Assessing the Value of Medical devices in the HSE

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Dr Anne Dee

IMSTA Annual Conference

11/04/2018

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HTA in Ireland

HIQA

- Independent authority
- National focus
- HTA's and HTA guidelines
- Training, support and advice

NCPE

- New drugs
- Drug company submissions
- HSE Corporate Pharmaceutical Unit
- Reimbursement decisions

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HTA of medical devices

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- The HSE spends €850 million on medical devices on an annual basis.
- Each year there are hundreds of new products brought to market, of which approximately 40 to 50 are new and innovative devices.
- Until recently there was no formal process to evaluate the effectiveness or the cost effectiveness of these products outside of the formal HTA process provided by HIQA.

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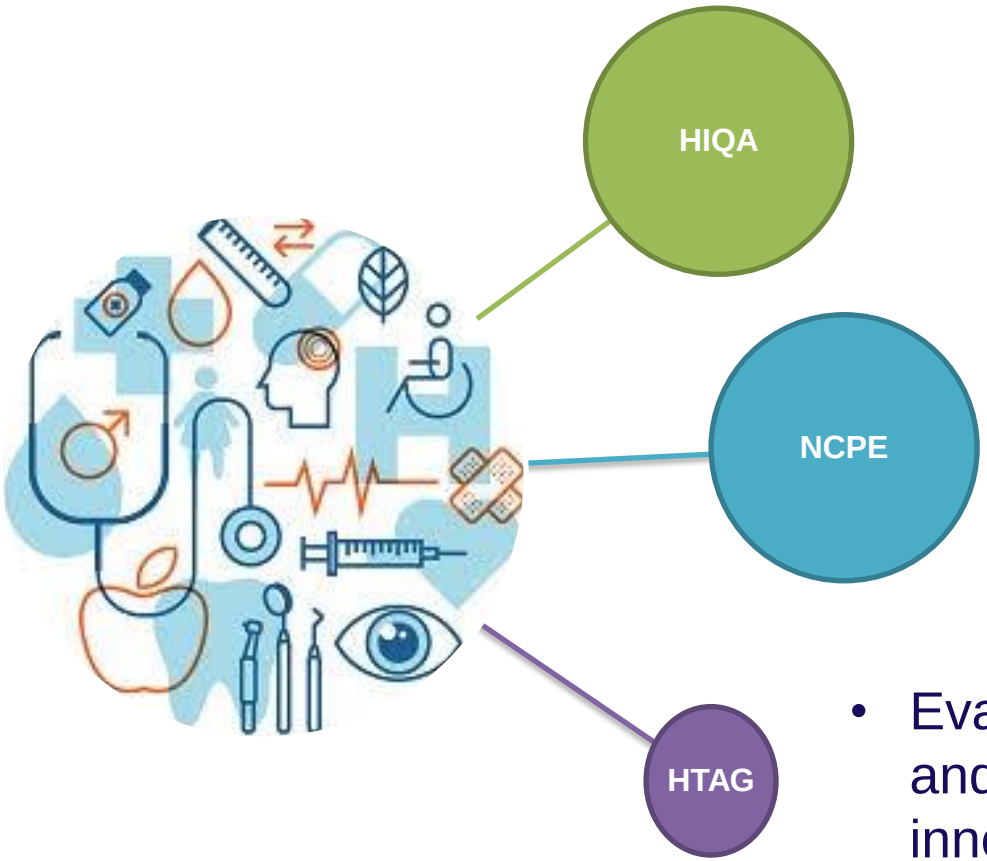
HSE Health Technology Assessment Group (HTAG)



- Evaluate the clinical effectiveness and cost effectiveness of new and innovative medical devices

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How medical devices differ from drugs

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- Devices are often diagnostic.
- Difficulty in conducting trials.
- Dependent on the user.
- Requirement for training and/or infrastructure.
- Non–comparable evidence.
- Prices/costs are not stable over time.

Four main features of medical devices

HEALTH ECONOMICS
Health Econ. **26**(Suppl. 1): 70–92 (2017)
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IMPROVING THE METHODS FOR THE ECONOMIC EVALUATION OF MEDICAL DEVICES

ROSANNA TARRICONE[a,b]*, GIUDITTA CALLEA[b], MARKO OGOREVC[c] and VALENTINA PREVOLNIK RUPEL[c]

[a]*Department of Policy Analysis and Public Management, Bocconi University, Milan, Italy*
[b]*Centre for Research on Health and Social Care Management (CERGAS), Bocconi University, Milan, Italy*
[c]*Institute for Economic Research, Ljubljana, Slovenia*

- Incremental innovation
- Dynamic pricing
- Learning curve
- Organisational impact

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Incremental Innovation

- Devices change rapidly and incrementally.
- Poses problems for trials or observational evidence generation (effectiveness).
- The timing of research does not align well with this pace of change.
- A device might be obsolete by the time a trial is completed.
- Seldom a ‘steady-state’.

‘Dynamic’ pricing

- Similarly, as devices change, the pricing changes as well.
- Not only of the new device, but also if the comparator is a device.
- For example, older technologies might become cheaper, changing their cost-effectiveness.
- Which price to include in economic evaluation: current? projected?
- Pricing is also different because of the way that devices are procured, which also varies by jurisdiction.
- How to evaluate cost-effectiveness of an intervention when we do not know the price?

Learning Curve

- This may be the most important characteristic in the use of medical devices.
- (i) the operators skills and experience (i.e. correctly identifying eligible patients)
- (ii) the scale (number of patients/procedures)
- Requirement for training?
- This has an associated cost.
- Will have implications for the effectiveness of the device.
- How do we incorporate variable effectiveness in economic evaluation?

Organizational Impact

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- Adoption of some medical devices often requires organizational impact or adaptations.
- This organizational impact can represent substantial, and potentially irrecoverable costs and/or resource use.
- Devoted space/room for larger diagnostic devices.
- Additional new equipment/consumables/maintenance
- Formation of multi-disciplinary teams.
- Certifications/supervision.

Two additional aspects:

- Evidence generation.
  - Trials are difficult for aforementioned reasons.
  - Also, blinded trials are difficult, maybe impossible.
- Device ‘failure’.
  - Devices are prone to failure.
  - The management of these failures can be costly.
  - Should these be a component of economic evaluation?

Other considerations

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International Journal of Technology Assessment in Health Care, 32:3 (2016), 122–125.

doi:10.1017/S0266462316000234

Methods

PROMISE AND PLAUSIBILITY: HEALTH TECHNOLOGY ADOPTION DECISIONS WITH LIMITED EVIDENCE

Bruce Campbell
Medical Technologies Advisory Committee, National Institute for Health and Care Excellence

Paul Knox
Medical Technologies Advisory Committee, National Institute for Health and Care Excellence
Department of Eye & Vision Science, Institute of Ageing & Chronic Disease, University of Liverpool
pcknox@liv.ac.uk

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They say…

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"*When scientific and clinical evidence is sparse, promise and plausibility play an increased part in decision-making. Drivers of promise include a clear design and mechanism of action, the possibility of radical improvement in care and/or resource use, and improving health outcomes for large numbers of patients. Plausibility relates to judgements about whether the promise is likely to be delivered in a "real-world" setting. Promise and plausibility need to be balanced against the amount of evidence available*."

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HTAG Scope

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- The scope of the HSE HTAG is confined to the area of medical devices and is:

➢ To assess the effectiveness and cost-effectiveness of new and innovative medical technologies or existing medical technologies with new and/or innovative indication based on a mini-HTA

- If full HTA deemed necessary, refer to HIQA

HTAG remit

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- Evaluate mini-Health Technology Assessment submissions on new and innovative medical devices, or established medical devices licensed for a new and innovative use.
- HTAG provides assistance to stakeholders when considering various health technologies and innovation in the medical devices field.
- The key stakeholders are Primary Care Reimbursement Service (PCRS), Procurement, other internal HSE divisions (Clinical Programmes etc.) and the device manufacturing industry.

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HTAG Team (Based in Limerick)

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Dr Anne Dee
HTAG Lead
(0.4 WTE)

Dr Marsha Tracey
Researcher
(1.0 WTE)

Mr Joe Heavey
Project Manager
(0.2 WTE,)

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HTA Expert Group Membership

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Operational Governance

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- HTAG reports and is supported by the HTA Expert Group.
- All advice notes are issued by the Expert Group.
- All reviews are presented to the EG for opinion and expertise.
- They also supply support and advice on a range of matters related to Industry, political representations etc.
- They have reviewed and approved all the HTAG documentation.
- They reviewed and approved the HTAG website.
- Is within the Knowledge Management function of the HSE

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HTAG Website

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HSE.ie > Health and Wellbeing > Health Technology Assessment Group

Health Technology Assessment Group

The work of the Health Technology Assessment Group (HTAG)

HTAG is a medical technology evaluation group that provides assistance to stakeholders when considering various health technologies and innovation in the medical devices field.

The unit reviews the clinical and cost effectiveness of innovative medical devices. This will inform and support clinical and business decisions relating to

In this section

- Meet the team
- Submit an Application
- Publications
- Contact Us

https://www.hse.ie/htag

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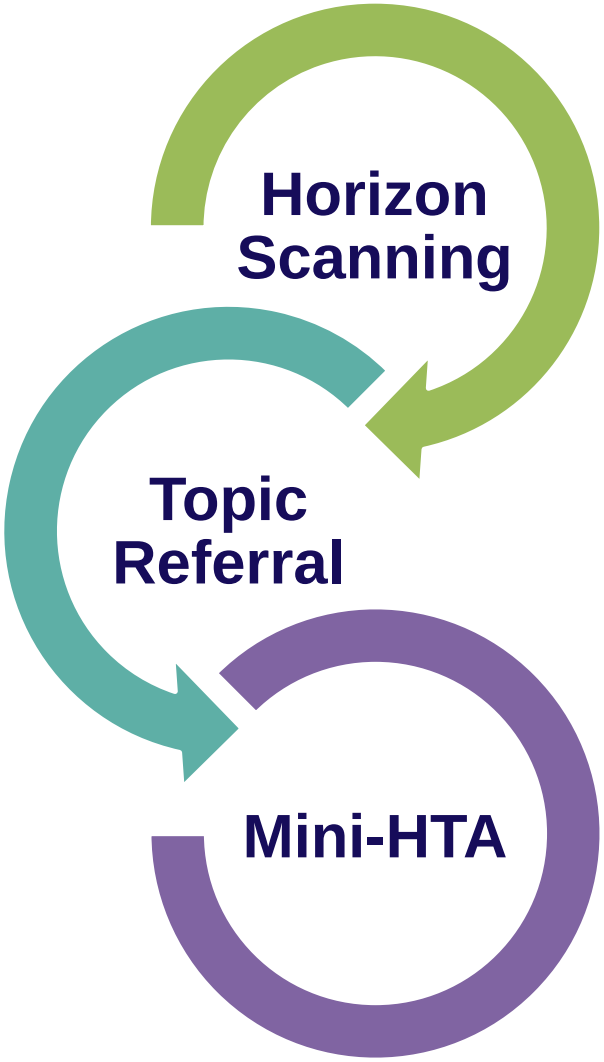
Process



- Expected applications for reimbursement in 12 month period
- Targeted at industry
- Is medical device relevant to HTAG scope?
- Future work plan, research activities, resource requirements

- Evidence to show that the device complies with minimum safety standards, that there is a clinician who supports the application and that the device is of potential benefit to patients.

- Review evidence for effectiveness; if there is evidence for effectiveness, proceed to review the evidence of cost-effectiveness
- Advice note

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Collaborations

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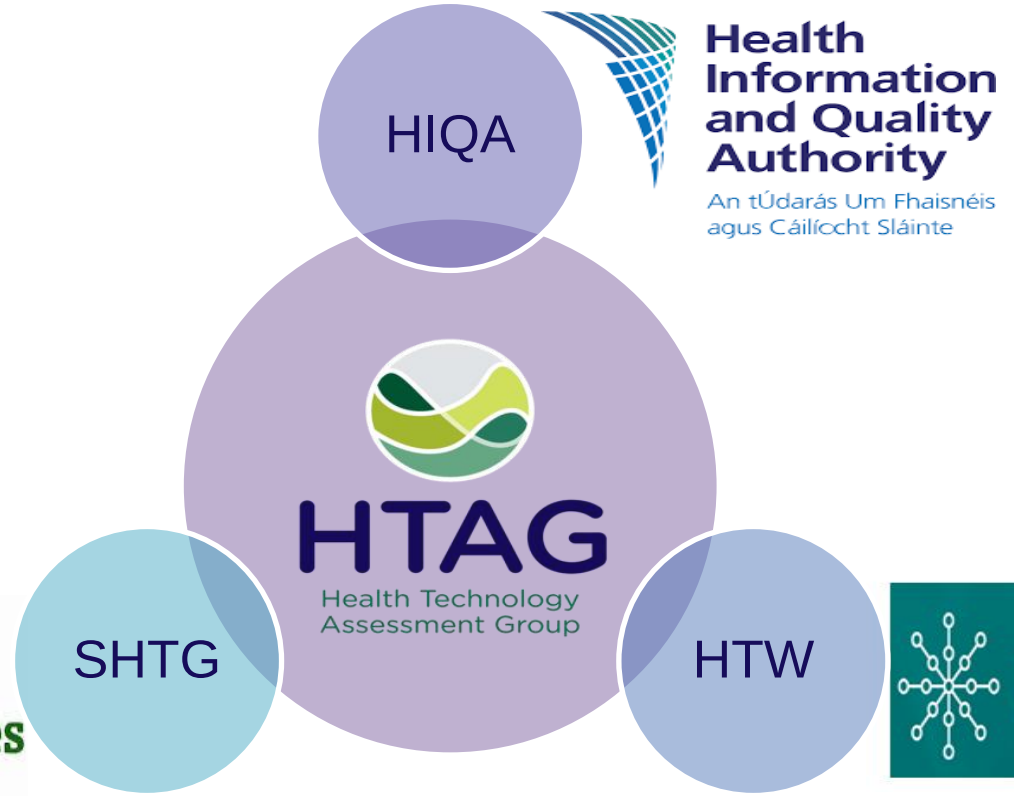

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Freestyle Libre

Abbott Diabetes Care Ltd.

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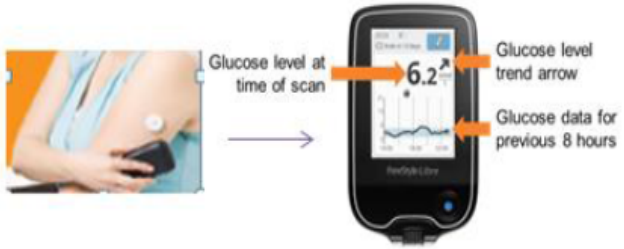
Recommend with conditions and review at one year

Advice Note 2017/ 001	Freestyle Libre
What is the clinical effectiveness, safety and budget impact of the Freestyle Libre System compared with current glucose monitoring methods for people aged 4 years and over with diabetes mellitus who use multiple daily injections of insulin?	
This advice has been produced following completion of an evidence review by the Health Technology Assessment Group (HTAG), in response to a request from the Primary Care Reimbursement Service of the Health Service Executive.	

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Reimbursement decision

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Press Release

Good news for children and teenagers with diabetes – approval given to reimburse blood glucose management system Freestyle Libre – Harris

19.1.2018

An Roinn Sláinte
DEPARTMENT OF HEALTH

"*The HSE will now make arrangements for the reimbursement of Freestyle Libre on an individual basis where specific criteria are satisfied* ***in line with the recommendations of the Health Technology Assessment Group*** *and I look forward to its being available for patients in the coming months*."
(Minister for Health Simon Harris TD)

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Acknowledgements

- Dr Adam Raymaker, CURAM Centre for Research in Medical Devices, Health Economics and Policy Analysis Centre, NUI Galway

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Questions?

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