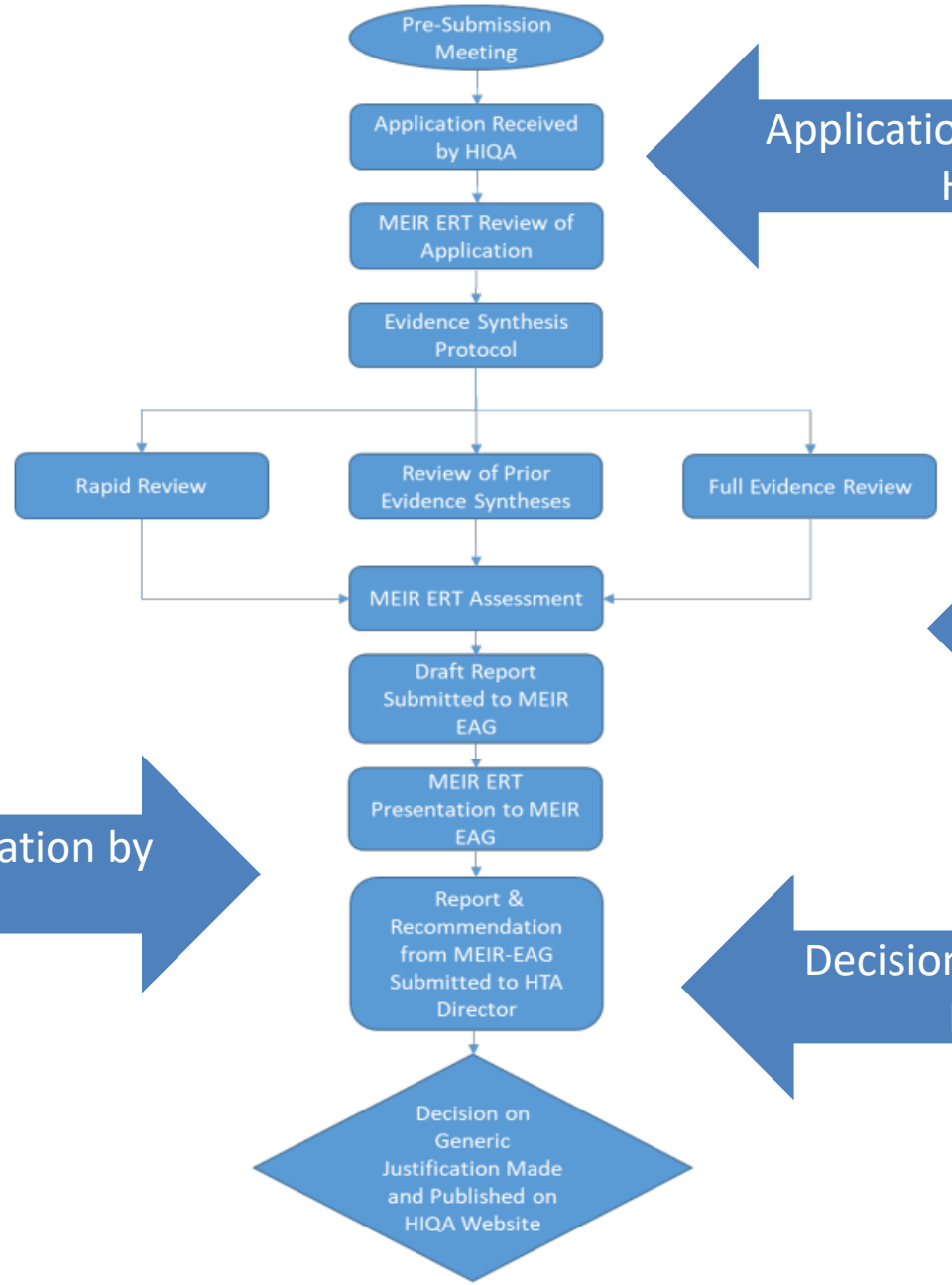


Figure 1: Simplified Schematic of the Generic Justification Process



Application received by HIQA

Varying levels of review

Evidence synthesis carried out by HIQA

Recommendation by EAG

Decision by HIQA's HTA Director

Evidence Synthesis Matrix

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Risk/Dose

International experience

	Dose significantly increased compared with current practice	Existing technology/methodology, but focus is a different anatomical region and there is no significant increase in dose	Practice decreases dose compared with current practice and *decreases* the diagnostic performance or clinical benefit of the practice	Changes to fractionation schedules at population level (e.g. hypo- or hyperfractionation)	Practice decreases dose compared with current practice but *does not decrease* the diagnostic performance or clinical benefit of the practice	Number or type of sources of radiation has changed, but there is no significant increase in dose
1.Completely new practice	Full Evidence Review	Full Evidence Review	Full Evidence Review	Full Evidence Review	Full Evidence Review	Full Evidence Review
2. New practice to Ireland, but is undertaken elsewhere with limited evidence available	Full Evidence Review	Full Evidence Review	Full Evidence Review	Review of Prior Evidence Syntheses	Rapid Review	Rapid Review
3. New practice to Ireland, but is undertaken elsewhere (EU or non EU), or generically justified by another EU country, with a good availability of evidence	Review of Prior Evidence Syntheses	Review of Prior Evidence Syntheses	Review of Prior Evidence Syntheses	Rapid Review	Rapid Review	Rapid Review

This matrix is provided for guidance purposes and should be read in the context of the typical definition of a new type or class of practice, as outlined in this document. Please consult HIQA if the practice does not fit the description of any of the categories described.

Moving from Evidence to Decision

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- HIQA's decisions will be informed by the evidence and input from its Expert Advisory Group known as the MEIR EAG.

- Application, evidence review and recommendation from the MEIR EAG considered in final decision:
  - Balance of benefits and harms

More information: https://www.hiqa.ie/areas-we-work/ionising-radiation/justification-practices

Observations

Stakeholder involvement

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- Requester (DoH / HSE Clinical Programmes)
- Patient representatives/advocates (e.g. Irish Cancer Society)
- Family/carer/comforter representatives
- Medical/surgical/radiology experts
- Allied health (e.g. occupational therapist, physiotherapist..)
- Laboratory scientists
- Public health practitioners
- Methodology experts (e.g. international expertise)

Approaches to assessing value

- What is needed to inform the decision? Where does the value lie?
  - *Full HTA* (e.g. HTA of HPV testing for cervical cancer screening)
  - *Rapid HTA* of GEPs – focus largely on clinical effectiveness
  - *Breast/bowel brief reports* – overview to inform prioritisation of full HTA (extent of evidence available)
  - *Generic justification* – value framed within safety, additional benefit (to individual, society)
- Importance of tailoring the product to answer the question in the most efficient manner
  - Rapid HTA
  - Scoping/briefing report to inform full HTA
  - Evidence synthesis

Other HTA domains and components

- Economic evaluation – (a) value for money; (b) affordability
  - Tumour profiling HTA – is cost utility analysis possible? Meaningful?
  - Cancer screening – possible to leverage existing work?

- Organisational considerations
  - Feasibility

- Ethical, social and legal issues

- Public consultation

Thank You.

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(Extra slides)